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PRIMARY ARTICLES

Outcomes of Posterior Lumbar Interbody Fusion With the 9-mm Width Lumbar I/F Cage and the Variable Screw Placement System

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Posterior lumbar interbody fusion (PLIF) using interbody cages and posterior pedicle screw fixation has increased the successful fusion rate to nearly 100% in the lumbar spine. In the design of the cage, only the surface area of the opening for bone graft contact with the endplates varied with the width of the cage. When space is limited, the 9-mm width cages may be the largest size that can be used. Fusion is potentially compromised by the smaller surface area of bone graft. It is important to study the clinical and fusion success of these narrow cages. The authors report 90 patients who had PLIF with 9-mm Lumbar I/F Cages and pedicle screws. Minimum follow-up was 24 months (range, 2–5 years). Seventy-five patients (83%) had clinical success, and 15 (17%) were clinically unsuccessful. Fusion was successful in 82 patients (91.1%). Fusion success with the 9-mm cage was statistically lower than previously reported for the implant system as a whole ($p = .0015$). Mechanical failure did not occur with 9-mm cage usage. (Journal of Surgical Orthopaedic Advances 18(2):77–82, 2009)

Key words: cage, degenerative disc disease, interbody fusion orthosis, intervertebral disk/pathology/surgery, pedicle screw, PLIF, spinal fusion/instrumentation/methods, treatment outcome

Posterior lumbar interbody fusion (PLIF) was introduced by Cloward (1–4) more than 50 years ago. Limitations of PLIF included inadequate compression strength of allograft bone (5) and low fusion rates (6). The Lumbar I/F Cage (DePuy Spine, Raynham, MA) was designed to enhance posterior lumbar interbody fusion results by providing the mechanical strength to provide load sharing during fusion and to allow the best biological healing with autologous bone graft (7, 8).

In an Investigational Device Exemption (IDE) study of the Lumbar I/F Cage, fusion success was reported in 176 of 178 patients (98.9%) (9). Based on this study, the Lumbar I/F Cage was approved by the FDA for treatment of degenerative disc disease at one or two contiguous levels from L2 to the sacrum, accompanied by posterolateral fusion and pedicle screw fixation using the VSP Spinal System. Since the release of the Lumbar I/F Cage in 1999, favorable results have been reported in Japan (10, 11), in clinical studies in the United States (12, 13), in an active military population (14), and in Europe (15). In a 10-year follow-up study of patients enrolled in the IDE study of the Lumbar I/F Cage, 77% of operated patients were evaluated from two participating institutions. In this subset, fusion success was achieved in 29 of 30 patients (96.7%) and clinical success was achieved in 29 of 33 patients (87.8%) (13).

When the Lumbar I/F Cage was first designed, the optimal dimensions were unknown. The 11-mm cage

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prototypes had the opening of 5.5-mm width and the combined strut width of 5.5 mm (or 2.75 mm each) (16). In the design of the 9-mm cage size the strut width was retained because of the concern for subsidence if the strut was weakened. This made the opening for bone graft 36% less than the standard 11-mm width cage. Because bone healing is potentially compromised with the 9-mm width cages by the proportionally greater reduction in bone graft surface area, it is clinically important to study the clinical and fusion success of these narrower cages, both to evaluate the possible limitations of this specific implant system and also to understand design parameters for interbody fusion devices in general.

In clinical practice, a patient may require a 9-mm-wide cage because of circumstances found at the time of surgery. The indications include not enough space for a larger cage in the disc space, nerve root anomalies that may limit access to the disc space, and limited ability to retract nerve roots due to epidural scarring.

The purpose of this study is to determine whether the fusion rates and clinical outcomes with the narrow 9-mm cages are as successful as with the recommended wider implants.

Materials and Methods

The Lumbar I/F Cage is a carbon fiber-reinforced polymer (CFRP) implant made of polyether-ether ketone reinforced with "chopped" or short carbon fibers. The available widths are 13 mm, 11 mm, and 9 mm, with 11-mm cages most commonly used. The cage is filled with autologous bone and placed in a flattened prepared channel in the disc space. Bony fusion is achieved from endplate to endplate across the bone graft within the cage. Because the cages are radiolucent, bridging bone can be accurately assessed by plain radiographs.

The Variable Screw Placement Spinal Fixation System (VSP) (DePuy Spine, Raynham, MA) includes pedicle screws and plates made of titanium or stainless steel. The Lumbar I/F Cage and the VSP System have been previously described (9).

From February 1999 to October 2003, we performed PLIF using the CFRP cages and VSP instrumentation on 425 patients in our practice. Surgical indications included disabling back and/or radicular pain refractory to conservative management with moderate to severe degenerative change, with instability and adjacent segment deterioration based on magnetic resonance imaging (MRI) or discogram. During the summer of 2004, we conducted a retrospective chart review of all patients. Follow-up was achieved on 377 of 425 patients (87%), including a 1-year clinical and radiographic evaluation. While 1 year is not long enough to define an exact rate of clinical success, it is sufficient follow-up to identify complications and failed fusions.

TABLE 1 Demographics of 9-mm cage study group

Total patients: 90
Men: 31
Women: 59
Average age: 54 (range, 34–79)
Insurance:
Workers compensation: 18
Private insurance: 68
Smoking history:
Positive smoking history: 22 (24%)
Mean smoking history: 21 pack years
Prior lumbar surgeries: 49
Total number of prior lumbar surgeries: 75
Number of patients with prior surgery: 49
Average number of prior surgeries: 0.83 (range, 1–4)
Mean interval from prior surgery: 5 years (range, 1–18 years)

The current study group is comprised of 90 consecutive patients from this larger group in whom the operative report and operating room log indicated that 9-mm cages were used in at least one operative level. Follow-up was achieved in all 90 patients at a minimum of 2 years after surgery. Demographics of the study group are summarized in Table 1.

Of 197 PLIF-treated lumbar levels in 90 patients, 116 levels received 9-mm-wide CFRP cages. Of these 116 levels, 105 levels received two 9-mm cages, five levels received one 9-mm cage with a wider cage (11 mm) on the contralateral side, and six received a single unilateral 9-mm cage when access was restricted to the other side. The primary indication for the use of the 9-mm CFRP cage was inadequate width exposure of the disc space to accommodate a larger cage. From the operative note, access was limited by previous surgery to one or both sides of the disc space in 26 and nerve root anomaly with low position of the exiting nerve root in five.

Patients were examined and data recorded before surgery, at surgery, and at postoperative intervals after surgery. Evaluations included ratings of pain, function, economic status, and medication. Patient satisfaction, sensory and motor function, tension signs, reflexes, and radiographic findings were recorded at each follow-up interval. The mean follow-up was 36 months (range, 24–65 months).

Clinical success was defined according to previous published literature parameters used over many years and modeled after an expanded Prolo scale (9, 12, 13, 17). Five-point Likert scales for pain, function, economic status, and medication usage are added to a combined 4- and 20-point scale as used for the IDE study of the Lumbar I/F Cage (8). This study defined a patient's result as a clinical success when the final rating was excellent (17–20 points), good (13–16 points), or fair (9–12 points) if the

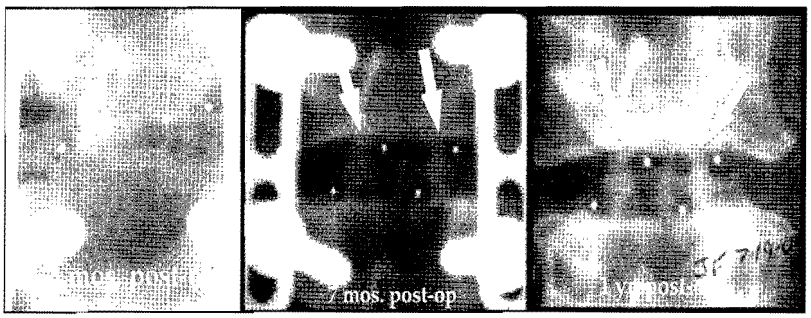

FIGURE 1 Serial Ferguson views of two 9-mm cages demonstrate progression to excellent fusion at 1 year on radiographs. The bone in the fusion area is radiographically more dense and mature than originally achieved in surgery. There is no interface between the autograft bone and the vertebral bone. Arrows point out bridging bone across the interspace through the fusion cage.

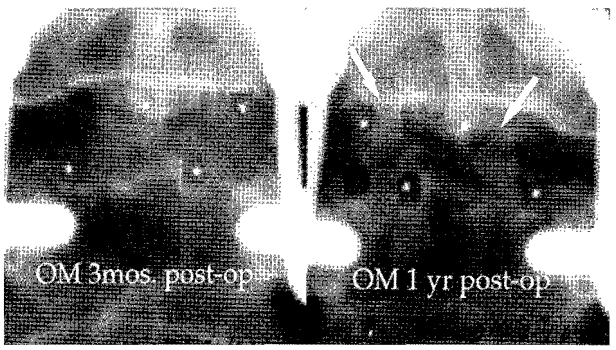

FIGURE 2 Serial Ferguson views of L4–5 show two 9-mm cages and a locked pseudarthrosis with lucency through midsubstance of each interbody graft. A small lucency or gap is visible involving just a portion of the fusion area with at least half of the graft area showing no lucency between the graft bone and vertebral bone. Bone graft is visible throughout the fusion area at approximately the density originally achieved surgically. Arrows point to bridging bone interrupted by 1-mm lucency through both cages at 1 year postop. This was a healed fusion at exploration.

patient achieved a minimum improvement of 3 points or more in the combined 20-point scale.

Fusion status was recorded for each surgically treated segment at each follow-up interval. All patients had 2-year follow-up plain static radiographs including antero-posterior, lateral, and Ferguson views with the x-ray beam parallel to the vertebral endplate in each view. *Fusion success* within the interbody space was defined by previous published parameters of radiographic fusion assessment of Brantigan and Steffee (8). The radiographs were read and results recorded by three of the authors (JST, AN, and JWB). A level was regarded as fused if there was radiographic evidence of bone bridging the disc space without lucency. If lucency was seen to extend across the cage, the level was considered not fused. For patients undergoing multiple-level fusion, all surgically treated segments must be fused for the patient to be considered a fusion success. Figure 1 shows a typical serial AP Ferguson radiograph demonstrating a solid fusion. Figure 2 shows the features of a pseudarthrosis with discontinuity in the bone graft and lucency adjacent to the cage.

Demographics, clinical, and fusion success rates were compared with the larger reviewed patient group, with the IDE study (9), and with the 10-year follow-up study (13) using chi-square analysis. Statistical significance was defined as $p < .05$.

Results

Clinical success was achieved in 75 of 90 patients (83%). The clinical results at last-recorded follow-up were excellent in 33 (37%), good in 34 (38%), fair in 8 (9%), and poor in 15 (17%). A common feature of poor results was previous lumbar surgeries; 12 patients had more than three previous surgeries. Other associated diagnoses were diabetes with poor control (2), pseudarthrosis (2), radiculopathy (2), infection (1), chronic back pain requiring pain management (3), multiple myeloma (1), and adjacent segment degeneration (4) with pain.

The overall fusion success with 9-mm-wide cages was 82 of 90 patients (91.1%). At the final radiographic evaluation, fusion success was achieved in 87 of 90 patients (97%) and 194 of 197 levels (98.5%). Of the three fusion failure patients, two were at the L1–2 level and one had

a surgical infection that required early removal of pedicle screws. Additionally, five levels of pseudarthrosis were diagnosed at surgical exploration and augmented with local bone or bone morphogenic protein (BMP). These five levels were judged healed on radiographs at last follow-up, but are considered failures of the index operation because they required augmentation of the posterolateral graft. Interestingly, the six levels with a single 9-mm cage were successful fusions.

Two patients had retropulsion of a cage that required revision. In one patient with a fusion at the L2–3 level using two 9-mm cages, one cage retropulsed into the canal at the 3rd month postoperatively. This was identified and watched. At 6 months the cage and pedicle screw instrumentation were removed because of increasing back and hip pain on the same side as the malpositioned cage. A second patient had a 9-mm cage retropulsed at L4–5 with radiculopathy. This cage was repositioned 2 weeks after the index surgery. Both patients with retropulsion went on to heal the fusion. Two patients had pseudarthrosis at L1–2, with screw loosening, requiring revision.

Two patients with a cerebral spinal fluid (CSF) leak required surgical repair and an epidural hematoma required debridement. Two patients had surgical infections that required debridement. One patient experienced persistent postoperative foot drop. A specific cause could not be determined after extensive diagnostic evaluation.

Forty-nine patients (54%) had one or more further surgeries at an average interval of 2 years (range, 1 month to 5 years) after the initial cage surgery. Five were revision of posterolateral fusion for pseudarthrosis. Two were revision of retropulsed cages. Three were for CSF leaks, one for epidural hematoma, and two for infection. Twenty-four had removal of pedicle screws for symptomatic hardware with findings of complete fusion healing. Sixteen patients had additional PLIF surgery because of adjacent segment pathology.

Discussion

Although all patients had a minimum follow-up of 2 years, the follow-up was 36 to 60 months with the data from the last-recorded follow-up reported. Compared with prospective studies that report time-contingent follow-up, this study reported symptom-contingent follow-up in which symptomatic patients were more likely to be seen. This allowed some patients to be clinical failures due to adjacent segment problems. This allowed inclusion of the results of further surgery within this review. In this study the incidence of previous surgery was 49/90 (54%) significantly greater than the historical IDE study (chi-square 24.7616, $p = .0001$). The incidence of further surgery was not significantly different from the IDE. Most of the further surgery was indicated for recurrent low back pain without pseudarthrosis. Wild et al. demonstrated that removal of symptomatic posterior instrumentation is beneficial in improving residual low back pain after fusion (18). Additionally, 16 patients had treatment of symptomatic adjacent segment disease. All of the patients who had further surgery within the 2- to 5-year follow-up were included in the final assessment of clinical and fusion status.

The Prolo Score has been widely accepted for study of interbody fusion cages and is used in this report to maintain continuity with the original IDE and the 10-year follow-up of the Lumbar I/F Cage. We believe the Prolo Scale produces results that may be compared with literature reports of outcomes over many years (9, 13).

The IDE cage study reported clinical success in 79 of 91 (86.8%). This included 52% excellent, 33% good, 15% fair, and no poor results (9). In the 10-year follow-up report, clinical success was maintained in 29 of 33 (87.8%). Our larger group had clinical success in 292 of 357 (81.8%). The 9-mm group had 83% clinical success including results that were excellent in 33 (37%), good in 34 (38%), fair in 8 (9%), and poor in 15 (17%). Clinical success rates were not statistically different when this 9-mm group is compared to the large clinical group, the IDE cage study, and the 10-year follow-up group (Table 2). In the IDE, all patients had failed discectomy. The current larger group included some primary degenerative disc disease cases, but also some patients with recurrent difficulty after prior fusion surgery.

In the IDE study of the Lumbar I/F Cage, fusion success was achieved in 176 of 178 (98.9%) (9). In the 10-year follow-up of the IDE study, fusion success was reported in 29 of 30 (96.7%) (13). In our large group, fusion success was found in 333 of 350 patients (95.1%). If the patients receiving 9-mm cages are removed from the larger series, fusion success was achieved with the larger cages in 251 of 260 of our patients (96.5%). When the fusion results of our larger series are compared with

TABLE 2 Clinical and fusion success

Study Group	9 mm	Large Group	IDE	10-Year Follow-up
Clinical success	$n = 90$	$n = 357$	$n = 92$	$n = 33$
Yes	75	292	79	29
No	15	65	13	4
% Yes	83.30%	81.80%	85.90%	87.90%
Fusion success	$n = 90$	$n = 350$	$n = 178$	$n = 30$
Yes	82	333	176	29
No	8	17	2	1
% Yes	91.10%	95.10%	98.90%	96.70%
Prolo scores	$n = 90$	$n = 357$	$n = 92$	$n = 33$
Excellent	36.70%	39.90%	47.00%	61.00%
Good	37.80%	37.00%	30.00%	27.00%
Fair	9.0%	17.30%	20.00%	12.00%
Poor	17.0%	5.80%	3.00%	0.00%

the IDE results using the chi-square statistic, the fusion rates were not statistically different (chi-square = 0.1414, $p = .7069$). When the fusion results of the 9-mm group are compared with the IDE study, the fusion success rates with the 9-mm cages are significantly lower (chi-square = 10.034, $p = .0015$). When the fusion results with the 9-mm cages are compared with our larger cage group, the results with the 9-mm cages are statistically lower (chi-square = 4.262, $p = .039$).

This cohort had a variety of socioeconomic and etiological backgrounds similar to the IDE study. Statistical analysis in that study indicated that the following factors had no effect on clinical or fusion success: gender, numbers of levels treated surgically, previous surgery, smoking history, and obesity (9). The major statistical difference between the demographics of the 9-mm group and the IDE study is patient gender. In the IDE study 43% of patients were women, and in the 9-mm group 66% were women. This difference is statistically significant ($p = .003$). This difference is not surprising, because women typically require smaller implants. The current demographic profile should not adversely bias our conclusions regarding clinical and fusion success in the 9-mm group.

Comparison of complication rates between the IDE and our large group shows a significantly lower rate in the large group (chi-square = 5.281, $p = .0215$). The rate of complications in the 9-mm group was significantly less than in the IDE (chi-square = 3.824, $p = .0505$). The rate of dural tears, deep infection, device complication, nerve root injury, and epidural hematoma were not significantly different when comparing the three groups (Table 3).

When the Lumbar I/F Cage was first designed, the optimal dimensions were unknown. It appeared that 11 mm was the average width that would allow bilateral cages to be placed in an interspace. Possible failure modes included subsidence into the vertebral bodies (which argued for maximal width of the struts) and fusion failure (which argued for maximal width of the opening for bone graft surface area). In the design of the 11-mm cages, the two concerns were given equal weight: the opening was 5.5 mm wide and the strut width was 5.5 mm (or 2.75 mm each) (16). This design performed well in mechanical testing and bore physiologic loads without subsidence in cadaver spines.

In clinical use, avoidance of subsidence was achieved in the IDE study of the Lumbar I/F Cage, in which 95% of the restored disc space height was maintained at final 2-year follow-up (9). Kaneda has independently reported a comparison of the Lumbar I/F Cage and the Harms titanium mesh cage in treatment of degenerative scoliosis (19). Although the Harms cage had generally satisfactory clinical results, the titanium mesh cage experienced significantly greater subsidence in this difficult patient group.

In the design of larger and smaller cage sizes, the width of the struts was retained at 2.75 mm because of the concern for subsidence if the support area had been reduced. Thus the 9-mm cage has an opening for bone graft of 3.5 mm wide, the 11-mm cage has an opening of 5.5 mm, and the 13-mm cage has an opening of 7.5 mm. The surface area of the average disc has been reported to be 1259 mm^2. Table 4 lists the surface area of bone graft of each size cage and the percentage of endplate coverage by a single cage of each size and by bilateral cages of each size. Although the sizing scheme has succeeded in the design objective of minimizing subsidence, it has sacrificed the percentage of bone graft area and potentially the fusion success.

Comparing surface areas of different size cages, the 9-mm cage is proportionately 18% narrower overall than the 11-mm cage but 36% smaller in surface area for bone graft. Because bony healing was potentially compromised with the 9-mm size cages by the proportionally greater reduction in bone graft surface area, it is clinically important to study the clinical and fusion success of these narrow cages. This study observed that clinical results with the 9-mm cages remain satisfactory, but there is a small but statistically significant decrease in fusion success using the narrower cages.

Although it is possible to avoid this problem by performing generous bone grafting in the disc space between, beside, and in front of the cages, the reason for using the 9-mm cages is usually that insufficient space is available for wider cages or for bone graft. The preponderance of women in the 9-mm patient group implies that the smaller cages were appropriately selected. The use of

TABLE 3 Complications

Study Group	9 mm	Large Group	IDE
Total number of complications	$n = 90$	$n = 426$	$n = 221$
Reoperation for dural tear	2.22%	1.82%	1.80%
Deep infection	2.22%	1.56%	2.71%
Major medical complication	0%	0.24%	0.45%
Reflex sympathetic dystropy	0%	0%	1.36%
Device complication	2.22%	6.02%	9.00%
Surgical death	0%	0%	0.90%
Nerve root injury	1.11%	0.47%	1.35%
Epidural hematoma	1.11%	0.26%	0%

TABLE 4 Bone graft surface area of each cage and percentage of endplate covered

Cage Size	Surface Area of Bone Inside Cage	Endplate Coverage Single Cage (%)	Endplate Coverage Bilateral Cages (%)
13 mm	138 mm^2	10.9%	21.8%
11 mm	101 mm^2	8.0%	16.0%
9 mm	64 mm^2	5.1%	10.2%

9-mm cages in men with larger vertebral endplates will likely result in a greater decrease in fusion success.

Biomechanical studies of the Lumbar I/F Cages demonstrated several differences between the 9-mm and the 13-mm cages (16). In static compression, the larger cages appeared stronger. With a 45° compressive shear force, the 9-mm cages were stronger. In fatigue tests, the 9-mm cages were stronger. Fatigue strength is defined as the load that the cages can bear to 5 million loading cycles without failure. Using two cages, the fatigue strength has a twofold safety factor compared with maximum loads of daily living. Using a single cage, the fatigue strength safety factor is nonexistent over the maximum loads of daily living.

This is the first report that correlates specific cage size parameters with clinical and fusion success. Surgeons should keep these factors in mind when selecting implant designs and sizes. The authors recommend that surgeons should routinely use bilaterally placed cages of maximal width allowable and should fill the disc space outside the cages with as much autologous graft as can be placed. However, if there is any question about width of exposure or safe retraction of a nerve root, a surgeon should not hesitate to use a 9-mm cage at that position.

Conclusions

This study reached the following conclusions:

1. A clinical study of 373 of 425 consecutive patients who underwent PLIF using the Lumbar I/F Cage with VSP pedicle screw fixation revealed 90 patients who had 9-mm cages implanted in at least one level.
2. Clinical success with the 9-mm cages was not statistically different from the clinical success rates of the larger group of 373 patients or from the IDE study.
3. Fusion success was achieved in 82 of 90 patients (91.1%).
4. Fusion success with 9-mm cages was 5% lower than achieved with the larger size cages. Although small, this difference is statistically significant.
5. Mechanical failure did not occur with the 9-mm cages.
6. The lower fusion success rate with the 9-mm cage is likely due to the proportionally smaller surface area of bone graft inside the cage.
7. Surgeons should routinely use bilaterally placed cages of maximal width allowable and should fill the disc space with as much autologous graft as can be placed.

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