Effect of PMMA Bone Cement Augmentation on the \textit{In Vitro} Fracture Load of the Osteoporotic Proximal Femur

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Introduction

Fractures of the hip are an important public healthcare concern and a major source of mortality and morbidity among the elderly. In 1990, an estimated 1.66 million hip fractures occurred throughout the world (Cooper, Campion et al. 1992), frequently resulting in functional limitations, reduced quality of life, social dependency, and a major increase of mortality within one year of injury (Keene, Parker et al. 1993; Barrett-Connor 1995; Johnell 1997). Continued growth in the elderly population will raise the incidence of hip fractures and their associated costs dramatically: It has been suggested that the incidence of hip fractures will increase to approximately 6.26 million worldwide by the year 2050 (Cooper, Campion et al. 1992). The majority of hip fractures among the elderly are thought to be primarily related to osteoporosis (Lewinnek, Kelsey et al. 1980; Melton, Wahner et al. 1986), a systemic skeletal disease which is characterized by the marked reduction in bone mineral density (BMD) and the microarchitectural deterioration of bone tissue (Consensus Development Conference, 1993). Efforts to maintain or increase bone mass in osteoporotic patients are currently based on systemic drug therapy (e.g., bisphosphonates, calcium, calcitonine, calcitriol, fluorides, hormone replacement therapy, selective estrogen receptor modulators). In the elderly, however, pharmacological trials demonstrated only modest increases in femoral neck BMD.

Although osteoporosis is a systemic disease, fractures are local events occurring once the applied loads produce stresses which exceed bone strength. Thus it may be a strategy of intervention to decrease the overall fracture risk in elderly patients by increasing the bone strength in regions of bone that are known sites of osteoporotic fractures. Consequently, prevention of hip fractures in the elderly could be achieved by increasing the strength of the proximal femur using an injectable bone cement (e.g., PMMA, Polymethylmethacrylate). The aim of the present study was (1) to investigate the feasibility of PMMA injection into the proximal femur (femoroplasty), and (2) to study the effect of bone cement augmentation on the \textit{in vitro} failure load of the osteoporotic proximal femur under two different loading configurations.

Methods

Twenty matched pairs of osteoporotic human cadaveric femurs were selected from Caucasian donors (median age $\pm$ SD: 76.0 $\pm$ 7.2 years). Dual-energy X-ray absorptiometry scans were performed of each proximal femur, using a Hologic QDR-4500A densitometer (Hologic Inc., Waltham, MA, USA). Osteoporosis was defined in accordance to the WHO criteria. The specimens were assigned randomly into two groups of ten matched pairs (group A and group B), each group to be mechanically tested in a separate loading case (single-limb stance configuration, and impact loading simulating a fall onto the greater trochanter). Specimens were retrieved within 24 hours post mortem, wrapped in saline soaked tissues, and stored at $-30^\circ$ Celsius in tightly sealed plastic bags. To rule out the presence of any focal bone pathology, radiographs in two planes were taken.

Of each pair, one femur was randomly selected for augmentation; the contralateral femur served as a control. Prior to augmentation, the femurs were thawed in a 37$^\circ$ Celsius water bath for sixteen hours. In the one femur assigned for augmentation, a 3.5 mm drill canal was set in the longitudinal axis of the femoral neck. A 4.0 mm x 150.0 mm bone marrow biopsy needle (Manan\textsuperscript{TM} Trapsystem\textsuperscript{TM}, MDTech Inc., Gainesville, FL, USA) was used to inject a low-viscous PMMA bone cement (Palacos\textsuperscript{TM} LV-40 with Gentamicin, Essex Chemie AG, Luzern, Switzerland) into the proximal femur. Cement application was performed under continuous monitoring of potential leakage, and was terminated at a volume of 41 ml or
earlier, if any leakage occurred. The injected volume was documented, and radiographs were taken of each augmented femur. The surface temperature of the femoral neck was monitored for 20 minutes following injection.

Biomechanical testing of both groups was accomplished using a Zwick 1475 universal material testing machine (Zwick GmbH, Ulm, Germany). Group A specimens (n = 10 matched pairs) were tested to failure in a configuration based on Pauwels’ model of single-leg stance (Pauwels, 1980). The distal one-third of the femur was encased in acrylic cement (Beracryl, Trolle AG, Fulenbach, Switzerland) and placed in a fixture that maintained the femoral shaft at an angle of 25° from the vertical within the coronal plane. The femoral head fit into a silicone acetabular component, and a ball bearing allowed free movement of the acetabulum within the horizontal plane. The load was applied to the femoral head at a displacement rate of 2 mm/min until failure occurred. Group B specimens (n = 10 matched pairs) were tested in a configuration simulating a fall onto the greater trochanter (Courtney, Wachtel et al. 1994; Courtney, Wachtel et al. 1995). The specimens were positioned with the femoral shaft at 10° from the horizontal plane, and the neck internally rotated 15°. The load was applied vertically at 2 mm/sec until failure occurred. For both configurations, the load-displacement curves were recorded. The fracture load (maximum load until fracture occurred) and the energy absorption (area under the curve to the point of maximum load) were calculated. For each specimen, fracture location was documented radiographically. The Wilcoxon signed rank test was used for statistical analysis of the data.

Results & Discussion

Low viscous PMMA cement was easy to inject, and volumes of 28 ml to 41 ml (mean volume, 36 ml) were applied. Extravasal leakage of bone cement occurred in three cases at volumes of 28 ml to 30 ml. Within the interval of 20 minutes after injection, the surface temperature at the posterior femoral neck was increased an average of 22.1 Kelvin (range, 18.4 K to 29.8 K). The fractures observed in the control specimens corresponded to those seen commonly in vivo. For group A (Pauwels’ configuration), fracture types were distributed as follows: subcapital (5), transcervical (4), and pertrochanteric simple (1). In group B (simulated fall onto the greater trochanter), all control specimens fractured in the trochanteric zone (8) with exception of two basicervical (lateral) femoral neck fractures. For the configuration simulating forces from a fall onto the greater trochanter, a direct correlation was found between fracture load and BMD of the trochanteric zone of the control femurs (r = 0.79). An inverse correlation was noted between fracture load and neck-shaft angle of the control femurs (r = 0.74). For the single-leg stance configuration, however, there was no significant relationship between fracture load or energy absorption and the densitometric data or the geometry of the control femurs. For both, the single-leg stance configuration and the simulated fall model, the fracture load and the energy absorption were significantly increased for the PMMA augmented femurs when compared to the matched pair control (Table 1).

<table>
<thead>
<tr>
<th>Fracture load &amp; Energy</th>
<th>Pauwels’ Configuration (Single-leg stance)</th>
<th>Simulated Fall onto the Greater Trochanter</th>
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<tbody>
<tr>
<td></td>
<td>Fracture load [N] Mean ± SD</td>
<td>Energy [Nm] Mean ± SD</td>
</tr>
<tr>
<td>Control Femurs</td>
<td>5764 ± 1394 (n = 10)</td>
<td>35 ± 10 (n = 10)</td>
</tr>
<tr>
<td>Reinforced Femurs</td>
<td>6986 ± 1208 (n = 10)</td>
<td>52 ± 14 (n = 10)</td>
</tr>
<tr>
<td>Significance for Difference</td>
<td>p &lt; 0.002</td>
<td>p &lt; 0.002</td>
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Table 1: Pooled data (mean fracture load / mean energy absorption at fracture) for each group (reinforced / control femurs) and each configuration showing a significant increase in fracture load and energy absorption.
Hip fracture is one of the most important consequences of osteoporosis in terms of cost, disability, and mortality. With respect to the AO/ASIF-Comprehensive Classification of Fractures, the overall incidence of different subtypes of hip fractures are distributed as follows: 53.0% pertrochanteric, 42.6% femoral neck fractures, 4.3% subtrochanteric (Schutz and Buhler 1993). Femoral neck fractures have been reported to be more common during the early stages of osteoporosis, and subsequently, as the disease progresses, pertrochanteric fractures occur more frequently (Aitken 1984; Hedlund, Ahlbom et al. 1986; Hinton and Smith 1993). In the present study, two distinct loading configurations were used to simulate clinically relevant hip fractures in vitro (Keyak 2000). For the configuration simulating a fall onto the greater trochanter, significant relationships could be found between the fracture load and the BMD of the trochanteric zone (direct correlation), and the neck-shaft-angle (inverse correlation), respectively. These results are in consistence to the results reported by Courtney, Wachtel et al. 1994 and Lotz and Hayes 1990. There was, however, no relationship between fracture load and densitometric or geometric data for the control femurs tested in single-leg stance configuration. This could be explained by the variety in fracture types that were generated with the Pauwels’ model.

For both conditions, however, reinforcement with PMMA cement significantly increased the fracture load and the energy absorption of the intact osteoporotic femur as compared to the contralateral native control. Using a simple and reliable technique, bone cement can be injected into the proximal part of osteoporotic femurs with good gross and radiologic filling. Due to the radiopaque properties of PMMA, the injection could be controlled by fluoroscopy. These results provide evidence that prophylactic PMMA augmentation of the osteoporotic proximal femur may be used in elderly patients at high risk of hip fracture. However, some problems remain before the clinical use of this technique is feasible: the exothermic polymerization of PMMA creates a high risk for thermal necrosis of the bone tissue. Additionally, the ability of PMMA to withstand long-term physiologic loading is unknown. Thus, there is a need to investigate alternative injectable bone cements or bone substitutes which have lower polymerization temperatures and can provide adequate mechanical properties over extended periods.

References

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