Calcium Phosphate Cement Augmentation of the Femoral Neck Defect Created After Dynamic Hip Screw Removal

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Objective: To determine the effect of reinforced calcium phosphate cement augmentation of the femoral neck defect created after dynamic hip screw removal in a cadaveric model.

Methods: The lag screws of dynamic hip screw implants were inserted and subsequently removed in 8 matched pairs of cadaveric, osteoporotic femurs to create a femoral neck defect. One of each pair had the defect augmented with osteoconductive calcium phosphate cement reinforced with poly(lactide-coglycolide) fibers (Norian Reinforced™, Synthes, West Chester, PA), and the other defect was not augmented. Each specimen was first cyclically loaded with 750 N vertical loads applied for 1000 cycles to simulate early weightbearing, and then loaded to failure.

Results: Calcium phosphate cement augmentation of the lag screw defect significantly increased the mean femoral neck failure strength (4819 N) compared to specimens in which the defect was left untreated (3995 N) ($P < 0.004$). The mechanism of failure for each specimen was a fracture through the femoral neck. Regression analysis demonstrated that load to failure was directly related to the bone mineral density at Ward's triangle, and the impact of cement augmentation on failure strength was greatest for specimens with the lowest bone mineral density (correlation coefficient: -0.82, $P < 0.0001$).

Conclusion: This study demonstrates that augmentation of the bony defect created by dynamic hip screw removal with reinforced calcium phosphate cement significantly improved the failure strength of the bone. Cement augmentation after hardware removal may decrease the risk of refracture and allow early weightbearing, especially in elderly patients with osteoporotic bone.

Key Words: intertrochanteric hip fracture, internal fixation, calcium phosphate cement, Norian, failure strength

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INTRODUCTION

Hip fractures are frequent injuries affecting elderly, osteoporotic patients leading to significant morbidity and mortality.[1–3] Surgical management of hip fractures remains the standard of care, utilizing either a lag screw with side plate (dynamic hip screw) or an intramedullary fixation device. Where the vast majority of these implants are left in situ subsequent to fracture healing, there are selected indications for hardware removal, including thigh pain secondary to hardware prominence or loosening. Although uncommon, there have been reports in the orthopedic literature of complications after proximal femoral hardware removal, most notably fracture of the femoral neck.[4,5] Kukla et al found that 8% of patients who underwent removal of cephalomedullary nails after hip fracture treatment sustained femoral neck fractures with weight bearing in the early postoperative period.[5]

It is not uncommon for bony defects created during the removal of orthopedic hardware to be visible on x-ray for months after the procedure. It is well accepted that these defects represent a loss of supporting bone and may act as foci for refracture due to stress concentration at these sites. There is no current consensus regarding the necessary protection time or weight-bearing limits after hardware removal.[6] On the basis of the available data, many surgeons limit postoperative weight-bearing for up to 4 months after implant removal of any kind.[6–8]

The biomechanical impact of residual screw holes has been evaluated in both animal and human cadaveric studies.[5,9] In an evaluation of proximal femoral failure strength, Kukla et al reported a 35% reduction after removal of implanted dynamic hip screws and cephalomedullary nails compared with intact matched pairs.[5] Similarly, Rosson et al demonstrated in a rabbit model that the energy absorbing capacity of the tibia was decreased by 50% in response to a single bicortical drill hole.[9] Clinical reports have shown rates of refracture ranging from 10% after removal of condylar plates for distal femur fractures[10] to 21% after removal of hardware used for fixation of forearm fractures.[11]

Injectable calcium phosphate cement has been developed to fill defects in metaphyseal bone and for use as an adjunct to fracture fixation, reducing the need for bone graft and improving implant fixation strength in poor quality bone.[12–14] Calcium phosphate cement is a non-exothermic material that cures in situ, forming an osteoconductive carbonated apatite with a compressive strength greater than that of normal cancellous bone.[12,13,15] Histologic evaluation has demonstrated that once cured the material has a crystallographic structure similar to bone, and it is remodeled over time and incorporated into the host bone.[12,15,16] Norian Reinforced™ (Synthes, West Chester, PA) is one such injectable calcium phosphate cement in development that is reinforced with poly(lactide-coglycolide) chopped fibers for improved biomechanical properties.

The current study evaluated the effect of reinforced calcium phosphate cement augmentation on femoral neck failure strength after removal of the lag screw of the dynamic hip screw in cadaveric proximal femurs. We hypothesized that specimens in which the lag screw defect was augmented with Norian Reinforced™ would have significantly higher loads to femoral neck failure compared with specimens in which the defect was left untreated.

MATERIALS AND METHODS

Eight matched pairs of fresh-frozen cadaver femurs were selected on the basis of age (>65 years), radiographed to exclude any specimens with occult pathology, and DEXA scanned using a Hologic Scanner (Boston, MA) with a water bath tissue phantom in order to determine bone mineral density. The femoral condyles were removed, and equal lengths of the femoral shafts of each specimen were potted with acrylic cement in 6-cm^2 steel tubes that were 20 cm long. Throughout the experiment, each specimen was kept tightly wrapped in an airtight apparatus with saline-soaked gauze during testing to avoid desiccation.

An experimental femoral neck lag screw defect was created in each potted cadaveric femur. First, a guide wire was drilled into the femoral head using the dynamic hip screw 130-degree drill guide placed on the lateral cortex. The wire was driven until the tip emerged from the center of the femoral head to ensure adequate placement in both the proximal-distal and medial-lateral planes. The guide wire was then backed out, and the exit of the drill hole in the femoral head was filled with high-strength epoxy. Next, the lag screw hole was created using an 11-mm drill bit, stopping 5 mm short of the chondral surface. After creation of the femoral neck lag screw defect, each specimen was radiographed to ensure appropriate defect positioning, with tip-apex distances being assessed (all <25 mm)[17,18] (Figure 1).

Specimens were then placed in a 37°C water bath to simulate an in vivo environment. One randomly selected specimen per pair had the lag screw defect filled with Norian Reinforced™ (Synthes, West Chester, PA) calcium phosphate cement injected in retrograde fashion (Figure 2). These experimental specimens were then radiographed to ensure complete defect filling (Figure 1) and then returned to the 37°C water bath for 24 hours of curing, per the manufacturer's instructions.

Mechanical testing was then performed by securing the potted constructs in a vise at 25-degree adduction in the coronal plane and neutral in the sagittal plane to simulate 1-legged stance (Figure 3).[19] An Instron 2000 Universal Material Testing Machine (Instron, Canton, MA) was used for loading, using a polished flat applicator that permitted free movement of the femoral head when loaded. Each specimen was cyclically loaded, with 750 N vertical loads applied at a rate of 3 Hz for 1000 cycles to simulate early weightbearing. Finally, each specimen was axially loaded to failure at 1.0 cm/min, and load-displacement data was recorded. Failure was defined as an acute 10% or more reduction in the amount of load borne by the construct. The specimens were visually and radiographically examined in order to determine the mode of failure.

Comparison of femoral neck failure strength was made between treatment groups using paired Student *t*-tests. Additionally, a Pearson correlation was performed between specimen bone mineral density and load to failure and also for the strength difference between the treatment groups. A *P*-value of <0.05 was considered to be statistically significant for all analyses.

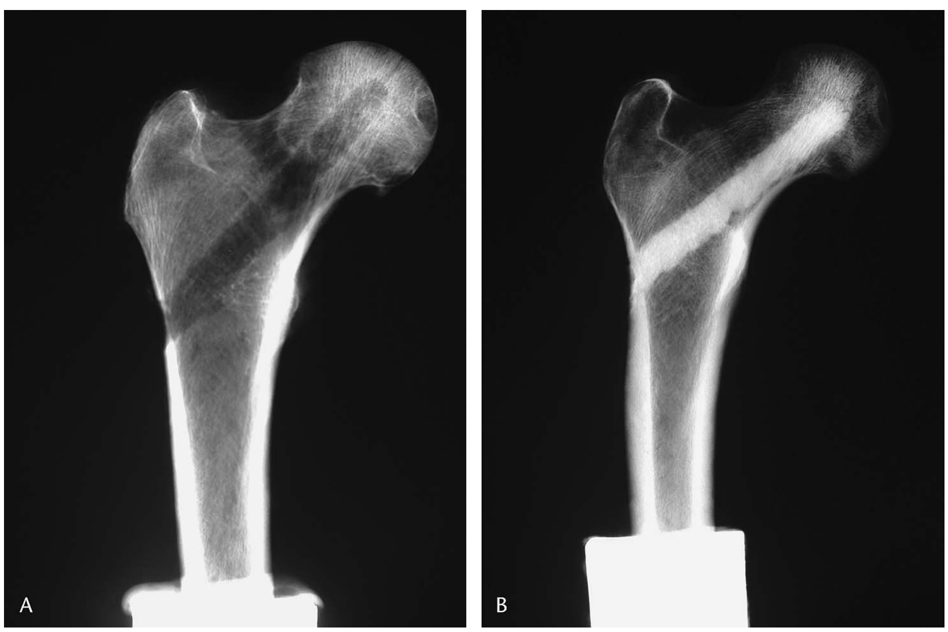

FIGURE 1. Anteroposterior radiographs of cadaveric right femur demonstrating the femoral neck defect created after dynamic hip screw removal (a) and augmentation of the defect with Norian calcium phosphate cement (b).

FIGURE 2. Femoral neck defect augmented with Norian calcium phosphate cement (right) and its untreated control (left).

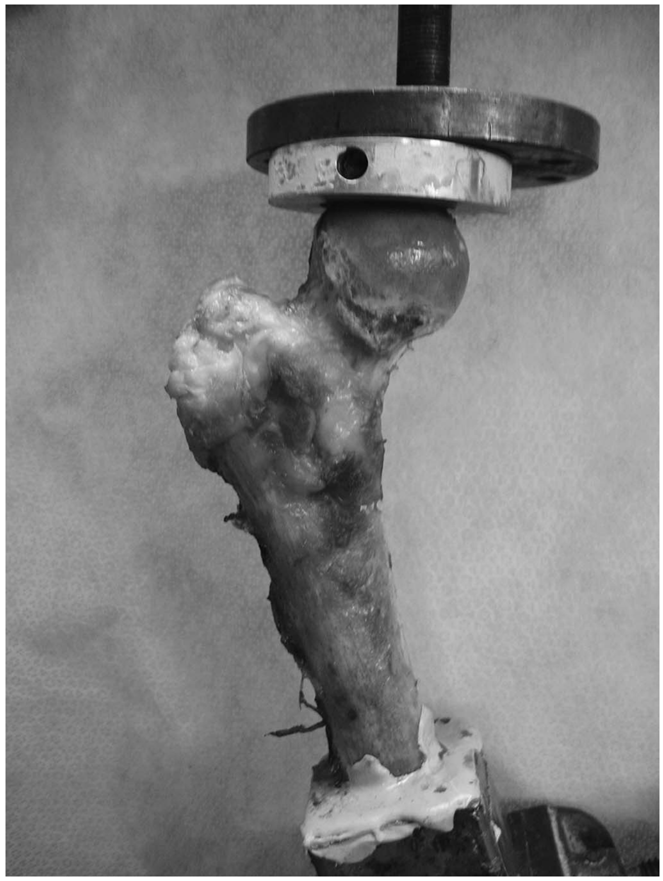

FIGURE 3. Mechanical testing of a potted specimen placed at 25 degrees of adduction in the coronal plane and neutral in the sagittal plane to simulate 1-legged stance.

RESULTS

DEXA scanning of the intact specimens demonstrated that the femurs were generally osteoporotic with a mean Ward's triangle bone density of 0.313 g/cm^2 (range, 0.177 to 0.499 g/cm^2) There was no significant difference in bone mineral density between the Norian Reinforced^{TM} and untreated specimen groups (P = 0.91).

Mean load to failure was significantly higher in the specimens in which the lag screw defect was augmented with Norian Reinforced^{TM} (4819 N; range, 2562 to 6859 N) compared to specimens in which the lag screw defect was left untreated (3994 N; range, 1833 to 5382 N) ($P < 0.004$) (Figure 4). Each augmented specimen's load to failure was higher than that of their nonaugmented matched pair. The mode of failure was similar in all specimens with fracture occurring through the femoral neck. (Figure 5). Ten specimens (6 Norian-treated and 4 control) fractured through the center of the neck, 3 (1 Norian-treated and 2 control) developed subcapital neck fractures, and 3 (1 Norian-treated and 2 control) failed secondary to the development of basicervical neck fractures.

Regression analysis of the failure load data demonstrated a linear relationship between femoral neck failure strength and bone mineral density at Ward's triangle. Additionally, there was a correlation between the increase in failure strength attributed to cement augmentation and bone mineral density with the most osteoporotic specimens having the largest improvement in failure strength (correlation coefficient: -0.82; $P < 0.0001$).

DISCUSSION

Our evaluation of the impact of calcium phosphate cement augmentation on femoral neck failure strength after lag screw removal demonstrated a significant increase in load to failure with cement reinforcement. The addition of Norian Reinforced^{TM} cement raised the force required to create a femoral neck fracture by 21%. As expected, failure strength and bone mineral density in our specimens were directly correlated. The greatest impact of augmentation on failure strength was observed in the specimens with the lowest Ward's triangle bone mineral density. Each specimen tested failed in a similar manner with fractures developing across the weakened femoral neck.

After observing an 8% incidence of femoral neck fracture subsequent to the removal of intramedullary fixation after healed intertrochanteric hip fractures, Kukla et al evaluated the load to failure after proximal femoral hardware

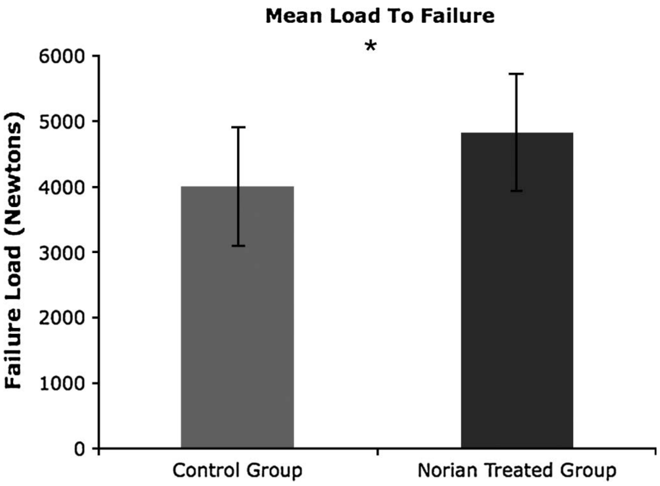

FIGURE 4. Mean load to failure was significantly higher in the specimens in which the lag screw defect was augmented with Norian calcium phosphate cement. Error bars represent standard deviation. $^{*}P < 0.004$.

removal in a cadaveric model.[5] The authors found that compared to untreated controls, implantation and explantation of dynamic hip screws and cephalomedullary nails reduced the mean failure strength from 5741 N to 4050 N, a decrease of approximately 35%. The failure strengths reported in this study were similar to the values we recorded during our testing. On the basis of their findings, the authors concluded that removing relatively large implants from the proximal femur can lead to significant complications, including femoral neck fracture and should be avoided if possible. Rosson et al used single photon absorptiometry to evaluate bony healing after hardware removal in young adult men.[8] The authors found that bone mass returned to near normal levels 18 weeks after implant explantation, leading them to recommend restriction of activities for 4 months after hardware removal. In a recent finite element analysis evaluating the distributions of stresses and strains in the proximal femur after trochanteric gamma nail removal, Mahaisavariya et al demonstrated significantly higher strains and total strain energy density in the region of the femoral neck defect created by lag screw removal. On the basis of their data, the authors concluded that these increased strains create the potential for femoral neck fracture after implant removal subsequent to hip fracture healing.[4]

Although the 21% improvement in femoral neck failure strength we observed with calcium phosphate augmentation is relatively modest, it corresponds to more than 800 N, which could potentially allow for earlier postoperative weightbearing while decreasing the risk of postremoval femoral neck fracture. Additionally, we tested the femurs only 24 hours after injection of the calcium phosphate cement. It is possible that the improved compressive and flexural strength of calcium phosphate cement coupled with improved bony ingrowth fostered by this osteoconductive material may have a greater impact on failure strength at later time points.

Previously, authors have evaluated the impact of cement augmentation to improve the mechanical properties of the proximal femur. Heini et al evaluated the efficacy of femoroplasty with the use of polymethyl-methacrylate cement in a cadaveric model.[20] The authors found that the peak load to fracture was increased by 21% in the single stance position and by 82% in a simulated fall on the hip after PMMA injection. However, this improvement in strength was associated with an 18 to 30°C increase in temperature within the femoral neck, a situation which may lead to thermal damage to bone and the supplying vessels to the femoral head. The nonexothermic and

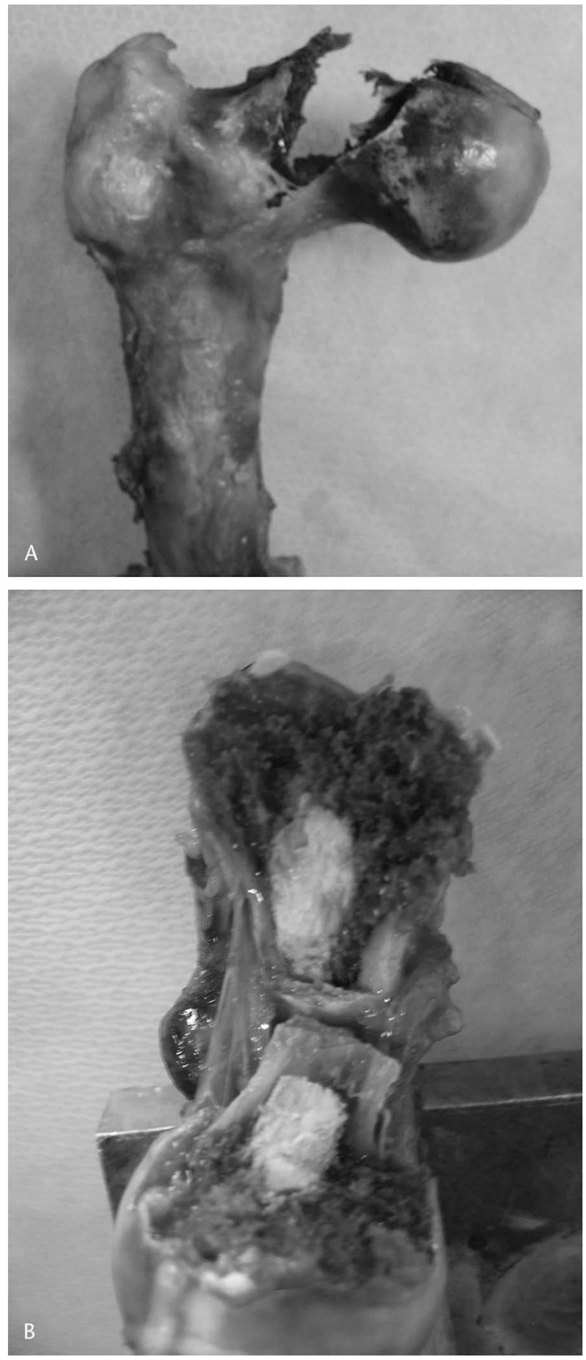

FIGURE 5. Failure with vertical loading occurred most commonly by fracture through the center of the femoral neck.

osteoconductive properties of reinforced calcium phosphate cement may provide similar reinforcement while limiting the potential for detrimental side effects. The reinforced calcium phosphate cement cures relatively quickly, setting within 10 minutes of mixing, and achieves approximately 90% of its final mechanical strength within 24 hours at physiologic temperatures. Theoretical risks associated with the injection of calcium phosphate cement into bony defects include cement extrusion or leak, which may cause local pressure symptoms or subsequent limited range of motion and the possibility of infection.

The incorporation of resorbable fibers into the calcium phosphate cement matrix material (Norian Reinforced™) results in an alteration of its biomechanical properties compared to nonreinforced calcium phosphate cement (Norian SRS™). Inclusion of the reinforcing fibers leads to a reduction in compressive strength in exchange for improved bending strength and work of fracture (toughness). The reinforced calcium phosphate cement has a compressive strength of 38 MPa, while the nonreinforced material has a compressive strength of 50 MPa (product testing data; Synthes, West Chester, PA). The advantage of fiber reinforcement is realized when employing flexural strength measurements via 3-point bend testing. Although the bend strength only increases 1 to 2 MPa, the stress-strain curves of the reinforced and nonreinforced calcium phosphate cement materials are very different. Analysis of the resultant stress-strain curves allows for the determination of work of fracture (area under the stress-strain curve divided by the cross-sectional area), an indication of a material's resistance to failure or crack propagation (ie, toughness). The work of fracture of fiber reinforced Norian is ~450 J/m^2 while nonreinforced Norian has a value of ~8 J/m^2. Thus, a large increase in work of fracture has been achieved via the incorporation of a small weight fraction of fibers added to the ceramic matrix.

It is possible that the improved biomechanical properties associated with calcium phosphate augmentation do not translate into improved clinical outcomes. In a recent randomized clinical study by Mattsson and Larsson, the authors evaluated the effect of cement augmentation on fracture fixation in 118 elderly patients with femoral neck fractures.[21] The authors found that, although augmentation allowed for improved function during the first few postoperative weeks, this difference was not maintained over time and patients treated with cement augmentation had a higher rate of reoperation compared with those treated without adjunctive cement. However, it is important to note that the methods employed in our study, using calcium phosphate cement to fill bony defects left after implant removal in a simulated healed femoral neck fracture model, varies considerably from the methods used by Mattsson and Larsson, making direct comparison of outcomes difficult.

There are several limitations of our investigation. They include the use of cadaveric specimens with their inherent variability. We attempted to standardize our treatment groups through pretesting DEXA scanning and X-ray evaluation to rule out any occult pathology that would alter the results. Although there was no significant difference in the bone mineral density between treatment groups in the study, there was a relatively large range of density among our specimen pairs. In our experimental model, the femoral neck lag screw defect was created in each potted cadaveric femur manually. Where we did our best to ensure that the initial guide wires had identical starting points and exited the center of the femoral head, there is always the possibility that the wires and resultant femoral neck defects were slightly different—whether due to variations in specimen anatomy or technical error, potentially impacting our results. The biomechanical evaluation performed in this study used axial loading to simulate the forces of a 1-legged stance. Where our testing apparatus attempted to recreate loading the mechanical axis, we acknowledge that physiologic loading during activity is more complex and that greater loads can occur. Additionally, we chose to cyclically load each specimen with 1000 vertical loading cycles before evaluating load to mechanical failure. It is possible that exposing each specimen to a greater number of cycles before loading them to failure would better represent the extent of cement fatigue that occurs before bony incorporation and remodeling in vivo. We plan on addressing these technical issues in future studies.

SUMMARY

Residual bony defects present after removal of hardware may lead to postoperative complications, including refracture. The current study demonstrated in a cadaveric model that augmentation of the bony defect created by dynamic hip screw removal with reinforced calcium phosphate cement significantly improved the femoral neck failure strength. Cement augmentation after hardware removal may decrease the risk of refracture and allow early weightbearing, especially in elderly patients with osteoporotic bone.

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