Timing of femoral prosthesis insertion during cemented arthroplasty: cement curing and static mechanical strength in an in vivo model

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Accepted for publication June 24, 2010

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DOI: 10.1503/cjs.001110

Background: Modern cementing techniques aim to fix the implanted femoral prosthesis in the medullary cavity to minimize long-term complications such as aseptic loosening. The cure stage of bone cement into which the femoral component is being inserted is an important variable that is decided at the time of surgery. Late-cure cement is more viscous than early-cure cement and requires greater force on the part of the surgeon to insert the femoral prosthesis. We compared 2 cementing techniques, femoral component insertion into early-cure cement and insertion into latecure cement, using an in vivo model to identify if cement cure stage affects the strength of the bone–cement interface.

Methods: We performed bilateral hemiarthroplasties using only the femoral component in vivo on paired porcine femora. The femora were harvested and crosssectioned in preparation for strength testing. We measured bond strength by peak load required to push the femoral prosthesis and surrounding cement mantle free of the cancellous bone.

Results: All radiographs showed good cement interdigitation with no evidence of radiolucent lines at the bone–cement interface. We could not differentiate the early-cure and late-cure groups on postoperative radiographs. The mean failure load for the late-cure arthroplasties was 908 N (standard deviation [SD] 420 N), whereas the mean failure load for the conjugate early-cure arthroplasties was 503 N (SD 342 N).

Conclusion: Femoral component insertion into late-cure cement required significantly higher loads for push-out than femoral component insertion into early-cure cement.

Contexte : Les techniques modernes de cimentage visent à fixer la prothèse fémorale implantée dans la cavité médullaire de façon à minimiser les complications à long terme comme le descellement aseptique. Le stade de la prise du ciment orthopédique dans lequel la pièce fémorale est insérée constitue une variable importante qui est déterminée au moment de l'intervention chirurgicale. Le ciment à prise lente est plus visqueux que le ciment à prise rapide et oblige le chirurgien à exercer plus de force pour insérer la prothèse fémorale. Nous avons comparé 2 techniques de cimentage, soit l'insertion de la pièce fémorale dans du ciment à prise rapide et dans du ciment à prise lente en utilisant un modèle in vivo pour déterminer si le stade de la prise du ciment a un effet sur la solidité de l'interface os–ciment.

Méthodes : Nous avons pratiqué des hémiarthroplasties bilatérales en utilisant seulement la pièce fémorale in vivo sur des fémurs de porc jumelés. Les fémurs ont été prélevés et nous y avons pratiqué une coupe transversale pour préparer l'essai de résistance. Nous avons mesuré la force du cimentage en fonction de la charge maximale requise pour détacher la prothèse fémorale et le manteau de ciment qui l'entoure de l'os spongieux.

Résultats : Toutes les radiographies ont révélé une bonne interdigitation du ciment sans signe de lignes transparentes aux radiographies à l'interface os-ciment. Sur les radiographies postopératoires, nous n'avons pu distinguer les groupes où l'on a utilisé le ciment à prise rapide de ceux où l'on a utilisé le ciment à prise lente. La charge maximale moyenne s'est établie à 908 N (écart-type [ÉT] 420 N) dans le cas des arthroplasties où l'on a utilisé un ciment à prise lente et à 503 N (ÉT 342 N) dans celui des arthroplasties conjuguées où l'on a utilisé un ciment à prise rapide.

Conclusion : La pièce fémorale insérée dans un ciment à prise lente a exigé des charges beaucoup plus lourdes pour se détacher que la pièce fémorale insérée dans un ciment à prise rapide.

septic loosening is the most common long-term complication of cemented total hip arthroplasty (THA).¹⁻⁹ Modern cementing techniques aim to securely anchor the implanted femoral prosthesis to surrounding cancellous bone.^{10,11} Many factors influence the quality of the bone–cement interface, including creation of an appropriately sized femoral cavity, cleaning and lavage of the femoral canal, use of an intramedullary plug, retrograde injection of cement, maintenance of pressure within the cement before and after prosthesis insertion and cement viscosity.^{8,12–15}

Cement viscosity is important at 2 points during a THA: first, during initial injection of the cement into the femoral canal and, second, during insertion of the femoral prosthesis.^{47,16} Under in vitro conditions, the use of low-viscosity cement (i.e., cement in an early-cure stage) during initial injection appears to achieve better penetration into the femoral canal than high-viscosity cement (i.e., cement in a late-cure stage).^{68,17} Late-cure cement has achieved better results in vivo,¹⁸⁻²⁰ but it requires greater force to insert the implant, and the effects of increased insertion force on the bone–cement interface in vivo are unknown.

The timing of femoral component insertion on initial fixation has, to our knowledge, only been studied in vitro. Theoretically, if the prosthesis is inserted into late-cure cement, the pressures in the cement mantle during insertion would be higher,^{4,17,21} resulting in greater interdigitation of the cement into cancellous bone and a stronger initial bone–cement interface.^{8,17,22,23} This has been shown in a synthetic bone model without the effect of bleeding from the cancellous bone surface.^{16,24,25}

It is possible that component insertion into late-cure cement may be detrimental to initial fixation. The extra time required for the cement to reach a late-cure stage may provide additional opportunity for the deleterious effects of bone bleeding to inhibit interdigitation of cement within cancellous bone.²⁶ Alternatively, inserting a prosthesis into early-cure cement may increase canal pressure at a critical time, resulting in more extensive penetration of cement. In either case, the intention is to press cement further into the cancellous bone, tamponade bleeding bone and provide better initial fixation.^{27,28} The purpose of our study was to examine the effect of cement viscosity during prosthesis insertion on the quality of initial fixation for femoral prostheses in a live pig model. We aimed to provide clinical guidance on the timing of prosthesis insertion and ultimately determine whether it is better to insert the component soon after initial cement pressurization or to wait until the cement has partially cured.

METHODS

Surgical description

We conducted a study of cemented femoral implants with early-cure and late-cure bone cements on 13 Yucatan miniature pigs. All animal research was subject to review and approval by Memorial University's Institutional Animal Care Committee, which is governed by the Canadian Council on Animal Care. To the greatest extent possible, we used surgical techniques and materials that would mimic a human hip arthroplasty.^{29,30} Pigs were weighed and sedated under general anesthetic (haloflurane). All pigs were female with a mean weight of 44 (range 40-49) kg. After sedation, the hip was exposed through a posterior approach through a 10-cm incision along the hind flank. The surgeon identified the hip joint capsule and performed a posterior capsulectomy. The hip was then dislocated. The femoral head and neck were removed and the proximal femur prepared to accept the implant. The surgeon used a hand drill to open the canal and the Exeter #0 broach was inserted to the recommended depth. The proximal femur was then dried with surgical sponges; the femoral canal was not irrigated with pulsed lavage.

Once the femoral canal had been prepared, the bone cement (Stryker Simplex P Radiopaque bone cement) was mixed at 21°C for 2 minutes in a mixing pot (Stryker Advanced Cement Mixing System). One person was responsible for all cement mixing to minimize variability in technique. The bone cement was transferred to a 60-mL syringe and installed into a cement gun. An aliquot of bone cement was retained to determine when the cement would no longer adhere to a surgeon's glove. This generally took 3–3.5 minutes from the start of cement mixing. At this time, the surgeon removed the packing gauze and injected the cement retrograde into the femoral cavity. We recorded the time at injection. The surgeon maintained pressure over the filled femoral cavity with his thumb. To mitigate the possibility of cement leaking past a distal cement restrictor, we filled the entire femoral canal.

Each pig was its own control. We randomly assigned 1 hip to early-cure and the other to late-cure cement. After injection of the cement, the stem of the femoral prosthesis was inserted to the same depth (referenced from the greater trochanter) into the femoral canal at 1 minute (early-cure) or 3 minutes (late-cure). The surgeon maintained thumb pressure over the proximal femur until the prosthesis was inserted. The prosthesis was tagged with a serial number for identification. The conjugate procedure was then performed on the contralateral femur. After the completion of both arthroplasties and complete cure of cement, we euthanized the pigs by anesthetic overdose. Femurs, complete with implanted prostheses, were harvested, imaged by portable radiograph and refrigerated for 24 hours at 4°C.

Our femoral components were polymethylmethacrylate replicas of a Stryker Exeter AP 30° prosthesis. Based on preoperative radiographic templates, this size of femoral component appeared to be most appropriate. We used replicas (Fig. 1), as we were interested solely in the bone– cement interface and not the component–cement interface.³¹ The replicas were dimensionally identical to the metal prosthesis to mimic the same pressurization characteristics in the femoral canal during insertion. Preparation for mechanical testing was simplified by using the replicas because of elimination of the heat and metal debris generated when attempting to cut through a metal prosthesis surrounded by bone and cement. We employed a professional dental laboratory to manufacture the implants using a split-mould investment casting technique. The dimensional accuracy of each replica was verified against a standard by measurement at 7 reference points. All measurements were required to be within 0.2 mm of the original metal prosthesis. Each replica was pigmented to allow identification of the prosthesis against surrounding bone cement once implanted in the femur (Fig. 1).

Static mechanical testing

Our static mechanical testing model was designed to investigate the bone–cement interface. We felt that the ability of the interface to resist shear should correlate with the quality and extent of the cement interdigitation within cancellous bone. Precise bond strength measurement in an in vivo model is a complex measurement and difficult to reliably and accurately reproduce given the scope of this experiment. To develop a reliable, reproducible and representative test, it was necessary to deviate from some anatomic loading parameters that are addressed in more detail in the discussion section. Whereas long-term failure of the interface differs in some aspects from the mode of testing, the model that we developed was intended to be a surrogate measure of the strength of initial fixation.

After 24 hours of refrigeration, cross-sectional samples of the femur prosthesis unit were prepared with a slice perpendicular to the long axis of the femur using a 152-mm diameter, 230-tooth precision jeweler's saw. The position



Fig. 1. Femoral prosthesis (bottom) and polymethylmethacrylate replica (top).

of the femur was indexed from the head of the prosthesis in 3 coordinate planes to ensure that samples were retrieved from similar locations on each pair of femora. This procedure minimized proximal–distal and rotational variance in sample location between paired samples. Each femur was cross-sectioned into 10-mm slices.³²

Samples were prepared from the proximal metaphyseal region of the pig femora to isolate cement interdigitation within cancellous bone. The more distal regions of pig femora demonstrate very thick cortical bone and a very thin transition zone between the prosthesis and surrounding cortical bone. After cementing, the cancellous margin was completely obliterated, and we observed that the cement had bonded directly with cortical bone. Samples were individually loaded into an Instron 8874 equipped with an axial-torsional load transducer (p/n 662.10A-03)and holder that was adjusted to provide support to the rim of cortical bone³² (Fig. 2). We applied a distal-to-proximal load (in Newtons, N) to each cement core using a ram advanced at 3.5 mm/s sampling at 35 Hz. The ram was stopped after 4-mm displacement of the cement core. We defined failure as a peak load followed by a decrease in load with further displacement. We used the point of failure to assess the strength of the bone-cement interface. We generated failure curves for each sample by plotting load against displacement, and we analyzed the results with a paired *t* test, using a 0.05 level of significance (Fig. 2).

RESULTS

We used the first 2 pigs to standardize the surgical procedures and verify the test apparatus. Two pig femurs



Fig. 2. Jig used to hold specimens for testing.

from 2 different animals were damaged during sample preparation cutting operations and could not be included. Thus, in total, 9 pairs of early-cure and late-cure cement arthroplasties were available for static mechanical testing. Our sample randomization is described in Table 1.

All radiographs showed good cement interdigitation with no evidence of radiolucent lines at the bone–cement interface. We could not differentiate the early-cure and late-cure groups on postoperative radiographs.

Cross-sectional samples were prepared from all femora. Mechanical testing ended with either normal failure (i.e., the cement core was ejected smoothly from the medullary canal) or cortical bone failure (i.e., destruction of the rim of cortical bone by 1 or more radial fractures). In the most proximal region, 1 sample pair showed cortical bone failure and was excluded from further analysis. The mean failure load for the 8 remaining late-cure arthroplasties was 908 N (standard deviation [SD] 420 N), whereas the mean failure load for the conjugate early-cure arthroplasties was 503 N (SD 342 N). A paired *t* test indicated significantly higher load failure rates in the late-cure versus the early-cure samples (t = 2.37, p = 0.049). One sample pair (pig 5) demonstrated a reversal in the trend (Table 2).

DISCUSSION

The purpose of our study was to examine the effect of cement viscosity at the time of prosthesis insertion on the strength of the bone–cement interface. To our knowledge, previous work on this subject had only been done in vitro;^{5,25} in vivo studies had not investigated the timing of insertion of the femoral prosthesis. We felt that investigating the effect of active bleeding on exposed cancellous surfaces in a realistic surgical model would offer surgeons valuable information related to the timing of prosthesis insertion.

Table 1. Sample randomization table with roomtemperature and test day											
Pig	Surgical order	Cement cure stage	Temp., °C	Test day							
1	1st	Late	19.8	1							
	2nd	Early	20.0	1							
2	1st	Early	20.1	1							
	2nd	Late	20.0	1							
3	1st	Early	19.9	1							
	2nd	Late	19.9	1							
4	1st	Late	21.6	2							
	2nd	Early	21.6	2							
5	1s	Early	21.3	2							
	2nd	Late	21.4	2							
6	1st	Early	21.6	3							
	2nd	Late	21.6	3							
7	1st	Late	21.5	3							
	2nd	Early	21.6	3							
8	1st	Early	21.7	4							
	2nd	Late	21.6	4							

Pressurization of cement has been shown to improve fixation. Cement is pressured at 2 points during THA. The first pressurization point occurs when cement is introduced to the canal. Multiple techniques and instruments have been studied to evaluate their effect on initial pressurization.³³ Distal cement restrictors, retrograde cement guns and proximal devices to seal and prevent cement extrusion during pressurization have been developed for use in the most recent generation of cementing techniques.

The focus of our study was the second pressurization point, which is the introduction of the femoral prosthesis. The timing of insertion has been debated as a potential trade-off between greater cement pressures on one hand and deleterious effects of ongoing bleeding on the other. A delay in the second pressurization point may allow for more bleeding, negate the effect of canal lavage and cause hydrostatic resistance to cement interdigitation. Alternatively, a delay in prosthesis insertion may facilitate greater intramedullary pressures, which may be advantageous to cement interdigitation.

The use of pigs in our study provided a reasonable surrogate to human testing. Proximally, the anatomy of human and porcine femora are similar. Most importantly, the model accommodates the deleterious effect of bleeding. The pigs' proximal femora easily accepted the small prosthesis; however, reaming removed much of the cancellous bone distally. Unfortunately, a stem with a better anatomic fit to accommodate distal bone geometry was not commercially available. We choose the Exeter stem as, based on our preoperative radiographs, it allowed us to use a realistic surgical technique with a commercially available stem. Polymethylmethacrylate replicas of the Exeter stem simplified sample preparation; however, thermodynamic properties differ between the 2 materials. The genuine metal prosthesis has higher heat capacity and greater thermal diffusivity than the replicas, which would effectively slow the rate of cement cure; however, we cannot quantify to what extent the cure rate would be affected. We felt that the reduced risk of thermal damage to samples during cutting operations outweighed the potential changes in cure rate by using replica stems.

The main purpose of the stem was to pressurize and displace cement. The long-term performance of the prosthesis implanted in a pig was not of interest. We appreciate that the Exeter stem is a polished stem with unique mechanical properties. It was used in this study as a convenient component to displace and pressurize the cement. The

Table 2. Load to failure in Newtons											
Cement cure stage	Pig 1	Pig 2	Pig 3	Pig 4	Pig 5	Pig 6	Pig 7	Pig 8	Mean (SD)		
Early	273	98	400	409	1231	396	716	500	503 (342)		
Late	713	210	1406	735	768	1410	1270	750	908 (420)		
SD = standard deviation.											

component-cement interface was not of interest in our study. We believe any cemented stem would have similar impact on the bone-cement interface during insertion.

Technically, we felt testing the bone–cement interface in shear to be the most robust and reproducible method. It is reasonable to assume that more extensive interdigitation of cement would better resist shear forces. We designed our test jig to push out the cement cores from the crosssectional samples in a distal-to-proximal direction to negate any "wedge" resistance that the trapezoidal shape of the cement plug may encounter against surrounding cortical bone (Fig. 3).

Axial loading of femoral samples in a distal-to-proximal direction is not typical for implanted femoral prostheses, nor is it solely responsible for common adverse events observed in human THAs. It is, however, a means of testing the strength of the bone-cement interface in a way that accommodates local bone geometry. Loading of samples in a distal-to-proximal direction allowed the cement core to push free of the cancellous bone and avoid impingement of bone cement against cortical bone. Loading of the cement core in a proximal-to-distal direction, while more representative of the loads seen in vivo, was observed to cause the cement core to act as a wedge and eventually impinge upon the surrounding cortical bone (Fig. 3). When the cement plug impinged upon cortical bone, we observed cortical bone failure. Cortical bone failed in a burst pattern that was not representative of early subsidence of femoral components and therefore was not felt to be a good test of the fixation strength.

Our data showed that femoral prostheses inserted into late-cure cement required higher loads to displace the cement core from surrounding bone compared with pros-



Fig. 3. Specimen loading direction.

theses inserted into early-cure cement; that is, cement of higher viscosity produced significantly stronger initial bone–cement interfaces. Greater force on the part of the surgeon was required to advance the prosthesis to the correct depth in the femoral canal; we believe this greater insertion force generated higher intramedullary pressure, which displaced blood and forced cement into the surrounding porous cancellous bone, thereby resulting in a stronger bone–cement interface.^{4,16} One sample pair (pig 5) demonstrated a reversal in the trend. We suspect that the load recorded for the early-cure sample was influenced by contact between the cement mantle and surrounding cortical bone that yielded an abnormally high value.

Total hip arthroplasties in humans usually fail through cyclical loading. We chose static loading in this trial because we were primarily concerned about the strength of initial fixation early in the postoperative period. We were also concerned about the length of time required to cycle each sample and biological degradation of specimens during testing. Cyclical loading may be a consideration for future testing.

The strength of this interface is one of several important factors that contribute to initial mechanical fixation of hip arthroplasties.¹⁶ It is reasonable to assume that improved initial static strength of the bone-cement interface leads to better overall fixation and potentially improved clinical outcome. To maximize initial mechanical fixation at the bone-cement interface, surgeons should consider delaying femoral prosthesis insertion until the late-cure stage.^{16,22} However, they must keep in mind that although delaying femoral prosthesis insertion may result in greater static mechanical strength, it carries the possibility of preventing advancement of the prosthesis to the proper depth. Further work may determine the ideal time to insert the prosthesis to obtain the best quality bone-cement interface, but our work suggests that the ideal time should involve working with late-cure cement.

Competing interests: None declared.

Contributors: All authors designed the study and acquired the data. Drs. Hunt and Stone analyzed the data and wrote the article. All authors reviewed the article and approved the final version for publication.

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