Investigation of Fatigue Failure of a Stainless Steel Orthopedic Implant Device

M. Sivakumar, U. Kamachi Mudali, and S. Rajeswari

An orthopedic implant (rush nail) fractured in a patient at a location that corresponded to the site of a prior fracture of the bone (right femur). The crack propagation in the implant proceeded from both sides of the nail, and the final fracture occurred by ductile shear in the midsection of the nail. Dimple structures and tear ridges between fatigue striation patches were observed on the fractured surface. Moreover, the device fractured within a short period of use. Contrary to post-procedure instructions, the patient placed the body's full weight on the implanted leg at least once, perhaps twice, causing overload-induced fatigue failure of the implant.

Keywords
fatigue failure, implant device, overload failure

1. Introduction

METALS have been chosen as implant materials because of their inherent mechanical properties. Implants experience high loads and intense wear due to repetitive patient movement. The consequent degradation effect on the metals is greatly increased by the fact that the environment surrounding the implant is corrosive. These surgical implants are usually made of either austenitic stainless steel, cobalt-chromium alloys, or titanium and titanium alloys.[1] Of these materials, type 316L stainless steel is the most commonly used implant material.[2]

Moreover, the design of the implant is dictated by the anatomy and physiology of the skeletal structure of the human body. Artificial mechanical devices are considered to have failed when they are prematurely removed from the body. In every orthopedic failure, the patient experiences the trauma of repeated surgeries in addition to severe pain experienced during rejection of the device. Moreover, its removal can cause great expense and hardship to the patient. Hence, it is highly desirable to limit the number of failures to a minimum.

Even though innovative metallurgical and technological advances have made striking progress in the design and selection of materials for implants, failures invariably occur due to fatigue[3-5] or corrosion,[6,7] or other general failure mechanisms.[8,9] However, the underlying causes for the initiation of these failure mechanisms are seldom determined.

The diagnostic study described in this article of the fatigue failure of a stainless steel rush nail aims at contributing to the understanding of the failure mechanisms of metal fixtures under the action of repeated stresses.

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2. Experimental Methods

The failed implant was examined in a Stereomicroscope (Leitz, Germany) to obtain information on the surface scratches, onset of corrosion, and other imperfections. Fractographic analysis was also carried out on the fractured surface of the failed implant with a scanning electron microscope (SEM) (Hitachi, Japan).[10]

A portion of the failed area of the implant was metallographically polished and subjected to electrolytic etching in 10% ammonium persulfate solution at 6 V for 1.5 min, and the microstructure was studied.[11] The Vickers hardness of the implant was determined using a diamond indenter with 5-kg load in a metallurgical microscope (Leitz, Germany).[12]

The specific composition of implant alloys may have a direct effect on their durability. Hence, the determination of the chemical composition of the implant was carried out using an inductively coupled plasma spectroscopic technique (ICP, Applied research Laboratory, USA). The grain size and inclusion content was measured according to ASTM methods.

3. Results and Discussion

The rush nail (INOR, India) currently is used as a fixing device for the treatment of fractures. In the present study, fracture of the left femur of a 62-year-old patient was internally fixed with a rush nail. Three weeks later, the patient complained of severe pain in the vicinity of the implant site. Moreover, the patient required physical assistance to walk. Hence, radiographs were taken of the implanted region. The radiograph revealed that the nail had fractured. The fracture on the nail coincided with the location of the previous fracture of the bone. The fractured nail was removed (Fig. 1) and was subjected to failure investigation.

Stereomicroscopic examination of the fractured surface, shown in Fig. 2, revealed that crack propagation proceeded from both sides of the nail, as indicated by the arrows A and B. Two sets of "beach marks" were noted, and the final fracture occurred by ductile shear on the midsection of the nail.

A magnified view of the fracture initiation point is shown in Fig. 3, which indicates the occurrence of fatigue striations. An-

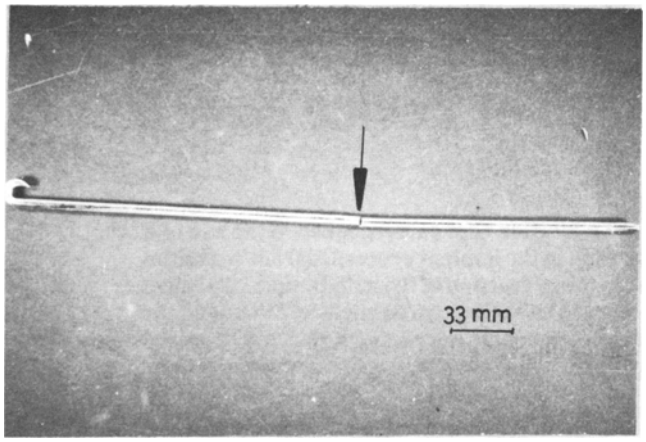

Fig. 1 Photograph of fractured rush nail. The unbalanced arrow indicates the fractured site of the implant.

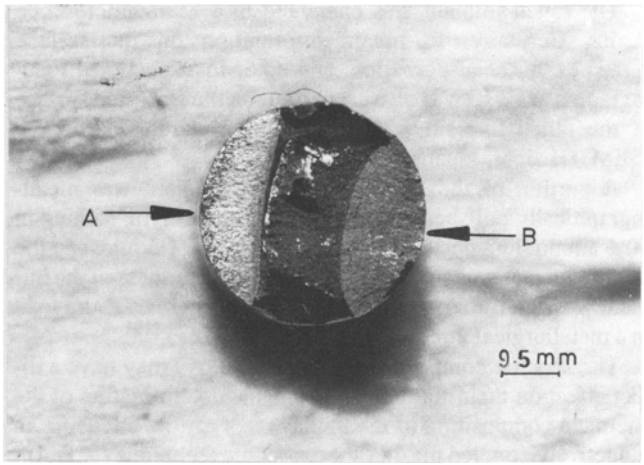

Fig. 2 Stereomicrograph of the fractured surface of the rush nail, revealing that crack propagation proceeded from both sides of the nail, as indicated by arrows A and B.

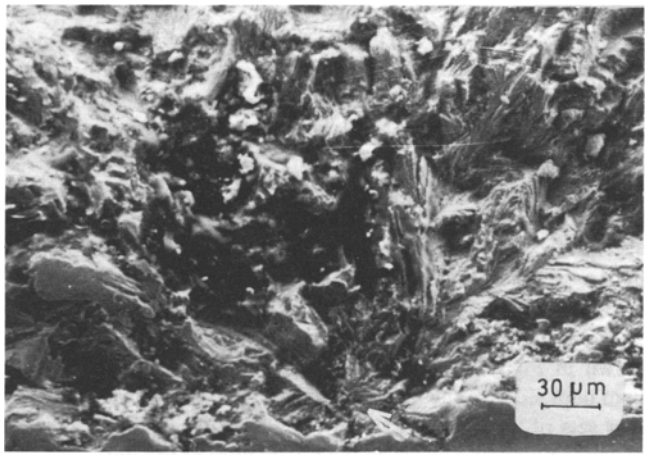

Fig. 3 Scanning electron micrograph showing a magnified view of the fracture initiation point (unlabeled arrow).

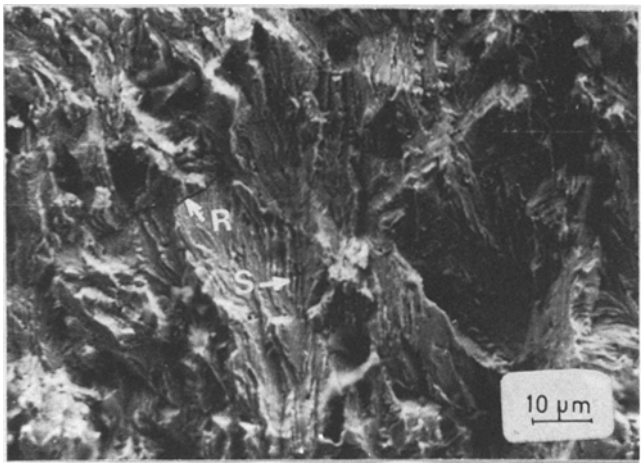

Fig. 4 Scanning electron micrograph of fractured surface, showing the tear ridges (R) between fatigue striation (S) patches.

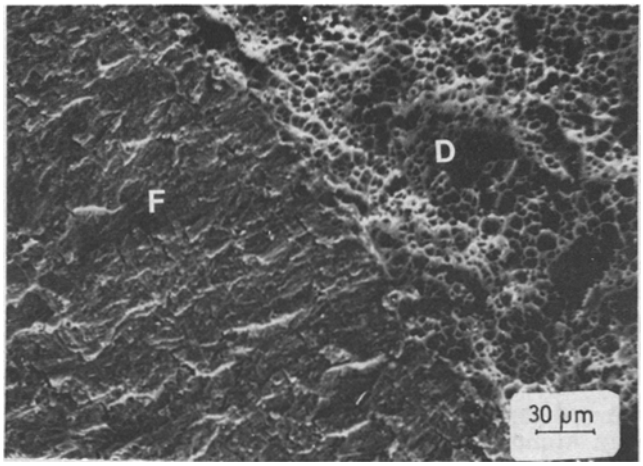

Fig. 5 Scanning electron micrograph showing the transition from fatigue striations to dimple structures. Fatigue striations (F), dimple structures (D).

other view of the fracture surface is shown in Fig. 4, which was taken near the crack initiation area. Tear ridges between fatigue striation patches are shown by arrow R. Intermixed regions of ductile tearing and striations are observed; that is, one grain may fracture by fatigue, whereas an adjacent grain may be oriented and sustain heavy shear band formation and fracture by tearing. The next grain may fracture by fatigue. A magnified view of the transition from fatigue striations to dimple structure is shown in Fig. 5. The fatigue striation is denoted by arrow F and dimple structures by arrow D in Fig. 5. The dimples are oriented uniformly in the deformation direction, as shown in Fig. 6. The longitudinal structures revealed the overload.

The Vickers hardness of the failed implant ranged from 230 to 240 HV. The inclusion content was 2 (ASTM unit). The grain size of the failed device was 6 (ASTM unit). In contrast, the ASTM recommended limit for inclusions is 2 (ASTM unit) and grain size is 4 (ASTM unit) for materials used for implant applications.[13] Moreover, chromium carbide precipitation was not

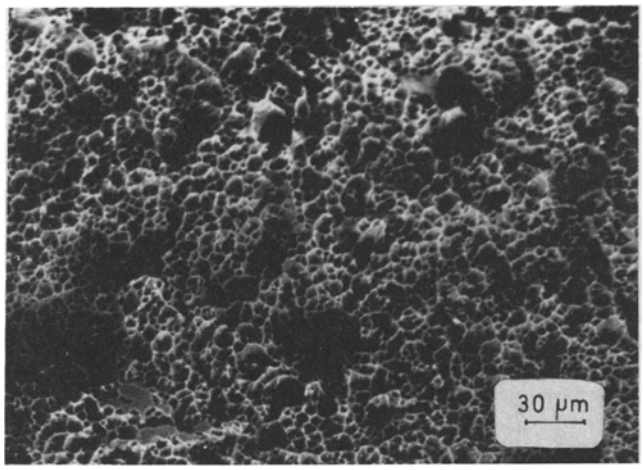

Fig. 6 Scanning electron micrograph showing the dimple structure oriented uniformly in the deformation direction.

observed at the grain boundaries after electrolytically etching the failed implant. The chemical composition of the implant is given in Table 1 with the ASTM standard values for an effective comparison. From Table 1, it is evident that the chemical composition of the implant examined in the present study is well within the limits recommended by ASTM standards for surgical implants.

Moreover, the studies of hardness, metallography, and chemical composition of the failed implant revealed that the implant material is in agreement with the current standards for surgical implants, and therefore, this cannot be implicated to be the cause of failure.

The purpose of using a fixation device is to hold the ends of the broken bone in close proximity so that healing is promoted. The load is supposed to be shared between the bone and the fixation device. Even with sharing of the load, it is necessary to limit the loading placed on the affected bone until it heals. If excess load (due to the inept mobility of the patient) is transmitted to the implant fixed on the fracture bone site, fracture of the implant occurs.

The fact that the device fractured within a short time of use also suggests overloading as a possible mechanism of fracture. This hypothesis received support when the patient admitted that the entire body weight had been placed on the leg once or twice in spite of post-operative instructions. Moreover, fractographic studies confirmed this mode of failure.

4. Conclusion

The presence of dimple structures and tear ridges between fatigue striations on the fractured surface confirms that the rush nail failed through overload-induced fatigue. The surgeon's role in counseling the patient, with emphasis on the need for the patient's full cooperation in following instructions not to place the body's full weight on the affected limb during the post-implantation recovery period, will help reduce this type of mechanical failure in orthopedic implant rush nails of the type described.

Table 1 Chemical composition of implant material

Element	Composition of the failed rush nail, %	Composition of type 316L stainless steel ASTM recommended limit, %
Cr	18.5	17.00 - 19.00
Ni	12.2	12.00 - 14.00
Mo	2.3	2.00 - 4.00
Mn	2.1	2.0
P	0.016	0.03 max
Si	0.04	0.05 max
S	0.005	0.03 max
C	0.03	0.03 max
Fe	Bal	Bal

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