INTRODUCTION

Distal flow of polymethylmethacrylate (PMMA) bone cement during insertion of the femoral implant results in reduced pressure and cement-bone interdigitation (Markolf, Amstutz, 1976). Insertion of femoral cement plugs in the intramedullary canal to prevent distal flow of PMMA cement in total hip replacement during cementing of femoral prostheses is well accepted and has become current practice (Prendergast et al., 1999). As a result, many designs of cement plugs exist on the market. The aim of this study is design an experimental set-up to compare the performance of the following four designs of cement plugs: (a) REX (A-one Medical B.V.), (b) Hardinge (DePuy), (c) Amber Flex (Summit Medical Ltd) and (d) Cemlock (Sulzer). This was done by recording data of proximal and distal pressures and migration of the cement plugs during cement pressurisation and insertion of the femoral prosthesis in prepared Sawbone femurs.

Prendergast and co-workers (1999), in their study to look at the stability of different cement plugs under typical cementing pressures, used wooden Iroko teak tubes to replicate well-reamed cortical medullary cavity. Iroko teak tube has closer material properties to human cortical bone than materials, such as artificial plastic femora, which has been used for similar studies (Bulstra et al., 1996). However, as Prendergast and co-workers pointed out, the reamed surface of the femur is not ideally replicated using Iroko tubes. In this study, we use Sawbone femurs to better replicate the reamed femur and also to maintain reproducibility and reduce variability.

MATERIALS AND METHODS

The four intramedullary plugs chosen for this study were:

1. REX plug, from A-one Medical B.V., the Netherlands, is an expandable and partly resorbable cement restrictor made of gelatine and PMMA covering 10mm–20mm canal diameters with 3 sizes (Figure 1).

2. Hardinge plug, from DePuy Ltd., UK, is manufactured from ultra high molecular weight polyethylene and is available in one size that deforms to the diameter of the medullary canal (Figure 2).

3. Amberflex plug, from Summit Medical Ltd, UK, is a bio-resorbable cement restrictor, with flexible fins, is derived from porcine material and is available in many sizes (Figure 3).

4. Cemlock, from Sulzer, UK, is made from pure polylactide, a fully biodegradable biomaterial and is available in two sizes – for medullary spaces of less than 10 mm diameter and 10-16 mm diameter (Figure 4).

Preparation of specimens for testing

Sawbones foam cortical shell femurs were prepared by the same orthopaedic surgeon. The femoral heads were transected and the medullary canals were reamed so that the diameter of the canals at the distal end was 12mm in diameter. Cement plugs were then inserted at 160mm from the medial proximal end for all the tests and according to manufacturers’ instructions.

Palacos PMMA cement was vacuum-mixed, as per manufacturer’s recommendation, and used in all the tests. Cement was introduced in the intramedullary canal of the prepared sawbone femur, using a cement gun, and pressurised for 30 seconds, using DePuy pressuriser. The femoral prosthesis (Charnley roundneck) was then introduced at a controlled speed of 10mm/s into the femur, when the cement was still in a doughy state (Figure 5).

Cement pressure and plug migration data capture method

Two holes were drilled through the femurs, at 40 mm and 150 mm below the medial proximal end of the prepared femur, to accommodate the pressure transducers. The pressure transducers (Entran, 35 bar) were carefully inserted through these holes so that their measuring surfaces flushed with the inner surface of the medullary canal of the reamed femur. The leads of the pressure transducers were connected to an analogue/digital converter (Instrunet 100) so that proximal and distal pressure data could be recorded electronically during cement insertion and pressurisation into the medullary canal and during insertion of the femoral prosthesis (Figure 6).
A linear potentiometric displacement transducer (LPDT) (Techni Measure) was used to measure migration of the cement plugs during cement pressurisation. A special jig was manufactured to hold the femur into the desired position and to accommodate the pressure transducers and LPDT during the tests. A groove was produced on the lower end of the jig to the LPDT. The pin of the LVDT was pressed against the base of the cement plug prior to testing.

The femoral component (Charnley roundneck) was fixed between the upper jaws of a mechanical testing machine (Instron 8874) and was used for all the tests. The jig, with prepared femur, pressure transducers and LPDT, was fixed to the lower jaws of the testing machine. The testing machine was used to control the speed at which the femoral prosthesis was inserted into the prepared femurs. Data captured by the pressure transducers and LPDT were digitized, using an analogue/digital converter (Instrunet 100) and recorded electronically. The room temperature was kept at 24°C. Figure 5 shows the experimental set-up and figure 6 shows the outline of the experiment set-up.

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An average number of 3 tests were carried out for each cement restrictor and average data of intramedullary pressures and migration of cement restrictor was computed.

**RESULTS AND DISCUSSION**

Typical graphs for the different stages of the whole test for each type of cement plug is shown in Figures 7-10. This includes phases during cement introduction and pressurisation (first set of low peak pressure on graphs), and femoral implant insertion (second set of high peak pressure on graphs). Peak pressures in the range of 548kPa to 1,112kPa were obtained for the different plugs during insertion of the prosthesis. This pressure is much higher than during cement pressurisation but lasts for about only 20 seconds and decreases sharply again. Migration values in the range of 0.19mm to 3.4mm were recorded. These values only include data when there was not excessive cement loss through the cement plug.

We attempted to keep the time between the cement introduction and pressurisation phase and insertion of femoral prosthesis constant for about 80 seconds for all the tests. This was not always possible, but we managed to keep the time between 65 to 90 seconds, as shown on the graphs. The specimens were not preheated to body temperature prior to the tests to mimic surgical environment. Due to the visco-elastic behaviour of bone cement, keeping the specimens at 24°C could have some influence on the actual values of cement pressure. However, we believe that the trend in pressure values for the specimens with different cement plugs would not be affected.
Since the highest pressures and migrations were produced during insertion of the femoral component, this stage of the test was considered for evaluating the performance of the different cement plugs. For each type of cement plug, cement distal pressure and plug migration data during insertion of the femoral implant were plotted on the same graph so that the peak values for each test coincided with time. The average values of distal pressure and migration for each type of cement plugs were computed and plotted on the same graph for comparison.

Figure 11 shows the average values of distal pressure for the four different types of cement restrictors used during controlled insertion of the femoral implant. Data on the graph shows that Hardinge and REX cement restrictors produce higher distal pressures of 881 and 725 kPa, respectively.

Figure 12 shows the average plug migration values for the four different types of cement restrictors used during controlled insertion of the femoral implant. Lower migration values of less than 0.3 mm were associated with Amberflex and REX cement restrictors.
Remarkably low distal intramedullary pressure and high migration values (beyond the scale shown on the graph) were recorded for Cemlock cement restrictors. This was because this cement restrictor usually broke during insertion, allowing cement to escape. This is confirmed by X-ray images showing significant amount of cement passing through the Cemlock restrictors. In the next step of this study we will investigate cement occlusion and amount of leakage through the cement plugs by cross-sectioning the specimens.

The values of peak pressures during insertion of prosthesis measured for the different cement plugs agree with the results of other investigators. Bourne and co-workers quoted peak distal cement pressures of 9.7 bar (970 kPa) (Bourne et al., 1985). Oh and co-workers quoted maximum distal pressures of 12 bar during stem insertion (Oh et al., 1993). Song and co-workers measured distal pressures exceeding 3710 mm/Hg (49.5 kPa) (Song et al., 1994).

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**REFERENCES**