



Is the Charnley evolution working ? A five-year outcome study

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Two hundred consecutive primary total hip arthroplasties (196 patients) carried out between January 1994 and May 1995 using the Elite Plus® cemented femoral components (DePuy International, Leeds, UK) were enrolled in a prospective study. Fifteen patients were lost to follow-up. The patients were evaluated clinically using the Harris Hip Score (HHS) and radiographically.

The mean HHS was raised from 39.3 preoperatively to 89.6 at 5 years. Radiologically the mean femoral subsidence was 1.40 mm at 5 years. The mean annual rate of re-operation was 0.2%. There were no revisions for aseptic loosening.

In the present series, the Elite Plus hip arthroplasty has produced clinical and radiological results, which are comparable with the Charnley hip at five years.

INTRODUCTION

The Elite Plus femoral hip prosthesis was introduced in 1994, and was a direct development of the Charnley, which has experienced excellent clinical success (3, 12, 17, 19, 28). The Elite Plus was developed by examining the patterns of failure in total hip replacements, and preserving the features of the Charnley, which were believed to have contributed to its outstanding performance.

The Elite Plus design is based on the Charnley Flanged 40 stem ; the basic shape of the stem with the undercut flange and surface finish has been retained. The flange has been narrowed slightly in

the anterior-posterior plane. The main changes have been to the sizing of the stem, which has been based upon anthropometric data. Modularity has also been introduced with regard to a choice of femoral head material, i.e. ceramic or stainless steel. The stem itself is made of stainless steel.

The developments outlined above, together with the option to use the Elite Plus hip in conjunction with impaction bone grafting techniques, have helped to make the Elite Plus a successful prosthesis commercially but as yet we are unaware of any long-term follow-up reported in the literature. This study follows up 200 consecutive non-selected

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Table I. — Demographics

	Number	%
Total number of THA's	200	N/A
Number of patients	196	N/A
Number of bilateral patients	4	2%
First Date of Surgery	06-01-1994	N/A
Last Date of Surgery	26-05-1995	N/A
Gender – Female	123	62%
– Male	77	38%
Mean age at surgery in years (range)	68.41 (35 to 94)	N/A
Mean age of men in years (range)	68.42 (37 to 94)	N/A
Mean age of women in years (range)	68.40 (35 to 89)	N/A
Number under 50 years (range)	8 (35 to 49)	4%
Number under 65 years (range)	60 (35 to 64)	30%

Table II. — Primary Diagnosis

Diagnosis	Number	Percentage
Osteoarthritis	179	90%
DDH	6	3%
Rheumatoid arthritis	9	4%
Avascular necrosis	4	2%
Other	2	1%

patients of varying age range and different diagnoses, who have received the Elite Plus primary total hip replacement. These patients have been assessed postoperatively at 5-years, paying particular attention to the femoral component, as this is the component that has been modified from the Charnley total hip replacement.

PATIENTS AND METHODS

The first 200 consecutive primary total hip replacements with the Elite Plus prosthesis at this centre underwent surgery between January 1994 and May 1995. All the arthroplasties were carried out by the senior author (K.J.D) or under his supervision by four registrars in training. The group consisted of 123 females and 77 males, the female : male ratio being 1.6:1. The mean age at surgery was 68.4 years (range 35-94) with 8 patients (4%) under the age of 50. The demographic breakdown is given in table I. The primary diagnoses are given in table II.

In all the operations, a standard anterolateral approach was used and the femur was reamed by hand to accept the appropriate femoral reamer. The femur was irrigated using pulse lavage and occluded distally using a distal intra-medullary bone block. The irrigated femur was packed with a swab soaked in cooled saline and hydrogen peroxide and adrenaline. Normal viscosity cement (Palacos R with Gentamicin) was used with a Howmedica cement gun and was thumb pressurised.

All patients received the same type of Elite Plus femoral stem used in combination with either stainless steel (in those mainly over 65 years of age) (64%) or zirconia femoral heads (36%) and cemented Charnley Ogee cups, using normal viscosity cement.

Twenty-four patients (12%) had died by the time of the 5-year review from causes unrelated to the arthroplasty. There were two patients who required revision prior to the 5 year follow-up : one was because of deep infection and one for component malposition. Fifteen patients had been lost to follow-up ; they had all been reviewed at the 1-2 year follow-up and did not have any significant clinical nor radiological problems with their hips.

All patients were assessed prior to surgery using the Harris Hip Score (11). Postoperatively they were assessed at 5 years using the Harris Hip Score and the patient administered Oxford Hip Score Questionnaire (7). All patients attending clinic were also radiographically reviewed. For those patients that were unwilling or unable to attend the clinic for follow-up, a postal review was carried out using the Oxford Hip Questionnaire.

Using this method, 155 patients (159 arthroplasties) had a 5-year follow up. Of these arthroplasties, 132 had clinical follow-up and a further 27 had postal follow-up. Of these 159 arthroplasties, there were 119 sets of radiographs available for review (table III).

Radiographic Method

Of the 119 sets of radiographs available for review, a number of radiographs were excluded because of poor radiographic quality and difficulties with interpretation (the numbers excluded are specified in each of the sections with results).

The 6-week postoperative images and the latest anterior/posterior films of the pelvis were digitised into a Pentium III computer and analysed with "Imagika" software. Magnification was corrected by measurement of the femoral head (22.25 mm).

Assessment of the cement mantle was carried out and recorded on the basis of the seven femoral zones as described by Gruen *et al* (9).

Table III. — Type of Follow-Up at 5 Years

Method	Total	%
Clinical	132	83%
Postal	27	17%
Total	159	100%

Table IV. — Clinical Outcome by Harris Hip Score at 5 Years

Outcome Grade (HH Score)	Number	Percentages
Excellent (90-100)	89	68%
Good (80-89)	19	15%
Fair (70-79)	9	7%
Poor (< 70)	14	10%
Total	131	100%

Subsidence of the femoral component was determined by the use of a modification of the method described by Loudon and Charnley in 1980 (18). A vertical line was drawn through measured midpoints on the distal (straight) part of the stem to define the central axis of the stem. Lines were then drawn perpendicular to this at the centre of the head and at the tip of the greater trochanter. The difference between the 6-week and the latest radiographs was then calculated correcting for magnification, which gave a measured indication of stem subsidence.

Loosening of the femoral component was defined as subsidence of the implant greater than 6 mm (i.e. > 1.2 mm/year) over the five year follow up – which is an indication of loosening and failure (8), fracture of the cement or the presence of a radiolucent line between prosthesis and cement that had not been present on the immediate postoperative radiograph (10). Subsidence was defined as a difference in measurement on the initial and final radiographs of greater than 5 mm (3) or the presence of a superior-lateral radiolucent line of > 1 mm at the cement prosthesis interface.

Heterotopic ossification was analysed by using the Brooker classification (2).

RESULTS

Clinical Assessment

The mean pre-operative Harris Hip score was 39.3 (range 15-67), which increased by an average

of 50 points to a mean final score of 89.6 (range 47-100) at 5 years post-operatively. Of these 83% were excellent or good, 7% were fair and 10% were poor (table IV).

Of the 14 patients with a poor Harris hip score, one had the opposite hip affected, 4 patients were in excess of 90 years of age and the remainder had other conditions affecting normal walking (e.g. rheumatoid, degenerative back, knee or leg prosthesis). All these patients were category C in the Charnley modification of the Merle d'Aubigné grading system.

A summary of the 5-year post-operative Harris Hip scoring components is shown in table V.

At 5 years 87% of hip arthroplasty patients had either no pain or only occasional pain ; 63% (versus 8% pre-operatively) did not need any support and 75% had an unlimited walking distance compared to 4% pre-operatively.

The results of the Oxford Hip Questionnaire were also recorded at 5 years. The mean score obtained at five years was 27 with a range of scores 20 to 60. Ninety nine percent reported mild or no pain (table VI).

Radiographic Results

Femoral Component Cement Mantle Deficiency (CMD) and Cement Fractures : From the original postoperative radiographs the average cement mantle thickness was 3.2 mm and was in the range of between 2 and 5 mm in 67% of all measurement points used for this study in the 112 hips in this series. These results have been discussed in more detail in a previous paper by our research department (16).

In the five-year radiographs there were no cement fractures seen.

Subsidence : Out of the 119 sets of radiographs available for review, 22 had to be excluded because either the initial radiographs or the 5-year radiographs were of poor quality and difficult to interpret.

The average subsidence was 1.40mm (range -3.00 to 5.79 mm, 95% CI of 1.09 to 1.72, t test to determine difference from zero, $p < 0.0001$), at

Table V. — Summary of Harris Hip Data at 5 Years

	Score	Percentage of Hips
Pain (44 points)		
None	44	75%
Slight	40	12%
Mild	30	8%
Moderate	20	3%
Marked	10	1%
Disabling	0	—
Function (33 points)		
Limp		
None	11	63%
Slight	8	24%
Moderate	5	11%
Severe / Unable to Walk	0	2%
Support		
None	11	63%
Stick for long walks	7	19%
Stick for most of time	5	14%
1 crutch	3	—
2 sticks	2	2%
2 crutches / Unable to Walk	0	2%
Distance walked		
Unlimited	11	75%
400-600yds	8	11%
200-300yds	5	11%
Indoors only	2	3%
Bed to chair	0	—
Stairs (4 points)		
Normally	4	53%
With banister	2	37%
Any method	1	8%
Not able	0	2%
Shoes and socks (4 points)		
With ease	4	79%
With difficulty	2	19%
Unable	0	2%
Sitting		
Any chair for 1 hr	5	88%
High chair for 1/2 hr	3	11%
High chair for < 1/2 hr	0	1%
Public transportation/car (1 point)		
Able to use	1	87%
Not able to use	0	11%
Not Recorded	—	2%

5 years. The overall subsidence per year over this period was on average 0.28 mm.

There was only one hip that had stem subsidence of greater than 5 mm (3). This was a patient with rheumatoid arthritis with a final Harris Hip Score

of 61. Over the five years of follow-up, none of the hips had subsidence greater than 6mm, which is an indication of loosening and failure (8) i.e. > 1.2 mm/yr.

Cement bone radiolucency : There were 39.4% (47/119) of hips where areas of radiolucency (> 1 mm width) in the interface between bone and cement were seen in occasional Gruen zones when compared to the immediate postoperative radiographs. The majority of these were in Gruen zones 1 and 5.

There were no stems that were definitely or probably loose, i.e. none had lucency throughout the bone cement interface. There were however three possibly loose stems (i.e. the radiolucency extending for more than 50%, but less than 100% of the cement-bone interface). The Harris Hip Scores were excellent for two of these and fair for one. Thus under the criteria as used by Callahan *et al* (3), all but one femoral component was considered radiologically stable.

There was no osteolysis present in the femur. Of all the radiographs reviewed, 62 hips had no evidence of any heterotopic ossification. Ten patients had either Brooker III or IV (i.e. 8.4%) appearances on the radiographs.

Survivorship Analysis

Survivorship tables were constructed according to the method described by Armitage (1) and Dobbs (5). Confidence limits were calculated for the survivorship curves using the Greenwood method. The loss to follow-up of 7.5% in our series is similar to most survival analyses of joint replacement (5-10%) and thus we feel is comparable to other studies (20). The cumulative numbers of survivors were 98.7% at 5 years. The mean annual rate of re-operation in this series was 0.2%. However there was no revision due to prosthetic loosening. (fig 1 : Survivorship Analysis).

DISCUSSION

The Elite Plus stem was introduced as a progressive development of the Charnley total hip replacement. It has introduced the concept of a better

Table VI. — Summary of Oxford Hip Results at 5 Years

Item	Scoring Categories	Score	Percentage
During the past 4 weeks, how would you describe the pain you <u>usually</u> had from your hip ?	None	1	67%
	Very mild	2	12%
	Mild	3	12%
	Moderate	4	3%
	Severe	5	3%
During the past 4 weeks, have you had any trouble with washing and drying yourself (all over) <u>because of your hip</u> ?	No trouble at all	1	75%
	Very little trouble	2	15%
	Moderate trouble	3	7%
	Extreme difficulty	4	3%
	Impossible to do	5	
During the past 4 weeks, have you had any trouble getting in and out of a car or using public transport, whichever you tend to use, <u>because of your hip</u> ?	No trouble at all	1	60%
	Very little trouble	2	24%
	Moderate trouble	3	11%
	Extreme difficulty	4	4%
	Impossible to do	5	1%
During the past 4 weeks, have you been able to put on a pair of socks, stockings or tights ?	Yes, easily	1	61%
	With little difficulty	2	24%
	With moderate difficulty	3	8%
	With extreme difficulty	4	4%
	No, impossible	5	3%
During the past 4 weeks, could you do the household shopping <u>on your own</u> ?	Yes, easily	1	71%
	With little difficulty	2	9%
	With moderate difficulty	3	7%
	With extreme difficulty	4	9%
	Not at all – pain severe on walking	5	4%
During the past 4 weeks for how long have you been able to walk before <u>pain from your hip</u> becomes severe (with or without a stick) ?	No pain/more than 30 minutes	1	72%
	16 to 30 minutes	2	11%
	5 to 15 minutes	3	8%
	Around the house only	4	7%
	Not at all – pain severe on walking	5	2%
During the past 4 weeks, have you been able to climb a flight of stairs ?	Yes, easily	1	60%
	With little difficulty	2	18%
	With moderate difficulty	3	13%
	With extreme difficulty	4	5%
	Not at all – pain severe on walking	5	3%
During the past 4 weeks, how painful has it been for you to stand up from a chair after a meal (sat at a table) <u>because of your hip</u> ?	Not Recorded		1%
	Not at all painful	1	71%
	Slightly painful	2	13%
	Moderately painful	3	9%
	Very painful	4	7%
During the past 4 weeks, have you been limping when walking <u>because of your hip</u> ?	Unbearable	5	–
	Rarely/never	1	58%
	Sometimes, or just at first	2	20%
	Often, not just at first	3	5%
	Most of the time	4	11%
During the past 4 weeks, have you had any sudden, <u>severe</u> pain – ‘shooting’, ‘stabbing’ or ‘spasms’ – <u>from the affected hip</u> ?	All of the time	5	5%
	Not Recorded		1%
	Not at all	1	81%
	Only 1 – 2 days	2	3%
	Some days	3	11%
During the past 4 weeks, how much has <u>pain from your hip</u> interfered with your usual work (including housework) ?	Most days	4	3%
	Every day	5	1%
	Not Recorded		
	Not at all	1	72%
	A little bit	2	11%
During the past 4 weeks, have you been troubled by <u>pain from your hip</u> in bed at night ?	Moderately	3	9%
	Greatly	4	5%
	Totally	5	3%
	Not at all	1	75%
	Only 1 – 2 days	2	7%
	Some days	3	13%
	Most days	4	4%
	Every day	5	1%

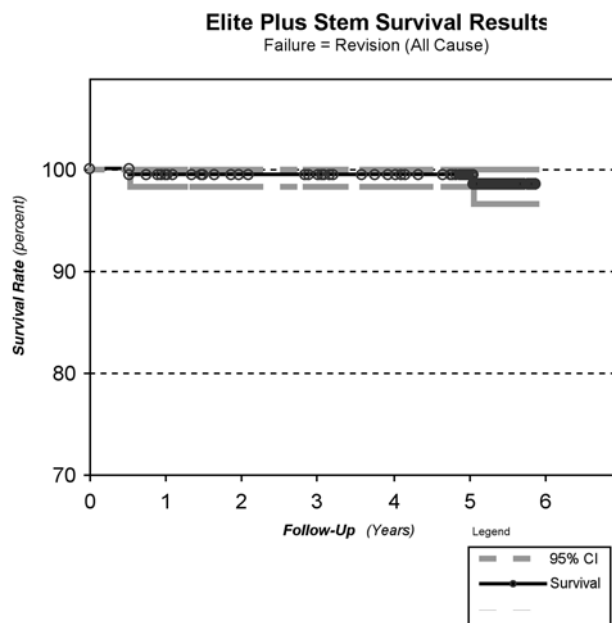


Fig. 1. — Survivorship analysis of the first 200 Elite plus total arthroplasties (Graph extended beyond 5 years as study is ongoing and incorporates the latest data).

cement mantle and modularity, preserving the established benefits of the Charnley arthroplasty. This study of the first 200 hips shows an excellent short to medium term survivorship and clinical and radiological results, which are comparable if not better than, those documented for the Charnley after a similar time period. The Harris Hip Scores compare favourably with published data for the original Charnley prosthesis at 5 years (17) and other cemented hips such as the Exeter (27). The Elite Plus also compares well in this respect to other types of hips such as the uncemented HA coated hips studied by Sharkey *et al* in 1998 (23). This achieved good or excellent results in 79% compared to this study's 83%. Similar results have also been achieved in comparison to the AML implant (15).

The radiographic reviews in this study using the stricter criteria defined by Callaghan *et al* show that almost all the femoral components (118/119) analysed were considered radiologically stable. If the criteria defined by Freeman *et al* were used for this study, none of the femoral components would

be regarded as potentially loose. The mean migration of 0.28 mm/year for the stem compares favourably with other studies – 0.3 mm/year – (6) and both these would indicate the potential for an improved long-term survivorship.

Heterotopic ossification with either Brooker III or IV was noted in 8.4%. These did not cause any significant functional restrictions or limitations of movements of the hip joint. The Harris Hip Scores for the Brooker IV hips were all greater than 80.

Survival of the Elite Plus at 5 years is comparable to survival curves of the Charnley in both the Norwegian and Swedish hip registers. The mean annual rate of re-operation in our series was 0.2% for any reason and 0% for stem loosening. These figures are also favourable when compared with other studies (for example Exeter hip and HA-coated Freeman hip) and fall well within the categories defined by the National Institute for Clinical Excellence (NICE) guidelines for total hip arthroplasty (24, 27).

Overall this study shows that the Elite Plus stem design inserted using a sound and uniform technique can be as good as other modern total hip replacement stems at 5 years and appears to have a low risk of future predicted failure.

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