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A Biomechanical Evaluation of Femoroplasty under Simulated Fall Conditions

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Abstract

Objectives—To test the hypotheses that, compared with controls 1) femoroplasty (the injection of bone cement into the proximal femur in an attempt to prevent fragility fracture) increases the yield and ultimate loads, yield and ultimate energies, and stiffness of the proximal osteoporotic femur in a simulated fall model; and 2) the manner in which the cement distributes in the proximal femur affects the extent to which those mechanical properties are altered.

Methods—In 10 pairs of osteoporotic human cadaveric femora, we injected 1 femur of each pair with 40 -- 50 mL of polymethylmethacrylate bone cement; the noninjected femur served as the control. The filling percentage was calculated in 4 anatomical regions of the femur: head, neck, trochanter, and subtrochanter. All specimens were biomechanically tested in a configuration that simulated a fall on the greater trochanter. Student's t test, linear regression, and multinomial logistic regression statistical analyses were conducted where appropriate, with significant difference defined as $P < 0.05$.

Results—Femoroplasty significantly increased yield load (22.0%), ultimate load (37.3%), yield energy (79.6%), and ultimate energy (154%) relative to matched controls, but did not significantly change stiffness (-10.9%). There was a strong ($r^2 = 0.7$) correlation between yield load and filling percentage in the femoral neck.

Conclusions—This study showed that 1) femoroplasty significantly increased fracture load and energy to fracture when osteoporotic femora were loaded in simulated fall conditions and 2) cement filling in the femoral neck may have an important role in the extent to which femoroplasty affects mechanical strength of the proximal femur.

Keywords

femoroplasty; hip fracture; osteoporosis; prophylactic; bone cement

Introduction

As the population increasingly ages, the incidence of hip fractures and the associated medical costs are expected to grow rapidly.^{1,2} After hip fracture, the 1-year mortality rate is 23%, only 30% to 40% of patients regain autonomy in daily life activities,^{3,4} and previous hip fracture is a significant risk factor for subsequent fracture.⁵ Prevention of osteoporotic fractures involve muscle strengthening exercises, the use of hip protectors,^{6,7} and an array of pharmacologic

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The bone cement has been approved by the FDA, but not for the manner in which it was used in this study.

options.⁸⁻¹⁰ However, there are many issues associated with the use of such agents, eg, cost, regimen, and time requirements, all of which can inhibit efficacy.¹¹⁻¹³ A surgical intervention to increase the strength of the proximal femur might be desirable, particularly for patients who have the highest risk of fracture and who cannot tolerate other treatment modalities. Femoroplasty, the injection of bone cement into the proximal femur to augment femoral strength and prevent fracture, is one option of mostly unknown potential.

Femoroplasty has experimentally been shown to increase fracture load and energy to fracture in quasi-static loading conditions.^{14,15} However, the quasi-static load rate used in those studies does not simulate the experience of a fall. The purpose of our study was to investigate the ability of femoroplasty as a prophylaxis to attenuate the potential for fracture under simulated fall conditions. Specifically, the purpose of our study was to test the hypotheses that 1) femoroplasty would increase the yield and ultimate load, yield and ultimate energy, and stiffness in an osteoporotic cadaver model subjected to a simulated fall; and 2) the manner in which the cement distributes in the proximal femur affects the extent to which the mechanical properties are altered.

Materials and Methods

Specimen Preparation

Ten pairs of fresh-frozen osteoporotic (t score < -2.516) human femora [5 males and 5 females; mean age ($\pm$ SD), 73.0 ± 8.7 years at time of death] were obtained from the State Anatomy Board. Osteoporosis was confirmed with Dual Energy X-Ray Absorptiometry (Discovery QDR Series, Hologic Inc., Bedford, Massachusetts) to measure bone mineral density (BMD). The mean t score was -3.1 ± 0.6 and the mean apparent BMD was 0.568 ± 0.079 g/cm². All specimens were scanned with computed tomography (CT) at 1-mm thick slice intervals with axial orientation (Aquilion 64 CT System, Toshiba America Medical Systems, Tustin, California). One femur from each pair was randomly chosen for femoroplasty, and the contralateral femur was used as the control specimen. All femora were stored in sealed plastic bags at -20°C until 1 day before testing, at which time they were removed from the freezer and allowed to thaw overnight to room temperature in the same sealed plastic bags.

In femora chosen for augmentation, an 11-gauge cannula with trocar (Stryker Instruments, Kalamazoo, Michigan) was inserted under fluoroscopic guidance into the lateral aspect of the intertrochanteric region parallel to the femoral neck axis. Spineplex bone cement (Stryker Instruments) was prepared, and immediately loaded into 5-mL syringes and manually injected under fluoroscopic guidance (Phillips BV 300 C-Arm, Eindhoven, Netherlands). Based on the results of pilot studies, 40 mL of cement were injected initially into all femoroplasty femora. If at that time the investigator could not depress the plunger of the syringe to inject additional cement into the femur, or if extravasation of the cement occurred, injection ceased. Otherwise, an additional 10 mL of cement were injected.

All femoroplasty specimens were again scanned with CT at 1-mm thick slice intervals to document cement filling before testing (Fig. 1). Volume measurements taken from CT data were made with Vitrea Imaging Software (Vital Images, Inc., Minnetonka, Minnesota) to determine the cement filling percentage in 4 regions of the femur (head, neck, trochanter, and subtrochanter) (Fig. 2). For each region, percentage filling was calculated by dividing the calculated cement volume by the calculated open volume (total volume less cortical and trabecular volume). The respective materials were segregated by defining the appropriate density range for each material. The Hounsfield scale from the CT scans was used in the Vitrea software to define threshold values for the respective materials. Because the Hounsfield scale is absolute, these values were consistent and standardized across all specimens. The same investigator performed all volume measurements and calculations. The accuracy of the volume

measurements taken from the CT data was verified by comparing the calculated volume of total cement taken from CT data with that of the known injected physical quantity for each of the 10 femoroplasty specimens. The average difference between these values was 5.1%, and calculated and measured volumes were strongly ($r^2 = 0.8$) correlated.

The femora were transected with a surgical oscillating saw 25 cm inferior to the superior aspect of the greater trochanter to remove the condyles, and the distal portion of the femur was potted in a polyvinyl chloride pipe using polymethylmethacrylate bone cement (FastTray, Bosworth Co., Skokie, Illinois) and loaded into the testing fixture. All specimens were biomechanically tested in a configuration that simulated a fall on the greater trochanter, as described in a previous study¹¹ (Fig. 3). The femurs were positioned so that the axis of the femoral shaft was rotated 10 degrees below a horizontal plane parallel to the MTS table and the shaft was rotated internally 15 degrees. The greater trochanter was supported by a dollop of bone cement to distribute reaction loads. The femora were free to translate in the horizontal plane and were fixed distally to prevent rotation about the diaphyseal axis. The femoral head was pre-loaded to 40 N through a nylon surrogate acetabulum attached to the actuator of a materials testing machine (MTS Bionix 858 Test System, MTS, Eden Prairie, Minnesota). The actuator was displaced downward at a rate of 100 mm/s until failure occurred.¹⁷ A displacement rate of 100 mm/s reportedly results in a time to peak force of approximately 30 ms,¹¹ which is consistent with a fall on the greater trochanter.¹⁷ Load and displacement data were recorded at 1024 Hz. Yield load was defined as the first inflection point of the load versus displacement curve (Fig. 4), and ultimate load was defined as the load immediately preceding a sharp drop in load. Yield energy and ultimate energy were calculated as the area under the load-versus-displacement curve to yield load and ultimate load, respectively. Stiffness was calculated as the slope of the linear portion of the load versus displacement curve.

After fracture, all specimens were again scanned with computed tomography to document fracture location and whether the fracture occurred through cement for femoroplasty specimens. Fracture locations were classified according to the Orthopaedic Trauma Association system¹⁸ and then summarized into 4 categories (intertrochanteric, subtrochanteric, basicervical, and subcapital).

Statistical Analysis

Significant differences, defined by $P < 0.05$, in the variables of interest (yield and ultimate load, yield and ultimate energy, and stiffness) between the femoroplasty and control groups were determined using a 2-tailed, paired t tests. Multiple linear regressions were used to check for effects of BMD, percentage filling, physical injected volume, and calculated injected volume on the variables of interest. For categorical outcome variables (fracture location and whether fracture occurred through cement), multinomial logistic regressions were used. All data were analyzed using Stata9 (StataCorp LP, College Station, Texas).

Results

For control specimens, there was no significant correlation between BMD and yield load, ultimate load, yield energy, stiffness, or fracture location; there was a weak ($r^2 = .4$) correlation between BMD and ultimate energy.

Compared with control specimens, the femoroplasty specimens had significantly higher values in the following parameters: mean yield load, mean ultimate load, mean yield energy, and mean ultimate energy. Stiffness was not significantly different between the 2 groups (Table 1).

In the 10 femoroplasty specimens, there was an array of fracture locations¹⁸: 4 intertrochanteric, 3 subtrochanteric, 2 basicervical, and 1 subcapital. In the 10 control

specimens, 1 fracture was basicervical and 9 fractures were through the trochanter (Fig. 5). Of the 10 femoroplasty specimens, 2 fractured at the cement boundary and 8 fractured through the cement. No significant associations were found between fracture through cement or fracture location and loads, energies, or stiffness.

The percentage filling in the neck ($95.7\% \pm 2.0\%$) and trochanter ($84.0\% \pm 7.3\%$) regions was less varied than the filling in the head ($45.0\% \pm 18.5\%$) and subtrochanteric ($76.9\% \pm 22.2\%$) regions. The only strong correlation was between neck regional percentage filling and yield load ($r^2 = 0.7$).

Three of the femoroplasty specimens were filled with 40 mL of cement and 7 were filled with 50 mL. No significant associations were found between physical total volume and loads, energies, or stiffness.

Discussion

The results support our original hypothesis that yield load and yield energy would be greater in femoroplasty specimens than in control specimens. It is unknown, however, if the 22.0% increase in yield load and 79.6% increase in yield energy would be enough to prevent fracture in a real fall. Our results also support our original hypothesis that ultimate load and ultimate energy would be greater in femoroplasty specimens than in control specimens. Femoroplasty appears to extend the plastic region of the force-displacement curve (Fig. 4). Thus, augmented specimens had higher ultimate loads and absorbed more energy than did controls. The major structural contribution of the cement appears to be that it load-shares after yield has initiated in the femur. Cement placed in the neck region appears to have the greatest effect on increasing the yield load. It is unknown if the increase in ultimate load and energy caused by femoroplasty would be sufficient to prevent propagation of a fracture and to limit damage during a fall.

In our study, femoroplasty had no significant effect on stiffness. This result may seem counterintuitive, but considering the lower modulus of elasticity of cement relative to cortical bone, one would expect the stiffening effect of cement to be modest.^{19,20} Based on the composite nature of the femoroplasty specimens, it appears that bone governs the pre-yield behavior of the femur. Once fracture occurs, it is likely that the composite formed by trabecular bone encased in cement determines the mechanical response.

Previous studies have investigated femoroplasty using the same setup configuration used in the current study that simulates the orientation of the hip during a fall on the greater trochanter.^{14,15} However, although these studies claim to reproduce a fall, they used a quasi-static loading rate (2 mm/s), which does not adequately simulate the dynamic nature of a fall.¹⁷ Our results are consistent with those previously reported by Heini et al,¹⁵ i.e., femoroplasty results in increased fracture load and energy to fracture. Because our specimens were osteoporotic and had substantially lower BMD than did those of Heini et al,¹⁵ one might anticipate a reduction in the outcome parameters. However, such a reduction seems to have been offset by the effects of the faster loading rate used in the current study. Courtney et al¹¹ showed that a 2-fold increase in stiffness occurs with the increased testing rate. However, Heini et al¹⁵ did not publish stiffness results, so a comparative analysis cannot confirm this finding.

The control specimens fractured in patterns defined clinically as intertrochanteric fractures.^{21,22} The femoroplasty group had a much more varied fracture location, which was not associated with cement location. We were originally concerned about creating a stress concentration near the cement margins (e.g., that the fracture would be diverted to the subtrochanteric region below the level of the cement), but our results did not substantiate this concern. The long-term effect of cement augmentation on bone remodeling is unknown.

This study had some limitations. First, we used paired cadaveric specimens to minimize the variability in specimens between treatment groups; however, differences in mechanical properties between femora from the same pair can be as great as 15%,²³ and differences in BMD between paired femora can be as high as 20%.²⁴ The greatest percent difference in BMD values between two paired femurs was 19%; however, the average percent difference across all pairs was 8%. Despite the use of paired specimens, the possibility of type-II error cannot be ruled out because of the limited number of specimens. Second, we did not address various issues regarding the clinical use of femoroplasty. As evidenced by our study, femoroplasty specimens sustained a wide range of fracture locations, some of which are not often seen clinically and, therefore, may not be easily treated if such fractures were to occur postaugmentation. Moreover, the presence of cement in the femur may make fixation processes, such as drilling and screw insertion, more difficult.¹⁴ Third, the model we used to produce fractures reliably creates intertrochanteric fracture locations. Because we did not model femoral neck and subtrochanteric fractures, we cannot predict how femoroplasty might strengthen a bone to prevent those fracture types.

Other limitations of our study were that we did not measure the temperature in the bone during the exothermic polymerization process of the injected polymethylmethacrylate cement,^{25,26} did not measure the intramedullary canal pressure during injection, and did not monitor the risk of embolization of fat and marrow displaced by the injected cement,²⁷ all of which can lead to clinically significant consequences. The focus of our study was on the potential for femoroplasty to strengthen the proximal femur mechanically, but before femoroplasty can become a viable option clinically, the importance of these potential adverse effects must be investigated.

In conclusion, we have shown that femoroplasty significantly increased fracture load and energy to fracture when osteoporotic femora were loaded in simulated fall conditions. Moreover, we have shown that cement filling in the femoral neck may have an important role in the strengthening potential of femoroplasty. Additional biomechanical investigation is needed to determine the minimum amount and position of cement for optimal augmentation.

Acknowledgments

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FIGURE 1. Representative anteroposterior view of a computed tomography scan slice showing an augmented specimen with bone cement (left) and a control specimen (right).

FIGURE 2.

Anteroposterior view of the proximal femur in the 4 designated regions: head (1), neck (2), trochanter (3), and subtrochanter (4).

FIGURE 3.

Experimental testing set-up simulating a fall on the greater trochanter using a materials testing machine (MTS Bionix 858 Test System, MTS, Eden Prairie, Minnesota). Specimens were positioned so that the axis of the femoral shaft was rotated 10 degrees below a horizontal plane parallel to the MTS table and the shaft was rotated internally 15 degrees.

FIGURE 4.

Representative force-versus-displacement plot used to determine loads and calculate energies. Data shown are yield (a) and ultimate (b) loads for the femoroplasty specimens, and yield (c) and ultimate (d) loads for the control specimens.

FIGURE 5. Anteroposterior view of a computed tomography scan slice showing a subtrochanteric fracture of a femoroplasty specimen (left) and an intertrochanteric fracture in a control specimen (right).

TABLE 1

Mean Mechanical Results of Control and Femoroplasty Specimens

Specimens	Yield Load (N)	Ultimate Load (N)	Yield Energy (J)	Ultimate Energy (J)	Stiffness (kN/m)
Control	2776.8 ± 386.8	2870.3 ± 483.6	8.1 ± 6.2	15.9 ± 8.1	968.1 ± 204.4
Femoroplasty	3387.9 ± 818.8	3941.1 ± 869.8	14.5 ± 10.0	40.4 ± 18.8	862.8 ± 428.6