ANIKA

CASE REPORT

Integrity™ implant for massive rotator cuff tear in 49-year-old active female

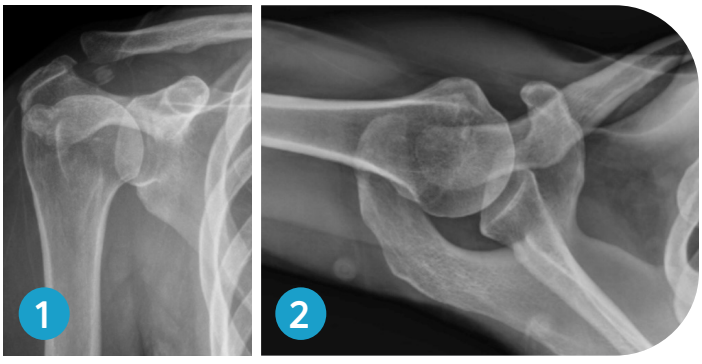
Brian Badman, MD

Shoulder Surgeon, Central Indiana Orthopedics

History

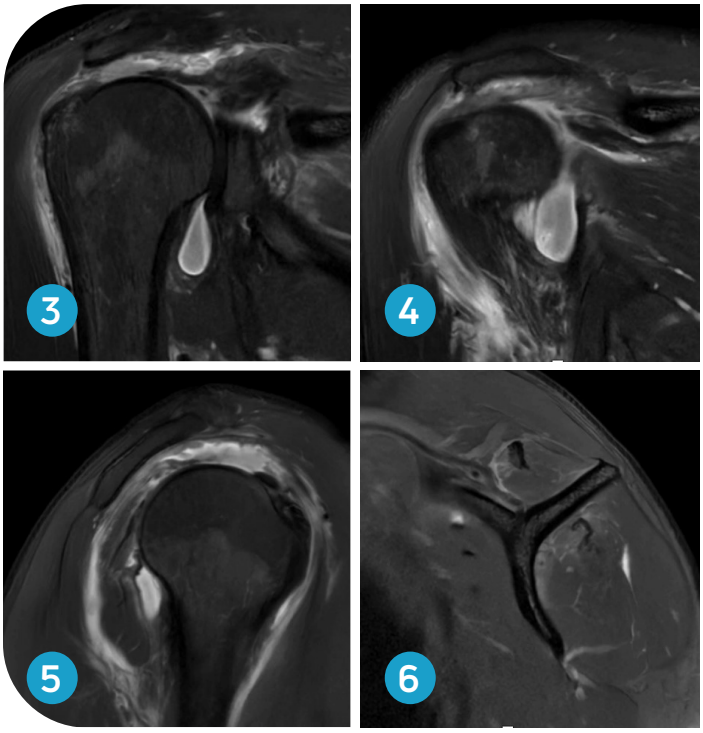
A 49-year-old active female physical therapist presented with a 9-month history of shoulder pain. She denied any trauma but noted progressive pain with working out, specifically while lifting weights overhead. She was initially seen by another provider and was given a steroid injection and prescribed physical therapy. The injection lasted for about four months and then her symptoms gradually returned. Based on the recurrent symptoms an MRI was ordered revealing a massive rotator cuff tear. The initial surgeon recommended a superior capsular reconstruction, and she presents now for second opinion.

A focused exam revealed a very fit patient who maintained full active and passive range of motion of her right dominant shoulder. There was a negative lag sign and Hornblower sign with pain provoked with the Hawkins test and weakness graded 4/5 with empty can testing and 4/5 external rotation strength testing. Belly press sign was intact and there was palpable crepitance with passive exam of her shoulder anterolaterally. She had some pain to her bicep groove and no pain to her distal clavicle.



Figures 1 & 2. *X-rays: Normal appearance without arthritic change (AP and axillary).*

Plain films of her right shoulder were normal with no evidence of proximal humeral migration and no evidence of glenohumeral joint disease. The MRI revealed a massive retracted tear of the supraspinatus and upper half of the infraspinatus tendons. The tendon was retracted greater than 3cm on the coronal plane and the width of the tear on the sagittal plane was also approximately 3cm. The supraspinatus was graded as Goutallier 1 and the infraspinatus was grade 0. The teres minor and subscapularis remained intact and there was notable tendinopathy of the intraarticular portion of the bicep tendon. The RoHi score was calculated at 8 [Figures 1-6].



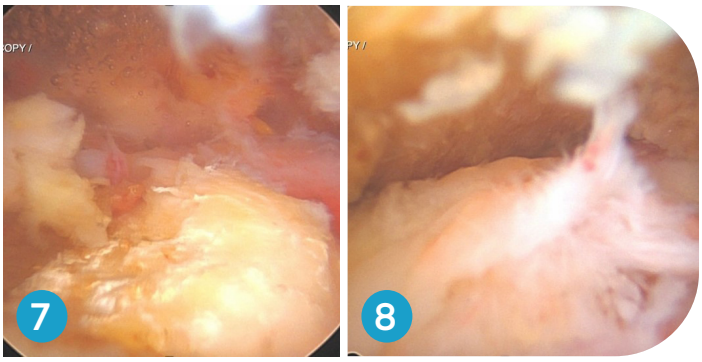
Figures 3 & 4. *Coronal MRI: Demonstrates retracted tear of supraspinatus and infraspinatus tendons.*

Figures 5 & 6. *Sagittal MRI: Supraspinatus with Goutallier 1 and infraspinatus with grade 0.*

Based on the patient's overall age, activity level and imaging findings, a recommendation was made to proceed with an arthroscopic rotator cuff repair with probable augmentation of the tendon. Other options were presented and discussed, in the event that a formal repair could not be performed, including a lower trapezius tendon transfer. The patient consented and was scheduled for outpatient surgery.

Surgery

The patient presented to the operating suite. A single shot of interscalene was administered by the anesthesia staff and general anesthesia was administered via laryngeal mask airway (LMA). She was positioned in beach chair manner and standard arthroscopic portals were made. Intraarticular survey showed bicep labral changes consistent with Type 2 SLAP pathology and there was disruption of the anterior column of her supraspinatus which also compromised the lateral pulley of the bicep tendon. The bicep was sutured and released and pulled into the subacromial space for later tenodesis. Cursory exam of the rotator cuff revealed a retracted L-pattern tear with disruption of the anterior column of the supraspinatus [Figures 7-8].



Figures 7 & 8. *Retracted anterior L-pattern tear with disruption of anterior column.*

Following suprapectoral bicep tenodesis, an anterior DrawTight™ anchor was initially placed to allow for repair of the anterior column [Figure 9]. A pair of mattress sutures from this anchor were passed with a suture passer and tied to initially simplify the tear pattern.

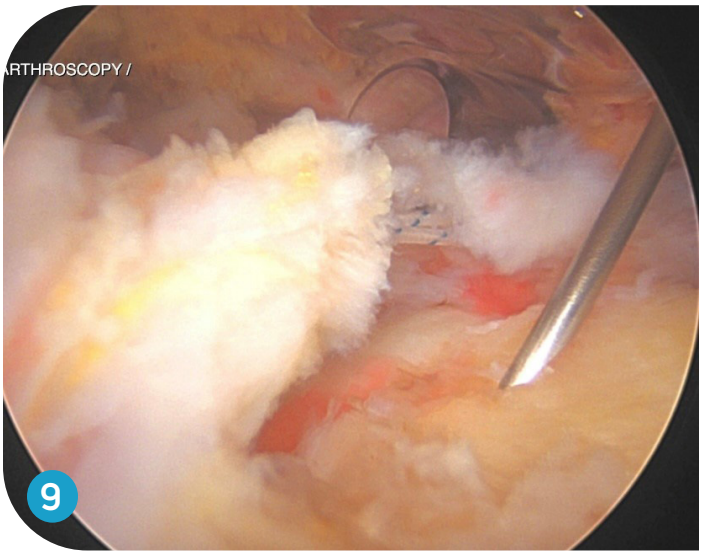
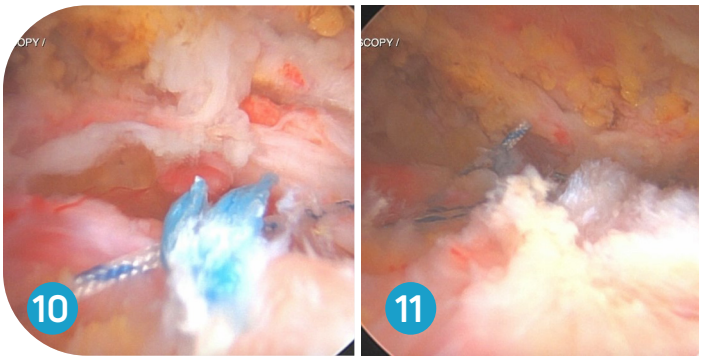


Figure 9. *Placement of anterior anchor for restoring anterior column.*



Figures 10 & 11. *Margin convergence of longitudinal split of supraspinatus.*

Next, a longitudinal split of the supraspinatus was noted, and three margin convergent sutures were passed and tied to convert the tear pattern from a large V-type tear to a more transverse pattern [Figures 10-11]. A second DrawTight anchor was then placed along the posteromedial footprint of the tuberosity. Five sutures from this anchor were once again passed with one pair tied in a mattress fashion to stabilize the posterior column of the supraspinatus tendon. Once all mattress stabilizing sutures were tied, all remaining sutures were then crisscrossed and pulled into two lateral row X-Twist™ PEEK anchors [Figure 12]. The second anchor was loaded with a nanofiber scaffold (ROTIUM®, Atreon Orthopedics) placed on top of the tuberosity and below the tendon.

ANIKA

Integrity™ Case Report

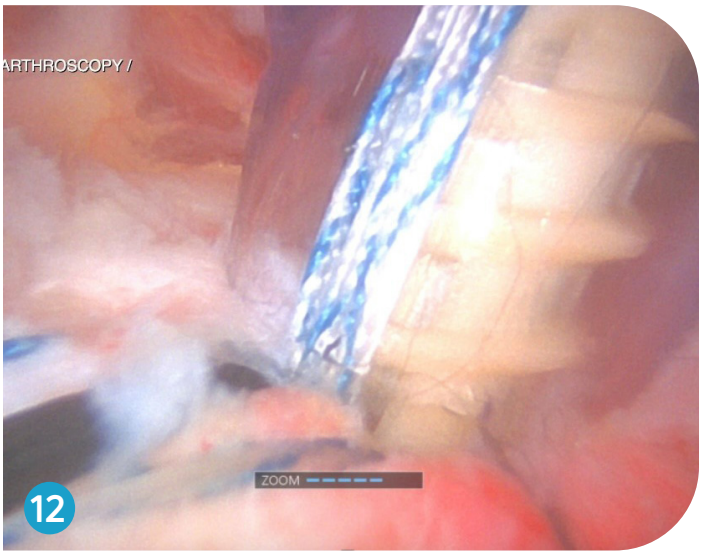


Figure 12. *Placement of lateral row anchors.*

Given the extent of the tear, a decision was made to also include the Integrity hyaluronic acid (HA)-based implant. The implant was inserted through the large cannula supplied with the Integrity instrument kit through a lateral portal and positioned at the fifty-yard line of the repair. The bone staple was impacted first and positioned just superior to the row of lateral X-Twist anchors. The footprint of the bone staple was small enough to allow for plenty of room for fixation [Figure 13].

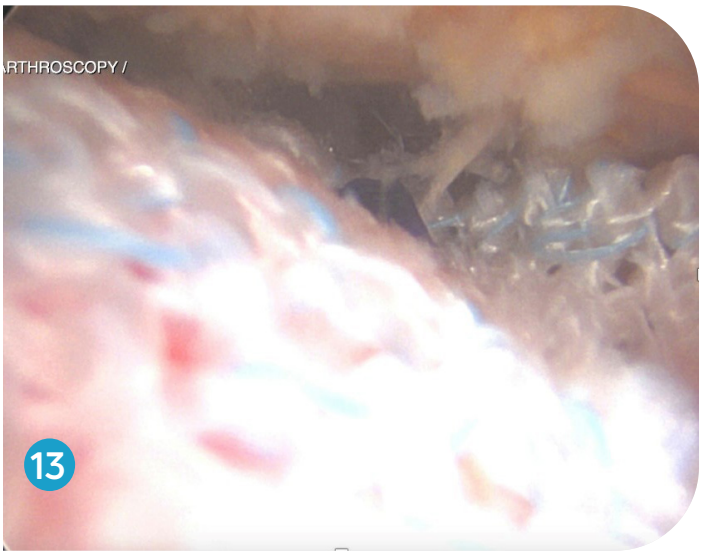


Figure 13. *Integrity implant deployed over repaired tendon.*

Next, using the rolling device, the implant was unfolded and deployed over the top of the repaired tendon covering the majority of the tendon insertion point laterally, from anterior to posterior, spanning approximately 20mm in length. Finally, working through two accessory percutaneous portals, five of the 7mm bioresorbable tacks were then used to fixate the implant medially and centrally [Figures 14-15].

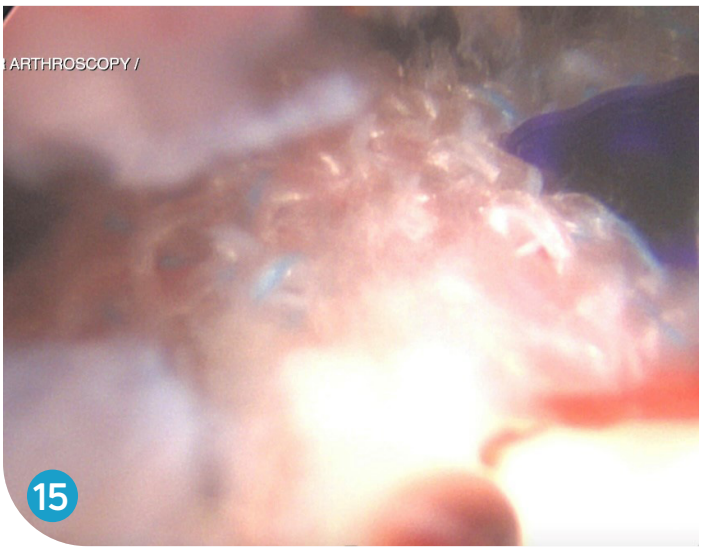


Figure 14. *Fixation of Integrity implant with tacks.*

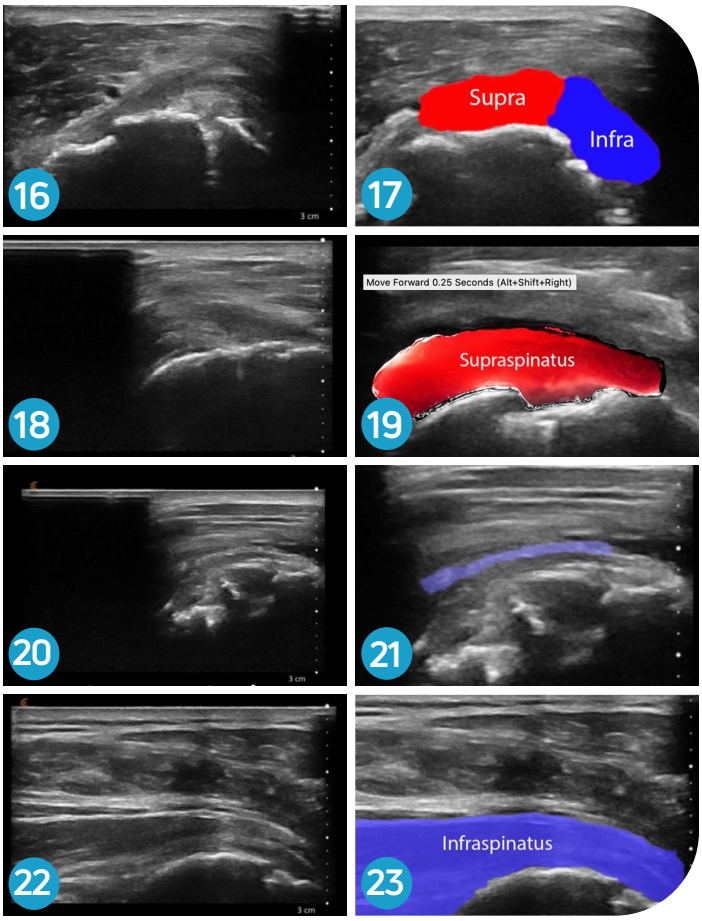
Figure 15. *Visualization of implant from lateral portal.*

ANIKA

Follow-up

The patient was immobilized in a sling for a total of 6 weeks. She was seen at 2 weeks to assess whether her incisions had healed well and was prescribed physical therapy to begin 4 weeks after surgery. Her therapy regimen was prescribed as a large cuff protocol which typically delays active motion to around 8-10 weeks and begins with passive motion to start. Strengthening is typically held for 12 weeks based on patient progress.

At 6 months, an in-office ultrasound was performed that showed an intact repair on both long and short axis. She had regained nearly full symmetric range of motion with forward elevation of 160°, abduction of 160°, external rotation of 70° and internal rotation to T7 [Figures 16-23].



Figures 16-17. *6-month ultrasound: Short axis view.*
Figures 18-19. *6-month ultrasound: Long axis supraspinatus view.*
Figures 20-21. *6-month ultrasound: Long axis supraspinatus view with Integrity implant over top.*
Figures 22-23. *6-month ultrasound: Long axis infraspinatus view.*

Patient reported outcomes also revealed an ASES score of 95 and VAS of 0. She was cleared at this visit to resume a progressive home strengthening program [Figures 24-26].

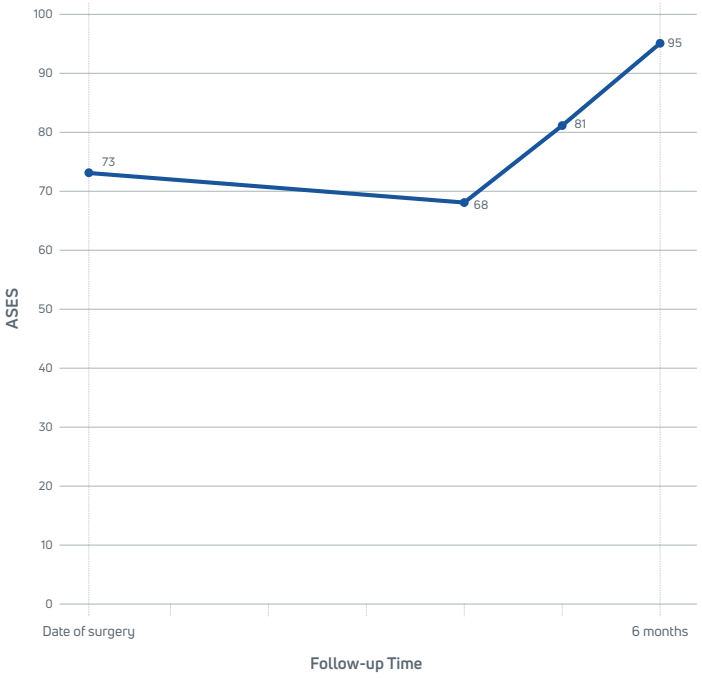


Figure 24. *Postoperative ASES score.*

Figures 25-26. *6-month postoperative clinical patient photos.*

ANIKA

Discussion

This case highlights the importance of providing proper biological support to improve rotator cuff repair outcomes. Tears of this magnitude have reported failure rates as high as 94%.[1] Based on the RoHi score, this would correspond to a greater than 34% chance of not healing.[2]

The Integrity implant offers enhanced biological integration while avoiding the issues associated with xenografts and the potential for inflammatory reactions.

I have used the Integrity implant in other tears of this severity, and it serves as an additional tool to potentially improve outcomes by providing excellent structural stability and handling characteristics. Repeating the same process and expecting different results is often called the definition of insanity—we must do better for our patients, and the Integrity implant is one valuable tool to help us achieve that.

References

1. Galatz, Leesa M., et al. "The outcome and repair integrity of completely arthroscopically repaired large and massive rotator cuff tears." JBJS 86.2 (2004): 219-224.
2. Kwon, Jieun, et al. "The rotator cuff healing index: a new scoring system to predict rotator cuff healing after surgical repair." The American journal of sports medicine 47.1 (2019): 173-180.

Anika Therapeutics, Inc.
32 Wiggins Ave., Bedford, MA 01730
1-888-721-1600 | customerservice@anika.com
www.anika.com | Anika. Restore Active Living.® | Stay Active®

AML-900-732 REV 01

ANIKA