

Technology

Influence of Cooling on Curing Temperature Distribution During Cementing of Modular Cobalt-Chromium and Monoblock Polyethylene Acetabular Cups

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Abstract

Total hip replacements for older patients are usually cemented to ensure high postoperative primary stability. Curing temperatures vary with implant material and cement thickness (30° C to 70° C), whereas limits for the initiation of thermal bone damage are reported at 45° C to 55° C. Thus, optimizing surgical treatment and the implant material are possible approaches to lower the temperature. The aim of this study was to investigate the influence of water cooling on the temperature magnitude at the acetabulum cement interface during curing of a modular cobalt-chromium cup and a monoblock polyethylene acetabular cup. The curing temperature was measured for SAWBONE and human acetabuli at the cement—bone interface using thermocouples. Peak temperature for the uncooled condition reached 70° C for both cup materials but was reduced to below 50° C in the cooled condition for the cobalt-chromium cup (P = .027). Cooling is an effective method to reduce curing temperature with metal implants, thereby avoiding the risk of thermal bone damage.

Keywords

acetabular replacement, cementing technique, curing temperature, thermal damage

Introduction

Cemented fixation of hip implants has been successfully established in clinical practice over the last 50 years.^{1,2} The cement bone interlock provides sufficient primary stability immediately after the operation and also in the long term.³ Despite this success, there are still controversial discussions concerning the influence of increased temperature during the curing process of bone cement made from polymethylmethacrylate (PMMA) on the bone tissue⁴⁻⁷ and the long-term stability of the cement mantle.8-13 Studies investigating the temperature thresholds for human bone found limits between 44°C and 47°C 1 minute until impaired bone regeneration takes place. Lowering of the curing temperature below these thresholds could consequently reduce the risk for thermal damage. This motivates the optimization of the implantation procedure and the implant materials themselves to lower curing temperatures. One approach to lower the

polymerization temperature is the manipulation of the chemical cement composition. ¹⁴⁻¹⁶ Other approaches address the variation of implant material or implantation method to decrease the temperature at the cement—bone interface. ¹⁷⁻¹⁹ The purpose of this study was to investigate whether the temperature distribution at the cement bone interface of acetabular cups during the curing process can be restricted by water cooling and implant material below clinically relevant temperature thresholds. Our hypothesis was that water cooling has a significant effect

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Table 1. Physical Properties of Materials Used in Thi
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	Density (g/cm³)	Thermal Conductivity (W/(K m))	Specific Heat Capacity (J/(K kg))
PUR	0.6	0.3	1400.0
PMMA	1.2	0.2	1500.0
PE	1.0	0.4	1680.0
CoCr	8.3	11.0	430.0

Abbreviations: PUR, polyurethane; PMMA, polymethylmethacrylate; PE, polyethylene; CoCr, cobalt-chromium.

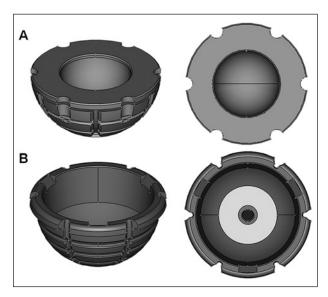


Figure 1. Cup designs used in this study: (A) polyethylene cup (Müller), (B) metallic cup (2000 + CMIC), both from ESKA Implants AG (Lübeck, Germany).

for metal cups but not for polyethylene cups. These 2 implant materials were chosen since they represent clinically relevant and often used implant types showing the largest difference in density and heat conductivity.

Material and Methods

A controlled laboratory experiment was carried out using modular cobalt-chromium (CoCr; 2000 + CMIC) and monoblock polyethylene (PE; Müller) cups with an outer diameter of 52 mm (both components were supplied by ESKA Implants, Lübeck, Germany; Table 1, Figure 1). Cups were cemented into "Medium Left Hemi Pelvis" made from polyurethane with a density of 20 pcf (pound force per cubic foot) (SAWBONES, Limhamn, Sweden) according to manufacture specifications using manually mixed fast curing cement (Palacos R without Gentamicin, Heraeus, Wehrheim, Germany). Both cup types were

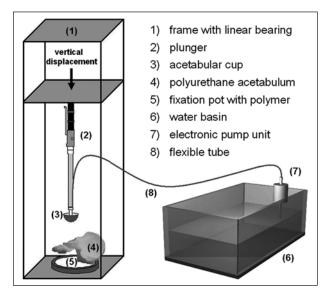


Figure 2. Test setup with custom implantation frame including axial bearing and polyurethane acetabulum (left) as well as reservoir with cooling water and electronic pump unit (right).

implanted with and without water cooling of the cup during polymerization of the cement. Three foam pelvises prepared with a 56-mm diameter hand-reamer were used for each of the 4 test conditions (CoCr cooled/uncooled, PE cooled/uncooled). The 12 pelvises were embedded into a 2-component resin "Ureol" (RenCast FC 53 Isocyanate/FC 53 Polyol, E = 1150 MPa, Huntsman Advanced Materials, Duxford, UK) with the acetabular cavity oriented perpendicular to the implant plunger (Figure 2). Reproducible cement thickness was ensured by using a custom-made implantation frame developed for this study and polyethylene spacers within the acetabulum (Figures 2).

The calculated half-spherical shell volume between cup and acetabulum was 10 cm³, whereas 15 cm³ was used as a base for cement mixing because of approximated volume shrinkage. Six temperature sensors (PT 100, Farnell, Oberhaching, Germany; temperature range = -200 to +850°C; resolution = 0.01°C) were placed in 2 circular latitudes with a spacing of 120° onto the reamed acetabular surface, one was fixed at the bottom of the acetabulum. Reproducibility of the sensor placement was secured with a silicone template (Chlorosil 35, Otto Bock Healthcare, Duderstadt, Germany), including marked sensor positions, which was placed within the acetabulum prior to sensor insertion.

All sensors were covered completely by the cement mantle. A constant volume flow (250 mL/min) of cooling water at room temperature into the cup center was realized for the cooled condition (Figure 2). The water was allowed to adapt to room temperature (~23°C) until equilibrium in

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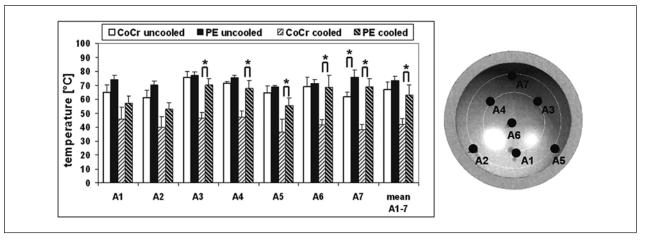


Figure 3. Maximum temperatures at the 7 sensor locations within the acetabulum for the uncooled and cooled condition (mean values and standard deviation of 3 foam experiments, * indicates significant differences between materials (CoCr vs PE).

a separate basin. The cups were inserted immediately after manual cement application by linear vertical displacement of the connected plunger into the acetabular cavity until complete seating onto the polyethylene spacers (Figure 2). A data acquisition system (UPM 100, Hottinger Baldwin, Darmstadt, Germany) was used to record the temperatures (data acquisition frequency = 1 Hz) during cement application for 3000 seconds. Data acquisition was started 10 minutes before cement application, and the initial mean temperature value for each sensor was adjusted to the measured room temperature. Maximum temperatures were analyzed as the mean for all sensors and for each individual sensor position (mean overall measurements; n = 3) for each material and cooling condition. To study the risk of thermal bone damage, the times exceeding a temperature of 47°C and 55°C^{20,21} were calculated as means for all sensors using a Matlab routine (Matlab, 7.0.4, MathWorks, Natick, MA). Additionally, the influence of sensor position on temperature (near the equator vs near the pole) was investigated.

To validate the polyurethane foam model, 1 cadaveric human pelvis specimen each was used for implantation in similar fashion for the 4 test conditions. The human specimens were defrosted 24 hours prior to testing and moistened with Ringer's solution during the measurements. All measurements were performed at room temperature.

Statistical evaluation for varying implant material and cooling condition was performed with a parametric analysis of variance test (post hoc Bonferroni) and a non-parametric Kruskal–Wallis test (post hoc Mann–Whitney U test, Bonferroni correction) depending on the distribution of the data. For all other comparisons (sensor positions, in vitro temperature results) a nonparametric Mann–Whitney U test was employed using IBM SPSS Statistics for Windows, Version 19.0.1 (Armonk, NY).

Results

For the foam experiments, no significant difference in the maximum temperatures between CoCr and PE cups was observed in the uncooled condition for the average maximum temperature (P = .121) as well as for 6 of the 7 sensors (Figure 3). During water cooled implantation, the average maximum temperature (P = .002) as well as 5 of the 7 sensors showed significantly lower maximum temperatures for the CoCr cups compared with the PE cups (Figure 3).

Cooling had a temperature-reducing effect for either material but was clearly higher for the CoCr cup (CoCr: P < .001; PE: P = .004): the difference in maximum temperature between the uncooled and cooled condition was significant for the CoCr cup at all 7 sensors within the acetabulum, but only for 2 of 7 sensors using a PE cup. In the uncooled condition, the temperature at the acetabular surface exceeded 70°C for both materials, while remaining below 50°C in the cooled condition for the CoCr cups (Table 2, Figure 3).

The mean time for all sensors at temperatures above a conservative threshold of 47°C was lowest for the cooled conditions (CoCr: 0.18 ± 0.26 minutes; PE: 2.43 ± 0.56 minutes) and highest for the uncooled (CoCr: 5.60 ± 2.12 minutes; PE: 7.03 ± 2.93 minutes). With a higher threshold of 55°C, the critical time exposure decreased (cooled—CoCr: 0.0 ± 0.0 minutes, PE: 1.21 ± 0.47 minutes; uncooled—CoCr: 1.81 ± 0.69 minutes, PE: 2.86 ± 1.1 minutes). Significant differences were found between both materials in the cooled condition and between uncooled and cooled condition for both materials (P < 0.01 for all comparisons). The temperature versus time characteristic showed that for the cooled CoCr cup the temperature dropped back to 23°C from the maximum

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Table 2. Mean Maximum Temperature (°C) Values (Mean) and Standard Deviation (SD) for the Foam and In Vitro Experiments for All Conditions and Materials.

Foam	Mean	SD	Human	Mean	SD
CoCr cooled	42.06	4.26	CoCr cooled	32.39	4.66
CoCr	66.82	5.33	CoCr	41.30	5.07
uncooled			uncooled		
PE cooled	62.96	7.34	PE cooled	41.56	5.53
PE uncooled	73.32	3.09	PE uncooled	48.93	7.34

Abbreviations: CoCr, cobalt-chromium; PE, polyethylene.

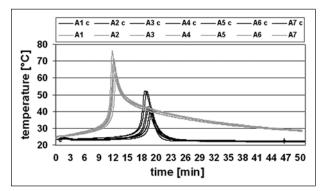


Figure 4. Example of temperature versus time data presented for the CoCr cup in the cooled (A1c-A7c, black) and uncooled (A1-A7, grey) condition with SAWBONES.

peak within 2 minutes, whereas it remained above 30°C for more than 35 minutes without cooling (Figure 4).

Temperature varied significantly with position between sensors near the pole and near the equator for both materials and cooling conditions (P < .05), except in the cooled PE group. The mean maximum temperature was higher for sensors near the pole especially for the cooled conditions (mean difference: PE = 9%; CoCr = 18%) compared with the uncooled (mean difference: PE = 5%; CoCr = 9%) and this effect was more evident for CoCr cups (Table 3).

Measurements on the human specimen revealed similar results as the foam experiments but absolute values were 20% to 30% lower (Table 2, Figure 5). All configurations except the PE cup (sensors A1, A2, A4) in the uncooled condition showed maximum temperatures below 50°C (Table 2, Figure 5). In the cooled in vitro experiments, the maximum temperature for both materials was below 40°C, with exception of sensors A1 and A2 for the PE cups (Figure 5).

Discussion

The current study investigated the influence of implant material and cooling condition on the polymerization

Table 3. Mean Maximum Temperature of Sensors Near the Pole and Near the Equator of the Acetabulum for All Conditions and Materials.

Condition	Position	Mean (°C)	Difference (%)	SD (°C)
CoCr cooled	Equator	38.01		6.49
	Pole	46.26	17.84	5.31
CoCr uncooled	Equator	62.36		4.40
	Pole	70.51	11.55	5.91
PE cooled	Equator	59.13		8.67
	Pole	64.99	9.02	7.40
PE uncooled	Equator	71.76		4.30
	Pole	75.55	5.01	2.58

Abbreviations: CoCr, cobalt-chromium; PE, polyethylene.

temperature during the curing process of PMMA cement for the fixation of acetabular cups. Our hypothesis that water cooling has a significant temperaturereducing effect at the cement-bone interface for metal cups was supported. This reduction in cement curing temperature for the CoCr cups in the water-cooled situation can be explained by the higher thermal conductivity of CoCr (11.0 W/(K m)) compared with PE (0.4 W/(K m); Table 1). CoCr enables a more efficient heat transport to the respective cup surface where waterinduced convection is dissipating the energy. The very low thermal conductivity of the PE delays the heat transport within the PE cup, thus leading to less temperature reduction in the cooled condition. Also, the thicker shell design of the PE cup (Figure 1) contributes to the delay in heat transport from the cement-cup interface to the cup surface.

A clear dependency of temperature on the sensor position could be seen between locations near the pole and near the equator, which may be related to the varying foam thickness in the polyurethane acetabulum and the central location inside the cement mantle (more heat is radiated at the equator). This would also explain why no dependency on locations at the same latitude was observed.

Not only the maximum temperature but also their duration is an important factor. ²¹⁻²³ The results show that water cooling could reduce the mean duration time above the critical limit of 55°C significantly for the CoCr cup (0 second) compared with the PE cup (1.2 minutes) in the foam experiments. Regarding the in vitro experiments, the critical temperature of 55°C was only exceeded for the uncooled PE cup at 2 of the 7 sensors for more than 30 seconds. In the study by Henrique and Moritz, ²¹ an exposure time of 0.4 minutes, which was still reached with the uncooled PE cups (in vitro), was considered the shortest time period to cause thermal damage. With the use of a more conservative threshold of 47°C, ²⁰ the critical

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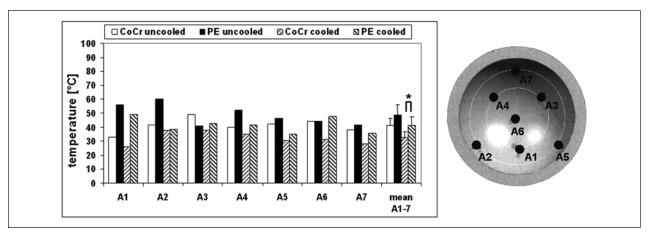


Figure 5. Maximum temperatures at the 7 sensor locations within the acetabulum for the uncooled and cooled condition (in vitro experiments with one specimen for each condition, significant differences between materials [CoCr vs PE] are indicated by *).

exposure time of more than 1 minute was reached for the uncooled PE cup but not for the uncooled CoCr cup (in vitro). A cooling time of approximately 2 minutes using CoCr cups was sufficient to reestablish the starting temperature, which is clinically feasible. Compared with the foam experiments, cooling also had also an effect for PE cups in the in vitro experiments. For the cooled PE cup (in vitro), the critical temperature of 47°C was only shortly (<10 seconds) reached in 1 sensor. Thus, it might also be feasible to use cooling for PE cups in vivo since the body fluid is improving the heat exchange to the environment, further reducing the temperature.

In this context, it has to be mentioned that beside temperature the monomer release and vascular damage during imperfect polymerization might also play an important role for postoperative bone necrosis.²⁴⁻²⁷ These factors could not be investigated and were beyond the focus of this study.

Beside the risk of thermal bone damage, the mechanical competence of the cement-bone interface and its dependency on curing temperature has to be taken into account. Several in vitro studies have shown that preheating the stem in hip endoprosthesis increases the shear strength at the cement-bone interface. 28,29 The evaluated stem temperatures ranged from 37°C to 50°C and were compared with stems at room temperature. The current study aims to reduce the peak temperatures at the cementbone interface below critical values of 47°C, as the in vitro experiments show these limits are only exceeded with uncooled PE cups. In the cooled conditions, peak values were reduced to 41°C and 32°C, respectively, for PE and CoCr, indicating that cooling might only be clinically relevant for PE cups. For the CoCr cups, curing temperature at the cup-cement interface might be reduced very drastically, which could compromise the mechanical

interface competence. The study by Iesaka et al³⁰ investigated the influence of initial monomer temperature on the shear strength of the cement–stem interface. A monomer temperature of 4°C reduced polymerization temperature and interface strength compared with room temperature and 37°C. Nevertheless, the study of Hsieh et al²⁸ showed that precooling the femoral canal could increase the shear strength at the cement–stem interface too. Regarding these literature data, a precise lower temperature limit compromising the polymerization process and mechanical competence of the cement is still not defined.

Limitations

The foam model did not imitate the in vitro situation with surrounding bone and soft tissue quantitatively very well. This is probably due to the higher density and fluid proportion of human bone, which enables better dissipation of thermal energy to the environment. In contrast, polyurethane lacks any fluid proportion leading to a lower heat conductivity than human bone and, consequently, to a delayed temperature response during cooling. It is expected that the temperature in an in vivo situation would be reduced even more, since the soft tissue and blood flow are supporting factors for the transport of thermal energy. 31,32 In the cited study, 32 the temperature in total knee arthoplasty without blood increased over the critical threshold of 55°C while remaining below that value with physiologic blood flow. Although a limited number of cadaver specimens were tested in the current study, the foam model used proved to be a good surrogate for the detection of qualitative differences between different implant materials or cooling methods when compared with the in vitro experiments.

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The current measurements were performed at room temperature and cannot be compared directly with the in vivo situation. Thus, somewhat higher temperatures during in vivo cement polymerization have to be expected. Nevertheless, the results of the cadaver experiments for the PE cup acquired in this study are consistent to a certain extent with in vivo experiments, 33 which showed median maximum temperatures of 49°C (41°C to 67°C) in the uncooled condition and 41°C (37°C to 48°C) in the cooled condition (Table 3). In another in vivo study,³⁴ the mean curing temperature for PE cups was 43°C. An explanation for the difference could be that the initial mean acetabulum temperature was reported at 32°C instead of 37°C body temperature. Thus, we expect that the measurements performed in the current study at room temperature lead to a certain temperature offset that lowers the absolute measured values. Nevertheless, we propose that the obtained qualitative differences between the conditions can be used to predict trends that are expected in vivo, although certain cross-interactions between the tissue and implant material especially in the cooled condition cannot be excluded.

Conclusion

This study has shown that the temperature at the bonecement interface can be significantly lowered when using water cooling, especially in combination with a metal cup. For PE cups, water cooling had an effect only when applied with the human bone specimen (in vitro) for which the peak curing temperature could be reduced below 45°C compared with more than 50°C in the uncooled condition. In conclusion, water cooling of acetabular cups could minimize any possible risk of thermal bone damage and subsequent postoperative necrosis. Since the peak temperatures for uncooled metal cups in vitro are already below 47°C, cooling might be clinically more relevant for PE cups where peak temperatures exceed this limit. This is of further importance, since drastically reduced implant temperatures (<37°C) might also negatively influence the mechanical competence of the cement-implant interface.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: ESKA Implants AG (Lübeck, Germany) provided the specimens. Heraeus Medical GmbH (Wehrheim, Germany) supplied the bone cement.

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