OPEN Research Article

Three-Dimensional Printed Anterior Cervical Standalone Combined Cage-Plate—300 Consecutive Medical Implants

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ABSTRACT

Objective: The primary objective was to investigate the perioperative parameters and clinical outcomes of a novel three-dimensional (3D) printed titanium interbody spacer and integral screws. The secondary objective was to compare the survivorship rate of the 3D-printed titanium integrated spacer (3D-printed spacer group) with that of a polyether-ether-ketone (PEEK) integrated spacer (PEEK group) and traditional allograft spacer combined with an anterior cervical plate (control group).

Study Design: This is a retrospective study comprising 157

consecutive patients (representing 300 surgical levels) investigating the perioperative and clinical outcomes of a novel 3D-printed titanium integrated spacer for anterior cervical diskectomy and fusion (ACDF). **Methods:** A consecutive series of 157 patients (N = 300 surgical levels) presenting with cervical radiculopathy, myelopathy, or spondylosis underwent ACDF with the 3D-printed titanium spacer. Perioperative outcomes including surgical time, estimated blood loss, length of hospital stay, and number of surgical levels were collected. Clinical outcomes including the American Spinal Injury Association neurologic impairment score and Neck Disability Index (NDI) were measured preoperatively and postoperatively. Survivorship was defined as no failures, no anterior revision surgeries, no instrumentation removals, and no subsidence requiring surgery.

Results: The mean surgical time for the 3D-printed spacer group was 126.3 ± 34.0 minutes, the estimated blood loss was 85.9 ± 30.5 cc, and the length of hospital stay was 1.5 ± 1.4 days. Surgical levels were distributed as follows: 33.8% single-level, 42.7% two-level, 21.6% three-level, and 1.9% four-level ACDF procedures. 98.7% of patients in the 3D-printed spacer group reported improved American Spinal Injury Association scores. The mean NDI preoperatively was 37.2 ± 18.7 , and the mean NDI postoperatively was 21.2 ± 18.3 , with

58.6% of patients reporting NDI improvement of 15% or greater. Survivorship was observed in 97.4% of patients in the 3D-printed spacer group, 98.0% in the PEEK group, and 93.3% in the control group (chi-square analysis: X^2 [1, N = 1529] = 16.9, P = 0.0002).

Conclusion: A novel 3D-printed titanium spacer with integral screws for ACDF demonstrated improved survivorship rates compared with the traditional allograft spacer and anterior plate. Among 157 patients, only two required supplemental posterior fixation, one required removal for excessive kyphosis and were successfully revised with a 3D-printed corpectomy spacer, and one had notable subsidence at 6 weeks postoperatively (4 total failures based on the survivorship criteria; 97.4% survivorship success rate (153/157 patients)). Not a single case of neurologic progression was observed in the 3D-printed spacer group—no iatrogenic progressive radiculopathy nor myelopathy, unlike the control group.

nterior cervical diskectomy and fusion (ACDF) serves as the benchmark in the surgical management of symptomatic cervical degenerative disk disease. There are many options for reconstruction of the defect after cervical diskectomy including autogenous iliac graft, polyether-ether-ketone (PEEK) and titanium spacers with and without plate, dynamic cages, and artificial disks. While the use of intervertebral spacers and anterior plates improve stabilization of the surgical reconstruction and decrease the risks of nonunion and graft extrusion, postoperative complications including accelerated adjacent disk degeneration, esophageal perforation, and dysphagia remain a clinical concern. 1-4 To mitigate the risks associated with anterior cervical plates, zero-profile standalone intervertebral devices with integrated screw fixation have been introduced.^{5,6} Zeroprofile interbody devices are designed to be contained within the disk space, with the anterior margin of the device positioned posterior to the anterior vertebral cortex.7 While some biomechanical studies have documented a satisfactory level of mechanical stability of these devices, most have suggested that the integrated design provides less stability in flexion and extension than traditional interbody cage and anterior plate constructs.⁸⁻¹⁰

In an effort to improve stability and promote fusion using zero-profile standalone devices with integral screw fixation, various implant materials and surface-coating technologies have been introduced. Titanium has a clinical reputation for biocompatibility and durability, and in combination with a modified surface, it facilitates osseointegration. The three-dimensional (3D) printed titanium spacer to be investigated in this study comprises biomimetic porous scaffolding that serves as an osteoconductive platform for bone formation. The primary objective of the study was to investigate the perioperative parameters and clinical outcomes of a novel 3D-printed titanium interbody spacer and integral

screws. The secondary objective was to compare the survivorship rate of the 3D-printed titanium integrated spacer with that of a PEEK integrated spacer and traditional allograft spacer combined with an anterior cervical plate.²⁰⁻²²

Table 1. Intraoperative Data and Patient Demographics

3D-Printed Spacer Study Group N = 157		
Sex		
Male	72	
Female	85	
Age	59.5 (10.68)	
Race		
Caucasian	138	
African American	13	
Hispanic	2	
Asian	1	
Other	1	
OR time (min)	126.3 (34.0)	
EBL (mL)	85.9 (30.5)	
LOS (d)	1.5 (1.4)	
Surgical levels		
One level	53 (33.8%)	
Two levels	67 (42.7%)	
Three levels	34 (21.6%)	
Four levels	3 (1.9%)	
Patient status		
Adjacent segment disease	26 (16.6%)	
Previous instrumentation	14 (8.9%)	
Myelomalacia	10 (6.4%)	

LOS = length of hospital stay

Table 2. Survivorship

Allograft + plate survivorship	851/912 = 93.3%
Integrated plate, PEEK spacer + integral screws	451/460 = 98.0% ^a
3D-printed titanium spacer	153/157 = 97.4% ^a

PEEK = polyether-ether-ketone $^{a}P < 0.05$ compared with control.

Methods

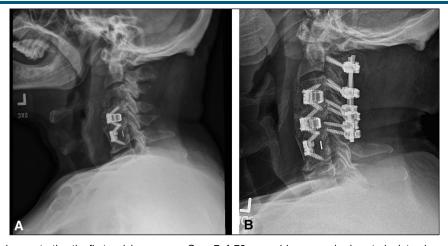
The current investigation is a retrospective review of data from a total of 157 clinical patients (300 surgical levels) receiving a 3D-printed titanium integrated spacer (HE-DRON IC spacer; Globus Medical) for single-level or multilevel ACDF in comparison with two historical control groups of 460 patients who received PEEK integrated spacers (PEEK group) and 912 patients who received allograft combined with an anterior cervical plate (control group) to determine survivorship success. Indications for surgery included objective clinical evidence of degenerative disk disease requiring an ACDF at a single or multiple intervertebral levels. The study protocol and all required documentation, as outlined by the MedStar Health Research Institute Institutional Review Board, were submitted to and approved by the MedStar Health Research Institute. The rights and privacy of all patient data were protected. No personally identifiable information was shared, and patients were identified only by a subject number.

The 3D-printed titanium spacer used in this study is an anterior cervical interbody fusion device designed to provide structural stability after cervical diskectomy in skeletally mature individuals. This zero-profile, standalone device is designed to preserve the anatomical profile and incorporates integrated screws and torsional stabilizers for intracorporeal purchase. The 3D-printed spacers are additively manufactured from titanium alloy and feature a porous scaffolding designed to promote appositional bone formation at the implant interface. The device is implanted through an anterior approach to the cervical spine and is available in various geometric options with varying amounts of lordosis to accommodate differences in patient anatomy.

Demographic and perioperative data for the 3D-printed titanium group including patient age, sex, surgical time, estimated blood loss, length of hospital stay, and number of surgical levels were recorded. The American Spinal Injury Association (ASIA) impairment score to measure neurologic status and the Neck Disability Index (NDI) to measure neck pain were evaluated preoperatively and postoperatively. Survivorship success was evaluated and compared between the 3D-printed titanium spacer group and the PEEK and control groups. Survivorship success was defined as no failures, no anterior revision surgeries, no instrumentation removals, and no subsidence requiring surgery.

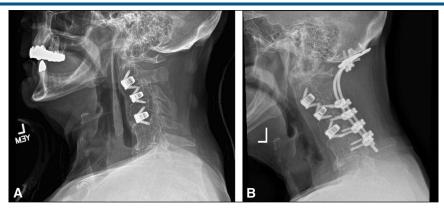
Continuous data were summarized using descriptive statistics (mean \pm SD). Categorical data were presented

Figure 1



A and **B**, Radiographs demonstrating the first revision surgery. Case 7: A 70-year-old man required posterior lateral mass supplemental fixation 2 months postoperatively for collapse at C3-C4 interspace—C2 to C5.

Figure 2



A and **B**, Radiographs demonstrating the second revision surgery. Case 19: A 65-year-old man with a tilting C2-C3 spacer required posterior occiput to C6 supplemental fixation 4 days postoperatively.

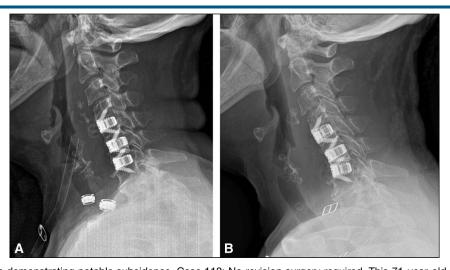
using frequency counts and percentages. Statistical analysis was conducted using IBM SPSS Statistics (SPSS v27, IBM). A Pearson chi-square test (3×2 contingency table) was used to assess differences in survivorship success between groups. Statistical significance was indicated at P < 0.05.

Results

A consecutive series of 157 patients (representing 300 surgical levels) presenting with cervical radiculopathy, myelopathy, or spondylosis underwent ACDF with the 3D-printed titanium spacer. Surgical levels were distributed as follows: 33.8% single-level, 42.7% two-level, 21.6%

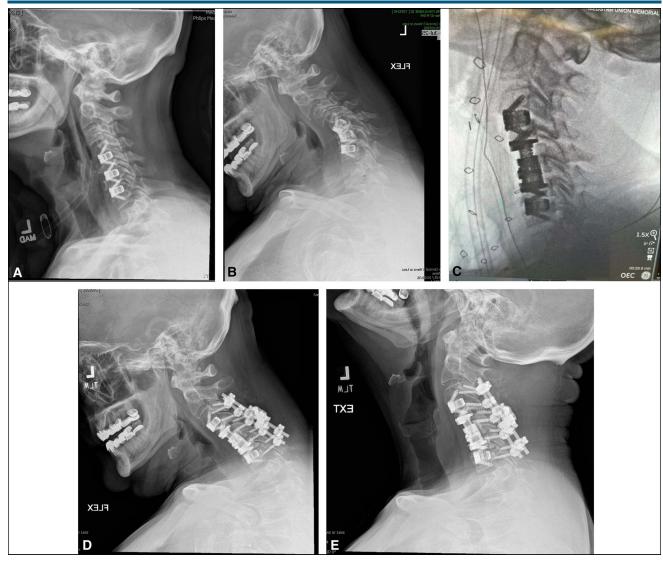
three-level, and 1.9% four-level ACDF procedures. Twenty-six procedures (16.6%) were performed because of adjacent segment disease, 14 (8.9%) were performed as revision procedures, and 10 patients (6.4%) had myelomalacia present preoperatively. Demographics of the study included 72 men (45.9%) and 85 women (54.1%). The mean age of patients in the study was 59.5 ± 10.68 years. One hundred thirty-eight patients (87.9%) were Caucasian, 13 African American (8.2%), 2 Hispanic (1.3%), 1 Asian (0.6%), and 1 (0.6%) other. The mean surgical time for the 3D-printed titanium spacer group was 126.3 ± 34 minutes, the estimated blood loss was 85.9 ± 30.5 mL, and the length of stay was 1.46 ± 1.4 days (Table 1). 98.7% of patients in the 3D-printed titanium spacer group

Figure 3



A and **B**, Radiographs demonstrating notable subsidence. Case 118: No revision surgery required. This 71-year-old woman demonstrated subsidence of the two implants on either side of the C6 vertebral body between surgery and the follow-up visit 6 weeks postoperatively. Because the implants subsided without kyphosis nor subluxation, she remains neurologically intact and asymptomatic at long-term follow-up.

Figure 4



A–E, Radiographs demonstrating the third revision surgery. Case 130: This 59-year-old man presented with myelopathy, profound right deltoid and biceps weakness, and spasticity. He underwent three-level anterior decompression, fusion, and integrated 3D spacer implantation at C4-5, C5-6, and C6-7. **A**, Unfortunately, at 3 months postoperatively, he had collapsed into osteoporotic kyphosis with persisting right arm weakness and pain (**B**). He is the only case requiring removal of any 3D implant (C4-5 and C5-6) in the entire series of 300 consecutive implants. He was successfully revised with an anterior expandable corpectomy implant, a 3D implant at C3-4, and an anterior and posterior stabilization from C3 to C7 (**C**). He recovered to intact neurologic function and is pain free and fully employed at follow-up. **D** and **E**, The lateral flexion and extension radiographs after revision surgery.

reported improved ASIA scores. The mean NDI preoperatively was 37.2 ± 18.7 , and mean NDI postoperatively was 21.2 ± 18.3 , with 58.6% of patients reporting NDI improvement of 15% or greater.

Survivorship was observed in 97.4% of patients in the 3D-printed titanium spacer group, 98.0% in the PEEK group, and 93.3% in the control group (X^2 (1, X^2 = 1529) = 16.9, Y^2 = 0.0002; Table 2).

In 157 patients with 3D-printed titanium spacer, only two patients required supplemental posterior fixation

(Figures 1 and 2), one patient had notable subsidence at 6 weeks postoperatively (Figure 3), and one patient required removals for excessive kyphosis, which were successfully revised with a 3D-printed corpectomy spacer (Figure 4). The 97.4% survivorship rate (153/154 patients) in the 3D-printed titanium spacer group was comparable with that in the PEEK group that had an observed survivorship of 98.0% (451/460 patients). It is also an improvement compared with the control group that had an observed survivorship of 93.3% (851/912 patients; Table 3).

Table 3. Control Group of 5 FDA Randomized Trials—Anterior Cervical Diskectomy and Fusion With Anterior Plate and Allograft

Study (2-Year FDA Results)	Revision Surgeries	Control Group ^a
Prodisc C	9	106
Murray et al, Spine Journal 2009		
Bryan	8	221
Heller et al, Spine 2009		
Prestige	24	268
PMA FDA SSE 2012		
Secure-C	10	133
PMA FDA SSE 2012		
PCM	10	184
Phillips et al, Spine 2013		
Totals	61	912

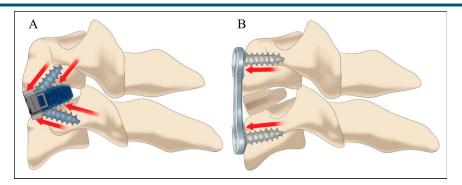
PCM = porous coated motion, PMA = premarket approval, SSE = summary of safety and effectiveness ^aTotals in the control group at 24 months.

Discussion

Anterior plates and intervertebral spacers are often used in ACDF procedures to improve segmental stability while decreasing risks of nonunion and graft extrusion. However, anterior plating has been associated with various complications including soft-tissue damage and dysphagia. To address these concerns, zero-profile standalone spacers with integrated screws have been developed as an alternative to traditional anterior cervical plates. Numerous studies, including finite element analyses and biomechanical and clinical evaluations, have compared zero-profile standalone spacers with traditional plate and spacer constructs. 6,24-29 Some studies have found that zero-profile standalone implants

offer comparable fusion rates and biomechanical stability while demonstrating lower incidence of postoperative dysphagia when compared with plate and spacer systems.^{6,24,30,31} However, conflicting rates of subsidence and subsequent rates of revision surgery with the use of zero-profile standalone spacers have also been reported.^{24,32,33} Nemoto et al³³ compared the clinical and radiological outcomes of ACDF using a standalone anchored spacer with those of a plate and spacer construct and reported a subsidence rate comparable between both groups. By contrast, Liu et al²⁴ conducted a meta-analysis of 12 studies on complication rates of zero-profile anchored spacers compared with plate-cage constructs and found that zero-profile spacers had a higher subsidence rate compared with plate-cage

Figure 5



A and **B**, Illustration of the Wolff law. (**A**) Representative image of a 3D-printed titanium spacer with integrated screws using the Wolff law. The integrated screws cross the interface where the fusion occurs and provide a lag effect allowing for compressive fixation. **B**, Representative image of a traditional anterior cervical plate and spacer construct that does not use the Wolff law. The screws run parallel with the vertebral end plate that does not generate compressive forces across the bone-graft interface.

Figure 6



Radiograph demonstrating stress concentration at the end of the multilevel plate and spacer construct.

constructs. This study found that integrated standalone spacers demonstrated a greater survivorship rate compared with a traditional allograft spacer and anterior cervical plate.

In traditional anterior cervical plating, screws are inserted anterior to posterior, running more or less parallel with the vertebral end plate. This screw orientation does not generate compressive forces across the bone-graft interface (Figure 5, B). The 3D-printed titanium spacer with integrated screws used in this study employs a screw trajectory starting from the anterior portion of the spacer, crossing the bone-implant interface, and following a diagonal course (Figure 5, A). Unlike the parallel screws in anterior cervical plating, integrated screws cross the interface where the fusion occurs and provide a lag effect allowing for compressive fixation. This design leverages the Wolff law, which states that bones will adapt to mechanical stresses and loading over time. Mechanical loading promotes bone remodeling, enhancing the strength and structure of the bone in response to increased forces.³⁴ If the bone is not osteoporotic, the surgeon often visualizes the bone marrow actually extruding from the vertebral body as the diagonally placed screws are tightened down. The compression across the bone-implant interface may increase the chance of successful fusion taking place. Furthermore, standalone integrated spacers allow for independent concentration of stresses at each level in long fusion constructs. By contrast, the stress accumulates and is unfavorably concentrated at the ends of multilevel plate and spacer constructs, which could potentially increase the risk of construct failure (Figure 6).

Implant material and design affect subsidence and fusion rate.³⁵ The 3D-printed titanium spacers used in this study are additively manufactured from titanium alloy and feature a porous scaffolding designed to mimic a bone-like trabecular structure, promoting bony ingrowth.³⁶ This porous design offers an advantage over solid titanium by reducing the elastic modulus to one similar to bone, thereby potentially reducing the risk of subsidence. While PEEK implants also have a modulus of elasticity similar to bone, their biochemical properties may lead to fibrous tissue formation around the implant surface.¹² By contrast, the 3D-printed titanium spacers have a microscale surface roughness designed to promote appositional bone formation at the implant interface.^{12,13,15}

Conclusion

A novel 3D-printed titanium spacer with integral screws for ACDF demonstrated improved survivorship results compared with a traditional allograft spacer and anterior plate. Most of the patients with a 3D-printed titanium spacer had at least a one-grade improvement in their ASIA neurologic score, and their average NDI score decreased by half. These results suggest that, objectively and subjectively, the 3D-printed titanium integrated spacer works as an ACDF device that alleviates patient symptoms that qualify them for an ACDF procedure.

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