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DIAGNOSTICS

A Multicenter Radiographic Evaluation of the Rates of Preoperative and Postoperative Malalignment in Degenerative Spinal Fusions

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Study Design. Multicenter, retrospective, institutional-review-board -approved study at 18 institutions in the United States with 24 treating investigators.

Objective. This study was designed to retrospectively assess the prevalence of spinopelvic malalignment in patients who underwent one- or two-level lumbar fusions for degenerative (non-deformity) indications and to assess the incidence of malalignment after fusion surgery as well as the rate of alignment preservation and/or correction in this population.

Summary of Background Data. Spinopelvic malalignment after lumbar fusion has been associated with lower postoperative health-related quality of life and elevated risk of adjacent segment failure. The prevalence of spinopelvic malalignment in short-segment degenerative lumbar fusion procedures from a large sample of patients is heretofore unreported and may lead to an under-appreciation of these factors in surgical planning and ultimate preservation or correction of alignment.

Methods. Lateral preoperative and postoperative lumbar radiographs were retrospectively acquired from 578 one- or two-level lumbar fusion patients and newly measured for lumbar lordosis (LL), pelvic incidence (PI), and pelvic tilt. Patients were categorized at preop and postop time points as aligned if PI-LL $< 10^{\circ}$ or malaligned if PI-LL $\geq 10^{\circ}$. Patients were grouped into categories based on their alignment progression from pre- to postoperative, with *preserved* (aligned to aligned), *restored* (malaligned to aligned), *not corrected* (malaligned to malaligned), and *worsened* (aligned to malaligned) designations.

Results. Preoperatively, 173 (30%) patients exhibited malalignment. Postoperatively, 161 (28%) of patients were malaligned. Alignment was *preserved* in 63%, *restored* in 9%, *not corrected* in 21%, and *worsened* in 7% of patients.

Conclusion. This is the first multicenter study to evaluate the preoperative prevalence and postoperative incidence of spinopelvic malalignment in a large series of short-segment degenerative lumbar fusions, finding over 25% of patients out of alignment at both time points, suggesting that alignment preservation/restoration considerations should be incorporated into the decision-making of even degenerative lumbar spinal fusions.

Key words: ASD, ASF, LL, lumbar lordosis, malalignment, pelvic incidence, pelvic tilt, PI, PT, reoperation, sagittal balance.

Level of Evidence: 3

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Postoperative spinopelvic alignment is understood to be a predictive factor for long-term clinical outcomes after spinal deformity surgery. The relationship between the postoperative pelvic incidence (PI) and lumbar lordosis (LL) appears to predispose patients to either clinical success or failure as measured by health-related quality-of-life (HRQOL) outcomes scales.[1–3] While these measurements are typically utilized in adult deformity surgery, their use and importance in short-segment degenerative conditions is less clearly understood. A few reports have described an increased incidence of adjacent segment degeneration and/or failure requiring reoperation in patients who had mismatched spinopelvic parameters,[3–9] suggesting that these same radiographic targets may be relevant for even one- or two-level lumbar fusion operations.

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While data continue to emerge on the effects of postoperative spinopelvic malalignment after short-segment fusions, the prevalence of spinopelvic malalignment before and incidence after these cases from large-sample studies is heretofore unreported. The purpose of this study was to assess spinopelvic alignment pre- and postoperatively in patients who had previously undergone one- or two-level lumbar fusions for nondeformity indications to determine the prevalence of malalignment preoperatively and the incidence of malalignment postoperatively.

MATERIALS AND METHODS

Study Design

A multicenter, retrospective, institutional-review-board approved study was undertaken at 18 institutions in the United States with 24 treating investigators. Patient records were eligible for inclusion if the patient had undergone a one- or two-level lumbar fusion for a degenerative (nondeformity) indication using any technique and had preoperative and postoperative (within 6 months of the index surgery) standing lateral radiographs available for review that included both femoral heads and visualization of the entire lumbar spine (L1 to S1), upon which retrospective sagittal spinopelvic alignment measurements were made. The surgeries were performed without objective spinopelvic alignment measures considered in the surgical decision-making. Primary exclusion criteria were fusion at more than two spinal levels, fusion for a nondegenerative condition (*i.e.*, deformity, tumor, or trauma), and images that were uninterpretable due to poor image quality or difficulty with visualization of anatomic structures.

Patient Sample

A total of 763 cases were submitted for analysis. One hundred twenty-four of those cases were withdrawn due to not meeting inclusion criteria and another 61 were incomplete (*i.e.*, missing a required image) at the time of study closure, yielding a final study population of 578 cases.

Data Collection

Radiographic measurements were made using NuVaMap (NuVasive, Inc, San Diego, CA) image analysis software and included PI, pelvic tilt, and LL (L1-S1) both pre- and postoperatively. A single reviewer, the submitting clinician, measured alignment on the set of plain films for each patient with the aid of measurement software. Study staff then visually inspected each image with measurements after submission. In cases with discrepancies or clearly inaccurate measurements, the issues were resolved through a query process or, if a resolution was not possible, the cases were removed from analysis. Spinopelvic alignment (PI minus LL) was calculated based on the measurements taken and spinopelvic malalignment was determined at either time point if the value of pelvis and lumbar lordosis (PI-LL) was 10° or greater (PI-LL$\geq$10°), based on prior malalignment threshold validation.[10] Of note, patients with PI minus LL of less than −10° are technically out of spinopelvic alignment per prior reports,[10] though were not considered as *malaligned* in the current analysis due to their having hyper, rather than hypolordosis (which is more commonly a goal of surgery to correct).

As there were two evaluated time points (pre- and postoperative) and two possible alignment categorizations (aligned or malaligned), each patient was grouped into one of four categories of alignment progression from before to after surgery: *Preserved*, *restored*, *not corrected*, or *worsened*. Patients who were aligned both pre- and postoperative were classified as *preserved*, those malaligned preoperative and aligned postoperatively were *restored*, patients malaligned both pre- and postoperatively were *not corrected*, and those aligned preoperatively and malaligned postoperatively were *worsened*.

Statistical Analysis

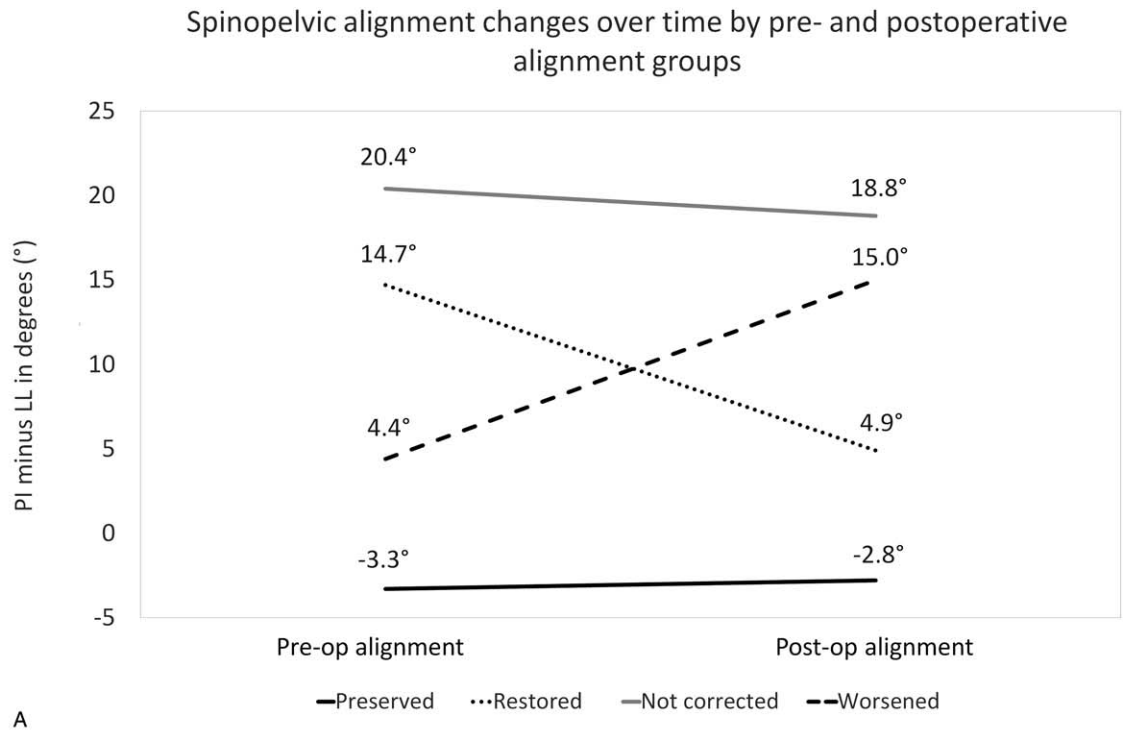
Statistical analysis was performed using JMP v13.0 (SAS Institute, Inc, Cary, NC). Descriptive statistics with frequency analyses were performed to characterize all categorical and continuous variables as a whole and grouped by alignment progression. Pre- to postoperative alignment changes within and between groups were evaluated using analysis of variance tests or paired *t* tests, where applicable, with significance defined at $P < 0.05$.

RESULTS

In the 578 evaluable patients, mean preoperatively LL was 52.9° (standard deviation (stdev), 13.3°), PT was 19.7° (stdev, 8.5°), PI was 56.6° (stdev, 11.8°), and mean PI minus LL calculation was 3.7° (stdev, 12.6°). Preoperatively, 173 (30.0%) patients had a PI-LL$\geq$10°, and were classified as malaligned. Another 71 (12.3%) patients had PI-LL$\leq -10°$. After surgery, mean LL was 53.2° (stdev, 11.9°), PT was 20.0° (stdev, 8.2°), PI was 56.8° (stdev, 11.7°), and the mean PI-LL calculation was 3.6° (stdev, 11.8°). Postoperatively, 161 (27.9%) patients were malaligned and another 72 (12.5%) had PI-LL$\leq -10°$. Figures 1A and B and 2 show alignment before and after surgery and the distribution of malalignment for the whole sample, with complete alignment outcomes included in Table 1.

Grouping of patients into categories based on preoperative and postoperative alignment changes revealed *preserved* alignment in 367 (63.5%), *restored* alignment in 50 (8.7%), alignment *not corrected* in 123 (21.2%), and *worsened* alignment in 38 (6.6%) patients (Figures 3 and 4). Mean alignment measures at preoperative and postoperative time points as well as the change from preoperative to postoperative were all statistically significantly different between groups, $P < 0.05$ (Table 2). As LL is the factor most directly influenced by lumbar fusion, change in LL from preoperative to postoperative is shown in Figure 1B.

For the 71 (12.3%) patients with PI-LL$\leq -10°$ preoperatively, mean PI was 47.5° and baseline LL was 62.6°, which decreased an average of 2.8° postoperatively to 59.9°. Preoperative PT was 10.7° which increased slightly to 12.2° postoperatively. All the patients were categorized, based on



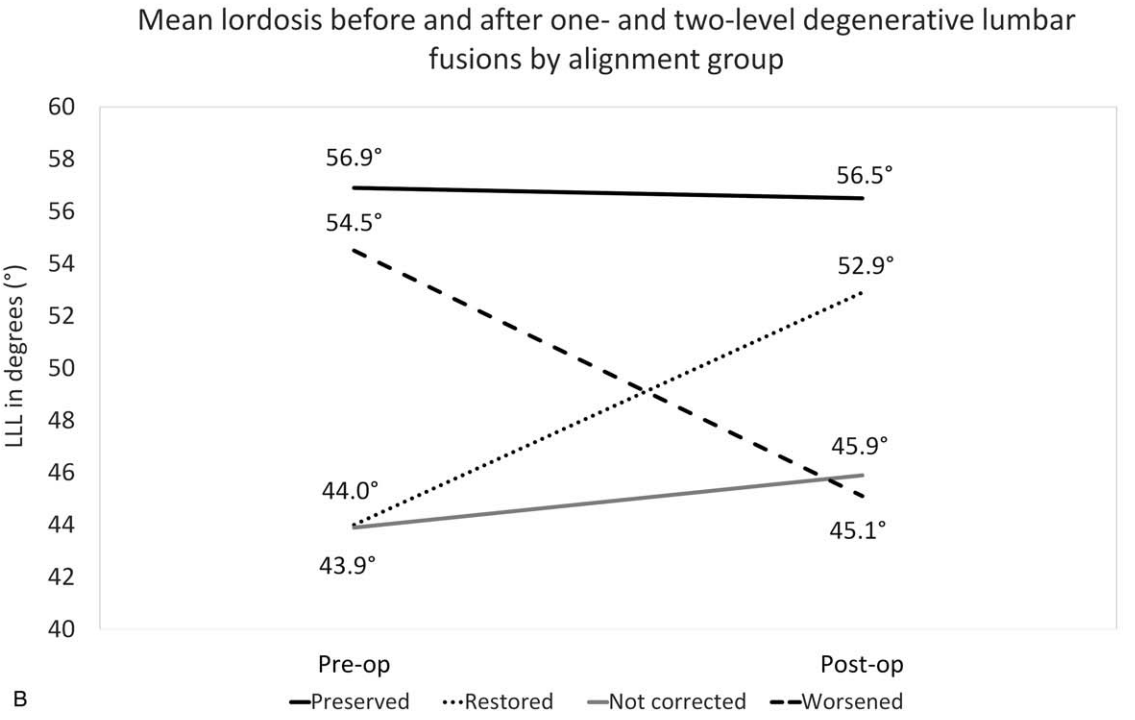


Figure 1. Graph showing change in spinopelvic alignment (pelvic incidence (PI) minus lumbar lordosis (LL)) from preoperative to postoperative time points between groups (**A**) and change in lordosis alone for the same groupings at the same time points (**B**).

the criteria previously described, as aligned both preoperatively and postoperatively (*preserved*). Of the 72 patients with PI-LL$\leq -10^{\circ}$ postoperatively, all were the same as those with PI-LL$\leq -10^{\circ}$ preoperatively except for one with a 35° improvement in lordosis from preoperative, who was categorized as *restored*, though with a final PI-LL$\leq -10^{\circ}$.

DISCUSSION

When surgically treating adult degenerative scoliosis, restoration or maintenance of appropriate lumbar lordosis and sagittal alignment appears to reduce the risk of implant failure and proximal junctional kyphosis.[3,4,8,9,11–18] The role of these spinopelvic parameters in degenerative

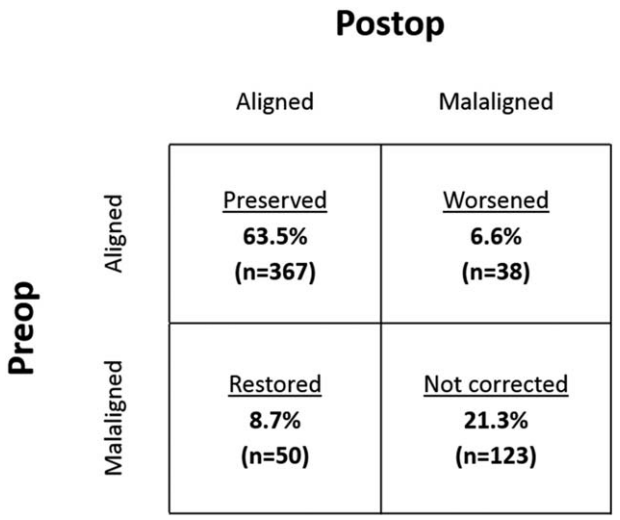


Figure 2. Distribution of patients as aligned or malaligned (based on PI-LL≥10°) at preoperative and postoperative time points.

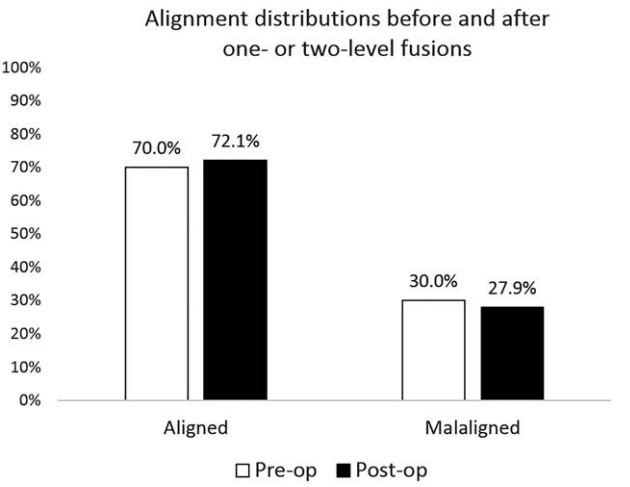


Figure 3. Changes in spinal alignment parameters for the entire cohort of one- and two-level fusion patients at pre and postoperative time points, including lumbar lordosis (LL), pelvic tilt (PT), pelvic incidence (PI), and the calculation of PI minus LL (PI-LL).

conditions has historically been less emphasized, as 1- or 2-level fusion procedures have been considered degenerative, rather than deformity, operations. Recent articles suggest, however, that mismatch of spinopelvic parameters may accelerate the rate of adjacent level failure and the need for early reoperation.[4,6–9,11,13,16–19]

Adjacent segment disease (ASD) manifests radiographically with or without clinical symptoms. Radiographically, ASD is typically defined as a change on magnetic resonance imaging/computed tomography or plain films in a level adjacent to a fusion construct, characterized by disc desiccation or herniation, facet hypertrophy, development of spondylolisthesis, or an increased degree of central canal stenosis resulting from ligamentum hypertrophy.[7] ASD without clinical symptoms is commonly referred to simply as ASD or as radiographic ASD. Once symptomatic, ASD is sometimes referred to as clinical ASD and may require surgical intervention. If surgery is indicated, ASD becomes classified as adjacent segment failure (ASF) and is typically treated by an extension of the previous fusion to include the newly degenerated level. These radiographic and clinical

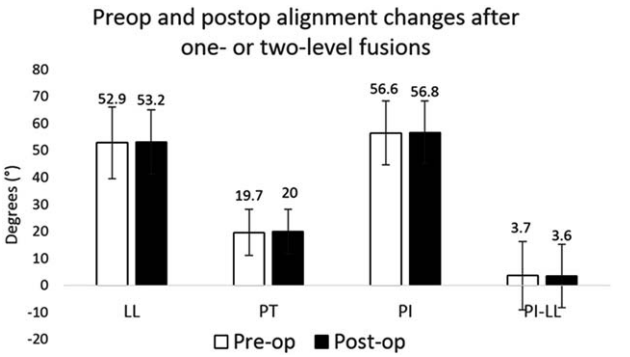


Figure 4. Illustration showing distribution of patients into groups based on alignment at pre- and postoperative time points.

conditions are analogous to proximal junctional kyphosis and proximal junctional failure after deformity procedures.[15] The rate of ASD (radiographic) ranges from 31% to 83% within a 5-year follow-up period, and the reoperation (ASF) rate by 5 years postindex fusion ranges from 0% to 17%, with most studies reporting

TABLE 1. Radiographic Information for the Full Sample

Characteristic	Preoperative	Postoperative	Pre to Postoperative Change	Significance ($P < 0.05$)
Lumbar lordosis—mean in degrees (stdev; range)	52.9 (13.3; 11–96)	53.2 (11.9; 10–86)	0.3 (7.6; −22–35)	0.287
Pelvic tilt—mean in degrees (stdev; range)	19.7 (8.5; −5–48)	20.0 (8.2; −1–46)	0.3 (4.5; −22–16)	0.120
Pelvic incidence—mean in degrees (stdev; range)	56.6 (11.8; 16–98)	56.8 (11.7; 12–98)	0.3 (3.1; −12–9)	0.976
Spinopelvic alignment (PI minus LL) —mean in degrees (stdev; range)	3.7 (12.6; −31–54)	3.6 (11.8; −40–53)	−0.1 (7.5; −36–22)	0.787
Patients with spinopelvic malalignment (PI minus LL ≥10°)—n (%)	173 (30.0)	161 (27.9)		0.475

LL indicates lumbar lordosis; n, number of patients; PI, pelvic incidence; stdev, standard deviation.

TABLE 2. Radiographic Information Separated into Pre and Postoperative Alignment Categories

Characteristics	Preserved n = 367 (63.5%)*	Restored n = 50 (8.7%)*	Not Corrected n = 123 (21.3%)*	Worsened n = 38 (6.6%)*	Sig† $P < 00.05$
Preoperative					
Lumbar lordosis—mean in degrees (stdev; range)	56.9 (11.2; 27–96)	44.0 (12.5; 15–71)	43.9 (14.1; 11–74)	54.5 (10.8; 35–82)	<0.001
Pelvic tilt–mean in degrees (stdev; range)	16.0 (6.9; −5–46)	24.3 (5.8; 8–37)	28.6 (6.5; 11–48)	20.2 (6.5; 4–34)	<0.001
Pelvic incidence–mean in degrees (stdev; range)	53.4 (10.5; 16–90)	58.7 (11.1; 34–81)	64.3 (12.4; 30–98)	58.9 (9.8; 39–77)	<0.001
Spinopelvic alignment (PI minus LL)–mean in degrees (stdev; range)	−3.3 (7.7; −31–9)	14.7 (4.4; 10–25)	20.4 (9.0; 10–54)	4.4 (3.9; −8–9)	<0.001
Postoperative					
Lumbar lordosis–mean in degrees (stdev; range)	56.5 (10.6; 23–86)	52.9 (11.0; 29–82)	45.9 (12.2; 10–74)	45.0 (10.0; 26–67)	<0.001
Pelvic tilt–mean in degrees (stdev; range)	16.5 (6.3; −1–46)	21.5 (6.6; 7–35)	28.7 (7.3; 11–46)	23.8 (5.9; 11–34)	<0.001
Pelvic incidence–mean in degrees (stdev; range)	53.7 (10.4; 12–89)	57.8 (10.8; 35–83)	64.7 (12.1; 32–98)	60.0 (9.9; 43–81)	<0.001
Spinopelvic alignment (PI minus LL)–mean in degrees (stdev; range)	−2.8 (8.0; −40–9)	4.9 (4.3; −11–9)	18.8 (7.3; 10–53)	15.0 (5.2; 10–28)	<0.001
Change from baseline					
Lumbar lordosis–mean in degrees (stdev; range)	−0.3 (6.6; −15–31)	8.9 (6.5; 0–35)	1.9 (7.0; −12–25)	−9.5 (6.0; −22–3)	<0.001
Pelvic tilt–mean in degrees (stdev; range)	0.4 (4.3; −15–16)	−2.8 (5.0; −21–7)	0.1 (4.6; −22–10)	3.6 (3.8; −5–13)	<0.001
Pelvic incidence–mean in degrees (stdev; range)	0.3 (3.0; −12–9)	−0.9 (2.4; −7–3)	0.4 (3.2; −10–8)	1.1 (3.3; −6–9)	0.020
Spinopelvic alignment (PI minus LL)–mean in degrees (stdev; range)	0.6 (6.2; −31–16)	−9.8 (6.2; −39–−1)	−1.6 (7.0; −25–13)	10.6 (5.6; 2–s22)	<0.001

**Numbers do not add up to 100% due to a rounding error.*

†One-way analysis of variance (ANOVA) tests were used to categorize differences for each alignment measure between all four alignment groups.

LL indicates lumbar lordosis; n, number of patients; PI, pelvic incidence; Sig, significance; stdev, standard deviation.

approximately a 10% reoperation rate at 5 years.[4,6–8,11,13,18,19] Maruenda *et al*[6] followed 73 patients with circumferential fusion for a period of 15 years and demonstrated progression of ASD and ASF over time, with a 9% reoperation rate at 5 years, a 25% reoperation rate by 10 years, and a 37.5% reoperation rate by 15 years after the index fusion. Within this study, 80% of all patients exhibited radiographic ASD by the end of the study period. These results have been supported by other longitudinal studies, including Yamasaki *et al* who demonstrated a radiographic ASD rate of 43% with a mean follow-up of 38 months, and Kumar *et al* in 2000 who demonstrated a radiographic ASD rate of 37% by 5 years postoperative.[4,8]

Technical characteristics of a degenerative lumbar fusion construct may decrease or increase the risk of ASD/ASF, and many authors have attempted to address the role that anterior, posterior, or combined procedures may play in this condition.[8,14,19,20] Regardless, a growing body of evidence has implicated spinopelvic mismatch as a risk factor for an accelerated rate of ASD and the ultimate development of ASF.[3,8,9,13,16–18] Several of these studies have compared the spinopelvic parameters of patients who underwent reoperation for ASF after lumbar fusion to a control group of matched patients without clinical ASD after lumbar fusion.[13,16–18] A 2017 study by Matsumoto *et al*[17] compared 20 patients treated for ASF after single-level, L4–5 posterior lumbar interbody fusion with 100 control patients who had a similar procedure, and reported that the PI-LL mismatch was >10° in 75% of the ASF patients yet only 40% of the control group, demonstrating at least a correlation between the mismatch and the need for reoperation. Similarly, a study published in 2015 by Rothenfluh *et al*[18] demonstrated that, at an average of 4 years after a primary one-, two-, or three-level lumbar fusion, 26% of patients with a PI-LL < 10° underwent revision for ASF, while 78% of patients with a PI-LL≥10° did. This yielded an approximately 10-times increased risk (odds ratio of 10.6) of development of ASF when the lumbar spine and pelvis are malaligned. Tempel *et al*[9] in 2017 analyzed 159 patients who underwent transforaminal lumbar interbody fusion at

either L4–5 or L5–1 and found that for every 1° PI minus LL increase, there was a 1.3 to 1.4-fold increase in the risk of clinical ASD and that if a patient had a PI-LL mismatch >11°, the positive predictive value for ASF was 75%.

These studies clearly suggest that achieving appropriate spinopelvic alignment should be considered as a goal of surgery, even in one- or two-level lumbar fusion procedures for degenerative conditions. Spinal alignment has long been a primary factor in long-construct deformity surgery decision-making. In light of the current and recent published evidence, many surgeons now believe it is worthwhile characterizing spondylolisthesis and multilevel degenerative changes as degenerative deformities, with restoration or maintenance of alignment as a central goal of surgery. Short-construct degenerative disease should therefore at least have alignment assessed and confirmed to be normal before, during, and after surgery to enhance the likelihood of long-term construct survivability. In this analysis, while a majority of patients (70%) were aligned preoperatively with PI-LL < 10°, only a roughly equivalent number (72%) were aligned postoperatively, and not all of the same patients from preoperative. In the remaining approximately one-quarter of patients, postoperative lordosis was not preserved or corrected to within the 10° threshold when compared with pelvic incidence and, therefore, their risk of subsequent ASD and need for reoperation (ASF) may be significantly higher than in the group who had maintenance or restoration of lordosis. The aligned–malaligned (*worsened*) group represents perhaps the most concerning situation, as these 7% of patients had an iatrogenic worsening of their aligned lumbar lordosis to a malaligned state postoperatively, and therefore any symptomatic improvement that they experience after the index lumbar fusion may be undone by a progressively increasing need for reoperation due to clinical ASD. Studies assessing HRQOL scores after lumbar fusion have demonstrated worsened scores in patients who have spinopelvic mismatch or malalignment in both deformity and degenerative lumbar fusion populations,[1,3] and these patients are therefore also at risk for viewing their surgical procedure as a "failed operation" in which postoperative pain or quality of life has not been significantly improved with surgical intervention. When addressing overlapping pathologies of degenerative and deformity conditions, one must individualize the treatment to that particular patient's complaints and goals. While it is not always possible to correct a large lumbosacral mismatch in a one- or two-level procedure, it is becoming more apparent that optimizing segmental lordosis toward spinopelvic harmony during the index procedure is essential in not further propagating or unmasking a potential sagittal malalignment issue.

These results also show that a substantial number of patients (13%) were hyperlordotic relative to their PI (PI-LL≤−10°). Although the current understanding of alignment suggests that hypolordosis relative to PI is a predictive factor for worsened HRQOL and elevated rates of ASF, the clinical results of hyperlordosis patients were not classified as "malaligned," as that description was reserved for patients who had a lumbar lordosis less than their measured PI (*i.e.*, were hypolordotic). The clinical and survivability consequences of hyperlordosis relative to pelvic incidence remain unknown in the adult population. In this series, the patients with PI-LL≤−10°, on average, had moderate PIs (48°) and normal LL (63°) with a normal PT (11°), suggesting a balanced spine, though still with significant PI-LL mismatch. Further work confirming the benign nature of a negative mismatch is needed.

This study does have some limitations that may limit its general applicability. It is a multicenter retrospective study encompassing differing fusion techniques performed by a fairly diverse group of surgeons and includes radiographic data only without any clinical outcomes (HRQOL). First, a prospective study with more narrow inclusion criteria may yield different results. Next, our primary purpose in this study was to quantify the incidence of spinopelvic alignment or mismatch after limited lumbar fusion procedures from a larger sample than had been previously reported. Therefore, it was not the intention of this study to speak to the direct clinical effect of this alignment or malalignment within this sample but instead to rely on the results of the studies described above (and other ongoing studies) to further define the relationship between alignment and clinical/survivability outcomes in degenerative conditions. Another weakness of the study was the lack of incorporation of global spinal alignment measures, most notably sagittal vertical axis (SVA), due to the lack of availability of long films in these retrospective short-segment fusions. While the relationship between the orientation of the PI-LL has been shown to be the most correlative factor with HRQOL, PT, and SVA also affect patient outcome. While the three radiographic parameters are related, they measure distinct alignment characteristics with PI-LL being an indicator of spinopelvic alignment, PT a measure of compensation, and SVA of global spinal alignment. While the primary focus of this work was on PI-LL, PT was also measured and showed significant differences between the PI-LL alignment outcome groups (*i.e.*, significant PT improvement in *restored* and worsening in *worsened* patients). In addressing the lack of SVA in the current analysis, within a recent study by Radovanovic *et al*,[3] 84 patients who had lumbar fusion for spondylolisthesis were retrospectively divided into those with a postoperative SVA < 5 cm and those with postoperative SVA >5 cm. The 54% of patients with an SVA >5 cm had worse postoperative HRQOL scores, and 77% of these patients had a PI-LL measuring > 9°. In the sagittally aligned group (SVA < 5 cm), only 49% of patients had a PI-LL >9°. The authors note, therefore, that the relationship between PI-LL and SVA holds true for the degenerative spondylolisthesis population as it does for the deformity population, and also report that the failure to achieve alignment of PI-LL in their study population was not the result of patients with a high pelvic incidence, but rather the result of undercorrection of lumbar lordosis. While the authors of the current study acknowledge that the number of patients defined as aligned and malaligned might be different in this

population based on an SVA measurement if it were available, the trends would likely remain constant, such that a large percentage of patients might have maintenance or restoration of lordosis yet a notable subset would have worsened alignment after surgical treatment. Also, it may not be feasible in many institutions to acquire long films in all lumbar fusion cases, so these data represent the variables more widely available during every-day surgical decision-making (*i.e.*, the lumbosacral measures: LL, PI, and PT).

CONCLUSION

This is the first large-scale multicenter study to evaluate the prevalence of radiographic spinopelvic malalignment in patients having undergone short-segment spinal fusion for degenerative indications, finding over one quarter of patients malaligned both pre- and postoperatively. As per recommendations in recent articles describing the effects of undercorrection on long-term outcomes, these authors therefore urge clinicians to assess spinopelvic parameters during the work-up of patients undergoing lumbar fusion, typically through at least upright lumbar standing films, if not full-length scoliosis (36-inch cassette) films. Much as spine surgeons rely on magnetic resonance imaging and/or computed tomography findings to guide surgical plans, these results, combined with others in the recent spine literature, demonstrate that incorporation of preoperative spinopelvic parameters to surgical decision-making in these patients is critical, whether by guiding the procedure/implant selection to match the alignment *restoration* needed or by the intentional *preservation* of the aligned preoperative spine.

➢ Key Points

- ❑ This study was designed to retrospectively assess the prevalence of spinopelvic malalignment in patients who underwent one- or two-level lumbar fusions for degenerative (nondeformity) indications and to assess the incidence of malalignment after fusion surgery as well as the rate of alignment preservation, correction, or worsening in this population.
- ❑ Retrospective analysis of lateral preoperative and postoperative lumbar radiographs in 578 patients at 18 institution undergoing one- or two-level lumbar fusion patients were newly measured for LL, PI, and pelvic tilt.
- ❑ Preoperatively, 173 (30%) patients exhibited malalignment. Postoperatively, 161 (28%) of patients were malaligned. Alignment was *preserved* in 63%, *restored* in 9%, *not corrected* in 21%, and *worsened* in 7% of patients.
- ❑ This is the first multicenter study to evaluate the preoperative prevalence and postoperative incidence of spinopelvic malalignment in a large series of short-segment degenerative lumbar fusions, with results suggesting that alignment preservation/restoration considerations should be incorporated into the decision-making of even degenerative lumbar spinal fusions.

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