RIGIDLOOP™ CORTICAL FIXATION SYSTEM, ENDOBUTTON CL ULTRA®, AND TIGHTROPE®: A COMPARISON OF MECHANICAL PROPERTIES

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OBJECTIVE

The use of fixed loop cortical buttons for fixation of soft tissue grafts during anterior cruciate ligament (ACL) reconstruction surgery has been widely described [Nebelung *Arthroscopy* 1998; Chen *Orthop Clin North Am* 2003]. Recently, adjustable loop buttons have been developed, but questions still remain as to the propensity of adjustable loops to loosen during cyclic testing [Petre *AJSM* 2013 and Barrow *AJSM* 2013].

The purpose of this study was to compare the ultimate strength, stiffness, and cyclic displacement of the RIGIDLOOP™ Cortical Fixation System, EndoButton CL Ultra®, and TightRope® RT. We hypothesized that the fixed loop devices would be similar in their mechanical properties, but superior to the adjustable loop device.

METHODS

A minimum of four samples of all three implant systems were evaluated in the 20 mm loop size. The mechanical test methods used in this research were based on previously-published, peer-reviewed studies [Kamelger *Arthroscopy* 2009; Brown *Arthroscopy* 2004; Petre *AJSM* 2012]. Briefly, all samples were inserted into a 37° C saline bath with the button supported on a stainless steel plate and the loop around a shackle in a servohydraulic load frame (Instron Corp. Norwood MA) (Figure 2). In order to prevent inadvertent pinching of the loops by the fixtures, the buttons were matched to fit inside steel inserts and the plate had a 4.5 mm through hole.

The direction of pull was perpendicular to the plane of the button. There were a total of 1000 cycles (no "pre-cycling") of 50 to 250 N followed by monotonic pulling at 20 mm/min.

The three output parameters were cyclic displacement, ultimate strength, and stiffness. Data among devices was compared with an ANOVA using a Tukey post hoc analysis and a p value of <0.05 was considered significant. The mode of failure was also recorded.

Figure 2: *Close up view of test set-up showing shackle with loop and metal test plate.*

RESULTS

The average (± one standard deviation) cyclic displacement, stiffness, and ultimate strength were tabulated (Table 1). The RIGIDLOOP System had a cyclic displacement of 0.068 mm, stiffness of 594.0 N/mm, and an ultimate load of 2136 N.

Ref: DVA-107393-RTM, DHF-102035-MEMO14, DHF-102035-MEMO16

Test Group	Cyclic Displacement (mm)	Ultimate Strength (N)	Stiffness (N/mm)
20 mm RIGIDLOOP System	0.68 ± 0.03	2136 ± 93	594.0 ± 21.3
20 mm EndoButton	**0.59 ± 0.03**	**1405 ± 112**	**448.5 ± 22.4**
20 mm (adjusted) TightRope	**1.36 ± 0.24**	**790 ± 97**	**729.6 ± 74.8**

Table 1: *Summary of mechanical properties (mean ± standard deviation) for all three devices.*

RESULTS (continued)

A statistically significant difference was found for cyclic displacement, with the RIGIDLOOP System and EndoButton both being significantly lower than TightRope ($p<0.001$), but not different from each other (Figure 2). For ultimate strength, the RIGIDLOOP System was significantly higher than both other devices and EndoButton was significantly higher than TightRope ($p <0.001$) (Figure 2). On the other hand, for stiffness, TightRope was significantly higher than both other devices and the RIGIDLOOP system was significantly higher than EndoButton ($p <0.001$). For all devices, the mode of failure was loop breakage for every sample.

CONCLUSION

The RIGIDLOOP System was significantly stronger than EndoButton and TightRope, while EndoButton was significantly stronger than TightRope. Both the RIGIDLOOP System and EndoButton exhibited significantly less cyclic displacement than TightRope. The allowable laxity prior to clinical failure for the entire tibial fixation—graft—femoral fixation construct is approximately 3 mm [Daniel *AJSM* 1985]. The cyclic displacement due to the TightRope loop alone represents 45% of this value.

Stronger fixation and lower cyclic displacement of femoral fixation devices could potentially positively impact rehabilitation programs.

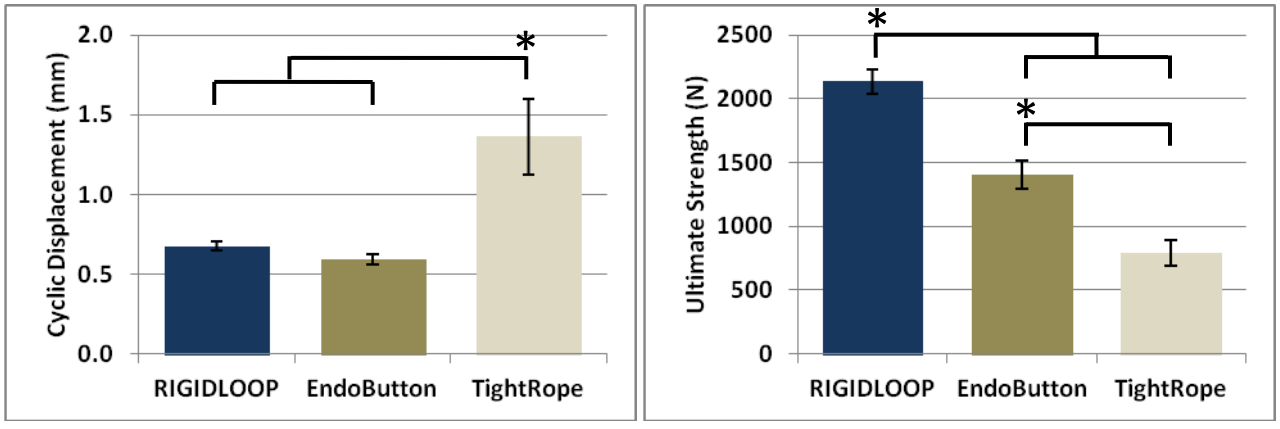

Figure 2: *Comparison of mean cyclic displacement (left) and ultimate strength (right). Asterisks indicate statistically significant differences.*