Histology of Periprosthetic Tissues and Analysis of Retrieved PEEK Spherical Nucleus Pulposus Replacements

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Significance: The study of patient tissues and retrieved implant components provides insight into the clinical performance and relevance of PEEK implant wear after lumbar nucleus pulposus replacement. A better understanding may ultimately help to improve the design of this prosthesis type.

Introduction: Every year, approximately 65 million Americans suffer from lower back pain, with about 12 million having degenerative disc disease (DDD) [1]. DDD is a painful, incapacitating condition that has traditionally been treated by spinal fusion. However, in the 1960s, total disc replacements (TDR) were developed to allow patients to retain spine mobility. Based on the early work of Fernström [2], one alternative to TDR is the implantation of a nucleus pulposus (NP) replacement system composed of a wear resistant polyetheretherketone (PEEK) sphere. Compared with Fernström’s spheres, which were originally fabricated from stainless steel ball bearings [2], the PEEK implants were developed to provide improved in situ imaging. These devices have not been approved by the FDA at the present time, and little is known about the biological response to these PEEK NP devices over time.

We hypothesized that PEEK wear debris will be generated, and that retrieved tissue surrounding revised PEEK implants may be inflamed and have undergone morphological changes that contribute to pain.

Methods: Eight periprosthetic tissue samples (n=8) were obtained from 4 patients during revision surgery of PEEK NP spinal systems. The tissue regions included endplate (1 sample) and disc (7 samples) tissue. Three of the PEEK spheres were manufactured by Medtronic (Satellite); in one case (008) the PEEK sphere manufacturer could not be verified.

Results: Two of the four patients (SP-001 and SP-006) showed relatively normal tissue morphology (Fig. 1A-B). Although an occasional blood vessel was observed (Fig. 1C), there were no degenerative areas, wear debris or inflammation. In contrast, the other two patients’ tissues contained largely degenerative areas. Specifically, marked necrosis, large cell clusters, isolated areas of inflammation (Fig. 2A-B) and an occasional PEEK wear debris particle (Fig. 3A-B) were prominent features of SP-005 tissue. The tissue morphology for SP-008 showed necrosis, degenerating large cell clusters, isolated blood vessels (Fig. 2C), and small amounts of PEEK wear debris (Fig. 3C-D), however inflammation was not observed.

Discussion: The clinical performance and relevance of PEEK implant wear after lumbar nucleus pulposus replacement were assessed based on patient tissue responses and retrieved implant component changes. The endplate and disc tissue from two patients showed relatively normal tissue morphology, except for the occasional blood vessel. The remaining patient tissue samples showed degenerative matrix and cellular morphology. Both also contained a few PEEK wear debris particles, however there was not enough wear debris in either patient tissue to account for the degenerative changes. The small amount of wear debris correlated with the minimal evidence of wear on the devices. A limitation of the study is that three of the four patients implanted with PEEK spheres, had a history of prior spine surgeries, which complicates the interpretation of the histology results.

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Table 1: Clinical information for the 4 retrieved devices.

<table>
<thead>
<tr>
<th>Implant ID</th>
<th>Implantation Time (y)</th>
<th>Revision Reason</th>
<th>Age (y)</th>
<th>Level</th>
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<td>Pain</td>
<td>45</td>
<td>L4/L5</td>
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<td>Pain</td>
<td>35</td>
<td>L5/S1</td>
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<tr>
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<td>Pain</td>
<td>18</td>
<td>L5/S1</td>
</tr>
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<td>Pain</td>
<td>49</td>
<td>L4/L5</td>
</tr>
</tbody>
</table>

Figure 1. Representative images of Satellite implant patient tissue morphology. Tissue from two patients with relatively normal morphology, (A) SP-001 patient endplate tissue had densely organized collagen and numerous chondrocytes (blue arrow), typical morphology for this region of the intervertebral disc. (B) SP-001 disc tissue had the expected sparsely dispersed chondrocytes and loosely organized collagen matrix (orange arrow). (C) SP-006 disc tissue blood vessel (green arrow).

Figure 2. Representative images of degenerative morphological tissue changes. (A) SP-005 patient disc tissue, (B) tissue from the same patient and (C) SP-008 implant patient tissue. Disc tissue from both patients showed predominantly degenerative changes including large cell clusters (orange arrows), some of which were undergoing cell death (C), and generalized loss of collagen matrix definition and tissue organization. Occasional areas of inflammation (yellow arrow) and blood vessels (green arrow) were also observed.

Figure 3. Presence of PEEK wear debris. (A) Satellite patient SP-005 disc tissue with degenerative morphology, (B) corresponding polarized light image (C) Patient SP-008 tissue with degenerative morphology, and (D) corresponding polarized light image. Yellow arrows indicate wear debris.