Title

Cement Brand and Preparation effects Cement on Cement Mantle Shear Strength

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Abstract

Creating bi-laminar cement mantles as part of revision hip arthroplasty is well-documented but there is a lack of data concerning the effect of cement brand on the procedure. The aim of this study was compare the shear strength of bi-laminar cement mantles using various combinations of two leading bone cement brands.

Bi-laminar cement mantles were created using Simplex P with Tobramycin, and Palacos R+G: Simplex-Simplex (SS); Simplex-Palacos (SP); Palacos-Simplex (PS); and Palacos-Palacos (PP). Additionally, specimens were produced by rasping (R) the surface of the original mantle, or leaving it unrasped (U), leading to a total of eight groups (n=10). Specimens were loaded in shear, at 0.1 mm/min, until failure, and the maximum shear strength calculated.

The highest mean shear strength was found in the PSU and PSR groups (23.69 and 23.89 MPa respectively), and the lowest in the PPU group (14.70 MPa), which was significantly lower than all but two groups. Unrasped groups generally demonstrated greater standard error than rasped groups.

In a further comparison to assess the effect of the new cement mantle brand, irrespective of the brand of the original mantle, Simplex significantly increased the shear strength compared to Palacos with equivalent preparation.

It is recommended that the original mantle is rasped prior to injection of new cement, and that Simplex P with Tobramycin be used in preference to Palacos R+G irrespective of the existing cement type. Further research is needed to investigate more cement brands, and understand the underlying mechanisms relating to cement on cement procedures.

Introduction

Cementing a new femoral stem within an existing cement mantle during revision hip arthroplasty is well documented (1, 2). Such a technique aims to minimise the hazards associated with removing the existing mantle during surgery (3), which include significant intra-operative bleeding, loss of bone stock, and an 8% risk of intraoperative femoral fracture (3-5). The cement-on-cement (COC) technique has been shown to be a reliable, with good to excellent mid-term outcomes providing the existing mantle is not compromised (1, 6-8).

Several mechanisms of adhesion between the bi-laminar cement mantles have been suggested. These include mechanical interlocking, polymer chain interdiffusion, chemical bonding and electrostatic interactions, with different mechanisms contributing to various degrees (9). Only limited chemical interaction would be possible at the cement-cement interface, as residual monomer within aged PMMA is characteristically less than 1%, and terminated PMMA chains within the old mantle have few reactive sites, further limiting polymerisation (10). It has therefore been hypothesised that the predominant mechanism of adhesion is by inter diffusion with high levels of monomer in the new cement layer diffusing into the original layer forming strong polymer chains across the interface (10).

Concerns remain that the integrity of the bi-laminar cement mantle is weaker than a uniform mantle and may be more likely to fail. Previous studies have shown the introduction of antibiotics to the cement, and age of the original mantle, do not significantly alter the shear strength of bi-laminar cement mantles (10). Large amounts of fluid between the cement layers has been shown to reduce strength by up to 85% compared to uniform mantles (11). Rasping of the original cement mantle prior to the addition of the new cement is recommended in order to increase the bonding of the mantles at a microscopic level (2, 7, 8, 10, 12-14). Greenwald et al. demonstrated the interfacial strength of a COC mantle was 93% of a uniform cement mantle when the existing mantle was rasped prior to insertion of new cement, and 86% when unrasped (2). However a further study has subsequently demonstrated that rasping may only make a significant difference when large amounts of fluid are present between mantles (15).

The effect of using different cement brands has not been well-studied despite the potential for a different cement brand to be used in revision surgery compared with the primary procedure. Different cement brands vary considerably in their compositions and properties, raising the possibility that they influence the strength of bi-laminar cement mantles. Dang et al. (16) found no significant differences between different cement combinations when testing flexural strength, but the effect of cement brand and rasping on the shear strength have not previously been investigated.

The purpose of this study was to investigate the shear strength of bi-laminar cement mantles comprising different brands of cement. The effect of rasping of the original cement surface on the shear strength was also assessed.

Materials and Methods

Two brands of commercially available bone cement were used to create bi-laminar cement mantles, which were tested in shear until failure.

The two bone cement brands investigated were Simplex P with Tobramycin (Howmedica International S. de R.L., Limerick, Ireland) and Palacos R+G (Heraeus Kulzer GmbH, Kulzer Division, Wehrheim, Germany). Bi-laminar cement samples were created in four combinations, where the first name denotes the original mantle, and the second name denotes the new cement mantle: Simplex-Simplex (SS); Simplex-Palocos (SP); Palacos-Simplex (PS); and Palacos-Palacos (PP) (Figure 1). Each of these groups was subdivided into either rasped (R) or unrasped (U), giving a total of eight test groups (SSU, SPU, PSU, PPU, SSR, SPR, PSR, and PPR). Ten test specimens were produced for each group.

Simplex cement was mixed using the Summit mixing syringe (Summit Medical Ltd, Bourton-on-the Water, Gloucestershire). The Palacos cement was mixed using a similar Palacos syringe mixing system. All cement was mixed for 1 minute under a vacuum of 67.7 kPa after the introduction of the liquid monomor to the PMMA powder. The plunger of the mixing system was cycled at approximately 1 Hz during the mixing process. The cement was injected into the mould 3 minutes after the introduction of the monomor to the PMMA. All cement was mixed and allowed to fully polymerise at room temperature.

The mould used was based on ISO 5833:2002 (17) for the determination of the bending modulus and bending strength of polymerised cement. The first layer of cement produced ten samples that were 3 mm in depth, 10 mm in width, and 75 mm in length. A second mould was used with identical measurements but with a depth of 4 mm for each sample. This allowed the existing samples to be inserted into the mould, and the new cement layer injected on top to produce bi-laminar samples with an old cement mantle depth of 3 mm and a new cement mantle depth of 1 mm.

After the production of the 3 mm deep samples, the edges were filed to ensure that they would fit into the second mould. The samples were then stored in air, in an incubator at a temperature of 37°C for a period of one week prior to the addition of the 1 mm layer. Samples were stored in the group of ten in which they were produced to ensure that the final samples in a group had been produced from the same cement mix.

On the day of the production of the second cement layers, samples in the rasped group were prepared by hand using 120 grit emery cloth. The method previously described was used to mix and inject the second layer of cement, and when fully polymerised, the samples were stored overnight, in air, at 37°C.

Shear tests were completed using a ball screw driven testing machine equipped with a 5 kN load cell (Instron 3365, Instron Ltd., Buckinghamshire, UK). Prior to testing, the samples were cut down to a length of 10 mm. Pilot testing had demonstrated that longer specimens remained intact under the maximum load capacity of the testing machine.

The length and width of each sample was measured using Vernier callipers prior to testing to ensure that an accurate value of the area could be calculated for each specimen.

A custom jig was used to mount the specimens (Figure 2), with the 3 mm deep cement layer fixed to the baseplate, and the 1 mm cement layer floating in line with the crosshead attachment. The crosshead fixture was designed so as to apply the load through the 1 mm deep cement layer along the length of the specimen. The specimens were tested quasistatically, in position control, at a rate of 0.1 mm/min until failure. The load and position data were acquired for each test at a frequency of 10 Hz.

The load data was used along with the calculated area over which the load was applied, to calculate the shear stress. The shear strength of each specimen was defined as the maximum shear stress of each test, and this value was used for the statistical comparisons between the test groups. All statistical analyses were completed using SPSS (IBM SPSS Statistics 19; IBM Corporation, Armonk, NY, USA).

Each group was tested for normality using the Shapiro-Wilke test. Six out of the eight groups were normally distributed ($p>0.05$), and therefore a comparison was made between all eight groups using a one-way ANOVA with a Bonferroni post-hoc test.

A further comparison was made in regard to the effect of the brand of the new layer of cement irrespective of the brand used in the original cement mantle, and on the effect of rasping prior to the injection of the new cement mantle. This analysis comprised four test groups (SU, SR, PU, PR), with the first letter denoting whether the new cement mantle was Simplex (S) or Palacos (P), and the second letter denoting whether the old cement mantle was rasped (R) or unrasped (U).

Three out of the four test groups in this latter comparison were found to be non-normally distributed using the Shapiro-Wilke normality test. Therefore, non-parametric tests were adopted. The groups were first compared using a Kruskal-Wallis test, with Mann-Whiteney tests used for post-hoc analysis. A Bonferroni correction was used to account for multiple comparisons, with $p< 0.0083$ required for statistical significance.

Results

The failure of test specimens tended to result in either a fracture directly down the cement-cement interface, or via a crack that started at the cement-cement interface, which then propagated into the original cement mantle. There was no observable pattern in the failure mechanism within or between test groups.

The shear strength varied considerably between groups, both in terms of the mean, and the standard error (SE) (Figure 3). The two groups with the highest mean shear strength were PSU and PSR with magnitudes of 23.69 and 23.89 MPa respectively. The lowest mean shear strength was 14.70 MPa in the PPU group, which also demonstrated the largest standard error of 2.2 MPa. The standard error was generally greater in the unrasped groups (range of SE 0.46-2.2 MPa) compared to the rasped groups (range of SE 0.19-0.55 MPa).

The statistical analysis of all eight groups demonstrated that there were significant differences in 7 of the 28 comparisons (Table 1). The shear strength of the PPU group was significantly lower that all but the SSU and SPU groups. The only other significant differences were that the SSU group had a significantly lower shear strength than the PSU and PSR groups ($p=0.014$ and 0.009 respectively).

The comparison of the effect of the second layer cement brand irrespective of the first layer brand showed that using Palacos on an unrasped surface resulted in a significantly lower shear strength than using Simplex with either unrasped ($p=0.007$) or rasped ($p<0.001$) surface preparation (Table 2Table). It was also found that Palacos on a rasped surface had a significantly lower shear strength than Simplex on a rasped surface ($p<0.001$). There was no significant difference between the unrasped and rasped groups with a second layer of Simplex ($p=0.201$) or between the two groups with Palacos as a second layer ($p=0.108$), though the spread of data was greater in the unrasped groups (Figure 4).

Discussion

The results demonstrate that the altering the combination and preparation of cements used in bi-laminar samples significantly affects the shear strength. The range of shear strength in unrasped groups was higher than in rasped groups, though the only group for which rasping created a significant difference was for Palacos- Palacos.

The cement mixing systems used in this study were both syringe systems, though they were not identical for each brand of cement. Whilst this may have introduced an additional variable, the study aimed to replicate the clinical situation. Therefore, the proprietary Palacos syringe system was used to mix the Palacos bone cement, and the Simplex bone cement was mixed with a Summit HiVac Syringe system.

It has previously been recommended that COC procedures prepare the old cement mantle with rasping prior to the introduction of new cement into the femoral canal (2, 10). The results of the present study support these recommendations, and although few significant differences were observed between unrasped and rasped groups of the same cement combination, the range and SE was lower with a rasped surface in all cases.

The comparison of all eight test groups suggests that the lowest shear-strength is obtained by injecting new cement onto an old cement mantle of the same brand without rasping. This combination of cement brands and preparation also resulted in the largest standard error in shear strength.

Comparing the effect of the brand of the new cement mantle and rasping preparation provides useful data for the clinical environment, as a surgeon undertaking revision total hip arthroplasty will not have a choice regarding the original cement mantle but instead must choose the most appropriate technique and cement brand for use in the revision procedure. This analysis demonstrated that from existing mantles of Simplex P and Palacos R+G, a bi-laminar mantle with greater consistency and shear strength can be achieved by rasping the existing mantle prior to the addition of Simplex P for the new mantle.

It is possible that the results of the present study relate to the curing of the respective cements. Cement that has low viscosity at the time of injection may be better able to integrate into the rasped surface of the existing mantle under the post-injection pressure that is applied during curing. However, it is possible that the presence of the existing cement may alter curing times, although there is no published evidence to date testing this hypothesis, and as such manufacturers recommendations do not include any alterations in cementing technique when cementing onto a pre-existing cement mantle. Further research is required to fully understand the polymerisation of bone cements in the presence of existing mantles, in order to further optimise the COC procedure.

Based on the findings of this study, it is recommended that all cement on cement procedures use rasping to prepare the existing cement mantle prior to injection of the new cement. It is also recommended that Simplex P bone cement be used in preference to Palacos R+G for the new cement irrespective of the existing cement type.

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Figures

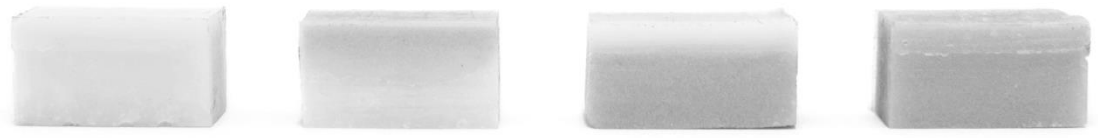

Figure 1: Bi-laminar cement mantles from left to right: SS; SP; PS; and PP

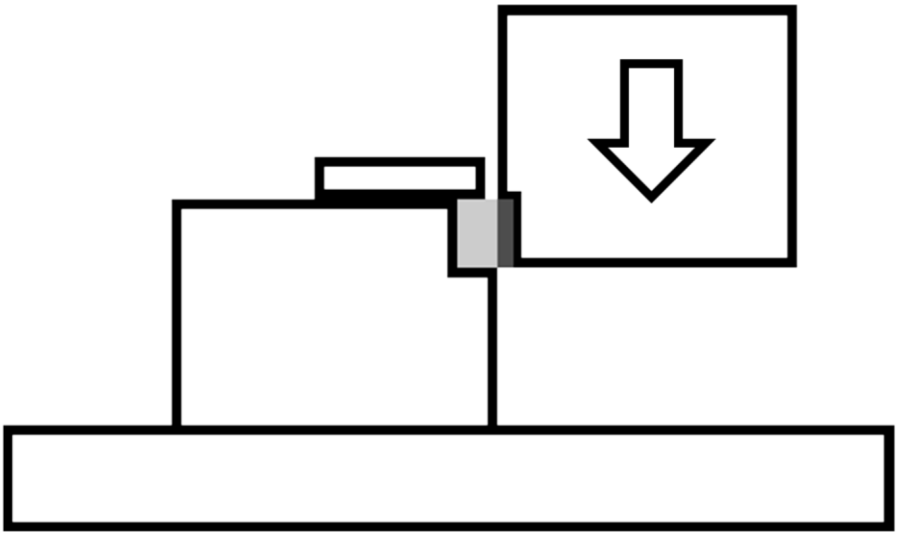

Figure 2: Diagram of the shear testing apparatus. The upper block was fixed to the crosshead of the Instron testing machine. The red area represents the original cement mantle, the grey area the second cement layer.

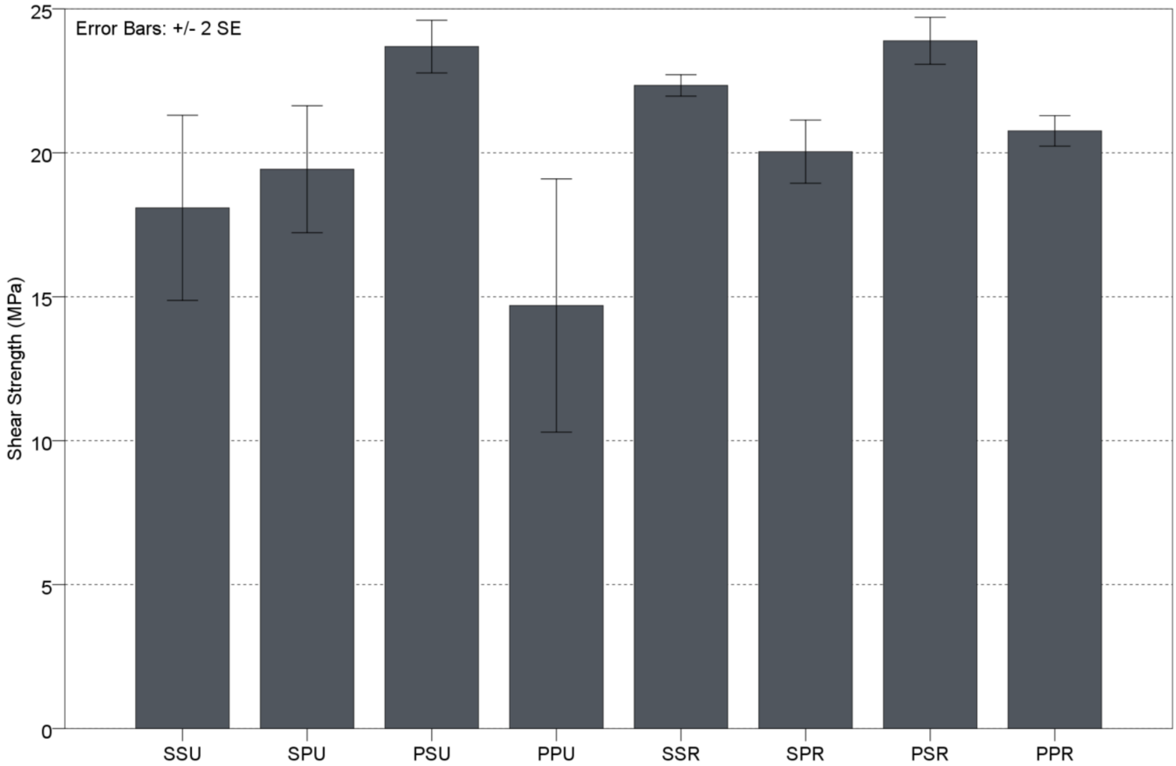

Figure 3: Mean shear strength of each cement-cement group (n=10). Error bars denote the confidence intervals

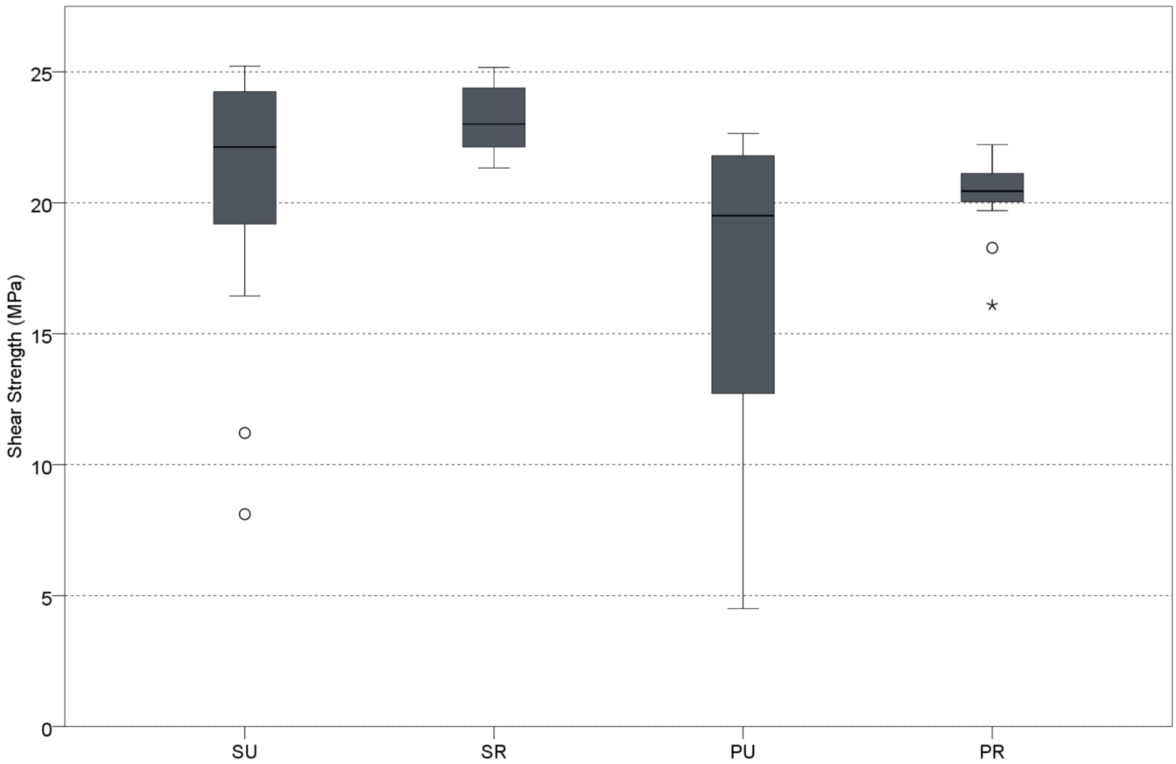

Figure 4: Boxplot of the shear strength for each cement-cement group based on the brand of the new cement mantle and preparation (n=20)

Tables

Table 1: Comparison of shear strength between bi-laminar cement test groups. Significance denoted with bold font ($p<0.05$)

BRANDS	SSU	SPU	PSU	PPU	SSR	SPR	PSR	PPR
SSU		>0.999	**0.014**	0.845	0.199	>0.999	**0.009**	>0.999
SPU	>0.999		0.196	0.081	>0.999	>0.999	0.136	>0.999
PSU	**0.014**	0.196		**<0.001**	>0.999	0.561	>0.999	>0.999
PPU	0.845	0.081	**<0.001**		**<0.001**	**0.024**	**<0.001**	**0.005**
SSR	0.199	>0.999	>0.999	**<0.001**		>0.999	>0.999	>0.999
SPR	>0.999	>0.999	0.561	**0.024**	>0.999		0.402	>0.999
PSR	**0.009**	0.136	>0.999	**<0.001**	>0.999	0.402		>0.999
PPR	>0.999	>0.999	>0.999	**0.005**	>0.999	>0.999	>0.999	

Table 2: Comparison of shear strength between bi-laminar cement test groups based on the new cement mantle and preparation. Significance denoted with bold font ($p<0.0083$)

BRANDS	SU	SR	PU	PR
SU		0.201	**0.007**	0.028
SR	0.201		**<0.001**	**<0.001**
PU	**0.007**	**<0.001**		0.108
PR	0.028	**<0.001**	0.108	