New Publication Provides Evidence Based Response to the 2014 Study by Barrow et al.

Citation (quotations within this document are taken directly from the manuscript)
Johnson JS, Smith SD, LaPrade CM, Turnbull TL, LaPrade RF, Wijdicks C, *A Biomechanical Comparison of Femoral Cortical Suspension Devices for Soft Tissue Anterior Cruciate Ligament Reconstruction Under High Loads.*
Am J Sports Med. 2014 Oct 17. [Epub ahead of print] www.ncbi.nlm.nih.gov/pubmed/?term=25326014

Three Evidence Based Points

1. Manuscript by Johnson et al. Highlights "Technical Error" Found in Barrow et al.

- *"Some authors have stated that technical error may have contributed to the reported increase in displacement of biomechanically tested adjustable-loop devices."*
- *"The authors [Barrow et al.] also reported that the TightRope resulted in significantly more displacement than the ENDOBUTTON or ToggleLoc, with approximately 42 mm of displacement under cyclic loading. This amount of displacement (42.45 mm) is almost 20 times higher than what we observed in the present study (2.20 mm)[without retensioning], which evaluated the devices under a higher cyclic loading protocol."*
- Johnson et al. utilizes similar devices only testing methodology and set-up, per prior literature (Petre et al. AJSM 2013 & Barrow et al. AJSM 2014). New fixture in Johnson et al. allows for TightRope Suture Tensioner handles to easily retension the adjustable fixation devices after cyclic preconditioning.

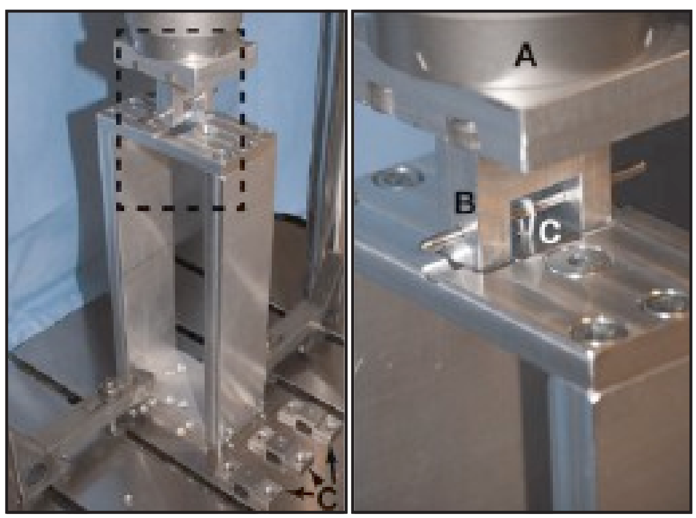

Figure 1. New device-only testing fixture used by Johnson et al.
**Note that this is not construct (graft) testing.*

2. TightRope is the Best Adjustable Device as Determined by Evidence Based Science.

•"Five different femoral soft tissue cortical suspension graft fixation devices (two adjustable-loop and three fixed-loop devices) under high loads that more accurately represent peak forces experienced by ACL grafts during early rehabilitation than previous studies."

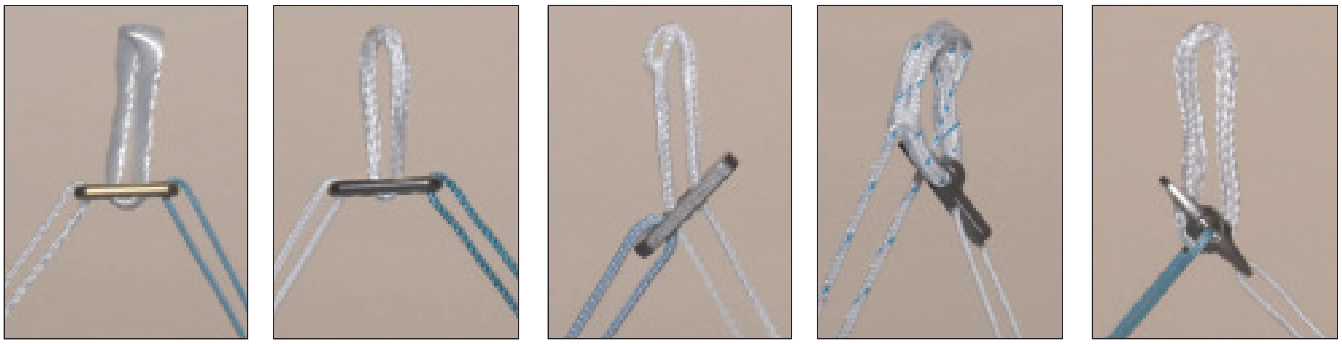

Figure 2. Cortical fixation devices from left to right (alphabetical order): ENDOBUTTON CL ULTRA, RIGIDLOOP, ACL TightRope RT, ToggleLoc with ZipLoop Inline, and XO Button.

• TightRope with retensioning is the only adjustable device that joins the below 2 mm group of fixed loop devices after cyclic displacement.

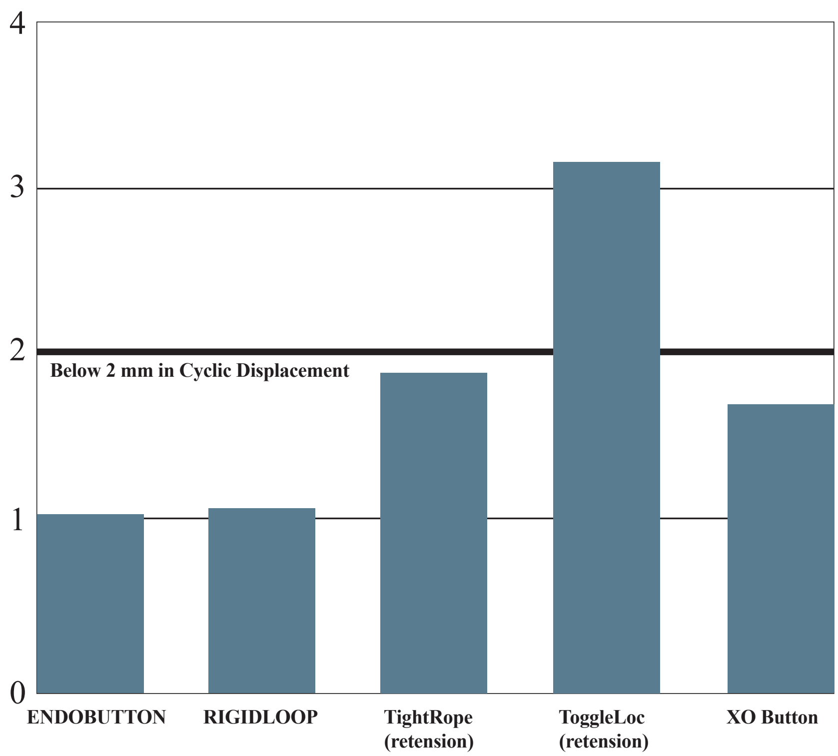

Figure 3. Graphical representation of cyclic displacement (mm) data from Table 1, demonstrating that the TightRope with retensioning is the only adjustable device that joins the below 2 mm group of fixed loop devices.

3. TightRope Has the Necessary Biomechanical Properties at Time-zero Based on Scientific Evidence.

- *"The forces acting across the ACL have been estimated to reach 150-590N in the early rehabilitation period, with walking reported to result in loads up to 411N."*
- *"We found that all soft tissue cortical fixation devices had ultimate failure strengths that were well above the higher range of peak forces that ACL grafts may experience during early rehabilitation."*
- TightRope with retensioning increases the ultimate strength (1020N) and reduces the cyclic displacement to 1.81 mm, and places itself in the sub-2 mm category of fixed loop devices.
- It is still important to note that retensioning has a positive effect and will most likely be further demonstrated in a construct (graft) model via tunnel docking.

TABLE 1
Biomechanical Properties of Femoral Cortical Suspension Devices*

	Preconditioning Displacement, mm	Retensioned	Cumulative Peak Cyclic Displacement, mm	Stiffness, N/mm	Ultimate Strength
ENDOBUTTON®	0.06 ± 0.01	NA	1.05 ± 0.05	927 ± 15	1530 ± 180
RIGIDLOOP™	0.05 ± 0.03	NA	1.09 ± 0.16	1628 ± 45	1976 ± 229
TightRope®	0.03 ± 0.02	No	2.20 ± 0.62	1354 ± 35	784 ± 45
TightRope®	0.04 ± 0.04	Yes	1.81 ± 0.51	1353 ± 60	1020 ± 421
ToggleLoc®	0.67 ± 1.49	No	3.69 ± 2.39	1480 ± 103	1995 ± 217
ToggleLoc®	0.24 ± 0.12	Yes	3.22 ± 1.41	1538 ± 57	2231 ± 511
XO Button®	0.16 ± 0.05	NA	1.65 ± 0.43	1747 ± 58	2218 ± 114

All data reported as mean ± SD. NA, not applicable.

Extra: What to Know About Retensioning Protocol Used in This Device-only Model.

- Retensioning occurred at point 'b' in the graph below.
  - *"The devices were preconditioned from 10-75N at 0.1 Hz for 10 cycles, followed by 1,000 cycles of sinusoidal cyclic loading between 100-400N at a frequency of 0.5 Hz."*
- This cyclic loading protocol applies higher loads than prior literature. Truly testing the construct at time-zero.
- This is not a construct (graft)/tunnel docking testing protocol. Full graft/TightRope construct testing is the next step in validating retensioning protocols
  - This is ongoing within Arthrex Research & Development
- The TightRope adjustable device has the added benefit of adjustability with varying tunnel depths.
- The TightRope has the ability to retension after preconditioning and graft fixation. This is not possible with fixed loop devices.
- Preconditioning can remove laxity within the device and also the graft.