TunneLoc® Tibial Fixation Device vs. IntraFix™ Tibial Device

Biomet Sports Medicine Research & Development

Objective

The DePuy Mitek IntraFix™ device is a commonly used ACL reconstruction tibial fixation device that has been used clinically since 1999. The TunneLoc® Tibial Fixation Device, manufactured by Biomet Sports Medicine, is a similar product that employs cortical and aperture fixation as the means for holding the ACL graft securely within the tibial bone tunnel. The distinguishing feature when comparing these implants is that the IntraFix™ device is a two piece design, sheath and screw, while the TunneLoc® device is a one piece design. The purpose of this testing was to determine the yield load, cyclic displacement, and stiffness of both products.

Methods & Materials

The TunneLoc® implants and the IntraFix™ implants were inserted into 15 lb/ft^3 solid rigid polyurethane foam block. Each piece of 15 lb/ft^3 solid rigid polyurethane foam block was cylindrical (2.5" diameter, 1.5" height) with an 8mm pilot hole drilled at a 45-degree angle. During implant insertion, hose clamps were used to constrain the foam block and prevent the polyurethane foam from cracking. Each implant was inserted flush with the polyurethane foam as indicated by the cortical stop while grafts were held under constant tension. The sizing and insertion technique was followed per the vendors' recommendations.

A uniform, synthetic graft material, braided nylon rope, was utilized during testing. The nylon graft substitute had a consistent gage length for each sample. Keeping a consistent gage length allows for accurate stiffness calculations regarding the implant-graft construct.

The test setup is shown in Figure 1 and the loading profile in this study included the following steps:

1. Sample was preloaded to 50 N and then held in place for 10 seconds.
2. Sample was cyclically loaded from 50 N to 250 N for 2000 cycles at 1 Hz.
3. After cyclic loading, the sample was pulled to failure at a rate of 50 mm/min.

Results

Table 1 summarizes the IntraFix™ device and TunneLoc® device data collected regarding cyclic displacement, yield load, and stiffness while Figures 2, 3, and 4 chart this data individually.

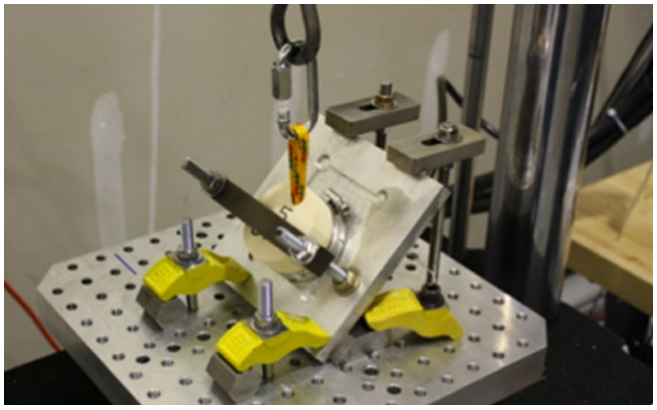

Figure 1

Product	Cyclic Displacement (mm)	Yield Loads (N)	Stiffness (N/mm)
TunneLoc® Tibial Device	2.03 +/-.15	1152 +/-52	314 +/-19
IntraFix™ Tibial Device	2.12 +/-.22	1050 +/-148	287 +/-15

Table 1

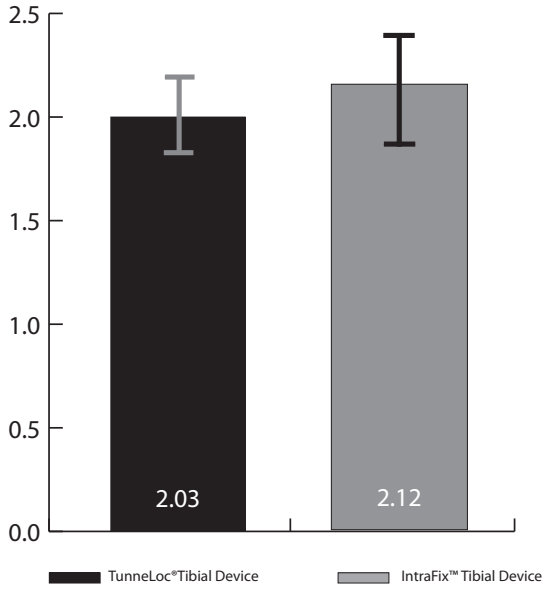

Figure 2: Residual Cyclic Displacement

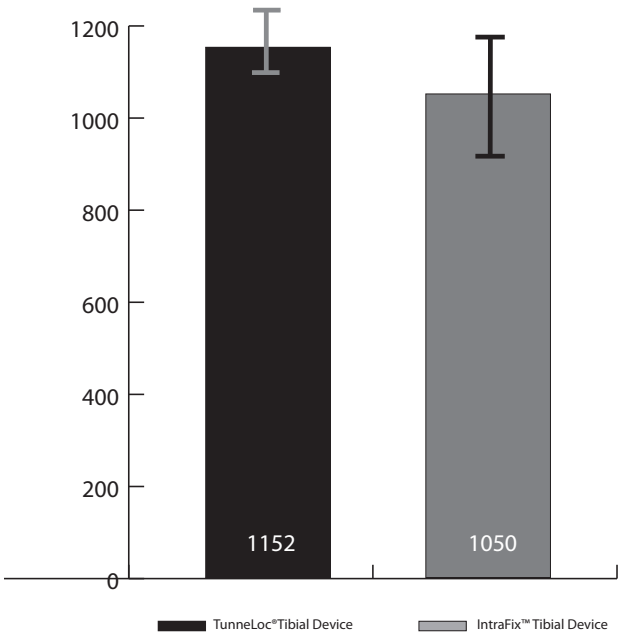

Figure 3: Yield Loads

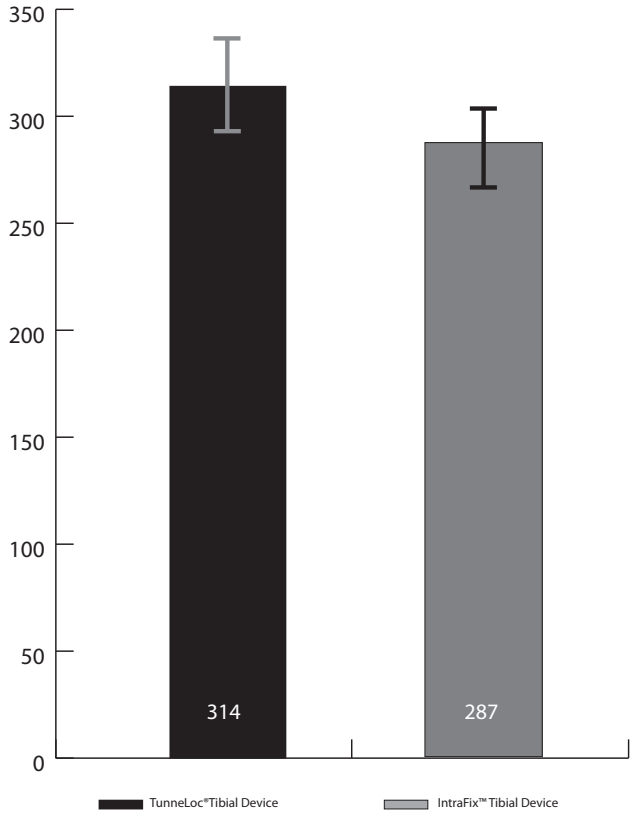

Figure 4: Stiffness Values

Conclusion

The mechanical test results indicate that there is no statistical significance between the IntraFix™ device and TunneLoc® devices with regard to cyclic displacement and yield load, but the TunneLoc® device's stiffness is significantly better than the IntraFix™ device's stiffness (p=0.023). In addition, the testing does verify that the TunneLoc® Tibial Fixation one piece design performs as well as the IntraFix™ Tibial Fixation two piece design.

Data on file at Biomet Sports Medicine. Bench testing is not necessarily indicative of clinical performance.

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P.O. Box 587, Warsaw, IN 46581-0587 • 800.348.9500 ext. 1501

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