



The effect of two different types of cement restrictors on the femoral cement mantle

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Cement restriction and pressurisation are helpful technical points in achieving a good cement mantle in cemented hip replacement.

In this prospective study, we compared 39 cases where a Hardinge polyethylene restrictor was used and 33 cases where a bone block restrictor was used during Charnley hip replacement. The preoperative radiographs were templated, calibrated holders for the cement restrictors were used intraoperatively, keeping the distal cement height within 2-3 cm from the tip of the femoral prosthesis. Postoperative radiographs were analysed. The Harris Hip scoring system was used for clinical assessment of results.

The preoperative target of having a distal cement height of 2-3 cm was achieved in only 60.6% of the bone block group and 30.6% of the Hardinge group. The difference between the two groups is statistically significant ($p = 0.001$).

Distal migration of the restrictors more than 3 cm from the tip of the femoral prosthesis was associated with a non-homogenous cement mantle in zones 3, 4 and 5 without affecting zones 1, 2, 6 and 7. The cement mantle was adequate when the distal cement mantle remained within 2-3 cm of the tip of the femoral prosthesis.

Keywords : cement restrictor ; hip replacement ; cement mantle.

INTRODUCTION

With the introduction of the Charnley low-friction arthroplasty, acrylic cement became the

standard for femoral component fixation (6). Despite the current investigation on biological fixation, cement is likely to remain an attractive option for femoral fixation for the near future. In England and Wales, 22,672 primary hip arthroplasties were carried out between 1 April and 31 December 2003. Out of these, 82.3% of cases were cemented hips (19). For this popular procedure, aseptic loosening is a common long-term complication. The longevity of the cemented hip replacements is determined by the integrity of the bone-cement mantle and its interfaces (20).

Recent advances in stem design and in the application of cement have dramatically improved the long-term survivorship of cemented stems (20, 21). A number of different techniques have evolved to improve cemented femoral fixation, including injection of low-viscosity cement, centralisation of the stem, occlusion of the medullary canal using cement restrictors, reduction of porosity and pressurisation of the cement (2, 12).

The restrictor can be either bone or synthetic materials in the form of PMMA, polyethylene, or

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metal based. It is recommended that the cement restrictor should be placed 2-4 cm beyond the tip of the prosthesis (3).

In the current study, we compared the femoral cement mantle in two groups of patients who had Charnley total hip replacement. In one group, a Hardinge polyethylene restrictor and in the other group a bone block taken from the femoral head was used for cement restriction.

PATIENTS AND METHODS

In our Institution, one surgeon (AAF) performed 72 consecutive primary Charnley cemented total hip arthroplasties (THAs) in 68 patients between 1 March 2003 and 30 April 2004. The mean age of patients was 72.4 years (range 58-84 years); there were 47 females and 21 males. Four patients had a bilateral procedure performed in different sessions. Ethical committee approval was deemed not necessary, as there was no change of the existing practice.

All patients in this study had primary osteoarthritis of the hip. Rheumatoid patients and patients with wide femoral canal requiring an extra large femoral stem (canal diameter of over 20 mm) were excluded from the study.

These patients were referred to the orthopaedic surgeon for joint replacement surgery. The main indication for surgery was hip pain interfering with rest and daily activities. The mean Harris hip score (11) of these patients was 18 (range of 5-25). The Harris hip scoring has a maximum score of 100 points. The lower score represents severe symptoms and disability. Pain makes up 44% of the total score. Functional activity of the patient accounts for 47%. Distance walked, range of movement, limb length discrepancy, and ability to use the public transport account for the remaining score.

An informed consent was taken for the procedure. The operations were all carried out through the Hardinge approach using a long posterior wall Charnley cup. The appropriate size femoral stem (offsets 40 or 45) as templated was chosen. The available sizes used were round back, flanged, extra heavy flanged femoral stems. The technique for femoral cementation involved cement restriction, medullary canal irrigation using pulse lavage, brushing, and dry packing with sponges, vacuum mixing, and retrograde cementation with pressurisation. When retrograde cementation was done, the tip of the cement gun was pulled back slowly in order to avoid forcing the restrictor down. Palacos normal viscosity cement was used.

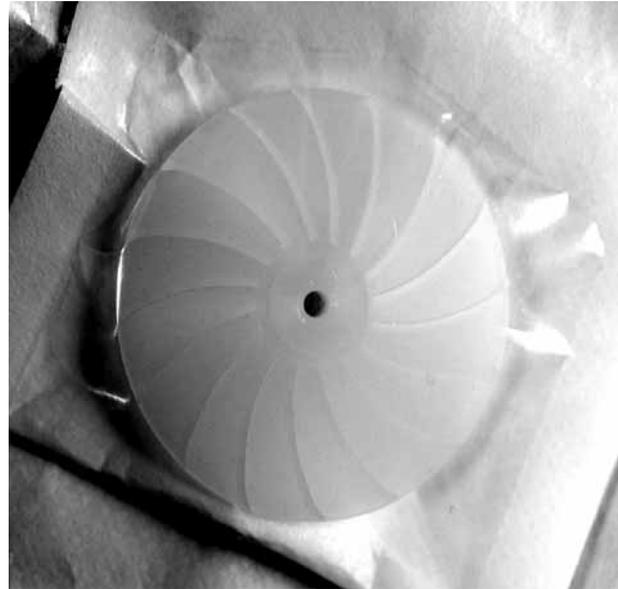


Fig. 1. — Hardinge Restrictor

The type of cement restrictor was chosen according to a double blind randomisation: in one group, a bone block taken from the femoral head using Charnley's kit and in the other group a Hardinge polyethylene restrictor was used. The thickness and diameter of the bone block was the same in all cases (18 mm) as it was cored using the same instrument (fig 1). The diameter of the Hardinge restrictor is 39 mm and once it is introduced (fig 2), it collapses to accommodate the diameter of the canal. The restrictor was aimed to seat between 2 and 3 cm (mean of 2.5 cm) below the tip of the stem.

To establish the position of the restrictor, preoperatively, standard full size anteroposterior and lateral radiographs of the hip were templated to size the component, to identify the site for femoral neck osteotomy and to assess where the tip of the chosen femoral stem would be. The width of the femoral canal was measured at the proposed site of the femoral cement restrictor.

During the operation, every attempt was made to seat the cement restrictor where it should be. After positioning the restrictor, the position was re-checked with the calibrated applicator. The line on the calibre coincides with the medial femoral neck cut. The trial prosthesis was tried again after the insertion of the restrictor to make sure that the restrictor was not too proximal.

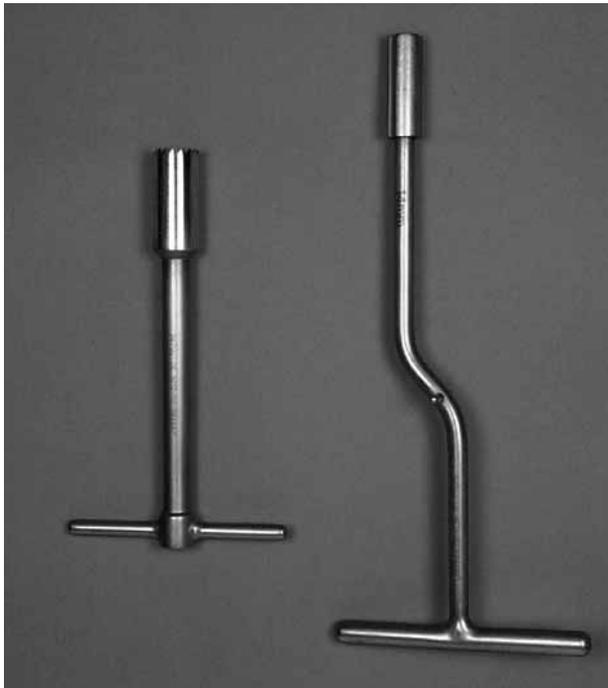


Fig. 2. — Charnley Bone block Kit corer

RESULTS

Following discharge from hospital, these patients were reviewed in the clinic at 6 weeks, at 6 months and then on a yearly basis. The mean period of follow-up was 30 months (range 25-38 months). The outcome was measured using the Harris hip score which was calculated during the second visit (6 months after operation). The mean postoperative Harris Hip Score was 70 (range, 60-90), with a mean improvement following hip replacement of 52 (range, 32-70). Seventy-two radiographs were studied for the cement mantle, type of the cement restrictor, canal diameter, and the distance between the tip of the stem and the restrictor (distal cement height). The main point of interest was the femoral cement mantle thickness in all zones.

Radiographic measurement method

All patients had an anteroposterior (AP) radiograph of the pelvis and a lateral radiograph of the

operated hip during the first or second postoperative day (fig 3, 4). In order to standardise the technique, for the AP view of the pelvis, patients were placed supine with the operated leg neutral so that the patella was facing the ceiling. This is to neutralise the anteversion and the method is reproducible. The distance between the film and the tube was set at 115 cm, which was constant in all cases. The tube was placed at 90° to the hip joint. The machine automatically adjusts the radiation exposure for the pelvic radiograph by the automatic exposure device. The digital image was printed in a film, which was 11 × 14 inches in all cases. The 10% magnification of the radiographs was accounted for the measurements.

An independent assessor who was not involved in the patient selection and the operation studied all the radiographs. Radiological assessment of the cement mantle in the different zones described by Gruen *et al* (9) was carried out. The assessor was not aware of the type of restrictors used in any particular patient before going through case notes and the radiographs. The Hardinge restrictor was identified by noting the radio-opaque marker placed in the centre of the restrictor. The bone block was identified by the homogenous opacity throughout. Stem migration was calculated from changes in the distance measured between the tip of the stem and the radio-opaque marker in the Hardinge restrictor. In the case of a bone block restrictor, its upper border was used as the reference.

Radiographic films were placed in the viewing board. One standard ruler was used to measure the mantle thickness in millimetres in all zones.

To eliminate intra-observer error, each film was measured at three different times and the mean value was taken as a final figure. The canal diameter was measured at the level of the intended restrictor level.

Statistical analysis of results

A Minitab programme (Minitab Inc. PA) was used to analyse all the measurements. The power of the study was calculated from the determinant variables, being in excess of 80%. The confidence level chosen for the study was 95% and a p value of 0.05



Fig. 3. — Gruen Zones markings (a Hardinge restrictor marker is shown).



Fig. 4. — Radiograph showing the bone block, as a dense opacity distal to the cement mantle (zone 4).

was considered significant. Regression analysis, one-way ANOVA, and chi-square tests were used to analyse the data.

In the bone block group, the height of the distal cement mantle remained within 20-30 mm of the tip of the prosthesis in 20 cases (60.6%), matching the pre-determined level. In the Hardinge restrictor group, only 15 cases matched the pre-determined level (30.6%). The mean canal diameter was 13.9 mm (8-20 mm). The mean zone 4 cement height was 18 mm (range, 0-75 mm). As the restrictor remained within 20-30 mm, the thickness of the cement mantle was maintained between 9 mm and 21 mm in zone 4. When the restrictor migrated beyond 30 mm from the tip of the femoral prosthesis, the cement mantle in zone 4 became

non-continuous and thin. This finding is statistically significant with the p value of 0.001.

The width of the femoral canal diameter had no significant effect on the cement mantle thickness in zone 4 ($p = 0.035$), and in zone 2 and 6 ($p = 0.389-0.653$), however the thickness of the cement mantle in zone 3 and 5 has increased with increased femoral canal diameter ($p = 0.00$).

DISCUSSION

Aseptic loosening has been a major cause of failure of cemented total hip replacements (3). Stem design, cement mantle thickness, and surgical technique are among the factors which determine the survival. The longevity of the cemented hip

replacements is determined by the integrity of the bone-cement mantle and its interfaces (20)). Among the implants, the Charnley Elite and the Exeter stems have different design concepts : the former is designed not to subside, whereas the latter is expected to subside. A thick cement mantle for the Exeter concept is recommended as compared to the Charnley group (1). Malik *et al* described the association between immediate post-operative radiological appearances and early aseptic failure of Charnley total hip replacement. They found that the thickness of the cement mantle in Gruen zones 6 and 7 had an influence on failure ($p = 0.040$ and 0.003 respectively) (16).

There are many studies addressing the ideal cement mantle thickness (3, 7, 8, 13, 14, 20) to withstand stress. The quality of the cement mantle that surrounds the femoral stem influences the manner in which load is transmitted from the stem through the cement to the surrounding bone. This in turn, influences the prevalence of fracture of the cement or the formation of gaps between the stem and the cement or between the cement and bone, both of which have been associated with loosening and clinical failure of the implants. The shape and thickness of the cement mantle are determined by the cross sectional geometry of the stem and diameter of the medullary canal, the orientation of the stem and the amount of cancellous bone removed during the procedure (7).

Kwak *et al* suggested aiming to achieve a uniform cement thickness of 3-4 mm all around the stem (15) ; however, several biomechanical studies have shown that the strongest cement mantle is not of a uniform thickness (4). During normal weight bearing activities, the stresses borne by the cement mantle are very uneven, tending to concentrate over the proximal end of the femur and the distal tip of the prosthesis where the greatest discontinuities in stiffness are present (13, 20). A proximal cement mantle of 2-5 mm thickness is recommended (7, 10, 20). Sarmiento and Gruen showed that once the proximal mantle became thinner than 2 mm, the incidence of subsidence and calcar resorption increased significantly (22). Narrower femoral stem designs are associated with failure of the cement mantle. The area of optimum compromise is that

70-80% of the canal diameter should be occupied by the femoral prosthesis and the remaining space by the cement mantle. This is especially so for the diaphyseal part of the femoral stem (14, 20).

Cement restrictors play an important part in preventing distal cement leakage and producing a thick cement mantle. By sealing the femoral cavity, the intramedullary pressure is increased during insertion of the stem ; thus, both the ability of the cement to interdigitate with bone and secondarily the shear strength of the cement bone interface are enhanced. The commonest restrictors still in use are the bone plug and polyethylene restrictors ; both are well recognised and have been proven associated with good survivorship for cemented femoral stems (14, 24). Wroblewski *et al* had reported that their use of intramedullary bone blocks has reduced both the radiological and the clinical incidence of aseptic loosening of the stem (24). None of these restrictors, however expand compared to newly designed ones (8). Recently expandable bio absorbable flexible gelatine plugs with superior canal occlusion and stability characters have come into use (13). A preformed plastic plug is the easiest to use, but it must be of the appropriate size.

The value of the more flexible and biodegradable restrictors compared to the polyethylene ones, in restricting the cement leak distal to the tip, is however still questioned as well (8). A tightly fit bone block was shown to seal off the femoral canal better than a polyethylene restrictor (18).

In the prospective study by Mofidi *et al* (17), the Biostop restrictor and the Hardinge restrictor were statistically compared with respect to the distal migration of the cement. The authors found no statistical difference between the two.

Wembridge *et al* prospectively compared the migration behaviour of the two different cement restrictors (23). They compared intraoperative and postoperative radiographs to determine restrictor migration. They found out that the biodegradable restrictor used in their study allowed significantly more migration than the UHMWPE restrictor.

In our study, we analysed the behaviour of Hardinge and bone block restrictors. Irrespective of the type of cement restrictors we used, we found that when a restrictor remained between 20-30 mm

distal to the tip of stem, the cement mantle thickness in zones 3, 4 and 5 was more predictable. When this distance was increased, the cement mantle became non-uniform and non-continuous, because of migration of the restrictor. Although the cement restrictor was positioned in all cases within 2-3 cm of the tip of the prosthesis, it seems to have migrated when the cement was injected and pressurised, forming irregular masses in zone 4. Void areas close to the restrictor in zone 4 were noticed when the cement restrictor had migrated more than 40 mm from the tip of the femoral prosthesis. This irregular shape of the cement also involves the mantle in zone 3 and 5. However, this migration did not have any significant effect in the proximal zones.

We conclude that in all cases, the type of cement restrictor should be decided depending upon the canal diameter. An ideal restrictor should withstand the effect of pressurisation. In order to have a predictable mantle thickness distally, the ideal seating distance of the restrictor in our view is between 20-30 mm below the tip of the stem. With a wider canal, more migration should be anticipated. Accordingly, a wider diameter restrictor, which snugly fits the canal, should be used. The currently available Hardinge restrictors should in our view be available in different dimensions to fit different canal diameters. The bone block results will only be reproducible when the canal diameter is no more than 16 mm, and the bone block is positioned 2-3 cm distal to the tip of the stem.

We suggest further dynamic studies using C-arm during cement pressurisation of the femur to check on the migration of the restrictor during the procedure, this can be done on cadavers before a particular cement restrictor is used.

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