

Excessive heat generation during cutting of cement in the Robodoc hip-revision procedure

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Submitted 00-11-29. Accepted 01-05-31

ABSTRACT – The ROBODOC system is a promising new method for removing cement with high-speed milling. Heat is generated during the milling process. This study was designed to measure temperatures in the cutting area, and to assess the risk of heat injury and the effectiveness of irrigation. We measured temperatures at the bone-cement cutting area in three experimental settings, two involving the proximal area comprising a cement mantle, and one the distal cement plug beneath the prosthesis. Without cooling facilities, a mean temperature of 94 °C was measured in proximal areas. However, this could effectively be reduced below 70 °C with irrigation. In the area of the distal cement plug, we measured a mean temperature of 172 °C without irrigation. In this area, the integrated irrigation system with an additional high-flow irrigation system could not guarantee cooling to an acceptable temperature of below 70 °C since the irrigation stream was impeded by the cutter in the narrow cavity. We need an integrated irrigation device that guarantees continuous cooling at the cutting interface in front of the cutter.

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In cemented hip-revision surgery, complete removal of the cement is important. Usually this can be easily achieved in the proximal area, but difficulties are often found in more distal parts, especially in the block of cement below the prosthetic stem (Klein and Rubash 1993, Taylor and Rorabeck 1999). In order to minimize its length, cement-stoppers were introduced, but they still leave a substantial cement plug. To remove this cement plug, it is often necessary to fenestrate the femur (Bauer et al. 1996), which increases operative exposure

and blood loss. Fenestration also introduces a weak point in the femur. Cement can also be removed with an extended trochanteric osteotomy.

Various devices have been designed for cement-removal with special emphasis on the distal plug. The ROBODOC® system (Integrated Surgical Systems, Davis, CA (ISS)) offers another promising new method of cement removal by high-speed milling. It permits exact preoperative planning of the cutting process from CT data on a computer planning station. During surgery, all cement is removed through the femoral cavity by the surgical robot, with a mean cutting time of 47 minutes in our first 16 cases, thereby avoiding fenestration or trochanteric osteotomy. The length of incision and exposure can be reduced.

Bone cement is a hard material, and consideration must be paid to the heat generated during such a milling process, with regard to the risk of heat injury. The milling-head rotates at a speed of 70,000 revolutions per minute (rpm). There is continuous irrigation, but smoke and burned debris consisting of blackened cement swarf have nevertheless been observed intraoperatively.

We studied the temperatures at the cutting interface in distal and proximal areas of the bone to assess the risk of heat injury and the effectiveness of irrigation during the ROBODOC milling process.

Material and methods

After removing the femoral component, all of the cement or part of it remains in the bone. Two distinct situations exist concerning its removal. Prox-

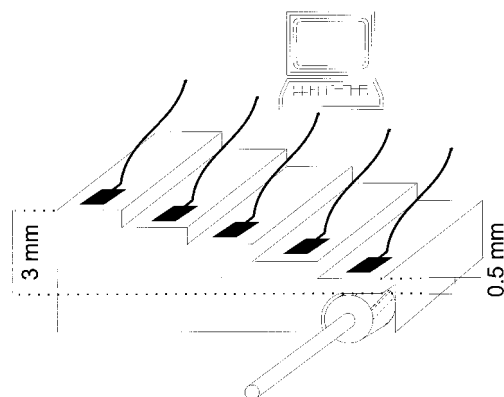


Figure 1. Design of the proximal cutting experiment.

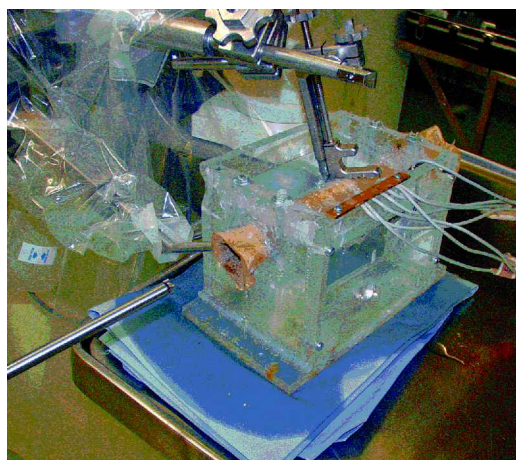


Figure 2. Water tank with cadaver bone mounted on the robot.

imally, an open cavity is surrounded by cement leaving enough space for the cutter to move. Distally, the cement plug remains in a narrow cavity. Three experiments were designed.

Cutting of cement blocks

The first test was done to measure the development of temperature in bone cement at given distances from the cutting interface. Blocks of PALACOS R cement (Merck, Darmstadt, Germany) (Figure 1) were cut using ROBODOC's cutting system (ISS) equipped with the Midas Rex motor (Midas Rex Institute, Forth Worth, TX), powered by compressed air (1500 KPa), which gave a speed of 70,000, using a 12.5 mm diameter flat cutter with a length of 286 mm (ISS). The temperature was measured at the top surface of the cement block, by means of a Resistance Temperature Device (RTD) model PT100 (Gatterbauer Messtechnik, Sipbachzell b. Wels, Austria) linked to a real-time data logger (Grant Instruments, Cambridge, UK), which recorded the temperature at two-second intervals throughout the cutting. 5 of these sensors, placed on precisely milled steps in the cement block, at distances of 0.5, 1, 1.5, 2 and 3 mm from the cutting interface were used. The cutter was advanced by 1.5 mm/s and cut 12.5 cm of cement (100% of the cutters diameter). The test was performed with and without irrigation. Irrigation was done using a Jet Lavage (Stryker Howmedica Osteonics, Rutherford, NJ) irrigation gun, at a constant maximum flow-rate of 30 mL/sec. Standard saline solution at

room temperature ($22 \pm 4^\circ\text{C}$) was used as irrigation fluid. Tests without irrigation were repeated 10 times and those with irrigation 6 times.

Proximal cutting in cadaver bones

We designed the second experiment to simulate the situation in the proximal portion of the cutting area. A human cadaver bone was used. RTDs were placed at the bone-cement interface. A PALACOS R (Merck) cement mantle remained in the cavity, after removal of a previously implanted cemented femoral component (Lubinus SPII, Link, Hamburg, Germany). To simulate body temperature, the bone was placed in a specially-built tank, and submerged in water at 37°C (Figure 2). Maintenance of this temperature at $\pm 2^\circ\text{C}$ was controlled using a PT 100 sensor (Gatterbauer). Hot or cold water was added, as required. Online reading of temperatures was done via links to the real-time data logger. Temperatures were measured at a distance of 0.2–0.8 mm from the cutting interface with the same apparatus described above, resulting in 10 series of temperatures without irrigation and with ROBODOCs integrated irrigation systems plus the Jet Lavage (Stryker).

Distal cutting in cadaver bones

We designed the third experiment to simulate the situation in the distal portion of the cutting area (Figure 3). A human cadaver bone was used. RTDs were placed at the cement-bone interface. A plug of PALACOS R (Merck) cement was placed in the

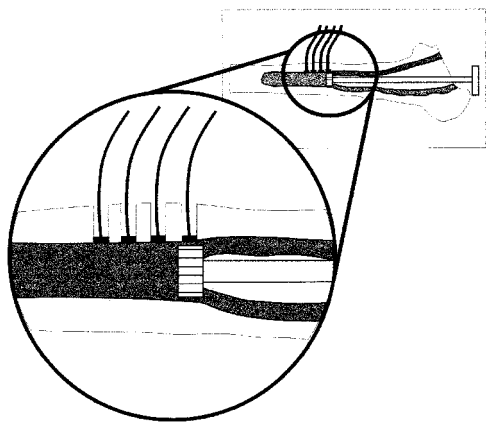


Figure 3. Design of the distal cutting experiment.

cavity. Body temperature simulation and measurements were done using the protocol of the second experiment.

Calculations and plotting were performed by using EXCEL 97 (Microsoft, Redmond, WA, USA) and SPSS 7.5 (SPSS Inc., Chicago, IL, USA).

Results

In the first experiment, we found temperatures

between 44 °C and 127 °C without irrigation. The highest temperature was measured at a distance of 0.5 mm from the cutter. During irrigation, the temperatures were lower, ranging from 30 °C to 45 °C. A temperature-distance graph was drawn (Figure 4).

In the proximal cadaver-bone simulation, a series of temperatures was recorded within a distance of 0.2–0.8 mm from the cutting interface. This experiment showed mean temperatures of 94 (41–210) °C without and temperatures of 53 (42–68) °C with irrigation. They were at levels comparable to those found in the cement-block experiments at the same distances from the cutter (Figure 4).

In the distal cadaver-bone simulation, we found mean temperatures of 172 (96–282) °C without and temperatures of 74 (43–133) °C with irrigation (Figure 5).

Discussion

Bone is routinely exposed to high temperatures in cemented hip replacement procedures. Wykman (1992) recorded temperatures between 41° and 67 °C at the bone-cement interface during implantation of cemented acetabular components. Reck-

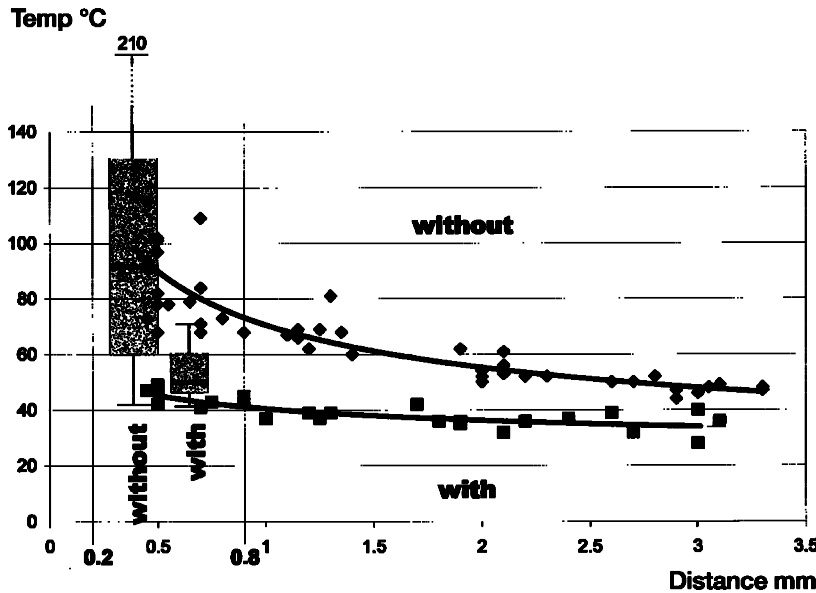


Figure 4. Proximal experiments: temperature distance plot from the cement block experiment, including box and whisker plots of proximal cadaver experiment.

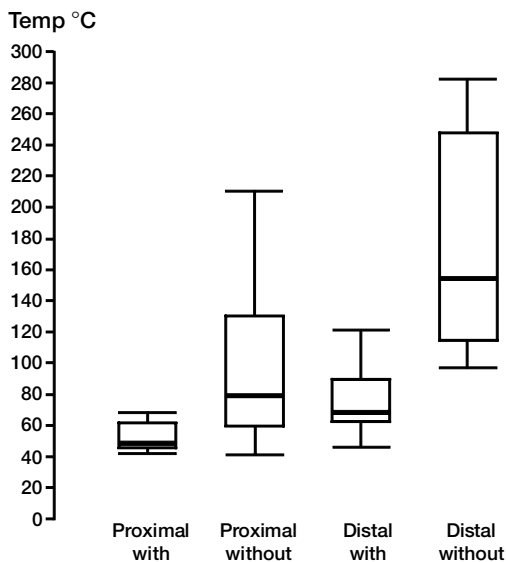


Figure 5. Box and whisker plots showing the results of proximal and distal cadaver experiments.

ling and Dillon (1977) found a maximum temperature of 48 °C at the bone-cement interface during 20 total joint replacement procedures. Berman et al. (1984) studied the risk of heat injuries in bone tissue in a rabbit model. They found bone necrosis in histological sections at temperatures equal to or greater than 70 °C and therefore recommend that temperatures be limited to below 70 °C when using cement. Although Wykman (1992) reported temperatures below 70 °C, he also reported thermal necrosis of bone in 9 of 11 cases. Eriksson et al. (1982) reported irreversible bone injuries occurring even at 53 °C in a rabbit model. Therefore, only temperatures below 50 °C can be regarded as completely safe. However, Berman et al. (1984) recommend temperatures of up to 70 °C for removal of cement.

Heat generation is affected by several factors: volume of the cement cut, shape of cavity where it is cut, speed of cutter and the effectiveness of irrigation in cooling and rinsing out the cement debris. After removal of the stem in a revision procedure, the cement lines up a wide proximal cavity. Distally, below the prosthesis, the cement is solid and the femoral cavity narrows. This means that in the distal area, there is more cement to cut in less space with no place for the debris to fall from the cutting area. Irrigation may also be impeded by narrowing

of the cavity and possible accumulation of debris.

In our first experiment, we showed the effect of cooling through an irrigation system and the rapidly declining temperature with increasing distance from the cutting interface in cement. A limitation is that temperature distribution may be different in living bone. However, the mean temperatures from the proximal cadaver experiment fit the temperature distance graph, which would suggest that these measurements are correct. The proximal peak temperature was 210 °C without irrigation and exceeded all temperatures recommended as safe. With irrigation, the peak temperature was 68 °C. This indicates that sufficient irrigation using high flows can cool to acceptable temperatures.

In the distal area, the temperatures reached without irrigation were higher than in the proximal area, up to 282 °C without irrigation and 133 °C with. They also exceeded all temperature thresholds that can be regarded as safe or acceptable for living tissue. Safe temperatures below 50 °C were seen only occasionally. The high standard deviations emphasize the unpredictability of a specific situation and show that heat generation depends on several factors, such as cavity size, amount of cement and, above all, the local effectiveness of irrigation. The increasing ineffectiveness of the irrigation distally is due to the narrowness of the cavity. In some areas the diameter of the cavity was just a little wider than that of the cutter. Any type of irrigation that does not direct the stream to the cutting interface can not guarantee sufficient cooling throughout the procedure.

It can be argued that the temperature quickly falls with distance from the cutting area, and only the tissue immediately adjacent to the cutter is at risk of heat injury. This may be true and would limit the damaging effects of even very high temperatures. Although heat injuries were not studied, we believe that the bone tissue at the interface is of particular concern since it will form the bone-implant or bone-cement interface after revision implantation. Our in vitro study simulated body temperature, but did not simulate blood flow and its possible cooling effects through convection, which might be increasingly effective with increasing distance from the cutting area. At the immediate area of cutting, we would not expect significant cooling by blood flow.

In conclusion, there is a risk of heat injury throughout the cutting procedure in the ROBODOC Revision system, which can be reduced by sufficient irrigation in the proximal part. It remains higher in the area of the distal cement plug, where sufficient irrigation can not be guaranteed with the devices used in this study.

We recommend that particular attention be paid to the maintenance of constant irrigation during cutting. Additional irrigation, apart from that of the ROBODOC system, is necessary when cutting the cement plug. A newly designed irrigation system, which irrigates via the cutter and leads the stream to the cutting interface might be a more attractive alternative.

The authors thank Steve Shimbles, Karima Khalifa, and Jasdip Mangat from the Department of Medical and Mechanical Engineering, University of Bradford, United Kingdom, for their technical assistance during these experiments.

No funds were received to support this study.

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