A comparison of polyethylene wear rates between cemented and cementless cups

A PROSPECTIVE, RANDOMISED TRIAL

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We selected randomly a consecutive series of 162 patients requiring hip replacement to receive either a cementless, hemispherical, modular, titanium acetabular cup or a cemented, all-polyethylene cup. These replacements were performed by two surgeons in four general hospitals. The same surgical technique was used and a 26 mm metal-head femoral component was used in every case.

After exclusions, 115 hips were studied for differences in rates of wear and osteolysis. The mean clinical follow-up was eight years and the mean radiological follow-up, 6.5 years. The cementless cups wore at a mean rate of 0.15 mm per year and the cemented cups at 0.07 mm per year. This difference was significant ($p < 0.0001$).

Our findings in this mid-term study suggest that cementless cups wear more than cemented cups.

Cementless total hip arthroplasty and hybrid prostheses (cemented femoral component with an uncemented cup) have become increasingly popular over the last decade. In some countries, approximately two-thirds of patients undergoing primary hip replacement have a cementless cup.¹ This popularity is not supported by long-term studies of effectiveness but in response to the perceived high rate of failure of cemented cups in the long term, particularly in younger patients.²⁻⁴

The long-term success of hip replacement relies on avoiding early complications such as infection and instability. It also requires lasting fixation of the components with avoidance of aseptic loosening and osteolysis. The successful combination of three factors is required to avoid the last two complications: fixation of the acetabular component, fixation of the femoral component and benign bearing surfaces. There is no doubt that lasting fixation of a hemispherical titanium acetabular component can be achieved,^{5,6} but there has been concern as to the rates of wear of the polyethylene within these shells.^{7,8} Many studies which compare the wear characteristics of cementless with cemented cups use historical controls,^{9,10} with prostheses which are no longer in use¹¹ or with differing femoral components.¹² As success rates improve, comparative studies, using revision for loosening as an end-point, require greater numbers and many years to complete. Other

methods are needed to gauge performance in the mid term.

There is ample evidence that high rates of wear of polyethylene and high rates of osteolysis are both associated with higher rates of failure from aseptic loosening.^{13,14} Linear penetration, as measured on plain radiographs, is indicative of the rate of wear.¹⁵ It includes a small component of creep with, in the early stages, the 'bedding-in' phenomenon which has been described in modular acetabular cups.¹⁶ Our aim was to perform a randomised controlled trial to compare the linear rates of penetration and rates of osteolysis of a typical hybrid hip replacement, with those of a typical cemented hip replacement using an all-polyethylene cup. The null hypothesis was that there was no difference in the rate of wear of the polyethylene between a Duraloc cementless cup and an Exeter cemented cup when articulating with a 26 mm stainless-steel femoral head.

Patients and Methods

All patients requiring primary hip replacement surgery between mid-1993 and 1995, under the care of one of the two authors, were entered into the trial after informed consent had been given. This was a consecutive series and there were no withdrawals. Only one hip in each patient was studied. Patients were selected to receive either an uncemented cup (Duraloc 100; Depuy, Mount Waverley,

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Fig. 1a

Fig. 1b

Radiographs showing a) the hybrid hip and b) the cemented hip used in the study.

Australia) or a cemented cup (Exeter; Stryker Australia, Artarmon, Australia) using computer-generated random numbers concealed in envelopes to be opened in the theatre immediately before surgery (Fig. 1). The surgery was performed by one of the two authors or under their direct supervision in one of four hospitals. There were 78 Duraloc and 84 Exeter stems. The mean age of the patients at surgery was 67.3 years and there were 76 men and 86 women. The primary diagnosis was osteoarthritis in 90%.

All patients were operated on through a posterolateral approach and all had a cemented polished double-taper stem (Exeter; Stryker Australia) with a 26 mm stainless-steel head. Simplex cement (Stryker Australia) was used with modern cementing techniques including lavage and pressurization.

The Duraloc cup is a hemispherical titanium shell with a Porocoat surface and a modular shell of machined 'Enduron' polyethylene, and is sterilised by gamma irradiation in air. The outer shell is of the screwless design (Duraloc 100; Depuy). The Exeter cup is all-polyethylene and was inserted using Simplex cement (Exeter; Stryker Australia). This polyethylene was also machined and gamma irradiated in air. Both cups had a 10° rim on the polyethylene, the Exeter subtending half the circumference, but the Duraloc subtending the full circumference.

Standardised radiographs were used as the basis of the study. The anteroposterior (AP) projection was based on the symphysis pubis and taken at a standard distance of 1 m. An early post-operative film and that taken most recently, were analysed for linear penetration according to the method described by Livermore, Ilstrup and Morrey.¹⁷

Table 1. Patient demographics and results

	Duraloc	Exeter
Patients randomised	78	84
Exclusions	26	21
Patients studied	52	63
Age (yrs)	68.2 (41 to 83)	66.6 (48 to 82)
Follow-up (yrs)	6.51 (5.1 to 9.1)	6.43 (5.0 to 8.03)
Polyethylene thickness (mm)	10.44 (7 to 13.2)	10.87 (9 to 15)
Acetabular inclination (degrees)	41.6 (28 to 56)	42.6 (30 to 52)
Pelvic osteolysis	2	0
Calcar osteolysis	13	3
Wear rate (mm/yr)	0.15 (0 to 0.4)	0.07 (0 to 0.22)

Edge-detection software cannot be used in all-polyethylene cups and therefore measurements were made using a digital caliper with subsequent calculations adjusted with reference to the metal head (diameter 26 mm). Measurements based on the Livermore method are associated with an error of approximately 0.1 mm.^{17,18}

Linear penetration was measured on the early post-operative and the most recent radiograph, and a calculation made to establish the wear rate per year. We assumed that this was linear. Any input of creep to the linear penetration rate was minimised by the fact that the initial radiograph was taken at a mean of three months after operation.

Osteolysis was assessed on the most recent AP and lateral films by the presence of lucent lines as described by DeLee and Charnley for the cup¹⁹ and Gruen, McNeice and Amstutz for the stem.²⁰ Pelvic and femoral osteolysis was assessed according to the definitions of Zicat, Engh and Gokcen.²¹

Acetabular inclination was measured on the AP pelvic film and recorded as the angle between a line joining the base of each teardrop with the line of the longest ellipse of the opening of the cup.²²

All patients were studied clinically in a prospective manner and post-operative complications such as death, infection and instability were recorded. Longer-term problems requiring revision for any reason were also recorded. Five patients with higher rates of wear underwent more detailed study. Linear penetration rates in these patients were measured on all available films to detect evidence of 'bedding-in' and to assess the wear for linearity. Only patients with a minimum of five years between radiographs were included. The initial post-operative films had been taken at a mean of 2.6 months after surgery. Four patients did not have post-operative films or they could not be found. They were therefore excluded from the wear studies. The mean radiological follow-up was 6.5 years and clinical follow-up, 8 years.

The rates of linear penetration were assessed and found not to be normally distributed, requiring the use of the Wilcoxon rank-sum (STATA program; Stata Corporation, College Station, Texas). Other variables, including the thickness of the polyethylene and the position of the cup, were also assessed. An analysis was undertaken before

Table II. Comparison of patient demographics between the lowest and the highest wearing hips in each group. All comparisons were statistically non-significant

	Duraloc		Exeter	
	Low wear (≤ 0.01 mm/yr)	High wear (> 0.22 mm/yr)	Low wear (≤ 0.01 mm/yr)	High wear (> 0.12 mm/yr)
Number	9	13	22	13
Mean follow-up (yrs)	5.99	6.83	6.40	5.78
Mean polyethylene thickness (mm)	10.5	10.52	11	10.6
Acetabular inclination (°)	43.6	39.2	42.9	42.6
Mean age (yrs)	69.7	67.5	68.7	66.7

commencement of the study to decide on the size of the sample. Assuming a difference of wear of 0.05 mm/year between the cups, the sample size necessary in each group to give a difference of 0.05 significance with a power of 0.8 was assessed to be 63 patients.

Results

There were no peri-operative deaths, no infections and no revisions or impending revisions for aseptic loosening. However, four acetabular prostheses were revised for recurrent dislocation; these were all Duraloc cups and the dislocations were thought to have been caused by the prominent 10° lip. These cases were excluded. During the course of the study 35 patients died (16 Duraloc, 19 Exeter). Four patients (Duraloc) were known to be clinically satisfactory but did not have appropriate radiographs and four were lost to follow-up (two from each group). This left 115 hips for study (52 Duraloc, 63 Exeter; Table I).

Fig. 2

Radiograph showing an example of pelvic osteolysis (arrow) in association with a cementless cup.

Table III. Breakdown of the numbers of patients with each polyethylene thickness

Duraloc		Exeter	
Number	mm	Number	mm
1	7	19	9
6	8	31	11
7	8.9	11	13
7	9.9	2	15
13	10.9		
12	11.7		
4	12.4		
2	13.2		

Rates of wear. The mean rate of wear of the patients with Duraloc prostheses was 0.15 mm per year and that of those with Exeter prostheses was 0.07 mm/year ($p < 0.0001$). A post hoc analysis revealed a power of 0.97 ($\alpha = 0.01$). The variation in wear rates was substantial in both groups, with the Duraloc results varying between zero and 0.4 mm/year and the Exeter group between zero and 0.22 mm/year. We looked at patient factors in the lowest and highest wear groups of each half of the study and found no significant difference. These results are shown in Table II. The wear rates of the five patients with Duraloc cups, studied at multiple points throughout the eight-year follow-up period, were assessed for extrapolated wear according to the method of Sychterz et al.²³ No evidence of 'bedding-in' was seen.

Osteolysis. Two patients in the cementless cup group had osteolysis of the ilium (Fig. 2). There was one thin complete lucent line (<1 mm) and one lucency in zone 1 in the cemented cup group. As a consequence of the somewhat arbitrary descriptions of pelvic osteolysis, no conclusions can be drawn from these findings.

On the femoral side, there were no significant lucent lines. Calcar erosion was seen in 13 patients in the cementless group, including one calcar cyst (Fig. 3). There were three cases of calcar erosion in the cemented cup group. In the uncemented group, those with calcar erosion had a mean rate of wear of 0.2 mm/year compared with 0.13 mm/year for those without erosion.

Thickness of the polyethylene. For each cup this was given by the manufacturer. Using a 26 mm head, the minimum thickness of the Duraloc polyethylene was 7 mm and for

Fig. 3

Calcar lysis. Case 1. Radiographs at a) three months and b) seven years. Case 2. Radiographs at c) two months and d) showing a significant calcar cyst at seven years.

the Exeter 9 mm. The distribution of the thickness in each group was similar and is shown in Table III and Figure 4. The mean thickness of polyethylene in the cementless cups was 10.44 mm and in the cemented cups 10.87 mm. This difference was not significant ($p = 0.147$).

A comparison was made in each group between the rates of wear in cups with a thickness of polyethylene <10 mm and those with a thickness >11 mm. For Duraloc of less than 10 mm (21 cups), the rate of wear was 0.17 mm/year and for more than 11 mm (17 cups) 0.17 mm/year. For the Exeter of less than 10 mm (19 cups), it was 0.075 mm/year and for more than 11 mm (13 cups) 0.08 mm/year. The polyethylene wear was also compared with varying levels of polyethylene; no significant difference was found in either the Duraloc or the Exeter group.

Positioning of the acetabular component. The only guide to positioning of the acetabular component which we could use, was that of inclination (from the horizontal) as measured on the AP radiograph. The mean inclination of the Duraloc prostheses was 41.6° and of the Exeter prostheses 42.6° . There is a danger in extrapolating these measure-

ments into an absolute guide to positioning of the cup as the difference between the two does not reach significance.

Fig. 4

Sizes of acetabular prostheses in each group expressed as polyethylene thickness v patient number (□ Duraloc; ■ Exeter).

Discussion

This randomised controlled trial has shown that there is a significant difference in the rate of polyethylene wear of a cementless metal-backed acetabular component (Duraloc 100), compared with an all-polyethylene cemented component (Exeter). Thus the original null hypothesis is rejected. The Exeter stem was used in all patients to limit the number of variables and because of its reliability in mid- to long-term studies. This choice has been validated by a reported survival of 100% of the stem at 12 years.²⁴

In a recent review of the literature by Dumbleton, Manley and Edidin,²⁵ a rate of wear of greater than 0.1 mm/year was thought to place the hip at a higher risk of developing osteolysis and eventual loosening. The authors concluded that "the literature suggests that osteolysis is infrequent when wear rates are 0.1 mm/yr and almost absent < 0.05 mm/yr". Sochart¹⁴ showed an increased loosening rate with wear in relationship to the Charnley prosthesis, and Barrack et al²⁶ showed a correlation between wear rates and osteolysis with an uncemented cup. Cementless cups have, at times, been shown to have high rates of wear. Perez et al²⁷ reported a mean rate of 0.25 mm/year at a mean follow-up of 68 months using a non-cemented, partially porous-coated, threaded acetabular component. Berger et al²⁸ reported a mean rate of 0.16 mm/year at 8.8 years after a primary cementless, hemispherical, porous-coated, acetabular reconstruction in younger patients and Clohissy and Harris⁶ showed a mean rate of 0.09 mm/year for the same acetabular prosthesis at ten years. Giannikas et al²⁹ reported a mean rate of 0.25 mm/year at 4.8 years when using an hydroxyapatite-coated hemispherical acetabular cup. In our study the mean rate of polyethylene wear of the Duraloc cups was 0.15 mm/year, when articulating with a 26 mm metal head. This is less than the 0.20 mm/year reported by Sychterz, Shah and Engh³⁰ using the same cup but with a 28 mm cobalt-chrome head. A multicentre retrospective study of a different hemispherical, titanium cup showed a mean wear of 0.11 mm/year, with more wear in younger patients.³¹

Reports of wear studies in cemented cups are less common. Charnley cups articulating with a 22 mm head showed wear of approximately 0.10 mm/year.² In the series of Livermore et al¹⁷ using a different all-polyethylene cup, there was a range between 0.08 and 0.13 mm/year depending on the size of the head. Despite the inference from the literature that there is a clear difference in the rates of wear between modular cementless cups and cemented cups, there are few studies which directly compare the two. We were able to find only one randomised trial. This was an RSA study comparing the Harris-Galante cup with the Ogee, using a 22 mm Charnley head. It showed no significant difference in wear or migration within five years.³²

The one other point of interest is the wide variation of the rates of wear. The range in the Duraloc group was from zero to 0.4, and in the Exeter group, zero to 0.22 mm/year. In a commentary by Schmalzried, Dorey and McKellop,³³

discussing polyethylene wear *in vivo*, a similar variation was seen in all the wear studies which they reviewed, with the mean wear varying by a factor of 40. Some of this variation may be due to inaccuracies of measurement which were estimated to be in the order of 0.07 mm in one study.¹⁸ However, even in the RSA study of Onsten et al,³² the range of wear rates varied by a factor of 13 (0.02 to 0.26 mm/year) at five years. Likewise, Jasty et al³⁴ found rates varying by a factor of 35 in a series of post-mortem and revision cup retrievals. These were measured by direct displacement methods which have a greater accuracy than radiological methods. We examined the patients at either end of the spectrum of wear and could find no difference in their clinical details and no relationship between wear and thickness of the polyethylene. Presumably, factors such as levels of activity, quality of fixation and possible third-body wear, play a role in this variation but this does not explain how a patient can have no measurable wear at seven or eight years. Perhaps a biological response or lack of it may be the unknown variable.

It emerges from our study that this all-polyethylene cup wears less than the particular cementless cup used in our series. Inaccuracies of measurement are unlikely to be important with such a marked difference in the results of the two arms of the study. Rates of wear were not significantly affected by the thickness of the polyethylene or acetabular inclination. In the mid-term, there were no signs of loosening of the cup in either arm. However, the rate of osteolysis associated with the uncemented cups remains a concern.

We believe that there are three possibilities for the observed differences. The first is the difference in the fixation of the cup. It is possible that the modulus of elasticity of the cement-polyethylene construct is more favourable compared with the rather inflexible metal shell. The second is that the modularity of the uncemented component contributes to the increased wear. Young et al³⁵ demonstrated a rate of wear of 0.11 mm/year in a non-modular component compared with 0.16 mm/year in a similar modular acetabular component. They suggested that the increased wear in the modular component may be explained by imperfect conformity of the liner shell, thinner polyethylene and 'backside' wear. The third possibility is that the variations are due to the use of different polyethylenes. The polyethylene used in each cup was machined and sterilised by gamma irradiation in air. The two polyethylenes came from different companies and therefore different resin stock. However, we feel that the very significant differences in the wear rates make this an unlikely cause.

We believe that the major variable in our study was the method of fixation of the cup. In the mid-term, fixation of either of these prostheses is not a problem but in the longer term osteolysis and loosening may well be. Our study suggests that this cemented all-polyethylene cup may well function better in the longer term than our particular uncemented cup. Studies of this nature are prosthesis-specific.

However, the particular cups under study were chosen because they were in common use when the study was conceived in 1992. We recommend caution in the widespread use of modular uncemented cups in total hip replacement.

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