An Evaluation of Soft (All-Suture) Anchors on Glenoid Bone in Patients Having Surgical Stabilization for Atraumatic Anterior Shoulder Instability

STUDY UPDATE: FEBRUARY 2015

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Background

Traditionally, surgical repair of shoulder instability is achieved using solid suture anchors. New soft (all-suture) anchors have been developed recently with several potential advantages over conventional solid anchors. They are smaller in size (preserve bone volume) and if dislodged, joint damage may be reduced because of their soft composition (suture).[1] They can also be inserted through curved guides or smaller percutaneous cannulas for increased surgical flexibility.

Currently, there is no clinical evidence in the published literature investigating these anchors. It is crucial to evaluate the new anchors in a human population to determine their effects on bone and their impact on clinical outcomes. Given the lack of information in the literature, a pilot study is being undertaken at the Southern California Orthopedic Institute (SCOI).

Study Design and Rationale

Literature Review

While all-suture anchors have been shown to perform as well as conventional solid anchors in biomechanical tests[2], an in vivo study performed on canines showed unfavorable results, including cystic enlargement around the anchor site.[3] The authors report that the dogs were fully ambulatory immediately following surgery for 8 weeks until euthanized for "a worst case scenario rather than a sling or immobilization" as is the rehabilitation protocol used in a clinical setting.

Primary Research Question

The primary research question being addressed in the study is: In patients having an arthroscopic Bankart repair for atraumatic anterior shoulder instability with an all-suture anchor, what is the condition of the anchor socket and surrounding glenoid bone on magnetic resonance images (MRI) image 3 months and 12 months post-operative?

Radiology

Pilot testing on a new MRI sequencing protocol was conducted by the research team and GE Healthcare during the summer of 2012 with the Y-Knot® all-suture anchor (ConMed Linvatec, Largo, FL) in bovine bone. These new protocols have the ability to evaluate bone (like CT) but without exposing the patient to radiation.

- 3 months – MRI scan (preliminary healing of labral tissue)
- 12 months – MRI scan (complete healing of labral tissue)

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Study Update

IRB Approval

The study received IRB approval in May of 2013 with a planned enrollment of 12 patients.

Surgery

First two initial surgeries were performed after 9/2014. There was no difficulty with implant placement, and all anchors had excellent strength at the time of insertion.

Clinical Exam

Both patients had no pain or recurrent dislocations at the 3-month follow-up and were advanced to a shoulder strengthening therapy program.

MRI Scans

The first 3-month MRIs were obtained in January of 2015 for review and exhibit no sign of cystic formation which was observed in ambulatory canines at 8 weeks[3]. The labrum was healed to the bone, and the bone appeared to be healing around the anchors without inflammatory reaction.

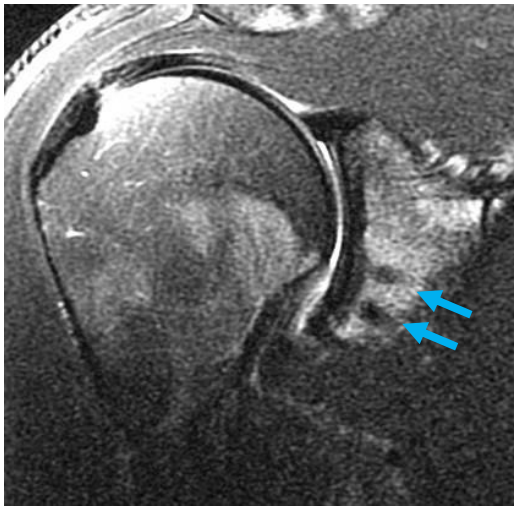

Figure 1: *MRI of Patient A shows no drill tunnel widening or cyst formation.*

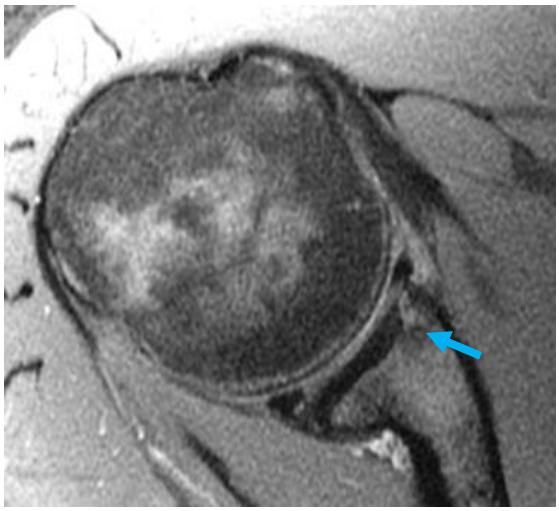

Figure 2: *MRI of Patient B shows the bony integrity to be maintained without cyst formation.*

Conclusion

Initial clinical outcomes show that the labrum was healed to the bone, and the bone appeared to be healing around the anchors without inflammatory reaction. There were no signs of cyst formation, increased anchor socket diameter, or implant migration.

Further clinical follow-up and imaging will continue to assess the clinical results of this pilot study.

References

[1]Dwyer, T. et al. Maximum load to failure and tensile displacement of an all-suture glenoid anchor compared with a screw-in glenoid anchor. *Knee Surg Sports Traumatol Arthrosc*. 2013.
[2] Barber, FA. et al. Cyclic Loading Biomechanical Analysis of the Pullout Strengths of Rotator Cuff and Glenoid Anchors: 2013 Update. *Arthroscopy*. 2013; 29:832-844.
[3] Pfeiffer, Ferris M. et al. The Histologic and biomechanical response of two commercially available small glenoid anchors for use in labral repairs. *J shoulder Elbow Surg*. 2014.

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