The Effect of Lordosis, Disc Height Change, Subsidence, and Transitional Segment on Stand-Alone Anterior Lumbar Interbody Fusion Using a Nontapered Threaded Device

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Abstract

In this study, we retrospectively evaluated 37 consecutive patients who underwent stand-alone anterior lumbar interbody fusion (ALIF) for indications that included degenerative disc disease, concordant pain on discography, disc space collapse of more than 50%, and failure of nonoperative management for at least 4 consecutive months.

Patient demographics, procedural data, and prospective Short Form 36 General Health Survey composite scores were collected. Mean follow-up was 24.2 months.

In this cohort of patients with degenerative disc disease, there was no loosening or migration of implants. Stand-alone ALIF using a threaded interbody fusion device provided excellent clinical results and return-to-work rates with few complications. Increased lordosis was associated with increased subsidence and less favorable outcome. Patients with a transitional segment displayed relatively smaller increases in lordosis and better outcomes than patients without a transitional segment.

Use of stand-alone anterior lumbar interbody fusion (ALIF) with a nontapered titanium threaded device has generated considerable controversy in the spine literature. Concerns about subsidence and lordosis and their effect on outcomes remain.

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We reviewed the cases of our patients who underwent stand-alone ALIF with a nontapered threaded device to examine outcomes and address the issues of lordosis, disc height change, postoperative subsidence, and transitional segment and their effect on radiographic and clinical measures.

Material and Methods

Patients

The cohort consisted of 37 consecutive patients treated with ALIF using the BAK Interbody Fusion System (Zimmer Spine, Minneapolis, Minnesota). Indications for this procedure were degenerative disc disease with low back pain. Some patients also had leg pain, though this was not a requirement for inclusion in the study. All patients had a primary diagnosis of degenerative disc disease, which includes disc space collapse of more than 50%, concordant low back pain on discography, and failure of nonoperative management (physical therapy regimen, use of nonsteroidal anti-inflammatory drugs) for at least 4 consecutive months. Nine patients (24%) had postlaminectomy syndrome and 4 patients (10.8%) demonstrated herniated nucleus pulposus.

Surgical Protocol

An ALIF procedure using a nontapered threaded titanium fusion device (BAK implant) was performed on all patients. In each case, a general surgeon used a standard retroperitoneal approach. Dr. Rahn and Dr. Shugart performed the procedures with a complete discectomy, standard reaming, and endplate preparation. For each patient, the BAK implant was sized to achieve the desired final disc height with adequate decompression of nerve roots at the operative level. The implant size was based on the size of the last dilator placed just before reaming. The appropriately sized cages were inserted under fluoroscopic guidance using standard techniques. Autogenous anterior iliac crest bone graft was harvested and used in and around the cages in each case to stimulate fusion.

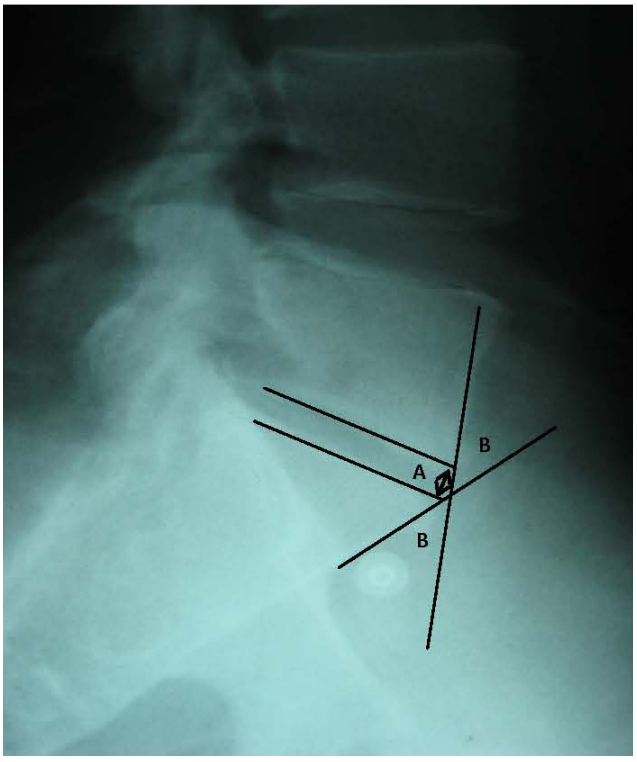

Figure 1. Preoperative (A) disc height (10 mm) and (B) lordotic angle (42°).

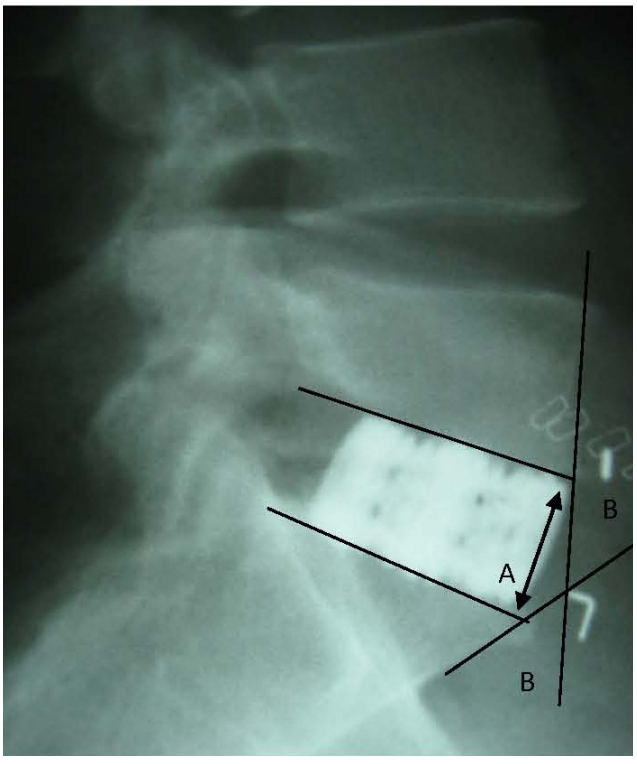

Figure 2. Postoperative (A) disc height (24 mm) and (B) lordotic angle (48°).

Data Collection

Patient demographics, diagnoses, and details of hospitalization were retrieved through chart review. Standing neutral lateral radiographs were obtained and used to measure preoperative, immediate postoperative, and late postoperative (12 to 57 months) segmental lordotic angle and anterior disc space height and to identify the presence or absence of a transitional segment (Figures 1, 2). Disc heights were measured uniformly as the distance between the most anterior aspects of the endplates on the lateral view of a standing neutral plain radiograph The lordotic angles were measured uniformly as the angle of intersection of 2 lines formed by the anterior surfaces of the 2 vertebrae surrounding the implant on the lateral view of a standing neutral plain radiograph. A transitional segment was defined as an extra non–rib-bearing lumbar vertebra and disc space. In addition, there could be no bridging bone surrounding the disc space. Fusion criteria for the involved segment were identified as presence of anterior "sentinel sign," or bridging trabecular bone on the lateral view of a standing neutral plain radiograph, and no evidence of pseudarthrosis by radiolucency at or around the implant on standing neutral radiographs. Evaluation of computed tomography was not used as a criterion for fusion in this study. The Short Form 36 (SF-36) General Health Survey was administered before surgery and at each postoperative evaluation. Patient perception of surgical outcome as a percentage of improvement was recorded at each postoperative visit.

Statistical Analysis

Descriptive statistics were calculated for demographic variables. Postoperative outcome measures were pooled into 4 assessment points covering 0 to 3 months, 4 to 6 months, 7 to 11 months, and 12 months or more. Analysis of variance was used on outcome and operative measures. When appropriate, postoperative comparisons were completed. Unpaired t tests were used to assess differences between fusion groups and between patients with and without transitional segments. The Spearman rank correlation coefficient was used to assess the association among lordosis, disc height, and subsidence and their effect on outcome measurements. Statistical significance was recognized at $P<.05$.

Results

Study Cohort

The 37-patient cohort consisted of 26 men (70%) and 11 women (30%). Mean age was 38.8 years (range, 25 to 56 years). Mean final follow-up after index procedure was 24.3 months (range, 12 to 57 months). Data were analyzed to reflect the characteristics of patient outcome at final follow-up visit (longest term results), though these were in no way standardized to varying follow-ups throughout the total cohort. Mean preoperative duration of symptoms was 27.9 months (range, 4 to 100 months). Mean body mass index (BMI) was 26.7 kg/m^2; 7 patients were classified as obese (BMI, >30 kg/m^2). Twelve patients (32.4%) had a psychiatric history, which included depres-

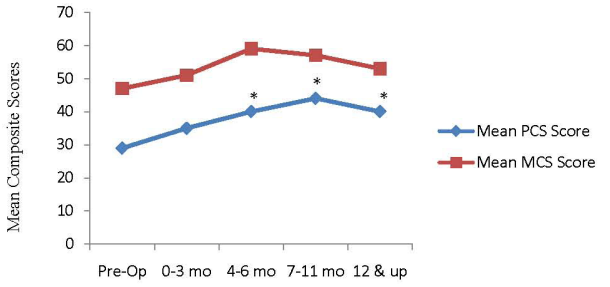

Figure 3. Short Form 36 General Health Survey composite scores.

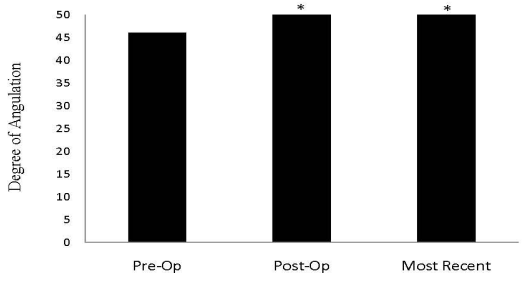

Figure 4. Lordotic angulation, L5–S1.

sion (11 patients) or anxiety (1 patient). Worker's compensation claims were active for 15 patients (40.5%), and 17 patients were smokers (45.9%). Fifteen patients (40.5%) underwent a total of 20 previous posterior procedures, with 12 patients (32.4%) undergoing previous posterior discectomy at the degenerative level.

Details of Hospitalization and Surgical Data

Mean operating room time was 2.6 hours (range, 1.5 to 4.5 hours). Mean estimated blood loss was 271 mL (range, 100 to 1500 mL). Twenty-six patients underwent 1-level fusion (1 fusion at L4–L5 and 25 fusions at L5–S1), and 11 patients underwent a 2-level procedure. Operating room time and blood loss were similar for 1- and 2-level fusions: 2.5 hours and 2.6 hours, and 304 mL and 372 mL, respectively.

Pain and Function

Short Form 36 Physical Functioning, Role Physical, and Bodily Pain scores showed significant improvement at postoperative time points relative to preoperative levels. The Physical Component score also showed a significant improvement in the same manner as the subscores (P = .032). The Mental Composite score showed an increase after surgery, but this change was not significant (P = .39) (Figure 3).

Pain reduction of 75% or more was reported by 32 patients (87%). Notably, 11 patients (30%) reported complete relief from preoperative pain. The remaining patients rated their postoperative pain improvement as 70% to 75% (1 patient), 60% to 69% (2 patients), or 50% to 59% (1 patient). One patient reported being worse; this patient subsequently was diagnosed with fibromyalgia and obtained disability status at his place of employment. Litigation was pending at discharge.

Fusion

Disc levels were judged fused if there was clear anterior "bridging" trabecular bone on standing neutral plain radiograph. By this rigorous criterion, 75.6% of levels were judged as definitely fused. In addition, radiographs of the remaining levels revealed no evidence of pseudarthrosis (eg, radiolucencies, motion on flexion/extension films) or lucency surrounding the BAK device at any point or final follow-up. We did not identify any effect of tobacco use on fusion status. Fusion status was not significant for patient outcome variables by SF-36 General criteria or subjective patient report of pain improvement.

Lordosis and Subsidence

Mean segmental preoperative lordosis was 42° at L5–S1. Lordosis was significantly increased by 6° to a mean of 48° at both the first postoperative visit and the latest follow-up visit (Figure 4). At the L4–L5 segment, mean lordotic angle for preoperative (14.4°), postoperative (15.6°), and latest (15.4°) follow-up did not change significantly (Figure 5). Increased lordosis was related to increased subsidence at the L4–L5 segment (P = .016) and at the L5–S1 segment (P = .038). In addition, increased lordosis at L5–S1 correlated to decreased Physical Component scores (P = .0446). No significant changes in lordosis were observed between postoperative time points. Therefore, the lordotic changes occurred after surgery (Figure 1) and did not change thereafter.

Disc Height

Mean preoperative anterior disc height at L5–S1 was 10 mm. Disc height was significantly increased after surgery (24 mm) and at latest follow-up (23 mm) (P<.001). Similarly, mean disc height at L4–L5 increased from a preoperative value of 13 mm to 21 mm and 18 mm at the same follow-up points, respectively. These preoperative–postoperative differences were statistically significant (P<.01) (Figure 6). Substantial disc height subsidence (8 mm) in the early postoperative period was observed at 1 level without effect on fusion or outcome. A significant

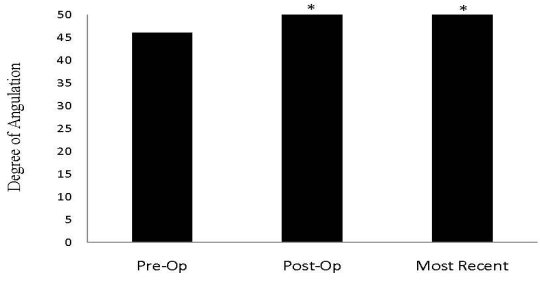

Figure 5. Lordotic angulation, L4–L5.

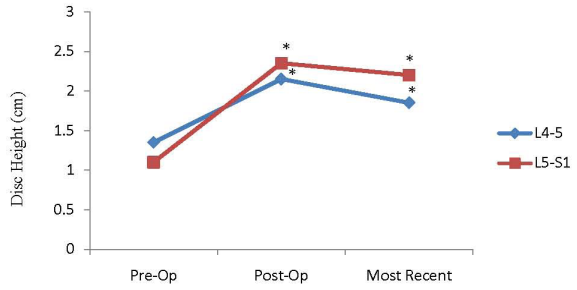

Figure 6. Intervertebral disc height.

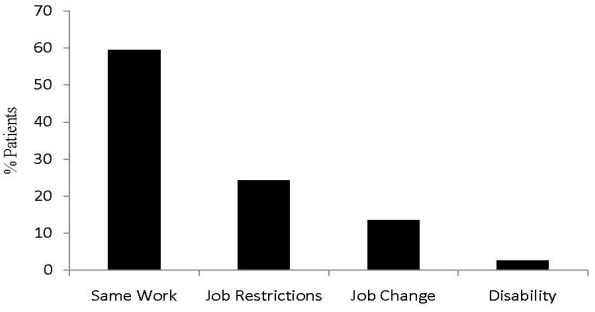

Figure 7. Postoperative employment status.

correlation was found between increases in lordotic angle and increases in disc height at the L5–S1 level. Increased disc height also correlated with increased subsidence at the L4–L5 segment (P = .016) and at the L5–S1 segment (P = .04).

Return to Work

Of the patients in this cohort, 97.3% returned to gainful employment; of these, 59.5% returned with no restrictions to their former occupation, which included construction, foundry, and other heavy labor activities. Some work restrictions were imposed on 9 patients (24.3%), while 5 patients (13.5%) went into a different occupation. Only 1 patient (2.7%) obtained disability. There were no outcome differences between patients who received worker's compensation and those who did not.

Transitional Segment

A transitional segment, defined as an extra non–rib-bearing lumbar vertebra and disc space, was identified in 11 patients (30.7%). Patients with a transition segment had significantly better outcomes, as measured by the Physical Component score, than patients without a transitional segment (P = .001). However, similar changes were not observed in patient perception of improvement (P = .17). Patients with a transitional segment also had a significantly smaller increase in lordotic angle than patients without a transitional segment (P = .02).

Reoperation

The first patient in this series required posterior decompression for retropulsion of a bony fragment into the neural foramen. This may have been related to the incorrect sequencing of reamers during endplate preparation. The patient was decompressed 9 months after the index procedure. Two years after the procedure, he reported complete pain relief and was working at his original occupation.

Complications

Complications included 2 cases of transient retrograde ejaculation, 1 wound seroma, and 1 retropulsed bony fragment that required revision. There were no wound infections. Both cases of retrograde ejaculation resolved spontaneously within 3 months and had no effect on outcome.

Discussion

Treatment of degenerative disc disease can be challenging and controversial. The goal of treatment is stabilization of the affected motion segment by promoting bony fusion from an anterior or posterior approach. Anterior interbody approaches, either open or laparoscopic, have been shown to increase stability more than posterior interbody approaches do,[1] and threaded interbody fusion cages, such as the device used in this study, have been shown to have more pullout strength and to yield more reduction in range of motion than pedicle screws in cadaveric models.[1] Further, in a cadaveric study, Oxland and colleagues[2,3] found increased segmental stiffness for all bending moments, except extension for stand-alone anterior threaded cages.

In the current literature, interbody fusion procedures have had mixed results.[4-10] A review of recent clinical literature showed that stand-alone ALIF can be an efficacious, well-tolerated procedure in select patients and avoids posterior exposure and canal violation.[4,7,9,11,12] In a 10-year follow-up study, by Penta and Fraser,[9] 78% of ALIF patients reported "complete relief" or a "good deal of relief." Our results are consistent with this idea, as they showed significant improvements in both pain (eg, Bodily Pain) and function (return to work). Further, patients were generally satisfied with the outcomes: 11 patients (30%) reported complete pain relief, and 32 (87%) reported more than 75% improvement. Patient improvement continued for the first 11 months after surgery, with improvement leveling off thereafter by SF-36 criteria (Figure 3). Our data indicate that stand-alone ALIF can be highly effective. Specifically, the good outcomes and low pseudarthrosis rate suggest that these constructs are biomechanically stable, and, with proper patient selection and technique, lead to good clinical outcomes. Adding synthetic bone morphogenetic protein in the cage could increase fusion rates while obviating the comorbidity associated with the donor site for autogenous bone graft.

Thirty-six patients (97.3%) returned to gainful employment. The 1 patient (2.7%) who obtained disability (Figure 7) engaged in significant drug-seeking behavior and was being treated by other physicians with

narcotics for multiple other complaints. Many patients returned to heavy labor activities, including foundry and construction, while 1 patient returned to national amateur-level competitive waterskiing and another to competitive weightlifting. These results are consistent with other published series.[5,9,12]

In this series, the 75% definite fusion rate observed is toward the lower end of that typically reported in the literature.[9] However, the criteria used in this study are more rigorous than is typical.[13] Further, lack of evidence of pseudarthrosis, radiolucencies, and motion on radiographs coupled with the good outcomes suggests that the motion segments were stable and may have been considered fused according to more inclusive standards. The current standard for prospective studies includes thin-cut computed tomography with reconstruction to assess bridging bone in and around the cages. Further, there were no significant differences between clinical outcome measures as a function of definitively or questionably fused groups. It may be interpreted that all levels were stable, given that late instability can compromise outcomes over the long term.[12] Pavlov and colleagues,[12] studying a similar device, reported that destruction of the anterior longitudinal ligament and the anterior portion of the anterior annulus fibrosus may result in late instability if solid fusion is not obtained, resulting in a poor prognosis. Although definitive fusion may not be necessary for excellent midterm results, we believe that solid arthrodesis is necessary for good long-term results.

Tobacco use and worker's compensation status did not correlate with fusion status or clinical outcome in this series, in contrast to multiple other reports.[5,10,12,14] This may be a result of the robustness of the procedure in our hands. Alternatively, the small sample of tobacco users and worker's compensation groups may not have been adequate to detect differences.

In addition, long-term adjacent segment disease is of some concern and the literature is inconclusive as to its validity.[9,15] In this series, we did not identify any subsequent adjacent disc space collapse on plain radiography and only 1 patient complained of continued low back pain. This patient was seeking disability, and, after the procedure, went to another institution for a discogram, which revealed nonconcordant pain at multiple levels. However, it is our belief that the natural history of degenerative disc disease may be slowed by arthrodesis, but that this degeneration is a multifactorial process and is likely present in other discs at various stages.

Our study revealed a significant increase in lordosis at the L5–S1 segment but not at the L4–L5 segment. The lordosis increase was directly associated with increased disc space height and inversely associated with Physical Composite score. The inverse association of lordosis and Physical Composite score is at odds with the popular notion that increasing lordosis or maintaining "proper" lordosis is a basis for good long-term clinical outcomes. Although restoring lordosis is essential to maintain long-term sagittal alignment, this series does not illustrate that increasing lordosis levels results in better Physical Composite scores. Here, the literature on normal lordosis is at best confusing—it shows that lordosis is neither measured consistently nor described adequately for a normal population.[6,9,11,16] Clearly, more research is needed to adequately characterize the role of lordosis in clinical outcomes. A significant correlation also was found between lordosis and disc height recovery, which suggests that, to some extent, the degree of lordosis can be controlled by cage size and distraction. For some patients, disc height was larger than the outer diameter of the cage used (the nonlordotic cage was in the lordotic space). When inserted in the posterior direction, the anterior space opened proportionately more than the posterior space where the leading edge of the cage was positioned. As the disc height was measured as the distance between the most anterior aspects of the vertebral endplates, an increased lordotic angle increased this distance and thus the measured disc height according to our measurement technique. No unusual technique or substantial removal of endplate tissue above what is used in standard discectomy and endplate preparation protocol for any ALIF procedure was used in any patient in the study cohort. These properties also explain the larger than expected lordotic angles achieved in this study, and any discrepancy with values in the published literature can be attributed to measurement techniques used.

What may be a novel and particularly intriguing observation in this study is that 30% of our patients presented with a transitional segment. This is roughly 22% to 27% larger than what has been found in the asymptomatic population. We might conclude that presence of transitional segments may be a risk factor for degenerative disc disease. However, patients with transitional segments and degenerative disc disease had significantly better SF-36 Physical Component scores, which suggests these patients also may benefit from better outcomes once treated. Identification of a transitional segment as a risk factor for degenerative disc disease could lead to better surgical treatments or even prophylactic early life changes (exercise, proper lifting) to reduce the risk for back problems. Although our study design limits speculation about the prognostic possibilities of transitional segments in the general population, the observation that these segments afforded superior outcomes in our data set merits further investigation into these rarities.

Surgical spine procedures are fraught with difficulties and the possibility of complications is ever present. The anterior approach has its unique set of challenges, including mobilization of the great vessels and potential damage to the autonomic nerve plexus. In fact, there is a 2-fold likelihood of complications with threaded devices for ALIF compared with nonthreaded devices.[17] Transabdominal approaches appear to have higher incidences of retrograde ejaculation.[18] Tiusanen and colleagues[18] reported a 17.5% incidence of permanent

retrograde ejaculation after use of a transabdominal approach, whereas Christensen and Bunger[19] reported an 8% incidence after a retroperitoneal approach. Our cohort, in addition to having a low general complication rate, had a lower rate of retrograde ejaculation: 2 patients, 7.6% of men. In addition, both cases resolved over 3 months and did not lead to permanent difficulties or adverse patient outcome. These data suggest that a retroperitoneal approach may be preferred over a transabdominal approach, especially in male patients.

Iatrogenic spinal nerve root compression is a complication of interbody cage placement.[5,20] In the first case in this series, incorrect reamer sequencing pushed a posterior vertebral wall fragment into the adjacent neural foramen. Although this did not affect the long-term outcome in that patient, it did require a second posterior procedure and it is a complication to be aware of and avoided.

Conclusions

Stand-alone ALIF for discogenic low back pain using a nontapered threaded titanium device resulted in considerable improvement in patient function, resolution of concordant pain, and high return-to-work rates with relatively few and short-lived complications. We believe that stand-alone ALIF with a nontapered threaded titanium fusion device is a safe and effective procedure.

Increasing segmental lordosis was inversely correlated with Physical Component scores, which suggests that too much lordosis may reduce the maximum benefits gained from the procedure over the midterm. Further, presence of a transitional segment may be a risk factor for development of degenerative disc disease as well as better outcome after its treatment.

The relatively small number of patients in this series calls for cautious interpretation of the results. However, these patients underwent a rigorous assessment with prospective data. These data show that stand-alone ALIF with a nontapered threaded cage can have excellent clinical results, excellent return-to-work rates, and few complications.

Authors' Disclosure Statement

The authors report no actual or potential conflict of interest in relation to this article.

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