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Reconstruction of acute distal biceps tendon ruptures with ToggleLoc. Clinical, functional and radiographic outcomes at 5-year follow-up.

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SUMMARY

Background. Distal biceps brachii tendon ruptures are a relatively uncommon injury, with a reported incidence of 0.9 to 1.8 per 100,000 people per year. The aim of this study is to report the clinical, functional, radiographic outcomes of the distal biceps tendon repair with Toggle Loc at 5 year follow up. **Methods.** All the patients operated on for distal biceps brachii reapair with Toggle Loc from April 2010 and April 2012 were enrolled in this study. The clinical follow-up was performed at 6, 12 months from surgery and at the final follow up with: DASH score, VAS scale, ROM, Physical examination. We measured Range Of Motion (ROM) of elbow flexion–extension and pronation–supination per kilogram of body weight as well as the peak and mean (three cycles) torque during the aforementioned movements and compared these findings with the contralateral side, respectively. Preoperative X-rays and Ultrasound were performed. **Results.** Clinical evaluation showed improved outcomes at the final and intermediate follow ups with a good recovery of the range of motion.Isokinetic evaluation showed a recovery of the strenght. Ultrasound evaluation showed no case of re rupture. **Conclusion.** the anatomic technique with Toggle Loc for the acute repair of distal biceps brachii rupture is a safe and effective surgical approach for this lesion.

KEY WORDS
Distal Biceps; Toggle Loc; Upper Extremity

INTRODUCTION

Distal biceps brachii tendon ruptures are a relatively uncommon injury, with a reported incidence of 0.9 to 1.8 per 100,000 people per year. The dominant arm is most commonly affected in the majority of cases, with a greater prevalence in males aged 30 to 50 years. (1) Pathophysiology of the injury has been attributed to advancing age, hypovascularity of the tendon, and inflammation within the radial bursa, all often with an acute eccentric load on the tendon; however, definitive etiology remains unclear. Moreover, for the hypovascularity of the tendon the incidence is quite common in bodybuildersn (2,3).

Prior to 1995, there were 53 published articles concerning the distal biceps, in contrast to more than 70 new publications on this topic over the past 3 years, reflecting an incidence trend or a possible increase in detection. In the appropriate patient, surgical repair of the distal biceps insertion reliably regains both supination and flexion strength. Many repair techniques have been developed over the past decade to match the structural properties of an intact tendon, with a goal of initiating early functional recovery (4).

Management options for distal biceps tendon rupture include nonoperative and operative treatment. Because of a significant operated limb forearm supination and flexion strength and endurance loss in patients treated nonoperatively in comparison to operatively treated groups (5–7), the nonoperative treatment concerns mainly older, low-demand patients and those with significant risks for surgery. Treatment options

for the distal biceps tendon rupture also include either one- or two-incision techniques (8). Several complications after surgical treatment have been reported, including nerve injuries, heterotopic ossification, and re-ruptures (9). To date, no consensus has been reached regarding the preferred fixation method (10), including suture anchors (11–13), bone tunnels, interference screws (14,15), or cortical buttons (16–18). The cortical button method has higher load to failure, as confirmed in biomechanical tests (19,20). However, it still has not been proven clinically (21,22), and suture anchor repairs also per- formed very well (23–25).
So the aim of this study is to report the clinical, functional, radiographic outcomes of the distal biceps tendon repair with Toggle Loc at 5 year follow up.

MATERIALS AND METHODS

Patients

The study was a retrospective cohort study in which the evaluation was performed in patients who underwent surgical anatomic reinsertion of the distal biceps brachii tendon. The study was carried out according to the ethics guidelines and principles of the Declaration of Helsinki (26-29).
All participants of the present study were informed about the goal of the study and approach to be used. The study was approved by the Local Bioethics Committee and written informed consent forms were signed by all of the participants prior to the study.
All the patients operated on for distal biceps brachii reapair with Toggle Loc from April 2010 and April 2012 were enrolled in this study.
Surgery was performed within 7 days from rupture. Inclusion criteria were active sporting patients, clinical and ultrasonographic diagnosis of tendon rupture, and age <18 years. Patients excluded from the study were those who had: previously rupture; undergone previous surgical procedures on the affected or contralateral side; a history therapies with ciprofloxacin or other drugs that can be dangerous to the tendon; systemic disease (diabetes, hypertension, inflammatory arthritis, sepsis, gout); undergone previous local corticosteroid injections; or received previous extracorporeal shock wave treatments.
From the original 47 patients 10 were excluded from the study population: 7 patients did not give their informed consent, 3 patients were <18 years old, the remaining 37 patients were enrolled in the study.
The mean age was 45.8 years (range = 18–55 years) with an average BMI of 26.2; 21% (7/33) had Type II Diabetes Mellitus, 30% (10/33) were active smokers. The average follow-up was 66 months (range = 6–182 weeks).

Clinical and Functional Evaluation

The clinical follow-up was performed at 6, 12 months from surgery and at the final follow up.
Functional assessment was provided by:

- Disabilities of the Arm, Shoulder and Hand (DASH score), with 0 reflecting no disability and 100 reflecting major disability, was performed when the receiving site was the upper limb.
- Pain was quantified using the Visual Analogic Scale (VAS), with 0 indicating absence of pain and 10 indicating maximum pain, both for the donor and receiving site.
- Range of Motion (ROM)
- Physical examination

Functional measurements were performed using dinamometric ergometer. We measured Range Of Motion (ROM) of elbow flexion–extension and pronation–supination per kilogram of body weight as well as the peak and mean (three cycles) torque during the aforementioned movements and compared these findings with the contralateral side, respectively.

Radiographic and Ultrasound Evaluation

Preoperative X-rays and Ultrasound were performed to detect any fractures associated to the tendon rupture and at the final follow up to detect any complications.

SURGICAL TECHNIQUE

The patient was placed in supine position with the arm on a surgical hand table. The arm was routinely prepared and draped from shoulder to hand, and a sterile tourniquet was applied. A longitudinal incision of about 4 cm was made 1-cm distal of the elbow skin crease to distal in correspondence of the bicipital tuberosity. The lateral antebrachial cutaneous nerve was identified and protected. Blunt dissection onto the proximal radius was done with protection of the radial nerve. With the elbow in full extension and supination, the radial bicipital tuberosity was exposed. Debridement of the footprint and the end of the tendon was performed.
With the arm in full supination, a guide wire was drilled into the anatomic insertion location of the biceps tendon, aiming just slightly distal and ulnarly to angle away from the posterior interosseous nerve. A 4.5-mm cannulated drill was advanced over the guide wire, through the posterior cortex. The anterior cortex was drilled based on the size of the tendon (usually 8-mm). Fixation of the cortical button on the distal biceps tendon was done with Toggle Loc. The cortical button was pulled through the radius using pin to

pass the sutures. The cortical button was engaged to the posterior cortex and locked into place. The fixation was tested, and intraoperative fluoroscopy was used to confirm the correct position of the cortical button. The passing sutures were removed.

POSTOPERATIVE PROTOCOL

The upper extremity was immobilized at 90° of flexion in a sling overnight. When wound healing was ensured and controlled motion was permitted, the patient was encouraged to use the arm for basic activities of daily living followed by gentle, gravity-assisted elbow motion, depending on the level of patient comfort as well as the security of the fixation. No patients were left immobilized for more than 14
days. For a period of 4 weeks, the patients were encouraged to mobilize within a flexion arc from 60° to 120°. Thiswas followed by assisted movement for another 2 weeks. In the next 6 weeks, the patient started moving the arm actively in full ROM and then gradual loading was applied to the arm until the 20th week from the time of surgical intervention. All athletes of our study returned to full sports activity schedule in a total time of 40 weeks postop.

STATISITICAL ANALYSIS

Statistical analysis (SPSS 20.0 IBM Corporation, Armonk, NY, USA) was performed using the paired T test, sign test and Wilcoxon signed ranks test to compare pre-operative and postoperative changes in numerical data. Changes in time in categorical data were analysed using the McNemar's test. The independent T test and the Mann–Whitney U test were used to compare numerical data and the Fisher's exact test and chisquared test for categorical data. Because of multiple testing, a P value
below 0.05 per test was considered to denote significance.

RESULTS

From the original 47 patients 10 were excluded from the study population: 7 patients did not give their informed consent, 3 patients were <18 years old, the remaining 37 patients were enrolled in the study.

All patients had a trauma mechanism of injury. Forty-five percent of patients were office workers with injury resulting from leisure activity and domestic duties such as gardening with a strong pull or catching action. The rest of the studied patients (55%) were manual workers with work-related injury (83%) or domestic-related injuries (27%); the most often described injury circumstances were lifting, catching, pulling, and pushing a heavy object. The pain intensity at the moment of injury was estimated by patients to exceed 6.5±3.8 at VAS scale. All of the studied patients were treated acutely. The mean time between the injury and surgery was 6.82±9.90 days.

Clinical Evaluation

At the operated site, the preoperatively DASH score was 70 ± 15.6 with 70% fair results, 20% unsatisfactory results and 10% good results; at 6 month follow-up was 21.51 ± 10.63 with 75% excellent results and 25% good results; at 12 month follow-up 18.0 ± 9.9 with 78% of excellent results and 22% of good results; at the final follow up was 16± 10.3 with 80% of excellent results and 20% of good results. Statistical analysis showed a significant difference ($p < 0.05$) about the preoperative and the postoperative DASH evaluation at 6 and 12 month and at final follow-up, but we did not record any statistical difference between the 6, 12 month and the final follow-up.

The mean preoperatively VAS was 6.75 ± 2; at 6-month follow-up was 2.1 ± 2; at 12-month follow-up was 1.8 ± 1.16; at the final follow up was 1.6± 0.9. Statistical analysis showed a significant difference ($p < 0.001$) about the preoperative and the post operative VAS evaluation at 6 and 12 month and at final follow-up, but we did not record any statistical difference between the 6, 12 month and the final follow-up.

The results of ROM measurements were comparable in the operated and non operated limbs in all patients (p-value 0.18).

Muscle strength measurements results

We found no statistically significant differences between the operated and nonoperated limbs in obtained and normalized to body mass values of muscles flexing the forearm (p-value=0.29). The comparison of normalized to body mass values of muscles supinating the forearm also showed no differences between the operated and nonoperated limb (p-value=0.21). The values obtained in case of operated nondominant limbs were lower comparing to nonoperated dominant limbs.

Radiographic and Ultrasound Evaluation

There were no abnormalities in terms of ultrasound examination and radiographic imaging of the surgical site any of the studied patients. No distal biceps tendon rerupture was noted.

Postoperative complications

There was 1 case of surgical site pain occurring during maximal biceps brachii contraction and 1 case of sensory

disturbances like tingling in the surgical site was observed (paraesthesia). One patient in reported tenderness in the soft tissue of the surgical site. There were no abnormalities in terms of ultrasound examination and radiographic imaging of the surgical site any of the studied patients. No distal biceps tendon rerupture was noted.

DISCUSSION

The most important finding of this paper is that the anatomic technique with Toggle Loc for the acute repair of distal biceps brachii rupture is a safe and effective surgical approach for this lesion.

In fact, the 5 years follow up showed poor post operative complication and good clinical and functional outcomes in our cohort of patients.

According to a study by Safran and Graham (2002), the distal biceps tendon rupture affects mostly males in their fourth decade of life (30). The findings of the present study were in a line with other authors, as the mean age of participants at the time of injury was 46 years and the initial sample comprised only male participants.

The surgical approaches utilizing in the distal biceps tendon repair can be divided into either one-incision or two-incision technique. The two-incision technique is most commonly used in bone tunnel fixation and the one-incision technique utilizing several fixation techniques like suture anchors or cortical buttons (8). The two-incision approaches are considered to recreate the normal anatomy more accurately, but there is still no clear evidence suggesting that this approach has a significant advantage (8). Originally, the one-incision technique was associated with a high rate of nerve palsies (31). In the present study, we found isolated cases of pain in the surgical site occurring during maximal biceps brachii contraction or after high-level physical effort, and sensory disturbances like tingling in the surgical site and tenderness in the soft tissue of the surgical site. As the results of VAS were close to no pain, they were considered as clinically irrelevant. No abnormalities were found in terms of ultrasound examination and radiographic imaging of the surgical site. No distal biceps tendon rerupture was noted.

Chavan et al. (32) performed a systematic review in 2008 and concluded that repairs using a cortical button performed better than other repair methods (transosseous tunnel, interference screw or suture anchors). The fixation of the cortical button is based on the cortical bone on the dorsal aspect of the radius. This is probably the explanation for the superior biomechanical characteristics over other types of fixation. Based on these biomechanical characteristics, the cortical button reconstruction provides a firm tendon refixation with good strength and little change on loosening, as is shown in the current study. Besides this biomechanics, the biology is also important in tendon refixation. The biceps tendon rests in a medullary canal of the radius, increasing the contact area between the bone and the tendon (33). Therefore, the healing process is not solely dependent on the hypovascular and degenerated distal end of the tendon (34).

There are technical challenges associated with fixation to the cortical button and tendon tensioning in a muscular forearm. The Toggle Loc is a modification on the Endobutton and allows the surgeon to attach the tendon to the implant by pulling on the sutures away from the wound. Furthermore it is possible to adjust the tension of the suture loops and subsequently the repair (35). Therefore, the Toggle Loc requires a potentially less demanding surgical technique. To our knowledge the Toggle Loc has only been evaluated by DiRaimo et al. (35) on 4 patients and by Kodde et al. (36) on 14 patients.

So at our knowledge this is the largest study population operated on for distal biceps rupture with Toggle loc with good clinical and radiographic results at 5 years follow up.

However, the retrospective design of the study might be considered as its limitation as patients' follow-up visits were at varying times from surgical intervention. Another limitation of the study is its small sample size, as not all of the operated patients were available for measurement. Moreover, a case control study to compare this technique to other techniques should be performed.

Conflict of Interest

The authors declare that they have no conflict of interest

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