Title:

Effect of geometry on the fixation strength of anterior cruciate ligament reconstruction using BASHTI technique

Running Title:

Geometric Parameters in BASHTI Technique

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Abstract

The goal of this study is to investigate the effects of tendon and cannulated drill bit diameter on the strength of the bone and site hold tendon inside (BASHTI) fixation technique for an anterior cruciate ligament (ACL) reconstruction. Bovine digital tendons and Sawbones blocks were used to mimic the ACL reconstruction. Mechanical strength of the specimens was measured using a cyclic loading continued by a single cycle pull-out load until failure to simulate the real post-surgical loading conditions. Finally, failure modes of specimens and ultimate failure load were recorded. The maximum possible tendon surface strain (i.e. tendon compression) for tendon diameters of 6, 7, 8, and 9 mm were 0.73, 0.8, 0.7, and 0.65, respectively. 80% of the specimens with tendon diameter of 6 mm and 20% of specimens with tendon diameter of 7 mm failed on the torn tendon. All samples with larger tendon diameters (i.e. 8 and 9 mm) failed on the fixation slippage. The maximum fixation strength according to the most suitable core bones for 6, 7, 8 and 9 mm tendons were 148±47 N (core 9.5 mm), 258±66 N (core 9.5 mm), 386±128 N (core 8.5 mm) and 348±146 N (core 8.5 mm), respectively. The mode of tendon failure was significantly influenced by the tendon diameter. Also, an increase in tendon compression (TC) raised the fixation strength for all tendon diameters; however, tendon over compression decreased the fixation strength for the 8 mm tendon group. Finally, an empirical equation was proposed to predict BASHTI fixation strength.

Keywords: BASHTI technique, Geometrical parameters, ACL reconstruction, Fixation strength, Core bone

1. Introduction

Anterior cruciate ligament (ACL) is among the most vulnerable ligaments in the human body, especially during sports activities. According to research in England [1], the rate of ACL damage has increased 12 times from 1997 to 2017. Also, a considerable failure rate (i.e. between 4 and 17%) has been reported after the ACL reconstruction [2]. Conventional ACL reconstruction methods may render some complications, including infections and/or pulmonary embolism [3]. Most conventional ACL reconstruction methods usually utilize metallic implants and stabilizers, such as interference screws and endo button [4]. These methods are criticized due to problems such as the cost of supplying equipment, inflammatory responses [5], the infection potential, and the production of germs [6-8].

Bone and site hold tendon inside (BASHTI) technique, as an organic and implant-less method, is a new reconstruction method that can reduce the problems associated with conventional fixation methods. In this surgical technique, a specific cannulated drill bit is used to cut and extract the bony core instead of destroying that during the drilling process. The core bone would then be inserted into the same tunnel following the tendon graft insertion. The core bone would be forced into the tunnel using a hammer. BASHTI technique, like other implant-less techniques, is believed to reduce the duration of treatment (i.e. by speeding up the healing process), to decrease the operating costs as no external implant would be used, and to minimize the chance of the post-surgical inflammation [9].

Press-fit is the most common implant-free ACL reconstruction technique [10], which utilizes the bone plug attached to a tendon graft that generally is obtained from a patellar site. The bone plug is shaped in the form of the tunnel and is press-fitted into a tibial or femoral tunnel [11,12]. Biomechanical studies have shown an acceptable fixation strength when a press-fit method is used [13,14]. Also, the results of a 20-year clinical study have shown the effectiveness of this method [15]. However, in this method, the patellar graft tissue is used, and since the bone plug must be used at the two ends of the tendon, this graft tissue has a length limitation. Generally, the two bone plugs are taken either from the femur or the tibia bones, and this can create a side effect and pain on the patient as the harvested site is left empty on the femur and tibia after the operation [16,17]. Unlike the press-fit method, the BASHTI technique uses a hamstring tendon as a graft and a core bone harvested from the tunnel. Therefore, the implications with the patellar tendon would be resolved in BASHTI technique.

BASHTI technique was first proposed in 2015 [18]. The project initially aimed to compare the mechanical strength of the BASHTI technique with conventional methods such as interference screw as the most common ACL reconstruction technique [19]. Results indicated that no significant difference in the failure force among the BASHTI technique and interference screw method [18]. Furthermore, it was observed that Sawbones blocks (Pacific Research Laboratories, Malmo, Sweden) -which are rigid sanitary foam blocks as an alternative material to the human bone for testing and demonstrating orthopedic implants- with a density of 320 kg/m^3 well represented the mechanical properties of the bone in the site of drilling [20]. Also, it was found that the most appropriate group of patients in this technique are youth and middle-aged patients [20]. Subsequently, Borjali et al [21], examined the impact of the sheath on the fixation strength, and it was found that using sheath for core bone resulted in lower friction at the contact zone between the core bone and the tunnel wall. Accordingly, since a lower number of hammer impacts were applied on the core bone, the insertion process was easier, and the damage on the core bone decreased. Recently, Nourani et al. [22] showed that the insertion procedure had a significant impact on the BASHTI fixation strength, and it was recommended to use a cyclical force with a frequency of fewer than 300 beats per minute (BPM) to push the core bone into the tunnel.

No studies mentioned above considered the influence of geometrical parameters on the fixation strength of BASHTI technique. This research aimed to address the effects of geometric parameters on the strength of the BASHTI method when used in an ACL reconstruction. As an objective of the study, a series of experiments were performed to understand the importance of the geometrical factors, including tendon and core bone diameters. The ultimate objective was to find out what graft sizes are more appropriate for this technique. Finally, the most suitable drill bit size was recommended in order to improve the efficiency of this technique, and an empirical equation was developed to estimate the BASHTI fixation strength.

2. Methods and Materials

2.1. Sample preparation

Fresh bovine digital flexor and extensor tendons were used to represent the human tissue [18]. Bovine samples were selected from the same race and close age. Bovine hoofs were bought freshly from a licensed butchery. Tendon harvesting from the bovine hoofs was carried out in Biomechanics Lab, Sharif University of Technology, considering Sharif ethical protocols (Fig. 1).

Fig. 1. Harvesting digital tendons (A) from a typical bovine hoof (B)

After trimming the tendons, the samples were kept in a freezer with adjusted temperature on -20°C. Storing the tendon at a temperature of -20°C for a maximum of 48 hours was shown to have no substantial influence on its mechanical properties [23]. The tendons were thawed at room temperature for testing. It was maintained moist using a saline water spray during test [23].

The diameters of double-strand (Fig. 2. a) tendons were trimmed to 6, 7, 8, and 9 mm to cover the range of the graft sizes used in ACL reconstruction [24]. To carefully check the tendon diameter, the looped tendon was passed through a suitable hole of the gauge template (Fig. 2. b). The tendon was trimmed to a smaller size if necessary.

The total length of the tendon was controlled after measuring the tendon diameter, so that 30 mm of the tendon length was out of the Sawbones surface (Fig. 2. c). This gauge length resembles the size of a typical ACL [23].

Fig. 2. a. Tendon preparation: double-strand tendon (A), gauge template (B); b. Tendon diameter controlling process; c. Gauge length for tendon

Sawbones blocks (Pacific Research Laboratories, Malmo, Sweden) were used in the experiments to represent the human tibial bone. Since most portion of the bony tunnel is located inside the cancellous part of the bone, a block density similar to the cancellous bone should be selected. According to the research performed by Dehestani et al [20], the Sawbones block with a density of 320 kg/m^3 can properly represent the mechanical properties of the tibial bone of a young person. Therefore, the Sawbones blocks with a density of 320 kg/m^3 were used to model the human tibial cancellous bone in the present study.

The BASHTI cannulated drill bit (Fig. 3. a) was designed and fabricated in Sharif Biomechanics Lab, Sharif University of Technology. This drill bit can cut the tunnel and harvest the core bone at the same time. The core bone, then, was inserted into the tunnel to secure the tendon graft inside the hole. The drill bit was fabricated in different sizes to create varying tunnel and core diameters (Fig. 3. b).

Fig. 3. a. Different BASHTI cannulated drill bits to cut the tunnel; b. Core bones harvested in different diameters

The diameter of 10 mm was found as a suitable size for a BASHTI tunnel [20,21] This tunnel size is also a common and recommended drill size in conventional ACL reconstruction surgeries [25]. Hence, the outer diameter (see Fig. 4) of the cannulated drill bit was set to 10 mm.

In order to obtain different core bone sizes and to match them with relevant tendon diameters, the inner diameter of the drill bit was made in different sizes, as indicated in Table 1.

Fig. 4. A schematic of cannulated drill bit geometric parameters

The BASHTI graft insertion procedure is illustrated in Fig. 5. After drilling, the looped tendon was passed through the tunnel. Then the core bone was placed between the tendon strands and inserted into the tunnel using a hand hammer. The hammer bit rate was lower than 300 beats per minute, as recommended by Nourani et al. [22]. To maintain the ligament's pre-tension, during the core bone insertion process, the looped tendon was pulled through the tunnel by the aid of a surgical suture. This ligament pre-tensioning, as well as easing the insert process, was keeping the tendon on a tension just to simulate an actual ACL reconstruction.

Fig. 5. BASHTI fixation procedure: a. Creating the tunnel and extracting the core using a cannulated drill bit; b. Using suture to pull the tendon through the tunnel when the core bone was inserted; c. Inserting the core bone into the tunnel and fixing the tendon using a hammer

2.2. Mechanical testing

The pull-out test was completed using a servo-hydraulic testing machine (Amsler HCT 25-400; Zwick/Roell AG, Germany) (see Fig. 6) to assess the intensity of the BASHTI fixation. The Sawbones block was carefully mounted on the machine to ensure the alignment of the actuator and the tunnel. The looped tendon then was hanged into the crosshead of the testing machine using a custom-made rig, as shown in Fig 6.

Fig. 6. Securing the Sawbones block (A) into the servo-hydraulic testing machine (B), and the looped tendon (C) hanged into the crosshead using a custom-made rig (D)

A preconditioning test was then applied to the specimens to make the tendon's fibers align, eliminate the tendon's dead length, and to remove the clearances of the rigs/fixtures [26]. For the preconditioning test, a cyclical preload of 10-50 N was applied to the graft with a frequency of 0.1 Hz for 10 cycles [26].

Immediately after the preconditioning test, the main pull-out test was performed using a cyclical load of 50-200 N with a frequency of 0.5 Hz for 150 cycles. This step simulates the ACL load bearing in a passive extension during the gait as well as modeling early rehabilitation protocols of flexion-extension loading in a reconstructed graft [27-29]. At the end of the cyclical loading, if the sample survived, a pull-out load with a loading rate of 20 mm/min was applied to the specimens in order to measure the ultimate strength of the fixation [30]. The mode of failure was observed and recorded for each test.

2.3. Tendon Compression (TC)

The change of tendon cross-section area may influence the insertion process and fixation strength in the BASHTI technique. In essence, squeezing the tendon between the tunnel wall and the core bone produces a force that represents the fixation strength.

In order to simplify the simulation, the core bone and the tunnel deformation were neglected (i.e. assumed to be rigid compared to the deformation of the tendon). Therefore, TC is defined using the following parametric equation:

$$\mathrm{TC} = \frac{\mathrm{S_{tendon}} + \mathrm{S_{core}} - \mathrm{S_{tunnel}}}{\mathrm{S_{tendon}}} \quad (1)$$

where TC is a unit-less parameter representing the tendon compression. S_{tendon}, S_{core}, and S_{tunnel} are the cross-section areas of the tendon, the core and the tunnel, respectively.

3. Results and Discussion

3.1. Maximum tendon compression (MTC)

According to Table 1, different MTCs are calculated using equation (1) depending on the tendon diameter (see Fig. 7).

Fig. 7. The calculated results of maximum tendon compression, MTC (mm^2/mm^2) as a function of tendon diameter

As seen in Fig. 7, except for the 6 mm tendon, there is an inverse relationship between MTC and tendon diameter due to the increase in tendon resistance when the tendon diameter increased.

3.2. Failure mode

Two different types of failure modes were observed for the tested samples: 1. Tendon tear, and 2. Tendon/core slippage. In the second failure type, the total displacement of 10 mm or more was considered as a failure in the fixation, since the fixation would lose its functionality at this displacement. The two failure modes are illustrated in Fig. 8.

Fig. 8. a. Tendon rupture during the tensile test; b. Tendon/core (fixation) slippage

A threshold of 200 N was assumed as the minimum strength required for a BASHTI fixation to simulate the daily activities and passive motions applied to the knee at the time of rehabilitation [18,28,31,32].

The experiments showed that the failure mode was a strong function of the tendon diameter. It was observed that excessive tendon compression might damage the tendon fibers, and consequently, it could result in the tendon failure.

80 percent of the 6 mm samples tore partially or completely (92% tore below 200 N), implying that the 6 mm double-strand tendon became so vulnerable when it experienced a high amount of compression. The rest of the specimens failed due to the fixation slippage in less than 200 N. Therefore, the 6 mm tendon diameter was found to be unsuitable to carry a reasonable pull-out force needed for the fixation (i.e. 200 N).

In the case of 7 mm tendon diameter, 20 percent of the specimens failed because of the tendon rupture, and the rest of the specimens failed because of the slippage at the fixation site. The tendon tearing in this group occurred in a higher pull-out force (i.e. with an average of 260 N) compared to that for the 6 mm tendon group (i.e. with an average of 129 N).

The tendons with a diameter of 8 or 9 mm experienced no tendon rupture during the pull-out test. Consequently, it was found that the strength of the tendon itself at diameters of larger than 7 mm was higher than the pull-out strength so that the structure failed before the tendon tearing.

3.3. Fixation strength $(\boldsymbol{F_u})$

Table 1 shows the BASHTI fixation strength for different geometric parameters.

Table 1. The failure load of different tendon groups was recorded during the pull-out test

The effect of the tendon diameter on the failure load is illustrated in Fig. 9. The higher tendon diameter yielded greater failure strength. However, scattering the data for the failure force for each tendon group indicates that tendon diameter cannot be sufficient to describe BASHTI fixation strength (Fig. 9).

Fig. 9. Effect of tendon diameter on the BASHTI fixation strength, the 200 N red line indicates the least required fixation strength for rehabilitation, the point mark for a 6 mm diameter represents the outlier data

Also, as shown in Fig. 10, all the cases with a TC of 0.47 or less are below the required fixation strength. For TCs of more than 0.5, however, no definite trend is observed.

Fig. 10. Effect of tendon compression (TC (mm^2/mm^2)) on the BASHTI fixation strength

A one-way analysis of variance (ANOVA) was used to compare the BASHTI fixation strength against TC for each tendon diameter groups (p-value < 0.05 was thought to be statistically significant). The outcomes for each group of tendon diameter are provided in the following sections.

3.3.1. Effect of TC on the fixation strength for the 6 mm tendon

All the cases for the 6 mm tendon failed in a load of less than 200 N. Tendon tearing was the only failure mode for 9 mm and 9.5 mm core bones and slippage in less than 100 N was observed for 8.5 mm core bones. As a result, the 6 mm tendon was so weak to meet the minimum strength required for BASHTI technique (Fig. 11).

Fig. 11 Effect of tendon compression (TC) on the failure load for the 6 mm tendon group

3.3.2. Effect of TC on the fixation strength for the 7 mm tendon

Fig. 12 indicates the significant dependence of failure load on the TC value in this group. Only a 9.5 mm core bone provided an average fixation strength of more than 200 N (i.e. with an average of 258 N). Tendon tearing occurred for 9.5 mm core bones in 60% of the cases with an average failure load of 260 N. Consequently, the tendon diameter of 7 mm with a 9.5 mm core block (i.e. TC = 0.8) could maintain the minimum strength required for the BASHTI technique.

Fig. 12 Effect of tendon compression (TC) on the failure load for the 7 mm tendon group

3.3.3. Effect of TC on the fixation strength for the 8 mm tendon

Similar to the 7 mm tendon, TC had a considerable impression on the fixation strength for the 8 mm tendon. In this case, the fixation strength decreased by about 45%, with an increase in TC from 0.57 to 0.7 (i.e. 23% increase in TC). This shows that over-compression might negatively affect BASHTI fixation strength. Using an 8.5 mm core bone provided a fixation strength of more than 200 N (i.e. with the average value of 386 N). In contrast, 40% of the cases with a 9 mm core bone (i.e. TC = 0.7) failed in less than 200 N. Hence, using an 8.5 mm core bone is suggested to obtain the best BASHTI fixation strength in this group.

Fig. 13 Effect of tendon compression (TC) on the failure load for the 8 mm tendon group

3.3.4. Effect of TC on the fixation strength for the 9 mm tendon

Using a 7.5 mm core bone (i.e. TC = 0.46) caused an improper BASHTI fixation that failed in a force less than 200 N. However, 8 mm and 8.5 mm core bones provided the required fixation strengths (i.e. 90% of the cases failed in more than 200 N). Moreover, an increase in TC between 8 mm and 8.5 mm core bones (i.e. 18%) did not significantly affect the fixation strength (p-value = 0.39). Accordingly, using the 8 mm or 8.5 mm core bone is suggested in the process of drilling in the BASHTI technique in this group.

Fig. 14 Effect of tendon compression (TC) on the failure load for the 9 mm tendon group

Overall, the study found that although increasing the TC in BASHTI technique results in a higher fixation strength, there is a peak point for the compression, and after the peak, the fixation strength will decrease. Similarly, this phenomenon has been observed for interference screws, in which the use of an oversized screw did not increase its pull-out strength [33].

3.3.5. Developing an empirical equation

It must be emphasized that the tendon diameter and TC parameters cannot solely determine BASHTI fixation strength. Hence, the interaction between the two parameters also must be added to consideration. Due to the non-linearity of results, a simple linear regression cannot appropriately model the fixation strength. Therefore, a polynomial format with variable powers for each term was proposed to obtain the best mathematically fit with the experimental data. The proposed polynomial form can accurately model the BASHTI fixation strength with a negligible error, even in comparison with exponential and logarithmic formats. Hence, the equation (2) with a polynomial format was chosen to be fitted to the experimental results.

$$F = \theta_1 T^{\theta_2} + \theta_3 (TC)^{\theta_4} + \theta_5 T^{\theta_6} (TC)^{\theta_7} + \theta_8 \quad (2)$$

where *F* is the estimated failure load; *T* is the tendon diameter in mm, and *TC* is the tendon compression. θ_i are constant coefficients that should be obtained in the experiment.

In order to find the θ_1 to θ_8 coefficients, residual sum of squares (RSS) from experimental data was minimized using the genetic algorithm optimization toolbox in MATLAB. Finally, the following equation was obtained in order to estimate BASHTI fixation strength:

$$F_u = 34\, T^{-0.67} - 98\, (TC)^{7.4} + 1.4\, T^{2.7} (TC)^{1.6} + 43 \quad (3)$$

3.4. Clinical considerations

In this study, a large number of experimental tests (more than 60 tests) were conducted to optimize geometrical parameters. Hence, providing an equal number of human bones and tendons was not practical. However, the use of human bones and tendons to mimic a real ACL reconstruction is recommended in future studies. Furthermore, the healing process of a bone to bone engagement at the fixation zone may need further investigations.

Moreover, although this study is investigating BASHTI fixation method that is applicable in ACL reconstruction, it is noteworthy that this is not a clinical study. Further study may need to make the process suitable for a clinical trial.

4. Conclusion

In the current study, 60 in-vitro tests were performed for 4 various tendon diameter groups. Three different cannulated drill bits for each tendon group were used to create the tunnel and the core bone. An experimental evaluation was conducted, aiming to assess the fixation strength and the mode of failure. The study found out that two variables, tendon compression (TC) and tendon diameter, had a significant impact on the fixation strength of the BASHTI technique. In addition, it was found that BASHTI fixation strength had a nonlinear relation with tendon diameter and TC, which was obtained based on the experimental results. Furthermore, using a double-strand tendon with a diameter of 6 mm led to the tendon tearing below the required fixation strength (i.e. 200 N). Therefore, the use of a 6 mm tendon diameter in BASHTI technique is not recommended. However, the use of tendon diameters larger than 7 mm can be considered in a BASHTI fixation. Also, increasing TC often increases the fixation strength. Nevertheless, for the tendon diameter of 8 mm, an over-compression might negatively influence the fixation strength.

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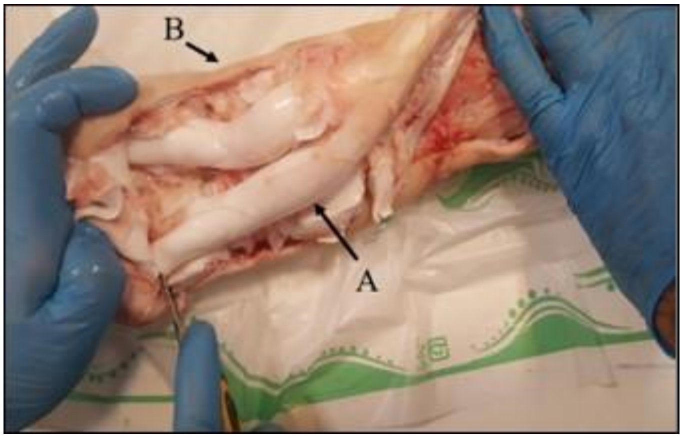
Figure Captions

Fig. 1. Harvesting digital tendons (A) from a typical bovine hoof (B)



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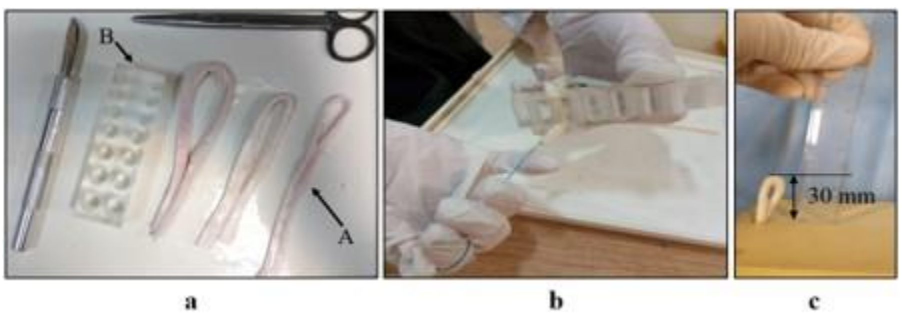

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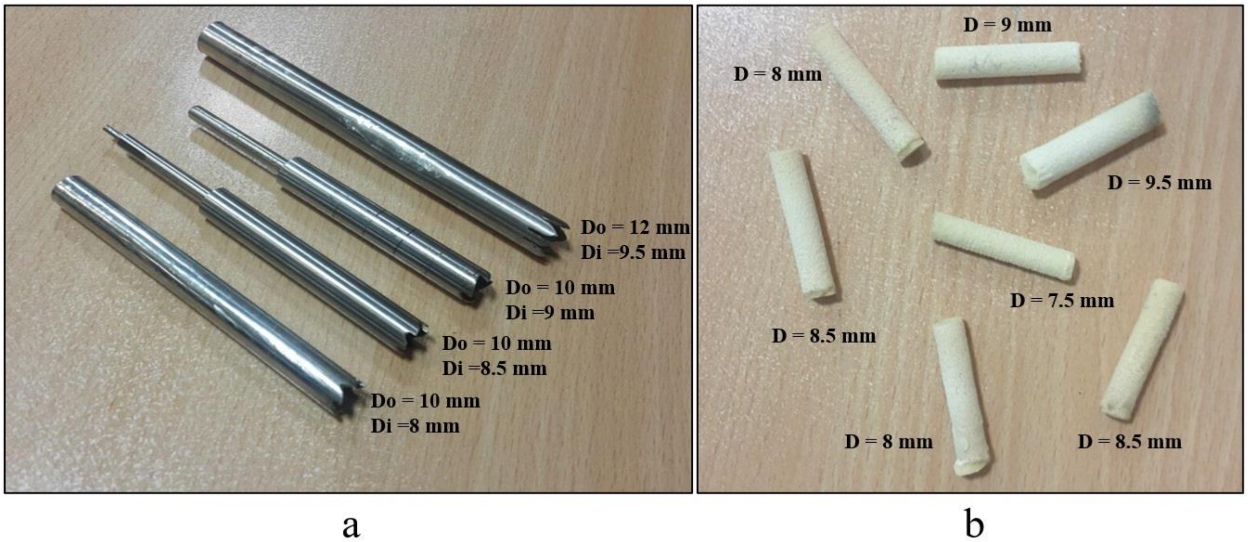


Fig. 4. A schematic of cannulated drill bit geometric parameters

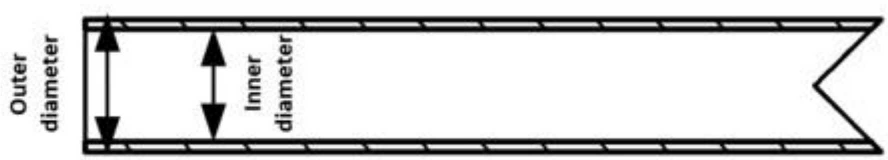


Fig. 5. BASHTI fixation procedure: a. Creating the tunnel and extracting the core using a cannulated drill bit; b. Using suture to pull the tendon through the tunnel when the core bone was inserted; c. Inserting the core bone into the tunnel and fixing the tendon using a hammer

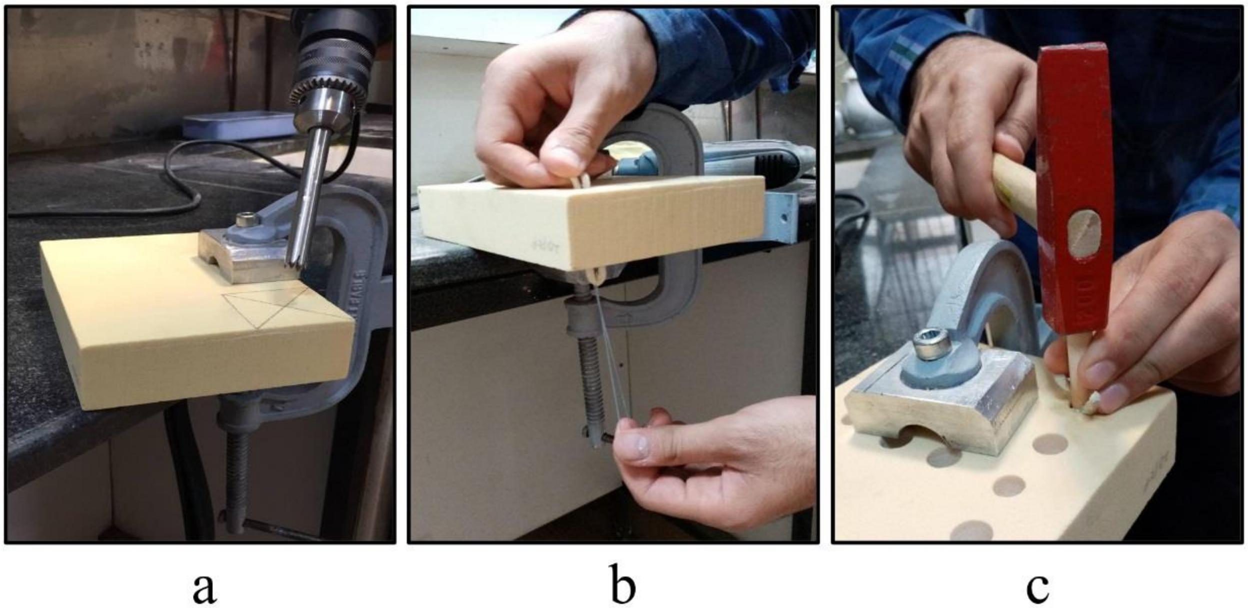


Fig. 6. Securing the Sawbones block (A) into the servo-hydraulic testing machine (B) and the looped tendon (C) hanged into the crosshead using a custom-made rig (D)

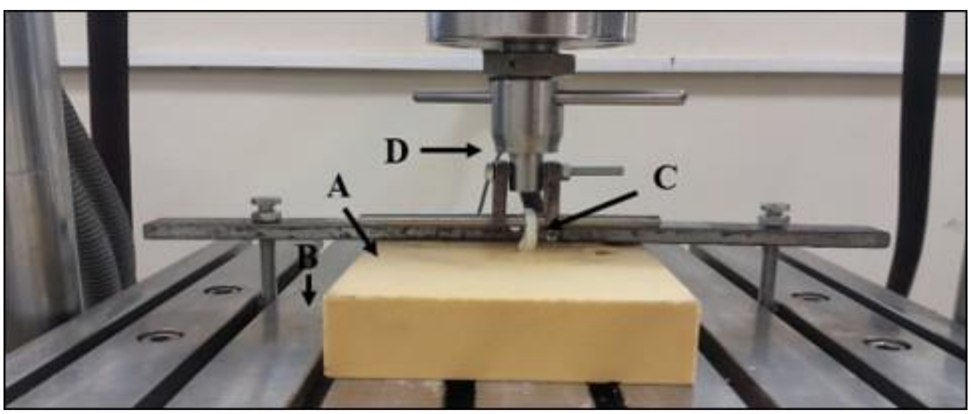


Fig. 7. The calculated results of maximum tendon compression, MTC (mm^2/mm^2) as a function of tendon diameter

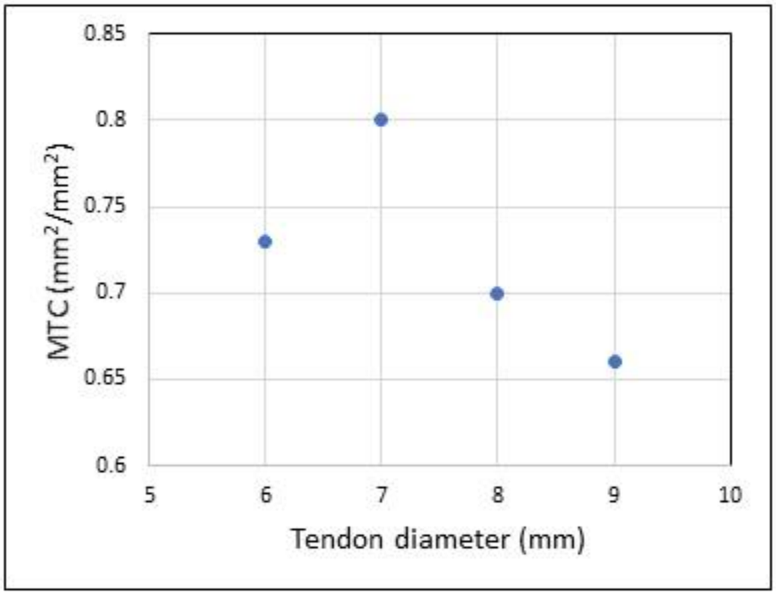
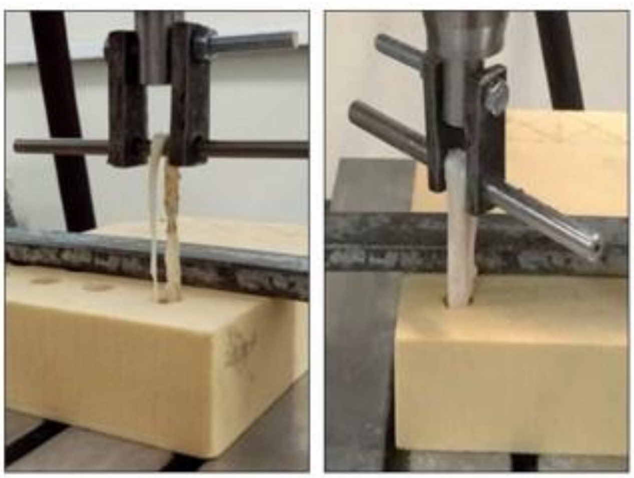


Fig. 8. a. Tendon rupture during the tensile test; b. Tendon/core (fixation) slippage



a b

Fig. 9. Effect of tendon diameter on the BASHTI fixation strength, the 200 N red line indicates the least required fixation strength for rehabilitation, the point mark for a 6 mm diameter represents the outlier data

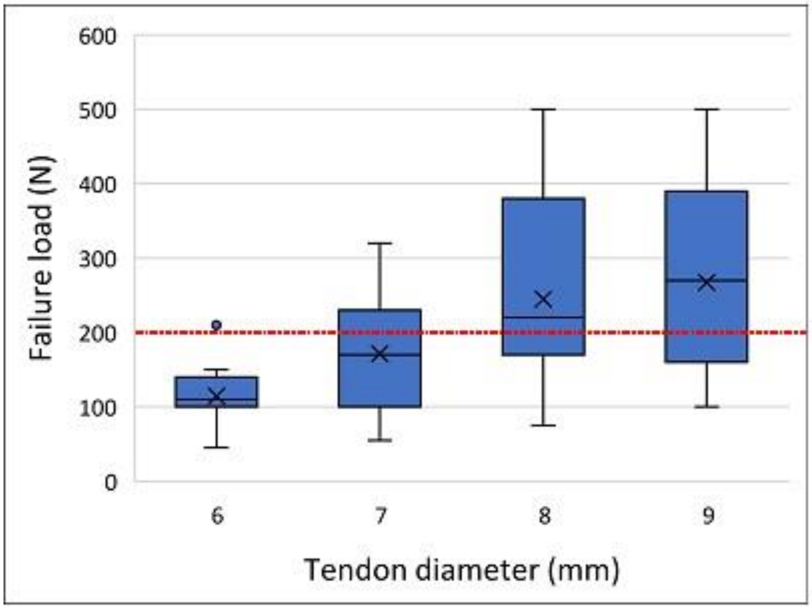


Fig. 10 Effect of tendon compression (TC (mm^2/mm^2)) on the BASHTI fixation strength

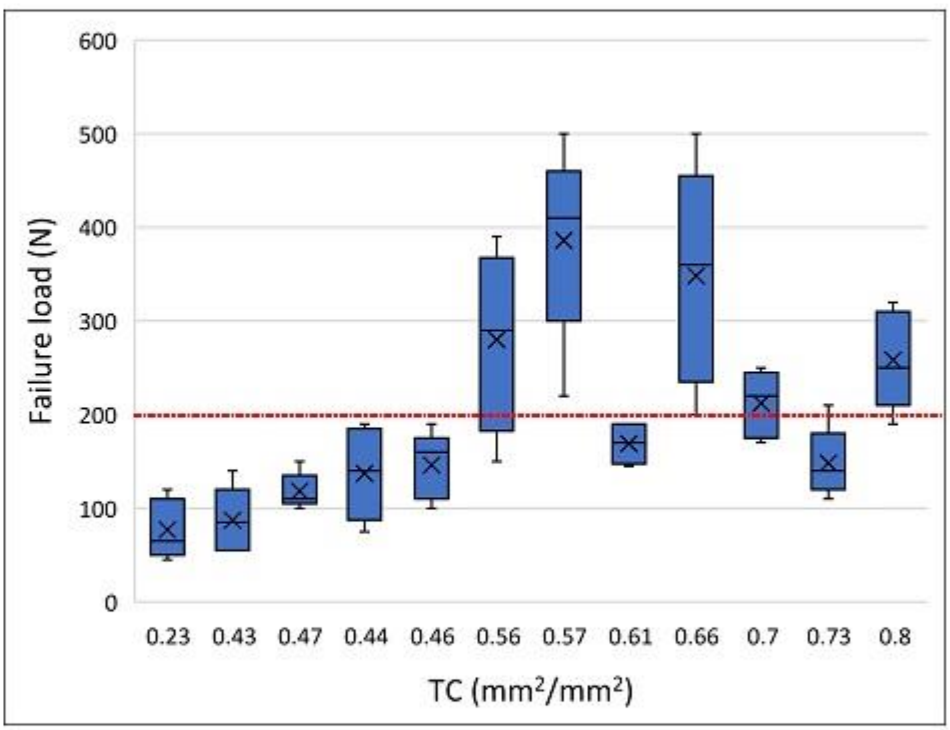


Fig. 11 Effect of tendon compression (TC) on the failure load for the 6 mm tendon group

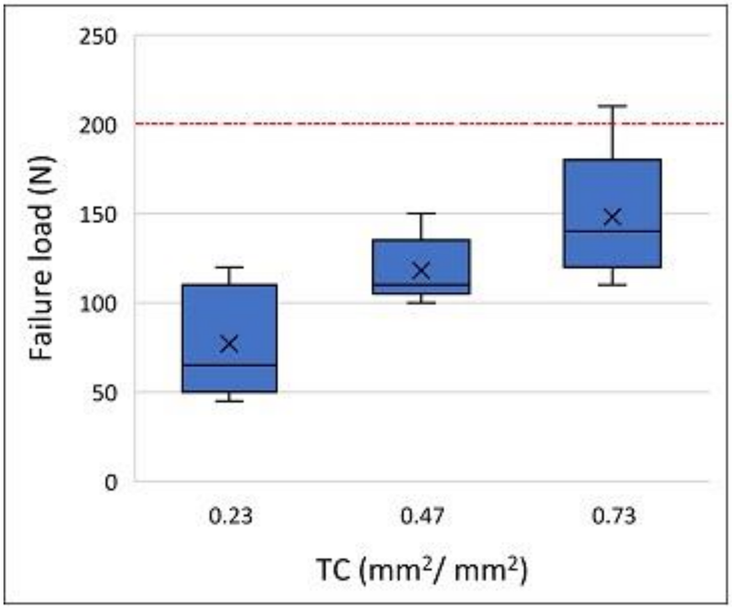


Fig. 12 Effect of tendon compression (TC) on the failure load for the 7 mm tendon group

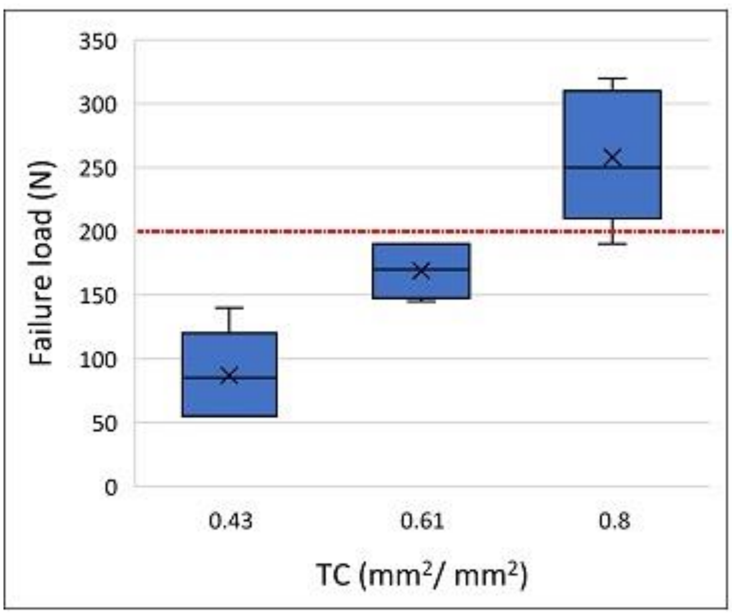


Fig. 13 Effect of tendon compression (TC) on the failure load for the 8 mm tendon group

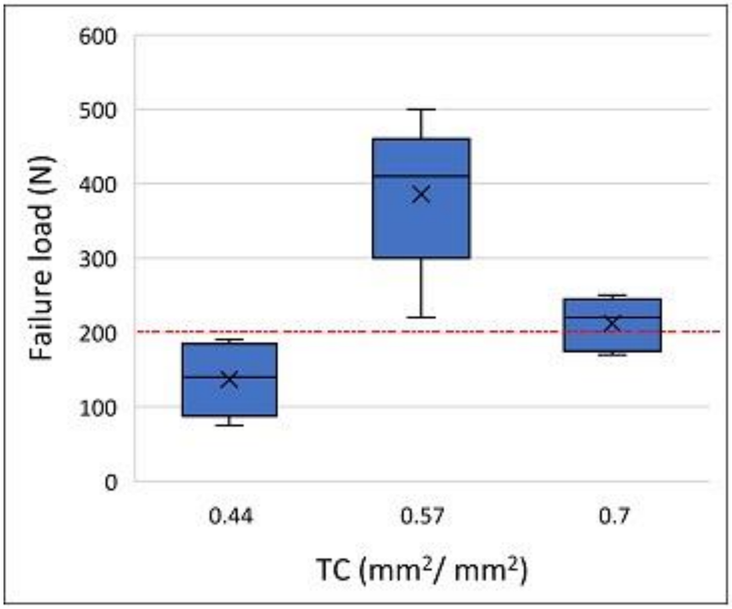
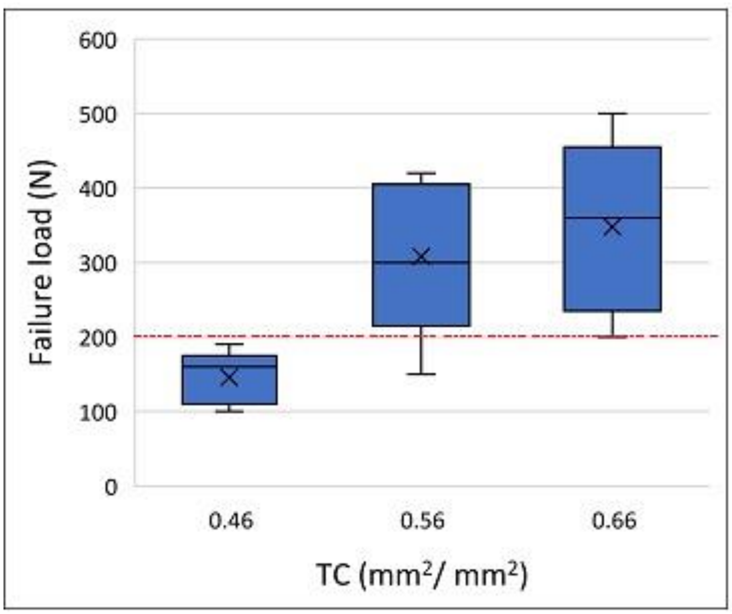


Fig. 14 Effect of tendon compression (TC) on the failure load for the 9 mm tendon group



Tables Captions

Table 1. The failure load of different tendon groups was recorded during the pull-out test

Geometry (mm)			TC [a] (mm^2/mm^2)	Failure Load (N)
Tendon	Tunnel	Core		
6	10	9.5	0.73	148±47
		9	0.47	118±24
		8.5	0.23	77±40
7	10	9.5	0.8	258±66
		9	0.61	169±27
		8.5	0.43	87±44
8	10	9	0.7	212±44
		8.5	0.57	386±128
		8	0.44	137±62
9	10	8.5	0.66	348±146
		8	0.56	308±132
		7.5	0.46	146±45

[a] Tendon Compression