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Comparison between a novel human cortical bone screw and bioabsorbable interference screw for graft fixation of ACL reconstruction

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Abstract. – OBJECTIVE: To compare the mechanical behavior of a novel bioabsorbable cortical interference screw (BCIS) with bioabsorbable interference screw (BIS; Polylactate hydroxyapatite) used for anterior cruciate ligament (ACL) reconstruction in femoral and tibial fixation with doubled Achilles tendon graft *in vitro*.

PATIENTS AND METHODS: 30 paired goat knee specimens were harvested from 15 male sheep aged 18 months. All soft tissues were stripped from the bones of 20 paired specimens, and the last 10 paired specimens were stripped all soft tissues besides ACL (femur-ACL-tibia complex). The Achilles tendon was harvested as graft for ACL reconstruction. The specimens were divided into several groups: BCIS femoral fixation (group A, n=10), BIS femoral fixation (group B, n=10), BCIS tibial fixation (group C, n=10), BIS tibial fixation (group D, n=10), Group E is femur-ACL-tibia complex (n=10). Cyclic loading test was performed from 50 to 250 N at 1 Hz for 1000 cycles and followed by a load-to-failure test at 25 mm/sec. A paired t-test was used to compare the biomechanical properties of group A, B, E and group C, D, E.

RESULTS: No fixation structures failed during the cyclic phase. Cyclic displacement for group B was superior to group A, and showed statistically significant difference after 30, 100, 500, 1000 cycles. Group E got minimum cyclic displacements compared with group A and group B, and showed statistically significant difference after 500, 1000 cycles compared with group A. Cyclic displacement for group D was superior to group C, and showed statistically significant difference after 100, 500, 1000 cycles. Group E got minimum cyclic displacements compared with group C and group D, and showed statistically significant difference after 500,1000 cycles compared with group C. Regarding MFL, group A was superior to group B (572.10±111.12 N *vs.* 413.96±34.56 N, *p*=0.118), group E was superior to group A (599.74±85.45N *vs.* 572.10±111.12 N, *p*=0.992), and group C was superior to group D (802.88±240.07 N *vs.* 415.63±51.9 N, *p*<0.001), group C was superior to group E (802.88±240.07 N *vs.* 599.74±85.45 N, *p*=0.024). Regarding YL, group A was superior to group B (521.57±93.96 N *vs.* 366.99±44.66 N, *p*=0.109), group E was superior to group A (565.37±66.05 N *vs.* 521.57±93.96 N, *p*=0.952), and group C was superior to group D (735.63±242.91 N *vs.* 394.49±31.90 N, p<0.001), group C was superior to group E (735.63±242.91 N *vs.* 565.37±66.05 N, *p*=0.063). Regarding stiffness, group A was superior to group B (157.36±34.31 N/mm *vs.* 91.98±25.57 N/mm, *p*=0.001), group E was superior to group A (181.35±25.42 N *vs.* 157.36±34.31 N/mm, *p*=0.529), and group C was superior to group D (175.28±43.19 N/mm *vs.* 128.24±18.92 N/mm, *p*=0.032), group E was superior to group C (181.35±25.42 N/mm *vs.* 175.28±43.19 N/mm, *p*=0.995).

CONCLUSIONS: *In vitro*, this experimental study suggested the biomechanical properties of novel bioabsorbable cortical interference screw (BCIS) were superior to bioabsorbable interference screw (BIS) used for femoral and tibial anterior cruciate ligament (ACL) reconstruction in a goat knee model.

Key Words
Anterior cruciate ligament reconstruction, Biomechanics, Cortical allograft bone, Absorbable interference screw.

Introduction

Due to the special characteristics of anterior cruciate ligament (ACL), it is difficult to heal itself after injury. Aiming to reestablish normal knee function, reconstruction of ACL is well-accepted in the last decades[1].

Various elements influence the outcome of ACL reconstruction, such as the choice of graft, mechanics, biology, surgical technique and rehabilitation[2]. Among these factors, the initial graft fixation strength has been looked as a determinant

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to the mechanics, biology and rehabilitation after surgery. More concretely, a strong and biocompatible fixation can prevent graft slippage or failure and offer good conditions for biological healing, which will affect the rehabilitation process[3]. The ideal interference screw would be easy to use, could provide strong fixation until the graft incorporates together to bone tunnel, and then undergoes full resorption being replaced by bone[4]. A large number of devices for femoral and tibial fixation, made of metal, biodegradable polymer or polyetheretherketone (PEEK), have been widely used[5-8]. Whereas clinical and functional outcomes are similar between bioabsorbable interference screws (BISs) and metallic interference screws (MISs). The former has no need for further surgery to remove, causing less graft damage; even though causing less distortion when imaging with MRI scans postoperative, the BISs fixation devices are more popular used in ACL reconstruction[9,10]. Pre-tibial swelling, pain, screw breakage, high rates of effusions, and decreased pull-out strength following ACL reconstruction using bioabsorbable fixation devices have been reported[11]. PEEK interface screws are radiolucent and not biodegradable[12,13]. Therefore, new interface screw designs continue to be released for graft fixation of anterior cruciate ligament reconstruction.

The use of bone allograft has a history of more than 120 years[14]. Cortical grafts could be used as a load-bearing scaffold exhibiting comparable mechanical properties to the host bone when being substituted by new host bone, and for their mechanical support and structural integrity, the bone allografts would have good mechanical properties[15]. Therefore, we choose to use the human cortical allograft bone for the design of novel interface screw.

The purpose of our study was to biomechanically compare the initial fixation strength of the novel biodegradable cortical bone screw to a similar absorbable interface screw using a sheep ACL reconstruction with a graft of double-bundle Achilles tendon model *in vitro*. We hypothesize that both interface screws would demonstrate equivalent primary biomechanical properties in the ACL reconstruction.

Patients and Methods

Patients

The experimental protocol used for the study was evaluated and approved by the Institutional Animal Care and Use Committee and the Human Ethics Committee of the Chinese PLA General Hospital. The human allogenetic cortical bone used for this experiment was harvested from the bone bank of Orthopedics of Chinese PLA General Hospital. Fifty paired sheep lower-limb specimens used in the study were harvested from 15 male sheep aged 18 months within 24 hours of death, frozen at -20°C. Before testing, all specimens were allowed to get a process of rewarming at room temperature (20-24°C) for 12 h and then kept moist by covered with 0.9% saline gauze. All soft tissues were stripped from the bones of forty paired specimens, and the last ten paired specimens were stripped all soft tissues besides ACL. The Achilles tendon was harvested as graft for ACL reconstruction. The knee was cut transversely with a distance of about 8 cm from the joint line in the tibia and the femoral side separately. All bony tunnels were drilled with a 7-mm reamer with the same center of the ACL footprint. The femoral holes were drilled at the 2 O'clock position for the left knee and at the 10 O'clock position for the right knee with a proximal exit in the lateral wall of the lateral femoral condyle. The tibial holes were drilled with a guide (Smith & Nephew Endoscopy, Andover, MA, USA) positioning at 50° and is maintained 20 to 25 medially with respect to the longitudinal axis of the tibia. The tendons were cleaned of muscle fibers and were made into 2 strands. The diameter of the tendon graft is 7mm, and the length is about 90 to 100 mm. One end of the tendon was sutured to achieve 30 mm prospectively under pretensioning (10 lb for 20 min) with whipstitches using No. 2 Ethibond suture (Ethicon, Somerville, NJ, USA) as the fixation portion.

The specimens were divided into five groups. Group A, ten femur specimens were performed ACLR with the graft fixed with the designed novel biodegradable cortical bone screw, which was 6.0 mm in diameter and 20 mm in length. The screw was struck into the tunnel not screw-in by a custom impactor. Group B, ten femur specimens were performed ACLR with the graft fixed with absorbable 7×20 mm BIORCI-HA® (Smith & Nephew Inc. Andover, MA, USA) interface screw (Figure 1) by an Interference Screwdriver (Smith & Nephew Inc. Andover, MA, USA). Group C and D, ten tibial specimens, were performed ACLR with screw mentioned above separately, and the tip of the screw below but close to the subchondral bone. Group E is femur-ACL-tibia complex (Figure 2).

After specimen preparation and ACLR complete, the specimens were placed in an Instron

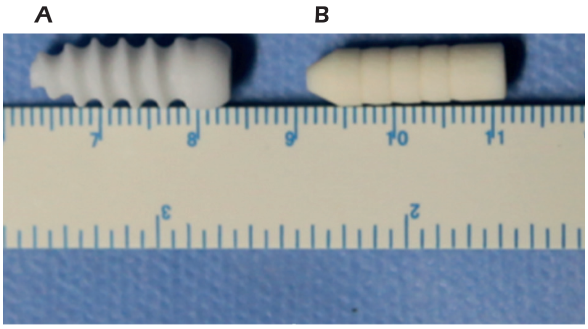

Figure 1. A, Absorbable interface screw. **B**, Cortical bone screw.

Figure 2. The condition of graft after fixation: **A**, The biological screw had no obvious damage to the grafts; **B**, The damage to the graft of absorbable interface screw.

E10000 materials testing machine (Instron, Canton, MA, USA) with a 10000-N maximum load cell. The bone was clamped at the dental stone by use of a specially designed made clamp connected to the testing machine (Figure 3). The free end of the soft tissue graft was securely fixed to the upper pneumatic fixture and the distance between the fixation points of the graft was assumed to be 50 mm. For specimens of group A, B, C, D, the tunnels were aligned to the axis of the loading rig precisely, and for group E, the angle of the longitudinal axis of femur and tibia was 120°. The construct was preloaded from 0 and 50 N at 1 Hz for 20 cycles to overcome the artifacts of the system. After this, the fixations were subjected to 1000 cycles between 50 and 250 N at a rate of 1 Hz which simulated a moderate level of activity. Then those specimens that survived the cycling test were subjected to an axial load at a rate of 25 mm/sec till the failure of the fixation. We defined the failure of the cycling test was at a displacement of 8 mm. The cyclic displacements were at 1, 30, 100, 500 and 1000 cycles (initial displacement was calculated after preload). The data were recorded at rate of 100Hz and were plotted in Origin Scientific Graphing and Analysis Software (OriginLab Corp, Northampton, MA, USA). The elongation curve was automatically obtained as well as the maximum failure load, yield load, stiffness, and the mode of failure was recorded (Figure 4). The yield load was defined as the load where the slope of the load-displacement curve first clearly decreased and the stiffness was the mean linear region of the force elongation curve in this phase.

Statistical Analysis

The statistical analysis was performed with statistic package for social science (SPSS) software package (version 20.0; SPSS, Inc., IBM, Armonk, NY, USA). Data were expressed as mean ± standard deviations (SD). Normal distribution of the continuous variable was tested with the Kolmogorov-Smirnov test. A paired Student's t-test was used to compare the biomechanical properties of the two ACLR screws systems and the femur-ACL-tibia complex separately, and the level of statistical significance was set at $p<0.05$.

Results

Cycling Test

All specimens endured the cycling load test without failed of the reconstruction. The mean cyclic displacement at 1, 30, 100, 500 cycles and 1000 cycles was recorded (Table I). In femoral, group A displaced less than group B, and the comparison was significantly different besides the first cycle ($p=0.425$, $p=0.013$, $p=0.000$, $p=0.000$, $p=0.000$). The group E had less displacement after the cycles recorded comparing with two femoral fixation constructs, and the differences was not significantly after 1 cycle with the two groups ($p=1.000$, $p=0.315$), and after 30, 100, 500 cycles with BICS group ($p=0.899$, $p=0.769$, $p=0.062$). In tibial, group C displaced less than group D, and the comparison was not significantly different besides 500 cycles ($p=0.998$, $p=0.996$, $p=0.395$, $p=0.028$,

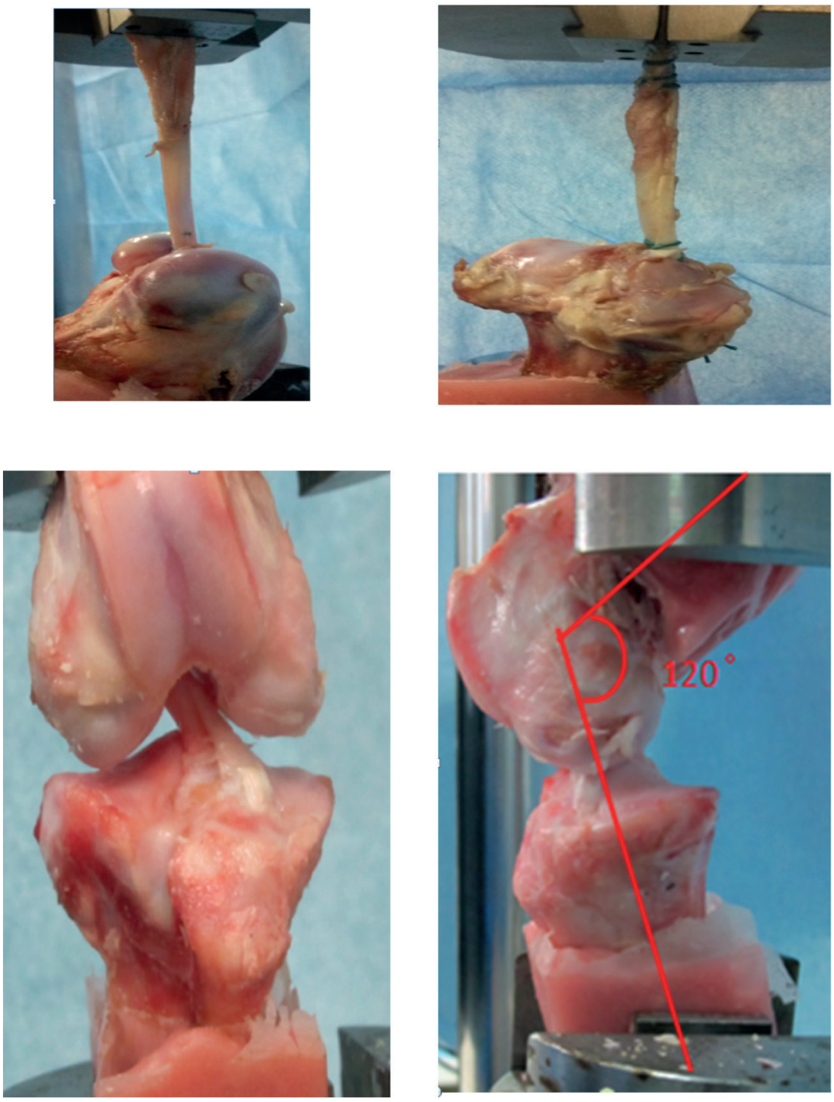

Figure 3. The specimens were fixed on the biomechanical machine.

p=0.076). The group E had less displacement after the cycles recorded comparing with two tibial fixation construct, and the differences was not significantly after 1,30 cycle with the two groups (*p*=0.461, *p*=0.642; *p*=0.929, *p*=0.768), 100 cycles with BICS group (*p*=0.550).

Ultimate Load

With regard to ultimate load, BICS fixation construct was comparable to the BIS group in femur (572.10±111.12 *vs.* 413.96±34.56, *p*=0.118) and tibial (802.88±240.07 *vs.* 415.63±51.9, *p*=0.000). The femur-ACL-tibia complex group had a superior ultimate load than femur BICS group (599.74±85.45 *vs.* 572.10±111.12, *p*=0.992) and femur BIS group (599.74±85.45 *vs.* 413.96±34.56, *p*=0.045), tibial BIS group (599.74±85.45 *vs.* 415.63±51.90, *p*=0.048), but not tibial BICS group (599.74±85.45 *vs.* 802.88±240.07, *p*=0.024) (Table I).

Yield Load

With regard to yield load, BICS fixation construct was comparable to the BIS group in femur (521.57±93.96 *vs.* 366.99±44.66, *p*=0.109) and tibial (735.63±242.91 *vs.* 394.49±31.90, *p*=0.000). The femur-ACL-tibia complex group had a superior yield load than femur BICS group (565.37±66.05 *vs.* 521.57±93.96, *p*=0.952) and femur BIS group (565.37±66.05 *vs.* 366.99±44.66, *p*=0.021), tibial BIS group (565.37±66.05 *vs.* 415.63±51.90, *p*=0.061), but not tibial BICS group (565.37±66.05 *vs.* 735.63±242.91, *p*=0.063) (Table I).

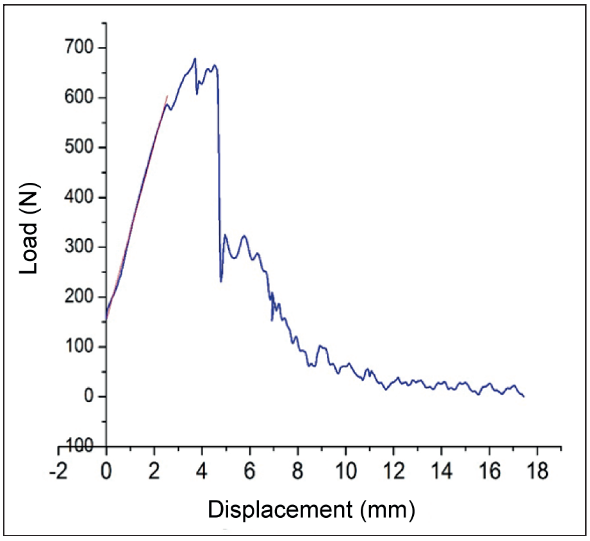

Figure 4. Load-displacement curves for the specimens under monotonic loading conditions. Stiffness, yield load, and maximum load were recorded.

Stiffness

BICS fixation construct had a superior stiffness than BIS group, and the comparison was significantly different in femur (157.36±34.31 *vs.* 91.98±25.57, p=0.001) and tibial (175.28±43.19 *vs.* 128.24±18.92, p=0.032). The group E had a superior stiffness (181.35±25.42) than all the other groups, and the difference was significantly (p=0.529, p=0.000, p=0.995, p=0.012) (Table I).

Failure Mode

Screw fixation failure mode was defined as "implant failure" in which the screws had broken into pieces during the test; "graft pulling out of the tunnel" in which the graft pulling out of the tunnel with or without the screws; "graft (or ACL) failure" in which the graft (or normal ACL) lacerated; and "fracture" in which the bone fracture or avulsion fracture of intercondylar eminence. The detailed quantities of failure mode for the five groups showed in Table II.

Discussion

A wide variety of interface screws have been developed for the ACLR graft fixation, with different shape, size, composition, insertion and fixation method and fixation strength. The materials used for the screws include titanium, various biodegradable copolymers (e.g., poly-levo-lactic acid [PLLA], etc.), and PEEK. Despite bone allograft has a long history of use more than 120 years[14], there is no interface screws entirely composed of cortical bone have been commercially available in the field of ACLR up to now. To evaluate the possibility novel biodegradable cortical bone screw served as a fixation device in ACLR, we tested the mechanics of the bone screw compared with absorbable BIORCI-HA® (Smith & Nephew Inc. Andover, MA, USA) interface screw.

In order to adequate the mechanical environmental requirement for ACL graft maturation, the ideal fixing device must offer a good initial fixation strength[16,17]. According to the previous research, ACL graft forces have been estimated to be approximately 500 N during early rehabilitation[18]. This study showed a superiority biomechanical properties of our novel bioabsorbable cortical interference screw over the absorbable interface screw for the yield load, maximum failure load, stiffness and cyclic-loading tests (less elongation), and the yield load of the cortical bone screw was over than 500 N whatever femoral (521.57±93.96 N) or tibial side (735.63±242.91 N), in addition the maximum failure load was much higher than its own yield load. Some previous biomechanical investigations[19-21] showed that absorbable interface

Table I. Comparison of clinical outcomes between the two groups in perioperative period.

	1	30	100	500	1000
Femoral fixation					
BCIS	2.08±0.42	2.55±0.45	2.85±0.45	3.39±0.50	4.09±0.57
BIS	2.43±0.39	3.38±0.75	3.92±0.62	4.40±0.49	5.07±0.28
Tibial fixation					
BCIS	1.69±0.22	2.53±0.17	2.93±0.13	3.59±0.23	4.03±0.11
BIS	1.75±0.96	2.62±0.17	3.30±0.27	4.18±0.24	4.50±0.35
Femur-ACL-tibia complex	2.03±0.63	2.34±0.58	2.61±0.44	2.85±0.36	3.06±0.28

BCIS: bioabsorbable cortical interference screw; BIS: bioabsorable interference screw.

Table II. Results of load-to-failure tests (n=10).

Index	Femoral fixation		Tibial fixation		Femur-ACL-tibia complex
	BCIS	BIS	BCIS	BIS	
MFL (N)	572.10±111.12	413.96±34.56	802.88±240.07	415.63±51.9	599.74±85.45
YL (N)	521.57±93.96	366.99±44.66	735.63±242.91	394.49±31.90	565.37±66.05
Stiffness (N/mm)	157.36±34.31	91.98±25.57	175.28±43.19	128.24±18.92	181.35±25.42

MFL: maximum failed load; YL: yield load; BCIS: bioabsorbable cortical interference screw; BIS: bioabsorable interference screw.

screw provided high pull-out strengths more than this study, perhaps because of the difference of model and the diameter of screw used.

The ideal fixation device for ACLR would be easy to use, provide strong fixation until the graft incorporates together to bone tunnel, and then undergoes full resorption being replaced by bone. The commonly available bioabsorbable components are Poly-L-lactide (PLLA), Poly-DL-lactide (PDLA), Poly-lactic acid (PLA), Polyglycolide (PGA) or a copolymer of the latter two, and Poly-lactate hydroxyapatite. The evolution of the implants aiming to do less damage to the graft, less distortion when imaging with MRI scans postoperatively, and less complications. To date, the goal is not reached. In our study, we found the absorbable interface screw could incise the graft, even though the graft was whip stitched using No. 2 Ethibond suture (Figure 2B). On the contrary, the novel biodegradable cortical bone screw did less damage to the graft (Figure 2A). We believe that the incision to the graft will decrease the fixation strength and this may be responsible for the graft failure in our test. The thread of the screws may be responsible for this. There is a high torque situation during the process of absorbable interface screw screwing-in, but the novel cortical bone screw was struck into the tunnel, which will reduce the risk of screw breakage during implant process. There still have some unique associated complications for the resorption of bioabsorbable and biocomposite implants. Sprowson et al[22] found that poly L-lactide bioabsorbable interference screw takes longer to resorb than initial *in vivo* data and there is a risk of developing cystic reaction as long as 7 to 10 years post ACL reconstruction. Thompson et al[23] found no resorption of the screw or bone formation had occurred at 4-year follow-up of patients with a PLLA bioabsorbable screws ACLR, and it took longer than 2 years to resorb than previously thought by the manufacturers. Ramsinghet et al[24] on his mean post-operative period of 26 months follow up study with 273 patients of ACL reconstructions using a bioabsorbable screw for tibial fixation showed that fourteen patients (5%) with pre-tibial pain and swelling over the tibial screw site. The acidic environment coming after the degradation of the screws combined with the initial fibrous encapsulation of the screw may contribute to the lack of bone ingrowth with bioabsorbable screws. The screw fragments from the degradation also cause macrophage activation causing bone resorption, and the incomplete integration of bioabsorbable screws maybe responsible for the bone tunnel enlargement[25], some even another complications have been reported with BIS use, including intra-articular screw migration[26,27], breakage during surgery[28]. The implants composed of polyetheretherketone (PEEK), a very chemically resistant crystalline thermoplastic material, has been used more and more popular. PEEK and PLLA interface screw sallow more comprehensive MR imaging post-operation without artifact, but for their radiolucency it is difficult to observe clearly on plain film radiography. PEEK material is not biodegradable and still has problems of osteointegration and osteoinduction capabilities[29]. In contrast, the novel cortical bone screw is designed to degrade *in vivo*, and has a good osteoconductive potential[30]. Compared to the interface screws introduced earlier, the cortical bone screw is visible for the X-ray and MRI imaging, which is more conducive to the imaging studies postoperative.

Matters needing attention with the use of the cortical bone screw including potential possibilities of immune response and disease transmission, limited remodeling and osteointegration experience of cortical bone allografts[31,32], and resource shortage of qualified human cortical bone material. Further evaluation of the novel cortical bone screw in an *in vivo* environment is needed, considering the different chemical and mechanical microenvironments.

Limitations

Our study has some inherent limitations. First, the goat model was chosen for cost and availability reasons considering the following study *in vivo*, which has slightly higher density than that found in young adult human bone. Second, the bone density of the paired goat knee specimen was not measured by DEXA or other devices. Third, biomechanical comparisons at "time zero" do not actually reflect the clinical situation. Additionally, whether the novel cortical bone screw could successfully fulfill the fixation target before incorporation to the host bone or be substituted completely by new bone still unknown, additional studies should be needed to further evaluate the novel screw in an *in vivo* environment.

Conclusions

The new type of screw constructed of human cortical bone demonstrate better initial fixation strength to a similar absorbable interface screw for ACL reconstruction in tibial and femoral, which would be suitable for an aggressive rehabilitation program. We believe the novel bone screw will become a new option for surgeons when faced with patients who need ACL reconstruction in the near future.

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Conflict of Interests:

The authors declare that they have no conflict of interest.

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