

Distal biceps tendon repair via new knotless endobutton fixation: A biomechanical study

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1	Distal biceps tendon repair via new knotless endobutton					
2	fixation: a biomechanical study					
3						
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14	Cortical button.					

15 Abstract

Background: Distal biceps tendon (DBT) repair using endobutton fixation has shown the best biomechanical results in terms of pullout strength. Sethi's enhanced tension adjustable endobutton technique known as the « tension slide technique » (TST) decreases the gap between bone tunnel and graft. Here we compared the TST to a new knotless endobutton fixation technique without a post-fixation screw. Our new approach is as effective as the TST in terms of pullout strength and gapping after early mobilization.

Methods: A biomechanical cadaveric study with 8 specimens was performed (16 arms). Right and left arms were paired and each arm was placed in either the knotless or the TST group. With the radius held in place, the DBT was loaded at 100 N for 500 cycles and the load was then increased until failure. Gapping after loading cycles and maximum load to failure were recorded and compared.

27 Results: Median bone-tendon gapping was 5.77 mm [interquartile range (IQR) 4.84-9.11] 28 for TST and 4.72 mm [IQR 1.77-6.16] for the knotless fixation (p = 0.047). Median load to 29 failure was 257.87 N [IQR 222.07-325.35] in the TST group and 407.78 N [IQR 358.54-30 485.20] in the knotless group (p = 0.047).

31 Discussion: The knotless endobutton is a reliable fixation technique for DBT repair. It

32 provides good pullout strength compared to the TST without the use of an interference screw,

33 allowing early mobilization in order to faster return to daily living activities.

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35 <u>Level of evidence:</u> Basic science study.

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Commentaire [DS1]: Higher?

Introduction

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Distal biceps tendon ruptures mainly affect a population between 40 and 60 years old. Representing 3% of biceps lesions, they generally occur during an eccentric load¹. If not surgically repaired, these lesions lead to loss of strength and range of motion². A strong and safe fixation is required to enable, after surgery, immediate and active mobilization and thus better and faster functional outcomes^{3,4}.

The current literature is as yet unable to single out any fixation technique as preferable in 44 terms of clinical results⁵⁻⁸. However, several biomechanical studies have shown that 45 endobuttons perform better on pullout strength than other fixations $^{9-12}$. The original method 46 described by Bain (2000)¹³ was subsequently improved by Sethi (2008)¹⁴ using the so called 47 Tension Slide Technique (TST). Sethi's technique allows for the ability to tension and dock 48 the repair through an anterior incision. Hence there is no need to predetermine the length of 49 the suture between the button and the biceps, it eliminate the technical concern for the button 50 flipping and it reduce the gap between the bone tunnel and the distal graft extremity¹⁵. 51 However after docking the tendon into the bone one suture end have to be passed through the 52 tendon to secure it. Securing the knot can be challenging in muscular patients and knots have 53 54 to be tied in a shoulder arthroscopic fashion to ensure a good knot fastening. Sethi's also inserted an interference screw to secure the tendon in high demand patients. The method 55 presented here uses Sethi's concept but involves a knotless endobutton with a looped suture, 56 57 without interference screw, making it easier to use. There is only one published study so far to have used a similar device¹⁶. 58

Our hypothesis was that our original distal biceps tendon repair technique using knotless
fixation was at least equivalent to the TST in terms of pullout strength and gapping at
physiological tension.

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Materials and Methods

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Eight fresh cadavers (5 females, 3 males, 87.25 ± 3.79 yo) were selected according to specimen availability (Table 1). The right and left elbow of the same specimen were paired to avoid any inter-individual variability. Each specimen's arm was randomely assigned to the TST or knotless group.

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Surgical technique

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Specimens were placed in a supine position with the forearm on a hand table. Using an anterior approach, a 4 cm longitudinal incision centered on the radial tuberosity was made. A C-arm was used to center the incision on the radial tuberosity. The biceps tendon was then cut from its footprint and a 2 cm proximal incision was made to allow tendon preparation. Tendon length was then measured.

77 Sethi's technique using the BicepsButtonTM(ArthrexTM, Naples, FL, USA) and n°2 Fiberloop® (ArthrexTM, Naples, FL, USA) device to prepare the tendon has already been 78 described in detail¹⁴. In our modified technique, the graft was prepared with a braided pre-79 looped suture n°5 Niceloop® (Tornier[™]-Wright[™], Memphis, TN, USA). The suture was 80 whipstitched through the tendon from proximal to distal, starting at 35mm from the distal free 81 82 end of the tendon. Four to five loops were made through the tendon before passing it through the loop of the knotless endobutton (Ziploop®, Zimmer-BiometTM, Warsaw, IN, USA). The 83 device was then secured to the distal end of the graft by passing the suture through the tendon 84 in backward direction, from distal to proximal three times more. The needle was cut and the 85 two free ends of the suture were tied on the graft (Fig.1). 86

87	A perpendicular or slightly radio-humeral direction was chosen for the bone tunnel to
88	reduce posterior interosseous nerve lesions while drilling ¹⁷ . The tunnel was placed as ulnarly
89	as possible, to preserve the cam effect of the radial tuberosity ¹⁸ . A pin guide and then a 4.5
90	mm bicortical tunnel were performed with a cannulated drill. Next, a second drill with a
91	diameter corresponding to the tendon diameter was used to go through the first cortical. The
92	endobutton was then pulled through the second cortical and into the bone tunnel by
93	alternatively pulling on the 2 sutures. At this point, a scopic control was performed. Our self-
94	locking system was knotless and didn't require a post-fixation screw.
95	Immediately following the repair, the biceps was cut at its musculo-tendinous junction.
96	Finally, a radius osteotomy was performed 10cm distally to the radial head and the samples
97	were collected.
98	All dissections and tendon repairs were performed by the same surgeon.
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100	Experimental protocol
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102	Tensile tests were performed with a servo-hydraulic testing system (Instron 8803™,
103	Elancourt, France). The proximal side of the radius was embedded into a resin bloc and
104	secured with a clamp on the machine. The proximal tendon graft was secured on a custom-
105	made system of clamps connected to the testing device. Traction was kept perpendicular to
106	the radius axis. Similar cyclic load model have been used in prior biomechanical testing of
107	tendon constructs ^{11,12,19} .
108	Traction force and total displacement was measured with a uni-axial strength sensor
109	(1000N, TME [™] , France) set on the Instron's actuator. A 10N-pre-tension load was applied to

the tendon and then 500 cycles at 100N were performed at a 1mm.s^{-1} speed. In several

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studies^{9,11,15,16}, the authors chose to load the tendon up to 50 N, which corresponds to the strength developed by the elbow during elbow flexion against gravity^{10,20}. We chose a 100 N load, which is roughly the strength developed during elbow flexion when lifting a 1kg-mass⁹. Following these cycles, all failures were numbered: transplant ruptures of any kind (suture, tendon, bone), all tendon elongations at the bone-tendon interface greater than 1cm (which could seriously alter tendon-to-bone healing²¹).

Total graft elongation was measured by the Instron displacement sensor. Tendon elongation at the bone-tendon interface, which represents tendon setback in the bone tunnel or gapping, was measured by means of a markers network set on the graft (Fig.2) and measuring the difference in distance between two points (on the bone at the tunnel extremity and another on the graft just at the exit from the tunnel) before and after the loading cycles. Images were recorded by cameras (Photron SA3TM, The Barn, UK) facing the transplant and measurements were analyzed with a video analysis software.

The tendon was then elongated to failure by applying an increasing displacement at 3.5 mm.s^{-1} .

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Statistical analysis

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A Shapiro-Wilk test was used to analyze statistical distributions because our sample was small (n<30), not from a normal distribution, and could be considered as a paired sample (JMP® software (SAS, Cary, NC, USA)). A non-parametric Wilcoxon test was used to analyze maximum load to failure (MLF) and graft elongation(p<0.05)..

134 Results

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Regarding graft characteristics, the difference between the median length and diameter ofthe grafts in each group was not statistically significant (Table 1).

138 The median total graft elongation after loading cycles was 12.09 mm [interquartile range (IQR): 9.12-14.61] in the TST group and 13.69 mm [IQR 12.39-16.410] in the knotless group 139 140 (p=0.1). For both groups, 90% of total graft elongation had already occurred at the 28th cycle [IQR 22.75-79]. The median elongation at bone-tendon interface was 5.77 mm [IQR 4.84-141 9.11] in the TST group and 4.72 mm [IQR 1.77-6.16] in the knotless group (p = 0.047)142 (Figure 3). During the cycles, 2 specimens failed in the TST group, while none failed in the 143 144 knotless group (Table 2). Both failures occurred during the first loading cycles and involved a pullout of the screw from the tunnel. 145

The median MLF was 257.87 N [IQR 222.07-325.35] in the TST group and 407.78 N [IQR 358.54-485.20] in the knotless group (p = 0.047) (Figure 4). In the TST group there were 5 ruptures by suture breakage that all occurred at the endobutton-suture junction. No bone breaking occurred in this group. One failure by graft slippage occurred into the proximal clamp. In the knotless group there were 3 posterior cortical breakages, 3 suture breakages and 2 graft slippages into the proximal clamp (Figure 5). In the posterior cortical breakage group the median MLF was 364 N [IQR 360.36-432.145].

Discussion:

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A new distal biceps tendon repair technique using knotless fixation was evaluated and compared to the TST. In the knotless group, a median of 407.78N MLF was reached. This result is similar to those reported in the literature, with MLF ranging from 259N to 584N $^{9-}$ ^{12,15,16} for endobutton repair. Moreover, the study presenting the best results¹⁰ used a n°5 suture, as in the present study. A thicker suture may therefore significantly enhance tendon repair performance regarding MLF.

162 The rupture mode, for 5 of the 6 specimens in the TST group was by suture breakage. Contrastingly, in the knotless group, 3 of the 8 specimens broke their posterior cortical bone 163 164 during the ultimate load to failure. This difference in rupture mode between the two groups may result from the larger diameter of the bone tunnel created by the knotless endobutton 165 ancillary than that created with the TST device (4.5mm vs 3.2mm). In the posterior cortical 166 breakage group the median MLF was 364N which is superior to the TST median MLF 167 168 257.87N and Idler et al. found a 221N to be the maximum pullout strength for a native biceps¹⁹ so there shouldn't be any concern about potential in vivo risk of fracture using our 169 170 procedure. Furthemore in a recent study of 38 patients Alech-Tournier et al. did not report cortical fracture using the same knotless device 22 . 171

Our elongations results are slightly higher than those published elsewhere. For classic endobutton techniques, Mazzocca et al.⁹ found 3.42 mm, Spang et al.¹¹ 2.58 mm, Sethi et al.¹⁵ 2.79mm and only 1.26mm when using the TST technique. On the other hand, Savin et al.¹⁶, in the only previous biomechanical study reporting on the knotless device, found 2.5mm elongation in the TST group but 10.4mm elongation in their knotless group with a standard locking whipstitch. To avoid this gapping, they reinforced their suture with a suture tape to

obtain a similar result to the TST with no significant difference. In the present study, a 4.24 mm elongation was measured, this may be due to the n°5 looped suture which is stronger than the suture used in Savin et al. study (n°2 Fiberwire®, ArthrexTM, Naples, FL, USA) and to our suture technique which may present less gapping than the one use in the former study.

During the loading cycles phase, two failures occurred in the TST group. Both failures followed early pullout of the screw from the bone at the beginning of the loading cycles, possibly because of cortical bone weakening during the screwing. However, this explanation cannot be confirmed without BMD and thus could not be correlated with the pullout screw occurrence here. In the light of this result and of Sethi et al.¹⁵ observations (the screw didn't generate any pullout strength nor displacement differences),we would not advise using the screw in addition to the endobutton, particularly with an elderly population.

We chose a 100 N load, which is roughly the strength developed during elbow flexion when lifting a 1kg-mass⁹ because we consider this the load bearing required for an early return to daily living and occupational activities. However, this heavier loading may also have increased our median graft elongation, explaining differences from the literature data.

During the loading cycles, elongation was observed to occur in the first stages before 193 reaching a plateau: at the 28th cycle, 90% of the total elongation had already occurred. Taken 194 195 together with the present encouraging experimental results, this suggests that our technique 196 reliably affords early rehabilitation and that an early return to daily activities can be envisaged 197 with no restriction other than a 1kg-lifting limit, as it is suggested in the literature to be associated with satisfactory clinical results and no re-rupture or transplant elongation^{3,23}. In 198 199 their recent study Alech-Tournier et al. using the same device allowed rehabilitation at one week post-operatively with good clinical result and no re-rupture rate²². 200

In endobutton repair using an anterior approach, drilling direction is chosen to reduce the risk of posterior interosseous nerve injury^{17,24}. As a consequence, the transplant insertion set

radially relative to the biceps footprint²⁵. Anterior drilling also impacts biceps tuberosity 203 height²⁶, and thus could affect supination strength by reducing the cam effect²⁷. Prud'homme-204 Foster et al.²⁸ found that direct repair led to a loss of 15% supination strength in neutral 205 position and 40% at 45°-supination. Seeking to recreate the cam effect, Sethi et al.¹⁴ proposed 206 207 adding the interference screw radially positioned in the bone tunnel. To date, however, there has been no biomechanical or clinical study attesting to its beneficial effect on supination 208 209 strength. Nor has any clinical publication used isometrical and isocinetical tests to show the difference in supination strength between patients who have undergone direct repair by 210 211 endobutton and anatomical repair with a posterior approach.

212 The main limitation of this study is that, being cadaveric, the specimens used were old 213 (average of 87.25 yo). Even though BMD measurements were not performed before testing, 214 the specimens' BMD can be assumed to be lower than those of the active population affected 215 by biceps tendon ruptures and requiring biceps reinsertion. However, the pairing mode 216 between each arm of each specimen allowed us to overcome this limitation. This study also assessed a limited population (8 specimens), for reasons of availability. Further experiments 217 218 on specimens from various age groups will be needed in order to draw more general 219 conclusions

220 Regarding our testing protocol, the fact that the measurements were performed on the 221 isolated radius via axial traction perpendicular to the radius axis, instead of using a poly-axial mechanism measurement protocol^{3,9,10,15,16} closer to elbow physiological use and movement, 222 can be considered as another limitation. The biceps is principally a supinator muscle, and our 223 224 protocol did not account for the potentially interesting issue of prono-supination strength. 225 However, this procedure provided accurate measurement of the exact tendon displacement 226 and elongation per cycle, as well as providing better reproducibility of the boundary conditions for each test. 227

228	The present technique performs better than the original TST in terms of elongation and
229	MLF. It is also more robust than the original technique as described by Sethi in 2010 ¹⁵ . Thus,
230	our new approach appears as a simple and reliable technique for distal biceps tendon repair
231	allowing early rehabilitation. As a consequence it could be recommended for active patients
232	wishing to return quickly to their daily living and occupational activities.

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318 Figures and Tables:

	Population
Sex ratio	5 women and 3 men
Specimen conservation type	5 fresh and 3 embalmed
$Age \pm SD$	$87.25^{1} \pm 3.79$
Tendon length cm ± SD	$9.09^{1} \pm 1.20$
Tendon diameter cm ± SD	$6.65^{1} \pm 0.53$
Tendon prepared diameter $cm \pm SD$	$7.38^{1} \pm 0.53$

 Table 1: Population included characteristic. ¹, average. SD, standard deviation.

Group	TST		Knotless		
Group	Average	SD	Average	SD	Р
Tendon length, cm	9.08	1.20	9.1	1.34	0.9
Tendon diameter, mm	6.7	0.57	6.6	0.55	0.7
Prepared tendon diameter, mm	7.08	0.49	7.67	0.41	0.05

322 Table 2: Graft and tendon anatomical characteristics. SD, standard deviation. IC 95 %,

323 confidence interval 95 %. P<0,05

	TST		Knotless		
Cycling achieved, n	6/8		8/8		Р
	Median	IQR	Median	IQR	
Total elongation, mm	12.09	[9.12-14.61]	13.69	[12.39-16.41]	0.1
Bone-tendon interface	5.77	[4.84-9.11]	4.72	[1.77-6.16]	0.047
elongation, mm					0.047
Load to failure, N	257.87	[222.07-325.35]	407.78	[358.54-485.20]	0.047
	5 sutures		3 sutures		
Failure mode	1 clamp-tendon slippage		3 posterior cortical ruptures		
			2 clamp-ten	don slippages	

Tableau 3: Main results in TST group vs knotless group. *IQR*, *interquartile range*.

P<*0*,*05*



Figure 1: A: Preparation of the tendon with Knotless technique. B: Tendon prepared, 331 before passing it beside the skin for bone fixation. C: Harvested tendon. 332

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Figure 2: Transplant before testing, bone embedded in resin, tendon maintained in custom-made clamp and secured to the servo-hydraulic machine. Landmarks are drawn directly on the tendon and the bone to measure displacement and distention. One point is drawn at the bone tendon junction to measured tendon pullout.







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Figure 5: C: Cortical breakage during ultimate load to failure.





maximum values.



