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BIOMECHANICS

Analysis of the Fracture Mechanism of Ti-6Al-4V Alloy Rods That Failed Clinically After Spinal Instrumentation Surgery

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Study Design. Retrieval analysis of 2 Ti-6Al-4V alloy rods that fractured after spinal instrumentation surgery.

Objective. To determine the mechanism that underlies fractures of Ti-6Al-4V alloy rods after spinal instrumentation surgery from a materials science viewpoint.

Summary of Background Data. Rod failures after spinal instrumentation surgery are often reported and many case-based studies have been published. However, the details of the mechanism that underlies the fractures have not yet been fully elucidated.

Methods. Two patients, a 71-year-old female and an 11-year-old male, underwent radiography and removal of their fractured rods. The latter patient had been treated using the growing-rod method. Metallurgical failure analysis of the retrieved rods was conducted, and material properties were compared between the unused and fractured rods.

Results. The microstructures and mechanical properties of the Ti-6Al-4V alloy rods that failed after spinal instrumentation surgery were similar to those of unused rods. Analysis of the fracture surfaces clearly identified fatigue cracking in both cases that would have lowered the resistance of the rods to failures caused by external stresses. Shot blasting the surfaces of Ti-6Al-4V alloy rods and bending the rods to fit particular contours, which is always conducted during spinal instrumentation surgery, probably introduced fatigue cracking because the alloy is highly notch sensitive.

Conclusion. Improvements should be made to rod design and/or rod material, because the fatigue resistance of titanium alloys is intrinsically lower than that of other commercially available rod materials, including cobalt-chromium alloys. These imperfections may have greater consequences for the growing-rod method and pseudarthrosis, where the rods are not completely fixed, and they subsequently suffer from severe long-arm moments.

Key words: spinal instrumentation surgery, Ti-6Al-4V alloy, rod fracture, metallurgical failure analysis, materials science, fatigue cracking, external stress, pseudarthrosis, growing-rod method, rod material selection, Co-Cr alloy, surface treatment.

Level of Evidence: N/A

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Spinal instrumentation surgery is commonly performed to stabilize the spine and correct spinal deformities. Spinal fixation devices principally comprise rods, hooks, and screws. In 1962, Harrington[1] introduced the "Harrington rod," which is made of stainless steel, for the surgical treatment of scoliosis. Subsequently, several different rod types made of commercially pure titanium, titanium alloy, cobalt-chromium (Co-Cr) alloy, or nonmetallic materials, such as polyether ether ketone, have been introduced.[2] Currently, titanium (Ti-6Al-4V) alloy is the material of choice for rods because of its excellent mechanical properties, biocompatibility, resistance to corrosion, and compatibility with magnetic resonance imaging procedures.

Fractures of spinal fixation devices and, in particular, pedicle screws and rods have often been reported after spinal instrumentation surgery. Indeed, 30 of 442 patients (6.8%) older than 18 years who underwent spinal instrumentation surgery had symptomatic rod fractures in one report, with fracture rates of 8.6% for titanium alloy, 7.4% for stainless steel, and 2.7% for Co-Cr alloy.[3] Rod failures also occur in patients who have undergone growing-rod instrumentation surgery.[4–6] Yang *et al*[6] reviewed the outcomes of 327 patients who underwent implantation with growing rods and found that 15% had rod fractures. Fractures were most commonly found above or below the tandem connectors and near the thoracolumbar junction of the spine. Rod failure is considered

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The device(s)/drug(s) is/are FDA approved or approved by corresponding national agency for this indication.

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primarily attributable to pseudarthrosis,[7,8] but inappropriate implant selection, unsatisfactory fixation points, implant corrosion, and excessive loads caused by patients' habitus and accidents must also be considered. Furthermore, the rods used in recent years have smaller diameters, and although this feature is advantageous for low-profile spinal fixation systems, the smaller diameters are also considered a risk factor for rod fracture.[9]

The fatigue characteristics of the rod material must play an important role in determining rod durability. Several studies[7,10–12] have investigated the fatigue performance of spinal rods made of different implantable materials subjected to various conditions. Furthermore, marks introduced onto rod surfaces during spinal instrumentation surgery, including indentations caused by benders, screws, and interconnection points, have been shown to affect the endurance limits of rods.[2] To reduce the rate of rod failure, it is crucially important to elucidate the rod fracture mechanism to determine how rod damage eventually leads to rod fractures. However, few studies have investigated the mechanism that underlies rod failure from a materials science perspective.

In the present study, we investigated Ti-6Al-4V alloy rods that had fractured and were retrieved after their clinical failure. The purpose of this study was to determine the factors that initiated the rod fractures. We discuss the selection of the material used to make the rods, rod design strategies, and ways in which the properties of materials are adjusted for spinal rods.

MATERIALS AND METHODS

Spinal Rods Investigated

Ti-6Al-4V alloy rods that had fractured under different circumstances in different patients were investigated. The circumstances under which each rod broke are given next.

Commercially produced Ti-6Al-4V alloy rods with diameters of 5.5 mm had been implanted into both sides of the spinal column of a 71-year-old female. Three months after instrumentation, the rods fractured simultaneously when the patient fell. Figure 1A shows radiographs of the rods within the patient.

Four years after spinal instrumentation surgery using the growing-rod method, undertaken for syndromic scoliosis, a commercially produced Ti-6Al-4V alloy rod with a diameter of 4.75 mm fractured when an 11-year-old male twisted his body (Figure 1B). The fracture occurred in the region above the tandem connecter located on the left-hand side of the spinal column.

Microstructural Analysis

Mechanical properties of metallic materials rely heavily on their microstructures, which can be described by several parameters, including grain size, grain morphology, crystallographic orientation, and the percentages of the phases and constituents. We investigated the microstructures of the fractured rods and compared them with those of 2 unused rods with 5.5-mm and 4.75-mm diameters, as had been used in the patients. After sterilization, samples for microstructural characterization were cut from them using electrical discharge machining. The sample surfaces were polished to a mirror finish in accordance with a standard metallographic sample preparation procedure.

A field emission scanning electron microscope (Ultra 55; Carl Zeiss AG, Oberkochen, Germany) was used to examine rod microstructure. Metallographic analysis was conducted in 2 planes, 1 parallel to the longitudinal direction of the rods and the other perpendicular to the longitudinal direction of the rods. The Ti-6Al-4V alloy consists of α and β phases of different chemical compositions. The α phase is enriched with aluminum, and the β phase is enriched with vanadium. We employed an angle-selective backscattered electron detector to visualize the distribution of the β phase on the basis of its elemental distributions, because the backscattered electron contrast varies with the atomic number of the scattering atoms.

Microindentation hardness testing was performed to characterize each sample mechanically. Measurements were conducted using an HMV Micro Vickers Hardness Tester (Shimadzu Corporation, Kyoto, Japan). A 9.8-N force was applied during an indentation time of 10 seconds. The mean hardness values and standard deviations were calculated.

Fracture Surface Investigations

The fracture surfaces of the rods were investigated by field emission scanning electron microscope to determine the mechanism underlying the incidental failures, because fracture surfaces generally vary with respect to failure mechanism. Images of the fracture surfaces were analyzed using ImageJ (National Institutes of Health, Bethesda, MD).

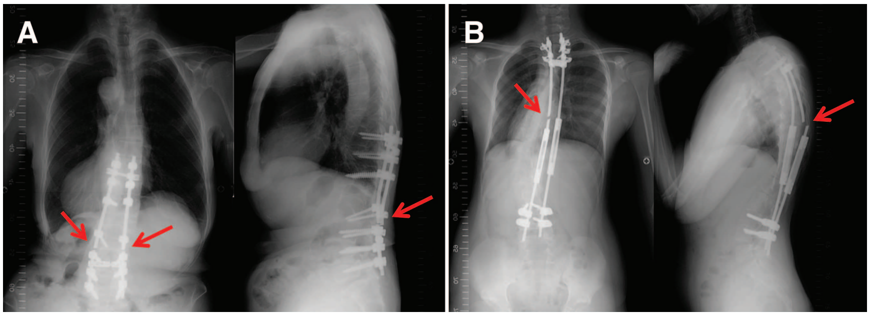

Figure 1. Coronal and sagittal radiographs of the rods removed from **(A)** the 71-year-old female and **(B)** the 11-year-old male after the rods had fractured. The arrows indicate the points where the rod fractures occurred.

RESULTS

Microstructural Analysis of the Fractured Rods Compared With an Unused Rod

Figure 2 shows microstructures of the unused 5.5-mm-diameter rod (Figures 2A, B) and the fractured Ti-6Al-4V alloy rods (Figures 2C, D) using a scanning electron microscope–angle-selective backscattered electron detector. Images were obtained on the perpendicular plane (Figures 2A, C) and also to show the microstructures that run in parallel to the longitudinal direction of the rod samples (Figures 2B, D). No appreciable differences were observed between the used and unused rods; this was also true for the case of the 4.75-mm-diameter rods (not shown here). Although the Ti-6Al-4V alloy is classified as an α + β-type titanium alloy, the microstructure predominantly comprised the α phase, seen in Figure 3 as dark contrast. The bright particles at the α-grain boundaries correspond to the vanadium-enriched β phase. The backscattered electron image shows a bright contrast when the average atomic number is higher than that of the surrounding material. The grains of the α phase were very fine, with diameters ranging from approximately 0.1 to 1 μm, and the diameter of the grains of the β phase was approximately 500 nm (Figures 3A, B). On the parallel plane, the submicron-sized β particles were aligned and somewhat elongated in the longitudinal direction, indicating that the manufacturing process of the rods included plastic deformation procedures.

The results of Vickers hardness measurements of the unused and fractured rods for each observational plane are presented in Table 1. The mean hardness values (~340 Hv) were consistent across both rod types and observational planes and similar to that of typical Ti-6Al-4V alloys.[13]

Fracture Surface Analysis and Determination of the Mechanism Underlying the Fractures

Figure 4A provides an overview of the fracture surface of the rod that had been implanted into the 71-year-old female. The crack initiation site was identified on the surface of the rod (Figure 4A). Two different morphological types were observed within the fracture surface. The first, seen in the vicinity of the crack initiation site, that is, the rod surface, was characterized by unique granular-like fine concave and convex agglutinates (Figure 4B). This type of fracture surface may have resulted from fatigue cracking and may have been followed by direct metal-metal contact that occurred during subsequent loading processes.[14] The second morphological type was characterized by fine dimples, which tend to be seen when materials are fractured in a ductile manner (Figure 4C). Because this type of fracture surface is not observed in fatigue fractures, it must have originated from the final fracture and been caused by external stresses. Image-based analysis determined that the surface comprised approximately 28.8% fatigue-related granular-like morphology.

A similar transition in fracture mode was observed in the rod from the 11-year-old patient. We identified the crack initiation site on the surface of the rod (Figure 5A). The fracture surface near the initiation site showed the presence of granular-like fine asperities (Figure 5B). We identified dimples on the other side of the fracture surface, which clearly differed from the morphology near the initiation site (Figure 5C). Image-based analysis determined that the surface

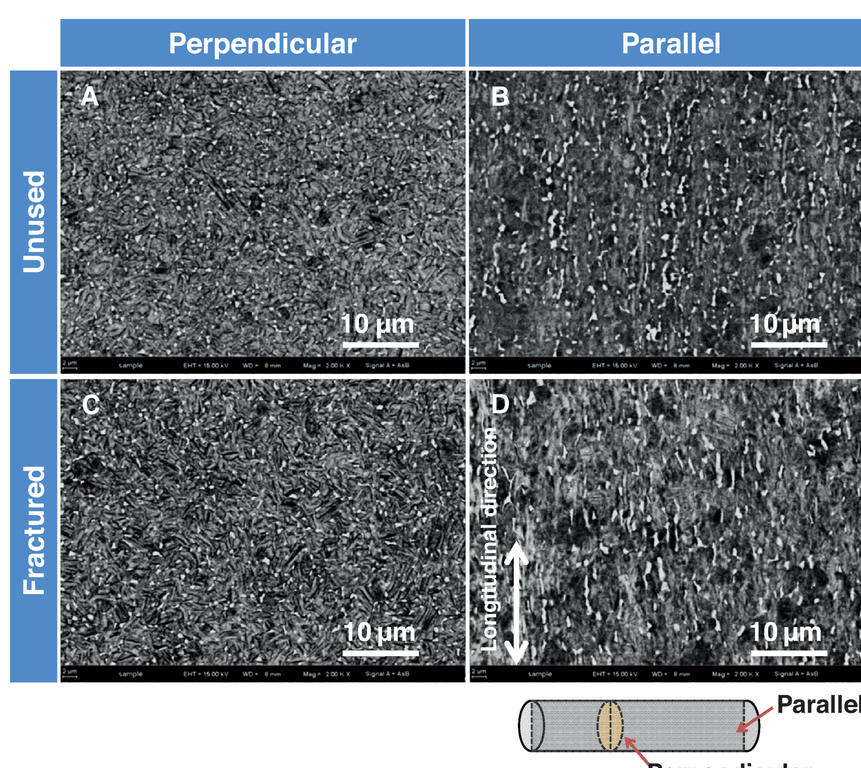

Figure 2. Scanning electron microscope–angle-selective backscattered images of the microstructures of the **(A, B)** unused and **(C, D)** fractured rods. The observations were conducted on the **(A, C)** perpendicular plane and **(B, D)** parallel to the longitudinal direction of the rods.

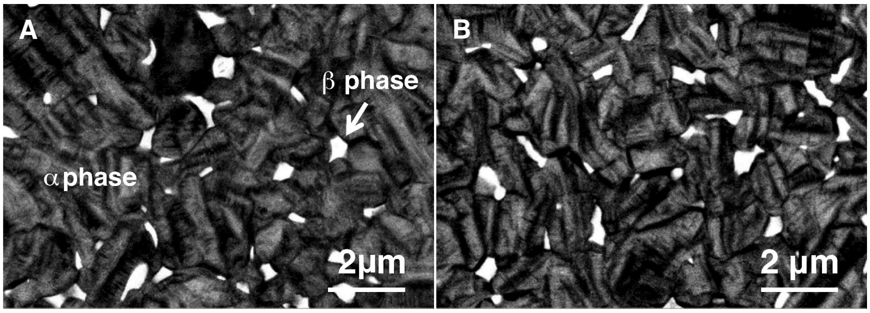

Figure 3. Magnified scanning electron microscope–angle-selective backscattered images of **(A)** the unused rod shown in Figure 2A and **(B)** the fractured rod shown in Figure 2C, both obtained on the perpendicular plane. The arrow indicates the presence of the β phase.

comprised approximately 59.9% fatigue-related granular-like morphology.

These results clearly indicated that 2 fracture types were initiated when the rod fractured (separated by a dashed line in Figures 4A and 5A), and that the fracture mechanism transitioned from initial fatigue cracking to the final fractures as a result of external loading along the path in which the crack was being propagated.

DISCUSSION

In the 71-year-old female, the rod fracture occurred just above the edges of the pedicle screws on both sides of the spinal column. In contrast, the rod fracture in the 11-year-old male was in the vicinity of the growing-rod connector, almost at the apex of the convex bent rod. These results are consistent with clinical findings suggesting that rod failure typically occurs at screw-rod junctions[3,12] and, in the case of the growing-rod method, in areas around tandem connectors.[6] The fracture mechanisms of the patients' rods were very similar, despite the very different circumstances surrounding the fractures.

The transition between the fracture types along the path of crack propagation was clearly defined in both fracture cases. It was not gradual but occurred suddenly because of external stresses, suggesting that the cracks propagated during clinical usage after spinal instrumentation surgery, and accidents, namely, falling over and twisting, caused the rods to fracture. The directions of crack propagation are schematically illustrated by yellow arrows in Figures 4A and 5A.

The fracture surfaces near the sites of initiation must have been associated with fatigue cracking, because the rods are subjected to large and frequent loads,[15] and the fracture surfaces resembled those of fatigue cracks described in a previous publication.[14] Several studies have investigated the fatigue performance of spinal rods.[7,10–12] In general, the Ti-6Al-4V alloy has adequate fatigue properties and is used in a variety of biomedical devices, including spinal rods, pedicle screws, and artificial hip joints. However, bending the rods considerably reduces their endurance limits, which might result from marks caused by benders and/or from tensile residual stresses, as summarized in the study by Slivka *et al*. The use of "prebent" rods could reduce residual stresses by stress relief heat treatment and surface marks before the spinal instrumentation surgery, leading to reduced risk of fatigue fractures.

As crack initiation occurred in the vicinity of the rod surfaces in both cases (Figures 4 and 5), we investigated the surface morphologies of an unused rod and the fractured rods (Figure 6). The surfaces of commercially produced spinal rods are often physically and/or chemically treated (shot blasting, chemical etching, *etc*.[2]). The investigated rods contained many asperities, probably due to shot blasting (Figure 6A), although the detailed manufacturing process is not clear. The surfaces of the fractured and unused rods were very similar. However, we identified cracking on the fractured rod surface (Figure 6B), which would have occurred as a result of large stresses impacting on the surface during bending or after spinal instrumentation surgery. Substantial surface defects can be introduced into titanium rods during intraoperative contouring.[10,11] Results from one study suggest that bending causes the fatigue properties of Ti-6Al-4V alloy rods to decline to a level similar to that of stainless steel.[7] Lindsey *et al*[11] demonstrated that contouring using a French bender reduced the fatigue strength of rods made of Ti-6Al-4V alloy constructs by 62% to 75%.

Titanium and titanium alloys are known as "notch sensitive,"[10] because the work hardening ability of titanium alloys tends to be low, resulting in local, nonuniform plastic deformations. Notches within components can result in local stresses that exceed the yield strength of the material, resulting in plasticity. Under cyclic loading, this localized plasticity can initiate and subsequently propagate fatigue cracks, leading to the failure of the component.[16] The surface roughness produced by shot blasting or other techniques creates "notches" or triggers of notch initiation, which leads to sites of crack initiation that are caused by high concentrations of stress, as shown in Figure 5.

TABLE 1. Vickers Hardness Measurements of the Unused and Fractured Rods Assessed on the Planes Perpendicular and Parallel to Their Longitudinal Direction

Rod	Plane	Vickers Hardness
Unused	Perpendicular	323.3 ± 2.8
	Parallel	344.5 ± 6.5
Fractured	Perpendicular	333.0 ± 5.1
	Parallel	333.8 ± 1.5

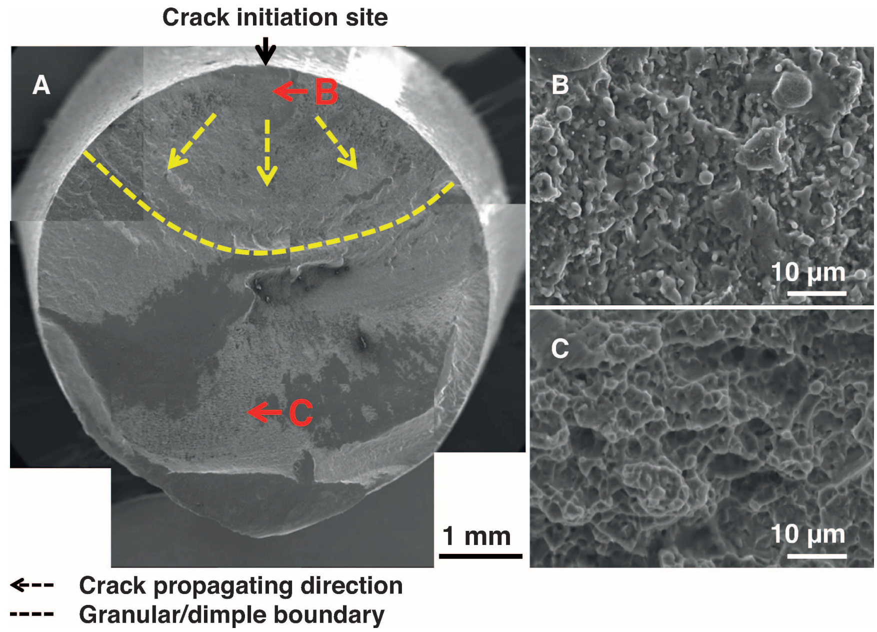

Figure 4. A, Scanning electron microscope (SEM) micrograph of the fracture surface of the rod implanted into the 71-year-old female patient. Magnified SEM images of areas "B" and "C" indicated in Figure 4A are shown in Figure 4B and Figure 4C, respectively. The arrows schematically illustrate the directions of crack propagation.

The fatigue properties of titanium alloys are highly dependent on their microstructures. A short crack, the length of which is small relative to the dimensions of the relevant microstructures,[17] has been shown to propagate faster than a long crack under specific conditions.[17–19] Therefore, β annealing or β processes that produce the fine lamellar α + β duplex microstructures are employed to enhance the fatigue resistance of high-strength titanium alloys.[16,20] The microstructures of the used and unused Ti-6Al-4V alloy rods were similar (Figure 2), which suggests that the fatigue properties of the Ti-6Al-4V alloy may not always be adequate for spinal rod applications.

External stress eventually caused the rods investigated in the present work to fracture when the patients either fell over or twisted. Approximately 30% and 60% of the surfaces of the rods from the 71-year-old patient and 11-year-old patient, respectively, comprised fatigue-related granular-like fracture material. The area of the fatigue fracture may depend on factors such as the duration for which the rods experienced the repetitive stress and the magnitude of the external stress that causes final fractures, although more fracture cases should be addressed to support this hypothesis. Surprisingly, fractures readily occurred in the titanium alloys, despite the fatigue fracture area comprising only 30% of the total area. This finding suggests that fatigued Ti-6Al-4V alloy rods are very brittle and fracture easily. Furthermore, given the absence of obvious microstructural differences between the fractured and unused rods, we concluded that although the failure incidents were not a consequence of inferior microstructures or mechanical properties, they must have originated from the intrinsic properties of the Ti-6Al-4V alloy.

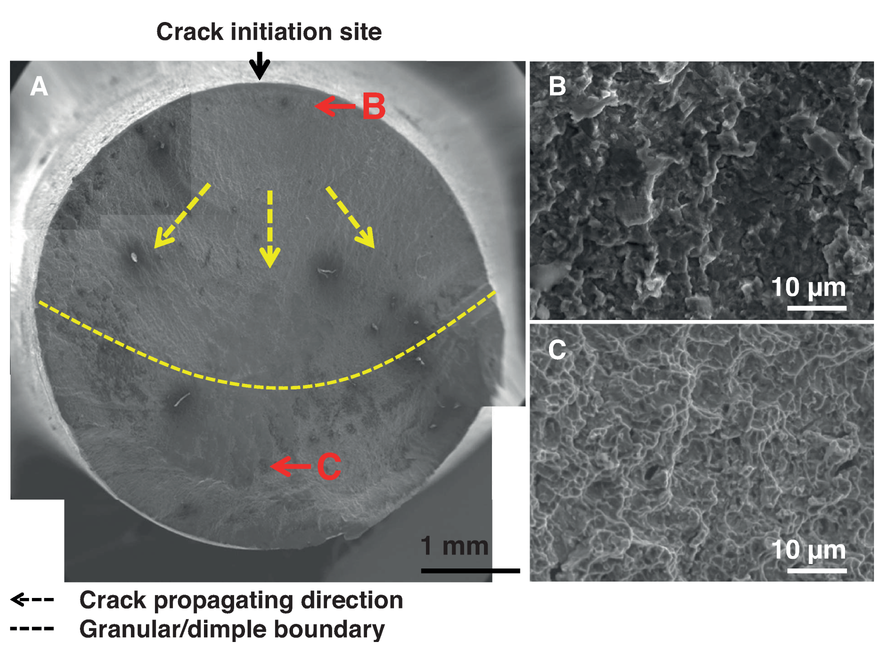

Figure 5. A, Scanning electron microscope (SEM) image of the fracture surface of the rod implanted into the 11-year-old male. Magnified SEM images of the areas "B" and "C" indicated in Figure 5A are presented in Figure 5B and Figure 5C, respectively. The arrows schematically illustrate the directions of crack propagation.

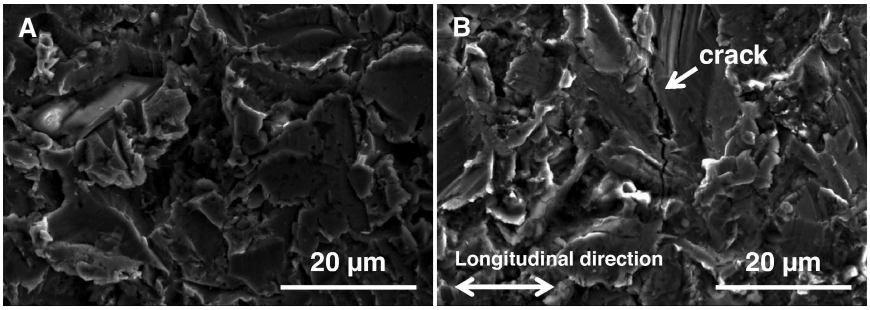

Figure 6. Scanning electron microscope images of the surface of **(A)** the unused 5.5-mm-diameter rod and **(B)** the fractured rod that had been implanted into the 71-year-old female patient. The arrow indicates the crack identified on the fractured rod surface.

We could not determine whether the surface cracks (Figure 5B) originated from rod bending. Rods with larger diameters will experience greater surface strain for the same bending radius and may consequently be more prone to crack initiation. Physiological loading after spinal instrumentation surgery may facilitate crack propagation, because it introduces a high concentration of stress at the tips of pre-existing cracks. Generally, shot peening, a severe cold working process that produces a compressive residual stress layer by impacting a surface with shot, is employed to enhance fatigue resistance. This process differs from shot blasting, which does not produce compressive residual stresses that prevent fatigue cracking. On the contrary, a shot-blasted rough surface may trigger crack initiation during loading. Therefore, manufacturing processes, including those associated with microstructure control and surface treatment, and strategies used to select materials should be reconsidered. For example, Co-Cr alloys currently used in spinal instrumentation[2,7] show superior fatigue resistance and stiffness, which influence the durability and stability of the rods in deformity correction, respectively.

From the clinical perspective, rod failure would be facilitated by pseudarthrosis. If bone fusion is not complete after spinal instrumentation surgery, a larger displacement as well as a longer moment arm must be imposed on the implanted rod. Similar situations occur in the growing-rod method in which the rods are not fixed between upper instrumented vertebrae and lower instrumented vertebrae. Hence, the current study clearly demonstrated the origin of rod failure, as has been reported in cases of pseudarthrosis[7,8] and in growing-rod surgery,[4–6] and provides information that will help prevent rod failure in the future.

CONCLUSION

We investigated the mechanism underlying rod fractures after spinal instrumentation surgery. The microstructures and hardness of fractured rods were similar to those of unused rods and typical Ti-6A1-4V alloys.[13] We clearly observed that fatigue cracking occurred during rod use, whereas external stress eventually caused the rods to fracture. Fatigue cracks initiated at the surface of the rod may propagate rapidly, because the Ti-6Al-4V alloy is very notch sensitive. Therefore, rod fractures are likely to become apparent in cases of pseudarthrosis and growing-rod surgery, both of which facilitate large rod displacements as well as longer moment arms under cyclic loading. The present study suggests that strategies for the selection of materials for spinal rod applications should be reconsidered.

➢ Key Points

- ❑ The microstructures and mechanical properties of the Ti-6Al-4V alloy rods that failed after spinal instrumentation surgery were similar to those of unused rods.
- ❑ We clearly observed that fatigue cracking occurred during rod use, whereas external stress eventually caused the rods to fracture.
- ❑ Imperfections in the fatigue resistance of titanium alloys may have greater consequences for the growing-rod method and pseudarthrosis, where the rods are not completely fixed.
- ❑ The obtained results suggested that the selection of materials and the surface treatment for spinal rods should be carefully considered in their clinical applications, including the planned surgical strategy.

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