In Vivo Randomized Controlled Study of the Bone Response of All-Suture Anchors and Biocomposite Anchors

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Background: Suture anchors are widely used for labral reconstruction surgery. However, there has been some concern over the development of osteolysis around the anchor. This has been reported for both biocomposite and all-suture anchors, but they have not been compared directly in vivo.

Purpose: To compare the bone response to 2 common suture anchors: a traditional biocomposite push-fit anchor and an all-suture anchor.

Study Design: Randomized controlled trial; Level of evidence, 2.

Methods: Included in this study were 17 patients with a total of 37 unique suture anchors. Magnetic resonance imaging scans were performed at 3 weeks and 6 months postoperatively. A total of 38 senior radiologists and shoulder surgeons evaluated the images using a previously validated system for grading the bone response around suture anchors. The mean difference in grading at 3 weeks and 6 months was calculated using unpaired *t* tests, and the interrater reliability was evaluated with an intraclass correlation coefficient (ICC).

Results: At 3 weeks, there was no statistically significant difference in the degree of osteolysis surrounding each suture anchor type ($P = .258$), with little bone response. However, on the 6-month scans, there was a significantly lower level of osteolysis seen in the all-suture anchors compared with the biocomposite anchors ($P = .040$). Interrater reliability was excellent, with an ICC value of 0.975 (95% CI, 0.962-0.985).

Conclusion: All-suture anchors cause significantly less osteolysis in glenoid bone at 6 months compared with biocomposite anchors.

Keywords: shoulder; instability; glenoid labrum; magnetic resonance imaging

Glenoid labrum tears occur as a result of trauma to the shoulder and can affect any region of the labrum.[5] These injuries often lead to recurrent instability, causing significant discomfort and disability to the individual. Labral reconstruction surgery is the mainstay of treatment for these injuries and can be performed as an open or arthroscopic procedure.[14] Arthroscopic procedures use suture anchors implanted in the glenoid to reconstruct the damaged labrum, aiming to restore the structural integrity of the joint and alleviate symptoms.[3] Historically, suture anchors were first constructed of metal; however, metallic anchors have largely been replaced because of concerns with excessive articular cartilage damage, migration, and loosening.[10] Polymers with excessively long degradation times are also avoided as a material for suture anchors because of concerns that complications similar to those found with metal anchors will occur.[10]

Biocomposite suture anchors are commonly used in arthroscopic labral reconstruction surgery[10] and can be composed of a number of different materials, with more than 40 different biocomposite polymers that have been developed for surgical use.[6] All-suture anchors are a relatively novel solution to glenohumeral instability and have the advantage of requiring a smaller pilot hole in the glenoid, which could be beneficial should revision surgery be required.[7]

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TABLE 1
Grading System Focusing on
Cystic Bone Changes Detected on MRI Scans[a]

Grade	Signal on T1FS	Signal on T2FS	Outcome Hypothesis
0	Normal	Normal	Normal postsurgical change up to 6 months
1	Normal	Increased signal/ minimal bony edema	
2	Low	Increased signal/mild edema	
3	Low	Cystic change	Potentially unstable
4	Low	Fluid surrounding anchor	

[a]MRI, magnetic resonance imaging; T1FS, T1-weighted with fat suppression; T2FS, T2-weighted with fat suppression.

These suture anchors have elicited some concern regarding the response that the glenoid bone appears to show postsurgery. Several studies[1,4,8,11,12] have found that various types of suture anchors can lead to osteolysis and cyst formation after labral reconstruction, and it is believed that these lytic changes can contribute to glenoid rim fracture, anchor pullout, or subsequent articular cartilage damage.[1,6]

This study aimed to compare the glenoid bone response and osteolytic changes in 2 different types of commercially available suture anchors: traditional push-fit biocomposite suture anchor (Osteoraptor; Smith & Nephew), and a 1.9-mm all-suture anchor (Suturefix Ultra; Smith & Nephew). These anchors have been compared in a previous cadaveric study by Erickson et al[7] and have been found to have biomechanically similar characteristics; however, whereas both types of anchors are used currently in clinical practice, no studies to date have compared the suture anchors directly in vivo. We aimed for multiple independent raters to use a magnetic resonance imaging (MRI)–based grading system to evaluate the osteolysis present at 3 weeks and 6 months after labral reconstruction. We hypothesized that there will be no difference in the bone response to the 2 anchor types that we tested.

METHODS

Grading System for Bone Response to Suture Anchors

We employed a previously validated grading system[13] that quantifies the bone response to suture anchors from a grade of 0 to 4. This system uses coronal T1-weighted and coronal T2FS (fat-suppressed) MRIs to visualize the shoulder and implanted suture anchors. MRI was used because it has the advantage of showing early bone changes before cyst formation or osteolysis. We utilized the grading system to compare the differences in glenoid bone response from 2 different types of glenoid suture anchors. Raters had access to a training resource detailing the criteria and expected lytic changes visible in each grade (Table 1) as well as some examples of the appearance of each grade on MRI (Figure 1). The grade assigned to each suture anchor suggests the ultimate stability of the suture anchor, with grades 0 and 1 suggesting the patient will experience normal postsurgical changes and

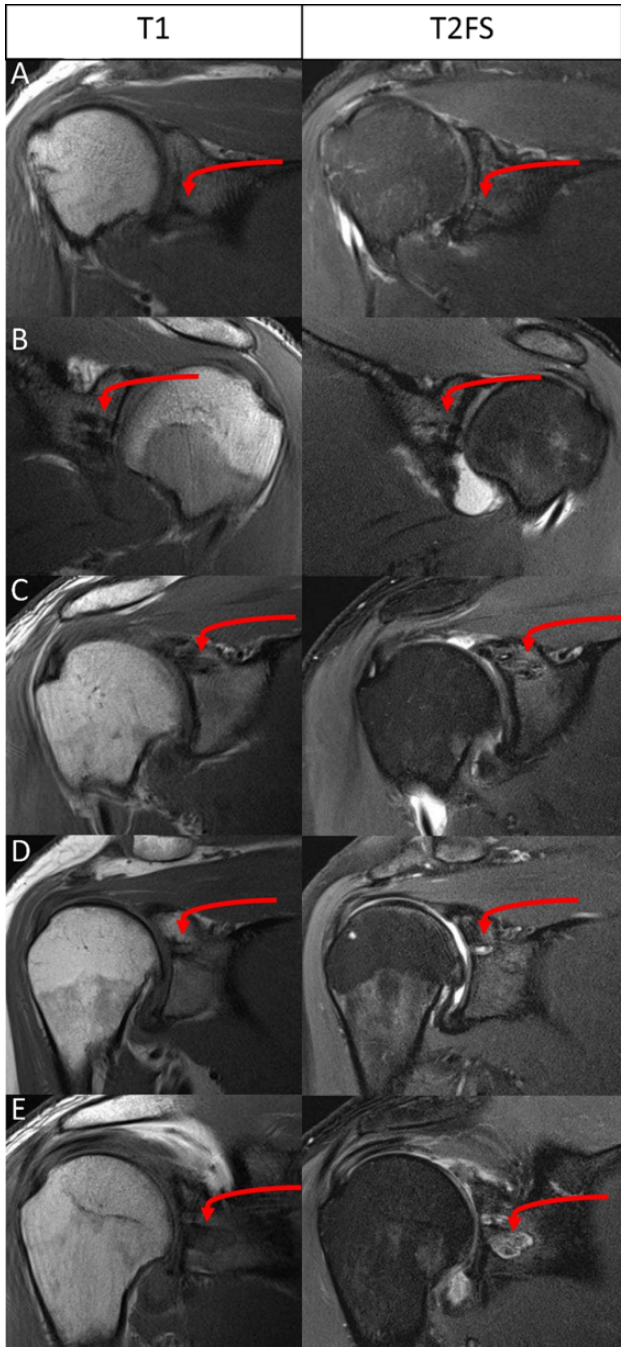

Figure 1. The examples of each grade as included in the training resource that was available to the raters in this study. Each anchor is visualized using both coronal T1- and T2-weighted fat-suppressed (FS) magnetic resonance images, and these are used to assign a grade to the suture anchor based on the bone response. (A) Grade 0, (B) grade 1, (C) grade 2, (D) grade 3, and (E) grade 4. The red arrows indicate the anchors.

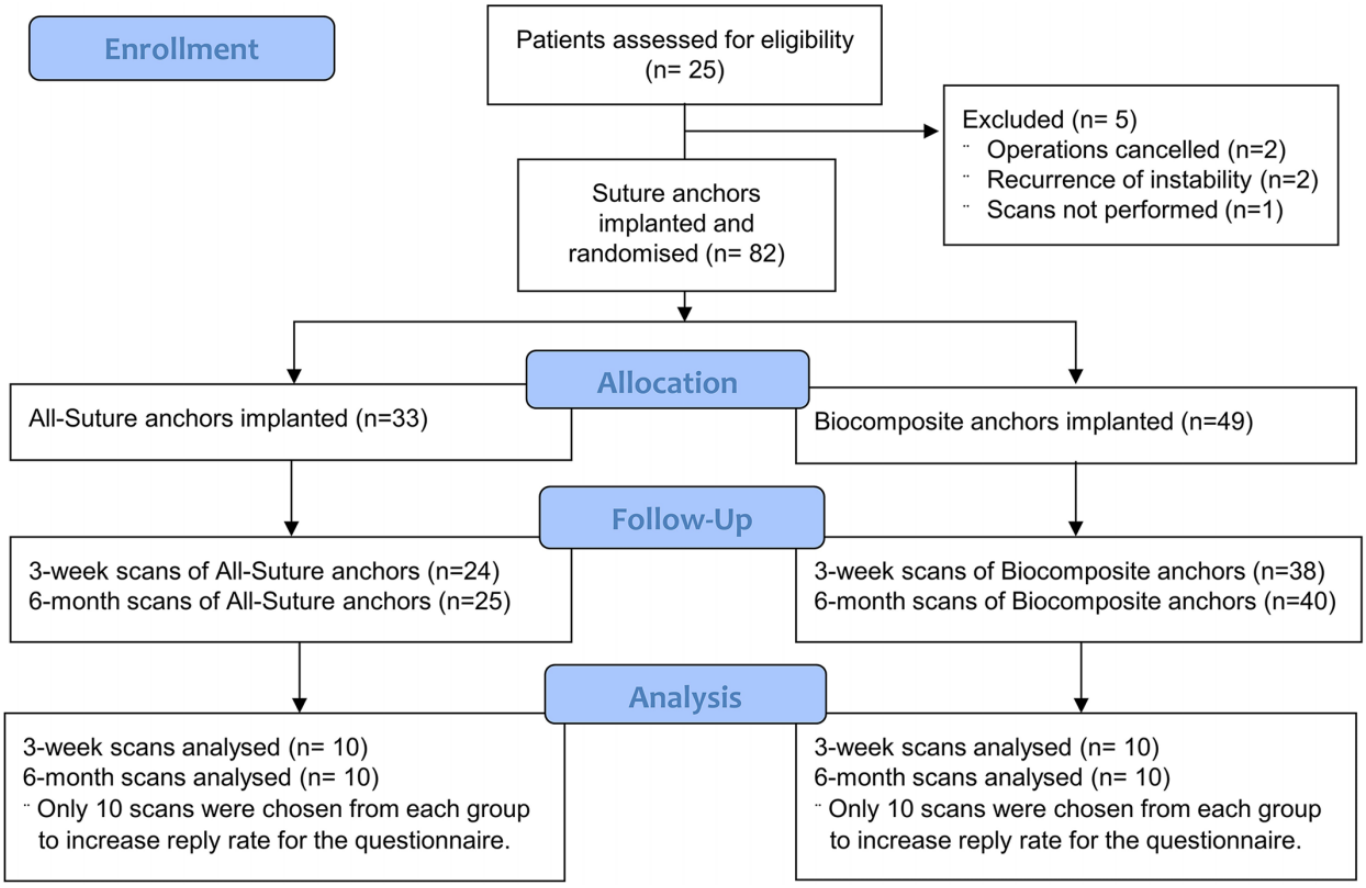

Figure 2. Flowchart detailing the enrollment, allocation of suture anchors implanted, and number of anchors included in analysis in this trial.

grades 3 and 4 suggesting the suture anchor could be potentially unstable.

Patient Selection

Ethical approval was obtained before this study. The inclusion criterion for this study was patients with a primary labral tear requiring an arthroscopic stabilization procedure. The exclusion criteria were patients not consenting to be included in research, revision surgery, and neither 3-week nor 6-month scans being performed. A total of 25 patients were originally recruited for this study, with 5 being excluded. Of the excluded patients, 2 had operations canceled, 2 had recurrences of instability, and 1 patient did not receive the required scans. Each participant had the surgical and study procedure explained to him or her, and written informed consent was obtained. Patients were chosen irrespective of age, sex, or ethnicity. The study patients had both 2.9-mm biocomposite push-fit suture anchor (Osteoraptor, Smith & Nephew) and 1.9-mm all-suture anchors (Suturefix Ultra, Smith & Nephew) implanted during arthroscopic shoulder stabilization procedures. The size of the drill bits used to create pilot holes for biocomposite and all-suture anchors was 2.9 and 1.9 mm, respectively.

The mean number of suture anchors implanted per patient was 4.1 (range, 2-7), with a total of 49 biocomposite anchors implanted and 33 all-suture anchors implanted. Each patient had at least 1 of each type of anchor implanted, and if more than 2 anchors were required, the type of the subsequent anchor used at each position was decided through a randomization software program. Postoperative rehabilitation procedures (including immobilization and physiotherapy) were not altered, and as such, athletes would have been aiming for return to sport by 4-6 months postsurgery (depending on the sport).

A mixture of 3-week and 6-month MRI scans of the stabilized shoulders were taken. These MRI scans were evaluated, and images that contained suture anchors were identified. This identification yielded 126 images, from which 40 were included in this study. These consisted of 10 scans at 3 weeks and 10 scans at 6 months of each suture anchor type, representing the best quality images available from each category. Selection of these images was carried out by an individual without training in musculoskeletal radiology and unfamiliar with evaluating bone response (H.R.). The 40 images used were of 37 different anchors from 17 unique patients. Figure 2 depicts a flow diagram outlining the recruitment and suture anchors that were implanted during this study.

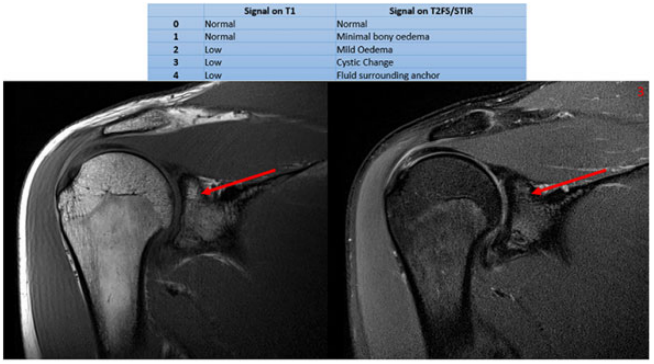

Figure 3. An example of one of the questions in the anchor-grading email questionnaire. The image includes coronal T1- and T2-weighted fat-suppressed magnetic resonance images, with a red arrow indicating the anchor to be graded. Raters had access to a training document to assist with grading on each question.

Image Analysis

Imaging was performed on a 3T MRI scanner at our institution. The images used for grading were coronal T1FS and T2FS scans. The T1FS and T2FS coronal images were placed together, and a red arrow was drawn to denote which anchor the raters were to grade, as on many images there was more than 1 anchor visible. A table outlining the bone response criteria for each grade was also included on each image.

The 40 images selected were incorporated into an email-based questionnaire and sent to senior shoulder surgeons and musculoskeletal radiologists. A total of 38 clinicians responded, with 33 raters completing the entire questionnaire. Only the results from the 33 raters who completed the entire questionnaire were included in the statistical analysis. The raters completed the questionnaire independently and were blinded to the identity of the patient and the type of anchor being graded. An example of a questionnaire item is depicted in Figure 3. The raters had the option of opening a larger, higher resolution image of the suture anchors and had access to a training document explaining the grading system.

TABLE 2
Interpretation of ICC Values for Interrater Agreement Used in This Study[a]

ICC Value	Interpretation
<0.50	Poor reliability
0.5-0.74	Moderate reliability
0.75-0.90	Good reliability
>0.90	Excellent reliability

[a]Adapted from Koo and Li.[9] ICC, intraclass correlation coefficient.

TABLE 3
Patient and Surgical Characteristics (N = 17)[a]

Sex	
Male	15 (88)
Female	2 (12)
Mean age (range), y	25.1 (17-37)
Sport	
Rugby Union or Rugby League	12 (70.6)
Boxing	1 (5.9)
Javelin thrower	1 (5.9)
Snowboarding	1 (5.9)
Not sporting related	2 (11.8)
Operation	
Anterior stabilization surgery	6 (35.3)
Anterior and posterior stabilization surgery	7 (41.2)
Anterior stabilization surgery and SLAP repair	3 (17.6)
360° stabilization with SLAP repair	1 (5.9)

[a]Data are presented as n (%) unless otherwise indicated. SLAP, superior labrum anterior and posterior.

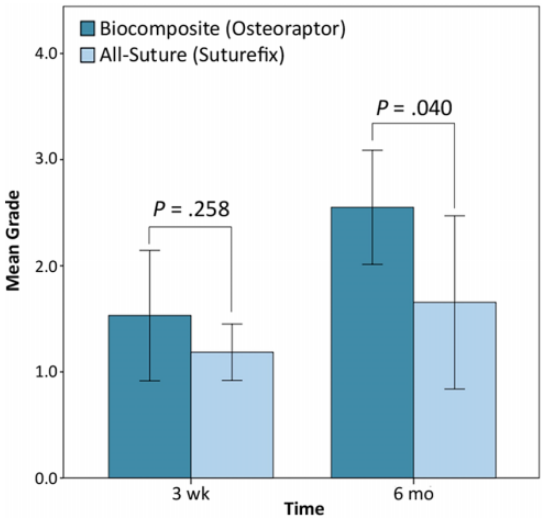

Figure 4. The differences in the mean ratings of each suture anchor type at each time point evaluated in this study.

Statistical Analysis

An independent t test was performed on both the 3-week and the 6-month scans to identify whether there was a difference between the mean grades of the anchors in the biocomposite and all-suture groups. Interrater reliability was assessed using an intraclass correlation coefficient (ICC) based on a mean-rating ($k = 33$), absolute-agreement, 2-way random-effects model. The interpretation of ICC values used in this study is shown in Table 2.

RESULTS

Of the 17 patients whose suture anchors were analyzed, the average patient age at the time of operation was 25.1 years (range, 17-37 years). There were 15 males and 2 females included in this study. The right shoulder was repaired in 12 of the patients, whereas the left shoulder was repaired in 5 patients. The majority of the patients required shoulder stabilization because of injuries sustained while playing rugby, and there was a mixture of anterior and posterior labral repairs performed. Patient characteristics are outlined in Table 3. Operations took place between June 2015 and June 2016.

Suture Anchor Grading

When the values for both 3-week and 6-month scans were averaged, the biocomposite anchors had a mean grade of 2.04 (SD, 0.944; 95% CI, 1.599-2.483), whereas the all-suture anchors had a mean grade of 1.420 (SD, 0.860; 95% CI, 1.017-1.823). An independent t test revealed that there was a statistically significant difference in the mean grading between the biocomposite and the all-suture anchors, with the all-suture anchors receiving a lower mean grade, $t(38) = 2.175$ ($P = .036$). The mean difference in grading was 0.621 (95% CI, 0.043-1.199), demonstrating a medium effect size ($d = 0.69$).

For the 3-week scans, the biocomposite anchors had a mean grade of 1.53 (SD, 0.858; 95% CI, 0.916-2.144), whereas the all-suture anchors had a mean grade of 1.18 (SD, 0.371; 95% CI, 0.920-1.450). An independent t test found no statistically significant difference between these grades, indicating a similar degree of osteolysis surrounding each suture anchor type, $t(18) = 1.169$ ($P = .258$) (Figure 4).

For the 6-month scans, the biocomposite anchors had a mean grade of 2.55 (SD, 0.753; 95% CI, 2.013-3.090), whereas the all-suture anchors had a mean grade of 1.62 (SD, 1.087; 95% CI, 0.847-2.402). An independent t test revealed a statistically significant difference, with the all-suture anchors having a lower level of osteolysis, $t(18) = 2.217$ ($P = .040$). The mean difference in grading was 0.927 (95% CI, 0.048-1.805), demonstrating a large effect size ($d = 1.05$).

Interrater Reliability

An ICC was used to determine the interrater reliability because of the high number of raters and ordinal data set. The ICC estimate for interrater reliability was 0.975 (95% CI, 0.962-0.985), suggesting excellent reliability between the raters.

DISCUSSION

The purpose of this study was to evaluate the development of osteolysis at the implantation sites of 2 types of glenoid suture anchor: a solid biocomposite anchor and an all-suture anchor. Specifically, we aimed to ascertain whether the relatively novel all-suture anchor caused a decreased level of osteolysis and bone cyst formation when compared with the biocomposite anchor. We found that 33 blinded raters independently graded all-suture anchors as having significantly less osteolysis at 6 months than biocomposite anchors, although at 3 weeks, the mean grade of the all-suture anchors was comparable with that of the biocomposite anchors (Figure 4).

A number of processes could have contributed to the difference in bone response seen between the biocomposite and all-suture anchors. While this may warrant further investigation, the cause of the difference in bone response was outside the remit of this study.

Each rater in this study had at least 5 years of experience as a surgeon or radiologist. A total of 40 scans were chosen from the 126 available to decrease the time taken to complete the questionnaire, with the aim of increasing the response rate. Of the 38 raters that started the questionnaire, 33 finished. The responses for the 5 raters who did not complete all questions were excluded from the statistical analysis. Since the grading system was novel, a certain amount of personal interpretation of the system was likely. We assumed the raters were consistent with their interpretation throughout the questionnaire, and hence including results from raters who did not finish could have affected the results of the questions at the end of the survey. Interrater reliability was assessed using an absolute-agreement, 2-way random-effects model ICC statistic, which showed excellent reliability between the raters (0.975; 95% CI, 0.962-0.985).

Clinically, fluid and osteolysis surrounding the suture anchors increases the risk of anchor pullout and failure.[6] The weakened bone is also a failure point for recurrent injury, as borne out by studies showing failure at anchor-related osteolytic bone cysts.[2] This bone response could also have implications for revision surgery because of the loss of suitable bone for further anchor implantation.

Our study had several limitations. First, the results are only valid for the anchors that were tested in this study. Other biocomposite and all-suture anchors may show different levels of bone response, and similarly, metal or nonresorbable polymer anchors may show further different levels of bone response. There was also a relatively small number of MRI scans in each type and time groups (n = 10); however, as mentioned, this was done as a trade-off to increase the rater response. Although statistically significant results were obtained, it would be sensible to repeat this study with a larger sample size, perhaps of solely 6-month scans. Further follow-up may also be needed to measure the full effect of resorption of biocomposite

anchors on the glenoid. Bone response could improve over time as biocomposite anchors resorb or osteolysis could further progress.

Another limitation was the novel grading system and the subtle differences between grades. A number of raters commented that they found it difficult to distinguish between the lower grades. Although the raters each had access to training material, perhaps a more involved training and understanding of the grading system is necessary. On the other hand, while raters may have felt that the grading system was difficult to use, interrater reliability was found to be excellent. An additional limitation concerns image selection. The images selected were not randomized but chosen based on the clarity of the MRI. This was done in an attempt to aid the raters, who would be inexperienced with the grading system, and to obtain more consistent results; the raters themselves were blinded to the identity of the patient and the suture anchor type they were grading. Finally, while raters were assumed to be consistent in their grading of suture anchors, this was not explored. In future studies, a washout period and repeat of the questionnaire could be performed to investigate intrarater reliability.

CONCLUSION

Our results indicated significantly lower levels of osteolysis developing around an all-suture anchor compared with the bone response to a biocomposite anchor at 6 months postsurgery. The rating system we used was found to have excellent interrater correlation and may be valuable for future studies measuring bone response to suture anchors. Further clinical significance could be explored by investigating the correlation between cyst formation at 6 months and repair failure at a timepoint further in the future.

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