Hybrid Femoral Fixation of Soft-Tissue Grafts in Anterior Cruciate Ligament Reconstruction Using the EndoButton CL and Bioabsorbable Interference Screws: A Biomechanical Study

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Purpose: The purpose of this study was to evaluate the effect of hybrid femoral fixation with bioabsorbable interference screws (BioRCI; Smith & Nephew Endoscopy, Andover, MA) and EndoButton CL (Smith & Nephew Endoscopy) fixation. **Methods:** Biomechanical testing of 3 different fixation techniques was performed by use of porcine hind-limb distal femurs and mature bovine extremity common extensor tendons. Two independent testing sessions were examined. The first testing session (group A) compared femoral fixation via the EndoButton CL device (n = 6) with femoral fixation via the EndoButton CL device with the addition of a BioRCI screw (n = 6). The second testing session (group B) compared femoral fixation via BioRCI screws alone (n = 6) with femoral fixation via the EndoButton CL device with the addition of a BioRCI screw (n = 6). The femur-graft complex was cyclically loaded between 50 and 250 N at 1 Hz for 1,000 cycles. After cycling, the amount of graft slippage was determined by measuring the change in grip-to-grip distance. The complex was then loaded to failure at 1 mm/s, and the ultimate tensile strength, stiffness, and mode of failure were determined. **Results:** In group A the addition of an interference screw to the EndoButton CL fixation increased the ultimate tensile strength (1,364.7 ± 102.4 N for EndoButton CL alone *v* 1,449.3 ± 94.4 N for combined technique, $P = .035$) and stiffness (195.5 ± 12.1 N/mm for EndoButton CL alone *v* 307.3 ± 54.9 N/mm for combined technique, $P = .004$) and decreased the amount of graft slippage (2.6 ± 0.5 mm for EndoButton CL alone *v* 2.0 ± 0.3 mm for combined technique, $P = .017$). In group B the addition of the EndoButton CL device to interference screw fixation significantly increased the ultimate tensile strength (643.5 ± 148.4 N for BioRCI screws alone *v* 1,290.3 ± 254.4 N for combined technique, $P = .004$) but had no effect on stiffness (315.7 ± 38.9 N/mm for BioRCI screws alone *v* 341.5 ± 64.0 N/mm for combined technique, $P = .267$) or graft slippage (2.7 ± 1.0 mm for BioRCI screws alone *v* 2.0 ± 0.6 mm for combined technique, $P = .087$). **Conclusions:** Our study shows 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. The addition of an interference screw to suspensory fixation via the EndoButton CL device increased the ultimate tensile strength from 1,360 N to 1,450 N, improved reconstruction stiffness from 200 N/mm to 300 N/mm, and decreased the amount of graft slippage resulting from cyclic loading from 2.6 mm to 2.0 mm. **Clinical Relevance:** The hybrid fixation of the EndoButton CL device and an interference screw is a stronger and stiffer construct than either device alone and allows for aperture fixation, which may translate into better clinical results.

Key Words: Graft fixation—Femoral fixation—EndoButton CL—Bioabsorbable interference screw—Hamstring tendon grafts—Mechanical testing.

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The anterior cruciate ligament (ACL) is the most commonly injured knee ligament, with over 100,000 ACL reconstructions being performed annually in the United States.[1] The goal of ACL reconstructions is a rapid return to desired activities with a functional, painless, and stable knee. To achieve this goal, ACL reconstruction techniques are constantly evolving with respect to different graft options and newer, stronger fixation techniques.

Because of increased donor-site morbidity of bone–patellar tendon–bone (BPTB) autografts,[2-8] double-looped gracilis-semitendinosus (DGST) grafts are becoming a popular alternative. Recently, Hamner et al.[9] reported an ultimate tensile strength of 4,140 N and a stiffness of 807 N/mm for human DGST grafts, whereas a standard 10-mm BPTB graft has been reported to have an ultimate tensile strength of 2,977 N and a stiffness of 455 N/mm.

The main disadvantage of DGST graft reconstruction has been related to intertunnel fixation of grafts. Traditional intertunnel fixation devices for soft-tissue grafts have been inferior to intertunnel fixation of bone plugs with respect to providing both strong initial fixation strength and aperture fixation. The EndoButton CL device (Smith & Nephew Endoscopy, Andover, MA), used for fixation of DGST grafts in the femoral tunnel, provides substantial initial fixation strength, but it does not provide aperture fixation. Suspensory fixation increases the effective graft length, which decreases stiffness and may lead to increased laxity and graft elongation.[10] In addition, the windshield-wiper (sagittal graft-tunnel motion) and bungee-cord (longitudinal graft-tunnel motion) effects may occur with EndoButton CL fixation (Fig 1), leading to tunnel expansion and delay of graft incorporation.[11]

The addition of a bioabsorbable interference screw to the EndoButton CL device adds the advantage of aperture fixation to one of the stronger femoral fixation devices available for DGST grafts. Although this type of hybrid fixation may be theoretically advantageous, there has been only 1 other study presented investigating this technique.[12] The biomechanical effect of the addition of a bioabsorbable interference screw to an EndoButton CL soft-tissue construct is unknown. The purpose of our biomechanical study is to investigate the hybrid femoral fixation of soft-tissue grafts with the addition of a bioabsorbable interference screw to EndoButton CL fixation. Our hypothesis is that the addition of the interference screw will significantly increase the strength and stiffness and decrease the amount of graft slippage.

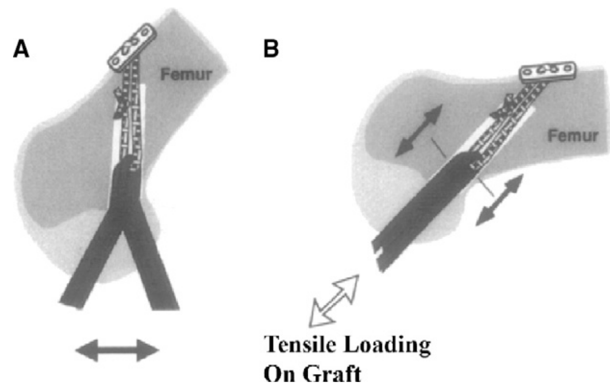

FIGURE 1. (A) Windshield-wiper effect resulting from sagittal motion of the graft with flexion and extension of the knee. (B) Bungee-cord effect of longitudinal motion between the graft and tunnel, which may occur with tensile loading of the graft. (Reprinted with permission.[35])

METHODS

We obtained 6 paired and 6 unpaired (18 total) fresh-frozen mature porcine hind limb distal femurs and 24 unpaired fresh-frozen bovine extremity common extensor tendons from an animal tissue supplier (Farm to Pharm, Warren, NJ). All specimens were stored at −20°C and thawed at room temperature 18 hours before use. The distal femurs and extensor tendons were cleaned of all extraneous soft tissue. The ends of each tendon were sutured with 5 throws of a baseball-type whipstitch by use of No. 2 Ticron suture (3146-81; Davis & Geck, Danbury, CT). The tendon was looped around a No. 5 Ticron suture (Davis & Geck), forming a double-tendon graft. The double-tendon grafts were standardized to fit a 7-mm sizing tube. If a graft was greater than 7 mm in diameter, it was carefully trimmed. If a graft was less than 7 mm in diameter, it was eliminated from the study. All specimens were standardized to have 7-mm-diameter bone tunnels and 30 mm of tendon length within the bone tunnels to eliminate the effects of increased graft size and tunnel length on the failure properties of the fixation methods.

Our study consisted of 2 independent test sessions. In the first test session (group A) 6 porcine femurs and 12 extensor tendons were used. Specimens were prepared in the following fashion. In each bone a 2.4-mm drill-tip guidewire was drilled through the femoral condyle in an open fashion at the femoral anatomic attachment site of the ACL. This position was chosen because it was believed to be the most reproducible site. A 4.5-mm cannulated EndoButton drill bit (Smith & Nephew Endoscopy) was used to drill a tunnel through the lateral cortex of the distal femur. The bone tunnel length was standardized to 70 mm to accommodate 30 mm of tendon and 40 mm of polyester continuous loop. The tunnel length was standardized by use of a tibial drill guide system that incorporates a graduated aiming bullet and adjustable aiming arm (Director Guide System; Smith & Nephew Endoscopy). A 6-mm-diameter bone tunnel was drilled in the lateral femoral condyle to a depth of 40 mm by use of a cannulated reamer. The bone tunnel was then progressively dilated by use of 0.5-mm incremental, cannulated, smooth tunnel dilators (Smith & Nephew Endoscopy) up to 7 mm. In specimens fixed with the EndoButton CL device, the graft loop was passed through the polyester continuous loop. The EndoButton CL device and graft were passed into the femoral bone tunnel and anchored on the lateral femoral cortex. After testing (as described later), the same bone specimens were then used for fixation with a new extensor tendon graft fixed with a new 40-mm EndoButton CL device and a 7 × 30–mm bioabsorbable interference screw (Fig 2). Each specimen was prepared in the same fashion as described previously. For the addition of the bioabsorbable interference screw, the femoral tunnel was notched at the 12-o'clock position by use of a Bio-Interference screw tunnel notcher (Smith & Nephew Endoscopy). A 1.5-mm nitinol guidewire was inserted into the notched area of the bone tunnel, parallel to the long axis of the bone tunnel. A 7 × 30–mm BioRCI interference screw (Smith & Nephew Endoscopy) was advanced over the guidewire until the round head of the screw was flush with the entrance of the bone tunnel. All specimens were kept moist with 0.9% sodium chloride solution throughout the entire fixation and testing process.

FIGURE 2. (Left) BioRCI bioabsorbable interference screw (7 × 30 mm) and (right) EndoButton CL (40 mm).

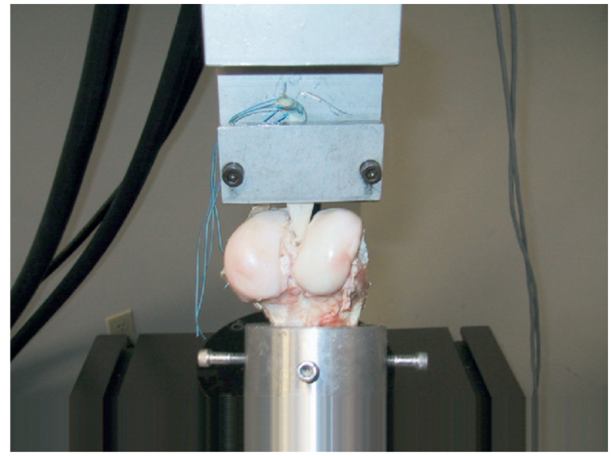

FIGURE 3. Testing apparatus with mounting of distal femur (model 8521; Instron).

In the second test session (group B) 6 pairs of porcine distal femurs (12 total bones) and 12 extensor tendons were used. In one bone, graft fixation was achieved by use of a 7 × 30–mm BioRCI bioabsorbable interference screw alone. In the contralateral bone, graft fixation was achieved by use of a 40-mm EndoButton CL device and a 7 × 30–mm BioRCI interference screw; this fixation was performed via the same technique described previously.

Graft displacement after cyclic loading (slippage), ultimate tensile strength, and linear stiffness of the femur-graft complex were measured with a servohydraulic materials testing system (model 8521; Instron, Canton, MA). The distal femur was mounted to the load frame via a custom-designed clamp similar in design to that used in previous studies examining various components of ACL reconstruction.[9,13-15] The clamping system allowed the axis of the bone tunnels in the lateral femoral condyle to be positioned parallel to the axis of the applied load. The free ends of the graft were secured to the top-mounted actuator by use of a custom-built tendon-freezing grip (Fig 3). The distance from the entrance of the bone tunnel to the tendon-freezing grip was approximately 30 mm to simulate the intra-articular length of the ACL. A marking pen was used to highlight the grip-tendon interface to confirm that no slippage of the tendon in the grip occurred. A 50-N preload was applied to the con-

TABLE 1. *Results of EndoButton Device Alone Versus Combination of EndoButton Device and Interference Screw Fixation*

	Ultimate Tensile Strength (N)	Stiffness (N/mm)	Slippage (mm)	Failure Mode
EndoButton (n = 6)	1364.7 ± 102.4	195.5 ± 12.1	2.6 ± 0.5	Continuous loop breakage
EndoButton and interference screw (n = 6)	1449.3 ± 94.4	307.3 ± 54.9	2.0 ± 0.3	Continuous loop breakage
P value	.035*	.0004*	.017*	

NOTE. Data are presented as mean ± SD.
*Statistically significant based on Student *t* test ($P < .05$).

struct, and the position of the actuator was recorded. The fixation was then subjected to uniaxial cyclic loading between 50 N and 250 N at 1 Hz for 1,000 cycles. The load was applied parallel to the axis of the bone tunnel with all other motions constrained. Immediately after cycling, a 50-N load was applied and the post-cyclic position of the actuator was recorded. Graft slippage was determined by calculating the difference between the actuator position before and after cyclic loading with a 50-N applied load. Once this measurement was recorded, the specimens were immediately tested to failure at 1 mm/s with the tensile load applied parallel to the axis of the bone tunnel and all other motions constrained.[13-15] Load-displacement curves were recorded and analyzed to determine ultimate tensile strength and linear stiffness by use of data acquisition and analysis software (Series IX; Instron). The mechanism of failure for each test was also recorded. Data were compared by use of the Student *t* test with significance set at $P < .05$.

RESULTS

In group A, EndoButton CL fixation was compared with the combination of the EndoButton CL device and BioRCI interference screw fixation. The combined fixation technique resulted in a significantly higher ultimate tensile strength (1,449.3 ± 94.4 N *v* 1,364.7 ± 102.4 N [5.8% increase], $P = .035$), significantly higher stiffness (307.3 ± 54.9 N/mm *v* 195.5 ± 12.1 [36.4% increase], $P = .004$), and significantly less slippage (2.0 ± 0.3 mm *v* 2.6 ± 0.5 mm [23% decrease], $P = .017$) than EndoButton CL fixation alone (Table 1). The mode of failure for all specimens was polyester continuous loop breakage.

In group B, BioRCI interference screw fixation was compared with the combination of the EndoButton CL device and BioRCI interference screw fixation. The combined fixation technique resulted in significantly higher ultimate tensile strength (1,290.3 ± 254.4 N *v* 643.5 ± 148.4 N [50.1% increase], $P = .004$) compared with the BioRCI interference screw fixation. However, stiffness (341.5 ± 64.0 N/mm *v* 315.7 ± 38.9 N/mm [7.1% increase], $P = .267$) and slippage (2.0 ± 0.6 mm *v* 2.7 ± 1.0 mm [25.9% decrease], $P = .087$) were not significantly different (Table 2). The mode of failure for all specimens undergoing BioRCI interference screw fixation was tendon pullout, with no screw movement, and the mode of failure for specimens undergoing the combined technique was polyester continuous loop breakage for all but 1 sample, which had tendon failure at the interference screw.

TABLE 2. *Results of Interference Screws Alone Versus Combination of EndoButton Device and Interference Screw Fixation*

	Ultimate Tensile Strength (N)	Stiffness (N/mm)	Slippage (mm)	Failure Mode
Interference screws (n = 6)	643.5 ± 148.4	315.7 ± 38.7	2.7 ± 1.0	Tendon pullout
EndoButton device and interference screw (n = 6)	1290.3 ± 254.4	341.5 ± 64.0	2.0 ± 0.6	Continuous loop breakage†
P value	.004*	.267	.087	

NOTE. Data are presented as mean ± SD.
*Statistically significant based on Student *t* test ($P < .05$).
†One sample with tendon failure at screw.

DISCUSSION

In an evaluation of quadrupled semitendinosus-gracilis autograft fixation in the femoral tunnel, Caborn et al.[16] reported pullout strengths of 242 N for a metal screw and 341 N for a bioabsorbable screw and believed that these strengths were able to withstand low-level rehabilitation loads. Steiner et al.[17] studied a number of different fixation techniques for both hamstring and BPTB grafts. Although they did not study soft-tissue interference screw fixation, they reported that the stiffest and strongest BPTB construct was a hybrid of interference screw aperture fixation and suspensory fixation via sutures tied around a post.

More recently, Brown et al.[13] reported that the strongest femoral fixation method was the DGST graft fixed with the EndoButton CL device (1,345 N) and that the stiffest fixation was achieved with the BPTB graft fixed with an interference screw (299 N/mm). Furthermore, in their study the stiffness of soft-tissue interference screw fixation was not significantly different than that of interference screw fixation of BPTB grafts (255 N/mm).

Kousa et al.[18] found the Bone Mulch Screw (Arthrotek, Warsaw, IN) (1,121 N) and EndoButton CL device (1,086 N) to be significantly stronger than the interference screw (546-794 N) used in their testing. They also found the Bone Mulch Screw to be the stiffest fixation device (189 N/mm), although it did not show significantly greater stiffness than one of the interference screws tested.

Ahmad et al.[19] reported the EndoButton and Biotransfix devices (Arthrex, Naples, FL) to be the superior fixation devices among those that they tested. They found the ultimate load of the EndoButton device to be 864 N and that of the interference screw to be 539 N. Total graft slippage for the EndoButton device was 1.75 mm compared with 5.44 mm for the interference screw. Our study would seem to use one of the stronger fixation devices in combination with one of the stiffer devices.

The study of Madsen et al.[12] is the only one that we could find in the literature that examined this form of hybrid femoral fixation. They found pullout strength to be significantly greater with hybrid fixation (1,071 N) than with interference screw fixation (515 N). They also found no difference in elastic deformation and elongation. Our results are comparable to these.

In addition to the favorable biomechanical characteristics of our hybrid femoral fixation, the utilization of the interference screw adds aperture fixation to our construct. L'Insalata et al.[11] showed that tunnel expansion was significantly greater after ACL reconstruction with a hamstring graft compared with a BPTB graft as seen on posteroanterior and lateral radiographs. They concluded that this difference was a result of the greater distance between the points of fixation associated with the hamstring graft, which could create a larger force moment during graft cycling. Clatworthy et al.[20] asserted that the lack of aperture fixation can lead to tunnel expansion, which may interfere with graft incorporation. Simonian et al.[21] reported that biodegradable interference screw augmentation reduces tunnel expansion after ACL reconstruction.

However, Buelow et al.[22] found that the insertion of a large interference screw enlarged the bone tunnel. Ma et al.[23] reported that the use of an interference screw did not lead to a decrease in the amount of tunnel expansion. Tunnel expansion is a multifactorial process,[24] and more investigation will be necessary to determine whether aperture fixation truly does decrease the amount of tunnel enlargement.

Another complication of suspensory fixation of the hamstring grafts stems from the use of sutures or tape. Hoher et al.[25] reported that when titanium button/tape fixation was used, shorter tape lengths resulted in less graft-tunnel motion. In another study, Hoher et al.[26] compared button/tape fixation with a cross-pin fixation. They concluded that a graft construct that includes tape or sutures exhibited increased permanent elongation during cyclic loading compared with a construct without tape or sutures. This permanent elongation may be a result of the tightening of knots used to link the titanium button to the axilla of the hamstring graft. Becker et al.[27] reiterated this conclusion in their study. They found Polylene tape (Genzyme, Boston, MA) to be the stiffest material; however, it was still greatly inferior to a graft alone. We attempted to minimize this problem in our study by using a closed loop design, which does not use knots. However, in this set of experiments it is possible that a portion of the femoral fixation elongation may be a result of continuous loop stretching or tightening of the graft axilla around the continuous loop.

This study has several limitations. First, it was performed in an animal model. We chose bovine extensor tendons because they exhibit biomechanical and viscoelastic properties similar to double-looped human semitendinosus and gracilis grafts.[28] To standardize tendon diameter to 7 mm, a number of tendons were carefully trimmed. It is our belief that trimming of the tendons did not significantly affect their mechanical properties. The mechanical properties of the tendons exceed the failure properties of the femoral fixation methods examined, as indicated by the failure modes, which in 23 of 24 tests were attributed to either implant or fixation failure. The lone graft failure occurred in a femoral fixation in which a trimmed specimen was not used. Porcine femurs were used because of their ready availability, as well as their use in similar studies measuring graft slippage with cyclic loading.[18,19,29] It is unclear how our results would compare with in vivo human surgeries, such as those reported by Madsen et al.,[12] and whether the significant differences seen with respect to strength, stiffness, and slippage have true clinical implications. However, this is a limitation of all in vitro biomechanical studies.

The second limitation of this study involves the examination of only one portion of ACL graft fixation—namely, femoral fixation. Historically, tibial fixation of ACL grafts has been considered the weak link of ACL reconstruction.[14,15] One of the reasons proposed for this is that the forces acting on the ACL are parallel to the drill hole.[30,31] Another reason suggested is the decreased bone quality of the proximal tibia.[32,33] We chose to examine femoral fixation in an effort to isolate failure properties and focus on improving one component of ACL reconstruction. Future studies examining hybrid femoral fixation and various tibial fixation methods seem warranted.

Finally, extrapolation of the results from this study to clinical practice should be done with caution because of the limitations inherent in in vitro biomechanical testing. Unidirectional tensile testing to failure does not stimulate the true geometry and loading of the intact ACL. As the knee joint travels through its range of motion, the relative loading in the strands of the ACL and graft changes.[34] This effect could not be studied in our model. To properly evaluate the clinical significance of this fixation technique, a randomized clinical trial is warranted, using hybrid fixation on one limb and EndoButton fixation alone on the other limb.

CONCLUSIONS

Our study shows that hybrid femoral fixation of DGST grafts via the EndoButton CL device and a bioabsorbable interference screw is stronger than interference screw or EndoButton CL fixation alone with respect to ultimate tensile strength, stiffness, and slippage. The addition of an interference screw to suspensory fixation via the EndoButton CL device increased ultimate tensile strength from 1,360 N to 1,450 N, improved reconstruction stiffness from 200 N/mm to 300 N/mm, and decreased the amount of graft slippage resulting from cyclic loading from 2.6 mm to 2.0 mm.

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