Basic Science

Does impaction of titanium-coated interbody fusion cages into the disc space cause wear debris or delamination?

Annette Kienle, MD\textsuperscript{a,*}, Nicolas Graf, Dipl-Ing (FH)\textsuperscript{b}, Hans-Joachim Wilke, PhD\textsuperscript{b}

\textsuperscript{a}SpineServ GmbH & Co. KG, Soeflinger Strasse 100, Ulm D-89077, Germany
\textsuperscript{b}Institute for Orthopedic Research and Biomechanics, Helmholtzstr. 14, Ulm D-89081, Germany

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Abstract

BACKGROUND CONTEXT: A large number of interbody fusion cages are made of polyetheretherketone (PEEK). To improve bone on-growth, some are coated with a thin layer of titanium. This coating may fail when subjected to shear loading.

PURPOSE: The purpose of this testing was to investigate whether impaction of titanium-coated PEEK cages into the disc space can result in wear or delamination of the coating, and whether titanium cages with subtractive surface etching (no coating) are less susceptible to such failure.

STUDY DESIGN/SETTING: A biomechanical study was carried out to simulate the impaction process in clinical practice and to evaluate if wear or delamination may result from impaction.

MATERIALS AND METHODS: Two groups of posterior lumbar interbody fusion cages with a similar geometry were tested: \(n = 6\) titanium-coated PEEK and \(n = 6\) surface-etched titanium cages. The cages were impacted into the space in between two vertebral body substitutes (polyurethane foam blocks). The two vertebral body substitutes were fixed in a device, through which a standardized axial preload of 390 N was applied. The anterior tip of the cage was positioned at the posterior border of the space between the two vertebral body substitutes. The cages were then inserted using a drop weight with a mass representative of a surgical hammer. The drop weight impacted the insertion instrument at a maximum speed of about 2.6 m/s, which is in the range of the impaction speed \(\text{in vivo}\). This was repeated until the cages were fully inserted. The wear particles were captured and analyzed according to the pertinent standards.

RESULTS: The surface-etched titanium cages did not show any signs of wear debris or surface damage. In contrast, the titanium-coated PEEK cages resulted in detached wear particles of different sizes (1–191 \(\mu\)m). Over 50% of these particles had a size \(< 10 \mu\)m. In median, on 26% of the implants’ teeth, the coating was abraded. Full delamination was not observed.

CONCLUSIONS: In contrast to the surface-etched implants, the titanium-coated PEEK implants lost some coating material. This was visible to the naked eye. More than half of all particles were of a size range that allows phagocytosis. This study shows that titanium-coated implants are susceptible to impaction-related wear debris. © 2015 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Keywords: Delamination; Impaction; Interbody fusion cage; Subtractive surface etching; Titanium coating; Wear

Introduction

Many different interbody fusion devices are on the market today. Polyetheretherketone (PEEK) is a material widely used for this type of implant. Its main advantage is its radiolucency, which is claimed to allow evaluation of the fusion progress using X-ray techniques. On the other hand PEEK is known not to be osteoconductive [1,2], which may have a negative effect on the fusion rate. Therefore, some PEEK implants are coated by a thin layer of titanium. This was shown to increase the shear strength between implant and bone [3,4] and thus may reduce the risk of loosening. On the other hand, coatings potentially bear the risk of wear or delamination.
Wear or delamination may be caused by shear loading. Therefore, shear loading is the basis for American Society for Testing and Materials (ASTM) standardized testing [5] required by regulatory bodies to clear these devices for the market. This standardized, quasi-static testing, however, does not mimic a specific clinical situation. Rather, it involves cementing two test specimens together using an adhesive bonding agent and subsequently loading the specimens at a rate of 0.25 cm/min until they separate. In clinical practice, shear loading occurs during impaction of the cages into the disc space. Impaction rates are simulated in the present study. These are more than 60,000 times faster than is specified in the standard. Further, this ASTM standard tests for complete separation of the components rather than discrete failure of the coating or the generation of particulate debris.

In clinical practice, shear loading occurs during impaction of the cages into the disc space. Shear loading may also be part of the micro-motion between a fusion cage and the end plate postoperatively. This micro-motion is much smaller in magnitude compared with the distance the cage covers on the end plates during insertion impaction. Impaction is therefore suspected to be the most critical situation for the coating.

Various animal studies investigated the mechanical characteristics of titanium plasma-sprayed coatings. Titanium particles were found in the peri-implant tissues of coated titanium implants even in cases where the implants were not loaded. It was concluded that this was due to the friction between the host bone and the implant during insertion [6–8]. Whether this phenomenon is also present after impaction of coated intervertebral fusion cages into the disc space is unknown. If wear debris or delamination occurs, this could increase the risk of inflammation and implant loosening [9–11].

The purpose of this mechanical testing was to investigate whether impaction of titanium-coated PEEK cages into the disc space can result in wear debris or delamination of the coating, and whether titanium cages with subtractive surface etching (no coating) are less susceptible to this kind of failure.

Materials and methods

Two groups of six posterior lumbar interbody fusion cages were included into this study (Fig. 1, Table 1). All implants were provided by Titan Spine (Mequon, WI, USA). Both had a similar geometry, but they differed in the material they were made of. The first group was made of PEEK, which was coated with a thin layer of porous, vacuum plasma-sprayed titanium on its upper and lower surfaces. The second group was fully made of titanium with a subtractive process acid-etched surface, not a coating (Titan Spine, Mequon). This surface has been shown to improve factors associated with osseointegration [12].

The cages were impacted into the space in between two vertebral body substitutes. These were made of polyurethane (PU) foam, grade 40 pcf (ERP #1522-05, Sawbones Europe AB, Sweden). This material is commonly used in testing as a cortical bone substitute [13]. The PU blocks were rectangular in shape (40×35×20 mm) and had a planar surface. A planar surface was chosen to mimic the surface of the end plates with mild disc degeneration [14].

Two vertebral body substitutes were fixed in a device, which incorporates a pneumatic cylinder (DFM-32-50-PA-KF, Festo, Germany) and a load cell (8524-6010, 10 kN, Burster, Germany), both aligned in the axial direction (Fig. 2). Using the cylinder, an axial preload of 390 N was applied to the surrogate vertebral bodies. This load was chosen to mimic the average clinical situation. The physiological preload in vivo in a relaxed lying position is about 140–240 N [15–19].

![Titanium-coated PEEK cage](image1)

![Subtractive surface-etched titanium cage](image2)

Fig. 1. Two different posterior lumbar interbody fusion cages were tested. One was made of polyetheretherketone (PEEK) and had a titanium-coating on its upper and lower surfaces. The second one was fully made of titanium with a subtractive-etched upper and lower surface. Both cages had a similar geometry and were of similar size.
contrast, the axial preload prescribed in various ASTM standards is 500 N for lumbar spine implants [20]. There are 390 N that lie in between these limits. The pneumatic cylinder of the axial preload device additionally acted as an air spring. Thus, the axial load increased when the segment was distracted.

The two vertebral body substitutes were not connected by a simulated fenestrated and nucleotomized disc because this was not necessary mechanically. The remaining disc structures after nucleotomy do not directly influence the impaction of the cages except for the axial preload. This preload was simulated as described above.

For impaction, the insertion instrument was connected to the cages, which were aligned in axis with the anterior-posterior direction of the two vertebral body substitutes. The anterior tip of the cages was manually inserted into the simulated disc space, in the position where the surgeon would begin impaction (Fig. 3).

The cages were then inserted using a drop weight with a mass representative of a 1-lb surgical hammer. The drop weight impacted the insertion instrument at a maximum speed of about 2.6 m/s. Because there are no data available concerning the real impaction force and the real impaction energy during surgery, care was taken to mimic the surgeon’s hammering as closely as possible. Only if the weight and its impaction speed are realistic, the impaction energy and the impaction force are realistic as well.

The impacts were repeated until the cages were fully inserted into the space. According to several surgeons’ experiences, three to four hits are customary. During impaction, the handle of the instrument glided along the gliding holder, which kept it aligned throughout the whole experiment.

The evaluation was focused on (1) the surface of the cages and (2) the wear particles captured:

1. The superior and inferior surfaces of each cage were visually inspected to search for areas that had worn off. To get an idea of how much of the cage’s surface was affected, a semiquantitative evaluation was carried out (Fig. 4). For this purpose, microscopic images were taken of the upper and lower surfaces of the cages. Each of the 79 teeth on the upper plus lower surfaces of the cage was subdivided into four triangular quadrants. Then, the degree to which each single tooth was worn off was evaluated: none; worn off no more than 25% of its surface; worn off more than 25% but no more than 50%, etc. Additionally, representative scanning electron microscopy images were made to get a closer view of some of the affected areas.

2. The wear particles were evaluated according to ASTM F1877 [21]. For this purpose, care was taken to capture all particles which spread away during impaction. For

Table 1
Characteristics of the cages tested in this study

<table>
<thead>
<tr>
<th>Material</th>
<th>PEEK OPTIMA (polyetheretherketone, ASTM F2026) with tantalum radiographic wires</th>
<th>Medical grade titanium alloy (Ti6Al4V ELI, ASTM F136)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surface</td>
<td>Porous, vacuum plasma-sprayed titanium coating</td>
<td>Surface etched</td>
</tr>
<tr>
<td>Roughness: Rz&lt;70 μm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thickness in mean: 108 μm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bond strength in mean: 35 MPa (ASTM F1147)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shear strength in mean: 35 MPa (ASTM F1044)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Design</td>
<td>Almost rectangular with holes in cranio-caudal and lateral direction; teeth on upper and lower surfaces</td>
<td>Increased roughness on cranio-caudal and lateral direction; increased roughness on cranio-caudal and lateral direction due to subtractive acid etching</td>
</tr>
<tr>
<td>Size</td>
<td>Height: 10 mm×length 24 mm</td>
<td>Height: 10 mm×length 22 mm</td>
</tr>
<tr>
<td></td>
<td>Height: 11 mm×length 24 mm</td>
<td>Height: 11 mm×length 22 mm</td>
</tr>
<tr>
<td>Angulation</td>
<td>4°</td>
<td>4°</td>
</tr>
<tr>
<td>Number of cages tested</td>
<td>n=3, height: 10 mm</td>
<td>n=3, height: 10 mm</td>
</tr>
<tr>
<td></td>
<td>n=3, height: 11 mm</td>
<td>n=3, height: 11 mm</td>
</tr>
</tbody>
</table>
this reason, the test blocks and the cage in between were wrapped in a plastic bag during impaction. Microscopic images of the particles were made, and representative areas of these pictures were evaluated (Fig. 5). For evaluation, the software ImageJ (ImageJ 1.48, NIH, Bethesda, MD, USA) was used. The final output was the size of the particles and their number-based size distribution. Because some particles were trapped rigidly inside the surface of the PU test blocks, these blocks were inspected as well.

**Results**

In both groups, two to four hits with the drop weight were necessary to fully insert the cages.

The macroscopic inspection of the cages after impaction showed differences between the two cage types. Whereas the surface-etched titanium cages did not show any signs of wear debris or surface damage, the coated PEEK cages showed some areas where the coating was fully worn off (Fig. 6). The semiquantitative evaluation of the area worn off showed that in median, 20% of all teeth of the PEEK cages were affected by up to 25% of their surface area and 6% by 25%–50% of their area (Table 2). None of the teeth were affected by more than 50%. Full delamination was not seen, but one of the cages showed a cracking through the PEEK material at its anterior inner edge (Fig. 7).

In the coated PEEK cage group, the captured particles were 1–191 μm in size (Fig. 8). Particles with a size <10 μm were more frequently captured than those with a size >10 μm (Table 3). The largest particles were found on the PU foam blocks (Fig. 9 Top and Bottom). Most of these particles were deriving from the titanium coating (not the PEEK) because they were dark in color.

In the surface-etched titanium cage group no wear particles could be captured—neither from the titanium implants themselves nor in the vertebral body substitutes.
Discussion

In this study, the wear behavior of titanium-coated PEEK cages and subtractive surface-etched titanium cages (no coating) was investigated during simulated impaction into the disc space. The surface-etched titanium cages did not show any signs of wear debris. An increased roughness created by subtractive surface etching therefore does not weaken the shear strength of the material.

Part of the coating of the PEEK cages was abraded. In median, 26% of the teeth of each cage were affected. The particle analysis showed that the debris particles had a size of 1–191 μm. Many particles stayed trapped inside the surface of the PU test blocks as well as on the surface of the cages themselves. The sizes of these particles could not exactly be determined because they were not removable without being destroyed. The exact size distribution of all particles (not

Table 2

Semiquantitative evaluation of the extent to which the surface of the coated PEEK cages was worn off

<table>
<thead>
<tr>
<th></th>
<th>0%≤x&lt;25%</th>
<th>25%≤x&lt;50%</th>
</tr>
</thead>
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<tr>
<td>#1</td>
<td>16%</td>
<td>10%</td>
</tr>
<tr>
<td>#2</td>
<td>22%</td>
<td>8%</td>
</tr>
<tr>
<td>#3</td>
<td>32%</td>
<td>6%</td>
</tr>
<tr>
<td>#4</td>
<td>30%</td>
<td>6%</td>
</tr>
<tr>
<td>#5</td>
<td>18%</td>
<td>5%</td>
</tr>
<tr>
<td>#6</td>
<td>18%</td>
<td>0%</td>
</tr>
<tr>
<td>Median</td>
<td>20%</td>
<td>6%</td>
</tr>
<tr>
<td>Minimum</td>
<td>16%</td>
<td>0%</td>
</tr>
<tr>
<td>Maximum</td>
<td>32%</td>
<td>10%</td>
</tr>
</tbody>
</table>

Percentage of all teeth which were worn off to a certain extent: 0%≤x<25%—worn off more than 0% but no more than 25% of the surface; 25%≤x<50%—worn off more than 25% but no more than 50%. No tooth was worn off more than 50% of its surface area.

Fig. 7. One of the cages showed a cracking through the PEEK material at its anterior inner edge (arrows).
only of those which could be captured) may therefore somewhat differ. However, the results showed that a vacuum plasma-sprayed titanium-coating that fulfills all FDA requirements for clearance still bears the risk of wear if the implant is impacted into the disc space. This may be due to the different loading in the present study compared with the loading according to ASTM F1044 and ASTM F1147 [5,22]. Further, the ASTM standard tests for complete separation of the components; however, discrete failure of the coating and the generation of debris may also be clinically relevant.

Titanium wear debris causes biological reactions in the human body. Local inflammatory reactions have been reported in various animal and clinical studies [9–11,23–29]. New Zealand white rabbits with a body weight of 4.1–4.5 kg received 200-mg titanium particles and 95% of these particles had a size <5 μm. The results showed that titanium particulate debris causes a cytokine-mediated pro-inflammatory response with increased osteoclastic activity and cellular apoptosis [9–11]. Also macrophages seem to mediate inflammatory reactions to titanium particles. However, titanium wear particles with a diameter larger than 5–10 μm are reported to be not phagocytosable [11,24,25].

In the present study, over 50% of all captured particles were within the range of up to 10 μm. An inflammatory reaction of the human body is therefore possible.

A critical titanium tissue concentration has also not yet been found perhaps because there are many additional risk factors discussed: particle size, material, shape, etc. Therefore, it remains unclear whether the amount of wear after impact and the resulting tissue concentration of these particles are high enough to cause postoperative complications.

There are several potential weaknesses in this study. The clinical situation can strongly vary from surgeon to surgeon and patient to patient. For example, other insertion techniques or other implant designs may result in a different wear behavior. In this experimental setup, one common clinical situation was simulated: impaction of posterior lumbar interbody fusion cages. Care was taken to mimic the clinical situation to generate realistic results. In preliminary experiments, hammering was conducted to measure the speed at which the hammer strikes the instrument. Several volunteers hammered at a speed they assumed they would use in clinical practice. The evaluation of the movies resulted in a maximum speed of 2.8 m/s (10 km/h).

<table>
<thead>
<tr>
<th>Size-range (μm)</th>
<th>Counts</th>
<th>Counts cum.</th>
<th>Counts (%)</th>
<th>Counts cum. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–10</td>
<td>1703</td>
<td>1703</td>
<td>53</td>
<td>53</td>
</tr>
<tr>
<td>11–50</td>
<td>1261</td>
<td>2964</td>
<td>39</td>
<td>93</td>
</tr>
<tr>
<td>51–191</td>
<td>231</td>
<td>3195</td>
<td>7</td>
<td>100</td>
</tr>
</tbody>
</table>

*Area shown on the scanning electron microscopy image.*

**Fig. 8.** Number-based size distribution of the particles captured during impaction of the surface-coated PEEK cages.

**Fig. 9.** (Left) Representative photograph of a polyurethane test block used as vertebral body substitute after impaction of a coated PEEK cage. Scratches were found on the surface of all blocks. Titanium particles were trapped inside the porous surface of the PU material. (Right) Representative scanning electron microscopy image of a PU test block used as vertebral body substitute after impaction of a coated PEEK cage. Titanium particles were trapped inside the porous surface of the PU material. *Area shown on the scanning electron microscopy image.*

**Table 3**

| Size analysis of the captured wear particles in the coated PEEK cage group. Absolute and relative number of particles per size interval
<table>
<thead>
<tr>
<th>Size-range (μm)</th>
<th>Counts</th>
<th>Counts cum.</th>
<th>Counts (%)</th>
<th>Counts cum. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–10</td>
<td>1703</td>
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<td>51–191</td>
<td>231</td>
<td>3195</td>
<td>7</td>
<td>100</td>
</tr>
</tbody>
</table>

cum., cumulative.
A more general deviation from the situation in vivo was the use of PU test blocks as a substitute for the human vertebral body. Human cadaveric vertebral bodies were not used for several reasons: First, their material properties vary strongly depending on the degree of osteoporosis and disc degeneration of the segments. Second, they also vary concerning their surface shape. Degenerated segments tend to have flat end plates whereas healthy end plates are rather concave [14]. All these factors influence the friction and loading of the cages during impaction. Only a synthetic material with homogenous material properties and reproducible surface shape guarantees standardized and reproducible test conditions. Although the amount of wear produced during impaction maybe somewhat less or more in patients compared with PU substitutes, the difference between different cages should qualitatively be the same.

Even in light of these limitations, the results of the present testing can more easily be interpreted than a standardized mechanical shear test such as that according to ASTM F1044 because it reflects a specific clinical situation. It therefore adds important information to ASTM testing. The results indicated that this situation bears a certain risk of wear if titanium-coated PEEK cages are used even if the coating complies with the FDA requirements for mechanical testing.

Conclusions

Wear or delamination may be caused by shear loading. The ASTM standardized testing required by regulatory bodies to clear titanium-coated devices for the market does not mimic a specific clinical situation. Surgical impaction rates may be more than 60,000 times faster in clinical practice than is specified in the ASTM standard. Further, this ASTM standard tests for complete separation of the components rather than discrete failure of the coating or the generation of particulate debris.

There was a clear difference between the two types of cages. The plasma-sprayed titanium-coated implants lost some coating material whereas the subtractive surface-etched implants did not show any surface damage. To date, it is not yet known how much wear debris of what size and shape of titanium particles is needed to induce postoperative complications. Particulate wear debris is always a clinical concern as it may lead to chronic inflammatory reactions. Whether any clinical complications have to be expected due to the wear debris observed in this study is unknown. In the coated PEEK cage group, the size of more than half of the captured particles was in a phagocytosable size range. Some risk of inflammation may therefore be expected.

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References