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ORIGINAL STUDY

Primary total hip arthroplasty with hydroxyapatite coated titanium femoral stems. Does design philosophy influence long term outcome ? : results of a prospective randomised controlled trial with follow-up of 10-15 years

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We present results of a prospective randomised controlled trial examining two cohorts of patients treated with proximally (Group A) and fully coated (Group B) femoral components with long term follow up. Patients were reviewed preoperatively and 6, 12, 26 and 52 weeks post operatively then annually. The Merle d'Aubigne Postel (MDP) hip score was used to assess clinical outcome. A Visual Analog Score (VAS) was also recorded. Statistical calculation was performed using the student's t- test and Kaplan Meier survival analysis. One hundred and four patients were included in group A and 103 patients in group B. Mean age was 60.4 years and 60.8 years respectively. Mean follow-up was 12.9 years. Mean pre-operative MDP scores were 8.8 and 9.5 in Groups A and B respectively. Mean pre-operative VAS score 7.8 and 7.4 respectively. At final follow up mean MDP and VAS were 16.9, 16.6 and 2.1, 2.4 respectively. Three femoral revisions occurred in Group A. Seven revisions occurred in Group B. Survival of the femoral component with revision for any reason as the end point was 96% in Group A and 94.8% in Group B. Both components produced symptomatic relief and similar revision rates. Thigh pain occurred only in Group A.

Keywords : Prospective ; randomised ; fully coated ; long term ; hydroxyapatite.

INTRODUCTION

Hydroxyapatite (HA) coated femoral components have been used in total hip arthroplasty (THA) for over two decades. Proposed advantages of HA coated stems include attainment of early stability (*1*), reduced micromotion of the prosthesis in the early post operative period and accelerated bone ongrowth to the surface of the prosthesis (*2*).

Encouraging medium to long term results have been reported with HA coated components (*3,4*). These results have encompassed a variety of different stems, each with differences in the extent,

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purity, crystallinity and thickness of the hydroxyapatite in which they are coated. These properties can all affect potential in vivo delamination of the HA (*5*). and influence loosening and failure. The main criticism of HA coated components has been the risk of and consequences of delamination hence examining the survival of partial and fully coated stems bears relevance to clinical practice.

Several authors have compared radiological results and revision rates for HA and non HA coated components (*6,7,8*). To our knowledge there have been no prospective studies examining the effect of the extent of HA coating on clinical results of uncemented femoral components. The aim of this study is to present the clinical and radiological results of a group of patients treated with fully HA coated femoral components compared to a group treated with partially HA coated femoral components at a minimum of ten years follow up.

PATIENTS AND METHODS

This prospective randomised controlled trial was performed between 1996 and 2001. Approval was granted by our ethics committee. All patients undergoing primary total hip arthroplasty (THA) in our unit were randomised to receive either a proximally coated femoral stem (Omnifit HA, Stryker, Mahwah NJ, USA) (Group A) or a fully coated (Furlong, Joint Replacement Instruments, Sheffield, UK) femoral component (Group B). Randomisation was achieved by assigning a number to each patient involved in the study and drawing a number from a hat in the operating theatre prior to surgery.

The Securfit uncemented acetabular component (Stryker, Mahwah NJ, USA) was used in group A. In group B either the Furlong Ultra high density polyethylene acetabular component or an HA coated threaded cup (Joint Replacement Instrumentation Ltd., UK) was used. A 32 millimetre modular femoral head was used in all cases.

Two hundred and seven consecutive patients were included. One hundred and four patients were assigned to group A and 103 to group B (Table I). All operative procedures were performed by or under the direct supervision of a consultant orthopaedic surgeon (JANS, ABM, BLH). All procedures were performed by an anterolateral approach in an operating theatre with laminar flow. Patients were routinely allowed to fully weight bear from day 1 post surgery and all underwent a similar rehabilitation programme prior to discharge. They were reviewed at 2 weeks, 6 weeks, 3 months and 6 months and one year post operatively and annually thereafter.

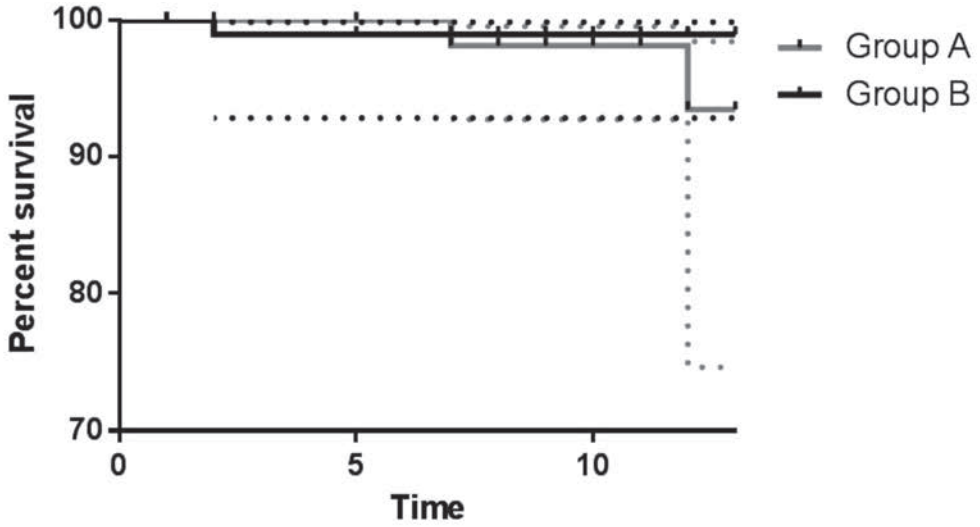
Table I. — Demographics of our patient cohorts

	Group A	Group B
Males	56	42
Females	48	61
Age/ years (range)	60.3 (33-72)	60.8 (24-76)
Pre operative diagnosis (numbers of patients)		
Primary osteoarthritis (OA)	100	99
Developmental dysplasia	2	1
Avascular necrosis	1	1
Rheumatoid arthritis	1	0
Post traumatic OA	0	1

Clinical and radiological assessments were made at each follow up. Pain, mobility and function were assessed using the Merle D'Aubigne Postel scoring system. Patient satisfaction was assessed using a visual analogue score (VAS) where 10 represented the most symptomatic and least satisfied patient and 1 represented the least symptomatic and therefore most satisfied patient.

Anteroposterior radiographs of the pelvis and lateral radiographs of the operated hips were obtained at each visit. Radiographs were examined for evidence of stem migration (measured as the difference between the shoulder of the implant and the greater trochanter), signs of loosening and integration as well as the presence of heterotopic bone. Loosening was suggested by the presence of lytic lesions and radiolucent lines. Spot welds at the bone implant interface and trabeculae extending to the uncemented stem as described by Engh *et al* (*9*) indicated solid fixation. Lytic lesions were defined as balloon-shaped lucencies around the prosthesis. Radiolucent lines were defined as linear lucencies at the bone-prosthesis interface > 2 mm wide and occupying $> 30\%$ of any Gruen zone. Significant stress shielding was considered to be present if there was selective resorption of bone from the calcar region of the femoral neck. Heterotopic ossification was classified according to the system of Brooker *et al* (*10*).

Statistical analysis was performed using the student t-test. The level of significance was set at $p = 0.05$. Survival analysis was performed using the Kaplan Meier method (Graph Pad software, CA, USA) and 95% confidence intervals (CI) were calculated.



Time (Years)	0	1	5	7	8	9	10	11	12	13
Group A	104	104	103	105	96	94	92	29	21	11
Group B	103	103	102	94	83	81	79	29	21	11

Fig. 1. — Kaplan Meier survival graph showing revision with aseptic loosening of the femoral component as the end point. The number of patients at risk is also shown for each time period.

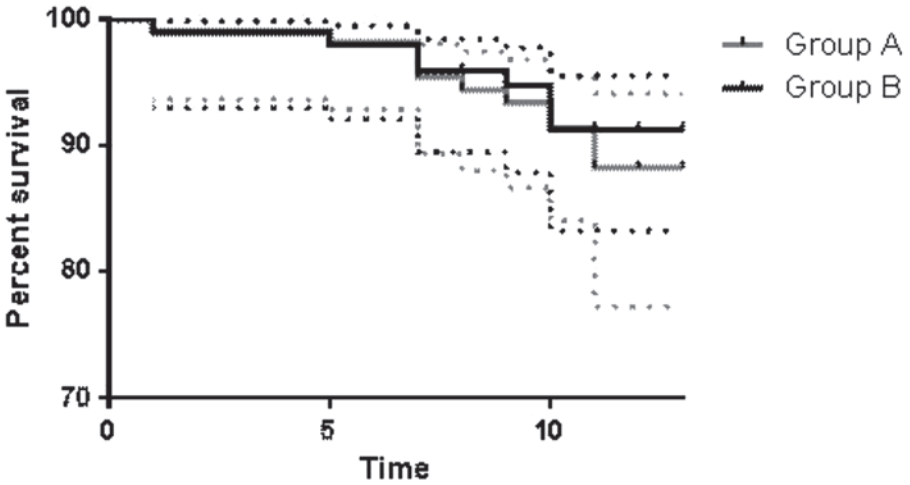
RESULTS

Two hundred and seven patients were included in this study. One hundred and four (56 males, 48 females) were randomised to group A and 103 (42 males, 61 females) to group B. Twenty one patients (10%) had bilateral procedures. Of these, 9 patients had one of each prostheses inserted (Fig. 3). The average age of patients included in group A and B were 60.4 years (range 33 years-72 years) and 60.8 (range 24 years-76 years) respectively. Average duration of follow up was 12.9 years (range 10-15 years). Patient demographics are shown in Table I.

Group A

Two patients (1.9 %) from this group were lost of follow up at 10 and 12 years as they moved out of the area. They were both reviewed within one year of their departure and were therefore included in the study. Average MDP score was 8.8 (range 3-16) pre operatively and 16.7 (13-18) at final follow up ($p < 0.0001$). Mean VAS score was 7.8 (range 1-10) before surgery and 2.1 (range 0-6) at final follow up ($p < 0.0001$). Nine patients in this group underwent revision surgery. The femoral component was revised in 3 cases. Reasons for revision of the femoral component included early dislocation (1 femoral component was revised to a higher offset stem at 1 week after the index procedure for recurrent dislocation), deep infection one year after the primary procedure (1 stem) and aseptic loosening at 5 years (1 stem). Six isolated acetabular component revisions were performed for aseptic loosening between 8 and 11 years after their index procedure.

Indications for revision are presented in table II. Survival of the femoral component at a mean of ten year was 96% and 92.9% at 12.9 years post op (95% CI 74.4%-98.4%) (Fig. 1). Survival with revision



Time (Years)	0	1	5	7	8	9	10	11	12	13
Group A	104	104	104	103	96	94	92	29	21	11
Group B	103	102	95	94	83	81	79	29	21	11

Fig. 2. — Kaplan Meier survival graph showing revision for any reason as the end point. The number of patients at risk is also shown for each time period.

for aseptic loosening as the end point was 98% (95% CI 92%-100%). If revision for any reason is considered to be the end point then survival at an average of 10 years was 91.3% (95% CI 84.3%-95.3%) and 881.% at an average 12.9 years post surgery (95% CI 77.4 %-94.1%) (Fig. 2).

The 10 year survivorship figures are presented for each component because the numbers at risk at 12 years are small compared to numbers at risk at 10 years post surgery.

Fourteen complications occurred in this group (Table III) including 1 intraoperative femoral fracture which was treated successfully with bed rest and protected mobilisation using crutches for 6 weeks post surgery. One patient suffered a pulmonary embolism at 5 weeks post operatively which was successfully managed with anticoagulants. Three dislocations occurred at one week, 1 year, and 6 years after the index procedure. The first case was thought to be due to a reduced femoral offset leading to instability. This was managed by revising the femoral component to one with a higher offset. The second case was due to suboptimal acetabular anteversion and required revision of the acetabular component. The third case was the result of a fall at 6 years post surgery. This was managed with closed reduction and an abduction brace for 6 weeks. Neither case has recurred. Four patients complained of anterior thigh pain in this group. This pain was progressive and restricted activity in one case.

Group B

No patients in this group were lost to follow up. Average MDP score pre operatively was 9.5 (range 3-14) and 16.6 (range 11-18) at the time of final follow up ($p < 0.0001$). Mean VAS score was 7.4 (range 1-10) pre operatively and 2.4 (range 1-6) and time of final follow up ($p < 0.0001$). Seven patients in this group required revision surgery (Table II). In 3 of these cases the femoral component was revised. These were due to a periprosthetic fracture which occurred secondary to a fall (1 case), subsidence of the femoral component in a patient with Paget's disease (1 case) and one patient who had deep infection which occurred 2 years post operatively. The

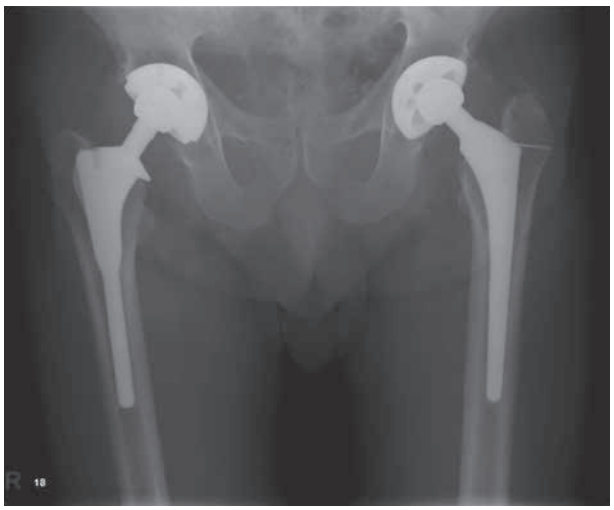


Fig. 3. — Bilateral total hip arthroplasties with the JRI Furlong fully HA coated prosthesis (Right side) and the proximally coated Omnifit prosthesis (Left side), uncemented acetabular components have been used bilaterally.

Table II. — Indications for revision

Indication	Group A (N = 9)	Group B (N = 7)
Acetabular component		
Aseptic loosening	7	4
Dislocation	1	0
Ceramic liner fracture	0	1
Infection	1	1
Femoral component		
Aseptic loosening	1	1
Infection	1	1
Dislocation	1	0
Periprosthetic fracture	0	1

patient with Paget's disease was treated by revision of his femoral component to a cemented stem. This was considered to be a failure due to aseptic loosening as infection was ruled out.

Survival of this femoral component was 94.8% at 10 years (95% CI 87.9%-97.8%) and 91.3% at a mean 12.9 years follow up (95% CI 81.3%-95.7%) with revision for any reason as the end point (Fig. 2). If aseptic loosening of the femoral component is considered the end point then survival of this femoral component is 99% at 10 years (95% CI 93.1%-99.5%) and 98.9% at 12.9 years post surgery (95% CI 93.0%-99.2%) (Fig. 1).

Table III. — Complications noted in both groups

Complications	Group A (N = 14)	Group B (N = 15)
Deep vein thrombosis (DVT)	3	1
Pulmonary embolism (PE)	1	2
Calcar crack	4	9
Acetabular fracture	0	1
Symptomatic Leg length discrepancy	0	2
Anterior thigh pain	4	0
Dislocations	3	0

Fifteen complications were recorded in this group (Table III). Two pulmonary emboli occurred which were treated medically, 9 cracks in the calcar region of the femur occurred during stem insertion. These were recognised at the time of insertion and treated by non weight bearing mobilisation with patients using crutches for the first 6 weeks post surgery. One undisplaced acetabular fracture occurred during impaction of the uncemented cup. This was treated by restricting weight bearing through he affected side for 6 weeks post surgery. The patient was then allowed to resume normal ambulation. No long term sequelae have resulted from these fractures. No dislocations occurred in this group.

Nine patients had bilateral THAs with one of each femoral component. These patients reported no discernable functional differences between their hips but one patient reported anterior thigh pain on the side with the partially coated femoral component.

At final follow up RLL's were noted in 3 femoral components in group A. These were found in zones 1 and 2 (2 cases) and zones 1 and 7 (1 case). These were noted within the first 10 years and were non progressive. They were not associated with clinical symptoms. No RLL's were noted in the fully coated cohort. In both groups bone trabeculae extended to the HA coated segment of the femoral stem. In group B spot welds were noted at the tip of the femoral component. No femoral intramedullary lytic lesions were found in either group.

Radiolucent lines were noted in zone 1 in 3 acetabular components in group A and 2 in group B at final assessment. These were not associated with clinical symptoms. They continue to be reviewed.

DISCUSSION

HA coating was introduced in order to augment osseointegration of the prosthesis to native bone. Involvement of calcium hydroxyapatite in the metabolic reaction of bone has been demonstrated. As a result of this some authors consider HA to provide a form of biological fixation which is separate from cemented as well as porous coated uncemented implants (*11*). This is the first prospective study to assess femoral stems with variations in their extent of HA coat and relate this to medium to long term survival to our knowledge. These results have to be interpreted with caution however as there were other design differences between the stems including their geometry.

New bone formation and bridging trabeculae extending across the bone prosthesis interval has been noted over 10% of the surface area of a hydroxyapatite coated femoral component as early as 3 weeks post surgery (*2*). Improved clinical function has also been reported at 6 months post surgery with hydroxyapatite coated components when compared to non coated stems (*12*). While no long term survival benefit has been demonstrated with the use of hydroxyapatite when compared to non hydroxyapatite stems, good medium and long term results have been reported with fully HA coated femoral components (*4,13*) as well as partially coated stems (*11*). The effect of the extent, quality and thickness of hydroxyapatite coating on fixation, survival and as a potential seal to the ingress of wear particles is not clear however.

Patients in groups A and B were well matched (Table I). There were more females in group B but this was not statistically significant ($p = 0.97$) and we believe this occurred by coincidence. Very few patients were lost to follow up. Randomisation was performed in an attempt to control for potential confounding variables between these groups. Both cohorts reported excellent clinical and functional results at final follow up as evidenced by improvements in their MDP and VAS scores. These improvements were noted from the early post operative period and maintained to the final review. At no point in the follow up period was a significant difference in outcome scores noted between the 2 components.

A major criticism of hydroxyapatite has been its solubility in vivo. This has been shown to occur at approximately 8 years post implantation and is independent of patient age (*5*). Theoretically as the HA layer dissolves, it can delaminate from the femoral stem with particles entering the bone prosthesis interval leading to loosening and failure. If this did indeed occur, our results suggest that there is no impact of the in vivo absorption process of HA on clinical function and survivorship of these components at 10-15 years post surgery, suggesting that this is potentially a theoretical risk rather than a real problem. The absence of intramedullary osteolytic lesions in the femora of both groups also support this. Patients continued to function without complaints as the corticomedullary ratio of their bone increased and osteopaenia occurred. Radiologically the presence of spot welds and trabeculae extending to the surface of the prosthesis in both groups suggested that a solid bone prosthesis bond was maintained. Similar radiological findings have also been reported by other authors (*8*).

Radiolucent lines were noted in zones 1,2 and 7 in 3 partially coated stems (2.9%). These were non progressive on serial radiographs and not associated with pain. In all stems with RLL'S the acetabular cups had been revised for aseptic loosening. In one case RLL's were noted in zones 1-6. The patient was symptomatic and required revision of this stem. No RLL's or stem migration were noted in the fully hydroxyapatite coated group. The thickness of the HA coat on the partially coated stem is 50 micrometers versus 150 micrometers on the fully coated prostheses. It might be that a thicker and more complete hydroxyapatite coating provides a better seal against wear particles. The two partially coated stems which subsided at 2 years stabilised on subsequent radiographs and continue to be followed. Anterior thigh pain occurred only in the partially coated group. These were not associated with reactive lives or RLL's around the stem, however it is pos-

sible that the smooth, uncoated diaphyseal segment of this stem is less stable in the medullary canal than the fully coated component resulting in micromotion, fibrous integration and pain. Infection and aseptic loosening have been ruled out in the patient whose activities have been limited by anterior thigh pain. She has refused revision surgery and continues to be monitored.

Nine calcar cracks occurred in the group treated with JRI components. One case occurred while a consultant was performing the procedure and all others occurred while trainees were performing the procedure. In 2 cases the lateral keel cutter had not been used during rasping. These were all managed by non weight bearing mobilisation using crutches during the initial 6 week post operative period.

Revision rates were similar for both stems at the final follow up period suggesting that the extent or thickness of the HA coat does not significantly affect overall survivorship in the medium term.

This paper has several limitations. The geometry of the stems used are different. It is possible that the results can be influenced by the shape of the components although this is unlikely given that the clinical results were similar. Several different surgeons with differing levels of experience performed these procedures. This factor alone could influence clinical success and survivorship of a prosthesis. To minimise this, all procedures were directly performed, or supervised, by an experienced consultant surgeon. This is likely a contributing factor the encouraging clinical results although this was not explicitly analysed. It also illustrates that such results with hydroxyapatite coated components can be achieved by a variety of surgeons and that relatively inexperienced surgeons can be trained to achieve encouraging results using these techniques. A power analysis was not performed although relatively large numbers of patients were included in both cohorts included in the study.

In conclusion no statistically significant difference was found between these stems in the medium to long term despite differences in their extent of HA coating and geometry. Patients are pain free and able to function independently at 10-15 years post surgery using either fully or partially hydroxyapatite coated components. It is possible that the thickness and extent of HA coating influences the occurrence of RLL's around the femoral component although this cannot be stated definitively given other design differences between the components used. There was no significant difference in the revision rates of the stems presented in this study. Both were associated with significant symptomatic as well as functional improvement and high levels of patient satisfaction in the medium to long term.

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