Published in final edited form as:

J Biomech. 2015 January 2; 48(1): 59–64. doi:10.1016/j.jbiomech.2014.11.002.

Subject-Specific Planning of Femoroplasty: An Experimental Verification Study

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Abstract

The risk of osteoporotic hip fractures may be reduced by augmenting susceptible femora with acrylic polymethylmethacrylate (PMMA) bone cement. Grossly filling the proximal femur with PMMA has shown promise, but the augmented bones can suffer from thermal necrosis or cement leakage, among other side effects. We hypothesized that, using subject-specific planning and computer-assisted augmentation, we can minimize cement volume while increasing bone strength and reducing the risk of fracture. We mechanically tested eight pairs of osteoporotic femora, after augmenting one from each pair following patient-specific planning reported earlier, which optimized cement distribution and strength increase. An average of 9.5(±1.7)ml of cement was injected in the augmented set. Augmentation significantly ($P<0.05$) increased the yield load by 33%, maximum load by 30%, yield energy by 118%, and maximum energy by 94% relative to the non-augmented controls. Also predicted yield loads correlated well ($R^2=0.74$) with the experiments and, for augmented specimens, cement profiles were predicted with an average surface error of <2mm, further validating our simulation techniques. Results of the current study

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Author Contributions: All authors were fully involved in the study and preparation of the manuscript. The material within has not been and will not be submitted for publication elsewhere.

Conflict of Interest Statement: None declared.

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suggest that subject-specific planning of femoroplasty reduces the risk of hip fracture while minimizing the amount of cement required.

Keywords

Femoroplasty; Cement Augmentation; Planning; Mechanical Test

1. Introduction

Osteoporotic hip fractures are costly and constitute a major health problem worldwide (Lane et al., 2000; Elffors, 1998). Current preventive measures include hip protectors, which cause discomfort and are limited due to patient non-compliance, and a variety of drugs, limited in efficacy due to long delays in restoring bone strength, high costs, and side effects such as an increased risk of cancer (Delmas et al., 1997; Ettinger et al., 1998; Khovidhunkit and Shoback, 1999; Kannus et al., 2000). In addition, previous hip fracture is a significant risk factor for subsequent hip fracture (Johnell et al., 2004); however, current preventive measures involving drugs target a long-term cure and are not effective for contralateral hip fracture, which occurs 6-10 times more frequently and within a year in patients who have already suffered an osteoporotic hip fracture (Dinah, 2002). An alternative preventive intervention is femoral bone augmentation—also referred to as femoroplasty—which is the process of injecting acrylic bone cement into the proximal femur to prevent osteoporotic hip fractures (Beckmann et al., 2007; Beckman et al., 2011; Heini et al., 2004; Sutter et al., 2010a). Femoroplasty increases the strength and energy to failure of the femur and can be performed minimally-invasively with less hospitalization costs and reduced recovery time (Beckmann et al., 2011; Fliri et al., 2012). However, the side effects associated with femoroplasty may include thermal necrosis, toxicity of the cement, and embolism (Jefferiss et al., 1975) and it is desirable to use the minimum amount of cement possible to achieve the goals of augmentation.

In a recent report (Basafa & Armand, 2014), we described our approach to computer-assisted planning of femoroplasty to optimize cement volume and placement. In summary, we showed that by introducing less than 10ml of bone cement into the femur (substantially less than the 40-50ml volumes used in previous experimental studies (Beckmann et al., 2007; Heini et al., 2004; Sutter et al., 2010a)), it is possible to increase the yield load of the femur specimens by greater than 30%. Our model predictions, however, have not been validated. The purpose of the current study is to experimentally augment cadaveric femora according to our specimen-specific plan using a navigation system to control volume and placement of cement injection. We hypothesize that the resulting cement augmentation will increase the mechanical strength of the femur compared to non-augmented controls. We also hypothesize that the experimentally measured augmented parameters of interest will not be significantly different than model predictions; moreover, these results will be achieved with cement volumes less than previously reported for significant augmentation. Outcome parameters of interest are femoral yield and maximum strength as well as energy to yield and failure.

2. Methods

Pre-Operative Planning

We have described in detail our proposed planning strategy of femoroplasty elsewhere (Basafa & Armand, 2014). Briefly, eight pairs of osteoporotic femur specimens, five males and three females, obtained from the Maryland State Anatomy Board, were cleaned of soft tissue, computed tomography (CT) scanned (Aquilion 64 CT System, Toshiba America Medical Systems, Tustin, CA), and subsequently frozen at -20°C . At time of death, average($\pm$ SD), age was $80(\pm 8)$ years, height was $172(\pm 10)\text{cm}$, and weight was $79(\pm 21)\text{Kg}$. Dual-Energy X-ray Absorptiometry (DEXA) scans (Lunar DPX-NT, Lunar Corp, Madison, WI) determined an average femoral neck T-score of $-3.63(\pm 0.62)$, confirming osteoporosis. One femur from each pair was selected randomly for augmentation. Augmentation planning consisted of two phases: first a finite element (FE) model of the femur was created following a procedure described earlier (Basafa et al., 2013a). The optimized cement distribution profile was determined using a modified method of Bi-directional Evolutionary Structural Optimization (BESO) (Basafa & Armand, 2013). The goal of BESO was to find minimum volume of cement that increased the predicted yield load of the specimens by 100%. In the second phase, a particle diffusion model (Basafa et al., 2013b) combined with local optimization attempted to find the closest match to the BESO-defined profile through simulating a surgically realistic injection of no more than 9ml through, at most, three injections of 3ml each (Figure 1).

The effect of augmentation plan was assessed by performing paired sample t-tests on the mean differences in the predicted yield load between control and augmentation sets.

Specimen Preparation and Pre-Operative Registration

One day before testing, femora were taken out of the freezer and left at room temperature to thaw. At the time of augmentation, we removed the remainder of soft tissue from the femur selected for augmentation and attached a tracking rigid body with reflective markers (NDI, Waterloo, ON, Canada) (Figure 2(A)). We used an in-house navigation system (Otake et al., 2009) to register the bone specimen in the tracking system's coordinate frame to its corresponding CT volume frame: first three landmarks—i.e., the most proximal point on the femoral head, lateral most point on the greater trochanter, and the protrusion point of the lesser trochanter—were manually identified on the surface model of the femur (Figure 2(B)). We then approximately identified the corresponding landmarks on the femur specimen using a tracked digitizer (Passive Probe, NDI, Waterloo, ON, Canada). A rigid transformation between the two sets of points provided a rough registration between the tracking camera coordinates and the CT coordinates. We then digitized patches of surface points on the femur and performed a point cloud-to-surface registration using the Iterative Closest Point (ICP) algorithm (Besl & McKay, 1992) to refine the patient-to-model registration (Figure 2(C)).

Intra-Operative Augmentation and Mechanical Testing

We used a cordless hand drill (DCD760, DeWalt Industrial Tool Co., Baltimore, MD) with a custom attachment for mounting the tracking rigid body, and the navigation system to drill

the (first) injection path. The navigation system visually guided the user to the desired location for drilling while providing real-time feedback of the distance and angle errors of drill placement. Once the bone was drilled, we proceeded to cement preparation: five grams of radiopaque Spineplex (Stryker Instruments, Mahwah, NJ) bone cement powder was mixed with 4.5ml of the monomer liquid for about 60 seconds. A 5ml syringe was then filled with the cement and a 15cm, 8G cannula (Scientific Commodities Inc., Lake Havasu, AZ) was attached to the syringe and mounted in a custom designed injection device (Kutzer et al., 2011). Since the number of viscosity estimations and hence the amount of cement needed for that was not known a priori, and also since some unused cement was left in the cannula after each injection, we filled the syringe with slightly more than the 3ml needed volume. After removing the air and a wait time of 12 minutes from the start of mixing, we estimated the cement viscosity at one minute intervals by ejecting 0.25ml of cement at a rate of 0.05ml/s (five seconds) and averaging the syringe pressure during the last second (Basafa et al., 2013b) until it approached the desired value of 200Pa-s. This value was found experimentally to result in a sufficiently dense cement shape while low enough not to increase the injection pressure beyond syringe and injector capacities (Basafa et al., 2013b). We then quickly moved the injection system to the desired injection location inside the bone and the injection device injected the remainder of the syringe content at a controlled rate of 0.05ml/s. Augmentation images were captured using fluoroscopic image snapshots at the end of each injection. The procedure of injection (and drilling, if necessary) was repeated for all of the planned injections. The injected volume in each specimen was estimated using the encoder recordings of the injector after each test.

After augmentation, specimens were CT scanned and then mechanically tested in a configuration simulating a fall to the side on the greater trochanter (Sutter et al., 2010a). For each specimen, yield load was determined as the first inflection point of the load-displacement curve (Figure 3) obtained from the servohydraulic testing machine (MTS 858, MTS Eden Prairie, MN). Maximum load was also recorded. Yield energy and maximum energy were calculated as the area under the load-displacement curve up to the yield and maximum loads, respectively. Paired sample t-tests for mean differences between control and augmented specimens determined the significance ($P < 0.05$) of augmentation on yield load, maximum load, yield energy, and maximum energy between control and augmentation sets.

Post-Operative Error Analysis

The post-injection CT scans of the augmented specimens were loaded in 3D Slicer (Pieper et al., 2006) and were manually aligned to their pre-injection counterparts. Automatic registration using rigid transformations followed this initial alignment for precise registration. FE analyses were then performed on the augmented specimen models developed from those post-injection scans to determine the yield load and stiffness.

To determine how closely the planned injections and actual cement distributions matched, we performed error analyses on the resulting cement profiles (Figure 4). We assumed two sources of error: 1) navigation (e.g., registration, tool calibration, final cannula placement, etc.), and 2) simulation (e.g., simplifying assumptions, non-exact segmentation, etc.). To

separate the effect of these sources of error we first created isosurfaces of the injected and planned cement clouds. An ICP registration between the two isosurfaces registered the post-operative CT-based cement surface to the one created using the simulated planned CT volume and estimated the navigation error. The ICP registration procedure identified a rigid transformation that moved the post-operative surface to a new pose where it better “fit” the simulated one. We decomposed this transformation (rotation and translation) into three X-Y-Z Euler angles, named ψ , Θ , and Φ , respectively (for rotation), and a linear distance (norm of the translation vector). These numbers represented the cumulative errors occurring in the placement of the cannula during augmentation. We then calculated the mean shape error between the registered isosurfaces by finding, for each vertex on one surface, the closest vertex on the other one and measuring their distance, representing the deviation of SPH diffusion simulations from the experiments.

3. Results

FE analyses predicted an average yield load of $2249(\pm 769)\text{N}$ for the control group, while that of the augmentation group *before augmentation* was $2348(\pm 879)\text{N}$ and not significantly different from the control group ($P=0.380$). BESO simulations generally suggested augmentation of superior and inferior aspects of the neck as well as supero-posterior aspect of the greater trochanter (Basafa & Armand, 2014) to achieve the desired outcome with the least amount of cement. For the simulated augmentation plans (using at most 9ml of cement injection to match the optimally found BESO volume), FE analyses predicted an average yield load of $3101(\pm 718)\text{N}$ for the augmented femora (38% increase compared to the control group, $P<0.001$). Of note, for seven specimens, 9ml of injection were planned while for specimen #8 the addition of a third injection did not improve the predicted yield load. Therefore only two injections (6ml) were planned.

On average, $9.5(\pm 1.7)\text{ml}$ of cement was injected inside the eight femora experimentally, which was slightly different than the plan due to the limitations mentioned in Methods section. Fracture experiments showed that augmentation significantly increased the yield load by 33% (3131N vs. 2351N , $P<0.001$), maximum load by 30% (3336N vs. 2576N , $P=0.026$), yield energy by 118% (12.0N.m vs. 5.50N.m , $P=0.030$) and maximum energy by 94% (17.8N.m vs. 9.16N.m , $P<0.001$) in the augmented specimens compared to the control group. There were no significant differences ($P>0.100$) between predicted and measured yield loads of femora. Also, predicted yield loads of augmented specimens based on plan and post-injection CT scans were not different ($P>0.100$). Table 1 details the results for each paired test. Overall both measured and predicted mechanical parameters improved after augmentation as compared to the controls (Figure 5). Also, the overall measured yield loads correlated well ($R^2=0.74$) with predictions (Figure 6).

Error analyses on the isosurfaces of the cement yielded the following average numbers for the ICP registration: $\psi=5.86(\pm 4.62)$, $\Theta=5.13(\pm 3.54)$, and $(\Phi=5.04(\pm 2.40)$ degrees (X-Y-Z Euler rotation angles) and 6.86mm average distance movement for the eight specimens. These represent the intra-operative error of the injector placement and navigation. The average surface distance error between the two isosurfaces after ICP registration, representing simulation errors, was $1.77(\pm 0.32)\text{mm}$. Figure 7 shows an example of

segmented cement isosurfaces before and after the ICP registration. Table 2 reports the individual errors for the specimens.

4. Discussions

Results of the current study support our original hypothesis that femoroplasty increases the load and energy to yield and failure compared to non-augmented controls. A few recent studies reported attempts at restoring the mechanical strength of femur specimens by relatively small amount of injection of bone cement, with limited or no success (Sutter et al., 2010b; Beckmann et al., 2011; Fliri et al., 2012; van der Steenhoven et al., 2011). Our preliminary experiments on eight pairs of osteoporotic femora showed that we can achieve significant improvement in the mechanical response of the specimens by injecting less than 10ml of PMMA bone cement. This is far less than the amounts used in the successful gross filling technique (40-50ml) (Beckmann et al., 2007; Heini et al., 2004; Sutter et al., 2010a). This supports the hypothesis that employing subject-specific models and optimization, along with intra-operative tools for precise cement delivery, reduces the required cement volume.

Our data also support the second assumption that there was no significant difference in predicted yield load and the experimentally measured loads, thus lending support to the value of FEM analysis in predicting the augmentation effect of femoroplasty. Furthermore there were relatively small errors (<7 mm distance and <6 degrees of rotation angles on average) in cannula placement and navigation. Contributing factors to this placement error include intra-operative patient registration and tool calibration. For the eight specimens, our patient-to-model registration error averaged at <0.6 mm. Moreover, the pivot calibration error for the drill attached to the injector was approximately 1mm due to the flexibility and length of the drill bit. These registration and calibration errors can be reduced with improved hardware design. We also note again that the navigation system provided visual feedback to the user who manually moved the drill and subsequently the injector to the desired location and that human error, presumably, constitutes a large portion of the errors. Use of robotic systems may alleviate the need for manual injector placement and reduce the overall error.

Another point of comparison was the shape difference between predicted and experimentally achieved cement clouds, averaging at <2 mm, further validating the diffusion simulation technique. In our original validation study of the cement diffusion model (Basafa et al., 2013b) we simulated smaller (3ml) volumes with a resulting surface accuracy of about 1mm. The similar error levels for larger volumes in the current study denote that the accuracy of capturing cement injection shapes is not affected by the injection volume. Of note, because of the previously mentioned limitations, some specimens were injected with a slightly different volume than the target 9ml and this also contributed to errors in cement shape as well as load predictions.

Among the other limitations of this study was the technique used to separate the sources of error, i.e., injector placement and diffusion simulation, which provides merely an approximation. The determination of the placement error may be improved by finding the location of the cannula tip during the surgery using X-ray images and 2D/3D registration methods (Otake et al., 2012).

We note that the FE simulations of yield load for augmented specimens were less predictive compared to those of control, as reflected in the lower coefficient of determination (Figure 6). The simplifying assumptions regarding the bone-cement integration and boundary (simulated as a rigid connection) could have contributed to the lesser accuracy. It is also possible that a larger sample size could yield better statistical inferences. These must be investigated in future research.

So far we have focused only on the falls to the side as, reportedly, they are the most prevalent causes of hip fractures (Parkkari et al., 1999). A recent study showed that, for single-legged stance loading condition, augmentation of superior and inferior of the femoral neck close to the cortex results in the most favorable outcome (Palumbo et al., 2014), which is consistent with what optimizations suggested in the current study. However, backward falls or even daily activities such as walking can cause fracture in osteoporotic hips. The best augmentation strategy for those loading conditions is currently unknown. A comprehensive planning strategy should, ideally, take into account several scenarios and decide on the best augmentation strategy for each patient.

The increase in the fracture loads and energies as reported in this study does not necessarily translate to zero fracture risk for these subjects. The risk of fracture also depends on a variety of factors including patient anatomy, height of fall, floor covering etc. (Parkkari et al., 1997; Kannus et al., 1999; Bhan et al., 2014). A patient-specific model of the fall such as the ones developed by Robinovitch et al. (1991; 1997) could help the surgeon estimate the impact load and set the goal of augmentation accordingly.

Future research must also verify the assumption that by keeping the injection volume to a minimum one can manage to avoid thermal necrosis caused by exothermic curing process of the cement. Such a study will involve monitoring the surface and/or internal temperature of the bone tissue. Attaching temperature sensors to the surface of the femur is fairly straightforward; however, measuring the internal temperature will likely require more sophisticated protocols and tools. Additionally, a validated model for the heat generation and propagation could be incorporated into the planning module in order to design safer augmentations by keeping the heat damage away from the more vulnerable sites such as the arteries.

In this study, we reported a promising first attempt at computer-assisted biomechanical planning and navigated execution of femoroplasty. We note that additional experiments are required to fully validate and refine the approach, prior to reaching our long-range goal of successful application of this preventive surgery as a routine clinical procedure.

Acknowledgments

We thank Mr. Demetrios Boston and Mr. Evan Langdale of the Johns Hopkins Bayview Medical Center for their help regarding harvesting and preparing the specimens, acquiring CT scans, and performing the mechanical tests. This work was supported by grants no. R21-EB007747 and R21-AR063815 from National Institutes of Health. The funders had no role in the study design, data collection, analysis of the data, writing of the manuscript, or the decision to submit the manuscript for publication.

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Figure 1. Schematic of an augmentation suggested by BESO simulations (green) and planned path and locations of injection (blue)

Figure 2.

(A): Injection setup, (B): Initial registration using the transformation between the picked points (yellow dots) and pre-determined landmarks (numbered red dots), (C): ICP registration results using surface traced points (yellow).

Figure 3.
Representative force-displacement curves for a pair of specimens.

Figure 4.

Two-dimensional schematics describing quantification of intra-operative (offset) and simulation (shape) errors. A: initial overlay of simulated (red) and experimentally obtained (blue) cement isosurfaces, after CT volume registration. The two isosurfaces are essentially triangular surface meshes that enclose the cement volumes (triangles and vertices not shown for clarity). B: corrective rotation (Θ) and translation (d) identified by ICP registration that align post-operative surface onto the simulated one. In three dimensions, there are two additional rotations along X and Z axes, and the translation is a three-dimensional vector. These numbers represent injector placement error. C: after alignment, average surface distance is measured to quantify shape discrepancy, represented by the light grey area, between the two isosurfaces.

Figure 5. Effect of augmentation on yield and maximum load (left) and yield and maximum energy (right). Error bars represent standard deviations.

Figure 6.

Measured vs. predicted yield loads. The overall correlation is $y = 1.00x + 147$, $R^2 = 0.74$.

Figure 7.
Comparison of cement isosurfaces before (left) and after (right) ICP registration. Red indicates the planned cement distribution while blue indicates the cement cloud obtained from post-operative CT scan.

Table 1

Results of femoroplasty. F_y and F_u represent yield and maximum loads in N, respectively, and E_y and E_u denote yield and maximum energies in N.m, respectively. “Pre”, “Plan”, and “Post” denote the FE analyses results performed on the augmented specimens based on preoperative, plan-based simulated, and post-operative CT volumes, respectively.

PairNumber	Control						Augmented					
	Predicted			Measured			Predicted			Measured		
	F_y	F_u	E_y	F_y	F_u	E_y	F_y (Pre)	F_y (Plan)	F_y (Post)	F_u	E_y	E_u
1	2105	2460	2490	4.98	5.49	2250	2250	2540	2655	2990	10.9	10.9
2	3300	3180	3180	8.78	8.78	3420	3420	3655	3850	4190	14.9	17.8
3	3495	4170	5410	7.95	16.8	3905	3905	4550	4520	4470	29.9	35.2
4	2215	2100	2150	5.91	7.21	1670	1670	3080	2470	3500	12.7	17.2
5	1890	1340	1460	1.89	2.87	2290	2290	2880	2875	2280	5.38	6.68
6	1320	1200	1510	2.23	17.0	1485	1485	3040	2350	2170	3.66	25.0
7	2075	2420	2420	5.51	5.51	2180	2180	2840	2815	3630	11.5	11.5
8	1590	1940	1990	6.72	9.64	1580	1580	2225	2030	3460	6.68	18.2
Mean ($\pm$ SD)	2249 ($\pm$ 769)	2351 ($\pm$ 970)	2576 ($\pm$ 1273)	5.50 ($\pm$ 2.46)	9.16 ($\pm$ 5.21)	2348 ($\pm$ 879)	2348 ($\pm$ 879)	3101 ($\pm$ 718)	2946 ($\pm$ 830)	3336 ($\pm$ 823)	12.0 ($\pm$ 8.22)	17.8 ($\pm$ 8.99)

Table 2

Summary of the errors. ICP measures denote the translation and rotations needed to register the post-operative isosurface to the corresponding simulated one. Shape errors are the average distance between the vertices of the experimental and simulated isosurfaces.

Specimen Number	Shape Error <i>Before</i> ICP Registration of the two Isosurfaces (mm)	ICP δd (mm)	ICP ψ (degrees)	ICP θ (degrees)	ICP ϕ (degrees)	Shape Error <i>After</i> ICP Registration of the two Isosurfaces (mm)
1	3.54	15.4	3.81	10.3	7.37	1.47
2	3.43	9.66	4.68	5.17	3.01	2.40
3	2.11	3.87	2.57	6.81	3.71	1.45
4	2.58	5.21	0.13	2.81	1.28	1.62
5	2.45	5.30	4.49	3.36	4.18	1.75
6	3.41	7.22	15.3	9.79	7.94	2.09
7	2.50	4.28	7.70	2.00	7.43	1.76
8	2.41	4.44	8.23	0.82	5.38	1.62
Mean ($\pm$ SD)	2.80 ($\pm$ 0.56)	6.92 ($\pm$ 3.92)	5.86 ($\pm$ 4.62)	5.13 ($\pm$ 3.54)	5.04 ($\pm$ 2.40)	1.77 ($\pm$ 0.32)