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Case Report

Polyetheretherketone (PEEK) intervertebral cage as a cause of chronic systemic allergy: a case report

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Abstract

BACKGROUND CONTEXT: Polyetheretherketone (PEEK) is an organic polymer thermoplastic with strong mechanical and chemical resistance properties. It has been used in industry to fabricate items for demanding applications such as bearings, piston parts, compressor plate valves, and cable insulation. Since the early 1980s, polyetheretherketone polymers have been increasingly used in orthopedic and spinal surgery applications. Numerous studies and years of clinical experience have confirmed the biocompatibility of this material.

PURPOSE: The purpose of the study was to report a case of chronic systemic allergy after anterior cervical decompression and fusion (ACDF) and implantation of an intervertebral PEEK cage, with resolution of symptoms after removal of PEEK cage.

STUDY DESIGN/SETTING: This study is a case report with clinical evidence for allergy to PEEK.

METHODS: The methods involve clinical findings and review of current literature.

RESULTS: After ACDF and implantation of an intervertebral PEEK cage, the patient had developed an angioedema-like picture marked by severe redness, itching, swelling of his tongue, and skin thickening. A skin patch test was positive for PEEK. Removal of the implant resulted in the resolution of his allergy symptoms shortly after surgery.

CONCLUSIONS: Tissue reactions to PEEK are extremely rare. Herein, we present the first report of a chronic allergic response to interbody PEEK material. © 2015 Elsevier Inc. All rights reserved.

Key words: Polyetheretherketone; PEEK; Spine; Implant; Allergy; Hypersensitivity

Introduction

Polyetheretherketone (PEEK) is an organic polymer thermoplastic with a variety of applications across multiple fields of industry including mechanical and biomedical engineering. There is a wide range of chemical modifications and composites commercially available for PEEK that make it suitable for applications in orthopedic and neurological surgeries [1–4]. The favorable biomechanical properties, radiolucency, longevity, and biocompatibility have made PEEK implants ideally suitable for spinal surgical applications, particularly as a material for intervertebral cages. Multiple studies have demonstrated the longevity and mechanical advantages of PEEK interbody cages since their inception in the 1990s [5,6].

Biocompatibility studies and years of clinical application have demonstrated the material to be relatively well tolerated [7–11], although some reports note a "minimal" inflammatory response [8,12]. Despite widespread use, no case of hypersensitivity or allergy related to PEEK has been reported. This case presentation reports the first case of confirmed delayed-type hypersensitivity reaction to the material PEEK.

Case report

History

A 54-year-old man presented to the Cleveland Clinic with a complaint of neck pain and significant left arm pain. He had

FDA device/drug status: Not applicable.

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a history of multiple anterior cervical surgical procedures. His initial surgery was a C5–C6 discectomy with insertion of a cylindrical titanium intervertebral cage. This was followed by a C5–C7 laminectomy. One year later, he underwent a C4–C5 anterior discectomy with insertion of an interbody allograft and application of a titanium plate and screws. Five years later, he underwent a C3–C4 anterior discectomy with an uninstrumented interbody fusion using allograft. He tolerated each of these procedures and reported transient relief of his symptoms at the time.

One year after the C3–C4 surgery, he underwent an anterior discectomy at C6–C7 with insertion of a PEEK interbody cage secured to the cervical spine with four small titanium screws (Zero-P anterior cervical fusion device; Synthes Spine, Paoli, PA, USA). A small amount of local bone graft was inserted into the device before its interbody placement. No other osteobiologic material was used.

Postoperatively, the patient reported some mild improvement of his neck pain. However, within 4 weeks of surgery, he began to develop generalized weakness and fatigue. He noticed a diffuse erythema and itching over most of his body, swelling of his tongue, redness in his throat, and swelling under both eyes. He reported a constant ''swollen tongue and redness in his throat. Given the unexplained onset of clearly allergic symptomatology, the patient underwent a broad spectrum of allergic patch testing by an allergist. The strong correlation between the implant of a foreign material and the onset of these symptoms prompted the inclusion of PEEK in the battery of testing.''

Skin patch testing using PEEK material was performed three times and found to be positive causing severe erythema and blistering at the site of skin contact. His allergist concluded that he was experiencing an allergy to PEEK material and recommended removal of his C6–C7 interbody device.

Examination and imaging

On examination, he was found to have generalized blanching erythema, mostly on face, arms, and palms, thickened skin, and macroglossia. His neurological examination was unremarkable. Plain radiographic imaging of his cervical spine revealed a lack of osseous bridging at C6–C7 with a moderate degree of prevertebral swelling. There was no evidence of any osteolysis, fractures, hardware failure, or clinical signs of infection (Fig. 1). There was no evidence of cervical instability on flexion-extension views. Photographs of the skin allergic response were not available.

Clinical course and operative intervention

The patient underwent an anterior cervical re-exploration procedure. There was no evidence of any abnormal tissue reaction or infection at the previous surgical site. The C6–C7 interbody device was noted to be only partially fused to the adjacent vertebrae and was removed without difficulty (Fig. 2). A structural graft was inserted into the C6–C7 interspace and secured with a titanium plate and screws. Histological analysis of the explanted device showed a small amount of new bone formation but no evidence of any significant inflammatory response.

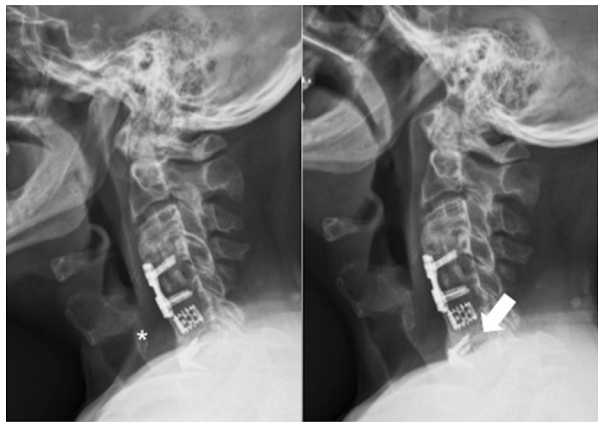

Fig. 1. Lateral upright radiographs depict previous anterior cervical instrumentation from C4 to T1. Neutral position radiograph (Left) depicts moderate prevertebral swelling (asterisk) anterior to C6, C7, and T1. In extension (Right), the C7–T1 pseudoarthrosis is visualized (arrow).

Postoperative course

Within hours of completion of the surgery, the patient reported subjective improvement of his itching. On examination, there was significant improvement of his erythema, periorbital swelling, and macroglossia. He was discharged home the following day. At his 8-week follow-up visit, he

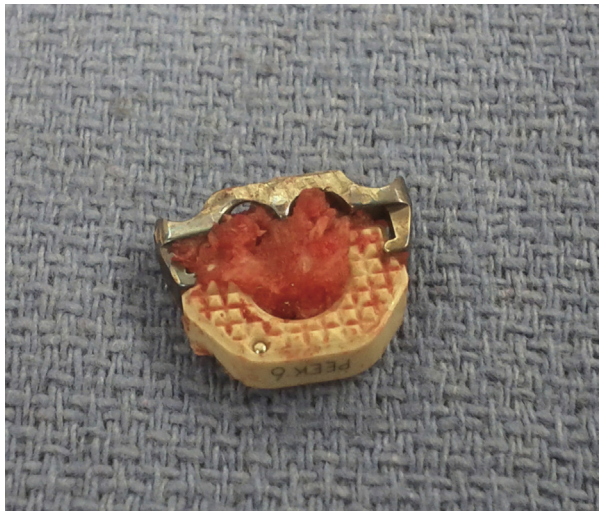

Fig. 2. Explanted polyetheretherketone device.

reported continued improvement of his symptoms, with almost complete resolution of his itching, erythema, periorbital swelling, and macroglossia.

Discussion

To our knowledge, this case represents the first report of a PEEK-related chronic allergic reaction after spinal surgery. The patient developed signs and symptoms of a chronic allergy shortly after insertion of a PEEK interbody device. The clear relationships between the implantation of the PEEK cage, the onset of allergic symptoms, skin patch testing results, and the resolution of symptoms after PEEK removal all provide compelling evidence of a PEEK-related allergy.

The use of PEEK spinal implants has increased significantly over the past decade. In addition to its use in intervertebral cages, it has also been used for fixation of plates and rods and for disc replacement devices. Numerous biocompatibility reports have demonstrated that a systemic allergic reaction to PEEK is extremely uncommon [7–11].

Given the exceptional rarity of this allergic response to PEEK, we do not suggest its removal from the spinal implant field but instead present this case to indicate that a PEEK allergy should be included in the differential diagnosis of any patient presenting with signs and symptoms of an allergic response and a recent history of exposure to PEEK. As the development of PEEK technology continues to progress and newer PEEK composites designed to improve the bone-graft interface are developed, manufacturers and physicians will need to be aware of this bioreactivity [8,12,13].

Conclusions

Polyetheretherketone materials have tremendous biological applications and are currently widely used in spinal surgery. Although relatively innocuous, the material may, in some individuals, be the source of a chronic allergic reaction. An allergy to this material should be considered in patients presenting with unexplained allergy after the implantation of PEEK materials.

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