



Fixation performance testing of the 10 mm **Poly-Tape** with Interference screws for MPFL reconstruction

Introduction

Medial patellofemoral ligament (MPFL) reconstruction is an established procedure whereby patellar subluxation and dislocation is treated through the reconstruction of the MPFL with a **Poly-Tape** and suitable fixation method.

Xiros have previously provided an MPFL reconstruction system set (now obsoleted) in which a Fastlok™ device comprising a staple and buckle was utilised as the fixation method of the tape onto the femoral attachment site. While this method has been used successfully, the staple is being replaced by an interference screw which will offer the following additional benefits:

- The interference screw fixation provides a low-profile fixation method, potentially offering reduced irritation and eliminating the need for removal of a staple.
- The use of a guidewire allows provisional positioning and testing of the desired femoral insertion site prior to drilling a 5 mm diameter tunnel with a cannulated drill.

Objectives

The purpose of this investigation was to determine the ultimate tensile strength (UTS) of the 10 mm **Poly-Tape** when tested with multiple Ø6 mm x 20 mm interference screws and compare these values to those of the native MPFL from published literature.

Test Methods

Tensile and fatigue testing simulating approximately six months of highly active, healthy use, was performed. A setup representative of the method described in the Surgical Technique Manual (LAB 292) was used, whereby a single 10 mm **Poly-Tape** was looped over a 10 mm mandrel, simulating the patella. The free ends of the **Poly-Tape** were fixed in a Sawbones laminated block with either the Medgal or Innovate Orthopaedics Ø6 mm x 20 mm Interference screw. The Sawbones laminated block (20pcf) had been selected as a representative bone substitute for extra-articular indications around the knee. The screws were inserted into a blind Ø5 mm hole that was 25 mm deep. A minimum of six replicates was tested in each group to ensure statistical relevance.

Test conditions were as follows:

Tensile Tests

- Gauge length = 60 mm (defined from the top edge of the screw to the centre of the mandrel).
- Uniaxial tensile load applied at a rate of 60 mm/min until failure.

Fatigue Tests

- Uniaxial sinusoidal tensile load
 - o Range = 50N to 250N
 - o Frequency = 25 Hz
 - o No. of cycles = 500,000
- Post fatigue UTS determined using same conditions as tensile tests.



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Test Material

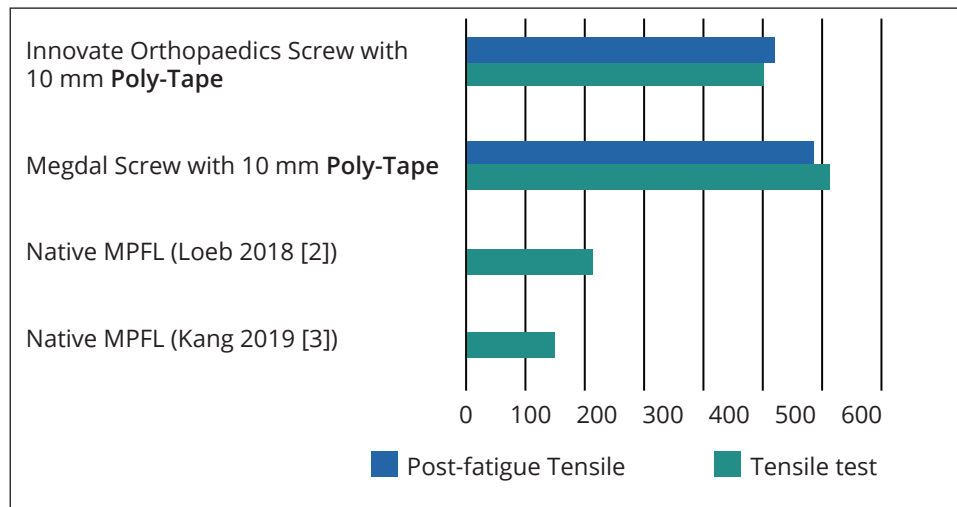
- 10 mm **Poly-Tape**, Part Number 102-1010
- Ø6 mm x 20 mm Medgal Screw, Part Number 1-01-61-01.20
- Ø6 mm x 20 mm Innovate Orthopaedics Quick-Start Screw, ref 10001
- Instron 8800 with 10kN Load cell
- Sawbones Laminated Cellular Block 20 PCF (SKU:1522-676)

Results

Table 1. Summary of tensile and fatigue test results [1]

	Medgal screw & 10 mm tape	IO screw & 10 mm tape
Mean UTS (N)	615.6 [SD = 45.28]	501.0 [SD = 57.6]
Mean UTS post-fatigue (N)	590.0 [SD = 45.1]	515.5 [SD = 62.5]

A review of the published literature has identified a range of ultimate tensile strength values for the native MPFL ranging from 147N (Kang 2019 [3]) up to 208N (Loeb 2018 [2]).



Conclusions

- For both screws, the UTS achieved for the **Poly-Tape** is significantly stronger than that of the native MPFL.
- For both screws, fatigue testing identified no decreases in UTS of the **Poly-Tape** that would present a risk to the safety and effectiveness of the repair.

References

1. DTR 159A - Mechanical Testing of Screws 10 mm **Poly-Tape** for MPFL Repair
2. Loeb AE, Tanaka MJ: The medial patellofemoral complex. Curr Rev Musculoskelet Med 2018; 11:201–208.
3. Kang H, Zheng R, Dong C, Fu K, Wang F: No influence of patellar fixation technique on clinical outcomes of double-bundle medial patellofemoral ligament reconstruction: a systematic review. Arch Orthop Trauma Surg 2019; 139:79–90.

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