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A MODIFIED PMMA CEMENT (SUB-CEMENT) FOR ACCELERATED FATIGUE TESTING OF CEMENTED IMPLANT CONSTRUCTS USING CADAVERIC BONE

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Abstract

Pre-clinical screening of cemented implant systems could be improved by modeling the longer-term response of the implant/cement/bone construct to cyclic loading. We formulated bone cement with degraded fatigue fracture properties (Sub-cement) such that long-term fatigue could be simulated in short-term cadaver tests. Sub-cement was made by adding a chain-transfer agent to standard polymethylmethacrylate (PMMA) cement. This reduced the molecular weight of the inter-bead matrix without changing reaction-rate or handling characteristics. Static mechanical properties were approximately equivalent to normal cement. Over a physiologically reasonable range of stress intensity factor, fatigue crack propagation rates for sub-cement were higher by a factor of 25 ± 19 . When tested in a simplified 2 1/2D physical model of a stem-cement-bone system, crack growth from the stem was accelerated by a factor of 100. Sub-cement accelerated both crack initiation and growth rate. Sub-cement is now being evaluated in full stem/cement/femur models.

Keywords

Arthroplasty; cement; fatigue; pre-clinical test; sub-cement

Introduction

Although cementless implants have become increasingly popular, particularly in the North American market, polymethylmethacrylate (PMMA) cement is still widely used to secure orthopaedic implants within bone. Despite its long clinical history, the behavior of the cement mantle in an implant/cement/bone construct is poorly understood. This has led to unexpectedly poor clinical outcomes for some novel cemented implants (Barrack, 2000; Huiskes, 1993; Walker, 2000). It is clear that we need to develop a better understanding of cement mantle

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function if the clinical efficacy of cemented implants is to be improved. This will require more detailed analyses of postmortem retrievals and improvements in both physical and computational models. Although computational models are steadily gaining in sophistication (Stolk et al., 2003), we believe that physical models are still important. A physical model can reveal certain “unknown unknowns”: unexpected phenomena that one would not have thought to include in a computational model. For example, computational models have generally treated cement mantle interfaces as homogeneous entities that were either bonded or frictional. However, recent work has shown that these interfaces are more complex than had been previously assumed. Interface gaps, residual stresses and micro-cracks are formed during cement curing, affecting stem stability and damage accumulation processes (Lennon and Prendergast, 2002; Race et al., 2002; Race et al., 2005; Race et al., 2006). Having observed an unexpected phenomenon it was then possible to generate an improved computational model (Mann et al., 2007)). The work reported herein was focused on developing better physical models of the implant/cement/bone system.

Laboratory-based models using cadaver bones provide the best opportunity to generate clinically realistic cement mantles. However, although it is possible to generate a realistic stress distribution in a proximal cadaver femur (Stolk et al., 2001), stress concentrations at loading points cause unrealistic cortical fatigue-fractures during long-term tests (Race et al., 2006). In addition, long-term cadaver based tests run into difficulties because of tissue degradation. Therefore, the key feature of our proposed physical model was formulation of bone cement with degraded fatigue fracture properties (Sub-cement) designed to have a time-scaling effect such that long-term fatigue could be simulated successfully in short-term cadaver tests.

Our goal was to develop Sub-cement that was equivalent to Standard PMMA cement, in terms of static material properties and handling characteristics, but which accelerated fatigue crack propagation sufficiently to allow reliable simulation of at least 2 million cycles of loading in a stem/cement/femur construct.

Methods

Criteria for Successful Sub-cement

In our previous cadaver testing work, we had found that most cadaver femora had reliably survived up to 100,000 cycles of loading in a stair-climbing simulator (Race et al., 2006). Longer fatigue loading had resulted in increasing frequencies of fracture of the greater trochanter or mid-diaphyseal spiral-fracture (both of these failure modes were due to the inevitable non-physiological stress concentrations close to the fatigue-loading fixtures). Therefore, reliably simulating 2 million loading cycles required that fatigue crack propagation be accelerated by a factor of at least 20 relative to Standard cement.

It has recently been shown that the degree of apposition of a cement mantle interface affected its function and that apposition was highly dependent on the viscosity of the cement used (Race et al., 2005; Race et al., 2006). Therefore, in order that our proposed physical model generate realistic interfaces, it was important to demonstrate that Sub-cement handled/cured in the same way as Standard cement.

Single-cycle failure strength was considered to be less important, since cement mantles generally fail through fatigue rather than static overload (Jasty et al., 1991). However, for the stress distribution in a stem/Sub-cement/bone construct to reasonably reflect that found in vivo, the modulus and yield stress of Sub-cement should match that of Standard cement.

A further factor to consider was the dynamic creep-rate of Sub-cement. Ideally, dynamic creep would be accelerated to the same degree as fatigue crack propagation, but this was beyond the

scope of the current work. Dynamic creep rates were measured for the selected Sub-cement formulation to complete the characterization of its material properties.

Sub-cement Formulation

We chose the commonly used Simplex-P (Stryker Orthopaedics Inc., Mawah, New Jersey) as our baseline Standard cement. Based on previous reports that reducing the molecular weight (Mw) of PMMA reduced its fatigue life (Graham et al., 2000), we attempted to create suitable Sub-cement by manipulating Mw. Two fundamental strategies were adopted, changing the make-up of the pre-polymerized powder and changing the polymerization process.

Our first approach was to substitute lower-Mw PMMA powder (~25Kg/mol, un-sterilized, Polysciences Inc, Warrington PA) into the powder component of Standard cement (~200Kg/mol in the case of sterilized Simplex-P). In order to match the viscosity/time profile of the Standard cement, the particle size distribution of the substitute powder had to be carefully controlled. We used commercially produced ~ 25Kg/mol PMMA which was supplied as 200micron beads. These beads were ground and sieved to give a range of particle sizes. The viscosity of these Sub-cement candidates was primarily controlled by altering the proportion of small particles (less than 20 microns).

In our second approach, we lowered the Mw of the polymerizing matrix. This was accomplished by adding a chain-transfer agent (1-dodecanethiol; Acros Organics USA, Morris Plains New Jersey) to the monomer component of the cement. During polymerization, a chain transfer agent can terminate a growing polymer chain and simultaneously generate a free-radical, which begins a new polymer chain. This allowed us to reduce the Mw of the inter-bead matrix without changing reaction-rate or handling characteristics.

Test Methods

Sub-cement candidates were compared to Standard control specimens manufactured and tested using the same protocols and equipment. Our evaluation of sub-cement candidates involved a total of 7 experimental procedures, which are summarized, along with relevant outcome measures, in Table 1. All mechanical tests were conducted at 37°C in de-ionized water using an MTS Mini-Bionix test frame with FlexTest II controller.

Candidate cements were initially screened by measuring fatigue crack propagation rates. Subsequently, promising formulations were tested for handling characteristics and static material properties. The best formulation was then tested for dynamic creep properties and validated in a simplified stem/cement/bone model.

Specimen preparation—The cement components were measured by weight, mixed for 1.5 minute in a Mixevac mixer (Stryker Orthopaedics Inc., Mawah, New Jersey), with the last minute under a vacuum of -27”Hg, and poured into an aluminum trough (8×45×125mm). Because 1-dodecanethiol (a mercaptan) is malodorous and potentially irritating, uncured Sub-cement containing it was handled in a fume-hood. When the cement had cooled it was transferred into de-ionized water at 37°C, where it was stored for 1–4 weeks. These bars were then machined into appropriate test specimens using a CNC milling machine (flat specimens for tensile testing) or a lathe (cylindrical specimens for compressive testing).

Fatigue Crack Propagation—Fatigue Crack Propagation (FCP) rates were measured over a physiologically reasonable range of cyclically applied loads. The test methods followed the ASTM-E647 Standard and details (and rationale for choice of loads) have been reported previously (Race and Mann, 2008). In brief, FCP testing measures the rate of crack-growth during cyclic loading of a standardized specimen. The rate of crack-growth per cycle (da/dN)

is then related to the Cyclic Stress Intensity Factor (ΔK), a measure of the crack driving force. FCP data are usually reduced to a power-law of the form: $da/dN = C \cdot \Delta K^m$. For a given standard specimen, ΔK increases with the applied load and with the crack length. Crack length was estimated using a compliance method (ASTM E647-A2; (Race and Mann, 2008)), which meant that the crack opening displacement had to be monitored during testing. This was done using a small, submersible LVDT, which required that the standard Compact Notched Tension (CNT) specimens were slightly modified (Fig 1).

Viscosity/time characteristics—In order to define the handling characteristics of Standard and Sub-cement, we measured viscosity/time characteristics using a couette flow viscometer (Brookfield Engineering, Middlefield, Mass). The viscosity of PMMA based powder/liquid cements is highly dependent on shear-rate. We chose to use the low shear-rate of 1/sec, believing that it was the best approximation of conditions during cement insertion and pressurization (lower shear rates were considered, but we were concerned that the cement flow would not equilibrate fast enough to capture accurate readings as the viscosity changed over time). The curing kinetics of PMMA cements are also highly dependent on ambient temperature during mixing and the humidity at which the powder was stored. Prior to making viscosity measurements, batches of powder were removed from their packaging and allowed to equilibrate for 3 days in laboratory air. All viscosity/time trials were conducted at a temperature of 21°C after the cement powders had been stored at a relative humidity of 13–22%. Preliminary trials demonstrated that vacuum mixing did not substantially change the viscosity results over the range we were concerned with, so the cement samples were hand-mixed.

Bulk Static Properties—Standard material property tests for plastics were performed to determine compressive (ASTM D695) and tensile (ASTM D638) material properties. Compressive tests were carried out using cylindrical specimens of diameter ~6.3mm and height ~13mm. Compressive strain was monitored using a submersible LVDT mounted across the compression platens. Tensile tests were performed using ASTM D 638 Type V “dog-bone” specimens. Within the 10mm gage-length, these specimens had a width of 3.8mm and depth of 4.0mm. Tensile strain was monitored using a submersible clip-on extensometer.

Bulk Dynamic Creep—Tensile and compressive dynamic creep was assessed using techniques similar to those previously applied to PMMA cement by other workers (Verdonschot and Huiskes, 1994; Verdonschot and Huiskes, 1995). Both compressive and tensile specimens were sinusoidally loaded from 0.5–10MPa at 3Hz for 250,000 cycles (a frequency of 3Hz was chosen to correspond to the frequency we are accustomed to using when testing stem/cement/femur specimens). Due to concerns over maintaining the position of a clip-on gage during the tensile dynamic creep tests, specimen elongation was monitored using an optical displacement mapping system. This required that the specimens be speckled, to provide contrast in the digital images. Speckling was achieved with an aerosol of black paint. Periodically, cyclic loading was intentionally interrupted and the specimens were digitally imaged over the course of a ramp loading cycle using a telecentric lens. Images were indexed to the load data by using a TTL signal from the camera to initiate the load-ramp. For the compressive dynamic creep tests, strains were determined using a submersible LVDT. Creep strains were deduced from linear fits of load/strain data.

Validation in a Simplified Stem/Cement Interface Model—Following the development phase, the most promising Sub-cement was validated against Standard bone cement in a simplified “2 1/2-D” torsional loading model of the stem/cement/bone system (Fig. 2). This model, which has been described previously (Hertzler et al., 2002), was developed to

look at crack development from the corner of a femoral stem. Unlike the FCP studies, this model incorporated not only crack propagation but also crack initiation.

The cements were vacuum mixed and poured into a short aluminum cylinder, representing the femur, which contained a section of satin-finished “stem”. The cured cement was then milled/ground flush with the “stem” and “femur”. Opposite to the ground face, the “stem” incorporated a square boss, which was used to apply a torque via a lever-arm connected to the axial actuator of the MTS (Fig. 2). During testing, the specimens were submerged in 37°C DI water. A sinusoidal load was applied to the lever arm at 5Hz, which resulted in a torque of 2 – 20Nm. Loading was stopped at regular intervals to allow crack lengths to be measured using a traveling microscope. It was found that proper visualization of the cracks required that they be stained with black ink. In order to accomplish this, the specimens were briefly removed from their water bath.

Results

Although many potential sub-cements were tested, the data we present in this paper are focused on the best formulations of each modification method. The cement compositions, for standard batches, were as follows:

Method 1 - POWDER { 19.2g Simplex-P powder [14.4g poly(methylmethacrylate-co-styrene), 2.6g PMMA, 1.9g BaSO₄, 0.3g Benzoyl Peroxide] + 20.8g 25kg/mol PMMA [70% 11–20 micron diameter, 30% 20–75 micron diameter] LIQUID { 19.6g Simplex-P liquid [19.1g MMA, 0.5g dimethyl-p-toluidine]};

Method 2 - POWDER {40g Simplex-P powder} + LIQUID (18.4g Simplex-P liquid + 0.2g 1-dodecanethiol).

Fatigue Crack Propagation Rates

Sub-cement formulation was firstly based on the addition of low molecular weight (Mw) PMMA beads to Standard cement. This strategy showed promise for lower values of ΔK . For Sub-cement made with 55% low Mw powder, the ratio of Fatigue Crack Propagation (FCP) rates for Sub-cement and Standard cement was between 5 and 10 (Fig 3). However, at higher (still clinically plausible) values of ΔK , the crack-growth rates of the Sub-cement were too high.

The addition of 1.1% 1-Dodecanethiol increased FCP rates by a factor of, on average, more than 20. Over a physiologically reasonable stress-intensity range (0.25–0.7MPa. $\sqrt{m}$), FCP rates were higher by a factor of between 6 and 44 (Fig 4).

Handling Characteristics

The viscosity/time characteristics of the 1-Dodecanethiol based sub-cement were indistinguishable from those of the Standard cement (Fig 5). This meant that we could be confident that cement mantles generated using Sub-cement would be morphologically equivalent to those using Standard cement.

Static Properties

With the exception of tensile failure stress (UTS), the static properties of 1.1% 1-Dodecanethiol Sub-cement were broadly equivalent to those of Standard cement (Table 2). Since tensile yield stresses were equivalent, the lower UTS of Sub-cement was not deemed a problem.

Dynamic Creep

Dynamic creep rates for tensile loading were significantly higher than those for compressive loading (Fig. 6). The responses of Sub-cement and Standard cement were very similar, both in tension and in compression.

Crack Development in a Simplified Stem/Cement Interface Model

In the 2-1/2-D model, crack development was accelerated by a factor of about 100 when using Sub-cement (Fig 7). This acceleration factor was greater than that predicted by the FCP tests. Some of this difference might be due to the increased tensile modulus (Table 2) raising the local stress intensity factor despite identical external loads. However, it is likely that the bulk of the difference in the rate of crack development was due to faster crack initiation.

Discussion

This study sought to develop a pre-clinical screening tool for cemented implants by time-scaling fatigue tests. Our plan was to develop fatigue susceptible cement, which would generate a normal mantle morphology and stress/strain distribution when used in an in vitro arthroplasty. We have shown that our proposed Sub-cement has the same handling/curing characteristics as Standard cement, so we can be confident that Sub-cement mantles will be morphologically correct. This, and the fact that Sub-cement's static material properties are broadly equivalent to those of Standard cement, means that we can also be confident that the stress/strain distribution in a Sub-cement mantle will be correct.

Relation to prior work

Other workers, recognizing the need for better pre-clinical assessment of cemented components and the problems inherent in using cadaver bones for fatigue studies, have recommended using synthetic femora (Britton and Prendergast, 2005; Cristofolini et al., 2003; Cristofolini et al., 2007; Maher and Prendergast, 2002) and have been able to show differences between stems with different clinical success rates. Whilst these studies are undoubtedly useful, we think that cadaver based testing (and, therefore, Sub-cement) is still important as it may reveal more subtle effects. Although synthetic femora simulate cortical bone very well (Cristofolini et al., 1996), the foam cancellous bone analog that they contain is not realistic for cemented applications. The closed cell foam does not permit realistic interdigitation, leading to non-clinical mantle morphology and making a clinical Grade-A mantle (showing 'whiteout' on X-ray) impossible. In addition, although the bulk mechanical properties of the foam may match those of cancellous bone, the trabecular scale properties are quite different. Because of the differences in trabecular structure and mechanical constraint, cement mantles made in synthetic femora do not display the same interface gaps or curing-induced microcracks that are seen in cadaver based mantles (Cristofolini et al., 2007).

Limitations

The primary limitation of our proposed cadaver based pre-clinical screening test is the lack of bone remodeling, in particular, the lack of osteolysis in response to wear debris and pressure cycling. There are two basic failure scenarios involving lysis: 1) osteolysis leads to failure of unsupported cement mantle; 2) cement mantle failure leads to osteolysis (Sundfeldt et al., 2006). The first scenario could not be predicted using a cadaver model. However, the second scenario, whilst it could not be directly modeled, could be inferred by combining cement fracture, stem micromotion, and stem roughness measures. If a through-crack is generated in a mantle, then greater cyclic stem motions would generate greater pressure cycles, transport debris from the joint space and interface, and, depending on stem finish, generate more debris at the stem/cement interface. The fact that, in clinical practice, early RSA measures strongly

predict later loosening prior to signs of osteolysis (Mjoberg et al. 1990; Karrholm et al., 1997) suggests that in vitro measures of cement fracture and micromotion could be predictive of clinical success.

A further limitation of our proposed method is that fatigue crack growth was accelerated more in the 2-1/2-D validation model (Fig. 7) than in the FCP tests (Fig. 4). We suspect that faster crack initiation (in the 2-1/2 D model) was the reason. This means that Sub-cement based models would be more conservative in estimating the risk of newly initiated cracks versus the extension of pre-existing cracks (induced during cement mantle curing).

The Sub-cement method is also limited by the fact that fatigue failure was accelerated but cyclic creep was not. This would likely result in an overestimate of fatigue damage, making the proposed pre-clinical screening test more conservative.

Concluding Remarks

Although our suggested Sub-cement is not a perfect time-scaled match for Standard cement (lower tensile strength, non-constant fatigue acceleration factor), it has the great advantage that its “normal” handling characteristics will produce “normal” cement mantles. Furthermore, it is very simple to produce. We believe that these factors make Sub-cement a useful tool for assessing the longer-term function of cemented implants.

Having succeeded in producing Sub-cement that can accelerate in-vitro fatigue testing of cemented components by about two orders of magnitude, it is now being evaluated in full stem/cement/femur models.

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Figure 1.

Compact Notched Tensile (CNT) specimen used for Fatigue Crack Propagation Rate experiments. The standard CNT specimen was modified to allow Crack Opening Displacements to be monitored using a Submersible LVDT (a more conventional clip-gage was not used as its spring force would have been of the same order as the applied loads). An aluminum clamp, which held the LVDT, was fixed to the CNT specimen with two 0–80 machine-screws. The LVDT core bore upon a semi-circular protrusion, which was centered on the V×1 standard measuring location defined by ASTM E647-A2. The initial crack tip was formed with a jeweler's saw followed by a razor-cut.

Figure 2.

Simplified torsional loading model used to validate the accelerated fatigue properties of Sub-cement versus Standard cement. A cyclic torque was applied, via a lever arm, to a bar that had the cross-section of a generic stem. The Cobalt-Chrome “stem” was satin-finished using a bead-blaster. The “stem” (12mm by 22mm) was embedded in vacuum mixed cement, which, in turn, was supported by a textured aluminum “cortex” (Ø36mm, 9mm long) fixed to the base of an MTS load-frame. The minimum mantle thickness was 8mm. Crack growth from the corners was monitored using a traveling microscope. The cracks were highlighted using black ink. Fatigue loading was conducted at 5Hz in 37°C DI water.

Figure 3.

Fatigue Crack Propagation (FCP) rates versus Cyclic Stress Intensity Factor (ΔK) for Standard cement ($n=8$) and Sub-cement ($n=4$) made with 55% low Mw powder. Note the marked discontinuity in the Sub-cement data at around $\Delta K = 0.5 \text{ MPa} \cdot \sqrt{\text{m}}$. Line fits are drawn to show 95% confidence intervals. $R^2 = 0.72$ (Sub-cement), 0.87 (Standard).

Figure 4.

Fatigue Crack Propagation (FCP) rates versus Stress Intensity Factor (ΔK) for Standard cement ($n = 8$) and Sub-cement ($n = 6$) made with 1.1% 1-Dodecanethiol in the monomer component. Line fits are drawn to show 95% confidence intervals. $R^2 = 0.97$ (Sub-cement), 0.87 (Standard).

Figure 5.

Chart of Apparent Viscosity versus Time (at a shear rate of 1/sec) for Standard cement and Sub-cement made with 1.1% 1-Dodecanethiol. Tests were conducted at temperatures ranging from 20.5 to 21.6 °C, storage humidity was in the range 15 to 22%. The Standard cement showed batch-to-batch variability, but had a consistent shape. The results for Sub-cement were indistinguishable from those of Standard cement. Times to reach 1000Pa.s (corresponding to the “does not stick to glove” criterion, when we would normally initiate cement injection) were 5.6 ± 0.2 min (Sub) and 5.4 ± 0.6 min (Standard). Times to reach 2000Pa.s (when we would normally insert a stem) were 6.8 ± 0.3 min (Sub) and 6.8 ± 0.8 min (Standard). Both times were statistically equivalent ($\alpha=0.05$, $\Delta=20\%$).

Figure 6.

Dynamic creep data for Sub-cement and Standard cement under both tensile and compressive cyclic loads of 0.5 – 10Mpa. Regression lines are the average of the power-law fits for each specimen. ANOVA was conducted for the *power-law exponents*, with *load* (compressive/tensile) and *cement* (sub/standard) as factors: *load* ($p = 0.0002$); *cement* ($p = 0.20$); *load*cement* ($p = 0.33$).

Figure 7.

Chart of Crack-length versus Cycles for Sub-cement ($n = 4$) and Standard cement ($n = 4$) in the 2-1/2D model. In this validation test, Sub-cement accelerated crack-growth by a factor of ~ 100 . The solid grey line is a logarithmic fit of the Sub-cement data. The dashed black line is a copy of the Sub-cement fit, shifted by two orders of magnitude. 95% confidence intervals (grey areas) are shown for the log-fits of both Sub-cement and Standard cement data.

Table 1

Summary of test methods and outcome measures.

Property	Method	Primary Outcome
Fatigue resistance	ASTM E647 Fatigue crack propagation Simplified stem-cement-bone model (Hertzler, 2002)	Fatigue crack propagation rate vs. ΔK (Figs. 1, 3 & 4) Crack length vs. loading cycles (Figs. 2& 7)
Handling characteristics	Viscosity measurement	Apparent viscosity vs. time (Fig 5)
Bulk static properties	ASTM D965, compressive failure test for plastics. ASTM D638, tensile failure test for plastics.	Compressive yield stress & secant modulus (Table 2) Tensile yield stress & secant modulus (Table 2)
Bulk creep properties	Dynamic compressive creep (Verdonschot & Huiskes, 1995) Dynamic tensile creep (Verdonschot & Huiskes, 1994)	Compressive creep vs. loading cycles (Fig 6) Tensile creep vs. loading cycles (Fig 6)

Table 2

	Compression data				Tension data			
	Ultimate Compressive Stress (MPa)	Yield stress (MPa)	Yield strain (%)	Secant Modulus (GPa)	Ultimate Tensile Stress (MPa)	Yield stress (MPa)	Yield strain (%)	Secant Modulus (GPa)
Standard cement (n = 6+6)	98.4 ± 2.5	70.0 ± 2.5	2.47 ± 0.08	2.84 ± 0.10	54.6 ± 2.1	34.4 ± 1.3	1.65 ± 0.10	2.09 ± 0.11
Sub-cement (n = 6 +6)	83.5 ± 2.8	61.3 ± 1.4	2.30 ± 0.06	2.66 ± 0.06	44.3 ± 1.2	33.9 ± 1.4	1.43 ± 0.07	2.37 ± 0.04
Sub/Simp %	85%	88%	93%	94%	81%	99%	87%	114%
p(Sub = Standard)	<0.0001	<0.0001	0.004	0.006	<0.0001	0.58	0.004	0.0007
Equivalence test $\alpha=0.05, \Delta=20\%$	Equivalent	Equivalent	Equivalent	Equivalent	Not	Equivalent	Equivalent	Equivalent