

**Research Article**

Dimensional assessment of continuous loop cortical suspension devices and clinical implications for intraoperative button flipping and intratunnel graft length<sup>†</sup>

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## Abstract

Continuous loop cortical suspension devices have been demonstrated to be more consistent and biomechanically superior compared to adjustable loop devices; however, continuous loop devices present unique challenges compared to adjustable loop devices, especially in short tunnel reconstruction applications. Specifically, adjustable loop devices have the advantage of a ‘one size fits all’ approach, and the ability to tension these devices following button flipping allows for the intratunnel graft length to be maximized. Nevertheless, the reliability of continuous loop devices has sustained their widespread use. We hypothesized that continuous loop cortical suspension devices from different manufacturers would exhibit equivalent 15 mm loop lengths, as advertised. Loop length was measured using a tensile testing machine. Contrary to our hypothesis, continuous loop cortical suspension devices with equivalent advertised lengths exhibited different loop lengths (up to 27% discrepancy). Inconsistencies with regards to manufacturers’ reported loop lengths for continuous loop devices could have serious clinical implications and additionally complicate technique transferal among devices. Consequently, the manufacturers’ accurate and complete disclosure of the dimensions and specifications associated with each continuous loop device is critical. Furthermore, surgeon awareness of true loop length dimensions and inconsistencies among devices is needed to ensure optimal implantation and resultant clinical outcomes. This article is protected by copyright. All rights reserved

**Key Words:** cortical button; flipping distance; loop length; ACL reconstruction; ligament reconstruction

## Introduction

Recent biomechanical studies have identified continuous loop cortical suspension devices to be more consistent and biomechanically superior to adjustable loop devices, especially with regard to cyclic displacement at time-zero.<sup>1,2</sup> Nevertheless, there remain challenges unique to the proper implementation of continuous loop compared to adjustable loop devices. Specifically, the fixed loop length of continuous loop devices necessitates careful surgical planning and execution to achieve the desired graft fixation and minimize the potential development of time-zero and/or future problems (e.g., inability to flip/deploy the button, cortical blowout or bone bridge collapse, insufficient intratunnel graft length, amount of unused tunnel, and tunnel widening).<sup>3-6</sup> These concerns are magnified for anteromedial femoral tunnel reaming for modern anterior cruciate ligament (ACL) reconstructions, in which anatomic femoral tunnel placement requires shorter femoral tunnels.<sup>5,7,8</sup> In contrast, adjustable loop devices have the advantage of a “one size fits all” approach, and the ability to tension these devices following button flipping allows for the intratunnel graft length to be maximized.

Given the inherent challenges associated with proper implementation of continuous loop cortical suspension devices, especially in cases of short reconstruction tunnels where intratunnel graft length needs to be maximized, surgeons depend on the manufacturers’ accurate and precise disclosure of pertinent dimensions and specifications. As such, one might reasonably assume that continuous loop cortical suspension devices from different manufacturers that are advertised as having an identical loop length would be correspondingly identical in loop length and have a high accuracy to the advertised loop length. However, as the present study demonstrates, these assumptions are inaccurate and could have serious clinical implications.

During pilot testing for another study,<sup>2</sup> we inadvertently identified differences between the loop lengths of continuous loop devices from different manufacturers that were advertised as having equivalent 15 mm loop lengths. To our knowledge, no other studies have reported on the differences in loop length between devices and the concomitant clinical implications. Therefore, our objective was to investigate differences in the loop length among advertised equivalent continuous loop cortical suspension devices. We hypothesized that continuous loop cortical suspension devices from different manufacturers would exhibit equivalent loop lengths, as advertised.

## Methods

### *Devices*

Continuous loop cortical suspension devices from three manufacturers, each with a manufacturer reported loop length of 15 mm, were evaluated in this study (Fig. 1). The devices were the ENDOBUTTON CL ULTRA (Smith&Nephew, Inc., Andover, MA, USA), XO Button (ConMed Linvatec, Inc., Largo, FL, USA), and RIGIDLOOP (DePuy Mitek, Inc., Raynham, MA, USA). Manufacturing lot numbers were identical for each device for a given manufacturer. All devices were donated gratis, and the study was funded internally to avoid any perceived bias.

### *Mechanical testing*

Twenty-four continuous loop devices from three different manufacturers ( $n = 8$ /each) were tested using an identical protocol. Testing was performed using a clinically relevant custom fixture (Fig 2) and a tensile testing machine (ElectroPuls E10000, Instron Systems, Norwood, MA, USA). Measurement error of the testing machine was certified by Instron to be less than or

equal to  $\pm 0.01$  mm and  $\pm 0.3\%$  of the indicated force. Two, 5 mm thick steel inserts, each with a single hole corresponding to different manufacturers' recommended drill hole diameter (4.5 mm for the ENDOBUTTON and RIGIDLOOP, and 5.0 mm for the XO Button), simulated the femoral cortex. Device loops were placed around a 4.5 mm diameter hardened, precision ground steel rod, simulating half the diameter of a 9 mm soft tissue graft,<sup>1</sup> which was rigidly attached to the testing machine actuator with a custom clevis. The cortical suspension devices were then passed through the hole of the steel insert using the passing sutures and secured against the inferior surface of the steel insert. The force vector was in-line with the suture loop and perpendicular to the button, as described previously.<sup>1,2</sup> Note that, prior to device insertion or testing, the actuator of the testing machine was independently positioned such that the steel rod was in 1 N of compression with each steel insert and these positions were recorded for subsequent loop length calculations.

Devices were subjected to a single tensile ramp loading profile from 1 to 75 N over 10 seconds. Loop lengths at 5 and 75 N were calculated as the sum of the steel insert thickness, the respective displacement of the testing machine actuator relative to the rod in contact with the top of the steel insert (-1 N), and the diameter of the steel rod (Fig. 2). The thickness of each steel insert and diameter of the rod were measured with digital calipers (Swiss Precision Instruments, Inc., Garden Grove, CA, USA) with a manufacturer reported accuracy of 0.03 mm.

### *Statistical analysis*

Analysis metrics included loop lengths at 5 and 75 N and the difference between them, as well as the difference between the loop length at 75 N and advertised loop length. The primary loop length was defined as the length of the continuous loop suture under a tensile load of 75 N to be representative of the load and corresponding length at which the device would be fixed

intraoperatively. Loop length was compared to the manufacturer advertised loop length via one-sample *t*-tests using IBM SPSS Statistics, Version 20 (Armonk, NY, USA). Intra-device elongation was assessed using paired-sample *t*-tests. Inter-device elongation and differences in loop length were assessed using Welch's analysis of variance (ANOVA) with a *Games-Howell* test for *post hoc* group comparisons.

## Results

### *Intra-device dimensional accuracy and precision*

Device loop lengths (mm) are reported here (mean  $\pm$  SD) and in Table 1. The Rigidloop loop length at 75 N ( $15.1 \pm 0.3$ ) was accurate and not significantly different from the manufacturer advertised loop length ( $P=0.264$ ) (Fig. 3). In contrast, the Endobutton and XO Button loop lengths at 75 N ( $17.7 \pm 0.3$ ,  $19.0 \pm 0.7$ , respectively) were not accurate and were significantly different from the manufacturer advertised loop length ( $P<0.001$ ,  $P<0.001$ ).

### *Intra-device elongation*

Increased loading of the devices from 5 N to 75 N resulted in a significant increase in loop length (mm) (mean  $\pm$  SD) for the Endobutton ( $0.5 \pm 0.1$ ,  $P<0.001$ ), Rigidloop ( $0.4 \pm 0.2$ ,  $P=0.001$ ), and XO Button ( $1.3 \pm 0.4$ ,  $P<0.001$ ). However, compared to both the Endobutton and Rigidloop, the XO Button loop length increased significantly more when loaded from 5 N to 75 N ( $P=0.003$  and  $P=0.001$ , respectively).

### *Inter-device dimensional variability*

In addition to the significant differences observed for measured device loop lengths at 75 N in comparison to the manufacturer advertised loop length, significant differences were also observed between devices (Fig. 3). The mean differences between loop lengths for the Endobutton compared to the Rigidloop (2.6 mm,  $P < 0.001$ ) and XO Button (1.3 mm,  $P = 0.002$ ) devices were significant. Similarly, the mean difference in loop length between the Rigidloop and XO Button (3.9 mm,  $P < 0.001$ ) was significant.

### Discussion

Contrary to our hypothesis, continuous loop cortical suspension devices from different manufacturers exhibited significantly different loop lengths, in spite of being advertised as equivalent in loop length. Deviations from the advertised loop length, whether as-manufactured and/or upon initial loading of the continuous loop, could negatively affect the outcome of surgical reconstructions. For example, in the setting of ACL reconstructions, several concerns may arise from deviations in the advertised loop length and include an inability to flip/deploy the button, cortical blowout or bone bridge collapse, insufficient intratunnel graft length, amount of unused tunnel, and tunnel widening.<sup>3-6</sup> Notably, several of these potential problems are compounding; e.g., in an attempt to facilitate button flipping, the socket must be drilled deeper which increases the risk of cortical blowout or bone bridge collapse<sup>5</sup> and the amount of unused tunnel correspondingly increases which could promote tunnel widening.<sup>6</sup> Similarly, a longer-than-advertised loop length may facilitate button flipping but may not provide sufficient intratunnel graft length<sup>9, 10</sup> and would increase the amount of unused tunnel and concomitant tunnel widening.

The above concerns are all worthy of consideration; however, the amount of unused tunnel (related to button flipping) and graft insertion distance have been shown to affect the quality and success of a reconstruction. First, femoral ACL reconstruction sockets are drilled deeper than the graft insertion distance (related to the advertised loop length) by necessity to provide additional distance to flip the button (i.e., the flipping distance). As such, the principal concern is the inherent tradeoff between the ease of button flipping (longer tunnels) and resultant effects of longer tunnels (e.g., increased amount of unused tunnel leading to tunnel widening<sup>6</sup> and risk of cortical blowout or bone bridge collapse<sup>5</sup>). The current literature is limited and does not contain a consensus regarding the effect of tunnel widening on graft function and knee laxity; nevertheless, tunnel expansion is generally undesirable and may lead to increased laxity.<sup>6, 11</sup> Second, a minimum of approximately 15 mm of graft insertion has been reported to be necessary for optimal reconstruction outcomes,<sup>9</sup> and graft insertions of only several millimeters less (e.g., 5, 9 and 14 mm compared to 17 mm) resulted in reduced strength and stiffness, especially in the critically important early postoperative healing period.<sup>10</sup> However, none of the devices achieved 15 mm of graft insertion in clinically relevant short tunnels, and only one device achieved the expected 10 mm insertion distance based on its advertised loop length in this study (Fig. 3). Additionally, current graft preconditioning protocols may not optimally reduce initial graft viscoelastic lengthening (approximately 2 mm using current clinical techniques).<sup>12</sup> Therefore, the concomitant effect of less-than-expected graft insertion and viscoelastic lengthening could have serious clinical implications.

The above concerns are magnified for anatomic ACL reconstructions, which utilize an anteromedial arthroscopic portal for femoral tunnel reaming and subsequently create shorter femoral tunnels, relative to the transtibial technique.<sup>5, 7, 8</sup> Recent studies have demonstrated an



ability to create femoral tunnels greater than 30 mm in length;<sup>13, 14</sup> however, Golish, et al. reported the median length to be 25 mm for anteromedial reamed tunnels<sup>7</sup> which is consistent with the technique and experience of the senior surgeon. Therefore, the current study results are schematically represented in 25 mm femoral tunnels for ACL reconstruction (Fig. 3). Note that in this clinically relevant example, the XO Button should technically not be deployed according to packaging literature which explicitly advises against deployment of the device in tunnels shorter than 30 mm. Moreover, upon inspection of the advertised loop length (15 mm), recommended flipping distance (15 mm), and requirement of a minimum 5 mm bone bridge, the XO Button packaging literature seems incorrect because tunnels shorter than 35 mm would violate the dimensional constraints. Additionally, the ENDOBUTTON was the only device with a 10 mm continuous loop option; therefore, although not tested in this study, the 10 mm device may be better suited to this short tunnel application and may provide an additional 5 mm of graft insertion (12.3 mm, assuming all else equal) compared to its 15 mm loop counterpart.

This study had some limitations. Only three manufacturers were represented; however, continuous loop devices chosen were consistent with those of other studies and among the most popular.<sup>1-3, 8, 9</sup> Additionally, loop length was measured to the end of the suture loop; however, other measurement references (e.g., to the middle or top of the doubled-over graft) could have resulted in shorter loop lengths and larger resultant graft insertion distances. Nevertheless, in measuring loop length (and corresponding graft insertion distance) to the end of the suture loop, the results of this study are conservative and not subject to unconstrained variables (e.g., graft size, graft spreading and thinning on the loop, etc.). Furthermore, differences in measurement references may be the underlying and previously underappreciated inconsistency among manufacturers.

The results of this study demonstrate inconsistencies with regards to manufacturers' reported loop lengths for continuous loop cortical suspension devices. As noted above, these inconsistencies could have potentially serious clinical implications. Consequently, we recommend the manufacturers' accurate and complete disclosure of the dimensions and specifications associated with each continuous loop device. Furthermore, surgeon awareness of true loop length dimensions and inconsistencies among devices is necessary to ensure optimal implantation and resultant clinical outcomes.

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## References

1. Petre, B.M., Smith, S.D., Jansson, K.S., et al., 2013. Femoral cortical suspension devices for soft tissue anterior cruciate ligament reconstruction: a comparative biomechanical study. *Am J Sports Med.* 41 (2), 416-422. <http://dx.doi.org/10.1177/0363546512469875>
2. Johnson, J.S., Smith, S.D., LaPrade, C.M., Turnbull, T.L., LaPrade, R.F., Wijdicks, C.A., 2014. A biomechanical comparison of femoral cortical suspension devices for soft tissue anterior cruciate ligament reconstruction under high loads. *Am J Sports Med.* [Epub ahead of print]. <http://dx.doi.org/10.1177/0363546514553779>
3. Brand, J., Weiler, A., Caborn, D.N., Brown, C.H., Johnson, D.L., 2000. Graft fixation in cruciate ligament reconstruction. *Am J Sports Med.* 28 (5), 761-774. <http://ajs.sagepub.com/content/28/5/761>
4. Beynon, B.D., Johnson, R.J., Abate, J.A., Fleming, B.C., Nichols, C.E., 2005. Treatment of anterior cruciate ligament injuries, part 2. *Am J Sports Med.* 33 (11), 1751-1767. <http://dx.doi.org/10.1177/0363546505279922>
5. Harner, C.D., Honkamp, N.J., Ranawat, A.S., 2008. Anteromedial portal technique for creating the anterior cruciate ligament femoral tunnel. *Arthroscopy.* 24 (1), 113-115. <http://dx.doi.org/10.1016/j.arthro.2007.07.019>
6. Weber, A.E., Delos, D., Oltean, H.N., Vadasdi K., Cavanaugh J., Potter H.G., Rodeo, S.A., 2015. Tibial and femoral tunnel changes after ACL reconstruction: a prospective 2-year longitudinal MRI study. *Am J Sports Med.* [Epub ahead of print]. <http://dx.doi.org/10.1177/0363546515570461>
7. Golish, S.R., Baumfeld, J.A., Schoderbek, R.J., Miller, M.D., 2007. The effect of femoral tunnel starting position on tunnel length in anterior cruciate ligament reconstruction: a

cadaveric study. *Arthroscopy*. 23 (11), 1187-1192.

<http://dx.doi.org/10.1016/j.arthro.2007.06.013>

8. Takeda, Y., Iwame, T., Takasago, T., et al., 2013. Comparison of tunnel orientation between transtibial and anteromedial portal techniques for anatomic double-bundle anterior cruciate ligament reconstruction using 3-dimensional computed tomography. *Arthroscopy*. 29 (2), 195-204. <http://dx.doi.org/10.1016/j.arthro.2012.08.020>
9. Zantop, T., Ferretti, M., Bell, K.M., Brucker, P.U., Gilbertson, L., Fu, F.H., 2008. Effect of tunnel-graft length on the biomechanics of anterior cruciate ligament-reconstructed knees: intra-articular study in a goat model. *Am J Sports Med*. 36 (11), 2158-2166. <http://dx.doi.org/10.1177/0363546508320572>
10. Yuan, F., Zhou, W., Cai, J., Zhao, J., Huangfu, X., Yin, F., 2013. Optimal graft length for anterior cruciate ligament reconstruction: a biomechanical study in beagles. *Orthopedics*. 36(5), e588-e592. <http://dx.doi.org/10.3928/01477447-20130426-20>
11. Järvelä, T., Moisala, A.-S., Paakkala T., Paakkala, A., 2008. Tunnel enlargement after double-bundle anterior cruciate ligament reconstruction: a prospective, randomized study. *Arthroscopy*. 24 (12), 1349-1357. <http://dx.doi.org/10.1016/j.arthro.2008.07.018>
12. Jaglowski, J.R., Williams B.T., Turnbull T.L., LaPrade R.F., Wijdicks C.A., 2014. High-load preconditioning of soft tissue grafts: an in vitro biomechanical bovine tendon model. *Knee Surg Sports Traumatol Arthrosc*. [Epub ahead of print]. <http://dx.doi.org/10.1007/s00167-014-3410-x>

13. Tompkins, M., Milewski, M.D., Carson, E.W., Brockmeier, S.F., Hamann, J.C., Hart, J.M., Miller, M.D., 2013. Femoral tunnel length in primary anterior cruciate ligament reconstruction using an accessory medial portal. *Arthroscopy*. 29 (2), 238-243. <http://dx.doi.org/10.1016/j.arthro.2012.08.019>
14. Iyyampillai, G., Raman, E.T., Rajan, D.V., Krishnamoorthy, A., Sahanand, S., 2013. Determinants of femoral tunnel length in anterior cruciate ligament reconstruction: CT analysis of the influence of tunnel orientation on the length. *Knee Surg Relat Res*. 25 (4), 207-214. <http://dx.doi.org/10.5792/ksrr.2013.25.4.207>

## FIGURE LEGENDS

Fig. 1. Photographs of continuous loop cortical suspension devices evaluated in this study and their respective product packaging descriptions with equivalent advertised lengths.

Note that devices were photographed and are displayed at an equivalent scale.

Fig. 2. Photograph (left) and section view schematic (right) depicting the fixtures and methodology, respectively, used to measure the loop length of continuous loop cortical suspension devices. Left: A = testing machine actuator; B = custom clevis and steel rod; C = steel insert with a single hole. Right: loop lengths at 5 and 75 N (Step 2) were calculated as the sum of the (C) steel insert thickness, (D) displacement of the testing machine actuator relative to the rod in contact with the top of the steel insert (Step 1), and diameter of the (B) steel rod.

Fig. 3. Illustration highlighting differences in the loop lengths and resultant graft insertion distances for continuous loop cortical suspension devices deployed in a clinically relevant, short tunnel representative of anatomically placed femoral tunnels for ACL reconstruction. In this example, the total tunnel length is 25 mm, and advertised 15 mm continuous loop devices with manufacturer recommended socket depths for device flipping distance are shown with the expected graft insertion distance of 10 mm (dashed line). \*The XO Button packaging literature explicitly advises against the deployment of the device in tunnels shorter than 30 mm.

Table 1. Lengths of advertised equivalent continuous loop cortical suspension devices under 5 and 75 N of force, and the differences between these states and between the manufacturer reported and 75 N loop length.

Device	Manufacturer Reported Loop Length (mm)	5 N Loop Length (mm) <sup>a</sup>	75 N Loop Length (mm) <sup>a,c,d</sup>	$\Delta$ 5 to 75 N (mm) <sup>a</sup>	$\Delta$ Reported & 75 N (mm) <sup>a</sup>
Endobutton	15	17.2 (0.3)	17.7 (0.3) <sup>b</sup>	0.5 (0.1)	2.7 (0.3)
Rigidloop	15	14.7 (0.4)	15.1 (0.3)	0.4 (0.2)	0.1 (0.3)
XO Button	15	17.8 (0.8)	19.0 (0.7) <sup>b</sup>	1.3 (0.4) <sup>e</sup>	4.0 (0.7)

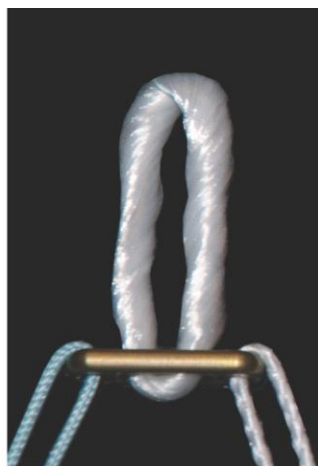
<sup>a</sup>Data reported as: mean (standard deviation)

<sup>b</sup>Loop length was significantly different from the manufacturer reported loop length ( $p < 0.001$ , one-sample *t*-test)

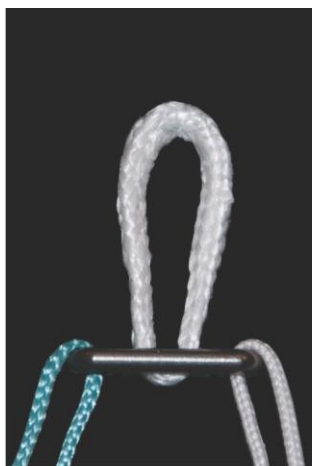
<sup>c</sup>Significant differences existed between the 5 N and 75 N loop length of each device ( $p \leq 0.001$  for all *post hoc* comparisons, paired-sample *t*-test)

<sup>d</sup>Significant differences existed between all pairings of devices ( $p \leq 0.002$  for all *post hoc* comparisons, *Games-Howell*)

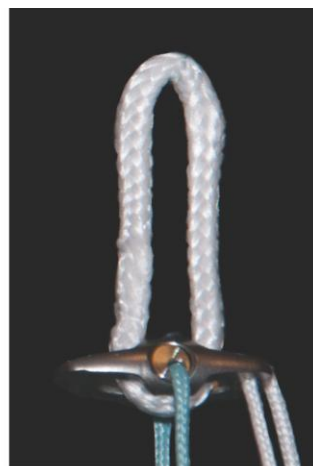
<sup>e</sup>Loop length increased significantly more compared to the other devices ( $p \leq 0.003$  for all *post hoc* comparisons, *Games-Howell*)



ENDOBUTTON® CL ULTRA Fixation Button  
with 15mm Continuous Loop Suture



**15mm**  
RIGIDLOOP™  
Cortical Fixation Implant



<b>15mm</b>
XO BUTTON™ with Continuous Loop

Figure 1



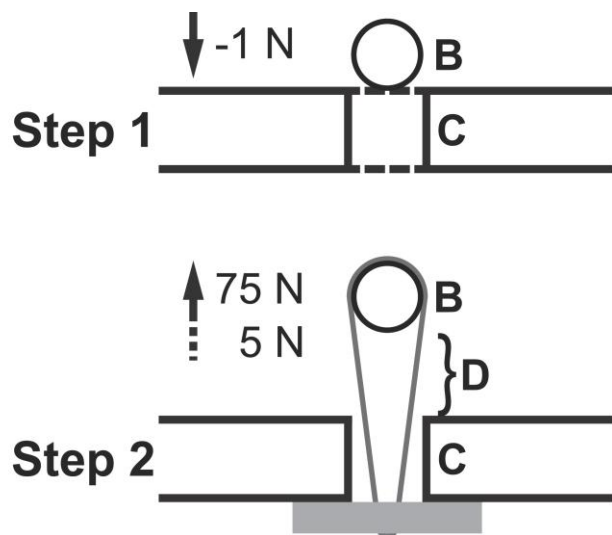
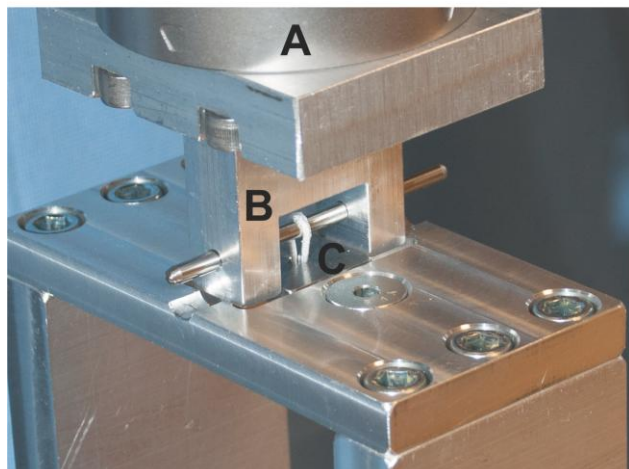


Figure 2

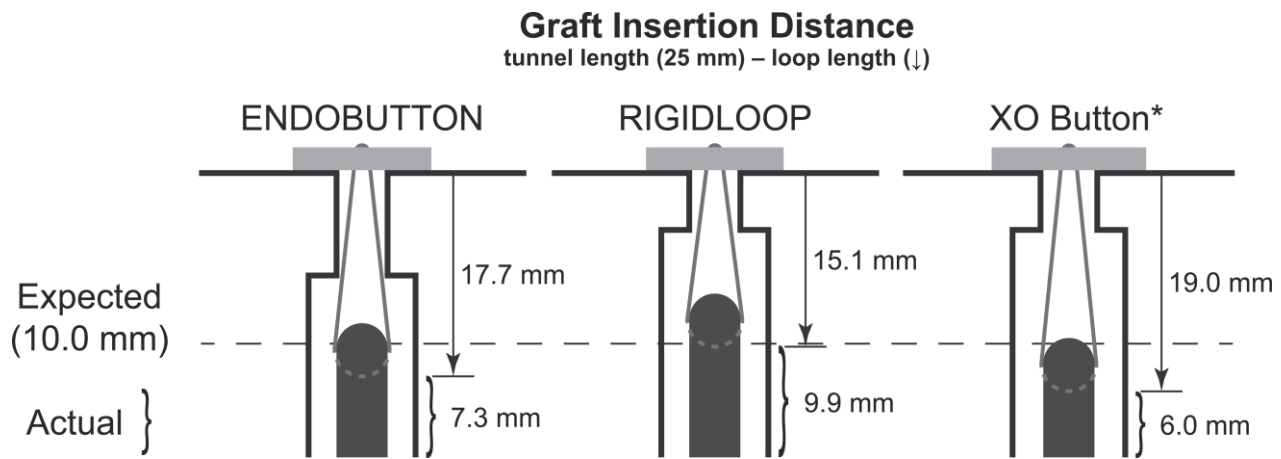


Figure 3