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Factors affecting the static shear strength of the prosthetic stem–bone cement interface

JIAN-SHENG WANG[1]*, MARK TAYLOR[1,2], GUNNAR FLIVIK[1], LARS LIDGREN[1]
[1]Biomaterials and Biomechanical Laboratory, Department of Orthopaedics, Lund University, Lund, Sweden
[2]Bioengineering Sciences Research Group, School of Engineering Sciences, University of Southampton, Highfield, Southampton, SO17 1BJ, UK
E-mail: jian-sheng.wang@ort.lu.se

Debonding of the stem–cement interface has been implicated in the initiation of failure of cemented femoral stems. The objective of this work was to examine some of the parameters which influence the interface static shear strength, including surface finish, cement type, pre-treatments and porosity. Surface finish was found to have the greatest effect on the interface strength. Increasing the surface roughness by a factor of 100 increases the interface shear strength by a factor of 20. However, increasing the surface roughness above a certain value was found to have no additional affect. This was due to failure in the cement itself rather than at the cement–stem interface. There were significant differences between some of the different cement types regarding the interface strength. Pre-heating the stem produced a six fold reduction in cement porosity at the stem–cement interface, however, resulting in only a minor influence on the static interface strength. Generally, no significant correlation was found between the cement porosity and the static interfacial shear strength.

Introduction

Studies have suggested that the failure of cemented hip stems is initiated by debonding of the stem–cement interface [1–5]. Debonding may occur as a result of excessive shear or tensile stresses at the interface or a combination of the two. Recent finite element studies have reported that the shear stresses at the stem–cement interface are approximately twice the tensile stresses [5–7]. In a finite element simulation of the debonding process, Verdonschot and Huiskes [5] noted that debonding was dominated by the shear failure of the interface, with tensile debonding only occurring late in the simulation. On the basis of this evidence, it would appear shear failure is one of the main drivers of the debonding process at the stem–cement interface. Improving the shear strength of this interface may delay the onset of the debonding process, with potential benefits to improving the longevity of total hip joint replacement. To date there has been considerable work examining the interfacial shear strength. There are a number of factors which may effect the strength of the stem–cement interface, including the cementation technique, pre-heating the stem, pre-chilling the cement, the type of cement used and the stem's surface roughness. Various experimental techniques have been used to assess the stem–cement interfacial shear strength. The most commonly used method is the push out test [8–11]. The majority of these studies have used a simplified experimental set-up, typically with a metallic rod to represent the stem, inserted into a layer of bone cement which in turn is surrounded by a cylindrical holder constructed from a stiff material. Push out tests of the stem–cement interface have also been performed on sections of implanted bones [9].

Crowninshield *et al.* [10] examined the influence of surface roughness on the static shear strength. They tested specimens with surface finishes ranging from 0.1 to 6.3 μm and reported push-out forces ranging from approximately 200–10 000 N. Barb *et al.* [9] used an animal model to examine the influence of pre-coating the stem with a thin layer of PMMA. Testing of transverse section of the bone revealed that pre-coating significantly increased the ultimate shear strength by up to 250% as compared to uncoated stems at all the time points examined.

Other methods have been used to examine the metal–cement interfacial shear strength. Bundy and Penn [12] and Davies *et al.* [13] used similar geometry to that of a push-out test, but used a torsional load rather than an axial load. Torsional loading is thought to generate a more uniform stress distribution at the interface. Bundy and Penn [12] performed a comprehensive study examining the influence of surface finish, substrate material, passivation, surface cleaning techniques and

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*Author to whom all correspondence should be addressed: Biomaterials Laboratory, Department of Orthopaedics, C12 BMC, Lund University, S-221 84 Lund, Sweden.

sterilization methods. They concluded that the surface finish had the greatest influence on the stem–cement interface strength, with the other factors contributing little to the interface strength. Davies *et al.* [14] examined the fatigue properties of pre-coated and non-coated stems. They found that the pre-coated stem significantly enhances the fatigue performance of the stem–cement interface. Another method that has been used is the shear coupon used by Chen *et al.* [15]. They examined the static (and fatigue) shear strength of a grit blasted (Ra = 8.6 μm) and plasma sprayed (Ra = 16.5 μm) cobalt–chrome coupon. They reported static shear strengths of 13.7 and 18.4 MPa for the grit blasted and plasma sprayed coating, respectively.

Although various parameters influencing the interfacial shear strength have been examined previously, often in isolation, due to limitations in the test methods and variations in the testing procedures direct comparison of the results is difficult. Porosity, both within the cement mantle itself and at the stem–cement interface, has been implicated in the failure of the stem–cement interface and within the bulk material of the cement itself [2, 4]. Various studies have examined the influence of various parameters on interface porosity [13, 16, 17], but none have attempted to correlated their findings with the static interfacial shear strength. There are many bone cements used clinically, but there are no reports regarding possible differences in stem–cement interface shear strength. Therefore, the aim of this study was to examine major factors that may influence the stem–cement interface porosity and the static shear strength of the stem cement interface and to relate the reported strength values to the stresses likely to be encountered *in vivo*.

Materials and methods

The experiments were divided into three studies to examine the influence of: stem surface finish; cement type and preheating of the stem. The same basic method was used in all of the experiments. Parallel sided stainless steel stems (rods) of different roughness, 10 mm in diameter and 37 mm long, were fabricated. The stems were cemented into an aluminum cylindrical holder using a custom made alignment jig which ensured accurate axial alignment of the stem within the cement mantle (Fig. 1). The aluminum holder had an internal diameter of 16 mm, giving a nominal cement mantle thickness of 3 mm and an internal depth of 20 mm. The base of the holder had an 11 mm diameter hole, to allow the stem to be pushed out in subsequent testing. During delivery of the cement and insertion of the stem this hole was capped with a silicone stopper. The cements were mixed according to the manufacturer's instructions. Unless otherwise stated, Palacos cement was used through out the study. This cement was mixed in an Optivac® (Scandimed, A Biomet Merck Company, Sjöbo, Sweden) under vacuum for 30 sce and injected into the cylinder with a delivery nozzle, distally to proximally, 2 min after mixing began. The stems were then inserted 4 min after mixing began. One mixing with 40 g of cement was sufficient for six stems. After the cement had cured the specimens were stored in a water bath at 37 °C for 72 h prior to testing.

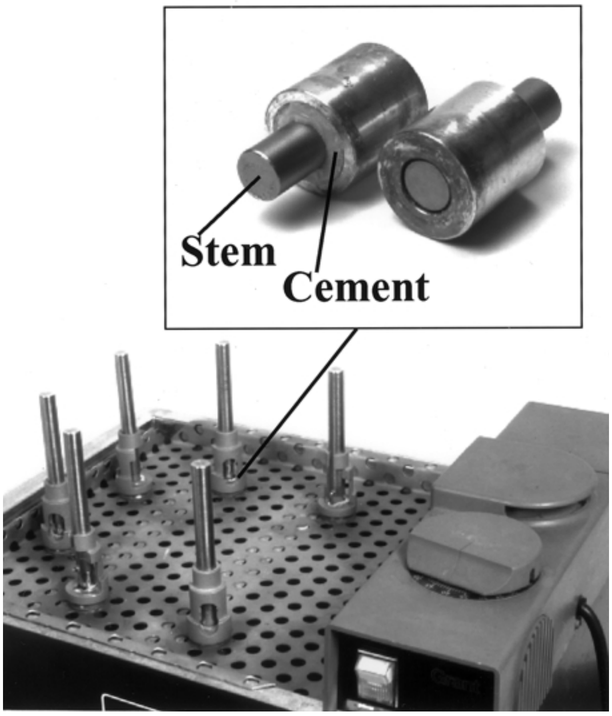


Figure 1 Experiment set-up: A custom made alignment jig in a water bath. Insert shows a cemented metal stem in the cylinder.

Preparation and cementing in different studies

Study 1. Investigating influence of surface roughness

Thirty six stainless steel stems were divided into four groups of nine and subjected to different surface treatments: polished (Ra = 0.03 μm ± 0.005), bead blasted (Ra = 0.64 μm ± 0.06), coarse grit blasted (Ra = 4.65 μm ± 0.74) and plasma sprayed with cobalt–chrome (Ra = 9.53 μm ± 2.84). In order to avoid bias due to different cement batches, the stems were ordered as follows: polished, bead blasted, grit blasted, plasma sprayed, polished, etc. The basic study method described above was used.

Study 2. Investigating influence of cement type

Thirty six stainless steel stems (Ra = 0.88 ± 0.15 μm), all bead blasted, were prepared. The stems were divided into six groups of six and allocated to different bone cement groups: Palacos R, CMW1, 2, 3, Simplex P, and an experimental HA loaded bone cement (20 wt % HA). In order to avoid bias due to different cement mixing batches, one mix of cement was only used for two samples. All the cements were mixed according to the manufacturer's instructions. Palacos R cement was prechilled to 4 °C and mixed under vacuum. The HA loaded cement and Simplex P were kept at room temperature (22 °C) and mixed under vacuum. These three cements were mixed for 30 s using the Optivac® system. The stems in these groups were then inserted

4 min after mixing began. The CMW1, 2 and 3 were mixed in a bowl at atmospheric pressure. They were mixed for 75, 45 and 45 s respectively. After mixing these cements were finger-packed into the mold. The stems were then inserted at 3.5, 2.5 and 3.5 min, respectively. In all other aspects the handling of the different cements were done in the same manner.

Study 3. Investigating influence of pre-heating the stem

Thirty six stainless steel stems were fabricated. Eighteen of the stems were polished (0.05 ± 0.01 μm) and the rest were bead blasted (0.88 ± 0.15 μm). Nine polished and nine bead blasted stems were preheated to 44 °C in an oven, while the rest were kept at room temperature (22 °C). The same basic study method as in study 1 was used.

Push out test

In all the studies, push out tests were performed using an Instron 8511.20 biaxial materials testing machine (Instron Ltd, High Wycombe, UK). The specimens, i.e. the cemented stem in an aluminum holder, were supported on a custom made fixture, which allowed free axial movement of the stem. The stem was displaced at a constant rate, 2 mm/min and the maximum force was recorded.

Porosity examination

After the push-out test, the cement mantles were removed from the aluminum holders and were cut longitudinally into four even sections. The inner surfaces of the specimens were stained using a black oil polish and measured using a direct light microscope which connected to a computerized video digital system (Videoplan TM, Zeiss) at a magnification of 40x. Each measuring area was 15 mm^2. There were four measuring areas in each section. The measurements were done blindly in a random order. The pore area on the surface was measured. The percentage of pore area was calculated by dividing the area of pores on the surface by the total surface area and multiplying by 100. The mean pore size was calculated by dividing the total area of pores by the number of pores on the surface. The mean value for the four sections from each specimen was calculated.

Scanning electron microscope (SEM) examination

Scanning electron micrographs of the interface, of both the cement and stem sides from part of samples, were taken after the push out test using a Philips SEM 515 machine. Micrographs were taken of both the stem and cement surfaces at 170 and 2500 times magnification. Backscatter SEM was used for identification of the PMMA particles on the stem surface. The element of HA on bone cement surface was examined by the SEM and the energy dispersive spectrometry (EDS) on a LINK ISIS X-ray microanalyzer.

Statistically significant differences between the various groups were sought using a one way ANOVA for studies 1 and 2, whereas Student's unpaired *t*-test was used for study 3.

Results

Study 1. Influence of surface roughness

The surface roughness values of the four groups achieved using standard surface finish processing methods varied over two orders of magnitude. The polished, bead and grit blasted surface treatments can produce controlled surface roughness, as can be seen by the low standard deviations (Table I). In comparison, the plasma sprayed surface appears to produce quite a variable surface finish.

The results of the interfacial shear strength tests are summarized in Table I. In general, as the surface roughness increases there is an increase in the interfacial shear strength. There were statistically significant differences $(p < 0.001)$ between all the interface strengths for all of the surface finishes, except between the grit blasted and the plasma sprayed groups and between the polished and bead blasted groups. Although the addition of the plasma sprayed coating produced a significant increase in the roughness of the stems, there was only a marginal increase in the interfacial shear strength as compared with the grit blasted stems.

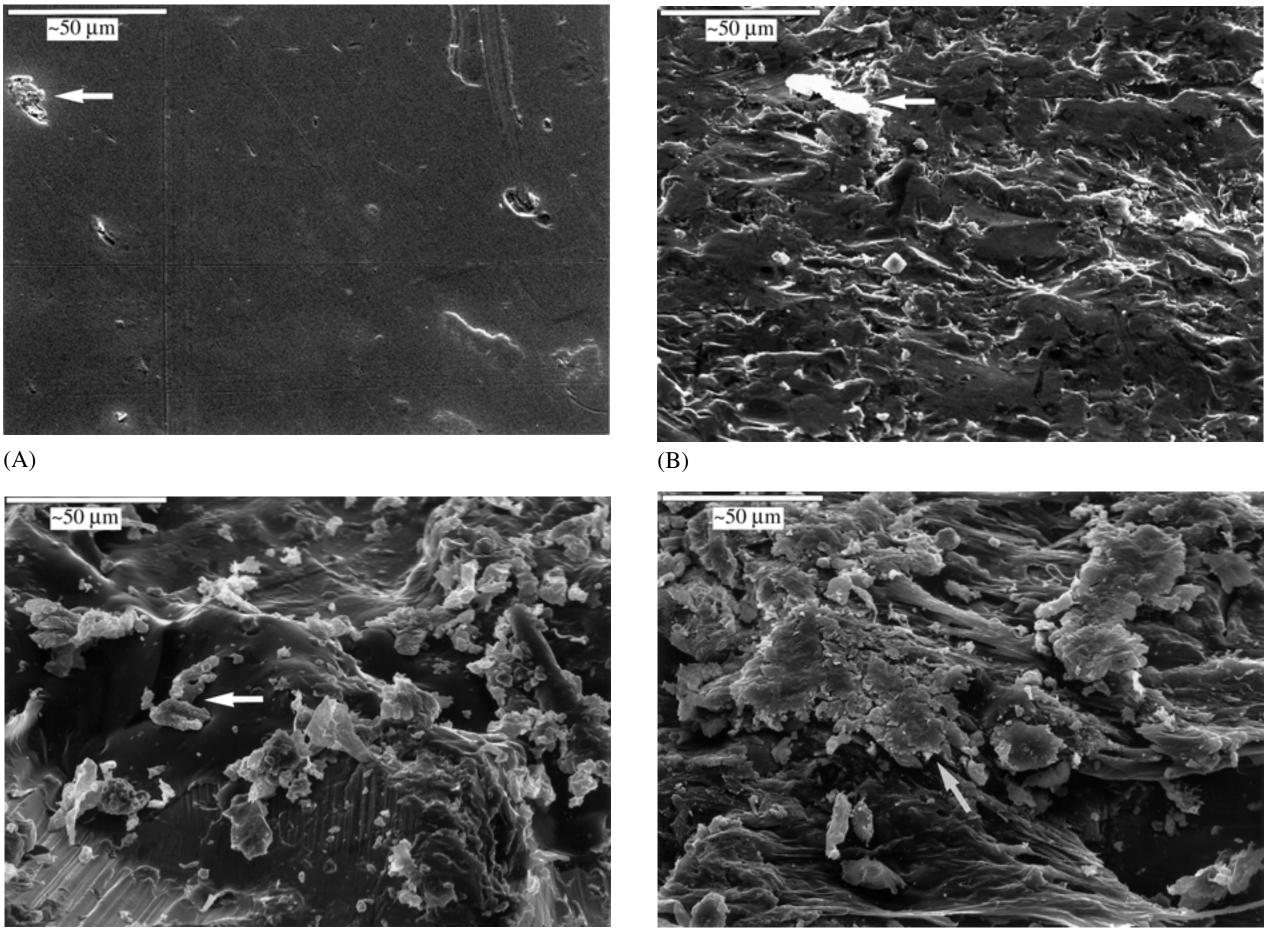
SEM micrographs of the four stem surfaces are shown in Fig. 2. The polished surface showed little or no cement debris. As the stem roughness increased there appeared to be more cement remaining on the stem. It was clearly seen on a visual inspection of the two roughest stem groups, even if this was not quantified.

Porosity measurements could only be performed on the cement adjacent to the polished and bead blasted surfaces because the cement adjacent to the grit blasted and plasma sprayed surfaces was too badly damaged by the push out tests. However, for the first two surfaces which could be examined, porosity appeared to have no effect on the push-out strength.

TABLE I Stem–cement interfacial shear strength (kN) and porosity in different stem roughness (mean ± SD)

Surface texture	Surface roughness (Ra) (μm)	Push out force (kN)	Percentage of pore area (%)	Mean pore size (mm^2)
Polished	0.03 ± 0.005	0.48 ± 0.18	6.74 ± 3.12	0.25 ± 0.10
Bead blasted	0.64 ± 0.06	2.01 ± 0.48	11.9 ± 6.70	0.32 ± 0.08
Grit blasted	4.65 ± 0.74	9.85 ± 2.48	—	—
Plasma sprayed	9.53 ± 2.84	11.13 ± 4.77	—	—

Note that porosity measurements could not be obtained for the grit blasted and plasma sprayed surfaces as the surface was destroyed during the push out test.



(A) (B) (C) (D)

Figure 2 SEM showing bone cement debris on the failed stem surface after push out testing. (A) polished stem. (B) Bead blasted stem. (C) Coarse grit blasted stem. (D) Plasma sprayed stem. The bar in the pictures indicates 50 µm. The arrows point to cement debris.

Study 2. Influence of cement type

There were significant differences between the interface strengths of the different cements at the $p < 0.001$ level (Table II), The values for the HA loaded cement was significantly lower than for the five other cements, and for CMW 3 it was significantly higher than for the others. There was no significant difference between the Palacos R, Simplex P, CMW 1 and CMW 2. The mean pore size and the overall porosity of the stem–cement interface showed a significant differences between the cements (Table II). CMW 2 and Palacos produced significantly higher porosity than the other cements ($p < 0.001$). In general it would appear that the higher viscosity cements produced greater porosity at the stem–cement interface than the medium and low viscosity cements. There was no relationship between either the mean pore size or the percentage of pore area and the push out strength. SEM and EDS analysis demonstrated 18% HA on the inner cement surface of the HA cement (Fig. 3).

Study 3. Influence of pre-heating the stem

Table III shows the static interfacial shear strength and the porosity for the four groups of stems. The shear strength of the bead blasted stems was approximately five times greater at room temperature and four times greater when preheated than that of the polished stems. There was no difference in the shear strength between 23 °C and 44 °C for either the bead blasted groups or the polished groups. The percentage of pore area was significantly lower in the polished groups compared with the bead blasted groups ($p < 0.01$). Pre-heating the stem also produced approximately one sixth the porosity for both the bead blasted and polished stems ($p < 0.001$,

TABLE II Stem–cement interfacial shear strength (kN) and porosity in different cements (mean ± SD)

Bone cement	Viscosity	Push out force (kN)	Percentage of pore area (%)	Mean pore size (mm^2)
Palacos R	High	1.39 ± 0.21	14.3 ± 8.5	0.58 ± 0.39
Simplex P	Medium	1.42 ± 0.20	4.8 ± 1.6	0.29 ± 0.08
HA cement	Medium	1.10 ± 0.21	1.7 ± 1.2	0.06 ± 0.03
CMW1	High	1.54 ± 0.22	9.5 ± 3.6	0.16 ± 0.06
CMW2	High	1.40 ± 0.22	16.5 ± 4.2	0.10 ± 0.06
CMW3	Low	1.77 ± 0.30	7.2 ± 2.6	0.06 ± 0.03

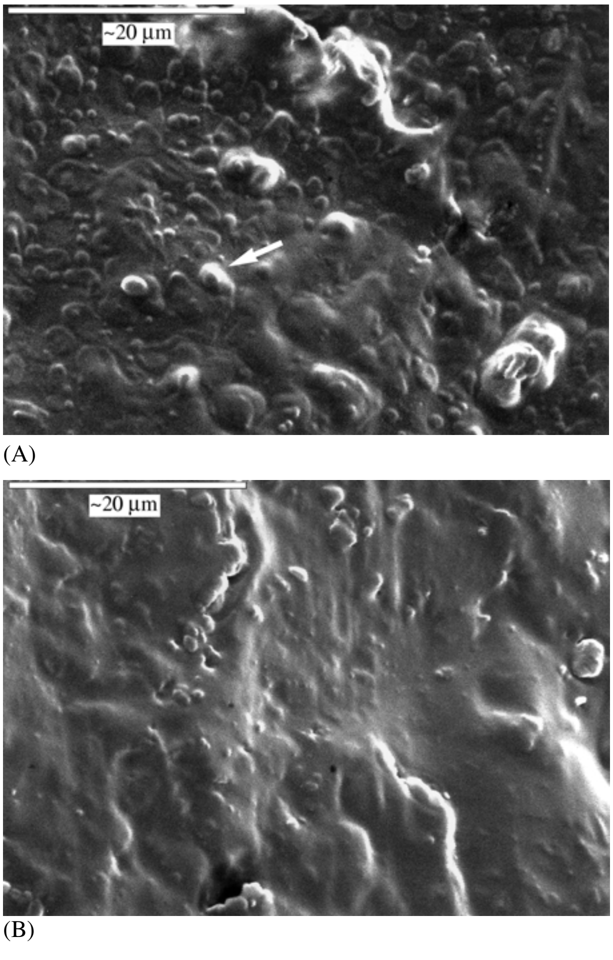
TABLE III Stem–cement interface shear strength and porosity for the different treated stems (mean ± SD)

Stem treatment	Stem temperature (°C)	Push out force/(kN)	Percentage of pore area (%)	Mean pore size (mm^2)
Matt	23	1.66 ± 0.21	11.9 ± 5.5	0.25 ± 0.09
Matt	44	1.46 ± 0.32	2.4 ± 2.7	0.20 ± 0.07
Polished	23	0.33 ± 0.16	4.4 ± 2.7	0.22 ± 0.09
Polished	44	0.38 ± 0.16	0.9 ± 1.2	0.12 ± 0.09

Fig. 4). However, the reduction of surface porosity by pre-heating the stem did not change the static shear strength for either the polished or the bead blasted stem groups.

Discussion

The stem–cement interface is subjected to a complex stress state consisting of tensile, compressive and shear stresses and the relative contribution of these stresses will vary depending on the location within the cement mantle. The damaging components are considered to be the tensile and shear stresses. Therefore, the risk of debonding at the stem–cement interface is dependent on the magnitude of the tensile and shear stresses generated at the interface (which is dependent on the stem design and to lesser extent the shape of the reamed cavity) and the strength of that interface in tension and shear. There is only limited data available on the magnitude of the stresses present at the stem–cement interface. In a static finite element study, Mann *et al.* [7] reported that a proximally bonded Charnley prosthesis produced stem–cement shear stresses of up to 7 MPa. In a similar study Chang *et al.* [6] examined two variants of a proximally bonded cement stem subjected to a variety of loading conditions (varying neck lengths and vaying activities). They reported typical mean stem-cement interface shear stresses of 5 MPa. Verdonschot and Huiskes [18] used the finite element method to simulate the debonding process at the stem–cement interface. They demonstrated that early in the debonding process, the peak interface stresses were up to 8 MPa. Once these high stress regions had become debonded, the peak interface shear stress was typically 2–4 MPa. In all three studies, the magnitude of the peak shear stresses were always greater than the peak tensile stresses by a factor of two or more. In order to assess the potential risk of failure, either due to tensile or shear loading, knowledge of both the stress state and the strength of the interface is required.



(A)

(B)

Figure 3 SEM showed (A) HA particles on the inner cement surface of the HA cement compared with (B) Palacos which is no HA particles in the cement. The bar in the pictures indicates 20 µm. Arrow shows HA particles.

If the interface shear strength is assumed to be the failure load divided by the surface area, then the polished, bead blasted, grit blasted and plasma sprayed surfaces produced interface shear strengths of 0.53, 2.00, 9.85 and 11.13 MPa, respectively. These values are comparable to other studies which have examined the static shear strength [9, 11]. These findings are similar to those reported previously by Bundy and Perm [12] and Crowninshield [10]. Crowninshield [10] reported that increasing the surface roughness from 0.1 to 6.33 µm produced approximately a 50 fold increase in the push out force. This compares with approximately a 20 fold increase in the push out force reported in this study for an increase in surface roughness from 0.03 to 4.65 µm. It is interesting to note that increasing the surface roughness

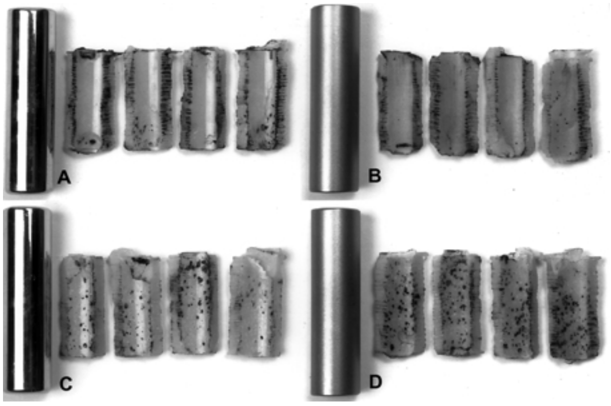


Figure 4 A significant difference regarding the porosity on the cement–stem interface between the temperature 23 and 44 °C. (A) Polished 44 °C. (B) Bead blasted 44 °C. (C) Polished 23 °C. (D) Bead blasted 23 °C.

from 4.65 μm (grit blasted surface) to 9.53 μm (plasma sprayed surface) only produced a marginal increase in the observed push out strength. Examination of the failed surfaces suggested that in the plasma sprayed surfaces, failure was no longer occurring at the interface but within the cement mantle itself, as seen in Fig. 2. Metallic plasma sprayed surfaces are expensive to produce and these results suggest that comparable interface strengths can be achieved by grit blasting the surface with a coarse medium. Only a few studies have reported the tensile failure strength of the stem–cement interface. Davies and Harris [19] reported a tensile strength of 5 MPa for a grit blasted stem tested against Simplex P bone cement. Keller *et al.* [20] reported tensile strengths between 6 and 11 MPa for a variety of metallic materials and surface treatments. Direct comparison of our shear strength data with the tensile strength data reported in the literature is difficult, as details of the surface roughness of the tensile test specimens has not been reported. However, comparison would suggest that the tensile strength of the stem–cement interface is similar to, if not greater than, the shear strength.

If it is assumed that the tensile strength is similar to or greater than the shear strength and that the peak shear stresses are approximately twice the tensile stresses, then it can be assumed that debonding is more likely to occur due to shear failure of the interface than tensile failure. Finite element studies have suggested that the peak shear stresses are approximately 4–8 MPa. The polished group produced a low interfacial shear strength of 0.48 MPa, as would be expected. Therefore, early debonding of the stem could be expected over the entire stem surface soon after surgery, as designed, e.g. the Exeter hip stem. The bead blasted group produced an interfacial shear strength of 2 MPa. Early debonding could be expected in high shear stress areas, typically found distally and anterior–medially [18]. In contrast, the grit blasted surface produced an interfacial shear strength which was approximately five times greater than the bead blasted surface and one and a half to two times greater than the peak shear stresses likely to be experience *in vivo*. The additional strength will delay the onset of debonding and will reduce the rate of propagation once it has begun. The plasma sprayed group only produced a marginal increase in the interface shear strength as compared to the grit blasted surface. The marginal gain in strength may be offset by the significantly increased cost due to the application of the coating.

We have shown that a rougher surface results in a better stem–cement bonding. However, one must consider that a rough prosthesis may produce more cement debris after debonding [15], and the debris is known to be involved in causing progressive loosening of the prosthesis [21, 22]. It is still not clear whether a rougher stem will produce more debris after prosthesis loosening. As the stem is rougher, it will also have a higher coefficient of friction and will require more load to generate micromotion. Therefore, it may be that rougher stems move less than smoother stems, producing less debris. Roughness of stem surface is thus an important compromise between getting as good interface strength as possible and the risk of later wear debris production once the prosthesis gets loose. However, stem debonding is, of course, not only dependent on the surface roughness but also on, for example, the design of the stem. When prosthesis is designed for minimizing the stresses at the stem–cement interface and ensuring a long term bond, it seems as an optimal rough surface should be considered.

For different cements some differences were observed in the interface shear strengths. The lowest interface strength was generated by an experimental HA loaded bone cement (20 wt % HA). The aim of this cement was to improve the strength of the bone–cement interface by promoting osseointegration. However, the addition of HA appears to adversely affect the stem–cement interface strength, because much of the interface is HA and not cement. The lowest viscosity cement (CMW3) produced significantly higher interface strength than all of the other cements. Although no relationship between interface strength and porosity has been demonstrated, it is interesting to note that the low viscosity cement produced the lowest porosity (in terms of both the percentage porosity and the mean pore size) and the highest interface shear strength.

Preheating the stem produces a statistically significant reduction in the porosity regardless of the surface finish of the stem. These findings are similar to those reported by Bishop *et al.* [16]. However, no difference could be demonstrated between the static interfacial shear strength for either the bead blasted or polished stem.

The results of this study would suggest that porosity at the interface has a minimal effect on the static interfacial shear strength. Significant differences were seen in the amount of porosity and the mean pore size produced by different cements and by pre-heating the stem. However, no relationship between either of the porosity measurements and interfacial shear strength could be demonstrated. The pores at the interface, however, may contain unfused and loose particles to a great extent [23] which might enter the joint space.

It must be emphasized that this study has only examined the static interface strength and care should be taken in interpreting this data. In particular the influence of porosity may become more pronounced when the interface is subjected to fatigue loading. The size and distribution of pores at the interface might influence the debonding mechanism in dynamic loading conditions. As such, this study is only a preliminary investigation and further work is required to fully assess the influence of porosity. A limitation of this study is the experimental set-up, that is the use of a simple push out test to assess the interfacial shear strength. Various finite element studies [24, 25] have demonstrated that such a test generates an uneven stress distribution at the stem–cement interface and that only the push out force can be reported for comparison purposes. This study has shown that the static shear strength of the interface increased with rougher stems but when the stem roughness reaches a certain level, failure will occur in cement mantle and not at the interface. The cement type only has a marginal influence on the interface shear strength and porosity on the cement surface. Preheating the stem reduces the porosity on the cement surface, but does not influence the interface static shear strength. In this relative simple test, there is no significant relationship between the porosity and static shear strength at the stem–cement interface could be demonstrated.

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