Comparison of two pressurisers for cementation of the proximal femur

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ABSTRACT

Purpose. To compare pressures generated by 2 different cement pressurisers at various locations in the proximal femur.

Methods. Two groups of 5 synthetic femurs were used, and 6 pressure sensors were placed in the femur at 20-mm intervals proximally to distally. Cement was filled into the femoral canal retrogradely using a cement gun with either the half-moon pressuriser or the femoral canal pressuriser. Maximum pressures and pressure time integrals (cumulative pressure over time) of the 2 pressurisers were compared.

Results. At all sensors, the half-moon pressuriser produced higher maximum pressures and pressure time integrals than the femoral canal pressuriser, but the difference was significant only at sensor 1 (proximal femur). This may result in reduced cement interdigitation in the proximal femur.

Conclusion. The half-moon pressuriser produced higher maximum cementation pressures and pressure time integrals than the femoral canal pressuriser in the proximal femur region, which is critical for rotational stability of the implant and prevention of implant fracture.

Key words: arthroplasty, replacement, hip; bone cements; femur

INTRODUCTION

Survival of a cemented femoral implant depends on a strong, stable cement-bone interface and hence the cementing technique. First-generation cementing techniques involved preparation of the femoral canal by bulb irrigation, no use of a cement restrictor, and finger packing of cement into the canal. Aseptic loosening secondary to incomplete mantles was the most common mode of failure, with an incidence of 30 to 40%.

Modern cementing techniques involve pulsatile lavage of the canal, use of a distal cement plug, retrograde cement delivery with a cement gun, and cement pressurisation. These techniques have led to a reduction in revision rates for aseptic loosening.
Compared with conventional finger packing, each of these steps reduces the risk for revision by 25%, apart from vacuum mixing. The addition of a distal bone plug, pulsatile lavage, and cement pressurisation leads to an increase in shear strength at the bone-cement interface of 82% and penetration of 74% which may account for the reduced risk ratios. Peak pressure is also greater with the use of a cement gun than with finger packing (156.9 vs. 81.1 kPa), and greater pressures can be attained with the addition of proximal femoral pressurisers (up to 300 kPa).

High cement pressures that are required for good cement penetration are generated by creating a sealed volume in the femoral canal. Proximal femoral pressurisers coupled with distal cement restrictors create a sealed volume in the femoral canal for injection using a cement gun. Studies of proximal cement pressurisers mainly focus on pressures generated (rather than pressures generated in each Gruen zone).

Two commonly used types of cement pressurisers are the Exeter MIS half-moon femoral cement seal (Stryker Orthopedics, Mahwah [NJ], USA) and the femoral canal pressuriser (Stryker Orthopedics, Mahwah [NJ], USA). The latter is designed to fit into the medullary canal of the proximal femur (Fig. 1). However, some surgeons have difficulty in obtaining an adequate seal with such a design, resulting in an increase in wasted cement through extrusion at the seal-bone junction during pressurisation. When used incorrectly, these seals also occlude the proximal femur, potentially preventing cement penetration into the proximal femur.

Most of the rotational stability of an implant is generated in the proximal femur. This study hypothesised that good proximal pressurisation during cementation of the femoral component enhanced implant stability. We compared pressures generated by the 2 different cement pressurisers at various locations in the proximal femur.

MATERIALS AND METHODS

10 Sawbones of the medium left femur (Pacific Research Laboratories, Vashon [WA], USA) were prepared. The neck was cut approximately 10 mm proximal to the lesser trochanter to replicate an ostotomt. The canal was then broached and prepared to accept an Exeter 50-mm offset size 1 stem.

The smallest of the 3 available sizes of the half-moon pressuriser and the femoral canal pressuriser were used, as they were the best fit for the Sawbones. A medium Artisan bone plug (Stryker Orthopedics, Mahwah [NJ], USA) was placed 15 mm distal to the stem tip, using the Exeter cement restrictor introducer as a guide for the appropriate depth. The medullary canal distal to the cement restrictor was back-filled with dental acrylic to prevent cement restrictor migration owing to the smooth medullary canal.

Six strain diaphragm pressure sensors, model PX600 (Omega Engineering, Stamford [CT], USA) were placed in the femur at 20-mm intervals proximally to distally from the centre laser mark on the Exeter stem (Fig. 1). The sensors were placed in an
alternately staggered position medially and laterally (as pressure is equal at the same depth).

Two batches of Simplex bone cement (Stryker Orthopedics, Mahwah [NJ], USA) were hand mixed in a bowl, and the timer was started. At 2 minutes, the cement was introduced into the femoral canal retrogradely using a long nozzle cement gun. The nozzle was then shortened, and from 2 minutes 30 seconds to 4 minutes 30 seconds pressurisation was applied using either the half-moon pressuriser or the femoral canal pressuriser. Further cement was gradually introduced while maintaining pressure.

The Exeter stem was then introduced at 4 minutes 30 seconds, aiming for complete seating at 5 minutes. Pressure was maintained on the stem to prevent it backing out during cement polymerisation and a stem seal was applied. Pressures generated at the 6 sensors were recorded simultaneously at 100 Hz from minutes 0 to 8. Pressure time integrals (cumulative pressure over time) were calculated by integrating the pressure trace with respect to the pressurisation time. Large pressure time integrals enabled displacement of bone marrow and forcing cement into the cancellous bone. Comparisons were made using analysis of variance once normality was confirmed. Adjustment for multiple testing was made using the Bonferroni correction, which meant that the p value of 5% significance became p=0.008 at each level of testing.

RESULTS

Neither device maintained a steady pressure over the pressurisation phase (Fig. 2). Pressures were maintained for the full 2 minutes of pressurisation. At all sensors, the half-moon pressuriser produced higher maximum pressures and pressure time integrals than the femoral canal pressuriser, but the difference was significant only at sensor 1 (proximal femur) [211 vs. 26 and 25 494 vs. 1369 kPa, respectively, both p<0.001, analysis of variance adjusted for multiple testing, Table]. This may result in reduced cement interdigitation in the proximal femur.

DISCUSSION

The maximum pressures in this study were similar to those reported in previous studies.7,10,11 Pressurisation of cement influences the cement-bone interface. Pressures during stem implantation can be much higher than pressures during cementation, but do not affect cement interdigitation or blood displacement, as the cement is too viscous at this time point.

The strength of the bone-cement interface is positively related to the depth of cement penetration and the quality of interlock between cement and cancellous bone.4,12 Major determinants of cement penetration are timing of cement introduction and

Figure 2  (a) Maximum pressures and (b) pressure time integrals during pressurisation: in sensor 1 for the proximal canal pressuriser, pressures do not exceed the back-bleeding pressure.
Cement pressure. Early introduction of cement enables its use at a lower viscosity and leads to greater flow rates, and therefore greater cement penetration.\textsuperscript{13,14}

In vivo, femoral bleeding produces back-pressure of up to 27.7 mmHg, which can displace cement in a low viscosity state.\textsuperscript{13} Pressure must be maintained above 10 kPa until the cement is viscous enough to resist displacement by bleeding pressure. Cement interface strength may also be reduced by seepage of blood between the cement and bone. In our study, the pressure was always maintained above the back-bleeding pressure, except for the proximal femur location when the femoral canal pressuriser was used.

The femoral canal pressuriser is designed to fit within the proximal femur to enable a better fit and seal. By seating the pressuriser within the intramedullary canal, cement penetration into the proximal cancellous bone during pressurisation was lower. The proximal medullary canal surfaces corresponding to the sensor 1 location were covered by the pressuriser, and therefore the mean maximum pressure at sensor 1 was significantly lower. With lower pressure during the low viscosity phase of the cement, cement penetration is likely to be reduced particularly in the proximal femur when the femoral canal pressuriser is used.

Survival of a cemented implant depends on the quality of the cement mantle. Advances in cementing techniques improve outcomes. Poor proximal cementation is associated with an increased risk of implant fracture,\textsuperscript{15,16} because the stem is better fixed distally than proximally. In addition, as most cemented implants are rectangular in their proximal portion and more rounded distally, good-quality proximal cementation is critical for rotational stability.\textsuperscript{9}

A modified seal designed to sit 5 to 6 mm within the proximal femur enables a better seal and improves cementation pressures.\textsuperscript{5} The proximal cancellous bone covered by the seal would have poorer cement penetration, but this was felt to be negligible compared with the improved pressurisation that was obtained.\textsuperscript{6} However, we believe that implant fixation and cement mantle quality around the proximal femur is essential, and an extramedullary seal can achieve even higher pressure.

Limitations of our study were that cement penetration, strength of the cement-bone interface, and stability of the implant were not measured. The sample size was small and may result in a type II error.

**CONCLUSION**

The half-moon pressuriser produced higher maximum cementation pressures and pressure time integrals than the femoral canal pressuriser in the proximal femur region, which is critical for rotational stability of the implant and prevention of implant fracture.

**DISCLOSURE**

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REFERENCES