ToggleLoc™ with ZipLoop™ Distal Biceps Tendon Reattachment

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Surgical Technique





Open Procedure

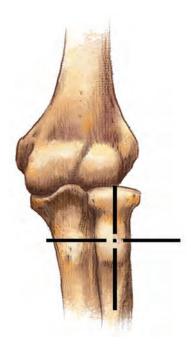
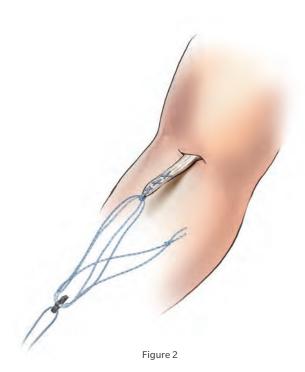


Figure 1



Incision

With the patient supine and the arm extended on a standard hand table, place the arm in maximum supination to protect the posterior interosseous nerve and expose the radial tuberosity (Figure 1). During exposure, care should be taken to identify and protect the lateral antebrachial cutaneous nerve and not to traumatize the interosseous membrane.

Tendon Preparation

Identify the ruptured biceps tendon and sharply debride the macerated portions of the tendon. Attach the ToggleLoc device to the end of the biceps tendon utilizing a whipstitch (Figure 2).

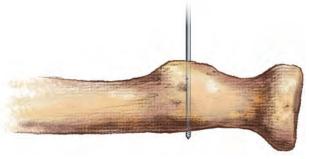


Figure 3

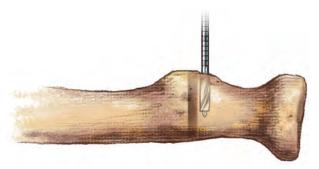


Figure 5

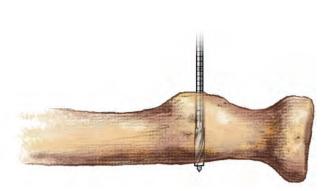


Figure 4



Figure 6

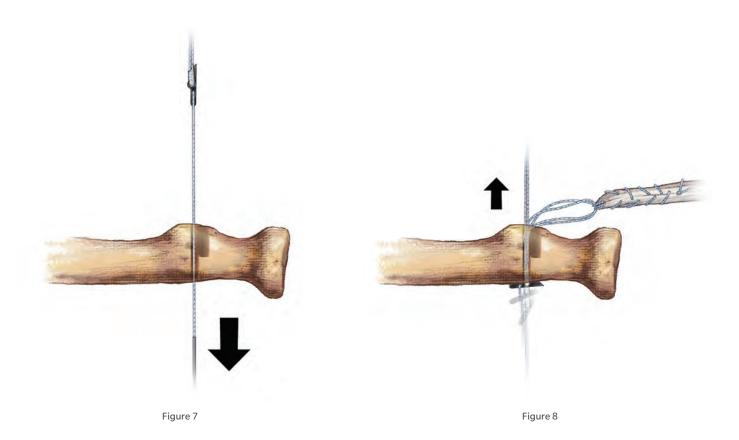
Drilling the Tunnel

With the arm in full supination, insert the 2.4mm guide pin into the footprint of the biceps tendon on the radial tuberosity (Figure 3). Aim the pin slightly distal and medial to angle away from the posterior interosseous nerve. The pin should be placed bicortically, but care should be taken not to plunge through the posterior cortex.

Carefully drill through the posterior cortex over the guide pin with the ToggleLoc cannulated 4.5mm drill (Figure 4).

Reinsert the 2.4mm guide pin approximately 3mm proximal to the first drill hole and to a depth of about 10mm. Ream over the guide pin with the 4.5mm drill (Figure 5).

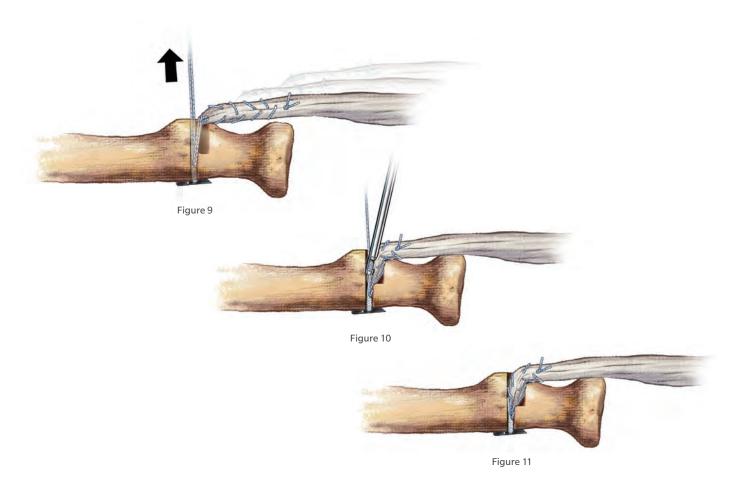
Use a ronguer to connect the two drill holes and create a smooth oval longitudinal bone socket (Figure 6).



Passing the ToggleLoc Fixation Device

Carefully pass a Beath pin with the passing sutures from the ToggleLoc fixation device with ZipLoop Technology through the 4.5mm hole in the posterior cortex (Figure 7).

Pull the device through the posterior cortex. Pull up on all of the sutures to engage the posterior cortex and lock the ToggleLoc Device into place (Figure 8).



Seating the Tendon

With the elbow in flexion, tension the "zip suture" to pull the tendon securely into the bone tunnel (Figure 9). Test the repair and retention as needed. Remove the passing sutures.

Use the Super MaxCutter™ Suture Cutter to cut the "zip suture" at the repair site (Figure 10).

The repair is now complete (Figure 11).

Percutaneous Method

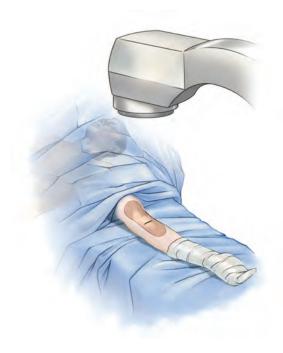


Figure 1

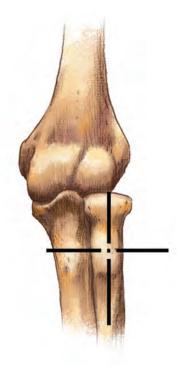


Figure 2

Technical Caveats

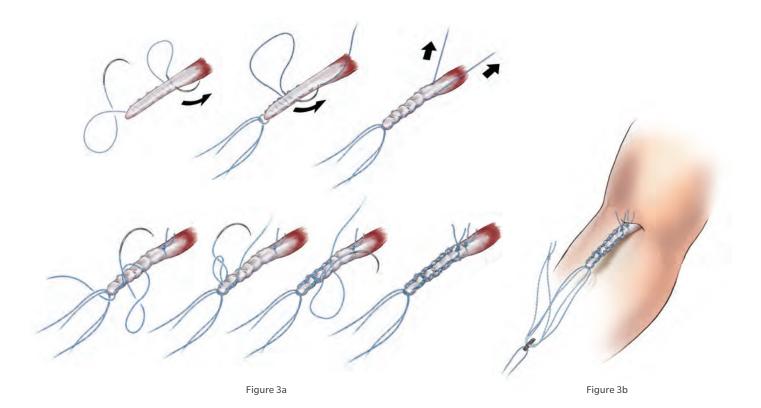
This technique is most effective for acute ruptures (2-3 weeks post-injury). In chronic tears, larger incisions are generally necessary for tendon mobilization. Begin with a local anesthesia injection in the skin to aid in hemostasis/pain control.

Setup

The patient is supine on a standard table with their arm on a radiolucent hand table. The large c-arm is used with the larger 'bell' end down to increase the field of view (Figure 1). After preparing the tendon, the c-arm is slid under the hand table and raised so that it is immediately under the hand table. This keeps it from interfering with the procedure and provides a wide field of view.

Incision

For an acute rupture, a 2.5 cm transverse incision 2 cm distal to the elbow flexion crease is used. This is directly overlying or immediately proximal to the bicipital tuberosity on the radius (Figure 2). Incision is just large enough to retrieve the tendon. The ruptured biceps is 'milked' externally towards the incision.



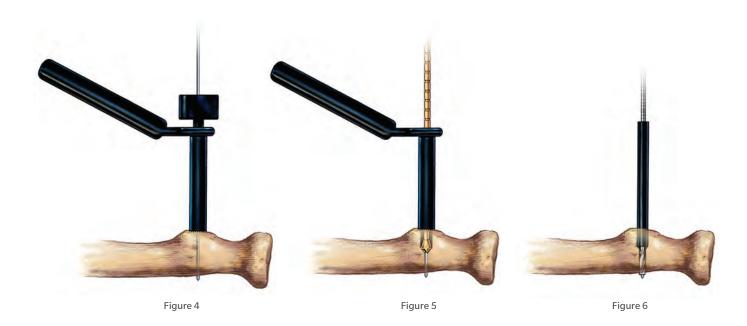
Dissection

After incising the skin, the bovie is used for hemostasis in the superficial tissues. The lateral antebrachial cutaneous nerve is identified and protected. Scissors are used to spread the superficial fascia and open the biceps tendon sheath. There is frequently a flush of serous fluid as the tendon sheath is opened in acute ruptures. Typically, the ruptured tendon is retrieved without difficulty by flexing the elbow and inserting a blunt retractor (Army Navy) for visualization. An alice clamp is used to retrieve the tendon.

Tendon Preparation

With the elbow flexed, the tendon can be prepared as it is easily externalized. In securing the tendon to the ZipLoop, the first suture is a Bunnell suture which prevents gap formation and secures the tendon to the ZipLoop (Figure 3a). The second suture is tied in a Krackow fashion which provides a stiff and secure attachment to the tendon (Figure 3b).

Preparing the tendon from distal to proximal will secure ToggleLoc device to the tendon, ensuring the knots used to secure the tendon are kept away from the radius where they may impede passage/flipping of the button.



Bony Preparation

The normal anatomic path of the biceps tendon is easily palpated in an acute rupture. By inserting your index finger in the incision and gently supinating/pronating the forearm, the bicipital tuberosity is palpated on the proximal radius. The cannulated system makes the bony preparation easy and safe. If there is significant debris/soft tissue on the bicipital tuberosity, debride it with a periosteal elevator. Care should be taken not to traumatize the interosseous membrane.

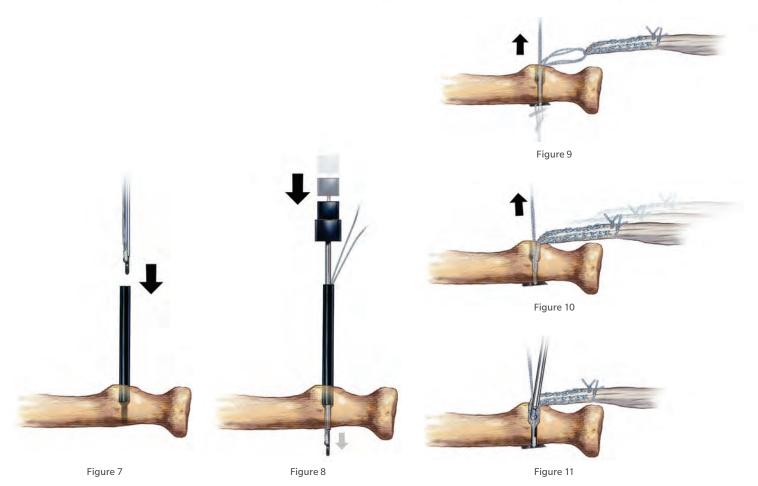
The cannula and cannulated obturator is inserted with the arm in a maximally supinated position. Radiolucent cannulas protect the soft tissues while enabling the surgeon to place the tip of the 2.4mm guide pin onto the bicipital tuberosity.

With the forearm supinated and flat on the table, fluoroscopy is used to confirm pin position. It is then advanced through the two cortices of the radius (~20mm depth stop and laser line referenced off of the cannulated obturator) (Figure 4). It is important to 'feel' both cortices as this confirms that the pin passed through the medullary canal and did not skive along the cortical margin.

The inner cannulated obturator is now removed and a 7 or 8mm acorn tip drill bit is inserted over the guide pin. It is drilled through the proximal cortex only (~10-12mm) (Figure 5). A clamp is placed on the guide pin while the acorn tip is drilled to prevent the guide pin from binding and spinning in the soft tissues. An oblique fluoroscopic view of the forearm is taken to confirm that the socket has been appropriately drilled.

Next, the slotted inner cannula is inserted into the radius. It has a 4.5mm inside diameter and the tip is in the contour of an acorn tip drill bit so that it fully seats in the radius.

The 4.5mm drill bit is used to drill the posterior cortex of the radius (Figure 6). The guide pin is again clamped to keep it from spinning in the soft tissues.

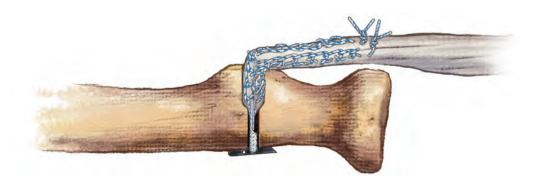


Passage of the Button

Leave the slotted inner cannula in place while removing the outer cannula. The ToggleLoc Fixation Device with ZipLoop Technology is inserted in the slotted cannula and pushed through the radius by using the ToggleLoc Pusher (Figure 7). The button of the ToggleLoc Device seats in the cannulation of the pusher. The position of the button is confirmed fluoroscopically and it is passed by gently tapping the black knob with a mallet.

After the ToggleLoc Device passes through the posterior cortex of the radius, the plunger is inserted into the pusher and used to disengage and flip the button (Figure 8). The sutures slide through the slot on the cannula and tension is placed on the sutures to flip/secure the button.

After confirming that the button is flipped, the zip strand is then tensioned and the tendon is seated (Figure 9 & 10). The tendon should be palpated in its socket in the radius. After fully tensioning the ToggleLoc device, the knot is cut off of the loop (Figure 11) and the free ends can be discarded or tied down alongside the tendon.



Closure

Subcutaneous tissues are closed with a Vicryl suture. Skin is closed with Dermabond.

Postoperative Rehabilitation

After repairing the tendon, the elbow is allowed to extend and lay flat on the table to assess the tension on the repair. If the repaired elbow lacks 20 degrees extension, the patient is placed into a hinged elbow brace that has a 20 degree extension block (Bledsoe hinged elbow brace).

Patient is allowed to perform gentle active range of motion within the limitations of the brace. Brace range of motion is increased at two weeks for goal of full range of motion by four weeks.

Discontinue brace at 4 – 6 weeks. Therapy is generally not necessary. Begin strengthening at 12 weeks postoperatively.

Technical Pearls

- 1. When drilling the guide pin across the radius, make sure the guide pin passes through 2 separate cortices. Crossing the medullary canal ensures that the bone bridge is adequate.
- 2. Drill the socket first and the 4.5 drill hole second — this allows placement of the slotted cannula and reduces the risk of accidentally drilling the opposite cortex with the larger drill bit.
- 3. When drilling the socket (7 or 8mm) and the 4.5 drill bit, have your assistant clamp the guide pin to ensure it doesn't spin in the soft tissues.
- 4. When passing the button, it is easier to remove the inside piece of the inserter and tap the button across the opposite cortex under fluoroscopic guidance.
- 5. Flip the button under fluoroscopic guidance and gently pull on the loop (not the knotted tensioning suture) to secure it against the cortex BEFORE removing the inserter. This keeps it from sliding back through into the radius.
- 6. Tension the zip strand with the elbow flexed 90 degrees and the forearm maximally supinated. The seated tendon will be palpable as it enters the socket.

INDICATIONS FOR USE

The ToggleLoc System devices, except the ToggleLoc XL device, are intended for soft tissue to bone fixation for the following indications:

Shoulder

Bankart lesion repair

SLAP lesion repairs

Acromio-clavicular repair

Capsular shift/capsulolabral reconstruction

Deltoid repair

Rotator cuff tear repair

Biceps Tenodesis

Foot and Ankle

Medial/lateral repair and reconstruction

Mid- and forefoot repair

Hallux valgus reconstruction

Metatarsal ligament/tendon repair or reconstruction

Achilles tendon repair

Ankle Syndesmosis fixation (Syndesmosis disruptions) and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures (only for ToggleLoc with Tophat/ZipTight™ Fixation Devices)

Elbow

Ulnar or radial collateral ligament reconstruction Lateral epicondylitis repair Biceps tendon reattachment

Knee

ACL/PCL repair / reconstruction

ACL/PCL patellar bone-tendon-bone grafts

Double-Tunnel ACL reconstruction

Extracapsular repair: MCL, LCL, and posterior oblique

ligament

Illiotibial band tenodesis

Patellar tendon repair

VMO advancement

Joint capsule closure

Hand and Wrist

Collateral ligament repair

Scapholunate ligament reconstruction

Tendon transfers in phalanx

Volar plate reconstruction

The ToggleLoc XL device is used for fixation of tendons and ligaments during orthopedic reconstruction procedures, such as Anterior Cruciate (ACL) or Posterior Cruciate (PCL) Reconstruction, as well as fixation in cases of unanticipated intraoperative complications, such as cortical breaching.

CONTRAINDICATIONS

- 1. Infection.
- Patient conditions including blood supply limitations, and insufficient quantity or quality of bone or soft tissue.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- 4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

Ordering Information

Part Number	Description
909874	ToggleLoc with ZipLoop Elbow Implant System includes:
	ToggleLoc Fixation Device
	• 2.4 mm Guide Pin
	• Two #2 MaxBraid™ Sutures with Tapered Needles on Each End
	Cannulation System
	ToggleLoc Pusher
900342	Super MaxCutter Suture Cutter

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