

FIXATION STRENGTH OF A NEW DEVICE FOR SOFT TISSUE ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

PURPOSE: To demonstrate the fixation strength of AperFix™ Femoral and AperFix™ Tibial implants used in Anterior Cruciate Ligament (ACL) reconstruction.

BACKGROUND: There exists a trend in ACL reconstruction toward soft-tissue grafts in lieu of the traditional gold-standard BPTB grafts. Soft-tissue grafts have been proven to provide lower patient morbidity at the harvest site, making them an attractive option for surgeons performing ACL reconstruction. Recent advances such as the AperFix™ System (Cayenne Medical, Inc., Scottsdale, Arizona), have greatly improved the fixation of soft-tissue grafts. Until the development of the AperFix technology, soft-tissue ACL reconstruction was perceived to have less-than-acceptable fixation strength. Cayenne Medical's AperFix ACL reconstruction system was proven to provide superior pull-out strengths of 1,253N and 1,165N for the femoral and tibial implants respectively. Compared to the gold-standard BPTB interference screws, which typically have pullout strengths of between 500N and 800N¹, AperFix provides at least 55% greater fixation strength, indicating a more reliable, more durable ACL reconstruction. In addition, the AperFix femoral implant has demonstrated superior resistance to movement under cyclic loading, showing less than 1mm of movement after 1,500 and 50,000 cycles. The cyclic loading was

performed in accordance with the protocol established by Koussa¹, with loads cycling between 50N and 200N for the full range of cycles, followed by testing the load to failure.

MATERIALS:

- AperFix Femoral Implants; 35mm
- AperFix Femoral Implants; 29mm
- AperFix Tibial Implants; 30mm
- Human tendon (DLSTG and Tibialis Anterior)
- Bovine Bone
- 20 pcf polyurethane foam block (Pacific Research Laboratories, Ltd.)
- Braided Nylon fiber
- Tensile tester – Chatillon TCD Series with Chatillon DFE 500 pound load cell
- Clamp fixture

METHODS: A combination of human tendon, bovine bone, and polyurethane foam blocks was used to evaluate the AperFix system. Bovine bone with human tendon was used in a number of tests to closely mimic clinical circumstances.

Appropriate size tunnels were drilled in the media, and tendons or substitute fiber was loaded on the implants and inserted. The implants were deployed per Cayenne Medical Instructions For Use.

RESULTS:

TABLE 1. *Single-cycle load to failure*

	Number of Samples Average Load to	Failure (N)	Std. Dev. (N)
AperFix Femoral, 35mm	30	1253.0	142.5
AperFix Femoral, 29mm	30	1221.6	165.8
AperFix Tibial, 30mm	30	1165.2	257.9

TABLE 2. *Cyclic loading followed by load to failure*

	Number of Samples	Cycles (50N to 200N)	Implant Movement	Average Load to Failure (N)
AperFix Femoral, 35mm	20	1,500	<1mm	1039.0
AperFix Femoral, 29mm	30	1,500	<1mm	1212.3
AperFix Femoral, 29mm	1	50,000	<1mm	Not tested

SUMMARY: The Cayenne Medical, Inc. AperFix System offers strong, rigid fixation for ACL reconstruction using soft tissue grafts. Results from Table 1 indicate superior graft fixation strength over other soft tissue reconstruction devices on the market¹. Results from Table 2 indicate a

rigid fixation with less than 1mm of movement after 1,500 and 50,000 cycles. Superior graft fixation at the aperture and highly biocompatible PEEK™ technology provides a reliable, soft tissue ACL reconstruction solution.

REFERENCES:

1. Kousa, P, et al. *The Fixation Strength of Six Hamstring Tendon Graft Fixation Devices in Anterior Cruciate Ligament Reconstruction*. The American Journal of Sports Medicine; 2003; Volume 31, No.2, pg. 174-188.