Quantification of stem-cement interfacial gaps

IN VITRO CT ANALYSIS OF CHARNLEY-KERBOUL AND LUBINUS SPII FEMORAL HIP IMPLANTS

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Interfacial defects between the cement mantle and a hip implant may arise from constrained shrinkage of the cement or from air introduced during insertion of the stem. Shrinkage-induced interfacial porosity consists of small pores randomly located around the stem, whereas introduced interfacial gaps are large, individual and less uniformly distributed areas of stem-cement separation. Using a validated CT-based technique, we investigated the extent, morphology and distribution of interfacial gaps for two types of stem, the Charnley-Kerboul and the Lubinus SPII, and for two techniques of implantation, line-to-line and undersized.

The interfacial gaps were variable and involved a mean of 6.43% (SD 8.99) of the surface of the stem. Neither the type of implant nor the technique of implantation had a significant effect on the regions of the gaps, which occurred more often over the flat areas of the implant than along the corners of the stems, and were more common proximally than distally for Charnley-Kerboul stems cemented line-to-line. Interfacial defects could have a major effect on the stability and survival of the implant.

Interfacial defects between a femoral hip implant and the cement mantle have been described in retrieval studies of well-functioning stems as well as in vivo experimental models. In general, the defects are small, being < 0.1 mm, 0.1 mm to 0.3 mm, and 0.1 mm to 3.0 mm in size, and cannot be assessed by standard radiological techniques. However, they can be visualised by direct inspection and scanning electron microscopy of either the stem-cement interface after removal of the implant, or in slices though the stem-cement construct.

According to these techniques, interfacial defects account for a variable percentage of the surface of the implant ranging from 0% to 50%, depending amongst other factors, on the location along the stem.

Several mechanisms may explain the formation of these defects. First, air trapped within the pre-polymerised cement powder or introduced during mixing and transfer to the cement cartridge tends to favour the formation of type-I interfacial pores. Another source of interfacial defects is shrinkage of acrylic cement during polymerisation under constrained conditions. These defects consist of small pores described as being < 0.1 mm to 1.0 mm in size, randomly distributed against and around the implant, and may be termed 'shrinkage-induced interfacial pores', or type-I interfacial defects. Interfacial porosity may be influenced by the formulation of the cement, but, more importantly, by the direction in which cement polymerisation proceeds. If the stem is cooler than the bone, polymerisation will begin at the cement-bone interface and cement will be anchored to the peripheral bone as the mantle hardens. Because the polymerisation process causes the mass of cement to shrink, the mantle will pull away from the cement-stem interface resulting in the formation of type-I interfacial pores. Reversal of the direction of polymerisation by pre-heating the stem or pre-cooling the femur reduces interfacial porosity.
because polymerisation and shrinkage of the cement close to the implant occurs before polymerisation of the outer layer of cement.

Interfacial defects may also arise from air dragged by the surface of the stem as it passes from outside the femur into the pool of liquid cement.\textsuperscript{2,3,8} This phenomenon is more common with rougher stems\textsuperscript{2,3,8} and is a function of the stem taper, the cement viscosity,\textsuperscript{10} the insertion rate of the stem into the cement,\textsuperscript{10} the insertion angle of the stem and the volume of cement displaced. Interfacial defects caused by such rheological phenomena may either be small, ranging from 0.1 mm to 0.3 mm for individual air bubbles,\textsuperscript{8,10} or very large ‘pancake-shaped’ air pockets squeezed in between the stem and the surrounding cement. Such large stem-cement separations are termed ‘interfacial gaps’, or type-II interfacial defects.

Although stem-cement interfacial defects have been studied in different experimental settings, few investigations have quantified such defects under conditions simulating the clinical setting. In practice, the shape of the implant (straight or anatomical) and the surgical technique (line-to-line or undersized implantation) may influence the location and extent of the interfacial defects since both affect the flow of cement during insertion of the stem, the thickness of the cement mantle and the distribution of cement along the stem. We used a CT-based \textit{in vitro} technique to evaluate the extent of interfacial gaps and to map their three-dimensional location. We compared the results obtained after line-to-line and undersized implantation of straight Charnley-Kerboul (CMK; Stratmed Medical, Oberdorf, Switzerland) and anatomical Lubinus SPII (Waldemar Link GmbH, Hamburg, Germany) stems.

Materials and Methods

\textbf{Implants and stem-cementing technique.} A total of 40 polymeric stems were implanted in 20 pairs of embalmed cadaver femora as described previously.\textsuperscript{24,25} There were 22 femora with replicas of the Charnley-Kerboul design and 18 with replicas of the Lubinus SPII design.

The Charnley-Kerboul stem is a straight canal-filling implant with a rectangular cross-section, a small medial collar and a polished surface finish with a roughness of 0.03 µm.\textsuperscript{26} The stem is widely used in France and Belgium and is routinely implanted line-to-line with the largest broach, which inevitably causes large regions of thin or deficient cement.\textsuperscript{24} However, and despite what would be considered a suboptimal cement mantle, the implant is successful in the long term. This apparent contradiction has recently been termed the ‘French paradox’.\textsuperscript{27}

The Lubinus SPII stem is an anatomical stem with a characteristic ‘S-shape’ in the lateral view, a large collar and a satin-to-matt surface finish with a surface roughness of 0.39 µm to 1.4 µm.\textsuperscript{26,28,29} The stem is widely used throughout Europe,\textsuperscript{30} especially in Germany and Scandinavia with satisfactory long-term results.\textsuperscript{31,32} Currently, the manufacturer recommends both the line-to-line and the undersized implantation techniques, but it remains unclear which method is preferred by most surgeons, and which is superior in the long term.

An experienced hip surgeon (TS) and a theatre nurse implanted all the stems according to a standardised third-generation cementing protocol.\textsuperscript{24,25} After radiological templating, the femoral neck was sectioned so that the implant would restore the centre of hip rotation. All femora were at a room temperature of 18˚C and were reamed and broached to accept the largest possible size according to the manufacturers’ recommendations. An 80 g mix of Palamed (Biomet, Warsaw, Indiana) bone cement was prepared under vacuum (30 seconds, 0.1 bar) at 18˚C with a mixing/pressurising system (Optivac; ScandiMed, Biomet). Three minutes after starting the mixing, the cement was injected into the femoral canal which had been plugged distally and cleansed by pressure lavage with 2 litres of water at 37˚C. The cement was pressurised with a proximal femoral seal for one minute, and, at four minutes, a replica stem was inserted manually. Pressure was maintained during the insertion of the stem, and until the cement was completely cured. On one side of the paired femora, the stem was cemented using the line-to-line technique, without a distal centraliser. On the other side, the stem was undersized by one size and implanted with a distal centraliser.

\textbf{CT-based evaluation.} All femora underwent CT scanning from the medial border of the resected neck to the distal tip of the prosthesis, using a Somatom Sensation 16 scanner (Siemens AG, Erlanger, Germany). Each set of adjacent CT slices were generated using the following scan parameters: beam collimation 6 mm × 0.75 mm, mean field of view 92.42 mm (SD 8.43), tube current for Kerboul stems 160 mAs and for Lubinus stems 200 mAs, and tube potential for Kerboul stems 120 kVp and for Lubinus stems 140 kVp. The CT scans were reconstructed based on the ‘U80 high-contrast bone filter’, with a reconstructed slice thickness of 1 mm, 0.5 mm increment, and 0.18 mm (SD 0.016) pixel spacing in the slice plane. The limiting special resolution of the scan protocol was measured by visual assessment of a bar pattern with air-filled cavities in a standard CT image quality phantom (model 76-410; Fluke Biomedical, Everett, Washington). The minimal resolvable diameter was 0.75 mm, which corresponds to a cut-off frequency of 6.7 line-pairs per cm. The CT scan resolution was also assessed with small air cylinders in a Plexiglas phantom (CDRAD model 07-652; Fluke Biomedical). The smallest air cylinders which could be identified had a diameter of 0.5 mm.

In some CT scans, dark lines were present between the stem and the cement. We confirmed that these lines showed the same pattern and distribution as interfacial gaps by examining several polished cross-sections stained with methylene blue (Fig. 1).

The contours of the outer and inner cortex of the bone, the cement mantle and the stem were defined using cus-
tom-made and validated segmentation software\textsuperscript{33} developed in Matlab 6.5 (MathWorks Inc., Natick, Massachusetts). The software allowed marking of interfacial gaps on the contours of the stem after segmentation (Fig. 1). Based on the contours of adjacent images, we calculated the area of the stem in direct contact with the cement and the area of the interfacial gaps. Areas were calculated by multiplying the length of the contour by the slice interval and integrating these values over adjacent CT slices. Within each image, the surface of the implant was divided into 72 segments of 5˚ around the centroid of the prosthesis with the medial part of the stem defined as the reference direction. Within each 5˚ segment, the surface of the implant was either in direct contact with the cement or with an interfacial gap or a combination of both. In total, over 700 000 segments were evaluated. Based on the contours averaged in 5˚ segments around the centroid, the thickness of the cement mantle was calculated in regions with and without interfacial gaps, as described previously.\textsuperscript{24,25,33}

\textbf{Statistical analysis.} The measurements are presented as the mean, SD and range as appropriate. The dimensional parameters were compared using a paired t-test when derived from paired femora and by an unpaired t-test when derived from unpaired femora. For unpaired variables, homogeneity of variance was assessed by an F-test and t-ratios were adjusted when needed. A repeated measures analysis of variance (ANOVA) was used to assess the distribution of the gaps within specimens. A general linear model was constructed to analyse the relationship between the gap areas and stem-broach sizing (line-to-line vs undersizing; within-subjects factors) as well as the type of stem (Charnley-Kerboul vs Lubinus SPII; between-subjects factors). Frequencies were compared using a chi-squared test. Statistical analysis was performed using Excel 2000 (Microsoft, Redmond, Washington) and SPSS 13.0 software (SPSS Inc., Chicago, Illinois). A p-value ≤ 0.05 was considered to be statistically significant.

\textbf{Results} We implanted 22 Charnley-Kerboul (11 line-to-line and 11 undersized) and 18 Lubinus SPII (nine line-to-line and nine undersized) stem replicas in 20 paired femora. The mean radius of undersized Charnley-Kerboul stems (6.13 mm (SD 0.54)), measured in the plane of the CT scans, was 0.89 mm (SD 0.13) smaller than the mean radius of stems cemented line-to-line (7.01 mm (SD 0.49)). For Lubinus SPII stems the mean radius of undersized implants was 5.45 mm (SD 0.30) and the mean radius of line-to-line implants was 6.00 mm (SD 0.22). The mean radial difference between both types of Lubinus SPII stems was 0.55 mm (SD 0.11). CT scanning of the 40 specimens resulted in 10 308 images (5330 Charnley-Kerboul and 4978 Lubinus SPII) which were individually segmented, marked for interfacial gaps and analysed. Other morphological data concerning the bone-cement-stem complex of both series have recently been published.\textsuperscript{24,25}

\textbf{Area and location of the interfacial gaps.} Overall, a mean of 6.43% (SD 8.99) of the surface of the stems was separated from the mantle by an interfacial gap. The extent of the formation of gaps was highly variable from one specimen to the other (SD 8.99; 0.15% to 31.69%). Using a general linear model, no statistically significant relationship was found between the extent of the interfacial gaps and the type of stem (Charnley-Kerboul 7.92% (SD 10.69); Lubinus SPII 4.61% (SD 6.14); p = 0.246) or the stem-broach sizing (line-to-line 7.73% (SD 10.25); undersized 5.13% (SD 7.57); p = 0.416). To analyse the incidence of interfacial gaps along the longitudinal axis of the implant, we divided the stem into six regions. For Charnley-Kerboul stems cemented line-to-line, the incidence of interfacial gaps increased from the distal to the proximal region (repeated measures ANOVA, p < 0.001). For the other groups the distribution pattern was less clear (Fig. 2).

In order to investigate the relationship between interfacial gaps and the morphology of the stem we defined four ‘corner’ and four ‘flat’ regions in each cross-section of a
Overall, the incidence of 5° segments containing interfacial gaps was higher in flat regions at 6.02% compared with corner regions at 4.36% (chi-squared test, p < 0.001). This was also true when all types of stem and all implantation techniques were considered separately (chi-squared test, p < 0.001 in all cases; Fig. 3b).

Within each CT scan, segments were grouped into four regions (anterior, medial, posterior, and lateral quarters; Fig. 4a). Overall, the incidence of 5° segments containing interfacial gaps was highest in the anterior quarter of the stems at 7.61%, compared with the medial at 4.99%, the posterior at 4.43% and the lateral quarters at 4.46% (chi-squared test, p < 0.001). However, when analysed for each type of stem and implantation technique separately, a predominance of gaps in the anterior aspect of the stem was only found for the Charnley-Kerboul stems inserted line-to-line (Fig. 4b).

Cement thickness in regions with and without interfacial gaps. Considering all specimens, no significant difference in the mean thickness of the cement mantle was found between 5° segments with interfacial gaps (3.45 mm (SD 0.58)) and areas where direct contact of cement was present (3.50 mm (SD 1.32); paired t-test, p = 0.798). In addition, when comparing the thickness in segments with and without gaps for the different subgroups (Charnley-Kerboul, Lubinus SPII, undersized, line-to-line), no significant differences were found (paired t-test, p > 0.8).

**Discussion**

Our study describes the incidence, distribution and localisation of interfacial gaps between the stem and cement. Neither the type of stem (Charnley-Kerboul or Lubinus SPII), nor the technique of implantation (line-to-line or undersized) had a significant effect on the incidence of such gaps. However, in all situations, interfacial gaps were more numerous in flat regions of the stem compared with corners.

We believe that the shape, distribution and extent of the voids described correspond to small pockets of air and/or fluid trapped on the surface of the stem during insertion,
and not coalesced voids generated by the shrinkage of cement during polymerisation (Fig. 5). This interpretation is consistent with a computational fluid dynamics simulation and observations made when inserting prostheses into femora filled with multiple layers of coloured cement. Sectioning of the mantle showed that a thin skin of cement which originated from the most proximal layer had been dragged down and surrounded the stem. Because cement has a high contact angle of between 50˚ and 100˚ on metal and polyethylene, it has difficulty in wetting the surface of the implant especially when it is curing. As such, air or other materials, such as blood, fat and water, could easily be dragged down along the surface and form interfacial gaps, especially when the stem is inserted in the later stages of polymerisation. We consider that the interfacial gaps described in our study are mainly of this nature.

In contrast to interfacial porosity, interfacial gaps with the same morphology and distribution as those which we have described were more extensive when in contact with rougher stems. This supports a rheological origin. However, if this was the case, they might be expected to predominate in the vicinity of Lubinus SPII stems because the S-shape of that stem could produce air-traps during implantation. This was not confirmed in our study.

Interfacial pores caused by shrinkage of cement in a constrained environment (type-I defects) have a random distribution and are not only found at the stem-cement interface but also within the cement around the implant. The gaps which we describe were irregularly distributed and represented large regions of stem-cement separation without voids outside the stem-cement interface (Fig. 5). Furthermore, interfacial pores of 0.1 mm to 0.3 mm in size are at the threshold of the resolution of the CT-technique of 0.5 mm to 0.75 mm and are associated with the corners of the implant, whereas the interfacial gaps which we described were easily identifi-
able and were seen predominantly in flat regions. If interfacial gaps were caused by shrinkage of cement, they would be expected to be more numerous in regions with a thick cement mantle where shrinkage would be more important. However, undersized stems, which resulted in thicker cement mantles, had a tendency to produce fewer interfacial gaps than those inserted line-to-line. Moreover, the thickness of the cement mantle was similar in gap and non-gap regions. As such we contend that type-I interfacial pores are unlikely to have contributed greatly to our results. However, it is possible that shrinkage, monomer evaporation into voids and thermal gap expansion enlarged existing interfacial gaps, but the role of shrinkage in that process may be limited.37

Another potential source of interfacial defects is micromovement of the stem during the curing of the cement. However, compared with stems implanted line-to-line, undersized stems are more likely to displace during cement polymerisation since they are less well stabilised by direct bone contact. As a result, more gaps would be expected along undersized stems, but we found the opposite.

Although a reproducible and validated CT-scan-based technique was used,33 our study still has some limitations. First, polymeric replica stems were used to avoid scatter artifacts during CT. These implants have a different heat capacity and surface finish characteristics from their metal equivalents. In theory, this may affect both type-I and type-II interfacial defects. However, studies have shown that the effect of the material of the implant and the surface finish on interfacial porosity is limited8 and that interfacial gaps, very similar to those which we describe, have been reported using metal implants with various surface finishes.3 Secondly, in our study blood and fat contamination was not simulated. In vivo, such contamination is expected to cause even more interfacial gaps. Thirdly, the temperature of the medullary canal was not measured. However, in a working environmental temperature of 18°C, cleansing the medullary canal with 2 litres of water at 37°C just before insertion of the cement would have elevated the femoral temperature. This simulated an in vivo situation in which a mean temperature of 32.3°C (95% confidence interval 29.6 to 35.0) was recorded after pulsatile lavage with saline at room temperature.18 Finally, although we used a realistic hand-driven technique for stem insertion, there were no soft tissues present to obstruct insertion into the proximal femur as would occur in vivo. It is likely that deviation of the stem in the longitudinal axis of the proximal femur or variation of the angulation between the stem and the shaft during insertion would increase interfacial gaps. However, insertion of a stem by an experienced surgeon is probably more realistic than the ideal machine-driven or jig-controlled introduction used by others.2-4,9

Since up to 30% of the surface of some stems was separated from the cement, the mechanical and clinical consequences of interfacial gaps may be important, but since interfacial defects cannot be quantified or easily visualised in patients,8,12 it is difficult to demonstrate their clinical relevance. However, in vitro mechanical testing and finite-element analysis models using commercially-available stems suggest that interfacial defects could encourage early migration of the stem6 and may explain inferior results obtained with some brands of cement.2 Attempts to improve the stem-cement junction by roughening the stem favours interfacial gap formation3 and has been counterproductive.23,26 However, reduction of interfacial defects without changing the surface of the stem improved the implant-cement shear strength,2,4,6,18 increased debonding energy11 and limited the possibility for the migration of fluid and particles along the stem-cement interface.14 Pre-heating the stem4,14,18,19,22,23 or pre-cooling the bone21 can eliminate interfacial pores (type-I defects) by reversing the normal direction of cement curing. A lower cement viscosity and a slower rate of insertion of the implant could also reduce the formation of interfacial pores10 but this remains controversial.9 However, vacuum cement mixing,7,13 cement centrifugation,9 the temperature of the
cement\textsuperscript{15}, the material of the implant, and the surface finish\textsuperscript{8,11} have no major effect. The amount of air introduced along the stem (type-II defects) could be reduced by using implants with a smoother surface finish,\textsuperscript{3} by inserting the stem through a diaphram\textsuperscript{38,39} or by pre-wetting the implant with monomer\textsuperscript{10} or cement. From our study we conclude that the shape of the implant and the technique of implantation have no major impact on interfacial gaps. Further studies will be needed to evaluate the importance of the timing of insertion of the implant as the viscosity of the cement changes.

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