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Predictability in Achieving Target Intervertebral Lordosis Using Personalized Interbody Implants

SAEED S. SADRAMELI, MD[1]; DONALD J. BLASKIEWICZ, MD[2]; JAHANGIR ASGHAR, MD[3]; CHRISTOPHER P. AMES, MD[4]; GREGORY M. MUNDIS, MD[5]; JOSEPH A. OSORIO, MD, PHD[6]; JUSTIN S. SMITH, MD, PHD[7]; CHUN-PO YEN, MD[7]; SIGURD H. BERVEN, MD[8]; ASHVIN I. PATEL, MD[9]; MICHELE TEMPLE-WONG, PHD[10]; RODRIGO J. NICOLAU, MD[10]; AND ROLAND S. KENT, MD[11]

[1]AdventHealth Celebration, Celebration, FL, USA; [2]St. Luke's Boise Medical Center, Boise, ID, USA; [3]Elite Spine Health and Wellness, Plantation, FL, USA; [4]Department of Neurological Surgery, University of California, San Francisco, CA, USA; [5]Department of Orthopedic Surgery, Scripps Clinic, La Jolla, CA, USA; [6]Department of Neurological Surgery, University of California, San Diego, CA, USA; [7]Department of Neurosurgery, University of Virginia, Charlottesville, VA, USA; [8]Department of Orthopedic Surgery, University of California, San Francisco, CA, USA; [9]Kennedy-White Orthopedic Center, Sarasota, FL, USA; [10]Carlsmed, Carlsbad, CA, USA; [11]Axis Spine Center, Coeur d'Alene, ID, USA

ABSTRACT

Background: Lumbar lordosis distribution has become a pivotal factor in re-establishing the foundational alignment of the lumbar spine. This can directly influence overall sagittal alignment, leading to improved long-term outcomes for patients. Despite the wide availability of hyperlordotic stock cages intended to achieve optimal postoperative alignment, there is a lack of correlation between the lordotic shape of a cage and the resultant intervertebral alignment. Recently, personalized spine surgery has witnessed significant advancements, including 3D-printed personalized interbody implants, which are customized to the surgeon's treatment and alignment goals. This study evaluates the reliability of 3D-printed patient-specific interbody implants to achieve the planned postoperative intervertebral alignment.

Methods: This is a retrospective study of 217 patients with spinal deformity or degenerative conditions. Patients were included if they received 3D-printed personalized interbody implants. The desired intervertebral lordosis (IVL) angle was prescribed into the device design for each personalized interbody (IVL goal). Standing postoperative radiographs were measured, and the IVL offset was calculated as IVL achieved minus IVL goal.

Results: In this patient population, 365 personalized interbodies were implanted, including 145 anterior lumbar interbody fusions (ALIFs), 99 lateral lumbar interbody fusions (LLIFs), and 121 transforaminal lumbar interbody fusions. Among the 365 treated levels, IVL offset was 1.1° ± 4.4° (mean ± SD). IVL was achieved within 5° of the plan in 299 levels (81.9%). IVL offset depended on the approach of the lumbar interbody fusion and was achieved within 5° for 85.9% of LLIF, 82.6% of transforaminal lumbar interbody fusions and 78.6% of ALIFs. Ten levels (2.7%) missed the planned IVL by >10°. ALIF and LLIF levels in which the plan was missed by more than 5° tended to be overcorrected.

Conclusions: This study supports the use of 3D-printed personalized interbody implants to achieve planned sagittal intervertebral alignment.

Clinical Relevance: Personalized interbody implants can consistently achieve IVL goals and potentially impact foundational lumbar alignment.

Level of Evidence: 4.

Lumbar Spine

Keywords: intervertebral, lordosis, lumbar fusion, personalized, interbody, cage, device, pre-operative planning

INTRODUCTION

Recreating normal sagittal alignment has become increasingly important in spinal fusion surgery.[1–3] Re-establishing the foundational alignment of the lumbar spine has a direct impact on overall sagittal alignment. Restoring sagittal alignment in lumbar fusion has been shown to improve long-term outcomes for patients,[1,4–9] reduce postoperative pain,[1–8,10–13] reduce the incidence of adjacent segment disease,[4–6,8–13] and reduce rates of spinal surgery revision.[1–5,7,9–11,13–17]

There have been many innovations in spine surgery to restore sagittal alignment, including hyperlordotic cages. However, there is often a lack of correlation between the lordotic shape of the cage and the resultant intervertebral alignment. Previously published clinical studies have reported a wide variability in additional lordosis achieved ranging from 11° to 23° for 6- to 8-degree cages, 1° to 16° for 10- to 12-degree cages, and 17° to 29° for 15- to

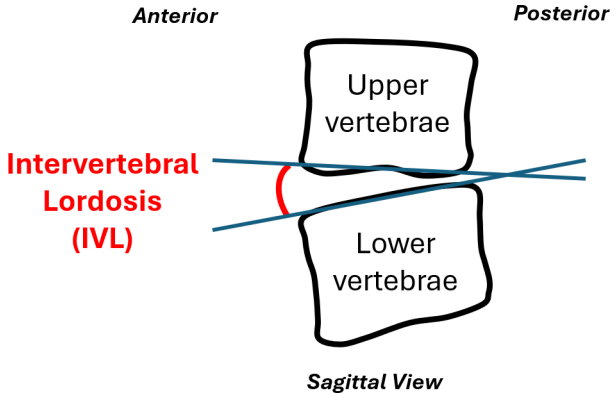

Figure 1. The focus of this study was on the intervertebral lordosis angle (IVL) as prescribed by the operating surgeon for the personalized device. It is defined as the angle between a tangent line to the upper (cranial) endplate of the lower vertebrae and a tangent line to the lower (caudal) endplate of the upper vertebrae.

20-degree cages.[18–22] While the alignment achieved with hyperlordotic cages may also be impacted by operative parameters such as surgical approach,[19] cage lordotic angle,[18–20,22,23] and the location of cage placement in the disc space,[18,19,23] a high degree of unpredictability still exists. Whether measuring segmental lordosis (the angle between the tangent lines to the cranial endplate of the upper vertebra of the fused level and the caudal endplate of the lower vertebra) or intervertebral lordosis (IVL, the angle between a tangent line to the upper endplate [cranial] of the lower vertebrae and the lower endplate [caudal] of the upper vertebrae, Figure 1), the fit of the flat interbody cage against the irregular contours of the vertebral endplate results in unpredictable changes in both intervertebral and segmental alignment.

The high prevalence of vertebral endplate abnormalities is one potential explanation for the significant discrepancy between the lordotic angle of stock cages and the IVL they create. Stock devices, which are essentially flat or slightly domed on the upper and lower surfaces, do not achieve a precise fit against the irregular bony topography of vertebral endplate surfaces. Vertebral endplate abnormalities are common in lumbar fusion patients, especially elderly patients. In a study of 1564 endplates in 133 patients with Modic changes on magnetic resonance imaging, 27.8% of all endplates exhibited defects, with 31% of L4-5 and 49% of L5-S1 endplates exhibiting a defect (Figure 2).[24]

Recent advancements in spine fusion surgery include 3D-printed personalized interbody implants. Computed tomography images are used to map the endplate anatomy, and the surgeon's treatment and alignment goals are used to determine implant configuration. The implant is created to fill the intervertebral space and match the topography of adjacent caudal and cranial endplates (Figure 3). Personalized 3D-printed interbody devices may be fabricated for anterior lumbar interbody fusion (ALIF), lateral lumbar interbody fusion (LLIF), and transforaminal lumbar interbody fusion (TLIF). In this study, the outcome measure of focus was the IVL, as this most closely demonstrates the influence of the endplate-matched characteristic of the personalized interbody device on achieving targeted alignment.

The purpose of this study was to evaluate the ability of 3D-printed patient-specific interbody implants to achieve planned postoperative intervertebral alignment.

METHODS

Study Design and Patient Populations

This multicenter, retrospective cohort study was conducted to assess radiographic outcomes of consecutive patients older than 18 years who underwent surgical treatment for spinal deformity or degenerative disease. Patients were from 9 centers across the United States. Treatment included one or more 3D-printed personalized interbody devices.

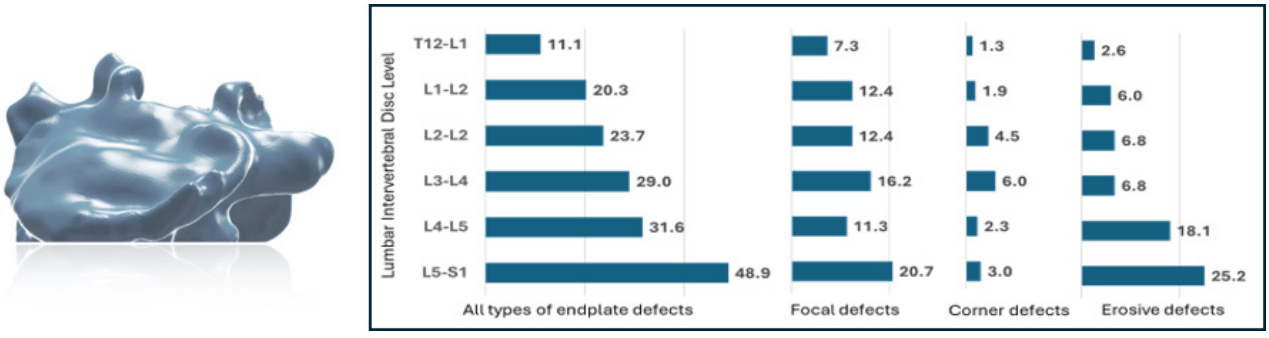

Figure 2. Example of vertebral endplate irregularity (left). Prevalence and distribution of endplate defects in the lumbar spine. Data presented are prevalence rates in percent, referring to the total samples studied for that specific disc level (right).[24]

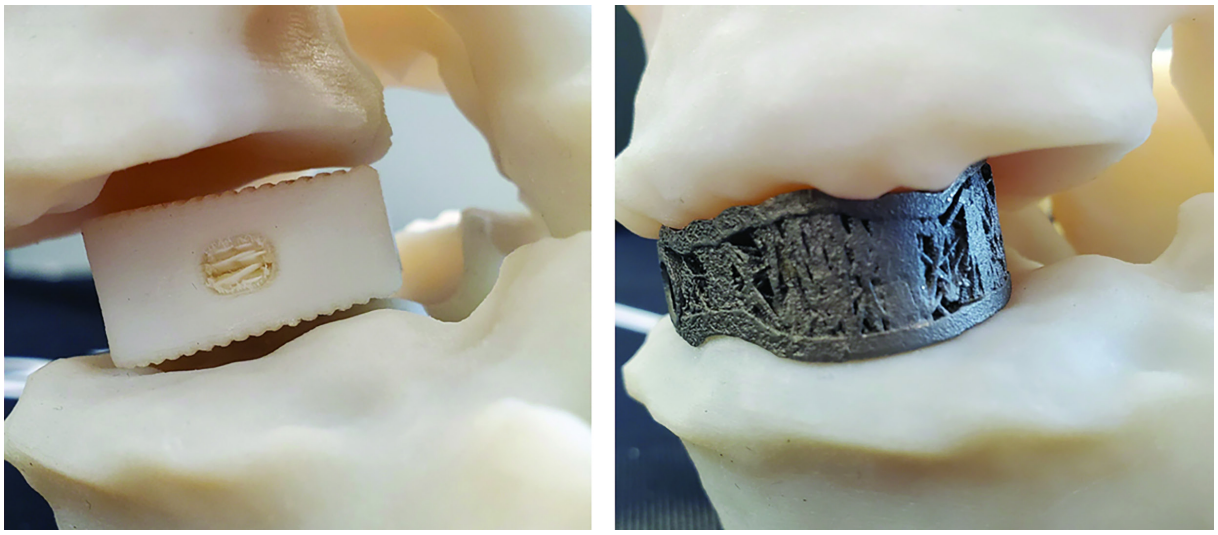

Figure 3. The fit of a stock interbody device against the endplate (left) is compared with the fit of a personalized device (right).

This study utilized secondary research consisting of deidentified data involving on-label use of an US Food and Drug Administration–cleared device and is therefore exempt from review by an institutional review board under Common Rule requirements. There was no direct patient involvement.

For inclusion in the present study, it was required that patients be treated with at least one personalized interbody device and have sufficient pre- and postoperative radiographs for lordosis measurements.

Data Collection

Computed tomography images and standing radiographs were obtained preoperatively for the implant planning process. IVL was prescribed by the operating surgeon during the planning process prior to surgery (goal IVL) for each personalized interbody device.

Standing radiographs of the lumbar spine were obtained for all patients postoperatively at approximately 6 weeks, 6 months, and 12 months. For this study, the latest radiograph was analyzed for each patient, resulting in 102 radiographs from 6-week follow-up, 68 radiographs from 6-month follow-up, and 47 from 12-month follow-up. Each postoperative radiograph was analyzed for IVL of the treated levels by an independent spine surgeon using a DICOM viewer and by a central site using validated software (SpineView, ENSAM Laboratory of Biomechanics, Paris, France),[25] resulting in 2 measures of IVL. These measures were averaged for each treated level to determine the IVL achieved. IVL offset was calculated as the achieved IVL minus the IVL goal for each treated level. The overall mean and SD were calculated for the IVL offset as well as the 95% CI. The distribution of the magnitude of the IVL offset (|ΔIVL|) was assessed to understand whether the personalized interbody–treated levels achieved the preoperative plan (IVL goal). In addition, the direction of IVL offsets of the treated levels was assessed to determine whether the intervertebral space was undercorrected (IVL offset < −5°) or overcorrected (IVL offset > 5°).

Statistical Methods

Statistical analysis was performed using SPSS version 29.0.2.0. Descriptive statistics were reported as mean and SD or median and range for continuous variables depending on the data distribution and frequencies with percentages for categorical variables.

The IVL was considered as having met the IVL goal if IVL offset ≤5°. This was used to define an equivalence margin to assess the agreement of IVL achieved and IVL goal. A mixed-model analysis of variance and Tukey pairwise comparisons were performed to evaluate IVL offsets. All tests were 2-tailed with a significance level of $\alpha = 0.05$.

RESULTS

Patient Population

For the 217 patients included in the study, demographic, baseline, and postoperative radiographic parameters (Table 1), as well as operative parameters

Table 1. Demographic and pre- and postoperative radiographic parameters for the 217 adults with spinal deformity who received personalized interbody devices.

Variable	Preoperative	Postoperative
N	217	NA
Sex, women, *n* (%)	128 (59)	NA
Age, y, mean (SD)	66 (11)	NA
Radiographic Parameters		
Time since surgery, mo, median (min, max)	NA	17 (3, 38)
LL, mean (SD)	41.8° (17.3°)	53.0° (28.3°)
PI-LL mismatch, mean (SD)	13.9° (16.8)	4.0° (16.6°)
IVL by level		
L1-L2, mean (SD)	3.3° (3.1°)	6.8° (2.6°)
L2-L3, mean (SD)	3.9° (3.7°)	6.7° (3.4°)
L3-L4, mean (SD)	5.3° (3.6°)	8.1° (2.9°)
L4-L5, mean (SD)	6.8° (5.3°)	11.4° (4.7°)
L5-S1, mean (SD)	11.1° (7.0°)	15.5° (4.8°)

Abbreviations: IVL, intervertebral lordosis angle; LL, lumbar lordosis; NA, not applicable; PI-LL, pelvic incidence and lumbar lordosis.

(Table 2), are summarized. Patients included 128 (59%) women, and the mean age was 66 years (SD = 11 years). The mean baseline lumbar lordosis and mismatch of pelvic incidence and lumbar lordosis (PI-LL) were 41.8° (SD = 17.3°) and 13.9° (SD = 16.8°), respectively, with the mean IVL for each fusion level as shown in Table 1.

The median overall number of vertebral levels fused was 4 with a range of 1 to 16. The mean number of interbody devices used per patient was 1.7 (SD = 0.8). The number of patients who received at least 1 ALIF, LLIF, or TLIF device was 99 (46%), 53 (24%), and 80 (37%), respectively. Patients were predominantly treated with an interbody device at

Table 2. Operative parameters for the 217 adults in this study cohort.

Parameter	Value
Levels fused, median (range)	4 (1,16)
Personalized interbody devices per subject, mean (SD, range)	1.7 (0.8, 1–5)
Patients with ALIF, *n* (%)	99 (45.6)
Patients with LLIF, *n* (%)	53 (24.4)
Patients with TLIF, *n* (%)	80 (36.9)
Personalized ALIF, *n* (% of total)	145 (39.7)
L3/L4, *n* (% of ALIF)	9 (6.2)
L4/L5, *n* (% of ALIF)	46 (31.7)
L5/S1, *n* (% of ALIF)	90 (62.1)
Personalized LLIF, *n* (% of total)	99 (27.1)
L1/L2, *n* (% of LLIF)	15 (15.2)
L2/L3, *n* (% of LLIF)	38 (38.4)
L3/L4, *n* (% of LLIF)	29 (29.3)
L4/L5, *n* (% of LLIF)	17 (17.2)
Personalized TLIF, *n* (% of total)	121 (33.1)
L1/L2, *n* (% of TLIF)	3 (2.5)
L2/L3, *n* (% of TLIF)	1 (0.8)
L3/L4, *n* (% of TLIF)	12 (9.9)
L4/L5, *n* (% of TLIF)	50 (41.3)
L5/S1, *n* (% of TLIF)	55 (45.5)

Abbreviations: ALIF, anterior lumbar interbody fusion; LLIF, lateral lumbar interbody fusion; TLIF, transforaminal lumbar interbody fusion.

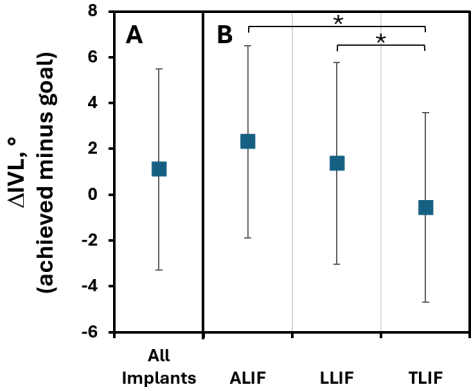

Figure 4. Intervertebral lordosis (IVL) offset for all levels treated (A) and for levels treated with anterior lumbar interbody fusion (ALIF), lateral lumbar interbody fusion (LLIF), or transforaminal lumbar interbody fusion (TLIF) with personalized interbody implants (B).

the L5-S1 (40%) and L4-5 (31%) intervertebral levels.

Equivalence of IVL Achieved and Goal

IVL achieved and IVL goal were equivalent. The 95% CI of the IVL offset (IVL achieved minus IVL goal) was calculated as (0.65, 1.56). Because the 95% CI was entirely within the equivalence margin, the two were determined to be equivalent. In addition, two one-sided tests were performed to show that IVL offset was between −5° and 5° (each $P < 0.005$).

IVL Offset

On average, the IVL was achieved with an offset of 1.1° (SD = 4.4; Figure 4a). IVL offset varied with implant type ($P < 0.001$; Figure 4b). The IVL offset was similar for levels treated with ALIF and LLIF implants ($P = 0.2$). The IVL offset for levels treated with TLIF implants was lower than those treated with ALIF ($P < 0.001$) or LLIF ($P < 0.005$) implants.

Distribution of IVL Offset

A majority of the 365 treated levels achieved the IVL goal (Figure 5). Of the treated levels, 299 (82%) were within 5° of the IVL goal, 56 (15%) were within 6° to 10° of the IVL goal, and only 10 (3%) were more than 10° from the IVL goal.

The ability to achieve the IVL goal was similar among implant types (Figure 6). The IVL goal was achieved to within 5° in 79%, 86%, and 83% of ALIF-, LLIF-, and TLIF-treated levels, respectively. The IVL goal was within 6° to 10° of the preoperative plan in 19%, 10%, and 16% of ALIF-,

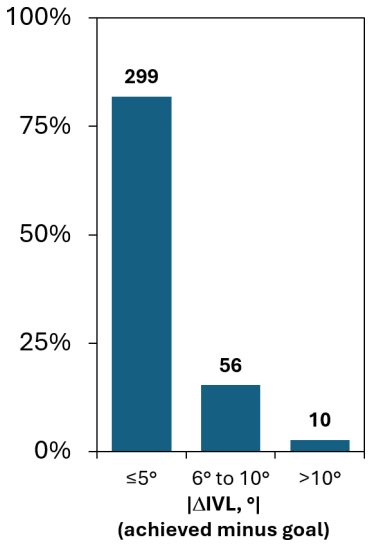

Figure 5. Distribution of the magnitude of the intervertebral lordosis (IVL) offset for all levels treated with personalized interbody implants of 217 adults who underwent spinal deformity surgery.

LLIF-, and TLIF-treated levels, respectively. Only 3%, 4%, and 2%, of ALIF-, LLIF-, and TLIF-treated levels were over 10° from the IVL goal.

While few levels treated with personalized interbodies missed the IVL goal by >5°, it was possible to analyze those cases for whether the achieved IVL undercorrected or overcorrected the lordotic angle of the treated levels relative to the preoperative plan (Figure 7). Of ALIF- and LLIF-treated levels, a larger number were overcorrected (25 and 11, respectively) vs undercorrected (6 and 3, respectively). The number of TLIF-treated levels was similarly overcorrected (8) and undercorrected (13).

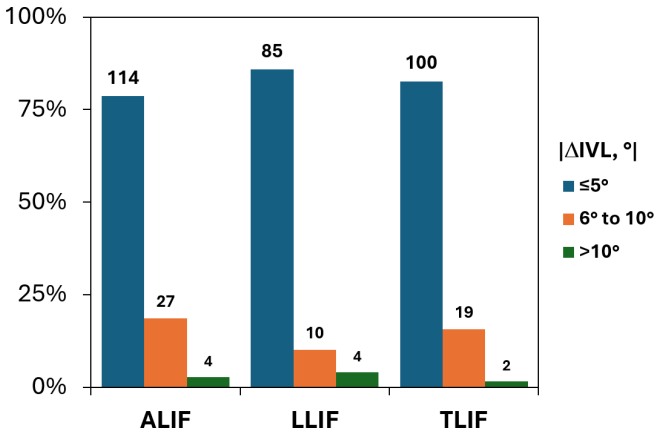

Figure 6. Distribution of the magnitude of intervertebral lordosis (IVL) offset stratified by implant type.

DISCUSSION

One of the primary goals of adult spinal deformity correction surgery is to achieve an appropriate alignment for favorable clinical outcomes and minimal risk of complications. While there has been progress in defining optimal sagittal alignment as it relates to clinical outcomes, it is complicated and has yet to be standardized. For example, the SRS-Schwab classification has defined targets for satisfactory alignment of PI-LL mismatch, pelvic tilt, and sagittal vertical axis. However, despite ideal correction according to the SRS-Schwab modifiers, complications and the need for revisions still commonly occur.[26,27] Further research into sagittal alignment targets has established references for cephalad-caudal lordotic distribution and PI-adjusted segmental lordosis values, which have further refined how ideal overall sagittal alignment is defined and achieved.[28] While creating an operative plan to achieve those targets may be very complex, the utilization of the personalized interbody cages, tailored by the surgeon, presents a significant advantage in attaining alignment objectives.

Based on this study of 217 patients, the achieved segmental lordosis at the level of the personalized cage was, on average, within 1.1° of the planned lordosis. While it is unclear in previous studies what the planned IVL was for each level, it was clear that previous studies using hyperlordotic stock cages varied in their achieved lordosis relative to the given cage lordosis by as much as 3° to 24°.[18–22] This study also provides additional information about the distribution of alignment and areas of improvement (over- and undercorrection). Personalized interbody implants achieved planned IVL to within ±5° in 82% of treated levels and to within ±10° in 97% of treated levels. Only 10 of 365 implant levels fell outside of this range (|ΔIVL| > 10°), making the ability to achieve planned IVL more reliable.

This study was not without its limitations. The focus of the study was on IVL as it is one of the main intervertebral measures that personalized interbodies influence and contribute to overall sagittal alignment. In addition, while personalized interbody implants can help achieve target IVL, the planning procedure and targets to achieve optimal sagittal alignment were not controlled across surgeons or patients. Future research may incorporate global alignment goals to better understand whether they can be achieved and whether they result in better patient outcomes. Alignment targets could be more standardized and coordinated with posterior instrumentation to achieve segmental, regional, and overall alignment goals.

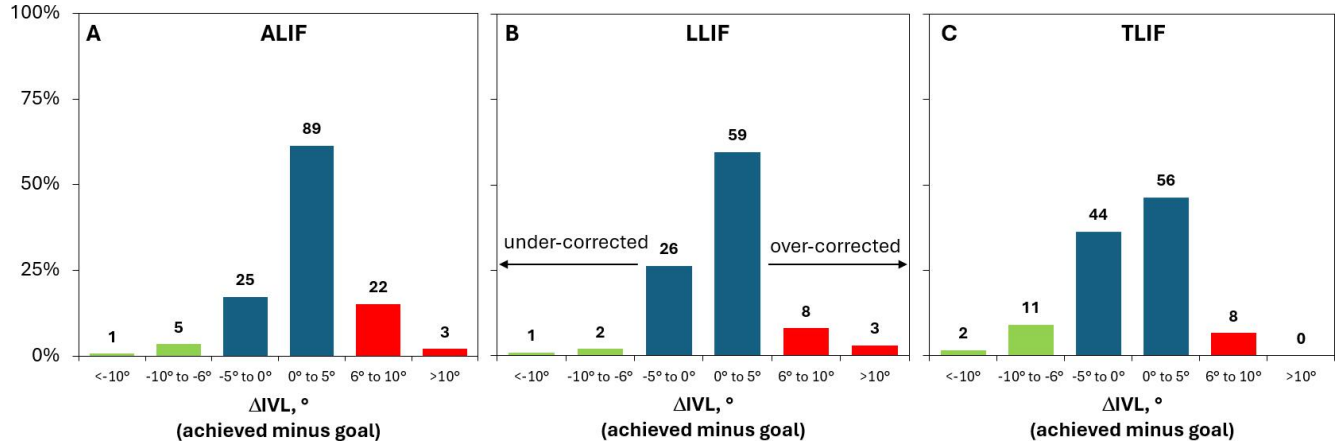

Figure 7. Distribution of intervertebral lordosis (IVL) offset stratified by implant type.

CONCLUSION

Personalized interbody implants successfully attained the IVL goal within a 1.1° margin, facilitating essential foundational alignment crucial for overall sagittal alignment. However, overcorrection observed with ALIF and LLIF implants implies the necessity for more coordinated planning to integrate alignment changes induced by posterior instrumentation. In sum, this study advocates for the adoption of personalized interbody cages as a reliable method for consistently achieving IVL objectives.

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Corresponding Author: Saeed S. Sadrameli, Advent Health Celebration 400 Celebration Place, Ste. A-360 Celebration, FL 34747, USA; Dr.Sadrameli@orlandoneurosurgery.com

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