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Causes of failure in total hip prostheses

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This paper reports a study of nine total-hip replacements removed from patients for infection, widespread loss of bone substance and fracture of the stem of the femoral component. The surfaces of the metal, the polymethylmethacrylate (PMMA) bone cement and the attached bone were examined by a variety of techniques, including scanning electron microscopy (SEM) and energy dispersive X-ray analysis (EDXA) produced by bombardment of the sample with electrons. Evidence of corrosion of the metal was found in both cobalt–chrome–molybdenum alloys and stainless steel. It is suggested that the products of metal corrosion may alter the balance of bone formation/resorption to produce a loss of bone substance. Two of the femoral stem fractures were considered to have developed from faults originating in manufacture; a third fracture originated from fretting between the wire used to re-attach the trochanter and the femoral stem; and the fourth fracture from high cyclic stress fatigue of the femoral stem induced through a previous fracture of the PMMA bone cement due to injury.

1. Introduction

The human hip joint is essentially a ball and socket joint, the socket (or acetabulum) being located on the pelvis and the ball (or head of the femur) being connected to the thigh bone (or femur) by a narrow neck of bone known as the neck of the femur. Failure of the joint is from two main causes, firstly due to accident, which in elderly people is usually fracture of the neck of the femur. If the fracture is not too severe the head may be re-attached by pinning, however, in more severe cases the entire head of the femur may be replaced by a metal component. The second reason for failure of the joint is degenerative processes such as osteoarthritis, or a pathological condition such as rheumatoid arthritis, when the total hip must be replaced, i.e. both the acetabular and the femoral component. Total hip prostheses are of two main types: either both components are made of metal alloy or the acetabular component is made of dense polyethylene and the femoral component of an alloy, usually stainless steel. The McKee–Farrar hip is an example of the first, the Charnley hip of the second. An example is shown in Fig. 1. The stem of the prosthesis is inserted into the medullary cavity of the femur and fixed in position with an acrylic cement which supports the whole length of the stem. The acetabular component is similarly cemented into the pelvis.

Removal of prostheses from patients is commonly due to one or more of the following reasons: (1) post operative infection, (2) adverse tissue

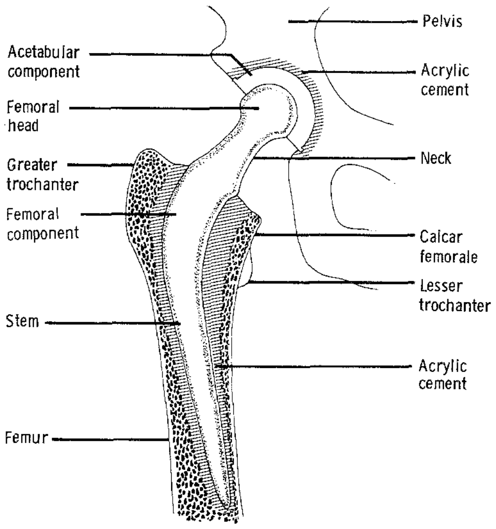

Figure 1 Schematic diagram of artificial hip joint. The stem is shown in the valgus position, i.e. the tip being nearer to the inner side of the bone.

TABLE I The patients and the total-hip replacements studied.

Age, sex, and body weight of patient	Disease for which total-hip replacement performed	Type of total-hip replacement	Duration of implantation (years)	Reasons for removal	Skin sensitivity tests
61 yr Female 50 kg	Osteoarthritis	McKee–Farrar	7	Severe bone loss	Negative to Co
72 yr Female 59 kg	Osteoarthritis	Ring–Thompson	3	Severe bone loss	Negative to Ni and Cr; slight response to Co
62 yr Female 71 kg	Osteoarthritis	Ring–Thompson	$3\frac{1}{2}$	Slight bone loss	Negative to Ni and Cr
55 yr Male not known	Osteoarthritis	McKee–Farrar	8	Prosthesis stem fracture	Not done
66 yr Male not known	Osteoarthritis	McKee–Farrar	6	Prosthesis stem fracture	Negative to Ni, Co and Cr
58 yr Male 80 kg	Osteoarthritis	Charnley	6	Prosthesis stem fracture	Not done
76 yr Male 80 kg	Osteoarthritis	Charnley	$1\frac{1}{2}$	Prosthesis stem fracture	Not done
42 yr Female not known	Previous fracture of the neck of the femur	McKee–Farrar	2	Deep infection	Not done
57 yr Female 55 kg	Osteoarthritis	Charnley	$1\frac{1}{2}$	Deep infection	Not done

reactions to corrosion or wear products, (3) mechanical failure of the component as a result of corrosion or fretting fatigue or gross overload resulting from failure of the cement.

Previous studies on the response to the metals used for implant purposes have been more concerned with the reactions to these metals when used in fracture surgery rather than when used in total-joint replacements [1–4]. Furthermore, such studies were confined to routine biomedical and metallurgical aspects, including incidence of corrosion, chemical composition, metallurgical state, clinical successes, and the examination of failures. Studies which identified the cause of removal of total-hip prostheses as loosening, infection, metal sensitivity and an adverse response to the PMMA bone cement have been recently reported [5–7], together with an examination of fractured femoral protheses [8].

The present study reports an investigation of nine total-hip replacements removed from patients. Two implants were removed for infection and exhibited no features of metallurgical interest and were not considered further. Three implants were removed for an adverse response to the presence of the Co–Cr–Mo–C alloy, and four implants were removed for fracture of the stem of the femoral component. These cases form the basis of this paper, which was delivered at a meeting of the British Orthopaedic Research Society [9].

2. The patients, materials and methods

2.1. The patients and total-hip replacements

The patients, the diseases, and the reasons for the removal of the implants, are shown in Table I, together with information about skin sensitivity to the metals.

2.2. SEM and EDXA

A Cambridge Type S600 console scanning electron microscope and a Cambridge Type IIA scanning electron microscope were used to examine the implants, the PMMA bone cement and the attached bone.

The console scanning electron microscope has the advantage of being able to examine large samples, such as the femoral component of a total-hip prosthesis. This means that it is unnecessary to section the implant before examination, thereby eliminating the risk of inadvertently destroying evidence.

The basis of one of the most useful techniques for examining the reactions at the surfaces of orthopaedic implants is the combination of the scanning electron microscope (optical mode) with the energy dispersive X-ray analysis (EDXA) attachment (analytical mode). With the EDXA attachment it is possible to analyse qualitatively, and with suitable calibration, quantitatively, elements above atomic number 11. In specimens where a more close examination of the metal/

tissue interface is required, the implants are coated with a thin layer of carbon to prevent destruction of the tissue by the beam of electrons.

2.3. Other metallurgical methods of analysis

In addition to scanning electron microscopy with EDXA and light microscopy other methods were used to examine the implants. Carbon arc emission spectroscopy was used for the semi-quantitative chemical analysis of the body tissues. The chemical analysis of a stainless steel was determined using direct reading vacuum spectroscopy and the carbon content confirmed using standard wet chemical analysis. The monomer content of PMMA bone cement was determined by monomer extraction and gas phase chromatography. The PMMA bone cement was examined by electron probe microanalysis which uses the wavelength dispersive analysis of X-rays after bombardment of the sample with electrons in contrast to EXDA. By use of suitable correction procedures the results obtained from this equipment can provide a more accurate quantitative analysis than EDXA; in addition, the electron probe microanalyser can detect elements with atomic numbers as low as 4 (carbon), compared with 11 (sodium) for EDXA.

Simple laboratory experiments were carried out in which the corrosion resistant properties of austenitic stainless steels were compared. These experiments involved a determination of the weight loss of the steels after immersion in 65% nitric acid and an examination of the surface of sensitized austenitic stainless steel immersed in 0.17 M NaCl solution buffered with bicarbonate to a pH of 7.4 and scratched with a diamond stylus. The standard specifications (BS 3531: 1968 and 1972 unadpoted) call for special ringing and bend tests to be done on the stainless steel implants and the laboratory tests can be considered equivalent to the methods specified in the standards.

2.4. Histological examination

Tissue removed at operation was examined using conventional staining and light microscopy.

2.5. Bacteriological examination

The fluid, pultaceous material, and tissues about the implants were examined for sterility using plate and broth cultures.

2.6. Skin sensitivity tests

Solutions of 2% cobalt chloride, 2% potassium dichromate and 2% nickel sulphate were applied to the skin for 48 h. The results were read at 48 h. An eczyematous reaction was read as a positive result, and an eczyematous reaction with induration was read as a strongly positive result.

3. Results

3.1. Specimens from Patient 1

3.1.1. Clinical findings and naked-eye observations

A McKee–Farrar total-hip replacement was removed seven years after implantation from a 68-year old female patient. Radiographic examination had revealed widespread loss of bone substance in the femur and pelvis about the left hip. At the time of its surgical removal it was observed that, apart from the presence of a small amount of joint fluid, the femoral component was tightly held in the bone, whereas both the acetabular component and the screws were loosening. On extraction of the acetabular component from the PMMA bone cement, it was noticed that the cement/metal bond was extremely tight. Similarly the one screw that was in the cement was tight. The fibrous tissue layer, which was immediately against the polished areas and the distorted and polished spikes of the acetabular pelvic surface, was coloured green. The tissue layer about the screw was also coloured green but in three places; in juxtaposition to the end of the screw; the first few (polished) threads of the screw; and the slot of the screw head. A green crystalline film or deposit was present on the articular surfaces of both the acetabular cup and the femoral head; on the pelvic side of the acetabular cup there were areas which showed polishing and some spikes were distorted. The screws also showed areas of distortion and polishing on their tips and on the first few threads which were screwed directly into pelvic bone.

3.1.2. Histological examination

Sections from the tissue around the implant showed abundant lymphocytes in a poorly cellular fibrous matrix. Prominent foreign-body giant cells surrounded spaces once occupied by material now dissolved out of the section, which in this situation might be indicative of corrosion. There was also much amorphous debris and fragments of either necrotic (dead) bone or plastic.

Figure 2 Tissue removed from Patient 1, embedded and examined in the optical mode of the SEM. The arrows point to embedding medium (EM) and the bone tissue (BT).

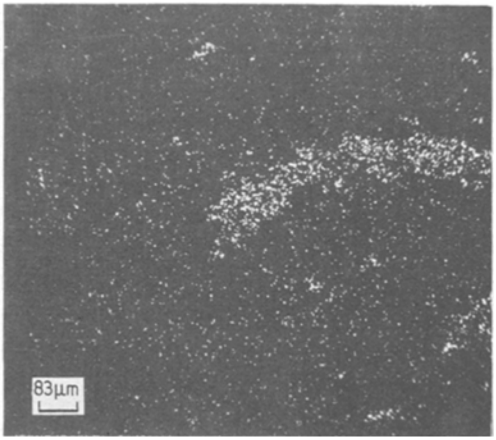

Figure 3 Tissue removed from Patient 1, embedded and examined in the analytical mode (EDXA) of the SEM for Ca. The bright areas show Ca enrichment.

3.1.3. SEM examination

The sections of tissue and PMMA bone cement associated with the femoral stem of the Co–Cr–Mo–C alloy implant were examined using the analytical and optical modes of the scanning electron microscope. Spicules of bone could readily be discerned and identified in the tissue. Fig. 2 shows the tissue as revealed by SEM, in which pieces of hard substance are evident. The analytical mode for the same field of view identifies calcium as shown in Fig. 3. Superpositioning of these two figures revealed the specific areas of bone. No trace of cobalt was detected in the tissue using these techniques.

Close examination of the inner surface of the PMMA bone cement form from around the femoral stem by scanning electron microscopy and EDXA revealed no evidence of metallic elements from the implants on the surface of the PMMA bone cement. Further examination of the PMMA bone cement with the aid of the electron probe microanalyser on both surfaces (that is adjacent to the femoral stem at the metal/cement interface and at the bone/cement interface) showed small quantitites of Cr and Mo on the side adjacent to the metal/cement interface and no Cr but significantly more Mo at the bone/cement interface. No trace of Co was found present in another sample of PMMA cement from the same area. The PMMA cement removed from this patient was found to contain 3% monomer, whereas 5% monomer was found present in a sample of PMMA cement as prepared during a revision operation and examined for monomer at 7 days.

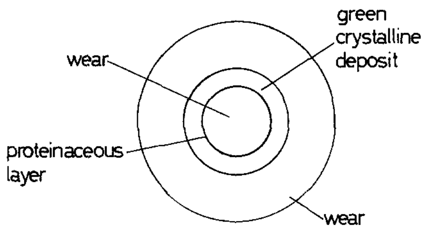

Figure 4 Schematic diagram of articular surface of the acetabular component removed from Patient 1 (not to scale). Note the four distinct areas as recorded in the test.

Fig. 4 shows schematically the appearance of the articulating surface of the acetabular component. There are four distinct areas; an inner surface showing wear, a green crystalline deposit, a thin ring of green proteinaceous material, and an outer zone of wear. The green crystalline deposit observed by SEM is shown in Fig. 5, which reveals the layering and its crystalline nature.

Table II lists the analytical results obtained from the samples of this deposit on the EDXA attachment. Molybdenum and cobalt were not

TABLE II EDXA of the green crystaline deposit.

Element	Count level (sample 1)	Count level (sample 2)
P	1217	1489
S	782	1172
Ca	1000	1143
Cr	972	943

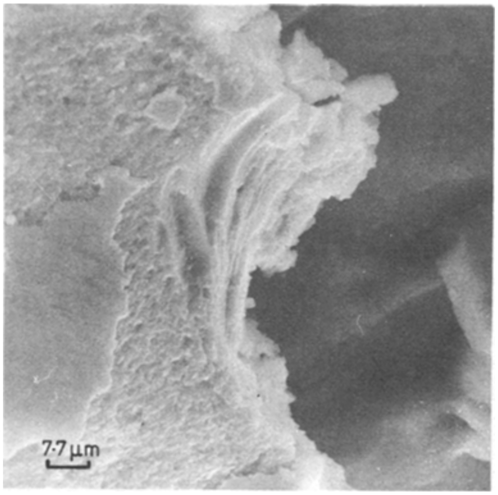

Figure 5 Scanning electron micrograph of green crystalline deposit on the articular surface of the acetabular component (patient 1). See Fig. 4.

detected. These figures are only to be interpreted semi-quantitatively. However, the presence of Ca, Cr, P and S in approximately equal proportions suggests a mixed crystal of chromic sulphate and calcium phosphate (apatite). This is consistent with the view that chromium is not easily soluble in the body fluids; in contrast cobalt and molybdenum more readily dissolve and become dispersed throughout the body.

A closer examination of one of the screws showed mild corrosion, or etching, both of the tip (Fig. 6) and of the first few threads which were screwed directly into the pelvis. A corrosion pit and areas of etching were found on the first thread and Ca was detected in the bottom of this corrosion pit. This finding suggests that the type of attack present in the acetabular component and the screws is similar. It is also to be noted that the screws were not manufactured by the commerical supplier of the prosthesis, so that the chemical reactions observed are likely to be specific to the Co–Cr–Mo–C alloy, rather than to the mode of manufacture.

A comparison of the type of attack observed at the screw tip (Fig. 6) with metallographic sections of the screw and the tip of the femoral stem showed that the distance between corrosion pits was of the order of microns whereas the grain, or crystallite, sizes of the screw and the stem were hundreds of microns and thousands of microns respectively – that is the attack was general rather than intergranular. The screw has a cored equiaxed grain structure whereas the femoral stem has a large grained dendritic cored structure; both structures are typical of Co–Cr–Mo–C alloys.

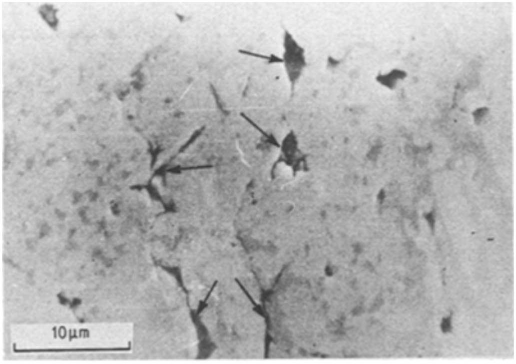

Figure 6 Scanning electron micrograph of the attacked surface at the tip of the Co–Cr–Mo–C alloy screw removed from Patient 1. The arrows point to areas of corrosion.

3.1.4. Discussion

The pathological and metallurgical findings from this patient together with the findings from Patients 2 and 3 suggest that dissolution of the Co–Cr–Mo–C alloy had occurred in life. This corrosion would lead to the ions of Co, Cr, Ni and Mo being absorbed locally into the tissues. Because Co, Ni and Mo ions appeared to be readily soluble in body fluids, they would be dispersed throughout the body. In contrast at least some of the Cr ions were not dispersed and have clearly combined with calcium and phosphate ions (possibly from the bone) and sulphate ions (possibly from the blood) to produce the mixed crystal of chromic sulphate with some form of apatite.

This interaction between chromium and calcium may have altered the balance of bone formation/resorption locally and contributed to the loss of bone substance from the femur and pelvis. It is possible that osteogenesis in this patient was particularly susceptible to the presence of such ions in her tissues. Moreover, bone necrosis may also have occurred due to the metallic ions released from the prosthesis; necrosis would also lead to local loss of bone substance.

These hypotheses supplement the findings of other workers on metal sensitivity [6] and the increased cobalt and chromium contents in the hair, blood and urine of such patients [10].

The chromium sulphate/apatite crystals could explain the green colouration observed by orthopaedic surgeons both on Co–Cr–Mo–C alloy implants and in fibrous tissue adjacent to such implants.

3.2. Specimens from Patients 2 and 3

3.2.1. Clincial findings

The next two specimens are both Ring–Thompson (metal on metal) total-hip prostheses with cemented femoral stems in female patients. In Patient 2, the prosthesis was removed after three years, when the patient showed widespread loss of bone substance in the femur and pelvis. In Patient 3 there was a slight loss of bone substance in the pelvis $3\frac{1}{2}$ years after implantation. Initially the wear and corrosion characteristics are examined.

3.2.2. Prosthesis wear

SEM of the articulating surface of the acetabular component removed from Patient 3 showed the normal type of wear behaviour as previously reported [11]. This type of wear was also present in the implant from Patient 1. Fig. 7 shows the articulating surface present in Patient 2. It is seen that the scratches are broadened and pitted, which is indicative of the presence of some form of corrosion. The articulating surface present after

Figure 7 Scanning electron micrograph of the articular surface of the acetabular component removed from Patient 2. Note the broad scratches resulting from corrosion.

Figure 8 Scanning electron micrograph of the pelvic surface of the acetabular component of the prosthesis removed from Patient 3. Note the irregular surface resulting from corrosion.

TABLE III Spark emission spectroscopic chemical analyses of tissues adjacent to orthopaedic implants.

Element	Patient 2: Tissue site		Patient 3: Tissue site		
	Femoral neck (ppm)	Acetabulum (ppm)	Lining from femoral stem (ppm)	Adjacent to articular surfaces (ppm)	Acetabular pelvic lining (ppm)
Ba	5–17	100–300	40–130	< 0.2	< 0.2
Co	17–50	50–170	40–130	7–20	6–20
Cr	50–170	50–170	400–1300	20–70	60–200
Fe	5–17	5–13	4–13	7–20	6–20
K	50–170	170–500	0.1	< 0.2	6–20
Mg	50–170	170–500	13–40	7–20	20–60
Mo	2–5	2–5	1–4	< 0.7	0.5–2
Na	> 1700	> 1700	400–1300	200–650	550–1900

TABLE IV EDXA of Ca/P ratios of bone specimens.

Specimen origin	Site	Ca	P	Ca/P ratio
Patient 1	Femoral cancellous bone attached to PMMA bone cement	19802	13230	1.5
Normal bone	Bone on flute of Co–Cr–Mo–C screw	19008	10612	1.8
Patient 1	Spicule of resorbed femoral cancellous bone attached to PMMA bone cement	305	388	0.8
Patient 2	Bone deposit on the thread of a Ring acetabular component	645	905	0.7
Paitent 1	Corrosion product on articular surface of McKee–Farrar acetabular cup	1072	1353	0.86

manufacture of a McKee–Farrar cup was also examined by SEM. The surface examined exhibited the normal type of finish that would be expected from polishing the metal. In Patient 3, the outer unpolished surface of both components of the prosthesis appeared to be attacked (Fig. 8).

3.2.3. The tissue

Table III lists the results of carbon-arc emission spectroscopy of adjacent tissue removed at time of operation from Patients 2 and 3. The presence of substantial amounts of chromium (up to 1000 ppm) was recorded in the soft tissue which lined the femoral stem removed from Patient 3. At operation the presence of necrotic bone, fluid and green tissue was seen. Furthermore, the analyses also show in most cases more chromium present in the tissue and less cobalt and molybdenum. This suggests that cobalt and molybdenum were more readily dispersed throughout the body.

3.2.4. The bone

The calcium/phosphorus ratios in bone adjacent to the prostheses, as examined by SEM and the EDXA attachment, are shown in Table IV. The Ca/P ratios of bone being laid down adjacent to two of the prostheses corresponds to that of resorbed bone. This low Ca/P ratio in these patients could result from the loss of calcium required to accommodate the large local concentrations of Cr ions released from the prosthesis as detected by carbon arc emission spectroscopy in the adjacent tissue.

Cancellous bond (bone from inside the shaft of the femur) attached to PMMA bone cement removed from Patient 1 was examined, together with bone deposit found present on the thread of the Ring acetabular component removed from Patient 2. These samples are compared with the corrosion product found present in the McKee–Farrar acetabular cup removed from Patient 1. A bone deposit found present on the surface of a Co–Cr–Mo–C alloy screw removed from an eighteen year old male patient is included as a control. This patient showed the more normal reactions to the presence of the Co–Cr–Mo–C alloy.

3.2.5. Discussion

The findings on specimens removed from Patients 1, 2 and 3 suggest that the prostheses and/or wear products were dissolving in life and caused necrosis of the adjacent soft and hard tissue. This necrosis could lead to eventual loss of bone both in the pelvis and femur as a by-product of the further dissolution of the wear products or the prostheses. The chemical reactions observed appear to be specific to the Co–Cr–Mo–C alloys used in the total-hip prostheses. Moreover these reactions possibly lead to the presence of resorbed bone adjacent to the prostheses.

The next part of the paper considers four separate femoral stem fractures. In each patient tissue samples removed for bacteriological examination were sterile on culture.

3.3. Specimen from Patient 4

3.3.1. Operative findings

This study concerns the fracture of the stem of a McKee–Farrar total-hip prosthesis implanted for just over 8 years in a 55 year old male patient. Radiography after four years showed a satisfactory appearance, but 4 years later the femoral stem was removed for fracture.

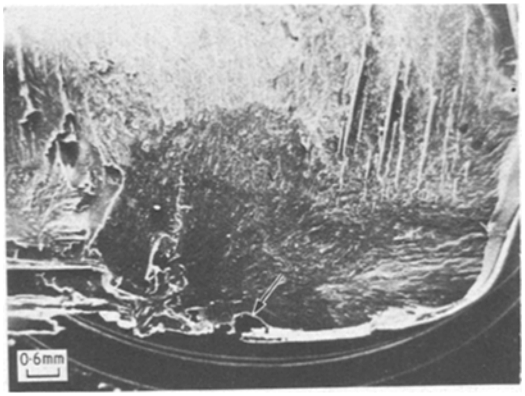

Figure 9 Scanning electron micrograph of the fracture surface of the metal stem removed from Patient 4. The arrow points to the area of porosity.

3.3.2. Metal fracture

The surface of the metal fracture was examined by SEM (Fig. 9). A large area of porosity is shown in the lower and middle part of the figure, and this area acted as a "stress-raiser" and eventually the fracture was inititated there.

3.3.3. Discussion

This phenomenon has also been observed by other workers [8]. It should be noted that this fault, attributed to shrinkage, occurs during manufacture. Since all manufactures claim 100% visual examination, 100% radiographic examination, and 100% dye penetration examination by illumination with ultra-violet light, it is difficult to understand how such a large defect was allowed to pass the thorough quality control methods adopted. One approach to improve quality control with these alloys would be for the manufacturers to adopt the rigorous investment casting production procedures used in the aerospace industries.

3.4. Specimen from Patient 5

3.4.1. *Clinical observations*

A McKee–Farrar total-hip replacement was inserted into a 66 year old male patient and removed 6 years later, for fracture of the stem. The patient was sure that no serious injury had occurred before the fracture of the stem of the femoral component was detected radiologically.

3.4.2. *Metal fracture*

The fractured surfaces of the metal were too damaged by fretting to isolate successfully the origin of the fracture, although the fracture itself is of a torsional nature (Fig. 10). It is possible that the fracture inititated from some type of surface flaw which had been sealed up by a welding process giving locally a much finer grain structure, Fig. 11. The high cyclic stresses occur in this situation if any cement loosening and/or cement fracture occurs in use around the upper third of the femoral stem as described in the specimen from Patient 7. Stresses can be as high as 54% of the yield stress in the extreme case of cantilever loaded prostheses in PMMA bone cement [12] and at such stresses the Co–Cr–Mo–C alloys could fail due to fatigue. The presence of surface markings and a microweld (Fig. 11) through which the fracture had propagated is thought to be of enough significance to suggest that either of these faults would act as stress-raisers and could be the origin of the fracture.

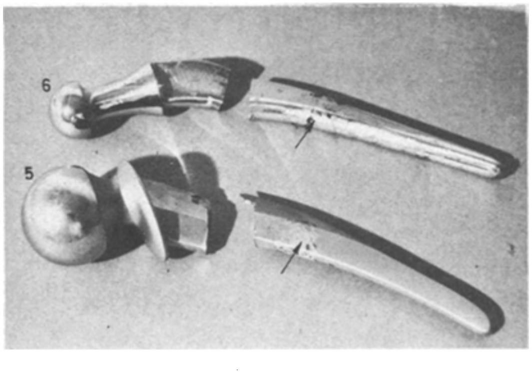

Figure 10 Physical appearance of femoral components removed from Patients 5 and 6. The arrows point to the areas of corrosion.

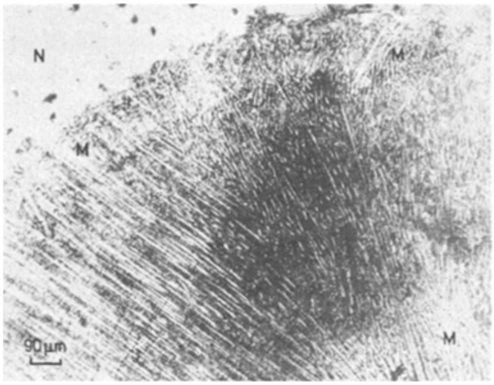

Figure 11 Optical micrograph of the polished and etched surface of the metal (Co–Cr–Mo–C alloy) stem through the fracture. This stem was removed from Patient 5. The microweld (M) and the more normal as-cast structure (N) are labelled. The area filled in by the manufacturer as a microweld occupies almost the whole field of view.

3.4.3. *Discussion*

In this patient it is suspected that a surface flaw was already present before the insertion of the femoral stem; the type of loads normally present at the cement/metal interface in a completely uncracked PMMA bone cement surrounded metal stem would readily lead to crack propagation in this specimen and eventual fracture of the stem. The industrial practice whereby surface porosity in air cast Co–Cr–Mo–C alloy stems is corrected by welding up with material of the same composition is unsatisfactory since a region of material of different grain size and therefore different properties is introduced into the surface and is likely to be the source of a fatigue failure.

The other point of note about this failure was the presence of corrosion 1 to 2 cm away from the fracture on the medial side of the metal stem (Fig. 10). This figure also shows corrosion at a similar site in the next paitient in which the alloy used was an austenitic stainless steel. It is possible that the corrosion present on the Co–Cr–Mo–C alloy stem was caused by micro-organisms, since rod-shaped particles, tentatively identified as bacilli, were found by SEM of this area of corrosion. The finding needs further detailed investigation before one can be certain that the corrosion was caused in the body by bacilli.

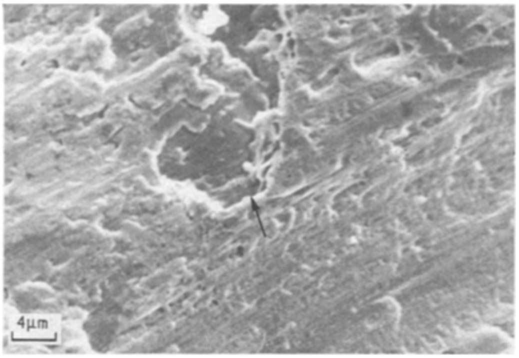

Figure 12 Scanning electron micrograph of fretted area from which the fracture of the metal stem occurred. This specimen was removed from Patient 6. The arrows shows the area of fretting.

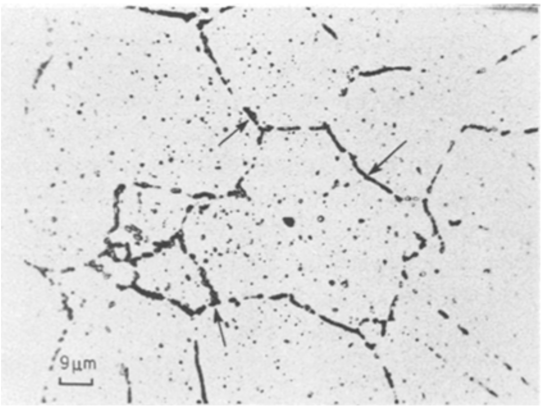

Figure 13 Optical micrograph of the polished and etched stainless steel stem removed from Patient 6. The arrows point to the areas of $Cr_{23}C_6$ precipitation.

3.5. Specimens from Patient 6

3.5.1. Clinical findings

This specimen was from a 58 year old male patient of about 80 kg body weight who had a bilateral total-hip replacement. 6 years later the metal femoral stem in the left hip fractured and was replaced. At the time of the first operation a stainless steel wire was used to re-attach the greater trochanter and placed in contact with the metal stem of the prosthesis. Movement of the wire loop during use wore the metal surface by fretting, a type of damage which commonly occurs at amplitudes of movement of less than 0.001 in. or 25 μm. The fretting initiated a fatigue crack and the stem failed after 6 years. A conservative estimate of the fatigue life in this case, which assumes that the patient walked an average of 4 miles per day over the period, is 15×10^6 cycles. The appearance of the fretted surface is shown in Fig. 12.

Fig. 10 shows that corrosive attack on the metal stem of the prosthesis has also occurred. The microstructure, revealed by chemical etching of a polished section, showed that the stainless steel was austenitic and in a 'sensitized' condition (Fig. 13). Further metallurgical examination of the wire and stem showed that the wire consisted of a lightly worked austenitic stainless steel. The chemical composition of the femoral stem as revealed by wet chemical analysis and direct reading vacuum spectroscopy is shown in Table V. While this steel conforms to the standard specifications of chemical composition and mechanical properties (BS 3531 : 1968 and 1972 unadopted), it is in a sensitized condition.

TABLE V Chemical composition of the stainless steel femoral stem in Patient 6 as revealed by direct reading vacuum spectroscopy.

Element	(wt %)	Element	(wt %)
Cr	17.3	Mn	1.5
Ni	11.5	S	0.01
Mo	2.7	P	0.02
C	0.046	Fe	balance
Si	0.7		

3.5.2. Discussion

Fretting corrosion is known as a source of fatigue failure. It is particularly damaging on a corrosion resistant material since the action disrupts the otherwise protective film and exposes the underlying metal to the corrosive environment, thereby enhancing the attack by corrosion fatigue [13]. It is therefore inadvisable to allow metal-to-metal contacts of this type in operative procedures.

The evidence that the stem of the prosthesis was in a sensitized condition is also a disturbing feature of this case. Tests in the laboratory to compare the corrosion rate of sensitized and non-sensitized austenitic stainless steel are reported in Table VI. The specimens, in the form of small bars, were refluxed in 65% nitric acid, a routine corrosion test, for 36 h. The sensitized metal lost two to three times more weight than the low-carbon stainless steel.

Fig. 14 shows an aggregation of corrosion pits on the flat polished surface of a sensitized stainless

TABLE VI Weight losses measured on stainless steels.

Stainless steel	Weight loss (g)
non-sensitized 316 L	0.0016
sensitized 316 S16	0.0041

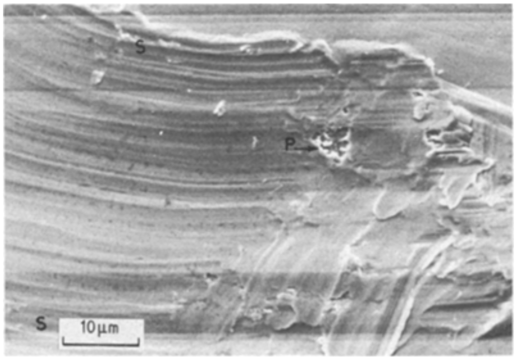

Figure 14 Scanning electron micrograph of a scratch (S) on the surface of 316 S16 sensitized stainless steel in buffered 0.17 NaCl solution (pH = 7.4) at 0 mV with respect to the standard calomel electrode. The arrow shows where the pitting (P) has occurred. This steel had been treated in the same way as stainless steel implants are treated before being supplied to hospitals.

steel which had been treated in nitric acid to produce a passive surface layer and then immersed in buffered 0.17 M NaCl solution (pH = 7.4). These corrosion pits had formed at the site of contact between a diamond stylus and the metal. The diamond stylus rested on the surface of the metal for 10 min. During this period the chloride ions had initiated corrosion at the point of contact even though the potential at the surface was 0 mV with respect to the Standard Calomel Electrode, i.e. the potential at which stainless steel implants passivate *in vivo*. The smeared material in which the pits are visible was produced by sliding the diamond over the surface. This formed part of a study of the repassivation of these materials after suffering mechanical surface damage, which will be reported elsewhere.

The British Standards Institute Specifications require special ringing and bend tests for intercrystalline corrosion on stainless steels used for implant purposes. The metal used as the femoral stem of the prosthesis in this patient would probably have failed these tests.

The findings from this patient suggest that since this type of prosthesis is being inserted in younger, more active patients, better fatigue life data on implant alloys need to be established. Most engineering fatigue data are based on high frequencies and a fatigue life of 10^7 cycles. The length of time that implants are now surviving in patients suggest that fatigue strengths at 10^8 or 10^9 cycles would be more relevant, but the time involved would be quite unrealistic. The most promising line of approach would therefore be the determination of crack propagation rates in these alloys at low frequencies in simulated body environments. More attention needs to be paid by manufacturers to routine microstructural sampling as well as to the tests for intercrystalline corrosion to eliminate sensitized material being supplied to hospitals.

3.6. Specimen from Patient 7

3.6.1. *Clinical findings*

The final specimen concerns a femoral stem failure in which the stainless steel metal stem failed due to high cyclic stresses induced through fracture of the PMMA bone cement. This male patient at the age of 76 years had a Charnley type stainless steel/high density polyethylene total-hip replacement inserted. His body weight was about 80 kg and he was actively disposed. 18 months later the patient suffered a heavy fall onto his knees, at which fall it was suspected that the PMMA bone cement, which held the femoral stem in place, had fractured. Fig. 15 and 16 show radiographs taken respectively after the fall and 8 months after the fall. These radiographs show the progressive bending of the femoral stem and the fracture. The implant was then replaced.

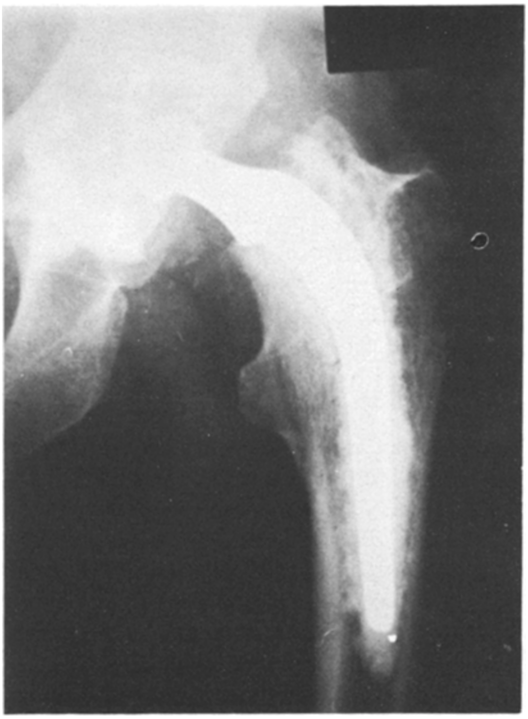

Figure 15 Radiograph of left hip of Patient 7 immediately after the injury.

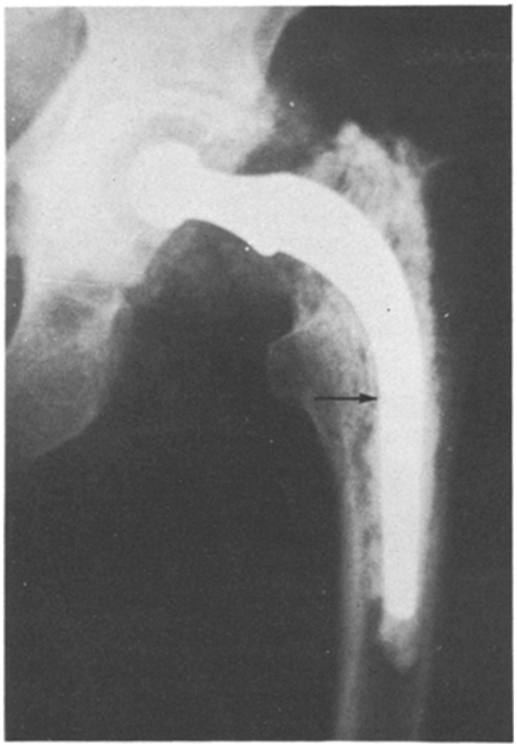

Figure 16 Radiograph of left hip of Patient 7–8 months after injury. Note firstly the deformation and, secondly, the fracture (arrow) of the metal stem.

3.6.2. Discussion

The type of stresses present on a partially held metal stem in a patient are a torsional stress and a bending moment. This bending moment is related to the prosthesis femoral head centre – the prosthesis femoral stem centre distance in the patient and the maximum force (3 to 4 x Body Weight) the patient applies when walking. Calculations show that with a patient of 80 kg BW the maximum stresses can be of the order of 465 MN m^{-2} or 30 tonf in.$^{-2}$. Metallographic examination of the metal stem removed from this patient showed that the material used was a coarse-grained fully annealed austenitic stainless steel. Such a steel would deform at stresses as low as 252 MN m^{-2} (or 16 tonf in.$^{-2}$) and fatigue at a stress of 282 MN m^{-2} (or 18 tonf in.$^{-2}$).

Fully cold-worked or forged austenitic stainless steels will withstand stresses as high as 787 MN m^{-2} (or 50 tonf in.$^{-2}$) without deformation and this accounts for the preference with some manufacturers of providing heavily cold-worked or forged stainless steel femoral components. It cannot be overemphasized that there is a decrease in corrosion fatigure properties through the cold-working or the forging of an austenitic stainless steel. The corrosion fatigue limits in Hanks solution at 3200 cpm of an annealed austenitic stainless steel and a cold-worked austenitic stainless steel determined in our laboratory were of the same order of magnitude, 360 MN m^{-2} (or 23 tonf in.$^{-2}$) although their ultimate tensile stress values were 720 MN m^{-2} and 1040 MN m^{-2} (or 46 and 66 tonf in.$^{-2}$ respectively.

The existence of high bending stresses in total-hip arthroplasties is somewhat lessened at operation by positioning the femoral stems in a valgus position relative to the neutral axis of the femur (Fig. 1); furthermore it is also advisable that the metal stems should be supported as well as possible by a thickened cement layer intervening between the bone of the calcar femorale and the concave aspect of the upper part of the prosthesis. Both objectives are more readily achieved by not preserving a bridge of cortical bone of the superior surface of the neck of the femur at operation [14].

4. Conclusions

The findings from this study suggest:

(1) Corrosion of Co–Cr–Mo–C alloy implants occurs in life. The presence of this corrosion and the products of such corrosion can lead to loss of bone substance through either Co ion or Cr ion release.

(2) From this limited sample of nine implants the majority were removed for corrosion or mechanical failure rather than for infection.

(3) There is a need to improve the production procedures adopted by manufactures with Co–Cr–Mo–C alloys. One approach would be for the manufacturers to adopt the rigorous investment casting procedures currently used in the aerospace industries.

(4) There is a need for materials scientists and engineers to establish better fatigue life data on implant alloys. A promising line of approach would be to determine the crack propagation rates in these alloys at low frequencies in simulated body environments.

(5) In order to eliminate the occurrence of sentisized austenitic stainless steel being supplied to hospitals more attention needs to be paid by manufacturers to routine microstructural sampling together with the tests for intergranular corrosion.

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