FAILURES OF ORTHOPEDIC FIXATION DEVICES

D. O. Cox, J. Pirs and C. N. J. Wagner*

INTRODUCTION

For many centuries materials have been implanted in the human body for surgical and dental purposes. However, with developments in radiography and the development of corrosion resistant alloys, recent years have seen an enormous increase in the number of prosthetic devices. Comprehensive reviews of the development of metallic implants have been given by Weisman [1] and Bechtold et al. [2]. Several reviews have also been given on the material systems used for biomedical applications, a very good survey being that of Krouskop and Nevell [3]. As the use of implanted devices has increased there has been a corresponding increase in the number of mechanical failures. Some investigators [4-7] have observed that general corrosive attack contributed significantly to the ultimate failure. In other instances [8,9] corrosion pits have served as initiation sites for subsequent fatigue cracks which lead to fracture. A number of cases where material defects have resulted in fracture have also been reported [10]. Stress corrosion cracking of the alloys commonly used and under the conditions present *in vivo* is a rare occurrence [11].

At the present time there are five basic metallic material groups which are used for clinical work [12]:

1) Ferrous base alloys : stainless steel primarily in wrought form
2) Cobalt - chromium base alloys : wrought or cast form
3) Titanium and titanium base alloys : wrought form
4) Tantalum : unalloyed, wrought
5) Precious metals and alloys.

A vast percentage of the surgical implants fabricated are made from three alloys from these accepted systems. These alloys are 316 L stainless steel, the cast Co - Cr - Mo - C alloy and Ti - 6 Al - 4 V.

A number of years ago the American Academy of Orthopedic Surgeons became interested in developing material and performance standards for orthopedic implants. In 1961 they approached ASTM and Committee F - 4 was subsequently organized to evolve standards which would cover the general field of surgical implants. At the present time standards for the common surgical implant materials and some implant devices have been developed. In many European countries standards have also been developed, however in many cases there are significant differences between the European and American standards. Since the common inplant materials had been in use for many years, the development of material specifications (chemistry, UTS, RA) was relatively easy. However, development of standards for design or performance of the implant components is much more difficult. This results from the fact that there is such great variability between patients. How the device is used, the type of trauma involved and the

*University of California, Los Angeles, U.S.A.

patient activities after surgery vary so much that the forces active on a device *in vivo* cannot be estimated with any certainty. These patient related factors vary so much that establishing a requirement on performance becomes almost impossible. This is one reason one finds variations in the standards developed in the United States and the European countries. This paper presents additional examples of implants which have failed *in vivo* and discusses how the patient related factors mentioned above contributed to the failures.

PROCEDURE AND RESULTS

The fracture surfaces of three broken wrought stainless steel fixation devices manufactured in Europe were examined using the scanning electron microscope (SEM). In addition, the dimensions of the parts were compared to American and European Standards (where available) and the microstructure of the various materials was examined.

Figure 1 shows an intramedulary nail which had been implanted for some years in a 36 years old man. SEM examination showed that approximately 60% of the circumference had fractured by fatigue. A typical fatigue region is shown in Figure 1b. The crack initiated at the end of one of three side groves on the nail. There was no evidence of a metallurgical defect in this origin region.

A bone plate shown in Figure 2 was removed from the leg of a 100 years old woman after one year *in vivo*. SEM examination of the fracture indicated that fatigue cracks had initiated at the outside surface/countersink junction in two locations diametrally opposed. These fatigue cracks propagated at least 75% across the cross-section before final separation (overload). There was no evidence of a material defect in the origin area. A comparison of the countersink angle on the broken bone plate with those shown in the American and European Standards [13-15] was made. It was found that the measured angle was larger than that specified in either standard.

Figure 3 shows a hip nail and intertrochant plate combination which again failed by fatigue. This device was removed from a 70 years old woman after many years *in vivo*.

CONCLUSIONS

In the three implant failures examined, there was no evidence of a metallurgical defect or a corrosion pit initiating the fatigue fractures which occurred. It appears that in each case the fixation device was subjected to high loads which resulted in stresses above the fatigue endurance limit of the stainless steel material. This could occur in two ways:

1) the design was inadequate for the expected (design) loads, or
2) the loads imposed on the component were larger than the expected (design) loads.

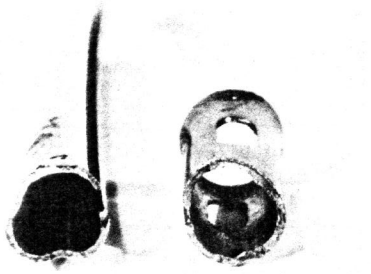
In the first case, the design of the device is such that under expected loading conditions failures can occur. In the bone plate studied here, it was found that the countersink angle was larger than that specified in either the European or American standards. This may have contributed to the initiation of the fatigue cracks. The development of and adherence to standards based on designs which have been successfully used in the past will help eliminate failures resulting from poor design.

The second case involves the patient related factors mentioned previously. If a fixation device is used in a situation where the bone failes to heal properly or the patient is more active than they should be after implantation, the loads imposed on the device can be much higher than those for which it was designed. In this case fatigue cracks will initiate even though the design and material are sufficient for the intended purpose. Other than develop stronger biocompatible alloys, there is very little a metallurgist can do to eliminate this type of failure. The only alternative the designer has in this case is to make a more massive, and therefore stronger, component which may be impractical due to constrains imposed by the application.

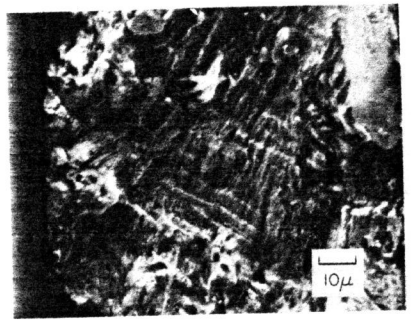
This investigation has shown that mechanical failures of fixation devices can occur in cases where no metallurgical defects are present. These failures might result from problems in design, but in most cases the high loads leading to failure result from patient activity before the bone completely heals.

REFERENCES

1. WEISMAN, S., "The Skeletal Structure of Metal Implants", Biomedical and Human Factors Symposium, ASME, New York, 1967, 87.
2. BECHTOL, C. O., FERGUSON, A. B. and LAING, P. G., Metals and Engineering in Bone and Joint Surgery, The Williams and Wilkins Comp., Baltimore, 1959.
3. KROUSKOP, T. A. and NEWELL, P. H., "A Review of Biomaterials Engineering", ASME Paper 73 - WA/Bio - 36, New York, 1973.
4. COHEN, J., J. of Materials, 1, 1966, 354.
5. CAHOON, J. R. and PAXTON, H. V., J. Biomed. Mater. Res., 2, 1968, 1.
6. COLANGELO, V. J., Trans. ASME, 91, 1969, 581.
7. COLANGELO, V. J. and GREENE, N. D., J. Biomed. Mater. Res., 3, 1969, 247.
8. WEINSTEIN and coworkers, J. Biomed. Mater. Res., 7, 1973, 297.
9. ROSE, R. M., SCHILLER, A. L. and RADIN, E. L., J. Bone and Joint Surg., 54, 1972, 854.
10. WHITE, W. E. and LE MAY, I., Microstructural Science, Volume 3, Part B, American Elsevier Publ. Comp., New York, London, Amsterdam, 1975, 911.
11. ZITTER, H., Werkstoffe und Korrosion, 22, 1971, 598.
12. WEISMAN, S., "Metals for Implantation - Trends and New Developments", Proc. of the New England 1973 Conference on Bioengineering, University of Vermont, April 1973, 124.
13. ASTM Standards for Surgical Implants, American Society for Testing and Materials, Philadelphia, July 1973.
14. Chirurgische Implantate, Knochenplatten aus nichtrostenden Stahl, DIN 58 825, Teil 1, September 1975.
15. "DIN Teaschenbuch 100", Eine Zusammenfassung der Normen über chirurgische Instrumente und Implantate, Beuth-Verlag GmbH, Berlin, Mai 1976.



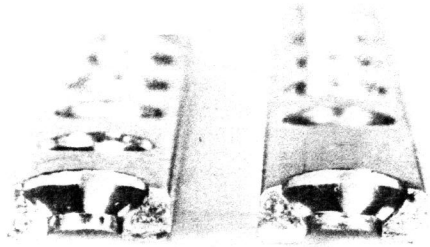
(a)



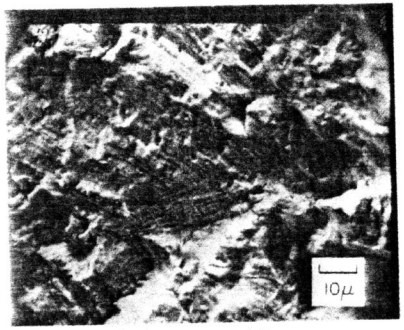
(b)

Figure 1 The Fracture Surface of the Broken Intramedullary Nail

(a) The Fractured Surface of the Nail. Dimensions of the Nail: Diameter 12 mm, Length 32 cm
(b) A Typical Fatigue Region on the Fracture Surface. Result of Investigation by SEM



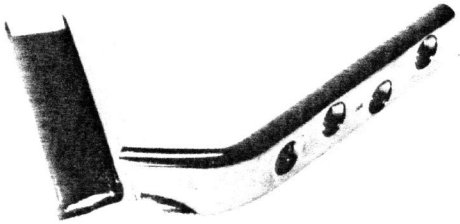
(a)



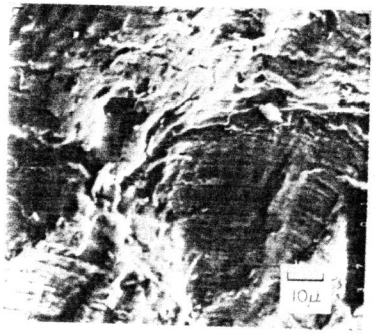
(b)

Figure 2 The Fracture Surface of the Bone Plate

(a) The Fractured Surface of the Bone Plate, Dimensions of the Bone Plate: Number of Holes: 12, Length of the Plate: 202 mm
(b) Fatigue Region on the Fracture Surface, Result of Investigation by SEM



(a)



(b)

Figure 3 The Fracture Surface of Hip Nail and Intertrochant Plate

(a) The Fractured Surface
(b) Fatigue Region on the Fractured Surface, Result of Investigation by SEM