An investigation of the performance of Biostop G and Hardinge bone plugs

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Abstract: Although distal plugging is a common procedure to prevent distal flow of polymethylmethacrylate (PMMA) cement during cementing of femoral prostheses, there is little biomechanical testing to confirm that (a) the plugs do not displace under cementing pressure, and (b) they do in fact occlude cement flow. Two designs of femoral intramedullary plugs, the Biostop G (Bioland, France) and Hardinge (De Puy, Leeds, UK) were examined to determine their performance under cement pressurization in a biomechanical test. A testing rig was fabricated in which distal migration could be measured as a function of cement pressurization. Sectioning of the samples after polymerization of the cement revealed the extent of cement flow. The results show that, even in this well controlled test, there is significant variability in plug performance. It is shown that the Biostop G displaces less than the Hardinge for similar cement pressures. Sectioning reveals that cement can escape around the Hardinge plug at high pressures. Furthermore, a pore forming effect of the Biostop G plug was occasionally observed indicating that design improvements may be possible for this plug.

Keywords: intramedullary plug, hip replacement, cement technique

1 INTRODUCTION

While many factors determine the long-term success of cemented hip replacements, loosening associated with inadequate cementing technique is recognized as a principal cause of failure [1, 2]. Distal flow of the curing polymethylmethacrylate (PMMA) bone cement during insertion of a femoral prosthesis is to be avoided because it dissipates the pressure build-up in the intramedullary cavity, which may exacerbate cement porosity or lead to poor cement/bone interdigitation [3]. Despite the acknowledged importance of intramedullary plugging to the effectiveness of cement pressurization, the stability of plugs under typical cementing pressures and the prevention of leakage around the plugs has not been confirmed experimentally.

Oh et al. [4] showed that using a bolus of PMMA to plug the canal prior to introducing the majority of the cement significantly raises cement pressures and improves cement/bone interdigitation. Cancellous blocks have also been used [5], but as Mallory [6] points out, (a) suitable bone may not be available during revision surgery, (b) it is difficult to match the femoral diameter closely enough to prevent leakage, and (c) the bone can fragment during insertion.

He proposed a flanged high density polyethylene plug and showed, using laboratory tests on cadaveric femurs, that it could resist 100 lbf/in2 (~700 kPa). Beim et al. [7] used reamed diaphysial femur sections and applied a pressure greater than 50 lbf/in2 (~350 kPa). They found that the ability to withstand distal migration was highest for a PMMA plug with the Hardinge plug being the next best; a Dow Corning polymeric plug, and a bone plug performed the worst. Thomsen et al. [8] compared the performance of cancellous blocks, a Richard’s flanged plug, and the Hardinge plug in 77 total hip arthroplasties. Postoperative radiographic assessment showed highest quality of cement packing with the Hardinge plug and poorest with the cancellous bone block. Greater distal migration was found with the Richard’s flanged plug compared to the Hardinge. The most recent study by Bulstra et al. [9] reported a
biomechanical analysis of a Hardinge plug. They used artificial plastic femora and measured the displacement and leakage under cement pressurization; they reported significant migration with pressures as low as 2 kPa.

The above studies have not quantified the extent of distal migration as a function of cement pressure, nor has sectioning been done to determine the extent of cement flow around the plugs. In this investigation, two commonly used intramedullary plugs are investigated and compared to ascertain their performance under the cementing pressures observed in cemented hip replacement.

2 METHODS

The two intramedullary plugs chosen for this study were (a) a Biostop G biodegradable cement restrictor of the following composition: gelatin (50 per cent), glycerol (30 per cent), water (20 per cent), methylparahydroxybenzoate (0.2 per cent) (Bioland, France) and (b) the Hardinge plug manufactured from ultra-high molecular weight polyethylene (De Puy, Leeds, UK). The Biostop G plug comes in a range of sizes (from 8 to 20 mm) where the size is chosen by the surgeon to fit the individual medullary canal, according to the manufacturer’s instructions. The Hardinge plug is a ‘one size fits all plug’ which deforms to the diameter of the medullary canal on insertion.

2.1 Experimental procedure

To minimize variation between tests to allow comparison of results, wooden Iroko teak tubes were used to replicate a well-reamed cortical bone medullary cavity. These were machined to the following dimensions in accordance with the measurements of an average femoral diaphysis [10]: an outer diameter of 34 mm, an inner diameter of 15 mm, and a height of 90 mm. A specimen stand was manufactured to facilitate testing using an Instron 1011 materials testing machine. This permitted the displacement of the bone plug to be measured during testing by means of an LVDT (linear variable displacement transducer, Solartron DG2.5) positioned against the base of the bone plug (see Fig. 1). A PC based data acquisition system (Amplicon PC-26 AT, Amplicon Liveline Limited, Brighton, UK) was used to simultaneously sample both the applied load and the displacement measured by the LVDT. The LVDT and Instron

![Fig. 1 Schematic of the experimental set-up consisting of the stand, tube, and loading rig, measurement of displacement by LVDT (linear variable displacement transducer), and computer data acquisition of load and displacement](image_url)
voltage outputs were both calibrated prior to testing. The cement was pressurized by means of a plunger, the diameter of which was chosen so as to be sufficiently wide to prevent cement flow around the sides and yet narrow enough not to incur a frictional resistance between the plunger and the walls of the tube. The test set-up is illustrated in Fig. 1.

Prior to testing, all Iroko tubes were heated to 37 °C for a period of at least 24 h, and then assessed for their suitability for testing: no frictional forces should occur between the plunger and the specimen tube. Unsuitable tubes were resized and reheated to 37 °C prior to testing. Heating was important because the gelatin material of the Biostop G plug has high temperature-dependent properties. A suitable sized plug (size 14 plug) was inserted according to the manufacturer’s instructions, to a depth of 40 mm (note that for the Hardinge plug this depth was measured from the top of its edges for the deformed inserted shape). The LVDT position was adjusted to touch the distal surface of the plug. Simplex Rapid bone cement (10 g PMMA powder, 5 ml liquid monomer) was mixed at a rate of approximately 1 Hz for 2 min (when the cement reached its doughy state) and it was packed by hand into the cavity. The plunger was lowered to the top of the cement, with testing commencing 4 min after initial mixing of the PMMA powder and liquid monomer. During testing the plunger was lowered at a rate of 20 mm/min, with the test ending on reaching 5.5 mm displacement. Data was obtained for 11 Biostop G plugs and 8 Hardinge plugs.

The resistance of the plugs to cement penetration was also studied by loading to various pressure levels (50, 70, 75, 100 and 200 N). These pressure levels span those measured by Song et al. [11], with the maximum pressure examined for an indication of performance under extreme conditions. The samples were sectioned along their longitudinal axis providing a means of visualizing the extent of cement penetration, if present.

3 RESULTS

The cement pressures (calculated by dividing the load by the area of the femoral canal) were determined for fixed displacement intervals of 0.25 mm up to 2.5 mm total displacement, and 0.5 mm intervals from 2.5 mm to 5.0 mm total displacement. Figure 2 illustrates the mean pressures and standard deviations plotted against displacement for both the Biostop G and Hardinge plugs; this shows that the Biostop G plug allows a higher pressure to be generated in the curing cement. It can be seen that, even in this well-controlled mechanical environment with reproducible ‘bone’ dimensions and controlled cement pressurization, a considerable variation in pressure under displacement exists. The mean pressures closely follow a linear pattern from 0.5 mm to 5.0 mm displacement, with Pearson correlation coefficients greater than 0.99 in both cases. An analysis of covariance for the cementing pressure data showed

![Pressure/displacement curves for Biostop G and Hardinge plugs, illustrating mean and standard deviation of pressures at fixed displacement intervals of 0.25 mm up to 2.5 mm and 0.5 mm to 5.0 mm. The maximum pressures given by Mallory [6] and Song et al. [11] are also shown for comparison.](image)
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(a) (b)

Fig. 3 Close-up views of examples of longitudinal sections of the Iroko tubes, bone cement and cement restrictors following cement penetration tests at the pressures indicated. (a) Biostop G plug (at 280 kPa) in intramedullary cavity showing cement extruded approximately half way down the central insertion hole with a pore occurring in the cement. (b) Hardinge plug (at 400 kPa) in the intramedullary cavity illustrating where cement has penetrated past one of the fins of the plug, pushing the fin into the central region of the cement. The cement has continued to extrude to the wall of the cavity, where it was found to continue past the plug at higher pressures.

that a significant difference exists between the Biostop G and Hardinge cement pressures \( p < 0.001 \).

Figure 3 shows typical longitudinal cross-sections for both the Biostop G and the Hardinge plugs. The Biostop G plug performed better than the Hardinge plug in preventing cement penetration around the sides of the respective plugs. Failure to occlude cement commenced at pressures of approximately 400 kPa for the Hardinge plugs (see Fig. 3b), with large amounts of penetration at pressures around 1 MPa. The Biostop G plug occasionally demonstrated a pore in the cement because air, trapped in the central insertion hole, was displaced to form a bubble, or pore (see Fig. 3a).

4 DISCUSSION

Plugging of the distal femoral canal is recognized as providing a higher cementing pressure with better cement filling and good cement/bone interdigitation. Despite the extensive use of intramedullary plugs in surgery, there is very little biomechanical evaluation of their performance as a function of cementing pressure. This study investigated two commonly used plug designs and showed that, on average, these plugs can sustain the kind of intramedullary pressures obtained in vivo. This would seem to be contrary to the results of Bulstra et al. [9].

While both designs demonstrated distal migration during pressurization, the performance of the Biostop G proved somewhat superior to that of the Hardinge under the conditions examined. The initial observed difference in rates of pressurization between the two plugs (Fig. 2) is accredited to elastic deformation of the Biostop G plug prior to the plug starting to slip down the medullary cavity. The Hardinge plug being made of a stiffer material (polyethylene) did not measurably demonstrate elastic deformation immediately before slippage. The main limitation of the test is that the reamed surface of the femur is not ideally replicated using Iroko tubes. Other studies used cadaveric material [9], which better represents the reamed intramedullary cavity, but has the problem of further increasing the variability of the experiments.

Given that cementing pressures have been measured
as high as over 100 kPa in some instances, it would seem that the Hardinge is uncomfortably close to undergoing significant slippage at this pressure, and in that regard this work supports previous studies on the failure of the Hardinge plug to fully occlude cement flow [7]. However, the advantage that the Hardinge plug has of being able to adapt to non-circular cavities is not appraised by this test. It is noteworthy that Thomsen et al. [8] found no problems with the Hardinge plug in post-operative radiographic assessment. An observation with the Biostop G revealed the presence of voids above the central hole (required for the inserter head) in the Biostop G plug. Such voids may be the result of trapped air expressed from the central hole during cement pressurization. Large pores formed at higher pressures, especially at the distal end of the cement mantle; these pores are sites of stress concentrations from which cracks may initiate and propagate during cyclic loading [12].

In conclusion, both cement restrictors demonstrated their ability to resist intramedullary cement pressures associated with insertion, with the Biostop G plug proving superior in resisting distal migration. The results here show that under well-controlled conditions, the Biostop G plug better occludes the cement than the Hardinge plug, with the Hardinge plug displacing at approximately 60 per cent of the loading resisted by the Biostop G plug. This may become important if even higher pressure cementing techniques are developed. The extreme variability of plug performance is one of the main results of this study. From our examination of longitudinal cross-sections after polymerization, we hypothesize that the variability is most likely to be due to slight differences in placement of the plugs during insertion, a process that may be prone to even greater variation in the clinic. The results suggest that even if, on average, plug performance is acceptable, they will occasionally perform inadequately leading to insufficient pressurization of the cement in the medullary cavity. It may be one of the many reasons for differences in hip replacement loosening rates observed clinically. Given the key role of intramedullary plugs in modern cementing techniques, it may be worth designing a plug less prone to variable performance.

REFERENCES
