SCIENTIFIC ARTICLE

Effects of Cemented Hip Stem Pre-heating on Stem Push-out Strength

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Objective: To determine the effect on ultimate push-out load and cement–stem surface shear strength of thermally manipulating the cobalt-chromium-molybdenum (CoCrMo) alloy stems of bone cement–stem constructs.

Methods: Satin-finished CoCrMo alloy stems were allocated to the following three groups with the predetermined temperatures: T24, ambient (24 °C); T37, body (37 °C); and T44, pre-heated stem (>44 °C). They were then inserted into hand-mixed high viscosity bone cement. Ultimate push-out load to failure was assessed with a servo hydraulic testing machine and the surface shear strength calculated. Data were compared among groups using the Kruskal–Wallis with Dunn's test. A P value of less than 0.05 was considered statistically significant.

Results: According to Kruskal–Wallis analysis, ultimate push-out load and surface shear strength differed significantly between the groups ($P = 0.001$). The T37 and T44 groups had higher ultimate push-out loads and surface shear strengths than the T24 group ($P = 0.04$ and 0.001, respectively). However, there was no statistically significant difference in these two variables between the T37 and T44 groups ($P = 0.08$).

Conclusions: Pre-heating CoCrMo alloy stems enhance the ultimate push-out load and surface shear strength *in vitro*. The suggested temperature is 37 °C. This technique is recommended for hip arthroplasty procedures.

Key words: Cobalt-Chromium-Molybdenum alloy; Hip arthroplasty; Pre-heated femoral stem; Push-out test; Surface shear strength

Introduction

Total hip arthroplasty (THA) using cemented femoral component is widely considered the preferred option for a variety of hip pathologies[1–4]. Nonetheless, aseptic loosening continues to be a major long-term challenge[5,6]. Micro motion of the stem or debonding of the cement–stem interface results in significantly increased stress in the bone cement mantle, leading to bone cement mantle failure[7]. Several procedures, such as increasing the roughness of the stem surface[8], pre-coating the stem with polymethyl methacrylate, improved the cementing technique[9] and thermal manipulation of the stem or bone cement[10], have been recommended for improving the surface shear strength at the cement–stem interface. However, some techniques have inadvertently increased bone cement debris, leading to an unacceptable rate of early stem failure[11–13].

Reduction of porosity of the bone cement at the cement–stem interface has been confirmed to improve the fatigue life of the bone cement mantle[14]. Modern bone cement handling techniques have improved the mechanical properties of the bone cement mantle; however, those techniques do not reduce the porosity at the cement–stem interface[9,15,16]. Thermal manipulation (heating) of the stem, first intended to accelerate bone cement polymerization and thus reduce operative time[17], has been found to reduce the porosity at the cement–stem interface[9] and improve the surface shear strength[10].

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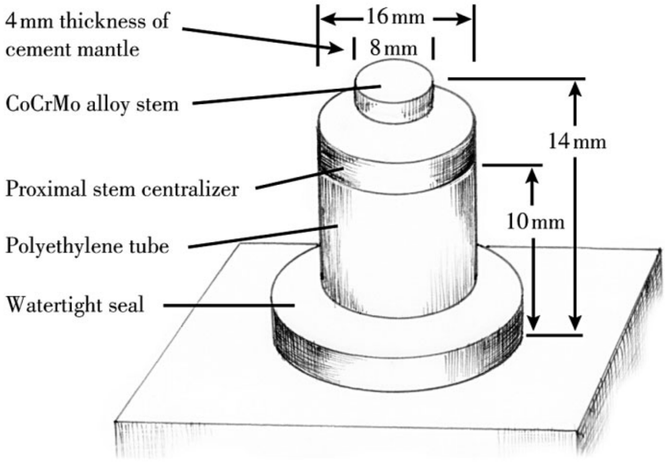

Fig. 1 Diagrammatic representation of the experimental set up of Cement-Cobalt-chromium-molybdenum alloy stem construct in a temperature controlled (37 °C) thermocycling unit.

Thus, intraoperative thermal manipulation of the stem could be a viable means of improving cemented femoral stem longevity.

The purposes of this study were to determine the effect of pre-heating alloy stems on ultimate push-out loads and the cement–stem surface shear strengths *in vitro* and to identify the optimal temperature to heat to.

Materials and Methods

Twelve Vitallium 2000 Plus cobalt-chromium-molybdenum (CoCrMo) satin finished alloy stems (Densply, York, PA, USA) with average surface roughness (Ra) of 0.67 ± 0.04 (range, 0.57–0.72) μm (SurfTest SJ-201; Mitutoyo, Kanagawa, Japan), 8 mm in diameter and 14 mm in length, were used[8,18]. Each stem was chemically cleaned using a recommended protocol[19] and thoroughly dried before testing. The alloy stems were allocated to three groups with the following temperature controlling process before insertion: T24, ambient temperature (24 °C); T37, body temperature (37 °C); and T44, pre-heated stem (44 °C). The stems were kept clean in a watertight container in a WB 22 thermocycling unit (Memmert GmbH, Schwabach, Germany) with a thermocouple recorder model 407401 (Extech Instruments, Nashua, NH, USA) at the designated temperature for at least one hour prior to insertion.

Polyethylene tubes, 16 mm in inner diameter and 10 mm in length, were secured vertically and water tight on a clear plastic plate in a temperature controlled (37 °C) thermocycling unit for one hour prior to cement injection and alloy stem insertion. Osteobond copolymer bone cement (Zimmer, Warsaw, IN, USA) was hand-mixed at ambient temperature for 30 s and injected into the polyethylene tubes using a 50 mL syringe. An alloy stem was then inserted manually into the polyethylene tube filled with bone cement while the bone cement was in the dough stage. Each alloy stem was held by a custom proximal stem centralizer to ensure uniform 4 mm thickness of the cement mantle and 10 mm effective longitudinal length of contact between bone cement and alloy stem in each tube (Fig. 1). The stem centralizer was removed after the bone cement had set. Cement-CoCrMo alloy stem constructs were allowed to cure for one day, then removed from the plate prior to testing.

The construct was mounted vertically and centered directly by a holder under the loading platform of a servo hydraulic testing machine model 8872 (Instron, Norwood, MA, USA) to avoid off-axis loads. A push-out test was performed by applying a compressive load vertically onto the alloy stem at a rate of 10 mm/min until the ultimate load had been attained[8,10]. The testing procedure was performed at ambient temperature. The ultimate load at failure (N) was defined as the highest load before the load dropped. The surface shear strength (MPa) for each alloy stem was calculated by dividing the ultimate load at failure by the effective surface area of the cement–stem interface (effective surface area = $2\pi 4 \times 10$ mm^2). Data were recorded as medians and interquartile ranges for each group.

The data for push-out load and surface shear strength were confirmed as normally distributed by the Shapiro–Wilk test. The push-out load and surface shear strength were compared among the three groups using the Kruskal–Wallis with Dunn's test. Statistical analysis was performed using Stata version 12.0 (StataCorp, College station, TX, USA). A *P* value of less than 0.05 was considered statistically significant.

Results

According to the Kruskal–Wallis test, data for push-out load (Fig. 2) and surface shear strength (Fig. 3) differed

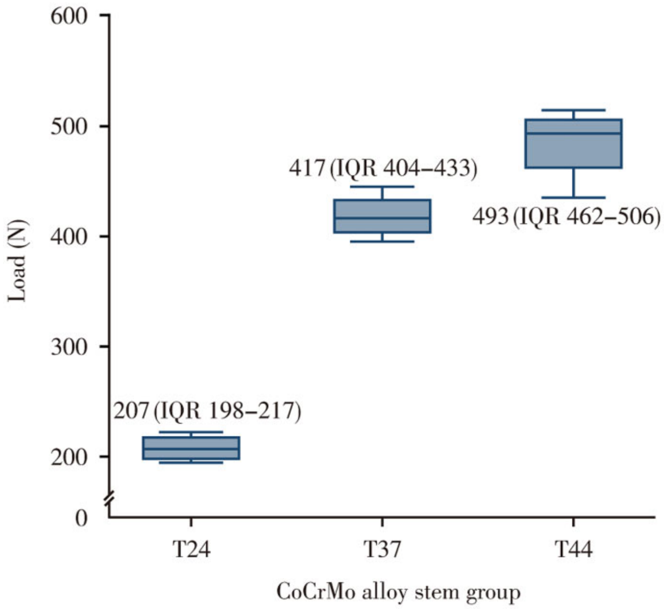

Fig. 2 Ultimate push-out load of CoCrMo alloy stems according to temperature.

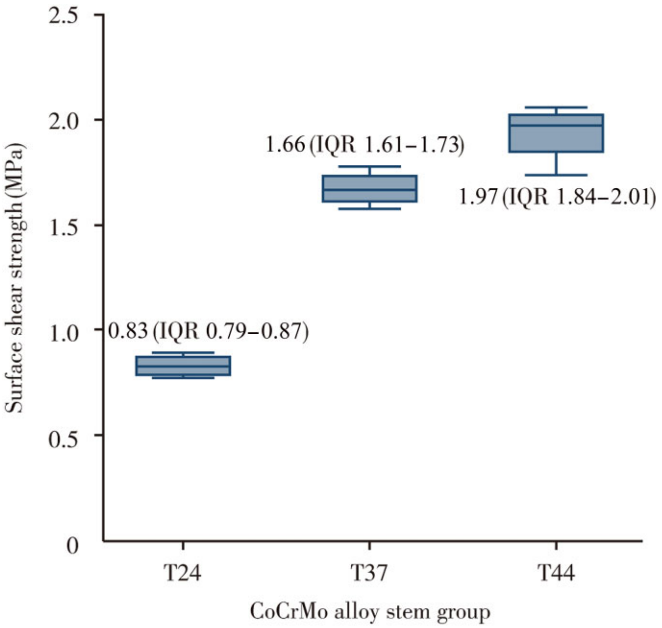

Fig. 3 Shear strength of CoCrMo alloy stems according to temperature.

significantly among the three groups ($\chi^2 = 9.269$, $P = 0.001$). A post hoc power analysis demonstrated that the present data obtained statistical power of 0.76. A Dunn's test revealed that push-out load and surface shear strength were significantly lower in the T24 group than in the T37 and T44 groups (P = 0.04 and 0.001, respectively). The push-out load and surface shear strength of the T44 group tended to be higher than that of the T37 group; however, this was not statistically significant ($P = 0.08$).

Discussion

Cemented femoral stems have been found to produce acceptable long term results and are suitable for a number of hip pathologies ranging from osteoarthritis to femoral neck and intertrochanteric fracture[1,2,5,6]; moreover, the procedure helps improve these patients' quality of life[4]. Durability of the cemented femoral stem is one crucial factor for long term outcomes after THA surgery. A number of procedures have been recommended to improve the cement–implant interface strength and thus increase the construct's longevity[8,9,12]. Thermal manipulation of the stem, which alters the porosity of the cement mantle and its interfaces, has had encouraging outcomes[10,20,21]. In this *in vitro* study, we found that increasing the alloy stem temperature to above the average ambient temperature prior to stem insertion increases the ultimate push-out load and surface shear strength consistent with previous reports[10,21].

Pre-heating of the stem, which was first recommended by Dall *et al.*[17] and later popularized by others[9,10,21], is a well-accepted method for reducing interfacial porosity at the cement–stem interface. Interfacial surface porosity can act to increase stress and thus serve as a starting point for the cement–stem debonding process[7]. The process of polymerization of bone cement starts at the warmer cement–stem interface rather than at the cement–bone interface as in other traditional techniques[22,23]. The cement at the cement–stem interface acts as a platform for the cement mantle to set and shrink away, thus shifting cement porosity towards the cement–bone interface[9,10,18,22–24]. Decreasing interfacial cement porosity at the cement–stem interface increases the contact area between the cement and the stem, thus helping to prevent fluid penetration[3,25,26]; this in turn decreases the chance of cement–stem debonding, a primary cause of cement mantle failure and aseptic loosening. Cement porosity (expressed as percentages) is positively correlated with reduction in shear strength[26].

The optimal temperature to which to pre-heat the stem is still under investigation. In this experiment, increasing the temperature to 44 °C did not result in significantly greater surface shear strength than pre-heating to 37 °C, a finding similar to that of a previous report[10]. Higher stem temperatures have been found to decrease cement polymerization time and interfacial porosity[17] but have potential disadvantages[7]. Firstly, shifting cement porosity towards the cement pre-heat bone interface[27] may cause untoward long-term clinical survival of the cemented stem because crack distribution has been confirmed to be associated with the cement–bone interface[28]. Secondly, increasing the temperature during cement polymerization by pre-heating the stem may cause thermal necrosis in the bone tissue in the femoral canal; however, previous experimental studies have found no difference in polymerization temperature between stem preparation at 23 °C and 44 °C. The temperature generated in the construct did not exceed 50 °C[29] and minimal heat is transferred to bone tissue[9,10,24]. Hsieh *et al.* reported that pre-cooling the femoral canal, rather than pre-heating the stem, also decreases the porosity at the cement–stem interface but reduces thermal necrosis of the bone at the cement-bone interface. They reported that pre-heating the stem resulted in greater shear strength at the cement–stem interface than pre-cooling the femoral canal; however this difference group was not statistically significant[20]. We thus recommend 37 °C is the optimal temperature to which to pre-heat the femoral stem. At this temperature, the polymerization process is initiated with balanced effects[24]. Stem warming techniques are relatively simple, requiring no additional or specialized equipment because the stem can be warmed by any available warming method in the operative theater.

The strength of the cement mantle is crucial for long term survival of the cemented femoral stem. Well known modern cementing techniques utilizing vacuum mixing, a distal cement plug and pressurized retrograde injection of the dough cement have been found to reduce cement mantle porosity. In contrast with a previous report in which vacuum mixing or centrifugation was endorsed[30], we used a conventional hand mixing technique in our experiment because a previous report had demonstrated that comparable porosity is achieved in the cement mantle with hand or vacuum mixing[15,16]. Pre-heating of the stem has also been found to reduce the porosity in the cement mantle[9,10,21]. The technique resulted in better fatigue strength of the cement mantle when tested for more than 1×10^5 cycles[14]. Generated porosity and temperature are reportedly comparable in an experimental femur. Elastic modulus and bending strength of the cement mantle were also similar when a pre-heated stem was used with either hand or vacuum mixed bone cement[29]. This further supports the use of hand mixing both in our experiment and if the stem is to be pre-heated in a clinical setting. Moreover, porosity-related cement mantle cracking is a minor concern compared to other interface areas[28].

The stem surface finish is another factor that may affect long term outcomes. It is generally recommended that the Ra of a stem used with bone cement should be less than 1 μm; however, this issue is still being debated[3,18,25]. Stems with matte surfaces initially have higher strength at the cement–stem interface but progressive loosening occurs once the surface has debonded. Previous clinical studies have shown that femoral components with a Ra of 0.5–0.8 μm have significant lower aseptic loosening rates than rougher surface femoral components over a mid-length follow up[11,13]. When compared with polished or satin finished stems, those with higher Ra have considerable gaps between the stem and cement mantle[18]. Although, the interface porosity of pre-heated polished and matte stems is comparable, polished stems have greater interfacial shear strength[25]. We believe that femoral stems with smooth surface finishes are preferable to those with matte surfaces for the pre-heating procedure.

Our study has several limitations that are worth noting. Firstly, the round CoCrMo alloy stems with an effective length of 10 mm used in the experiment could yield different surface shear strengths than commercially available femoral stems. Secondly, a fatigue loading test would be necessary to assess the fatigue life of the construct. Performing an experiment with a variety of stem designs and sizes, surface finishes and cementing techniques with the pre-heating stem protocol would yield more detailed data on potential outcomes.

In conclusion, pre-heating of CoCrMo alloy stems before insertion into a cement mantle enhances their ultimate push-out load and surface shear strength. Heating the stems to the recommended temperature of approximately 37 °C can easily be achieved without additional equipment in the operative theater. This technique may improve the longevity of femoral hip stems and we therefore advocate it during THA procedures.

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