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Biomechanical evaluation of six femur-graft-tibia complexes in ACL reconstruction

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Abstract Soft tissue graft-tibial tunnel fixation is considered the weak point in reconstruction of the anterior cruciate ligament (ACL). We hypothesized that the biomechanical properties of fixation devices used in ACL reconstruction can be better evaluated by testing complete constructs (femoral tunnel fixation-graft-tibial tunnel fixation). Porcine knees were reconstructed with bovine digital extensor tendons using 6 different commercially available fixation device combinations, and biomechanically tested with cyclic loads (1000 cycles, 0–150 N, 0.5 Hz) and until failure (crosshead speed, 250 mm/min). The device combinations tested (in groups of 6) were EndoButton CL-BioRCI, Swing Bridge-Evolgate, Rigidfix-Intrafix, Bone Mulch-Washerlock, Transfix-Retroscrew, and Transfix-Deltascrew. Ultimate failure load, stiffness, slippage at cycles 1, 100, 500 and 1000 and mode of failure were evaluated. The statistical differences between pairs of groups were assessed with Student's unpaired *t* test. The ultimate failure load of complexes made with the Swing Bridge-Evolgate was significantly higher than any other device (968 N; $p<0.05$), while that of devices made with Transfix-Retrofix was significantly lower than the others (483 N, $p<0.05$). The stiffness of Swing Bridge-Evolgate complexes was significantly higher than the others (270 N/mm, $p<0.05$). Regarding mode of failure, Rigidfix-Intrafix complexes showed a failure of the femoral fixation in all specimens. All failures of the other specimens occurred at the tibial side, except one specimen in the EndoButton CL-BioRCI group. Many commercially available tibial fixation devices showed biomechanically appreciable properties, sometimes better than femoral devices.

Key words ACL reconstruction • Biomechanics • Ligaments • Semitendinosus

Introduction

Central-third bone-patellar tendon-bone and hamstring tendon autografts are commonly used as substitutes for the anterior cruciate ligament (ACL) [1–3]. These autografts are fixed to the femur and tibia using various fixation devices. In the last 20 years, the use of hamstring tendon grafts in ACL reconstruction has increased [4].

Successful restoration of ACL function using soft tissue grafts [5] requires rigid fixation with sufficient stiffness to withstand the repetitive loading forces that occur in the early postoperative rehabilitation period and during routine activities of daily living. These forces have been estimated to range from 67 N to 454 N, depending on the activities involved [6]. A stable mechanical environment is required for graft maturation, incorporation and healing.

Although several studies have focused on the biomechanics of hamstring fixation devices on femur and tibia [7, 11, 15, 16, 19], there is a paucity of literature on the biomechanics of the complete femur-graft-tibia complex. The few previous biomechanical studies dealt only with the tensile properties of the femur-graft-tibia complex after ACL reconstruction without cyclic loading [5, 8–12]. Therefore, the aim of this study was to compare the biomechanical properties of 6 different femur-graft-tibia complexes. The peak load was chosen to represent ACL forces in normal walking activity [13, 14]. Structural properties such as stiffness and slippage were assessed in addition to pullout strength, because they each may affect the ability of a ligament replacement to restore and ensure stability of the reconstructed knee, especially during intensive rehabilitation [15].

Materials and methods

Femur-graft-tibia complexes were constructed using bovine digital extensor tendons, porcine knees and 6 different commercially available fixation device combinations (Fig. 1):

- EndoButton CL and BioRCI (Smith & Nephew)
- Swing Bridge and Evolgate (Citieffe)
- Reigidfix and Intrafix (Mitek)
- Bone Mulch and Washerlock (Biomet)
- Transfix and Retroscrew (Arthrex)
- Transfix and Deltascrew (Arthrex)

For each fixation device, 6 specimens were prepared for a total of 36 femur-graft-tibia complexes. Animal tissues were obtained fresh from a local abattoir. Porcine knees were used in this study because they were readily available, inexpensive and already used in previous, similar studies [11, 15, 16].

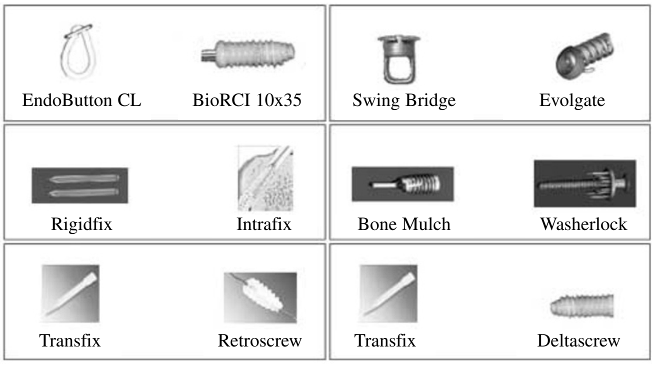

Fig. 1 The 6 commercially available fixation device combinations tested in porcine knees reconstructed with bovine digital extensor tendons

Construction of femur-graft-tibia complexes

Bovine digital extensor tendons were harvested from 36 bovine hindlimbs, from 20-month-old animals. The tendons typically had cross-sectional diameters of 8 mm (long direction) and 5 mm (short direction), in agreement with the mean cross-sectional area of 43 mm^2 reported by Noyes et al. [6] for a 4-strand semitendinosus-plus-gracilis tendon graft. If there was a delay between collection and use, the tendons were stored at -22° C and than thawed before use. They were kept moist until testing by being wrapped in tissue paper soaked with Ringer's solution and stored in sealed polyethylene bags.

The bifurcated tendon was divided into two halves. A double looped bovine tendon graft was prepared by placing the two tendon halves side by side and folding them in half. The tendons grafts were prepared following a standard surgical protocol until the graft passed through a 9-mm diameter cylinder. A N°1 suture was used to sew 4 cm of both ends of each tendon using a crisscrossing stitch.

Skeletally mature porcine knee were cleared of all soft tissues, wrapped in saline-soaked gauze, and stored at -25° C in sealed plastic bags until use. From each knee, the ACL was resected and then reconstructed with the bovine graft and one of the fixation devices combinations. The bones were prepared for tendon anchorage using instruments provided by the manufacturers and methods described personally by the originators of the devices tested. The bone tunnels were placed in their normal surgical orientations in the femur and tibia, using impaction drills that packed the bone debris into the tunnel walls rather than removing it.

Biomechanical measurements

Each reconstructed knee was mounted on a tensile machine (model Z010, Zwick-Ruell, Ulm, Germany) and fixed with wires in a 50-mm diameter cylinder. The complex was mounted with specially designed grips at 45° of knee flexion, so that the longitudinal axis of the graft coincided with the axis of the bone tunnels. Preconditioning was performed with 100 cycles of loading and unloading between the tensile loads of 10 N and 50 N at a crosshead speed of 50 mm/min. A tensile load of 90 N was then applied to the graft for 2 min as an initial graft tension. Then, 1000 cycles between 0 and 150 N were applied to the complex with a crosshead speed of 250 mm/min and a frequency of 0.5 Hz before the final pullout. Data were recorded with Textexpert 8.1 software (Zwick-Roell) and evaluated with a load-displacement curve. Stiffness and strength were evaluated at the final pullout, as was the displacement (slippage) at cycles 1, 100, 500, and 1000. Mode of failure of each specimen was also recorded.

Statistical analysis

Differences between pairs of groups were assessed using Student's unpaired (two-tailed) *t* test. A value of $p<0.05$ was accepted as significant.

Results

Femur-graft-tibia complexes, constructed with 6 different fixation device combinations, were tested biomechanically with 1000 cycles of loading at 150 N (Table 1). At the first cycle, mean slippage values ranged from 0.2 mm (Transfix-Deltascrew) to 0.6 mm, recorded for 3 devices (*p*=NS; Student's *t* test). Mean slippage values increased with the number of cycles of loading for all fixation devices. At cycle 1000, these values ranged from 1.4 mm (SD=0.5) for Bone Mulch-Washerlock to 2.6 (SD=1.0) for Rigidfix-Intrafix.

At the final pullout, we measured both ultimate failure load (UFL) and stiffness (Fig. 2). UFL was significantly higher for the Swing Bridge-Evolgate combination (*p*<0.05, Student's *t* test), and it was significantly lower for the Transfix-Retroscrew combination (*p*<0.05), for all single comparisons with other devices. Mean stiffness values ranged from 117 N/mm to 270 N/mm. Stiffness of complexes constructed with the Swing Bridge-Evolgate device combination was significantly higher than any other value (*p*<0.05, Student's *t* test).

Mode of failure of each complex was classified as femoral device rupture, tendon rupture, or tibial device slippage (Table 2). The femoral device ruptured in 1 Endo-Botton-BioRCI complex and in 4 Rigidfix-Intrafix devices. Tendon rupture on the femoral side was only observed in 2 Rigidfix-Intrafix devices, while rupture on the tibial side occurred overall in 22 of the 36 tested complexes. Finally,

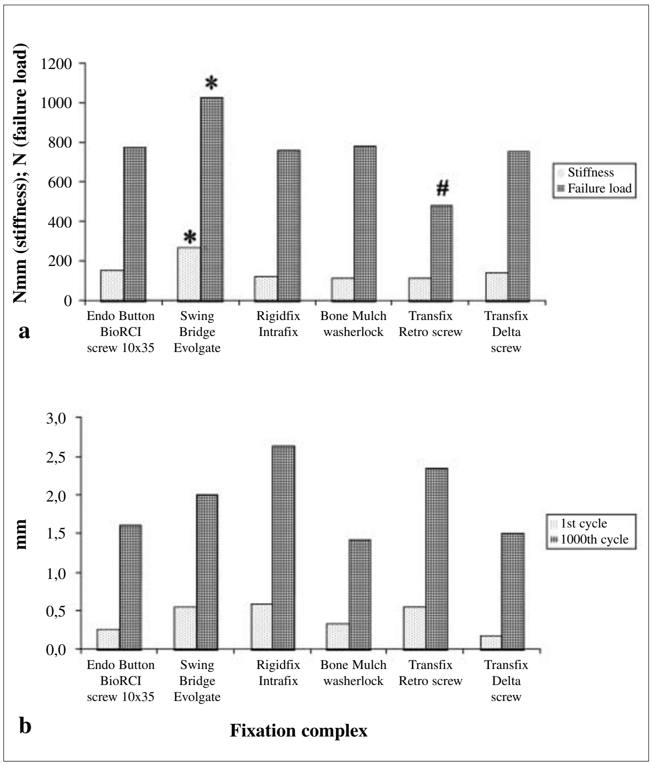

Fig. 2a, b Biomechanical properties of fibia-graft-tibia complexes constructed with 6 fixation device combinations, at final pullout. **a** Ultimate failure load. **b** Stiffness. Values are mean and SD of 6 complexes.
**p*<0.05 vs. all other devices (Student's *t* test)

Table 1 Slippage of femur-graft-tibia complexes over 1000 cycles of loading at 150 N, for 6 different fixation device combinations. Values are mean (SD) for 6 complexes each

Fixation device combination	Slippage, mm			
	Cycle 1	Cycle 100	Cycle 500	Cycle 1000
EndoButton CL-BioRCI	0.3 (0.1)	0.8 (0.3)	1.3 (0.4)	1.6 (0.4)
Swing Bridge-Evolgate	0.6 (0.1)	1.4 (0.3)	1.9 (0.4)	2.0 (0.4)
Rigidfix-Intrafix	0.6 (0.4)	1.6 (0.5)	2.3 (0.8)	2.6 (1.0)
Bone Mulch-Washerlock	0.3 (0.2)	0.8 (0.3)	1.2 (0.4)	1.4 (0.5)
Transfix-Retroscrew	0.6 (0.4)	1.1 (0.4)	1.8 (0.5)	2.4 (0.7)
Transfix-Deltascrew	0.2 (0.1)	0.6 (0.1)	1.4 (0.7)	1.5 (0.5)

Table 2 Mode of failure at final pullout, for femur-graft-tibia complexes, according to the fixation device used. Values are number of complexes

Group	Femoral device rupture	Tendon rupture, femoral side	Tendon rupture, tibial side	Tibial device slippage
EndoButton CL-BioRCI	1	0	3	2
Swing Bridge-Evolgate	0	0	6	0
Rigidfix-Intrafix	4	2	0	0
Bone Mulch-Washerlock	0	0	6	0
Transfix-Retroscrew	0	0	1	5
Transfix-Deltascrew	0	0	6	0

tibial slippage was observed in 2 EndoButton-BioRCI complexes and 5 Transfix-Deltascrew complexes.

Discussion

The first limitation of this study is that we used animal tissues. In testing of graft fixation techniques with an animal model, the species is chosen for low cost and availability. We used porcine specimens because they can be frozen immediately after harvesting, and the age of the donors and the bone quality are more uniform than in specimens obtained from human donors [8, 15]. Although the use of young human cadaver tibiae would be the ideal material for testing tibial side ACL graft fixation, the majority of human cadaver tibiae are from elderly donors. A recent paper by Pena et al. [17] emphasized the influence of bone mineral density (BMD) on the in vitro ultimate failure loads in human cadaver specimens; the reduced BMD decreases the validity of soft tissue ACL graft fixation measurements. When older human cadaver bone tissue is used for biomechanical testing, ultimate failure loads are generally underestimated compared to the in vivo situation of ligament reconstruction in the younger patient [18]. Although the use of animal specimens has been criticized [11], porcine specimens can help minimize specimen-related bias. In fact, porcine bone models are commonly used for biomechanical graft fixation tests. Bovine tendons were used because the stiffness and viscoelastic behavior are not significantly different from a human double-looped semitendinosus and gracilis graft [19].

The second limitation of this study is that we stretched the complex along the tunnel axis to apply cyclic displacement to the complex. Therefore, we could not obtain direct information on flexion-extension motion of the knee from this study [20].

Moreover, the results of this ex vivo study reflect only the initial mechanical characteristics of the complex for the ACL reconstruction without any biologic healing and remodelling responses. So caution should be used in extrapolating the results of our study to clinical estimates as we cannot assume that the structural properties of fixation devices determined in animal tissue and laboratories studies predict its performance in human knees. On the other hand, this study was performed in the laboratory of our university by a team with substantial experiences in biomechanics of ligaments and tendons [16, 20, 21].

The present study shows that, in all but one of the tested groups, the mean strength (UFL) of the femur-graft-tibia complex was higher than the minimum required for an accelerated rehabilitation [6, 22]. Only in complexes assembled with the Transfix-Retroscrew device combination was the mean value (483 N) inferior than the recommended value of 500 N.

An interesting remark comes from the comparison with other studies that utilized a similar protocol [12, 13, 15, 16, 23]. In fact, we found that the ultimate failure load in a "femur device-graft-tibial device" was always lower than that obtained with a single device (tibial or femoral). We speculate that the best performance of a fixation device is achieved only if, at the other end of the graft, a firm point is available. This phenomenon, if confirmed by further studies on complete constructs, should be considered in evaluating the structural properties of single fixation devices.

Regarding the mode of failure, our study shows that some constructs have a well identifiable and reproducible weak point. It is well known, for example, that the loop of the EndoButton fails under a stress of more than 1000 N. In our series, the loop of the EndoButton failed in the specimens in which the tibial device resisted up to 1127 N. Therefore, should the EndoButton be used with strong tibial fixation device, it could actually become the weak point of the construct. A similar feature was found with the Rigidfix-Intrafix device combination, where failure occurred at the femoral side due to structural and biomechanical properties of the Rigidfix as compared with the stronger Intrafix. In Transfix-Retroscrew complexes, failure almost always occurred due to slippage of the graft at the tibial side, propably due to the scanty length of the Retroscrew [24]. In other constructs, the site of failure was variable, depending probably on the modality of insertion of the device and structural properties of the graft.

It must be highlighted that biomechanical testing provides only an estimated portrayal of construct properties, as they might appear immediately after surgery. Although cyclic testing increases the validity of these results [11, 13, 15] it does not provide insight as to the biological behavior of graft-tunnel healing after surgery that will ultimately determine the success or failure of the ACL reconstruction [14, 25, 26]. Despite these limitations, we believe that these data provide useful information to the knee surgeon.

For the patient with good bone density, five of these six fixation systems tested should resist enough to allow an early intensive rehabilitation without risk of graft-tunnel fixation failure from excessive slippage [10, 21, 27]. However, the choice of best fixation device depends on a combination of factors, such as the preferred surgical technique, the gender, age and the sport expectations of the patient, and last but not least, the cost of the device.

On the basis of our experience, testing the entire construct seems to be a more reliable method to evaluate initial mechanical properties of various fixation devices. In this way, despite the opinion of the majority of the experts [28], in some cases the femoral fixation is the weak point of the reconstruction.

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