

# FIXATION STRENGTH OF A NEW INTERFERENCE SCREW FOR BONE-PATELLAR TENDON-BONE ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

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**PURPOSE:** To demonstrate the fixation strength of the iFix™ PEEK™ (polyetheretherketone) interference screw during and after cyclic loading.

**BACKGROUND:** The iFix™ PEEK™ interference screw is the first bone-patellar tendon-bone fixation device of its kind in the orthopedic market. The development of a PEEK screw addresses specific needs not currently fulfilled by current interference screw fixation technologies and represents a paramount development within traditional gold-standard ACL reconstruction advancements. A PEEK interference screw offers the fixation strength of a metal screw, the radiolucency of a bioabsorbable screw and a modulus of elasticity that closely mimics bone. Furthermore, PEEK possesses none of the potential for adverse immunological reaction that are common to some bioabsorbables<sup>1,2</sup>. The iFix technology satisfies the market gap by offering safer, superior fixation strength and higher durability than current resorbable interference screw technology. Cayenne Medical's iFix interference screw has demonstrated superior resistance to movement under cyclic loading showing less than 1mm of movement after 1,500 cycles. The cyclic loading was performed in accordance with the protocol established by Kouza<sup>3</sup> with loads cycling between 50N and 200N for the full range of cycles followed by testing the load to failure of the bone screw

fixation. The average post-cyclic pull to failure ultimate load for the samples was 824N.

## **MATERIALS:**

- iFix Interference Screw, 8x20mm
- Immature Porcine (6-9 mo.)
- Bone-Patellar Tendon-Bone Grafts
- Mature Porcine (1-2 yr.) Femurs
- Small iFix™ Driver with Guide Wire Inserter
- iFix 1.1mm Nitinol Guide Wire
- Tensile tester – Chatillon TCD Series with Chatillon DFE 500 lb Load Cell
- Clamp Fixture
- Nexygen TCD Data Acquisition Software
- Saline Solution
- Surgical Gauze

**METHODS:** Fifteen immature porcine bone-patellar tendon-bone grafts were sized to fit a 10mm diameter tunnel. Corresponding 10mm tunnels were drilled into mature porcine femurs. Grafts and interference screws were inserted following the product instructions for use (IFU). Only one end of the bone graft was inserted into the porcine media. The other end was clamped to the load frame of the tensile testing machine. Grafts were pre-tensioned to 200N and location of the graft was marked relative to the tunnel. Screw head orientation was also marked to determine whether screw

loosening occurred during cyclic loading. Saline moistened surgical gauze was placed around the porcine patellar tendon to prevent it from drying out during testing.

**TABLE 1.**

*Cyclic Loading Followed by Load to Failure*

iFix 8x20mm	
Number of Samples	15
Cycles (50N to 200N)	1500
Implant Movement	<1mm*
Average Load to Failure (N)	824
Std Dev. (N)	204

\* None of the fifteen samples cyclically loaded displayed any sign of screw loosening or noticeable graft displacement.

**RESULTS:** The Cayenne Medical, Inc. iFix System offers strong, rigid fixation for ACL reconstruction using bone-patellar tendon-bone fixation. Results from Table 1 indicate high pull-out strengths with a superior resistance to movement after 1,500 cycles. Graft fixation strength combined with highly biocompatible PEEK technology provides a reliable, bone-patellar tendon-bone ACL reconstruction solution.

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## REFERENCES

1. Böstman, OM, and HK Pihlajamäki. *Adverse tissue reactions to bioabsorbable fixation devices.* Clinical Orthopaedics and Related Research; Feb. 2000; Volume 371, pg. 216-27.
2. Kwak, JH, et al. *Delayed intra-articular inflammatory reaction due to poly-L-lactide bioabsorbable interference screw used in anterior cruciate ligament reconstruction.* Arthroscopy; Feb. 2008; Volume 24(2), pg. 243-6.
3. Kousa, P, et al. *Initial Fixation Strength of Bioabsorbable and Titanium Interference Screws in Anterior Cruciate Ligament Reconstruction.* The American Journal of Sports Medicine; 2001; Volume 29, No.4, pg 420-25.