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A Wax Barrier to Simulate Bone Resorption for Pre-Clinical Laboratory Models of Cemented Total Hip Replacements

Anjuli R Cherukuri¹, Mark A Miller¹, Amos Race¹, Timothy H Izant^{1,2}, and Kenneth A Mann¹

¹ SUNY Upstate Medical University, Syracuse, NY

² Syracuse Orthopaedic Specialists, Syracuse, NY

Abstract

Pre-clinical tests are often performed to screen new implant designs, surgical techniques and cement formulations. In this work, we developed a technique to simulate the cement-bone morphology found with postmortem retrieved cemented hip replacements. With this technique, a soy wax barrier is created along the endosteal surface of the bone, prior to cementing of the femoral component. This approach was applied to six fresh frozen human cadaver femora and the resulting cement-bone morphology and micromotion following application of torsional loads were measured on a transverse section of each bone. The contact fraction between cement and bone for the wax barrier specimens ($6.4 \pm 5.7\%$, range: 0.5 – 15%) was similar to that found in post-mortem retrievals ($10.5 \pm 10.3\%$, range: 0.4–32.5%). Micro-motions at the cement-bone interface for the wax barrier specimens (0.5 ± 1.06 mm, range: 0.005–2.66) were similar, but on average larger, than those found with postmortem retrievals (0.092 ± 0.22 mm, range: 0.002–0.73). The use of a wax barrier coating technique could improve experimental pre-clinical tests because it produces a cement-bone interface similar to those of functioning cemented components obtained following in vivo service.

Keywords

Pre-clinical model; arthroplasty; aseptic loosening; cement; hip replacement

INTRODUCTION

Pre-clinical experimental models are often used to test new implant designs, surface treatments, and cement formulations (Cristofolini et al., 2003; Jamali et al., 2006; Speirs et al., 2000; Stolk et al., 2002). Typically, cadaveric or composite saw bones are used with these model systems. With cemented implant systems, it is possible to simulate the surgical operation with control of thermal and haemodynamic conditions (Miller et al., 2007); but it is not possible to simulate the bony resorption that occurs at the cement-bone interface. Recent work in our lab from a series of radiographically well fixed en bloc retrievals has found that the cement-bone interface often has a thin gap and the presence of this gap allows

Corresponding Author: Kenneth A Mann, PhD, Upstate Orthopedics, SUNY Upstate Medical University, 3216 Institute for Human Performance, 750 East Adams Street, Syracuse, New York 13210, 315-464-9963, 315-464-6638 (fax), mannk@upstate.edu.

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for appreciable micromotion when functional loads are applied (Mann et al., 2010). In this work, we present an approach to create a thin interposed layer between the cement and bone using a compliant wax barrier. We asked three research questions: (1) are femora lined with a wax barrier comparable to en bloc retrieved cemented total hip replacements with regards to morphology and micro-motion?; (2) does apposition at the cement-bone interface correlate with micro-motion at the cement-bone interface in the wax barrier specimens?; (3) does the wax barrier approach give more realistic morphology and micro-motion when compared to conventional lab-prepared specimens?

METHODS

Six fresh-frozen cadaver femora (ave: 79 Yr, range: 61–90, all female) were obtained from our medical school willed body program. The proximal femora were stripped of soft tissue and the canals were broached and brush lavaged. Prior to cementing a femoral component, a wax layer was created along the endosteal surface of the femur for the purpose of creating a thin barrier to prevent direct apposition between the cement and bone during the cementing process. A soy-based wax (EcoSoya™CB-135, Maryville, TN) at 74° C was poured into the femoral canal (at 37° C) and immediately poured out. This process was completed two separate times to build up the wax layer. A soy-based wax was chosen because of its low melting point (43° C) and high compliance at body temperature. A mock Exeter stem (cast from PMMA cement) was then cemented into each femur with the bone temperature maintained at 33° C. The femur with the cemented implant was sectioned transversely into 10mm slices using a water irrigated silicon carbide blade. One section from each construct, located 10mm distal to the lesser trochanter, was chosen for morphologic analysis and mechanical testing. Prior to mechanical testing, the wax was re-melted leaving a gap between cement and bone. Images were captured of the specimen surface and a multi-step image processing approach was used to document contact fraction and gap thickness between the cement and bone (Mann et al., 2010). The specimens were then mounted to a torsional loading device that was placed in a saline bath. Details of the loading device and micro-motion measurements can be found in (Race et al., 2010). Torques to 0.73N-m of retroversion and 0.22N-m of anteversion were applied and motion of the transverse section during loading was captured. The retroversion torque was chosen to insure that the specimens were not damaged during testing, and was representative of a torque generated during gait by a 78 kg individual (Race et al., 2010). The anteversion torque was chosen to be a fraction (30%) of the retroversion torque such that a full excursion of interface micro-motion could be achieved without damaging the specimen. The relative motion (micro-motion) across the cement-bone interface was quantified using a digital image correlation (DIC) technique and was calculated at the extremums of loading. That is, the total micro-motion at the cement-bone interface was calculated moving from the anteversion to retroversion loading states.

The results from the wax barrier specimens were compared to eleven post-mortem retrieval specimens from a previous study (Mann et al., 2010) which had been in service from 0.2 to 20 years. The postmortem retrievals represent the gold standard for comparison purposes. Two types of conventional laboratory-prepared specimens using the same approach as described above but without wax barrier served as negative controls; one using a cadaveric femur and one using a synthetic femur (SawBones, Vashon, WA). An Analysis of Covariance (ANCOVA) was used to determine if contact fraction had the same effect on micromotion for wax barrier and postmortem retrieval specimens.

RESULTS

The wax barrier successfully created a gap between the cement and bone (Figure 1a) and resembled typical retrieval specimens (Figure 1b). The contact fraction between cement and bone for the wax barrier specimens ($6.4 \pm 5.7\%$, range: 0.5 – 15%) was similar to that found in post-mortem retrievals ($10.5 \pm 10.3\%$, range: 0.4–32.5%) (Table 1). Cement-bone gap thicknesses were larger for the wax barrier approach (median thickness 0.45 ± 0.23 mm, range: 0.12–0.73 mm) when compared to post-mortem retrievals (0.19 ± 0.15 mm, range: 0.05–0.57 mm). Micro-motions at the cement-bone interface for the wax barrier specimens (0.5 ± 1.06 mm, range: 0.005–2.66) were similar, but on average larger, than those found with post-mortem retrievals (0.092 ± 0.22 mm, range: 0.002–0.73). The relationship between interface micro-motion and interface apposition (Figure 2) illustrates how the wax barrier method and postmortem retrievals exhibit similar responses. ANCOVA results showed a strong inverse relationship between (log) contact fraction and (log) micromotion ($r^2=0.87$, $p<0.0001$) following a log-log transformation. The interaction term (contact fraction * type, $p=0.372$) indicated that (log) contact fraction had the same effect on (log) micromotion for the postmortem and wax barrier specimens. There was not a significant difference ($p=0.073$) effect of 'type' (postmortem or wax barrier), but the wax barrier had, on average, slightly higher micromotion for the same contact fraction. This is likely due to the larger gap size.

In contrast, the standard lab-prepared specimen with cadaver bone had greater cement-bone contact fraction ($58.5 \pm 4.8\%$) and lower micro-motion (0.0016 ± 0.0018 mm) when compared to the post-mortem retrievals. Similar behavior was found for the synthetic bone specimen, which had 37% contact fraction and 0.0004 mm micro-motion.

DISCUSSION

The results of this study suggest that lining the inside of the femoral canal with a thin wax barrier can produce a cement-bone morphology and interface micro-motions in laboratory-prepared specimens that are similar to that of post-mortem retrievals. While showing promise, the wax barrier method used here resulted in cement-bone interface gaps that were thicker than what was found in retrievals. Modifications to the wax fill and drain method could be made to result in a thinner wax barrier in the future.

In our retrievals, gaps between the cement and bone were usually not filled with organized fibrous tissue. Our goal with the wax was to create a barrier to cement infiltration into trabecular spaces during the cementing process which, when subsequently warmed to 37°C, would become very compliant and not resist loading at the interface. The utility of the approach is better appreciated when the results for laboratory prepared specimens with cadaver bone and synthetic bone, created without the wax barrier, are contrasted with the retrieved and wax barrier specimens. For standard lab prepared specimens there were very large amounts of cement-bone apposition and correspondingly small micro-motions at the cement-bone interface. This provides evidence that traditional laboratory prepared specimens, even when applied to cadaver bones using simulated surgical conditions, do not result in constructs that adequately reproduce the morphology and micromechanics of the cement-bone interface, beyond the immediate postoperative state. It is interesting to note that the micro-motion of the most well fixed (least motion) postmortem retrievals (0.002 mm) had motions that were similar to the laboratory prepared specimens with the most motion (0.002 mm) despite the laboratory prepared specimens having a much larger contact fraction.

Barrier methods have been used successfully to simulate extensive fibrous tissue at the cement-bone interface through use of a thick (1mm+) silicone layer (Waide et al., 2004a;

Waide et al., 2004b) in synthetic femurs. While the silicone layer is useful to understand the biomechanics of a loose component, it would not be as relevant for investigating the early progression of loosening. In addition, the elegant technique used by Waide and coworkers to create the silicone layer would be much more challenging to achieve in a cadaver bone. The use of a wax barrier coating technique developed here could improve experimental pre-clinical tests because it produces a cement-bone interface similar to those of functioning cemented components obtained following in vivo service. This technique could be extended to other cemented applications including knee and shoulder implants.

Acknowledgments

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Figure 1.

Transverse sections of wax barrier (A & B), postmortem retrieval (C & D), and laboratory prepared (E & F) cemented femoral components. A white paint layer was added to the regions of cement-bone gaps to more clearly render the interface morphology. The close up images illustrate the cement (c), wax (w), and bone (b). Note the large amount of interdigitation between cement and bone in the laboratory prepared specimen (E).

Figure 2.

Median micro-motion at the cement-bone interface was inversely proportional to interface contact fraction for the cemented femoral components tested in torsion. The cadaver specimens with the wax barrier method gave responses within the range found for the postmortem retrievals.

Table 1

Measures of morphology and micro-motion at the cement-bone interface for post mortem retrievals, cadaver femora cemented following coating endosteal surface using the wax barrier method, and standard laboratory prepared specimens using a cadaver femur and synthetic femur. Mean, (standard deviation), and [range] shown.

	Contact Fraction (%)	Median Gap Thickness (mm)	Median Interface Micromotion (mm)
Post-mortem Retrievals (n=11)	10.48 (10.26) [0.4 – 32.5]	0.19 (0.15) [0.05 – 0.57]	0.092 (0.216) [0.002 – 0.73]
Cadaver Bone with Wax Barrier Method (n=6)	6.40 (5.68) [0.5 – 15.02]	0.45 (0.23) [0.12 – 0.73]	0.50 (1.06) [0.005 – 2.66]
Cadaver Bone w/o Wax Barrier Method (n=5)	58.6 (4.80) [52.9 – 64.2]	0.0*	0.0012 (0.0011) [0.0002 – 0.002]
Synthetic Bone w/o Wax Barrier Method (n=1)	37.5	0.034	0.0003

* because more than 50% of the interface was in contact between cement and bone, the median gap thickness was zero for all cases using cadaver bone without wax barrier.