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Original Articles

Failure of the Stem in Total Hip Replacement

A Study of Aetiology and Mechanism of Failure in 13 Cases

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Summary. Thirteen failed stem of Total Hip Replacement were studied: 9 were Charnley THR from an homogeneous series, which gives an incidence of 2.4% of stem fractures with a follow-up of 9–16 years; 4 were Mueller THR. Fatigue fracture of the stem occurred by defective support of the proximal part of the femur, following resorption of the calcar. In all cases reactive tissue to foreign body particles, metal and polyethylene, was found where bone resorption occurred. In Mueller THR wear of the cup produced the large amount of polyethylene particles; in Charnley THR metal particles prevailed and corrosion of the stem is suggested to be the initiating factor.

The fracture of the stem is recognized as a relatively unfrequent complication of total hip replacement, with figures varying from 0.23 to 11% [1, 3, 4, 13, 19].

In most of the series so far reported fracture occurred within 6 years from the insertion of the prosthesis, average 3 years and 8 months for Carlsson et al. [1], 3 years and 6 months for Charnley [3], 2 years and 2 months for Collis [4], 1 year and 8 months for Galante et al. [9], 1 year and 7 months for Martens et al. [13]. Only Charnley [3] mentioned two patients whose prostheses fractured after 12 and 13 years, but they were not included in his study. Wroblewski [19] reported a large study where failure of the stem was observed late: 2.5% after 11 years and 90.8% between 2 and 11 years.

A variety of factors have been investigated, like the weight and the activity of the patient, the positioning of the stem, the defects of the alloy, the torsional load on the proximal stem and the design of the prosthesis [2, 8, 18, 19].

Most studies agree that the failure of the stem results from a metal fatigue fracture secondary to defective medial support of the cement [4, 6, 9, 11, 15].

We present a series of 13 patients where fracture of the stem occurred late, and where histology of the tissues as well as metallographic study of the stem surface were carried out.

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Patients and Methods

The series includes 9 patients in whom a Charnley total hip replacement was performed in the Orthopaedic Clinic of the University of Pavia between 1969 and 1976.

The same type of prosthesis was used in all cases (flat back air-melted EN58J stainless steel and vacuum-melted 316L stainless steel) produced by the same manufacturer (Thackray, Leeds, England).

Replacements were performed by different surgeons but with the same technique: antero-lateral approach, manual insertion of the cement (radiopaque CMW), without osteotomy of the great trochanter. Of these patients periodical clinical surveys and X-rays were available. Four patients had Mueller total hip replacement performed in other hospitals; all these stems were cast in Co-Cr alloy (Protasul). Early postoperative radiographs of two of them were obtained.

All but two of the patients had satisfactory results from total hip replacement with a pain-free interval varying from 5 to 11 years and a good functional recovery; only case 1 and 12

Table 1. Clinical data of the 13 patients with fracture of the femoral stem

Name	Sex	Age	Diagnosis	THR	Operation	Pain-free interval	Prosthesis removed	Controlateral hip
1. N.E.	M	63	OA R	Ch	4. 1973	1y	2y 1m	–
2. P.M.	F	64	OA L	Ch	6. 1971	11y	11y 5m	–
3. S.F.	F	58	OA R	Ch	4. 1976	5y 8m	5y 9m	–
4. F.P.	M	65	OA R	Ch	9. 1971	5y	6y 4m	THR
5. P.F.	M	51	OA R	Ch	5. 1972	10y	11y 1m	–
6. T.R.	F	69	OA R	Ch	10. 1971	12y	12y 1m	–
7. M.D.	F	64	OA R	Ch	1. 1972	11y 8m	11y 9m	–
8. M.W.	F	76	OA R	Ch	5. 1972	11y 9m	11y 9m	–
9. B.D.	F	61	OA L	Ch	1. 1971	12y 10m	13y	THR
10. F.P.	F	58	CDH L	Mu	5. 1973	8y	9y 3m	THR
11. A.P.	M	61	OA L	Mu	8. 1975	4y	7y	–
12. S.A.	M	52	OA R	Mu	1. 1982	1y	3y 6m	THR
13. F.C.	F	75	OA R	Mu	9. 1970	13y	15y	THR
						Average:	9y 2m	

OA, Osteoarthritis; *Ch*, Charnley; *CDH*, Congenital hip displacement; *Mu*, Mueller

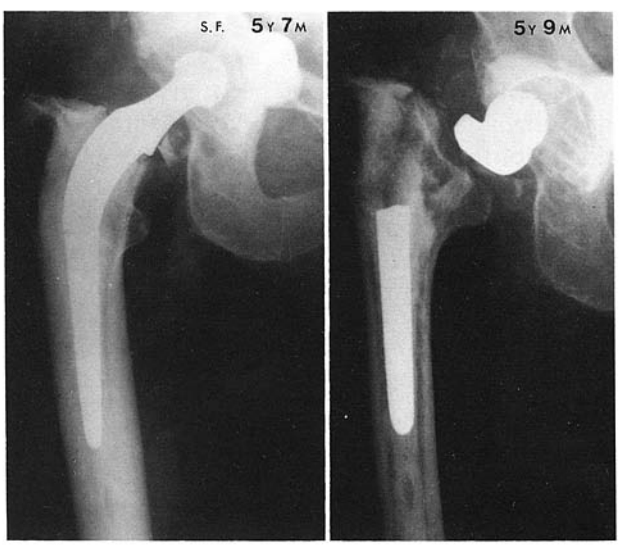


Fig. 1. Fracture of the stem 5 years and 7 months after implantation and displacement of the proximal fragment two months later after load

started to complain of pain after about one year. Data on the patients are summarized in Table 1.

Revision before the failure of the stem was suggested to two patients (cases 5 and 8) because of pain and loss of bone stock around the implant, but they refused operation at that time. In three cases [6, 7, 9] the fracture of the stem was heralded by a sudden onset of pain, while in the others pain remained unchanged also after the fracture. This experience is well exemplified by the patient (case 3) who continued to walk, against advice, also after the fracture of the stem had been diagnosed (Fig. 1). The interval between fracture of the stem and removal varies between 0 and 12 months in Charnley THR, since X-rays of the hip were taken once a year; no statement is possible for Mueller THR. No case had local signs of infection; this was confirmed by bacteriological cultures and histology. At revision, specimens were obtained from the bone-cement interface on the medial side of the neck (calcar femoris); they were fixed in neutral formalin, processed and embedded in paraffin; sections were stained with haematoxylin-eosin and observed in bright field and in polarized light. The coverslips were then removed with xylene and the sections coated with gold-palladium for SEM examination (secondary and backscattered mode). X-ray microanalysis was performed using an energy-dispersive spectrometer.

The removed components of prostheses were immediately washed in hot water and left to dry in air. Metallurgical examination was performed in one stem (case 1) and no defect of the alloy was observed [16].

The other stems were studied with a low-power stereoptic microscope; a graticule was used to determine the percentage of corroded surface. Detailed study of corrosion was performed with a scanning electron microscope (JEOL JSM 35C), after coating with gold-palladium.

Results

Since between 1969 and 1976 we performed 365 Charnley total hip replacements, this gives an incidence of 2.4% of stem fractures, with a follow-up of 9–16 years.

Patients with stem failure were equally distributed among male ($n = 5$) and female ($n = 8$).

Weight and age did not differ significantly from the 365 Charnley prosthesis population.

Stem position as well as radiographic aspects are reported in Table 2. The common features in all cases were a progressive resorption of the medial side of the proximal femur and varus bending of the stem

Table 2. Radiographical and histological data of the 13 patients with fracture of the stem

			Stem position	Bone-cement interface (X-rays)	Histology (type of particles observed)
1.	N.E.	Ch	Neutral	Calcar res., cement fracture	Metal
2.	P.M.	Ch	Varus	Calcar res.	Polyethylene & metal
3.	S.F.	Ch	Varus	Calcar res.	Polyethylene & metal
4.	F.P.	Ch	Varus	Calcar res.	Metal
5.	P.F.	Ch	Neutral	Calcar res.	Metal
6.	T.R.	Ch	Neutral	Calcar res., cement fracture	Metal
7.	M.D.	Ch	Neutral	Wide res., subtrochanteric fracture	Metal, few polyethylene
8.	M.W.	Ch	Varus	Calcar res., cement fracture	Metal, few polyethylene
9.	B.D.	Ch	Neutral	Calcar res.	Metal
10.	F.P.	Mu	Varus	Calcar res., cup wear	Polyethylene
11.	A.P.	Mu	Varus	Calcar res., cup loosening	Polyethylene
12.	S.A.	Mu	Neutral	Calcar res.	Polyethylene, few metal
13.	F.C.	Mu	Varus	Calcar res., cup loosening	Polyethylene

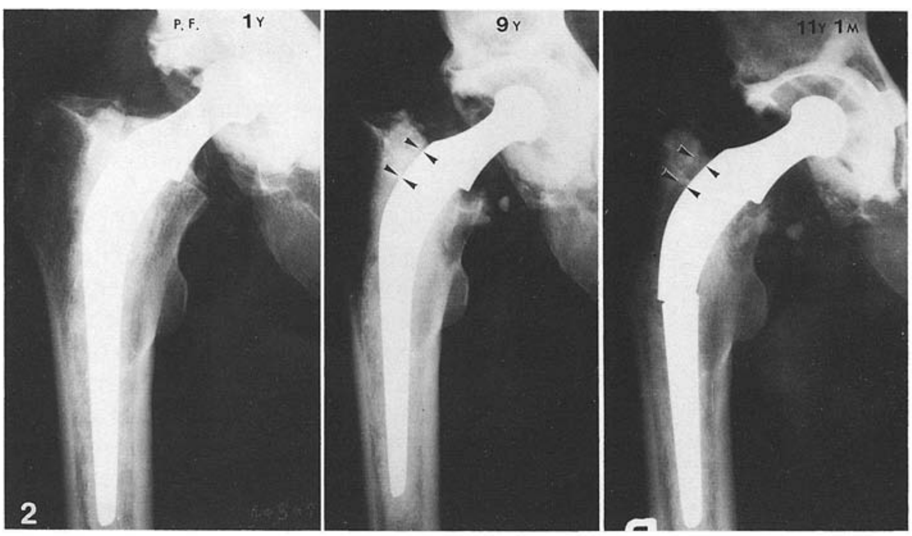


Fig. 2. Progressive resorption of the calcar femoris in a Charnley THR 9 years after insertion, varus bending of the stem *(arrows)* and fracture of the stem 2 years and 1 month later

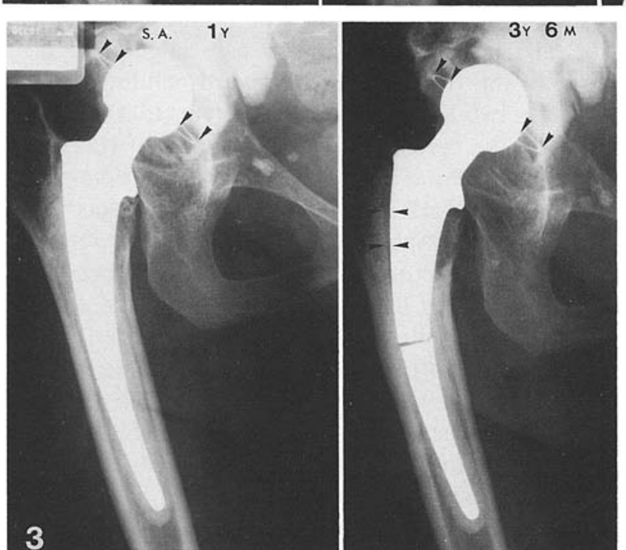


Fig. 3. Resorption of the calcar femoris and wear of the cup was observed in a Mueller THR 1 year after insertion; varus bending *(arrows)* and fracture of the stem 2 years and 6 months later. Wear of the cup is also progressed *(small arrows)*

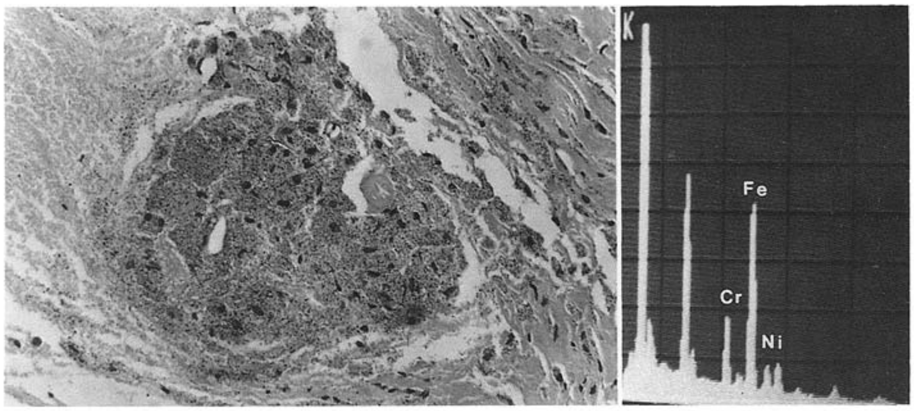


Fig. 4. Macrophages loaded by opaque, stainless-steel particles. On the left side an amorphous material is present; on the right a well organized connective tissue. X-ray micro-analysis was performed on the same section after the coverslip had been removed and the specimen observed with SEM (HE × 190)

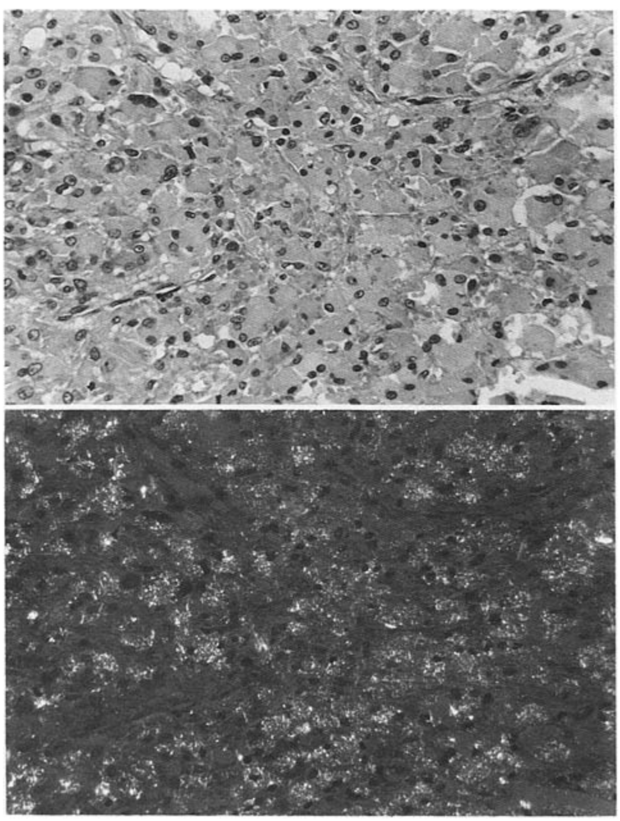


Fig. 5. Sheet of macrophages, apparently without cytoplasmatic inclusions. In polarized light the same cells contain a large amount of small polyethylene particles (HE × 190)

(Figs. 2 and 3); fracture of the cement was a less constant finding.

The tissue curetted from the medial femur was in continuity with the tissue around the neck and the head of the prosthesis and presented the same macroscopic characters.

Two varieties were observed: a very pigmented, gray, tissue in some cases; a white, caseous, material in others.

Microscopically an amorphous material or a loose connective tissue were observed, the cellular component was formed by macrophages; two main cytoplasmic inclusions were found:

- small (less than 1 micron), opaque particles, which at microanalysis gave the characteristic pattern of the metal alloy of the stem (stainless-steel or Co-Cr) (Fig. 4);
- birefringent polyethylene particles (Fig. 5).

The histological findings for each prosthesis are reported in Table 2.

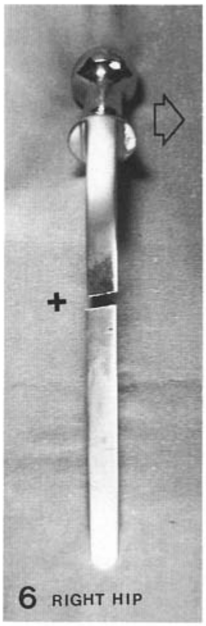
The level of the fracture was higher in Charnley prostheses (average 79.1 mm from the tip of the stem) than in Mueller prostheses (56.0 mm). When viewed on the back of the stem (lateral aspect) the fracture line was oblique in all cases except two. According to the right or left side of the prosthesis the slope was considered − when it was direct downwards anteriorly and + when it was downwards posteriorly; 0 marked neutral fracture slope (Table 3). Bending of the proximal stem fragment was observed in eight cases, all Charnley THR with stainless-steel stem. Forward bending was always associated with a + slope of the fracture and backward bending with − slope. In two Mueller Co-Cr-Mo stems there was a − slope of the fracture, but no bending of the stem. Both forward and backward bending were observed in Charnley THR; no bending was appreciable in Mueller stems (Table 3). Fatigue striations were evident on the fracture surface in most prostheses, although polishing had occurred and in some cases it rendered recognition of striations difficult.

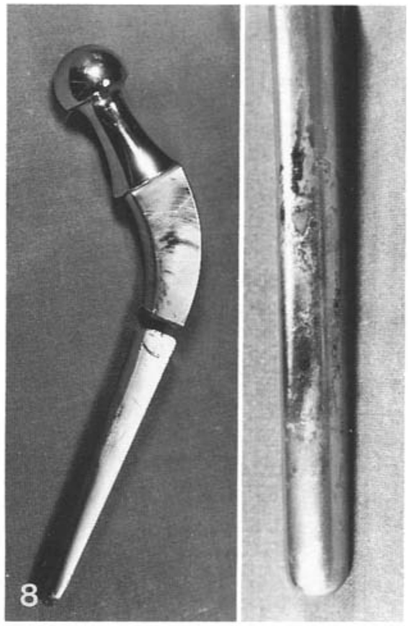
Fretting was evident on all proximal stem fragments (Fig. 8), while pitting corrosion was observed exclusively in stainless steel prostheses (Fig. 9). The extension of the corroded area is given in Table 3; it can be observed that corrosion occurred mainly in the distal stem fragment (Fig. 7), while the proximal showed extensive involvement only in one case. In

Table 3. Data of the 13 broken stems and cup

			Alloy	Stem fracture		Proximal stem bending	Stem surface		Cup
				Level (mm from tip)	Obliquity (ant. +; post. −; neu. 0)		Proximal	Distal	
1.	N.E.	Ch R	S.S. J7/8″MK1S	76	ND	ND	Fretting	ND	ND
2.	P.M.	Ch L	S.S. J7/8″MK1S	80	−	Backward	Fretting	Corrosion (10%)	Wear
3.	S.F.	Ch R	S.S. 128-22SR	83	−	Backward	Fretting	Corrosion (3%)	Impingement of the neck
4.	F.P.	Ch R	S.S. J7/8″MK1S	81.5	+	Forward	Fretting & corrosion (trace)	Corrosion (3%)	NA
5.	P.F.	Ch R	S.S J7/8″MK1S	79.5	−	Backward	Fretting	Corrosion (5%)	NA
6.	T.R.	Ch R	S.S. J7/8″MK1S	84	−	Backward	Fretting & corrosion (10%)	Corrosion (5%)	NR
7.	M.D.	Ch R	S.S. S14-26	78.5	+	Forward	Fretting	Corrosion (trace)	NA
8.	M.W.	Ch R	S.S. J7/8″MK1S	61	−	Backward	Fretting & corrosion (trace)	Corrosion (trace)	NR
9.	B.D.	Ch L	S.S J7/8″MK1S	88.5	+	Forward	Fretting	Corrosion (10%)	NA
10.	F.P.	Mu L	Co-Cr-Mo Francobal	63	0	0	Fretting	0	Wear
11.	A.P.	Mu L	Co-Cr-Mo Vitallium	39	0	0	Fretting	0	Impingement of the neck
12.	S.A.	Mu R	Co-Cr-Mo unspecified	70	−	0	Fretting	0	Wear
13.	F.C.	Mu R	Co-Cr-Mo Protasul	52.5	−	0	Fretting	0	Wear

SS, stainless-steel; *ND*, not determined; *NR*, not removed; *NA*, not available





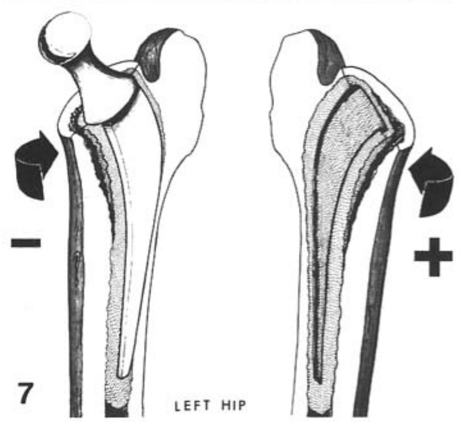


Fig. 6. M. D.: right Charnley prosthesis slope of the fracture line on the back of the stem (+) and forward bending of the proximal fragment

Fig. 7. Diagram illustrating the mechanism of forward and backward bending when the loss of bone stock extends anteriorly or posteriorly

Fig. 8. Failed stem: fretting is evident on the proximal fragment, while areas of pitting corrosion are observed on the distal stem

the latter fretting was superimposed on pitting corrosion.

Discussion

Fatigue fracture of the stem occurs by combination of defective support of the proximal part with a firm bonding of the lower part: bending cantilever fatigue or mode IV according to the classification of Gruen et al. [10].

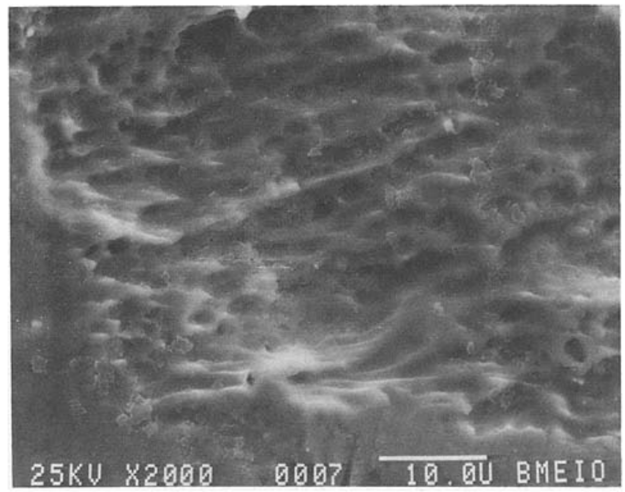


Fig. 9. Pitting corrosion of a stainless-steel stem (SEM × 1700)

The loss of support is due to the resorption of bone in the medial part of the proximal femur or calcar area; the load on the proximal stem is the resultant of flexion (in the sagittal plane) and forward bending (in the coronal plane) when the loss of bone stock extends anteriorly, the opposite when resorption extends posteriorly. The stem is therefore subjected to a combination of bending and torsion and a crack is started on the tensile surface. Bending of the proximal stem in stainless-steel prostheses results from plastic deformation of the metal, which precedes brittle fracture. Since cracks develop approximately at right angles to the direction of the principal tensile stress, the + slope of the fracture always matchs forward bending and viceversa. The absence of appreciable bending in Mueller stems may be the result of design, fracture level (which is lower than in Charnley) and lower plasticity of the Co-Cr-Mo alloy; however in two Mueller's stems the − slope of the facture suggests a backward load, the 0 slope in the other two the absence of a component in the coronal plane.

Factors as positioning of the stem and patient's weight may increase the load on the stem, but only bone resorption in the medial part of the proximal femur can start the bending cantilever fatigue mechanism.

The factors which control local bone resorption are not yet fully understood. As regards the loss of bone stock in the calcar area of prosthetic hips two theories are in the field: mechanical overload in the area or foreign-body reaction to particulate materials produced by prostheses. No definitive evidences have been so far produced to exclude one of them.

There is however a large weight of evidence that foreign-body reaction may be one of the factors that cause bone resorption around loosened prostheses

[14, 17]. In this study reactive tissue to particulate materials was found in all case in the sites where bone resorption occurred.

Failure of the cement for mechanical or structural causes has been reported as a possible ethiological factor of calcar resorption, loosening and stem failure [3, 12]. Our findings however do not substantiate this hypothesis since the granulation tissue found in the calcar area was histologically characterized by polyethylene or metal debris.

Radiographic evidences of cement breakage were observed late, when osteolysis of the calcar was far advanced.

In Mueller total hip replacements wear of the cup was the more constant finding, in accord with the very high quantity of polyethylene particles found in the tissues; metal particles in these cases are the result of fretting or polishing of the fracture surface, therefore they are produced when the process is far advanced and the stem already brocken.

In Charnley total hip replacements corrosion of the stem was the most remarkable finding: although polyethylene also was produced by these prostheses, the tissues were mainly loaded by metal particles (only two cases showing an equal mixture of the two type of material).

Corrosion has been cited as a possible cause of crack propagation leading to the fracture of the metal [5], however the aspect that is of interest here is the corrosion as a source of metal particles in the early stages of proximal loosening. Corrosion was observed mainly on the distal stem fragment, which in this type of loosening remains firmly anchored in the bone; when corrosion was observed in the proximal fragment, fretting was superimposed, therefore corrosion precedes fretting of the stem against the cement and, in time sequence, it is the first source of metal particles.

The question arises how the metal particles can escape from the cement envelope that surrounds the stem. Fracture of the cement is a late phenomenon and it is not worth in this case. It is possible that an incomplete envelope of cement surrounds the stem, leaving exposed areas of metal; in this case however one would expect an histiocytic reaction nearby the source of foreign material, namely distally in the femoral diaphysis. A shrinkage of the cement after polymerization is known to occur; this, together with micromovement, which probably follows the settlement of the implant in its bony bed with the passage of time, may lead to formation of a narrow gap between the metal and the cement, sufficient for the passage of small size metal particles. These particles are then pumped out around the neck, which is the critical site of bone resorption.

Support for this hypothesis is given by the occurrence in a few cases of a thin fibrin film between the cement and the metal surface in prostheses firmly bonded to their cement envelope; the same observations have been reported by Fornasier and Cameron [7].

In the studied population fracture of the stem occurred late; it is possible that earlier stem failures have a different cause. However in the two patients of this series where fracture of the stem occurred after 2 years and 1 month and 3 years and 6 months the same reactive tissue was found. Also Charnley [3] described in his patients a necrotic, caseous material with foreign body reactive tissue on the medial aspect of the proximal femur.

It seems therefore that foreign body reaction could be the common instigating factor which leads to stem failure in all cases.

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