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Evaluating Screw Stability After Pedicle Screw Fixation With PEEK Rods

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Abstract

Study Design: Animal experiment.

Objective: To evaluate whether the use of polyetheretherketone (PEEK) rods for posterior spinal fixation can improve screw stability.

Methods: Sheep models of anterior-posterior cervical fusion were used in this study. Six sheep were randomly assigned to the PEEK rod group and titanium alloy group. A total of 8 screws and 2 fixing rods were implanted in each sheep. At 24 weeks postoperatively, a computed tomography (CT) evaluation, pull-out test, micro-CT evaluation and histological evaluation were conducted to evaluate screw stability in the harvested surgical segments.

Result: According to the CT evaluation, there were no signs of screw loosening in either group. The pull-out force and energy of the PEEK rod group were significantly higher than those of the titanium alloy rod group. Denser and thicker trabecular bone around the screw was observed in the PEEK rod group according to the micro-CT reconstructed images, and quantitative analysis of the micro-CT data confirmed this finding. In the histological evaluation, more abundant and denser bone trabeculae were also observed in the PEEK rod group. However, there was no significant difference in the bone-screw interface between the 2 groups.

Conclusion: Posterior spinal fixation with PEEK rods can increase screw stability by promoting bone growth around the screw but cannot promote bone integration at the bone-screw interface in an animal model study. This finding presents a new idea for clinical practices to reduce screw loosening rate.

Keywords

PEEK rod, pedicle screw, screw loosening, cervical vertebra

Introduction

With population aging, the number of patients with degenerative lumbar disease, such as lumbar spinal stenosis, lumbar instability and lumbar disc herniation, has increased each year, severely affecting people's quality of life.[1,2] For cases that do not respond to conservative treatment, surgical treatment is often required. Pedicle screw fixation is considered the gold standard surgical treatment for lumbar degeneration.[3] However, postoperative screw loosening is a common complication.[4-6] Many techniques have been used to improve fixation strength. Augmentation of the pedicle screws with bone cement is the most commonly used technique. However, this technique has some shortcomings, as complications such as thermal necrosis caused by cement curing and leakage of the cement can occur, and complex revision surgery may be required due to difficulty removing the cement.[7-9] Expandable pedicle screws are also a good alternative, but there is currently a lack of relevant, high-quality clinical research.[5,10,11] In addition to individual patient factors, such as the presence of osteoporosis,[12,13] device-related factors such as stress shielding[14] and local high strains[15] are also considered important factors of such complications.

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Polyetheretherketone is a linear aromatic polymer compound with excellent properties.[16] Spinal fixation rods designed with PEEK material have good biocompatibility, a low elastic modulus (3.2 GPa), and transmission linearity.[17] They have been used in spinal fusion surgeries to reduce the stress shielding of traditional titanium alloy rods, improve the bone fusion rate and reduce the incidence of adjacent segment degeneration. According to biomechanical research results,[18,19] compared with traditional titanium alloy rods, PEEK rods can increase anterior-column load sharing and reduce the stress on the bone-screw interface, which is believed to be beneficial for reducing the incidence of screw loosening and pullout.[17,20] In an in vitro fatigue test, Aakas et al[21] observed loosening at the bone-screw interface in the titanium rod group. On the other hand, the PEEK rod group showed higher stability after fatigue testing, which means that fixation with PEEK rods is beneficial for screw stability.

Therefore, the use of PEEK rods for fixation may reduce the incidence of screw loosening without complications caused by augmentation with cement. To our knowledge, no studies on the effectiveness of PEEK rod fixation in reducing the occurrence of screw loosening in vivo have been conducted. The purpose of this study was to evaluate whether PEEK rods can increase screw stability to a greater extent than titanium alloy rods. Using animal model, we adopted CT evaluations, pull-out tests, micro-CT examinations, and histological examinations to accurately assess the mechanical stability of the screws in sheep models of anterior-posterior cervical fusion.

Materials and Methods

Animals and Experimental Design

This investigation was approved by the ethics committee of the Fourth Military Medical University. Six mature, female small-tailed Han sheep with a mean age of 1.5 $\pm$ 0.5 years and a mean body weight of 40.0 $\pm$ 4.5 kg were selected and randomly divided into an experimental group that received PEEK rods and a control group that received titanium alloy rods. All sheep were euthanized by an intravenous overdose of xylazine hydrochloride at 24 weeks postoperatively, and the C3-C4 vertebrae were harvested for the pull-out test and CT, micro-CT and histology evaluations.

The diameter of the PEEK rods and titanium alloy rod was 3.2 mm. The length and outer diameter of the pedicle screws were 15.0 mm and 4.5 mm, respectively (PCF, Weigao Orthopedic Device, Weihai, China). The diameter and height of the porous titanium alloy cages were 12.0 mm and 6.0 mm, respectively.

Surgical Procedures

The sheep were fasted for 24 hours before surgery, and antibiotics were injected intramuscularly 30 minutes before surgery (cefazolin sodium, 1 g/sheep, Harbin Pharmaceutical Group, Harbin, China). Each sheep was placed on a sterile operating table in dorsal recumbency after general anesthesia and sterilized. An X-ray was taken at the C3-C4 level. Through

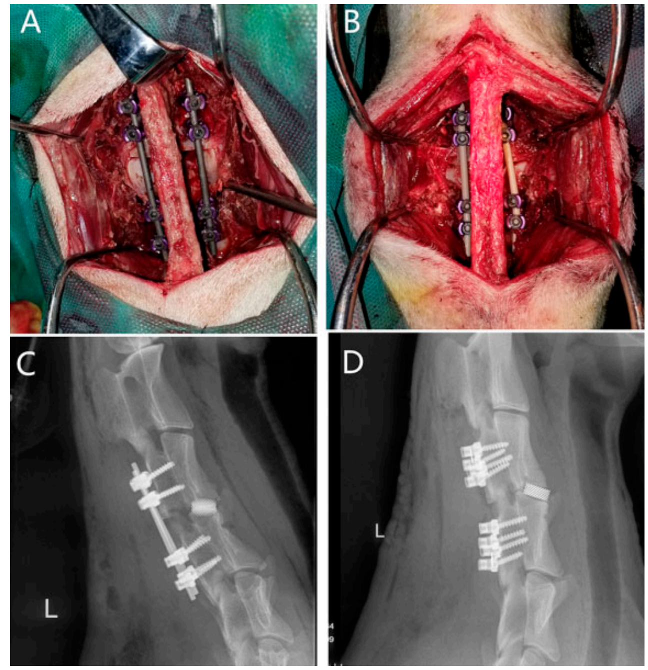

Figure 1. Intraoperative internal fixation and implantation in the titanium alloy rod group (A) and PEEK rod group (B). The X-ray images show that the internal fixation position is appropriate in the titanium alloy rod group (C) and PEEK rod group (D).

an anterior midline skin incision, the longus colli muscle was incised in the midline, and the intervertebral disc of C3-C4 was exposed. The annulus fibrosus was incised to remove the nucleus pulposus. Then, the intervertebral discs were separated, and the endplate was polished until the subchondral bone was exposed. A titanium alloy cage was inserted in the C3-C4 intervertebral space. Then, the operative incision was irrigated sequentially with hydrogen peroxide and normal saline and sutured layer by layer. The sheep was positioned in a prone position. The surgical regions were sterilized, and a midline incision was made from the C3 to C4 segments. Then, the paraspinal muscles were peeled subperiosteally along the spinous process and lamina to expose the articular process joints. The joint capsule of the C3-C4 facet joints was removed, and the lower part of the inferior articular process of C3 was resected to establish a spine instability model. Eight pedicle screws were placed in C3 and C4 bilaterally and were connected with titanium alloy or PEEK rods (Figure 1A, B), according to the experimental design. Then, the incision was irrigated and sutured in the same way. X-ray images were taken immediately after the surgery to confirm whether the position of the fixation system was appropriate. Ceftriaxone sodium was administered intramuscularly for 3 days postoperatively. The sheep were permitted to perform physical activity without any restrictions postoperatively. The sheep were euthanized at 24 weeks by exsanguination upon anesthesia. The spinal segments of C3-C4 were harvested carefully, and the bony structures were left intact.

CT Evaluation

Twenty-four weeks after the operation, the spinal column segment that had been removed was subjected to a CT scan with a scan layer thickness of 0.625 mm. A 1 mm radiolucent zone around the screw was defined as a diagnostic criterion for screw loosening.[12]

Pull-Out Tests

Each specimen had 8 screws distributed across 4 horizontal planes. Two screws on the same horizontal planes were randomly selected for the pull-out test or for micro-CT and histological examinations. The vertebral body was fixed on the MTS 858 biomaterial testing machine (MTS System, Minneapolis, USA) with a special jig, and the pull-out test was carried out along the long axis of the pedicle screw at a loading speed of 5 mm/min.[13,22] After the screw became damaged, the test was stopped. The force recorded when the screw was pulled out was defined as the maximum pull-out strength reached before the load decreased abruptly. The energy (E) absorbed to failure was determined as the area under the curve before the onset of failure. The maximum pull-out strength and energy (E) absorbed were recorded.

Micro-CT Evaluation

The 4 screws of each specimen remaining after pulling out the test were used for micro-CT evaluation. Sawing the specimen to the appropriate size, a micro-CT system (Inveon Multimodality gantry STD, Siemens) was used to evaluate the bone growth around the screws. Micro-CT scanning was carried out at 80 kV, 500 μA and a spatial resolution of 20 μm, and the region of interest (ROI) was defined as a cylinder with a diameter of 5 mm centered on the screw. MicroView image analysis software (GE Healthcare, Canada) was used to automatically determine the 3-dimensional parameters of each ROI. The bone volume fraction (BVF, bone volume/total volume BV/TV, %), BS/BV (bone surface/bone volume, mm^{-1}), Tb.Th (trabecular thickness, mm), Tb.N (trabecular number, mm^{-1}), and Tb.Sp (trabecular spacing, μm) were determined.

Histological Evaluation

Specimens that have completed nondestructive micro CT experiments are used for histological evaluation. The specimens were dehydrated in ascending concentrations of ethanol (80–100%). Then, all specimens were embedded in methyl methacrylate. Serial transverse sections that were 80-100 μm thick were obtained by using a microtome (Leica SP1600, Leica, Wetzlar, Germany) and a microgrinder (RF-1; Rui-Feng equipment, Xi'an, China). Then, the prepared specimens were stained with 1.2% trinitrophenol and 1% acid fuchsin. An optical microscope (Leica La microsystems, Bensheim, Germany) was used to observe and analyze the sections.

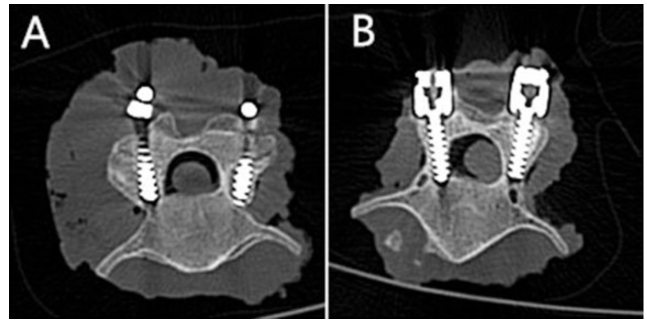

Figure 2. CT images of harvested specimens were taken at 24 weeks postoperatively. No radiolucent zones were observed in the titanium alloy rod group (A) or PEEK rod group (B).

Statistical Analysis

The quantitative data are expressed as the mean ± SD, and unpaired Student's t test was used to test the data. *P* values less than 0.05 indicated statistical significance. Statistical analysis was performed with SPSS software, version 19.0 (SPSS Inc., Chicago, USA).

Results

General Observation

All the sheep survived during the entire experimental process. One sheep in the experimental group was unstable after the operation and recovered after 24 hours without special treatment. No complications, such as infection, cage migration or breakage of the screws/rods, were observed. The postoperative X-ray examination showed that the screws and fixation rods were properly positioned (Figure 1C, D).

CT Evaluation

At 24 weeks postoperatively, no loose screws were found, according to the aforementioned evaluation criteria (Figure 2). A total of 5 screws penetrated the pedicle, 2 of which were included in the PEEK rod group and 3 of which were included in the titanium alloy rod group. These 5 screws were excluded from the subsequent experiment.

Pull-Out Tests

After the screws that penetrated the pedicle were excluded, 11 screws were randomly selected from each group for the pull-out test. Fmax and E in the PEEK rod group were 1125.4 ± 285.3 N and 2.53 ± 0.481 J. These values were significantly higher than those in the titanium alloy rod group, which had an Fmax of 874.9 ± 240.9 N ($P = 0.044$) and E of 2.02 ± 0.36 J ($P = 0.014$). The Fmax and E values were 28.6% and 25.2% higher, respectively, in the PEEK rod group than in the titanium alloy group.

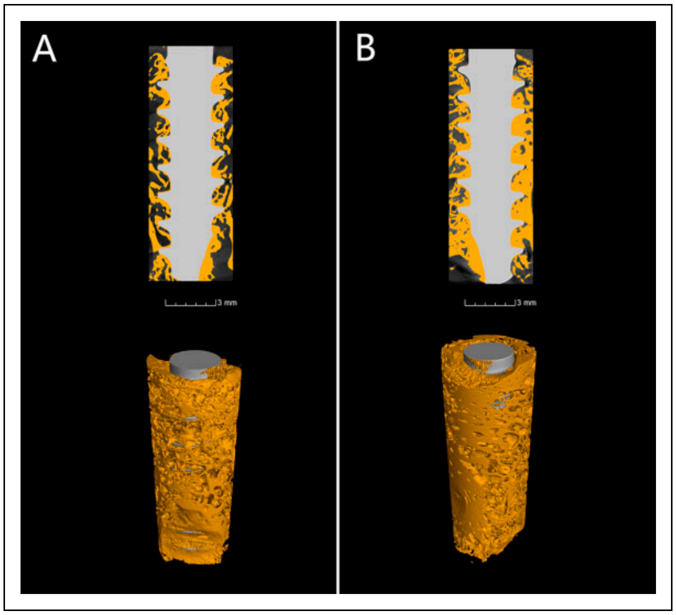

Figure 3. Sagittal and 3D reconstruction images of the micro-CT in the titanium alloy rod group (A) and PEEK rod group (B). Screws encompassed by bone trabeculae were observed in the 2 groups. The bone trabeculae in the PEEK rod group were visually thicker and denser than those in the titanium alloy group.

Micro-CT Evaluation

After the screws that penetrated the pedicle were excluded, 10 and 11 screws were randomly assigned to the titanium alloy rod group and PEEK rod group respectively. The ROI that was selected was reconstructed, and screws encompassed by bone trabeculae were observed in the reconstructed 3D image (Figure 3). The bone trabeculae around the screws in the PEEK rod group were visually denser and thicker than those in the titanium alloy rod group. Through quantitative analysis, we found that BVF, Tb.Th and Tb.N in the PEEK rod group were significantly higher than those in the titanium alloy rod group. Moreover, BS/BV and Tb.Sp in the PEEK rod group were significantly lower than those in the titanium alloy rod group (Table 1).

Histological Evaluation

No inflammatory response was detected in the histological evaluation. The screws in both groups were encompassed by bone trabeculae. The bone trabeculae were visually more abundant and denser in the PEEK rod group than in the titanium rod group (Figure 4A, B). However, there was no visual difference in the bone-screw interface between the 2 groups (Figure 4a, b). The trabecular bone was tightly wrapped around the screws, with a small amount of soft tissue doped in the bone-screw interface in the 2 groups.

Discussion

Screw loosening is a common complication of posterior spinal fixation, especially in patients with osteoporosis.[5,23] Clinical research shows that the screw loosening rate ranges from 1% to 15% in nonosteoporotic patients, and the loosening rate can be as high as 63% in osteoporotic patients.[24] Stress shielding is an important risk factor; it can reduce the formation of bone calli around screws and even lead to microfractures.[5,14,25] In addition, inadequate anterior support caused by stress shielding can increase the local strain at the bone-screw interface, which may induce screw loosening.[15,17] Wear debris[26,27] and infection[28] have also been reported as risk factors for screw loosening. Many techniques are used to reduce the incidence of screw loosening. Augmenting screws with cement[24,29,30] and expandable pedicle screws[10,11,31] has yielded good clinical results, but these techniques can cause some complications and do not specifically solve the problem of stress shielding.

Improving the material used in rods for fixation can overcome the problem of stress shielding, which can thereby reduce the screw loosening rate and prevent complications caused by

Table 1. Three Dimensional Parameters of Region of Interest in PEEK Rods and Titanium Rods Groups (Mean ± SD).

Parameters	Titanium rods (n = 10)	PEEK rods (n = 11)	*P* value
BVF (%)	52.31 ± 8.01	61.98 ± 9.72	0.023
BS/BV (mm^{-1})	11.73 ± 3.44	8.86 ± 2.32	0.036
Tb.Th (um)	234.9 ± 37.33	283.4 ± 49.15	0.021
Tb.N (mm^{-1})	2.37 ± 0.37	2.78 ± 0.33	0.014
Tb.Sp (um)	194.4 ± 27.54	166.8 ± 21.69	0.019

Abbreviations: PEEK, polyetheretherketone; BVF, bone volume fraction; BS/BV, bone surface/bone volume; Tb.Th, trabecular thickness; Tb.N, trabecular number; Tb.Sp, trabecular spacing.

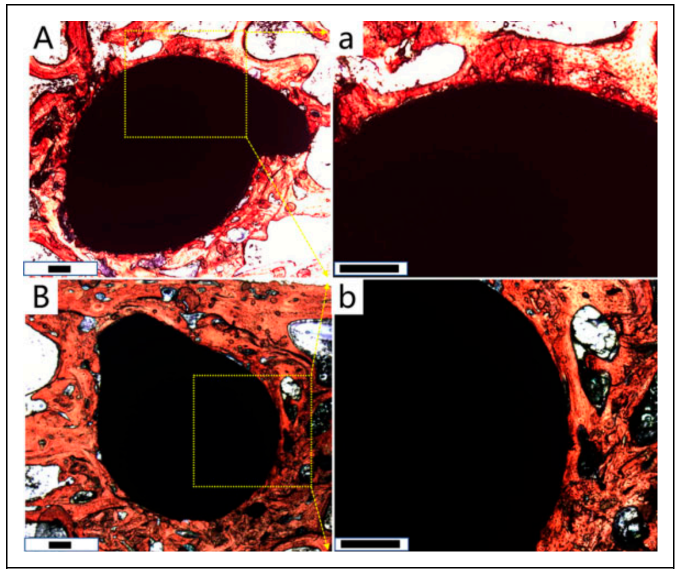

Figure 4. Histological images with Van-Gieson staining. Bone trabeculae were more abundant and denser in the PEEK rod group (B, b) than in the titanium rod group (A, a). There was no visual difference in the bone-screw interface between the 2 groups. (The bone tissue is indicated in red, and the screw is indicated in black. Scale bar = 200 μm.)

augmenting with cement. The advantages of PEEK include its good biocompatibility, its low elastic modulus, and its ability to linearly transmit forces, and it has been widely used in clinical applications.[16,17,32] Compared to titanium alloys with high elastic moduli (114 GPa), pedicle fixation systems based on PEEK rods are considered to have many biomechanical advantages.[20] A finite element analysis conducted by Ahn et al.[33] showed that pedicle dynamic stabilization rods (Ni-Ti, PEEK) increase the anterior-column load distribution and decrease the stress values of pedicle screws by 75.5%–90% compared to those of the rigid fixation system, which can slow the degeneration of bony structures and decrease the possibility of screw loosening. Similar results were revealed by other finite element analyses[34] and in vitro biomechanics experiments.[18,35,36] The biomechanical advantages need to be verified by clinical studies. However, the small sample sizes are a major limitation in current clinical studies on screw stability after fixation with PEEK rods.[37-39] It is difficult to draw conclusions from studies with small sample sizes. In addition, X-ray imaging is commonly used in clinical practice, but it is difficult to accurately detect screw loosening with X-ray imaging, and CT scans are usually performed only in symptomatic patients.

In animal experiments, irrelevant variables can be controlled more easily than in human studies, and more precise experimental methods, such as those for micro-CT and histological evaluations, can be adopted. Therefore, we adopted sheep models with anterior-posterior cervical spinal fusion.[40] The advantage of this model is that its biomechanical and structural characteristics are similar to those of humans.[41,42] Furthermore, the directions of motion include flexion-extension and lateral bending, whereas the thoracolumbar vertebrae of quadrupeds often allow only lateral bending movements.[43] In addition, compared to in vitro biomechanics experiments, in vivo experiments can take into account osseointegration and bone remodeling around the screws, so the results reflect the actual situation to a greater extent. Based on this model, we investigated whether PEEK rods can improve screw stability to a greater extent than titanium alloy rods. In the CT evaluation, the bone-screw interface in the 2 groups was tightly connected, and no signs of screw loosening, such as a radiolucent zone, were observed. By comparison, in the micro-CT evaluation, which uses an imaging modality with a higher resolution, validated our hypothesis that fixation with PEEK rods can improve screw stability. Denser and thicker trabecular bone was observed in the PEEK rod group according to the the 3D reconstruction images, which was consistent with the quantitative analysis results of the micro-CT data.

This result indicates that the PEEK rod leads to a better biomechanical distribution and promotes the growth of bone trabeculae around the screw. Moreover, fixation with PEEK rods can yield earlier fusion, thereby further reducing the stress on the bone-screw interface and promoting osseointegration around the screw.[5,40] The results also show that differences can be better detected by higher resolution imaging modalities. The pull-out test results reported in this study again supported our conjecture that fixation with PEEK rods can improve screw stability. It is well known that screws encompassed by thicker and denser bone trabeculae are more difficult to pull out. In the histological evaluation, more abundant and denser bone trabeculae were also observed in the PEEK rod group than in the control group. However, there was no significant difference in the bone-screw interface between the 2 groups. A possible explanation for this finding is that the same traditional titanium alloy screws, without any surface modifications, were used in the 2 groups, and they restricted osseointegration in the bone-screw interface.

This study has several limitations. First, the sample size was insufficient, which may decrease the credibility of the conclusions. Additionally, compared to the pull-out tests used in this study, cyclic cranio-caudal loading is considered more appropriate to assess and simulate screw loosening.[44] Moreover, because screw loosening mostly occurs in patients with osteoporosis, an osteoporosis model needs to be adopted in future studies. Finally, the study period was only 24 weeks, and screw loosening mostly occurs clinically 1 year after surgery. Therefore, the research period should be prolonged.

Conclusion

In this study, we indicated that, with the biomechanical advantages, PEEK rods can increase screw stability by promoting bone growth around the screw but cannot promote bone integration at the bone-screw interface. This finding presents a new idea for clinical practices to reduce screw loosening rate. Since this study is an animal experiment, more clinical studies are needed to further verify this view.

Authors' Note

Jie Wu and Lei Shi contributed equally to this study.

Declaration of Conflicting Interests

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