

EFFECTS OF PREHEATING OF HIP PROSTHESES ON THE STEM-CEMENT INTERFACE

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Background: Debonding of the cement from metal implants has been implicated in the loosening of cemented total hip prostheses. Strengthening of the stem-cement interface has been suggested as a way to prevent loosening of the component. Previously, it was reported that preheating the stem to 44°C reduced the porosity of the cement at the stem-cement interface. The purpose of this study was to determine the effect of stem preheating on the characteristics of the stem-cement interface.

Methods: The effects of stem preheating, at temperatures of 37°C, 44°C, and 50°C, on the stem-cement interface were studied in a test model and a preparation that closely simulated the clinical situation. Static interface strength was determined initially and after the stems had been kept in isotonic saline solution at 37°C for two weeks. Fatigue lifetimes were measured, and the nature and extent of porosity at the interface were quantified.

Results: Stem preheating had significant effects on the stem-cement interface. Stems preheated to 37°C had greater interface shear strength than stems at room temperature both initially (53% greater strength) and after simulated aging (155% greater strength). Fatigue lifetimes were also improved, and there was a >99% decrease in interface porosity. The setting time of the cement decreased 12%, and the maximum temperature at the cement-bone interface increased 6°C. Similar effects were found after preheating to 44°C and 50°C.

Conclusions: Stem preheating had significant effects on the stem-cement interface, with significant improvements in the shear strength and cement porosity of the interface. Also, polymerization temperatures at the cement-bone interface increased. The possible biological effects of these increased interface temperatures at the cement-bone interface require further study.

Debonding of the cement from metal implants has been implicated in the loosening of cemented total hip prostheses¹⁻¹³. Various methods for strengthening of the stem-cement interface have been tried to prevent loosening.

Roughening of the surface of a cemented femoral component can improve the initial mechanical strength of the stem-cement interface; however, if the interface debonds, considerable amounts of cement or metal wear debris can be produced as a result of micromotion of the stem¹⁴⁻¹⁷. Precoating of the femoral stem with a thin layer of polymethylmethacrylate bone cement has also been shown to improve the strength of the stem-cement interface in vitro¹⁸⁻²⁰; however, some clinical reports have suggested that this results in a higher failure rate at the cement-bone interface^{4,6,21-25}.

Another method of improving fixation at the stem-

cement interface is reduction of the interfacial porosity, as increased porosity has been associated with failure of femoral components^{4,7,26-28}. James et al. found extensive cement porosity at the stem-cement interface of every autopsy-retrieved, surgically retrieved, or laboratory-developed specimen in their study²⁷. These pores were considered to be an important factor in the initial debonding of the stem-cement interface and were also found on a precoating layer-cement interface²⁷.

Although pressurization, centrifugation, or vacuum mixing of bone cement have dramatically improved the porosity, mechanical properties, creep characteristics, and fatigue strength of bone cement²⁹⁻⁴⁰, these techniques have not reduced interfacial porosity at the stem-cement interface^{27,41}. Preheating of the stem, a technique used to reduce interfacial porosity, was originally introduced by Dall et al. to accelerate cement polymerization in order to reduce operative time⁴². Later, Bishop et al.⁴³ and others⁴⁴ found that preheating the stem to 44°C reduced porosity of the cement at the stem-cement interface.



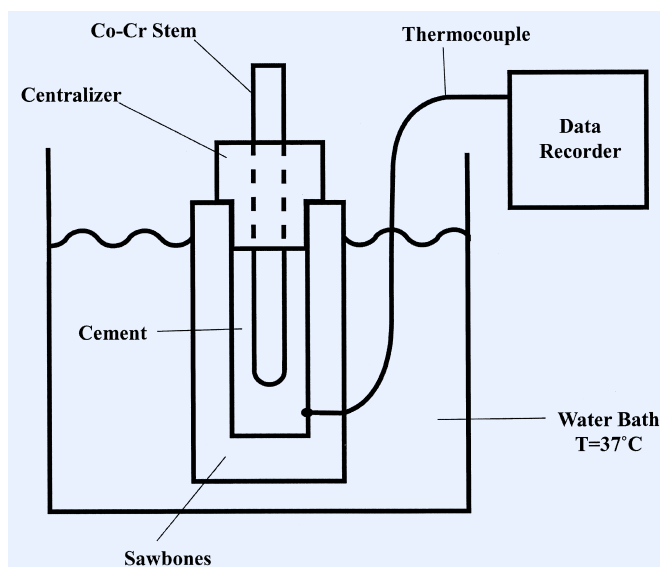


Fig. 1
The method for sample preparation. The simulated stem was inserted with a centralizer to produce a cement mantle thickness of 4 mm along the stem and 10 mm at the tip of the stem.

The purpose of this study was to determine how the shear strength, polymerization temperature and time, and porosity distribution of the stem-cement interface were affected by the amount of stem preheating.

Materials and Methods

Sample Preparation

The experimental model and techniques used in this study were designed to duplicate *in vivo* stem insertion as closely as possible, with comparable materials, dimensions, and cementing techniques (Fig. 1). Cobalt-chromium cylinders (12.6 mm in diameter and 140 mm in length, with an implant-grade satin finish of 35 μm , Ra) with rounded ends were used to simulate femoral stems. Stems initially at room temperature were heated to 37°C, 44°C, or 50°C for a minimum of one hour in a temperature-controlled oven (Isotemp Lab Oven 106G; Fisher Scientific, Pittsburgh, Pennsylvania), and the temperatures were maintained until just before insertion. The stem temperatures prior to insertion were selected to represent normal room temperature, body temperature (37°C), a previously reported theoretical minimum temperature to reduce the interfacial porosity (44°C)⁴³, and a temperature higher than the theoretical minimum temperature (50°C). A custom proximal stem-holder was used during polymerization to keep the simulated stem centered and to produce a uniform thickness of the cement mantle. A Sawbones cylinder (Pacific Research Laboratories, Vashon, Washington), 36 mm in diameter and 75 mm in height with a 20-mm-diameter 60-mm-deep hole, was used as a simulated femur. A thermocouple (model 5TC-GG-J-20-36; Omega Engineering, Stamford, Connecticut) to determine maximum polymerization temperature was inserted through the Sawbones cylinder to the cement-bone interface at 5 mm from the

bottom of the cement mantle. In prior experiments, in which multiple thermocouples had been spaced 2 mm apart along the distal cement mantle, we had determined that the thermocouple measured the maximum polymerization temperature in this position.

The Sawbones cylinders were held in a water bath at 37°C for one hour prior to and during the insertion of the simulated cobalt-chromium stem and during cement polymerization. Simplex-P bone cement (Stryker-Howmedica-Osteonics, Allendale, New Jersey) was mixed for ninety seconds at room temperature with use of a vacuum mixing system (Stryker-Howmedica-Osteonics) and was injected into the Sawbones canal retrograde with a cement gun (Stryker-Howmedica-Osteonics). Three minutes after the start of the cement mixing, the simulated cobalt-chromium stem was inserted with use of the proximal stem-holder to produce a uniform 4-mm-thick cement mantle along the simulated stem and a 10-mm-thick mantle at the tip of the simulated stem^{45,46}. The temperature at the cement-bone interface was measured on a chart recorder (Omegaline 790 recorder, Omega Engineering) until twenty minutes after the stem insertion. Polymerization setting times were determined by the duration from the insertion of the stem until one minute after the maximum temperature was reached³². Twenty specimens in each group were kept in 37°C saline solution for two weeks before static testing to determine the effect of aging on the stem-cement interface. Aging has been shown to affect maximum cement strength^{47,48}. During the experiment, the ambient room temperature ranged from 19°C to 23°C.

Test Methods

The cement mantle and the surrounding Sawbones were machined to create a 20-mm-thick ring, the base of which was located 10 mm above the tip of the simulated stem, for static and fatigue testing. The samples were mounted on an MTS servohydraulic testing machine (MTS Systems, Eden Prairie, Minnesota) in a self-centering stem-holder to ensure true axial load with minimal side loads on the test specimen. Compression tests (push-out tests) were carried out to determine the shear strength of the stem-cement interface. The specimens were inserted into an aluminum anulus, with a hole 12.7 mm in diameter, at a rate of 10 mm/min. Failure was defined as a marked drop in load or 1 mm of displacement of the cement mantle along the stem. Cyclic fatigue tests of the room-temperature and 37°C samples were performed with use of the same experimental setup. Loading was at 3 Hz, with a load to produce an interface stress of 90% of the average static failure value of the room-temperature group. Testing was stopped when the stem was displaced 1 mm through the cement mantle, or 100,000 cycles were reached, whichever occurred first.

Porosity Distribution

After mechanical testing, the cement mantle was removed and cut into radial and longitudinal sections. The sections were sanded with 240 and 400-grit emery paper, and pores on the interface and cut surface were then highlighted with black ink.

TABLE I Polymerization Time and Maximum Polymerization Temperature of the Four Groups

	Room Temperature	37°C	44°C	50°C
Polymerization time* (min)	8.1 ± 1.3	7.1 ± 1.1	7.6 ± 0.9	5.9 ± 0.7†
Maximum temperature* (°C)	50.2 ± 2.1	56.4 ± 5.3†	56.6 ± 5.1†	54.4 ± 6.2†

*The values are given as the mean and standard deviation. There were twenty samples in each group. †The value was significantly different from that in the room-temperature group ($p < 0.01$).

The pores were photographed with a digital still camera (Fine-Pix 4700Z; Fujifilm, Tokyo, Japan) and analyzed with use of Photoshop 5.5 (Adobe Systems, San Jose, California) and NIH image (National Institutes of Health, Bethesda, Maryland) to determine pore sizes and distributions parallel and perpendicular to the stem and at the stem-cement interface.

A minimum of twenty specimens in each group was prepared for each testing condition, except for the fatigue tests. The specimens were first used for the polymerization time and temperature measurements and then were used for mechanical testing and porosity measurements. Results were analyzed with analysis of variance with a post hoc Tukey test; significance was set at $p < 0.05$.

Results

Polymerization Time and Temperature at the Cement-Bone Interface

The mean polymerization times (and standard deviation) for the room-temperature, 37°C, 44°C, and 50°C stems were 8.1 ± 1.3 minutes, 7.1 ± 1.1 minutes, 7.6 ± 0.9 minutes, and 5.9 ± 0.7 minutes, respectively. The mean maximum temperatures during polymerization were $50.2^\circ \pm 2.1^\circ\text{C}$, $56.4^\circ \pm 5.3^\circ\text{C}$, $56.6^\circ \pm 5.1^\circ\text{C}$, and $54.4^\circ \pm 6.2^\circ\text{C}$, respectively (Table I). The difference between the maximum temperature during po-

lymerization in the room-temperature group and those in the other groups was significant ($p < 0.01$), whereas the values did not differ significantly among the preheated groups.

Shear Strength at the Stem-Cement Interface

The shear strength of the stem-cement interface was responsive to stem preheating (Fig. 2), with the values in all preheated groups significantly higher than the values in the room-temperature group ($p < 0.001$). After two weeks of immersion in 37°C isotonic saline solution, the shear strength significantly decreased 57% in the room-temperature group and 34% in the preheated groups ($p < 0.001$). The differences between the room-temperature group and the three preheated groups were greater after aging than they were in the initial static testing. The fatigue strength of the 37°C group was significantly greater than that of the room-temperature group ($p < 0.05$, Table II).

Porosity Distribution

Interfacial porosity: Every sample in the room-temperature group exhibited extensive porosity in the cement mantle at the stem-cement interface (Fig. 3, Table III). These pores were 0.1 to 1 mm in diameter. The mean pore area density at the stem-cement interface significantly decreased from 16% in the room-temperature group to 0.1% in all three preheated groups ($p < 0.001$).

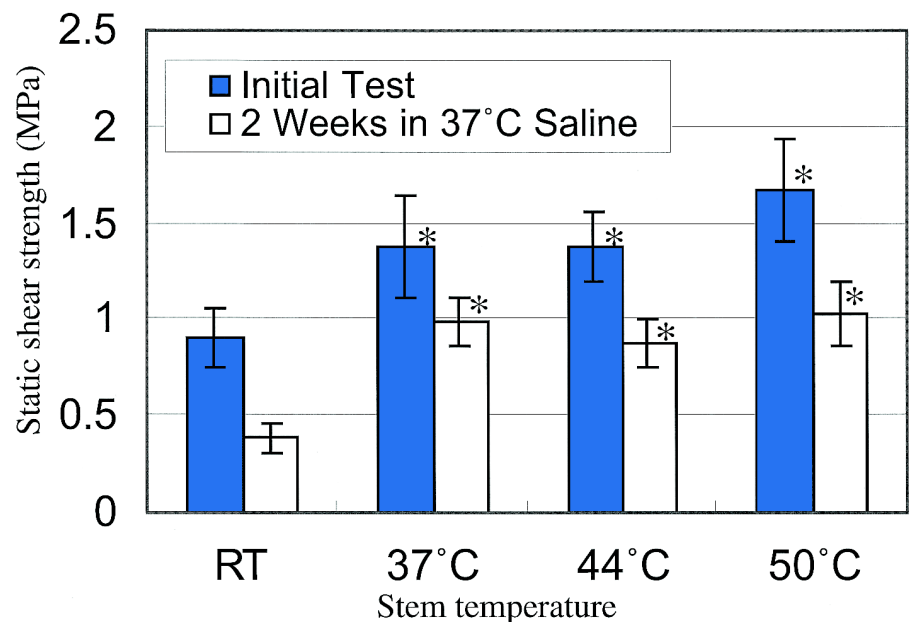


Fig. 2

Shear strength of the stem-cement interface as a function of the stem-preheating temperature. A minimum of twenty samples was used for each testing condition in each group. RT = room temperature.

(one-tailed unpaired student t-test, * $P < 0.001$ vs. RT group)

TABLE II Results of Fatigue Lifetime Testing for the Room-Temperature and 37°C Groups

	Room Temperature	37°C
Total no. of samples	13	13
No. of samples lasting >10 ⁵ cycles	7	12†
Lifetime of failed samples* (cycles)	7440‡ ± 8382	6120

*The values are given as the mean and standard deviation. †The value was significantly different from that in the room-temperature group (p < 0.05). ‡Range, 540 to 20,160 cycles.

TABLE III Porosity Distributions for the Four Test Groups

	Room-Temperature	37°C	44°C	50°C
Stem-cement interface*	16.4 ± 3.0	0.1 ± 0.2†	0.1 ± 0.2†	0.1 ± 0.3†
≤2 mm from interface*	11.3 ± 2.7	2.6 ± 1.9	2.8 ± 2.8	1.9 ± 1.8
>2 mm from interface*	2.6 ± 2.6	2.8 ± 2.1	3.8 ± 2.2	6.9 ± 3.0†

*The values, which represent the percentage of the total area, are given as the mean and standard deviation. There were twenty samples in each group. †The value was significantly different from that in the room-temperature group (p < 0.001).

Porosity within the cement mantle: In the room-temperature group, virtually all pores occurred within 2 mm of the stem-cement interface (Fig. 3, Table III). The 37°C group had reduced porosity within this region compared with the room-temperature group. The 44°C and 50°C groups also had reduced porosity within 2 mm of the stem-cement interface compared with the room-temperature group as well as moderate porosity within 2 mm of the cement-bone interface (Fig. 3, Table III). Several large pores (>1 mm in diameter) were found in almost every sample in the four groups.

Discussion

This study demonstrated that stem preheating has three marked effects on the stem-cement interface. One effect is a change in the porosity distribution. In the room-temperature group, extensive porosity was observed at the stem-

cement interface and within 2 mm of the interface, a finding that is consistent with the observations of James et al.²⁷ and Bishop et al.⁴³. The porosity at and close to the stem-cement interface almost disappeared in the three preheated groups. In the 44°C and 50°C groups, moderate porosity was observed close to the cement-bone interface. The large pores observed in all samples were probably due to cement handling and insertion^{27,32,35,43,49}. Porosity of bone cement has been attributed to several sources, such as shrinkage of the cement^{43,50}, evaporation of the monomer³², or rheological characteristics of the cement²⁷. Because the observed porosity was associated with the cooler surface of either the stem or the simulated bone, and polymerization would be initiated at the warmer surface, it is likely that polymerization shrinkage was responsible. This is analogous to the shrinkage that occurs in metal castings in the last region to solidify. In this case,

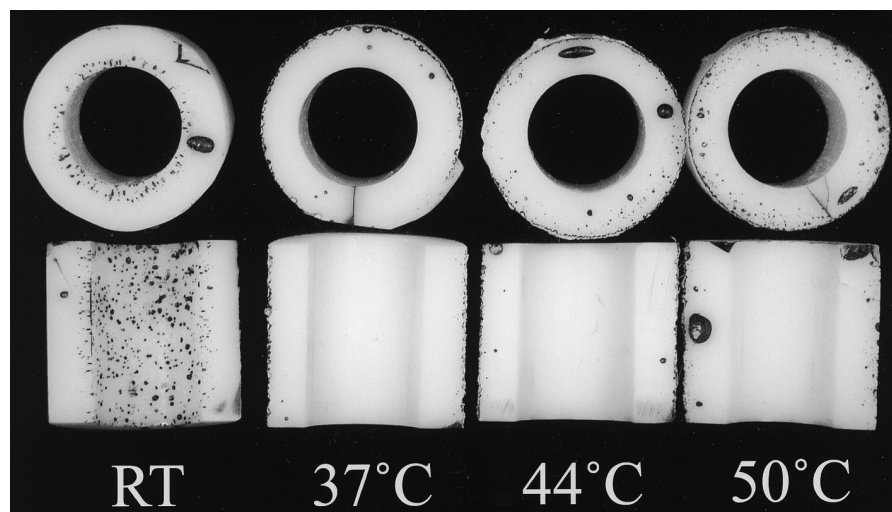


Fig. 3
Typical porosity in the four test groups. (Radial cracks occurred during sample preparation.) RT = room temperature.

having the stem and bone at the same temperature (37°C) seemed to minimize interfacial porosity.

A second effect of preheating was an increased shear strength of the stem-cement interface (Fig. 2). The shear strength of the interface in the three preheated groups was significantly greater than that of the room-temperature group; it was approximately 53% greater in the immediately tested samples and 155% greater in the samples subjected to simulated aging. While storage for two years in bovine serum at 37°C was not shown to result in significant deterioration of static properties or compression fatigue behavior of Simplex-P bone cement⁵¹, it was reported that the shear strength of the interface after immersion at 37°C for sixty days was reduced >80%^{52,53}. Ohashi and Dauskardt reported an up to 84% reduction in the interface strength of nonprecoated cobalt-chromium stems and an up to 64% reduction in that of polymethylmethacrylate-precoated stems after only twenty-four hours of immersion in 37°C Ringer solution⁵⁴. In the current study, the 37°C group retained >70% of the original interface strength after fourteen days of immersion whereas the room-temperature group retained only 43% of its strength. These differences in reduction of shear strength during aging suggest that stem preheating might be superior to precoating with polymethylmethacrylate in terms of shear strength at the stem-cement interface⁵⁴.

The final effect of stem heating is increased polymerization temperature at the cement-bone interface. The maximum temperature at the cement-bone interface in the preheated groups increased by 6°C. Although it has been reported that polymerization of bone cement heated to 50°C has no adverse effects on the mechanical properties of the cement⁵⁵, increased temperatures may create a potential for thermal injury to bone. The critical thermal factors for bone necrosis depend on both temperature and duration of exposure. It takes about 380 seconds for a temperature of 50°C^{56,57} or sixty seconds for a temperature of 70°C⁵⁸ to kill osteocytes. The highest temperature observed in this study was 56°C, and the temperature remained higher than 50°C for 220 seconds. Although these temperatures may have the potential to damage tissue after implantation, it is probable that maximum temperatures at other sites at the interface were lower and shorter in duration than those at the tip of the cement mantle. Bishop et al. found no differences in maximum polymerization temperature between stems preheated to 23°C and those preheated to 44°C⁴³. Dall et al. reported the maximum cement-bone interface temperature to be 56°C in a study in which they used preheated stems and a Teflon cylinder as a simulated femur, which has lower thermal conductivity than natural bone^{42,56,59}. The maximum polymerization temperature at the cement-bone interface also depends on the size, local thickness, and surface area of the cement mantle^{42,60-62}. In addition, a metal stem in curing bone cement has a "heat sink" effect, as does perfusion of blood. As the thermal conductivity of Sawbones⁶³ is about 50% lower than that of fresh human femora⁵⁹, the increased polymerization temperatures found in this study may represent a worst-case scenario.

The higher interface shear strength of preheated stems appears to be related to reduction of porosity at the stem-cement interface resulting in an increase in the contact area between the cement mantle and the metal prosthesis. A reduction in porosity area of 16%, which was the average reduction in the preheated groups in this study, should result in an approximately 20% increase in shear strength. However, an increase of >50% was observed, which indicates that other factors influence interface strength, such as the hoop stress caused by the relative thermal expansion and contraction of the stem and cement^{32,64,65}.

From a functional point of view, preheating stems to 37°C before implantation should be easier than heating them to 44°C or 50°C. There is usually some device in the operating room that can be used to warm materials to body temperature, such as those used for intravenous fluid bags or saline solution. As the temperature of a preheated stem decreases during handling, surgeons should insert it promptly. We currently use a laboratory incubator and heat the stems in their original packages overnight prior to use in our patients. With this method, different stem sizes are available, and the box acts as an insulator.

Although we tried to duplicate clinical procedures and materials, our study had several limitations. We used only one kind of stem material, shape, and surface finish as well as one type of mixing device and one type of bone cement. Micropores (<50 µm in diameter) were not accounted for because of the resolution of the imaging techniques. Also, because of the length of time and the number of samples required, fatigue tests were not done for other temperature groups or immersed samples.

In conclusion, stem preheating had significant effects on the stem-cement interface. The shear strength and cement porosity of the interface were improved significantly. Polymerization temperatures of the cement-bone interface also increased, and the possible biological effects of these increased temperatures require further study. The use of this stem preheating technique should be investigated for other prosthetic applications as well. ■

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