Is galvanic corrosion between titanium alloy and stainless steel spinal implants a clinical concern?

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Abstract

BACKGROUND CONTEXT: Surgeons are hesitant to mix components made of differing metal classes for fear of galvanic corrosion complications. However, in vitro studies have failed to show a significant potential for galvanic corrosion between titanium and stainless steel, the two primary metallic alloys used for spinal implants. Galvanic corrosion resulting from metal mixing has not been described in the literature for spinal implant systems.

PURPOSE: To determine whether galvanic potential significantly affects in vitro corrosion of titanium and stainless steel spinal implant components during cyclical compression bending.

STUDY DESIGN/SETTING: Bilateral spinal implant constructs consisting of pedicle screws, slotted connectors, 6.35-mm diameter rods and a transverse rod connector assembled in polyethylene test blocks were tested in vitro. Two constructs had stainless steel rods with mixed stainless steel (SS-SS) and titanium (SS-Ti) components, and two constructs had titanium rods with mixed stainless steel (Ti-SS) and titanium (Ti-Ti) components.

METHODS: Each construct was immersed in phosphate-buffered saline (pH 7.4) at 37°C and tested in cyclic compression bending using a sinusoidal load-controlling function with a peak load of 300 N and a frequency of 5 Hz until a level of 5 million cycles was reached. The samples were then removed and analyzed visually for evidence of corrosion. In addition, scanning electron microscopy (SEM) and energy dispersive spectrometry (EDS) were used to evaluate the extent of corrosion at the interconnections.

RESULTS: None of the constructs failed during testing. Gross observation of the implant components after disassembly revealed that no corrosion had occurred on the surface of the implants that had not been in contact with another component. The Ti-Ti interfaces showed some minor signs of corrosion only detectable using SEM and EDS. The greatest amount of corrosion occurred at the SS-SS interfaces and was qualitatively less at the SS-Ti and Ti-SS interfaces.

CONCLUSIONS: The results from this study indicate that when loaded dynamically in saline, stainless steel implant components have a greater susceptibility to corrosion than titanium. Furthermore, the galvanic potential between the dissimilar metals does not cause a discernible effect on the corrosion of either. Although the mixture of titanium alloy with stainless steel is not advocated, the results of this study suggest that galvanic corrosion is less pronounced in SS-Ti mixed interfaces than in all stainless steel constructs.

Keywords: Corrosion; Dynamic testing; Pedicle screw implants

Introduction

Titanium and its alloys are regarded as highly biocompatible materials and are becoming increasingly popular in spinal implant applications. The use of titanium alloys for spinal implants has increased because of their advantageous mechanical properties, biocompatibility, corrosion resistance and compatibility with magnetic resonance imaging procedures. Nonetheless, with their introduction came the risk of inadvertent mixing with stainless steel components of
compatible systems. Additionally, surgeons may wish to mix components of different metals in order to use the best properties from them (e.g., stainless steel sublaminar wires with titanium rods, which was not tested in this study).

The main concern with mixing titanium and stainless steel is the fear of galvanic corrosion, a process that occurs when materials of different electrochemical potential are placed in close proximity in an electrolytic environment. Galvanic potential resulting from metal mixing may negatively influence the implants by hastening their corrosion and fretting, resulting in a vicious cycle that could lead to severe complications, such as aseptic loosening of the spinal implant. Corrosion can also reduce the fatigue performance of the implants, leading to mechanical failure, as previously reported [1]. Furthermore, the release of corrosion byproducts may elicit an adverse biological reaction in the host tissue. Multiple authors have reported increased concentrations of local and systemic trace metals in association with metal implants [2–4]. Finally, late-appearing infection at the spinal instrumentation site is of a major concern and may be exacerbated by corrosion [5–6]. This type of infection is treated with short-term oral antibiotics, primary skin closure and even device removal. Primarily, the infections affect soft tissues, not the bone, and the highest areas of metal debris concentration are the interconnection interfaces [5–12].

Although there is no specific histological evidence of the slow release of metal species from all metal implants, accelerated corrosion and a tissue response (e.g., discoloration, foreign body response) related to identifiable corrosion products have been demonstrated in the tissues surrounding multiple-part devices [5–7, 12–14]. Evidence of fretting and crevice corrosion has been reported for stainless steel spinal implants in retrieval studies [5–11]; particularly, Dubousset et al. [6] attributed the occurrence of late operative site infection to fretting corrosion. Even in the absence of infection, corrosion products may play a role in causing local pain and swelling at the spinal implant site [7]. The presence of particulate corrosion and wear products in the tissue surrounding the spinal implant may ultimately result in a cascade of events leading to bone loss, pseudarthrosis and possible implant failure [5, 8, 14].

The typical spinal stainless steel material contains enough chromium to give corrosion resistance by passivity. This type of stainless steel is vulnerable to pitting and to crevice corrosion at the interconnections (e.g., screw–rod interfaces) under certain circumstances, such as in a highly stressed and oxygen-depleted region [15]. Titanium forms an adherent porous layer (TiO2) and remains passive under physiological conditions. Titanium implants remain virtually unchanged in appearance and offer superior corrosion resistance [15]. Titanium-based alloys have lower overall corrosion rates when compared with stainless steel and cobalt chromium alloys.

Corrosion of spinal implants may occur as a result of mechanical or electrochemical means. Mechanical forms of corrosion include fretting, which occurs at contact areas between materials under load subjected to repeated cyclic loading or vibration. Electrochemical means include crevice, pitting and galvanic corrosion. Crevice corrosion is a form of local corrosion occurring in a confined space as a result of low oxygen concentration, high concentration of electrolytes, low pH or any combination of these effects caused by inhibited diffusion of chemicals into and out of the space, such as in the crevices between a screw and a plate [16]. Pitting occurs as a result of elemental impurities or corrosion-susceptible alloying elements on the surface of the metal. Last, galvanic corrosion occurs when materials with different electrochemical potentials are in close proximity in an electrolyte solution (such as saline) [1]. One material undergoes an oxidation reaction (anode), whereas the other material undergoes a reduction reaction (cathode). Therefore, the objective of this study was to investigate the effect of galvanic potential in mixed-metal spinal implant constructs, specifically titanium alloy and stainless steel, subjected to cyclic loading in an in vitro environment.

Materials and methods

Posterior spinal fixation systems generally consist of several components that connect together to form a final spinal implant assembly. When constructed, the fixation system provides mechanical stability to the affected vertebrae while fusion through arthrodesis occurs. To investigate the effect of galvanic corrosion on spinal implants, this study used a commercially available posterior lumbar spinal fixation system (ISOLA/VSP Spine System; DePuy Spine, Inc., Raynham, MA) with interchangeable components available in both stainless steel (316L) and titanium alloy (Ti-6Al-4V).

The study followed the F1717 test standard for spinal implants adopted by the American Society for Testing and Materials, “Static and Fatigue for Spinal Implants in a Vertebractomy Construct.” This test standard uses a bilateral construct that models a vertebrectomized spinal segment with a missing middle vertebra with the spinal implants resisting all the applied loads. Each construct consisted of spinal implants attached to two ultra-high molecular weight polyethylene (UHMWPE) test blocks simulating upper and lower vertebral bodies. The nominal gauge length, the distance between the pedicle screw insertion locations of the top and bottom blocks, was set at 76 mm.

For each construct, two pedicle screws were inserted in the top test block bilaterally and another two in the bottom block. Afterward, each pedicle screw was secured to a slotted connector, using a nut. The two slotted connectors on the left side, one from the top block and one from the bottom, were attached to a 6.35 mm diameter rod using a setscrew, and the other two slotted connectors on the right side were attached to another rod, thus creating a bilateral construct. Finally, a single transverse rod connector joined the two rods. The connector consisted of a threaded rod and two sets of securing components, each containing a pair of clamps and...
a single nut for each rod. Tightening the nut firmly secured the clasps around both sides of the rod (Fig. 1). Following the manufacturer’s recommendation, the nuts connecting the pedicle screw to the slotted connector torques were tightened to 11.3 Nm (100 inch-pounds), the set-screws connecting the slotted connector to the transverse rod to 6.8 Nm (60 inch-pounds), measured using a torque meter.

Because each implant component used in this study is available in both stainless steel and titanium alloy, components of different metals were intentionally mixed to produce galvanic corrosion. A total of four constructs were tested in this study: two constructs consisted of titanium alloy rods and titanium pedicle screws, and the other two consisted of stainless steel rods and stainless steel pedicle screws. To create mixed metal interfaces in each construct, a titanium alloy slotted connector was used in one end of the rod, and a stainless steel slotted connector was used in the opposite end of the rod. Furthermore, because the transverse rod connector contained two sets of securing components, a titanium set was used on one rod and a stainless steel set on the other rod. Therefore, titanium rods contacted both titanium components (Ti-Ti interface) and stainless steel components (Ti-SS interface) in two constructs (Fig. 2), and stainless steel rods contacted titanium components (SS-Ti interface) and stainless steel components (SS-SS interface) in another two constructs (Fig. 3).

All constructs were loaded dynamically in compression through a pin in the anterior portion of each test block, creating a flexural bending of the rods. All tests were performed using a computer-controlled material testing machine (MTS 858 Mini-Bionix, MTS Systems Corporation, Eden Prairie, MN). Cyclic sinusoidal loads were applied at 5 Hz with maximum and minimum compression loads of 300 N and 30 N. These loads were chosen to ensure that the constructs would reach a run-out of 5 million cycles without structural failure, at which time the test was stopped. To simulate the in vivo environmental conditions, all tests were performed in a 0.1 M phosphate-buffered saline bath (pH 7.4) at a temperature of 37°C.

After testing, the constructs were rinsed thoroughly in distilled water several times and disassembled. Qualitative visual observations were made of the implant surfaces, with focus on implant interfaces. After visual observation, the component surfaces were further analyzed through scanning electron microscopy (SEM; JEOL JSM-6900LV, Tokyo, Japan) and energy dispersive spectrometry (EDS; Oxford Instruments, Concord, MA). All SEM micrographs were obtained through a secondary electron imaging, and EDS quantitative analysis was performed using ZAF correction and filtered least squares deconvolution, with copper as the calibration material. The SEM and EDS analysis primarily concentrated on examination of the rods, because their convex surfaces could be most readily examined. EDS quantitative analysis was performed to obtain representative elemental information and was not statistically powered to compare differences between groups.

Results

For all constructs, no visual evidence of corrosion was found on surfaces not in contact with another surface, as confirmed using SEM and EDS (Fig. 4, A and B and Table 1). Upon visual inspection, Ti-Ti interfaces appeared slightly darker with a clearly outlined contact area. Although corrosion was not visually evident (Fig. 2), SEM showed evidence of minor surface cracking and peeling in some regions of the interconnection area (Fig. 5). Furthermore, EDS confirmed the changes in material composition by showing an increase in oxygen content, suggesting that titanium oxide was formed on the surface (Table 1).

For the SS-SS interface, the evidence of surface corrosion was clearly visible as a reddish and greenish color, suggesting a chemical corrosion process (anodic oxidation) with iron and chromium oxides. The corrosion extended beyond the boundary of surface contact area (Fig. 3). SEM showed evidence of minor surface cracking and peeling in some regions of the interconnection area (Fig. 5). Furthermore, EDS confirmed the changes in material composition by showing an increase in oxygen content, suggesting that titanium oxide was formed on the surface (Table 1).

When mixed-metal interfaces were examined, titanium alloy surfaces of Ti-SS interfaces showed some visual evidence of corrosion with its darker appearance (Fig. 2). SEM again confirmed the visual inspection, showing surface cracking and peeling throughout the contact area (Fig. 4, D). Furthermore, EDS demonstrated material transfer from the stainless steel components to titanium rods with existence of chromium, molybdenum and iron (Table 1), although EDS could not confirm whether this was the result of transferring of the particles or leaching of the material from the...
Fig. 2. Setup of test construct according to ASTM F1717 and evidence of corrosion at implant component interfaces. Two constructs in this study consisted of titanium alloy rods and pedicle screws with mixed titanium alloy and stainless steel rod–screw connectors and transverse rod connector components, as shown with arrows.
Fig. 3. Setup of test construct according to ASTM F1717 and evidence of corrosion at implant component interfaces. Two constructs in this study consisted of stainless steel rods and pedicle screws with mixed titanium alloy and stainless steel rod–screw connectors and transverse rod connector components, as shown with arrows.

All parts are stainless steel except as noted.
opposing stainless steel surface. The EDS results also showed an increase in oxygen content between the Ti rod with Ti contact (28.4\%) compared with the Ti rod with SS contact (35.4\%), although it could not be confirmed whether this occurred as a result of transfer of SS corrosion products to the Ti rod or whether the Ti rod had accelerated corrosion resulting from the galvanic coupling.

Finally, stainless steel surfaces from SS-Ti interfaces visually showed corrosion (Fig. 3), and the extent of corrosion was not qualitatively different from that of SS-SS
Table 1
Results of the energy dispersive spectrometry quantitative analysis of representative interconnection surfaces (element %)

<table>
<thead>
<tr>
<th>Element</th>
<th>Ti rod No contact</th>
<th>Ti rod Ti contact</th>
<th>Ti rod SS contact</th>
<th>SS rod No contact</th>
<th>SS rod Ti contact</th>
<th>SS rod SS contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>7.10</td>
<td>7.60</td>
<td>8.75</td>
<td>6.02</td>
<td>5.02</td>
<td>4.75</td>
</tr>
<tr>
<td>O</td>
<td>—</td>
<td>28.40</td>
<td>35.41</td>
<td>—</td>
<td>33.00</td>
<td>35.76</td>
</tr>
<tr>
<td>Na</td>
<td>—</td>
<td>1.38</td>
<td>0.60</td>
<td>—</td>
<td>2.28</td>
<td>1.67</td>
</tr>
<tr>
<td>Al</td>
<td>6.21</td>
<td>4.00</td>
<td>2.49</td>
<td>—</td>
<td>0.33</td>
<td>0.24</td>
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<tr>
<td>Si</td>
<td>1.20</td>
<td>1.07</td>
<td>1.18</td>
<td>0.98</td>
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<td>P</td>
<td>—</td>
<td>1.34</td>
<td>1.68</td>
<td>—</td>
<td>10.70</td>
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<td>K</td>
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<td>—</td>
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<td>—</td>
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<td>0.33</td>
</tr>
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<td>Ca</td>
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<td>—</td>
<td>0.26</td>
<td>—</td>
<td>—</td>
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<tr>
<td>Ti</td>
<td>81.20</td>
<td>53.48</td>
<td>39.6</td>
<td>—</td>
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<td>—</td>
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<tr>
<td>V</td>
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<td>2.73</td>
<td>1.93</td>
<td>—</td>
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<td>—</td>
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<tr>
<td>Cr</td>
<td>—</td>
<td>—</td>
<td>5.82</td>
<td>16.51</td>
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<tr>
<td>Mn</td>
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<td>1.66</td>
<td>0.55</td>
<td>—</td>
</tr>
<tr>
<td>Fe</td>
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<td>—</td>
<td>0.61</td>
<td>55.60</td>
<td>19.20</td>
<td>4.34</td>
</tr>
<tr>
<td>Ni</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>13.52</td>
<td>3.78</td>
<td>1.18</td>
</tr>
<tr>
<td>Mo</td>
<td>—</td>
<td>—</td>
<td>1.68</td>
<td>3.18</td>
<td>2.37</td>
<td>12.31</td>
</tr>
<tr>
<td>Dy</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>2.52</td>
<td>1.88</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100</td>
<td>100</td>
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surfaces. SEM again showed extensive surface cracking and roughness on the stainless steel surface (Fig. 4, C), and EDS confirmed the extensive corrosion with a substantial increase of oxygen. However, unlike the opposing titanium alloy surface, no evidence of titanium alloy composition was found on the stainless steel surface.

Discussion

The results from this study indicate that when loaded dynamically in saline, stainless steel implant components have a greater susceptibility to corrosion than titanium. Furthermore, the galvanic potential between the dissimilar metals does not cause a discernible effect on the corrosion of either. Previous studies have shown that the corrosion resistance of stainless steel is the same when measured for stainless steel alone or in contact with Ti-6Al-4V alloy [17], which agrees with the results of this study.

The greater susceptibility of stainless steel to corrosion occurs as a result of the mechanical breakdown of the passive oxide layer at the interface, which is much slower to reform on stainless steel than titanium. Furthermore, low oxygen concentration at the interface (crevice conditions) accelerates the corrosion. With the combination of high rest potential for stainless steel and crevice corrosion occurring, the effects of galvanic corrosion, if any, were undetectable.

The lack of corrosion seen on Ti-Ti surfaces was not surprising because of the high corrosion resistance of titanium. The excellent corrosion resistance of titanium is...
attributable to the stable, impervious, fast-forming titanium oxide layer on the surface. However, under reducing environments, such as acidic environment or low oxygen environment, the oxide layer does not reform and thus titanium will become more susceptible to corrosion. These conditions are likely to occur in crevices where the corrosion process consumes the oxygen but oxygen cannot diffuse easily from the surrounding media into the crevice. Therefore, the corrosion of stainless steel in the interconnection, which could be considered a crevice environment, could accelerate the corrosion of titanium. Furthermore, because stainless steel has twice the elastic modulus of titanium, fretting of titanium is more likely to occur when in contact with stainless steel than with another titanium surface. Crevice or fretting corrosion of titanium may, in turn, reduce the fatigue life of the implant.

Galvanic effects, however, are a less likely cause of the titanium corrosion. Titanium is considered a more noble metal than stainless steel in a saline environment [18] and therefore acts as the cathode while stainless steel is the anode. Therefore, titanium would be expected to accelerate the corrosion of stainless steel in a galvanic couple and not the opposite. However, stainless steels are very close to titanium in the galvanic series [18] and therefore may not exhibit the degree of galvanic corrosion as other coupled surgical alloys. In this study, the effect of galvanic potential did not appear to influence the corrosion of either metal.

Clinical situations of mixing metals in spinal surgery include not only compatible interconnections of spinal implant systems, but also the use of interbody cages with supplemental anterior or posterior fixation, which was not tested in this study. Interbody cages are most often titanium or carbon fiber composite material, whereas anterior and posterior fixation systems are usually titanium or stainless steel. Therefore, there is a potential for galvanic corrosion when using, for example, a titanium interbody fusion cage with stainless steel fixation. However, the results from this study and others [17] suggest that the likelihood of adverse clinical effects is very low, particularly because interbody cages typically do not contact or come in close proximity to fixation implants.

Some limitations are important to recognize when interpreting the results of this study. Although proteins have been suggested to affect the corrosion of metals in saline [19], this study used a physiologically relevant electrolyte solution of phosphate-buffered saline (pH 7.4, 37°C) without proteins; however, addition of proteins to the media would not likely change the relative differences between metal combinations. This study also used UHMWPE blocks to simulate vertebrae. Because UHMWPE is a relatively inert material, the blocks or any particles it may have generated would have a negligible effect of metal corrosion. Furthermore, the test method used an in vitro–accelerated simulation of 5 million cycles at 5 Hz, which takes approximately 12 days to complete. In actual use, 5 million loading cycles of average daily living activity occurs over approximately 2 years (ASTM F1717). This difference could affect the test results in several ways. First, because mechanical forces at the implant interconnections cause physical breakdown of the passive oxide layer, loading the implants at 5 Hz could prevent reformation of the oxide layer, particularly for stainless steel. Furthermore, whereas galvanic corrosion is time dependent, fretting corrosion is time independent; hence, the latter may be favored in this dynamic test method.

Conclusions

The results from this study suggest that galvanic corrosion does not play a significant role in mixed titanium–stainless steel spinal implant constructs.

Using the dynamic, in vitro test method of this study, crevice corrosion and fretting were dominant over galvanic potential. Based on this finding, coupling titanium components with stainless steel systems may not significantly accelerate corrosion of stainless steel in load-bearing implants. However, coupling stainless steel components with titanium systems may induce fretting and crevice corrosion of titanium that would not otherwise occur. Further studies are needed before it can be recommended clinically to use such materials as titanium and stainless steel in direct contact for spinal implants.

References


previous fall to the Annual Meeting of the New England Surgical Society. The paper cited the work of Schmorl in describing Knorpel-knochen, prolapsed discs, in pathologic specimens and the several previous clinical observations of disc herniations and often-made erroneous labelling of them as enchondromas or chondromas. Their own work described 19 cases of ruptured discs, including two detailed clinical descriptions, one cervical and one lumbar. Among their conclusions was, “… the treatment of this disease is surgical …”. Dr. John Homans in the Discussion commented, “… I should like to ask … why operation should be of any value whatever. I can’t get that through my head.”

Reference