

Novel Femoral Fixation Of Quadrupled ACL Reconstruction Graft Using Cancellous Bracing. Biomechanical Comparison With Established Devices



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Background

The goal was to determine the pullout characteristics of a new ACL femoral fixation device versus those of currently-used devices.

- The majority of the 300,000 annual reported ACL injuries are complete ruptures (1).
- Long term success rates after arthroscopically-assisted ACL reconstruction range from 69-90%, with a majority of failures related to graft fixation and surgical error (2).
- Biomechanical studies suggest greatest construct strength and stiffness is obtained with a transversely-fixed, over-the-top graft (3). But, this two-hole technique, using an additional crosspin, may risk excessive morbidity.
- The new, single-hole unicortical device is designed to gain purchase by laterally engaging the cancellous bone. We postulated its strength to be greater than that of established one-hole devices and less than that of a two-hole device, based on the difference in purchase.

Fig. 2. Single static pull test to failure was performed on an Instron 1011 materials test machine (a). Degrees of freedom were in A-P translation, axial graft twist, and varus / valgus femur rotation (a,b). Flash-freezing of graft and clamp yielded integration with 20-25 mm free graft length (c).

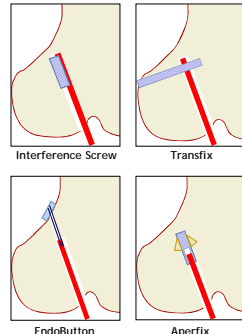
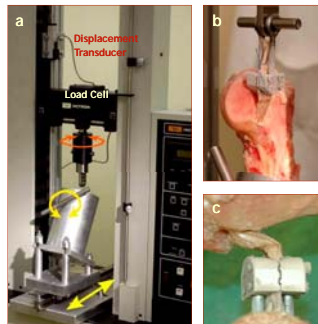
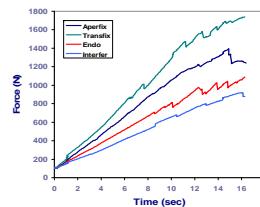


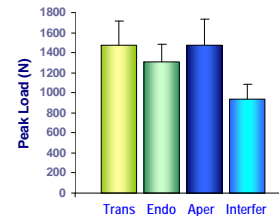
Fig. 1. 2 of the 4 styles of fixation were unicortical (Interference Screw, Aperfix); 2 were bicortical (Transfix, EndoButton). Aperfix provides wings that spread with tightening through the shaft.



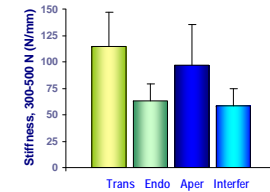
	Peak Load N	Low Stiffness N/mm	High Stiffness N/mm	Energy N-cm	Displcmt to Peak mm
Transfix	1472	114.3	169.4	11.0	11.4
Endo	244	32.2	38.9	2.8	2.1
Aperfix	1311	62.7	113.7	9.6	13.6
Interference	178	16.4	25.3	1.4	2.4
Aperfix	1479	97.2	119.0	17.5	16.8
Endo	261	38.5	34.8	5.9	5.1
Interference	935	58.3	11.4	11.4	17.4
Aperfix	147	16.4	4.0	6.2	6.2

Results

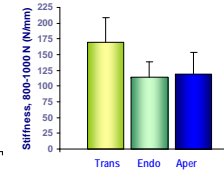
- Device breakage was the cause of failure consistently in the TransFix® and EndoButton® groups. In contrast, both the Interference Screw and the Aperfix® constructs failed as a result of graft tearing, with some lengthening due to plastic deformation and possibly device movement.



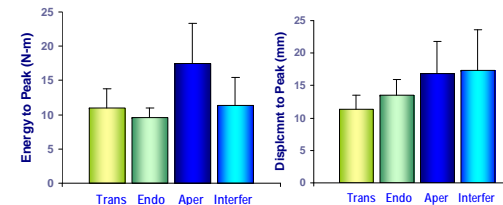
- The lowest construct strength was found for the Interference Screw, averaging 935 N (SD, 147 N; p<0.05 vs. the other 3; Table 1). The EndoButton® produced the next highest strength at 1311 N (178 N; p<0.05 vs. TransFix® and Aperfix®). The strengths of the TransFix® group at 1472 N (244 N) and the Aperfix® group at 1479 N (261 N) were nearly identical.



- Stiffness in the low range (300-500 N) was trendwise greatest in the Transfix®, at 114.3 N/mm (32.2 N/mm), followed by Aperfix®, EndoButton®, and Interference Screw®. Stiffness in the high range (800-1000 N) was greatest in the Transfix® at 169.4 N/mm (38.9 N/mm), followed by Aperfix® and EndoButton®.



Averaged load-displacement curves for static tests. Clear differences are evident in construct stiffness throughout the test range, with Transfix resulting in the highest stiffness at the upper load range.



Energy-to-peak was highest in the Aperfix due to its long distension while in graft-tearing mode of failure. The Interference Screw and Aperfix had the largest displacements to failure, with a possible contribution from device slippage.

Methods

- 10 constructs each were used to compare the following devices: (1) TransFix® (Arthrex), with two pins; (2) EndoButton® (Smith & Nephew), a bicortical device; (3) Interference Screw (Arthrex); and (4) Aperfix® (Cayenne Medical; Fig. 1), with cancellous bone engagement.
- Fresh-frozen quadrupled hamstring tendon / semitendinosus used in 6-8 month bovine femur.
- Limited notchplasty was performed at the native femoral ACL insertion to prevent graft impingement during testing (Fig. 2). Tunnels were drilled from the ACL femoral footprint toward the lateral wall of the lateral condyle, and the selected system implanted.
- After matching the tension in each of the free tendon ends, the soft tissue graft was wrapped in sandpaper and clamped in a rippled compression fixture. The clamp-graft unit was then immersed in liquid nitrogen to solidify the fixation.
- Single static tensile test to failure performed at 10 mm/min, recording at 10 Hz, after pre-tensioning with 50 N for 2 minutes. Degrees of freedom included: A-P translation of construct, twist of graft, varus/valgus rotation of femur. Initial angle of pull was 30° anteriorly.
- Stiffness was analyzed in low- and high-load regions; failure load was determined from the peak force.

Conclusions

The cancellous bracing design of the new, unicortically-placed Aperfix® produced the same strength as that of the two-hole TransFix®. Thus, it is possible to provide optimal strength for ACL femoral fixation with reduced iatrogenic involvement.

- References** (1) Miyasaka KC, et al. Am J Knee Surg 4:3-8, 1991. (2) Brand J, et al. Am J Sports Med 28: 761-774, 2000. (3) Kousa P, et al. Am J Sports Med 31:174-181, 2003.

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