CORROSION BETWEEN THE COMPONENTS OF MODULAR FEMORAL HIP PROSTHESES

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We studied the tapered interface between the head and the neck of 139 modular femoral components of hip prostheses which had been removed for a variety of reasons. In 91 the same alloy had been used for the head and the stem; none of them showed evidence of corrosion. In contrast, there was definite corrosion in 25 of the 48 prostheses in which the stem was of titanium alloy and the head of cobalt-chrome. This corrosion was time-dependent: no specimens were corroded after less than nine months in the body, but all which had been in place for more than 40 months were damaged.

We discuss the factors which may influence the rate of these changes and present evidence that they were due to galvanically-accelerated crevice corrosion, which was undetected in previous laboratory testing of this type of prosthesis.

In recent years, an evolution from fixed-head femoral prostheses to modular designs has allowed combination of the wear resistance of a cobalt-alloy femoral head with the flexibility of a titanium-alloy femoral stem. The satisfactory resistance of this mixed-alloy combination to galvanically-accelerated crevice corrosion has been reported by several authors (Rostoker, Galante and Lereim 1978; Lucas, Buchanan and Lemons 1981; Griffin, Buchanan and Lemons 1983). A detailed examination of their results, however, revealed that there were indications of the potential for corrosion and that our recent finding of significant crevice corrosion of the taper between cobalt-alloy heads and titanium-alloy stems is less surprising. We found that 17 of 30 mixed-metal femoral prostheses showed time-dependent evidence of corrosion, while 49 all cobalt-alloy modular prostheses and nine all titanium-alloy prostheses revealed no corrosion (Collier et al 1991).

These preliminary results led us to study a larger series in more detail to investigate the influence of a number of implant-specific factors on the rate at which the galvanically-accelerated corrosion progresses and the involvement of fretting in the corrosion process. We also attempt to explain why the earlier research by Rostoker, Lucas, Griffin and their colleagues had not demonstrated significant corrosion in cobalt-alloy/titanium-alloy couples and to predict the clinical symptoms and mechanical failures which may result if such corrosion is allowed to progress indefinitely.

METHODS

We studied the tapered interface between the head and the neck of 139 modular femoral hip prostheses, removed for a variety of reasons and sent to us by 87 surgeons. The devices were not solicited but were sent to us usually for examination of the bone–implant interfaces and not specifically for corrosion. We looked for evidence of corrosion, using a Nikon dissecting microscope at magnifications up to ×60. Where any corrosion was observed, the femoral head was bi-valved so that the entire internal taper area could be mapped and the extent of the corrosion measured. The surface of the tapered neck was also examined. We performed scanning electron microscopy to determine the presence of pitting which is the most conclusive evidence of corrosion.

In cases of significant corrosion, both tapered surfaces were analysed by a Bendicts Formax 5050 proficorder (Bendix, Dayton, Ohio) to measure the depth of corrosion penetration of both the titanium-alloy and cobalt-alloy surfaces. We determined an average penetration depth and integrated this with the surface area of corrosion to give the volume of lost material. Where

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patient information was available, it was entered into a computer and analysed statistically to determine any correlations between the extent of corrosion and the age, weight, sex and activity of the patient or duration of implantation.

Selected samples from the prostheses were prepared for metallurgical examination and quantitative analysis to ascertain whether corrosion was related to any abnormality in chemical composition or alloy structure. Finally, we assessed the extent of fretting of all tapered surfaces, independently of the presence or absence of corrosion.

RESULTS

None of the 91 single-alloy modular prostheses made from either cobalt-alloy or titanium-alloy showed any evidence of corrosion (Table I). Of the 48 mixed-alloy components (Table I), 25 had evidence of corrosion (Table II), occurring on both the cobalt-alloy head and the titanium-alloy neck (Fig. 1). We found no statistical correlation between the extent of surface area corroded and the age, weight, sex or activity of the patient, or the reason for retrieval of the specimen. There was, however, a direct correlation between the duration of implantation and the extent of surface area corroded. All mixed-alloy prostheses retrieved at periods later than 40 months and none retrieved earlier than 9.8 months showed evidence of corrosion. We found no evidence of fretting of either single-alloy or mixed-alloy tapers under stereoscopic examination.

The 25 mixed-alloy femoral components with corrosion came from four manufacturers; 23 had as-cast heads (Zimmer, Orthomet), one had a solution-annealed cobalt-alloy head (Osteonics), and one head was machined from ASTM 799 cobalt alloy (Biomet). Twenty-two of the corroded mixed-alloy prostheses, received from 14 surgeons throughout the USA, were of the Harris-Galante type. These have fibre-mesh pads on the stem to allow biological ingrowth, greatly increasing the ratio of surface area of titanium-alloy (cathode) to cobalt-chrome (anode). Of the other three corroded prostheses one had a smooth, press-fit stem (Omnifit), and two had plasma-sprayed, porous-coated surfaces, (Perfecta, Head/Mallory). Quantitative analysis of several metal samples from the most severely corroded components indicated that they were within the ASTM specifications.

Scanning electron microscopy showed pitting of both the cobalt-alloy head (Fig. 2) and the titanium-alloy neck (Fig. 3), and profilometry indicated that the most severe corrosion was on the cobalt-alloy femoral heads

Table I. Details of the 48 mixed-alloy and the 91 single-alloy modular prostheses sent to us by 87 surgeons

Alloy combination	Type*	Number received	Number corroded
Titanium-alloy + cobalt-alloy	Harris-Galante/Bias (Zimmer)	39	22
	Head/Mallory (Biomet)	1	1
	Omnifit (Osteonics)	1	1
	Perfecta (Orthomet)	1	1
	Other	6	0
		48	25
All cobalt-alloy	AML (DePuy)	35	0
	PCA (Howmedica)	37	0
	Other	8	0
		80	0
All titanium-alloy	Head/Mallory (Biomet)	6	0
	Other	5	0
		11	0

* Zimmer, Warsaw, Indiana; Biomet, Warsaw, Indiana; Osteonics, Allendale, New Jersey; Orthomet, Minneapolis, Minnesota; DePuy, Warsaw, Indiana; Howmedica International, Rutherford, New Jersey

Table II. Details of 25 corroded cobalt-alloy/titanium-alloy components*

Type	Maker†	Duration (months)	Reason for retrieval	Corrosion (*per cent*)
Head/Mallory	B	11.5	Subsidence, dislocation	*3*
Harris-Galante	Z	18.6	Pain	*5*
Harris-Galante	Z	12.0	Pain	*10*
Harris-Galante	Z	54.2	Pain	*80*
Harris-Galante	Z	32.5	Not known	*95*
Harris-Galante	Z	30.1	Loosening	*60*
Harris-Galante	Z	60.4	Pain	*70*
Harris-Galante	Z	30.9	Subsidence, malposition, pain	*25*
Harris-Galante	Z	51.0	Dislocation	*80*
Harris-Galante	Z	60.0	Not known	*2*
Harris-Galante	Z	22.7	Pain	*50*
Harris-Galante	Z	28.4	Infection	*45*
Harris-Galante	Z	15.2	Infection	*1*
Harris-Galante	Z	25.0	Pain	*3*
Harris-Galante	Z	26.5	Pain, varus position of stem	*80*
Harris-Galante	Z	78.3	Pain, malposition	*65*
Harris-Galante	Z	23.1	Dislocation	*8*
Harris-Galante	Z	30.3	Dislocation	*2*
Harris-Galante	Z	66.9	Dislocation	*2*
Harris-Galante	Z	43.9	Dislocation	*35*
Harris-Galante	Z	9.8	Dislocation	*10*
Harris-Galante	Z	55.9	Dislocation	*5*
Harris-Galante	Z	28.8	Dislocation	*3*
Omnifit	O	32.8	Post-mortem	*3*
Perfecta	Om	12.9	Post-mortem	*10*

* numbers and types of components sent to the authors' laboratory for analysis do not in any way relate to the numbers of devices in use or their rates of failure
† Z = Zimmer; B = Biomet; O = Osteonics; Om = Orthomet

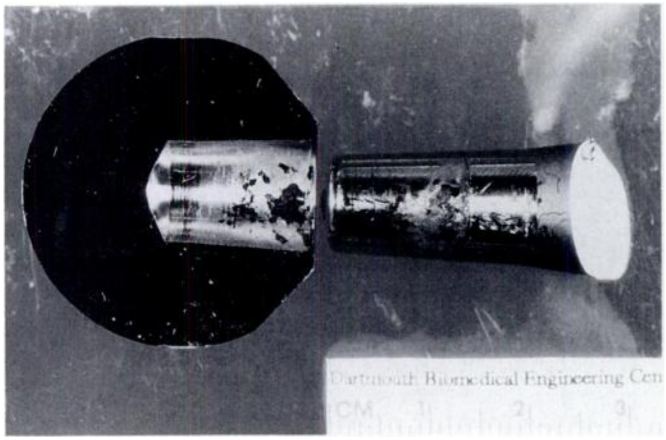

Fig. 1

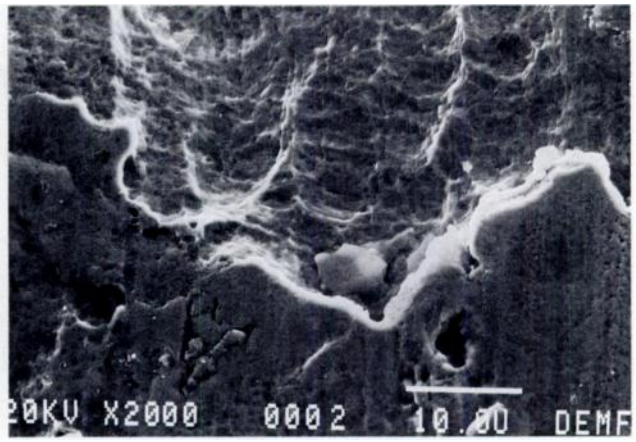

Fig. 2

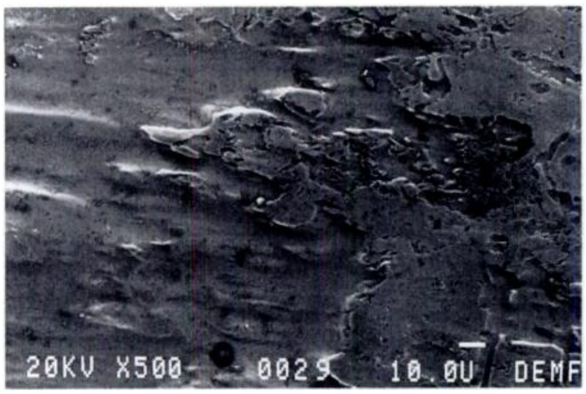

Fig. 3

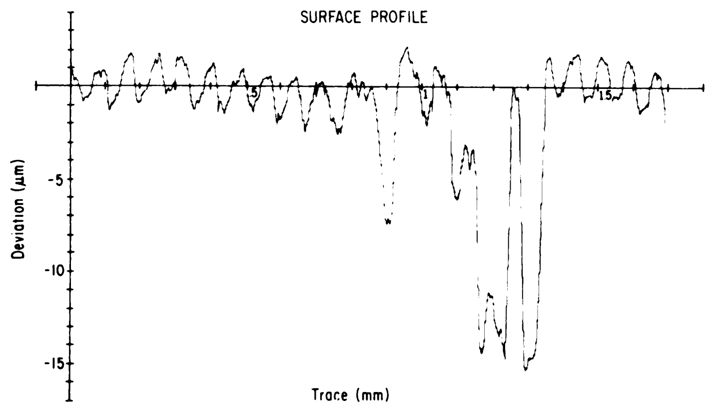

Fig. 4

Specimens from a Harris-Galante prosthesis retrieved 28 months after insertion, because of infection. Figure 1 – The stem has been rotated by 180° to show the matching corroded surfaces of the taper (× 1.25). Figure 2 – Scanning electron micrograph showing the pitting of the inner surface of the cobalt-alloy head (× 980). Figure 3 – Scanning electron micrograph of the corroded surface of the titanium-alloy neck (× 225). Figure 4 – Surface profilometry trace of the taper of the cobalt-alloy head. The depth of corrosion is seen to be 15 μm.

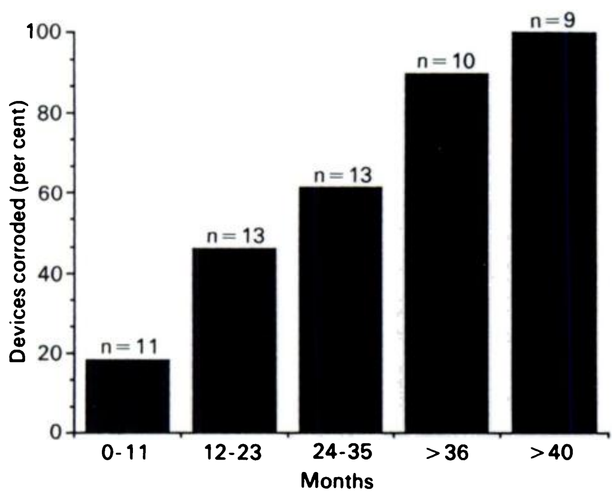

Fig. 5

Bar graph showing the percentage of mixed-alloy prostheses corroded, related to time since implantation.

and was approximately 0.015 mm deep (Fig. 4). We estimated that the metal release from these most corroded samples was approximately 500 mg in five years.

The extent of corrosion increased with duration of implantation (Fig. 5). No components were corroded in less than 9.8 months. From 12 to 23 months, 46% showed corrosion, and the average surface area of corrosion was 6.5%. From 24 to 35 months, 61.5% of the mixed-alloy prostheses showed corrosion of an average of 22% of their surface area. After 40 months, all the mixed-alloy prostheses were corroded to an average of 36%. Four of these prostheses had corrosion of more than 80% of the tapered interface between head and neck.

The appearance of corrosion can be most easily identified by the loss of material and the elimination of the machining marks on the taper of the cobalt-alloy head (Fig. 6) and pitting of the titanium-alloy taper neck (Fig. 7).

DISCUSSION

The presence of corrosion in mixed-alloy modular femoral prostheses and the absence of any evidence of corrosion in the single-alloy modular components are evidence that there is a galvanic element in the crevice corrosion. Mathiesen et al (1991) reported crevice corrosion in four of nine retrieved Lord hip prostheses of modular design. The corrosion was confined to the interface at the head-neck junction. They state that "porosities and chemical

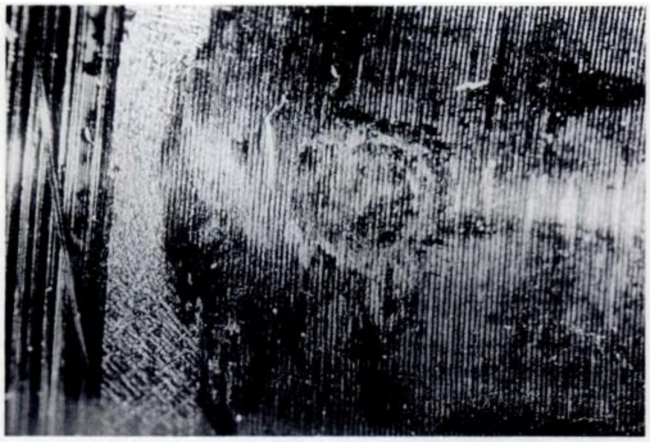

Fig. 6

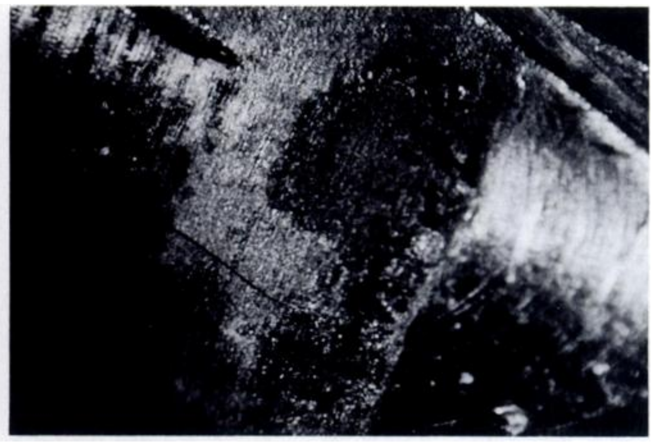

Fig. 7

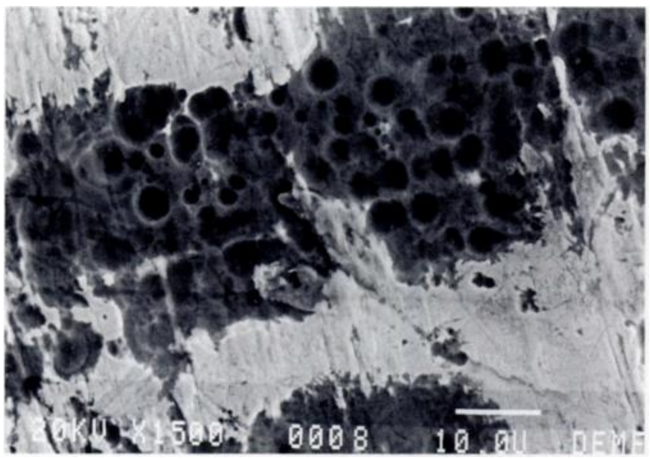

Fig. 8

Figure 6 – A Harris-Galante prosthesis retrieved 23 months after insertion because of a fracture. Machining marks on the inside taper of a cobalt-alloy head are clearly seen on the right, but on the left, the etched dendritic structure and the absence of machining marks are evidence of loss of material (× 30). Figure 7 – Deep pits are visible in the centre of a micrograph of the surface of the tapered neck of a titanium-alloy stem retrieved after 30 months because of loosening (× 7.5). Figure 8 – The inner taper of a cobalt-chrome head shows pitting and complete absence of fretting (× 750).

inhomogeneity have been observed close to these interfaces". They concluded that "... fretting as a cause of corrosion seems unlikely" and that "Crevice corrosion, facilitated by structural imperfections, is probably a better explanation". We believe that inadequate metallurgy of the cobalt alloy would make it susceptible to corrosion, but this was not the case in our series of similar well-treated cobalt-alloy components. As we discussed in our earlier paper (Collier et al 1991) the crevice provided between the head and neck will function as a corrosion site if it is wide enough to allow aqueous intrusion, but sufficiently narrow to maintain a stagnant zone. As corrosion progresses in this zone, oxygen is depleted, resulting in an excess of positively charged metal ions in the aqueous environment of the crevice. This is then balanced by the migration of negatively charged chloride ions. The resulting product is hydrochloric acid, which is capable of dissolving both the otherwise stable cobalt and titanium alloys.

From the standard EMF series of metals it is difficult to determine this galvanic potential: cobalt is adjacent to titanium with a potential of -0.28 V compared with titanium's -0.33 V (Boltz and Tuve 1973). This difference is hardly enough to cause the degree of corrosion seen in our samples. Testing in our own laboratory, however, revealed a potential between fully passivated cobalt alloy and depassivated titanium alloy of 780 mV; this is significantly higher than the 400 mV required to break down the passive layer on the cobalt alloy. Both Fontana (1986) and Fraker (1987) point out that the galvanic series is a more accurate predictor of galvanic potential than the EMF series. The medium within which the testing is carried out is also important: the corrosion potential between titanium and cobalt alloys is much greater in equine serum than in salt water. Clarke and Hickman (1953) reported that the potential between titanium and cobalt in equine serum is 3.85 V, more than enough to be a galvanic stimulus, and nearly twice the potential of a standard lead-acid battery cell. Our laboratory testing failed to confirm the increased potential in serum: our readings were approximately 600 mV. This is less than the potential in saline but more than enough to accelerate corrosion. Our test samples were cut from retrieved prostheses. We do not know the source or the metallurgy of the Clarke and Hickman samples.

The influence of design and material-related characteristics is difficult to assess from our series of clinically retrieved prostheses in that 40 of the 48 of mixed-alloy prostheses and all but three of the corroded mixed-alloy prostheses came from a single manufacturer (Zimmer).

Some insight can be gained, however, into the potential influences of the metallurgy of the materials, the fit of the taper, the passivation status of the materials, and the stress intensity at the interface. Metallurgists recognise that it is much easier to etch as-cast material than solution-annealed material. Etching is a form of corrosion attack, and it can be extrapolated that as-cast femoral heads are less resistant to corrosion attack than solution-annealed components. Most of the cobalt-alloy heads in the mixed-metal prostheses that we studied were of the as-cast type, but one which was solution-annealed showed evidence of corrosion at 32.8 months, indicating that even this more resistant structure is not sufficient to resist the galvanic stimulus.

The geometry of the taper may influence the rate of corrosion by controlling the rate of fluid transfer within the crevice, or by allowing fretting of the head on the tapered stem, which would accelerate the rate of corrosion. As will be discussed later, fretting did not appear to play a part. There was no doubt some variation in the fit of the tapered heads on the stems, but unless fluid is completely eliminated from this crevice, it can be predicted that somewhere within it, the conditions will be suitable for corrosion to occur.

The corrosion resistance of titanium is dependent upon the presence of a stable oxide film (Schutz and Thomas 1988). Furthermore, Kummer and Rose (1983), using open-circuit potential measurement, found that the resistance of a cobalt-alloy/titanium-alloy couple is related to the maintenance of the passive film on both materials. It is highly probable that the impaction of the head on to the stem breaks down the passive layer of one or both of the alloys. It is also possible that articulation of the femoral head against a polyethylene socket may cause continuing breakdown of the cobalt passive layer, and that micromotion of the femoral stem against bone and soft tissue may cause breakdown of the titanium passive layer. It is not necessary for the passive-film breakdown to occur within the crevice, but it is within the crevice that the two alloys are in electrical contact, and therefore where current flow may result in corrosion. It is much more likely, however, that the mechanism for corrosion is the breaking of the passive film of the softer titanium stem by the harder cobalt alloy of the femoral head when they are impacted. Schutz and Thomas (1988) note that "anhydrous conditions in the absence of a source of oxygen may result in titanium corrosion because the protective film may not be regenerated if damaged". They also state that the titanium oxide passive film "being an n-type semi-conductor, possess electronic conductivity. As a cathode, titanium permits electrochemical reduction of ions in an aqueous electrolyte". In mixed-metal prostheses in the electrolytic environment of the body, the titanium-alloy stem is cathodic compared with the smaller anodic cobalt-alloy head.

We speculate that in the conditions of the crevice of a mixed-alloy prosthesis, the galvanic stimulus accelerates the rate of crevice corrosion. As stated by Schutz and Thomas (1988), "Titanium chlorides formed within the crevice are unstable and tend to hydrolise, forming hydrochloric acid and titanium oxide/hydroxide corrosion products. Because of the small restricted volumes of solution in these crevices, crevice pH levels as low as 1 or below can develop. These local reducing acidic conditions can result in severe and rapid localised active corrosion within the crevices . . . crevice corrosion on titanium typically generates irregularly shaped pits" (Fig. 7).

In the majority of the corroded mixed-metal prostheses that we studied, the femoral stems had porous titanium pads designed for uncemented fixation. These resulted in a surface area ratio of cathodic titanium femoral component to anodic cobalt-alloy head of approximately 13:1, as measured in our laboratory. Fontana (1986) noted that "Corrosion of the anodic area may be 100 or 1000 times greater than if the anodic and cathodic areas were equal in size". This effect of surface area ratio may accelerate the rate of corrosion, but, it appears to be unnecessary to produce it, as we saw in a smooth, press-fit prosthesis.

Titanium alloy is known to be notch sensitive, but it is less well known that under certain conditions it is also stress-corrosion sensitive (Schutz and Thomas 1988). The size and geometry of the neck, as well as the age, weight, and activity of the patient, may help to determine the rate of penetration of the titanium component by corrosion. We were unable to correlate the extent of corrosion of the titanium neck with the age, weight, or activity of the patient, partly because we did not have complete clinical records for many of the components. It may also be hypothesised that, as corrosion reduces the cross-sectional dimensions of the titanium neck and increases the depths of the pits in its surface, stress corrosion will play an increasing role.

Why was the corrosion that we observed not seen or predicted by laboratory testing? Rostoker et al (1978) based their report on implantation of titanium-alloy/cobalt-alloy couples in vivo into the paravertebral muscles of a dog for 30 months. In contrast to the clinical setting, however, these mixed-metal couples were unloaded, of equal size, and of non-equal passivation status. Also, their single series was followed for only 30 months, and we found that some clinical mixed-metal prostheses showed no corrosion at nearly 40 months. Our specimens had been loaded by walking and their passivation was probably broken by the impaction of the modular head on the stem. It is interesting to note that Rostoker et al (1978) did find some evidence of corrosion: "The existence of the tarnish film, which indicates some level of corrosion activity, correlated with increased average fibrous membrane thickness, cellularity immediate to the membrane and minor indications of inflammation".

Lucas et al (1981) carried out short-term electrochemical tests on solution-annealed cobalt-alloy samples in a 0.9% sodium chloride solution at pH7. It was not stated in the article whether the cobalt and titanium samples were of the same size, but they concluded that "... the cobalt alloy exhibited a hysteresis loop which indicates a possible susceptibility to pitting and crevice corrosion", and that "galvanic coupling did not significantly enhance corrosion rates for these alloys under any of the conditions studied". They also evaluated three clinically retrieved Sivash cobalt-on-titanium hip prostheses and reported that "Careful observation revealed no significant corrosion products for either alloy", but they also observed that around a machined notch in the cobalt seat, "... an enhanced circular zone of wear and/or corrosion-wear features existed". They reported further that "the cobalt femoral head component showed regions of uniform hazy appearance, an indication of corrosion or corrosion-wear phenomenon", and "Additionally, surface pits and holes were observed in these regions, especially for the two-year prosthesis". They were unable to identify whether the pits were a function of corrosion, corrosion-wear, or porosity.

Griffin et al (1983) expanded the electrochemical studies of Lucas and concluded that "The relative corrosion resistance predicted for the couple between titanium 6% Al 4% V and cobalt-chrome-molybdenum alloy indicated that no detrimental changes due to galvanic effects are expected". These were short-term tests carried out in isotonic saline, and appeared to use samples of identical size, although that was not specifically stated, and standard ASTM passivation treatments.

In two of the three studies just described, corrosion phenomena were demonstrated. Rostoker et al (1978) were against the coupled use of cast cobalt-chrome alloy and titanium-6-4 alloy. It should be noted that they were also co-developers of the titanium mesh ingrowth system. While Lucas et al (1981) showed only the susceptibility of cobalt alloy to pitting corrosion, and Griffin et al (1983) presented no evidence of corrosion, it must be noted that in neither test were loads applied to the specimens, nor was any other effort made to break down the initial passivation film. As mentioned earlier, it is this breakdown on one or both of the materials that results in a radically increased electrochemical potential. Finally, the work of Lucas et al (1981) and Griffin et al (1983) was carried out in saline; Clarke and Hickman (1953) have shown that the galvanic potentials are far greater in equine serum.

How can we determine that corrosion of mixed-metal prostheses is not fretting or fretting-corrosion rather than galvanically-accelerated corrosion? The answer is in four parts:

1. We observed corrosion only in mixed-metal prostheses, and not in single-alloy, modular components, even after longer implantation.
2. Scanning electron microscopy of the affected areas showed the deep pits which are characteristic of corrosion, not fretting (Fig. 8).
3. Contact between cobalt and titanium components, such as that seen when polyethylene wear in a knee replacement allows a cobalt-chrome femoral component to contact a titanium tibial component, shows that the cobalt is much harder than the titanium, and suffers much less damage. In hip replacements in which a polyethylene acetabular liner has dislodged, we have seen the cobalt femoral head penetrate the titanium acetabular backing by more than a centimetre; it was still spherical in shape and showed little evidence of wear. Fretting in the taper would therefore produce much more loss of material from the titanium than from the cobalt-chrome component. We found more loss of material and deeper pits on the tougher, but anodic, cobalt-alloy head.
4. Fontana (1986) considered that oxygen accelerated fretting attack. The taper crevice is, however, expected to be oxygen-depleted; this favours crevice corrosion and is against fretting.

We have seen no clinical failures in mixed-alloy femoral prostheses due to corrosion at the interface, but it is reasonable to deduce that this may occur by two mechanisms. First, because the extent of corrosion within the taper increases with time (in four cases more than 80% of the taper was corroded), we may expect complete breakdown of the interface in some of these prostheses eventually. It is unlikely that the head would separate from the stem, but it is possible that corrosion will eventually result in a trunnion fit. The head would then be free to rotate on the stem, resulting in severe fretting and the generation of large amounts of wear debris. Secondly, the pitting of the titanium-alloy may reach sufficient depth to act as a notch (Fig. 7) and result in fracture of the titanium neck. There must also be some concern about the effect of corrosion products and of large amounts of metal debris on the body's immune system.

Conclusions. The combination of a cobalt-alloy femoral head on a titanium-alloy femoral stem results in the potential for galvanically-accelerated crevice corrosion. The effect of the resulting corrosion products in causing pain or suppressing the immune system is unknown, but there is a real possibility of mechanical failure of the prostheses.

There are alternatives: these include the use of a hardened titanium head on a titanium stem, of cobalt-on-cobalt modular prostheses, or of ceramic heads on either cobalt or titanium stems. If some method can be developed to guarantee elimination of fluid from the tapered interface, then the aqueous environment required for corrosion will be eliminated.

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