INTRODUCTION
Fractures of the hip are an important public healthcare concern and a major source of mortality and morbidity among the elderly. Continued growth in the elderly population will raise the incidence of hip fractures and their associated costs dramatically [1, 2]. Hip fractures are thought by most to be primarily the sequelae of osteoporosis, a systemic disorder which is characterized by the marked reduction in bone mineral density (BMD) and a microarchitectural deterioration of bone tissue. Efforts to maintain or increase bone mass in the elderly are based on systemic drug therapy, but pharmacological trials have at best demonstrated increases of only a few percent in femoral neck BMD [3]. Moreover, it has been suggested that an increase of more than 20% in femoral neck BMD would be required to raise the mean fracture threshold to the level of impact loads from a fall on the hip [4]. Thus, there is a need for inexpensive and efficient strategies of intervention in the elderly. Although osteoporosis is a systemic disease, fractures are local events occurring once the applied loads produce stresses which exceed bone strength. Consequently, prevention of hip fractures in the elderly could be achieved by increasing the strength of the proximal femur using an injectable, low viscous bone cement (Poly(methylmethacrylate, PMMA). The aim of the present study was (i) to investigate the feasibility of PMMA injection into the proximal femur (femoroplasty), and (ii) to study the effect of bone cement augmentation on the in vitro failure load of the osteoporotic proximal femur under two different loading configurations.

MATERIAL AND METHODS
Twenty matched pairs of osteoporotic human cadaveric femurs were selected from Caucasian donors (median age ± SD: 76.0 ± 7.2 years). The specimens were assigned randomly to two different groups of ten matched pairs, each group to be mechanically tested in a separate loading case (single-limb stance configuration, and impact loading simulating a fall on the greater trochanter). Specimens were retrieved within 24 hours post mortem, wrapped in saline soaked tissues, and stored at ~30° Celsius in tightly sealed plastic bags. To rule out the presence of any focal bone pathology, radiographs in two planes were taken. 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. Prior to augmentation, the femurs were thawed in a 37° Celsius water bath for sixteen hours. From each pair, one femur was randomly assigned for augmentation, with the contralateral femur serving as a control. 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™ Trasymph™, MDTech Inc., Gainesville, FL, USA) was used to inject a low-viscous PMMA bone cement (Palacos™ 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. Additionally, the surface temperature at the femoral neck was recorded until twenty minutes after injection. The fracture tests were conducted in a Zwick 1475 universal material testing machine (Zwick GmbH, Ulm, Germany). The first group of ten matched pairs was tested to failure in a configuration based on Pawel’s model of single-leg stance [5]. Force was applied to the femoral head at a displacement rate of 2 mm/min and was directed at 25° to the shaft axis within the coronal plane. The second group of femoral pairs was loaded to simulate forces from a fall on the hip at a displacement rate of 2 mm/s [4, 6]. The femoral head fit into a silicone acetabulum while the distal half of the specimen was fixed in the testing apparatus with the femoral shaft at 10° to the horizontal, and the neck internally rotated at 15°. For both configurations, load-displacement curves were recorded. The fracture load (maximum load) 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 to test for differences in fracture load and energy absorption between the reinforced femurs and the native controls.

RESULTS
Low-viscous PMMA bone cement was easy to inject, and volumes of 28 ml to 41 ml (mean, 36 ml) could be applied. After injection, a temperature elevation (mean, +22.1 K) was noted in all specimens, with peak temperatures measured at the posterior surface of the femoral neck ranging from 38.2° C to 49.2° C. The fractures observed in the control femurs corresponded to those often seen in vivo. In the first group (single-limb stance), fracture types were distributed as follows: subcapital (5), transcervical (4), and pertrochanteric simple (1). In the second group (fall on the greater trochanter), all control femurs fractured in the trochanteric zone (8) with exception of two basiscervical neck fractures. For both testing configurations, the load at fracture (p < 0.002) and the energy absorption at the point of fracture (p < 0.002) were significantly increased for the reinforced (PMMA augmented) femurs in comparison to the contralateral native controls. Mean values (± standard deviation) of the load at fracture and the energy absorption, pooled for each group, are shown in Table 1.

<table>
<thead>
<tr>
<th>Fracture configuration</th>
<th>Fracture load [N] Mean ± SD</th>
<th>Energy absorption [Nm] Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>5764 ± 1394 (n = 10)</td>
<td>35 ± 10 (n = 10)</td>
</tr>
<tr>
<td>Reinforced</td>
<td>6986 ± 1208 (n = 10)</td>
<td>52 ± 14 (n = 10)</td>
</tr>
</tbody>
</table>

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.

DISCUSSION
In the present study, two distinct loading configurations were used to simulate clinically relevant hip fractures in vitro [7]. For both conditions, reinforcement with PMMA significantly increased the fracture load and energy absorption of the intact osteoporotic femur as compared to the contralateral native control. A simple, reliable injection technique provided a reproducible filling design of the proximal femur. These results provide evidence that prophylactic PMMA augmentation of the osteoporotic proximal femur may be used in elderly patients at high risk of fracture. However, it is not known whether PMMA can stand the biomechanical loads placed on it in the long-term. Moreover, the rise in temperature due to the polymerization of PMMA excludes its application in vivo because of the risk of thermal necrosis. Thus, there is a need for further evaluation of injectable bone cements with lower polymerization temperature, or alternative bone substitutes with mechanical properties similar to PMMA.

REFERENCES

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REINFORCEMENT OF THE OSTEOPOROTIC PROXIMAL FEMUR USING PMMA BONE CEMENT - AN IN VITRO STUDY