Displacement of a Fixed Versus Adjustable Suspensory Fixation Device for Anterior Cruciate Ligament Reconstruction

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Summary
Suspensory fixation devices in anatomic anterior cruciate ligament (ACL) reconstruction commonly feature a button that rests on the cortex of the femur, and a loop that holds the graft in position until healing can occur. While this loop can be closed and fixed in length, some contemporary designs feature a loop that is adjustable. The purpose of this study was to assess the displacement of the fixed ENDOBUTTON™ CL ULTRA (Smith & Nephew, Inc., Andover, MA, USA) and TightRope® (Arthrex, Inc., Naples, FL, USA) fixation devices. All loop samples were securely fixed to a metal plate and axial loading apparatus. Next, a zero to 60N static load was applied to each sample a total of ten times. Following completion of the loading regimen, loop displacement and final distance were measured. Results of this study demonstrated significantly less displacement for the ENDOBUTTON CL ULTRA device vs the TightRope device (0.58mm versus 9.95mm; p < 0.05). Furthermore, the mean distance from the button to the top of the hook for the devices was 8.93mm (ENDOBUTTON) and 14.63mm (TightRope), respectively (p < 0.05). The results of this study suggest that the adjustable TightRope loop can slip and elongate under load after it has been adjusted to its minimum length. It also suggests that ENDOBUTTON CL Ultra may allow for more graft in the femoral tunnel following ACL reconstruction.

Introduction
Short femoral tunnel length is recognized as a problem during anatomic anterior cruciate ligament (ACL) reconstruction. Specifically, a short tunnel can effectively reduce graft length, potentially reducing the strength of the graft-bone tunnel construct [1-3]. Furthermore, reduced ACL graft length is thought to adversely affect healing following reconstruction [4]. This has led to the introduction of suspensory fixation devices capable of maximizing the amount of graft in the femoral tunnel, thereby improving the outcome of ACL reconstruction [1, 4].

Suspensory devices commonly feature a button that rests on the cortex of the femur, and a loop that holds the folded soft tissue ACL graft in position until healing can occur. The ENDOBUTTON® CL ULTRA (Smith & Nephew, Inc., Andover, MA, USA) is a fixation device that features a closed, fixed length loop. However, adjustable loop devices have recently been introduced to the market. The TightRope (Arthrex, Inc., Naples, FL, USA) is one such cortical fixation device, featuring two sutures that can be pulled to enable intraoperative adjustment of graft tension.

While there are clear benefits to suspensory fixation during anatomic ACL reconstruction, the rigidity of adjustable loop devices has not been fully established. Therefore, the purpose of the current study was to assess displacement and final distance following loading of the ENDOBUTTON CL ULTRA and TightRope devices.
Materials and Methods

Twenty ENDOBUTTON™ CL ULTRA, 10mm and twenty TightRope® sample loops were tested utilizing an Insight® 30 axial loading apparatus (MTS Systems Corp., Eden Prairie, MN, USA). Each button was fixed securely to a metal plate and vise construct, with the loop attached to the loading apparatus using a metal hook (Figure 1). Prior to testing, all ENDOBUTTON CL ULTRA loops were held taught with a minimum load of 5 Newton’s (N). For the TightRope device, all loops were tightened so that the loading hook was in contact (or nearly in contact) with the construct plate at the start of loading. This simulated the optimal surgical situation where the surgeon is able to adjust the device so that the ACL graft is touching the cortex of the femoral tunnel.

The Insight 30 apparatus was then used to apply a zero to 60N static load to each sample a total of ten times. This load is approximate to the force applied by the surgeon during intraoperative tensioning of an ACL graft [5]. Following the completion of the loading regimen, displacement of the hook was assessed. Furthermore, the length of each loop was determined by using a 1 kilogram mass to hold each loop taut, at which point the distance from the top of the loading hook to the construct plate was measured.

A statistical comparison of mean displacement and final distance between device groups was performed using a two-sample t-test with a significance level of p < 0.05.

Results

Study results for displacement and final distance are illustrated in Figures 2 and 3, respectively. The average displacement for ENDOBUTTON CL ULTRA was significantly less than that observed for TightRope (0.58mm versus 9.95mm; p < 0.05). Displacement of the TightRope loop is illustrated in Figure 4. Furthermore, the average measurement from the bottom of the plate to the top of the hook for ENDOBUTTON CL ULTRA was significantly shorter than that of TightRope (4.91mm versus 10.61mm; p < 0.05). Taking the thickness of the plate (4.02mm) into account, the mean distance from the button to the top of the hook for the devices was 8.93mm (ENDOBUTTON) and 14.61mm (TightRope), respectively (p<0.05).

Figure 2: Mean displacement for TightRope® and ENDOBUTTON™ CL ULTRA

![Figure 2: Mean displacement for TightRope® and ENDOBUTTON™ CL ULTRA](image)

Figure 3: Mean distance for TightRope® and ENDOBUTTON™ CL ULTRA plate, device, and hook construct

![Figure 3: Mean distance for TightRope® and ENDOBUTTON™ CL ULTRA](image)
The results of this study suggest that the adjustable TightRope® loop can slip and elongate under load after it has been adjusted to its minimum length. This is evidenced by a statistically significant increase in mean displacement and distance following loading, as compared to the fixed loop ENDOBUTTON® CL ULTRA device. Furthermore, the minimum length of the TightRope device after loading was longer than that of ENDOBUTTON CL ULTRA under a 1 kilogram load.

The excellent loading performance of the ENDOBUTTON CL ULTRA loop corroborates a recent report from Conner et al [6], who evaluated the in vitro performance of suspensory fixation devices in a porcine ACL reconstruction model. Cyclic testing was performed under loads ranging from 50N to 450N, which represents the range of in vivo ACL loads during human activities of daily living [6-9]. Following 2,000 loading cycles, a first generation ENDOBUTTON CL device demonstrated significantly less graft-implant elongation, as compared to competitive femoral fixation devices (p = 0.005). These results are noteworthy, as the efficacy of suspensory fixation devices depends upon their ability to maintain graft tension [4, 10]. It also suggests that ENDOBUTTON CL Ultra may allow for more graft in the femoral tunnel following ACL reconstruction.

Study results originally reported in Smith & Nephew test report #15001530.

Figure 4: TightRope® displacement from initial (A) to final position (B). Illustration of displacement distance (C)

References

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