Dual pitch titanium-coated pedicle screws improve initial and early fixation in a polyetheretherketone rod semi-rigid fixation system in sheep

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Abstract

Background: Reports on the efficacy of modifications to the thread design of pedicle screws are scarce. The aim of the study was to investigate initial and early fixation of pedicle screws with a plasma-sprayed titanium coating and dual pitch in the pedicle region (dual pitch titanium-coated pedicle screw [DPTCPS]) in a polyetheretherketone (PEEK) rod semi-rigid fixation system.

Methods: Fifty-four sheep spine specimens and 64 sheep were used to investigate initial ("0-week" controls) and early (post-operative 6 months) fixation, respectively. Sheep were divided into dual pitch pedicle screw (DPPS), standard pitch pedicle screw (SPPS), DPTCPS, and standard pitch titanium-coated pedicle screw (SPTCPS) groups. Specimens/sheep were instrumented with four screws and two rods. Biomechanical evaluations were performed, and histology at the implant-bone interface was investigated.

Results: At 0-week, mean axial pull-out strength was significantly higher for the DPTCPS and SPTCPS than the SPPS (557.0 ± 25.2 *vs.* 459.1 ± 19.1 N, $t = 3.61$, $P < 0.05$; 622.6 ± 25.2 *vs.* 459.1 ± 19.1 N, $t = 3.43$, $P < 0.05$). On toggle-testing, the DPTCPS was significantly more resistant than the SPPS and SPTCPS (343.4 ± 16.5 *vs.* 237.5 ± 12.9 N, $t = 3.52$, $P < 0.05$; 343.4 ± 16.5 *vs.* 289.9 ± 12.8 N, $t = 3.12$, $P < 0.05$; 124.7 ± 13.5 *vs.* 41.9 ± 4.3 cycles, $t = 2.18$, $P < 0.05$; 124.7 ± 13.5 *vs.*79.5 ± 11.8 cycles, $t = 2.76$, $P < 0.05$). On cyclic loading, maximum displacement was significantly lower for the DPTCPS than the SPPS and SPTCPS (1.8 ± 0.13 *vs.* 3.76 ± 0.19 mm, $t = 2.29$, $P < 0.05$; 1.8 ± 0.13 *vs.* 2.46 ± 10.20 mm, $t = 2.69$, $P < 0.05$). At post-operative 6 months, mean axial pull-out strength was significantly higher for the DPTCPS and SPTCPS than the SPPS (908.4 ± 33.6 *vs.* 646.5 ± 59.4 N, $t = 3.34$, $P < 0.05$; 925.9 ± 53.9 *vs.* 646.5 ± 59.4 N, $t = 3.37$, $P < 0.05$). On toggle-testing, the DPTCPS was significantly more resistant than the SPPS and SPTCPS (496.9 ± 17.9 *vs.* 370.3 ± 16.4 N, $t = 2.86$, $P < 0.05$; 496.9 ± 17.9 *vs.* 414.1 ± 12.8 N, $t = 2.74$, $P < 0.05$; 249.1 ± 11.0 *vs.*149.9 ± 11.1 cycles, $t = 2.54$, $P < 0.05$; 249.1 ± 11.0 *vs.*199.8 ± 7.2 cycles, $t = 2.61$, $P < 0.05$). On cyclic loading, maximum displacement was significantly lower for the DPTCPS than the SPPS and SPTCPS (0.96 ± 0.11 *vs.* 2.39 ± 0.14 mm, $t = 2.57$, $P < 0.05$; 0.96 ± 0.11 *vs.* 1.82 ± 0.12 mm, $t = 2.73$, $P < 0.05$). Resistance to toggle testing (370.3 ± 16.4 *vs.* 414.1 ± 12.8 N, $t = 3.29$, $P < 0.05$; 149.9 ± 11.1 *vs.*199.8 ± 7.2 cycles, $t = 2.97$, $P < 0.05$) was significantly lower and maximum displacement in cyclic loading (2.39 ± 0.14 *vs.*1.82 ± 0.12 mm; $t = 3.06$, $P < 0.05$) was significantly higher for the SPTCPS than the DPTCPS. Bone-to-implant contact was significantly increased for the DPTCPS compared to the SPPS ($58.3\% \pm 7.0\%$ *vs.* $36.5\% \pm 4.4\%$, $t = 2.74$, $P < 0.05$); there was no inflammatory reaction or degradation of coated particles.

Conclusion: DPTCPSs might have stronger initial and early fixation in a PEEK rod semi-rigid fixation system.

Keywords: Dual pitch titanium coating; Pedicle screws; Axial pull-out; Toggle testing; Cyclic loading

Introduction

Lumbar degenerative diseases seriously impact daily life and functional capacity. Conventional surgical treatment includes spinal fusion combined with instrumentation.[1] However, evidence suggests that spinal fusion may increase stiffness at the level of fusion and accelerate adjacent level degeneration and implant failure.[2] To minimize these adverse outcomes, dynamic or semi-rigid stabilization systems are used for the treatment of lumbar degenerative diseases. These systems are designed to

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maintain physiological intervertebral motion, stabilize abnormal segments, remove stress from lumbar discs, decrease interface stress of implants, improve load-sharing, and sustain segmental balance.[3]

Polyetheretherketone (PEEK) is a fully biocompatible and minimally toxic inert semi-crystalline thermoplastic polymer, with a modulus of elasticity between that of cortical bone and cancellous bone, and significantly lower than that of titanium alloy.[4] PEEK rod semi-rigid stabilization systems have the potential to maintain physiological motion of the spinal segment, improve anterior column load sharing, and reduce stress at the bone-screw interface. This decreases the rate of implant failure and reduces the incidence of long-term adjacent-level disc degeneration.[5]

Previous studies demonstrated that pedicle screw loosening remains the most common complication for pedicle screw-based non-fusion systems.[6] Stoll *et al*[7] reported radiological signs of screw loosening in 7 of 83 patients with lumbar instability conditions treated with the dynamic neutralization system for the spine (Dynesys). Several strategies, such as modifications in the shape and surface coatings of pedicle screws have been developed to augment pedicle screw fixation; these have shown favorable outcomes in both basic and clinical studies.[8] In contrast, reports on the efficacy of modifications to the thread design of pedicle screws are scarce. Therefore, the aim of this study was to evaluate the biomechanical and implant-bone interface histological characteristics of pedicle screws with a plasma-sprayed titanium coating and dual pitch in the pedicle region (dual pitch titanium-coated pedicle screw [DPTCPS]) in a PEEK rod semi-rigid fixation system during initial and early fixation in sheep spines.

Methods

Sheep management practices and surgical techniques were performed according to the regulations and laws of China and in accordance with the welfare and ethical review of experimental animals in China. The animal experiments were approved by the Xi'an Jiaotong University College of Medicine Committee on Animal Care (Source of animals: The Animal Experiment Center of Fourth Military Medical University, Permit No: SYXK2015-001). All efforts, including animal management procedures and accurate size calculations, were made to minimize animal suffering and reduce the number of animals used.

Anesthesia in sheep was induced with hydrochloric acid sierra oxazine (0.5 mL/kg) and was maintained with pentobarbital (1.0 mL/kg). After 6 months, sheep were euthanized with an overdose of xylazine hydrochloride by intra-muscular injection (2 mg/kg). Sheep spines were harvested for biomechanical testing or were fixed in 4% paraformaldehyde for immunohistochemical staining.

Study design

From March 2016 to June 2018, fifty-four fresh spine specimens from 2-year-old female sheep of similar weight (35–40 kg), type, and size served as "0-week" controls and were used to investigate initial fixation; 64 1.5-year-old sheep (32 males; 32 females) of similar weight (35–40 kg), type, and size were used to investigate early fixation. Sheep used to investigate initial and early fixation were randomly divided into four groups: the dual pitch pedicle screw (DPPS) group, the standard pitch pedicle screw (SPPS) group, the DPTCPS group, and the standard pitch titanium-coated pedicle screw (SPTCPS) group. All pedicle screws were composed of Ti-6Al-4V alloy with an outer diameter of 4.5 mm and length of 25.0 mm. DPPS (Weigao Orthopaedic Device Co., Ltd., Shandong, China) had a single-threaded design with a pitch of 6.0 mm in the pedicle region. SPPSs (Weigao Orthopaedic Device Co., Ltd.) had a double-threaded design with a pitch of a 3.0 mm in the pedicle region. DPTCPSs (Weigao Orthopaedic Device Co., Ltd.) had a porous plasma-sprayed titanium-coating with a roughnesses (Ra) of 4.54 μm, coating thickness of 386.6 μm, a porosity (Rz,%) of 29, and tensile bond strength of 47.0 Mpa over 10 mm and a single-threaded design with a pitch of 6.0 mm in the pedicle region [Figure 1]. SPTCPSs (Weigao Orthopaedic Device Co., Ltd.) had a porous plasma-sprayed titanium-coating and a double-threaded design with a pitch of 3.0 mm in the pedicle region. All screws had a double-threaded design with a pitch of 3.0 mm in the vertebral body region.

Bone mineral density (BMD; g/cm^2) of the second through fifth lumbar vertebrae (L2–L5) of each sheep was measured by dual-energy X-ray absorptiometry. To investigate early fixation, sheep were anesthetized, a posterior midline incision was made, and the L3 and L4 vertebral bodies were bilaterally exposed. Four DPPS, SPPS, DPTCPS or SPTCPS were implanted into L3 and L4 using regular procedures. Two PEEK rods (diameter, 6.35 mm; length, 55.0 mm) were used for semi-rigid fixation in each sheep. The reconstructed computed tomography (CT) images of eight animals that were included in a pilot study conducted

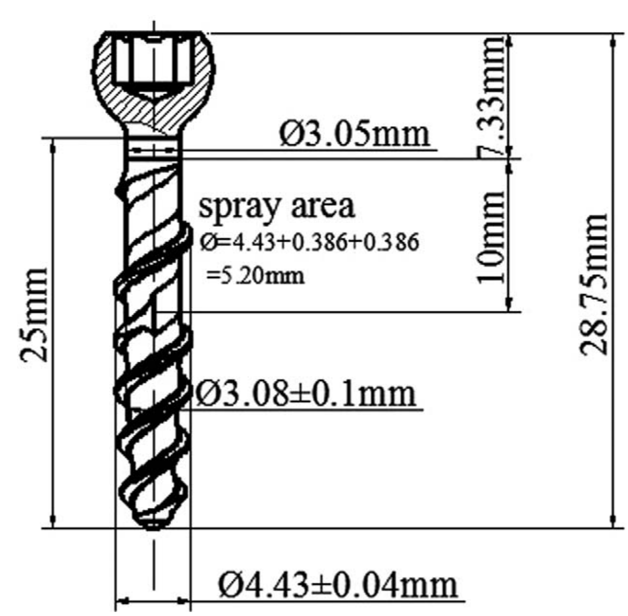

Figure 1: Schema of dual pitch titanium-coated pedicle screws. Pedicle screws are composed of Ti-6AL-4V alloy with an outer diameter of 4.5 mm and length of 25.0 mm.

before surgery were used to determine the diameter, length of the pedicle, transverse screw angle, and pedicle screw starting points. Post-operative CT images were obtained to evaluate screw and rod placement. After 6 months, all animals were euthanized, and the spines were resected en bloc from L2 to L5. Paravertebral soft tissue was removed from the fresh specimens.

Pedicle screws were applied in an identical manner in the 54 fresh spine specimens for the "0-week" controls.

Biomechanical evaluation

Axial pull-out testing was conducted, as previously described,[9] on 32 bone specimens from eight sheep spines, including two 0-week and four post-operative 6-month spines from each group. Briefly, specimens were mounted in a jig secured to a material testing system (MTS; Instron 3367, Instron Corp., Canton, MA, USA) [Figure 2A]; and testing was conducted at a constant crosshead speed of 5.0 mm/min. The pull-out direction was parallel to the long axis of the pedicle screws. The maximum pull-out load (*N*) was determined from a tensile curve recorded by a tensiometer.

Toggle testing was conducted, as previously described,[10] on 32 bone specimens from eight sheep spines, including two 0-week and four post-operative 6-month spines from each group. Briefly, the testing equipment consisted of a connecting rod and a hinge attached through an inline load cell to the MTS crosshead. The hinge was placed perpendicular to the pedicle screw axis and allowed an angular deviation of the screwhead. A ±200.0 N craniocaudal load was applied through the MTS (Instron 3367, Instron Corp), increasing by 25.0 N every 20 cycles. Cyclic toggling was stopped when 2 mm of crosshead displacement was detected. The number of craniocaudal cycles and the load (N) required to move the pedicle screws was determined.

Cyclic loading of pedicle screw assemblies was conducted, as previously described,[11] on 32 sheep spines, including six 0-week and 32 post-operative 6-month spines from each group. Briefly, specimens were rotated clockwise around their own axis, and a cyclic load was applied off-center with a 60.0 mm lever arm [Figure 2B]. In the first period of 1000 load cycles (2 Hz), a load magnitude of 20.0 to 100.0 N (resultant bending moment of 100.0 N × 60.0 mm = 6.0 Nm) was applied using the MTS (Instron 3367, Instron Corp.). The second period of cyclic loading was designed to cause loosening of the constructs; therefore, 1000 load cycles with a load magnitude of 20.0 to 200.0 N (resultant bending moment of 200.0 N × 60.0 mm = 12.0 Nm) were applied. The maximum displacement for each screw type was compared.

Histology

Histological examination was conducted on 32 bone specimens from eight post-operative 6-month sheep spines from each group. Specimens from the bone-implant

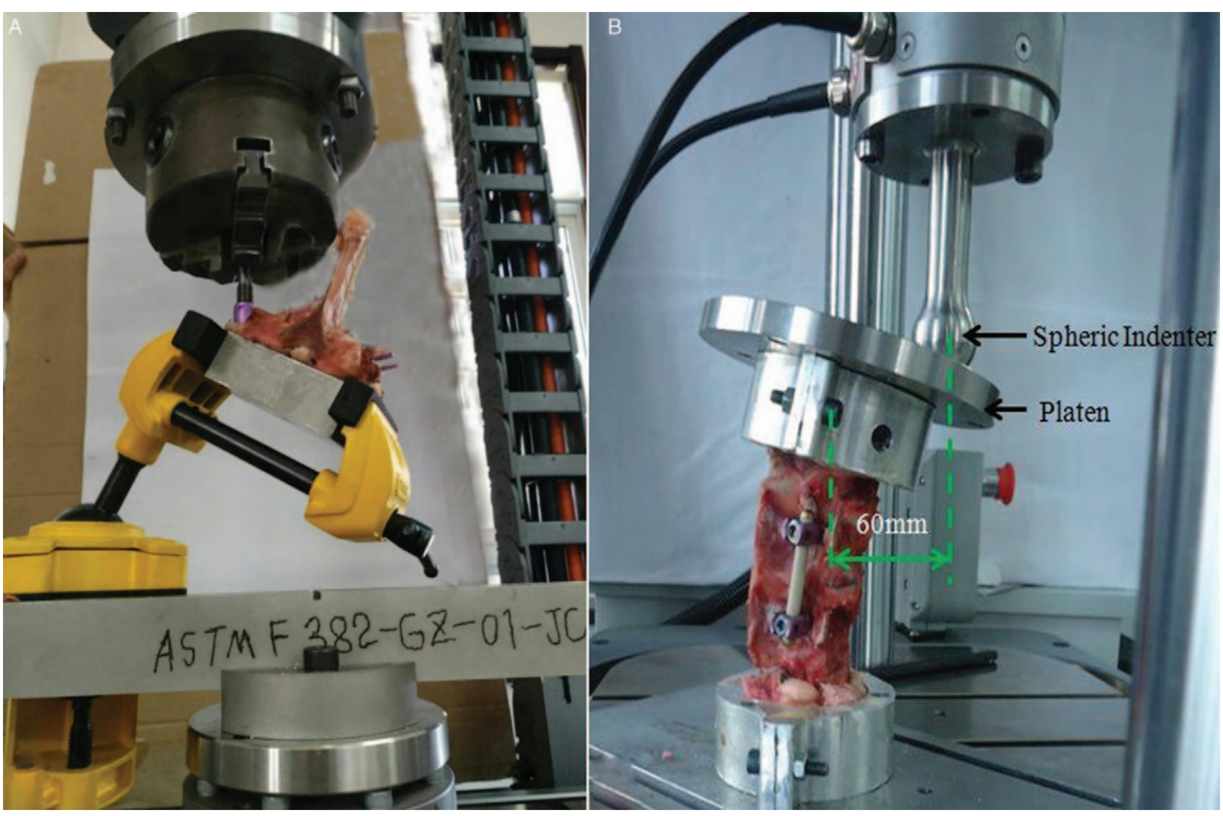

Figure 2: Biomechanical testing: axial pull-out (A) and cyclic loading of pedicle screw assemblies (B) using the material testing system.

interface were fixed in 80% ethanol for 14 days, dehydrated in graded ethanol (80%–100%), cleared with toluene, and embedded in methylmethacrylate. Serial transverse sections (70–80 μm thick) were obtained (Leica Microtome, Wetzlar, Germany), stained with 1.2% trinitrophenol and 1% acid fuchsin (Van-Gieson staining), and examined using a standard light microscope (Leica LA Microsystems, Bensheim, Germany) equipped with a digital camera (Penguin 600CL, Pixera Corp., Santa Clara, CA, USA). A digital image analysis system was used to measure bone-implant contact (Image-ProPlus software, Silver Spring, USA), which was calculated based on Van Gieson staining.

Statistical analysis

Statistical analyses were performed using SPSS software, version 12 (SPSS Inc., Chicago, IL, USA). Quantitative data are reported as mean ± standard deviation (SD). Data distribution was evaluated using the Kolmogorov–Smirnov test. Between-group differences were assessed using the t test. Statistical significance was set at $P < 0.05$.

Results

All 64 adult sheep in the early fixation group completed the study; no major complications such as infection or lower limb motor dysfunction were noted from the time of surgery to sacrifice. The position of all screws was good and available for biomechanical testing.

There was no significant difference in BMD at 0-week (initial fixation) or post-operative 6 months (early fixation) ($t = 0.84$, $P > 0.05$) [Table 1].

Biomechanical studies

At 0 week (initial fixation), mean axial pull-out strength was significantly higher for the DPTCPS and SPTCPS than the SPPS (DPTCPS *vs.* SPPS: 557.0 ± 25.2 *vs.* 459.1 ± 19.1 N, $t = 3.61$, $P < 0.05$; SPTCPS *vs.* SPPS: 622.6 ± 25.2 *vs.* 459.1 ± 19.1 N, $t = 3.43$, $P < 0.05$) [Figure 3A]. On toggle-testing, the DPTCPS was significantly more resistant than the SPPS and SPTCPS (DPTCPS *vs.* SPPS: 343.4 ± 16.5 *vs.* 237.5 ± 12.9 N, $t = 3.52$, $P < 0.05$; DPTCPS *vs.* SPTCPS: 343.4 ± 16.5 *vs.* 289.9 ± 12.8 N, $t = 3.12$, $P < 0.05$; DPTCPS *vs.* SPPS: 124.7 ± 13.5 *vs.* 41.9 ± 4.3 cycles, $t = 2.18$, $P < 0.05$; DPTCPS *vs.* SPTCPS 124.7 ± 13.5 *vs.* 79.5 ± 11.8 cycles, $t = 2.76$, $P < 0.05$) [Figure 3B and 3C]. On cyclic loading, maximum displacement was significantly lower for the DPTCPS than the SPPS and SPTCPS (DPTCPS *vs.* SPPS: 1.80 ± 0.13 *vs.* 3.76 ± 0.19 mm, $t = 2.29$, $P < 0.05$; DPTCPS *vs.* SPTCPS 1.80 ± 0.13 *vs.* 2.46 ± 0.20 mm, $t = 2.69$, $P < 0.05$) [Figure 3D].

At post-operative 6 months (early fixation), mean axial pull-out strength was significantly higher for the DPTCPS and SPTCPS than the SPPS (DPTCPS *vs.* SPPS: 908.4 ± 33.6 *vs.* 646.5 ± 59.4 N, $t = 3.34$, $P < 0.05$; SPTCPS *vs.* SPPS 925.9 ± 53.9 *vs.* 646.5 ± 59.4 N, $t = 3.37$, $P < 0.05$) [Figure 3A]. On toggle-testing, the DPTCPS was significantly more resistant than the SPPS and SPTCPS (DPTCPS *vs.* SPPS: 496.9 ± 17.9 *vs.* 370.3 ± 16.4 N, $t = 2.86$, $P < 0.05$; DPTCPS *vs.* SPTCPS: 496.9 ± 17.9 *vs.* 414.1 ± 12.8 N, $t = 2.74$, $P < 0.05$; DPTCPS *vs.* SPPS: 249.1 ± 11.0 *vs.* 149.9 ± 11.1 cycles, $t = 2.54$, $P < 0.05$; DPTCPS *vs.* SPTCPS: 249.1 ± 11.0 *vs.* 199.8 ± 7.2 cycles, $t = 2.61$, $P < 0.05$) [Figure 3B and C]. On cyclic loading, maximum displacement was significantly lower for the DPTCPS than the SPPS and SPTCPS (DPTCPS *vs.* SPPS: 0.96 ± 0.11 *vs.* 2.39 ± 0.14 mm, $t = 2.57$, $P < 0.05$; DPTCPS *vs.* SPTCPS: 0.96 ± 0.11 *vs.* 1.82 ± 0.12 mm, $t = 2.73$, $P < 0.05$) [Figure 3D].

At 0-week, axial pull-out strength, resistance to toggle testing, and maximum displacement in cyclic loading were significantly higher for the SPTCPS than the DPTCPS (622.6 ± 25.2 *vs.* 557.0 ± 25.2; $t = 2.62$, $P < 0.05$). At post-operative 6 months, there was no difference in axial pull-out strength (908.4 ± 33.6 *vs.* 925.9 ± 53.9 N, $t = 0.76$; $P > 0.05$) [Figure 3A], but resistance to toggle testing (370.3 ± 16.4 *vs.* 414.1 ± 12.8 N, $t = 3.29$, $P < 0.05$; 149.9 ± 11.1 *vs.* 199.8 ± 7.2 cycles, $t = 2.97$, $P < 0.05$) was significantly lower and maximum displacement in cyclic loading (2.39 ± 0.14 *vs.* 1.82 ± 0.12 mm, $t = 3.06$, $P < 0.05$) was significantly higher for the SPTCPS than the DPTCPS.

Histological results

At post-operative 6 months, histological examination with Van-Gieson staining of the dual pitch titanium-coated screws showed no inflammatory cells, the inter-spaces between the screw threads had been filled with new bone, moderate regenerative bone tissue was observed, and there was ingrowth into the titanium coating with a minimal gap at the interface between the pedicle screw and bone [Figure 4B]. With standard screws, less bone ingrowth was observed in the inter-spaces between the screw threads and there was less bonding, as evidenced by the presence of fibrous tissue and gaps at the interface between the pedicle screw and bone [Figure 4A]. Bone-to-implant contact was significantly higher for the dual pitch titanium-coated

Table 1: The sheep's BMD in the 0-week and 6-month groups (g/cm^2).

Time	DPPS	SPPS	DPTCPS	SPTCPS
0-week	0.988 ± 0.072	0.986 ± 0.074	0.977 ± 0.083	0.989 ± 0.071
6-month	0.973 ± 0.072	0.956 ± 0.650	0.981 ± 0.510	0.992 ± 0.068

BMD: Bone mineral density; DPPS: Dual pitch pedicle screw; SPPS: Standard pitch pedicle screw; DPTCPS: Dual pitch titanium-coated pedicle screw; SPTCPS: Standard pitch titanium-coated pedicle screw.

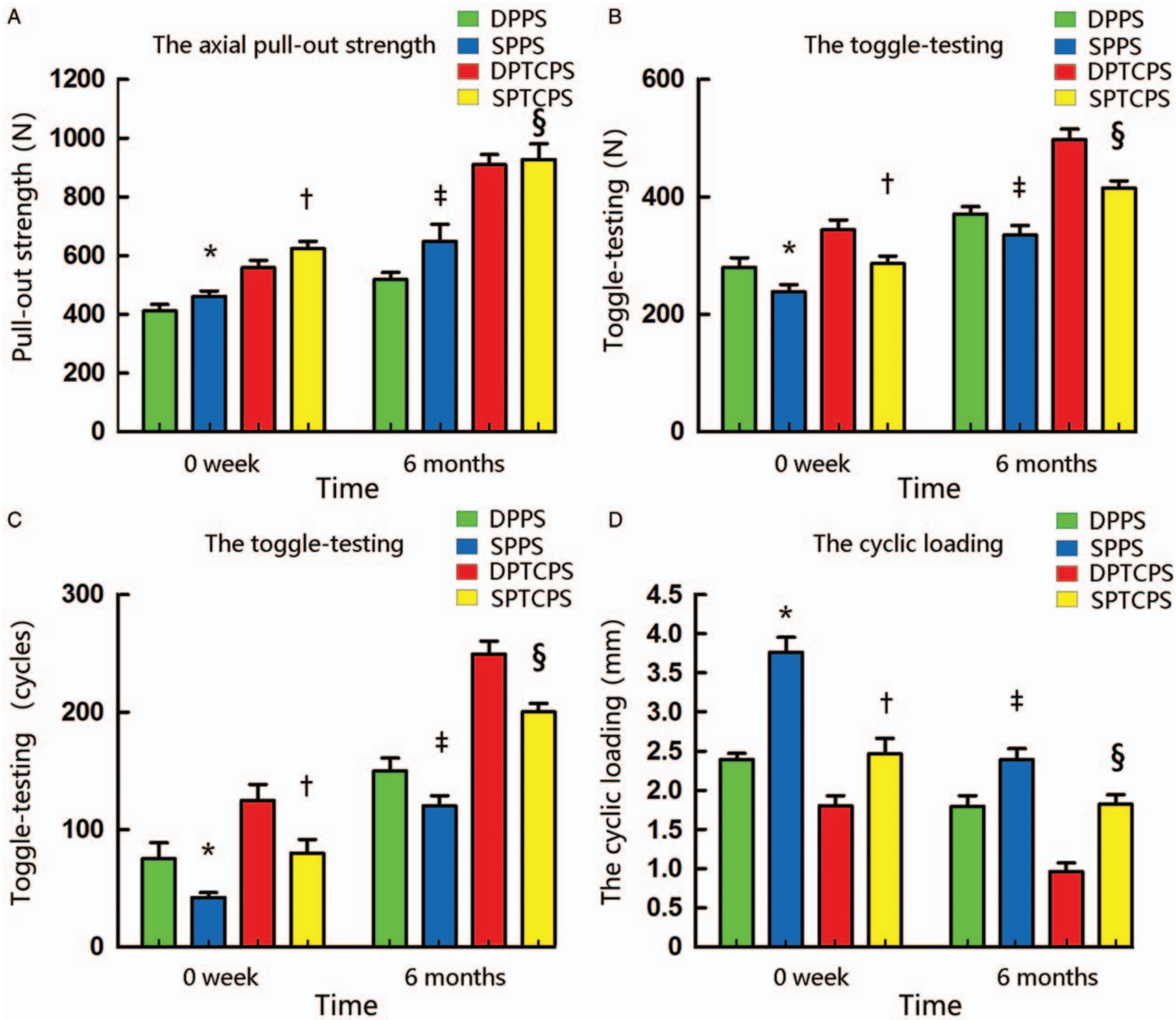

Figure 3: Biomechanical studies: At 0-week, mean axial pull-out strength was significantly higher for the DPTCPS and SPTCPS than the SPPS ($^{*,\dagger}P < 0.05$). At post-operative 6 months, mean axial pull-out strength was significantly higher for the DPTCPS and SPTCPS than the SPPS ($^{\ddagger}P < 0.05$); there was no difference between the DPTCPS and SPTCPS ($^{\S}P > 0.05$; A). On toggle-testing, at 0-week, the DPTCPS was significantly more resistant than the SPPS and SPTCPS ($^{*,\dagger}P < 0.05$). At post-operative 6 months, the DPTCPS was significantly more resistant than the SPPS and SPTCPS ($^{\ddagger,\S}P < 0.05$; B and C). On cyclic loading, at 0-week, maximum displacement was significantly lower for the DPTCPS than the SPPS and SPTCPS ($^{*,\dagger}P < 0.05$). At post-operative 6 months, maximum displacement was significantly lower for the DPTCPS than the SPPS and SPTCPS ($^{\ddagger,\S}P < 0.05$; D). Data are reported as mean ± standard deviation. DPPS: Dual pitch pedicle screw; DPTCPS: Dual pitch titanium-coated pedicle screw; SPPS: Standard pitch pedicle screw; SPTCPS: Standard pitch titanium-coated pedicle screw.

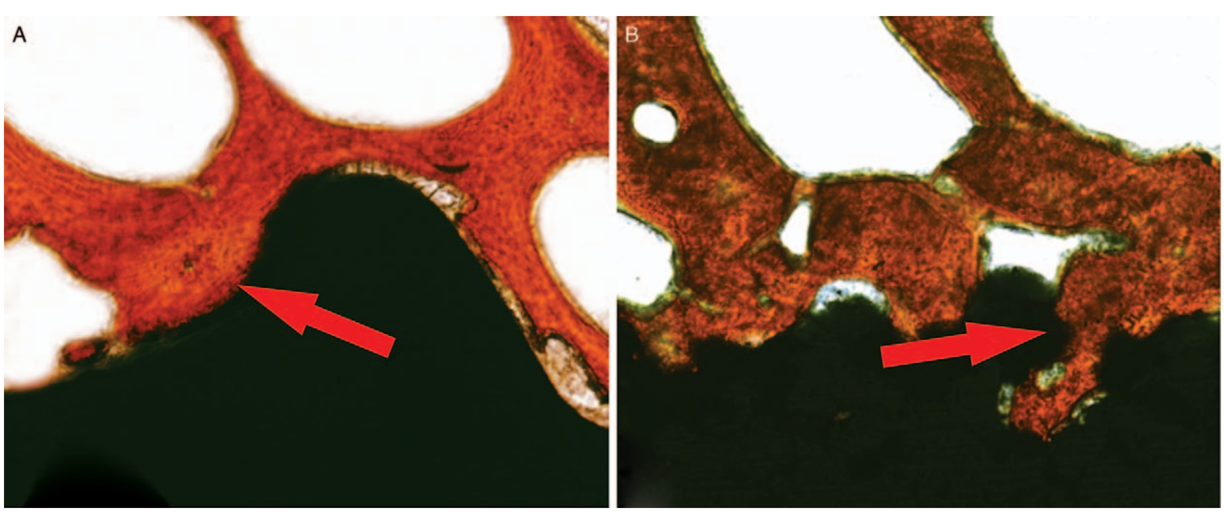

Figure 4: Histological examination with Van-Gieson staining: standard spinal implant pedicle screws showed gaps with little interface formation (A, original magnification ×20); Dual pitch titanium-coated pedicle screws clearly revealed new bone bonding with the coating, no inflammatory reaction, and barely any gap (B, original magnification ×20).

screws compared to the standard screws (58.3% ± 7.0% *vs.* 36.5% ± 4.4%, $t = 2.74$, $P < 0.05$).

Discussion

In spinal surgery, failed internal fixation may result from pedicle screw loosening and lead to a delay in the healing process and the need for revision surgery. Although a variety of surgical techniques and instrumentation systems for enhancing the stability of pedicle screw fixation are currently available, in pedicle-based dynamic stabilization systems, many studies argue against the non-fusion procedure, with screw loosening cited as the most common complication.[12,13]

Recently, design alterations, including different screw lengths, diameters, thread depth, and pitch, dual-lead pedicle screws, and various coatings, have been introduced to improve pedicle screw fixation by increasing the bonding strength between the pedicle screws and the vertebral bone. However, outcomes in biomechanical evaluations of these screws vary.[14] Kueny *et al*[15] showed that increasing the diameter of the pedicle screws by 1 mm when instrumenting human osteoporotic lumbar vertebrae increased the pullout force by 24% and the fatigue force by 5%; but the differences were not significant. Hasegawa *et al*[9] found that hydroxyapatite- coated pedicle screws with a thickness of 20.00 mm had a significantly increased mean axial pull-out force compared to standard pedicle screws (165.6 ± 26.5 N *vs.* 103.1 ± 30.2 N; $P < 0.001$) in a dog model of an osteoporotic lumbar spine. Wiendieck *et al*[16] investigated the effect of thread depth and pitch on the strength of pedicle screw fixation after repeated insertion. They found no significant correlation between tightening torque and pull-out strength during two repetitive insertions when using a standard 6.5 × 45-mm conical screw, a standard 7.2 × 45-mm conical screw, and a novel 6.5 × 45-mm (6T) dual-core pedicle screw. In the current study, at 0-week (initial fixation), mean axial pull-out strength was significantly higher for the DPTCPS and SPTCPS compared to the SPPS. On toggle-testing, the DPTCPS was significantly more resistant than the SPPS and SPTCPS. In cyclic loading, maximum displacement was significantly lower in the DPTCPS compared to the SPPS and SPTCPS. At initial fixation, axial pull-out and toggle testing are measures of the friction between the pedicle screws and the bone. Cyclic loading shows the stability of the pedicle screw construct. The DPTCPS has less thread, which effectively decreases the surface area of the screw and reduces the friction between the cancellous bone and pedicle screws, as well as the stability of the pedicle screw construct. However, this was countered by the increased diameter of the dual pitch screw due to the porous plasma-sprayed titanium coating and the increased surface roughness of the DPPS compared to the SPPS.

Establishment of sufficient osteointegration at the bone-pedicle screw interface is a key factor for successful screw fixation. Some adaptations to the surface design of pedicle screws, such as increasing the roughness at the bone-screw interface and varying the porosity and type of coating, stimulate bone ingrowth, improve the rate of osteointegration, and reduce the rate of implant failures.[17] Several studies showed titanium was a biologically inert material with good histocompatibility and adhesion, and it does not influence the biological activity of bone.[18] However, when pedicle screws connected to titanium alloy rods were used for stabilization without fusion, the internal fixation system allowed stresses generated by vertebral micro-motion during ambulation to be transmitted to the bone-pedicle screw interface, which could impede bone ingrowth and cause implant failure.[19] In contrast, materials such as hydroxyapatite cause an inflammatory reaction between bone and the coating interface that may induce osteolysis, weaken the adhesion between the coating and the bone, and result in loosening of pedicle screws.[20] In the current study, pedicle screws were connected to monosegmental semi-rigid PEEK rods. When dual pitch titanium-coated screws were used, histological examination at early fixation showed no inflammatory cells and the inter-spaces between the screw threads were filled with cancellous bone. There was good bonding, evidenced by the presence of moderate regenerative bone tissue and ingrowth into the titanium coating. With SPPS, there was less ingrowth of bone at the inter-spaces between the screw threads. Furthermore, there was a lesser degree of bonding, evidenced by the presence of fibrous tissue and gaps at the interface between the pedicle screw and bone. Bone-to-implant contact was significantly greater for the dual pitch titanium-coated screws *vs.* the standard screws. These results suggested that the porous plasma-sprayed titanium coating on the dual pitch screws resulted in better osteointegration, increased the amount of bone ingrowth into the surface-coating, and induced no inflammatory reaction or degradation of coated particles, which would have weakened the adhesion between the pedicle screws and bone.

Our data confirmed the findings from other studies showing that bone ingrowth into porous plasma-sprayed titanium coatings forms a mechanical bone-implant interlock that increases the resistance to axial pull-out force and enhances fixation. Kim *et al*[21] found that atmospheric plasma-sprayed titanium-coated pedicle screws exhibited the greatest mean extraction peak torque at 12 weeks after surgery compares to uncoated and hydroxyapatite-coated pedicle screws (8.11 ± 1.07 Ncm *vs.* 6.47 ± 1.10 Ncm *vs.* 5.63 ± 0.73 Ncm, respectively; $P < 0.05$). Upasani *et al*[8] showed that surface coatings on pedicle screws improve fixation in non-fusion spinal constructs. Accordingly, in the current study, at post-operative 6 months (early fixation), mean axial pull-out strength was significantly improved for the DPTCPS and SPTCPS compared to the SPPS. On toggle-testing, the DPTCPS was significantly more resistant than the SPPS and SPTCPS. In cyclic loading, maximum displacement was significantly decreased in the DPTCPS compared to the SPPS and SPTCPS. At 0 weeks, axial pull-out strength, resistance to toggle testing, and maximum displacement in cyclic loading were significantly higher for the SPTCPS compared to the DPTCPS. At post-operative 6 months, there was no difference in axial pull-out strength, but resistance to toggle testing and maximum displacement in cyclic loading were significantly higher for the SPTCPS compared to the DPTCPS. This finding may reflect the strong bonding at the interface between the DPTCPS and the bone, which strengthened over time as increased bone ingrowth provided an anchoring effect.

This study had several limitations. First, it was performed in a sheep model, which is a quadruped. Further, screw loosening in dynamic fixation is caused by rotational shear forces, which are not the same in humans and sheep. Therefore, vertebral interface micro-motion maybe less, and the gravitational pull may be different compared to humans. Second, we did not conduct a long-term follow-up.

In conclusions, DPTCPSs induce better osteointegration and increased the amount of bone infiltrating into the implant compared to SPPS. DPTCPSs result in markedly stronger initial and early fixation in a PEEK rod semi-pitch rigid fixation system with no inflammatory reaction or degradation of coated particles. Further studies with a longer-term follow-up in animal models are required before clinical application.

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Conflicts of interest

None.

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