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ORIGINAL ARTICLE

Retrieval analysis of PEEK rods for posterior fusion and motion preservation

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Abstract
Introduction The purpose of this study was to analyze explanted PEEK rod spinal systems in the context of their clinical indications. We evaluated damage to the implant and histological changes in explanted periprosthetic tissues.
Methods 12 patients implanted with 23 PEEK rods were revised between 2008 and 2012. PEEK rods were of the same design (CD Horizon Legacy, Medtronic, Memphis TN, USA). Retrieved components were assessed for surface damage mechanisms, including plastic deformation, scratching, burnishing, and fracture. Patient history and indications for PEEK rod implantation were obtained from analysis of the medical records.
Results 11/12 PEEK rod systems were employed for fusion at one level, and motion preservation at the adjacent level. Surgical complications in the PEEK cohort included a small dural tear in one case that was immediately repaired. There were no cases of PEEK rod fracture or pedicle screw fracture. Retrieved PEEK rods exhibited scratching, as well as impressions from the set screws and pedicle screw saddles. PEEK debris was observed in two patient tissues, which were located adjacent to PEEK rods with evidence of scratching and burnishing.
Conclusion This study documents the surface changes and tissue reactions for retrieved PEEK rod stabilization systems. Permanent indentations by the set screws and pedicle screws were the most prevalent observations on the surface of explanted PEEK rods.

Keywords PEEK rods · Posterior fusion · Retrieval analysis · Tissue response · Revision

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Introduction

Polyaryletheretherketone (PEEK) rod systems were clinically introduced in 2006 as an alternative to metallic posterior rod fusion systems for the lumbar spine [1]. Biomechanical testing suggests that PEEK rods provide equivalent stability to the instrumented spine as titanium (Ti) alloy rods, but may also increase anterior column load sharing and reduce torques at the interface between pedicle screws and bone [2, 3]. In addition, PEEK rods are radiolucent in radiographs and CT scans, and do not create artifacts in MRI [1, 4].

Few studies have documented the clinical outcomes of PEEK rods used for fusion [5]. De Iure et al. [5] retrospectively reviewed 30 fusion cases in a single-cohort observational study with average follow-up of 18 months. All but one of the patients achieved satisfactory fusion, but the authors recommended longer follow up to better judge the effectiveness of PEEK rods for fusion.

PEEK rods have also been used in posterior dynamic stabilization without fusion [4]. Highsmith and colleagues [4] outlined two nonfusion indications in which the flexibility of PEEK rods could be exploited. One of the proposed nonfusion indications was to dynamically stabilize levels adjacent to a previous lumbar fusion for treatment of adjacent segment disc disease. As a second nonfusion indication, Highsmith et al. [4] proposed the use of PEEK rods as a posterior tension band construct to treat spondylolisthesis and stenosis. Recently, a third, so called "hybrid," dynamic stabilization strategy has emerged in the literature [6–8] that combines both fusion and nonfusion approaches to treat patients with multilevel lumbar disease, and represents a subtle extension of the ideas proposed by Highsmith [4]. A variety of devices are proposed in the literature for prophylactically "topping off" a fusion in a multilevel construct [7], including artificial discs, interspinous devices, and posterior flexible rod systems. In theory, PEEK rods could be used in either of the fusion and nonfusion segments of a hybrid construct, or in both. As of yet, no data is available on the use of PEEK rods as components of hybrid dynamic stabilization.

Little is known about in vivo changes to PEEK rods or how these changes affect periprosthetic tissue responses. In 2004, we started a multi-institutional retrieval program to analyze explanted motion preserving spinal implants [9], including PEEK rods, and their associated explanted devices and tissues. The purpose of this study was to analyze the indications for implantation of PEEK rod systems and reasons for revision, including mechanisms of surface implant damage and histological changes within periprosthetic tissues removed at revision surgery.

Methods

This work was completed as a part of a prospective study, organized to analyze explanted spinal devices and associated retrieved periprosthetic tissues collected at revision surgery. This initiative is a part of an ongoing collaboration between three high volume spine surgery centers and a university-based biomedical engineering retrieval center, for which IRB approval has all been obtained [9]. Consent was obtained from patients to participate in this research and to donate their explanted devices to the retrieval program. Patients who were previously treated with PEEK rods were consecutively revised between 2008 and 2012 in routine clinical practice, and not as part of a prospective clinical trial.

Twelve patients with PEEK rods were revised, and their posterior hardware was retrieved. The patient age ranged from 35 to 64 years (mean ± SD 52 ± 10 years), 8/12 patients were female, and the implantation time of the PEEK rods ranged from 0.5 to 2.8 years (mean ± SD 1.7 ± 0.8 years). All of the rods were of the same design (CD Horizon Legacy: Medtronic, Memphis TN, USA). The PEEK rods were pre-curved in the sagittal plane to accommodate lumbar lordosis, have an elliptical cross-section to optimize bending resistance, and are designed with metallic end caps for visualization in medical imaging. The rods varied in length depending upon the number of treated levels (Table 1).

Indications for surgery and reasons for revision

Patient history and indications (fusion vs. nonfusion stabilization) were obtained from analysis of the medical records. Diagnostic imaging and the complete set of retrieved posterior instrumentation (rods, set screws, and pedicle screws) were obtained in all cases. Judging the indications was more complex in cases with a history of previous spinal surgeries and involving multiple spinal devices. In these complex cases, a distinction was made between the indications for initial surgical intervention and the indications for treating the level(s) with PEEK rods. The indications were inferred from the medical records and diagnostic imaging.

Assessment of wear and surface damage

The 12 sets of retrieved components ($n = 23$ retrieved PEEK rods, total) were cleaned in a 10 % bleach solution and sonicated to remove loose debris. The rod surfaces were examined under a stereomicroscope equipped with a digital camera (Leica DFC490) to assess for surface damage, including gross fracture and for the presence of fatigue cracks [9]. We inspected the PEEK rods to identify surface damage mechanisms, including plastic deformation, scratching, burnishing, pitting, and the presence of embedded debris [9]. Special attention was paid to the areas where the rods and screws interfaced. We also inspected the metallic components for evidence of scratching, wear, or signs of corrosion.

PEEK rods were also imaged with a MicroCT (μCT 80: Scanco, Paoli, PA, USA) to provide 3-dimensional reconstructions for rod curvature evaluation. The radius of curvature was determined by matching circles of known radii to each rod's sagittal cross-section. Circles were aligned to each rod along the inside edge, at the midline, and along the outer edge of the rods, resulting in three localized radii measurements for each rod. All rods were analyzed and subsequently reviewed by the same investigators (G.H. and D.M.)

Histologic and wear particle analysis of periprosthetic tissues

Periprosthetic tissue samples were obtained during revision surgery from eight of the 12 patients. The tissues were

Table 1 Summary of clinical data for PEEK rod revision cases

Case	Gender	Age at insertion	Primary diagnosis (index surgery)	Revisions prior to PEEK rod implantation	Intention to treat patient	PEEK rod treated level	Intention to treat levels w PEEK rods	Concurrent spinal devices (Levels)	Implantation time (years)	Reason for revision (in addition to pain)
1	F	64	Disc degeneration	1	Fusion	L2/L3–L4/L5	Fusion	Cages (L2–3, 3–4, 4–5)	2.22	Motor vehicle trauma
2	F	43	Disc degeneration	1	Fusion	L3–L4–L5/S1	Fusion	Cages (L3–4, L4–5, L5–S1)	2.63	Painful hardware, residual osteophytes L5–S1
3	F	43	Disc degeneration	2	Fusion	L2/L3–L4/L5	Fusion	Cages (L2–3, 3–4, 4–5)	0.76	Adjacent level instability and deformity, L5–S1
4	M	58	Facet arthropathy	1	Fusion	L5/S1	Fusion	Cages (L5/S1)	0.75	Hardware-related muscular paravertebral pain
5	M	50	Disc degeneration	0	Hybrid	L5/S1	Fusion	TDR (L4/5), Cages (L5/S1)	2.75	Screw impingement of the L4–5 facet, nerve root encroachment
6	F	60	Spondyloarthropathy, radiculopathy, instability	1	Fusion	L4/L5–L5/S1	Fusion	None	1.75	Epidural seroma
7	F	64	Disc degeneration	1	Fusion	L4/L5–L5/S1	Fusion	Cages (L5/S1)	2.25	Adjacent segment instability at L3–L4 and radiculopathy
8	M	48	Disc degeneration, facet arthropathy, radiculopathy	0	Fusion	L4/L5–L5/S1	Fusion	None	1.75	Adjacent segment disease at L3–L4
9	M	45	(reason for TDR placement)—Disc degeneration, disc herniation (reason for PEEK rod implantation)—TDR revision, pt refused TDR removal	4+	Hybrid	L4/L5	Fusion (TDR Revision)	TDR (L4/5), Cages (L5/S1)	0.49	Pseudoarthrosis
10	F	44	Disc degeneration L4/L5 and L5/S1; Disc herniation at L5/S1	0	Hybrid	L4/L5–L5/S1	Hybrid	Cage (L5/S1)	2.18	Screw loosening
11	F	35	Right leg radicular pain, failed decompression	1	Fusion	L3/L4–L5/S1	Fusion	None	2.00	Pseudoarthrosis
12	F	64	Disc degeneration	0	Fusion	L4/L5–L5/S1	Fusion	Cage (L5/S1)	1.00	Adjacent (prexisting) stenosis L3–4, facet arthritis, pseudoarthrosis

fixed in universal molecular fixative (Sakura Finetek USA, Inc.) for 4 days, transferred into 100 % ethanol, and stored at 4 °C. Based on the gross appearance of each tissue, two to four 4-mm representative areas of each tissue were selected for analysis. The 4-mm tissue punches were embedded in paraffin, sectioned (6 μm), dewaxed, and stained with Hematoxylin and Eosin (H&E). Using a Motic BA300 polarizing microscope operable with a stepper motor-controlled stage and a Jenoptik microscope camera (resolution 2,580 × 1,944 pixels; 20X objective), a 16-image montage was obtained for a representative region of each tissue section under brightfield and polarized light conditions. Brightfield images were visually scored for the presence of inflammation (histiocytes and giant cells), calcification, degeneration and the presence of wear debris.

Polarized light microscopy was used to determine the number and size of PEEK particles embedded in tissues as a result of implant wear, and the image array was repeated to collect the same 16 images that corresponded with the brightfield images. PEEK wear particle properties were determined using a customized macro in NIH ImageJ. In brief, polarized light images were split into three 8-bit channels (red, green, and blue). Two of the three 8-bit channels (green and blue) were summated and converted into two sets of masks according to particle size. All images were manually reviewed to ensure that false positive signals from birefringent collagen did not contribute to particle results. The resulting particle number, reported in number per image, was then converted to number per mm^2 area of tissue using a measured conversion factor of 0.27 μm/pixel.

Results

Indications for surgery and reasons for revision

Fusion was the original indication for the majority of the patients this study (9/12; Table 1). In 6/9 fusion cases, the PEEK rods were used as part of a salvage procedure during the revision of a previous failed fusion (Fig. 1). These re-revision patients generally had a longer and more complex history of low back pain and surgical intervention than the primary surgery candidates.

Three patients were treated with hybrid spine stabilization (Table 1) from L4–S1, but the PEEK rods were used for a different purpose in each patient. In only one hybrid case were the PEEK rods themselves used to also dynamically stabilize the adjacent segment (L4/L5) in a two-level construct in which L5/S1 was fused (Fig. 2); this female patient was revised for two loose pedicle screws after 2.2 years of implantation. In a second hybrid case, a

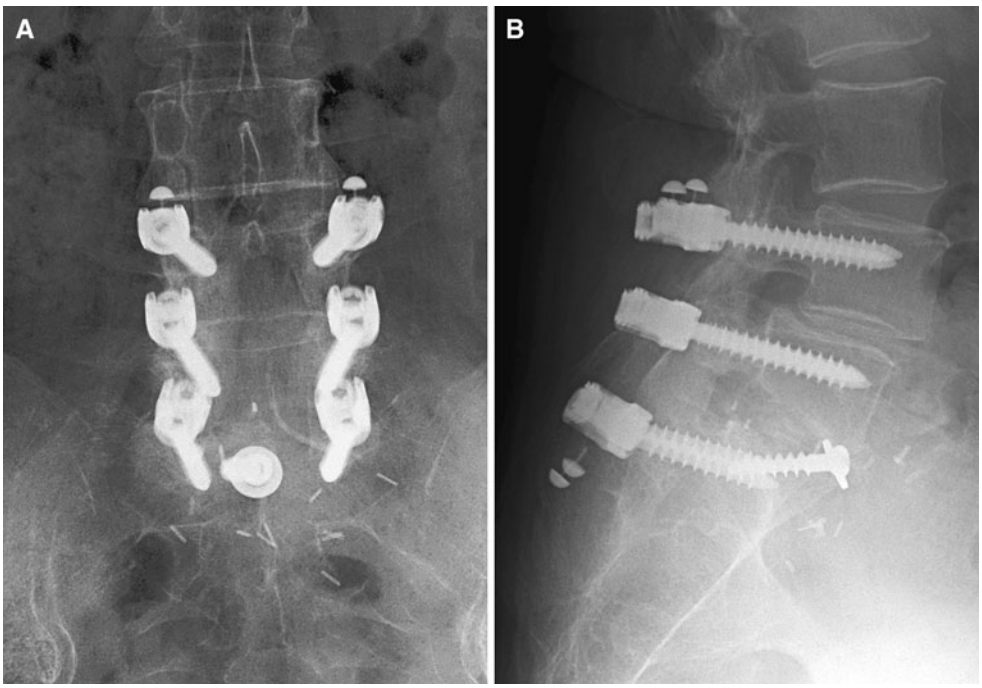

Fig. 1 Pre-revision antero-posterior and lateral radiographs of a 64 year-old female patient, implanted with PEEK rods as an adjunct to fusion L4–S1 (Case 12, Table 1). Revision took place 1 year after implantation due to the adjacent, preexisting stenosis at L3–L4, facet arthritis, and bilateral L5–S1 pseudoarthrosis

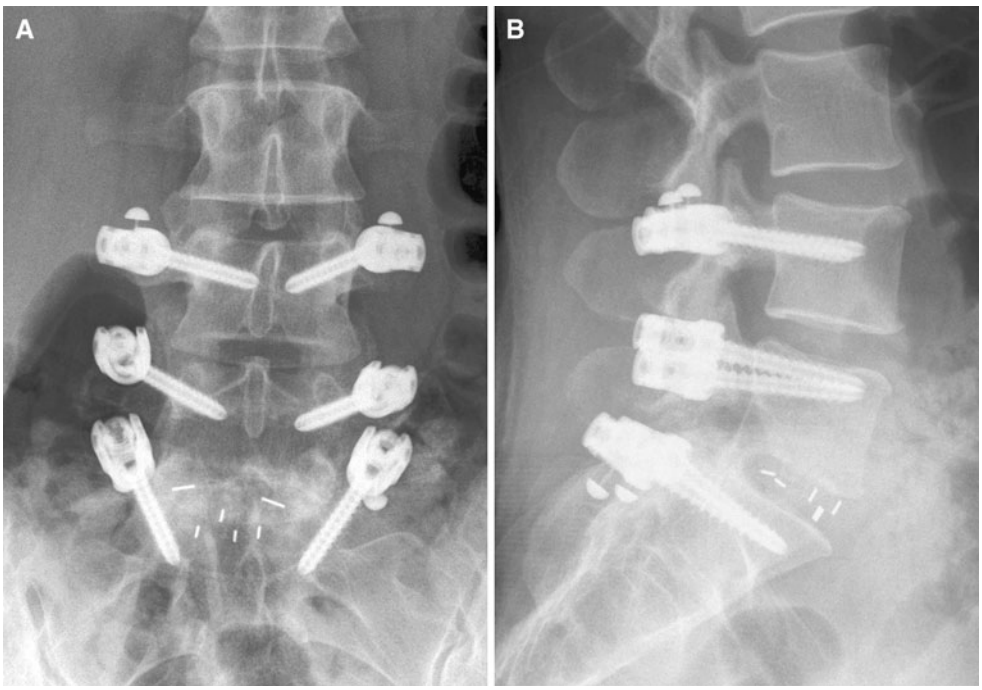

Fig. 2 Pre-revision antero-posterior and lateral radiographs of a female patient, implanted with PEEK rods as a hybrid stabilization of L4–S1 (Case 10, Table 1), in which the original intent to treat the patient was nonfusion L4–L5 and fusion L5–S1. Revision took place 2.2 years after implantation due to the loosening of two right pedicle screws at the screw/bone interface of L4 and L5. All of the set screws were secure at the time of revision

lumbar artificial disc was used at L4/L5 while the PEEK rod system was implanted along with a cage at L5/S1 to fuse the segment (Fig. 3); this 50 year old male was revised for screw impingement of the L4/L5 facet after 2.8 years of implantation. In the third hybrid case, the patient had a lumbar artificial disc at L4/L5; along with previous cages for fusion at L5/S1 prior the PEEK rod implantation (Fig. 4). The PEEK rods were used in a salvage procedure to fuse the segment with the artificial disc because this patient, a 45 year-old male, initially refused disc retrieval. Ultimately, the PEEK rods and artificial disc at L4/L5 were revised for nonunion after 0.5 years of implantation. Overall, only in one of the patients (Fig. 2) treated with hybrid stabilization were PEEK rods used solely for motion preservation. For two of the hybrid cases (Figs. 3, 4), the intent to treat the local segment using PEEK rods was for fusion. Thus, when analyzing the indications for the specific spinal segments, 11/12 retrieved PEEK rod systems were actually used for fusion.

All of the patients in this study were revised for intractable pain, although the mechanism varied and was confirmed by intraoperative findings (Table 1). The most frequently reported reasons for revision among fusion PEEK rod patients included adjacent segment disease in three patients, hardware-related muscular paravertebral pain in two patients, and pseudoarthrosis in two patients. The revision reasons for the PEEK rod patients are summarized in Table 1. The revision procedure for PEEK rods was via posterior approach. Surgical complications in the PEEK cohort included a small dural tear in one case that was immediately repaired.

Assessment of wear and surface damage

There were no cases of PEEK rod fracture or pedicle screw fracture in this series. The predominant observation on the rods was plastic deformation by the pedicle screws and set screws (Fig. 5a, b). Burnishing and scratching were also noticed on the rods, however their extent appeared to be minor. On the rods from Case 10 (revised for screw loosening, Table 1) scratches and indentations were deeper and more prevalent than in the other cases we examined (Fig. 5c). Damage to the metallic components consisted primarily of scratching. In six rods used in four of the PEEK rod systems, mild discoloration was observed of the PEEK at the titanium end caps. It was, at times, difficult to determine whether the surfaces were mildly scratched by surgical instrumentation upon removal or if the scratching occurred in vivo.

The radius of curvature varied among the retrieved rods and averaged 119 ± 19 mm (range 92–160 mm). There was no significant correlation between implantation time and the radius of curvature of the retrieved rods ($P = 0.35$).

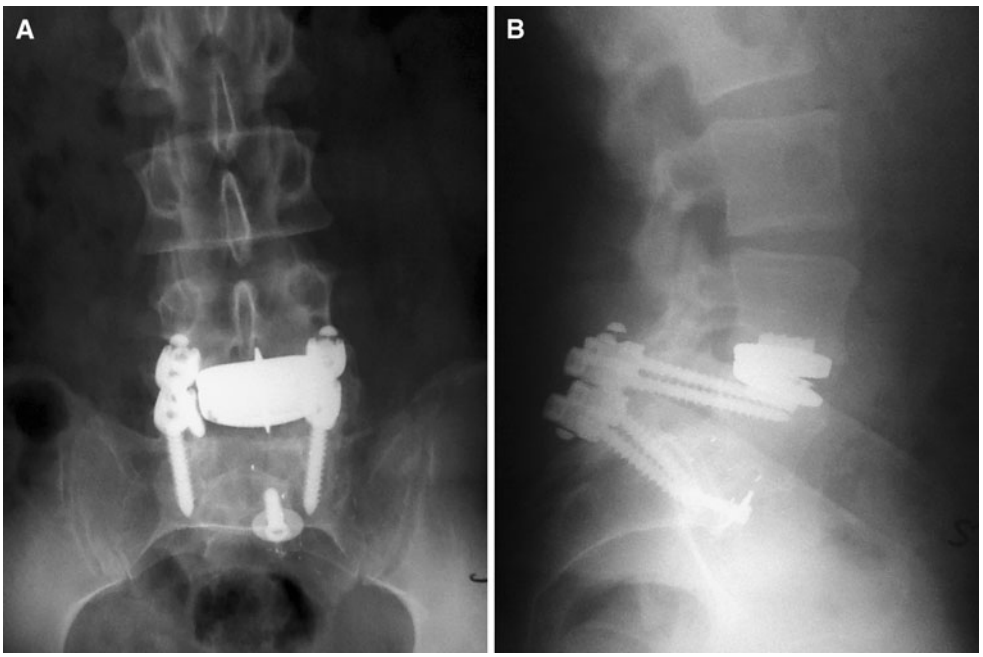

Fig. 3 Pre-revision antero-posterior and lateral radiographs of a 50 year-old male patient, implanted with an artificial disc as a hybrid stabilization of L4–S1 (Case 5, Table 1), in which the original intent to treat the patient was nonfusion L4–L5 and fusion using PEEK rods at L5–S1. Revision of the PEEK rods took place 2.8 years after implantation due to the screw impingement of the L4–5 facet and nerve root encroachment

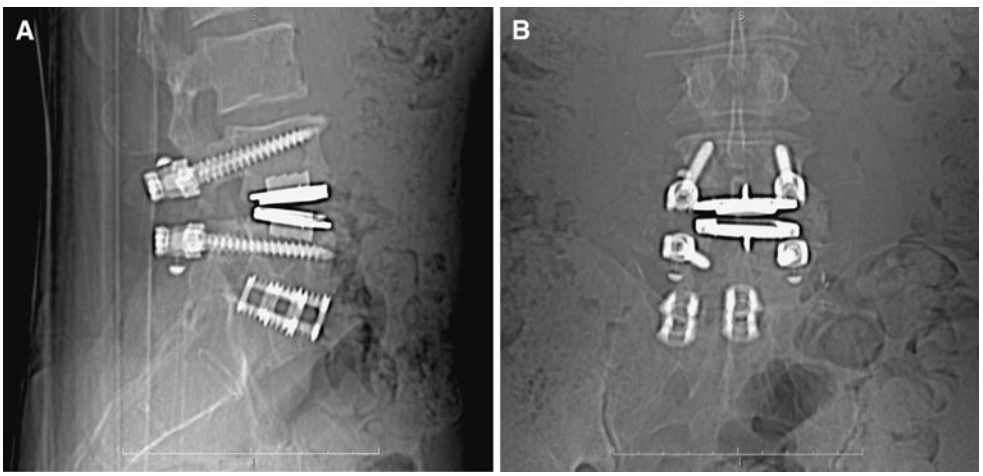

Fig. 4 Pre-revision antero–posterior and lateral radiographs of a 45 year-old male patient, implanted with PEEK rods as a salvage procedure for hybrid stabilization using an artificial disc at L4–L5 (Case 9, Table 1). Revision took place 0.5 years after implantation due to nonunion

Histologic analysis of periprosthetic tissues

Using brightfield and polarized light microscopy, PEEK debris was observed in 2 of the 8 patient tissues. The PEEK debris was located adjacent to rods with evidence of scratching and burnishing. The PEEK wear debris from these two patients was irregularly shaped, and based on their equivalent circular diameter (ECD), both small (0.5–2 μm) and large (> 2 μm; 2–61 μm) wear debris were observed. The average ECD of the small wear debris was 1.3 ± 0.35 μm; the particle number for the small wear debris was $2.0 \pm 4.6/mm^2$ tissue area. The average ECD of the large wear debris was 10.0 ± 11.5 μm; the particle number for the large wear debris was $4.9 \pm 10.2/mm^2$ tissue area. Twenty one percent of the large wear debris was >10 μm in size. The larger wear debris was encapsulated and associated with limited inflammation (Fig. 6). Metal debris was observed in 2/8 patient tissues that did not

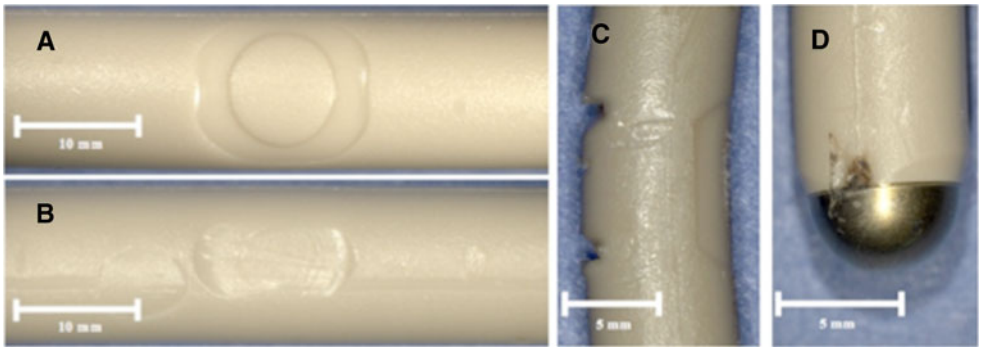

Fig. 5 Examples of surface damage in retrieved PEEK rods. Plastic deformation of the convex (**a**) and concave (**b**) surfaces of Case 12 due to impressions from the pedicle screw and set screw, (respectively). (**c**) Rod from Case 10 exhibiting scratching at the screw-rod interface. (**d**) Titanium end cap discoloration of a PEEK rod from Case 12

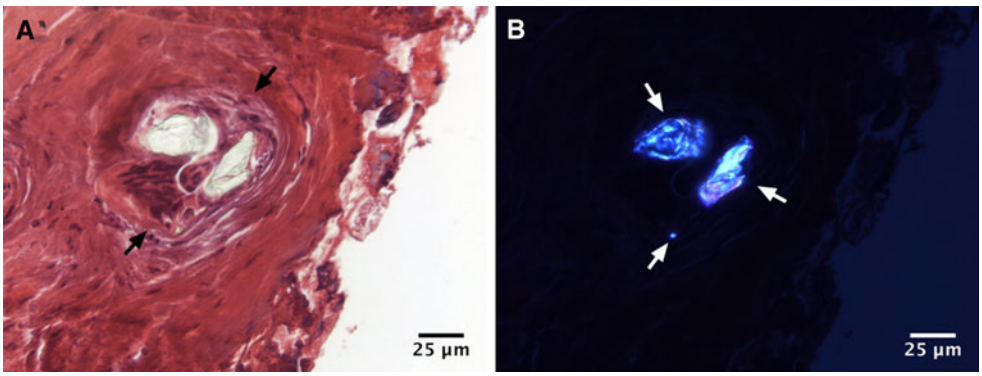

Fig. 6 Histologic and polarized images of PEEK rod tissues from Case 4. (**a**) Brightfield image of a representative H&E stained tissue. The *black arrows* indicate the encapsulated PEEK wear debris and associated inflammation, (**b**) corresponding polarized light image showing birefringent PEEK wear particles (*white arrows*). Images acquired at 400× magnification

contain PEEK wear debris. These tissues were located adjacent to metallic components showing evidence of scratching.

Seven of the eight periprosthetic tissue samples retrieved with the PEEK rods showed signs of isolated or extensive degeneration. Four of these patient tissues also had areas of tissue calcification. Isolated areas of chronic inflammation were observed in tissues from the four patients with calcification, and one of the other patients with tissue degeneration (5/8). Mixed inflammation was observed in two other patient tissues with evidence of metal wear debris.

Discussion

This study documents the surface changes and tissue reactions for retrieved PEEK rod stabilization systems. To the authors' knowledge, this study represents the first analysis of retrieved PEEK posterior fusion rods. Thus, the present series provides crucial, previously unavailable data regarding the clinical failure modes, in vivo surface damage mechanisms, and tissue response associated with revised PEEK rods. Detailed analysis of revision cases with device retrieval analysis is essential to completely understand the safety profile for new implant systems after clinical introduction, because preclinical testing cannot always predict the complete spectrum of clinical failure mechanisms.

Our data suggest that PEEK fusion rods are associated with similar clinical risks to traditional metal rod systems used for posterior lumbar fusion. The revision reasons for the PEEK rod systems, including arthrodesis, hardware-related pain, disease progression, and unrecognized adjacent level disease, are well documented in the literature for metallic posterior fusion systems. One concern regarding PEEK rods is their durability, which has been assessed in laboratory fatigue studies [10]. During preclinical testing, fatigue fracture of PEEK rods has been shown to initiate at the rod-screw interface [10]. In our examination of the retrieved rods, we documented screw impressions in both PEEK and metal rods, but no evidence of fatigue cracks or fracture. We did note a 68 mm range of rod curvature among retrievals suggesting that rods do permanently

deform in vivo, although a trend with implantation time could not be identified. Another concern with PEEK rods is the release of wear debris, however we found limited evidence of PEEK wear debris release. The large PEEK debris observed in this study was encapsulated and was associated with limited inflammation.

Screw loosening, while a known failure mechanism for posterior instrumented fusion, is especially a concern for nonfusion applications in which the screw interface may be loaded for a longer duration and with greater loads than in fusion applications. For example, previous retrieval studies of the Dynesys posterior dynamic stabilization system documented screw loosening as a reason for revision in 11/17 (65 %) of the retrieved cases, all of which were used for nonfusion [11]. In our series, screw loosening was only observed in 1/12 revisions, albeit in the sole nonfusion application of PEEK rods of the study. We will need additional cases to perform a quantitative comparison of the relative incidence of screw loosening among revised cases with both fusion and nonfusion applications of PEEK rods.

Like all revision retrieval studies, our research is limited to a relatively small number of cases requiring surgical intervention and hardware removal, and thus cannot be used to establish the overall revision or complication risk for the clinical use of PEEK rod systems. Furthermore, many of our cases were salvage procedures with a history of previous spinal surgeries, which are more difficult than primary fusions. Nevertheless, the findings from this relatively small series of revision cases are a useful complement to the data obtained in prospective clinical studies. Additional characterization of long-term in vivo changes in the retrieved PEEK rods and explanted tissues is also warranted and ongoing at our institutions.

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Conflict of interest Institutional support has been received from Medtronic and Invibio for research unrelated to the current study. One of the authors (TL) is a consultant for Medtronic and collaborated on the design of PEEK rod systems.

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