ADJUSTABLE LOOP BUTTON DISPLACEMENT IN LAXITY

A comparison of adjustable loop button displacement properties under cyclic loading conditions incorporating laxity

Several peer-reviewed biomechanical studies have examined the cyclic displacement of adjustable loop devices. Authors have concluded that adjustable loop devices see more displacement compared to fixed loop devices. The data presented in this paper presents a new biomechanical test methodology which more closely mimics the forces seen in the knee during the ACL reconstruction and initial rehabilitation.

Background

Adjustable loop cortical fixation devices have inherent appeal for graft fixation due to their less technically demanding surgical technique compared to fixed loop designs: greater ease of insertion, complete graft fill of the femoral tunnel, and elimination of calculations.[1] However, recent biomechanical studies have shown an increase in displacement with adjustable loop designs, compared to fixed loop devices.[2] Further questions remain surrounding adjustable loop button designs, and their ability to prevent migration of the graft, especially in the presence of knee-joint laxity. This "slack" can occur in the mid-range of flexion,[3] and this could contribute to the increased displacement seen with other adjustable button designs.

This study is designed to assess the relative displacement properties of three adjustable loop devices in the presence of simulated knee-joint laxity. The incorporation of periods of slack (no load) is intended to test the structural integrity of the locking mechanisms of each implant design. The following adjustable loop designs were tested in this study: GraftMax™ Button, Tightrope™ RT and ToggleLoc™ with ZipLoop™ Technology. A fixed loop button design, XO Button®, was also tested.

Methods

The methods utilized are adapted from studies previously reported in literature. The main difference being the incorporation of 0N of force between each load cycle, and a sixty second rest period at laxity (0N) every one-hundred cycles. This protocol tests the structural integrity of the locking mechanism

Each sample was lubricated with fetal bovine serum to mimic the conditions *in situ*. An initial tensile load of 5N was applied to each implant, and then they were conditioned from 10-50N for 10 cycles at 1 Hz in order to mimic intra-operative cycling of the knee. Cyclic loading from 0N to 250N at 1 Hz for 1,000 cycles continued, with a rest period of sixty seconds at no load (0N) every one-hundred cycles. The total displacement was calculated as the total amount of creep that resulted from the first to the 1,000th cycle (at 50N) after preconditioning.

A minimum of five implants were tested for each group, with the exception of the ToggleLoc group, which had 1 test sample. Results were analyzed using a t-test with a p-value of 0.05.

Results

The average results and standard deviations for each device are reported in Table 1.

This study showed that the GraftMax Button had the lowest total displacement among other adjustable loop devices. The average total displacement of the GraftMax Button was only 0.1mm greater than that of the XO Button fixed loop device. The Tightrope RT had 6.7mm of displacement while the ToggleLoc with ZipLoop Technology had 11.7mm of total displacement. There was a statistical significant difference between GraftMax Button and TightRope RT ($p < 0.05$)

	Precond. Creep (mm)	Initial Creep (mm)	Cyclic Creep (mm)	Total Displacement (mm)	Standard Deviation
XO Button®	0.82	1.07	0.79	1.86	0.15
GraftMax™ Button	0.56	0.89	1.08	1.97	0.34
Tightrope™ RT	0.83	0.82	5.89	6.71	2.58
ToggleLoc™ with ZipLoop™ Technology	1.16	1.26	10.43	11.69	N/A

TABLE 1: Comparison of displacement properties of cortical fixation implants.[4]

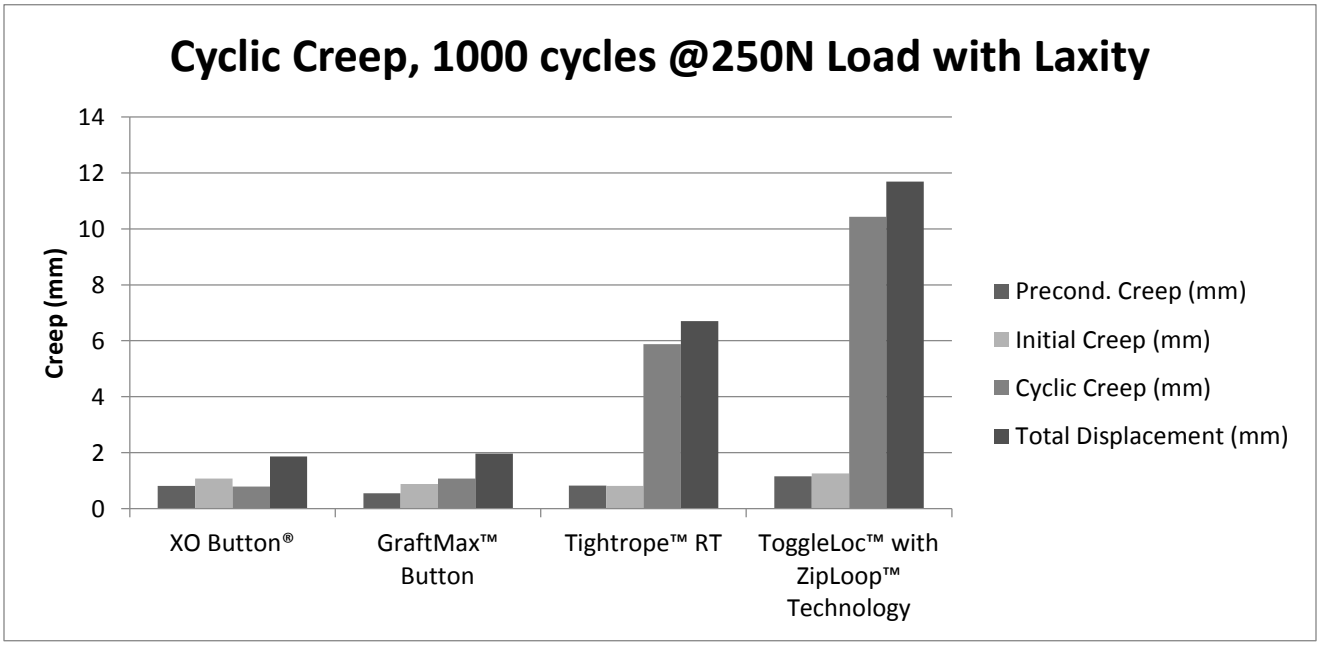

FIGURE 2: Comparison of displacement properties of cortical fixation implants.[4]

The results of this study show that the GraftMax Button adjustable cortical fixation device provides a 70% reduction in displacement compared to other adjustable loop devices as shown in Table 1 and Figure 2. Additionally, the graft fixation of the GraftMax Button is more comparable to the XO Button fixed loop button design than to other adjustable loop designs.

References

[1] Barrow et al. AJSM 2014

[2] Johnson et al. AJSM 2012

[3] Wascher et al. J Bone and Joint Surg 1993.

[4] Data on file TR14-464, TR14-464-1.