Case Report

Talar and fibular histiocytic-driven massive expansile osteolysis following polyetheretherketone interference screw implantation: a case report

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ABSTRACT

Numerous interference screws of different compositions exist including titanium screws, bioabsorbable screws, and polyetheretherketone (PEEK) screws. PEEK-based implants are frequently used in orthopaedic surgery due to their biocompatibility, similar elastic modulus to cortical bone, and purported negligible risk of osteolysis compared with bioabsorbable screws. In this case report, we present the case of a 48-year-old healthy female who experienced a massive osteolytic reaction in the talus and fibula after 11 weeks following implantation of PEEK-based interference screws during lateral ankle ligament reconstruction. The patient subsequently underwent removal of the PEEK screws and specimens were sent for microbiological and histopathological analysis. The specimens report demonstrated fibrotic tenosynovial soft tissue with patchy chronic inflammation, oedematous reactive changes, and histiocytic reaction, with no evidence of any significant acute inflammation. The patient recovered well and was asymptomatic at 6 months postoperatively. To our knowledge, this is the first case report of a massive osteolytic reaction to PEEK-based interference screws.

The case

1. A 48-year-old female presented with left chronic lateral ankle instability that warranted surgical intervention via hybrid lateral ankle ligament reconstruction with the tendon graft secured via polyetheretherketone-based interference screws.
2. Computed tomography scan at 11 weeks postoperatively demonstrated massive expansile osteolysis and the talar and fibular tunnels.
3. The screws were removed, and the specimens sent for further analysis demonstrated fibrotic tenosynovial soft tissue with patchy chronic inflammation, oedematous reactive changes, and histiocytic reaction, with no evidence of any significant acute inflammation.

Lessons learnt

1. Osteolysis is a potential complication of polyetheretherketone-based interference screws
2. Although massive osteolysis is a rare complication, surgeons should consider osteolysis as a potential cause of severe pain in the subacute period following the use of polyetheretherketone-based implants

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INTRODUCTION

Lateral ankle ligament sprains following an acute ankle inversion injury are a commonly encountered pathology, sustained by 27,000 Americans on a daily basis [1]. Patients who remain symptomatic despite conservative management typically warrant surgical intervention [2]. In patients with adequate remnants of the anterior talo-fibular ligament (ATFL), repair of the lateral ligament complex is required. For patients with poor-quality ATFL remnants, patients with generalised ligamentous laxity, and morbidity obese patients, reconstruction of the lateral ligament complex is indicated [3]. Hybrid anatomic reconstruction of the ATFL first described by Kennedy et al., which involves sectioning one-third of the diameter of the peroneus longus tendon and transposing this construct to the anatomic footprint of the ATFL, which is secured with 2 interference screws [4].

Adequate fixation and tensioning of the tendon graft in the tibial and femoral tunnels via 2 biotenodesis interference screws is crucial for a successful outcome. Interference screws can be composed of various materials including titanium screws, bioabsorbable screws (predominantly composed of polyglycolic acid), biocomposite materials, and polyetheretherketone (PEEK) [5,6]. PEEK screws are frequently utilised in orthopaedic implants due to their radiolucency, compatibility, and favourable elastic modulus [7]. In addition, PEEK-based implants are purported to be biologically inert, thus circumvent potential osteolytic reactions are seen with bioabsorbable implants. However, in recent years, a growing reservoir of case series have been published highlighting concerns regarding osteolysis following implantation of PEEK-based structure anchors and cages [8–10]. However, to the best of the authors’ knowledge, there have been no cases of massive osteolytic reactions following implantation of PEEK interference screws.

We present the case of a massive, expansile osteolytic reaction in the talar and fibular osseous tunnels following implantation of PEEK interference screws. In addition, we attempt to evaluate the current literature regarding osteolytic reactions and complications associated with PEEK-based implants in orthopaedic surgery.

CASE REPORT

Clinical history, physical examination, and imaging findings

A 48-year-old female presented to a tertiary referral centre with a 5-month history of persistent left ankle pain and instability. This achy, dull, nonradiating pain was primarily located at the lateral aspect of the left ankle along the distribution of the left ATFL and left peroneal tendons, for which she graded as 5/10 on the pain scale. She also reported a chronic history of left lateral ankle instability, which was exacerbated following an acute ankle inversion injury 5 months prior. During the preceding 5 months, she described multiple episodes of less severe ankle sprains. The patient was treated conservatively via physical therapy. Of note, the patient had a prior history of right lateral ankle ligament reconstruction secondary to right chronic lateral ankle instability.

On examination, there was tenderness to palpation at the lateral aspect of the ankle, lateral gutter, and along the distribution of the peroneal tendons. The patient displayed a positive anterior drawer test and positive talar tilt test. Her strength was 5/5 in all muscle groups and was neurovascularly intact.

Her plain film radiographs of the left ankle were unremarkable; thus, a magnetic resonance imaging (MRI) scan was obtained, which demonstrated chronic tears of the ATFL and the proximal fibres of the calcaneofibular ligament (CFL).

As the patient had failed conservative management, the patient was referred for surgical intervention to address the torn ATFL.

Hybrid lateral ligament reconstruction

With the patient under conscious sedation, standard anteromedial and anterolateral ankle arthroscopy portals were created with a number-11 blade. A blunt trocar entered the joint, followed by exchange of the 1.9-mm needle arthroscope (Nanoscope; Arthrex, Naples, FL). Cicatrised scar tissue at the anterolateral aspect of the joint was resected using the 3.0-mm shaver. A hypertrophic Bassett’s ligament was identified and was trimmed with the biter and 3.0-mm shaver. No osteochondral lesions were identified. Following completion of the ankle arthroscopy, portal sites were closed with Steri-Strips (3M, Saint Paul, MN). Next, attention was directed toward the lateral aspect of the ankle, where a 4-cm incision was made obliquely from the most distal aspect of the fibula to the talar attachment of the ATFL. The remnant of the ATFL was dissected from the talar footprint and released from the fibular attachment. Gross inflammation throughout the peroneal tendon sheath was observed, which was resected using a synovial rongeur. As the CFL was noted to be attenuated, and a longitudinal incision was made in the broad band that is the CFL, subtalar capsule, and peroneal retinaculum. This fascial structure was then plicated in a vest-over-pants fashion using 0-Vicryl sutures (Ethicon, Somerville, NJ). Next, approximately one-third of the width of the peroneus longus was excised and was tubularized with 2.0 Vicryl (Ethicon), allowing 2 free ends for tendon-passing. The remaining peroneus longus tendon was then tubularized using 4-0 polydioxanone suture (Ethicon, Somerville, NJ).

Using a rasp, the fibula and talus were then excoriated to provide bony fixation for the reconstructed CFL. Two drill holes were created using a standard 4.5-mm bio-tendonesis drill (Arthrex, Naples, FL). To minimise potential osteonecrosis due to heat dissipation during bone drilling, the drill sleeve was irrigated with sterile saline. The native talar and fibular footprint of the ATFL were overdrilled. The tendon was fixed in the talus using a 5.5 × 15mm PEEK screw. The tendon graft was then passed through the fibular tunnel and was appropriately tensioned. The fibular PEEK screw was advanced to provide adequate fixation of the graft. The remaining ATFL remnant was secured over the graft to provide additional stability to the construct. The ankle and subtalar joint were put through a range of motion, and stability of the lateral aspect of the ankle was confirmed. All soft tissue layers were subsequently closed.

The patient was placed into an Arbeitsgemeinschaft für Osteosynthesezwecke (AO) splint and was instructed to remain non-weight-bearing for 2 weeks, followed by 4 weeks of gradual increase in weight-bearing until the patient could weight-bear as tolerated by week 6 post-operatively. This was followed by physical therapy with an emphasis on proprioceptive exercises, ankle strengthening exercises, and a range of motion exercises.

Pain at 11 weeks postoperatively

At 11 weeks postoperatively, the patient presented with a 3-day history of progressively worsening left lateral ankle pain and swelling. The pain was located over the lateral aspect of the ankle with no preceding trauma. The patient described “excruciating, severe” ankle pain, graded as a 9/10, and was unable to bear weight. On examination, there was swelling and tenderness to palpation at the lateral aspect of the ankle particularly at the site of the screws at the fibula and talus, with fully healed incisions with no signs of infection.

A computed tomography (CT) scan demonstrated expansive osteolysis around both the talus and fibular screws with evidence of significant widening of the osseous tunnels (Fig. 1). In addition, a displaced fracture of the posterior facet of the talus was observed.

It was advised that the patient return to the operating room (OR) for removal of the screws, with histological and microbiological analysis of...
the surrounding soft tissue and inspection of the displaced fracture of the posterior facet of the talus.

**Surgical intervention**

Under conscious sedation, a 4-cm incision was made along the previous scar. The ATFL remnant was identified and preserved. The fibular PEEK screw was noted to be loose and protuberant. Synovial rongeurs were utilised to resect the surrounding scar tissue and inflamed synovial tissue adjacent to the screw, which were sent for cultures and histological analysis. The fibular PEEK screw was subsequently removed (Fig. 2) and was also sent for cultures and histological analysis. A small curette was placed into the screw track and, a cavitary cyst was excavated. Demineralised bone matrix mixed with autologous platelet-rich plasma (DBM-PRP) was backfilled into the fibular defect. In a similar fashion, the talar PEEK screw was also noted to be loose and protuberant. The surrounding scar tissue and inflamed synovial tissue were resected, and the PEEK screw was removed (Fig. 2). The defect was not backfilled with DBM-PRP due to the concern that it would lead to an intra-articular reaction. A 5-mm fragment of the posterior facet of the talus was removed with rongeurs, and the articular cartilage of the subtalar joint was probed and deemed normal. Once mechanical stability was determined to be satisfactory, the wound was copiously irrigated with saline and was subsequently closed. The patient followed a similar postoperative rehabilitation protocol as the index procedure, which entailed remaining non-weight bearing for 2 weeks, followed by 4 weeks of gradual increase in weight-bearing until the patient could bear weight as tolerated by week 6 postoperatively.

**Specimen findings and postoperative course**

The cultures from the specimens returned as sterile. The histological findings from both PEEK screws and surrounding tissue demonstrated fibrotic tenosynovial soft tissue with patchy chronic inflammation, oedematous reactive changes, and a histiocytic reaction with no evidence of any significant acute inflammation.

The patient was closely monitored over a period of 4 weeks, for which she reported gradual improvement in left ankle pain. She was asymptomatic at 6 months postoperatively, and her corresponding plain film radiographs demonstrated evidence of progressive infill of the defect in the tibial and fibular tunnels (Fig. 3).

**DISCUSSION**

We presented the case of a 48-year-old woman who experienced a histiocytic driven, massive osteolytic reaction to both talar and fibular PEEK interference screws 3 months after undergoing hybrid lateral ankle ligament reconstruction. To the authors’ knowledge, this is the first case of a massive osteolytic reaction following the implantation of PEEK-based biotenodesis interference screws.

PEEK is a chemically inert polyaromatic semicrystalline thermoplastic polymer with the following chemical formula: 

$$(-C_6H_4-O-C_6H_4-O-C_6H_4-CO-)_n$$ [11]. It belongs to the polyaryletherketone (PAEK) family of thermoplastic polymers and is the monomer unit of etheretherketone [12]. The other member of the PAEK family is polyetherketoneketone, the monomer unit of
which either a PEEK cage or a titanium cage was implanted [9]. The derwent instrumented transforaminal lumbar interbody fusion (TLIF), in compared clinical and radiological outcomes between patients un-

Furthermore, a retrospective comparative study by Nemoto et al. (100

authors found superior osseous union rates in the titanium-cage cohort

crystallisation peak temperature of 343 °C [13], making it a stable construct when implanted in humans. The modulus of elasticity of PEEK is 3–4 GPa, which is com-

table to that of human cortical bone [14]. PEEK is not a source of secondary radiation after gamma sterilisation due to its high resistance to gamma and electron beam radiation [7]. PEEK is compatible with many reinforcing agents, including carbon and glass, and is stronger on a per mass basis than various metals. Finally, a major benefit of PEEK is its MRI compatibility and low artifact on MRI imaging [7]. Due to its favourable inherent biomechanical properties, PEEK has been utilised across multiple implants in orthopaedic surgery including anchors, cages, and screws over the last 2 decades.

It is widely reported in the literature that a major benefit of PEEK-based implants is that they avoid osteolytic reactions classically associ-

ated with bioabsorbable implants. However, all implants regardless of their composition are subjected to wear debris [15]. The bio-reactivity of wear debris particles is determined by various particle characteristics including size, concentration, composition, and functional biological activity [16]. For a particle to induce a proinflammatory reaction, it must have a phagocytosable size between 0.24 and 7.2 μm [15], for which PEEK has a size of <5μm [16]. Phagocytosis of the wear particle by various macrophages triggers the release of pro-osteoclastic factors including receptor activator of nuclear factor κB ligand (RANKL), and proinflammatory cytokines including TNF-α and IL-1, which drive the recruitment, differentiation, and activation of bone-resorbing osteoclasts [17]. An in vivo study by Du et al. compared the rates of osteolysis across implants exposed to wear particles including PEEK, highly cross-linked polyethylene and cobalt–chromium–molybdenum in a rabbit model via immunohistochemical and micro-CT analysis [16]. The authors found elevated levels of pro-osteocitary biomarkers across the PEEK cohort including TNF-α, IL-1, and RANKL. Furthermore, micro-CT analysis PEEK wear particles induced severe osteolysis in the peripheral regions around the implant.

There are a growing number of reports of osteolytic reactions following the use of PEEK-based implants in orthopaedic surgery; how-

ever, none have been described following the use of PEEK-based screw implants. A retrospective review of 26 PEEK suture anchors in 14 patients who underwent various hand and wrist procedures by Chen et al. reported osteolysis in 26.9% of their cohort at the final follow-up [8]. Furthermore, a retrospective comparative study by Nemoto et al. compared clinical and radiological outcomes between patients who un-
derwent instrumented transforaminal lumbar interbody fusion (TLIF), in which either a PEEK cage or a titanium cage was implanted [9]. The authors found superior osseous union rates in the titanium-cage cohort (100%) compared to those in the PEEK-cage cohort (76%) at a 2-year follow-up. However, osteolysis was found in 14.4% of the PEEK-cage cohort on postoperative CT scans, which was significantly associated with the rates of nonunion in the cohort [9]. In addition, Cuzzocrea et al. compared functional and radiological outcomes between patients un-

dergoing metal- and PEEK-cage implantation during TLIF at a mean follow-up of 1 year [10]. Lower fusion rates were reported in the PEEK-cage cohort (15%) than in the metal cage cohort (40%). Similar to Nemoto’s study, there was a statistically significant increased osteol-

ysis rate in the PEEK-cage cohort compared to that in the metal-cage cohort. This reinforces that PEEK-based materials may be at a higher risk of osteolysis than previously thought.

Although osteolysis has been observed in various PEEK-based implants, as previously described, this is the first case of PEEK-based interference screws leading to a massive expansile osteolytic reaction. The histological analysis of the various specimens demonstrated a histiocytic-driven reaction, consistent with the current basic science literature. Massive osteolytic reactions secondary to interference screws are a rare occurrence and have been sparsely reported in the literature. Galiveeti et al. described the case of a 54-year-old male who underwent a cemented total knee arthroplasty, in which the tibial component was fixed with bioabsorbable screws [18]. At 1-year postoperatively, the patient presented with recurrent knee pain and swelling with a large radiolucency noted at the tibial component. Intraoperatively, a frag-

mented unabsorbed bioabsorbable screw in a large cavity in the tibial component of the implant was encountered. The histological analysis demonstrated an inflammatory infiltrate primarily composed of pigment-laden macrophages, and thus, the screw was identified as the primary cause of the osteolytic reaction. Given the dearth of available data regarding osteolytic reactions secondary to interference screws, it is difficult to ascertain the precise reason for why our patient had a massive osteolytic reaction rather than a more modest osteolytic reaction. Although our patient never obtained formal dual x-ray absorptiometry scans, their radiographic imaging demonstrated low bone mineral density. It is plausible that osteopenic and/or osteoporotic patients with altered bone metabolism may be at risk of a more extensive osteolytic reaction and thus, may benefit from oral bisphosphonate therapy to reduce the risk of osteolysis.

There have been recent reports of further complications associated with PEEK-based implants. Fang et al. reported extra-articular migration of PEEK interference screws utilised for fixation of a hamstring graft during anterior cruciate ligament reconstruction, which is considered to be due to an aberrant biologic reaction from the screw [19]. Further-

more, hypersensitivity to PEEK-based implants have been reported in the literature. Bueno et al. reported 1 case of a hypersensitivity reaction to a carbon-fibre-reinforced PEEK cage implanted at the C6/C7, which was confirmed by skin-patch testing [20]. Shields et al. reported an allergic reaction to PEEK cranioplasty in a 7-year-old male resulting in subgaleal and epidural effusions, which resolved following a repeat cranioplasty with replacement of the PEEK flap with autologous bone. Finally, Kofer et al. [21] described the case of a 62-year-old male who developed an allergic reaction to a PEEK-suture anchor repair utilised for a rotator cuff tear repair, which was subsequently revised.

CONCLUSIONS

This is the first case of a massive osteolytic reaction following PEEK interference screw implantation in orthopaedic surgery. Although massive osteolytic reactions secondary to PEEK-based implants are rare, there appears to be a growing body of evidence to suggest that PEEK-based implants are not as chemically inert as once thought and that they may be subject to osteolytic reactions.

Ethical approval

Ethical approval was not sought for the present study because this is a case report. However, informed consent was obtained from the patient.
Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests. John G. Kennedy reports a relationship with Arthrex Inc that includes: consulting or advisory. John G. Kennedy reports a relationship with In2Bones Global Inc. that includes consulting or advisory. John G. Kennedy reports a relationship with Arthrocute Medical Systems Inc that includes the following: John G. Kennedy receives financial support from the O'Neill Family Foundation and from Mr Winston Fisher.

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