Titanium-interlayer Mediated Hydroxyapatite Coating on Polyetheretherketone: A Prospective Study in Patients with Single-level Cervical Degenerative Disc Disease

Ce Zhu, Ganjun Feng, Limin Liu, Yueming Song

Department of Orthopedics and Orthopedic Research Institute

West China Hospital of Sichuan University

INTRODUCTION

- Anterior cervical discectomy and fusion (ACDF) was the most widely used method for the surgical treatment of cervical degenerative disc disease (CDDD). The implant for replacement of diseased disc can provide a mechanical support between the two endplates as well as facilitate bone growth between the two vertebral bodies.
- The two main materials currently used are titanium (Ti) alloys and polyetheretherketone (PEEK). Titanium alloys are advantageous in their excellent corrosion resistance, high mechanical strength and cytocompatibility, but they are susceptible to stress shielding and may result in subsidence due to its high elastic modulus. In addition, the inherent high radiopacity of titanium alloys may produce metal artifacts in computed tomography (CT) images, which would interfere the assessment of fusion results.
- PEEK is a semi-crystalline, synthetic thermoplastic polymer that exhibits excellent fracture toughness, thermal stability, environmental resistance, and radiolucency. Furthermore, PEEK has an elastic modulus similar to that of natural bone, which prevent the stress shielding that is often observed in titanium alloys implants. Nonetheless, the osteoconductive and osteoinductive properties of the PEEK are relatively unsatisfactory due to its bioinert surfaces. To improve osteoblast responses and bone integration of the PEEK, surface modifications of the PEEK have been proven to be an effective strategy.

INTRODUCTION

- Hydroxyapatite (HA) is a bioactive calcium phosphate with similarities to the mineral phase of natural bone, which has been used for the coating on PEEK to improve its osseointegration with promising results. The coating techniques include plasma spraying, spin coating, sandblasting, diazonium chemistry, sputtering and etc. Among them, plasma spraying is the most widely used commercial coating technique with good reproducibility and high deposition rates. Nevertheless, the adhesion strength of plasma-sprayed HA coatings on PEEK is very poor.

- However, to our knowledge, the studies concerning the investigation of the biological properties of PEEK coated with Ti and HA in human are limited. In the present study, a PEEK cage with Ti and HA coatings using a plasma spraying technique was prepared and applied to ACDF for the treatment of patients with single-level CDDD. The objective of this study is to evaluate the in vivo response of the PEEK cages coated with Ti and HA versus those uncoated PEEK cages after ACDF in patients with single-level CDDD.

METHODS

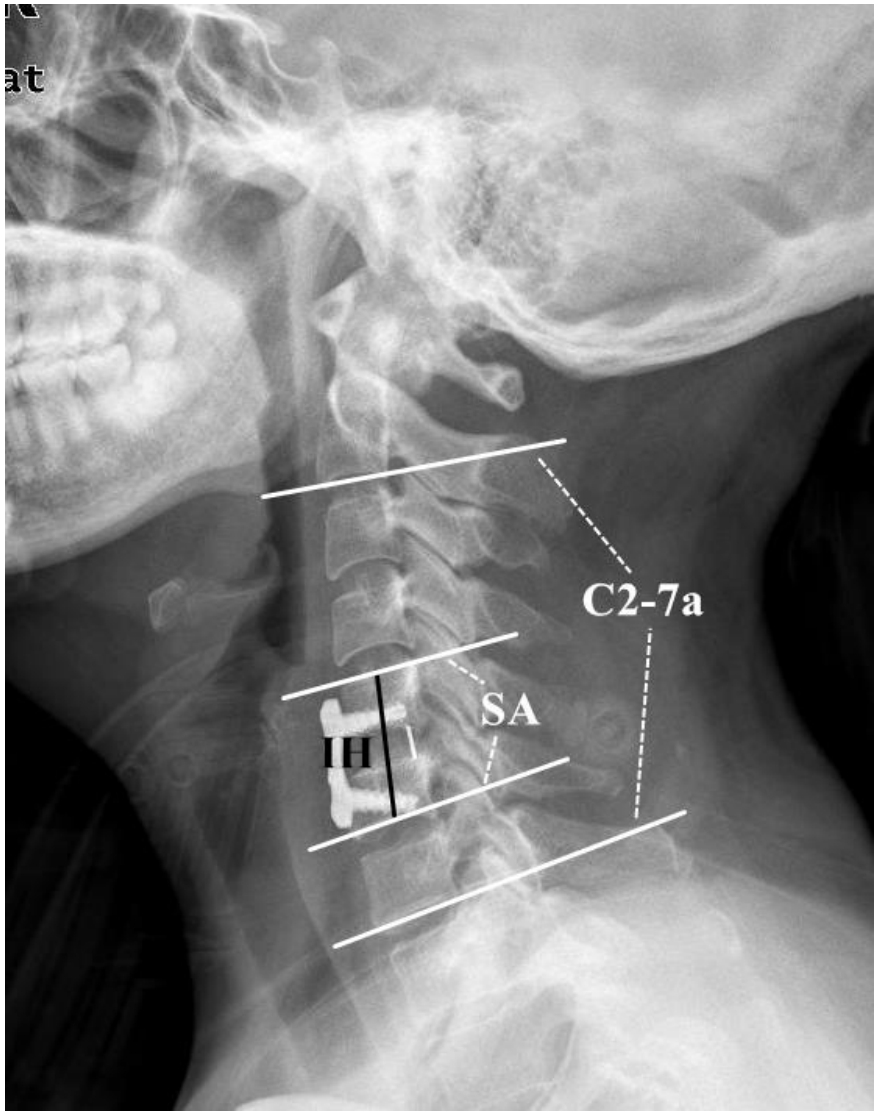
- This was a prospective and non-randomized study. Twenty-four patients with single-level CDDD between August 2016 and October 2017 in our department who underwent ACDF with PEEK cages coated with Ti and HA (PEEK/Ti/HA group) were included in the study. For comparison, 24 patients who underwent single-level ACDF with uncoated PEEK cages (PEEK group) were matched one-to-one to the patients in the PEEK/Ti/HA group. Matching characteristics included age (within 1 year of one another), gender, and operative segment.

- The inclusion criteria were: (1) age≥18 years, (2) radiculopathy and/or myelopathy from single-level cervical disc herniation, (3) no response to 3 months of non-surgical management, and (4) no previous spine surgery. Exclusion criteria included previous spine surgery, active infection, and inflammatory spondyloarthropathies.

METHODS

- Frontal and lateral radiographs and three-dimensional CT scans(3d-CT) of the cervical spine were obtained at baseline and the 3-month and final follow-up after surgery. The following parameters were observed on lateral neutral radiographs: intervertebral height (IH); C2-7 angle(C2-7a); segmental alignment (SA). Subsidence was defined as loss of height of more than 3 mm. The fusion status was evaluated on 3d-CT by the 5-grade criteria proposed by Brantigan et al. The Grades 4 or 5 were defined as fused while Grade 1 or 2 as unfused and Grade 3 was uncertain.

- The Japanese Orthopedic Association (JOA) scores and Visual Analogue Scale (VAS) were used for the evaluation of clinical outcomes before surgery, 3 months after surgery and at the final follow-up.



RESULTS

- The average postoperative follow-up period time ranged from 24 to 41 months (mean 31.5±6.2 months). Twenty-two patients (45.8%) had radiculopathy (PEEK: PEEK/Ti/HA = 12:10), 16 patients (33.3%) had myelopathy (PEEK: PEEK/Ti/HA = 7:9), and 10 patients (20.8%) had both radiculopathy and myelopathy (PEEK: PEEK/Ti/HA = 5:5). There was no significant difference between the two groups regarding their diagnoses (p = 0.806). The operative segments included C3/4, C4/5, C5/6 and C6/7 (4, 10, 22, 12, respectively). There were no significant differences in age, gender, smoker, operative time, and blood loss between the PEEK/Ti/HA group and PEEK group.

	PEEK/Ti/HA group	PEEK group	P
Age(y)	49.2±5.7	49.0±5.8	0.901
Gender (Male/Female)	14/10	14/10	1.000
Smoker	7/24	5/24	0.740
Operative Time(min)	107.2±15.6	108.5±15.5	0.782
Blood Loss(mL)	76.8±18.0	74.2±19.7	0.633

RESULTS

- There was no statistical difference in SA, IH, and C2-7a at baseline, 3-month and at the final follow-up after surgery between the two groups (P > 0.05). The cage subsidence rate was the same in both two groups (1/24, 4.2%). The fusion rate of the patients in the PEEK/Ti/HA group was significantly higher than that of patients in the PEEK group at 3-month post-operation (87.5% vs. 62.5%, P < 0.05).

	PEEK/Ti/HA group	PEEK group	P
SA (°)			
Pre-op	2.0±1.1	1.8±1.1	0.531
3m Post-op	6.2±3.3*	6.0±3.7*	0.841
Final Follow-up	4.9±2.2*	4.7±2.5*	0.806
IH (mm)			
Pre-op	34.5±1.5	34.7±1.6	0.646
3m Post-op	36.7±1.1*	37.1±1.2*	0.215
Final Follow-up	35.5±1.1*#	36.0±1.1*#	0.135
C2-7a (°)			
Pre-op	12.7±7.4	13.0±6.9	0.894
3m Post-op	18.0±7.8*	19.3±6.9*	0.533
Final Follow-up	18.5±8.3*	18.3±10.0*	0.960
Fusion Rate			
3m Post-op	87.5% (21/24)	62.5% (15/24)	0.046
Final Follow-up	100%	100%	1.000

* p < 0.05 compared with pre-op.
# p < 0.05 compared with 3m post-op.

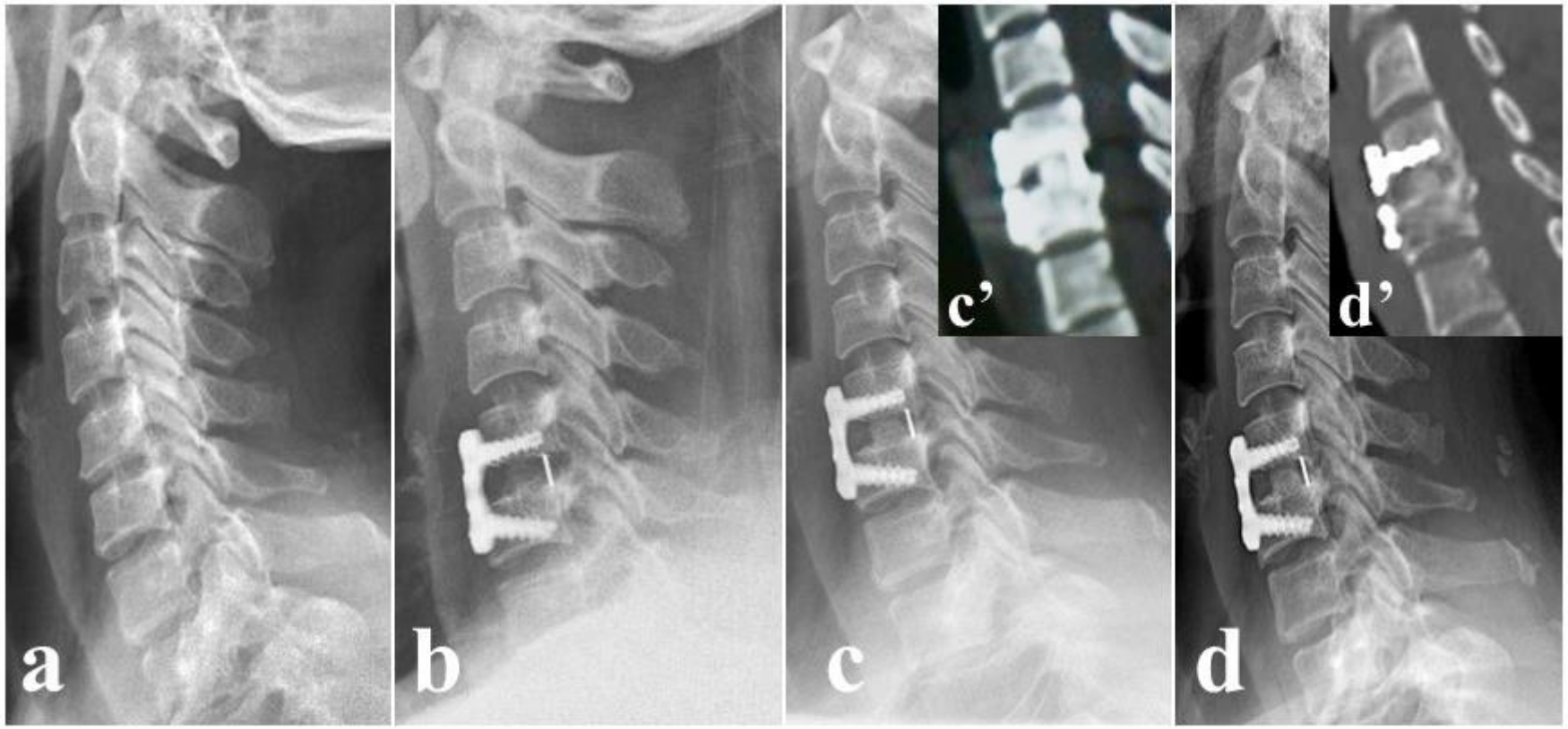
RESULTS

- No intergroup significant difference was found in terms of the clinical outcomes.The JOA score and VAS score of the patients in both two groups were improved after the surgery.

	PEEK/Ti/HA group	PEEK group	P
JOA score			
Pre-op	10.5±1.2	10.1±1.1	0.217
3m Post-op	15.4±0.8*	15.0±0.9*	0.114
Final Follow-up	15.8±0.9*#	15.5±1.1*#	0.407
VAS score			
Pre-op	7.9±1.3	7.7±1.5	0.772
3m Post-op	2.5±1.0*	2.3±1.0*	0.690
Final Follow-up	2.4±1.1*	2.3±1.1*	0.797

* $p < 0.05$ compared with pre-op.
# $p < 0.05$ compared with 3m post-op.

RESULTS



A 46-year-old woman undergoing anterior cervical discectomy and fusion surgery with a PEEK/Ti/HA cage. (a) Preoperative plain lateral radiographs image. (b) Postoperative lateral radiograph image. (c) Lateral radiograph image at 3-month follow-up. (c') CT scans at 3-month follow-up. (d) Lateral radiograph image at the final follow-up. (d') CT scans at the final follow-up.

DISCUSSION

- It is generally believed that fusion rate is a critical prognostic factor in ACDF. In the present study, patients in the PEEK/Ti/HA group achieved higher fusion rate than patients in the PEEK group (87.5% vs. 62.5%, $P < 0.05$) 3 months postoperatively. Meanwhile, solid osseous fusion was found in all the patients of the both two groups since 1-year post-operation (100% fusion rate). These results indicated an excellent fusion capability of the PEEK cages coated with Ti and HA. The reasons are both of biological and physical nature of the Ti and HA layers: first of all, the biocompatibility and osteoconductivity of Ti and HA is higher than that of PEEK, which have been proved by previous studies. In addition, the rough coating surface provides high initial fixation of the intervertebral space by increasing frictional forces and limiting micromotion.

DISCUSSION

- Cage subsidence is a common complication of ACDF which relates to kyphotic deformity, instrument failure and postoperative neurologic deterioration. In our study, the cage subsidence rate was the same in both two groups (1/24, 4.2%). The IH in the PEEK/Ti/HA group increased from 34.5 mm preoperatively to 36.7 mm postoperatively, but decreased to 35.5 mm at final follow-up, while the IH in the PEEK group increased from 34.7 mm preoperatively to 37.1 mm post-operatively, but decreased to 36.0 mm at the last follow-up. The average loss of height of the fusion segment the PEEK/Ti/HA group and PEEK group was 1.2mm and 1.1mm, respectively($P > 0.05$). Fortunately, both of the two patients with cage subsidence did not suffer any associated clinical symptoms and the intervertebral fusion of them was not interfered.

DISCUSSION

- The restoration of physiological lordosis of the cervical spine is crucial to obtaining better dorsal shifting of the decompressed spinal cord and better postoperative clinical outcomes in ACDF. In this study, the segmental and overall cervical lordosis of all the patients were restored postoperatively and maintained well at the final follow-up. These results were comparable with the previous studies.

- As for the clinical outcomes, the JOA and VAS scores were significantly improved after surgery in both the PEEK/Ti/HA and PEEK groups, and there was no significant difference between the two groups.

CONCLUSION

A PEEK cage with Ti and HA was successfully fabricated via a plasma spraying technique. In patients with single-level ACDF, PEEK cage coated with Ti and HA provided a higher fusion rate than uncoated PEEK cage at 3-month post-operation, while both of the two cages could achieve solid osseous fusion at the last follow up (100% fusion rate). Compared with the uncoated PEEK cage, PEEK/Ti/HA cage yielded similar favorable segmental and overall cervical lordosis, IH, and clinical outcomes after the surgery.

Conflict of Interest Disclosure Form

- I have no potential conflict of interest to report

O I have the following potential conflict(s) of Interest to report

Type	Name of commercial company
Receipt of grants/research supports	Not Applicable
Receipt of honoraria or consultation fees	Not Applicable
Participation in a company sponsored speaker's bureau	Not Applicable
Stock shareholder	Not Applicable
Spouse/partner	Not Applicable
Other support (please specify)	Not Applicable