The handle http://hdl.handle.net/1887/29721 holds various files of this Leiden University dissertation.

Author: Steenhoven, Timothy Jason van der
Title: On prevention of second hip fracture surgery: epidemiological and biomechanical aspects of elastomer femoroplasty
Issue Date: 2014-11-11
Feasibility of osteosynthesis of fractured cadaveric hips following preventive elastomer femoroplasty

W. Schaasberg
T.J. van der Steenhoven
S.K Van de Velde
R.G.H.H. Nelissen
E.R. Valstar

Clinical Biomechanics June 2014
ABSTRACT

Background

In vitro cadaveric studies showed that elastomer femoroplasty (EF) prevents displacement of fracture parts after proximal hip fracture allowing for non-operative treatment. In the event that secondary displacement does occur, the purpose of the present study was to determine the feasibility of performing osteosynthesis of a fractured hip that has been treated with EF.

Methods

Ten pairs of human cadaveric femurs were fractured in a simulated fall configuration. From each pair, one femur was randomly selected for EF prior to fracture generation and the contralateral femur was used as control. Following hip fracture generation, osteosynthesis was performed in all femurs and the operative time, technical difficulties during the procedure, and postoperative failure-load were recorded.

Results

The mean (SD) time to perform osteosynthesis was 20 (6) minutes in the control-group and 19 (5) minutes in the EF-group ($P=0.69$). During osteosynthesis of the fractured hip in the EF-group, no difficulties (including the need for additional instruments to remove elastomer from the proximal femur) were recorded. Postoperative failure-load was similar in the control-group and the EF-group.

Conclusion

Fixation with routine osteosynthesis of displaced cadaveric hip fractures is not hindered by the presence of previously injected elastomer.
INTRODUCTION

Among survivors of an initial hip fracture, up to 16% of elderly patients are at increased risk of sustaining a second, contralateral hip fracture [1, 2]. The risk of a second hip fracture increases with age [1, 2], weakened cognitive and motor function [3], respiratory disease [4] and solitary life [5]. Recent literature suggests that the outcome of surgery for a second, contralateral fracture may be worse than that of a first hip fracture [6-8] in terms of early postoperative complications, discharge institutionalization, independent mobility and survival [6].

Given the detrimental impact of a second hip fracture on elderly patients, different strategies have been proposed to prevent the sequential trauma, including pharmaceutical treatment for osteoporosis [9-11], external mechanical protection with hip protectors [12], and cement augmentation of osteoporotic bone [13, 14]. The injection of cement into osteoporotic cadaveric proximal femurs resulted in an 82% increase in peak fracture loads for a simulated fall on the hip, compared to non-injected femurs [15]. However, cement augmentation is associated with significant heat generation due to polymethyl-methacrylate polymerization. The exothermic reaction of cement could cause thermal necrosis of healthy bone and potentially lead to avascular necrosis of the femoral head [16, 17]. In addition, osteosynthesis of fractured femurs that were beforehand reinforced with cement may be challenging, with particular difficulty recorded in the removal of the composite [13].

We recently introduced the concept of elastomer femoroplasty (EF), i.e. preventive stabilization with elastomer, injected in the contralateral femur during ipsilateral hip fracture surgery [18-20]. Unlike cement augmentation, the intention of EF is not to prevent the occurrence of a second, contralateral fracture. In fact, fracture loads of EF-treated cadaveric femurs were approximately 10% lower than those of non-augmented femurs [18]. Rather, EF has been shown to prevent displacement of the fracture as measured with the Neck Shaft Angle (NSA) directly after impact. Similar to the well-established conservative treatment of undisplaced hip fractures, Garden types 1 and 2 [21], the prevention of fracture displacement by EF at the time of injury could result in primary fracture healing, thereby eliminating the need for a surgical intervention in these often, frail elderly patients. In addition, EF has been shown to prevent secondary displacement of the fracture during subsequent cyclic loading of cadaveric femurs [19, 20]. In the event that EF fails to stabilize the fracture parts and secondary displacement does occur, fracture fixation with routine osteosynthesis should remain possible and equally stable compared to hip fractures without preventive EF. The objective of the present in-vitro biomechanical study was to determine the feasibility of performing osteosynthesis of a fractured proximal femur that has been treated with EF and its subsequent construct stability. We hypothesized that there is no difference in surgical time, difficulty in performing the osteosynthesis, or failure load after osteosynthesis of
fractured proximal femurs that were stabilized with elastomer femoroplasty (EF-group) and fractured proximal femurs without elastomer femoroplasty (control group).

METHODS

Cadaveric femurs

Ten pairs of human cadaveric femurs from donors with a mean age of 81 years (SD 7.6 years) were obtained from the Department of Anatomy, Leiden University Medical Centre (LUMC). Five donors were male and five donors were female. Preservation of the cadavers was performed by injection an embalming fluid into the femoral artery. The embalming fluid consisted of 36% formaldehyde (CH$_2$O) with a mixture of ethanol (C$_2$H$_5$OH), glycerin (C$_3$H$_5$(OH)$_2$), phenol (C$_6$H$_5$OH), potassium sulfate (K$_2$SO$_4$), sodium sulfate (Na$_2$SO$_4$), sodium carbonate (NaHCO$_3$), sodium nitrate (NaNO$_3$), and sodium sulfite (NaSO$_3$).

Plain radiographs were made of all specimens to exclude the presence of focal bone pathology. The femoral neck shaft angle (NSA) was measured from the plain anteroposterior radiograph of each femur using IQ-view web-viewer (V2.1.0, Image Information Systems Ltd., London). We calculated the degree of osteoporosis of each proximal femur using dual-energy X-ray absorptiometry (DXA) with a Discovery A, QRD scanner (Hologic Inc., Bedford, USA). All femurs were scanned in air. Osteopenia and osteoporosis were defined according to the WHO using T-scores of, respectively, < -1 standard deviation and < -2.5 standard deviation from the young adult mean value (Report WHO Study Group, 1994).

Elastomer Femoroplasty

From each pair, one femur was randomly selected for elastomer femoroplasty (EF-group, n=10). The contralateral femurs were used as control (control-group, n=10). Mean (± SD) bone mineral density (BMD) was 0.703 g/cm$^2$ (0.111) in the control group and 0.702 g/cm$^2$ (0.120) in the EF-group, respectively. Mean (± SD) T-score, a score used to express BMD in standard deviation from the mean BMD of a young adult, was -2.14 (0.74) in the control group and -2.14 (0.81) in the EF-group, respectively. The mean (± SD) NSA in the control group was 129˚ (3) compared to 128˚ (4) in the EF-group.

Elastomer femoroplasty was performed as described in detail previously [18]. The femurs were prepared by drilling a 3 mm hole in the lateral cortex. A channel was made in the femur neck with a 10 mm eccentric drill. Finally, a 15 mm eccentric drill hole was made in the femur head to form an “anchor site” for the elastomer. After drilling, the hole was rinsed out using a pulsed lavage system (Stryker, Kalamazoo, Michigan, USA) using a saline solution. The elastomeric compound, polydimethylsiloxane (PDMS,
ViaZym BV, Delft, The Netherlands), was manually injected into the proximal femur using a commercially available, hand held injector gun (Mixpac, Sulzer, Haag, Switzerland). PDMS is an elastomer that has a low initial viscosity, cures without exothermic heat and without the formation of by-products as it hardens in an aqueous environment [22, 23]. Filling the proximal femur continued until either the elastomer overflowed from the lateral cortex hole or exited vascular penetrations in the femur neck. The mean volume of silicone per femur was 35 ml (range: 28–42 ml). The radiographs after elastomer filling showed a regular and reproducible pattern of silicone distribution in the head, neck and trochanteric regions of the proximal femur.

**Hip Fracture Generation**

Biomechanical testing was done using an LR5KPlus 5 kN load testing machine with a XLC-50K-A1 Load-cell and NEXYGEN/Plus material test and data analysis software (Lloyd Instruments, Fareham Hants, UK). Fractures were generated by simulating a fall on the greater trochanter in a modified Hayes-fall configuration [24]. The femoral shaft was held firmly by a steel arm at a 20-degree angle from the horizontal plane and with the femur head 15 degrees internally rotated (Figure 1). The load was applied using a silicone-coated cup attached to the crosshead of the testing machine. The crosshead moved with 2mm/s and stopped automatically when the load cell registered an abrupt reduction in load of 75%. The recorded load was defined as fracture load (N). After each specimen was fractured plain anteroposterior radiographs were made to calculate the NSA. In case of complete displacement of the fracture the NSA was defined as 180 degrees. The type of generated fracture was classified according to the AO-classification.

**Osteosynthesis**

Simple and multifragmentary pertrochanteric (AO-A1 and AO-A2) fractures were treated with a dynamic hip screw (DHS) with a 4 hole plate and intertrochanteric (AO-A3) fractures were treated with a proximal femoral nail-antirotation (PFNA small, Synthes, Zuchwil Switzerland, length 200mm) following AO guidelines. The collum screws of both the DHS and the PFNA were placed with a maximum tip apex distance of 25mm, as noted in the study of Baumgaertner et al. [25]. During the osteosynthesis procedures, the operative time (min) and any technical difficulties during the procedure were recorded.

**Failure Load Following Osteosynthesis**

After osteosynthesis, each specimen was replaced in the load-testing machine in the same single leg stance configuration (Fig. 1).

The actuator moved with a speed of 2 mm/s and stopped when an abrupt reduction in load of 75% was detected. The recorded load was defined as failure load
(N). X-rays of all three stages, fracture after EF- osteosynthesis after EF with fracture-after failure of osteosynthesis, are shown in figure 2.

![Figure 1. Graphic display of the single leg stance configuration, with the femur fixed upright at a 20° angle from the vertical plane and 15° endorotation. The 'L' marks the load cell.](image)

**Statistical Analysis**

Statistical analysis was done using SPSS (SPSS 16.0, SPSS Inc., Chicago, IL, USA). Within the control and EF-group, proximal femurs were grouped according to implant used for osteosynthesis and descriptive statistics including mean and standard deviation were used. In addition, unpaired Student-T tests were performed to detect significant differences in operative time and failure load between the EF-group (n=10) and the control group (n=10). P-values were considered significant when <0.05.
RESULTS

After loading in both groups five fractures were pertrochanteric and five were intertrochanteric. In both the control-group and the EF-group, five out of ten osteosynthesis procedures were performed with a DHS and five out of ten procedures were performed with a PFNA (Table 1).

The overall mean (± SD) time to perform osteosynthesis was 20 (± 6) min in the control-group and 19 (± 5) min in the EF-group. During osteosynthesis of the fractured hip in the EF-group, no difficulties including the need for additional instruments to remove elastomer from the proximal femur were recorded.

After osteosynthesis of the fractured hip no difference in overall mean failure load was recorded between the control-group and the EF-group (3783 ± 527 N and 3472 ± 754 N, respectively) (Table 2).

DISCUSSION

The feasibility of performing standard osteosynthesis of a fractured proximal femur after preventive elastomer femoroplasty (EF) was evaluated in an in-vitro biomechanical study. We found no statistically significant differences in either operative time to perform osteosynthesis or postoperative energy-to-failure load between fractured human cadaveric femurs that were beforehand treated with EF and fractured proximal femurs without the elastomer stabilization. In addition, no technical difficulties or the need for
specific instrumentation to remove the elastomer was necessary for osteosynthesis of the fracture in the EF group.

This feasibility study has certain limitations. We did not compare the performance of osteosynthesis in fractured hips augmented with elastomer with osteosynthesis in fractured hips reinforced with bone cement. The concept of femoroplasty with polymethyl-methacrylate (i.e. bone cement) as a prophylactic reinforcement of the femur has been introduced previously [14, 15]. Heini et al. injected cement into osteoporotic cadaveric proximal femurs [15]. By doing so, peak fracture load for a simulated fall on the hip was increased by 82%, with a corresponding increase in energy absorption of up to +188%, compared to noninjected femurs, indicating that cement

### Table 1. Time (minutes) required to perform osteosynthesis of the proximal femur in the control-group and the elastomer femoroplasty (EF)-group, stratified by type of implant used. DHS, dynamic hip screw; PFNA, proximal femoral nail-antirotation.

<table>
<thead>
<tr>
<th>Femur</th>
<th>Control-group</th>
<th>EF-group</th>
<th>Unpaired Student t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Implant</td>
<td>Min</td>
<td>Implant</td>
</tr>
<tr>
<td>#1</td>
<td>DHS</td>
<td>14</td>
<td>DHS</td>
</tr>
<tr>
<td>#2</td>
<td>DHS</td>
<td>13</td>
<td>DHS</td>
</tr>
<tr>
<td>#3</td>
<td>DHS</td>
<td>18</td>
<td>DHS</td>
</tr>
<tr>
<td>#4</td>
<td>DHS</td>
<td>14</td>
<td>DHS</td>
</tr>
<tr>
<td>#5</td>
<td>DHS</td>
<td>13</td>
<td>DHS</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>14 (2)</td>
<td>14 (2)</td>
<td></td>
</tr>
<tr>
<td>#6</td>
<td>PFNA</td>
<td>28</td>
<td>PFNA</td>
</tr>
<tr>
<td>#7</td>
<td>PFNA</td>
<td>22</td>
<td>PFNA</td>
</tr>
<tr>
<td>#8</td>
<td>PFNA</td>
<td>28</td>
<td>PFNA</td>
</tr>
<tr>
<td>#9</td>
<td>PFNA</td>
<td>29</td>
<td>PFNA</td>
</tr>
<tr>
<td>#10</td>
<td>PFNA</td>
<td>20</td>
<td>PFNA</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>25 (4)</td>
<td>23 (3)</td>
<td>P = 0.3171</td>
</tr>
</tbody>
</table>

### Table 2. Failure load (N) after osteosynthesis of the proximal femurs in the control-group and the elastomer femoroplasty (EF)-group, with either proximal femoral nail-antirotation (PFNA) or dynamic hip screw (DHS).

<table>
<thead>
<tr>
<th>Femur</th>
<th>Control-group</th>
<th>EF-group</th>
<th>Unpaired Student t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Implant</td>
<td>Failure load (N)</td>
<td>Implant</td>
</tr>
<tr>
<td>#1</td>
<td>DHS</td>
<td>4510</td>
<td>DHS</td>
</tr>
<tr>
<td>#2</td>
<td>DHS</td>
<td>3750</td>
<td>DHS</td>
</tr>
<tr>
<td>#3</td>
<td>DHS</td>
<td>3200</td>
<td>DHS</td>
</tr>
<tr>
<td>#4</td>
<td>DHS</td>
<td>3930</td>
<td>DHS</td>
</tr>
<tr>
<td>#5</td>
<td>DHS</td>
<td>3200</td>
<td>DHS</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>3718 (550)</td>
<td>3346 (1016)</td>
<td>P = 0.4920</td>
</tr>
<tr>
<td>#6</td>
<td>PFNA</td>
<td>3200</td>
<td>PFNA</td>
</tr>
<tr>
<td>#7</td>
<td>PFNA</td>
<td>3680</td>
<td>PFNA</td>
</tr>
<tr>
<td>#8</td>
<td>PFNA</td>
<td>4740</td>
<td>PFNA</td>
</tr>
<tr>
<td>#9</td>
<td>PFNA</td>
<td>3820</td>
<td>PFNA</td>
</tr>
<tr>
<td>#10</td>
<td>PFNA</td>
<td>3800</td>
<td>PFNA</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>3848 (558)</td>
<td>3598 (455)</td>
<td>P = 0.5717</td>
</tr>
</tbody>
</table>
augmentation might prevent hip fractures in elderly patients. Unfortunately, cement augmentation was associated with significant heat generation due to polymethylmethacrylate polymerisation. In addition, osteosynthesis of fractured femurs that were beforehand reinforced with cement was a challenging procedure, with particular difficulty recorded in the removal of the composite [13].

As an alternative to bone cement to reinforce the proximal femur, we introduced femoroplasty using polydimethylsiloxane [18], an elastomer that cures without exothermic heat [22, 23]. The resultant construct stability of femoroplasty with elastomer is different from that with bone cement. Unlike cement augmented femurs, peak fracture load for a simulated fall on the hip in elastomer augmented femurs was not significantly different from untreated control femurs [18]. Dislocation according to Neck Shaft Angle was significantly reduced in the EF group [18, 19]. Furthermore, during subsequent cyclic loading, the failure load of fractured femurs stabilized by EF was 2709 N [20] - well exceeding the peak loads of approximately 1500 – 2025 N during normal gait in a 75 kg individual [26, 27]. These findings suggested that EF might both reduce initial displacement of hip fractures at the time of injury as well as reduce secondary displacement rates during subsequent conservative treatment of undisplaced hip fractures. In contrast to the data available on cement femoroplasty, we found in the present study that - if surgical stabilization was necessary after all, i.e. in the event of secondary dislocation - osteosynthesis of fractured femurs that were preventively treated with EF is not associated with any additional challenges.

In this cadaveric study, we did not evaluate the presence of debris and its potential biological response elicited after osteosynthesis in EF treated hips. Elastomer is already widely used in-vivo, e.g. for the augmentation of nasal bones and in vascular grafts, because of its physiological inert properties [28-30]. These studies did not show any biological response. However, the biocompatibility of elastomer with the unique environment of cortical and cancellous bone and the marrow space is unknown. In addition, EF remains an invasive technique with possible complications including emboli, infection and hematoma. Future studies will have to investigate the in-vivo behavior of elastomer in fractured hips and subsequent osteosynthesis, and evaluate the cost-benefits of the intervention. An additional limitation of this study was that, similar to our previous experiments, we used fixed specimens instead of fresh frozen cadaveric bones. We justified this choice of material because contralateral side femurs were used for the control group.

There was a large variability in failure loads after osteosynthesis in the control-group and the EF-group (Table 3). A possible explanation for this large spread in failure loads could be the differences in hip geometry between individual proximal femora. Previous studies using cadaveric materials also found large standard deviations in the load to fracture [15, 18]. Finally, the study sample was relatively small and more cadavers would be needed to reduce the chance of a possible type II error. However,
in the present feasibility study no clinically significant difficulties in performing osteosynthesis after stabilization with EF were encountered.

In conclusion, duration of surgery, difficulty in performing the osteosynthesis, and failure load after osteosynthesis of fractured proximal femurs that were stabilized with EF were comparable to the untreated contralateral femurs. This indicates that fixation with routine osteosynthesis of secondary displaced cadaveric hip fractures is not hindered by the presence of preventive EF.
REFERENCES
