CLINICAL ARTICLE

Biphasic Calcium Phosphate Contained within a Polyetheretherketone Cage with and without Plating for Anterior Cervical Discectomy and Fusion

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Objective: To evaluate the properties of a combination bone graft consisting of biphasic calcium phosphate ceramic, polyetheretherketone (PEEK) cage in one- and two-level surgery.

Methods: Over a 12-month time period, a prospective single surgeon series of 75 patients were included in the study and 58 patients selected based on adequate data points. From these 58 patients, 32 were supplemented with anterior plate fixation and 26 patients without plating. Duration of clinical follow-up was a mean of 12.4 months (range, 6–26 months) in the Plated Group and 10.5 months (range, 6–21 months) in the Non-Plated Group.

Results: A 100% fusion rate with nil graft related complications was achieved in the Plated group compared with 96.2% fusion and 11.5% subsidence rates reported in the Non-Plated group. Patients in both groups experienced statistically significant improvement in pain and functional outcomes compared to their pre-operative status; however, there was no significant difference in outcome between the Plated and Non-Plated Groups.

Conclusions: Biphasic calcium phosphate ceramic contained within a PEEK cage is an effective implant for use in anterior cervical surgery with high fusion rates and good clinical outcome.

Key words: Bone plates; Calcium phosphate; Cervical vertebrae; Spinal fusion

Introduction

The use of interbody fusion devices following anterior decompression is a widely accepted procedure in patients suffering degenerative or posttraumatic conditions of the cervical spine. Degenerative disease of the cervical spine including spondylosis, stenosis, herniated intervertebral discs and ossification of the posterior longitudinal ligament can cause significant radiculopathy and/or myelopathy[1], resulting in functional limitations, disability and loss of quality of life. The goals of surgical intervention are decompression of neural elements through removal of the pathological intervertebral disc structures and restoration of spinal alignment and stability.

Anterior cervical discectomy and fusion (ACDF) is one of the most commonly performed spinal procedures and has good to excellent clinical results in the majority of cases in treating cervical disc disease and associated radiculopathy and myelopathy[2,3]. The advantages of an anterior approach are minimal soft tissue injury, direct visualization of the spinal cord and nerve roots to be decompressed, complete removal of degenerative or traumatized intervertebral disc and access to two endplates with a considerable surface area to facilitate fusion[4,5]. According to one meta-analysis, fusion rates in ACDF range from 92.1% to 94.6% in one- and two-level disc disease[1]. Although complications are rare the most commonly

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occurring problems are isolated dysphagia, wound haematoma and recurrent laryngeal nerve palsy[2].

While autograft remains the gold standard in ACDF[6,7], the graft harvesting process can result in a range of complications and short- and long-term morbidity, namely donor site pain, haematoma, lateral cutaneous nerve palsy and infection[8,9]. Allograft, which gained popularity in the efforts to circumvent the need for autograft, has its own associated complications including the risk of disease transmission, infection and histocompatibility differences[10]. Graft collapse and pseudoarthrosis were also seen in bone graft only fusion[11]. Thus the impetus behind the creation of intervertebral cages with bone graft substitute technologies has been to minimize or eliminate autograft and allograft use with the aim of improving clinical outcomes[3,6].

In this study, we evaluate the properties and effectiveness of a biphasic calcium phosphate ceramic contained within a polyetheretherketone (PEEK) cage for one- and two-level cervical arthrodesis. Another purpose of this study was to evaluate the fusion rates and outcomes in patients with or without internal plate fixation. Thus our aim in this preliminary report is to ascertain the usefulness of these materials in anterior cervical fusion and to determine whether there are any significant differences in radiological and clinical outcomes between the Plated and Non-plated Groups.

Materials and Methods

Patient Data

Over a 12-month time period, 75 patients were operated and data prospectively collected. Seventeen patients were excluded from the study due to inadequate follow-up. The operative surgeon (RJM) has a large catchment area from regional Australia and given the litany of distance, there was a large dropout from the prospective cohort due to difficulty with follow-up. All 17 patients were contacted via phone; however, they could not return for a face-face consultation and therefore were excluded. From 58 remaining patients, 32 patients were identified as having undergone ACDF with plate fixation, 25 of which were for one-level and seven for two-level disease. There were 26 patients who had ACDF without plating, which included 16 one-level and 10 two-level operations. There were 37 males and 21 females, with a mean age of 50.3 years (range, 21–81). There were 15 smokers, six people with diabetes and 10 workers compensation cases. Within the non-traumatic injury patients, the mean preoperative symptom length was 11.9 months (range, 0.75–60 months). Both groups had similar mean demographics for age (50.0 vs 50.6 years), symptom length (12.5 vs 12.2 months), operative levels (C5/6 and C6/7 the most common operative levels) and time to follow-up.

Inclusion criteria were traumatic injury or degenerative disc disease causing radiculopathy, myelopathy or radiculomyelopathy and unresponsive to conservative treatment. One patient who underwent one-level ACDF without plating suffered from Klippel-Feil Syndrome affecting adjacent levels. These data are summarized in Table 1.

Surgical Procedure

All patients were operated on by the same surgeon (RJM) and interbody grafting with a biphasic calcium phosphate implant contained within a PEEK cage. A modified Smith-Robinson technique was used under general anaesthesia for all operations. After a right antero-lateral incision, Caspar retracting pins were positioned in the adjacent vertebral bodies for adequate distraction. Under the direct observation of an operating microscope, the removal of pathological disc was performed using rongeurs and curettes. Osteophytes were removed and the posterior longitudinal ligament divided. In all cases, complete decompression and visualization of the dura and nerve roots was achieved. Decortication of the vertebral endplates was performed to optimize the bone-graft interface.

A trial cage was inserted to confirm the height of the disc space. Biphasic calcium phosphate (KG Bone, Kasios Biomaterials, Launaguet, France) was packed into the centre of the PEEK cage. The interbody implant was inserted using forceps and tapped into place (Fig. 1).

With the implant in place, anterior plate fixation was inserted for the Plated Group. Antero-posterior and lateral plain radiographs were obtained intraoperatively to check correct positioning before wound closure. All Non-Plated were advised to wear a cervical orthosis postoperatively for a period of 6 weeks.

Interbody Graft

KG Bone (Kasios Biomaterials) is composed of biphasic calcium phosphate (BCP): an amalgamation of two ceramics already in use in the cervical spine–hydroxyapatite (HA) and beta-tricalcium phosphate (β-TCP), combined respectively in a 60/40 ratio to provide a biologically and biomechanically stable graft with osteoconductive properties. KG Bone has a fully interconnected architecture, with a mean porosity of 60% and a 600 micron pore size, facilitating osteointegration. It is supplied sterile by the manufacturer. KG Bone is specifically designed to fit precisely into a corresponding cervical cage made of PEEK ("Kage" cervical cage, Kasios Biomaterials) and together they are implanted into the empty disc space. The PEEK cage (Fig. 2) has an anatomical shaped design with retention grooves that help anchor the graft once implanted and discourage graft migration.

Outcome Measures

A prospective review of patient files and imaging was performed to determine clinical and radiographic outcome following anterior cervical spine surgery. Surgical and graft complications, need for additional surgery/re-operation and fusion rates were noted.

Radiographic fusion was assessed at every follow-up by an independent radiologist. Plain radiographs were the first choice of modality for radiographic assessment. Ethics board approval was for X-ray studies, including flexion/extension radiographs, for the assessment of fusion. Approval for CT scan was given only if there was the suggestion or potential for

TABLE 1 Demographic data of patients included in this study

Variables	Plated group	Non-plated group
Total number	32	26
Age (years)	50.0 (22–81)	50.6 (21–71)
Sex (M:F)	25:7	12:14
Tobacco smokers	10	5
Diabetics	3	3
Workers compensation	2	8
Previous cervical surgery	1	6
Neurological deficit		
Radiculopathy	27	23
Myelopathy	14	6
Pathology		
Degenerative disease	24	25
Trauma	7	1
Redo ACDF	1	0
Preoperative pain (VAS)	7.9 ± 1.5 (n = 31)	7.78 ± 1.1 (n = 26)
Preoperative ODI (%)	52.0 ± 17.0 (n = 29)	52.5 ± 15.5 (n = 25)
Symptom length (months) in non-traumatic patients	12.5 (0.75–48)	12.2 (0.5–60)
Bone mineral aspirate (BMA)	18	20
Number of levels		
One level surgery	25	16
Two level surgery	7	10
Operated levels		
C3/4	4	3
C4/5	2	6
C5/6	17	13
C6/7	16	12
C7/T1	0	2

ODI, Oswestry Disability Index; VAS, visual analog score

non-union. Radiographs were routinely taken intraoperatively then at one day, 6 weeks, 3 months, 6 months and one year postoperatively. Fusion was considered successful if bridging bone incorporating the graft and adjoining endplates was apparent (Figs 3,4), with additional loss of radiolucency, restoration of interbody space and no hardware failure. Lack of movement on flexion/extension X-rays were also used to confirm status. We defined subsidence as a decrease in disc space height of at least 3 mm, and movement as change in anterior or posterior displacement of the graft by at least 3 mm[12]. If required, computed tomography (CT) was performed to verify the fusion status of an operated level.

Clinical outcome was assessed using a variety of parameters. Patients were asked to quantify their overall pain on a Visual Analog Scale (VAS) for pain ranging from 0 (no pain/discomfort) to 10 (worst pain/discomfort imaginable) pre- and postoperatively. Functional outcome was measured using the Oswestry Disability Index (ODI). Patients were also assessed according to Odom's criteria[13] (Table 2) for their overall clinical outcome. Patient satisfaction with their procedure was elicited using the Patient Satisfaction Index (PSI) as described by Palit *et al.*[14] (Table 3) at final follow up. Length of stay and time before return to work were recorded where applicable.

Statistical Analysis

Descriptive data are represented as means ± standard deviation (range, minimum–maximum). All datasets were tested for normality with the D'Agostino and Pearson omnibus normality test. Nonparametric data was analyzed using the Mann–Whitney U-test and parametric unrelated data with the unpaired t-test for comparison of the results between the Plated and Non-Plated Groups. A paired t-test was used for comparison between pre- and postoperative continuous variables within patient groups. Statistical significance was set at level of $P < 0.05$. All analyses and graphs were generated using a commercial software package (GraphPad Prism version 5.01, GraphPad Software, Inc., La Jolla, CA, USA).

Results

From 75 patients in the original dataset, 58 patients were available for follow-up observation with adequate data points. Duration of clinical follow-up was a mean of 12.4 months (range, 6–26 months) in the Plated Group and 10.5

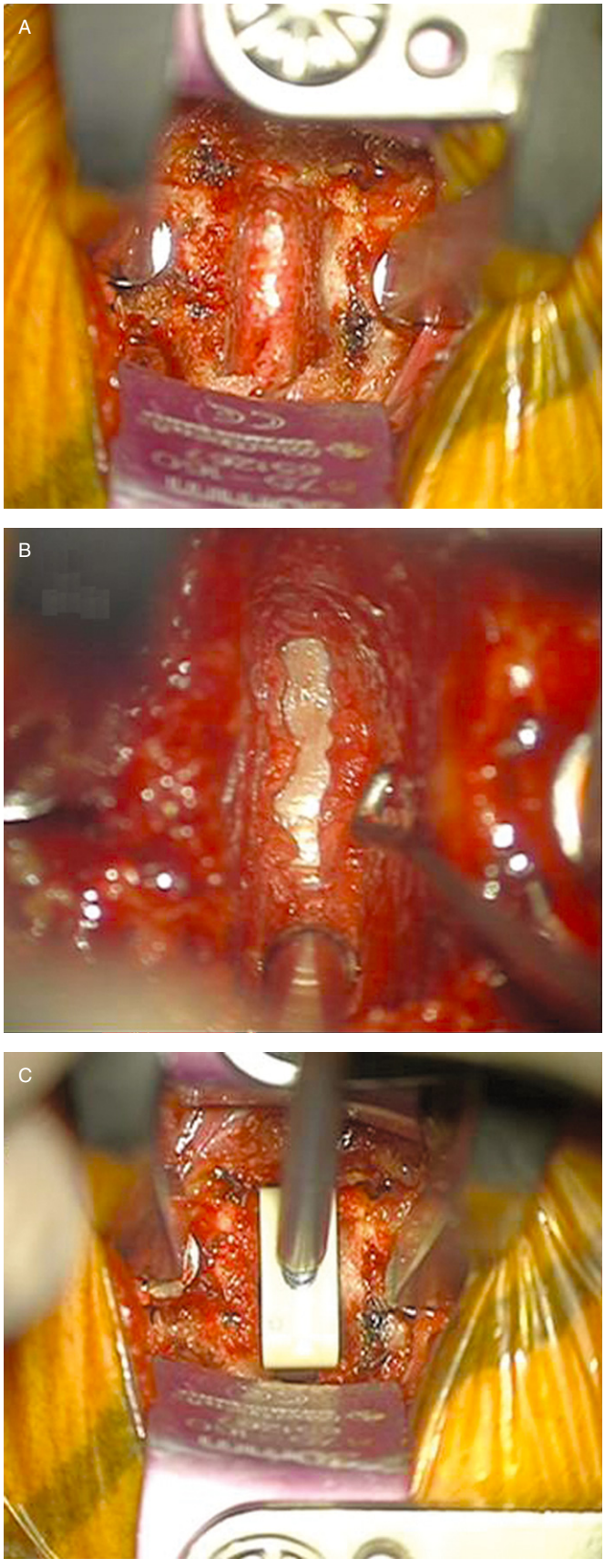

Fig. 1 Surgical technique including four steps: discectomy and distraction of the interbody space (A), microsurgical decompression (B), trial spacer for graft choice(c), and insertion of interbody polyetheretherketone (PEEK) cage (D).

Fig. 2 Photograph showing a polyetheretherketone (PEEK) cervical cage (Kage) containing 60:40 hydroxyapatite : tricalcium phosphate (HA:TCP) biphasic calcium phosphate (KG Bone).

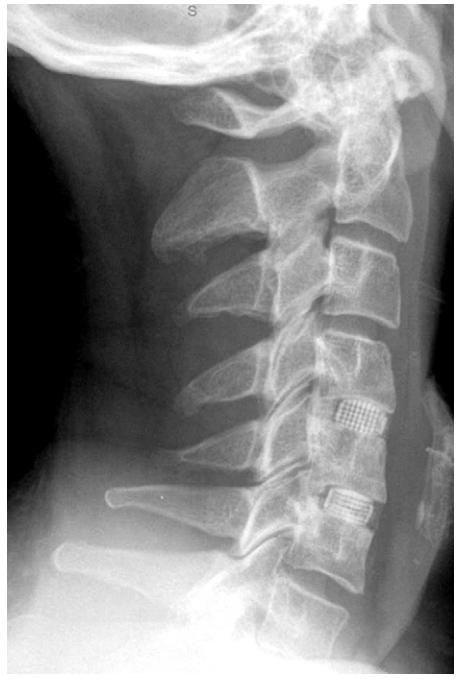

Fig. 4 X-ray of two-level polyetheretherketone (PEEK) cage fusion without plating 6 months postoperatively demonstrating solid union posterior and through the PEEK cage implants.

months (range, 6–21 months) in the Non-Plated Group. In both groups there were clear trends in clinical improvement in terms of pain and functional outcomes at final clinical assessment.

Radiological Outcomes

In the Plated Group, 100% fusion rate was achieved by 6 months postoperatively and remained unchanged throughout patient follow-up. Grafts demonstrated no movement on

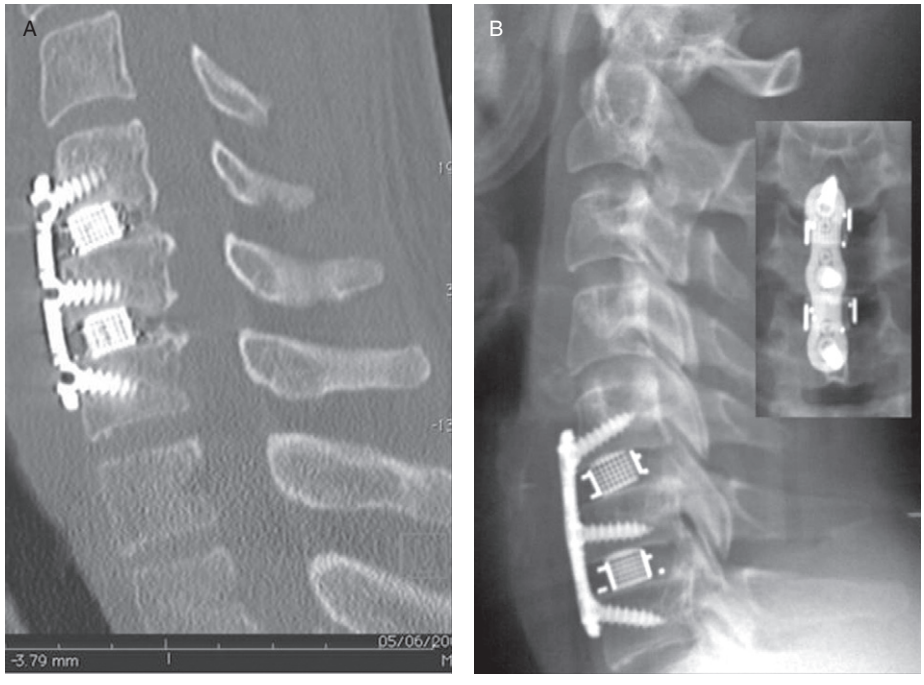

Fig. 3 Fine-cut CT scan (A) demonstrating fusion of a two-level graft with plating at 3 months post-operatively with pain-free range of motion, and the day-1 postoperatively corresponding neutral sagittal and antero-posterior X-rays (B).

TABLE 2 The Odom clinical outcome scoring system

Excellent	No complaint referable to cervical disease. Able to perform daily occupation without impairment
Good	Intermittent discomfort referable to cervical disease. No significant interference with work.
Fair	Subjective improvement in symptoms. Physical activity significantly impaired.
Poor	Worsening or no improvement

TABLE 3 Patient satisfaction index (PSI) scoring system

1	Surgery met my expectations
2	I did not improve as much as I had hoped but I would undergo the same operation for the same results
3	Surgery helped but I would not undergo the same operation for the same outcome
4	I am the same or worse as compared to before surgery

flexion/extension X-rays (Fig. 5). There were no incidences of radiological complications such as graft subsidence, movement or fracture. One X-ray demonstrated a 2 mm loss of disc space height; however, this did not qualify as graft subsidence and there were no associated symptoms developing over the course of 26 months of follow up.

Inferior radiological results were achieved in the Non-Plated Group. Of the 26 patients, four patients (15.4%) experienced delayed fusion (set at 3 months postoperatively). One patient had a non-union (3.8%) of one level from a two-level operation, which required re-operation. There were three cases of graft subsidence (11.5%) and one graft migration (3.8%), which required reoperation; however, fusion was achieved within 3 months. In the plating group, subsidence experienced was less than 3 mm in all patients. Additionally, one patient showed evidence of new adjacent segment degeneration on magnetic resonance imaging 9 months after a one-level ACDF without plating.

Comparison of *VAS*

In the two groups, the average postoperative neck or arm pain as measured by VAS showed significant relief ($P < 0.0001$) when compared with the preoperative scores (Fig. 6), but no significant difference of improvement in VAS scores was observed between the two groups ($P = 0.1836$). Overall pain in the Plated group improved on average from 7.9 preoperatively to 1.5 postoperatively, with a mean improvement of 6.5 ± 2.1 (range, 1–9), while in the Non-Plated group pain improved from 7.8 to 2.2 on average with a mean improvement of 5.6 ± 2.8 (range, 0–10).

Comparison of ODI

Three patients in the Plated Group and one patient in the Non-Plated Group returned incomplete ODI questionnaires either pre- or postoperatively, so they were excluded from this subset analysis, although their Odom's Criteria were good or excellent according to their last consultation. The average ODI score showed significant improvement with surgery ($P < 0.0001$) (Fig. 7); however, there was no significant difference in improvement between the Plated and Non-Plated Groups ($P = 0.9170$). Mean improvement in ODI score for the Plated Group was 34.3 ± 19.7 (range, 2–78) while in the Non-Plated Group mean improvement was 34.9 ± 20.6 (range, 4–72).

Odom's Criteria and PSI

No significant difference was found between the Plated and Non-Plated groups when comparing their Odom's criteria and PSI. Ninety-seven per cent of Plated patients achieved either excellent ($n = 16$) or good ($n = 15$) outcomes according to Odom's criteria, with one attaining a fair result. Comparatively, of the Non-Plated Group, 77% achieved an excellent ($n = 14$) or good ($n = 5$) outcome, with 23% only attaining a fair

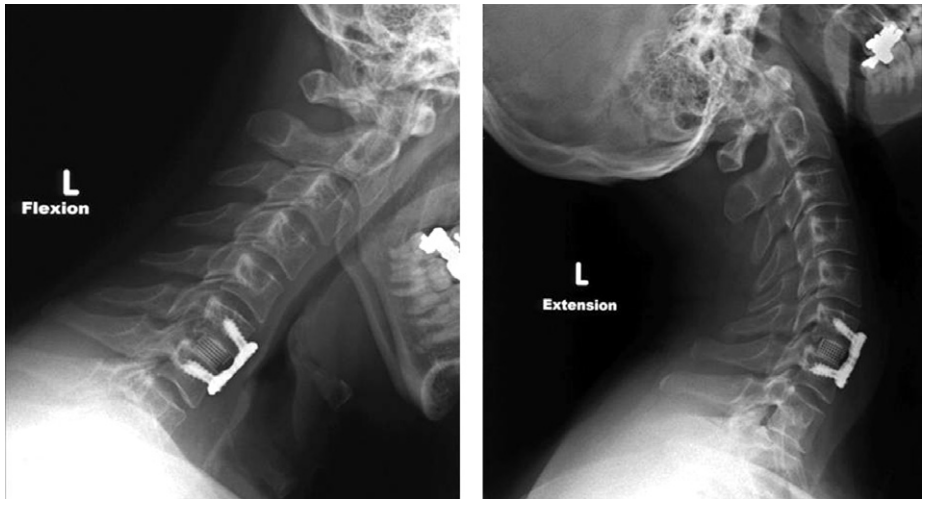

Fig. 5 F/E X-rays demonstrating a mechanically stable one-level graft with plate fixation.

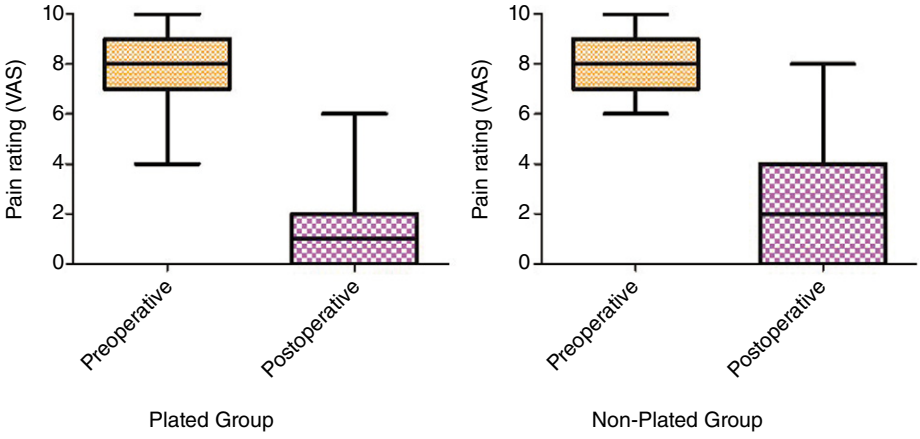

Fig. 6 Preoperative and postoperative pain rating (Visual Analog Scale [VAS]) in the Plated (left) and Non-Plated (right) Groups.

($n = 6$) result and one patient having a poor result. Within the Plated Group ($n = 29$), there were 21 patients with a PSI of 1, six patients with a PSI of 2 and one patient with a PSI of 3. Within the Non-Plated Group ($n = 26$), there were 14 patients with a PSI of 1, seven patients with a PSI of 2, four patients with a PSI of 3 and one patient with a PSI of 4. Hence, 93% of Plated patients were satisfied with their surgical outcome (PSI of 1 or 2) compared with 54% of Non-Plated patients. No significant difference was found in length of hospital stay or time to return to work.

Complications

Within the Plated group, there were two cases of dysphagia (6.3%). One case of dysphagia lasted 3 months with only the sensation of an "annoying lump in the throat" persisting at one year postoperatively. One patient who had undergone a two-level Plated ACDF experienced ongoing dysphagia, with symptoms only resolving following surgical removal of the plate. One patient reported new neck pain after an initial good recovery following an episode of severe vomiting involving rapid flexion and extension. However, this complication self-resolved after 4 weeks.

Of the three cases of subsidence within the Non-Plated Group, no re-operations were performed. One symptomatic subsidence patient who refused re-operation improved without surgery. Another subsidence patient had only a 1 point improvement in their VAS score; however, their PSI was 2, indicating that they "would undergo the same operation for the same results". This patient also experienced recurrent laryngeal nerve palsy for 5 months, likely sustained during the removal of a plate from a previous adjacent level ACDF during this surgery. The third subsidence patient presented for an ACDF re-operation from 1 year prior. This patient experienced improvement in radicular symptoms and pain; however, the patient developed ongoing 5 out of 10 pain after 3 months postoperatively, which is being managed with Gabapentin. Of note, all three of the graft subsidence cases had undergone previous neck surgeries.

Graft migration was experienced in a non-plated ACDF patient with complex cervical problems, including Klippel-Feil Syndrome affecting adjacent levels, previous fusion surgery and scoliosis, complicating their management. In this case fusion was achieved within 3 months of re-operation and although there was no accurately detectable improvement in function (less than 10% improvement in ODI score[15]), there

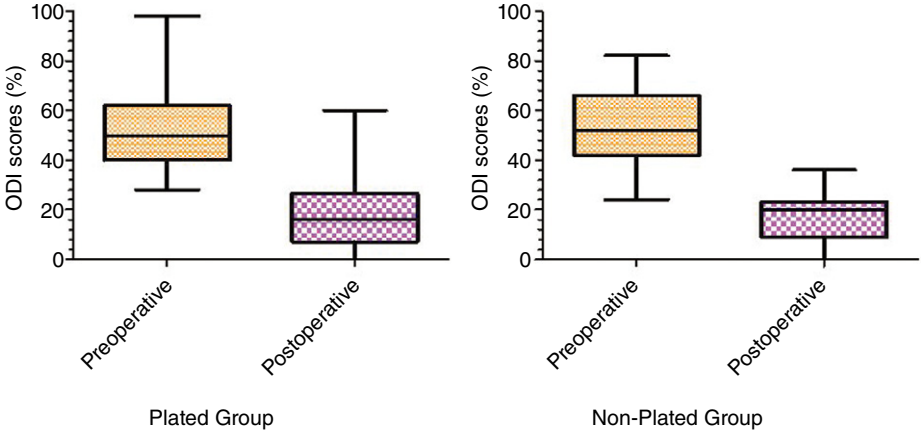

Fig. 7 Preoperative and postoperative Oswestry Disability Index (ODI) scores in the Plated (left) and Non-Plated (right) Groups.

TABLE 4 Summary of complications in plated and non-plated groups

Complications	Plated group	Non-plated group
Non-union	0 (0%)	1 (3.8%)
Graft subsidence	0 (0%)	3 (11.5%)
Graft migration	0 (0%)	1 (3.8%)
Dysphagia	2 (6.3%)	0 (0%)
Recurrent laryngeal nerve palsy	0 (0%)	1 (3.8%)
Adjacent disc disease (asymptomatic)	0 (0%)	1 (3.8%)

was improvement in pain and the patient rated their PSI as a 2. One patient developed new symptoms, within 3 months postoperatively, of parasthesias down the left arm and leg, exacerbated by neck flexion. Nerve conduction studies indicated irritation of the left posterior column, suggesting it was sequelae of surgery. There were no instances of infection, wound haematoma or chronic inflammation in either group. The data are summarized in Table 4.

Discussion

Autograft is still widely considered as the gold standard in ACDF[7]. A Cochrane systematic review concluded that fusion techniques using autograft yielded higher fusion rates than allograft and synthetic bone substitute techniques; however, other outcomes were not able to be assessed due to the lack of standardized outcome measures within the literature[4]. Hence, donor site morbidity associated with autograft has fuelled the growing interest in alternative materials[16], namely ceramics, as fusion substrates for anterior cervical arthrodesis. Ceramics provide a safe option with demonstrated biocompatibility, osteoconductive potential, abundant and affordable supply, and a means of avoiding morbidity at the iliac crest. In this study, the combination of PEEK cage with BCP, proved to be an effective and safe graft combination, resulting in statistically significant improvements in pain and function, both with and without plate fixation.

Graft Properties

PEEK is a semicrystalline polyaromatic linear polymer and thermoplastic material of high molecular weight, which is biologically inert, radiolucent and non-resorbable[17]. Moore and Rhoad[18] reported that PEEK elicits minimal cytotoxic and inflammatory response from the host in a rat air pouch model. Its other biomechanical properties include resistance to chemical and radiation damage, compatibility with many reinforcing agents (e.g. titanium, carbon fiber) and greater strength (per mass basis) than many metals[19]. Hence the PEEK cage provides a hard frame able to resist spinal loading and has an elastic modulus similar to that of bone, minimizing graft subsidence and shrinkage[20]. It is also able to maintain spinal alignment despite remodeling of bone graft within the cage cavity.

Radiological assessment of 42 patients who undertook ACDF with a PEEK/TCP stand-alone cage achieved 94.5% fusion and 8.1% subsidence rate[21]. Cho *et al*. conducted a prospective study of 40 patients who underwent one-level ACDF with a PEEK/TCP cage versus iliac crest autograft. The PEEK/TCP group achieved 100% solid fusion, increased cervical lordosis and increased height and cross-sectional area of foramina. Additionally, a minimal complication rate (2.5% experienced pharyngitis) was noted in the PEEK group compared with 17.5% complication rate in the autograft group (including graft collapse, dislodgement and donor site morbidity)[20]. Similar outcomes were achieved in a study comparing PEEK cage filled with BCP to autograft, with the authors deeming this graft combination a suitable alternative to autograft, with shorter hospital stay, decreased operative time, less blood loss and no donor site complications[22,23].

The role of a PEEK/TCP combination without plating was also compared to autograft with and without plate fixation in multilevel ACDF[24]. By 12 months the PEEK/TCP cage option and autograft with plate fixation demonstrated 100% and 98% fusion rates, respectively, whereas autograft alone achieved 87% fusion. Complication rates of autograft alone were also much higher at 50% (owing to graft collapse, pseudoarthrosis, dislodged graft) compared with 0% in the PEEK/TCP group and 4% in autograft with plating. Overall, the authors indicated preference for the PEEK/TCP cage in treating multilevel cervical degenerative disease due to its significantly lower complication rate.

Anterior Cervical Plating

Fixation plates reduce micromotion at the graft-host interface, and resist graft settling and kyphotic deformity, but add to costs, risks and operative time[25]. While anterior cervical plating is commonly used to stabilize fusions and preserve disc space height, there have also been reports of associated morbidity, namely instrumentation failure[26] (of which there are none in this series) and dysphagia. The largest prospective study of dysphagia following ACDF reported an overall incidence of 30% at 3 months postoperatively. Risk of dysphagia increased with increasing number of operated levels and operative time; however, no significant difference was found between Plated and Non-Plated Groups[27].

We believe there may be a role for plating in cage-supported fusions as a precautionary measure against graft subsidence. Gercek *et al*. reported on the use of a standalone titanium cage to result in graft migration or subsidence in five out of eight patients, with one patient experiencing symptom recurrence and requiring reoperation[12]. Other authors have noted relatively high rates of subsidence without plate use, although with little correlation to clinical outcome[6,28,29]. A meta-analysis of 21 studies by Fraser and Hartl revealed that anterior plate systems significantly improve fusion rates in one- and two-level disease, with a $P < 0.0001$[1].

As was demonstrated by our study, plate fixation in one- and two- level disease may achieve earlier fusion and decrease subsidence rates; however, this made no significant difference to clinical outcomes. Our results were confirmed by a prospective, randomized controlled trial with 2 years

follow-up in which a PEEK cage filled with β-TCP was assessed with and without plating. This study demonstrated a significantly higher fusion rate at 3 months in the Plated ACDF patients; however, all patients fused by 6 months. There was also a significantly higher rate of graft migration in the Non-Plated Group ($P < 0.05$), with 21.2% of Non-Plated patients affected, compared to 0% of Plated patients. However clinical outcomes were not significantly better than non-plating, indicating that in one- and two-level ACDF, plate fixation may not be necessary[6].

Although the benefits and costs associated with internal fixation in single-level fusions is contentious[30], its use in these procedures has nevertheless been found to be safe incurring no increased complications[31], or increased tendencies for adjacent segment disease[32]. Plates also circumvent the need for cumbersome external immobilization collars postoperatively and may hasten patient recovery.

Limitations

A chief limitation of this study is the relatively small numbers involved. Also, a number of patients have also had previous surgeries performed in the neck region, which may have contributed to their pathology. A review conducted by Hilibrand and Robbins concluded that the prevalence of adjacent segment disease is 13.6% at 5 years follow up, with the annual incidence of adjacent segment disease requiring additional surgery being between 1.5% and 4%[33]. Additionally, patients were not randomized to treatment groups hence selection biases cannot be excluded. The uneven distribution of patients among the groups also limits the statistical power of our conclusions.

Assessment of interbody fusion 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. Fine-cut CT scans with reconstructions have been shown to be more reliable and sensitive for the detection of pseudarthrosis than plain radiography[34,35]; however, subjecting patients to CT scanning at regular intervals purely for an assessment of fusion was deemed to be unnecessary, costly and potentially harmful to patients. We have only used CT scanning where there has been a query regarding fusion status or pseudoarthrosis in the context of unexpected/poor clinical outcomes and recurrence of symptoms at follow up. X-ray with flexion/extension was performed for the majority of patients (76%). The authors agree that this may result in a higher apparent fusion rate, as compared with a CT scan of every patient.

In this study, we have found that using a PEEK cage containing BCP in one- and two-level anterior cervical discectomy and fusion proved to be an effective treatment for cervical spondylotic radiculopathy and/or myelopathy and is a means of avoiding morbidity at the iliac crest. While anterior plate fixation may promote early fusion rates and prevent cage subsidence, no statistically significant difference was found in clinical outcomes, (mean follow up was 11.5 months), when compared with outcomes of non-plated ACDF patients.

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