Evaluation of the ACL TightRope Cyclic Displacement Results Reported by Barrow et al

Arthrex Research and Development

Objective

The Arthrex TightRope allows adjustable cortical fixation for cruciate ligament reconstruction. Approximately 300,000 devices have been sold with no documented reports of failure due to slipping or excessive creep of the mechanism.[1] AJSM recently electronically published an article by Barrow et al. claiming 42 mm of displacement during cyclic loading of the TightRope.[2] These results are not consistent with previously reported cyclic displacement of the TightRope or clinical experiences. The objective of this white paper is as follows:

1. Report clinical outcomes of ACL fixation using the TightRope device;
2. Compare the Barrow results to previous testing of the TightRope;
3. Compare the Barrow result to independent testing using the methods described by Barrow; and
4. Evaluate variables that may explain the Barrow results.

Clinical Outcomes of ACL Fixation using the TightRope Device

Subjective clinical outcomes were prospectively collected for cohorts of ACL reconstruction, utilizing soft tissue grafts fixated with the TightRope and BTB grafts fixated with interference screws. For the TightRope group, data was collected from 60 subjects at 1 year and 19 subjects at 2 years postoperative. For the BTB group, data was collected from 63 subjects at 1 year and 24 subjects 2 years postoperative. Components of the KOOS score can be seen for both cohorts in Figure 1 and Marx Activity Scores can be seen in Figure 2. There was no difference in clinical outcomes between the two cohorts ($P > .05$) except for the Sport and Recreation component of the KOOS at 1 year, which was significantly greater for the TightRope cohort ($P = .004$).

If the TightRope was prone to excessive displacement like reported by Barrow, one would hypothesize poor clinical outcomes. Prospectively collected subjective clinical outcomes suggest that the TightRope utilized for ACL reconstruction performs equally compared to the gold standard reconstruction method, BTB graft fixation with interference screws. Thus, the TightRope is not prone to excessive cyclic displacement and there is a discrepancy between the Barrow results and actual clinical outcomes.

Comparison to Previous Testing

In addition to the cyclic displacement reported by Barrow not being consistent with clinical outcomes, the displacement is not consistent with other biomechanical testing of the device. Petre et al. cyclically loaded the TightRope from 50 to 250N for 1,000 cycles and reported 1.1 ± 0.2 mm of displacement.[3] White et al. used a similar protocol and reported 0.34 ± 0.07 mm after 1,000 cycles.[4] In an Arthrex white paper *(Arthrex ACL TightRope and Biomet ZipLoop with ToggleLoc: Mechanical Testing)*, 1.13 ± .01 mm of cyclic displacement was reported after 500 cycles.[5] In another Arthrex white paper *(Fatigue Testing of the ACL TightRope)*, TightRope constructs were dynamically loaded from 50 to 250 for 500,000 cycles and cyclic displacement of 0.78 ± 0.10 mm was reported.[6] The Barrow results are not consistent with previous testing of the TightRope.

Figure 1: KOOS scores for soft-tissue fixation utilizing theTightRope and BTB fixation with interference screws

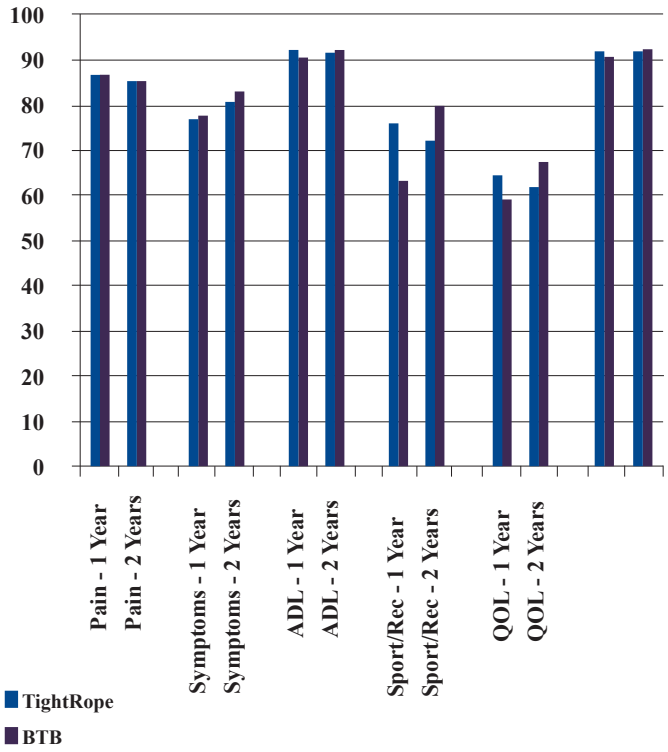
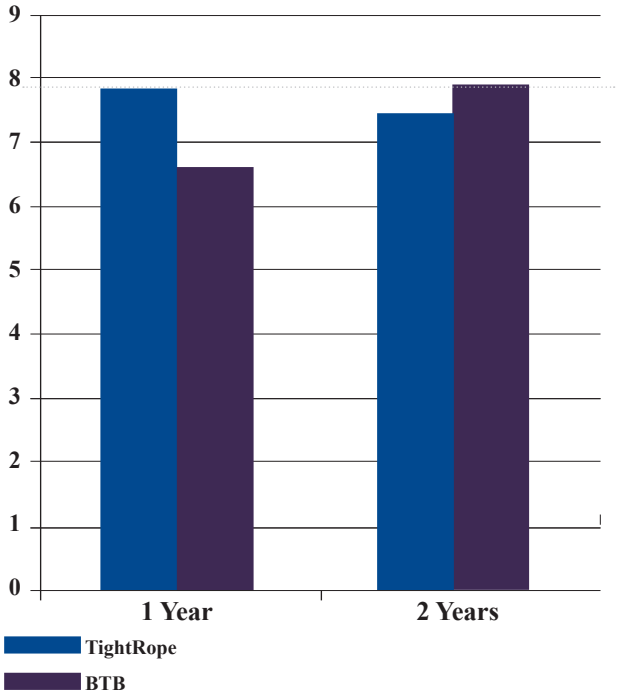


Figure 2: Marx Activity Scale



Replication of Barrow Testing

Two independent laboratories tested the TightRope devices using the identical methods and materials described by Barrow. The results can be seen in Table 1. The results are consistent amongst the different laboratories and the previously reported cyclic displacement for the TightRope. This discrepancy between the Barrow results suggests the 42 mm of cyclic displacement reported by Barrow may be erroneaus or contain additional variables not investigated by the independent laboratories.

Table 1: ***Cyclic displacement (mm) results for independent testing utilizing the Barrow protocol****

Lab	*DeBerardino*		*Cook/Smith*
Sample#	Knotted	Unknotted	Unknotted
1	1.24	1.42	2.8
2	1.03	2.16	3.1
3	1.03	1.85	3.2
4	1.2	2.02	2.4
5	-	-	2.6
Avg	**1.13**	**1.87**	**2.8**
Std Dev	**0.10**	**0.32**	**0.33**

**data on file*

Possible Explanation for Barrow Results

Supplementary data was provided to AJSM by Barrow and can be viewed on the AJSM website. The supplementary data clearly illustrates improper tuning of the test machine and the loading profile deviated from the profile described in their methods and materials. Furthermore, the loading profile was variable amongst the different devices tested.

Figure 3 illustrates an ideal load displacement curve for the cyclic loading profile described by Barrow. There are nine distinct loading regimes with all consistently cycling between the values Barrow reported. Figure 4 shows the load displacement curves included in the supplementary data provided by Barrow. The shape of the load displacement curves differ drastically from the ideal curve shown in Figure 3 and differ drastically from each other. The peak loads were not consistent within individual cyclic blocks and consistently over and under shot the intended peaks as described by Barrow. For example, during the last 500 cycles of the knotted TightRope, the minimum peak loads averaged 0.4 ± 0.28 N and maximum peak loads averaged 430.7 ± 42.92 N. The maximum loads were 1.7 times higher than described in the materials and methods. For the EndoButton constructs the minimum peak load averaged 3.53 ± 2.46 N and the maximum peak load averaged 313.91 ± 18.54 N (1.3 times higher than described in the methods and materials).

The lack of control of the test machine and discrepancy between the description of the cyclic loading profile and the actual loads applied may be an explanation why the Barrow results are inconsistent with previously reported cyclic displacement values for the TightRope. In addition, it partially explains why the independent testing resulted in drastically different results compared to the Barrow testing, as in actuality the same loads were not applied.

Despite the erroneous loading profile, the cyclic displacement values reported by Barrow were exceedingly large. To further explore the discrepant cyclic displacement, additional design of experiment testing was conducted to determine if the Barrow results could be replicated by altering the recommended orientation of the TightRope or the cyclic loading regime.

Figure 3: Example of ideal load displacement curve for the profile described by Barrow

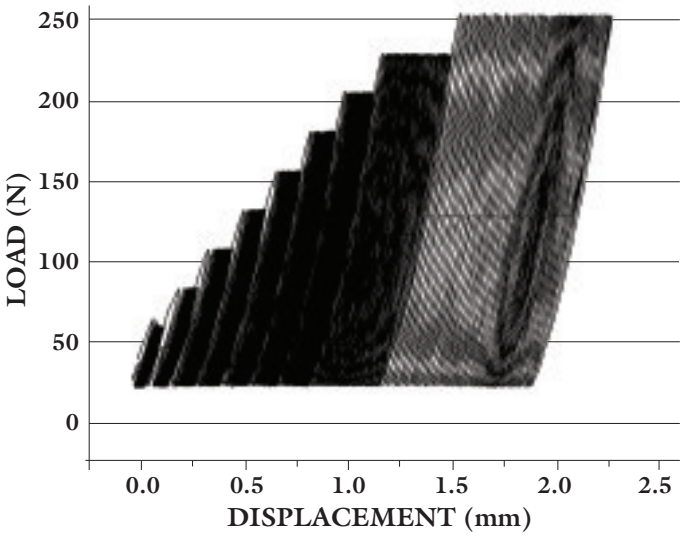
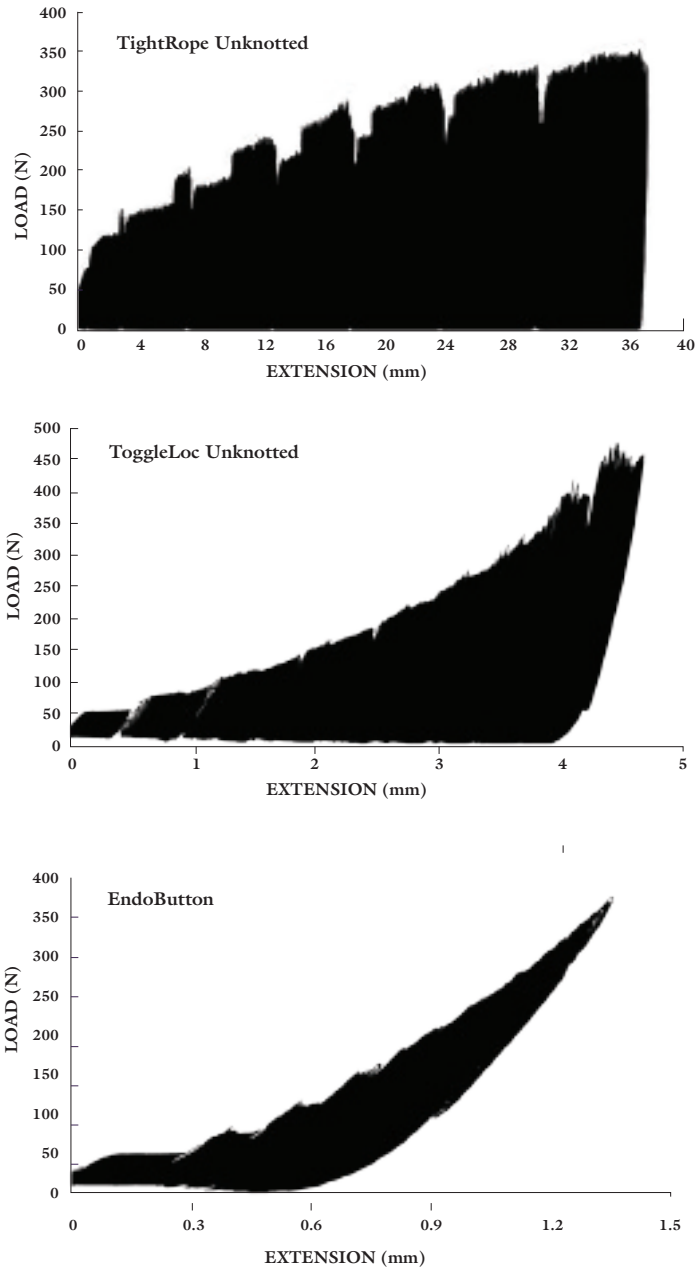
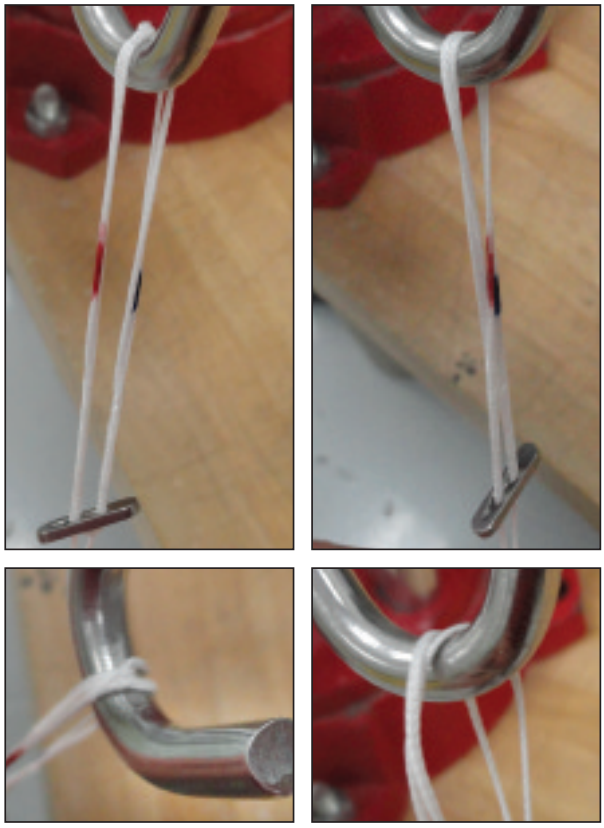


Figure 4: Load displacement curves provided by Barrow



The two orientations depicted in Figure 5 were evaluated. Figure 5-left is the orientation recommended by Arthrex, while Figure 5-right is not an orientation recommended by Arthrex, and the loops are manipulated so that both tension tails are on the same side of the hook as illustrated by the colored sutures. In addition, minimum cyclic peak loads of 0N were utilized to mimic the actual minimum cyclic peak loads applied during the Barrow study, instead of the 10N minimum peak loads falsely described in the materials and methods. The maximum cyclic peak loads described in the methods and material section of the Barrow paper were utilized as the actual load, as illustrated in their supplementary data, were too inconsistent to replicate. When combining the nonrecommended orientation with minimum cyclic loads of 0N, cyclic displacement increased to 41.1 ± 6.6 mm (n=3).[7] This combination of TightRope manipulation and alteration to the cyclic loading regime produced results that are similar to those reported by Barrow, and this may be an explanation for the falsely high cyclic displacement results reported.

Figure 5: (left) recommended orientation; (right)nonrecommended orientation. The colored suture indicates the tensioning tail strands.



Conclusion

Subjective clinical outcomes of ACL reconstruction utilizing the TightRope are similar to the gold standard reconstruction method, the BTB fixation with interference screws. This indicates that the TightRope is clinically successful, not prone to cyclic displacement as reported by Barrow, and the Barrow methodology does not accurately mimic the clinical scenario. The Barrow results are not consistent with previously reported mechanical results for the TightRope nor could be replicated by independent laboratories. The supplementary data provided by Barrow revealed a lack of control of the test machine as the loads actually applied to the constructs were not consistent with the description in the methods and materials or amongst the different constructs. Lastly, only through manipulation of the TightRope orientation prior to testing was the displacement reported by Barrow able to be replicated.

1. Product Data 2010-2013. Data on File. Arthrex, Inc. 2013.
2. Barrow AE, Pilia M, Guda T, Kadrmas WR, Burns TC, *Femoral Suspension Devices for Anterior Cruciate Ligament Reconstruction: Do Adjustable Loops Lengthen?* Am J Sports Med, October 24, 2013, 10.1177/0363546513507769.
3. Petre BM, Smith SD, Jansson KS, et al, *Femoral Cortical Suspension Devices for Soft Tissue Anterior Cruciate Ligament Reconstruction*, Am J Sports Med, February 2013, vol. 41 no. 2 (416-422).
4. White MJ, Baer, GS, *Suspensory ACL Fixation: A Biomechanical Study of Fixed and Adjustable Length Implants*, 2011 Annual AANA Meeting, San Francisco, CA. http://www.aana.org/VideoEducationLibrary/CourseListings/Knee/ACL/SuspensoryACLFixation/tabid/787/Default.aspx. Accessed January 2, 2014.
5. *Arthrex ACL TightRope and Biomet ZipLoop with ToggleLoc: Mechanical Testing,* Vol LA0179A, Naples, FL: Arthrex Inc; 2010.
6. *Fatigue Testing of the ACL TightRope*, Vol LA0180A, Naples, FL: Arthrex Inc. 2011.
7. Arthrex Research and Development. Data on File. Arthrex Inc. 2013.