

Integral fixation titanium/polyetheretherketone cages for cervical arthrodesis: Two-year clinical outcomes and fusion rates using β -tricalcium phosphate or supercritical carbon dioxide treated allograft

ABSTRACT

Context: Despite increasing promising reports regarding composite titanium (Ti)/PolyEtherEtherKetone (PEEK) cages, further longer-term, quality research is required. Synthetic bone graft substitutes are another rapidly developing area of spinal surgical research.

Aims: The purpose of this study is to evaluate the outcomes of an integral fixation composite Ti/PEEK cage for anterior cervical discectomy and fusion (ACDF) and compare a synthetic bone graft substitute (β -tricalcium phosphate; [β TCP]) with allograft processed using supercritical fluid technology.

Methods and Design: Data from 195 consecutive patients were prospectively collected from a single centre. Indications were largely degenerative. Allograft and β TCP were used in a 3:1 randomization protocol. Patients were followed up for a minimum of 6 months and up to 48 months. Clinical outcomes included visual analogue scale and neck Oswestry disability index. Radiographic outcomes included fusion rates, subsidence rates and implant complications.

Results: Graft sub-cohorts were largely comparable and included 133 and 52 patients in the allograft and β TCP sub-cohorts, respectively. Clinical outcomes overall significantly improved ($P < 0.001$), with no significant inter-cohort differences. There were no implant-related complications. Overall fusion rate was 94.1% (175/186). The allograft cohort produced a significantly greater fusion rate of 97.7% (126/129) compared to 77.6% (38/49) for the β TCP cohort ($P = 0.001$).

Conclusions: This study demonstrates the viability of an integral fixation composite Ti/PEEK ACDF device in effectively and safely improving patient outcomes and achieving fusion. Allograft is more effective in achieving fusion compared to β TCP, though both were similarly efficacious in improving clinical outcomes.

Keywords: Allograft, anterior cervical discectomy and fusion, composite titanium/polyetheretherketone, integral fixation anterior cervical discectomy and fusion cage, β -tricalcium phosphate

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INTRODUCTION

Key objectives of current research into anterior cervical discectomy and fusion (ACDF) include optimising cage design and graft options.^[1-3] Combined titanium (Ti) and PolyEtherEtherKetone (PEEK) cages are theorised to harness the favourable properties of both,^[4-6] though further research is required.^[1,7-16] Several synthetic bone graft alternatives are

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available, with β -tricalcium phosphate (β TCP) presenting an attractive alternative.^[17,18] This study builds on reports of excellent clinical and radiographic outcomes for an integral fixation Ti/PEEK cage for ACDF, using supercritical carbon dioxide (SCCO₂) treated allograft,^[8] by investigating into the longer-term and comparing β TCP and SCCO₂-treated allograft outcomes.

SUBJECTS AND METHODS

Ethics approval

This research has been approved by the Institutional Review Board of the authors' affiliated institution.

Patient data

Over a 48-month period from March 2016 to October 2020, 195 patients were operated on at a single centre, resulting in 196 operations. Data were collected prospectively.

Inclusion criteria:

- (i) Age between 18 and 75 years old
- (ii) Symptomatic cervical degenerative disc disease or spine trauma with neurological deficit
- (iii) Patients unsuitable for, or unresponsive to conservative treatment.

Exclusion criteria:

- (i) Significant comorbidities, including systemic infection and terminal cancer
- (ii) Patients with ossification of the posterior longitudinal ligament
- (iii) Osteoporosis on preoperative bone mineral density.

Patients were followed up for a minimum of 6 months, with assessments postoperatively at day 1, weeks 2 and 6 to assess overall clinical status, and months 3, 6, 12 and 24. All patients were operated on using the composite integral fixation Ti/PEEK Redmond cage (A-Spine ASIA, Taiwan, China) [Figure 1]. This cage includes features of an integral fixation $\times 2$ screw design, with porous Ti-endplates, and a PEEK body and is available in the dimensions 14 mm \times 15 mm (depth \times width), 15 mm \times 15 mm, 15 mm \times 17 mm, 16 mm \times 18 mm and 17 \times 20 mm, ranging in height from 5 mm to 10 mm. Implant size choice was based on: (i) The height of the implant to mirror an adjacent normal disc height; and (ii) the maximum coverage of the endplate to distribute load evenly.

Implant

The integral fixation Ti/PEEK cage was constructed with a porous Ti plate architecture rather than a spray coating, to reduce the risk of delamination/wear of the implant

surface. The integral fixation design consists of $\times 2$ screws to prevent implant migration with an anterior anti-backout design [Figure 1].

Indications

The indications for ACDF in this cohort of 196 operations include: 177 degenerative pathologies (including discogenic neck pain, acute disc herniation with radiculopathy, foraminal stenosis, myeloradiculopathy, degenerative kyphosis), 20 acute traumatic cases and 1 spinal cancer. Almost 90% of the operations in this cohort were degenerative in nature. Examples of these indications include Figures 2 and 3.

Surgical technique

All surgeries were conducted using a modified Smith–Robinson technique under general anaesthesia. A right-sided linear antero-lateral incision was performed, then retraction of the musculo-visceral column achieved using the Trim-Line retractor system (TeDan, USA) with distraction of the vertebral bodies using customized Caspar retraction pins (A-Spine ASIA, Taiwan). Pathological disc material was removed using a combination of Kerrison rongeurs and curettes under the direct observation of an operating microscope (Pentaro, C. Zeiss, Germany). Visible osteophytes were removed using a high speed 2-mm drill and $\frac{1}{2}$ mm Kerrison rongeurs, then division of the posterior longitudinal ligament in all cases. Thorough decompression and visualization of the dura and nerve roots was accomplished. Decortication of the vertebral endplates was performed to optimize the bone-cage/graft interface.

The appropriate size cage was determined through the usage of a trial spacer to confirm the height of the disc space.

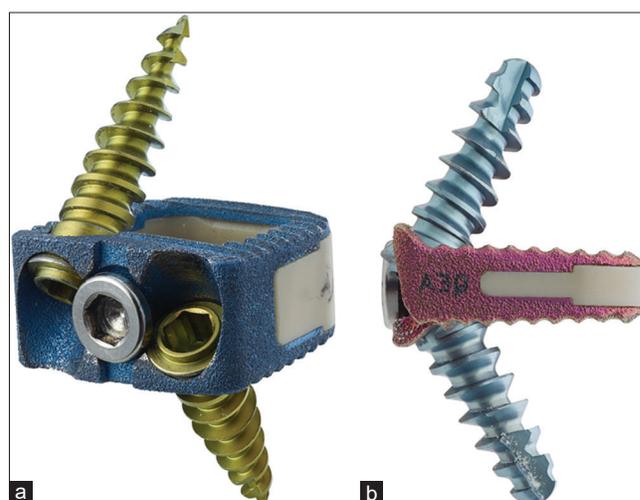


Figure 1: Redmond (A-Spine ASIA, Taiwan, China) integral fixation composite titanium/polyetheretherketone cage, with polyetheretherketone body, titanium endplates and integral fixation screws with anti-backout plate. (a) 8mm height device with self-tapping/self-drilling screws (b) 5 mm height device with oversize screws

Cages were filled with either allograft (Alloavance CrunchPlus, Australian Biotechnologies, Sydney Australia), β TCP (uDesis, Ulrich Medical, Germany) or Autograft (Iliac crest harvest), as determined preoperatively. The selected graft was firmly packed into the cage with the aim of distributing the axial loading through the implant. Cages were inserted using standard instrumentation and tapped into place. In all cases, following implant impaction and verification on lateral X-ray, integral fixation was applied via the use of $\times 2$ self-tapping screws [Figure 4]. Prior to wound closure, intraoperative antero-posterior and lateral plain radiographs were obtained to confirm the correct implant and screw positioning. All patients were advised to wear a cervical orthosis postoperatively for a 2-week period. Postoperative pain relief included a low dose of nonsteroidal anti-inflammatory drug and paracetamol.

Graft type

Allograft

The allograft used was human allograft (Alloavance CrunchPlus (1–3.5 cc), (Australian Biotechnologies, Sydney, Australia) that was processed and sterilized using a proprietary SCCO₂ process. The process involves the treatment of donor bone with a supercritical fluid which is a substance that exists as both a liquid and a gas above its critical temperature and pressure (i.e., 31.1°C and 1099 psi for carbon dioxide [CO₂]). As the CO₂ enters this phase it retains its gas-like viscosity and diffusibility and is able to permeate the bone matrices, while also retaining its liquid-like density and solvation power which enables it to improve sterilization efficacy.¹⁹⁻²¹ SCCO₂ has been shown to preserve mechanical properties of bone^{22,23} and soft²⁴⁻²⁶ tissue allografts compared to gamma sterilisation while reducing inflammation that can lead to delayed healing.²⁷

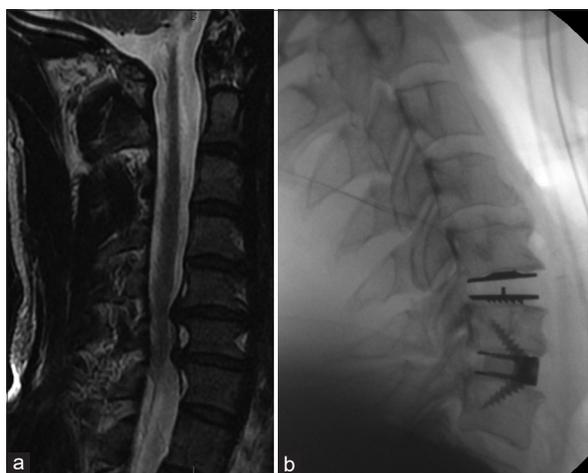


Figure 2: Anterior Cervical Discectomy and Fusion using β TCP/Total Disc Replacement (Mobi-C, LDR, France) hybrid for disc height loss and foraminal stenosis (a) Sagittal MRI of cervical level (b) Intraoperative X-ray

β TCP

Cages were filled with β TCP (uDesis TCP, Ulrich Medical, Germany).

Autograft

Autograft was harvested from the right iliac crest using standard techniques.

Randomisation of graft choice

Allograft and β TCP were used in a 3:1 randomization protocol, with 3 consecutive cases of allograft followed by a single case of β TCP. When allograft was not available, β TCP was used until the randomization schedule could continue. Autograft was used for all acute trauma cases with spinal fracture or dislocation and was not included in the randomisation.

Outcome measures

Clinical outcomes

Clinical outcomes were assessed preoperatively and postoperatively at 6 months, 24 months and variable timepoints depending on patient requirements. Patients were asked to quantify neck and arm pain on a visual analogue scale (VAS) ranging from 0 (no pain/discomfort) to 10 (worst pain/discomfort imaginable) preoperatively and postoperatively. Functional outcome was measured using the neck Oswestry disability index (NODI).

Radiographic outcomes

Radiographic fusion was assessed by an independent radiology practice with no conflict of interest with regards to the study outcome. Antero-posterior and lateral cervical radiographs were performed at day 1 and week 6 postoperatively for radiographic assessment of the implant to confirm that there was no implant failure, delamination or movement from the original implantation position. Evidence

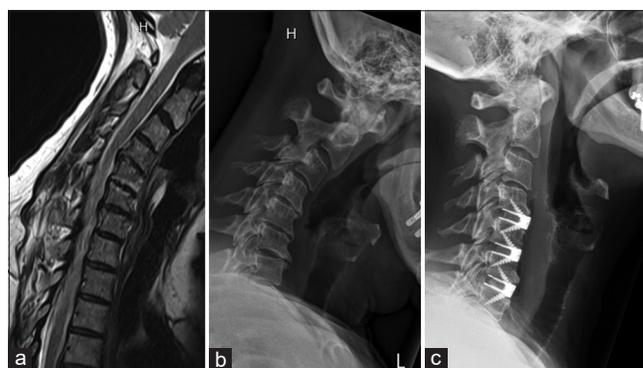


Figure 3: Triple-level anterior cervical discectomy and fusion (anterior cervical discectomy and fusion, Allograft) for degenerative disc disease and foraminal stenosis. (a) Sagittal T2WI magnetic resonance imaging of cervical level (b) sagittal standing X-ray (c) Postoperative X-ray demonstrating implanted anterior cervical discectomy and fusion devices and improved alignment

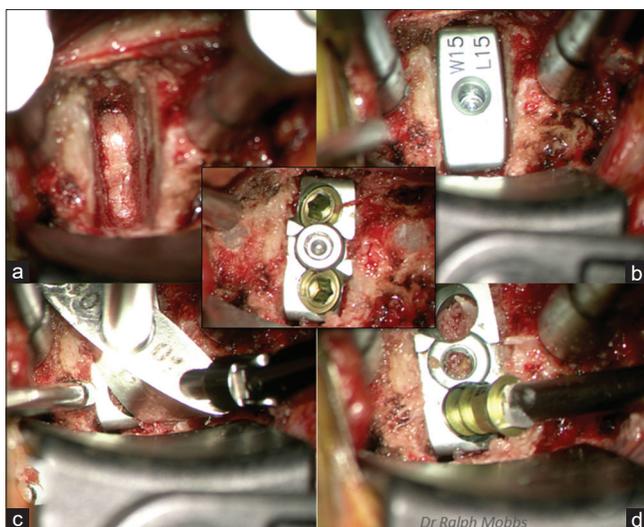


Figure 4: Workflow with allograft inside anterior cervical discectomy and fusion device: (a) Discectomy and decompression (b) Trial implant (c) Implanted Redmond (A-Spine ASIA, Taiwan, China) Integral Fixation composite titanium/polyetheretherketone cage (d) Integral fixation. (Inset) Final result with anti-backout screw

of delamination of the Ti/PEEK interface was determined at each follow-up time point.^[28] Computed tomography (CT) scans were performed at 3 months to assess the early fusion status of bone growth through the implant and the absence of lucency, and at 6 months if unsure of fusion status. If ongoing concerns as to fusion status was identified, further scans were performed at 12 and 24 months. Fusion was considered successful if bridging bone incorporating the graft and adjoining endplates was apparent, with evidence of graft remodelling and new bone formation, restoration of inter-body space, and no hardware/implant failure.^[29]

The assessment of interbody fusion and the integration of the Ti endplate remains a challenge. As there are no universally accepted criteria for determining radiological fusion, it is often difficult to arrive at a true assessment of fusion based on plain radiography alone, particularly when synthetic cages are used. Our study utilized fine-cut CT scans with reconstructions, which have been shown to be more reliable and sensitive for the detection of pseudoarthrosis than plain radiography.^[30,31] In addition, it was noted that the Ti-endplates did not interfere with fusion assessments on either radiographs or CT as based on radiology observer feedback.

Statistical analysis

Descriptive data are represented as means (standard deviation [SD]). All percentages are reported based on total valid dataset. All datasets were tested for normality with the Kolmogorov-Smirnov and Shapiro-Wilk normality tests. Given the objectives of the study and the low numbers of

the autograft cohort, inferential statistical analysis was conducted on the allograft and β TCP cohorts only. Cohort characteristics were analysed using the independent *t*-test for parametric data and the Mann–Whitney U test for nonparametric data, as well as Pearson Chi-square or Fisher’s Exact test, as appropriate. Clinical outcomes were analysed across timepoints and between cohorts, using the paired *t*-test, independent *t*-test, Mann–Whitney U test, and Pearson Chi-square or Fisher’s Exact test, as appropriate. Statistical significance was set at $P < 0.05$. All analyses and graphs were generated using SPSS version 26 (IBM Corporation, Armonk, New York, USA) and a commercial software package (GraphPad Prism version 5.01, GraphPad Software, USA).

RESULTS

Patient demographics

A total of 195 patients met the inclusion criteria and underwent 196 operations at a total of 310 operative levels, with their details summarised in Tables 1 and 2. Of these, 68 received single level procedures (38.2%), 90 received double level (50.1%), 18 received triple level (10.1%) and 2 (1.1%) patients received quadruple level procedures. For multi-level procedures, all were contiguous excepting 8 double level procedures and 1 triple level procedure. Operative levels included C₂ to T₂. Patients received either ACDF alone (72.6%) or a hybrid ACDF and total disc replacement procedure. One patient received a ACDF and postero-lateral fusion. The single patient re-operated on was indicated by C4/5 adjacent segment disease following a double level ACDF inferiorly. Neck pain was present in almost all patients, with the major surgical indications being cervical disc herniation/foraminal stenosis associated with radiculopathy or spinal stenosis and cervical myelopathy. There were also 20 operations indicated by trauma (11 with acute deficit and 9 with delayed presentation), and 1 due to malignancy. A total of 133 patients received allograft, 52 received β TCP, and 11 received autograft. The cohort was largely male (55.6%), Caucasian (63.3%) and had a mean age and body mass index of 59.3 years (range: 25–90) and 28.4, respectively. There were 29 (17.2%) current smokers and 22 diabetic patients (12.4%). Patient demographics for the β TCP and allograft sub-cohorts were largely similar, with operative levels being the only significant difference ($P = 0.024$).

Clinical outcomes

Visual analogue scale score

Whole cohort mean VAS pain scores improved significantly from preoperative to postoperative follow up at 24 months ($P < 0.001$). This change from 6.8 (SD: 2.1) to 1.5 (1.7) included a mean improvement of 5.3. This is

Table 1: Patient demographics, for whole cohort, as well as β tricalcium phosphate and allograft cohorts

Characteristic	Whole cohort (n=196), n (%)	β TCP cohort (n=52), n (%)	Allograft cohort (n=133), n (%)	P
Age	59.3 (12.9)**	59.2 (10.9)	59.4 (13.5)	0.887
Male sex	100 (55.6)	23 (50.0)	73 (57.0)	0.411
Ethnicity				
Caucasian	119 (63.3)	31 (64.6)	82 (62.6)	0.942
Asian	48 (25.5)	12 (25.0)	33 (25.2)	
African	21 (11.2)	5 (10.4)	16 (12.2)	
BMI	28.4 (4.9)**	28.9 (5.6)	28.1 (4.6)	0.468
Smoking status				
Current	29 (17.2)	8 (17.0)	20 (16.9)	0.996
Quit	12 (7.1)	3 (6.4)	8 (6.8)	
Never	128 (75.7)	36 (76.6)	90 (76.3)	
Diabetic	22 (12.4)	5 (10.9)	16 (12.5)	0.771
Primary diagnosis				
DDD	22 (12.0)	8 (16.0)	13 (10.0)	0.295
Stenosis	86 (46.7)	27 (54.0)	59 (45.4)	
Trauma	20 (10.9)	6 (12.0)	13 (10.0)	
Listhesis	3 (1.5)	1 (2.0)	1 (0.8)	
Other	1 (0.5)	0	1 (0.8)	
DDD + stenosis	36 (19.6)	5 (10.0)	30 (23.1)	
Trauma + DDD/stenosis	10 (5.4)	1 (2.0)	9 (6.9)	
Other Combined	6 (3.3)	2 (4.0)	4 (3.1)	
ACDF only*	130 (72.6)	36 (78.3)	90 (67.7)	0.454

*Patients received either ACDF alone or with either TDR or PLF, though only one patient received both ACDF and PLF. **Mean (SD). All percentages (%) calculated for valid data only. DDD - Degenerative disc disease; ACDF - Anterior cervical discectomy and fusion; TDR - Total disc replacement; PLF - Posterolateral fusion; SD - Standard deviation; BMI - Body mass index; TCP - Tricalcium phosphate

Table 2: Operative levels, for whole cohort, as well as β tricalcium phosphate and allograft cohorts

Operative levels	Whole cohort (n=196), n (%)	β TCP cohort (n=52), n (%)	Allograft cohort (n=133), n (%)	P
C2/3	2 (1.1)	0	2 (1.6)	0.024
C3/4	7 (3.9)	2 (4.3)	5 (3.9)	
C4/5	16 (9.0)	1 (2.2)	15 (11.8)	
C5/6	26 (14.6)	12 (26.1)	13 (10.2)	
C6/7	14 (7.9)	2 (4.3)	11 (8.7)	
C7/T1	3 (1.7)	0	3 (2.4)	
C3/4 + C4/5	8 (4.5)	0	8 (6.3)	
C4/5 + C5/6	23 (12.9)	9 (19.6)	14 (11.0)	
C5/6 + C6/7	48 (27.0)	13 (28.3)	34 (26.8)	
C6/7 + C7/T1	3 (1.7)	0	3 (2.4)	
Two level noncontiguous	8 (4.5)	1 (2.2)	6 (4.7)	
Three level	18 (10.1)	5 (10.9)	12 (9.4)	
Four level	2 (1.1)	1 (2.2)	1 (0.8)	

All percentages (%) calculated for valid data only. SD - Standard deviation; TCP - Tricalcium phosphate

consistent with reported outcomes for ACDF surgery in the degenerative population.^[32] Scores were similar for β TCP and allograft cohorts at all assessed timepoints, with no significant differences [Figure 5].

Neck Oswestry disability index score

NODI scores improved significantly for the whole cohort at 24 month postoperative follow up ($P < 0.001$). This change from 42.4% (SD: 16.0) to 12.9% (11.5) included a mean improvement of 29.5%. Inter-cohort scores were

similar at all assessed timepoints, with no significant differences [Figure 6]. Table 3 details all clinical outcomes.

Radiographic outcomes

An overall fusion rate of 94.1% (175/186) was achieved, with evidence of bridging bone between endplates on CT scanning at 6 months postoperation. The presence of Ti endplates did not interfere with fusion assessments. Evidence of graft remodelling at the interface with the endplate was noted. There was a significant difference in fusion rate between

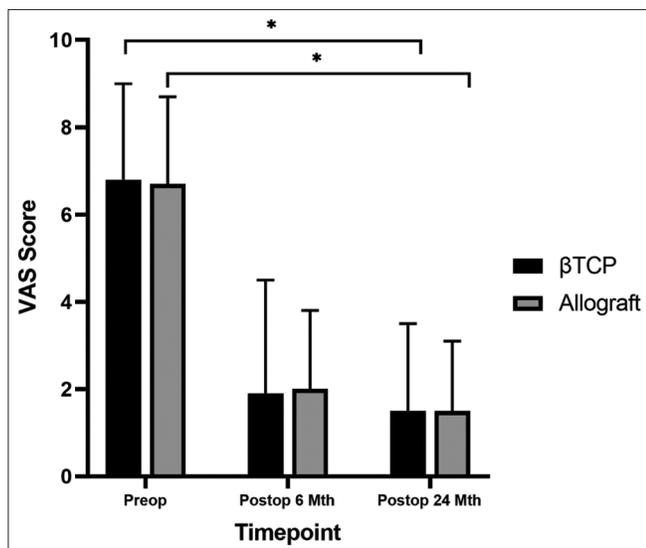


Figure 5: Mean visual analogue scale pain score for β -tricalcium phosphate and allograft cohort at all assessed timepoints. Significant intra-cohort improvement by 24 month follow-up. No significant inter-cohort differences. Note: * = ($P < 0.001$)

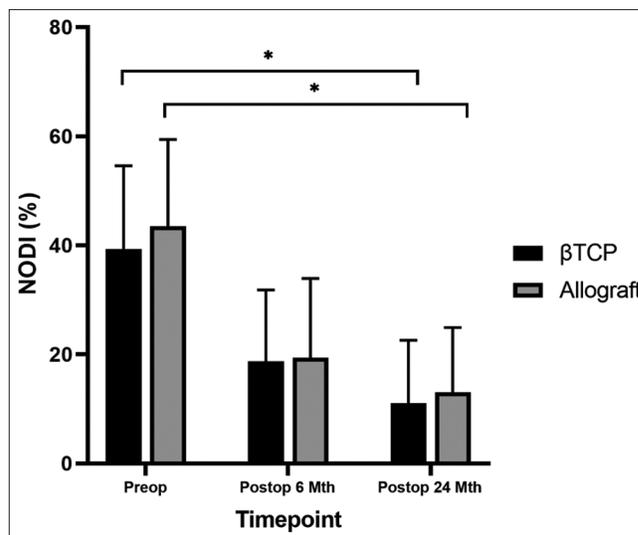


Figure 6: Mean neck Oswestry disability index scores for β -tricalcium phosphate and allograft cohort at all assessed timepoints. Significant intra-cohort improvement by 24 month follow-up. No significant inter-cohort differences. Note: * = ($P < 0.001$)

the β TCP cohort, 77.6% (38/49), and the allograft cohort, 97.7% (126/129) ($P = 0.001$) [Table 4]. All autograft patients achieved fusion (8/8) at a minimum of 12 months follow-up. Additionally, Table 5 outlines clinical outcomes by fusion outcome.

Complications

Complications were divided into approach-related and implant-related issues. There were no implant complications and no evidence of delamination in any case. Additional attention was focused on 6-month fine-cut CT to determine the presence of implant failure at the Ti/PEEK junction, which was not present in any case. Approach-related complications included three cases of recurrent laryngeal nerve palsy that improved by the 3-month follow-up mark. There was 1 case of postoperative hematoma requiring an additional procedure for clot removal within 12 h of the index procedure. The patient proceeded to have an excellent clinical outcome at 6 months follow-up.

DISCUSSION

A Ti/PEEK cage aims to combine the favourable properties of both materials and thereby improve patient and surgical outcomes, as well as minimise complications. Using this unique design integral fixation Ti/PEEK cage with allograft over a 6-month follow-up period, Phan *et al.* reported mean improvements of 5 and 22 for VAS and NODI scores, respectively, as well as a 94% fusion rate. The authors concluded that these findings were consistent with the literature describing early outcomes for single-material

cages.^[8] In this study, the use of the same integral fixation Ti/PEEK device was overall an effective and safe ACDF design and material combination, resulting in statistically significant improvements to pain and function at 24 months follow up, as well as an excellent fusion rate of 94.1%. There were no implant-related complications at any timepoint, and only 4 approach-related, all of which improved and did not compromise overall successful clinical outcome. These results are generally either superior or comparable to other reports of ACDF outcomes over similar time periods, including using Ti/PEEK^[1,12,16] and conventional single-material cages.^[33-35]

Despite their efficacy, the drawbacks of autograft and allograft have led researchers to consider alternatives including SCCO_2 -treated allograft and synthetics such as β TCP. Both allograft and β TCP have been generally reported to be safe and efficacious, though possessing specific disadvantages and demonstrating sub-optimal fusion rates.^[18,36-40] In this study, SCCO_2 -treated allograft was more effective in achieving fusion (97.7%) than β TCP (77.6%), though there was no significant inter-cohort difference in pain or functional outcomes at any assessed time point. This fusion rate is comparable to the 69%–70% fusion rates^[18,38] reported for β TCP in ACDF at 1 year postoperatively. While these results may support the use of both graft options, the combination of clinical improvement, excellent fusion rate and lack of adverse events, both in this study and as reported by the manufacturer (Australian Biotechnologies, Sydney, Australia), may designate SCCO_2 -treated allograft as the more favourable option. Despite an approximately 20% difference in fusion rate between the graft cohorts, the

Table 3: Clinical outcomes

Outcome scores	Preoperative	Postoperative 6 months	Postoperative 24 months
VAS			
Whole	6.8 (2.1)	1.8 (2.1)	1.5 (1.7)
β TCP	6.8 (2.2)	1.9 (2.6)	1.5 (2.0)
Allograft	6.7 (2.0)	2.0 (1.8)	1.5 (1.6)
P	0.715	0.480	0.976
NODI (%)			
Whole	42.4 (16.0)	18.3 (14.7)	12.9 (11.5)
β TCP	39.3 (15.3)	18.7 (13.1)	11.0 (11.6)
Allograft	43.5 (15.9)	19.4 (14.5)	13.1 (11.8)
P	0.761	0.483	0.452

Mean (SD). SD - Standard deviation; TCP - Tricalcium phosphate; VAS - Visual Analogue Scale; NODI - Neck Oswestry disability index

Table 4: Radiographic outcomes.

Cohort	Fusion by last follow up, n (%)
Whole	175/186 (94.1)
β TCP	38/49 (77.6)
Allograft	126/129 (97.7)
P	0.001

All percentages (%) calculated for valid data only. TCP - Tricalcium phosphate

Table 5: Clinical outcomes by fusion outcome

Outcome scores	Preoperative	Postoperative 6 months	Postoperative 24 months
VAS			
Fusion	6.7 (2.1)	1.5 (1.8)	1.4 (1.5)
Nonfusion	7.8 (1.3)	6.3 (1.9)	5.0 (2.6)
P	0.076	0.000	0.018
NODI (%)			
Fusion	41.7 (15.9)	16.6 (13.1)	11.8 (10.1)
Nonfusion	48.9 (17.5)	42.2 (17.3)	32.0 (19.1)
P	0.151	0.000	0.048

Mean (SD). SD - Standard deviation; VAS - Visual Analogue Scale; NODI - Neck Oswestry disability index

similar clinical outcomes may reflect integration of the porous Ti endplates of the device, thereby supporting the notion of a “locked nonunion,” a stable, nonmobile nonfused motion segment. Therefore, it may not be absolutely necessary to achieve a solid fusion using these newer devices if the porous endplate of the device fuses with the endplate to accomplish motion segment stability.

Limitations include patient drop-out in our follow-up data, a small autograft cohort and our largely degenerative cohort limiting external validity to other indications. While there was a significant difference in operative levels between cohorts, this was negligible considering the overall similarity in cohort characteristics and the proportions of the most prevalent operative levels. Future research should extend these findings to 5–10 years postoperatively, allowing for complications possibly arising in the longer-term^[41] to be

excluded and the trajectories of clinical outcomes to be determined.

CONCLUSIONS

The uniquely designed integral fixation Ti/PEEK interbody cage allowed for effective and safe ACDF for the treatment of degenerative and traumatic cervical pathologies. Though SCCO2-treated allograft was more effective in achieving fusion compared to β TCP, both graft types produced similar improvements in clinical outcomes.

Financial support and sponsorship

Nil.

Conflicts of interest

Prof Ralph Mobbs is a research and design consultant for A-Spine ASIA. Prof William Walsh is a research and design consultant for SeaSpine, USA. None of the other authors have any relevant conflicts of interest to declare.

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