Original Study

Symptomatic pseudarthrosis requiring revision surgery after 1- or 2-level ACDF with plating: peek versus allograft

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Background: Polyetheretherketone (PEEK) and machined allograft interbody spacers are among devices used as fusion adjuncts in anterior cervical discectomy and fusion (ACDF). Most results are good to excellent but some patients develop pseudarthrosis. We compared the reoperation rates for pseudarthrosis following 1- or 2-level ACDF with PEEK or allograft cages.

Methods: This was a retrospective cohort study. We reviewed patients who underwent 1- or 2-level ACDF. The rate of subsequent surgery for pseudarthrosis was calculated for cases confirmed by computerized tomography. Patient-reported outcomes were collected at post-index surgery follow-up and post-revision ACDF follow-up. Radiographic parameters were assessed at a minimum of 1-year post-op on all patients.

Results: Two hundred and nine patients were included: 167 received allograft and 42 received PEEK. Subsidence was demonstrated in 31% of allograft and 29% of PEEK patients. There were no significant differences in clinical outcomes between allograft and PEEK groups. Clinical outcomes were not adversely affected by subsidence. Reoperation for pseudarthrosis was performed in 8% of allograft patients and 14% of PEEK patients (not statistically different). Improvement in patient-reported outcome was significantly better for patients without symptomatic post-operative pseudarthrosis.

Conclusions: Both allograft and PEEK spacers are acceptable options for ACDF surgery. Similar clinical outcomes and rates of radiographic subsidence were found. Subsidence was not a factor in clinical outcomes. Reoperation for pseudarthrosis was associated with poor outcomes. A higher incidence of revision for symptomatic pseudarthrosis occurred in the PEEK group, but this was not statistically significant.

Keywords: Anterior cervical discectomy and fusion (ACDF); pseudarthrosis; allografts; polyetheretherketone (PEEK); reoperation

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Introduction

Cervical spondylosis may present with a combination of neck pain, radiculopathy, and/or myelopathy. Any of these manifestations can impair a patient's quality of life. Anterior cervical discectomy and fusion (ACDF) is the conventional surgical treatment when non-operative measures have failed to improve the patient's symptoms (1-4). ACDF involves removing the intervertebral disc and fusing the adjacent vertebrae to stabilize the diseased segment(s). An interbody spacer (artificial or biologic) can be placed between the vertebrae, providing structural support, and serving as a fusion substrate scaffold. Smith

and Robinson first described the ACDF procedure (4). They advocated iliac crest autograft as the interbody graft material, but this has been shown to be associated with donor site morbidity such as pain and infection (5). Interbody implants have been designed to avoid these complications while maintaining good fusion rates and clinical outcomes. Commonly used materials include allograft bone, metal, and polyetheretherketone (PEEK) (6). A number of studies have been performed to describe and compare the clinical efficacy of these materials (7-9). Most of these studies compared titanium to PEEK spacers. There are some regional preferences in interbody devices of choice—PEEK is most commonly used in Europe but allograft is more commonly used in the United States (6). There is a scarcity of literature showing a head to head comparison of PEEK and allograft spacers in the context of ACDF surgery and the incidence of postoperative symptomatic pseudarthrosis (10).

The aim of this study was to compare the clinical outcomes of PEEK and allograft spacers in ACDF surgery with respect to the incidence of symptomatic pseudarthrosis requiring revision surgery. Symptomatic pseudarthrosis included patients with radiographic signs of pseudarthrosis at a minimum of 6 months post-operatively with new or recurrent clinical symptoms.

Methods

Subjects and surgery

We retrospectively reviewed patients who underwent 1- or 2-level ACDF at a single spine center from January 2010 to December 2014. Subjects who had more than a 2-level ACDF, prior cervical spine surgery, local/systemic infection, neoplasm, or cervical trauma were excluded. Patients who were under 18 or over 70 years old or who did not consent to research were also excluded from this study. Patients requiring revision surgery for other reasons (e.g., adjacent segment level disease and kyphosis) were not included. This study was approved by the Allina Health Institutional Review Board (1046904-2) under Expedited review category #5, with a waiver of consent granted. Study outcomes will not affect the future management of the patients. Patients' personal data have been secured for subject privacy.

All surgeries were performed under general anesthesia, by a left sided Smith-Robinson approach. After removal of the disc and decompression of neural structures, an interbody spacer was placed, either an allograft or PEEK cage. The type of spacer was based on surgeon's preference. The graft or cage was sized to as much as possible fill the space between the uncinate processes and between the anterior and posterior edges of the endplates. A combination of locally harvested autograft and cancellous allograft chips was used in both PEEK and allograft interbody groups to augment fusion. In some cases, demineralized bone matrix (DBM) was added as a graft extender. Anterior plates and screws were used in all cases. Patients were discharged within 24–48 hours after surgery. A soft collar was used for comfort for 2 to 4 weeks following surgery. Revision surgery for patients with symptomatic pseudarthrosis is typically posterior instrumented fusion with local autograft with or without allograft at our practice.

Clinical evaluation

Clinical outcomes were evaluated using the Neck Disability Index (NDI) and Visual Analogue Scale (VAS) for neck and arm pain. Patient charts were reviewed for subsequent anterior or posterior cervical spine surgery.

Radiographic evaluation

Anterior-posterior and lateral radiographs of the cervical spine were taken at 1-, 3-, 6-, 12-, and 24-month postoperatively. The intervertebral heights of the operative segments were measured at immediate postoperative follow-up and at last follow-up. Subsidence was defined as a decrease in the intervertebral height of 2 mm or more between the immediate postoperative and final postoperative radiographs. Patients with inadequate radiographic follow-up were excluded from radiographic analyses. A computed tomography (CT) scan was performed on all patients suspected to have a pseudarthrosis. Pseudarthrosis was defined as no bridging bone seen across the intervertebral space and/or radiolucency between the spacer and an adjacent vertebral body.

Data source

Data were extracted from the patients' electronic health records within our local hospital.

Statistical analysis

Subjects were divided into two cohorts, allograft and PEEK, to compare demographics, functional outcomes, reoperation

Table 1 Patient demographics

Factor	Allograft (n=167)	PEEK (n=42)	P value
Sex (F:M)	98:69	20:22	0.20
Age (years), mean [range]	49 [30–70]	51 [27–70]	0.37
Smoker	35	8	0.65
Worker's compensation	26	8	0.59
Diabetes mellitus	12	5	0.32
Fused levels (1:2)	64:103	20:22	0.29
Operation time (min), mean [range]	84 [33–224]	83 [45–147]	0.59
Length of stay (days), mean [range]	1 [1–7]	1 [1–3]	0.70
Follow up (months), mean [range]	24 [21–80]	24 [21–49]	0.88

PEEK, polyetheretherketone.

rates, and subsidence. Data were analyzed using SPSS 12.0 (SPS, Inc., Chicago, IL, USA). Statistical tests included chi-square or Fisher's exact tests for categorical variables and Student's *t*-tests and paired *t*-tests for continuous variables. Two multinomial logistic regression analyses were conducted with material (allograft or PEEK) and number of levels (1 or 2) as independent categorical variables and dependent outcomes of pseudarthrosis or subsidence. The threshold for statistical significance was P=0.05. Additional statistical analyses on functional outcomes, plate type and graft type were conducted by dividing subjects into cohorts according to subsidence or pseudarthrosis.

Results

Subjects and surgery

A total of 209 patients (91 males and 118 females) who met the selection criteria with a 21-month minimum follow up were analyzed. Median follow-up was 24 months in the allograft group (range 21 to 80) and 24 months in the PEEK group (range 21 to 49). One hundred and sixty-seven patients had an allograft spacer and 42 patients had a PEEK spacer. There was no significant difference in demographics, smoking status, or workers compensation status between the two groups (*Table 1*). All patients received anterior plates and screws.

Clinical outcomes

Patients improved significantly when comparing index preoperative and final follow-up NDI, VAS-neck, and VAS-arm (P<0.01, P<0.01, and P=0.02, respectively). Allograft and PEEK cohorts were not statistically different with respect to improvements in patient-reported outcomes (*Figure 1*). The proportions of patients who achieved minimal clinically important difference (MCID) in patient-reported outcomes were not different between cohorts (*Table 2*).

Reoperations

The rate of revision surgery for pseudarthrosis was 8% (13/167) in the allograft group and 14% (6/42) in PEEK patients; this difference was not statistically significant (P=0.19) (*Table 3*). Pseudarthrosis rate was not significantly different between 1- and 2-level surgeries with respect to interbody material type (allograft or PEEK) and number of levels (1 or 2) (P=0.07). In allograft bone cases, there was a trend toward more pseudarthrosis in 2-level cases, but this was not significant (P=0.06, Pearson's correlation coefficient). Patients who developed symptomatic pseudarthrosis had significantly less function (higher NDI scores) at final follow-up compared to asymptomatic patients (P=0.02) (*Figure 2*). However, this difference was not observed in the VAS-neck and VAS-arm. The proportions of patients who achieved MCID in patient-reported outcomes were not different (*Table 4*).

Radiographic outcomes

Of the 209 patients included in the study, 135 had radiographs that allowed measurement of subsidence with

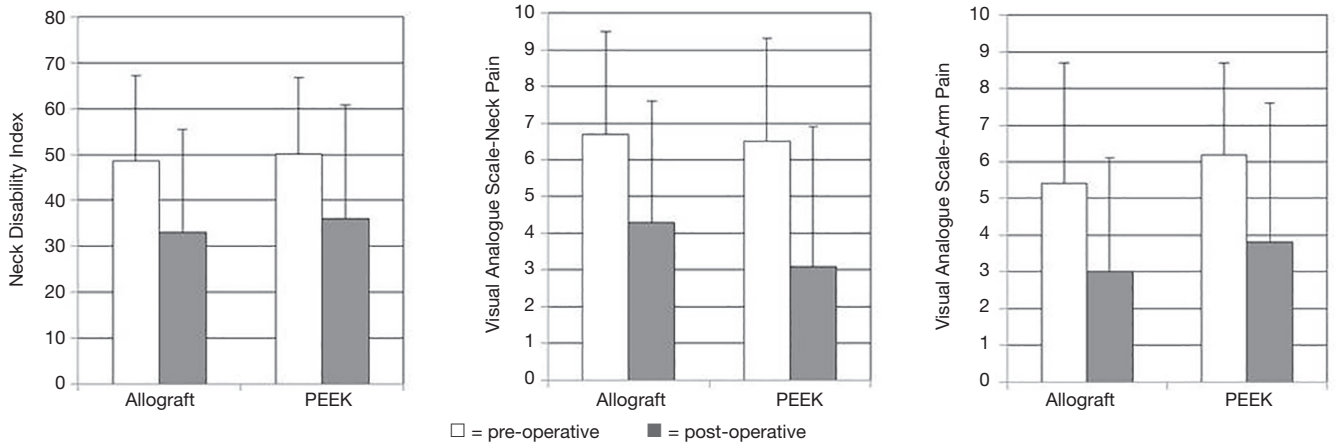

Figure 1 Patient-reported functional outcomes and interbody type. PEEK, polyetheretherketone.

Table 2 MCID and interbody type

Outcome measure	Allograft	PEEK	P value
NDI (n=209)	100/167	27/42	0.60
VAS neck pain (n=141)	50/116	15/25	0.12
VAS arm pain (n=126)	49/106	13/20	0.12

MCID, minimal clinically important difference; NDI, Neck Disability Index; VAS, Visual Analogue Scale.

Table 3 Clinical outcomes and interbody type

Outcome measure	Allograft	PEEK	P value
Pseudarthrosis (reoperation) (n=209)	13/167 (8%)	6/42 (14%)	0.19
Cage subsidence (n=135)	33/107 (31%)	8/28 (29%)	0.82

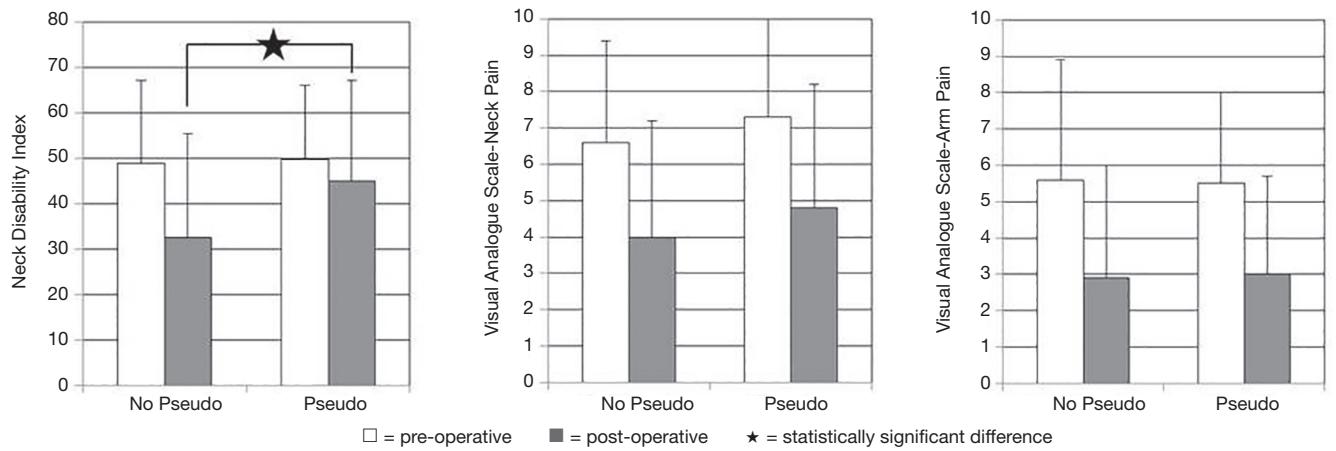

Figure 2 Patient-reported functional outcomes and reoperations for pseudarthrosis.

Table 4 MCID and reoperation for pseudarthrosis

Outcome measure	No pseudarthrosis	Pseudarthrosis	P value
NDI (n=209)	116/190	11/19	0.79
VAS neck pain (n=141)	59/129	6/12	0.78
VAS arm pain (n=126)	56/115	6/11	0.71

MCID, minimal clinically important difference; NDI, Neck Disability Index; VAS, Visual Analogue Scale.

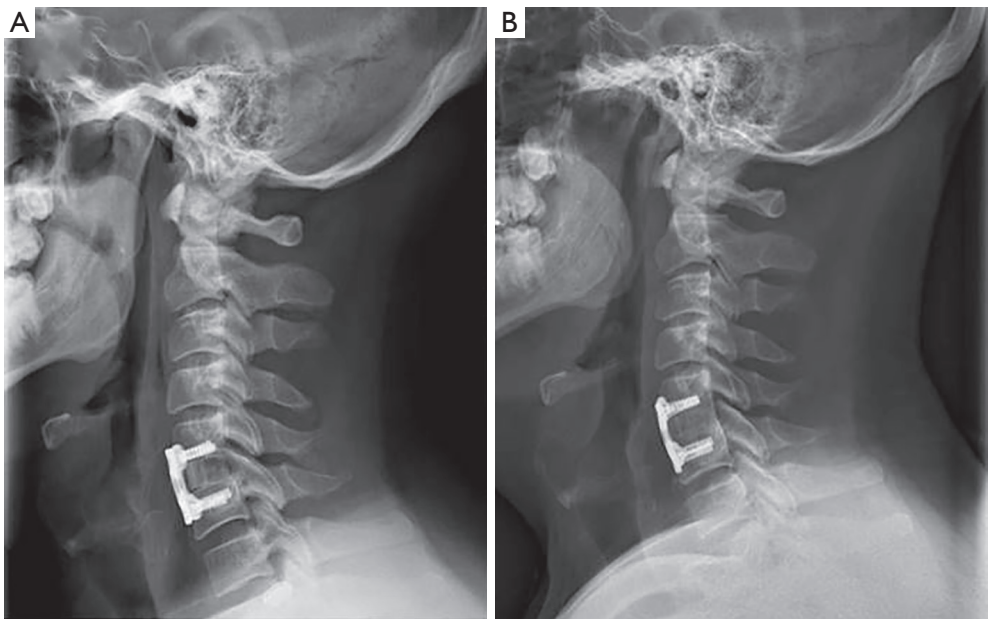

Figure 3 Radiographs of a C5/6 ACDF using an allograft spacer at 6 weeks (A). At 2 years there is bridging bone and no subsidence, indicating a robust fusion (B). ACDF, anterior cervical discectomy and fusion.

a minimum 1 year follow up. *Figures 3-6* depict typical examples of radiographic outcomes. The rates of subsidence were 31% in the allograft group and 29% among the PEEK patients (*Table 3*). This difference was not statistically significant (P=0.82). Subsidence and pseudarthrosis trended together, but there was no statistically significant association between clinical outcomes and subsidence (*Table 5*). Subsidence was not significantly different between 1- and 2-level surgeries with respect to interbody material type (allograft or PEEK) and number of levels (1 or 2) (P=0.65). Patients who developed subsidence had a significantly less function (higher NDI scores) at final follow-up compared to asymptomatic patients (P=0.01). However, this difference was not observed in the VAS-neck and VAS-arm (*Figure 7*). The proportions of patients who achieved MCID in patient-reported outcomes were not different (*Table 6*). There were five groups for grafting technique (*Table 7*). There were no differences in subsidence or reoperation for according to graft type. There were no differences in subsidence or reoperations between the allograft and PEEK cohorts with respect to plate manufacturer (data not shown).

Discussion

Allograft and PEEK are the most commonly used spacers for ACDF surgery (11). Good and excellent outcomes have been reported for both (12-14). However, Krause *et al.* reported a lower rate of pseudarthrosis among allograft patients compared to PEEK in 1-level ACDF (10). Likewise, Pirkle *et al.* reported a higher union rate with allograft compared to other cages such as PEEK, titanium and porous mesh metal (9). The current study is in concordance with the above trends: revision surgery for pseudarthrosis was 8% for allograft bone and 14%

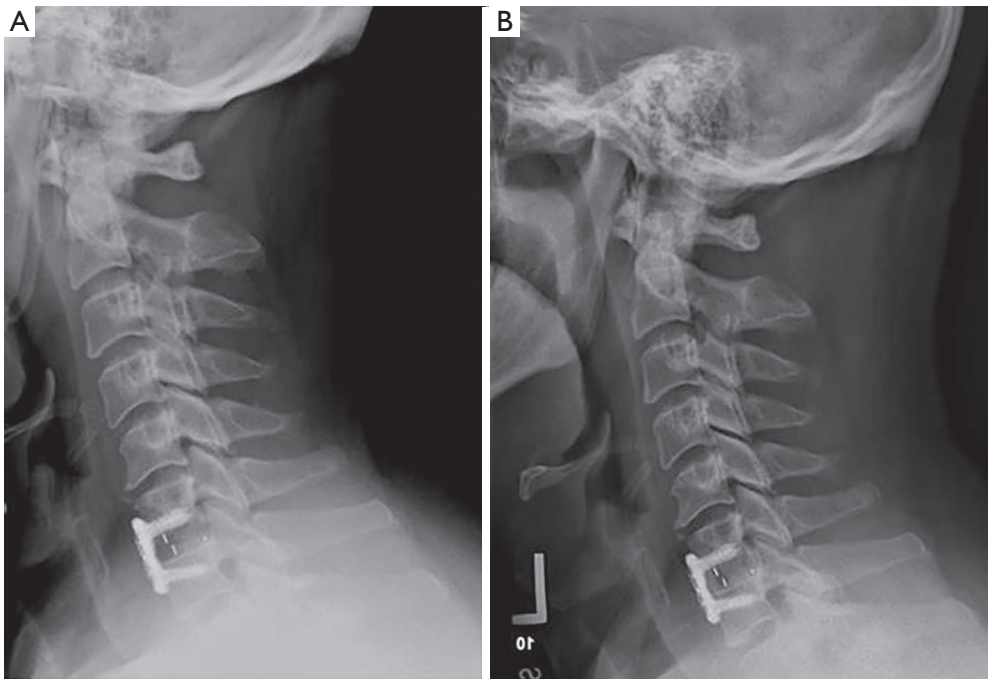

Figure 4 Radiographs of a C6/7 ACDF using a PEEK spacer at 6 weeks (A). At 2 years there is bridging bone and no subsidence, indicating a robust fusion (B). ACDF, anterior cervical discectomy and fusion; PEEK, polyetheretherketone.

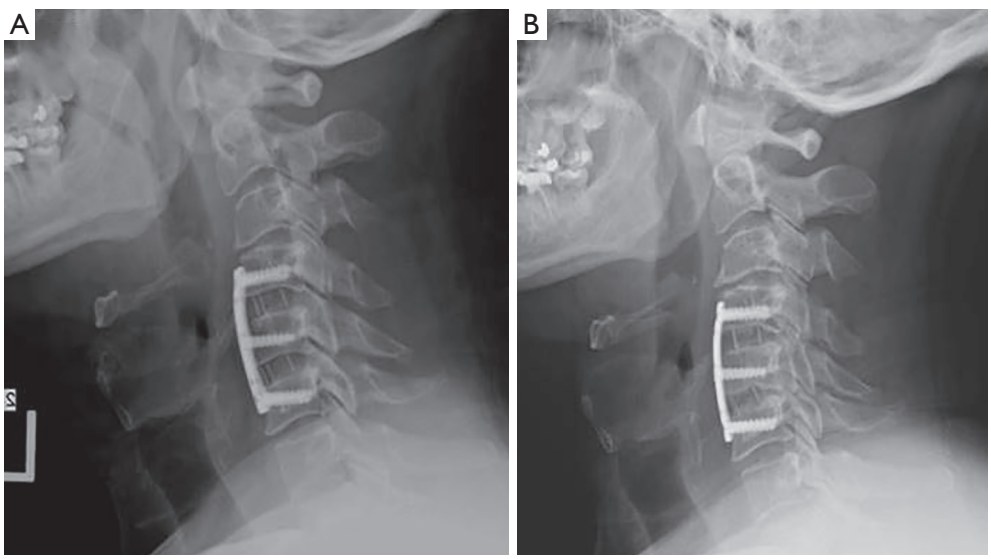

Figure 5 Radiographs of a C4–6 ACDF using a PEEK spacer at 6 weeks (A). At 2 years there is subsidence of the spacers into the vertebral endplates (B). ACDF, anterior cervical discectomy and fusion; PEEK, polyetheretherketone.

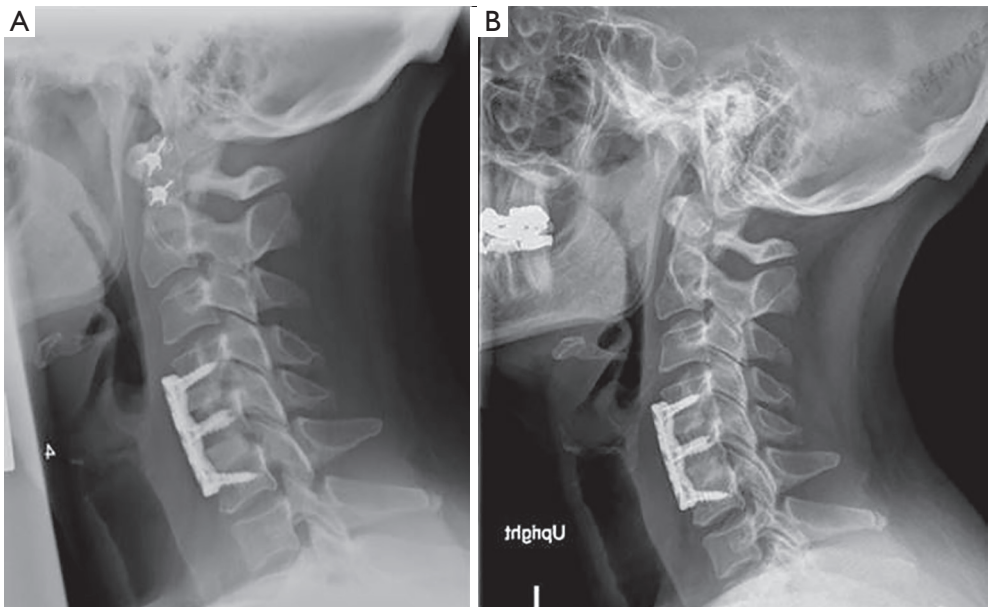

Figure 6 Radiographs of a C4–6 ACDF using an allograft spacer at 6 weeks (A). At 2 years there is subsidence of the spacers into the vertebral endplates (B). ACDF, anterior cervical discectomy and fusion.

Table 5 Radiographic outcomes and pseudarthrosis status

Result	No pseudarthrosis	Pseudarthrosis	P value
No subsidence (n=94)	85	9	0.05
Subsidence (n=41)	32	9	

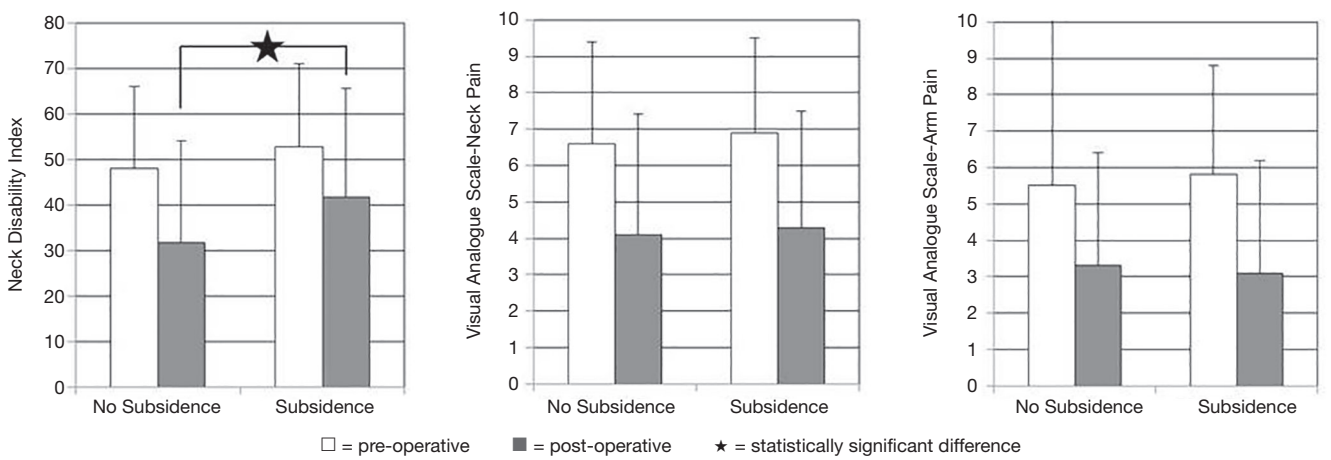

Figure 7 Patient-reported functional outcomes and subsidence status.

Table 6 MCID and subsidence

Outcome measure	No subsidence	Subsidence	P value
NDI (n=209)	106/168	21/41	0.17
VAS neck pain (n=141)	52/111	13/30	0.73
VAS arm pain (n=126)	48/99	14/27	0.76

MCID, minimal clinically important difference; NDI, Neck Disability Index; VAS, Visual Analogue Scale.

Table 7 Graft type versus pseudarthrosis status and subsidence

Graft type	Subsidence results			Pseudarthrosis results		
	No subsidence	Subsidence	P value	No pseudarthrosis	Pseudarthrosis	P value
A/A	26	8		46	5	
DBM	32	16		64	11	
A/A + DBM	18	9	0.78	39	1	0.09
Unspecified	0	0		14	0	
Nothing	18	8		27	2	

A/A, autograft/allograft; DBM, demineralized bone matrix.

for PEEK, however, this difference was not statistically significant.

Pseudarthrosis is not an uncommon complication of ACDF surgery. However, it is not routinely symptomatic and as such can be deemed 'stable' and not require revision surgery. The reported incidence of pseudarthrosis was reported as high as 20% and 50% for single and multilevel ACDF, respectively (15-18). Phillips *et al.* reported poor clinical outcomes in the majority of patients with pseudarthrosis, 67% of whom required revision surgery (19). Similarly, Buttermann *et al.* reported poor outcomes in patients with pseudarthrosis in a 10+ year prospective study. Reported revision surgery for pseudarthrosis repair was performed in 10% of patients—most often within 2 years of the primary surgery (2).

In this study, revision surgery for pseudarthrosis was 8% for allograft bone and 14% for PEEK spacers in 1- or 2-level ACDF. These results are comparable to the literature. Reoperation rates for pseudarthrosis was almost twice as high in the PEEK group compared to allograft, though this was not statistically significant. Nonetheless, revision surgery for any reason may be considered to be clinically significant. Patients needing a revision do not do as well functionally as those who do not receive a revision. As such, this information could be useful in clinical practice and surgeons will want to be aware of the potentially higher revision rate for PEEK.

The reported subsidence rates of different intervertebral spacers in ACDF surgery range from 0% to 48% (20,21). Yson *et al.* compared allograft and PEEK cages and found subsidence rates of 28% and 29%, respectively (22). Cabraja *et al.* compared titanium and PEEK cages and found subsidence rates of 20.5% and 14.3%, respectively (7). The literature shows that the type of intervertebral spacer might not be the only factor that affects subsidence rates. Other factors such as implant geometry, distraction during surgery, cervical alignment, age, surgical technique and use of plates may also play a role (23-25). It is not clear if subsidence is only a radiographic finding, or if it adversely affects clinical outcomes. While some studies reported worse clinical outcomes with subsidence, others have shown no correlation between subsidence and clinical outcomes (22,26-29). In the current study, subsidence was associated with worse functional outcomes (post-operative NDI scores were statistically higher for patients with subsidence). Karikari *et al.*, in a meta-analysis of 35 articles, concluded that the type of implant did not affect the subsidence rate. They also found that neither clinical outcomes nor fusion rates were affected by subsidence (30). In this study, the subsidence rate was 29% for PEEK and 31% for allograft, which is concordant with the literature.

We found that the symptomatic pseudarthrosis rate was

not different between 1- and 2-level surgeries. Veeravagu *et al.* reported that the rate of reoperations increases with increasing number of levels fused (31). The reasons for the difference between their study and ours may be that we included only reoperations for symptomatic pseudarthrosis and only considered allograft and PEEK as interbody materials. Veeravagu did not differentiate for interbody type or reasons for reoperation. Likewise, we found that subsidence did not depend on the number of levels. Our result agrees with Lin *et al.* (14). They found no difference in subsidence between 1-, 2-, and 3-level reconstructions among ACDF procedures using a PEEK interbody cage.

Limitations to this study include those inherent of any retrospective review. However, given the paucity of data regarding this topic this represents the first step towards a higher level study (randomized prospective trial) to answer the research question of which spacer option has a higher association with symptomatic pseudarthrosis following 1- or 2-level ACDF. Secondly, the disproportion sample sizes (allograft, 167 patients, and PEEK, 42 patients) may have an effect on the results. We note, however, that this disparity mirrors North American surgeon preferences for allograft over PEEK (6). Third, we studied only symptomatic pseudarthrosis. Other important diagnoses that may require revision surgery (e.g., adjacent segment level disease and kyphosis) are not included (11). Fourth, all of our subjects were plated. Therefore, we are unable to study this as a factor. However, the question "to plate or not to plate" has been the considerably discussed elsewhere in the literature (32). Finally, differences in surgical techniques have the potential to affect outcomes. The projected effects of these technical differences on fusion and symptomatic pseudarthrosis are difficult to assess given the nature of the study. A future prospective study by a single surgeon, comparing both PEEK and allograft with equal number of patients in each group could yield more definitive conclusions to the research question.

Conclusions

This study analyzed allograft and PEEK ACDF spacers with regards to clinical outcome (NDI, VAS-neck, VAS-arm), radiographic measurement (subsidence), and revision rate for symptomatic pseudarthrosis. Both allograft and PEEK interbody spacer showed similar improvement in clinical outcomes following index ACDF surgery. Patients with pseudarthrosis requiring revision surgery had lower functional outcomes. Subsidence rates were similar between allograft and PEEK. Patients with subsidence had lower functional outcomes. Reoperation rates for symptomatic pseudarthrosis following index 1- or 2-level ACDF was higher in the PEEK interbody group, but this was not statistically significant.

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Footnote

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/jss-19-419). AAM reports personal fees from Stryker, personal fees from Zimmer, outside the submitted work; TAG reports personal fees from Medtronic, outside the submitted work; JDS reports personal fees from Medtronic, personal fees from Stryker, outside the submitted work; The other authors have no conflicts of interest to declare.

Ethical Statement: 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 (as revised in 2013). This study was approved by the Allina Health Institutional Review Board (1046904-2) under Expedited review category #5, with a waiver of consent granted. Study outcomes will not affect the future management of the patients. Patients' personal data have been secured for subject privacy.

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