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The Effect of Viscosity on Cement Penetration in Total Knee Arthroplasty, an Application of the Squeeze Film Effect

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ABSTRACT

The authors present a prospective randomized blinded cadaver study designed to evaluate the engineering concept of a squeeze film effect and the effect of cement viscosity on cement penetration in total knee arthroplasty. This was done in response to an earlier clinical study demonstrating inferior tibial cement penetration using early, often liquid, phase cement. Paired cadaver tibias were implanted with the tibial component using either liquid or dough phase cement. Based on an AP fluoroscopic image, the dough phase cement penetrated deeper than liquid in all four zones. This was statistically significant in zones 1, 2 and 3. Deeper cement penetration has been shown to provide a stronger cement–bone interphase. As a result dough phase cement is recommended to obtain optimal cement penetration.

Total knee arthroplasty (TKA) is an important procedure for restoring quality of life in patients troubled by damaged or arthritic joints. Over the past few decades, many improvements in implant design and procedural techniques have been developed. However, one of the important remaining complications of modern total knee arthroplasty (TKA) is aseptic loosening [1,2].

Walker et al [3] studied the relationship between cement penetration and the strength of the cement–bone interface. The cement must penetrate to a level where it encounters transversely oriented trabeculae and sufficient curves in the cancellous proximal tibia. Other investigators have described multiple factors with significant effects on cement penetration such as component design, pulse lavage and cementation techniques [4,5–9,10–12]. Cement penetration has previously been shown to have a significant effect on strength of fixation and stability of the tibial component [3,13]. Ideal penetration has been shown to be 3–4 mm, with concern for increasing rates of thermal necrosis with depths greater than 5 mm [3].

Cement pressurization can be caused in one of two ways, either by reducing a completely enclosed volume or by creating cement flow through a restricted orifice. In the first case, the only requirements to create the pressure are the enclosed volume and a liquid cement of any viscosity. In the second case, the mass of cement is not completely enclosed, but is being forced through an exit orifice. In this case, the cement flow rate and pressure are controlled by the cement viscosity. In an analogous fashion, a syringe with no orifice can be pressurized by pushing on the plunger. The internal pressure is controlled only by the applied force. If the syringe has an orifice, then the fluid flow rate and pressurization are controlled by the magnitude and rate of applied force and the fluid viscosity. These simple laws of fluid flow allow us to understand the mechanisms of cement pressurization during total knee component insertion and the associated cement intrusion into porous bony structures.

There has been debate on the best timing for cement application (early phase vs. dough phase) during total knee arthroplasty surgery [14]. The senior author had previously had 14 years experience with a specific implant lineage without tibial loosening issues [15,16]. After a change in cementing technique, multiple cases of early aseptic tibial loosening were observed [17]. As a result, strictly dough phase cement was used. A previously presented, retrospective, study demonstrated that the dough phase group showed a statistically significant increased depth of cement penetration, a statistically significant increased likelihood of achieving 3 mm of cement penetration, and an absence of tibial loosening [17].

The current study was designed to test the hypothesis, generated by the retrospective work, that dough phase cement penetrates deeper than liquid phase cement in the tibial component of TKA.

All authors have participated in the research for this paper. The manuscript has not been submitted elsewhere for publication. Institutional review board approval was not required for the current study. The work was performed on cadaver tibias procured by the Max Biedermann Institute for Biomechanics. The current study is a cadaver trial, which confirms retrospective work presented at a national meeting. The findings of the study will have implications in minimizing cases of aseptic tibial loosening, a cause of early failure.

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Materials and Methods

A sample size calculation determined that 5 cadaver tibia pairs were needed to have a power of 80% to detect a difference of 2 mm between the liquid and dough phase groups using a paired *t*-test assuming an alpha of 0.05, standard deviation of 1 mm, and correlation of 0.3.

Five matched pairs of tibias, stripped of all soft tissue, were prepared for tibial component insertion. For each pair, the left and right tibias were randomly assigned to receive either liquid or dough phase cement with coin flips. The tibias were cut using the standard oscillating saw and extra-medullary guides. The cut surfaces were then cleaned with copious amounts of irrigation via pulse lavage system and dried with lap sponges.

All bone cement was maintained at 20 °C [68 °F] for the duration of the trial. Each batch was mixed using an automatic mixer for 95 seconds. The cement cartridge was then placed in a cement gun and applied immediately to the "liquid phase" tibia, followed by insertion of the appropriately sized tibial component. Cement was not pressurized into the bone surface with the gun. The same batch of cement was then held in the cement gun until it had reached the dough phase. This was typically approximately 60–90 seconds after the mixing was complete. Dough phase was judged by the senior author based on the ability to manipulate the cement in a gloved hand. At this point it was applied to the prepared tibial surface of the contralateral "dough phase" tibia and the component was inserted.

The prepared tibia was measured using the standard trials and the appropriate size was determined by the senior author for each tibia. The tibial trays were impacted in the standard fashion with a mallet and impactor until the metal baseplate contacted the tibial surface. A 50 N static force was then applied using 11.2 pounds in lead weights and this was maintained until cement polymerization. The 50 N force was applied to simulate extension of the knee after all components have been implanted in a standard TKA [11]. Polymerization was confirmed after 15 minutes by examining unused cement. AP fluoroscopic images were then obtained orthogonal to the tibial tray. The authors used the same implant and cement that were used in the retrospective clinical study [17]. The implant was the Optetrak modular tibial tray with a trapezoidal peg. The tray has a 0.5 mm elevated peripheral rim on the undersurface (Exactech, Inc.; Gainesville, FL). Cemex System Fast Genta cement was used (Tecres, Italy) [18].

Using the image processing and analyzing software program, ImageJ64, developed by the Research Services Branch of the National Institutes of Health, a single blinded examiner, using the same technique, evaluated all radiographs for cement penetration, with all measurements confirmed by a senior orthopedic resident. The zoom function of ImageJ64 was utilized to measure the height of the tibial plate down to the pixel. Measurements were adjusted for magnification using the 7 mm tibial baseplate height as a reference. The cement–bone interface was drawn using the program at the pixel level. After this, a second line was drawn along the bottom of the tibial baseplate. The medial and lateral sides were then each split in half to create the 4 zones in accordance with The Knee Society [19]. The area between the lines represents the area of cement penetration; this value divided by the width of the zone gives an average depth of penetration (Fig. 1).

Statistical Analysis

The average penetration was compared between the liquid and dough phase groups. Since each pair of tibias had liquid cement on one side and dough cement on the other, the differences in average penetration could be paired for statistical analysis.

A randomized block design with the donor cadaver serving as the blocking variable was employed to control for cadaver specific factors such as comorbidities, sex, age, and race.

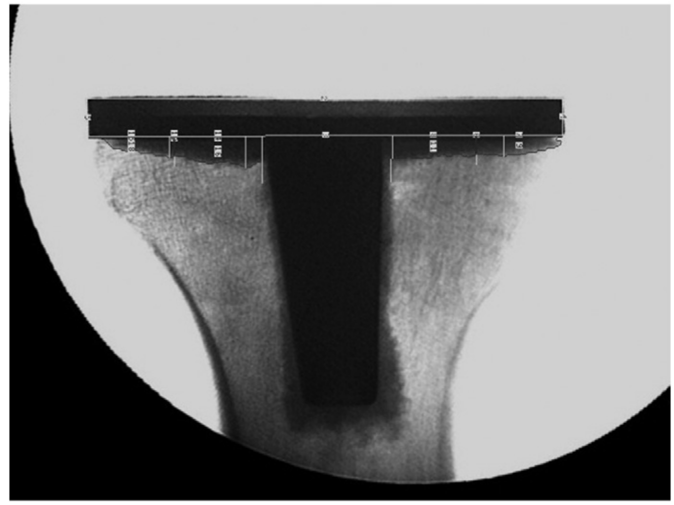

Fig. 1. A fluoroscopic image of a sample tibia with measurements is provided. The area of cement penetration in each zone was measured which was then used to calculate the average depth of cement penetration.

The mean cement penetration of the liquid and dough phase groups was compared in each x-ray zone using the paired *t*-test to account for matching. *P*-values are two-sided and considered significant at less than 0.05. All analyses were conducted and figures generated using SAS 9.2 (SAS Institute; Cary, NC).

Results

The five cadaver pairs came from a population of three males and two females with an overall mean age at death of 59.8 years. The overall average height, weight and BMI were 69 inches, 277.8 pounds, and 41 respectively. The BMIs of the individuals indicate that four of five were obese with BMIs of 33 kg/m^2, 44 kg/m^2, 53 kg/m^2 and 61 kg/m^2, while one male was underweight with a BMI of 13 kg/m^2. The underweight male (BMI 13) died at 79 years of age due to laryngeal cancer. The individuals with BMIs of 33, 44, 53 and 61 died due to renal cancer (70 years), congestive heart failure (51 years), breast cancer (52 years), and unknown (47 years). Three of the five cadavers were Caucasian, one was Hispanic and one was African American.

The size of the tibial component was chosen based on best fit with standard trials. Three tibia pairs received the same size component on both sides. Two of the five pairs differed in size by one. The patients are identified based on BMI. A patient with a BMI of A, a right tibial component size of B, and a left tibial component with size of C will be denoted as A (BR, CL). The patients are represented via the following: 13 (4R, 5L), 33 (4R, 4L), 44 (6R, 6L), 53 (4R, 3L), and 61 (5R, 5L).

The average cement penetration was greater in the dough phase tibia compared to the liquid phase tibia in all 5 cadaver pairs in AP zones 1 and 2, for 4 of 5 pairs in AP zone 3 and for 3 of 5 pairs in AP zone 4 (Fig. 2).

The mean average cement penetration was greater for the dough phase group compared to the liquid phase group across all x-ray zones and this difference was statistically significant in AP zones 1, 2, and 3 (Fig. 2).

Discussion

Much work has been dedicated to investigating the optimum conditions for cementation in total joint arthroplasty. Pulse lavage and bone surface preparation have been linked to improved cement penetration [6–8]. Other authors have investigated cement pressurization and suction [5,8]. The current study used third generation cementing techniques to compare cement penetration based on the viscosity of the cement.