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Non-suppurative Tissue Reaction to Polyether Ether Ketone Anchor in Rotator Cuff Repair

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Learning Point of the Article:

Peek material is not free from tissue reaction and inflammation in such setting is not always infection.

Abstract

Introduction: Interferential screws and anchors have played a major role in fixation of soft tissue to bony tunnel. With advent of time, there developed metal anchors, biodegradable anchors, bioinert anchors, etc. Biodegradable anchors had complications such as reactive synovitis, cyst formation, soft-tissue inflammation, and local osteolysis. Polyether ether ketone (PEEK) which was biologically inert and radiolucent was introduced to overcome the disadvantages of anchors. We present a case of non-suppurative tissue reaction to PEEK anchor following rotator cuff repair.

Case Report: A 58-year-old male patient presented to us with signs of rotator cuff tear following injury to his shoulder. Magnetic resonance imaging depicted a massive cuff tear with retraction of cuff. Considering the degree of cuff tear, cuff was repaired with mini open method using two metallic suture anchor and two PEEK knotless bioraptor foot print suture anchor. Surgical wound healing was uneventful and suture was removed on 14th day following surgery. Three weeks following surgery, the patient had pain and rise in temperature over shoulder with raised erythrocyte sedimentation rate and C-reactive protein which subsided in 7 days with empirical antibiotics. Later, at 3 months, the patient had serous discharge from surgical site, on which exploration revealed pale yellow material vicinity to PEEK anchor. Other than pus cells in smear, discharge was negative to routine culture, grams stain, and cartridge-based nucleic acid amplification test for tuberculosis. Surprisingly, surrounding muscles were healthy, red in color, and contracting to stimulation. Following removal of both the PEEK anchors, local symptoms subsided with improvement in patients shoulder function.

Conclusion: There were cases of tissue reaction to PEEK material in the literature such as osteolysis and cyst formation. In addition, non-suppurative inflammation can occur in response to PEEK material. Awareness about the non-suppurative inflammation property of PEEK material may help future surgeons to manage the condition better than us.

Keywords: Polyether ether ketone, anchor, inflammation, non-suppurative.

Introduction

Interferential screws and anchors have played a major role in fixation of soft tissue to bony tunnel. It has enhanced enormous possibilities in the treatment of rotator cuff tear and shoulder instability. With advent of time, there developed metal anchors, biodegradable anchors, bioinert anchors, etc. Metal anchors had promising results along with complication of glenohumoral chondral damage secondary to exposed implant, implant migration, implant breakage, etc. [1]. Bioabsorbable anchors preferred over metal anchors due to their similar pull out strength to that of metallic anchor and minimal interference with post-operative magnetic resonance imaging (MRI) [2, 3, 4].

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Author's Photo Gallery


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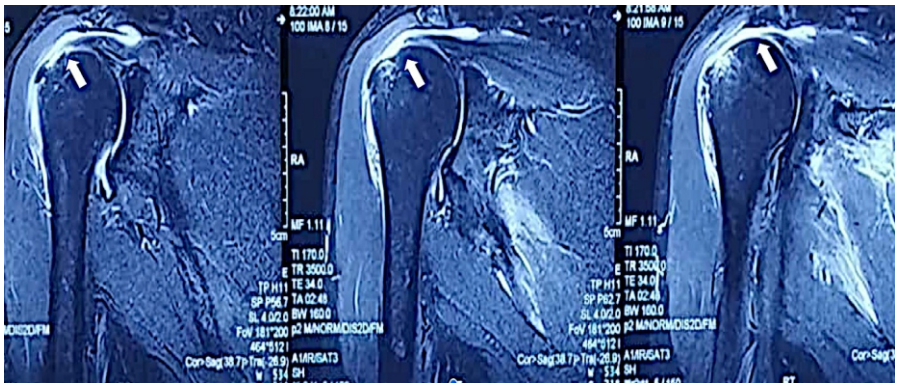

Figure 1: Magnetic resonance imaging of shoulder, full-thickness tear of supraspinatus (white arrow).

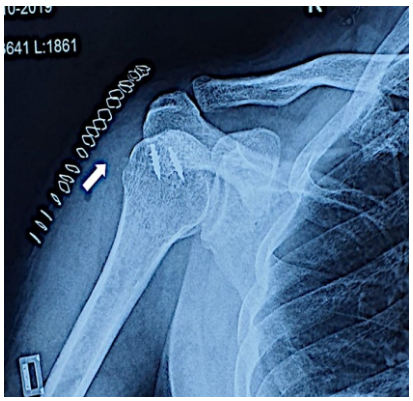

Figure 2: Post-operative X-ray (White arrow: PEEK foot print anchor).

Biodegradable anchors had complications such as reactive synovitis, cyst formation, soft-tissue inflammation, and local osteolysis [5, 6, 7, 8]. Polyether ether ketone (PEEK) which was biologically inert and radiolucent was introduced to overcome the disadvantages of biodegradable anchors. These implants have shown no cytotoxicity, irritation, or microscopic reaction in animal studies with high pull-out strength [9]. PEEK does not interfere with MRI imaging and complications related to degradation and tissue reaction [10, 11, 12]. It has no local inflammatory reaction as per animal studies, but it has very poor osteointegration [13]. Despite wide spread orthopedic use, only few cases of minimal inflammatory reaction and a single case of hypersensitivity reaction have been documented [14]. Case involving osteolysis and foreign body reaction following rotator cuff repair with PEEK material suture anchor/screw has not been reported till now. We present a case of non-suppurative tissue reaction to PEEK anchor following rotator cuff repair.

Case Presentation

A 58-year-old male patient presented to us with chief complain of pain in the right shoulder for 2 months with difficulty in raising the arm. Pain is localized to shoulder joint that aggravates with exertion and relieved with rest and medication. He had a history of trivial injury 2 months back. Pain was not relived with physiotherapy and medication.

On examination, there was not any sign of infection such as redness, swelling, or increased local temperature. Shoulder had not witnessed any previous fracture or surgery. Clinical sign for rotator cuff tear was positive. He had flexion 0°–80°, abduction 0°–15°, external rotation 0°–10°, and internal rotation 0°–15°. There was no visible muscle wasting around shoulder or scapula. At the time of presentation, the visual analog score was six. On investigation, his plain radiograph was normal other than minimal proximal migration of humeral head. MRI detected a full thickness tear of supraspinatus and infraspinatus tendon with proximal migration of humerus head and break in Maloney line (Fig. 1).

After all pre-operative preparations, mini open rotator cuff repair was done with two metallic suture anchor and two PEEK foot print suture anchor (Fig. 2). Suture removal was done 14 days following the operation and was uneventful. Nearly 3 weeks after operation, the patient complained of pain and mild rise of local temperature over shoulder. Clinical signs were normal other than mild warm at stich site compared to nearby skin. VAS score was five at this point of time with normal neutrophil and leucocyte count. Erythrocyte sedimentation rate and C-reactive protein (CRP) both positive with

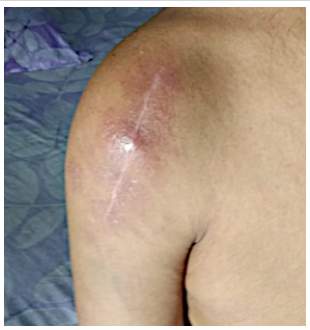

Figure 3: Skin inflammation after 106 days of index surgery.

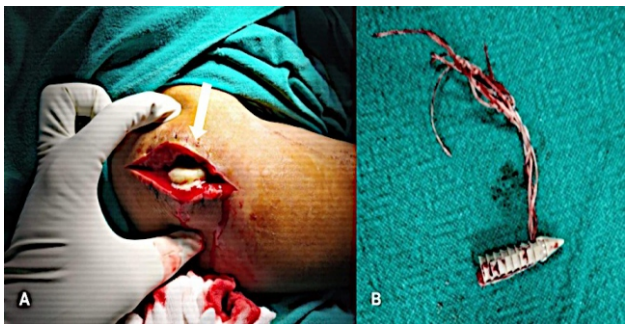

Figure 4: (a) Intraoperative picture showing necrotic material on the PEEK screw (white arrow), (b) PEEK screw after removal.

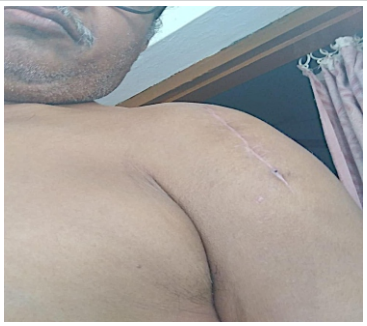

Figure 5: Healed skin after PEEK screw removal.

Figure 6: Satisfactory shoulder function at 2 years follow-up.

borderline procalcitonin test. We administered cefuroxime 500 mg twice daily for 7 days empirically. The patient improved clinically but his VAS score was 5 only. In 10 weeks from operation, his ESR decreased, but CRP was positive with normal neutrophil and leukocyte count. VAS score did not improve from a score of five. Nearly 3 months after operation, he presented with redness and serous discharge from stich site (Fig. 3). We immediately underwent an incision and drainage presuming all is not well. On incision, we found nearby muscles and soft-tissue healthy with collection of some pale-yellow semisolid substance near the screw site. At times, we were confused with tubercular affection. Sample was sent for routine culture sensitivity, grams stain, and cartridge-based nucleic acid amplification test (CBNAAT) for tuberculosis; all the test result was negative other than presence of pus cells in smear (Table 1). Empirically, broad-spectrum antibiotic was administered. The patient was better than before but there was serous discharge from the stitch margin. We planned for a thorough debridement and nearly 4 months after first operation, we did another debridement under general anesthesia. We found similar straw color semisolid in consistency material near the screw site. Nearby, muscles were red, healthy, and contractile to stimulation. All the visible sutures and PEEK screw were removed (Fig. 4). Sample again sent for routine culture sensitivity, grams stain and CBNAAT; all the tests were negative other than increase number of WBC. Fortunately, patients improved from his symptoms and wound healed normally (Fig. 5). Patients present VAS score reduced to one at 6 months from the first surgery and 2 months from second surgery. There is marginal improvement of shoulder movement, no pain, and no rise of local temperature at 4 months following second surgery. At 25 months of follow-up, shoulder function is excellent without sign of local inflammation or recurrence of similar symptoms with VAS score one or less (Fig. 6).

Discussion

Healing of soft tissue to bone needs stable fixation for a minimum period of 12 weeks. In the absence of this biomechanical stability, tissue will fail to heal [13, 15]. Soft tissue can be fixed to bone either by transosseous fixation or by anchors to bone. Metallic suture anchors have proved to replicate similar pull out strength as that of transosseous fixation [16, 17]. In due course time, metal anchors presented with complications such as loosening of fixation, migration of

Table 1: Biological parameters									
Parameter	21.10.2019	First surgery 22.10.2019	24.10.2019	11.12.2019	27.11.2020	10.01.2020	08.02.2020 I/D	20.02.2020	Second Surgery 21.02.2020 22.02.2020
TLC/Cu mm	6700		12920	7660		8180		8920	6320
Neutrophil %	63.5		81.1	63.8		68.3			84.8
ESR mm				59		36			
CRP mg/dl				Positive		Positive			
Procalcito-nin					Borderline				
Culture							Negative		Negative
CBNAT									Negative
Smear/ Grams Strain							Pus cell plenty/no organism		No organism/WBC >100/ Micro L

TLC: Total leukocyte count, ESR: Erythrocyte sedimentation rate, CRP: C- Reactive protein, CBNAAT: Cartridge-based nucleic acid amplification test

Table 1: Biological parameters

anchor, incarceration of the implant within the joint, and chondral damage, and most importantly, they interfered with the images in MRI [18, 19]. With the advent of biodegradable implants from 1990, it was postulated that they could avoid the complications of metallic screw. Pietschmann found that the pull-out strength of the biodegradable screws is as that of metallic screws [20]. As the biodegradable screws loose the mechanical strength with time due to degradation, the force is transferred to the soft tissue which helps in healing of the tissue [21]. Biodegradable screws degrade at different rate depending on their composition, ranging from few months for polyglycolic acid (PGA) to up to 5 years or more for poly-L-lactic acid (PLLA) [22, 23]. The first generation implants were made of PGA which degrades quickly before body could reabsorb the monomer debris leading to foreign body reactions [24]. The PLLA biodegradable implants were better in the sense that, they degraded slowly and allowed time for healing of the graft [25]. Biodegradable implants are associated with complication such as cyst formation, soft-tissue inflammation, and loose implant fragments in the joint and local osteolysis or foreign body Granulomas [5]. Rokkanen et al., in their study, described the occurrence of non-infectious foreign body reaction after 2–3 months following the use PGA suture anchors. This type of reaction was seen in 2% of patients with PGA implants but not seen in patients who received polylactide implants [26]. Freehill et al. documented substantial number of foreign body reactions, resulting in multiple osteolytic lesions and synovitis at the PLLA implant site in arthroscopic shoulder stabilization surgery. The usual presentation of symptoms was after 8 months of index surgery. Many of these patients had to manage with arthroscopic debridement, complete synovectomy, and implant removal [27]. Glueck et al. documented a case of extensive osteolysis in the humeral head 8 months after repair of a SLAP lesion with a poly L-lactide-co-D and L-lactide suture anchor [25]. In comparison to biodegradable materials, PEEK is a stable, which is resistant to chemical, thermal, and radiation induced degradation. PEEK does not interfere with MRI imaging which is an added advantage of PEEK and does not have tissue reaction to monomers [10, 11]. Even in animal studies, PEEK has been found be very stable without signs of acute inflammatory reaction, cytotoxicity, or immunogenicity to PEEK implants [13]. Ro et al. compared the bone reaction to different anchors used for repair of rotator cuff tear by post-operative MRI. At 9.6 months of operation, they found that 23 (10.8%, 23 of 213 patients) patients had developed peri-anchor cysts. It was 8.8%, 16.7%, and 12.5% in the all-suture-type, bioabsorbable, and PEEK-type anchor groups, respectively. There was no difference in all the groups in terms of visual analogue scale and Constant scores; re-tear rates, and peri-anchor bone reactions [28]. Haneveld et al. analyzed the osseous reaction in patients undergoing double row cuff repair, that is, using PLLA and PEEK suture anchors. He observed more tunnel widening with PLLA anchors compared to PEEK material (0.9 ± 0.7 mm in PLLA and 0.8 ± 0.6 mm in PEEK with $P < 0.05$) [29]. Kim et al., in their study on bone ingrowth into anchors, found that PEEK anchor had better bone ingrowth compared to non-vented biocomposite suture anchor at 12 months in patients with arthroscopic rotator cuff repair [30]. However, the rate of cyst formation around the anchor showed no difference between the two groups on the 6 months post-operative computed tomography.

We learn from the literature that PEEK is a more stable material compared to other biocomposite materials, but it has witnessed osteolysis, cyst around anchor, etc. We could not find any article depicting about the non-suppurative inflammation related to PEEK implant. We present the first such case of rotator cuff repair with metallic anchor and PEEK screws with significant non-suppurative inflammation around the PEEK anchor. In our case, none of the samples were positive for any culture or CBNAAT. The collection was purely non-suppurative and none of the samples revealed any organism in Gram's stain. After the initial debridement, inflammation did not subside till removal of PEEK anchor at second debridement. Inflammation subsided to near completion with removal of the PEEK screw and debridement. Most importantly, the necrotic material was directly at the vicinity of screw with normal contractile healthy musculature all around. The underlying mechanism for such a non-suppurative inflammation with PEEK is not clear. It could be a reaction to PEEK implant or to the non-absorbable suture material attached to the anchor is a matter of debate. Although there is hardly any literature on non-suppurative reaction of PEEK material, few cases of local inflammation, osteolysis, and cyst around anchor have been reported. Further studies are needed to describe the biological reaction of PEEK monomer and the mechanism for non-suppurative inflammation around the suture anchor.

Conclusion

There were cases of tissue reaction to PEEK material in the literature such as osteolysis and cyst formation. In addition, non-suppurative inflammation can occur in response to PEEK material. Awareness about the non-suppurative inflammation property of PEEK material may help future surgeons to manage the condition better than us. Further studies on PEEK material can substantiate the relation of PEEK to non-suppurative inflammation.

Clinical Message

PEEK material produces local cyst and bone osteolysis as depicted in the literature. However, non-suppurative inflammation can occur in response to PEEK material. Early suspicion and action will prevent propagation of disease and osteolysis of bone.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given the consent for his/ her images and other clinical information to be reported in the journal. The patient understands that his/ her names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Conflict of interest: Nil **Source of support:** None

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