

Magnetic resonance appearance of bioabsorbable anchor screws for double row arthroscopic rotator cuff repairs

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ABSTRACT

Background: Little is known about the bioabsorbable, anchor related postoperative changes in rotator cuff surgery, which has become more popular recently. The purpose of the present study was to use magnetic resonance imaging (MRI) to analyze the degradation of bioabsorbable anchors and to determine the incidences and characteristics of early postoperative reactions around the anchors and their mechanical failures.

Materials and Methods: Postoperative MRIs of 200 patients who underwent arthroscopic rotator cuff repair were retrospectively analyzed. The tissue reactions around the bioanchors included fluid accumulations around the anchor, granulation tissue formation and changes in the condition of the surrounding osseous structure. The condition of the bioanchor itself was also examined, including whether the bioanchor failed mechanically. In the case of mechanical failure, the location of the failure was noted. Serial MRIs of 18 patients were available for analysis.

Results: The total number of medial row bioanchors was 124, while that of the lateral row was 338. A low signal intensity rim suggestive of sclerosis surrounded all lateral row bioanchors. Ninety three lateral row bioanchors (27%) showed a rim with signal intensity similar to or less than that of surrounding bone, which was granulation tissue or foreign body reaction (FBR). Similar signal intensity was seen around nine medial row bioanchors (7%). Fluid accumulation was seen around 4 lateral row bioanchors (1%) and around 14 medial row bioanchors (11%). Five lateral row bioanchors showed the breakage, while there was none in the medial row bioanchors. There were nine cases with a cuff re-tear (4.5%). There was no evidence of affection of glenohumeral articular surfaces or of osteolysis around any bioanchor. In serial MRI, there was no change in appearance of the bioanchors, but the granulation tissue or FBR around four bioanchors and the fluid around one bioanchor showed a decrease in successive MRI.

Conclusion: This study highlights the normal and adverse reactions to Bioabsorbable anchors that surgeons can expect to see on MRI after rotator cuff repairs.

Key words: Anchor screws, bioabsorbable screws, magnetic resonance imaging, rotator cuff repair

MeSH terms: Shoulder, rotator cuff, magnetic resonance imaging, arthroscopy, bone screws

INTRODUCTION

Rotator cuff surgery has evolved over time, with more surgeons making the transition from open surgery to arthroscopic repair; the demand for

a suitable implant has increased. Metal anchors were initially promising, but their use was associated with several complications.¹ Bioabsorbable anchors were introduced to overcome the shortcomings of the metal anchors. They provide equivalent fixation strength as metal anchors are absorbed over time and make imaging easier after surgery.^{2,3} With regard to the latter, postoperative magnetic resonance imaging (MRI) evaluation allows the adjacent soft tissue and bone reactions to be imaged, which is not feasible with other imaging methods. Despite these advantages of bioabsorbable anchors, various reactions around the bioabsorbable screws, especially those used in anterior cruciate ligament (ACL) reconstruction have been reported.⁴ However, little is known about the bioabsorbable, anchor related postoperative changes when these anchors are used in rotator cuff surgery, especially in double row repairs such as the suture bridge technique, which has become more popular recently.⁵

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The present study analysed the use of MRI for bioabsorbable anchors degradation the incidences and characteristics of early postoperative reactions around the anchors and their mechanical failures.

MATERIALS AND METHODS

659 patients who had undergone rotator cuff repair between January 2006 and November 2011 were included in study. A retrospective study was carried out after approval from the institutional review board and the Ethical Committee. The postoperative MRI of these patients were collected and analyzed. The inclusion criterion was patients with bioanchors inserted in the greater tuberosity for the rotator cuff repair. MRI of patients with metal anchors in addition to the bioanchors without artifacts was included. MR of the patients who had open cuff repairs, repairs with trans-osseous stitches, repairs with metal anchors only and MRI with artifacts due to metal anchor were excluded. After the exclusions, the MRI of 200 patients were included in the study.

The average duration of followup MRI after surgery was 4.7 months (range 3–17 months). All the MRIs were done on a 1.5-T unit (Signa; GE Medical Systems, Milwaukee, WI) with a shoulder coil. The sequences used for the examination included an oblique coronal T2-weighted spin-echo sequence (echo time, 80 m s; repetition time, 2988 m s), an oblique sagittal T2 weighted spin-echo sequence (echo time, 80 m s; repetition time, 5739 m s), and an axial T2 weighted spin-echo sequence (echo time, 12 m s; repetition time, 575 m s).

The MRI were assessed by two radiologist with fellowship in musculoskeletal radiology. The age and sex of the patient and the side involved were noted, as were the duration after surgery and the number of bioanchors in the medial and lateral row.

The tissue reactions around the bioanchors included fluid accumulations around the anchor, granulation tissue formation and changes in the condition of the surrounding osseous structure. The condition of the bioanchor itself was also examined, including whether the bioanchor failed mechanically. In the case of mechanical failure, the location of the failure was noted. Retearing of the rotator cuff and the condition of the glenohumeral joint surfaces were also noted. The tissue reactions around the bioanchors were defined as follows. Signal intensities around the bioanchor that matched the signal intensity of cortical bone were considered to indicate bone sclerosis, whereas signal intensities around the bioanchor that matched the signal intensity of bone marrow were considered to indicate granulation tissue or foreign body reaction (FBR). Hyperintensity was considered to indicate fluid. Osteolysis

was diagnosed when the normal marrow fat around the suture anchors was replaced by tissue whose signal was hypointense to water on T2-weighted images (T2WI).⁶ The postoperative cuff condition was classified as described by Sugaya *et al.*³ We also made a note of any abnormal signals in the proximal humerus in the preoperative MRI so as not to falsely label the findings in postoperative MRI.

Material properties of the bioanchor screw

The medial row anchor used in this series was Bio-Corkscrew (Arthrex, Naples, FL) and the lateral row anchor was Pushlock (Arthrex, Naples, FL). The medial row anchors were composed of poly (L-lactide): Poly (D, L-lactide) (PL/DLA) in a ratio of 70:30, while the lateral row anchors were composed of poly-L-lactic acid (PLLA) in the anchor and polyetheretherketone (PEEK) in the eyelet. PEEK is a nonabsorbable material. There were no anchors completely made of PEEK.

RESULTS

The average age ($n = 200$) was 56.9 years (range 36–75 years). There were 109 males and 91 females. The right shoulder was involved in 149 patients and the left shoulder in 51 patients. The number of medial row bioanchors used was 124, while 338 lateral row bioanchors were used.

All of the lateral row bioanchors had the same or higher MRI signal intensity relative to the surrounding cancellous bone tissue in T2WI. There was a low signal intensity rim around all lateral row bioanchors in T2WI. In the sagittal section, this gave these anchors a “fried egg” appearance [Figure 1]. This rim signal intensity in T2WI was similar to the signal intensity of the cortical bone and was interpreted as bone sclerosis induced by impaction of the bone during the insertion of the anchor.

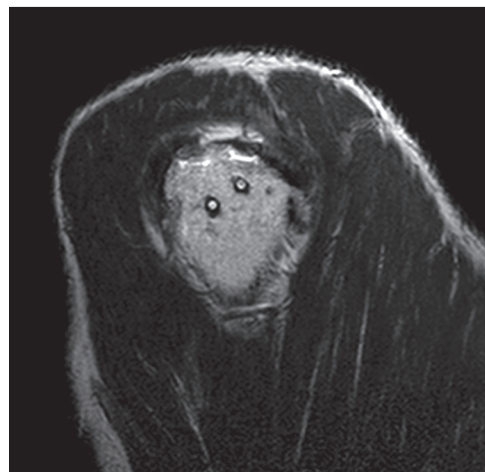


Figure 1: Sagittal T2-weighted images shows the high signal intensity of the lateral row bioanchors surrounded by the low signal intensity bone sclerosis that gives the bioanchors a “fried egg” appearance

Ninety-three lateral row bioanchors (27%) had a rim whose signal intensity was similar to or less than the signal intensity of the surrounding bone but brighter than the signal intensity of the sclerotic rim [Figure 2]. This rim was generally enclosed within the sclerotic rim. This was interpreted as granulation tissue or FBR around the bioanchor.

Fluid accumulation or cystic changes around the bioanchor was noted in four (1%) cases who received lateral row anchors. Two had small fluid collections around the bioanchor, one had a large cystic collection around the bioanchor and the remaining had diffuse fluid collection around the tip of a bioanchor. The anchor with a large cyst around it also had a broken anchor tip [Figure 3]. Three of these bioanchors had an adjoining metal anchor in the medial row, while one had a bioanchor in the medial row.

In contrast to the lateral row bioanchors, the medial row bioanchors had the same signal intensity as cortical bone [Figure 4]. This was observed for all medial row bioanchors. Nine medial row bioanchors (7%) showed some evidence of surrounding granulation tissue or FBR.

Fluid accumulation was seen around 14 medial row bioanchors (11%) [Figure 5], five of which also showed evidence of granulation tissue or FBR [Table 1].

Five of the lateral row bioanchors (1.5%) showed breakage [Figure 5]. Notably, all of the anchors had broken near the tip at the junction of the anchor shaft and its eyelet [Figure 6]. Only one of the broken anchors had a large fluid collection around it. There was no anchor breakage involving the medial row anchors. There was no cuff re-tear adjacent to any broken anchor.

The postoperative condition of the cuff as described by Sugaya *et al.* Types 4 and 5 are considered to be retears. There were nine cases (4.5%) of retearing in total that

Table 1: MRI findings of reactions around the bioanchors

Reaction	Medial row (n=124) (%)*	Lateral row (n=338) (%)*	Total (n=462) (%)*
Granulation	9 (7)	93 (27)	102 (22)
Fluid collection	14 (11)	4 (1)	18 (4)
Breakage	0	5 (1.5)	5 (1)

*Number in parentheses indicates the number of bioanchors. Percentages in parentheses are relative to the respective sample number. MRI=Magnetic resonance imaging

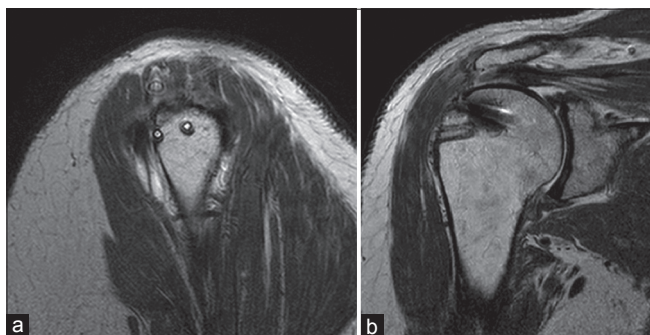


Figure 2: The high signal intensity of a lateral row bioanchor surrounded by isointense granulation tissue and low signal intensity bone sclerosis. (a) Sagittal and (b) Coronal T2-weighted images

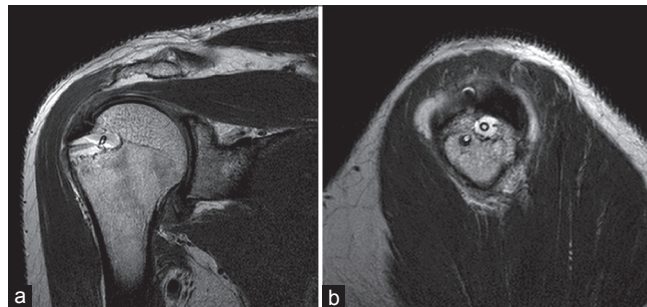


Figure 3: Images showing a large cystic collection around a lateral row bioanchor with anchor breakage. (a) Sagittal and (b) Coronal T2-weighted images

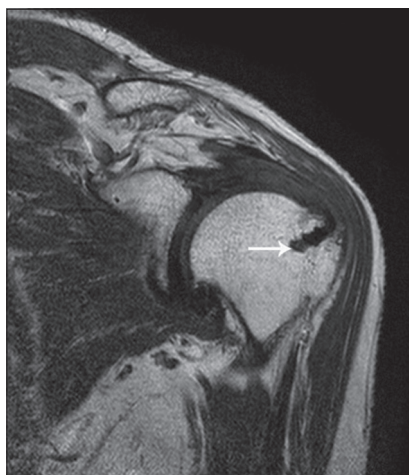


Figure 4: Coronal image showing a medial row bioanchor (arrow)

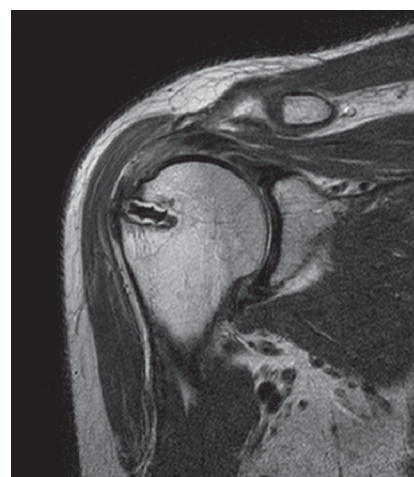


Figure 5: Coronal image of fluid accumulation around a medial row bioanchor

were of small to medium size. When the condition of the glenohumeral joint surface was examined, there was no evidence of glenohumeral arthritis in any of the MRIs. In addition, none of the bioanchors demonstrated osteolysis around them [Table 2].

Serial followup MRIs were available for 18 patients. The average duration of the first followup MRI was 3.8 months (range 3–5 months), while the average duration of the last MRI was 10 months (range 6–17 months). The bioanchors did not change in appearance during this followup period. However, there appeared to be a decrease over time in the granulation tissue or FBR surrounding four bioanchors and in the fluid surrounding one bioanchor [Figure 7]. In the case of two bioanchors with broken tips, neither the bioanchor itself nor the broken fragment had changed at 9 and 17 months, respectively.

Table 2: The postoperative condition of the cuff as described by Sugaya et al.³

Type	Number of cuffs	Definition of type
1	4	Repaired cuff appears to have sufficient thickness compared to the normal cuff, with homogeneously low intensity on each image
2	14	Sufficient thickness compared with normal cuff/associated with partial high intensity area
3	47	Insufficient thickness with less than half the thickness when compared with normal cuff, but without discontinuity, suggesting a partial-thickness delaminated tear
4	6	Presence of a minor discontinuity in only 1 or 2 slices on both oblique coronal and sagittal images, suggesting a small, full-thickness tear
5	3	Presence of a major discontinuity observed in more than 2 slices on both oblique coronal and sagittal images, suggesting a medium or large, full-thickness tear

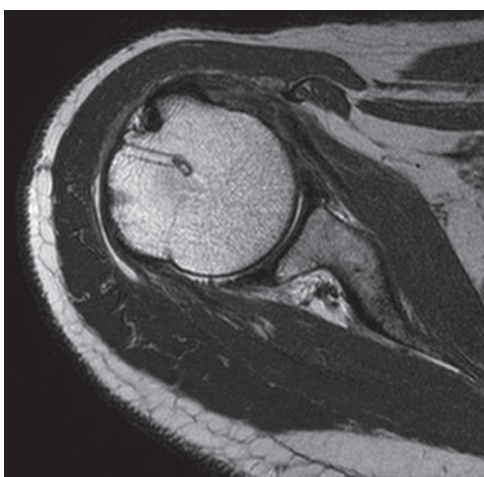


Figure 6: Axial image showing mechanical failure at the junction between the shaft and the eyelet of a lateral row bioanchor

DISCUSSION

Most studies on bioabsorbable screws are based on knee ligament surgery, while the studies on bioabsorbable screws in the shoulder involved only a small number of patients.⁷ The present retrospective study examined the followup MRIs of rotator cuff repair using absorbable implants in 338 lateral row anchors and 124 medial row anchors.

The main advantage of using absorbable suture anchors is that they are absorbed over time, thereby theoretically minimizing or avoiding the problems of migration or interference with revision surgery. They are also generally radiolucent and thus interfere little with imaging studies.⁸ In addition, they appear to be as effective in secure tendon-to-bone repair as metallic suture anchors.⁹ Metallic suture anchors are known to undergo loosening causing failure of fixation, intraarticular loose bodies and articular damage.^{1,10,11} However, the use of absorbable anchors has also been associated with complications, including foreign-body reactions, cyst formation, fluid collection, sterile drainage, osteolysis and chondral damage.⁷

The anchors undergo five stages in terms of bio-absorption. In stage 1, water is absorbed into the rotator cuff anchor from the surrounding environment. In stage 2, the polymer in the rotator cuff anchor undergoes hydrolysis, resulting in decreased holding strength. In stage 3, the rotator cuff anchor fragments and begins to be absorbed, with a resultant decrease in fixation strength. In stages 4 and 5, the implant fragments are phagocytized, and the products enter the Krebs cycle and are eliminated through respiration. The entire process of bio-absorption takes between 5 months and 2 years.¹²

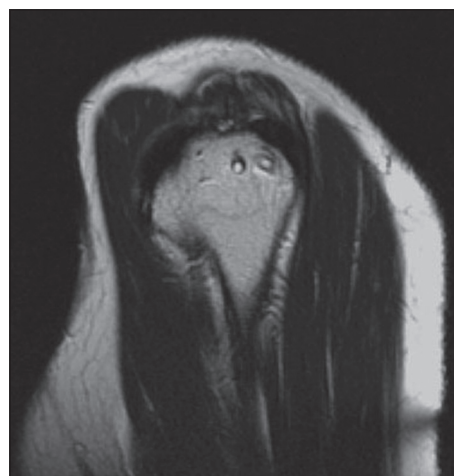


Figure 7: Serial magnetic resonance imaging showing a decrease in the high signal intensity surrounding lateral row anchors at 8 months

In the present study, in the T2WI, a rim of low signal intensity around the lateral row bioanchors that matched the signal intensity of the cortical bone was observed. This sclerotic rim may be caused by the traumatic impaction of the cancellous bone during tapping and the introduction of the bioabsorbable anchors. This gives the anchor a “fried egg appearance” in the sagittal MR images. A similar rim could not be detected around the medial row bioanchors because the anchors had the same signal intensity as the sclerotic rim. This could also be related to the variation in the bone density of the proximal humerus¹³ with denser trabecular regions producing a higher sclerotic reaction than the rarer ones.

Surrounding some anchors was a rim whose signal intensity was similar to that of cancellous bone. This indicated granulation tissue or an FBR to the implant. It was observed in 27% of the lateral row anchors and 7% of the medial row anchors and in 22% of the anchors overall. Some absorbable internal fracture fixation devices are associated with a local sterile inflammatory reaction as early as 8 weeks after the implantation.¹⁴ Microscopic analysis of biopsy material from these cases indicates an intense inflammatory reaction composed of neutrophilic polymorphonuclear leukocytes and small lymphocytes. Monocyte-macrophages and foreign body type giant cells in a granulomatous pattern are also observed.

Saikku-Bäckström *et al.*¹⁵ fixed osteotomies of the femoral diaphysis in 43 adult rabbits with the intramedullary nails of poly-96L/4D-lactide copolymer. The animals were followed up from 3 weeks to 3 years. The bones were studied histologically, microradiographically and by oxytetracycline-fluorescence. In early samples, the implant was surrounded by a thin sheath of connective tissue and after 12 weeks by bone. A small amount of giant cells and foamy macrophages were seen between the implant and the bony capsule. The implant slowly disintegrated and the polymer debris was phagocytosed by macrophages. The implant disappeared almost totally within 3 years, and histology showed only a minor FBR. Macarini *et al.*¹⁶ studied the degradation of poly-D, L-lactic acid interference screws with MRI for 3 years after surgery. In 34 of 35 patients the screw could not be detected as a result of degradation. They noted cyst like formations during the screw degradation process. PLLA has been shown to be completely absorbed by 7 years when used in ACL reconstruction. When complete reabsorption is seen, screws were not replaced with bone but instead consisted of a partially calcified fibrous tissue.¹⁷

Polyetheretherketone on the other hand is a nonbiodegradable, very chemically resistant crystalline thermoplastic. PEEK offers the advantages of good

postoperative imaging¹⁸ and stable fixation while not having the complications associated with polymer degradation. PEEK implants in animals have shown no acute inflammatory response and only mild chronic inflammation.¹⁹ Similar to metals, the major problem has been poor osseointegration. In animals, PEEK implants showed direct bone contact in some areas but cartilage and fibrous interfaces as well.¹⁹ This decreased bone-implant interaction is because the inertness and hydrophobicity of PEEK's surface hinder protein and cell adhesion.^{18,20}

Edwards *et al.* have commented on the adverse reactions to absorbable implants in the shoulder.²¹ These reactions consist of nonspecific granulomatous responses and involve implants made of polyglyconate, not polylactic acid. These investigators also emphasize that significant foreign body giant cell reactions occur with polyglycolide polymers, lactide-glycolide copolymers, and polydioxanone polymers. However, polymers of pure poly L-lactide are not implicated.

Warden *et al.* also observed a variable amount of increased signals around the tibial and femoral tunnels at 2 year followup using bioabsorbable screws in their knee series, but this was only detected on the fat suppressed T2-weighted scans and resolved with time.²² They also detected similar areas of increased signal at the patellar bone plug harvest site. They suggested that the changes noted on the fat suppressed T2-weighted scans indicate a general reaction to a surgical insult (such as thermal necrosis) rather than a specific reaction to the bioabsorbable screws; they speculated that the increased signal may reflect edema or the increased water levels in healing marrow (fibrovascular changes). In their followup at 10 years, they observed that all of the screws had been absorbed. However, all had evidence of intraosseous fluid collections at the tibial screw site and 4 of 6 had fluid collections at the femoral screw site.²³

Fluid accumulation around the anchors was seen in 4% of the bioanchors. The incidence was higher for the medial row bioanchors (11%) than for the lateral row bioanchors (1%). Frank cystic collection was only seen around one lateral row bioanchor. This bioanchor also showed tip breakage. Around all other bioanchors, the fluid accumulation was in the form of a small circumferential collection. Gonzalez-Lomas *et al.* postulated that cysts in arthroscopic ACL reconstructions occur in some patients when a bioabsorbable PLLA interference screw is used.²⁴ They may arise from a foreign body response to the screw breakdown. The incidence of cyst formation in their series was 5%, occurring 2–3 years after reconstruction. None of the cysts recurred once the screw material was removed.

They speculated, therefore, that the presence of screw material played a role in cyst formation. Considering the average period of followup in our series, the presence of fluid could either indicate the initial phase of cyst formation or it could be a normal response to the surgical insult. A longer followup and an extended study may have a different outcome.

Screw breakage has been reported in the literature.^{3,25,26} Glueck *et al.* reported the case of a 20 year old American football player with osteolysis around the site of insertion of PLLA bioabsorbable suture anchors after 8 months of postoperative followup.²⁷ Since the lytic reaction was seen around the anchors that were used to repair a rotator cuff tear and not the anchors (also PL/DLA) that were placed in the glenoid for superior labral tear from anterior to posterior repair, the authors suggested the osteolysis was due to a mechanical cause, rather than a biological cause. Müller *et al.* reported on seven cases of glenoid osteolysis after shoulder stabilization procedures using PLLA anchors.²⁸ None of these patients were symptomatic, showed progressive arthritis, or required repeat surgery. Pilge *et al.* reported osteolysis after rotator cuff surgery using bioabsorbable anchors.⁶ We did not observe any osteolysis in our series.

Chondral damage in response to bioabsorbable implants has also been reported. Athwal *et al.* described four patients in who repeat shoulder arthroscopy was performed between 3 and 18 months after the index surgery.²⁹ All four patients were found to have extensive cartilage destruction of the glenohumeral surfaces, loose bodies, one or more loose anchors and reactive synovitis. In the present study, the appearance of the bioanchors did not change over time. In a study of ACL reconstructions, Warden *et al.* observed that all but one of the 20 bioabsorbable screws was still visible in serial scans until 24 months after surgery.²² These screws showed a minimal decrease in size over time. The one screw that had completely disappeared 8 months after reconstruction had cracked during insertion. Drogset *et al.* measured the volumes of the absorbable screws used in ACL reconstruction 2 years after surgery.³⁰ They observed that approximately two-thirds of the screws had been absorbed. In our series, there appeared to be a decrease over time in the granulation surrounding four bioanchors and in the fluid surrounding one bioanchor. This is similar to the observation of Warden *et al.*, who found that the abnormal signal around the ACL graft and anchor resolved with time and who suggested the abnormal signals were probably the results of surgical insult.

The weakness of the present study is that the average period of followup at which the MRIs were obtained was

only 4.7 months (range 3–17 months). This did not allow us to comment on long term complications or the natural history of the anchors and the reactions seen around them. Within the established literature there are no clear guidelines which can differentiate normal from abnormal signal changes in the early postoperative period, this study intends to open a discussion in the shoulder community so that further long term prospective studies can be carried out to know the behavior of the implanted bioanchors in rotator cuff repair. In addition, the radiological findings were not correlated with clinical and functional outcomes of the patients. This prevented us from commenting on the long term complications or the natural history of the anchors and the reactions seen around them or on how those radiological changes present clinically and affect the functional scoring in the patient. A correlation with histopathology of the observed lesions would have also helped in further understanding the processes around the bioanchors, but it would be ethically inappropriate to subject patients to a biopsy just for research purposes.

CONCLUSION

The present study aimed to highlight some of the normal responses and adverse reactions that are associated with the use of bioabsorbable anchors in rotator cuff repair. In early postoperative period, 27% presented granulation tissue around the lateral bioanchor screws and 11% fluid accumulation around the medial bioanchor screws. A longer followup period with a large series such as ours can help to delineate the normal from the abnormal responses and provide direction in the development of safer and more reliable materials.

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