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Mismatch Between Pelvic Incidence and Lumbar Lordosis After Personalized Interbody Fusion: The Importance of Preoperative Planning and Alignment in Degenerative Spine Diseases

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ABSTRACT

Background: Emerging data have highlighted the significance of planning and aligning total and segmental lumbar lordosis with pelvic morphology when performing short-segment fusion with the goal of reducing the risk of adjacent segment disease while also decreasing spine-related disability. This study evaluates the impact of personalized interbody implants in restoring pelvic incidence–lumbar lordosis (PI–LL) mismatch compared with a similar study using stock interbody implants.

Methods: This multicenter retrospective analysis assessed radiographic pre- and postoperative spinopelvic alignment (PI–LL) in patients who underwent 1- or 2-level lumbar fusions with personalized interbody implants for degenerative (nondeformity) indications. The aim was to assess the incidence of malalignment (PI–LL ≥ 10°) both before and after fusion surgery and to determine the rate of alignment preservation and/or correction in this population.

Results: There were 135 patients included in this study. Of 83 patients who were aligned preoperatively, alignment was preserved in 76 (91.6%) and worsened in 7 (8.4%). Among the 52 preoperatively malaligned patients, alignment was restored in 23 (44.2%), and 29 (55.8%) were not fully corrected. Among patients who were preoperatively aligned, there was no statistically significant difference in either the "preserved" or "worsened" groups between stock devices and personalized interbody devices. In contrast, among patients who were preoperatively malaligned, there was a statistically significant increase in the "restored" group ($P = 0.046$) and a statistically significant decrease in the "worsened" groups in patients with personalized interbodies compared with historical stock device data ($P < 0.05$).

Conclusions: Compared with a historical cohort with stock implants, personalized interbody implants in short-segment fusions have shown a statistically significant improvement in restoring patients to normative PI–LL. Using 3-dimensional preoperative planning combined with personalized implants provides an important tool for planning and achieving improvement in spinopelvic parameters.

Level of Evidence: 3.

Lumbar Spine

Keywords: lumbar, interbody, fusion, PI-LL, personalized, interbody, fusion, spinopelvic parameters, short-segment

INTRODUCTION

Initially described by Hasegawa and Dubosset,[1] the "cone of economy" highlighted the correlation of the different joints in the lower limbs, pelvis, and spine in promoting optimal balance and requiring minimum muscle activity. Since then, several classifications and parameters have been created to focus on diagnosing sagittal imbalance and guiding surgical treatment to restore a harmonious spine and pelvic alignment, aiming to improve outcomes and avoid reoperation in adult spinal deformity.[2–4] Hasegawa et al[5] showcased the importance of incorporating 3-dimensional (3D) analysis due to the lack of information regarding the 3D orientation of all bony elements in relation to the gravity line when analyzing sagittal alignment. They emphasized the findings from previous authors that standing spinal curvature fundamentally correlates with the pelvic anatomy, especially with pelvic incidence (PI).

Despite the value of other spinopelvic parameters, the relationship between postoperative PI and lumbar

lordosis (LL) still presents significant importance and predisposes patients to either clinical success or failure as measured by health-related quality-of-life outcomes scales.[6] A proper relationship between LL and PI has also gained more importance in surgeries for short-segment lumbar fusions and degenerative conditions.[7–12] Rothenfluh et al[11] and Yoon et al[8] showed that in cases where the postoperative PI–LL mismatch was greater than 10°, there was an increase in adjacent segment disease (ASD) and reoperation rate. Leveque et al[6] emphasized that incorporating preoperative spinopelvic parameters into surgical decision-making in short-segment fusion is critical, whether by guiding the procedure/implant selection to match the alignment restoration needed or by carefully preserving the aligned preoperative spine.

Although the need to achieve functional spinopelvic alignment with fusion surgeries is recognized, achieving this remains challenging. Several authors have demonstrated that stock hyperlordotic cages can result in different degrees of segmental and overall alignment of the lumbar spine.[13–15] Smith et al also showed that achieving a targeted sagittal alignment for an adult spinal deformity patient is only accomplished 37.2% of the time.[16]

This study analyzes the PI–LL mismatch achieved through personalized spine surgery for short-segment fusions in both preoperatively aligned and malaligned patients compared with stock implants. 3D preoperative imaging is utilized to prescribe the desired alignment at the levels to be treated, and patient-specific 3D-printed interbody implants are produced to achieve planned correction at each level.[17]

MATERIALS AND METHODS

This multicenter, retrospective cohort study was conducted to assess the radiographic outcomes of patients older than 18 years who underwent surgical treatment at 6 centers across the United States with treatment that included one or two 3D-printed, personalized interbody fusion cages. Patients were eligible for inclusion if the patient had undergone a 1- or 2-level lumbar fusion for a degenerative indication using any technique and had pre- and postoperative (within 6 months of the index surgery) standing lateral radiographs available for review that included femoral heads and visualization of the entire lumbar spine (L1–S1), allowing retrospective sagittal spinopelvic alignment measurements to be determined. All patients had supplemental posterior instrumentation. Primary exclusion criteria were fusion at more than 2 spinal levels, fusion for a nondegenerative condition (ie, deformity, tumor, or trauma), and uninterpretable images due to poor image quality or difficulty visualizing anatomic structures. This retrospective review consisted of deidentified data for which consent is not required, and no direct patient involvement occurred; thus, this study was exempt from institutional review board review.

Radiographic measurements of PI and LL were performed on all standing anteroposterior and lateral radiographs taken pre- and postoperatively by both an independent radiologist and an independent spine surgeon, using Dicom viewer software (Microdicom). Any measurement discrepancies of more than 5° were subjected to adjudication, and the discrepancy was resolved through a query process.

Patients were grouped similarly as in the study by Leveque et al.[6] Although several studies have assessed interbody fusion and alignment with stock devices,[18–20] the Leveque et al study was selected for comparison in the present study due to the multicenter design, large number of patients, and the level of detail that was used for alignment results, which enabled appropriate comparison with the current cohort. Our study assessed the spinopelvic alignment of patients based on the mismatch between PI and LL (PI–LL). Although some authors have advocated for the use of age-adjusted alignment goals,[4] the optimal alignment classification system and thresholds for PI–LL mismatch remain matters of debate.[21] Since these issues remain unsettled, we chose to use the classic (not age-adjusted) thresholds for PI–LL mismatch. This approach also enables broader comparisons with previous studies that have predominantly used the classic thresholds.[6,11,12] Spinopelvic malalignment was identified if the PI–LL mismatch was equal to or greater than 10° (PI–LL ≥ 10°). It is worth noting that patients with a PI–LL value less than –10° were not considered malaligned in this analysis, as their condition was due to hyperlordosis rather than hyporlordosis. Patients were evaluated preoperatively and at follow-up, within 6 months of surgery, and were classified into 4 groups based on alignment status: preserved, restored, not corrected, or worsened. Patients who were aligned both pre- and postoperatively were classified as preserved, while those who were malaligned preoperatively but aligned postoperatively were categorized as restored. Patients who were malaligned at both time points were considered not corrected, while those who were aligned

preoperatively but malaligned postoperatively were deemed worsened.

Personalized Interbody Implants

Patient-specific interbody devices were designed based on patient imaging studies and surgeon specifications, which included the type of implant: anterior lumbar interbody fusion, lateral lumbar interbody fusion, or transforaminal lumbar interbody fusion; footprint preferences; surgical correction goals for anterior and posterior height; and sagittal and coronal correction of the intervertebral space for which the fusion is planned. Computed tomography images were used to create a 3D lumbar spine model from which each vertebral body was individually segmented, and endplate anatomy was mapped. The surgeon's treatment and alignment goals were determined and translated into a surgical plan where the vertebral bodies adjacent to the disc spaces being treated were positioned to achieve these goals. The negative space arising between the vertebral endplates was mapped to define the geometry of the device, and the superior and inferior device surfaces were matched to the topography of the caudal and cranial vertebral endplates. The implants were then manufactured of titanium alloy using an additive manufacturing process.

Statistical Analysis

Statistical analysis was performed using SPSS version 29.0.2.0. Descriptive statistics were performed with mean and SD for continuous variables and frequencies with percentages for categorical variables for the group as a whole, as well as grouped by preoperative to postoperative alignment progressions. Pre- and postoperative data were compared using a paired *t* test. Pre- to postoperative alignment changes were compared by 1-way analysis of variance. Resulting alignment progressions of patients treated with stock implants from the Leveque et al,[6] study and patients treated with personalized interbodies were compared using *z* tests for independent proportions. All tests were 2-tailed with a significance level of $\alpha = 0.05$

RESULTS

In the 135 patients, mean preoperative LL was 50.9 (SD 12.4), mean PI was 57.5 (13.0), and mean PI–LL calculation was 6.6 (11.5). Preoperatively, 52 (38.5%) patients had a PI–LL ≥ 10° and were classified as malaligned. After surgery, mean LL was 54.2° (13.5), mean PI was 58.4° (12.5), and the mean PI–LL mismatch was 4.2° (12.0). Alignment before and after surgery and the distribution of malalignment for the entire group, with complete alignment outcomes, are shown in Table 1.

Patients were grouped into categories based on pre- and postoperative alignment. Among the 83 preoperatively aligned patients, 76 (91.6%) had preserved alignment and 7 (8.4%) had worsened alignment. Among the 52 preoperatively malaligned patients, 23 (44.2%) were restored to aligned and 29 (55.8%) were not corrected (Figure 1). Among patients who were preoperatively aligned, there was no statistically significant difference in either the "preserved" or "worsened" groups between stock devices and personalized interbody devices. Among patients who were preoperatively malaligned, there was a statistically significant increase in the "restored" group ($P = 0.046$) and a statistically significant decrease in the "worsened" group ($P = 0.046$) compared with stock device data published by Leveque et al.[6]

Looking specifically at pre- vs postoperative status, 83 (61.5%) of the patients were preoperatively aligned, and 99 (73.3%) were aligned postoperatively; 52 (38.5%) patients were preoperatively malaligned, and 36 (26.7%) were malaligned postoperatively. This represents a statistically significant improvement ($P < 0.005$) when compared with the data published by Leveque et al,[6] which showed that 405 (70.0%) of the patients were preoperatively

Table 1. Radiographic information for the full sample.

Characteristics	Preoperative	Postoperative	Pre- to Postoperative Change	Significance ($P < 0.05$)
Lumbar lordosis, degrees, mean (SD; range)	50.9 (12.4; 21–77)	54.2 (13.5; 17–85)	3.3 (8.2; –25–32)	<0.001
Pelvic incidence, degrees, mean (SD; range)	57.5 (13.0; 33–88)	58.4 (12.5; 37–88)	0.9 (3.3; –10–11)	0.002
Spinopelvic alignment (PI–LL mismatch), degrees, mean (SD; range)	6.6 (11.5; –18–32)	4.2 (12.0; –29–42)	–2.5 (8.6; –30–29)	0.001
Patients with spinopelvic malalignment (PI–LL mismatch ≥ 10°), *n* (%)	52 (38.5)	36 (26.7)		0.006

Abbreviations: LL, lumbar lordosis; PI, pelvic incidence.

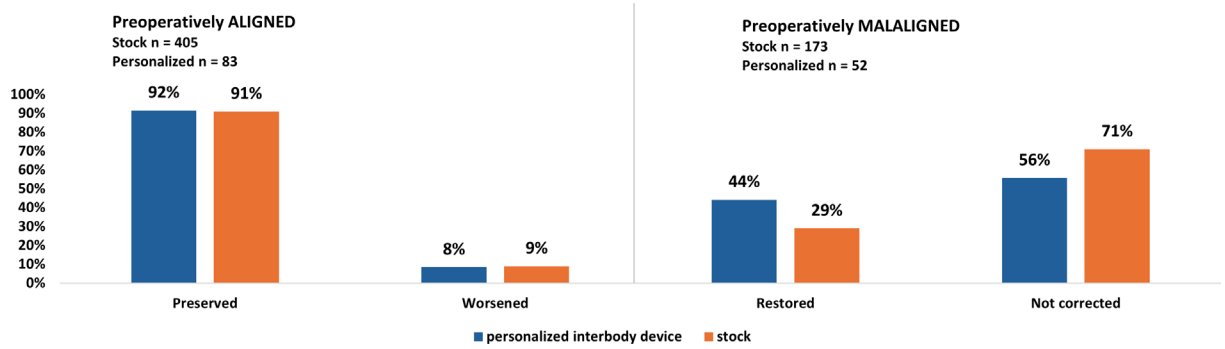

Figure 1. Left: Among patients who were preoperatively aligned, there was no statistically significant difference in either the "preserved" or "worsened" groups between stock devices and personalized interbody devices. Right: Among patients who were preoperatively malaligned, there was a statistically significant increase in the "restored" and a statistically significant decrease in the "worsened" groups compared with stock devices ($P < 0.05$; stock device data from Leveque et al[6]).

aligned, and 417 (72.1%) were aligned postoperatively; 173 (30.0%) patients were preoperatively malaligned, and 161 (27.9%) were malaligned postoperatively (Figure 2).

Table 1 provides radiographic data for the full sample. Table 2 provides radiographic data separated into pre- and postoperative alignment categories.

DISCUSSION

Spinopelvic Parameters and PI–LL in Short-Segment Fusion

A growing number of reports have documented a significant correlation between spinopelvic alignment mismatch and the occurrence of ASD and revision surgeries in the short and long term.[8,22,23] Rothenfluh et al[11] investigated the impact of PI–LL mismatch on ASD, revealing that a disparity between PI and LL >9.8° correlated with a 10-fold higher risk for requiring revision surgery among patients undergoing lumbar fusion surgery for 1 to 3 segments. They noted that failure to address an intrinsic deformity of the degenerative lumbar spine exposes these patients to a markedly higher risk for ASD. In a study focusing solely on single-level fusion surgery, Matsumoto et al[9] found that spinopelvic imbalance (PI–LL mismatch ≥10°) emerged as the primary risk factor for ASD. Tempel et al[12] also documented a significant association between elevated PI–LL mismatch and symptomatic ASD following single-level transforaminal lumbar interbody fusion surgery, indicating a threshold PI–LL mismatch >11° for the development of symptomatic ASD. More recently, Yoon et[8] al showed that after a single-level anterior lumbar interbody fusion at L4/L5, high pelvic tilt and PI–LL mismatch were significant risk factors for symptomatic ASD, concluding that spine surgeons should prevent a PI–LL mismatch value >10° after single-level fusion surgery.

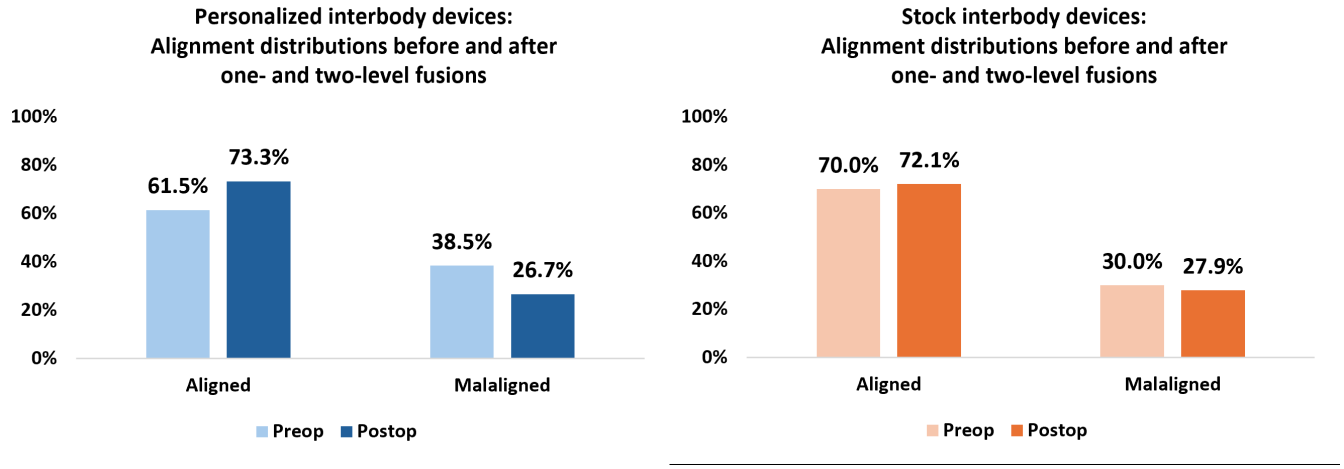

Figure 2. Changes in spinal alignment parameters for the entire cohort of 1- and 2-level fusion patients at pre- and postoperative time points, including lumbar lordosis (LL), pelvic incidence (PI), and the calculation of PI–LL mismatch. Comparison between personalized interbody devices (left) and stock interbody devices (right).

Table 2. Radiographic information separated into pre- and postoperative alignment categories.

Characteristics	Degrees, mean (SD; range)				Significance[a]
	Preserved *n* = 76 (56.3%)	Restored *n* = 23 (17.0%)	Not Corrected *n* = 29 (21.5%)	Worsened *n* = 7 (5.2%)	*P* < 0.005
Preoperative					
Lumbar lordosis	55.0 (10.1; 30–76)	45.1 (13.8; 21–73)	44.7 (11.2; 26–62)	50.3 (17.8; 24–77)	<0.001
Pelvic incidence	54.0 (10.9; 36–83)	61.4 (14.5; 41–88)	64.7 (11.9; 42–83)	53.3 (18.5; 33–85)	<0.001
Spinopelvic alignment (PI–LL)	–1.0 (7.1; –18–10)	16.3 (5.6; 10–30)	20.0 (5.9; 11–32)	3.0 (8.0; –13–9)	<0.001
Postoperative					
Lumbar lordosis	58.3 (11.1; 37–85)	56.3 (13.5; 29–81)	45.3 (12.2; 17–62)	39.9 (16.7; 22–71)	<0.001
Pelvic incidence	55.4 (10.9; 37–84)	60.6 (14.7; 38–88)	65.1 (11.3; 42–84)	55.8 (16.0; 42–84)	0.003
Spinopelvic alignment (PI–LL)	–2.9 (8.1; –29–9)	4.3 (4.6; –9–10)	19.8 (8.2; 10–42)	15.9 (4.2; 12–23)	<0.001
Change from baseline					
Lumbar lordosis	3.3 (6.3; –10–22)	11.2 (7.4; 2–32)	0.5 (7.1; –21–21)	–10.4 (7.8; –25 to –2)	<0.001
Pelvic incidence	1.4 (2.9; –5–11)	–0.8 (3.4; –10–4)	0.4 (3.8; –5–11)	2.5 (3.6; –1–10)	0.017
Spinopelvic alignment (PI–LL)	–1.9 (6.5; –21–11)	–12.0 (6.9; –30 to –2)	–0.2 (7.0; –13–21)	13.0 (8.2; 5–29)	<0.001

Abbreviations: LL, indicates lumbar lordosis; PI, pelvic incidence; PI–LL, pelvic incidence minus lumbar lordosis.
[a]One-way analysis of variance tests were used to categorize differences for each alignment measure between all 4 alignment groups.

Achieving a Proper PI–LL

Achieving adequate postoperative alignment for short-segment fusion remains a challenge,[15,16] and several factors not directly controlled by the fusion may play a role. These include varying degrees of degeneration in the adjacent levels,[24–26] the impact of compensatory and reciprocal changes on the levels above the fusion, and the lordosis distribution index.[27,23,28] The present study assesses whether the ability to control the intervertebral space alignment with personalized interbody implants designed to achieve a specific intervertebral lordosis can aid in optimizing spinopelvic parameters. In a similar study using stock implants, 29% of patients preoperatively malaligned had PI–LL restored to <10°, whereas 71% remained malaligned.[6] In this study, in cases treated with personalized interbody implants, 44% had PI–LL restored to <10°, representing a statistically significant improvement compared with stock implants. Among patients receiving personalized interbody devices, from pre- to postoperative, the number of aligned patients increased by 19.2% in contrast to an increase among patients receiving stock devices of 3.0%. Similarly, when analyzing the decrease in percentage for the malaligned category, among patients receiving personalized interbody devices, from pre- to postoperative, the number of malaligned patients decreased by 30.6% in contrast to a decrease among patients receiving stock devices by 7.0%. These findings support prior observations by Diebo et al[29] that specific approaches to the spine and the use of interbody devices can impact spinopelvic parameters and regional alignment.

Despite the improvement in alignment in patients treated with personalized interbody implants, a significant number of preoperatively malaligned patients were not restored to a PI–LL of <10°. In this not-corrected group, the preoperative mean LL was 44.7° and PI of 64.7°, with a PI–LL of 20° and a final postoperative PI–LL of 19.8°. In the restored group, the preoperative mean LL was 45.1° and PI of 61.4°, with a PI–LL of 16.3° and a final postoperative PI–LL of 4.3°. Although the preoperative LL and PI of the restored and not-corrected groups were very similar, it is possible that achieving appropriate spinopelvic alignment was not a goal in these 1- or 2-level lumbar fusion procedures for degenerative conditions. Alternatively, the surgeon may have planned to increase the lordosis more than what was achieved.

Using preoperative planning to achieve a target alignment, personalized interbody implants can promote a better segmental alignment than stock implants as they provide the capability of filling the interbody space to achieve an expected final lordotic disc space angle, as well as coronal angle and a specific disc height.[17] However, other variables affecting these outcomes must be better understood and addressed. Meticulous preoperative planning of LL for patients undergoing short-segment fusion needs to continue to be pursued, with the aim of achieving improved spinopelvic parameters through an increased understanding of the contribution to lordosis from each segment. It is important to recognize that this varies from 1 patient to another, even in the nonpathologic spine,[29] and compensatory changes can interfere with the final alignment. In a recent review, Diebo et al[29] suggested that a detailed examination of segmental (level-specific) lordosis is likely even more important in degenerative conditions than in spinal deformity due to the performance of short fusions for degenerative conditions rather than long-segment deformity fusion crossing the spinal junctions.

Herrington et al identified that a decrease in the L4 to S1 lordotic angle led to a reciprocal change at L3 to L4, leading to instability and increased revision surgery rate.[30] Careful consideration of these factors will help to better determine the optimal corrections in the intervertebral spaces and what to expect in the final alignment based on other parameters such as PI, lordotic distribution index, and spinopelvic angles. Because the angles in the disc space can be optimized with the use of personalized interbody implants, there is an option to more precisely plan and achieve optimal alignment and avoid severe discrepancies from targeted PI–LL.[17]

This study is not without limitations. The number of patients included was relatively small; the preoperative alignment plan is not standardized, and the goals for alignment may have differed based on surgeon preferences. Since the personalized implant specifications vary with the plan, different surgeons could have planned the cases differently, impacting the design of the implant and, consequently, the final achieved alignment. The primary purpose of the study was to identify the lumbar parameters and the effect of the use of personalized implants in restoring spinopelvic alignment based on normative goals. It is a multicenter retrospective review encompassing different fusion techniques performed by a diverse group of surgeons based only on radiologic data. We did not include global sagittal alignment parameters because full-length radiographs were not consistently available and might not be the standard of care across all institutions. The number of patients included did not permit meaningful stratification of patients based on surgical approach for interbody placement. In addition, although we would not expect the personalization of interbody spacers to have an increased risk of any particular complications, the present data set does not permit specific assessment of complications or reoperations.

CONCLUSION

Compared with a historical cohort with stock implants, the use of personalized interbody implants in short-segment fusions has shown a statistically significant improvement in restoring patients to normative PI–LL. The planning process can be improved by incorporating spinopelvic parameters, particularly for patients with high PIs. Personalized interbody implants can help to improve the alignment of preoperatively malaligned patients. In addition, the use of 3D preoperative planning, combined with personalized implants to achieve the plan, provides an important tool to clinicians to aid in planning and achieving optimal sagittal alignment and minimizing increased stress concentrations at adjacent discs.

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