Ankle Syndesmosis Repair System with Acu-Sinch® Knotless: Third-Party Biomechanical Testing Summary

Comparative Fatigue Displacement

Objective

The purpose of this study is to evaluate the performance of Acu-Sinch Knotless, Arthrex Syndesmosis TightRope XP Implant System, and Zimmer Biomet ZipTight Ankle Fixation System in dynamic fatigue displacement and ultimate load to failure.

Scope

This study evaluated the Acu-Sinch Knotless System device (46-0023-S, 46-0024-S), the Arthrex TightRope XP (AR-8925SS, AR-8295T), and the Zimmer Biomet ZipTight (909853, 909857).

Method

Testing was performed by third-party test house Element Materials Technology.

Devices were installed per the surgical technique across separated 10 pcf foam blocks with a 2 mm laminated shell simulating a cortical bone layer. Testing constructs were loaded onto a test machine between two brackets that were separated axially to apply a tensile force onto the fixation construct. Each device was tested with a sample size of 8.

In dynamic testing, devices were preloaded to 53 N, and subsequently cycled between 53 N and 113 N at 2 Hz for 420,000 cycles or until 3 mm of displacement from the preloaded position. The 420,000 cycles simulate 12 weeks of walking 5,000 steps per day on the affected limb. A 3 mm displacement, or suture creep, represents loosening to a point of syndesmotic instability.

Ultimate load testing was conducted postcycling at a rate of 20 mm/min to determine maximum load and failure mode. A minimum result of 625 N was considered as a clinically relevant benchmark. Postcycling failure load best represents the strength of the device when faced with high impact postsurgery.

Results

Ultimate Load to Failure

The ultimate load of the Acu-Sinch Knotless device after the cycling testing was 1018 +/- 46 N, and the Arthrex TightRope XP device was 890 +/- 118 N, with the most common failure mode of both being run out and suture failure following static pull. The ultimate load of the Zimmer Biomet ZipTight device was 424 +/- 122 N with the most common failure mode being knot pull out (Figure 1).

Suture Creep

The suture creep measured over the duration of cyclic testing for the Acu-Sinch Knotless device was 1.94 +/- 0.26 mm, the Arthrex TightRope XP was 1.97 +/- 0.16 mm, and the Zimmer Biomet ZipTight was 2.95 +/- 0.11 mm (Figure 2).

Figure 1: Comparative Ultimate Load to Failure

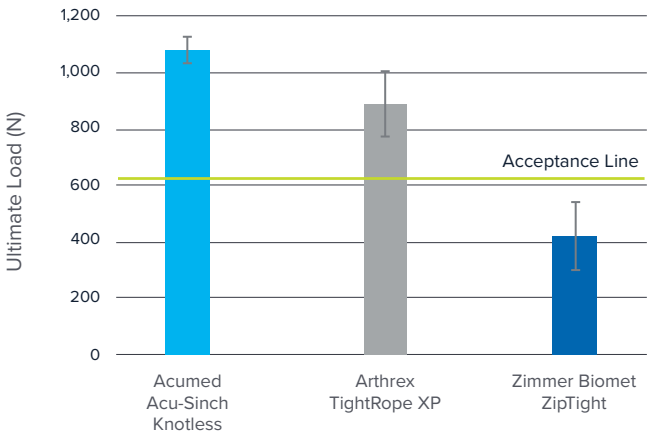
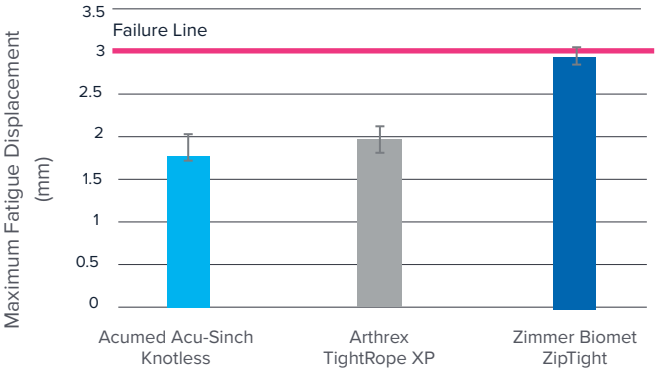


Figure 2: Comparative Fatigue Displacement



Discussion

The results of this test show **that the Acu-Sinch Knotless device achieves statistically significantly higher ultimate failure loads following cyclic testing when compared to the Arthrex TightRope XP** (p= .018) **and the Zimmer Biomet ZipTight** (p= .000) using a two-sample t-test.

Additionally, the results show that **Acu-Sinch Knotless and Arthrex TightRope XP demonstrate comparable mean fatigue displacement of less than 2 mm of creep over the cycling duration, with the Acu-Sinch Knotless showing statistically significantly lower fatigue displacement when compared to the Zimmer Biomet ZipTight** at 2.95 mm of creep. Performance under 2 mm is a stricter clinical requirement than the tested 3 mm, but has been shown to maintain stability.[1]

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References

Acumed Test Report Summary: TR-011789

1. Michel P J van den Bekerom Diagnosing syndesmotic instability in ankle fractures. *World J Orthop.* 2011 Jul 18;2(7):51–56.

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