

Fluid flow around model femoral components of differing surface finishes

In vitro investigations

Ross W Crawford^{1,2}, Mervyn Evans¹, Robin S Ling³ and David W Murray^{1,2}

We studied fluid flow at the stem-cement interface of bonded and debonded, polished and rough model femoral components.

In a first series of experiments, fluid flow along the interface between bone cement and well-fixed model femoral components, differing in surface finish, and in shape, was measured. Fluid migration along the bone-cement interface of rough stems (Ra 3 μm) was greater than that on polished stems ($p < 0.001$). This was true of cylindrical and conical tapered stems. On stems with the same surface finish, shape did not influence fluid migration.

In a second series of experiments, fluid flow along the stem-cement interface of 5 highly polished and 10 rough-finished (5 of Ra $\sim 1.5 \mu\text{m}$ and 5 of Ra ~ 3

μm), debonded, tapered circular stems was measured. None of the rough stems could prevent fluid flow along the stem-cement interface. Polished tapered stems sealed the interface and, after 48 hrs of continuous pressure, no fluid flow was observed. This difference in the ability to seal the stem-cement interface between rough and polished stems was significant ($p < 0.001$).

The difference in fluid migration along the stem-cement interface of rough and polished stems which we observed offers a plausible explanation of the occurrence of osteolysis distal to the articulation of cemented THR in the presence of cement mantle defects. It may also explain why osteolysis is uncommon with polished double-tapered stems.

¹Oxford Orthopaedic Engineering Centre, ²Nuffield Orthopaedic Centre, Windmill Road, Headington, Oxford OX3 7LD, U.K. Tel + 44 1865-22 74 82. Fax -74 23 48, ³Princess Elizabeth Orthopaedic Hospital, Exeter
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The effective joint space includes all periprosthetic regions accessible to joint fluid and thus to particulate debris (Schmalzried et al. 1992) and fluid pressure (Aspenberg and van der Vis 1998). In cemented femoral components, the stem-cement interface must be considered part of the effective joint space, as fluid has been shown to pass along this interface at revision surgery (Anthony et al. 1990) and on autopsy studies of loose femoral component (Roberts et al. 1997, Inadome et al. 1998). Furthermore retrieval studies have shown a membrane at the stem-cement interface in all cases in which it has been sought (Fornasier and Cameron 1976, Anthony et al. 1990). Experimental evidence suggests that due to differences in thermal expansion and contraction of metal and bone cement, when the stem is not modified by sintering or precoating, a gap will appear at the stem-cement interface as soon as the cement has finished polymerisation (Ahmed et al.

1982). This would mean that no stem is truly bonded to its cement mantle and that a space, along which fluid and particles may migrate, is established between the stem and the cement, from the moment of implantation.

Focal osteolysis is commoner around rough-surfaced (Rockborn and Olsson 1993, Mohler et al. 1995, Berry et al. 1998) than highly-polished stems (Fowler et al. 1988, Schulte et al. 1993), even in those that differ in no feature except surface finish (Crawford et al. 1998). These zones of focal osteolysis commonly occur around the mid-stem and tip of the stem, even when the cement mantle proximal to the lesion is intact (Scott et al. 1985, Willert et al. 1990, Ellis et al. 1997). It is possible that the differences in rates of osteolysis are due to differences in the ability for fluid from the joint articulation to migrate along the stem-cement interface to defects in the cement mantle. The fluid may carry polyethylene wear particles

or produce osteolysis, secondary to pressure.

We investigated the influence of surface finish on fluid flow along the stem-cement interface of cemented femoral components in an *in vitro* model.

Material and methods

Experiments were performed to investigate fluid flow between bone cement (polymethylmethacrylate-PMMA) and stainless steel tapered rods of differing surface characteristics. Rods were inserted into PMMA to produce a model stem/cement composite. In a first series of experiments, the composites were soaked in normal saline stained with methylene blue for 6 weeks before being sectioned and the stem-cement interface inspected for evidence of fluid migration.

In a second series of experiments, the composites were debonded at the stem-cement interface, loaded for 48 hours and then fluid under pressure was applied to the upper surface of the stem-cement interface. Fluid flow along the stem-cement interface was measured at the tip of the prosthesis.

Femoral stems

A number of corrosion-resistant stainless steel cylinders and tapers were produced. The tapered components, 70 mm in length, had an upper diameter of 9 mm and a lower of 2.5 mm, with an even taper throughout. The cylindrical components had the same length and a constant diameter of 9 mm throughout. The components were either highly polished or roughened. Surface roughness was produced by shot-blasting. Surface finishes with an Ra of 1.5 μm and 3 μm were modelled, and were selected because they were representative of the surface roughness of commonly inserted cemented femoral components.

Casting jig

To ensure adequate pressurisation of cement and even reproducible cement mantles, a purpose-built rig was designed. The rig consists of a 3-piece brass casing and a 2-piece polytetrafluoroethylene (PTFE) mould. The upper piece of the casting rig has a proximal extension to ensure centralisation of the rods. Distally, a central hole al-

lowed the cylinders to pass through the cement mantle whilst still maintaining pressure on the cement throughout curing. This design feature produced 2 potential entry points for the fluid to enter the stem-cement interface in the soaking experiments and allowed the stems to be controllably debonded and fluid flow to be measured in the second experiments. The dimensions of the rods and the PTFE mould meant that a minimum 5 mm mantle was produced.

Pressurisation of cement was ensured by producing a closed system apart from vent holes which allowed controlled escape of the cement.

Preparation technique

Simplex (Howmedica, Rutherford, N.J.) cement was used for all cases. The preparation of the polymethylmethacrylate PMMA was performed with the same technique as that used for cementing femoral components during total hip replacement. While still in a low viscous state, at approximately 1 minute, the cement was poured into the PTFE mould. The mould was contained by the casting jig. The lid of the casting jig was then fitted and the stem was introduced. Pressurisation of cement was maintained until it hardened. The presence of the proximal extension ensured that the stem was centred and prevented micro-motion.

5 smooth and 5 roughened stem-cement composites of both cylinders and tapers were soaked in saline stained with methylene blue for 6 weeks at room temperature. After 6 weeks, the cement mantles were sectioned and the stems and cement mantles inspected. The distance to which dye had penetrated the interfaces was recorded.

To investigate the contribution of capillary flow to fluid movement, 1 rough stem-cement composite was inverted and placed so that the saline stained with methylene blue reached only to the junction of the stem and cement. Any fluid which passed along the interface was travelling against gravity by capillary flow.

In the second study, stems were debonded from the cement mantle in an Instron 1,122 material-testing machine. Debonding was produced by inverting the specimens and gradually increasing a retrograde load on the stem tips, which protruded below the cement mantle. Load was applied at

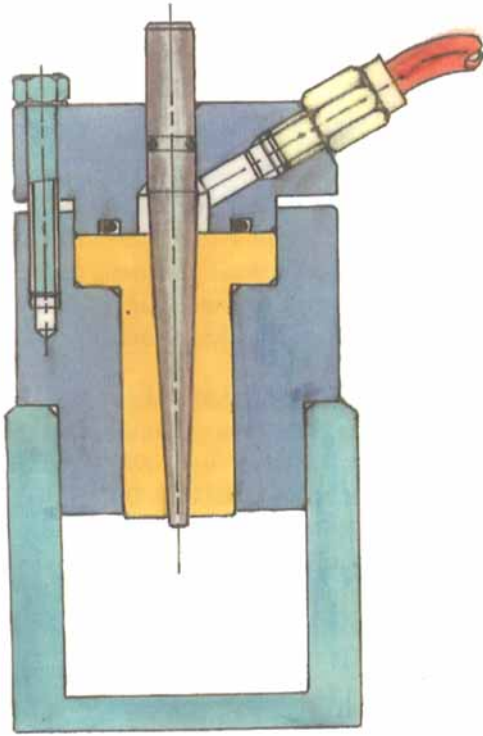


Figure 1. Line drawing showing stem-cement construct in pressure system. Stem is shown centred within cement (represented in yellow), which is contained within the pressure chamber. Fluid under pressure is delivered to the upper stem-cement interface. Any fluid which passes along the stem-cement interface is collected in the chamber below the stem tip.

0.05 mm/min (the lowest possible rate). Following debonding, the stems were returned to their cement mantle and loaded in an antegrade fashion in the Instron machine at 500 N for 48 hours. The load was removed before the stem-cement interface was subjected to fluid under pressure.

Pressure chamber and cycling rig

In order to apply pressure to the fluid at the upper interface of the stem/cement composites, a pressure chamber was constructed. The pressure chamber was connected to an external air source, which was controlled by a pressure valve. This allowed the fluid around the composite to be delivered at controlled pressures.

The pressure chamber was designed to prevent fluid flow from the delivery point (the upper surface) to the collecting chamber, except along the stem/cement interfaces. All other interfaces were

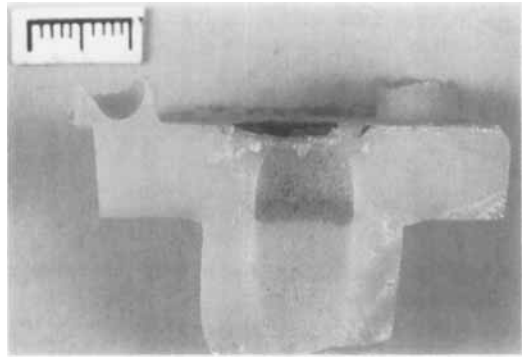


Figure 2. Photograph of fluid and dye penetration at the stem-cement interface of a rough cylinder showing staining of interface (scale in cm).

sealed with O-rings. Fluid was collected in the base of the pressure chamber and measured, to determine flow rates along the stem cement interface (Figure 1).

Fluid was applied at 150 mmHg to the upper surface of the cement and thus to the stem-cement interface. If no flow was observed within the first hour, pressure was applied for a total of 48 hrs and any flow occurring was measured. If fluid flowed along the stem-cement interface in the first hour, it was collected and measured.

The series of debonded experiments was repeated 5 times for each of the 3 different stem types.

Statistical comparison of mean migration distance of fluid and flow rates was made using the Student's t-test. Comparison of the absolute ability to seal the stem-cement interface between debonded stems was made, using Fisher's exact test. For comparison of flow rates of the 3 different stem type, the fact that a statistical difference was present was established by using ANOVA. The difference in the means was then studied, using a 2-tailed Student's t-test.

Results

Bonded stems

Rough versus smooth cylindrical stems. In all cases, methylene blue penetrated the implant/stem interface of the matt composites at the proximal and distal ends (Figure 2). The mean and range of the penetration are presented in Table 1. In 3 specimens, the cement was sectioned to examine it for

Table 1. Fluid penetration (mm) at rough and smooth interfaces with a cylindrical stem

Interfaces	Mean	Range	SD
Rough (n 10)	8.4	5-14	2.9
Polished (n 10)	0.8	0-3	1.1

Table 2. Fluid penetration (mm) at rough and smooth interfaces with a tapered stem

Interfaces	Mean	Range	SD
Rough (n 10)	8.2	4-14	3.2
Polished (n 10)	0.9	0-2	0.87

Table 3. Fluid flow (mm/hr) at the stem-cement interface

Stem	Mean flow	Range	SD
Polished (n 5)	0	0	0
Rough 1.5 μm (n 5)	1.1	0.8-1.4	0.23
Rough 3 μm (n 5)	7.5	4-11	2.7

evidence of fluid or dye penetration. In no case was there any macroscopic evidence of fluid penetration through the cement, which excluded this as a path of fluid migration. Of the polished stems, 6 interfaces showed a tide mark at the border of the cement, where it was in contact with the fluid. There was no macroscopic evidence of dye or fluid penetration along the stem/cement interface at any of these 6 interfaces. The difference in fluid penetration along the stem-cement interface of smooth and rough cylindrical stems was highly significant ($p < 0.001$).

Rough v smooth-tapered stems. The pattern of fluid migration observed with tapered stems was similar to that in cylindrical stems and is presented in Table 2. The difference in fluid penetration along the stem-cement interface of smooth- and rough-tapered stems was highly statistically significant ($p < 0.001$).

Stem shape. There was no significant difference between the fluid penetration along the stem-cement interface of well-cemented cylindrical and tapered stems when the influence of surface finish was excluded. This was true of both rough ($p = 0.9$) and smooth stems ($p = 0.8$).

Capillary flow. In the inverted specimen, fluid had moved 6 mm up the stem-cement interface after 6 weeks.

Debonded stems

All 5 polished tapered stems effectively sealed the stem-cement interface and after 48 hrs of continuous pressure no fluid flow was observed. In each of the 10 rough stems, fluid flow along the stem-cement interface was observed when pressure was applied. Mean flow rates and standard deviation are presented in Table 3.

This difference in the ability to seal the stem-cement interface (fluid flow versus none) between rough and polished stems was highly significant (Fisher's exact test $p < 0.0001$). Differences in mean flows between polished and both 1.5 μm - and 3 μm -surface finishes were observed ($p < 0.001$ and $p < 0.001$, respectively) and also between the rough stems with different surface finishes ($p < 0.001$).

Discussion

Fluid penetration along an interface in which there had been controlled pressurisation of the cement, in which motion of the stem was minimised and in which there was no blood or fluid contamination, was an unexpected finding. The fact that the fluid penetrated only the interface of the rough-surfaced composites suggests a fundamental difference in the ability of the different interfaces to move fluid.

The failure of fluid to move along the polished interface may mean either that there is no space at this interface or that the surface somehow prevents fluid movement. A study of the bonding forces between stems with different surface finishes and PMMA found an unexplained increase in the bonding force as the stem became smoother (Bundy and Penn 1987). The increased bonding force between increasingly smooth surfaces and the PMMA was ascribed to an atomic (or chemical) interaction. The situation is analogous to "the adhesion between two highly polished optical flat disks placed in contact due to the closer proximity of the surfaces. An increased electrostatic interaction between the metal and bone cement due to

van der Waals forces could be involved.” (Bundy and Penn 1987).

The reason why fluid moved along the stem-cement interface of the roughened components is not certain. Fluids move and flow differently at microscopic levels compared to macroscopic levels (Knight 1998). In this series of experiments, no pressure was exerted on the fluid to promote flow. Capillary flow is a possible mechanism by which fluid moved along the rough interface and that this to some extent may be the mechanism is demonstrated by the movement of fluid against gravity in the inverted specimen.

The fact that fluid moved along the stem-cement interface of the roughened components implies the presence of a space at this interface. There are a number of reasons why a space could be found at the stem-cement interface of the roughened components. Even under controlled experimental conditions, cement is a poor adhesive (Mann et al. 1991), since the fixation at the stem-cement interface of roughened stems is due to interdigitation of the cement into the asperities of the femoral component. If perfect interdigitation does not occur then a space could exist between the troughs and asperities. A second possibility is that the space appears due to differences in thermal expansion and contraction of metal and bone cement. These differences have been shown, on finite element modelling, to lead to a gap at the stem-cement interface as soon as the cement has finished polymerisation (Ahmed et al. 1982). In vivo, loss of pressurisation of cement during curing, movement of the stem as it is held by the surgeon and the presence of blood at the interface could all contribute to the enlargement of this space. Hydration of the cement mantle which occurs over the first month when it is soaked in saline may also lead to the formation or enlargement of a space at the stem-cement interface.

The cementing technique in this study, and thus the quality of the stem-cement interface, was better than could realistically be expected in an operating theatre. High pressures were placed on the cement following implant insertion, the stem was held rigidly by the casting jig during cement curing, and no biological material contaminated the cement or the stem-cement interface. This study thus represents ideal conditions and shows that

even in these circumstances, after 6 weeks, fluid has penetrated 10–15% of the stem-cement interface of rough surfaced components.

Finite element modelling is widely used to predict the behaviour of cemented total hip replacements (Harrigan et al. 1992, Mann et al. 1997, Verdonshot and Huiskes 1997). Such models are considered less predictive of the true behaviour in vivo of these hip replacements than bench-top experiments (Verdonshot and Huiskes 1996), such as the one performed here. As we have demonstrated the ability of fluid to reach the stem-cement interface of roughened femoral components, theoretical studies which consider bonding strength and behaviour at the stem-cement interface should allow for the presence of fluid and perhaps a membrane, even under ideal cementing conditions.

Increasing evidence from published literature suggests that attempts to establish a perfect bond at the stem-cement interface by increasing the surface roughness of the femoral component are detrimental to implant survival (Dall et al. 1993, Mohler et al. 1995, Sporer et al. 1998) and lead to increased rates of periprosthetic femoral osteolysis (Crawford et al. 1998). This is believed to be due to increased stresses at the bone-cement interface in implants which have an enhanced bond at the stem-cement interface (Mann et al. 1991) and to the increased production of wear particles generated by debonded roughened components (Hale et al. 1990). This study shows a further fundamental difference between rough and smooth implants, related to the ability of fluid to migrate along the stem-cement interface. This may have an influence on component loosening and, in particular, on the formation of focal osteolysis. We believe that this is the first model to consider the influence of stem-surface finish on the ability of fluid to migrate along the stem-cement interface.

Polished tapered stems which were reintroduced to their cement mantle and loaded for 48 hrs were able to seal completely the stem-cement interface against fluid, indicating that the surface attraction between the stem and the cement was re-established following debonding. It is probable that, as a polished tapered stem subsides in the cement mantle, it will conform more closely to the

mantle, putting the cement under compression (Miles et al. 1990). The creep properties of the PMMA allow it to accommodate small amounts of stem migration (Norman et al. 1995, Hughes et al. 1997) and may also contribute to the effective sealing of the stem-cement interface.

The fact that no fluid flowed along the stem-cement interface of smooth stems, although they were unloaded for 48 hours, suggests that the stems behave as true tapers—that is, they do not back out of the cement mantle once unloaded. This behaviour is consistent with that predicted for polished femoral components by finite element analysis (Verdonschot and Huiskes 1995). The low incidence of osteolysis around polished tapered stems suggests that this observation is comparable to what occurs in vivo.

As distinct from the behaviour of polished stems, loaded rough-surfaced stems which debond from the cement mantle damage the cement which becomes entrapped between the taper and the cement, providing a potential pathway for fluid migration along the interface (Hale et al. 1990). Debonded rough stems become polished, producing metal and acrylic debris with damage to the cement mantle, further opening the stem-cement interface to fluid and particle flow (Hale et al. 1990, Mohler et al. 1995). Debonding at the stem-cement interface, of rough-surfaced stems under physiological loads, has been predicted on finite element analysis (Crowinshield et al. 1980) and confirmed on cadaveric (Jasty et al. 1991) and ultrasound (Davies and Tse 1992) studies and recently by RSA, providing evidence that migration at this interface is probably universal (Alfaro et al. 1999). Thus all rough stems, even if asymptomatic, are probably at least partially debonded at the stem-cement interface and thus associated with potential channels for fluid flow along this interface.

We elected to deliver pressure at 150 mmHg to the stem-cement interface as pressures of 160 mmHg have been measured in the pseudocapsule of loose total hip replacements during hip rotation (Robertsson et al. 1997). Others have measured pressures of 700 mm Hg in the pseudojoint (Hendrix et al. 1983), while pressures transmitted from the hip joint along the stem-cement interface can reach almost 200 mm of Hg at zones of focal os-

teolysis (Anthony et al. 1990).

Experimentally, pressures of between 50 and 150 mmHg have recently been shown to produce osteonecrosis, even in the absence of wear particles (Aspenberg and van der Vis 1998). Our model has shown low flow rates at low pressures, with stems that had not been cycled or subjected to rotational moments. However, even low flow rates can lead to high pressures in confined systems and thus pressures that may produce osteonecrosis at sites of defects in the cement mantle are consistent with this model. As the stem-cement interfaces of debonded, rough stems accumulate debris and the stem and the cement become further damaged, the interface would be expected to enlarge and even larger volumes of fluid may be transported along this interface. Micromovement of loose stems, particularly under rotational loads, may also act to force any fluid at the stem-cement interface into defects in the cement mantle under high pressure.

We have shown a difference in fluid migration along the stem-cement interface of model cemented femoral components, depending on their surface finish. This may explain how focal osteolysis may develop around even seemingly well fixed components (Jasty et al. 1986) and gives a rational explanation of focal osteolysis around the middle and distal parts of cemented femoral components. Furthermore, it does not contradict published theories on the possible causes of focal endosteal femoral osteolysis.

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