



Research Article

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Early Clinical Outcomes Comparing Porous PEEK, Smooth PEEK, and Structural Allograft Interbody Devices for Anterior Cervical Discectomy and Fusion

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Abstract

Background: Recently, material surface advancements have been promoted to improve spinal implant osseointegration. While rough and porous titanium implants have gained traction due to their osteoconductive properties, polyetheretherketone (PEEK) devices have remained popular due to their radiographic properties and similar modulus of elasticity to bone. However, traditional smooth PEEK devices elicit fibrous tissue responses leading to poor implant osseointegration. Recently, PEEK implants have been developed with surface porosity allowing for direct bone in-growth. Despite preclinical data suggesting implant osseointegration with porous PEEK implants, comparative clinical results between implants with and without porous surface architecture are heretofore reported. The objective of this single-site retrospective study was to comparatively evaluate early clinical efficacy in patients undergoing ACDF treated with porous PEEK interbody implants to patients treated with structural allograft or traditional smooth PEEK implants.

Methods: 167 consecutive patients presenting with cervical degenerative disc disease and radiculopathy underwent ACDF using one of three implants (porous PEEK (Cohere®, NuVasive Inc., San Diego, CA), structural allograft, or smooth PEEK). After pre-op evaluation and surgery, patients were followed per standard of care 0.5, 1.5, 3, 6, and 12 months post-op. At each time, patient outcomes were measured by disability (Neck Disability Index) and pain (visual analogue score (VAS) neck/arm pain).

Results: Patients treated with porous PEEK implants achieved significantly greater NDI and neck pain improvement by 6 weeks post-op when compared to patients receiving structural allograft or smooth PEEK devices. These significantly greater NDI and neck pain improvements for patients treated with porous PEEK devices compared to structural allograft and smooth PEEK were sustained through 12 months post-op.

Conclusion: 12 month follow-up data in patients with degenerative disc disease and radiculopathy demonstrates a clear benefit of porous PEEK in promoting improved early outcomes over structural allograft and smooth PEEK in ACDF procedures.

Keywords

Porosity; Porous PEEK; Structural allograft; Smooth PEEK; ACDF; Fusion; In-growth; Radiolucent

Introduction

Cervical degenerative disc disease (DDD) can lead to debilitating pain and motor weakness. The primary route of care involves physical therapy and pain management [1]; however, if these approaches fail to provide symptomatic relief, surgery can deliver cervical decompression to alleviate these symptoms [2]. Successful anterior cervical discectomy and fusion (ACDF) procedures require anterior cervical decompression, removal of diseased or degenerated disc, removal of radial osteophytes and bone spurs, and enlargement of the central foramen, which can lead to effective decompression, restoration of cervical lordosis, and restoration of intervertebral height. In order to increase stability after removal of the diseased disc, a rigid graft (interbody spacer/implant/cage/device) is placed in the intervertebral space to maintain decompression and disc space height, and a metal plate with screws is attached to fixate the adjusted adjacent levels to mediate fusion of the adjacent vertebral bone [3-9].

Interbody spacers made of iliac crest autograft bone and cadaver-derived structural allograft bone were once the gold standard for ACDF procedures, adding stability and maintaining intervertebral disc space height during fusion, while also providing osteoinductive and osteoconductive properties, respectively [8-15]. The desire to eliminate the need for a second surgical site with potential for host site morbidity motivated the shift towards allograft spacers [12,15]. While structural allograft interbody spacers are popular for 1-level fusions due to their perceived high fusion rates [8,10,15], fusion rates decrease with multi-level fusions and allograft spacers subside or collapse more than autograft spacers [12,16]. In addition, the time it takes for full fusion to occur is debatable, and allograft spacer use presents a race between resorption of the non-viable spacer and fusion across the intervertebral space [13], which can result in loss of intervertebral height either due to resorption or subsidence [12,13,16]. Additionally, in patients with comorbidities such as smoking or diabetes, non-unions are more likely to occur [17].

Synthetic interbody devices have gained popularity due to concerns of host-site morbidity with autograft spacers and donor variability with allograft spacers [12,18]. Polyetheretherketone (PEEK) is a popular polymer for spine and orthopaedics use due to its radiolucency, which allows for easy radiographic assessment of fusion and a modulus of elasticity that closely mimics that of native cortical bone [19]. While PEEK interbody spacers have gained popularity, traditional smooth PEEK devices do not typically support osseointegration and can potentially induce fibrous tissue responses leading to radiolucencies around the device or even a “PEEK-halo effect” in radiographs that indicates poor osseointegration [20]. This lack of osseointegration of the device can cause micro-motion of the device in the intervertebral space leading to delays in fusion and

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motion of the segment in the intervertebral space. This can then be followed by loss of segmental lordosis, non-unions, or migration of the spacer out of the intervertebral space, possibly leading to physical pressure of the spacer on sensitive nervous tissue.

In order to provide synthetic interbody devices that actually promote an osteogenic response to facilitate fusion, the use of titanium and titanium alloys, which can be readily modified to create rough or porous surfaces shown to be osteoconductive, have gained traction in the spine as well. Specifically, porosity has consistently been shown to elicit a greater osteoconductive response and stronger implant osseointegration compared to either micro- or nano roughness [21-24]. However, titanium is radioopaque on X-ray and CT imaging and has a modulus of elasticity that is 50 times greater than native cortical bone [19]. This modulus mismatch between titanium and bone can promote undesired consequences such as subsidence and implant migration that can potentially lead to loss of intervertebral height, and compression on surrounding neural tissue. Given these shortcomings of titanium, recent efforts have focused on improving the ability for PEEK to osseointegrate to bone by making it porous.

Novel PEEK interbody devices with surface porosity have been developed that present a seamless transition from solid PEEK to surface porous PEEK that mimics the structure of vertebral bone and is resistant to expulsion, compression, and shear [25-28]. Preclinical data shows that a specifically optimized porous architecture at the interbody surface promotes bone in-growth with an osseointegration strength that is stronger than rough titanium surfaces and just as strong as that achieved with porous titanium devices [25,29,30]. Clinically, these porous PEEK devices for cervical fusion have exhibited desirable outcomes in a prospective case series of 50 consecutive patients including those with debilitating comorbidities that typically inhibit fusion [31]. Despite these clinical data and extensive preclinical data showing interbody devices with rough or porous surfaces improve osseointegration no published comparative study currently shows a clear clinical improvement due to these osteoconductive surfaces. The objective of this single site retrospective study was to compare early radiographic and clinical outcomes in patients undergoing ACDF treated with a porous PEEK device to those treated with either a structural allograft spacer or a smooth PEEK spacer with no differences in anterior fixation instrumentation or graft aperture packing material.

Methods

The present study is a retrospective comparative study to evaluate the role of three different interbody fusion materials on early outcomes in patients undergoing ACDF. This study includes patients on which ACDF was performed at Baptist Health Hospital and Mercy Health-Lourdes Hospital with all pre-operative and post-operative procedures performed at The Orthopaedic Institute of Western Kentucky in Paducah, Kentucky.

ACDF was performed on 189 consecutive patients in whom a total of 380 cervical levels were operated. All patients received a standard cervical interbody fusion procedure in which the interbody spacer was packed with a cellular allograft material and accompanied by anterior fixation with standard plates and screws [5,6,8,32]. The only difference among the patients was the choice of interbody material used in the fusion procedure. The first 42 patients enrolled (93 levels) received a structural allograft interbody spacer (ALLOFUSE[®] Cervical Graft, AlloSource, Centennial, Colorado, USA), the next 61 patients (115 levels) received a standard smooth PEEK interbody spacer

(BRECKENRIDGE[™], Zimmer-Biomet, Warsaw, Indiana, USA), and the final 86 patients (172 levels) received a porous PEEK interbody fusion device (COHERE[®], NuVasive, San Diego, California, USA). All patients were followed up to 12 months post-operatively. Inclusion and exclusion criteria are provided in Table 1.

The medical procedures performed by the study surgeons followed standard-of-care procedures for these cases and did not expose patients to more-than-minimal-risk. Institutional Review Board (IRB) approval was obtained, but due to the retrospective nature of the study and non-randomization, informed consent by the IRB was not required. Patients were not given a choice of interbody material and the interbody material used was purely based on which interbody material was preferred by the surgeon at the time of the procedure. All patient data were de-identified in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Demographics, comorbidities, and operative details

Patient demographics, relevant comorbidities, and operative details were analyzed in the patient data set to determine if any of these variables were differentially distributed among the three patient groups. With regards to patient demographics, age at time of surgery, body mass index (BMI), and patient sex were included. As for relevant comorbidities, smoking status and whether a patient was diabetic, hypertensive, or arthritic were analyzed among all groups. Finally, the number of operated levels among the three groups was included.

Outcome measures

At pre-op and post-op visits, patients were evaluated for neck function by the Neck Disability Index (NDI), a modification of the Oswestry Lower Back Disability Index [33], and the Visual Analog Pain Scale (VAS) for neck and left/right arm pain. Data for NDI scores and pain scores are presented as improvement at each follow-up compared to baseline pre-op scores due to patient-specific differences in baseline scores.

Statistical analyses

All statistical analyses were performed using GraphPad Prism 8.0. Categorical data such as patient demographics, comorbidities, and operative details were examined by Fisher's exact test. Time point specific outcome data were analyzed by one-way Browne-Forsythe and Welch analysis of variance (ANOVA) followed by the Tamhane T2 test for multiple comparisons due to unequal variances and unequal sample sizes among the groups. NDI and neck pain score improvements over time were analyzed by least-sum-of-squares non-linear regression to determine a best-fit curve function.

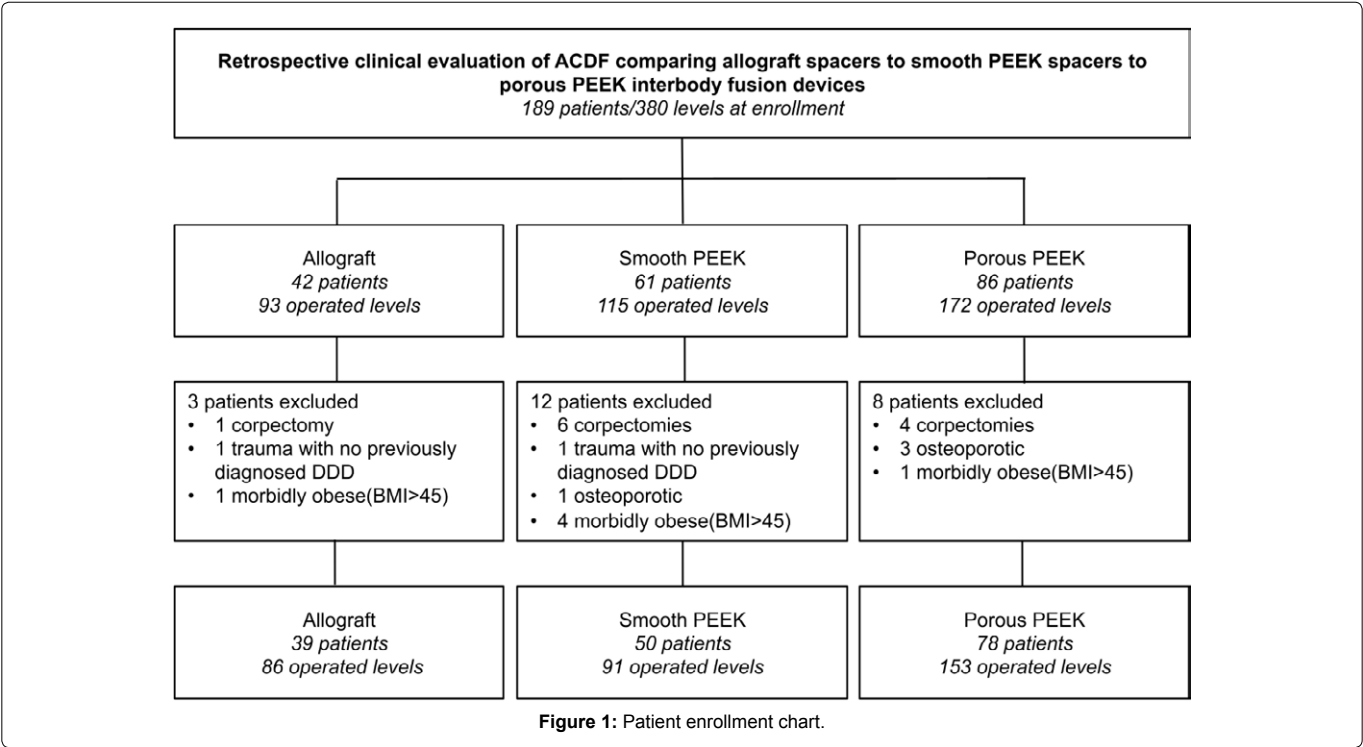
Results

A total of 189 total patients between January 2015 and December 2017 underwent a standard ACDF procedure. The first 42 patients (93 levels) received a structural allograft interbody spacer, the next 61 patients (115 levels) received a standard smooth PEEK interbody spacer, and the final 86 patients (172 levels) received a porous PEEK interbody fusion device. A patient enrollment chart is provided in Figure 1. From the group of patients treated with structural allograft, 1 patient was excluded because a corpectomy was required, 1 was excluded because the patient suffered cervical trauma with no previously diagnosed degenerative disc disease (DDD), and 1 patient was excluded due to a BMI greater than 45 (morbidly obese). From the group of patients treated with smooth PEEK, 6 patients were

Table 1: Inclusion and Exclusion Criteria.

Inclusion Criteria	≥ 18 years of age
	Degenerative disc disease with cervical radiculopathy as diagnosed by a spine surgeon based on patient history, physical examination, and radiographic assessment
Exclusion Criteria	Corpectomy partial corpectomy
	Cervical trauma with no previously diagnosed degenerative disc disease
	Posterior fixation
	Osteoporotic
	Morbid obesity (BMI ≥ 45)

BMI, body mass index



excluded due to corpectomies or partial corpectomies, 1 was excluded due to cervical trauma with no previously diagnosed DDD, 1 was excluded due to osteoporosis, and 3 were excluded due to morbid obesity. From the group of patients treated with porous PEEK, 4 were excluded due to corpectomies or partial corpectomies, 3 were excluded due to osteoporosis, and 1 was excluded due to morbid obesity.

Demographics and patient characteristics

Demographics, comorbidities, and operative details are provided in Table 2. The average age at the time of surgery (allograft, 53.8 ± 8.8 ; smooth PEEK, 54.8 ± 9.6 ; porous PEEK, 55.0 ± 8.9) was not significantly different among the three groups. The average BMI (allograft, 31.0 ± 5.1 ; smooth PEEK, 29.9 ± 5.4 ; porous PEEK, 29.9 ± 6.2) were also not statistically significantly different among the treatment groups. As for patient sex, each group had consistently more female than male patients and the distribution was not statistically significantly different among the groups (Table 2). Among comorbidities analyzed including smoking status, or whether the patients were diabetic, hypertensive, or arthritic, none were significantly altered in distribution among the three groups (Table 2).

As for operative details (Table 2), specifically the number of levels

fused per patient (from 1-level fusions to 4-level fusions), there were significantly fewer 1-level fusions in the structural allograft group (1 patient, 2.6% of allograft patients) compared to both the smooth PEEK group (17 patients, 34.0% of smooth PEEK patients) and the porous PEEK group (16 patients, 20.5% of porous PEEK patients). The majority of patients in all three groups were either 2-level or 3-level ACDFs (greater than 65% in all three groups). There was only one 4-level fusion, which was within the porous PEEK group.

Clinical outcomes

Differences in sample sizes (reported with figures) at each time point arose from incomplete data due to patient loss-to-follow-up. Porous PEEK patients achieved greater mean improvements in both NDI and neck pain scores by 6 weeks post-op over it's pre-op baseline (Figure 2A and 2B respectively), and this was maintained to 12 months post-op when compared to both smooth PEEK and structural allograft (NDI, Figure 3; neck pain, Figure 4). Furthermore, by 6 weeks post-op, porous PEEK exhibited statistically significant improvements in NDI scores compared to both allograft and smooth PEEK patients at 6 weeks post-op (Figure 2A). Smooth PEEK did not show statistically significant improvement in NDI scores over baseline at 6 weeks post-op (Figure 2A) but began to improve at 3

Table 2: Demographics, comorbidities and operative details after patient exclusion.

Patient characteristics	All patients after exclusion (167)			p-values for significant differences in demographics, comorbidities, and number of levels			Analysis performed
Demographics	Allograft (39)	Smooth PEEK (50)	Porous PEEK (78)	Allograft vs Smooth PEEK	Allograft vs Porous PEEK	Smooth PEEK vs Porous PEEK	
Average Age (SD)	53.8 (8.8)	54.8 (9.6)	55.0 (8.9)	n.s.	n.s.	n.s.	ANOVA
Average BMI (SD)	31.0 (5.1)	29.9 (5.4)	29.9 (6.2)	n.s.	n.s.	n.s.	ANOVA
Female (%)	22 (56.4)	31 (62.0)	44 (56.4)	n.s.	n.s.	n.s.	Fisher's exact test
Male (%)	17 (43.6)	19 (38.0)	34 (43.6)				
Comorbidities							
Smoker (%)	8 (20.5)	10 (20.0)	15 (19.2)	n.s.	n.s.	n.s.	Fisher's exact test
Diabetic (%)	8 (20.5)	9 (18.0)	9 (11.5)	n.s.	n.s.	n.s.	Fisher's exact test
Hypertensive (%)	25 (64.3)	20 (45.9)	41 (54.7)	n.s.	n.s.	n.s.	Fisher's exact test
Arthritic (%)	20 (51.3)	19 (38.0)	34 (43.6)	n.s.	n.s.	n.s.	Fisher's exact test
Operative details (Number of levels)							
Multi-level (%)	38 (97.4)	33 (66.0)	62 (79.5)	0.0001	0.0105	n.s	Fisher's exact test (1-level vs. Multi-level)
1-level (%)	1 (2.6)	17 (34.0)	16 (20.5)				
2-level (%)	29 (74.4)	25 (50.0)	50 (64.1)	0.0002	0.0002	n.s	Fisher's exact test (1-level vs. 2-level)
3-level (%)	9 (23.1)	8 (16.0)	11(14.1)	n.s.	n.s.	n.s.	Fisher's exact test (2-level vs. 3-level)
4-level (%)	0 (0)	0 (0)	1 (1.3)	n/a	n/a	n/a	n/a
Total Levels	86	91	153	n/a	n/a	n/a	n/a

PEEK, polyetheretherketone; SD, standard deviation; BMI, body mass index; n.s., not significant; n/a, not applicable; ANOVA, analysis of variance

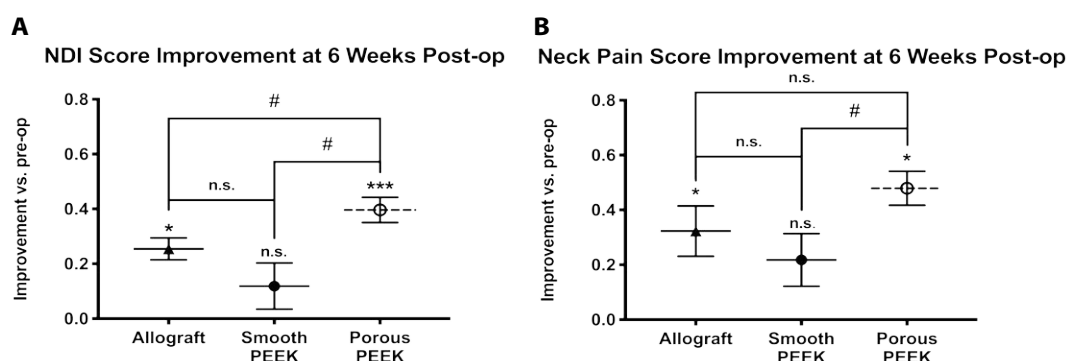


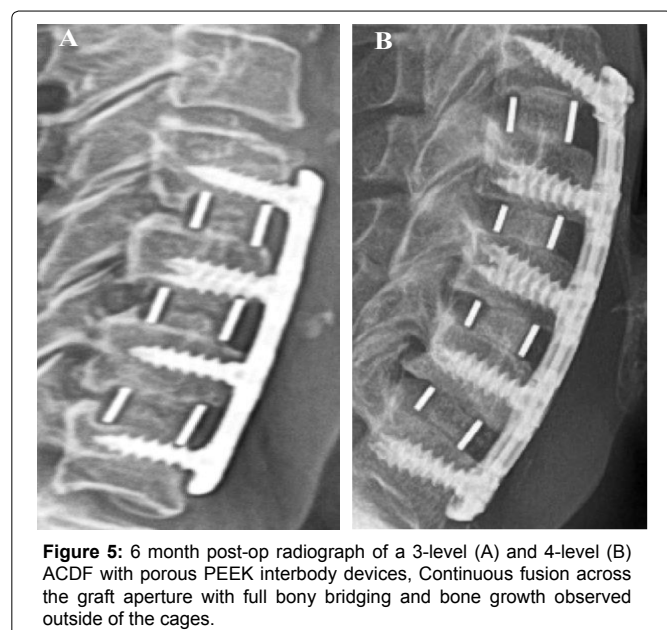
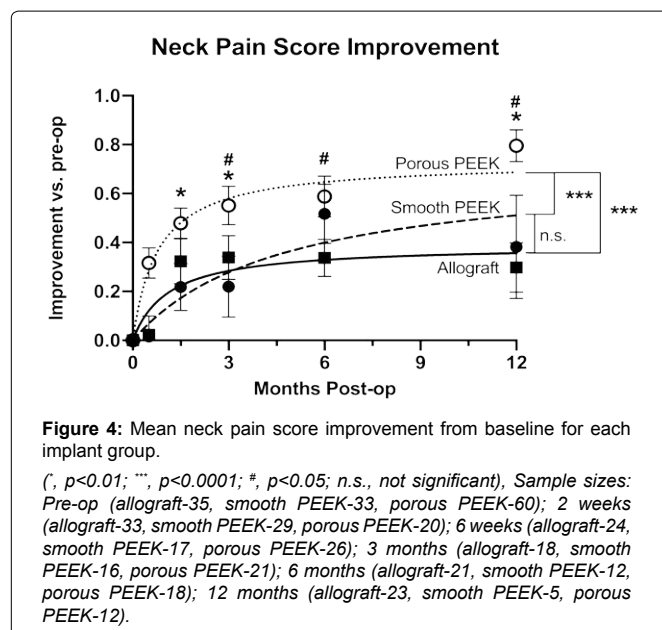
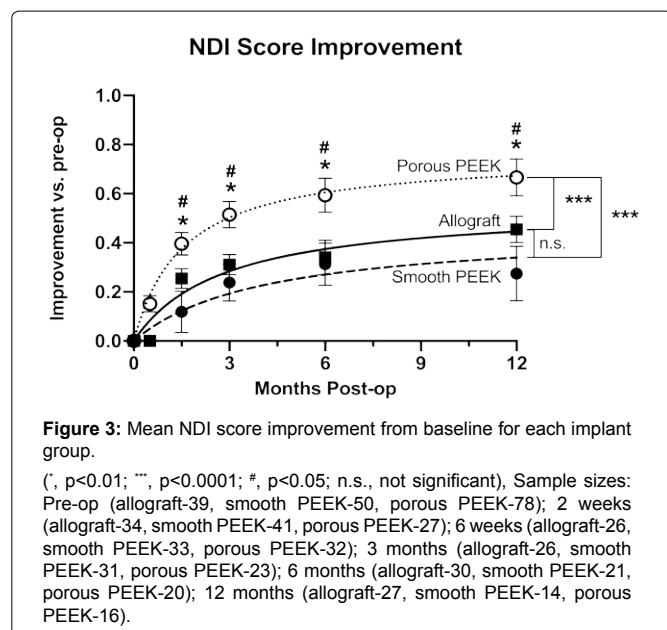
Figure 2: Mean NDI score improvement (decrease).

(A) and mean neck pain score improvement (B) at 6-weeks post-op compared to baseline for each implant group; porous PEEK, structural allograft, and smooth PEEK (*, $p < 0.01$; **, $p < 0.0001$; #, $p < 0.05$; n.s., not significant). Sample sizes: Pre-op NDI (allograft-39, smooth PEEK-50, porous PEEK-78); 6 week NDI (allograft-26, smooth PEEK-33, porous PEEK-32); Pre-op neck pain (allograft-35, smooth PEEK-33, porous PEEK-60); 6-week neck pain (allograft-24, smooth PEEK-17, porous PEEK-26).

months post-op and continued to improve at similar rates to allograft until 12 months post-op (Figure 3). Interestingly, porous PEEK trended towards improvement as early as 2 weeks post-op ($p = 0.0107$ compared to porous PEEK pre-op); however, neither allograft nor smooth PEEK significantly improved over their respective pre-op scores, and porous PEEK was not significantly different than either allograft or smooth PEEK at 2 weeks post-op (data not shown). Among all patients, improvements in NDI scores (Figure 3) and neck pain (Figure 4) were observed in all groups from pre-op to 12 months post-op. In addition, as can be seen by the data for all groups, the best-fit curve for the porous PEEK group is statistically significantly different from both the smooth PEEK and allograft groups ($p < 0.0001$) with a rates of increase over time statistically greater ($p < 0.0001$), suggesting that porous PEEK patients improve faster at early time points and continue to improve faster than both smooth PEEK and allograft at later post-op times. These best-fit-curve models may hold at later time points, but 24 month or later follow-up data are required

to determine the effect of the different interbody materials on longer term clinical outcomes. While all patients in this dataset presented with radiculopathy, left and right arm pain scores were also analyzed and exhibited similar trends (data not shown).

Because of statistically significant differences in distribution of 1-level vs. multi-level fusions between structural allograft and smooth PEEK (Table 2; $p = 0.0105$) or porous PEEK (Table 2, $p = 0.0001$), we also performed analysis of outcome data with all 1-level fusion data excluded to determine if inclusion of this data may have confounded results. After excluding all 1-level ACDF data, multi-level data exhibited the same trends in NDI and pain score improvements (data not shown). Improvements in NDI scores and neck pain scores were still observed at earlier times in porous PEEK patients than both smooth PEEK and structural allograft patients (data not shown).



Adverse events

No adverse events were reported during the course of this study. Estimated blood loss (EBL) was minimal for all patients (<250mL) and no post-operative infections were reported.

Discussion

While most studies place an emphasis on radiographic fusion rates, those results do not necessarily show an improvement in functional clinical outcomes in patients. Therefore, the objective of this study was to evaluate early functional clinical outcomes such as improvements in neck function and pain. These data are the first evidence that interbody devices designed to enhance bone in-growth into a porous architecture incrementally and significantly improve clinical outcomes compared to traditional implants [25,30]. Unlike

structural allograft cages that need to remodel during the fusion process [13,15,18,34] or smooth PEEK interbody spacers that do not osseointegrate [20,35,36], porous PEEK interbody fusion devices are non-resorbable and can osseointegrate with the vertebral endplates [28,30,31].

This single-center retrospective study comparing early outcomes of ACDF in 189 consecutive patients with 380 operated levels is the first to demonstrate a definitive early and sustained clinical benefit of porous PEEK compared to traditional smooth PEEK and structural allograft interbody devices in which the interbody material was the only procedural difference between cohorts. Every patient received the same standard ACDF procedure using the same instrumentation for anterior fixation and the same cellular allograft material to fill the graft aperture prior to implantation in the intervertebral space. While some patients were excluded from analysis due to potential confounding variables, the overall cohort was still represented by 167 patients with a total of 330 operated cervical levels. Patients who were treated with porous PEEK interbody fusion devices achieved clear improvements in NDI scores and pain by 6 weeks post-op, while patients treated with smooth PEEK only began to show improvements at 3 months post-op. While structural allograft patients began to improve over baseline by 6 weeks, porous PEEK patients showed statistically significant improvements over baseline by 2 weeks and significantly greater improvements than allograft and smooth PEEK patients by 6 weeks post-op. This early improvement was maintained at all time points up to 12 months post-op, demonstrating clear superior outcomes in patients treated with porous PEEK interbody fusion devices. These data along with preclinical data that demonstrate early bone in-growth into porous PEEK [25,28-30] suggest that porous PEEK promotes earlier functional fusion, possibly due to early bone in-growth minimizing micro-motion during the fusion process. This early stabilization may allow fusion to proceed across the device more easily than a smooth PEEK device that does not osseointegrate or a structural allograft device that must remodel during the fusion process. Sustained mean NDI and pain score improvement of porous PEEK patients compared to allograft and smooth PEEK patients at 12 months post-op further supports accelerated fusion and maintenance

of intervertebral height previously demonstrated in a clinical case series of ACDF patients treated with porous PEEK [31].

This comparative study demonstrates that porous PEEK implants that are durable under clinical loads [37], closely mimic the modulus of elasticity of bone, and support bone in-growth, promote better early outcomes by 6 weeks post-op than traditional smooth PEEK and structural allograft implants in patients that require cervical fusion. However, it is unknown how porous PEEK may perform clinically compared to a porous architecture made from a material with a higher modulus of elasticity such as titanium or silicon nitride. A previous study suggests that bone in-growth into porous PEEK is stress-shared, whereas bone in-growth into porous titanium is stress-shielded [38]. Furthermore, clinical data have demonstrated that stiffer implants such as those made of titanium have a greater risk of subsidence and implant migration [39]. Therefore, the improved outcomes attributed to porous PEEK in this study along with the preclinical data exhibiting improved osteoconductive response not only contradicts the assumption that PEEK itself does not osseointegrate, but these data suggest that porous PEEK may be the optimal surface modification for early and sustained clinical improvement.

The data presented in this study may also be particularly important to consider for patients such as those with confounding comorbidities or multi-level fusions in which fusion is more difficult to achieve. In a prior comprehensive analysis of 50 consecutive patients among which 24% were smokers, 40% were obese, 14% were diabetic, and 26% had previously failed fusions, all achieved radiographic fusion by 6 months with porous PEEK [31]. Along with this study and its indication for use in multi-level ACDFs with allograft filler, porous PEEK presents a safer alternative to osteoinductive biologics traditionally used to promote fusion under challenging conditions such as the use of BMP-2, which is not indicated for use in the cervical spine.

Conclusion

This is the first retrospective case study directly comparing porous PEEK, smooth PEEK, and structural allograft interbody devices for ACDF, and furthermore, it is the first study to show that porous PEEK patients have greater early clinical improvements than smooth PEEK or structural allograft patients. The early comparative improvement in NDI and pain scores in patients treated with porous PEEK are consistent with preclinical results showing bone in-growth into the porous endplates [25,30] and clinical results in which early fusion (6-12 months postoperative) was achieved in a challenging patient population potentially due to mechanical interlock eliminating micro-motion [31].

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