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ORIGINAL STUDY

Radiographic analysis of a bone plug in 275 primary cemented total hip arthroplasties

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Various designs of cement restrictors for total hip arthroplasty have shown a variability in resistance to intramedullary pressure and migration.
The performance of a conical bone plug was studied in 275 cemented total hip arthroplasties with a follow-up between 5 and 19 years . In a radiographic analysis the relation between the plug position and the cement mantle quality was investigated. The results were compared to the performance of other cement restrictors as reported in the literature.
Good to excellent cement mantles were observed in 80% of the femurs. A significant correlation between the stability of the plug and the quality of the cement mantle was found. Forty-nine percent of the plugs were within 1 to 3 centimetres of the Exeter stem hollow centraliser. We also demonstrated that bone plugs performed almost always better than polyethylene or gelatine restrictors reported in other studies.

Keywords : hip arthroplasty ; cemented femoral implant ; cement restrictor.

INTRODUCTION

During the last decade conventional total hip arthroplasty has somewhat been overshadowed by the interest in resurfacing arthroplasty. However, problems and higher revision rates with large diameter metal-on-metal resurfacing arthroplasty have renewed the awareness into the success of traditional cemented hip arthroplasty. Since the introduction of cemented total hip arthroplasty the technique of cementation has significantly changed. Initially, the doughy cement was forced down the track of the femoral canal by simple thumb packing. Charnley had already recognised the importance of achieving adequate cement pressure (*8*). Further research gave more detailed information on the importance of an effective pressurization (*1,5*). In 1975 retrograde cement delivery became possible with the introduction of a cement gun (*12*). The use of an intramedullary cement restrictor was first described in 1978 ; it allowed a more accurate filling and pressurization of the canal (*21*). It is universally recognised that an optimal cementing technique improves the lifespan of a cemented stem. Cement penetration into cancellous bone, the mechanical mode of component fixation, is better achieved with adequate pressurization (*3,21*). Sufficient and sustained pressure levels are mandatory to achieve this interlock and are equally important to withstand the potentially detrimental effect of

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intramedullary bleeding (5,16). As a consequence of enhanced pressurization, increased shear strength has been demonstrated between the cement and surrounding bone (1,5). To achieve sufficient pressurization the use of an intramedullary cement obturator that distally occludes the femur in an optimal way is mandatory. Ideally a cement restrictor should prevent cement leakage and should resist prolonged and high intramedullary pressure during cement injection and stem insertion. In addition it should disappear soon after the operation in order to facilitate revision procedures if required for septic or aseptic loosening or periprosthetic fracture.

Currently, several systems are available to obtain distal femoral occlusion, including polyethylene plugs, absorbable gelatine plugs, PMMA plugs and bone plugs harvested from the femoral head. Data on the stability and performance of bone plugs and non-degradable and biodegradable plugs are not universally conclusive (6,10,11,13,14,22,25). Even within obturators made of one single material i.e. polyethylene, various grades of stability have been reported (4,6). This is most likely related with the design of the different plugs. The common conclusion from reports in the literature is that biodegradable restrictors are inferior to other systems, with more migration and lower intramedullary pressure as the main weaknesses. On the other hand they have a vast advantage in case of potential revision surgery. This benefit in our experience is also present when bone harvested from the femoral head is used as a cement restrictor. Some studies, however, suggest that sufficient stability with bone plugs is not always achieved and that the technique is less reliable than the use of artificial plugs (4,25). In addition some authors suggest that there exists a relationship between the length of the cement column distal to the stem tip and the quality of the cement mantle (22,23). This may be related in some cases with inaccurate placement of the restrictor, but it is thought that in a number of THAs, distal migration of the cement restrictor occurs whilst applying pressure during cementation or stem insertion.The aim of this study is to investigate the performance of a bone plug as an intramedullary cement restrictor in primary cemented total hip arthroplasty.

MATERIALS AND METHODS

The radiographs of 275 cemented THAs in 251 patients were analyzed. The patient population included 147 male and 104 female patients, with an average age of 65 years (range : 25-95 years). The preoperative diagnosis was osteoarthritis in 211 hips, femoral head necrosis in 35 hips, inflammatory arthritis in 24 hips and another diagnosis in 5 hips. Inclusion criteria for the study were primary cemented femoral component THA, with a bone plug used as an intramedullary cement restrictor. All patients underwent the same operative procedure performed by either the senior surgeon (JPS) or a trainee surgeon in the presence and under supervision of the senior surgeon, using the posterolateral approach. The femoral canal was prepared using manual broaching. Plugging of the femur was achieved using a conical bone plug. Prior to the placement of the bone plug, pulse lavage was used to avoid fat embolism during plug insertion. The bone plugs were prepared after transversally cutting the removed femoral head halfway between the neck resection line and the head surface. The size of the bone plug was chosen according the diameter of the femoral canal, estimated from the preoperative radiographs and additionally measured using stainless steel rods with 1 mm increments. The plug was inserted using the same stainless steel metal rod, used for determining the canal diameter. These rods carry a mark which is referenced to the medial calcar cut. After intramedullary pulsed lavage, Simplex P (Stryker Inc, Caen, France) hand mixed cement was applied in a retrograde fashion with a cement gun and pressurised using a proximal Sorbothane® (Stryker Inc, Caen, France) seal. A double tapered polished Exeter™ (Stryker Inc, Caen, France) cemented stem was used in all hips. The aim was to insert the bone plug 1 to 2 cm below the hollow centralizer which is applied on the tip of the Exeter stem.

Post-operative antero-posterior and lateral radiographs were available for all patients at 6 weeks, 1 year and at the latest follow-up. The radiographs taken between 5 and 10 year follow-up were reviewed for 150 THAs. In addition for the remaining 125 THA's exceeding 10 years follow-up, radiographs between 11 and 19 years were likewise analysed.

All measurements were adjusted for magnification using the femoral head diameter as a reference. In addition, the quality of the cement mantle was assessed using the classification system described by Barrack, Mulroy and Harris (2) (Table I). The correlation between the distance from the plug to the hollow centralizer and the Barrack grade of the cement mantle was assessed

Table I. — Barrack classification of cement mantle quality

BARRACK	Number	Percentage
A	172	62.5
B	54	19.6
C1	29	10.5
C2	17	6.2
D	2	0.7

using the Spearman correlation test. Cement leakage distal to the plug was also considered. We also investigated the correlation between the cement mantle quality and the operating surgeon and compared the Barrack classification for the senior surgeon (JPS) with trainee orthopaedic surgeons. This was done by an independent observer, evaluating the latest radiographs, but unaware of the operating surgeon. The study was approved by the hospital ethics committee and no additional radiographs were taken. The treatment of the patients was in no way altered as a result of the investigation.

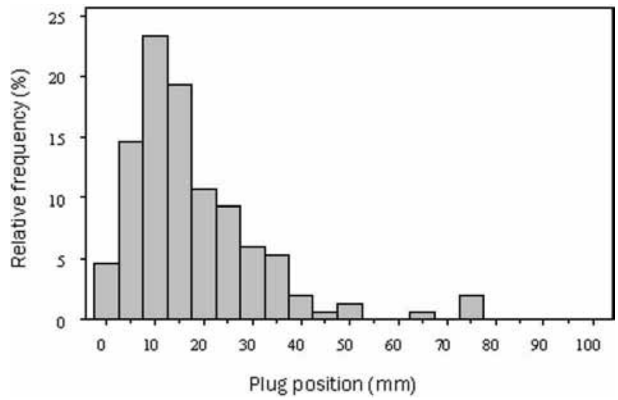

Fig. 1. — Histogram indicating the relative proportion of the plug position intervals. The mean distance from the plug to the tip of the prosthesis measured 17.7 mm (range : 2-76 mm, SD = 13.8 mm).

RESULTS

Plug Position

The mean distance from the plug to the tip of the hollow centraliser was 17.7 mm (range : 2-76 mm, SD = 13.8 mm). The distance was divided into regular intervals of 10 mm and the relative frequency was determined for each category. In 36% of the cases the plug position was 0-10 mm below the prosthesis. In 33% the distance was 11-20 mm. In 16% this was in the 21-30 mm interval. In 10%, 2% and 3% the plug position was respectively 31-40 mm, 41-50 mm and > 50 mm. Figure 1 shows a histogram describing the relative proportions of the distance intervals. The plug position was not correlated to the experience of the senior surgeon versus various trainee surgeons. This may be explained because the plug was always introduced with a calibrated metal rod bearing a mark referenced to the calcar cut.

Cement grading

Using the classification system described by Barrack *et al* (2), 62.5% (95% CI : 54.9% - 70.4%) of the radiographs showed grade A, 19.6% (95% CI : 13% - 25.7%) grade B, 10.5% (95% CI : 6.3% - 16.4%) grade C1, 6.2% (95% CI : 2.2% - 9.8%) grade C2 and only 0.7% (95% CI : 0% - 2%) grade D (Table I). A significantly better cement mantle quality (p = 0.01) and fewer radiolucent lines were observed when the operation was carried out by the senior surgeon versus the trainee surgeons.

Correlation between plug position and cement quality

In each Barrack classification category, the distribution of the plug positions was determined. In Barrack grade A the mean distance was 13.87 mm (2-40 mm, SD = 8.73 mm), in grade B 23.66 mm (5-76 mm, SD = 17.7 mm). The mean distance in grade C1 was 23.35 mm (4-76 mm, SD = 17.57 mm) and 22.44 mm (5-48 mm, SD = 16.39 mm) in grade C2. In the only patient with bilateral grade D cement mantles, the distances measured 64 and 68 mm. A box plot diagram is given in figure 2. The correlation between the distance from the plug to the tip of the prosthesis and the Barrack grade of the cement mantle was assessed using the Spearman correlation test. A significant correlation between the obtained data was found (p = 0.0003).

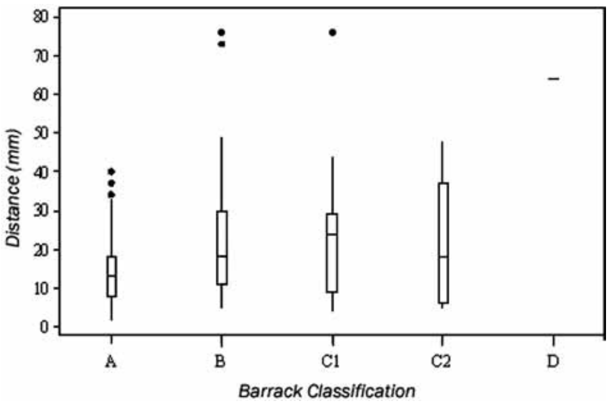

Fig. 2. — Box plot diagram indicating the distribution of the distances between plug and stem in each Barrack grade. The small horizontal lines indicate the median distance, the edges of the box indicate the Q1 and Q3 value and the ends of the lines or dots indicate the smallest and highest distance in each group. The Spearman correlation test shows a significant correlation between distance and Barrack grade.

Cement leakage

Cement leakage beyond the plug was noted in only 11 cases (4%) and did not adversely affect the cement mantle. Cement leakage was not related to the femoral diameter and did not occur more often in stovepipe femora.

Stem subsidence

The mean subsidence of the stem in Barrack A, B and C categories was 1.2 (0-2.2) millimetres. In the only patient with 2 grade D cement mantles, subsidence was 1.6 centimetres This patient, however, suffered a bleeding disorder that was only revealed following surgery. Uncontrollable bleeding in the femoral cavity prior to and during cement insertion occurred despite the use of adrenaline soaked swabs and a venting tube. The patient, however is functionally well and has no pain, but restricted mobility of both hips.

DISCUSSION

Cement restrictors are an integral part of modern techniques in cemented THA. Various cement restrictors are available and have been tested *in vitro* and *in vivo* (*4,6,7,9,10,11,13,14,18,21,22,23,25,26*). A disadvantage of artificial plugs is the fact that they must generally be removed when revision surgery becomes necessary, particularly when a long stem with its extension beyond the bone restrictor is needed to bridge a femoral defect. The extraction of a synthetic cement restrictor carries the risk of non intended femoral perforation especially when the bone becomes weak or deformed by osteolysis. Safe removal can in many problematic cases only be done by using an extended femoral osteotomy. Biodegradable restrictors are attractive, at least in some of these situations, to overcome this problem. Data on the stability of resorbable restrictors are open to doubt. Although promising results have been shown in *in vitro* studies and in a few clinical trials, most *in vivo* studies indicate an inferior performance, steadiness and resistance to high intramedullary pressure of biodegradable plugs as opposed to polymer materials and bone plugs (*6,7,9,10,11,13,14,22*). As a consequence the use of biodegradable restrictors has led to inferior cement mantle quality and therefore their use has been discouraged by several authors (*10,11,22*). We are convinced that bone plugs combine several advantages of synthetic and biodegradable restrictors and have the advantage of being composed of autologous bone, which is safer than artificial material. It has been shown that, during the insertion of a plastic plug, small polyethylene particles are deposited in the femoral canal. Particles of less than 10 μm were found to be appropriate for phagocytosis by macrophages and thus for a potential contribution to osteolysis (*15*). In a revision situation it is the senior author's experience that bone plugs have either been resorbed or in case they have become vascularised and incorporated in the femoral cavity they can easily be drilled through using a simple bone drill of 6 mm diameter with almost no risk of perforating the femur. Another advantage, especially in times of expensive medical technologies, is the evident fact that bone plugs are costless. The senior author (JPS) has used a bone plug since 1990 in over 3500 cemented femoral hip replacements and has never encountered a femoral crack or fracture whist introducing the plug, indicating its safe use. If the bone plug is accidently chosen too small and

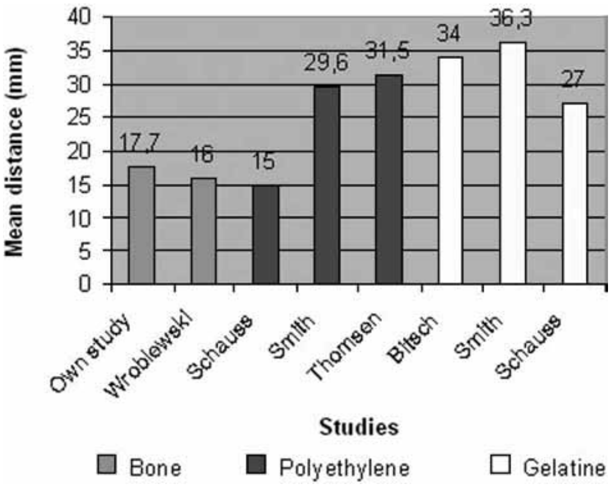

Fig. 3. — Overview of the mean distances between the plug and the tip of the prosthesis in studies with a comparable study design.

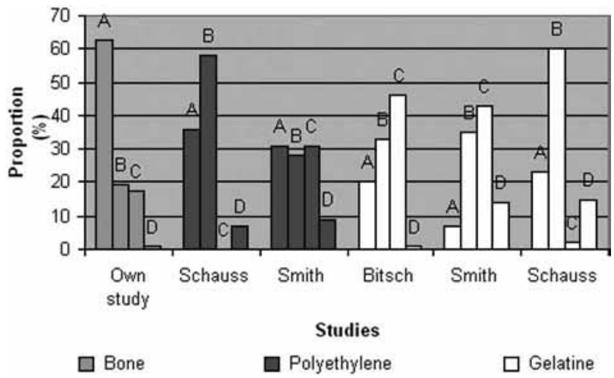

Fig. 4. — Overview of the distribution of Barrack grades for the cement mantles in studies with a comparable study design.

during insertion is pushed beyond the isthmus, sufficient bone almost always remains from the femoral head to prepare a larger diameter plug. A number of studies, however, suggest that sufficient stability with a bone plugs is not always achieved and that the technique is less reliable than an artificial plugs (4,25). Beim *et al* (4) and Mallory (18) based their statement on *in vitro* studies with a limited number of test objects and without statistical analysis. Thomsen *et al* (25) performed a prospective randomised study, but with a relatively small number of test objects. To answer the question whether bone plugs are able to yield satisfactory stability and cement mantle quality, we compared our results to other series with different plug materials and a comparable study design. In our study a significant correlation between the stability of the plug and the quality of the cement was found. An overview of the mean distances between plug and prosthesis is given in Figure 3. Bone plugs performed almost always better than polyethylene or gelatine restrictors. Only Schauss (22) reported a smaller mean cement length with polyethylene plugs. These results indicate that a bone plug achieves a good intramedullary fixation perhaps because of better strutting within the canal due to hardness and high friction of bone to bone which better resists the high pressure during cementing. Figure 4 illustrates the overall cement quality in the different study designs. Excellent cement grade (grade A) was achieved in 62.7% of the cases where bone plugs were used. This was always better compared to series describing polyethylene or gelatine restrictors. Inferior cement grades (grade C and D) were seen in only 18% of the cases. Only Schauss (22) reported better results with 7% grades C and D in the polyethylene series and 17% in the gelatine series.

Clinically, Smith *et al* (22) demonstrated that no femoral component loosened on long-term follow-up with a cement grade A or B. This highlights the assumption that bone plugs yield adequate stability and hence sufficient cementation pressure.

To our knowledge, this is the first *in vivo* study describing the performance of bone plugs in a statistically relevant population. In addition in our study the radiographic analysis was performed in hip arthroplasties with a follow-up extending between 5 and 19 years postoperatively. The length of follow-up increases the reliability compared to when only immediately postoperative radiographs would be analyzed.

A criticism that might be raised related to the use of a bone plug is the fact that a certain amount of cancellous bone is lost which otherwise could be stored and used as allograft bone. We determined the volumes of bone for a small and large bone plug used in this study and determined the loss of bone in relation to the volume of the femoral head con-

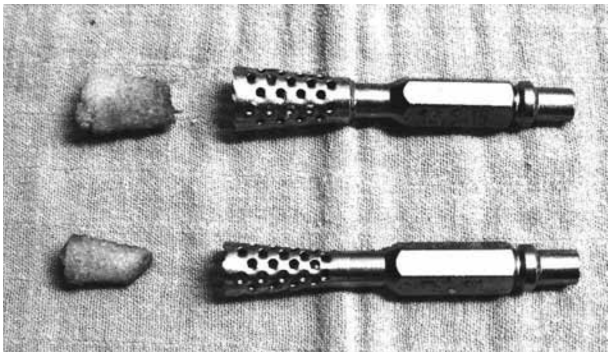

Fig. 5. — Example of a small bone plug

sidering several femoral diameters. Although the plugs are shaped as a truncated cone, the shape cut out the femoral head is cylindrical. The volume of the femoral head, in the theoretical assumption it would be a perfect sphere is 33.5 cm^3, 65.45 cm^3 and 113.1 cm^3 for a 40 mm, 50 mm or 60 mm diameter respectively. The volume of the bone cylinder removed to form a small (height 2.5 cm, radius 0.5 cm) or a large (height 2.8 cm, radius 0.7 cm) bone plug is 1.96 cm^3 and 4.31 cm^3 respectively. For a smaller bone plug this means a bone loss of 5.85% for a 40 mm diameter femoral head, 2.99% for a medium sized femoral head and 1.73% for a large femoral head. For a large diameter femoral plug this implies a bone loss of 12.8% for a 40 mm diameter femoral head, a 6.58% loss for a medium sized femoral head and a 3.8% loss for a large femoral head. The highest percentage (12.8%) estimated loss of bone is, however, a rather theoretical assumption since a small diameter femoral head rarely coincides with a large femur. On the contrary a large femoral head with a small distal diameter canal, requiring a small diameter plug only is not exceptional in male patients.

Hence when saving the femoral head for the bone bank and simultaneously using a bone plug to block the femur the total amount of lost bone to be saved will rarely exceed 5%. In addition this estimate does not include the bone that may be harvested from the partially removed femoral neck and some cancellous bone from the calcar area.

A weakness of our study is the fact that no intraoperative measurement of the plug position was done before the introduction of the cement and stem. The radiographic plug position and cement quality were determined at the same time. Therefore, a certain degree of bias in the radiographic assessment seems to be inevitable. Further, as revealed in other studies a significantly better cement mantle quality and fewer radiolucent lines were observed when the operation was carried out by an experienced surgeon versus the trainee surgeons.

Our study has nevertheless established some important trends that influence cementing results. The distance travelled by the plug, and hence the stability of the cement restrictor, directly correlates with the overall cement grade and stresses the importance of choosing a cement restrictor that can withstand adequate pressurization. Although bone plugs are by some considered to be less reliable for routine practice, it is our experience that they have some important advantages since they performed better in our study compared to polyethylene or gelatine plugs of most other studies. Therefore, we positively recommend the use of a bone plug as intramedullary cement restrictor in routine primary cemented total hip arthroplasty.

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