Biomechanical Evaluation of a Novel Loop Retention Mechanism for Cortical Graft Fixation in ACL Reconstruction

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Background: Implant fixation by means of a cortical fixation device (CFD) has become a routine procedure in anterior cruciate ligament reconstruction. There is no clear consensus whether adjustable-length CFDs are more susceptible to loop lengthening when compared with pretied fixed-length CFDs.

Purpose: To assess biomechanical performance measures of 3 types of CFDs when subjected to various loading protocols.

Study Design: Controlled laboratory study.

Methods: Three types of CFDs underwent biomechanical testing: 1 fixed length and 2 adjustable length. One of the adjustable-length devices is based on the so-called finger trap mechanism, and the other is based on a modified sling lock mechanism. A device-only test of 5000 cycles (n = 8 per group) and a tendon-device test of 1000 cycles (n = 8 per group) with lower and upper force limits of 50 and 250 N, respectively, were applied, followed by ramp-to-failure testing. Adjustable-length devices then underwent further cyclic testing with complete loop unloading (n = 5 per group) at each cycle, as well as fatigue testing (n = 3 per group) over a total of 1 million cycles. Derived mechanical parameters were compared among the devices for statistical significance using Kruskal-Wallis analysis of variance followed by post hoc Mann-Whitney *U* testing with Bonferroni correction.

Results: All CFDs showed elongation <2 mm after 5000 cycles when tested in an isolated manner and withstood ultimate tensile forces in excess of estimated peak in vivo forces. In both device-only and tendon-device tests, differences in cyclic performance were found among the devices, favoring adjustable-length fixation devices over the fixed-length device. Completely unloading the suspension loops, however, led to excessive loop lengthening of the finger trap device, whereas the modified sling lock device remained stable throughout the test. The fixed-length device displayed superior ultimate strength over both adjustable-length devices. Both adjustable-length devices showed adequate fatigue behavior during high-cyclic testing.

Conclusion: All tested devices successfully prevented critical construct elongation when tested with constant tension and withstood ultimate loads in excess of estimated in vivo forces during the rehabilitation phase. The finger trap device gradually lengthened excessively when completely unloaded during cyclic testing.

Clinical Relevance: Critical loop lengthening may occur if adjustable-length devices based on the finger trap mechanism are repeatedly unloaded in situ.

Keywords: ACL reconstruction; cortical fixation; adjustable button; biomechanical testing; cyclic loading

In anterior cruciate ligament (ACL) reconstruction, rigid primary fixation of the tendon graft is essential to enable adequate biological incorporation.[6] Nonrigid fixation may allow repetitive micromotion and migration of the graft, leading to joint laxity, instability, or even functional failure of the repair.[20] Graft fixation is most frequently achieved through bone interference screws or cortically via small button-like cortical fixation devices (CFDs).[12] CFDs provide either fixed- or adjustable-length fixation, with the
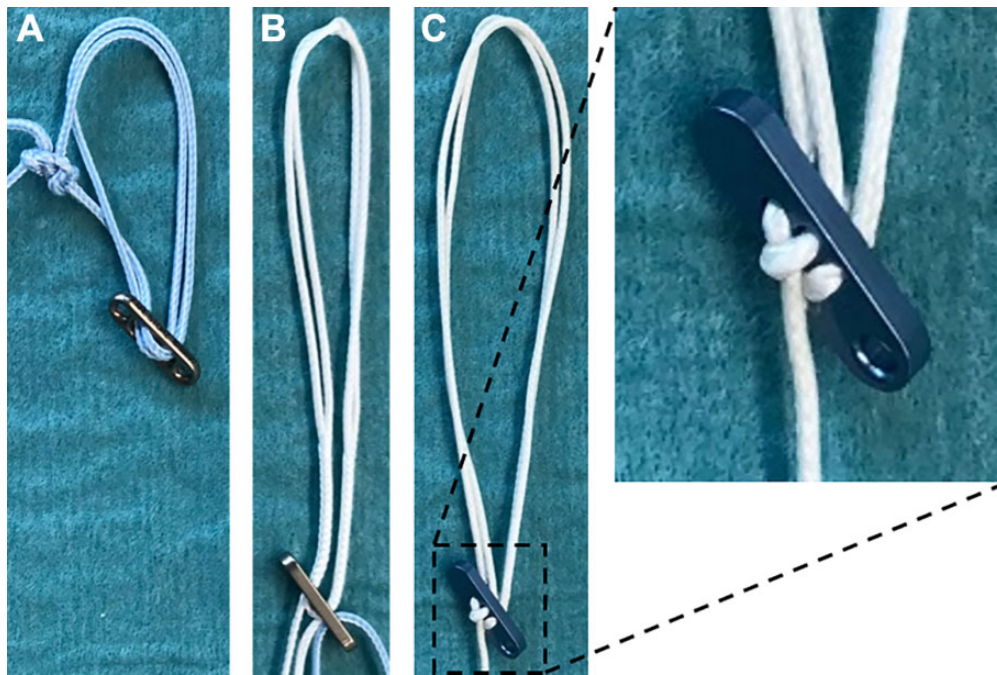
main advantages of the latter seen in providing the possibility of intraoperative graft-length adjustment and maximization of graft-bone contact.[1] Adjustable-length devices rely on either of 2 mechanisms of loop retention. In the first technique—generally referred to as the "finger trap"—the tensioning suture is sheathed by an additional load-carrying loop, which tightens when load is applied, thereby securing the tensioning suture in place.[19] In the second technique, the loading loop slings around the tensioning suture, and the resulting pressure prevents loop elongation (hereafter, "sling lock" mechanism). Fixed-length devices (FLDs) either rely on a continuous loop or are pretied to the specified length before insertion. Although clinical

Figure 1. The cortical fixation devices tested included (A) a pretied fixed-length device, (B) an adjustable-length device based on the finger trap, and (C) a single-strand adjustable-length device based on the modified sling lock mechanism.

results are generally satisfactory,[5,7,13,14] multiple biomechanical studies have raised concern regarding inferior fixation characteristics of adjustable-length CFD alone when compared with interference screw fixation[25] and fixed-length suspensory fixation.[1,2,18,20,30] Moreover, in an ex vivo biomechanical study, Glasbrenner et al[19] pointed out that adjustable-length fixation devices that rely on the finger trap mechanism can be sensitive to complete graft unloading during cyclic testing, with partial failure of the fixation within 2500 cycles of loading. Adjustable CFDs based on the sling lock mechanism, however, have exhibited unsatisfactory mechanical performance even when subjected to moderately high-cyclic forces.[1]

The present study describes an adjustable-length fixation device based on a modified sling lock mechanism. The device comprises 1 loading suture with a stopper knot and a titanium suspension button with 6 holes. The stopper knot allows 1 suture end to be connected to the button; therefore, the construct can be shortened by pulling only 1 suture strand. The suture strand is first looped twice through the button and then passed underneath the static

loop, thereby creating a self-blocking sling system (Figure 1).

The purpose of this study was to assess biomechanical performance measures related to cyclic behavior, ultimate strength, and high-cyclic fatigue of 3 CFDs: a pretied FLD, an adjustable-length device based on the finger trap, and a single-strand adjustable-length device based on the modified sling lock mechanism. To this end, the 3 CFDs underwent multiple testing protocols to determine cyclic and ultimate strength, as well as potential construct fatigue. The devices were tested in an isolated-device setup as well as in a more application-related setup by adding a tendon graft to the construct. The 2 adjustable-length devices underwent additional evaluation in a cyclic test with complete unloading of the suspension loop. Furthermore, both adjustable-length devices were subjected to high-cyclic testing to assess their fatigue behavior.

We introduce an optimized approach for the characterization of loop lengthening during cyclic testing by appropriately parameterizing lengthening behavior of the construct. We hypothesized that all CFDs would prevent

clinically critical loop lengthening and withstand forces in excess of those required during early rehabilitation after ACL surgery.

METHODS

Study Design

Three CFDs underwent biomechanical testing in 2 test setups: (1) a pretied FLD (Flipptack; Karl Storz GmbH & Co KG), (2) an adjustable-length device based on the finger trap mechanism (TightRope RT; Arthrex Inc), and (3) an adjustable-length device based on the modified sling lock mechanism (VariLoop; ZuriMED Technologies AG). First, the devices underwent cyclic testing in an isolated manner ("device-only setup"). The applied testing protocols consisted of cyclic loading with standard parameters established in the literature followed by ramp-to-failure testing, a cyclic loading protocol including complete loop unloading, and a protocol applying high-cyclic testing. Second, devices were equipped with a bovine superficial digital flexor tendon graft and cyclically loaded (tendon-device testing). A sample size of 8 per group for cyclic tests without complete unloading was adapted from previous literature.[1,11,20,27,30] A priori power calculations were performed for cyclic testing with complete loop unloading based on pilot and literature data.[19] Effect sizes for this experiment were anticipated to be large (Cohen $d \geq 3$); therefore, 5 samples per group were deemed to yield sufficient statistical power ($P = .98$). Cyclic testing with complete loop unloading and high-cyclic testing was performed with the finger trap device (FTD) and modified sling lock device (MSLD) but not with the FLD. For the latter experiment, 3 samples of each group were tested; no statistical testing was planned.

Materials

The FLD was tested with its nonadjustable loop tied to a loop length of 30 mm with surgical suture FiberWire No. 5 (Arthrex Inc). Four square knots were tied in a 1=1=1=1 configuration according to Tera and Åberg.[39] This knotting protocol conformed to the instructions for use of the manufacturer. FTD devices were tested without additional safety knotting according to the instructions for use. The MSLD consists of a titanium cortical button and an ultrahigh molecular weight polyethylene suture with a stopper knot tied into 1 end. This stopper knot sits on the surface of the cortical button, and loop shortening can be acquired by tightening only 1 suture strand.

　Bovine hallucis longus tendons served as models for the tendon grafts and were purchased from a local slaughterhouse. Excess muscle from the ends of the tendons was removed, and the tendons were thinned in diameter so that their doubled-over total diameter was 8 mm. After the tendons were prepared, they were bathed in phosphate-buffered saline, wrapped in gauze, and stored in the freezer at -20°C. During testing, tendons were kept moist by being sprayed with phosphate-buffered saline in 10-minute intervals to prevent them from drying out.

Testing Setup

Mechanical testing was conducted with a material testing machine (Zwick Roell 1456; Zwick GmbH) equipped with a 20-kN load cell. Force, crosshead position, and cycle number were recorded with the associated sampling software (TestXpert; Zwick GmbH). The testing machine was equipped with custom-made parts for sample fixation.[8,9] For isolated device testing, the loading suture was looped around a steel pin with a diameter of 6 mm, and the cortical button was placed behind a steel plate (Figure 2). For tendon-device testing, a clamp was mounted onto the load cell to hold the tendon graft in place. In both test setups, the suture loop length was set to 30 mm. For graft-device testing, the length of the tendon graft was set to 30 mm.

Mechanical Testing

To account for the forces acting on the CFD during device insertion, a preconditioning protocol was applied with forces between 10 and 50 N and a total of 10 cycles. Cyclic testing of the devices was then performed at forces between 50 and 250 N at a maximum crosshead velocity of 1 mm/s for a total of 5000 and 1000 cycles in isolated device testing and graft-device testing, respectively. After cyclic loading, test samples underwent ramp-to-failure testing at a rate of 20 mm/min. To assess fatigue behavior, adjustable-length devices additionally underwent high-cyclic testing with 1 million cycles and identical loading parameters. In a separate experiment, the 2 adjustable-length devices were loaded over a total of 1000 cycles with complete loop unloading at each cycle.

Data Analysis

Mechanical data were recorded at an irregular grid with a basic spatial resolution of 0.1 mm and a minimum sampling rate of 10 Hz. Elongation per cycle was defined as construct elongation from the position at 50 N at the start of cyclic testing to the position at 50 N of the respective cycle. Cyclic stiffness was defined as the slope of the linear curve connecting minimum and maximum positions of the last recorded cycle. Ultimate tensile elongation was defined as construct elongation from the position at 50 N at the end of cyclic testing to the length at maximum force achieved (ie, ultimate tensile strength). Data analysis was conducted with Matlab (MATLAB 2018a; The MathWorks, Inc).

Statistical Analysis

Statistical analysis was conducted using SPSS (v 24.0; IBM Corp); for data visualization, Stata software (release 15; StataCorp LLC) was used. Visual data inspection and Kolmogorov-Smirnov testing indicated data were nonnormally distributed. Consequently, nonparametric methods for statistical inference testing were used. Construct elongation during cyclic testing was described with the 2 factors
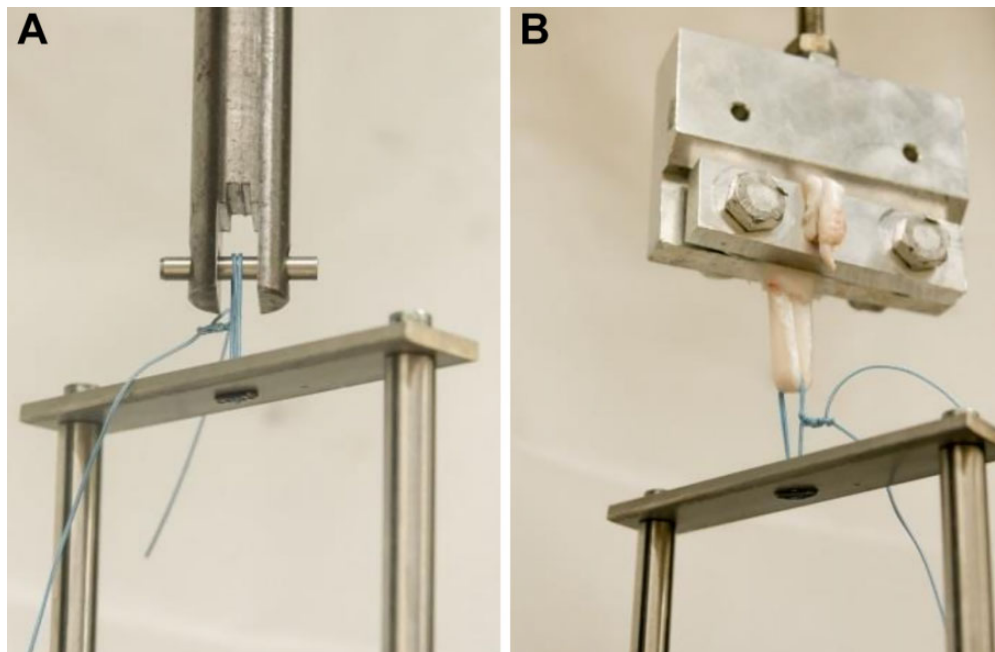
Figure 2. Test setups for (A) isolated device testing and (B) tendon-device testing.

of initial elongation (ie, first cycle) and cyclic elongation. Cumulative elongation was thereby parameterized with the least squares linear fit of the construct length at the log-transformed number of cycles, yielding the following formula to predict cumulative construct elongation (E) at any given number of cycles (N_{cycle}) as a function of initial elongation (E_I) and cyclic elongation (E_C):

$$E(N_{cycle}) = E_I + E_C \times \log_{10}(N_{cycle}).$$

This representation showed an excellent fit, with a minimum coefficient of determination (r^2) of 0.901, and allowed meaningful, concise interpretation and statistical testing. Initial elongation, cyclic elongation, cyclic stiffness, ultimate tensile strength, and ultimate tensile elongation were compared among fixation devices using Kruskal-Wallis analysis of variance. Significant variables were further investigated using pairwise Mann-Whitney U testing with Bonferroni correction. If not stated otherwise, data are reported as median and range.

RESULTS

Isolated Device Testing

In isolated device testing, all assessed parameters—namely, initial elongation ($\chi^2[2] = 18.074$; $P < .001$), cyclic elongation ($\chi^2[2] = 10.267$; $P = .006$), and cyclic stiffness ($\chi^2[2] = 13.823$; $P = .001$)—displayed statistically significant differences among the devices (Figure 3). Pairwise comparison revealed MSLD to be superior to FLD in all assessed performance measures, whereas FTD outperformed FLD only in initial elongation and cyclic stiffness.

Comparing MSLD with FTD revealed no statistically significant differences (Table 1).

Tendon-Device Testing

As in isolated device testing, tendon-device testing revealed statistically significant differences among the CFDs in initial elongation ($\chi^2[2] = 18.395$, $P < .001$), cyclic elongation ($\chi^2[2] = 15.765$, $P < .001$), as well as cyclic stiffness ($\chi^2[2] = 6.305$, $P = .043$) (Figure 3). Post hoc pairwise comparison indicated superior biomechanical performance of MSLD over FLD in initial elongation and cyclic elongation but not cyclic stiffness. MSLD outperformed FTD in terms of initial elongation, cyclic elongation as well as cyclic stiffness. Pairwise comparison of FLD and FTD revealed initial elongation but not cyclic elongation or cyclic stiffness to be different (Table 1).

Complete Loop Unloading

When the fixation loops were unloaded completely in the isolated device setup, all MSLD samples survived the 1000 test cycles with a median (range) initial elongation of 0.30 mm (0.28-0.31 mm) and a median cyclic elongation of 0.13 (0.11-0.21 mm), whereas all FTDs failed with an initial elongation of 0.34 mm (0.11-0.21 mm; $P = .690$) and a cyclic elongation of 1.90 mm (1.30-2.10 mm; $P = .008$) (Figure 4).

High-Cyclic Testing

All MSLD samples survived high-cyclic testing with a mean ± SD additional elongation of 0.39 ± 0.11 mm from the 5000th to the end of the test at 1 million cycles,
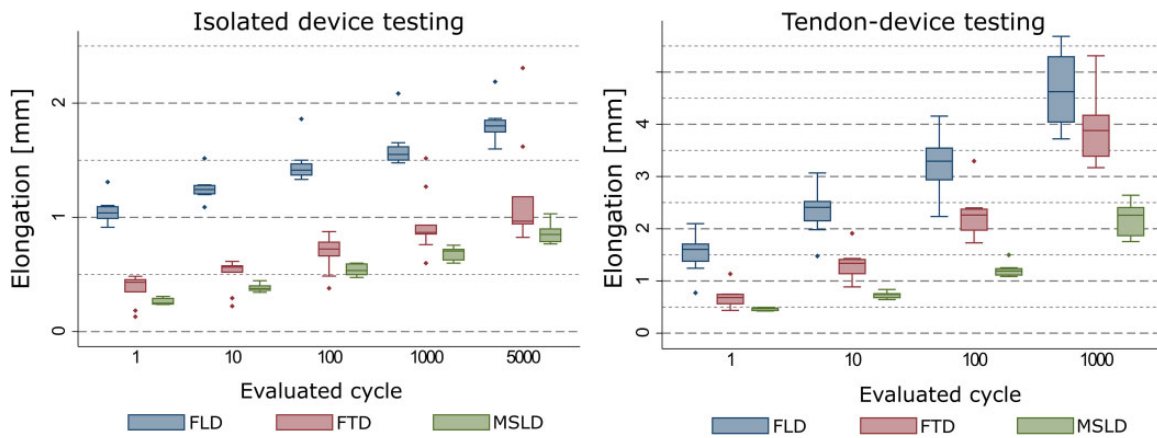
Figure 3. Cumulative construct elongation during cyclic testing for the 2 test setups. Values are presented as median (line), interquartile range (box), range (error bars), and outliers (diamonds). FLD, fixed-length device; FTD, finger trap device; MSLD, modified sling lock device.

TABLE 1
Cyclic Performance Measures for FLD, FTD, and MSLD
During Isolated Device and Tendon-Device Testing[a]

Outcome:	Median (Range)	P Value vs FTD	vs MSLD
Isolated device testing			
Initial elongation, mm			
FLD	1.04 (0.91-1.31)	<.001	<.001
FTD	0.42 (0.10-0.48)		.396
MSLD	0.25 (0.24-0.31)		
Cyclic elongation, mm			
FLD	0.17 (0.15-0.25)	≥.999	.003
FTD	0.17 (0.13-0.42)		.087
MSLD	0.14 (0.12-0.17)		
Cyclic stiffness, N/mm			
FLD	752 (714-779)	.009	<.001
FTD	985 (745-1059)		≥.999
MSLD	940 (859-1051)		
Tendon-device testing			
Initial elongation, mm			
FLD	1.61 (0.77-2.10)	.001	<.001
FTD	0.68 (0.44-1.14)		.014
MSLD	0.47 (0.43-0.49)		
Cyclic elongation, mm			
FLD	0.82 (0.72-1.13)	≥.999	<.001
FTD	0.88 (0.74-1.29)		<.001
MSLD	0.39 (0.38-0.56)		
Cyclic stiffness, N/mm			
FLD	309 (190-350)	≥.999	.391
FTD	289 (257-327)		.014
MSLD	248 (234-283)		

[a]*P* values are of post hoc pairwise comparisons (Bonferroni corrected). FLD, fixed-length device; FTD, finger trap device; MSLD, modified sling lock device.
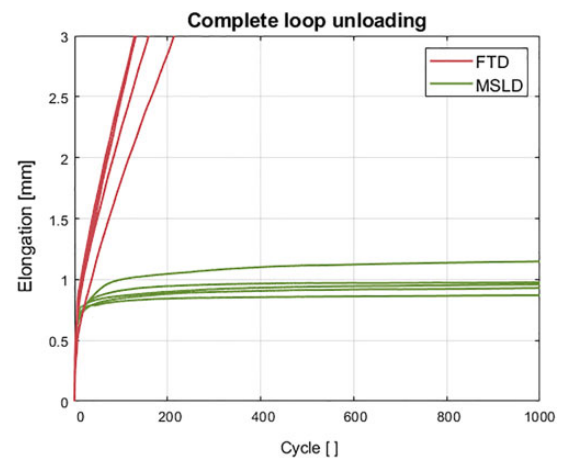
Figure 4. With complete loop unloading, the finger trap device (FTD) displayed critical loop lengthening within the first hundreds of load cycles, whereas the modified sling lock device (MSLD) exhibited loop lengthening <1.5 mm over the 1000 test cycles.

displaying high fatigue strength. One FTD sample failed after approximately 400,000 cycles. Moreover, all MSLD samples displayed less elongation throughout the entire test as compared with FTD (Figure 5).

Ramp-to-Failure Testing

Cause of failure during ultimate tensile testing was suture breakage in all cases. Suture breakage usually occurred at the knot for FLDs and on top of the fixation button for FTDs and MSLDs. In isolated device and tendon-device tests, ultimate tensile strength ($\chi^2[2] = 12.033$, $P = .002$; $\chi^2[2] = 6.045$, $P = .049$, respectively) and ultimate elongation
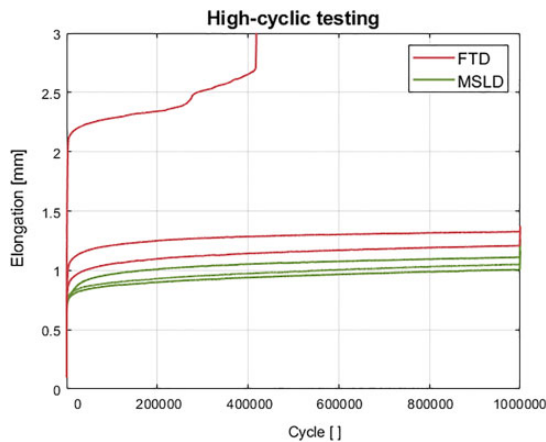
Figure 5. Cumulative cyclic elongation of the 2 tested adjustable-length fixation devices in high-cyclic testing. FTD, finger trap device; MSLD, modified sling lock device.

($\chi^2[2] = 14.408$, $P = .001$; $\chi^2[2] = 12.575$, $P = .002$, respectively) were different among the 3 fixation devices (Figure 6). FLDs showed superior ultimate tensile strength over FTDs ($P = .002$ vs $P = .039$) and MSLDs ($P = .002$ vs $P = .039$) in isolated device and tendon-device tests. Conversely, ultimate elongation was higher for FLD fixation when compared with FTD ($P = .004$ vs $P = .002$) and MSLD ($P = .002$ vs $P = .002$) between tests. Comparing FTD and MSLD revealed MSLD fixation to have superior ultimate elongation (ie, lower; $P = .028$) in the isolated device test but not in the tendon-device test. Ultimate tensile strength revealed no statistically significant differences in both tests.

DISCUSSION

The current investigation examined the mechanical performance of a pretied fixed-length cortical button, an adjustable-length cortical button based on the finger trap mechanism, and an adjustable-length cortical button based on a novel modified sling lock mechanism in an isolated manner, as well as in a more application-based approach by adding a tendon graft to the test construct.

Failed ACL reconstruction has been associated in part with improper graft fixation.[10] In the early rehabilitation phase—usually within the first 24 weeks postoperatively[40,41]—it is crucial that CFDs are able to withstand forces in excess of 590 N[23,32,34-36] and limit elongation to keep the graft in place until biological incorporation has occurred. Previous literature has shown that CFDs withstand greater forces than those needed during surgery and subsequent rehabilitation.[2,15,18,20,21,24,27,29] However, several studies have found differences in the elongation behavior of CFDs, favoring fixed- over adjustable-length devices.[2,18,20,27,30]

Whereas confident estimations on repetitive ACL forces during rehabilitation activities are lacking,[27] a review of the relevant literature revealed the force interval between 50 and 250 N is the most common used for cyclic testing.[2,18,21,24,29-31,37]

To date, it is unclear what amount of fixation lengthening constitutes clinical failure.[30] Tibial anterior translation >3.0 mm is indicative for ACL rupture with high sensitivity[16,17] and is, therefore, often used as a threshold to determine clinical failure in isolated device testing.[2,20,27,30]

In this regard, when put under constant tension, all tested CFDs performed successfully clinically, although initial elongation of FLD was considerably greater than that of the adjustable-length devices. We attributed this difference to suture slippage and plastic deformation of the knot during initial tensioning, which could be circumvented by applying a higher preload. MSLD performed well in cyclic testing, as well as in ultimate tensile testing, with initial elongation, cyclic elongation, cyclic stiffness, and ultimate tensile strength comparable with that of FTD. When tested in combination with a tendon graft, however, MSLD outperformed FTD in cyclic elongation. In agreement with a previous investigation,[19] the finger trap mechanism displayed a substantial shortcoming when subjected to complete unloading during cyclic testing, with loop elongation exceeding 3 mm at approximately 200 loading cycles. As it is unknown whether CFDs experience complete unloading after implantation during early rehabilitation, the clinical significance of this finding remains unclear.[19] Although the pretied FLD displayed higher ultimate tensile strength than did the adjustable-length devices, this is unlikely of clinical importance, as all tested devices withstood forces higher than estimated in vivo forces. Moreover, the high mean elongation of the FLD at a construct failure of 7.57 ± 2.81 mm implied that other stabilizing structures may be loaded before the maximum strength of the device is reached, additionally diminishing the clinical value of such ultimate tensile performance.

FTDs have been extensively tested in vivo[4,5,22,26,33] and ex vivo in isolated device setups,[1,11,20,27,30] as well as in porcine knee ACL reconstructions.[11,24,25,27,28,30,37,38] Petre et al[30] implemented an isolated device testing protocol with the same preload and cyclic loading limits and similar travel velocity. After a total of 1000 cycles, FTD elongated 1.10 ± 0.20 mm on average, which is in approximate agreement with the mean 1000-cycle displacement 1.00 ± 0.31 mm in the current investigation. This also holds true for the reported ultimate tensile strength of 841 ± 55 N as compared with 827 ± 34 N in the current investigation. Adjustable-length devices displayed high fatigue strength, with all tested samples surviving more than 400,000 cycles, which corresponds to the number of estimated loading cycles on the ACL reconstruction in vivo in 78 days in normally active individuals.[3] Within this period, partial biological incorporation of the graft would most likely suffice to prevent critical construct fatigue.

There are limitations of this study to be noted. Real-world loading of the ACL is unknown in magnitude and multiaxial in direction. The current testing protocol was, therefore, a crude approximation of the mechanical regime in vivo. Additionally, animal tendon grafts served as a model for human auto-/allografts, given the limited availability. Finally, the experiments were conducted in a dry environment; therefore, effects of biological fluids on the

Figure 6. Ultimate tensile and elongation test results. Significant pairwise differences are indicated with an asterisk ($P < .05$, Bonferroni corrected). Values are presented as median (line), interquartile range (box), range (error bars), and outliers (diamonds). FLD, fixed-length device; FTD, finger trap device; MSLD, modified sling lock device.

performance of the different devices cannot be taken into account.
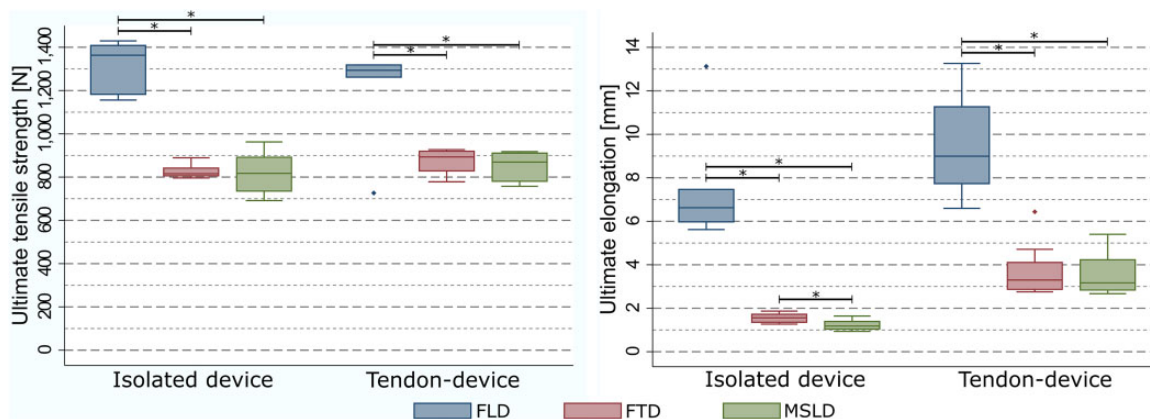
CONCLUSION

The 3 devices tested successfully prevented critical construct elongation when put under constant tension and withstood ultimate loads in excess of estimated in vivo forces. When subjected to complete loop unloading, however, the adjustable-length device based on the finger trap displayed excessive elongation, whereas the adjustable-length device based on the modified sling lock mechanism displayed only minor deterioration in mechanical performance as compared with the loading protocol with constant tension.

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