HOSPITAL INNOVATIONS

Business Case: PULLUP®

Fixed loop Suspensory Fixation Devices
These original suspensory fixation devices, e.g. Endobutton®, have a fixed-loop length and whilst they are extremely popular due to their fixation strength (UTS) and stability[3], they do have inherent weaknesses:

- Fixed loop devices limit the surgeon in terms of tunnel length and graft choice, and can lead to cumbersome pre-operative calculations in theatre[4]. This is particularly relevant with the recent shift towards anatomic tunnel positioning leading to smaller tunnel lengths (from traditional 45mm to between 32-36mm tunnel lengths)[5]. This in turn, with the fixed-loop design, leads to less graft in the femoral tunnel.

Qi *et al.* (2011)[6], have demonstrated that graft lengths of less than 15mm in the femoral tunnel can result in lower pull-out strength and delayed healing. With tunnel lengths as small as 32mm, there is growing concern over graft pull-out strength and healing.

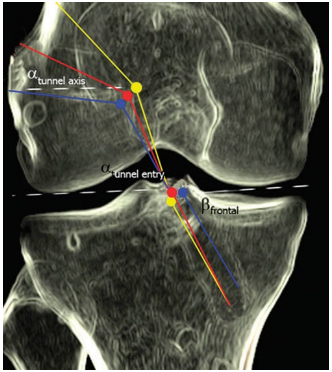


Figure 2: Change in femoral tunnel lengths from longer transtibial (yellow) to shorter AM portal (red) and outside-in (blue) ACL reconstruction philosophies. Image from Osti *et al.* (2015).[5]

Sports Medicine Market Overview

- 6mm over-drilling is required to flip the button, which may impact graft stability and bone tendon healing[7].

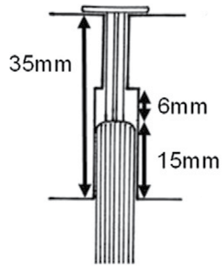


Figure : 6mm overdrilling required to flip an Endobutton. Image adapted from Eguchi *et al.* (2014).[7]

Adjustable loop Suspensory Fixation Devices

The traditional adjustable loop fixation devices, e.g. TightRope® and ToggleLoc™, were introduced to combat issues with fixed loop devices. Whilst these designs allow greater flexibility, fill the tunnel and eliminate the need for pre/intra-operative calculations[3], they do not come without problems:

- Adjustable-loop suspensory fixation devices have demonstrated problems with loop lengthening after fixation, and subsequent graft displacement, loosening and surgical failure[8].

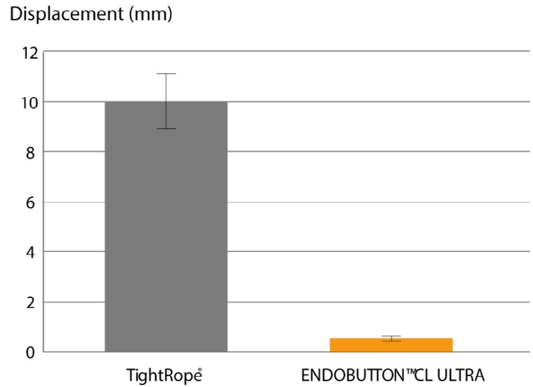


Figure 5: Average displacement for TightRope® and Endobutton® CL Ultra when loaded with a 60N static load over 10 cycles. Endobutton® was significantly less at 0.58mm displacement, compared to 9.95mm seen in TightRope®.
Image adapted from Perriello, Berube and Moore (2012)[8].

Sports Medicine Market Overview

- An increased risk in elongation during the rehabilitation phase due to increased tension over a longer number of load cycles[4].

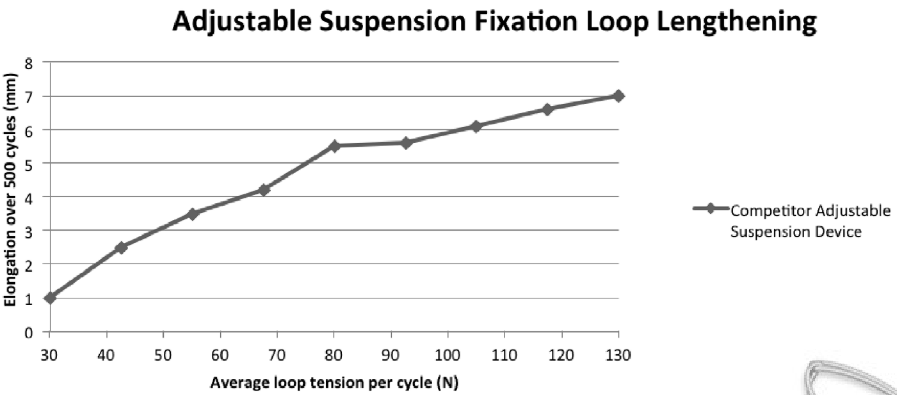


Figure 6: Increased elongation of TightRope® over 500 cycles with increasing load.
Image adapted from Barrow *et al.* (2014)[4].

- A lack of a positive flip feature which can lead to false judgment in seating of the button against the lateral cortex. On tensioning from the tibial end this can lead to slippage and graft displacement. If this isn't spotted during surgery this can also lead to graft loosening and surgical failure[9].

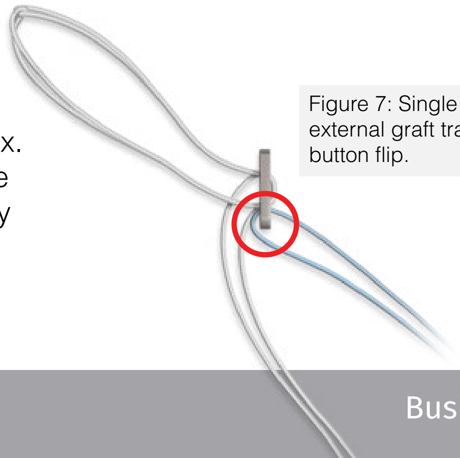


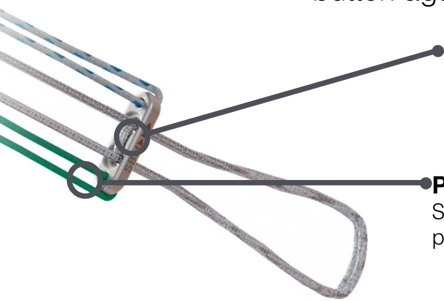
Figure 7: Single suture for external graft traction and button flip.

PULLUP Value Proposition

Designed by renowned ACL guru Dr Philippe Colombet, PULLUP® offers a novel solution, addressing concerns with both fixed loop and adjustable loop suspensory fixation devices, offering the surgeon the best of both worlds. Since 2013, 1427 PULLUP® devices have been implanted worldwide with no reported adverse events to date[10].

1 Confident Stability

- Novel, patented locking mechanism with simultaneous tensioning of loop sutures eliminates slippage of graft loop during tibial fixation[10]
- UHMWPE central loop provides appropriate material stiffness to eliminate material stretch post-operatively seen with other competitors[10]
- Secondary green suture, providing a positive flip function to ensure accurate seating of the button against the femoral cortex[10]



PULLUP Value Proposition

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1 Confident Stability

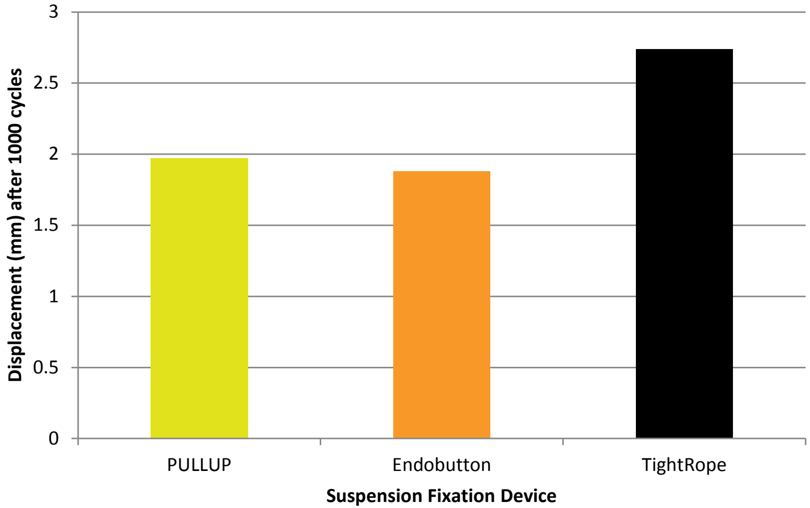

Figure 8: Graft displacement of PULLUP® and competitor suspension fixation devices after 1000 cylces in a construct. PULLUP® (1.97mm), Endobutton® (1.88mm) and TightRope® (2.74mm). TightRope® is closer to the clinical failure of 3mm displacement than both PULLUP® and Endobutton®. Data from Petre *et al.* (2012).[3]

Offering the best of **both**...

PULLUP Value Proposition

2 Intra-operative choice with PULLUP® adjustable loop

- Easy graft insertion eliminating the need for intra-operative calculations and limitations in tunnel and graft length choice
- Accommodates use of the same graft independent of surgical philosophy avoiding issues with shorter tunnel lengths and subsequent impact on graft length within the tunnel when using fixed loop devices
- Bone preserving: PULLUP® fills the tunnel with tendon graft avoiding concerns on over-drilling, graft stability and bone-tendon healing

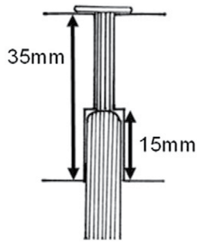

Figure 6: PULLUP® allows complete tunnel filling with the tendon graft, avoiding concerns on graft stability and healing. Image adapted from Eguchi *et al.* (2014)[7].

Stability and **Choice**

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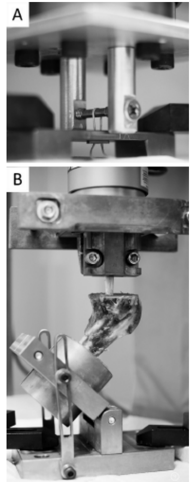
Traditional adjustable loop suspensory fixation Loop Lengthening - Petre, B *et al.* (2012)[3]



Study Objective:
To assess and compare the fixation strength of 4 common cortical suspension fixation devices; S&N Endobutton® CL, Arthrex TightRope RT®, Biomet ToggleLoc™ and Conmed XO Button™.

Methodology:
All four devices were tested under both cyclic and pull-to-failure conditions using a tensile testing machine. The devices were tested in a device-only construct (a) and a bone-device-tendon construct (B) in porcine femurs.

Results:
3.00mm is the displacement threshold defined as a clinical failure. ToggleLoc™ exceeded the 3.00mm threshold, whilst TightRope® came close at 2.74mm.

	Cyclic displacement after 1000 cycles (mm)
Endobutton®	1.88
TightRope®	2.74
ToggleLoc™	3.34
XO Button™	1.82

Conclusion:

- Graft displacement of up to 3.34mm was seen in adjustable loop fixation devices close to the clinical failure threshold. However, PULLUP® overcomes this with a novel loop locking system, with comparable displacement to Endobutton®.

Clinical Evidence

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Limitations with fixed loop suspensory devices
Shorter Tunnels - Osti, M *et al.* (2015)[5]

Study Objective:
To evaluate the bone tunnel parameters of three different surgical techniques: AM portal (AMP), outside-in (OI), and the traditional transtibial (TT) approach.

Methodology:
The study included 36 patients (TT technique), 32 (AMP) and 32 (OI). CT scans were used to measure characteristics of the femoral bone tunnels.

Results:
Both AMP and OI techniques resulted in a more precise replication of tunnel depth and height, leading to a more native ACL attachment site. As a consequence surgeons are more inclined to use these modern techniques.

	Transtibial	AM Portal	Outside-In
Tunnel Length (mm)	42.31	33.35	35.58

Conclusion:

- A move toward a more anatomic approach for tunnel positioning has lead to smaller femoral tunnels resulting in reduced graft length within the femur. For example, fixed loop suspension fixation devices with a loop length of 20mm would lead to as little as 13mm of graft in the femoral tunnel.
- Qi *et al.* (2011)[6] have demonstrated that graft lengths of less than 15mm can result in lower pull-out strength and delayed healing.

Technical Specification

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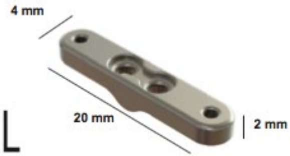
PULLUP®

For cortical tunnels with ø 4.5 mm

PULLUP® XL



For cortical tunnels with ø from 5 to 10 mm

PULLUP®	Technical Parameters
Composition Plate Braid Pull & flip sutures	 Titanium Ultra High Molecular Weight Polyethylene (UHMWPE) Polyester (PE)
Ultimate tensile strength	823N (up to 600N required for post-op rehabilitation)
Stiffness	199N/mm (Endobutton=201N/mm, TightRope=208N/mm)
Loop elongation on cyclic loading	1.97mm (Endobutton=1.88mm, TightRope=2.74mm)
Loop length	40mm
Loop braid diameter	1mm (USP 8-0)
Pull & flip suture diameter	0.7mm (USP 5-0)
Pull suture strength	500N
Flip suture strength	250N
MRI Compatibility	Yes
CE classification	IIb (93/42/CEE Directive)

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