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Adjustable loop ACL suspension devices demonstrate less reliability in terms of reproducibility and irreversible displacement

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Abstract
Purpose The aim of this study was to perform a comprehensive biomechanical examination of frequently applied femoral cortical suspension devices, comparing the properties of both fixed and adjustable fixation mechanisms. It was hypothesized that adjustable loop devices demonstrate less consistent fixation properties with increased variability compared to fixed loop devices.
Methods Nine frequently applied fixation button types were tested, six adjustable and three rigid loop devices. Six samples of each device type were purchased. Each device was installed in a servo-hydraulic mechanical testing machine, running a 2000 cycle loading protocol at force increments between 50 and 500 N. Irreversible displacement in mm was measured for all of the tested samples of each implant. Ultimately, maximum load to failure was applied and measured in Nm. An irreversible displacement of 3 mm was considered failure of the implant.
Results Three of the six adjustable devices (GraftMax™, TightRope® ToggleLoc™) demonstrated a median displacement above the threshold of clinical failure before completion of the cycles. All adjustable loop devices showed a wide intragroup variation in terms of irreversible displacement, compared to fixed-loop devices. Fixed-loop devices provided consistent reproducible results with narrow ranges and significantly lower irreversible displacement ($p < 0.05$), the maximum being 1.4 mm. All devices withstood an ultimate force of more than 500 N.
Conclusion Adjustable loop devices still show biomechanical inferiority and demonstrate heterogeneity of fixation properties with wide- and less-reproducible displacement ranges resultant to the mechanism of adjustment, denoting less reliability. However, three adjustable devices (RIGIDLOOP™ Adjustable, Ultrabutton ◊, ProCinch™) demonstrate fixation capacities within the margins of clinical acceptance. RIGIDLOOP™ Adjustable provides the most comparable fixation properties to fixed loop devices.

Keyword ACL reconstruction · ACL repair · Irreversible displacement · Fixed button · Adjustable button · ENDOBUTTON◊ CL ULTRA · RetroButton · RIGIDLOOP · GraftMax™ · RIGIDLOOP™ Adjustable · ACL TightRope® · Ultrabutton◊ · ToggleLoc™ · ProCinch™ · Femoral cortical suspension device

Introduction

Adequate graft fixation is fundamental in anterior cruciate ligament (ACL) reconstruction surgery, occupying a significant position in clinical and basic research [1, 2]. Cortical

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suspension devices represent a first choice for many surgeons [5]. Two main forms of these devices exist, differing in either providing for fixed or adjustable fixation mechanisms [5]. The predominant advantage of adjustable loop fixation is seen in the possibility of providing individual graft length adjustment, allowing for maximization of the graft–bone interface area. However, the concern of secondary displacement has been highlighted in several biomechanical investigations [6, 7, 9]. The influence of these devices on clinical outcome is also beginning to receive attention [4]. Yet, fact is that the choice of suspensory device remains based on individual preference, rather than true evidence.

It was hypothesized that adjustable loop fixation devices demonstrate inconstant fixation properties with higher variability compared to fixed loop devices.

The aim of this study was to perform a comprehensive controlled labaratory investigation to examine the biomechanical properties of nine commonly applied cortical fixation devices.

Materials and methods

Implant description

Nine different types of commercially available femoral suspension devices were purchased for testing (6 samples each) (Fig. 1). These included three fixed loop suspension systems: (1) ENDOBUTTON$^{\Diamond}$ CL ULTRA (Smith & Nephew Inc, UK), (2) RetroButton® (Arthrex Inc., Naples, FL, USA), (3) RIGIDLOOP™ (Mitek Sports Medicine, DePuy Synthes, Switzerland) and six adjustable-loop suspension systems: (1) GraftMax™ Button (ConMed Linvatec Inc. FL, USA), (2) RIGIDLOOP™ Adjustable (Mitek Sports Medicine, DePuy Synthes, Switzerland), (3) ACL TightRope® (Arthrex Inc., Naples, FL), (4) Ultrabutton $^{\Diamond}$ (Smith & Nephew Inc, UK), (5) ToggleLoc™ (Biomet, Warsaw, Indiana, USA), (6) ProCinch™ (Stryker, Michigan, USA).

Six samples of each of the nine suspension devices underwent loading with a standard biomechanical testing protocol, which is described below.

Three independent investigators (two arthroscopic surgeons and one biomedical engineer) installed the devices in a standardized manner in a servo-hydraulic mechanical testing machine (MTS) (MiniBionix 858, MTS, USA) for cyclic loading.

The devices were immerged in a saline solution 1 h before mechanical testing to mimic the intra-articular environment. The buttons were placed in a stainless steel disc with a slotted hole for the button loop to cross to the lower chamber (Fig. 2). A stainless steel pin with a diameter of 5 mm was installed in the lower chamber for loop tensioning (Fig. 2). The bottom plate of the chamber was fixed to a loading cell (15 kN, MTS, USA) filled with saline solution to ensure that the devices were fully immerged during testing.

The setup was mounted on the MTS machine. For adjustable buttons, the disc-pin distance was set at 20 mm and the adjustment threads manually pulled with a force greater than 200 N distally. Zero point calibration at 5 N was performed, since a minimum base tension is required for the MTS machine (Fig. 3). The cortical suspension devices were all initially preconditioned (Fig. 3a) to a force of 100 N at a rate of 0.1 mm/s, followed by gradual unloading until 0 N was reached. Displacement measurement was then reset to 0 mm. Cyclic loading (Fig. 3b) was initiated with a force between 0 and 50 N at 1 Hz with increasing steps of 50 N up to a force of 500N, maintaining 200 cycles per increment, resulting in a total of 2000 cycles. Finally, each suspension device was loaded to the point of failure at a rate of 0.2 mm/s (Fig. 3c). A 3 mm irreversible displacement was considered a failure. A modified loading protocol was applied for fixation devices reaching a displacement of 6 mm (therefore, exceeding the threshold of failure) during cyclic loading increments, which involved immediate interruption and finalization by pull to failure.

The irreversible displacement was measured at the end of each force increment (200th cycle) as the distance at zero force. The stiffness was measured as the slope between the minimal and maximal displacements at each 200th cycle in the force–displacement graph.

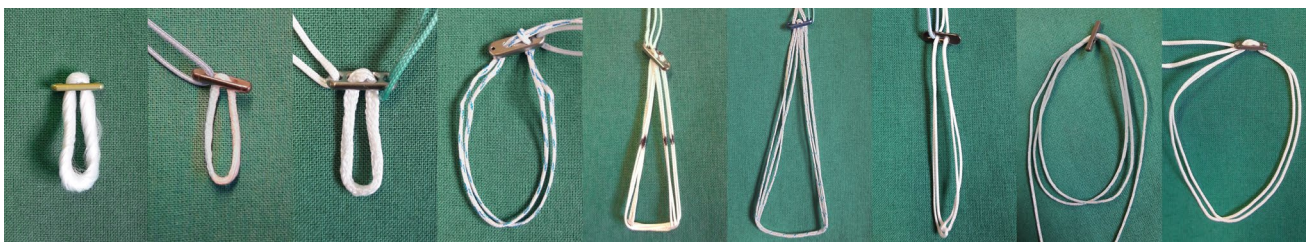

Fig. 1 femoral fixation devices (from left to right): ENDOBUTTON$^{\Diamond}$ CL ULTRA, RetroButton®, RIGIDLOOP™, GraftMax™, RIGIDLOOP™ Adjustable, ACL TightRope®, Ultrabutton $^{\Diamond}$, ToggleLoc™, ProCinch™

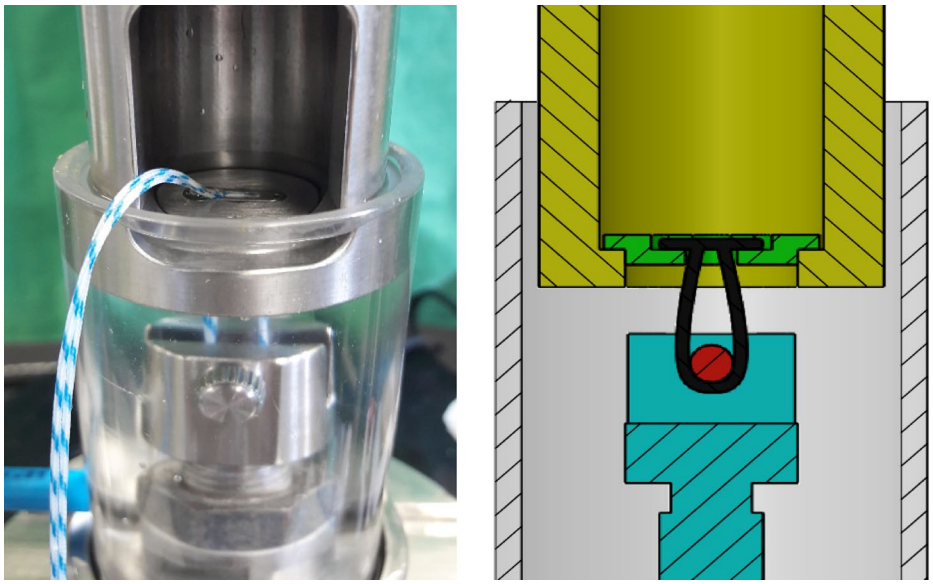

Fig. 2 Left: loading setup; right: transsection view of the setup for femoral fixation testing. The sample is drawn in black, the chamber for the saline solution in gray. The sample is tensioned between the disc (green) and the pin (red)

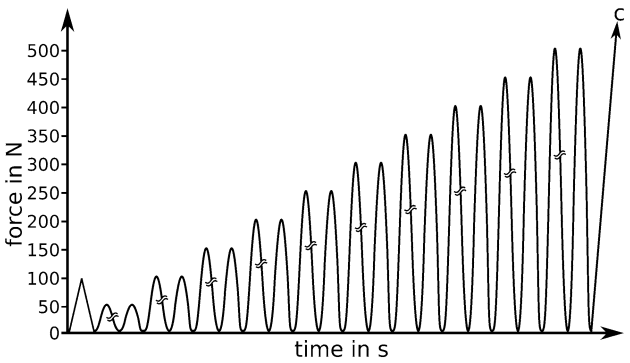

Fig. 3 The loading protocol starts with a preconditioning of 100 N at 0.1 mm/s (**a**). Then 200 cycles at 1 Hz were performed with a force between 5 N and 50 N (**b**). The upper force was increased stepwise up to 500 N for a total of 2000 cycles and a pull to failure terminated the test (**c**)

Measurement accuracy

Six samples of each of the nine device types were obtained for testing. After an initial pilot test, five repetitions were conducted on five separate buttons. A total of 54 buttons were tested. Two ACL surgeons and one biomedical engineer randomly performed the repetitions. The median values of irreversible displacement were finally calculated and illustrated as median [min, max] for each device type.

This study did not involve biological material, animal experiments or patient data. An institutional review board approval was, therefore, not necessary for the conduction of the study.

Statistical analysis

The non-parametric Mann–Whitney test was used to determine significant differences between median values of irreversible displacement measures. A cubic regression model was applied for fixation devices reaching a displacement of 6 mm before completion of the experimental protocol. Statistics were performed using python 2.7 library scipy stats (Python Software Foundation, Delware, USA). Post-hoc power analysis revealed that a power of 84.6% would be achieved with a sample size of 6 per group, for detection of a 0.5 mm difference in irreversible displacement.

Results

Three of the nine tested cortical suspension devices (GraftMax™, TightRope® ToggleLoc™) failed before completion of the experiment, before reaching the final 500 N force increment, given that 3 mm displacement was considered the threshold of failure (Fig. 4).

RIGIDLOOP™ Adjustable, withstood all loading cycles without failure of any of the six tested samples and showing least irreversible displacement amongst adjustable buttons ($p < 0.05$) (Fig. 4). The median irreversible displacement of RIGIDLOOP™ was 1.75 mm [1.2, 2.1 mm] at the final increment of 500N, representing a significantly higher value than any of the three fixed loop devices ($p < 0.05$). Table 1 illustrates the displacement of each device in detail.

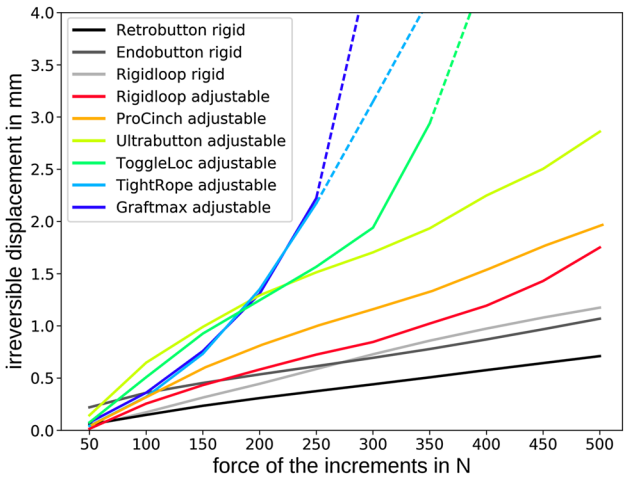

Fig. 4 Results of irreversible displacement at each force increment upon cyclic loading. Groups containing a sample with an early failure are displayed with dashed lines

Range of displacement

The irreversible displacement of each of the tested buttons is illustrated in Fig. 5. A wide intragroup variation amongst adjustable loop devices was clearly observed, compared to rigid loop devices which proved to maintain narrow and consistent ranges (Fig. 5).

Stiffness

Regardless of the suspension device, a gradual increase in stiffness was noted with every force increment. Adjustable and fixed loop devices did not significantly differ regarding stiffness at any of the measured force interval (n.s).

A diagram is available alongside the online version of the manuscript.

Ultimate force to failure

The median ultimate force necessary to induce failure in each of the tested suspension devices is illustrated in Fig. 6. All three fixed loop devices withstood a force of more the 1000 N. Three of the six adjustable loop devices withstood 1000 N, and all withstood 500 N (Fig. 6).

Discussion

The most important finding of the study was that the six frequently applied adjustable loop cortical suspension devices show inferior biomechanical properties compared to fixed loop devices. Three, however, passed the margins of clinical acceptance. The mechanical properties of adjustable loop

Table 1 Presenting the median values and ranges of irreversible displacement for each fixation device

	50 N median [min, max]	100 N median [min, max]	150 N median [min, max]	200 N median [min, max]	250 N median [min, max]	300 N median [min, max]	350 N median [min, max]	400 N median [min, max]	450 N median [min, max]	500 N median [min, max]
Retrobutton rigid	0.06 [0.05, 0.06]	0.15 [0.13, 0.16]	0.23 [0.21, 0.25]	0.31 [0.28, 0.32]	0.38 [0.34, 0.39]	0.44 [0.39, 0.46]	0.51 [0.45, 0.53]	0.58 [0.51, 0.60]	0.64 [0.56, 0.67]	0.71 [0.61, 0.74]
Endobutton rigid	0.22 [0.20, 0.25]	0.36 [0.33, 0.41]	0.45 [0.42, 0.52]	0.54 [0.49, 0.61]	0.61 [0.56, 0.70]	0.69 [0.63, 0.79]	0.78 [0.70, 0.89]	0.87 [0.79, 0.98]	0.97 [0.87, 1.08]	1.07 [0.97, 1.18]
Rigidloop rigid	0.04 [0.03, 0.06]	0.17 [0.15, 0.21]	0.31 [0.28, 0.37]	0.45 [0.41, 0.54]	0.59 [0.55, 0.71]	0.73 [0.69, 0.87]	0.86 [0.81, 1.03]	0.97 [0.92, 1.16]	1.08 [1.01, 1.29]	1.17 [1.10, 1.41]
Rigidloop adjustable	0.01 [0.00, 0.03]	0.26 [0.14, 0.42]	0.43 [0.27, 0.77]	0.58 [0.42, 0.92]	0.73 [0.54, 1.05]	0.85 [0.66, 1.21]	1.02 [0.76, 1.34]	1.19 [0.86, 1.55]	1.43 [1.02, 1.79]	1.75 [1.16, 2.08]
ProCinch adjustable	0.05 [0.04, 0.27]	0.33 [0.26, 0.73]	0.60 [0.47, 1.11]	0.82 [0.65, 1.36]	1.01 [0.79, 1.55]	1.17 [0.93, 1.70]	1.33 [1.06, 1.85]	1.55 [1.18, 2.88]	1.77 [1.30, 5.37]	1.97 [1.44, 7.98]
Ultrabutton adjustable	0.14 [0.05, 0.29]	0.65 [0.41, 1.39]	0.99 [0.72, 3.05]	1.29 [1.00, 3.38]	1.51 [1.27, 3.64]	1.70 [1.56, 3.82]	1.93 [1.85, 3.98]	2.25 [2.03, 4.15]	2.50 [2.15, 4.32]	2.86 [2.29, 4.51]
Ziploop adjustable	0.08 [0.05, 0.75]	0.51 [0.34, 1.52]	0.93 [0.62, 2.06]	1.25 [0.94, 2.50]	1.57 [1.24, 2.84]	1.94 [1.71, 3.57]	2.94 [2.00, 4.97]	–	–	–
TightRope adjustable	0.04 [0.03, 0.11]	0.32 [0.18, 0.76]	0.73 [0.37, 1.61]	1.35 [0.62, 2.59]	2.17 [0.99, 3.67]	3.15 [1.45, 4.78]	–	–	–	–
Graftmax adjustable	0.07 [0.06, 0.08]	0.36 [0.29, 0.79]	0.76 [0.55, 1.34]	1.31 [0.92, 2.55]	2.22 [1.23, 5.35]	3.82 [1.62, 10.15]	–	–	–	–

devices also showed a wide variability compared to fixed loop devices with consistent narrow margins of displacement. These limitations of adjustable loop devices need to be carefully considered by treating surgeons to ensure best device choice.

The academic orthopaedic community did not neglect the fact that the industry is continually producing new technology by correctly responding with a sequel of investigative studies [3, 6, 7, 10]. Based on our findings, the general conclusion is that adjustable loop devices provide sufficient mechanical properties to withstand a high ultimate force, but demonstrate significant inferiority when resisting cyclic forces, compared to fixed loop devices. Despite the noted inferiority, the industry is competing on developing adjustable devices, possibly in an attempt to complement a product portfolio.

The results of this study support previous findings as to the general capacity of all fixation devices to withstand a high ultimate force, regardless of device type. The knee is, however, a dynamic joint exerting a cyclic force on the ACL during natural movement [8], therefore, the more appropriate measure to be considered is irreversible displacement upon cyclic loading. Although significant inferiority was noted amongst adjustable fixation devices, it is fair to mention that three adjustable fixation devices, namely Ultrabutton$^{\Diamond}$, ProCinch™ and RIGIDLOOP™ Adjustable, demonstrated displacement within the margins of clinical acceptance. The adjustable device possessing properties closest to fixed loop devices in all terms was the RIGIDLOOP™ Adjustable.

No relationships between displacement and stiffness of the individual buttons were found, denoting the dependence of irreversible displacement on the fixation mechanism rather than the stiffness of the construct, which is in terms

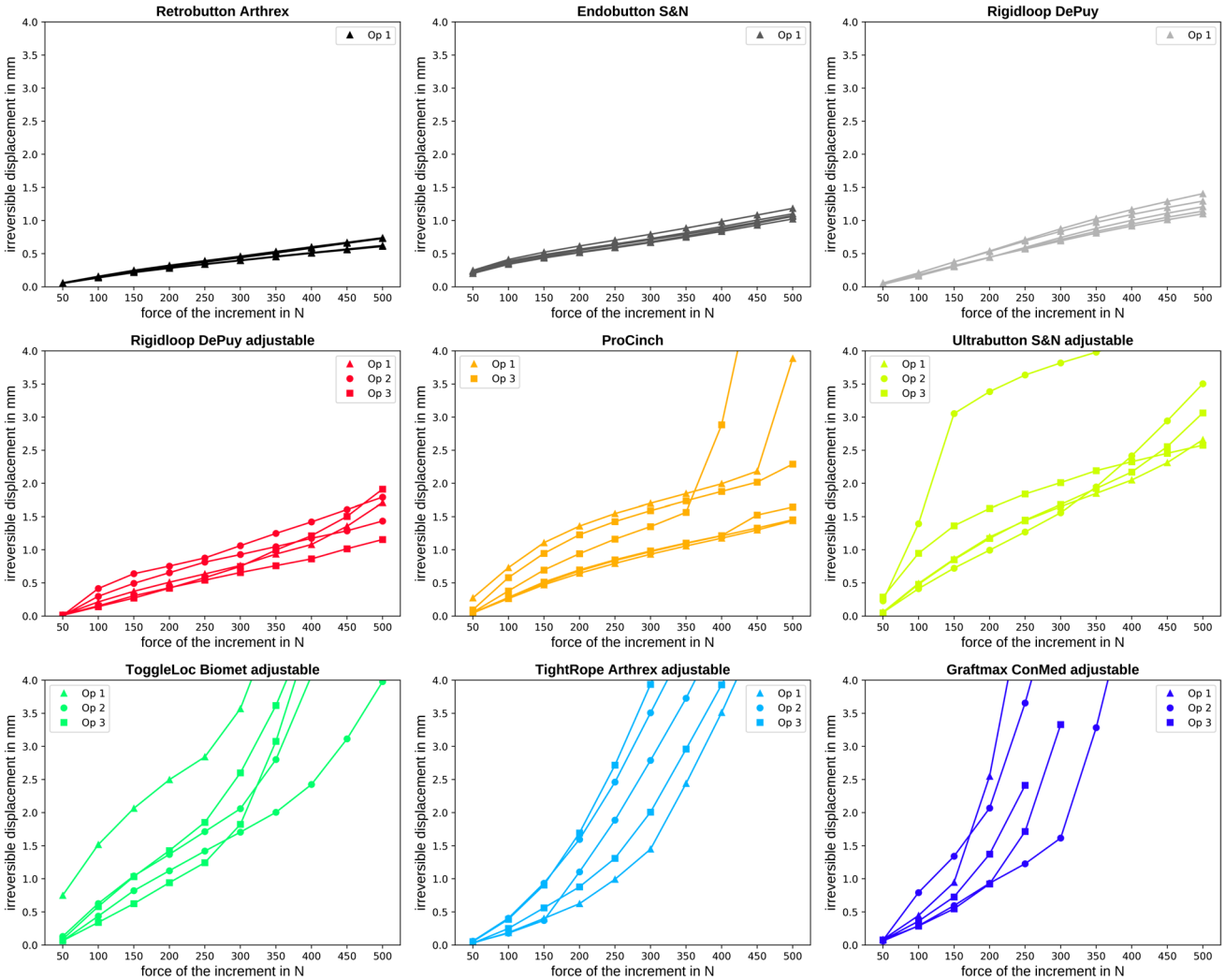

Fig. 5 Graph illustrating the per-investigator results of irreversible displacement for each of the tested fixation devices. *OP* Operator

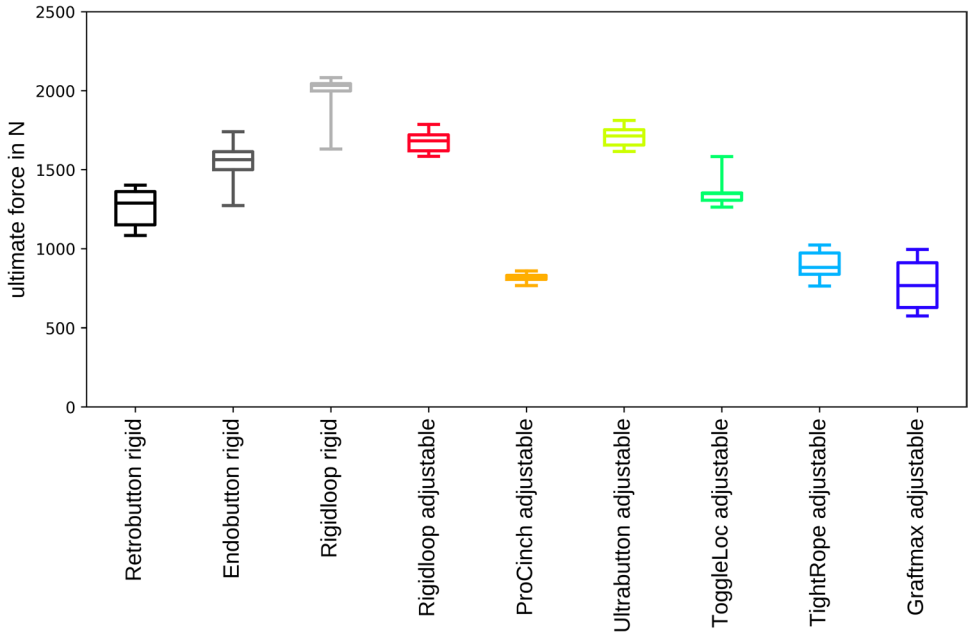

Fig. 6 Box plot illustrating median and ranges of the ultimate force necessary to induce failure in each of the tested suspension devices

dependent on the materials used. Therefore, stiffness of the fixation devices presents less of a valuable measure when evaluating cortical fixation devices.

The novel finding of this study highlights the problematic issue of inconsistency regarding fixation capacity seen amongst each of the six adjustable loop device types. Fixed loop devices on the other hand show steady reproducible fixation properties with narrow margins. The introduction of an adjustment mechanism was, therefore, associated with the introduction of additional variables influencing the potency of fixation. Further investigation will be necessary to identify such variables.

The results are purely biomechanical and do not account for the additional support of the graft–bone interface present in the true clinical setting. They also do not provide information about the effect of the fixation form on the graft. Both points presenting limitations to this study. The study does, however, provide a controlled comparison between commercially available and frequently utilized cortical fixation devices.

The relevance of this work can be reflected in clinical practice when choosing an appropriate fixation device. Clinicians should be aware of the fact that adjustable loop devices of any type cannot provide for consistent fixation properties, indicating poor reproducibility of results. Whether the observation impacts clinical graft failure, remains a question to be answered by upcoming clinical studies.

Conclusion

Adjustable loop cortical suspension devices show inferior biomechanical properties with less consistency and reproducibility compared to rigid loop devices. It is important to consider these issues as a clinician when intending to introduce a fixation device in clinical practice.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest

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Ethical approval The controlled biomechanical study did not require an ethical approval.

Informed consent Not necessary for this type of study

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