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Original article

Corrosion of spinal implants retrieved from patients with scoliosis

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Abstract Spinal implants retrieved from 11 patients with scoliosis were examined. All the implants were posterior instrumentation systems made of 316L stainless steel and composed of rods, hooks, and crosslink connectors. Corrosion was classified into grades 0 to 3 based on macroscopic findings of the rod surface at the junction of each hook or crosslink connector. Grade 0 was defined as no sign of corrosion, grade 1 as surface discoloration, grade 2 as superficial metal loss, and grade 3 as severe metal loss. The depths and characteristics of metal loss areas were examined. Spinal implants showed more corrosion after long-term implantation than after short-term implantation. Corrosion was seen on many of the rod junctions (66.2%) after long-term implantation, but there was no difference between the junction at the hook and those at the crosslink connector. It is thought that intergranular corrosion and fretting contributed to the corrosion of implants. The current study demonstrated that corrosion takes place at many of the rod junctions in long-term implantation. We recommend removal of the spinal implants after solid bony union.

Key words Corrosion · Spinal implants · Long-term implantation

Introduction

Although spinal instrumentation is widely used, there are few reports analyzing retrieved spinal implants.[3,11,13] Therefore, the extent to which these implants corrode, especially after long-term implantation, is not well understood.

Stainless steel and titanium alloys are generally used for spinal instrumentation. Stainless steel has been used as a biomaterial for a long time, being most popular in scoliosis surgery. However, stainless steel corrodes in the presence of chloride ions, and the corrosion occasionally becomes a problem in vivo when it causes the metal implant to degrade. The degradation process decreases the structural integrity of the implants, and the release of metal degradation products can elicit adverse biological reactions in the patient.[7] Therefore, corrosion of spinal implants is a key factor in their failure.

The purposes of this study were to evaluate the corrosion of spinal implants and to discuss removal of the implant.

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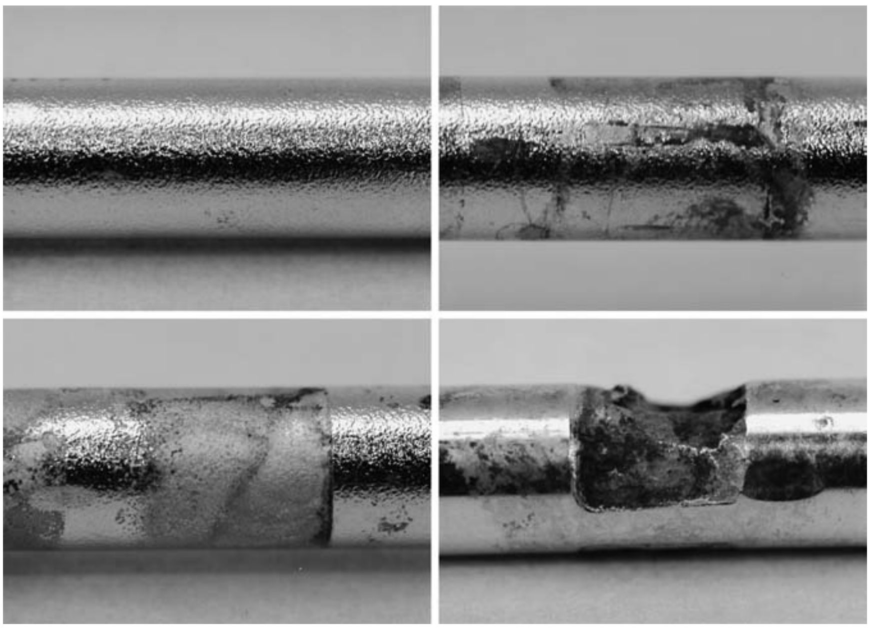
Materials and methods

Spinal implants retrieved from 11 patients with scoliosis were examined. All of the implants were posterior instrumentation systems made of 316L stainless steel and composed of rods, hooks, and crosslink connectors. Six Paragon spinal systems (Medtronic Sofamor-Danek, Memphis, TN, USA), four pediatric Paragon spinal systems, and a Chiba spinal system[10] were retrieved. Diagnoses were adolescent idiopathic scoliosis in five patients, congenital scoliosis in three, infantile idiopathic scoliosis in two, and Noonan syndrome in one. The reasons for removal were patient request in four patients, rod revision after instrumentation without fusion in three, late infection in two, and prominent implant in two. The mean age at the time of removal was 15.0 years (range, 5 to 21 years). The mean duration of implantation was 42.8 months (range, 2 to 100 months). The patients whose implants were retrieved before bone union (case 1) or after instrumentation without fusion (cases 2 to 5) were defined as the group with short-term implantation. The mean duration of implantation in that group was 16.1 months (range, 2 to 37 months). The patients whose implants were retrieved after bone union (cases 6 to 11) were defined as the group with long-term implantation. The mean duration of implantation in the long-term group was 65.1 months (range, 49 to 100 months) (Table 1).

Table 1. Subject data

Case no.	Age (years), sex	Diagnosis	Reason for removal	Location of implant	Duration of implantation (months)	Grade of corrosion (no. of junctions)			
						0	1	2	3
1	14, m	CS	Prominent Implant	T3-L1	2	10	0	0	0
2	5, m	IIS	Late infection	T5-L2	8	5	1	0	0
3	6, f	CS	Instru. w/o fusion	T3-L2	12	1	0	2	0
4	5, f	CS	Instru. w/o fusion	T3-L1	22	3	0	0	0
5	11, f	IIS	Instru. w/o fusion	T3-L1	37	2	0	1	0
6	20, f	AIS	Late infection	T3-T12	49	7	7	0	0
7	21, m	Noonan	Prominent implant	T2-L2	58	3	4	7	0
8	19, f	AIS	Patient request	T4-L1	60	6	1	7	0
9	19, f	AIS	Patient request	T3-L3	61	5	4	4	0
10	21, f	AIS	Patient request	T3-L3	62	6	4	3	0
11	21, f	AIS	Patient request	T4-L2	100	0	4	7	1

AIS, adolescent idiopathic scoliosis; CS, congenital scoliosis; IIS, infantile idiopathic scoliosis; Instru. w/o fusion, rod revision after instrumentation without fusion



A B C D

Fig. 1A–D. Corrosion was classified into grades 0 to 3 based on the macroscopic findings of the rod surface at the junction with each hook or crosslink connector. **A** Grade 0 was defined as no sign of corrosion; **B** grade 1 as surface discoloration; **C** grade 2 as superficial metal loss; and **D** grade 3 as severe metal loss

Corrosion was classified into grades 0 to 3 based on the macroscopic findings of the rod surface at the junction of each hook or crosslink connector. Grade 0 was defined as no sign of corrosion, grade 1 as surface discoloration, grade 2 as superficial metal loss, and grade 3 as severe metal loss (Fig. 1). Macroscopic examination was made of 105 rod junctions with the hooks and crosslink connectors retrieved from the patients.

The depths of the metal loss areas were measured in cases 9 and 11. The characteristics of the corroded spinal implant were recorded in case 11. The depths of corrosion for grades 1 to 3 were measured using a Keyence VK-8510 (Osaka, Japan) color laser microscope. The resolution of the color laser microscope was set to 0.2 μm in grades 1 and 2, and to 1 μm in grade 3. Corroded spinal implants were analyzed using a Hitachi S-4000 (Tokyo, Japan) scanning electron microscope (SEM) combined with an energy dispersive X-ray (EDX) analysis. The examination was performed using an acceleration voltage of 15 keV. EDX was employed to determine the elemental compositions of the corrosion products of the rod surface.

For statistical analyses, the Wilcoxon rank-sum test was used. A P value of less than 0.01 was considered statistically significant.

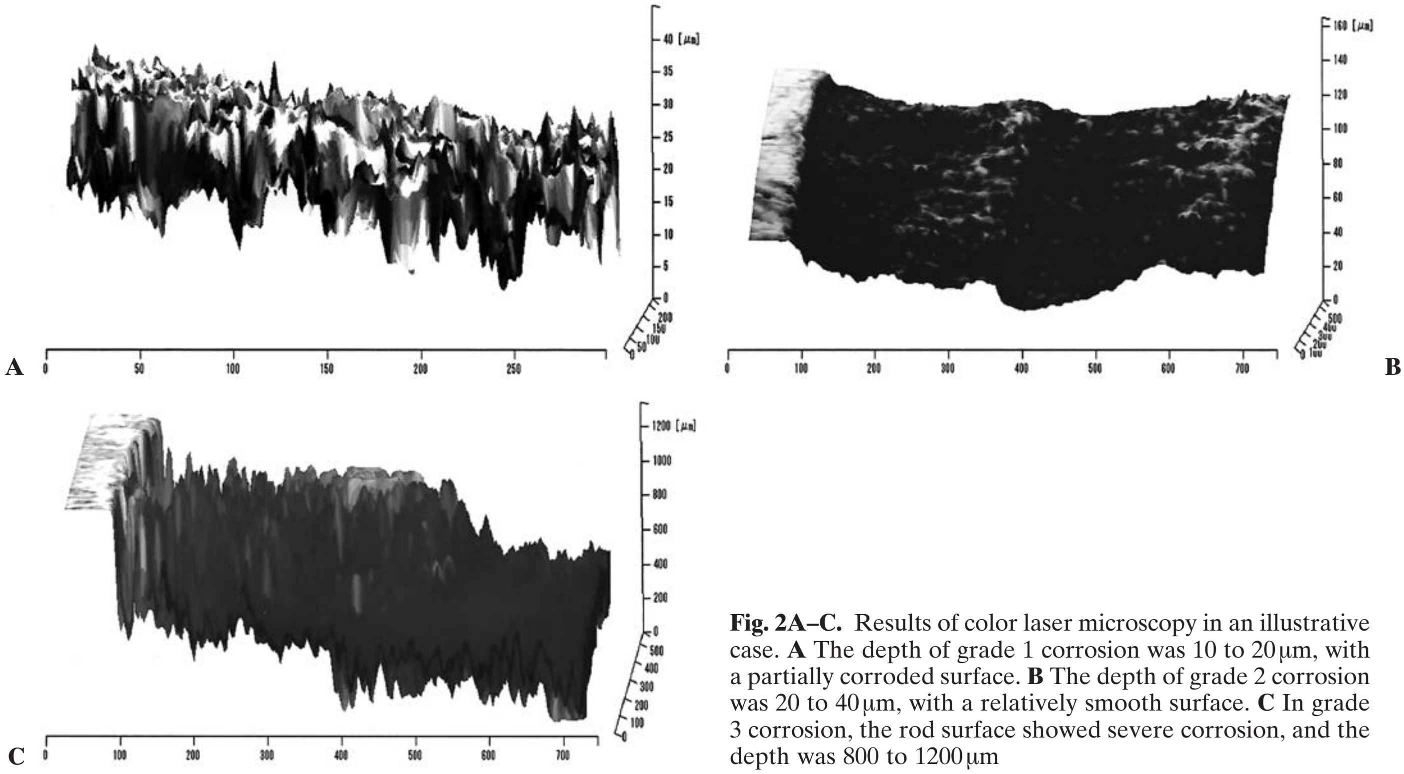


Fig. 2A–C. Results of color laser microscopy in an illustrative case. **A** The depth of grade 1 corrosion was 10 to 20 μm, with a partially corroded surface. **B** The depth of grade 2 corrosion was 20 to 40 μm, with a relatively smooth surface. **C** In grade 3 corrosion, the rod surface showed severe corrosion, and the depth was 800 to 1200 μm

Results

Macroscopic findings: corrosion grade

Corrosion was seen on the rod surfaces only at the junctions with the hooks or the crosslink connectors. The number and incidence of junctions were, without corrosion (Grade 0), 48 (45.7%); grade 1 corrosion, 25 (23.8%); grade 2 corrosion, 31 (29.5%); and grade 3 corrosion, 1 (1.0%) (Table 1).

In the group with long-term implantation, the number and incidence of junctions were, without corrosion (grade 0), 27 (33.8%); grade 1 corrosion, 24 (30.0%); grade 2 corrosion, 28 (35.0%); and grade 3 corrosion, 1 (1.2%). In the group with short-term implantation, the number and incidence of junctions were, without corrosion (grade 0), 21 (84.0%); grade 1 corrosion, 1 (4.0%); grade 2 corrosion, 3 (12%); and grade 3 corrosion, 0 (0%). The incidence of high-grade corrosion was significantly higher ($P < 0.01$) in the group with long-term implantation than in that with short-term implantation.

For the 73 junctions at the hook, the number and incidence were, without corrosion (grade 0), 36 (49.5%); grade 1 corrosion, 15 (20.5%); grade 2 corrosion, 22 (30.1%); and grade 3 corrosion, 0 (0%). For the 32 junctions at the crosslink connector, the number and incidence were, without corrosion (grade 0), 12 (37.5%); grade 1 corrosion, 10 (31.3%); grade 2 corrosion, 9 (28.1%); and grade 3 corrosion, 1 (3.1%). There was no significant difference in corrosion grade between the junctions at the hook and those at the crosslink connector ($P = 0.39$).

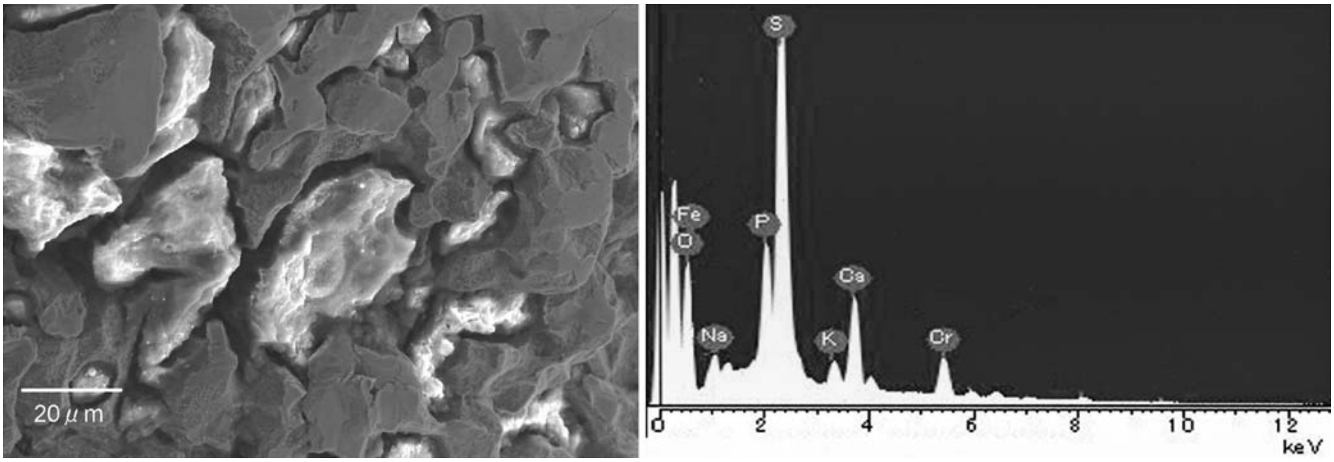
Color laser microscopy

The color laser microscopy showed that the samples with grade 1 corrosion had partially corroded and irregular surfaces, with depths of corrosion of 10 to 20 μm. Samples with grade 2 corrosion had relatively smooth surfaces, with depths of corrosion of 20 to 40 μm. In grade 3 corrosion, the rod surface showed severe corrosion with depths of 800 to 1200 μm (Fig. 2).

SEM and EDX analysis

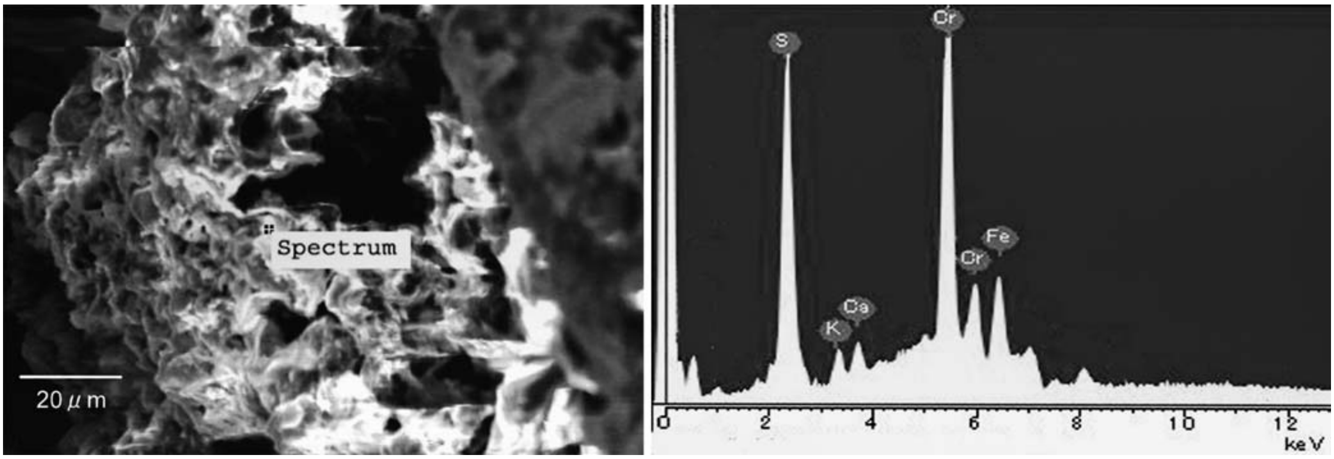
In grade 2 corrosion, SEM showed intergranular corrosion at the surface of the rod. The EDX analysis detected iron, chromium, sulfur, phosphorus, and calcium in the corrosion products, but nickel was not detected (Fig. 3).

In grade 3 corrosion, SEM showed severe corrosion. The EDX analysis detected iron, chromium, sulfur, and calcium in the corrosion products, but, again, nickel was not detected (Fig. 4).



A B

Fig. 3A,B. Scanning electron microscope (SEM) and energy dispersive X-ray (EDX) analyses of grade 2 corrosion in case 11. **A** SEM showed intergranular corrosion at the surface. The bar represents 20 μm. **B** EDX analysis detected iron, chromium, sulfur, phosphorus, and calcium among the corrosion products, but nickel was not detected



A B

Fig. 4A,B. SEM and EDX analysis of grade 3 corrosion in case 11. **A** SEM showed severe corrosion. The bar represents 20 μm. **B** The EDX analysis detected iron, chromium, sulfur, and calcium as the corrosion products, but nickel was not detected

Discussion

Retrieved orthopedic implants have been reported to be corroded at the junctions of composed materials, including screw-plate interfaces of bone plates,[4] head–neck junctions of modular hip prostheses,[8] and junctions between internal rods and external shells of spinal implants.[13] The corrosion is attributed to fretting, which is induced in the presence of repeated surface motion, and/or crevice corrosion, which occurs in the crevice of a metal-to-metal interface. In Harrington and Luque rods, corrosion fatigue is the predominant factor resulting in failure. Fretting and crevice corrosion have been found to play an important role in instrumentation failure.[11] In the current study, the spinal implants were also found to be corroded at the junction of the composition materials, namely, at rod–hook or rod–crosslink junctions.

The presence of corrosion in the spinal implants retrieved from patients with scoliosis has been demonstrated.[3,11] However, no study has examined the extent of corrosion by focusing on the duration of implantation or the types of rod junctions. The current study demonstrated that corrosion was seen on many of the rod junctions (66.2%) after long-term implantation and that there was no significant difference between the types of junctions.

Rating methods based on visual examination have been used in engineering analyses to evaluate the extent of corrosion. The American Society for Testing and

Materials (ASTM) has defined standard guidelines for the visual examination of pitting corrosion,[2] electroplated panels exposed to corrosive environments,[1] and corrosion under the other circumstances. In the current study, the extent of corrosion of the retrieved spinal implants was examined visually and graded from 0 to 3 based on macroscopic findings.

The corrosion resistance of stainless steel alloys is provided by their surface oxide film. In the presence of chloride ions, crevice corrosion begins at the interfaces of alloys. There are few reports of corrosion in retrieved spinal implants made of stainless steel, and the influence on the human body of corrosion and dissolution of the materials has not been well established, but corrosion may affect the safety of implants. Nickel ions are a particular cause of allergic reactions to metal implants in humans.[5] In addition, intraspinal metallosis formed by a loosened lamina hook made of stainless steel has been reported as a cause of delayed neurologic symptoms after spinal instrumentation.[12]

The EDX analysis of the elemental composition of grade 2 and 3 corrosion revealed iron, chromium, sulfur, phosphorus, and calcium, but not nickel. Nickel has been found to be depleted the surface oxide film of 316L stainless steel immersed in quasi-biological environments, and the surface oxide film was found to be composed of iron and chromium, calcium, sulfite, and sulfate on the top surface.[6] Similar changes might occur in vivo, and these changes may effect corrosion of spinal implants. When an alloy is abraded, metal ions are released. However, the type of element and the amount released cannot be predicted from the nominal composition of the alloy. A greater proportion of nickel was detected compared to iron and chromium in a filtrate after a fretting fatigue test of 316L stainless steel in phosphate-buffered saline solution without calcium or magnesium.[14] The relatively higher solubility of nickel was confirmed by a fretting corrosion test in the presence of protein.[9] It is thought that since nickel was not detected in the corrosion products, nickel ion was not bound to corrosion products but was released to tissues.

Color laser microscopy showed that the depth of grade 1 corrosion was 10 to 20 μm in the context of a partially corroded surface, and the depth of grade 2 corrosion was 20 to 40 μm with a relatively smooth surface. SEM analysis of grade 2 corrosion showed that the surface had undergone intergranular corrosion, and that the grain size was 20 to 30 μm in diameter. Grade 1 corrosion was considered to be the initial stage of this intergranular corrosion, involving only the top surface and resulting in a partially corroded surface. Grade 2 corrosion was considered to be a more progressive stage in which metal was lost from the top layer of the grains. Grade 3 corrosion was severely progressive and found at only one junction among the 105 specimens. That is, the majority of the junctions had sustained no more than grade 2 corrosion. In addition to intergranular corrosion, fretting is also thought to be a cause of corrosion. Fretting from the micromotion of implants might scrape the grains off after a certain extent of intergranular corrosion has occurred on the top surface (Fig. 5). As a result, most of the junctions did not progress beyond grade 2 corrosion. Grade 3 corrosion was found at only one junction. Although we investigated the related factors using color laser microscope, SEM, and EDX analyses, we could not find any definite factors.

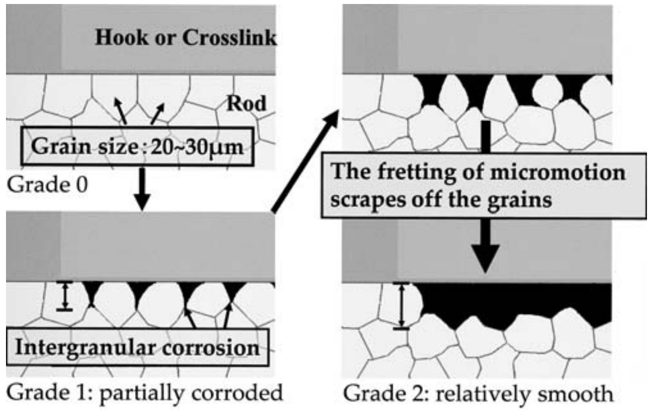


Fig. 5. Grade 1 corrosion was considered to be the initial stage of intergranular corrosion, involving only the top surface and resulting in a partially corroded surface. Grade 2 corrosion was considered to be a more progressive stage in which metal is lost from the top layer. In addition to intergranular corrosion, fretting is also a cause of corrosion. The fretting from micromotion of implants may scrape the grains off after a certain extent of intergranular corrosion has occurred on the top surface

There are several limitations to the present study. This study was retrospective and included instrumentation with and without fusion. Implant corrosion may be more rapid in cases of instrumentation without fusion than in that with fusion. We could not compare the cases without fusion with those with fusion in the group with short-term implantation. We had no patients with fusion that needed to have implants removed in the short term because of rod failure.

The roles of spinal instrumentation for scoliosis are to maintain correction of the spinal deformity and to achieve solid bony union. To achieve solid bony union, long-term implantation is necessary. The present study demonstrated corrosion of the spinal implants occurred after long-term implantation. Taking into consideration that spinal instrumentation for scoliosis is commonly performed in young patients, the spinal implants should be removed after solid bony union.

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