NRC Publications Archive Archives des publications du CNRC

Does stem preheating have a beneficial effect on PMMA bulk porosity in cemented THA?

Madrala, A.; Nuno, N.; Bureau, M. N.

This publication could be one of several versions: author's original, accepted manuscript or the publisher's version. / La version de cette publication peut être l'une des suivantes : la version prépublication de l'auteur, la version acceptée du manuscrit ou la version de l'éditeur.

For the publisher's version, please access the DOI link below. / Pour consulter la version de l'éditeur, utilisez le lien DOI ci-dessous.

Publisher's version / Version de l'éditeur:

<https://doi.org/10.1002/jbm.b.31673>

Journal of Biomedical Materials Research Part B : Applied Biomaterials, 95B, October 1, pp. 1-8, 2010-08-24

NRC Publications Record / Notice d'Archives des publications de CNRC:

<https://nrc-publications.canada.ca/eng/view/object/?id=4aa824b3-5d46-46f8-b675-23cd50a9d1cf>

<https://publications-cnrc.canada.ca/fra/voir/objet/?id=4aa824b3-5d46-46f8-b675-23cd50a9d1cf>

Access and use of this website and the material on it are subject to the Terms and Conditions set forth at

<https://nrc-publications.canada.ca/eng/copyright>

READ THESE TERMS AND CONDITIONS CAREFULLY BEFORE USING THIS WEBSITE.

L'accès à ce site Web et l'utilisation de son contenu sont assujettis aux conditions présentées dans le site

<https://publications-cnrc.canada.ca/fra/droits>

LISEZ CES CONDITIONS ATTENTIVEMENT AVANT D'UTILISER CE SITE WEB.

Questions? Contact the NRC Publications Archive team at

PublicationsArchive-ArchivesPublications@nrc-cnrc.gc.ca. If you wish to email the authors directly, please see the first page of the publication for their contact information.

Vous avez des questions? Nous pouvons vous aider. Pour communiquer directement avec un auteur, consultez la première page de la revue dans laquelle son article a été publié afin de trouver ses coordonnées. Si vous n'arrivez pas à les repérer, communiquez avec nous à PublicationsArchive-ArchivesPublications@nrc-cnrc.gc.ca.

Does stem preheating have a beneficial effect on PMMA bulk porosity in cemented THA?

A. Madrala,¹ N. Nuño,¹ M. N. Bureau²

¹École de technologie supérieure, Laboratoire de recherche en imagerie et orthopédie, Département de génie de la production automatisée, Université du Québec 1100, rue Notre-Dame O., Montréal, Québec, Canada H3C 1K3

²Industrial Materials Institute, National Research Council Canada 75, de Mortagne, Boucherville, Québec, Canada J4B 6Y4

Received 4 September 2009; revised 26 February 2010; accepted 14 April 2010

Published online 24 August 2010 in Wiley Online Library (wileyonlinelibrary.com). DOI: 10.1002/jbm.b.31673

Abstract: In cemented total hip arthroplasty (THA), porosity plays a major role in the fatigue failure of bone cement. Stem preheating procedure is known to reduce the stem/cement interfacial porosity. In the literature, no information is available about the effect of such procedure on cement bulk porosity. This study helps to find out if stem preheating can have a beneficial effect on bulk porosity, thus enhancing long-term bone cement integrity. A simplified experimental model of a stem/cement/bone construct of a cemented THA is designed to reproduce the mechanical boundary conditions of polymerizing cement. Effect of stem preheating and polymethylmethacrylate prechilling and mixing method (hand mixed and vacuum mixed) on cement porosity are investigated. Bulk porosity is analysed within three zones across the cement mantle in terms of pore number, pore area, and mean pore size. The results demonstrate that bulk

cement porosity is strongly influenced by stem preheating, cement precooling as well as cement composition and mixing method. Stem preheating procedure displaces the porosity away from stem/cement interface toward bone; consequently reducing the pore area within the zone near the stem and increasing it in the middle and bone/cement zone. The most pronounced beneficial effect of stem preheating before implantation is visible for vacuum mixed procedure as the cement contains few pores of very small size (<100 μm). However, if stem is preheated, cement precooling should be avoided as it could counteract the beneficial effect of reduced porosity inside cement mantle. Published 2010 Wiley Periodicals, Inc. *J Biomed Mater Res Part B: Appl Biomater* 95B: 1–8, 2010.

Key Words: bone cement (PMMA), porosity, stem preheating, hip prosthesis

INTRODUCTION

Total hip arthroplasty (THA) has a long and increasingly successful clinical history. In cemented THA, the quality of bone cement polymethylmethacrylate (PMMA) used to fix the prosthesis to the bone is an important factor in the long-term fixation of a cemented hip implant. PMMA polymerization is a complex exothermic phenomenon during which residual stresses and porosity formation are observed^{1–4} resulting from thermal and volumetric changes. The combination of residual stress and porosity can compromise the implant long-term fixation.⁵ However, it is still unclear whether porosity has a negative or positive effect on the bone cement integrity. In the majority of these studies, the bone cement polymerizes under unrealistic conditions.^{6–9} It is generally accepted that porosity plays a major role in the fatigue failure of bone cement;⁸ its fatigue strength decreases with increased porosity.^{6,10} It is also an important factor in crack propagation.^{11,12} The adverse effect of porosity on PMMA fatigue life is reported in the literature: the pores across the cement mantle act as stress raisers and nucleation sites for microcracks.^{6,12–14} Mann et al.¹⁵ reported a negative effect of porosity on debond energy of the stem/cement interface. Interestingly, Topoleski et al.¹² have suggested that bulk porosity can have a benefi-

cial effect on the fracture properties of bone cement, hypothesizing that pores forming larger damage zones slow down crack propagation in the cement mantle as the energy at the crack tip is dispersed. This hypothesis is supported by the recent numerical study of Janssen et al.¹⁴ The dominant role of pores in the process of damage accumulation also depends on number of pores, pore size, and location of pores in the stress field.¹⁶

Microstructural features of bone cement, namely the interfacial and bulk porosity, have long been of interest. However, most experimental models^{6,7,9,13,17–21} do not reflect the stem/cement/bone construct of cemented THA since during polymerization, the bone cement is not mechanically constrained, that is, externally by the bone and internally by the femoral stem. Lennon and Prendergast⁵ noted that geometry and boundary conditions of the structure is an important aspect in laboratory studies since these will affect the polymerization direction.

Previous studies^{2,9,22–24} have shown that polymerization process, and the unavoidable porosity formation, are considerably affected by a number of factors, including mixing method, cement type, initial temperature of implanted stem, PMMA storage temperature, mold characteristics, and so forth. In particular, vacuum mixing was found to reduce

Correspondence to: A. Madrala; e-mail: amadrala@gmail.com

FIGURE 1. Schematic representation of cemented hip implant: (a) experimental model, (b) cross-section with specific zones of analysis, (c) physical cross-section. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

considerably bulk porosity.^{20,25,26} Recently, Messick et al.,²⁷ with a realistic model representing stem/cement/bone system, showed that vacuum mixing does not affect the overall cement bulk porosity; however, the distribution of pores in terms of mean pore size and pore number-density can be affected by mixing technique. Another factor affecting the porosity is stem preheating procedure which is known to reverse the direction of polymerization reaction locally displacing porosity away from the region that polymerizes first, stem/cement interface, and results in lower interfacial porosity.^{2,22,28,29} However, no information is available in the literature about the effect of stem preheating on cement bulk porosity.

The aim of this study is to analyse the bone cement microstructure: (1) to determine the pore distribution in terms of pore number, mean pore size, and pore area inside the cement mantle for two commercially available cements (Simplex P and Palacos R) and two mixing techniques (hand and vacuum mixing); (2) to find out how such porosity distribution is influenced by the initial temperature of the stem (24 and 50°C) and PMMA storage temperature (6 and 24°C).

MATERIALS AND METHODS

Experimental model

A simplified experimental model [Figure 1(a,b)], previously developed³⁰ to measure the radial compressive stress at stem/cement interface, is designed to reproduce the mechanical boundary conditions for polymerizing cement of a THA. It consists of an idealized femoral stem placed inside a cylindrical synthetic bone filled with bone cement. The idealized femoral stem made from W1 standard steel (20 mm in diameter and 120 mm in length) has a satin polished surface finish ($R_a = 0.5 \mu\text{m}$). The idealized bone is

simulated by synthetic bone cylinder, representing the cortical bone, from Sawbones (Pacific Research Laboratories, Vashon, Washington), 40 mm and 30 mm external and internal diameters [Figure 1(b)], respectively, and 140 mm long. The distal part of the bone is designed to ensure central positioning of the stem [Figure 1(a)].

Experimental protocol

Two different stem temperatures (T_{stem}) are tested: standard room temperature (RT) condition ($T_{\text{stem}} = 24^\circ\text{C}$) and preheating condition ($T_{\text{stem}} = 50^\circ\text{C}$). To provide a preheated condition, the stem is placed in a 12-140E incubator (Quincy Lab, Chicago, IL) for at least 5 hours before cementation. Before the experiment, the idealized bone is kept in the DigiThermTM incubator (Tritech Research, Los Angeles, CA) at 37°C for at least 5 hours.

Two commercially available bone cements of different viscosities are used. Medium viscosity Simplex P (Howmedica Int., Limerick, Ireland) is hand and vacuum mixed while high viscosity Palacos R (Biomet, Warsaw, IN) is only hand mixed. These choices are made from the recently published experimental study on residual stress measurement at stem-cement interface.³⁰ The advanced cement mixing system from Stryker (Kalamazoo, MI) is used to vacuum mix Simplex P cement. The initial cement temperatures (T_{cement}) of both liquid and powder component are 24°C and 6°C to simulate both room and low temperature storage conditions. Each cement is prepared according to the manufacturer's instructions. Bone cement is stored at low temperature until the beginning of the experiment; a time span of less than 1 minute passes between taking the 6°C cement out of the refrigerator and the start of cement mixing.

The onset of the experiment ($t = 0$) is defined as the moment when the liquid monomer comes in contact with

the powder. For each specimen, mixing time is controlled, however it depends on the cement type and PMMA initial temperature. Simplex P stored at RT and precooled is mixed for 1 min 30 s and 2 min, respectively. Palacos R mixing time is 30 s and 40 s for cement at RT and precooled, respectively. Once cement mixing is completed, hand mixed cement is injected inside the bone with a syringe and vacuum mixed cement using the cement gun. In both cases, retrograde filling is applied. Then, within 40 next seconds, the stem is inserted into the bone cavity and the cemented specimen is placed in a temperature controlled DigiTherm™ incubator (Tritech Research, Los Angeles, CA) at 37°C. A minimum of three cemented specimens are prepared for each of the 11 different cases considered (Table I), for a total of 34 specimens. Cement thickness varies with stem geometry from 5 to 8 mm [Figure 1(b,c)].

Sample preparation

Each idealized cemented specimen is sectioned transversely into three discs of 20 mm in height using a band saw [Figure 1(a)]. The top surface of each disc is progressively polished with 320–4000 grit silicon carbide paper and diamond solution (DP-suspension 3 µm, Struers). Grinding debris are removed with an ultrasonic bath after each polishing stage. The porosity is analysed in the proximal part (disc 1), in the middle part (disc 2) and in the distal part (disc 3) as presented in Figure 1(a).

Porosity analysis

Bone cement bulk porosity is observed with the aid of a scanning electron microscope (S-3600 N, Hitachi). Three micrographs are taken at low magnification (35×) on both sides of the flat surfaces of the stem [Figure 1(b)] to obtain a representation of the entire cement thickness from stem/cement interface to cement/bone interface. This magnification results in high-resolution (5.6 µm/pixel) images. The image processing and pores contour is done with image analysis software PhotoStudio 5 (ArcSoft®, Fremont, CA). First, the micrographs are superimposed to reconstruct the cement mantle on each side of the stem flat surface. Then the three specific zones of analysis, presented in Figure 1(b) (stem/cement zone: area adjacent to the stem, bone/cement zone: area adjacent to the bone, and middle zone: area in the middle of cement mantle thickness) are delimited and pore contours are drawn (Figure 2).

Each zone of analysis covers an area of 1.5 mm × 1.5 mm. Within each specific zone, bone cement microstructure is measured in terms of number of pores, mean pore size (diameter) and pore area (%) using NIH Image J 1.37v software (National Institute Health). Pore area is a percentage of the specific zone area (1.5 mm × 1.5 mm) covered by pores. The mean values presented in Table I are calculated from 18 samples (three specimens for Cases No 1 to 8), and from 24 samples (four specimens for Cases No 9 to 11). Each specimen includes three discs [Figure 1(a)], and for each disc, porosity was analysed on each side of the stem [Figure 1(b,c)].

TABLE 1. Detailed characteristics of PMMA bulk porosity for different initial conditions of stem and bone cement

Case no.	Cement type	T_{stem} (°C)	T_{cement} (°C)	Zone											
				Nb of pores ^a			Pore size (µm) ^a			Pore area (%) ^a			S/C zone	Middle zone	B/C zone
				S/C zone	Middle zone	B/C zone	S/C zone	Middle zone	B/C zone	S/C zone	Middle zone	B/C zone			
1	Group I hand mixed Simplex P	50	RT	28 ± 9	11 ± 6	17 ± 10	80 ± 9	211 ± 134	129 ± 46	6.3 ± 1.5	15.0 ± 8.8	11.8 ± 8.4			
2			6 N = 18	14 ± 5	10 ± 3	12 ± 5	125 ± 29	266 ± 76	177 ± 83	8.2 ± 3.4	23.8 ± 18.7	13.7 ± 6.8			
3			RT	18 ± 5	11 ± 5	17 ± 6	136 ± 34	177 ± 56	89 ± 15	10.7 ± 3.8	11.9 ± 6.4	4.7 ± 1.1			
4	Group II vacuum mixed Simplex P	50	6 N = 18	19 ± 4	7 ± 3	10 ± 5	126 ± 15	221 ± 61	133 ± 48	10.3 ± 2.8	11.5 ± 5.4	7.2 ± 5.5			
5			RT	2 ± 1	6 ± 3	6 ± 3	32 ± 10	68 ± 39	60 ± 23	0.1 ± 0.1	2.0 ± 3.2	0.8 ± 0.6			
6			6 N = 18	2 ± 7	7 ± 3	7 ± 4	40 ± 9	158 ± 72	111 ± 49	0.1 ± 0.1	7.8 ± 7.1	4.3 ± 3.9			
7	Group III hand mixed Palacos R	RT	RT	7 ± 5	2 ± 1	2 ± 2	178 ± 86	38 ± 17	36 ± 10	8.8 ± 7.0	0.1 ± 0.1	0.1 ± 0.2			
8			6 N = 18	6 ± 3	3 ± 2	3 ± 2	167 ± 101	52 ± 37	34 ± 14	9.5 ± 11.2	0.9 ± 1.7	0.1 ± 0.1			
9			RT	21 ± 18	6 ± 3	15 ± 11	119 ± 48	245 ± 88	181 ± 63	6.4 ± 4.1	10.1 ± 5.6	11.6 ± 4.7			
10		50	6 N = 24	39 ± 26	13 ± 8	22 ± 12	109 ± 39	223 ± 77	174 ± 57	10.6 ± 2.4	14.7 ± 5.6	16.9 ± 4.7			
11			RT	17 ± 11	5 ± 3	7 ± 3	158 ± 85	220 ± 150	123 ± 50	10.1 ± 5.1	8.0 ± 7.9	3.4 ± 2.8			

S/C, stem/cement zone; B/C, bone/cement zone; RT, room temperature (24°C); N, number of samples.

^a The values are given as the mean and standard deviation.

FIGURE 2. Bone cement mantle representing specific analyzed zones and pore contours drawn for each zone of analysis.

First, the effect of stem preheating and of PMMA prechilling on pore characteristics are investigated for each cement group (hand mixed Simplex P, vacuum mixed Simplex P and hand mixed Palacos R) in the three zones of analysis. Then the effect of mixing method (hand vs. vacuum mixed Simplex P) and of cement type (hand mixed Simplex P vs. Palacos R) are analysed. A two-way ANOVA with a *post hoc* Tukey test is performed for normal distribution data (Shapiro-Wilk; $p > 0.05$). For data that is not normally distributed (Shapiro-Wilk; $p < 0.05$), a Kruskal-Wallis variance analysis, a nonparametric equivalent, is performed to determine significant differences.

RESULTS

Effect of stem preheating on cement bulk porosity

Figure 3(a,b) presents typical pore distribution for hand mixed Simplex P stored at RT (Table I, Case 1 vs. 3). The visual inspection of the discs suggests that pores concentrating near the stem interface for $T_{\text{stem}} = 24^\circ\text{C}$ [Figure 3(a)] are displaced toward the bone interface when stem is preheated and a large number of very small pores appear near the stem [Figure 3(b)]. Table I confirms these observations with details: stem preheating (Case 1 vs. 3) significantly increases ($p < 0.001$, *post hoc*) the pore number near the femoral stem. However, the pore area within this zone is significantly smaller ($p < 0.05$, *post hoc*), which results from significantly reduced ($p < 0.001$, *post hoc*) mean pore size by $\sim 59\%$. For $T_{\text{cement}} = 6^\circ\text{C}$, stem preheating (Table I, Case 2 vs. 4) only affects the pore area in the middle and stem/cement zones: the pore area is doubled compared to $T_{\text{stem}} = 24^\circ\text{C}$.

Figure 3(c,d) clearly demonstrates that for vacuum mixed Simplex P stored at RT (Table I, Case 5 vs. 7), stem preheating displaces the bulk porosity away from stem toward the bone. All analysed parameters are affected significantly in all three zones of analysis. The same tendency is observed for vacuum mixed Simplex P stored at low temperature (Table I, Case 6 vs. 8). Table I shows that the pore area within stem/cement zone is significantly reduced ($p < 0.001$, Kruskal-Wallis) due to significant lower ($p < 0.001$, Kruskal-Wallis) pore number and pore size. The opposite effect is observed within the middle and bone/cement zones; stem preheating increases significantly ($p < 0.001$, *post hoc*) the pore number and doubles the mean pore size which results in greater pore area ($p < 0.001$, Kruskal-Wallis).

For hand mixed Palacos R stored at RT (Table I, Case 9 vs. 11), stem preheating affects the pore distribution within the stem/cement zone in a similar way to hand mixed Simplex P. The number of pores within bone/cement zone is not affected significantly by stem preheating. However, pores are significantly larger ($p < 0.001$, Kruskal-Wallis) which results in greater pore area ($p < 0.01$, Kruskal-Wallis).

Effect of bone cement precooling on cement bulk porosity

For Simplex P, independently of the mixing method, the cement precooling has little effect on pore distribution when $T_{\text{stem}} = \text{RT}$. In fact, only the pore number of hand mixed Simplex P (Table I, Case 4 vs. 3) is significantly reduced ($p < 0.01$, *post hoc*) within bone/cement zone, although the pore area is not affected considerably since the mean pore size also increased significantly ($p < 0.05$, *post hoc*).

Figure 4 shows the effect of PMMA precooling on bulk porosity for preheated stem ($T_{\text{stem}} = 50^\circ\text{C}$). For hand mixed Simplex P, cement precooling (Table I, Case 2 vs. 1) leads to a significant reduction of the pore number near the stem ($p < 0.001$, *post hoc*) and near the bone ($p < 0.05$, *post hoc*). In addition, the increased mean pore size is observed in all three zones of analysis and the pore area within the middle zone doubled ($p < 0.05$, *post hoc*).

For hand mixed Palacos R when $T_{\text{stem}} = 50^\circ\text{C}$, cement precooling (Table I, Case 10 vs. 9) has the opposite effect than Simplex P. A significant increase of pore number within all three zones (Figure 4) results in a greater pore area across the cement mantle. A 65% increase of pore area for stem/cement zone and a 45% increase for middle and bone/cement zones are observed, while the mean pore size remains unaffected.

For vacuum mixed Simplex P when $T_{\text{stem}} = 50^\circ\text{C}$, cement precooling (Table I, Case 6 vs. 5) does not affect pore number (Figure 4). However, larger pores within middle and bone/cement zones are observed (Figure 5): the pore area increased significantly ($p < 0.001$, *post hoc*) from 2 and 0.8% to 7.8 and 4.3% inside middle and bone/cement zones, respectively.

FIGURE 3. Pore distributions inside a Simplex P cement mantle ($T_{\text{cement}} = \text{RT}$): (a) hand mixed, $T_{\text{stem}} = 24^\circ\text{C}$; (b) hand mixed, $T_{\text{stem}} = 50^\circ\text{C}$; (c) vacuum mixed, $T_{\text{stem}} = 24^\circ\text{C}$; (d) vacuum mixed, $T_{\text{stem}} = 50^\circ\text{C}$.

FIGURE 4. Effect of PMMA precooling on pore number across cement mantle when stem is initially preheated ($T_{\text{stem}} = 50^{\circ}\text{C}$).

Effect of mixing method on cement bulk porosity

Figure 3 clearly shows that the pore number in Simplex P samples is significantly reduced by vacuum mixing. Indeed, the comparison of Case 3 vs. 7 confirms the significant pore number reduction (Kruskal-Wallis) within the stem/cement, middle and bone/cement zones (from 18, 11 and 17 to 7, 2 and 2, respectively). The same tendency is observed for other combinations of stem and cement initial temperatures (Table I, Case 5 vs. 1, Case 6 vs. 2, Case 7 vs. 3; Case 8 vs. 4).

Figure 6 presents the mean pore area distribution across the Simplex P cement mantle. Independently of the mixing method and cement initial temperature, when $T_{\text{stem}} = 50^{\circ}\text{C}$ (Table I, Case 5 vs. 1 and Case 6 vs. 2), the greatest pore area is observed in the middle zone. Vacuum mixing of Simplex P reduces significantly (Kruskal-Wallis) the pore area within this zone from 15 and 24% ($T_{\text{cement}} = 24^{\circ}$ and $T_{\text{cement}} = 6^{\circ}\text{C}$) to 2 and 8%, respectively. In addition, the pores observed for vacuum mixed cement are significantly smaller ($p < 0.001$, Kruskal-Wallis) compared to hand mixed samples, except stem/cement zone when $T_{\text{stem}} = 24^{\circ}\text{C}$ where no significant difference in mean pore size is found (Table I, Case 7 vs. 3 and Case 8 vs. 4).

FIGURE 5. Porosity of vacuum mixed Simplex P when $T_{\text{stem}} = 50^{\circ}\text{C}$: (a) $T_{\text{cement}} = 24^{\circ}\text{C}$ and (b) $T_{\text{cement}} = 6^{\circ}\text{C}$.

Effect of cement type on cement bulk porosity

The typical pore distributions of hand mixed Simplex P and Palacos R are presented in Figure 7. For standard cementation procedure ($T_{\text{stem}} = T_{\text{cement}} = \text{RT}$), bulk porosity is more uniformly distributed for hand mixed Simplex P compared to Palacos R, where higher concentration of pores is noted near the stem. Simplex P and Palacos R (Table I, Case 3 vs. 11) result in similar pore number near the stem; however significantly less pores was found in the middle zone and near bone using Palacos R. For $T_{\text{stem}} = 50^{\circ}\text{C}$ and $T_{\text{cement}} = 24^{\circ}\text{C}$ (Table I, Case 1 vs. 9), no significant difference is found in pore number and pore area between the two cement types, however the mean pore size is significantly greater for Palacos R than for Simplex P.

FIGURE 6. Pore area distributions inside hand and vacuum mixed Simplex P samples for $T_{\text{stem}} = 50^{\circ}\text{C}$.

FIGURE 7. Porosity distribution across cement mantle for the three zones of analysis $T_{\text{stem}} = T_{\text{cement}} = 24^{\circ}\text{C}$: (a) hand mixed Simplex P (b) hand mixed Palacos R.

DISCUSSION

In the present experimental study, the cement microstructure was analysed in terms of pore number, mean pore size and pore area within three specific zones (near stem, middle zone and near bone). Such measurements allowed determining the radial distribution of bulk porosity and investigating the effect of initial temperature of the stem ($T_{\text{stem}} = 24^{\circ}\text{C}$ vs. $T_{\text{stem}} = 50^{\circ}\text{C}$) and bone cement ($T_{\text{cement}} = 24^{\circ}\text{C}$ vs. $T_{\text{cement}} = 6^{\circ}\text{C}$) on such porosity across the cement mantle. In this study, the boundary conditions of stem/cement/bone construct of THA were respected. The polymerizing bone cement was mechanically restrained internally by an idealized hip stem and externally by synthetic bone. It is to be noted that the porosity within the stem/cement zone is not interfacial but bulk porosity.

Considering all three zones of analysis of all 34 specimens, the bulk porosity in terms of pore number, pore area and mean pore size varied from 2 to 39, 0.1 to 24% and 32 to 266 μm , respectively. For standard cementation procedure, pore area of hand mixed Simplex P and Palacos R ranged from 5 to 12% and 4 to 10%, respectively which is comparable with other studies where pore area varies from 3 to 9%.^{3,9,18,21,32} However, the direct comparison is limited since in previous studies, the bulk porosity was analysed globally in the cement mantle and not separated into stem/cement, middle and bone/cement zones, and also in numerous studies, the stem/cement/bone construct was not reproduced.

Cement type

For standard cementation procedure where $T_{\text{stem}} = T_{\text{cement}} = \text{RT}$, both hand mixed cements (Simplex P and Palacos R) presented similar microstructure. Pore areas across the cement mantle as well as the mean pore size were comparable. However, pore distributions within cement mantle were different for these two commercial cements. Although the Simplex P presented more pores than Palacos R, its distribution was more uniform; Palacos R resulted in higher concentration of pores near stem/cement interface compared to middle and bone/cement zones. Such differences can result

from chemical composition of each cement which will influence the PMMA polymerization reaction including heat generation, setting time, curing rate, residual stress generation as well as bulk and interfacial porosity formations. The high concentration of pores near stem/cement interface presented in Palacos R may be a determining factor in the mechanical stability of the stem since the pores across the cement mantle act as stress raisers and nucleation sites for microcracks.^{6,12–14}

Mixing method

Previous laboratory studies suggest the improvement of bone cement fatigue life for vacuum mixed cement due to reduced porosity;^{9,20,26} however the clinical benefit of reducing porosity is difficult to demonstrate.²⁷ The present results showed that although the pore area of hand mixed Simplex P was greater compared to vacuum mixed Simplex P, its distribution across the cement mantle was more uniform which agrees with the findings of Murphy and Prendergast.³³ For vacuum mixed Simplex P, when $T_{\text{stem}} = T_{\text{cement}} = \text{RT}$, the majority of pores presented within the cement mantle was located within stem/cement zone. Since the mean size of these pores was $\sim 30\%$ greater for vacuum mixed than for hand mixed cement, the pore area of 9% for vacuum mixed was comparable to 10% observed for hand mixed Simplex P.

It is generally accepted that vacuum mixing lowers overall porosity, however few large pores still remain in the bulk cement.^{7,22,26,29,32,34} In the present study, the visual inspection of vacuum mixed Simplex P specimens confirmed the presence of air bubbles (i.e., large pore) in the cement. Janssen et al.¹⁴ found that the presence of a single large pore in the cement mantle clearly affects the crack propagation process.

Stem preheating

Stem preheating procedure is relatively recent. No clinical outcome of stem preheating on cement long term performance for cemented hip implants can be found in national registries such as the Swedish National Hip Arthroplasty Register³⁵ or Canadian Joint Replacement Registry.³⁶ Stem preheating was initially introduced by Dall et al.³⁷ to accelerate the PMMA polymerization reaction to reduce the time of bleeding into the bone/cement interface. Later, Bishop et al.² demonstrated the beneficial effect of this procedure on the reduction of stem/cement interfacial porosity which is supported by other studies.^{2,22,28,29} In addition, Iesaka et al.²² showed that preheating of the stem not only reduces interfacial porosity but also improves significantly the stem/cement interfacial shear strength and has an effect on the maximum temperature at bone/cement interface; a 6°C increase of such temperature was measured. A concern with this procedure is possibly the increased risk of bone necrosis due to greater heat generated at bone/cement interface. Recently, Madrala et Nuño³⁰ have shown that stem preheating procedure strongly affects the maximum temperature at bone/cement interface, setting time at both interfaces, polymerization rate, polymerization direction thus also the

radial stress formation at stem/cement interface. In addition, the authors have also shown experimentally that for standard cementation procedure, bone acts as the main mechanical constraint (instead of the stem) to the polymerizing cement, resulting in shrinkage away from the stem because of the reaction starting at the warmer interface, in this case the bone/cement interface will form a stiff shell toward which cement shrinks. However, for preheated stem, the warmer interface is the stem/cement forming the stiff shell toward which cement will shrink generating residual radial stresses. Consequently, this preferential direction for polymerization will affect cement porosity.

For vacuum mixed Simplex P stored at RT, stem preheating reduced significantly the pore number, mean pore size and pore area within the stem/cement zone. Iesaka et al.²² also observed the reduction of pore area near the stem. On the other hand, these three parameters increased within middle and bone cement zones compared to $T_{\text{stem}} = 24^{\circ}\text{C}$; however, the pore areas were relatively small (<2%) and the pores were very small (a mean pore size of $\sim 60\text{ }\mu\text{m}$). If we hypothesize that the greatest fatigue lifetime is obtained with the cement containing a reduced amount of pores of very small size (<100 μm), the most favourable condition is achieved for vacuum mixed Simplex P stored at RT with preheating stem. The authors believe that stem preheating for vacuum mixed Simplex P stored at RT can have a beneficial effect on cement fatigue performance.

The beneficial effect of stem preheating was less pronounced for hand mixed cements. The bulk porosity of both hand mixed cements (Simplex P and Palacos R) was affected in the same manner by stem preheating: a decrease of pore area and mean pore size within stem/cement zone and an increase within bone/cement zone were observed. The porosity in the middle zone remained unaffected with a mean pore size around 200 μm and pore area around 10%. For Palacos R, pores were spread out more uniformly within the cement mantle when stem was preheated compared to $T_{\text{stem}} = \text{RT}$.

Cement precooling

It is well-known that bone cement precooling lengthens the PMMA dough phase, thus the working time during operation. This is an important feature which allows a surgeon to control the time needed to inject the cement into the femoral canal, to pressurize it and then to safely install the femoral stem.³⁸ Jasty et al.¹⁸ demonstrated experimentally, that for a stem at RT, precooling the monomer of Simplex P or Palacos R before hand mixing resulted in higher bulk porosity; however in their experiments the stem/cement/bone construct was not reproduced. In contrast, the present results showed little effect of PMMA precooling on bulk porosity across cement mantle for $T_{\text{stem}} = \text{RT}$ which support previous study of Iesaka et al.²³

For preheated stem at $T_{\text{stem}} = 50^{\circ}\text{C}$, the cement precooling affected significantly bulk porosity. For all cement groups, the pore area within the middle zone increased significantly with the greatest pore area, up to 24%, observed for hand mixed Simplex P. This rise of pore area within middle zone resulted from significant increased pore size

(Simplex P) or pore number (Palacos R). Li et al.³⁹ have demonstrated that the highest residual stresses are situated within the cement mantle. The large pores located in regions of high local stress may have an important effect on stem loosening by inducing the formation of crack under loading.²⁷ Thus the beneficial effect of stem preheating for $T_{\text{cement}} = \text{RT}$ can be counteracted by cement precooling; this can compromise the cement fatigue performance since pores with larger diameter initiate more and larger fatigue cracks than small pores.⁶ The literature has shown that bone cement fatigue strength decreases with increased porosity.^{6,10}

Limitations

In the simplified stem/cement/bone experimental model, bone is simulated by a Sawbones cylinder. The thermal conductivity of such material is about 50% lower than that of fresh femur,²² thus the maximum temperatures reached at interfaces, especially the bone/cement interface are considerably influenced since the heat transfer is affected.³⁰ In addition, synthetic bone used in the present study is a nonporous material, representing the cortical bone, thus there is no interdigitation with cement. In fact, bone irregularities increase the effective contact area with PMMA, which contributes to heat dispersion.³¹ In addition, the interdigitation will create an additional constraint for polymerizing cement. Gilbert et al.¹ showed that pore formation is affected by certain constrained conditions. Recent studies^{4,30} demonstrated experimentally that for preheated stem, the bone cement shrinks towards the stem. Nuño et al.⁴ noted that for no adhesion at bone/cement interface the main mechanical constraint for shrinking cement is the stem. However, when adhesion was simulated at this interface in addition to stem constraint, the cement/bone construct (effect of interdigitation) acts as a supplementary constraint, slightly preventing shrinkage. To conclude, the porosity formation can be affected by using the non porous synthetic bone simulating the cortical bone.

CONCLUSION

The present results yield important information on the bone cement microstructure: amount of porosity inside the cement mantle, its quality and radial distribution in function of initial conditions of the cemented specimen for further numerical study. Bulk porosity across the cement mantle is strongly influenced by cement type (cement composition) and mixing method. This article demonstrates how such porosity is affected by other factors including the initial temperature of the stem (RT vs. preheated stem) and of bone cement (RT vs. precooled PMMA). For both hand mixed cements, it is not so evident whether such procedure can have a beneficial effect in terms of bulk porosity, thus indirectly on cement fatigue performance.

The stem preheating procedure seems to be promising for cemented THA, possibly prolonging the cement fatigue lifetime. The most pronounced beneficial effect is visible for vacuum mixed cement since it contains few pores of very small size (<100 μm). However, if stem is preheated, cement precooling should be avoided since it could counteract the beneficial effect of reduced porosity inside cement mantle.

Further investigation needs to be done to determine the acceptable pore size having the less negative effect on bone cement lifetime. In addition, it is important to determine which zone within the cement mantle (near stem, middle, near bone) is the critical zone for cement fatigue life that should be studied more carefully.

REFERENCES

- Gilbert JL, Hasenwinkel JM, Wixson RL, Lautenschlager EP. A theoretical and experimental analysis of polymerization shrinkage of bone cement: A potential major source of porosity. *J Biomed Mater Res* 2000;52:210–218.
- Bishop NE, Ferguson S, Tepic S. Porosity reduction in bone cement at the cement-stem interface. *J Bone Joint Surg-Brit Volume* 1996;78B:349–356.
- James SP, Schmalzried TP, McGarry FJ, Harris WH. Extensive porosity at the cement-femoral prosthesis interface: A preliminary study. *J Biomed Mater Res* 1993;27:71–78.
- Nuño N, Madrala A, Plamondon D. Measurement of transient and residual stresses during polymerization of bone cement for cemented hip implants. *J Biomech* 2008;41:2605–2611.
- Lennon AB, Prendergast PJ. Residual stress due to curing can initiate damage in porous bone cement: Experimental and theoretical evidence. *J Biomech* 2002;35:311–321.
- James SP, Jasty M, Davies J, Piehler H, Harris WH. A fractographic investigation of pmma bone-cement focusing on the relationship between porosity reduction and increased fatigue life. *J Biomed Mater Res* 1992;26:651–662.
- Wang JS, Toksvig-Larsen S, Muller-Wille P, Franzen H. Is there any difference between vacuum mixing systems in reducing bone cement porosity? *J Biomed Mater Res* 1996;33:115–119.
- Jeffers JRT, Browne M, Roques A, Taylor M. On the importance of considering porosity when simulating the fatigue of bone cement. *J Biomech Eng-Trans Asme* 2005;127:563–570.
- Lewis G. Effect of mixing method and storage temperature of cement constituents on the fatigue and porosity of acrylic bone cement. *J Biomed Mater Res* 1999;48:143–149.
- Baleani M, Fognani R, Toni A. The influence of stem insertion rate on the porosity of the cement mantle of hip joint replacements. *Proc IMechE Part H: J Eng Med* 2003;217:199–205.
- Topoleski LDT, Ducheyne P, Cuckler JM. Fractographic analysis of in vivo poly(methyl methacrylate) bone cement failure mechanisms. *J Biomed Mater Res* 1990;24:135–154.
- Topoleski LDT, Ducheyne P, Cuckler JM. Microstructural pathway of fracture in poly(methyl methacrylate) bone cement. *Biomaterials* 1993;14:1165–1172.
- Murphy BP, Prendergast PJ. The relationship between stress, porosity, and nonlinear damage accumulation in acrylic bone cement. *J Biomed Mater Res* 2002;59:646–654.
- Janssen D, Aquarius R, Stolk J, Verdonchot N. The contradictory effects of pores on fatigue cracking of bone cement. *J Biomed Mater Res Part B: Appl Biomater* 2005;74B:747–753.
- Mann KA, Damron LA, Race A, Ayers DC. Early cementing does not increase debond energy of grit blasted interfaces. *J Orthop Res* 2004;22:822–827.
- McCormack BAO, Prendergast PJ. Microdamage accumulation in the cement layer of hip replacements under flexural loading. *J Biomech* 1999;32:467–475.
- Lewis G, Nyman JS, Trieu HH. Effect of mixing method on selected properties of acrylic bone cement. *J Biomed Mater Res* 1997;38:221–228.
- Jasty M, Davies JP, Oconnor DO, Burke DW, Harrigan TP, Harris WH. Porosity of various preparations of acrylic bone cements. *Clin Orthop Related Res* 1990;122–129.
- Muller-Wille P, Wang J-S, Lidgren L. Integrated system for preparation of bone cement and effects on cement quality and environment. *J Biomed Mater Res* 1997;38:135–142.
- Smeds S, Goertzen D, Ivarsson I. Influence of temperature and vacuum mixing on bone cement properties. *Clin Orthop Related Res* 1997;326–334.
- van de Belt H, Neut D, Uges DRA, Schenk W, van Horn JR, van der Mei HC, Busscher HJ. Surface roughness, porosity and wettability of gentamicin-loaded bone cements and their antibiotic release. *Biomaterials* 2000;21:1981–1987.
- Iesaka K, Jaffe WL, Kummer FJ. Effects of preheating of hip prostheses on the stem-cement interface. *J Bone Joint Surg Am* 2003;85:421–427.
- Iesaka K, Jaffe WL, Kummer FJ. Effects of the initial temperature of acrylic bone cement liquid monomer on the properties of the stem-cement interface and cement polymerization. *J Biomed Mater Res Part B: Appl Biomater* 2004;68B:186–190.
- Vallo CI. Theoretical prediction and experimental determination of the effect of mold characteristics on temperature and monomer conversion fraction profiles during polymerization of a PMMA-based bone cement. *J Biomed Mater Res* 2002;63:627–642.
- Lidgren L, Drar H, Möller J. Strength of polymethylmethacrylate increased by vacuum mixing. *Acta Orthop Scand* 1984;55:536–541.
- Wixson R, Lautenschlager E, Novak M. Vacuum mixing of acrylic bone cement. *J Arthroplasty* 1987;2:141–149.
- Messick KJ, Miller MA, Damron LA, Race A, Clarke MT, Mann KA. Vacuum-mixing cement does not decrease overall porosity in cemented femoral stems: An in vitro laboratory investigation. *J Bone Joint Surg Br* 2007;89-B:1115–1121.
- Damron LA, Kim D-G, Mann KA. Fatigue debonding of the roughened stem-cement interface: Effects of surface roughness and stem heating conditions. *J Biomed Mater Res Part B: Appl Biomater* 2006;78B:181–188.
- Wang JS, Taylor M, Flivik G, Lidgren L. Factors affecting the static shear strength of the prosthetic stem-bone cement interface. *J Mater Sci: Mater Med* 2003;14:55–61.
- Madrala A, Nuño N. Effect of stem preheating and precooling on residual stress formation at stem/cement interface for cemented hip implants. *J Biomed Mater Res Part B: Appl Biomater* 2010;93B:258–265.
- Talbot JC, Shaw DL. Effects of pre-cooling and pre-heating procedures on cement polymerisation and thermal osteonecrosis in cemented hip replacements. *Med Eng Phys* 2005;27:439.
- Dunne NJ, Orr JF, Mushipe MT, Eveleigh RJ. The relationship between porosity and fatigue characteristics of bone cements. *Biomaterials* 2003;24:239–245.
- Murphy BP, Prendergast PJ. On the magnitude and variability of the fatigue strength of acrylic bone cement. *Int J Fatigue* 2000;22:855–864.
- Hoey D, Taylor D. Fatigue in porous PMMA: The effect of stress concentrations. *Int J Fatigue* 2008;30:989–995.
- Kärrholm J, Garellick G, Herberts P. Swedish hip arthroplasty register—Annual report 2006, Department of Orthopaedics, Sahlgrenska University Hospital; 2007.
- CIHI. Canadian joint replacement registry report: Total hip and total knee replacements in Canada. Toronto, Canada: Canadian Institute for Health Information; 2004.
- Dall DM, Miles AW, Juby G. Accelerated polymerization of acrylic bone cement using preheated implants. *Clin Orthop Relat Res* 1986;211:148–150.
- Jiranek W. Thermal manipulation of bone cement. *Orthopedics* 2005;28:S863–S866.
- Li C, Wang Y, Mason J. The effects of curing history on residual stresses in bone cement during hip arthroplasty. *J Biomed Mater Res Part B: Appl Biomater* 2004;70B:30–36.