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Fracture of titanium orthopaedic implants

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At the Royal National Orthopaedic Hospital, in 1964, the first titanium-containing bone and joint replacement was inserted. By now over 250 titanium-containing endoprostheses of various kinds have been inserted. In 1972 Ti318 (Ti–6 wt% Al–4 wt% V) was introduced and this alloy replaced the previously used commercially pure titanium. Over 200 Ti318 total hip replacements have been inserted, as have a variety of other titanium devices. This article is concerned with the fracture of these components in the body. The cause of fracture is discussed and the importance of good design and good surface finish is emphasized. The incidence of fracture is determined and on preliminary evidence Ti318 is found to be at least as satisfactory as other presently used implant alloys.

1. Introduction

In the UK the use of titanium in orthopaedic implants began in the mid 1950s when Down Bros and Zimmer GB (now OEC Orthopaedic) carried out clinical trials. Shortly thereafter these companies began marketing titanium products. The products included nails, plates, screws and Austin Moore and Thompson prostheses. Commercially pure titanium was used, namely Ti 160 and other grades. By the early 1970s these companies were selling at least 6000 prostheses each. In 1972, titanium alloy Ti318 (Ti–6 wt% Al–4 wt% V) became generally available, and because of its superior mechanical properties it replaced Ti 160 for most applications. In certain applications where extra hardness was required Ti550 and Ti680, were used both of which contained Sn, Mo, Al and Si.

In 1962 the British Standard Institute issued a standard, BS 3531, entitled "Metal surgical implants, drills and screwdrivers used for bone surgery". This standard, up-dated in 1968, included the various grades of commercially pure titanium, but did not include titanium alloy Ti318. In the early 1970s Ti318 for implant use was supplied against an aerospace standard since it was not included in BS3531 until 1980 and in the International Standard (ISO 5832) until 1978. Similar standards exist in the USA but the American standard for Ti–6 Al–4 V requires a lower level of interstitials than do the British or International standards. This difference remains a matter of interest on account of the supposed superiority of the "extra low interstitial" material.

Since the early report of Leventhal in 1951 [1] clinical and laboratory experience demonstrated the suitability of titanium for implant use, namely its excellent strength [2, 3], corrosion resistance [4, 5] and biocompatibility [6, 7]. However a few problems were encountered. In 1973 Scales *et al.* [8] reported on their experience with Ti160 after examining 74 multicomponent devices removed from patients. Although there was no evidence of simple corrosion, 40% of implants used in weight-bearing situations (i.e., lower limbs) exhibited "interface attack", i.e., fretting, and 2.6% fractured in the patient. In 1972 Hughes and Jordan reported a fracture of a commercially pure titanium hip replacement, which had initiated at a surface stress concentration [9]. The following year Meachim and Williams [10, 11] noted the presence of Ti in tissue adjacent to titanium implants, but found no adverse tissue reactions. Meanwhile laboratory tests suggested that in combination with polyethylene Ti was less wear resistant than other presently used alloys, especially when acrylic bone cement debris was present [12–14]; however, Rae showed

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TABLE I Use of titanium 160 and 318 in endoprostheses of all types

Alloy	First insertion (month/year)	Number inserted	Average duration of service (years)	Number in service for > 5 years
160	1/64	36	7.99	21
318	2/72	227	1.96	16
160 + 318	1/64	263	2.80	41

that Ti–6 Al–4 V wear debris produced in a joint simulator was not harmful to human synovial fibroblasts [15].

At the Royal National Orthopaedic Hospital (RNOH) major prosthetic replacement of long bones began in 1949. Subsequently, over 250 major bone and joint endoprostheses of various types containing titanium have been made by the Department of Biomedical Engineering and inserted at the RNOH and elsewhere. In addition to these endoprostheses over 220 titanium total hip replacements have been inserted at the RNOH since 1972. In addition, various titanium plates, nails and screws have been implanted. The general performance *in vivo* of all these implants has been described in an earlier article [16], and the present article concentrates on *in vivo* fracture. The incidence of fracture is estimated for intramedullary stems and for total hip replacements, and on this basis Ti318 is compared with Ti160 and with other presently used alloys. The cause and mechanism of fracture is discussed. The paper presents, to the author's knowledge, the first recorded cases of *in vivo* fracture of Ti318.

2. Uses, design and materials specification of components

Table I gives details of the titanium containing-endoprostheses. The heading "160" implies that the only titanium used in the component was Ti160. The heading "318" implies that Ti318 was used in the component, either without other titanium being used or in conjunction with Ti160. Components containing Ti318 had an intramedullary stem of this alloy. At present (April, 1981) there has been a total implantation time of 289 years for Ti160 and 447 years for Ti318. The design and construction of the endoprostheses has been described elsewhere [17]. Fixation to bone was by means of acrylic bone cement.

Table II gives details of the Ti318 total hip replacements inserted at the RNOH. Except for the special prostheses, which were custom-made, these components were of the standard Stanmore design. At present the total implantation time for these components is 282 years.

Table III gives the composition and heat treatment of typical batches of Ti160 and Ti318 used in the prostheses, and Table IV gives typical mechanical properties. Both the metal and the alloy were supplied by IMI Ltd in rod form of various diameters and both complied with BS 3531. Before implantation all titanium components were passivated in nitric acid solution in accordance with BS 3531 and some were anodized in a solution of orthophosphoric and sulphuric acids at 70V. Metal components were steam sterilized or gamma-irradiated at 2.5 to 3.0 MRad.

3. Results

Table V shows the incidence of intramedullary stem fracture for upper and lower femoral replacements. There were four fractures of Ti160 and one of Ti318. The average annual incidence can be used as a means of comparison and on this basis Ti318 appears better than Ti160. It is still too soon, however, to be certain about the superiority of Ti318, since although there has been only one fracture, the average duration has been relatively short, and less than ten Ti318 stems have been in service for the length of time that it took the Ti160 stems to break, i.e., 6 years on average. The one Ti318 fracture occurred after less than a

TABLE II Use of titanium 318 in total hip replacements

Type	First insertion (month/year)	Number inserted	Average duration of service (years)	Number of service for > 5 years
Special	4/72	39	2.65	6
Standard (all Ti)	1/73	22	3.38	5
Ceramic head	7/78	25	0.68	0
Co–Cr–Mo head	7/79	135	0.85	0

TABLE III Details of typical batches of Ti160 and Ti318 alloys

Detail	Alloy	
	Ti160	Ti318
Composition (wt %)	0.30 O_2, 0.01 N_2, 0.02 C, 0.04 Fe, 0.05 each Al, Cr, Mn, Ni, V, 0.02 each Cu, Si, Sn, Balance Ti	0.15–0.22 Fe, 6.24–6.52 Al, 4.14–4.46 V, 0.15–0.20 O_2 < 0.01 N_2, 0.01–0.03 C, Balance Ti
Heat treatment	1 h at 700° C, AC	1 h at 700° C, AC

year, but this was certainly the result of a design fault, as explained below.

There were no fractures of Ti318 total hip replacements. This result was to be expected in view of the relatively small number of insertions, only 11 of which had been in place for more than 5 years.

Fig. 1a shows an upper femoral replacement with a fractured Ti160 intramedullary stem. The component survived an implantation period of 85 months in an active female (CK) weighing 58 kg, following the excision of a chondrasarcoma. Fig. 1b show the appearance of the fracture surface. The stem diameter was 11.7 mm. Fracture initiated on the lateral side in the vicinity of a circumferential machining mark. There was no metallurgical defect in the alloy itself, and it is almost certain that this component failed because of the presence of the machining mark. To prevent similar failures, currently produced components are carefully polished. Since failure might also result from fretting between the stem and the inside of the shaft, these surfaces were examined but there was no evidence of fretting. Given the nature of the construction of these components, this was an encouraging result; however, the need for a tight fit between the stem and the shaft must be emphasized.

The details of the three other Ti160 intramedullary stem fractures are as follows: one, an upper femoral replacement, survived 83 months in an active male (FP) weighing 85 kg following a failed osteotomy, and the two others, both lower femoral replacements survived 88 months and 69 months respectively, the first of these was in a patient (JO) weighing 66 kg treated for osteoclastoma and the second was in a very active tennis playing male (PS) of medium-build also treated for osteoclastoma. Two of these fractures were examined. Both were fatigue fractures and both initiated in the vicinity of a longitudinal groove or flute in the stem (see Fig. 2a and b). These grooves were intended to prevent component rotation, but they reduced the cross-sectional area and acted as stress concentrations. In currently produced components rotation is prevented by means of a small flat on the stem.

Fig. 3a shows a lower femoral replacement with a fractured Ti318 femoral intramedullary stem. This component survived an implantation period of seven months in a male (JV) weighing 72 kg treated for fibrosarcoma. The stem was found to be broken at amputation of the leg following spread of the disease. Fig. 3b shows the appearance of the fracture surface. The stem diameter was 12.8 mm. Fracture propagated through a rivet hole, the rivet being the proximal one of two rivets used to attach the stem to the shaft. The rivet was 6 mm in diameter and the rivet hole resulted in a 60% reduction in the load-bearing cross-sectional area. Fig. 3c shows the fracture surface in greater detail. Fatigue striations are evident. This component failed by metal fatigue as a result of poor design. Currently produced components have a larger stem diameter (16 to 19 mm) and are usually attached by bolts. The bolt hole is placed a minimum of one and a half stem diameters from the mouth of the shaft in order to minimize the bending stress.

Fig. 4a shows a fractured Ti318 McLaughlin plate used in combination with a Smith–Petersen nail. The component was implanted in an eldery light-weight female with a femoral neck fracture, and it survived only six months. Fig. 4b shows the appearance of the fracture surface. Fracture initiated in the most distal groove or serration and propagated by metal fatigue as evident from Fig.

TABLE IV Typical mechanical properties of Ti160 and Ti318 alloy bar in annealed condition (data from IMI Ltd)

Property	Alloy	
	Ti160	Ti318
0.2 % Proof stress (MPa)	530	988
Tensile strength (MPa)	675	1050
Fatigue limit (MPa)	376	556

TABLE V Incidence of intramedullary stem fracture for upper and lower femoral replacements

Alloy	Number fractured	Number inserted	Average duration of service (years)	Average annual incidence (%)	Number in service for > 5 years
Ti160	4	22	8.65	2.10	18
Ti318	1	164	2.08	0.29	10

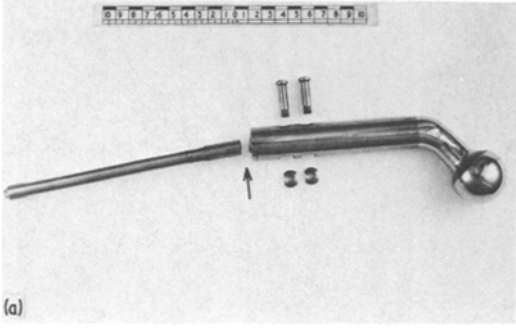
4c. No metallurgical defect was found, but machining marks within the groove probably acted as additional stress concentrators. Also, two similar McLaughlin plates, which fractured in 1970 and which were Ti160, were examined. All three fractured at a similar location on the flange, a result which supports the view that these were design failures.

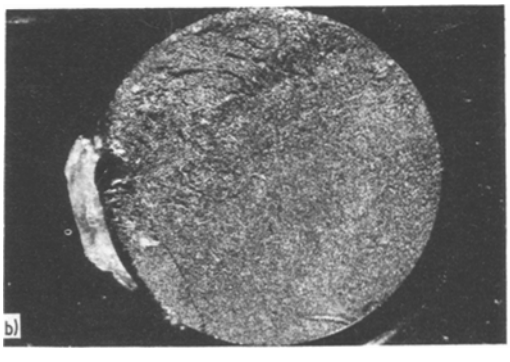
Fig. 5a show the fracture surface of a fatigue test-piece, machined from the stem of a forged Ti318 total hip replacement. The test-piece survived more than ten million cycles at an applied stress of 575 MPa at 50 Hz in Ringers solution. This lifetime and stress level are equivalent to over five years of use at three times the stress likely to be experienced in a total hip replacement. Fig. 5b shows fatigue striations clearly visible on the fracture surface. These striations are similar to those observed on the fracture surfaces of components fractured in the body.

4. Discussion

Hughes and Jordan [9] demonstrated the susceptibility of commercially pure titanium to surface stress concentrations. In their opinion there were two causes for the fracture of the hip prosthesis they examined. The first was the presence of an identifying mark on the lateral surface of the stem and the second was the fact that the patient had imposed a high load on the implant as the result of a fall. They considered that fracture was due to impact loading, since they found no evidence of metal fatigue. The present article confirms the findings of Hughes and Jordan, namely the susceptibility of commercially pure titanium to surface stress concentrations, and a similar susceptibility is observed for Ti318. In addition, it is demonstrated that titanium components, whether commercially pure or Ti318, can fail in the body by metal fatigue.

In the same article Hughes and Jordan reported on the fracture of a stainless steel McLaughlin plate, and noted the poor design of the component and the likely deleterious effect of machining marks at the root of the serrations. The fractured McLaughlin plate described in the present article was almost identical to the one examined by Hughes and Jordan, and it is evident that even the use of the mechanically superior titanium





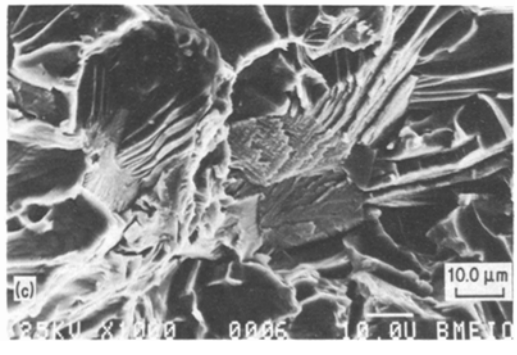


Figure 1 (a) Upper femoral replacement with fractured Ti160 intramedullary stem (CK) (scale in cm). (b) Appearance of fracture surface, the stem diameter was 11.7 mm. (c) Details of fracture surface.

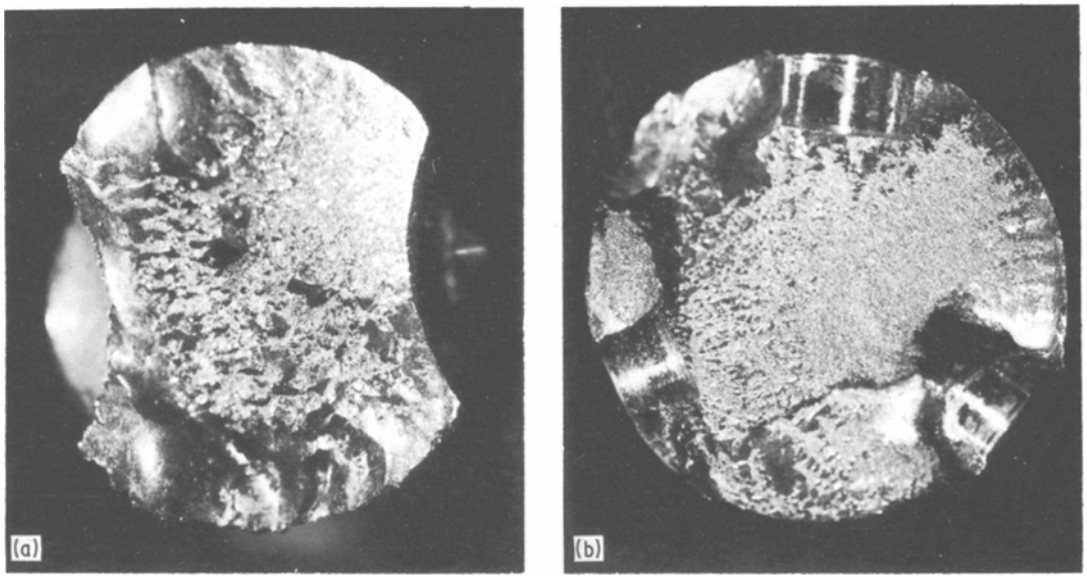
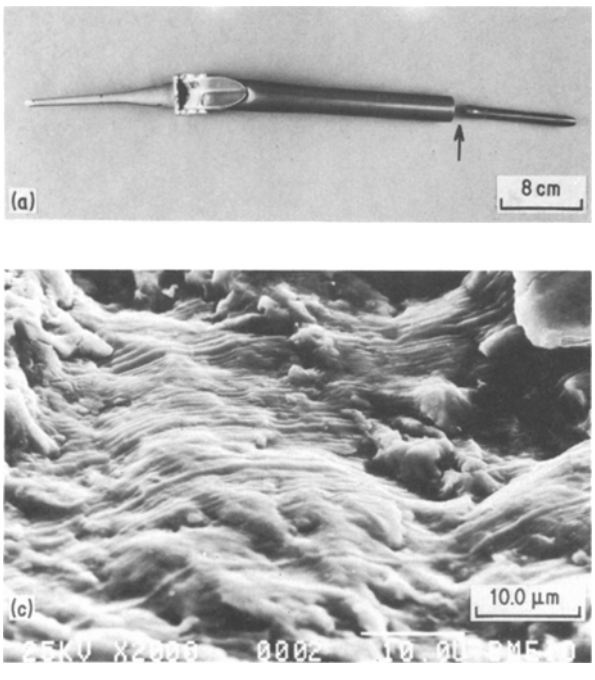


Figure 2 (a) Appearance of fractured intramedullary stem with two grooves (FP), the stem diameter was 11.3 mm. (b) Appearance of fractured intramedullary stem with three grooves (PS), the stem diameter was 11.8 mm.

alloy cannot compensate for the poor design of the component. A simple calculation shows that the stress in the fractured region was high, and that a relatively minor modification to the design, a thicker section for example, together with better machining would improve the performance considerably. It is the opinion of the present author that without such improvements the component is unsuitable for clinical use, and this is now recognized by the manufacturer, who has recently altered the design.

In previous work the incidence of fracture was determined for cast cobalt chromium molybdenum total hip replacements and an average incidence of 0.2% per annum was obtained [18, 19]. In earlier work Charnley [20] obtained a similar



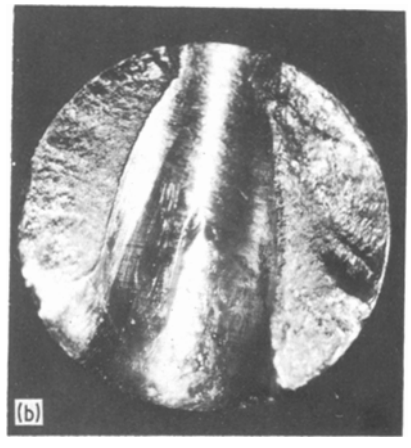
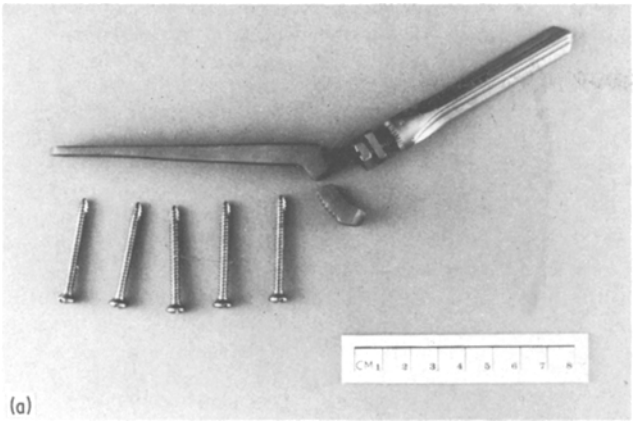
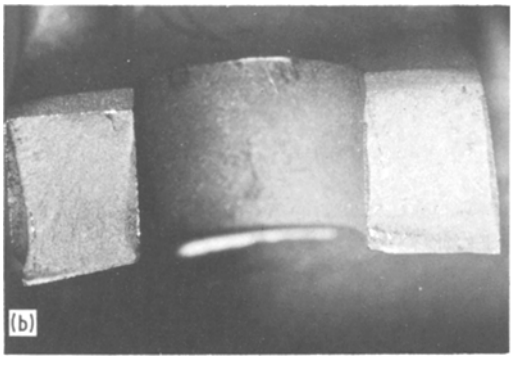


Figure 3 (a) Lower femoral replacement with fractured Ti318 femoral intramedullary stem (JV). (b) Appearance of fracture surface, the stem diameter was 12.8 mm. (c) Detail of fracture surface.





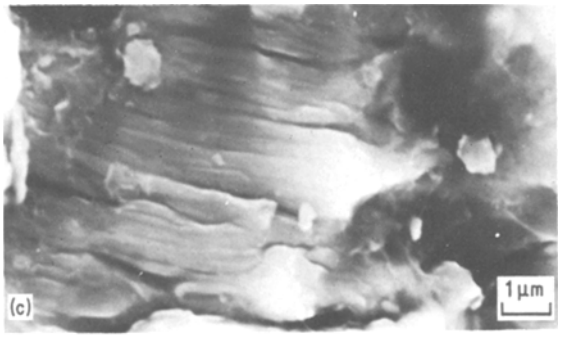
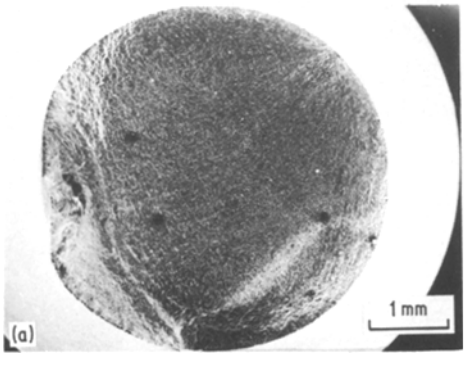


Figure 4 (a) Fractured Ti318 McLaughlin plate with Smith–Petersen nail and screws. (b) Appearance of fracture surfaces. (c) Detail of fracture surface.

value for stainless steel components, and found that the failure rate was greater the heavier the patient. In the present study there were no fractures of Ti318 total hip replacements. This result does not indicate the superiority of Ti318 when compared with either cobalt chronium molybdenum alloy or stainless steel. This is so, since a failure rate of 0.2% per annum would give on average only one failure in one hundred components after five years, and in the present study only eleven components have been implanted for this length of time. On the other hand the manufacturers of Ti318 components have sold many thousands of partial and total tip replacements since the alloy was introduced in 1972, and neither OEC Orthopaedic nor Down Bros are aware of any fractures. From this result it may be concluded, therefore, that in all prob-



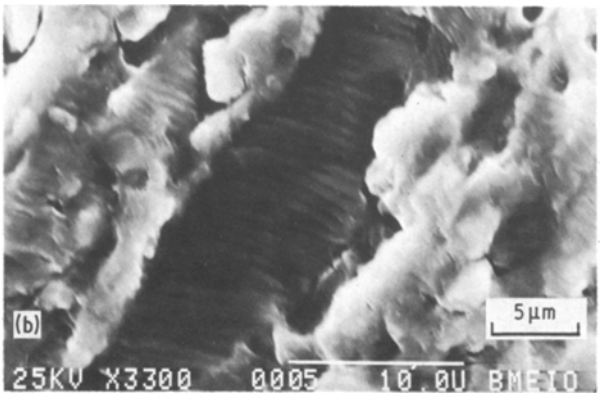


Figure 5 (a) Fractured fatigue test-piece from forged Ti318 total hip replacement stem, the test-piece diameter was 3.8 mm. (b) Detail of fracture surface showing fatigue striations.

ability relatively few fractures have occurred and, if this is so, the suitability of Ti318 is confirmed.

As mentioned earlier, the present results appear to demonstrate the superiority of Ti318 as compared with Ti160 and, although the superiority is yet to be confirmed, it is in keeping with the materials data, especially the fatigue data. In addition, the importance of good design, good surface finish, optimum stem or section size and the elimination of stress concentrations is now recognized, and this realization should help to reduce mechanical stress and minimize the likelihood of fracture. Consequently, the continued use of Ti318 for orthopaedic implant applications can be recommended. Similarly, good results could be expected from the "extra low interstitial" grade of Ti–6 Al–4 V and, as described in an earlier report [21], even better results can be expected from other titanium alloys, for example Ti550 (Ti–4 wt % Mo–4 wt % Al–2 wt% Sn). On the other hand, it is possible that better properties are unnecessary, since Ti318 may be adequate for most existing total joint replacement applications.

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