Interface gap after implantation of a cemented femoral stem in pigs

Jian-Sheng Wang, Herbert Franzén and Lars Lidgren

We studied the interface gap around cemented femoral stems. Fresh pig femora were used. Bone cement mixed under vacuum or at atmospheric pressure was injected into the femoral canal and a cobalt chrome stem was then implanted. The femora were sectioned transversely from the minor trochanter and distally by using a high-pressure water cutter. Most of the interfaces had intimate contact. However, in all specimens, small gaps were found at the bone-cement and cement-stem interfaces. The gaps at the interfaces between the bone and cement and the cement and stem were measured, using a computerized video digital system. They occupied about 10% of the circumference at the bone-cement interface and about 15% of the circumference at the cement-stem interface, irrespective of the mixing procedures. Most gaps were less than 100 μ at the interfaces. In conclusion, cemented implants in the animal model showed that small gaps are found at the interfaces directly after implantation. These gaps may be weak points and initiate debonding when loading the prostheses.

Department of Orthopedics, Lund University Hospital, SE-221 85 Lund, Sweden. Tel +46 46-17 71-64. Fax -67. E-mail: Jian-Sheng.Wang@ort.lu.se
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Bone cement is subject to volumetric shrinkage in the range of 1–5% (Haas et al. 1975). Rimnac et al. (1986) found that the volumetric shrinkage of Simplex P cement increased with reduction of the cement porosity by centrifugation. They concluded that the increased shrinkage of the centrifuged simplex P could compromise the integrity of the cement-bone interface. Davies and Harris (1995) showed that porosity reduction by centrifugation did not change the linear dimensions of Simplex P cement and subsequently suggested that linear shrinkage was more important than volumetric shrinkage for fixation of the implant. Several studies have also revealed that extensive porosity is aggregated at the cement-stem interface in retrieved cement mantle and laboratory-prepared specimens (Jasty et al. 1991, James et al. 1993, Bishop et al. 1996). This aggregation of pores could influence the interface bonding between the stem and the cement. Therefore, it is important to determine the nature of the interface integrity for cemented prostheses.

The main purposes of this study were first to determine the interface integrity immediately after implantation and then to determine if vacuum-mixing of bone cement had any effect on the interface integrity, as compared to mixing at atmospheric pressure.

Animals and methods

5 paired fresh pig femora were used for the experiment. The bone marrow cavity was prepared with a rasp followed by brushing and high-pressure irrigation. A cement plug was inserted 1 cm distal to the tip of the stem. Prechilled (4 °C) Palacos R bone cement was used and the cement was mixed for 30 seconds in the Optivac mixing system with or without vacuum. One of the paired femora was filled with vacuum-mixed bone cement (0.1 bar) and the other matching pair was filled with cement, mixed at atmospheric pressure. 2 minutes after mixing was started, the cement was inserted via a cement gun with a delivery nozzle into the bone in a retrograde fashion, and a proximal seal was used to exert pressure on the cement. A femoral stem, maintained at room temperature (22 °C) and fitted with a centralizer, was implanted in the cement at 3.5 minutes and held under constant

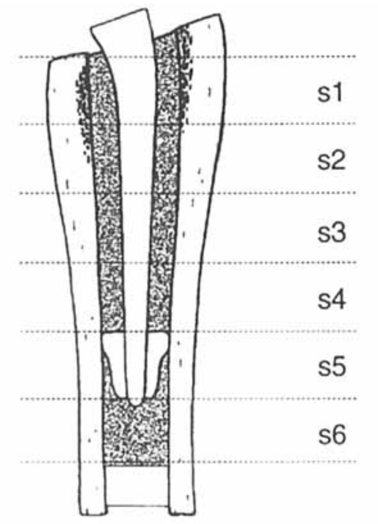

Figure 1. The location of the cemented implant in the femur and 5 levels which were examined histologically. "s" indicates the section.

pressure until the cement had cured. The stem was made of cobalt chrome alloy and had a fine grid-blasted surface finish. All stems had the same length (60 mm), thickness (7 mm) and width (12 mm proximal and 7 mm at the tip). Before implantation, the femora were warmed in a physiological saline bath at 37 °C. After implantation, the stem-femora constructs were kept in the bath for 12 hours. The implanted femora were sectioned transversely from the minor trochanter and distally (Figure 1), using a high-pressure water cutter (Wang and Lidgren 1997). The machine produced a water pressure of 3500 bar through a nozzle with an inside diameter of 1.0 mm. A smooth and clean surface was obtained with this cutting method. 5 consecutive 10 mm thick sections were used to evaluate the morphology. This was done blindly—i.e., each specimen was given a code number and all specimens were investigated at random. The integrity of the interfaces between bone and cement, and between the cement and stem interfaces were examined using a microscope with a computerized video digital table system (Videoplan™, Zeiss) at a magnification of 40 ×. When the interfaces showed a separation between bone and cement, or between cement and stem, the separation was named an interface gap. The circumferences of the interfaces at the bone-cement and cement-stem were measured. The length and width of all the gaps between bone and cement, and between cement and stem on the cross-section were measured by the Videoplan. The width of the gaps was graded—i.e., grade I < 100 μm, grade II 100–500 μm and grade III more than 500 μm. The percentage of the circumference of the interface occupied by the gap was calculated by dividing the distance of the gap part of the circumference by the total distance of the interface circumference in each section, and multiplying by 100.

The mean values of all sections from each femur were used to analyze the gap differences between the different bone cement-mixing procedures. The data were evaluated with the Student's paired t-test.

Results

The analysis of serial sections showed that there was 85% contact between the cement and stem and 90% contact between bone and cement with gaps found both in the cement-stem and the bone-cement interfaces. Most of the gaps at the cement-stem interface occurred at the same position in the different sections and were not affected by the cutting direction (Figures 2 and 3). A complete circumferential gap was not found in any of the specimens. Some gaps were associated with pores at the cement-stem interfaces. These gaps were irregular, with a saw-tooth appearance, and were often seen in the sections with cement mixed at atmospheric pressure (Figure 2). Other gaps showed a clear edge without pores, they were often seen in the vacuum-mixed sections (Figure 3). The appearance of the gaps at the bone-cement interface looked the same regardless of mixing procedure (Figure 4). The total percentage of the circumference occupied by the gaps in both bone-cement and cement-stem interfaces did not differ significantly, regardless of the mixing technique (Table). The majority of the gaps were less than 100 μ (gap grade I) (73 % at bone-cement interface and 83 % at the cement-stem interface). Grade III gaps (> 500 μ) were found in only a few sections in all specimens.

The cement mantle ranged from 2 to 6 mm thickness at different femoral levels. The cement layers in the proximal sections were thicker than

Figure 2. a. Overview of the cemented stem in the femur. The bone cement was mixed at atmospheric pressure. The arrow shows cutting direction (magnification 4 ×).

b. The close-up shows a gap with "saw tooth" edge at the cement-stem interface.

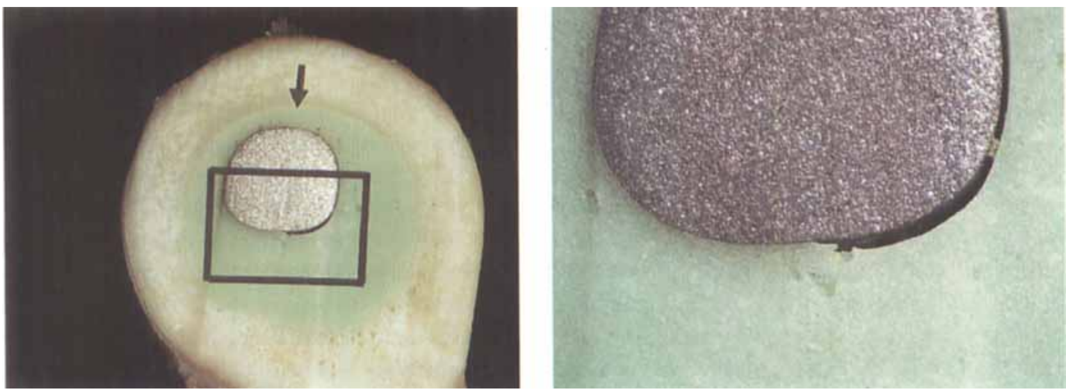

Figure 3. a. Overview of a cemented stem. The bone cement was mixed under vacuum. The arrow shows a cutting direction (magnification 4 ×).

b. The close-up shows a gap with a sharp edge at the cement-stem interface.

Comparison of the percentage of the gap length at the interfaces between the bone (B) and the bone cement (C), and the cement and the stem (S) for the different mixing procedures. The p-value is obtained from a comparison between vacuum and nonvacuum-mixed specimens, paired t-test, mean (SE)

Cement mixing	Total gap length %		< 100 μ gap length %	
	B-C	C-S	B-C	C-S
No vacuum	9.4 (1.4)	13 (2.2)	8.1 (1.3)	11 (3.0)
Vacuum	10.9 (1.5)	17 (3.5)	8.6 (1.6)	9.7 (2.8)
P-value	0.6	0.3	0.9	0.7

in the more distal sections (Figure 5). The interface gap was seen not only in the section with the thicker cement layer but also in the sections with a thinner cement layer. The highest proportion of gaps was seen in the sections from the middle part of the stem (Figures 6 and 7).

Discussion

Improving interface integrity is essential to the longevity of cemented femoral components. Initial prosthetic instability seems important (Freeman and Plante-Bordeneuve 1994, Mjöberg 1994, Walker et al. 1995, Franzén 1996). To our knowledge, no previous study has quantified the interface gaps. The present study showed initial gaps in 10–15 % of the interface area, which may influence the early stability of the prosthesis. Debonding found early after operations (Jasty et al. 1991, Verdonschot 1995) may thus already be present directly after the implantation (Brumby et al.

Figure 4. The gap between the bone and the cement (×12).

a. The cement was mixed at atmospheric pressure.

b. The cement was mixed under vacuum.

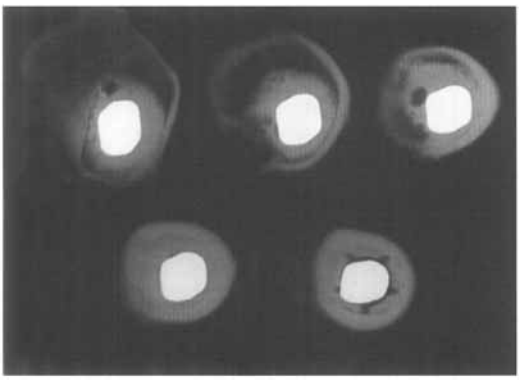

Figure 5. Different thicknesses of the cement mantle at the different levels. Upper left is the proximal section, the lower right shows the centralizer surrounding the distal part of the stem.

1997). According to the debonding theory of cemented stems, some debonded regions will expand until the whole interface is debonded (Verdonschot and Huiskes 1997). Interface gaps present at insertion may initiate debonding. Early instability in total hip replacement has been documented by roentgen stereophotogrammetric analysis for primary hip replacement with rough finished stems (Mjöberg et al. 1990).

With respect to the formation of the gaps at the interfaces, some of the gaps might be caused by the pores created when mixing the cement or by the insertion of the stem (Wixson et al. 1987, James et al. 1993, Wang et al. 1993, Brumby et al. 1997). However, our study indicates that most of

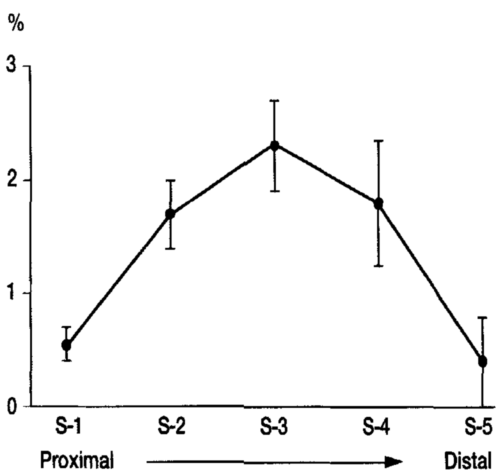

Figure 6. The percentage of the circumference occupied by gaps in the interface between the cement and the stem from proximal to distal sections of the femur in all 10 samples (mean ± SE).

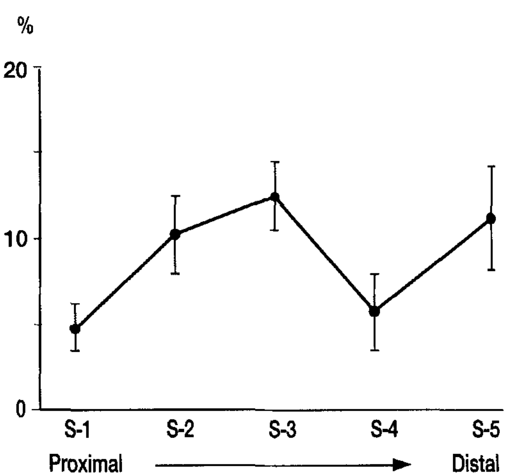

Figure 7. The percentage of the circumference occupied by gaps in the interface between the bone and the cement from proximal to distal sections of the femur in all 10 samples (mean ± SE).

the gaps are caused not by pores but rather by linear shrinkage of the cement around a stem. Bishop et al. (1996) suggested that when a stem at room temperature is implanted into bone, the polymerization of bone cement will progress from the bone towards the stem. This might induce shrinkage and pore formation in the cement mantle at the cement-stem interface. There was no significant gap in the most proximal section of the stem-femora construct. This may be related to a greater surface area of the cement exposed to air at this level, with subsequent cement shrinkage away from the femoral orifice. Most of the gaps were usually seen in the sections surrounding the middle part of the stem or on the side where the cement layer was thickest. Therefore, an even and thinner cement mantle may improve the interface integrity.

Vacuum mixing of bone cement has been shown to reduce porosity and increase the mechanical strength (Lidgren et al. 1984, Wixson et al. 1987, Wang et al. 1993). How much porosity reduction, by centrifugation or vacuum mixing, will influence the shrinkage of bone cement has been debated for a long time (Rimnac et al. 1986, Connelly et al. 1987, Jay et al. 1987, Hamilton et al. 1988, Davies and Harris 1995). In this study, the reduction of pores by vacuum mixing did not lead to a significant change at the interface integrity, i.e., the contact interface area was the same with the different mixing techniques. The data were in agreement with the finding of a previous study by Davies and Harris (1995).

Our animal model has certain limitations. One is the absence of influence of the normal hydrostatic pressure from bleeding during insertion of bone cement. If this model was applied in live animals, with a normal hydrostatic pressure from the body fluids against the cement, one might expect larger gaps between cement and bone (Becker et al. 1998) with less influence at the cement-stem interface. Another limitation is the shape of the pig femur which is short, wide proximally and curved. This produces a thicker cement layer in the proximal end and thinner in the distal end compared to human femora.

In conclusion, cemented implants in the animal model showed that small gaps are present at the interfaces directly after implantation, i.e., acrylic cement does not provide a complete contact at the interfaces. Such gaps may contribute to early stem debonding. The interface integrity did not differ between the vacuum-mixed samples, compared to those mixed at atmospheric pressure.

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