ZipTight[™] Fixation Device with **ZipLoop**[™] Technology for Chronic Anatomic AC Joint Reconstruction



Surgical Technique

Surgical Protocols by Eric McCarty, M.D.



One Surgeon. One Patient.®

Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it's meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally invasive surgical technique, advanced biomaterials or a patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.

Table of Contents

| ZipTight [™] Fixation Device for Chronic Anatomic AC Joint Reconstruction | |
|--|----|
| Patient Positioning | 2 |
| Graft Selection | 2 |
| Coracoid Exposure | 3 |
| Rotator Interval | |
| Subacromial Space | |
| Clavicle/Coracoid Drilling | 5 |
| Prepare Graft Socket in Coracoid | 6 |
| Clavicle Preparation | 6 |
| Passing the Implant | 7 |
| Place Graft in the First ZipLoop™ Construct | 8 |
| Tension the Device | 8 |
| Tie the Graft | 10 |
| Alternate Technique | 11 |
| Clavicle/Coracoid Drilling | 11 |
| Prepare Graft Socket in Coracoid | 12 |
| Closure | 13 |
| Post Operative Protocol | 13 |
| Part Numbers | 14 |

for Chronic Anatomic AC Joint Reconstruction



Figure 1

Chronic Reconstruction

This technique details the use of the ZipTight[™] Fixation Device for chronic acromioclavicular joint dislocation and use of graft as determined by the surgeon. Traditionally, dislocations left untreated for more than four weeks are considered chronic.

Patient Positioning

Position the patient in the preferred beach chair or lateral decubitus position.

Graft Selection

Graft choice is up to the surgeon's preference, but allografts are most commonly used. If using an autograft, the suggested grafts which work well would be the gracilis or semitendinosus hamstring and are the appropriate sizes for reconstruction. If autograft is chosen, prepare the ipsilateral knee and leg, and harvest the graft with appropriate technique. Place a whipstitch along both ends of the graft. This may facilitate later passage of the graft through or around the clavicle.

Perform a general diagnostic arthroscopy via the posterior portal (Figure 1).

This brochure is presented to demonstrate the surgical technique and postoperative protocol utilized by Eric McCarty, M.D. Biomet Sports Medicine, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques and products for each individual patient.



Figure 2



Coracoid Exposure

Create a subsequent anterior portal utilizing a spinal needle for desired positioning of the portal. This portal should be on same level as the coracoid tip, but at least 2 cm lateral to it. Introduce a cannula into the glenohumeral joint. Once the glenohumeral joint is examined and any pathology addressed, proceed with exposing the coracoid.

Expose the coracoid by approaching it through either the rotator interval (the area between the supraspinatus and subscapularis anteriorly) or from the subacromial space.

Rotator Interval (Option 1)

Exposing the coracoid through the rotator interval involves having the arthroscopic camera in the glenohumeral joint, viewing from the posterior portal toward the rotator interval. Take down the rotator interval with either an arthroscopic shaver or an ablation device. Once the rotator interval is taken down, the tip of the coracoid can be visualized medially, just above the subscapularis (Figure 2).

Subacromial Space (Option 2)

Exposing the coracoid from the subacromial space involves placing the arthroscopic camera into the anterior aspect of the subacromial space from the posterior portal. In this area there is typically very little bursa and the space is easily visualized. Utilize a spinal needle to ensure an adequate location for an anterolateral portal. It should be lateral and inferior to the anterolateral tip of the acromion. Next, identify the coracoacromial (CA) ligament anteriorly and follow its course down medial and inferior to its attachment on the coracoid tip. Some bursa may need to be debrided to follow the ligament (Figure 3).

for Chronic Anatomic AC Joint Reconstruction

Coracoid Exposure (cont.)

Once the coracoid tip is visualized with an arthroscopic camera, expose it with an alternating combination of shaver and ablation devices. Continue visualization of the coracoid with the arthroscope in this position from the posterior portal with either the 30 or 70° lens. At some point, place the camera into the lateral portal so that the entire coracoid can be visualized. Keep the ablation unit on bone as the coracoid is exposed and watch carefully as the coracoid curves posteriorly.

Bursa in this area will also need debriding. The shaver and/or ablation device should not drop inferiorly below the level of the bottom of the coracoid process to avoid potential injury to the axillary nerve. Begin by exposing the coracoid bone and its posterior curve, and then expose the area on top and just inferior along the curve. This area will be referred to as the arch. Utilize the ablation device on the bone to expose the superior and inferior aspects of the arch.

Clavicle Exposure

Create a 1.5 cm longitudinal incision over the clavicle, approximately 2.5 cm from the distal clavicle. Then incise the deltotrapezial fascia to expose the clavicle. Preserve the fascia as this will aid in completing the closure after the procedure. Additionally, sometimes to aid in reduction, it may be necessary to resect 5 - 8 mm of the distal clavicle.



Figure 5

Figure 6

Clavicle/Coracoid Drilling

Utilizing an arthroscopic point and shoot guide, drill through both the clavicle and coracoid. These can be drilled either together if proper alignment can be achieved with reduction of the clavicle, or as is often the case; the bones can be drilled independently (for independent drilling, see "Alternate Technique" section).

If drilling both, visualize the guide tip arthroscopically as it is placed in the inferior mid aspect of the coracoid arch (Figure 4). Reduce the clavicle down and place the bullet in the mid aspect of the clavicle at approximately 35 mm from the end of the clavicle. This location is midway between the attachments of the conoid and trapezoid coracoclavicular ligaments. Next, drill the 2.4 mm guide pin through the clavicle and the coracoid (Figure 5). Check location of the guide pin using direct visualization under the coracoid and re-drill if placement is incorrect. If satisfied with position of the guide pin, use a 4.5 mm ToggleLoc[™] reamer to slowly drill over the guide pin through the clavicle and coracoid (Figures 6 & 6a).

for Chronic Anatomic AC Joint Reconstruction





Figure 7

Figure 8

Prepare Graft Socket in Coracoid

Next make an area on top of the coracoid where the reconstructed ligament graft will be implanted. Place the 2.4 mm guide pin through a small split in the deltoid fascia anterior to the clavicle, and into the previously drilled 4.5 mm hole in the coracoid. Hand ream a 6.0 mm acorn reamer down on top of the coracoid (Figure 7). Exercise care when reaming this by hand and do not go further than 5 mm into the bone to minimize risk of fracturing the coracoid.

If using a suture relay to pass the implant, re-insert the 4.5 mm reamer through both the clavicle and coracoid. Pass the blue end of the Nitinol wire relay through the reamer and retrieve it out through a portal.

Clavicle Preparation

Drill two holes to replicate the position of the anatomic attachments of the coracoclavicular ligaments. The graft will have to be sized, but typically a 3.2 mm size hole will suffice. The first hole will be more anterior on the clavicle at approximately 25 mm from the distal end of the clavicle. The other will be more posterior and medial on the clavicle at approximately 40 – 45 mm from the distal end. The central hole used for passing the ZipLoop[™] round button will be between the anterior and posterior positions on the clavicle (Figure 8).



Pass the Implant

After the coracoid and clavicle have been prepared, pass the ZipTight[™] Fixation Device with the double ZipLoop[™] through the clavicle and insert the ToggleLoc[™] implant from the top using the ToggleLoc[™] Pusher/Plunger instrument. Be sure to place the shorter beveled/angular end of the ToggLoc button inside the cannulated pusher so that the rounded end is facing outward (Figure 9). Push the ZipTight[™] AC Joint implant down through the clavicle and coracoid using the plunger to deploy the ToggleLoc implant on the undersurface of the coracoid under direct arthroscopic visualization (Figure 10). Take care to hold the pusher steady while pushing down on the plunger. Do not let the pusher slide upward during this motion. Remove the pusher/plunger instrument and pull up gently on the implant to ensure the button is fixed below the coracoid.

Alternatively, the ToggleLoc[™] button can be passed using a relay system. This may be performed by using the Nitinol kite that was previously placed to pass the implant. The passing sutures of the ZipTight[™] Fixation Device are placed through the kite, and then pulled through both the clavicle and the coracoid. The implant button is then advanced by pulling on the passing sutures, until the button reaches the undersuface of the coracoid. Once the button gets to the undersuface of the coracoid, a grasper may be needed to pull it inferiorly so that it may flip to properly set on the distal cortex. For more information on the alternative technique please go to page 11.

for Chronic Anatomic AC Joint Reconstruction



Figure 12

Pass the Graft

Next, before pulling down the first ZipLoop[™] (nearest the ToggleLoc[™] button) through the clavicle, place a Nitinol kite through the ZipLoop[™] (Figure 11 and 11a). Then pull the first ZipLoop[™] down slowly so it enters into the space above the coracoid as visualized arthroscopically. Once the loop is visualized, retrieve the kite end of the Nitinol with a looped grasper or curved suture retriever and pull it out through the medial hole in the clavicle. Retrieve the other end of the Nitinol in similar fashion out through the lateral hole in the clavicle. Place the sutures attached to the graft through the kite and shuttle them through the ZipLoop[™] and out through the lateral hole (Figure 12). Pull the graft through the first Ziploop[™] and out of the lateral hole in the clavicle. The graft should now be through the Ziploop,[™] as well as both the medial and lateral hole in the clavicle.

Tension the Device

Center the graft in the first Ziploop^m and tension it down onto the coracoid (Figure 13).



Figure 15

Tension the Device (cont.)

Next, place the strands of the second ZipLoop[™] into the slots of the round button (Figure 14). Pull on the blue tensioning strand to provide back tension while pulling the zip strand to tighten the second Ziploop[™] over the round button (Figure 15). Tensioning the second ZipLoop[™] over the button provides reduction of the clavicle.

Remove the blue back tensioning strands by pulling on one end of the suture. Utilizing a slotted MaxCutter[™] device cut the zip strands as close to the button as possible (Figure 16).

ZipLoop™ Technology for Chronic Anatomic AC Joint Reconstruction



Figure 17

Tie the Graft

After tensioning and secure fixation of the ZipLoopTM device, tie the graft over the top of the round button and clavicle in a knot and stitch the ends together with # 2 MaxBraidTM sutures (Figures 17 & 17a).

Alternative Technique





Figure 19

Figure 18

Alternate Technique

This technique can be used if the clavicle and coracoid cannot be drilled simultaneously. They should still be exposed in the manner described above.

Clavicle/Coracoid Drilling

If the clavicle and coracoid have become misaligned, it will be necessary to drill the tunnels for the ZipTight[™] implant independently of each other (Figure 18). This is usually accomplished with the use of fluoroscopy.

Reduce the clavicle down as much as possible and place the tip of the guide pin in the mid aspect of the clavicle approximately 35 mm from the end of the clavicle. This location is midway between the attachments of the conoid and trapezoid coracoclavicular ligaments. Next, drill the 2.4 mm guide pin through the clavicle. Leave the guide pin in place and ream bicortically using the 4.5 mm ToggleLoc[™] reamer.

Remove the reamer and guide pin and address the coracoid. The guide pin should be placed so that it will exit in the inferior mid aspect of the coracoid arch. Fluoroscopy can be used to confirm placement of the guide pin. Drill the 2.4mm guide pin through the coracoid and ream bicortically with the 4.5 mm ToggleLoc[™] reamer (Figure 19).

for Chronic Anatomic AC Joint Reconstruction



Figure 21

Figure 23

Prepare Graft Socket in Coracoid

The next step involves making an area on top of the coracoid where the reconstructed ligament graft will be implanted. Place the 2.4 mm guide pin through a small split in the deltoid fascia anterior to the clavicle, and into the previously drilled 4.5 mm hole in the coracoid. Hand ream a 6.0 mm acorn reamer down on top of the coracoid. Exercise care when reaming this by hand and do not go further than 5 mm into the bone to minimize risk of fracturing the coracoid. Pass the blue end of the Nitinol kite through the 6.0 mm cannulated acorn reamer, and use a grasper to begin pulling it out through the portal (Figure 20). Remove the cannulated reamer, and be sure to leave the kite end of the Nitinol wire in the space between the coracoid and the clavicle (Figure 21).

Using a straight suture grasper, pull the kite end of the Nitinol up through the hole in the clavicle (Figure 22). Continue with clavicle preparation as described in the main technique (Figure 23).

Closure

Close the tissues in standard fashion and apply sterile dressing. Apply a sling and cryotherapy in peri-operative period.

Post Operative Protocol

Patient should be immobilized for at least six weeks to avoid stress on the healing tissue around the acromio-clavicularjoint. Motion and gentle strengthening exercises can then be initiated with plan on full return to activities 4 - 6 months following the surgery.

Part Numbers

ZipTight[™] Implants

| Part Number | Description |
|-------------|---|
| 904835 | ZipTight [™] AC Joint with 2 ZipLoops |
| 904837 | ZipTight [™] for AC Joint Disposable Kit |
| 909864 | ToggleLoc™ Pusher/Plunger |
| 948084 | 3.2 mm Cannulated Drill |

Other

| Part Number | Description |
|-------------|---|
| 909846 | ToggleLoc™ Disposable Kit |
| 904004 | Speedpass [™] 2.3 mm Straight |
| 900312 | MaxBraid [™] 5 Suture, Blue with C Needles |
| 909511 | Point and Shoot Guide |
| 904011 | Nitinol wire 10 pk |

Indications for Use

The ToggleLoc $^{\scriptscriptstyle \mathrm{M}}$ System devices 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)

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

Hip

Acetabular labral repair

Contraindications

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

| Notes | |
|-------|--|
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |

| Notes | |
|-------|--|
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |

All trademarks herein are the property of Biomet, Inc. or its subsidiaries unless otherwise indicated.

This material is intended for the sole use and benefit of the Biomet sales force and physicians. It is not to be redistributed, duplicated or disclosed without the express written consent of Biomet.

For complete product information, including indications, contraindications, warnings, precautions, and potential adverse side effects, see the package insert and patient risk information at www.Biomet.com.



One Surgeon. One Patient:

©2013 Biomet Sports Medicine • Form No. BMET0660.0 • REV0513

Responsible Manufacturer

Biomet Sports Medicine P.O. Box 587 56 E. Bell Drive Warsaw, Indiana 46581-0587 USA

www.biomet.com

Authorized Representative

Biomet UK, Ltd. Waterton Industrial Estate Bridgend, South Wales CF31 3XA UK €€ 0086

www.biometeurope.com