Biomechanical comparison of adjustable loop femoral cortical suspension devices for soft tissue ACL reconstruction

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Top level summary

Several new adjustable-loop devices (ALDs) for anterior cruciate ligament reconstruction (ACLR) have not been tested in vitro. The purpose of this study is to compare biomechanical performances of five ALDs under a high cyclic load and forces in a servohydraulic test machine, representative of the return-to-play conditions seen in the recovering athlete.

ALDs under evaluation:[‡]

1. ProCinch (Stryker)
2. ToggleLoc (Zimmer Biomet)
3. TightRope (Arthrex)
4. UltraButton (Smith and Nephew)
5. RigidLoop Adjustable (DePuy Mitek)

Methods

A total of ten for each of the five manufacturer's devices were tested in a device-only model. A custom apparatus was constructed to allow space for in-line tensioning. Once the loop length was set and the device was tensioned to 75 N to simulate intraoperative tensioning, each ALD was tested in response to cycling and pull-to failure loading using a servohydraulic test machine, as described in Table 1.

Phase	Test Parameters	Rationale
Preconditioning	10-75 N at a rate of 0.5 Hz for 20 cycles	To simulate intraoperative cycling of the knee and to remove slack from the construct
Cyclic Loading	100-500 N at a rate of 1 Hz for 4,000 cycles	To simulate the possible peak forces experienced by the ACL graft during postoperative rehabilitation The higher than usual number of cycles was chosen to accommodate for the variability in time for ACL graft incorporation among different graft types
Pull to Failure	Pulled to failure at a rate of 50mm/min	To determine load to failure for each device

Table 1. Biomechanical testing protocol.

Data collected:

- Preconditioning displacement (mm)
- Permanent deformation (mm)
- Cumulative peak displacement (mm)
- Stiffness coefficient (N/mm)
- Load to failure (N)

It was determined that ten samples of each device were required to detect a statistically significant difference with 80% power. The primary statistical analysis consisted of an ANOVA (Analysis of Variance) for each biomechanical property, additionally the Games-Howell test was used to determine the devices with statistically significant comparisons for which the initial ANOVAs demonstrated a significant result.

Results

Of the 50 possible comparisons between these five products, 17 comparisons yielded significant differences (Figure 1).

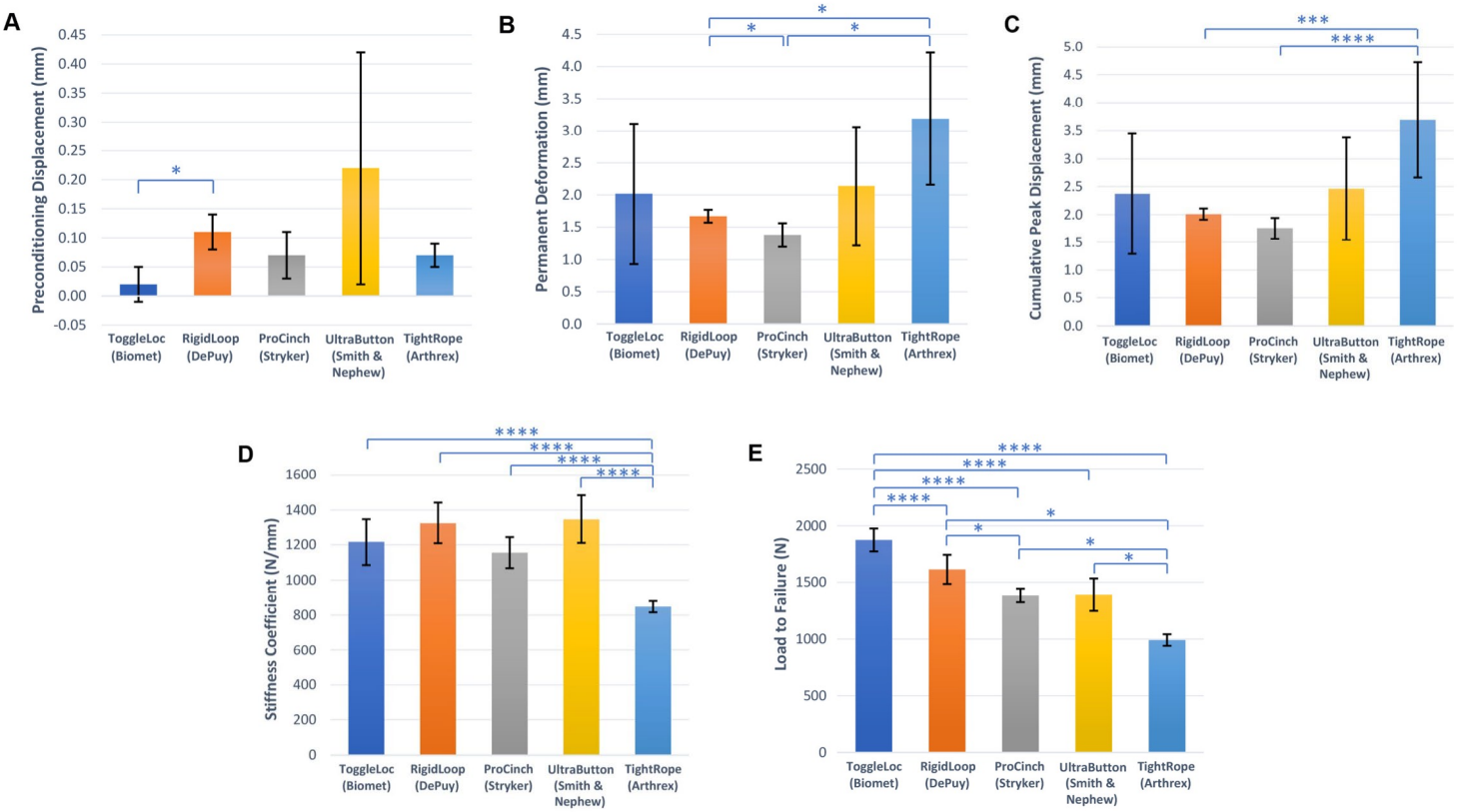

Figure 1. Results of biomechanical testing of the adjustable-loop devices. (A) Preconditioning displacement, (B) permanent deformation, (C) cumulative peak displacement, (d) stiffness, and (E) load to failure. Statistically significant differences: *P < 0.05, ***P < 0.001, ****P < 0.0001.

Clinical relevance

Significant differences in performance between devices were found among the five biomechanical properties studied:

- The most important finding of this study was that none of the tested devices had confidence intervals for cumulative peak displacement that were ≥3mm. TightRope was found to have significantly larger cumulative peak displacement as compared with UltraButton, ProCinch, ToggleLoc and RigidLoop
  - The clinical landmark of 3mm of maximal displacement has been accepted by multiple studies to represent ACLR failure. ProCinch and RigidLoop were the only two devices for which the confidence intervals did not encompass this established landmark (Figure 1C).
  - ProCinch exhibited the lowest cumulative peak displacement (1.75 +/- .19mm) of the five devices tested.
- All ALDs displayed adequate failure loads that exceeded estimated in vivo forces; however significant differences in cumulative peak displacement were observed between devices in these studies as well.
- No single device can be hypothesized to have a higher rate of clinical failure as compared with others.
- These results contrast with those that have been previously published. A combination of the evolutionary nature of these devices and differences in methodology (force range and cycle number) may explain the different results.
- **Limitations**
  - A controlled laboratory study is unable to draw inferences regarding the clinical performance of the studied ALDs.
  - It remains unknown as to how the force environment of the graft changes during different stages of rehabilitation, during lower than 100 N force, during graft incorporation. Therefore, additional quality research is required.

References

† Chapman G, Hannah J, Vij N, Liu JN, Morrison MJ, Amin N. Biomechanical Comparison of Adjustable Loop Femoral Cortical Suspension Devices for Soft Tissue ACL Reconstruction. Orthop J Sports Med. 2023 Feb 15; 11(2):23259671221146788.

‡ All devices were donated by the companies.

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