Clinical Outcomes of Lumbar Degenerative Disc Disease Treated With Posterior Lumbar Interbody Fusion Allograft Spacer: A Prospective, Multicenter Trial With 2-Year Follow-Up

Paul M. Arnold, MD, Stephen Robbins, MD, Wayne Paullus, MD, Stephen Faust, MD, Richard Holt, MD, and Robert McGuire, MD

Abstract

The clinical benefits and complications of posterior lumbar interbody fusion (PLIF) have been studied over the past 60 years. In recent years, spine surgeons have had the option of treating low back pain caused by degenerative disc disease using PLIF with machined allograft spacers and posterior pedicle fixation.

The purpose of this clinical series was to assess the clinical benefits of using a machined PLIF allograft spacer and posterior pedicle fixation to treat degenerative disc disease, both in terms of fusion rates and patient outcomes, and to compare these results with those in previous studies using autograft and metal interbody fusion devices. Results were also compared with results from studies using transverse process fusion.

This prospective, nonrandomized clinical series was conducted at 10 US medical centers. Eighty-nine (55 male, 34 female) patients underwent PLIF with a presized, machined allograft spacer and posterior pedicle fixation between January 2000 and April 2003. Their outcomes were compared with outcomes in previous series described in the literature.

All patients had experienced at least 6 months of low back pain that had been unresponsive to nonsurgical treatment. Physical examinations were performed before surgery, after surgery, and at 4 follow-up visits (6 weeks, 6 months, 12 months, 24 months).

At each interval, we obtained radiographs and patient outcome measures, including SF-36 Bodily Pain Score, visual analog scale pain rating, and Oswestry Disability Index. The primary outcome was fusion results at 12 and 24 months; the secondary outcomes were pain, disability, function/quality of life, and satisfaction.

One-level PLIFs were performed in 65 patients, and 2-level PLIFs in 24 patients. Flexion-extension radiographs at 12 and 24 months revealed a 98% fusion rate. Of the 72 patients who reached the 12-month follow-up, 86% reported decreased pain and disability as measured with the Oswestry Disability Index. Decreased pain as measured with the SF-36 Bodily Pain Score was reported by 74% of patients who reached the 12-month follow-up. The graft-related complication rate among all patients who underwent PLIF was 1.61%.

When performed with machined allograft spacers and posterior pedicle fixation, PLIF is a safe and effective surgical treatment for low back pain caused by degenerative disc disease. The patients in this clinical series had outcomes equal or superior to the outcomes in previous series.

Dr. Arnold is Director of Spinal Cord Injury Center and Professor of Neurosurgery, Department of Neurosurgery, University of Kansas Medical Center, Kansas City, Kansas.

Dr. Robbins is Department Chair of Orthopedics, Columbia St. Mary's Hospital, Columbia Campus, Milwaukee, Wisconsin; and Physician, Milwaukee Spinal Specialists, Milwaukee, Wisconsin.

Dr. Paullus is Clinical Associate Professor, Department of Neurosurgery, Texas Tech University, Amarillo, Texas; and Physician, Southwest Neuroscience, Amarillo, Texas.

Dr. Faust is Chair of Surgery, Anne Arundel Medical Center, Annapolis, Maryland; and Co-Director, Orthopaedic and Sports Medicine Center, Annapolis, Maryland.

Dr. Holt is an Orthopedic Surgeon, Spine Surgery PSC, Louisville, Kentucky.

Dr. McGuire is Professor and Chairman, Department of Orthopedic Surgery, University of Mississippi Medical Center, Jackson, Mississippi.

Address correspondence to: Paul M. Arnold, MD, Department of Neurosurgery, 3901 Rainbow Blvd, MS-3021, University of Kansas Medical Center, Kansas City, KS 66160 (tel, 913-588-7587; fax, 913-588-7596; e-mail, parnold@kumc.edu).

Am J Orthop. 2009;38(7):E115-E122.

Posterior lumbar interbody fusion (PLIF), originally described by Cloward[1] 60 years ago, has grown in popularity and is now a commonly performed procedure for degenerative low back pain. The surgical approach, originally advocated by Cloward and later modified by Lin[2] and others, is now well known to spine surgeons.

Over the past 25 years, surgical treatment for low back pain has rapidly evolved from uninstrumented fusions with varying results.[3] The advent of transpedicular fixation revolutionized spine surgery, allowing rigid fixation and enhancing the likelihood that fusion will occur.[3-40]

Previously, lumbar fusions were performed using the intertransverse technique, necessitating wide exposure and possible use of iliac crest graft.[3-6] Recent technologic advances in cage technology, instrumentation, and

Table I. Patient Characteristics at Baseline (N = 72)

Characteristic	n
Mean Age	
45 years	
Sex	
Male	38
Female	34
Preoperative Diagnosis	
Disc failure or prolapse	53
Osteophytic spondylosis	21
Facet hypertrophy osteoarthritis	24
Congenital spinal stenosis	2
Spondylolysis	10
Spondylolisthesis, par defect	16
Spondylolisthesis, degenerative	8
Degenerative scoliosis	3
Trauma-induced instability	3
No. Levels Fused	
1	52
2	20
Body Mass Index	
Underweight	0
Healthy	17
Overweight	31
Obese	24
Employment	
Office job	17
Service job	11
Manual labor	8
Homemaker	3
Unemployed	5
Student	0
Retired	8
Temporary medical disability	20
Smoking Status	
Past smoker	25
Current smoker	24
Never smoked	23
Legal Action	
Current	9
Past	2
None	61
Disability Compensation	
Unemployment compensation	4
Worker's compensation	10
Social Security disability	4
Private disability	12

bone biology have widened the scope of fusion options, allowing the surgeon a variety of interbody devices and surgical methods to access the disc space, provide anterior column support, secure rigid fixation, and achieve solid fusion.[7-24,30,32-34] All these goals can be achieved through the well-known posterior approach.

Despite initial enthusiasm for use of threaded interbody cages, long-term fusion rates are not as high as initially reported.[7-10] Cage placement often requires total or nearly total facet removal for adequate access to the disc space.[11,12] The metal of the cage limits surface area for bone-to-bone contact and makes radiographic fusion assessment difficult. Revision surgery is often difficult.[7,13,14]

Because of these drawbacks, surgeons looked for other surgical means of treating back pain. Earlier use of allograft bone required time-consuming carpentry by the surgeon. Use of machined allograft is an alternative to threaded fusion cages, as well as nonmachined allograft or autograft. Machined allograft spacers often require less bone removal for insertion and allow surgeons to visualize bone incorporation with standard radiographic techniques.

Bone can be impacted to allow restoration of disc space height and provide anterior column support. Iliac crest grafting, with its potential complications, is not required. The machined allograft can be supplemented with bone removed during decompression, which can be placed in either the interbody or intertransverse space. A successful biological cage needs to both address the lordosis of the lumbar spine and provide stability to the spine. The quality of the bone graft, both biologically and as a load-bearing device, is crucial in achieving solid fusion.[15,16]

The PLIF biological cage, used since January 1999, is an innovative lumbar interbody allograft, harvested and processed by the Musculoskeletal Transplant Foundation (MTF, Edison, NJ) and designed and available through Synthes Spine (West Chester, Pa). The PLIF spacer is a contoured, wedge-shaped machined cortical allograft that comes in 6 anterior heights (in 2-mm increments) for precise fit of the disc space of each patient. The 6 sizes permit preservation of the facets and minimal nerve root retraction. The sawtooth pattern on the superior and inferior surfaces grips the adjacent vertebrae, thereby minimizing migration and increasing the stability of the spacer and its resistance to pullout (Figures 1-3).[15,16]

We present our experience with machined allograft PLIF spacers and pedicle fixation in the treatment of degenerative low back pain and compare our study data with the data of controls from the literature.

Methods

Eighty-nine (55 male, 34 female) patients underwent PLIF with machined allograft spacers and pedicle fixation. The study protocol was reviewed and approved by the institutional review board of each participating center. This was a prospective, multicenter study of treatment for 1- and 2-level degenerative disc disease between L2 and S1. In each case, the PLIF spacers (2 per level) were used with posterior instrumentation. At the discretion of the surgeon, autograft material, with or without allograft extender, may have been impacted around and between the PLIF spacers. All material implanted was documented.

For each patient, a history was obtained and a physical examination was performed. Imaging included T_2-weighted magnetic resonance imaging (MRI) and anteroposterior (AP) and lateral radiography. Whether to perform discography, myelography/computed tomography (CT), or both was decided by the surgeon on the basis of the results of other diagnostic studies. Preoperative flexion-extension (F-E) radiographs were not used, as has been the case in

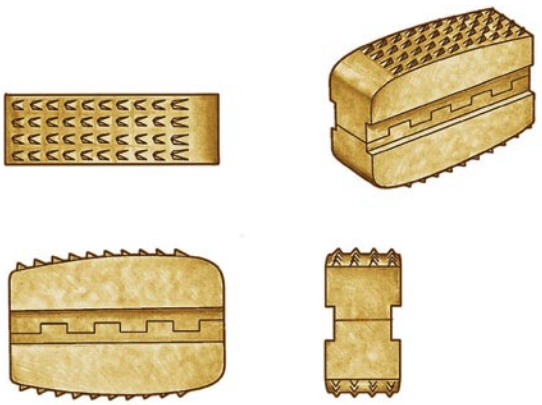

Figure 1. Multiple views of posterior lumbar interbody fusion allograft spacer.

many studies.[17-23] AP, lateral, and F-E radiographs were obtained 6, 12, and 24 months after surgery. Demographic data collected included Spinal Outcomes Lumbar–History and Demographics (SOL–HD), SF-36 Bodily Pain Score (SF-36 BPS), visual analog scale (VAS) pain rating, and Oswestry Disability Index (ODI). Employment status, smoking history, and litigation status were also tabulated (Table I).

Inclusion Criteria

All patients were skeletally mature and at least 18 years old and had undergone at least 6 months of nonsurgical treatment for back pain, functional deficit, or neurologic deficit. Each patient had 1 or 2 consecutive levels of degenerative disc disease between L2 and S1, defined by recurrent disc herniation, positive discogram with negative controls, or Modic type 2 endplate changes on T_2-weighted MRI[41,42] (Table II).

Exclusion Criteria

A patient was excluded from the study for having disease at more than 2 levels, previous fusion at the involved level, more than 2 previous open lumbar procedures, lumbar scoliosis of more than 20°, and grade II or higher spondylolisthesis.

Treatment

All patients meeting the inclusion criteria underwent PLIF with placement of 2 machined allograft spacers (at each symptomatic level) and pedicle fixation.

The PLIF spacer (Figures 1-3) is a contoured, wedge-shaped allograft with a sawtooth pattern on the superior and inferior surfaces. It is available in 6 anterior heights, from 7 to 17 mm, in 2-mm increments.

Intraoperative radiograph or fluoroscopy was used to determine the correct level. A bilateral discectomy was performed, and the endplates were prepared for spacer insertion. Distractors were used to open the disc space, and trial sizer implants were used to ensure appropriate graft size. Autograft from the decompression was packed into the disc space before spacer placement. Iliac crest graft was not used. Fluoroscopy was used to assess graft placement. Pedicle screws could be placed before or after graft placement, and the construct was loaded in compression (Figure 4). The wound was then closed in standard fashion. No patient received recombinant human bone morphogenetic protein (rhBMP), osteogenic protein 1, or other bone graft enhancers.

Patients were evaluated before, during, and after surgery and at 4 follow-up visits (6 weeks, 6 months, 12 months, 24 months). Plain radiographs were obtained at each visit. SF-36 BPS, VAS, and ODI were collected before surgery and at the 6-, 12-, and 24-month visits (Table III).

Table II. Inclusion and Exclusion Criteria

Inclusion Criteria (All)

- 1- or 2-level (consecutive) degenerative disc disease between L2 and S1, defined as at least 1 of the following: recurrent disc herniation; positive discogram with negative controls; Modic type 2 endplate changes on T_2-weighted magnetic resonance imaging
- Pain, functional deficit, or neurologic deficit for 6 months (minimum) preceding enrollment
- No response to nonoperative treatment modalities for 6 months (minimum) preceding enrollment
- Skeletally mature; age, 18 years or older
- Signed approved informed-consent document
- Available for long-term follow-up and interval visits

Exclusion Criteria (Any)

- >2 levels to be instrumented
- Spondylolysthesis above grade 1 at either or both levels to be instrumented
- Scoliosis >20° in lumbar region
- Previous fusion attempt at involved level(s)
- >2 previous open, posterior, lumbar spine surgical procedures at involved levels(s)
- Now implanted with anterior or posterior instrumentation at involved level(s)
- Previously documented osteopenia or osteomalacia
- Active localized or systemic infection
- Disease entity or condition precluding possibility of bony fusion
- Had immunosuppressive disorder
- Pregnant, mentally incompetent, or prisoner
- Known sensitivity to device materials
- Now being treated with other investigational devices for same disorder

Table III. Data Collection Schedule

	Preoperative	Intraoperative	Postoperative	6 Weeks	6 Months	12 Months
Follow-up tolerance	*Within 3 months before surgery*	*Before patient stands*	*Before discharge*	*1 week*	*2 weeks*	*4 weeks*
Imaging						
T_2-weighted MRI	X					
Any imaging		X				
Straight lateral	X		X	X	X	X
Straight anteroposterior	X		X	X	X	X
Lateral extension					X	X
Lateral flexion					X	X
Data Forms						
Physician	Diagnostic	Treatment		Evaluation	Evaluation	Evaluation
Patient	SOL-HD (history & demographic data)				SF-36 BPS	SF-36 BPS
	SF-36 BPS				SOL-20	SOL-20
	SOL-20					
	ODI				ODI	ODI

Abbreviations: MRI, magnetic resonance imaging; SOL–HD, Spinal Outcomes Lumbar–History and Demographics; SF-36 BPS, SF-36 Bodily Pain Score; SOL–20, Spinal Outcomes Lumbar–20; ODI, Oswestry Disability Index.

Radiographic Evaluation

At 6, 12, and 24 months, each patient had AP, lateral, and F-E radiographs taken and occurrence of stable fusion assessed. Fusion parameters included but were not limited to the following: less than 12% anterior/posterior translation on F-E radiographs, less than 5° rotation (Cobb angle) between F-E radiographs, and maintenance of disc height from 6 to 12 and 24 months, plus radiographic evidence of bridging trabecular bone. These criteria are similar to those used by other authors.[17-20] Radiographs were reviewed independently by 2 radiologists. When the radiologists disagreed, another radiologist helped make a final determination. For 2-level fusion to be deemed successful, both levels had to meet the fusion criteria.

Clinical Outcome Measures

Four parameters were used to determine clinical outcome: diagnostic data, function/quality of life, pain, and satisfaction. The control group consisted of comparable patients from other studies.[3,4,7-9,12,13,20-23,25,34,39]

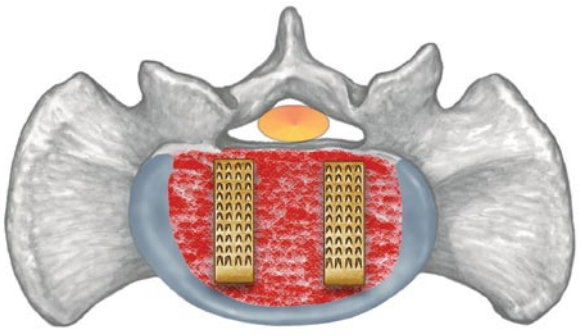

Figure 2. Schematic view shows placement of 2 posterior lumbar interbody fusion allograft spacers in interbody space.

Diagnostic data included verification of inclusion and exclusion criteria, diagnosis, and patient demographics. Function/quality of life was measured with Spinal Outcomes Lumbar–20 (SOL–20), SF-36 BPS, and ODI. Neurologic function was evaluated in terms of sensory, motor, and reflex function at each postoperative visit. Pain in the back and legs was evaluated with VAS. Satisfaction was assessed with questionnaires at 6, 12, and 24 months.

Statistical Analysis

Logistic regression statistical analysis was used to evaluate outcomes.

Results

Eighty-nine patients enrolled in the study. Of those, 72 (81%) completed the 12-month follow-up visit, and 68 (76%) completed the 24-month visit.

Fusion Outcomes

Of the 72 patients at 12-month follow-up, 52 had undergone 1-level fusions, and 20 had undergone 2-level fusions. The fusion rate at 12 months and 24 months was 98% of levels, as judged by an independent panel of radiologists using F-E radiographs and radiographic examination of trabecular bridging bone. In a 2-level procedure, both levels had to fuse for fusion to be considered successful.

At 12 months, 98% of levels had less than 12% anterior/posterior translation on flexion radiographs, and 98% of levels had less than 12% anterior/posterior translation on extension radiographs. Eighty-nine percent of patients had less than 5° of rotation (Cobb angle) between F-E radiographs. Maintenance of disc height from 6 to 12 months was demonstrated in 100% of patients.

At 24 months, 98% of levels had less than 12% anterior/posterior translation on flexion radiographs, and 98% of levels had less than 12% anterior/posterior translation

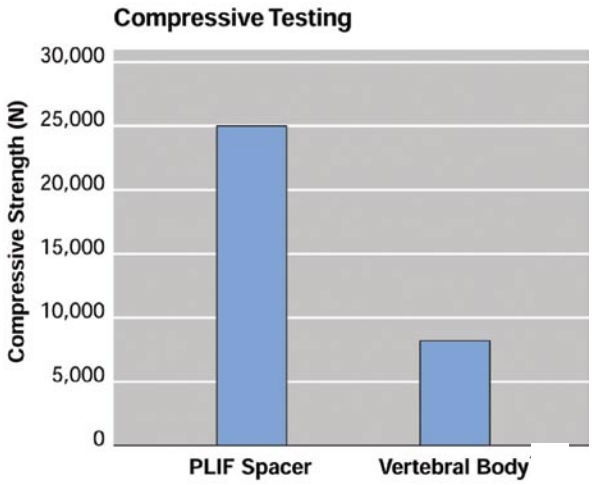

Figure 3. Graph shows compressive strength of posterior lumbar interbody fusion allograft spacer compared with the vertebral body.

on extension radiographs. Less than 5° of rotation between F-E radiographs was demonstrated at 75% of levels. These data are comparable with data from several other studies, all of which achieved fusion rates of 90% or higher. Although some patients in these studies received rhBMP,[18,19,21,40] many did not.[7,8,14,20,22,23]

Clinical Outcomes

Of the 72 patients at 12-month follow-up, 87.5% reported decreased pain and disability as measured with ODI, and 75.7% reported decreased pain as measured with SF-36 BPS.

Of the 68 patients at 24-month follow-up, 77.9% reported decreased pain and disability as measured with ODI, and 69.1% reported decreased pain as measured with SF-36 BPS.

At 12 months, 86.7% of patients noted that their pain was improved or much improved, and only 5% reported worse pain. At 24 months, 68% noted that their pain was improved or much improved, and only 3% reported worse pain. The remaining patients reported no change.

Higher education (college degree or higher), mild alcohol intake (<2 drinks per day), and middle age (40-60 years) correlated with positive surgical outcome. Negative predictors of success included tobacco use, more than 1 previous surgery, unresolved litigation (including worker's compensation issues), disability before surgery, low job satisfaction, and baseline poor health image.

Complications

Evaluation of the integrity of the construct was based on radiographic examination of the implants. A construct change that did not lead to an adverse effect on the patient or to surgical intervention was not considered a complication. A complication was (a) an adverse effect associated with a construct change or with loss of construct integrity or (b) a surgical intervention (including revision, removal with or without replacement, or revision or removal of supplemental fixation) necessitated by failure or movement of the implant or posterior supplemental fixation.

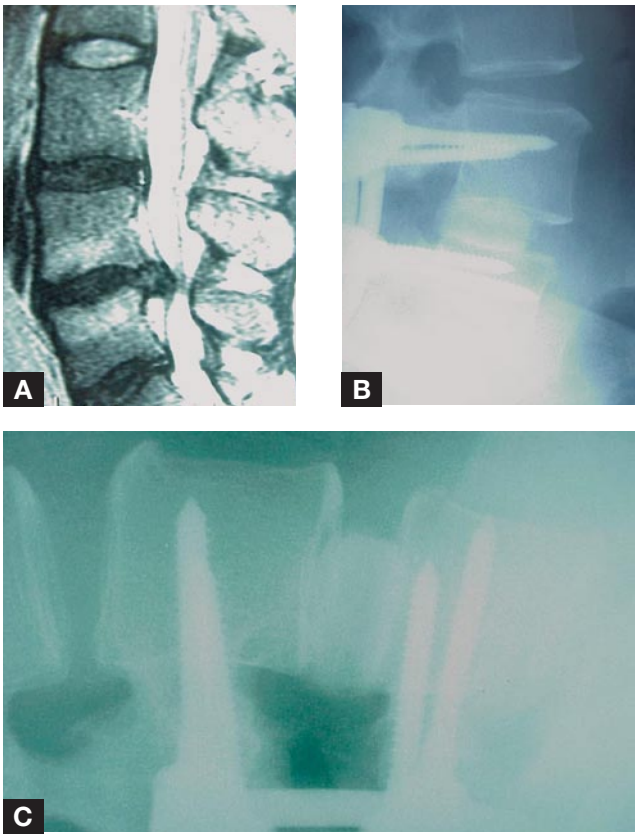

Figure 4. (A) A woman in her late 40s with 9-month history of back pain refractory to nonsurgical treatment. Magnetic resonance imaging shows herniated, degenerative L4–L5 disc with Modic changes in vertebral bodies. Discogram confirmed L4–L5 disc was only source of pain. (B) Patient underwent L4–L5 posterior lumbar interbody fusion. Back pain resolved. Lateral radiograph at 12 months shows solid interbody fusion. (C) Lateral radiograph at 24 months shows solid interbody fusion.

There were no neurologic complications. The graft-related complication rate at all levels undergoing PLIF was 1.61%. Three patients underwent reoperation. One patient required repositioning of bone grafts because of posterior migration 2 months after original surgery. One patient had cephalad extension of fusion plus decompression caused by stenosis above the level of original surgery. This procedure was performed 42 months after initial surgery. Nine patients had intraoperative dural tears, and 1 patient underwent surgery for repair of a pseudomeningocele. There were no cerebrospinal fluid leaks. Four patients had superficial wound infections, which resolved with local care and intravenous antibiotics.

Discussion

Surgical management of degenerative low back pain is perhaps the most controversial issue in spine surgery.[1-42] The large number of current techniques and approaches speaks to a lack of consensus on the subject. As no consensus exists on

optimal treatment for these patients, we chose to place them all in the treatment group and use historical controls.

Since spinal arthrodesis was first reported 90 years ago, various techniques have been developed for lumbar spine fusion.[22] The field has evolved from uninstrumented fusion to use of 1 or more of the following: allograft, autograft, metallic cages, carbon fiber cages, BMP, and supplemental instrumentation.[1-42]

In managing these patients, the spine surgeon faces several other issues, including approach (anterior, posterior, both), indications for the posterior approach, bone placement (interbody, intertransverse, interfacet, some combination), and 1- or 2-sided approach to disc space (PLIF or transforaminal lumbar interbody fusion [TLIF]).[24,25] These choices do not address the most important variable in a successful surgical outcome: which patients should undergo surgery, and which studies are best for making this determination.

Despite these shortcomings, lumbar fusion has been recommended in some patients who did not improve after an extended, multimodality trial of nonsurgical therapy.[22,26] Other common indications for fusion include symptomatic spinal stenosis with segmental instability, degenerative disc disease, spondylolisthesis, spondylolysis, and recurrent disc herniation.[24,27,37]

Rates of spinal fusion with bone graft alone have ranged from 46% to 90%.[3,22] Given the difficulty in achieving fusion and maintaining spinal alignment and position, spinal instrumentation has become an important and popular adjunct to bone grafting in lumbar arthrodesis surgery, further increasing fusion rates (80%-90%).[22,29]

The goal of lumbar interbody fusion (LIF) surgery is to achieve a solid, stable, load-sustaining arthrodesis of spinal segments while maintaining proper disc height and restoring sagittal plane alignment.[24,30] Maintaining intervertebral disc height is needed to achieve adequate decompression of existing neural structures while preserving foraminal dimensions.[30] Recently, interbody fusion techniques have also shown high fusion rates with distinct advantages.[22,31] Compared with posterolateral techniques, interbody fusion has several advantages, including immediate anterior column load sharing, large surface area for fusion, bone graft subjected to compressive loads (advantageous to achieving fusion), and ability to restore normal sagittal contour while indirectly decompressing the neuroforamen.[22]

The disc, which may be the pain source, can be almost completely removed. Intraoperative distraction of the disc space after discectomy allows placement of an appropriate-size spacer and restoration of disc height. Machined allograft can be shaped lordotically, and thus sagittal balance can be achieved. The graft is placed in the weight-bearing center of the spine, where 80% of axial load occurs. Pedicle screw fixation allows the graft to be loaded in compression, enhancing blood supply from adjacent endplates. Autogenous bone can be placed in the disc space before allograft placement. The machined allograft can be designed with ridges on its surface, diminishing the likelihood of graft migration. The posterior approach is well known to most spine surgeons. All these features of PLIF with machined allograft enhance the likelihood of successful fusion.[7-24,30,32-34]

In recent years, metal cages have been an option for instrumented interbody fusion procedures.[7-11] Threaded interbody fusion cages have become more popular in the management of degenerative pathologies of the lumbar spine[32] and have had good success rates.[9,23,33,34] Approximately 80,000 LIF cages have been implanted internationally over the past 5 years, with the United States accounting for 5,000 implants per month.[20,35]

These devices are biomechanically adequate for restoring disc height and allowing fusion. They can be inserted through the anterior or posterior approach, and several studies have documented their efficacy in achieving fusion and relieving back pain. However, their use has several potential risks. They may require supplemental fixation when placed anteriorly, and the use of iliac crest graft associated with anterior lumbar interbody fusion (ALIF) can potentially increase surgical morbidity. Posterior cage placement requires extensive bony removal and may require extensive neural retraction. If not placed properly, metallic cages may migrate, with the potential for increased pain and neurologic deficit. Revision surgery for metallic cages can be technically demanding, given their size and extensive scarring. The bone–metal interface may not allow sufficient bony contact for fusion.

Cage migration can be reduced by supplemental pedicle fixation, which markedly increases construct stiffness with respect to axial compression and F-E torque. Diminished bone-on-bone endplate contact can be overcome by designing threaded dowels out of bone rather than metal.

More recently, rhBMP has been used as an adjunct for lumbar fusion, in both the interbody space and the intertransverse space. This procedure has been associated with very high fusion rates, but the financial cost is higher than that of using autograft and allograft.[18,19,21,40]

Patient Selection

Patients in this study fulfilled extensive inclusion criteria. For all patients, nonsurgical therapy had failed for at least 6 months, and several patients had had low back pain for more than 1 year. Failed therapies included physical therapy, acupuncture, injection therapy, work hardening, chiropractic, and rehabilitation. Confirmatory diagnostic tests were required to correlate symptoms with anatomical abnormalities. These tests included MRI to evaluate Modic changes and/or recurrent disc herniation,[41,42] plain radiographs with F-E views to evaluate for spondylolisthesis and bone quality, myelography/CT to evaluate recurrent disc herniation, and discography to assess disc quality and pain reproducibility. Several demographic questionnaires were completed by each patient, and information on smoking history, employment status, and current or past litigation was collected. These inclusion criteria are similar to, and in some cases more rigorous than, criteria used in similar studies.

Follow-Up

In this study, 81% (72/89) of patients were available for 1-year follow-up, and 76% were available for 2-year follow-up. These percentages are somewhat lower than those in most studies but are equivalent to those in some other studies.

Fusion Outcomes

The fusion rate for our series was 98% at 12 and 24 months, as judged by an independent panel of radiologists. Criteria for fusion included less than 12% translation in the AP plane on F-E views and less than 5° of rotation between flexion and extension views. These findings compare favorably with findings in other large series.

Agazzi and colleagues[8] reported a 90% fusion rate in patients who underwent PLIF with impacted carbon cages and pedicle fixation. Mean follow-up was 28 months. Chitnavis and colleagues,[14] in a series of 50 patients who underwent PLIF with carbon fiber cages, found a 95% fusion rate at 2 years. All their patients had undergone previous discectomy. In both studies, autologous bone was placed in the cage. Lowe and colleagues[22] reported a radiographic fusion rate of 90% and an objective clinical good/excellent rate of 85%, which compared favorably with rates in previous studies using other fusion techniques. Several other studies have found fusion rates of more than 90%.[7(95% for PLIF patients),8,14,18-23] The earlier studies did not use BMP.

We used dynamic methods to assess fusion and visual examination to assess bony union. With this method, results can be measured mathematically, in contrast to examination of AP and lateral radiographs to grade fusion and assess the amount of trabecular bone. The latter method is notoriously unreliable, and the only completely accurate method of fusion assessment is by open operation.[36] The vast majority of studies reported in the literature uses similar methods to assess fusion.

Clinical Outcomes

To assess clinical success, we used several standard outcome instruments, including SF-36 BPS, VAS, and ODI. Measured outcomes included pain, satisfaction, disability, and function/quality of life. Of the 68 patients at 12-month follow-up, 87% reported decreased pain and disability as measured with ODI; the percentage was slightly lower, 79%, at 24 months. Forty percent of patients had a significant reduction (>20 points) at 12 months. On the SF-36 BPS, 76% reported decreased pain, which fell to 68% at 2 years. On this parameter, 46% had significant improvement (>20 points). At 12 months, 87% of patients noted that their pain was improved or much improved, and only 5% reported worse pain. At 2 years, 68% noted that their pain was improved or much improved, and only 3% reported worse pain. The remaining patients reported no change in pain since surgery.

There were several demographic predictors of success for the patients in this study. There was a positive correlation with education level and mild alcohol intake. Tobacco use and worker's compensation claims were neither positive nor negative predictors for fusion. These findings are somewhat in contrast to those in other studies. Not surprisingly, previous surgery, poor health image, manual labor job, and being unemployed were negative predictors of successful outcome. Our study was not randomized, and we compared our outcomes with those in other, similar series. Several other studies have used this method of comparison.[7,13-16,22,23]

Our findings compare favorably with those in other series with follow-ups of similar length. Lowe and colleagues[22] found an 80% success rate (good/excellent results according to pain and activities-of-daily-living scores) at 2-year follow-up in 40 patients who underwent TLIF. Agazzi and colleagues[8] reported a 67% satisfaction rate at 2 years in 71 patients who underwent PLIF with cages. At 1 year, Barnes and colleagues[7] noted 70% satisfactory outcomes in PLIF patients but only 38% satisfactory outcomes in ALIF patients. Chitnavis and colleagues[14] noted 66% good/excellent outcomes on the Prolo scale at 2 years,[37] and Rivet and colleagues[13] noted 73% good/excellent results at 1 year.

Complications

Patients in our series had a low complication rate. Three underwent repeat surgery: 1 each for pseudomeningocele, fusion extension, and graft repositioning. There were no neurologic complications. This low complication rate is in line with rates in other large series.[7-10,12,13,38,39]

Only 1 patient required bone graft repositioning. This surgery was performed 2 months after the original procedure. Use of pedicle screws has drastically reduced incidence of graft back-out in PLIF procedures and has increased rates of PLIF fusion and transverse process fusion. Benefits of pedicle screws include immediate stability, early rehabilitation, and restoration of sagittal alignment. Once grafts are placed, they can be loaded in compression with the pedicle screws, enhancing the likelihood of fusion.

For PLIF, the posterior approach has several advantages over the anterior approach. With the posterior approach, an anterior interbody graft can be placed, and critical vascular, abdominal, and urologic structures are avoided. In addition, the posterior approach is well known to practicing spine surgeons. Early mobilization and normal alignment can be achieved, and direct neural decompression can be performed.

Conclusions

Our study results show that PLIF can be safely performed and that excellent fusion and clinical results can be attained over a sustained period. The procedure can be performed with minimal complications. In carefully selected patients, PLIF with machined allograft and pedicle fixation is a safe, efficacious treatment for surgical management of degenerative low back pain.

Authors' Disclosure Statement

Dr. Robbins wishes to note that he is a member of the Medical Advisory Board for Pioneer Surgical Technology.

Dr. McGuire wishes to note that he is a consultant for Synthes Spine. The other authors report no actual or potential conflict of interest in relation to this article.

References

1. Cloward RB. The treatment of ruptured lumbar intervertebral discs by vertebral body fusion. I. Indications, operative technique, after care. *J Neurosurg*. 1953;10(2):154-168.
2. Lin PM. A technical modification of Cloward's posterior lumbar interbody fusion. *Neurosurgery*. 1977;1(2):118-124.
3. Herkowitz HN, Sidhu KS. Lumbar spine fusion in the treatment of degenerative conditions: current indications and recommendations. *J Am Acad Orthop Surg*. 1995;3(3):123-135.
4. Parker LM, Murrell SE, Boden SD, Horton WC. The outcome of posterolateral fusion in highly selective patients with discogenic low back pain. *Spine*. 1996;21(16):1909-1916.
5. Bridwell KH, Sedgewick TA, O'Brien MF, Lenke LG, Baldus C. The role of fusion and instrumentation in the treatment of degenerative spondylolisthesis with spinal stenosis. *J Spinal Disord*. 1993;6(6):461-472.
6. Brodsky AE, Kovalsky ES, Khalil MA. Correlation of radiologic assessment of lumbar spine fusions with surgical exploration. *Spine*. 1991;16(6 suppl): S261-S265.
7. Barnes B, Rodts GE, McLaughlin MR, Haid RW Jr. Threaded cortical bone dowels for lumbar interbody fusion: over 1-year mean follow-up in 28 patients. *J Neurosurg*. 2001;95(1 suppl):1-4.
8. Agazzi S, Reverdin A, May D. Posterior lumbar interbody fusion with cages: an independent review of 71 cases. *J Neurosurg*. 1999;91(2 suppl):186-192.
9. Hashimoto T, Shigenobu K, Kanayama M, et al. Clinical results of single-level posterior lumbar interbody fusion using the Brantigan 1/F carbon cage filled with a mixture of local morselized bone and bioactive ceramic granules. *Spine*. 2002;27(3):258-262.
10. Elias WJ, Simmons NE, Kaptain GJ, Chadduck JB, Whitehill R. Complications of posterior lumbar interbody fusion when using a titanium threaded cage device. *J Neurosurg*. 2001;93(1 suppl):45-52.
11. Onesti ST, Ashkenazi E. The Ray threaded fusion cage for posterior lumbar interbody fusion. *Neurosurgery*. 1998;42(1):200-204.
12. Okuyama K, Abe E, Suzuki T, Tamura Y, Chiba M, Sato K. Posterior lumbar interbody fusion: a retrospective study of complications after facet joint excision and pedicle screw fixation in 148 patients. *Acta Orthop Scand*. 1999;70(4):329-334.
13. Rivet DJ, Jeck D, Brennan J, Epstein A, Lauryssen C. Clinical outcomes and complications associated with pedicle screw fixation-augmented lumbar interbody fusion. *J Neurosurg Spine*. 2004;1(3):261-266.
14. Chitnavis B, Barbagallo G, Selway R, Dardis R, Hussain A, Gullan R. Posterior lumbar interbody fusion for revision disk surgery: review of 50 cases in which carbon fiber cages were implanted. *J Neurosurg*. 2001;95(2 suppl):190-195.
15. Janssen ME, Nguyen C, Beckham R, Larson A. Biological cages. *Eur Spine J*. 2000;9(suppl 1):S102-S109.
16. Janssen ME, Lam C, Beckham R. Outcomes of allogenic cages in anterior and posterior lumbar interbody fusion. *Eur Spine J*. 2001;10(suppl 2):S158-S168.
17. Burkus JK, Dorchak JD, Sanders DL. Radiographic assessment of interbody fusion using recombinant human bone morphogenetic protein type 2. *Spine*. 2003;28(4):372-377.
18. Burkus JK, Sandhu HS, Gornet MF, Longley MC. Use of rhBMP-2 in combination with structural cortical allografts: clinical and radiographic outcomes in anterior lumbar spinal surgery. *J Bone Joint Surg Am*. 2005;87(6):1205-1212.
19. Burkus JK, Sandhu HS, Gornet MF. Influence of rhBMP-2 on the healing patterns associated with allograft interbody constructs in comparison with autograft. *Spine*. 2006;31(7):775-781.
20. Sasso RC, Kitchel SH, Dawson EG. A prospective, randomized controlled clinical trial of anterior lumbar interbody fusion using a titanium cylindrical threaded fusion device. *Spine*. 2004;29(2):113-122.
21. Anand N, Hamilton JF, Perri B, Miraliakbar H, Goldstein T. Cantilever TLIF with structural allograft and rhBMP2 for correction and maintenance of segmental sagittal lordosis: long-term clinical, radiographic, and functional outcome. *Spine*. 2006;31(20):E748-E753.
22. Lowe TG, Tahernia AD, O'Brien MF, Smith DA. Unilateral transforaminal posterior lumbar interbody fusion (TLIF): indications, technique, and 2-year results. *J Spinal Disord Tech*. 2002;15(1):31-38.
23. Brantigan JW, Sieffee AD, Lewis ML, Quinn LM, Persenaire JM. Lumbar interbody fusion using the Brantigan 1/F cage for posterior lumbar interbody fusion and the variable pedicle screw placement system. Two-year results from a Food and Drug Administration Investigational Device Exemption clinical trial. *Spine*. 2000;25(11):1437-1446.
24. Humphreys SC, Hodges SD, Patwardhan AG, Eck JC, Murphy RB, Covington LA.. Comparison of posterior and transforaminal approaches to lumbar interbody fusion. *Spine*. 2001;26(5):567-571.
25. Rosenberg WS, Mummaneni PV. Transforaminal lumbar interbody fusion: technique, complications, and early results. *Neurosurgery*. 2001;48(3):569-574.
26. Derby R, Howard MW, Grant JM, Lettice JJ, Van Peteghem PK, Ryan DP. The ability of pressure-controlled discography to predict surgical and non-surgical outcomes. *Spine*. 1999;24(4):364-371.
27. Brodke DS, Dick JC, Kunz DN, McCabe R, Zdeblick TA. Posterior lumbar interbody fusion. A biomechanical comparison, including a new threaded cage. *Spine*. 1997;22(1):26-31.
28. Fraser RD. Interbody, posterior, and combined lumbar fusions. *Spine*. 1995;20(24 suppl):167S-177S.
29. Yashiro K, Homma T, Hokari Y, Katsumi Y, Okumura H, Hirano A. The Steffee variable screw placement system using different methods of bone grafting. *Spine*. 1991;16(11):1329-1334.
30. Groth AT, Kuklo TR, Klemme WR, Polly DW, Schroeder TM. Comparison of sagittal contour and posterior disc height following interbody fusion: threaded cylindrical cages versus structural allograft versus vertical cages. *J Spinal Disord Tech*. 2005;18(4):332-336.
31. Newman MH, Grinstead GL. Anterior lumbar interbody fusion for internal disc disruption. *Spine*. 1992;17(7):831-833.
32. Vishteh AG, Crawford NR, Chamberlain RH, et al. Biomechanical comparison of anterior versus posterior lumbar threaded interbody fusion cages. *Spine*. 2005;30(3):302-310.
33. Togawa D, Bauer TW, Lieberman IH, Sakai H. Lumbar intervertebral body fusion cages: histological evaluation of clinically failed cages retrieved from humans. *J Bone Joint Surg Am*. 2004;86(1):70-79.
34. Kuslich SD, Ulstrom CL, Griffith SL, Ahern JW, Dowdle JD. The Bagby and Kuslich method of lumbar interbody fusion. History, techniques, and 2-year follow-up results of a United States prospective, multicenter trial. *Spine*. 1998;23(11):1267-1278.
35. McAfee PC. Interbody fusion cages in reconstructive operations on the spine. *J Bone Joint Surg Am*. 1999;81(6):859-880.
36. Kant AP, Daum WJ, Dean SM, Uchida T. Evaluation of spine fusion: plain films versus direct surgical exploration and observation. *Spine*. 1995;20(21):2313-2317.
37. Prolo DJ, Oklund SA, Butcher M. Toward uniformity in evaluating results of lumbar spine operations. A paradigm applied to posterior lumbar interbody fusion. *Spine*. 1986;11(6):601-606.
38. Tay BB, Berven S. Indications, techniques, and complications of lumbar interbody fusion. *Semin Neurol*. 2002;22(2):221-230.
39. Brantigan JW. Pseudarthrosis rate after allograft posterior lumbar interbody fusion with pedicle screw and plate fixation. *Spine*. 1994;19(11):1271-1280.
40. Pradhan BB, Bae HW, Dawson EG, Patel VV, Delamarter RB. Graft resorption with the use of bone morphogenetic protein: lessons from anterior lumbar interbody fusion using femoral ring allografts and recombinant human bone morphogenetic protein-2. *Spine*. 2006;31(10):E277-E284.