Acta orthop. scand. 49, 8–18, 1978

A PHYSICAL EXAMINATION OF ORTHOPAEDIC IMPLANTS AND ADJACENT TISSUE

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This paper reports a metallurgical study of five metal-on-metal total hip replacements removed from patients because of varying degrees of loss of bone substance and/or proven sensitivity to Ni and Cr. Evidence of corrosion of the Co–Cr–Mo–C alloy used to fabricate the prostheses was found. It is suggested that the products of this corrosion may alter the balance of bone formation/resorption to produce a loss of bone substance. An unusual tissue response which included rod-like particles (1–2 μm long × 0.2 μm in cross section), of possible immunological origin, was seen on examination of the articulating surface of one of the prostheses by scanning electron microscopy.

Key words: hip arthroplasty; bone calcification; corrosion; immunology; metallurgy; metal sensitivity

Accepted 21.viii.77

Total hip replacements in need of revision are removed from patients because of post-operative infection, adverse tissue responses to the corrosion or wear products, which include metal sensitivity and loosening, and because of mechanical failure of the femoral component as a result of corrosion fatigue, fretting fatigue or gross overloading resulting from failure of the PMMA bone cement. This paper is concerned with the metallurgical interactions of five metal-on-metal total hip replacements which were removed from patients who each showed different adverse responses to the presence of the Co–Cr–Mo–C alloys used to fabricate the prostheses.

PATIENTS, MATERIALS AND METHODS

Patients and total-hip replacements

The patients, the diseases, and the reasons for the removal of the implants, are shown in Table 1, together with information about skin sensitivity to the metals.

Scanning electron microscopy and energy dispersive X-ray analysis (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 for 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,

Table 1. 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	Reasons for removal	Skin sensitivity tests
61 years Female 50 kg	Osteoarthritis	McKee-Farrar	7 years	Severe bone loss	Negative to Co
72 years Female 59 kg	Osteoarthritis	Ring-Thompson	3 years	Severe bone loss	Negative to Ni and Cr; slight response to Co
62 years Female 71 kg	Osteoarthritis	Ring-Thompson	3½ years	Slight bone loss	Negative to Ni and Cr
56 years Female wt. not known	Osteoarthritis	McKee-Farrar	6 years	Bone loss and proven sensitivity to Co and Cr	Positive to Co and Cr
52 years Female wt. not known	Osteoarthritis	McKee-Farar	10 months	Developed a sinus within three months – at no time was there any infection	Positive to Ni and Cr

elements above atomic number 11. In specimens where a closer examination of the metal/tissue interface is required, the implants are coated with a thin layer of carbon to prevent destruction of the tissues by the beam of electrons.

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 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 EDXA. By the 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.

Histological examination

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

Bacteriological examination

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

Skin sensitivity tests

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

FINDINGS

Specimens from Patient 1

Clinical findings and naked-eye observations. A McKee-Farrar total-hip replacement was removed, 7 years after its 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 firmly 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 firm. 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 only 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.

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.

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. Figure 1 shows the tissue as revealed by the scanning electron microscope, in which pieces of hard substance are evident. The analytical mode for the same field of view identifies calcium as shown in Figure 2. 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 quantities of Cr and Mo on the side adjacent to the metal/cement interface and no Cr and significantly more Mo at the bone/cement interface. No trace of Co was found in another sample of PMMA-cement from the same area.

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

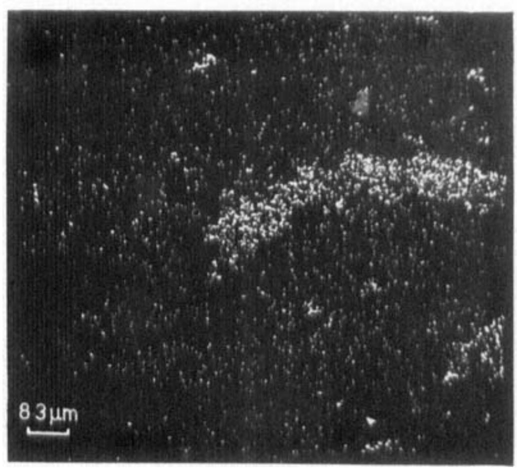


Figure 2. Tissue removed from Patient 1, embedded and examined for Ca in the analytical mode (EDXA) of the scanning electron microscope. The bright areas show Ca enrichment.

The PMMA-cement removed from this patient was found to contain 3 per cent monomer; whereas 5 per cent monomer was found in a sample of PMMA-cement as prepared during a revision operation and examined for monomer at 7 days.

Figure 3 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 scanning electron microscopy is shown in Figure 4 which reveals the layering and its crystalline nature.

Table 2 lists the analytical results obtained from the samples of this deposit on the EDXA attachment. Molybdenum and cobalt were not 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 (Figure 5) 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 should also be noted that the screws were not manufactured by the commercial supplier of the prothesis, 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.

Table 2. EDXA of the green crystalline deposit

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

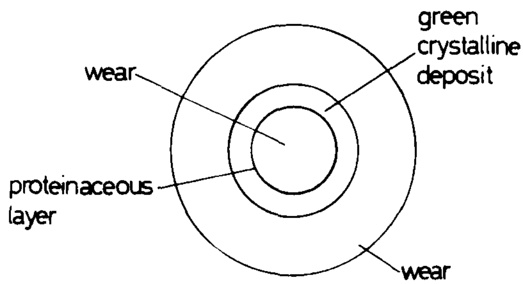
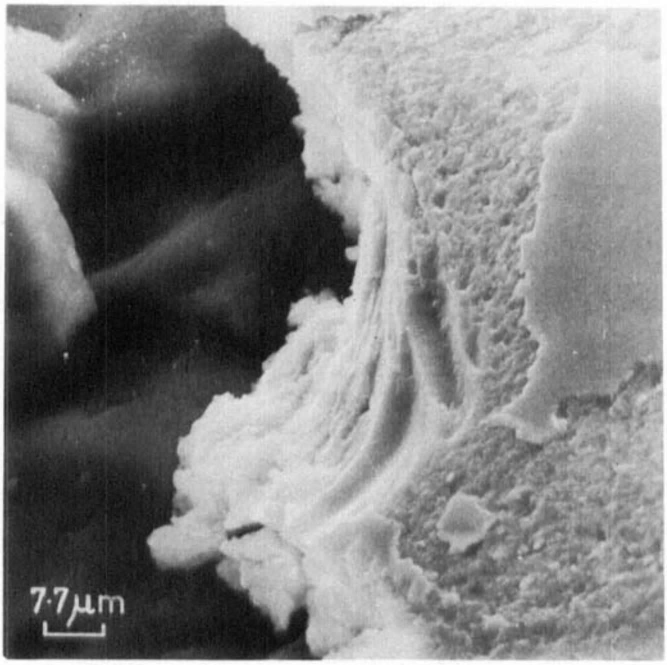


Figure 3. Schematic diagram of articular surface of the acetabular component removed from Patient 1 (not to scale). Note the four distinct areas as recorded in the text.

A comparison of the type of attack observed at the screw tip (Figure 5) with the 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 crystalline, 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.

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



igure 4. Scanning electron icrograph of green crystalline eposit on the articular surface of ıe acetabular component (Patient). See Figure 5.

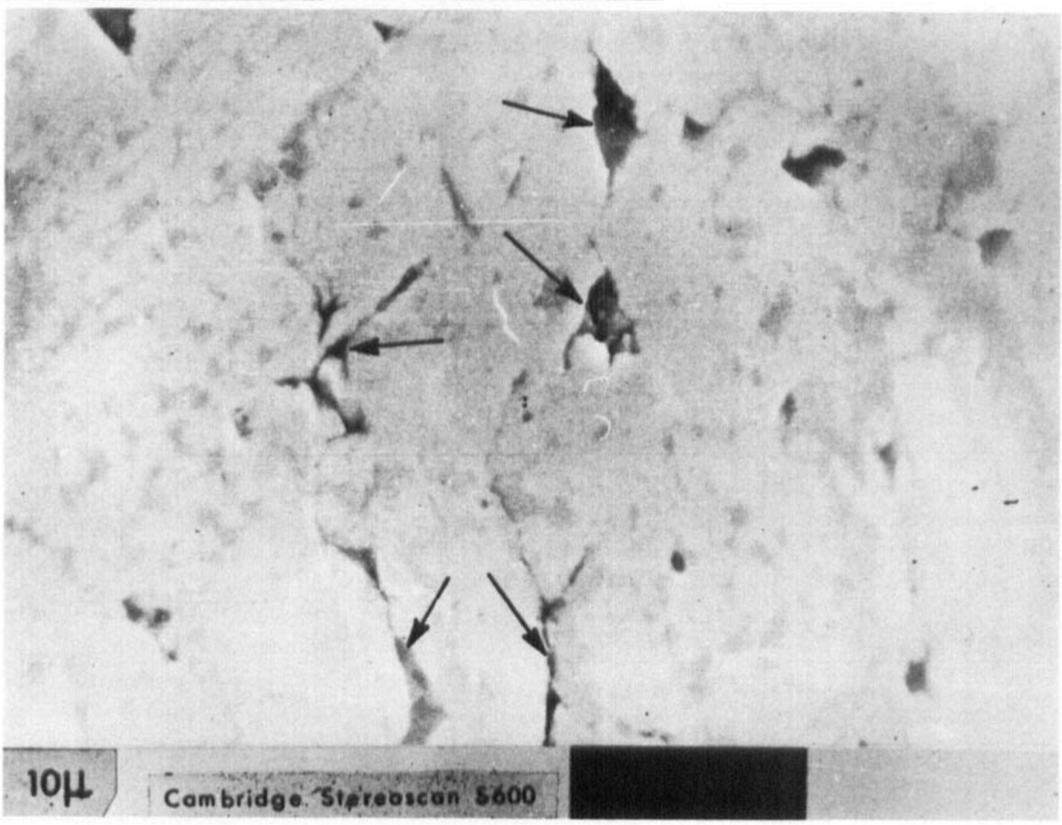


Figure 5. Scanning electron micrograph of the attacked surface at the tip of the Co–Cr–Mo–C alloy screw removed from Patient 1. The arrows point to areas of corrosion.

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 (Evans et al. 1974), and the increased cobalt and chromium contents in the hair, blood and urine of such patients (Coleman et al. 1973).

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.

Specimens from Patients 2 and 3

Clinical findings. The next two specimens are similar in that they were both Ring-Thompson total-hip prostheses with cemented femoral stems in female patients. In Patient 2, the prosthesis was removed after 3 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 three and a half years after implantation. Initially the wear and corrosion characteristics are examined.

Prosthesis wear. Scanning electron microscopy of the articulating surface of the acetabular

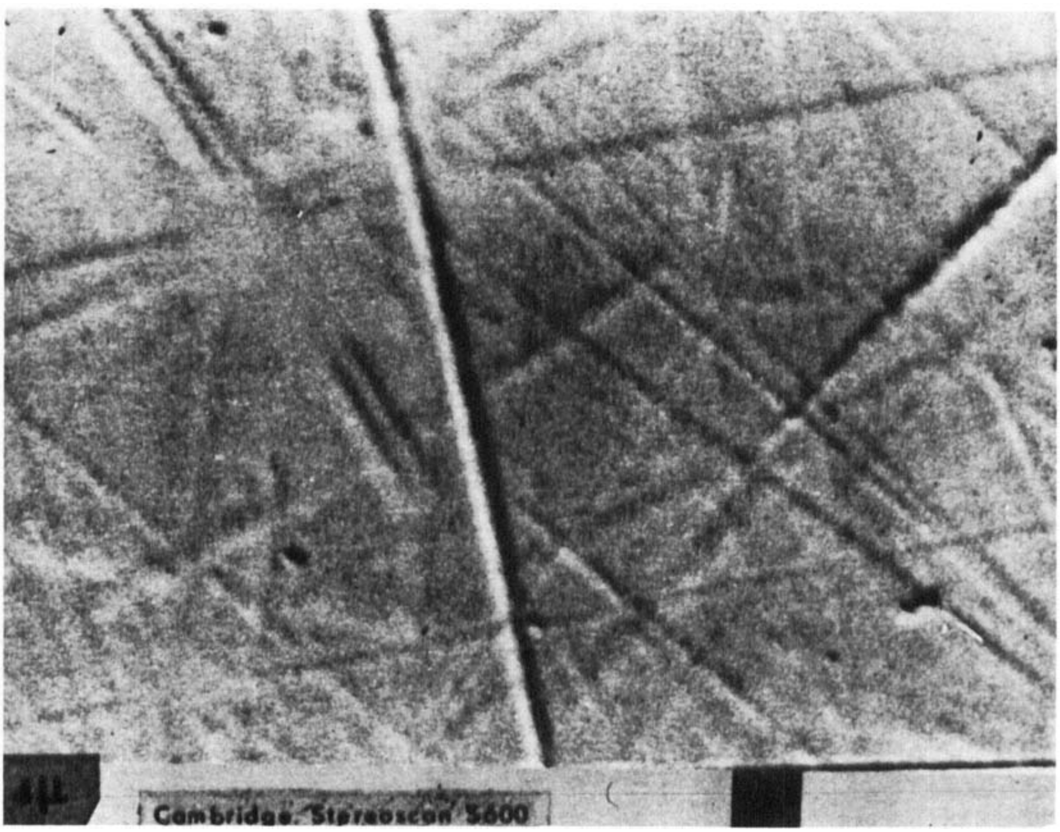


Figure 6. Scanning electron micrograph of the articular surface of the acetabular component removed from Patient 2. Note the broad scratches resulting from corrosion.

component removed from Patient 3 showed the same type of wear behaviour as reported previously (Walker & Gold 1971). This type of wear was also present in the implant from Patient 1. Figure 6 shows the articulating surface present in Patient 2. It is seen that the scratches are broad and pitted, which is indicative of the presence of some form of corrosion. The articulating surface present after manufacture of a McKee-Farrar cup was also examined by scanning electron microscopy. 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 have been attacked (Figure 7).

Tissue. Table 3 lists the results of carbon arc emission spectroscopy of adjacent tissue removed at the time of operation from Patients 2 and 3. The presence of substantial amounts of chromium (up to 1,000 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 showed 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.

Bone. The calcium/phosphorus ratios in bone adjacent to the prostheses, as examined by scanning electron microscopy and the EDXA attachment, are shown in Table 4. The Ca/P ratios of bone being laid down adjacent to two of the prostheses correspond 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 con-

Figure 7. 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.

centrations of Cr ions released from the prosthesis as detected by carbon arc emission spectroscopy in the adjacent tissue.

Cancellous bone attached to PMMA-bone cement removed from Patient 1 was examined, together with bone deposit found on the thread of the Ring acetabular component removed from Patient 2. These samples are compared with the corrosion product found in the McKee-Farrar acetabular cup removed from Patient 1. A bone deposit found on the surface of a Co–Cr–Mo–C alloy screw removed from an 18-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.

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

Table 3. Spark emission spectroscopic chemical analyses of tissues adjacent to orthopaedic implants

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

Table 4. 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
Patient 1	Corrosion product on articular surface of McKee-Farrar acetabular cup	1072	1353	0.86

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 for the Co–Cr–Mo–C alloys used. Moreover these reactions possibly lead to the presence of resorbed bone adjacent to the prostheses.

The next part of the paper considers the responses observed to the presence of two McKee-Farrar total hip replacements in patients with proven sensitivity to Co, Cr or Ni.

Specimens from Patient 4

Clinical findings. A McKee-Farrar total-hip replacement was removed 6 years after its implantation from the right hip of a 62-year-old female patient. The patient had recently complained of pain and radiographic examination had revealed slight bone loss. Tests had revealed that the patient was sensitive to Co and Cr. At operation there was a large amount of bone loss in the acetabular wall.

SEM examination. Scanning electron microscopy of the articulating surface of the acetabular component revealed the presence of rod-like particles embedded in the collagenous tissue that surrounded the prosthesis (Figure 8). The particles were 1–2 μm long × 0.2 μm in cross section. Table 5 shows the results obtained with the EDXA attachment. There is enrichment of Cr within the particles. These particles have been observed from time to time in the last few years in our laboratory both on bone plates and on prostheses removed from patients. They are usually

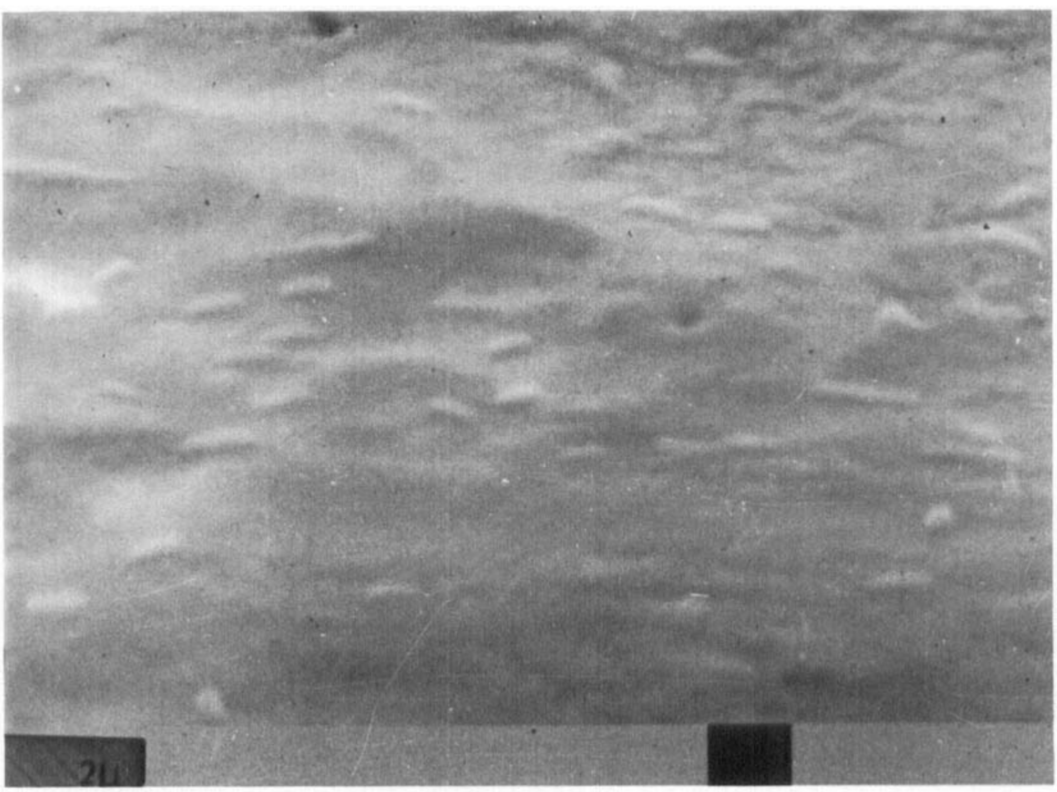


Figure 8. Scanning electron micrograph of collagenous tissue and rod-like particles. Note the size of particle, 1–2 μm long × 0.2 μm in cross section.

Table 5. EDXA of the particle

	Energy	Integral
Layer	2.30 (S)	491
	5.42 (Cr)	1262
Particle	2.30 (S)	909
	5.42 (Cr)	2899

Similar Co levels were present in each specimen.

Table 6. Semi-quantitative chemical analyses of tissue and fluid removed from Patient 4

Element	Tissue adjacent to acetabular component	Fluid in capsule
Ba	500–1700 ppm	<0.02 ppm
Ca	>1%	200 ppm
Co	<50 ppm	<1 ppm
Cr	170–500 ppm	<1 ppm
Fe	500–1700 ppm	20–60 ppm
K	>1%	>200 ppm
Mg	500–1700 ppm	20–60 ppm
Mo	<2 ppm	<0.2 ppm

associated with implant corrosion. Other workers (Vernon-Roberts 1976, personal communication), have observed similar particles and they are only found on implants from patients of proven sensitivity to one of the constituent elements of the Co–Cr–Mo–C alloy used to fabricate the prostheses.

Tissue. Table 6 lists the results of carbon arc emission spectroscopy of adjacent tissue and fluid removed at the time of operation. A substantial amount (up to 500 ppm) of Cr was recorded in the soft tissue which lined the outer surface of the acetabular component.

Discussion

The association of the particles with implant corrosion and metal sensitivity suggests that they could be of immunological origin. Figure 9 outlines the possible formation mechanism, via chelation of the metal ion with protein in the tissue to produce an antigen which would lead to an antibody response. It is therefore likely that the particles are

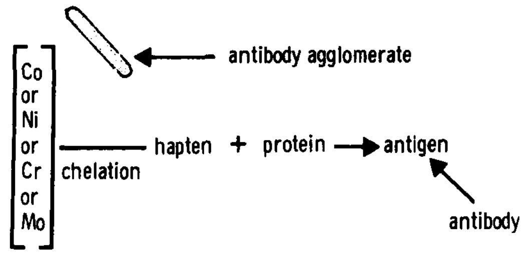


Figure 9. Antibody agglomerate formation mechanism.

antibody agglomerates produced as a consequence of the patient's sensitivity to one of the constituent metals in the alloy, in this instance Cr.

Specimens from Patient 5

Clinical findings. This patient in her early fifties with severe bilateral osteoarthritis had a McKee-Farrar artificial hip joint inserted in her left hip. Two weeks after the operation the wound was healed, the patient was free from pain on the operated side and was walking satisfactorily. Within 3 months the patient developed a sinus; both the sinus discharge and the sinus tissue were sterile on culture. Subsequent dermatological tests showed that the patient was sensitive to Ni and Cr. An inconclusive result was obtained from the test for Co. The prosthesis was removed 10 months after operation after which the wound healed without any difficulty.

Where there is minimal tissue response to the presence of Co–Cr–Mo–C alloys the colour of the soft collagenous tissue, which forms within a few days of insertion and remains throughout the implant's use, is white. In this instance there was a grey deposit present in the articulating parts of the prosthesis, on the neck of the femoral component and the outer surface of the acetabular component.

SEM examination. The grey deposit immediately adjacent to the outer rims of the acetabular component was examined under the optical and analytical modes of the scanning

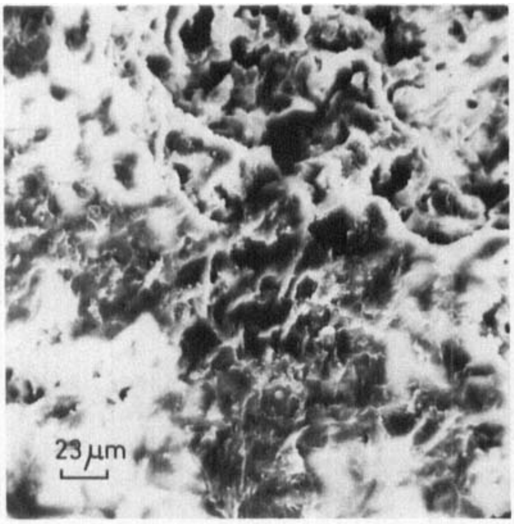


Figure 10. Grey deposit attached to the acetabular component removed from Patient 5 examined in the optical mode of the scanning electron microscope.

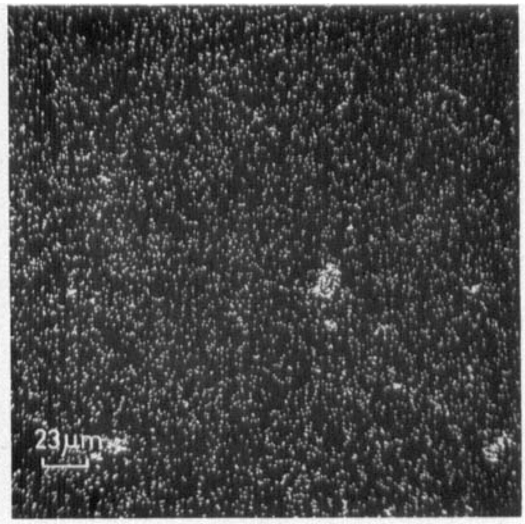


Figure 11. Grey deposit attached to the acetabular component removed from Patient 5 examined for Cr and Co in the analytical mode (EDXA) of the scanning electron microscope. The bright areas show Cr and Co enrichment.

electron microscope. Figure 9 shows the appearance of the deposit and Figure 10 shows the analytical mode of the same field of view identifying Cr and Co. There are areas of Cr and Co enrichment.

Discussion

The patient's metal sensitivity in this instance produced an unusual tissue response. This tissue became enriched in Cr and Co and a sinus formed. Nothing short of complete removal of the prosthesis was successful in getting the wound to heal.

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) The occurrence of metal sensitivity can possibly induce an immunological response or sinus formation.

ACKNOWLEDGEMENTS

The authors wish to acknowledge with gratitude the help and encouragement of the members of staff of the Harlow Wood Orthopaedic Hospital, the City Hospital, Nottingham, the Royal Hospital, Chesterfield, and the Medical School, University of Nottingham.

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