Biomechanical Comparison of Hamstring Tendon Fixation Devices for Anterior Cruciate Ligament Reconstruction: Part 2. Four Tibial Devices

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Abstract

We conducted a study to biomechanically compare 4 tibial hamstring tendon fixation devices commonly used in anterior cruciate ligament reconstruction.

Quadrupled human semitendinosus–gracilis tendon grafts were fixed into porcine tibias using 4 separate fixation devices. For each device, 10 specimens were tested (1500-cycle loading test at 50-200 N). Specimens surviving the cyclic loading then underwent a single load-to-failure test. Failure mode, stiffness, ultimate load, and residual displacement were recorded.

Eight of 10 Delta screw (Arthrex), 2 of 10 Retroscrew (Arthrex), 10 of 10 WasherLoc (Arthrotek), and 10 of 10 Intrafix (Depuy Mitek) devices completed the 1500-cycle loading test. Residual displacement was significantly ($P < .001$) lower for Intrafix (2.9 mm), WasherLoc (5.6 mm), and Delta (6.4 mm) than for Retroscrew (25.5 mm). Mean stiffness was significantly ($P < .05$) higher for Intrafix (129 N/mm) than for the other devices. Mean load to failure was highest for Intrafix (656 N), then WasherLoc (630 N), Delta (430 N), and Retroscrew (285 N).

The Intrafix device demonstrated superior strength in the fixation of hamstring grafts in the tibia. WasherLoc was close behind.

Of the procedures performed by surgeons specializing in sports medicine and by general orthopedists, anterior cruciate ligament (ACL) reconstruction remains one of the most common.[1] Recent years have seen a trend toward replacing the "gold standard" of bone–patellar tendon–bone autograft with autograft or allograft hamstring tendon in ACL reconstruction.[2] This shift is being made to try to avoid the donor-site morbidity of patellar tendon autografts and decrease the incidence of postoperative anterior knee pain. With increased use of hamstring grafts in ACL reconstruction, it is important to determine the strength of different methods of graft fixation.

Rigid fixation of hamstring grafts is recognized as a crucial factor in the long-term success of ACL reconstruction. Grafts must withstand early rehabilitation forces as high as 500 N.[2] There is therefore much concern about the strength of tibial fixation, given the lower bone density of the tibial metaphysis versus the femoral metaphysis. In addition, stability is more a concern in the tibia, as the forces are directly in line with the tibial tunnel.[3,4]

The challenge has been to engineer devices that provide stable, rigid graft fixation that allows expeditious tendon-to-bone healing and increased construct stiffness. Many new fixation devices are being marketed. There is much interest in determining which devices have the most fixation strength,[4-9] but so far several products have not been compared with one another.

We conducted a study to determine if tibial hamstring fixation devices used in ACL reconstruction differ in fixation strength. We hypothesized we would find no differences.

Materials and Methods

Forty porcine tibias were harvested after the animals had been euthanized for other studies at our institution. Our study was approved by the institutional animal care and use committee. Specimens were stored at −25°C and, on day of testing, thawed to room temperature. Gracilis and semitendinosus tendon grafts were donated by a tissue bank (LifeNet Health, Virginia Beach, Virginia). The grafts were stored at −25°C; on day of testing, tendons were thawed to room temperature.

We evaluated 4 different tibial fixation devices (**Figure 1**): Delta screw and Retroscrew (Arthrex, Naples, Florida), Wash-
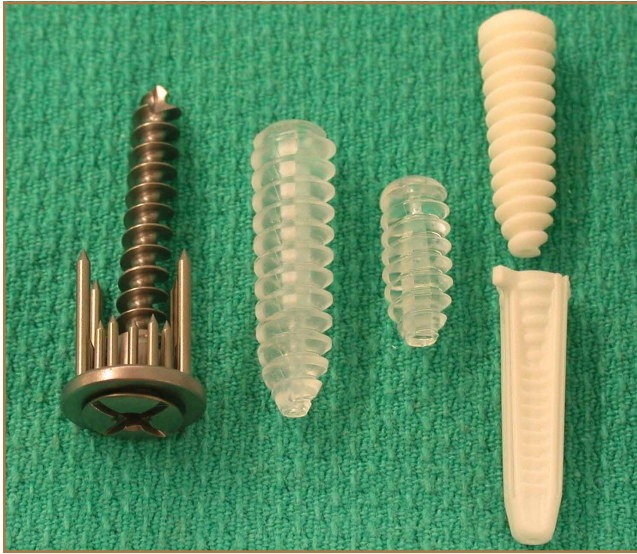
Figure 1. Four tibial fixation devices (left to right): WasherLoc, Delta screw, Retroscrew, Intrafix.

Figure 2. Testing apparatus. Tibias were potted in epoxy, custom clamp was placed on hamstring tendons about 25 mm from bone tunnel, and specimen was oriented so load was applied parallel to axis of tibial tunnel.

erLoc (Arthrotek, Warsaw, Indiana), and Intrafix (Depuy Mitek, Raynham, Massachusetts). For each device, 10 ACL fixation constructs were tested.

Quadrupled human semitendinosus–gracilis tendon grafts were fixed into the tibias using the 4 tibial fixation devices. All fixations were done according to manufacturer specifications. All interference screws were placed eccentrically. The testing apparatus and procedure are described in an article by Kousa and colleagues.[6] The specimens were mounted on the mechanical testing apparatus by threaded bars and custom clamps to secure fixation (**Figure 2**). Constant tension was maintained on all 4 strands of the hamstring grafts to equalize the tendons. After the looped end of the hamstring graft was secured by clamps, 25 mm of graft was left between the clamp and the intra-articular tunnel.

In the cyclic loading test, the load was applied parallel to the long axis of the tibial tunnel. A 50-N preload was initially applied to each specimen for 10 seconds. Subsequently, 1500 loading cycles between 50 N and 200 N at a rate of 1 cycle per 120 seconds were performed. Standard force-displacement curves were then generated. Each tibial fixation device underwent 10 cyclic loading tests. Specimens surviving the cyclic loading then underwent a single-cycle load-to-failure (LTF) test in which the load was applied parallel to the long axis of the drill hole at a rate of 50 mm per minute.

Residual displacement, stiffness, and ultimate LTF data were recorded from the force-displacement curves. Residual displacement data were generated from the cyclic loading test; residual displacement was determined by subtracting preload displacement from displacement at 1, 10, 50, 100, 250, 500, 1000, and 1500 cycles. Stiffness data were generated from the single-cycle LTF test; stiffness was defined as the linear region slope of th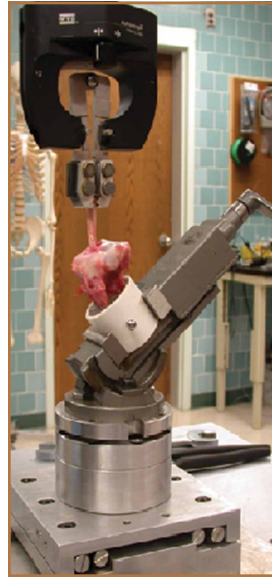e force-displacement curve corresponding to the steepest straight-line tangent to the loading curve. Ultimate LTF (yield load) data were generated from the single-cycle LTF test; ultimate LTF was defined as the load at the point where the slope of the load displacement curve initially decreases.

Statistical analysis generated standard descriptive statistics: means, standard deviations, and proportions. One-way analysis of variance (ANOVA) was used to determine any statistically significant differences in stiffness, yield load, and residual displacement between the different fixation devices. Differences in force (load) between the single cycle and the cyclic loading test were determined by ANOVA. $P < .05$ was considered statistically significant for all tests.

Results

The modes of failure for the devices were similar. In all 10 tests, Intrafix was pulled through the tunnel with the hamstring allografts. WasherLoc failed in each test, with the tendons eventually being pulled through the washer and thus out through the tunnel. Delta screw and Retroscrew both failed with slippage of the fixation device and the tendons pulled out through the tunnel.

For the cyclic loading tests, 8 of the 10 Delta screws and only 2 of the 10 Retroscrews completed the 1500-cycle loading test before failure. The 2 Delta screws that did not complete the testing failed after about 500 cycles, and the 8 Retroscrews that did not complete the testing failed after about 250 cycles. All 10 WasherLoc and Intrafix devices completed the testing.

Residual displacement data were calculated from the cyclic loading tests (**Table**). Mean (SS) residual displacement was lowest for Intrafix at 2.9 (1.2) mm, followed by WasherLoc at 5.6 (2.2) mm and Delta at 6.4 (3.3) mm. Retroscrew at 25.5 (11.0) mm had the highest residual displacement, though only 2 completed the cyclic tests. Intrafix, WasherLoc, and Delta were not statistically different, but there was a statistical difference between Retroscrew and the other devices ($P < .001$).

Stiffness data were calculated from the LTF tests (**Table**). Mean (SD) stiffness was highest for Intrafix at 129 (32.7) N/mm, followed by WasherLoc at 97 (11.6) N/mm, Delta at 93 (9.5) N/mm, and Retroscrew at 80.2 (8.8) N/mm. Intrafix had statistically higher stiffness compared with WasherLoc ($P < .05$), Delta ($P < .01$), and Retroscrew ($P < .05$). There were no significant differences in stiffness among WasherLoc, Delta, and Retroscrew.

Mean (SD) ultimate LTF was highest for Intrafix at 656 (182.6) N, followed by WasherLoc at 630 (129.3) N, Delta at 430 (90.0) N, and Retroscrew at 285 (33.8) N (**Table**). There were significant differences between Intrafix and Delta (P < .05) and Retroscrew (P < .05). WasherLoc failed at a significantly higher load compared with Delta (P < .05) and Retroscrew (P < .05). There were no significant differences in mean LTF between Intrafix and WasherLoc.

Discussion

In this biomechanical comparison of 4 different tibial fixation devices, Intrafix had results superior to those of the other implants. Intrafix failed at higher LTF and lower residual displacement and had higher stiffness. WasherLoc performed well and had LTF similar to that of Intrafix. The interference screws performed poorly with respect to LTF, residual displacement, and stiffness, and a large proportion of them failed early into cyclic loading.

Intrafix is a central fixation device that uses a 4-quadrant sleeve and a screw to establish tensioning across all 4 hamstring graft strands. The theory is this configuration increases the contact area between graft and bone for proper integration of graft into bone. Intrafix has performed well in other biomechanical studies. Using a study design similar to ours, Kousa and colleagues[7] found the performance of Intrafix to be superior to that of other devices, including interference screws and WasherLoc. Starch and colleagues[10] reported that, compared with a standard interference screw, Intrafix required significantly higher load to cause a millimeter of graft laxity. They concluded that this demonstrates superior fixation strength and reduced laxity of the graft after cyclic loading. Coleridge and Amis[4] found that, compared with WasherLoc and various interference screws, Intrafix had the lower residual displacement. However, they also found that, compared with Intrafix and interference screws, WasherLoc had the highest ultimate tensile strength. Their findings may be difficult to compare with ours, as they tested fixation of calf extensor tendons, and we tested human hamstring grafts.

An important concern in the present study was the poor performance of the interference screws. Other authors recently expressed concern with using interference screws in soft-tissue ACL grafts—based on biomechanical study results of increased slippage, bone tunnel widening, and less strength.[11] Delta screws and Retroscrews have not been specifically evaluated,

and their fixation strengths have not been directly compared with those of other devices. In the present study, Delta screws and Retroscrews consistently performed the poorest with respect to ultimate LTF, residual displacement, and stiffness. Twenty percent of the Delta screws and 80% of the Retroscrews did not complete 1500 cycles. The poor performance of the interference screws was echoed in studies by Magen and colleagues[12] and Kousa and colleagues,[7] in which the only complete failures were in the cyclic loading of the interference screws.

Three possible confounding factors may have affected the performance of the interference screws: bone density of porcine tibia, length of interference screw, and location of screw placement. In addition, in clinical practice these screws may be used with other modes of graft fixation. Combined fixation (interference screws, other devices) was not evaluated in this study.

Porcine models have been used in many biomechanical graft fixation studies.[4,6,7,12,13] Some authors have found porcine tibia to be a poor substitute for human cadaver tibia because the volumetric density of porcine bone is higher than that of human bone.[14,15] Other authors have demonstrated fairly similar bone density between human and porcine tibia.[16] The concern is that interference screw fixation strength correlates with the density of the bone in which screws are fixed.[17] Therefore, one limitation of our study is that we did not determine the bone density of the porcine tibias for comparison with that of young human tibias.

Another important variable that could have affected the performance of the interference screws is screw length. One study found no significant difference in screw strength between various lengths, and longer screws failed to protect against graft slippage.[18] However, Selby and colleagues[19] found that, compared with 28-mm screws, 35-mm bioabsorbable interference screws failed at higher LTF. This is in part why we selected 35-mm Delta screws for our study. Both 35-mm Delta screws and 20-mm Retroscrews performed poorly. However, we could not determine if the poorer performance of Retroscrews was related to their length.

We used an eccentric placement for our interference screws. Although some studies have suggested concentric placement might improve fixation strength by increasing bone–tendon contact,[20] Simonian and colleagues[21] found no difference in graft slippage or ultimate LTF between eccentrically and concentrically placed screws. Although they were not biomechani-

Table. Summarized Results for the 4 Fixation Devices, Sorted by Load to Failure

Fixation Device	Residual Displacement, mm		Stiffness, N/mm		Load to Failure, N	
	Mean	SD	Mean	SD	Mean	SD
Intrafix	2.9	1.2	129	33	656	183
WasherLoc	5.6	2.2	97	12	630	129
Delta screw	6.4	3.3	93	9.5	430	90
Retroscrew	25.5	11	80.2	8.8	285	34

cally tested in our study, a few grafts were fixed with concentrically placed screws, and these tendons appeared to be more clinically damaged than the eccentrically placed screws.

Combined tibial fixation techniques may be used in clinical practice, but we did not evaluate them in our study. Yoo and colleagues[9] compared interference screw, interference screw plus cortical screw and spiked washer, and cortical screw and spiked washer alone. They found that stiffness nearly doubled, residual displacement was less, and ultimate LTF was significantly higher in the group with interference screw plus cortical screw and spiked washer. In a similar study, Walsh and colleagues[13] demonstrated improved stiffness and LTF in cyclic testing with the combination of retrograde interference screw and suture button over interference screw alone. Further study may include direct comparisons of additional tibial fixation techniques using more than one device. Cost analysis of use of additional fixation devices would be beneficial as well.

Study results have clearly demonstrated that tibial fixation is the weak point in ACL reconstruction[3,17] and that early aggressive rehabilitation can help restore range of motion, strength, and function.[22,23] Implants that can withstand early loads during rehabilitation periods are therefore of utmost importance.

Conclusion
Intrafix demonstrated superior strength in the fixation of hamstring grafts in the tibia, followed closely by WasherLoc. When used as the sole tibial fixation device, interference screws had low LTF, decreased stiffness, and high residual displacement, which may have clinical implications for early rehabilitation after ACL reconstruction.

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References
1. Garrett WE Jr, Swiontkowski MF, Weinsten JN, et al. American Board of Orthopaedic Surgery Practice of the Orthopaedic Surgeon: part-II, certification examination case mix. *J Bone Joint Surg Am*. 2006;88(3):660-667.
2. West RV, Harner CD. Graft selection in anterior cruciate ligament reconstruction. *J Am Acad Orthop Surg*. 2005;13(3):197-207.
3. Brand J Jr, Weiler A, Caborn DN, Brown CH Jr, Johnson DL. Graft fixation in cruciate ligament reconstruction. *Am J Sports Med*. 2000;28(5):761-774.
4. Coleridge SD, Amis AA. A comparison of five tibial-fixation systems in hamstring-graft anterior cruciate ligament reconstruction. *Knee Surg Sports Traumatol Arthrosc*. 2004;12(5):391-397.
5. Fabbriciani C, Mulas PD, Ziranu F, Deriu L, Zarelli D, Milano G. Mechanical analysis of fixation methods for anterior cruciate ligament reconstruction with hamstring tendon graft. An experimental study in sheep knees. *Knee*. 2005;12(2):135-138.
6. Kousa P, Järvinen TL, Vihavainen M, Kannus P, Järvinen M. The fixation strength of six hamstring tendon graft fixation devices in anterior cruciate ligament reconstruction. Part I: femoral site. *Am J Sports Med*. 2003;31(2):174-181.
7. Kousa P, Järvinen TL, Vihavainen M, Kannus P, Järvinen M. The fixation strength of six hamstring tendon graft fixation devices in anterior cruciate ligament reconstruction. Part II: tibial site. *Am J Sports Med*. 2003;31(2):182-188.
8. Weiler A, Hoffmann RF, Stähelin AC, Bail HJ, Siepe CJ, Südkamp NP. Hamstring tendon fixation using interference screws: a biomechanical study in calf tibial bone. *Arthroscopy*. 1998;14(1):29-37.
9. Yoo JC, Ahn JH, Kim JH, et al. Biomechanical testing of hybrid hamstring graft tibial fixation in anterior cruciate ligament reconstruction. *Knee*. 2006;13(6):455-459.
10. Starch DW, Alexander JW, Noble PC, Reddy S, Lintner DM. Multistranded hamstring tendon graft fixation with a central four-quadrant or a standard tibial interference screw for anterior cruciate reconstruction. *Am J Sports Med*. 2003;31(3):338-344.
11. Prodromos CC, Fu FH, Howell SM, Johnson DH, Lawhorn K. Controversies in soft-tissue anterior cruciate ligament reconstruction: grafts, bundles, tunnels, fixation, and harvest. *J Am Acad Orthop Surg*. 2008;16(7):376-384.
12. Magen HE, Howell SM, Hull ML. Structural properties of six tibial fixation methods for anterior cruciate ligament soft tissue grafts. *Am J Sports Med*. 1999;27(1):35-43.
13. Walsh MP, Wijdicks CA, Parker JB, Hapa O, LaPrade RF. A comparison between a retrograde interference screw, suture button, and combined fixation on the tibial side in an all-inside anterior cruciate ligament reconstruction: a biomechanical study in a porcine model. *Am J Sports Med*. 2009;37(1):160-167.
14. Nurmi JT, Järvinen TL, Kannus P, Sievänen H, Toukosalo J, Järvinen M. Compaction versus extraction drilling for fixation of the hamstring tendon graft in anterior cruciate ligament reconstruction. *Am J Sports Med*. 2002;30(2):167-173.
15. Nurmi JT, Sievänen H, Kannus P, Järvinen M, Järvinen TL. Porcine tibia is a poor substitute for human cadaver tibia for evaluating interference screw fixation. *Am J Sports Med*. 2004;32(3):765-771.
16. Nagarkatti DG, McKeon BP, Donahue BS, Fulkerson JP. Mechanical evaluation of a soft tissue interference screw in free tendon anterior cruciate ligament graft fixation. *Am J Sports Med*. 2001;29(1):67-71.
17. Brand JC Jr, Pienkowski D, Steenlage E, Hamilton D, Johnson DL, Caborn DN. Interference screw fixation strength of a quadrupled hamstring tendon graft is directly related to bone mineral density and insertion torque. *Am J Sports Med*. 2000;28(5):705-710.
18. Stadelmaier DM, Lowe WR, Ilahi OA, Noble PC, Kohl HW 3rd. Cyclic pull-out strength of hamstring tendon graft fixation with soft tissue interference screws. Influence of screw length. *Am J Sports Med*. 1999;27(6):778-783.
19. Selby JB, Johnson DL, Hester P, Caborn DN. Effect of screw length on bioabsorbable interference screw fixation in a tibial bone tunnel. *Am J Sports Med*. 2001;29(5):614-619.
20. Shino K, Pflaster DS. Comparison of eccentric and concentric screw placement for hamstring graft fixation in the tibial tunnel. *Knee Surg Sports Traumatol Arthrosc*. 2000;8(2):73-75.
21. Simonian PT, Sussmann PS, Baldini TH, Crockett HC, Wickiewicz TL. Interference screw position and hamstring graft location for anterior cruciate ligament reconstruction. *Arthroscopy*. 1998;14(5):459-464.
22. Shelbourne KD, Nitz P. Accelerated rehabilitation after anterior cruciate ligament reconstruction. *Am J Sports Med*. 1990;18(3):292-299.
23. Shelbourne KD, Wilckens JH. Current concepts in anterior cruciate ligament rehabilitation. *Orthop Rev*. 1990;19(11):957-964.

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