*Spinal Restabilization Procedures*
*Edited by D.L. Kaech and J.R. Jinkins*




CHAPTER 14

# Lumbar interbody fusion with PEKEKK composite cages

JEAN PIERRE ELSIG [a], ETIENNE LALOUX [b], JACQUES COMMARMOND [c], MICHEL BISSERIÉ [d] and KAREN E. WARDEN [e]

[a] *Forschstrasse 136, CH-8125 Zollikerberg, Switzerland*
[b] *Point Médical, Ronde Point de la Nation, F-21000 Dijon, France*
[c] *Clinique de Montargis, F-45200 Montargis, France*
[d] *Clinique Jouvenet, 6 Square Jouvenet, F-75016 Paris, France*
[e] *Mechanical and Aerospace Engineering, Case Western Reserve University, Cleveland, OH 44026, USA*

## 1. INTRODUCTION

Anterior lumbar interbody fusion (ALIF) was proposed by Capener [1] in 1932 for the treatment of lumbosacral spondylolisthesis and later by Lane and Moore [2] for the treatment of lumbar disc degeneration. Posterior lumbar interbody fusion (PLIF) was first attempted by Briggs and Milligan [3] who noted that interbody used bone chip graft material "to obtain an intercorporal fusion, but without success". Jaslow [5] reported the successful use of an intercorporal bone peg (as suggested by Briggs) for PLIF in 1946. Certainly, Ralph Cloward has tirelessly popularized and promoted the procedure since his classic 1953 publication [4]. While various authors [6–13] have supported these procedures, with diverse fusion and clinical success rates [14–20], they have, in essence, lain dormant for 50 years.

Cloward [4] attributed low back pain to disc space collapse and the resulting unstable joint complex, and sciatica to the compression of the nerve root at the level of the spinal neural foramen. The ideal operation, he felt, would be one that immobilized adjacent segments while simultaneously, if possible, restoring disc space height. These two goals are theoretically achieved by interbody vertebral fusion and have been described in the biomechanical [21–23] and clinical literature [4,9,12,24,25].

To accomplish these goals, surgeons have utilized allograft and autograft materials in a variety of forms including femoral cortical rings [26–28], tricortical iliac crest blocks [18,29–31] and corticocancellous dowels [32,33]. Cortical grafts have sufficient immediate postoperative strength; however, in practice they will lose 40% to 50% of their mechanical strength during the first 6 months of graft incorporation [34,35] and so are predisposed to some degree of collapse. Corticocancellous autografts can result in donor site complications [36] and can be insufficient in older adults or in the multiply operated patient [37]. Commercially available corticocancellous allografts can have questionable mechanical strength [38] and higher non-union rates [39]. Three studies [26,27,40], have reported a significant loss of restored disc space height in their ALIF patients, and all agreed that the height loss could be due to a combination of graft remodeling and resorption. Recently, interbody fusion cages [41,42,45] have been introduced to aid in promoting fusion by separately addressing the mechanical and biological functions of the bone graft.

Bagby [43] was the first to use this type of device (i.e., the 'Bagby basket') for the treatment of 'wobbler' syndrome in horses. This basket was a hollow, perforated cylindrical stainless-steel dowel filled with autologous bone graft and implanted horizontally into the cervical disc space. This design was independently modified by Kuslich et al. [42] and Ray [44] for human use by, among other things, adding threads which obviated the need to hammer the device into place which paralleled Wiltberger's [11] model of bilateral bone dowel placement. Brantigan

[45] introduced a rectangular, non-metallic polymer composite cage used in combination with posterior pedicle screw instrumentation. This design more closely follows Cloward's concept of using bone blocks and has the advantage of being radiolucent. In all of these, the restoration of lordosis relies on patient positioning or vertebral distraction prior to device implantation; there is no sagittal plane arc correction inherent in the device. The GII™ cage is an extension of the Brantigan design, but incorporates a wedge shape to aid in reestablishing physiologic lordosis at the operative level(s) and has a larger area for graft bone–host bone contact. This series reports the results of patients treated by PLIF, ALIF or a combined anteroposterior fusion (CAPF) using interbody fusion cages (GII™ cage, Co-Ligne Ag, Zürich, Switzerland). See also/or: 360° fusion, three column fusion.

## 2. MATERIALS AND METHODS

### 2.1. Implant

The lumbar GII interbody fusion cages are made from Osta-Pek™, a carbon-fiber-reinforced polymer (PEKEKK). Osta-Pek is a radiolucent material and, as such, bony fusion within and through the cage can be assessed by conventional radiographic methods without overlying artifact or obscuration [46]. Because the carbon fibers are encapsulated within the polymer, fiber migration will not occur [47]. In-vivo and in-vitro toxicity testing, based upon the European and International Standards (EN-ISO 10993), has shown the Osta-Pek material to be biocompatible [48,49]. Mechanical testing of the devices has shown them to have properties that exceed usual physiologic requirements.

The posterior GII cages (Figure 1) are available in numerous sizes consisting of a variety of lordotic arc, height and width combinations. There are three lordotic angulations (2°, 5° and 7°), anterior heights of 9 mm, 11 mm and 13 mm, and widths that range from 10 mm to 13 mm. Cages come in lengths of 20 mm and 25 mm and are used in pairs, side by side. The ALIF GII cages (Figure 2) are available in three lordotic angulations (5°, 9° and 13°) and three anterior heights (11 mm, 13 mm, 15 mm). These cages, used one per level, are 36 mm wide and can be either 20 or 25 mm in length.

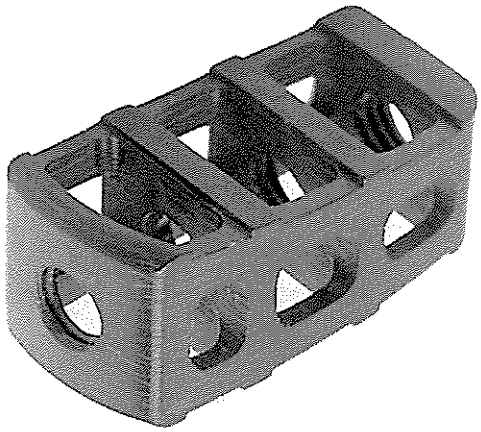

Figure 1. PLIF cage in Osta-Pek.

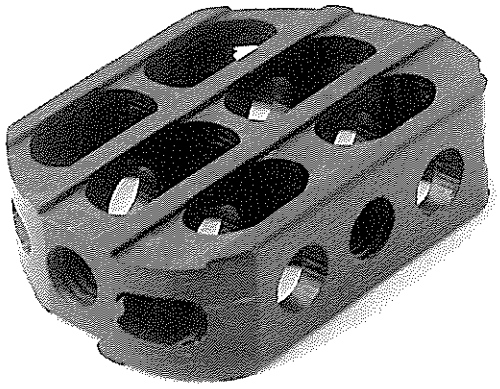

Figure 2. ALIF cage in Osta-Pek.

### 2.2. Operative technique

Interbodys fusion has proven to be very beneficial for the treatment of lumbar disc disease. However, surgeons must be selective in choosing the patients in which to use this procedure. There must be a close correlation between the patient's clinical symptoms and the radiographic and neurologic findings before one can have a reasonable expectation of a good surgical outcome. Only patients with severe disc disease are considered candidates for interbody fusion procedures with this device. The presence of hypermobile instability, the need to correct a spinal deformity (e.g., spondylolisthesis, kyphosis), the presence of multi-segmental disease and any combination of these are indications for interbody fusion. Once the surgical determination to perform interbody fusion is made, then the approach must be chosen. If there is no need to enter the spinal canal or to revise the posterior spinal structures, then an ALIF is appropriate, though very often a surgeon's training and experience will dictate the level of enthusiasm for this procedure. ALIF is often indicated in the presence

of disc disease with minor posterior degenerative changes. If there is a need to enter the central spinal canal (e.g., severe spinal stenosis, postoperative scar tissue, ossification of the posterior longitudinal ligament) or if posterior degenerative change requires further potential operative destabilization of the segment (e.g., from patial facetectomy), then a PLIF with posterior spinal instrumentation or CAPF is called for. Above all, the primary goal and desire is to treat the pathology where it occurs.

### 2.3. ALIF surgical technique

The patient is positioned on the table in strict dorsal decubitus position and upon a buttressing pad positioned beneath the level to be fused. Once the operative level is verified, the buttress pad is raised upward under the patient to physically open the level and/or to reduce any degree of preexisting spondylolisthesis, thereby improving the lumbar–pelvic alignment.

A vascular access (either central arterial, central venous or peripheral venous) is performed so that the option of intraoperative blood transfusion is readily available should inadvertent intraoperative vascular complications occur. A urinary catheter is also inserted to decompress the bladder and to enlarge the operative cavity in cases of $L_5$–$S_1$ operation.

The anatomical references for the approach to the $L_4$–$L_5$ disc are the anterior–superior iliac crest and the umbilicus. Under general anesthesia, abdominal palpation of the spinal column is simple in a lean patient, more difficult in an obese one. The incision must follow an arc-like path resembling an elongated J; this pattern should be offset to the left and in a subumbilical location for the $L_5$–$S_1$ disc space, but supraumbilical for the $L_4$–$L_5$ disc space. For two-level surgery, the incision is extended as necessary in order to have good aortic vascular monitoring, if needed.

A left-hand pararectal passageway is performed to avoid the pitfalls of posterior lumbar incision and the risk of deventration or parietal herniation. As the rectus abdominis muscle is enveloped in two very solid fascial structures, they can be bluntly separated using the fingers through the anterior fold, 2 or 3 cm from the median line. After pushing the rectus abdominis medially, the left-hand lateral dihedral angle is cleared. After hemostasis of the neurovascular elements in this region, the posterior fold is opened after coagulation using electrocautery. When the peritoneum is pushed back by a mounted swab, peritoneal separation can be obtained using a finger. Finally, the incision in the posterior aponeurosis fold is made between 5 mm and 10 mm from the semilunar line.

The literature suggests the transperitoneal approach to be appropriate for only the $L_5$–$S_1$ level. Our experience, in both single-level and two-level fusions has shown that these can be easily done from a retroperitoneal approach. The peritoneal separation is done using a mounted swab, a finger or even the hand on a dry compress. The peritoneal sac is reflected medially, separating the parietocolonic groove. By bringing the whole of the peritoneal contents over the psoas muscle, the ureter is exposed. It should be left completely on the peritoneum, thus avoiding problems of vascularization and secondary fibrosis of the ureter.

For the $L_5$–$S_1$ level, the aortic bifurcation makes disc identification and exposure easy. Vessel loops should be passed around the aorta, iliac arteries and veins, and the inferior vena cava. In addition to providing elevation of the great vessels, these structures can be controlled with the vascular loops in order to prevent excessive hemorrhage in case of an inadvertent tear.

In certain cases, the left common iliac vein and/or the iliac bifurcation itself overlie the $L_5$–$S_1$ disc space. The latter should be raised without major stretching forces being applied to the central portion of the iliac bifurcation to avoid tension on a possibly fragile vein wall, thereby preventing tearing of the bifurcation. Vascular mobilization is obtained using a mounted swab and an aspirator with a foam ball. Removing the fatty tissue flush with the disc surface exposes the anterior longitudinal ligament. Once the disc has been exposed, Hohmann retractors are inserted into the $L_5$ and $S_1$ vertebral bodies taking care not to pierce the endplates.

For $L_4$–$L_5$, the left common iliac vein normally crosses the anterior aspect of the disc surface. In addition, the iliolumbar vein originates over the left-hand lateral aspect of the disc. This vein can be single or double and is sometimes non-continuous. The exposure of the $L_4$–$L_5$ disc and the installation of a wide implant necessitate mobilization of the great vessels with deflection of these vessels to the right side. If the left iliolumbar vein is taut, it can be exposed using a mounted swab, ligated in two places, and then sectioned between the two ligatures. Vascular translation is done using mounted swabs, and the Hohmann retractors are installed.

The anterior longitudinal ligament is opened in an upright (longitudinal orientation with the spinal

column) 'H' shape, and the two flaps are sutured in traction. Disc dissection is performed using incrementally sized rongeurs. The cartilaginous portions of the vertebral endplates are removed using an upside-down curette and the endplates are scraped down to the subchondral bone, until found to be oozing blood. If the disc space is extremely collapsed, a portion of the posterior annulus fibrosus will be hidden within the resulting circumferential disc bulge and will invade the anterior aspect of the central spinal canal — following distraction, this material must be removed. Contrast medium followed by radiography can be used to check the extent of the discectomy, and, upon cage insertion, will show the cage location.

A left iliac autologous graft is used. The grafts are harvested before the laparotomy, through a short incision over the left iliac crest. An internal and superficial cortical osteotomy is performed after which cancellous bone is removed, using gouge scissors. The volume of cancellous and corticocancellous bone depends upon the number of cages to be used. It is preferable to leave the outer cortical bone if the iliac wing and crest for aesthetics, especially when the patient is lean. The graft donor site is infiltrated with anesthetic and adrenaline prior to closure in an effort to reduce the occurrence of immediate postoperative graft donor site pain.

A trial cage is impacted into the interbody disc space. Fit, stability and the desired amount of segmental correction will determine the correct implant size. Cancellous and some corticocancellous bone graft material is packed into the cage cavity so that some degree of expansion of the graft takes place once the device is implanted. Using a hammer, the filled cage is gently impacted into the disc space. After verification of cage location, the lumbar buttressing pad is lowered. This closes the segment upon the cage and provides anterior compression.

The anterior longitudinal ligament is closed using the traction sutures. Drainage is carried out in contact with the implant and the hemostasis areas. A vascular check is essential after removal of the retractors as the tension exerted can arrest the blood flow through the deep or lateral small vein branches. Washing with warm serum is performed, with aspiration to control this step. Parietal closure is performed carefully with strong sutures at each operative level, followed by closure of the subcutaneous tissue and then the skin. An Elastoplast™ dressing is applied to maintain the abdominal wall intact during the initial postoperative stage prior to mobilization. If the procedure is solely an anterior one, external stabilization is recommended. Mobilization can be as early as 24–48 h after surgery. Thromboembolic prevention is continued according to the autonomy of the patient, often for 4–6 weeks.

The patient is told to avoid sitting, as this will prevent hinge movements on the implant and the anterior graft. The corset is removed after 3 months as the patient returns to greater independence and autonomy.

### 2.4. PLIF surgical technique

The patient is positioned in an intermediate flexion position. This prevents abdominal compression, allows freedom of the diaphragm and preserves the anatomic lumbar lordotic curvature.

A conventional posterior midline incision is used to expose the spinous processes. Lateral resection of the paraspinal muscles from the lamina should be conservative in an effort to limit muscular sequelae. The insertion of pedicle screws and the desire for intertransverse grafting dictate the degree of lateral exposure, but do not affect the insertion of an interbody cage.

A conservative decompression is usually sufficient for PLIF placement; the exceptions are central stenosis and spondylolysis. However, the extent of the posterior bone resection will vary according to the specific morphology of the canal and the presence and magnitude of scar tissue.

In a primary lumbar surgery in the absence of a narrow central spinal canal, sufficient bone resection consists of a partial (one-third) resection of the upper lamina, extending the resection laterally until it is aligned with the upper pedicle. A slightly more conservative partial lower laminectomy is completed along with a partial bilateral facetectomy (about half the width of the posterior spinal facet joints) and a partial resection of the lower edge of the spinous process, such that its base does not hinder the insertion of the root retractor and the medial, upper edge of a rectangular cage. With the proper exposure, the nerve roots are explored and decompressed as necessary.

Posterior instrumentation is particularly recommended whenever a major spatial spinal correction (scoliosis, spondylolisthesis, etc.) is necessary. Plate implantation, performed before curvature correction and cage insertion, reestablishes the vertebral alignment prior to the interbody excavation.

It is essential to place the pedicle screws such that the medial edge of the placed plate does not prevent insertion of the PLIF cage. Screw convergence

should follow the inherent convergence of the pedicle, usually between 5° and 15°. However, the entry point and insertion angle will vary with the anatomy of the operated level as well as the customary practice and the convictions of the surgeon.

Taps are sized based on preoperative measurements and are used to prepare the pedicle for pedicle screw insertion. The pedicle sounder is used to check the tapped depth and to insure the integrity of the pedicular wall. Once the screws have been inserted, the intervertebral disc height is restored using paired disc spreaders, one to the right and the other to the left, in sequence from 9 mm to the chosen disc space height (i.e., usually to the corresponding cage size). The amount of distraction should ensure freedom of the roots within the spinal neural foramen, allow adequate canal exposure for cage implantation and restore craniocaudal soft tissue tension so that intersegmental stability and bony fusion will optimally ensue. Excess distraction, even of a temporary nature, should be avoided, as it may be a source of stretch injury within the underlying nerve roots. During these maneuvers, attention must be paid to the position of the canal retractors so that the neurological structures, particularly the upper nerve roots, are protected. Once the intended vertebral position has been obtained, the plates are contoured, applied and fastened in place.

The final size of the cage is determined at this point, as this establishes the reamer and broach sizes to be used. In sequence, the 7.5-mm pilot drill, the pilot reamer, the finishing reamer, the pilot broach and the final broach are used to prepare the PLIF channel. The channel is reamed and broached to a depth of 30 mm according to the markings on each instrument so that, upon insertion, the implant will be recessed 3 to 4 mm. The position of the canal retractors and the protection of the neurological structures is here again emphasized. The tension applied to the underlying nerve roots by the retractors can be released for a few seconds between the various steps. Once the preparation of the implant site is completed, a trial implant spacer can be used to check the expected fit and depth of the final cage implant. If impaction of the trial implant is difficult, the quality of the prepared site should be checked. Radiographs can be taken with the trial implant in place in order to check the implant position and the spinal alignment correction.

We recommend that cancellous bone graft material from the iliac crest be used to fill the cages, although grafts recovered from laminectomy fragments may be suitable if the attached soft tissue is thoroughly removed. It is important that the upper and lower 'windows' for the cages show a bed of good quality cancellous bone, preferably slightly extruding from the surface of each window. About 5 $cm^3$ of bone will be required to fill each cage. The graft donor site is then infiltrated with anesthetic and adrenaline prior to closure to reduce the occurrence of immediate postoperative graft site pain.

The anterior corners of the cage are centered within the posterior opening of the rectangular channel. Before the impaction of the interbody cage, the axial alignment of the cage and inserter is checked to insure it exactly corresponds with the orientation of the channel. Incorrect positioning can result in cage breakage. The cage is then carefully impacted to the bottom of the excavation site. This should position the posterior wall of the cage at least 2 mm (preferably 3 or 4 mm) in front of the posterior edges of the vertebral endplates. This cage impaction should be accomplished without undue force. Once more, special attention must be paid to the protection of regional neurological structures during this final part of the procedure. Before removing the canal retractors, ensure that no cancellous bone fragments have dislodged from the cage and entered the central spinal canal.

Loosening the nuts on the pedicle screws releases any remaining distraction and preloads the intervertebral level. The plates should be removed and the remaining articular masses should be reamed and grafted. Plates are replaced over the pedicle screws and, if required, additional compression is applied with pedicle screw maneuvers, in order to gain adequate 'nesting' of the plate.

Patients are allowed to ambulate as soon as they are able to do so without unreasonable discomfort, although they are encouraged to wear a light body brace. Its purpose is more to remind the patient they have had surgery than to restrain or restrict actual trunk motion. Discharge is usually between the first and second postoperative week. Heavy activities should be avoided, and the brace should be worn for 4 weeks postoperatively.

## 3. RESULTS

### 3.1. Data collection and analysis

For the past 13 years, a multicenter database has been used to monitor interbody fusion patients and

Table 1
Definitions for the 5-point scales used pre- and postoperatively to evaluate patient outcome

| Score | Back and leg pain | Walking capacity | Working capacity (%) | Level of independence | Neurologic |
|---|---|---|---|---|---|
| 0 | Intolerable | <3 min | 0 | Immobile | Muscle function 0 |
| 1 | Severe | <15 min | 25 | Dressing | Muscle function 1–2 |
| 2 | Moderate | <30 min | 50 | House work | Muscle function 3–4 |
| 3 | Mild | <1 h | 75 | Light work | Sensory deficit |
| 4 | None | No limit | 100 | Heavy work | Normal |

their clinical outcomes. The participating surgeons voluntarily record patient data using four case report forms. Patient demographics, prior surgeries, associated pathologies, diagnoses, operative details, implant specifications, complications, etc., are included in the data collection. Five-point scales for pain (back and leg), neurologic status and patient function (walking, working and independence capacities) are recorded for each of these six endpoints at the preoperative and subsequent postoperative follow-up visits (Table 1). For example, a patient may present preoperatively with a back pain score of 0 (intolerable), a leg pain score of 1 (severe), a neurologic score of 3 (sensory deficit), a working capacity score of 1 (25%) and a level of independence score of 2 (house work). Medication usage and frequency, any late complications, reinterventions and the radiographic diagnosis of fusion are recorded at these same intervals.

To date, 1126 lumbar patients have been enrolled retro- and prospectively. For this report, the database was queried for prospective patients having a minimum of 1 year follow-up. From this group, subsets of patients were selected using the length of follow-up and the primary diagnosis as the criteria of analysis. From the resulting patient population distribution it was determined that the outcomes for patients treated for degenerative disc disease (DDD) or the failed back surgery syndrome (FBSS) could be grouped according to this approach and compared. Paired Student *t*-tests were used to compare pre- and postoperative patient endpoint means, and ANOVA and unpaired *t*-tests were used to compare endpoint improvements between groups.

### 3.2. Outcomes

The demographic and operative data for the patient subsets is contained in Table 2. All patients were enrolled prospectively and had a minimum of 1 year follow-up. The determination of radiographic fusion was made by the operating surgeon at each follow-up timepoint and was based upon the presence of a continuous trabecular bone structure visualized across the disc space with no intrinsic radiolucencies vertically through the cage, and the observation of bone quality (density) within the cage which matched that within the adjacent vertebral bodies. Disc space craniocaudal height correction was determined by

Table 2
Patient demographics and operative data

| | DDD | | | FBSS | |
|---|---|---|---|---|---|
| | CAPF | ALIF | PLIF | ALIF | PLIF |
| Patients: | | | | | |
| Total | 26 | 60 | 98 | 54 | 57 |
| Male, female | 14, 12 | 22, 38 | 30, 68 | 20, 34 | 26, 31 |
| Mean follow-up: | | | | | |
| Days | 710 | 599 | 789 | 558 | 699 |
| Years | 1.9 | 1.6 | 2.2 | 1.5 | 1.9 |
| Age (years): | | | | | |
| Mean | 40.0 | 44.1 | 54.5 | 41.5 | 44.3 |
| Minimum | 27.1 | 28.6 | 23.3 | 29.8 | 24.8 |
| Maximum | 57.4 | 89.6 | 85.3 | 53.8 | 74.8 |
| Secondary diagnosis (a patient may have more than one): | | | | | |
| Spondylolisthesis | 18 | 1 | 6 | 2 | 3 |
| Stenosis | 1 | 5 | 76 | 0 | 28 |
| Instability | 18 | 47 | 84 | 49 | 38 |
| Herniation | 1 | 14 | 53 | 17 | 38 |
| Mean hospital stay (days): | | | | | |
| Total | 7.8 | 7.8 | 12.8 | 8.5 | 12.4 |
| Postoperative | 6.6 | 6.7 | 11.6 | 7.1 | 11.5 |
| Mean operative time (min): | | | | | |
| Anesthesia | 202.7 | 92.7 | 227.7 | 93.5 | 243.0 |
| Surgery | 147.3 | 74.3 | 191.6 | 72.7 | 203.8 |
| Mean blood usage (ml): | | | | | |
| Loss | 187.5 | 22.3 | 482.8 | 61.9 | 487.9 |
| Autologous | 0.0 | 5.3 | 296.7 | 0.0 | 352.1 |
| Banked | 26.9 | 0.0 | 35.1 | 0.0 | 5.8 |

comparing the postoperative disc space height of the operative and the adjacent levels. A partial correction indicated that the adjacent disc space height was greater than that at the operative level postoperatively, while a complete correction indicated that the two measurements were the same. A loss of correction was determined when there was a loss of greater than 1 mm in the restored disc space height, and when there was a measurable loss of lordotic curvature.

### 3.3. DDD

Of the 184 patients with this surgical indication, 26 were treated with ALIF, 60 treated with CAPF and 98 received a PLIF. Iliac crest autograft material was used for all ALIF patients, 24 of 26 CAPF patients but only 64 PLIF patients; in the remaining patients, laminar bony fragments were used to fill the cages. Posterior instrumentation with a posterolateral fusion (PLF) was used in all of the CAPF patients. While posterior instrumentation was used in all of the PLIF patients, only 54% received bone grafting for a PLF. The most frequently operated PLIF level was $L_4$–$L_5$ (50%). For ALIF and CAPF, the most commonly operated level was $L_5$–$S_1$ (70% and 60%, respectively). The most commonly used ALIF cages had a 9° wedge with a 13-mm height. Conversely, PLIF cages of 2° and 5° angulation in 9-mm and 11-mm heights were used most often. Complete disc space height and lordosis correction was achieved in all ALIF and CAPF patients, and partial or complete correction resulted in all but one PLIF patient.

Nineteen operative complications occurred in the 184 patients; 68% of these occurred in the PLIF group. These included one transient nerve root stretch injury (resolved with no impairment), three dural sac tears (successfully repaired at the time of surgery), four instances of excessive bleeding, one malpositioned cage (placed too far superior to the disc space and into the vertebral body above), one difficult cage insertion and 3 instances of intraoperative pedicle screw repositioning.

Operative complications in the CAPF and ALIF groups included: peritoneal tear (1 ALIF, 1 CAPF), excessive epidural bleeding (1 ALIF, 1 CAPF), and one iliac vein tear (ALIF); all were repaired during surgery without further complications.

No ALIF or CAPF patients experienced postoperative implant complications. Within the PLIF group, five patients (5%) experienced a total of seven implant-related complications. In one patient, posterior cage migration was coupled with a broken screw; the cage and broken screw were removed and replaced without further incident. In another patient, eventual cage subsidence and a broken screw were found; this level was reoperated and an additional adjacent level was included into the fusion. Use of too long a length plate caused facet irritation in one patient; instrumentation was removed without consequence. There were two additional broken screws; in one patient, this was asymptomatic, and in the other the posterior instrumentation was removed with patient improvement.

Graft donor site pain occurred in 3.8% (3 ALIFs and 4 PLIFs) of patients. Late degeneration at an adjacent segment was observed in 13 of the 184 patients (2 CAPFs, 4 ALIFs and 7 PLIFs) and sacroiliac joint pain, which resolved with time, occurred in 2 CAPF, 6 ALIF and 3 PLIF patients. The two patients with cage complications had a loss of correction; no CAPF, ALIF or other PLIF patients had any loss of correction.

Twelve of the PLIF patients had plates and screws removed in a secondary procedure after fusion occurred, and in only the two mentioned above was the removal performed for painful or broken hardware. The remaining ten patients had posterior instrumentation removed following fusion as this is routine in one surgeon's practice. One PLIF patient had a reoperation due to a postoperative pseudomeningocele formation and in another patient, a PLIF was performed at an additional level nine months postoperatively. Some form of reintervention occurred in two (3%) of the ALIF patients; in one patient an additional level was decompressed, and in another, a PLIF was performed two levels above the initial operative level due to an interim traumatic fall.

All patients achieved evidence of radiographic fusion by the 1-year follow-up. Sixty-five percent of the ALIF, 77% of the CAPF and 85% of the PLIF patients returned to their previous profession following surgery. The usage of pain medication was reduced from the preoperative timepoint in both strength of medication and number of patients using medication (Figure 3). By the 1-year follow-up, only one PLIF patient was using opiates, whereas preoperatively a total of 49 patients were using a drug of this potency. The subjective, patient-rated satisfaction with the surgical procedure is given in Table 3.

The score definitions used for measurement of pre- and postoperative patient outcome are listed in Table 1. A comparison of the primary endpoint means for those patients treated for DDD is shown

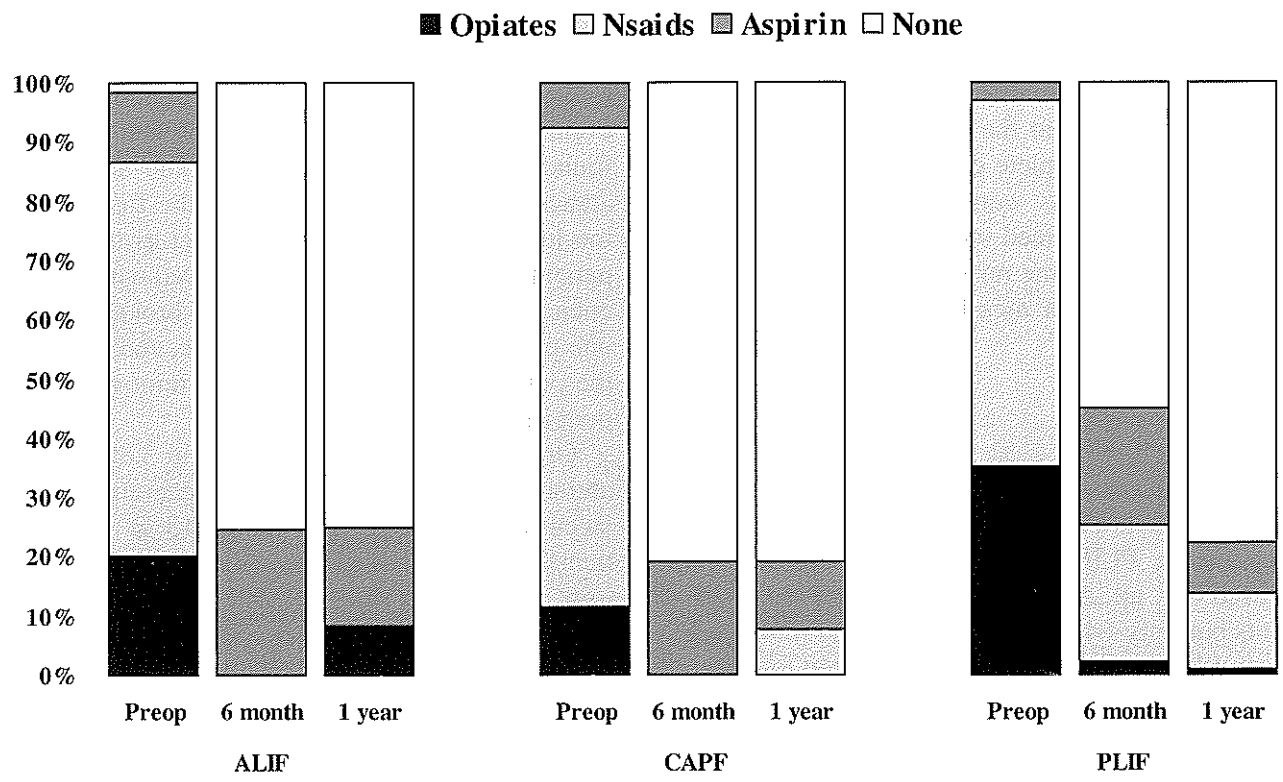


Figure 3. DDD patient medication usage (as percentage of patient population).

Table 3
Patient-rated satisfaction

| | DDD | | | FBSS | |
|---|---|---|---|---|---|
| | CAPF ($n = 26$) | ALIF ($n = 60$) | PLIF ($n = 98$) | ALIF ($n = 54$) | PLIF ($n = 57$) |
| Good | 20 (77%) | 48 (80%) | 77 (78%) | 33 (61%) | 29 (51%) |
| Improved | 6 (23%) | 11 (18%) | 19 (19%) | 19 (35%) | 24 (42%) |
| Not improved | 0 | 1 (2%) | 0 | 2 (4%) | 4 (7%) |
| Worse | 0 | 0 | 2 (2%) | 0 | 0 |

in Figure 4. The mean back pain, leg pain and neurologic scores achieved at the immediate postoperative timepoint are statistically significant ($P < 0.0005$), as compared to the preoperative status, regardless of the operative approach used. Within each analysis group, the mean 6-month postoperative patient function parameters (Figure 5) were significantly improved ($P < 0.0001$) as compared to the preoperative status. The mean change in score from the preoperative to the next postoperative timepoint for neurologic evaluation, leg pain and walking was statistically greater (i.e., more improved) in the PLIF group than either the CAPF or the ALIF group. However, the initial mean scores for each of these parameters in the CAPF and ALIF groups were statistically higher than in the PLIF group. For example, 80% of PLIF patients had preoperative leg pain scores of 0 or 1 compared to 54% of the CAPF and 27% of the ALIF patients. At the 1-year follow-up, no patient had leg pain, back pain or neurologic scores that were worse than the preoperative status. In all other statistical comparisons, the level of statistical insignificance was accompanied by relatively low statistical power.

### 3.4. FBSS

There are 57 PLIF and 54 ALIF patients in this series. The PLIF patients had had an average of 1.8 prior surgical interventions including discectomy ($n = 43$), spinal cord/nerve root decompression ($n = 41$), posterolateral fusion (PLF, $n = 8$)

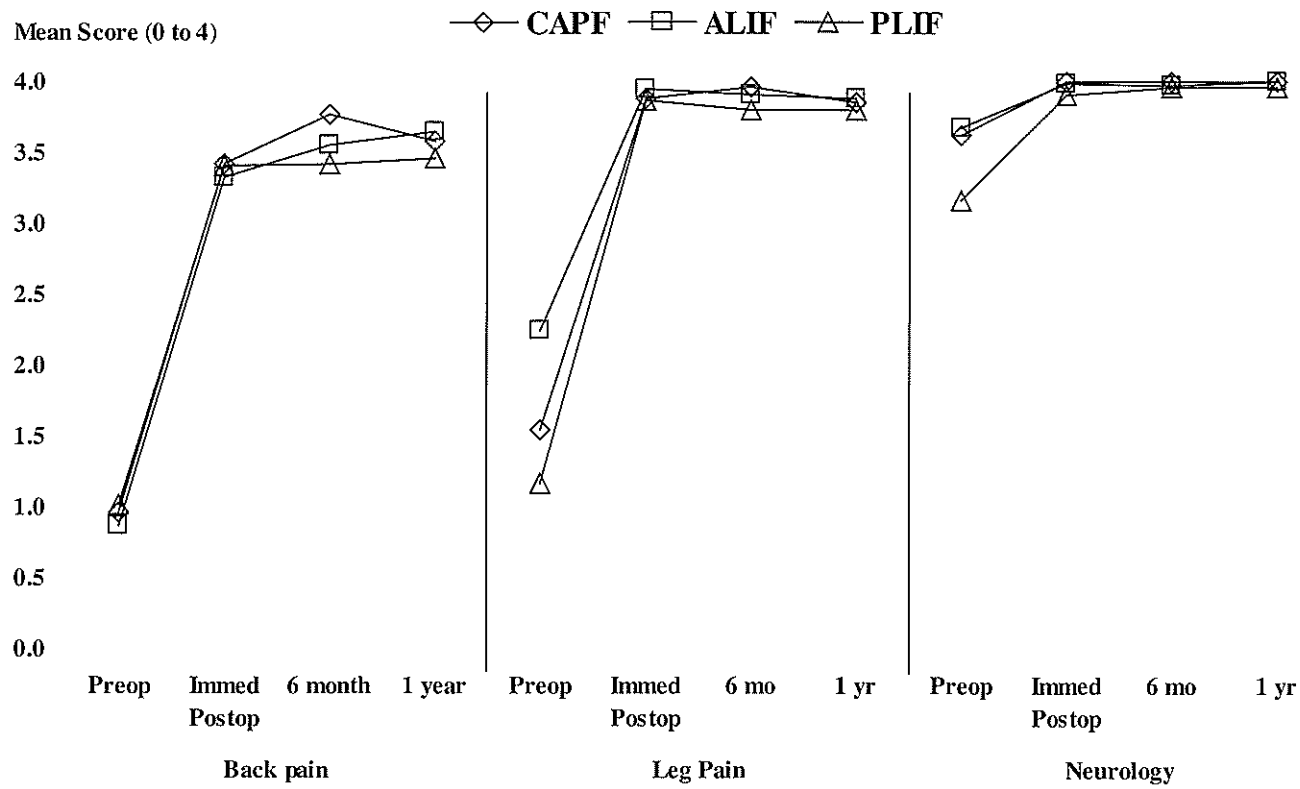


Figure 4. Mean primary endpoint scores for DDD.

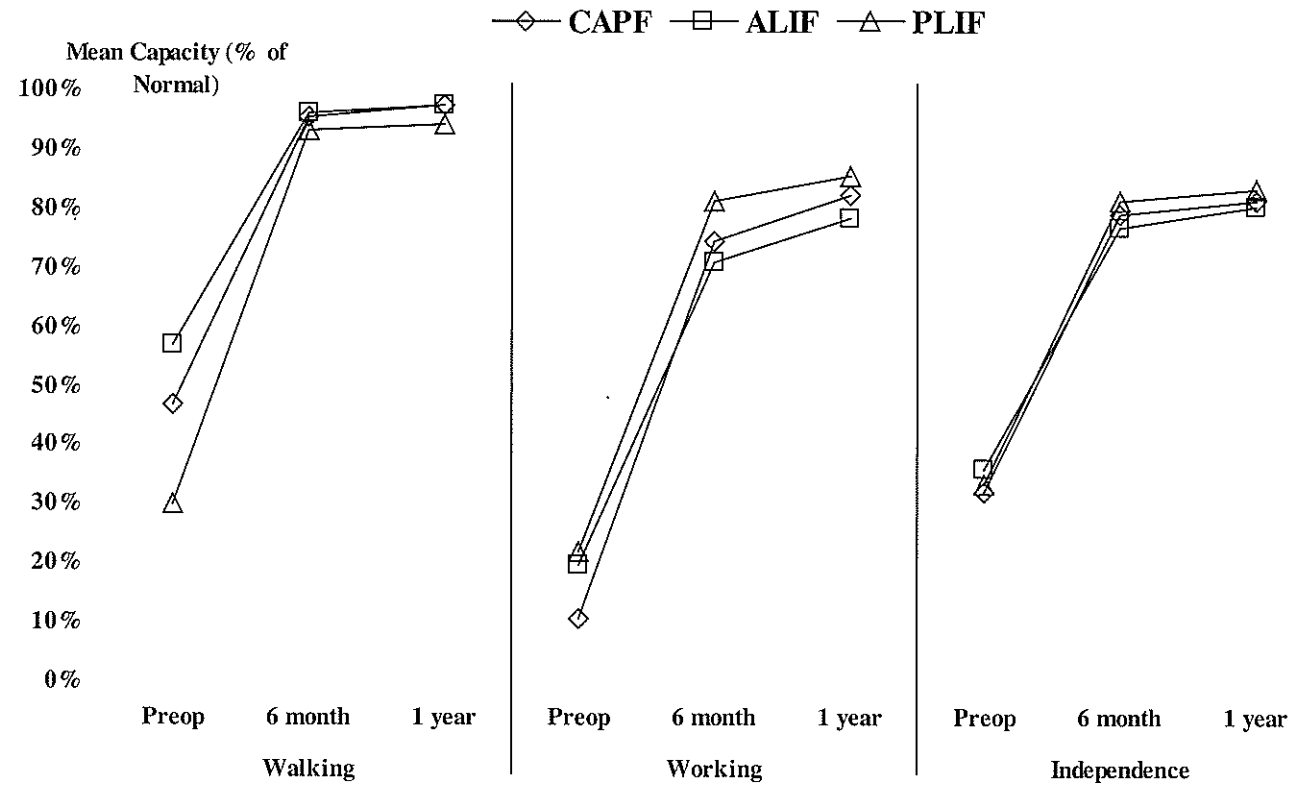


Figure 5. DDD functional capacity endpoints (mean as % of normal).

and PLIF ($n = 2$). There were 81 prior interventions in the ALIF group including discectomy ($n = 49$), spinal cord/nerve root decompression ($n = 17$), posterolateral fusion ($n = 5$) and PLIF ($n = 3$). Patient demographics, operative data and the major secondary diagnoses are listed in Table 2. Iliac crest

autografts were used in all of the ALIF but only 49% of the PLIF surgeries (laminar fragments were used in the remaining cases). The PLIF procedures took place at the $L_4$–$L_5$ and $L_5$–$S_1$ levels in 53% and 33% of the time, respectively, whereas $L_5$–$S_1$ was the most common site for ALIF operations (71%). The 2° and 5° cage angulations were used most commonly in the PLIF patients (45% and 42%, respectively), whereas the 9° was used in 79% of the ALIF patients. Cages with an anterior height of 11 mm were used in 60% of the PLIF patients, and the remainder received 9-mm cages. Forty-five (78%) ALIF patients received 13-mm cages, and the remainder the 11-mm cages. One ALIF and one PLIF patient had no disc space height correction; the remainder of ALIF patients (98%) achieved a complete correction and the remainder of PLIF patients had either a partial or a complete correction. All patients had either a partial or complete lordosis correction.

No operative complications occurred in 48 (89%) of the ALIF and in 41 (72%) of the PLIF patients. There were 11 dural tears repaired during surgery (PLIF), two cases of excessive bleeding (1 PLIF, 1 ALIF), one cemented and four repositioned pedicle screws (PLIF) and five peritoneal tears repaired during surgery (ALIF). There were no postoperative ALIF implant-related complications but a plate in one PLIF patient was painful; this was removed without consequence and the pain resolved. One of the ALIF (1.9%) and five of the PLIF (8.8%) patients reported some postoperative donor graft site pain at the first postoperative follow-up. Fourteen (24.6%) of the PLIF patients have had a reintervention; in addition to the above-mentioned painful plate removal, 12 patients underwent elective hardware removed, and one 2-level (non-consecutive levels) patient underwent an ALIF at 6 months at the intervening segment due to a traumatic fall. One ALIF patient required an additional posterior decompression procedure for central spinal stenosis. No PLIF or ALIF patient had loss of disc space height or lordosis correction.

All patients were considered radiographically fused by the 1-year timepoint. Of the ALIF patients, 50% returned to their previous profession, 15% changed profession, 28% are receiving disability and the balance are unemployed. Sixty-three percent of the PLIF patients returned to their previous profession, 17% changed profession, and only 5% are on disability but 14% are unemployed. Medication usage and severity for each recorded follow-up timepoint is shown in Figure 6. The subjective, patient-rated satisfaction with the surgical procedure is given in Table 3.

The score definitions used for measurement of pre- and postoperative patient outcome are listed in Table 1. The mean primary endpoint results for

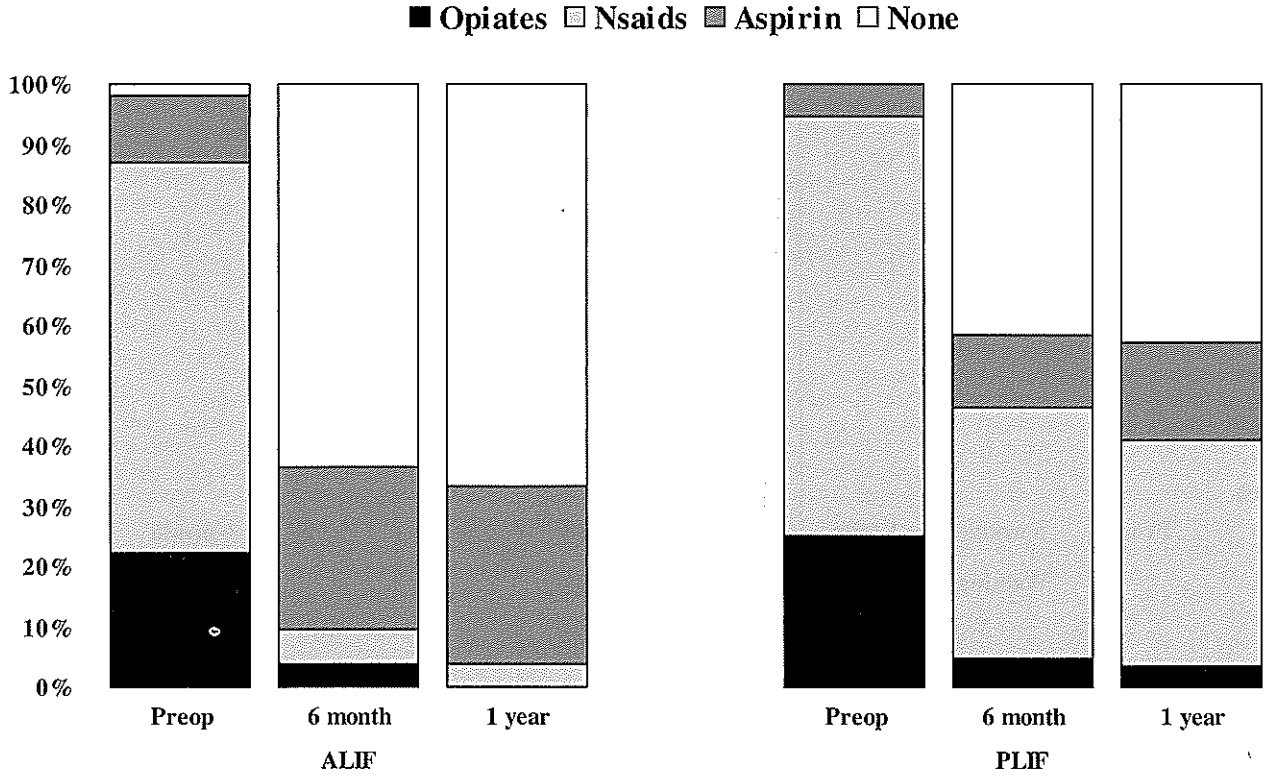


Figure 6. Medication usage for FBSS patients.

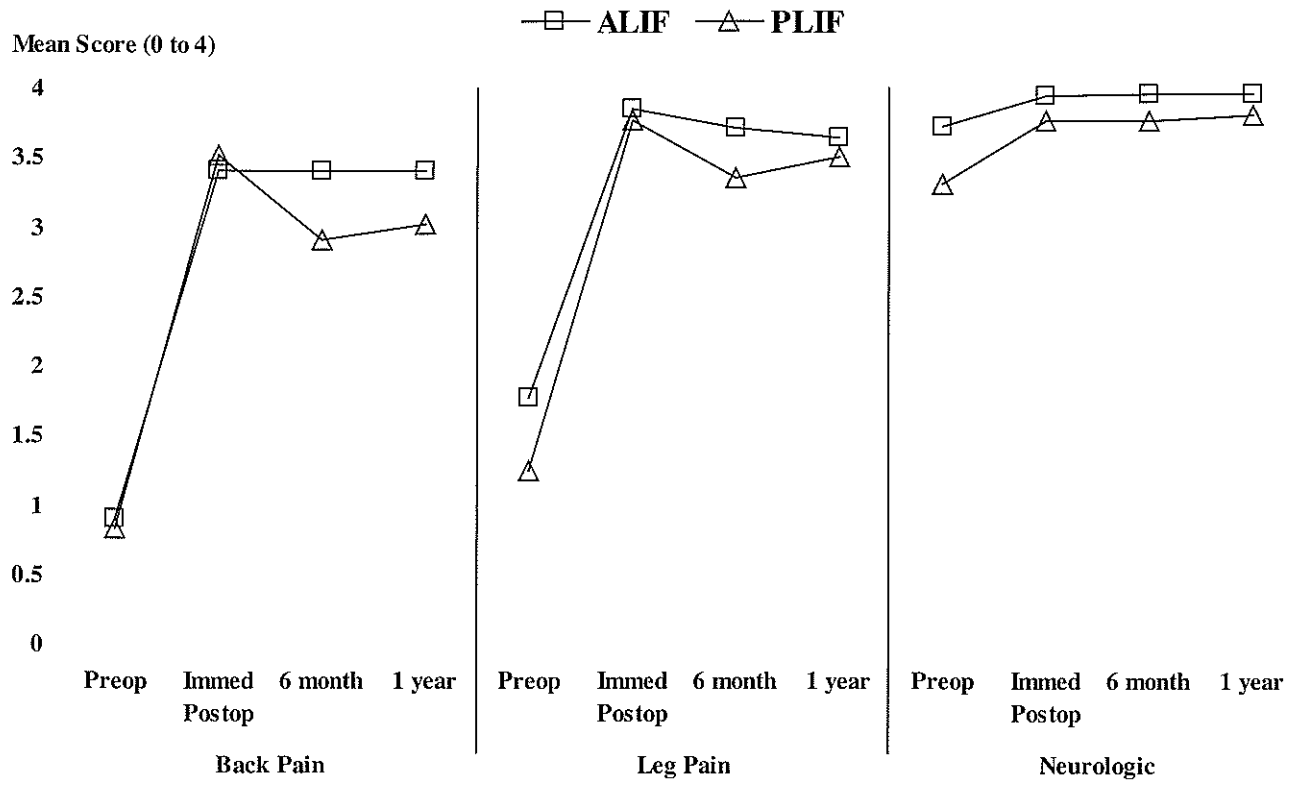


Figure 7. Mean primary endpoint results for FBSS.

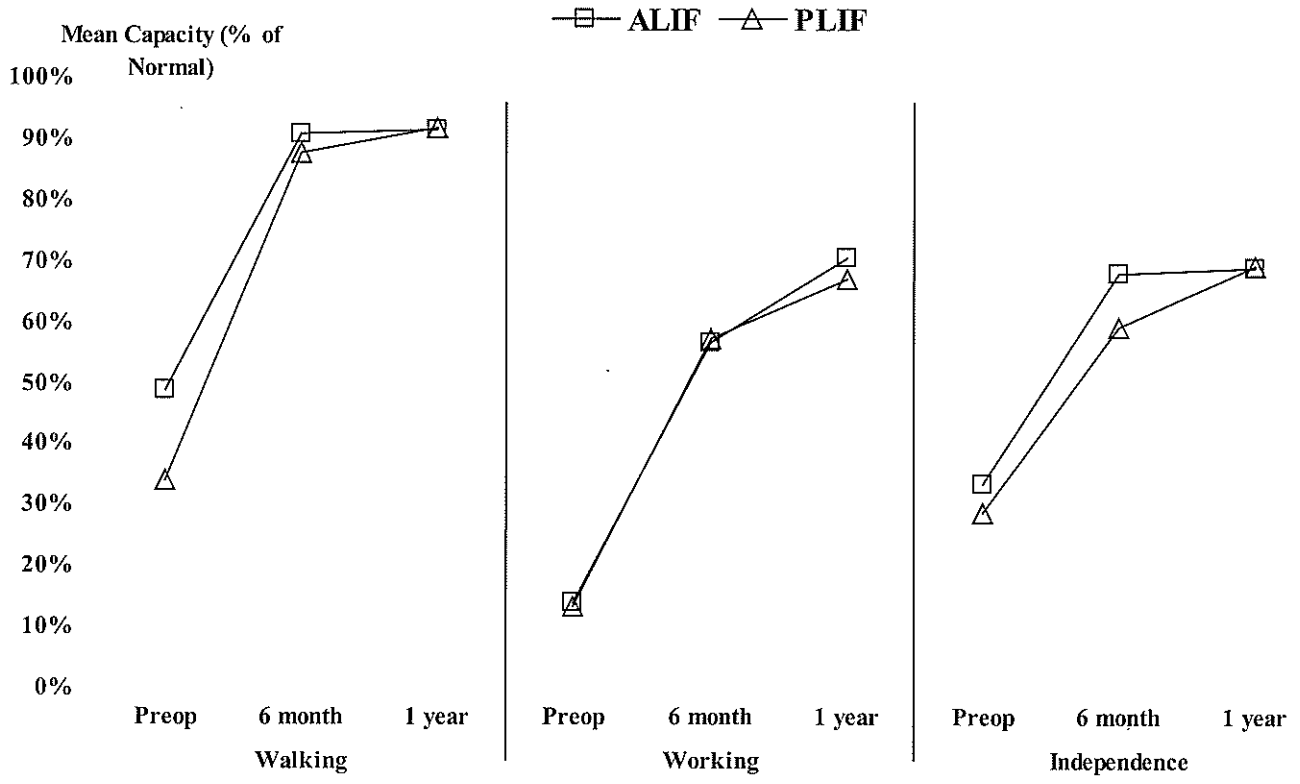


Figure 8. Functional capacity results for FBSS (mean as % of normal).

the FBSS patients are presented in Figure 7, and Figure 8 contains their mean functional capacities. Compared to the preoperative mean score, the immediate postoperative mean score for each of these endpoints was statistically improved ($P < 0.0001$ for back and leg pain, $P < 0.005$ for neurology) within

each approach group (e.g., ALIF or PLIF). Likewise, the functional capacity means at 6 months were statistically better than preoperative status, regardless of the operative approach used ($P < 0.0001$). The leg pain score from pre- to postoperative timepoints was statistically more improved in the PLIF group than ALIF ($P < 0.05$), but as in the DDD population, the initial leg pain scores in the ALIF group were statistically higher. We found a statistically significant difference between the two groups in the change in back pain score from the immediate to the 6-month postoperative period (i.e., while there was no change in the ALIF group score, there was a 0.5-point loss in mean score for the PLIF patients). In all other statistical comparisons, statistical insignificance was accompanied by relatively low statistical power.

### 3.5. Illustrative cases

#### *3.5.1. Case 1*

The patient is a 58-year-old female presenting with moderate leg and severe back pain. Walking and working capacities were <15 min and 25%, respectively. Medication usage consisted of mild opiates taken twice daily. Radiographic and clinical examinations revealed DDD with disc herniation, discopathy and instability (Figure 9, left) at the $L_5$–$S_1$ level. The patient underwent an ALIF using a 13 mm, 9° cage filled with iliac crest autograft material. There were no operative, implant or late complications. At the 3-month follow-up, the patient was no longer taking medication and back and leg pain, neurology and her functional capacities had returned to normal by 6 months. Radiographic fusion was determined at the 6-month follow-up. Columns of bone, indicating fusion through the cage, can be clearly seen in the 3-year postoperative X-rays (Figure 9, right). She has returned to her previous profession, and her patient-rated satisfaction is good.

#### *3.5.2. Case 2*

The patient is a 51-year-old male presenting with severe back and leg pain. Walking and working capacities were <15 min and 25%, respectively. Medication usage consisted of mild opiates taken more than twice per day. Radiographic and clinical examinations revealed DDD with disc herniation, discopathy, spondylolisthesis and instability (Figure 10, left and center) at the $L_5$–$S_1$ level and moderate canal stenosis at $L_4$–$L_5$. The patient underwent a CAPF using a 13 mm, 9° cage filled with iliac crest autograft material, a posterolateral fusion using plates and pedicle screws posteriorly at $L_5$–$S_1$, and a decompression from $L_4$–$S_1$. There were no operative, implant or late complications. At the 3-month follow-up, the patient was not taking any medication and back and leg pain, neurologic features and all functional capacities had returned to normal. Radiographic fusion was determined at the 3-month follow-up. Columns of bone, indicating fusion through the cage, can be clearly seen in the 2-year postoperative X-rays (Figure 10, right). He has returned to his previous profession, and his patient-rated satisfaction is good.

#### *3.5.3. Case 3*

The patient is a 60-year-old female presenting with severe back and leg pain. Walking capacity was <3 min and she was unable to work. Medication usage consisted of mild opiates taken more than twice per day. The patient underwent a prior discectomy at $L_4$–$L_5$ and a decompression from $L_4$–$S_1$. The preoperative examinations revealed instability and severe canal stenosis at $L_4$–$L_5$ (Figure 11, left and center), with accompanying degenerative changes at $L_3$–$L_4$. The patient underwent a PLIF using two 11 mm, 5° cages filled with iliac crest autograft material at $L_4$–$L_5$, a posterolateral fusion using plates and pedicle screws posteriorly from $L_3$ to $L_5$, and an extension of prior decompression up to $L_3$. There were no operative, implant or late complications. At the 3-month follow-up, the patient was not taking any medication, and leg pain had returned to normal. Radiographic fusion was determined at the 3-month follow-up. The 3-year postoperative radiographs are shown in Figure 11 (right). She has returned to her previous profession, and her patient-rated satisfaction is good.

## 4. DISCUSSION

The use of interbody fusion cages has escalated since their introduction a little over ten years ago. Yet, despite the estimate of over 80,000 cages implanted worldwide [50], there is a relative paucity of published literature describing the clinical outcomes with the use of these devices. The results of three FDA monitored clinical trials to evaluate the safety and efficacy of lumbar interbody fusion devices for the treatment of DDD have been published within the last 3 years [41,42,51]. However, we found only six additional published clinical series using interbody devices with sufficient operative and clinical outcome data to which comparisons could be made [26,46,52–55].

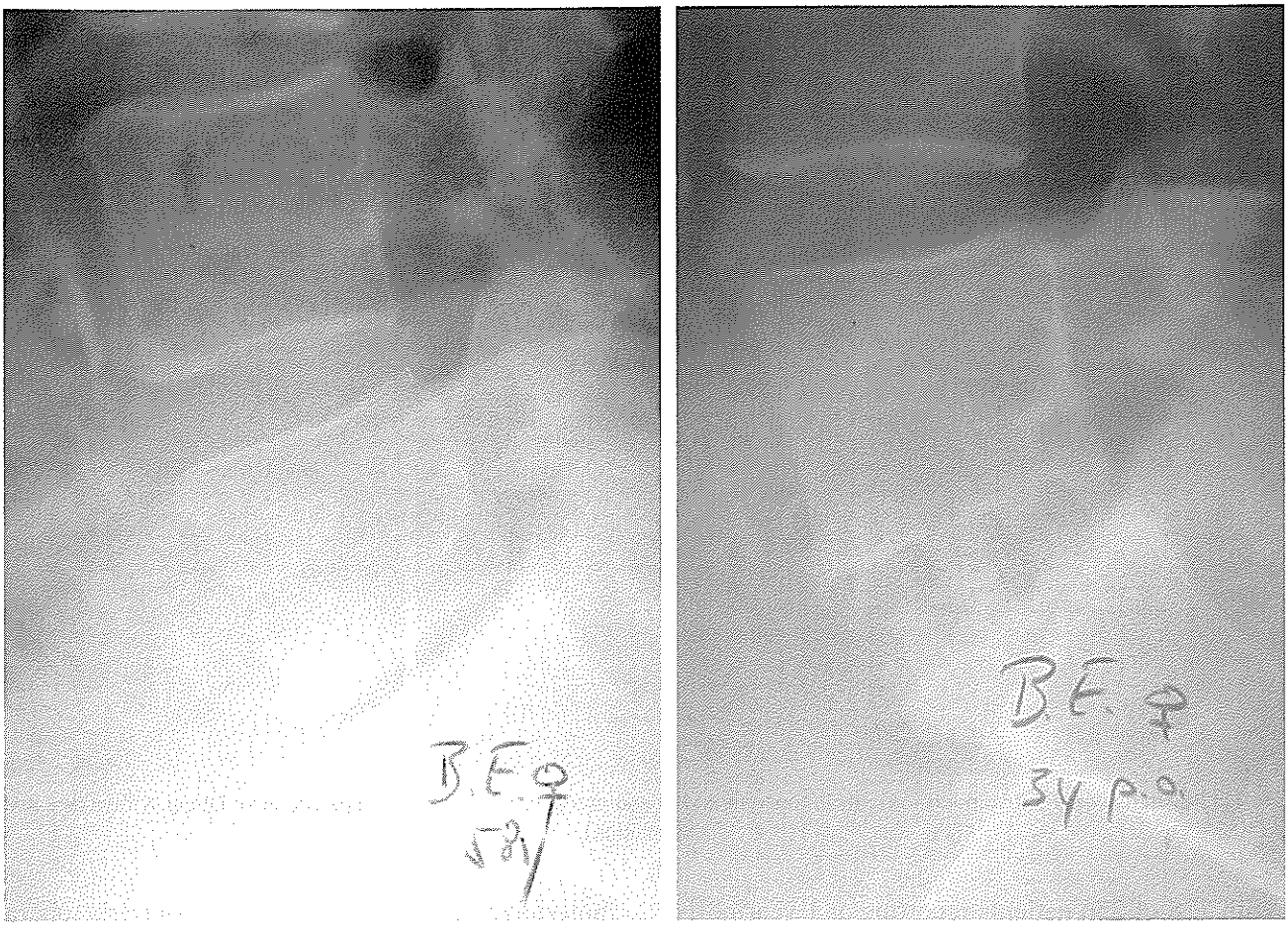

Figure 9. Illustrative case 1. Preoperative lateral (left) and 3-year postoperative (right) X-rays (see text for explanation).

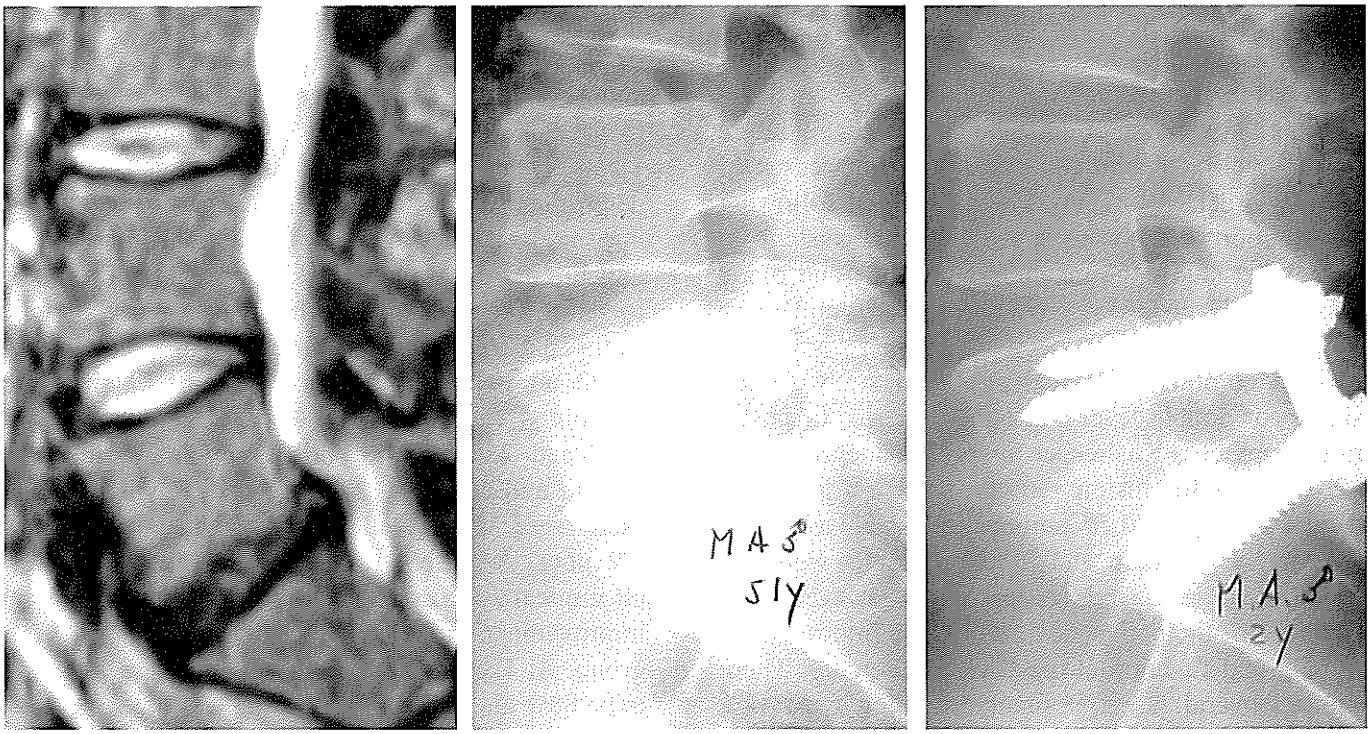

Figure 10. Illustrative case 2. (from left to right) Preoperative MRI and preoperative, and 2-year postoperative lateral X-rays (see text for explanation).

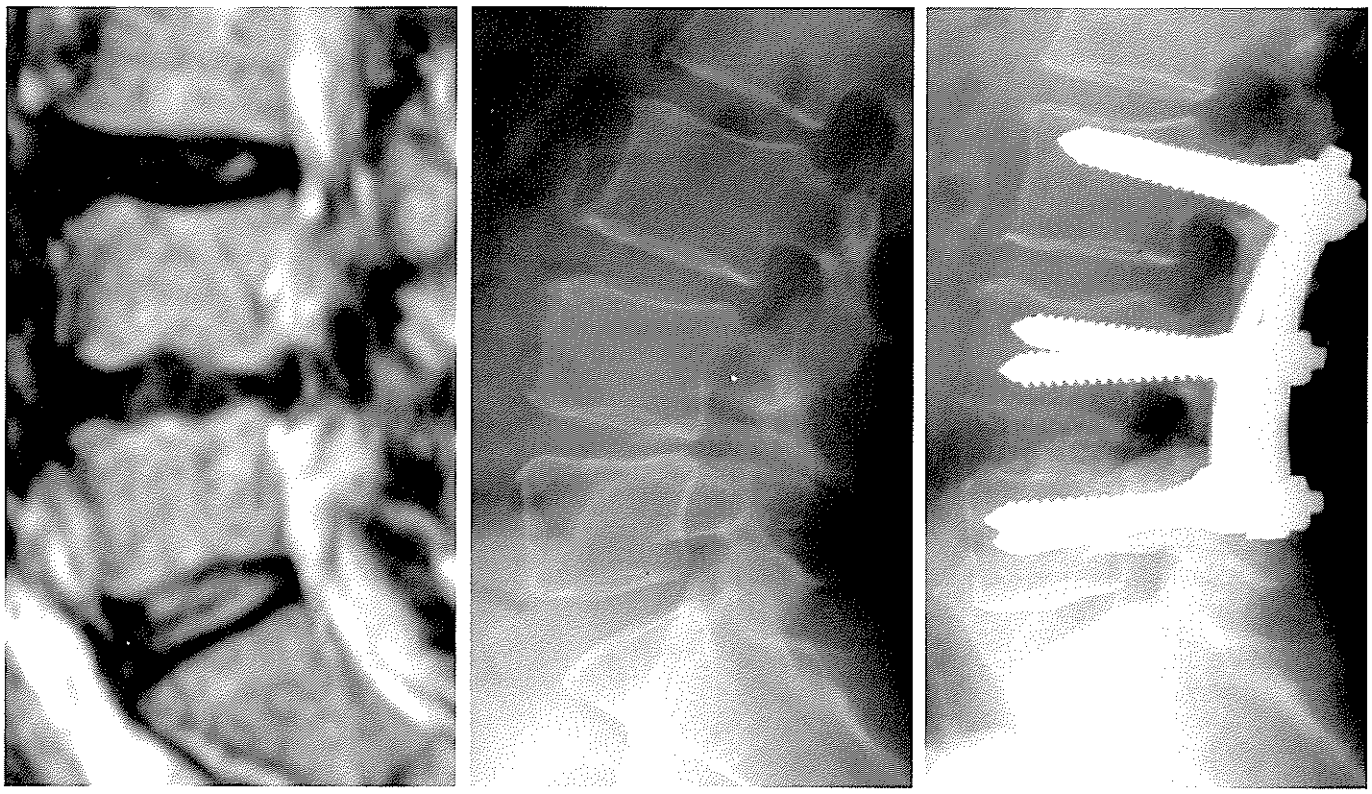

Figure 11. Illustrative case 3. (from left to right) Preoperative MRI and preoperative, and 2-year postoperative lateral X-rays (see text for explanation).

With 228 of 236 patients reporting at 1 year postoperatively, Ray [41] found a 96% successful fusion rate using Ray threaded fusion cages (TFC™) in PLIF. The clinical outcome was found to be excellent or good in 60%, fair in 23% and poor in 14%, using the Prolo socioeconomic/functional improvement scale for evaluation. Complications included the surgical revision of three cages, one cage fracture (without clinical consequences) and four cases of pseudarthrosis formation which resolved following the addition of a posterior pedicle screw system. In an adjunct study, the mean surgical time and blood loss for 1-level CAPF procedures was found to be 289 min and 364 ml, respectively [56].

In a combined surgical approach study (either single- or double-level and either anterior or posterior approach), Kuslich et al. [42] found 87% and 92% successful fusion rates at 1 year for single-level PLIF and ALIF surgeries, respectively. Unfortunately, the pain and function results were not reported by level and/or approach; however, 85% and 91% of the patients overall had an improvement in pain and function at the 2-year follow-up. There was an overall 2.7% implant migration rate, 44% of which required reoperation. Intraoperative dural tears were reported in 10.1% of the PLIF patients and vessel damage was reported in 1.7% of the anteriorly and in 0.3% of the posteriorly operated patients.

Brantigan et al. [51] reported the results of 221 patients treated by PLIF, 110 of whom were treated for DDD. Mean surgical time and blood loss for all patients were 297 min (±82, range 175–633 min) and 1577 ml (±1246, range 100–8200 ml), respectively. Fusion rates of 96% and 100% were found at 1 and 2 years, respectively. Radiographic fusion was determined when there was evidence of bone bridging the disc space with no intrinsic lucency. Using the sum of four 5-point scales (ranging from 1 to 5) for pain, function, medication usage and economic status, patient outcomes were rated as excellent (17 to 20 points), good (13 to 16 points), fair (9 to 12 points) and poor (4 to 8 points). Preoperatively, 64% and 28% of the patient population fell into the fair and poor categories, respectively. By 1 year, there were 41% excellent, 39% good 15% fair and 4% poor. A patient was determined to have overall clinical success if they had a minimum 3-point improvement and was in the excellent, good or fair group. At 1 year, overall clinical success was found to be 88% and patient satisfaction was 82%.

Using the same implant system, Tullberg et al. [52] found fusion rates of 86% and 89% by patient (44/51) and level (58/65), respectively. There were

three instances of dural tears and no screw breakages, although in one patient a screw was believed to be loose.

Liljinqvist et al. [26] reported the follow-up of 41 patients undergoing a CAPF using autograft-filled femoral rings. While not technically a device, the femoral ring mimics the intent of an interbody fusion device (i.e., it is used in the short-term to fulfill the mechanical requirements of interbody fusion). The mean operating time was 234 min, and the mean blood loss was 604 ml. Intraoperative complications included one dural tear, one peritoneal tear, and one tear of the left common iliac vein which were all repaired at the time of surgery without further consequence. There was one reoperation due to nerve root irritation; a further decompression was successful in resolving the radicular symptoms. Two of the femoral rings fractured, though both levels went on to a successful bony fusion. The fusion rate by patient was 93% and by levels operated was 95%. A visual analog scale (VAS) was used to measure a patient's improvement; the mean score at follow-up was $6.7 \pm 3.2$ out of 10. There were two patients who reported being worse after surgery. Subjectively, 82% of the patients were satisfied or highly satisfied, and 6% were dissatisfied; the remainder were subjectively uncertain. At a mean follow-up of 38 months, eight patients reported chronic donor site pain at the iliac crest.

Agazzi et al. [46] used the same PLIF implant system reported in this series and found a fusion rate of 89% in the 66 patients with radiographic follow-up. The clinical outcome for 71 patients was based upon the Prolo economic and function score; 39% had a good or excellent outcome, 25% were fair and 34% were poor. Subjectively, 66% of the patients were satisfied with their surgery, and the same percentage would have the surgery again were it necessary to do so. There were two intraoperative dural tears repaired during surgery and seven patients with persistent radicular symptoms longer than 2 days postsurgery. All resolved with time, although in two patients removal of the hardware was required.

Hacker [53] compared 21 CAPF patients to 54 PLIF patients with BAK cages. The mean operative time for the two groups was 250 min and 120 min, respectively. Mean blood loss was 300 ml in the BAK group and 900 ml in the CAPF group. Patient-rated satisfaction was 88% in the CAPF and 89% in the PLIF. There were five reoperations for pseudarthrosis in the CAPF group; the remaining patients were considered fused. Twenty-four PLIF BAK patients had completed the radiographic sequential assessment; 20 were fused, 3 partially fused and 1 had a non-union. There were four reoperations in the PLIF group, one to revise implant placement, two had surgery at an adjacent level and one required partial removal of a pedicle for nerve root impingement due to a too laterally placed implant.

Pavlov et al. [54] report the use of Ray TFCs in ALIF on 13 patients with a mean follow-up of 24 months. Mean surgical time and blood loss were 78 min (range 60–110) and 391 ml (range 150–850), respectively. There were no intraoperative complications. However, there were seven reoperations for clinically suspected, and intraoperatively confirmed, pseudarthrosis. At 1 year, using the Prolo economic and function score, five patients were considered good, four fair and two poor. The revised patients contributed the two poor, three of the fair and one of the good outcomes to the overall figures.

Matgé and Leclercq [55] used Ray TFC and BAK cages for PLIF in 222 patients and 243 levels. At 1 year postoperatively, there was a 91% fusion rate; this had increased to 96% by 2 years. Eighty percent of the patients had a good or excellent outcome based on the Prolo economic and function score. Improvement was found in 15% and there was no or minimal improvement in 5%. There were ten intraoperative dural tears, and transient neurologic deficits were observed in nine patients. Two early reoperations to revise cage placement took place, one due to lateral migration and another to correct a too prominent (i.e., superficial) placement.

Proponents of the ALIF approach cite reduced operative time/blood loss as one of the advantages of the surgery [28]. We found this to be true as well. In our present series, the ALIF surgeries had the lowest mean blood loss and the shortest surgical time followed by CAPF and PLIF. Even though our results contain a mix of 1- and 2-level surgeries, in comparison to other studies these values are low [26,41,51,53,54]. We found an earlier patient data review that advocated the use of systemic hypotension intraoperatively to reduce blood loss by nearly half; it is therefore now used by us in virtually every surgery [57]. Surgical times are easily affected by the presence of scar tissue, existing instrumentation, presence of a fusion mass, etc. In our FBSS groups, only 9% of the PLIF and 10% of the ALIF prior interventions had been PLIF or PLF, whereas in the Brantigan report [51] for example, fully 27% of the patients had failed prior fusions. Forty-five percent of the patients included in the Ray study had prior

surgeries including PLF, but the proportion of these was not mentioned.

While the radiographic determination of fusion remains controversial, the use of flexion–extension radiographs is still the most common method. Four published studies utilized these to determine the fusion status of their patients. As one of the criteria for fusion, two specified no intersegmental motion [41,55], while one allowed up to 2° arc of motion [54] and another up to 7° arc of motion [42]. Because these devices rely on restoring annular tension for stability, we wonder if this tension has the ability to mask an asymptomatic pseudarthrosis. Likewise, the presence of posterolateral instrumentation in our PLIF and CAPF groups reduces the possibility of observing any motion due to underlying pseudarthrosis in these patients. Instead, the inherent radiolucency of the cages permits radiographic fusion assessment without the need for flexion–extension radiographs. In the present series, we had no bony non-unions. However, we recognize the lack of independent review of the imaging data to be a relative limitation of the current report.

The percentage of patients with good or excellent Prolo or modified Prolo outcomes from the above-described studies range from 38% [54] to 80% [51,55]. We did not, a priori, define an index by which 'clinical success' could be assessed. Rather we analyzed the mean determinations for each of the six endpoints and found that all were statistically improved at the first postoperative follow-up. The decrease in mean back pain score from 3.5 to 2.9 between the immediate and 6-month postoperative timepoints for the PLIF FBSS patients was dismaying at first. We believe this is because at the immediate postoperative follow-up, patients are still restricted in their activities. By 6 months, they have become more active, and partly because of this their back pain was more prominent. Because the decreased mean score is equivalent to the presence of mild back pain, and this score represents a full 2-point improvement compared to the mean preoperative, we believe it to be an indicator of successful outcome for this patient population. The preoperative leg pain for the PLIF group, regardless of indication, was significantly worse than for those patients treated by an anterior approach. It is our philosophy to reserve PLIF and/or CAPF surgery for those patients suffering a circumferential stenosis (i.e., disc collapse with posterior element degeneration). These patients, therefore, present with more severe leg pain in addition to their back pain than patients for whom an ALIF procedure was chosen. We find that the determining factor in choosing between PLIF and CAPF lies with surgeon training. PLIF requires passage across the canal and manipulation of neural structures, while CAPF requires manipulation of vascular structures. The surgeon's comfort level with either of these will most often dictate the approach used.

The comparison of complication rates is notoriously difficult. Even in these few reviewed papers, if complications were clearly reported at all, they could be found grouped as intraoperative, early and late postoperative, major and minor, and device- and non-device-related. We have, therefore, attempted to find the most commonly occurring complications. All but one PLIF study reported the incidence of intraoperative dural tears. In our DDD and FBSS groups, there was a 3% and a 19% incidence rate which mirrors the 2.8% [46], 4.5% [55], 5.5% [56] 10.1% [42] and 18.5% (excluding a 3% reoperation rate to repair dural tears) [51] rates given in the other studies. Dural tears are more common and difficult to repair in revision surgeries [58], and so it is not surprising that in both the Brantigan study [51] and ours, similar rates were found. Importantly, all tears were repaired without consequence during the time of the operation.

The risks associated with anterior spinal surgery have been reported as great vessel injury [33], retrograde ejaculation with sterility in men [16,19] and low intersegmental bony fusion rate [14,16,19,59]. We found none of these phenomena to occur in either our DDD or FBSS group, although the first two of these were noted in two other reviews [26,42]. We reported the intraoperative repositioning of an implant as an operative complication and found an intraoperative repositioning rate of 2.7% and 3.6% in the DDD and FBSS groups, respectively, though all were without long-term clinical significance.

In our series, reintervention was required in 24.6% of the PLIF FBSS, 1.9% of the ALIF FBSS, 0% of the CAPF DDD, 2.9% of the ALIF DDD and 16.3% of the PLIF DDD. The high reoperation rate in the PLIF series was predominantly due to routine removal of hardware.

Eliminating these cases, the PLIF DDD reintervention rate was 4.1%, and the PLIF FBSS was 3.5%. In the cases of hardware-induced pain requiring implant removal, this was primarily in thin patients who complained of discomfort. Excluding those studies in which reoperations occurred only for pseudarthrosis (which were 24% [54] and 54%

[53], respectively), and the reoperation for routine removal of hardware, the rate of reoperation ranged from 0.01% [55] to 9.9% [51]. Most of these reports, including our results, were for repositioning of implants or for surgery on an additional level.

Finally, in comparing patient-rated satisfaction, we found 98.3% and 94.5% of the patients felt that their outcome was either good or improved in the DDD and FBSS groups, respectively (Table 3). Patient satisfaction rates in the other studies ranged from 66% [46] to 89% [53].

## 5. CONCLUSIONS

There are a few limitations associated with this report. First, while one of the advantages of the GII cages is its lordotic shape, we cannot absolutely confirm that their use improves postoperative sagittal balance, as no non-wedge-shaped cages were reported in this study. In addition, we are not providing comparisons with conventional (non-cage) approaches to intersegmental spinal fusion. A 1-year follow-up may be considered short by some readers, but our results at the 2-year follow-up coincide with those at 1 year. Analyses are in progress to determine if there is statistical validation to this observation. Finally, in all cases the radiographic determination of fusion was made by the operating surgeon, not by an independent radiologist. We recognize this as a potential weakness in this analysis. In our defense, considering the number of participating surgeons and their respective geographic locations, coordinating data flow to a single independent reviewer or reviewer group would be most cumbersome. Submission of patient data for inclusion in this database is done in an independent and voluntary manner. On the other hand, the finding of an obvious radiolucency within or surrounding the cage greatly simplifies the assessment of fusion status — there is no artifact and for this reason, the presence or absence of bony trabeculations is clearly visible. Regardless of this, we are in the process of database queries to find a patient subset small enough so that independent radiographic review can be realistically and accurately arranged.

In conclusion, we feel that interbody spinal fusion can be very beneficial for the treatment of DDD and FBSS, but the patients and the procedure must be critically selectively chosen. There must be a correlation between the patient complaint and the clinical, radiographic and neurologic findings before a good surgical outcome can begin to be expected. Only patients with severe DDD are candidates for interbody fusion. In this regard, the presence of instability, the need to correct a spinal deformity (e.g., spondylolisthesis, kyphosis), the presence of multi-segmental spinal degenerative disease or any combination of these are also indications for interbody fusion. ALIF is a good alternative to either CAPF or PLIF when the pathology is anterior central spinal canal stenosis resulting primarily in back with secondary mild leg pain. The decision to use CAPF or PLIF resides with surgeon confidence either in entering the spinal canal and manipulating neural structures or in manipulating vascular structures from an anterior approach. Above all, the primary desire and ultimate goal is to treat the pathology where it occurs.

## REFERENCES


1. Capener N. Spondylolisthesis. Br J Surg, 1932; 19: 374–386.
2. Lane LE, Moore ES. Transperitoneal approach to the intervertebral disc in the lumbar area. Ann Surg, 1948; 127: 537–551.
3. Briggs H, Milligan PR. Chip fusion of the low back following exploration of the spinal canal. J Bone Joint Surg, 1944; 27(1): 125–130.
4. Cloward RB. The treatment of ruptured lumbar intervertebral discs by vertebral body fusion. J Neurosurg, 1953; 10: 154–168.
5. Jaslow IA. Intercorporal bone graft in spinal fusion after disc removal. Surg Gynecol Obstet, 1946; 82: 215–218.
6. Hutter CG. Spinal stenosis and posterior lumbar interbody fusion. Clin Orthop, 1985; 193: 103–114.
7. Takeda M. Experience in posterior lumbar interbody fusion: unicortical versus bicortical autologous grafts. Clin Orthop, 1985; 193: 120–126.
8. Lin P. A technical modification of Cloward's posterior lumbar interbody fusion. Neurosurgery, 1977; 1(1): 118–124.
9. Lin PM, Cautilli RA, Joyce MF. Posterior lumbar interbody fusion. Clin Orthop, 1983; 180: 154–168.
10. Crock HV. Anterior lumbar interbody fusion, indications for its use and notes on surgical technique. Clin Orthop, 1982; 165: 157–163.
11. Wiltberger BR. The dowel intervertebral-body fusion as used in lumber-disc surgery. J Bone Joint Surg, 1957; 39A(2): 284–292.
12. Wiltberger BR. Intervertebral body fusion by the use of posterior bone dowel. Clin Orthop, 1964; 35: 69–79.
13. Kozak JA, Heilman AE, O'Brien JP. Anterior lumbar fusion options. Clin Orthop, 1994; 300: 45–51.
14. Calundruccio RA, Benton BF. Anterior lumbar fusion. Clin Orthop, 1964; 35: 63–68.
15. Fujimaki A, Crock HV, Bedbrook GM. The results of 150 anterior lumbar interbody fusion operations performed by two surgeons in Australia. Clin Orthop, 1982; 165: 164–167.

[53], respectively), and the reoperation for routine removal of hardware, the rate of reoperation ranged from 0.01% [55] to 9.9% [51]. Most of these reports, including our results, were for repositioning of implants or for surgery on an additional level.

Finally, in comparing patient-rated satisfaction, we found 98.3% and 94.5% of the patients felt that their outcome was either good or improved in the DDD and FBSS groups, respectively (Table 3). Patient satisfaction rates in the other studies ranged from 66% [46] to 89% [53].

## 5. CONCLUSIONS

There are a few limitations associated with this report. First, while one of the advantages of the GII cages is its lordotic shape, we cannot absolutely confirm that their use improves postoperative sagittal balance, as no non-wedge-shaped cages were reported in this study. In addition, we are not providing comparisons with conventional (non-cage) approaches to intersegmental spinal fusion. A 1-year follow-up may be considered short by some readers, but our results at the 2-year follow-up coincide with those at 1 year. Analyses are in progress to determine if there is statistical validation to this observation. Finally, in all cases the radiographic determination of fusion was made by the operating surgeon, not by an independent radiologist. We recognize this as a potential weakness in this analysis. In our defense, considering the number of participating surgeons and their respective geographic locations, coordinating data flow to a single independent reviewer or reviewer group would be most cumbersome. Submission of patient data for inclusion in this database is done in an independent and voluntary manner. On the other hand, the finding of an obvious radiolucency within or surrounding the cage greatly simplifies the assessment of fusion status — there is no artifact and for this reason, the presence or absence of bony trabeculations is clearly visible. Regardless of this, we are in the process of database queries to find a patient subset small enough so that independent radiographic review can be realistically and accurately arranged.

In conclusion, we feel that interbody spinal fusion can be very beneficial for the treatment of DDD and FBSS, but the patients and the procedure must be critically selectively chosen. There must be a correlation between the patient complaint and the clinical, radiographic and neurologic findings before a good surgical outcome can begin to be expected. Only patients with severe DDD are candidates for interbody fusion. In this regard, the presence of instability, the need to correct a spinal deformity (e.g., spondylolisthesis, kyphosis), the presence of multi-segmental spinal degenerative disease or any combination of these are also indications for interbody fusion. ALIF is a good alternative to either CAPF or PLIF when the pathology is anterior central spinal canal stenosis resulting primarily in back with secondary mild leg pain. The decision to use CAPF or PLIF resides with surgeon confidence either in entering the spinal canal and manipulating neural structures or in manipulating vascular structures from an anterior approach. Above all, the primary desire and ultimate goal is to treat the pathology where it occurs.

## REFERENCES


1. Capener N. Spondylolisthesis. Br J Surg, 1932; 19: 374–386.
2. Lane LE, Moore ES. Transperitoneal approach to the intervertebral disc in the lumbar area. Ann Surg, 1948; 127: 537–551.
3. Briggs H, Milligan PR. Chip fusion of the low back following exploration of the spinal canal. J Bone Joint Surg, 1944; 27(1): 125–130.
4. Cloward RB. The treatment of ruptured lumbar intervertebral discs by vertebral body fusion. J Neurosurg, 1953; 10: 154–168.
5. Jaslow IA. Intercorporal bone graft in spinal fusion after disc removal. Surg Gynecol Obstet, 1946; 82: 215–218.
6. Hutter CG. Spinal stenosis and posterior lumbar interbody fusion. Clin Orthop, 1985; 193: 103–114.
7. Takeda M. Experience in posterior lumbar interbody fusion: unicortical versus bicortical autologous grafts. Clin Orthop, 1985; 193: 120–126.
8. Lin P. A technical modification of Cloward's posterior lumbar interbody fusion. Neurosurgery, 1977; 1(1): 118–124.
9. Lin PM, Cautilli RA, Joyce MF. Posterior lumbar interbody fusion. Clin Orthop, 1983; 180: 154–168.
10. Crock HV. Anterior lumbar interbody fusion, indications for its use and notes on surgical technique. Clin Orthop, 1982; 165: 157–163.
11. Wiltberger BR. The dowel intervertebral-body fusion as used in lumber-disc surgery. J Bone Joint Surg, 1957; 39A(2): 284–292.
12. Wiltberger BR. Intervertebral body fusion by the use of posterior bone dowel. Clin Orthop, 1964; 35: 69–79.
13. Kozak JA, Heilman AE, O'Brien JP. Anterior lumbar fusion options. Clin Orthop, 1994; 300: 45–51.
14. Calundruccio RA, Benton BF. Anterior lumbar fusion. Clin Orthop, 1964; 35: 63–68.
15. Fujimaki A, Crock HV, Bedbrook GM. The results of 150 anterior lumbar interbody fusion operations performed by two surgeons in Australia. Clin Orthop, 1982; 165: 164–167.

16. Stauffer RN, Coventry MB. Anterior lumbar interbody fusion. J Bone Joint Surg, 1972; 56A: 756–767.
17. Inoue IS, Watanabe T, Hirose A, et al. Anterior discectomy and interbody fusion for lumbar disc herniation. Clin Orthop, 1984; 183: 22–31.
18. Chow SP, Leong JCY, Ma A, Yau ACMC. Anterior spinal fusion for deranged lumbar intervertebral disc. Spine, 1980; 5: 452–458.
19. Wetzel FT, LaRocca H. The failed posterior lumbar interbody fusion. Spine, 1991; 16(7): 839–845.
20. Flynn JC, Hogue MA. Anterior fusion of the lumbar spine end-result study with long-term follow-up. J Bone Joint Surg, 1979; 61A: 1143–1150.
21. Evans JH, Eng B. Biomechanics of lumbar fusion. Clin Orthop, 1985; 193: 38–46.
22. White AA, Panjabi MM. Biomechanical considerations in the surgical management of the spine. In: Clinical Biomechanics of the Spine. Lippincott, Philadelphia, PA, 1990; Chapter 8.
23. Larson S. Biomechanical principles of lumbar stabilization procedure. In: Lin PM (Ed), Posterior Lumbar Interbody Fusion. Thomas, Springfield, IL, 1982; 72–81.
24. Cautilli RA. Theoretical superiority of posterior lumbar interbody fusion. In: Lin PM (Ed), Posterior Lumbar Interbody Fusion. Thomas, Springfield, IL, 1982; 82–93.
25. Rish BL. A critique of posterior lumbar interbody fusion: 12 years' experience with 250 patients. Surg Neurol, 1989; 31: 281–289.
26. Liljinqvist U, O'Brien JP, Renton P. Simultaneous combined anterior and posterior lumbar fusion with femoral cortical allograft. Eur Spine J, 1998; 7: 125–131.
27. Kumar A, Kozak JA, Doherty BJ, Dickson JH. Interspace distraction and graft subsidence after anterior lumbar interbody fusion with femoral strut allograft. Spine, 1993; 18(16): 2393–2400.
28. Kozak JA, Heilman AE, O'Brien JP. Anterior lumbar fusion options. Technique and graft materials. Clin Orthop, 1994; 300: 45–51.
29. Freebody D, Bendall R, Taylor RD. Anterior transperitoneal lumbar fusion. J Bone Joint Surg, 1971; 53B(4): 617–627.
30. Van Rens JG, Van Horn JR. Long term results in lumbosacral interbody fusion for spondylolisthesis. Acta Orthop Scan, 1982; 53: 383–392.
31. Tiusanen H, Seitsalo S, Osterman K, Soini J. Anterior interbody lumbar fusion in severe low back pain. Clin Orthop, 1996; 234: 153–163.
32. Penta M, Fraser RD. Anterior lumbar interbody fusion. a minimum 10-year follow-up. Spine, 1997; 22(20): 2429–2434.
33. Crock HV. Anterior lumbar interbody fusion — indications of its use and notes on the surgical technique. Clin Orthop, 1982; 165: 157–163.
34. Burchardt H. The biology of bone graft repair. Clin Orthop, 1983; 174: 28–42.
35. Prolo DJ, Oklund SA. Bone healing and grafting in spinal surgery. In: Hitchon PW (Ed), Techniques in Spinal Fusion and Stabilization. Thieme Medical Publishers, New York, NY, 1995, pp. 72–78.
36. Banwart JC, Asher MA, Hassanein RS. Iliac crest bone graft harvest donor site morbidity. A statistical evaluation. Spine, 1995; 20: 1055–1060.
37. Kurz LT, Herkowitz HN. Complications of bone graft harvest. Sem Spine Surg, 1993; 5(2): 145–152.
38. Brantigan JW, Cunningham BW, Warden KE. Compression strength of donor bone for posterior lumbar interbody fusion. Spine, 1993; 18(9): 1213–1221.
39. Goldberg VM, Stevenson S. Natural history of autografts and allografts. Clin Orthop, 1987; 225: 7–16.
40. Dennis S, Watkins R, Landaker S, Dillin W, Springer D. Comparison of disc space heights after anterior lumbar interbody fusion. Spine, 1989; 14(8): 876–878.
41. Ray CD. Threaded titanium cages for lumbar interbody fusions. Spine, 1997; 22(6): 667–680.
42. Kuslich SD, Ulstrom CL, Griffith SL, Ahern JW, Dowdle JD. The Bagby and Kuslich method of lumbar interbody fusion. Spine, 1998; 23(11): 1267–1279.
43. DeBowes RM, Grant BD, Bagby GW, Gallina AM, Sande RD, Ratzlaff MH. Cervical vertebral interbody fusion in the horse: a comparative study of bovine xenografts and autografts supported by stainless steel baskets. Am J Vet Res, 1984; 45(1): 191–199.
44. Ray CD. Threaded fusion cage: new technique for lumbar interbody fusions. In: Proceedings of the Annual Meeting of the North American Spine Society, Quebec City, Quebec, June 29, 1989.
45. Brantigan JW, Steffee AD. A carbon fiber implant to aid interbody lumbar fusion. Two-year clinical results in the first 26 patients. Spine, 1993; 18(14): 2106–2117.
46. Agazzi S, Reverdin A, May D. Posterior lumbar interbody fusion with cages: an independent review of 71 cases. J Neurosurg, 1999; 91: 186–192.
47. McMillin C. Biocompatibility testing of PEKEKK. 2nd International SAMPE Technical Conference, November 6–8, 1990.
48. Sigot-Luizard MF. Biological evaluation of the Osta-Pek (Carbon-PEKEKK) composite used in spinal surgery. Rachis, 2000; 12(1): 1–8.
49. Sigot-Luizard MF. The biocompatibility of the Osta-Pek intervertebral disc cage. Riv Neuroradiol, 1999; 12 (Suppl 1): 99–101.
50. McAfee PC. Interbody fusion cages in reconstructive operations on the spine. J Bone Joint Surg (Am), 1999; 81A(6): 859–880.
51. Brantigan JW, Steffee AD, Lewis ML, Quinn LM, Persenaire JM. Lumbar interbody fusion using the Brantigan I/F cage for posterior lumbar interbody fusion and the variable pedicle screw placement system. Spine, 2000; 25(11): 1437–1446.
52. Tullberg T, Brandt B, Rydberg J, Fritzell P. Fusion rate after posterior lumbar interbody fusion with carbon fiber implant: 1-year follow-up of 51 patients. Eur Spine J, 1996; 5: 178–182.
53. Hacker RJ. Comparison of interbody fusion approaches for disabling low back pain. Spine, 1997; 22(6): 660–666.
54. Pavlov PW, Spruit M, Havinga M, Anderson PG, van Limbeek J, Jacobs WC. Anterior lumbar interbody fusion with threaded fusion cages and autologous bone grafts. Eur Spine J, 2000; 9: 224–229.
55. Matgé G, Leclercq TA. Rationale for interbody fusion with titanium threaded cages at the cervical and lumbar levels. Acta Neurochir, 2000; 142: 425–434.
56. Ray CD. Threaded titanium cages for lumbar interbody fusions. Spine, 1997; 22(6): 681–685.

57. Elsig JP, Uehlinger K, Bisserie M, Laloux E, Commarmond J, Warden K. PLIF with composite cages: outcome in 205 patients. 2me Journées Internationales R. Roy Camille du Rachis. Paris, January 28–30, 1998.
58. Amory DW, DeWald RL. Revision spinal surgery — an overview. In: Margulies JY (Ed), Revision Spine Surgery 37. Mosby, St Louis, MO, 1999; 12–37.
59. Batchelor JS. Anterior interbody spinal fusion. Guy's Hosp Rep, 1963; 112: 61–65.