Since posterior lumbar interbody fusion was introduced by Cloward in the 1950s, it has been among the most widely performed surgical procedures for lumbar degenerative disease. In particular, implants for interbody fusion have advanced considerably in terms of material, design, and surface coating since the mid-1970s, and these implants have greatly improved the biomechanical stability of posterior lumbar interbody fusion with pedicle screws. Clinical trials have shown that advanced materials, such as demineralized bone matrix, recombinant human bone morphogenetic proteins, and cultured stem cells, can produce promising results, but these materials are expensive and have adverse effects.

Characteristics and Efficacy of a New 3-Dimensional Printed Mesh Structure Titanium Alloy Spacer for Posterior Lumbar Interbody Fusion

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abstract

This study evaluated the characteristics of a newly developed 3-dimensional printed mesh structure titanium spacer and its efficacy for posterior lumbar interbody fusion. Posterior lumbar interbody fusion with this spacer was performed at 53 segments (40 patients; mean age, 64 years; range, 51-73 years). Data were collected prospectively. Radiographic characteristics were analyzed with changes in interbody height, instability of the segments, formation of bone bridges around the implants, and pseudarthrosis, as determined by dynamic radiographs and postoperative computed tomography scans. Clinical outcomes were evaluated with the visual analog scale for the low back and extremities, the Oswestry Disability Index, and the 36-Item Short Form Survey. Radiographically, preoperative anterior and posterior interbody height was significantly increased immediately postoperatively (P<.05), and this increase was maintained until the last follow-up. No segmental motion of 3° or greater was noted at the last follow-up. Sagittal computed tomography images showed complete anterior bone bridges for 94.3% of cases and complete posterior bone bridges for 86.7% of cases. Coronal computed tomography images showed bilateral complete bone bridges for 94.3% of cases and unilateral bone bridges for 5.7% of cases without incomplete bilateral bone bridges. No pseudarthrosis or revision, particularly including posterior lumbar interbody fusion at L5-S1, was noted. Compared with preoperative values, the visual analog scale score for the low back and extremities, the Oswestry Disability Index, and the 36-Item Short Form Survey score showed significant improvement at the last follow-up (P<.05). Posterior lumbar interbody fusion with a newly developed 3-dimensional printed mesh structure titanium spacer showed satisfactory radiographic and clinical results, with no cases of pseudarthrosis or revision, including posterior lumbar interbody fusion at L5-S1. [Orthopedics. 2017; 40(5):e880-e885.]

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Despite remarkable advances in intervertebral implants and posterior spine instruments, cage subsidence and pseudarthrosis during posterior lumbar interbody fusion still occur. Porous titanium alloy offers greater contact area between the bone and implants as well as bone ingrowth and a high coefficient of friction that can improve initial segmental stability. These implants provide mechanical support during the early postoperative stage, induce recovery of lordosis, and achieve higher fusion rates that are similar to those for autogenous bone grafts. However, few studies have assessed the efficacy of mesh structure titanium alloy implants during spinal surgery.

This study evaluated the characteristics of a newly developed 3-dimensional printed mesh structure titanium alloy spacer and its efficacy for posterior lumbar interbody fusion.

**Materials and Methods**

**Implant Materials**

The Medussa-PL implant (Medyssey, Seoul, Republic of Korea) is a newly developed 3-dimensional printed mesh structure titanium alloy spacer that is used to treat skeletally mature patients at 1 or 2 contiguous levels of disease in the lumbosacral region (L2-S1). The spacer uses additive manufacturing with electron beam melting technology to offer the benefit of a trabecular structure implant. It is manufactured with Ti6Al-4V ELI powder. The efficacy of foam-type implants was shown in previous studies that reported ingrowth of osteoblasts through the interconnected porosity of the metal foam. The implant used in the study has 87.4% porosity, which is similar to the human bone perforation rate (pore size, 535 μm), and it uses the most advanced rapid production technology to enable proliferation of osteoblasts and integration of osteocytes (Figure 1). This characteristic allows for bony ingrowth into the implant, helps bone to implant surface fusion, and prevents migration or expulsion of the implant.

**Study Participants**

This study was based on the results obtained from 2 hospitals in Korea. Data were collected prospectively. All components used in this study were approved for sale and use at all study sites. Ethics committee approval was obtained before initiation of the study. Before study entry, all patients were evaluated by the investigator to ensure that they met the inclusion criteria and that they did not meet the exclusion criteria.

**Inclusion Criteria**

The study included men and women who were 20 to 80 years old. All patients were candidates for 1- or 2-level posterior lumbar interbody fusion between L3 and S1 and had undergone unsuccessful nonsurgical treatment for at least 6 months. All patients received 2 Medussa-PL implants of identical shape and size, with a minimum follow-up period of 12 months, and all had grade 1 or 2 degenerative or ischemic spondylolisthesis, degenerative spinal stenosis, failed discectomy syndrome, degenerative disk disease such as disk herniation, or instability.

**Exclusion Criteria**

Patients were excluded from the study if they had any of the following diagnoses: rheumatologic or other inflammatory joint disease, scoliosis or other deformity of the spine, congenital malformation of the spine, or trauma. Also excluded were patients with severe osteoporosis (bone density T-score less than -4.0) and patients with other concurrent physical or mental conditions that would be likely to affect outcomes, such as sickle cell disease, systemic lupus erythematosus, or renal disease requiring dialysis.

A total of 42 patients who underwent posterior lumbar interbody fusion with Medussa-PL implants were assessed for eligibility. Among them, 2 patients were excluded from the study because of postoperative infection and withdrawal from study participation. Posterior lumbar interbody fusion procedures were performed on 53 segments (40 patients; mean age, 64 years [range, 51-73 years]). Between June 2014 and May 2016, the 1- or 2-level posterior lumbar interbody fusion procedures on 53 segments were performed with 2 mesh structure titanium alloy lumbar spacers of identical shape and size. Posterior lumbar interbody fusion was supplemented with posterior instrumentation. The surgeon was free to choose any legally approved rigid standard pedicle screw system for additional posterior instrumentation. After surgery, all patients were asked to wear a rigid lumbosacral orthosis for 3 months postoperatively and were advised to avoid taking nonsteroidal anti-inflammatory drugs that might influence fusion rates.

Patients were diagnosed with grade 1 or 2 degenerative spondylolisthesis (n=13), followed by grade 1 or 2 ischemic spondylolisthesis (n=11), degenerative spinal stenosis or disk disease (n=11), and failed disectomy syndrome (n=5). Two mesh structure titanium alloy spacers were inserted at L3-L4 for 7 segments, at L4-L5 for 27 segments, and at L5-S1 for 19 segments. All diagnoses were confirmed by postoperative computed tomography scans.

**Figure 1:** Illustrations of newly developed 3-dimensional printed mesh structure titanium alloy lumbar spacers (Medussa-PL; Medissey, Seoul, Republic of Korea) that use rapid production technology (electron beam melting) to enable proliferation of osteoblasts and integration of osteocytes. Illustration showing the pore size, porosity, and pore structure of the implant (A). Photograph showing the superior surface of the implant (B). Photograph showing the lateral surface of the implant (C).
and procedures were performed by 2 experienced surgeons at each institution (S.-S.C, K.-C.K.). Preferentially, autogenous local bone obtained during surgery was used for fusion, and irradiated allograft bone chips also were used if there was insufficient local bone. No bone morphogenetic protein, demineralized bone matrix, or other type of bone substitute was used.

Radiographic and Clinical Evaluation
Plain radiography was performed preoperatively and at 3, 6, and 12 months postoperatively. The decrease in intervertebral disk space height was determined with interbody height. To ensure the accuracy of these measurements, instead of disk height measurement, uniformly magnified films were used and interbody height was measured between the superior end plate of the upper vertebrae and the inferior end plate of the lower vertebrae (Figure 2). To evaluate segmental instability, segmental range of motion was measured on dynamic full flexion and extension radiographs with the Cobb method between the superior end plate of the upper vertebrae and the inferior end plate of the lower vertebrae. At 12 months postoperatively, isodense bone bridge formation in the anterior and posterior regions of the implants was investigated with computed tomography (CT) scan. For the formation of bone bridges around the spacers, the authors modified the CT classification that Nagahama et al.17 reported previously. The description is as follows: (1) anterior complete or incomplete bone bridge formation in the sagittal plane; (2) posterior complete or incomplete bone bridge formation in the sagittal plane; (3) bilateral, unilateral, or absent complete bone bridge formation in the coronal plane (Figure 3). Pseudarthrosis was defined as device migration, translucency around the implants, or segmental motion of 5° or greater on dynamic radiographs.18-20

Clinical results were evaluated with the visual analog scale for pain for the low back and extremities, the Oswestry Disability Index, and the 36-Item Short Form Survey (SF-36). All patients were asked to complete these questionnaires before surgery and at each follow-up examination.

Statistical Analysis
Statistical analysis was performed by a professional medical statistical consultant with SPSS, version 19.0 (IBM Corp, Armonk, New York). Values were recorded as mean±SD. Pre- and postoperative radiographic and clinical results were compared with a paired Student’s t test. Significance was set at \( P<.05 \).

RESULTS
Radiographic Outcomes
A total of 53 segments were analyzed. Preoperative anterior interbody height (75.1±8.2 mm) was significantly increased immediately postoperatively (78.1±6.7 mm, \( P=.002 \)), and the increase was maintained until the last follow-up (76.0±6.6 mm) without significant subsidence. Posterior interbody height increased from 61.9±4.8 mm to 63.2±5.1 mm, and the increase was maintained until 12 months postoperatively (62.2±5.0 mm). Anterior interbody height showed a significant increment immediately postoperatively, but a significant decrease occurred between 1 month postoperatively and 3 months postoperatively (Figure 4). No segmental motion of 5° or greater was noted at the last follow-up. Mean segmental motion of the upper and lower vertebral bodies between dynamic flexion and extension radiographs was 0.74°±0.5° (range, 0°-2.2°) 6 months postoperatively.
and 0.72°±0.5° (range, 0°-2.0°) at the last follow-up (Figure 5). Sagittal CT scan showed complete bone bridges on the anterior surface for 94.3% (50 of 53) of cases and on the posterior surface for 86.7% (46 of 53) of cases. Meanwhile, coronal images showed bilateral complete bone bridges for 94.3% (50 of 53) of cases and unilateral bone bridges for 5.7% (3 of 53) of cases without incomplete bilateral bone bridges. No translucency around the spacers or device migration was noted, and there were no cases of pseudarthrosis or revision, including the posterior lumbar interbody fusion procedures at L5-S1.

**Clinical Outcomes**

Visual analog scale scores for pain in the low back and extremities improved significantly from 5.8±2.7 and 5.8±2.9, respectively, preoperatively to 2.3±2.4 (P<.001) and 1.0±1.3 (P<.001), respectively, at the last follow-up. Preoperative Oswestry Disability Index (46.6±3.7) also improved at the last follow-up (17.0±10.1) (P<.001).

For the SF-36, mean preoperative physical and mental component scores (41.1±18.2 and 44.6±19.3, respectively) were significantly increased at the last follow-up (61.5±20.9 and 66.7±20.2, respectively; P<.001). For each section of the SF-36, most of the preoperative scores, including physical functioning (41.2±25.9), physical role functioning (40.3±24.6), bodily pain (35.1±16.1), vitality (38.4±19.4), social role functioning (42.9±25.5), emotional role functioning (42.9±26.5), and mental health (53.1±20.9), were significantly increased at the last follow-up (65.0±21.4, 60.5±23.9, 68.1±20.2, 57.7±21.1, 78.7±26.5, 63.5±27.4, and 67.1±19.1, respectively; P<.05). In contrast, the score for general health perceptions did not show a significant increase (preoperative, 44.0±24.4; last follow-up, 52.1±26.7; P=0.63) (Figure 6).

**DISCUSSION**

Since the 1990s, with autologous bone grafts, a cage has been used as a spacer in the intervertebral disk space to provide early stability and a high fusion rate. At that time, however, some problems occurred with donor site morbidity after iliac bone harvest and difficulty with thorough removal of soft tissue and cartilage for interbody fusion. Afterward, shapes, materials, and insertion methods for intervertebral implants have improved greatly.9,10,21 Porous titanium devices have been reported to promote bone ingrowth, provide initial fixation stability, and achieve intersegmental fusion in many orthopedic departments.11,13,22 However, few studies have shown their efficacy and safety in spinal surgery.25

This study found that posterior lumbar interbody fusion with 3-dimensional printed mesh structure titanium alloy spacers showed satisfactory radiographic and clinical results without significant complications. No significant changes in interbody height, segmental instability, incomplete bone bridge formation, or pseudarthrosis were noted at the last follow-up. Although mean interbody height decreased from immediately after surgery to 3 months postoperatively (Figure 4), the decrements stopped after 3 months postoperatively, and no incomplete bilateral bone bridges were seen on sagittal or coronal plane CT images. These results suggest that mesh structure titanium alloy spacers offer many advantages, such as initial stability, no significant subsidence, and high fusion rates, compared with conventional spacers. The mesh structure titanium alloy spacer could be a novel alternative to the traditional lumbar metal or polyetheretherketone spacer for posterior lumbar interbody fusion.

Specifically, the authors were interested in the radiographic results of posterior lumbar interbody fusion at the L5-S1 segment. Because of high rates of pseudarthrosis at L5-S1, spine surgeons are usually con-
Figure 5

These studies showed that the coarse surface of mesh structure spacers is believed to provide initial stability and allow rapid bone ingrowth. The mesh structure is believed to increase contact area of the end plate area and facilitate rapid bone ingrowth. The coarse surface of mesh structure spacers is believed to provide initial stability and allow early interbody fusion through surface-to-surface fusion (Figure 5). However, because of the rough surface of the titanium alloy, insertion of the implants without causing neural tissue injury or destruction of the cartilage end plate of the vertebral bodies can be technically difficult. The authors were careful during implant insertion and protected the surrounding nerve root and dura mater with a root retractor and a freer and protected the bony end plate by distracting the intervertebral space.

Before the beginning of this study, the authors were concerned about the small contact area of Medussa-PL implants that could influence postoperative cage subsidence or pseudarthrosis. Approximately 10% to 15% of the cross-sectional area of the spacer is less than the area of several existing polyetheretherketone or metal cages.

However, several previous reports showed that posterior lumbar interbody fusion with a single spacer achieves adequate biomechanical stability, regardless of bone grafting.24,25 These studies showed that the wide contact surface of inserted spacers is not an integral part of solid intervertebral fusion under the condition of stable posterior instrumentation, and minimal contact surface may be sufficient for load transmission.26 This evidence supports the claim that posterior lumbar interbody fusion with a mesh structure titanium alloy spacer can be a viable treatment option. In practice, no significant problems were associated with cage subsidence or pseudarthrosis.

Limitations

This study had several limitations. First, the study did not use a control group to compare the efficacy and safety of these new implants. This is an inherent weakness of the study. However, the data for this study were collected prospectively, and postoperative fusion rates were analyzed in detail with various measurement tools. These methods warrant accuracy of the fusion rate measurements. Second, the study did not include cases of long lumbar fusion (3 or more segments). For long fusion surgery, the mechanical properties and concentration of stress are different from those for 1- or 2-level posterior lumbar interbody fusion. Therefore, a study of long fusion surgery performed with these spacers is necessary. Nevertheless, no significant subsidence was noted after 3 months postoperatively, and no pseudarthrosis was noted without any other bone graft substitute or enhancer, such as bone morphogenetic protein or demineralized bone matrix. These results suggest that this mesh structure titanium lumbar spacer could be a valuable alternative in most cases that require posterior lumbar interbody fusion surgery.

Conclusion

Posterior lumbar interbody fusion with a newly developed 3-dimensional printed mesh structure titanium alloy spacer showed satisfactory radiographic and clinical results. No pseudarthrosis or revision was noted, including cases of posterior lumbar interbody fusion at L5-S1. The mesh-type structure and the coarse surface of the spacer seem to offer initial stability and early fusion and prevent pseudarthrosis.

References

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