In 1953, Cloward first described his PLIF technique as a surgical treatment option for lumbar disc disease. Although the PLIF procedure slowly gained acceptance thereafter, it was not until the advent of pedicle screw spinal instrumentation that this operation became widely performed.14,15 The unilateral transforaminal approach for segmental lumbar interbody arthrodesis was first described in the 1980s by Blume1 to address some of the complications associated with instrumented (bilateral) PLIF described by Steffee and Sitkowski.14 In the 1990s the TLIF procedure was modified and popularized by Harms, et al.5

The TLIF procedure is an interbody combined with a unilateral posterior (facet and/or interlaminar) arthrodesis performed with or without a bilateral posterolateral arthrodesis that is stabilized with pedicle screw instrumentation. This procedure is performed via a single midline posterior or surgical approach. Access to the intervertebral disc is gained by a unilateral resection of the lamina, pars interarticularis, and zygapophysial (facet) joint at the level or levels to be fused. An aggressive discectomy and interbody arthrodesis can thus be performed unilaterally with relatively minimal medial retraction (compared with the PLIF procedure) of the traversing nerve root and thecal sac, and with essentially no retraction of the exiting nerve root. A number of materials have been used in the TLIF procedure for structural interbody support, including autograft and allograft bone, metal, composites, and, recently, nonresorbable and resorbable polymers. In this paper the details of this procedure, intermediate (1- to 2-year) clinical and radiographic outcomes, and the basic science and rationale for the use of bioabsorbable polymers are discussed. At a mean of 18.4 months of follow up, 30 patients (96.8%) were judged to have attained solid fusions and 25 patients (81%) had good to excellent results. Three patients (9.7%) experienced complications, none of which were directly or indirectly attributable to the use of the bioabsorbable polymer implant. Only one implant in one patient (3.2%) demonstrated mechanical failure on insertion, and that patient experienced no clinical sequelae.

Conclusions: This is the first clinical series to be published in which the mean follow-up duration equals or exceeds the biological life expectancy of this material (12–18 months). Both the clinical and radiographic results of this study support the use of interbody devices manufactured from biodegradable polymers for structural interbody support in the TLIF procedure.

**KEY WORDS** • transforaminal • lumbar interbody fusion • bioabsorbable implant
Indications for the TLIF procedure include mechanical low-back pain related to degenerative disc disease with or without disc herniation, isthmic or degenerative spondylolisthesis, spinal stenosis with instability, degenerative scoliosis, and failed previous lumbar surgery. This last indication occurs most commonly in patients with recalcitrant low-back pain after discectomy for disc herniation, which results in instability of one or more levels in patients whose disease has failed to respond to a comprehensive 3- to 6-month nonsurgical treatment program.\(^5\,^9\)

**CLINICAL MATERIAL AND METHODS**

**Surgical Procedure**

The patient is placed prone on a suitable spine frame or table with the hips in maximum extension, helping to maintain lumbar lordosis; this position affords partial reduction of an isthmic or degenerative spondylolisthesis, when present. A standard midline approach is used. Careful subperiosteal dissection is extended to the tips of the transverse processes of the levels included in the fusion. Through the same incision, one iliac crest is exposed but muscles are left attached. A small window is made in the posterior iliac crest and an adequate amount of cancellous bone is removed from between the cortical tables of the crest to use for bone grafts. The fascia over the iliac crest is closed with interrupted sutures. I routinely reconstruct the iliac defect with coralline hydroxyapatite granules and demineralized bone matrix, and am aware of little or no postoperative donor site pain associated with this method.

The pedicles are cannulated and radiopaque markers are placed therein. A localizing radiograph is then obtained to verify pedicle cannulation and to confirm level identification. The pedicles are tapped in preparation for screw placement. At this point the transverse processes are decorticated and iliac crest bone is used to perform the intertransverse (posterolateral) fusion. Multiaxial pedicle screws are then inserted at the appropriate levels and proper placement is confirmed with subsequent radiographic imaging and direct electrical stimulation of the screws performed while recording electromyographic responses in the myotomes of the adjacent exiting nerve roots (evoked electromyographic responses).

The side of the spine selected for the TLIF is chosen on the basis of preoperative radicular symptoms and/or imaging studies. Generally the most symptomatic and/or diseased side is selected for the transforaminal approach; that is, if a disc herniation or foraminal stenosis is present and is predominantly one-sided, that side is chosen. If symptoms are bilaterally equal, an approach on the left side is used. Rods are contoured in lordosis and cut approximately 0.5 to 1 cm longer than usual to allow for disc space distraction. The rod and locking screws are inserted into the multiaxial screw heads, bilateral distraction is applied, and the locking screws are tightened.

Alternatively, particularly on the side of the TLIF approach, a device designed to distract the heads of the multiaxial pedicle screws while maintaining wide access to the foramens can be used, facilitating access to the intervertebral disc between the heads of the multiaxial screws (Fig. 2). After distraction has been applied, a 10-mm osteotome and Kerrison rongeurs are used to remove the inferior articular process and upper portion of the superior articular process on the side chosen for the TLIF. The ipsilateral pars interarticularis and the caudal and medial aspect of the ipsilateral lamina are resected. At this stage of the procedure, except at levels with bilateral spondylolisthesis, the cephalad lamina is left intact to protect the attached pedicles during distraction, and the midline lamina and spinous process are left intact to prevent excessive retraction of the traversing nerve root and thecal sac.

Exposure of the underlying disc space is facilitated by removal of the lateral margin of the ligamentum flavum. Identifying the exiting nerve root inferior and medial to the upper (cephalad) instrumented pedicle as well as the superior and medial aspect of the lower (caudal) one helps orient the surgeon because the remainder of the anatomy is consistent in relations to these structures. Epidural bleeding is frequently encountered at this point during separation of the nerve root from epidural fat and venous plexus. An irrigating bipolar electrocautery device is useful in controlling epidural bleeding and thrombin-soaked Gelfoam and cottonoids also can be used if...
needed. Once hemostasis is achieved, the underlying disc space (lateral one third), dural sac, and exiting nerve root should be readily visible. The exiting nerve root rarely needs retraction except at the L5–S1 level. Gentle use of an angled nerve root retractor protects the dural sac and facilitates exposure and access to the underlying disc space. Except when sharp instruments are used, however, use of the nerve root retractor is not mandatory.

A No. 15 blade scalpel is used to create an anular window. The medial border of the window is at the lateral margin of the dural sac, and the lateral border is the lateral edge of the visible anulus. The incised anulus is removed with a pituitary rongeur. A 0.25-in osteotome or a box chisel is used to enlarge the window and remove posterior osteophytes, allowing easy access to the disc space. Specialized straight and angled osteotomes, pituitary rongeurs, rasps, and curettes are used to elevate and remove disc material and cartilaginous endplate (Fig. 3). At this point, additional distraction of the pedicle instrumentation can be applied, relying on ligamentotaxis and tactile feedback to prevent overdistraction. The disc space is irrigated with bacitracin-containing saline and then reinspected to confirm complete removal of disc material. A disc spanner or other measuring device is inserted to determine the appropriate size of the bioabsorbable polymer cage, which should be 0.5 to 1 mm shorter than the spanner measurement to allow for lordosis when compression is applied to the posterior instrumentation; 13-mm-diameter cages with heights ranging from 8 to 12 mm are most commonly used.

A 10-mm angled osteotome is used to decorticate only the anterior one third of the adjacent endplates. This decortication provides an excellent graft bed adjacent to the anterior anulus. The posterior two thirds of the adjacent endplates are less aggressively decorticated in order to provide support for the cages. Previously harvested iliac crest bone graft then is packed tightly into the anterior one third of the disc space with a bone tamp. In multilevel cases, crushed cancellous allograft as well as iliac crest and local autograft (“morcellized” laminectomy and spinous process bone) is used for this step. Two HYDROSORB bioabsorbable polymer cages packed with iliac crest autograft are then inserted into the disc space (Fig. 4 left). The first spacer is inserted into the posterior interbody interspace and maneuvered across the disc space to the contralateral side by using an angled insertion device as well as straight and angled impactors (Fig. 4 right). The second spacer is inserted into the ipsilateral posterior disc

Fig. 2.  
Left: Photograph showing the distractor. This device is designed to distract the heads of the multiaxial pedicle screws while maintaining wide access to the foramen.  
Right: Intraoperative photograph showing the distractor in situ. Note how the intervertebral disc can be easily approached between the heads of the multiaxial screws. Photographs are reprinted with permission from Slack, Inc.

Fig. 3.  
Photograph showing a left-facing angled and serrated curette that facilitates preparation of the vertebral endplate during the TLIF procedure. Not shown are similar straight and right-facing serrated curettes. Photograph is reprinted with permission from Slack, Inc.
space (Fig. 5), and distraction is then released. Direct inspection of the spacer and palpation with the use of an elevator are performed to ensure that the ipsilateral cage is contained within the intervertebral space. Ideally, the devices should be placed in the posterior one third of the disc space. This provides structural support close to the center of rotation for the motion segment, and allows later radiographic assessment of fusion anterior to the cages.

Additional levels are treated as necessary. If distractors were used, the rods are inserted and compression is then applied to lock the cages in place and maximize segmental lordosis. Device placement and stability are again confirmed by inspection and palpation with straight and angled elevators. Further decompression, as indicated, is then performed. The contralateral facet and any residual contralateral lamina are decorticated and packed with the remaining autograft bone, and one or two crosslinks are placed to connect the rods on each side. The wound is closed in layers over closed suction drainage to complete the procedure.

Patients are mobilized on postoperative Day 1 and are usually discharged from the hospital on Day 4; no external orthosis is required. For the first 6 weeks postoperatively, patients are encouraged to walk as much as possible. Physical therapy, beginning with aquatic conditioning exercises and progressing to land-based therapy with strengthening and aerobic exercises, is then progressively instituted. By 6 months, patients are allowed to resume full activities as tolerated. Typically, solid fusion is confirmed radiographically at 12 months postoperatively.

**Patient Population**

Between December 2001 and September 2002, 31 patients (22 men and 9 women) with a mean age of 45.5 years (range 30–64 years) underwent the TLIF procedure at a total of 58 levels (mean 1.9 levels per patient, range one–three levels). This procedure was performed for a variety of lumbar conditions. Two 13 to 12–mm HYDROSORB bioabsorbable spacers were used per interbody fusion level for anterior column support (116 total spacers were implanted). Two more patients underwent posterior fusion at one additional level (transitional L5–S1) without supplemental anterior column support. One patient with a Grade I isthmic spondylolisthesis at L5–S1 (below a previous anterior fusion from L2–4 for an L-3 burst fracture) underwent the TLIF procedure at L4–5 and L5–S1 with instrumentation and posterior fusion from L2–S1 (Fig. 6).

Nine patients in this series had undergone previous decompressive lumbar surgery at one or more of the surgically treated levels. One patient had undergone a previous TLIF procedure with implantation of metallic cages at L3–4 and L4–5 3 years before her TLIF procedure at L5–S1 with HYDROSORB spacers. In all patients in this series low-back pain was their predominant complaint,

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**Fig. 4.** *Left:* Photograph showing two HYDROSORB spacers loaded on straight and angled inserters and packed with autologous bone graft in preparation for insertion into the prepared intervertebral disc space. *Right:* These straight and angled impactors are used to adjust the implant position after insertion. To avoid cracking the HYDROSORB implants, it is important to avoid excessive force when using these impactors. Photographs are reprinted with permission from Slack, Inc.

**Fig. 5.** Intraoperative photograph showing a HYDROSORB bioabsorbable spacer visualized through the anular window after insertion. The top of the photograph is oriented medial, left is oriented caudally. Photograph is reprinted with permission from Slack, Inc.
with varying degrees of radicular pain and neurological symptoms. All patients in this series underwent at least 12 months of nonsurgical care before receiving surgery.

Twenty-one patients (67%) underwent treatment for work-related disorders of the lumbar spine. All patients in this series had some component of degenerative disc disease. A complete listing of the other diagnoses is shown in Table 1. The most cephalad level undergoing operation in this series was L2–3. The distribution of fused levels is shown in Table 2. The mean estimated blood loss was 1070 ml (range 350–3500 ml) and the mean postoperative length of stay was 5.1 days (range 2–11 days).

Lumbar radiographs with anteroposterior, lateral, and Ferguson views were obtained at 2 weeks and at 3, 6, 12, and 24 months postoperatively. Lateral standing flexion–extension films were obtained as well, beginning with the 6-month set. Fusion status was judged on the 12-month (and when available, the 24-month) films based on the criteria listed in Table 3. The clinical results of this study were analyzed using the method of Prolo, et al. Additionally, the SF-36 outcomes instrument was administered preoperatively in all patients, 12 months postoperatively in 19 patients, and 24 months postoperatively in four patients. The preoperative and 12-month postoperative scores were compared and analyzed for the purposes of this study.

Fig. 6. This 41-year-old man with isthmic Grade I spondylolisthesis had undergone an anterior decompression, titanium mesh cage implantation, fusion, and instrumentation for an L-3 burst fracture with neurological deficit (which resolved postoperatively) 6 years before a lifting injury that rendered his spondylolisthesis symptomatic. Upper Left: Lateral radiograph demonstrating the anterior implants spanning L2–3. Upper Center: A detailed lateral radiograph of the lumbosacral junction indicating the loss of intervertebral disc height in addition to the spondylolisthesis. Upper Right: Lateral radiograph obtained 2 weeks postoperatively demonstrating the restoration of the L5–S1 intervertebral disc height and partial reduction of the spondylolisthesis as well as the posterior transpedicular implants spanning L2–S2. Note that the lumbosacral lordosis between L-3 and S-1 is preserved. Preoperative discography had indicated that the L4–5 disc was too degenerated and symptomatic not to be included in the fusion. Lower Left: Postoperative anterior–posterior radiograph obtained at 2 weeks. Lower Right: Lateral radiograph obtained 1 year postoperatively indicating solid interbody fusion at L4–5 and L5–S1 with preservation of disc height and lumbar lordosis.
RESULTS

The mean follow-up duration in this series was 18.4 months (range 16–24 months). Four postoperative complications were noted in three patients (9.7%) and are listed in Table 4. None of these complications was attributable to the use of the bioabsorbable polymer. In one patient (3.2%) one cracked implant was noted immediately after insertion. No subsidence or other evidence of further structural failure has been observed subsequently in this patient and he was judged to have attained solid fusion at his most recent follow-up visit. No patient has displayed evidence of allergic or inflammatory reactions to the polymer. Specifically, there have been no adverse events related either directly or indirectly to use of the bioabsorbable implants.

In one patient (3.2%) a nonunion developed as determined by obvious motion on flexion–extension lateral radiographs obtained after increasing reports of low-back pain at 9 months postsurgery; this patient has undergone subsequent revision surgery. The outcome in the remaining 30 patients (96.8%), however, has progressed to a solid fusion, as illustrated in Fig. 7.

According to the criteria of Prolo, et al.,12 25 (80.6%) of the 31 patients had good to excellent results, five (16.1%) had a fair result, and one (3.2%), the only patient in this series with a nonunion, had a poor result (assessed before his revision surgery; see Table 5). The SF-36 outcomes analysis demonstrated a statistically significant improvement in the 12-month mean pain scores and the 12-month mean physical function scores, compared with the preoperative scores assessed according to the same scales (Fig. 8). Other SF-36 scores showed improvement, but only some results reached statistical significance.

DISCUSSION

Surgical procedures that include both posterolateral and interbody fusion have demonstrated high fusion rates and good clinical results.7,11–13,15 These procedures have distinct advantages including anterior column load sharing, large surface areas for fusions, restoration of a normal sagittal profile, and the achievement of passive foraminal decompression. The posterior unilateral transformaminal approach allows the surgeon to address all of these issues concurrently via one approach without the need for a second anterior incision and its associated morbidity and complications (particularly vascular complications in all patients and retrograde ejaculation in male patients). Compared with the PLIF, the TLIF has the advantage of requiring exposure and manipulation of the neural elements (for the purpose of achieving interbody fusion) on only one side per level, and even that only minimally.

A number of interbody devices have been used for this procedure, including structural allograft, structural autograft, titanium mesh, cylindrical threaded devices, and both resorbable and nonresorbable polymers. I believe that there are some definite advantages of using resorbable polymers, including the facilitation of imaging to assess fusion (an advantage shared with nonresorbable polymers and bone) and the unique bioresorption process, which allows the anterior column fusion mass to share the load progressively with the posterior column.
Instrumented TLIF with bioabsorbable implants

Currently, there are two Food and Drug Administration–approved resorbable materials that are most commonly used in orthopedic and/or neurosurgical applications. The first is a copolymer of poly-L-lactic acid and polyglycolic acid that retains 70% of its strength for 6 to 9 weeks, with nearly complete loss of strength at 12 weeks, and essentially complete resorption (mass loss) within 12 months. The other is a copolymer of poly-L-lactide and D,L-lactide, which retains approximately 70% strength for 6 to 9 months and is resorbed between 18 and 36 months. HYDROSORB is made of the latter copolymer, which is believed to have the ideal spinal implant characteristics, including a slow degradation with retention of strength over a sufficiently long period to provide stability while the interbody fusion mass matures and progressively assumes anterior column loading over time (load sharing).

Concerns about the safety of bioabsorbable devices have been addressed in several basic science studies. The biocompatibility of PLA has been demonstrated in both dural and neural tissues within the spinal cord by Lundgren, et al. Gautier, et al., have shown that the presence of PLA has no effect on neuronal cells, non-neuronal cells, or axonal growth. Likewise, De Miniaceli, et al., have demonstrated biocompatibility with peripheral nerves on both gross and histological examination. It has also been demonstrated that pH changes are absent in the degradation of PLA implants placed in the femoral shafts of sheep.

The mechanical properties of HYDROSORB have shown 100% retention of strength at 3 months, 90% at 6 months, 70% at 9 months, and 50% at 12 months. Resorption of PLA occurs by bulk hydrolysis into carbon dioxide and water; thus there are no detrimental degradation products.

In 2002 Toth and coworkers published a study in which they used stand-alone resorbable threaded interbody spine implants to compare autograft against rhBMP-2 implants. In their study they demonstrated no significant inflammatory response related to the polymer and gradual replacement of the polymer spacer by precursors of osseous tissue and ultimately bone, indicating good biocompatibility in the 12-, 18-, and 24-month groups of sheep. In the 12-month group, two of four sheep (one with autograft, one with rhBMP-2) achieved fusion and two (one with autograft and one with rhBMP-2) did not achieve fusion, ostensibly because of increased segmental mobility related to mechanical degradation of the resorbable polymer spacers. In the 18- and 24-month groups, however, all five sheep (three with autograft and two with rhBMP-2) went on to attain solid fusion determined both radiographically and histologically.

Only preliminary clinical results of the use of cylindrical HYDROSORB bioabsorbable spacers have been reported to date. Lowe and Coe reported the preliminary results in a combined (two-center) series of 60 patients who underwent the TLIF procedure for implantation of HYDROSORB mesh cages. Early clinical results were found to be encouraging in that study, but the follow-up duration was short (mean 4.7 months; longest follow-up period only 9 months). No complications attributable to the use of the resorbable implants were noted, however.

This is the first series in which the clinical results of interbody fusion with spacers manufactured from 70:30 poly(L-lactide-co-D,L-lactide) copolymer are reported after a follow-up period that equals or exceeds the biological life expectancy of the material (12–18 months).
of the procedures were performed by the same surgeon at one institution, with 100% follow up. Clinical results are equivalent to those published in comparable series in which nonresorbable spacers were used for interbody structural support. This is particularly noteworthy because more than two thirds of the patients in this series were from a traditionally difficult-to-treat patient population (those with Worker’s Compensation claims).7,11–13,15

Limitations of this study include a relatively small series size (31 patients), lack of a control group in which nonresorbable implants were used, and a relatively short follow-up duration for long-term assessment of clinical results. Nevertheless, this series represents the largest one involving the clinical use of bioabsorbable polymer interbody implants yet published in which the mean follow-up duration exceeds 18 months.

The future of bioabsorbable technology in spinal surgery appears to be quite exciting. Bone morphogenetic protein appears to be well suited for use in combination with resorbable polymer interbody implants.16 I began to use rhBMP-2 clinically in lieu of iliac crest autograft with HYDROSORB mesh interbody spacers in the fall of 2002. In more than 30 cases treated so far, the blood loss has been less, the length of stay has been shorter, and, most significantly, fusion has been achieved earlier than in the cases reported in the present series. Results in these patients will be formally reported when at least 1 year of follow up has been achieved in most of them.

CONCLUSIONS

In this study I have evaluated the clinical and radiographic results in 31 patients from one center who underwent instrumented TLIF for primarily degenerative indications. Cylindrical bioabsorbable polymer spacers manufactured with a 70:30 copolymer of poly L-lactide and D,L-lactide (HYDROSORB) and packed with iliac crest autograft bone were used to stabilized the spine. At a mean of 18.4 of months follow up, 30 patients (96.8%) were judged to have attained solid fusions and 25 patients (81%) had good to excellent results. Three patients (9.7%) experienced complications, none of which were directly or indirectly attributable to the use of the bioabsorbable polymer implant. Only one implant in one patient (3.2%) demonstrated mechanical failure on insertion; there were no clinical sequelae. This is the first clinical series to be published in which the mean follow-up duration equals or exceeds the biological life expectancy of this material (12–18 months). Both the clinical and radiographic results of this study support the use of interbody devices manufactured from biodegradable polymers for structural interbody support in the TLIF procedure.

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![Fig. 8. Bar graph showing SF-36 data in 19 of 31 patients in whom 12-month postoperative mean scores are compared with preoperative mean scores. Note that there were statistically significant improvements in the mean pain and physical function scores.](image-url)
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