

# The Fixation Strength of Six Hamstring Tendon Graft Fixation Devices in Anterior Cruciate Ligament Reconstruction

## Part I: Femoral Site\*

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**Background:** Strength of graft fixation is the weakest link in anterior cruciate ligament reconstruction.

**Hypothesis:** There is no difference in initial fixation strength between different hamstring tendon graft femoral fixation devices.

**Study Design:** Randomized experimental study.

**Methods:** Each of six devices was used in the fixation of 10 quadrupled human semitendinosus-gracilis tendon grafts in tunnels drilled in porcine femora and tested 10 times with a single-cycle load-to-failure test at a rate of 50 mm/min and 10 times with a 1500-cycle loading test between 50 and 200 N at one cycle every 2 seconds. The specimens that survived the cyclic loading were subjected to a single-cycle load-to-failure test.

**Results:** The Bone Mulch Screw (1112 N) was strongest in the single-cycle load-to-failure test, followed by EndoButton CL (1086 N), RigidFix (868 N), SmartScrew ACL (794 N), BioScrew (589 N), and RCI screw (546 N). It also showed the lowest residual displacement (2.2 mm) and was strongest in the single-cycle load-to-failure test after cyclic loading.

**Conclusions:** The Bone Mulch Screw was superior to all other devices.

**Clinical Relevance:** Caution may be warranted in employing aggressive rehabilitation after reconstruction with these devices. Preconditioning of the graft-implant complex before fixation is important.

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Bone-patellar tendon-bone grafts have been the accepted standard for use in ACL reconstructive surgery. Recently, as a way to avoid the morbidity associated with harvest of the patellar tendon, use of quadrupled hamstring tendon grafts has grown in popularity.<sup>4,8,9</sup> It has been shown that an equally tensioned four-strand hamstring tendon graft provides better biomechanical properties than a 10-mm patellar tendon graft, and, thus, from a biomechanical

point of view, a hamstring tendon graft seems to be a reasonable alternative to a bone-patellar tendon-bone graft.<sup>7,11,18,21,24</sup> However, the strength of the fixation, rather than the strength of the graft, has been thought to be the weakest link in the stability of an ACL reconstruction during the early postoperative period.<sup>4</sup>

In comparison with bone-patellar tendon-bone graft, the increased anterior-posterior laxity, slower healing of the tendon graft to the bone tunnel, and graft motion within the tunnel leading to enlargement of the tunnel opening are commonly considered the most serious problems associated with use of hamstring tendon grafts in ACL reconstruction.<sup>4,8</sup> Since the evolution of hamstring tendon grafts from single- or double-strand to four-strand grafts, the concern surrounding use of hamstring tendon grafts has focused primarily on fixation.<sup>4,8</sup> Optimal initial fixa-

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Several authors have a commercial interest or affiliation with products named in this study.

tion of an ACL graft requires sufficient initial strength to avoid fixation failure, sufficient stiffness to restore stability of the knee, anatomic fixation to minimize graft movement within the tunnel, and sufficient resistance against slippage under cyclic loading conditions to avoid gradual loosening during the early postoperative period after ACL reconstruction.<sup>4,8,9</sup>

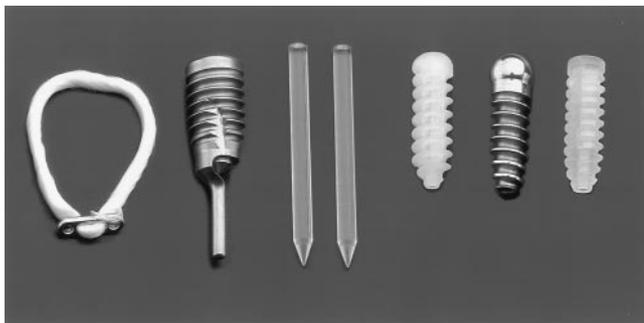
The purpose of this two-part study was to test the strength and stiffness of commonly used devices for the fixation of quadrupled hamstring tendon grafts in ACL reconstruction. In Part I, we evaluated six frequently used devices for fixation of the graft in the femoral tunnel and in Part II, devices used in the tibial tunnel.

## MATERIALS AND METHODS

### Specimens

We evaluated six different implants for fixation of hamstring tendon grafts in the femoral site (Fig. 1) using mature porcine femora and 120 fresh human cadaveric semitendinosus and gracilis tendons as the reconstruction material. After harvesting, the tendons were cleared of adherent muscle and soft tissue, wrapped in gauze soaked in saline solution, and stored frozen at  $-25^{\circ}\text{C}$  in small sealed plastic freezer bags. In addition, 120 skeletally mature fresh porcine femora were obtained from a local slaughterhouse, similarly treated, and stored ( $-25^{\circ}\text{C}$ ) in sealed plastic bags. These preservation procedures have been shown not to affect the mechanical properties of the tendons or bones.<sup>20,28</sup> The specimens were randomly assigned into six study groups of 20 specimens each.

On the day of testing, the tendons and femora were thawed to room temperature. All of the specimens were kept moist with physiologic saline solution during specimen preparation, fixation procedures, and biomechanical testing. All fixations were performed by the same surgeons (PKo, MV) according to specific instructions provided by the manufacturers of the implants (through product inserts, surgical technique manuals, instructional videos, and the advice of company representatives) and with the appropriate instruments for each implant tested. The femoral drill holes were directed from the original



**Figure 1.** The implants used in this study are from left to right: EndoButton CL, Bone Mulch Screw, RigidFix, Bio-Screw, RCI screw, and SmartScrew ACL.

femoral insertion site of the ACL toward the lateral wall of the lateral femoral condyle of the knee (at the 1-o'clock position for the left knee, and at the 11-o'clock position for the right knee).

### Study Groups and Fixation Procedures

**EndoButton CL.** The semitendinosus and gracilis tendons were doubled over the loop of the EndoButton CL (Acufex Microsurgical, Inc., Mansfield, Massachusetts) to produce a quadrupled graft. The diameter of the graft was then measured by using Graft Sizing Tubes (Acufex Microsurgical, Inc.) in 0.5-mm increments. A femoral socket matching the graft diameter was drilled with a compaction drill (Acufex Microsurgical, Inc.). The size of the EndoButton CL device was chosen so that 20 to 25 mm of the graft was in the femoral tunnel. With use of a traction suture, the EndoButton CL was pulled through the femoral socket and the passing channel, which was 4.5 mm in diameter, until it exited the lateral cortex. Then the EndoButton CL was deployed by pulling on the suture that followed.

**Bone Mulch Screw.** We sutured 4 to 5 cm of each end of the semitendinosus and gracilis tendons with a whipstitch (No. 2-0 Vicryl suture, Ethicon, Johnson & Johnson, Arlington, Texas). The diameter of the quadrupled graft was then measured with an Arthrotek sizing sleeve (Arthrotek, Inc., Warsaw, Indiana) in 1-mm increments. A cannulated reamer corresponding to the diameter of the graft was selected to drill a 25-mm femoral socket. For the insertion of the  $10.5 \times 25$  mm Bone Mulch Screw (Arthrotek, Inc.), a U-shaped drill guide and an 8-mm cannulated reamer were used to drill a tunnel from the lateral condyle of the femur perpendicular to the femoral socket. The Bone Mulch Screw was then inserted into this tunnel, and the graft was pulled around the tip of the screw with the assistance of a suture loop passer. Finally, cancellous bone was compacted through the Bone Mulch Screw by using a compaction rod, according to the manufacturer's recommendations.

**RigidFix.** The graft was folded over a leading suture and the looped-over part of the quadrupled graft was sutured in a whipstitch fashion (No. 2 Vicryl suture). The diameter of the graft was measured in 0.5-mm increments by using Graft Sizing Tubes. A femoral socket 25 mm in length and equal to the graft diameter was drilled with a conventional femoral reamer. A RigidFix crosspin guide (Mitek Products, Norwood, Massachusetts) was then used to make two parallel drill holes from the lateral femoral condyle perpendicular to the femoral socket. Finally, the graft was pulled into the socket and two bioabsorbable (poly-L-lactide) RigidFix crosspins (Mitek Products) were inserted through the previously made drill holes across the graft.

**Interference Screws.** The semitendinosus and gracilis tendons were doubled, and the looped-over end was sutured with a whipstitch to create a 40-mm bundle. The diameter of the bundle was measured and the appropriate size femoral tunnel was drilled with a compaction drill (Acufex Microsurgical, Inc.). The looped end of the graft

was pulled into the femoral socket, and the interference screw was inserted by use of the inside-out technique over a guide pin until the base of the screw was flush with the intraarticular tunnel opening.

**BioScrew.** Before the insertion of the  $7 \times 25$  mm bioabsorbable poly-L-lactide BioScrew (Linovatec, Inc., Largo, Florida) interference screw, a notcher provided by the manufacturer was used to enhance starting and to accommodate the screw heads.

**RCI screw.** A conventional  $7 \times 25$  mm RCI (Acufex Microsurgical, Inc.) titanium screw was used in left knees and a reverse-threaded screw was used in right knees.

**SmartScrew ACL.** As with the BioScrew, a notcher provided by the manufacturer was used to enhance starting and to accommodate the screw heads before the insertion of the  $7 \times 25$  mm bioabsorbable self-reinforced L-lactide/D-lactide (PLA96/4) copolymer SmartScrew ACL (Bionx Implants Inc., Blue Bell, Pennsylvania) interference screw.

### Biomechanical Testing

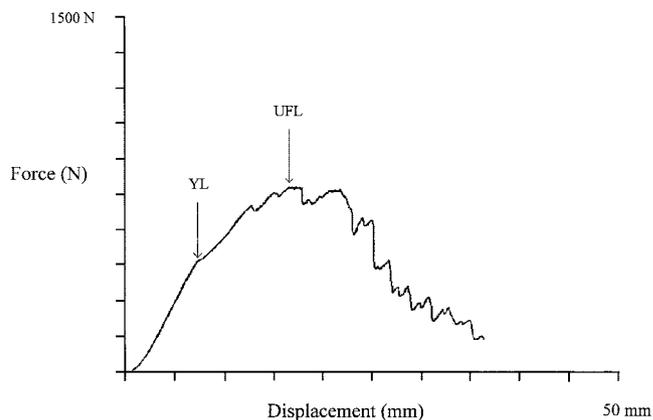
Biomechanical tests were performed with use of a Lloyd LR 5K mechanical testing machine (J. J. Lloyd Instruments, Southampton, United Kingdom), and the testing data were recorded with the accompanying software package (Rcontrol 3.2, J. J. Lloyd Instruments). The femora were mounted to the testing machine by threaded bars and specially designed clamps to enable secure fixation.<sup>13</sup> The graft was prepared for testing by suturing the free ends of the four individual tendons together in whipstitch fashion (No. 2 Vicryl suture). Meanwhile, a constant tension was maintained on all four strands of the graft with the aid of a work station type of apparatus. The sutured end was secured to a specially designed soft tissue clamp described previously.<sup>26</sup> A 25-mm length of graft was left between the clamp and the intraarticular tunnel opening, corresponding to the intraarticular portion of the ACL. The biomechanical testing consisted of a single-cycle load-to-failure test and a cyclic-loading protocol.

### Single-Cycle Load-to-Failure Test

In the single-cycle loading test, each specimen was evaluated with a load to failure applied parallel to the long axis of the drill hole at a rate of 50 mm/min. The response of the specimen to loading was automatically obtained in the form of a force-displacement curve (Fig. 2). The stiffness (determined as the slope of the linear region of the force-displacement curve corresponding to the steepest straight-line tangent to the loading curve) and yield load (described as the load at the point where the slope of the load-displacement curve first clearly decreased) were determined. The mode of failure was also determined.

### Cyclic-Loading Test Followed by Single-Cycle Load-to-Failure Test

In the cyclic-loading test, a 50-N preload was first applied to the specimens for 10 seconds. Thereafter, the graft fixation constructs were loaded for 1500 loading cycles

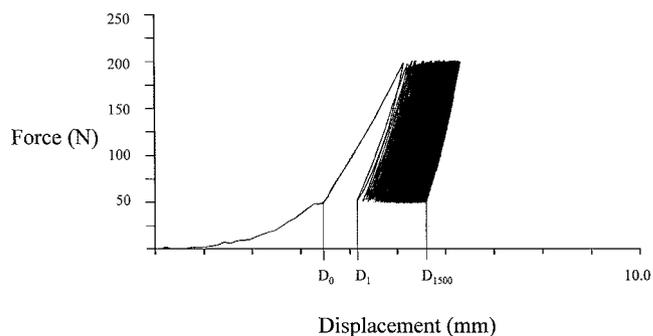


**Figure 2.** A typical force-displacement curve of the single-cycle load-to-failure test. The response of the specimen to loading is virtually linear until the yield load (YL), where the slope of the force displacement curve first clearly decreased. After the yield load, the specimen underwent significant stretching, but the load still increased until the ultimate failure load (UFL) was reached.

between 50 and 200 N at a frequency of one cycle every 2 seconds. The loading was parallel with the long axis of the femoral tunnel. The response to loading was automatically obtained in the form of a force-displacement curve. The rigidity of the fixation was evaluated by determining the loading-induced increase in the displacement from the preload level after 1, 10, 50, 100, 250, 500, 1000, and 1500 loading cycles (Fig. 3). After 1500 loading cycles, a single-cycle load-to-failure test was conducted on the surviving specimens, as described earlier.

### Statistical Analysis

One-way analysis of variance with the Tukey's test as the post hoc test was used to test the differences between the study groups. The difference between the single-cycle and the single-cycle subsequent to cyclic-loading yield loads was compared with an unpaired *t*-test. A *P* value of less



**Figure 3.** A typical force-displacement curve of the cyclic loading test. The rigidity of the graft fixation construct was evaluated by subtracting the displacement at the preload level ( $D_0$ ) from the corresponding displacement after 1 ( $D_1$ ) to 1500 ( $D_{1500}$ ) cycles of loading.

TABLE 1  
Results of Single-Cycle Loading Test for Each Fixation Device

Fixation	N	Yield load (N) (mean ± SD)	Stiffness (N/mm) (mean ± SD)
EndoButton CL	10	1086 ± 185	79 ± 7.2 <sup>a</sup>
Bone Mulch Screw	10	1112 ± 295	115 ± 28
RigidFix	10	868 ± 171	77 ± 17 <sup>a</sup>
BioScrew	10	589 ± 204 <sup>a,c,e</sup>	66 ± 28 <sup>a,f</sup>
RCI screw	10	546 ± 174 <sup>a,c,e</sup>	68 ± 15 <sup>a,f</sup>
SmartScrew ACL	10	794 ± 152 <sup>b,d</sup>	96 ± 20

<sup>a</sup> Significantly different from Bone Mulch Screw ( $P < 0.001$ ).  
<sup>b</sup> Significantly different from Bone Mulch Screw ( $P < 0.05$ ).  
<sup>c</sup> Significantly different from EndoButton CL ( $P < 0.001$ ).  
<sup>d</sup> Significantly different from EndoButton CL ( $P < 0.05$ ).  
<sup>e</sup> Significantly different from RigidFix ( $P < 0.05$ ).  
<sup>f</sup> Significantly different from SmartScrew ACL ( $P < 0.05$ ).

than 0.05 was considered statistically significant in all tests.

RESULTS

Single-Cycle Load-to-Failure Test

The results of the single-cycle load-to-failure test are summarized in Table 1. The mean yield loads for the Bone Mulch Screw and the EndoButton CL were significantly higher than those for the interference screws. The mean yield load for the RigidFix was significantly higher than that for the BioScrew and the RCI screw. The highest stiffness was found with use of the Bone Mulch Screw (115 ± 28 N/mm), which was significantly stiffer than the

EndoButton CL, RigidFix, RCI screw, and BioScrew groups. No significant difference was observed between the Bone Mulch Screw and the SmartScrew ACL. The stiffness of the SmartScrew ACL group was also significantly higher than that of the BioScrew and RCI screw groups.

In the EndoButton CL group, five specimens failed by rupture of the tendon loop and five failed by rupture of the continuous loop. In the Bone Mulch Screw group, three specimens failed by bending of the tip of the screw and seven specimens failed by rupture of the tendon loop. In the RigidFix group, seven specimens failed by fracture of the bioabsorbable crosspins and three by slippage and partial rupture of the graft. In the BioScrew and SmartScrew ACL groups, all specimens failed by tendon pullout. In the RCI screw group, tendon pullout occurred in eight cases, and the graft slipped and partially ruptured in two specimens. The mean size of the grafts used in the single-cycle load-to-failure test was virtually identical between the groups: EndoButton CL (7.7 mm), Bone Mulch Screw (7.5 mm), RigidFix (7.5 mm), BioScrew (7.4 mm), RCI screw (7.4 mm), and SmartScrew ACL (7.4 mm).

Cyclic-Loading Test

The only specimens that failed during the cyclic-loading test were one in the BioScrew group and one in the RCI screw group. The residual displacement after 1500 cycles was as follows: EndoButton CL, 3.9 ± 0.7 mm; Bone Mulch Screw, 2.2 ± 0.7 mm; RigidFix, 3.7 ± 1.0 mm; BioScrew, 4.0 ± 1.4 mm; RCI screw, 3.9 ± 1.4 mm; and

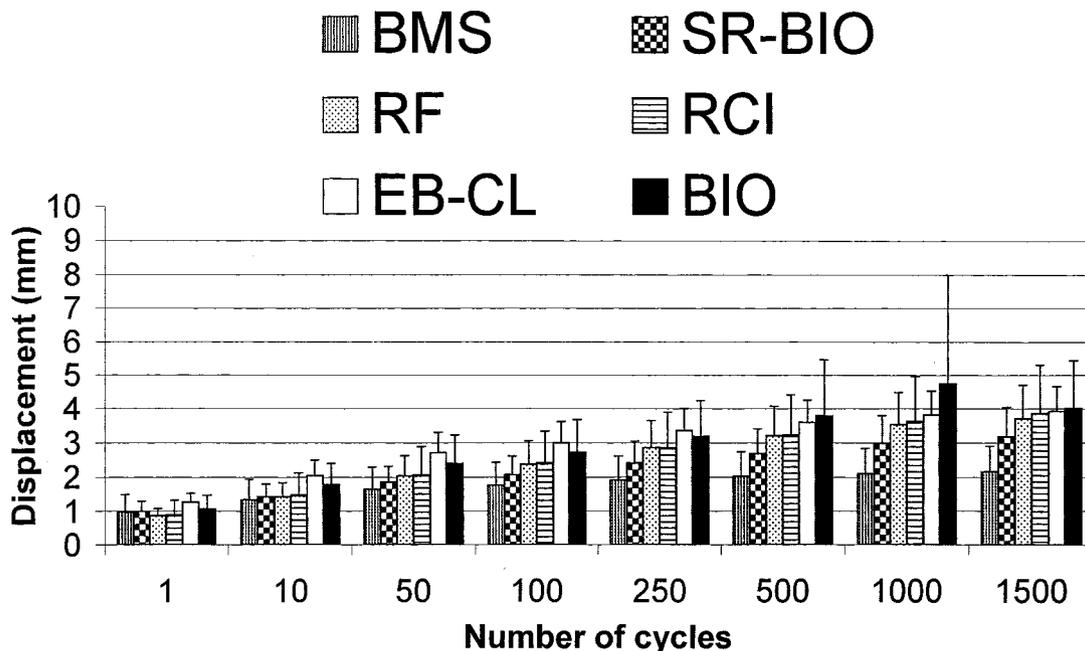


Figure 4. The mean displacement of the fixation after 1, 10, 50, 100, 250, 500, 1000, and 1500 loading cycles. The bars represent the mean and standard deviation. After 1500 cycles, the following displacement differences were statistically significant: Bone Mulch Screw (BMS) versus EndoButton CL (EB-CL), BioScrew (BIO), and RCI screw (RCI) ( $P < 0.01$ ); and Bone Mulch Screw (BMS) versus RigidFix (RF) ( $P < 0.05$ ). SR-BIO, SmartScrew ACL.

TABLE 2  
Results of Single-Cycle Loading after Cyclic Loading for Each Fixation Device

Fixation	N	Yield load (N) (mean $\pm$ SD)	Stiffness (N/mm) (mean $\pm$ SD)
EndoButton CL	10	781 $\pm$ 252	105 $\pm$ 13 <sup>a,b,c</sup>
Bone Mulch Screw	10	925 $\pm$ 280	189 $\pm$ 38
RigidFix	10	768 $\pm$ 253	136 $\pm$ 13 <sup>a</sup>
BioScrew	9	565 $\pm$ 137 <sup>d</sup>	113 $\pm$ 15 <sup>a,e</sup>
RCI screw	9	534 $\pm$ 129 <sup>d,f</sup>	134 $\pm$ 23 <sup>a</sup>
SmartScrew ACL	10	842 $\pm$ 201	162 $\pm$ 28

<sup>a</sup> Significantly different from Bone Mulch Screw ( $P < 0.001$ ).

<sup>b</sup> Significantly different from RigidFix ( $P < 0.05$ ).

<sup>c</sup> Significantly different from Smart Screw ACL ( $P < 0.001$ ).

<sup>d</sup> Significantly different from Bone Mulch Screw ( $P < 0.05$ ).

<sup>e</sup> Significantly different from SmartScrew ACL ( $P < 0.01$ ).

<sup>f</sup> Significantly different from SmartScrew ACL ( $P < 0.05$ ).

SmartScrew ACL,  $3.2 \pm 0.9$  mm (Fig. 4). The residual displacements in the EndoButton CL, RigidFix, BioScrew, and RCI screw groups were significantly greater than that in the Bone Mulch Screw group. However, there was no significant difference in the residual displacement between the Bone Mulch Screw and SmartScrew ACL groups.

The results of the single-cycle load-to-failure test subsequent to the cyclic loading are presented in Table 2. The mean yield load in the Bone Mulch Screw group was significantly greater than that in the BioScrew and RCI screw groups, and the yield load in the SmartScrew ACL group was significantly higher than that in the RCI screw group. Similar to the results of the single-cycle load-to-failure test, the highest stiffness was found in the Bone Mulch Screw group ( $189 \pm 38$  N/mm); it was significantly higher than that in the EndoButton CL, RigidFix, RCI screw, or BioScrew groups. The stiffness of the RigidFix group was significantly higher than that of the EndoButton CL group, and the stiffness of the SmartScrew ACL group was significantly higher than that in the EndoButton CL and BioScrew groups.

Analysis of the failure mode showed that in the EndoButton CL group, four specimens failed by rupture of the tendon loop and six failed by rupture of the continuous loop. In four specimens of the Bone Mulch Screw group, the tip of the device bent, allowing the graft to disengage, and six specimens in that group failed by rupture of the tendon loop. In the RigidFix group, a failure of the bioabsorbable crosspins occurred in eight specimens, whereas, in the remaining two cases, the tendons slipped and partially ruptured. In the BioScrew group, a tendon pullout occurred in nine specimens and tendon pullout/laceration occurred in one. In the RCI screw group, tendon pullout occurred in eight specimens and tendon pullout and laceration occurred twice. As in the single-cycle load-to-failure test, the mean size of the grafts used in the single-cycle subsequent to cyclic-loading test was very comparable in the different groups: EndoButton CL (7.4 mm), Bone Mulch Screw (7.6 mm), RigidFix (7.6 mm), BioScrew (7.4 mm), RCI screw (7.5 mm), and SmartScrew ACL (7.5 mm).

The mean decreases in the yield load values between the single-cycle and the single-cycle loading subsequent to cyclic-loading tests were greatest in the EndoButton CL ( $-305$  N), followed by the Bone Mulch Screw ( $-187$  N), RigidFix ( $-100$  N), BioScrew ( $-24$  N), RCI screw ( $-12$  N), and SmartScrew ACL groups ( $+48$  N). The reduction in yield load was significant in the Bone Mulch Screw and EndoButton CL groups.

## DISCUSSION

There are many choices of device to use for femoral fixation of a hamstring tendon graft, but none of the currently used soft tissue fixation devices has been proven to be biomechanically superior to the others. We compared three extraarticular or suspensory hamstring tendon graft femoral fixation methods (the EndoButton CL as a cortical suspensory sling, the Bone Mulch Screw as a proximal tunnel toggle, and RigidFix as a double crosspinning device that skewers the graft in midtunnel through the two pins that cross the graft in any place) and three apertural or anatomic fixation methods (interference screws). The results of this study showed no significant difference between the EndoButton CL, Bone Mulch Screw, and RigidFix in single-cycle load-to-failure testing. These devices generally provided better strength of fixation than did the interference screws. However, although the EndoButton CL, Bone Mulch Screw, and RigidFix implants provided significantly better strength of fixation than did the RCI screw and the BioScrew, the difference in the yield load values between the RigidFix and the SmartScrew ACL did not reach statistical significance. Thus, it cannot be generalized that the extraarticular fixation methods are superior to the anatomic ones, as it appears that variation in the characteristics of the implants within both the extraarticular and apertural fixation groups resulted in considerably different strengths of fixation. In comparing the EndoButton CL, the Bone Mulch Screw, and the RigidFix, it appears that the rigidity of the device itself improves the fixation characteristics of the implant, especially its stiffness, as the Bone Mulch Screw was found to be superior to the other two. Similarly, significant differences were observed in the fixation characteristics between the interference screws, as the SmartScrew ACL proved to be significantly better than the RCI screw or the BioScrew.

Although it has been previously speculated that the bioabsorbable material itself (mainly poly-lactide in various forms) would somehow enhance the strength of fixation of interference screws over that of metal counterparts,<sup>26</sup> we suggest instead that the difference in strength of fixation is attributable to the differences in the design (geometry, core diameter, and pitch/thread height) among the screws. Increased thread height has previously been shown to increase the strength of fixation of the bone-patellar tendon-bone graft,<sup>27</sup> whereas an increase in the thread height was shown to be less important in the fixation of hamstring tendon graft.<sup>25</sup> In comparison with the RCI screw, the lower pitch/thread height and the greater core diameter of the bioabsorbable screws is especially evident in the SmartScrew ACL, as can be readily seen in

Figure 1. In accordance with common engineering principles, this type of design results in higher compressive forces between the screw and the surrounding bone, possibly resulting in the improved strength of fixation in the SmartScrew ACL group compared with the BioScrew and especially the RCI screw groups.

In agreement with our findings, Giurea et al.<sup>10</sup> recently showed that design of the interference screw indeed has an effect on slippage of soft tissue fixation under cyclic loading conditions. After 1100 loading cycles at 150 N, the RCI screw allowed a mean displacement of  $6.8 \pm 5.6$  mm, which was more than three times higher than that observed with interference screws specifically designed for the fixation of soft tissue grafts. The authors further reported that the tendon grafts were damaged in the specimens fixed with a metal RCI screw, apparently by the sharp proximal thread of the screw. However, there was no damage when the titanium interference screw specifically designed for soft tissue grafts was used.

During early aggressive rehabilitation, an ACL reconstruction is subjected to periodic incidental high loads and thousands of loading cycles that potentially progressively decrease the failure load before graft-to-tunnel healing. Experimental single pullout and cyclic loading, as performed in this and other studies, more closely resembles the actual loading circumstances that occur in vivo to the ACL reconstruction. The considerable differences seen in the results of the single-cycle and the cyclic-loading tests show the importance of inclusion of both of these methods in the testing protocol. Despite very comparable initial strength of fixation in the single-cycle load-to-failure test, the EndoButton CL and RigidFix groups showed increased residual displacement compared with the Bone Mulch Screw in the cyclic-loading test. Because the titanium button of the EndoButton CL did not show any visible changes during cyclic loading, the difference in residual displacement compared with the Bone Mulch Screw was most likely attributable to either change in the continuous loop of polyester or in the implant-graft interface. The increased residual displacement seen in the RigidFix was most likely due to gradual bending and ultimately failure of one or both of the two bioabsorbable pins. The BioScrew and the RCI screw showed significantly higher residual displacement than did the Bone Mulch Screw, whereas the SmartScrew ACL and the Bone Mulch Screw had comparable residual displacement. The only complete failures of fixation observed during the cyclic testing of all 120 specimens was one in the BioScrew group and one in the RCI screw group, which supports the results of previous biomechanical studies that question the suitability of interference screws in the fixation of hamstring tendon grafts.<sup>11,14,15</sup> However, the SmartScrew ACL performed second-best in the cyclic-loading tests, demonstrating that the design of the screw clearly has an influence on the strength of fixation and indicating that more study on this matter is necessary before interference screws are condemned for use in soft tissue fixation.

It is difficult to compare one study with another because the experimental methods vary so widely. For instance, To

et al.,<sup>24</sup> in their study of quadrupled hamstring tendon grafts fixed to human cadaveric bone, found the stiffness of the Bone Mulch Screw construct to be twice that found in our study. In their study, the grafts were preconditioned for a longer period and at higher loads than in our study, and they used the same grafts for performing multiple studies. This preconditioning and repetitive loading of grafts eliminated the natural elastic creep in the graft before testing the Bone Mulch Screw. In our study, stiffness of the Bone Mulch Screw fixation increased by 64% after cyclic loading, although the loads in our cyclic-loading protocol (between 50 and 200 N) were well within the presumed elastic region of hamstring tendons. Our findings of increased stiffness values in all of the study groups in the single-cycle test after cyclic testing compared with single-cycle testing alone supports the concept that grafts should be subjected to preconditioning before fixation.<sup>8,9</sup> Furthermore, it seems reasonable that grafts were used only once (single use only) in the biomechanical testing of the ACL reconstruction.

The results of our study showed that all of the tested graft fixation constructs yielded 1 to 2 mm during the first 10 loading cycles between 50 and 200 N. This initial increase in the residual displacement most likely resulted from stretching of the normal creep in the graft fixation construct and could be minimized in the clinical setting by meticulous preconditioning of the graft. In comparison, in an identical cyclic-loading testing protocol that used porcine knee specimens,<sup>13</sup> we found that a bone-patellar tendon-bone graft fixed with an interference screw yielded only 0.65 and 1.5 mm residual displacement after 10 and 1500 loading cycles, respectively. The bone-patellar tendon-bone graft, a considerably stiffer material that is usually fixed securely bone-to-bone, apparently does not require preconditioning before in vitro biomechanical testing.<sup>13</sup> However, in the clinical setting, a few loading cycles are generally recommended after fixation of the femoral side to stretch out the fibers of the graft and to test the femoral fixation before tibial fixation.

Nagarkatti et al.<sup>16</sup> demonstrated the importance of preconditioning soft tissue ACL grafts. In their study, free central quadriceps tendon grafts fixed with bioabsorbable screws were first subjected to 250 cycles of preconditioning at 0 to 75 N. They were then cycled 5000 times at a load of 0 to 150 N and had an average of only 1.3 mm of residual displacement at the end of the study. In this respect, if the first 250 cycles of the cyclic loading protocol of our study were considered preconditioning, then the residual displacement during cyclic loading of all six fixation devices would be considerably reduced, particularly so for the EndoButton CL and the Bone Mulch Screw (Fig. 4). We did not precondition the grafts in this study because we used the same protocol that was used in our previous patellar tendon graft fixation study.<sup>13</sup> Although this lack of preconditioning did not invalidate the findings of our study, we recommend preconditioning of hamstring tendon grafts in future studies of this nature. Additionally, our findings support the clinical work of Yasuda et al.,<sup>30</sup> which showed that hamstring tendon grafts preconditioned to 80 N before fixation resulted in significantly less

knee laxity at 2 years compared with those pretensioned at 20 N.

By studying each device with single-cycle load-to-failure testing and single-cycle load-to-failure testing after cyclic loading, we were able to demonstrate deterioration of fixation during cyclic loading. There was a statistically significant decrease in the strength of fixation of the EndoButton CL and the Bone Mulch Screw and a substantial decrease in the fixation of the RigidFix, whereas the fixation strength of the interference screws was practically unchanged. The Bone Mulch Screw still remained significantly superior to the BioScrew and the RCI screw after cyclic loading.

Some methodologic issues should be addressed to permit better interpretation of the results of this study and to adequately compare them with those of previous studies comparing various hamstring tendon graft fixation alternatives.<sup>2,3,5,6,10,12,15,17,22–25,29</sup> First, the quality of bone has been shown to influence strength of fixation of hamstring tendon grafts in ACL reconstruction.<sup>3,10,15</sup> Porcine knees are the most commonly used source of bone for testing various ACL fixation methods, despite their clearly higher (*volumetric*) bone density than human bones.<sup>19</sup> It has been shown that the strength of fixation of the interference screw for a quadrupled hamstring tendon graft is strongly related to the density of the bone to which it is attached<sup>3</sup> and that bone density may also have an effect on other hamstring tendon graft fixations. Therefore, human cadaveric bone from a young healthy donor would be optimal for biomechanical testing of different ACL fixation methods. In a previous study from our institution,<sup>19</sup> the true *volumetric* trabecular bone density (in grams per cubic centimeter), as assessed by a peripheral quantitative CT scanner, of 60% of the porcine specimens used in the biomechanical hamstring tendon graft fixation tests were within the range observed in our human control sample. The biomechanical data from these less-dense porcine specimens did not differ significantly from data from porcine specimens with higher density. Furthermore, the quality of human bone specimens often varies considerably. Thus, porcine knee specimens, with presumably more uniform bone quality, offer a reasonable alternative to use of human bone, especially if comparisons are made between various implants *within* one study.

Second, the protocol used in this study allowed for isolation of a single attachment site, a method that has been suggested to provide more accurate information about a specific fixation device at a specific location.<sup>1</sup> Coupled with application of force parallel to the femoral tunnel, this means of testing provided the purest test for pullout strength, but under circumstances that less precisely mimicked the actual reconstruction situation.

Third, contrary to most of the previous studies,<sup>3,5,10,12,17,22–25,29</sup> we used the yield load as the outcome parameter instead of the ultimate failure load. However, we strongly believe that the ultimate failure load has little clinical relevance, because the first significant slippage of the ACL graft typically occurs at a yield load point that is the beginning of abnormal laxity. The difference between the yield and ultimate failure load was previously

discussed and illustrated in detail<sup>6,19</sup> and is readily demonstrated in Figure 2.

In conclusion, of the six different fixation devices subjected to identical, comprehensive biomechanical testing, the Bone Mulch Screw was superior in securing quadrupled hamstring tendon graft in the femoral drill hole. In all tested implants, the majority of residual displacement developed during the first 250 loading cycles of the cyclic-loading regimen, bringing attention to the importance of graft preconditioning. However, although the observed increase in residual displacement might actually be considerably diminished by meticulous preconditioning of the graft-implant complex before fixation, some caution should be exercised during rehabilitation when the EndoButton CL, RigidFix, BioScrew, or RCI screw is used for femoral fixation in ACL reconstruction.

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