EXPERIMENTAL CHARACTERIZATIONS OF BONE CEMENT CURING
SETTING TEMPERATURE AND TIME

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ABSTRACT: In thermal characterization tests of bone cement according to the ASTM Standard Specification for Acrylic Bone Cement, time-temperature profiles of bone cement were observed to be sensitive to the thickness of the cement patty and the mold material. Due to the heat transfer from cement to the surrounding mold, such tests might underestimate the exothermic temperature of bone cement. Developing test methods to better characterize cement thermal behavior is necessary for accurate cement investigations. In this paper, the effects of the mold material and geometry on experimental characterizations of bone cement setting temperature and setting time were evaluated by conducting the polymerization with different test molds. Finite element (FE) numerical simulations were also performed to provide a further understanding of these effects. It was found that the mold materials and geometry significantly influence the values of the parameters measured with the ASTM standard F-451. Results showed that the setting temperature measured was about 50°C lower in a polytetrafluoroethylene (PTFE) mold than in a polyurethane (PU) foam mold for the 6 mm thickness cement. The measured peak temperature with PTFE molds varied about 75°C for different mold heights (6 mm vs. 40 mm), but only by 28°C with PU molds. The measured setting time with PTFE molds varied by about 740 seconds for different mold heights (6 mm vs. 40 mm), while only by about 130 seconds for PU molds. The measured setting time with PTFE molds varied by about 740 seconds for different mold heights (6 mm vs. 40 mm), while only by about 130 seconds for PU molds. Using PU foam materials for the test mold decreases cement heat transfer effects due to the poor heat conductivity of PU foam and provides more consistent measured results. Finite element parametric studies also support these observations. Therefore, poor conductivity materials, like polyurethane foam, make better molds for the characterization of bone cement thermal behavior.

KEYWORDS: Bone cement curing, Setting temperature, Setting time, Characterization, Finite Element

1. INTRODUCTION

Bone adjacent to the prosthesis is exposed to heat generated by the polymerization of bone cement in cemented hip arthroplasties [1]. The elevated temperatures in the bone may lead to thermal necrosis of bone, and subsequently induce implant loosening. It has been found that the extent of bone necrosis depends on temperature rise and duration [1-4]. One critical problem for the bone cement thermal investigations is how to accurately characterize bone cement thermal parameters. ASTM standard F-451: The ASTM Standard Specification for Acrylic Bone Cement [5] provides the methods for determining bone cement setting temperature and setting time. However, in the thin patty (6 mm) tests described by the ASTM standard, temperature-time profiles of bone cement in the tests were observed to be sensitive to the thickness of the patty and the mold material [6,7]. Due to heat transfer from cement to the surrounding mold, such tests might underestimate the exothermic temperature of bone cement. Few investigations have been performed to study bone cement heat generation and conduction behavior related to the surrounding mold to fully recognize such effects. The goal of this study is to better understand how test molds affect the temperature history in the bone cement during characterization experiments. The aim of this paper is to improve the test method for experimental characterization of bone cements for joint replacements. The effects of the mold materials and the geometry were evaluated by conducting the polymerization of bone cement with different designed molds. The influence of mold material and geometry on the measured thermal parameters of bone cements was also parametrically investigated by the FE numerical method to provide a further understanding of these effects.

2. MATERIALS AND METHODS

2.1 Materials:

The material examined is an experimental bone cement, manufactured by Zimmer, Inc. (Warsaw, Indiana, USA). This bone cement, like many other bone cement systems, is formed by mixing the co-polymer poly(methyl methacrylate)-poly(styrene) solid powder with methylmethacrylate liquid. The experimental bone cement used in this study consisted of a solid phase made of poly(methyl methacrylate)-co-poly(styrene) powder with an average particle diameter of
all tests were conducted at 23 ± 2°C for at least 2 hours prior to testing and all tests were conducted at 23 ± 2°C and 50 ± 10% relative humidity. The utilization of the bone cements consists of three steps: mixing of the solid and liquid phases, gel formation and polymerization of the monomer [1]. The solid component was placed in a glass beaker and mixed with liquid component for one minute. The mixture was then gently packed into the cylindrical mold filling it and the thick cover was immediately pressed down to thermally isolate the cement (Figure 1). Immediately, the cover was set in place with a C-clamp to produce the desired height of the bone cement specimen. Then, the excess materials and the C-clamp were removed. The temperature with respect to time was continuously measured by the thermocouple placed at the center of the mold.

In this paper, two important bone cement curing parameters were studied: setting temperature and setting time. The setting temperature was taken as the maximum temperature reached during the polymerization reaction. The setting time was taken as the time when the temperature rise was at a point halfway between the maximum temperature and the ambient temperature, as defined by ASTM Standard F-451.

2.3 Finite Element Analysis:

In order to provide a better understanding of the tests, numerical finite element parametrical studies were performed to investigate the influence of the mold material’s geometry and on characterization of bone cement. The polymerization kinetics of the bone cement are modeled by the following expression:

$$\frac{\partial \alpha}{\partial t} = Z_0 \exp\left(\frac{E_a}{RT}\right) \alpha^m (1 - \alpha)^n$$  

(1)

where $Z_0$ is a constant; $E_a$ is the activation energy; $R$ is the universal gas constant; $T$ is the absolute temperature, $\alpha$ is the degree of reaction or the reaction completion parameter, and $m$ & $n$ are the reaction order constants. The reaction completion parameter, $\alpha$, ranges between zero and one. Typically the values of $Z_0$, $E_a$, $m$ and $n$ must be obtained from experiments. Here, the test results with the thick (20 mm) PU foam mold were selected as the correct experimental data. Experimental data was gathered for polymerization at five different values of $T_0$ ranging between room temperature (23°C) and human body temperature (37°C). An optimization parametric study was then performed to minimize the error between numerical predictions using the kinetic model and the experimental results for various $T_0$ [6,7]. Thus, we obtain the unknown parameters by best fitting the experimental results. Coupling the cement kinetic model with the energy balance equation, a finite element method has been developed to simulate bone polymerization heat generation and conduction. The numerical method implementation was described in detail elsewhere [6,7]. With the input data of the mold material properties and geometry, the initial and boundary conditions of the thermal tests, the numerical method was used to predict the temperature development at the position of the thermocouples. In the simulations, the heights of the mold and mold materials were varied for parametric evaluations of their effects.

3. RESULTS AND DISCUSSION

The bone cement curing temperature-time curves in experiments following the ASTM Standard F-451 are shown in Figure 2 (internal height of the mold is 6 mm). The measured setting temperature with the PU foam material mold is about 95°C, while it is only about 45°C with PTFE mold. Also, it is seen that thermal tests with PU molds are more consistent (setting temperature varies by 2°C between
The experimentally measured setting temperature and setting time for the two mold materials and various heights of the molds are shown in Figure 3 and Figure 4. As shown in Figure 3, the setting temperature increased with the thicker molds. In Figure 4, a decrease of the setting time as the mold height increased can be observed. The variations of setting time (1623 ~ 2389 seconds) and temperature (45°C ~ 120°C) using different height (6 mm ~ 40 mm) PTFE molds are larger than those measured using different height PU molds (setting time: 1635 ~ 1778 seconds; setting temperature: 95°C ~ 124°C). These result show that the setting temperature during curing not only depends on the total polymerization heat release over a period of time, but also on the heat conducted to the surrounding materials, i.e. test molds. Although the polymerization reactions occur in a very short time (about 200 seconds) comparing to setting time, the effect of the heat release to the mold on the bone cement setting temperature and the setting time is still significant, especially for relatively high conductivity materials. A thicker patty reduced the effects of the thickness variation and mold materials on the characterization parameters of bone cement to a more manageable level. When the mold is sufficiently thick, the setting time and setting temperature with different mold materials converge to a limiting value, independent of mold materials (Figure 3 and Figure 4).

Results showed that the setting temperature measured was about 50°C lower in the PTFE mold than that in the polyurethane mold for a 6 mm patty thickness. The measured peak temperature with PTFE mold varies by about 75°C with different mold heights (6 mm vs. 40 mm), but only by 28°C with PU molds. The measured bone cement setting time with PTFE molds varied by about 740 seconds for different mold heights (6 mm vs. 40 mm), but only by 130 seconds for polyurethane molds. It is clear that the mold material and geometry (mold height in this study) significantly influence the values of the thermal parameters measured with the test methods described by the ASTM standard F-451.

Finite element parametric studies on the effects of mold material and height support the experimental observations. Best fitting the bone cement thermal test results in the thick patty (20 mm) PU molds, the parameters of the bone cement kinetic models were obtained. Comparisons between the experimental data and the model predictions are shown in Figure 3 – Figure 6. Comparing the finite element predictions with the thermal experiments, the results indicate that the kinetic model can represent the polymerization behavior of the bone cement quite well. In figures 5 and 6, the errors between the predictions of setting time and setting temperature and the experiments are very small: setting temperature is within less than 4°C and setting time is within less than 40 seconds. In figures 3 and 4, for very thick molds, the predicted setting temperature and setting time converge for the two different mold materials as observed experimentally. This is due to the nearly adiabatic conditions in the cement with very thick molds. The thinner the mold, the larger the difference in predicted peak temperature with different materials. As shown in Figure 3, in thin patties, the setting temperature predicted is very sensitive to the height of the molds. For the thick patties, the curves tend to a horizontal line, which indicates that the predicted peak temperature was nearly unchanged due to the good heat isolation. Such characteristics were also found in the setting time predicted curves shown in Figure 4. As seen in both Figure 3 and Figure 4, the setting temperature and time are less sensitive to the height of the mold using PU foam as compared to PTFE. This is due to the poor heat conductivity of PU foam.

Finite element parametric studies on the effects of the mold
material and geometry are consistent with the experimental observations.

4. CONCLUSION

In this study, experimental and numerical finite element methods were used to characterize bone cement curing setting temperature and setting time. It was found that the mold materials and geometry significantly influence the values of these parameters measured with the ASTM standard due to the heat transfer from cement to the surrounding mold. Ignoring such heat conduction effects may underestimate the exothermic temperature of bone cement which is a critical parameter in the concern of the thermal necrosis of bone. Thermal tests with thicker or poor conductivity material molds can limit such effects and can provide more consistent experimental results. Therefore, using poor thermal conductivity materials for the test molds, while with the same mold geometry, is better for the characterization of bone cement polymerization thermal behavior.

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REFERENCES