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ORIGINAL ARTICLE - SPINE - OTHER

PEEK versus titanium-coated PEEK cervical cages: fusion rate

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Abstract

Background Anterior cervical discectomy and fusion (ACDF) is one of the most commonly performed procedures for degenerative cervical disease. The evaluation of fusion status is still not fully standardized, and a variety of measurement methods are used. This study presents our own evaluation of fusion by comparing two types of implants.

Methods A total of 170 disc spaces were operated on in 104 patients using PEEK (polyetheretherketone) cages and titanium-coated (TC) PEEK cages. Patients were assigned to a specific implant using a randomisation table. Fusion status was evaluated based on functional radiographs and CT scans obtained at 12 months post-surgery. Multivariate mixed-effects logistic regression models were performed to assess the association of type of implant with different fusion rates.

Results At 12 months post-surgery, CT scans were performed in 86 patients (a total of 144 disc spaces) and conventional radiographs were obtained in 102 (a total of 166 disc spaces). Complete fusion was demonstrated in 101 cases (71.1%), partial fusion in 43 cases (29.9%). There were no cases of absence of fusion. A total of 85 PEEK cages (59%) and 59 TC-PEEK cages (41%) were implanted. For PEEK cages, complete fusion was seen in 75 (88.2%) disc spaces, compared to 26 (44.1%) achieved with TC-PEEK cages. A significantly higher proportion of complete fusions ($B = 15.58$; $P < 0.0001$) after 12 months was observed with PEEK implants compared to TC-PEEK implants.

Conclusion Complete fusion was noted at 12 months post-surgery significantly more frequently with PEEK implants compared to TC-PEEK implants.

Keywords Cervical spine · Polyetheretherketone (PEEK) · Titanium-coated PEEK · Fusion · This article is part of the Topical Collection on *Spine—Other*

Introduction

Anterior cervical discectomy and fusion (ACDF) is one of the most commonly performed procedures for degenerative cervical disease. Apart from decompression of the spinal cord and nerve roots, surgery aims to produce fusion and correct sagittal cervical alignment. The replacement of a cervical intervertebral disc with a stand-alone cage can restore physiologic disc height, provide immediate load-bearing support to the cervical spine and may promote osseous fusion. Interbody implants are made of a variety of materials, differing in structural design, shape, and surface topography. PEEK cages and TC-PEEK cages are commonly used in spinal surgery. The elasticity modulus of PEEK is similar to that of bone, which results in minimizing cage subsidence and optimizing the interaction of the compressive forces at the graft-host interface. PEEK also offers benefits in subsequent post-operative imaging follow-up as it does not distort the anatomical image. TC-PEEK cages were developed to improve osteointegration. They preserve the biomechanical and radiographic advantages of PEEK, with improved osseointegration being achieved by adding a plasma-sprayed layer of titanium [9, 13, 16, 18]. Evaluation of fusion status is still not fully standardized among specialists in this area,

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and a variety of measurement methods are in use [12, 17, 27]. We present a method of evaluation of fusion status with two types of implants by analysing functional radiographs and CT scans obtained at 12 months post-surgery.

Material and methods

A total of 170 disc spaces were operated on in 104 patients. Two types of implants were used as follows: (1) PEEK (polyetheretherketone) cages and (2) TC-PEEK cages. Patients were randomised to receive a specific implant using a randomisation table. One or two disc spaces were operated on during one surgical procedure. The interior of an implant was always filled with nanoparticle hydroxyapatite. Fusion status was evaluated based on functional (flexion, neutral, extension) radiographs of the cervical spine and CT scans obtained at 12 months post-surgery. Fusion status was classified as (1) complete fusion, (2) partial fusion, and (3) absence of fusion. The classification criteria are presented in Table 1. Examples of cases classified as complete fusion and partial fusion on CT scans are shown in Fig. 1. Additionally, we evaluated implant subsidence over the 12-month follow-up. The height of interbody spaces was measured in the central part of the vertebral bodies by assessing the distance between the endplates of adjacent bodies, rounding the result to an accuracy of 1 mm. The measurements were performed on radiographs obtained at one centre always using the same equipment and following the same procedure. The radiographic indices were assessed on five occasions as follows: (a) before surgery, (b) one day after surgery, (c) one month after surgery, (d) six months after surgery, and (e) 12 months after surgery. Implant subsidence was diagnosed if the implant had migrated ≥ 3 mm within the adjacent endplates compared to radiographs obtained one day after the surgery. Consent for the study was obtained from the relevant ethical review board (Resolution 4/2019 of the Bioethics Committee at Andrzej Frycz Modrzewski Cracow University in Cracow of 24 January 2019). Standard descriptive statistics were used to describe baseline characteristics of the patients. The Chi^2 and Fischer exact test were used for categorical variables and the Student's *t* test for continuous variables to assess differences between the study arms. To account for clustering of disc spaces in individual patients, mixed-effects logistic regression modeling was used for different types of radiologic outcomes as follows: (1) fusion rate (complete, partial, absence of fusion), (2) subsidence (yes, no), and (3) optimal radiographic outcome /complete fusion without subsidence. Implant type was treated as a fixed effect and patient ID as a random effect in the model. A 2-sided $P < 0.05$ was considered statistically significant.

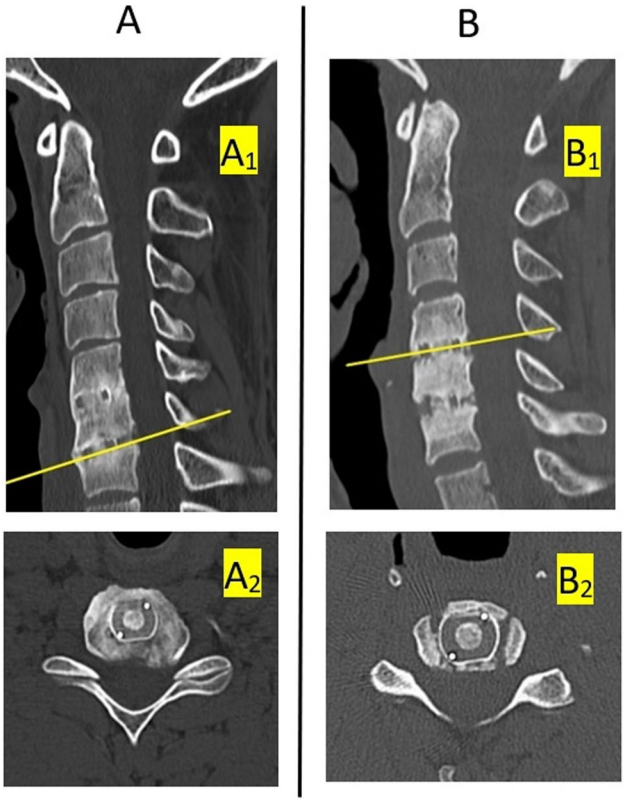

Fig. 1 Sample presentations or complete and partial fusion on CT scans at 12 months post-surgery: **A** complete fusion, patient no. 4 (A_1, sagittal view; A_2, transverse view at the level of the implant in C6/C7 disc space). **B** Partial fusion, patient no. 14 (B_1, sagittal view; B_2, transverse view at the level of the implant in C4/C5 disc space)

Table 1 Criteria for evaluation of fusion based on CT scans and functional plain ra diographs of cervical spine at 12 months post-surgery

Modality	Criterion	Complete fusion	Partial fusion	Absence of fusion
Functional radiographs (flexion, neutral extension)	Mobility of implants against vertebral bodies on functional radiographs	No mobility	No mobility	Visible mobility
Computed tomography images	Continuity of bone tissue immediately anterior, posterior, medial, and lateral to implant on CT scan	Visible bone tissue continuity	No continuity of bone tissue	No continuity of bone tissue

Results

A total of 170 disc spaces were operated on in 104 patients. PEEK implants were used in 59% ($n=100$) of the cases and TC-PEEK implants in the remaining 41% ($n=70$). There was no correlation between the type of implant and patients' sex (Chi^2 test; $Chi^2=1.36$; $df=1$; $P=0.2427$) or level treated (Chi^2 test; $Chi^2=1.46$; $df=3$; $P=0.69$), and no differences in patient age between those who received different types of implants (Student's t test; $t=1.55$ $df=142$; $P=0.122$). These results indicate an effective randomisation procedure (cf. Table 2). At 12 months post-surgery, CT scans were performed in 86 patients (a total of 144 disc spaces) and conventional radiographs were obtained in 102 (a total of 166 disc spaces).

Table 2 Parameters of the study population* by type of implant

Parameter	Type of implant		Statistic (*df*)	*p*
	TC-PEEK	**PEEK**		
Age, mean(*SD*)	51.1 (11.95)	52.28 (9.86)	0.703[a] (168)	0.4829
Female sex, *n* (%)	54 (77.14)	69 (69.0)	1.36[b] (1)	0.2427
Level treated, *n* (%)			1.46[b]	0.6915
C3/C4	4 (5.71)	5 (5.0)	(3)	
C4/C5	8 (11.43)	8 (8.0)		
C5/C6	39 (55.71)	52 (52.0)		
C6/C7	19 (27.14)	35 (35.0)		

Key to abbreviations and symbols:

*As some patients underwent surgery on several levels, the study population comprised disc spaces treated; ‡column percentages; [a]value of the Student's t test statistic; [b]value of the statistic of the Chi^2 test for independence; *df*, degrees of freedom; *p*, two-tailed test probability for test statistic; underline marks significant associations for $p<\alpha=0.05$; α, level of statistical significance; sample size differences are due to missing data

Fusion

As the method we employed for classifying fusion status relied on simultaneous evaluation of CT scans and radiographs, the final sample comprised 144 disc spaces, while implant subsidence was evaluated in a sample of 166 disc spaces. Complete fusion was demonstrated in 101 cases (71.1%) and partial fusion, in 43 cases (29.9%). There were no cases that could be considered absence of fusion. A significantly higher proportion of complete fusions after 12 months was noted for PEEK implants compared to TC-PEEK. For PEEK implant recipients, complete fusion was seen in 75 disc spaces (88.2%), compared to 26 (44.1%) of cases of complete fusion achieved with TC-PEEK implants. Mixed-effects logistic regression analysis revealed significant differences in the type of fusion (partial vs complete) between the study arms ($B=15.58$; $P<0.0001$). These results are shown in Table 3.

Subsidence

As regards implant subsidence at 12 months post-surgery, 166 complete sets of radiographic measurement data were available to assess changes in interbody space height and the presence of implant subsidence, 98 (59%) for PEEK cages and 68 (41%) for TC-PEEK cages. Subsidence was identified in 35 disc spaces, representing 21% of the 166 measurement data sets. These included 21 PEEK cages (21.4%) and 14 TC-PEEK cages (20.6%). Mixed-effects logistic regression analysis failed to find an association between subsidence and implant type ($B=0.069$; $P=0.875$). These results are shown in Table 3.

Table 3 Radiographic outcomes at 12 months post-surgery according to type of implant

Parameter	Level	Implant type‡ *N* (%)		*B*	*SE*	95% CI for *B*	*Z*	*p*
		TC-PEEK	**PEEK**					
Subsidence (*N* = 166)	Yes	14 (20.59)	21 (21.43)	0.069	0.44	(-0.794 to 0.932)	0.157	0.8753
	No	54 (79.41)	77 (78.57)					
Fusion (*N* = 144)	Complete	26 (44.07)	75 (88.24)	15.58	3.234	(9.24–21.921)	4.82	<0.0001
	Partial	33 (55.93)	10 (11.76)					
Optimal radiographic outcome[&] (*N* = 150)	Yes	22 (36.07)	61 (68.54)	1.936	0.667	(0.629–3.243)	2.904	0.0037
	No	39 (63.93)	28 (31.46)					

Key to abbreviations and symbols:

[&]Variable is Yes, if subsidence = No; fusion = complete; ‡column percentages; *B*, logistic regression coefficient estimate; *SE*, standard error of the estimate; *CI*, confidence interval; *z*, standardized statistics for the Wald test; *p*, two-tailed test probability for *Z* statistic; underline marks significant associations for $P<\alpha=0.05$; α, level of statistical significance; sample size differences are due to missing data

Optimal radiographic outcome/complete fusion without subsidence

An optimal radiographic outcome following ACDF is complete fusion without implant subsidence. The 101 treated levels assessed as complete fusion included 18 (17.8%) cases of subsidence and 83 (82.2%) cases without subsidence. Among the 43 cases of partial fusion, subsidence was present in 11 cases (25.6%) and 32 cases (76.4%) did not demonstrate implant subsidence. Thus, optimal treatment outcome (complete fusion without implant subsidence) was obtained in 83 of the 144 disc spaces analysed, which represents 57.6%. Mixed-effects logistic regression analysis revealed significant differences in the frequency of the optimal radiographic outcome between the study arms at 12 months following ACDF ($B = 1.936$; $P = 0.0037$). A significantly higher proportion of disc spaces demonstrated the optimal radiographic outcome at 12 months post-surgery in the PEEK arm compared to the TC-PEEK arm. There was no association between the type of fusion and the presence of implant subsidence ($B = 0.461$; $P = 0.2903$). Mixed-effects logistic regression analysis revealed no significant association between the level treated and the type of fusion (complete vs partial) (Chi^2 omnibus test = 5.52; $df = 3$, $P = 0.1376$) or the presence of subsidence (Chi^2 omnibus test = 7.3; $df = 3$; $P = 0.0629$) at 12 months following ACDF. These results are shown in Tables 3 and 4.

Table 4 Crosstabulation of subsidence in relation to fusion and implant type

Subsidence	Fusion		Implant type		Total
			TC-PEEK	PEEK	
No	Complete	*N*	22	61	83
		% Within row	26.5%	73.5%	100.0%
		% Within column	46.8%	89.7%	72.2%
	Partial	*N*	25	7	32
		% Within row	78.1%	21.9%	100.0%
		% Within column	53.2%	10.3%	27.8%
	Total	*N*	47	68	115
		% Within row	40.9%	59.1%	100.0%
		% Within column	100.0%	100.0%	100.0%
Yes	Complete	*N*	4	14	18
		% Within row	22.2%	77.8%	100.0%
		% Within column	33.3%	82.4%	62.1%
	Partial	*N*	8	3	11
		% Within row	72.7%	27.3%	100.0%
		% Within column	66.7%	17.6%	37.9%
	Total	*N*	12	17	29
		% Within row	41.4%	58.6%	100.0%
		% Within column	100.0%	100.0%	100.0%
Total	Complete	*N*	26	75	101
		% Within row	25.7%	74.3%	100.0%
		% Within column	44.1%	88.2%	70.1%
	Partial	*N*	33	10	43
		% Within row	76.7%	23.3%	100.0%
		% Within column	55.9%	11.8%	29.9%
	Total	*N*	59	85	144
		% Within row	41.0%	59.0%	100.0%
		% Within column	100.0%	100.0%	100.0%

N, number of disc spaces with or w/o the outcome

Discussion

Polyetheretherketone (PEEK) cages and TC-PEEK cages are commonly used in spinal surgery. Introduced in the 1990s, PEEK has been universally accepted on account of its good mechanical properties. PEEK also offers benefits in subsequent post-operative imaging follow-up as it does not distort the anatomical image. PEEK is radiolucent, allowing for good assessment of bone in-growth, and produces fewer artifacts than metallic implants on MRI and CT scans. A documented weakness of this material is its relatively poor osteointegration. Histologic studies have shown that fibrous tissue forms in the immediate vicinity of the implants, a phenomenon known as fibrous encapsulation. To improve osteointegration, TC-PEEK cages were developed. They retain the biomechanical and radiological advantages of PEEK, with improved osseointegration being achieved by adding a plasma-sprayed surface layer of titanium [9, 13, 16, 18]. There are published studies in favour of TC-PEEK cages over PEEK cages, but they generally present results of laboratory biomechanical research. At the same time, there is a scarcity of clinical studies comparing fusion status in patients who received these two types of implants [9, 10, 20, 25, 26]. Our study compared the two types of implant with regard to fusion status achieved by

12 months post-surgery. Complete fusion after a year was obtained significantly more frequently with PEEK implants compared to TC-PEEK implants. Where PEEK cages were used, complete fusion was achieved in 75 (88.2%) of the treated disc spaces, compared to 26 (44.1%) following the placement of TC-PEEK cages. Mixed-effects logistic regression analysis revealed significant differences in the type of fusion (partial vs complete) achieved between the study arms ($B = 15{,}58$; $P < 0.0001$). We understand that our results may be perceived as controversial and incompatible with certain assumptions and manufacturers' expectations. Similar data were published by Kotsias et al., finding that partial coating of a PEEK cage with titanium does not improve the fusion rate sufficiently [15]. Our classification of fusion status is based on a simultaneous analysis of functional plain radiographs and sagittal and coronal CT scans. Despite attempts at standardisation, there are still no standardized methods for assessing fusion status [4, 12, 17]. Available approaches are based on functional plain radiographs, CT scans, and, less often, also MRI images. Relevant aspects of analysis of functional radiographs include the difference in interspinous distance (the distance between spinous processes of adjacent joints) at flexion and extension. The interspinous distance can be measured either between the bases or the apices of spinous processes. A difference less than 2 mm is classified as fusion, and one greater or equal to 2 mm is classified as pseudarthrosis. Another approach focuses on change in Cobb's angle values of the operated motor segment between flexion and extension. The literature describes two threshold values below which fusion is diagnosed, namely, change in Cobb's angle of less than 2° or less than 4°; by the same token, a pseudoarthrosis is diagnosed at values of ≥ 2° or ≥ 4°, yet another approach assesses bone bridging by the anterior and/or posterior surface of the treated disc spaces on sagittal radiographs. Fusion is diagnosed when bridging bone is present, and incomplete bony bridging leads to a diagnosis of pseudoarthrosis. Modifications and original classifications of fusion status abound, with different numerical values and different changes in angle values used. In some papers, fusion is diagnosed only when there is evidence of fusion according to two evaluation methods applied. Plain radiograph-based methods are not ideal as they are considerably subjective and the same patients can be classified differently by different evaluators. Even more, Obermuller et al. studied the same patient group assessed by the same evaluators performing measurements but using different plain radiograph-based methods as described above, and found that the results were vastly different depending on the approach to discerning fusion and pseudoarthrosis (Fig. 2) [1, 2, 4, 7, 12, 17, 24]. The use of computed tomography is a more modern and reliable approach to evaluating fusion status. Buchowski et al. compared assessment of fusion status based on plain radiographs, CT scans, and MRI scans with subsequent intraoperative findings during repeat surgery. Assessment of the fusion status using CT scans agreed with the results of intraoperative exploration in an average of 83.3% of cases, compared to 81% using radiographs and 66.7% using MRI. CT imaging, especially when combined with coronal and sagittal reconstructions, can increase the accuracy of fusion assessment. Although MRI scans can be used to assess fusion, the magnetic susceptibility artifact makes this modality less reliable than CT scans [3, 4, 6, 21, 23]. Our own classification involving both functional radiographs and sagittal and coronal CT scans shows potential as a universal method for assessing fusion status.

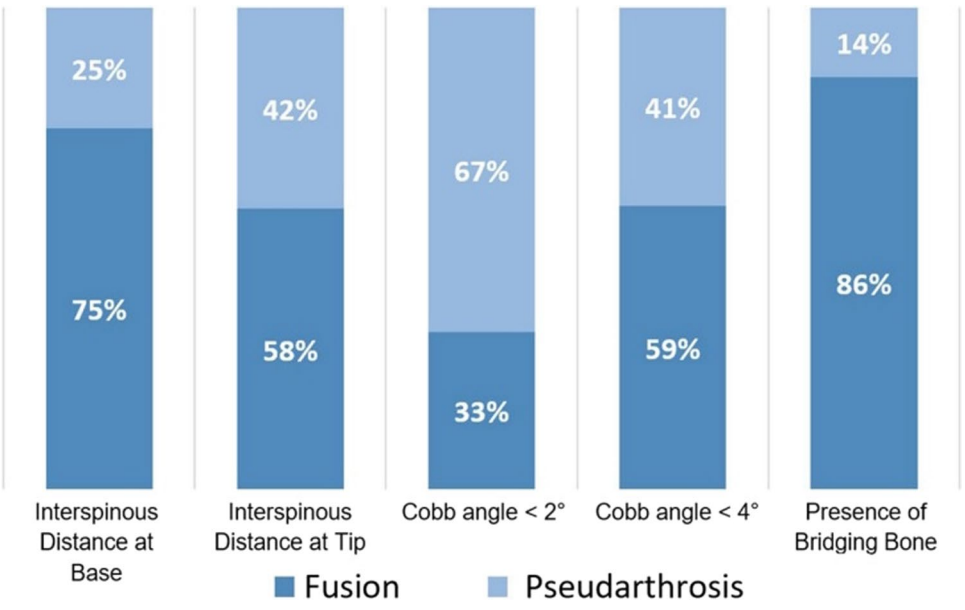

Fig. 2 Fusion rates in percentages according to various assessment methods. Reprinted by permission from Springer Nature: Acta Neurochirurgica 2020; 162: 89-99. Radiographic measurements of cervical alignment, fusion, and subsidence after ACDF surgery and their impact on clinical outcome. Obermueller T, Wagner A, Kogler L, Joerger AK, Lange N, Lehmberg J, Meyer B, Shiban E

Fusion, subsidence, and optimal radiographic outcome

Implant subsidence after ACDF is an undesirable effect that should be prevented. Cage subsidence may affect spinal biomechanics and alignment and cause segmental kyphosis and acceleration of adjacent segment disease. Reduced disc space height may lead to foraminal stenosis [5, 8, 11, 14, 17, 19, 22, 28]. An optimal radiographic outcome following ACDF is complete fusion without implant subsidence. The finding of cage subsidence does not, however, preclude the possibility of complete fusion at the implant placement site later on. Even if endplate continuity is broken at an early stage and the implant subsides towards a neighbouring vertebral body, complete fusion can still be achieved around the implant in the longer term. Our study demonstrated that there was no association between the type of fusion and the presence of implant subsidence ($B = 0.461$; $P = 0.2903$). The 101 levels assessed as complete fusion included 18 (17.8%) cases of subsidence and 83 (82.2%) cases without subsidence. Thus, optimal treatment outcome (complete fusion without implant subsidence) was obtained in 83 of the 144 disc spaces analysed, which represents 57.6%. Mixed-effects logistic regression models identified no significant association between the type of implant used and subsidence at 12 months following surgery ($B = 0.069$; $P = 0.875$). A significantly higher proportion of complete fusions ($B = 15.58$; $P < 0.0001$) and optimal radiographic outcomes ($B = 1.936$; $P = 0.0037$) after 12 months was observed with PEEK implants compared to TC-PEEK implants.

Conclusion

Complete fusion was noted at 12 months post-surgery significantly more frequently when PEEK cages were used compared to TC-PEEK implants.

Declarations

Ethics approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the relevant institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Consent to participate Informed consent was obtained from all individual participants included in the study.

Conflict of interest The authors declare no competing interests.

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