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Improvement of primary stability in ACL reconstruction by mesh augmentation of an established method of free tendon graft fixation. A biomechanical study on a porcine model

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ABSTRACT

Purpose: The aim of the present study was to compare primary stability in ACL reconstruction and ultimate load to failure of a mesh augmented hamstring tendon graft fixed with two cross pins to established hamstrings and bone-patellar-tendon-bone (BTB) graft fixation methods.

Methods: Forty fresh porcine femora were divided into four groups: (A): BTB graft fixed with two RigidFix® pins, (B): hamstring tendon graft fixed with a Milagro® interference screw, (C): hamstring tendon graft fixed with two RigidFix® pins, and (D): hamstring tendon graft augmented with Ultrapro® mesh fixed with two RigidFix® pins. Each graft underwent cyclic loading in tension and load to failure. Elastic and plastic displacements were measured by 3-dimensional digital image correlation. Groups were compared by one-way ANOVA and Tukey–Kramer post-hoc tests.

Results: After 1000 cycles, the mean plastic displacement was lowest in the BTB graft ($p<0.001$). Plastic displacement was significantly lower in the mesh augmented group compared to the plain hamstring graft and the Milagro screw group ($p<0.05$). Load to failure was highest in the mesh-augmented group; significant to the hamstring tendon ($p=0.023$).

Conclusion: Although the BTB-graft represented the most stable construct against plastic displacement in our study, mesh augmentation of free tendon grafts significantly increased primary stability and reduced plastic displacement of femoral cross pin fixation. This new augmentation device may better protect the hamstrings graft from secondary elongation during postoperative rehabilitation.

Clinical relevance: Mesh augmentation seems to be an effective technique to stabilise free hamstring tendon autografts during postoperative rehabilitation with significant reduction of graft slippage.

1. Introduction

A primary aim of anterior cruciate ligament (ACL) reconstruction is to achieve sufficient mechanical properties of the ligament for post-operative rehabilitation and thereby reinstate normal knee stability, range of motion, and strength [1,2]. Early post-operative rehabilitation is a major factor in the success of ACL reconstruction as this prevents arthrofibrosis and promotes re-establishment of muscle activation patterns with a concomitant return to full weight bearing without bracing [1,3–5]. A fast and stable integration of the graft in the bone tunnel is a prerequisite for accelerated rehabilitation [6].

Currently-available graft fixation devices demonstrate large variation in mechanical properties [7–14]. Tsuda et al. found in their biomechanical study that EndoButton fixation of a soft-tissue graft resulted in significantly larger graft-tunnel motion, and consequently, greater anterior knee laxity compared with an interference screw closer to the intra-articular entrance of the bone tunnel [12]. Oh et al. stated that hybrid femoral fixation of double-looped gracilis-semitendinosus grafts via the EndoButton CL device and a bioabsorbable interference screw is stronger than interference or EndoButton CL fixation alone with respect to ultimate tensile strength, stiffness, and slippage [9]. There is no consensus in the literature for the clinical outcome of ACL reconstruction with BTB grafts compared to those of hamstring grafts fixed by biodegradable pins. Several clinical studies have shown no significant difference in stability between the two methods [15,16]. Furthermore both free tendon graft and bone-tendon-bone graft fixations with interference screws are likely to fail by slippage of the transplant, whereas the failure mode of cross pin fixation of BTB grafts is commonly described as either bone block fracture or pin fracture [17]. Free hamstring tendon graft fixation to the femoral bone tunnel is thought to be less solid than BTB because of slippage of the tendon past the fixation screw or because the cross pins cut through the tendon. This may limit an early postoperative rehabilitation protocol [12,18] and lead to graft elongation.

The use of hamstring tendons has become very common in ACL grafting. However because of the controversial biomechanical results

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published for reliability of hamstrings graft fixation, we wanted to assess two commonly used fixation techniques such as interference screw and cross pins and compare them to the BTB cross pin fixation. In their clinical study Harilainen et al. did not find any statistically or clinically relevant differences in both fixation techniques — cross pin versus interference screw [19]. However, they did not make any comparison to BTB graft fixation. Dargel et al. showed already that when using cross pins just suturing the graft in a whipstitch fashion creates a supplementary support against graft slippage especially because the resulting position of the cross pin relative to the tendon graft cannot be predicted [20]. To improve this established approach we explored a new method for increasing the initial stability of cross pin fixation by providing an even better support for hamstring ACL grafts against graft slippage than just suturing in a whipstitch fashion. A mesh such as that widely used in general surgery for example for hernia repair was incorporated into the hamstrings graft at the bone tunnel site. The Ultrapro® mesh consists of Monocryl® and Prolene® in similar parts. It provides good strength and less foreign material as well as a bigger pore size for better tissue ingrowth and better passage of the cross pins than pure Prolene® mesh grafts. Its biocompatibility, strength and soft tissue ingrowth are proven [21].

As mentioned above the weak point at cross pin fixation of hamstring grafts seems to be that the cross pins cut through the tendon despite of a good preparation by suture [20,22]. Additionally other studies showed a significant drop of graft tension mainly during the first testing cycles [18,23]. Therefore we focused our study on graft slippage out of the bone tunnel and the enhancement of graft fixation to prevent even further loss of graft tension in the postoperative rehabilitation period.

The purpose of this study was to compare primary stability (i.e. plastic displacement) in ACL reconstruction and ultimate load to failure of a mesh augmented hamstring tendon graft fixed with two cross pins to established hamstrings and bone-patellar-tendon-bone (BTB) graft fixation methods.

The hypothesis of the present biomechanical study is that primary stability of cross pin fixation of hamstring grafts can be increased significantly by minimising slippage of the graft out of the femoral bone tunnel by adding an incorporated mesh graft and thereby prevents loss of graft tension in the postoperative rehabilitation.

2. Methods

2.1. Specimen preparation

Foot flexor tendons from 40 fresh porcine specimens were used to simulate human hamstring tendons and BTB grafts were prepared from porcine patellar tendons. All porcine femora and tendons were stored at −40 °C and thawed at room temperature for 24 h before testing. They were obtained by a local butcher with a mean age of 16 ± 4 weeks. Muscles and soft tissue were dissected completely, leaving the distal femur intact. The specimens were regularly moistured with 0.9% saline during preparation and testing.

The specimens were divided into four groups:(A) 10 BTB grafts, fixed in the bone tunnel with two BTB cross pins (diameter: 2.7 mm); (B) 10 hamstring tendon grafts, fixed with a bioabsorbable interference screw; (C) 10 hamstring tendon grafts, fixed with two soft-tissue cross pins (diameter: 3.3 mm); and (D) 10 hamstring tendon grafts with mesh augmentation, fixed with two soft-tissue cross pins (diameter: 3.3 mm).

A bone tunnel of 10 × 30 mm was drilled at the 11 o'clock respectively at the 1 o'clock position to simulate a physiological insertion of the ACL [22,24]. BTB grafts were prepared with a bone block of 30 × 10 × 10 mm size including the associated patellar tendon. The tendons were prepared according to the RigidFix® surgical technique (DePuy Mitek, Inc.).

In the mesh group, a 10 × 60 mm partially-absorbable mesh usually used for repair of inguinal hernias (Ethicon Ultrapro®, Monocryl-Prolene-Composite, Johnson & Johnson MEDICAL Inc.) was inserted within the tendon transplant (Fig. 1). The mesh was cut into 10 × 60 mm pieces and folded in half. The mesh was then inserted between the tendons and sutured using the technique recognised for regular hamstring tendon graft suturing (RigidFix® surgical technique, DePuy Mitek, Inc.). The pore size of the mesh was 3–4 mm.

Fixation was performed by two biodegradable RigidFix® cross pins for each graft in groups A, C and D. The bone block of the BTB graft was fixed through the cortical portion of the femur. The tendons were prepared in a similar way as the hamstrings and hamstrings with mesh group. In group B the hamstrings were prepared according to the RigidFix® surgical technique (DePuy Mitek, Inc.) as well and then fixed with a 10 mm bioabsorbable Milagro® interference screw into the bone tunnel. The surgical procedures were performed by one surgeon who was trained similarly in all four procedures. The free tendon was fixed to the testing apparatus by a soft tissue clamp in all groups.

2.2. Mechanical testing

Uniaxial tensile testing was performed using a Zmart.Pro® Material Testing Machine (Zwick Z010, Zwick/Roell, Germany). All tests were performed at constant room temperature. Axial loads were applied to the graft which was inserted in a physiological position — 11 o'clock respectively at the 1 o'clock position — into the bone tunnel [14,22,24,25]. Loads were applied parallel to the longitudinal axis of the bone tunnel (Fig. 2).

Cyclic tensile loading (1000 cycles, 20–150 N) was performed to all subjects. All specimens were first preconditioned (40 cycles, 10–50 N) and consequently preloaded with 10 N of tensile force before cyclic testing. This preloading regimen was used to create a reliable starting position for the following displacement measurement during cyclic loading. Cyclic loading was performed at a displacement rate of 150 mm/min. All grafts were finally loaded to failure at 150 mm/min.

Femoral cartilage and graft surface motion were continuously captured with a three-dimensional digital image correlation system with a displacement accuracy of ± 1 μm (Limess Messtechnik GmbH). One point on each of these two surfaces (femoral articular cartilage and tendon graft) along the graft-axis was identified by a two camera system and processed by the Vic 3D® software. The distance between these points was defined as displacement distance to calculate graft slippage within the femoral bone tunnel (Fig. 2b). An accurate measurement of the tendon slippage within the bone tunnel could be performed by this method. Therefore any displacement occurring within the tendon-graft outside the bone tunnel, or at the diaphysial bone-fixation could be excluded. This plastic displacement (i.e. irreversible graft slippage) and elastic movement (movement of the graft out of and back to the tunnel within a single loading cycle) were calculated.

Elastic movement of the graft was defined as the difference of the displacement distance (as defined above) between the states of minimal and maximal loads within a single loading cycle, either within cycle 1 or cycle 1000.

Plastic displacement (i.e. slippage) was calculated by subtracting displacement at cycle 1 from the plastic displacement at cycle 1000. Plastic displacement after cycle 1 is understood as a replication of the intraoperative technique of manually tensioning the graft in the axial direction with a load of approximately 150 N after fixation by the chosen fixation technique.

After cyclic testing, the ultimate pullout strength of each graft-fixation-bone-construct was measured and the mode of failure was documented. Widening of the bone tunnel in the interference