A ported, proximally-cemented femoral stem for total hip arthroplasty

DEVELOPMENT AND CLINICAL APPLICATION

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We describe the development and early clinical application of a ported, proximally-cemented titanium stem for cemented total hip arthroplasty. PMMA bone cement is delivered to the proximal femur under pressure after the stem has been positioned within the femoral canal. A mid-stem cement occluder contains the cement to the proximal stem only. A tapered body is incorporated in the design of the stem to reduce the structural stiffness and hence the degree of stress shielding within the reconstructed joint.

We performed preclinical studies to measure the reduction in porosity and the pressurisation achieved. The porosity, as measured by the void percentage within the cured cement mantle, was reduced by more than 50% and there was an almost threefold increase in the mean pressure. Mechanical testing of the stem, using a three-point bend test, showed that the addition of cement injection ports on the anterior and posterior sides of the body of the proximal stem did not reduce its strength. Finite-element analysis indicated that, compared with a fully-cemented conventional stem, there was no change in the stresses within the cement mantle. In a series of 40 proximally-cemented stems followed for up to six years (mean 51 months) the mean Harris hip score was 91, and 85% of patients had good or excellent results. There was excellent pain relief, an increased level of activity and good patient satisfaction. One mechanical failure of the stem required revision at three years after implantation.

The early results indicate that the clinical performance was equal to that achieved with other modern cemented stems. Radiological evaluation showed excellent results with no evidence of stress shielding. Further follow-up will determine if long-term stress shielding is reduced and if revision is made easier by the absence of a distal cement mantle.

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Loosening of cemented femoral components is a cause of failure of total hip arthroplasty (THA) in the long term. Revision rates solely for femoral loosening vary considerably. Low rates of loosening of 2.4% at ten years to around 4% at 15 years have been reported. Dall et al described a revision rate of second-generation Charnley stems of 11.4%. Dorr, Luckett and Conaty found that 27% of younger patients had needed revision by nine years and 50% at 16 years. Thomas, Salvati and Small described a revision rate of 6% at five to ten years along with a rate of cement-bone lucency greater than 12% after seven years.

Radiological lucencies at the cement-bone interface, which often mark implant loosening and precede clinical failure, may be caused by mechanical debonding or by biological actions leading to local bone resorption. Second- and third-generation cementing techniques which use a combination of pulsatile lavage and mantle pressurisation improve the cement-to-cancellous bone interdigitation and therefore the strength and longevity of this interface. In these techniques pressurisation is achieved by applying force to the body of the stem and proximal pressuriser in situ, thereby applying pressure only to the surface layer of the cement. Techniques which allow the cement mantle itself to be pressurised during surgery should yield higher pressures and more consistent results.

Press-fit stems often use enhancement of the proximal interface to encourage transfer of the proximal load, but this technique is less often used in cemented arthroplasty. Reports of breakdown and cracking of the distal cement mantle suggest that load transfer in cemented THA may occur more distally than is desirable for the optimum maintenance of proximal bone quality. In stems with...
enhancement of the proximal surface, the distal cement remains and may still be a site for breakdown of the cement mantle and release of particles. Furthermore, removal of the distal cement mantle is time-consuming and difficult.

Proximal stress shielding occurs in THA although it may be less marked in cemented procedures because of the placement of smaller stems in order to leave space for an adequate cemented mantle. In the long term, however, stress shielding is of concern in cemented THA and thus designs which feature low-modulus alloys and/or reduced cross-sectional moments of inertia should have less stress shielding.

We have developed a new cemented stem which is intended to reduce or eliminate some of the disadvantages of contemporary designs. We used a combination of new techniques and technologies to design a femoral stem for cemented THA with increased pressurisation of the cement mantle, decreased implant stiffness, enhanced transfer of proximal load, and elimination of distal cement. Our aim in this study was to investigate the mechanical strength, the mechanism of load transfer, the characteristics of the cement mantle, and the initial clinical application of the design.

Patients and Methods

Stem description. The femoral component consists of a metaphysis-filling proximal body with an aggressively tapered distal stem to which a modular tip is fitted to gain endosteal contact within the diaphysis. The tapered distal stem decreases the structural stiffness of the implant and hence increases the proportion of bending loads transmitted to the femur, thus reducing stress shielding. The proximal part is designed with a central canal which communicates with four exit holes (two anterior, two posterior) to allow extrusion of the centrally-injected cement. The metaphyseal portion is also grit-blasted to enhance the stem-to-cement interface bond. Cement is injected into the body of the stem through a screw-in attachment in the proximal portion of the stem located just laterally to the neck-stem junction. A specially adapted cement gun is used both to fill and pressurise the cement as it is injected and flows out through the ports in the stem into the proximal femur. There is a provision for a modular collar. Cement is prevented from migrating distally during injection by a polyethylene occluder placed over the body of the stem. It is sized to the stem and provides for a cement mantle along approximately 50% of the length of the stem. Fan-like serrations in the occluder allow deformation to match the contour of the femoral canal. Figure 1 shows a cross-section of the stem and the occluder.

Mechanical testing. We tested the mechanical integrity and fatigue limits of the stem in a three-point bend test fixture. A sinusoidal load of approximately five to six times body-weight or 506 kg was applied through a femoral head incorporating a 10 mm neck extension to represent the ‘worst-case’ applied bending moment. Stems were tested to ten million cycles. The effectiveness of the occluder in preventing cement extrusion beyond the mid-diaphysis was tested by implanting stems into both cadaver and synthetic femora which were radiographed after implantation to determine cement extrusion. During insertion of the stem we measured the pressure developed within the cement using pressure transducers. We then compared the pressures in the proximally-ported stem injected with cement and the same stem implanted using a conventional procedure in which the femur was filled with bone cement before insertion of the stem. Porosity in the cement mantle was measured in laboratory specimens made while applying the pressure determined for the investigational and conventional techniques. After curing, the specimens were ground flat, stained with Indian ink, and evaluated for porosity at ×20 magnification using an image-processing program (SIS, Chattanooga, Tennessee). Resistance to subsidence was measured using only the proximal segments of the investigational and conventional stems pushed out proximally to distally from the stem-cement-bone construct at a rate of 2.54 mm/min. Failure load representing construct failure was recorded.

Finite-element analysis. We generated a three-dimensional model of a proximal femur from CT data using image extraction and contour-stacking techniques. An appropriately sized model of the femoral component (titanium, modulus of elasticity (E) = 110 GPa) with a distal bearing tip
(cobalt chromium (CoCr), E = 210 GPa) was inserted. A 3 mm cement mantle was used and a stem-cement interface using a continuum element which exhibited no strength in tension and Coulomb friction ($\mu = 0.3$) behaviour in shear. The interface of the distal bearing tip with the endosteal wall had the same element with a zero coefficient of friction. Each bone element was assigned a unique, isotropic, Young's modulus directly from the CT data using a volume-weighted averaging technique. Ten noded brick and 15 noded wedge elements were used throughout.

We applied a head load of 3400 N and a greater trochanter load of 2600 N.

We studied three cases of interest. First, the model was constructed so that the cement mantle fully encased the prosthesis to stimulate the conventional technique. It was then modified so that the cement elements distal to the location of the midshaft occluder were assigned a very low modulus (E = 0.2 MPa) to simulate the proximal cement mantle and distal tip of the investigational technique. Lastly, the distal-bearing tip elements were assigned an elastic modulus of 0.1 MPa to simulate the investigational technique in a worst-case situation in which the distal tip became disassociated from the stem. Figure 2 shows these cases.

Clinical study. Between January 1991 and December 1993, we implanted 40 proximally-cemented stems in 35 patients, 20 women and 15 men, with a mean age of 71.7 years (60 to 86). Their mean height was 161.0 cm (127.0 to 188.0) and mean weight was 71.8 kg (48.3 to 117.3). Fourteen hips were Dorr type A, 25 type B, and one type C. The mean operating time was 75 minutes and the mean hospital stay 5.2 days (3 to 14).

The primary diagnoses included osteoarthritis, rheumatoid arthritis, avascular necrosis, and post-traumatic arthritis. Nine patients had bilateral simultaneous arthroplasties; in four, proximally-cemented stems were implanted on both sides and in five, a proximally-cemented stem on one side with a fully-cemented (three hips) or un cemented (two hips) stem on the contralateral side. The acetabular components were of the press-fit, porous-ingrowth type (PSL; Osteonics Corp, Allendale, New Jersey) and were implanted with and without secondary screw fixation. We used a posterior approach with preservation of the greater trochanter. Patients were restricted to having either type-A or type-B femora according to the Dorr classification to ensure sealing of the cement in the proximal canal by the occluder. We assessed pain, function and outcome before operation and at each follow-up period. The Harris hip scores were calculated before operation and at each follow-up. The clinical and radiological evaluation of each hip was based on a standardised scheme agreed by the American Academy of Orthopaedic Surgeons, SICOT, and the Hip Society. Radiological evaluation was performed by an independent investigator and measured stem migration, stem deformation or breakage, radiolucencies, and thickness of the cement mantle. If cement extruded beyond the occluder its extent was measured and compared with the previous examination to determine if cement fragmentation or osteolysis was present.

Femoral fixation was assessed according to the criteria of Harris and McGann in which the femoral component was characterised as definitely loose, probably loose, possibly loose, or fixed. Gruen zones 1, 2, 6, 7, 8, 9, 13 and 14 were evaluated due to the absence of cement in other zones. Heterotopic ossification was assessed according to the classification of Brooker.
Results

Mechanical testing. All sizes of the ported proximally-cemented stem survived ten million cycles under three-point bend loading conditions. We found the mean cement mantle pressure to be 138 kPa around the proximally-ported stem when the cement was injected and pressurised through the stem body and 69 kPa for the same stem cemented in a conventional manner. Laboratory specimens of polymethylmethacrylate (PMMA) polymerised with overpressures of 138 kPa had a mean porosity of 0.6% while specimens pressurised to 69 kPa had a mean porosity of 1.6%. The ported proximally-cemented construct failed at an applied load of 28 900 ± 2800 N, and the conventional construct at a load of 19 000 ± 2400 N when tested by forcing the proximal portion of the stem to subside. Occluders made of polyethylene and PMMA were successful in preventing extrusion of bone cement into the diaphysis. Testing suggested that type-C or ‘stovepipe’ femora would not be suitable for the ported proximally-cemented stem because of insufficient taper in the metaphysis to seal the occluder properly.

Finite-element study. Comparison of the maximum principal stresses in the proximal cement mantle in the three models showed similar stress distribution. The maximum principal stress for the fully-cemented and proximally-cemented stems varied less than 1%. The model with proximal cement and no contact distally showed a higher proximal stress (8.2 MPa) compared with the other two

Radiographs of a 72-year-old woman with osteoarthritis who had a conventional cemented stem on the left side and a ported proximally-cemented stem on the right. Figure 3a – AP view at a follow-up of seven years. Figures 3b and 3c – Lateral views of the left hip implanted using a conventional technique at three and seven years. Figures 3d and 3e – Lateral views of the right hip implanted using the proximally-cemented technique at three and seven years.
cases (7.0 MPa). Stresses in the diaphyseal region of the cement mantle in the fully-cemented model were found to be quite low (<1 MPa). We also evaluated the effect of changing the parameters of the model on stresses in the bone. There was little difference in the different models.

Clinical results. The mean follow-up was 4.5 years (2.1 to 6). There was one failure three years after operation because of aseptic loosening in a patient with a vertically-orientated cup, a 32 mm femoral head, and radiologically measurable liner wear. Osteolysis was present at the lateral aspect of the femur at the mid-stem level and the hip was revised to a hydroxyapatite-coated stem; the patient was free from pain at the one-year follow-up. The mechanical rate of failure of the stem is therefore 2.5%.

The average Harris hip score was 44 before and 91 after operation with 34 hips having good to excellent results, five were fair, and one poor. Pain was moderate to severe in 39 hips (98%) preoperatively; the remaining hip was in a patient who was bedridden. Postoperatively, 80% of patients described their pain as none or mild. The remaining 20% complained of moderate to marked pain, but also had considerable pain in non-involved joints.

Function was significantly improved by the arthroplasty; 78% of patients reported that they could perform normal activities as opposed to 24% before surgery. No patient was unable to put on socks and shoes and 69% were able to climb stairs easily with and without a rail. Half of the patients were able to walk without aids after surgery whereas only 17% could do so before. Preoperatively, only three patients had no limp and 70% had a moderate limp, while 90% had either no limp or only a slight limp after surgery. Trendelenberg gait was absent in 91% of patients post-operatively and 72% had no Trendelenberg sign. Of the 35 patients, 94% indicated that the THA had met their expectations and 84% were able to reduce their pain medication after surgery.

Radiological results. All acetabular components were implanted without cement and none showed radiological evidence of loosening. At the time of the latest follow-up no cup had migrated, no screw had broken and no radiolucency was present around any screw. One cup showed 1 mm of wear on the three-year radiograph; the femoral head was 32 mm in diameter and the acetabular component had been placed in 55° of abduction. This patient was subsequently revised after the femoral component subsided. All stems were within 3° of neutral in both anteroposterior and lateral views. There were no stem breakages and no cement fractures. Five stems had radiolucent lines that were less than 2 mm in width in the proximal cemented portion of the implant; none of these lines was progressive. The mean thickness of the cement mantle was 6 mm (2 to 12). Extrusion of the cement past the occluder occurred in five stems (12.5%) and averaged 13 mm (2 to 30). The extruded cement did not fragment and there was no evidence of osteolysis in any hip in which cement extruded past the occluder. Heterotopic ossification occurred in 10% of hips but no case progressed beyond Brooker grade I.

There was no evidence of stress shielding on radiographs at up to six years. Two patients had a proximally-cemented stem on one side and a fully-cemented stem on the contralateral side. There was some evidence of stress shielding on the fully-cemented side, but not in the proximally-cemented stem (Fig. 3). One patient had a proximally-cemented stem on one side and a proximally-hydroxyapatite-coated stem on the contralateral side (Fig. 4).
Discussion

The ported proximally-cemented stem which we describe was developed both to remove possible failure mechanisms of cemented stems and to improve the load transfer between the stem and the host bone. Since it is known that failure of the distal cement mantle can occur, and since stress shielding is seen to varying degrees around conventional stainless-steel and CoCr alloy prostheses, it may be deduced that a stem which dispenses with the distal cement mantle while having a low structural stiffness should reduce stress shielding. To reduce the structural stiffness the modulus of elasticity must be lowered and/or the cross-sectional moment of inertia reduced. The latter has the effect of making the stem less stiff in bending which forces the femur to carry more of the load thereby reducing the degree of stress shielding. Both techniques were used in the design of the ported proximally-cemented stem which is made of titanium with a modulus half that of CoCr or stainless-steel and is sharply tapered distally to reduce its cross-sectional moment of inertia. On a size-to-size basis, this new stem is approximately four times more flexible than an equally-sized non-tapered stem made of CoCr.

Studies have shown a link between the porosity of the cement mantle and its strength. Void within the mantle may act as crack nucleation sites, leading to fracture of the mantle if enough voids communicate with one another. The design which we describe pressurises the PMMA while it polymerises to reduce the degree of porosity within the mantle and to force the cement more deeply into the cancellous bone tissue, further enhancing the ability to achieve ‘white out’ between the cement and host bone.

The finite-element method has been used previously to assess the effects of changing implant designs on implant and bone stresses. It has also been used to predict the effects of stem-cement interface debonding on stresses in the bone and stem and in the cement mantle. We used the method to gauge the changes in stress on the cement mantle brought about by removing the distal cement. A fully-cemented or conventional representation served as the control and a proximally-cemented model with distal-bearing tip represented the investigational case. A third model in which the distal bearing tip was removed was the worst-case analysis. The difference in stress on the cement mantle between the first two models was negligible indicating that the distal cement is not transferring any substantial load. Since stresses in the diaphysis are primarily due to bending and since the cement mantle contributes to less than 1% of the composite bending stiffness of the structure, its removal does not measurably alter the overall stress state.

Cemented hip replacement has definite advantages. Initial excellent fixation gives a ‘custom fit’ and resistance to axial and torsional stresses allows early pain-free function. The use of improved cementing techniques has significantly increased success rates. The disadvantages, however, may be significant. Cement is inherently weak and it may incite a soft-tissue response resulting in membrane formation. In cases of failure, the cement may be difficult to remove and in proximal stress shielding there may be significant bone loss.

The proximally-cemented stem is easily and reproducibly placed in the femoral canal before injection of the cement allowing easy visualisation of the valgus/varus position. As the cement is injected through the stem and pressurised into the proximal femur, the flow of cement forces out any remaining blood and debris. The degree of pressurisation is equal to or greater than the most optimal conventional technique, and it is uniform about the periphery of the implant. No complications have been observed either during the operation or in the follow-up period. There have been no symptomatic pulmonary or cardiovascular effects.

The proximal containment of cement allows for easy access during revision. There is no distal cement to extract. In the one patient in the series who had a revision the cement was easily removed and the operating time was less than two hours.

There has been no evidence of stress shielding at the six-year follow-up. The proximal femur appears to be loaded in such a way as to preserve osseous integrity. In cases in which the opposite hip has been fully cemented providing an internal control, there is a visible difference with the proximally-cemented stem having no discernible proximal osteopenia.

The initial clinical results up to six years have been encouraging. The ported proximally-cemented stem was easily implanted in a reproducible fashion and gave a repeatable ‘white out’ with concomitant cement-bone interdigitation. Mechanical testing and finite-element analysis showed that the construct was comparable to a fully-cemented stem. Revision was easily accomplished in the one stem which failed. The clinical and functional results were encouraging at early follow-up and there is a high degree of patient satisfaction.

Our study outlines the early results of a new type of stem which is designed to combine the advantages of proximal load transfer achieved by some press-fit stems with the canal-sealing properties and ‘customisation’ of cemented stems. The stem is straightforward to implant, the cementing technique is easily reproducible, and the clinical results show a high degree of patient satisfaction. Continued monitoring of our series will indicate whether or not the early to mid-term advantages with this technique carry through to the long term.

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References


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