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Transforaminal lumbar interbody fusion rates in patients using a novel titanium implant and demineralized cancellous allograft bone sponge

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Abstract

Background: Transforaminal lumbar interbody fusion (TLIF) with grafting and implant options like iliac crest bone graft (ICBG), recombinant bone morphogenetic protein (rhBMP), and polyetheretherketone (PEEK) cages have been reported to achieve extremely high fusion rates. Unfortunately, these options have also been frequently cited in the literature as causing postoperative morbidity and complications at a high cost. Knowing this, we sought to investigate TLIF using an acid-etched, roughened titanium cage that upregulates osteogenesis to see if similar fusion rates to those cited for ICBG, rhBMP, and PEEK cages could be safely achieved with minimal morbidity and complications.

Materials and methods: A radiographic fusion study of 82 patients who underwent TLIF using an acid-etched, roughened titanium cage with demineralized cancellous bone graft was conducted. Fusion was assessed and graded by an independent radiologist using computed tomography scan with sagittal and coronal reconstructions.

Results: Fusion rates at 6 months were 41 of 44 (93.2%) and at 12 months were 37 of 38 (97.4%). There were no radiographic device-related complications.

Conclusions: TLIF with an acid-etched, roughened titanium cage filled with a decalcified bone graft achieved similar fusion rates to historical controls using ICBG, rhBMP, and PEEK.

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Keywords: TLIF; Lumbar; Fusion; Graft; Recombinant human bone morphogenetic protein (rhBMP); Iliac crest bone graft (ICBG); PEEK cage

Introduction

Lower-back pain, radiculopathy, and other indications for lumbar fusion have been rising exponentially for years, making lumbar fusion one of the most common orthopedic surgical procedures. In fact, since the advent of lumbar cages in 1996, lumbar fusions have more than doubled, whereas hip replacement and knee arthroplasty—2 of the most common orthopedic surgical procedures—have risen at only a fraction of that amount.[1]

Research devoted to lumbar fusion has traditionally focused on fusion rates as primary outcome measures as considerable evidence has associated optimal bony fusion with clinical outcome and patient satisfaction.[2–4] For example, Jiya et al.[5] compared lumbar fusion rates and clinical outcome—measured with visual analog scale and clinical questionnaires—between interbody fusions using polyetheretherketone (PEEK) cages and poly-L-lactide-co-D,L-lactide cages and showed that patients with PEEK cages had significantly better fusion rates and clinical outcome scores than those with poly-L-lactide-co-D,L-lactide cages.

Lumbar fusion is one of the most commonly performed orthopedic surgical procedures. Advances in lumbar fusion due to innovations in spinal fusion implants and grafting options have been dramatic—leading to improvements in the rates of successful fusions. Early studies showed posterolateral fusions with iliac crest bone graft (ICBG) to have fusion rates ranging from 73%–90%.[6–9] Later studies investigating anterior lumbar interbody fusion with alternatives to ICBG, such as calcium sulfate and PEEK cages with local autograft, demonstrated fusion rates exceeding 90%.[5,9] More recently, investigators have reported fusion

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rates of 95%–100% for anterior lumbar interbody fusion performed with recombinant human bone morphogenetic protein (rhBMP) and PEEK cage implants.[7,8] Finally, studies reporting on transforaminal interbody fusion approach (TLIF) and posterior lumbar interbody fusion (PLIF), a recent interbody fusion procedural advance—with and without rhBMP, have shown fusion rates nearing 100%.[7,10–14] Schwender et al.[14] reported fusions in all 45 patients who underwent TLIF with PEEK cage and rhBMP, while Rihn et al.[7] reported fusions in 95.8% of patients.

In addition to advances in grafting options and implant technology, the surgical techniques for lumbar fusion have evolved considerably. Currently, interbody fusions such as TLIF and PLIF have gained popularity, as they can achieve higher fusion rates than traditional posterolateral surgical approaches.[3,13–21] Both TLIF and PLIF achieve interbody fusion from a posterior approach and lead to wider areas of intervertebral bone-to-graft contact than posterolateral fusion, while restoring disc space height, lumbar lordosis, and coronal-sagittal balance of the spine.[17] TLIF has surpassed PLIF in popularity as TLIF—owing to its more lateral exposure of the interspace—allows preservation of the posterior longitudinal ligament complex as well as other supporting bony and ligamentous structures, which are often compromised in PLIF.[13,14,16,21] In addition, minimal neural retraction or epidural dissection is required in TLIF, as compared with PLIF.[3,14,21]

Although the innovations in spinal fusion technology have improved fusion rates, there is concern that these achievements come at the cost of greater patient morbidity and dissatisfaction. Firstly, the morbidity associated with ICBG—largely owing to pseudarthrosis and donor site complications—has been the impetus for use and development of safer graft options.[2,9] Secondly, PEEK cages frequently require revision surgery owing to fibrous union, subsidence, posterior migration, and impingement on the thecal sac.[18,22,23] Lastly, lumbar fusion with rhBMP has consistently led to reports of osteolysis, postoperative radiculitis, ectopic bone formation, and other serious complications requiring revision surgery.[3,7,14–16,21,22,24–33]

Appreciating these complication rates for lumbar fusion utilizing ICBG, rhBMP, and PEEK cages, this study sought to determine whether TLIF using an acid-etched, roughened titanium cage that upregulates osteogenesis could safely achieve lumbar fusion rates similar to those cited for the aforementioned grafting and implant options at 6 and 12 months after the index procedure.

Clinical materials and methods

Study design

The authors selected 86 consecutive patients who underwent TLIF with a titanium cage and biological demineralized bone graft. These patients were divided into 2 separate cohorts—according to time after surgery—6 and 12 months. A period of 6 months was chosen as this is a common short-term follow-up period used in comparable TLIF studies[2,12]; 12 months was chosen because it is widely accepted as the cutoff when patients can be considered to have achieved fusion or not. Indications for surgery included diagnoses of spondylolisthesis, recurrent herniated disc, degenerative disc disease, or spinal stenosis. All patients underwent TLIF using the same implants and allograft (*Titan Spine's* Endoskeleton TT with *Bacterin's* OsteoSponge). Clinical results are reported for 44 patients at 6 months and 38 patients at 12 months.

Surgical procedure

A standard posterior approach with complete laminectomy and medial facetectomy, along with decompression if indicated, was performed. After decompression, standard pedicle screw instrumentation was utilized. Before insertion of the screws, 3 mL of bone marrow aspirate (BMA) was aspirated from the vertebral body. The BMA was used to reconstitute the OsteoSponge allograft.

A standard annulotomy was performed, and starting incrementally from 7 up to 14 mm, serial dilators were used to distract the interspace. In addition, the dilators served to clean the disc material and meticulously prepare the disc space. Once the disc space was prepared, an appropriate size trial was inserted and fluoroscopy was obtained to verify position and correct sizing.

A strip of OsteoSponge was placed as anteriorly as possible in the disc space, followed by placement of OsteoSponge into the cage, with the cage inserted obliquely and turned to sit in parallel to the endplates as anteriorly as possible in the intervertebral space. The posterior aspect of the interspace was then packed with ground autologous bone harvested during the laminectomy. Finally, the pedicle screws were compressed and locked.

Titan Endoskeleton TT and OsteoSponge/BMA

The Endoskeleton TT (Fig. 1) is a titanium alloy interbody device designed to aid in the fusion of 1 or 2 contiguous levels between L2 and S1 through a TLIF. This device features a surface treatment that includes a combination of textures at the macrolevel and the microlevel. In vitro studies indicate that this surface may upregulate significantly critical bone growth factors necessary for fusion.[34]

The OsteoSponge allograft (Bacterin International, Belgrade, Montana) is a nonstructural bone void filler composed of human demineralized cancellous bone, with no additional carrier materials.[38] When hydrated with BMA, the graft becomes compressible, exhibits shape memory, and can be compressed and inserted into an interbody device where it expands to enhance connectivity at the graft-bone interface. OsteoSponge maintains the porosity of cancellous bone (Fig. 2), allowing it to serve as a scaffold to facilitate bony fusion.