Original Research

Biomechanical Comparison of Adjustable-Loop Femoral Cortical Suspension Devices for Soft Tissue ACL Reconstruction

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Background: Several new adjustable-loop devices (ALDs) for anterior cruciate ligament reconstruction (ACLR) have not been tested in vitro.

Purpose: To compare the biomechanical performances of 5 ALDs under a high cyclic load and forces representative of the return-to-play conditions seen in the recovering athlete.

Study Design: Controlled laboratory study.

Methods: A total of 10 devices for each of 5 chosen ALDs (UltraButton [Smith & Nephew], RigidLoop [DePuy Mitek], ProCinch [Stryker], TightRope [Arthrex], and ToggleLoc [Biomet]) were tested in a device-only model. The devices were secured to a servohydraulic test machine and preconditioned from 10 to 75 N at a rate of 0.5 Hz for 20 cycles. They were then subjected to high cyclic forces (100-500 N for 4000 cycles) and subsequently pulled to failure at 50 mm/min. The preconditioning displacement, permanent deformation, cumulative peak displacement, stiffness coefficient, and load to failure data were collected.

Results: The UltraButton displayed the greatest preconditioning displacement (0.22 ± 0.20 mm), followed by the RigidLoop (0.11 ± 0.03 mm), ProCinch (0.07 ± 0.04 mm), TightRope (0.07 ± 0.02 mm), and ToggleLoc (0.02 ± 0.03 mm). The TightRope displayed the greatest permanent deformation (3.19 ± 1.03 mm) followed by the UltraButton (2.14 ± 0.92 mm), ToggleLoc (2.02 ± 1.09 mm), RigidLoop (1.67 ± 0.1 mm), and ProCinch (1.38 ± 0.18 mm). The TightRope displayed the greatest cumulative peak displacement (3.69 ± 1.03 mm) followed by the UltraButton (2.46 ± 0.92 mm), ToggleLoc (2.37 ± 1.08 mm), RigidLoop (2.01 ± 0.1 mm), and ProCinch (1.75 ± 0.19 mm). The UltraButton displayed the largest stiffness coefficient (1347.22 ± 136.33 N/mm) followed by the RigidLoop (1325.4 ± 116.37 N/mm), ToggleLoc (1216.62 ± 131.32 N/mm), ProCinch (1155.56 ± 88.04), and TightRope (848.48 ± 31.94). The ToggleLoc displayed the largest load to failure (1874.42 ± 101.08 N) followed by the RigidLoop (1614.12 ± 129.11 N), UltraButton (1391.69 ± 142.04 N), ProCinch (1384.85 ± 58.62 N), and TightRope (991.8 ± 51.1 N.)

Conclusion: The 5 ALDs exhibited different biomechanical properties. None of them had peak cumulative displacements for which the confidence interval lay above 3 mm, thus no single device was determined to have a higher rate of clinical failure compared with the others.

Clinical Relevance: ALD choice may affect biomechanics after ACLR.

Keywords: ACL; adjustable loop device; cortical button; ligament reconstruction; sports medicine

Studies have shown that anterior cruciate ligament (ACL) reconstructions (ACLRs) require 6 to 12 weeks for tendon–bone incorporation for autografts and up to 6 months for allografts.[6,7,9] Rigid fixation is required for proper healing. A lack of secure fixation during this period may lead to instability and ultimately failure.

Adjustable-loop devices (ALDs) were designed to allow surgeons to accommodate for small variations in graft and tunnel lengths that are sometimes produced intraoperatively during ACLRs. Over traditional closed-loop femoral cortical suspension devices, ALDs may be advantageous in terms of minimizing graft-tunnel mismatch. However, there is some concern within the orthopaedic community that when subjected to the rigors of early rehabilitation, ALDs may exhibit cumulative displacement or "slippage." The minimum clinically significant cumulative displacement is well-established at $\geq$3 mm. ALDs that allow for displacement $\geq$3 mm may lead to failure.[2-4]

Several studies have focused on evaluating the biomechanical properties of ALDs[2,7,8]; however, previous studies

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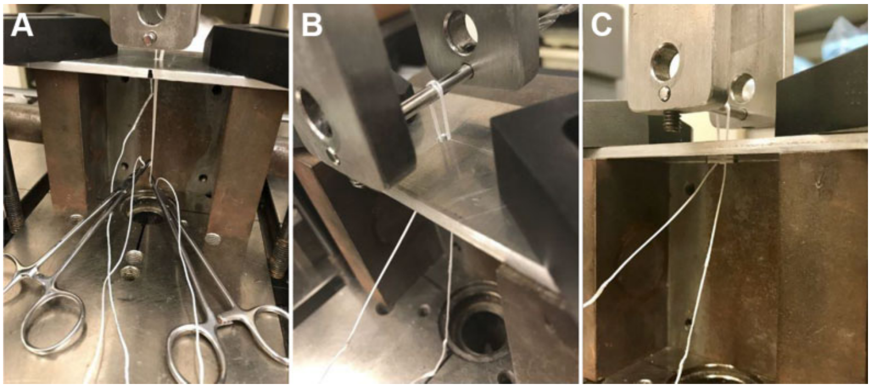

Figure 1. (A) Custom apparatus designed to allow space for in-line tensioning with the use of hemostats. (B) Replicating the femoral cortex, 5 mm–thick stainless steel plates were used with corresponding 4.0-mm and 4.5-mm holes. ALD cortical buttons were secured against the inferior side of the stainless-steel plates. (C) ALDs were connected to the actuator of the testing machine via a 4.5-mm steel rod. ALD, adjustable-loop device.

have focused more on comparing ALDs with traditional fixed-loop femoral cortical suspension devices or have compared only 2 or 3 ALDs. Some of these previous studies used loading protocols with fewer loading cycles or lower ranges of force than the currently accepted estimate of peak force that ACLs experience in vivo (590 N).[2,5,8,10] Further, several of the devices in our study have not yet been studied in an external controlled laboratory setting.

The purpose of this study was to compare the biomechanical performances of 5 ALDs in a head-to-head pairwise comparison under the rigors of a high cyclic load and forces representative of the return-to-play conditions seen in the recovering athlete. The hypothesis was that there would be no significant difference in the preconditioning displacement, permanent deformation, cumulative peak displacement, and load to failure between the devices.

METHODS

Cortical Suspension Devices

Five ALDs were tested in this study: UltraButton (Smith & Nephew), RigidLoop (DePuy Mitek), ProCinch (Stryker), TightRope (Arthrex), and ToggleLoc (Biomet). For each device, 10 samples were tested using the same protocol (N = 50). All devices were donated by the companies.

Experimental Setup

This study involved a device-only model to isolate the mechanical properties of each ALD. A custom apparatus was constructed to allow space for in-line tensioning (Figure 1A). The fixture was secured to a servo hydraulic test machine (ElectroPuls E10000; Instron). To replicate the femoral cortex, 5 mm–thick stainless steel plates were attached to the top of the construct, each plate with a single hole corresponding to each manufacturer's recommended drill hole diameter (Figure 1B). The hole diameters were 4.0 mm for the TightRope and 4.5 mm for the ToggleLoc, UltraButton, ProCinch, and RigidLoop. The device loops were placed around a 4.5 mm–diameter steel rod. The steel rod was then secured to the dynamic tensile test machine actuator and the custom fixture with the steel insert fixed to the base plate (Figure 1C). The ALDs were then passed through the hole in the steel plate and secured against the inferior portion of the plate. This setup allowed for the dynamic tensile machine actuator to pull tension in line

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Ethical approval was not sought for the present study.

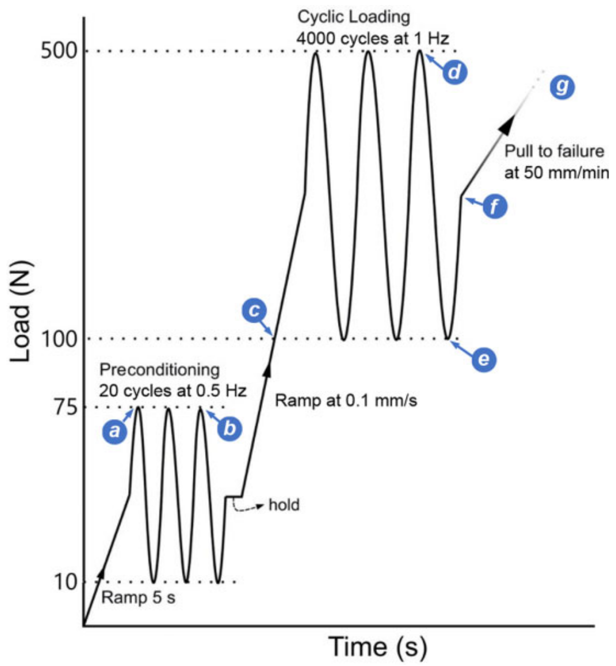

Figure 2. Graphical representation of the testing protocol and points of data analysis: preconditioning displacement (Δ_{ab}), permanent deformation (Δ_{ce}), cumulative peak displacement (Δ_{cd}), stiffness between 100 and 600 N (Δ_{fg}), and ultimate failure load (not depicted).

with the device loops and perpendicular to the cortical button. Each subsequent run for each adjustable-length loop device was tested at this same initial length by securing it to the baseplate and steel rod at the preset distance. Once the loop length was set, the device was tensioned to 75 N to simulate intraoperative tensioning.

Biomechanical Testing

Each ALD was tested in response to cyclic and pull-to-failure loading using a servohydraulic test machine. The devices were preconditioned from 10 to 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. After cyclic preconditioning, construct displacement was recorded and the devices were retensioned to 75 N. The devices were subsequently subjected to a sinusoidal cyclic loading from 100 to 500 N at a rate of 1 Hz for 4000 cycles. This protocol was chosen to simulate the possible peak forces experienced by the ACL graft during postoperative rehabilitation. The high number of cycles was chosen to accommodate for the variability in time for ACL graft incorporation among different graft types. After cyclic loading, each ALD was pulled to failure at a rate of 50 mm/min. The preconditioning displacement (in millimeters), permanent deformation (in millimeters), cumulative peak displacement (in millimeters), stiffness coefficient (in Newtons per millimeter) between 100 and 500 N, and load to failure (in Newtons) for each device were collected (Figure 2). Load-displacement curves were recorded using Wave Matrix software (Instron).

TABLE 1
Results of Biomechanical Testing Overall and According to Each ALD[a]

Variable	Mean ± SD
Preconditioning displacement, mm	0.09 ± 0.12
ToggleLoc	0.02 ± 0.03
RigidLoop	0.11 ± 0.03
ProCinch	0.07 ± 0.04
UltraButton	0.22 ± 0.20
TightRope	0.07 ± 0.02
Permanent deformation, mm	2.08 ± .98
ToggleLoc	2.02 ± 1.09
RigidLoop	1.67 ± 0.1
ProCinch	1.38 ± 0.18
UltraButton	2.14 ± 0.92
TightRope	3.19 ± 1.03
Cumulative peak displacement, mm	2.45 ± 1.02
ToggleLoc	2.37 ± 1.08
RigidLoop	2.01 ± 0.1
ProCinch	1.75 ± 0.19
UltraButton	2.46 ± 0.92
TightRope	3.69 ± 1.03
Stiffness coefficient, N/mm	1178.66 ± 208.66
ToggleLoc	1216.62 ± 131.32
RigidLoop	1325.4 ± 116.37
ProCinch	1155.56 ± 88.04
UltraButton	1347.22 ± 136.33
TightRope	848.48 ± 31.94
Failure load, N	1451.37 ± 310.05
ToggleLoc	1874.42 ± 101.08
RigidLoop	1614.12 ± 129.11
ProCinch	1384.85 ± 58.62
UltraButton	1391.68 ± 142.04
TightRope	991.8 ± 51.1

[a]n = 10 samples for each device. ALD, adjustable-loop device.

Statistical Analysis

A sample-size analysis was conducted before ALD testing. With the difference in group means set at 10% and a standard deviation of 6%, it was determined that 10 samples of each device were required to detect a statistically significant difference with 80% power. The primary statistical analysis consisted of an analysis of variance (ANOVA). 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 5 products, 17 comparisons yielded significant differences. The results are summarized in Table 1 and Figure 3.

The UltraButton displayed the greatest preconditioning displacement (0.22 ± 0.20 mm) followed by the RigidLoop (0.11 ± 0.03 mm), ProCinch (0.07 ± 0.04 mm), TightRope (0.07 ± 0.02 mm), and ToggleLoc (0.02 ± 0.03 mm). Only the difference between the RigidLoop and ToggleLoc was statistically significant ($P < .05$) (Figure 3A).

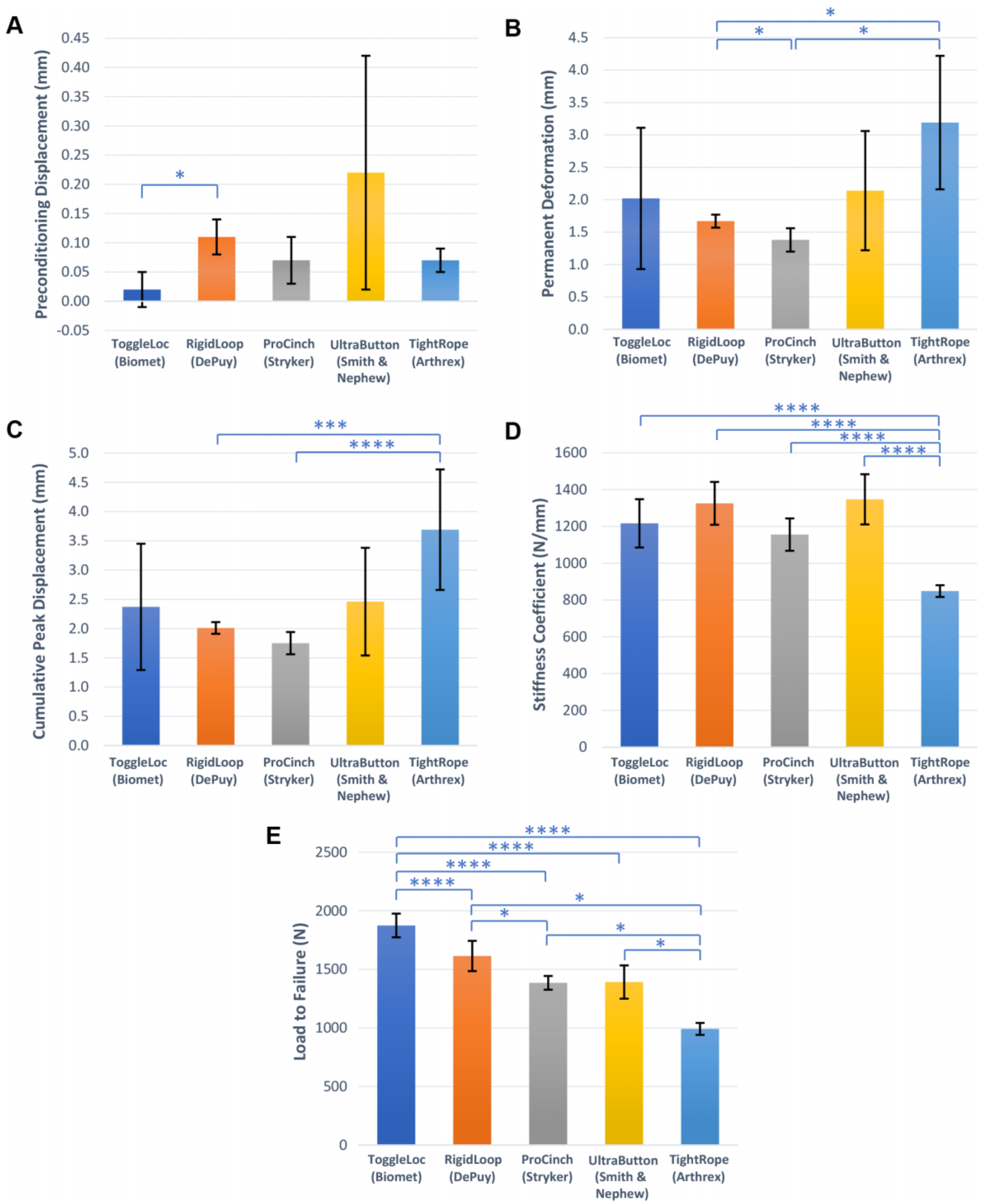

Figure 3. Results of biomechanical testing of the adjustable-loop devices. (A) Preconditioning displacement, (B) permanent deformation, (C) cumulative peak displacement, (D) stiffness, and (E) load to failure. Statistically significant differences: *$P < .05$, ***$P < .001$, ****$P < .0001$.

The TightRope displayed the greatest permanent deformation (3.19 ± 1.03 mm) followed by UltraButton (2.14 ± 0.92 mm), ToggleLoc (2.02 ± 1.09 mm), RigidLoop (1.67 ± 0.1 mm), and ProCinch (1.38 ± 0.18 mm). The differences between TightRope and RigidLoop, TightRope and ProCinch, and RigidLoop and ProCinch were statistically significant ($P < .05$ for all) (Figure 3B).

The TightRope displayed the greatest cumulative peak displacement (3.69 ± 1.03 mm) followed by the UltraButton (2.46 ± 0.92 mm), ToggleLoc (2.37 ± 1.08 mm), RigidLoop (2.01 ± 0.1 mm), and ProCinch (1.75 ± 0.19 mm). The differences between TightRope and RigidLoop ($P = .0002$), and between TightRope and ProCinch ($P < .0001$) were statistically significant (Figure 3C).

The UltraButton displayed the largest stiffness coefficient (1347.22 ± 136.33 N/mm) followed by RigidLoop (1325.4 ± 116.37 N/mm), ToggleLoc (1216.62 ± 131.32 N/mm), ProCinch (1155.56 ± 88.04 N/mm), and TightRope (848.48 ± 31.94 N/mm). ToggleLoc, RigidLoop, ProCinch, and UltraButton each had significantly greater stiffness than TightRope ($P < .0001$ for all) (Figure 3D).

The ToggleLoc displayed the largest load to failure (1874.42 ± 101.08 N) followed by RigidLoop (1614.12 ± 129.11 N), UltraButton (1391.69 ± 142.04 N), ProCinch (1384.85 ± 58.62 N), and TightRope (991.8 ± 51.1 N.) The load to failure for ToggleLoc was significantly larger than that of RigidLoop, ProCinch, UltraButton, and TightRope ($P < .0001$ for all). The load to failure for RigidLoop was significantly larger than that of ProCinch and TightRope ($P < .05$ for both). The load to failure for ProCinch and UltraButton were each significantly larger than that of TightRope ($P < .05$ for both) (Figure 3E).

DISCUSSION

In our head-to-head pairwise comparison simulating the forces encountered by ALDs during early rehabilitation, we found significant differences in performance between devices among the 5 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 $\geq$3 mm. TightRope was found to have a significantly larger cumulative peak displacement as compared with UltraButton, ProCinch, ToggleLoc, and RigidLoop.

The clinical landmark of 3 mm of maximal displacement has been accepted by multiple studies to represent ACLR failure.[3,4,6] The average value for TightRope did exceed this established landmark; however, values <3 mm were encompassed by its confidence interval. No other ALD displayed an average cumulative peak displacement of $\geq$3 mm. ProCinch and RigidLoop were the only 2 devices for which the confidence intervals did not encompass this established landmark (Figure 3C). Our results contrast with those that have been previously published. Petre et al[9] demonstrated that ToggleLoc crossed the clinical threshold for cyclic displacement. However, in their study, Toggle Loc did have sufficient ultimate failure strength. A combination of the evolutionary nature of these devices and differences in methodology (force range and cycle number) may explain our different results.[9] In particular, our force range had a minimum of 100 N, whereas Petre et al cycled their devices as low as 25 N. We are unable to comment as to whether or not the differences seen by Petre et al would have been seen in our study if tested under the same force range.

In our study, significant differences were found with regard to permanent deformation in 3 of the 10 comparisons made (Figure 3B). Maintenance of the time-zero position is an important consideration, as rigid graft fixation is critical during early recovery period. Without secure fixation, progressive instability of the knee may arise. Continual strain can lead to frank failure of the construct. As an alternative to traditional rigid fixation, it is implicit that ALDs must be able to handle the forces upon the healing ACL in the high-level athlete while avoiding elongation. Our results further support that biomechanical differences between the 5 studied ALDs may exist. Previous studies have also demonstrated that differences in the cumulative peak displacement between fixed-loop and adjustable loop devices may exist and thus the results of our study need to be interpreted in that context.[7]

In our study, 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. The performance of ALDs have been tested in several previous studies. There is a much variability in the published literature on this topic both with regard to loading cycle and range of forces. Common force maximums include 250 N and 400 N.[1,7,9] Generally, the devices are tested for 1000 cycles, although a well accepted study does utilize 4500 cycles.[7] The results of our study elaborate on the aforementioned studies in the context of a higher number of loading cycles over a larger range of forces. Thus, our results may represent the conditions of cyclical loading of the knee and the force range experienced by the recovering athlete undergoing ACLR.

Given previous concern regarding ALDs,[9] there has been much excitement regarding the newer generation devices tested in our study. An important additional consideration in the conversation regarding the biomechanics of the ALD is that of knot tying over an ALD. It has been demonstrated that doing so may substantially reduce total displacement.[2] Further, studies are required regarding the entire biomechanical profile after tying a knot over the cortical button.

Limitations

Our study is not without its limitations. As a controlled laboratory study, our study is unable to draw inferences regarding the clinical performance of the studied ALDs. As a device-only model, our study is unable to shed light on the effect that these devices may have on femoral bone cut-through or graft incorporation. Thus, the variables preconditioning displacement (mm), permanent deformation (mm), and cumulative peak displacement (mm) may only represent a portion of the in vivo graft displacement that may take place in the recovering athlete. Since our load cycles did not encompass force values below 100 N, our study does not account for the possibility of ALDs unlocking when the tension is removed. Further, it remains unknown as to how the force environment of the graft changes during different stages of rehabilitation. High-quality clinical research is required before comparative statements between the studied devices can be made.

CONCLUSION

These 5 adjustable-loop–femoral cortical systems may exhibit different biomechanical properties. None of the tested devices had peak cumulative displacements for which the confidence interval lay above 3 mm and thus no single device can be hypothesized to have a higher rate of clinical failure as compared with the others. Future studies should determine whether there are any clinical ramifications to the biomechanical differences seen in our study.

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