# Fixation Strength of the Arthrex GraftBolt and the Mitek INTRAFIX

Arthrex Research and Development

## Objective

The purpose of this testing is to determine and compare the mechanical strength characteristics of the Arthrex GraftBolt and the Mitek INTRAFIX.

## Methods and Materials

Porcine tibias, potted in fiberglass, were used for this study. Double-stranded, 8 mm diameter, bovine extensor tendons were prepared by whipstitching each arm of the double strand configuration. 45 mm tunnels were drilled into the tibias using an 8 mm drill for a line-to-line fit. A C-ring and 2.4 mm drill pin were used to maintain tunnel placement accuracy.

The samples were prepared by pulling a graft into the socket. With the strands held separated and in tension, the grafts were dilated with a 6 mm Dilator, followed by a 6 mm/7 mm stepped Dilator. The 8 mm GraftBolt sheath was inserted between the four tensioned graft strands using the custom driver. A 7 x 28 mm Delta Tapered PEEK Interference Screw was inserted to engage the barbs on the sheath. Mitek INTRAFIX samples were prepared by dilating with the 9 mm INTRAFIX Trial (REF: 254651).

The potted tibias were secured to an adjustable angle fixture positioned in the materials testing machine (Instron 8871), to create pull-to-failure in line with the tunnel, to simulate worst case loading conditions. The tendon loop was secured to the cross-head with a clevis and dowel fixture. The test set-up is shown in Figure 1.

**Figure 1:** A porcine tibia sample positioned in the Instron for mechanical testing with the digital video camera recording the graft position.

The graft was precycled from 10 to 50 N at 1 Hz for 10 cycles, followed by cycling from 50 to 250 N at 1 Hz for 500 cycles. Post-cycling, pull-to-failure was conducted at 20 mm/min.

The ultimate load, yield load, load at 5 mm displacement, stiffness, plastic (Xp) and elastic (Xe) cyclic displacement, and the mode of failure were recorded for each sample. Additionally, digital video tracking was used to determine the displacement at the fixation site, as shown in Figure 1.

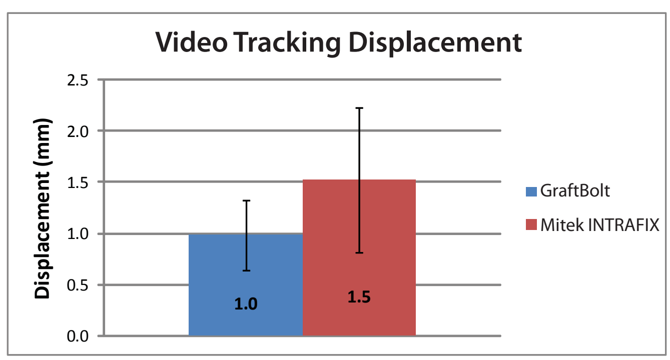
## Results

The results of the biomechanical testing are listed in Table 1. The lower video tracking displacement of the GraftBolt samples was significantly different than that of the INTRAFIX samples (p = 0.019), as shown in Figure 2. No other comparisons were significantly different, although on average, the GraftBolt had higher values for ultimate load, yield load and the load at 5 mm displacement than the INTRAFIX.

**Table 1:** Biomechanical testing results of the Arthrex GraftBolt and the Mitek INTRAFIX. Xp and Xe refer to the plastic and elastic displacement, respectively, as measured from the Instron cross-head. The video tracking measured only the displacement of the graft at the tibial tunnel orifice.

| Device | Samples Size | Ultimate Load (N) | Yield Load (N) | Load @ 5 mm (N) |
|---|---|---|---|---|
| GraftBolt | 14 | 1181 ± 308 | 1117 ± 301 | 732 ± 164 |
| Mitek INTRAFIX | 13 | 1004 ± 272 | 961 ± 273 | 650 ± 223 |
| **Device** | **Stiffness (N/mm)** | **Cyclic Displacement (mm)** | | **Video Track (mm)** |
| | | **Xp** | **Xe** | |
| GraftBolt | 206 ± 49 | 1.8 ± 0.4 | 0.8 ± 0.1 | 1.0 ± 0.3 |
| Mitek INTRAFIX | 201 ± 53 | 2.2 ± 0.8 | 0.8 ± 0.1 | 1.5 ± 0.7 |

**Figure 2:** The graft displacement at the tibial orifice was significantly lower for the GraftBolt.




## Conclusion

The mechanical strength characteristics of the Arthrex GraftBolt are, on average, superior to those of the Mitek INTRAFIX.