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# Osteolysis is observed around both bioabsorbable and nonabsorbable anchors on serial magnetic resonance images of patients undergoing arthroscopic rotator cuff repair

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ABSTRACT

*Objectives:* The objective of this study was to evaluate the incidence of osteolysis around the bioabsorbable and nonabsorbable anchors using serial magnetic resonance imaging (MRI) and to determine the relationship between osteolysis and the retear rate after arthroscopic rotator cuff repair.
*Methods:* From July 2012 to July 2014, 50 patients [28 men and 22 women; mean age, 56.4 (range: 45–56) years] underwent arthroscopic rotator cuff repair for a medium-to large-size tear with double-row suture-bridge technique. The bioabsorbable anchors used in the medial row comprised hydroxyapatite-polylactic acid enantiomer, and the nonabsorbable anchors in the lateral row were polyetheretherketone (PEEK)-type anchors. All patients underwent MRI evaluation at 3, 6, and 12 months postoperatively to determine osteolysis and identify any retear.
*Results:* The incidences of osteolysis at 3, 6, and 12 months postoperatively were 1%, 4%, and 6% with nonabsorbable anchors and 13%, 29%, and 39% with bioabsorbable anchors, respectively. The incidences of osteolysis were significantly higher with the bioabsorbable anchors than with the nonabsorbable anchors ($P < 0.005$ for all three follow-ups). There was no significant difference between osteolysis and non-osteolysis groups regarding the retear rate or retear size ($P = 0.189$ and 0.069, respectively).
*Conclusions:* Osteolysis was common around bioabsorbable anchors used for arthroscopic rotator cuff repair, and it also occurred around the PEEK-type nonabsorbable anchors. The incidence of osteolysis of nonabsorbable anchors was significantly lower than that of bioabsorbable anchors. Osteolysis did not significantly affect rotator cuff retear after arthroscopic repair with either bioabsorbable or nonabsorbable anchors.
*Level of evidence:* Level III, Therapeutic Study.


## Introduction

The use of suture anchors for rotator cuff repair has created a transosseous option for surgeons.[1] and has greatly improved arthroscopic rotator cuff repair procedures. When using metallic anchors, potential complications include loosening, migration, and chondral injury. An additional major drawback includes their interference with postoperative MRI evaluation, which can yield artifacts.[2,3] These limitations have encouraged researchers to develop bioabsorbable anchors; however, issues related to the material used, i.e., polyglycolic acid (PGA), remain to be resolved.

*Abbreviations:* MRI, magnetic resonance imaging; HA, hydroxyapatite; PEEK, polyetheretherketone; PGA, polyglycolic acid; PLLA, polylactic acid enantiomer.

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The first generation of bioabsorbable anchors (PGAs) provides sufficient strength to the soft tissue to co-opt the bone, but obvious complications such as rapid loss of fixation, mechanical failure, loose body formation, synovitis, and osteolysis have been reported.[4,5] The next generation of bioabsorbable anchors was manufactured from polylactic acid enantiomers (PLLAs). These bioabsorbable anchors degrade at a slower rate than PGA anchors,[6] but have been associated with foreign body reactions, osteolysis, synovitis, anchor failure, and chondrolysis.[4,7]

Polyetheretherketone (PEEK) is a nonabsorbable, highly unreactive compound that is resistant to chemical, thermal, and radiation-induced degradation. Moreover, PEEK is a rigid, semi-crystalline thermoplastic polymer with excellent mechanical properties.[8] However, a previous study has shown that PEEK resulted in mild chronic inflammation in an animal model.[9] Moreover, a case report has described osteolysis around PEEK suture anchors.[10]

However, only few studies have focused on the incidence of osteolysis around PEEK anchors compared with that around PLLA-type anchors, with no studies to date assessing the relationship between osteolysis and rotator cuff retear.

Thus, the aims of this study were (1) to prospectively evaluate the incidence of osteolysis around the bioabsorbable (PLLA-type) and nonabsorbable (PEEK-type) anchors in a cohort using serial MRI; (2) to study the relationship between osteolysis and the retear rate. Our null hypotheses were that (1) osteolysis occurs around both bioabsorbable and nonabsorbable anchors and (2) there is no correlation between osteolysis and the retear rate.

## Material and methods

Institutional Review Board approval was obtained before starting this study. From July 2012 to July 2014, 50 patients (28 men and 22 women) who underwent arthroscopic rotator cuff repair were enrolled. Inclusion criteria were patients who had undergone arthroscopic rotator cuff repair for a medium- or large-size full-thickness rotator cuff tear. Surgery was performed using the double-row suture-bridge technique with bioabsorbable (PLLA-type) anchors in the medial row and nonbioabsorbable anchors in the lateral row. Patients underwent serial MRI at 3, 6, and 12 months postoperatively. Exclusion criteria were patients who had undergone revision surgery, open rotator cuff repair, single-row arthroscopic rotator cuff repair, or glenohumeral surgery; patients with metal anchors; and patients with inadequate serial MRI follow-up images.

Patients were divided into two groups: osteolysis and non-osteolysis groups. The mean patient age was 56.4 (range: 45–76) years. In this study, 100 bioabsorbable 4.5 mm anchors (TwinFix Ultra Suture Anchor, Smith & Nephew, MA, USA) and 100 nonabsorbable knotless 4.5 mm anchors (Footprint Ultra Suture Anchor, Smith & Nephew, MA, USA) were used. The Twinfix Ultra HA 4.5 mm Anchor comprised 25% hydroxyapatite (HA) and 75% PLLAs. The Footprint Ultra PK Knotless 4.5 mm anchor comprised PEEK. Each patient received two bioabsorbable and nonabsorbable anchors on the medial and lateral sides, respectively.

All patients underwent serial follow-up MRI in the same setting. All MRI examinations were performed using a 3.0-T Gyroscan Intera Achieva scanner (Philips Medical Systems, Best, The Netherlands) and evaluated by two musculoskeletal radiologists, with any discrepancies resolved in a consensus meeting; if a disagreement persisted, a senior radiologist was consulted.

As previously reported,[11] osteolysis was defined as high signal intensity around the bioabsorbable anchor in a T2 coronal image with definite fluid collection. Grade 1 osteolysis was defined as linear fluid collection around the anchor; grade 2 osteolysis was defined as local fluid collection around any part of the anchor; grade 3 osteolysis was defined as fluid collection around the entire length of the anchor, with a cyst diameter less than twice the anchor diameter; and grade 4 osteolysis was defined as a cyst diameter greater than that in grade 3 osteolysis.[11] When a rotator cuff retear was identified, the retear size was measured using images in both the coronal and sagittal planes according to the criteria reported by Sugaya et al.[12] T2-weighted MR images were used to assess the incidence and timing of osteolysis. Follow-up MR images were divided into two groups based on whether the patients exhibited changes in osteolysis on their serial MR images. Subsequently, the retearing rates were compared.

### *Statistical analyses*

Statistical analyses were performed using Student's paired *t*-test to determine whether there was any significant difference between the 3- and 6-month, 6- and 12-month, and 3- and 12-month follow-up groups in terms of the incidence of osteolysis using both the bioabsorbable and nonabsorbable anchors. To determine significant differences between the osteolysis and non-osteolysis groups in terms of the retear rate, Student's independent *t*-test was used. The threshold for significance was set at $P < 0.05$.

## Results

The demographic data of all patients included in the study is described in Table 1. The incidence of osteolysis at 3, 6, and 12 months was 1%, 4%, and 6% for nonabsorbable anchors, whereas it was 13%, 29%, and 39% for bioabsorbable anchors, respectively. Overall, the incidence of osteolysis was significantly higher with the bioabsorbable anchors than with nonabsorbable anchors ($P < 0.05$ for all three follow-ups).

Our results show that the incidence of osteolysis around bioabsorbable and nonabsorbable anchors significantly increased with follow-up times (Fig. 1). Regarding bioabsorbable anchors, significant differences were observed between 3- and 6-month and between 3- and 12-month follow-ups in terms of the incidence of osteolysis ($P = 0.001$ and 0.001, respectively); however, no significant difference was observed between 6- and 12-month follow-up ($P = 0.07$). Regarding nonabsorbable anchors, no significant differences were observed between 3- and 6-month and between 6- and 12-month follow-ups ($P = 0.08$ and 0.26, respectively); however, the incidence of osteolysis was found to be significantly higher at 12 months than at 3 months ($P = 0.03$).

Of 20 cases in the osteolysis group, 2 retear cases were detected 6 months postoperatively, whereas of 30 cases in the non-osteolysis group, 6 retear cases were detected. Nevertheless, there was no significant difference between the osteolysis and non-osteolysis groups regarding the rate or size of retear ($P = 0.189$ and 0.069, respectively; Table 2). The postoperative rotator cuff repair integrity of both the groups is described in Table 3.

## Discussion

In the present prospective study involving MRI of 50 patients using 100 bioabsorbable (HA-PLLA) and 100 nonabsorbable (PEEK) anchors, the incidence of osteolysis for rotator cuff repair using bioabsorbable anchors was 13%, 29%, and 39% at 3, 6, and 12 months postoperatively, respectively. These findings are in accordance with those of a previous study that reported a 46.4% incidence rate of osteolysis in 209 cases at 10 months postoperatively and a rate of 46.7% in 30 cases from 12 to 36 months postoperatively.[11,13] Previous studies have described a high incidence of osteolysis around the bioabsorbable anchors after rotator cuff repair; however,

**Table 1**
Patient demographic data.

| Descriptive | | No. of Subjects | % |
|---|---|---|---|
| Age (years) | 30–39 | 2 | 4 |
| | 40–49 | 4 | 8 |
| | 50–59 | 26 | 52 |
| | 60–69 | 16 | 32 |
| | >70 | 2 | 4 |
| Sex | Female | 22 | 44 |
| | Male | 28 | 56 |
| Initial presenting symptoms | Night pain | 50 | 100 |
| | ROM pain | 18 | 36 |
| | Pseudo-paralysis | 10 | 20 |
| Involved shoulder | Right | 40 | 80 |
| | Left | 10 | 20 |
| Operation on dominant extremity | Yes | 35 | 70 |
| | No | 15 | 30 |
| Tear size | Small | None | 0 |
| | Medium | 40 | 80 |
| | Large | 10 | 20 |
| Rotator cuff re-tear | Yes | 9 | 18 |
| | No | 41 | 82 |
| Sugaya classification of post-operative cuff integrity | Type 1 (Sufficient thickness of repaired cuff) | 11 | 22 |
| | Type 2 (Sufficient thickness of repaired cuff with partial high intensity area) | 30 | 60 |
| | Type 3 (Insufficient thickness of repaired cuff with less than half cuff thickness without discontinuity) | None | 0 |
| | Type 4 (Small full thickness tear) | 5 | 10 |
| | Type 5 (Medium to Large full thickness tear) | 4 | 8 |

osteolysis around nonabsorbable anchors has rarely been described.[11,13] Shahrulazua et al have reported a case of perianchor radiolucency after the use of a PEEK suture anchor.[10] However, in the present study, osteolysis was observed around 6 nonabsorbable anchors (Fig. 2). To our knowledge, this is the first study reporting 6 cases with osteolysis, observed on postoperative serial MR images, after using a PEEK suture anchor.

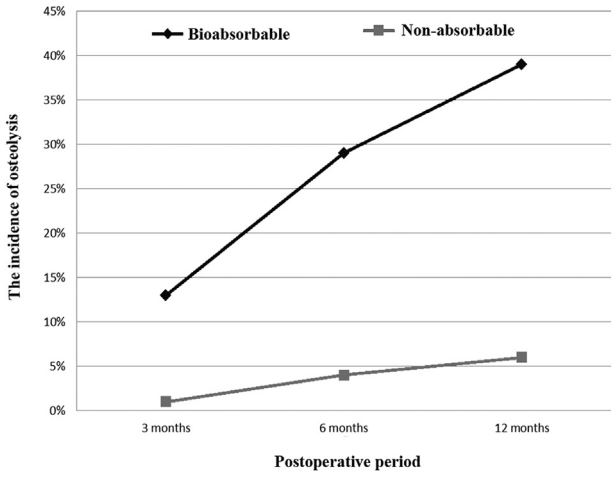


**Fig. 1.** The incidences of osteolysis of bioabsorbable and non-absorbable anchors were increasing with times.

The main underlying cause of osteolysis in the shoulder remains debatable. Generally, three factors are thought to contribute to osteolysis: foreign body reaction, mechanical factors, and biological factors.[13–16] The most important consideration regarding mechanical factors is the location of anchor placement in the greater tuberosity. Regional variance regarding greater tuberosity microarchitecture suggests that the optimal placement for an anchor expands from the articular margin (proximal region) to the apex of the greater tuberosity (intermediate region).[17] In the present study, no migration of the anchor or "pull-out" phenomenon was observed in follow-up MRI assessments, despite serial MR images showing severe osteolysis (Fig. 3). Thus, we oppose the idea that excessive tractive load and mechanical factors are the main reasons for osteolysis in the humeral head.

In this study, osteolysis was observed around not only bioabsorbable but also nonabsorbable anchors. Furthermore, in some cases, the grade of osteolysis was higher than that at the preceding follow-up around bioabsorbable anchors compared with that around nonabsorbable anchors (Fig. 4). In this study, bioabsorbable anchors comprising HA-coated PLLA were used. HA exists naturally in the body and, thus, represents a naturally biocompatible compound with excellent osteoconductive activity on degradation.[18,19] Conversely, it has been reported that complete PLLA degradation may require several years and that osseous replacement might never be complete.[20,21] Furthermore, several authors have reported

**Table 2**
The fundamental information about osteolysis and non-osteolysis group.

| | Age (year) | Re-tear rate | Re-tear size (no. of cases) |
|---|---|---|---|
| Osteolysis group (n = 20) | 57.8 | 10% | small = 2 |
| Non-osteolysis group (n = 30) | 56.1 | 20% | small = 3, medium = 3, large = 1 |
| p-value[a] | 0.264 | 0.189 | 0.069 |

[a] Student's independent t-test.

**Table 3**
Comparison of postoperative rotator cuff integrity with Sugaya criteria between osteolysis and non-osteolysis group.

| Sugaya classification of post-operative cuff integrity | Osteolysis group (n = 20) | Non-osteolysis group (n = 30) |
|---|---|---|
| Type 1 | 4 (20%) | 7 (23.3%) |
| Type 2 | 14 (70%) | 16 (53.3%) |
| Type 3 | None | None |
| Type 4 | 2 (10%) | 3 (10%) |
| Type 5 | None | 4 (13.4%) |

significant incidences of osteolysis after using PLLA anchors for rotator cuff repair.[11,13,22] The nonabsorbable anchors used in this study comprised PEEK, a nonabsorbable, highly unreactive material that is resistant to chemical, thermal, and radiation-induced degradation[8] but has been reported to cause mild chronic inflammation in an animal model.[9] Considering all these findings, we propose that the main cause of osteolysis in the humeral head is the biological factors involved in the degradation of anchors as well as articular and synovial fluid, rather than mechanical factors. Although the pathophysiology of cysts in the humeral head with rotator cuff tears remains controversial, a previous study has suggested that the main reasons are bare bones and synovial fluid.[23] However, based on our knowledge, we propose that the integrity of the bone is damaged when the surgeon drills a hole to screw-in the anchor, and simultaneously the articular and synovial fluid penetrates into the bone through the crack between the bone and anchor, thus creating a cyst. Alternatively, as a consequence of the natural design of the bioabsorbable anchor, articular and synovial fluid can permeate into the bone along the sutures and through the hole in the center of the anchors. These hypotheses are in agreement with the findings of Simoman et al[24] and Manhan et al.[25]

Previous studies have also assessed the importance of various aspects of screw geometry.[26] However, to date, no study has compared the influence of osteolysis with different screw geometries. In this study, a significantly higher incidence of osteolysis was observed around bioabsorbable anchors (suture anchors) than around nonabsorbable anchors (knotless suture anchors). The main difference between the suture and knotless suture anchors is that the former has a hole in its center. We postulate that an anchor with a center hole promotes additional fluid penetration into the bone. Thus, it increases the chance of occurrence of osteolysis and escalates the osteolysis grade. Hence, we hypothesized that the main causes for osteolysis are degradation of anchors, and penetration of synovial and articular fluid. Alternatively, an anchor with a center hole could be a sole catalyst for osteolysis. These factors may explain a higher incidence of osteolysis around bioabsorbable anchors than around nonabsorbable anchors in our study.

Additionally, no significant difference was found between the osteolysis and non-osteolysis groups regarding the retear rate ($P = 0.189$). Therefore, osteolysis in the humeral head around the anchors had no significant correlation with the retear incidence in rotator cuff repair. Pilge et al have also reported a high rate of osteolysis after rotator cuff repair with bioabsorbable anchors; they found that the recurrent tears were not significantly different between the osteolysis and non-osteolysis groups.[11,13] Shahrulazua et al have also shown that osteolysis around PEEK anchors was

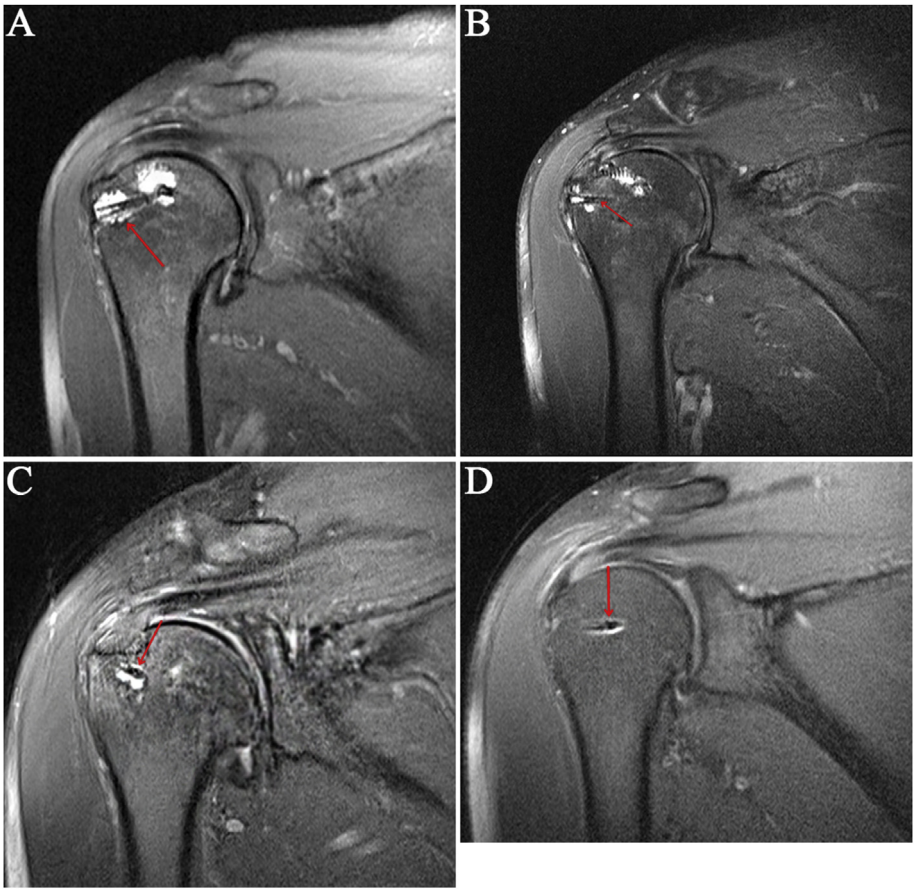


**Fig. 2.** (A), (B), (C), and (D) MR images of four patients shown severe osteolysis around non-absorbable anchors (red arrow direct a non-absorbable anchor).

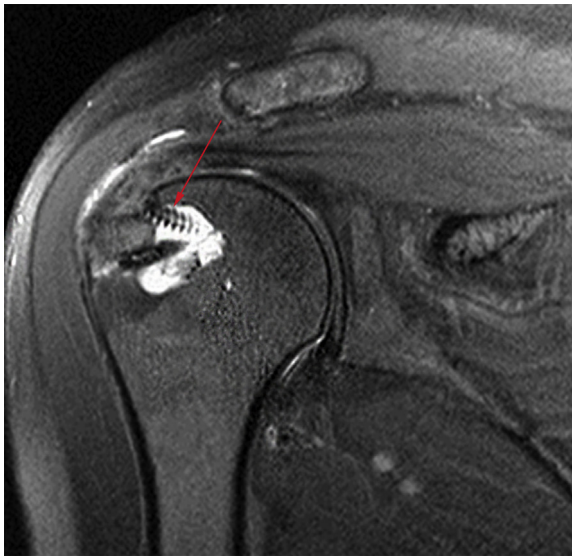

**Fig. 3.** MR images of a patient 12 months after surgery showing severe osteolysis (red arrow direct a bioabsorbable anchor).

related to the recurrent shoulder instability after arthroscopic shoulder stabilization with PEEK anchors, although several other studies did not find a correlation between outcomes and the osteolysis after arthroscopic rotator cuff repair with bioabsorbable anchors. On the basis of our study results and previous reports, we suggest that osteolysis is a common complication after arthroscopic rotator cuff repair with both bioabsorbable and nonabsorbable anchors and that it does not significantly affect postoperative outcomes.

This study had some limitations. We did not evaluate the postoperative function of the shoulders; thus, we could determine the correlation between osteolysis in the humeral head and the postoperative function of the shoulder. We included all double-row rotator cuff repairs that used bioabsorbable anchors in the medial row and nonabsorbable anchors in the lateral row. We believe that conducting formal statistical analysis to compare the functional outcomes between the osteolysis and non-osteolysis groups is unequivocal, which may lead to a weak conclusion. However, previous studies have reported that the bioabsorbable anchors did not significantly affect postoperative clinical outcomes in shoulder or knee joints and instead osteolysis occurred at the surgical site.[11,13,27] The relatively high cost of MRI examination also limits our MRI follow-up period. Despite the relatively short period of serial MRI collected in this study, we believe such consecutive MRI information will provide salient clinical information for shoulder surgeons. Another limitation is that the number of cases enrolled was relatively small; thus, it was difficult to detect certain patterns in the pathophysiology of osteolysis around bioabsorbable and nonabsorbable anchors in rotator cuff repair.

In summary, and despite the aforementioned weaknesses, important conclusions can be drawn from the present findings for homogenous patients in a prospective cohort using serial MRI. The

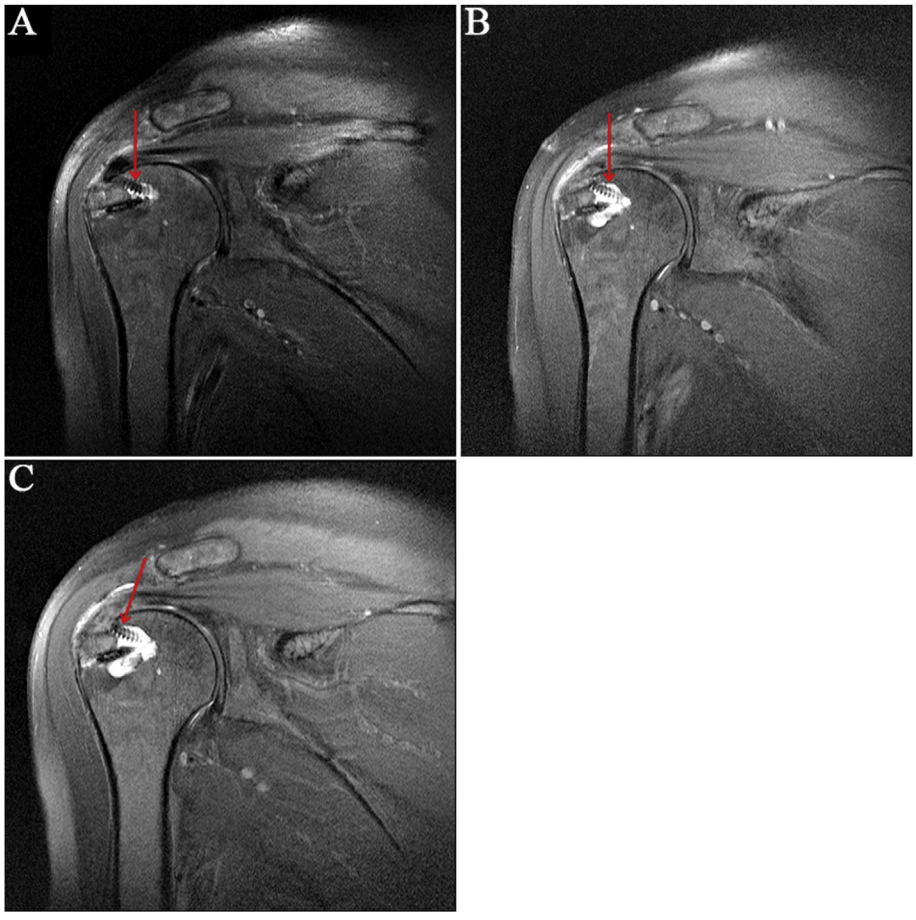


**Fig. 4.** (A), (B), and (C) Progression of bioabsorbable osteolysis detected from 3 to 12 months after surgery (red arrow direct a bioabsorbable anchor).

incidence of osteolysis after rotator cuff repair with bioabsorbable anchors was high (39%). Osteolysis occurred around nonabsorbable (PEEK) anchors after arthroscopic double-row rotator cuff repair. However, the incidence of osteolysis was significantly higher using bioabsorbable anchors than using nonabsorbable anchors. No correlation was detected between osteolysis and the retear rate.

## Conclusions

Osteolysis is a common observation around bioabsorbable anchors used for arthroscopic rotator cuff repair and also occurs around the PEEK-type nonabsorbable anchors. However, the incidence of osteolysis around nonabsorbable anchors is significantly lower than that around bioabsorbable anchors. Osteolysis does not significantly affect rotator cuff retear after arthroscopic repair with bioabsorbable and nonabsorbable anchors.

## Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

## Conflicts of interest

None declared.

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