1	<u>Title:</u>
2	Effect of geometry on the fixation strength of anterior cruciate ligament reconstruction
3	using BASHTI technique
4	Running Title:
5	Geometric Parameters in BASHTI Technique
6	
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39 Abstract

The goal of this study is to investigate the effects of tendon and cannulated drill bit diameter on 40 41 the strength of the bone and site hold tendon inside (BASHTI) fixation technique for an anterior 42 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 43 44 cyclic loading continued by a single cycle pull-out load until failure to simulate the real postsurgical loading conditions. Finally, failure modes of specimens and ultimate failure load were 45 recorded. The maximum possible tendon surface strain (i.e. tendon compression) for tendon 46 diameters of 6, 7, 8, and 9 mm were 0.73, 0.8, 0.7, and 0.65, respectively. 80% of the specimens 47 with tendon diameter of 6 mm and 20% of specimens with tendon diameter of 7 mm failed on 48 the torn tendon. All samples with larger tendon diameters (i.e. 8 and 9 mm) failed on the fixation 49 slippage. The maximum fixation strength according to the most suitable core bones for 6, 7, 8 50 and 9 mm tendons were 148±47 N (core 9.5 mm), 258±66 N (core 9.5 mm), 386±128 N (core 51 52 8.5 mm) and $348 \pm 146 \text{ N}$ (core 8.5 mm), respectively. The mode of tendon failure was significantly influenced by the tendon diameter. Also, an increase in tendon compression (TC) 53 raised the fixation strength for all tendon diameters; however, tendon over compression 54 55 decreased the fixation strength for the 8 mm tendon group. Finally, an empirical equation was proposed to predict BASHTI fixation strength. 56

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

61 **1. Introduction**

Anterior cruciate ligament (ACL) is among the most vulnerable ligaments in the human body, 62 especially during sports activities. According to research in England¹, the rate of ACL damage 63 64 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 reconstruction². Conventional ACL reconstruction 65 66 methods may render some complications, including infections and/or pulmonary embolism³. Most conventional ACL reconstruction methods usually utilize metallic implants and stabilizers, 67 such as interference screws and endo button⁴. These methods are criticized due to problems such 68 69 as the cost of supplying equipment, inflammatory responses ⁵, the infection potential, and the production of germs ⁶⁻⁸. 70

71 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 72 73 conventional fixation methods. In this surgical technique, a specific cannulated drill bit is used to 74 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 75 76 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 77 process), to decrease the operating costs as no external implant would be used, and to minimize 78 the chance of the post-surgical inflammation ⁹. 79

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 84 method ¹⁵. However, in this method, the patellar graft tissue is used, and since the bone plug 85 must be used at the two ends of the tendon, this graft tissue has a length limitation. Generally, the 86 two bone plugs are taken either from the femur or the tibia bones, and this can create a side effect 87 and pain on the patient as the harvested site is left empty on the femur and tibia after the 88 operation ^{16,17}. Unlike the press-fit method, the BASHTI technique uses a hamstring tendon as a 89 graft and a core bone harvested from the tunnel. Therefore, the implications with the patellar 90 tendon would be resolved in BASHTI technique. 91

BASHTI technique was first proposed in 2015¹⁸. The project initially aimed to compare the 92 mechanical strength of the BASHTI technique with conventional methods such as interference 93 screw as the most common ACL reconstruction technique ¹⁹. Results indicated that no significant 94 difference in the failure force among the BASHTI technique and interference screw method ¹⁸. 95 Furthermore, it was observed that Sawbones blocks (Pacific Research Laboratories, Malmo, 96 Sweden) -which are rigid sanitary foam blocks as an alternative material to the human bone for 97 testing and demonstrating orthopedic implants- with a density of 320 kg/m³ well represented the 98 mechanical properties of the bone in the site of drilling ²⁰. Also, it was found that the most 99 appropriate group of patients in this technique are youth and middle-aged patients 20 . 100 Subsequently, Borjali et al ²¹, examined the impact of the sheath on the fixation strength, and it 101 102 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 103 applied on the core bone, the insertion process was easier, and the damage on the core bone 104 decreased. Recently, Nourani et al. ²² showed that the insertion procedure had a significant 105

106	impact on the BASHTI fixation strength, and it was recommended to use a cyclical force with a				
107	frequency of fewer than 300 beats per minute (BPM) to push the core bone into the tunnel.				
108	No studies mentioned above considered the influence of geometrical parameters on the				
109	fixation strength of BASHTI technique. This research aimed to address the effects of geometric				
110	parameters on the strength of the BASHTI method when used in an ACL reconstruction. As an				
111	objective of the study, a series of experiments were performed to understand the importance of				
112	the geometrical factors, including tendon and core bone diameters. The ultimate objective was to				
113	find out what graft sizes are more appropriate for this technique. Finally, the most suitable drill				
114	bit size was recommended in order to improve the efficiency of this technique, and an empirical				
115	equation was developed to estimate the BASHTI fixation strength.				
116					
117	2. Methods and Materials				
118	2.1. Sample preparation				
119	Fresh bovine digital flexor and extensor tendons were used to represent the human tissue ¹⁸ .				
120	Bovine samples were selected from the same race and close age. Bovine hoofs were bought				
121	freshly from a licensed butchery. Tendon harvesting from the bovine hoofs was carried out in				
122	Biomechanics Lab, Sharif University of Technology, considering Sharif ethical protocols (Fig.				
123	1).				
124					
125	Fig. 1. Harvesting digital tendons (A) from a typical bovine hoof (B)				
126					

127	After trimming the tendons, the samples were kept in a freezer with adjusted temperature on -
128	20°C. Storing the tendon at a temperature of -20°C for a maximum of 48 hours was shown to
129	have no substantial influence on its mechanical properties ²³ . The tendons were thawed at room
130	temperature for testing. It was maintained moist using a saline water spray during test ²³ .
131	The diameters of double-strand (Fig. 2. a) tendons were trimmed to 6, 7, 8, and 9 mm to
132	cover the range of the graft sizes used in ACL reconstruction ²⁴ . To carefully check the tendon
133	diameter, the looped tendon was passed through a suitable hole of the gauge template (Fig. 2. b).
134	The tendon was trimmed to a smaller size if necessary.
135	The total length of the tendon was controlled after measuring the tendon diameter, so that 30
136	mm of the tendon length was out of the Sawbones surface (Fig. 2. c). This gauge length
137	resembles the size of a typical ACL ²³ .
138	
139	Fig. 2. a. Tendon preparation: double-strand tendon (A), gauge template (B); b. Tendon diameter
140	controlling process; c. Gauge length for tendon
141	
142	Sawbones blocks (Pacific Research Laboratories, Malmo, Sweden) were used in the
143	experiments to represent the human tibial bone. Since most portion of the bony tunnel is located
144	inside the cancellous part of the bone, a block density similar to the cancellous bone should be
145	selected. According to the research performed by Dehestani et al ²⁰ , the Sawbones block with a
146	density of 320 kg/m ³ can properly represent the mechanical properties of the tibial bone of a
147	young person. Therefore, the Sawbones blocks with a density of 320 kg/m^3 were used to model
148	the human tibial cancellous bone in the present study.

149	The BASHTI cannulated drill bit (Fig. 3. a) was designed and fabricated in Sharif
150	Biomechanics Lab, Sharif University of Technology. This drill bit can cut the tunnel and harvest
151	the core bone at the same time. The core bone, then, was inserted into the tunnel to secure the
152	tendon graft inside the hole. The drill bit was fabricated in different sizes to create varying tunnel
153	and core diameters (Fig. 3. b).
154	
155	Fig. 3. a. Different BASHTI cannulated drill bits to cut the tunnel; b. Core bones harvested in
156	different diameters
157	
157	
158	The diameter of 10 mm was found as a suitable size for a BASHTI tunnel ^{20,21} This tunnel
159	size is also a common and recommended drill size in conventional ACL reconstruction surgeries
160	²⁵ . Hence, the outer diameter (see Fig. 4) of the cannulated drill bit was set to 10 mm.
161	In order to obtain different core bone sizes and to match them with relevant tendon
162	diameters, the inner diameter of the drill bit was made in different sizes, as indicated in Table 1.
163	
164	Fig. 4. A schematic of cannulated drill bit geometric parameters
165	
166	The BASHTI graft insertion procedure is illustrated in Fig. 5. After drilling, the looped
167	tendon was passed through the tunnel. Then the core bone was placed between the tendon strands
168	and inserted into the tunnel using a hand hammer. The hammer bit rate was lower than 300 beats
169	per minute, as recommended by Nourani et al. ²² . To maintain the ligament's pre-tension, during
170	the core bone insertion process, the looped tendon was pulled through the tunnel by the aid of a

171	surgical suture. This ligament pre-tensioning, as well as easing the insert process, was keeping
172	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

177

178 **2.2. Mechanical testing**

179 The pull-out test was completed using a servo-hydraulic testing machine (Amsler HCT 25-400;

180 Zwick/Roell AG, Germany) (see Fig. 6) to assess the intensity of the BASHTI fixation. The

181 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.

184

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)

187

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.

199

200 **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:

207
$$TC = \frac{S_{tendon} + S_{core} - S_{tunnel}}{S_{tendon}}$$
(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.

211 **3. Results and Discussion**

212	3.1. Maximum	tendon	compression	(MTC)
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According to Table 1, different MTCs are calculated using equation (1) depending on the tendon
diameter (see Fig. 7).

215

Fig. 7. The calculated results of maximum tendon compression, MTC (mm²/mm²) as a function
of tendon diameter

218

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.

222 **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.

227

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.

243 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.

248

249 **3.3. Fixation strength** (F_u)

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

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 (mm²/mm²)) 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.

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

273	3.3.1. Effect of TC on the fixation strength for the 6 mm tendon
274	All the cases for the 6 mm tendon failed in a load of less than 200 N. Tendon tearing was the
275	only failure mode for 9 mm and 9.5 mm core bones and slippage in less than 100 N was
276	observed for 8.5 mm core bones. As a result, the 6 mm tendon was so weak to meet the
277	minimum strength required for BASHTI technique (Fig. 11).
278 279 280	Fig. 11 Effect of tendon compression (TC) on the failure load for the 6 mm tendon group
281	3.3.2. Effect of TC on the fixation strength for the 7 mm tendon
282	Fig. 12 indicates the significant dependence of failure load on the TC value in this group. Only a
283	9.5 mm core bone provided an average fixation strength of more than 200 N (i.e. with an average
284	of 258 N). Tendon tearing occurred for 9.5 mm core bones in 60% of the cases with an average
285	failure load of 260 N. Consequently, the tendon diameter of 7 mm with a 9.5 mm core block (i.e.
286	TC = 0.8) could maintain the minimum strength required for the BASHTI technique.
287 288	Fig. 12 Effect of tendon compression (TC) on the failure load for the 7 mm tendon group
289	3.3.3. Effect of TC on the fixation strength for the 8 mm tendon
290	Similar to the 7 mm tendon, TC had a considerable impression on the fixation strength for the 8
291	mm tendon. In this case, the fixation strength decreased by about 45%, with an increase in TC
292	from 0.57 to 0.7 (i.e. 23% increase in TC). This shows that over-compression might negatively
293	affect BASHTI fixation strength. Using an 8.5 mm core bone provided a fixation strength of
294	more than 200 N (i.e. with the average value of 386 N). In contrast, 40% of the cases with a 9

295	mm core bone (i.e. $TC = 0.7$) failed in less than 200 N. Hence, using an 8.5 mm core bone is
296	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

315	3.3.5. Developing an empirical equation				
314					
313	which the use of an oversized screw did not increase its pull-out strength ³³ .				
312	strength will decrease. Similarly, this phenomenon has been observed for interference screws, in				
311	higher fixation strength, there is a peak point for the compression, and after the peak, the fixation				
310	Overall, the study found that although increasing the TC in BASHTI technique results in a				
309					
308	Fig. 14 Effect of tendon compression (TC) on the failure load for the 9 mm tendon group				
307					
306	in the BASHTI technique in this group.				
305	= 0.39). Accordingly, using the 8 mm or 8.5 mm core bone is suggested in the process of drilling				
304	8 mm and 8.5 mm core bones (i.e. 18%) did not significantly affect the fixation strength (p-value				
303	strengths (i.e. 90% of the cases failed in more than 200 N). Moreover, an increase in TC between				
302	force less than 200 N. However, 8 mm and 8.5 mm core bones provided the required fixation				
301	Using a 7.5 mm core bone (i.e. $TC = 0.46$) caused an improper BASHTI fixation that failed in a				

It must be emphasized that the tendon diameter and TC parameters cannot solely determine 316 BASHTI fixation strength. Hence, the interaction between the two parameters also must be 317 added to consideration. Due to the non-linearity of results, a simple linear regression cannot 318 appropriately model the fixation strength. Therefore, a polynomial format with variable powers 319 for each term was proposed to obtain the best mathematically fit with the experimental data. The 320 321 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 322 323 a polynomial format was chosen to be fitted to the experimental results.

324
$$F = \theta_1 T^{\theta_2} + \theta_3 (TC)^{\theta_4} + \theta_5 T^{\theta_6} (TC)^{\theta_7} + \theta_8$$
(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:

330
$$F_u = 34 T^{-0.67} - 98 (TC)^{7.4} + 1.4 T^{2.7} (TC)^{1.6} + 43$$
 (3)

331

332 **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.

341

342 **4.** Conclusion

In the current study, 60 in-vitro tests were performed for 4 various tendon diameter groups.

344 Three different cannulated drill bits for each tendon group were used to create the tunnel and the 345 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 346 347 diameter, had a significant impact on the fixation strength of the BASHTI technique. In addition, 348 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 349 tendon with a diameter of 6 mm led to the tendon tearing below the required fixation strength 350 (i.e. 200 N). Therefore, the use of a 6 mm tendon diameter in BASHTI technique is not 351 recommended. However, the use of tendon diameters larger than 7 mm can be considered in a 352 353 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. 354

355

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462 **Figure Captions**

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



464

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



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

⁴⁶⁹ different diameters



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



473 Fig. 5. BASHTI fixation procedure: a. Creating the tunnel and extracting the core using a

474 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



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



- 479
- 480 Fig. 7. The calculated results of maximum tendon compression, MTC (mm^2/mm^2) as a function
- 481 of tendon diameter





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



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
- 487 represents the outlier data





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





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



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











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



500 Tables Captions

Geo	metry (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

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

502

503

^a Tendon Compression