

Mechanical and Biomechanical Comparison Testing of 1.3 mm SutureTape™ Sutures

Arthrex Research and Development

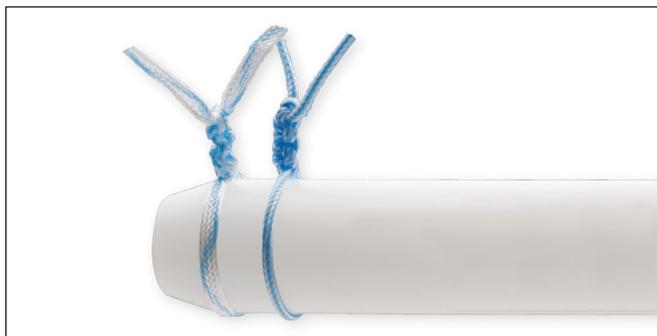
Objective

Determine the knot security and tissue pull-through characteristics of 1.3 mm SutureTape™ sutures, and compare the results to #2 FiberWire® sutures.

Methods and Materials

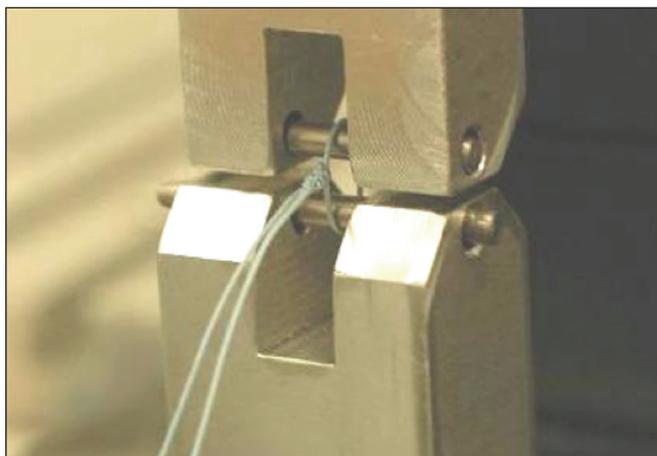
Knot Security Testing: Six samples, each, of 1.3 mm SutureTape and #2 FiberWire were used to create six throw surgeon's knots (alternating half-hitches), over a 3/8" dowel, as shown in Figure 1. All samples were prepared by orthopedic surgeon, Stephen S. Burkhart, MD.

Figure 1: Six-throw surgeon's knot tied over a 3/8" dowel with 1.3 mm SutureTape (left) and #2 FiberWire (right).



Mechanical testing was performed using an INSTRON®* 5544 Electromechanical Dynamic Testing Machine with a 2kN load cell secured to the cross-head. Custom fixtures with 3.95 mm dowel pins were secured to the testing surface and cross-head, as shown in Figure 2. A pull-to-failure was performed at 12 in/min, and load and displacement data were recorded at 500 Hz. The failure load and maximum load at 3 mm displacement were determined for each sample.

Figure 2: Knot security test setup.



Tissue Pull-Through Testing: Matched pairs of male shoulders (59 ± 8 years) were dissected leaving the glenoid and attached labrum. One sample of each suture type was passed under the labrum in a simple stitch configuration at the 5:00 and 7:00 positions of the glenoid "clock face" for each glenoid sample. Biomechanical testing was performed using an E10kN INSTRON ElectroPuls™, with a 1 kN load cell secured to the cross-head. Glenoid samples were mounted to the testing surface on a three-degree of freedom fixture allowing the sample to be positioned such that the sutures were being pulled perpendicular to the labrum and parallel to the glenoid face. The suture tails were secured in a pneumatic clamp, as shown in Figure 3. A pull-to-failure was conducted at 12 in/min and load and displacement data were recorded at 500 Hz.

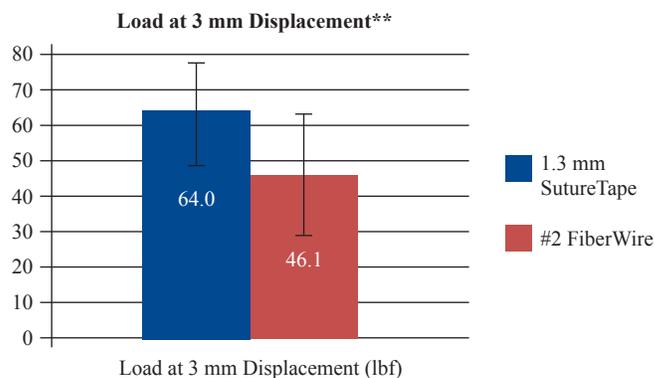
Figure 3: Tissue pull-through test setup.



Results

Knot Security Testing: Both suture sample groups had average failure loads above 60 lbf, and there was no significant ultimate load difference between the two groups ($p = 0.219$). However, the load at 3 mm displacement for the 1.3 mm SutureTape (64.0 ± 13.4 lbf) was significantly larger than the #2 FiberWire (46.1 ± 16.6 lbf) ($p = 0.026$). The load at 3 mm displacement is shown graphically in Figure 4.

Figure 4: Load at 3 mm displacement.

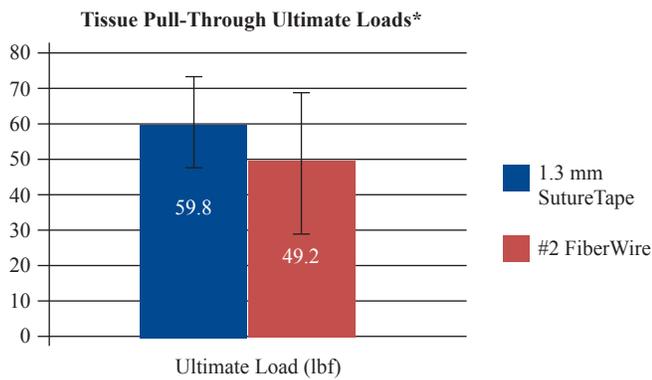


*Registered by respective owner
**Data on file

The ultimate failure loads of the 1.3 mm SutureTape™ suture samples occurred between 2 and 3 mm displacement, while the failure loads of the #2 FiberWire® suture samples occurred between 3 and 11 mm displacement; further demonstrating the superior knot security of the 1.3 mm SutureTape.

Tissue Pull-Through Testing: The tissue pull-through ultimate load of the 1.3 mm SutureTape samples and #2 FiberWire samples was 59.8 ± 13.9 lbf and 49.2 ± 19.6 lbf, respectively. The difference between the groups was not significantly different ($p = 0.219$). The results are shown graphically in Figure 5.

Figure 5: Tissue pull-through ultimate loads.



Conclusion

The 1.3 mm SutureTape demonstrated significantly superior knot security when compared to #2 FiberWire. Also, though not significant, the average tissue pull-through ultimate load was 21% greater than that of the #2 FiberWire.