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Osteolysis after Charnley primary low-friction arthroplasty

A COMPARISON OF TWO MATCHED PAIRED GROUPS

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We reviewed 249 consecutive Charnley primary low-friction arthroplasties in 191 patients performed by one surgeon using a transtrochanteric approach at a minimum follow-up of ten years. Of these, 37 hips in 32 patients showed osteolysis and were compared with 41 hips in 37 matched patients with no osteolysis.

We assessed in each case the wear rate, stability of the prosthesis, acetabular angle, socket angle, thickness of the acetabular and femoral cement mantle, canal flare index, femoral score, stem alignment, implant:canal ratio and stem:canal ratio.

We found that a high rate of wear, component instability and osteolysis were associated. Osteolysis was three times more common in men than in women. Factors which reduced osteolysis were cement mantles of 6 mm at the acetabulum and of 3 mm in all zones of the femur, a stem:canal ratio of 60% to 70% and an implant:canal ratio of over 99%.

The overall incidence of osteolysis was 14.9% but when these technical criteria were met, the incidence was 5.2%. This suggests that careful technique can dramatically reduce the risk of this complication.

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In 1963, Charnley[1] described osteolysis after the use of Teflon cups in total hip arthroplasty, and in 1975 he reported finding cavities around loose as well as stable components.[2] The basic mechanism of osteolysis is still controversial[2-8] and a number of mechanical and biological theories have been postulated.[1,7-20] Many factors have been implicated in the time-dependent development of osteolysis[17,21] and its reported incidence varies from less than 1% to 46%.[9,10,17,22,23]

We aimed to establish the incidence of osteolysis in a series of Charnley low-friction arthroplasties (LFA) after a minimum follow-up of ten years, and to identify any associated factors. We therefore compared two matched groups of patients, one with acetabular or femoral osteolysis or both and the other with no evidence of osteolysis.

Patients and Methods

From 1970 to 1985, a total of 678 hips in 534 patients had a primary LFA, but 40 patients (45 hips) had inadequate postoperative serial films and were excluded. This left 633 hips with adequate follow-up ranging from two to 25 years. From these we selected a cohort with a minimum follow-up of ten years (mean 13.8, range 10 to 25). There were 191 patients with 249 primary LFAs; details are given in Table I.

We examined all the radiographs and selected two groups: a study group of 37 hips in 32 patients which showed definite osteolysis and a matched control group of 41 hips without osteolysis in 37 patients. The control group was selected randomly and in a blinded fashion. The groups were shown to be reasonably matched for age, gender, weight, diagnosis, Charnley class (Table I), surgical technique, surgical approach, type of prosthesis and follow-up and matching was accidental.

All the operations had been performed by one author (NSE) using a transtrochanteric approach, Charnley femoral components with a 22.25 mm head, and Charnley acetabular components fixed with cement (CMW 1; CMW Laboratories Ltd, Blackpool, UK). The standard Charnley methods had been followed.[24,25] After operation, each patient was reviewed clinically and radiologically at six months and then annually.

We defined osteolysis as any newly developing expansile, cystic lesion, with endosteal scalloping and/or migration which had not been seen on the immediate postoperative radiograph. We excluded hips showing osteolysis associated with infection, tumour or metabolic bone disease as diagnosed on clinical, radiological and haematological studies.

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Table I. Details of patients in the whole series and in the study and control groups

	Whole series	Study group	Control group
Number of hips (patients)	249 (191)	37 (32)	41 (37)
Mean age in years (range)	58 (17 to 79)	52 (19 to 75)	56 (17 to 72)
Gender			
Male	73	21	22
Female	118	11	15
Mean weight in kg (range)	77.0 (39 to 125)	76.0 (56.6 to 98.2)	77.8 (51.6 to 102.7)
Aetiology*			
OA	95	17	22
RA	30	6	5
DDH	30	4	3
AVN	14	2	3
Other	22	3	4
Charnley class†			
A	44	11	5
B	91	12	19
C	56	9	13

* OA, osteoarthritis; RA, rheumatoid arthritis; DDH, developmental dysplasia of the hip; AVN, avascular necrosis; Other, Perthes' disease, slipped capital femoral epiphysis, Gaucher's disease, post-traumatic arthritis, protrusio acetabuli

† A, unilateral hip disease with no other disability; B, bilateral hip disease with no other disability; C, unilateral or bilateral hip disease with generalised systemic factor affecting function

The time of the first appearance of an osteolytic lesion was noted and its progress determined by serial measurements of area (mm^2) using a digitiser. The site of the lesion was recorded as being in one or more of the three zones of the acetabulum[26] and the 14 femoral zones.[27]

Wear of the high-density polyethylene was measured by the method described by Charnley and Halley[28] as modified by Livermore, Ilstrup and Morrey.[29] We recorded any wear of 2 mm or more at ten years as 'high' and under 2 mm as 'low'.

We assessed the stability of the acetabular components by serial measurements of the height and angle of the socket and its horizontal distance from the teardrop line.[30,31] A change in the angle of more than 4°, of height of over 3 mm and of horizontal distance of over 3 mm were taken as evidence of an unstable cup. Subsidence of the femoral component was measured by the Loudon and Charnley method[32,33] and changes in stem alignment were recorded. Subsidence of over 2 mm and a change in alignment of more than 2° were considered as evidence of an unstable stem.

Table II. Mean (SD) thickness of the femoral cement mantle (mm) in the AP and lateral zones in the study and control groups

	Study group	Control group	p value
AP zone			
1	2.87 (1.18)	5.45 (1.59)	0.002
2	1.90 (1.12)	3.05 (1.36)	0.004
3	2.20 (1.82)	3.10 (1.35)	0.046
5	1.99 (0.62)	3.86 (1.02)	0.002
6	1.96 (1.20)	3.19 (1.23)	0.001
7	4.05 (1.67)	5.06 (1.73)	0.048
Mean	2.33	3.95	
Lateral zone			
8	4.41 (1.18)	5.06 (1.55)	0.132
9	3.68 (1.15)	3.17 (1.60)	0.252
10	2.04 (1.23)	3.99 (1.50)	0.002
12	2.94 (1.93)	3.52 (1.34)	0.204
13	2.05 (1.76)	3.23 (1.95)	0.040
14	1.23 (1.27)	3.98 (1.80)	0.007
Mean	2.73	3.83	

In addition to wear and stability assessments, we measured the acetabular angle, socket angle and thickness of the cement mantle in all three acetabular zones. The canal flare index,[34] femoral score,[35] implant (stem plus cement):canal ratio, stem:canal ratio and the thickness of the cement mantle were measured in all 14 zones of the femur.

All measurements were made by one author (RPJ) using a digitiser (Ortho-graphics, Salt Lake City, Utah). The accuracy of the digitising tablet was ± 0.25 mm and the system takes magnification into account. This has shown to be more accurate than manual measurement.[36-38]

We assessed differences in continuous parameters and prosthesis characteristics by multivariate analysis of variance against the independent variable of osteolytic status using SAS Proc GLM (SAS Institute, Cary, North Carolina). The multivariate analysis was in two stages. The first was an analysis of variance of hips with the dependent variables of surgical and prosthetic characteristics and the independent variables of cases *versus* control. The second stage was a stepwise multiple regression to identify the particular combinations of surgery and prosthesis which best separated cases from controls. The level of significance was as shown in Tables II, III and IV).

We analysed the time to the appearance of osteolysis by Kaplan-Meier lifetable analysis, and assessed the influence of categorical parameters on time to failure using log-rank tests in a stratified analysis with the SAS Proc LIFETEST method (SAS Institute, Cary, North Carolina).

Table III. Results for the acetabular side in the study and control groups

	Study group	Control group	p value
Mean (SD) acetabular angle in degrees	36.2 (5.5)	38.2 (5.9)	0.246
Mean (SD) socket angle in degrees	43.4 (6.9)	42.4 (6.2)	0.532
Mean (SD) cement mantle (mm)			
Zone 1	4.26 (2.83)	6.21 (2.84)	0.008
2	5.34 (2.38)	7.10 (2.58)	0.007
3	5.01 (1.82)	6.42 (2.16)	0.008

Table IV. Results for femoral side in the study and control groups

	Study group	Control group	p value
Mean (SD) canal flare index	4.1 (1.1)	3.8 (0.8)	0.161
Mean (SD) femoral score	55.3 (13.0)	51.7 (11.6)	0.318
Mean (SD) implant:canal ratio (%)	*95* (*3*)	*99* (*1*)	0.0001
Mean (SD) stem:canal ratio (%)	*72* (*1*)	*67* (*2*)	0.028
Mean (SD) stem alignment in degrees	1.4 (2.2)	1.5 (2.2)	0.834

Results

Of the 249 LFAs, 37 (14.9%) showed evidence of osteolysis. The incidence was higher in men than in women and in patients with inflammatory arthropathy rather than primary osteoarthritis. There was a higher incidence in Charnley class-A patients than in those in classes B and C. To examine whether socket wear developed before or after instability we studied four groups as follows: group 1 (13 hips), stable component with low wear; group 2 (3 hips) stable component with high wear; group 3 (14 hips) unstable component with low wear; and group 4 (7 hips) unstable component with high wear. When osteolysis was first visible, ten hips had high wear and 21 had unstable component(s). When we excluded the hips with both unstable components *and* a high wear rate, the incidence of osteolysis was only 5.2% (13 of 249 hips).

An unbiased estimate of the incidence of osteolysis requires adjustment for patients lost to follow-up or dying within ten years.[39] The changing number of patients at each follow-up led us to calculate the probability of survival without osteolysis by the Kaplan-Meier method. This overall assessment showed that the probability of survival at five years was 98.9%, at ten years 94.2%, at 15 years 88.7% and at 20 years 83.1% (Fig. 1).

Of the 37 hips with evidence of osteolysis, 13 (35%) had femoral and 21 (57%) acetabular changes and three had both (8%) (Figs 2 and 3). The mean time of the first appearance of osteolysis was 73.5 months (28 to 192) after the LFA.

Osteolysis was always progressive, regardless of its location. The average area of acetabular osteolysis when first noticed was 36.2 mm^2 (1.8 to 36.7), and at the latest follow-up it was 88 mm^2 (7.1 to 289.9). The annual rate of progression was 13.5 mm^2/year.

The average area of femoral osteolysis at first diagnosis was 70.5 mm^2 (8.9 to 134.9) and at latest follow-up 123.7 mm^2 (22.2 to 243.9). The annual rate of progression was 11.8 mm^2/year.

High wear was seen in 27% of the hips in the study group and in 4.9% of those in the control group ($p = 0.001$). Instability was diagnosed in 56% of the hips in the study group and in none of the control group ($p = 0.001$).

Details of the radiological analysis and the level of statistical significance are shown in Tables II to IV. We found no statistically significant differences between the study and the control groups for preoperative acetabular angle or postoperative socket angle, but the thickness of the cement mantle in all three acetabular zones together differed significantly between the two groups. In zone 1, the mean thickness was under 5 mm in the study group and over 6 mm in the control group. In zones 2 and 3, the thickness was just over 5 mm in the study group and over 6 mm in both zones of the control group.

We found no difference between groups for flare index, femoral score, or stem alignment. The implant (cement plus stem):canal ratio and the stem:canal ratio were significantly different: in the study group, cement plus the stem occupied 95% as against 99% in the control group. In all the femoral zones a thickness of the mantle of 3 mm or less was associated with osteolysis in the study group; the control group had a mean thickness of more than 3 mm.

Discussion

We studied consecutive arthroplasties by one surgeon using a standard technique in one hospital. The total incidence of osteolysis was 14.9%, but in the absence of wear or instability of the implant it was only 5.2%. We have shown reasonable matching for age, gender, weight and other factors, and believe this to be the first study which is controlled

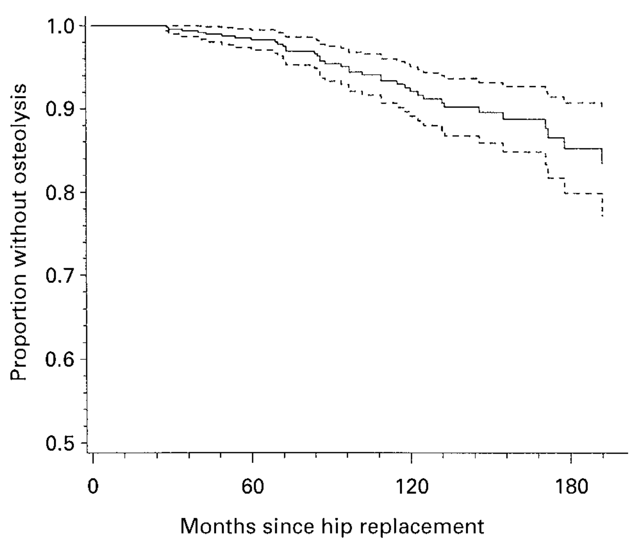

Fig. 1

Kaplan-Meier life-table analysis with time to osteolysis as the endpoint.

Fig. 2

Radiograph of a 45-year-old woman with inflammatory arthritis who developed acetabular osteolysis at 34 months on the left and 97 months on the right side after LFA. There is bilateral acetabular osteolysis, high wear of the sockets, but stable components.

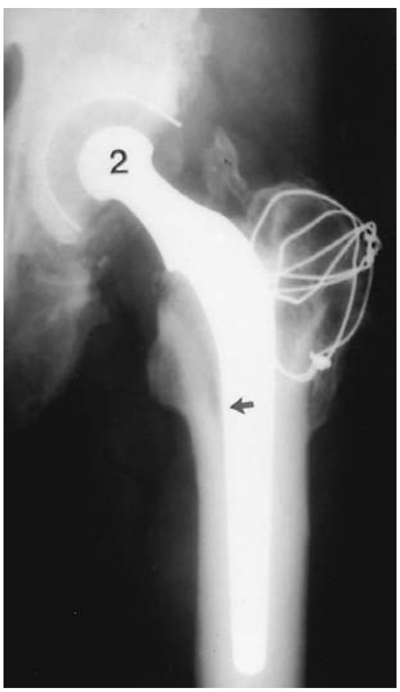

Fig. 3a

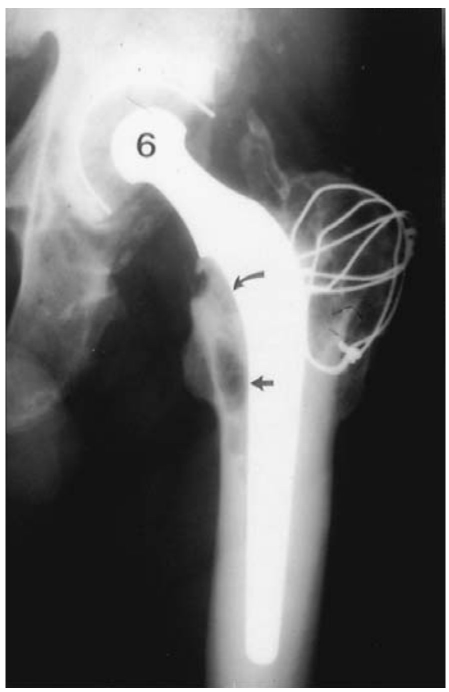

Fig. 3b

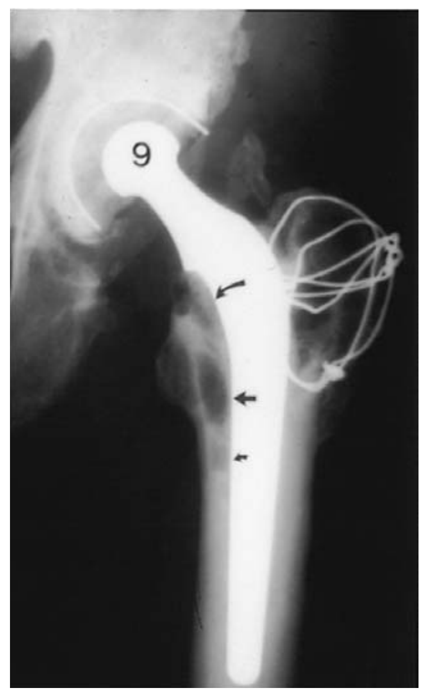

Fig. 3c

Radiographs of a 62-year-old man who developed osteolysis at the medial aspect of the femur at two years (a), which had increased at six years (b) and at nine years although stability of the stem was maintained (c). The wear rate remained low, at less than 2 mm in ten years.

for many variables with over ten years of follow-up.

Other studies of osteolysis are difficult to compare because of differences in prosthesis, technique, approach, surgeon and other demographic and technical factors. Huddleston[22] in 1988 studied 260 femoral components of a 'Charnley-type' prosthesis that had failed without infection, and found an incidence of osteolysis in *failed* femoral components of 23.8%, but gave no figures for the total incidence of osteolysis in the entire series. Maloney et al[17] reported 25 hips with focal femoral osteolysis in stable cemented components, but included seven different types of prosthesis. Mulroy and Harris[23] reported a radiological review of 105 hips in 93 patients at 10 to 12.7 years, with an incidence of localised osteolysis of 6.8%, but used four different types of prosthesis.

Maloney et al[17] reported that in 70% of their 25 hips osteolysis had first appeared after five years, and was unrelated to age, gender or diagnosis. We have confirmed the finding of Huddleston[22] that men were more affected than women, but we found no statistically significant differences between patients with different types of arthritis or between Charnley class-A, class-B and class-C patients.

Progression of osteolysis was usually slow, but may be alarmingly rapid and destructive.[22] Tallroth et al[15] reported that the size of lesions doubled every 2.2 years. We found progression in all zones at 13.5 mm^2/year on the acetabular side and 11.8 mm^2/year on the femoral side.

An association between thickness of the cement and osteolysis was first described by Bocco, Langan and Charnley,[40] who reported that destructive changes (type III) were associated with a thin cement mantle in the calcar femorale. The mean thickness was 4.5 mm in hips with these changes and 10 mm in hips without them. Seven hips in our study showed destructive changes at the calcar; they had a mean local thickness of the mantle of 3.8 mm. Calcar osteolysis involved only this zone in three hips; the other four had involvement of other zones.

We found significant differences between groups in mean thickness of the mantle about the cup, confirming that the acetabular mantle should be of adequate thickness, preferably over 6 mm. In the femoral zones a thickness of 3 mm or less was associated with osteolysis.

Ebramzadeh et al[41] showed better radiological results with a thickness of 2 to 5 mm in the proximal medial femur, stem fill of more than half of the medullary canal and with stem orientation in neutral or valgus. We found no significantly different canal flare index, femoral score and stem alignment between our two groups, but the implant (cement plus stem):canal ratio and the stem:canal ratio were significantly different. One of us has shown that a stovepipe canal with low canal flare index (<3), a low femoral score (40.8) and varus alignment was associated with failure of fixation.[42] These three factors were not significantly different in our present groups, with canal flare indices of over 3.8, femoral scores of over 51.7 and mean alignment over 1.4° of valgus. The significant difference in the cement plus stem ratio in the medullary canal between the two groups shows the importance of filling the full space without leaving any voids or gaps between the implant and host bone.

We found that LFAs in which stems occupied more than 70% of the femoral canal had a significantly greater chance of developing osteolysis. Kobayashi, Eftekhar and Terayama[42] and Kobayashi and Terayama[43] reported that a stem:canal ratio of under 60% was associated with mechanical loosening, and that 66% filling was associated with less failure. These results and our findings suggest that there may be an optimum percentage for the stem within the femoral canal. A thick prosthesis occupying the whole femoral canal tends to give a high incidence of osteolysis, while a thin prosthesis in a large medullary canal may predispose to mechanical loosening. A cement mantle of adequate thickness, over 3 mm, with stem filling of between 60% and 70% appears to protect the host bone from lysis. Stem filling of over 70% will decrease the thickness of the mantle and probably give earlier failure due to osteolysis.

Conclusions. At a mean of 13.8 years after primary Charnley LFA we found an overall incidence of osteolysis of 14.9%, but only 5.2% in the absence of high wear and instability. The survival at five years was 98.9%, at ten years 94.2%, at 15 years 88.7% and at 20 years 83.1%. Osteolysis was always progressive, appearing at about six years, and being more common in male patients, inflammatory arthritis, joint class A, and hips showing high wear and instability. We recommend a cement mantle of 6 mm in the acetabulum and 3 mm in all zones of the femur. The stem:canal ratio should be 60% to 70% and the implant (cement plus stem):canal ratio over 99% for optimum prevention of osteolysis.

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