

Synd-EZ™ Syndesmosis Repair System Bench-Top Performance Test Results

The industry has seen two important trends in the surgical fixation of syndesmotic injuries. These are the move away from trans-syndesmotic screw fixation in lieu of dynamic suture-button systems and the subsequent move away from knotted fixation systems to knotless ones.

As with any ligament repair in the body, the time zero strength and the stability of the repair construct in loading conditions during the healing phase are key to support proper healing. For this reason, Anika's Synd-EZ Repair System with GFS Ultimate Graft Fixation System adjustable suture construct technology was designed for ease of use, maximum initial fixation strength and minimal construct elongation from cyclic loading during the healing phase.

To demonstrate the excellent biomechanical performance of the Synd-EZ Syndesmosis Repair System, Anika conducted cyclic loading and load to failure tests and benchmarked against the leading US knotless suture-button system.

Cyclic Loading

The Anika Synd-EZ Ti and Arthrex Knotless TightRope® devices were cyclically tested on an MTS Tensile Test Machine.

Set up

Each device was loaded on their respective test plates through a hole that corresponds to the appropriate size for each button as per each device IFU; Synd-EZ - 3.5mm hole and TightRope - 3.7mm hole. All slack was removed from each suture loop and set-up blocks were used to consistently set the distance of all test specimens so that there was approximately a 66mm span between the buttons.

Prior to cyclic loading, a preconditioning run of 20 cycles was performed to simulate surgical evaluation of the device.



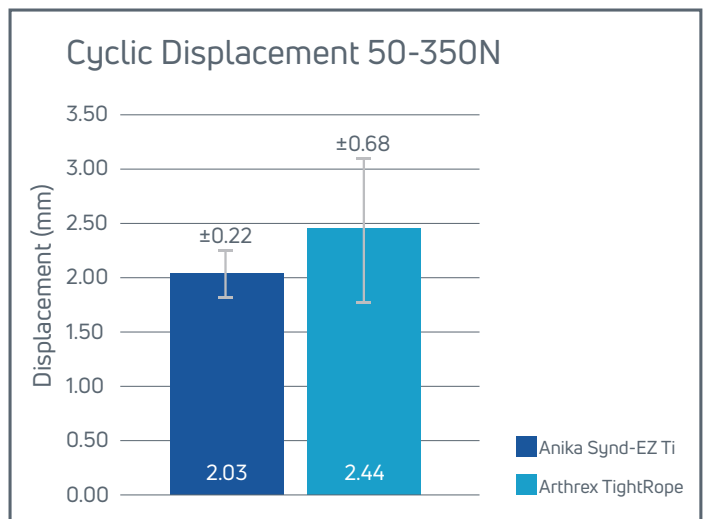
Preconditioning Load (N)	Preconditioning Cycles	Cyclic Load (N)	# Cycles	Cycle Frequency (Hz)
20-100	20	50-350	2000	2.5

Cycle testing was performed from 50-350N on each test specimen. A test was deemed a failure if the device did not complete all 2000 cycles or if the elongation exceeded 5.0mm after cycling. The results of these tests are listed in the following tables.

Elongation After Cyclic Loading 50-350N

Cyclic loading	Synd-EZ Ti P/N 11223	TightRope P/N AR-8926SS
	Elongation after cycling (mm)	
Specimen 1	1.693	3.239*
Specimen 2	2.123	1.602
Specimen 3	2.180	2.355
Specimen 4	2.238	2.573
Specimen 5	1.935	-
Mean	2.034	2.442
Std. Dev.	0.222	0.675

*The TightRope device failed on cycle 1303 as a result of suture failure near the round button.



Cyclic Loading Performance Summary

- After completing 2000 cycles, the Synd-EZ Ti test specimens showed, on average, **a 20% superior biomechanical performance** against elongation after cyclic loading by elongating an average of 2.034 ± 0.222 mm versus the Arthrex TightRope's results in which test specimens elongated an average of 2.442 ± 0.675 mm
- **None** of the Synd-EZ Ti test specimens experienced failure during cycling
- One Arthrex device failed on cycle 1303 as a result of suture failure near the round button
- Immediately prior to failure, the failed TightRope test specimen exhibited 3.239mm of elongation
- At 0.222mm, the standard deviation of elongation of the Synd-EZ Repair System was less than that of Arthrex at 0.675mm, meaning that **within this test, the Anika devices performed more consistently.**

Ultimate Loading

In addition to testing for cyclic displacement, load-to-failure tests were performed to measure the force required to get each device to fail. Ultimate load testing was performed immediately following the completion of cyclic testing of each specimen at a rate of 1.5 in/min.

Ultimate Loading	Synd-EZ Ti P/N 11223		TightRope P/N AR-8926SS	
	Failure Load (lbf)	Elongation at Failure (mm)	Failure Load (lbf)	Elongation at Failure (mm)
Specimen 1	254.818	4.028	78.683*	3.239*
Specimen 2	244.670	4.107	185.590	2.551
Specimen 3	255.731	4.163	229.603	3.988
Specimen 4	239.494	3.815	195.632	3.819
Specimen 5	256.162	3.885	-	-
Mean	250.175	3.999	172.377	3.399
Std. Dev.	7.627	0.147	65.240	0.650

All Data On File, Anika Therapeutics, Inc. Test report date 11/12/2019.

Anika Therapeutics, Inc.

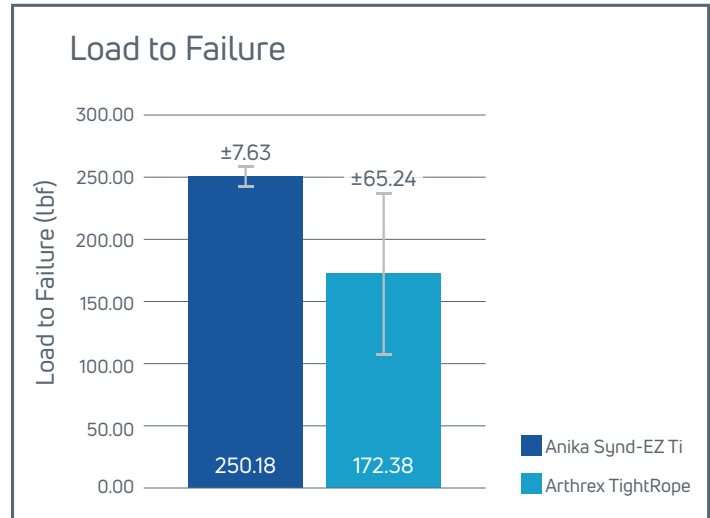
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AML 900-584 REV 01



Ultimate Loading Performance Summary

- **The Synd-EZ Ti test specimens mean load-to-failure was observed to be biomechanically superior**
 - Anika Synd-EZ Ti: 250.175 ± 7.627 lbf with an elongation of 3.999 ± 0.147 mm at failure
 - Arthrex TightRope: 172.377 ± 65.239 lbf with an elongation of 3.399 ± 0.650 mm at failure
- **Synd-EZ Ti's lowest load-to-failure was higher than TightRope's best performance**
- The standard deviation of load to failure was much lower for Synd-EZ meaning that **the Anika device's construct strength was more consistent and predictable throughout this test.**

Synd-EZ Ti Repair System Performance Bottom Line

Not only did the Synd-EZ Ti Repair System outperform the Arthrex TightRope construct in ultimate strength and elongation after cyclic loading, but it exhibited tighter standard deviations in both tests. These results are indicative of a stronger and more reliable performance of the Anika Synd-EZ Ti in the biomechanical performance parameters that matter most: time zero strength and the stability of the repair construct in loading conditions during the healing phase.