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Effects of Ti2448 half-pin with low elastic modulus on pin loosening in unilateral external fixation

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Abstract The objective of this study was to compare the benefits of titanium 2448 (Ti2448) half-pin and titanium-6 aluminium-4 vanadium (TAV) half-pin on reducing pin loosening during external fracture fixation. Although having similar strength, Ti2448 half-pin had even lower elastic modules(33 GPa)when compared with TAV half-pin (110 GPa), which was similar to that of cortical bone (20 GPa). In the external fixation of tibial model fractures and canine cadaveric tibia fractures, Ti2448 half-pin had greater recoverable deformation and less stress concentration at the pin–bone interface in compression, torsion, and four-points bending test. Then, tibial fractures were created in 24 dogs and stabilized with four half-pins of either Ti2448 or TAV in each animal. At 4 and 8 weeks postoperatively, fracture healing and pin loosening was assessed by radiographic grading scale. The scores of Ti2448 group were significantly higher than those of TAV group. Micro-CT analysis also indicated larger quantity and higher quality of newly formed bone at pin–bone interface in Ti2448 group. Histology observation showed the newly formed bone integrated well into the threads of Ti2448 half-pins. In contrast, there was a layer of necrotic tissue between the bone tissue and TAV half-pin at pin–bone interface in TAV group. The extraction torque values of Ti2448 half-pins near the fracture line were significantly higher than those TAV pins. In conclusion, the Ti2448 half-pin with low elastic modulus could enhance osseointegration and reduce pin loosening when compared with TAV half-pin. It is a promising biomaterial for constructing external fixation system in clinical application.

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1 Introduction

Unilateral external fixator is widely used to manage open fractures, even under unfavorable soft-tissue conditions. It well follows the principle of minimal invasive surgery. The pins for fixation are inserted into the cortex away from the fracture site without disturbing the biological environment of fracture. The main advantages of external fixation are simple manipulation and easy regulation. However, both pin loosening and pin tract infection are still the most common postoperative complications coupled with this technique [1–3]. Because the pins transmit all the force applied to bone fragments, from the skeleton to the external fixation support, and bear heavy loads, the pin–bone interface is the most critical component of fixator system. These complications are mainly associated with the mechanical deterioration of pin–bone interface. Therefore, the osteointegration of pin at interface is crucial for preventing pin loosening.

It has been generally accepted that excessive micromotion (greater than 150 μm) of implanted pins can inhibit osteointegration and result in fibrous tissue formation around pins [4, 5]. The resultant mechanical failure at pin–bone interface can lead to consequent pin loosening and tract infection. To minimize the micro-motion of pins,

various approaches have been used in recent years. The pin diameter is enlarged to increase contact area. But its size is limited by the diameter of fractured bone. The pin diameter exceeding 20% of bone diameter will reduce torsional strength by 34%, and if the diameter is greater than 50% the reduction is 62% [6, 7].In practice it is usually advisable to keep pin sizes to within a third of the diameter of the bone, which can reduce the risk of fracture on removal of the pin [8]. Recently, the pin surface modification with osteoconductive materials such as hydroxyapatite (HA), poly(lactic acid) (PLA), and poly(glycolic acid) (PGA) have attempted to enhance the pin–bone integration [9, 10]. Although the studies in animals and patients showed promising results, the limitations are also obvious. HA coating is susceptible to bacterial adherence. PLA and PGA coating have acidic degradation products, which results in local inflammation [11, 12]. Furthermore, the approach to enhance the physical compatibility between pin and coating can be challenging because the shear stress can induce micro cracks of coating followed by fixation failure [13]. The material of pin is another consideration to improve the osteointegration at pin–bone interface. Traditionally, external fixator pin is composed of stainless steel offering substantial stiffness. Finite element analysis of the pin–bone interface cortex revealed stress values were significantly increased by using stainless steel as opposed to the titanium pins. This location coincided with the area where loosening was usually first observed radiologically. With better biocompatibility and lower elastic modulus, titanium and titanium alloy pins can reduce the stress at pin–bone interface, which results a lower rate of pin sepsis and loosening [14]. In a prospective trial, 80 patients with unstable radius fractures were treated by external wrist fixators with stainless steel or titanium alloy pins. The rate of pin tract infection (5 vs. 0%) and pin loosening (10 vs. 5%) were higher in stainless steel group. The use of titanium alloy pins yields a trend of reduced pin-related complications and significantly reduced pain levels [15].

Ti-6Al-4V (TAV) is the most commonly used titanium alloy. It has a chemical composition of 6% aluminium, 4% vanadium, 0.25% (maximum) iron, 0.2% (maximum) oxygen, and the remainder titanium. It is significantly stronger than commercially pure titanium while having the same stiffness and thermal properties. It is used extensively in medicine, especially in surgical implants. However, the elastic modulus of TAV (110 GPa) is much higher compared with that of human bone (10–20 GPa). Ti2448 is a newly developed β-type titanium alloy for biomedical applications by our group. It has a chemical composition of 24.1% niobium, 3.92% zirconium, 7.85% stannum and 64% titanium [16]. Ageing treatment in the ($\alpha + \beta$) two-phase field results a higher strength (800–900 MPa) and relatively low elastic modulus (33 GPa) in comparison with those of TAV (110 GPa). Its elastic modulus is similar to that of native bone. So we hypothesize that Ti2448 pin not only has enough strength to obtain apposition and alignment of fragments but also reduces the stresses at pin–bone interface. It may have less incidence of loosening compared with TAV pin.

In order to prove this hypothesis, the study was designed (1) to examine the strains of Ti2448 half-pin at pin–bone junction in tibia model and canine cadaveric tibia under compression, torsion, and bending conditions, (2) to observe bone remodeling around the Ti2448 half-pin in dog tibia fracture model using micro-CT and histological staining, and (3) to test extraction torque of Ti2448 half-pin for assessing osseointegration.

2 Materials and methods

2.1 Mechanical testing of tibial model and cadaveric tibia

Mechanical testing was performed on synthetic tibial model and canine cadaveric tibia. The cylinder tibial model (diameter: 24 mm; length: 240 mm) was made of epoxy resin and glass fiber composite. It had a central canal (diameter: 12 mm) along its long axis. The synthetic bone models have been shown to simulate physical behavior of cadaveric bone [17]. Transverse fracture pattern was created with a power saw. It was set at 12 cm distal to the tip of tibial model. The fracture was fixed with unilateral external fixation system, which consisted of nipples, carbon fiber rod (length: 15.0 cm, diameter: 6.0 mm), and pins (length: 10.0 cm, diameter: 3.0 mm) (Fig. 1a). Four 3.0 mm-diameter TAV and Ti2448 half-pins were inserted in group A and group B, respectively. Two pins were proximal and two distal to the fracture site. The proximal half-pins were located 15 mm and 60 mm to the fracture line, and the distal pins were located at the same distances. Four nipples were used to connect half-pins and carbon rod for constructing a stable external fixation. The distance between the rod and cortex was 20 mm. The strain gages (Zhonghang Electronic Measuring Instruments CO., China; size: 0.2 × 0.2 mm) were used to detect the strains of half-pin and cortex. Two strain gages were adhered to each half-pin oppositely at the site of pin–cortex junction (Fig. 1b, c). In addition, the canine cadaveric tibias were harvested and stripped of all soft tissue. A reciprocating saw was then used to resect a 10 mm long segment of central diaphysis in each tibia. Four half-pins were screwed into the tibia symmetrically and external fixation was constructed. Then, the gages were placed at the same sites as those in tibial model fixation described above. The data transmission lines from gages were connected to DH3816 static strain

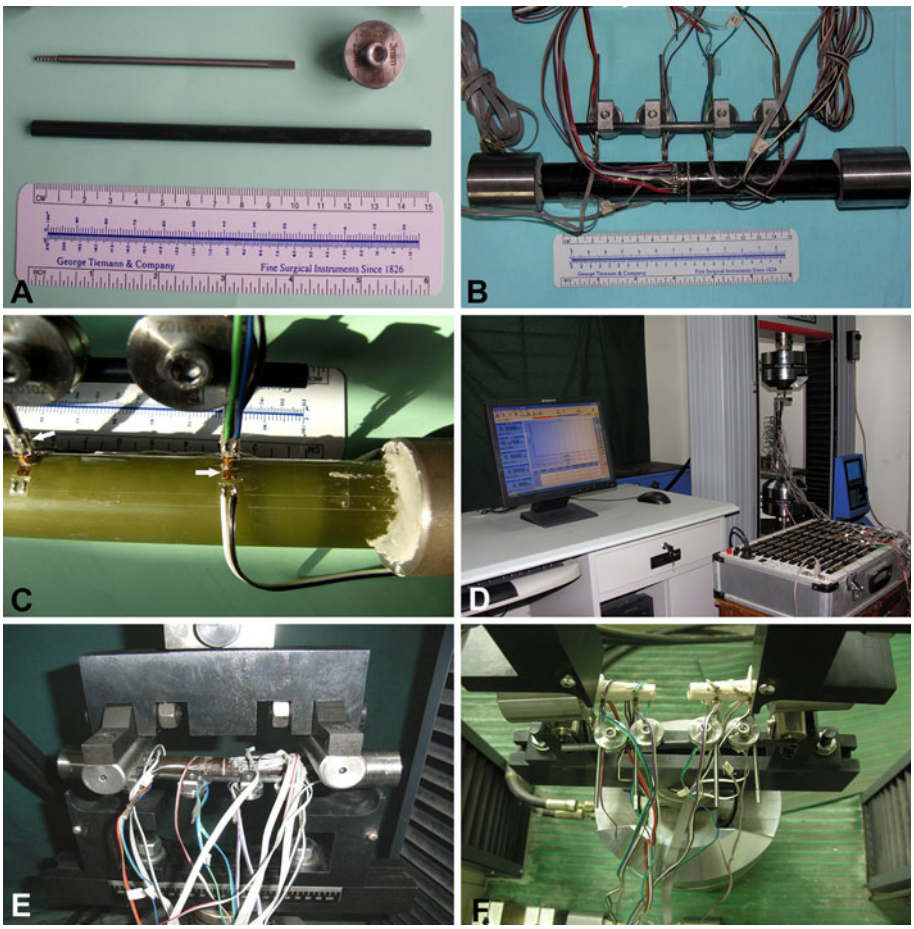

Fig. 1 **a** Gross observation of unilateral external fixation system consisting of nipples, carbon fiber rod, and pins. **b** Unilateral external fixation of fractures created in tibial model. The strain gages were used to detect the strains of half-pin. **c** Two strain gages were adhered to each half-pin oppositely at the site of pin–cortex junction. **d** The data transmission lines from gages were connected to DH3816 static strain testing system. **e**, **f** Mechanical testing of unilateral external fixation system in synthetic tibial model and canine cadaveric tibia model

testing system (Donghua Testing Technology CO., China) (Fig. 1d). All biomechanical testing was performed using a universal mechanical testing system (Hualong Test Instruments Co., China). Each specimen was placed into a custom-fit, removable polymethyl methacrylate mold and secured in testing machine. The specimens were subjected to separate four points bending, torsion, and lateral compression test (Fig. 1e, f). In each testing configuration, five trials were performed. Four points bending test, torsional test, and lateral compression test was performed. The strains were recorded and compared between groups. None of the specimens were loaded to failure.

2.2 Surgical procedures

The pin stability of unilateral external fixation was further studied in dogs. Animal experiment was approved by Institutional Animal Care and Use Committee of the Fourth Military Medical University. Twenty-four mature dogs (12 months old; 15–21 kg) were randomly assigned into two groups for fracture fixation: Ti2448 pin fixation group (group A, $n = 12$) and TAV pin fixation group (group B, $n = 12$). The surgery was performed under strictly aseptic conditions. Food and water was withdrawn 12 h before induction of anesthesia. Medetomidine (5 mg/kg intramuscularly) served as premedication before induction of anesthesia with atropine (0.5 mg/kg) and ketamine (2 mg/kg). Anesthesia was maintained by intravenous ketamine drip. The right hind limb was prepared for surgery. Four pilot holes (numbered 1–4, with 1 being most proximal and 4 most distal) were drilled in the tibia using a 2.0 mm diameter drill bit. A positioning template ensured a spacing of 4.5 cm between pins in the proximal and distal portions and of 3 cm between pins 2 and 3 (the same as those positioned during in vitro tests). The pin 1 was inserted approximately 50 mm below the tibial plateau. Then, the Ti2448 pin or TAV pin (diameter: 3.0 mm) were threaded manually into the pilot holes with a T handle until the threads fully engaged both cortices. Thereafter, a midshaft tibial osteotomy was performed between pins 3 and 4. Briefly, the tibia was exposed through longitudinal incision. The tibialis anterior muscle was retracted and the diaphysis was exposed. The tibia was cut using a reciprocating saw and the fibula was transected using bone cutters. The incision was closed in layers. A unilateral external fixation frame incorporating pins 1, 2, 3, and 4 was used to

stabilize the bone fractures. A 6.0 mm diameter carbon fiber connecting rod was used in frame. Antibiotics were administered to prevent infection. All dogs were allowed free, unrestricted weight-bearing movement after surgery.

2.3 X-ray analysis

The dogs ($n = 24$) from both groups were anesthetized with atropine (0.5 mg/kg) and ketamine (2 mg/kg) at 2, 4, 8 weeks postoperatively. Then the standardized antero-posterior and lateral radiographs of tibia were taken. The exposure conditions were 42 kV, 100 mA, and 0.12 s. The films were analyzed according to a modified Yang's scoring system [18].The scale was composed of three categories: (1) The first category evaluated osteotomy line graded from 0 to 2 points. (3) The second category evaluated callus formation graded from 0 to 3. (4) The third category evaluated pin–bone interface graded from 0 to 2 points (Table 1). The stable external fixation and solid union of the fracture would receive a maximum total score of 13 points. The films were scored and compared between groups.

2.4 Mirco-CT scan and extraction torque measurement

The dogs were sacrificed and tibias were collected at 8 weeks postoperatively. Before mechanical test and histology staining, the specimens were firstly scanned with micro-CT (Explore Locus SP, GE, US) to determine the bone quality at pin–bone interface in groups. The specimens were fixed in sample holder and placed in micro-CT specimen chamber. The optimal threshold value of 300 was set for scan in this study. The parameters were set with the energy of 50 kV, the intensity of 80 μA, and the isotropic voxel resolution of 27 μm. The scanned slices were reconstructed to show the cutaway views of implanted pins. Region of interest (ROI, 6.0 mm in diameter) is a circular area including the central implanted pins and surrounding bone tissues. Bone histomorphometry parameters including bone mineral content (BMC), bone mineral density (BMD), tissue mineral density (TMD), tissue mineral content (TMC), and bone volume/tissue volume (BV/TV) were compared between groups. Thereafter, six specimens from each group were used for extraction torque measurement with torque gauge. During the test, the specimens were always kept moist with phosphate buffered saline (PBS) solution. The maximum extraction torque was recorded. All extraction procedures and recordings of extraction torque were carried out by the same surgeon.

Table 1 Radiographic grading system

Osteotomy site	Score
Osteotomy line completely radiolucent	0
Osteotomy line partially radiolucent	1
Osteotomy line invisible	2
Callus Formation	
None	0
Minimal	1
Moderate	2
Abundant	3
Pin–bone interface[a]	
Interface completely radiolucent	0
Interface partially radiolucent	1
Interface fully integrated	2
Maximum total score	13

[a] Pin 1–4 scored individually

2.5 Histological analysis

All specimens were fixed in 10% neutral buffered formaldehyde (pH 7.2) for 2 weeks, then rinsed in tap water for 12 h. For decalcified histology study, the samples ($n = 6$) after torque examination were decalcified in 50 mM ethylenediaminetetraacetic acid (EDTA), embedded in paraffin, and sectioned at 5 μm thickness. For undecalcified histology study, the remaining specimens ($n = 6$) from each group were dehydrated through gradient alcohols, cleared with toluene before being embedded in polymethylmethacrylate. Then, the cross sections were cut to about 200 μm thick with a hard tissue microtome (Reichert-Jung, Leica SP1600, France). Thereafter, the sections glued onto a plastic support were polished to 80 μm thickness with an Exakt Grinder (Norderstedt, Germany). Then, the slides were stained with modified ponceau trichrome staining [19] and toluidine blue staining. The results were evaluated by three individuals who were blinded to the treatments.

2.6 Statistical analysis

All data were analyzed using SPSS software and statistically significant values were defined as $P < 0.05$. The data were expressed as mean ± standard deviation (SD). Student's *t*-test was used to detect the differences between groups.

3 Results

3.1 Biomechanical analysis of tibial model and cadaveric tibia

In the mechanical testing of pin stability in tibial model, the strain of pins increased continuously with the increment of mechanical load. The curves in both groups changed

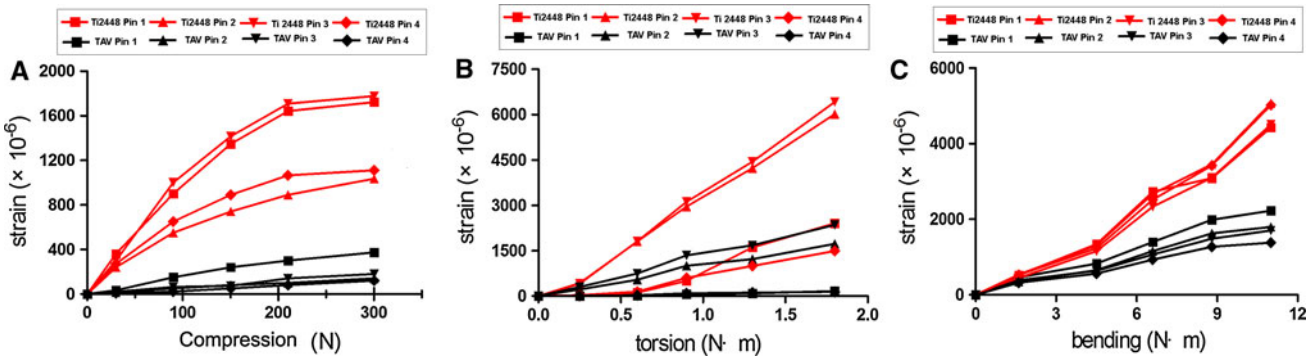

Fig. 2 The load–strain curve of each pin in tibial model fracture under compression (**a**), torsion (**b**), and bending (**c**) test at 8 weeks postoperatively

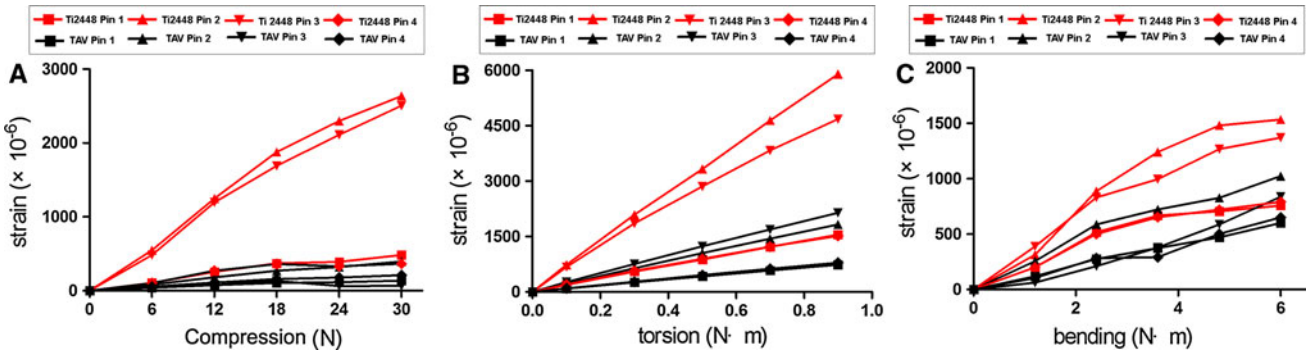

Fig. 3 The load–strain curve of each pin in canine cadaveric tibial fracture model under compression (**a**), torsion (**b**), and bending (**c**) test at 8 weeks postoperatively

smoothly, which illustrated a stable external fixation. The strain curve of each Ti2448 pin was steeper in comparison with that of TAV pin under the same mechanical load in compression, torsion, and four-points bending test (Fig. 2). In compression test, the strain values showed no significant difference between groups when the mechanical load was under 30 N. However, when then mechanical load increased from 90 N to 300 N, the strain values of Ti2448 pins increased from 550, 650, 900, and 1000–1035, 1110, 1723, and 1777, respectively. They were significantly higher than those of TAV Pins (Fig. 2a). When the torsion load was 0.3 N and 0.6 N m, the strain values showed no significant difference between groups. Then the Ti2448 pins showed significantly higher strain values with the increasing torsion load (Fig. 2b). In four points bending test, the strain values showed significant difference only when the load was over 4.5 N m. The Ti2448 pins recorded maximum strains of 4428, 4508, 5022, and 5070 under the load of 11.0 N m. While the TAV pins had the strain values of 1384, 1702, 1798 and 2228, which were significantly lower than those experiment group (Fig. 2c).

In the mechanical testing of pin stability in canine cadaveric tibia fracture, the strain graphs showed the similar trends as those in tibial model. In compression test, the strains showed significant difference between groups only when the mechanical load was over 18 N (Fig. 3a). Similarly, the strains of Ti2448 pins showed significant higher value when the mechanical load was over 0.5 N m and 3 N m in torsion test and four-points bending test, respectively (Fig. 3b, c). Compared with TAV half-pins, the Ti2448 pins had greater recoverable deformation and less stress at the pin–bone interface under the same load.

3.2 X-ray evaluation

The X-ray films of both groups were evaluated at 2, 4, and 8 weeks postoperatively. The results showed the external fixation was stable and the callus formed around the fracture line with time (Fig. 4a, b). At 8 weeks postoperatively, the newly formed bone connected both ends of fractures in groups. However, due to different stress at pin–bone interface, the bone remodeling around the implanted half-pins showed different radiological changes. After 8 weeks, the radio-lucent areas around half-pins in group A remained much smaller than those of group B (Fig. 4c–f). The radiographic grading score showed a time-dependent increase in both groups. There was no significant difference

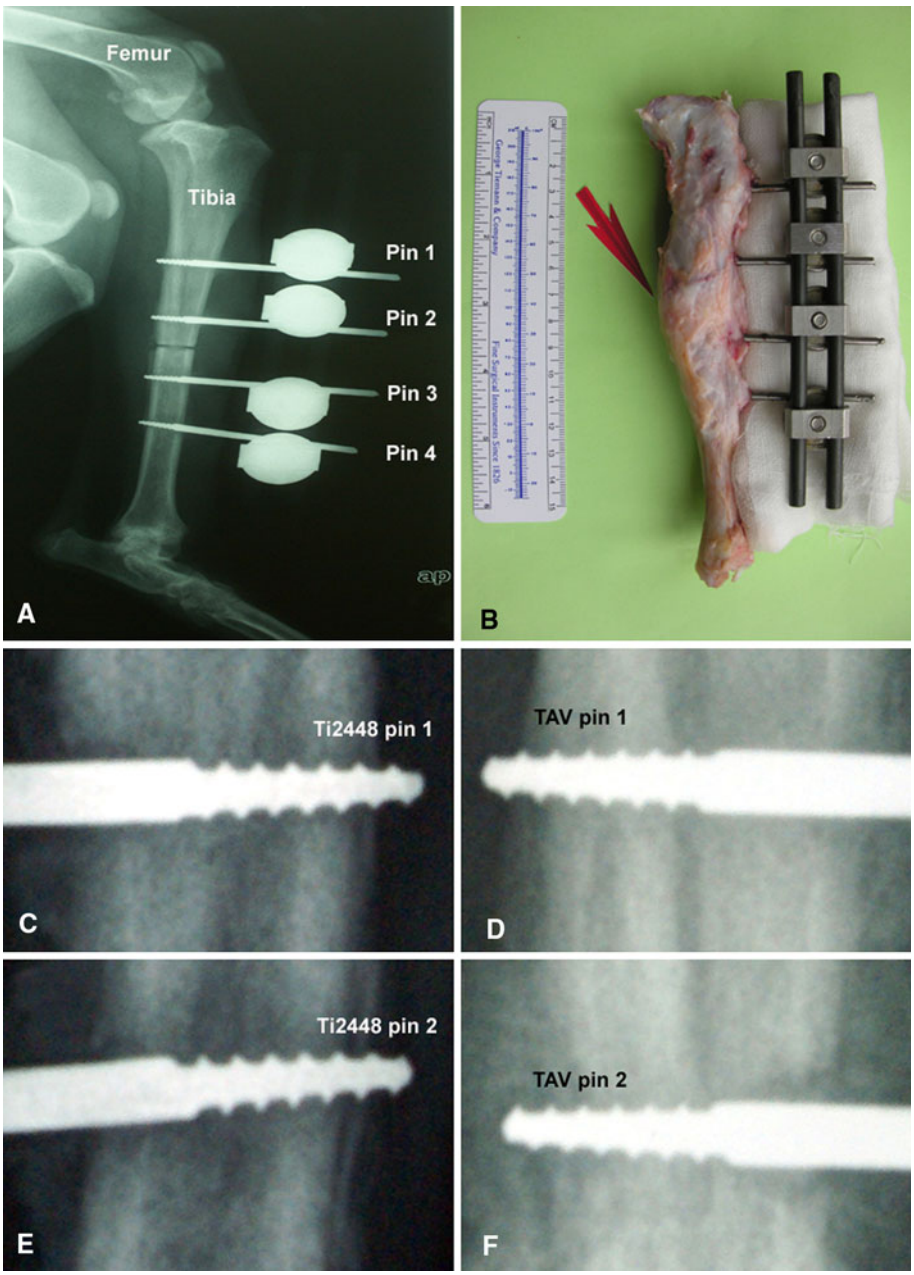

Fig. 4 The X-ray film (**a**) and gross observation (**b**) of unilateral external fixation to indicate the pin sites at 8 weeks postoperatively. **c**–**f** indicated the interface between bone and Ti2448 pin1, TAV pin1, Ti2448 pin2, and TAV pin2, respectively (*Note*: the arrow pointed to the fracture line)

Table 2 Summary of radiographic grading score between groups (Data in mean ± SD, $n = 12$)

Post-operation time	Group A	Group B
2 weeks	3.3 ± 1.3	3.2 ± 0.9
4 weeks	5.3 ± 0.8*	4.3 ± 0.7
8 weeks	10.2 ± 1.2*	7.9 ± 0.7

* $P < 0.05$ compared with group B

between groups after 2 weeks. However, the scores of group A increased steeply with the value of 5.3 ± 0.8 and 10.2 ± 1.2 at 4 and 8 weeks, which were all significantly higher than those of group B (Table 2).

3.3 Micro-CT analysis

The cross sectional images perpendicular to the longitudinal axis of half-pin were reconstructed in high resolution with micro-CT. The reconstructed images indicated that the half-pin's thread and the bone wall of pin track kept intact (Fig. 5a, b). In the same volume of ROI, more pores resulting from unmineralized tissue or necrotic bone tissue could be observed in group B (Fig. 5c, d). The changes of bone remodeling in pin track could be examined by screening all slices of each sample. The histomorphometry analysis of pin track indicated that the BMC, BMD, TMC, TMD, and BV/TV in group A were 59.7 ± 4.7 mg,

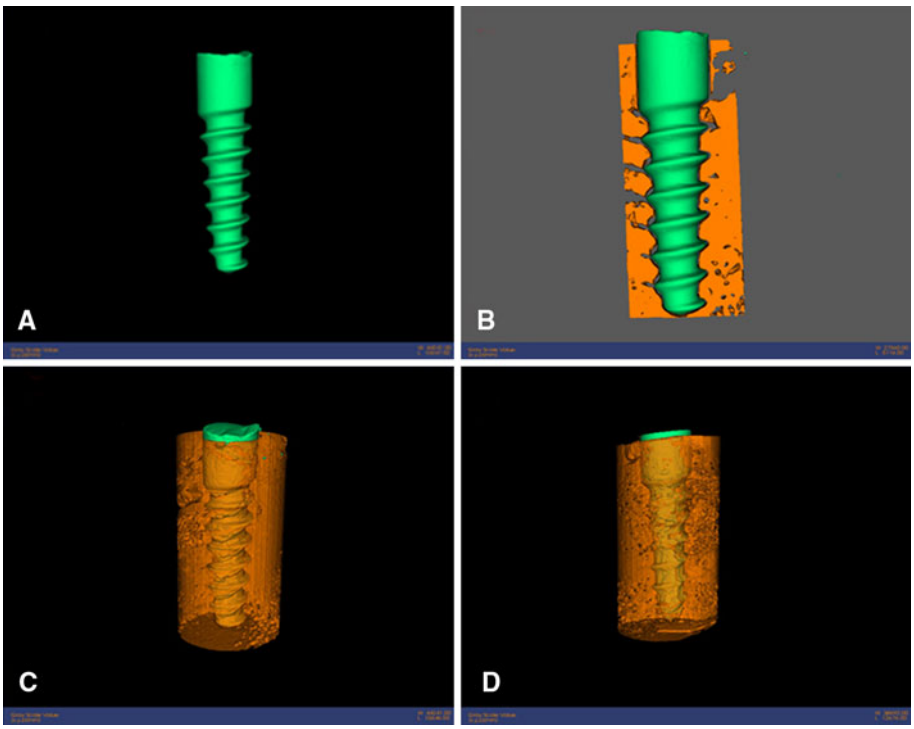

Fig. 5 Reconstructed 3-D images by micro-CT. **a** image of half-pin, **b** image of pin–bone interface, **c**, **d** images of ROI in Ti2448 group and TAV group, respectively (ROI: region of interest)

Table 3 Bone histomorphometry analysis by MicroCT

	BMC (mg)	BMD (mg/cc)	TMC (mg)	TMD (mg/cc)	BV/TV
Group A	59.7 ± 4.7*	162.2 ± 9.1*	170.2 ± 11.3*	637.2 ± 18.2*	0.73 ± 0.04*
Group B	45.7 ± 1.9	124.5 ± 7.5	136.8 ± 10.7	585.7 ± 6.2	0.64 ± 0.05

* $P < 0.05$ compared with group B

162.2 ± 9.1 mg/cc, 170.2 ± 11.3 mg, 637.2 ± 18.2 mg/cc, and 0.73 ± 0.04, which were significantly higher than those of group B (Table 3).

3.4 Extraction torque measurement

The loosening of each half-pin in both groups was examined by a torsion strength test. The extraction torques of Ti2448 pin 2 and pin 3 were 1.163 and 1.008 N m, which were significantly higher than those TAV pins ($P < 0.05$). On the contrary, the extraction torques of Ti2448 pin 1 and pin 4 showed no significant difference when compared with those of TAV pins (Fig. 6).

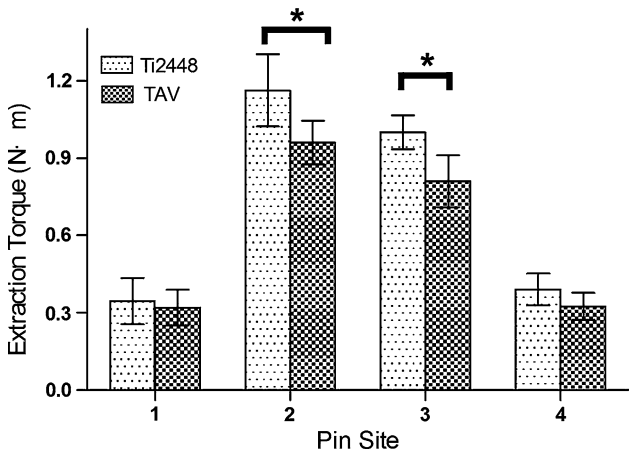

Fig. 6 The extraction torque values of Ti2448 and TAV pins at different pin sites at 8 weeks postoperatively

3.5 Histological observation

The pin–bone interface at different pin site in each group demonstrated the similar histology changes. The modified ponceau trichrome staining showed a layer of homogenous, orange-red color inter-blended with blue staining around the pin track in group A at 8 weeks postoperatively. From surface to deep layer of interface, the newly formed woven bone became mature. The color of staining changed from orange-red, light blue to dark blue. It indicated the newly formed bone integrated well into the threads of half-pins. In contrast, group B showed fibrotic tissue formation at the pin–bone interface, which stained blue with striated

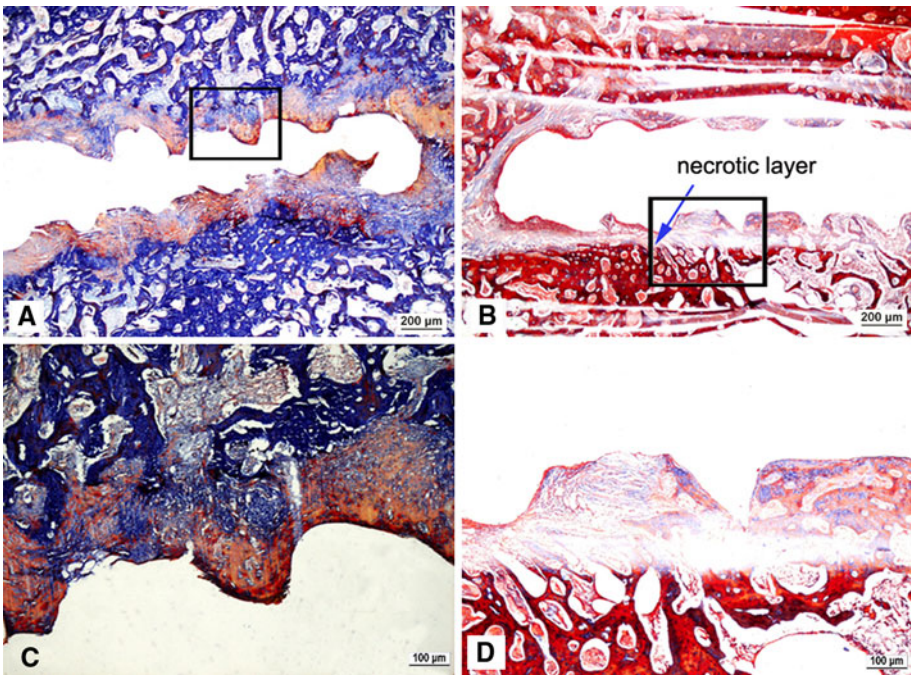

Fig. 7 Histological observation of decalcified pin–bone interface in group A (**a**, **c**) and group B (**b**, **d**) by modified ponceau trichrome staining at 8 weeks postoperatively. (*Note*: **a**, **b** × 16, *scale bars* = 200 μm; **c**, **d** × 100, *scale bars* = 200 μm; **c** and **d** were magnified views of *black rectangles* from **a** and **b**, respectively.)

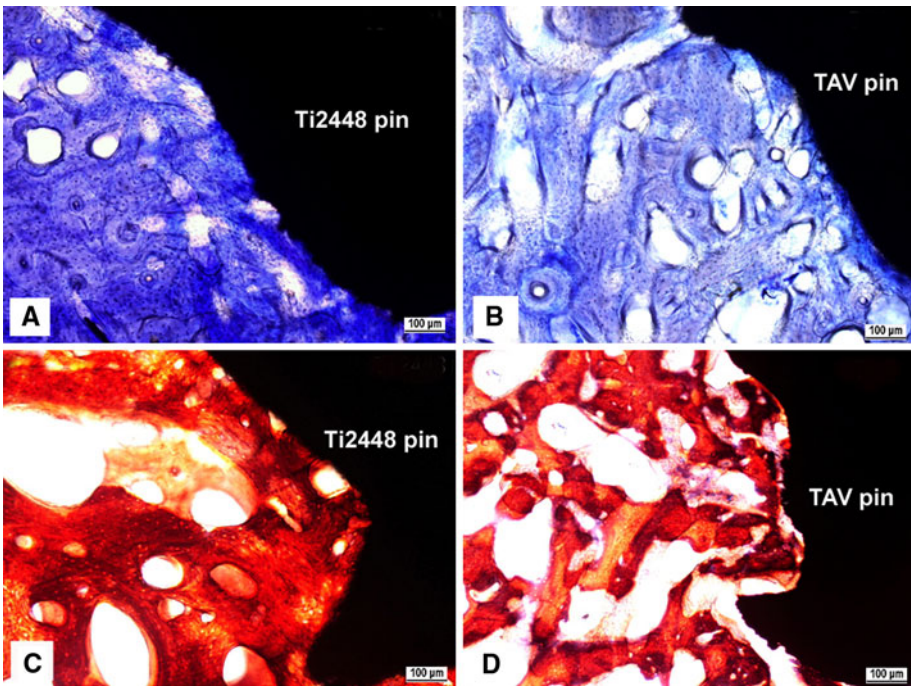

Fig. 8 Histological observation of un-decalcified pin–bone interface in group A (**a**, **c**) and group B (**b**, **d**) by toluidine blue staining (**a**, **b** × 100) and modified ponceau trichrome staining (**c**, **d** × 100) at 8 weeks postoperatively. *Scale bars* = 100 μm

appearance. In addition, there was an obvious layer of necrotic tissue between the fibrotic tissue and normal bone tissue (Fig. 7). The un-decalcified slides were evaluated with toluidine blue staining and modified ponceau trichrome staining. The results indicated the large quantity and high quality of newly formed bone around the half-pins in group A when compared with those of group B. The trabecular thickness was increased with the development of less trabecular separation and more trabecular number in group A (Fig. 8).

4 Discussion

This study demonstrated that Ti2448 half-pins in external fixation system could provide enough strength as well as

lower elastic modules to enhance the bone fracture healing. When compared with TAV half-pin, Ti2448 half-pin had greater recoverable deformation, which reduced the stress concentration at the pin–bone interface. It facilitated the bone remodeling and larger quantity and higher quality of new bone formation around Ti2448 half-pins. Furthermore, after 8 weeks of fixation, extraction torque values of Ti2448 half-pins near the fracture line were significantly higher than those TAV pins. The results provide strong evidence that Ti2448 is a promising biomaterial for constructing external fixation system.

The pin loosening was assessed by examining the radiographical appearance of bone resorption around the pins. This method is commonly used in clinics. Radiolucency is an indication of resorbed bone around the pins, creating a weak bond between the bone and the implant. This weak bond is reflected by a poor fit of the bone to the screw threads. A weak bond allows for micro-motion of the pin with respect to the bone [20].Clinically, over 1 mm thickness of radiolucency usually indicates the pin loosening [21]. The radiographic grading system used in this study was validated by previous reports [22, 23]. It can well record the bone fracture healing and bone remodeling around the pin. Higher grades were related to stable external fixation, less pin loosening, and solid bone healing. The group A (Ti2448 half-pin group) showed significantly higher scores at 4 and 8 weeks postoperatively. The cortical bone around TAV half-pins did not have morphology of tubular bone. In contrast, the bone around Ti2448 half-pins kept normal tubular morphology. These changes indicated that the Ti2448 half-pins seldom disturbed the bone remodeling at the pin–bone interface. These findings are in accordance with histological results.

The pin loosening after external fixation remains a challenging problem. The reported incidence ranged from 0 to 69% [24, 25]. It is generally accepted that micro-motion of the pin with respect to the bone will disrupt bone remodeling and induce fibrous tissue formation at the pin–bone interface. These histological changes finally lead to pin loosening [26]. Furthermore, micro-motion of the pin may disrupt the sealing effect of the soft tissues with the pin, giving external bacteria greater access to the internal environment and increase the chance of infection [20]. Therefore, less micro-motion will reduce the pin loosening and pin track infection. This can be achieved by increasing the stiffness of the external fixation frame, such as using stiffer rods and pins. However, excessive rigid external fixation can also cause stress shielding at fracture line and stress concentration in pin track. These might result in pin loosening and pin track infection, which finally interfere with bone healing. On the contrary, when the pin's elastic modulus was similar to that of cortical bone, the relative micromotion between pin and bone is greatly reduced.

Nowadays the clinically accepted pin materials for external fixation are TAV and stainless steel (SS). TAV is the flexible material with an elastic modulus of 110 GPa, while SS is much stiffer with an elastic modulus of 207 GPa. Compared with elastic modulus of human cortical bone (20 GPa), both have much higher elastic modulus. The Ti2448 used in this study has the lowest elastic modulus (33 GPa) in all known β titanium alloy [16]. Furthermore, its strength (800–900 MPa) is also higher than that of commonly used TAV (600 MPa). In this study, the strain of Ti2448 half-pin was much higher than that of TAV half-pin under the same mechanical load in compression, torsion, and four-points bending test. Due to greater recoverable deformation of Ti2448 half-pin at the site of pin–cortex junction, the relative micro-motion between half-pin and bone was lesser (Figs. 2, 3). Since pin loosening is highly related to the micro-motion, it is reasonable to assume that the lower elastic modules of Ti2448 half-pin account for the stability of pins.

Pin surface modification was reported to enhance pin osseointegration. The hydroxyapatite-coated external fixation pins can reduce pin loosening effectively, but its fragile coating and high price limit clinical application [27, 28]. After surface treatment with anodic plasma chemical calcium-phosphate (APC-CaP), Schanz screws can reduce pin loosening after implantation [29]. Polymers such as poly (D,L-lactide) were also used as surface coating reagent [30]. In current study, Ti2448 and TAV half-pins did not have any surface modification. The peak extraction torque was compared between groups to assess pin osseointegration. After 8 weeks of implantation, there would be no friction effect between the pin and cortical bone as the bone in the regions of high stress would have been remodeled [31]. Therefore, the Ti2448 and TAV pins have identical geometry. The extraction torque values could be analyzed as absolute values due to osseointegration. This study found significant difference in torque values between these two materials at the site of pin 2 and pin 3. This suggests that after 8 weeks implantation, Ti2448 pin has more osseointegration capability. There was no significant difference at the site of pin 1 and pin 4. The stress of pin–bone interface at these two sites was comparatively lower. It seemed the osseointegration capability of these two materials were similar in lower stress condition.

The osseointegration was also analyzed with Micro-CT. The Ti2448 pin thread was intact in reconstructed image. It was proved this new material had enough strength. The bone apposition to the pin threads in group A (Ti2448 group) was more abundant than that of group B (TAV group), which increased the pin track holding. Furthermore, the bony trabecula around TAV pin became thinning and the distance between trabeculae was much larger.

The histological results were consistent with the Micro-CT analysis and biomechanical test (Fig. 7). These indicated higher stress concentration interfered with bone remodeling around half-pins in group.

5 Conclusion

In present study, a kind of new half-pin was fabricated by β-type titanium alloy Ti2448, which had lower elastic modulus as well as enough strength. In vitro and in vivo experiments demonstrated Ti2448 half-pin could enhance osseointegration and reduce pin loosening in external fixation system. Our findings may help guide clinicians choose half-pin with low elastic modulus for treatment of bone fractures, especially in patients with poor bone quality such as osteoporosis. It would also seem interesting to explore the possible use of Ti2448 into fabricating plate or intramedullary nail for internal fixation. This material has promising potentials in various clinical applications.

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