The premature failure of the Charnley Elite-Plus stem

A CONFIRMATION OF RSA PREDICTIONS

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We performed a clinical and radiological study to determine the rate of failure of the Charnley Elite-Plus femoral component. Our aim was to confirm or refute the predictions of a previous roentgen stereophotogrammetric analysis study in which 20% of the Charnley Elite-Plus stems had shown rapid posterior head migration. It was predicted that this device would have a high early rate of failure.

We examined 118 patients at a mean of nine years after hip replacement, including the 19 patients from the original roentgen stereophotogrammetric study. The number of revision procedures was recorded and clinical and radiological examinations were performed.

The rate of survival of the femoral stems at ten years was 83% when revision alone was considered to be a failure. It decreased to 59% when a radiologically loose stem was also considered to be a failure. All the patients previously shown in the roentgen stereophotogrammetric study to have high posterior head migration went on to failure. There was a highly significant difference ($p = 0.002$) in posterior head migration measured at two years after operation between failed and non-failed femoral stems, but there was no significant difference in subsidence between these two groups.

Our study has shown that the Charnley Elite-Plus femoral component has an unacceptably high rate of failure. It confirms that early evaluation of new components is important and that roentgen stereophotogrammetric is a good tool for this. Our findings have also shown that rapid posterior head migration is predictive of premature loosening and a better predictor than subsidence.

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The Charnley low-friction implant (De Puy International, Leeds, UK) is a successful device, with clinical follow-up of over 30 years.^{1,2} In this time many small modifications of design have been undertaken including changes in surface finish and the introduction of a flanged version.³ The Charnley Elite-Plus femoral component (De Puy International) was introduced in 1993, with the intention of preserving the major features of the Charnley stem and enhancing survival. Changes in design included a modification of the shoulder flange to reduce subsidence,⁴ altered geometry of the stem and surface finish, improved material, and new instrumentation.⁵

We undertook a roentgen stereophotogrammetric analysis (RSA) of the Charnley Elite-Plus femoral component, shortly after its release. The aim was to measure migration and to predict the long-term outcome. The migration of the Charnley Elite-Plus was also compared with that of the Exeter stem. In this study we measured the three-dimensional migration over two years of the head, shoulder

and tip of the implant to an accuracy of 0.3 mm. We analysed the distal migration or subsidence of the implant since this had been shown to be related to early failure. In addition, we focused on the posterior head migration, which is associated with internal rotation of the stem relative to the femoral shaft (Fig. 1). Since internal rotation is related to loosening we felt that posterior head migration would be predictive of failure. Our study confirmed that the manufacturers had fulfilled their design brief and that the Charnley Elite-Plus stem, with subsidence of centroid of about 0.22 mm,⁶ during the first year; about half that of the conventional Charnley prosthesis.⁷ However, our study also identified a substantial posterior head migration of the Charnley Elite-Plus stem, which was greater than that found with the Exeter stem. In addition, we identified a subgroup (20%) of Charnley Elite-Plus patients who had a significantly higher rate of posterior head migration ($p < 0.05$), a mean of approximately 2.8 mm per year in comparison with 0.3 mm per year for the

Fig. 1

Diagram showing the relationship between internal rotation of the stem about the femoral shaft axis and posterior head migration (PHM).

remainder of the patients. We predicted that overall the implant would have a high rate of failure and that the subgroup of patients with high rates of posterior head migration would go on to have premature fracture of the component.⁶ We advised surgeons not to use this device.

There are no long-term clinical follow-up data on the Charnley Elite-Plus femoral component. Early clinical studies have conflicting findings, with some suggesting a similar outcome to that of the conventional Charnley stem,⁸ while others suggest a worse outcome.^{9,10}

Our aim, therefore, was to evaluate the outcome of the Charnley Elite-Plus femoral component clinically and radiologically at ten years, and to determine if the predictions of the previous RSA study were correct.

Patients and Methods

Between 1994 and 1997, 118 patients received the Charnley Elite-Plus femoral component at the Nuffield Orthopaedic Centre. These patients included all 19 Charnley Elite-Plus patients from the RSA study which began in 1994. In all the patients a Charnley Elite-Plus femoral component was implanted through a Hardinge approach using low-viscosity cement. The femoral canal was prepared in the recommended fashion, washed out and a peroxide swab was used to dry the canal. Cement was non-vacuum mixed. A cement restrictor was used, followed by retrograde filling of the

canal using a cement gun. The stem was inserted as the cement began to thicken and a proximal seal was not used. A 28-mm head was used in all patients. Charnley LPW (De Puy International) or Ogee (De Puy International) cemented acetabular components were used. Details of the patients in both the general and RSA groups are given in Table I.

Ethical approval for the follow-up study was obtained and the patients were contacted between May and November 2004. They were interviewed and asked whether they had undergone a revision procedure. If so, their records were scrutinised to determine the cause. If the original hip was still in place they were invited to attend for radiological and clinical assessment. Radiological examination consisted of anteroposterior and lateral radiographs of the hip which were scored according to the classification of Gruen, McNeice and Amstutz.¹¹ Patients with a radiolucent zone 2 mm or more in width in three or more Gruen zones were counted as radiological failures.¹¹ Clinical assessment was performed using the Oxford, Harris and Charnley scoring systems.¹²

The number of failures was recorded, as was the mode of failure and the time to revision. Life-table analysis was then performed with death and loss to follow-up recorded as censored observations.

The data from our previous RSA study¹³ were also examined in relation to the recorded failures. Karrholm et al,¹⁴ on the basis of their RSA studies, stated that subsidence of the femoral stem was highly predictive of failure for an anatomically cemented stem. In our study we were interested to see which RSA measurements were more predictive of failure of the Charnley Elite-Plus femoral component, either subsidence or posterior head migration. The patients from the RSA study were divided into failed and non-failed groups. Both radiological failures and revisions were included in the failed RSA group. The overall subsidence of the femoral stem in the first two years after operation was calculated for each patient. We measured the three-dimensional migrations of the head, shoulder and tip and calculated the overall subsidence as the distal migration of the centroid formed by these three landmarks on the stem. The posterior head migration over the same two-year post-operative period was noted.

Statistical analysis. The subsidence and posterior head migration data were compared between the failed and non-failed RSA groups using a Mann-Whitney test. All statistical analyses were performed using SPSS 12.0 (SPSS Inc., Woking, UK). $p < 0.05$ was considered to be significant.

Table I. Details of the patients in the Charnley Elite-Plus RSA* group and in the non-RSA Charnley Elite-Plus group

	Total (n = 118)	Charnley Elite-Plus RSA group (n = 19)	Non-RSA Charnley Elite-Plus group (n = 99)
Mean age in yrs (range)	69.5 (43 to 88)	68 (54 to 78)	71 (43 to 88)
Mean time to follow-up in yrs (range)	9.1 (7.9 to 9.8)	9.2 (8.2 to 9.8)	8.9 (7.9 to 9.8)
Mean cup size in mm (range)	46 (43 to 53)	46 (43 to 53)	46 (43 to 53)
Cup allocation LPW:OGEE (%)	69:31	72:28	65:35

* RSA, roentgen stereophotogrammetric analysis

Table II. Life table for failures of the femoral component

Interval (yrs)	Number at start of interval	Number withdrawn	Stem failures	Died	Number at risk	Surviving proportion	Cumulative survival at interval end	SEM	95% CI*
0 to 1	111	0	1	0	111	0.99	0.991	0.009	1.000 to 0.973
1 to 2	110	2	1	1	109	0.99	0.982	0.013	1.000 to 0.957
2 to 3	107	1	1	1	106.5	0.99	0.973	0.016	1.000 to 0.942
3 to 4	105	3	1	3	103.5	0.99	0.963	0.018	0.998 to 0.928
4 to 5	101	1	1	1	100.5	0.99	0.954	0.020	0.994 to 0.914
5 to 6	99	4	1	4	97	0.99	0.944	0.022	0.998 to 0.900
6 to 7	94	4	1	4	92	0.99	0.934	0.024	0.982 to 0.886
7 to 8	89	8	1	3	85	0.99	0.923	0.026	0.975 to 0.871
8 to 9	80	32	4	0	64	0.94	0.865	0.037	0.938 to 0.792
9 to 10	44	43	1	1	22.5	0.96	0.827	0.052	0.929 to 0.725

* CI, confidence interval

Table III. Results for the 19 patients in the Charnley Elite-Plus roentgen stereophotogrammetric analysis (RSA) study including those with a high and low posterior head migration, respectively (> 2.8 mm/yr; $n = 4$; < 0.8 mm/yr; $n = 15$)

	Revised		Radiological		Clinical scores		
	Number	%	Number	%	Oxford	Charnley	Harris
All RSA patients	2	11	3	16	19.9 (13 to 50)	14.9 (9 to 18)	49.3 (23 to 97)
High PHM* subgroup	2	50	2	50	49.5 (49 to 50)	10 (9 to 11)	29.6 (28.4 to 30.7)
Low PHM subgroup	0	0	1	7	16 (13 to 21)	15.6 (10 to 18)	51.9 (22.9 to 96.8)

* PHM, posterior head migration

Results

A total of 18 patients died and seven were lost to follow-up. The mean time to follow-up in all patients was 9.0 years (7.9 to 10.9). In total, failure due to aseptic loosening occurred in 14 patients (10% of study cohort) and one acetabular revision was performed for aseptic loosening. Of these 14 failed hips, 11 had revision for loosening of the femoral stem, one for a periprosthetic fracture which was deemed to be secondary to the loosening. One patient died while waiting for revision and one declined revision. Survival analysis showed a survival rate of 83% (95% confidence interval (CI) $\pm 10\%$) for the femoral component at ten years in all patients (Fig. 2, Table II). Twelve patients had significant signs of radiological loosening, with radiolucency in three or more Gruen zones. The survival rate at ten years fell to 59% (95% CI $\pm 15\%$) when radiological failures were included (Fig. 2). The mean Oxford hip score at ten years was 22.6 (12 to 56), the mean Charnley hip score 13.4 (5 to 18) and the mean Harris hip score was 48.4 (22 to 97).

Failure due to aseptic loosening occurred in two of the RSA study patients. Three other patients had signs of radiological loosening. Both patients who had been revised and two with radiological loosening were identified as those who had a high rate of posterior head migration in the previous RSA study (Table III). Combining revision and radiological failure, there was a failure rate of 100% in the patients with a high posterior head migration and of 7% in those with a low posterior head migration ($p < 0.001$). The patients with a high posterior head migration and radiological failure had worse Oxford ($p < 0.01$), Charnley ($p < 0.01$) and Harris hip scores ($p = 0.21$) than those with a low posterior head migration (Table III).

Fig. 2

Life table analysis curve showing predicted survival at ten years for the Charnley Elite-Plus stem. Predictions are based on failure of the stem and also on stem failure plus radiological failure. The 95% confidence intervals are shown. The curves are slightly horizontally displaced for illustrative reasons.

The failed RSA patients had a significantly greater (12-fold) posterior head migration ($p = 0.002$) than the non-failed RSA patients (Fig. 3) at two years after operation. The failed group also had greater subsidence (threefold) than the non-failed group (Fig. 4), but this was not significant ($p = 0.104$).

Fig. 3

Mean (95% confidence interval) posterior head migration for the failed and non-failed RSA groups. RSA, roentgen stereophotogrammetric analysis.

Fig. 4

Mean (95% confidence interval) subsidence of the femoral stem for the failed and non-failed RSA groups. RSA, roentgen stereophotogrammetric analysis.

Discussion

We anticipated that the Charnley Elite-Plus femoral component would have a high rate of failure, and also that the femoral components with a high posterior head migration in the previous RSA study⁶ would be more likely to loosen than those with a low posterior head migration. Our study confirmed both of these predictions and, additionally, that the early assessment of implants is essential and that RSA is an accurate method for predicting loosening of an implant.

The Charnley Elite-Plus femoral components in our study have an unacceptably high rate of revision and radiological failure. The failure rate exceeds that published for the Charnley stem. The reason for the higher failure rate could relate to changes in design or surgical technique or cement. At least one centre appears to have been able to achieve good short-term results with the Charnley Elite-Plus femoral component,⁸ which suggests that some of the failures may be related to surgical technique. However, we have found that both the clinical outcome and the RSA data for the Charnley Elite-Plus stem are considerably worse than those for the Exeter stem, for which we use similar surgical techniques. This suggests, therefore, that the design of the stem of the Charnley Elite is not ideal. We therefore stand by our recommendation that the Charnley Elite-Plus femoral component should not be generally used.

It is not clear why the Charnley Elite-Plus femoral component has performed poorly. Our studies have shown that fundamentally it is rotationally unstable. This instability probably results from the many small changes made at its introduction. For example, the femoral stem is more cylindrical and anatomical than the conventional Charnley design. The reaming for the Charnley Elite-Plus femoral stem is in-line with cylindrical reamers. The enhanced

shoulder flange of the component gives decreased subsidence compared with the Charnley stem, and this may affect the way in which load is transmitted between the implant and bone.

We predicted after the two-year RSA study that the Charnley Elite-Plus femoral component would not be successful.⁶ It has taken approximately ten years for an adequate clinical study to reach the same conclusion. During the intervening period, many Charnley Elite-Plus components have been implanted and a substantial number of these will fail or have failed. This reinforces the need for early RSA studies of modifications to hip replacement femoral stems even if such changes are deemed to be minor. Furthermore, in the event of an adverse prediction from an RSA study, widespread marketing of femoral stems should be deferred until satisfactory screening studies have been completed.

Before our RSA study was undertaken it had been clearly demonstrated that RSA could be used to predict failure of a femoral stem.¹⁴ However, it was believed that subsidence was the best predictor of failure. We found, however, that the Charnley Elite-Plus femoral component subsided a mean of 0.3 mm over two years which was less than the amount of subsidence for a Charnley⁷ or Exeter femoral stem.¹³ This would suggest that the Charnley Elite-Plus femoral component is superior to the Charnley or Exeter. Our opinion has been that internal rotation of the femoral stem within the bone is the main cause of failure in cemented hip replacement. We have shown that the implants which failed had on average, 12 times more posterior head migration ($p < 0.002$) than those which did not, whereas subsidence was only three times greater ($p = 0.104$). This suggests that an abnormally large posterior

head migration is a better predictor of premature failure than abnormally large subsidence. It cannot be measured from uniplanar radiographs. Only RSA can accurately quantify this movement. In addition, our findings confirm that internal rotation of the femoral stem is a potent cause of failure for the Charnley-Elite femoral component.

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