Clinical Outcomes of the JuggerKnot™ Soft Anchor for Shoulder Repair

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Study is still on-going. Study will be Completed May 2013

Purpose

The JuggerKnot™ Soft Anchor is a soft tissue to bone fixation device that consists of a coreless sleeve and suture construct. As such, it is unique in that the device does not require a rigid body for bone engagement. The purpose of this study is to clinically evaluate the use of this device for shoulder repair.

Methods

This ongoing, single center, prospective study was designed to include 48 patients with up to two-year follow-up after undergoing arthroscopic shoulder repair using the JuggerKnot™ Soft Anchor. The primary endpoint uses the Constant-Murley Shoulder Score (CS)[1] to measure the improvement in shoulder pain and function at one and two years post-op. One secondary endpoint similarly uses the Flexilevel Scale of Shoulder Function (FLEX-SF)[2]. Another secondary endpoint assesses bone tunnel healing in postoperative shoulders via Magnetic Resonance Imaging (MRI) scanning in all patients at two-year follow-up.

Currently, 23 patients (21 male, 2 female), mean age 34.2 years (range: 14.2-62.3 years), and mean body mass index 27.3 (range: 21.5-37.9) have been enrolled in the study with five patients having two-year follow-up. The procedures performed included capsular shift/capsulo-labral reconstruction, Bankart lesion repair, and SLAP lesion repair. Nine right shoulders and 14 left shoulders (11 on dominant side) underwent repair. Mean follow-up was 1.2 years (range: 0.9-2.0 years). Pre-operative and post-operative scores were compared using a paired student t-test with significance taken for $p<0.05$.

Results

Summary statistics for the CS and the FLEX-SF at the pre-op, one-year, and two-year intervals are shown in Figures 1 and 2, respectively. There was general improvement in both from pre-op to one-year, with little change beyond one-year. One complication occurred (4%) when a patient fell down the stairs at eight-weeks, requiring a revision capsular shift and labrum repair.

Table 1 compares the pre-op with the one-year CS and its components. There was significant improvement in all values during this interval ($p<0.0001$).

Table 1. Statistical comparison of Constant-Murley score at pre-op and one-year intervals.

Score	n	Pre-Op (mean±SD)	1-Year (mean±SD)	P value
Pain	20	6.5±4.0	12.5±3.8	<0.0001
Activities of Daily Living (AOL)	10	11.4±3.1	19.6±0.8	<0.0001
Power	20	8.1±7.1	18.1±4.8	<0.0001
Range of Motion (ROM)	16	26.8±5.6	36.0±2.8	<0.0001
Total	10	55.8±15.2	87.2±9.3	<0.0001

Table 2 compares the pre-op with the 1-year FLEX-SF. There was significant improvement during this interval ($p<0.0001$).

Table 2. Statistical comparison of FLEX-SF at pre-op and one-year intervals.

n	Pre-Op (mean±SD)	1-Year (mean±SD)	P value
23	29.1±5.0	39.2±7.5	<0.0001

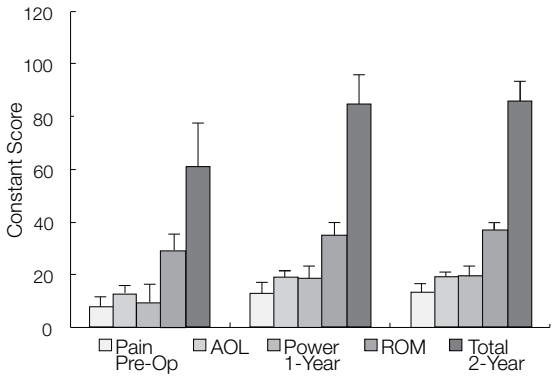

Figure 1.
Descriptive statistics for total Constant-Murley score and its components at pre-op, one-year, and two-year intervals (mean+SD). Note that the number of patients represented by each column varied because not all patients have yet reached the two-year follow up*.

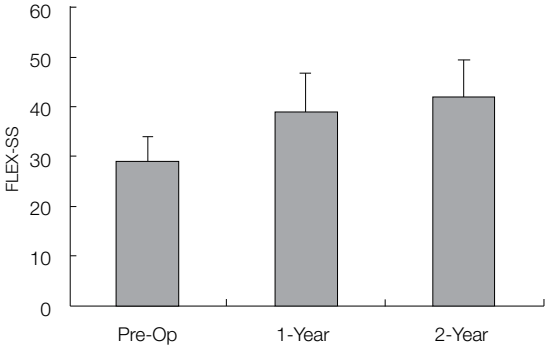

Figure 2.
Descriptive statistics for the Flexilevel Scale of Shoulder Function (FLEX-SF) at pre-op, one-year, and two-year intervals (mean+SD). Note that the number of patients represented by each column varied because not all patients have yet reached the two-year follow up*.
* Two-year follow up will be completed May of 2013

Imaging

All patients at the two-year follow-up had an MRI utilizing a 1.5 Tesla high-field scanner (Signa; GE Medical Systems, Milwaukee, WI, USA). Gradient-echo axial, proton density and T2-weighted oblique coronal and sagittal, and coronal fat suppressed imaging of the shoulder was performed utilizing a dedicated shoulder coil. Sagittal T1 series were also obtained. Two musculoskeletal fellowship trained radiologists, who were aware that the patients had undergone surgery for shoulder instability but were blinded to the specific details of each patient's repair, reviewed the images. As expected, the all suture JuggerKnot™ Soft Anchor did not hinder diagnostic imaging. There were no instances of subchondral cyst formation or tunnel expansion. The suture anchor tracts appeared to heal with fibrous tissue, complete bony healing, or some combined fibro-osseous healing of the tunnels (Figure 3A-3D). As demonstrated in these MRI images, especially noteworthy in the patient requiring a revision repair, despite having multiple anchors/ anchor tracts adjacent to each other, no evidence of fracture propagation or tunnel expansion/collapse from having multiple adjacent tunnels, especially in a revision setting.

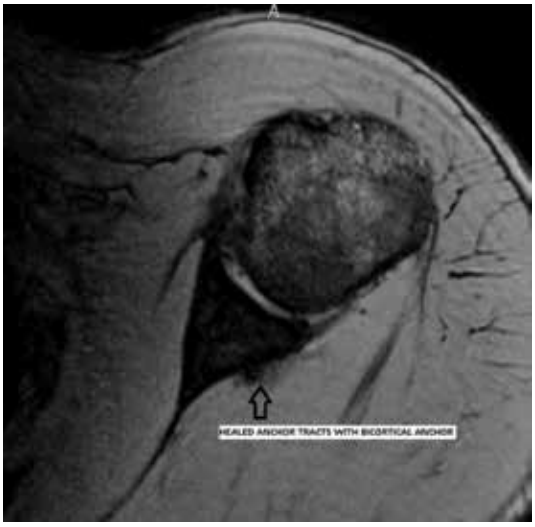

Figure 3A.
Two-year MRI of a collegiate baseball player with a circumferential labrum repair and capsular shift utilizing 12 JuggerKnot™ Soft Anchor–1.4 mm implants. Axial image shows ossified anchor tracts with a bicortical anchor.

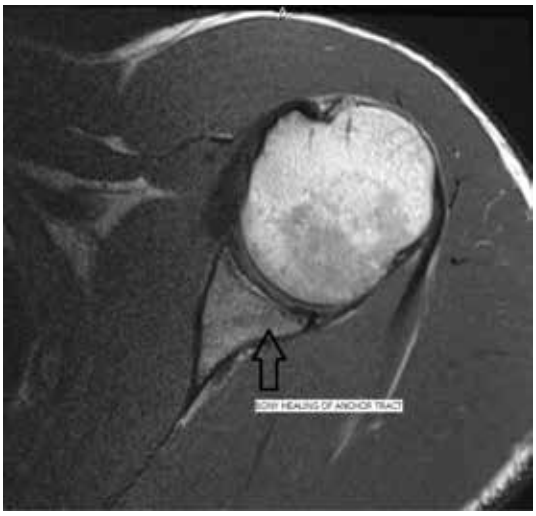

Figure 3B.
Two-year MRI of a collegiate baseball player with a circumferential labrum repair and capsular shift utilizing 12 JuggerKnot™ Soft Anchor–1.4 mm implants. Axial image shows ossified anchor tract.

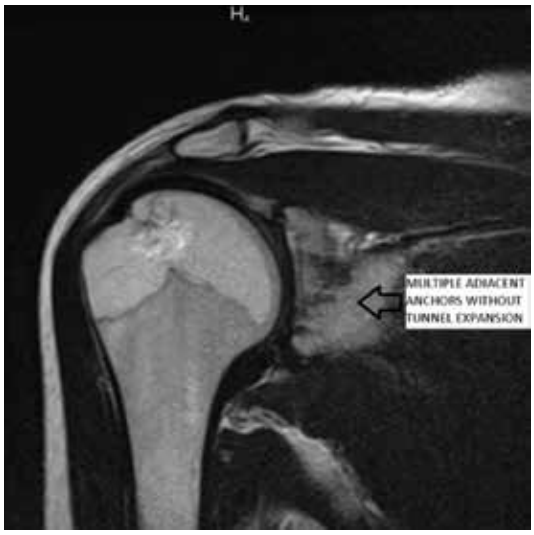

Figure 3C.
Two-year MRI of a competitive swimmer with traumatic postoperative injury requiring revision capsular shift and labrum repair utilizing 10 JuggerKnot™ Soft Anchor–1.4 mm implants. Coronal image shows multiple adjacent anchor tracts with combined fibrous and osseous healing.

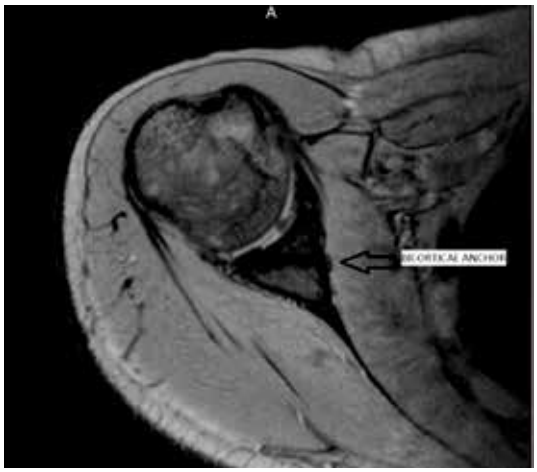

Figure 3D.
Two-year MRI of a competitive swimmer with traumatic postoperative injury requiring revision capsular shift and labrum repair utilizing 10 JuggerKnot™ Soft Anchor–1.4 mm implants. Axial image shows ossified anchor tracts with a bicortical anchor.

Discussion

The JuggerKnot™ Soft Anchor provided effective treatment for labral and capsular repair/reconstructive shoulder procedures. There was significant improvement in pain and function as indicated by the Constant-Murley score and FLEX-SF scores at one year. There were no device-related complications.

Suture anchoring devices have allowed the ability to repair soft tissues utilizing arthroscopic surgery to advance significantly over the past few decades.[3-5] Unfortunately, complications have also been reported with these devices including: implant migration, loosening, breakage, third body wear, interference with postoperative imaging, draining sinuses, osteolysis, inflammation, joint damage and repair failure. Through an internal Zimmer Biomet complaint review, the JuggerKnot™ Soft Anchor–1.4 mm has shown no instances of osteolysis or inflammatory resorption response, and has shown no fracture propagation in patients requiring multiple anchors for effective repair. Another benefit of the JuggerKnot™ Soft Anchor, in comparison to larger anchors, is the very small bony tunnel (1.4 mm), which allows a revision surgery to be significantly less complicated. This includes the removal of the previous anchor with a new tunnel easily drilled without concern for glenoid bone loss and poor fixation. As the number of sutures and/or fixation points increase, the strength of soft tissue repair has also been shown to increase.[6] The significantly smaller size of the anchor also allows the JuggerKnot™ Soft Anchors to be placed in very close proximity to each other (even during complex cases with minimal bone accessible) allowing multiple sutures/fixation points per unit area of soft tissue.

Since this clinical study remains ongoing, additional data will become available to more fully assess the use of the JuggerKnot™ Soft Anchor for shoulder repair.

Conclusion

This ongoing two-year clinical study provides evidence that the JuggerKnot™ Soft Anchor can be used for labral and capsular repair/reconstructive shoulder procedures to improve shoulder function and pain with a low complication rate. The all suture construct and small size of the JuggerKnot™ Soft Anchor allow greater flexibility for complex and revision cases while preserving future imaging and treatment options for both the patient and surgeon.

References

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