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A new intramedullary fixation method for distal biceps tendon ruptures: a biomechanical study.

'The Belgian biceps button'

Pieter Caekebeke¹, MD Joris Duerinckx¹, MD Johan Bellemans¹, MD, PhD Roger van Riet^{2,3}, MD, PhD

Corresponding author: Pieter Caekebeke Schiepse Bos 6 3600 Genk Belgium +3289 32 6123

- 1: Ziekenhuis Oost-Limburg, Department of orthopaedic surgery and traumatology. Schiepse Bos 6, 3600 Genk, Belgium
- 2: AZ Monica, Department of orthopaedic surgery, Stevenslei 20, 2100 Deurne, Belgium
- 3: University Hospital Antwerp, Department of orthopaedic surgery, Wilrijkstraat 10, 2650 Edegem, Belgium

Key words: button, elbow, distal, biceps, tendon, fixation, rupture, intramedullary

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Declaration of conflicting interests

Roger van Riet is a consultant with Acumed and Wright Medical

Abstract

Background: Various techniques have been described for distal biceps tendon reinsertion. All current

techniques have specific shortcomings with complications such as heterotopic ossification, nerve damage, gap

formation.

Hypothesis: The purpose of the present study is to biomechanically evaluate a new intramedullary fixation

device that might reduce the risk of well-known complications

Study Design: We compared the fixation strength of this new intramedullary button with an extramedullary

placed classic extracortical button.

Methods: A standard bicortical button was compared to the new intramedullary fixation device using fresh-

frozen cadaveric specimens. The fixation strengths were tested both cyclically and statically. Load to failure

and method of failure were also recorded.

Results:

cyclic loading

There were no failures during the cyclic load testing. The mean tendon-bone displacement was 0.87 ± 0.13 mm

for the bicortical group and 0.83 ± 0.13 mm for the new button.

Static loading

The mean load to failure for the bicortical group was 296 ± 97 N, whereas the new button group showed a

higher mean load to failure of 356 ± 37 N. Breakout through the anterior cortex was recorded in two out of six

bicortically placed button and one out six in the new device.

Conclusions: The new intramedullary fixation device yields comparable loads to failure compared with

currently used techniques in a biomechanical setup. These findings together with the theoretical advantages

suggest that this technique might be a viable solution in distal biceps tendon rupture repair.

Key Words:

Distal biceps; fixation; intramedullary, new; novel; repair; safe

Introduction

Distal biceps tendon ruptures are relatively uncommon. Their incidence is estimated to be 1.2 in 100000.^{1, 2} The most common mechanism is a forced eccentric contraction of the biceps brachii muscle with the elbow positioned in flexion and supination.³ Operative treatment is usually indicated to ensure maximal recovery of elbow strength and endurance.^{4, 5} Various fixation methods have been described, including suture anchors, interference screws and fixation buttons.⁶⁻⁹ The construct with the highest load to failure is the extramedullary bicortical fixation button method as first described by Bain and colleagues.^{8, 10} This allows for early active range of motion, and loading, almost immediately after surgery. A second advantage of this fixation technique is the intra-osseous placement of the distal biceps tendon, minimizing the chance of gap formation between the tendon stump and the bone during active biceps contraction.^{10, 11} The main disadvantage of the extramedullary cortical button is that the distal biceps tendon cannot be anatomically reattached at the insertion site at the radial tuberosity as this would place the posterior interosseous nerve at significant risk for entrapment behind the cortical button.¹² the protect the nerve, the biceps tendon has to be attached more anterior on the radius but this potentially decreases final supination strength.¹³

The purpose of the present study is to evaluate a new intramedullary fixation device. Because this button is placed inside the intramedullary canal of the radius, it allows safe reattachment of the distal biceps tendon at its anatomical footprint. We compared the fixation strength of this new intramedullary button with the classic bicortical button. We hypothesize that both buttons provide comparable fixation strength.

Material and methods

Specimens

12 elbows were harvested from 6 fresh frozen cadavers and thawed at room temperature. The contralateral specimens were used to compare the standard extramedullar bicortical endobutton technique (Endobutton, Smith &Nephew, Watford, United Kingdom) to the new intramedullar fixation button.

New button design

The button was designed using 3D software (Autodesk fusion 360) and printed in Titanium (Materialize, Leuven, Belgium) (Figure 1). The initial designs were printed in a polyamide plastic and tested on 12 radius specimens to determine size. The design features a bel shape to allow the tendon to be pulled into the bone with a maximum depth of 3mm plus the thickness of the proximal cortex. The button has a width of 4mm and a length of 23 mm to span the single drill hole of 8mm that is made at level of the radial tuberosity to insert the distal biceps tendon into the bone. This length also allows purchase on the thick cortical bone alongside the thinner bone of the tuberosity (Figure 2)

Surgical technique and biomechanical testing

In each specimen, the distal biceps tendon was transected at its insertion on the radial tuberosity. A partially absorbable suture (FiberLoop 2; Arthrex, Naples, FL, USA) was passed in a whipstitch fashion in the distal 20 mm of the distal biceps tendon so that its ends emerged at the distal tendon stump. Both ends of the suture were passed though the holes in the button.

The commercial extramedullary fixation button is made of titanium. A 4.5-mm guide pin is drilled through the radius at level of the radial tuberosity. Next, an 8mm cannulated drill is used to open the near cortex. A 4.5 mm cannulated drill is used to drill through the far cortex. The button is passed through the drill holes in the radius and flipped extramedullary on the posterior cortex. Fluoroscopy was used to confirm the correct position of the button.

For the intramedullary button, the guide pin was drilled only through the near cortex at the footprint of the biceps tendon, and overdrilled with a cannulated 8mm drill. The button is inserted intramedullary and positioned by pulling on both the sutures simultaneously. The tendon is pulled into the radius by pulling the

sutures separately, using the tension slide technique described by Sethi.¹⁴ The tendon is fixed by tying the suture. Fluoroscopy was again used to confirm the correct position of the button. (Figure 3)

Following preparation, the radii and reconstructed biceps were removed from the forearm. All soft tissues were removed. The proximal 10 cm of radial bone were preserved. The radii were clamped to a custom mount (Figure 4). The tendon was firmly attached to a metal clamp. The line of pull on the biceps was chosen to be at a 30-degree flexion angle as this was deemed to be a physiological loading condition. Specimens were cyclically loaded for 1,000 cycles at 2.5 Hz from 5 to 100 N. Following each 1,000 cycles, the load was returned to 5 N (preload) and a strict lateral view of the mounted constructs was photographed. For displacement measurements, three hand-drawn regions of interest (ROIs) were appointed at the proximal, central and distal area of the restored footprint of distal biceps tendon (Figure 3). Afterwards, all specimens in which failure did not occur during cyclic loading were loaded to failure with an extension rate of 4 mm/s. Maximum load to failure was defined at a sudden drop in force of >50 % from the applied maximum force. Stiffness of the construct was calculated using the linear portion of the load-displacement graph from the load to failure testing. The mode of failure for each repair was recorded. Measurements were compared using Student's T test.

Results

Cyclic loading

All constructs completed the cyclical testing without failure. After 1,000 cycles with 100 N, the mean tendon—bone displacement was 0.87 ± 0.13 mm for the bicortical group and 0.83 ± 0.13 mm for the new button group.

Static loading

The mean load to failure for the bicortical group was 296 ± 97 N. Mean load to failure for the new intramedullary button group was 332 ± 44 N (P=0.19). The mean difference in load to failure between both repair groups was not statistically significant. The mean stiffness of the bicortical group was 58.2 ± 9.2 N/mm, and 61.1 ± 9.7 N/mm in the new button group (P=0.6).

There was one failure in the bicortical group due to knot failure in an early stage of testing (16%). Three constructs (50%) failed by suture tearing through the tendon and 2 constructs (33%) failed by button pull-out with fracture avulsion of the anterior cortex. In the new intramedullary button group one construct failed due to button pull-out with fracture avulsion of the anterior cortex (16%). The remaining five (83%) failed by suture tearing through the tendon.

Discussion

The anterior single incision approach has gained popularity over the two-incision technique. ¹⁵ The latter has a higher risk of forearm bone synostosis and loss of forearm rotation or rotational strength ¹⁶, and a higher risk of posterior interosseous nerve injury. ¹⁷

Several implant types have been described to reattach the distal biceps tendon to the radius through the single incision approach. Extramedullary cortical button fixation is favorable because it provides the strongest initial fixation. However, the local anatomy with the posterior interosseous nerve curving around the radius on the opposite side of the tuberosity creates an increased risk of damaging the nerve when using this device. As a result, it is advised to insert the tendon in a non-anatomical position. However, this leads to decreased supination strength. However, this leads to decreased

An intramedullary fixation device that does not violate the posterior cortex of the radius has been advocated to decrease the risk of nerve injury, while allowing an anatomical repair. ^{19, 20} however, fixation on the thin cortex of the radial tuberosity may lead to suboptimal fixation strength and possible button breakout. Previous biomechanical studies ¹⁹ showed that both the load to failure of the unicortical fixation is lower than the bicortical fixation and that the method to failure is potentially catastrophic with a fracture of the anterior cortex. Siebenlist and colleagues therefore advised a stronger double button unicortical fixation method. ¹⁹ However, in their technique the buttons are essentially used as an anchor with fixation of the tendon onto the bone and not in a bone tunnel. This can, in turn, lead to gap formation due to tendon pistoning. This is inherent of tendon fixation against the bone instead of in a bone tunnel. ^{10, 11}

The goal of this study was to biomechanically evaluate a novel fixation device developed in response to these concerns. The unicortical fixation decreases the risk of nerve injury while allowing an anatomical position of the repaired tendon. The increased length of the button allows the button to hold against the thicker anterior cortex of the radius instead of the weaker tuberosity. Due to the bell shape of the button the tendon can be pulled into the bone tunnel, decreasing potential tendon to bone gap formation.

The biomechanical results of the new button are comparable to other currently used techniques. ^{10, 19} Both load to failure (356N) and stiffness (61N/mm) are similar to the excellent results of the bicortical button

technique. ^{10, 19} Noteworthy in our bicortical groups is that one construct of the bicortical group failed early at 116N due to knot failure. Without this the mean load of failure would be 332 ± 44N which is similar to previous reported results of the bicortical fixation. Fracture avulsion of the anterior cortex was only found in one single specimen at maximal load to failure. The load to failure of these technique and our described results are higher than the native tendon as described by Idler and colleagues. ²¹ Tendon re-rupture is seldomly seen due to the high initial fixation strength of currently used techniques. ¹⁶ The new button yields the same initial fixation strength as most other techniques. ^{10, 19, 21} This allows for immediate postoperative mobilization and loading.

One possible concern with the new button is the risk of toggling of the button in larger radius during the insertion. Fluoroscopy is used to ensure proper positioning.

There are some limitations of our study. First, the human cadaveric specimens were of an older age than the typical age for distal biceps ruptures, but comparable with the specimen age in other studies. It is possible that in younger specimens with better bone quality, less failures with bony avulsions would occur. This may be especially relevant for classical intramedullary buttons where this was the predominant failure mode. Even in these older specimens a clear difference is present between the new button and the classical button. Second, a relatively small group of specimens was used although this is comparable to other reported biomechanical studies.

In conclusion, the new intramedullary fixation device yields comparable loads to failure compared with ¹³currently used techniques in a biomechanical setup. These findings together with the theoretical advantages suggest that this technique might be a viable solution in distal biceps tendon rupture repair.

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Figures

Figure 1: The fixation device



Figure 2: The peddles of the new button span over the radial tuberosity and get support on the thick anterior cortex.



Figure 3 (a and b): The two different setups showing one with an intramedullary and one with an bicortical fixation.



Figure 4: The test setup with a custom mount at 30° to simulate the native line of pull. Hand drawn lines were used for measurement of displacement.

