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Emerging Technologies in the Treatment of Adult Spinal Deformity


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Outcomes for adult spinal deformity continue to improve as new technologies become integrated into clinical practice. Machine learning, robot-guided spinal surgery, and patient-specific rods are tools that are being used to improve preoperative planning and patient satisfaction. Machine learning can be used to predict complications, readmissions, and generate postoperative radiographs which can be shown to patients to guide discussions about surgery. Robot-guided spinal surgery is a rapidly growing field showing signs of greater accuracy in screw placement during surgery. Patient-specific rods offer improved outcomes through higher correction rates and decreased rates of rod breakage while decreasing operative time. The objective of this review is to evaluate trends in the literature about machine learning, robot-guided spinal surgery, and patient-specific rods in the treatment of adult spinal deformity.

Keywords: Machine learning, Rods, Robot, Spine surgery, Artificial intelligence

INTRODUCTION

Adult spinal deformity (ASD) is characterized by loss of spinal alignment in the sagittal and coronal planes, including scoliosis, kyphosis, spondylolisthesis, and rotatory subluxation. ASD may develop due to degenerative changes, deformities in childhood development, infection, trauma, or tumors that affect the vertebral column. While rates of adult scoliosis are as high as 32% of the general population, spinal deformity may affect up to 68% of individuals 65 years or older. Advances in medical care, increasing life expectancy, and a growing elderly population contribute to an increase in expenditures on spine-related care, accounting for over $86 billion annually.

Advances in surgical techniques and perioperative care have increased the prevalence of surgical treatment for ASD. Challenges remain with respect to complication rates, patient selection, and outcomes prediction. Recent advances in outcome predictions have led to enhanced patient care through improved perioperative planning and risk counseling. Current models implemented computational tools that can analyze large sets of data to predict outcomes and complications. Traditional statistical models have demonstrated some success in predicting postoperative length of stay and clinical outcomes. However, there is room for improvement.

Machine learning (ML) shows promise to improve clinical decision-making and patient outcomes. It is a collection of statistical techniques that uses large quantities of data to develop a model to determine nuanced patterns and predicting outcomes. ML is poised to revolutionize the management of ASD, with its broad-ranging applications in preoperative planning,
outcomes prediction, improving research quality, diagnostic tool development, and assistance with surgical performance.^

Robotic-guided spine surgery (RGSS) is another area of rapid advancement in the treatment of ASD. In spinal fusion surgery, RGSS has led to increased intraoperative accuracy for pedicle screw placement while decreasing radiation exposure, complication rates, operative time, blood loss and recovery time for patients.^

Historically, surgeons relied on fluoroscopy-assist ed free-hand screw placement, but many studies have now shown the superior accuracy that RGSS provides. The ability of robotics to guide surgeon screw placement can yield fewer mistakes and reduce inter-surgeon variability.

Another growing technology in ASD is the use of patient-specific rods (PSR). PSRs are rods made during preoperative surgical planning to provide a frame specific for each patient's correction. This removes intraoperative rod bending, which has been shown through postoperative radiographs to often undercorrect. By implementing PSRs, we can expect to see better corrections for patients, lower rates of rod breakage, and decreased operative times. Additionally, this allows for more precise and reproducible results as opposed to manual bending which presumably cannot be recreated accurately. As the future of ASD surgery continues to advance technologies, we can expect more successful surgeries, more accurate predictions, and fewer complications for patients.

Thus, ML, PSR, and RGSS lead to improvements in preoperative planning and postoperative management of complications. The objective of this paper is to assess the current status of these tools in ASD, and discuss their future applications in spine surgery.

MACHINE LEARNING

1. Overview

ML is a collection of statistical techniques that allow algorithms to "learn" patterns contained in large quantities of data. The statistical algorithms span a wide range from simple to exceptionally complicated. More complicated algorithms can learn more nuanced patterns in data than might be possible using standard statistical methods. Thus, the rise of ML has brought about more intelligent methods for data analysis. When applied correctly to high-quality data, complicated ML algorithms may obtain great fidelity to the phenomena they are designed to model. Clinically, this means that a ML model might emulate surgeon thinking very well in complex tasks like diagnosis or outcomes prognostication. In addition to improved accuracy, ML techniques have simplified the application of computer modeling to complicated types of data such as images or text. ML algorithms are often able to conduct both data preprocessing and analysis steps. Traditional statistical methods may associate surgeon-appreciated radiographic features with a diagnosis or with quality of life metrics. A ML algorithm may go a step further and examine the radiograph directly to find unique image features associated with the same diagnosis or quality of life metrics. With text, a ML model may read the medical record directly and obviate the need for a human-mediated coding step. In this way, ML models may perform both data preprocessing and analysis. Altogether, ML is an exciting emerging technology due to its sophistication, its improved performance relative to traditional statistical methods, and its ability to use complex datasets.

In recent years, ML has emerged as a prominent topic in spine research. Armed with the unique features described above, ML algorithms bring high accuracy models for classification and regression tasks to the spine community. Within ASD, ML techniques are being applied clinically to assist preoperative planning, predict operative outcomes, and predict complications following spine procedures.

2. ML for Preoperative Planning

One area where ML use cases are emerging in spine surgery is in preoperative planning.

Radiographic measurement is an important step in preoperative planning for spine surgery, and several studies have investigated ML techniques for automating radiographic measurements for analysis of spinal deformity. In one work, Galbusera et al. developed an algorithm that automated measurement of important preoperative parameters such as T4–12 kyphosis, L1–5 lordosis, Cobb angles, and pelvic tilt (PT) from biplanar radiographs. Similar works by Schwartz et al. and Cho et al. have created algorithms to measure lumbar lordosis and pelvic parameters using lateral radiographs alone. These automated algorithms perform with similar accuracy to manual measurement by surgeons. Automated analysis of spine shape is useful because it saves time and energy in the preoperative planning process for an individual patient. In addition, automated measurement can remove the interrater variation seen when taking important measurements. Furthermore, automated analysis of spine shape may enable research on alignment goals to be conducted on an unprecedented scale. This may help build upon systems for guiding ASD correction, such as the Scoliosis Research Society (SRS)-Schwab classification. In turn, this could...
translate into more personalized treatment plans for greater patient benefit.

In addition to automated measurement, ML techniques may assist in preoperative decision-making more directly. Lafage et al.\textsuperscript{25} investigated a ML model to predict the selection of upper treated vertebrae by expert surgeons in ASD cases based on preoperative radiographic measurements and correction goals. Their model was able to identify upper treated vertebrae 87.5\% of the time correctly. Although there may be room for growth before such an algorithm would be used clinically, the results demonstrate the capacity for ML methods to learn an important preoperative decision-making process. Algorithms such as this could garner deeper insight into surgeon decision making and help to generate improved objective decision methodologies in the future.

ML may be used in surgical planning to predict intraoperative events. Raman et al.\textsuperscript{26} utilized a ML technique to predict the need for major intraoperative blood transfusion during fusion surgery. Studying risk factors for intraoperative events such as major transfusion may not be new. However, the application of ML models to these problems enables analysis of more complicated relationships between variables of interest. ML techniques may offer greater predictive power, and in turn, better resource allocation for events like major intraoperative blood transfusion.

3. ML for Outcomes Prediction

Patient-reported improvements in pain and function are an increasingly important metric of success in spine surgery.\textsuperscript{27} Accurate prediction of surgical outcomes is useful to indicate patients for spine surgery properly, and several prediction tools have been previously developed to assist in this process.\textsuperscript{28} More recently, newer ML techniques have begun to take the place of traditional statistical techniques to create these tools. In many instances, ML techniques such as neural networks offer improved predictive accuracy compared to more traditional techniques.\textsuperscript{16} One notable study by Ames et al.\textsuperscript{29} examined 8 different algorithms for predicting the achievement of minimal clinically important difference (MCID) in ASD surgery. The authors employed ML algorithms to predict postoperative changes in 8 patient-reported outcomes (PROs) measured at both 1 year and 2 years postoperative. The authors could produce models with mean absolute errors less than the MCID for each PRO instrument across each time horizon. These results indicate that the models are sufficient to predict if a procedure will achieve MCID for a given patient using a given outcome instrument across a given time interval. Clinical application of predictive tools such as those created by Ames et al.\textsuperscript{29} may improve shared decision making and represent a step towards more customized care in ASD.

In addition to PROs, ML has been used to predict outcomes such as changes in spine morphology following ASD surgery. Lee et al.\textsuperscript{30} created an algorithm to accurately predict thoracic kyphosis and PT following fusion from the lower thoracic spine to the sacrum. This algorithm could be utilized to minimize proximal junctional kyphosis following ASD surgery.

4. ML for Predicting Complications

Risk factors for readmissions and various postoperative complications have been well studied in spine literature. However, the application of ML techniques to identify risk factors and predict complications is new. For example, Kim et al.\textsuperscript{31} compared the ability of an artificial neural network and logistic regression to predict cardiac complications, wound complications, venous thromboembolism, and mortality following elective surgery for ASD. They compared these 2 ML methods to the predictive ability American Society of Anesthesiologists (ASA) physical status classification. The authors found that the neural network outperformed logistic regression in predicting cardiac complication, wound complication, and mortality. In addition, both methods outperformed ASA physical status across all complication categories. Other studies have utilized similar ML models to predict adverse events. Martini et al.\textsuperscript{31} utilized a ML algorithm to predict drivers of unplanned 30-day readmission. The authors applied their technique to a large, variable-rich dataset well-suited for analysis using ML techniques. As a result, the authors could elucidate several factors that contribute to readmission with greater nuance than may be seen using other statistical techniques. Taken together, these 2 studies demonstrate the capacity for ML models to improve the capacity to predict adverse events following spine surgery for ASD.

ROBOTIC-GUIDED SPINAL SURGERY

1. Role of Robotics in Spine Surgery Planning and Execution

Surgical correction of major spinal deformities associated with ASD (i.e., scoliosis, kyphosis, lordosis) necessitate precise placement of instrumentation, namely pedicle screw, plate, and rod fixation. In recent years, robotic-assisted surgery has been implemented with growing frequency in spinal procedures. The technology for RGSS first became approved for clinical use in 2004 with the introduction of the SpineAssist/Renaissance ro-
This initial system showed promising results with successful pedicle screw placements being achieved with high accuracy, igniting rapid growth in literature supporting the use of these systems in spine procedures. And while the use of more advanced technology like unmanned-operative robotics still needs U.S. Food and Drug Administration approval, RGSS is actively being employed within the field. Currently, RGSS is utilized for screw-based spinal joint immobilization, pelvic instrumentation, dura mater tumor removal, and ASD procedures.

There is an extensive body of literature that evaluates the technical aspects of RGSS. While individual steps may differ based on the robot type being utilized, generally, preoperative computed tomography scans are uploaded to the robotic system to help construct a plan for screw size and course. Surgically, the RGSS system uses preplanned images to map the anatomical positioning of the patient where screw trajectories will be completed. Mapped positions are confirmed by perioperative fluoroscopy. In this role, robots act as a coautonomous system to help establish the optimal placement of stabilizing hardware, guiding the surgeon who ultimately places the screw. In this work, we will impart focus on the current status of clinical results obtained using RGSS for ASD correction.

2. Current Status of RGSS Accuracy Compared to Traditional Means

The conventional standard of care for instrumentation placement, primarily pedicle screws, in spinal deformity correction is free-hand fluoroscopy-guided (FH) surgery. In a large-scale analysis of 6,816 pedicle screws placed using a FH approach, 51.2% of which were in deformity corrections, Parker et al. found that only 115 screws (1.7%) breached the pedicle or vertebral body. In a scoliosis-specific study, Chang et al. found a 93% accuracy out of 992 placed screws using this approach which corroborates with what Zhu et al. found in an analysis of 625 screws placed in a pediatric scoliosis population. Nevertheless, a FH approach has inherent perioperative disadvantages that are propelling the frequency of RGSS utilization. In a systematic review comparing FH (672 screws) and RGSS (688 screws), it was shown that RGSS exposure and dosage were respectively 12.38 seconds (95% confidence interval [CI], -17.95 to -6.80; p < 0.001) and 0.64 milli-Sieverts smaller on average (95% CI, -0.85 to -0.43; p = 0.00001). Later, Fan et al. expanded upon this finding showing that RGSS screw placement resulted in less radiation dosage compared to other guided techniques in ASD correction, including FH-CT-navigation. In a recent meta-analysis, it was found that RGSS can decrease both complication and revision rates when compared to FH. Hu and Lieberman showed that RGSS is associated with a flattened learning curve for experienced spine surgeons with rates of successful placement increasing from 82% to 93% after only 30 operations.

A principal source of perioperative and postoperative complications in ASD surgeries are mal-positioned pedicle screws. Thus, a major question within the field is what accuracy can RGSS provide for pedicle screw placement compared to more traditional techniques? At present, there exist inconsistencies within the literature as to which approach is superior. Perdomo-Pantoja et al. found that in a multiapproach analysis, FH (n = 20,439 screws) (93.1%), fluoroscopy assisted (n = 17,336 screws) (91.5%), and computed tomography navigation guided (n = 10,848 screws) (95.5%) correction had better screw accuracy than RGSS (n = 2,538 screws) (90.5%). However, multiple other studies do not corroborate these findings and in general trend towards RGSS outperforming FH. In a meta-analysis of 1,255 FH and 1682 RGSS placed screws, Fan et al. demonstrated that RGSS significantly outperformed FH in screw accuracy (odds ratio [OR], 1.69; 95% CI, 1.38–2.07; p < 0.01). In an analysis that compared FH to 2 separate RGSS systems, it was shown that the TINAVI robot system had significantly higher screw accuracy than FH (relative risk, 1.10; 95% CI, 1.06–1.14; p < 0.01), but the Renaissance robot system did not (OR, relative risk, 1.00; 95% CI, 0.96–1.05; p = 0.95). However, in a separate meta-analysis, it was shown that both TINAVI (OR, 0.19; 95% CI, 0.09–0.38) and Renaissance (OR, 0.19; 95% CI, 0.07–0.56) systems promoted fewer cranial facet joint violations than FH. Gao et al. found that both proximal joint violation and pedicle screw accuracy were significantly improved in RGSS (688 screws) compared to FH (672 screws) procedures.

Given the current status of these meta-analyses on RGSS versus FH screw accuracy, it appears as though there are some inconsistencies within the literature, necessitating further research. Of the 5 meta-analyses above, 24 individual studies were analyzed in total, of which only 14 directly compared RGSS to FH. However, when these 14 reports are broken down by year, there is a noticeable improvement in RGSS results. Between 2012 and 2015, RGSS was found to either perform worse than or similar to FH when directly compared in 5 separate studies analyzing pedicle screw accuracy. Then, from 2016 to 2019, RGSS was found to perform similarly to FH in 5 analyses.

In that same period, 4 separate studies showed RGSS significantly outperforming FH with no studies reporting FH outperforming RGSS. Undoubtedly, more research is needed to further ascertain the potential advantage RGSS has in this re-
spect. Currently, there is a growing body of literature comparing these 2 approaches, and with billions of dollars expected to be invested in spinal robotics in the coming years, the clinical results for RGSS will likely continue to be strengthened.32

The growing clinical success of RGSS has in part driven the publication of additional studies in just the past year that utilizes robotics in spinal deformity-specific cases. Using clinical results from 2018–2019 for the correction of ASD, Chen et al.33 showed that RGSS (378 screws) improved blood loss (p < 0.001) and pedicle screw accuracy (p < 0.001) when compared to FH (786 screws).11 Additionally, they showed that both RGSS and FH had comparable operative times (p = 0.31) and length of hospitalization (p = 0.36). In 2020, Le et al.34 reported that RGSS (46 screws) resulted in less superior facet joint violation compared to FH (109 screws) (p = 0.04). Further in 2020, Edström et al.35 showed that RGSS (2.2%) required less need for additional instrumentation (i.e., hooks) compared to FH patients (9.7%) (p < 0.001). Lastly, Gonzalez et al.36 accomplished 98.7% accuracy in the placement of 314 screws in adolescent idiopathic scoliosis (AIS) correction, one of the highest accuracies seen to date for RGSS. This surge in recent literature supporting RGSS in just the last year coincides with Hu and Lieberman37 reporting a flattening of the curve to be expected for successful RGSS implementation. With surgeons likely growing more comfortable with robotic devices as they become a staple in the operating room, it should be expected that these high success rates will persist.

PATIENT-SPECIFIC RODS

1. Role of PSR in Adult Spine Deformity Surgery

Successful realignment of spinal deformities associated with ASD requires diligent preoperative planning and execution of the preoperative plan by a skilled surgeon. PSR has emerged as a novel technology that can reduce errors in executing a surgical plan due to imprecise intraoperative rod contouring. PSRs are relatively new in realignment surgery with the first set of rods implanted in 2013. Targets for realignment surgery in ASD follow the Schwab-Lafage recommendations and consider factors such as a sagittal vertical axis (SVA), PT, and a pelvic incidence lumbar lordosis mismatch (PI–LL).65 Despite established goals for realignment, neutral sagittal alignment was only achieved in 32% of patients following realignment surgery.66 Failure in surgical correction of spinal angles in ASD patients can be attributed to either a failure in preoperative planning or a failure in execution of the preoperative plan.67 The advent of robotic devices has been highlighted as a new approach to reigament surgery, aiming to improve the success rates of these procedures.68

2. How They Work

PSRs are designed from a preoperative surgical plan to fit the unique sagittal profile of each patient.69 Surgeons use spine preoperative planning software to simulate realignment and develop a preoperative plan. These softwares allow surgeons to import a patient’s radiographs into the software, manipulate the image to achieve target PT angle and SVA, simulate planned osteotomies, and develop a finalized surgical plan with achievable target angles.67,68,70 From the surgical plan developed in a planning software, rod curvature and length specific to the patient are determined and 2 identical PSRs are manufactured by MEDICREA (UNiD technology, MEDICREA, Lyon, France) to fit the precise specifications of the preoperative plan. Landmarks on the rods such as superior limit vertebra, S1 screw, and sagittal line are laser printed on the rods to aid in placement and all other surgical steps are similar to typical realignment surgery.67 PSRs are delivered to the operating room ready to implant, reducing time of operation, eliminating notching in rods that can compromise integrity, and increasing precision and symmetry of the rod bending.71

3. How Do PSRs Compare to Traditional Rods?

PSRs have led to excellent correction of ASD and spinopelvic alignment with postoperative radiographs demonstrating strong adherence to the preoperative plan.72,73 In 2019, Solla et al.,48 in a study focused on PI–LL, found significant improvements with PSR implementation and found patients with PSR implants to be 2.6 times more likely to be optimally corrected in comparison to published data from conventional surgery. This study highlighted the added benefits of a prebent rod to include reduced operation time and decreased mechanical complications,74 conducted a study focusing on thoracic kyphosis correction and found a mean increase in kyphosis of 14° and found kyphosis at last follow-up to be close to or at target value.74 A study examining 43 ASD cases using PSRs with no intraoperative adjustments to the prebent rods found improvements in SVA and PI–LL, confirming the clinical feasibility of their use.14 Other studies have demonstrated strong and stable treatment effects at a 2-year follow-up in patients treated with PSRs, with particular improvements noted in SVA and PI–LL.75 Two armed studies comparing PSRs to the current standard of care are lacking. A study comparing PSR use with preopera-
tive planning to absence of planning in cervical decompression and fusion found patients with pre-contoured rods to have greater correction of T1 slope minus cervical lordosis. SVA and cervical lordosis improvements were found to be similar between the PSR group and the conventional treatment group. Additionally, found that PSRs demonstrated more acute radius of curvature and sagittal alignment than standard rods in spinal surgeries involving 4 or fewer levels. Currently, a multicenter, controlled, double-blind, randomized trial entitled “The PROFILE Study” is underway which will provide an important comparison of this novel technology to the current standard of care.

While the advantages of PSR compared to traditional rods are not yet determined, several advantages to PSRs have already been established. By eliminating the need for intraoperative bending, PSRs reduce the time and difficulty of operation which decreases the likelihood of intraoperative infection. PSRs demonstrate improved mechanical resistance than typical rods due to the absence of notching from intraoperative bending techniques. Rod breakage was found in 2.2% of patients with PSR implants compared to 9.3% in patients with traditional rod implants. Lastly, exact knowledge of rod curvature preoperatively will allow further postoperative analysis and improved surgical planning research.

THE FUTURE OF ASD

Advances in treatment for ASD will continue to improve preoperative planning and reduce complication rates for patients. Technological strides in ML, robotic-assisted spine surgery, and PSR are poised to reduce complication rates and improve patient satisfaction with surgical intervention for ASD.

1. ML: Increased Patient Satisfaction

Management of patient expectations can be challenging in spine surgery. Previous research has evaluated patient expectations about symptom relief, physical function, and mental well-being, and the results indicated that 66% of lumbar patients were only “somewhat fulfilled” 2 years postoperatively. ML can improve patient satisfaction following surgery through its ability to

Fig. 1. Two examples of utilizing machine learning (ML) in the prediction of postoperative radiographs. For panels A and B, the left is the predicted postoperative radiographs, middle is real preoperative radiographs, and right is the real postoperative radiographs for 2 separate patients. ML has the potential to predict outcomes for patients from a radiographic perspective accurately.
generate postoperative radiographs using preoperative imaging and characteristics. Preliminary research within our institution has shown that ML can do this accurately. Thus, there is room for ML to be used on an individual patient level as well as its current role in analyzing large datasets.

Preliminary work by this lab has examined use of ML to predict postoperative radiograph appearance from preoperative radiographs (Fig. 1). A tool to accurately predict the postoperative appearance of patient radiographs could assist in shared decision-making and facilitate preoperative planning.

2. ML: Limitations

Despite the increasing integration of ML in ASD treatment, it still has some inherent limitations. ML algorithms conform very specifically to the data set used for training, and this frequently creates a lack of algorithm generalizability. An algorithm created using a dataset of only male patients may not have accurate results if used to study trends in a dataset of female patients. The Black Box problem is worth acknowledging; it is sometimes difficult to understand the methodology, or “thinking,” behind a complex algorithm. This creates a barrier where both patients and providers lack trust in ML as they are unable to understand it. Additionally, there have not been any randomized control trials or prospective studies that evaluate the efficacy of ML in ASD care.

FUTURE OF ROBOTIC-ASSISTED SPINE SURGERY

1. Extension of RGSS Beyond Conventional ASD Correction

The utilization of RGSS in other aspects of spinal deformity include the correction of AIS and S2-alar-iliac screw (S2AI) placement. S2AI screws, in particular, are utilized in ASD corrections extending to the sacrum, but are notoriously difficult to place. In an early study of S2AI placement for ASD correction at the sacrum, Schillingford et al. saw that a fluoroscopy-guided FH approach only resulted in cortical breaches 5% of the time. In the first study of their kind, both Bederman et al. and Hyun et al. saw that the accurate placement of all 31 and 35 S2AI screws they analyzed, respectively, using RGSS. Hyun et al. noted no iliac or sacral breaches. However, Bederman et al. saw that longer screws (≥ 80 mm) were associated with posterior pelvic violations in part because the software could not map beyond 60-mm projections; they later note that the software has since been modified. For AIS cases, Macke et al. saw that 92.8% of screws were not misplaced by more than 2 mm in a report of 662 screws. This agrees with later reports that showed only 2.8% of screws being inaccurately placed in a sample of 844 screws as determined by electromyography stimulation. 

2. PROs in RGSS

Given the novelty of RGSS, however, there is a paucity of literature on PROs associated with robotics in spinal procedures. In the limited literature, Li et al. showed in their meta-analysis that visual analogue score (p = 0.24) and Oswestry Disability Index (p = 0.12) scores did not differ between FH and RGSS reported scores. Of note, these comparisons only included 3 studies that published PROs for RGSS procedures, only one of which had greater than 2-year follow-up time. Similarly, in a 2020 publication, Chen et al. showed that SRS 22 pain scores were improved using both FH (n = 55) and RGSS (n = 31) at average 6-month follow-up in scoliosis correction; These scores did not significantly differ when compared between approaches. While the preliminary PRO results are promising, they are limited. To validate the clinical usefulness of RGSS in ASD correction, more studies will need to report on longer-term PROs. This data will come to light in the coming years with increasing consistency. However, given that RGSS is trending towards improvement in perioperative clinical spheres, it is a viable surgical technique in ASD correction.

FUTURE OF PATIENT-SPECIFIC RODS

The integration of PSR into everyday spine practices will heavily depend on it becoming a cost-effective alternative to the conventional options. At this time, PSR can cost 2–4x compared to traditional options, take about 2–4 weeks to prepare, and lead to greater implant waste as the manufacturer will provide multiple sizes to the surgeon. Surgeons may not be able to delay care for 2–4 weeks in emergent cases, and patients may opt for conventional options if it means the surgery can be scheduled sooner. Additionally, the variability within each specific rod makes it challenging to conduct large-scale clinical trials to evaluate its safety and efficacy.

Preliminary research in small sample sizes has shown that PSR has positive outcomes, but further research and advances in accessibility are necessary to understand its role long-term in ASD. Overcoming the challenges related to cost and time for preparation will lead to significant improvements in preoperative planning and reductions in postoperative complications for spinal surgery patients.
CONCLUSION

Overall, given the success of ML, robotics, and PSR in ASD, it is likely that these 3 tools will become staples in spine surgery. We hypothesize that the body of literature surrounding these up-and-coming advancements will expeditiously grow to provide more clinical data, preoperative images, postoperative outcomes, and postoperative radiographs. With this predicted increase in available data, we suggest the future integration of ML with robotics and PSR to further improve patient care in ASD correction.

CONFLICT OF INTEREST

The authors have nothing to disclose.

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Commentary on “Emerging Technologies in the Treatment of Adult Spinal Deformity”

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I read the article titled “Emerging Technologies in the Treatment of Adult Spinal Deformity” with great interest, as these technologies such as machine learning (ML) and robot are popular icons of the era. Dr. Patel and colleagues thoroughly assessed the current status of ML, patient-specific rods (PSRs), and robot-guided spine surgery (RGSS) in adult spinal deformity (ASD), and discuss its future applications in spine surgery. Through meticulous review of the literatures, the authors suggested the future integration of ML with robotics and PSRs to further improve patient care in ASD correction. I do agree with their suggestion in some particular ASD cases. However, surgical- and radiographic outcomes following ASD correction surgery are associated with so many factors. Furthermore, the optimal value for ML can be variable in ASD surgery. Unfortunately, it’s hard to say “perfect” value to predict excellent surgical- and clinical outcome in most ASD correction surgery, there is a gray zone between “perfect” and “poor.” For example, the optimal target lumbar lordosis can be frequently changed by theories or classifications such as Scoliosis Research Society-Schwab, Roussouly type, global alignment and proportion score, age-matched adjustment, etc. A bunch of studies have reported too many risk factors related with poor clinical- and radiographic outcomes following ASD correction surgery. Even tricky thing is that results of the affecting factors vary on each study. I feel sometimes ASD seems to be an unwinnable castle. Nevertheless, I hope these emerging technologies will continue to improve pre-operative planning, reduce complication rates and patient satisfaction with surgical intervention for ASD. Besides the ML, PSR, and RGSS, other emerging techniques such as artificial intelligence, virtual/augmented reality seem to be quite promising. Lastly, I’d like to appreciate the authors’ contribution to body of the literatures for overcoming ASD.

CONFLICT OF INTEREST
The author has nothing to disclose.

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Intraoperative Neuromonitoring During Lateral Lumbar Interbody Fusion

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Objective: To review the evidence for the use of electromyography (EMG), motor-evoked potentials (MEPs), and somatosensory-evoked potentials (SSEPs) intraoperative neuromonitoring (IONM) strategies during lateral lumbar interbody fusion (LLIF), as well as discuss the limitations associated with each technique.

Methods: A comprehensive review of the literature and compilation of findings relating to clinical studies investigating the efficacy of EMG, MEP, SSEP, or combined IONM strategies during LLIF.

Results: The evidence for the use of EMG is mixed with some studies demonstrating the efficacy of EMG in preventing postoperative neurologic injuries and other studies demonstrating a high rate of postoperative neurologic deficits with EMG monitoring. Multimodal IONM strategies utilizing MEPs or saphenous SSEPs to monitor the lumbar plexus may be promising strategies based on results from a limited number of studies.

Conclusion: The use of traditional EMG during LLIF remains without consensus. There is a growing body of evidence utilizing multimodal IONM with MEPs or saphenous SSEPs demonstrating a possible decrease in postoperative neurologic injuries after LLIF. Future prospective studies, with clear definitions of neurologic injury, that evaluate different multimodal IONM strategies are needed to better assess the efficacy of IONM during LLIF.

Keywords: Lateral lumbar interbody fusion, Intraoperative neuromonitoring, Electromyography, Somatosensory, Motor-evoked potentials

INTRODUCTION

Lateral lumbar interbody fusion (LLIF) is a minimally invasive technique that can improve patient-reported outcomes, while possibly reducing the risks associated with anterior, oblique-lateral, or posterior interbody approaches to the spinal column.¹,² Compared to posterior approaches, LLIF allows for preservation of the posterior ligamentous complex and indirect decompression of spinal stenosis.³ Additionally, a larger cage can be placed which may allow for greater improvement in sagittal alignment and foraminal height, and a more favorable biomechanical environment for arthrodesis.⁴,⁵ When compared to anterior or oblique-lateral interbody techniques, the LLIF may be associated with a lower risk of vascular injury as the working corridor is further away from the major abdominal vessels.

Despite these advantages, LLIF is associated with a unique set of complications secondary to traversing the psoas muscle with dilators and retractors, which is avoided in anterior and oblique-lateral approaches. This transpsoas approach can result in a high incidence of nerve complications due to direct injury or prolonged retraction of the lumbar plexus. Some studies have reported motor weakness in up to 33.6% of patients and sensory complications in up to 75% of patients postoperatively after LLIF.⁶-¹⁰ Although the majority of nerve injuries during LLIF...
result in transient postoperative symptoms, permanent motor and sensory deficits from femoral nerve injury are a significantly feared complication which can result in marked morbidity for patients.10-13

Possible reasons for the high incidence of reported neurologic complications in some studies include less direct anatomical visualization compared to traditional anterior or posterior approaches to the lumbar interbody space, anatomic variability of the lumbar plexus, and transitional lumbosacral anatomy. In most patients, the lumbar plexus includes the T12–L4 nerves which exit posteriorly in the foramen and migrate ventrally and caudally relative to the lumbar disc spaces. Multiple prior studies have demonstrated that, at the upper lumbar levels, the lumbar plexus nerves are typically posterior to the surgical approach resulting in a relatively large safe zone for LLIF;14-18 but this safe zone becomes progressively smaller at more caudal lumbar levels and, at L4–5, the safe zone may be less than 50% the width of the disc, significantly increasing the risk for nerve injury.14,17

Given the required traversing of the lumbar plexus during LLIF, the approach has traditionally been marketed to require intraoperative neuromonitoring (IONM) to potentially minimize the risk of neurologic injury caused by direct interaction with the lumbar plexus or indirect injury secondary to stretching or compression. To date, several studies have investigated the use of electromyography (EMG), motor-evoked potentials (MEPs), and somatosensory-evoked potentials (SSEPs) as well as multimodal IONM techniques. In this paper, we will review the evidence for the use of each IONM modality as well as discuss the limitations associated with each technique.

**METHODOLOGY**

The study design included a review of MEDLINE and PubMed databases for human clinical studies restricted to the English language published between 2010 and 2020; the search terms included “lateral lumbar interbody fusion neuromonitoring,” “lateral lumbar interbody fusion electromyography,” “lateral lumbar interbody fusion motor evoked potentials,” and “lateral lumbar interbody fusion somatosensory evoked potentials.” We included all studies assessing the efficacy of EMG, MEP, or SSEP IONM during LLIF. The references cited in the articles that met inclusion criteria after screening were reviewed to identify potential studies not captured by the initial database queries. We did not include studies assessing neuromonitoring in anterior, oblique, transforaminal, or posterior lumbar interbody fusion techniques. We did not exclude studies based on small sample

| Table 1. Clinical studies evaluating EMG utilization during LLIF |
|-----------------|-----------------|-----------------|-----------------|
| **Study**       | **Sample size; treatment; study design** | **Key findings—benefits of EMG** | **Key findings—limitations of EMG** |
| Tohmeh et al.19 (2011) | 102 Patients; LLIF at L3–4 and/or L4–5; Prospective, multicentered | No significant long-lasting neurological deficits in any patients with dynamic, discrete-threshold EMG; 3 new postoperative motor neural deficits that all resolved by 6-month follow-up. | |
| Uribe et al.20 (2015) | 323 Patients; LLIF at L4–5; Prospective, multicentered | Positive relationship between change in triggered EMG thresholds and postoperative symptomatic neuropraxia. | Triggered EMG specificity to detect nerve injury was low but increased with longer retractor time. Monitoring of triggered EMG motor nerves does not predict sensory function outcomes. |
| Bendersky et al.21 (2015) | 107 Patients; LLIF at any level; Prospective, single-centered | No postoperative motor deficits seen with free-run EMG. | Transient anterior thigh sensory symptoms in 17.75% of patients, all of which resolved by 3-month follow-up. |
| Sofianos et al.10 (2012) | 45 Patients; LLIF at any level; Retrospective case series | - | 40% Rate of complications in the setting of normal dynamic, discrete-evoked EMG readings. |
| Cahill et al.11 (2012) | 118 Patients; minimally invasive LLIF at any level; Retrospective review | No femoral nerve injuries at any disc level except at L4–5. | 4.8% Rate of femoral nerve injuries performed at L4–5 level with continuous EMG monitoring |
| Cummock et al.29 (2011) | 59 Patients; minimally invasive LLIF at any level; Retrospective review of prospectively collected data | - | 62.7% Rate of thigh symptoms with continuous EMG monitoring, 90% of which resolved by 1 year following surgery. |

EMG, electromyography; LLIF, lateral lumbar interbody fusion.
size or short duration of follow-up as the literature on neuro-monitoring during LLIF is sparse and the purpose of this paper was to summarize the available evidence regarding IONM during LLIF; as opposed to focused systematic review.

In this literature review, we summarize the key findings from the included studies evaluating EMG, MEP, and saphenous SSEP use during LLIF. The study design, patient numbers, and key findings for studies included in the literature review are also presented in Tables 1-3.

**ELECTROMYOGRAPHY**

EMG is commonly used during LLIF in part due to historical precedent, but also because EMG has been the most researched IONM modality during LLIF (Table 1).1 Free-run EMG allows for monitoring muscle activity throughout the entire LLIF procedure, and mechanical stimulation of a lumbar nerve root or the lumbar plexus can result in repetitive EMG discharges, signaling potential nerve injury. Triggered EMG in specific directions within the psoas muscle provides data on the direction and, possibly, the proximity of the lumbar plexus with respect to the dilation probes or retractor blades used during LLIF.

Tohmeh et al.19 conducted one of the first studies validating the use of free-run and triggered EMG during LLIF in a prospective, multicenter study enrolling 102 patients. Across the 102 patients, no significant long-last neural deficits were identified and all transient deficits had resolved by the 6-month follow-up visit.19 In a similar study, Uribe et al.20 conducted a prospective, multicenter EMG validation study in 323 patients undergoing LLIF at L4–5. In this study, they assessed the efficacy

Table 2. Clinical studies evaluating MEP utilization during LLIF

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample Size, treatment, study design</th>
<th>Key findings—benefits of MEP</th>
<th>Key findings—limitations of MEP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Riley et al.13 (2018)</td>
<td>479 Patients; LLIF with or without posterior decompression and fusion at any level; Retrospective review</td>
<td>Patients who received additional transcranial electric MEP (tcMEP) monitoring had a lower rate of postoperative neurologic deficits compared to patients receiving EMG monitoring only. tcMEP monitoring was associated with decreases in both sensory and motor deficits; tcMEP has potential to monitor sensory function indirectly via monitoring of mixed sensory-motor nerves.</td>
<td>-</td>
</tr>
<tr>
<td>Berends et al.21 (2016)</td>
<td>23 Patients; LLIF at various levels from L1–4; Prospective, single-centered</td>
<td>In 9% of patients, MEP amplitude decreased due to psoas retractor deployment, without a corresponding change in EMG signals.</td>
<td>-</td>
</tr>
<tr>
<td>Chaudhary et al.16 (2015)</td>
<td>3 Patients; LLIF at L4–5; Case series</td>
<td>Intraoperative MEP changes detected without corresponding abnormal EMG activity.</td>
<td>-</td>
</tr>
<tr>
<td>Houten et al.25 (2011)</td>
<td>2 Patients; LLIF at L3–5; Case series</td>
<td>-</td>
<td>Postoperative motor deficits not detected by either EMG or MEP. Motor potentials may vary depending on depth and choice of anesthetic agents.</td>
</tr>
</tbody>
</table>

MEP, motor-evoked potential; EMG, electromyography; LLIF, lateral lumbar interbody fusion.

Table 3. Clinical studies evaluating saphenous SEP utilization during LLIF

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample size, treatment, study design</th>
<th>Key findings—benefits of saphenous SEPs</th>
<th>Key findings—limitations of saphenous SEPs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silverstein et al.30 (2014)</td>
<td>41 Patients; LLIF at any level; Retrospective case series</td>
<td>In 5 patients, SSEP changes were noted after retractor expansion, without associated EMG changes; 3 of these patients had postoperative femoral nerve deficits. No false-negative SSEP alerts.</td>
<td>Signals may be affected by anesthetic agents, body habitus, depth of saphenous nerve, and medical comorbidities.</td>
</tr>
<tr>
<td>Jain et al.37 (2020)</td>
<td>62 Patients; LLIF at any level; Retrospective review</td>
<td>Saphenous SEPs demonstrated 52%–100% sensitivity and 90%–100% specificity in detecting postoperative femoral nerve complications.</td>
<td>Saphenous SEP could not be reliably established in 16% of patients.</td>
</tr>
</tbody>
</table>

SSEP, somatosensory-evoked potential; LLIF, lateral lumbar interbody fusion; EMG, electromyography.
of triggered EMG thresholds in response to posterior retractor blade stimulation and EMG values collected every 5 minutes throughout retraction. The authors found a positive relationship between the change in triggered EMG thresholds and postoperative symptomatic neuropraxia; however, triggered EMG specificity to detect nerve injury was low but increased with longer retractor time. In a third study, Bendersky et al. used a free-run EMG protocol specifically designed to monitor every branch of the lumbar plexus and reported zero motor deficits postoperatively. Additional studies have found the efficacy of integrating EMG into stimulation probes or finger electrodes in preventing or decreasing postoperative nerve deficits after LLIF.

Although several studies have demonstrated the efficacy of EMG use during LLIF, there are several limitations. First, EMG has low specificity due to both false-positive and false-negative readings which can be misleading, particularly when using triggered EMG for anatomical mapping of the lumbar plexus. Additionally, EMG is not a test of neural integrity; it may not detect compression, stretch, or focal ischemia resulting in nerve injury. EMG may also be unreliable at estimating a distance from a nerve as higher values may not always correspond to a safe zone, and it cannot reliably monitor sensory-specific nerves. Given these limitations, several studies have concluded that the use of only EMG for IONM during LLIF is likely inadequate and there may be a high rate of postoperative nerve complications in the setting of normal IONM EMG readings (Table 1).

**MOTOR-EVOKED POTENTIALS**

The potential limitations of EMG as a unimodal IONM strategy have led to recent studies investigating the additive benefit of MEP to monitor the integrity of the lumbar plexus during LLIF (Table 2). Transcranial MEPs are action potentials generated by transcranial brain stimulation via electrode placement. MEPs allow for monitoring of motor pathways and spinal cord function. The use of MEPs during traditional posterior approaches to the lumbar spine has been limited because MEP changes may not be sensitive in detecting injury to a single lumbar nerve root; however, MEPs may be able to accurately monitor fully formed peripheral nerves of the lumbar plexus which innervate the quadriceps muscle.

In one of the largest studies to date, Riley et al. analyzed the rate of postoperative neurologic deficits in 479 patients undergoing LLIF in which either EMG only or EMG and MEP IONM strategies were utilized. Analysis of their results demonstrated that patients who received additional MEP monitoring had a lower rate of postoperative neurologic deficits compared to patients only receiving EMG monitoring. Further analysis revealed that MEP monitoring decreased both sensory and motor deficits and the authors suggested that MEPs can provide an indirect assessment of sensory nerve fiber integrity by monitoring mixed sensory-motor nerves that originate off the lumbar plexus. In a smaller study, without a control group, Berends et al. reviewed 23 patients undergoing LLIF who were monitored with EMG and MEPs, and found that in 9% of patients MEP amplitude decreased due to psoas retractor deployment, without a corresponding change in EMG signals. However, whether additive MEP changed postoperative neurologic outcomes was unclear. Lastly, in a case series, Chaudhary et al. reported 3 patients with intraoperative MEP changes without corresponding abnormal EMG activity during LLIF; and 2 of these patients had postoperative quadriceps weakness.

While EMG and MEP multimodal IONM during LLIF may prevent intraoperative neurologic injury to the lumbar plexus, the addition of MEPs is not without its own set of limitations. The utilization of MEPs requires intravenous anesthesia as opposed to inhalational agents, and long-acting paralytics cannot be used, making positioning, exposure, and retraction more possibly challenging; thus, the choice of anesthesia technique can have a significant effect on MEP interpretation and reliability. Additionally, MEP monitoring is evoked at a certain point in time and does not allow for continuous neuromonitoring, thereby possibly delaying detection of injury to the lumbar plexus. Lastly, the interpretation of MEP data requires extensive training, is highly subject to variability, is dependent on establishing accurate and reproducible baseline MEP responses, and can be subject to both false-positive and false-negative alerts. These limitations of MEP monitoring may in part explain why some studies have demonstrated nerve injury during LLIF even when utilizing MEPs.

**SOMATOSENSORY-EVOKED POTENTIALS**

SSEP in addition to EMG may provide an alternative multimodal IONM strategy during LLIF. SSEPs allow for monitoring of sensory transmission through the dorsal column pathways. SSEP signals allow for continuous monitoring and are thought to be sensitive to ischemic changes. However, traditional SSEP techniques only track the lower lumbar-sacral plexus (L4–S2) by

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https://doi.org/10.14245/ns.2142440.220
monitoring the posterior tibial or peroneal nerves. SSEP monitoring of the saphenous nerve may allow monitoring of the upper lumbar plexus as the saphenous nerve, a continuation of the posterior division of the femoral nerve, is a purely sensory nerve that is superficially found between the sartorius and gracilis muscles.

Two studies have examined the utility of saphenous SSEP monitoring during LLIF (Table 3). Silverstein et al. monitored saphenous SSEPs in 46 consecutive patients undergoing LLIF. In 5 patients, they noted SSEP changes after retractor expansion, without associated EMG changes; 3 of these patients had postoperative femoral nerve deficits, and there were no false-negative SSEP alerts. A similar study by Jain et al. monitored saphenous SSEPs in 52 patients, in addition to EMG and MEPs. In this study, saphenous SSEPs demonstrated 100% sensitivity (95% confidence interval, 52%–100%) and 100% specificity (95% confidence interval, 90%–100%) in detecting postoperative femoral nerve complications. However, the authors did not provide an analysis of the additive utility of saphenous SSEPs compared to the use of EMG and/or MEPs. Given the lack of an additive utility analysis and control group, it is currently unclear whether saphenous SSEP monitoring definitively can prevent femoral nerve complications.

While saphenous SSEPs represent a promising approach to multimodal IONM during LLIF, they are associated with their own set of limitations. In the studies by Silverstein et al. and Jain et al., reliable saphenous SSEP signals could not be established in 11%–16% of patients. The ability to establish reliable signals can be affected by anesthetic agents, similar to MEP monitoring, as well as body habitus, limb length, depth of the saphenous nerve, and medical comorbidities.

CONCLUSION

Lateral lumbar interbody fusion is an evolving technique and is currently used to treat a wide array of spinal pathology ranging from degenerative spinal stenosis, adult deformity, tumor, and infection. While LLIF continues to grow in popularity, the safety of the technique needs to continue to improve. The LLIF approach was originally designed to be executed with concurrent EMG surveillance. However, subsequent studies demonstrated a high rate of postoperative neurologic deficits, even with EMG monitoring. Targeted EMG specifically designed to evaluate the lumbar plexus may be a more efficacious unimodal monitoring strategy during LLIF. Additionally, a multimodal IONM strategy utilizing MEPs or saphenous SSEPs to monitor the lumbar plexus may be promising strategies based on results from a limited number of studies. However, the additive benefit of multimodal IONM during LLIF remains without consensus and whether the increased cost of multimodal IONM justifies the unknown clinical benefit is without consensus. Ultimately, prospective studies, with clear definitions of postoperative neurologic injury, that evaluate different unimodal or multimodal IONM strategies are needed to accurately assess the efficacy of IONM during LLIF.

CONFLICT OF INTEREST


All other authors have no disclosures.

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The Effect of Brace Treatment on Large Curves of 40° to 55° in Adolescents With Idiopathic Scoliosis Who Have Avoided Surgery: A Retrospective Cohort Study

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Objective: To evaluate the effect of Milwaukee brace treatment on adolescents with idiopathic scoliosis (AIS) with large curves (40° to 55°) who refuse to do surgery.

Methods: In this retrospective cohort study, we gathered the clinical records of all adolescents with AIS with an initial curve of 40° to 55°. They had been referred to our center from December 1990 to January 2017. Although they had been advised to do surgery, they had all refused to do it. Their clinical data were recorded, such as sex, age, Risser sign, scoliosis, and kyphosis curve magnitude (at the beginning of brace treatment, weaning time, brace discontinuation, and minimum of 2 years after the treatment). Based on treatment success, the patients were divided into 2 groups: progressed and nonprogressed.

Results: Sixty patients with an average initial Cobb angle of 44.93° ± 4.86° were included. The curve progressed in 57%, stabilized in 25%, and improved in 18% of the patients. In the progressed group (34 patients), 31 patients had undergone surgery. There was no significant association between the age of beginning the brace treatment and the final Cobb angle of nonprogressed group (p > 0.05). However, in-brace correction and initial Risser sign had a significant correlation with curve magnitude at the final follow-up (p < 0.05).

Conclusion: Brace treatment seems to be effective in controlling the further curve progression in AIS with 40° and 55° curves. Our results can help physicians make sound decisions about the patients with larger curves who refuse to do surgery.

Keywords: Adolescent idiopathic scoliosis, Spine, Brace, Surgery, Outcome

INTRODUCTION

Adolescent idiopathic scoliosis (AIS) is the most prevalent type of spinal deformity. It is the frontal plane displacement of the spine more than 10° plus vertebral rotations. Its incidence is 0.47% to 5.2% among people aged 10 to 16 years old.1

Bracing is the most effective nonsurgical treatment for AIS.2,3 Based on the Scoliosis Research Society (SRS) Committee and the International Scientific Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT), if the scoliosis curvature is 25° to 40° at the beginning of wearing a brace, the treatment result can be optimal.4,5 For patients with more than 40° curves, brace’s effectiveness decreases and surgery is often recommended.4,6 However, despite the recommendation for doing surgery, some patients strongly refuse to do it and prefer to wear a brace. The effectiveness of brace treatment on AIS cases with > 40°...
curves is still in argue. Nevertheless, some reports in the literature show that brace treatment can have 35% to 91% effectiveness. A reason for this vast difference is the heterogeneity of the inclusion criteria and brace type. Therefore, this study investigated the effectiveness of brace treatment on AIS with 40° to 55° curves who had refused to do surgery. Assessment of potential risk factors which can be associated with brace treatment failure such as prebrace Cobb angle, curve type, Risser sign, and in-brace curve improvement had been the secondary objectives of our study. We hypothesized that these parameters have a role in brace treatment effectiveness in AIS with 40° to 55° curves.

MATERIALS AND METHODS

The ethics committee of Iran University of Medical Sciences approved this study (No. 1397.751). We gathered the clinical records of all AIS with an initial curve of 40° to 55° who had been referred to our center from December 1990 to January 2017. During the initial review, we found 117 cases that had more than 40° initial curve magnitude (Fig. 1). They had all been advised to undergo surgery at the first visit, but they had refused to do so. Thus, they had been recommended to do brace treatment. Among them, 57 were excluded as they had not continued the treatment until the end of skeletal maturity. Therefore, 60 patients met the inclusion criteria of the study. The inclusion criteria were having: (1) AIS with at least one curve ≥ 40°, (2) Risser sign 0–2 at the beginning of brace treatment, (3) no history of treatment or surgery, and (4) being older than 10 years old.

All patients received a Milwaukee brace (Fig. 2). The Milwaukee brace is a cervicothoracic-lumbosacral orthosis that has a custom-made pelvic section (to delordosing the lumbar spine) and a superstructure that attaches to the pelvic section. The superstructure has an anterior and 2 posterior uprights, and a neck ring. It provides an end-point control system to increase load-carrying capacity of the spinal column and, more importantly, a location for the attachment of the spinal pads to be positioned over the most displaced ribs on the convex side of the curvature. The brace pads had been maintained at the most tolerable pressure during treatment.

In this study, the Milwaukee brace had been customized for each patient. The treating physician had confirmed its standards. The patients had been asked to wear their braces full-time (23 hours a day). They had been asked to carry out the Moe and Blount protocol exercise for 2 hours per day (i.e., 1 hour while wearing the brace and 1 hour while not wearing it). These exercises aim to keep the strength of the trunk muscles and maintain the patient in the right posture. They include pelvic tilt and active trunk shifts away from the thoracic pad of the brace. Then, we ask the patient to do a deep inhalation and chest expansion and reach back next to the posterior bars of the brace. The patients were asked to do pelvic tilt in the supine position with the knees in flexion and extension, during sit-up motion.
push-ups, and standing position. The details of the exercises had been given in a brochure to each patient.

The clinical data of the patients were recorded, including sex, age, Risser sign, scoliosis, and kyphosis curve magnitude (at the beginning of brace treatment, weaning time, brace discontinuance, and a minimum of 2 years after cessation of brace treatment). The brace compliance was evaluated subjectively and via questioning the patients and based on their braces’ appearance.

Weaning from the brace had been initiated after growth cessation and reaching the Risser stage 4 (for girls) or 5 (for boys). At the end of skeletal maturity, the curve stability had been assessed by a radiographic image that was obtained 4 hours after removing the brace. If the curve magnitude had increased to less than 5°, the patient could not wear the brace 4 hours a day. After 4 months, the next radiographic image had been obtained 8 hours after removing the brace. If the curve was stable, the patient had been allowed not to wear the brace for 8 hours a day. This process was reiterated with taking the next radiographic image 12 hours after removing the brace. Again, if the curve was further stable, the patient had been allowed to wear the brace only at night for 6 to 12 months. Afterward, the patient did not wear the brace at all (Fig. 3).

In each visit, the clinical and radiological information of the patients were recorded. An experienced spinal surgeon (MSG) had measured and recorded all the radiographic parameters. Successfully treated patients were followed up for a minimum of 2 years after cessation of brace treatment. We used the modified Lenke (mLenke) categorization method to classify the curve pattern. Sanders et al. first introduced the mLenke classification system in 2007 for the nonsurgical curves. However, they had not clearly expressed the rigidity of the secondary curves. Therefore, Thompson et al. considered a secondary curve as a...
major curve when its size reached ≥ 80% of the major curve. According to them “using the simple mLenke categorizations, we can evaluate the relationship between curve morphology (main thoracic curve vs. main lumbar curve) and brace success in AIS.”

According to the SRS committee, progression is ≥ 6° increase in the curve magnitude. Stabilization refers to a change in curve by ± 5°; and nonprogression is ≥ 6° reduction in the curve. We divided the patients into 2 groups based on treatment success: progressed and nonprogressed groups.

We used the SPSS ver. 17.0 (SPSS Inc., Chicago, IL, USA) to do the statistical analyses. The Kolmogorov-Smirnov test was used to evaluate the data normality. We used the independent sample t-test to compare the patient’s characteristics regarding prebrace Cobb angle, Risser sign, age at initiation of brace treatment and menarche, Cobb angle at cessation of brace treatment, and in-brace curve correction between the progression and nonprogression groups. We used the Spearman correlation coefficient to assess the relationship between the prebrace Cobb angle, age, Risser sign, and in-brace curve correction with outcome of brace treatment in successfully treated patients. Chi-square test was used for categorical variables such as curve pattern and curve magnitude. We used the Friedman test to assess the changes in curve magnitude during the brace treatment process. The significance level was considered 0.05 for all tests.

RESULTS

Sixty AIS (7 boys and 53 girls) with 40° to 55° curves were included in this study. The means of age and scoliosis Cobb angle at the beginning of brace treatment were 12.63 ± 1.44 years old, and 44.93° ± 4.86°, respectively. The average of Risser sign was 1.73 ± 0.57. The average of brace-wearing time was 37.23 ± 20.70 months (16 to 84 months). The average of age at menarche was 12.32 ± 0.84 years old. All the studied patients had had full compliance. The average follow-up duration for the patients successfully treated with brace was 27.92 ± 10.03 months (24 to 60 months). Based on the treatment results, we divided the patients into 2 groups: nonprogressed (n = 26) and progressed (n = 34) groups. If the final Cobb angle had decreased (n = 11) or stabilized (n = 15), the patients were categorized in the nonprogressed group. However, if the curve magnitude had increased (n = 34), they were placed in the progressed group.

Generally, the scoliosis curve had increased in 57% of patients, stabilized in 25%, and improved in 18% of the patients. There was a significant difference between the 2 groups in terms of the curve magnitude at the initiation of brace treatment (Table 1) (p < 0.001). The mean of age at the beginning of brace treatment was significantly higher in the nonprogressed group compared to the progressed group (p < 0.05). In the nonprogressed group, the average duration of wearing the brace was 37.23 ± 20.70 months (16 to 84 months) and the average follow-up period was 27.92 ± 10.03 months (24 to 60 months). At the beginning of brace treatment, there were 8 cases with > 50° curve magnitude. The other 52 cases had a major Cobb angle of 40° to 50°. At the final follow-up session, there were 21 patients with a major Cobb angle of ≤ 40°, 15 patients with a Cobb angle of 40° to 50°, and 24 patients with a Cobb angle of > 50°. Among them, 31 patients had undergone surgery before skeletal maturity. The mean age at the time of surgery was 14.16 ± 1.26 years old (12 to 17 years old). The average Cobb angle at the time of spinal fusion was 54.45° ± 6.78° (40° to 69°).

Fig. 4 summarizes the average of Cobb angle in different phases of brace treatment (at the beginning of brace treatment, weaning time, brace discontinuation, and final follow-up). There were significant differences in Cobb angle values across these phases.

| Table 1. The patient’s characteristics
<table>
<thead>
<tr>
<th>Variable</th>
<th>All patients (n = 60)</th>
<th>Nonprogression (n = 26)</th>
<th>Progression (n = 34)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at initiation of bracing (yr)</td>
<td>12.63 ± 1.44</td>
<td>13.4 ± 1.34</td>
<td>12.32 ± 1.47</td>
<td>0.04</td>
</tr>
<tr>
<td>Age at menarche (yr) (n = 53)</td>
<td>12.32 ± 0.84</td>
<td>12.45 ± 0.85</td>
<td>12.22 ± 0.84</td>
<td>0.33</td>
</tr>
<tr>
<td>Brace wearing time (mo)</td>
<td>37.23 ± 20.70</td>
<td>55.62 ± 13.74</td>
<td>23.18 ± 12.37</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Initial Risser sign</td>
<td>1.73 ± 0.57</td>
<td>1.69 ± 0.61</td>
<td>1.76 ± 0.55</td>
<td>0.60</td>
</tr>
<tr>
<td>Scoliosis Cobb angle at initiation of bracing (°)</td>
<td>44.93 ± 4.84</td>
<td>42.94 ± 3.69</td>
<td>46.47 ± 5.13</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Kyphosis Cobb angle at initiation of bracing (°)</td>
<td>46.30 ± 10.94</td>
<td>42.17 ± 9.79</td>
<td>49.06 ± 11.04</td>
<td>0.09</td>
</tr>
<tr>
<td>Scoliosis Cobb angle at cessation of bracing (°)</td>
<td>47.29 ± 10.58</td>
<td>38.15 ± 6.89</td>
<td>54.48 ± 6.68</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>In-brace curve correction (%)</td>
<td>15.73 ± 13.78</td>
<td>24.79 ± 16.40</td>
<td>8.80 ± 4.64</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation.
Brace Treatment of Large Scoliosis Curves

Razeghinezhad R, et al.

There was no significant association between the age of beginning to use the brace and the final Cobb angle of non-progressed group (Table 2). However, in-brace curve correction and initial Risser sign had a significant correlation with curve magnitude at the final follow-up (p < 0.05). The progression rate was higher in mLenke thoracic curves compared to mLenke lumbar curves (Table 3).

There were 34 cases (56.6%) with main thoracic curve, 15 (25%) with main thoracolumbar curve, and 11 (18.3%) with main lumbar curve. For the cases with double curves, the largest curve was considered for statistical analysis. The least curve progression was in those with 40° to 45° curves and the most in those with 51° to 55° curves.

**DISCUSSION**

Natural history studies on adolescents with idiopathic scoliosis suggest that the progression rate is high in severe curves (≥ 40°). Therefore, the physicians’ advice for such cases is surgery. However, some patients completely refuse to do surgery and insist on using a brace. Our main finding is that the Milwaukee brace has 43% overall success rate for AIS cases with 40° to 55° Cobb angles. However, the subgroup analysis based on the curve severity reveals that the success rate is higher (57%) for 40° to 45° curves. This is consistent with the findings of Verhofste et al. The progression rate was only 7% to 10% if the patients wore their braces for a minimum of 12.9 hours per day. The success rate of brace treatment for AIS cases with curve magnitude of 20° to 40° has been 64% to 77% in 3.5 to 8 years follow-up periods. The Milwaukee brace is the first approved orthosis in halting the further progression of AIS curves worldwide. The largest case series study on its effectiveness on AIS was conducted by Lonstein and Winter that involved 1,020 cases with 20° and 39° Cobb angle. They observed that this brace has 22% failure rate in treating AIS. However, its effect has not been thoroughly studied for patients with more severe curves (≥ 40°). This study evaluated the appropriateness of the Milwaukee brace for patients with ≥ 40° curves and its use in clinical decision-making.

The first report on brace effectiveness on AIS with ≥ 45° curves was published by Negrini et al. In their study, curve progression up to > 50° occurred in only 2 patients. These findings provide valuable information about brace effectiveness for patients who avoid surgery. In this study, there were 16 patients with a low-risk of curve progression (Risser sign of 3 or 4) and 12 patients with a high-risk of curve progression (Risser 0–2). More...
over, only 14 patients cooperated until the final follow-up of 2 years after cessation of brace treatment. Lusini et al.\textsuperscript{10} studied 57 AIS patients with $>45^\circ$ curve and Risser sign 0–4 who received Sforzesco brace treatment. Their results revealed that brace treatment has 23.5% failure rate. However, the number of patients who had undergone surgery before skeletal maturity was not reported. Furthermore, in 2 other studies, the success rate of bracing has been $>90\%$.\textsuperscript{9,12} The progression rate in our study was significantly higher than these studies.

In our study, all cases had a Risser grade of 0–2 at the beginning of bracing. They were followed up until the end of the skeletal maturity or spinal fusion. We found out that all patients were very motivated to use the braces because of their fear of surgery. We did the radiographic evaluations and brace check-ups every 4 to 6 months. Nonetheless, the curve magnitude increased by more than 6° in 57% of the patients. In this study, there were 7 cases of $<50^\circ$ major Cobb angle at the time of spinal fusion. A key factor on brace effectiveness in AIS is the flexibility across the scoliosis curves, where sufficient flexibility affords a satisfactory in-brace curve correction.\textsuperscript{25} For these cases, flexibility across the scoliosis curves was insufficient and the degrees of in-brace curve corrections were minimal (with a mean of 9.29%, ranging between 6% and 12%). Therefore, they underwent spinal fusion.

Recently, Zhu et al.\textsuperscript{13} reported the data of 54 AIS patients with $40^\circ$ to $50^\circ$ curves who were treated with a Boston bracing system or a Milwaukee brace. Our results are consistent with the findings of Zhu et al. in terms of the number of cases who had undergone spinal fusion before puberty. They had 35% success rate for bracing. In our case series, we found out that in the non-progressed group, the curve magnitude had significantly reduced at all stages of brace treatment compared to the prebrace measures. The greatest in-brace curve correction occurred at the weaning phase of treatment (25%). At the final follow-up, 12% of the curve magnitude had increased by more than 5°.

The patient’s age at the beginning of brace treatment, Cobb angle, curve location, Risser stage, and in-brace correction are important factors for predicting treatment effectiveness in AIS.\textsuperscript{26-28} In our study, although the mean of age was noticeably different between the progressed and nonprogressed groups at the beginning of brace treatment, there was no significant relationship between the prebrace age and brace effectiveness. This is consistent with the findings of Zhu et al.\textsuperscript{13}

We found out that the prebrace Cobb angle in the nonprogressed group was significantly lower than the progressed group. Furthermore, there was a significant relationship between the in-brace curve correction and initial Risser sign, and treatment effectiveness. These results suggested that prebrace curve magnitude, initial Risser sign and in-brace curve correction are prognostic factors for the effectiveness of brace treatment in AIS.\textsuperscript{26,29} Katz and Durrani\textsuperscript{29} observed that a threshold of 25% is required for in-brace correction to anticipate the positive long-term results of bracing on AIS cases with large curves. According to the findings of Zhang et al.,\textsuperscript{27} the initial Risser sign is not a strong prognostic factor for brace treatment outcome in AIS unless it is considered with other parameters such as the initial curve magnitude, degrees of vertebral rotation, and the spinal height.

Thompson et al.\textsuperscript{30} found out that curve type is significantly associated with brace treatment success. Accordingly, they saw that the curve progression rate was greater in cases with major thoracic curves than in cases with major lumbar curves. In our study, most of the cases had a major mLenke thoracic curves pattern (57%). Among them, the curves of 20 patients (59%) progressed to $>50^\circ$. However, Van den Bogaart et al.\textsuperscript{32} found no significant relationship between curve patterns and treatment effectiveness.

Firstly, we had no control group (untreated cases). So, we cannot compare our outcomes with the natural history of the AIS cases with large curves ($>40^\circ$). Secondly, the number of male patients was too low to compare the outcome of brace treatment in terms of sex differences. A larger sample size is required to compare the effectiveness of brace treatment between the males and females with AIS with $>40^\circ$ curves. Thirdly, the brace compliance was evaluated subjectively (reported by patients) and examining the brace’s appearance. To measure the brace compliance objectively, reliable temperature or pressure data loggers are used which offer researchers more accurate information on in-brace pressure values and adherence of patients to the brace.\textsuperscript{31,32} Due to the retrospective nature of our study, measuring the brace wear compliance objectively was not possible. However, at each follow-up during brace treatment, the treating physician had recorded the average hours of wearing the brace by evaluating the brace appearance and asking the patients and their parents.

Fourthly, it is important to consider patients’ health-related quality of life as the clinical and radiological parameters to evaluate the impact of scoliosis and brace treatment.\textsuperscript{33} We found out that all patients tolerated their braces well during the treatment periods. However, because of the retrospective nature of the study, we cannot evaluate the health-related quality of life of the studied patients. Further research is needed to evaluate the
impact of brace treatment on health-related quality of life of patients with > 40° scoliosis curves. Lastly, our results were limited to the available medical history in the clinical profiles. Still, the clinical examinations of all patients had been done in a uniform fashion.

CONCLUSIONS

Brace treatment seems to have a lower success rate in AIS with larger curves (40°–55°) than those with moderate curves (< 40°). Still, if the patient's family refuses to do surgery, the physician can help them to make better decisions.

CONFLICT OF INTEREST

The authors have nothing to disclose.

ACKNOWLEDGMENTS

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REFERENCES

Is There a Role for Conservative Treatment for Large Curvatures in Patients With Adolescent Idiopathic Scoliosis?: Commentary on “The Effect of Brace Treatment on Large Curves of 40° to 55° in Adolescents With Idiopathic Scoliosis Who Have Avoided Surgery: A Retrospective Cohort Study”

Adolescent idiopathic scoliosis (AIS) is a condition that has been treated by spine surgeons around the world for many years. With a good understanding of the natural history and modern day successes in anaesthesia, neuromonitoring, and instrumentation, most surgeons would recommend surgeries for curves of over 45° to 50°. However, a gap exists for those curves that are over 40° that have not quite reached the indications for surgery and also for those who are not willing to accept surgical treatment.

The article by Razeghinezhad et al. on “The Effect of Brace Treatment on Large Curves of 40° to 55° in Adolescents With Idiopathic Scoliosis Who Have Avoided Surgery: A Retrospective Cohort Study” is a timely reminder that other options are available. This is quite a sizable study with 60 subjects, all of which were skeletally immature as indicated by a Risser sign of 0 to 2, and all were uniformly treated using one type of brace. They showed in this study that some patients may still benefit from bracing and that the indicators of response to brace treatment include older chronologic age at brace initiation, a longer duration of brace wear, smaller Cobb angle at presentation, and higher in-brace correction (indicating more flexible curves). They were able to show that 43% of their subjects either did not progress or even had some improvement. Their results are in line with other studies of a similar nature.

They showed in this study that some patients may still benefit from bracing and that the indicators of response to brace treatment include older chronologic age at brace initiation, a longer duration of brace wear, smaller Cobb angle at presentation, and higher in-brace correction (indicating more flexible curves). They were able to show that 43% of their subjects either did not progress or even had some improvement. Their results are in line with other studies of a similar nature.

A weakness in this study was that daily brace wear duration was quantified based on patient self-report, as this is recognised not to be accurate. Another issue is the use of Risser sign as a maturity indicator. While this is commonly quoted, most spine surgeons are aware of the deficiencies of the Risser sign, as there could be inconsistencies between the left and right sides.
right iliac crest, and also the location of first appearance of the iliac wing apophysis along the iliac crest, making grading difficult. Indeed, this may explain why the authors found chronologic age to be marginally correlated with nonprogression, since these subjects may be more skeletally mature than the Risser sign may suggest.

While it was consistent that Milwaukee braces were used for all patients, in my institution, we have tended to treat most AIS with thoracolumbosacral orthoses (TLSO or Boston type braces) which can be easily worn underneath clothing and therefore cosmetically more acceptable. Milwaukee brace is reserved for those with high thoracic curves whose apex is above T7. Even then, our own experience is that compliance with Milwaukee braces is considerably worse than TLSO.

Overall, the authors should be commended with carrying out this study and is a timely reminder of the importance of good brace treatment.

**CONFLICT OF INTEREST**

The author has nothing to disclose.

**REFERENCE**

Characteristics and Risk Factors of Rod Fracture Following Adult Spinal Deformity Surgery: A Systematic Review and Meta-Analysis

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Objective: The aim of study is to investigate the features and risk factors of rod fracture (RF) following adult spinal deformity (ASD) surgery.

Methods: We searched the PubMed, Embase, Web of Science, and Cochrane Library databases to identify relevant studies. Patient’s data including age, sex, body mass index (BMI), previous spine surgery, pedicle subtraction osteotomy (PSO), interbody fusion, fusion to the pelvis, smoking history, preoperative sagittal vertical axis (SVA), preoperative pelvic tilt (PT), preoperative pelvic incidence minus lumbar lordosis, preoperative thoracic kyphosis (TK), and change in the SVA were documented. Comparable factors were evaluated using odds ratio (OR) and weighted mean difference (WMD) with 95% confidence interval (CI).

Results: Seven studies were included. The overall incidence of RF following ASD surgery was 12%. Advanced age (WMD, 2.8; 95% CI, 1.01–4.59; p < 0.002), higher BMI (WMD, 1.98; 95% CI, 0.65–3.31; p = 0.004), previous spine surgery (OR, 1.47; 95% CI, 1.05–2.04; p = 0.02), PSO (OR, 2.28; 95% CI, 1.62–3.19; p < 0.0001), a larger preoperative PT (WMD, 6.17; 95% CI, 3.55–8.97; p < 0.0001), and a larger preoperative TK (WMD, 5.19; 95% CI, 1.41–8.98; p = 0.007) were identified as risk factors for incidence of RF.

Conclusion: The incidence of RF in patients following ASD surgery was 12%. Advanced age, higher BMI, previous spine surgery, and PSO were significantly associated with an increased occurrence of RF. A larger preoperative PT and TK were also identified as risk factors for occurrence of RF following ASD surgery.

Keywords: Rod fracture, Meta-analysis, Adult spinal deformity, Surgery, Risk factors, Incidence

INTRODUCTION

Compared with other spinal diseases, adult spinal deformity (ASD) has a significant impact on a patient’s quality of life. Treatment of ASD has evolved significantly over the past decade and involves improved spinal instrumentation, surgical techniques, and perioperative management. Thus far, the data shows that selected adults with spinal deformities have great potential for improvement following surgical treatment; however, the overall rate of complications is still high, indicating scope for improvement. Mechanical complications that may occur following ASD surgery include proximal junctional kyphosis (PJK), proximal junctional failure (PJF), distal junctional kyphosis, distal junctional failure, rod fracture (RF), and other implant-related complications. RF is a frequent implant-related complication of ASD surgery. It causes significant pain and deterioration of spinal alignment, which can then adversely affect clinical outcomes and the patient’s mental health. The incidence of RF
following ASD surgery in symptomatic RF patients has been reported by Smith et al. as 6.8%. Another study by Smith et al. reported that 9% of the patients who underwent ASD surgery developed RF at a mean of 14.7 months postsurgery, and 22% of the patients who underwent pedicle subtraction osteotomy (PSO) developed RF by the their 1-year follow-up. To date, extensive research has been conducted on PJK and PJF, but research on RF is lacking. To the best of our knowledge, no study has summarized the characteristics of RF, which is essential for understanding this complication. Through this systematic review and meta-analysis, we analyzed the characteristics and risk factors of RF following ASD surgery, in order to expand the literature available on this complication.

**MATERIALS AND METHODS**

1. **Data Sources and Searches**
   We searched the PubMed, Embase, Web of Science, and Cochrane Library databases to identify differences between the groups with and without RFs and to investigate risk factors for RF in patients who underwent ASD surgery. The Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines were followed. The search terms included: “adult spinal deformity” OR “ASD” AND “rod fracture” OR “RF”. The language was restricted to English, and only published articles were considered. The studies were then screened by 2 authors independently based on the inclusion and exclusion criteria, and data on the risk factors were collected from the eligible studies. We also searched the reference lists of the selected studies, reviews, or comments to identify any other relevant studies.

2. **Inclusion and Exclusion Criteria**
   To assess the suitability of a study, the Population Intervention, Comparative Results and Study Design methodology and PRISMA guidelines were applied. The inclusion criteria for our meta-analysis were: (1) the patient was diagnosed with ASD and underwent ASD surgery, (2) had more than 1-year follow-up, (3) ASD patients with RF, (4) retrospective or prospective studies comparing risk factors between patients with and without RFs, and (5) sufficient data was available (the mean ± standard deviations of continuous variables and the number of count variables). The exclusion criteria were as follows: (1) ASD patients resulting from secondary disease such as autoimmune diseases, infectious disease, tumors, or other pathological conditions, and adolescent idiopathic scoliosis; (2) available data was not reported; and (3) duplicate reports and review articles.

3. **Data Extraction**
   Data were extracted from eligible studies by 2 authors (SHN, DKC) according to the inclusion and exclusion criteria. In case of discrepancies, consensus was reached through discussion. The extracted data included information on study design, patient characteristics, sample size, detailed follow-up information, intervention time, and results. All relevant data reported in each eligible study, including the demographic factors, surgical variables, and the preoperative and postoperative radiological parameters, were collected and analyzed, and the risk factors for RF were investigated. Radiological parameters at the time of follow-up were analyzed to detect the characteristics of RF in ASD patients.

4. **Quality Assessment**
   The Newcastle-Ottawa Quality Assessment Scale (NOQAS) was used to assess the quality of each included study, as most were nonrandom comparative studies. The NOQAS consists of 3 major assessment categories (selection, comparability, and exposure). A maximum of 9 stars could be assigned to a study, and more than 6 stars in the final score indicated high quality.

5. **Statistical Analysis**
   This meta-analysis employed Review Manager Software 5.3 (Cochrane Collaboration, Oxford, UK). Funnel plots were marked using Meta Essentials. Effect size of the continuous data was measured using weighted mean differences (WMDs) and the corresponding 95% confidence interval (CI). Effect size of the variable data was calculated using a 95% CI corresponding to an odds ratio (OR). Heterogeneity among studies was evaluated according to the I² index. If there was serious heterogeneity between studies, pooled effect size was calculated using a random-effect model (p < 0.05 or I² > 50%); otherwise, a fixed-effect model was applied. A p-value of < 0.05 was considered significant.

**RESULTS**

1. **Studies Included**
   A total of 191 studies were originally found in the PubMed (91), Embase (60), Web of Science (38), and Cochrane Library (2) databases. Ninety-nine studies remained after duplicate trials were excluded. After reviewing the titles and summaries, 20 studies were removed, and 55 studies were excluded in accordance with the exclusion criteria. Ten studies were eliminated due to inadequate data. Finally, 7 studies were selected for this meta-analysis. Fig. 1 shows the document selection process. The
follow-up period of all studies was more than 12 months. The study characteristics are summarized in Table 1.

2. Quality Assessment of the Studies

Based on the NOQAS, 6 studies scored 8 points, and 1 study scored 7 points (Table 2). Thus, the quality of each study was relatively high.

3. Incidence of RF in ASD

A total of 209 patients developed RF following ASD surgery. Based on the 7 studies, the overall incidence of RF following ASD surgery was 12%. As presented in 6 papers, RF developed after a mean time of 23.2 months after ASD surgery.

Fig. 1. Flow chart of study selection process.

Table 1. Characteristics of studies included in the meta-analysis

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Country</th>
<th>Type of scoliosis</th>
<th>Study period</th>
<th>Rod Fx.</th>
<th>No rod Fx.</th>
<th>Mean age (yr)</th>
<th>Mean fusion level</th>
<th>Mean period from surgery to rod fracture (mo)</th>
<th>F/U period (mo)</th>
<th>Study type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith et al.⁴</td>
<td>2012</td>
<td>USA</td>
<td>ASD</td>
<td>2004–2010</td>
<td>30</td>
<td>412</td>
<td>Rod Fx. 61 (29–79)</td>
<td>ND</td>
<td>15.7 (2–73)</td>
<td>≥ 12 Retrospective</td>
<td></td>
</tr>
<tr>
<td>Smith et al.⁵</td>
<td>2014</td>
<td>USA</td>
<td>ASD</td>
<td>ND</td>
<td>18</td>
<td>182</td>
<td>54.8 ± 15.8</td>
<td>12 ± 4</td>
<td>14.7 (3–27)</td>
<td>≥ 12 Prospective</td>
<td></td>
</tr>
<tr>
<td>Barton et al.²</td>
<td>2015</td>
<td>USA</td>
<td>ASD</td>
<td>ND</td>
<td>7</td>
<td>68</td>
<td>59 ± 12.9</td>
<td>ND</td>
<td>20 (11–58)</td>
<td>≥ 35 Retrospective</td>
<td></td>
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<tr>
<td>Daniels et al.⁸</td>
<td>2018</td>
<td>USA</td>
<td>ASD</td>
<td>ND</td>
<td>38</td>
<td>364</td>
<td>57.4 ± 14.8</td>
<td>11.1 ± 4.1</td>
<td>ND</td>
<td>≥ 24 Retrospective</td>
<td></td>
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<tr>
<td>Lertudomphonwanit et al.⁷</td>
<td>2018</td>
<td>USA</td>
<td>ASD</td>
<td>2004–2014</td>
<td>97</td>
<td>429</td>
<td>58.9 ± 9.2</td>
<td>14 (6–17)</td>
<td>39.6 (6–121)</td>
<td>≥ 24 Retrospective</td>
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<tr>
<td>Zhao et al.¹⁴</td>
<td>2019</td>
<td>China</td>
<td>ASD</td>
<td>2009–2017</td>
<td>10</td>
<td>20</td>
<td>ND</td>
<td>ND</td>
<td>22.1 (6–73)</td>
<td>≥ 12 Retrospective</td>
<td></td>
</tr>
<tr>
<td>Jung et al.²¹</td>
<td>2020</td>
<td>Korea</td>
<td>ASD</td>
<td>2012–2018</td>
<td>9</td>
<td>67</td>
<td>68.7</td>
<td>ND</td>
<td>27.3 (20–42)</td>
<td>≥ 12 Retrospective</td>
<td></td>
</tr>
</tbody>
</table>

Fx., fracture; F/U, follow-up; ASD, adult spinal deformity; ND, not described.

Table 2. Quality assessment of included studies in the meta-analysis according to Newcastle-Ottawa Quality Assessment Scale

<table>
<thead>
<tr>
<th>Study</th>
<th>Selection</th>
<th>Comparability</th>
<th>Exposure</th>
<th>Total score</th>
</tr>
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<tr>
<td>Smith et al.⁴</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>8</td>
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<tr>
<td>Smith et al.⁵</td>
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<td>2</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Barton et al.²</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Daniels et al.⁸</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>8</td>
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<tr>
<td>Lertudomphonwanit et al.⁷</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>8</td>
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<tr>
<td>Zhao et al.¹⁴</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Jung et al.²¹</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>8</td>
</tr>
</tbody>
</table>

https://doi.org/10.14245/ns.2040832.416
4. Risk Factors for RF in ASD

Among the demographic risk factors, advanced age (WMD, 2.8; 95% CI, 1.01–4.59; p < 0.002), higher body mass index (BMI) (WMD, 1.98; 95% CI, 0.65–3.31; p = 0.004), and prior spinal surgery (OR, 1.47; 95% CI, 1.05–2.04; p = 0.02) were significantly associated with RF (Figs. 2–4). Among the surgical risk factors, PSO (OR, 2.28; 95% CI, 1.62–3.19; p < 0.0001) was significantly associated with RF (Fig. 5). Among the radiologic risk factors, larger preoperative pelvic tilt (PT) (WMD, 6.17; 95% CI, 3.55–8.97; p < 0.00001) and larger preoperative thoracic kyphosis (TK) (WMD, 5.19; 95% CI, 1.41–8.98; p = 0.007) were identified as risk factors for RF (Figs. 6, 7). Sex, the number of fused segments, osteoporosis/osteopenia, interbody fusion, fusion to pelvis, rod diameter, rod materials, smoking history, preoperative sagittal vertical axis (SVA), change of SVA, and preoperative pelvic incidence minus lumbar lordosis (PI–LL) did not differ significantly between the groups with and without RF. Table 3 shows the number of studies that reported each risk factor and the results of our forest plot.

5. Publication Bias

All funnel plots were symmetric, indicating an absence of significant publication bias among the studies. The Egger test results for each risk factors were age (p = 0.8803), BMI (p = 0.9248), prior spine surgery (p = 0.0526), PSO (p = 0.2636), preoperative PT (p = 0.7836), and preoperative TK (p = 0.7382). These results show that there is no real evidence of publication bias in the data set.
Rod Fracture Following Adult Spinal Deformity Surgery

Noh SH, et al.

DISCUSSION

ASD surgery techniques have advanced in the past decade. The results of ASD surgery are constantly improving, but a high proportion of major complications following this surgery still persist. This meta-analysis was performed to evaluate the characteristics and risk factors of RF following ASD surgery.

Among the demographic factors, age, BMI, and previous spinal surgery were the risk factors associated with RF. Smith et al.5 Lertudomphonwanit et al.7 and Daniels et al.8 reported that age and BMI had a statistically significant effect on the incidence of RF. Smith et al.3 also reported that previous spinal surgery was significantly associated with RF. In our meta-analysis, advanced age and high BMI were significantly associated with a high incidence of RF. Patients who had undergone previous spine surgeries were also more likely to develop RF (OR, 1.47; 95% CI, 1.05–2.04; p = 0.02). Among the demographic factors, sex, bone mineral density (BMD), and smoking history were not significantly associated with the incidence of RF. And Charlson Comorbidity Index (CCI) was also not statistically significant.

Fig. 5. Forest plot showing the relationship between pedicle subtraction osteotomy and rod fracture occurrence. df, degrees of freedom; CI, confidence interval.

Fig. 6. Forest plot showing the relationship between preoperative pelvic tilt and rod fracture occurrence. df, degrees of freedom; CI, confidence interval.

Fig. 7. Forest plot showing the relationship between preoperative thoracic kyphosis and rod fracture occurrence. SD, standard deviation; CI, confidence interval; df, degrees of freedom.

factor for PJF in ASD surgery. These factors are not statistically related to RF in each article, but are related to other mechanical complications such as pseudoarthrosis and other implant-related problems. Therefore, it is necessary to quit smoking or increase BMD in ASD surgery. And Yilgor et al. created a Global Alignment and Proportion score (GAP) system that predicts mechanical complication after ASD surgery, where sacral slope and lower lumbar lordosis distribution were reported as risk factors for mechanical complication. And Noh et al. made GAPB system in which BMI and BMD were added to the GAP system, and reported that the higher the BMI and the lower the BMD, as well as the GAP score, the greater the risk of mechanical complications. Therefore, it is difficult to say that the ASD surgery was successful when there was no RF. Therefore, the efforts are needed to reduce mechanical complications after ASD surgery.

Among the surgical factors, PSO and a larger number of fused segments had statistically significant influences on RF. These results are in accordance with several studies that reported a statistically significant influence of PSO on RF. Smith et al. reported that RF occurred in 22.0% of the patients who underwent PSO and in 4.7% of those who did not; they also stated that PSO is a powerful way to drastically correct discrepancy in the sagittal spinopelvic alignment and that this added force is likely to contribute to an increase in the incidence of RF in these cases. Moreover, Bridwell et al. and Upadhyaya et al. have documented cases of RF associated with PSO. During PSO, an interbody fusion is performed to provide anterior support or multiple rods are inserted at the PSO site to reduce the chances of RF occurrence. In the study by Lertudomphonwanit et al., the proportion of RF patients who underwent PSO was high, but the difference in the RF incidence was not statistically significant. This was because multirod structures were used at the osteotomy site, interbody fusion was performed at the segment adjacent to the osteotomy site, and high doses of recombinant human bone morphogenetic protein-2 (rhBMP-2) and sufficient autologous bone grafts were used. Lertudomphonwanit et al. reported that a longer fused segment was associated with RF occurrence. Specifically, for patients receiving a high dose of rhBMP-2 per level fused, the total number of levels fused was not a significant risk factor for RF; but for patients receiving a low dose of rhBMP-2 per level fused, it was a significant risk factor. In our meta-analysis, PSO (OR, 2.28; 95% CI, 1.62–3.19; p < 0.0001) was shown to be a risk factor of RF. However, a longer fused segment (WMD, 1.01; 95% CI, 2.70 to 4.72; p = 0.59) was not significantly associated with RF.

Among the intraoperative factors, interbody fusion, cross link, fusion to the pelvis, and approach to interbody fusion were not significantly associated with the incidence of RF. Regarding rod diameter, Smith et al., Daniels et al., and Lertudomphonwanit et al. individually compared rods with diameters of 5.5 mm, 6.0 mm, and 6.35 mm. The 5.5-mm rod diameter induced more RF, but the difference in the RF incidence was not statistically significant. This was because multirod structures were used at the osteotomy site, and high doses of recombinant human bone morphogenetic protein-2 (rhBMP-2) and sufficient autologous bone grafts were used. Lertudomphonwanit et al. reported that a longer fused segment was associated with RF occurrence. Specifically, for patients receiving a high dose of rhBMP-2 per level fused, the total number of levels fused was not a significant risk factor for RF; but for patients receiving a low dose of rhBMP-2 per level fused, it was a significant risk factor. In our meta-analysis, PSO (OR, 2.28; 95% CI, 1.62–3.19; p < 0.0001) was shown to be a risk factor of RF. However, a longer fused segment (WMD, 1.01; 95% CI, 2.70 to 4.72; p = 0.59) was not significantly associated with RF.

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of cobalt-chromium caused more RF, but this result was also not statistically significant in our meta-analysis.

Among the radiological factors, larger preoperative PT and TK had a statistically significant influence on occurrence of RF. A great amount of force is applied to the rod to correct a large preoperative PT and TK. Thus, inferior radiological parameters before the surgery may cause an increased incidence of RF. In our meta-analysis, larger preoperative PT (WMD, 6.17; 95% CI, 3.55–8.97; p < 0.00001) and larger preoperative TK (WMD, 5.19; 95% CI, 1.41–8.98; p = 0.007) were the risk factors associated with RF. We found preoperative SVA, change of SVA, and PI–LL were not significantly associated with RF.

Several papers have proposed methods to reduce RF. Gupta et al. recommended the 4-rod technique for the PSO site. The point of maximum stress on the body is at its apex, where the spine becomes unstable by osteotomy. As such, RF usually occurs at the osteotomy site. The advantage of the 4-rod technique is that it does not require a surgeon to bend the rod sharply at the PSO site over the length of the fusion. This technique also helps to significantly reduce the potential for premature RF due to biomechanical damage of the rod. Banno et al. reported that multirod structure use improved stability compared to use of the standard 2-rod structure, which was effective in preventing implant failure and symptomatic pseudoarthrosis.

There were some limitations to this meta-analysis. First, only 7 matching studies were selected, and most of them were retrospective, which may have affected the reliability of our results. Second, patients, surgical adaptations, and techniques may have varied in each center. Finally, other factors commonly considered, such as rod diameter, rod material, access to intervertebral fusion, CCI were not considered in the analysis due to insufficient data. Despite these limitations, the results from this study will broaden the understanding of RF and provide potential guidance for the prevention of RF after ASD surgery. However, further studies are required to form a comprehensive understanding of RF incidence and risk factors among patients with ASD.

CONCLUSION

The incidence of RF following ASD surgery was 12%. Advanced age, higher BMI, previous spine surgery, and PSO were significantly associated with an increased occurrence of RF. Larger preoperative PT and TK were also identified as risk factors for RF following ASD surgery. Surgeons should ensure they understand these risk factors before performing ASD surgery.

CONFLICT OF INTEREST

The authors have nothing to disclose.

REFERENCES


Commentary on “Characteristics and Risk Factors of Rod Fracture Following Adult Spinal Deformity Surgery: A Systematic Review and Meta-Analysis”

Junseok Bae
Department of Neurosurgery, Wooridul Spine Hospital, Seoul, Korea

Rod fracture is not an uncommon postoperative complication after spinal deformity surgery.1 The authors performed a well-established systemic review to analyze rod fracture characteristics and risk factors in this paper.2 Thus, it is meaningful, up-to-date research for summarizing features of rod fracture, which I believe will be very helpful for readerships.

As I read this article and the results, I could learn a few critical things about rod fracture. First, their results showed a 12% rod fracture out of 209 enrolled patients after a mean of 23.2 months after index surgery. Rod fracture is a relatively late complication, and surgeons should pay attention to this complication.1 Adult spinal deformity correction is a complicated surgery, and postoperative patient care should be time-dependent. The early postoperative period within the first year after surgery is vulnerable for patients. There are many tasks to care for within the first year; time takes for solid fusion, high risk of early proximal junctional failure, rehabilitation, and complaining of surgical burdens. Surgeons may be less intensive in treating after 1–2 years later. However, 12% of risk complications is not too minimal to lose attention. Between 1–2 years after surgery, patients are much mobilized and adapted to their new lifestyle. Repetitive motion with daily activity causes stress fracture of rod in case of high-stress concentration like pedicle subtraction osteotomy (PSO).

Interestingly, only PSO was a significant surgical risk factor. Fusion level, rod diameter, rod material, change of sagittal parameters were not effective between groups with and without rod fracture. Although rod diameter and material did not show statistical significance in their meta-analysis, authors reviewed the importance of multiple rod construct in preventing the complication.3 As the authors’ insightful discussion of the radiologic risk factor, a significant amount of force applied to the rod to correct deformity increases the risk of rod fracture. This study implies some intraoperative recommendations to prevent rod fracture. First, it is necessary to avoid sharp angular rod bends. Repetitive rod bending can crack the rod cortex, causing susceptibility to stress fracture. Second, multiple rods construct in corrective surgery with PSO is an effective option other than strong or thick rods.

The authors showed demographic risk factors such as advanced age, higher body mass index (BMI), and prior spinal surgery, of which only BMI is adjustable with a weighted mean difference of BMI of 1.98. Therefore, weight control to reduce BMI before and after surgery...
is necessary to decrease the risk of rod fracture, especially for patients whose radiological and demographic factors are susceptible.

Adult spinal deformity is a complicated disease category that is difficult to describe in one word. Each patient has different individual deformities and baseline demographic and radiological variables. Various surgical endeavors are required for each patient, and additional postoperative care is needed depending on the period. Thanks to the authors’ extensive review of previous research, we can watch for this famous late complication’s nature and learn more about prevention and adult spinal deformity patient care.

CONFLICT OF INTEREST

The author has nothing to disclose.

REFERENCES

Seung-Jae Hyun¹, Lawrence G. Lenke², Yongju Kim³, Keith H. Bridwell⁴, Meghan Cerpa², Kathy M. Blanke⁴

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⁴Department of Orthopaedic Surgery, Washington University School of Medicine, St. Louis, MO, USA

Objective: To compare and identify risk factors for distal adding-on (AO) or distal junctional kyphosis (DJK) in adolescent idiopathic scoliosis (AIS) treated by anterior- (ASF) and posterior spinal fusion (PSF) to L3.

Methods: AIS patients undergoing ASF versus PSF to L3 from 2000–2010 were analyzed. Distal AO and DJK were deemed poor radiographic results. New stable (SV) and neutral vertebra (NV) scores were defined for this study. The total stability (TS) score was the sum of the SV and NV scores.

Results: Twenty of 42 (ASF group: 47.6%) and 8 of 72 patients (PSF group: 11.1%) showed poor radiographic outcome. Fused vertebrae, correction rate of main curve, coronal reduction rate of L3 were significantly higher in PSF group. Multiple logistic regression results indicated that preoperative SV-3 at L3 in standing and side benders (odds ratio [OR], 2.7 and 3.7, respectively), TS score -5, -6 at L3 (OR, 4.9), rigid disc at L3–4 (OR, 3.7), lowest instrumented vertebra (LIV) rotation > 15° (OR, 3.3), LIV deviation > 2 cm from center sacral vertical line (OR, 3.1) and ASF (OR, 13.4; p < 0.001) were independent predictive factors. There was significant improvement of the Scoliosis Research Society (SRS)-22 average scores only in PSF group. Furthermore, the ultimate scores of PSF group were significantly superior to ASF group.

Conclusion: The prevalence of AO or DJK at ultimate follow-up for AIS with LIV at L3 was significantly higher in ASF group. Ultimate SRS-22 scores were significantly better in PSF group.

Keywords: Adolescent idiopathic scoliosis, Anterior spinal fusion, Posterior spinal fusion, Lowest instrumented vertebra, Adding-on, Distal junctional kyphosis

INTRODUCTION

Selection of fusion levels is the most important single factor that influences the surgical result following adolescent idiopathic scoliosis (AIS) surgery.¹ Inappropriately choosing the extent of fusion may result in under- or overcorrection of the major and compensatory curves. The under- or overcorrection may result in failure to stabilize the index curve and can aggravate
the unfused curve and cause trunk imbalance and decompensation. Although surgical correction appears to be relatively straightforward in AIS patients, inadequate selection of fusion levels may cause adding-on (AO) phenomenon and distal junctional kyphosis (DJK).\textsuperscript{1,4} Lowest instrumented vertebra (LIV) with rotation more than Nash–Moe grade II and significant disc angulation below LIV postoperatively and is known as the “adding-on phenomenon.”\textsuperscript{22} Furthermore, for distal fusion level selection in major lumbar and thoracolumbar curves, the selection between L3 or L4 is a debatable issue. DJK is a junctional angle >10° measuring or at least 10° more than the preoperative value. These poor radiographic results including AO and DJK should be avoided even though we do not have a long-term follow-up study. However, few studies have focused on the distal junctional problem, when LIV stopped at L3 for AIS corrective surgery. Furthermore, there has been no comparative study focusing on the issue between anterior- (ASF) and posterior spinal fusion (PSF) stopping at L3. The purpose of this study was to compare the prevalence and identify risk factors for distal AO or DJK in AIS patients treated by ASF and PSF to L3.

**MATERIALS AND METHODS**

1. Patient Population

Inclusion criteria were as follows: (1) any AIS patients treated with ASF or PSF; (2) the LIV at L3, and (3) with a minimum 2-year follow-up. Patients with neuromuscular disease or congenital spinal deformity and those who underwent revision surgery were excluded. A hundred and fourteen consecutive AIS patients between 2000 and 2010 who met the inclusion criteria were identified from a single institution database. The 114 patients consisted of 104 girls and 10 boys. The mean age at surgery was 14.7 years (range, 10.0–19.6 years). The average follow-up duration was 3.2 years (range, 2.0–10.2 years). All enrolled patients were surgically treated by 2 senior attending surgeons (LGL and KHB).

2. Surgical Details for ASF or PSF

The indication of which patient should be operated from anterior or who from posterior is complex. This study includes patients having LIV at L3. ASF was chosen only for patients who have Lenke 5 or 6 curve, meanwhile PSF for all kinds of Lenke types. Determination for surgical approach was also based on surgeons preference. ASF was chosen for patients who want to preserve their lumbar motion segment maximally for their major such as dancer, athlete, etc. Patients who had prior chest- or abdominal surgery underwent PSF. As pedicle screw system has developed, the frequency for PSF selection has increased.

For PSF, patients were flipped to a prone position on the Jackson table. Intraoperative neurophysiologic monitoring was set up. Every level facetectomy was done. Pedicle screws or sublaminar/pedicle hooks were inserted for segmental instrumentation. After screw placement, various deformity correction maneuvers including posterior column osteotomies, translation technique, rod derotation, and direct vertebral rotation were utilized. Then, balance of the shoulders and junctional discs was evaluated by intraoperative portable whole spine radiographs. Sequentially PSF was performed by abundant bone grafting using local bone with or without allograft bone chips.

For ASF, patients were flipped to lateral decubitus position on the operative table. Intraoperative neurophysiologic monitoring was set up. Every level discectomy was done. Mostly, Harm’s cage with bone graft material was inserted into interbody space for bone fusion and restoring lumbar lordosis. Bicortical vertebral body screws were inserted for segmental instrumentation. After screw placement, compression or distraction maneuver was utilized. Then, coronal/sagittal alignment and junctional discs were evaluated by intraoperative portable whole spine radiographs.

3. Demographic and Surgical Data Collection

After obtaining approval from the Institutional Review Board of Washington University School of Medicine, extensive review of the patients’ medical record was performed to identify demographic, surgical and complication data, including age at surgery, sex, height, weight, curve type by Lenke classification,\textsuperscript{3} number of fused vertebrae, correction rate of the main curve, length of follow-up. For clinical outcome evaluation, Scoliosis Research Society (SRS)-22 questionnaires score was investigated.

4. Radiographic Measurements

Measurements were made on upright posterioranterior, side bending, and lateral radiographs of the entire spine. Distal AO was defined as a progressive increase in the number of vertebrae included distally within the primary curve combined with either an increase of more than 3 cm in deviation of the center of the LIV from the center sacral vertical line (CSVL) or an increase of more than 10° in the coronal angulation of the first disc below the instrumentation at ultimate follow-up. DJK was defined if sagittal disc angle below the LIV is more than 10°. In this study, poor radiographic outcomes were defined as the distance from CSVL to the center of L3 ≥ 3 cm, or a discal angle at L3–4 > 10° in the coronal or sagittal plane at ultimate follow-up.
Investigated radiographic parameters included: Risser grade, correction rate, preoperative coronal rotation angle using Perdriolle method⁶ and deviation distance of L3, coronal and sagittal disc angle at L3–4 (Fig. 1), gravity stability score in standing and side bender (new stable vertebra [SV] was defined for this study: SV-1, CSVL is passing between medial borders of pedicles of the LIV; SV-2, CSVL touching body of LIV; SV-3, CSVL does not touch LIV body), rotational stability score (neutral vertebra [NV]: vertebra without rotation; NV-1: 1 vertebra proximal to NV; NV-2: 2 vertebra proximal to NV; NV-3: 3 vertebra proximal to NV), and total stability score (summation of gravity and rotational stability score) (Table 1, Fig. 2).

5. Assessment of Disc Flexibility at L3–4

L3–4 disc angle was measured between straight lines along the inferior endplate of the upper and the superior endplate of the lower vertebra in a segment. This was done on the upright and side bending radiographs. The following equation was used for the disc flexibility at L3–4:

\[
\text{Disc flexibility index (\%) } = \left( \frac{\text{upright disc angle} - \text{bending disc angle}}{\text{upright disc angle}} \right) \times 100
\]

When the disc flexibility index was more than 25%, the L3–4 disc was defined as flexible. Similarly, rigid disc at L3–4 was defined if the disc flexibility index was less than 25%.

6. Statistical Analysis

Distributions of variables were given as a mean and standard deviation (±). For most variables for which data were collected preoperatively and postoperatively, paired t-tests were used to determine whether there was a significant change between time-points. Student t-test was used to assess the difference of continuous measures between the groups. Fisher exact test was used for dichotomous data analysis depending on the number of sub-

<table>
<thead>
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<th>Gravity Stability</th>
<th>Rotational Stability</th>
<th>Total Stability</th>
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<tr>
<td>L1</td>
<td>SV-3</td>
<td>NV-3</td>
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<tr>
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<td>L4</td>
<td>SV</td>
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<tr>
<td>L5</td>
<td>SV</td>
<td>NV-3</td>
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SV, stable vertebra; SV-1, CSVL is passing between medial borders of pedicles of the LIV; SV-2, CSVL touching body of LIV; SV-3, CSVL does not touch LIV body; LIV, lower instrumented vertebra; TS, total stability.

Fig. 1. An example of radiographic measurement for deviation of the center of the L3 from the center sacral vertical line, distal junctional discal angulation at L3–4 in the coronal or sagittal plane.

Fig. 2. An example of radiographic evaluation for gravity, rotational and total stability scoring system. Gravity stability score (new stable vertebra [SV] was defined for this study: SV-1, CSVL is passing between medial borders of pedicles of the LIV; SV-2, CSVL touching body of LIV; SV-3, CSVL does not touch LIV body), rotational stability score (neutral vertebra [NV]: vertebra without rotation; NV-1, 1 vertebra proximal to NV; NV-2, 2 vertebra proximal to NV; NV-3, 3 vertebra proximal to NV), and total stability score (summation of gravity and rotational stability score). CSVL, center sacral vertical line; LIV, lower instrumented vertebra; TS, total stability.
Table 2. Demographic and radiographic factors between ASF and PSF groups

<table>
<thead>
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<th>Variable</th>
<th>ASF group (n = 42)</th>
<th>PSF group (n = 72)</th>
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<td><strong>Demographic data</strong></td>
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<tr>
<td>Sex, male:female</td>
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<td>5:67</td>
<td>0.421</td>
</tr>
<tr>
<td>Age at surgery (yr)</td>
<td>15.0 ± 1.9</td>
<td>14.8 ± 2.0</td>
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<tr>
<td>F/U duration (yr)</td>
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<td>3.2 ± 2.0</td>
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<td>Risser grade</td>
<td>3.2 ± 2.0</td>
<td>3.6 ± 1.5</td>
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<td><strong>Preoperative radiographic factors</strong></td>
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<td>Rigid disc at L3/4</td>
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<td>2</td>
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<td>Coronal disc angle at L3/4</td>
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<td>-8.3 ± 2.3</td>
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</tr>
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<td><strong>Postoperative radiographic factors</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>No. of fused vertebrae</td>
<td>4.6 ± 0.8</td>
<td>11.4 ± 2.6</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Correction rate of major curve (%)</td>
<td>48.6 ± 18.5</td>
<td>67.6 ± 16.6</td>
<td>0.013*</td>
</tr>
<tr>
<td>Coronal reduction rate of L3 (%)</td>
<td>19.8 ± 3.8</td>
<td>33.0 ± 5.1</td>
<td>0.003*</td>
</tr>
<tr>
<td>Distal PX (%)</td>
<td>20 (47.6)</td>
<td>8 (11.1)</td>
<td>&lt; 0.001*</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation or number (%).
ASF, anterior spinal fusion; PSF, posterior spinal fusion; F/U, follow-up; PX, poor radiographic outcome.
*p < 0.05, statistically significant difference.

Fig. 3. An example of radiographic outcomes of patients having similar Lenke 6CN curve and same Risser grade following posterior spinal fusion and anterior spinal fusion to L3. Two-year postoperative plain films with good- (left) and poor radiographic outcome (right) showing 3.14-cm deviation of the center of the L3 from the center sacral vertical line in the coronal plane.
Distal failure between ASF and PSF to L3

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RESULTS

Twenty of 42 (ASF group: 47.6%) and 8 of 72 (PSF group: 11.1%) patients showed poor radiographic outcome. The other 22 and 64 patients of ASF and PSF group experienced good radiographic outcome. Patient demographic data and radiographic features of both groups are summarized in Table 2. Sex, age at surgery and Risser grade did not show differences between the groups. However, follow-up duration was significantly higher in ASF groups (4.9 years vs. 3.2 years) (p < 0.001). Fused vertebrae (4.6 vs. 11.4, p < 0.001), correction rate of main curve (48.6% vs. 67.6%, p = 0.013), coronal reduction rate of L3 (19.8% vs. 33.0%, p = 0.003) were significantly higher in PSF group (Fig. 3).

1. Radiographic Factors Causing Poor Outcomes

More SV-3 on standing (p = 0.019) and side bending films (p < 0.001), more proximal to NV (p = 0.004), lesser total stability score (p = 0.002), rigid L3–4 disc (p < 0.001), more rotation (p < 0.001) and deviation (p < 0.001) of L3 and ASF (p < 0.001) were identified risk factors for AO or DJK (Table 3).

Multiple logistic regression results indicated that preoperative SV-3 at L3 in standing and side benders (odds ratio [OR], 2.7 and 3.7, p = 0.012 and p < 0.001, respectively), total stability score -5, -6 at L3 (OR, 4.9; p < 0.001), rigid disc at L3/4 (OR, 3.7; p < 0.001), L3 rotation > 15° (OR, 3.3; p = 0.003), L3 deviation > 2 cm from CSVL (OR, 3.1; p = 0.007) and ASF (OR, 13.4; p < 0.001) were independent predictive factors associated with radiographic poor radiographic outcomes.

2. Clinical Outcomes

Any patients did not undergo revision surgery in PSF group. However, one patient having distal AO experienced fusion extension to L4 in ASF group (1 of 42, 2.3%). There was a significant improvement of the average scores of SRS-22 questionnaires only in PSF group (p = 0.019) versus ASF group (p = 0.084). Furthermore, the ultimate SRS-22 questionnaires scores of PSF group were significantly superior to ASF groups (p = 0.013) (Table 4).

DISCUSSION

ASF has been widely chosen because of its advantages such as releasing intervertebral discs directly, reducing fusion levels, avoiding approach-related damage to paraspinal muscle. However, as pedicle screw system has developed, frequency for PSF selection has increased. Furthermore, direct vertebral derotation maneuver during PSF can correct the rotational deformity effectively. In this study, a longer follow-up period in the ASF group than PSF group reflects the trend to select ASF or PSF.

Optimal LIV to avoid AO or DJK is extremely idiosyncratic. Various concepts and rules were introduced by previous researchers such as Harrington stable zone, SV and NV theory, disc reversal, and LTV. However, poor interrater reliability for LIV selection was reported even among 17 SRS surgeons. In their study, 50% agreement was observed and Kappa value was 0.38 (poor reliability). Moreover, there has been no comparative study focusing on the issue between ASF and PSF stopping at L3. Therefore, this study was aimed to compare the prevalence and identify risk factors for distal AO or DJK in AIS patients treated by ASF and PSF to L3.

In this series, the prevalence of AO or DJK at ultimate follow-
up with LIV at L3 was 47.6% and 11.1% in ASF and PSF group, respectively. The prevalence of AO or DJK in PSF group is similar to a study focusing the prevalence (13.6%) of AO or DJK following PSSIF for AIS with LIV at L2 or above. However, the prevalence (47.6%) of AO or DJK in ASF group is significantly higher compared to their result (13.6%). In their study, open tri-radiate cartilage, not touching of the LIV by the CSVL, and more rotation of the LIV was identified as risk factors for AO or DJK.

In the present study, lower Risser grade, more SV-3 on standing and side bending films, lesser rotational and total stability score, rigid L3–4 disc, more rotation, and deviation of L3 were identified risk factors for AO or DJK. Furthermore, multiple logistic regression results indicated that preoperative SV-3 at L3 in standing and side benders (OR, 2.7 and 3.7, respectively), total stability score -5, -6 at L3 (OR, 4.9), rigid disc at L3-4 (OR, 3.7), LIV rotation > 15° (OR, 3.3), LIV deviation > 2 cm from CSVL (OR, 3.1) and ASF (OR, 13.4) were significant predictive factors for poor radiographic outcomes. For these analyses, we utilized a new gravity, rotational and total stability scoring system. In our new scoring system, the difference between SV-2 and SV-3 are whether CSVL does touch LIV or not. It means that SV-2 and SV-1 are LTV and substantial LTV, respectively. Total stability score is the sum of gravity and rotational stability score. By the multiple logistic regression analysis, total stability score -5 or less at L3 (OR, 4.9) is the second most significant factor associated with poor radiographic outcomes after stopping at L3. To the best of our knowledge, there are no published reports using gravity, rotational and total stability scoring system to determine optimal LIV level.

In the current study, ASF (OR, 13.4) is the most significant single factor for poor radiographic outcomes following fusion to L3. ASF can reduce fused vertebrae (4.6 vs. 11.4), however, was inferior to PSF group in terms of correction rate of main curve (48.6% vs. 67.6%), coronal reduction rate of L3 (19.8% vs. 33.0%). Furthermore, the ultimate SRS-22 questionnaires scores of ASF group were significantly inferior to ASF groups (p = 0.013).

In major thoracolumbar of lumbar structural curves, it had been considered that fusion should be extended down to L4 in the era of Harrington instrumentation. However, stopping at L3 instead of L4 has been proposed in the era of segmental pedicle screw-based instrumentation. Lenke et al. proposed the criteria for stopping of distal fusion at L3, as follows: (1) less than Nash-Moe grade 1 rotation of L3; (2) tilt of L3 < 30° and tilt of L4 < 20°; (3) L4 vertebra body was bisected by the CSVL; (4) apical disc should be located at T12–L1 or above; (5) the direction of opening at the L3–L4 level should be parallel to or opposite the L4–L5 disc level; and (6) the location of L3 should be centered by bending. Recently, selecting the last touching vertebra by CSVL as an optimal LIV can decrease the incidence of distal AO. The previously reported factors or criteria are valuable to determine distal fusion levels in AIS. However, absolute guidelines for the selection of LIV have not been defined. In the current study, we found several key risk factors for AO or DJK. Moreover, we introduce the odds ratio of each risk factor by multiple logistic regression analysis. We can share and discuss the information of predicting factors for poor radiographic outcomes with AIS kids and their guardians.

This study has several limitations. Since the study design was retrospective, criteria for ASF or PSF were not identifiable in all cases. Moreover, although PSF was chosen for all kinds of Lenke types, ASF was selected for Lenke type 5 or 6 curve in this study. Additionally, the follow-up period was significantly longer in the ASF group. The difference in follow-up period could have influenced the results. A further study between ASF and PSF for only Lenke type 5 or 6 curve might elucidate whether L3 is optimal as a LIV.

CONCLUSION

The prevalence of AO or DJK at ultimate follow-up for AIS with LIV at L3 was significantly higher in ASF group (47.6% vs. 11.1%). Ultimate SRS-22 scores were significantly better in PSF group.

CONFLICT OF INTEREST

Dr. Lenke shares numerous patents with Medtronic (unpaid). He is a consultant for DePuy Synthes Spine, K2M, Medtronic (monies donated to a charitable foundation). He receives substantial royalties from Medtronic and modest royalties from Quality Medical Publishing. Dr. Lenke also receives or has received reimbursement related to meetings/courses from AOSpine, BroadWater, DePuy Synthes Spine, K2M, Medtronic, Scoliosis Research Society, Seattle Science Foundation, Stryker Spine, The Spinal Research Foundation. Except for that, the other authors have nothing to disclose.

ACKNOWLEDGMENTS

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REFERENCES


Commentary on “The Incidence of Adding-On or Distal Junctional Kyphosis in Adolescent Idiopathic Scoliosis Treated by Anterior Spinal Fusion to L3 Was Significantly Higher Than by Posterior Spinal Fusion to L3”

Morio Matsumoto
Department of Orthopedic Surgery, Keio University, School of Medicine, Tokyo, Japan

The selection of a fusion area is the most critical process in the surgical treatment for adolescent idiopathic scoliosis. Especially, the selection of the lower instrumented vertebra (LIV) will influence the correction of unfused curves and trunk balance, which may have significant impact on long-term clinical results. An inadequate selection of LIV may cause adding-on phenomenon (AO) and distal junctional kyphosis (DJK), and decompensation. In the previous reports, the factors related to the postoperative distal adding-on were bone maturity, type 1A-R or L, and the position of LIV. Usually, the selection of LIV is determined by the relative position of a neutral vertebra (NV), stable vertebra (SV), end vertebra (EV), and last touching vertebra (LTV).

To discuss this topic, we have to separate patients with the major curve in the thoracic spine (Lenke type 1 or 2) and those with the major curve in the thoracolumbar/lumbar spine (Lenke type 5 or 6). Regarding the patients with the major thoracic curve, Matsumoto et al. evaluated 112 patients who underwent posterior spinal fusion (PSF) for Lenke type 1A curve. Postoperative distal AO was observed in 19% of the patients, and the logistic regression analysis revealed that LIV shorter than LTV was a significant risk factor for AO. The selection of LIV in relation to LTV also be applicable in Lenke type 2 curve. For patients with the major lumbar curve (Lenke type 5), the selection between L3 or L4 is a debatable issue. The level of LIV level has been chosen at lower EV (LEV), LEV+1, and LEV-1, depending on the magnitudes of curves.

The study design of the present study is unique. The authors focused on the patients whose LIV were selected at L3 regardless of the surgical approach (anterior or posterior) and curve types, then evaluate the risk factors for AO or DJK. However, the present study has several issues to be considered.

First, the authors only described that the anterior spinal fusion (ASF) group included more type 5 and type 6. To discuss the superiority between ASF and PSF, the background of the patients, including curve type, should be similar.
Second, the postoperative shoulder imbalance was not evaluated in the present study. If the cases included in the study were all type 5 curves, the authors do not need to assess the postoperative shoulder imbalance since it is rare. While, if patients with major thoracic curves were included, it would be ideal to evaluate shoulder imbalance since AO and shoulder imbalance is related to each other.

Third, the detail of the Lenke types was not described in the present study. I supposed that the PSF group included patients with the major thoracic curve and that the ASF group included those with the major thoracolumbar/lumbar curve, considering the large difference in mean number of fused vertebrae between the 2 groups (4.6 vs. 11.4). Even in patients with the major thoracic curve, the reason to extend the fusion to L3 has huge differences among the lumbar modifier A, B, and C. While, in some patients with major lumbar curves, LIV was selected at L3 to preserve motion segment, knowing the possibility of the residual curve at L3–S. To use the results of the present study in the clinical setting, the details of materials including Lenke types and lumbar modifiers would help the readers understanding the results of the study.

In spite of these issues of the study, the authors should be commended for this valuable study. Of note, the total stability score, the sum of gravity and rotational stability score, is the most commendable topic of the present study. The authors defined the gravity stability score using the relative position of SV, and the rotational stability score using the relative position of NV, and the total stability score as the summation of the 2 scores. I hope that these simple new parameters will be tested for clinical significance in determination of LIV in each Lenke curve type by future research.

CONFLICT OF INTEREST

The author has nothing to disclose.

REFERENCES

Thoracolumbar Slope Is Useful Parameter for Evaluating Health-Related Quality of Life and Sagittal Imbalance Aggravation in Adult Spinal Deformity: A Prospective Observational Cohort Study

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Department of Neurosurgery, Chonnam National University Medical School & Research Institute of Medical Sciences, Gwangju, Korea

Objective: The purpose of the present study was to evaluate the natural course of primary degenerative sagittal imbalance (PDSI), its aggravating factors, and health-related quality of life (HRQoL) associated with various spinal alignment parameters (SAPs) in patients with PDSI who have not undergone surgery.

Methods: One hundred three participants volunteered to participate. The SAPs, including T1 pelvic angle (T1PA), thoracolumbar tilt, and thoracolumbar slope (TLS), were measured on whole-spine standing radiographs. The back and lumbar muscle volumes were measured. To determine HRQoL at baseline and at 2-year follow-up, face-to-face questionnaires were administered, which included visual analogue scale of the back and leg, physical component summary/mental component summary of 36-item Short Form Health Survey, Oswestry Disability Index (ODI), and Mini-Mental State Examination.

Results: Overall HRQoL measures had improved after 2 years of follow-up compared to baseline. PDSI aggravation was observed in 18 participants (26.1%). TLS, sagittal vertical axis (SVA), and T1PA were strongly correlated with each other. TLS, SVA, and T1PA were correlated with ODI score. Among them, TLS was most highly correlated with ODI score. TLS greater than -3.5° was a predicting factor for PDSI aggravation (p = 0.034; 95% confidence interval, 1.173–63.61; odds ratio, 8.636).

Conclusion: The present study implied that PDSI does not necessarily worsen with aging. TLS is an appropriate parameter for assessing the clinical situation in patients with PDSI. Furthermore, a TLS greater than -3.5° predicts PDSI aggravation; thus, TLS may be a useful parameter for predicting prognosis in PDSI.

Keywords: Sagittal imbalance, Health-related quality of life, Thoracolumbar slope, Adult spinal deformity, Spinal alignment parameter

INTRODUCTION

Primary degenerative sagittal imbalance (PDSI) is an adult spinal deformity that has become increasingly common in elderly patients, with an estimated prevalence rate of 20%–60% in that age group.1,2 It causes severe back pain and functional disability. Several reports have described a significant relationship between PDSI and health-related quality of life (HRQoL).3,4 With advances in surgical instruments and technology, surgical treatment of PDSI has become more widespread, and several
studies have reported that surgery improved HRQoL in patients with PDSI. Additionally, to understanding sagittal imbalance, various sagittal alignment parameters (SAPs) have been discovered and applied clinically, including sagittal vertical axis (SVA), pelvic incidence (PI), pelvic tilt (PT), sacral slope (SS), T1 pelvic angle (T1PA), and thoracolumbar slope (TLS). However, these SAPs are generally applied to evaluate patients immediately before and after surgery. In high-risk patients such as the elderly, deformity correction surgery is not usually recommended because it involves extensive surgery, long operation time and high blood loss, which lead to marked perioperative morbidity.

If clinicians better understand the natural course of the PDSI without surgical treatment, they may be able to predict sagittal imbalance aggravation, prevent further aggravation, and thus improve HRQoL in patients with PDSI. Therefore, the purpose of the present study was to evaluate the natural course of PDSI, its aggravating factors, and HRQoL associated with various SAPs in patients with PDSI who have not undergone surgery.

MATERIALS AND METHODS

1. Patient Population and Study Design

The study was approved by the Institutional Review Board of Chonnam National University Medical School Research Institute (approval number: CNUH-2016-127). Informed consent was obtained from all individual participants included in this study. This prospective longitudinal cohort study included a follow-up of PDSI cases for 2 years in patients with PDSI to determine which SAPs were associated with the natural course of PDSI and HRQoL.

We recruited volunteers who were older than 65 years, exhibited a stooping posture in daily living, but had not received medication or surgical treatment. Before enrolling subjects, we checked the whole-spine standing radiographs to confirm that the volunteers had SVA larger than 50 mm. In total, 103 participants volunteered to participate. The exclusion criteria were as follows: (1) coronal deformity (Cobb angle > 10°); (2) less than 2 years of clinical or radiological follow-up; (3) history of spine, hip, or knee surgery; (4) prescription of pain medication; (5) history of Parkinson disease or other neuromuscular disorder; (6) presence of infection, fracture, or malignancy. Date of the following variables related to patient demographics were recorded at baseline and at the 2-year follow-up: age, sex, body mass index (BMI), bone mineral density, whole-spine standing radiograph, lumbar spine magnetic resonance imaging (MRI), and plasma clinical chemistry.

2. Radiological and Clinical Evaluation

The following SAPs were measured on whole-spine standing radiographs based on Scoliosis Research Society–Schwab radiological classification: SVA, PI, PT, SS, lumbar lordosis (LL), and thoracic kyphosis (TK). Additionally, T1PA, TLS, and thoracolumbar tilt (TLT) were measured (Fig. 1). Based on serial analysis, PDSI aggravation was defined as a T1PA increase of more than 3° and SVA increase of more than 30 mm compared to baseline value. The back and lumbar muscle volumes were measured based on the cross-sectional areas of the lumbar multifidus muscle (MF), lumbar erector spinae muscle (ES), and psoas muscle (PS). These measurements were obtained from MRI at the lumbar 4/5-disc level using the region of interest measurement tool of the picture archiving and communication system (M-view; INFINITT Healthcare, Seoul, Korea). Furthermore, fatty change in the lumbar muscle was measured according to the grading...
system of Goutallier et al.\textsuperscript{12} (Fig. 2).

Laboratory tests were performed on peripheral venous blood samples to determine the levels of the following parameters: total cholesterol, triglyceride, high-density lipoprotein, hemoglobin A1c, rheumatoid factor, vitamin D, osteocalcin, and C-terminal telopeptide.

To determine HRQoL at baseline and at 2-year follow-up, face-to-face questionnaires were administered, which included visual analogue scale of the back and leg, physical component summary (PCS)/mental component summary (MCS) of 36-item Short Form Health Survey (SF-36), Oswestry Disability Index (ODI), and Mini-Mental State Examination. In addition, after the participants had provided written consent for participation, they were educated about the etiology, natural course, and surgical treatment of PDSI; they underwent brief training on the importance of core and lumbar extensor muscle strengthening exercises (lumbar extension, hip extension, trunk flexion, and leg press exercise) and rest.\textsuperscript{13-15}

3. Statistical Analysis

Data of continuous variables were expressed as mean ± standard deviation. The paired t-test was used to compare measurements taken at baseline and 2-year follow-up. The radiological and muscle parameters at 2-year follow-up were also compared between the aggravation and nonaggravation groups. Pearson correlation coefficient test was performed to analyze correlations between SAPs and HRQoL measures. Correlation strengths were interpreted according to the method described by Evans\textsuperscript{16} (r = 0.00–0.19: very weak, r = 0.20–0.39: weak, r = 0.40–0.59: moderate, r = 0.60–0.79: strong, r = 0.80–1.00: very strong). Multivariate logistic regression analysis was used to identify predictive factors for PDSI aggravation. All statistical analyses were performed using the IBM SPSS Statistics ver. 26.0 (IBM Co., Armonk, NY, USA). A p-value of < 0.05 was considered significant.

RESULTS

Among 103 participants, 34 were excluded from the study due to refusal of lumbar MRI check, nursing hospital admission, hip fracture, or loss to follow-up. Therefore, 69 participants with PDSI were enrolled.

After 2 years of follow-up, the overall HQRoL measures had improved when compared with those at baseline. Among them, ODI, PCS of SF-36, and MCS of SF-36 had improved significantly (p = 0.047, p < 0.001, and p < 0.001, respectively). Among SAPs, SVA, T1PA, and TLS had also improved significantly after 2 years of follow-up (p = 0.007, p = 0.038, and p = 0.024, respectively). Conversely, PT had increased, and TK had decreased significantly after 2 years of follow-up (p = 0.003 and p < 0.001, respectively), meaning a compensatory change. These results confirmed that PDSI is not necessarily aggravated by the aging
Table 1. Patient clinical and laboratory characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline (n = 69)</th>
<th>2-Year F/U (n = 69)</th>
<th>p-value *</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical characteristics</strong></td>
<td></td>
<td></td>
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<tr>
<td>Age (yr)</td>
<td>70.6 ± 4.00</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Female sex</td>
<td>57 (82.6)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>24.29 ± 2.77</td>
<td>24.77 ± 2.87</td>
<td>0.34</td>
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<td>BMD (g/cm²)</td>
<td>-1.49 ± 0.88</td>
<td>-1.59 ± 0.80</td>
<td>0.043*</td>
</tr>
<tr>
<td>VAS back</td>
<td>7.67 ± 2.63</td>
<td>7.43 ± 2.24</td>
<td>0.068</td>
</tr>
<tr>
<td>VAS leg</td>
<td>7.16 ± 2.93</td>
<td>7.02 ± 2.81</td>
<td>0.059</td>
</tr>
<tr>
<td>ODI</td>
<td>20.58 ± 7.35</td>
<td>19.63 ± 7.22</td>
<td>0.047*</td>
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<td>SF-36 PCS</td>
<td>36.18 ± 13.72</td>
<td>26.83 ± 11.77</td>
<td>&lt; 0.001*</td>
</tr>
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<td>SF-36 MCS</td>
<td>47.64 ± 15.49</td>
<td>40.14 ± 14.81</td>
<td>&lt; 0.001*</td>
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<td>MMSE</td>
<td>26.16 ± 3.22</td>
<td>25.77 ± 3.42</td>
<td>0.064</td>
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<td><strong>Laboratory characteristics</strong></td>
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<td>Cholesterol (mg/dL)</td>
<td>193.90 ± 47.04</td>
<td>181.84 ± 40.14</td>
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</tr>
<tr>
<td>TG (mg/dL)</td>
<td>136.26 ± 89.43</td>
<td>142.65 ± 65.06</td>
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</tr>
<tr>
<td>HDL (mg/dL)</td>
<td>55.77 ± 12.50</td>
<td>55.32 ± 12.54</td>
<td>0.683</td>
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<td>HbA1c (%)</td>
<td>5.87 ± 1.09</td>
<td>5.96 ± 0.93</td>
<td>0.278</td>
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<tr>
<td>RF (IU/mL)</td>
<td>6.69 ± 11.53</td>
<td>7.11 ± 14.73</td>
<td>0.495</td>
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<tr>
<td>Vitamin D (ng/mL)</td>
<td>21.66 ± 8.13</td>
<td>18.09 ± 8.65</td>
<td>0.003*</td>
</tr>
<tr>
<td>CTX (ng/mL)</td>
<td>0.42 ± 0.22</td>
<td>0.49 ± 1.33</td>
<td>0.649</td>
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<tr>
<td>Osteocalcin (ng/mL)</td>
<td>21.30 ± 8.48</td>
<td>18.12 ± 7.89</td>
<td>0.002*</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation or number (%). F/U, follow-up; BMI, body mass index; BMD, bone mineral density; BMI; VAS, visual analogue scale; ODI, Owestry Disability Index; SF-36, 36-item Short Form Health Survey; PCS, physical component summary; MCSI, mental component summary; MMSE, Mini-Mental State Examination; TG, triglyceride; HDL, high-density lipoprotein; HbA1c, hemoglobin A1c; RF, rheumatoid factor; CTX, C-terminal telopeptide.

*p < 0.05, statistically significant differences. *A comparison of mean values between the baseline and 2-year follow-up.

The relationship between HRQoL measures and SAPs was assessed at baseline and at 2-year follow-up (Table 4). TLS, SVA, and T1PA were strongly correlated with each other. TLS showed a strong correlation with SVA (r = 0.892, p < 0.001 at baseline; r = 0.773, p < 0.001 at 2-year follow-up) and T1PA (r = 0.670, p < 0.001 at baseline; r = 0.747, p < 0.001 at 2-year follow-up). T1PA showed a strong correlation with SVA (r = 0.672, p < 0.001 at baseline; r = 0.695, p < 0.001 at 2-year follow-up). TLS, SVA, and T1PA were correlated with ODI score at baseline. Among them, TLS was most highly correlated with ODI score (r = 0.326, p < 0.001). TLS and T1PA were correlated with ODI score at the 2-year follow-up. Among them, TLS most highly correlated with ODI score (r = 0.374, p < 0.001).

Multivariate logistic regression analysis showed that TLS greater than -3.5°, which is the mean value in patients with PDSI who require surgical treatment due to clinical symptoms, was a predicting factor for PDSI aggravation (p = 0.034; confidence in-

Table 2. Patient radiological and muscle characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline (n = 69)</th>
<th>2-Year F/U (n = 69)</th>
<th>p-value *</th>
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</thead>
<tbody>
<tr>
<td><strong>Radiological characteristics</strong></td>
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<tr>
<td>SVA (cm)</td>
<td>12.32 ± 6.38</td>
<td>9.85 ± 9.20</td>
<td>0.007*</td>
</tr>
<tr>
<td>PI (°)</td>
<td>56.53 ± 11.30</td>
<td>57.28 ± 9.99</td>
<td>0.574</td>
</tr>
<tr>
<td>PT (°)</td>
<td>26.99 ± 11.81</td>
<td>29.90 ± 10.63</td>
<td>0.003*</td>
</tr>
<tr>
<td>SS (°)</td>
<td>29.61 ± 12.10</td>
<td>27.37 ± 9.76</td>
<td>0.069</td>
</tr>
<tr>
<td>LL (°)</td>
<td>25.36 ± 20.72</td>
<td>25.50 ± 20.43</td>
<td>0.94</td>
</tr>
<tr>
<td>TK (°)</td>
<td>30.35 ± 23.68</td>
<td>19.53 ± 15.81</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>T1PA (°)</td>
<td>32.13 ± 13.94</td>
<td>30.68 ± 14.31</td>
<td>0.038*</td>
</tr>
<tr>
<td>TLS (°)</td>
<td>2.97 ± 15.36</td>
<td>0.69 ± 16.27</td>
<td>0.024*</td>
</tr>
<tr>
<td>TLT (°)</td>
<td>7.32 ± 10.34</td>
<td>8.80 ± 9.48</td>
<td>0.062</td>
</tr>
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<td><strong>Muscle characteristics</strong></td>
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<td></td>
</tr>
<tr>
<td>Goutallier grade of MF</td>
<td>2.29 ± 0.96</td>
<td>2.32 ± 0.95</td>
<td>0.159</td>
</tr>
<tr>
<td>Goutallier grade of ES</td>
<td>2.10 ± 0.88</td>
<td>2.12 ± 0.87</td>
<td>0.321</td>
</tr>
<tr>
<td>Goutallier grade of PS</td>
<td>2.15 ± 0.82</td>
<td>2.16 ± 0.80</td>
<td>0.321</td>
</tr>
<tr>
<td>CSA of MF (mm³)</td>
<td>713.10 ± 208.50</td>
<td>704.90 ± 211.69</td>
<td>0.306</td>
</tr>
<tr>
<td>CSA of ES (mm³)</td>
<td>1,704.30 ± 1,080.5</td>
<td>1,688.8 ± 1,077.8</td>
<td>0.249</td>
</tr>
<tr>
<td>CSA of PS (mm³)</td>
<td>2,364.50 ± 420.8</td>
<td>2,323.60 ± 420.8</td>
<td>0.217</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation or number (%). F/U, follow-up; SVA, sagittal vertical axis; PI, pelvic incidence; PT, pelvic tilt; SS, sacral slope; LL, lumbar lordosis; TK, thoracic kyphosis; T1PA, T1 pelvic angle; TLS, thoracolumbar slope; TLT, thoracolumbar tilt; MF, multifidus; ES, erector spinal muscle; PS, psoas muscle; CSA, cross-sectional area.

*p < 0.05, statistically significant differences. *A comparison of mean values between the baseline and 2-year follow-up.
Table 3. Radiologic, muscle parameters, and HRQoL measures in the aggravation and nonaggravation group

<table>
<thead>
<tr>
<th>Variable</th>
<th>AG</th>
<th>Non-AG</th>
<th>p-value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients (%)</td>
<td>18 (26.1)</td>
<td>51 (73.1)</td>
<td>0.874</td>
</tr>
<tr>
<td>Female sex</td>
<td>15 (83.3)</td>
<td>42 (82.4)</td>
<td>0.052</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.13 ± 4.46</td>
<td>24.98 ± 3.88</td>
<td>0.328</td>
</tr>
<tr>
<td>BMD (g/cm²)</td>
<td>-1.58 ± 1.81</td>
<td>-1.46 ± 1.24</td>
<td>0.325</td>
</tr>
<tr>
<td>Radiological measures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS back</td>
<td>7.61 ± 2.33</td>
<td>7.28 ± 1.94</td>
<td>0.061</td>
</tr>
<tr>
<td>VAS leg</td>
<td>7.63 ± 2.52</td>
<td>6.99 ± 2.73</td>
<td>0.052</td>
</tr>
<tr>
<td>ODI</td>
<td>20.11 ± 7.28</td>
<td>18.28 ± 7.05</td>
<td>0.374</td>
</tr>
<tr>
<td>SF-36 PCS</td>
<td>29.41 ± 10.75</td>
<td>25.92 ± 12.07</td>
<td>0.224</td>
</tr>
<tr>
<td>SF-36 MCS</td>
<td>42.97 ± 14.47</td>
<td>39.14 ± 14.94</td>
<td>0.234</td>
</tr>
<tr>
<td>MMSE</td>
<td>25.78 ± 2.88</td>
<td>25.76 ± 3.63</td>
<td>0.789</td>
</tr>
<tr>
<td>Muscle parameters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Goutallier grade of MF</td>
<td>2.28 ± 0.75</td>
<td>2.34 ± 1.03</td>
<td>0.635</td>
</tr>
<tr>
<td>Goutallier grade of ES</td>
<td>2.05 ± 0.87</td>
<td>2.14 ± 0.89</td>
<td>0.487</td>
</tr>
<tr>
<td>Goutallier grade of PS</td>
<td>2.11 ± 0.83</td>
<td>2.18 ± 0.80</td>
<td>0.505</td>
</tr>
<tr>
<td>CSA of MF (mm²)</td>
<td>708.00 ± 234.97</td>
<td>702.78 ± 207.22</td>
<td>0.702</td>
</tr>
<tr>
<td>CSA of ES (mm²)</td>
<td>2,107.10 ± 2011.7</td>
<td>1,543.2 ± 317.4</td>
<td>0.332</td>
</tr>
<tr>
<td>CSA of PS (mm²)</td>
<td>2,326.6 ± 462.7</td>
<td>2,327.5 ± 412.5</td>
<td>0.707</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation or number (%). HRQoL, health-related quality of life; AG, aggravation; BMI, body mass index; BMD, bone mineral density; BMI, VAS, visual analogue scale; ODI, Owestry Disability Index; SF-36, 36-item Short Form Health Survey; PCS, physical component summary; MCS, mental component summary; MMSE, Mini-Mental State Examination; SVA, sagittal vertical axis; PI, pelvic incidence; PT, pelvic tilt; SS, sacral slope; LL, lumbar lordosis; TK, thoracic kyphosis; T1PA, T1 pelvic angle; TLS, thoracolumbar slope; TLT, thoracolumbar tilt; MF, multifidus; ES, erector spinal muscle; PS, psoas muscle; CSA, cross-sectional area.

*p < 0.05, statistically significant differences. †A comparison of mean values between the aggravation and nonaggravation group.

Table 4. Pearson correlation coefficient of sagittal alignment parameters and health-related quality of life measures at baseline and 2-year follow-up

<table>
<thead>
<tr>
<th>Variable</th>
<th>TLS</th>
<th>SVA</th>
<th>T1PA</th>
<th>ODI</th>
<th>SF-36 PCS</th>
<th>SF-36 MCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TLS (°)</td>
<td>0.782*</td>
<td>0.670*</td>
<td>0.336*</td>
<td>-0.223</td>
<td>-0.136</td>
<td></td>
</tr>
<tr>
<td>SVA (°)</td>
<td></td>
<td>0.672*</td>
<td>0.250*</td>
<td>-0.236</td>
<td>-0.224</td>
<td></td>
</tr>
<tr>
<td>T1PA (°)</td>
<td></td>
<td></td>
<td>0.293*</td>
<td>-0.234</td>
<td>-0.129</td>
<td></td>
</tr>
<tr>
<td>ODI (%)</td>
<td></td>
<td></td>
<td></td>
<td>-0.714*</td>
<td>-0.531*</td>
<td></td>
</tr>
<tr>
<td>SF-36 PCS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.672*</td>
<td>0.672*</td>
</tr>
<tr>
<td>SF-36 MCS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-Year follow-up</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TLS (°)</td>
<td>0.737*</td>
<td>0.747*</td>
<td>0.374*</td>
<td>-0.181</td>
<td>-0.102</td>
<td></td>
</tr>
<tr>
<td>SVA (°)</td>
<td></td>
<td>0.695*</td>
<td>0.234</td>
<td>-0.156</td>
<td>-0.200</td>
<td></td>
</tr>
<tr>
<td>T1PA (°)</td>
<td></td>
<td></td>
<td>0.370*</td>
<td>-0.201</td>
<td>-0.159</td>
<td></td>
</tr>
<tr>
<td>ODI (%)</td>
<td></td>
<td></td>
<td></td>
<td>-0.779*</td>
<td>-0.688*</td>
<td></td>
</tr>
<tr>
<td>SF-36 PCS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.730*</td>
</tr>
<tr>
<td>SF-36 MCS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 5. Multivariate analysis of factors predicting primary degenerative sagittal imbalance aggravation

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. of preservations (%)</th>
<th>Multivariate analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>p-value</td>
<td>95% CI</td>
</tr>
<tr>
<td>TLS (°)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; -3.5</td>
<td>3/30 (10)</td>
<td>0.034</td>
</tr>
<tr>
<td>≥ -3.5</td>
<td>15/39 (38.5)</td>
<td></td>
</tr>
<tr>
<td>T1PA (°)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 30</td>
<td>6/36 (16.7)</td>
<td>0.442</td>
</tr>
<tr>
<td>≥ 30</td>
<td>12/33 (36.4)</td>
<td></td>
</tr>
<tr>
<td>SVA (cm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 9.5</td>
<td>5/30 (16.7)</td>
<td>0.057</td>
</tr>
<tr>
<td>≥ 9.5</td>
<td>14/39 (35.9)</td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 25</td>
<td>9/32 (28.1)</td>
<td>0.512</td>
</tr>
<tr>
<td>≥ 25</td>
<td>9/37 (24.3)</td>
<td></td>
</tr>
</tbody>
</table>

CI, confidence interval; OR, odds ratio; TLS, thoracolumbar; T1PA, T1 pelvic angle; SVA, sagittal vertical axis; BMI, body mass index.

A BMI greater than 25 kg/m², which is the criterion for overweight; an SVA greater than 9.5 cm, which is the criterion for marked deformity; and a T1PA greater than 30° were not significant predictors for PDSI aggravation (Table 5). No variables other than TLS were significantly associated with PDSI aggravation, including volume and

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DISCUSSION

PDSI is understood as the cumulative result of degenerative changes and the natural progression of aging. In a longitudinal study of age-related changes in sagittal spinal alignment in 237 individuals over a 4-year period, Oe et al. reported that SAPs deteriorated with age, including SS, PT, LL, T1 slope, cervical lordosis, and SVA in the seventh-decade female group. Many elderly individuals experience mild sagittal imbalance, but PDSI does not deteriorate in all individuals with aging. Interestingly, in the present study, overall SAPs had not deteriorated, and overall HRQoL measures had improved after 2 years of follow-up compared to baseline. Although, we included a smaller number of individuals and our follow-up period was shorter than that in the study of Oe et al., the result that the PDSI has not deteriorated is significant. Participants were not given any special treatment, but only at the beginning of the study, they were educated about the etiology, natural course, and surgical treatment of PDSI; they were also trained briefly on the importance of core and lumbar extensor exercises and rest. Although it is difficult to find out the evidence of PDSI improvement only with this study, it is assumed that PDSI aggravation can be prevented by education, and further, prevalence can likely be reduced.

PDSI causes back pain and functional disability that leads to severe quality of life disturbance. Indeed, several reports have described a significant relationship between PDSI and HRQoL. Along with these perceptions, various SAPs are being discovered to evaluate PDSI and HRQoL in patients. Schwab et al. reported that sagittal imbalance severity, assessed using SVA, PT, and PI minus LL (PI–LL), was correlated with HRQoL measures. Banno et al. found that T1PA was correlated with HRQoL measures. However, because the SAPs are usually applied in surgical planning to restore the ideal global spinal alignment, and because they are related to pre- or postoperative HRQoL, questions have arisen concerning their clinical suitability in patients with PDSI who have not undergone surgical treatment. In addition, global SAPs that require spinopelvic alignment, such as SVA and T1PA, may involve measurement errors because it is difficult to obtain clear visualization of both femoral heads, the S1 endplate, and the T1 vertebral body using whole-spine lateral radiography. Moreover, SAPs that are measured using Cobb angle through 2 or more endplates are more likely to have erroneous measurements. Recently, Moon et al. reported novel SAPs of the thoracolumbar junction, including TSL and TLT, categorizing them as thoracolumbar junction orientation (TLJO). To measure TLS, whole-spine lateral radiography is not required, and because only the L1 endplate needs to be clearly identified, measurement errors are reduced and the reliability is high (Fig. 1C). Moon et al. did not reveal an association between TLJO and HRQoL in patients with PDSI who had not undergone surgical treatment, but they argued that TLJO was correlated with spinopelvic alignment and global SAPs in various clinical situations. Similarly, in the present study, TLS was correlated with global SAPs such as SVA and the T1PA. In particular, TLS was correlated strongly with SVA at baseline and 2-year follow-up (r = 0.782 and r = 0.737, respectively, p < 0.001), as well as with T1PA at baseline and 2-year follow-up (r = 0.670 and r = 0.747, respectively, p < 0.001). In addition, TLS was significantly correlated with those at baseline and 2-year follow-up HRQoL measures in this study, and the correlations between the HRQoL were stronger than those for SVA and T1PA.

PDSI is a multifactorial complex spinal deformity that can arise from various causes such as spinal stenosis, sarcopenia, osteoporosis, vertebral fracture, high BMI, and neuromuscular diseases. As such, it is difficult to clearly identify the predictive factors for aggravation in patients with PDSI. Several studies have attempted to predict the PDSI aggravation using various SAPs, but most have focused on identifying predictive factors associated with postoperative PDSI aggravation. Moreover, in high-risk patients such as the elderly, deformity correction surgery cannot be easily recommended because perioperative morbidity is greater in such patients. A comprehensive understanding of the natural course of the PDSI without surgical treatment may be able to predict the aggravation of sagittal imbalance, prevent further aggravation, and thus improve HRQoL in patients with PDSI. Several prospective observational cohort studies have been carried out in patients with PDSI, but no predictive factors for PDSI aggravation have been identified. Similarly, we previously reported that marked sagittal imbalance is associated with small MF volume, high PI, and working for a long time in a crouched posture, as do agricultural workers, but we failed to identify predictive factors for PDSI aggravation. The present study was the first to reveal that TLS greater than -3.5° is a predictive factor for PDSI aggravation in patients who have not undergone surgical treatment (p = 0.034), regardless of various other SAPs. In their retrospective study, Moon et al. revealed that TLS of -3.5° is the mean value in patients with PDSI who require surgical treatment due to clini-
cal symptoms and that proximal junctional kyphosis can be reduced when the postoperative TLS change is less than 9.4°. Based on these results, they argued that TLS is a useful parameter that could be used as a guidelines in sagittal realignment surgery. Consequently, TLS may be a useful and highly reliable additional global SAP to evaluate PDSI in various clinical situations in asymptomatic, non-surgical patients and in those requiring correction surgery.

This prospective cohort study had some limitations. First, we found no evidence for improvement in overall SAPs or HRQoL. Second, because of the relatively small number of subjects, our results cannot be generalized to all patients with PDSI aggravation. Further investigations utilizing a larger number of subjects should be performed to reduce bias. Third, the follow-up period may have been too short to evaluate PDSI aggravation and a longer follow-up cohort study will be necessary.

CONCLUSION

The present study implied that PDSI does not necessarily worsen with aging, even though it is a multifactorial complex spinal deformity associated with the natural progression of aging. Moreover, TLS is more accessible and more strongly correlated with HRQoL than other SAPs. As such, it is an appropriate parameter for assessing the clinical situation in patients with PDSI. Furthermore, a TLS greater than -3.5° predicts PDSI aggravation; thus, TLS may be a useful parameter for predicting prognosis in PDSI.

CONFLICT OF INTEREST

The authors have nothing to disclose.

ACKNOWLEDGMENTS

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REFERENCES


Obeid-Coronal Malalignment Classification Is Age Related and Independently Associated to Personal Reported Outcome Measurement Scores in the Nonfused Spine

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Objective: To evaluate Obeid-coronal malalignment (O-CM) modifiers according to age, sagittal alignment, and patient-reported outcome measures (PROMs), in the mobile spine.

Methods: Retrospective review of a prospective multicenter adult spinal deformity (ASD) database with 1,243 (402 nonoperative, 841 operative) patients with no prior fusion surgery. Patients were included if they were aged over 18 years and were affected by spinal deformity defined by one of: Cobb angle ≥ 20°, pelvic tilt ≥ 25°, sagittal vertical axis ≥ 5 cm, thoracic kyphosis ≥ 60°. Patients were classified according to the O-CM classification and compared to coronally aligned patients. Multivariate analysis was performed on the relationship between PROMs and age, global tilt (GT) and coronal malalignment (CM).

Results: Four hundred forty-three patients had CM of more than 2 cm compared to 800 who did not. The distribution of these modifiers was correlated to age. After multivariate analysis, using age and GT as confounding factors, we found that before the age of 50 years, 2A1 patients had worse sex life and greater satisfaction than patients without CM. After 50 years of age, patients with CM (1A1, 1A2) had worse self-image and those with 2A2, 2B had worse self-image, satisfaction, and 36-item Short Form Health Survey physical function. Self-image was the consistent determinant of patients opting for surgery for all ages.

Conclusion: CM distribution according to O-CM modifiers is age dependent. A clear correlation between the coronal malalignment and PROMs exists when using the O-CM classification and in the mobile spine, this typically affects self-image and satisfaction. Thus, CM classified according to O-CM modifiers is correlated to PROMs and should be considered in ASD.

Keywords: Spine, Deformity, Scoliosis, Coronal malalignment
INTRODUCTION

Adult spinal deformity (ASD) describes a complex array of spinal conditions causing spinal deformity. ASD is common with a reported prevalence of 32% of patients aged over 50 years and 68% of patients aged over 70 years. The degree of deformity typically correlates with the patient’s disability (quality of life, QoL). The predominant reason for this disability is that the spinal deformity induces spinal imbalance that prevents the normal economic resting posture of the spine, increasing the physiological demands of the spine and perispinal musculature. The resulting disability has been shown to directly relate to the degree of spinal imbalance. It is now well recognized that an imbalanced spine severely affects patient’s function and QoL. Due to its high incidence and severe effects, ASD is estimated to have the greatest global disease burden of all common long-term disorders, including arthritis, chronic lung disease, congestive heart failure, diabetes, and ischemic heart disease.

The most well-recognized correlation between spinal imbalance and disability is that of sagittal imbalance. Glassman and colleagues were the first to study the effects of spinal sagittal imbalance on functional outcomes and found that an increase in sagittal imbalance worsened functional outcomes. This finding has been confirmed in a number of subsequent publications.

More recently the effects of coronal malalignment (CM) have been reported, with new classification systems developed to further understand the effect of coronal deformities on pain, function, and QoL. CM reflects the lateral deviation of the trunk over the pelvis and can be represented by the C7 plumb line, with substantial displacement from the midline of the pelvis considered to be more than 20 mm. In a recent classification, proposed by Obeid and colleagues, the Obeid-CM (O-CM) classification, the authors incorporate specific modifiers for each curve type, dependent on the direction of the CM in relation to the main curve of the deformity. The classification defines a concave CM (type 1) as the coronal plumbline being on the ipsilateral side of the concavity of the curve, in contrast to a convex CM (type 2) where the plumbline is on the convex side of the curve. This is further subtyped with type 1A having the main curve apex between T12 and L4 and type 1B having its apex above T12. Type 1A1 is flexible and type 1A2 is rigid. Type 2A has the apex of the main curve between T12 and L4, whereas type 2B has the apex below L4. Type 2A1 has a normal lumbosacral junction and type 2A2 has a degenerative lumbosacral junction (Fig. 1). Patients with no CM are defined as a C7 plumb line being within 2 cm of the central sacral vertical line.

### TABLE 1. Obeid-coronal malalignment classification.

<table>
<thead>
<tr>
<th>Types</th>
<th>Subtypes</th>
<th>First modifier: the apex of the curve</th>
<th>Second modifier: flexibility of curve</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main coronal curve types</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 1</td>
<td>Concave</td>
<td>Type 1A between T12 and L4</td>
<td>Type 1A1 flexible</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Type 1B above T11-12</td>
<td>Type 1A2 rigid</td>
</tr>
<tr>
<td>Type 2</td>
<td>Convex</td>
<td>Type 2A between T12 and L4</td>
<td>Type 2A1 flexible</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Type 2B Lumbosacral junction: below L4-5</td>
<td>Type 2A2 rigid</td>
</tr>
</tbody>
</table>

The purpose of this study was to evaluate O-CM modifiers according to age, sagittal alignment, CM, and patient-reported outcome measures (PROMs), in the mobile spine.

MATERIALS AND METHODS

We performed a retrospective review of a prospective multicenter ASD database with 1,243 ASD patients with no prior spinal fusion surgery. Ethical approval was obtained from Centre Hospitalier Universitaire de Bordeaux (IRB number: CE-GP-2019-14). Patients were included if they were aged at least 18 years, had no prior spinal fusion, and were affected by spinal deformity defined by at least one of the following: Cobb angle ≥ 20°, pelvic tilt ≥ 25°, sagittal vertical axis ≥ 5 cm, or thoracic kyphosis ≥ 60°.

All patients completed Numerical Rating Scale back and leg pain scores, Oswestry Disability Index (ODI), 36-item Short Form Health Survey (SF-36), and Scoliosis Research Society 22 (SRS-22) scores. All patients were radiologically assessed according to the O-CM classification as well as global tilt (GT). Patients were classified according to the 6 modifiers of the O-CM classification and were compared to coronally aligned patients. We then subsequently compared those patients that decided to undergo deformity correction to those that did not in order to determine which reported PROMS affected this decision.

Univariate and multivariate analysis was performed on the relationship between PROMs and age, sagittal GT, and CM using IBM SPSS Statistics ver. 25.0 (IBM Co., Armonk, NY, USA). We used GT as our sagittal parameter to exclude the confounding effect of sagittal balance on PROMs. Cross-tabulation was generated and chi-square test was used to compare all the dis-
tributions of the modifiers according to age. Impaired t-tests or analysis of variance were performed to compare all groups of CM and to assess differences in means for PROMs. For each distribution, we used linear regression analysis to analyze the correlation between health-related QoL scores with GT and age and to determine if GT and/or age were confounding factors. In this case, we carried out a multivariate analysis using an analysis of covariance (ANCOVA) test for the PROMs for which we had a p-value less than 0.05 to determine if statistical significance persisted when taking into account the effect of GT and/or age.

RESULTS

A total of 1,243 patients were included. The mean age was 52 years (range, 18–90 years). Four hundred forty-three patients had CM of more than 2 cm compared to 800 who did not and the age distribution of CM appeared bimodal (Fig. 2). Eight hundred forty-one patients were subsequently elected for operative intervention and 402 elected for nonoperative treatment.

The distribution of the modifiers was correlated to age; mean age was 35 years for 2A1 patients, 44 years for 1B, and around 64 years for all other modifiers (Table 1).

When patients are grouped into an age of under 50 years compared to those older than 50 years, 76% of patients affected by CM who are under 50 years of age have subtype 2A1. In contrast over the age of 50 years, the distribution of the O-CM varied more broadly (Table 2).

On univariate analysis, comparing the PROMs of those patients aged under 50 years with O-CM type 2A1 to those without coronal imbalance, the only statistically significant differences were a reduction in the ODI sex life (0.52 vs. 0.77, p = 0.033) and higher satisfaction (3.56 vs. 3.22, p = 0.015). No age or radiological confounders were identified and therefore no multivariate analysis performed in this group.

After 50 years of age, on univariate analysis, patients with coronal malalignment (O-CM classification 1A1/2) had a worse SRS-22 self-image (2.2 vs. 2.5, p = 0.000) and SF-36 physical function (33.3 vs. 35.2, p = 0.044) than those with no CM. Similarly, patients with coronal malalignment O-CM classification 2A2 and 2B had worse SRS-22 self-image (2.3 vs. 2.5, p = 0.000), SRS-22 satisfaction (2.8 vs. 3.2, p = 0.002) and SF-36 physical function (32.9 vs. 35.2, p = 0.015) than those with no CM. In contrast, only those with O-CM classification 1A1/2 had significantly greater GT (40.6 vs. 30.7, p = 0.000). On multivariate analysis, accounting for age and GT as confounders in patients with O-CM classification 1A1/2, only the SRS-22 self-image remained significant (2.2 vs. 2.5, p = 0.014).

When comparing those patients that subsequently elected for continued nonoperative care to those who undergo deformity correction, in those younger than 50 years, we found that the nonoperative cohort O-CM 2A1 initially presented with a worse ODI sex life (0.26 vs. 0.55, p = 0.026) than their coronally balan-

---

**Table 1.** The distribution of modifiers correlated to age

<table>
<thead>
<tr>
<th>Subtype</th>
<th>No.</th>
<th>Age (yr), mean (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A1</td>
<td>56</td>
<td>65.0 (19–90)</td>
</tr>
<tr>
<td>1A2</td>
<td>71</td>
<td>64.9 (19–85)</td>
</tr>
<tr>
<td>1B</td>
<td>23</td>
<td>43.6 (18–75)</td>
</tr>
<tr>
<td>2A1</td>
<td>140</td>
<td>34.9 (18–74)</td>
</tr>
<tr>
<td>2A2</td>
<td>113</td>
<td>63.7 (28–82)</td>
</tr>
<tr>
<td>2B</td>
<td>40</td>
<td>62.7 (20–82)</td>
</tr>
<tr>
<td>No coronal malalignment</td>
<td>800</td>
<td>50.9 (18–87)</td>
</tr>
<tr>
<td>Total</td>
<td>1,243</td>
<td>52.0 (18–90)</td>
</tr>
</tbody>
</table>

**Table 2.** The frequency of Obeid-coronal malalignment subgroups under and over the age of 50 years

<table>
<thead>
<tr>
<th>Subtype</th>
<th>Age &lt; 50 yr</th>
<th>Age ≥ 50 yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A1</td>
<td>5 (1.0)</td>
<td>51 (6.7)</td>
</tr>
<tr>
<td>1A2</td>
<td>1 (0.2)</td>
<td>70 (9.2)</td>
</tr>
<tr>
<td>1B</td>
<td>13 (2.7)</td>
<td>10 (1.3)</td>
</tr>
<tr>
<td>2A1</td>
<td>110 (22.9)</td>
<td>30 (3.9)</td>
</tr>
<tr>
<td>2A2</td>
<td>9 (1.9)</td>
<td>104 (13.6)</td>
</tr>
<tr>
<td>2B</td>
<td>7 (1.5)</td>
<td>33 (4.3)</td>
</tr>
<tr>
<td>No coronal malalignment</td>
<td>335 (69.8)</td>
<td>465 (60.9)</td>
</tr>
</tbody>
</table>

Values are presented as number (%).
cated counterparts. All other PROMs and GT were similar. However, age was a confounding factor (ANCOVA, \( p = 0.104 \)), and on multivariate analysis no difference when accounting for age between the 2A1 and coronal balanced patients. ODI sex life was found. In contrast, those that subsequently elected for surgical correction had a worse SRS-22 self-image (2.5 vs. 2.8, \( p = 0.020 \)) and better SRS-22 satisfaction (3.5 vs. 3.0, \( p = 0.014 \)) than their coronally balanced counterparts. The age and GT were again similar.

For those aged over 50 years, the nonoperative group with O-CM 1A1/2 had worse SF-36 physical function (36.0 vs. 40.0, \( p = 0.039 \)) than those who were coronally aligned. There was no significant difference in GT (35.0 vs. 27.1, \( p = 0.066 \)) and therefore no multivariate analysis was performed. For those with O-CM 2A2 and 2B, there were no identifiable differences in PROMs or GT between the coronally aligned and mal-aligned groups that elected for nonoperative care.

In contrast, those aged over 50 years that elected for operative intervention with O-CM 1A1/2 had worse SRS-22 self-image (2.0 vs. 2.3, \( p = 0.000 \)) than those who were coronally aligned. They also had a greater GT (42.9 vs. 32.1, \( p = 0.000 \)). On multivariate analysis, accounting for age and GT, the SRS-22 self-image remained lower for those with O-CM 1A1/2 (2.0 vs. 2.3, \( p = 0.007 \)). Patients with O-CM 2A2 and 2B had worse SRS-22 self-image (2.1 vs. 2.3, \( p = 0.014 \)) and SRS-22 satisfaction (2.7 vs. 3.1, \( p = 0.004 \)) than those who were coronally aligned. When accounting for age and GT the trend remained with a worse SRS-22 self-image (2.1 vs. 2.3, \( p = 0.031 \)) and SRS-22 satisfaction (2.7 vs. 3.1, \( p = 0.003 \)) in the O-CM 2A2 and 2B group. There was no other statistically significant difference between the groups in relation to PROMs or GT.

**DISCUSSION**

While sagittal imbalance is well recognized as correlating to patient outcomes, there is inconsistent evidence about the effect of coronal deformities on patient pain, function, and QoL.\(^{1,3,14}\) However, with a number of new classifications recently proposed there is a resurgence of interest in CM.\(^{12,14-17}\) In a recent study published by Plais et al.,\(^{18}\) the authors assessed the effect of CM in relation to the Qui classification in mobile spines and found an age-dependent variance in the curve type and a relationship between the degree of CM greater than 3 cm to functional outcomes.

In the present study, we assessed similar variables, but utilized the O-CM classification. We found that a CM of 2 cm or greater affected PROMs, suggesting that the O-CM classification is more sensitive than other published classifications for detecting the effects of CM on patient outcomes. We found a similar age variance to the curve type reported by Plais et al.,\(^{18}\) with most patients under the age of 50 years being affected by O-CM subtype 2A1, and those older than 50 years being more evenly affected by different subtypes. We chose 50 years because our dataset suggested a bimodal distribution with 50 years being between the peaks (Fig. 1). In addition, the article by Fujishiro et al.\(^{19,20}\) used an age of 40 years as a cutoff because the authors noted patients typically start to become symptomatic after this age. Furthermore, Yilgor et al.\(^{21}\) used age 60 years for the Global Alignment and Proportion score because most complications were thought to present around this age. In our study, we were assessing the deformity itself and age 50 years was therefore deemed appropriate.

We also identified that coronal imbalance variably affects specific outcomes according to the age and curve type. Patients aged under 50 years with CM have a worse sex life, but higher satisfaction. In contrast, those older than 50 years with O-CM 1A1 or 1A2 had worse self-image and those with 2A1 and 2B had worse self-image, satisfaction, and physical function.

In addition, when assessing which patients subsequently elected for spinal deformity correction, irrelevant of age, self-image was the only consistent factor. Unexpectedly, patient satisfaction was in fact higher in those aged less than 50 years who subsequently elected for surgery in contrast to those older than 50 whose satisfaction was lower. This suggests that self-image is the predominant determinant of surgical intervention in younger patients, whereas satisfaction and self-image drive decision making in older patients.

Furthermore, the fact that only specific PROMs, notably self-image and satisfaction, rather than overall QoL and function were altered suggests that surgeons contemplating surgical intervention for CM should recognize these factors as predominant determinants of patient decision making and counsel them accordingly.

This study offers several advantages to previous literature: notably its large sample size, its multivariate analysis, the consideration of different curve types to subanalyse CM, and the effects on specific PROMS. However, despite these advantages, this study has a number of limitations. Firstly, for each age bracket, we analyzed the most common deformity patterns and therefore our results cannot be translated to more rare deformity subtypes. Secondly, we used GT as a composite of sagittal imbalance and therefore other parameters of sagittal deformity can-
not be excluded as confounders. Lastly, we have not assessed the effect of surgical intervention on improving patient outcomes.

Despite these limitations, this study shows that CM clearly affects PROMs and the disparity with the previous literature is due probably to the fact that only general types of CM were described, bypassing the different subtypes and eventually confusing them. In addition, the current study has shown that the CM pattern is age related and that the age distribution is not homogeneous which we believe needs to be understood for the patient’s best management and eventual operative planning if surgery is indicated.

CONCLUSION

CM distribution according to O-CM modifiers is age dependent. Despite previous reports failing to correlate CM with PROMs, our study shows that when each modifier is considered a clear correlation exists. In the nonfused spine, an independent correlation between CM and PROMs affecting specifically self-image and satisfaction was shown. Thus, CM classified according to O-CM modifiers is correlated to PROMs and should be considered in ASD.

CONFLICT OF INTEREST

The authors have nothing to disclose.

ACKNOWLEDGMENTS

We appreciate Glynny Kieser for her grammatical and editorial input.

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Adult Spinal Deformity and Novel Classifications: Is Coronal Malalignment Making a Comeback?: Commentary on “Obeid-Coronal Malalignment Classification Is Age Related and Independently Associated to Personal Reported Outcome Measurement Scores in the Nonfused Spine”

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²Department of Neurological Surgery, University of Virginia Health System, Charlottesville, VA, USA

Hippocrates, the prominent Greek physician of antiquity, introduced novel evidence-based practices to improve diagnosis, management, and prevention of diseases.¹ Protocols and guidelines for the classification of diseases were fundamental to Hippocratic medicine.¹ Since then, countless classification systems for various medical diseases have been proposed and refined, culminating in the numerous standardized algorithms and treatment paradigms available for today's physicians. Although classification systems for adult spinal deformity (ASD) have been previously proposed,²,³ there is currently no clear consensus regarding the optimal assessment and/or classification of global coronal malalignment (CM; lateral displacement of coronal C7 plumbline from center sacral vertical line) and its potential coronal deformity subtypes (e.g., CM ipsilateral to major curve concavity vs. convexity).⁴,⁵

After the success of the Lenke classification for guiding treatment of adolescent idiopathic scoliosis,⁶ the Scoliosis Research Society (SRS) developed a novel classification for ASD in 2006.³ This initial ASD classification included a global CM modifier, but the CM modifier was subsequently removed in the 2012 SRS-Schwab ASD classification.²,³ This may have partly been due to several landmark studies emphasizing the importance of sagittal spinal malalignment and its significant impact on pain and disability, while also suggesting that the magnitude of coronal deformity and extent of coronal correction were less critical.⁷,⁸ However, more recent studies suggest that the clinical impact of CM may have been previously underestimated.⁹ Furthermore, novel classifications of CM have been proposed, which include the Qiu classification and Obeid-Coronal Malalignment (O-CM) classification.⁴,⁵

Given the resurgence of interest and focus on coronal deformity in contemporary ASD
literature,$^{4,5,10}$ we commend Kieser et al.$^{11}$ for their timely analysis and rigorous investigation of the O-CM classification and its treatment modifiers. Briefly, the O-CM classification (from Obeid et al.$^4$) includes the following modifiers: type 1A1 (concave CM with flexible thoracolumbar/lumbar [TL/L] main curve), type 1A2 (concave CM with rigid TL/L main curve), type 1B (concave CM with main cervicothoracic/thoracic curve), type 2A1 (convex CM with flexible, non-degenerated lumbosacral junction), type 2A2 (convex CM with rigid, degenerated lumbosacral junction), type 2B (main short lumbosacral deformity [convex-like CM]).$^4$ Based on these different coronal deformity patterns and modifiers, Obeid et al.$^4$ proposed a novel surgical algorithm to guide operative planning.

In the current study by Kieser et al.,$^{11}$ the authors evaluated the 6 O-CM classification modifiers according to patient age, sagittal alignment (using global tilt), CM, and various patient-reported outcome measures (PROMs) in ASD patients without prior spinal fusion. Their results demonstrated that CM subtypes according to the 6 O-CM modifiers were age-dependent.$^{11}$ That is, the distribution of the O-CM modifiers correlated to patients’ age, with mean age 35 years for 2A1, 44 years for 1B, and approximately 63–65 years for all other O-CM modifiers (1A1, 1A2, 2A2, 2B). Next, CM patients were dichotomized using age cutoff 50 years and results demonstrated that most (76%) patients < 50 years were 2A1. In comparison, patients > 50 years had more broad distribution of O-CM modifiers, with 2A2 and 1A2 being the most common at 35% and 23%, respectively.$^{11}$

Kieser et al.$^{11}$ then utilized the O-CM modifiers to determine the clinical impact of coronal deformity on ASD patients at baseline. For age < 50 years, 2A1 demonstrated worse Oswestry Disability Index sex life (0.52 vs. 0.77, p = 0.033) but higher satisfaction (3.56 vs. 3.22, p = 0.015) than coronally-aligned patients. For age > 50 years, 1A1 and 1A2 had worse SRS-22 self-image (2.2 vs. 2.5, p = 0.014) than coronally-aligned patients. Also, 2A2 and 2B patients had worse SRS-22 self-image (2.3 vs. 2.5, p = 0.000), SRS-22 satisfaction (2.8 vs. 3.2, p = 0.002), and SF36 physical function (32.9 vs. 35.2, p = 0.015) than coronally-aligned patients.$^{11}$

An interesting finding from the subgroup analysis of patients < 50 years was the association of CM with significantly higher satisfaction scores.$^{11}$ The authors reported no age or radiological confounders, but since the only investigated sagittal parameter was global tilt, the possibility of another sagittal deformation parameter confounding these study results (or any of the other results in the study) could not be excluded.$^{11}$ We commend Kieser and colleagues for recognizing and acknowledging this potential study weakness in their discussion.$^{11}$

The authors consistently identified SRS-22 self-image as being significantly different among CM vs. coronally-aligned patients.$^{11}$ For example, significant differences in SRS22 self-image scores were reported as 0.2 and 0.3 in several of the study’s comparisons.$^{11}$ Although these comparisons achieved statistically significant, it was not clear if such small differences in this subdomain truly represent a clinically meaningful difference. If the analysis had focused on assessing treatment outcomes, then using a previously reported value of minimum clinically important difference for SRS-22 self-image (0.8) could be useful.$^{12}$ However, the lack of literature regarding subdomains of the SRS-22 instrument and minimum measurement differences for various subpopulations may limit interpretation of these results.

Next, Kieser et al.$^{11}$ investigated the various factors that may have impacted the decision to pursue operative treatment rather than continue nonoperative care. The analysis revealed that worse SRS-22 self-image was the consistent determinant among CM patients of all ages who elected for operative treatment.$^{11}$ Of note, Bess et al.$^{13}$ previously reported that operative treatment of younger adults with scoliosis was driven by coronal deformity whereas operative treatment of older adults with scoliosis was driven by pain and disability. Collectively, these results contribute to the literature and data available to surgeons for preoperative counseling of ASD patients and the decision to transition from nonoperative to operative management.

In conclusion, the current study by Kieser et al.$^{11}$ represents an important contribution and progress towards a clinically relevant classification of CM in ASD. Their analysis of a large ASD cohort (n = 1,243) demonstrated that the Obeid classification of CM provides clinically useful modifiers that can potentially facilitate surgical counseling and decision-making.$^3$ Notably, the authors reported that the Obeid-CM modifiers correlated to both patient age and various PROMs, with SRS22 self-image being the most consistent subdomain to manifest statistically significant differences among coronally-malaligned versus aligned patients.$^{4,11}$ In the future, a study utilizing the Obeid-CM classification modifiers to assess the clinical impact of operative intervention could provide further evidence in support of this classification system.$^4$ Until then, no definitive recommendations can be made as to whether recently published CM classifications, such as the Qiu classification$^9$ and/or Obeid classification,$^4$ warrant a potential update to the SRS-Schwab ASD classification with inclusion of novel coronal modifiers.$^5$
CONFLICT OF INTEREST

The author has nothing to disclose.

REFERENCES


Title: Naked woman with dripping hair
Artist: Pablo Picasso
Year: 1902
© 2021 - Succession Pablo Picasso - SACK (Korea)
Modified Global Alignment and Proportion Scoring With Body Mass Index and Bone Mineral Density Analysis in Global Alignment and Proportion Score of Each 3 Categories for Predicting Mechanical Complications After Adult Spinal Deformity Surgery

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Objective: This study aimed to analyze the prediction rate of the modified Global Alignment and Proportion (GAP) scoring system with body mass index and bone mineral density (GAPB) in each GAP of the 3 categories.

Methods: Between January 2009 and December 2016, 203 consecutive patients with adult spinal deformity (ASD) underwent corrective fusion of more than 4 levels and were followed-up for more than 2 years. As a validation of the GAPB, the GAPB was divided into tertiles (Q1, Q2, Q3) for each section of the GAP score. Each patient's GAP score and GAPB system complication rate were examined.

Results: Of the 203 patients, 89 patients (44%) developed mechanical complications after ASD surgery. A GAP score analysis of the patients found that 42 patients were proportioned, 85 patients were moderately disproportioned, and 76 patients were severely disproportioned. Mechanical complications occurred with increasing GAPB in the proportioned group, but were not statistically significant (p = 0.0534). However, mechanical complications occurred in a statistically significant manner in the moderately disproportioned and severely disproportioned groups as GAPB increased (p < 0.001).

Conclusion: The GAPB system showed improved predictability for mechanical complications after surgery for ASD in each category of the GAP score.

Keywords: Adult spinal deformity, Mechanical complication, Body mass index, Bone mineral density, Retrospective study, Global alignment and proportion scoring
INTRODUCTION

The incidence of spinal deformities in adults has been increasing with the age of the population. Currently, the incidence of spinal deformities ranges from 29% in adults who are 54 years of age to over 65% in adults who are over 65 years of age.\(^1\) Comprehensive surgical planning of adult spinal deformity (ASD) is possible with a better understanding of the sagittal alignment of the spine, which is key to achieving optimal surgical alignment and improved results. A recent study of outcomes after ASD surgery reported high rates of complications (8.4%–42%) and revision rates (9%–17.6%).\(^2-5\) Among complications, proximal junctional kyphosis (PJK) and proximal junctional failure (PJF) are common, and morbidity has been reported at 20%–40%.\(^6\)

Furthermore, revision surgery is often performed because of pseudoarthrosis, implant failure, adjacent segment disease, or infection, resulting in increased medical costs.\(^7\)

Many studies have presented optimal radiologic targets and reported formulas for predicting mechanical complications. The Scoliosis Research Society (SRS)-Schwab classification, age-adjusted alignment goals, the Global Alignment and Proportion (GAP) score, modified GAP scoring system with body mass index (BMI) and bone mineral density (GAPB) have been reported as formulas related to surgery for ASD. In particular, the recently introduced GAPB system adds BMI and BMD to the GAP score to combine the characteristics of the patient.\(^8\) In a study by Noh et al.,\(^9\) compared to the GAP score, the modified GAPB system improved the predictive value of mechanical complications after surgery for ASD. However, the prediction rates of GAPB in the 3 categories of the GAP score (portioned, moderately disproportioned, severely disproportioned) have not been analyzed. Therefore, this study aims to analyze the prediction rate of GAPB in each of the 3 categories of the GAP score.

MATERIALS AND METHODS

1. Patient Population

The current study is a 2-center cohort review of patients suffering from ASD using posterior spinal fusion and instrumentation between January 2009 and December 2016. The inclusion criteria were as follows: (1) patients who underwent surgical deformity surgery for ASD; (2) patients who had a coronal spinal curvature >20°, sagittal vertical axis > 5 cm, pelvic tilt (PT) > 25°, or thoracic kyphosis (TK) > 60° as indicated by radiologic examinations; (3) patients who underwent surgery for posterior instrumented fusion of ASD for more than 4 levels; and (4) those with a follow-up period of more than 2 years. The exclusion criteria were as follows: (1) ASD patients secondary to syndromic, infectious, tumor, autoimmune, or other pathologic conditions; (2) those who underwent surgery for ASD at level 4 or below; and (3) patients with a follow-up period less than 2 years. From January 2009 to December 2016, 456 patients with ASD underwent spinal surgery at Gangnam Severance Hospital. We excluded 253 patients with a follow-up period of less than 2 years, those who were not indicated for correction surgery for ASD, or those with a surgical level below level 3. From January 2009 to December 2016, 203 patients who underwent surgery for ASD were contained. The study was approved by each hospital’s Institutional Review Board and all participants provided written consent.

2. Radiographic Measurements and Scoring

All radiographs were analyzed using validated software (Surgimap, Nemaris Inc., New York, NY, USA). The measured pelvic parameters were pelvic incidence (PI), PT, and sacral slope (SS). Local spinal parameters contained PI–LL, L1–S1 Lordosis, L4–S1 lordosis, and TK. The sagittal alignment was evaluated by T1 pelvic angle and global tilt. All radiographic evaluations were performed 4 weeks after surgery.

GAP scoring was conducted according to the formula by Yilgor et al.\(^9\) The GAP score consists of relative pelvic version, relative lumbar lordosis, lumbar distribution index, relative sagittal alignment, and age. The GAP score ranges from 0 to 13 points. The selected GAP score cutoff point was consistent with the cutoff value determined by the report of Yilgor et al.\(^9\) Relative pelvic versions of < 15° (with measured SS minus ideal SS) were considered to be severe retroversion; -15° to -7.1°, moderate retroversion; -7° to 5°, aligned; and > 5°, anteverision. Relative lumbar lordosis < 25° (measured lumbar lordosis minus ideal lumbar lordosis) were considered severe hypolordosis; -25° to -14.1°, moderate hypolordosis; -14° to 11° aligned; and > 11°, hyperlordosis. Less than 40% of the lumbar distribution index (L4–S1 lordosis divided by L1–S1 lordosis multiplied by 100 loadsheets) was considered to be a severe hypolordotic maldistribution; 40%–49%, moderate hypolordotic maldistribution; 50%–80%, aligned; and > 80%, hyperlordotic maldistribution. Relative spinopelvic alignment > 18° (measured global tilt minus ideal global tilt) was considered a severe positive malalignment; 10.1°–18°, moderate positive malalignment; 10° to -7° aligned; < -7°, negative malalignment. A GAP score of 0–2 was classified as indicating the state of the proportional spinopelvic state; 3–6, moderately disproportioned; > 6, severely disproportioned.
The modified predictive model included the GAP score, BMI, and BMD (GAPB). As described above, GAP scores were obtained, and BMI and BMD were measured before surgery. The standards of the World Health Organization (WHO) using BMD measured by double energy x-ray absorption measurements are the most widely used in the diagnosis of osteoporosis. The BMD was measured according to the WHO criteria to use the worst of the spine and femur measurements. The mechanical complication rate was calculated through the nomogram of the GAPB as described by Noh et al.

3. Mechanical Complications

Mechanical complications were defined as PJK or PJF, distal junctional kyphosis (DJK) or distal junctional failure (DJF), rod fracture, and implant-related complications. Implant-related complications were defined as screw loosening, breakage, pull-out or interbody graft, hook, or set-screw dislodgement.

4. Statistical Analysis

As a validation of the GAPB score, the GAPB score (predicted probability) was divided into tertiles (Q1, Q2, Q3) for each section of the GAP score: proportioned, 0–2 points; moderately disproportioned, 3–6 points, and severely disproportioned, 7–13 points. In addition, the Cochran-Armitage trend test was conducted to determine whether the probability of actual replication increased. A p-value < 0.05 was considered to indicate statistical significance. All statistical analyses were performed using SAS 9.3 (SAS Institute Inc., Cary, NC, USA).

RESULTS

1. Patients Demographics

Two hundred three patients underwent surgery for ASD (170 women [84%], 33 men [16%]). Their demographic data are listed in Table 1. The average age of the patients was 66.8 ± 12.28 years (range, 54–83 years), and the average follow-up duration was 30.54 ± 6.25 months (range, 24–118 months). The number of prior cases of spine surgery was 55 cases (27%), the mean BMI was 23.75 ± 2.57 kg/m², and the mean BMD was -1.95 ±
Among the diagnoses, there were 196 degenerative cases (97%), 6 posttraumatic cases (2.9%), and 1 neuromuscular case (0.1%). Mechanical complications occurred in a total of 89 cases (44%), among which 60 cases occurred in the PJK and PJF, and 22 cases in the rod fracture. Implant-related complications occurred in 4 cases, and DJK/DJF occurred in 3 cases.

2. Range of GAPB by GAP Score Group

There were a total of 203 cases. Each count was converted back to the GAPB score system. Then, each group was divided into Q1, Q2, and Q3 groups. The minimum and maximum values of Q1, Q2, and Q3 are shown in Table 2 and Fig. 1. The proportioned group had 42 cases, resulting in 14 cases each in the Q1 (0.012–0.036), Q2 (0.038–0.133), and Q3 (0.136–0.928). The moderately disproportioned group had 85 cases, with 28, 29, and 28 cases in the Q1 (0.008–0.114), Q2 (0.117–0.482), and Q3 (0.485–0.999) groups, respectively. The severely disproportioned group had 76 cases, with 25, 26, and 25 cases divided Q1 (0.175–0.617), Q2 (0.632–0.883), and Q3 (0.886–0.993) groups, respectively.

Table 3. Observed probability of complication by GAP score group

<table>
<thead>
<tr>
<th>Group</th>
<th>Total</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Observed probability</td>
<td>Standard error</td>
<td>No.</td>
</tr>
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<td>Proportioned</td>
<td>42</td>
<td>0.000</td>
<td>0.000</td>
<td>14</td>
</tr>
<tr>
<td>Moderately disproportioned</td>
<td>85</td>
<td>0.036</td>
<td>0.035</td>
<td>29</td>
</tr>
<tr>
<td>Severely disproportioned</td>
<td>76</td>
<td>0.560</td>
<td>0.099</td>
<td>26</td>
</tr>
</tbody>
</table>

GAP, Global Alignment and Proportion.

Table 4. Cochran-Armitage trend test

<table>
<thead>
<tr>
<th>Group</th>
<th>Total</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>p-value</th>
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<tbody>
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<td>Observed probability</td>
<td>Standard error</td>
<td>No.</td>
<td>Observed probability</td>
</tr>
<tr>
<td>Proportioned</td>
<td>42 (100)</td>
<td>14 (100)</td>
<td>14 (100)</td>
<td>14 (100)</td>
<td>0.0534</td>
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<tr>
<td>Total</td>
<td>85 (100)</td>
<td>28 (100)</td>
<td>29 (100)</td>
<td>28 (100)</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Complication (-)</td>
<td>58 (68.24)</td>
<td>27 (96.43)</td>
<td>21 (72.41)</td>
<td>10 (35.71)</td>
<td></td>
</tr>
<tr>
<td>Complication (+)</td>
<td>27 (31.76)</td>
<td>1 (3.57)</td>
<td>8 (27.59)</td>
<td>18 (64.29)</td>
<td></td>
</tr>
<tr>
<td>Moderately disproportioned</td>
<td>76 (100)</td>
<td>25 (100)</td>
<td>26 (100)</td>
<td>25 (100)</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Total</td>
<td>18 (23.68)</td>
<td>11 (44.00)</td>
<td>6 (23.08)</td>
<td>1 (4.00)</td>
<td></td>
</tr>
<tr>
<td>Complication (+)</td>
<td>58 (76.32)</td>
<td>14 (56.00)</td>
<td>20 (76.92)</td>
<td>24 (96.00)</td>
<td></td>
</tr>
</tbody>
</table>

Values are presented as number (%).

*p < 0.05, statistically significant differences.
3. Observed Probability of Complication by GAP Score Group

Table 3 shows the observed probability of complications by the GAP score group. The observed probability of complications (observed probability ± standard error) of Q1, Q2, Q3 were 0.000 ± 0.000, 0.071 ± 0.069, and 0.214 ± 0.110, respectively, in the proportioned group; 0.036 ± 0.035, 0.276 ± 0.083, and 0.643 ± 0.091, respectively, in the moderately disproportioned group; and 0.560 ± 0.099, 0.769 ± 0.083, and 0.960 ± 0.039, respectively, in the severely disproportioned group.

4. Cochran-Armitage Trend Test

Table 4 shows the frequencies of mechanical complications in each group using the Cochran-Armitage trend test. As the score was converted to GAPB in each group of the GAP scoring system increased, the number of mechanical complications increased. In addition, there were statistically significant findings in the moderately disproportioned and severely disproportioned groups (p < 0.0001).

5. Subgroup Analysis: Pelvic Fixation (+) / (-)

The trend of GAPB in the GAP of each group was analyzed.
In addition, the shape/alignment, which is not ideal, can be recognized early after surgery, so treatment of osteoporosis, rehabilitation, and correction of activity can be performed as needed. However, the disadvantage of this formula is that only patient-specific factors other than radiologic parameters are included. In this formula, there was a limitation of simply dividing by 60 and more. Furthermore, the GAP study group consisted of subjects who were 18 years of age or older, and the age range was too wide for use in the ASD group.

Therefore, a new model that included BMI and BMD that was suitable for the ASD group, is characteristic of patients, and affects ASD surgery was needed. The GAPB system, including BMI and BMD, showed improved predictability for forecasting mechanical complications compared to the GAP scoring system \cite{[8]}. Many studies have reported that obesity and age are important risk factors for PJK, PJF, and other mechanical complications\cite{[14]-[17]}. In surgery for ASD, BMI and osteoporosis are essential when discussing mechanical complications because most elderly patients have low muscle mass and severe osteoporosis.

Noh et al\cite{[8]} reported that the area under the curve of the GAPB system is more than that of GAP score system. But the prediction rates of the GAPB system for the 3 categories of the GAP score (with severe imbalances in the middle of the proportion) were not analyzed. Because the GAP score was used to predict the possibility of complications within the three categories, there was no difference between 3 and 6 points in the GAP score, and there was no difference between 7 and 13 points. According to the GAP score, the incidence of mechanical complications was only 6% in patients in the proportioned group, but not 47% and 100% in the disproportioned group.

Many studies have been performed to reduce mechanical complications in surgery for ASD, and several studies have suggested ideal targets. Schwab et al\cite{[11]} proposed a clinically relevant classification for surgery for ASD, which may be advantageous because the surgeon can then treat the disease by highlighting the patient’s sagittal alignment. Although it was corrected according to the Schwab classification, there have been many cases of mechanical complications. Lafage et al\cite{[13]} proposed an ideal target by considering changes in radiologic parameters with age. However, this was also incomplete.

Yilgor et al\cite{[9]} reported the GAP scoring system. The proportional parameter according to the PI was related to the rate of mechanical complications, and the mechanical complication rate was lower in the proportioned group. In contrast to absolute values such as SRS-Schwab classification’s target and age-adjusted alignment goals, these parameters fit well with individual variability in human anatomy. According to the PI-based global alignment and “ratio concept,” the spine pelvic alignment can be used to set up separate radiologic targets for surgical planning. In addition, the shape/alignment, which is not ideal, can be recognized early after surgery, so treatment of osteoporosis, rehabilitation, and correction of activity can be performed as needed. However, the disadvantage of this formula is that only patient-specific factors other than radiologic parameters are included. In this formula, there was a limitation of simply dividing by 60 and more. Furthermore, the GAP study group consisted of subjects who were 18 years of age or older, and the age range was too wide for use in the ASD group.

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Fig. 2. No pelvic fixation group. The observed probability of complications (observed probability ± standard error) of Q1, Q2, Q3 were 0.000 ± 0.000, 0.2 ± 0.179, and 0.000 ± 0.000, respectively, in the proportioned group; 0.000 ± 0.000, 0.2 ± 0.126, and 0.7 ± 0.145, respectively, in the moderately disproportioned group; and 0.429 ± 0.187, 0.625 ± 0.171, and 1.0 ± 0.000, respectively, in the severely disproportioned group.

Fig. 3. Pelvic fixation group. The observed probability of complications (observed probability ± standard error) of Q1, Q2, Q3 were 0.000 ± 0.000, 0.000 ± 0.000, and 0.3 ± 0.145, respectively, in the Proportioned group; 0.056 ± 0.054, 0.316 ± 0.107, and 0.579 ± 0.113, respectively, in the Moderately disproportioned group; and 0.588 ± 0.119, 0.833 ± 0.088, and 0.944 ± 0.054, respectively, in the Severely disproportioned group.
95% in the moderately and severely disproportioned group. However, since GAPB can be used to predict the possibility of mechanical complications in each case, it can provide accurate information to the surgeon. In our study, the incidence of mechanical complications increased as the GAPB score increased in the 3 categories of the GAP scoring system. Especially in the moderate disproportioned and severely disproportioned groups, there was a statistically significant increase (p < 0.0001). In predicting mechanical complications using GAPB, the fact that it came out meaningfully within the 3 categories of GAP suggests that GAPB can provide more accurate information than GAP to the surgeon.

There are some limitations to this study. This was a retrospective study, and the possibility of mechanical complications can only be evaluated based on the immediate postoperative results. Therefore, the possibility of mechanical complications before surgery cannot be predicted. Furthermore, the reason for mechanical complications after ASD correction is multifactorial. The focus was on postoperative radiation alignment and recovery of patient factors. Many factors, such as surgical method, upper instrument level, muscle volume, and various underlying diseases that the patient may have will influence the outcome of the operation.

The GAPB system is meant to more accurately predict mechanical complications compared to other scoring systems and to present ideal surgical goals. There is evidence demonstrating that patient bone quality and obesity are also important factors in mechanical complications. Even if the risk of failure is expected to be high, there are some things that must be done in patients at high risk. We believe that this system will help the patient in consultation with the surgeon about the prognosis.

CONCLUSION

The GAPB system, which includes BMI and BMD, showed improved predictability for mechanical complications after surgery for ASD in each category of the GAP scoring system. In particular, the GAPB system was more meaningful in the moderately disproportioned and severely disproportioned groups. These results require the surgeon to keep in mind the quality and proportionality of bone quality and BMI when planning surgery for ASD.

CONFLICT OF INTEREST

The authors have nothing to disclose.

REFERENCES

Commentary on “Modified Global Alignment and Proportion Scoring With Body Mass Index and Bone Mineral Density Analysis in Global Alignment and Proportion Score of Each 3 Categories for Predicting Mechanical Complications After Adult Spinal Deformity Surgery”

Dean Chou
Department of Neurosurgery, University of California San Francisco, San Francisco, CA, USA

The authors have performed a retrospective review of 203 patients who underwent adult spinal deformity (ASD) surgery with minimum 2-year follow-up.1 The authors have analyzed the global alignment and proportion (GAP) score, incorporating bone mineral density (BMD) and body mass index (BMI). The authors found that when incorporating BMI and BMD into the GAP score (GAPB), the GAPB score correlates with mechanical failure in patients when they are moderately or severely disproportioned in their alignment.

I commend the authors for their work in incorporating BMI and BMD into the evaluation of mechanical failures in ASD surgery. This represents important work because Bari et al.2 had reported that the GAP score alone—without the incorporation of BMI and BMD—has been unable to predict mechanical failure in ASD patients undergoing 4 or more levels of fusion. However, the original GAP score alone does not incorporate the BMI and BMD. Many mechanical failures can be related to poor bone quality because of the implant-bone junction interface failure. In our practice, all patient’s bone densities are checked prior to any fusion surgery, and by incorporating bone density into decision making, we have anecdotally seen fewer screw pull-out failures. Thus, it makes sense that the current authors’ findings of incorporating BMD in the form of the GAPB score create a more accurate predictor of mechanical failure. In addition, the incorporation of BMI as a predictor makes sense. In patients with high BMI, the failure of mainly posterior-based constructs in the face of significant anterior trunk weight can potentially be predicted using the GAPB score instead of the GAP score. By incorporating BMI and BMD into the GAP score, the current authors have shown that incorporation of these 2 elements has made the GAP score more accurate by converting it into the GAPB score.

The original GAP score takes into account age, pelvic incidence, sacral slope (SS), L4–S1...
lordosis, L1–S1 lordosis, and the global tilt, as measured from C7 down to the sacrum. However, the reliability and accuracy of the GAP score alone have been called into question. Kwan et al. have recently reported that a higher GAP score does not predict mechanical complications after ASD surgery using 272 patients from the Scoli-RISK-1 prospective trial data. As mentioned above, Bari et al. also could not find an association with the GAP score and mechanical complications. Given that large studies could not find a direct correlation with the GAP score and mechanical complications, the study performed by the current authors sheds new light and insight onto the GAP score. The current authors’ inclusion of BMI and bone density add 2 very important factors that were not originally included in the GAP score. Increasingly, it is becoming clear that bone density is a very important factor in spinal fusion, not just in deformity cases, but also in degenerative conditions. In addition, it makes sense that BMI also plays an important role given the primarily posterior-based support structure in most adult deformity surgery. It stands to reason that a patient with a high BMI and low bone density may have a higher mechanical failure rate than a patient who has a low BMI with high bone density. The authors have taken these 2 factors into consider, improving upon the GAP score.

Another consideration that may be useful in the prevention of mechanical failure is taking into consideration the Roussouly type, spinal shape, and location of the 3-column osteotomy, if performed. Pizones et al. showed that placing the pedicle subtraction osteotomy at the natural apex of the Roussouly type was associated with a lower rate of mechanical failure. Based upon this finding, the natural shape of the spine based upon the Roussouly type should ideally be recreated if possible. This may also be a very important factor in patients who are Roussouly types I and II (SS less than 35°). These low Roussouly type patients may not be amenable to large amounts of lordosis induction because of the low SS. Such patients may live with relatively flat backs, and induction of large amounts of lordosis in such patients may increase the propensity for proximal junctional kyphosis (PJK). Xi et al. showed that as the L1 vertebral body is posteriorly displaced relative to the gravity line, there is an increased risk of PJK. This is consistent with potential over induction of lordosis in low Roussouly type patients with concomitant dorsal L1 displacement. This significant posterior L1 displacement results in reciprocal hyper-kyphosis at the thoracolumbar junction or at the thoracic spine in order for the patient to maintain neutral a sagittal vertical axis. It is this reciprocal kyphosis that results in increased stress at or above the upper instrumented vertebra. This increased stress may result in PJK. This combination of a low Roussouly type and over induction of lordosis may be one contribution to PJK.

The authors of this manuscript have done a nice job of showing that the incorporation of BMI and bone density into the GAP score increases the GAP score’s validity. This study provides support to the notion that PJK has a multifactorial etiology. It is the totality of these factors that need to be considered, not simply the radiographic measurements. I commend the authors of taking the GAP score to the next level to improve and validate its utility with the incorporation of these non-radiographic elements.

CONFLICT OF INTEREST

The author has nothing to disclose.

REFERENCES

6. Pizones J, Perez-Grueso FJS, Moreno-Manzanaro L, et al. Ideal sagittal profile restoration and ideal lumbar apex posi-
tioning play an important role in postoperative mechanical complications after a lumbar PSO. Spine Deform 2020;8:491-8.
Correlation of Paraspinal Muscle Mass With Decompensation of Sagittal Adult Spinal Deformity After Setting of Fatigue Post 10-Minute Walk

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Objective: The purpose of this study was to investigate the changes in spinopelvic parameters before and after the setting of muscle fatigue along with its correlation with pre-existing paraspinal and psoas muscle mass.

Methods: Single-center retrospective review of prospectively collected data was conducted on 145 adults with symptomatic loss of lumbar lordosis (LL). Radiographs were taken before and after walking for 10 minutes. Magnetic resonance imaging was used to calculate paraspinal muscle (PSM) cross-sectional area (CSA), mean signal intensity, fatty infiltration (FI), and lean muscle mass at thoracolumbar junction (T12) and lower lumbar level (L4). Psoas CSA was calculated at L3. Patients were divided into 2 groups namely compensated sagittal deformity (CSD) (SVA ≤ 4 cm, PT > 20°) and decompensated sagittal deformity (DSD) (SVA > 4 cm, PT > 20°) based on prewalk measurements.

Results: Initial mean SVA was 1.8 cm and 11 cm for CSD and DSD respectively (p < 0.01). After walking, significant deteriorations in SVA, PT–LL (p < 0.01) were observed in CSD without significant change in thoracic kyphosis (TK). All sagittal parameters in DSD deteriorated significantly. DSD group had significantly poorer PSM quality at T12 and L4 compared to CSD group. In CSD group, sagittal decompensation correlated with muscle quality, i.e., decreases in LL (∆LL) correlated with CSA of PSM/vertebral body (VB) at L4 (r = -0.412, p = 0.046) while increases in TK (∆TK) correlated with CSA of PSM/VB at T12 (r = 0.477, p = 0.018). ∆SVA and ∆PT correlated with FI at L4 (r = 0.577, p = 0.003 and r = -0.407, p = 0.048, respectively). DSD group, had weak correlations (-0.3 < r < -0.1) between changes in sagittal and PSM parameters.

Conclusion: PSM quality in adults with spinal deformity correlates with patients’ ability to maintain an upright posture and sagittal decompensation after walking for 10 minutes.

Keywords: Deformity, Kyphosis, Fatigue, Paraspinal muscles

INTRODUCTION

The physiological sagittal alignment of the human spine is the most energy efficient position adapted by the spine while maintaining the erect posture. Sagittal imbalance causes accessory muscles to overwork in order to maintain the erect posture and thereby, inducing inefficient energy expenditure.¹ Thus, the skeletal muscles supporting the spine can mask the actual sagittal malalignment in some cases, while in others due to the magnitude of the deformity or reduced muscle strength, the muscles fail to compensate for the imbalance, leaving the deformity unmasked.

As the sagittal imbalance has direct bearing on the patient’s functional outcome and quality of life,² it is important to understand if a patient is masking his/her sagittal imbalance by recruiting the supporting muscles. It has been observed that
when a person with sagittal malalignment exercises and exhausts the supporting muscle strength, the deformity is unmasked/ exaggerated. It is clear that patients with lower muscle strength will tend to have lower capacity for compensation and will have decompensated deformity while some patients can mask their sagittal imbalance owing to their muscle strength.

The purpose of this study was to investigate the changes in spinopelvic parameters before and after the setting of muscle fatigue along with its correlation with pre-existing paraspinal and psoas muscle mass.

MATERIALS AND METHODS

After the approval of the Institutional Review Board of Wooridul Spine Hospital (2021-05-WSH-005), retrospective review of prospectively collected radiological data in a series of 145 adults (age > 18 years) who presented in outpatient clinic of a single specialty spine hospital, during the years 2015 to 2020 with symptomatic loss of lumbar lordosis (“flatback”; pelvic incidence minus lumbar lordosis > 10°) without a major coronal deformity (Cobb angle < 30°). We excluded patients with inadequate radiological examinations, history of vertebral compression fractures, spondylolysis, spondylolisthesis, symptomatic lumbar stenosis with neurogenic claudication or sciatica, idiopathic or neuromuscular scoliosis, Cobb angles > 30°, hip joint disease, and Scheuermann’s kyphosis.

1. Radiographic Evaluation

All analyses were performed on preoperative full length, 36-inch exposure radiographs of the spine that extended from the base of the skull to the proximal femur in the anteroposterior and lateral planes. All radiographs were obtained with the patients standing and looking forward trying to maintain a horizontal gaze and with their arms flexed, hands placed on their clavicles without any support, and knees extended. After the first standing radiographs were completed, the patients were immediately asked to walk for 10 minutes at their usual walking speed in the same hallway (no inclination) of one clinic without resting on a chair or the walls. The manager of the radiology suite in the clinic who was not involved in image acquisition observed each patient for the entirety of the 10-minute walk. The walking time was exactly 10 minutes, as timed by the radiology supervisor. Immediately after the 10-minute walk, repeat radiographs were obtained.

Each patient’s paraspinal muscles (PSMs) and psoas muscles were analyzed on prewalking MRIs. The cross-sectional areas (CSAs) of the psoas at L3 and of the PSM at T12 and L4 were analyzed on axial T2-weighted images (Figs. 1 and 2). The ratio of muscle CSA at each of these levels to the corresponding vertebral body’s CSA was calculated. The mean signal intensity (SI) of the muscle was measured using a histogram (Fig. 3A, B). The fatty infiltration (FI) of the PSM was also determined with pseudo-color mapping at each level (Fig. 4). The lean muscle mass (LM) was calculated by extracting FI from CSA of PSM. An independent observer (spinal neurosurgeon in our hospital) measured the muscle parameters using computer-based picture-archiving communication system (PiView; INFINITT Co. Ltd., Seoul, Korea) and spinopelvic parameters were measured with Surgimap (Nemaris Inc., Methuen, MA, USA) software.
2. Cohorts

The patients were divided into 2 groups based on their initial/ptwalk C7–S1 SVA measurement. The first group with C7–S1 SVA ≤ 4 cm and PT > 20° was termed as compensated sagittal deformity (CSD) while the second group was considered to have a decompensated sagittal deformity (DSD) with a C7–S1 SVA > 4 cm and PT > 20°.

3. Statistical Analysis

Student t-tests were used to compare variables between groups. Pearson correlation coefficients were used to assess correlations between changes in sagittal radiographic parameters after walking 10 minutes and variable of muscles within each group. Multiple regression analysis was used to analyze predictive variables for changes of sagittal parameters. A p-value of < 0.05 defined statistical significance. All analyses were performed using SPSS.
Table 1. Comparison between spinopelvic parameters of initial standing versus 10 minutes after walking in sagittal compensated balance (n = 24) and imbalance (n = 121) groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Compensated sagittal deformity (n = 24)</th>
<th>Decompensated sagittal deformity (n = 121)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial</td>
<td>10 min</td>
<td></td>
</tr>
<tr>
<td>PT</td>
<td>35.8 ± 9.2</td>
<td>31.2 ± 13.2</td>
<td>0.006*</td>
</tr>
<tr>
<td>LL</td>
<td>-22.0 ± 21.5</td>
<td>-8.6 ± 25.4</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>TK</td>
<td>11.8 ± 14.2</td>
<td>12.2 ± 15.5</td>
<td>0.828</td>
</tr>
<tr>
<td>PI–LL mismatch</td>
<td>32.8 ± 17.1</td>
<td>46.3 ± 23.3</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>SVA</td>
<td>18.0 ± 11.2</td>
<td>139.5 ± 90.6</td>
<td>&lt; 0.001*</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation.
PT, pelvic tilt; LL, lumbar lordosis; TK, thoracic kyphosis; PI, pelvic incidence; SVA, sagittal vertical axis.
*p < 0.05, statistically significant differences.

Table 2. Comparison demographic factors and parameters of paraspinal muscle degeneration in sagittal compensated balance (n = 24) and imbalance (n = 121) groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Compensated sagittal deformity (n = 24)</th>
<th>Decompensated sagittal deformity (n = 121)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age (yr)</td>
<td>66.7 ± 7.1</td>
<td>68.2 ± 5.7</td>
</tr>
<tr>
<td></td>
<td>BMD</td>
<td>-1.6 ± 1.2</td>
<td>-2.3 ± 1.4</td>
</tr>
<tr>
<td></td>
<td>Psoas/VB</td>
<td>30.6 ± 7.8</td>
<td>31.0 ± 10.2</td>
</tr>
<tr>
<td></td>
<td>PSM/VB at T12</td>
<td>111.9 ± 27.8</td>
<td>92.8 ± 35.8</td>
</tr>
<tr>
<td></td>
<td>PSM mean at T12</td>
<td>529.8 ± 1,106.2</td>
<td>279.8 ± 273.0</td>
</tr>
<tr>
<td></td>
<td>PSM SI at T12</td>
<td>279.8 ± 503.1</td>
<td>153.1 ± 117.6</td>
</tr>
<tr>
<td></td>
<td>FI T12</td>
<td>46.1 ± 20.8</td>
<td>42.4 ± 22.6</td>
</tr>
<tr>
<td></td>
<td>LM/VB T12</td>
<td>60.5 ± 28.2</td>
<td>53.9 ± 32.9</td>
</tr>
<tr>
<td></td>
<td>PSM/VB at L4</td>
<td>106.8 ± 30.9</td>
<td>93.8 ± 34.2</td>
</tr>
<tr>
<td></td>
<td>PSM mean at L4</td>
<td>435.9 ± 763.3</td>
<td>260.8 ± 184.5</td>
</tr>
<tr>
<td></td>
<td>PSM SI at L4</td>
<td>266.2 ± 408.1</td>
<td>168.2 ± 110.2</td>
</tr>
<tr>
<td></td>
<td>FI L4</td>
<td>39.1 ± 16.2</td>
<td>40.9 ± 18.8</td>
</tr>
<tr>
<td></td>
<td>LM/VB L4</td>
<td>64.9 ± 23.8</td>
<td>55.7 ± 28.6</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation.
BMD, bone mineral density; VB, vertebral body; PSM, paraspinal muscle; SI, signal intensity; FI, fatty infiltration; LM, lean mass; CSA, cross-sectional area.
*p < 0.05, statistically significant differences.

RESULTS

One hundred forty-five patients (mean 68.1 ± 5.9 years old, 136 females) were included. Initial mean SVA was 1.8 cm for CSD and 11 cm for DSD (p < 0.01). After walking, significant deteriorations in SVA were observed, decreased PT minus LL was observed (p < 0.01) in CSD without significant change in TK, while all the sagittal parameters in DSD were significantly deteriorated (Table 1). Patients with DSD had significantly poorer muscle quality (i.e., less CSA, SI) in the PSM at the thoracolumbar junction and lower lumbar spine, compared to the patients with CSD. FI and LM were not different between the groups. DSD group had significantly lower value of BMD (p = 0.031) (Table 2).

In CSD patients, sagittal decompensation correlated with muscle quality, i.e., decreases in LL (ΔLL) correlated with CSA of PSM/VB at L4 (r = -0.412, p = 0.046), increases in TK (ΔTK) correlated with CSA of PSM/VB at T12 (r = 0.477, p = 0.018)). ΔSVA and ΔPT correlated with FI at L4 (r = 0.577, p = 0.003 and r = -0.407, p = 0.048, respectively) (Table 3). Multiple regression analysis showed that CSA of PSM at L4 was predictive of ΔLL (R² = 0.170, p = 0.046) and FI at L4 was predictive of ΔSVA (R² = 0.330, p = 0.003) and ΔPT (R² = 0.166, p = 0.048) in CSD. For DSD patients, there were weak correlations (-0.3 < r < -0.1) between changes in sagittal parameters and PSM FI, BMD (Table 4).

DISCUSSION

The spinal alignment is the consequence morphology of the vertebra and the discs as well as the forces acting on them. The compressive forces acting on the spine are countered by the vertebrae as well as the discs. However, as the disc degenerates with advancing age, there is an imbalance of the forces acting on the spine which may result in kyphosis (asymmetric disc degeneration in sagittal plane) or scoliosis (asymmetric disc degeneration in coronal plane) or kypho-scoliosis. The body tries to compensate for this imbalance with various mechanisms such as discopathies, retrolisthesis, changes in the pelvic tilt, knee flexion, and the use of paraspinal muscular forces to improve overall sagittal alignment, in order to maintain center of gravity.
and horizontal gaze. Barrey et al. classified 3 types for the sagittal alignment in adult spinal deformities (ASDs): balanced, balanced with compensatory mechanisms, and imbalanced. The compensatory mechanisms can be intraspinal or extraspinal in the latter 2 groups. Intraspinal mechanisms include pelvic retroversion, thoracic or adjacent lumbar hyperextension, retrolisthesis at the immediate adjacent level in the lumbar spine, and cervical hyperlordosis. Extraspinal mechanisms include knee and hip flexion and extension at the ankle.

We published in 2017, that there is a change in sagittal spinal

Table 3. Correlation between paraspinal muscle parameters and changes of sagittal parameters after 10 minutes walking in overall, compensated sagittal deformity group

<table>
<thead>
<tr>
<th>Variable</th>
<th>Change in sagittal spine deformity parameters</th>
<th>ΔPT</th>
<th>ΔLL</th>
<th>ΔTK</th>
<th>ΔSVA</th>
<th>ΔPI–LL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Correlation coefficient</td>
<td>p-value</td>
<td>Correlation coefficient</td>
<td>p-value</td>
<td>Correlation coefficient</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td>-0.084</td>
<td>0.684</td>
<td>-0.145</td>
<td>0.480</td>
<td>0.182</td>
</tr>
<tr>
<td>BMD</td>
<td></td>
<td>0.281</td>
<td>0.183</td>
<td>-0.323</td>
<td>0.124</td>
<td>0.418</td>
</tr>
<tr>
<td>Psoas</td>
<td></td>
<td>0.185</td>
<td>0.386</td>
<td>-0.078</td>
<td>0.718</td>
<td>0.167</td>
</tr>
<tr>
<td>PSM/VB at T12</td>
<td></td>
<td>-0.105</td>
<td>0.626</td>
<td>-0.352</td>
<td>0.092</td>
<td>0.477</td>
</tr>
<tr>
<td>PSM mean at T12</td>
<td></td>
<td>0.042</td>
<td>0.845</td>
<td>0.189</td>
<td>0.378</td>
<td>0.065</td>
</tr>
<tr>
<td>FI T12</td>
<td></td>
<td>0.291</td>
<td>0.168</td>
<td>-0.042</td>
<td>0.847</td>
<td>-0.183</td>
</tr>
<tr>
<td>PSM area at L4</td>
<td></td>
<td>-0.134</td>
<td>0.534</td>
<td>-0.245</td>
<td>0.249</td>
<td>0.221</td>
</tr>
<tr>
<td>PSM/VB at L4</td>
<td></td>
<td>-0.170</td>
<td>0.428</td>
<td>-0.412</td>
<td>0.046*</td>
<td>0.324</td>
</tr>
<tr>
<td>PSM mean at L4</td>
<td></td>
<td>0.054</td>
<td>0.802</td>
<td>0.159</td>
<td>0.459</td>
<td>0.085</td>
</tr>
<tr>
<td>FI L4</td>
<td></td>
<td>0.407</td>
<td>0.048*</td>
<td>-0.342</td>
<td>0.102</td>
<td>0.191</td>
</tr>
</tbody>
</table>

PT, pelvic tilt; LL, lumbar lordosis; TK, thoracic kyphosis; SVA, sagittal vertical axis; PI, pelvic incidence; BMD, bone mineral density; PSM, paraspinal muscle; VB, vertebral body; FI, fatty infiltration.

*p < 0.05, statistically significant differences.

Table 4. Correlation between paraspinal muscle parameters and changes of sagittal parameters after 10 minutes walking in overall, decompensated sagittal deformity groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Change in sagittal spine deformity parameters</th>
<th>ΔPT</th>
<th>ΔLL</th>
<th>ΔTK</th>
<th>ΔSVA</th>
<th>ΔPI–LL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Correlation coefficient</td>
<td>p-value</td>
<td>Correlation coefficient</td>
<td>p-value</td>
<td>Correlation coefficient</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td>-0.003</td>
<td>0.976</td>
<td>0.078</td>
<td>0.378</td>
<td>-0.095</td>
</tr>
<tr>
<td>BMD</td>
<td></td>
<td>0.137</td>
<td>0.170</td>
<td>-0.203</td>
<td>0.041*</td>
<td>0.008</td>
</tr>
<tr>
<td>Psoas</td>
<td></td>
<td>0.175</td>
<td>0.055</td>
<td>0.049</td>
<td>0.591</td>
<td>-0.051</td>
</tr>
<tr>
<td>PSM area at T12</td>
<td></td>
<td>0.047</td>
<td>0.612</td>
<td>-0.131</td>
<td>0.153</td>
<td>-0.137</td>
</tr>
<tr>
<td>PSM/VB at T12</td>
<td></td>
<td>0.006</td>
<td>0.950</td>
<td>-0.207</td>
<td>0.023*</td>
<td>-0.142</td>
</tr>
<tr>
<td>PSM mean at T12</td>
<td></td>
<td>-0.067</td>
<td>0.466</td>
<td>-0.093</td>
<td>0.315</td>
<td>-0.024</td>
</tr>
<tr>
<td>FI T12</td>
<td></td>
<td>-0.092</td>
<td>0.342</td>
<td>-0.026</td>
<td>0.785</td>
<td>-0.040</td>
</tr>
<tr>
<td>PSM area at L4</td>
<td></td>
<td>-0.036</td>
<td>0.695</td>
<td>-0.081</td>
<td>0.376</td>
<td>-0.035</td>
</tr>
<tr>
<td>PSM/VB at L4</td>
<td></td>
<td>-0.062</td>
<td>0.503</td>
<td>-0.168</td>
<td>0.065</td>
<td>-0.040</td>
</tr>
<tr>
<td>PSM mean at L4</td>
<td></td>
<td>-0.184</td>
<td>0.043*</td>
<td>-0.063</td>
<td>0.492</td>
<td>-0.029</td>
</tr>
<tr>
<td>FI L4</td>
<td></td>
<td>-0.077</td>
<td>0.427</td>
<td>-0.079</td>
<td>0.414</td>
<td>0.058</td>
</tr>
</tbody>
</table>

PT, pelvic tilt; LL, lumbar lordosis; TK, thoracic kyphosis; SVA, sagittal vertical axis; PI, pelvic incidence; BMD, bone mineral density; PSM, paraspinal muscle; VB, vertebral body; FI, fatty infiltration.

*p < 0.05, statistically significant differences.
alignment after 10-minute walking in compensated/uncompensated ASDs after setting of fatigue (Fig. 5A, B). In the current study, we went further to investigate the correlation of paraspinal and psoas muscle mass on the changes in sagittal spinal alignment before and after setting of fatigue.

A reduction of muscle CSA and presence of FI are considered as indicators of muscle degeneration. We used the CSA of iliopsoas and PSMs (after deducting the area of FI from overall CSA) at thoracolumbar and lower lumbar level as a measure to quantify the muscle mass. The precise definition of the muscle quality is the amount of force generated by each volumetric unit of muscle tissue. However, there is no consensus as to how measure this force generated/strength. Although the relationship between the muscle mass and muscle strength is not linear, CSA is considered as a reliable indicator for the evaluation of the muscle strength in the maintenance of sagittal spinal balance.

Yagi et al. studied the effect of paraspinal and iliopsoas muscles in the maintenance of the sagittal balance in degenerative lumbar scoliosis patients. They recruited 60 patients each of lumbar canal stenosis and lumbar degenerative scoliosis. They found that the multifidus and iliopsoas areas were significantly smaller in the sciotic patients. Also, multifidus CSA was correlated with progression of kyphosis at the unfused thoracic vertebrae in scoliosis group. In our study, we excluded patients with more than 30° coronal deformity and mainly focused with the sagittal plane deformity. Similar to abovementioned study we found significantly lower mass in the paraspinal and psoas muscle in DSD group as compared to CSD group.

PSM atrophy has been associated with multitudes of spinal disorders like lumbar canal stenosis, isthmic spondylolisthesis, facet arthropathy, degenerative lumbar kyphosis. Moreover, it is also associated with worse postsurgery outcomes. The most important part of our study was exaggerating the deformity by nullifying the role of the compensatory muscular forces, thereby unmasking the pivotal role played by the paraspinal and iliopsoas muscles in compensating the sagittal spinal deformity.

The average age in the entire study population was 68.1 years (66.7 and 68.2 years in CSD and DSD, respectively) which corresponds to existing literature of ASD which affects mainly the old persons. Cho et al. studied the relationship between BMD and sagittal imbalance in elderly and found that there was no statistically significant correlation between the two. However, Mika et al. demonstrated that decreased BMD influences TK but despite decreased BMD, if the back muscles are sufficiently strong, spinal deformities do not occur. The BMD in our study was significantly lower in DSD group as compared to CSD group and most of the parameters measuring muscle mass at thoraco-
lumbar as well as lower lumbar level were significantly lower in DSD group. This may indicate an association between the BMD, PSM mass, and severity of sagittal imbalance.

Takahashi et al. studied the correlation of back muscles and knee extensors with the compensatory mechanism of sagittal alignment in community-dwelling elderly persons. They found that thoracic kyphosis demonstrated a negative correlation with back muscle strength and positive correlation with vertebral fracture. Back muscle strength was important for the decrease in thoracic kyphosis, and knee extensor strength was associated with pelvic tilt. In our study, we focused on back and psoas muscle mass and its correlation with sagittal alignment. In our study, there was no significant change in thoracic kyphosis after 10-minute walk in CSD group while the change in DSD was significant. In order to nullify the individual variation in the muscle mass and body size, we used CSA/VB as a measure for comparison.

We found that the change in thoracic kyphosis correlated with PSM/VB at T12 level in CSD group, implying that the PSM mass at thoracolumbar junction was an important determinant affecting changes thoracic kyphosis.

In the CSD group, after a 10-minute walk, there was a significant derangement of spinopelvic parameters which included lumbar lordosis (reduced from -22.0 to -8.6), PI–LL mismatch (increased from 32.8 to 46.3), pelvic tilt (reduced from 35.8° to 31.2°), and the SVA (increased from 18.0 mm to 139.5 mm). The change in thoracic kyphosis was not significant. These findings clearly suggest that as the activity causes muscles to fatigue, the compensatory effect of the muscular activity on sagittal balance of the spine is lost and the spinopelvic parameters derange. The findings were similar in DSD group which included derangement of lumbar lordosis (reduced from -7.9 to -1.3), PI–LL mismatch (increased from 46.8 to 53.4), pelvic tilt (reduced from 34.2° to 29.9°), SVA (increased from 110.5 mm to 208.2 mm), and thoracic kyphosis (increased from 8.6° to 12.0°) with statistically significant derangement in all the spinopelvic parameters in this group. However, in DSD group the parameters were already abnormal to begin with, which further deranged after the 10-minute walk. In the DSD group, significantly poorer muscle quality (i.e., less CSA, SI) was observed at the thoracolumbar junction and lower lumbar spine. The changes in the sagittal parameters after 10 minutes walk and the PSM MRI parameters at T12 and L4 were not significantly correlated in this group as muscle quality was already poor. Hence, it had little contribution in maintaining the sagittal alignment at rest in these patients.

The CSA of PSM at T12 and L4 level was significantly lower in DSD than CSD group suggesting the patients in whom the muscle mass was lower could not have compensated their deformity using PSMs while patients with higher muscle mass could compensate for the deformity. This also means that the patients in whom the PSM mass is lower are unlikely to show compensation and will have a decompensated deformity. On the other hand, patients with better muscle mass will show compensation of the deformity. This emphasizes the need to have strategies for extensive preoperative physiotherapy program in order to improve PSM mass before a patient with sagittal spinal deformity is operated. This will help in compensating the deformity of the patient at rest and also, this will have better outcome for the patients in the postoperative period with improved sagittal balance.

The changes in some of the sagittal parameters in CSD group had correlation with the parameters measuring muscle quality. For example, PSM/VB at T12 correlated with the change in thoracic kyphosis, suggesting that reduced muscle mass at T12 level can result in thoracic decompensation in the form of increased kyphosis. PSM/VB at lower lumbar level (L4) correlated significantly with the change in the lumbar lordosis and changes in PI–LL mismatch. This means that the reduction of PSM mass at L4 level may result in lumbar decompensation by reduction of lordosis as well as abnormal pelvic alignment. Also, FI at L4 level significantly correlated with changes in pelvic tilt as well as changes in SVA indicating that FI at L4 can predict decompensation of SVA and PT.

In the DSD group, the paraspinal as well as psoas muscle SA and FI did not correlate significantly with the changes in sagittal parameters. Thus, the changes of sagittal parameters after walking were less related to muscle status in DSD. As already degenerated muscles are causes of initial decompensation of DSD, their roles in maintaining upright position are insignificant. This emphasizes the fact that since the muscle quality is poorer and the sagittal balance is already abnormal at rest in these patients, the remaining muscle mass doesn't have bearing on how much more the decompensation will occur after the 10-minute walk.

These observations can be extrapolated for the clinical practice, whereby a patient with CSD will benefit significantly more by strengthening the PSMs by undergoing physiotherapy, while the benefit of muscle strengthening on sagittal alignment in decompensated patients may be limited. Nonetheless, as muscle and body balance training and maintenance of spinal sagittal alignment can lead to prevention of fall in elderly patients, we believe that this should become a part of treatment strategy in
all the elderly patients with sagittal imbalance. There are some limitations of our study. As muscle fatigue is a dynamic factor, whether patient walked before coming to clinic and whether the patient was examined in the morning or in evening when the fatigue might have set in due to the activities throughout the day may bring about some variation. However, we had standardized the 10-minute duration for all the patients whereby bringing uniformity to the evaluation. We also have not included the coronal plane malalignment and assessment for the parameters of lower limb in compensation of the deformity. We did not measure muscle strength using hand grip as a baseline for comparing the muscle strength amongst the patients as the muscle volume alone may not perfectly correlate with muscle strength. In addition, we could not include the effect of compensation by the lower limbs in our study as we used 36-inch radiographs which cannot accommodate the entire skeleton starting from basiocciput up to the legs. However, with recent availability of full-length standing radiographs using EOS imaging, this type of study can become feasible in future. Also, a single spinal neurosurgeon measured the radiological parameters using computer-based software, which can be regarded as a limitation. Lastly, we did not include quality of life parameters, as the focus of this study was mainly on radiological parameters and thus can indirectly indicate the patients' disability.

CONCLUSION

PSM quality in adults with spinal deformity correlates with patients' ability to maintain an upright posture and sagittal decompensation after walking for 10 minutes. As such, patients who present with compensated sagittal deformities may benefit from dedicated exercise programs to maintain PSM quality/strength so as to prevent sagittal decompensation.

CONFLICT OF INTEREST

The authors have nothing to disclose.

REFERENCES

The Important Role of Paraspinal Muscle Quality for Maintaining Sagittal Balance While Walking: Commentary on “Correlation of Paraspinal Muscle Mass With Decompensation of Sagittal Adult Spinal Deformity After Setting of Fatigue Post 10-Minute Walk”

Kyung-Hyun Kim

Department of Neurosurgery, Spine and Spinal Cord Institute, Yonsei University College of Medicine, Seoul, Korea

In this paper authored by Bae et al., the authors reported important findings regarding the role of paraspinal muscle quality in maintaining sagittal balance. Specifically, they found differences in sagittal spinal alignment after a 10-minute walk in compensated versus uncompensated adult spinal deformities after the onset of fatigue. This article will be followed by a project to determine the cause for this finding and the differences in muscle quality and quantity between compensated and decompensated groups.

As all we know, balance is dynamic, whereas malalignment is static. Thus, patients with malalignment could have a balanced erect posture using various compensatory mechanisms, which is why we referred to this group as “compensated sagittal imbalanced.” However, maintaining this erect posture using intra- and extracompensatory mechanisms requires energy consumption, which is dependent on the muscles around the lower extremities and vertebrae in the thoracolumbar and lumbosacral areas. The relationship between the paraspinal muscles and sagittal spinal malalignment has been associated with sarcopenia, which refers to degenerative changes in the muscle and is regarded as a disease that decreases patients’ quality of life and precipitates or aggravates their spinal problems.

Yagi et al. also reported that the paravertebral muscle and psoas play an important role in the maintenance of global spinal alignment in patients with degenerative lumbar scoliosis. According to their results, a moderate correlation was obtained between the multifidus cross-sectional area and global spinal alignment, as well as spinopelvic alignment. Kim et al. published similar results, finding that sarcopenia and back muscle degeneration were risk factors for sagittal imbalance in patients with degenerative adult spinal deformity.

The original finding of this study is that the researchers found worse changes in spinal alignment and balance after a 10-minute walk in the compensated sagittal deformity group. Tho-
Racemic lordotic compensation using the paravertebral muscles at T12 is a very important factor for maintaining a balanced erect posture, as shown by their results (decreased thoracic kyphosis was correlated with an increased cross-sectional area of the paravertebral muscles at T12). Finally, the authors should embark upon a new project to substantiate their message that patients with compensated sagittal deformity will benefit significantly more from strength-building exercises.

CONFLICT OF INTEREST

The author has nothing to disclose.

REFERENCES


Title: Blue nude
Artist: Pablo Picasso
Year: 1902
© 2021 - Succession Pablo Picasso - SACK (Korea)
Prioritization of Realignment Associated With Superior Clinical Outcomes for Cervical Deformity Patients

Katherine E. Pierce, Peter G. Passias, Avery E. Brown, Cole A. Bortz, Haddy Alas, Lara Passfall, Oscar Krol, Nicholas Kummer, Renaud Lafage, Dean Chour, Douglas C. Burton, Breton Line, Eric Klineberg, Robert Hart, Jeffrey Gum, Alan Daniels, Kojo Hamilton, Shay Bess, Themistocles Protopsaltis, Christopher Shaffrey, Frank A. Schwab, Justin S. Smith, Virginie Lafage, Christopher Ames; on behalf of the International Spine Study Group (ISSG)

Departments of Orthopaedic and Neurologic Surgery, New York University Langone Medical Center, New York, NY, USA

Objective: To prioritize the cervical parameter targets for alignment.

Methods: Included: cervical deformity (CD) patients (C2–7 Cobb angle > 10°, cervical lordosis > 10°, cervical sagittal vertical axis [cSVA] > 4 cm, or chin-brow vertical angle > 25°) with full baseline (BL) and 1-year (1Y) radiographic parameters and Neck Disability Index (NDI) scores; patients with cervical [C] or cervicothoracic [CT] Primary Driver Ames type. Patients with BL Ames classified as low CD for both parameters of cSVA ( < 4 cm) and T1 slope minus cervical lordosis (TS–CL) ( < 15°) were excluded. Patients assessed: meeting minimum clinically important differences (MCID) for NDI ( < -15 NDI). Ratios of correction were found for regional parameters categorized by primary Ames driver (C or CT). Decision tree analysis assessed cutoffs for differences associated with meeting NDI MCID at 1Y.

Results: Seventy-seven CD patients (mean age, 62.1 years; 64% female; body mass index, 28.8 kg/m²). Forty-one percent six percent of patients met MCID for NDI. A backwards linear regression model including radiographic differences as predictors from BL to 1Y for meeting MCID for NDI demonstrated an R² of 0.820 (p = 0.032) included TS–CL, cSVA, McGregor’s slope (MGS), C2 sacral slope, C2–T3 angle, C2–T3 SVA, cervical lordosis. By primary Ames driver, 67.5% of patients were C, and 32.5% CT. Ratios of change in predictors for MCID NDI patients for C and CT were not significant between the 2 groups (p > 0.050). Decision tree analysis determined cutoffs for radiographic change, prioritizing in the following order: ≥ 42.5° C2–T3 angle, > 35.4° cervical lordosis, < -31.76° C2 slope, < -11.57-mm cSVA, < -2.16° MGS, > -30.8-mm C2–T3 SVA, and ≤ -33.6° TS–CL.

Conclusion: Certain ratios of correction of cervical parameters contribute to improving neck disability. Prioritizing these radiographic alignment parameters may help optimize patient-reported outcomes for patients undergoing CD surgery.

Keywords: Spine, Cervical deformity, Alignment
INTRODUCTION

Incidence of adult cervical deformity (CD) as a distinct clinical diagnosis is rising, along with the literature concentrating on methodology for appropriately assessing the disease.¹ As the condition is often associated with major disability and neurologic compromise, surgical correction of malalignment and addressment of symptoms are often warranted.²,³ Numerous studies have demonstrated radiographic alignment and achievement of sagittal balance as significant drivers of health-related quality of life (HRQoL) improvement in deformity patients, not specific to the cervical spine.⁴⁻⁶ Moreover, studies investigating the connection between cervical alignment parameters and HRQoL outcomes are limited.

Restoration of cervical sagittal alignment involves neural element decompression and/or fusion of the cervical and caudal spinal regions, often invasive in nature and poses risks for major complications and poor patient-reported outcomes.⁷ Many patients are unable to undergo these major, invasive CD corrective procedures due to deformity severity, old age, comorbidities, and severe frailty status. And, often baseline characteristics (body mass index [BMI], age, Charlson Comorbidity Index [CCI] score, frailty score) imply increased risk for certain postoperative complications and decline in HRQoL outcomes.⁸,⁹ Alignment-adjustments have been explored in the adult spinal deformity (ASD) population. Lafage et al.¹⁰ proposed a modified version of the validated SRS-Schwab ASD classification accounting for varying age ranges. More rigorous alignment objectives were determined to be warranted for younger patients, while less rigorous alignment objectives for elderly patients, in order to achieve normative HRQoL scores for each age population.¹⁰ This alignment specificity for the individual patient needs to be considered in order to optimize patient-reported outcomes.

Explicitly, when assessing deformity specific to the cervical spine, a standardized classification system of deformity severity is in its preliminary stages. The most well-known classification was created by Ames and the International Spine Study Group, but it has yet to be formally validated with connection to HRQoL outcomes.¹¹⁻¹³ Little is known regarding the order of addressing correction of certain cervical alignment parameters for peak improvement in postoperative patient-reported outcomes.¹⁴,¹⁵ Using a prospective multicenter collection of CD surgical patients, this study investigated the prioritization of cervical alignment parameters and their minimal degree of correction that contributes to optimal quality of life.

MATERIALS AND METHODS

1. Data Source and Inclusion Criteria

This was a retrospective cohorts study of a prospective, multicenter International Spine Study Group (ISSG) database of CD patients enrolled from 2013–2018 at 13 participating centers around the United States. Institutional Review Board approval was required protocol by each site and informed patient consent was obtained. Patients enrolled in the database were greater than 18 years with evidence of one of the following CD baseline radiographic parameters: cervical kyphosis (C2–7 Cobb angle > 10°), cervical scoliosis (C2–7 coronal Cobb angle > 10°), C2–7 sagittal vertical axis (SVA) > 40 mm, or chin-brow vertical angle (CBVA) > 25°. Database exclusion criteria comprised of patients with spinal deformity of neuromuscular etiology, presence of active infection, or malignancy. The study inclusion criteria required complete baseline (BL) and 1-year (1Y) radiographic measurements and the HRQoL measure, Neck Disability Index (NDI), as well as demonstrated cervical or cervicothoracic Ames sagittal deformity driver descriptor. The Ames deformity driver consists of 5 categories, detailing the primary driver of cervical deformity as follows: C, a primary sagittal deformity apex in cervical spine; CT, a primary sagittal deformity apex in the thoracic spine; S, a primary coronal deformity (C2–7 Cobb angle greater than or equal to 15); and CVJ, a primary craniovertebral junction deformity. In order to analyze a more homogenous CD population, patients were excluded if they were categorized with another Ames driver (thoracic [T], coronal [S]) or were classified as a low Ames CD modifier for both the parameters of cervical SVA (cSVA) (< 4 cm) and T1 slope minus cervical lordosis (TS–CL) (< 15°).

2. Data Collection, Radiographic, and HRQoL Assessment

Patient demographic and clinical data assessed patient age, sex, BMI, and CCI. Operative factors assessed: surgical approach, levels fused, operative time, and estimated blood loss (EBL). Full-length free-standing lateral spine radiographs were used to assess the patient population at BL and 1Y. Radiographs were analyzed with SpineView (ENSAM, Laboratory of Biomechanics, Paris, France) software according to the literature.¹⁶⁻¹⁸ Radiographic parameters assessed included cSVA, C2–7 lordosis, TS–CL, CBVA, McGregor's slope (MGS), C2–T3 SVA, C2–T3 angle, C2 slope. The health-related-quality of life questionnaire utilized in this study was the NDI administered by each of the participating centers.
3. Statistical Analysis

Descriptive analyses determined demographic, clinical, and surgical data. Frequency analysis evaluated categorical variables with chi-square analysis determining significant variance of expected versus observed values. Patients were assessed based on meeting the minimal clinically important difference (MCID) for NDI scores at 1 year (< -15 ΔNDI). Proportion (%) and difference of correction from preoperative measurement to 1 year were calculated for the following regional parameters: cSV A, CL, T1 Slope, TS–CL, CBVA, MGS, C2–T3 SVA, C2–T3 angle, and C2 slope. Backwards linear regression model including the radiographic differences (1Y–BL) as predictors for meeting MCID for NDI found the parameters that contributed the greatest variation (with a significantly large R² value). The radiographic measures included in the model were then assessed for proportion of correction stratified by C or CT Ames primary driver type. Analysis of variance compared the C and T ratios for any significant differences. Decision tree analysis determined cutoff values of the radiographic difference variables included in the backwards regression model, accomplished through iteration of multivariate regression equations. Radiographic change cutoffs were prioritized based upon their ordinal regression values when entered as sole predictors for meeting MCID for NDI through binary logistic regressions. All statistical analyses were performed using IBM SPSS Statistics ver. 21.0 (IBM Co., Armonk, NY, USA) and R-statistical package (www.r-project.org). All analyses were 2-sided and the level of significance was set to < 0.05.

Table 1. Demographic and surgical characteristics of the cohort

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (yr)</td>
<td>62.1</td>
</tr>
<tr>
<td>Female sex (%)</td>
<td>64</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>28.8</td>
</tr>
<tr>
<td>Race (%)</td>
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</tr>
<tr>
<td>White</td>
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</tr>
<tr>
<td>Black</td>
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<tr>
<td>Other</td>
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</tr>
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</tr>
<tr>
<td>Approach (%)</td>
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<tr>
<td>Anterior only approach</td>
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<tr>
<td>Total levels fused</td>
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<tr>
<td>Osteotomy (%)</td>
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<tr>
<td>Decompression (%)</td>
<td>53.2</td>
</tr>
<tr>
<td>Operative time (min)</td>
<td>553.1</td>
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<tr>
<td>Estimated blood loss (mL)</td>
<td>1,128.1</td>
</tr>
<tr>
<td>Revision (%)</td>
<td>13</td>
</tr>
</tbody>
</table>

Table 2. Radiographic parameters at baseline and 1 year, as well as the difference between baseline and 1 year for cervical (C) and cervicothoracic (CT) Ames driver types

<table>
<thead>
<tr>
<th>Radiographic parameter</th>
<th>C</th>
<th>CT</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline cSV A (mm)</td>
<td>35.7 ± 24.4</td>
<td>66.6 ± 14.5</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Baseline CL (°)</td>
<td>-17.5 ± 18.4</td>
<td>-4.5 ± 20.5</td>
<td>0.009*</td>
</tr>
<tr>
<td>Baseline T1 slope (°)</td>
<td>20.6 ± 12.6</td>
<td>41.4 ± 12.6</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Baseline TS–CL (°)</td>
<td>37.7 ± 18.2</td>
<td>45.5 ± 16.4</td>
<td>0.086</td>
</tr>
<tr>
<td>Baseline CBVA (°)</td>
<td>0.41 ± 2.0</td>
<td>0.48 ± 2.3</td>
<td>0.893</td>
</tr>
<tr>
<td>Baseline MGS (°)</td>
<td>2.9 ± 10.6</td>
<td>8.6 ± 12.6</td>
<td>0.042*</td>
</tr>
<tr>
<td>Baseline C2–T3 angle (°)</td>
<td>-18.6 ± 20.5</td>
<td>-27.0 ± 20.8</td>
<td>0.113</td>
</tr>
<tr>
<td>Baseline C2–T3 SVA (mm)</td>
<td>57.2 ± 34.0</td>
<td>110.2 ± 22.4</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Baseline C2 slope (°)</td>
<td>35.9 ± 19.1</td>
<td>49.2 ± 18.7</td>
<td>0.008*</td>
</tr>
<tr>
<td>At 1-year cSV A (mm)</td>
<td>33.4 ± 18.4</td>
<td>49.3 ± 12.2</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>At 1-year CL (°)</td>
<td>4.4 ± 12.2</td>
<td>10.9 ± 16.9</td>
<td>0.064</td>
</tr>
<tr>
<td>At 1-year T1 slope (°)</td>
<td>28.3 ± 11.4</td>
<td>44.7 ± 10.1</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>At 1-year TS–CL (°)</td>
<td>23.9 ± 10.7</td>
<td>33.8 ± 13.5</td>
<td>0.001*</td>
</tr>
<tr>
<td>At 1-year CBVA (°)</td>
<td>0.81 ± 6.5</td>
<td>3.3 ± 6.5</td>
<td>0.558</td>
</tr>
<tr>
<td>At 1-year MGS (°)</td>
<td>-2.2 ± 8.8</td>
<td>1.2 ± 9.2</td>
<td>0.150</td>
</tr>
<tr>
<td>At 1-year C2–T3 angle (°)</td>
<td>-0.29 ± 20.5</td>
<td>-2.3 ± 20.8</td>
<td>0.580</td>
</tr>
<tr>
<td>At 1-year C2–T3 SVA (mm)</td>
<td>63.2 ± 34.0</td>
<td>92.7 ± 22.4</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>At 1-year C2 slope (°)</td>
<td>21.9 ± 11.0</td>
<td>33.3 ± 14.3</td>
<td>&lt; 0.001*</td>
</tr>
</tbody>
</table>

SV A, sagittal vertical axis; cSV A, cervical SV A; CL, cervical lordosis; TS–CL, T1 slope minus CL; CBVA, chin–brow vertical angle; MGS, McGregor's slope.

*p < 0.05, statistically significant difference.
RESULTS

1. Overall Cohort Patient Characteristics

Seventy-seven CD patients with complete radiographic and HRQoL data met inclusion criteria for Ames driver descriptors of C or CT. Twelve patients with S or T Ames driver descriptors were excluded. Mean patient age was 62.1 years, mean BMI of 28.8 kg/m², with 64% of the cohort as female. The average CCI score was 0.94. By approach, these CD patients underwent majorly posterior surgeries (41.6%), while 39% had combined approaches and 19.4% anterior. Forty-four point two percent of patients underwent osteotomies and 53.2% decompression. Average levels fused was 7.5 (posterior, 8.3; anterior, 3.5). The mean total operative time was 553.1 minutes, with an EBL of 1,128.1 mL. Thirty-two patients (41.6%) met MCID for NDI. Ten patients (13%) had a revision procedure. Table 1 summarizes the demographic and basic surgical factors for the cohort.

2. Baseline and 1-Year Radiographic Parameters Between C and CT Ames Drivers

Between C and CT groups, there were significant differences for both baseline and 1-year cohort means of cSV A, T1 Slope, C2–T3 SVA, and C2 slope. CT patients exhibited significantly more malalignment at baseline for cSV A (66.6 mm vs. 35.7 mm, p < 0.001), T1 slope (41.4° vs. 20.6°, p < 0.001), C2–T3 SV A (110.2 mm vs. 57.2 mm, p < 0.001), as well as MGS (p = 0.042) and C2 slope (p = 0.008). C driver patients had greater CL malalignment preoperatively (-17.5° vs. -4.5°). At 1-year CT patients remained significantly more malaligned in cSV A, T1 slope, C2–T3 SV A, and C2 slope (all p < 0.001) (Table 2).

3. Radiographic Corrective Measures Predictive of Meeting MCID for NDI

A backwards linear regression model found the following radiographic differences as predictors of meeting MCID for NDI from baseline to 1 year: TS–CL, cSV A, MGS, C2 slope, C2–T3 angle, C2–T3 SVA and CL demonstrated the greatest variation contributing to MCID for NDI with an R² of 0.820 (p = 0.032). When assessing individual Ames driver type cohorts, C driver patients demonstrated an R² value of 0.844 (p = 0.029) without inclusion of the TS–CL or C2–T3 SVA parameter. CT patients had an R² value of 0.778 (p = 0.025), without the TS–CL angle.

4. Ratios (%) of Correction in Predictors by Ames Driver

Ratios of change in predictors for MCID NDI patients (BL-1Y) for C driver patients: 260.8% MGS, 140.3% CL, 121.2% C2–T3 angle, 49.6% C2 slope, 41.1% cSV A, 20.5% TS–CL, 3.1% C2–T3 SVA. Correction in CT driver patients included: 168.7% CL, 93% MGS, 70.8% C2–T3 angle, 27.5% C2 slope, 24.9% TS–CL, 13.7% C2–T3 SVA. The ratios of radiographic differences were not significant between the C and CT driver groups (p > 0.050) (Table 2).

5. Prioritization of Realignment Parameters and Their Corrective Cutoff Values

Decision tree analysis determined cutoffs for radiographic change, prioritizing in the following order (based upon ordinal regression values): a correction ≥ 42.5° C2–T3 angle (odds ratio [OR], 5.667; 95% confidence interval [CI], 1.074–29.871; p = 0.041), > 35.4° CL (OR, 4.636; 95% CI, 0.857–25.071; p = 0.075), < -31.76° C2 slope (OR, 3.2; 95% CI, 0.852–12.026; p = 0.085), < -11.57-mm cSV A (OR, 3.185; 95% CI, 1.137–8.917; p = 0.027), < -2.16° MGS (OR, 2.724; 95% CI, 0.971–7.636; p = 0.057),

Table 3. Order of prioritization based off of binary logistic ordinal regression values of radiographic parameters and cutoff values for correction

<table>
<thead>
<tr>
<th>Radiographic parameter</th>
<th>OR</th>
<th>95% CI</th>
<th>p-value</th>
<th>Cutoffs of correction prioritized in order</th>
</tr>
</thead>
<tbody>
<tr>
<td>C2–T3 angle</td>
<td>5.667</td>
<td>1.074–29.871</td>
<td>0.041*</td>
<td>C2–T3 angle Δ ≥ 42.5°</td>
</tr>
<tr>
<td>C2–C7 lordosis</td>
<td>4.636</td>
<td>0.857–25.071</td>
<td>0.075</td>
<td>CL Δ &gt; 35.4°</td>
</tr>
<tr>
<td>C2 slope</td>
<td>3.200</td>
<td>0.852–12.026</td>
<td>0.085</td>
<td>C2 slope Δ &lt; -31.76°</td>
</tr>
<tr>
<td>cSV A</td>
<td>3.185</td>
<td>1.137–8.917</td>
<td>0.027*</td>
<td>cSV A Δ &lt; -11.57 mm</td>
</tr>
<tr>
<td>MGS</td>
<td>2.724</td>
<td>0.971–7.636</td>
<td>0.057</td>
<td>MGS Δ &lt; -2.16°</td>
</tr>
<tr>
<td>C2–T3 SVA</td>
<td>0.462</td>
<td>0.116–1.849</td>
<td>0.275</td>
<td>C2–T3 SVA Δ &gt; -30.8 mm</td>
</tr>
<tr>
<td>TS–CL</td>
<td>0.271</td>
<td>0.048–1.1516</td>
<td>0.137</td>
<td>TS–CL Δ ≤ -33.6°</td>
</tr>
</tbody>
</table>

OR, odds ratio; CI, confidence interval; SVA, sagittal vertical axis; cSVA, cervical SVA; CL, cervical lordosis; TS–CL, T1 slope minus CL; MGS, McGregor’s slope.

*p < 0.05, statistically significant difference.

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Table 4. NDI and mJOA scores at 1 year between patients who met proposed prioritization cutoff values and those who did not

<table>
<thead>
<tr>
<th>Variable</th>
<th>Met improvement threshold</th>
<th>Did not meet improvement threshold</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDI scores at 1 year</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C2-T3 angle</td>
<td>23.8</td>
<td>38</td>
<td>0.035*</td>
</tr>
<tr>
<td>CL</td>
<td>24.7</td>
<td>37.6</td>
<td>0.071</td>
</tr>
<tr>
<td>C2 slope</td>
<td>31.8</td>
<td>37</td>
<td>0.398</td>
</tr>
<tr>
<td>cSVA</td>
<td>32.6</td>
<td>39.3</td>
<td>0.158</td>
</tr>
<tr>
<td>MGS</td>
<td>32.9</td>
<td>42.4</td>
<td>0.055</td>
</tr>
<tr>
<td>C2–T3 SVA</td>
<td>34.7</td>
<td>45.5</td>
<td>0.130</td>
</tr>
<tr>
<td>TS–CL</td>
<td>28.2</td>
<td>37</td>
<td>0.253</td>
</tr>
<tr>
<td>mJOA scores at 1 year</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C2–T3 angle</td>
<td>15.78</td>
<td>14</td>
<td>0.087</td>
</tr>
<tr>
<td>CL</td>
<td>15</td>
<td>14.15</td>
<td>0.442</td>
</tr>
<tr>
<td>C2 slope</td>
<td>14.58</td>
<td>14.19</td>
<td>0.673</td>
</tr>
<tr>
<td>cSVA</td>
<td>14.8</td>
<td>13.73</td>
<td>0.152</td>
</tr>
<tr>
<td>MGS</td>
<td>14.58</td>
<td>13.61</td>
<td>0.197</td>
</tr>
<tr>
<td>C2–T3 SVA</td>
<td>14.38</td>
<td>13.5</td>
<td>0.422</td>
</tr>
<tr>
<td>TS–CL</td>
<td>15</td>
<td>14.17</td>
<td>0.477</td>
</tr>
</tbody>
</table>

NDI, Neck Disability Index; mJOA, modified Japanese Orthopedic Association; SVA, sagittal vertical axis; cSVA, cervical SVA; CL, cervical lordosis; TS–CL, T1 slope minus CL; MGS, McGregor’s slope. *p < 0.05, statistically significant difference.

> -30.8-mm C2–T3 SVA (OR, 0.462), and ≤ -33.6° TS–CL (OR, 0.271) (Table 3).

6. HRQoLs for Patients With Ideal Prioritization

Patients who met thresholds for recommended cervical parameter prioritization trended toward improvement in both NDI and modified Japanese Orthopedic Association (mJOA) scale for all measurements at 1 year (Table 4).

7. Case Examples

Fig. 1 shows the baseline and 1-year lateral cervical and whole spine radiographs of a 72-year-old female (BMI, 33.3 kg/m²) and a history of diabetes mellitus and osteopenia who underwent CD corrective surgery. She presented with cervical type Ames driver. According to proposed CD prioritization guidelines, this patient did not meet proposed prioritization correction thresholds for C2–T3 angle (-1.60°), CL (+11.9°), C2 slope (-0.54°), cSVA (-2.03 mm), MGS (+4.11°), and TS–CL (-0.69°). She did meet the threshold for C2–T3 SVA (+16.8 mm). The patient had a 1-year NDI score of 46, did not meet MCID for NDI, and patient-reported mJOA score of 15.

Fig. 2 shows the baseline and 1-year lateral cervical and whole spine radiographs of a 61-year-old male (28.97 kg/m²) who underwent CD corrective surgery. He presented with cervical type Ames driver. According to proposed CD prioritization guidelines, this patient did meet all proposed prioritization correction thresholds for C2–T3 angle (+76.1°), CL (+67.9°), C2 slope (-44.9°), cSVA (-11.9 mm), MGS (-10.8°), C2–T3 SVA (+11.7 mm), and TS–CL (-45.8°). The patient had a 1-year NDI score...
Prioritization of Cervical Deformity Alignment

DISCUSSION

High-risk cohorts undergoing treatment of adult CD include patients with advanced age, obesity, greater comorbidity burden, and severe frailty status. While classification systems, such as the one created by Ames and the ISSG, provide correction guidelines for the representative majority of CD patients, operating on patients with preoperative presentation of increased risk for poor outcomes has facilitated the need for a prioritization of alignment scheme for CD surgery. Therefore, the goal for this analysis was to establish an order of targeting alignment parameters and their projected minimal corrective degree to benefit operative decision-making and inherently improve HRQoL outcome management.

Utilizing a CD prospective multicenter database and biplanar stereoradiography, allowing for the acquisition of full-body imaging in the weight-bearing position, our analysis determined that prioritizing regional cervical radiographic alignment parameters in a certain order to a specific degree optimized reaching the MCID in a patient’s self-reported neck disability. Despite regional driver of CD (cervical or cervicothoracic), radiographic correction for patients who reached MCID for NDI were similar. The prioritization of parameters are as follows: C2–T3 angle, C2–7 lordosis, C2 slope, cSVA, MGS, C2–T3 SVA, and, lastly, TS–CL.

First, we found that the C2–T3 angle should be corrected. This angle connects each of the regions of the spine, by incorporating the unequivocal relationship between the cervical and thoracolumbar spine morphology. By prioritizing next the C2–7 lordosis correction, the natural cervical curvature is addressed secondarily. Cervical kyphosis is a major radiographic presentation of CD, with a strong connection to clinical impact, so direct correction to parameters encompassing the curve is imperative for improved patient-reported outcomes. In a previous study by Passias et al., the preoperative cervical degree of lordotic compensation and higher C2–T3 angle were identified as risk factors for sagittal malalignment and decline in HRQoL outcomes after thoracolumbar surgery. With prioritization of the lordosis of the spine, combined with the cervicothoracic junction as a site of transition between the highly mobile cervical and rigid thoracic systems, we can address the inherent relationship between cervical sagittal malalignment and clinical measures of disability.

The third parameter to prioritize in correction of CD is the C2 slope. We found that correction of this radiographic measurement, led to increased neck disability improvement. This parameter is a singular CD factor, a mathematical approximation of the mismatch between T1 slope and cervical lordosis. By factoring in the occipitocervical spine, the C2 slope accounts for an additional aspect of radiographic alignment improvement and should be prioritized accordingly.

Then, the cSVA was found to be prioritized. The restoration of this parameter has been correlated with improved postopera-

Fig. 2. Baseline (BL) and 1-year (1Y) cervical and whole spine radiographs for a 61-year-old male who met proposed radiographic prioritization of alignment.

of 11.1, met MCID for NDI, and patient-reported mJOA score of 18.
tive outcomes and prevention of disability.\textsuperscript{22} It incorporates a global assessment of CD by measuring the distance between the C2 and C7 plumblines.\textsuperscript{24} Tang et al.\textsuperscript{29} suggested that an increasing cervical SVA is a cause for clinical concern of cervical malalignment, as > 40 mm was correlated with worse NDI outcomes. As one of the main objectives of CD surgery is the maintenance or restoration of horizontal gaze, the next parameter to prioritize was found to be MGS.\textsuperscript{26} By correcting this angle, the symptoms of inability to look straight ahead or lie down flat that contribute to overall disability can be addressed. Another parameter appreciating cervical sagittal alignment is the C2–T3 SVA, which was found to be 6th measure of prioritization. Prioritizing the 2 large measures of cervical sagittal alignment (C2–C7 SVA and C2–T3 SVA), accounting for the alignment of subjacent segments, including the thoracolumbar spine and pelvis, along with horizontal gaze measurement, the global outlook of the spine is assessed.

Lastly, the mismatch between T1 slope and CL parameter was prioritized. This relationship accounts for the intrinsic compensation of T1 slope on the CL to balance the head over the thoracic inlet and maintain the physiological neck tilting.\textsuperscript{31,32} The measure accounts for the patient’s center of gravity, and contributes to overall cervical integration into global alignment.

Through the combination of regional cervical radiographic factors, we found that prioritizing the lordosis of the cervical spine (through C2–C7 and C2–T2), followed by occipitocervical incorporation (C2 slope) global assessment (cSVA, C2–T3 SVA, TS–CL), and horizontal improvement (MGS). This proposed prioritization involves the innate interdependence of the spine: cervical lordosis depends on both thoracic kyphosis and lumbar lordosis. With the distinct diagnosis of CD, cervical lordosis adaptation is due to the cervical spinal segment changes relative to the global spine to attempt to maintain the head over the pelvis and horizontal gaze.\textsuperscript{28} Addressing the intertwined cervical parameters in a specific order to a certain degree of correction can contribute to improved patient-reported neck disability.

Our study is not without limitations, including the retrospective nature of this study and the small number of patients. While the multicenter methodology used for database construction increases the generalizability of our findings, the data analyzed for the purposes of this study may be skewed toward more complex cases. Another limitation lies in the heterogeneous nature of the patient population in regards to cervical procedure and complexity, which may have been accounted for by removing thoracic and coronal Ames type CD drivers. The method of radiographic measurement is also not without limitation. Although the measurements were standardized to be taken with the patient standing in a relaxed position looking forward, these images remain as a representation of a point in time and are not reflective of force plate of dynamic motion studies. However, the horizontal gaze tends to stay stable and lower extremities tend to affect lumbo-pelvic alignment the most. Future studies should investigate the proposed prioritization and thresholds on a prospective trial with a larger, homogenous population of patients undergoing CD corrective surgery.

**CONCLUSION**

Certain ratios of correction of cervical parameters contribute to improving neck disability. Specific cutoffs of radiographic differences from baseline to 1 year were found prioritizing C2–T3 angle, followed by cervical lordosis, C2 slope, C2–7 plumb line, MGS, C2–T3 SVA, and TS–CL all strongly associated with meeting the MCID for the NDI score. Prioritizing these radiographic alignment parameters may help optimize patient-reported outcomes for patients undergoing CD surgery.

**CONFLICT OF INTEREST**

The authors have nothing to disclose.

**ACKNOWLEDGMENTS**

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**REFERENCES**


Incidence of Chronic Periscapular Pain After Adult Thoracolumbar Deformity Correction and Impact on Outcomes

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Objective: Extension of the posterior upper-most instrumented vertebra (UIV) into the upper thoracic (UT) spine allows for greater deformity correction and reduced incidence of proximal junction kyphosis (PJK) in adult spinal deformity (ASD) patients. However, it may be associated with chronic postoperative scapular pain (POSP). The goal of this study was to assess the relationship between UT UIV and persistent POSP, describe the pain, and assess its impact on patient disability.

Methods: ASD patients who underwent multilevel posterior fusion were retrospectively identified then administered a survey regarding scapular pain and the Oswestry Disability Index (ODI), by telephone. Univariate and multivariate analysis were utilized.

Results: A total of 74 ASD patients were included in the study: 37 patients with chronic POSP and 37 without scapular pain. The mean age was 70.5 years, and 63.9% were women. There were no significant differences in clinical characteristics, including mechanical complications (PJK, pseudarthrosis, and rod fracture) or reoperation between groups. Patients with persistent POSP were more likely to have a UT than a lower thoracic UIV (p = 0.018). UT UIV was independently associated with chronic POSP on multivariate analysis (p = 0.022). ODI score was significantly higher in patients with scapular pain (p = 0.001). Chronic POSP (p = 0.001) and prior spine surgery (p = 0.037) were independently associated with ODI on multivariate analysis.

Conclusion: A UT UIV is independently associated with increased odds of chronic POSP, and this pain is associated with significant increases in patient disability. It is a significant clinical problem despite solid radiographic fusion and the absence of PJK.

Keywords: Scapular pain, Adult spinal deformity, Thoracic spine, Postoperative pain, Complications, Health-related quality of life

INTRODUCTION

Up to one-third of the general population,¹-³ including 68% of the population over the age of 60, is affected by adult spinal deformity (ASD).⁴ ASD can cause severe back and leg pain as well as neurologic deficits as a result of compression of the neural elements.⁵ This symptomology can lead to significant disability and declines in health-related quality of life (HRQoL) measures; deformity severity, as measured by radiographic spinal alignment measures, is directly related to worse disability.⁶-¹³ Surgery plays an important role in the management of ASD patients that fail conservative therapy. Surgical correction of sagittal and spinopelvic malalignment can result in significant decreases in pain and disability and improved appearance.¹³-¹⁶
The correction of thoracolumbar ASD frequently requires the use of long constructs from the sacrum or ilium to the thoracic spine in order to adequately correct spinal deformity. Where to place the upper-most instrumented vertebrae (UIV) of a construct is influenced by a variety of factors, including the degree of correction required, magnitude of thoracic kyphosis, bone quality, and location of the deformity.\textsuperscript{17,18} UIV placement in the upper thoracic (UT) spine (T1–6) has been associated with an increased degree of correction and reduced rates of proximal junctional kyphosis (PJK) relative to those in the lower thoracic (LT) spine (T7–12).\textsuperscript{18,19} However, UT UIVs are also associated with longer operative times and increased operative blood loss.\textsuperscript{17,18} Long-term HRQoL measures are not significantly different in patients with UIVs in the UT vs. those in the LT.\textsuperscript{18} Anecdotally, however, many patients with UT UIV complain of chronic scapular pain following surgery.

Numerous studies have described persistent local axial pain following posterior cervical spine surgery, including incidence, predictors, impact on quality of life, and preventative measures.\textsuperscript{20–25} Nevertheless, there is a paucity of similar research investigating scapular pain following placement of a UIV in the UT spine, despite the commonality of this pain in the clinic. Sakaura et al.\textsuperscript{26} investigated the relationship of thoracic spine surgery and persistent local pain in 29 patients, and suggested the pain may result from dissection of muscle insertions at the cervicothoracic junction. Therefore, the goal of this study was to formally describe the potential relationship between UIV in the UT spine and development of chronic scapular pain, when accounting for other potential confounders, as well as the impact of this pain on self-reported Oswestry Disability Index (ODI) scores. The characteristics of the pain, how it limits patients, and pain-specific treatment methods are also described.

**MATERIALS AND METHODS**

1. **Patient Population**

ASD patients over the age of 18 who underwent a multilevel posterior fusion of either 7–12 segments or greater than 13 segments were retrospectively identified from 2012 to 2019 using the electronic medical record. This study was formally approved by the Institutional Review Board of University of California, San Francisco (No. 18-26789). Exclusion criteria included constructs that were extended into the cervical spine and patient self-reported construct extensions at outside institutions. Patients were initially grouped based on the location of the UIV (UT vs. LT). UT levels were defined as T1–6. LT levels were defined as T7–12. All patients had constructs ending in the lumbar spine or pelvis.

2. **Clinical Data**

Patient demographics, surgical characteristics, and clinical outcomes were retrospectively collected and reviewed, including age, sex, history of prior spinal surgery, surgical indication, UIV, lower-most instrumented vertebrae, the need for reoperation, and mechanical complications such as PJK, pseudarthrosis, and rod fracture. Patients were subsequently administered a standard telephone survey regarding scapular pain (Fig. 1), as well as the ODI.\textsuperscript{27} Verbal consent was obtained for each patient prior to administering the surveys. The scapular pain survey (Fig. 1) administered to patients assessed the presence and characteristics of persistent scapular pain, including the time of onset, pain score, the timing of pain, pain radiation, aggravators, limitations caused by the pain, and treatments attempted. Survey administrators were not blinded to the clinical characteristics of patients, but all patients were administered standard questions read from the survey in Fig. 1.

The primary outcomes of interest were the presence of chronic postoperative scapular pain, disability, and a description of the scapular pain in patients with chronic postoperative scapular pain. Chronic postoperative scapular pain was defined as scapular pain that was not present prior to surgery or was significantly different from any preoperative pain. Disability was measured using an ODI survey administered over the phone. Descriptions of the scapular pain were collected using a standardized predetermined telephone survey.

3. **Statistical Analysis**

Chi-square test and Student t-test were used for categorical and continuous outcomes, respectively. A multivariate backward likelihood binary logistic regression model was used to further elucidate variables independently associated with chronic scapular pain, including UIV location. Variables initially included in the model included: patient age, UIV location, patient sex, history of prior spine surgery, rod fracture, pseudarthrosis, and PJK. A multivariate backward likelihood linear regression model was also used to identify variables independently associated with ODI score. Variables initially included in the model included: patient age, persistent scapular pain, patient sex, history of prior spine surgery, rod fracture, pseudarthrosis, and PJK. A p-value of less than 0.05 was used as the threshold of statistical significance. All statistical analysis was performed using IBM SPSS Statistics ver. 26.0 (IBM Co., Armonk, NY, USA).
RESULTS

1. Overall Patient Demographics

A total of ASD 265 patients were identified for possible inclusion: 173 UT patients and 92 LT patients as a control group. Following the removal of patients who met exclusion criteria, 161 UT patients and 83 LT patients were called. Successful administration of the telephone surveys was accomplished in 60 of 161 (37.2%) and 15 of 83 (18.0%) of UT and LT patients, respectively. One patient was excluded from the LT group following the identification of a previous cervical spine surgery during the phone call (Fig. 2).

Overall patient demographics and clinical outcomes can be seen in Table 1. A total of 74 patients were included in the study with a minimum follow-up to survey administration of 23 months. The cohort was 63.9% women with an average age of 70.5 years. Almost half of the patients had had prior spine surgery (45.8%). Most patients had a UIV in the UT (83.3% UT vs. 18.9% LT).
LT). A minority of patients required a reoperation (18.1%) or had a mechanical complication, including PJK (12.5%), pseudarthrosis (1.4%), rod fracture (15.3%). The average length of follow-up was 22.6 and 47.5 months with regards to clinic and phone follow-ups, respectively. The minimum phone follow-up for all patients was 24 months.

2. Comparison of Patients With and Without Chronic Postoperative Scapular Pain

There were 37 patients in each group (Table 2). There were no significant differences in mean patient age (69.9 years vs. 71.0 years, p = 0.689), patient sex (73.0% vs. 54.1%, p = 0.091), or history of prior spine surgery (45.9% vs. 45.9%, p = 1.000). Similarly, there was no difference in incidence of mechanical complications between the groups (32.4% vs. 21.6%, p = 0.295), including PJK (16.2% vs. 8.1%, p = 0.479), pseudarthrosis (2.7% vs. 0.0%, p = 0.314), and rod fracture (16.2% vs. 13.5%, p = 0.744).

However, patients with chronic postoperative scapular pain were more likely to have a UT UIV than those without pain (34 of 37 [91.9%] vs. 26 of 37 [74.3%], p = 0.018). Only 3 of 14 patients (21.4%) with an LT UIV developed postoperative scapular pain versus 34 of 60 patients (56.7%) with a UT UIV. Patients with scapular pain also had significantly higher ODI scores, indicat-

**Table 1. Overall patient demographics (n = 74)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (yr)</td>
<td>70.5 (27–87)</td>
</tr>
<tr>
<td>Female sex</td>
<td>46 (63.9)</td>
</tr>
<tr>
<td>Prior spine surgery</td>
<td>33 (45.8)</td>
</tr>
<tr>
<td>Upper-most instrumented vertebra</td>
<td></td>
</tr>
<tr>
<td>Upper thoracic</td>
<td>60 (83.3)</td>
</tr>
<tr>
<td>Lower thoracic</td>
<td>14 (18.9)</td>
</tr>
<tr>
<td>Comorbid mechanical complications</td>
<td></td>
</tr>
<tr>
<td>Proximal junction kyphosis</td>
<td>9 (12.5)</td>
</tr>
<tr>
<td>Pseudarthrosis</td>
<td>1 (1.4)</td>
</tr>
<tr>
<td>Rod fracture</td>
<td>11 (15.3)</td>
</tr>
<tr>
<td>Reoperation</td>
<td>13 (18.1)</td>
</tr>
<tr>
<td>Follow-up (mo)</td>
<td></td>
</tr>
<tr>
<td>Clinic</td>
<td>23.58 (1–78)</td>
</tr>
<tr>
<td>Phone</td>
<td>47.53 (24–89)</td>
</tr>
</tbody>
</table>

Values are presented as mean (range) or number (%).

**Table 2. Comparison of patients with chronic postoperative scapular pain to those without pain**

<table>
<thead>
<tr>
<th>Variable</th>
<th>No scapular pain (n = 37)</th>
<th>Chronic scapular pain (n = 37)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (yr)</td>
<td>71.0</td>
<td>69.9</td>
<td>0.689</td>
</tr>
<tr>
<td>Female sex</td>
<td>10 (54.1)</td>
<td>27 (73.0)</td>
<td>0.091</td>
</tr>
<tr>
<td>Prior spine surgery</td>
<td>17 (45.9)</td>
<td>17 (45.9)</td>
<td>1.000</td>
</tr>
<tr>
<td>Upper-most instrumented vertebra</td>
<td></td>
<td></td>
<td>0.018</td>
</tr>
<tr>
<td>Upper thoracic</td>
<td>26 (74.3)</td>
<td>34 (91.9)</td>
<td></td>
</tr>
<tr>
<td>Lower thoracic</td>
<td>11 (29.7)</td>
<td>3 (8.1)</td>
<td></td>
</tr>
<tr>
<td>Comorbid mechanical complications</td>
<td>8 (21.6)</td>
<td>12 (32.4)</td>
<td>0.295</td>
</tr>
<tr>
<td>Proximal junction kyphosis</td>
<td>3 (8.1)</td>
<td>6 (16.2)</td>
<td>0.479</td>
</tr>
<tr>
<td>Pseudarthrosis</td>
<td>0 (0)</td>
<td>1 (2.7)</td>
<td>0.314</td>
</tr>
<tr>
<td>Rod fracture</td>
<td>5 (13.5)</td>
<td>6 (16.2)</td>
<td>0.744</td>
</tr>
<tr>
<td>Reoperation</td>
<td>7 (19.4)</td>
<td>6 (16.2)</td>
<td>0.719</td>
</tr>
<tr>
<td>Mean follow-up (mo)</td>
<td>21.6</td>
<td>25.5</td>
<td>0.855</td>
</tr>
<tr>
<td>Clinic follow-up</td>
<td>50.4</td>
<td>44.7</td>
<td>0.153</td>
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<tr>
<td>Phone follow-up</td>
<td>25.4%</td>
<td>41.2%</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Values are presented as number (%) unless otherwise indicated. ODI, Oswestry Disability Index.
ing more severe disability, that those without scapular pain (41.2% vs. 25.4%, p = 0.001) (Fig. 3).

A multivariate logistic regression model demonstrated the significant independent association of UT UIV with the development of chronic postoperative scapular pain (OR, 5.0; 95% confidence interval [CI], 1.3–19.8, p = 0.022) (Table 3). A backward likelihood ratio linear regression model showed both chronic postoperative scapular pain (β = 15.2%; 95% CI, 6.2–24.3; p = 0.001) and prior spine surgery (β = 9.7%; 95% CI, 0.6–16.8; p = 0.037) to be independently associated with increased ODI scores (Table 4). There was no difference in ODI scores between LT and UT patients (24.5% vs. 35.0%, p = 0.105).

3. Description of Chronic Postoperative Scapular Pain

Table 5 presents pain characteristics and treatments attempted in patients who described chronic postoperative scapular pain. The mean pain score associated with the scapular pain was 6.2. The majority of patients first noticed the pain immediately after surgery (83.3%), described it as waxing and waning (73.0%), and stated it was either worse (48.6%) or the same (24.3%) as their low back pain. Almost one-half of the patients (43.4%) described the pain as radiating outside of the scapular region. Common aggravators of the pain included the raising of the arms above the head (45.9%), sitting (16.2%), standing/walking (10.8%), lifting objects (10.8%), or another activity (32.4%). Scapular pain limited the activities of most patients (75.7%). Modalities used by patients to reduce the pain included medication (86.5%), heat/ice (70.3%), physical therapy (78.4%), and epidural steroid injections (32.4%). Most patients had seen a pain specialist for the pain (54.1%), and 11 of 37 (29.7%) were currently seeing a pain specialist at the time of the interview (Table 5).

![Fig. 3. Bar graph highlighting a significantly higher mean Oswestry Disability Index (ODI) score in patients with chronic scapular pain (***p = 0.001).](image-url)

### Table 3. Binary logistic regression model for chronic scapular pain

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper thoracic UIV</td>
<td>5.0</td>
<td>1.3–19.8</td>
<td>0.022</td>
</tr>
</tbody>
</table>

UIV, Upper-most instrumented vertebra; OR, odds ratio; CI, confidence interval.

### Table 4. Linear regression model for ODI score

<table>
<thead>
<tr>
<th>Variable</th>
<th>β</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic postoperative scapular pain</td>
<td>15.2</td>
<td>6.2–24.3</td>
<td>0.001</td>
</tr>
<tr>
<td>Prior spine surgery</td>
<td>9.7</td>
<td>0.6–18.8</td>
<td>0.037</td>
</tr>
</tbody>
</table>

ODI, Oswestry Disability Index; CI, confidence interval.

Values are presented as mean (range) or number (%).
DISCUSSION

Constructs with extension into the UT spine have been associated with greater amounts of spinal alignment correction and reduced rates of PJK in ASD patients. A common postoperative complaint among patients with a UT UIV is the presence of persistent scapular pain. While studies exist investigating persistent local pain following cervical spine surgery, there is a lack of similar studies investigating chronic scapular pain following the extension of long constructs into the UT spine. Therefore, the present study sought to describe the chronic postoperative scapular pain, assess patient demographics and clinical variables associated with the onset of the pain, and evaluate the impact of the pain on patient disability (ODI scores).

The first goal was to identify patient demographics and clinical characteristics associated with the development of persistent postoperative scapular pain. Previous studies in the cervical spine literature have assessed risk factors for the development of local axial pain following cervical spine surgery. In a systematic review of 33 studies relating to postoperative axial pain after posterior cervical spine surgery, Wang et al. identify many potential risk factors including surgical technique; less invasive surgical techniques and reconstruction of neck musculature appear to be associated with less postoperative axial pain in some studies. However, they conclude that there is a paucity of high-quality evidence supporting any particular risk factor, and that further research is needed. The development of chronic postoperative scapular pain in thoracic spine surgery patients has had minimal investigation relative to postoperative pain in cervical patients. Sakaura et al. investigate the relationship of thoracic spine surgery and persistent local pain in 29 patients undergoing posterior-based thoracic spine surgery. They suggest that the pain is caused by dissection of muscle insertions into the cervicothoracic junction, as 5 of 7 patients with muscle dissection into the cervicothoracic junction (C6–T1) developed postoperative pain as compared to 1 of 22 patients with midlower thoracic surgeries (T2 and lower). Their study was limited, however, by the heterogeneous population included in the study (20 patients had instrumentation and 9 did not) and the failure to assess other variables associated with the development of persistent pain, such as age and presence of instrumentation on univariate or multivariate analysis. The present study showed a similar trend as Sakaura et al. as patients with a UT UIV were more likely to have postoperative scapular pain on univariate analysis. We also accounted for additional patient demographics and clinical variables with the potential to impact chronic scapular pain, including age, reoperation, and mechanical complications on multivariate analysis, and demonstrated the independent association of UT UIV with the development of postoperative pain. Unlike Sakaura et al., however, all of the patients in the present study had long posterior spinal instrumentation. As a result, it is possible that the scapular pain seen in UT patients is as a result of their spinal instrumentation, which has been demonstrated to elicit back pain in previous studies. Anecdotally, it has been observed that some patients demonstrate an improvement in their scapular pain following instrumentation removal. Indeed, the cause of the scapular pain in UT patients is unclear and could have multiple potential etiologies. Additional research is required to fully define the cause of the chronic postoperative scapular pain in UT patients, and whether it is related to muscle dissection, instrumentation, changes in alignment, or another cause. Future studies involving larger patient cohorts and measuring pain outcomes following instrumentation removal are warranted.

After assessing the relationship between UT UIV and persistent postoperative scapular pain, the impact of the pain on patient disability through the ODI was evaluated. Previous literature in the cervical spine has demonstrated a reduction in HRQoL outcomes in patients with persistent axial pain following cervical spine surgery. In a study of 162 postoperative cervical spine patients, Kimura et al. demonstrated significant reductions in multiple HRQoL outcomes, including the Japanese Orthopaedic Association score, the EuroQol 5 Dimension Questionnaire, and the 36-item Short Form Health Survey, in patients with postoperative axial pain following cervical laminoplasty. The results of the present study show a similar impact on quality of life in patients with chronic postoperative scapular pain. In fact, the majority of patients described their scapular pain as significantly limiting their daily activities (Table 5). In addition, there was a significant increase in ODI score, a validated measure of patient disability that can be reliably administered over the phone, in patients with chronic postoperative scapular pain relative to those without (Table 2), indicating worse disability. On multivariate analysis, persistent postoperative scapular pain, as well as prior spine surgery were independently associated with increases in ODI (Table 4). This corresponds with the findings of Kimura et al. regarding axial pain following cervical spine surgery. To our knowledge, no previous studies have evaluated the relationship between postoperative scapular pain following UT spine surgery and ODI score outcome. The findings demonstrate the significant impact of chronic interscapular pain on patient disability and highlight the need for better prevention.
and treatment methods.

Given the paucity of literature surrounding postoperative scapular pain following UT spine surgery, no previous studies have evaluated potential treatment strategies. In the current study, patients with postoperative scapular pain described a variety of treatment strategies, including medications, heat/ice, physical therapy, epidural injections, and seeing a pain specialist (Table 5); these treatments align with common treatments for back pain. While the response to specific treatments was not specifically evaluated, the continued pain and increased ODI in the patients with scapular pain suggest that the modalities attempted by patients provided limited benefit. Given the potential contribution of the instrumentation itself to the development of postoperative scapular pain, its removal could be another potential treatment in some cases. As previously mentioned, there is anecdotal evidence of reduced scapular pain following instrumentation removal. While studies evaluating implant removal following spine surgery for indications, such as thoracolumbar spine fractures, have shown improved patient quality life and demonstrated adequate safety, there remains a paucity of literature surrounding instrumentation removal in ASD patients. Available studies, however, suggest it should be approached with significant caution. In a study of 116 patients with long posterior instrumented fusions, Deckey et al. found that 4/14 patients experienced increased pain, loss of sagittal plane correction, and spinal collapse following implant removal despite intraoperative confirmation of solid fusion, highlighting the risk of instrumentation removal in these patients. Studies within adolescent deformity have also demonstrated the risk of deformity progression with instrumentation removal. As a result, the possibility of instrumentation removal should be approached with caution, especially in ASD patients. Future studies should fully evaluate the response of postoperative scapular pain to various conservative treatment modalities using validated pain measures. The risks and benefits of implant removal in ASD patients require additional investigation before consideration as a treatment modality outside of severe, debilitating cases.

The limitations of our study mainly relate to its limited sample size, with a total of 74 patients and 37 per group. While there were strongly significant findings despite the relatively small sample size, it is possible that the low number of patients in each group limited our ability to identify more granular differences between them. The use of a telephone survey to collect information also potentially introduces bias, including nonresponse bias. Nonresponse bias could potentially decrease the reported incidence of postoperative scapular pain as these patients may be unsatisfied with their care and unwilling to participate in a telephone survey. However, only 4 patients out of the 244 called refused to participate in the survey; all other nonresponders were unable to be reached due to not answering the telephone or a disconnected phone number. Similarly, patients without a telephone or with limited access to a telephone were unable to participate in our survey, although this would impact both groups equally. All patients were called at least twice to maximize patient responses and reduce nonresponse bias. Similarly, all known phone numbers for a patient were used to, including cell phone, work, and home numbers, to further reduce any potential bias. Previous research on telephone surveys has also indicated that response rate is a poor predictor of bias. A number of political polling methodologies have response rates below 10%, but still provide valuable information on population trends. Other survey-based studies with lower response rates have also been published (20%, 25%, and 31%) in the spine literature. Another limitation of the study is its retrospective design; this may introduce bias for specific survey questions, such as if patients had postoperative pain immediately following surgery, as some patients had surgery over 5 years ago. The present study also lacks information regarding the efficacy of specific treatments for the scapular pain. Finally, cervical pathology may also impact the findings of this study. However, we attempted to account for this by: (1) specifically asking patients about pain between the shoulder blades, which we believe is less likely to be related to the cervical spine, (2) excluding patients with additional surgeries in the cervical spine (self-reported or noted in the medical record). A large prospectively collected study to assess postoperative scapular pain at interval time points, as well as the efficacy of treatments, would help to eliminate these many of these limitations and is warranted. This would allow for the monitoring of the pain over time and additional insight into the best treatment practices. In addition, while the ODI is a validated HRQoL measure that has been validated for telephone use in spinal deformity patients, the scapular pain questionnaire utilized was unvalidated. Thus, the development of a validated measure of scapular pain may also aid in future research into this topic. Studies into the prevention of postoperative scapular pain are also needed. As minimally invasive spine surgery (MIS) limits muscle dissection, the incidence of postoperative scapular pain in patients with UT UIV who underwent MIS surgery may provide additional insight into the contribution of muscle dissection in the development of the pain.

Nevertheless, the present study is the only one, to our knowl-

https://doi.org/10.14245/ns.2040576.288
edge, to evaluate the relationship between UT UIV and the development of chronic scapular pain in a homogenous population of ASD patients with long posterior constructs, while accounting for reoperations and mechanical complications. In addition, we provide a detailed description of the pain and highlight its significant impact on patient activities and disability. Therefore, we believe persistent postoperative scapular pain is a significant long-term complication of instrumentation extending into the UT spine and requires additional investigation into the incidence, treatment, and prevention. We hope that this study aids with patient counseling regarding postoperative scapular pain following the placement of an UT UIV and also spurs additional investigation into this important clinical phenomenon.

CONCLUSION

Posterior instrumentation extending into the UT spine is independently associated with the development of persistent postoperative scapular pain. The resulting scapular pain is subsequently associated with a significant increase in ODI scores, indicating greater disability in these patients. A majority of patients also describe the scapular pain as limiting their activities and the continuation of the pain despite attempting multiple treatment modalities. Despite the limitations associated with a retrospective study, we hope these findings will aid with preparative discussions with patients and prompt additional research into postoperative scapular pain in ASD patients with UT UIVs. Larger, prospective studies further investigating the incidence, risk factors, and potential treatments of postoperative scapular pain in patients with UT spine instrumentation are needed. These studies will allow for improved future counseling and treatment of patients with posterior-based instrumentation extending into the UT spine.

CONFLICT OF INTEREST

The authors have nothing to disclose.

REFERENCES


A Comparison of Mortality and Morbidity Between Complex and Degenerative Spine Surgery in Prospectively Collected Data From 2,280 Procedures

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1Copenhagen Spine Research Unit (CSRU), Section of Spine Surgery, Center of Rheumatology and Spine Diseases, Rigshospitalet, Glostrup, Denmark
2Department of Epidemiological Research, Statens Serum Institut, Copenhagen, Denmark
3Spine Unit, Department of Orthopedic Surgery, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark
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Objective: The reported incidence of complications and/or adverse events (AEs) following spine surgery varies greatly. A validated, systematic, reproducible reporting system to quantify AEs was used in 2 prospective cohorts, from 2 spine surgery centers, conducting either complex or purely degenerative spine surgery; in a comparative fashion. The aim was to highlight the differences between 2 distinctly different prospective cohorts with patients from the same background population.

Methods: AEs were registered according to the predefined AE variables in the SAVES (Spine AdVerse Events Severity) system which was used to record all intra- and perioperative AEs. Additional outcomes, including mortality, length of stay, wound infection requiring revision, readmission, and unplanned revision surgery during the index admission, were also registered.

Results: A total of 593 complex and 1,687 degenerative procedures were consecutively included with 100% data completion. There was a significant difference in morbidity when comparing the total number of AEs between the 2 groups (p < 0.001): with a mean number of 1.42 AEs per patient (n = 845) in the complex cohort, and 0.97 AEs per patient (n = 1,630) in the degenerative cohort.

Conclusion: In this prospective study comparing 2 cohorts, we report the rates of AEs related to spine surgery using a validated reproducible grading system for registration. The rates of morbidity and mortality were significantly higher following complex spine surgery compared to surgery for degenerative spine disease.

Keywords: Prospective study, Complications, Adverse events, Complex spine surgery, Degenerative spine surgery

INTRODUCTION

The reported incidence of complications and/or adverse events (AEs) following spine surgery varies greatly.1-7 This is in large part due to the fact that there is no clear consensus of what a complication entails, and that they are often arbitrarily defined by investigators; which makes comparisons between studies difficult.6,8-11 Furthermore, the retrospective nature of the majority...
of previous studies is vulnerable to bias and has been shown to underestimate the incidence of complications.\textsuperscript{6} This has led to a limited general applicability of the results.

A difference in the occurrence of complications or AEs between complex and degenerative spine surgery is intuitive given the greater invasiveness of surgery and frailty among the patients undergoing complex spine surgery. However, there have been inconsistencies in the reporting,\textsuperscript{12-19} and this difference has not previously been examined in large prospective cohorts from the same patient population using a validated registration system that is ideal for reproducibility.

The primary objective of the present study was to quantify and compare the occurrence of AEs in 2 prospective cohorts undergoing either complex or purely degenerative spine surgery. In this way, we would highlight the differences from these 2 distinctly different prospective cohorts with patients from the same background population. A validated, systematic, reproducible reporting system was used to register all AEs and the complex groups was also stratified into major diagnostic groups for more nuanced comparison.

The secondary objectives were to compare length of stay (LOS), wound infection requiring revision, readmission at 30 and 90 days, revision surgery during the index admission and mortality.

With the design of the study, we also hope to facilitate further studies utilizing a systematic reporting system and by so doing contributing to data aggregation that could lessen the disparities in the reporting on the incidence of AEs in spine surgery.

MATERIALS AND METHODS

1. Patient Selection

This study was a prospective observational analysis performed at 2 academic tertiary referral centers serving the same population of approximately 2.5 million people. All adult patients (≥ 18 years old) undergoing spine surgery at the 2 centers from February 1, 2016 to January 31, 2017, were prospectively and consecutively included.

The surgical procedures have been allocated and divided between these 2 centers. Longer fusion procedures for deformities, major revision surgery, surgery due to trauma, removal of primary tumors and decompression for metastatic cancer lesions, and surgery due to infections are classified as complex and performed at the center for complex spine surgery. Surgery for purely degenerative cervical or lumbar spine diseases, such as decompression surgery with or without arthrodesis for radiculopathy/myelopathy and spinal stenosis, is performed at the center for degenerative spine surgery. The centers are part of the same organization—Rigshospitalet—but are located at different hospitals within the same region. Both centers have postoperative care facilities as well as an intensive care unit and a ward for admittance pre- and postoperatively. Since both centers are a part of Rigshospitalet which is a university hospital the surgeons performing the procedures are both consulting specialists and residents under specialization. Both centers employ both neurosurgical and orthopedic specialists.

2. Data Collection

Demographic, surgical, and postoperative data were registered for all in addition to in-hospital, 30- and 90-day mortality. Additionally, the number of unplanned revision surgeries during the index admission and unplanned readmissions within 90 days postoperatively were also recorded. Procedures were classified as elective or emergency and into major diagnostic subgroups: elective (deformity, degenerative, oncology, infection, and other) and emergency (degenerative, oncology, trauma, infection, and other). The surgical etiology was classified as deformity rather than degenerative if it involved instrumented fusion of more than 5 consecutive spinal levels, more than 3 levels of interbody fusion, or involved any type of osteotomy due to the corrective nature of the procedure. These cases were performed at the center for complex spine surgery. Elective infection included planned biopsy and decompression surgery for infectious conditions. Emergency oncology cases were primarily metastatic lesions causing medullary cord compression, whereas elective oncology cases predominantly were spinal tumors of bone or the neural elements.

Informed written consent was obtained from all patients participating in the study. Since written informed consent was obtained and the study exclusively concerned information obtained by patient journals and did not involve biological materials; under Danish law no approval from the Danish Research Ethics Committee was required. The study was approved by the Danish Data Protection Agency (approval number: 2014-41-2820).


The Spinal AdVerse Events Severity (SAVES) system version 2 is a validated registration tool for the prospective registration of AEs in spine surgery. A detailed description of the center for degenerative spine surgery study cohort has been published previously in a study further validating the SAVES system in a European population.\textsuperscript{20} This system was used to record all intra- and perioperative AEs in the current study and contains 14
predefined intraoperative AEs, 29 predefined perioperative AEs and categories for "other" (miscellaneous) intra- or perioperative AEs. All AEs was categorized as major if the AE lead to intensive care, prolonged hospital stay, prolonged poor outcome (> 6 months), or death. Individual SAVES forms were filled out prospectively for each included patient by a research coordinator. The research coordinator was not involved in the treatment of the patients. Once weekly, all forms were reviewed for additional AEs by the surgical staff, and questions raised by the research coordinator were clarified. All forms were concluded on the day of discharge.

4. Statistical Data Analysis
Statistical data analysis was performed using IBM SPSS Statistics ver. 25.0 (IBM Co., Armonk, NY, USA). Normality was determined graphically by histogram and qq-plot as well as the Kolmogorov-Smirnov test. Incidences were compared using Fischer exact test. Continuous, normally distributed data were compared using the Student t-test or 1-way independent analysis of variance. Mann-Whitney U-test was applied when assumptions of normality were not met. We used multivariable logistic regression to analyze the effect of undergoing complex spine surgery compared to degenerative spine surgery on AEs and mortality, adjusted for patient characteristics (sex and age), comorbidities (American Society of Anesthesiologists [ASA] physical status classification), type of admission (elective or emergency), and length of surgery. Stepwise backward multivariable logistic regression as well as examination for multicollinearity with Pearson bivariate correlation was performed in order to evaluate the results of the regression. A p-value of < 0.05 was considered statistically significant. Results were reported as odds ratios (ORs) with 95% confidence intervals (95% CIs) and/or standard deviation (SD).

### Table 1. Patient characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Complex cohort (n = 593)</th>
<th>Degenerative cohort (n = 1,687)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>309 (52.1)</td>
<td>930 (55.1)</td>
<td>0.204</td>
</tr>
<tr>
<td>Male</td>
<td>284 (47.9)</td>
<td>757 (44.9)</td>
<td></td>
</tr>
<tr>
<td>Age (yr)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>58.4 ± 18.0</td>
<td>60.4 ± 14.9</td>
<td>0.186</td>
</tr>
<tr>
<td>Range</td>
<td>18-95</td>
<td>19-94</td>
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</tr>
<tr>
<td>Length of stay (day)</td>
<td>6.6 ± 8.7</td>
<td>3.0 ± 3.3</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Type of admission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elective (n)</td>
<td>254 (42.8)</td>
<td>1,570 (93.1)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>55.1 ± 19.1</td>
<td>61.0 ± 14.7</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Emergency (n)</td>
<td>339 (57.2)</td>
<td>117 (6.9)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>60.9 ± 16.7</td>
<td>52.9 ± 15.8</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Comorbidity, ASA PS classification</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>130 (21.9)</td>
<td>433 (25.7)</td>
<td>0.054</td>
</tr>
<tr>
<td>II</td>
<td>261 (44.0)</td>
<td>961 (57.0)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>III</td>
<td>188 (31.7)</td>
<td>291 (17.2)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>IV</td>
<td>14 (2.4)</td>
<td>2 (0.1)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>ASA PS classification</td>
<td>2.1 ± 0.8</td>
<td>1.9 ± 0.7</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Mortality</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total in-hospital deaths (n)</td>
<td>12</td>
<td>2</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Overall mortality rate</td>
<td>2.0%</td>
<td>0.1%</td>
<td></td>
</tr>
</tbody>
</table>

Values are presented as number (%) or mean ± standard deviation (SD) unless otherwise indicated.
ASA PS, American Society of Anesthesiologists physical status.
*p < 0.05, statistically significant difference.

### Table 2. Incidence of most common adverse events

<table>
<thead>
<tr>
<th>Variable</th>
<th>Complex cohort (n = 593)</th>
<th>Degenerative cohort (n = 1,687)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraoperative adverse events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dural tear</td>
<td>31 (5.2)</td>
<td>120 (7.1)</td>
<td>0.086</td>
</tr>
<tr>
<td>Nerve root injury</td>
<td>9 (1.3)</td>
<td>2 (0.1)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Hardware malposition requiring revision</td>
<td>6 (1.0)</td>
<td>6 (0.4)</td>
<td>0.058</td>
</tr>
<tr>
<td>Major blood loss</td>
<td>6 (1.0)</td>
<td>4 (0.2)</td>
<td>0.014*</td>
</tr>
<tr>
<td>Cord injury</td>
<td>4 (0.7)</td>
<td>1 (0.1)</td>
<td>0.006*</td>
</tr>
<tr>
<td>Visceral injury</td>
<td>4 (0.7)</td>
<td>0 (0)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Anesthesia related event</td>
<td>4 (0.7)</td>
<td>8 (0.5)</td>
<td>0.563</td>
</tr>
<tr>
<td>Airway/ventilation</td>
<td>3 (0.5)</td>
<td>3 (0.2)</td>
<td>0.179</td>
</tr>
<tr>
<td>Perioperative adverse events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrolyte imbalance</td>
<td>269 (45.5)</td>
<td>279 (16.5)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>111 (18.7)</td>
<td>435 (25.8)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Fever of unknown origin</td>
<td>80 (13.5)</td>
<td>108 (6.4)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Anemia</td>
<td>67 (11.3)</td>
<td>30 (1.8)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Cardiac arrest/failure/arrhythmia</td>
<td>52 (8.8)</td>
<td>3 (0.2)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>17 (2.9)</td>
<td>64 (3.8)</td>
<td>0.260</td>
</tr>
<tr>
<td>Hematoma</td>
<td>17 (2.9)</td>
<td>57 (3.4)</td>
<td>0.540</td>
</tr>
</tbody>
</table>

Values are presented as number (%).
*p < 0.05, statistically significant difference.
RESULTS

We included 2,280 procedures in the 2 cohorts combined—593 in the complex spine surgery cohort and 1,687 in the degenerative cohort—with 100% completion of AE forms using the SAVES system. A comparison of the 2 cohorts regarding patient characteristics and surgical data (Table 1) showed that the complex cohort had longer mean (± SD) LOS (6.6 ± 8.7 days vs. 3.0 ± 3.3 days), more frequently underwent emergency procedures (57.2% vs. 6.9%) and had higher comorbidity burden (mean ASA PS classification grade 2.1 ± 0.8 vs. 1.9 ± 0.7). There were no significant differences in age or sex.

When comparing age across major groups; patients in the trauma (55.5 ± 18.7) and deformity group (55.7 ± 20.1) were younger than the patients in the degenerative (60.3 ± 15.0), oncology (61.7 ± 16.1), and infection groups (62.2 ± 13.2).

1. Adverse Events

AEs affected overall 382 patients (64%) in the complex cohort compared to 800 patients (47%) in the degenerative and the mean number of AEs per patients were also higher in the complex 1.4 ± 1.7 vs. 0.8 ± 1.0 (p < 0.001) with a total of 844 AEs vs. 1,288 AEs. When examining mean AE per patient among the major groups in the complex cohort we found no significant difference among infection (1.5 ± 2.0, 58 AEs in 38 patients), oncology (1.4 ± 1.6, 309 AEs in 219 patients), deformity (1.4 ± 1.7, 172 AEs in 124 patients), and trauma (1.4 ± 1.7, 183 AEs in 136 patients). Table 2 summarizes the most common AEs. Following multivariable analysis (Table 3), the odds of having any AEs remained significantly increased in the complex cohort (OR, 1.6; 95% CI, 1.3–2.1; p < 0.001).

There was a higher number of perioperative AEs per patients in the complex group (1.3 vs. 0.7, p < 0.01) with 18.4% of patients being affected compared to 14.5% in the degenerative cohort. The difference remained significant in multivariable analysis (OR, 1.6; 95% CI, 1.4–1.9; p < 0.001) (Table 3). When comparing the number of perioperative AEs per patient among the major groups in the complex cohort we found no significant difference among infection (1.4 ± 1.7, 52 AEs in 38 patients), oncology (1.3 ± 1.5, 285 AEs in 219 patients), deformity (1.3 ± 1.6, 155 AEs in 124 patients), and trauma (1.2 ± 1.5, 166 AEs in 136 patients) (p = 0.971).

Intraoperative AEs were more frequent in the complex cohort (12.5% [n = 74] vs. 8.5% [n = 144], p = 0.024). This difference was however, not significant in subsequent multivariable analysis (OR, 1.1; 95% CI, 0.7–1.6; p = 0.804) (Table 3). Across the major groups in the complex cohort, we found no difference in the frequency of intraoperative AEs: infection (15.8% [n = 6]), deformity (13.7% [n = 17]), trauma (12.5% [n = 17]), and oncology (11.0% [n = 24]) (p = 0.927).

Further subanalysis of patients undergoing either emergency or elective surgery was performed for the complex and degenerative cohort separately. We found no significant difference in the incidence of AEs in either cohort when comparing emergency and elective patients.

Continuing subanalysis in the 2 respective cohorts, multivariable regression models revealed increased odds of AEs associated to ASA PS classification (OR, 1.3; 95% CI, 1.0–1.6) in the complex cohort, whereas sex (female) (OR, 1.7; 95% CI, 1.4–2.1) was associated to increased odds in the degenerative cohort (Table 4). Increasing length of operation was associated with a modest increase in the likelihood of having an AE in both cohorts. Additionally, age was associated with a modest increase in the likelihood of having an AE in the degenerative cohort.

2. Length of Stay

Mean LOS was longer in the complex cohort (6.6 ± 8.7 days vs. 3.0 ± 3.3 days) and significantly associated to increased odds of overall, intraoperative, and perioperative AEs in both cohorts (p < 0.001). We found no significant difference in mean LOS comparing the major groups in the complex cohort: oncology (6.8 ± 10.2), deformity (6.8 ± 8.8), infection (6.5 ± 9.4), and trau-

Table 3. Univariable and multivariable logistic regression analysis and the risk of adverse events

<table>
<thead>
<tr>
<th>Complex surgery compared to degenerative surgery</th>
<th>Univariable analysis</th>
<th>Multivariable analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR</td>
<td>95% CI</td>
</tr>
<tr>
<td>Total AE</td>
<td>2.1</td>
<td>1.7–2.6</td>
</tr>
<tr>
<td>Intraoperative AE</td>
<td>1.4</td>
<td>1.0–1.9</td>
</tr>
<tr>
<td>Perioperative AE</td>
<td>2.3</td>
<td>1.9–2.8</td>
</tr>
</tbody>
</table>

OR, odds ratio; CI, confidence interval; AE, adverse event; ASA PS, American Society of Anesthesiologists physical status.
*p < 0.05, statistically significant difference. *Adjusted for age, sex, type of admission (elective/emergency), comorbidity (ASA PS classification), and length of operation.
Mean LOS was significantly longer for patients who underwent unplanned revision surgery in both the complex cohort (23.8 ± 19.4 days vs. 6.1 ± 7.8 days, p < 0.001) and in the degenerative cohort (9.0 ± 4.9 days vs. 2.8 ± 3.1 days, p < 0.001).

3. Infections Requiring Revision

There were 12 cases (2.0%) with postoperative wound infections requiring revision surgery within the follow-up period of 90 days; 4 of these occurred during the index admission. Only 1 of the cases (0.06%) was seen in the degenerative cohort. The distribution for the 12 cases among the major diagnostic subgroups was: 7 emergency oncology (58%), 3 elective deformity (25%), 1 emergency deformity (8%), and 1 elective trauma (8%) patient (originally operated electively due to pain after previous trauma fusion surgery).

4. Readmissions

The overall incidence of readmission in the study period was significantly higher in the complex spine cohort (8.6% vs. 4.8%, p = 0.001) (Table 5). This difference remained significant in terms of 30-day readmission but not in 90-day readmission. The most common reason for readmission within 30 days was surgical site infection in the complex cohort; which was the second most common in the degenerative cohort. In the degenerative cohort, pain issues were the most common reason for readmission; which was seldom seen in the complex cohort (Table 5). In the degenerative cohort, mean AEs per patient were significantly higher in patients with an unplanned readmission with 1.2 ± 1.0 vs. 0.7 ± 1.0 AEs (93 AEs in 81 patients vs. 1195 AEs in 1,606 patients) (p < 0.001) compared to the nonreadmitted. The difference was not significant in the complex cohort with 1.4 ± 1.7 versus 1.3 ± 1.5 AEs (p = 0.818) (779 AEs in 542 patient vs. 65 AEs in 51 patients).

5. Unplanned Revision Surgery

When comparing rates of unplanned revision surgery during the index admission, we found no significant difference between the complex cohort (2.5%) and the degenerative cohort (2.8%). The mean number of AEs per patient undergoing revisions was

Table 4. Multivariable logistic regression analysis showing the effect of patient characteristics on the occurrence of AEs overall, perioperatively and intraoperatively

<table>
<thead>
<tr>
<th>Variable</th>
<th>Complex cohort OR (95% CI)</th>
<th>p-value</th>
<th>Degenerative cohort OR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall AEs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (reference male)</td>
<td>1.164 (0.820–1.653)</td>
<td>0.396</td>
<td>1.690 (1.378–2.073)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Age</td>
<td>1.006 (0.996–1.016)</td>
<td>0.232</td>
<td>1.015 (1.007–1.023)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Length of operation</td>
<td>1.003 (1.001–1.005)</td>
<td>0.005*</td>
<td>1.012 (1.010–1.014)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>ASA PS classification</td>
<td>1.279 (1.025–1.598)</td>
<td>0.030*</td>
<td>1.013 (0.853–1.202)</td>
<td>0.886</td>
</tr>
<tr>
<td>Type of admission (reference elective)</td>
<td>1.389 (0.961–2.007)</td>
<td>0.080</td>
<td>1.286 (0.854–1.937)</td>
<td>0.229</td>
</tr>
<tr>
<td>Perioperative AEs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (reference male)</td>
<td>1.123 (0.793–1.590)</td>
<td>0.514</td>
<td>1.842 (1.499–2.264)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Age</td>
<td>1.005 (0.996–1.015)</td>
<td>0.279</td>
<td>1.013 (1.005–1.021)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Length of operation</td>
<td>1.003 (1.001–1.005)</td>
<td>0.004*</td>
<td>1.011 (1.009–1.013)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>ASA PS classification</td>
<td>1.304 (1.046–1.626)</td>
<td>0.018*</td>
<td>1.032 (0.869–1.225)</td>
<td>0.723</td>
</tr>
<tr>
<td>Type of admission (reference elective)</td>
<td>1.343 (0.933–1.934)</td>
<td>0.113</td>
<td>1.332 (0.877–2.024)</td>
<td>0.179</td>
</tr>
<tr>
<td>Intraoperative AEs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (reference male)</td>
<td>1.058 (0.474–2.361)</td>
<td>0.891</td>
<td>0.918 (0.642–1.313)</td>
<td>0.639</td>
</tr>
<tr>
<td>Age</td>
<td>1.056 (0.624–1.787)</td>
<td>0.839</td>
<td>1.025 (1.011–1.040)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Length of operation</td>
<td>1.011 (0.996–1.026)</td>
<td>0.167</td>
<td>1.009 (1.006–1.011)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>ASA PS classification</td>
<td>1.004 (1.001–1.007)</td>
<td>0.005*</td>
<td>0.882 (0.656–1.187)</td>
<td>0.408</td>
</tr>
<tr>
<td>Type of admission (reference elective)</td>
<td>1.222 (0.717–2.082)</td>
<td>0.462</td>
<td>1.058 (0.474–2.361)</td>
<td>0.891</td>
</tr>
</tbody>
</table>

AE, adverse events; OR, odds ratio; CI, confidence interval; ASA PS, American Society of Anesthesiologists physical status.

*p < 0.05, statistically significant difference.
significantly increased in both the complex and degenerative cohort (4.2 ± 2.3 vs. 1.4 ± 1.6 and 2.2 ± 1.7 vs. 0.7 ± 1.0, p < 0.001). Unplanned revision surgeries are further detailed in Table 6.

6. Mortality

There were 12 in-hospital deaths (2.0%) in the complex cohort and 2 (0.1%) in the degenerative cohort. Of the 12 in-hospital deaths in the complex cohort, 1 was in the elective group, and the remaining were emergency admissions. The 2 mortalities in the degenerative cohort were both electively admitted.

**DISCUSSION**

The main findings of this study were the significantly increased incidences of AEs and mortality in the complex cohort. LOS, infections requiring revision surgery and readmission rates were also significantly increased in the complex cohort. Rates of unplanned revision during the index admission were not significantly different. When examining the occurrence of AEs in the major groups within the complex cohort such as infection, trauma, deformity, and oncology, we found no difference either over-

<table>
<thead>
<tr>
<th>Variable</th>
<th>Complex cohort (n = 593)</th>
<th>Degenerative cohort (n = 1,687)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-Day readmissions</td>
<td>45 (88%)</td>
<td>59 (73%)</td>
</tr>
<tr>
<td>Incidence of unplanned readmission</td>
<td>7.6%</td>
<td>3.5%</td>
</tr>
<tr>
<td>Reason for unplanned readmission</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain issues</td>
<td>1</td>
<td>19</td>
</tr>
<tr>
<td>Surgical site infection</td>
<td>26</td>
<td>12</td>
</tr>
<tr>
<td>Hardware revision</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>CSF leak</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Wound dehiscence</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>90-Day readmissions</td>
<td>6 (12%)</td>
<td>22 (27%)</td>
</tr>
<tr>
<td>Incidence of unplanned readmission</td>
<td>1.0%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Reason for unplanned readmission</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain issues</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Surgical site infection</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Hardware revision</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>CSF leak</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Unsatisfactory decompression</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total unplanned readmissions</td>
<td>51</td>
<td>81</td>
</tr>
</tbody>
</table>

**Table 6. Reasons for unplanned revision surgery during index admission**

<table>
<thead>
<tr>
<th>Cohort</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complex cohort (n = 593)</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>4 (27)</td>
</tr>
<tr>
<td>Unsatisfactory decompression</td>
<td>3 (20)</td>
</tr>
<tr>
<td>Hardware malposition requiring revision</td>
<td>2 (13)</td>
</tr>
<tr>
<td>Postoperative hematoma</td>
<td>2 (13)</td>
</tr>
<tr>
<td>Supplemental fixation</td>
<td>2 (13)</td>
</tr>
<tr>
<td>Suture esophageal tear</td>
<td>1 (7)</td>
</tr>
<tr>
<td>CSF leakage</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Total</td>
<td>15 (2.5)</td>
</tr>
<tr>
<td>Degenerative cohort (n = 1,687)</td>
<td></td>
</tr>
<tr>
<td>Postoperative hematoma</td>
<td>20 (43)</td>
</tr>
<tr>
<td>Recurrent disc herniation</td>
<td>9 (19)</td>
</tr>
<tr>
<td>Residual disc herniation</td>
<td>5 (11)</td>
</tr>
<tr>
<td>Unsatisfactory decompression</td>
<td>4 (9)</td>
</tr>
<tr>
<td>Hardware malposition requiring revision</td>
<td>3 (6)</td>
</tr>
<tr>
<td>CSF leakage</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Construct failure without loss of correction</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Surgery performed at wrong level</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Infection</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Drainage equipment was accidentally sutured to the muscle</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Total</td>
<td>47 (2.8)</td>
</tr>
</tbody>
</table>

Values are presented as number (%) and incidence. CSF, cerebrospinal fluid.
intuitive understanding that complex spine surgery is associated with more AEs and therefore contribute to the body of evidence in the literature that can be used for evaluation regarding allocation of different procedures across spine disease and severity within regions or countries.

1. Adverse Events

Perioperative AEs were, as expected, more frequent in the complex cohort. We found no significant difference in the occurrence of perioperative AEs between the major diagnostic groups within the complex cohort. The mean perioperative AE per patient in these groups were similar to that found by Karstensen et al.10

When examining the cohorts separately (Table 4), increasing ASA-score was the predictor associated with the highest OR of having any perioperative AE in the complex cohorts. This corresponds well with the notion that the higher frailty and/or concomitant injuries across the patients in complex cohort should contribute to a higher occurrence of perioperative AEs. The ASA-score is however more of an indicative measure than an exhaustive measure of the higher frailty and/or concomitant injuries, and this study was not set up for a definitive evaluation of this effect; therefore, further studies are warranted.

Electrolyte imbalance, nausea, and vomiting were the most prevalent perioperative AEs in both cohorts, in agreement with previous studies using the SAVES system.5,10,21 In contrast to the studies by Rampersaud et al.21 and Street et al.,1 the prevalence of the “medication-related” AEs was less apparent in our 2 cohorts. Our results were, however, comparable to the rates reported by Karstensen et al.,10 who validated the SAVES system in a European population undergoing complex spine surgery.

A significantly higher incidence of intraoperative AEs in the complex cohort was also expected, although not apparent in multivariable analyses, possibly due to unknown confounders. As with the perioperative AEs, we could not find a statistically significant difference when comparing the major groups of infection, oncological, trauma, and deformity within the complex cohort.

Analyzing the cohorts separately (Table 4), increasing ASA PS classification was associated to increased odds of intraoperative AEs in the complex cohort whilst the same applied for age and length of operation in the degenerative cohort. When doing a stepwise backward regression removing the variable length of operation led to being in the complex cohort compared to the degenerative cohort becoming statistically significant. When comparing the mean length of surgery, we saw a significant longer surgery time in the complex cohort (149 ± 85 minutes vs. 91 ± 55 minutes, p < 0.001). The length of surgery is often used as a surrogate for the extent, and thus the invasiveness, of surgery which subsequently contributes to the significant higher occurrence of intraoperative AEs in the complex cohort. By adjusting the multivariable model for surgical invasiveness, a major trait differences between the cohorts are thus removed, possibly explaining the diminishing effect seen in the OR.

2. Length of Stay

We found significantly longer LOS in the complex cohort, comparable to the previous study by Karstensen et al.10 We found no significant difference between the major groups within the complex cohort. It is reasonable to argue that patients undergoing deformity or tumor surgery undoubtedly need longer time to mobilize, and that the frailty of patients undergoing tumor surgery or the concomitant injuries of a trauma patient can result in medical complications requiring further intervention which extends LOS compared to patients undergoing surgery on the basis of degenerative spine disease. The significantly longer LOS for patients undergoing unplanned revisions surgery in both cohorts underlines the added burden on patients and increased costs to the healthcare provider.

3. Infections Requiring Revision

A significant higher incidence of infections requiring revision surgery in the complex cohort was in accordance with our expectations as there previously has been shown an association with larger procedures with greater invasiveness.23

4. Readmissions

The 30-day readmission rate was higher in the complex cohort corresponding well with significantly higher incidence of AEs and a more morbid patient population. However, the effect diminished when looking at 90-day readmission.

An unexpected finding was that there was no difference in the occurrence of AEs of readmitted patients in comparison to nonreadmitted patients in the complex cohort. A possible explanation could be that since patients in the degenerative cohort were primarily elective patients their main active illness was related to the operation and hence also their main hospital admission. Whereas, patients in the complex cohort had competing morbidities. In addition, patients in the major diagnostic subgroups such as infection, trauma, and oncology were often transferred to a different department following discharge for further treatment and; therefore, did not require readmission to
the spine surgery department for minor complications that could be addressed by their respective departments. The significantly increased rate of AEs in the complex cohort—hence the more even distribution of AEs—could also contribute to balance the difference in AEs in patients who were readmitted and those who were not.

5. Unplanned Revision Surgery
The rate of unplanned revision surgery during index admission was similar in both cohorts, in contrast to expectations. It is important to note that recurrent and residual disc herniation made up 30% of the unplanned revisions in the degenerative cohort, but then again, the occurrence of postoperative hematoma was threefold in the degenerative cohort compared to the complex. The reasons for unplanned revisions in the degenerative cohort were also more varied, and the frequency too low for further subanalysis. Additional assessment of 2-year revision might reveal a difference between patients undergoing either complex or degenerative surgery; however, beyond the scope of this study.

6. Mortality
We found significantly increased in-hospital mortality in the complex cohort (2.0%) compared to the degenerative (0.1%). This was to be expected due to the greater invasiveness of deformity surgery, concomitant injuries in trauma patients, and frailty of patients with ongoing infection or malignancy.

7. Strength and Limitations
Prospective and systematic registrations of AEs more accurately describes the true incidence. Both cohorts were 100% complete, thus minimizing selection bias and adding to the external validity. All AEs were registered by a team of healthcare providers and a research coordinator, which further minimizes the effect of recall bias as has been previously shown when AEs are reported by the surgeon. The variables in the SAVES system are commonly registered variables in a clinical setting at our 2 hospitals and we did therefore not need to train the staff specifically for this project which in turn was beneficial for the validity of the prospective collection of data. The prospective nature and the use of the predefined categories in the SAVES system allow for a more objective assessment and aggregation of data to more thoroughly understand the complexity of factors that determine outcome. Both minor and major complications have previously been associated with increased costs of care in spine surgery. Thus, this study adds to our understanding of the occurrence of AEs in both a wide array of complex and degenerative spine surgery and facilitates the possibility for future comparative studies.

This study also has its weaknesses. Despite exhaustive efforts to detect every predefined AE; all AEs may not have been captured. Although the SAVES system incorporates a category for miscellaneous AEs, there may be subtypes of relevance not included in the predefined categories. Furthermore, this was an observational cohort study, and therefore, the decision to operate was at the surgeon’s discretion in accordance with relevant guidelines. Therefore, an extent of selection bias may be present by excluding patients with severe comorbidities from undergoing surgery. Complex spinal pathologies often necessitate surgical treatment despite severe comorbid conditions. Finally, although both cohorts are large, there is a risk of type II errors in negative findings which warrants future validation. The differences in main and secondary outcomes could possibly be more nuanced within the degenerative cohort and in comparison, if stratified by cervical and lumbar procedures as well as fusion and/or decompression alone, of interest for future studies.

CONCLUSION
In this study, we prospectively included 2 complete cohorts of patients undergoing either complex or degenerative spine surgery, consisting of 2,280 consecutive patients. In a comparative fashion, using the SAVES system, we found increased morbidity related to complex spine surgery not previously demonstrated in a prospective study. The results warrant further studies, hopefully using the same registration system, for additional validation and comparison.

CONFLICT OF INTEREST
The authors have nothing to disclose.

REFERENCES
Association of Spinal Alignment Correction With Patient-Reported Outcomes in Adult Cervical Deformity: Review of the Literature

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Objective: Adult cervical deformity (ACD) is a debilitating spinal condition that causes significant pain, neurologic dysfunction, and functional impairment. Surgery is often performed to correct cervical alignment, but the optimal amount of correction required to improve patient-reported outcomes (PROs) are not yet well-defined.

Methods: A review of the literature was performed and Fisher z-transformation (Zr) was used to pool the correlation coefficients between alignment parameters and PROs. The strength of correlation was defined according to the following: poor (0 < r ≤ 0.3), fair (0.3 < r ≤ 0.5), moderate (0.5 < r ≤ 0.8), and strong (0.8 < r ≤ 1).

Results: Increased C2–7 sagittal vertical axis was fairly associated with increased Neck Disability Index (NDI) (pooled Zr = 0.31; 95% confidence interval [CI], -0.03 to 0.58). Changes in T1 slope minus cervical lordosis poorly correlated with NDI (pooled Zr = -0.04; 95% CI, -0.23 to 0.30). Increased C7–S1 was poorly associated with worse EuroQoL 5-Dimension (pooled Zr = -0.22; 95% CI, -0.36 to -0.06). Correction of horizontal gaze did not correlate with legacy metrics. Modified Japanese Orthopedic Association correlated with C2-slope, C7–S1, and C2–S1.

Conclusion: Spinal alignment parameters variably correlated with improved health-related quality of life and myelopathy after corrective surgery for ACD. Further studies evaluating legacy PROs, Patient-Reported Outcomes Measurement System, and ACD specific instruments are needed for further validation.

Keywords: Cervical alignment, Cervical deformity, Spine, Surgical correction, Patient-reported outcomes, Quality of life

INTRODUCTION

Adult cervical spine deformity (ACD) can negatively impact the quality of life of patients by causing pain, myelopathy, radiculopathy, sensorimotor deficits, as well as inability to maintain horizontal gaze.\textsuperscript{1} The severity of kyphosis and cervical deformity may also affect the global sagittal alignment and negatively impact overall posture, gait, and ambulation as cervical deformity may overwhelm compensation mechanisms to maintain normal physiologic function. The highly heterogeneous clinical and radiographic presentations of ACD have led to its designation as a distinct clinical entity within spinal disorders, culminating in development of the Ames-International Spine Study Group (ISSG) Cervical Spine Deformity classification system that incorporates anatomical, radiographic, and clinical characteristics, thereby providing a systematic approach for...
classifying ACD (Table 1). This classification seeks to further optimize the treatment of ACD with respect to clinical evaluation, radiographic analysis, operative planning, and outcomes assessment. A study by the ISSG demonstrated a substantial health impact of symptomatic ACD of different deformity types in a prospective cohort evaluating various health-related quality of life (HRQoL) measures.

Moving toward a patient-centered treatment approach, surgical goals for ACD typically include correction of the deformity, restoration of horizontal gaze and posture, decompression of the neural elements, and alleviation of pain. Given the wide range of techniques utilized to address cervical deformity, such as multilevel anterior approaches, combined anterior and posterior approaches, and various osteotomy techniques including posterior 3-column osteotomies, studying the impact of the invasiveness of surgery and potential complications on patient outcomes is critical to not only guide surgical strategy but to also determine how much correction is needed to provide benefit from the patients’ perspective. Achieving radiographic correction is certainly feasible now with improvements in surgical implant technology, intraoperative imaging, and technical innovations. However, assessing patient-reported outcomes (PROs) and HRQoL measures are necessary to understand the full impact of deformity and correction on patients’ health and daily functioning. As such, considerable efforts have been made by special study groups including but not limited to the International Spine Study Group (ISSG) and other study groups in North America, Europe, and Asia.

Many HRQoL and PRO instruments have been used to assess general health, pain, disability, and function for cervical spine disorders. These include but are not limited to the Euro-QoL 5-Dimension (EQ-5D), the modified Japanese Orthopedic Association (mJOA) score, the Oswestry Disability Index, Neck Disability Index (NDI), and the Patient-Reported Outcomes Measurement System (PROMIS). A number of PRO instruments are used in practice and there is variability in adoption and implementation. Various PROs study-specific parameters such as pain, function, depression, and anxiety, among others. The Scoliosis Research Society-22r questionnaire (SRS-22r), developed to assess PROs in adult spinal deformity, was designed to play an important role in personalized treatment of spinal deformity by addressing specific symptoms and expectations of patients seeking treatment for correction of the deformity. Moreover, prediction models for SRS-22r were designed to accurately predict a probability of achieving the patient’s goal from surgery, exploring a new horizon where the patient goals play a central role in the decision to undergo correction for a spinal deformity. Along these lines, a greater understanding of

Table 1. Ames-ISSG Cervical Deformity Classification by Ames et al.

<table>
<thead>
<tr>
<th>Deformity descriptor</th>
<th>Grade 0</th>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. C2–7 sagittal vertical axis (SVA)</td>
<td>&lt; 4 cm</td>
<td>4 cm–8 cm</td>
<td>&gt; 8 cm</td>
<td>-</td>
</tr>
<tr>
<td>2. Horizontal gaze (CBVA)</td>
<td>1°–10°</td>
<td>-10°–0° or 11°–25°</td>
<td>&lt; -10° or &gt; 25°</td>
<td>-</td>
</tr>
<tr>
<td>3. Cervical lordosis minus T1 slope (TS–CL)</td>
<td>&lt; 15°</td>
<td>15°–20°</td>
<td>&gt; 20°</td>
<td>-</td>
</tr>
<tr>
<td>4. Myelopathy (mJOA)</td>
<td>18 (none)</td>
<td>15–17 (mild)</td>
<td>12–14 (moderate)</td>
<td>&lt; 12 (severe)</td>
</tr>
<tr>
<td>5. SRS-Schwab classification</td>
<td>T, L, D, or N: Curve type</td>
<td>0, +, or ++: PI minus LL</td>
<td>0, +, or ++: Pelvic tilt</td>
<td>0, +, or ++: C7–S1 SVA</td>
</tr>
</tbody>
</table>

ISSG, International Spine Study Group; CBVA, correction of horizontal gaze; mJOA, modified Japanese Orthopedic Association; SRS, Scoliosis Research Society; PI minus LL, pelvic incidence minus lumbar lordosis.
PROs would help overcome the challenges associated with the existing heterogeneity and difficult interpretation and transportability of the collected data.

Considering the variability in adoption, utilization, and implementation of such outcome measures for adult cervical deformity (ACD), we reviewed the current literature to determine associations between corrections in spinal alignment and PROs and their significance. Understanding the association and relevance of such outcomes assessments may help surgeons implement such metrics in their clinical practice.

**MATERIALS AND METHODS**

1. **Search Strategy and Selection Criteria**

   Following the Cochrane methodology, a literature review was performed to identify studies involving patients diagnosed and treated for ACD and reporting PROs. Our search was completed on OVID encompassing the MEDLINE, and Embase databases to identify English articles published from inception to July 2020. We used the search terms “cervical deformity,” “patient-reported outcomes,” “quality of life,” “treatment outcomes” other PRO-associated terms “pain,” “depression,” “activity,” and commonly used PRO instruments in spine surgery “EQ-5D,” “Neck Pain NRS,” “NDI,” “mJOA,” “VAS,” “SF12,” “SF-36,” “PROMIS.” In addition to electronic databases search, the references of selected studies were searched. Literature reviews and conference abstracts were excluded (Supplementary method 1).

2. **Data Extraction and Quality of Assessment**

   Two authors (EM and JS) independently screened titles and abstracts of all search results to identify potential articles for full-text review. All screening steps were done on Covidence, a web-based platform for managing and streamlining systematic reviews. Information from eligible articles, including senior author’s name and year of publication, study group, study design (observational, interventional), study setting (single institutional vs. multi-institutional), sample size, definition of ACD, PROs, timepoints of PROs assessment, and specification of how PROs were used in each study (i.e., outcome, main predictor, covariable, descriptor, or other) were extracted. Our primary goal was to identify the role of PROs in guiding the treatment of ACD at baseline, in the perioperative setting, and after treatment. Given that none of the retrieved studies was a randomized controlled trial, the quality of the included studies was assessed using the Newcastle-Ottawa Quality Assessment Form for Cohort Studies, which is recommended by Cochrane for evaluation of nonrandomized cohort studies (Supplementary Table 1). Each study was evaluated independently by 2 authors (EM and JS) based on selection of study groups, comparability of study groups, and outcomes assessment.

3. **Outcomes Assessment and Statistical Analysis**

   We used descriptive statistics to summarize the characteristics of the included studies. Correlation coefficients (r) were reported and the strength of the correlation was defined according to the following: poor (0 < r ≤ 0.3), fair (0.3 < r ≤ 0.5), moderate (0.5 < r ≤ 0.8), and strong correlation (0.8 < r ≤ 1). Results of regression analyses, χ² tests for categorical variables, and unpaired t-tests for continuous variables were also reported if present. Owing to the heterogeneity of the data available, we performed a meta-analysis only when 3 or more independent correlation coefficients were available. Correlation coefficients between cervical deformity parameters and PROs were converted into Fisher z-scores (Zr) to be used in the meta-analyses. Z-scores were pooled to obtain overall effect sizes as the inverse variance weighted average of an independent study z-score. The degree of heterogeneity of the pooled effect size was assessed by the χ² test and the inconsistency index (I²). If I² < 50% and p > 0.1, the fixed-effect model was assumed because of the homogeneous effects of parameters. With I² ≥ 50% and p ≤ 0.1, the random-effect model was selected due to heterogeneous effects. All statistical analyses were conducted using ‘meta’ and ‘metaphor’ packages in the R ver. 4.0.5 (R Foundation for Statistical Computing, Vienna, Austria). The threshold for statistical significance was α = 0.05. All tests were 2-sided.

Fig. 1. Summary of systematic review search strategy.
RESULTS

We identified 19 studies that studied a correlation between cervical parameters and PROs used to assess pain, disability, and quality of life in ACD surgery (Fig. 1). Across the 19 studies, 10 studies were conducted by the ISSG representing 19 sites in the United States (US), 2 sites in Japan, and 1 site in Canada. The remaining studies were conducted in single institutions in the US, Lebanon, China, Japan, and South Korea. The characteristics of each study are summarized in Supplementary Table 2. In the following analysis, we examine the association of radiographic parameters with PROs, with

Fig. 2. Summary of the association between patient-reported outcome measures (PROMs) and cervical modifiers appearing in the Ames-ISSG Cervical Spine Classification. Panel A shows the association between cervical C2–7 sagittal vertical axis (SVA) and PROMs. Panel B shows the association between T1 slope minus C2–7 lordosis (TS–CL) and PROMs. Panel C shows the association between chin-brow vertical angle (CBVA) and PROMs. Panel D shows the association between Schwab-SRS parameters, including pelvic tilt (PT), PI minus LL, C7-SVA, and PROMs. Red color indicates a poor correlation (0 < r ≤ 0.3), orange color indicates a fair correlation (0.3 < r ≤ 0.5), light green indicates a moderate correlation (0.5 < r ≤ 0.8), and green indicates a strong correlation (0.8 < r ≤ 1). (* indicates the correlation was significant (p < 0.05). (a) indicates the correlation was not significant. (First Author et al.) refers to the study in the reference list. mJOA, modified Japanese Orthopedic Association; VAS, visual analogue scale; NDI, Neck Disability Index; EQ-5D, EuroQol 5-Dimension; PROMIS, Patient-Reported Outcomes Measurement System; SF-36, 36-item Short Form Health Survey; TS–CL, T1 slope minus cervical lordosis; TK, thoracic kyphosis; PT, pelvic tilt; PI, pelvic incidence; LL, lumbar lordosis.)
specific interest in identifying the association between the deformity modifiers in the Ames cervical deformity classification system and PROs (Fig. 2).

1. Association of Cervical Alignment Parameters and PROs

Cervical C2–7 sagittal vertical axis (C2–7 SV A) was investigated in 9 of the included studies, including 3 studies by the ISSG. Meta-analyses of correlation coefficients showed that C2–7 SV A and NDI correlated fairly (random effect; $Z_r = 0.31 [95\% CI, -0.03$ to $0.58]$; $p < 0.001$) C2–7 SV A correlated poorly with EQ-5D (fixed effect; $Z_r = -0.01 [95\% CI, -0.0$ to $0.06]$; $p = 0.57$) (Fig. 3). Lee et al. found that an increase in C2–7 SV A significantly predicted more pain and disability measured by visual analogue scale (VAS), NDI, and Neck Pain and Disability Scale in multiple regression. Moreover, the ISSG highlighted a significant improvement in Numerical Rating Scale (NRS)-neck and EQ-5D in patients who showed improvement of C2–7 SV A 3 months after surgery. Using a composite outcome of NDI, mJOA, and NRS-neck, Virk et al. found that a good outcome following surgery for cervicothoracic deformity was associated with better postoperative C2–7 CVA. Only one study investigated the relationship between C2–7 SV A categories in CD Ames-ISSG severity groups (score 0, C2–7 SV A < 4 cm; score 1, C2–7 SV A 4–8 cm; score 2, C2–7 SV A > 8 cm), and PROMIS domains showing no difference in PROMIS scores between C2–7 SV A categories. The authors used conditional tree analysis to determine thresholds for PROMIS domains that were independent of C2–7 SV A severities, but did not reach statistical significance.

Eight studies investigated the relationship between T1 slope minus cervical lordosis (TS–CL) and PROs. Meta-analyses of correlation coefficients showed that NDI and EQ-5D correlated poorly with TS–CL (NDI random effect; $Z_r = 0.04 [95\% CI, -0.23$ to $0.30]$; $p = 0.001$) and EQ-5D random effect; $r = 0.07 [95\% CI, -0.24$ to $0.37]$; $p = 0.02$) (Fig. 3). Of these 8 studies, 2 studies looked at PROMIS domains (physical function, pain intensity, pain interference) and found a weak to fair correlation with TS–CL (Fig. 2). Bao et al. demonstrated no difference in average TS–CL between symptomatic (defined by NDI > 15, VAS neck > 3, or VAS arm > 3) and asymptomatic

Fig. 3. Forest graphs showing the meta-analyses of correlation coefficients (converted to z-scores) between C2–7 sagittal vertical axis (SVA) (A, B), T1 slope minus cervical lordosis (TS–CL) (C, D), C7–S1 SVA (E), and patient-reported outcomes. NDI, Neck Disability Index; COR, correlation; CI, confidence interval; EQ-5D, EuroQoL 5-Dimension.
(defined by NDI ≤ 15, VAS neck ≤ 3, and VAS arm ≤ 3) ACD. In parallel, Passias et al.\(^{12}\) found that TS–CL modifier grade improvement (score 0, TS–CL < 15°; score 1, TS–CL 15°–20°; Score 2, TS–CL > 20°; Table 1) at 3 months after surgery showed significant amelioration of both NRS-back and -neck scores. Similarly, Horn et al.\(^{19}\) found that 1-year postoperative poor outcome (defined as failing to meet minimal clinically important difference [MCID] for NDI, or modified mJOA Ames modifier score 0–11) were associated with a higher mean TS–CL than those who did not have a poor 1-year postoperative outcome. Bakouny et al.\(^{25}\) found similar 36-item Short Form Health Survey scores across TS–CL Ames modifier grades (Table 1 for reference) at baseline. Fair (r = 0.327\(^{22}\)) and weak (r = 0.14\(^{11}\); r = -0.218\(^{19}\)) correlations between TS–CL and EQ-5D were reported in 3 studies indicating that there was a low likelihood that a change TS–CL was associated with a strong change in EQ-5D.\(^{21,11,32}\)

The correlation of chin-brow vertical angle (CBVA) with PROs was examined in 2 studies.\(^{24,25}\) Neither of these studies identified that a change in CBVA modifiers (grade 0: CBVA 1°–10°; grade 1: CBVA -10°–0° or 11°–25°; grade 3: CBVA < -10° or > 25°; Table 1) was associated with a strong change in PROs. Furthermore, no correlation of CBVA with NDI, VAS, and EQ-5D was identified.\(^{25}\) One of 2 studies\(^{16,24}\) examining the association of McGregor slope with PROs, showed that 1-year postoperative McGregor slope was significantly correlated with NDI. Johnson et al.\(^{22}\) found C1–2 lordosis did not correlate significantly with any PROMIS domain or legacy metric. However, Zhong et al.\(^{26}\) reported a significant correlation between the change in C1–2 lordosis after surgery and JOA (r = -0.060), NDI (r = 0.676), and SF-12 (r = -0.592). Protopsaltis et al.\(^{21}\) showed that higher C2-slope, which correlated with upper cervical and subaxial parameters including TS–CL, C0–2 angle, cSVA, and CL, was correlated with worse NDI, mJOA, NRS for neck pain, and EQ-5D in cervicothoracic deformities.

2. Association of Myelopathy and PROs

Horn et al.\(^{19}\) reported 24% of patients still had severe disability (mJOA score < 12) after correction surgery, and that poor clinical outcomes were associated with baseline global SVA > 4 cm (odds ratio [OR], 3.2; 95% CI, 0.9–10.3), baseline C2–T3 SVA > 5.4 cm (OR, 1.101; 95% CI, 0.9–1.1), and baseline pelvic tilt (PT) > 20° (OR, 0.92; 95% CI, 0.85–0.98). Passias et al. reported only 29 of 63 patients (46%) had improved mJOA, and only 12 of 63 (19%) reached MCID in mJOA 1 year after surgery. However, both mJOA mean improvement and mJOA MCID were not significantly correlated with neither cSVA, TS–CL, CBVA, SVA, PT, nor PI–LL.\(^{31}\) In another study, the same study group found that corrected C2–S1 SVA (r = -0.424, p = 0.002) and C7–S1 SVA (r = -0.434, p < 0.001) at 1 year were the only radiographic parameters significantly correlated to 1-year mJOA score.\(^{16}\) Ailon et al.\(^{14}\) examined patients with moderate and severe myelopathy (mJOA < 15) showing a slight improvement in mJOA (11.8 ± 1.9 to 12.2 ± 2.6 (p = 0.43) after surgery without reaching statistical significance. Studying the importance of C2 slope as a marker of cervical deformity, Protopsaltis et al. showed that C2 slope and mJOA were correlated (r = -0.65, p = 0.02).\(^{21}\) An assessment of depression in ACD showed that mJOA scores were found similar between patients who were depressed and those who were not depressed at all timepoints, including baseline and postoperative outcomes followed to 1 year.\(^{15}\)

3. Association of Global and Spinopelvic Sagittal Parameters and PROs

3.1 Analysis of Pearson correlation

In parallel, the effect of global and pelvic parameters on PROs was commonly examined in ACD.\(^{16,19,24,26,30,33}\) Oe et al.\(^{26}\) demonstrated a negative but weak correlation between EQ-5D and PT (r = -0.216, p < 0.001), pelvic incidence minus lumbar lordosis (PI–LL; r = -0.206, p = 0.001), C7 SVA (r = -0.265 and p = 0.001), and C2 SVA (r = -0.262, p = 0.001) in ACD. Subanalysis revealed that these correlations were observed more in women than men. Horn et al.\(^{19}\) did not record a difference in average PT, PI–LL, and T4–12 kyphosis between those who had a poor 1-year postoperative outcome (failing to reach MCID for NDI, and having severe symptoms measured by mJOA 0–11) and those without a poor 1-year postoperative outcome. Passias et al.\(^{16}\) demonstrated a significant correlation between C2–S1 SVA and C7–S1 SVA, and 1-year mJOA, EQ-5D, and NDI. Also, Virk et al.\(^{18}\) found that improvements in NDI, mJOA, and NRS-neck were associated with better global spine alignment at 1 year after surgery. In another study comparing baseline to 3-month postoperative HRQoL, significant changes in any disability parameters occurred in patients that deteriorated in PT grade (NRS-neck) and PI–LL grade (NDI score) surgery.\(^{32}\) Meta-analyses of correlation coefficients showed that C7-SVA and NDI were poorly correlated (random effect; r = -0.22 [95% CI, -0.36 to -0.06]; p = 0.19) (Fig. 3).

DISCUSSION

A wide variety of PRO instruments are available and used in contemporary spine surgery practices. These consist of legacy...
instruments such as NDI and mJOA and newer instruments such as PROMIS. The ideal PRO measuring tool is a scale that adapts to a patient’s responses in order to generate the most personalized questionnaire. Development of computerized adaptive testing (CAT) can offer a dynamic system that can generate specific questions based on a patient’s prior answers to provide the most reliable and complete assessment. In 2004, the National Institutes of Health created the Patient-Reported Outcomes Measurement Information System (PROMIS) to improve the reporting of patient-driven responses of symptoms, including pain, function, and quality of life. PROMIS utilizes Item Response Theory, which ensures that each individual question is validated for application to the objective of the test as a whole. PROMIS is increasingly being used to study outcomes from spine surgery and has been compared to more traditional spine PRO assessment scales. As highlighted in this analysis, only one study to date has used PROMIS to assess PROs in ACD.

Considering the variability in the tools used to assess PROs in ACD and the uncertainty with how best to measure clinical improvement, we sought to review and analyze these metrics as they related to alignment correction. This meta-analysis shows that PROs correlated with some cervical and global spine alignment parameters better than others. Notably, increases in C2–7 SVA and C7–S1 SVA were associated with worse NDI and EQ-5D respectively. The correction of other spinal parameters correlated poorly with improvements in HRQoL, revealing that at present, PROs explain and capture a small proportion of the variance in cervical and global spinal parameters. In fact, PROs were broadly used to assess pain, physical activity, mental status, and daily activity, without asking about more specific symptoms that are commonly associated with ACD, including difficulty with swallowing, maintaining horizontal gaze, and respiration. Although studies have validated PROs in cervical myelopathy and radiculopathy using legacy instruments, ACD arguably represents a more complex entity of cervical spine pathology for which conventional outcomes assessments may not capture the extent of impact or benefit on HRQoL.

Defining ACD and postoperative clinical outcomes through identification of specific domains and validated PROs is an important step toward phenotyping ACD. Ames et al. proposed a novel classification system for ACD based on determining the plane (sagittal and coronal), location, and apex of the cervical deformity complemented by 5 modifiers including sagittal parameters (C2–7 SVA, CBVA, TS–CL), myelopathy severity, and SRS-Schwab classification for global spine assessment. The Ames-ACD classification was used in many of the included studies to objectively report, and study ACD, yet the association between global and regional spine sagittal parameters, and present PROs need further investigation to better characterize severity and disability. Having identified drivers of cervical deformity, further work is now needed to determine which PROs can best measure the variance in ACD modifiers as well as postoperative recovery, taking into consideration the presenting symptoms of patients seeking correction of their deformity. Studies are required to validate PROs that can be used to guide the extent of sagittal correction, measure postoperative clinical outcomes at difference time points, and meet patient expectations after an intervention has been performed. Given the invasiveness of surgery and the techniques used to achieve such correction, better stratification of alignment correction goals with PROs is critical.

This review shows that there is clearly interest in studying these measures in ACD. More studies utilizing and reporting PROs to evaluate interventions for ACD suggest that this aspect of spine care is clinically important yet still incompletely defined or understood. A detailed understanding of the influence of segmental, regional, and global spine balance on outcomes in ACD is key to correlate PROs including HRQoL following cervical deformity correction. Most studies examined the association between cervical regional parameters (C2–7 SVA, C2–7 Cobb angle, TS–CL) and PROs, with still nonconclusive results regarding how these parameters relate to clinical outcomes. Many of these parameters including the T1 slope has been studied in recent years and our understanding of these parameters and how they relate to global spinal parameters continue to evolve. For instance, the T1 slope is a measure that is increasingly being studied as a surrogate for the amount of cervical lordosis required. It is defined as the angle between a line drawn across the upper endplate of the T1 vertebra and the horizontal axis. Similar to the relationship between PI and LL, a greater T1 slope suggests that a greater degree of cervical lordosis is required to maintain neutral sagittal alignment. As such, a mismatch in cervical lordosis relative to T1 slope is important to recognize, particularly when planning surgery. Recent studies have sought to compare T1 slope as well as TS–CL with other measures of cervical misalignment as potential markers of deformity severity and postoperative outcomes.

Though the aforementioned cervical parameters are the most common radiographic parameters used for preoperative planning and postoperative radiographic assessment, a more detailed assessment of subjacent segments, including thoracolumbar and pelvis should be factored in the analysis of clinical outcomes, considering the chain of correlation between regional
sagittal parameters and the related compensatory mechanisms that take place. Another challenge is determining the MCID for PROs, defined as the smallest change that patients perceive as beneficial after ACD correction, considering that statistically significant improvements after treatment does not guarantee that the person with corrected ACD has an improved functional capacity or quality of life.

In addition to demographic, clinical, and surgical factors, radiographic parameters such as severe TS–CL, and global parameters such as severe C2–T3 SVA, global C7–S1 SVA, and PT were associated with poor outcomes after ACD correction. These findings could be reflective of coincidental thoracolumbar malalignment, which is often noted in ACD and evidently recognized by the Ames-ACD classification, further highlighting the importance of subjacent deformity and the chain of correlation between cervical-specific and global alignment. While cSVA, TS–CL, and CBVA improvements were associated with better postoperative HRQoL, more severe spinopelvic mismatch and pelvic retroversion had a negative impact on cervical pain and discomfort after surgery. Improving the sagittal balance was associated with improved myelopathy and HRQoL in cervical deformity. Moreover, an improvement in myelopathy was found to be more important to overall patient outcomes than improvement in spinal alignment alone. A better understanding of myelopathy recovery in relation to the degree of correction of the cervical deformity and compensation of global spine parameters is needed during follow-up after ACD correction.

By summarizing the available literature, we demonstrate that cervical and global spine parameters were variably associated with present PROs, suggesting that more research is still needed to guide the correction of the deformity based on predicted changes in PROs. However, it is key to note that association does not imply causation, meaning that a change in alignment can be associated with a change in PROs but does not mean that a change in alignment actually causes a change in PROs. Other factors including frailty, progressive myelopathy, symptoms duration and severity, complications, and rehabilitation could influence clinical outcomes following surgical correction of ACD. Passias et al. demonstrated that improvements in myelopathy contribute to better PROs following ACD corrective surgery than just improving the alignment alone. The respective roles of both cervical realignment and direct decompression on PROs need further investigation, since cervical kyphosis can cause flattening of the spinal cord and increase the intramedullary cord pressure leading to neuronal loss and atrophy of the anterior fasciculus and anterior horn. Also, the long-term clinical outcome could be worse in deformities showing intramedullary signal intensity changes on magnetic resonance images, owing to cellular necrosis secondary to ischemia of the anterior spinal artery and from the repeated microtrauma inflicted on the spinal cord from an unstable cervical spine. Moreover, the ISSG demonstrated an association between frailty and HRQoL, suggesting that one of the goals of surgery for ACD should be to reduce frailty by addressing the modifiable factors of the proposed frailty index for cervical deformity like anxiety, unsteady gait, and leg weakness.

This review has several limitations restricting the ability to study the association of cervical parameters and PROs in a meta-analysis. Although a large number of studies was included, we were limited by the granularity of the data extracted and the lack of availability of correlation coefficients and confidence intervals. Most studies put more emphasis on p-value and statistical significance, rather than the magnitude of the observed correlations (with r = 0 indicating no correlation and r = 1 a perfect correlation). The low p-value of the correlation coefficients only indicates that the chance that the actual correlation coefficient is very different from the observed value is small. Considering that the pooled effect estimate could not be calculated for all parameters given the limitations, the correlation between cervical parameters and PROs requires further study. Furthermore, MCID thresholds should be interpreted with caution, considering the variability of the reported values for legacy metrics. An additional limitation is that most postoperative outcomes were collected at 1 year and information about PROs beyond this timepoint is limited. Only one study attempted to compare PROMIS with legacy metrics but this study had a small sample size which limited subgroup analysis for ACD. Further study with PROMIS domains, which utilizes CAT methods, could potentially avoid the floor and ceiling effects associated with commonly used metrics and may provide more sensitive tools to detect HRQoL changes in ACD.

CONCLUSION

This review demonstrates that correcting ACD to specific alignment parameters inconsistently translates to improvement in PROs. Despite these limitations, we found that increases in C2–7 SVA and C7–S1 SVA were associated with worse NDI and EQ-5D respectively. Given the lack of specific PRO assessment tools for ACD, further study is needed to better quantify goals for alignment correction to maximize the HRQoL benefits for patients.
CONFLICT OF INTEREST
The authors have nothing to disclose.

SUPPLEMENTARY MATERIALS
Supplementary method 1, Tables 1 and 2 can be found via https://doi.org/10.14245/ns.2040656.328.

REFERENCES
22. Johnson B, Stekas N, Ayres E, et al. PROMIS correlates with legacy outcome measures in patients with neck pain and improves upon NDI when assessing disability in cervical


SUPPLEMENTARY MATERIALS

Supplementary Method 1. Literature Search Strategy
Search Strategy: ((Cervical Vertebrae[MeSH Terms]) OR (cervical deformity[Title/Abstract])) AND (((Patient-Reported Outcomes[Title/Abstract]) OR (PROs[Title/Abstract])) OR (Health-related quality of life[Title/Abstract])) OR (HRQoL[Title/Abstract]) OR (treatment outcome[Title/Abstract]))

Supplementary Table 1. Quality of included studies per Newcastle-Ottawa Scale for quality assessment of cohort studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Selection</th>
<th>Comparability</th>
<th>Outcome</th>
<th>Adequacy of follow-up of cohorts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Representativeness of the exposed cohort</td>
<td>Selection of the nonexposed cohort</td>
<td>Ascertainment of exposure</td>
<td>Ascertainment of outcome</td>
</tr>
<tr>
<td>Johnson22 (2019)</td>
<td>**</td>
<td>-</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Pierce4 (2019)</td>
<td>**</td>
<td>-</td>
<td>**</td>
<td>**</td>
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<tr>
<td>Bakouny25 (2018)</td>
<td>**</td>
<td>-</td>
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<tr>
<td>Ailon14 (2017)</td>
<td>**</td>
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<td>Hyun28 (2018)</td>
<td>**</td>
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<tr>
<td>Poorman15 (2017)</td>
<td>**</td>
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<td>Oe26 (2017)</td>
<td>**</td>
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<td>Passias16 (2018)</td>
<td>**</td>
<td>-</td>
<td>**</td>
<td>**</td>
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<tr>
<td>Passias32 (2018)</td>
<td>**</td>
<td>-</td>
<td>**</td>
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<tr>
<td>Grosso23 (2013)</td>
<td>**</td>
<td>-</td>
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<tr>
<td>Virk18 (2020)</td>
<td>**</td>
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<tr>
<td>Zhong29 (2018)</td>
<td>**</td>
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<tr>
<td>Smith3 (2017)</td>
<td>**</td>
<td>-</td>
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<tr>
<td>Horn19 (2019)</td>
<td>**</td>
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<tr>
<td>Bao42 (2017)</td>
<td>**</td>
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<td>Segreto20 (2019)</td>
<td>**</td>
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<tr>
<td>Protopsaltis30 (2018)</td>
<td>**</td>
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<tr>
<td>Lee27 (2015)</td>
<td>**</td>
<td>-</td>
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</tr>
</tbody>
</table>

Asterisks are the star ratings per the Newcastle-Ottawa Scale; * and ** indicate the highest ratings for these categories.
### Supplementary Table 2. Summary of studies examining the association of cervical parameters with patient-reported outcomes in adult cervical deformity

<table>
<thead>
<tr>
<th>Study</th>
<th>Study design</th>
<th>Country/organization</th>
<th>Study population</th>
<th>No.</th>
<th>Intervention</th>
<th>PRO instruments</th>
<th>Timing of PRO collection</th>
<th>Main findings</th>
</tr>
</thead>
</table>
| Johnson<sup>b</sup> (2019) | Retrospective analysis of a prospective registry of a single institution | USA                  | Patients presenting with a chief complaint of neck pain and diagnosed with cervical deformity (ACD) (defined as cSVA > 40 mm) | 36  | No surgical intervention - Questionnaires were completed before each ambulatory clinic visit for neck pain | NDI, EQ-5D, VAS neck pain, VAS arm pain, PROMIS physical function, PROMIS pain intensity, and PROMIS pain interference, mFI, CCI | Baseline                      | - In patients with cervical deformity, less subaxial cervical lordosis (CL) had low but significant correlations with PROMIS pain intensity (CL r = -0.347, p = 0.022) and EQ-5D (CL r = 0.344, p = 0.024) but not NDI.  
  - C1–2 lordosis did not correlate significantly with any PROMIS domain or legacy metric, nor did PROMIS physical function or PROMIS pain interference correlate with any alignment parameter. |
| Pierce<sup>c</sup> (2019)     | Retrospective analysis of single center database | USA                  | Patients with ACD defined as (C2–7 Cobb > 10° or cSVA > 4 cm or TS–CL > 15°) - Based on cSVA Ames-ISSG modifier 83.2% had low and 16.8% had moderate ACD - Based on TS–CL: Ames-ISSG modifier 18.8% had low, 22.1% had moderate, and 59.1% had severe ACD. | 208 | 79.3% posterior approach; 5.7% anterior surgery, and 14.9% combined approach | PROMIS scores for pain interference, PI, and PF | Baseline                      | - PROMIS domain scores for Pain intensity did not differ between cSVA and TS–CL modifier severity groups.  
  - Moderate cSVA patients and Moderate/Severe TS–CL modifier groups both trended toward lower PF scores and higher pain interference scores, though this was not statistically significant (p > 0.05). |
| Bakouny<sup>a</sup> (2018)   | Cross-sectional observational study | Lebanon             | Patient's age ≥ 18 years with absence of cervical or back-related complaints - 96.5% Subjects had at least one: Ames-ISSG modifier at grade 1 or 2 | 141 | No intervention                                                          | SF-36 HRQoL questionnaire         | Baseline                      | All SF-36 components were similar (p > 0.05) between grades for both the TS–CL and CBVA modifiers.                                                                                           |
| Ailon<sup>d</sup> (2017)     | Retrospective analysis of a prospective, multicenter CD database | International Spine Study Group (ISSG) | Surgically treated ACD patients eligible for 1-yr follow-up - 56.4% had cervical sagittal imbalance; 54.5% cervical kyphosis; 7.3% proximal junctional kyphosis, 9.1% coronal deformity | 55  | 14.5% Anterior approach; 47.3% posterior-only; 38.2% Combined anterior and posterior; 18.2% PSO; 5.5% vertebral column resection | EQ-5D, NDI, and neck pain NRS, mJOA | Change from baseline to 1-yr follow-up after surgery | - Improvement in global health status as measured by mean EQ-5D (0.51 ± 0.2 to 0.66 ± 0.2, p < 0.001); 56.6% of patients improved by at least 1 MCID for EQ-5D  
  - Reduction in neck pain and neck related disability; corresponded to an increase greater than or equal to the MCID for neck pain NRS (1.3) 25 in 61.8% of patients. A reduction of NDI by at least 1 MCID (19%) was achieved in 55.6% of patients.  
  - Minimal change in myelopathy from a mean baseline mJOA of 13.3 ± 2.6 to 13.5 ± 3.0 (p = 0.675)                                                                                                                |

(Continued to the next page)
**Supplementary Table 2. Continued**

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<thead>
<tr>
<th>Study</th>
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<th>Main findings</th>
</tr>
</thead>
</table>
| Hyun<sup>a</sup> (2018) | Retrospective cohort study of a single institution experience | South Korea | Patients with a minimum 5-yr follow-up having 3- or more level posterior cervical fusion for ACD | 30 | Posterior cervical correction | NDI, VAS | Postoperative | - Regression models predicted a threshold C2–7 SVA value of 40.8 mm and 70.6 mm correlated with moderate and severe disability based on the NDI score, respectively.  
- Regression analyses revealed that a C2–7 SVA value of 40 mm and 70 mm corresponded to a TS–CL value of 20° and 25°, respectively.  
- No other significant correlations were identified between the radiographic parameters and VAS scores for axial neck pain |
| Poorman<sup>5</sup> (2017) | Retrospective analysis of a prospective, multicenter ACD database | International Spine Study Group (ISSG) | Patient diagnosed with ACD and underwent surgical correction of the deformity  
-Cohort divided between those with depression vs. no depression | 66 | Depressed group: Anterior approach (n = 24.2), posterior approach (n = 17/51.5%), combined approach (n = 24.2%)  
Nondepressed group: anterior approach (n = 24.1%); posterior approach (n = 17/51.5%); combined approach (n = 14/42.4) | NRS, EQ-5D, Neck NDI, mJOA | 3 mo, 6 mo, and 1 yr postoperatively | - At 3 months, EQ-5D scores remained lower in the depressed group, and NDI scores were similar. Neck pain improved in the depressed group and mJOA scores remained similar.  
- At 6 months and 1 year, all HRQoL scores were similar between depressed and nondepressed groups |
| Oe<sup>6</sup> (2017) | Retrospective cohort study of a single institution experience | Japan | Patients diagnosed with ACD (defined as cSVA > 40 mm) | 118 | No intervention | EQ-5D | Baseline | - In males EQ-5D in showed significantly greater deterioration the ACD group than in the non-ACD group  
- In females, no difference in EQ-5D between ACD and non-ACD groups.  
- Correlation between EQ-5D and PT, C7 SVA and C2 SVA in females  
- No correlation of EQ-5D and cervical parameters in males. |

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<tbody>
<tr>
<td>Passias16 (2018)</td>
<td>Retrospective analysis of a prospective, multicenter ACD database</td>
<td>International Spine Study Group (ISSG)</td>
<td>Patients diagnosed with ACD as defined by the presence of at least 1 of the following on baseline imaging: cervical kyphosis (C2–7 Cobb angle &gt;10), cervical scoliosis (C2–7 coronal Cobb angle &lt;10), cSVA &gt;4 cm, or CBV &gt;25</td>
<td>73</td>
<td>Posterior approach</td>
<td>EQ-5D; NDI; mJOA</td>
<td>Baseline and 1-yr postoperative visits</td>
<td>- Within primary drivers (PD) patients operated at cervical driver level showed significant 1-year HRQL improvements (Table 4) and trended toward improvement in Ames TS–CL modifier at a greater rate than did patients with PDs not included in surgery.</td>
</tr>
<tr>
<td>Passias16 (2018)</td>
<td>Retrospective analysis of a prospective, multicenter ACD database</td>
<td>International Spine Study Group (ISSG)</td>
<td>Patients diagnosed with ACD as defined by the presence of at least 1 of the following on baseline imaging: cervical kyphosis (C2–7 Cobb angle &gt;10), cervical scoliosis (C2–7 coronal Cobb angle &lt;10), cSVA &gt;4 cm, or CBV &gt;25</td>
<td>70</td>
<td>EQ-5D; NDI; mJOA</td>
<td>Baseline and 1-yr postoperative visits</td>
<td>- Global parameters of C2–S1 SVA and C7–S1 SVA showed significant correlations with overall 1-year mJOA, EQ-5D, and NDI.</td>
<td></td>
</tr>
<tr>
<td>Horn19 (2020)</td>
<td>Retrospective analysis of a prospective, multicenter ACD database</td>
<td>International Spine Study Group (ISSG)</td>
<td>Patients diagnosed with ACD as defined by the presence of at least 1 of the following on baseline imaging: cervical kyphosis (C2–7 Cobb angle &gt;10), cervical scoliosis (C2–7 coronal Cobb angle &lt;10), cSVA &gt;4 cm, or chin-brow vertical angle (CBVA) &gt;25, and mJOA scores 17 or lesser baseline imaging: cervical kyphosis (C2–7 Cobb angle &gt;10), cervical scoliosis (C2–7 coronal Cobb angle &lt;10), cSVA &gt;4 cm, or CBVA &gt;25</td>
<td>63</td>
<td>49.2% Posterior approach, 17.5% anterior approach, and 33.3% combined approach</td>
<td>mJOA; EQ-5; NDI</td>
<td>1-yr postoperative improvement</td>
<td>- Improvements in functional outcomes, as defined by mJOA score, were correlated with changes in neck-based disability and general health state, defined by NDI and EQ-5D respectively. - While correlations exist between outcome measures, when modeling these outcomes while controlling for confounders including cSVA change, surgical invasiveness, age and CCI, these HRQoLs were not strongly correlated.</td>
</tr>
</tbody>
</table>

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### Supplementary Table 2. Continued

<table>
<thead>
<tr>
<th>Study</th>
<th>Study design</th>
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<th>PRO instruments</th>
<th>Timing of PRO collection</th>
<th>Main findings</th>
</tr>
</thead>
</table>
| Grosso23 (2013) | Retrospective cohort study of a single institution experience | USA                  | Patients with myelopathic symptoms who underwent cervical deformity correction surgery | 36  | 34% posterior approach, 8% anterior approach, and 55% combined approach | mJOA                   | Baseline and postoperative | - A significant relationship was observed between a greater degree of focal kyphosis correction and improved neurological outcomes (mJOA).  
- Patients with severe neurological symptoms (mJOA score < 12) a trend toward improved outcomes with greater global kyphosis correction.  
- Patients with an mJOA score less than 16 who attained lordosis postoperatively had a significantly greater improvement in total mJOA score than patients who maintained a kyphotic position. |
| Virk18 (2020)  | Retrospective analysis of a prospective, multicenter ACD database | International Spine Study Group (ISSG) | Patients diagnosed with ACD as defined by the presence of at least 1 of the following on baseline imaging: cervical kyphosis (C2–7 Cobb angle > 10), cervical scoliosis (C2–7 coronal Cobb angle < 10), cSVA > 4 cm, or CBVA > 25 | 153 | Details of surgical approaches not provided | NDI, mJOA, NRS-neck  
- Postoperative outcomes were defined as "good" if a patient had ≥ 2 of the 3 following criteria  
  (1) NDI < 20 or meeting MCID, (2) mild myelopathy (mJOA ≥ 14), and (3) NRS-Neck ≤ 5 or improved by ≥ 2 points from baseline | Baseline and 1-yr postoperative | - Within the FD cohort, maximal focal kyphosis (i.e., kyphosis at one level) was better corrected in patients with a "good" outcome.  
- In the FN cohort, patients with "good" outcomes presented preoperatively with worse horizontal gaze (McGregor slope 21° vs. 6°, p = 0.061) and cSVA (72 mm vs. 60 mm, p = 0.030).  
- In the CT cohort, patients with "good" outcomes had superior global alignment both pre- (SVA: -17 mm vs. 108 mm, p < 0.001) and postoperatively (50 mm vs. 145 mm, p = 0.001).  
- CT patients with "good" outcomes also had better postop cervical alignment (cSVA 35 mm vs. 49 mm, p = 0.030), and less kyphotic segments during extension.  
- In the FD cohort, there were no differences between "good" and "poor" outcomes in preoperative alignment. |
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Smith³</td>
<td>Retrospective analysis of a prospective, multicenter ACD database</td>
<td>International Spine Study Group (ISSG)</td>
<td>ACDSD patients presenting for surgical treatment</td>
<td>115</td>
<td>No intervention</td>
<td>EQ-5D</td>
<td>Baseline</td>
<td>Mean ACSD EQ-5D index was 0.511 (standard definition = 0.224), which is 34% below the bottom 25th percentile (0.780) for similar age- and gender-matched US normative populations</td>
</tr>
<tr>
<td>Zhong²⁰</td>
<td>Prospective cohort study in a single institution</td>
<td>China</td>
<td>Chronic AAD-related kyphosis</td>
<td>21</td>
<td>C1–2 reduction and correction surgery</td>
<td>NDI, SF-12 PCS, and JOA</td>
<td>Baseline and postoperative</td>
<td>An improvement in the JOA score was associated with changes in the C1–2 Cobb angle, C0–2 Cobb angle, and C2–7 Cobb angle</td>
</tr>
<tr>
<td>Horn¹⁹</td>
<td>Retrospective analysis of a prospective, multicenter ACD database</td>
<td>International Spine Study Group (ISSG)</td>
<td>Patient with ACD, no history of cervical surgery, and a well-compensated thoracolumbar profile (defined as a T1-pelvic angle &lt; 15).</td>
<td>89</td>
<td>Posterior approach (49.4%); anterior approach (16.9%); combined (33.7%)</td>
<td>NDI, EQ-5D, mJOA</td>
<td>Baseline and postoperative</td>
<td>80% and 60% of patients did not reach MCID for EQ-5D and NDI, respectively, and 24% of patients had severe symptoms (mJOA score 0–11)</td>
</tr>
<tr>
<td>Bao²⁴</td>
<td>Retrospective cohort study of a single institution experience</td>
<td>USA</td>
<td>No intervention</td>
<td>171</td>
<td>No intervention</td>
<td>NDI, VAS arm, VAS neck</td>
<td>Baseline</td>
<td>C2–7 SVA and SLS as independent risk factors for low health-related quality of life</td>
</tr>
</tbody>
</table>

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<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Segreto&lt;sup&gt;30&lt;/sup&gt; (2019)</td>
<td>Retrospective analysis of a prospective, multicenter ACD database</td>
<td>International Spine Study Group (ISSG)</td>
<td>Operative ACD patients (&gt; 18 years old), undergoing a primary or revision procedure, with complete preoperative to 1-yr postoperative HRQoL data</td>
<td>83</td>
<td>Surgical intervention (primary and revision surgery)</td>
<td>NRS-neck, NRS back, NDI, mJOA, and EQ-5D</td>
<td>Baseline and 1-yr postoperative</td>
<td>Primary patients (compared to revision surgery group) exhibited significantly lower normalized NRS-neck pain scores by 6 mo (0.48 vs. 0.68; p = 0.037), as well as lower normalized NRS-neck pain (0.51 vs 0.83, p = 0.017) and improved normalized mJOA (1.11 vs. 0.97, p = 0.007) by 1-yr follow-up</td>
</tr>
<tr>
<td>Protopsaltis&lt;sup&gt;30&lt;/sup&gt; (2018) ISSG</td>
<td>Retrospective analysis of a prospective, multicenter ACD database</td>
<td>International Spine Study Group (ISSG)</td>
<td>ACD surgical patients with apex of deformity in the cervical or cervicothoracic regions</td>
<td>104</td>
<td>Surgical correction</td>
<td>EQ5D, mJOA, NRS-neck pain, NDI</td>
<td>Baseline and 1-yr postoperative</td>
<td>Worse 1-yr postoperative C2 slope correlated with worse health outcomes</td>
</tr>
<tr>
<td>Lee&lt;sup&gt;27&lt;/sup&gt; (2014)</td>
<td>Retrospective case-control</td>
<td>Republic of Korea</td>
<td>Patients diagnosed with ankylosing spondylitis (AS)</td>
<td>102 AS patients and 50 controls</td>
<td>No intervention</td>
<td>VAS for neck pain, NDI, NPAD, scale and bath ankylosing spondylitis disease activity index were administered to evaluate QoL</td>
<td>Baseline</td>
<td>Correlation analysis revealed significant relationships between radiographic parameters and QoL. In particular, C2–7 SVA was found to be a significant predictor of QoL in AS patient</td>
</tr>
</tbody>
</table>

PRO, pedicle subtraction osteotomy; ACD, adult cervical deformity; cSVA, C2–7 sagittal vertical axis; NDI, Neck Disability Index; EQ-5D, EuroQoL 5-Dimension; VAS, visual analogue scale; PROMIS, Patient-Reported Outcomes Measurement Information System; mFI, Charlson Comorbidity Index; TS–CL, T1 slope minus cervical lordosis; PI, pelvic incidence; PE, physical function; SF-36, 36-item Short Form Health Survey; HRQoL, health-related quality of life; CBVA, correlation of chin-brow vertical angle; NRS, Numerical Rating Scale; mJOA, modified Japanese Orthopedic Association; MCID, minimal clinically important difference; FD, focal deformity; FN, flat neck; ACSD, adult cervical spine deformity; AAD, atlantoaxial anterior dislocation; SF-12 PCS, 12-item Short Form health survey physical composite score; SLS, slope of line of sight; NPAD, neck pain and disability.
Lordosis Distribution Index in Short-Segment Lumbar Spine Fusion – Can Ideal Lordosis Reduce Revision Surgery and Iatrogenic Deformity?

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2Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark
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4Department of Orthopedics and Scoliosis Surgery, Texas Children’s Hospital & Baylor College of Medicine, Houston, TX, USA

Objective: The demand for spinal fusion is increasing, with concurrent reports of iatrogenic adult spinal deformity (flatback deformity) possibly due to inappropriate lordosis distribution. This distribution is assessed using the lordosis distribution index (LDI) which describes the upper and lower arc lordosis ratio. Maldistributed LDI has been associated to adjacent segment disease following interbody fusion, although correlation to later-stage deformity is yet to be assessed. We therefore aimed to investigate if hypolordotic lordosis maldistribution was associated to radiographic deformity-surrogates or revision surgery following instrumented lumbar fusion.

Methods: All patients undergoing fusion surgery (≤ 4 vertebra) for degenerative lumbar diseases were retrospectively included at a single center. Patients were categorized according to their postoperative LDI as: “normal” (LDI 50–80), “hypolordotic” (LDI < 50), or “hyperlordotic” (LDI > 80).

Results: We included 149 patients who were followed for 21 ± 14 months. Most attained a normally distributed lordosis (62%). The hypolordotic group had increased postoperative pelvic tilt (PT) (p < 0.001), pelvic incidence minus lumbar lordosis (PI–LL) mismatch (p < 0.001) and decreased global lordosis (p = 0.007) compared to the normal group. Survival analyses revealed a significant difference in revision surgery (p = 0.03), and subsequent multivariable logistic regression showed increased odds of 1-year revision in the hypolordotic group (p = 0.04). There was also a negative, linear correlation between preoperative pelvic incidence (PI) and postoperative LDI (p < 0.001).

Conclusion: In patients undergoing instrumented lumbar fusion surgery, hypolordotic lordosis maldistribution (LDI < 50) was associated to increased risk of revision surgery, increased postoperative PT and PI–LL mismatch. Lordosis distribution should be considered prior to spinal fusion, especially in high PI patients.

Keywords: Lordosis distribution, Spine fusion, Lumbar spine, Ideal lordosis, Adult spinal deformity

INTRODUCTION

Degenerative lumbar spine diseases are common and related to pain and disability. These conditions are among the most important causes of decreased health-related quality of life, and often treated using spinal fusion.1-4 Meanwhile, iatrogenic causes of adult spinal deformity is a growing concern—possibly due to previous fusion in relative kyphosis (flatback deformity).5,6 Adult
spinal deformity is a condition related to severe pain, disability, in addition to high procedure-related costs and complications including mechanical complications requiring revision surgery.\textsuperscript{7-10} Hypolordosis is established as a risk-factor of iatrogenic deformity while further in-depth assessment, beside the extent, of lordosis is not well understood.

Optimal lordosis is also well established as a cornerstone in treating patients with adult spinal deformity and should reflect pelvic incidence (PI). A PI minus lumbar lordosis (PI–LL) mismatch has been associated with poor postoperative outcome.\textsuperscript{11,12} By fusing part of the lumbar segments, the lumbar curvature may be compromised or not adequately restored to suit the ideal sagittal shape.\textsuperscript{13} Symptomatic loss of lumbar lordosis can cause sagittal imbalance or deterioration of lordosis and may require major, extensive revision surgery. So-called iatrogenic deformity is considered to be a leading cause of adult spinal deformity besides degenerative ageing processes.\textsuperscript{5,6} Lordosis extent and PI–LL interaction are parameters to consider prior to fusion surgery; however, the PI–LL concept may be simplifying a more complex issue. Distribution of lordosis between the upper and lower arc has been proposed as a considerable factor in attaining a well-balanced spine and in reducing postoperative complications.\textsuperscript{14} Berthonnaud et al.\textsuperscript{15} proposed to separate the lordosis into 2 segments. Roussouly and Pinheiro-Franco\textsuperscript{16} further elaborated the concept and demonstrated how the lower arc of lordosis should represent 2/3 of global lordosis, as proposed by Barrey et. al.\textsuperscript{17} Finally, the lordosis distribution index (LDI) was proposed as a ratio of lordosis distribution between the lower arc (L4–S1) and the global lordosis.\textsuperscript{14} LDI is calculated as a ratio from 0–100 characterizing the increasing lordosis towards the lower segments (Fig. 1). Normal values span from 50%–80%, LDI < 50% suggests hypolordotic maldistribution and LDI > 80% suggests hyperlordotic maldistribution. In a recent study of patients undergoing lumbar interbody fusion, the authors found that maldistributed lordosis was associated to postoperative adjacent segment disease (ASD).\textsuperscript{18} To our knowledge, the LDI has not been assessed in patients undergoing instrumented spine surgery which we sought to assess.

MATERIALS AND METHODS

1. Study Design

We retrospectively screened all patients undergoing short-segment instrumented spine surgery for degenerative lumbar pathologies in a 2-year period from January 1st, 2015 through December 31st, 2016 at a single tertiary institution. Short-segment fusion was defined as instrumented fusion of ≤ 4 vertebrae. Only adult patients (≥ 18 years) were eligible for inclusion. Exclusion criteria were: a history of previous instrumented fusion. Inclusion criteria were sufficient preoperative or postoperative radiographs including both femoral heads, sacral endplate, and all lumbar vertebrae up until the inflection point to the thoracic kyphosis. This study was retrospective, noninterventional and LDI was therefore not considered at the time of surgery. This study was approved by the National Health and Medical authority and The National Data Protection Agency.

2. Patient Sample

Patients screened for inclusion underwent surgical treatment for degenerative lumbar spine pathologies including spondylolisthesis (< grade 3), spinal stenosis, disc herniation, degenerative disc disease, or a combination. Surgical treatment included posterior instrumented fusion of 2–4 vertebral levels. Decompression or interbody fusion was performed when deemed necessary. Patient characteristics, medical history, and surgical data were obtained using electronic medical records. Follow-up consisted of clinical and radiographic assessment at 3 months and 1-year following surgery. Radiographic measurements were performed using the online imaging system KEOPS (SMAIO, Lyon, France).\textsuperscript{19} LDI was calculated as the ratio between the
lower arc (upper endplate of L4 to S1) and the global lordosis (lordosis/kyphosis inflection point as upper limit). Patients were subcategorized according to their postoperative LDI as: normal (LDI 50–80), hypolordosis (LDI < 50), or hyperlordosis (LDI > 80). Postoperative complications were registered and subcategorized as minor or major. Major complications were defined as a complication leading to prolonged length of hospital stay (LOS) (> 75th percentile), intensive care, invasive procedures, permanent effect on outcome (e.g., neural injury) or death. Complications were further categorized as “mechanical”: proximal junctional kyphosis or proximal junctional failure; distal junctional failure; rod breakage; or other. The primary outcome was revision surgery excluding revision due to hematoma, wound dehiscence, and infection. Secondary outcomes were other recorded complications and radiographic parameters related to poor outcome in patients with adult spinal deformity. Patient-reported outcome measures were not evaluated.

### 3. Statistical Analyses

We performed all statistical analyses using the language and environment R (R Core Team 2020, Vienna, Austria) version 4.0.1. Data distribution was assessed using histograms and reported as means with standard deviations (SDs), medians with interquartile ranges (IQRs), or proportions (%). Student t-test was used to compare approximated Gaussian distributed data and Wilcoxon rank-sum test for non-Gaussian data (paired tests when comparing pre- and postoperative parameters). Categorical variables were analyzed using Pearson chi-square test of independence or Fisher exact test when the expected counts were below 5 for 20% of frequencies. Analysis of variance (ANOVA) was performed when comparing LDI groups, followed by pairwise analyses as described above. Correlation between preoperative PI and postoperative LDI was assessed using linear regression. Uni- and multivariable logistic regression was used to assess postoperative LDI on 1-year revision, adjusted for number of instrumented vertebra and preoperative PI. Overall revision was estimated using Kaplan-Meier (KM) survival analyses, plotted as cumulative incidences (1-KM), stratified by LDI subgroups and compared using log-rank tests. Estimated parametric accelerated failure was further assessed for all 3 groups using a Weibull regression model (proportional and accelerated) for relative event rates and relative extension in survival time. Results were presented as odds ratios (ORs) with 95% confidence intervals (CIs). All p-values are 2-sided, unadjusted for multiple comparisons and were considered significant if < 0.05.

### RESULTS

We identified 249 adult patients undergoing instrumented fusion of which 75 (30%) were excluded due to history of previous fusion. Out of 174 eligible patients, 23 (13%) were excluded due to insufficient preoperative radiographs and 2 (1%) due to insufficient postoperative radiographs leaving 149 for final analyses (eligibility ratio: 86%). Table 1 details patient characteristics. Mean age ± SD at time of surgery was 59 ± 13 and a majority of patients were female (66%, n = 98). The most common etiology was a combination of multiple pathologies (34%), followed by spondylolisthesis (22%), disc herniation (14%), and spinal stenosis (12%). Previous noninstrumented spinal surgery was common (43%, n = 64). Surgery was performed for a mean of 177 ± 51 minutes, most cases involved interbody cages (79%, n = 118) and the median (IQR) number of instrumented vertebrae was 3 (3–4). A majority of procedures included the S1 (n = 108, 72%). Median (IQR) LOS was 4 days (4–6 days) and patients were followed for a mean ± SD of 21 ± 14 months.

#### Table 1. Patient characteristics and surgical data (n = 149)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>59 ± 13</td>
</tr>
<tr>
<td>Female sex</td>
<td>98 (66)</td>
</tr>
<tr>
<td>Etiology</td>
<td></td>
</tr>
<tr>
<td>Multiple</td>
<td>51 (34)</td>
</tr>
<tr>
<td>Listhesis</td>
<td>32 (22)</td>
</tr>
<tr>
<td>Disc herniation</td>
<td>21 (14)</td>
</tr>
<tr>
<td>Degenerative disc disease</td>
<td>18 (12)</td>
</tr>
<tr>
<td>Stenosis</td>
<td>16 (11)</td>
</tr>
<tr>
<td>Other</td>
<td>11 (7)</td>
</tr>
<tr>
<td>Carlson Comorbidity Index</td>
<td>2 ± 2</td>
</tr>
<tr>
<td>ASA PS classification</td>
<td>2 ± 1</td>
</tr>
<tr>
<td>Surgery time (min)</td>
<td>177 ± 51</td>
</tr>
<tr>
<td>Interbody cage</td>
<td>118 (79)</td>
</tr>
<tr>
<td>Minimal invasive</td>
<td>4 (3)</td>
</tr>
<tr>
<td>Instrumented vertebra</td>
<td>3 (3–4)</td>
</tr>
<tr>
<td>Length of stay</td>
<td>4 (4–6)</td>
</tr>
<tr>
<td>Follow-up (mo)</td>
<td>21 ± 14</td>
</tr>
<tr>
<td>Previous spine surgery</td>
<td>64 (43)</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation, number (%), or median (interquartile range).

ASA PS, American Society of Anesthesiologists physical status.
1. Sagittal Radiographic Parameters

Differences between preoperative and postoperative radiographic measurements were assessed and found with significant increase in pelvic tilt (PT) (18° ± 9° vs. 20° ± 9°, p < 0.001) and PI–LL (4° ± 14° vs. 7° ± 14°, p < 0.001). These remained significant at 1-year follow-up (p < 0.001). A modest, although significant, decrease was seen in sacral slope (37° ± 11° vs. 35° ± 11°, p < 0.001) and without significant difference at 1-year follow-up (p = 0.072). Global lordosis decreased from 53° ± 14° preoperatively to 49° ± 13° postoperatively (p < 0.001) and remained decreased at 1-year follow-up (50° ± 15°, p < 0.001). Long-standing radiographs were only available in select patients, as deemed by the surgeon, although analyses were performed when available and without significant differences between groups.

2. LDI and Sagittal Parameters

Mean ± SD postoperative LDI was 59% ± 22% and without significant difference when compared to preoperative (62% ± 23%) and 1-year measurements (59% ± 22%). Patients were further subcategorized according to their postoperative LDI:

<table>
<thead>
<tr>
<th>Variable</th>
<th>Normal (LDI: 50–80) (n = 93)</th>
<th>Hypolordosis (LDI &lt; 50) (n = 36)</th>
<th>Hyperlordosis (LDI &gt; 80) (n = 20)</th>
<th>Total (n = 149)</th>
<th>p-value†</th>
<th>p-value‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative radiographic measurements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pelvic incidence (°)</td>
<td>54.5 ± 13.7</td>
<td>58.8 ± 13.5</td>
<td>47.1 ± 11.2</td>
<td>54.6 ± 13.7</td>
<td>0.007*</td>
<td>0.112</td>
</tr>
<tr>
<td>Pelvic tilt (°)</td>
<td>16.5 ± 8.1</td>
<td>22.3 ± 10.1</td>
<td>18 ± 6</td>
<td>18.1 ± 8.7</td>
<td>0.002*</td>
<td>0.003*</td>
</tr>
<tr>
<td>Pelvic tilt &gt; 20°</td>
<td>27 (29.0)</td>
<td>18 (50.0)</td>
<td>7 (35.0)</td>
<td>52 (34.9)</td>
<td>0.081</td>
<td>0.039*</td>
</tr>
<tr>
<td>Sacral slope (°)</td>
<td>38 (11.4)</td>
<td>36.6 (8.2)</td>
<td>29.1 (10.9)</td>
<td>36.5 (11)</td>
<td>0.003*</td>
<td>0.426</td>
</tr>
<tr>
<td>Global lordosis (°)</td>
<td>55.7 ± 14.7</td>
<td>50.8 ± 13.2</td>
<td>43.9 ± 10.9</td>
<td>53 ± 14.4</td>
<td>0.001*</td>
<td>0.069</td>
</tr>
<tr>
<td>SVA (mm)³</td>
<td>34.5 ± 49</td>
<td>61.1 ± 51.5</td>
<td>47.3 ± 32.6</td>
<td>43.3 ± 47.8</td>
<td>0.111</td>
<td>0.064</td>
</tr>
<tr>
<td>SVA &gt; 40 mm³</td>
<td>15 (33.3)</td>
<td>11 (57.9)</td>
<td>7 (46.7)</td>
<td>33 (41.8)</td>
<td>0.174</td>
<td>0.096</td>
</tr>
<tr>
<td>PI–LL (°)</td>
<td>0.1 ± 11.5</td>
<td>11.7 ± 17.2</td>
<td>8 ± 11.7</td>
<td>4 ± 14</td>
<td>&lt; 0.001*</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>PI–LL ≥ 10°</td>
<td>12 (12.9)</td>
<td>16 (44.4)</td>
<td>7 (35.0)</td>
<td>35 (23.5)</td>
<td>&lt; 0.001*</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>LDI</td>
<td>65.2 ± 14.4</td>
<td>38.5 ± 24.8</td>
<td>85.8 ± 15.7</td>
<td>61.5 ± 22.9</td>
<td>&lt; 0.001*</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>LDI groups</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt; 0.001*</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>50–80</td>
<td>69 (74.2)</td>
<td>9 (25.7)</td>
<td>5 (25.0)</td>
<td>83 (56.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 50</td>
<td>12 (12.9)</td>
<td>25 (71.4)</td>
<td>0 (0.0)</td>
<td>37 (25.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 80</td>
<td>12 (12.9)</td>
<td>1 (2.9)</td>
<td>15 (75.0)</td>
<td>28 (18.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative radiographic measurements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pelvic incidence (°)</td>
<td>54.6 ± 14.1</td>
<td>58.5 ± 13.5</td>
<td>47 ± 10.8</td>
<td>54.5 ± 13.9</td>
<td>0.009*</td>
<td>0.145</td>
</tr>
<tr>
<td>Pelvic tilt (°)</td>
<td>17.8 ± 7.9</td>
<td>25 ± 11.2</td>
<td>20.8 ± 5.5</td>
<td>20 ± 9</td>
<td>&lt; 0.001*</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Pelvic tilt &gt; 20°</td>
<td>38 (40.9)</td>
<td>22 (61.1)</td>
<td>12 (60.0)</td>
<td>72 (48.3)</td>
<td>0.063</td>
<td>0.049*</td>
</tr>
<tr>
<td>Sacral slope (°)</td>
<td>36.9 ± 10.1</td>
<td>33.5 ± 8.9</td>
<td>26.2 ± 9.7</td>
<td>34.6 ± 10.4</td>
<td>&lt; 0.001*</td>
<td>0.065</td>
</tr>
<tr>
<td>Global lordosis (°)</td>
<td>52.2 ± 12</td>
<td>45.3 ± 12.6</td>
<td>40.6 ± 11.3</td>
<td>48.9 ± 12.8</td>
<td>&lt; 0.001*</td>
<td>0.007*</td>
</tr>
<tr>
<td>SVA (mm)³</td>
<td>68.8 ± 54.4</td>
<td>127.5 ± 41.9</td>
<td>88.7 ± 51.8</td>
<td>91.4 ± 53.1</td>
<td>0.195</td>
<td>0.092</td>
</tr>
<tr>
<td>SVA &gt; 40 mm³</td>
<td>4 (66.7)</td>
<td>4 (100.0)</td>
<td>3 (100.0)</td>
<td>11 (84.6)</td>
<td>0.252</td>
<td>0.467</td>
</tr>
<tr>
<td>PI–LL (°)</td>
<td>3.2 ± 11.1</td>
<td>16.1 ± 16.9</td>
<td>11 ± 11.4</td>
<td>7.4 ± 13.9</td>
<td>&lt; 0.001*</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>PI–LL ≥ 10°</td>
<td>21 (22.6)</td>
<td>19 (52.8)</td>
<td>11 (55.0)</td>
<td>51 (34.2)</td>
<td>&lt; 0.001*</td>
<td>0.001*</td>
</tr>
<tr>
<td>LDI</td>
<td>63 ± 8.6</td>
<td>32.8 ± 22.3</td>
<td>90.6 ± 8.5</td>
<td>59.4 ± 22</td>
<td>&lt; 0.001*</td>
<td>&lt; 0.001*</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation or number (%).

SVA, sagittal vertical axis; PI–LL, pelvic incidence minus lumbar lordosis.

A p-value was derived using analysis of variance comparing all 3 LDI groups, followed by pairwise comparison of the “normal” and “low (LDI < 50)” LDI groups using either Student t-test or Fisher exact test.

*p < 0.05. SVA was available in n = 79 preoperatively and n = 13 postoperatively.
(62%) were classified as normal (LDI 50–80), 36 (24%) as hypolordotic (LDI < 50) and 20 (13%) as hyperlordotic (LDI > 80). Table 2 details radiographic parameters according LDI groups and ANOVA suggested differences between groups in both preoperative and postoperative PI, PT, sacral slope, global lordosis, and PI–LL. Patients with normal postoperative LDI had predominantly normal preoperative LDI (74%). Similarly, patients with hypolordotic postoperative LDI were mainly hypolordotic preoperatively (71%) and patients with postoperative hyperlordosis were also hyperlordotic preoperatively (75%). Subsequent pairwise analyses were performed comparing the postoperative normal and hypolordotic groups. Results showed that the hypolordotic LDI group, compared to the normal LDI group, had increased preoperative PT (22° ± 10° vs. 17° ± 8°, p = 0.03) and 50% had a preoperative PT > 20° compared to 29% in the normal group (p = 0.039). This increase remained significant postoperatively (25° ± 11° vs. 18° ± 8°, p < 0.001). PI–LL was also increased in the hypolordotic group, both preoperatively (12° ± 17° vs. 0° ± 12°, p < 0.001) and postoperatively (16° ± 17°).

![Fig. 2.](https://doi.org/10.14245/ns.2040744.372) Linear regression model of postoperative lordosis distribution index (LDI) and preoperative pelvic incidence (PI). We found a negative linear correlation between PI and postoperative LDI illustrating the complexity of achieving adequate lower arc lordosis in high PI patients. OR, odds ratio; CI, confidence interval.

### Table 3. Complications and revision surgery according to lordosis distribution index (LDI) groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Normal (LDI: 50–80) (n = 93)</th>
<th>Hypolordosis (LDI &lt; 50) (n = 36)</th>
<th>Hyperlordosis (LDI &gt; 80) (n = 20)</th>
<th>Total (n = 149)</th>
<th>p-value †</th>
<th>p-value ‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Early (&lt; 3 mo)</td>
<td>33 (35.5)</td>
<td>16 (44.4)</td>
<td>7 (35.0)</td>
<td>56 (37.6)</td>
<td>0.621</td>
<td>0.419</td>
</tr>
<tr>
<td>Late (&gt; 3 mo)</td>
<td>43 (46.2)</td>
<td>13 (36.1)</td>
<td>8 (40.0)</td>
<td>64 (43.0)</td>
<td>0.558</td>
<td>0.328</td>
</tr>
<tr>
<td>Minor</td>
<td>45 (48.4)</td>
<td>16 (44.4)</td>
<td>7 (35.0)</td>
<td>68 (45.6)</td>
<td>0.544</td>
<td>0.700</td>
</tr>
<tr>
<td>Major</td>
<td>36 (38.7)</td>
<td>16 (44.4)</td>
<td>10 (50.0)</td>
<td>62 (41.6)</td>
<td>0.600</td>
<td>0.556</td>
</tr>
<tr>
<td>Mechanical complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major</td>
<td>5 (5.4)</td>
<td>5 (13.9)</td>
<td>3 (15.0)</td>
<td>13 (8.7)</td>
<td>0.126</td>
<td>0.140</td>
</tr>
<tr>
<td>Minor</td>
<td>2 (2.2)</td>
<td>1 (2.8)</td>
<td>0 (0)</td>
<td>3 (2.0)</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Any</td>
<td>7 (7.5)</td>
<td>6 (16.7)</td>
<td>3 (15)</td>
<td>16 (10.7)</td>
<td>0.229</td>
<td>0.188</td>
</tr>
<tr>
<td>Adjacent segment disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major</td>
<td>8 (8.6)</td>
<td>3 (8.3)</td>
<td>0 (0)</td>
<td>11 (7.4)</td>
<td>0.587</td>
<td>1.00</td>
</tr>
<tr>
<td>Minor</td>
<td>1 (1.1)</td>
<td>0 (0.0)</td>
<td>0 (0)</td>
<td>1 (0.7)</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Any</td>
<td>9 (9.7)</td>
<td>3 (8.3)</td>
<td>0 (0)</td>
<td>12 (8.1)</td>
<td>0.550</td>
<td>1.00</td>
</tr>
<tr>
<td>Any complication</td>
<td>57 (61.3)</td>
<td>25 (69.4)</td>
<td>12 (60.0)</td>
<td>94 (63.1)</td>
<td>0.659</td>
<td>0.422</td>
</tr>
<tr>
<td>Revision§</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revision 1 yr</td>
<td>6 (6.5)</td>
<td>7 (19.4)</td>
<td>3 (15.0)</td>
<td>16 (10.7)</td>
<td>0.082</td>
<td>0.046*</td>
</tr>
<tr>
<td>Revision 2 yr</td>
<td>15 (16.1)</td>
<td>10 (27.8)</td>
<td>7 (35.0)</td>
<td>32 (21.5)</td>
<td>0.100</td>
<td>0.143</td>
</tr>
<tr>
<td>Revision any time</td>
<td>27 (29)</td>
<td>12 (33.3)</td>
<td>9 (45.0)</td>
<td>48 (32.0)</td>
<td>0.378</td>
<td>0.672</td>
</tr>
</tbody>
</table>

Values are presented as number (%).

A p-value was derived using analysis of variance comparing all 3 LDI groups, followed by pairwise comparison of the “normal” and “low (LDI < 50)” LDI groups using either Student t-test or Fisher exact test.

*p < 0.05. Revision surgery due to infection, hematoma, or wound complications was not included.
vs. $3^\circ \pm 11^\circ$, $p < 0.001$). Finally, postoperative global lordosis was smaller in the hypolordotic group compared to the normal ($45^\circ \pm 13^\circ$ vs. $52^\circ \pm 12^\circ$, $p = 0.007$) whilst remaining parameters were without significant differences.

Linear regression analysis (Fig. 2) was found with a linear, negative correlation between preoperative PI and postoperative LDI ($\text{OR}, -0.51; 95\% \text{ CI}, -0.76 \text{ to } -0.27; p < 0.001$).

3. Complications and All-Cause Revision

We found no differences in complications across LDI groups (Table 3). Regarding all-cause revision (including infection, hematoma, and wound dehiscence), we found an overall 1-year all-cause revision rate of 11%; 22% at 2 years and 32% at any time point in follow-up (mean, 21 ± 14 months). Comparing LDI groups, results showed a significantly increased 1-year all-cause revision rate in the hypolordotic group compared to the normal LDI group (19.4% vs. 6.5%, $p = 0.046$). Similarly, the 2-year rate was lowest in the normal LDI group, although the difference was not significant (Table 3).

4. Revision Excluding Infection, Hematoma, and Wound Dehiscence

The main outcome of this study was revision due to other causes than infection, hematoma or wound dehiscence and rates were assessed across LDI groups (Fig. 3). One- and 2-year revision rates were highest in the hyperlordotic group and lowest in the normal LDI group. KM survival models plotted as 1-KM (Fig. 4) was with similar results, suggesting lowest revision incidence in the normal LDI group ($p = 0.030$, Fleming-Harington weighted $p = 0.036$). Incidence of revision remained highest in the hyperlordotic group, although an apparent increase was seen at the 2-year mark (Fig. 4). For clinically relevant extrapolation, an accelerated time and event model was performed using Weibull survival regression and plotted over a 4-year period following surgery (Fig. 5). Results suggested lower risk of revision in patients with normal postoperative LDI and highest in the hypolordotic group. Logistic regression analyses were used to assess the degree of association between predefined parameters and revision surgery (Table 4). Univariate analyses showed increased odds of revision with increased LOS; increased preoperative SVA and PI–LL; and increased postoperative SVA, PI–LL, and PT. The parameters with greatest increased odds were postoperative PT $> 20^\circ$ (OR, 3.65; 95% CI, 1.20–13.59;
Lordosis Distribution Index in Lumbar Spine Fusion

Bari TJ, et al.

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www.e-neurospine.org

DISCUSSION

The demand for spinal fusion is increasing, with concurrent reports of iatrogenic causes of adult spinal deformity. The role of lordosis maldistribution following short-segment fusion is not fully understood. Therefore, we aimed to assess-postoperative LDI after short-segment fusion for degenerative lumbar disease resulting in 3 main findings. Firstly, most patients had adequate postoperative distribution of their lordosis. Secondly, radiographic parameters related to poor outcome in adult spinal deformity were more frequent in patients with maldistributed postoperative LDI. Thirdly, LDI maldistribution was associated to increased risks of revision surgery. In addition, postoperative LDI was inversely, and significantly, correlated to PI.

1. Radiographic Parameters

Overall, surgical alteration in radiographic parameters related to poor outcome was found in several analyzed measurements, including increased PT suggesting compensated sagittal imbalance and inadequate attention to lordosis. Similarly, global lordosis decreased during surgery and PI–LL mismatch increased. Failure to restore adequate lordosis has previously been proposed as a leading cause of iatrogenic deformity. Joelson et al. found that 10% of patients treated for high-grade spondylolisthesis developed sagittal imbalance and compensated deformity was even more common.

The ideal lordosis can be estimated as roughly equal to the PI (PI–LL mismatch). In adult spinal deformity, recent studies suggest sagittal spinal curvatures are more complex. It is now well established that the lordosis is unequally distributed with an increasing lordosis towards the lower segments. The LDI was; therefore, proposed as part of the Global Alignment and Proportion score for predicting postoperative mechanical complications.

2. Lordosis Distribution Index

Recently, Zheng et al. assessed the LDI in 215 consecutive patients undergoing posterior lumbar interbody fusion. They found that LDI maldistribution was associated to postoperative ASD. Similarly, we found that postoperative LDI < 50 was associated to poor radiographic outcome in several measured parameters, including high PT, increased PI–LL mismatch and decreased global lordosis. These parameters have previously been related to poor outcome in patients with adult spinal deformity and are possible precursors to later-stage sagittal imbalance. The main outcome of the current study was revision surgery (for other causes than hematoma, infection, or wound dehiscence) which was considerably more common in patients with maldistributed postoperative LDI. The 1-year revision incidence was similar in the LDI < 50 and LDI > 80 groups, and considerably higher compared to the normal group (Fig. 3). At 2-year following surgery, the incidence for the LDI > 80 groups increased considerably while remaining lowest in the normal group. The 1-KM plot (Fig. 4) suggested that this sudden deviation was due to a possibly random peek in the LDI > 80 group, close to the 2-year mark. Therefore, extrapolation using Weibull accelerated event and time regression was performed in efforts to smoothen the effect of the low sample size (Fig. 5). Results suggested that risk of revision surgery was highest in the LDI < 50 (hypolordotic), similar to the findings of Zheng et al.
Table 4. Logistic regression analyses of 1-year revision†

<table>
<thead>
<tr>
<th>Variable</th>
<th>Univariable</th>
<th>Multivariable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95% CI)</td>
<td>p-value</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>1.04 (0.99–1.09)</td>
<td>0.140</td>
</tr>
<tr>
<td>Male sex</td>
<td>1.57 (0.53–4.50)</td>
<td>0.398</td>
</tr>
<tr>
<td>CCI</td>
<td>1.06 (0.78–1.38)</td>
<td>0.688</td>
</tr>
<tr>
<td>ASA PS classification</td>
<td>1.27 (0.52–3.08)</td>
<td>0.590</td>
</tr>
<tr>
<td>Surgery time (min)</td>
<td>1.00 (0.99–1.01)</td>
<td>0.784</td>
</tr>
<tr>
<td>Interbody cage</td>
<td>0.53 (0.18–1.82)</td>
<td>0.282</td>
</tr>
<tr>
<td>Instrumented vertebra (per 1 increase)</td>
<td>0.71 (0.28–1.26)</td>
<td>0.374</td>
</tr>
<tr>
<td>Sacral fusion</td>
<td>0.75 (0.07–8.55)</td>
<td>0.820</td>
</tr>
<tr>
<td>Previous spine surgery</td>
<td>1.37 (0.48–3.95)</td>
<td>0.548</td>
</tr>
<tr>
<td>Length of hospital stay</td>
<td>1.10 (1.02–1.18)</td>
<td>0.010*</td>
</tr>
<tr>
<td>Preoperative radiographic measurements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pelvic incidence</td>
<td>1.01 (0.97–1.04)</td>
<td>0.752</td>
</tr>
<tr>
<td>Pelvic tilt</td>
<td>1.05 (0.99–1.11)</td>
<td>0.108</td>
</tr>
<tr>
<td>Pelvic tilt ≥ 20</td>
<td>2.69 (0.94–7.99)</td>
<td>0.065</td>
</tr>
<tr>
<td>Sacral Slope</td>
<td>0.97 (0.92–1.02)</td>
<td>0.263</td>
</tr>
<tr>
<td>Global lordosis</td>
<td>0.97 (0.93–1.00)</td>
<td>0.065</td>
</tr>
<tr>
<td>SVA (mm)</td>
<td>1.01 (1.00–1.03)</td>
<td>0.024*</td>
</tr>
<tr>
<td>SVA ≥ 40</td>
<td>3.94 (1.15–15.82)</td>
<td>0.036*</td>
</tr>
<tr>
<td>PI–LL</td>
<td>1.04 (1.00–1.07)</td>
<td>0.029*</td>
</tr>
<tr>
<td>PI–LL ≥ 10</td>
<td>1.56 (0.46–4.66)</td>
<td>0.441</td>
</tr>
<tr>
<td>LDI</td>
<td>0.98 (0.96–1.00)</td>
<td>0.104</td>
</tr>
<tr>
<td>LDI groups (reference: 50–80)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>LDI &lt; 50</td>
<td>2.10 (0.63–6.82)</td>
<td>0.213</td>
</tr>
<tr>
<td>LDI &gt; 80</td>
<td>0.84 (0.12–3.72)</td>
<td>0.829</td>
</tr>
<tr>
<td>Postoperative radiographic measurements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pelvic incidence</td>
<td>1.00 (0.97–1.04)</td>
<td>0.853</td>
</tr>
<tr>
<td>Pelvic tilt</td>
<td>1.05 (1.00–1.11)</td>
<td>0.058</td>
</tr>
<tr>
<td>Pelvic tilt ≥ 20</td>
<td>3.65 (1.20–13.59)</td>
<td>0.032*</td>
</tr>
<tr>
<td>Sacral Slope</td>
<td>0.96 (0.91–1.01)</td>
<td>0.144</td>
</tr>
<tr>
<td>Global lordosis</td>
<td>0.95 (0.91–0.99)</td>
<td>0.024*</td>
</tr>
<tr>
<td>SVA (mm)</td>
<td>1.01 (0.98–1.03)</td>
<td>0.574</td>
</tr>
<tr>
<td>SVA ≥ 40</td>
<td>NA</td>
<td>0.997</td>
</tr>
<tr>
<td>PI–LL</td>
<td>1.03 (1.00–1.07)</td>
<td>0.076</td>
</tr>
<tr>
<td>PI–LL ≥ 10</td>
<td>3.74 (1.30–11.64)</td>
<td>0.016*</td>
</tr>
<tr>
<td>LDI</td>
<td>0.99 (0.97–1.02)</td>
<td>0.596</td>
</tr>
<tr>
<td>LDI groups (reference: 50–80)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>LDI &lt; 50</td>
<td>3.50 (1.08–11.70)</td>
<td>0.036*</td>
</tr>
<tr>
<td>LDI &gt; 80</td>
<td>2.56 (0.50–10.75)</td>
<td>0.213</td>
</tr>
</tbody>
</table>

OR, odds ratio; CI, confidence interval; CCI, Carlson Comorbidity Index; ASA PS, American Society of Anesthesiologists physical status; SVA, sagittal vertical axis; PI–LL, pelvic incidence minus lumbar lordosis; LDI, lordosis distribution index. NA, upper or lower CI = infinity.

*p < 0.05. †Revision surgery due to infection, hematoma, or wound complications were not included.
3. The High PI Controversy

Sagittal spine shape is not only complex but also varying between individuals. Using asymptomatic individuals, Roussouly et al.\textsuperscript{13} assessed this variation and proposed 4 spine shapes correlated to PI. The system has since been revised, and accompanied by studies of surgical algorithms and assessments of postoperative outcome in adult spinal deformity.\textsuperscript{38,42-44} Individual PI is often considered important, as high PI requires larger lordosis in efforts to avoid mismatch. Achieving such adequate lordosis may prove difficult in complex cases. In the current study, we found an inverse linear correlation between PI and postoperative LDI suggesting that achieving adequate lordosis distribution may be even more complicated, and important, in patients with high PI.

4. Limitations

The results of the present study should be evaluated in light of several limitations. The current cohort consisted of patients with various spinal pathologies, complicating interpretation. However, the aim was to assess LDI as a viable concept and we acknowledge that further detailed estimates are required in different etiologies as effects may vary. The retrospective nature both reduces external validity and increases risks of selection and sampling bias. Although, the fully disclosed inclusion process and the short enrollment period add to reducing these risks. Further, the short minimum follow-up is unsatisfactory as previous studies have suggested up to 5-year follow-up in efforts to appropriately detect postoperative complications.\textsuperscript{45} Results of our Weibull analyses suggested declining incidence just prior to 2 years after surgery which may be an appropriate follow-up in future studies. Also, patient-reported outcome measures were not assessed in the current study and assessing the effect of lordosis maldistribution on measures of health-related quality of life would be of most interest in future studies. Finally, data on preoperative disc or facet degeneration was not obtained in the current study which could influence the effect of postoperative ASD.

CONCLUSION

Most patients undergoing short-segment fusion for lumbar degenerative spine disease had adequate postoperative lordosis distribution. Patients with postoperative maldistributed LDI had increased PT, increased PI–LL mismatch and an overall reduced global lordosis following surgery. Revision surgery was most frequent in patients with postoperative hypolordotic maldistribution (LDI < 50). Our results suggest that inadequate lordosis distribution may predispose iatrogenic deformity and should be considered in short-segment spinal fusion. Special care should be allocated to high PI patients as LDI maldistribution and PI were linearly correlated.

CONFLICTS OF INTEREST

BD (consulting fees from Stryker outside of the submitted work), MG (institutional grants from K2M and Medtronic outside of the submitted work), the remaining authors report no conflicts of interest.

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Utilization of S1 Foraminal Hooks for Augmentation of S1 Screws in Adult Spinal Deformity Surgery: Comparative Study With Iliac Screws

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2Department of Neurosurgery, College of Medicine, Kangwon National University, Chuncheon, Korea

Objective: To compare the outcomes of S1 foraminal hooks and iliac screws regarding fusion rate at the lumbosacral junction and protective effects on S1 screws.

Methods: From January 2017 to December 2019, consecutive patients who underwent long fusions (uppermost instrumented vertebra at or above L1) to the sacrum for adult spinal deformity were enrolled. Patients were divided into S1 foraminal hook group and iliac screw group. Radiographic parameters and the incidence of pseudarthrosis and instrument failure at the lumbosacral junction were compared between the groups.

Results: Twenty-nine patients (male:female = 1:28) with a mean age of 73.6 ± 6.8 years were evaluated. Sixteen patients (55.2%) had S1 foraminal hook fixation and 13 patients (44.8%) had iliac screw fixation. Lumbar lordosis, sacral slope, and sagittal vertical axis did not differ between the groups preoperatively and postoperatively. The rate of L5/S1 pseudarthrosis was significantly higher in S1 foraminal hook group (5 of 16, 31.3%), compared to iliac screw group (0 of 13, 0%; p = 0.048). Instrument failure at the lumbosacral junction trended toward a higher rate in S1 foraminal hook group (6 of 16, 37.5%) than in iliac screw group (1 of 13, 7.7%), without statistical significance (p = 0.09). Proximal junctional kyphosis/failure occurred less often in S1 foraminal hook group (2 of 16, 12.5%) than in iliac screw group (3 of 13, 30.8%) without statistical significance (p = 0.36).

Conclusion: Treatment with S1 foraminal hooks achieved equivalent satisfactory sagittal correction with proportioned alignment compared to that with iliac screws. However, S1 foraminal hooks did not provide enough structural support to the lumbosacral junction in long fusions to the sacrum.

Keywords: Adult spinal deformity, Hook, Fusion to sacrum, Iliac screw, Sacroiliac joint, Spinopelvic

INTRODUCTION

Failure of S1 screw fixation and distal pseudarthrosis are common complications following long fusions to the sacrum.1,9 To address these problems, extending fixation to the ilium became a common practice in long fusions to the sacrum in order to provide a strong distal foundation to sustain the cantilever forces above and reduce strain on the sacrum.10,11 However, pelvic fixation remains challenging and is associated with substantial rates of complications.2,8,9,12-14 Furthermore, pelvic fixation involves longer lever arm and stiffer construct, which can increase the risk of proximal junctional kyphosis (PJK).15,16 Elimination of the most caudal motion segment by instrumentation is another potential concern because rotational and translational movement exists at the sacroiliac joint (SIJ).17 Laminar hooks or sacral foraminal hooks have been utilized...
for a long time since the Harrington rod system was invented.\textsuperscript{18-20} With the advancement of modern pedicle screw instrumentation, however, hooks have lost their popularity. Although some experimental studies have reported increased pullout strength by laminar or foraminal hooks, no clinical studies regarding the utility of hooks in conjunction with a pedicle screw system have been reported.\textsuperscript{21-23} We have utilized S1 foraminal hooks as an alternative to iliac screws in long-level fusion surgery to the sacrum. We hypothesized that S1 foraminal hooks could protect S1 screws and provide structural support to the lumbosacral junction comparable to those of iliac screws with preservation of the mobile segment of the SIJ and shortened the construct.

The purpose of this study was to compare the surgical outcomes of S1 foraminal hooks and iliac screws regarding fusion rate at the lumbosacral junction and the protective effects on S1 screws. Also, the correction amount of sagittal alignment was compared between the 2 instruments.

**MATERIALS AND METHODS**

From January 2017 to December 2019, consecutive patients who underwent long-level instrumentation and fusion to the sacrum for adult spinal deformity were enrolled. Long-level instrumentation was defined as an uppermost instrumented vertebra at or above L1 (at least 6 segments of instrumentation). Patients were divided into 2 groups by mode of augmentation of S1 screws, that is, the S1 foraminal hook group and iliac screw group. Patients who underwent previous fusion surgery across L5/S1 or surgery for infectious disease (including pyogenic spondylitis and tuberculous spondylitis) or trauma were excluded from the study. Patients who did not complete at least 1 year of follow-up were also excluded. Finally, 29 patients were included in the present study.

All patients underwent a staged operation that was a posterior approach for instrumentation and facetectomy and/or laminectomy in the first stage and an oblique retroperitoneal approach followed by oblique lateral interbody fusion (OLIF) and posterior rod assembly in the second stage. In the case of OLIF for L5/S1 due to complex vascular anatomy or retroperitoneal adhesion, a posterior lumbar interbody fusion (PLIF) was done alternatively. In the S1 foraminal hook group, hooks were placed at the first dorsal sacral foramen in an upward fashion, after foraminal preparation with a hook trial (Fig. 1). All procedures were performed by a single surgeon at one academic institution.

Clinical data, including sex, age, body mass index, period of follow-up, comorbidities, American Society of Anesthesiologists physical status classification, and primary or revision surgery status (any lumbar surgeries except the lumbosacral junction), length of hospital stay, and operative details were collected retrospectively through medical chart review. Spinopelvic parameters including pelvic incidence (PI), lumbar lordosis (LL), sacral slope (SS), sagittal vertical axis (SVA), and proximal junctional angle (PJA) were obtained from the picture archiving and communication system. Postoperative values were measured by standing x-ray at an early postoperative period (from 4 to 6 weeks postoperatively) and the last visit. LL was defined as the angle between the superior endplate of L1 and S1. We calculated the global alignment and proportion (GAP) score, which were further categorized as proportioned, moderately disproportioned, and severely disproportioned.\textsuperscript{24} The PJA was defined as the angle between the caudal endplate of the uppermost instrumented vertebrae and the cephalad endplate of the 2 supra-
adjacent vertebrae above those vertebrae. PJK was defined as a PJA of at least 10° greater than the early preoperative value. Proximal junctional failure (PJF) was defined as a fracture of uppermost instrumented vertebrae (UVI) or UVI+1, a pullout of instrumentation at UVI, and/or sagittal subluxation. The stability of the S1 screws was determined by the incidence of pseudarthrosis at the L5/S1 level and instrument failure (including pullout, periprosthetic halo, or instrument fracture) around S1 screws. The instrument failures of the iliac screws were also assessed separately. Three-dimensional reconstructed computed tomography as well as x-ray were conducted in all patients to determine pseudarthrosis and instrument failure at the lumbo-sacral junction.

For statistical analyses, we used IBM SPSS Statistics ver. 22.0 (IBM Co., Armonk, NY, USA). A chi-square test or Fisher exact test was used for dichotomous data analysis. A t-test or Mann-Whitney test was employed to analyze differences in categorical variables. A p-value of less than 0.05 was considered statistically significant.

This study was approved by the Institutional Review Board (IRB) of Kyung Hee University Hospital at Gangdong (IRB No. KHNMC 2021-01-032).

RESULTS

Data from 29 patients (1 man and 28 women) with a mean age of 73.6 ± 6.8 years were evaluated (Table 1). The mean follow-up period was 48.1 ± 22.4 months. Thirteen patients (44.8%) had a history of previous spinal surgery. Regarding the mode of sacropelvic fixation, 16 patients (55.2%) had S1 foraminal hook fixation, and 13 patients (44.8%) had iliac screw fixation.

Table 1. Demographic data from patients with S1 hooks and iliac screws

<table>
<thead>
<tr>
<th>Variable</th>
<th>S1 hook (n = 16)</th>
<th>Iliac screw (n = 13)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>71.4 ± 7.1</td>
<td>76.3 ± 5.4</td>
<td>0.05†</td>
</tr>
<tr>
<td>Sex, male:female</td>
<td>1:15</td>
<td>0:13</td>
<td>1.00‡</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>24.8 ± 3.2</td>
<td>25.8 ± 4.0</td>
<td>0.44§</td>
</tr>
<tr>
<td>Follow-up period (mo)</td>
<td>17.8 ± 4.5</td>
<td>27.8 ± 7.7</td>
<td>0.86†</td>
</tr>
<tr>
<td>Previous operation (%)</td>
<td>37.5</td>
<td>53.8</td>
<td>0.38§</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>75.0</td>
<td>76.9</td>
<td>1.00‡</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>12.5</td>
<td>15.4</td>
<td>1.00‡</td>
</tr>
<tr>
<td>Osteoporosis (%)</td>
<td>31.3</td>
<td>38.5</td>
<td>0.71‡</td>
</tr>
<tr>
<td>Antiplatelet medication (%)</td>
<td>18.8</td>
<td>30.8</td>
<td>0.67‡</td>
</tr>
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<td>ASA PS classification</td>
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<tr>
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<td>II</td>
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<tr>
<td>III</td>
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</table>

Values are presented as mean ± standard deviation or number unless otherwise indicated.
ASA PS, American Society of Anesthesiologists physical status.
† Mann-Whitney test. ‡ Fisher exact test. § Independent t-test.

Table 2. Operative details in patients with S1 hooks and iliac screws

<table>
<thead>
<tr>
<th>Variable</th>
<th>S1 hook (n = 16)</th>
<th>Iliac screw (n = 13)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of instrumented vertebrae</td>
<td>7.9 ± 1.6</td>
<td>8.5 ± 1.1</td>
<td>0.27†</td>
</tr>
<tr>
<td>No. of interbody fusions</td>
<td></td>
<td></td>
<td>0.14‡</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>11</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>3.9 ± 0.6</td>
<td>4.2 ± 0.4</td>
<td></td>
</tr>
<tr>
<td>Mode of L5/S1 interbody fusion</td>
<td></td>
<td></td>
<td>0.52‡</td>
</tr>
<tr>
<td>OLIF</td>
<td>13</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>PLIF</td>
<td>2</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Surgical time (min)</td>
<td>373.9 ± 145.3</td>
<td>362.2 ± 87.0</td>
<td>0.80§</td>
</tr>
<tr>
<td>Estimated blood loss (mL)</td>
<td>1,268.8 ± 551.0</td>
<td>1,138.5 ± 290.2</td>
<td>0.42‡</td>
</tr>
<tr>
<td>Length of hospital stay (day)</td>
<td>20.0 ± 4.4</td>
<td>25.8 ± 9.0</td>
<td>&lt; 0.05†</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation or number.
† Mann-Whitney test. ‡ Fisher exact test. § Independent t-test.
sex, body mass index, length of follow-up, comorbidities, and previous operation history did not differ significantly between the 2 groups.

The operative details are summarized in Table 2. The mean number of instrumented vertebrae was 8.1 ± 1.4, with a mean level of interbody fusion of 4.1 ± 0.5. The most common mode of interbody fusion at the lumbosacral junction was OLIF (n = 21, 72.4%), followed by PLIF (n = 7, 24.1%). The S1 foraminal hook group and iliac screw group did not show significant differences in terms of the number of instrumented vertebrae (7.9 ± 1.6 vs. 8.5 ± 1.1, p = 0.27), level of interbody fusion (3.9 ± 0.6 vs. 4.2 ± 0.4, p = 0.14), mode of interbody fusion at the lumbosacral junction (OLIF in 81.3% vs. 61.5%, p = 0.52), operation time (373.9 ± 145.3 minutes vs. 362.2 ± 87.0 minutes, p = 0.80), and surgical bleeding (1,268.8 ± 551.0 vs. 1,138.5 ± 290.2, p = 0.42). The mean length of hospital stays was significantly longer in the iliac screw group (25.8 ± 9.0 days) than in the S1 hook group (20.0 ± 4.4 days, p = 0.049).

The radiographic outcomes are summarized in Table 3. For all patients, the mean PI was 55.3° ± 8.4°. The mean preoperative LL was -7.3° ± 25.8°, which was corrected to -56.2° ± 10.1°. Preoperative LL (-14.6° ± 28.5° vs. 1.3 ± 20.2, p = 0.14), and postoperative LL (-55.5° ± 11.6° vs. -57.0° ± 8.2°, p = 0.70) did not differ between the groups. The correction amount of LL was greater in the iliac screw group (-57.5° ± 22.4°) compared to that of the S1 hook group (-40.9° ± 21.2°); however, the difference was not statistically significant (p = 0.08). Regarding SS, the preoperative value (24.8° ± 11.3° vs. 24.2° ± 8.1°, p = 0.88) and postoperative value (39.3° ± 7.7° vs. 40.4° ± 5.8°, p = 0.71) did not show significant differences. Also, the correction amount of SS was not different between the groups (17.8° ± 12.8° vs. 16.7° ± 8.2°,

Table 3. Radiographic characteristics in patients with S1 hooks and iliac screws

<table>
<thead>
<tr>
<th>Variable</th>
<th>S1 hook (n = 16)</th>
<th>Iliac screw (n = 13)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic incidence (°)</td>
<td>53.6 ± 8.6</td>
<td>57.5 ± 7.9</td>
<td>0.22†</td>
</tr>
<tr>
<td>Lumbar lordosis (°)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>-14.6 ± 28.5</td>
<td>1.3 ± 20.2</td>
<td>0.14‡</td>
</tr>
<tr>
<td>Postoperative</td>
<td>-55.5 ± 11.6</td>
<td>-57.0 ± 8.2</td>
<td>0.70‡</td>
</tr>
<tr>
<td>Final follow-up</td>
<td>-50.4 ± 13.8</td>
<td>-51.7 ± 8.8</td>
<td>0.79‡</td>
</tr>
<tr>
<td>Correction</td>
<td>-40.9 ± 21.2</td>
<td>-57.5 ± 22.4</td>
<td>0.08†</td>
</tr>
<tr>
<td>Loss of correction</td>
<td>5.1 ± 9.4</td>
<td>5.3 ± 4.1</td>
<td>0.93†</td>
</tr>
<tr>
<td>Sacral slope (°)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>24.8 ± 11.3</td>
<td>24.2 ± 8.1</td>
<td>0.88†</td>
</tr>
<tr>
<td>Postoperative</td>
<td>39.3 ± 7.7</td>
<td>40.4 ± 5.8</td>
<td>0.71†</td>
</tr>
<tr>
<td>Final follow-up</td>
<td>39.2 ± 9.1</td>
<td>38.8 ± 8.1</td>
<td>0.90†</td>
</tr>
<tr>
<td>Correction</td>
<td>17.8 ± 12.8</td>
<td>16.7 ± 8.2</td>
<td>0.81†</td>
</tr>
<tr>
<td>Loss of correction</td>
<td>-0.1 ± 4.4</td>
<td>-2.9 ± 4.9</td>
<td>0.14†</td>
</tr>
<tr>
<td>Sagittal vertical axis (mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>125.8 ± 94.9</td>
<td>145.9 ± 107.5</td>
<td>0.86†</td>
</tr>
<tr>
<td>Postoperative</td>
<td>25.5 ± 49.7</td>
<td>-5.1 ± 27.8</td>
<td>0.05§</td>
</tr>
<tr>
<td>Final follow-up</td>
<td>58.7 ± 49.0</td>
<td>53.6 ± 48.7</td>
<td>0.79†</td>
</tr>
<tr>
<td>Correction</td>
<td>-109.8 ± 87.9</td>
<td>-147.8 ± 109.3</td>
<td>0.36†</td>
</tr>
<tr>
<td>Loss of correction</td>
<td>33.2 ± 41.0</td>
<td>57.2 ± 38.9</td>
<td>0.15†</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation. †Independent t-test. ‡Mann-Whitney test.

Table 4. Comparison of GAP score categories between S1 hooks and iliac screws

<table>
<thead>
<tr>
<th>GAP score category (n)</th>
<th>S1 hook (n = 16)</th>
<th>Iliac screw (n = 13)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportioned</td>
<td>12</td>
<td>10</td>
<td>0.38‡</td>
</tr>
<tr>
<td>Moderately disproportioned</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Severely disproportioned</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>NA</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

GAP, global alignment and proportion; NA, not available. †Fisher exact test.

Table 5. Pseudarthrosis and mechanical complications in patients with S1 hooks and iliac screws

<table>
<thead>
<tr>
<th>Variable</th>
<th>S1 hook (n = 16)</th>
<th>Iliac screw (n = 13)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>L5/S1 pseudarthrosis</td>
<td>5/16 (31.3)</td>
<td>0/13 (0)</td>
<td>&lt;0.05†</td>
</tr>
<tr>
<td>Instrument failure at lumbosacral junction*</td>
<td>6/16 (37.5)</td>
<td>1/13 (7.7)</td>
<td>0.09†</td>
</tr>
<tr>
<td>Instrument failure of iliac screw</td>
<td>-</td>
<td>4/13 (30.8)</td>
<td>-</td>
</tr>
<tr>
<td>PJK/PJF</td>
<td>2/16 (12.5)</td>
<td>4/13 (30.8)</td>
<td>0.36†</td>
</tr>
<tr>
<td>Additional surgery</td>
<td>0/16 (0)</td>
<td>2/13 (15.4)</td>
<td>0.19†</td>
</tr>
</tbody>
</table>

Values are presented as number (%). PJK, proximal junctional kyphosis; PJF, proximal junctional failure.

*Includes pullout, loosening, or fracture of S1 screws, or rod fracture at the lumbosacral junction. †Fisher exact test.
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DISCUSSION

In this study, we evaluated the outcomes of augmentation methods using S1 screws (S1 foraminal hook and iliac screws) in long fusions to the sacrum. In terms of correction of spinopelvic parameters, including LL, SS, and SVA, the results of S1 foraminal hooks seemed acceptable and comparable to those of iliac screws. Also, regarding parameters associated with GAP scores, the results did not differ between the groups. Therefore, utilization of S1 hooks resulted in proportional global alignments as well as corrections of the sagittal curve that were comparable to those of iliac screws. However, S1 foraminal hooks were associated with significantly higher rates of L5/S1 pseudarthrosis (31.3% vs. 0%, p = 0.048) and an insignificant trend toward higher instrument failure rates (37.5% vs. 7.7%, p = 0.09) compared to iliac screws. Regarding structural support to S1 screws, therefore, utilization of S1 foraminal hooks seemed to provide insufficient structural support to the lumbosacral junction.

Pseudarthrosis and instrument failure at the lumbosacral junction are well-known complications of long fusions to the sacrum. To address these problems, recent studies have recommended several methods to reduce the pseudarthrosis rate, including bicortical S1 screws, additional pelvic fixation, and anterior col-

Fig. 2. A 79-year-old woman who underwent fusion from L1 to the sacrum with S1 foraminal hooks. (A) Follow-up x-ray showed mild residual sagittal imbalance (SVA = 6.6 cm). (B and C) Computed tomography revealed L5/S1 pseudarthrosis and a periprosthetic halo (thick arrows) was identified around the S1 screws. LL, lumbar lordosis; SS, sacral slope; PI, pelvic incidence; SVA, sagittal vertical axis; GAP, global alignment and proportion.

the lumbosacral junction were 17.2% (5 of 29) and 24.1% (7 of 29), respectively. All cases of instrument failure at the lumbosacral junction were S1 screw loosening (Fig. 2). There were no cases of screw pullout or instrument fracture. The incidence of PJK/PJF was 20.7% (6 of 29). Significantly more patients suffered from L5/S1 pseudarthrosis in the S1 foraminal hook group (5 of 16, 31.3%) than in the iliac screw group (0 of 13, 0%; p = 0.048). Instrument failure at the lumbosacral junction showed a trend toward greater frequency in patients with S1 foraminal hooks (6 of 16, 37.5%) than in those with iliac screws (1 of 13, 7.7%); however, the difference did not reach statistical significance (p = 0.09). There were 4 patients (30.8%) with failure of iliac screws (periprosthetic halo in 3 patients and set screw extraction in 1 patient) among 13 patients. The rate of PJK or PJF was lower in patients with S1 foraminal hooks (2 of 16, 12.5%) than in those with iliac screws (3 of 13, 30.8%), without statistical significance (p = 0.36). Among patients with iliac screws, 2 patients underwent additional surgery due to bilateral rod fractures and 1 patient refused revision surgery for PJK. In patients with S1 foraminal hooks, however, no patient underwent revision surgery until the last follow-up. The rates of revision surgery did not reach statistical significance (p = 0.19).

p = 0.81). Regarding the SVA, the preoperative value (125.8 ± 94.9 mm vs. 145.9 ± 107.5 mm, p = 0.86) and postoperative value (25.5 ± 49.7 mm vs. -5.1 ± 27.8 mm, p = 0.05) did not differ between the groups. Also, the amount of correction (-109.8 ± 87.9 mm vs. -147.8 ± 109.3 mm, p = 0.36) of the SVA did not differ between the groups.

Postoperative GAP scores were calculated and compared between the groups (Table 4). In total, most cases (22 of 29, 75.9%) were classified into the proportioned category, followed by the moderately disproportioned (5 of 29, 17.2%), and severely disproportioned (1 of 29, 3.4%) categories. The GAP score was not available for one patient who could not sustain an upright position. GAP scores did not differ significantly between the 2 groups (p = 0.30).

The incidence of pseudarthrosis and mechanical complications at the lumbosacral junction are summarized in Table 5. In total, the rates of pseudarthrosis and instrumentation failure at
umn support at the lumbosacral junction. In recent years, iliac screw fixation and S1 alar-iliac screw fixation have been considered common procedures for pelvic fixation. The routine conduction of pelvic fixation for augmentation of S1 screws often ignores or thinks less of the segmental motion of SIJ. However, SIJ is the most caudal mobile segment with 1° to 4° of rotation and 1 to 3 mm translation, known as nutation and counternutation. Therefore, following a long fusion surgery that eliminates segmental motion through the lumbosacral area, the SIJ becomes the only mobile segment. The residual motion of SIJ following long fusions, including sacropelvic fixation, could lead to failure of iliac screws. The reported rates of iliac screw failure ranges from 7.2% to 52% of patients, which is consistent with our findings (4 of 13, 30.8%).

Previous studies reported lumbar stiffness following lumbar fusion could restrict activities of daily living (ADL) of patients. Kimura et al. demonstrated that as the number of fused segments increased, the number of limitations in ADL increased. Although the impact of sacropelvic fixation on ADL is inconclusive, no studies have been conducted on direct comparisons between sacral fixation and pelvic fixation. We speculate that pelvic fixation across the SIJ may further restrict ADL by sacrificing the entire mobile segment, thus S1 foraminal hooks can be utilized as an alternative to the iliac screws. Although sufficient and proportioned correction of sagittal alignment was produced, S1 foraminal hooks did not provide enough structural support at the lumbosacral junction, which was inferred from higher rates of pseudarthrosis.

We suggest a possible explanation for the inferior stability of S1 foraminal hooks. First, S1 foraminal hooks have biomechanically inherent vulnerability because the implant must stand behind the lumbosacral pivot point. As McCord et al. described previously, the more anterior position of the construct achieved with respect to the lumbosacral pivot point, the more stable the construct. Theoretically, S1 foraminal hooks tend to move apart from the pivot point during flexion, resulting in decreased resistance against pullout strength. Utilizing S1 foraminal hooks, however, we achieved an equivalent sagittal realignment by cantilever force without any case of S1 screw or S1 foraminal hook pullout. Moreover, the loss of sagittal correction did not differ between groups in terms of LL (5.1° ± 9.4° vs. 5.3° ± 4.1°, p = 0.93) and SVA (33.2 ± 41.0 mm vs. 57.2 ± 38.9 mm, p = 0.15). Previous researchers also demonstrated that utilizing hooks could increase the bending stiffness of the construct and pullout strength of S1 screws in experimental studies. Therefore, we assume S1 foraminal hooks could protect S1 screws at least in terms of pullout strength. Second, variable types of functional loading exist on the transverse plane and coronal plane as well as sagittal plane to the spinal column. Even if S1 foraminal hooks, by their claws, could resist the pullout strength during stress on the sagittal plane, they could hardly resist the toggling moments, unlike the iliac screws, because only a part of the surface maintains bone to hardware contact. Therefore, the inability of S1 foraminal hooks to resist 3-dimensional functional loading could be the cause of failure to achieve sufficient stability at the lumbosacral junction.

It is interesting that the incidence of PJK/PJF was lower in the S1 hook group (12.5%), compared to that of iliac screw group (30.8%), although the difference did not reach statistical significance (p = 0.36). A longer and stiffer construct is known to result in a higher prevalence of PJK owing to increased range of motion and higher stress at the adjacent segment. In addition to sacral fixation, iliac fixation was described as a distinct risk factor for PJK by Bridwell et al. We think that utilizing S1 foraminal hooks, instead of iliac screws, may protect adjacent segment degeneration and subsequent PJF by reducing the length and stiffness of the construct. The relationship between S1 foraminal hooks and PJK, however, is beyond the scope of this study.

This study is limited by its retrospective nature and lack of randomization. The enrolled population was small with a short follow-up period. Because there were beginning cases of OLIF at the L5/S1 level, surgical results could be biased because of technical problems such as incomplete endplate preparation or cage positioning. Lastly, the lack of patient-reported clinical outcomes is another weakness. Although this study focused on the radiographic outcomes of S1 foraminal hooks, future studies assessing clinical outcomes with larger populations and longer follow-up periods are necessary.

CONCLUSION

We compared the surgical outcomes of S1 foraminal hooks and iliac screws in long fusions to the sacrum. S1 foraminal hooks achieved equivalent satisfactory correction of the sagittal alignment with proportioned global alignment compared to iliac screws. However, S1 foraminal hooks showed a significantly higher rate of L5/S1 pseudarthrosis and a trend toward higher rates of instrument failure without statistical significance compared to those of iliac screws. Utilization of S1 foraminal hooks seemed to have insufficient structural support to the lumbosacral junction in long fusions to the sacrum.
CONFLICT OF INTEREST

The authors have nothing to disclose.

REFERENCES


Outcomes of Posterior Lumbar Hemivertebra Resection and Short Fusion in Patients With Severe Sacral Tilt

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Objective: To introduce surgical strategies to restore coronal balance during limited fusion for early lumbar hemivertebra resection in patients with severe sacral tilt.

Methods: Sacral tilt was defined as a sacral tilt angle ≥ 5, and severe sacral tilt was defined as a sacral tilt angle > 10. From July 2004 to December 2017, 73 consecutive patients treated with posterior hemivertebra resection and short fusion in our institution were evaluated. Severe sacral tilt was noted in 26 patients (14 boys and 12 girls), and all were enrolled in this study. Undercorrection of the primary lumbar curve as compensation for the sacral tilt and short fusion was performed in these patients. The medical charts and imaging data of the patients were retrospectively reviewed to evaluate the outcomes.

Results: All patients were followed for at least 2 years. The mean age at the time of surgery was 3.7 (2–9) years old, with a total of 31 lumbar hemivertebra excised. On average, 2.8 (2–5) segments were fused for each patient. Sacral tilt minimally improved from 14.5° preoperatively to 13.6° postoperatively (p = 0.15) and remained stable at the follow-up. The overall lumbar curve was 41.9° preoperatively, 11.7° immediately postoperatively, and 14.6° at the final follow-up. The segmental scoliosis curve was 39.1° preoperatively, 9.7° immediately postoperatively, and 11.2° at the final follow-up. Segmental kyphosis was corrected from 27.2° to 6.5° after the surgery and was 7.1° at the latest follow-up.

Conclusion: Sacral tilt is seen in patients with congenital scoliosis in lumbar hemivertebra. Undercorrection of the lumbar curve and segmental scoliosis to compensate for sacral tilt and short fusion after hemivertebra resection may be helpful to restore coronal balance and preserve mobility in segments in patients with pronounced severe sacral tilt.

Keywords: Congenital scoliosis, Coronal balance, Lumbar hemivertebra, Sacral tilt, Surgical strategy, Undercorrection

INTRODUCTION

The main goals of spinal deformity surgery are to prevent progression, restore the alignment of the spine in both the coronal and sagittal planes and preserve mobility and function in segments to the greatest extent possible. The sacrum plays an important role in the balance of the spine and pelvis, as it is located at the base of the spine and serves as a foundation for mechanical loading. The importance of treating lumbosacral deformities in patients with degenerative scoliosis has been well studied.1 The etiologies of lumbosacral deformities in young patients with spinal deformities may be different from those in patients with degenerative scoliosis. It has been reported that lumbosacral deformities due to sacral tilt exist in patients with adolescent idiopathic scoliosis (AIS) and may influence surgical outcomes, especially in the restoration of coronal balance.2-4 Un-
till now, there have been no reports on sacral tilt in patients with congenital scoliosis (CS).

The natural history of CS has been well studied.\textsuperscript{5-7} Hemivertebra is the most common type of CS, and some curves due to hemivertebra are progressive due to the growth potential of the spine, most notably in the lower thoracic, thoracolumbar or lumbar spine.\textsuperscript{7,8} In addition to the primary curve, compensatory secondary structural curves may develop in response to asymmetric development. Delayed treatment will lead to higher risks related to surgery and necessitate the fusion of more vertebral levels.\textsuperscript{8} As a result, early surgical intervention is mandatory for most patients with CS due to hemivertebra to achieve better correction while preserving as many motion segments as possible. Hemivertebra resection, first performed via a combined anterior-posterior approach, has become the most popular surgery for CS.\textsuperscript{10,11} Many studies have described the outcomes of posterior hemivertebra resection.\textsuperscript{12-17} However, no studies have described sacral tilt in CS and the role of sacral tilt in restoring coronal balance in patients with lumbar hemivertebra resection and short fusion. Therefore, this study was conducted to evaluate sacral tilt in patients who have undergone lumbar hemivertebra resection, introduce surgical strategies for the treatment of sacral tilt during surgery, and determine the influence of these strategies on coronal balance.

**MATERIALS AND METHODS**

Inclusion criteria: After the institutional review board approved this study, 73 consecutive patients with CS undergoing posterior or hemivertebra resection and short fusion (fewer than 5 segments) in our institution from July 2004 to December 2017 were included. Sacral tilt was defined as a sacral tilt angle $\geq 5^\circ$. Considering the Scoliosis Research Society’s definition of scoliosis, a Cobb angle $> 10^\circ$, the authors defined severe sacral tilt as a sacral tilt angle $> 10^\circ$. When the sacral tilt $\leq 10^\circ$, the compensatory changes were considered mild and no special strategies were taken and these patients were excluded in this study. The authors utilized strategies to undertreat the segmental curve in the patients with severe tilt, and these patients were enrolled in this study. For these patients, the medical charts and radiographs were studied. All patients were followed up in the outpatient department at 3 months, 6 months, and then yearly after surgery. All patients were followed for at least 2 years.

This study was approved by the Institutional Review Board of Peking Union Medical College Hospital (approval number: S-K1729).

1. **Radiographic Evaluation**

Full-length standing posteroanterior and lateral x-ray films were taken preoperatively, at 1–2 weeks postoperatively, and at each follow-up. All patients underwent preoperative computed tomography (CT) scans and 3-dimensional reconstruction of the spine to assess the morphology of the hemivertebra and sacrum.

Coronal and sagittal parameters were measured according to the method provided by Bollini et al.\textsuperscript{10} The segmental curve was measured between one level above and below the hemivertebra, whereas the entire lumbar curve was the maximal Cobb angle obtained in the lumbar spine. The cranial compensatory curve was measured as the maximal Cobb angle of the proximal unfused spine. The trunk shift (TS) was the horizontal distance between the center of C7 and the central sacral vertical line (CSVL). In addition, upper instrumented vertebral translation (UIVT) and lower instrumented vertebral translation (LIVT) were measured as the distances between the center of the instrumented vertebra and the CSVL, respectively.

The degree of sacral tilt was typically defined as the angle between the horizontal line and the upper end plate of the sacrum on the posteroanterior x-ray films. However, changes in sacral tilt, which is parallel to the bi-iliac crest tangent line, can occur secondary to abnormalities of the spine and lower extremities and can be corrected with the correction of the primary abnormalities. The authors excluded secondary sacral tilt by defining the tilt angle as the angle between the bi-iliac crest tangent line and the upper endplate of the sacrum. Sacral tilt was defined as an angle $\geq 5^\circ$, and severe sacral tilt was defined as an angle $> 10^\circ$. Upper instrumented vertebra (UIV) tilt was measured as the angle between the upper endplate of the UIV and the bi-iliac crest tangent line (Fig. 1).

On the sagittal plane, true segmental kyphosis was defined as the difference between the measured segmental kyphosis angle (between the 2 vertebrae adjacent to the hemivertebra) and normal segmental kyphosis angle, as noted by Bernhardt and Bridwell.\textsuperscript{18} Global sagittal balance was the distance from the C7PL (C7 plumb line) to the perpendicular line drawn from the superior posterior endplate of the S1 vertebral body. Thoracic kyphosis was measured from T5 to T12, and lumbar lordosis was measured from L1 to S1. The thoracolumbar junction was assessed from T10 to T12. All measurements were performed with Surgimap 2.2 (Nemaris, Inc., Methuen, MA, USA).

All radiographic assessments were performed by 2 attending spine surgeons, and repeated measurements were performed by the same surgeons. The means of all measurements were used
in the final analysis to reduce measurement error.

2. Surgical Technique

To preserve the function of the lumbosacral region, the sacral tilt was left untreated in all patients. However, the lumbar curve in the patients with severe sacral tilt was undercorrected during surgery to compensate for the pronounced severe sacral tilt.

All patients were treated with posterior hemivertebra resection and short fusion. After general anesthesia, the patient was placed in a prone position and draped in a routine sterile fashion. A standard midline incision was made, and the levels to be treated were exposed. Once the levels were prepared to be excised and instrumented, instrumentation and hemivertebra resection were performed. The vertebral body of the hemivertebra and its upper and lower discs were completely removed, and the contralateral disc and bar were also resected. A titanium mesh cage was implanted into the gap for undercorrection, and compression was applied to close the gap and correct the deformity (Fig. 2). Additional compression or distraction was applied to improve the degree of correction. The residual segmental curve was preserved instead of fully correction of the segmental curve. Intraoperative fluoroscopy was used to check the position of the UIV and the residual segmental curve. The magnitude of the residual segmental curve was intended to be similar to the degree of sacral tilt. In other words, the correction angle was intended to be similar to the degree of segmental curve minus sacral tilt. Then, the screws were locked, and pos-

![Fig. 1. The angle between lines a and b was the sacral tilt angle. The angle between lines b and c was the upper instrumented vertebral tilt angle. CSVL, central sacral vertical line.](image)

![Fig. 2. A 7-year-old boy had hemivertebra between L4 and L5, with a sacral tilt of 16°. The major lumbar curve was 33°. A severe sacrum tilt was noted on the computed tomography scan. Posterior hemivertebra resection with monosegmental fusion was performed. A titanium cage was implanted in the osteotomy gap for undercorrection to compensate for the sacral tilt, leaving a residual curve of 12°. The correction after the surgery was satisfactory. The residual curve progressed to 13°, and good coronal alignment was well maintained during the 2-year follow-up period. C7PL, C7 plumb line.](image)
terolateral fusion was performed. The incision was closed with a subfascial drain.

Multimodality neurophysiologic monitoring of the spinal cord, including motor evoked potential and somatosensory evoked potential monitoring, was performed in all surgeries. Postoperatively, patients ambulated with a 2-piece plastic brace for 6 months.

3. Statistical Analysis

The results are presented as the means and standard deviations for the continuous variables and frequencies for the categorical variables. The p-values were calculated using t-tests or nonparametric tests, and p < 0.05 indicated a significant difference.

RESULTS

Sacral tilt was found in 49 patients (67.1%). Severe sacral tilts were noted in 26 patients, with an incidence of 35.6%. Twenty-six consecutive patients (14 boys and 12 girls) were enrolled. The mean age at the time of surgery was 3.7 (2–9) years old, with an average follow-up duration of 36.5 (24–88) months. A total of 31 (above L3–9, at or below L3–22) lumbar hemivertebrae were excised, averaging 1.2 (1–2) hemivertebrae per patient. The average number of fused segments was 2.8 (2–5) for each patient. The demographics of all patients are summarized in Table 1.

### Table 1. Demographic data

<table>
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<tr>
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<td>Sex</td>
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<td>Female</td>
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<td>14</td>
</tr>
<tr>
<td>Age (yr)</td>
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<tr>
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</tr>
<tr>
<td>L2</td>
<td>9</td>
</tr>
<tr>
<td>L3</td>
<td>9</td>
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<td>L4</td>
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</tr>
<tr>
<td>L5</td>
<td>6</td>
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<td>Segmentation</td>
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<td>5</td>
</tr>
<tr>
<td>Full</td>
<td>26</td>
</tr>
<tr>
<td>No. of vertebrae excised</td>
<td>1.2 (1–2)</td>
</tr>
<tr>
<td>Fused segments</td>
<td>2.8 (2–5)</td>
</tr>
</tbody>
</table>

Values are presented as number or mean (range).

### Table 2. Comparison of radiographic outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>Follow-up</th>
<th>p-value†</th>
<th>p-value‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sacral tilt (°)</td>
<td>14.5 ± 4.6</td>
<td>13.6 ± 4.3</td>
<td>13.3 ± 3.1</td>
<td>0.15</td>
<td>0.64</td>
</tr>
<tr>
<td>Whole lumbar scoliosis (°)</td>
<td>41.9 ± 11.0</td>
<td>11.7 ± 10.9</td>
<td>14.6 ± 12.6</td>
<td>&lt; 0.05</td>
<td>0.15</td>
</tr>
<tr>
<td>Segmental scoliosis (°)</td>
<td>39.1 ± 8.9</td>
<td>9.7 ± 9.3</td>
<td>11.2 ± 10.3</td>
<td>&lt; 0.05</td>
<td>0.09</td>
</tr>
<tr>
<td>Cranial compensatory scoliosis (°)</td>
<td>20.3 ± 8.9</td>
<td>7.8 ± 6.4</td>
<td>10.6 ± 6.4</td>
<td>&lt; 0.05</td>
<td>0.06</td>
</tr>
<tr>
<td>Caudal compensatory scoliosis (°)</td>
<td>18.3 ± 5.6</td>
<td>6.4 ± 4.3</td>
<td>7.4 ± 6.1</td>
<td>&lt; 0.05</td>
<td>0.17</td>
</tr>
<tr>
<td>UIVA (°)</td>
<td>4.5 ± 5.3</td>
<td>2.9 ± 2.6</td>
<td>3.2 ± 3.1</td>
<td>&lt; 0.05</td>
<td>0.51</td>
</tr>
<tr>
<td>LIVA (°)</td>
<td>6.1 ± 8.0</td>
<td>3.7 ± 3.9</td>
<td>3.8 ± 3.4</td>
<td>&lt; 0.05</td>
<td>0.88</td>
</tr>
<tr>
<td>UIV tilt (°)</td>
<td>27.3 ± 6.5</td>
<td>6.7 ± 5.4</td>
<td>9.5 ± 5.8</td>
<td>&lt; 0.05</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>UIVT (mm)</td>
<td>16.4 ± 13.8</td>
<td>8.2 ± 7.0</td>
<td>6.5 ± 7.1</td>
<td>&lt; 0.05</td>
<td>0.09</td>
</tr>
<tr>
<td>LIVT (mm)</td>
<td>11.5 ± 9.4</td>
<td>5.5 ± 5.1</td>
<td>4.6 ± 4.9</td>
<td>&lt; 0.05</td>
<td>0.13</td>
</tr>
<tr>
<td>TS (mm)</td>
<td>15.7 ± 13.1</td>
<td>15.6 ± 11.0</td>
<td>10.5 ± 6.7</td>
<td>0.99</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Segmental kyphosis (°)</td>
<td>27.2 ± 17.2</td>
<td>6.5 ± 9.0</td>
<td>7.1 ± 11.0</td>
<td>&lt; 0.05</td>
<td>0.69</td>
</tr>
<tr>
<td>Thoracic kyphosis (°)</td>
<td>18.1 ± 8.7</td>
<td>17.7 ± 5.3</td>
<td>18.8 ± 11.4</td>
<td>0.87</td>
<td>0.65</td>
</tr>
<tr>
<td>Thoracolumbar junction (°)</td>
<td>-2.3 ± 10.2</td>
<td>-3.3 ± 5.3</td>
<td>-4.1 ± 9.3</td>
<td>0.56</td>
<td>0.62</td>
</tr>
<tr>
<td>Lumbar lordosis (°)</td>
<td>-27.4 ± 25.2</td>
<td>-34.4 ± 11.2</td>
<td>-37.7 ± 11.9</td>
<td>0.14</td>
<td>0.25</td>
</tr>
<tr>
<td>SVA (mm)</td>
<td>6.3 ± 33.6</td>
<td>7.0 ± 34.4</td>
<td>0.8 ± 33.7</td>
<td>0.94</td>
<td>0.55</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation. Kyphosis is marked with (+), and lordosis is marked with “–.”

UIVA, upper instrumented vertebral angle; LIVA, lower instrumented vertebral angle; UIV, upper instrumented vertebral; UIVT, UIV translation; LIVT, lower instrumented vertebral translation; TS, trunk shift; SVA, sagittal vertical axis.

†Preoperative vs. postoperative. ‡Postoperative vs. follow-up.
There were no significant differences in sacral tilt from before to after surgery (p = 0.15). In the coronal plane, undercorrection of segmental scoliosis and the major lumbar curve was performed. The major lumbar curve was 41.9° preoperatively, 11.7° postoperatively, and 14.6° at the latest follow-up. The segmental scoliosis curve was 39.1° preoperatively, 9.7° postoperatively, and 11.2° at the latest follow-up. There was no significant correction loss of the segmental scoliosis curve (p = 0.09) or major lumbar curve (p = 0.15). The cranial and caudal compensatory scoliosis curves significantly improved after surgery and maintained correction during the follow-up period. The UIV tilt improved from 27.3° to 6.7° after the surgery, and a 2.8° loss of correction was found at the latest follow-up. The TS was 15.7 mm preoperatively, 15.6 mm immediately after surgery and improved significantly (p < 0.05) at the latest follow-up. Significant improvements in upper instrumented vertebral angle, lower instrumented vertebral angle, UIVT, and LIVT were found immediately after the surgery and maintained during the follow-up period. In the sagittal plane, segmental kyphosis significantly improved from 27.2° to 6.5° after the surgery, and no significant correction loss occurred during the follow-up period. No significant changes were found in thoracic kyphosis, thoracolumbar junction alignment, lumbar lordosis, or the sagittal vertical axis. The correction results are shown in Table 2.

Poor wound healing occurred in 1 patient, who was treated with irrigation and debridement. Malpositioning of a pedicle screw occurred in 1 patient, but revision surgery was not indicated since there were no related symptoms. Transient root irritation occurred in 2 patients. Both of them had radicular pain after surgery. A CT scan was performed to rule out root and dura compression. Both of the patients recovered completely during the follow-up period. No major neurologic complications occurred.

**DISCUSSION**

Sacral tilt can result from primary problems such as sacral rotation, compensation for a scoliotic spine, and leg length discrepancy or primary congenital sacrum deformities. Secondary sacral tilt is nearly parallel to the pelvis obliquity and can be improved with correction of the primary deformities. CS is more likely to be associated with other skeletal deformities, and congenital sacral malformation may have been the most common cause of sacral tilt in our study.

The role of the sacral tilt in surgeries for spinal deformities in children has not been well studied. We found some studies evaluating the role of sacral tilt in correction surgeries for AIS. Lee et al. first described sacral tilt in AIS, and the frequencies of sacral tilt were 19.5%, 29.6%, and 40.6% when using the criteria of 5°, 4°, 3°, respectively. Cho et al. found that the proportion of patients with ≥ 5° of sacral tilt among those with < 3° of pelvic obliquity was 8.9% in their cohort of AIS patients. They found that sacral tilt may be a compensatory mechanism for large lumbar curves that are accompanied by pelvic obliquity abnormalities. Of note, a congenitally tilted upper sacrum may contribute to scoliosis in some AIS patients. The authors reported that leg length discrepancy is not directly correlated with sacral tilt. Joo et al. reported that the frequency of sacral tilt ≥ 3° was 28.6% (36 of 126 patients) in their study of AIS patients. However, the authors defined the degree of sacral tilt as the angle between the horizontal line and the upper endplate of the sacrum with the sacral tilt in most cases, likely due to compensatory secondary pelvic obliquity, which may be corrected after spinal surgeries.

To date, no studies have described sacral tilt in patients with CS. In the present study, the authors defined the degree of sacral tilt as the angle between the bi-iliac crest tangent line and the upper endplate of the sacrum to rule out the impact of lower limb discrepancies, patient habitus, and pelvic obliquity due to spinal deformities such as those reported in patients with neuromuscular scoliosis caused by cerebral palsy. Due to difficulty in distinguishing angles of 5°, 4°, and 3°, measurement bias may have been a source of error in the study. This error has been investigated and was suggested to be approximately 5° but could be as small as to 3° in CS. Most investigators have considered changes ≥ 5° to be clinically important, and a difference of more than 5° can minimize the measurement variation. As a result, sacral tilt was defined as a sacral tilt angle ≥ 5°. The frequency of sacral tilt in the present study was 67.1%, which was much higher than that reported in patients with AIS.

Sacral tilt may affect the coronal balance in correction surgeries for spinal deformities in children. When the sacral tilt is not addressed, coronal imbalance may occur after correction surgery for spine deformities (Fig. 3). Lee et al. noted that sacral tilt should be considered when the distal fusion level is selected to avoid coronal decompensation when planning corrective surgery in patients with AIS. Joo et al. found that sacral tilt typically occurred to the left in the Lenke 4-L type cases and to the right in the Lenke 4-R type cases and was associated with a higher probability of the adding-on phenomenon. In this study, the lumbosacral curve was not severe and was left untreated to preserve the important function of the lumbosacral region. However, the existing lumbosacral curve should be considered in...
the reconstruction of coronal balance. In children undergoing hemivertebal resection and short fusion, coronal imbalance with progressive deterioration of the coronal TS is rare because there are many mobile segments for compensation. However, correction loss or an “adding-on”-like phenomenon may lead to a longer lumbar curve extending to adjacent mobile segments. This occurs after surgery as a result of compensation for the lumbosacral curve with sacral tilt if the primary lumbar scoliosis curve is completely corrected. Thus, attention should be placed to the lumbosacral curve with severe sacral tilt in preoperative planning. In this study, special strategies were not taken during the surgery in patients with sacral tilt ≤ 10° because the compensatory changes for sacral tilt were usually mild in these patients. Considering the Scoliosis Research Society (SRS)’s definition of scoliosis, a Cobb angle > 10°, the authors defined severe sacral tilt as a sacral tilt angle > 10°. For patients with lumbosacral curves with severe sacral tilt, maximal correction of the main lumbar curve may lead to an increase in UIV tilt (Fig. 4). With UIV deviation, the lumbar curve may deteriorate and extend to the proximal mobile spine. Cranial compensatory curves or wedge-shaped discs may lead to issues that will negatively impact the spine. Thus, undercorrection with asymmetric cage placement in the osteotomy gap is recommended to compensate for the residual lumbosacral curve in patients with severe sacral tilt. A titanium mesh cage was inserted to the convex side to decrease the postoperative UIV tilt and achieve a median UIV (Fig. 5). The degree of residual segmental scoliosis should be similar to that of the sacral tilt.

Although we first described the role and treatment of lumbosacral curves with sacral tilt in patients who underwent lumbar hemivertebra resection for CS in this study, there are some po-

Fig. 3. A 15-year-old female had L3/4 hemivertebra with severe sacral tilt. Surgery was indicated for low back pain at a local institution. The hemivertebra was resected, and the whole lumbar curve was corrected with long-segment fusion from T12 to L5. However, coronal decompensation worsened significantly after the surgery and did not improve during the 9-year follow-up period.

Fig. 4. (A) Maximal correction of the primary lumbar curve in patients with a severe sacral tilt will lead to tilt and deviation of the fusion mass from the central line. (B) Undercorrection can compensate for the sacral tilt and provide a more level and medial upper instrumented vertebral at the base of the mobile proximal spine.
tential limitations. First, this was a retrospective study, and avoid-
ing maximal correction was an empirical conclusion; and the au-
thors did not conduct a case-control study due to obvious ethical
concerns. Second, some patients were still too young to complete
the SRS-22 questionnaire at the latest follow-up, thus we could
not acquire the SRS-22 questionnaire at latest follow-up.

CONCLUSION

Sacral tilt may exist in patients with CS with lumbar hemi-
vertebra. In patients with a significant severe sacral tilt, if the
lumbosacral curve is left untreated, surgical treatment with un-
dercorrection of the major lumbar curve and segmental scolio-
sis curve to compensate for the lumbosacral curve with sacral
tilt should be performed to achieve better coronal alignment in
cases requiring short fusion.

CONFLICT OF INTEREST

The authors have nothing to disclose.

ACKNOWLEDGMENTS

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submitted does not contain information about medical device(s)/
drug(s).

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Be Prepared: Preoperative Coronal Malalignment Often Leads to More Extensive Surgery Than Sagittal Malalignment During Adult Spinal Deformity Surgery

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Objective: To evaluate the effect of coronal alignment on: (1) surgical invasiveness and operative complexity and (2) postoperative complications.

Methods: A retrospective, cohort study of adult spinal deformity patients was conducted. Alignment groups were: (1) neutral alignment (NA): coronal vertical axis (CVA) \(\leq 3\) cm and sagittal vertical axis (SVA) \(\leq 5\) cm; (2) coronal malalignment (CM) only: CVA \(> 3\) cm; (3) Sagittal malalignment (SM) only: SVA \(> 5\) cm; and (4) coronal and sagittal malalignment (CCSM): CVA \(> 3\) cm and SVA \(> 5\) cm.

Results: Of 243 patients, alignment groups were: NA 115 (47.3%), CM 48 (19.8%), SM 38 (15.6%), and CCSM 42 (17.3%). Total instrumented levels (TILs) were highest in CM (14.5 ± 3.7) and CCSM groups (14 ± 4.0) (p < 0.001). More 3-column osteotomies (3COs) were performed in SM (21.1%) and CCSM (28.9%) groups than CM (10.4%) (p = 0.003). CM patients had more levels instrumented (p = 0.029), posterior column osteotomies (PCOs) (p < 0.001), and TLIFs (p = 0.002) than SM patients. CCSM patients had more TLIFs (p = 0.012) and higher estimated blood loss (EBL) (p = 0.003) than SM patients. CVA displayed a stronger relationship with TIL (p = 0.002), EBL (p < 0.001), and operative time (p < 0.001) than SVA, which had only one significant association with EBL (p = 0.010). Both SM/CCSM patients had higher readmissions (p = 0.003) and reoperations (p < 0.001) than CM patients.

Conclusion: Amount of preoperative CM was a better predictor of surgical invasiveness than the amount of SM, despite 3COs more commonly performed in SM patients. CM patients had more instrumented levels, PCOs, and TLIFs than SM patients.

Keywords: Adult spine deformity, Coronal malalignment, Sagittal malalignment, Adult spine surgery

INTRODUCTION

Adult spinal deformity (ASD) affects 15%-20% of the adult population, with higher rates seen in older age groups.\(^1\) Given the pain, disability, and decreased quality of life associated with ASD, and surgery rates have increased.\(^2\) Despite the benefits of operative management, spinal reconstruction surgeries are long and complex operations, require significant recovery, and are associated with high rates of complications.\(^3,4\) Correction of coronal and/or sagittal malalignment represents a formidable...
challenge to any deformity surgeon.

The technical objective of ASD surgery is to correct spinal alignment, and the operative plan depends heavily on the amount of coronal malalignment (CM) and/or sagittal malalignment (SM) present. Postoperative sagittal alignment targets are well-defined, with sagittal vertical axis (SVA) < 5 cm and pelvic incidence to lumbar lordosis within 10°.4 However, coronal alignment goals are not fully understood, as previous thresholds to define CM range from a coronal vertical axis (CVA) of 2 cm,7,8 3 cm,9,10 4 cm,11-13 to even 5 cm,14 though most prior studies use a threshold value of 3 cm.

Sagittal-specific correction maneuvers include 3-column osteotomies (3COs), cantilever techniques, and construct-to-construct resection. Coronal-specific correction techniques include asymmetric interbodies, asymmetric 3-column osteotomy (3CO), and “kickstand rod” placement.15 While those mentioned above sagittal and coronal correction maneuvers have been shown to correct alignment with proper patient selection, it remains unknown which techniques are associated with more operative morbidity.19 Whether correcting CM or SM, higher complication rates are associated with more invasive osteotomies, revision surgeries, or combined anterior-posterior approaches.19-21

Given our incomplete understanding of how CM and SM influence operative complexity and postoperative complications, we attempted to study further the role of preoperative alignment patterns in ASD surgery. In a cohort of ASD patients undergoing corrective surgery, we sought to evaluate whether preoperative alignment affected 2 principal outcomes: (1) surgical invasiveness and operative complexity, and (2) postoperative complications.

MATERIALS AND METHODS

1. Study Design

A retrospective cohort study was conducted based on prospectively collected data from a single institution, spinal deformity center consisting of 2 spine deformity surgeons (LGL and RAL). All patients undergoing spinal reconstruction 06/01/2015-12/31/19 were included. Institutional Review Board approval was obtained.

2. Patient Population

Enrollment criteria were similar to prior studies of ASD patients undergoing spinal reconstruction.14,22 The inclusion criteria were: age > 18 years undergoing ≥ 6 level instrumented fusion with at least one of the following radiographic criteria (Cobb angle > 30°, SVA > 5 cm, CVA > 3 cm, pelvic tilt of > 25°, or thoracic kyphosis [TK] > 60°).23 All patients underwent a standing, full-body low dose Stereoradiograph (EOS Imaging, Paris, France) prior to surgery. Patients were excluded if they were under age 18, undergoing < 6-level instrumented fusion, or lacked a whole-body Stereoradiograph at any of the follow-up time points. Patients were followed on a pattern of 8 weeks, 6 months, 1 year, 2 years, and 5 years.

Operatively, all but 2 patients underwent a posterior-only approach, and both patients underwent oblique, preposa approach for lumbar interbody cage placement. Patients with significant CM extending to the midthoracic spine usually had an upper-instrumented vertebra (UIV) of T1-3, whereas patients with solely lumbar deformity that did not include SM/CM above the midthoracic spine had a UIV of T10. Occasionally, in the case of significant proximal TK, the UIV will be C7.

3. Independent Variables

Demographic and perioperative variables were collected, including age, sex, body mass index, American Society of Anesthesiology (ASA) physical status classification, self-reported diagnosis of depression, deformity diagnosis, and primary versus revision surgery. Several preoperative radiographic variables were collected to determine the preoperative alignment group. To measure global alignment, both the continuous variables of CVA and SVA in cm were obtained. The CVA was measured by subtracting the coronal C7-plumb-line (C7PL; a vertical line dropped down from the middle of the C7 vertebral body) distance from the central sacral vertical line (a vertical line that passes through the center of the sacrum).24 Similarly, the SVA was the distance from the sagittal C7PL (a vertical line drawn dropped down from the middle of the C7 body) and the posterior superior aspect of the S1 vertebral body.24 Though CVA to the left was considered negative and to the right is positive, absolute values were used given the lack of clinical difference between left or right CM. In accordance with prior literature, CM was defined at a threshold of CVA ≥ 3 cm.9,11 Similarly, though SVA can be negative or positive in relation to where C7 lies compared to the superior posterior aspect of S1, absolute values were used to standardize the malalignment; however, positive and negative values were used for each regression analysis. Additional radiographic variables included: pelvic obliquity (angle of line between superior iliac crest and horizontal) and leg length discrepancy (difference in height from femoral head to tibial plafond on full-body x-rays). The previously published Qiu clas-

https://doi.org/10.14245/ns.2142384.192

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sification was used to assess directionality, which categorized CM into 3 groups based on a value of 3 cm as follows: type A: CVA < 3 cm; type B: CVA > 3 cm and C7PL shifted to the concave side of the curve; and type C: CVA > 3 cm and C7PL shifted to the convex side of the curve.10

4. Alignment Groups

Preoperatively, patients were divided into the following 4 groups based on alignment:

(1) Neutral alignment (NA): CVA < 3 cm and SVA < 5 cm; neither CM nor SM.
(2) CM only: CVA ≥ 3 cm and SVA < 5 cm; CM only without SM. A case example is seen in Fig. 1.
(3) SM only: SVA ≥ 5 cm and CVA < 3 cm; SM only without CM.
(4) Combined coronal and sagittal malalignment (CCSM): both CVA ≥ 3 cm and SVA ≥ 5 cm, presence of both CM/SM. A case example is seen in Fig. 2.

5. Primary and Secondary Outcomes

The primary outcome of interest was defined as surgical invasiveness and operative complexity. Variables involving the primary outcome included: total instrumented levels (TILs), number of posterior column osteotomies (PCOs), 3CO performed (binary), transforaminal lumbar interbody fusion (TLIF) performed (binary), unintended durotomy (binary), number of rods (continuous), presence of pelvic instrumentation (either S2-alar-iliac screws or iliac screws; binary), estimated blood loss (mL), operative time (minute), or presence of an intraoperative neuromonitoring (IOM) data loss (binary), as defined in previous studies.25 The secondary outcome of interest was defined as postoperative complications. Variables involving the secondary outcome included: major complication according to prior literature,26 readmission, and reoperation, defined as requiring revision spine surgery. Contrary to other studies, to answer our previous research question, the variables used for outcome measures were TIL, osteotomies, and estimated blood loss to indicate surgical invasiveness.
6. Statistical Analysis

Descriptive statistics were used to summarize patient demographics and radiographic data. Categorical data were presented as frequencies and percentages, whereas continuous data were presented with mean and standard deviations. Absolute values were used for SVA and CVA to allow for statistical analysis. Based on Shapiro-Wilk tests, all variables were considered to be non-parametrically distributed, except operative time. Kruskal-Wallis tests were used to assess for differences between continuous variables, except for operative time, where a 1-way analysis of variance test was used. Chi-square proportion tests were used for count data. Univariate linear regression was used to determine an association with amount of coronal or sagittal malalignment (CVA/SVA) with the continuous variables of TIL, EBL, and operative time, followed by multivariate regression controlling for age, sex, body mass index (BMI), maximum Cobb

Fig. 2. Case example of a 62-year-old female with adult idiopathic kyphoscoliosis and pseudarthrosis at L1–3, preoperative combined coronal and sagittal malalignment (CCSM) patient with full-spine preoperative and 2-year postoperative anteroposterior (AP) and lateral x-rays (A) and full-body preoperative and 2-year postoperative AP and lateral x-rays (B). Preoperative coronal malalignment (CM) was 6.62 cm and sagittal malalignment (SM) was 11.24 cm. Preoperative CM is underrepresented on x-ray as the patient is compensating on the right side by standing on the tips of her toes and bending her knee to elevate her ipsilateral hemipelvis to prevent further right-sided leaning. She had a prior T3-sacrum instrumented fusion and L2 pedicle subtracion osteotomy at an outside institution. Revision surgery consisted of instrumentation removal T3-sacrum, posterior instrumentation T1-sacrum, posterior column osteotomies T1–5/T9–L5, and placement of a right-sided kickstand rod for resolution of CCSM. Postoperative CM was 1.3 cm and SM was 0.5 cm. Postoperatively the patients’ pelvis is now level and both legs are straight demonstrating the marked improvement in alignment.
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angle, and amount of CM/SM. Statistical significance was set at an alpha level of < 0.05. All statistical analyses were performed in STATA 14 (StataCorp LP, College Station, TX, USA).

RESULTS

1. Demographics
A total of 243 patients underwent ASD surgery with a mean age was 49.3 ± 18.3 and mean instrumented levels was 13.5 ± 3.9. Mean preoperative CVA absolute value was 2.9 ± 2.7 cm, and mean preoperative SVA absolute value was 5.4 ± 5.5 cm. Overall alignment of all patients preoperatively was: NA 115 (47%), CM 48 (20%), SM 38 (16%), and CCSM 42 (17%). Demographic and preoperative variables of all patients based on alignment group are summarized in Table 1. Qiu classification preoperatively was: type A (153; 63%), type B (53; 22%), and type C (37, 15%). As expected, several between group differences were seen based on preoperative alignment.

2. Primary Outcome: Surgical Invasiveness and Operative Complexity
For the primary outcome of surgical invasiveness and operative complexity, significant across group differences were seen in 8 of the 10 individual variables (Table 2). The only 2 variables that did not demonstrate statistical significance across all alignment types were TIL and IOM changes. The remaining 8 variables all showed significant variability depending on alignment type, which included: PCOs (p < 0.001, highest in NA and CM), 3CO (p = 0.002, highest in SM/CCSM), TLIF performed (p < 0.001, highest in CM and CCSM), durotomies (p = 0.009, highest in CM and CCSM), number of rods (p < 0.001, lowest in NA), pelvic instrumentation (p < 0.001, lowest in NA), EBL (p < 0.001, highest in CM and CCSM), and operative time (p < 0.001, highest in CM and CCSM).

Comparing CM to SM directly, groups were not significantly different except for 3 variables. The CM group had significantly more levels instrumented (14.5 ± 3.7 vs. 12.7 ± 4.2, p = 0.029) more PCOs performed (5.8 ± 2.9 vs. 3.1 ± 2.4, p < 0.001), and more TLIFs performed (64.6% vs. 31.6%, p = 0.002) (Table 2).

Comparing SM to CCSM directly, groups were not significantly different except for 2 variables. The CCSM group had more TLIFs (58.1% vs. 31.6%, p = 0.0123) and higher EBL (1,825 ± 1,062 mL vs. 1,225 ± 803 mL, p = 0.003) (Table 2).

The relationship between amount of CM or SM and 3 inde-
Table 2. Surgical invasiveness and operative complexity based on each alignment group

<table>
<thead>
<tr>
<th>Variable</th>
<th>Neutral alignment (n = 115)</th>
<th>Coronal malalignment (n = 48)</th>
<th>Sagittal malalignment (n = 38)</th>
<th>Combined coronal and sagittal malalignment (n = 42)</th>
<th>Comparing all 4 groups</th>
<th>Comparing CM to SM</th>
<th>Comparing SM to CCSM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total instrumented levels</td>
<td>13.1 ± 3.8</td>
<td>14.5 ± 3.7</td>
<td>12.7 ± 4.2</td>
<td>14 ± 4.0</td>
<td>0.072</td>
<td>0.029*</td>
<td>0.145</td>
</tr>
<tr>
<td>No. of PCOs</td>
<td>5.1 ± 3.2</td>
<td>5.8 ± 2.9</td>
<td>3.1 ± 2.4</td>
<td>4.1 ± 2.8</td>
<td>&lt; 0.001*</td>
<td>&lt; 0.001*</td>
<td>0.084</td>
</tr>
<tr>
<td>Three-column osteotomy</td>
<td>9 (7.8)</td>
<td>5 (10.4)</td>
<td>8 (21.1)</td>
<td>13 (28.9)</td>
<td>0.002*</td>
<td>0.171</td>
<td>0.315</td>
</tr>
<tr>
<td>TLIF performed</td>
<td>43 (37.1)</td>
<td>31 (64.6)</td>
<td>12 (31.6)</td>
<td>25 (58.1)</td>
<td>&lt; 0.001*</td>
<td>0.002*</td>
<td>0.012*</td>
</tr>
<tr>
<td>Durotomy</td>
<td>14 (12.2)</td>
<td>16 (33.3)</td>
<td>7 (18.4)</td>
<td>12 (28.6)</td>
<td>0.009*</td>
<td>0.121</td>
<td>0.287</td>
</tr>
<tr>
<td>No. of rods</td>
<td>2.8 ± 0.9</td>
<td>3.8 ± 1.5</td>
<td>3.6 ± 1.2</td>
<td>3.9 ± 1.1</td>
<td>&lt; 0.001*</td>
<td>0.365</td>
<td>0.064</td>
</tr>
<tr>
<td>Pelvic instrumentation</td>
<td>65 (56.5)</td>
<td>37 (77.1)</td>
<td>31 (81.9)</td>
<td>39 (92.9)</td>
<td>&lt; 0.001*</td>
<td>0.611</td>
<td>0.128</td>
</tr>
<tr>
<td>Estimated blood loss (mL)</td>
<td>1,086 ± 521</td>
<td>1,451 ± 777</td>
<td>1,225 ± 803</td>
<td>1,825 ± 1062</td>
<td>&lt; 0.001*</td>
<td>0.106</td>
<td>0.003*</td>
</tr>
<tr>
<td>Operative time (min)</td>
<td>427 ± 109</td>
<td>513 ± 107</td>
<td>476 ± 133</td>
<td>538 ± 176</td>
<td>&lt; 0.001*</td>
<td>0.152</td>
<td>0.085</td>
</tr>
<tr>
<td>IOM changes</td>
<td>5 (4.3)</td>
<td>3 (6.3)</td>
<td>3 (7.9)</td>
<td>6 (14.0)</td>
<td>0.192</td>
<td>0.766</td>
<td>0.366</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation or number (%). PCOs, posterior column osteotomies; TLIF, transforaminal lumbar interbody fusion; IOM, intraoperative monitoring. *p < 0.05, statistically significant differences; Kruskal-Wallis or chi-square test performed.

![Graph A](image1.png)

![Graph B](image2.png)

![Graph C](image3.png)

Fig. 3. Univariate linear regressions for coronal vertical axis (CVA) with total instrumented levels (A), estimated blood loss (B), and operative time (C). CI, confidence interval.
Preoperative Coronal Malalignment Often Leads to More Extensive Surgery

Zuckerman SL, et al.

Fig. 4. Univariate linear regressions for sagittal vertical axis (SVA) with total instrumented levels (A), estimated blood loss (B), and operative time (C). CI, confidence interval.

Table 3. Multivariate linear regression for CVA and SVA controlling for age, sex, body mass index, maximum Cobb angle, and coronal/sagittal malalignment

<table>
<thead>
<tr>
<th>Variable</th>
<th>CVA</th>
<th>p-value</th>
<th>SVA</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total instrumented levels</td>
<td>0.33 (0.13–0.54)</td>
<td>0.002*</td>
<td>-0.05 (-0.13–0.04)</td>
<td>0.287</td>
</tr>
<tr>
<td>Estimated blood loss</td>
<td>83.13 (46.59–119.67)</td>
<td>&lt;0.001*</td>
<td>21.59 (5.24–37.94)</td>
<td>0.010*</td>
</tr>
<tr>
<td>Operative time</td>
<td>14.62 (8.42–20.81)</td>
<td>&lt;0.001*</td>
<td>2.36 (-0.41–5.13)</td>
<td>0.095</td>
</tr>
</tbody>
</table>

CVA, coronal vertical axis; SVA, sagittal vertical axis; CI, confidence interval.
*p < 0.05, statistically significant differences.

Table 4. Postoperative complications

<table>
<thead>
<tr>
<th>Variable</th>
<th>Neutral alignment (n = 82)</th>
<th>Coronal malalignment (n = 32)</th>
<th>Sagittal malalignment (n = 28)</th>
<th>Combined coronal and sagittal malalignment (n = 32)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major complication</td>
<td>13 (11.4)</td>
<td>12 (26.1)</td>
<td>8 (22.2)</td>
<td>8 (19.1)</td>
<td>0.113</td>
</tr>
<tr>
<td>Readmission</td>
<td>10 (8.9)</td>
<td>6 (13.0)</td>
<td>11 (30.1)</td>
<td>11 (26.2)</td>
<td>0.003*</td>
</tr>
<tr>
<td>Reoperation</td>
<td>8 (7.0)</td>
<td>5 (10.9)</td>
<td>10 (27.8)</td>
<td>11 (26.2)</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

Values are presented as number (%).
*p < 0.05, statistically significant differences.

CI, 8.42–20.81; p < 0.001). For SVA, no significant relationship was seen between TIL (β = -0.05; 95% CI, -0.13–0.04; p = 0.287) and operative time (β = 2.36; 95% CI, -0.41–5.13; p = 0.095), yet a significant relationship was seen between SVA and EBL (β = 21.59; 95% CI, 5.24–37.94; p = 0.010), where a higher SVA was associated with increased EBL.
3. Secondary Outcome: Postoperative Complications

Follow-up at 2 years was seen in 174 patients, allowing for a 71.6% 2-year follow-up rate. Two-year alignment breakdown was: NA 82 (47.1%), CM 32 (18.4%), SM 28 (16.1%), and CCSM 32 (18.4%). For secondary outcomes, there was no difference in rates of major complications were seen across all 4 groups, yet readmission and reoperation were significantly different (Table 4). Both readmission (p = 0.003) and reoperation (p < 0.001) were significantly different across all 4 groups, and highest for the SM and CCSM groups.

DISCUSSION

The current study aimed to determine the effect of preoperative sagittal malalignment on surgical invasiveness and operative complexity, as well as postoperative complications. We found that preoperative alignment led to a significantly different level of surgical invasiveness and operative complexity in 8 of the 10 surgical primary outcome variables. When comparing CM to SM directly, the CM group had more instrumented levels, underwent more PCOs, and had more TLIFs performed. Comparing SM to CCSM, the CCSM group had TLIFs performed more often and higher blood loss. Multivariate linear regression revealed that CVA held a statistically significant and stronger linear association with 3 operative complexity variables of instrumented levels, blood loss, and operative time compared to SVA. For the secondary outcomes of postoperative complications, SM and CCSM patients had the highest rate of readmission and reoperation. Together, these findings suggest that the amount of CM is a strong driver of the invasiveness and complexity in ASD surgery.

Perhaps the most interesting finding was that the amount of CM had a stronger association with operative invasiveness and complexity than the amount of SM. Compared to its well-studied sagittal counterpart, coronal alignment in ASD surgery has been less emphasized.\(^18\) Whether it be due to the technical difficulties of correcting coronal plane abnormalities or lesser weight placed in operative decision-making, postoperative rates of CM remain high, ranging from 19.3%\(^18\) to 34.8%\(^10\) with some studies reporting higher levels of CM postoperatively than preoperatively.\(^10,14,17,18\) One potential reason for this is that techniques to correct CM, such as adding a kickstand rod, can take additional time, leading to more blood loss and longer operative time. With respect to operative invasiveness and complexity, other studies have shown equally high rates of blood loss and operative time. Comparing 338 PSO patients to 52 asymmetric PSO patients, Lau et al.\(^12\) reported higher EBL in the asymmetric PSO group (2,096 mL vs. 1,989 mL), though this was not statistically significant. The same trend was seen for operative time—319 minutes for asymmetric PSO compared to 307 minutes for PSO—without statistical significance. Comparisons were not different between both groups as well (40.3% asymmetric PSO vs. 33.1% PSO).\(^12\) In a cohort of patients with severe CM, Buell et al.\(^17\) reported that patients with CVA ≥ 10 cm had an EBL of 2.5 L compared to patients SVA ≥ 10 cm with an EBL of 2.4 L. Interestingly, operative time was virtually the same for patients with SVA ≥ 10 cm (8.2 hours) compared to CVA ≥ 10 cm (8.1 hours). However, despite an informative report on severe CM, it was unknown if these patients had CCSM or CM and SM in isolation, making a comparison to the current study difficult. To our knowledge, no other reports have compared CM patients exclusively to SM patients.

Additional differences in our series showed that patients with CM and CCSM were more likely to undergo TLIFs, which likely represents the importance of horizontalizing the lumbosacral fractional curve, and creating a strong, symmetric base across the lumbosacral junction. CM patients also underwent more PCOs than 3COs, reflecting that without significant sagittal plane abnormalities, multilevel PCOs are all that is needed to correct the coronal deformity, in the absence of a rigid, fixed, sagittal deformity. Additionally, CCSM patients had longer operative time than SM patients, reinforcing the difficulty of correcting biplanar deformities. Lastly, CM patients had higher TIL than the SM group, which likely reflects that CM often occurs in the MT or TL/L segment of the spine. The cranial end of the scoliosis stops in the midthoracic area, which is a suboptimal stopping point. In comparison, SM patients may have only focal loss of lumbar lordosis that stops in the upper lumbar or distal thoracic segment, lending itself to an appropriate lower thoracic UIV.

Despite a strong association between several operative complexity variables and CVA, 3COs and reoperations were more common in patients with SM. In the setting of a prior fusion, 3COs are often required to correct fixed sagittal plane deformities and are associated with significant blood loss and high rates of complications.\(^22,28,29\) However, despite increased frequency of 3COs in SM patients, CM still required more time to correct. Taken together, though less invasive osteotomies were performed for CM deformities, the coronal correction took more time, especially in CCSM patients. Potential reasons for this include need for a kickstand rod and difficulty placing screws in coronally malaligned patients, which is often more straightfor-
ward if only SM is seen, without lateral subluxation often encountered with significant scoliosis. Moreover, the spinal cord may not be able to tolerate extensive coronal correction over a short period, causing the surgical team to correct the coronal deformity slowly, over multiple rounds of compression and distraction. Moreover, despite longer operative time and blood loss seen with CM, SM and CCSM had the highest rate of readmissions and reoperations, highlighting the increased risk with sagittal and biplanar corrections. Others have reported similar findings, with greater preoperative SVA being a predictor of revision surgery. The high rate of revision surgery among SM patients may be due to the ensuing risk of pseudarthrosis, rod fractures, and other mechanical complications seen with 3COs compared to PCOs.

The present study is not without limitations. First, as a retrospective single-center study with 2 surgeons involved, differences may exist when including additional centers and surgeons with varying approaches and techniques. There were 2 surgeons who made the preoperative decision-making, which may limit the generalizability of our results. It is common practice at our hospital to employ an all-posterior approach, and lateral, oblique, or anterior approaches may yield different findings. To that end, larger, prospective studies are needed to assess the validity and applicability of our findings. Second, postoperative outcomes measured here were limited to overall complications, reoperations, and readmissions. Future research should examine the relationship between alignment groups and more granular complications, as well as the impact on patient-reported outcomes. Particularly understudied are patients with CCSM, and this difficult subset of patients should be an area of future work.

CONCLUSION

In patients undergoing ASD surgery, preoperative alignment led to significantly different surgical invasiveness and operative complexity. The CM group had more instrumented levels, underwent more PCOs, and had more TLIFs than the SM group, and the CCSM group had TLIFs performed more often and higher blood loss than the SM group. The amount of CM (CVA) held a stronger linear association with 3 operative complexity variables than amount of SM (SVA). Both SM and CCSM patients had the highest rate of readmission and reoperation. Together, these findings suggest that CM is significantly associated with increased invasiveness and complexity in ASD surgery.

CONFLICT OF INTEREST

The authors have nothing to disclose.

REFERENCES


Ligament Augmentation With Mersilene Tape Reduces the Rates of Proximal Junctional Kyphosis and Failure in Adult Spinal Deformity

Pope Rodnoi, Hai Le, Luke Hiatt, Joseph Wick, Joshua Barber, Yashar Javidan, Rolando Roberto, Eric O. Klineberg

Department of Orthopedic Surgery, University of California, Davis, Sacramento, CA, USA

Objective: To investigate prevention of proximal junctional kyphosis (PJK) and failure (PJF) following adult spinal deformity (ASD) surgery utilizing a novel technique of posterior liga- ment augmentation with polyester fiber tether.

Methods: This study evaluated ASD adult patients who underwent posterior decompression and instrumented fusion from the thoracolumbar junction (T9–L1) to the pelvis from 2011–2017. Basic demographic data were obtained. Radiographic outcomes included proximal junctional angle (PJA), sagittal vertical axis, PJK, and PJF. The study population was divided into patients who had ASD surgery with and without ligamentous augmentation.

Results: A total of 43 subjects were evaluated, including 20 without and 23 with ligamentous augmentation. PJA increased over time for both groups. PJA was smaller for the augmented group, and rate of increase in PJA was slower in the augmented group (p < 0.0001). The rate of PJK was significantly higher in the nonaugmented group (p = 0.01). PJF was significantly less common in the augmented group (p = 0.003). Time to revision surgery was lower in the nonaugmented group (p = 0.003).

Conclusion: Our novel ligament augmentation technique utilizing polyethylene tape is an effective technique to slow progression of the PJA and lower the risk for proximal junctional disease in ASD surgery.

Keywords: Adult spinal deformity, Adjacent segment disease, Proximal junction disease, Proximal junctional kyphosis, Proximal junctional failure, Proximal junctional angle

INTRODUCTION

Patients with thoracolumbar adult spinal deformity (ASD) present with significant pain and disability as they expend supraphysiologic energy to maintain their global alignment.1,2 Many patients require major spinal reconstructive surgery to correct their coronal and sagittal balance.2 Surgery greatly improves quality of life and health status,3 yet poses significant complication risks,4 with complication rates as high as 69.8%.5 Proximal junctional disease (PJD), including proximal junctional kyphosis (PJK) and proximal junctional failure (PJF), is a major delayed complication of ASD surgery.4,5 PJK typically occurs within 2 years of surgery, with rates ranging from 17% to 39%.6 Radiographic PJK can progress to PJF, necessitating revision surgery for hardware failure, vertebral body fracture, neurologic injury, and/or pain and disability.7,8 Rates of progression to PJF range between 1.4%–5.6%.8,9,10

Substantial efforts in ASD research have focused on PJD prevention and treatment. Multiple risk factors have been identified and prevention strategies proposed.11 Specifically, one of the major PJD risk factors is instrumentation rigidity at the upper instrumented vertebra (UIV). Sudden transition from a rigid...
posterior spinal instrumented fusion construct to flexible non-instrumented vertebrae places significant mechanical stress on the UIV and its adjacent vertebrae. Over time, this predisposes the transition zone to PJD. Many techniques have been developed to lessen instrumentation rigidity and suddenness of transition at the UIV, including use of hook fixation, transition rods, and ligament augmentation. Since 2016, we have performed ligament augmentation at the level above the UIV (UIV+1) for all ASD surgeries using a braided, nonabsorbable 5-mm suture made of polyethylene-terephthalate polyester fiber tape (Mersilene, Ethicon, Somerville, NJ, USA) tensioned over a crosslink. Herein, we describe our technique and evaluate the rates of PJK and PJF following ASD surgery with and without ligament augmentation.

**MATERIALS AND METHODS**

1. **Patient Enrollment**

This study received approval from the Institutional Review Board (IRB) of University of California, Davis (approval number: 1156618-1). Since this was a retrospective study with no direct patient interaction, informed consent was exempted. After IRB approval was obtained, patients ≥ 18 years who had undergone posterior decompression and instrumented fusion from the thoracolumbar junction (T9–L1) to the pelvis for ASD between 2011 to 2017 were identified in a single-center ASD database. The minimum follow-up was 2 years. All patients underwent surgery by the senior author. The study population was divided into patients who had ASD surgery without ligamentous augmentation (nonaugmented group) versus with ligamentous augmentation (augmented group). Patients who underwent surgery between 2011 and 2015 were part of the nonaugmented group whereas patients who underwent surgery between 2016 and 2017 were part of the augmented group. The study’s sample size was calculated based on previously published studies on the incidence of PJF in augmented versus nonaugmented cohorts. Two independent study groups were used, and the primary endpoint was dichotomous (i.e., was there PJF or...
not), with alpha set at 0.05 and power set at 0.80. The number of patients required to detect statistically significant differences was calculated to be 154 patients, or 77 patients in each cohort.

2. Surgical Technique

Ligament augmentation (Fig. 1) was performed after completion of posterior decompression and instrumented posterolateral spinal fusion. First, the base of the UIV+1 spinous process was exposed, taking care to not violate the posterior ligamentous complex and paraspinal musculature. A sharp towel clamp was used to create a hole across the base of the spinous process, through which the polyester tape was passed. The ends of the tape were marked, cut, and securely tied over a crosslink such that the crosslink would be positioned between the spinous processes of the UIV and UIV-1 after final tensioning. After crosslink insertion on the rods, a compressor was used to appropriately tension the tape, and the crosslink was final-tightened. A UIV hook was not used on patients in the ligamentous augmentation group. As PJK is a result of flexion deforming forces, we tension enough to maintain neutral alignment between the spinous processes of the UIV and UIV+1. In our experience, tensioning the tape by compressing the crosslink provides greater force and is more reliable than tensioning by knot tying alone. At present, we do not have a reliable way to objectively measure the amount of tension force on the tether.

3. Covariates and Data Collection

Demographic data, including age, sex, and body mass index, as well as operative data, including anterior fusion and 3-column osteotomy, were collected. The proportion of patients with preoperative diagnosis of osteoporosis was also determined for each cohort. Radiographic parameters were measured on full-length standing scoliosis films obtained at the preoperative, immediate postoperative, 6-week, 3-month, and 24-month postoperative timepoints. Radiographic parameters included sagittal Cobb proximal junction angle (PJA), sagittal vertical axis (SVA), lumbar lordosis (LL), and pelvic incidence. PJA was defined as the sagittal Cobb angle of the UIV+1 superior endplate and the UIV inferior endplate. PJK was defined as PJA ≥ 10° and at least 10° greater than the preoperative angle. The primary clinical outcome of interest was PJF, defined as need for revision surgery for PJD including symptomatic PJK and fracture or hardware failure at the UIV or its adjacent vertebrae. In our study, PJF included ligamentous failure, bone failure (fracture), and implant/bone interface failure (hardware fracture, hook pull-out).

4. Statistical Analysis

Two-sample t-tests were used to compare quantitative variables between cohorts. Chi-square tests and Fisher exact tests were used to compare categorical variables. A linear mixed-effect model was used to model PJA versus main effects for each group (augmented vs. nonaugmented), time in days since surgery, and the interaction between groups and the time terms. Several functional forms for the relationship between PJA and time were considered, including a logarithmic term. Models were compared based on Akaike Information Criteria (AIC). For the logarithmic time value, 0.1 was added to days since surgery because the logarithm of 0, which was the baseline time of surgery, is undefined. A random intercept was included for each subject to account for correlation of values within the same subject. The trajectory of SVA values over time was similarly analyzed. Kaplan-Meier survival curves were constructed for time to revision surgery and compared using a log-rank test. Statistical analyses were performed using R version 3.4.0 (R Foundation for Statistical Computing, Vienna, Austria), and PROC MIXED in SAS 9.4 (SAS Institute Inc., Cary, NC, USA). All hypothesis testing was 2-sided based on a significance level of 0.05.

RESULTS

1. PJA and PJK

A total of 43 subjects were evaluated, including 20 patients without and 23 with ligament augmentation. Patient characteristics and demographics did not differ significantly between the groups (Table 1). In our study, 3 of 20 (15%) of nonaugmented patients had documented osteoporosis, while 7 of 23 (30%) of augmented patients had documented osteoporosis. In the nonaugmented group, 2 of the patients with osteoporosis required revision surgery during the 2-year follow-up period. In the augmented group, none of the patients with osteoporosis required revision surgery during the 2-year follow-up period. The UIV for the augmented group was between T9–L1, while the UIV for the nonaugmented group was between T9–12. Preoperative PJA was lower in the augmented group but not statistically significant. Preoperative SVA was significantly higher in the augmented group (p = 0.001).

The best-fitting model for PJA based on AIC values was the logarithmic model. Predicted trajectories with each model and at preoperative diagnosis of osteoporosis were also determined for each cohort. Radiographic parameters were measured on full-length standing scoliosis films obtained at the preoperative, immediate postoperative, 6-week, 3-month, and 24-month postoperative timepoints. Radiographic parameters included sagittal Cobb proximal junction angle (PJA), sagittal vertical axis (SVA), lumbar lordosis (LL), and pelvic incidence. PJA was defined as the sagittal Cobb angle of the UIV+1 superior endplate and the UIV inferior endplate. PJK was defined as PJA ≥ 10° and at least 10° greater than the preoperative angle. The primary clinical outcome of interest was PJF, defined as need for revision surgery for PJD including symptomatic PJK and fracture or hardware failure at the UIV or its adjacent vertebrae. In our study, PJF included ligamentous failure, bone failure (fracture), and implant/bone interface failure (hardware fracture, hook pull-out).
Table 1. Patient baseline preoperative characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Nonaugmented (n = 20)</th>
<th>Augmented (n = 23)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female sex</td>
<td>13 (65)</td>
<td>15 (65.2)</td>
<td>1.00</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>68.0 ± 5.8</td>
<td>69.1 ± 6.7</td>
<td>0.57</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>27.4 ± 5.5</td>
<td>28.4 ± 6.0</td>
<td>0.58</td>
</tr>
<tr>
<td>Anterior procedure</td>
<td>2 (10)</td>
<td>1 (4)</td>
<td>0.59</td>
</tr>
<tr>
<td>3-Column osteotomy</td>
<td>3 (15)</td>
<td>2 (8.7)</td>
<td>0.65</td>
</tr>
<tr>
<td>Pelvic incidence (PI)</td>
<td>56.1 ± 10.0</td>
<td>58.8 ± 11.8</td>
<td>0.42</td>
</tr>
<tr>
<td>Delta lumbar lordosis (LL)</td>
<td>16.6 ± 15.1</td>
<td>24.0 ± 14.0</td>
<td>0.11</td>
</tr>
<tr>
<td>Preoperative PI–LL</td>
<td>-0.2 ± 9.8</td>
<td>3.2 ± 6.1</td>
<td>0.19</td>
</tr>
<tr>
<td>Preoperative PJA</td>
<td>5.2 ± 4.8</td>
<td>3.0 ± 6.4</td>
<td>0.21</td>
</tr>
<tr>
<td>Preoperative SVA</td>
<td>44.8 ± 31.6</td>
<td>88.1 ± 50.7</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Values are presented as number (%) or mean ± standard deviation. PJA, proximal junctional angle; SVA, sagittal vertical axis.

Fig. 2. Observed (specific data points) and predicted (logarithmic curves) proximal junctional angle (PJA) over time by group assuming a logarithmic relationship between PJA and days since surgery. Grey indicates the augmented group while black indicates the nonaugmented group. Illustrates the pattern of changes in PJA deviation from baseline over time for the 2 groups under the fitted model. While PJA increased over time for both groups, on average, the PJA was smaller for the augmented group, and rate of increase in PJA was slower in the augmented compared to the nonaugmented group (p < 0.0001). The rate of PJK was significantly higher in the nonaugmented group (17 of 20 patients, 85%) compared to the augmented group (10 of 23 patients, 43.5%) (p = 0.01). The median UIV for PJK in the nonaugmented group was T10. The median UIV for PJK in the augmented group was T11.

2. Proximal Junctional Failure

PJF was significantly less common in the augmented group (0 of 23 patients, 0%) than the nonaugmented group (7 of 20 patients, 35%) (p = 0.003) as shown in Table 2. This resulted in the nonaugmented group having 7 revision surgeries within the first 2 years due to fracture, hook pull-outs, or symptomatic PJK. Kaplan-Meier curves were generated for time to revision surgery for each group (Fig. 3), and a log-rank test was performed to compare times between groups. Time to revision surgery differed significantly between the 2 groups (p = 0.003).

Table 2. Patient surgical characteristics and outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Nonaugmented (n = 20)</th>
<th>Augmented (n = 23)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative SVA</td>
<td>40.6 ± 42.4</td>
<td>51.3 ± 40.0</td>
<td>0.4</td>
</tr>
<tr>
<td>Revision surgery within 2 years of surgery</td>
<td>7</td>
<td>0</td>
<td>0.003</td>
</tr>
<tr>
<td>Mean time to revision surgery (day)</td>
<td>462.9</td>
<td>N/A</td>
<td>0.003</td>
</tr>
<tr>
<td>Fracture</td>
<td>5</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>Symptomatic PJK</td>
<td>1</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Hook pull-out</td>
<td>7</td>
<td>0</td>
<td>-</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation or number. SVA, sagittal vertical axis; PJK, proximal junctional kyphosis; N/A, not applicable.

Fig. 3. Kaplan-Meier survival curves for time to revision surgery for augmented and nonaugmented groups.
Fig. 4. Observed (specific data points) and predicted (logarithmic curves) sagittal vertical axis (SVA) over time by group assuming a logarithmic relationship between SVA and days since surgery. Grey indicates the augmented group while black indicates the nonaugmented group.

3. SVA Over Time

The best-fitting model for SVA based on AIC values was the logarithmic model (AIC of 1,619.8). The logarithmic model best represented the original data in regard to explaining the greatest amount of variation in our dataset. Predicted trajectories with each model and observed SVA are shown in Fig. 4. SVA values did not change significantly over time in the nonaugmented group (p = 0.61) or in the augmented group (p = 0.20). Preoperatively, SVA was significantly higher in the augmented group (p < 0.0001). Postoperatively, SVA was not significantly different between the groups (Table 2).

DISCUSSION

In this study, we compared rates of PJK, PJF, and SVA over time, as well as need for revision surgery, between patients who underwent surgical correction of ASD both with and without posterior ligament augmentation with a novel polyethylene tape technique. Patients who underwent augmentation were found to have a significantly slower increase in PJA and significantly lower rate of PJK. Similarly, development of PJF was significantly lower, and time to revision surgery was significantly longer amongst patients who underwent augmentation.

Results of this study suggest that our novel technique may be employed to successfully reduce rates of PJD, in turn reducing the need for revision surgery. The benefits of decreasing revision rates following ASD surgery include avoiding the morbidity and costs associated with additional surgical procedures. Additionally, ligament augmentation slows the progression of the PJA such that patients who go on to develop PJK typically develop it much later than patients who are not augmented. It is important to note that the only significant difference between the 2 cohorts in our study was the preoperative SVA, with the augmented group having a greater preoperative SVA. However, the degree of sagittal imbalance did not impact the need for anterior procedures or 3-column osteotomies, and no significant difference was noted in the postoperative SVA. Furthermore, while the augmented group had higher baseline SVA, the development of PJF was lower in this cohort, which further supports the advantage of ligament augmentation.

Our results are consistent with previous studies, which have shown that disruption of the posterior soft tissues in ASD surgery is a major risk factor for PJD. These results have led to the relatively new technique of ligamentous augmentation. In cadaveric models, violation of the posterior soft tissue structures has been shown to destabilize the posterior column and decrease thoracic motion segment flexion stiffness. Therefore, the objective of ligament augmentation is to reproduce the tethering effect of the posterior ligamentous structures, specifically the interspinous and supraspinous ligaments. In theory, ligament augmentation helps maintain flexion stability, thereby reducing PJD risk.

Ligament augmentation can be achieved with various tethering materials and techniques. Overall, we found higher rates of PJK in both the nonaugmented (85%) and augmented (43.5%) cohorts compared to prior published studies. Zaghloul et al. were among the first to describe check-rein strap stabilization using Mersilene tape. However, their application was slightly different from ours. In their technical description, the authors placed the tape above or through the spinous process of the UIV+1 and made a figure of 8 loop under the spinous process of the UIV. The tape was then passed under the rods or around a crosslink, and the ends were subsequently tied together. They reported no development of PJD in their series of 18 patients at a mean follow-up of 11.9 months (range, 2–31 months). In a follow-up study from the same group, the rate of PJK at 2 years was lower with polyethylene tape stabilization compared to the matched control cohort (15% vs. 38%, p = 0.04). Their results suggest that ligament augmentation lowers, but does not eliminate the risk for PJD. Similarly, Safaee et al. reported their experience tensioning soft sublaminar cables through the spinous processes and anchoring them to rods using special connectors.
Surgical nylon tape and semitendinosus allograft have also been used to reinforce the posterior ligamentous structures. Similar to our results, Rodriguez-Fontan et al. reported an increased latent period to development of PJD of 20 months in an augmented cohort, compared to 7.5 months in the control group (p = 0.018).

This study is not without limitations. First, this study was a retrospective review of patients treated by a single surgeon at a single institution, which limits generalizability. Our study populations were small and therefore underpowered, potentially predisposing our statistical analyses to type II error. Additionally, there was no “washout period” between the change in practice between groups when the tether technique was introduced. The senior author transitioned directly from using a nonaugmented technique to using an augmented technique in 2016. Indeed, an initial surgeon learning curve associated with implementing the tethering technique may have biased results to show a lesser effect size of the tethering technique described in the latter group. A period of time between the 2 treatment options may have reduced a “carryover” effect, or at least provided enough experience with the technique to demonstrate a greater effect size, which may be expected after the surgeon has gained more experience with the technique. Although there was no transition period between cohorts, these were consecutive patients and there was no self-selection for treatment. Once switched to ligamentous augmentation, all patients received ligamentous augmentation. Moreover, T12 and L1 are often avoided as choices for the UIV as they tend to be located at the transition from thoracic kyphosis to LL. Overall, only 2 patients from the augmented group developed PJK at these UIV positions so this should not take away from our results. Moreover, this should not affect the interpretation of the results as patients in the nonaugmented group had UIV ranges between T9–12.

Additionally, the patient cohorts had different preoperative SVAs. Greater baseline SVA, reflecting greater baseline deformity in the augmented group, may have masked the effect size of the tethering, as patients with greater baseline deformity may be at increased risk of developing PJD. If preoperative SVAs were similar, there likely would be a greater effect seen in this study. Lastly, follow-up timing for proximal junctional failure is limited by 2 years for our given data set at this time. However, even at the 2-year mark, we see that there is a significant difference in PJK between the 2 treatment groups. Similarly, Zaghloul et al. show that 1-year follow-up may be short, but at 2 years they found higher rates of PJF. Improving upon this data may lead to contributions of time to PJF in ligament augmentation if it were to eventually occur. With this limitation on follow-up time, we still gain insight on resistance to PJF in our ligament augmentation technique.

CONCLUSION

In summary, our results show that ligament augmentation in ASD surgery utilizing a novel technique with polyethylene tape is effective in slowing the progression of the PJA and lowering the risk for PJF and revision surgery. In turn, this may help patients avoid the risks and morbidity associated with revision surgery, while providing substantial cost savings to the healthcare system.

CONFLICT OF INTEREST

The authors have nothing to disclose.

REFERENCES


A Comparative Biomechanical Analysis of Various Rod Configurations Following Anterior Column Realignment and Pedicle Subtraction Osteotomy

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²Department of Orthopaedic Surgery, Sibley Gildenhorn Institute, Johns Hopkins University, Washington, District of Columbia, USA

Objective: The objective of this study was to compare the biomechanical differences of different rod configurations following anterior column realignment (ACR) and pedicle subtraction osteotomy (PSO) for an optimal correction technique and rod configuration that would minimize the risk of rod failure.

Methods: A validated spinopelvic (L1-pelvis) finite element model was used to simulate ACR at the L3–4 level. The ACR procedure was followed by dual-rod fixation, and for 4-rod constructs, either medial/lateral accessory rods (connected to primary rods) or satellite rods (directly connected to ACR level screws). The range of motion (ROM), maximum von Mises stress on the rods, and factor of safety (FOS) were calculated for the ACR models and compared to the existing literature of different PSO rod configurations.

Results: All of the 4-rod ACR constructs showed a reduction in ROM and maximum von Mises stress compared to the dual-rod ACR construct. Additionally, all of the 4-rod ACR constructs showed greater percentage reduction in ROM and maximum von Mises stress compared to the PSO 4-rod configurations. The ACR satellite rod construct had the maximum stress reduction i.e., 47.3% compared to dual-rod construct and showed the highest FOS (4.76). These findings are consistent with existing literature that supports the use of satellite rods to reduce the occurrence of rod fracture.

Conclusion: Our findings suggest that the ACR satellite rod construct may be the most beneficial in reducing the risk of rod failure compared to all other PSO and ACR constructs.

Keywords: Adult spinal deformity, Anterior column realignment, Multirod constructs, Finite element analysis, Rod fracture, Pedicle subtraction osteotomy

INTRODUCTION

Adult spinal deformity (ASD) is prevalent in up to 68% of the population and is associated with poor health-related quality of life.¹ There is an estimated 27.5 million people with ASD in the United States alone, and as life expectancy continues to increase, the number of people with ASD will also see a spike.²³ For ASD patients, pedicle subtraction osteotomy (PSO) is a common surgical procedure that shortens the spine posteriorly and uses 2 or more rods and pedicle screws to restore spinal alignment. However, there are serious complications associated with PSO including excessive bleeding and implant failure.⁴ Some studies estimate a 61% complication rate with the most common being rod fracture, with an occurrence of 22%.⁵⁻⁸ The spinal segment
is further stiffened with additional rods to reduce rate of implant failure, but the risk associated with excessive bleeding still remains.\(^9\)

To address this concern, anterior column realignment (ACR) has become a trusted, minimally invasive alternative to PSO. In an ACR procedure, an interbody cage is used to replace an intervertebral disc and the anterior longitudinal ligament (ALL) is released. ACR has shown similar radiographic correction as PSO, with lesser complications.\(^10,11\) Additionally, classifications of different ACR procedures make it a useful surgery in a variety of clinical situations.\(^12\) However, similar to PSO, rod constructs are used in ACR, meaning there are similar risks of implant failure. An \textit{in vitro} study done by La Barbera et al.\(^13\) concluded that bilateral posterior rod fixation following ACR surgery may not be enough to stabilize the operated region. Thus, the use of 4-rod constructs is recommended, just as in PSO.\(^14\) Literature suggests an optimal 4-rod construct configuration following PSO to reduce rate of rod fractures, but similar literature on optimal 4-rod configurations following ACR is sparse.\(^13,15\)

Thus, the objective of this study was to use finite element analysis (FEA) to suggest the most optimal procedure and rod configuration for ASD correction. For this purpose, 4 different rod configurations were investigated following ACR: dual-rod configuration, additional medial accessory rods (ACR-MED), additional lateral accessory rods (ACR-LAT), and additional short satellite rods (ACR-SAT). These rod combinations were chosen being among the common configurations seen in clinical practice. Also, these rods configurations have been investigated following PSO in our previous study.\(^15\) Thus this study simulated the same rod configurations following ACR to draw comparison among different rod configurations in PSO versus ACR.

**MATERIALS AND METHODS**

A previously validated osteo-ligamentous spinopelvic model (L1-pelvis) was used to simulate ACR at the L3–4 level in this study.\(^15-18\) The geometry of the initial model was based on computed tomography (CT) scans of a healthy 55-year-old adult male. The CT data were used to reconstruct the 3-dimentional (3D) geometry of the model in MIMICS (Materialize Inc., Leuven, Belgium). The 3D geometry of the model was meshed in IAF- MESH (University of Iowa, Iowa) and HyperMesh (Altair Engineering, Michigan, USA) software. The meshed parts were assembled and assigned material properties for computational analysis in Abaqus (Dassault Systemes, Simulia Inc., Providence, RI, USA). The cancellous bone in the pelvis and vertebrae was

<table>
<thead>
<tr>
<th>Component</th>
<th>Element type</th>
<th>Young modulus (MPa)</th>
<th>Poisson ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cortical bone</td>
<td>C3D8</td>
<td>12,000</td>
<td>0.3</td>
</tr>
<tr>
<td>Cancellous bone</td>
<td>C3D8</td>
<td>100</td>
<td>0.2</td>
</tr>
<tr>
<td>Pelvic cortical bone</td>
<td>C3D8</td>
<td>17,000</td>
<td>0.3</td>
</tr>
<tr>
<td>Pelvic cancellous bone</td>
<td>C3D8</td>
<td>10</td>
<td>0.2</td>
</tr>
<tr>
<td>Intervertebral disc</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nucleus</td>
<td>C3D8H</td>
<td>C1 = 0.12, C2 = 0.003, D1 = 0.0005</td>
<td>0.49</td>
</tr>
<tr>
<td>Annulus ground substance</td>
<td>C3D8</td>
<td>Hyperelastic (C10, 0.348; D1, 0.3)</td>
<td></td>
</tr>
<tr>
<td>Annulus fibers</td>
<td>Rebar</td>
<td>357–550</td>
<td></td>
</tr>
<tr>
<td>Ligaments</td>
<td>T3D2</td>
<td>Non-Linear</td>
<td></td>
</tr>
<tr>
<td>Apophyseal joints</td>
<td>Nonlinear, soft contact, GAPUNI elements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sacroiliac joints</td>
<td>Nonlinear, soft contact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACR cage (PEEK)</td>
<td>C3D8</td>
<td>3,600</td>
<td>0.25</td>
</tr>
<tr>
<td>Screw head (CoCr)</td>
<td>C3D4</td>
<td>241,000</td>
<td>0.3</td>
</tr>
<tr>
<td>Primary/supplementary rods</td>
<td>C3D8</td>
<td>241,000</td>
<td>0.3</td>
</tr>
<tr>
<td>TiAlV pedicle screw shaft</td>
<td>C3D4</td>
<td>11,500</td>
<td>0.3</td>
</tr>
</tbody>
</table>

ACR, anterior column realignment; PEEK, polyether ether ketone; CoCr, cobalt-chromium.
surrounded by an outer layer of cortical bone with a thickness of 1 mm and 0.5 mm, respectively.\textsuperscript{19-23} The intervertebral disc consisted of nucleus and annulus ground substances with fibers embedded in it. The ligaments in the model were represented using truss elements. The material properties for all the components were acquired from literature (Table 1).\textsuperscript{20,23,24}

1. FE Model of ACR Procedure

To simulate the ACR surgery at the L3–4 level, the intervertebral disc at the index segment was completely removed along with the ALL. Additionally, resection of the posterior elements (facets, lamina) was performed at L3–4 level.\textsuperscript{25} Next, a 30° hyperlordotic cage was inserted at the index segment and secured to L3 and L4 level by short titanium alloy (Ti\textsubscript{6}Al\textsubscript{4}V) screws, followed by L1–S1 bilateral pedicle screw posterior fixation using 5.5-mm pedicle screws with a length of 45 mm and cobalt-chromium (CoCr) rods with a diameter of 5.5 mm. The pedicle screw shaft was assigned a material property of Ti\textsubscript{6}Al\textsubscript{4}V whereas the screw head was assigned the property of CoCr.\textsuperscript{14} Additionally, the supplementary rods (accessory/satellite) were assigned the property of CoCr. The interaction between the screw shaft and bone was simulated by the “TIE” contact formulation to simulate the complete osteointegration of screw shaft with the bone. The rods were also constrained using the TIE formulation to the screw head. The interaction between cage-bone interface was simulated with a coefficient of friction of 0.2 using the surface-to-surface contact formulation. The same interactions were used in our previously study, simulating different rod configurations following PSO.\textsuperscript{25}

Overall, the ACR surgery was simulated with 4 different rod configurations (Figs. 1 and 2):

- A 30° hyperlordotic cage at L3–4 level and bilateral rod fixation from L1–S1. (ACR)
- A 30° hyperlordotic cage at L3–4 level and bilateral rod fixation from L1–S1 + short satellite rods at L3–4. In this configuration, primary rods are not connected to the L3–4 pedicle screws. (ACR-SAT)
- A 30° hyperlordotic cage at L3–4 level and bilateral rod fixation from L1–S1 + medially affixed accessory rods connected to the primary rods via connectors at L2–3 and L4–5 regions. (ACR-MED)
- A 30° hyperlordotic cage at L3–4 level and bilateral rod fixation from L1–S1 + laterally affixed accessory rods connected to the primary rods via connectors at L2–3 and L4–5 regions. (ACR-LAT)

![Fig. 1. Posterior view of the different anterior column realignment (ACR) rod configurations. (A) Bilaterally fixated ACR model (ACR). (B) Four-rod instrumented ACR model with short satellite rods at L3–4 (ACR-SAT). (C) Four-rod instrumented ACR model with medially affixed accessory rods (ACR-MED). (D) Four-rod instrumented ACR model with laterally affixed accessory rods (ACR-LAT).](https://doi.org/10.14245/ns.2142450.225)

![Fig. 2. Two lateral views of the anterior column realignment (ACR) model. The magnified views show the 30° hyperlordotic cage at L–4.](https://www.e-neurospine.org)
2. Boundary Conditions and Loading

The pelvis was constrained in all of the models. All of the models were subjected to a 400 N physiological compression load followed by a 7.5 Nm pure moment applied to the L1-superior endplate to simulate flexion/extension, lateral bending, and axial rotation.26

3. Data Analysis

The global ROM (L1–S1) for all of the models was analyzed. Also, the maximum von Mises stress in the rod for all of the rod configurations was used to calculate the factor of safety (FOS). FOS was determined by dividing the yield stress of CoCr by the maximum von Mises recorded for a given rod configuration. The higher the FOS lesser are the chances of rod fracture. The data for ACR rod configurations were also compared to the same rod configurations following PSO. The percentage change for ACR 4-rod constructs was calculated with respect to the dual-rod ACR construct while percentage change for PSO 4-rod constructs was calculated with respect to the dual-rod PSO construct.

\[
FOS = \frac{\text{CoCr yield stress}}{\text{maximum von Mises stress}}
\]

where, CoCr yield stress = 989 MPa.

RESULTS

1. Range of Motion

The predicted global ROM showed that the use of more rods correlated to the lower ROM as higher ROM was observed in the dual-rod ACR model when compared to the 4-rod constructs (Fig. 3). Under extension loading, the ACR-SAT, ACR-LAT, and ACR-MED showed similar changes in ROM with a 62% decrease for all models. Under flexion loading (clinically most crucial motion), the ACR-SAT model showed the greatest reduction in ROM with a 51% decrease compared to the ACR model. The ACR-LAT and ACR-MED models demonstrated a 48% and 41% decrease in ROM, respectively, when compared to the ACR model. Under all other loadings, the ACR-SAT generally showed the lowest percentage decrease in ROM compared to ACR-LAT and ACR-MED. The ACR-SAT, ACR-LAT, and ACR-MED models showed that ROM decreased by 34%, 40%, 51% under left bending and 25%, 29%, and 47% under right bending, respectively. The greatest changes in ROM were found under axial rotation conditions for both the ACR-LAT and ACR-MED models where there was a 66% and 68% decrease in left rotation and 70% and 69% decrease in right rotation, respectively. Meanwhile, the ACR-SAT model only showed a 44% and 46% decrease in left and right rotation, respectively.

2. Maximum Rod Stress

The maximum von Mises stress in rods was computed under all loading conditions (Fig. 4). The dual-rod ACR construct was associated with the highest maximum von Mises stress on the rods. All models except the ACR-SAT model showed the highest rod stresses under flexion loading. The ACR-SAT model, however, showed the highest rod stresses under left rotation. Extension loading consistently showed the lowest rod stresses for all models.

The location of the maximum rod stress and percentage differences of rod stress when compared to the ACR model are

![Fig. 3. Comparison of the instrumented L1–S1 global range of motion (ROM) for different loading directions and configurations. ACR, anterior column realignment; ACR-SAT, ACR-short satellite rods; ACR-LAT, ACR-lateral accessory rods; ACR-MED, ACR-medial accessory rods.](image-url)
summarized in Table 2. In the ACR model, it was found that the maximum von Mises stress occurred at the index segment. For the ACR-SAT model, the maximum stress was found at L5–S1 under flexion, right bending, and left bending and found at L1–2 under extension, right rotation, and left rotation. Additionally, the ACR-SAT model showed the highest reduction of rod stresses under all loadings except extension. A 42% decrease in rod stress was observed for extension for the ACR-SAT model compared to a 48% and 49% decrease for the ACR-LAT and ACR-MED models, respectively. Both the ACR-LAT and ACR-MED model demonstrated a 20% reduction under flexion loading while the ACR-SAT showed a 47% decrease when compared to the ACR model. The ACR-LAT model showed the lowest reduction in rod stresses under lateral bending and axial rotations with only a 32%, 25%, 17%, and 20% decrease found for left bending, right bending, left rotation, and right rotation, respectively. However, all 4-rod models showed a decrease in maximum rod stresses compared to the ACR model, and all maximum rod stresses were located on the primary rods.

The FOS was 3.35 in the ACR model. All 4-rod constructs

![Comparison of the maximum von Mises stress (MPa) found for the primary rods in the ACR, ACR-SAT, ACR-LAT, and ACR-MED models under all loading conditions. ACR, anterior column realignment; ACR-SAT, ACR-short satellite rods; ACR-LAT, ACR-lateral accessory rods; ACR-MED, ACR-medial accessory rods.]

Table 2. Values and locations of the maximum von Mises stress recorded on the rods for the 4-rod configurations tested

<table>
<thead>
<tr>
<th>Motion</th>
<th>ACR</th>
<th>ACR-SAT</th>
<th>ACR-LAT</th>
<th>ACR-MED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>277.3</td>
<td>-47.35%</td>
<td>-19.73%</td>
<td>-20.34%</td>
</tr>
<tr>
<td></td>
<td>ACR Index</td>
<td>L5–S1</td>
<td>Adjacent to domino</td>
<td>Adjacent to domino</td>
</tr>
<tr>
<td>Extension</td>
<td>200</td>
<td>-41.50%</td>
<td>-47.80%</td>
<td>-49.10%</td>
</tr>
<tr>
<td></td>
<td>ACR Index</td>
<td>L1–2</td>
<td>Adjacent to domino</td>
<td>Adjacent to domino</td>
</tr>
<tr>
<td>Right bending</td>
<td>228</td>
<td>-35.53%</td>
<td>-25.44%</td>
<td>-28.07%</td>
</tr>
<tr>
<td></td>
<td>ACR Index</td>
<td>L5–S1</td>
<td>Adjacent to domino</td>
<td>Adjacent to domino</td>
</tr>
<tr>
<td>Left bending</td>
<td>253</td>
<td>-41.50%</td>
<td>-32.41%</td>
<td>-34.51%</td>
</tr>
<tr>
<td></td>
<td>ACR Index</td>
<td>L5–S1</td>
<td>Adjacent to domino</td>
<td>Adjacent to domino</td>
</tr>
<tr>
<td>Right rotation</td>
<td>267</td>
<td>-36.33%</td>
<td>-20.30%</td>
<td>-24.72%</td>
</tr>
<tr>
<td></td>
<td>ACR Index</td>
<td>L1–2</td>
<td>Adjacent to domino</td>
<td>Adjacent to domino</td>
</tr>
<tr>
<td>Left rotation</td>
<td>260</td>
<td>-25.00%</td>
<td>-16.54%</td>
<td>-20.85%</td>
</tr>
<tr>
<td></td>
<td>ACR Index</td>
<td>L1–2</td>
<td>Adjacent to domino</td>
<td>Adjacent to domino</td>
</tr>
<tr>
<td>Factor of safety</td>
<td>3.35</td>
<td>4.76</td>
<td>4.17</td>
<td>4.20</td>
</tr>
</tbody>
</table>

Maximum values are reported for the ACR model, but percent difference with respect to the ACR model is reported for the ACR-SAT, ACR-LAT, and ACR-MED models. The factor of safety for each rod is also recorded.

ACR, anterior column realignment; ACR-SAT, ACR-short satellite rods; ACR-LAT, ACR-lateral accessory rods; ACR-MED, ACR-medial accessory rods.

https://doi.org/10.14245/ns.2142450.225
saw this number increase with the ACR-SAT model showing the greatest FOS at 4.76. The ACR-LAT and ACR-MED showed a FOS of 4.17 and 4.20, respectively.

3. Comparison of ACR and PSO Rod Configuration Results

The previous study done by Vosoughi et al. also recorded the percent change in both ROM and maximum von Mises rod stress between dual-rod and 4-rod constructs after PSO implementation (Tables 3 and 4). The global ROM decreased by 12%, 11%, 1%, 1%, and 7% for their lateral accessory rod construct and 16%, 15%, 8%, 8%, 8%, and 8% for their medial lateral rod construct under extension, flexion, left bending, right bending, left rotation, and right rotation, respectively. Additionally, their satellite rod construct showed a 4%, 11%, 54%, 61% decrease in global ROM while a 31% increase in global ROM during axial rotation loading. Overall, the PSO models demonstrated an average 6% and 11% decrease in ROM for the lateral and medial accessory rod configurations, respectively, but the ACR models showed a 52% and 56% average decrease in ROM. The PSO satellite rod model showed an average ROM decrease of 11% while the ACR satellite rod model showed an average ROM decrease of 44%.

The PSO models done by Vosoughi et al. additionally explored the change in maximum rod stress when compared to the 2-rod PSO construct (Table 4). However, their PSO constructs that utilized lateral accessory rod construct only showed a 4% decrease in flexion loading while showing a 5%, 0%, 3%, 11%, and 8% increase in maximum rod stress in extension, left bending, right bending, left rotation, and right rotation, respectively. Similar results were shown by the medial accessory rod constructs as the maximum rod stress decreased by 2%, 8%, 3%, and 3% in extension, flexion, left bending, and right bending but increased by 2% and 0% in left and right rotation, respectively. These are in contrast to much higher stress reductions.

Table 3. Values for the percentage change of global ROM of the 4-rod construct when compared to its respective ACR or PSO dual-rod model under all loading types

<table>
<thead>
<tr>
<th>Variable</th>
<th>Satellite rods</th>
<th>Lateral accessory rods</th>
<th>Medial accessory rods</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ACR model</td>
<td>PSO model</td>
<td>ACR model</td>
</tr>
<tr>
<td>Extension</td>
<td>-62%</td>
<td>-4%</td>
<td>-62%</td>
</tr>
<tr>
<td>Flexion</td>
<td>-51%</td>
<td>-11%</td>
<td>-48%</td>
</tr>
<tr>
<td>Left bending</td>
<td>-34%</td>
<td>-54%</td>
<td>-40%</td>
</tr>
<tr>
<td>Right bending</td>
<td>-25%</td>
<td>-61%</td>
<td>-29%</td>
</tr>
<tr>
<td>Left rotation</td>
<td>-44%</td>
<td>31%</td>
<td>-66%</td>
</tr>
<tr>
<td>Right rotation</td>
<td>-47%</td>
<td>31%</td>
<td>-70%</td>
</tr>
<tr>
<td>Average</td>
<td>-44%</td>
<td>-11%</td>
<td>-52%</td>
</tr>
</tbody>
</table>

The average percent difference is also reported.
ROM, range of motion; ACR, anterior column realignment; PSO, pedicle subtraction osteotomy.

Table 4. Values for the percentage change of maximum rod stress of the 4-rod construct when compared to its respective ACR or PSO dual-rod model under all loading types

<table>
<thead>
<tr>
<th>Variable</th>
<th>Satellite rods</th>
<th>Lateral accessory rods</th>
<th>Medial accessory rods</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ACR model</td>
<td>PSO model</td>
<td>ACR model</td>
</tr>
<tr>
<td>Extension</td>
<td>-42%</td>
<td>-10%</td>
<td>-48%</td>
</tr>
<tr>
<td>Flexion</td>
<td>-47%</td>
<td>-34%</td>
<td>-20%</td>
</tr>
<tr>
<td>Left bending</td>
<td>-42%</td>
<td>-12%</td>
<td>-32%</td>
</tr>
<tr>
<td>Right bending</td>
<td>-36%</td>
<td>-14%</td>
<td>-25%</td>
</tr>
<tr>
<td>Left rotation</td>
<td>-25%</td>
<td>-11%</td>
<td>-17%</td>
</tr>
<tr>
<td>Right rotation</td>
<td>-36%</td>
<td>-12%</td>
<td>-20%</td>
</tr>
<tr>
<td>Average</td>
<td>-38%</td>
<td>-16%</td>
<td>-27%</td>
</tr>
</tbody>
</table>

The average percent difference is also reported.
ACR, anterior column realignment; PSO, pedicle subtraction osteotomy.
predicted in the ACR models. The average stress reductions for all loadings in the ACR-LAT, ACR-MED, and ACR-SAT models were 27%, 30%, and 38%, respectively, while its PSO counterparts demonstrated a 4% increase and 2% and 16% decrease in maximum rod stress, respectively.

**DISCUSSION**

1. **Comparison of Rod Configurations in PSO Versus ACR**

Since PSO and ACR are among the most used procedures in correcting ASD, the dual and 4-rod configurations in either PSO or ACR were compared. Data from a previous study for dual and 4-rod constructs following PSO was used for comparison. Vosoughi et al.\textsuperscript{15} observed a decrease in global ROM after the inclusion of accessory and satellite rods to the dual-rod construct. Following PSO, they observed a reduction in global ROM of 11%, 6%, and 11% for satellite rod, lateral accessory rod, and medial accessory rod constructs, respectively. Comparatively, in our ACR model, a reduction in global ROM of 44%, 52%, and 56% was observed for satellite rod, lateral accessory rod and medial accessory rod constructs, respectively. The possible reason for less mobility in the ACR constructs could be the presence of a 30° hyperlordotic cage at L3–4 level which is secured to the L3 and L4 vertebrae via titanium alloy (TiAl6V) screws, providing additional stability to the ACR constructs.

Moreover, the study by Vosoughi et al.\textsuperscript{15} found that the use of satellite rods decreased the maximum rod stress by 16% while the use of lateral and medial accessory rods increased rod stress by 4% and decreased rod stress by 2%, respectively. In comparison, the addition of satellite rods to our ACR model decreased the maximum rod stress by 38% while the addition of lateral and accessory rods decreased the maximum rod stress by 27% and 30%, respectively.

A possible explanation for why the use of additional rods in ACR leads to higher reduction of rod stresses is the use of an interbody cage at the index segment, which has been shown to reduce rod stresses in PSO models as well.\textsuperscript{27} These comparisons suggest that the ACR constructs are generally better at reducing maximum rod stresses when compared to PSO. This conclusion is backed by a study done by Januszewski et al.\textsuperscript{27} which compared PSO to ACR and came to a similar conclusion. Additionally, the results from the study of Vosoughi et al.\textsuperscript{15} and present study point to satellite rod configurations as the recommended 4-rod construct in reducing the occurrence of rod fracture following PSO and ACR, respectively.\textsuperscript{22} However, in vitro and clinical studies would be required to support this recommendation. Moreover, comparisons among the ACR models of this study and PSO models of Vosoughi et al.\textsuperscript{15} must be interpreted considering that factors such as the length of the constructs and material for the screw-heads were not identical to our model. Although these factors may influence the results marginally, the conclusions should remain the same.

2. **Comparison of Dual Versus 4-Rod Constructs Following ACR**

The results of our numerical analyses demonstrate a decreased global L1–S1 ROM in all 4-rod constructs compared to the 2-rod construct, suggesting that the use of additional rods leads to a reduction in motion. Our results also indicated that the maximum von Mises stresses on the primary rods were considerably lower in all of the 4-rod constructs compared to the 2-rod construct. Our findings are consistent with the study of Januszewski et al.\textsuperscript{27} in which they observed the addition of rods led to a decrease in stresses on the primary rods. However, the comparison of rod configurations done in that study were different from the present study.

Godzik et al.\textsuperscript{1} conducted a multicenter retrospective study on rod fractures after ACR surgery and found that the rod fractures occurred adjacent to the ACR site. Our dual-rod ACR construct model also predicted higher stresses on the rods at the ACR site. Thus, a possible explanation for rod fracture at the ACR site could be the fact that the stress concentration occurs in this region.

However, with the addition of accessory rods, the high-stress regions on the primary rods migrated away from the ACR site to adjacent to the domino. Shen et al.\textsuperscript{28} also observed rod fractures adjacent to the domino after the addition of accessory rods. Although the incidence of rod fracture decreases with the addition of accessory rods, drawbacks such as the addition of more metal mass and hindrance in wound closure can become problematic, especially in the case of lateral accessory rods. In contrast, the satellite rod construct does not have such drawbacks but demonstrates a lower value of stresses and thus a higher FOS (4.76). The superiority of the satellite rod constructs over accessory rods in PSO and ACR could be possibly explained by the fact that the satellite rod construct eliminates the need for domino requirement for connecting additional rods to the primary rods. Thus, the notch effect is absent in satellite rod construct that tends to affect the stress on the primary rods. Additionally, satellite rods reduce the need for severe rod contouring of the primary rods. However, the primary rods in accessory rod construct require severe rod contouring that enhances the
risk for rod failure. In summary, our FEA assessed the global (L1–S1) ROM and maximum von Mises stress for a dual-rod construct and 3 different 4-rod constructs. The addition of accessory/satellite rods models resulted in higher reduction of maximum von Mises stress on the primary rods when used in the ACR models as compared to the PSO models. The ACR-SAT rod construct showed the highest FOS compared to all other ACR and PSO constructs. The findings of this study are consistent with the literature. Studies done by La Barbera et al. and Godzik et al. have observed that four-rod constructs successfully decrease rod fracture in ACR. Additionally, biomechanical study by Godzik et al., comparing dual versus satellite rod construct following ACR concluded satellite rod construct to be superior to dual-rod construct in terms of reduction of ROM and rod strain. However, the stresses on the rods were not evaluated neither a comparison for other rod configurations following ACR or PSO was not done in that study. Additionally, La Barbera et al. found that simple, 2-rod constructs suffered from much lower stability and higher rod fracture as compared to 4-rod constructs. The results of our computational study also predicted that 4-rod constructs experience lower maximum rod stresses when compared to the dual-rod model following both ACR and PSO. Thus, we highly recommend the use of supplementary rods to reduce the risk for implant failure in ACR and PSO. Due to relatively high failure rate of bilateral rods in PSO, supplementary rods are often used in PSO. On contrary, ACR is relatively a new technique, limited data are available to compare it with the failure rates of rods in PSO. In a recent study, failure rate of 4.4% was reported for rods following ACR. However, the study did not state that if the ACR constructs had supplementary rods or not. Thus, we believe more clinical data are required that compares failure in bilateral ACR construct vs bilateral rods plus supplementary rods.

3. Limitations

As with any computational study, our FEA also had certain limitations. This study did not consider the adverse effects of notches that are created on rods during manual rod contouring in a surgical environment. This study also did not simulate cyclic loading and thus how soon the rod construct will fail cannot be predicted. Another limitation of our study was that the model did not include paraspinal muscles. However, this limitation was addressed by the addition of follower loads that mitigate the muscle contractions and the bodyweight as proposed by Patwardhan et al. Other limitations of this FEA include the simplification of material properties and interactions between the different components of the model. Additionally, the use of rods with different materials that can influence the stress values of the rod constructs was not studied. However, this aspect should be explored and may prove to be beneficial in understanding the failure mechanism in rod constructs of different materials.

CONCLUSION

In conclusion, the 4-rod constructs consistently demonstrated lower maximum rod stresses when compared to the dual-rod model following both ACR and PSO. The results of our study suggest that the 4-rod constructs proved to be more effective in ACR models rather than PSO models. These findings were consistent with existing literature that suggested the occurrence of rod fracture decreased when 4-rod constructs were implemented. Additionally, the ACR-SAT model is associated with the highest FOS and lowest maximum rod stress when compared to all other models. ACR reduces the risk for complication compared to PSO, but the use of 4-rod constructs may also be more beneficial in ACR compared to PSO. However, additional in vitro and clinical studies are required to confirm that this type of construct is superior to other constructs tested in this study.

CONFLICT OF INTEREST

The authors have nothing to disclose.

ACKNOWLEDGMENTS

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Objective: In this study, we investigate about relationship between postoperative global sagittal imbalance and occurrence of mechanical complications after adult spinal deformity (ASD) surgery. In global sagittal balance parameters, odontoid-hip axis (OD-HA) angle and T1 pelvic angle (TPA) were analyzed.

Methods: Between January 2009 and December 2016, 199 consecutive patients (26 males and 173 females) with ASD underwent corrective fusion of more than 4 levels and were followed up for more than 2 years. Immediate postoperative and postoperative 2 years whole spine x-rays were checked for evaluating immediate postoperative OD-HA, TPA, and other parameters. In clinical outcomes, back and leg pain visual analogue scale, Scoliosis Research Society-22 spinal deformity questionnaire (SRS-22), Oswestry Disability Index (ODI), 36-item Short Form Health Survey (SF-36) were evaluated.

Results: Based on the occurrence of mechanical complications, a comparative analysis was performed for each parameter. In univariable analysis, mechanical complications were significantly much more occurred in OD-HA abnormal group (odds ratio [OR], 3.296; p < 0.001; area under the curve [AUC] = 0.645). In multivariable analysis, the result was much more related (OR, 2.924; p = 0.001; AUC = 0.727). In contrast, there was no significant difference between normal and the occurrence of mechanical complications in TPA. In clinical outcomes (normal vs. abnormal), the differences of SRS-22 (0.88 ± 0.73 vs. 0.68 ± 0.64, p = 0.042), ODI (-24.72 ± 20.16 vs. -19.01 ± 19.95, p = 0.046), SF-36 physical composite score (19.33 ± 18.55 vs. 12.90 ± 16.73, p = 0.011) were significantly improved in OD-HA normal group.

Conclusion: The goal of ASD surgery is to improve patient life quality through correction. In our study, TPA was associated with spinopelvic parameter and OD-HA angle was associated with health-related quality of life and complications. OD-HA angle is predictable factor for mechanical complications after ASD surgery.

Keywords: Cervical deformity, Thoracolumbar deformity, Posture balance, Complication
INTRODUCTION

Degenerative changes have the potential to greatly disrupt the normal curvature of the spine, leading to sagittal malalignment.\(^1\) The interaction between deformity and compensatory mechanisms depicts the final presentation of patients with adult spinal deformity (ASD).\(^2\) ASD is a debilitating condition that often requires surgical correction. In case of severe deformity, surgical treatment has been shown to offer better clinical and radiological outcomes compared with nonoperative treatments.\(^3\)\(^,\)\(^4\)

However mechanical failure, such as proximal junctional kyphosis (PJK), proximal junctional failure (PJF), or rod fracture is one of the most common complication and have substantial incidence in ASD surgery. There were many studies to investigate about risk factors or predictive factors of mechanical failure after ASD surgery.\(^5\)\(^,\)\(^6\)\(^,\)\(^7\) Among these radiologic parameters, increasing evidence implies that sagittal vertical axis (SVA) alone does not fully reflect sagittal malalignment, and global spinal pelvic alignment such as the T1 pelvic angle (TPA) assessment provides a more complete picture of the mechanisms for maintaining an upright posture.\(^8\) Thus, TPA is one of the global tilt parameters that is not affected by posture with good parameter for showing thoracolumbar alignment. On the other hand, as Le Huec et al.\(^9\) summarized the sagittal balance of the spine, odontoid-hip axis (OD-HA) angle includes a cervical alignment and have been proven to represent a constant global sagittal parameter which could show current patients posture according to gravity line.\(^10\)

TPA corresponds to the angle between a line connecting the center of T1 to the center of the femoral heads and the line to the center of the S1 endplate. It has been correlated with pelvic tilt (PT) and SVA, but does not account for pelvic incidence (PI) value. The TPA target value is under 14° and OD-HA angle is the angle between the vertical and the highest point of the dens connecting the center of the acetabulum.\(^11\)\(^,\)\(^12\) The OD-HA angle target value is +2° to -5°. This angle takes into account the position of the cervical spine, the thoraco-lumbar spine and pelvis, and may benefit an overall analysis and assessment of the risk of PJK after ASD surgery (Fig. 1).\(^13\)\(^,\)\(^14\)\(^,\)\(^15\)

Although both of these parameters have been proved to reflect global balance, there is little comparative study between these 2 parameters with regard to impact on mechanical complications or patients’ reported outcome.

Therefore, this study aimed to investigate which one would be a good representation of a patient’s global balance, to predict clinical outcome and the occurrence of mechanical complications after surgery for patients with ASD.

MATERIALS AND METHODS

1. Patient Population

We retrospectively reviewed patients with ASD who underwent posterior spinal fusion and instrumentation in 2 centers. Inclusion criteria were as follows: (1) patients who underwent surgical corrective surgery for ASD; (2) those with at least one of the following radiologic criteria: coronal Cobb angle more than 20°, SVA more than 5 cm, PT more than 25°, and/or tho-
racic kyphosis (TK) more than 60°; (3) those who underwent posterior spinal fusion and instrumentation as ASD surgery for more than 4 levels; and (4) those with a follow-up period of more than 24 months. Exclusion criteria were (1) patients with ASD secondary to syndromic, autoimmune, infectious, tumor, or other pathologic conditions; (2) those who underwent ASD surgery for fewer than 4 levels; and (3) those with a follow-up period less than 24 months.

Between February 2011 and January 2018, 454 patients with ASD underwent spinal surgery in our institute. Among them, we excluded 253 patients whose follow-up period was less than 2 years, and those who were not indicated for corrective surgery for ASD or whose surgery level was 3 levels or less. Finally, 199 consecutive patients with sagittal imbalance who underwent ASD surgery were included.

The demographics of patients, such as age, sex, bone mineral density (BMD), body mass index (BMI) were also conducted. Dual-energy x-ray absorptiometry scan to measure BMD at the spine and hip.

This study was approved by each hospital’s Institutional Review Board, and all participants provided written informed consent.

2. Radiological Assessments

In order to minimize the error, our study used the radiographic measurement manual introduced by the Scoliosis Research Society for whole spine radiograph imaging. A 36-inch whole spinal anteroposterior and lateral planar radiographs were collected at a distance of 72 inches from the film. The patient was standing in a comfortable position with the knees fixed, feet shoulder-width apart, looking straight ahead, elbows bent, and the knuckles of the supraclavicular fossa bilaterally. 18,19

All radiologic evaluation of OD-HA angle and TPA were conducted at 4 weeks postoperatively. The normal value of OD-HA angle is +2° to -5°, and normal value of TPA was under 14°. 13

And whole spine anteroposterior/lateral was performed at postoperatively 2 years to evaluate mechanical complications; such as PI, sacral slope, L1-S1 lordosis (LL), PT, SVA, and PI–LL. In order to reduce the error between individual measurements, a software program called Surgimap (https://www.surgimap.com/) was used. Also, level of fusion vertebra, uppermost instrumented vertebra (UIV) and lowest instrumented vertebra (LIV), and state of spinopelvic fixation (SPF) were conducted.

3. Mechanical Complications and Clinical Outcomes

Mechanical complications were defined as PJK or PJF, distal junctional kyphosis (DJK) or distal junctional failure, rod fracture, and implant-related complications. 20,21 Implant-related complications were defined as rod breakage or prominence, painful implant, screw breakage, loosening, or malposition, implant (interbody graft, hook, or set-screw) dislodgement. 20,22

In clinical assessments, patients reported pre- and postoperative 24-month back and leg pain using a visual analogue scale (VAS) scored from 0–10. The Oswestry Disability Index (ODI), Scoliosis Research Society-22 spinal deformity questionnaire (SRS-22), and 36-item Short Form Health Survey (SF-36) were used to measure health-related quality of life (HRQoL) measures.

4. Statistical Analysis

Statistical analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC, USA). Demographic and radiological data were compared using independent t-test and categorical variables using chi-square test or Fisher exact test. The logistic regression model is established with mechanical complications, PJK, PJF, and implant-related failure as outcome. The results are expressed as mean± standard deviation or number (percentage). A p-value less than 0.05 was considered statistically significant.

RESULTS

A total of 199 patients (26 males and 173 females) were retrospectively reviewed. The average age was 67.36 years (range, 49–80 years), and they were followed for an average of 30.54 months (range, 24–118 months).

Patients were classified according to normal TPA and OD-HA angle values. In the OD-HA angle group, 102 patients were in the normal range and 97 patients were in the abnormal range. In the TPA group had 59 patients with a normal range and 140 patients with an abnormal range. Although the OD-HA angle group showed no difference between normal and abnormal groups in demographic comparisons, the TPA group had a high average age and female ratio in the abnormal group. In radiological assessments, postoperative sagittal balance parameters were compared with fusion segment, UIV, LIV, and SPF via whole spine radiographs anteroposterior/lateral view for the 2 years after surgery. In postoperative parameters, in OD-HA angle groups, the normal group was on average close to normal compared to the abnormal group, but there was no statistical significance. On the other and, the TPA group showed differences in SVA, PI–LL, PI, and PT values, which were statistically
significant. For instrumentation, on average, there were 7 fusion segments, T11–12 for UIV, L5–S1 for LIV. In these results, both OD-HA angle and TPA were not different in normal and abnormal groups. In SPF, 91 patients were administered and 108 were not. In this result, OD-HA angle was significantly more frequent in the normal group, and there was no difference between the 2 groups in TPA (Table 1).

In clinical assessments, back and leg VAS related to pain and ODI, SRS-22, SF-36 related to functional impairment were analyzed. First of all, there was no significant difference in pain between normal and abnormal groups in the OD-HA angle group. However, there were significant differences in the change values of ODI, SRS-22, and SF-36 physical composite score related to the functional impairment. On the other hand, in the TPA group, there was no significant difference in functional impairment between normal and abnormal groups, but in the case of pain, the results were particularly favorable in the back pain, which was statistically significant (Table 2).

A simple comparison of the patients’ mechanical complication, PJK, PJF, and implant-related complication was conducted. In the entire patient population, the incidence of complications (n, %) was mechanical complication (84 of 199, 42.2%), PJK (80 of 199, 40.2%), PJF (43 of 199, 21.6%), implant-related complication (26 of 199, 13.1%). In simple comparison, there was no difference between normal and abnormal groups in TPA, but in C2HA, there was a difference between normal and ab-

Table 1. Demographic variables and radiographic data between OD-HA and TPA

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total (n = 199)</th>
<th>OD-HA</th>
<th>TPA</th>
<th>p-value</th>
<th>OD-HA</th>
<th>TPA</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
<td>Normal (n = 102)</td>
<td>Abnormal (n = 97)</td>
<td>p-value</td>
<td>Normal (n = 59)</td>
<td>Abnormal (n = 140)</td>
<td>p-value</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>67.36 ± 8.28</td>
<td>66.71 ± 8.23</td>
<td>68.05 ± 8.32</td>
<td>0.253</td>
<td>64.61 ± 8.97</td>
<td>68.52 ± 7.71</td>
<td>0.002*</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td>Male 26 (13.07)</td>
<td>Female 173 (86.93)</td>
<td>0.162</td>
<td>Male 13 (22.03)</td>
<td>Female 127 (90.71)</td>
<td>0.015†</td>
</tr>
<tr>
<td>BMD</td>
<td>-1.98 ± 1.05</td>
<td>-1.91 ± 1.03</td>
<td>-2.06 ± 1.07</td>
<td>0.299</td>
<td>-1.84 ± 0.85</td>
<td>-2.04 ± 1.12</td>
<td>0.170</td>
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<tr>
<td>BMI (kg/m²)</td>
<td>23.98 ± 2.61</td>
<td>23.71 ± 2.37</td>
<td>24.26 ± 2.82</td>
<td>0.133</td>
<td>24.26 ± 2.85</td>
<td>23.86 ± 2.50</td>
<td>0.328</td>
</tr>
<tr>
<td>Postoperative parameters</td>
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<td></td>
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</tr>
<tr>
<td>SVA</td>
<td>38.18 ± 39.98</td>
<td>34.73 ± 26.00</td>
<td>41.80 ± 50.60</td>
<td>0.221</td>
<td>26.98 ± 37.95</td>
<td>42.89 ± 40.01</td>
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</tr>
<tr>
<td>PI–LL</td>
<td>15.81 ± 12.82</td>
<td>14.69 ± 11.88</td>
<td>16.98 ± 13.70</td>
<td>0.208</td>
<td>9.60 ± 10.44</td>
<td>18.43 ± 12.86</td>
<td>&lt;0.001*</td>
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<tr>
<td>LL</td>
<td>35.03 ± 12.97</td>
<td>35.13 ± 13.43</td>
<td>34.92 ± 12.54</td>
<td>0.906</td>
<td>35.63 ± 11.67</td>
<td>34.78 ± 13.51</td>
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<td>PI</td>
<td>50.84 ± 11.91</td>
<td>49.82 ± 12.33</td>
<td>51.90 ± 11.42</td>
<td>0.220</td>
<td>45.22 ± 9.47</td>
<td>53.20 ± 12.07</td>
<td>&lt;0.001*</td>
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<tr>
<td>PT</td>
<td>24.01 ± 9.77</td>
<td>23.22 ± 8.39</td>
<td>24.85 ± 11.02</td>
<td>0.243</td>
<td>18.19 ± 8.38</td>
<td>26.47 ± 9.29</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>SS</td>
<td>27.53 ± 10.39</td>
<td>27.65 ± 10.54</td>
<td>27.40 ± 10.29</td>
<td>0.862</td>
<td>27.90 ± 8.69</td>
<td>27.37 ± 11.06</td>
<td>0.718</td>
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<td>Instrumentation</td>
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<td>Segments³</td>
<td>7.13 ± 2.41</td>
<td>6.95 ± 2.18</td>
<td>7.32 ± 2.62</td>
<td>0.282</td>
<td>7.12 ± 2.36</td>
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<td>UIV§</td>
<td>11.40 ± 2.54</td>
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<td>11.10 ± 2.81</td>
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<td>11.39 ± 2.60</td>
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<td>LIV§</td>
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<td>17.51 ± 1.37</td>
<td>17.52 ± 1.09</td>
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<td>SPF</td>
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<td>No</td>
<td>108 (54.27)</td>
<td>62 (60.78)</td>
<td>46 (47.42)</td>
<td>0.862</td>
<td>30 (50.85)</td>
<td>78 (55.71)</td>
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<td>Yes</td>
<td>91 (45.73)</td>
<td>40 (39.22)</td>
<td>52 (52.58)</td>
<td>0.29</td>
<td>29 (49.15)</td>
<td>62 (44.29)</td>
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</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation or number (%).
OD-HA, odontoind-hip axis angle; TPA, T1-pelvic angle; BMD, bone mineral density; BMI, body mass index; SVA, sagittal vertical axis; PI, pelvic incidence; LL, lumbar lordosis; PT, pelvic tilt; SS, sacral slope; UIV, upper most instrumented vertebra; LIv, lower most instrumented vertebra; SPF, spinopelvic fixation.

*p < 0.05, statistically significantly differences in independent t-test. †p < 0.05, statistically significantly differences in chi-square test (Fisher exact test).
³The number of instrumented vertebral segments. §Numbering the spine. It starts with 1 for C1 and ends with 18 for S1. Number 11 stands for T11, and number 17 for L5.
Predictive Value for Mechanical Complications: TPA vs. ODHA


Predictive Value for Mechanical Complications: TPA vs. ODHA


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Table 2. Clinical data between OD-HA versus TPA

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total (n=199)</th>
<th>OD-HA</th>
<th>TPA</th>
<th>p-value</th>
<th>OD-HA</th>
<th>TPA</th>
<th>p-value</th>
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<tr>
<td></td>
<td>Normal (n=102)</td>
<td>Abnormal (n=97)</td>
<td></td>
<td>Normal (n=59)</td>
<td>Abnormal (n=140)</td>
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<tr>
<td>Back VAS</td>
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<td>Preoperative</td>
<td>7.41 ± 1.98</td>
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<td>7.38 ± 1.94</td>
<td>0.860</td>
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<td>7.36 ± 2.08</td>
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<td>Postoperative</td>
<td>4.73 ± 2.47</td>
<td>4.51 ± 2.44</td>
<td>4.96 ± 2.48</td>
<td>0.200</td>
<td>4.12 ± 2.39</td>
<td>4.99 ± 2.46</td>
<td>0.023*</td>
</tr>
<tr>
<td>Changes</td>
<td>-2.68 ± 2.23</td>
<td>-2.92 ± 2.29</td>
<td>-2.42 ± 2.15</td>
<td>0.115</td>
<td>-3.41 ± 2.20</td>
<td>-2.37 ± 2.18</td>
<td>0.003*</td>
</tr>
<tr>
<td>Leg VAS</td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>6.76 ± 2.88</td>
<td>7.03 ± 2.82</td>
<td>6.49 ± 2.93</td>
<td>0.183</td>
<td>6.48 ± 3.00</td>
<td>6.89 ± 2.83</td>
<td>0.359</td>
</tr>
<tr>
<td>Postoperative</td>
<td>4.44 ± 2.90</td>
<td>4.40 ± 2.79</td>
<td>4.47 ± 3.03</td>
<td>0.861</td>
<td>3.71 ± 2.59</td>
<td>4.74 ± 2.98</td>
<td>0.022*</td>
</tr>
<tr>
<td>Changes</td>
<td>-2.33 ± 2.89</td>
<td>-2.63 ± 2.95</td>
<td>-2.01 ± 2.82</td>
<td>0.133</td>
<td>-2.76 ± 3.20</td>
<td>-2.14 ± 2.75</td>
<td>0.168</td>
</tr>
<tr>
<td>ODI</td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>60.02 ± 17.04</td>
<td>59.91 ± 15.81</td>
<td>60.14 ± 18.32</td>
<td>0.923</td>
<td>60.57 ± 14.77</td>
<td>59.79 ± 17.96</td>
<td>0.770</td>
</tr>
<tr>
<td>Postoperative</td>
<td>38.09 ± 19.85</td>
<td>35.19 ± 18.40</td>
<td>41.13 ± 20.93</td>
<td>0.034*</td>
<td>35.07 ± 17.03</td>
<td>39.36 ± 20.85</td>
<td>0.165</td>
</tr>
<tr>
<td>Changes</td>
<td>-21.94 ± 20.21</td>
<td>-24.72 ± 20.16</td>
<td>-19.01 ± 19.95</td>
<td>0.046*</td>
<td>-25.50 ± 17.05</td>
<td>-20.44 ± 21.28</td>
<td>0.107</td>
</tr>
<tr>
<td>SRS-22</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>2.38 ± 0.47</td>
<td>2.37 ± 0.49</td>
<td>2.39 ± 0.45</td>
<td>0.762</td>
<td>2.38 ± 0.47</td>
<td>2.38 ± 0.47</td>
<td>0.931</td>
</tr>
<tr>
<td>Postoperative</td>
<td>3.16 ± 0.72</td>
<td>3.25 ± 0.72</td>
<td>3.07 ± 0.72</td>
<td>0.081</td>
<td>3.29 ± 0.71</td>
<td>3.11 ± 0.72</td>
<td>0.120</td>
</tr>
<tr>
<td>Changes</td>
<td>0.78 ± 0.69</td>
<td>0.88 ± 0.73</td>
<td>0.68 ± 0.64</td>
<td>0.042*</td>
<td>0.91 ± 0.66</td>
<td>0.73 ± 0.70</td>
<td>0.092</td>
</tr>
<tr>
<td>SF-36 PCS</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>27.18 ± 17.95</td>
<td>25.44 ± 17.19</td>
<td>29.01 ± 18.62</td>
<td>0.162</td>
<td>27.04 ± 17.75</td>
<td>27.24 ± 18.10</td>
<td>0.943</td>
</tr>
<tr>
<td>Postoperative</td>
<td>43.38 ± 21.65</td>
<td>44.77 ± 20.90</td>
<td>41.91 ± 22.44</td>
<td>0.354</td>
<td>44.96 ± 20.50</td>
<td>42.71 ± 22.16</td>
<td>0.506</td>
</tr>
<tr>
<td>Changes</td>
<td>16.20 ± 17.93</td>
<td>19.33 ± 18.55</td>
<td>12.90 ± 16.73</td>
<td>0.011*</td>
<td>17.92 ± 16.22</td>
<td>15.47 ± 18.61</td>
<td>0.381</td>
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<tr>
<td>SF-36 MCS</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>35.85 ± 18.94</td>
<td>34.99 ± 18.35</td>
<td>36.76 ± 19.59</td>
<td>0.512</td>
<td>36.42 ± 20.74</td>
<td>35.61 ± 18.20</td>
<td>0.783</td>
</tr>
<tr>
<td>Postoperative</td>
<td>53.44 ± 23.28</td>
<td>55.02 ± 23.74</td>
<td>51.77 ± 22.80</td>
<td>0.326</td>
<td>54.03 ± 23.55</td>
<td>53.19 ± 23.25</td>
<td>0.818</td>
</tr>
<tr>
<td>Changes</td>
<td>17.59 ± 18.61</td>
<td>20.04 ± 20.01</td>
<td>15.02 ± 16.74</td>
<td>0.057</td>
<td>17.61 ± 19.25</td>
<td>17.58 ± 18.41</td>
<td>0.993</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation. OD-HA, odontoid-hip axis; TPA, T1-pelvic angle; VAS, visual analogue scale; ODI, Oswestry Disability Index; SRS, scoliosis research society; SF-36, 36-item Short Form Health Survey; PCS, physical component summary; MCS, mental component summary. *p < 0.05, statistically significantly differences in independent t-test.

normal groups. [Normal (n, %) vs. abnormal (n, %), p-value, mechanical complication (29 of 102, 28.4%) vs. (55 of 97, 56.7%), p < 0.001; PJK (28 of 102, 27.5%) vs. (52 of 97, 53.6%), p < 0.001; PJF (13 of 102, 12.8%) vs. 30 of 97, 30.9%, p = 0.002; implant-related complication (7 of 102, 6.9%) vs. 19 of 97, 19.6%, p = 0.008] (Table 3).

In order to investigate the correlation more closely, a logistic regression was constructed using mechanical complication, PJK, PJF, and implant-related complication as outcomes. In univariate analysis, OD-HA angle, age, BMD, BMI, postoperative SVA was related with postoperative mechanical complication. In multivariable analysis, OD-HA angle was related with postoperative mechanical complication (OR, 2.924; p = 0.001; AUC = 0.727) (Table 4, Fig. 2).

DISCUSSION

Recent studies on outcomes following ASD surgeries have shown high rates of complications (8.4%–42%) and revision rates (9%–17.6%). In our study, the overall mechanical complication occurred in about 42%, and revision rate was about 21%. This is slightly higher than other studies, but does not show much difference.

The occurrence of mechanical complications after ASD surgery has already been dealt with in several studies. In previous studies, thoracoplasty, posterior spinal fusion, combined an-
Table 3. Occurrence of complications between OD-HA versus TPA

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total (n = 199)</th>
<th>OD-HA</th>
<th>TPA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal (n = 102)</td>
<td>Abnormal (n = 97)</td>
<td>Normal (n = 59)</td>
</tr>
<tr>
<td>Mechanical complication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occurred</td>
<td>84 (42.2)</td>
<td>29 (28.4)</td>
<td>55 (56.7)</td>
</tr>
<tr>
<td>Not occurred</td>
<td>115 (57.8)</td>
<td>73 (71.6)</td>
<td>42 (43.3)</td>
</tr>
<tr>
<td>PJK</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occurred</td>
<td>80 (40.2)</td>
<td>28 (27.5)</td>
<td>52 (53.6)</td>
</tr>
<tr>
<td>Not occurred</td>
<td>119 (59.8)</td>
<td>74 (72.5)</td>
<td>45 (46.4)</td>
</tr>
<tr>
<td>PJF</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occurred</td>
<td>43 (21.6)</td>
<td>13 (12.8)</td>
<td>30 (300.9)</td>
</tr>
<tr>
<td>Not occurred</td>
<td>156 (78.4)</td>
<td>89 (87.3)</td>
<td>67 (690.1)</td>
</tr>
<tr>
<td>Implant related complication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occurred</td>
<td>26 (13.1)</td>
<td>7 (6.9)</td>
<td>19 (190.6)</td>
</tr>
<tr>
<td>Not occurred</td>
<td>173 (86.9)</td>
<td>95 (93.1)</td>
<td>78 (80.4)</td>
</tr>
</tbody>
</table>

Values are presented as number (%).
OD-HA, odontoid-hip axis; TPA, T1-pelvic angle; PJK, proximal junctional kyphosis; PJF, proximal junctional failure.
*p < 0.05, statistically significantly differences in chi-square test.

Fig. 2. Receiver operating characteristic (ROC) curve. Logistic regression (mechanical complication) in odontoid-hip axis angle. Odds ratio, 2.924; p = 0.001; area under the curve = 0.727.

Yagi et al.\(^1\) demonstrated that PJK can be minimized by postoperative normalization of global spine alignment and balance. Thus, we analyzed the difference according to whether normality of the postoperative global balance parameters TPA and OD-HA angle.

It is done through cervical curvature and lumbar lordosis in order to maintain a horizontal gaze and to free the upper limbs. It is important to analyze the problem statically and dynamically to understand the conditions required for this balance. Recently, several studies demonstrated that OD-HA angle was characterized the overall spinal balance, remains constant whatever the age and despite variations of lordosis (which decreases with loss of disc height) and the presence of compensation mechanism. And it hardly varies and is a good way to study the overall sagittal balance. It integrates the cervical spine and head and stays constant even in elderly if they are asymptomatic.\(^{13-15}\)

In Dubousset’s conus of economy (ref), the concept of balance includes from head to lower limbs. Therefore, the center of the head, that is, the center of C2, which is a line descending from the center of the external auditory meatus, can be regarded as the center of gravity. For that reason, OD-HA could be a good indicator of global balance in terms of the concept of Dubousset’s conus of economy that global balance is the ability of a person to stand upright with respect to gravity and that it is efficient to use the least energy. However, there are not many stud-
ies yet analyzed whether this indicator can predict mechanical complications in ASD.

Protopsaltis et al. introduced about TPA, and several studies reported it is related with clinical outcomes of patients' mechanical complication after ASD surgery. TPA is similar to the spinopelvic angle, allows the patient to check thoracolumbar alignment well, and is not affected by changes in the patient's posture, so it can be evaluated objectively. It can be assumed that there may be a downside to being difficult to know exactly in terms of the ability to stand in the Dubousset's conus of economy. In our study, the normality of TPA was related to the normal value of the spinopelvic parameter after surgery, and was related to the pain parameters. The sagittal spinopelvic parameters were related with chronic back pain and/or HRQoL. It can be seen that this contributed to the improvement of back pain by sufficiently making lordosis through correction of the sagittal imbalance. TPA has a certain value even in the stooping posture of the patient because the alignment of cervical spine and the horizontal gaze of the patient are missing. There was no research on whether these differences were related to the prediction of mechanical complications. In postoperative stooping posture related with global imbalance of the patient after ASD surgery, it may be due to pain, and there may be various reasons. Such as, PJK, DJK, pain, insufficient decompression. If the patient's global balance cannot be maintained due to various reasons, assuming that the OD-HA angle might come out

<table>
<thead>
<tr>
<th>Variable</th>
<th>Univariable (n = 199)</th>
<th>Multivariable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95% CI)</td>
<td>p-value</td>
</tr>
<tr>
<td>OD-HA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Abnormal</td>
<td>3.296 (1.830–5.938)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>TPA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Abnormal</td>
<td>1.642 (0.872–3.094)</td>
<td>0.125</td>
</tr>
<tr>
<td>Age</td>
<td>1.038 (1.000–1.077)</td>
<td>0.048*</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>0.832 (0.363–1.904)</td>
<td>0.663</td>
</tr>
<tr>
<td>BMD</td>
<td>0.634 (0.473–0.850)</td>
<td>0.002*</td>
</tr>
<tr>
<td>BMI</td>
<td>1.199 (1.066–1.349)</td>
<td>0.003*</td>
</tr>
<tr>
<td>SVA</td>
<td>1.009 (1.001–1.017)</td>
<td>0.020*</td>
</tr>
<tr>
<td>PI–LL</td>
<td>1.016 (0.994–1.039)</td>
<td>0.152</td>
</tr>
<tr>
<td>PI</td>
<td>1.005 (0.981–1.029)</td>
<td>0.690</td>
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<tr>
<td>LL</td>
<td>0.988 (0.967–1.010)</td>
<td>0.292</td>
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<tr>
<td>PT</td>
<td>1.013 (0.984–1.043)</td>
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</tr>
<tr>
<td>SS</td>
<td>0.995 (0.968–1.022)</td>
<td>0.702</td>
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<td>Fusion level segments</td>
<td>1.022 (0.909–1.148)</td>
<td>0.719</td>
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<tr>
<td>UIV</td>
<td>0.996 (0.891–1.113)</td>
<td>0.939</td>
</tr>
<tr>
<td>LIV</td>
<td>1.073 (0.836–1.377)</td>
<td>0.582</td>
</tr>
<tr>
<td>SPF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Done</td>
<td>1.731 (0.980–3.055)</td>
<td>0.059</td>
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</table>

OD-HA, odontoid-hip axis; OR, odds ratio; CI, confidence interval; AUC, area under the curve; TPA, T1 pelvic angle; BMD, bone mineral density; BMI, body mass index; PI, pelvic index; LL, lumbar lordosis; PT, pelvic tilt; SS, sacral slope; SVA, sagittal vertical axis; UIV, uppermost instrumented vertebra; LIV, lowest instrumented vertebra; SPF, spinopelvic fixation.

*p < 0.05, statistically significantly differences in logistic regression.
Table 5. Risk factors according to occurrence of complications

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total (n = 199)</th>
<th>Mechanical complication</th>
<th>Proximal junctional kyphosis</th>
<th>Proximal junctional failure</th>
<th>Implant related complication</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Normal (n = 115)</td>
<td>Occurred (n = 84)</td>
<td>Normal (n = 119)</td>
<td>Occurred (n = 80)</td>
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<tr>
<td>Demographics</td>
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<tr>
<td>Age</td>
<td>67.36 ± 8.28</td>
<td>66.36 ± 8.75</td>
<td>68.74 ± 7.42</td>
<td>0.045*</td>
<td>66.72 ± 8.45</td>
</tr>
<tr>
<td>Sex</td>
<td>0.676</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>26 (13.07)</td>
<td>14 (12.17)</td>
<td>12 (14.29)</td>
<td>14 (11.76)</td>
<td>12 (15.00)</td>
</tr>
<tr>
<td>Female</td>
<td>173 (86.93)</td>
<td>101 (87.83)</td>
<td>72 (85.71)</td>
<td>105 (88.24)</td>
<td>68 (85.00)</td>
</tr>
<tr>
<td>BMD</td>
<td>-1.98 ± 1.05</td>
<td>-1.78 ± 0.93</td>
<td>-2.26 ± 1.14</td>
<td>-1.81 ± 0.93</td>
<td>-2.24 ± 1.16</td>
</tr>
<tr>
<td>BMI</td>
<td>23.98 ± 2.61</td>
<td>24.49 ± 2.46</td>
<td>24.64 ± 2.67</td>
<td>23.59 ± 2.35</td>
<td>24.55 ± 2.87</td>
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<tr>
<td>Postoperative parameters</td>
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<tr>
<td>SVA</td>
<td>38.18 ± 39.98</td>
<td>32.36 ± 30.77</td>
<td>46.14 ± 49.01</td>
<td>31.44 ± 30.38</td>
<td>48.20 ± 49.57</td>
</tr>
<tr>
<td>PI-LL</td>
<td>15.81 ± 12.82</td>
<td>14.69 ± 12.11</td>
<td>17.34 ± 13.66</td>
<td>15.16 ± 12.08</td>
<td>16.77 ± 13.87</td>
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<tr>
<td>LL</td>
<td>35.03 ± 12.97</td>
<td>35.86 ± 13.28</td>
<td>33.89 ± 12.52</td>
<td>35.81 ± 13.10</td>
<td>33.85 ± 12.76</td>
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<tr>
<td>PI</td>
<td>50.84 ± 11.91</td>
<td>50.55 ± 12.49</td>
<td>51.23 ± 11.14</td>
<td>50.98 ± 12.52</td>
<td>50.62 ± 11.01</td>
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<tr>
<td>PT</td>
<td>24.01 ± 9.77</td>
<td>23.50 ± 8.75</td>
<td>24.72 ± 11.03</td>
<td>23.97 ± 8.92</td>
<td>24.07 ± 10.98</td>
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<tr>
<td>SS</td>
<td>27.53 ± 10.39</td>
<td>27.77 ± 10.21</td>
<td>27.20 ± 10.69</td>
<td>27.67 ± 10.10</td>
<td>27.31 ± 10.87</td>
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<td></td>
</tr>
<tr>
<td>Segments†</td>
<td>7.13 ± 2.41</td>
<td>7.08 ± 2.30</td>
<td>7.20 ± 2.56</td>
<td>7.01 ± 2.29</td>
<td>7.31 ± 2.58</td>
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<tr>
<td>UIV‡</td>
<td>11.40 ± 2.54</td>
<td>11.41 ± 2.39</td>
<td>11.38 ± 2.75</td>
<td>11.51 ± 2.37</td>
<td>11.23 ± 2.77</td>
</tr>
<tr>
<td>LIV‡</td>
<td>17.52 ± 1.18</td>
<td>17.48 ± 1.05</td>
<td>17.57 ± 1.34</td>
<td>17.51 ± 1.01</td>
<td>17.53 ± 1.40</td>
</tr>
<tr>
<td>SPF</td>
<td>0.063</td>
<td>0.081</td>
<td>0.084</td>
<td>0.063</td>
<td>0.081</td>
</tr>
<tr>
<td>No</td>
<td>108 (54.27)</td>
<td>69 (60.00)</td>
<td>39 (46.43)</td>
<td>71 (59.66)</td>
<td>37 (46.25)</td>
</tr>
<tr>
<td>Yes</td>
<td>91 (45.73)</td>
<td>46 (40.00)</td>
<td>45 (53.57)</td>
<td>48 (40.34)</td>
<td>43 (53.75)</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation or number (%).

BMD, bone mineral density; BMI, body mass index; SVA, sagittal vertical axis; PI, pelvic incidence; LL, lumbar lordosis; PT, pelvic tilt; SS, sacral slope; UIV, upper most instrumented vertebra; LIV, lower most instrumented vertebra; SPF, spino-pelvic fixation.

*p < 0.05, statistically significantly differences in independent t-test. †The number of instrumented vertebral segments. ‡Numbering the spine. It starts with 1 for Cl and ends with 18 for S1. Number 11 stands for T11, and number 17 for L5.
poorly and TPA remains constant, we studied whether this difference is different in the prediction of the patient's postoperative prognosis, that is, the mechanical complication. Results in our paper, OD-HA angle showed better results.

In several studies have reported that spinopelvic fixation affects the occurrence of PJK. In several studies reported SPF with iliac screws had high rates of lumbosacral fusion and low incidence of mechanical complications and revision surgery for PJK and reduced sacroiliac joint pain after multisegment spinal fusion after SPF with S2 alar iliac screws. Otherwise, some studies reported although the rigid SPF has decreased the risk for distal screw loosening, cyclic loading during daily activities might lead to fatigue of the posterior instrumentation, which can result in mechanical long-term complications such as non-union and eventually increase the risk of iliac screw loosening, development of PJK, PJF, and pseudarthrosis or pedicle screw loosening at L5–S1 level. In our study, statistical significance was not observed, but there was a force to SPF was related with development of mechanical complication especially PJK/PJF.

Also, many articles reported that older age, osteoporosis, and obesity are important risk factors of mechanical complication, PJK, and PJF. Lau et al. demonstrated that age was an important risk factor of PJK and PJF. And high BMI was related with worse sagittal alignment after ASD surgery and worse postoperative scores in HRQoL, and development of PJK. And osteoporosis was related with PJK and PJF. Especially, Yagi et al. reported low BMD (T score < -1.5) was a significant risk factor for the incidence of PJF. In our study, older age was related with occurrence of mechanical complication, BMD was related with all types of complications, and BMI was related with occurrence of mechanical complication and PJK. Sexual difference was not related with occurrence of complications. In radiological assessments, postoperative SVA was related with occurrence of mechanical complication and PJK. The other postoperative sagittal parameters were not related with complications. And UIV and LIV were similar between the 2 groups as T11–12 and L5–S1. In SPF, there is no significant difference between the 2 groups, but it shows approaching an acceptable significance level. The results of our study were also similar to previous other studies (Table 5).

The present study had several limitations. Because this was not a randomized and prospective study, but rather retrospective in design, a control population that received standard conservative care was not included. In addition, we did not control for selected surgical method or the period of preoperative conservative management. Meanwhile, the clinical score was not an absolute result because it was entirely patient specific. The images of the patients were measured by whole spine x-ray. Due to this, there may be some correction by the patient's position. Finally, the results of this study may be limited because it was conducted only in a single country and a single institution. Further studies are needed with multicenter, multinational, and multiracial data for more reliable results in the future.

**CONCLUSION**

The goal of ASD surgery is to improve patient life quality through correction. In our study, TPA was associated with spinopelvic parameter and clinical parameters related with pain, OD-HA angle was associated with clinical parameters with functional impairment and complications. OD-HA angle is predictable factor for mechanical complications after ASD surgery.

**CONFLICT OF INTEREST**

The authors have nothing to disclose.

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Clinical, Radiographic, and Genetic Analyses in a Population-Based Cohort of Adult Spinal Deformity in the Older Population

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Objective: This study aimed to identify the sagittal parameters associated with health-related quality of life and genetic variations that increase the risk of adult spinal deformity (ASD) onset in the older population.

Methods: We recruited 120 participants who had a sagittal vertical axis > 50 mm in a sagittal imbalance study. Sagittal radiographic parameters, cross-sectional area, and intramuscular fatty infiltration using the Goutallier classification in the paraspinal lumbar muscles were evaluated. Functional scales included the self-reported Oswestry Disability Index (ODI), 36-item Short Form Health Survey (SF-36), and visual analogue scales (VAS) for back and leg pain. We performed whole-exome sequencing and an exome-wide association study using the 100 control subjects and 63 individuals with severe phenotypes of sagittal imbalance.

Results: Pelvic incidence minus lumbar lordosis (PI–LL) mismatch was negatively associated with the SF-36 and positively correlated with ODI and VAS for back and leg pain. PI–LL was related to the quality and size of the paraspinal muscles, especially the multifidus muscle. We identified common individual variants that reached exome-wide significance using single-variant analysis. The most significant single-nucleotide polymorphism was rs78773460, situated in an exon of the SVIL gene (odds ratio, 9.61; p = 1.15 × 10⁻⁹).

Conclusion: Older age, higher body mass index, and a more significant PI–LL mismatch were associated with unfavorable results on functional scales. We found a genetic variation in the SVIL gene, which has been associated with the integrity of the cytoskeleton and the development of skeletal muscles, in severe ASD phenotypes. Our results help to elucidate the pathogenesis of ASD.

Keywords: Adult spinal deformity, Sagittal imbalance, Health-related quality of life, Genome-wide association study, SVIL, supervillin
INTRODUCTION

Adult spinal deformity (ASD) consists of a heterogeneous spectrum of abnormalities of the lumbar or thoracolumbar spine in adult patients. The causes of ASD range from de novo onset to progressive degeneration from a pre-existing deformity or accelerated development after previous spinal surgery. Spinal deformity has a substantially debilitating effect on patients’ general health. The prevalence of ASD is likely between 32% and 68% of the older population. An understanding of sagittal plane alignment has become essential for improving the health care of older adults.

The radiological parameters most closely related to pain and disability are sagittal vertical axis (SVA), pelvic tilt (PT), and the balance of pelvic incidence (PI), and lumbar lordosis (LL). In particular, PI–LL mismatch (hereafter, PI–LL) has been reported as a critical radiological parameter for reducing postoperative pain and disability. PI–LL is not correlated with preoperative symptoms because preoperative symptoms, including pain caused by nerve root compression, spinal instability, and spinopelvic alignment, are more complex than postoperative symptoms. Therefore, PI–LL is significantly correlated with postoperative lower back pain, but not with preoperative back pain.

With aging, the sagittal curvature of the normal spine tends to become stooped. Multiple age-related factors are implicated in this development, including reduced bone mineral density (BMD), spinal degeneration, reduced mobility and balance, and fatty degeneration of the paraspinal muscle. Individuals with ASD are usually characterized by back pain and an inability to stand erect. Significantly, low back pain while standing is more influenced by spinopelvic malalignment. Various radiological parameters have been reported to influence functional daily life activities.

In recent years, genetic involvement in the development of spinal deformities has garnered increasing recognition in clinical investigations of adolescent idiopathic scoliosis, and studies have provided new insights into the etiology and pathogenesis of spinal deformity. Genetic factors include a wide spectrum of variations, such as single-nucleotide polymorphisms (SNPs), which may contribute significantly to the etiology of spinal diseases; furthermore, environmental factors may additionally complicate the impact of genetic factors. Genetic studies using next-generation sequencing have remarkable potential as means of elucidating the genetic background of a disease.

We evaluated the influence of postural changes, osteoporosis, and the quality and size of the paraspinal muscles on health-related quality of life (HRQoL). In addition, we investigated the influence of genetic variants on ASD by applying whole-exome sequencing obtained from the participants of an observational cohort. This study aimed to examine the relationship of radiological parameters associated with HRQoL and to identify genetic variations associated with ASD.

MATERIALS AND METHODS

1. Cohort Design and Participants

This study was approved by the Institutional Review Board of Chonnam National University Hospital (approval number: CNUH-2016-127). To perform an analysis of genetic associations, we recruited 228 Korean participants over 65 years old who had a SVA of > 50 mm on whole-spine standing x-rays in the Korean Elderly Sagittal Imbalance Cohort Study. A total of 228 adults with a nonneutral sagittal standing posture were recruited from July 2016 to December 2016. The inclusion criteria were as follows: (1) Korean men and women aged ≥ 65 years and (2) an SVA of > 50 mm as measured from a whole-spine standing lateral radiograph (Fig. 1). Participants who had previously undergone spinal surgery or had been diagnosed with present spinal disease, including acute compression fracture, tumor, trauma, and infectious diseases, were excluded. Out of 228 participants, we assessed radiographic and clinical data in 120 consecutive adults (52.6%) who demonstrated a stooping standing posture with a higher severity of ASD according to SVA imbalance. Severe sagittal imbalance was defined as an SVA

![Fig. 1. Participants enrolled in the prospective cohort study. SVA, sagittal vertical axis; MRI, magnetic resonance imaging; BMD, bone mineral density; BMI, body mass index; SF-36, 36-item Short Form Health Survey; ODI, Oswestry Disability Index; VAS, visual analogue scale.](https://doi.org/10.14245/ns.2142544.272)
≥150 mm after adjusting for spinopelvic parameters. Whole-exome sequencing was performed in 63 participants (27.6%) with severe phenotypes of SVA (≥ 150 mm). Data regarding age, sex, body mass index (BMI), medical history, smoking status, alcohol consumption, nutritional status, education, occupation, and socioeconomic status were also obtained. This experiment was performed in accordance with the Declaration of Helsinki and with the approval of our institutional review board. All participants provided written informed consent.

Evaluations of the participants’ whole spine and general health were performed using sagittal radiographic parameters (SVA, thoracic kyphosis, PT, PI, LL, and PI–LL), blood laboratory examinations, BMD, cross-sectional area (CSA), and intramuscular fatty infiltration in the paraspinal lumbar muscles.2–10 The Goutallier classification system was used to grade intramuscular fatty infiltration in the paraspinal lumbar muscles such as the multifidus muscle (MF), erector spinae (ES; including the longissimus muscle and iliocostalis muscle), and psoas muscle (PS). According to the Goutallier grade using axial T2-weighted images (T2WI), grade 0 was defined as no fatty infiltration, grade 1 as some fatty streaking of the MF, grade 2 as less fat than muscle, grade 3 as equal amounts of fat and muscle, and grade 4 as more fat than muscle. The CSA of the paraspinal lumbar muscles was evaluated on T2WI magnetic resonance images. All measurements were performed with a 3.0-T magnetic resonance imaging device (Skyra, Siemens, Germany). Functional scales were assessed through self-reported Oswestry Disability Index (ODI), 36-item Short Form Health Survey physical component summary (SF-36 PCS), and visual analogue scale (VAS) for back and leg pain.

2. Whole-Exome Sequencing
Genomic DNA samples were purified from whole blood samples in 63 participants with severe sagittal imbalance (SVA ≥ 150 mm). The genomic DNA samples were used for exome capture with the SureSelect XT Human All Exon + UTR v5 exome kit (Agilent Technologies, Santa Clara, CA, USA). The Illumina HighSeq 2000 platform (Ilumina, San Diego, CA, USA) was used for sequencing with a mean coverage of 150x. We aligned the sequencing using the Burrows-Wheeler Aligner (bwa) algorithm and generated a binary alignment map file using the ‘bwa mem’ package.11 Following genome analysis tool kit best practices, the genomic variant call format file was generated by HaploType Caller after recalibration, and the result was annotated using ANNOVAR (annotate variation).12 As control data, we used 100 samples from the whole-genome sequencing dataset obtained from the general Korean adult cohort of the Korean Genome and Epidemiology Study (KoGES) (Supplementary Table 1).13

3. Statistical Analysis
Pearson correlation analysis was used to evaluate the relationships between ODI, VAS for back and leg pain, HRQoL, CSA, and sagittal radiographic parameters (SVA, PT, PI, LL, and PI–LL). Univariate and multivariate regression analyses were performed to examine the relationships between variables such as age, sex, BMI, radiographic parameters, CSA, and functional scales (SF-36 PCS). All statistical analyses were performed using MedCalc ver. 20 (MedCalc, Mariakerke, Belgium), and p-values of < 0.05 were considered to indicate statistical significance. We conducted linear mixed-model analyses in open-source PLINK/SEQ software (v0.10, released 14-July-2014) to test all associations. Plink/SEQ supports the -glm function for regression on every single variant and gene-based tests (low frequency and rare variants). Sex was used as a covariate in all statistical tests. The burden and SKAT-O (sequence kernel association test and the optimal unified test) were performed for low frequency and rare variants.

RESULTS
Sagittal imbalance was present in 120 persons (27 men and 93 women). The mean age was 70.57 ± 4.61 years (range, 65–80 years). Baseline patient demographics and information are represented in Table 1.

1. Univariate Regression Analysis of Sagittal Parameters, Disability, and Pain
Pearson correlation analysis demonstrated that the SF-36 PCS, ODI, and VAS for back pain and leg pain were correlated with PI–LL. Furthermore, PI–LL was negatively associated with SF-36 PCS (r = -0.252, p = 0.0056). ODI, VAS for back and leg pain, and outside working hours per week were positively correlated with PI–LL (r = 0.276, p = 0.0023; r = 0.284, p = 0.0017; and r = 0.181, p = 0.0478, p = 0.0095, respectively) (Table 2).

2. Univariate Regression Analysis of Sagittal Imbalance and CSA and Intramuscular Fatty Infiltration of the Paraspinal Muscles
Pearson correlation analysis showed that CSA and intramuscular fatty infiltration in paraspinal lumbar muscles correlated with recovery. In particular, the CSA of the MF was negatively...
associated with PI–LL \((r = -0.520, p < 0.0001)\), but not correlated with the CSA of the ES and PS. Spearman rank-order correlation analysis revealed that the Goutallier grade of the paraspinous muscles, such as ES \((\rho = 0.187, p = 0.0411)\), MF \((r = 0.215, p = 0.0186)\), and PS \((r = 0.302, p = 0.0008)\), were positively associated with PI–LL.

3. Univariate and Multivariate Regression Analysis of HRQoL

Multivariate analysis revealed that age, BMI, and PI–LL were negatively associated with HRQoL \((p = 0.0120, p = 0.0007, \text{and } p = 0.0308, \text{respectively})\) (Table 3). Based on our results, older age, higher BMI, and more significant PI–LL mismatch are significant predictors of poor HRQoL.

4. Association and Gene-Based Tests

To identify disease-associated genetic variants, we annotated 23,844 SNPs in the 63 patients with severe ASD phenotypes as well as the 100 control subjects based on the following filtration.
Table 3. Univariate and multivariate regression analyses of health-related quality of life

<table>
<thead>
<tr>
<th>Variable</th>
<th>Univariate analysis</th>
<th>Multivariate analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Coef. (95% CI)</td>
<td>p-value</td>
</tr>
<tr>
<td></td>
<td>β-coefficient</td>
<td>p-value</td>
</tr>
<tr>
<td>Age</td>
<td>-0.2089 (-0.3741 to -0.03077)</td>
<td>0.0221*</td>
</tr>
<tr>
<td>BMI</td>
<td>-0.2178 (-0.3822 to -0.04017)</td>
<td>0.0168*</td>
</tr>
<tr>
<td>PI–LL</td>
<td>-0.2515 (-0.4122 to -0.0769)</td>
<td>0.0056*</td>
</tr>
<tr>
<td>CSA-MF</td>
<td>0.1385 (-0.04179 to 0.3100)</td>
<td>0.1314</td>
</tr>
<tr>
<td>Goutallier-MF</td>
<td>-0.2421 (-0.4039 to -0.06575)</td>
<td>0.0077*</td>
</tr>
<tr>
<td>BMD</td>
<td>0.1687 (-0.01089 to 0.3377)</td>
<td>0.0655</td>
</tr>
</tbody>
</table>

Coef, regression coefficient; CI, confidence interval; BMI, body mass index; PI–LL, pelvic incidence minus lumbar lordosis; CSA-MF, cross-sectional areas-multifidus muscle; Goutallier-MF, Goutallier-multifidus muscle; BMD, bone mineral density.

*p < 0.05, statistically significant differences.

Table 4. Top 4 hits in the single-variant analysis of the severe sagittal imbalance phenotype

<table>
<thead>
<tr>
<th>rsID</th>
<th>Chr:position</th>
<th>Gene</th>
<th>REF</th>
<th>ALT</th>
<th>AF SVA</th>
<th>AF KoGES</th>
<th>p-value</th>
<th>A.A change</th>
<th>SIFT score</th>
</tr>
</thead>
<tbody>
<tr>
<td>rs78773460</td>
<td>chr10:29783908</td>
<td>SVIL</td>
<td>A</td>
<td>G</td>
<td>0.288</td>
<td>0.04</td>
<td>1.15 x 10^{-9}</td>
<td>Met→Thr</td>
<td>0.124</td>
</tr>
<tr>
<td>rs76740888</td>
<td>chr9:33796673</td>
<td>PRSS3</td>
<td>G</td>
<td>A</td>
<td>0.269</td>
<td>0.031</td>
<td>1.91 x 10^{-9}</td>
<td>Val→Ile</td>
<td>0.234</td>
</tr>
<tr>
<td>rs20092677</td>
<td>chr11:1093610</td>
<td>MUC2</td>
<td>C</td>
<td>G</td>
<td>0.127</td>
<td>0</td>
<td>6.08 x 10^{-7}</td>
<td>Thr→Arg</td>
<td>-</td>
</tr>
<tr>
<td>rs140991770</td>
<td>chr17:5036249</td>
<td>USP6</td>
<td>G</td>
<td>T</td>
<td>0.097</td>
<td>0</td>
<td>0.000007</td>
<td>Met→Ile</td>
<td>0.001</td>
</tr>
</tbody>
</table>

REF, reference allele; ALT, altered allele; AF, allele frequency; SVA, sagittal vertical axis; KoGES, Korean Genome and Epidemiology Study; SIFT, Sorting Intolerant From Tolerant.

*Fig. 2.* Manhattan plot for single-variant analysis. The y-axis shows -log10 (p-value) for common variants (minor allele frequency > 0.01), and the x-axis shows chromosomal positions for each variant. The threshold for statistical significance (p = 1 x 10^{-7}) is shown by the pink horizontal line.
criteria: (1) a depth of < 30 ×, (2) a Hardy-Weinberg p-value of < 10^{-3}, (3) a genotype-quality score of < 20, (4) synonymous/nonfunctional variants, (5) a SIFT (Sorting Intolerant From Tolerant) score of 1, and (6) a difference in allele frequency of more than 100 times that of the Exome Aggregation Consortium.

As the clinical information of the control subjects was limited, we only used sex as a covariate for the single-variant regression test. We ranked SNPs based on the -logP; the top 4 genetic variants are presented in individuals with severe sagittal imbalance (Table 4). These 4 top SNPs were rs78773460, rs76740888, rs200926577, and rs140991770. The most significant SNP was rs78773460, situated in an exon of the SVIL gene (odds ratio, 9.61; p = 1.15 × 10^{-9}). Supervillin (SVIL) genetic variations have been associated with the integrity of the cytoskeleton and the development of skeletal muscles. Fig. 2 shows a Manhattan plot obtained from the single-variant association tests: its x-axis shows the positions of genetic variants across the chromosomes. In contrast, the y-axis shows the negative log of the p-values (higher values on the y-axis thus indicate higher significance levels). Fig. 3 shows the quantile and quantile (Q-Q) plot for the single variant test (the relevant fit of the observed to expected significance values after applying the covariates).

**DISCUSSION**

ASD is defined as a complex spectrum of spinal diseases, including adult scoliosis, degenerative scoliosis, sagittal and coronal imbalance, and iatrogenic deformity, with or without spinal stenosis, that present in adulthood. We conducted a prospective observational cohort study to investigate the relationship of radiological parameters associated with HRQoL and to assess genetic factors in older adults with severe sagittal imbalance in Korea. Older age, higher BMI, and more significant PI–LL were significantly correlated with poor HRQoL. PI–LL was related to the quality and size of the paraspinal muscles, particularly the MF muscle. We found SNPs associated with the integrity of the cytoskeleton and the development of skeletal muscles in individuals with severe sagittal imbalance.

1. Sagittal Parameters

The prevalence of ASD among older people has been reported to be as high as 60%. Although most cases of ASD are asymptomatic, others have pain, neural symptoms, functional limitation, or disability. Sagittal imbalance has a significant relationship with HRQoL deterioration and surgical outcomes in symptomatic adults with degenerative spinal disorders; therefore, correction of sagittal imbalance is essential for achieving good surgical results and HRQoL. Among various sagittal alignment parameters, LL is the most changeable by positional adjustments or surgical operations, in contrast to PI, which is a fixed morphological parameter in each person. With the gradual loss of LL that occurs with aging, there is a further compensatory increase in PI as the pelvis rotates to maintain global spinal alignment. PI–LL was reported to be consistently associated with the quality of life of patients receiving operative treatment. Schwab et al. stated that one of the target spinopelvic

Fig. 3. Quantile and quantile plot for the single-variant analysis, showing the observed versus expected ordered -log10 (p-value) for the single-variant analysis.
parameters for corrective surgery was that PI–LL should be within ± 10°. PI–LL is not correlated with preoperative symptoms because preoperative symptoms, including pain caused by nerve root compression, spinal instability, and spinopelvic alignment, are more complex than postoperative symptoms. Therefore, PI–LL is significantly correlated with postoperative lower back pain, but not with preoperative back pain. However, this study revealed that PI–LL was negatively associated with HRQoL scores in older participants. ODI and VAS for back and leg pain were positively correlated with PI–LL. In individuals with sagittal imbalance, PI–LL had an impact on clinical symptoms, such as lower back and leg pain, back disability, and HRQoL.

2. Body Mass Index

BMI has been proposed as a potential risk factor for ASD. Obesity has traditionally been considered a protective factor against osteoporotic fractures. In contrast, Gonnelli et al. suggested that obesity might be a risk factor for fractures at various anatomical sites. Possible mechanisms include the production of inflammatory cytokines (interleukin-6 and tumor necrosis factor-alpha) in excessive abdominal fat and changes in 25-hydroxyvitamin D levels (a fat-soluble vitamin), which might lead to a reduction in bone strength. In the present study, higher BMI was correlated with poor HRQoL. This finding indicated that overweight individuals with sagittal imbalance had a poor HRQoL.

3. Bone Mineral Density

The most established metabolic factors related to ASD are osteoporosis and poor bone quality. Vertebral fractures and lower BMD may confer reduced structural integrity within the spinal column, thereby decreasing the capacity of the spine to withstand the load and leading to more significant kyphosis. Vertebral compression fractures, for which osteoporosis is the major risk factor, contribute to sagittal plane deformity. In the present study, a relationship between BMD and HRQoL was not found. Eight participants had experienced vertebral compression fractures; the lack of an observed association between vertebral compression fractures and sagittal imbalance most likely occurred because the number of vertebral fractures was too small to analyze. This discrepancy is likely related to the average characteristics of the older population recruited from the local community.

4. Quality and CSA of Muscles

The paraspinal and psoas muscles have been considered crucial for stabilizing the spinal column, and fatty infiltration in the muscle decreases the proportion of contractile tissue capable of producing force. Among the paraspinal muscles, including the MF, ES (including the longissimus muscle and iliocostalis muscle), and the PM, the lumbar MF muscle is essential for lumbar segmental stability, and defects in the paraspinal muscles are thought to be a cause of spinal deformity. Muscular atrophy due to denervation, disuse, or other causes can manifest as decreased muscular size and increased infiltration by fat or connective tissue. Parkkola et al. reported that the amount of fat infiltration in the paraspinal muscles was related to muscle atrophy in chronic low back pain. In the current study, the quality of lumbar muscularity—as shown by the degree of fatty change of the paraspinal muscles—was positively associated with PI–LL. An increase in fat infiltration in the lumbar paraspinal muscles was correlated with severe sagittal imbalance in older individuals. The CSA of the paraspinal muscle compartment, especially the MF muscle, was significantly lower in individuals with ASD, consistent with a previous report. Lee et al. insisted that spinal sagittal imbalance may cause a discrepancy in muscle degeneration between the extensor and flexor muscles. In contrast, we thought that reducing the size and fat infiltration of the paraspinal muscle could lead to sagittal imbalance and chronic low back pain. Further research is needed to determine which of these factors causes degenerative spinal deformity.

5. Primary Degenerative Sagittal Imbalance

Takemitsu et al. suggested that lumbar degenerative kyphosis (LDK) was caused by degenerative changes such as disk narrowing, collapsed vertebral bodies due to osteoporosis, or atrophy of the lumbar extensor muscles without prior surgery. Recently, Lee et al. suggested the name “primary degenerative sagittal imbalance” (PDSI), which includes degenerative sagittal imbalance of the whole spine of unknown origin and is associated with paraspinal muscle wasting. LDK may be regarded as a subgroup of PDSI related to agricultural occupations. Bouxsein et al. demonstrated that biomechanical stress on the spine increased vertebral wedging as BMD decreased, leading to more significant kyphosis. Hong et al. reported that lifestyle factors common in Asia, such as squatting and sitting on the floor, were major causes of degenerative spinal kyphosis, back pain, and poor quality of life. They demonstrated that farmers had more sagittal imbalance and back pain in proportion to their working hours. In the current study, PI–LL was positively correlated with outside working time \( r = 0.2357, p = 0.0095 \) (Table 2). Par-
ticipants who experienced increased outside working hours had more sagittal imbalance, but HRQoL and back VAS were not correlated with outside working time (p = 0.0657 and p = 0.3525, respectively).

6. Genetic Evaluation

Genetic variants associated with spinal disorders such as adolescent idiopathic scoliosis, ossification of the posterior longitudinal ligament, and intervertebral disc degeneration have been reported. Until now, the genetic contribution of the development of ASD has been unknown, and it has been thought that ASD is influenced only by biomechanical or socio-environmental factors. To our knowledge, this is the first report describing genetic variations associated with ASD. We acquired exome-sequencing data to investigate potential genetic factors associated with severe sagittal imbalance phenotypes. In the present study, the supervillin protein, which is encoded by the SVIL gene, was found to be associated with ASD. Supervillin (SVIL) is a large eukaryotic protein from the villin/gelsolin superfamily of actin-binding proteins involved in many cellular processes. SVIL binds both myosin II and filamentous actin and interacts with several cytoskeletal proteins; it is most abundant in skeletal muscle, followed by the heart and other organs containing secretory or smooth muscle cells. SVIL protein regulates all stages of cell motility, is involved in early cytokinesis, and plays a role in myofibrillar assembly. Knockdown experiments involving SVIL reduced cell division and increase cell death in HeLa and U2OS cell lines. This indicates that genetic variation in SVIL might be important for predicting the development of spinal deformity. Diseases associated with SVIL include myofibrillar myopathy, an autosomal recessive structural muscle disorder characterized by the onset of muscle pain, cramping, exercise fatigue, and then a slowly progressive course, leading to limited mobility in the first or second decades of life. Researchers recently demonstrated the importance of supervillin for the structural integrity of muscle fibers in humans. They showed that recessive loss-of-function mutations in SVIL caused a distinctive myopathy.

The current study did not prospectively evaluate genetic information from normal older adults without spinal deformity and those with severe ASD. We faced several obstacles, such as cost, recruitment of healthy volunteers, and research period limitations. We used 100 samples from a whole-genome sequencing dataset obtained from the general Korean adult cohort of the KoGES (Supplementary Table 1). As a result, one SNP (rs78773460) situated in an exon of the SVIL gene was detected in adults with severe ASD but not in the whole-genome sequencing dataset from KoGES. Due to the lack of a control group in this study and no previous whole-exome sequencing studies on the role of the SVIL gene in ASD, many questions remain about the genetics of ASD. The absence of normal candidate genes does not exclude a role for genetic variation at these loci in influencing severe ASD, but their contribution may be small compared with the genes identified. Nevertheless, this finding improved our understanding of ASD development and may assist in identifying a subgroup of severe ASD development.

Our results demonstrate the need for more extensive population-based longitudinal studies to illustrate the role of SVIL in the pathogenesis of ASD.

This study is subject to several limitations. First, it analyzed a small inhomogeneous older population recruited from the local community. Therefore, our results cannot be generalized as indicating factors associated with aggravated sagittal imbalance in other populations. Second, the genetic signature of ASD is not as clearly defined as is the case for Mendelian disorders. The application of a suitable model for the association was therefore limited. The nature of the disease favors the possibility of common diseases like heart disease, type II diabetes, and asthma, implying that genome-wide studies with much larger sample sizes that consider the effect size may be a more optimal method of detecting association signals. Third, as data from the control group were lacking, the case-control comparisons were not adequately controlled, and information from age/gender-matched control subjects with relevant covariates of clinical information was not incorporated into the regression analysis. The fact that the age group of the control population was largely biased to younger ages limited the usage of age as an acceptable covariate. The availability of information for normal controls may help to expand the interpretations of our results. However, a validation study applying targeted sequencing to a separate, older population of a relevant size that shows the effect of the risk allele on the susceptibility to the disease could be performed as an alternative approach.

CONCLUSION

PI–LL has been found to be useful for predicting individualized quality of life in inhomogeneous populations. Individuals with older age, higher BMI, and more significant PI–LL had poorer HRQoL. Reduced paraspinous muscle size and fat infiltration could lead to sagittal imbalance and chronic low back pain. The present study sought to find associations between SNPs

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and severe ASD phenotypes. Variants of the \textit{SVIL} gene, which have been associated with the structural integrity of muscle fibers in humans, were among the SNPs identified. Further studies that recruit proper control subjects and conduct clinical validation are needed for our findings to be clinically applicable.

**CONFLICT OF INTEREST**

The authors have nothing to disclose.

**ACKNOWLEDGMENTS**

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**SUPPLEMENTARY MATERIAL**

Supplementary Table 1 can be found via https://doi.org/10.14245/ns.2142544.272.

**REFERENCES**

**Supplementary Table 1.** Demographics of control cohort of the Korean Genome and Epidemiology Study (n = 100)

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>49.33 ± 7.93</td>
</tr>
<tr>
<td>Sex, male:female</td>
<td>40:60</td>
</tr>
<tr>
<td>Body mass index</td>
<td>21.41 ± 1.19</td>
</tr>
<tr>
<td>Smoking</td>
<td>21 (21)</td>
</tr>
<tr>
<td>Bone mineral density</td>
<td>0.36 ± 1.30</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>No formal education</td>
<td>30 (30.0)</td>
</tr>
<tr>
<td>Middle school graduation</td>
<td>27 (27.0)</td>
</tr>
<tr>
<td>High school graduation</td>
<td>32 (32.0)</td>
</tr>
<tr>
<td>University graduate or higher</td>
<td>11 (11.0)</td>
</tr>
<tr>
<td>Socioeconomic status</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>5 (5.0)</td>
</tr>
<tr>
<td>Middle</td>
<td>44 (44.0)</td>
</tr>
<tr>
<td>Low</td>
<td>47 (47.0)</td>
</tr>
<tr>
<td>Unknown</td>
<td>4 (4.0)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>96 (96.0)</td>
</tr>
<tr>
<td>Divorce</td>
<td>2 (2.0)</td>
</tr>
<tr>
<td>Bereavement</td>
<td>2 (2.0)</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation or number (%).
The Relationship Between Preoperative Cervical Sagittal Balance and Clinical Outcome of Patients With Hirayama Disease Treated With Anterior Cervical Discectomy and Fusion

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Department of Orthopaedics, Huashan Hospital, Fudan University, Shanghai, China

**Objective:** Anterior cervical discectomy and fusion (ACDF) is a common surgical method used to treat patients with Hirayama disease. And sagittal balance indexes have been revealed to be predictors of clinical outcomes in patients with cervical diseases, but their relationships with ACDF-treated Hirayama disease outcomes remain unknown. The purpose of this study is to evaluate the relationship of preoperative cervical sagittal balance indexes and clinical outcomes in ACDF-treated Hirayama disease patients.

**Methods:** Eighty patients with Hirayama disease treated by ACDF were reviewed retrospectively. Six cervical sagittal balance parameters were collected including Cobb angle, T1 slope, C1–7 sagittal vertical axis (SVA), C2–7 SVA, center of gravity of the head (CGH)-C7 SVA, range of motion. The recovery outcomes of the patients were divided into 2 groups by Odom score and the differences in recovery between the 2 groups were confirmed by electromyography. The correlation between imaging parameters and postoperative outcome was evaluated with logistic regression. The receiver operating characteristic (ROC) curve and area under the ROC curve (AUC) were used to evaluate the significant result of logistic regression and the optimal diagnostic value.

**Results:** Only 2 parameters, Cobb angle and CGH-C7 SVA, showed statistical correlation with the postoperative outcome assessment by logistic regression. Six cervical sagittal balance parameters were collected including Cobb angle, T1 slope, C1–7 sagittal vertical axis (SVA), C2–7 SVA, center of gravity of the head (CGH)-C7 SVA, range of motion. The recovery outcomes of the patients were divided into 2 groups by Odom score and the differences in recovery between the 2 groups were confirmed by electromyography. The correlation between imaging parameters and postoperative outcome was evaluated with logistic regression. The receiver operating characteristic (ROC) curve and area under the ROC curve (AUC) were used to evaluate the significant result of logistic regression and the optimal diagnostic value.

**Conclusions:** A larger Cobb angle and smaller CGH-C7 SVA seemed to correlate with a better postoperative outcome. These 2 factors could be used to predict the outcome of surgical treatment of Hirayama disease preoperatively.

**Keywords:** Cobb angle, CGH-C7 SVA, Sagittal balance, Hirayama disease, Clinical outcome

**INTRODUCTION**

Hirayama disease is a progressive disease caused by compression of anterior horn of cervical spinal cord under cervical flexion. It is mainly seen in young men of Asian descent. The onset age is generally less than 20 years old.\(^1\) The patients were mainly manifested as asymmetric muscle weakness and atrophy at the distal extremity, leaving them with different degrees of hand and forearm dysfunction.\(^4\) For some patients with early onset, short course of disease, and mild spinal cord atrophy, nonurgical treatment like neck brace can be used. While surgical treatment is recommended for patients with ineffective conservative
treatment and rapid progress of symptoms. And the operation effect is good, most patients' condition no longer progress. Studies have shown that sagittal balance of cervical spine exerts a significant impact on the prognosis of patients undergoing spinal surgery. And compared with normal people, patients with Hirayama disease have differences in sagittal balance parameters of cervical spine, and surgery can reduce this difference. Many factors were confirmed associated with progression and poor prognosis of Hirayama disease, however, the relationship between the postoperative effect and the sagittal balance of cervical spine has not been studied. Sagittal imbalance of spine has been proven to be correlated with many other diseases such as cervical spondylosis, ossification of the posterior longitudinal ligament. The purpose of this study is to analyze the correlation between the sagittal balance parameters of cervical spine and the postoperative outcomes of Hirayama disease.

MATERIALS AND METHODS

1. Patients

The data of patients with Hirayama disease who were diagnosed and treated surgically in authors' institution from August 2010 to February 2019 were retrospectively analyzed.

1) Inclusion criteria: (1) the diagnosis was clear, with typical amyotrophy and weakness of the distal upper limbs; (2) flexion position magnetic resonance imaging showed that the epidural space on the dorsal side of the spinal cord widened, vascular emptiness could be seen in it, and the corresponding segment of the cervical spinal cord was obviously compressed; (3) electromyography (EMG) showed that the number of multipoint motor units of thenar muscle and/or hypothenar muscle was less than the normal value; (4) conservative treatment such as neck brace was ineffective for 3 months; (5) the disease progressed rapidly and significantly affected the life of the patients.

2) Exclusion criteria: (1) unclear diagnosis; (2) improvement of symptoms within 3 months after neck brace treatment; (3) local infection in neck operation area or infection in other parts of the body; (4) titanium metal allergy. A total of 80 cases were enrolled, and the surgical procedures were performed by doctors in the same specialty group (Fig. 1).

2. Operation

The patient was placed in a flat position after general anesthesia, the right lateral incision of the anterior neck was taken, which was approximately 3.5 cm in length, and the anterior vertebra was exposed along the inner edge of the sternocleidomastoid muscle, and the operation segment was determined after fine-needle positioning. The anterior cervical distractor properly opened the intervertebral space and removed the intervertebral disc of the target segment to the posterior edge of the vertebral body to expose the posterior longitudinal ligament. The posterior longitudinal ligament was preserved, the endplate cartilage was removed with curette, and the interbody fusion device with appropriate height and artificial bone was placed into the intervertebral space. Titanium plate fixation was placed in front of the corresponding vertebral body after decompression of the intervertebral space at all target segments. Close the incision layer by layer after placing the drainage. The drainage tube was removed 48 hours after operation. The neck brace was fixed and immobilized for 4–6 weeks.

Fig. 1. A 20-year-old male patient underwent anterior cervical discectomy and fusion because of ineffective conservative treatment in the diagnosis of Hirayama disease. (A) Muscular atrophy of distal upper extremity. (B-D) Preoperative lateral, hyperflexion, and hyperextension x-ray. (E-G) Preoperative neutral, flexed T2-weighted magnetic resonance imaging on sagittal plane and flexed horizontal plane. (H, I) Frontal and lateral views in x-rays 5 years after operation.
3. Radiographic Assessment

In order to minimize the error, the measurement was carried out by 2 doctors independently, and the final results were averaged. The preoperative and postoperative sagittal balance index of cervical spine was measured on the lateral x-ray, and the required measurement indexes were defined as follows (Fig. 2).

Make a horizontal line under the inferior endplate of C2 and C7, and then make 2 vertical lines respectively. The angle between the 2 vertical lines is called Cobb angle. T1 slope is the angle between the superior endplate of T1 and the horizontal line. Make a vertical line at the anterior edge of C1 body, and the distance from the posterior upper corner of C7 to this vertical line is called C1–7 sagittal vertical axis (SVA). Make a vertical line in the center of C2 body, and the distance from the posterior upper corner of C7 to this vertical line is called C2–7 SVA. Make a vertical line at the front edge of the external auditory meatus, and the distance from the posterior upper corner of C7 to this vertical line is called center of gravity of the head (CGH)-C7 SVA. The difference of Cobb angle between hyperextension and hyperflexion was range of motion (ROM).

4. Follow-up and Evaluation of Clinical Status

All surgical patients were followed up by 2 professionally trained clinicians in the outpatient clinic. X-ray of lateral cervical verte-

Table 1. Selected Brief-Michigan Hand Questionnaire

<table>
<thead>
<tr>
<th>Domain</th>
<th>Item</th>
<th>5</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function</td>
<td>Overall, how well did your hand work?</td>
<td>Very good</td>
<td>Good</td>
<td>Fair</td>
<td>Poor</td>
<td>Very poor</td>
</tr>
<tr>
<td>Activities of daily living</td>
<td>How difficult was it for you to hold a frying pan?</td>
<td>Not at all difficult</td>
<td>A little difficult</td>
<td>Somewhat difficult</td>
<td>Moderately difficult</td>
<td>Very difficult</td>
</tr>
<tr>
<td>Activities of daily living</td>
<td>How difficult was it for you to button a shirt?</td>
<td>Not at all difficult</td>
<td>A little difficult</td>
<td>Somewhat difficult</td>
<td>Moderately difficult</td>
<td>Very difficult</td>
</tr>
<tr>
<td>Work</td>
<td>How often were you unable to do your work in the last week because of your hands/wrists?</td>
<td>Never</td>
<td>Rarely</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>Work</td>
<td>How often did you take longer to do tasks in your work because of problems with your hands/wrists?</td>
<td>Never</td>
<td>Rarely</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>Satisfaction with the motion of your fingers</td>
<td>Very satisfied</td>
<td>Somewhat satisfied</td>
<td>Fair</td>
<td>Somewhat dissatisfied</td>
<td>Very dissatisfied</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>Satisfaction with the motion of your wrist</td>
<td>Very satisfied</td>
<td>Somewhat satisfied</td>
<td>Fair</td>
<td>Somewhat dissatisfied</td>
<td>Very dissatisfied</td>
</tr>
</tbody>
</table>

Table 2. Odom scoring criteria

<table>
<thead>
<tr>
<th>Classification</th>
<th>Option</th>
<th>Criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ideal</td>
<td>A</td>
<td>All preoperative symptoms were relieved and daily life was not limited.</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>Leave mild preoperative symptoms, daily life was not significantly affected.</td>
</tr>
<tr>
<td>Poor</td>
<td>C</td>
<td>Some of the preoperative symptoms were relieved, but life was obviously affected.</td>
</tr>
<tr>
<td></td>
<td>D</td>
<td>The symptoms have not changed or worse.</td>
</tr>
</tbody>
</table>

Fig. 2. Sagittal balance parameters of cervical spine. SVA, sagittal vertical axis; CGH, center of gravity of the head.
brae after surgery was included for imaging evaluation. The clinical assessment was based on the Odom scale and the Selected Brief-Michigan Hand Questionnaire (SB-MHQ). SB-MHQ was described as Table 1. Divided into A, B, C, and D 4 levels, a Odom score of A or B was defined as the ideal improvement of postoperative symptoms, and the rest was defined as the poor improvement (Table 2).

5. EMG Parameters
All neurophysiological measurements were performed by a Nihon Kohden MEB-940 EMG unit (Tokyo, Japan). The oscilloscope was scanned at a rate of 5 msec/cm with a magnification of 200–500 volts/cm, and the room temperature was controlled at 25°C. The skin temperature of the forearm was kept between 32°C and 34°C. To exclude the effect of intermeasurer variation, the same experienced neurophysiologist performed all tests. The median nerve was stimulated at the wrist and elbow. The ulnar nerve was stimulated at the wrist, above and below the elbow. During the motor nerve examination, the maximal compound muscle action potential (CMAP) values of the abductor pollicis brevis (APB) and abductor digiti minimi (ADM) were recorded during stimulation of the median and ulnar nerves, respectively. We also recorded the fibrillation and positive sharp wave of APB and ADM pre- and postoperative, presented as the number of plus signs.

6. Statistical Analysis
Stata 16.0 (StataCorp LLC, College Station, TX, USA) was used for all the statistical calculation. We divided the patients into 2 groups according to the Odom score, the ideal improvement group and the poor improvement group. Then the basic situation and sagittal balance parameters of cervical spine pre- and postoperation were compared between the 2 groups. T-test was used for continuous variables and chi-square test was used for discrete variables. Logistic regression was used to analyze the correlation between the 5 parameters of sagittal balance of cervical spine and the Odom score of postoperative curative effect. Whether the improvement of postoperative symptoms is ideal or not is regarded as the dependent variable, and the sagittal balance parameter of the cervical vertebra is the independent variable. The value of test level α is 0.05 on both sides. For the positive results obtained from the analysis, we plotted the correlation curve with the Odom score as the horizontal coordinate. The positive results obtained by logistic regression analysis and their judgment threshold were tested and quantitatively analyzed by the receiver operating characteristic (ROC) curve and the area under the curve (AUC).

RESULTS

1. Radiographic Assessment
Six of 80 were excluded because preoperative EMG data could not be obtained, 5 withdrew from follow-up halfway for personal reasons, and finally, only 69 (86.25%; 65 males, 4 females) had complete follow-up data. The follow-up time range 2.16 to 10.38 years (5.17 ± 1.76 years). The preoperative Cobb angle range -28.90° to 27.00° (3.95° ± 10.93°), T1 Slope range 4.50 to 43.30 mm (21.73 ± 7.63 mm), C1–7 SV A range 0.00 to 56.80 mm (31.33 ± 12.60 mm), C2–7 SV A range -7.69 to 44.02 mm (18.91 ± 10.17 mm), C2–7 SV A range -7.69 to 44.02 mm (18.91 ± 10.17 mm), CGH–C7 SV A was -17.73 to 45.57 mm (15.92 ± 14.87 mm), and ROM was 24.20° to 109.60° (69.37° ± 17.34°). Comparing the sagittal balance parameters of cervical spine before and after operation, we could find that there are obvious differences between some parameters, such as Cobb angle, T1 slope, and CGH–C7 SV A (Table 3). The differences between radiological parameters indicate that the operation has successfully interfered with the balance of the cervical sagittal

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cobb angle (°)</td>
<td>3.95 ± 10.93</td>
<td>10.72 ± 10.27</td>
<td>0.019*</td>
</tr>
<tr>
<td>T1 Slope (°)</td>
<td>21.73 ± 7.63</td>
<td>25.05 ± 6.52</td>
<td>0.007*</td>
</tr>
<tr>
<td>C1–7 SVA (mm)</td>
<td>31.33 ± 12.60</td>
<td>32.14 ± 15.07</td>
<td>0.731</td>
</tr>
<tr>
<td>C2–7 SVA (mm)</td>
<td>18.91 ± 10.17</td>
<td>15.47 ± 10.82</td>
<td>0.057</td>
</tr>
<tr>
<td>CGH–C7 SVA (mm)</td>
<td>15.92 ± 14.87</td>
<td>9.81 ± 17.03</td>
<td>0.026*</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation.
SVA, sagittal vertical axis; CGH, center of gravity of the head.
*p < 0.05, statistically significant difference.

<table>
<thead>
<tr>
<th>SB-MHQ domains</th>
<th>Preoperative</th>
<th>Final follow-up</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function</td>
<td>2.01 ± 0.89</td>
<td>3.15 ± 0.97</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Activities of daily living</td>
<td>5.21 ± 1.09</td>
<td>5.91 ± 1.24</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Work</td>
<td>4.65 ± 1.34</td>
<td>5.99 ± 1.56</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>5.17 ± 1.35</td>
<td>5.42 ± 1.45</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Total</td>
<td>17.04 ± 4.32</td>
<td>20.47 ± 4.98</td>
<td>&lt; 0.001*</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation.
*p < 0.05, statistically significant difference.
plane, which is consistent with our previous studies.9

2. Evaluation of Postoperative Curative Effect

Imaging evaluation: lateral x-ray of cervical vertebra showed that the position of internal fixation was satisfactory in all cases, and there was no loosening or fracture of internal fixation. As for clinical evaluation of patient status before and after surgery, the hand functional scores in Table 4 suggested a remarkable progress in patient recovery. During the postoperative follow-up for Odom scoring, 69 patients were scored as follows: A, 7 cases; B, 25 cases; C, 37 cases; and no cases were evaluated as D. Besides, we reconfirmed the existence of differences between

Table 5. Comparison of EMG before and after operation between the ideal improvement and poor improvement groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Ideal development</th>
<th>Poor development</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preoperative</td>
<td>Postoperative</td>
<td></td>
</tr>
<tr>
<td>CMAP (median nerve)</td>
<td>9.38 ± 2.84</td>
<td>13.71 ± 3.38</td>
<td>0.009*</td>
</tr>
<tr>
<td>CMAP (ulnar nerve)</td>
<td>5.30 ± 2.97</td>
<td>8.65 ± 3.36</td>
<td>0.001*</td>
</tr>
<tr>
<td>Amount of fibrillation and positive sharp wave (APB)</td>
<td>0.74 ± 0.71</td>
<td>0.25 ± 0.44</td>
<td>0.003*</td>
</tr>
<tr>
<td>Amount of fibrillation and positive sharp wave (ADM)</td>
<td>1.11 ± 0.89</td>
<td>0.40 ± 0.50</td>
<td>0.582</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation.
EMG, electromyography; CMAP, maximal compound muscle action potential; APB, abductor pollicis brevis; ADM, abductor digiti minimi.
*p < 0.05, statistically significant difference.

Fig. 3. The relationship between postoperative electromyography and Odom score. (A) Odom score and CMAP in median nerve. (B) Odom score and CMAP in ulnar nerve. (C) Odom score and amount of sharp wave. CMAP, maximal compound muscle action potential; APB, abductor pollicis brevis. Odom score: A, All preoperative symptoms were relieved and daily life was not limited; B, Leave mild preoperative symptoms, daily life was not significantly affected; C, Some of the preoperative symptoms were relieved, but life was obviously affected.
the 2 groups using EMG (Table 5). The results suggested no significant difference in the parameters between the 2 groups preoperatively. And there were significant differences in CMAP of the median and ulnar nerves, and the number of the fibrillation and positive sharp wave of APB postoperatively (Table 5, Fig. 3).

From Table 6, the age of patients at the time of operation, the number of operative segments, and the follow-up time had no relationship with the surgical effect. For the 6 preoperative imaging parameters, only there were differences between Cobb angle and CGH-C7 SVA, and the patients with better surgical outcomes had smaller CGH-C7 SVA and larger Cobb angle (Fig. 4).

Table 6. Comparison of pre- and postoperative factors and clinical outcomes in the ideal improvement and poor improvement groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Ideal improvement (n = 27)</th>
<th>Poor improvement (n = 42)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>19.45 ± 4.02</td>
<td>18.77 ± 4.97</td>
<td>0.537</td>
</tr>
<tr>
<td>No. of operative segments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>33</td>
<td>33</td>
<td>0.572</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Follow-up time (yr)</td>
<td>5.22 ± 1.14</td>
<td>5.71 ± 2.42</td>
<td>0.258</td>
</tr>
<tr>
<td>Preoperative imaging parameters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cobb angle (°)</td>
<td>8.52 ± 9.68</td>
<td>2.94 ± 11.66</td>
<td>0.042*</td>
</tr>
<tr>
<td>T1 slope (°)</td>
<td>21.54 ± 8.73</td>
<td>22.02 ± 19.79</td>
<td>0.801</td>
</tr>
<tr>
<td>C1–7 SVA (mm)</td>
<td>29.27 ± 12.53</td>
<td>34.54 ± 12.24</td>
<td>0.090</td>
</tr>
<tr>
<td>C2–7 SVA (mm)</td>
<td>17.23 ± 10.09</td>
<td>21.53 ± 9.91</td>
<td>0.087</td>
</tr>
<tr>
<td>CGH–C7 SVA (mm)</td>
<td>11.86 ± 15.21</td>
<td>22.23 ± 12.05</td>
<td>0.004*</td>
</tr>
<tr>
<td>ROM (°)</td>
<td>70.19 ± 16.26</td>
<td>68.08 ± 19.14</td>
<td>0.625</td>
</tr>
<tr>
<td>Postoperative imaging parameters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cobb angle (°)</td>
<td>-1.22 ± 9.88</td>
<td>1.20 ± 10.36</td>
<td>0.332</td>
</tr>
<tr>
<td>T1 slope (°)</td>
<td>24.23 ± 6.58</td>
<td>26.32 ± 6.33</td>
<td>0.195</td>
</tr>
<tr>
<td>C1–7 SVA (mm)</td>
<td>27.76 ± 15.56</td>
<td>35.21 ± 14.00</td>
<td>0.047*</td>
</tr>
<tr>
<td>C2–7 SVA (mm)</td>
<td>14.59 ± 10.65</td>
<td>16.85 ± 11.14</td>
<td>0.399</td>
</tr>
<tr>
<td>CGH–C7 SVA (mm)</td>
<td>8.89 ± 19.00</td>
<td>11.24 ± 13.63</td>
<td>0.580</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation.
SVA, sagittal vertical axis; CGH, center of gravity of the head; ROM, range of motion.
*p < 0.05, statistically significant difference.

Fig. 4. The relationship between preoperative imaging parameters and Odom score. (A) Odom score and CGH-C7 SVA. (B) Odom score and Cobb angle. CGH, center of gravity of the head; SVA, sagittal vertical axis. Odom score: A, All preoperative symptoms were relieved and daily life was not limited; B, Leave mild preoperative symptoms, daily life was not significantly affected; C, Some of the preoperative symptoms were relieved, but life was obviously affected.
4). Since only anteroposterior and lateral x-ray of cervical vertebra was routinely performed in postoperative reexamination, there were only 5 postoperative parameters excluding ROM, and only C1–7 SVA had a significant difference.

Meanwhile, we also analyzed the correlation between preoperative imaging parameters and EMG, which showed that the degree of EMG recovery was positively correlated with preoperative Cobb angle and negatively correlated with preoperative CGH-C7 SVA (Fig. 5).

### 3. Logistic Regression Analysis

Logistic regression analysis showed that among the 6 preoperative parameters of sagittal balance of cervical vertebrae, the Cobb angle ($p = 0.037$) and the CGH-C7 SVA ($p = 0.007$) were correlated with the evaluation of curative effect during postoperative follow-up. As for the 5 postoperative indicators, the results showed that they were not the factors affecting the surgical effect (Table 7).

#### Table 7. Multivariate logistic regression results of risk factors

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Odds ratio</th>
<th>95% Confidence interval</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cobb angle</td>
<td>1.096</td>
<td>1.005–1.196</td>
<td>0.037*</td>
</tr>
<tr>
<td>T1 slope</td>
<td>0.911</td>
<td>0.811–1.024</td>
<td>0.117</td>
</tr>
<tr>
<td>C1–7 SVA</td>
<td>1.012</td>
<td>0.869–1.177</td>
<td>0.879</td>
</tr>
<tr>
<td>C2–7 SVA</td>
<td>0.972</td>
<td>0.821–1.151</td>
<td>0.743</td>
</tr>
<tr>
<td>CGH–C7 SVA</td>
<td>1.098</td>
<td>1.026–1.175</td>
<td>0.007*</td>
</tr>
<tr>
<td>ROM</td>
<td>0.985</td>
<td>0.953–1.017</td>
<td>0.351</td>
</tr>
<tr>
<td>Postoperative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cobb angle</td>
<td>1.021</td>
<td>-0.053 to 0.096</td>
<td>0.570</td>
</tr>
<tr>
<td>T1 slope</td>
<td>1.034</td>
<td>-0.079 to 0.147</td>
<td>0.560</td>
</tr>
<tr>
<td>C1–7 SVA</td>
<td>1.067</td>
<td>-0.014 to 0.144</td>
<td>0.110</td>
</tr>
<tr>
<td>C2–7 SVA</td>
<td>0.990</td>
<td>-0.070 to 0.050</td>
<td>0.757</td>
</tr>
<tr>
<td>CGH–C7 SVA</td>
<td>0.968</td>
<td>-0.094 to 0.030</td>
<td>0.319</td>
</tr>
</tbody>
</table>

SVA, sagittal vertical axis; CGH, center of gravity of the head; ROM, range of motion.

*p < 0.05, statistically significant difference.

**Fig. 5.** The relationship between preoperative imaging parameters and EMG. (A) EMG and Cobb angle. (B) EMG and CGH-C7 SVA. EMG, electromyography; CGH, center of gravity of the head; SVA, sagittal vertical axis. APB, abductor pollicis brevis.

**Fig. 6.** The receiver operating characteristic (ROC) curve of preoperative imaging parameters. (A) The ROC curve of CGH-C7 SVA. (B) The ROC curve of Cobb angle. CGH, center of gravity of the head; SVA, sagittal vertical axis.
4. ROC Curve Analysis and Prediction Threshold

ROC curve analysis showed that the AUC (95% confidence interval) of Cobb angle and CGH-C7 SVA were 0.559 (0.421–0.697) and 0.702 (0.580–0.824), respectively. The reference value of CGH-C7 SVA is higher than that of Cobb angle. When the sum of sensitivity and specificity reached the maximum, the best predictive thresholds for judging Cobb angle and CGH-C7 SVA were 1.50° and 5.40 mm, respectively (Fig. 6).

DISCUSSION

The pathogenesis of Hirayama disease is still unclear, and researchers have advanced numerous hypotheses, mainly including the doctrine of spinal cord motility, the doctrine of growth and development, the doctrine of motor neuron disease, and the doctrine of immune mechanisms.13-16 In addition, some scholars believe that Hirayama disease is due to abnormal dural traction and restriction, which not only injure the spinal cord in the upright position but also aggravate the injury when flexing the neck.17 In view of the fact that cervical flexion may be the pathogenic factor of Hirayama disease,18,19 the application of neck brace fixation in the early stage of the disease can prevent the progression of the disease.20 For patients with a long course of disease and severe atrophy of the muscles of the hand and forearm, it is difficult for patients to wear a neck brace for a long time, so it is not suitable for this treatment.21 Surgical treatment can limit the further development of the disease. Anterior cervical discectomy and fusion (ACDF) limits cervical hyperflexion activity, fuses unstable segments, and restores the normal physiological arc of the cervical spine, thus limiting the progression of neurological symptoms.22-24 Paredes et al.25 suggested that ACDF is able to directly decompress and to correct cervical kyphosis better compared with posterior surgery and is recommended as the preferred procedure for the treatment of Hirayama disease. However, it still needs to be confirmed by further studies with long-term follow-up.

Unlike cervical spondylosis myelopathy, there are few obvious compression-causing objects, such as herniated nucleus pulposus, in patients with Hirayama disease. The vast majority of patients present with anterior displacement of the spinal cord in the flexed cervical position. This displacement results in dynamic anterior compression of the spinal cord. Rebuilding the curvature of the cervical spine becomes more crucial for patients with Hirayama disease.26

In recent years, as research into cervical spondylosis has advanced and surgical approaches have advanced, spine surgeons have placed greater emphasis on cervical sagittal balance. Previous studies have shown that parameters of the cervical sagittal plane can predict the outcome of surgery. For example, it is used to predict the postoperative effect of patients with ossification of the posterior longitudinal ligament.27 Patients with Hirayama disease may possess lower uncinate process, smaller inclination angle of inferior endplate of the upper vertebra, and greater disc-facet angles.27,28 These abnormal structures may be the cause of cervical sagittal imbalance in patients with Hirayama disease,9 the consequential cervical instability may play a significantly important role in the pathogenesis and progress of Hirayama disease. It has been reported that the improvement of neurological function after ACDF in patients with sagittal imbalance is limited.29,30 However, the relationship between the effect of ACDF and preoperative cervical sagittal balance in patients with Hirayama disease has not been studied.

In our present study, we first confirmed that the included patients had differences in their sagittal parameters and clinical symptoms (SB-MHQ scoring) after ACDF surgery. The patients were divided into 2 groups by a simple and easy-to-use Odom score. Since the Odom score is more subjective, we reconfirmed the statistical difference in the recovery of EMG between the 2 groups, which reaffirmed the simplicity and ease of the Odom score. In the better recovered group, we noticed higher CMAP and less amount of fibrillation and positive sharp wave. Then we further evaluated the differences in sagittal parameters and tried to find the reason for the difference in recovery between the 2 groups.

According to the result of multivariate regression analysis, only Cobb angle and CGH-C7 SVA are the key factors that affect the effect of operation. Patients with a smaller Cobb angle and a larger CGH-C7 SVA seemed to have a poor recovery. The AUC of the 2 is 0.559 and 0.702 respectively, which indicates that they have a certain reference value. A cutoff of 1.50° for the Cobb angle was associated with a sensitivity of 85.19% and specificity of 38.10% in predicting operative effect, and a cutoff of 5.40 mm for the CGH-C7 SVA was associated with a sensitivity of 100% and specificity of 35.71% in predicting operative effect. The balance of the gravity center of the head is a better index, which can more truly reflect the load of the cervical spine, so it can be used to predict the surgical effect of cervical degenerative diseases.31 Our study shows that sagittal balance of the gravity center of head can affect the final outcome and cervical alignment in patients with Hirayama disease after ACDF, which is consistent with previous reports that larger CGH-C7 SVA may lead to postoperative adjacent segment disease or increase the
risk of other complications.\textsuperscript{32} Since the introduction of the Cobb angle in 1948, it has been an important tool for spine surgeons to examine the alignment of the cervical spine.\textsuperscript{33} In a report by Lau et al.\textsuperscript{34} C2–7 Cobb angle was (9.1 ± 11.4) in 145 patients with cervical spondylotic myelopathy. In another research by Wang et al.\textsuperscript{26} C2–7 Cobb angle was (5.27 ± 10.68) in 50 patients with Hirayama disease. From these reports, we may conclude to some extent that the degree of cervical lordosis in patients with Hirayama disease may be less. A smaller degree of lordosis results in more tension on the spinal cord in the flexed position, which may be the reason why we found a larger Cobb angle in the better recovered group.

This study also has some limitations. First of all, this study is retrospective, and there may be selection bias. Secondly, the number of people included in the study is not enough, and the sample size needs to be increased in the future. Finally, Odom score is more subjective, and we need to introduce some more objective scoring standards in the future.

In summary, according to the average follow-up of more than 5 years in patients with Hirayama disease treated with ACDF, surgical treatment can control or improve the clinical symptoms of the patients. Patients with larger preoperative Cobb angle and smaller CGH–C7 SVA have a high probability of developing sagittal imbalances, and these 2 parameters can be used as predictors of outcomes in ACDF-treated Hirayama disease patients.

**CONFLICT OF INTEREST**

The authors have nothing to disclose.

**ACKNOWLEDGMENTS**

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**REFERENCES**


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Impact of Myelopathy Severity and Degree of Deformity on Postoperative Outcomes in Cervical Spinal Deformity Patients

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Objective: Malalignment of the cervical spine can result in cord compression, leading to a myelopathy diagnosis. Whether deformity or myelopathy severity is stronger predictors of surgical outcomes is understudied.

Methods: Surgical cervical deformity (CD) patients with baseline (BL) and up to 1-year data were included. Modified Japanese Orthopaedic Association (mJOA) score categorized BL myelopathy (mJOA = 18 excluded), with moderate myelopathy mJOA being 12 to 17 and severe myelopathy being less than 12. BL deformity severity was categorized using the mismatch between T1 slope and cervical lordosis (TS-CL), with CL being the angle between the lower endplates of C2 and C7. Moderate deformity was TS-CL less than or equal to 25° and severe deformity was greater than 25°. Categorizations were combined into 4 groups: group 1 (G1), severe myelopathy and severe deformity; group 2 (G2), severe myelopathy and moderate deformity; group 3 (G3), moderate myelopathy and moderate deformity; group 4 (G4), moderate myelopathy and severe deformity. Univariate analyses determined whether myelopathy or deformity had greater impact on outcomes.

Results: One hundred twenty-eight CD patients were included (mean age, 56.5 years; 46% female; body mass index, 30.4 kg/m²) with a BL mJOA score of 12.8 ± 2.7 and mean TS-CL of 25.9° ± 16.1°. G1 consisted of 11.1% of our CD population, with 21% in G2, 34.6% in G3, and 33.3% in G4. At BL, Neck Disability Index (NDI) was greatest in G2 (p = 0.011). G4 had the lowest EuroQol-5D (EQ-5D) (p < 0.001). Neurologic exam factors were greater in severe myelopathy (p < 0.050). At 1-year, severe deformity met minimum clinically important differences (MCIDs) for NDI more than moderate deformity (p = 0.002). G2 had significantly worse outcomes compared to G4 by 1-year NDI (p = 0.004), EQ-5D (p = 0.028), Numerical Rating Scale neck (p = 0.046), and MCID for NDI (p = 0.001).

Conclusion: Addressing severe deformity had increased clinical weight in improving patient-reported outcomes compared to addressing severe myelopathy.

Keywords: Myelopathy, Correction, Cervical, Deformity, Outcomes

INTRODUCTION

The skull rests on the cervical spine to maintain erect posture and horizontal gaze.¹,² Additionally, cervical spine offers range of motion and protects neurologic and vascular structures.³ Therefore, optimal alignment of the cervical spine is vital to its functionality. Degenerative malalignment of the cervical spine leads to cervical or cervicothoracic kyphosis, which often results in
severe axial neck pain and spinal cord compression, ultimately leading to a diagnosis of cervical spondylotic myelopathy (CSM).\(^4\),\(^5\)

The main goal of cervical deformity (CD) surgery with neurologic compromise is to perform decompression and restoration of cervical lordosis (CL) which results in realignment of the spine. These corrective procedures have a significant impact on patient-reported and complication outcomes.\(^6\),\(^7\) However, it is not fully understood whether deformity severity or the degree of myelopathy is the most significant predictors of these outcomes.\(^7\) For instance, if the patient’s main complaint is gaze disturbance or dysphagia, both of which could be directly attributed to cervical kyphosis therefore, deformity correction is prioritized to restore these functions.\(^8\),\(^9\) In contrast, when surgery is indicated mainly for compressive myelopathy, the primary goal is to ensure sufficient decompression and it is unclear whether deformity correction may impact the outcomes of these patients.\(^10\)

When accounting for initial deformity severity and myelopathic severity of a patient at baseline, it is unclear whether the malalignment of the cervical spine or the neurologic deficits put more impact on surgical outcome and/or patient satisfaction, postoperatively. Main objective of this study was to investigate the simultaneous impact of myelopathy and baseline deformity stratified by severity of each, upon postoperative outcomes.

## MATERIALS AND METHODS

### 1. Study Inclusion Criteria

Consecutive adult patients (≥18 years) with cervical spine deformity undergoing cervical fusion by a single spine surgeon at an academic center were included. Database inclusion criteria for CD were defined using radiographic imaging and the following established parameters: cervical kyphosis (C2–7 sagittal Cobb angle ≥ 10), cervical scoliosis (C2–7 coronal Cobb angle ≥ 10), C2–7 sagittal vertical axis (C2–7 SVA) ≥ 4 cm, or chin-brow vertical angle ≥ 25. Patient consent and Institutional Review Board (IRB) approval was obtained at the Center for Neurmuscular Care at Hospital for Joint Diseases (IRB number: i14-000) prior to enrolling patients.

### 2. Data Collection

Patients included had baseline and up to 1-year health-related quality of life (HRQoL) data. Baseline and 3-month radiographic measurements were maintained for these patients as well. Demographic data included age, sex, body mass index (BMI), and baseline comorbidity index as described the Charlson Comorbidity Index (CCI). Surgical data collected included number of levels fused, surgical approach, decompression type (discectomy, foraminotomy, corpectomy, laminectomy), and osteotomy type (Smith-Peterson, incomplete/complete facet). Clinical outcomes including neck disability (as assessed by the Neck Disability Index [NDI]), EuroQol 5-Dimension Questionnaire [EQ-5D], and pain Numerical Rating Scale [NRS]), and myelopathy score (as assessed by the modified Japanese Orthopaedic Association [mJOA]) were obtained via patient surveys at baseline up to 1 year. For the purposes of this study, the EQ-5D-3 Level was used as an unweighted total score. Each response was scored between 1 and 3, with a maximum score of 15 indicating extreme problems and a minimum score of 5 indicating no problems. Previously published criteria for meeting minimum clinically important differences (MCIDs) for these metrics were also used to assess patient outcomes.\(^11\),\(^14\)

Radiographs were measured using validated software programming (SpineView; ENSAM Laboratory of Biomechanics, Paris, France) at a single academic center. Cervical sagittal alignment and balance were evaluated using C2–7 Cobb angle for CL (angle between the lower endplates of C2 and C7), cervical SVA (cSVA: C2 plumbline offset from the posterosuperior corner of C7), and the mismatch between T1 slope and CL (TS-CL).

### 3. Patient Grouping: Myelopathy vs. Deformity Severity

The mJOA was utilized to assess baseline myelopathy severity. Patients with a baseline mJOA of 18 were excluded to account for the ceiling effect. Moderate myelopathy was defined as having a score of 12–17 at baseline, while a severe myelopathy: patient presented with a baseline score of <12. In terms of deformity severity, patients were classified with moderate deformity with a TS-CL ≤ 25°, and severe deformity when baseline values of TS-CL mismatch exceeded 25°. Patients were stratified into 4 groups based upon their myelopathy and deformity severity as described: group 1 (G1), severe myelopathy and severe deformity; group 2 (G2), severe myelopathy and moderate deformity; group 3 (G3), moderate myelopathy and moderate deformity; group 4 (G4), moderate myelopathy and severe deformity. G2 and G4 were identified as mismatched myelopathy/deformity groups, and were assessed accordingly (Table 1).

### 4. Statistical Analysis

Statistical analysis was performed using licensed IBM SPSS Statistics ver. 23.0 (IBM Co., Armonk, NY, USA). Univariate analyses were performed with a statistical cutoff p < 0.05 to de-
termine whether myelopathy severity or deformity severity had a greater impact on patient-reported outcomes via means comparison and analysis of variance analyses.

RESULTS

1. Demographic and Surgical Data

One hundred twenty-eight CD patients met inclusion criteria (mean age, 56.5 years; 46% female; BMI, 30.4 kg/m²; CCI, 0.56 ± 0.85). Eighteen percent of patients were current smokers. Most patients underwent a posterior-only approach (47.5%), followed by a combined (24.6%) or anterior-only approach (27.9%). Mean total number of levels fused for the cohort was 5 ± 3.2, mean operative time was 588.5 minutes, and mean estimated blood loss was 766.9 mL. Demographic and surgical data by myelopathy and deformity grouping is shown in Table 2.

Table 1. Patients stratified by groups based upon their myelopathy and deformity severity

<table>
<thead>
<tr>
<th>Severity &amp; group</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myelopathy and deformity severity</td>
<td></td>
</tr>
<tr>
<td>Moderate myelopathy</td>
<td>69.5</td>
</tr>
<tr>
<td>Severe myelopathy</td>
<td>30.5</td>
</tr>
<tr>
<td>Moderate deformity</td>
<td>35.2</td>
</tr>
<tr>
<td>Severe deformity</td>
<td>64.8</td>
</tr>
<tr>
<td>Groups</td>
<td></td>
</tr>
<tr>
<td>1: severe myelopathy and severe deformity</td>
<td>11.1</td>
</tr>
<tr>
<td>2: severe myelopathy and moderate deformity</td>
<td>21.0</td>
</tr>
<tr>
<td>3: moderate myelopathy and moderate deformity</td>
<td>34.6</td>
</tr>
<tr>
<td>4: moderate myelopathy and severe deformity</td>
<td>33.3</td>
</tr>
</tbody>
</table>

2. Overall Cohort Alignment

Baseline cervical alignment in our cohort was as follows: C2–7 CL was 1.30° ± 17.7°, mean C2–7 SVA was 28.8 ± 16.4 mm, mean TS-CL was 25.9° ± 16.1°. Spinopelvic alignment at baseline included a mean T2–12 angle of -46.8 ± 14.0, mean C7-S1 SVA of 0.74 ± 57.2 mm, mean pelvic tilt (PT) of 18.3 ± 10.1, and mean pelvic incidence minus lumbar lordosis (PI–LL) of -0.87 ± 15.3.

At 3 months following surgery, patients saw significant improvement in cervical sagittal realignment. CL increased significantly (p = 0.002) and TS-CL improvement trended towards significance (p = 0.056). Cervical translation (cSVA) did not change significantly from baseline (p = 0.883). No significant differences in spinopelvic alignment were observed between pre- and postoperative PT, PI–LL, and SVA (all p > 0.05).


Baseline mJOA score was 12.8 ± 2.7, with a mean TS-CL of 25.9° ± 16.1°, as stated above. 30.5% of patients had severe baseline myelopathy, 69.5% moderate myelopathy, via the mJOA
guidelines noted in the methods. By baseline deformity severity, 35.2% were moderately deformed per TS-CL measurements, while 64.8% were severely deformed (Table 1).

Patients were then categorized into the 4 myelopathy/deformity groups, which found that G1 consisted of 11.1% of our CD population, with 21% in G2, 34.6% in G3, and 33.3% in G4 (Table 1). Table 3 details radiographic measurements by grouping at baseline and postoperatively. Case examples for each of these groupings can be seen in Figs. 1-4.

4. Myelopathy/Deformity Group HRQoL Comparison

At baseline, NDI score was the greatest in G2 at 69.4 (G1: 69.1, G3: 57.1, G4: 52.6, p = 0.011), whereas G4 had the lowest EQ-5D scores (p < 0.001). G2 had the lowest mJOA score at baseline (9.35), while G4 had the greatest (14.5) (p < 0.001) (Table 4). According to baseline neurologic exam factors were significantly greater in the groups with severe myelopathy (G1 and G2, p < 0.05).

At 1 year, 55.6% of patients with severe myelopathy and severe deformity, G1, met MCID for NDI, while 6.9% of G2, 25% G3, and 55.6% G4 met the threshold for MCID for the NDI.

Table 3. Radiographic measurements by grouping at baseline and 3 months

<table>
<thead>
<tr>
<th>Radiographic measurement</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Group 4</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical lordosis (C2–7)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
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<td>2.59</td>
<td>4.59</td>
<td>-4.79</td>
<td>0.085</td>
</tr>
<tr>
<td>3 Months</td>
<td>6.57</td>
<td>13.99</td>
<td>9.94</td>
<td>12.31</td>
<td>0.756</td>
</tr>
<tr>
<td>TS-CL</td>
<td>43.79</td>
<td>16.35</td>
<td>15.79</td>
<td>36.54</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>3 Months</td>
<td>33.07</td>
<td>23.19</td>
<td>23.10</td>
<td>24.56</td>
<td>0.317</td>
</tr>
<tr>
<td>cSV A</td>
<td>39.53</td>
<td>22.26</td>
<td>21.24</td>
<td>44.24</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>3 Months</td>
<td>39.35</td>
<td>39.75</td>
<td>31.82</td>
<td>32.65</td>
<td>0.600</td>
</tr>
</tbody>
</table>

Group 1, severe myelopathy and severe deformity; group 2, severe myelopathy and moderate deformity; group 3, moderate myelopathy and moderate deformity; group 4, moderate myelopathy and severe deformity; TS-CL, T1 slope and cervical lordosis; cSV A, cervical sagittal vertical axis.

Fig. 1. Group 1 (severe myelopathy and severe deformity) patient example.

Fig. 2. Group 2 (severe myelopathy and moderate deformity) patient example.

Fig. 3. Group 3 (moderate myelopathy and moderate deformity) patient example.

https://doi.org/10.14245/ns.2040456.228
Table 4. Baseline mean health-related quality of life measures by group

<table>
<thead>
<tr>
<th>Group</th>
<th>NDI score</th>
<th>EQ-5D score</th>
<th>mJOA score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td></td>
<td>p-value</td>
<td>p-value</td>
<td>p-value</td>
</tr>
<tr>
<td>1</td>
<td>69.1 ± 13.9</td>
<td>10.4 ± 3.85</td>
<td>10.3 ± 1.00</td>
</tr>
<tr>
<td>2</td>
<td>69.4 ± 14.7</td>
<td>10.8 ± 1.80</td>
<td>9.35 ± 1.73</td>
</tr>
<tr>
<td>3</td>
<td>57.1 ± 21.0</td>
<td>10.1 ± 2.96</td>
<td>13.6 ± 1.35</td>
</tr>
<tr>
<td>4</td>
<td>52.6 ± 17.4</td>
<td>6.14 ± 4.88</td>
<td>14.5 ± 1.53</td>
</tr>
</tbody>
</table>

Group 1, severe myelopathy and severe deformity; group 2, severe myelopathy and moderate deformity; group 3, moderate myelopathy and moderate deformity; group 4, moderate myelopathy and severe deformity; NDI, Neck Disability Index; EQ-5D, Euro-Quality of Life-5 Dimension; mJOA, modified Japanese Orthopaedic Association; SD, standard deviation.

Table 5. Year 1 mean health-related quality of life measures by group

<table>
<thead>
<tr>
<th>Group</th>
<th>NDI score</th>
<th>EQ-5D score</th>
<th>mJOA score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td></td>
<td>p-value</td>
<td>p-value</td>
<td>p-value</td>
</tr>
<tr>
<td>1</td>
<td>43.7 ± 18.5</td>
<td>9.57 ± 1.99</td>
<td>12.3 ± 4.99</td>
</tr>
<tr>
<td>2</td>
<td>57.0 ± 21.9</td>
<td>9.67 ± 1.37</td>
<td>12.2 ± 2.14</td>
</tr>
<tr>
<td>3</td>
<td>51.8 ± 17.5</td>
<td>9.80 ± 2.99</td>
<td>13.8 ± 2.98</td>
</tr>
<tr>
<td>4</td>
<td>28.1 ± 18.3</td>
<td>5.22 ± 4.51</td>
<td>14.5 ± 2.57</td>
</tr>
</tbody>
</table>

Group 1, severe myelopathy and severe deformity; group 2, severe myelopathy and moderate deformity; group 3, moderate myelopathy and moderate deformity; group 4, moderate myelopathy and severe deformity; NDI, Neck Disability Index; EQ-5D, Euro-Quality of Life-5 Dimension; mJOA, modified Japanese Orthopaedic Association; SD, standard deviation.

DISCUSSION

A diagnosis of CD presents symptomatically as poor horizontal gaze, dysphagia, axial neck pain, neurological dysfunction, and functional disabilities. With an increasing degree of malalignment of the cervical spine anterior to the cervical segment of the spinal cord, CSM results. Myelopathy combined with deformity is a severe threat to a patient's spinal health and treatment requires complex surgical procedures. Patients who
meet this criteria require simultaneous surgical decompression and correction surgery. The case for which optimal surgical strategy is often debated and the various approaches (anterior, posterior, or combined) carry different risks and benefits. After surgical intervention, it is unclear the impact that preoperative factors of deformity severity and neurologic compromise from myelopathy have on postoperative HRQoL metrics.

When encountering CSM, a thorough understanding of etiological factors is important. During the normal aging process, disc desiccation leads to progressive disc degeneration, resulting in disc collapse and a decrease in disc height. Sequential mechanical endplate damage results in formation of disc osteophytyc complexes by subperiosteal bone formation. This creates more stress on the facet joints leading to facet arthropathy. This change gets accentuated during both static and dynamic states. Degenerative changes are further accentuated by the ligamentum flavum hypertrophy accounting for an additional spinal stenosis. During normal range of cervical spine motion, any flexion or extension can lead to an intermittent compression which further worsens spinal stenosis. All these changes have cumulative effect on impedance of blood supply to the spinal cord and therefore cause additional progressive neurological deficits.

When treating minor spinal deformity, the surgeons should understand the goal of postoperative alignment and its implication on the outcomes when myelopathic symptoms prevail. Kyphosis in the cervical spine plays an important role in development of myelopathy, as it decreases the space between the anterior compressive pathology and the spinal cord. Major causative factors are multilevel disc herniations, spondylotic disc osteophyte complexes, and an ossified posterior longitudinal ligament. Therefore, cervical realignment aims to increase this space and relieve compression and tension on the spinal cord. It has been previously shown that sufficient decompression can be achieved even in minor deformity and severe myelopathic patients. Thus, our study may reflect the severe spondylitic changes seen in major myelopathic CD patients who present with mild deformity (group 2).

In our study, we sought to investigate the impact of myelopathy severity on outcomes and satisfaction postoperatively over baseline deformity severity. The results showed that when assessing greater baseline myelopathy over deformity severity, significantly worse patient-reported outcomes occurred compared to patients with greater deformity over myelopathy severity. In the literature, we see that surgical restoration of sagittal alignment and balance appears to correlate with functional outcomes.

In 2018, a study by Ailon et al. investigated how surgical correction affected 77 CD patients postoperatively in terms of their HRQoLs. They found significant improvement in NDI, NRS neck, and EQ-5D, despite minimal change in myelopathy outcomes. This study suggested that improvement across multiple quality of life measures without significant recovery of neurologic function may be related to the pathophysiology and chronicity of myelopathy in the setting of cervical kyphosis. Kato et al. showed in their 2018 study, that preoperative CD was associated with postoperative HRQoL scores in an entirely myelopathic cohort. These results may be true within our cohort as well. The patients who met criteria for severe myelopathy and moderate deformity may have been neurologically impaired beyond improvement, ultimately resulting in minimal functionality return.

Severe deformity correction, in the setting of moderate baseline myelopathic symptoms, directly impacted patient-reported outcomes postoperatively. With better improvement in NDI, EQ-5D, and NRS neck, our study supports the literature on surgical intervention for majorly deformed patients for ultimate improvement of quality of life.

The retrospective nature of the cohort can inherently lead to potential reporting or observer bias. Using data collected from a one surgeon operating in an academic setting may not be representative of the average physician and average hospital a primary cervical diagnoses patient receives treatment at in the United States. Furthermore, a study of this nature cannot examine causality and both sagittal spinal alignment parameters and HRQoL may be influenced by another confounding factor such as the underlying spinal diagnoses for which the patient was receiving spinal fusion surgery. At 1 year postoperative, this study may be hindered by a relatively short follow-up time. Additionally, myelopathy severity was defined via mJOA scores rather than magnetic resonance imaging findings, which may not accurately reflect the physiologic actuality of the patient’s disease.

**CONCLUSION**

CSM and the spinal deformity are strongly related. Patients who present with more severe myelopathy than deformity have worse patient-reported outcomes than the opposite case. In moderate deformity, myelopathy decompression and symptomatic alleviation are substantial. However, this intervention is inadequate in the case of severe deformity, where realignment is necessary due to cord tension. Surgical intervention to address severe deformity had increased clinical weight with respect to
improving patient-reported outcomes in comparison to addressing severe myelopathy, which further indicates the gravity of deformity as a formidable and complex illness.

CONFLICT OF INTEREST

The authors have nothing to disclose.

REFERENCES

Influence of Lumbar Lordosis on Posterior Rod Strain in Long-Segment Construct During Biomechanical Loading: A Cadaveric Study

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Department of Neurosurgery, Barrow Neurological Institute, St. Joseph’s Hospital and Medical Center, Phoenix, AZ, USA

Objective: The lordotic shape of the lumbar spine differs substantially between individuals. Measuring and recording strain during spinal biomechanical tests is an effective method to infer stresses on spinal implants and predict failure mechanisms. The geometry of the spine may have a significant effect on the resultant force distribution, thereby directly affecting rod strain.

Methods: Seven fresh-frozen cadaveric specimens (T12-sacrum) underwent standard (7.5 Nm) nondestructive sagittal plane tests: flexion and extension. The conditions tested were intact and pedicle screws and rods (PSR) at L1-sacrum. The posterior right rod was instrumented with strain gauges between L3–4 (index level) and the L5–S1 pedicle screw. All specimens underwent lateral radiographs before testing. Lordotic angles encompassing different levels (L5–S1, L4–S1, L3–S1, L2–S1, and L1–S1) were measured and compared with rod strain. Data were analyzed using Pearson correlation analyses.

Results: Strong positive correlations were observed between lordosis and posterior rod strain across different conditions. The L3–S1 lordotic angle in the unloaded intact condition correlated with peak rod strain at L3–4 with PSR during flexion (R = 0.76, p = 0.04). The same angle in the unloaded PSR condition correlated with peak strain in the PSR condition during extension (R = -0.79, p = 0.04). The unloaded intact L2–S1 lordotic angle was significantly correlated with rod strain at L3–4 in the PSR condition during flexion (R = 0.85, p = 0.02) and extension (R = -0.85, p = 0.02) and with rod strain at L5–S1 in the PSR condition during flexion (R = 0.84, p = 0.04).

Conclusion: Lordosis measured on intact and instrumented conditions has strong positive correlations with posterior rod strain in cadaveric testing.

Keywords: ACR, Lumbar lordosis, Rod strain

INTRODUCTION

The lordotic shape of the lumbar spine differs substantially between subjects and is intimately related to spinopelvic geometry.1 Lumbar curvature disturbance is potentially involved in the genesis of several spinal disorders, rendering the study of sagittal balance critical for planning spine surgery. Restoration of lumbar lordosis (LL) is an essential element of spinal deformity correction surgery and has a direct impact on clinical outcomes.2-6

The upper arch of LL is more constant, whereas the lower arc is more variable and plays a greater role in overall lordosis. The lower arc also corresponds with and reacts to the sacral slope angle. Mild changes in any of these factors can dramatically affect the distribution of mechanical loading in the entire spine, pelvis, and lower limbs.7-11
The failure to restore the ideal LL shape might be associated with postoperative mechanical failures on long-segment constructs, such as pseudoarthrosis or rod fracture. Excessive postoperative lordosis has also been reported to be a potential cause of mechanical failure. In spite of extensive efforts investigating the clinical relevance of sagittal balance, the rate of rod fractures remains high. 

Measuring strain during spinal biomechanical tests effectively infers the stresses on spinal implants and predicts failure mechanisms. Strain is the ratio of change of the material length to the initial length in response to the application of force, with low strain rates on implants associated with better outcomes and lower rates of mechanical failures. In solid mechanics, the resulting stress and strain distributions through a load-bearing structure depend not only on the applied load but also on the shape of the structure. However, no previous biomechanical study has analyzed the effect of LL or the shape of a surgical construct on the resultant instrumentation strain during loading. In the current study, we hypothesized that the geometry of the lumbosacral spine may have an impact on the resultant force distributions during loading, directly affecting rod strain (measurable using strain gauges).

MATERIALS AND METHODS

Seven fresh-frozen lumbar spine cadaveric specimens (T12-sacrum) were studied. The same specimens were also part of a separate study conducted in our laboratory to assess the subsequent stability and rod strain of different construct designs during anterior column realignment. Informed consent was not needed because this was a cadaver study, and Institutional Review Board approval was not sought due to the nature of the investigation. Donor medical records and plain film radiographs were reviewed, and direct manual inspection was performed to ensure that the specimens had no obvious pathologic conditions. Dual-energy x-ray absorptiometry scans were performed to assess bone mineral density (Table 1).

Specimens were stored at -20°C until test day and then thawed in normal saline at 21°C. Muscles and soft tissues were cleaned while keeping intact all ligaments, joint capsules, and intervertebral discs. The sacrum was reinforced with household wood screws placed in a rectangular metal mold and embedded using fast-curing resin (Smooth-Cast; Smooth-On, Easton, PA, USA) to permit attachment to the base of the testing apparatus. The top vertebra (T12) was also reinforced with household screws and embedded in the same resin in a cylindrical-shaped pot (=200 g) for test frame attachment and loading.

1. Instrumentation

In all cases, polyaxial pedicle screws with a cobalt-chrome head and titanium alloy shaft (Ti-6Al-4V) were used (L2–5: 6.5 × 45–55 mm, S1: 7.5 × 55 mm; NuVasive, San Diego, CA, USA). Cobalt-chrome rods were chosen over titanium because they have been gaining importance in the adult spinal deformity surgery setting. Two 5.5-mm diameter cobalt-chrome rods were contoured bilaterally to fit screw heads from L1 to S1 to minimize the need for reduction. We did not intend to change the lordosis curvature when the rod was locked in place, although minimal changes can always occur during the implantation.

2. Biomechanical Tests

In each case, a robotic 6-degree-of-freedom apparatus test frame was used to apply standard nondestructive pure moment loads up to 7.5 Nm at a mean global rotation rate of 1.5° per second. The pure moments were applied in the sagittal plane: flexion and extension. Using pure moments has the advantage of distributing the same load to each level of the spine, ensuring an equivalent comparison among all levels, regardless of the

<table>
<thead>
<tr>
<th>Table 1. Demographic variables for cadaveric spinal segments</th>
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<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>BMD (g/cm²)</td>
</tr>
<tr>
<td>Sex</td>
</tr>
<tr>
<td>Age (yr)</td>
</tr>
<tr>
<td>Cause of death</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
</tr>
</tbody>
</table>

BMD, bone mineral density; BMI, body mass index; SD, standard deviation.

distance from the point of loading.23,24

During all tests, 3-dimensional motion measurements were made with the Optotrak 3020 camera apparatus (Northern Digital, Waterloo, Ontario, Canada). This system stereophotogrammetrically measures 3-dimensional displacement of infrared-emitting markers rigidly attached in a noncollinear arrangement to each vertebra at the ends of three 4-cm surgical guide wires drilled into each vertebral body. Range of motion was measured using custom software to convert the marker coordinates to angles about each of the anatomical axes.25 The conditions tested were (1) intact and (2) pedicle screws and rods (PSR) at L1-sacrum.

Because there were no statistically significant differences between right-side and left-side rod strains in a previous study,26 only right-side rod strain was monitored in the current study. Rods were instrumented with stacked rosette strain gauges (CEA-06-062UW-350/P2, Vishay Micro-Measurements, Raleigh, NC, USA) at the index level (L3–4) and at the lumbosacral junction (L5–S1), with the gauges facing posteriorly. The gauges were positioned at the midpoint distance between L3 and L4, as well as at the L5 and S1 pedicle screw heads, respectively (Fig. 1). Strain on the posterior rods during specimen loading was recorded at 10 Hz using the StrainSmart data acquisition system (Vishay Micro-Measurements, Raleigh, NC, USA). Only the vertical or longitudinal component strains were used for analysis.

The specimens underwent lateral radiographs, and LL encompassing different levels (L1–S1, L2–S1, L3–S1, L4–S1, and L5–S1) was measured using the Cobb method in all different spine conditions before loading (Fig. 2). Angles were measured using the sacral endplate and the superior endplate of each lumbar vertebra with exception of L1, which was measured using the inferior endplate. The films used were not large enough to encompass the superior endplate of L1. The angle measurements were performed using ImageJ software (US National Institutes of Health, Bethesda, MD, USA) and encompassed the inferior endplate of the upper vertebra and the sacral endplate. The superior endplate was not used because of the inability to include the superior L1 endplate on the film for all specimens. These angles were compared with peak recorded rod strains for each test condition. Angle value comparisons between conditions were performed using paired t-tests. Data were analyzed using a Pearson product moment correlation analysis (SigmaPlot v14); p-values < 0.05 were considered statistically significant.

RESULTS

There were no significant differences in mean angles of the intact condition compared with the PSR condition (p > 0.51),
with the exception of the L4–S1 angle (p = 0.01). Angles measured in intact and PSR conditions are shown in Table 2, and

Table 2. Lordotic angles measured at different levels in intact and pedicle screws and rods (PSR) conditions

<table>
<thead>
<tr>
<th>Lordotic angle</th>
<th>Intact</th>
<th>PSR</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>L1-S1 lordosis</td>
<td>54.91 ± 14.61</td>
<td>53.51 ± 9.86</td>
<td>0.76</td>
</tr>
<tr>
<td>L2-S1 lordosis</td>
<td>45.80 ± 11.88</td>
<td>43.84 ± 9.34</td>
<td>0.51</td>
</tr>
<tr>
<td>L3-S1 lordosis</td>
<td>36.91 ± 10.55</td>
<td>36.55 ± 6.05</td>
<td>0.89</td>
</tr>
<tr>
<td>L4-S1 lordosis</td>
<td>29.68 ± 6.00</td>
<td>25.46 ± 5.02</td>
<td>0.01*</td>
</tr>
<tr>
<td>L5-S1 lordosis</td>
<td>7.36 ± 7.02</td>
<td>7.22 ± 4.12</td>
<td>0.95</td>
</tr>
</tbody>
</table>

Values are presented as mean ± standard deviation.

PSR, pedicle screws and rods.

*p < 0.05, statistically significant differences. The comparison was performed using paired t-tests.

Table 3. Strain peak mean values

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>L3–4 rod strain (µε) FL</td>
<td>307</td>
</tr>
<tr>
<td>L3–4 rod strain (µε) EX</td>
<td>-364</td>
</tr>
<tr>
<td>L5–S rod strain (µε) FL</td>
<td>204</td>
</tr>
<tr>
<td>L5–S rod strain (µε) EX</td>
<td>-290</td>
</tr>
</tbody>
</table>

PSR, pedicle screws and rods; SD, standard deviation; FL, flexion; EX, extension; NA, not applicable.

strain values are shown in Table 3. The mean and standard deviation (SD) rod strain value reported for L3–4 during flexion was 238.6 ± 64.4 µε, and during extension, it was -263.9 ± 88.1 µε. The mean and SD strain value reported for L5–S during flexion was 145.1 ± 118.1 µε, and during extension, it was -222.7 ± 185.9 µε. The strain values reported are within the same range as other biomechanical studies.27

Several correlations between lordosis angles at rest and peak posterior rod strains during loading were statistically significant (Fig. 3) (p ≤ 0.04). L2–S1 and L3–S1 lordotic angles in intact and PSR conditions were significantly correlated with rod strain at various spinal levels, conditions, and directions of loading, as shown in Table 4 and discussed below.

Fig. 3. Correlations between posterior rod strain (RS) and lordotic angles in different conditions. (A) RS at L3–4 during pure moment bending versus intact L3–S1 lordosis. (B) RS at L3–4 and L5–S1 versus intact L2–S1 lordosis. (C) RS at L3–4 versus pedicle screws and rods (PSR) L3–S1 lordosis. A p-value of < 0.05 were considered statistically significant. R, coefficient of correlation. Adapted with permission from Barrow Neurological Institute, Phoenix, AZ, USA.
Intact Condition

The L3–S1 angle measured in the intact condition at rest was significantly correlated with rod strain at L3–4 in the PSR condition during bending in flexion (R = 0.76, p = 0.04) and without significance during extension (R = -0.73, p = 0.06). L2–S1 angles measured intact during rest correlated with rod strain at L3–4 in the PSR condition during bending in flexion (R = 0.85, p = 0.02) and extension (R = -0.85, p = 0.02), as well as with rod strain at L5–S1 in PSR during bending in flexion (R = 0.84, p = 0.04). For other comparisons, correlations were not statistically significant (p ≥ 0.05).

PSR Condition

The correlation between the L3–S1 angle measured in the PSR condition at rest and rod strain at L3–4 in the PSR condition during bending was significant during extension (R = -0.79, p = 0.04), but not during flexion (R = 0.74, p = 0.06). For other comparisons, correlations were not statistically significant (p ≥ 0.05).

DISCUSSION

Human bipedalism is possible because peculiarities of the spinopelvic anatomy allow humans to reach maximum equilibrium in the erect position with minimal activation of the back muscles. The most notable of these singularities is the verticalization of the pelvis and successive opposing sagittal curvatures. LL is found in no other species; great apes can achieve an upright position but only with a semierect trunk. The extensor muscles are also critical for maintaining stability during movement. Recent modeling suggests that a spine with large lordosis requires a greater follower load in the standing position than one with minimal lordosis. Increased LL requires larger extensor musculature to provide sufficient follower loads and sagittal stability.26

Global lordosis increases as the sacral slope becomes more vertical, demonstrating a reciprocal association between the orientation of the sacrum and the degree of LL curvature. Patients with greater pelvic incidence and sacral slope, and consequently higher LL, are predisposed to develop lumbar spondylolisthesis because of higher shear stress on posterior elements directly affecting the isthmus, which leads to failure of this structure.29 Lumbar spines with greater curvature tend to experience increased shear forces on posterior joints. Our study results suggest a strong relationship between native lordosis and an immediate postoperative increase in rod strain, which could potentially translate into increased rod fracture rates. During rod implantation, no specific maneuver was performed with the objective to increase lordosis, and caution was taken to not change the native curvature. The rod was carefully bent to meticulously meet the screw heads without the need to reduce the spine, even though the L4–S angle following PSR was significantly smaller than the corresponding intact angle (Table 2) (p = 0.01). It should be noted that this level corresponds exactly to the lower arc of lordosis, which is the most important region with regard to lumbar spine curvature.

Strain monitoring during biomechanical tests has been spotlighted recently because these measurements are a good predictor of metal fatigue and risk of rod breakage.27 Few biomechanical studies have addressed the influence of LL on load distribution.30,31 No previous in vitro study has addressed the influence of LL on rod strain measurements. Previous studies have, however, demonstrated that posterior rod strain can be attenuated by certain techniques.26,27 For example, the addition of anterior

Table 4. Correlations between different lumbar lordosis angles and rod strain during different conditions by direction of loading

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Lordosis</th>
<th>Rod strain</th>
<th>Direction of loading</th>
<th>R</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Specimen ID</td>
<td>Spinal level</td>
<td>Spine condition</td>
<td>Spinal level</td>
<td>Spine condition</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>L2–S1</td>
<td>Intact</td>
<td>L3–L4</td>
<td>PSR</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>L2–S1</td>
<td>Intact</td>
<td>L3–L4</td>
<td>PSR</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>L2–S1</td>
<td>Intact</td>
<td>L5–S1</td>
<td>PSR</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>L3–S1</td>
<td>Intact</td>
<td>L3–L4</td>
<td>PSR</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>L3–S1</td>
<td>Intact</td>
<td>L3–L4</td>
<td>PSR</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>L3–S1</td>
<td>PSR</td>
<td>L3–L4</td>
<td>PSR</td>
</tr>
<tr>
<td>7</td>
<td>7</td>
<td>L3–S1</td>
<td>PSR</td>
<td>L3–L4</td>
<td>PSR</td>
</tr>
</tbody>
</table>

PSR, pedicle screws and rods at L1-sacrum; R, coefficient of correlation.
*p < 0.05, statistically significant differences. †p ≥ 0.05, not statistically significant but are included for completion.
column support using a cage with a large footprint at the base of the construct, or additional supplemental posterior rods, can mitigate rod strain. Further studies are necessary to investigate whether these supplemental methods are influenced by variations in LL.

The correlations observed in the current study are difficult to rationalize, especially under pure moment loading. As illustrated in Fig. 4, an applied pure torsional load (i.e., bending moment) is the mechanical equivalent to a pair of applied force vectors equal in magnitude and opposite in direction. Thus the anterior spine, for example, can be considered to be in tension, while the posterior region is effectively compressed in extension (and vice versa in flexion). An online finite element analysis calculator designed and validated for 2-dimensional structural truss calculations, with a simplified analysis that assumes that a single posterior rod spanning 6 levels (screw locations) supports the resulting tensile or compressive load, illustrates (Fig. 5) that a rod with increased curvature (lordosis) experiences greater stress than a less-curved rod of the same length, with maximum stresses occurring at the apex region (approximately the L3–4 region). Although greatly simplified, this illustration provides a rationale for the observed increase in L3–4 rod strains with increasing lordosis.

We found significant correlations between LL and rod strain for PSR instrumentation spanning L1 to S1. This finding supports the hypothesis that, with hyperlordotic spines, the stress distributions tend to concentrate more on the posterior column in the lumbar spine. L2–S1 intact lordosis at rest correlated with increasing strain at both the index level and lumbosacral junction in the PSR condition during loading. This finding suggests that overall intact lordosis at rest can translate to instrumented strain during loading. Both intact and PSR L3–S1 lordosis at rest correlated to L3–4 rod strain in at least one direction of bending, e.g., flexion (intact lordosis) and extension (PSR lordosis).

The current study results also corroborate the general hypothesis that sagittal alignment restoration must necessarily seek an ideal spinal equilibrium, which raises a concern of possible effects from overcorrection. In a clinical study of 96 patients (74% of whom had overcorrection), Pizones et al. demonstrated that 77.4% of the patients who had overcorrection developed mechanical complications compared to 15% of those who were matched to their ideal shape, or to 58% of those who ended up with undercorrection. Pizones et al. also suggested that sagittal alignment should be restored to match the ideal Roussouly classification sagittal shape dictated by pelvic index to decrease the rate of mechanical complications. Zhang et al. performed a clinical study with 160 patients who underwent lumbar spine decompression and fusion and reported that patients who returned to the standard Roussouly type not only improved the sagittal curvature but also improved the functional score.

Although restoration of LL in adult spinal deformity has been spotlighted as an important factor for favorable surgical outcomes, excessive postoperative lordosis, or sagittal overcorrection is not desired because of the increased risk of mechanical complication. Sebaaly et al. reported that the most important factor in limiting mechanical complications is the restoration of the sagittal shape of the spine to its original profile according to the Roussouly classification. Correction techniques to the whole spine according to a simple formula involving a fixed angle and the LL might not be the ideal restoration. Lordotic apex, as well as lordosis length, which is variable and may be shorter or longer than anatomical LL, should also be considered.

This study has several limitations. The strain gauges were only able to measure rod strain at specific locations and not throughout the instrumentation. Furthermore, cadaveric biomechanical studies have well-known limitations, including the lack of muscle activities and the use of healthy spines without a target disease that might represent the indication for the stud-
ied surgical technique. The testing paradigm used herein evaluated immediate stability and strain distributions that can affect longer-term mechanical failure in the clinical scenario. Cyclic loading was beyond the scope of the current study and is problematic because it is not possible to truly simulate the long-term in vivo environment. That is, low-loading high-cycle paradigms with cadaver tissue tend to degrade the tissue before any instrumentation failure occurs. Further research is required to determine the effect of the curvature on the strain distribution throughout the lumbar spine and its repercussion on patient outcomes. A more detailed in vitro strain distribution study involving multiple levels and more complex types and direction of loads, including axial rotation, lateral bending, and compression, is recommended. Because the native L4–S1 curvature changes with a significant difference before and after the procedure, the influence of the procedure cannot be excluded.

**CONCLUSION**

Native LL measurements before loading demonstrated strong correlations with in vitro immediate postoperative posterior rod strains during loading. LL has a strong positive linear cor-

Fig. 5. (A) Flexion-extension models simulating a 150-mm long, 5.5-mm diameter titanium alloy rod fixed at the distal end, with a slight curve (model I) and a more lordotic curve (model II), subjected to axial loads as seen during construct bending (see Fig. 4, tensile during flexion, compressive during extension). The blue arrows indicate applied forces (input), and green arrows indicate reaction forces (output, equal and opposite). (B) Resulting maximum stresses for the same magnitude axial load. Model II (rod with more lordotic curvature) is subjected to a higher maximum stress than model I (rod with a less lordotic curvature). Simulations were performed using an online 2-dimensional finite element analysis calculator.33 Elem, element; Fy, force along the y-axis; MPa, megapascal; N, Newton; Ry, resultant force along the y-axis. Adapted with permission from MechaniCalc, Inc.
relation with in vitro posterior rod strain. These relationships should be strongly considered when interpreting biomechanical test results in long-segment fusion models. Further studies are necessary to characterize and illuminate the underlying mechanisms that determine rod strain, as well as to correlate the impact of lumbar curvature correction on rod strain in clinical practice and postoperative surgical outcomes.

CONFLICT OF INTEREST

Jay D. Turner has served as a consultant for NuVasive (San Diego, CA) and SeaSpine (Carlsbad, CA). Juan S. Uribe has served as a consultant for NuVasive (San Diego, CA), SI Bone (Santa Clara, CA), and Misonix (Farmingdale, NY). Other authors have nothing to disclose.

ACKNOWLEDGMENTS

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REFERENCES


Commentary on “A Universal Craniometric Index for Establishing the Diagnosis of Basilar Invagination”

Mehmet Bilgin Eser, Begumhan Baysal
Department of Radiology, Istanbul Medeniyet University Faculty of Medicine, Goztepe Training and Research Hospital, Istanbul, Turkey

To the editor,
We read with great enthusiasm the latest paper of Sardhara et al. in Neurospine, and they offer a novel universal diagnostic test for all types of basilar invagination (BI). They conclude that the distance from the line between the posterior tip of the hard palate-internal occipital protuberance (P-IOP line) was an accurate diagnosis of all types of BI. The study reached a 0.853 area under the curve (AUC) value for 8.99 mm with 76.2% sensitivity and 79.3% specificity. However, we have some concerns regarding the content of this article.

Congenital atlas occipitalization is mentioned in the second paragraph of the introduction; it is not mentioned that these anomalies accompany type B BI.

Type A BI is acquired so that congenital anomalies do not accompany.

Two to five measurements were performed in 10 patients were not different. However, Koo and Li stated that at least 3 observers and 30 measurements were required for reproducibility studies.

Although the authors state that their methods are highly applicable in conclusion, there is not enough evidence to support this hypothesis. Moreover, the 0.886 AUC value found for type B BI is lower than, Nascimento et al. found for the vertical line drawn from Chamberlain line to the odontoid tip, AUC is 0.963 (accuracy: 0.904), and Baysal et al. found AUC for Boogaard’s angle to be 0.977 (accuracy: 0.954). We recommend using classical di-
agnostic tests for BI. Atul Goel stated that in a recent editorial, “Basilar invagination was for long considered to be a radiological curiosity rather than a surgically treatable clinical entity.” Radiology is only helpful in diagnosis.\(^2,4\) Whichever diagnosis your patient’s radiological measurements indicate, it is the patient’s clinical complaints that matter.

Apart from these criticisms, another issue that attracted our attention was related to the figures. In Fig. 1A and B, the basion and opisthion are not shown in the correct positions.\(^2,4,7\) If the patient shown in Fig. 1C is visualized with a more appropriate window, we can observe a sclerotic separation line even with an atlas fusion.\(^1\) In Fig. 3A, B, and D, the vertical lines to be drawn to the P-IOP line are not perpendicular to the odontoid tip, each extending from the odontoid tip to the P-IOP line at different angles.

**CONFLICT OF INTEREST**

The authors have nothing to disclose.

**REFERENCES**

Reply to Commentary on “A Universal Craniometric Index for Establishing the Diagnosis of Basilar Invagination”

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To the editor,

We read with great interest the commentary on “A Universal Craniometric Index for Establishing the Diagnosis of Basilar invagination”. The critical appraisal given by author is commendable. Craniovertebral anomalies are more frequently found in the Indian subcontinent (Uttar Pradesh, Bihar, Rajasthan, and parts of Gujarat states) than anywhere else in the world. Due to unknown geographical factor, at our institute (SGPGIMS, Uttar Pradesh, India) it is one the most common spine anomalies we frequently encountered in our day-to-day routine practice. In our previous extensive research work on craniovertebral junction (CVJ) anomalies, we found that type A basilar invagination (BI), is usually coexisted with atlantoaxial dislocation, rotational dislocation, and coronal tilt due to underlying anomalous facet joints. Multiple CVJ congenital anomalies simultaneously coexist usually. Goel classification of basilar invagination (type A and B) is not based on etiological factors but rather purely is on radiological and clinical basis depend upon presence or absence of atlantoaxial dislocation and/or Chiari malformation. Basilar invagination is congenital or acquired is still debatable and hence not yet proven. Pang and Thompson suggested that the common embryological basis for the association of congenital atlantoaxial dislocation (AAD), BI, platybasia, Arnold-Chiari malformation type I, and rotational deformity is the presence of congenital occipital dysplasia. Therefore, all the subsequent events of facet joint dislocation are probably mechanical events influenced by congenital etiological factors.

In the study of 154 patients of congenital CVJ anomalies, more than 70% patient of BI (both the type A and B) were associated with occipitalised atlas. Similar result has found in our own different studies. In our study, out of 268 patients, 89 cases were irreducible AAD with BI (all the reducible BI cases excluded), means the relationship of proposed landmarks (tip of the hard palate and inion) and odontoid tip has not changed with flexion and extension (as BI does not reduce on dynamic study). The fact is confirmed that, the minimum perpendicular distance from odontoid tip to palate-internal occipital protuberance (P-IOP) line remain same in all the dynamic state of the neck. The P-IOP line does not affect by head position in the diagnosis of BI.

Study is written under highly standard STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines. Moreover, we have also fulfilled the majority criteria of STARD (Standards for Reporting of Diagnostic Accuracy) statement in the study.
to propose newer diagnostic index (sensitivity, specificity, area under the curve [AUC], receiver operating characteristic analysis, cutoff value of our newer diagnostic study, rationale of the diagnostic method over alternative method to diagnose the BI, eligibility of the patients for study, flow of participants using flow diagram and diagnostic accuracy and precision).

We appreciated the critical observation and admit that the reproducibility which we have found in our 2 different groups observations during BI measurement by P-IOP line should have been mentioned in details in the method and result section. Further study on reproducibility is desired, and we are being currently focusing on it with the planning to published in the literature as a upcoming separate study.

The Boogard’s angle is highly reliable index for type B BI, however, on comparison, the measurement of BI by P-IOP line can provide added advantage of diagnosing both the types of BI (A and B) by single universal index with comparable accuracy with 0.853 AUC value for 8.99 mm with 76.2% sensitivity and 79.3% specificity. The degree of severity of myelopathy is directly depend upon the effective canal diameter at CVJ. High basilar invagination would produce further severe compression of cervical medullary junction due to compromised effective canal diameter by odontoid tip.\(^9,10\) More the compression by odontoid tip more the severity of compressive symptoms and myelopathy.\(^2,9-11\) If tip of odontoid is crossed the P-IOP line we referred it high BI in our article, off course it helps in decision making during planning of surgical decompression compare to normal basilar invagination.

A comparison of the distance of odontoid tip to the P-IOP line and the Chamberlain line for establishing the diagnosis BI is already mentioned in the discussion part (using Spearman rho correlation test) revealed a significant negative correlation (correlation coefficient = -0.39, p = 0.002) in these patients.

Comment on figures is genuine, as Fig. 3 graphics could have been better than represented in the article, but the precise idea is to measure the minimum perpendicular distance from P-IOP line to tip of odontoid process could be appreciable. Fig. 1A and B is the representative images of BI with occipitalised atlas where basion and opisthion could not appreciated separately but anomalously attached with clivus and occiput respectively. That is actually the rationale behind the criticism of this two-landmark utilization for diagnosis of BI. In Fig. 1C, opisthion could not find separately that could appear as a false reading during BI measurement. Finally, we would like to congratulate the author for nice commentary and review of our article, we are grateful for the same.

**CONFLICT OF INTEREST**

The authors have nothing to disclose.

**REFERENCES**

To the editor,

As an old global epidemic, tuberculosis (TB) has been threatening human lives for thousands of years. Still today, about 2 billion people are infected with TB, and 1.7 million deaths occur each year worldwide. In addition, many TB patients are undiagnosed or not reported.

Spine is the most common site of extrapulmonary TB, accounting for 50% of skeletal TB. Spinal TB caused by mycobacterium tuberculosis (Mtb) typically spreads via hematogenous path, and then erodes the vertebral body from anterior to posterior. Spinal TB has a characteristic loss of bone density in anterior part of vertebra at first, which tends to create a kyphotic deformity historically named as Pott disease. The intervertebral disc is often the last to be affected, which differs from a typical pyogenic infection. This is often distinguished with the use of magnetic resonance imaging. Spinal TB can be confirmed by histological cultures and laboratory testing.

The typical symptoms and signs of patients infected with TB include fatigue, back pain, weight loss, night sweats, and fevers. Spinal TB generally has an insidious progression with 3 major clinical features: cold abscess, neurologic deficits, and a kyphotic deformity. Compression of the neurological elements from either an abscess or from the kyphotic deformity, often leads to neurologic deficits. In adults with spinal TB, the kyphotic deformity is commonly less than 30°. In children patients, kyphosis may continue to progress during the course of disease, leading to a much larger deformity. This population may require a more timely surgery. Globally, TB is a major cause of death and disability among children, especially in low-income and middle-income countries, yet children have often been neglected in TB control efforts.

To prevent relevant complications, spinal TB requires prompt antitubercular chemotherapy, but delays are more commonplace compared with pulmonary TB. Preventive therapy for the susceptible is an effective strategy to eliminate this disease. People with high-risk factors including immunodeficiency (such as human immunodeficiency virus [HIV] coinfection), malnutrition, and overcrowded living conditions, tend to be at higher risk of TB. Adolescents with spinal TB are an at-risk group for contracting and spreading TB in school. Treatment and prevention of spread, can include some social distancing, relative isolation, and the wearing of a facemask. Throughout this process, psychosocial support should not
be ignored. The most widely used regimen to prevent TB is isoniazid for 6–12 months, while rifampicin or rifapentine combined isoniazid for 3 months can also be used. Furthermore, a 90% reduction in the risk of TB development among contacts that were provided by fluoroquinolone.7 In high-burden countries, preventive therapy is usually limited to spinal TB patients with HIV. In low-burden countries, it can be used for immigrants and latent patients. To avoid cross-infection in suspected patients, the wearing of a surgical mask can become a vitally important part of disease control. Recently, vaccination and detection with whole genome sequencing (WGS) were included in the preventive strategies. Immunization with Bacillus Calmette-Guérin vaccine can protect infants, children, and adults from TB infection. Due to the higher confidence in strain identity, rapid detection of drug resistance with WGS may be available for outbreak investigations.

The understanding of tuberculotic epidemiology and pathophysiology continues to evolve and refine TB treatment. Therapeutic strategies for spinal TB include holistic treatment for TB, and local therapy for spine. The both approaches are related. Holistic antituberculous medication is the cornerstone that consists of isoniazid, rifampicin, pyrazinamide, and ethambutol given for 2 months, followed by isoniazid and rifampicin managed for an additional 4 months.7 World Health Organization (WHO) recommends that TB patient should be offered with daily fixed-dose combinations.8 The medical managements of adults and children with spinal TB are almost identical except the dosing of medications. Surgery is a supplementary therapy for patients with neurological deficits, kyphosis greater than 60°, or for pediatric patients with "spine-at-risk" signs. Local debridement for cold abscess, decompression for neurologic deficits, and realignment for kyphosis could be performed for selected patients with spinal TB (Fig. 1). In our experience, spinal instrumentation with the use of titanium cages, plates, and screws, can stabilize and correct the spinal deformity, without the risk of graft rejection or inflammatory response.9

Drug-resistant TB is a threat that leads to high mortality and one third of deaths in patients with TB worldwide.10 The incidence of rifampicin-resistant TB is increasing in Russia, Myanmar, China, and South Africa.11 The WHO updated guidelines have recommended a multiple drug resistance regimen for TB treatment.12 And WHO suggests fluoroquinolones to cure pa-

**Fig. 1.** A patient with kyphotic spinal tuberculosis (white arrows indicate tuberculotic lesions). The written informed consent had been received from the patient for publication.
tients with isoniazid-resistant TB. In addition, the combination of bedaquiline, pretomanid, and linezolid treating patients with drug-resistant TB led to a favorable outcome after 6-month therapy (90% had the favorable outcomes). However, whether infected patients can clear Mtb is still unclear, as between 1% and 11% of patients with TB immunoreactivity continue to carry viable bacteria capable of recurring disease. The critical principle for treating TB is to obtain culture samples to make an optimal regimen. But even when the diagnosis is achieved in developing countries, treatment adherence is still difficult to be maintained in long-term. Germicidal ultraviolet irradiation is an affordable assistance method to treat spinal TB. Another problem is that serious adverse drug reaction may interrupt therapeutic course. Fortunately, bedaquiline and delamanid are being used to change the care of people with all forms of TB. In addition, usage of vaccine against TB can offer a wonderful protection.

To understand the natural history of spinal tuberculous infections, preventive and therapeutic strategies need to be developed to adequately contain and treat this challenging disease. Newer rapid nucleic acid tests facilitate to diagnose spinal TB. Community-based interventions are efficient to prevent disease's outbreak. Anti-TB chemotherapy, nutritional support, and favorable public health are critical to reduce the trigger of spinal TB. In addition, an in-depth psychotherapy should be provided throughout therapeutic course because patients with productive cough, hemoptysis, and spinal kyphosis tend to be self-contemptuous and scared. Also, a multidisciplinary approach should be developed for tuberculous diagnosis and treatment, which involving epidemiologists, pharmacologists, spine surgeons, and radiologists.

CONFLICT OF INTEREST

The authors have nothing to disclose.

REFERENCES

I. General Information

Neurospine provides spine clinicians and researchers with peer-reviewed articles on basic and clinical investigation of spine and spinal cord to enhance patient management, education, clinical or experimental research, and professionalism. The journal will consider submissions in areas on cranio cervical to lumbosacral spine including the following; neuroscience and pain research, bone mineral research, disc and joint research, bio and industrial technology, pathophysiology, risk factors, symptomatology, imaging, treatment, rehabilitation of spine, and spinal cord/ peripheral nerve diseases. Specifically, basic and technology researches include the most influential research papers from all fields of science and technology, revolutionizing what physicians and researchers practicing the art of spinal neurosurgery worldwide know. Thus, we welcome valuable basic and translational technology research articles to introduce cutting-edge research of fundamental sciences and technology in clinical spinal neurosurgery. Clinical or Basic Research Articles, Review Articles, Case Reports, Technical Notes, and Letters to the Editor written in English will be accepted.

Neurospine, the official journal of ASIA SPINE, the Neurospinal Society of Japan, Taiwan Neurosurgical Spine Society, and the Korean Spinal Neurosurgery Society, is an international peer-reviewed open-access journal which published quarterly (last day of March, June, September, and December). It was first published in March 31, 2004 with Volume 1 and Number 1 with the name “Korean Journal of Spine,” and renamed as “Neurospine” since March 2018. Neurospine is indexed/tracked/covered by Emerging Sources Citation Index (ESCI), PubMed, PubMed Central, KoreaMed, KoMCI, EBSCO host, and Google Scholar.

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3. All authors should sign on the Copyright Release, Author Agreement and Disclosure of Conflict of Interest form to certify that the contents of the manuscript have not been published and are not being considered for publication elsewhere. If any research grant has been given by any private company or group, this information should be described on the form. All authors must sign their autograph by themselves. The form can be downloaded at the homepage of the Neurospine (https://e-neurospine.org), and should be submitted at the time of paper submitting.
4. Regarding author information, the list of the authors in the manuscript should include only those who were directly involved in the process of the work. Authors can refer to the guideline by Harvard University in 1999 to find details on authorship (https://hms.harvard.edu/sites/default/files/assets/Ombuds/files/AUTHORSHIP%20GUIDELINES.pdf).
5. Decision for the publication of the submitted manuscript will be made solely by the editorial board.
6. Professional editing in English is recommended for non-native speakers. Editorial office may request an English editing. In cases of accepted manuscripts, we may provide copy editing and English proofreading free of charge.
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Authors should refer to “Uniform Requirements for Manuscripts Submitted to Biomedical Journals” (http://www.icmje.org/about-icmje/faqs/icmje-recommendations/).

1. Title Page
1) The title pages must be composed of external and internal title pages.
2) The external title page must contain the article title, and full names of all authors with their institutional affiliations both. The type of manuscript (original articles, review articles, case reports, technical notes, letters to the editor, brief communications) should also be addressed. When the work includes multiple authors with different affiliations, the institution where the research was mainly conducted should be spelled out first, and then be followed by foot notes in superscript Arabic numerals.
Instructions for Authors

beside the authors’ names to describe their affiliation in a consecutive order of the numbers. Running head must be included consisting of no more than 65 characters/spaces. The external title page must also contain the address, telephone and facsimile numbers, and e-mail address of the corresponding author at the bottom of the page, as well as information on the previous presentation of the manuscript in conferences and funding resources, if necessary.

3) The internal title page should only contain the article title. The internal title page must not contain any information on the names and affiliations of the authors.

2. Manuscript Format
1) The manuscript should be composed of no more than 5,000 English words for original and review articles, 3,000 English words for technical reports and case reports except for references, tables, and figures. It should be composed of no more than 600 English words for letters to the editor.

2) The article should be organized in the order of title, abstract, introduction, materials and methods, results, discussion, conclusion, references, tables, and figures or illustrations.

3) There should be no more than 40 references in original articles. In case reports, materials and methods and results can be replaced with cases. The number of references should be 20 or less and the figure number 5 or less.

4) Manuscript format may vary in review articles. There should be no more than 100 references in review articles.

5) Text should be written in 11 point fonts with double line spacing.

3. Abstract
1) Objective, Methods, Results, and Conclusion sections should be included in abstract of clinical or laboratory research, but are not necessary in other types of studies.

2) The abstract should include brief descriptions on the objective, methods, results, and conclusion as well as a detailed description of the data. An abstract containing 250 words or less is required for original articles and 200 words or less for case reports and review articles.

3) Abstract can be revised by the decision of editorial board, and some sentences can be modified as a result of revision.

4) A list of key words, with a minimum of two items and maximum of six items, should be included at the end of the abstract.

5) The selection of Key Words should be based on Medical Subject Heading (MeSH) of Index Medicus and the web site (http://www.nlm.nih.gov/mesh/MBrowser.html).

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The introduction should address the purpose of the article concisely, and include background reports mainly relevant to the purpose of the paper. Detailed review of the literature should be addressed in the discussion section.

5. Materials and Methods
1) The article should record research plans, objective, and methods in order, as well as the data analysis strategies and control of bias in the study. Enough details should be furnished for the reader to understand the method(s) without reference to another work in the study described.

2) When reporting experiments with human subjects, the authors must document the approval received from the local Institutional Review Board. When reporting experiments with animal subjects, the authors should indicate whether the handling of the animals was supervised by the research board of the affiliated institution or such. Approved number of IRB must be noted.

3) Photographs disclosing patients must be accompanied by a signed release form from the patient or family permitting publication.

4) Ensure correct use of the terms sex (when reporting biological factors) and gender (identity, psychosocial or cultural factors), and, unless inappropriate, report the sex and/or gender of study participants, the sex of animals or cells, and describe the methods used to determine sex and gender. If the study was done involving an exclusive population, for example in only one sex, authors should justify why, except in obvious cases (e.g., prostate cancer). Authors should define how they determined race or ethnicity and justify their relevance.

6. Results
1) The authors should logically describe their results of observations and analyses performed using methodology given in the previous section and provide actual data.

2) For biometric measurements in which considerable amount of stochastic variation exists, a statistical evaluation is mandatory. The results must be solely from the findings of the current study and not refer to any previous reports.

3) While an effort should be made to avoid overlapping descriptions by Tables and by main text, important trends and points in the Table should be described in the text.

7. Discussion
Discussions about the findings of the research and interpretations in relation to other studies are made. It is necessary to emphasize the new and critical findings of the study, not to repeat the results of the study presented in the previous sections. The meaning and limitation of observed facts should be described, and the conclusion should be related to the objective of the study only when it is supported by the results of the research.
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The conclusion section should include a concise statement of the major findings of the study in accordance with the study purpose.

9. References
The authors are responsible for the accuracy of the references. Key references (double-spaced) at the end of the manuscript. End-Note users can access a direct download of the updated Neurospine Publications style at https://www.e-neurospine.org. References should be numbered consecutively in the order in which they are first mentioned in the text. All references cited in the text must be both listed and cited by the reference number (footnotes are not accepted). Use superscript numerals outside periods and commas, inside colons and semicolons. When more than 2 references are cited at a given place in the manuscript, use hyphens to join the first and last numbers of a closed series; use commas without space to separate other parts of a multiple citation (e.g., As reported previously,1,4-9...The derived data were as follows3,4,12:)
Do not link the references to the text. Cite unpublished data, such as papers submitted but not yet accepted for publication or personal communications, in parentheses in the text. If there are more than three authors, name only the first three authors and then use et al. Refer to the List of Journals Indexed in Index Medicus for abbreviations of journal names, or access the list at https://www.nlm.nih.gov/archive/20130415/tsd/serials/lji.html. Sample references are given below:

- Journal article

- Book chapter

- Entire book

- Software

- Online journals
  5. Friedman SA. Preeclampsia: A review of the role of prostaglan-


- Database

- World Wide Web

10. Tables
1) Tables should be created using the table formatting and editing feature of Microsoft Word. The title of the table must be noted. Tables cannot be submitted in a picture format.
2) Tables should be prepared in detail, in order to understand the contents of the manuscript without further reference.
3) Tables should be submitted separately from manuscript. Do not include vertical lines in table, and refer to the table formats in formal papers in Neurospine.

11. Figures and Illustrations
1) Figures should have resolution of 300 dpi or above and should be submitted individually (Namely, if Figure 1 is divided into A, B, C, and D, do not combine them into one, but submit each of them separately). Allowable file format for figures are JPG or TIF (TIFF) only.
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3) Authors should submit figures in black and white if they want them to be printed in black and white. Authors are responsible for any additional costs of producing color figures (Additional cost for color printing is determined by the editorial board).
4) Line art should have resolution of 1,200 dpi or more in JPG or TIF format.

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2) The page numbers in the manuscript should be counted from the page with the abstract, and the name and affiliation of the
authors should not appear thereafter.
3) Author check list should be prepared, signed by corresponding author, submitted with manuscripts, and then registered online. Relevant forms can be downloaded at manuscript submission site.

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All manuscripts are considered confidential. They are peer-reviewed by at least 2 anonymous reviewers selected by the Editor. The corresponding author is notified as soon as possible of the Editor’s decision to accept, reject, or ask for revisions. The average time interval for an initial review process that involves both editorial and peer reviews is approximately 1 month; occasionally, there are unavoidable delays, usually because a manuscript needs multiple reviews or several revisions. When manuscripts are returned for revision, a cover letter from the Editor provides directions that should be followed carefully. When submitting the revised manuscript, authors should include a Response Letter, which describes how the manuscript has been revised. A point-by-point response to the Editor should be included with the revised manuscript. Authors who plan to resubmit but cannot meet this deadline should contact the Editorial Office. Manuscripts held for revision will be retained for a maximum of 90 days. The revised manuscript and the author's comments will be reviewed again. If a manuscript is completely acceptable, according to the criteria set forth in these instructions, it is scheduled for publication in the next available issue.

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2. Conflict of Interest

1) The corresponding author of an article is asked to inform the Editor of the authors’ potential conflicts of interest possibly influencing their interpretation of data. A potential conflict of interest should be disclosed in the cover letter even when the authors are confident that their judgments have not been influenced in preparing the manuscript. Such conflicts may be financial support or private connections to pharmaceutical companies, political pressure from interest groups, or academic problems. Disclosure form shall be same with ICMJE Uniform Disclosure Form for Potential Conflicts of Interest (http://www.icmje.org/coi_disclosure.pdf).
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3) The editorial committee checks the similarity by using the iThenticate (http://www.ithenticate.com/) program for all submitted articles to prevent plagiarism. The editorial committee rejects the article suspected of plagiarism and asks the author to check whether it is plagiarized and make a resubmission.

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It is primarily for clinicians and researchers who care patients with spine and spinal cord diseases. They are able to obtain tailored information to adopt for their research and practice. Its readership can be expanded to other positions: • Researchers can get the recent topics of clinical research in spine and spinal cord field and detailed research methods; • Clinicians in the field can get the new information and recent development for care of patients; • Medical teacher can access and adopt a variety of data in medical education; • Allied health professionals including nurses are able to get the recent information for care of patients with spine and spinal cord diseases; • The public, especially family of patients with spine and spinal cord diseases are able to read the advance in their family’s diseases so that they have a better knowledge on the diseases and a confidence in the clinicians’ devotion to their family.

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1) Clinical trial defined as “any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome” should be registered to the primary registry to be prior publication.


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Who is responsible to resolve and handle complaints and appeals?
The Editor, Editorial Board, or Editorial Office is responsible for them.

- What may be the consequence of remedy?
  It depends on the type or degree of misconduct. The consequence of resolution will follow the guidelines of the Committee of Publication Ethics (COPE).

9. Postpublication Discussions and Corrections
The postpublication discussion is available through letter to the editor. If any readers have a concern on any articles published, they can submit letter to the editor on the articles. If there founds any errors or mistakes in the article, it can be corrected through errata, corrigenda, or retraction.

10. Policies on data sharing and reproducibility
Until 2020, authors will be encouraged to share their data openly, but starting in 2021, they will be mandated to do so. The related regulation follows the open data sharing policy outlined below.

1) Open data sharing policy
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