

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

Part II: Tibial Site*

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Background: Tibial fixation is more problematic than femoral fixation in anterior cruciate ligament reconstruction.

Hypothesis: There is no difference in initial fixation strength among hamstring tendon graft tibial fixation devices.

Study Design: Randomized experimental study.

Methods: Each of six devices used to fix 120 quadrupled human semitendinosus-gracilis tendon grafts into porcine tibiae was tested 10 times with a single-cycle load-to-failure test and 10 times with a 1500-cycle loading test. Specimens surviving cyclic loading were subjected to a single-cycle load-to-failure test.

Results: Intrafix (1332 N) was the strongest in the single-cycle load-to-failure test, followed by WasherLoc (975 N), tandem spiked washer (769 N), SmartScrew ACL (665 N), BioScrew (612 N), and SoftSilk (471 N). After cyclic-loading tests, Intrafix showed the lowest residual displacement (1.5 mm) and was also strongest (1309 N) in the single-cycle load-to-failure test after the cyclic-loading test, followed by WasherLoc (3.2 mm; 917 N).

Conclusion: The Intrafix provided clearly superior strength in the fixation of hamstring tendon grafts to the tibial drill hole.

Clinical Relevance: Some caution may be warranted when using the implants that showed increased residual displacement, especially if aggressive rehabilitation is to be used. Preconditioning of the hamstring tendon graft-implant complex before tibial fixation is needed.

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Rigid fixation of the ACL graft has been recognized as one of the most important factors determining the long-term success of ACL reconstruction, especially when hamstring tendon grafts are used.³⁻⁵ Tibial fixation is commonly considered more problematic than femoral fixation because forces on the ACL substitute are parallel to the tibial drill hole,^{3,9} the bone quality of the tibial metaphy-

sis is inferior to that of the femur,^{2,17} and the four-tailed end of the hamstring tendon graft that is fixed to the tibia is more difficult to secure. Through whipstitching, the looped end of the graft can also be packaged into a more compact form than the four-tailed end and more easily pulled through the tibial drill hole and the knee joint space into the femoral drill hole than vice versa. When interference screws are used in the tibia, they are inserted from the outside-in, producing forces that are counter to the direction of the tension on the graft, as opposed to the femoral side, where the screw is placed from the inside-out, thus wedging the graft during screw insertion.

Previous studies comparing different tibial fixation methods have provided somewhat controversial results. Magen et al.⁸ used human tendons and bones to show that

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

tandem washers and the WasherLoc (Arthrotek, Inc., Warsaw, Indiana) provided significantly higher yield loads and significantly less slippage compared with a titanium interference screw in resisting a rapidly increasing progressive cyclic-loading protocol. Giurea et al.⁶ found that a stirrup anchoring the looped end of the quadrupled hamstring tendon graft in the tibial drill hole and the interference screws specifically designed for the fixation of soft tissue graft in the femoral drill hole showed superior resistance to slippage at low loading levels (0 to 150 N) of cyclic loading compared with a clawed washer and a normal round-headed cannulated interference (RCI) screw. In regard to interference screws in general, it has been shown that the strength of fixation of the soft tissue graft is influenced by several variables, such as the density of the bone,² the insertion torque,² and the geometry,^{6,18} and material of the screw.¹⁹ However, there is controversy over the effects of screw length on graft fixation strength.^{13,16,19}

The objective of this second part of our study was to evaluate the strength of fixation of six different devices in the fixation of quadrupled hamstring tendon graft to the tibia by using both single-cycle load-to-failure and cyclic-loading testing.

MATERIALS AND METHODS

Specimens

Six different tibial fixation devices (Fig. 1) were evaluated with the use of 120 mature porcine tibiae and 120 pairs of human cadaveric semitendinosus and gracilis tendons. The freshly harvested tendons were cleared of adherent muscle fibers and surrounding soft tissues, wrapped in gauze soaked in saline solution, and stored at -25°C in small sealed plastic bags. The 120 skeletally mature porcine tibiae were obtained fresh from a local slaughterhouse, treated in similar fashion, and stored at -25°C in sealed plastic bags. These preservation procedures have no deleterious effect on the mechanical properties of the tendons or bones.^{11,20}

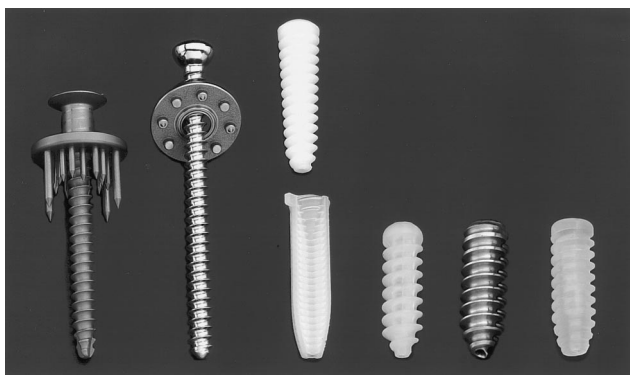


Figure 1. The implants used in this study were, from left to right, WasherLoc, tandem spiked washer, Intrafix, BioScrew, SoftSilk interference screw, and SmartScrew ACL.

Preparation and testing were performed at room temperature, and the specimens were kept moist with saline spray throughout the study. All fixations were performed according to the manufacturer's instructions by using device-specific instrumentation. The tibial drill holes were drilled from the anteromedial tibial cortex to the original tibial insertion site of the ACL. The 120 specimens were randomly assigned into six study groups of 20 specimens each.

Study Groups and Fixation Procedures

WasherLoc. For preparation of the hamstring tendon grafts, 4 to 5 cm of each end of the semitendinosus and gracilis tendons were first sutured with a running 3-0 suture and then with a 1-0 whipstitch suture (Vicryl suture, Ethicon, Somerville, New Jersey). The diameter of the quadrupled tendon graft was then sized in 1-mm increments with sizing sleeves, and the corresponding cannulated reamer was used to drill the tibial tunnel. The looped end of the graft and the tibia were secured while manual traction was applied to the four tendon limbs to equalize the tendons. The 20-mm WasherLoc was then impacted with a mallet into a 17-mm counterbore recess at the distal tunnel opening perpendicular to the tibial tunnel and secured with a self-tapping WasherLoc compression screw. Each of the four tendon limbs of the graft was carefully positioned between the four longer peripheral spikes of the washer.

Tandem Spiked Washer. Each of the four limbs of the quadrupled graft was sutured in a whipstitch fashion (No. 2-0 Vicryl suture, Ethicon). The graft diameter was then measured in 0.5-mm increments with Graft Sizing Tubes (Acufex, Mansfield, Massachusetts), and a tibial tunnel equal to the graft diameter was drilled with a tibial compaction drill bit. In a procedure similar to that used for the WasherLoc, the looped end of the graft and the tibia were first secured. The graft was then fixed under manual traction to the anteromedial tibial cortex distal to the tibial tunnel opening by using a figure-of-8 technique to weave the tendons in opposite directions around two 14×1.3 mm metal spiked washers (Linva-tec Inc., Largo, Florida) and two 4.5-mm bicortical AO screws in tandem fashion.^{1,8}

Intrafix. Four to five centimeters of each end of the semitendinosus and gracilis tendons were whipstitched with 2-0 braided polyglycolic acid suture. The diameter of the graft was measured in 0.5-mm increments, and a tibial tunnel was drilled 0.5 mm larger than the graft by using a compaction drill. Once the looped end of the graft and the tibia were secured on the testing machine, the sutures extending from each of the four free ends of the gracilis and semitendinosus tendons were tied together and looped over the arms of a Tie Tensioner (Innovative Devices Inc., Marlborough, Massachusetts). While the Tie Tensioner was pulled distally to equalize the tendons, a Sheath Trial (Innovative Devices Inc.) was first gently tapped with a mallet to separate the tendons, and then the Intrafix Sheath (Innovative Devices Inc.) was inserted into the tibial tunnel. Finally, an 8.0-mm diameter Intra-

fix tapered screw (Innovasive Devices) was inserted into the sheath.

Interference Screws. The semitendinosus and gracilis tendons were looped, and both ends of the graft were sutured together in whipstitch fashion for 40 mm to create a compact bundle while constant tension was maintained on all four strands. The diameter of the graft was measured by using sizing tubes in 0.5-mm increments to determine the correct size of the tibial tunnel. A guide wire was drilled into the tibia in the desired position, and the tunnel was drilled with a compaction drill (Acufex Microsurgical, Inc.). With the aid of the passing suture, the looped end of the graft was pulled through the tibial tunnel, leaving the tightly sutured four-tailed end of the graft within the tibial tunnel. The looped end of the graft and the tibia were then secured on the testing machine. Finally, with a constant manual tension maintained on all four tendon strands, a guide wire was passed on the anterior surface of the graft up the tunnel. The interference screw was inserted over the guide wire through the external orifice to a point flush with the internal orifice.

BioScrew. Before the insertion of an 8 × 25 mm bioabsorbable poly-L-lactide BioScrew (Linvatec Inc., Largo, Florida) interference screw, a notcher provided by the manufacturer was used to enhance starting and to accommodate the screw heads.

SoftSilk. A conventional 8 × 25 mm SoftSilk titanium interference screw (Acufex Microsurgical, Inc.) was used.

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 8 × 25 mm bioabsorbable self-reinforced L-lactide/D-lactide (PLA96/4) copolymer SmartScrew ACL (Bionx Implants Inc., Blue Bell, Pennsylvania) interference screw was inserted into the tibial drill hole.

Biomechanical Testing

Biomechanical testing was performed according to the methods described in our previous article on bone-patellar tendon-bone graft fixation⁷ and in Part I of this study. Briefly, the tibiae were mounted to the testing machine (Lloyd LR 5K, J. J. Lloyd Instruments, Southampton, United Kingdom) by threaded bars and specially designed clamps. The tendons were equalized by maintaining a constant manual traction on all four strands of the graft. Then the looped end was secured into a specially designed soft tissue clamp (Fig. 2).¹⁹ A 25-mm length of graft, corresponding to the intraarticular portion of the ACL, was left between the clamp and the intraarticular tunnel opening. The testing protocol consisted of a single-cycle load-to-failure test and a cyclic-loading test. After the cyclic loading, the surviving specimens were subjected to a single-cycle load-to-failure test.

Statistical Analysis

One-way analysis of variance with 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

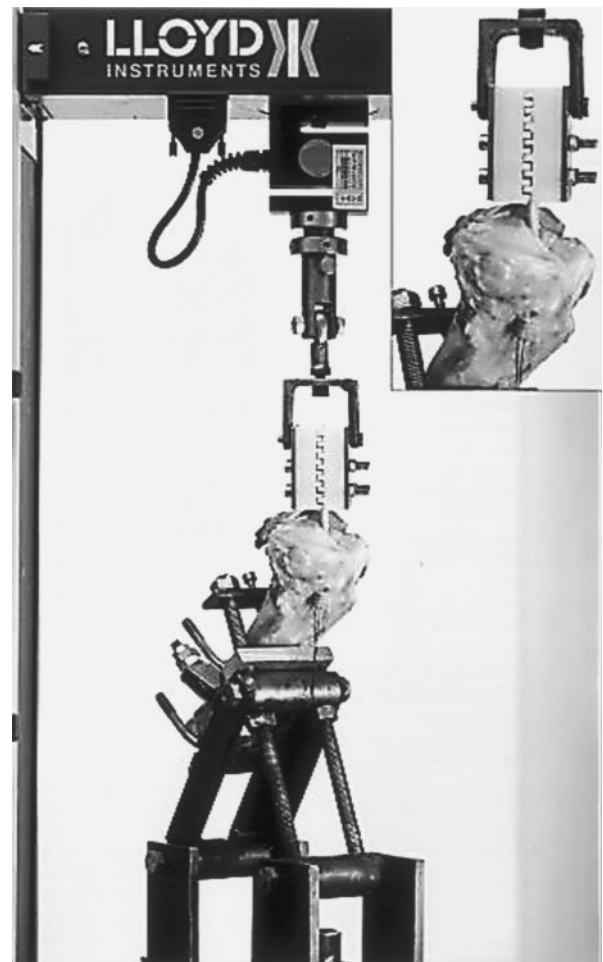


Figure 2. The specimen was mounted in the materials testing machine so that the load was applied parallel to the long axis of the tibial drill hole.

single-cycle subsequent to cyclic-loading yield loads was compared by using an unpaired *t*-test. A *P* value of less than 0.05 was considered statistically significant for 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 yield load for the Intrafix (1332 N) was significantly greater than those in the other fixations. The yield load for the WasherLoc (975 N) was significantly higher than for all of the interference screws. The highest stiffness was found in the Intrafix group (223 ± 62 N/mm), which had significantly higher stiffness than the other fixations. The stiffness of the SmartScrew ACL group was also significantly higher than that of the SoftSilk group.

In the WasherLoc and tandem spiked washer groups, all specimens failed by slippage and partial tearing of the tendon. In the Intrafix group, seven tendons were pulled past the implant and partially ruptured and in one spec-

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

Fixation	N	Yield load (N) (mean ± SD)	Stiffness (N/mm) (mean ± SD)
WasherLoc	10	975 ± 232 ^a	87 ± 23 ^a
Tandem spiked washers	10	769 ± 141 ^b	69 ± 14 ^b
Intrafix	10	1332 ± 304	223 ± 62
BioScrew	10	612 ± 176 ^{b,c}	91 ± 34 ^b
SoftSilk	10	471 ± 107 ^{b,d,e}	61 ± 12 ^{a,f}
SmartScrew ACL	10	665 ± 201 ^{b,g}	115 ± 34 ^b

^a Significantly different from Intrafix ($P < 0.01$).
^b Significantly different from Intrafix ($P < 0.001$).
^c Significantly different from WasherLoc ($P < 0.01$).
^d Significantly different from WasherLoc ($P < 0.001$).
^e Significantly different from tandem spiked washer ($P < 0.05$).
^f Significantly different from SmartScrew ACL ($P < 0.05$).
^g Significantly different from WasherLoc ($P < 0.05$).

imen the implant moved forward; in two specimens one of the four tendon strands of the graft was ruptured. In the BioScrew and SmartScrew ACL groups, all specimens failed by tendon pullout. In the SoftSilk group, tendon pullout occurred in eight specimens and the graft was partially ruptured in two.

Cyclic-Loading Test

The residual displacements induced by cyclic loading for the different fixation devices are summarized in Figure 3. The only failure that occurred during the cyclic-loading test was of one specimen in the SoftSilk group. The residual displacements after 1500 cycles were as follows:

WasherLoc, 3.2 ± 1.5 mm; tandem spiked washer, 4.2 ± 2.6 mm; Intrafix, 1.5 ± 0.3 mm; BioScrew, 4.1 ± 1.2 mm; SoftSilk, 4.7 ± 1.5 mm; and SmartScrew ACL, 3.8 ± 1.5 mm. The residual displacement in the tandem spiked washer, BioScrew, SoftSilk, and SmartScrew ACL groups was significantly greater than that in the Intrafix. However, the residual displacements of the Intrafix and WasherLoc groups did not differ significantly.

The results of the single-cycle load-to-failure test subsequent to cyclic loading are presented in Table 2. The yield load in the Intrafix group was significantly greater than that in the other fixation groups, and the yield load for the WasherLoc group was significantly higher than that in the tandem spiked washer, BioScrew, and SoftSilk groups. As in the single-cycle load-to-failure test, the highest stiffness was found in the Intrafix group (267 ± 36 N/mm); it was significantly higher than that of the other fixation groups. The stiffness of the SmartScrew ACL group was significantly higher than that of the tandem spiked washer, BioScrew, and SoftSilk groups.

Failure mode analysis showed that in the WasherLoc and tandem spiked washer groups all specimens failed by slippage and partial tearing of the tendon. In the Intrafix group, tendon pullout occurred in eight specimens, the Intrafix moved in one specimen, and the tendon ruptured in one specimen. In the BioScrew group, tendon pullout occurred in nine specimens and tendon pullout/laceration occurred in one. In the SoftSilk group, tendon pullout occurred in six specimens and pullout/laceration occurred in four. In the SmartScrew ACL group, all specimens failed by tendon pullout.

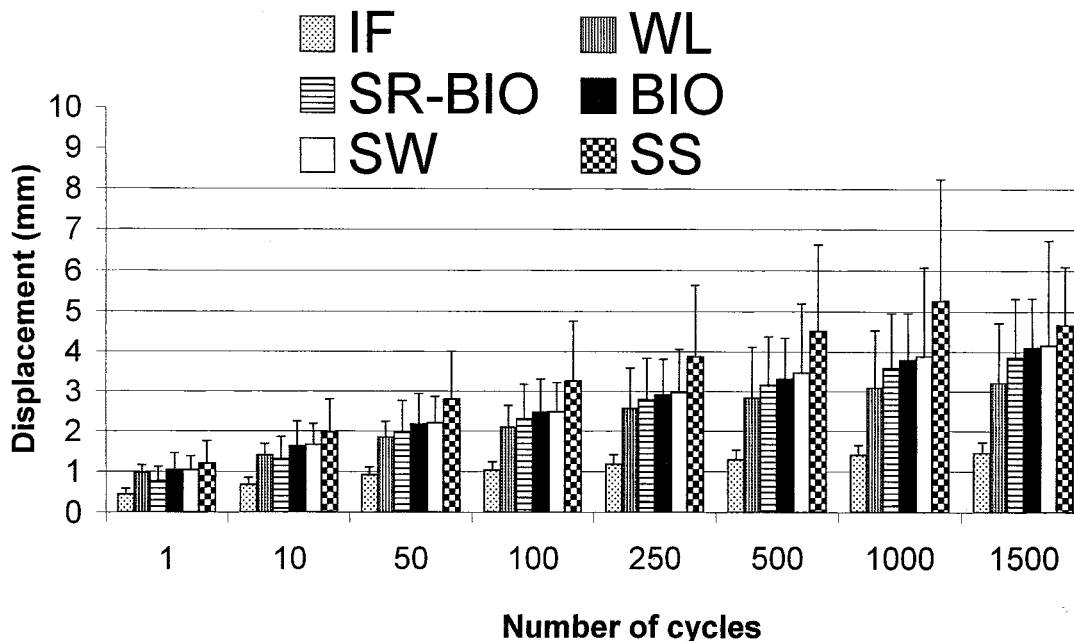


Figure 3. The mean displacement of the fixation after 1, 10, 50, 100, 250, 500, 1000, and 1500 loading cycles. After 1500 cycles, the following displacement differences were statistically significant: Intrafix (IF) versus SoftSilk (SS) ($P = 0.001$); Intrafix (IF) versus BioScrew (BIO), tandem spiked washer (SW), and SmartScrew ACL (SR-BIO) ($P < 0.05$). The bars represent the mean and standard deviation. WL, WasherLoc.

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)
WasherLoc	10	917 \pm 234 ^a	127 \pm 22 ^b
Tandem spiked washers	10	675 \pm 190 ^{b,c}	108 \pm 26 ^{b,d}
Intrafix	10	1309 \pm 302	267 \pm 36
BioScrew	10	567 \pm 156 ^{b,e}	125 \pm 23 ^{b,d}
SoftSilk	9	423 \pm 75 ^{b,f}	120 \pm 18 ^{b,d}
SmartScrew ACL	10	694 \pm 173 ^b	159 \pm 25 ^b

^a Significantly different from Intrafix ($P < 0.01$).

^b Significantly different from Intrafix ($P < 0.001$).

^c Significantly different from WasherLoc ($P < 0.05$).

^d Significantly different from SmartScrew ACL ($P < 0.05$).

^e Significantly different from WasherLoc ($P < 0.01$).

^f Significantly different from WasherLoc ($P < 0.001$).

The decrease in yield load values between the single-cycle test and the single-cycle test subsequent to cyclic loading was not significant between the groups.

DISCUSSION

In this second part of our comprehensive biomechanical evaluation of different fixation alternatives for use with hamstring tendon graft in ACL reconstruction, the tested fixation implants for the tibia were chosen to differ by type and location of fixation. The WasherLoc secures the graft at the external tibial aperture, and the tandem spiked washers have an even longer working length because they are placed completely outside the tibial tunnel. The Intrafix may be considered a semi-aperture fixation, as the 30-mm plastic sheath extrudes distally from the entrance of the tibial drill hole, and, thus, in a normal tibial tunnel of 35 to 45 mm in length, leaves 5 to 15 mm of free graft within the proximal opening (aperture) of the drill hole. Finally, interference screws can be considered truly anatomic (apertural) fixations because they can be advanced to the internal tibial tunnel orifice.

In regard to the most appropriate biomechanical criteria for use in assessing the quality of an ACL fixation device, Magen et al.⁸ recently proposed that, instead of simply evaluating the yield load and the maximum load to failure of a fixation device, other equally important characteristics should be included in the analysis. For instance, the ability of a fixation to resist slippage under cyclic loading and the ability to restore normal stiffness of the knee were mentioned as other important characteristics. They followed this proposed principle in their two-phase study design, in which six different fixation devices were initially used in porcine bones and tendons, after which the three best were tested again with use of human cadaveric tissues.⁸ For assessment of the strength of hamstring tendon graft fixation in the tibia, their study also included a cyclic-loading protocol in which loads were progressively increased in 50-N increments until failure of the fixation.⁸ Their cyclic-loading protocol of rapidly increasing loading has to be considered relatively strenuous and was also quite different from our constant loading

between 50 and 200 N. Therefore, comparison of the loading-induced residual displacements between the two studies is difficult. However, in both studies, the only complete failures of fixation during cyclic loading were observed in the interference screw fixation group, suggesting that caution may be warranted in the early phase of postoperative rehabilitation of an ACL reconstruction when soft tissue grafts are fixed with interference screws.

The cyclic loading-induced slippage of the grafts fixed with interference screws was further exacerbated in the second part of the study of Magen et al.,⁸ in which the experiments were performed on young human cadaveric specimens. The tandem washers and WasherLoc were shown to provide significantly higher yield load values and significantly less slippage compared with the titanium interference screw. Furthermore, similar to the series that used porcine knees, complete failures of the fixation were considerably more common in the interference screw group than in the other two groups. On the basis of the substantially lower yield loads and greater slippage obtained when interference screws were used to fix hamstring tendon grafts in human bone compared with porcine tendons fixed in porcine bone, the authors concluded that caution is warranted when animal tissues are used for predicting the performance of interference screws in human ACL fixation. They stated that the possible explanation may be the difference in bone density between tissue sources.

Although there are methodologic differences between our study and that of Magen et al.⁸ that make any direct comparison of the results difficult, the similar failure load values seen for the titanium interference screws and the WasherLoc in our study compared with their human bone and tendon studies suggest that porcine bones with human cadaveric tendons provide a relatively good surrogate for the evaluation of human ACL reconstruction. Thus, the clearly higher values that Magen et al.⁸ obtained when using porcine specimens seem to be attributable to the tendons they used rather than to the difference in the density of the bones, suggesting that the denser porcine tendons apparently provided the implants with a better grip than did the human cadaveric tendons. However, given the obviously denser (also volumetrically denser)¹⁰ bone in porcine specimens than in humans, the effect of which can naturally not be overlooked, the results of our study presumably err toward being overly optimistic in comparison with the situation in humans. As also previously speculated by Giurea et al.,⁶ this possible "bone-density-engendered" excess strength of fixation especially concerns fixations that rely on friction to secure the tendons, such as the interference screws and the Intrafix, and to a lesser extent, the WasherLoc and the tandem spiked washers. The authors also proposed that single-cycle load-to-failure tests are not sufficient for testing hamstring tendon graft fixation, and, thus, they added low-level cyclic loading to mimic walking and high-level cyclic loading to mimic running to their testing protocol.⁶ On the basis of the results of their cyclic-loading experiments, the authors concluded that ACL reconstructions with hamstring tendons will slacken if rehabilitation is too aggressive before

tendon-to-bone healing is achieved.⁶ In our study, the Intrafix showed its superiority in the ability to resist slippage under cyclic loading.

The methods used for determining stiffness of an ACL reconstruction vary widely. As a way to investigate the contribution of the location of tibial fixation to the stiffness of the graft-fixation complex, the length of the graft from the clamp to the internal tibial orifice was kept constant at 25 to 30 mm, equal to normal ACL length. Again, the Intrafix was found to provide superior stiffness to all other implants in both tests. However, disproving the current theory on the effect of location of the fixation implant within the drill hole, the shorter working length of the apertural methods did not appear to improve the stiffness of the constructs in comparison with that of the more distal WasherLoc and cortical tandem spiked washers (Tables 1 and 2). It was also readily discernible that cyclic loading induced a substantial increase in the stiffness of the reconstructions, as the stiffness values of the single-cycle loading test were considerably higher after cyclic loading (Table 2) than those of single-cycle loading only (Table 1). This cyclic loading-induced increase in the stiffness of ACL reconstruction is likely attributable to the altered viscoelastic properties (diminished creep) of the tendon graft, as has been demonstrated earlier with human patellar and quadriceps tendons.¹² Because of the improvements in certain implant groups, recommendations favoring careful preconditioning of soft tissue grafts before fixation to prevent graft tension loss might actually be warranted. Simultaneously, it also has to be realized that the need to precondition appears to be "implant-specific." With some implants, vigorous preconditioning could merely result in overtensioning of the graft, rather than the desired improved stability. In fact, location of the drill holes is the most important factor determining success of ACL reconstruction, as a grossly nonisometric placement of the graft can hardly be compensated for by other factors, such as rigid fixation or proper intraoperative preconditioning. Among the unfavorable consequences, a poor graft placement can result in excessive intraarticular graft excursions, which can be further exacerbated if the tibial end of the graft is fixed with the knee in flexion and not in full extension, where the graft will be longest.

As also discussed in the first part of this study, the strength of interference screw fixation has been shown to be affected by many variables. In the evaluation of factors influencing strength of fixation of hamstring tendon grafts in ACL reconstruction, Brand et al.² concluded that the fixation strength of a quadrupled hamstring tendon graft fixed with interference screws is closely related to the density of the bone. The higher bone mineral density of porcine tibia in comparison with human tibia might have worked in favor of the Intrafix in comparison with the WasherLoc and the tandem spiked washers, which depend less on friction. The higher bone density should also favor the Intrafix over the interference screws because the concentrically placed screw forces a larger surface area of the tendons against the wall of the tunnel. It was shown by Shino

and Pflaster¹⁴ that concentric placement of the screw could improve the fixation of hamstring tendon graft in the tibial tunnel, whereas Simonian et al.¹⁵ found no difference in fixation strength when hamstring tendons were fixed in polyurethane tunnels by either concentric or eccentric placement of interference screws.

It has also been previously shown that bioabsorbable screws provide a better strength of fixation than their metal counterparts.¹⁹ In our study, despite an apparent trend, the only statistically significant difference between metal and bioabsorbable screws was observed in stiffness of the fixation (SmartScrew ACL versus SoftSilk). Concerns regarding the adequacy of strength of fixation of interference screws in securing soft tissue grafts into the biomechanically more demanding tibial bone tunnel led to the introduction of longer screws. To date, there are two studies showing improved strength of fixation of the soft tissue graft in the tibia with increased screw length,^{13,18} whereas, in the study by Stadelmeier et al.,¹⁶ no extra benefit was found by increasing the screw length from 20 to 40 mm.

In conclusion, the results of this study showed that the Intrafix provided clearly superior strength of fixation to that of all the other tested implants in fixation of hamstring tendon graft in the tibial drill hole.

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