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Twelve-Month Fusion Outcomes of Three- and Four-Level Anterior Cervical Discectomy and Fusion Using a 3D-Printed Fully Porous Polyetheretherketone Interbody Implant

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Abstract

Background

When conservative treatments fail to treat cervical degenerative disc disease (DDD) and/or instability, anterior cervical discectomy and fusion (ACDF) is a widely used and effective surgical approach. ACDF is commonly performed for one- or two-level cervical disc disease but is increasingly used to treat multi-level pathology, as degenerative cervical spine pathology may affect three or more levels. However, data regarding the radiographic outcomes of long-segment (⩾3-level) ACDF using contemporary-era interbody implants are limited. This study aimed to report 12-month fusion rate outcomes following three- and four-level ACDF using a novel 3D-printed, fully porous, trabecular polyetheretherketone (PEEK) interbody implant.

Methods

This ambispective cohort study included 43 patients identified from a consecutive surgical series who underwent three- or four-level ACDF using the 3D-printed porous PEEK interbody implant and anterior plating. Twelve-month postoperative outcomes are reported. Fusion status was assessed using CT by multiple independent, blinded reviewers, flexion/extension X-ray analysis, and a composite score of both.

Results

A total of 43 patients (152 treated levels), with a mean age of 61.5 years and a mean BMI of 31.2, were included. Twenty-three patients (53.5%) underwent a four-level ACDF, and 20 (46.5%) underwent a three-level ACDF. Successful fusion was observed at 95.4% of treated levels. On a per-patient basis, 86% were fused by CT at all treated levels.

Conclusion

This 3D-printed, fully porous trabecular PEEK interbody implant achieved high fusion across both per-level and per-patient assessments in three- and four-level ACDF at 12 months, with low rates of revision or symptomatic nonunion. These findings support its use in long-segment cervical reconstruction, though longer-term follow-up is warranted to confirm the durability of fusion.

Categories: Orthopedics, Healthcare Technology, Neurosurgery
Keywords: 3d-printed peek, acdf, cervical fusion, multi-level, trabecular peek cage

Introduction

Cervical degenerative disc disease (DDD) can result in significant pain, instability, and radiculopathy and/or myelopathy [1]. The causes of these symptoms can include loss of disc height, loss of foraminal area, and disc bulging or protruding osteophytes that cause neural compression, all of which may result in pain and disability [2,3]. When conservative treatments fail, anterior cervical discectomy and fusion (ACDF) is a widely used and effective surgical approach to treat cervical DDD and/or instability [4].

ACDF is widely used to treat multi-level spine disease [5]. However, data regarding the outcomes of long-segment (⩾3-level) ACDF are limited and conflicting, with previous studies reporting fusion rates between 11.1% and 100% [6-9]. Despite these reports, contemporary series continue to identify concerning pseudoarthrosis rates and implant-related complications in multi-level ACDF, particularly at the caudal levels of the constructs [6-11]. Moreover, there is valid concern about higher rates of nonunion in long-segment ACDF, adverse events, and revision surgeries compared to one- and two-level ACDF procedures [10,11].

Precise operative techniques and appropriate patient and interbody fusion device selection are essential for restoring the normal physiological curvature of the vertebrae, rebuilding spinal stability, and obtaining fusion, especially with an increased number of mobile segments, surface area, and motion arm across the fusion construct in long-segment ACDF [3,5,12]. Accordingly, there is growing interest in interbody technologies that can improve osseointegration while maintaining favorable biomechanical and imaging characteristics in this high-risk setting [6-9,11,13].

The ideal interbody fusion material should be biocompatible with appropriate mechanical strength, facilitate osteoconductive bone growth throughout the implant and osseointegration at the implant-bone interface, and provide sufficient fatigue resistance to withstand the repetitive mechanical loading of the spine [12].

Conventional (nonallograft) interbody devices are fabricated from polyetheretherketone (PEEK) and titanium alloy materials; however, legacy PEEK implants are hydrophobic and lack osteoconductive properties [13]. Titanium implants provide high strength and can be engineered with sophisticated surfaces to promote bone ingrowth, but their radiopaque nature and potential stiffness mismatch with host bone may complicate fusion assessment and increase the risk of subsidence [9,13].

Implant materials have recently evolved as advancements in engineering and manufacturing techniques have expanded 3D printing capabilities, enabling the production of implants with a fully porous, trabecular-like architecture that combines the load-sharing and imaging advantages of PEEK with the osseointegrative benefits of a trabecular bone-like lattice [10,11]. The primary objective of this study was to report 12-month radiographic fusion outcomes following three- and four-level ACDF using a novel 3D-printed, fully porous trabecular PEEK interbody implant. Secondary objectives included assessing device-related complications, reoperations, and hospital length of stay.

Materials And Methods

This was an ambispective cohort study, which consisted of retrospective identification of surgical procedures and baseline characteristics, followed by prospective collection of 12-month primary and secondary endpoint data under Institutional Review Board (IRB) oversight. The study received IRB approval in June 2025 and was conducted until October 2025. Medical records were reviewed to identify consecutive patients who underwent surgery between April 2023 and December 2024 and to screen them for eligibility. A total of 68 consecutive patients who underwent three- or four-level anterior cervical fusion using a 3D-printed porous PEEK interbody fusion implant (Inspire, Curiteva Inc., Huntsville, Alabama) (Figure *1*) for the treatment of cervical DDD were identified. All procedures were performed by a single surgeon over a 20-month period.



FIGURE 1: 3D-printed porous trabecular polyetheretherketone (PEEK) interbody implant

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Surgical technique

A standard anterior cervical approach was used in all cases. Following anterior exposure and fluoroscopic level confirmation, discectomy and endplate preparation were performed to achieve neural decompression and optimize the fusion surfaces while preserving bony endplate integrity. Interbody implant sizing was determined intraoperatively using trial spacers to restore disc height and alignment. Interbody cages were packed with a combination of graft materials, including autograft, allograft, demineralized bone matrix (DBM), and/or synthetic graft, and were inserted under fluoroscopic guidance. All patients underwent anterior plate fixation across the treated levels using standard plating principles to provide construct stability and maintain alignment.

Postoperative protocol

Postoperative management included routine cervical orthosis use, activity restrictions limiting heavy lifting and excessive cervical motion, and scheduled clinical and radiographic follow-up to assess recovery, alignment, and fusion progression.

Screening and enrollment

Prior to performing the prospective assessments, informed consent was obtained from participants. All research-related questions were addressed, and participants provided written consent using the IRB-approved form. Eligible patients were consecutive individuals who underwent ACDF using this specific PEEK interbody fusion implant at three or four cervical levels, were at least 18 years of age, and had postoperative

imaging obtained at a minimum of 12 months (defined as equal to or greater than 10 months), including two-view radiographs (lateral flexion and lateral extension) and a CT scan, or were willing to obtain imaging per the study protocol. Patients were excluded if they were incarcerated, had an active infection, were undergoing treatment for medical conditions known to affect bone density, or had active or suspected malignancy.

Of the 68 eligible patients, nine declined to participate in the study, and 16 patients could not be reached despite multiple contact attempts. All consecutive patients were identified, screened, and invited to participate, resulting in a final study population of 43 patients and 152 treated levels.

Primary endpoint

The primary endpoint of the study was radiographic fusion at approximately 12 months postoperatively. Fusion was defined as a CT fusion grade of 3A or 2A (complete bridging bone, or cranial downgrowth and caudal upgrowth; no sign of supplemental fixation failure). The numeric-alpha scale of CT grades for bridging bone is provided in Figure *2* [14]. CT imaging was interpreted by two independent reviewers who were blinded to clinical outcomes. If the two primary reviewers disagreed, a third independent, blinded reviewer adjudicated the assessment based on a majority-rule tie-break determination.



FIGURE 2: Fusion grading criteria for CT imaging

Numeric classification:

0 = No bony ingrowth

1 = Cranial downgrowth OR caudal upgrowth

2 = Cranial downgrowth AND caudal upgrowth but NOT bridging

3 = Complete bridging trabecular bone fusion

Alpha classification:

A = No evidence of supplemental fixation failure/no halo seen

B = Evidence of supplemental fixation failure/halo seen

Permission was obtained from the original publisher [14].

Flexion and extension X-rays were analyzed using an FDA-cleared AI software tool (SpineCamp™, Medical Metrics, Inc., Houston, Texas). The AI tool reported angular and translational motion at each treated level. If a level was not adequately visualized on the X-ray, a result could not be obtained, and that level was excluded from the X-ray and composite fusion analyses. Fusion was defined as less than five degrees of angular motion and less than 3 mm of translational motion on flexion/extension X-ray [15,16]. A composite fusion grading was also evaluated, combining both CT and X-ray evaluations.

Fusion outcomes were primarily reported on a per-level basis to account for the level-dependent nature of fusion in multi-level (3-4 level) ACDF constructs, where variability between segments, particularly at more caudal levels, is well documented.

Secondary endpoint

Secondary endpoints included length of stay, interbody device-related complications, and revision or reoperation within the 12-month postoperative period. Postoperative progress notes were reviewed to identify and document all complications, including dysphagia and subsidence, along with associated treatments and their resolution status. The surgeon assessed the severity of each adverse event and its relationship to the device.

Statistical analysis

Descriptive analyses were performed for all primary and secondary endpoints. The 95% confidence intervals were calculated using the Wilson method. Analyses were performed using Microsoft Excel, Version 16.0 (Microsoft Corporation, Redmond, Washington), and IBM SPSS Statistics for Windows, Version 28 (Released 2021; IBM Corp., Armonk, New York).

Results

Patient demographics are presented in Table *1*. The mean age was 61.5 years, and 58.1% were female. The mean BMI was 31.2, with 86.0% (37/43) of the cohort overweight, obese, or extremely obese. Two patients were current tobacco users (4.8%), and one had a previous fusion (2.3%).

Patient characteristic	N	Value or n	% or Min/Max
Mean age (years)	43	61.5	28/83
Sex	43		
Male		18	41.9%
Female		25	58.1%
Mean BMI	43	31.2	19.8/53.3
Underweight (<18.5)		0	0.0%
Normal (18.5-24.9)		6	14.0%
Overweight (25-29.9)		15	34.9%
Obese (30-39.9)		18	41.9%
Extremely obese (>40)		4	9.3%
Comorbidities			
BMI > 25	43	37	86.0%
Current tobacco use	42	2	4.8%
Previous surgery	43		
Fusion		1	2.3%

TABLE 1: Demographics

BMI: body mass index.

Twenty patients (46.5%) underwent a three-level procedure and 23 (53.5%) underwent a four-level ACDF. All cases were performed with an interbody fusion implant, graft placement, and anterior cervical plating. None of the patients received primary posterior fixation. The mean length of hospitalization was 1.1 days. Table *2* presents the operative details for the study population.

Surgical characteristic	n	% or Mean (Min, Max)
Number of levels		
Three-level	20	46.5%
Four-level	23	53.5%
Total procedures	43	100.0%
Treated levels		
C2-C3	1	0.7%
C3-C4	28	18.4%
C4-C5	41	27.0%
C5-C6	42	27.6%
C6-C7	38	25.0%
C7-T1	2	1.3%
Total levels	152	100.0%
Graft material		
Autograft + Allograft + DBM	16	37.2%
Autograft + Allograft + Synthetic	16	37.2%
Autograft + Allograft + DBM + Synthetic	11	25.6%
Ave. blood loss (mL)		81.3 (range 50-200)
Ave. length of stay (days)		1.1 (range 1-2)

TABLE 2: Operative details

DBM: demineralized bone matrix.

Radiographic outcomes

The mean follow-up was 14.5 months (range, 10-23 months). Based on CT criteria, 95.4% of all treated levels were graded as fused. On dynamic flexion/extension X-ray imaging, 90.2% of treated levels demonstrated fusion. When a composite definition requiring both CT fusion and dynamic radiographic stability was applied, 87.2% of treated levels achieved fusion. In the per-patient analysis, 86% of patients were graded as fused by CT (fusion present at each level) (Tables *3*, *4*).

Criteria	N	n (%)	95% Confidence Interval (CI)
CT	152	145 (95.4%)	(90.8-97.8)
X-ray*	133	120 (90.2%)	(84.0-94.2)
Composite	133	116 (87.2%)	(80.5-91.9)

TABLE 3: Fusion by levels

*X-ray analysis could not be performed on 19 levels due to limitations in image quality related to patient body habitus.

Operative level	N	CT n (%)	N	X-ray n (%)	N	Composite n (%)
C2-C3	1	1 (100%)	1	1 (100%)	1	1 (100%)
C3-C4	28	25 (89.3%)	28	27 (96.4%)	28	25 (89.3%)
C4-C5	41	41 (100%)	39	39 (100%)	39	39 (100%)
C5-C6	42	42 (100%)	38	36 (94.7%)	38	36 (94.7%)
C6-C7	38	34 (89.5%)	27	17 (63.0%)	27	15 (55.6%)
C7-T1	2	2 (100%)	0	-	0	-

TABLE 4: Fusion by levels treated

Clinical outcomes

Four patients required reoperations with posterior supplemental fixation: pseudarthrosis (n = 2), adjacent segment disease (n = 1), and an endplate fracture (n = 1) secondary to a fall two months postoperatively. Two patients required surgical evacuation for postoperative hematomas.

Nine patients (20.9%) reported dysphagia as noted by the treating surgeon and were treated conservatively until resolution. Symptomatic subsidence as noted by the treating surgeon was observed in four subjects (9.3%) and did not require reoperation. There were no device-related complications.

Discussion

ACDF is a well-established approach in which the intervertebral disc is removed through an anterior approach and an implant is placed between the two vertebral bodies to maintain foraminal height, and ideally, bone fusion is achieved [17,18]. One- and two-level ACDF is well documented in the literature, with fusion rates reported in randomized controlled trials ranging from 82.0% to 97.5% at one level and from 79.8% to 82.1% at two levels [19-27]. Increasingly, ACDF is being performed across more than two levels, where an increased number of mobile segments, surface area, and motion are present across the fusion construct [3,5]. However, long-segment (≥3-level) ACDF has consistently been associated with higher pseudarthrosis rates, adverse events, and revision surgeries compared to one- or two-level procedures, leading many surgeons to consider concomitant posterior fixation in high-risk cases [6-12,28-31].

A recent randomized trial of three-level ACDF demonstrated that anterior-only structural allograft constructs achieved fusion in only one-third of patients and required revision in nearly one-quarter [11]. Adding posterior fixation improved fusion rates and reduced the need for revision surgery; however, these benefits came at the cost of longer operative times, additional blood loss, and increased resource utilization [5,11,12,28-34]. These data underscore the challenging nature of multi-level ACDF and the desire for strategies that can reliably achieve fusion without routine use of posterior instrumentation.

In the current study, using a fully porous trabecular PEEK interbody implant with anterior plating resulted in fusion rates of 90.2% based on dynamic X-rays and 95.4% based on CT, with a low incidence of clinically relevant nonunion and only 2 of the 43 patients (4.7%, 95% CI: 1.3-15.5) requiring revision surgery for pseudarthrosis. Figures *3A*-*3C* illustrate a representative case of a successful multi-level fusion. With fusion confirmed using both CT and quantitative dynamic radiography, anterior-only multi-level ACDF with this implant achieved fusion rates that compare favorably with those reported in many historical multi-level cohorts [3,4,6-9].

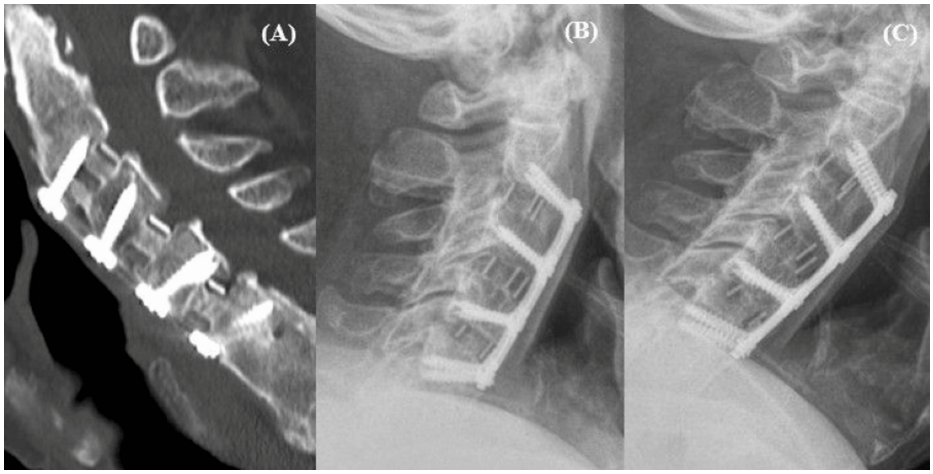


FIGURE 3: (A) A CT scan, (B) flexion, and (C) extension X-rays for an illustrative fusion case

Prior studies support combining CT assessment of bridging bone with flexion-extension radiographs to assess fusions with high sensitivity and specificity [30,31]. In the current study, fusion on CT was defined as complete bridging bone, or cranial downgrowth and caudal upgrowth, with no sign of supplemental fixation failure, and fusion on dynamic radiographs as less than 5 degrees of angular motion and less than 3 mm of translational motion. This composite approach to assessing bridging bone and residual motion aligns with Food and Drug Administration (FDA) guidance [12]. Despite the challenging biomechanics and multiple implant-bone interfaces in multi-level ACDF, the current study yielded a high composite fusion rate of 87.2% based on CT and dynamic X-rays.

A systematic review reported pseudarthrosis rates of 37.3% for three-level and 33.3% for four-level procedures without significant difference between the two [34]. Although complete fusion is associated with a greater likelihood of sustained symptom relief, stable nonunions can occur [11]. Jack et al. reported a fusion rate of greater than 80% in 48 patients undergoing four-level ACDF, with no patients requiring reoperation for nonunion [35]. Stable asymptomatic pseudarthrosis rates of 33% have been reported in one-, two-, and three-level ACDF patients [32]. In the current study, asymptomatic pseudarthrosis (at one or two levels) was observed in 9.3% of patients and did not require reoperation.

Reported rates of subsidence and dysphagia after multi-level ACDF vary widely, with subsidence described in up to 21% of cases and dysphagia in approximately 6-7% [36-38]. In our cohort, subsidence occurred in 9.3% of patients, with no subsidence-related reoperations, despite a high prevalence of elevated BMI and female sex, both of which have previously been associated with an increased risk of subsidence. Dysphagia was more common in our series (20.9%) than in prior reports, although all cases were managed conservatively and none required further intervention [10,11].

Correlating basic science results with clinical outcomes can be difficult; however, the high fusion rates in this cohort series are consistent with the biologic mechanisms described by Cohen et al. for this implant [39]. In that study, the 3D-printed porous PEEK enabled rapid mesenchymal stem cell (MSC) colonization, osteoblastic differentiation, and elevated vascular endothelial growth factor (VEGF) without osteogenic media. Hydrophilic hydroxyapatite (HA) nanocrystals on the PEEK struts enhanced protein adsorption and MSC attachment and shifted macrophage signaling toward a more pro-regenerative, VEGF-rich milieu, favoring early vascular invasion and bone formation rather than the fibrous encapsulation typically seen with legacy smooth PEEK. These factors support our observed robust bone through growth, lack of halo or erosive changes, and high CT-confirmed bridging across multiple levels, contrasting historical pseudarthrosis risks with traditional allograft or solid PEEK implants.

Porous and trabecular interbody designs have been developed to enhance osseointegration while preserving favorable mechanical and imaging characteristics compared with smooth PEEK or traditional metal cages [11-13,40]. In a multi-center series of porous-surface PEEK cages for ⩾3-level ACDF, fusion was reported to be 97% with a pseudarthrosis rate of 3%. Other porous or HA-enhanced PEEK implants have shown similarly high fusion rates, although these findings have been reported mainly in 1-2 level constructs [6,7,10,41]. Within this context, our results show per-level- and per-patient data showing high fusion rates and low revision for pseudarthrosis in three- and four-level ACDF using this novel PEEK implant in a cohort of patients with elevated BMI and other risk factors [1,3-5].

Limitations

This study has several limitations. It was a single-surgeon, nonrandomized study, which introduces potential bias. To mitigate selection bias, consecutive patients were identified, and all eligible patients were invited to participate. Nine declined participation, and 16 could not be reached for consent and follow-up, raising the possibility of nonresponse bias, although no patients were excluded based on clinical characteristics. Variability in graft composition may also have acted as a confounder. Larger, multi-center studies with standardized grafting protocols are needed to isolate its effect on fusion outcomes and to improve generalizability. Hardware artifact on CT is a further limitation, although its impact was mitigated by a standardized single-center radiographic protocol and independent grading by two blinded reviewers, with third-reviewer adjudication of discrepancies. Formal interobserver reliability statistics were not calculated. A predefined quantitative threshold for subsidence was not applied. Future studies should incorporate standardized radiographic subsidence criteria as a potential formal endpoint. The AI-based motion and strain analysis required adequate radiographic visualization, and the caudal level was not visible at 19 levels, limiting assessment and potentially affecting the composite fusion denominator. Nonetheless, this tool provided standardized, objective measurements that may have strengthened the robustness and reproducibility of fusion assessment.

Conclusions

In this cohort of 43 patients undergoing three- or four-level ACDF, the 3D-printed, fully porous trabecular PEEK implant achieved high 12-month fusion rates, with low rates of revision surgery and symptomatic nonunion. These findings suggest that an anterior-only construct with this implant can achieve fusion in long-segment ACDF without the routine use of posterior supplemental fixation. They also support a patient-specific approach in which circumferential fusion is reserved for the highest-risk constructs rather than applied uniformly to all multi-level cases. Longer-term follow-up and larger multi-center studies are needed to confirm the durability of fusion and the broader generalizability of these findings.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Acquisition, analysis, or interpretation of data: Isabella Lucyk, Adaire O'Brien, Paul Slosar, Christopher C. Harrod

Drafting of the manuscript: Isabella Lucyk, Paul Slosar

Critical review of the manuscript for important intellectual content: Isabella Lucyk, Marcus B. Stone, Adaire O'Brien, Paul Slosar, Christopher C. Harrod

Concept and design: Marcus B. Stone, Christopher C. Harrod

Supervision: Marcus B. Stone

Disclosures

Human subjects: Informed consent for treatment and open access publication was obtained or waived by all participants in this study. Western Institutional Review Board issued approval 20251998. The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki and its subsequent amendments. The study was approved by the Western Institutional Review Board-Copernicus Group (WCG IRB) (IRB Study No.: 20251998), and informed consent was obtained from all individual participants requiring a prospective visit. **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** This study was financially supported by Curiteva Inc. (Huntsville, Alabama). **Financial relationships:** Paul Slosar declare(s) personal fees from Curiteva. Isabella Lucyk, Adaire O'Brien, Marcus Stone declare(s) Institutional payment received for the conduct of the study and writing of manuscript. from Curiteva. Christopher C. Harrod declare(s) personal fees and royalties from Curiteva. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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