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Effect of shape on bone cement polymerization time in knee joint replacement surgery

Jung-Ro Yoon, MD, Young-Rok Ko, MD, Young-Soo Shin, MD*

Abstract

Background: Although many factors are known to influence the polymerization time of bone cement, it remains unclear which bone cement shape predicts the precise polymerization time. The purpose of this study was to investigate whether different cement shapes influenced polymerization time and to identify the relationship between cement shape and ambient operating theater temperature, relative humidity, and equilibration time.

Methods: Samples were gathered prospectively from 237 patients undergoing primary total knee arthroplasty. The cement components were made into 2 different shapes: lump and pan. The time at which no macroscopic indentation of both cement models was possible was recorded as the polymerization time.

Results: There was no significant difference between hand mixing (lump shape: 789.3±128.4 seconds, $P=.591$; pan shape: 899.3±152.2 seconds, $P=.584$) and vacuum mixing (lump shape: 780.2±131.1 seconds, $P=.591$; pan shape: 909.9±143.3 seconds, $P=.584$) in terms of polymerization time. Conversely, the polymerization time was significantly shorter for Antibiotic Simplex (lump shape: 757.4±114.9 seconds, $P=.001$; pan shape: 879.5±125.0 seconds, $P<.001$) when compared with Palacos R+G (lump shape: 829.0±139.3 seconds, $P=.001$; pan shape: 942.9±172.0 seconds, $P<.001$). Polymerization time was also significantly longer ($P<.001$) for the pan shape model (904±148.0 seconds) when compared with the lump shape model (785.2±129.4 seconds). In addition, the polymerization time decreased with increasing temperature (lump shape: $R^2=0.334$, $P<.001$; pan shape: $R^2=0.375$, $P<.001$), humidity (lump shape: $R^2=0.091$, $P<.001$; pan shape: $R^2=0.106$, $P<.001$), and equilibration time (lump shape: $R^2=0.073$, $P<.001$; pan shape: $R^2=0.044$, $P<.001$).

Conclusions: The polymerization time was equally affected by temperature, relative humidity, and equilibration time regardless of bone cement shape. Furthermore, the pan shape model better reflected the cement polymerization time between implant and bone compared with the lump shape model. The current findings suggest that, clinically, constant pressure with the knee in <45° of flexion needs to be applied until remaining pan shaped cement is completely polymerized.

Abbreviations: MMA = methylmethacrylate, PMMA = polymethylmethacrylate.

Keywords: bone cement, cement shape, polymerization time, temperature

1. Introduction

Bone cements are usually based on 2 component systems, including a powder polymethylmethacrylate (PMMA) copolymer and a liquid methylmethacrylate (MMA) monomer.[1] An exothermic reaction called the polymerization process starts when these 2 component systems are mixed at an approximate ratio of 2:1 and can be divided into 4 different phases: mixing, waiting, working, and setting.[2,3] In cemented knee joint arthroplasty, the polymerization process of bone cement is of clinical importance as it determines the amount of time surgeons have to optimally position an implant. Additionally, accurate bone cement applications are critical to ensuring the stability and longevity of the prosthesis.[4,5] Many factors are known to influence the polymerization time of bone cement. These variations are highly dependent on both intrinsic factors associated with the composition of the cement itself and extrinsic factors, including mixing method, ambient operating theater temperature, relative humidity, storage temperature, and equilibration time.[1,6,7] In addition, extrinsic factors appear to play a more substantial role than the intrinsic factors of bone cements.[8] For example, the storage temperatures and equilibration times can potentially affect the handling characteristics of bone cement.[9] However, it remains unclear which shape of bone cement predicts the precise polymerization time. Furthermore, there is still little medical literature regarding the relationship between cement shape and polymerization time of the cement. The purpose of this study was to investigate whether different cement shape influenced polymerization time and to identify the relationship between cement shape and ambient operating theater temperature, relative humidity, and equilibration time.

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Department of Orthopedic Surgery, Veterans Health Service Medical Center, Seoul, Republic of Korea.

* Correspondence: Young-Soo Shin, Department of Orthopedic Surgery, Veterans Health Service Medical Center, 61 Jinhwangdoro-gil, Gangdong-Gu, Seoul, 134-791, Republic of Korea (e-mail: sysoo3180@naver.com).

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It was hypothesized that the polymerization time of bone cement would be longer for a lump shaped model compared with a pan shaped model and would decrease with increasing temperature, humidity, and equilibration time for both cement shapes.

2. Materials and methods

2.1. Materials

Two commercially available types of samples: Palacos R+G (Zimmer Biomet, Warsaw, Indiana) and Antibiotic Simplex (Stryker, Kalamazoo, Michigan) bone cement were gathered prospectively from 237 patients undergoing primary total knee arthroplasty. The study was approved by our institutional review board for exemption from review because it used de-identified patient data for the purposes of this study (project number NON2016-002).

2.2. Sample preparation and equilibration time

Two components, including a powder PMMA copolymer and a liquid MMA monomer were precooled in a thermostatic controlling refrigerator (4 °C) at least 24 hours prior to mixing. All other tools used in mixing were kept in ambient conditions. Manufacturers' recommended ratios were followed to determine powder and monomer proportions. For each test (Palacos R+G/ Antibiotic Simplex), one ampoule of the liquid (20/20 mL) was added to 1 packet of the powder (40.8/41.0 g). The prepared 2 components of the cement were brought into a room with temperature and humidity controlled at 22 ± 2 °C and 50 ± 10%. The clock was started and the cement components were allowed to equilibrate at 30 and 60 minutes prior to the components being mixed.

2.3. Cement mixing and polymerization time

The cement components were mixed with the use of an advanced vacuum mixing device (ACM, Stryker) or hand mixing with a mixing bowl and spatula (Fig. 1A and B). The clock began when the liquid components of the cement were completely added to the powder components. For vacuum mixing, the handle was turned around twice per second for 60 seconds. For hand mixing, a spatula was turned at a frequency of 2 turns per second for 60 seconds until the powder was visually dissolved in the liquid. When the cement no longer adhered to the glove, remaining cement was made into 2 different shapes: lump and pan. The lump shaped model was made into a sphere about 3 × 3 cm

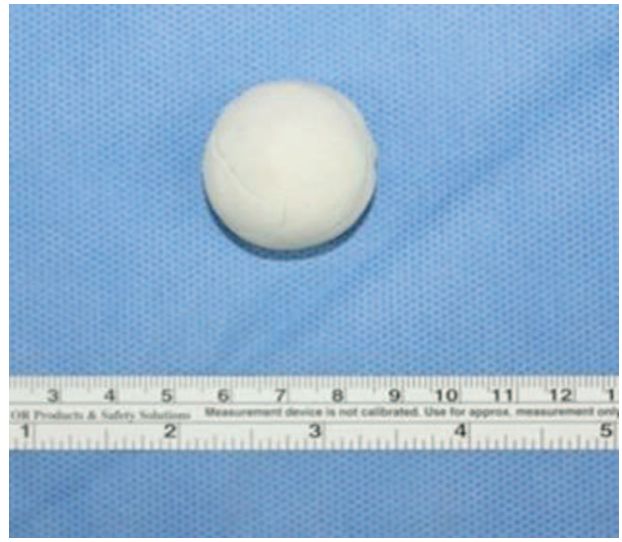

Figure 2. An intraoperative photograph showing lump shaped model with a sphere about 3 × 3 cm.

(Fig. 2), whereas the pan shaped model was made into a 5 × 5 cm circle with a 1.5 mm thick like thin mantle entering between the prosthesis and bone (Fig. 3A and B). Ambient operating theater temperature and relative humidity were recorded. The remaining 2 different shapes of cement were tested every 30 seconds using the tip of a k-wire. The time at which no macroscopic indentation of both cement models was possible was recorded as the polymerization time.

2.4. Statistical analyses

An a priori power analysis was conducted to determine sufficient sample size using a two-tailed hypothesis test with an alpha level of 0.05 and a power of 0.8. The results of our pilot study indicated that 230 (lump shaped) and 230 (pan shaped) cements were required to detect significant differences in mean polymerization time for the 2 shapes of bone cement. This study ultimately included 474 cements, indicating adequate power (0.950) to detect a significant correlation between the 2 groups. Statistical analyses were performed using SPSS statistical software version 24 (IBM Corp., Armonk, NY). Variables, such as cement shape, cement type, and mixing method were compared between the study groups using an independent samples *t* test. A *P*-value <.05

Figure 1. (A) Example of the advanced vacuum mixing device (ACM, Stryker). (B) Example of the hand mixing with a mixing bowl and spatula.

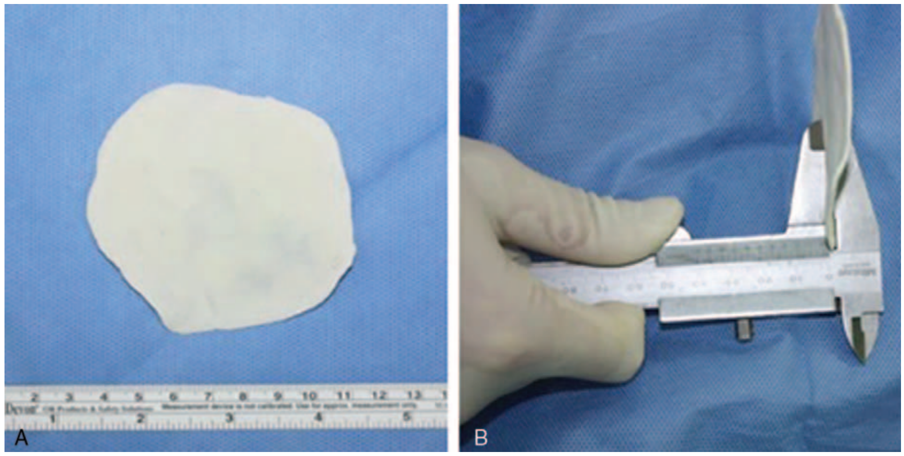

Figure 3. (A), (B) An intraoperative photograph showing pan shaped model with a 5×5 cm circle and a 1.5 mm thick.

was considered statistically significant. Multiple linear regression analysis was performed to assess the impact of independent variables on the polymerization time of the 2 bone cement shapes. Statistically significant independent variables, which were associated with the dependent variables, had *P*-values of <.05.

3. Results

The study resulted in 12 experimental groups, of which 6 were for the lump shaped model and 6 for the pan shaped model, and included 2 cement types (low vs high viscosity), 2 mixing methods (hand vs vacuum mixing), and 2 equilibration times (30 minutes vs 60 minutes).

There was no significant difference between hand mixing (lump shape: 789.3±128.4 seconds, $P=.591$; pan shape: 899.3±152.2 seconds, $P=.584$) and vacuum mixing (lump shape: 780.2±131.1 seconds, $P=.591$; pan shape: 909.9±143.3 seconds, $P=.584$) in terms of polymerization time (Table 1). Conversely, the polymerization time was significantly shorter for Antibiotic Simplex (lump shape: 757.4±114.9 seconds, $P=.001$; pan shape: 879.5±125.0 seconds, $P<.001$) compared with Palacos R+G (lump shape: 829.0±139.3 seconds, $P=.001$; pan shape: 942.9±172.0 seconds, $P<.001$) (Table 2). Polymerization time was also significantly longer ($P<.001$) for the pan shape model (904±148.0 seconds) compared with the lump shape model (785.2±129.4 seconds). In addition, the polymerization time decreased with increasing temperature (lump shape: $R^2=0.334$, $P<.001$; pan shape: $R^2=0.375$, $P<.001$), humidity (lump shape: $R^2=0.091$, $P<.001$; pan shape: $R^2=0.106$, $P<.001$), and equilibration time (lump shape: $R^2=0.073$, $P<.001$; pan shape: $R^2=0.044$, $P<.001$) (Table 3).

Table 1

Summary of the data from the 2 mixing methods for 2 different shapes.

Cement shape	Hand mixing (n=129)	Vacuum mixing (n=108)	*P*-value
Lump shape	789.3±128.4	780.2±131.1	.591
Pan shape	899.3±152.2	909.9±143.3	.584

Table 2

Summary of the data from the 2 mixing methods for 2 commercially available types of cements.

Cement shape	Antibiotic Simplex (n=102)	Palacos R+G (n=135)	*P*-value
Lump shape	757.4±114.9	829.0±139.3	.001*
Pan shape	879.5±125.0	942.9±172.0	<.001*

* $P<0.05$.

4. Discussion

The most important finding of this study was that the polymerization time of bone cement did not significantly differ between hand and vacuum mixing methods for both model shapes. Conversely, the low viscosity cement resulted in a significantly shorter polymerization time than the high viscosity cement. In contrast with our expectations, the pan shaped model resulted in a significantly longer polymerization time than the lump shaped model. We also found that the polymerization time

Table 3

Associations of polymerization time with temperature, humidity, and equilibration time by multiple linear regression analyses.

	Lump shape			Pan shape		
Variables	β±SE	Partial R^2	*P*-value	β±SE	Partial R^2	*P*-value
Temperature, °C	−45.7±4.1	0.334	<.001*	−52.7±4.4	0.375	<.001*
Humidity, %	−2.1±0.4	0.091	<.001*	−2.6±0.4	0.106	<.001*
Equilibration time, s	0.018±0.003	0.073	<.001*	0.015±0.004	0.044	<.001*

SE=standard error.
* $P<.05$.

decreased with increasing temperature, humidity, and equilibration time regardless of bone cement shape.

Inconsistencies in methods of cement mixing can negatively affect the results of cement properties. Vacuum mixing has been shown to be superior to hand mixing because of reduced porosity between adjacent powder particles, which can cause complete wetting of the particles, thereby increasing the homogeneity of the mixture and improving tensile fatigue strength.[10,11] However, there is no consensus on which mixing method has the greater impact on polymerization time, although both mixing methods are commonly used. In 1 study that compared the handling characteristics of bone cement between the 2 mixing methods, vacuum mixing showed a delay in the setting phase by approximately 1 minute compared with hand mixing.[12] In contrast, reducing oxygen concentration by vacuum mixing decreased the setting phase by nearly 2 minutes, but not the waiting phase compared with hand mixing,[13] suggesting that as oxygen concentration in the mixing bowl increased, the setting phase increased. The current study showed that hand mixing required 789.3 seconds for bone cement made into a lump shape and 899.3 seconds for the pan shape, while the vacuum mixing was 780.2 seconds for the lump shape and 909.9 seconds for the pan shape in terms of polymerization time, but these differences were not statistically significant. The similar outcomes for the 2 mixing methods were likely due to hand mixing transferring more kinetic energy, suggesting that the person doing the mixing tended to handle the cement more vigorously than vacuum mixing which affected the polymerization time. This could result in much shorter polymerization time than expected. Another possible reason that vacuum mixing resulted in a slightly longer polymerization time may be due to inconsistent negative pressures, which are dependent on wall suction or a dedicated vacuum pump during vacuum mixing.[14]

Previous studies that compared the phases of bone cement hardening between cement types yielded similar results in that a low viscosity cement had a long waiting phase and the viscosity increased rapidly during the working phase, creating a short working phase, whereas high viscosity cement had a short waiting phase and a long working phase.[3,15] Another laboratory study investigating the effect of mixing method on the temperature-mixing time for 3 acrylic cements found that the polymerization time was longer for the high viscosity cement than the low viscosity cement.[1] This finding corresponds well with the results of the current study showing that the polymerization time was longer for Palacos R+G when compared with Antibiotic Simplex for both shapes of cement (lump shape: 829.0 seconds; pan shape: 942.9 seconds for Palacos R+G vs lump shape: 757.4 seconds; pan shape: 879.5 seconds for Antibiotic Simplex), subsequently leading to a prolonged working phase which provided the surgeon with a longer time between cement preparation and application when using high viscosity cement. Furthermore, precooling high viscosity cements at 4 °C led to a drop in peak temperature, allowing easier mixing, a prolonged working phase, and probably better bone–cement interface strength, even though the cement components were in a room temperature controlled to 22 ± 2 °C where they were allowed to equilibrate from 30 to 60 minutes prior to being mixed.[16] These situations may lessen the likelihood of suboptimal bone cement application at the time of implantation and improve cement tensile strength, making the prosthesis more successful with the high viscosity cement regardless of shape.[17]

This current study also showed a significantly longer polymerization time for the pan shaped model than the lump shaped model (904 seconds for the pan shape vs 785.2 seconds for the lump shape). These results may be attributable to the fact that the lump shaped model had approximately 10 times larger volume when compared with the pan shaped model, suggesting that the larger surface area to volume ratio of the pan shape model contributed to a higher amount of residual liquid monomer and a lower peak temperature, subsequently leading to a longer polymerization time.[18,19] Another factor that could explain these results are differences in cement thickness between the 2 shape models, which can cause reduced working and setting phases responsible for approximately 70% of the polymerization process in cements with a thickness of ≥5 mm,[20] thus decreasing the polymerization time for the lump shaped model.

We acknowledge the limitations of this study. Our findings might not reflect the in vivo performance of the cements, which may be influenced by bone debris and the presence of blood. However, the use of pulsatile lavage and a pneumatic tourniquet during surgery is routine practice at our institution to achieve a debris-free and blood-free bone surface. Second, we did not compare many types of cement with different chemical and physical properties, which may influence the polymerization time results. Thus, further studies are required to definitively investigate the wider range of commercially available cements. Finally, we did not compare relationship between cement interdigitation and different knee positions during surgery. However, >45° of flexion should be avoided because the contact point between the femoral and tibial component shifts backwards significantly and may cause increased pressures posteriorly and thus tilting of the component occurs during the cementation process.[21]

5. Conclusions

In summary, polymerization time was equally affected by temperature, relative humidity, and equilibration time regardless of the bone cement shape. Furthermore, the pan shaped model can better reflect the polymerization time of cement between implant and bone compared with the lump shaped model. The current findings suggest that, clinically, constant pressure with the knee in <45° of flexion needs to be applied until remaining pan shaped cement is completely polymerized.

Author contributions

Conceptualization: Jung-Ro Yoon, Young-Soo Shin.
Data curation: Young-Rok Ko, Young-Soo Shin.
Formal analysis: Young-Rok Ko, Young-Soo Shin.
Investigation: Jung-Ro Yoon, Young-Soo Shin.
Methodology: Young-Soo Shin.
Resources: Young-Soo Shin.
Software: Young-Soo Shin.
Supervision: Young-Soo Shin.
Validation: Young-Soo Shin.
Visualization: Young-Soo Shin.
Writing – original draft: Young-Soo Shin.
Writing – review and editing: Young-Soo Shin.

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