The Elite Plus total hip arthroplasty

THE NEED FOR RADIOLOGICAL SURVEILLANCE

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We prospectively studied 217 patients who underwent 234 Elite Plus total hip arthroplasties. At a mean of 6.4 (SD 0.7) years post-operatively, 39 patients had died and 22 were either lost to follow-up or had no radiographs available. Clinical (Oxford hip score) and radiological assessments were performed on 156 patients (168 hip arthroplasties) who had a mean age of 67.7 (SD 9.7) years at operation.

In the assessed group, 26 of 159 (16.4%) of femoral stems which had not already been revised and 19 of 159 (11.9%) of acetabular cups were definitely loose. In total, 52 of 168 (31%) of hips had either been revised or had definite evidence of loosening of a component. We could not establish any relationship between clinical and radiological outcomes.

Despite the fact that the clinical outcome and rate of revision for the Elite Plus appeared to meet international standards, our findings give us cause for concern. We believe that joint registries should include radiological surveillance in order to provide reliable information about medium-term outcomes for hip prostheses.

The Elite Plus total hip arthroplasty system (DePuy, Warsaw, Indiana), introduced in 1994, is the second modular evolution of the original Charnley low friction arthroplasty. It is a cemented prosthesis with a modular, stainless-steel femoral stem and an ultra-high-molecular-weight polyethylene (UHMWPE) acetabular component. The standard head is also made from stainless steel (Ortron 90; DePuy).

To date, there have been no reports in the literature of standard metal-UHMWPE bearing Elite Plus components. The only study involving its stem reported catastrophic early failure when used with a zirconia ceramic head and a cross-linked UHMWPE (Hylamer) acetabular component.¹

National hip registries have been established to assess the outcome of new and modified prostheses such as the Elite Plus. These registries often use revision and clinical information but rarely include radiological data.

We have, therefore, reviewed the medium-term outcome of the Elite Plus and addressed the need for hip registries to include radiological surveillance if they are to provide accurate data on outcome.

Patients and Methods

All 217 patients, who were to undergo an Elite Plus total hip arthroplasty (THA) in one centre during 1995, were recruited prospectively into

Table I. Details of the 156 patients and 168 replacements for which the follow-up outcome was known

	Patients	Replacements
Age at surgery in yrs		
Mean (SD)	67.7 (9.7)	67.4 (9.6)
Time to follow-up in mths		
Mean (SD)	6.4 (0.7)	6.3 (0.7)
Gender		
Men	54	59
Women	102	109
Side		
Left		70
Right		98

a post-operative clinical and radiological surveillance programme. Review took place at a mean of 6.4 (SD 0.7) years after surgery. Data were gathered about the surgical teams involved, the grade of surgeon, the surgical approach and the type of cement used. Patients were reviewed clinically using the Oxford hip score.²

Of the 217 patients (234 THAs), 39 had died before our follow-up review, ten were lost to follow-up and 12 had no follow-up radiographs available. Nine patients (nine THAs) had already been revised by the time of our review. There were 156 patients (168 THAs) available with the required follow-up data. At the time of our study, the nine patients who had undergone revision were still alive and being reviewed. Table I gives the details of

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patients and replacements when a follow-up outcome was known.

All the patients had a cemented Elite Plus THA with a 28 mm Ortron 90 head. Eighty-four THAs had been performed by one surgical team, 37 by another and 38 by five other teams. Ninety-two operations had been performed by consultants and 67 by specialist registrars. All but three procedures had been undertaken through an anterolateral approach.

Palacos R cement (Biomet Inc, Warsaw, Indiana) was used in 142 THAs, Palacos LV (Biomet Inc) in seven and a mixture of Palacos LV and Palacos R in ten. For these, the Palacos LV cement was placed distally in the femur and the standard (Palacos R) was placed proximally.

Radiological review involved taking plain anteroposterior radiographs of the pelvis immediately after surgery and five years later. The radiographs were taken in a standard manner, with patients lying supine with their anterior superior iliac spines equidistant from the table top, their femora internally rotated and their heels separated. The film and beam were centred 2.5 cm above the symphysis pubis with a focal film distance of 115 cm and the beam collimated to include the proximal femora. The radiographs were assessed by two independent observers (NPW, CD) using the criteria of Johnston et al.³ Agreement between observers was necessary for data to be included and, when disagreement occurred, a consensus view was obtained with the help of a third observer if necessary.

Radiological data were further assessed to determine whether prostheses were loose or at risk. The criteria used were: 1) those of Harris, McCarthy and O'Neill⁴ for definite loosening of the femoral stem as modified by Madey et al⁵ and Loudon and Charnley;⁶ 2) the refined criteria of Kobayashi et al⁷ for loosening of the femoral stem which defined the presence of a lytic lesion (≥ 2 mm) or migration of the stem (≥ 2 mm) as predictors of failure; 3) those of Hodgkinson, Shelley and Wroblewski⁸ for definite acetabular loosening as modified by Mulroy and Harris;⁹ 4) the criteria of Harris et al for definite loosening and/or Hodgkinson et al for definite acetabular loosening;^{4,6,8,9} and 5) the criteria of Harris et al and Hodgkinson et al for definite loosening plus any revisions for aseptic loosening.^{4,6,8,9}

The survival of the prosthesis was calculated, with 95% confidence intervals (95% CI) using these definitions.

Table II. Number of replacements with evidence of loosening at follow-up

Criteria used	Number of THAs	Percentage (95% CI)
Harris ⁴⁻⁶	26/159	16.4 (14.2 to 18.5)
Refined Kobayashi ⁷	29/159	18.2 (15.9 to 20.6)
Hodgkinson et al ⁸	19/159	11.9 (10.3 to 13.6)
Harris and/or Hodgkinson	43/159	27.0 (23.9 to 30.2)
Revision or any loosening	52/168	31.0 (27.7 to 34.3)

Statistical analysis. This was performed using Fisher's exact test for categorical data and a two-tailed *t*-test for continuous data. A *p* value of less than 0.05 was considered to be significant.

Results

Evaluation of the cementation on the immediate post-operative radiographs showed that 99.4% of THAs had a grading of A or B according to the criteria of Barrack, Mulroy and Harris¹⁰ and 0.6% of C or D. There was no leakage of cement below the cement restrictor in 117 (73.6%) of cases but some leakage in 26.4%. No deficiency of the femoral cement mantle was identified in 149 (94%) of THAs, but there was some deficiency in the remainder. The position of the femoral stem was neutral in 111 (69.8%) of THAs, while 30 (18.9%) of stems were in $> 4^\circ$ of varus and 18 (11.3%) in $> 4^\circ$ of valgus.

For the 168 THAs for which loosening data were available, 52 (31%, 95% CI 27.7 to 34.3) showed either definite evidence of loosening of the component or had been revised for loosening of the component within six years (Table II).

There was not, however, any relationship between the incidence of loosening and either the age of the patients or their Oxford hip score. There was no significant relationship between clinical and radiological outcomes (*p* = 0.884, excluding revisions; Table III).

Some factors were significantly associated with loosening and/or revision. These were deficiency of the femoral cement mantle (*p* = 0.0075) and the type of bone cement used (*p* = 0.036, using Harris's criteria; Table IV).

Discussion

Prostheses evolve in an attempt to optimise the outcome of joint replacement surgery, but inherent risks accompany these changes to a tried and tested implant. As experience

Table III. Relationship of age at surgery and Oxford hip score to signs of loosening

	Harris ⁴⁻⁶ score	Hodgkinson ⁸ score	Harris and/or Hodgkinson score	Revision or any loosening
Age at surgery in yrs				
Mean (SD) with loosening	68.1 (9.9)	67.5 (8.1)	67.7 (9.2)	68.1 (9.9)
Mean (SD) without loosening	67.3 (9.4)	67.4 (9.7)	67.3 (9.6)	67.3 (9.4)
<i>p</i> value	0.685	0.945	0.819	0.685
Total Oxford hip score				
Mean (SD) with loosening	20.9	19.9 (12.4)	23.0 (11.1)	20.9 (9.8)
Mean (SD) without loosening	23.7	21.0 (10.4)	23.3 (10.6)	23.7 (10.8)
<i>p</i> value	0.246	0.253	0.884	0.246

Table IV. Incidence of loosening using the different criteria

	Number	Harris ⁴⁻⁶ (%)	Hodgkinson ⁸ (%)	Harris and/or Hodgkinson (%)	Revision or any loosening (%)
Gender					
Men	116	17.5	14.0	29.8	32.2
Women	43	15.7	10.8	25.5	30.2
p value		0.824	0.613	0.580	0.862
Side					
Left	116	9.5	9.5	19.1	27.1
Right	43	20.8	13.5	32.3	33.7
p value		0.078	0.618	0.071	0.401
Barrack grade ¹⁰					
A or B	158	16.5	12.0	27.2	29.9
C or D	1	0	0	0	66.7
p value		1.0	1.0	1.0	0.221
Cement leakage below restrictor					
Yes	40	15.0	5.0	20.0	20.0
No	117	17.1	14.5	29.9	32.2
p value		1.0	0.160	0.305	0.164
Femoral cement mantle deficiency					
Yes	11	63.6	27.3	72.8	72.8
No	149	12.7	10.8	23.5	30.9
p value		0.0003	0.127	0.0013	0.0075
Femoral stem position					
Neutral	111	15.3	10.8	24.3	25.7
Varus	30	13.3	20.0	33.3	35.5
Valgus	18	27.8	5.6	33.3	36.8
p value		0.365	0.341	0.461	0.392
Acetabular progressive radiolucent lines					
Yes	19	21.1	15.8	36.8	42.9
No	139	15.8	11.5	25.9	27.0
p value		0.521	0.705	0.409	0.195
Femoral bone cement					
Low viscosity*	7	57.1	14.3	71.4	71.4
High viscosity†	130	13.9	13.1	25.4	28.2
Low and high viscosity	10	10.0	0	10.0	18.2
p value		0.036	0.730	0.022	0.070
Surgical team					
A	84	15.5	13.1	28.6	30.2
B	37	18.9	10.8	24.3	31.7
Others	38	15.8	10.5	26.3	31.7
p value		0.885	0.949	0.891	1.0
Surgeon					
Specialist registrar	67	16.4	11.9	26.9	29.0
Consultant	92	16.3	12.0	27.2	32.3
p value		1.0	1.0	1.0	1.0

* Palacos LV

† Palacos R

with the 3M Capital hip (3M Company, St. Paul, Minnesota) has shown, small changes can have a major effect.¹¹ The Elite Plus stem evolved by altering the Charnley low friction arthroplasty femoral stem in two stages. Initially, modularity and optional larger femoral heads were introduced into the Charnley Elite system while maintaining an Ortron 90 femoral stem. The Elite Plus system then had additional changes which involved the geometry of the stem. This entailed alteration to the flange, the use of a 135° neck-shaft angle which increased incrementally with stem size, and the addition of a slot in the tip of the stem and a centraliser.

Survival data for the original Charnley low friction arthroplasty show excellent results,¹²⁻¹⁷ and the Elite Plus appears to perform well in our study. A revision rate of 3.75% at six years for our initial cohort of 234 THAs is

acceptable, based upon the benchmark for an acceptable rate of revision of 0.7% per annum according to the Swedish Hip Register.¹⁸ A survival rate at six years of 96.25% for our series also agrees with the findings of the Swedish Hip Register for the Elite Plus, in which survival was 96.2% (93.8% to 98.5%) at six years.¹⁹ Equally, our results are also acceptable when based upon the Oxford hip score. We selected the Oxford hip scoring system since it has been shown to relate accurately to patient satisfaction with the surgical outcome² and also provides data on pain and immobility.²⁰ This view is supported by other studies, which recommend the Oxford hip score for the assessment of THA compared with other scores.²¹

However, the use of revision as a standard end-point for survival analysis in THA is a coarse method of assessing prostheses in the medium term. Evidence of radiological

loosening is a refinement of this end-point and is, perhaps, preferable. When the radiological data were examined in more detail the results were less satisfactory, with 31% of our THAs showing clear evidence of loosening of a component according to recognised criteria^{4,6,8,9} or having undergone revision for aseptic loosening within six years.

Defining radiological loosening of a cemented implant is difficult. The literature lacks uniformity, although the criteria for loosening of the femoral stem according to Harris et al,⁴⁻⁶ or for acetabular loosening according to Hodgkinson et al,^{8,9} are widely accepted. Kobayashi et al⁷ considered a lucency of 2 mm which occupies more than one-third of any zone around the stem or migration of the stem of 2 mm, as individual predictors of aseptic loosening over ten years if present on a radiograph at two years. If both features were present at two years, the risk of loosening increased further. The same study also stated that if a lytic lesion of ≥ 2 mm was present at two years, there was a 50% chance of failure within five years. The criteria of Kobayashi et al⁷ appear to be more stringent than those proposed by Harris et al⁴⁻⁶ and are, perhaps, more applicable to a medium-term review such as ours. Using refined Kobayashi criteria, 18.2% of our femoral stems were at risk of failure within five years, even without considering either revisions or acetabular components.

Our results highlight the value of medium-term radiological follow-up after THA. This has been recommended in standard guidelines²² and suggests that joint registries should attempt to address the issue. If a registry has no budget to assess patients radiologically, only clinical assessment and revision rates can be used as measures of outcome. We were unable to establish a statistically significant relationship between the clinical and radiological outcome for our patients and this calls into question the sensitivity of a register which does not include radiological data. This view is supported by the failure of hip scores in the Swedish Hip Registry to reflect radiological findings.^{18,19}

The reasons for these radiological results of the Elite Plus are not clear. Surgical technique must obviously be considered. To define good surgical technique accurately is difficult, although assessment of immediate post-operative radiographs gives an objective measurement of cement mantles and the position of the implant. A number of radiological features have been noted, which might predict early prosthetic failure.²³ Most important of these is the grading of cementation by Barrack et al.¹⁰ Other important predictors of failure are a deficient cement mantle (< 1 mm),²⁴ stem-cortex contact and marked ($> 4^\circ$) varus or valgus positioning of the stem.^{20,21} However, it is well recognised that reliable radiological assessment of cementing is difficult and that observer variation is an issue.^{20,25,26}

The immediate post-operative radiographs in our series revealed few poorly cemented or poorly positioned implants. The Barrack grading was A or B in 99.4% of THAs and no statistically significant relationship between failure and grading could be established ($p = 0.221$; Table

IV). However, a defective femoral cement mantle was a statistically significant factor in loosening, supporting the views of other authors.^{20,21} We found that the type of cement was also significant, with Palacos LV performing significantly worse than Palacos R cement, a finding which agrees with other, well-established studies on low-viscosity cements.^{27,28} No significant statistical relationship could be established between varus or valgus placement of the femoral stem and loosening, nor between the surgical team or the grade of surgeon and subsequent loosening. The use of low-viscosity cement and the presence of defective cement mantles could be blamed for the evidence of loosening seen in our series. However, only seven of 159 (4%) THAs were secured with low-viscosity cement and only 11 (6.9%) had evidence of a defective cement mantle. This does not account for our rate of loosening of 31%.

In conclusion, we have concerns about the long-term survival of the Elite Plus, despite acceptable clinical results and revision rates. The definition of the radiological loosening of prostheses and the use of revision as an end-point in the medium term are also questionable. The lack of any statistical relationship between clinical and radiological outcomes should be considered carefully since, if joint registries are to be successful in identifying early prosthetic failures radiological surveillance must be included.

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