Mid-term results of a custom-made short proximal loading femoral component

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Bone preservation and physiological distribution of forces on the proximal femur are key elements in introducing a successful uncemented total hip replacement. In order to achieve this, in the mid 1990s, we developed an ultra short proximal loading custom-made component with a lateral flare, a high femoral neck osteotomy and without a diaphyseal stem.

We report the outcome of 129 custom-made hydroxyapatite-coated uncemented short femoral components inserted into 109 patients between June 1995 and May 2004. The mean age of the patients was 51 years (21 to 71) and the mean follow-up was eight years (4.9 to 14.1). Bone behaviour around the implant was studied on the post-operative radiographs. The mean Harris hip score improved from 44 (8 to 66) pre-operatively to 95 (76 to 100) at final follow-up. The Western Ontario MacMaster University Osteoarthritis index was 93 of 100 at final review. None of the patients reported thigh pain. A total of five hips were revised, three for polyethylene liner exchange and two for complete revision of the acetabular component. No femoral components were revised. The radiological changes in the proximal femur were generally good, as evidenced by spot welds both on the medial and lateral aspects of the femur. No component migrated. The presence of a lateral flare and use of a high osteotomy of the femoral neck provided good clinical and radiological results. The absence of a diaphyseal portion of the stem did not impair stability.

Proximal stress-shielding and thigh pain are among the main concerns following uncemented total hip replacement (THR). An optimal fit of the stem into the metaphyseal part of the femur is known to be crucial to achieve proximal load transfer. Commencing in 1992, we have investigated the option of a short conservative metaphyseal proximal femoral implant. The intention was to reproduce natural load transfer with a short stem whilst obtaining optimal stability using the morphology of the proximal femur. In our design, vertical stability was provided by the wedge shape of the prosthesis with the addition of a lateral flare. This ensured all loading was transmitted to the proximal femur, medially and laterally, and no forces were transferred by the distal portion of the stem which became redundant.

A second feature involved preservation of the osseous femoral neck with a more proximal and horizontal osteotomy. This created a more oval cross-sectional shape to the proximal femur than the conventionally cut femoral neck (Fig. 1) which afforded greater resistance to torsional stresses as described elsewhere. These authors have demonstrated that a more proximal femoral neck resection provided greater torsional stability and reduced distal migration of the implant.

The third aspect of our implant was the absence of the distal portion of the stem which can be allowed due to the greater stability given by the lateral flare and proximal sectioning of the femoral neck. The absence of the distal portion of the stem therefore ensures proximal load transfer, avoidance of stress shielding, absence of thigh pain, preservation of the femoral canal and femoral elasticity, and ease of revision.

Patients and Methods
A total of 131 THRs using the custom-made uncemented ultra-short femoral component (Stanmore Implant Worldwide, Stanmore, United Kingdom and DePuy International, Leeds, United Kingdom) were performed in a selected series of 111 patients between June 1995 and May 2004. The indications for using this implant were age < 60 and good bone stock. Only two very active patients above this limit received this implant (64 and 71 years old respectively). The expense of the custom-made
devices and the time required to produce them restricted their more general use. Exclusion criteria included: poor bone stock, previous metaphyseal fractures and congenital hip dysplasia.

Two patients died at 5.5 and six years respectively from unrelated causes and were excluded from the study; neither patient underwent further surgery before death. The senior author (FSS) performed all the operations. Full patient details are presented in Table I.

Of the remaining patients, 101 (121 hips) had complete clinical and radiographic follow-up with only eight patients declining to return for a clinical review; in five patients unrelated medical co-morbidities discouraged the patients from participating. All these patients were contacted by telephone at a mean of 9.8 years (7.2 to 13.1) from the time of surgery. Thus, we had 129 hips in 109 patients with complete clinical review by the authors at a mean interval of eight years (4.9 to 14.1).

A Hardinge direct lateral9 or a posterolateral (only in patients with severe limitation of movement) approach to the hip was used in every patient. The technique for femoral broaching and insertion of the implant is specific to it as the presence of the lateral flare produces a risk of damaging the greater trochanter and the abductor muscles if a conventional technique of femoral preparation and insertion is used. Accordingly, the reduced dimensions of the implant permit preparation of the femur with a curved movement of the broach distal to the greater trochanter. The broach is inserted into the divided femoral neck and driven distally in a varus direction by hammer blows and then, steadily tilted in the correct alignment whilst advancing into the femoral metaphysis. We refer to this technique as 'round the corner'.

A specially designed external guide was developed to ensure the correct alignment of the broach. In addition, an intra-operative image intensifier assessment was used in this series to check the final implant position. Leg-length discrepancy was measured pre-, intra- and post-operatively.

All the implants were manufactured as customised components based on pre-operative data obtained from conventional radiographs. In the final two years of the study, 23 implants were produced using a CT scan of the proximal femur. The custom-production allowed a continuous development of the design with the manufacturer with minor modification of the shape of the implant to ease the surgical technique. All implants were made of titanium and coated with a 55 μm layer of hydroxyapatite excluding the distal tip.

In the initial period, between 1995 and 1998 (20 hips), the implants were produced with a short diaphyseal stem never extending more than 3 cm below the lesser trochanter. These implants are described as type A (Fig. 2). Subsequently between 1999 and 2004, the distal aspect of the stem was completely removed (109 hips). These implants are type B (Fig. 3). The mean follow-up of type A and type B implants is 11.8 (10.6 to 14.1) and 6.9 (4.9 to 10.4) years respectively.

The removal of the distal stem simplified femoral broaching and implant introduction. Only one broach of the same size and shape as the final implant was provided by the manufacturer. Femoral head size was 28 mm in 110 hips, the

**Table I.** Patient characteristics of 109 patients (129 hip replacements)

<table>
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<th>Variables</th>
<th>Values</th>
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<tr>
<td>Age in years (mean, range)</td>
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<td>Weight in kg (mean, range)</td>
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<td>Height in cm (mean, range)</td>
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<td>5</td>
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<tr>
<td>Rheumatoid arthritis</td>
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</table>

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**Fig. 1a**

Cross-section CT scan of the metaphysis at the level of a) high osteotomy for the short implant and b) conventional femoral neck cut.
remaining being 32 mm in 16 hips and 36 mm in three hips. The selection of the articulating materials was based on the age of the patient. In 73 hips a ceramic head was matched with a polyethylene metal-backed acetabular component, in 41 hips a metal head was articulated on metal-backed polyethylene and in 15 hips a metal-on-metal bearing was used.

Patients were restricted to partial weight-bearing for the initial two post-operative weeks followed by full weight-bearing with two crutches for a further two weeks and then a single crutch for a further four weeks. Abduction exercises were performed throughout this period, with use of increasing resistance.

Harris hip scores (HHS)\textsuperscript{10} were recorded pre-operatively and at final follow-up by one of the authors (NS). All patients were asked to complete the self evaluation Western Ontario McMaster University Osteoarthritis Index (WOMAC).\textsuperscript{11}

**Radiological evaluation**

Standardised anteroposterior (AP) and lateral radiographs of the proximal femur at a focal distance of 120 cm were taken immediately post-operatively and at three months, six months, one year, and annually thereafter. The radiographs were reviewed by a single observer (NS) measuring alignment of the implant with the femoral axis, subsidence, radiolucent lines, calcar rounding, proximal bone resorption, endosteal hypertrophy (spot welds),\textsuperscript{12} distal cortical hypertrophy,\textsuperscript{13} osteolysis and femoral fit. Stem position was defined as the angle formed by the intersection of a line drawn through the longitudinal axis of the femoral canal and a line drawn through the longitudinal axis of the stem. The implant was considered neutral with an angle below 2°. Because of the absence of the diaphyseal portion of the stem, the location of radiographic findings in the femur have been restricted to five zones (Fig. 4) instead of the conventional seven Gruen zones.\textsuperscript{14}

Calcar rounding was defined as smoothing of the sharp definition of the osteotomy of the femoral neck. Proximal bone resorption was defined as loss of trabecular bone density (mottling) or loss of definition between the cortical and cancellous bone blending into a uniform density. Endosteal spot welds were defined as local deposition of new bony
trabeculae bridging the cortex and the surface of the implant. Cortical hypertrophy was defined as new bone of cortical density resulting in an increase in cortical thickness. Formation of intramedullary bone at the distal tip of the implant was classified as none, slight – as indicated by a radiopaque halo – or complete with a pedestal according to the criteria described by Engh et al.13 Osteolysis was defined as the presence of endosteal erosion or progressive radiolucent lines.

The femoral implants were classified as oversized, normal or undersized. Normal sized implants were those where we could identify an interval of 2 mm to 4 mm between the cortex and the device. Undersized implants had a gap of more than 4 mm. Implants were considered oversized where extensive direct contact occurred between the implant and the cortex.

The proportion of the femoral canal occupied by the implant at proximal border of the lesser trochanter (metaphyseal fit)15 and that at 1.5 cm below the lesser trochanter (diaphyseal fit) were measured on the post-operative true AP radiograph. Canal fill was defined as contact of the implant with the medial and lateral endosteal cortices.

The size of the femoral head was used to correct for magnification in the AP view. Vertical subsidence was evaluated by measuring the change in distance from the centre of the femoral head to the lesser trochanter. Subsidence was considered present if the change in distance exceeded 2 mm.13 The radiographs were also studied for heterotopic bone formation according to the system of Brooker.16

Radiological data of type A (1995 to 1998) and type B (1999 to 2004) are presented separately because of differences in the bone responses to the presence of the implant.

The standard leg-length discrepancy measurement protocol included an AP view of the pelvis in the upright position and 10° internal rotation obtained pre-operatively and three months post-operatively. Intra-operatively, leg length was measured before and after joint replacement using the distance between a 3 mm diameter pin fixed to the pelvis and a pre-determined point on the greater trochanter marked with a suture. The accuracy of this method requires precise reproduction of the position of the femur in abduction/adduction.

Results

Clinical results

The overall clinical result was satisfactory with an improvement from a mean pre-operative HHS of 44 points (8 to 66) to 95 points (76 to 100) at a mean final follow-up of eight years (4.9 to 14.1). A good or excellent score (90 to 100 points) was recorded for 127 hips (98.4%). Two patients had a fair score and sporadic pain (slight, occasional, no compromise in activity, no need of pain relief medication). One further patient had mild pain with no effect on activities of daily living, hardly ever moderate with unusual activity, with intermittent use of pain medications, and scored 83 points with the HHS. The WOMAC evaluation was recorded only at the latest follow-up with a mean of 93 of 100 (81.5 to 100). The mean shortening of the operated leg was 0.9 cm pre-operatively (-0.9 to +0.5) and 0.2 cm post-operatively (-0.9 to +0.5).

Complications. Thigh pain was not reported at any of the follow-up evaluations. No patient required revision of the stem and there were no infections. As each custom device was supplied with only one broach, the lack of progressively increasing sizes of the broaches made preparation of the femur technically difficult and time consuming, especially in young patients with good bone stock.

In 25 patients, 16 with type A and nine with type B, the stem size used was too large (Fig. 5). In this group, fractures of the proximal femur occurred in seven hips during implantation, two in female and five in male patients. In six hips the primary diagnosis had been osteoarthritis and in the other rheumatoid arthritis. In all cases, the fracture was recognised intra-operatively. None extended below the lesser trochanter. Six occurred during the first 48 procedures and one occurred in the last 81. In each case the stem was extracted and cerclage wiring undertaken after which the same implant was re-inserted.17 These patients were required to remain partial weight-bearing for six weeks. None of these stems migrated. In five of the seven patients, Brooker grade II or III heterotopic ossification was present. No patients had any other complication as a result of the fracture, and the mean HHS for these patients was 92 (76 to 100). Re-operation for wear of polyethylene liner was performed in five patients. In two hips the acetabular component was revised in its entirety, in three patients an isolated liner exchange was performed. In all cases the stem appeared stable and was left in place. Other complications included two dislocations which were treated conservatively with a brace for four weeks, one trapped drain which required surgical removal and two superficial wound infec-
tions which were managed conservatively with prolonged antibiotic therapy.

Radiological results

The final radiographs were examined in all patients. Alignment of the implant with the shape of the proximal femur was satisfactory in 124 (96%) of the stems. Alignment was rated as neutral in 115 (89%) of the cases, varus in ten (7.5%) and valgus in four (3.5%). No implant underwent subsequent change in its alignment or subsided. Radiolucent lines were not observed at any point during the follow-up. Detailed data of bone behaviour around type A and B stems are shown in Table II.

All type A implants used during the first period (1995 to 1998) developed a distal pedestal and all these were oversized according to our criteria. In 11 hips (8.5%) some degree of proximal bone resorption was identified at the metaphysis, but in only two hips did this amount to definite loss of trabecular bone density. Again, ten of these implants were type A with a short oversized diaphyseal stem. Calcar rounding was present in 97 hips (75%) and had mostly stabilised by six months post-operatively. In most cases (Table II), a progressive bone remodelling with deposition of new bone around the implant was observed. Endosteal spot welds bridging the implant and suggestive of load transfer were a common finding with this kind of implant (Fig. 6). Generally bone bridging the endosteum and a porous surface were found in zones 2 and 4 of the modified Gruen zones. It was more obvious in patients with good bone stock and radiologically undersized implants. Cortical hypertrophy was seen, close to the tip of the stem, only in three oversized type A implants. In 14 hips proximal femoral osteolysis was present due to supposed polyethylene debris. No distal osteolysis was recorded. There was no evidence of shedding of the porous coating and no case of breakage of the stem. Most of the type A implants were oversized. In contrast most of type B devices were correctly sized. Detailed data on radiological measurements of type A and B implants are displayed in Table III.
Discussion
As a result of the production of the customised femoral components in this series the opportunity to modify length and dimension of the implant was available. As experience grew the implants were made shorter and smaller. The decision to remove the distal stem entirely from the type A implant and produce the type B component was taken because of the technical difficulties encountered in the insertion of type A implants and the high rate of intra-operative fractures.

The presence of a lateral flare and the high neck cut provided satisfactory implant stability both in the immediate post-operative period and in the long term.

The finding of spot welds in zone 2 in 85 hips (78%) carrying type B implants offers confirmation that with the addition of a lateral flare, the lateral column of the femur preserves its natural function of strain distribution.\(^{18-21}\) In these biomechanical conditions, Jasty et al.\(^{22}\) predicted that the diaphyseal portion of the stem is at best redundant and at worse detrimental. Adverse bone reactions in our series were seen in type A oversized implants with pedestal formation, cortical hypertrophy and proximal stress-shielding. This behaviour was already recorded at the five-year follow-up and it seems to deteriorate over time.\(^{23}\) A tight diaphyseal fit, even if only in the proximal diaphysis, enhances stress shielding similar to conventional, standard length, femoral devices.\(^{1,2,24}\)

Radical shortening of the implant did not decrease implant stability or comprise the clinical results\(^{23}\) and no failures have occurred. A smaller implant is easier to insert and preserves more bone at the time of the primary procedure and over time. The stress distribution in the proximal femur obtained with shorter and smaller implants appears to be advantageous with no cortical hypertrophy or pedestal formation. In type A implants ten hips (50\%) showed proximal bone resorption, and either a pedestal was found in seven hips (35\%) or a halo in six (30\%), around the stem tip. However, only one patient (1\%) operated with a type B implant had signs of stress-shielding. No pedestal formation was detected in type B implants and only six (6\%) had a halo. It is accepted these differences could be partly explained with the different durations of mean follow-up, 11.8 (106 to 14.1) versus 6.9 (4.9 to 10.4) yrs, between type A and B implants.

A comparative study of bone mineral density (BMD) at three years follow-up between type A and type B implants had recently been published.\(^{25}\) In that study, type A implants caused bone loss in all zones when compared with the contralateral unoperated hip. Type B implants showed a 9.5\% and 9.4\% BMD increase in zone 2 and 4 respectively. The differences in proportional changes in the latter between type A and type B were statistically significant in regions 4 and 5. This BMD data re-inforces our radiological findings of better periprosthetic bone behaviour with ultra short type B implants. Generally after insertion of an uncemented stem periprosthetic bone undergoes a reduction in BMD.\(^{3,26}\) The increases in BMD in zones 2 and 4 reported for the type B implants\(^{25}\) are an unusual occurrence. The absence of the intramedullary stem and the addition of the lateral flare seem to be the only possible explanations for these findings. Finite element studies do not give cause for concern over load-distribution in short femoral implants.\(^{27}\)

Of particular note was the lack of thigh pain with both type A and B implants. We believe, this is due to the lack of interference with the diaphysis. Thigh pain is known to be related to stem design and implant stiffness.\(^{4,28}\) The normal modulus of elasticity of cortical bone is < 20 GPa\(^{29}\) whilst most conventional metal implants occupying the diaphysis have a modulus of elasticity between 80 GPa and 200 GPa.\(^{30,31}\) Therefore, removing the intramedullary stem is the best way to preserve femoral elasticity and avoid symptoms in this region.

At eight years follow-up, we have observed neither a varus nor vertical migration. Other short stems, without a lateral flare, present as early as two years after surgery, with lateral cortical hypertrophy at the level of the stem tip. According to Falez et al.,\(^{32}\) this phenomenon is the result of bending forces acting on this region. Most currently available conservative metaphyseal implants share the same concept, with load delivered on the calcar and a short intramedullary stem neutralising any varus forces.\(^{33}\)

Our biomechanical model is different. The addition of the lateral flare, by delivering compressive forces in the very proximal region of the lateral column of the femur, almost abolishes the moment which can lead to varus til\(^{16,20,22}\).

In conclusion, this geometry produces a sound initial stability and physiological load transmission on the proximal femur over time. Clinical and radiological results support the rationale of ultra-short implants.

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References


