



## Deltoid fascia disruption from the use of a bioinductive collagen scaffold and polyether ether ketone (PEEK) bone staples: a case report



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Bioinductive implants have been used in the repair of partial-thickness and full-thickness rotator cuff tears (RCTs) with successful results.<sup>2–8</sup> Most complications reported with the use of a bioinductive implant have been transient and resolve with time.<sup>2–4,6,7</sup> Rarely is reoperation needed, and the reason for reoperation is often not due to the use of the implant itself. We report a case of implant-related complication involving the polyether ether ketone (PEEK) bone staple used to secure the implant to the lateral aspect of the greater tuberosity resulting in damage to the deltoid fascia and further impingement in a 40-year-old woman. The patient consented to allowing her case to be reported for research purposes.

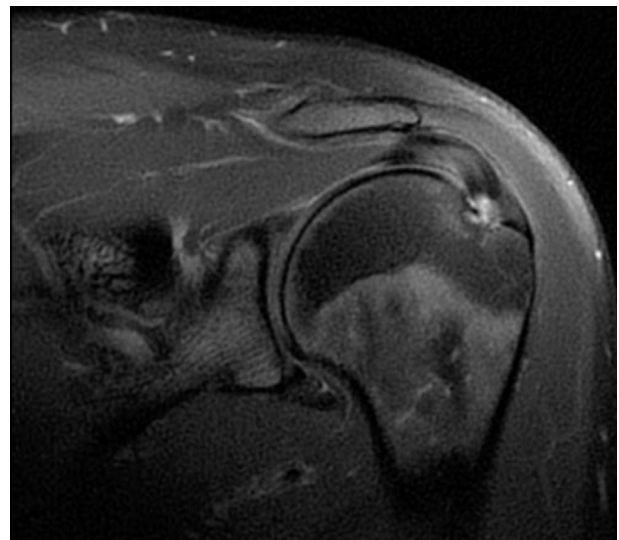
### Case report

An otherwise healthy 40-year-old woman presented with 8 months of left shoulder pain. She was previously treated by her primary care physician for 4 months before arrival at our clinic with two rounds of physical therapy, a subacromial corticosteroid injection. She initially injured her shoulder while moving a heavy object. Her pain was located at the anterior and lateral shoulder with radiation down the biceps. On examination, she had full range of motion (ROM) with full strength grading of the rotator cuff (RC). However, she had pain with resistance during isolated examination of the supraspinatus and a positive Hawkins test for impingement. Specifically, she had full strength to resistance with an empty can maneuver although experienced pain with resistance. She was also tender over the proximal region of the long head of the biceps tendon and at the acromioclavicular joint (ACJ).

Aside from some mild ACJ arthrosis, initial plain radiographs were negative. Joint space was well maintained, and there was no evidence of other acute abnormality. She arrived with a previous MRI, which demonstrated ACJ arthritis, biceps tendonitis, edema, and a low-grade partial articular sided tendon avulsion (PASTA) of the supraspinatus that involved approximately 40% of the tendon thickness (Fig. 1). Because she had failed 4 months of nonoperative

treatment consisting of rest, activity modification, subacromial corticosteroid injection, and physical therapy, it was determined that her next stage would be a planned left shoulder arthroscopy with subacromial decompression (SAD), distal clavicle excision, open subpectoral biceps tenodesis, and possible RC repair pending the status of the RC tendon.

The procedure was performed under general anesthesia in the beach chair position. At the time of surgery, the following was found on arthroscopic examination: long head of the biceps tendon tenosynovitis, PASTA tearing/fraying of the supraspinatus (Fig. 2, A and B), an intact supraspinatus bursal surface (Fig. 2, C), subacromial bursitis with downsloping acromial enthesophyte, torn articular disc with degenerative joint disease, and eburnated cartilage of the ACJ visualized through the arthroscope. Surgery proceeded as planned, and the SAD, distal clavicle excision, and open subpectoral biceps tenodesis were completed without



**Figure 1** Preoperative MRI. T2-weighted coronal view of partial articular sided tendon avulsion (PASTA) tear of the supraspinatus in the left shoulder consisting of approximately 40% of the tendon width. MRI, magnetic resonance imaging.

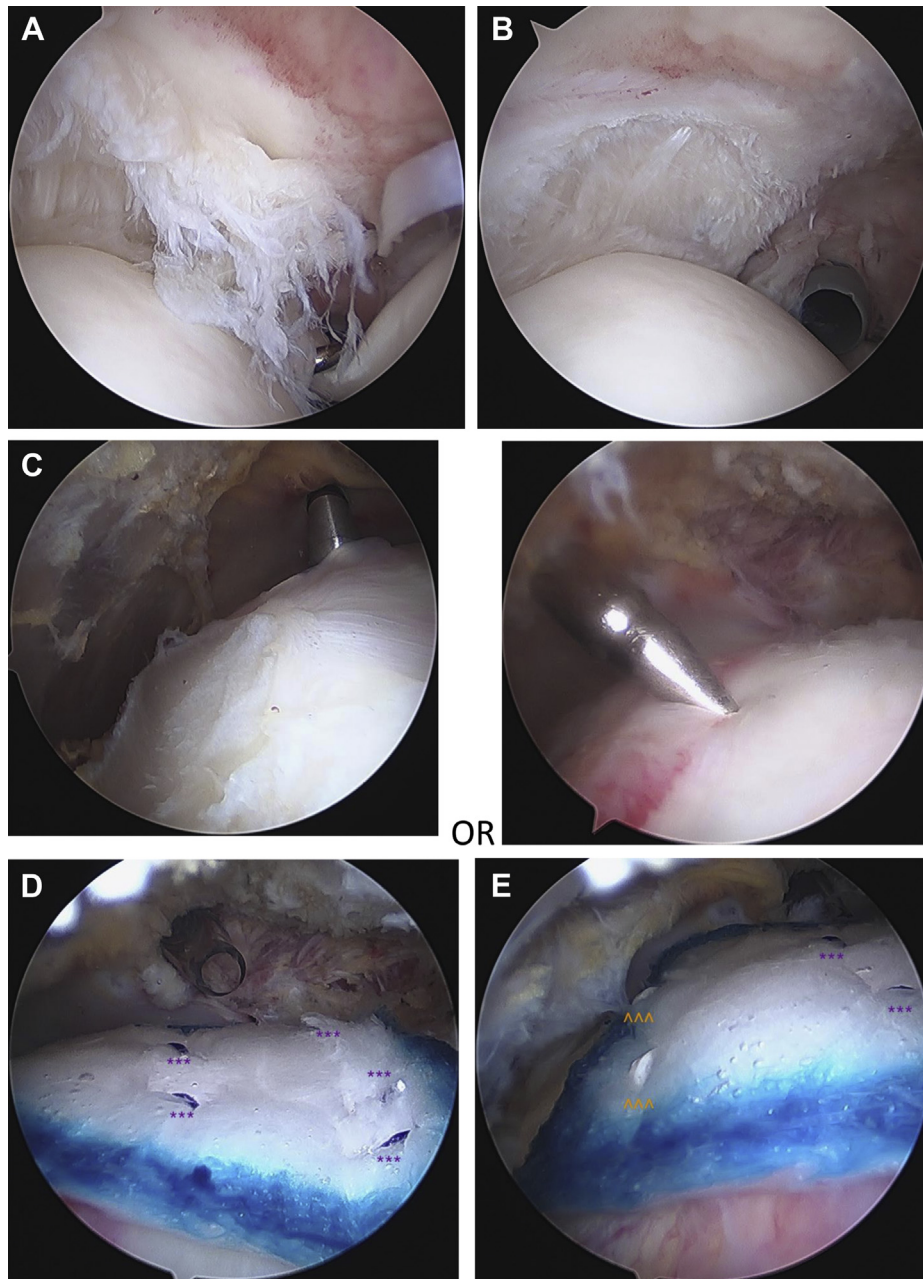
Institutional review board approval was not required for this case report.

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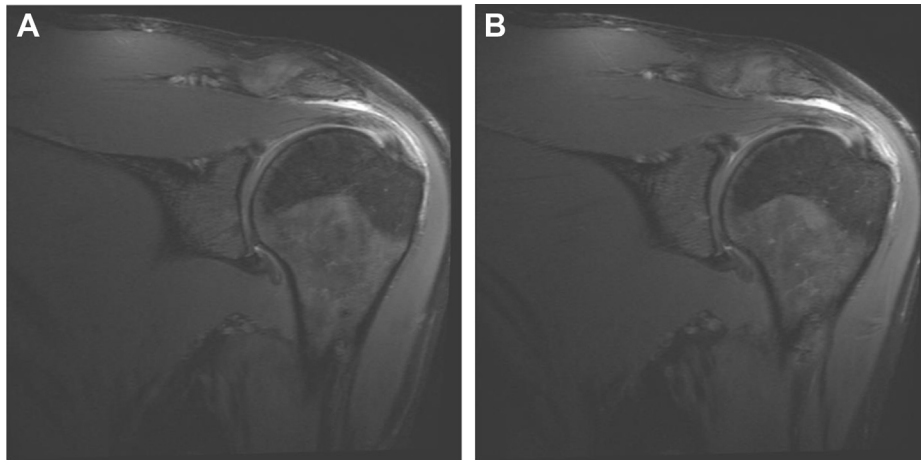
**Figure 2** (A) Partial articular sided tendon avulsion (PASTA) tear. (B) PASTA tear after debridement. (C) Intact bursal surface of supraspinatus. (D and E) Completed rotator cuff repair of PASTA tear with bioinductive implant secured with 5 PDS tendon staples and 2 PEEK bone staples. Purple \*\*\* denote PDS tendon staples. Orange ^^ denote PEEK bone staples. PEEK, polyether ether ketone; PDS, polydioxanone.

complication. The decision was made to repair the RC with a bioinductive collagen implant<sup>3–6</sup> after assessing the appearance of the RCT after debridement (Fig. 2, B and C). The tear was not significant enough to warrant complete takedown with repair as it was less than 50% of the overall tendon width, and the bursal surface was completely intact (Fig. 2, C). The bioinductive collagen implant was secured with 5 polydioxanone (PDS) tendon staples medially and two PEEK bone staples laterally on the greater tuberosity (Fig. 2, D and E). The technique for application of the bioinductive collagen implant has been previously described.<sup>2–8</sup>

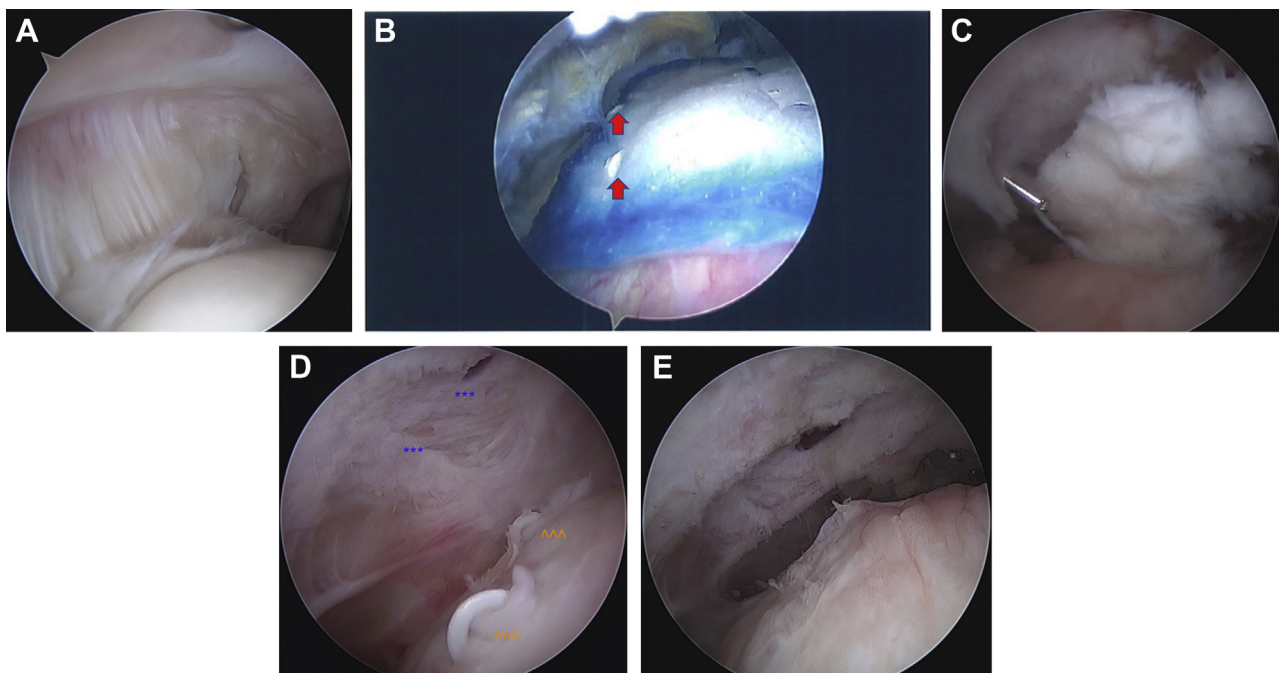
The patient’s initial postoperative period proceeded without issue. She followed our standard physical therapy protocol for subpectoral biceps tenodesis for the first six weeks to protect that repair and then followed it with the protocol for the RC repair with

bioinductive implant according to Schlegel et al.<sup>6</sup> By her 3-month visit, she stated her shoulder was feeling “better and better, but still (subjectively) weak”. At this time point, her therapy was advanced to more aggressive strengthening and functional ROM.

One month later (4 months postoperatively), she returned with complaints of a “grinding sensation” that could be reproduced when the shoulder was brought into abduction followed by internal rotation (IR) and external rotation (ER) of the shoulder. At this time point, she pointed to a specific spot on her anterior deltoid where her pain was localized and consistently reproducible at this specific point. Active ROM was nearly full with active forward flexion (FF) to 170° and active ER to 50°. A follow-up MRI was obtained at that time, which revealed improvement of the supraspinatus defect, evidence of scaffold placement, significant



**Figure 3** (A and B) T2-weighted coronal cuts of repeat MRI of left shoulder 4 months after application of bioinductive collagen implant. Intact PASTA repair with improvement in articular defect. Significant bursal fluid/edema is seen in both cuts, and evidence of implant integration is seen into the supraspinatus. MRI, magnetic resonance imaging; PASTA, partial articular sided tendon avulsion.



**Figure 4** (A) Intact articular portion of supraspinatus after treatment with bioinductive collagen implant 7 months prior. (B) Prominent PEEK staple on the anterior aspect of the greater tuberosity. (C) Loose body found in subacromial space. (D) Deltoid fascia disruption from PEEK bone staple. Blue \*\*\* denote area of deltoid fascia disruption with hole in fascia. Orange ^^ denote PEEK bone staples. (E) Intact bursal surface of the supraspinatus with PEEK bone staples removed. PEEK, polyether ether ketone.

subacromial bursitis with a possible loose body, fluid in the subacromial/subdeltoid bursa, and an intact subjectoral biceps tenodesis (Fig. 3, A and B).

The patient desired to allow more time to heal to see if the problem resolved. She continued physical therapy and a home exercise program for two additional months. At that time, her physical examination was relatively unchanged with the exception of continued and worsening crepitus in the anterior shoulder with FF followed by IR and ER of the shoulder. Tenderness continued at the same point described before at the anterior aspect of deltoid. After no improvement and subjective worsening of pain, a decision was made to return to surgery for a planned arthroscopic evaluation, revision SAD, with possible hardware removal/evaluation 7 months after her initial surgery.

During revision arthroscopy, intra-articular evaluation revealed improvement in the PASTA tear from the articular side (Fig. 4, A) and intact joint space with no chondral degeneration. When brought into the subacromial space, significant bursitis, a prominent PEEK staple on the anterior aspect of the greater tuberosity (Fig. 4, B), and a 1 × 1-cm loose body were encountered (Fig. 4, C). The subacromial bursa was thoroughly debrided, and the loose body removed. An area of the anterior deltoid fascia was then encountered with significant disruption and degeneration. After thorough evaluation, the deltoid fascia lesion was found to correspond with the anterior PEEK staple during the same ROM that caused the patient discomfort preoperatively. The disruption resulted in a hole in the deltoid fascia with underlying deltoid muscle seen past the lesion (Fig. 4, D). As the shoulder was brought

into increasing abduction and FF, the PEEK staple came into contact with the anterior deltoid. This contact was made worse with IR and ER of the shoulder in this position (Fig. 4, D). Because of this, both PEEK staples were then removed arthroscopically. Evaluation of the RC from the bursal side was intact, and the remainder of the implant appeared to have been integrated as expected at this time point (Fig. 4, E).<sup>1,8</sup> The arthroscopic incisions were then closed in standard fashion, and the patient was placed into a brace post-operatively for comfort.

The patient expressed significant improvement on her first postoperative visit 9 days after surgery. At that time, she had full active ROM without any evidence of crepitus and full strength with minimal pain on provocative testing. She underwent a short course of physical therapy followed by a transition to a home exercise program. She came back to clinic at the 6-week mark with no deficits that was continued until her 3-month follow-up appointment. She had no pain with either the empty can maneuver or Hawkins test. With her physical therapy completed and no further complaints, she was discharged from clinic and told to follow-up as needed if her shoulder pain returned.

## Discussion

This report is of a rare complication with the use of a bio-inductive collagen implant. The authors attribute the patient's symptoms to the use of the PEEK bone staple used to secure the implant. The RCT was improved on follow-up arthroscopy, and the patient's pain with RC provocative testing (specifically the empty can maneuver) had resolved. The contact of the PEEK bone staple with the anterior deltoid fascia correlated well with the patients' preoperative symptoms, and the point tenderness over the anterior deltoid was almost completely resolved immediately after its removal at the first postoperative visit. While it is unclear what the origin of the loose body in the subacromial space was, the best hypothesis is that it was either a remnant of the implant itself or from the deltoid fascia that was in contact with the PEEK bone staple. Regardless, the articular surface of the RCT appeared to have improved from the index surgery, leading us to believe that despite the presence of the loose body, the implant itself still played a significant role in treating the patients partial RCT.

The authors report on this complication as it appears to be rare but is directly related to the use of this implant and the included PEEK bone staples. Surgeons should be aware that this complication can occur, and if patients describe symptoms similar to the ones presented here, a revision SAD with hardware removal might be warranted. In retrospect, there are multiple solutions to avoid this complication in future cases. Proper insertion/utilization of the PEEK bone staples to ensure that they are inserted down to the bone and not proud is a simple solution that can be directly influenced by the treating surgeon. Alternatively, after the PDS tendon staples are placed and the implant is provisionally secured, the shoulder can be taken through a gentle ROM sequence before placement of the PEEK bone staples to determine if any points possibly impinge on the fascia. This can help dictate where the

PEEK bone staples can be placed safely without impinging or coming into contact with the deltoid fascia. If performed, great care must be taken at this point to not disturb or cause loosening of the implant itself. And finally, the PEEK bone staples may also be foregone completely as long as the implant is completely secured with the PDS tendon staples alone.

## Conclusion

Proper insertion/utilization of the PEEK bone staples to ensure that they are inserted down to the bone and not proud is a simple solution that can be directly influenced by the treating surgeon.

## Disclaimers

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Conflicts of interest: Dr. Bravman is a board member of AOSSM; a consultant of DJ Orthopaedics, Shukla Medical, and Smith & Nephew; receives royalties from Shukla Medical; and receives financial/research support from Stryker, Smith & Nephew, and Biomet. None of these affiliations are related to the subject of this work. The other authors, their immediate families, and any research foundation 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.

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