Biomechanical Comparison of Hamstring Tendon Fixation Devices for Anterior Cruciate Ligament Reconstruction: Part 1. Five Femoral Devices

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Abstract

We conducted a study to biomechanically compare 5 femoral hamstring tendon fixation devices commonly used in anterior cruciate ligament reconstruction.

Quadrupled human semitendinosus–gracilis tendon grafts were fixed into porcine femurs using 5 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 (LTF) test. Failure mode, stiffness, ultimate load, and rigidity were recorded.

Two of 10 Delta screw (Arthrex), 10 of 10 Bio-TransFix (Arthrex), 10 of 10 Bone Mulch screw (Arthrotek), 10 of 10 EZLoc (Arthrotek), and 10 of 10 Zip Loop (Arthrotek) devices completed the 1500-cycle loading test. Residual displacement was lowest for Bio-TransFix (4.1 mm) followed by Bone Mulch (5.2 mm), EZLoc (6.4 mm), Zip Loop (6.8 mm), and Delta (8.2 mm). Mean stiffness was significantly ($P < .001$) higher for Bone Mulch (218 N/mm) than for Bio-TransFix (171 N/mm), EZLoc (122 N/mm), Zip Loop (105 N/mm), or Delta (84 N/mm). Mean LTF was significantly ($P < .001$) higher for Bone Mulch (867 N) than for Zip Loop (615 N), Bio-TransFix (552 N), EZLoc (476 N), or Delta (410 N).

The Bone Mulch screw demonstrated superior strength in the fixation of hamstring grafts in the femur. Bio-TransFix was close behind. The Delta screw demonstrated poor displacement, stiffness, and LTF.

When used as the sole femoral fixation device, a device with low LTF, decreased stiffness, and high residual displacement should be used cautiously in patients undergoing aggressive rehabilitation.

Anterior cruciate ligament (ACL) reconstruction remains one of the most common orthopedic procedures; almost 100,000 are performed in the United States each year, and they are among the procedures more commonly performed by surgeons specializing in sports medicine and by general orthopedists.[1,2] 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.[3] 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, graft fixation strength has become a priority in attempts to optimize recovery and rehabilitation.[4]

Rigid fixation of hamstring grafts is now recognized as a crucial factor in the long-term success of ACL reconstruction. Grafts must withstand both early rehabilitation forces as high as 500 N[5] and stresses to the native ACL during healing, which may take up to 12 weeks for soft-tissue incorporation.[6]

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, and there is controversy regarding which provides the best stability and strength.[7] Several studies have tested various fixation devices,[8-16] but so far several devices have not been compared with one another.

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

Materials and Methods

Fifty porcine femurs 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 commit-

Authors' Disclosure Statement: All implants used in this study were donated by Biomet Sports Medicine (Arthrotek), Depuy Mitek, and Arthrex. Hamstring allografts were donated by LifeNet Health. Dr. D'Alessandro wishes to report that he is a paid consultant to Biomet Sports Medicine, and Dr. Connor wishes to report that he is a paid consultant to Biomet Sports Medicine and Zimmer. The other authors report no actual or potential conflict of interest in relation to this article.

tee. 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 5 different femoral fixation devices (**Figure 1**): Delta screw and Bio-TransFix (Arthrex, Naples, Florida) and Bone Mulch screw, EZLoc, and Zip Loop (Arthrotek, Warsaw, Indiana). For each device, 10 ACL fixation constructs were tested.

Figure 1. Five femoral fixation devices (left to right): EZLoc, Bio-TransFix, Delta screw, Bone Mulch screw, Zip Loop.

Quadrupled human semitendinosus–gracilis tendon grafts were fixed into the femurs using the 5 femoral fixation devices. All fixations were done to manufacturer specifications.

Cyclic loading was followed by testing with the load-to-failure (LTF) protocol described by Kousa and colleagues.[13] Specimens were tested in a custom load fixture (**Figure 2**). The base fixture used an adjustable angle vise mounted on a free rotary stage and a free x-y translation stage. This system allowed the load axis to be oriented to and aligned with the graft tunnel in the porcine femur, preventing off-axis or torsional loading of the grafts.

Pneumatic grips equipped with a custom pincer attachment allowed the graft to be grasped under a constant grip force during testing, regardless of graft thinning under tensile loads. Graft specimens were initially looped over a 3.8-mm horizontal metal shaft, and the 2 strands were double-looped at the graft insertion site. The 2 free strands were then drawn up around the metal shaft, and the shaft was placed above the serrated jaws. The metal shaft with enveloping tendon strands rested on a flat shelf at the top of the grip serrations. This configuration prevented the metal shaft and tendon strands from being pulled through the serrations when compressive force was applied to the jaws.

Before the study, the grip design was tested. There was no detectable relative motion of the strands at the grip end during graft testing to failure. The pincer attachment allowed close approach of the grips to the specimen at all femoral condyle orientations, so that a 25-mm length of exposed graft could be obtained for each specimen under initial conditions.

In the cyclic loading test, the load was applied parallel to the long axis of the femoral tunnel. A 50-N preload was initially applied to each specimen for 10 seconds, and the length of the exposed graft between grips and graft insertion was recorded. Subsequently, 1500 loading cycles between 50 N and 200 N at a rate of 1 cycle per 2 seconds (0.5 Hz) were performed. Standard force-displacement curves were then generated.

Figure 2. Test configuration for load tests. Load fixture used (top to bottom): pneumatic grips, custom pincer attachment, angled vise mounted to base with free-moving rotation and x-y stages for centering graft under load applicator. Tibial specimen after cyclic testing.

Specimens surviving the cyclic loading then underwent a single-cycle 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 the force-displacement curve corresponding to the steepest straight-line tangent to the loading curve. Ultimate LTF data were generated from the single-cycle LTF test; ultimate LTF was defined as the maximum load sustained by the specimen during a constant-displacement-rate tensile test for graft pullout.

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 differed slightly (**Table**). Bone Mulch screw failed with a fracture through the femoral condyle extending to the bone tunnel. Zip Loop and EZLoc failed by pulling through their cortical attachment on the lateral femoral condyle. Bio-TransFix broke in the tunnel during LTF. Delta screw failed with slippage of the fixation device, and the tendons pulled out through the tunnel.

For the cyclic loading tests, only 2 of the 10 Delta screws completed the 1500-cycle loading test before failure. Of the 8 Delta screws that did not complete this testing, the majority failed after about 100 cycles. All 10 tests of Bone Mulch, Zip Loop, EZLoc, and Bio-TransFix completed the 1500-cycle loading test.

Residual displacement data were calculated from cyclic loading tests (**Table**). Mean (SD) residual displacement was lowest for Bio-TransFix at 4.1 (0.4) mm, followed by Bone Mulch at 5.2 (1.0) mm, EZLoc at 6.4 (1.1) mm, and Zip Loop at 6.8 (1.3) mm. Delta screws at 8.2 (1.4) mm had the highest residual displacement, though only 2 completed the cyclic tests. Bio-TransFix had significantly ($P < .001$) less residual displacement compared with EZLoc, Zip Loop, and Delta. Bone Mulch had significantly less residual displacement compared with Zip Loop ($P < .05$) and Delta ($P < .01$).

Stiffness data were calculated from LTF tests (**Table**). Mean (SD) stiffness was highest for Bone Mulch at 218 (25.9) N/mm, followed by Bio-TransFix at 171 (24.2) N/mm, EZLoc at 122 (24.1) N/mm, Zip Loop at 105 (18.9) N/mm, and Delta at 84 (16.4) N/mm. Bone Mulch had significantly ($P < .001$) higher stiffness compared with Bio-TransFix, EZLoc, Zip Loop, and Delta. Bio-TransFix had significantly ($P < .001$) higher stiffness compared with EZLoc, Zip Loop, and Delta.

Mean (SD) ultimate LTF was highest for Bone Mulch at 867 (164) N, followed by Zip Loop at 615 (72.3) N, Bio-TransFix at 552 (141) N, EZLoc at 476 (89.7) N, and Delta at 410 (65.3) N (**Table**). Bone Mulch failed at a statistically significantly ($P < .001$) higher load compared with Zip Loop, Bio-TransFix, EZLoc, and Delta. There were no significant differences in mean LTF among Zip Loop, Bio-TransFix, EZLoc, and Delta.

Discussion

In this biomechanical comparison of 5 different femoral fixation devices, the Bone Mulch screw had results superior to those of the other implants. Bone Mulch failed at higher LTF and higher stiffness. Bio-TransFix performed well and had residual displacement similar to that of Bone Mulch, but significantly lower LTF. Overall, EZLoc and Zip Loop were similar to each other in performance. The Delta (interference) screw performed poorly with respect to LTF, residual displacement, and stiffness; a large proportion of these screws failed early into cyclic loading.

Bone Mulch and Bio-TransFix overall outperformed the other fixation devices. These 2 devices are cortical-cancellous suspension devices, which provide transcondylar fixation and resist tensile forces perpendicular to the pullout force. Multiple biomechanical studies have found superior performance for these types of devices compared with various implants.[10,13,15,16]

Our results were similar to those of Kousa and colleagues,[13] who found the Bone Mulch screw to provide highest LTF, highest stiffness, and lowest residual displacement. Another study found significantly higher stiffness for the Bone Mulch screw than for the Endobutton, a cortical suspensory fixation device.[14] Bone Mulch failure modes differed, however. In the study by Kousa and colleagues,[13] 3 specimens failed with bending of the screw tip, and 7 failed with rupture of the tendon loop. All specimens in our study failed with fractures through the condyle. It is unclear why the failure modes differed, as we followed similar manufacturer protocols for inserting the device. It is possible the bone mass density of the porcine femurs differed between studies. This was not reported by Kousa and colleagues,[13] and we did not perform testing either. However, all the porcine femurs were about the same age for testing of each device in this study.

Bio-TransFix has also been compared with various implants, but not in the same study. Brown and colleagues[8] found the TransFix device significantly stiffer than the Endobutton CL. Shen and colleagues[16] determined that TransFix had significantly lower residual displacement compared with Endobutton CL. Milano and colleagues[15] compared multiple cortical suspensory fixation devices, including Endobutton CL, with TransFix and Bio-TransFix, and concluded the cortical-cancellous devices (TransFix, Bio-TransFix) offered the best and most predictable results in terms of elongation, fixation strength, and stiffness. TransFix has also been shown to be superior to interference screw fixation in biomechanical studies.[10,15]

Clinical outcomes of studies using TransFix for femoral fixation have been favorable, with improved Lysholm scores and improved laxity according to the KT-1000 test.[17] However, multiple prospective studies have found no clinical difference in knee laxity between interference screw and Endobutton at 1- to 2-year follow-up[18-20] and no difference in clinical outcome scores, such as the International Knee Documentation Committee score.[11,18-20]

Although these studies have shown no major clinical differences at short-term follow-up, the early aggressive rehabilita-

Table. **Summarized Results for the 5 Fixation Devices, Sorted by Load to Failure**

		Residual Displacement, mm		Stiffness, N/mm		Load to Failure, N	
Fixation Device	**Failure Mode**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Bone Mulch screw	Fracture through bone tunnel	5.2	1.0	218	26	867	164
Zip Loop	Lateral cortex failed	6.8	1.3	105	19	615	72
Bio-TransFix	Device fractured in tunnel	4.1	0.4	171	24	552	141
EZLoc	Lateral cortex failed	6.4	1.1	122	24	476	90
Delta screw	Slippage of fixation	8.2	1.4	84	16	410	65

tion period is the larger concern. Our study clearly demonstrated the biomechanical strength of transcondylar devices over other devices. The concern with transcondylar devices (vs other devices) is the increased difficulty that inexperienced surgeons have inserting them. In addition, when removed, transcondylar devices leave a large bone void.

In the present study, an important concern with femoral graft fixation is the poor performance of 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.[7] In the present study, Delta screws consistently performed poorest with respect to ultimate LTF, residual displacement, and stiffness. Only 20% of these screws completed 1500 cycles. Poor performance of interference screws has also been seen in other studies in tibial graft fixation[21,22] and femoral graft fixation.[13-15] Given their poor biomechanical properties, as seen in our study and these other studies, we think use of an interference screw alone is a poor choice for fixation.

Combined fixation techniques—interference screw plus other device(s)—may be used in clinical practice, but the present study did not evaluate any. In a biomechanical study, Yoo and colleagues[23] compared an interference screw; an interference screw plus a cortical screw and a spiked washer; and a cortical screw and a spiked washer used alone in the tibia. Stiffness nearly doubled, residual displacement was less, and ultimate LTF was significantly higher in the group with the interference screw plus the cortical screw and the spiked washer. In a similar study involving femoral fixation, Oh and colleagues[24] demonstrated improved stiffness, residual displacement, and LTF in cyclic testing with the combination of interference screw and Endobutton CL, compared with Endobutton CL alone. Further studies may include direct comparisons of additional femoral fixation techniques using more than 1 device.

The Zip Loop, or Toggle Loc with Zip Loop technology, is a suspensory cortical fixation device. It was initially designed for use in ACL fixation but has also been used in other surgeries, including distal biceps repair[25] and ulnar collateral ligament reconstruction.[26] The device itself is easy to use; more important, it allows for adjustment of graft length within the bone tunnel after deployment of the cortical fixation. Few biomechanical studies have been conducted with Zip Loop.[9,12] The present study is the first to compare Zip Loop with devices other than suspensory cortical fixation devices. Zip Loop performed very well in LTF testing but had lower stiffness and higher residual displacement compared with the transcondylar fixation devices. Despite these findings, we have continued to use this device for femoral fixation in ACL reconstruction because of its ease of insertion, the ability to adjust graft tension within the bone tunnel, and the difficulties encountered inserting and removing transcondylar fixation.

We recognize the limitations in our study design with respect to how axial and cyclical loading compares with the physiologic orientation of the ACL during ambulation and running activities. This biomechanical study was not able to replicate these types of activities. However, it did provide good data supporting early rehabilitation with various fixation devices, though concern with use of interference screws remains.

Conclusion

Superior strength in fixation of hamstring grafts in the femur was demonstrated by Bone Mulch screws, followed closely by Bio-TransFix. Delta screws demonstrated poor displacement, stiffness, and LTF. When used as the sole femoral fixation device, a device with low LTF, decreased stiffness, and high residual displacement should be used cautiously in patients undergoing aggressive rehabilitation.

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