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Design of an alternative implant to suturing in ACL reconstruction: a biomechanical in vitro study

Seyed Amir Hossein Sajedi¹, Amir Nourani^{1*}, Solmaz Mojadam Mofrad¹ and Mahmoud Chizari^{1,2}

Abstract

Background Anterior Cruciate Ligament (ACL) reconstruction using a triple hamstring semitendinosus graft is a commonly used technique for optimal hamstring function, flexion strength, and rapid recovery. In the conventional method, the end of the tendon graft is whipstitched to a suspensory loop, which reportedly can lead to graft failure due to tendon laceration or slippage. This study aims to enhance ACL fixation by introducing a novel implant device replacing conventional sutures.

Methods Six initial designs were introduced, and a product design specification (PDS) chart was used to select one. The design named (Zip-Tie) was chosen based on the PDS scoring and three variants of it were prototyped and subjected to in-vitro experiments to optimize the design. The best performing variant was chosen as the final design which underwent additional validation tests. The mechanical experiments consisted of three loading steps, a preconditioning, a main cyclic, and a pull-out loading.

Results The mechanical properties of the three device variants were compared, and the best performing one was selected as the final design. The final design exhibited superior mechanical properties compared to similar studies, with an average cyclic stiffness (ACS) of $37,637 \pm 8,910$ N/mm, average pull-out stiffness (APS) of 132.8 ± 28.9 N/mm, and cyclic elongation of 1.11 ± 0.27 mm. The load-to-failure results showed that 80% of the samples exceeded 1000 N.

Conclusions The introduced novel implant device for preparing tripled semitendinosus grafts in ACL reconstruction, demonstrated superior mechanical performance compared to conventional suturing methods. The integration of friction plates and straps enhanced graft fixation and stability. These results support the potential of a new fixation approach, laying the groundwork for future in vivo studies and the exploration of optimal biocompatible materials for clinical application.

Keywords Hamstring graft, ACL reconstruction, Implant design, In-vitro experimentation, Orthopedic biomechanics, Femoral ACL fixation

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Introduction

Anterior Cruciate Ligament (ACL) reconstruction using hamstring semitendinosus graft is a commonly used arthroscopic surgical technique for patients requiring optimal hamstring function, flexion strength, and rapid recovery [1]. Hamstring autografts are also readily available and considered the gold standard for grafts, particularly in patients under 30, such as professional athletes [2]. Often, both the gracilis and semitendinosus tendons are harvested to prepare the graft. However, several authors have suggested that using only the semitendinosus while preserving the gracilis tendon may offer significant advantages in postoperative knee function, particularly in maintaining flexion strength and muscle torque [3–6]. Tripling the semitendinosus is an effective method to obtain a graft with both adequate length and sufficient diameter specially for patient with inadequate hamstring tendon length [7]. To perform this technique, a tunnel is drilled in the femur and another in the tibia during ACL reconstruction [8]. The hamstring semitendinosus tendon is harvested and folded into three equal parts to create a tripled semitendinosus ACL graft, which has an N-fashion configuration. This procedure is illustrated in Fig. 1 [9]. One end of the graft is fixed in the tibial tunnel using an interference screw, while the other

end is tensioned and secured with a suspensory device, like an Endobutton [8, 10].

Although triple ACL grafts are considered a less invasive option compared to four- or five-strand grafts, adverse clinical outcomes have been reported. While some studies have demonstrated favorable results with tripled grafts in clinical trials [11, 12], concerns remain regarding their resistance to higher loads, and unsatisfactory outcomes have been observed in follow-ups of patients with tripled ACL reconstructions [13]. Cadaveric and in-vitro studies have also evaluated tripled ACL grafts. Hageman et al. [14] found that three-strand grafts are less stiff than four-strand grafts and do not yield satisfactory outcomes. These limitations were attributed to the anatomical characteristics of the suspensory fixation method. Such methods intend to fix the graft by passing the suspensory device loop through the folded part; a third limb was not intended to be incorporated [15]. Therefore, to secure this unrestrained part properly, the free strand is stitched to either the suspensory device loop or the doubled strand via sutures [16]. Proper incorporation of the third limb during fixation is crucial to avoid stress shielding, which may weaken the graft and lead to eventual failure [17].

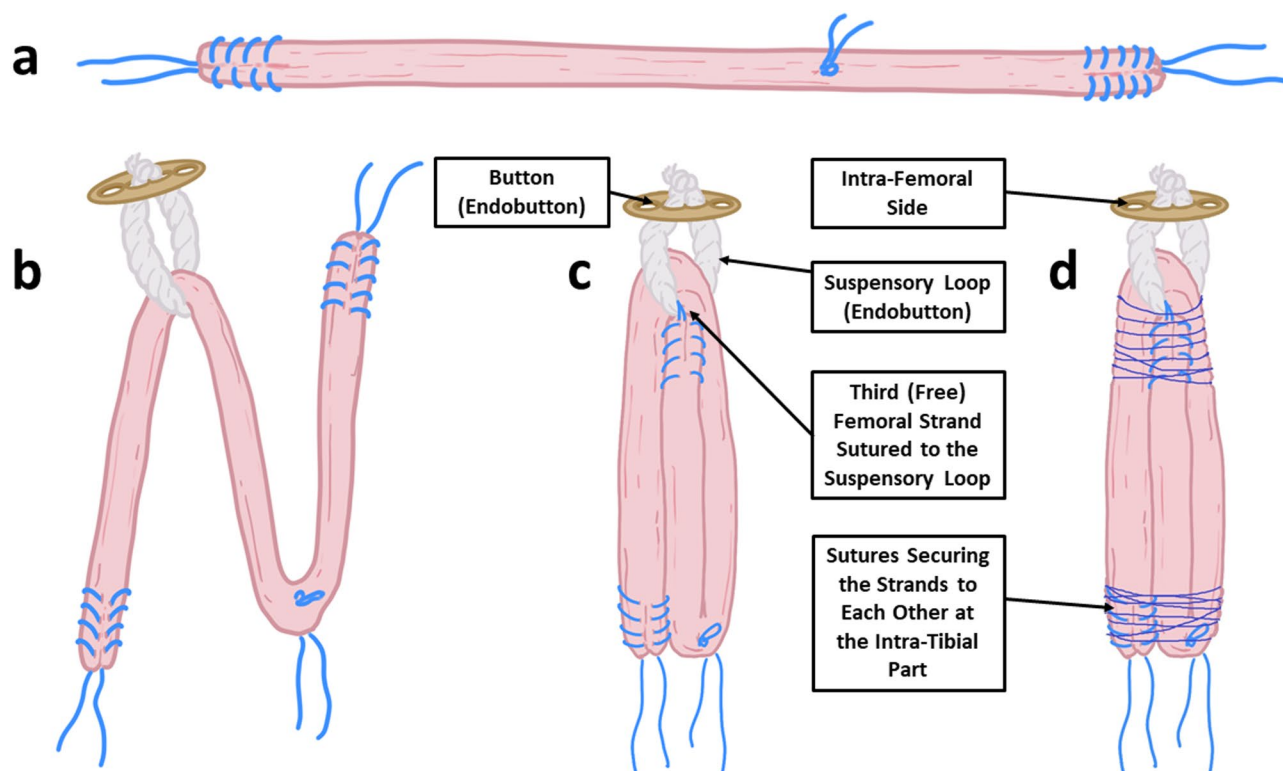


Fig. 1 Preparation of a tripled hamstring semitendinosus graft. **a** The harvested semitendinosus with sutures added at both ends, with a small suture indicating one-third of its length. **b** and **c** The tendon is bent into an N-shaped form, with the femoral side passed through the suspensory loop. The third strand is sutured to either the other two strands or the suspensory loop on the femoral side. **d** The final tripled ACL graft. The strands are sutured into each other at the intra-femoral and tibial tunnel sections of the graft.

Although suturing is the conventional graft preparation method, concerns have been raised regarding tissue laceration and graft failures associated with sutures [18, 19]. The third limb of a tripled graft is typically secured to other limbs or the suspensory device using sutures. Studies suggest that elongation occurs more frequently in the third limb compared to the doubled portion [15]. Furthermore, most triple-stranded graft failures occur due to tendon split across the suture [20]. Certain authors suggest that whip stitching the third limb does not maintain the desired performance. Thus, the best method of incorporating the tripled strand into the construct remains unknown [15]. Excessive movement of the third limb relative to the fixation and the other two limbs has been identified as a sign of weak fixation in the mentioned studies [17].

While previous clinical and biomechanical studies on triple grafts have focused primarily on suturing techniques and suture thread selection, none has attempted to eliminate sutures. This study introduces a novel fixation concept using a combination of a friction plate and zip-tie mechanism to replace conventional sutures, an unreported approach in ACL tripled graft preparation.

This study aims to enhance graft fixation and minimize relative motion between tendon limbs [21] by introducing the novel implant device along with an integrated graft preparation method which is proposed to strengthen both fixation and the quality of the ACL. We hypothesize that eliminating sutures will improve load distribution, reduce relative motion between the limbs, and lower the risk of tissue laceration, ultimately resulting in a stiffer and more reliable graft-femoral fixation. This study investigates this concept by mechanical bovine in-vitro experiments [22].

Materials and methods

Study approach

Six designs were initially presented. A product design specification (PDS) chart was developed to compare and choose the best design based on handling limitations and medical requirements. Three variants of the selected design were prototyped and subjected to in-vitro experiments to examine the influence of key design parameters. Based on these results, the best-performing variant was selected as the ultimate design. This final version was further validated through fatigue and pullout testing. It is important to note that the prototypes were constructed using non-biocompatible materials for mechanical verification only. The focus of this study is limited to assessing mechanical performance; future research will investigate biocompatible materials and in-vivo applicability. Figure 2 illustrates the overall workflow of the study.

Design

Design selection and the PDS chart

The PDS chart (Table 6 in Appendix 1) was used to define the functional, clinical, and design requirements of the device. These criteria were informed by logical analysis, current literature, and consultation with orthopedic surgeons and rehabilitation specialists. The six preliminary design options (Fig. 3) were evaluated using a scoring system derived from the PDS chart. A summary of this evaluation is presented in Table 7 in Appendix 2. Only one design, referred to as the Zip-Tie design, met all essential requirements, justifying its selection for prototyping and mechanical testing.

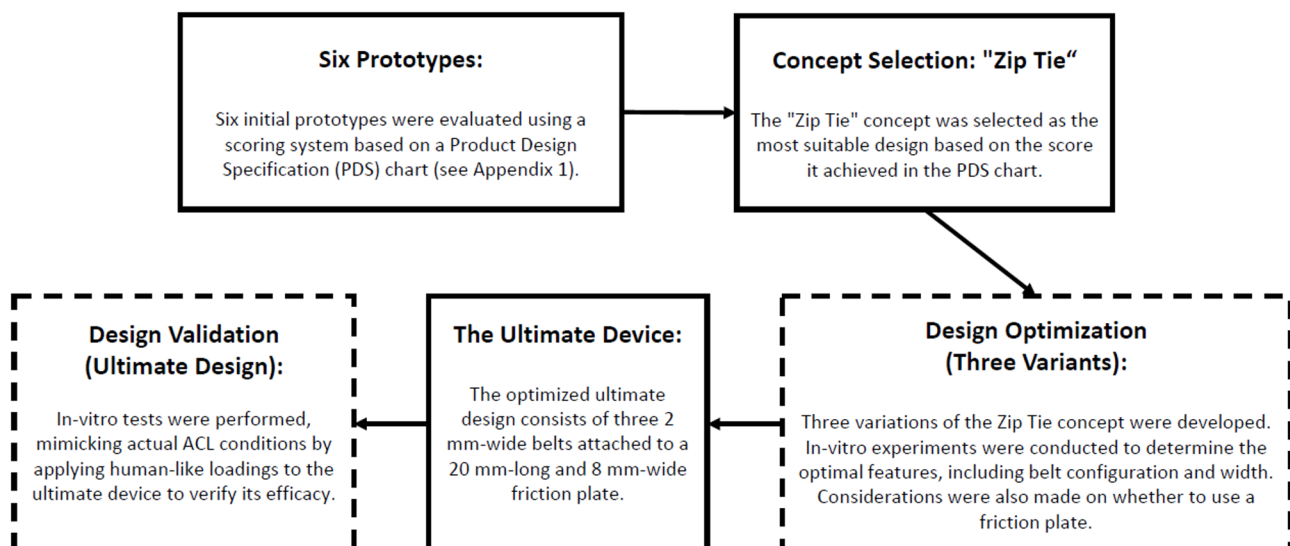


Fig. 2 The flowchart of the study's approach.

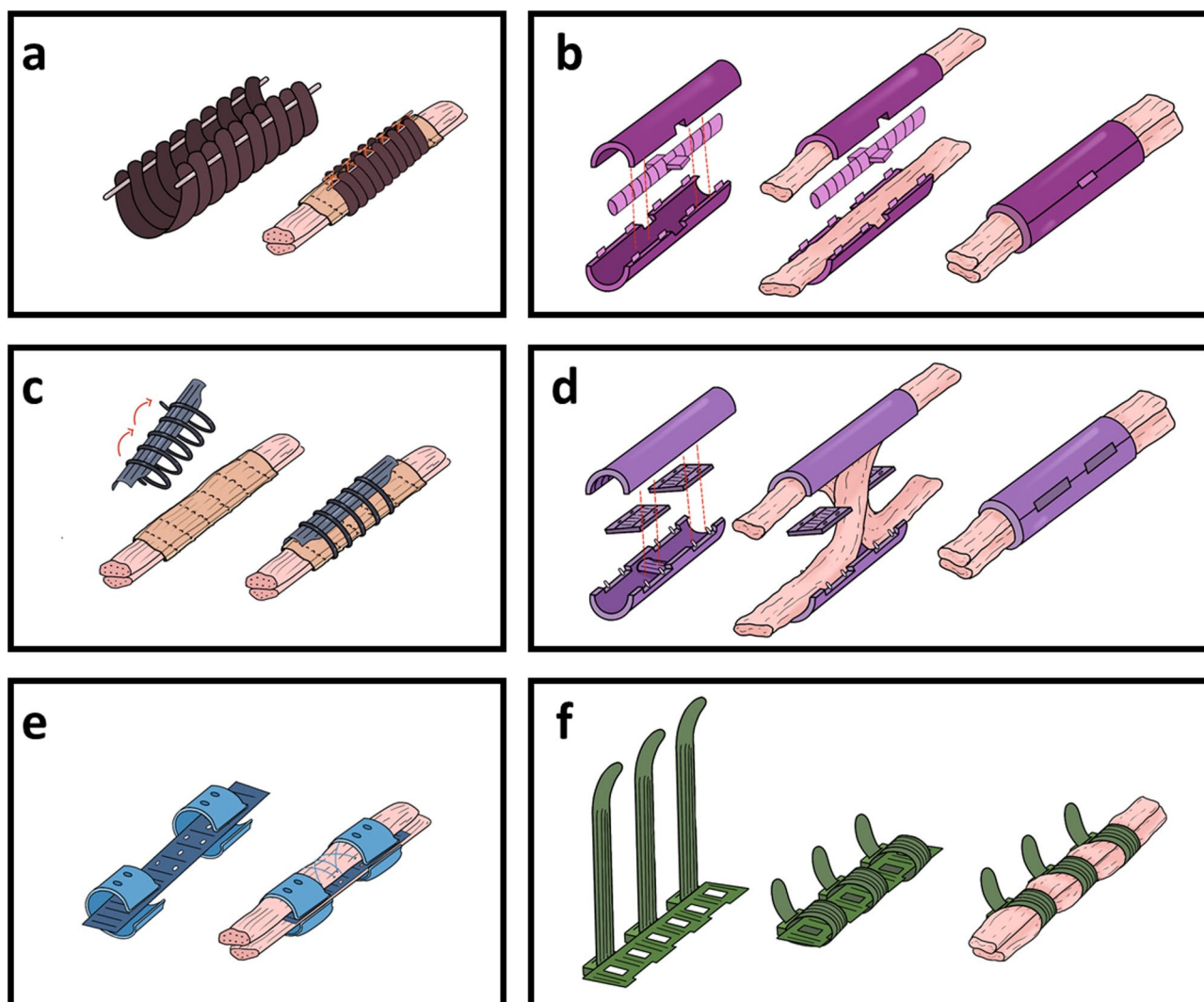


Fig. 3 Illustrates the sketches of the six proposed designs for tendon attachment device **(a)** Flex Duct Hose. **b** Rigid Capsule + Friction Pin. **c** Spring on a Sheathed Graft. **d** Rigid Capsule + Friction Plates. **e** Suture Pad. **(f)** Zip Tie.

Prototyping

Figure 4 illustrates the final monolithic design of the device. A thin square sheet called the Friction Plate (Fig. 4a) is positioned in the center to enhance friction between the two tendon strands and maintain their position. Holes are punched on the surface of the friction plate to facilitate direct contact between the strands (Fig. 4b), promoting healing and tissue bonding during the healing period. Surface sandblasting is proposed to further increase the friction coefficient. Three belts (Fig. 4c) and their locks (Fig. 4d) are attached to one side of this plate in a row. These belts rotate around the tendons with the friction plate in between, securing firmly by entering the bottom hole of the lock, similar to zip ties. To prevent axial misplacement, notches were introduced

on the opposite side of the plate, directly under the belt paths, allowing the belts to sit flush within the surface. This design smooths the outer profile of the device and facilitates easier insertion into bone tunnels.

To determine the optimal number and width of belts and evaluate the friction plate's effectiveness, in-vitro experiments were conducted on three variants of the device (section "Crafting the devices"). The outcomes, discussed in (section "Discussion"), revealed that three 2 mm wide belts attached to a 20 mm long, 8 mm wide friction plate provided the best results. Neighboring belts were placed 4 mm apart and 3 mm away from the sides of the friction plate. This optimized ultimate prototype underwent evaluation through experimental in-vitro tests mimicking actual ACL Reconstruction configuration.

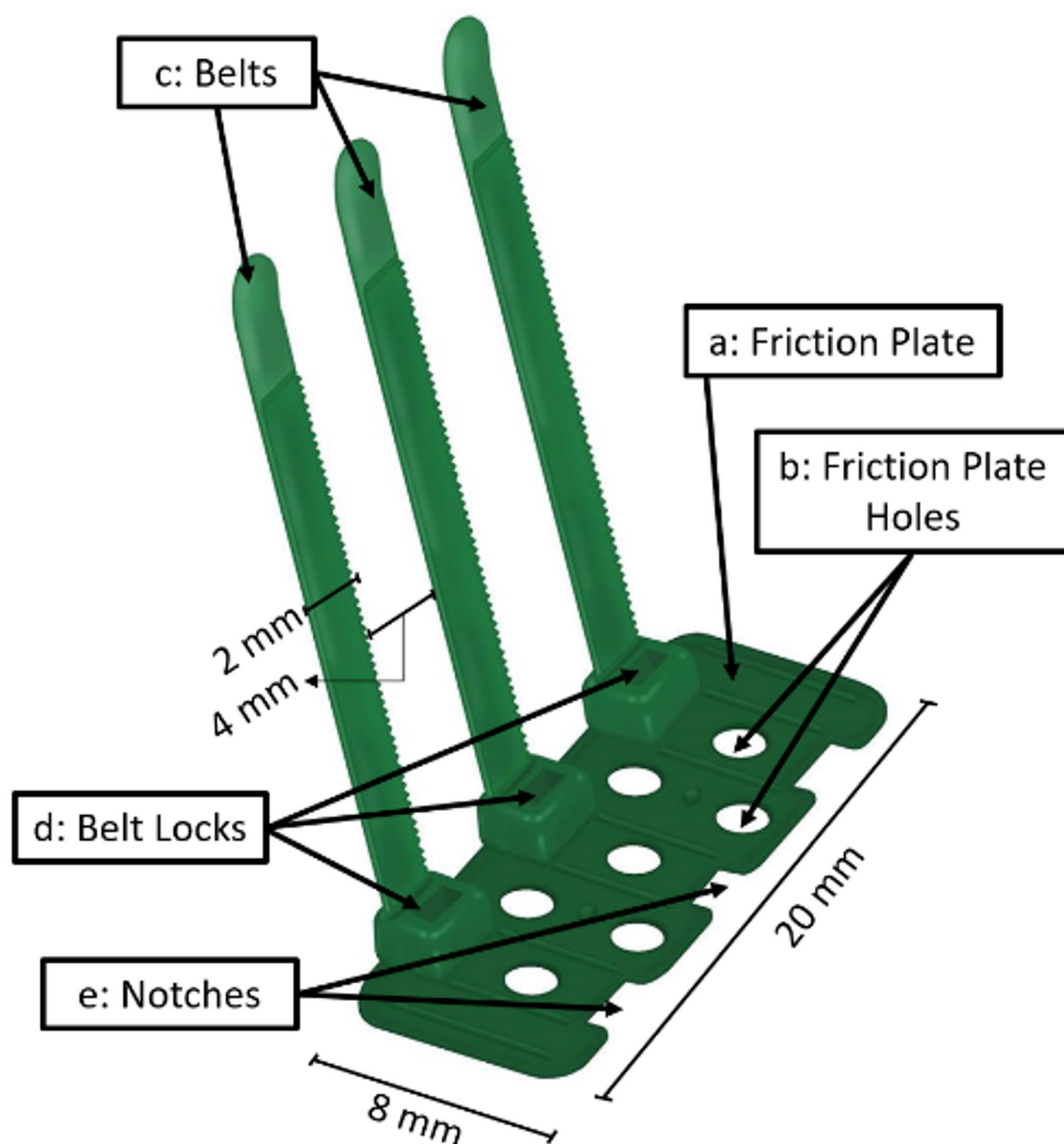


Fig. 4 Design of the ultimate device.

In-vitro modeling

Preparing the tendons

Digital flexor and extensor tendons were harvested from fresh bovine hooves obtained after slaughter from a licensed butchery (Nemuneh Super Protein, Tehran, Iran). The animals were Holstein × Simmental cross-bred cattle aged 12 to 14 months, ensuring a consistent genetic background and age across samples. The

butchery sourced the animals from a high-throughput commercial slaughterhouse operating under routine veterinary inspection and in compliance with national animal welfare and hygiene regulations. Studies have shown that these tendons have similar mechanical properties to human hamstring [23]. The tendons were manually trimmed under slight tension [8], resulting in two sets: five 30 cm tendons and twenty 20 cm long grafts (Fig. 5c).

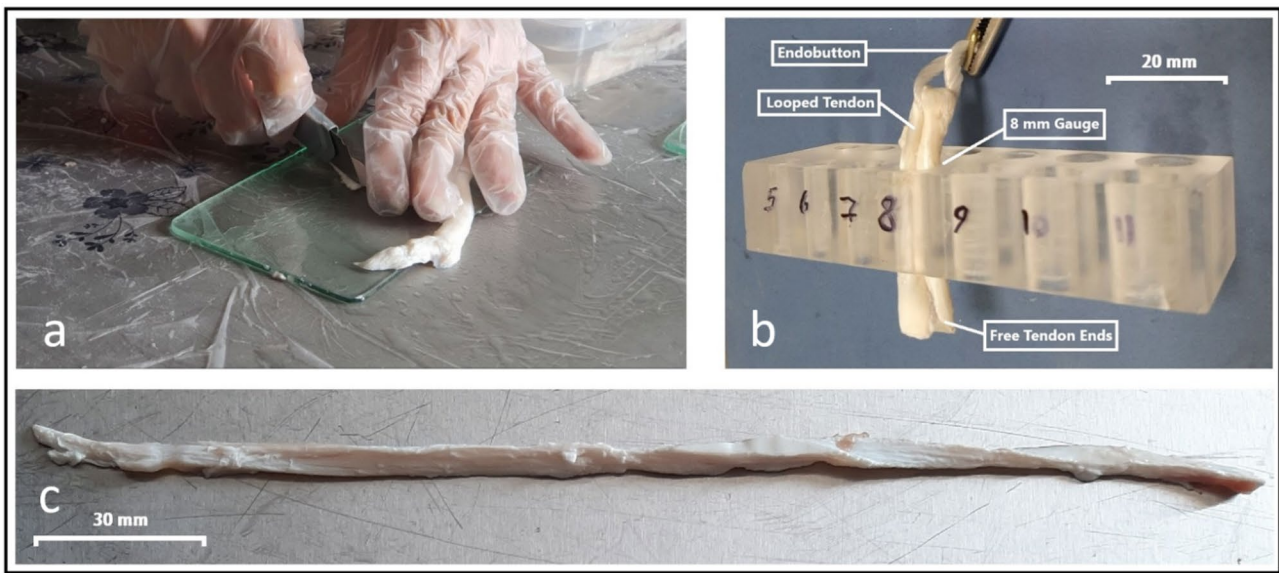


Fig. 5 Preparation setup performed in the Sharif Orthopedic Biomechanics Laboratory; **(a)** Trimming the bovine tendon to the desired size. **b** Evaluating the diameter of a 20 mm long doubled graft by a gauge template; **(c)** A 30 mm long trimmed tendon, ready to be sutured for a three-strand graft.

The first set represented a tripled ACL graft for optimized design verification (section."Preparing the tendons"), while the second set was used for device optimization, comparing three design variations (sect."Crafting the devices"). Tendon diameters were trimmed to form a diameter of 8–9 mm for doubled and tripled grafts [24, 25] which was verified using a gauge template as shown in Fig. 5b.

Sharif Ethics Committee approved the bovine tendon harvesting procedure, and the harvested hooves were stored following food health and safety protocols. Tendon graft samples were frozen at −20 °C, as storage for up to two days at this temperature does not significantly affect mechanical properties [22, 26]. Prior to the testing, samples were thawed at room temperature for 4–8 h, kept moist with Ringer’s solution, and stored in sealed polyethylene bags [27]. Saline spray was used to maintain graft moisture during testing [28].

Crafting the devices

To craft the ultimate design (used for design verification), Three 2 mm zip-ties mimicked belts and locks, along with a 440-grit sandpaper as the friction plate. The sandpaper was trimmed to a 20 mm × 8 mm square. The zip tie locks were glued to the sandpaper. Minor details from the original design, such as friction plate holes, notches, and the reduced lock size, were intentionally overlooked to specifically focus on the mechanical interaction between the straps, friction plate, and the tendons. The friction plate holes, intended to promote tissue healing following the surgery [25], depend on the final material choice, and their size and pattern will be optimized in future biological studies. The notches and lock sizes are

Table 1 The specifications and details of each model.

The device used to prepare the sample	Specifications		
	Strap width	Using a friction plate	Sample size
Model I	2 mm	No	5
Model II	2 mm	Yes	10
Model III	3 mm	Yes	5
Model of the ultimate design	2 mm	Yes	5

unrelated to mechanical fixation; they aid tunnel insertion [23] by smoothing the device’s outer profile and are not in contact with the tendons during testing, therefore, their omission does not affect the mechanical outcome of this study. The simplified model allowed us to focus solely on evaluating the fixation mechanism, without confounding influences from biological or ergonomic features.

The device’s three variants were modeled earlier aiming to optimize the device: Model I had three 2 mm wide zip ties without a friction plate, Model II resembled the ultimate design, and Model III had a friction plate with three 3 mm wide zip ties. The preparation process for these models was like the ultimate design (see Table 1). Five samples of each variant were tested.

Experimental setup

Mechanical testing was conducted at Sharif Orthopedic Biomechanics Laboratory using a servo-hydraulic testing machine (Amsler HCT 25–400; Zwick/Roell AG, Germany). Samples were maintained at room temperature and kept moist with normal saline spray during the tests [21]. The test setup and objectives for the ultimate design

differed from the other sample sets and are described separately.

Experimental setup of the ultimate design

This series of tests aimed to evaluate the qualities of an tripled ACL graft prepared with the optimized device under conditions resembling those experienced by actual ACL grafts. Figure 6 illustrates the graft preparation steps. The thicker end of each 30 mm tendon was defined as the tibial end and was whip-stitched by nonabsorbable sutures covering 20 mm of the tendon's length. The tendons were then folded into a tripled N-shaped configuration, with each side consisting of a loop-like folded portion and a free end. The presence of the stitched strand determined the tibial end, and the looped part at that side was also sutured, similar to a conventional triple graft [9]. The tibial free strand was then passed through the loop of an Endobutton [8].

The designed device was applied by placing the friction plate between the free femoral strand and the strand of the looped portion closer to it. Zip ties were used to secure the device and graft, with adjustments to ensure

proper positioning. The tendon compression (TC) was employed to account for variations in graft size and represented the compression applied to the graft under the straps [28]. TC is defined as

$$TC = \frac{S_{Tendon} - S_{gripped}}{S_{Tendon}} \quad (1)$$

Where S_{Tendon} is the sum of cross-sectional areas of the two tendon strands under no tension (before compression), and $S_{gripped}$ is the crosssectional area enclosed inside the tightened zip ties (after compression). An average TC of 0.27 was considered to be safe in our previous work [29] and the literature [30]. This TC corresponds to compressing an 8 mm diameter tendon to 6.8 mm.

The samples were mounted on the testing machine using an Endobutton for femoral fixation and a bench vise for tibial fixation. The femoral side of the graft was suspended using a cylindrical rod connected to the actuator of the testing machine, simulating suspensory fixation [27, 31, 32]. The tibial side was secured by gripping the 20 mm extended sutured portion between the jaws of the

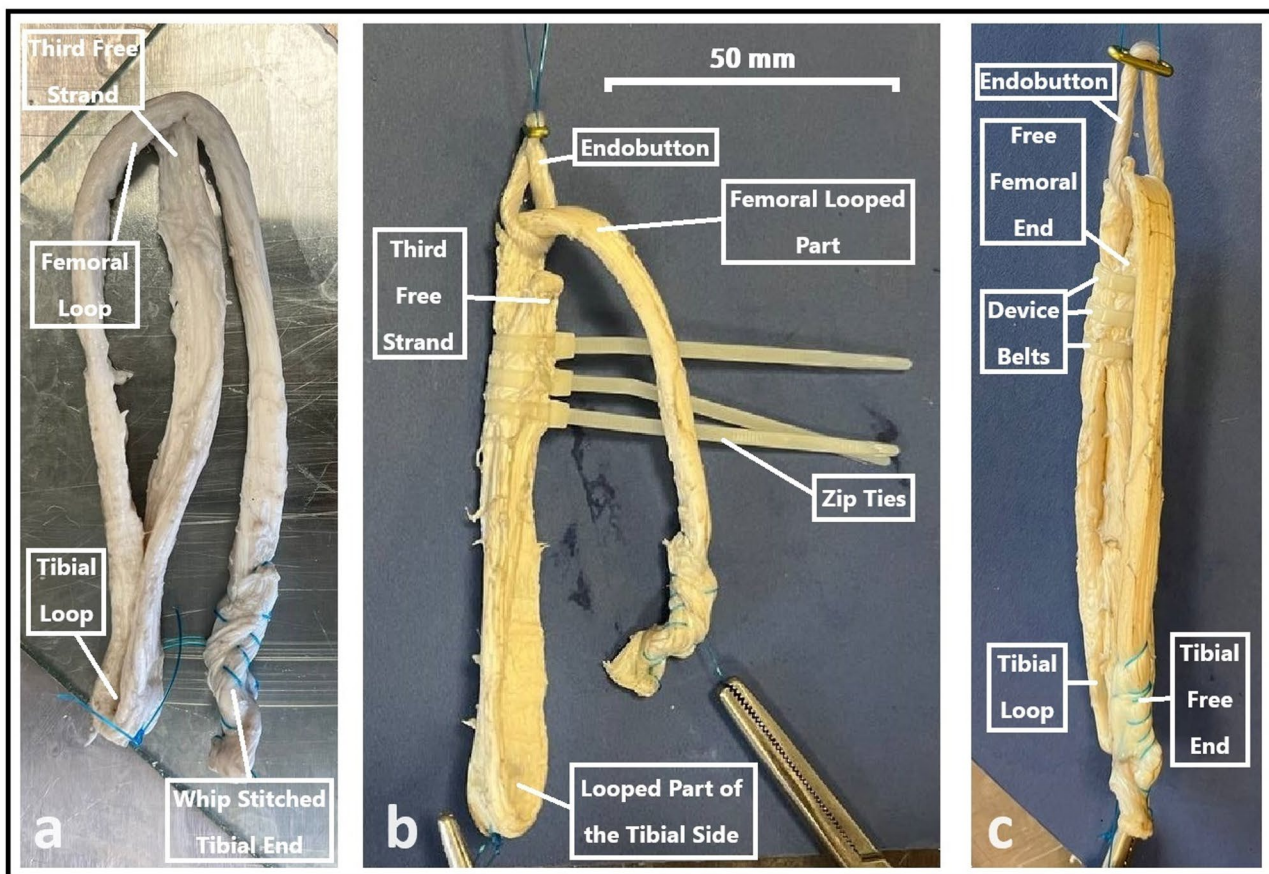


Fig. 6 **a** A 30 mm tendon graft folded to make a tripled graft. The whip-stitched side is the tibial side. **b** Applying the model of the ultimate design to the tendons. The free-end tibial strand is also passed through the loop of an Endobutton. **c** A prepared tripled graft is ready to be mounted on the test machine. The tibial ends are sutured, and the free-end strand at the femoral side is nested in the looped portion of the graft.

bench vise [16]. The sutured portion was covered with a gauze sheet to prevent graft tearing during jaw compression (Fig. 7). This configuration replicated the compression experienced by an interference screw to the graft against the tibial tunnel walls, eliminating variations in tibial fixation quality and facilitating accurate measurement of tendon slippage. By eliminating displacement on the tibial side, any displacement and elongation observed in the samples were related to the femoral fixation and the introduced device.

Experimental setup of the three variants

These experiments were designed to optimize the belt configuration and assess the inclusion of a friction plate in the final design. The primary aim was to evaluate how each model defined by specific strap and friction plate configurations, could maintain two tendon strands securely side by side. To isolate this effect, variables such as tendon-Endobutton interaction, skill-based variations in suturing, and uneven load distribution among tendon strands in a tripled graft were intentionally excluded. Therefore, instead of replicating an actual ACL graft as in (section "Experimental setup of the ultimate design"), a simplified setup was used in which a single tendon was looped and its ends connected by the device, allowing solely focus on the device's ability to hold the tendons.

Each 20 cm long tendon was looped like a single chain link. The two ends were placed side by side to create a 20 mm contact surface and were secured using one of the three devices variants (Fig. 8). Models II & III were applied following the procedure described for the ultimate design. Model I consisted of three zip ties fixed 4 mm apart around the tendons. The tendons were slightly tensioned manually. Initially, five samples of each model were tested, and an additional five samples of the selected model (model II) were tested to ensure repeatability. The samples were mounted on the testing machine using pins as described by Yoo et al. [20].

Biomechanical testing

The objective of the biomechanical testing was to evaluate the qualities of grafts prepared with the ultimate device under human-like loadings. The assessment involved a three-step loading process. First, a cyclic preconditioning load of 10–50 N for ten cycles at 0.1 Hz conditioned the grafts and eliminated loose tendon length [15, 16, 22] by straightening the tendon's collagen fibers [33]. Second, a cyclic loading of 50–250 N [8, 16, 20] for 200 cycles at 1 Hz [8, 34–36] simulated the forces experienced during early-stage rehabilitation after ACL reconstructive surgery [37–39]. The maximum forces applied to an intact ACL during normal walking and slope climbing are 169 N and 67 N, respectively [40]. Finally,

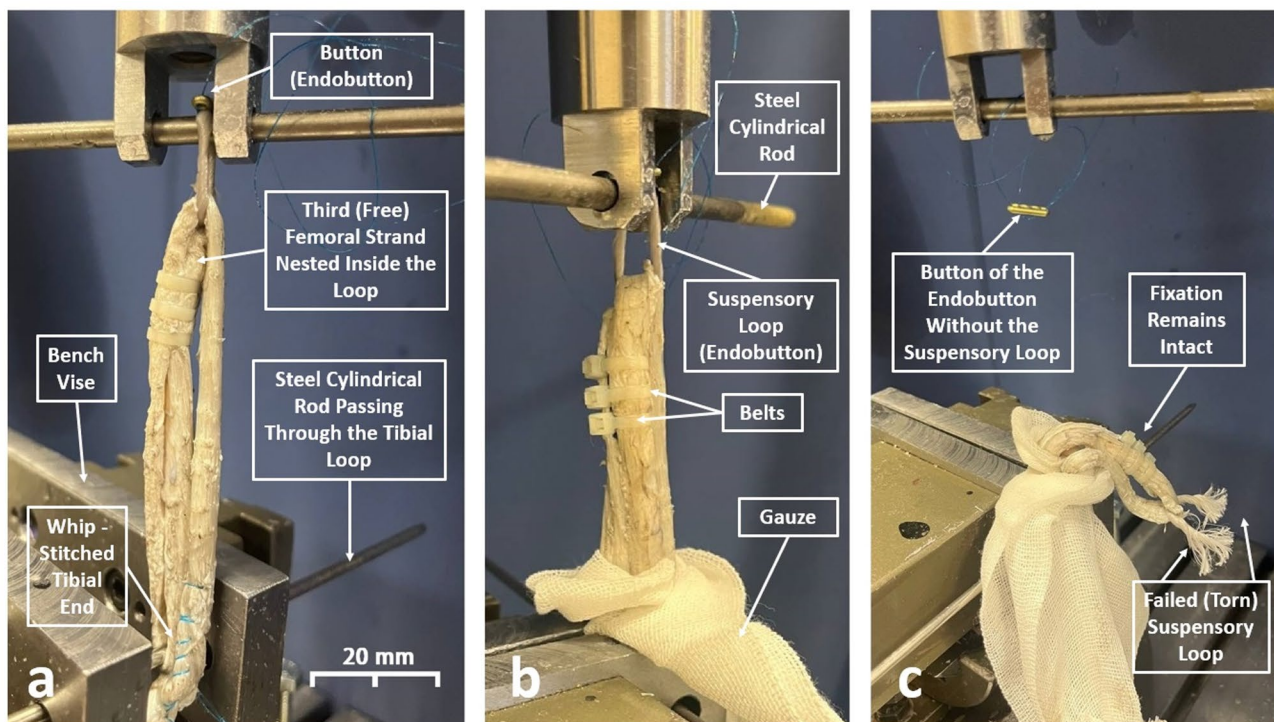


Fig. 7 **a** Mounting a graft prepared with the model of the ultimate design on the testing machine. A cylindrical rod is passed through the Endobutton, and the tibial side is secured inside a bench vise. To ensure stability, a rod is also passed through the looped portion at the tibial side of the graft. **b** The sample mounted on the machine and ready for the tests. **c** The sample failed during the final pullout.

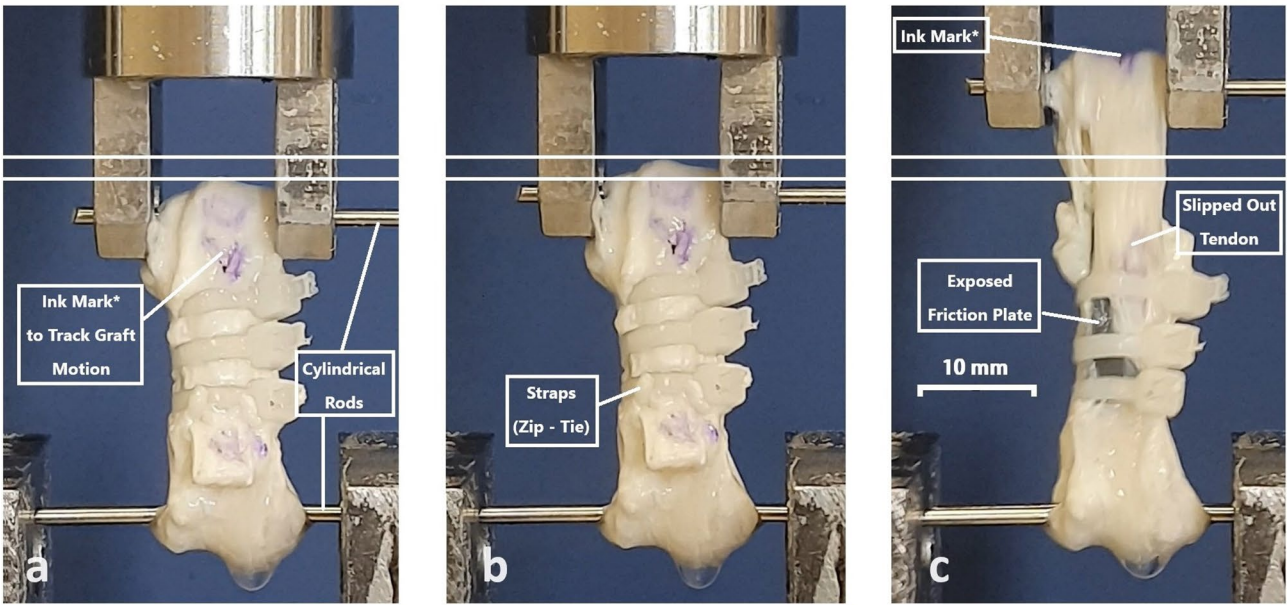


Fig. 8 Biomechanical testing of a graft prepared with Model II fixation. **a** A graft was mounted on the machine under no tension. **b** 120 N tensile load **c** Failure due to tendon slippage out of the fixation at the final pullout. The friction plate is visible.

Table 2 Mechanical testing protocols and specifications. Protocol 1: simulating anatomical loads in a tripled tendon graft configuration for the ultimate design. Protocol 2: evaluates three design variants using a simplified looped tendon model.

Step	Frequency/ Loading Rate	Loading Protocol		The number of cycles
		Protocol 1	Proto- col 2	
Preloading	0.1 Hz	10–50 N	10–20 N	10
Main cyclic loading	1 Hz	50–250 N	50–120 N	200
Final pullout	20 mm/min	250 - failure N (Limited to 1000 N)	120 - failure N	1

a tensile pullout test measured the fixation strength if the structure survived the cyclic loading. The specimens were loaded with a loading rate of 20 mm/min [41] until structural failure occurred, with a limit of 1000 N due to Endobutton loop rupture in the first specimen. This limit exceeded the reported ultimate loads for triple grafts [8, 16, 20] and tibial fixation methods in previous studies [34–36]. Hence, it was presumed that any graft surviving the 1000 N limit demonstrated superior strength compared to conventional grafts and fixation methods. The loading range for this assessment is presented as Protocol 1 in Table 2.

The assessment of the three variants of the ultimate design was like the procedure explained in the paragraph above. However, since these tests aimed to compare the three variants with each other rather than with actual ACL grafts, and the samples had one less tendon strand, the loading upper limits were reduced to prevent sample

failures before the final pullout step. The details are presented as Protocol 2 in Table 2.

Failure modes

In assessing failure modes, two criteria were employed. Displacements exceeding 10 mm during cyclic loading were considered failures to ensure graft functionality and prevent excessive laxity [42]. Additionally, if multiple peak points appeared on the force-displacement graph, the second peak point was deemed the failure load provided the drop after the first peak was within 10% of the initial peak load. This drop indicated a healable local microfracture without compromising the overall structure [33]. All failure modes, along with corresponding loads and displacements, were recorded.

Average Cyclic stiffness (ACS)

To determine graft function under customary loads, the average cyclic stiffness (ACS) was introduced [34, 36]. This was particularly vital to estimate how the graft behaves in the early stages of recovery following an ACL reconstruction surgery. ACS is defined as: [2]

$$ACS = \frac{F_c}{D_c/N_c} \text{ N/mm}$$

(2)

where F_c is the difference between the upper and lower values in the cyclical loading, D_c is the pure displacement in the main cyclic loading (cyclic elongation), and N_c is the number of completed cycles in the second loading step. Beside ACS, the average pullout stiffness (APS) was

Table 3 The mechanical properties of the three variants.

Sam- ple Sets	Load to Failure <i>n</i>	Cyclic Elongation mm	ACS N/mm	APS N/mm	Sam- ples Count
Model I	240.8 ± 70.1	2.47 ± 0.93	6300 ± 2806	67.1 ± 11.8	5
Model II	309.8 ± 44.2	1.79 ± 0.28	7776 ± 1349	115.1 ± 29.9	9
Model III	303.4 ± 52.5	2.43 ± 0.45	5762 ± 1196	79.9 ± 6.8	5
P Value	0.087	0.059	0.129	0.003	

defined as a measure of the slope of the linear region of the pullout force-displacement curve.

Statistical analysis methods

The results were analyzed using Student’s t-distribution to calculate 95% confidence intervals. Normality of the data was assessed using the Shapiro–Wilk test. Additionally, a one-way ANOVA was conducted to assess the recorded data. Significance of the differences between results was determined using the probability value (P-value). A P-value equal to or less than 0.05 indicated a significant difference between the two groups with 95% confidence.

Results

In models I, II, and III, failure modes were primarily attributed to tendon slippage from the fixture, with no gross tendon laceration observed. One sample of model II failed during cyclic loads at the 181st cycle, while the remaining failures occurred during the final pull-out tests. Average values of load to failure, cyclic elongation, ACS, and APS are presented in Table 3. Model II exhibited significantly higher APS ($P=0.003$), while there were no significant differences in other criteria. Model II also demonstrated higher average values for ACS and Load to failure, along with lower values for elongation (Fig. 9). Consequently, the combination of 2 mm straps with a friction plate was chosen for the ultimate design.

The impact of the friction plate on load to failure and APS was significantly favorable ($P=0.042$ and $P=0.005$, respectively) (see Table 5). However, no significant effect was observed on cyclic elongation and ACS ($P=0.058$ and $P=0.202$, respectively). Notably, Model I, lacking a friction plate, exhibited much greater variability in load to failure and ACS, as reflected by its higher standard deviations compared to Models II and III. This increased variability likely stems from the absence of the friction plate acting as a structural connector between straps, resulting in substantial relative motion between the

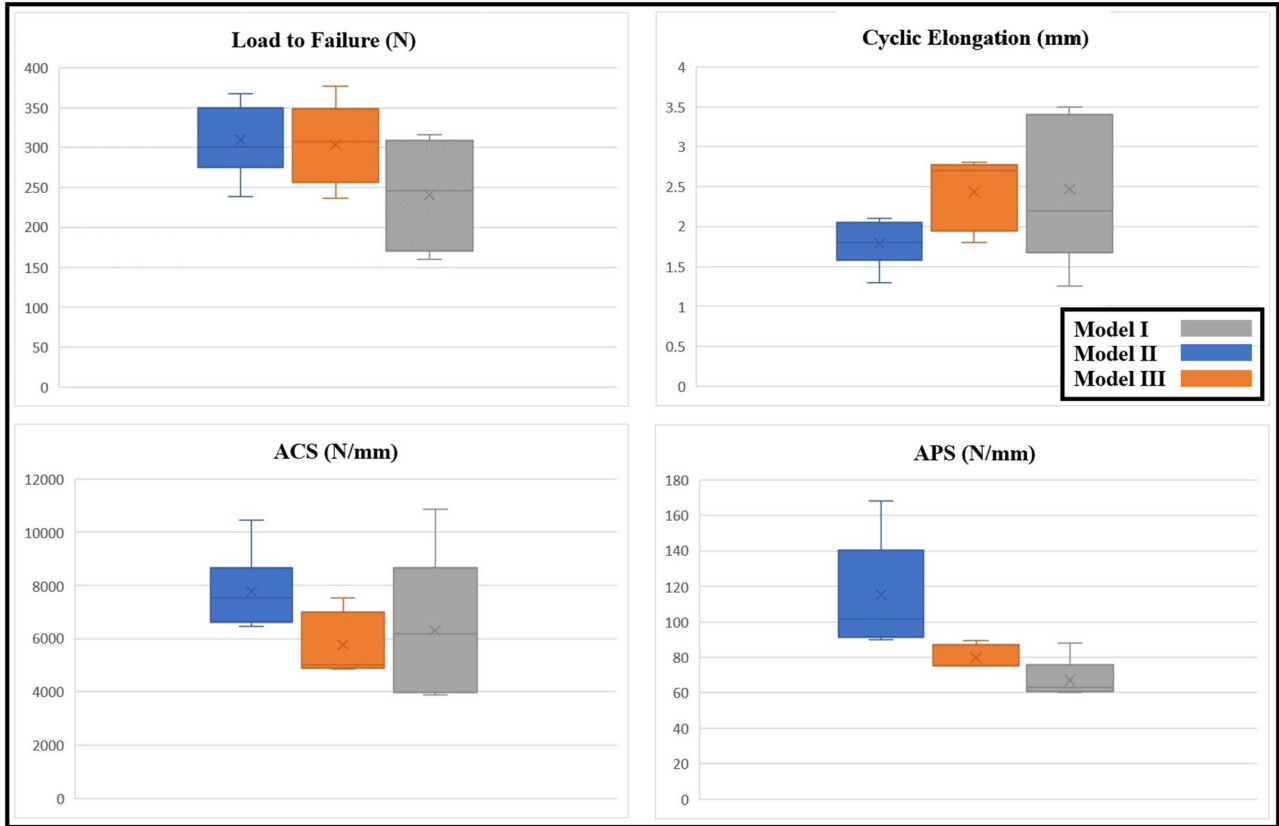


Fig. 9 Comparing the mechanical properties of the three variants. Models I, II and III are depicted respectively in grey, blue, and orange.

Table 4 P-Values of comparing different sets to evaluate the effect of using friction plates and straps with different widths.

Com- pared Groups	Aim of Comparison	P – Values			
		Load to Failure	Cyclic Elongation	ACS	APS
Model I vs. Model II	Assessing the effect of friction plate in samples completely similar in other aspects	0.042	0.058	0.202	0.005
Model II vs. Model III	Comparing graft properties with 2 and 3 mm wide straps in samples completely similar in other aspects	0.812	0.006	0.017	0.025

straps and consequently compromised structural integrity. This, in turn, contributed to inconsistent mechanical performance, underscoring the critical role of the friction plate in enhancing device stability and repeatability.

Regarding strap width, grafts utilizing 2 mm wide straps exhibited significantly improved cyclic elongation, ACS, and APS (Table 4). It could be concluded that a combination of friction plate with 2 mm wide straps can limit the cyclic elongation of the grafts due to fatigue and regular loading conditions and provide stiffer grafts (effect of 2 mm wide straps) and on the same time, the friction plate would increase the load to failure of the graft meaning that this stiff graft would withstand higher loads and traumas. Comparative analysis among the three models confirmed these findings (P-Values reported in Table 3), demonstrating higher averages for the load to failure and ACS, reduced cyclic elongation Fig. 9, and significantly higher APS (indicating increased stiffness) ($P=0.003$).

In the final design tests, the first sample failed due to suspensory loop tearing under a load of 1191 N. Considering that ACL grafts rarely experience such high loads and that tibial/femoral fixations commonly fail at lower loads [34, 43], a limit of 1000 N was imposed in the experiment due to limitations in providing Endobuttons. Three samples were subjected to this limit, and one failed at 729 N due to tendon slippage. Detailed results can be found in Table 5.

Figure 10 (A) depicts a typical load-displacement graph for model II samples, showing three distinct steps in the loading condition. Figure 10b provides a magnified view of step 2, the main cyclic loading phase. The graph illustrates the viscoelastic behavior of the tendon, characterized by hysteresis loops that indicate time dependency. The hysteresis loops gradually became thinner over time, suggesting that the energy loss caused by internal friction between the tendon fibers reached its lowest point. As a result, the graph reached a stable condition, and there was no longer any observed creeping of the specimen. Once the cyclic step became stable, we proceeded to apply a pull-out loading to the sample.

A similar effect is observed in the time displacement graph Fig. 11. The slope of the line connecting displacement peaks during cyclic loads decreases rapidly in the initial cycles and eventually becomes horizontal in the final cycles. This indicates an increased stiffness of the fixation and elimination of elongation after a certain number of loading cycles. Clinically, this suggests that subjecting the graft to sufficient cyclic loads before tunnel insertion, coupled with proper tibial and femoral fixation, can prevent significant graft elongation and ensure rigid fixation.

Discussion

This study presents a novel approach to enhancing tripled hamstring graft preparation for ACL reconstruction by introducing a new fixation device based on two key concepts: the use of straps to secure the tendon and the integration of friction plates to minimize tissue damage. This is the first study to explore these mechanisms in tendon fixation, offering a potential advancement over conventional suturing techniques. The clinical relevance of this work lies in its support for tripling the semitendinosus tendon alone, allowing the Gracilis to be preserved [6]. While existing literature primarily focuses on variations in suturing techniques for tripled grafts [8], this study introduces a fundamentally different fixation strategy.

This study revealed that the ACL graft prepared using our design exhibited comparable characteristics to grafts created using conventional methods in the existing literature. Moreover, the graft demonstrated superior load-bearing capacity compared to most tibial and femoral

Table 5 The mechanical testing results of the final design. 5 samples were tested to ensure the repeatability.

Sample No	Load to failure (N)	Cyclic elongation (mm)	ACS (N/mm)	APS (N/mm)	Mode of failure
1	1191	1.26	31,746	142	Endobutton failure
2	1000 (limited)	0.95	42,105	116	--
3	1000 (limited)	0.81	49,382	160	--
4	729	1.04	38,461	154	Tendon slippage out of the device
5	1000 (limited)	1.51	26,490	90	--
Mean $\pm$ SD	--	1.11 $\pm$ 0.27	37,637 $\pm$ 8,910	132.8 $\pm$ 28.9	--
95% CI	--	0.87–1.35	29,827–45,446	107.5–158.1	--

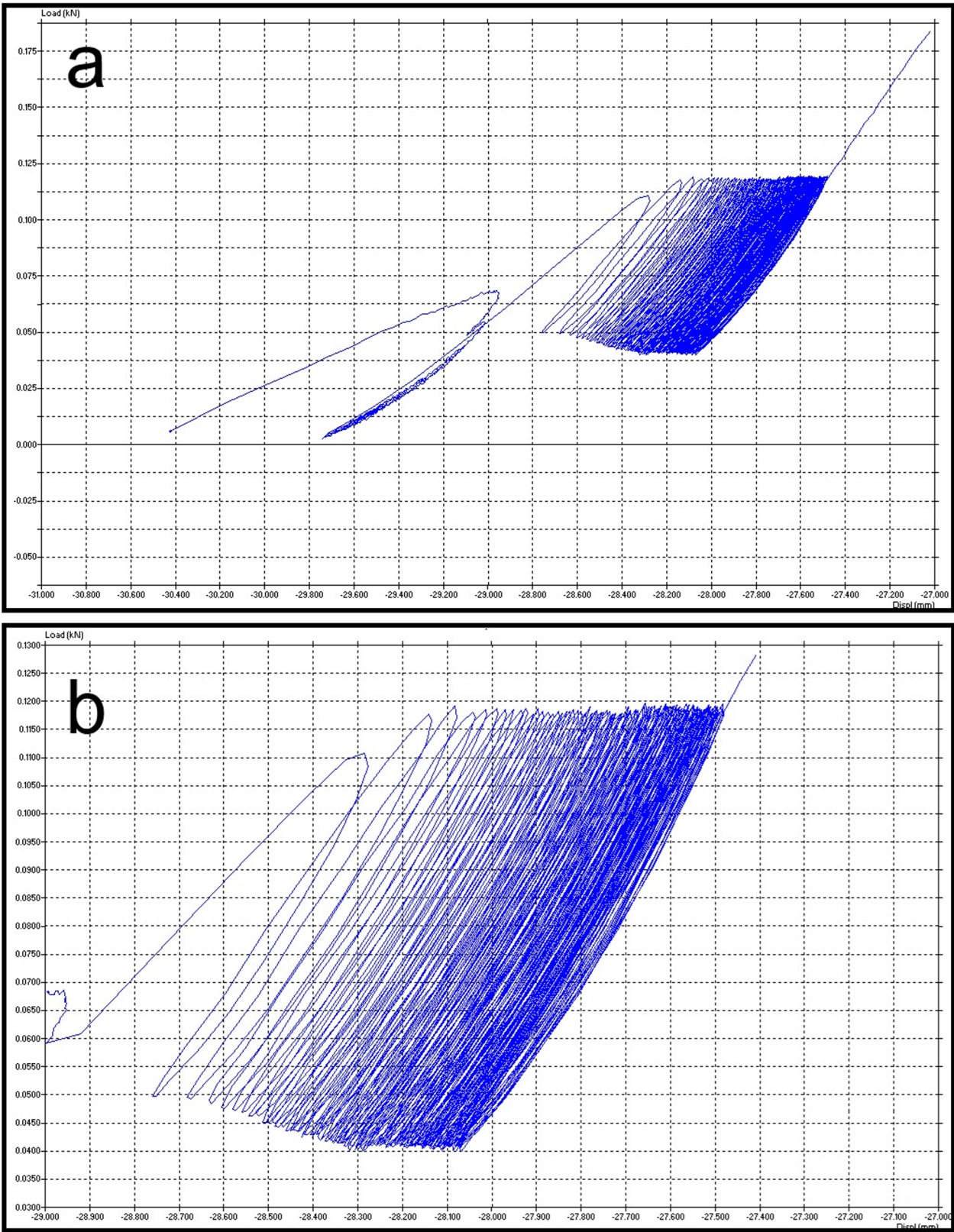


Fig. 10 **A** A typical load-displacement graph when a Model II graft was used. **B** Hysteresis loops become stable at the end of main cyclical loading.

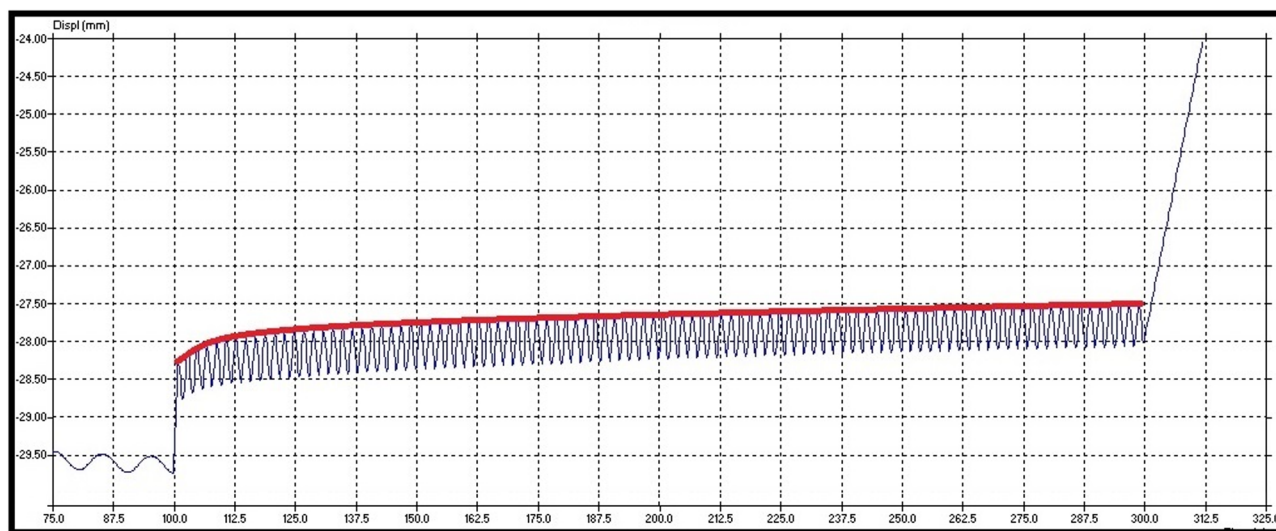


Fig. 11 A typical time-displacement graph when a Model II graft was used. The red line connects the peak displacements in the main loading cycles showing regression of graft elongation.

fixations, including BASHTI and interference screws [34, 43]. Additionally, we aimed to evaluate the effectiveness of a friction plate and the impact of strap diameter on graft strength. Results demonstrated that the use of a friction plate significantly increased the load to failure and stiffness of the grafts, supporting our hypothesis on the benefits of using straps with a friction plate for graft fixation.

The results for APS, ACS, and Cyclic elongation can be compared with similar studies. Borjali et al. [34], reported average ACS and APS values ranging from $10,300 \pm 5,300$ to $2,400 \pm 1,200$ N/mm and 79 ± 27 to 111 ± 40 N/mm for doubled grafts under different conditions. Cyclic elongation and load to failure for models I-III were respectively twice and half the values reported in the literature [8] for a regular tripled graft. It is important to note that these models were comparative samples and were not fixed to the testing machine in the same manner as actual ACL grafts. However, the recorded elongation and load to failure are comparable to several tibial fixation studies [34, 36].

80% of ultimate fixation samples surpassed 1000 N load to failure, with one sample failing at 729 N. These values exceed the reported average load to failures for four types of tripled hamstring grafts by 50 to 75% (569.1 ± 107.8 , 632.3 ± 167.5 , 571.7 ± 101.5 , 615.9 ± 147.9 N) [8] and two types by Snow et al. by over 60% (586.7 ± 138.8 and 601.8 ± 113.6 N) [15]. This does not directly imply that the introduced fixation is stronger, since variables including the age and race of the bovine hooves may differ in the mentioned study. But it can be assumed safely that comparable and strong fixation is achieved. Our device exhibited an average cyclic elongation of 1.11 ± 0.27 mm after 200 cycles which is close to the values Pavan et

al. reported for graft elongation after both one and 500 cycles [8]. All tests, including the three models and the ultimate device, showed no tendon tearing or gross tissue laceration, demonstrating successful prevention of tissue lacerations by acquiring straps instead of sutures.

Due to the diverse methods of tripled hamstring graft preparation reported in the literature [8], a direct comparison with existing techniques was not feasible. Instead, the device was tested under conditions comparable to prior studies. The findings demonstrate that the introduced design offers a viable alternative to existing tendon fixation methods, laying the foundation for a new approach to ACL reconstruction. This study also introduces the innovative concept of using straps for tendon fixation, which could inspire further advancements in graft stabilization techniques.

This study has several limitations that should be acknowledged. The sample sizes were relatively small, which, while common in early-stage biomechanical research involving large animal models such as bovine tendons [8, 28, 35, 36, 43], limits statistical power and generalizability. Load-to-failure testing was capped at 1000 N, which prevented the assessment of true ultimate strength and failure modes in some samples. Additionally, although the device showed promising mechanical performance up to 200 cycles, higher-cycle fatigue testing (e.g., 500 or 1000 cycles) was not conducted, leaving long-term mechanical durability unassessed. As an in vitro study, this work does not address biological healing, graft incorporation, or the tissue response over time, critical aspects that must be explored through in vivo studies. Furthermore, the study did not compare the device directly with conventional fixation methods, limiting the context for evaluating its relative performance. While

the use of straps and friction plates was mechanically effective, the current friction plate design warrants further refinement. Future work should also address the use of bio-absorbable materials and surface patterning for enhanced biocompatibility, as well as the optimization of strap width, which was limited in this study by available sizes.

Conclusions

This study introduced and mechanically validated a novel implant device for preparing tripled semitendinosus grafts for ACL reconstruction. The design incorporated two novel concepts, friction plates and straps, which

enhanced graft fixation and mechanical stability. Through experimental testing, the device was mechanically optimized, and the final design demonstrated superior biomechanical performance, including high load-to-failure, minimal cyclic elongation, and increased graft stiffness in an in-vitro bovine model. These findings suggest that the device can address common limitations of existing tripled techniques, such as graft elongation and soft tissue laceration, contributing to more stable and durable ACL reconstructions. By demonstrating this potential, the study lays the groundwork for future in vivo investigations aimed at further development and clinical validation of the device.

Appendix 1

Table 6 Product design specification

Specification	Requirements
Ease of use	It must be easy to apply and assemble, even for untrained staff.
Appliance time	Any reduction in the time needed for surgery lowers risks and complications [11].
Manufacture	The prototype must be easy to manufacture and contain the list number of parts possible.
Materials	The part must be manufacturable with commonly used clinical-grade biocompatible materials.
Adjustability	The design must be suitable for grafts with different sizes and diameters.
Flexibility	Since the device should be passed through the tunnels along with the graft, it is better to be flexible enough.
Tensile elongation	Having a small amount of tensile elongation ability reduces any chance of tissue laceration under the grip by providing a damper-like ability.
Bending capability	To mimic the mechanical properties of ACL, the clip must not limit any movement of the tendon graft, including its reactions to torsion and bending.
Dimensions	The clip must not have a length longer than 25 mm, which is limited by the depth of the femoral tunnel. It also must be placed inside a tunnel with diameters varying from 6 to 10 mms.
Fragments/Debris	The design must not emit any wear debris or any other free particles under any conditions, even in the case of failure.
Tendon-bone contact surface	A vast tendon-bone contact surface is essential for ligamentization. The clip must cover the list area possible on the graft surface.
Grip strength	Various studies have stated that a standard sutured tripled ACL hamstring graft must withstand loads varying from 400N to 800N. The graft prepared using this clip must withstand loads in this range or above.

Appendix 2

Table 7 This table briefly introduces the prototypes. The evaluations and the scores assigned to each prototype regarding their properties are also included. The prototypes are graded on a scale of one to five for each quality. The scores are presented at the end of each evaluation

Prototype No.	1	2	3	4	5	6
Prototype Name	Suture pad	Zip tie	Flexible duct hose	Springs on a sheathed graft	Rigid capsule + friction plate	Rigid capsule + friction pin
Prototype Description.	This prototype consists of a square plate called a friction plate. It must be placed between two strands of tendons. Two ring clamps are also added to hold the tendons in place. The free surfaces of the graft must be sutured.	This prototype has a friction plate similar to prototype No:1, but instead of clamps, it has three zip ties on the sides that can be fastened around the tendons to provide the necessary grip. Suturing is not required either.	The idea is to use a duct hose-like sheet that forms a semicircle around the tendon strands. The diameter of this semicircle must be smaller than the graft diameter in order to transmit the required tension to the graft.	The core idea of this prototype is based on the changes in the inner diameter of a spring as it is released. The pre-tensioned spring is passed around the specimen, and as the radial tension is released, the diameter of the spring decreases and tightens around the tendon.	This design consists of two stiff parts that can be joined together to form a capsule. As shown in (Fig 2. E), the two strands of the tendon are wrapped around each other, and two stiff plates are placed between them to increase friction and grip strength.	This design is almost identical to the No:5 prototype, but a roughened shaft is placed between the strands instead of two plates
Ease of insertion	Inserting the tendons into the clips of the pad is easy. Still, the suturing process should be done and may take time.	This prototype may be the easiest to use, and the surgeon only needs to fasten the zip ties.	Wrapping the hose around tendons is considered easy, but securing depends on the method of securing. If pins secure it, it may take less time than wrapping a spring around the hose or suturing the sides.	Guiding the spring around the tendon requires some skill and time, but some devices can be developed to guide it automatically, although this may increase manufacturing costs.	Since the parts are rigid and non-elastic, assembling the four parts with their pins is considered easy, but since the space inside is less than the volume of the tendons, constant pressure must be applied to the tendon. The surgeon must ensure that all the tendons are correctly located inside the Capsule and that no tissue is outside. Adding a sheath or pre-tensioning the tendon may reduce complications.	All of the concerns mentioned for Prototype #5 also apply to this prototype, but since the number of parts is less than that of Prototype #5, its application may be easier.
Score:	3	5	1	1	2	2
Materials and production	Production costs are low as its central part is just a flexible sheet. The sheet can be made from clinical-grade polyamides like nylon 6.6.	It may cost more than prototypes 1,3, and 4 as making details for Ziplock with bionic materials may be costly. It also can be made with polyamides.	The cost for this prototype is relatively low, and the hose can also be made of polyamides.	The main design is simple, and the manufacturing costs can be negligible. However, the cost of any metallic biocompatible material, including clinical-grade stainless steel or Platinum, must be considered.	The parts can be 3D printed during experiments but making parts with such details out of stiff materials may cost as much as an interference screw or even more.	All the concerns mentioned for prototype NO.5 apply to this prototype.

Table 7 (continued)

Prototype No.	1	2	3	4	5	6
Prototype Name	Suture pad	Zip tie	Flexible duct hose	Springs on a sheathed graft	Rigid capsule + friction plate	Rigid capsule + friction pin
Score:	5	4	3	3	1	1
Fastening and Adjustability	Users can fasten the sutures as tight as required.	The tension on the tendons can be easily determined by fastening the zip ties.	It is adjustable to some extent (tension is determined by adjusting the distance of corners of the pipe).	Tension is determined by the thickness of the tendon graft (it is not adjustable).	It is not adjustable as the parts are rigid, so each rigid Capsule is specifically designed for a specific tendon diameter.	The Capsule itself is not adjustable, but it can come with different sizes of the Pin, making it applicable to a broader range of tendon diameters.
Score:	5	5	4	3	1	2
Flexibility and adaptivity	It may restrict the tensile elongation of the graft (the portion located inside the clip) but is still flexible in other directions.	It may restrict the tensile elongation of the graft (the portion located inside the clip) but is still flexible in other directions.	It is flexible and capable of tensile elongation, so its effects on the mechanical properties of the tendon are small or negligible.	It is flexible and is capable of tensile elongation, but the spring constant may have little effect on the tensile strain, while it is considered negligible.	The portion of graft covered by the Capsule loses its elasticity and acts as a rigid capsule with no capability to bend. (the clip should be made as small as possible)	all the concerns mentioned for prototype NO.5 apply to this prototype.
Score:	4	5	5	5	1	1
Fragments/Debris	If produced with proper materials, there is no concern.	If produced with proper materials, there is no concern.	If produced with proper materials, there is no concern.	If produced with proper materials, there is no concern.	Tiny links and pins may detach from the device if hit.	Tiny links and pins may detach from the device if hit.
Score:	5	4	4	3	2	1
Healing contact	Dose not cover a considerable fragment of the graft's area.	Does not cover a considerable fragment of the graft's area.	The duct hose's surface must be porous to provide bone-tendon surface contact.	Bone-tendon surface contact is possible through the gaps between the spring rings.	This prototype blocks bone-tendon surface contact.	This prototype blocks bone-tendon surface contact.
Score:	5	5	3	4	1	1
Surface Tension Distribution	Tension is not distributed well at the sutures.	The belts distribute tension to a broader surface.	Tension is distributed along all the tendon surfaces, and the device is soft.	Tension is distributed along all the tendon surfaces, and the device is soft.	Although the tension is distributed along the length of the device, the rigidness of the parts may harm the tendon tissue.	Concerns mentioned for prototype NO.5 apply to this prototype.
Score:	1	3	5	5	4	4
Total score	28	30	25	24	12	12

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12891-025-09152-3>.

Supplementary Material 1.

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Authors' contributions

S.S. developed the main idea, designed alternative implants to suturing, performed the experiments and wrote the original draft. A.N. supervised and administrated the project and reviewed the manuscript. S.M. helped doing the experiments and did postprocessing of the data obtained. M.C. conceptualized the project and reviewed the manuscript.

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Data availability

Data supporting the findings of this study are available within the manuscript. Raw output from mechanical tests and videos recorded during experiments are preserved in the Sharif Orthopedic Biomechanics Lab's database and will be made available upon reasonable request.

Declarations

Ethics approval and consent to participate

All procedures involving animals were conducted in accordance with the ethical standards of the institution and were approved by the Sharif Ethics Committee (Institutional Review Board) with 45792 permit number. Each author certifies that their institution approved the animal protocol for this study and that all procedures were performed in conformity with national, and international guidelines for research involving animals, including the Basel Declaration. All experimental protocols were carried out in accordance with the Guide for the Care and Use of Laboratory Animals.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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