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CHAPTER 6
Elastomer femoroplasty prevents hip fracture displacement. An in vitro biomechanical study comparing two minimal invasive femoroplasty techniques

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ABSTRACT

The purpose of this study was to test femur strength and the ability to prevent fracture displacement of two minimal invasive elastomer femoroplasty techniques.

Methods

A total of sixteen fixed human cadaveric femur pairs were used. From each pair one femur was randomly assigned for elastomer femoroplasty. In these femurs we drilled a 3.5 mm entrance in the lateral cortex. Cavities for the elastomer were created by: group A, balloon and group B an excentric drill. All femurs were fractured by simulating a fall on the greater trochanter. Neck-Shaft-Angles on plain anterior posterior radiographs were measured to determine fracture displacement.

Findings

There was no significant difference in fracture load between controls and treated femurs for group A, 2904 N (SD 1091) versus 2803 N (SD 627) and group B, 2773 N (SD 747) versus 2597 N (SD 834). In group A the mean displacement was 35° (SD 14) for the control femurs and 3° (SD 2) for the treated femurs ($P < 0.001$). In group B the mean displacement was 38° (SD 10) for the controls and 8° (SD 13) for the treated femurs ($P < 0.001$).

Interpretation

The results of this study show that minimal invasive elastomer femoroplasty prevents fracture displacement of the proximal femur. We found no significant compromise in load-to-fracture after minimal invasive balloon or excentric drill femoroplasty.
INTRODUCTION

Hip fracture and consequent hip fracture surgery is associated with increased morbidity, functional decline, and death, as well as increased use of health care services [1]. Different strategies to prevent hip fractures have been introduced in the last three decades. These preventive measures have however not yet led to a reduction in second hip fracture incidence [2-8]. The one-year risk of a second hip fracture is still as high as 10% [9]. The lifetime risk of a second hip fracture has been estimated at 20% but may be as high as 55% and people sustaining one hip fracture are 5-9 times more likely to fracture their contralateral hip compared to age matched controls [10, 11]. Treatment of osteoporosis after hip fracture is probably too late to prevent second hip fractures in the first 2 years. Ideally people at risk of osteoporotic fractures should begin treatment of osteoporosis in childhood in order to minimize bone loss during life [12].

Preventive stabilization or augmentation of the contralateral hip during ipsilateral hip fracture surgery on the other hand could be an instantly available modality to reduce the incidence of second hip fracture surgery in the high-risk patient. In a recently published study, we showed that elastomer femoroplasty (EF) prevents fracture displacement, however, the load to fracture was 10% percent lower in the femurs treated with EF [13]. Similar to previous biomechanical cadaver studies on proximal femur strength after implant removal, the decrease in load to fracture was attributed to the 10 mm diameter entrance hole in the lateral cortex [14].

Minimizing the entrance hole in the lateral cortex for EF using small entrance techniques could therefore reduce this decrease in load to fracture of the proximal femur.

Unpublished pilot studies pointed out that injection of elastomer into the proximal femur without drilling a hole in the cancellous bone does not result in a sufficient volume of elastomer to restore geometry after fracture. Therefore after drilling the entry hole in the lateral cortex, a channel has to be created in the proximal osteoporotic femur to suit the elastomer. Two techniques are possible: drilling a hole using an eccentric drill or cancellous bone compression similar to kyphoplasty. The aim of the current study is to evaluate the effect of a 3.5 mm hole in the lateral cortex of the proximal femur with respect to the load to fracture. Furthermore two different EF techniques are compared, an eccentric drill excavating technique and cancellous bone compression technique.

MATERIALS AND METHOD

A total of 16 pairs of osteopenic or osteoporotic femurs from human cadaveric donors were used. Five donors were male and 11 donors were female. The mean age of the donors was 76.8 years (SD 11.4). All cadaver femurs were obtained from the Department
of Anatomy, Leiden University Medical Centre. Fixation and preservation of all cadavers was performed by injection of embalming fluid into the femoral artery, consisting of 36% formaldehyde ($\text{CH}_2\text{O}$) with a mixture of ethanol ($\text{C}_2\text{H}_5\text{OH}$), glycerin ($\text{C}_3\text{H}_5(\text{OH})_2$), phenol ($\text{C}_6\text{H}_5\text{OH}$), potassium sulfate ($\text{K}_2\text{SO}_4$), sodium sulfate ($\text{Na}_2\text{SO}_4$), sodium carbonate ($\text{NaHCO}_3$), sodium nitrate ($\text{NaNO}_3$), and sodium sulfite ($\text{NaSO}_3$).

To exclude the presence of focal bone pathology, plain X-rays were made of all specimens. The femoral Neck-Shaft-Angle (NSA) was measured from the plain anterior-posterior radiograph of each femur. 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 [15].

From each femur pair, one femur was randomly selected for femoroplasty; the contralateral femur of the same donor was used as a control. In the femurs selected for femoroplasty we used a regular electric drill to drill a 3.5mm hole with a standard Ø 3.5mm, length 165mm, drill bit (Synthes inc, Solothurn, Switzerland) in the lateral cortex and channel in the femur neck.

The femurs were than randomly assigned to two groups, group A and group B. In group A the cavity for EF in the femoral neck was created by compressing the cancellous bone with an inflatable balloon, KyphX Xpander inflatable bone tamp (Kyphon inc., Sunnyvale, USA). To make a solid ‘anchor’ in the femoral head we used the 20 mm excentric drill (fig1a). In group B the cavity for EF was created using a specially designed excentric drill set (Department of Fine Mechanics, Leiden University Medical Center) (fig 1b). We used a 15 mm excentric drill for the femoral neck followed

![Fig 1](example_of_the_balloon_compression_technique_using_a_kyphoplasty_balloon_(a)_and_an_example_of_the_20_mm_excentric_drill_in_the_femur_head_(b))

by a 20 mm eccentric drill to create the ‘anchor’ for the elastomer femoroplasty in the femoral head. To achieve reproducible cavities all femurs were drilled using fluoroscopy with a mobile X-ray machine (Pulsera® Mobile C-arms, Philips Healthcare, Eindhoven, The Netherlands). The drilled cavity was cleaned before EF by pulsed lavage system (Interpulse Stryker®, Kalamazoo, USA). Plain anterior-posterior and lateral radiographs and DXA-scans were made after drilling.

The elastomer used in the experiments is a two-component room-temperature addition-cure liquid silicone formulation, obtained from Viazym BV (ViaZym BV; Delft, the Netherlands). The two components consist of: A platinum containing vinyl-terminated polydimethylsiloxane (PDMS) with an optimized molecular weight with regard to viscosity versus mechanical properties of the cured end-product (elongation to break, modulus). This component further contains surface-treated amorphous silica and a sesquisiloxane-like material known as Vinyl Q, which increases tear-strength of the final cured elastomer without much increase in viscosity. The second component is a methylhydrodimethylsiloxane co-polymer containing vinyl-terminated PDMS. This component further contains surface-treated amorphous silica and Vinyl Q. PDMS is widely used in vivo because of its physiological inert properties [16, 17]. The elastomer we used was designed to have a low viscosity initially, to cure without exothermic heat, without the formation of by-products as it hardens (polymerization and cross linking) in a watery environment [18, 19]. The elastomer was injected into the proximal femur using a commercially available injector gun. The two components of the elastomer were mixed at room temperature using a static mixer attached to the nozzle of the injector gun.

Filling the proximal femur took place under fluoroscopy to evaluate the distribution of the elastomer in the proximal femur. We continued filling until either the elastomer overflowed from the lateral cortex hole or came out of vascular penetrations in the femur neck. All femurs were placed with the femoral head pointing down to prevent the silicon from running out while curing. Although the curing time of our silicone is approximately 10 minutes at room temperature all femurs were left to rest for 24 hours. During curing and in between examinations and tests the femurs were kept moist with cloths drenched in formaldehyde mixture. Plain radiographs were made to record the distribution of Elastomer.

Treated and control femurs were biomechanically tested using a material test machine (LR5KPlus 5 kN, Lloyd Instruments, Fareham Hants, UK) with a load-cell (XLC-50K-A1, Lloyd Instruments, Fareham Hants, UK) and material test and data analysis software (NEXYGENPlus, Lloyd Instruments, Fareham Hants, UK) with a data acquisition rate of 8kHz. All femurs were fractured by simulating a fall on the greater trochanter in a modified Hayes-fall configuration [20]. The femoral shaft was firmly held by a steel arm in a 20-degree angle from the horizontal plane and with the femur head 15 degrees internally rotated (Figure 2).
The load was applied using a silicone-coated cup attached to the crosshead of the testing machine. The crosshead moved with a speed of 2mm/s and stopped when a 75% reduction in peak load was recorded by the load cell. The recorded load was defined as fracture load. After each specimen was fractured plain anterior-posterior radiographs were made to calculate the NSA. In case of complete displacement of the fracture we defined the NSA as 180 degrees.

After biomechanical testing the proximal femurs were immersed in sulphuric acid (H2SO4) until all cadaveric tissue was dissolved, and elastomer casts were left. The Elastomeric casts were rinsed thoroughly and volumes were measured by water immersion.

Statistical analysis of the data was done using SPSS (SPSS 16.0, SPSS Inc., Chicago, IL, USA). Paired student–T tests were performed to determine significance in fracture-load, load until displacement and NSAs, calculating \( P \)-values and 95% confidence intervals. \( P \)-values of <0.05 were accepted as significant. Correlation between fracture load and DXA results, and the correlation between fracture load and elastomer volume was determined by calculating the Pearson’s \( r \) correlation.

**RESULTS**

The results of all treated femurs were compared to paired controls. Therefore, the treated and control femurs were similar with respect to age, bone mineral density (BMD) and NSA (Table 1).

Out of the sixteen femur pairs 18 femurs were osteopenic with a T score < -1 and > -2.5 (5 pairs in group A and 4 pairs in group B) and 14 femurs were osteoporotic with a T score < -2.5 (3 pairs in group A and 4 in group B). The average T-score was -2.4 (SD 0.8) in group A and -2.6 (SD 0.7) in group B. DXA-scans made after excavation of the

**Fig 2.** Modified Hayes-fall configuration. The femur is fixed at an angle of 20° with the horizontal plane simulating a fall on the greater trochanter.
proximal femur for femoroplasty showed no significant decrease in T-score -2.0 (SD 0.9) in group A and -2.3 (SD 0.7) in group B.

Fracture loads for each femur in both groups are displayed in Table 2. In group A, the mean fracture load in the simulated fall configuration was 2904 N (SD 1091) for the controls versus 2803 N (SD 627) for the EF treated femurs ($P = 0.742$, 95% CI of the difference: -799 N – 597 N). This is a 3.5% drop in fracture load after EF treatment. The correlation coefficient between BMD and fracture load for the controls was $r = 0.81$ and for EF femurs was $r = 0.79$.

In group B the mean fracture load in the simulated fall configuration was 2773 N (SD 747) for the controls versus 2597 N (SD 834) for the EF treated femurs ($P = 0.534$, 95% CI of the difference: -809 N – 458 N). This is a 6.3% drop in fracture load after treatment. The correlation between BMD and fracture load for control femurs was $r = 0.45$ and for the EF treated femurs $r = 0.95$.

The NSAs measured on plain anterior-posterior radiograph before and after fracture in both groups are displayed in figure 3 and 4. The controls of femur pair 6,7 and 8 from group A and the controls of femur pair 3, 4, and 5 were completely displaced after fracture and were scored as 180° NSA.

### Table 1. Baseline characteristics of all cadaver femurs before fracturing

<table>
<thead>
<tr>
<th></th>
<th>Group A Balloon technique</th>
<th>Group B Drill technique</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control Mean (SD)</td>
<td>EF Mean (SD)</td>
</tr>
<tr>
<td>BMD</td>
<td>0.655 g/cm² (0.126)</td>
<td>0.668 g/cm² (0.107)</td>
</tr>
<tr>
<td>T-score</td>
<td>-2.44 (0.74)</td>
<td>-2.35 (0.81)</td>
</tr>
<tr>
<td>NSA</td>
<td>130° (5)</td>
<td>128° (5)</td>
</tr>
</tbody>
</table>

### Table 2. Fracture load in Newton for both control and EF treated femurs in Group A and B

<table>
<thead>
<tr>
<th>Femur pair</th>
<th>Control</th>
<th>EF</th>
<th>Control</th>
<th>EF</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>1817</td>
<td>2314</td>
<td>1820</td>
<td>1217</td>
</tr>
<tr>
<td>#2</td>
<td>1846</td>
<td>1522</td>
<td>2643</td>
<td>1813</td>
</tr>
<tr>
<td>#3</td>
<td>2008</td>
<td>3146</td>
<td>3513</td>
<td>2300</td>
</tr>
<tr>
<td>#4</td>
<td>2794</td>
<td>2807</td>
<td>2462</td>
<td>2400</td>
</tr>
<tr>
<td>#5</td>
<td>2726</td>
<td>2943</td>
<td>3210</td>
<td>3151</td>
</tr>
<tr>
<td>#6</td>
<td>4963</td>
<td>3207</td>
<td>2043</td>
<td>3288</td>
</tr>
<tr>
<td>#7</td>
<td>3276</td>
<td>2942</td>
<td>2480</td>
<td>2839</td>
</tr>
<tr>
<td>#8</td>
<td>3804</td>
<td>3546</td>
<td>4010</td>
<td>3770</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>2904 (1091)</td>
<td>2803 (627)</td>
<td>2773 (747)</td>
<td>2597 (834)</td>
</tr>
</tbody>
</table>
In group A the mean NSA of the control femurs before fracture was 130° (SD 5) and after fracture 165° (SD 14). This is a mean displacement (ΔNSA) of 35°. In the EF treated femurs the mean NSA before fracture was 128° (SD 5) and 132° (SD 4) after fracture. This is a ΔNSA of 4° ($p < 0.001$, 95% CI of the difference 21° - 43°). In group B the mean NSA of the controls before fracture was 129° (SD 6) and after fracture 167° (SD 13). This is a ΔNSA of 38°. In the EF treated femurs the average NSA before fracture was 130° (SD 6) and 138° (SD 17) after fracture. This is a ΔNSA of 8° ($p < 0.001$, 95% CI of the difference 16° - 43°). There were 2 outliers one in each group. In group A, EF treated femur number 2 after fracture had an outlying NSA of 123° but did not differ significantly from its pre-fracture NSA of 122°. In group B, EF treated femur number 3 failed after fracture and was scored at 180° and therefore had an outlying observation.

The mean volume of elastomer in group A, 18.5 ml (SD 2.4) was significantly higher than in group B 14.5 ml (SD 2.7), $P=0.05$ (95% CI -0.02 – 7.97 ml). The correlation between fracture load and volume in group A was $r = 0.60$, and group B, $r = -0.47$ both correlations were statistically non-significant.

**Fig 3.** Boxplots of Neck Shaft Angle’s (NSA) in control femurs and elastomer femoroplasty treated femurs, before and after fracture in group A (balloon femoroplasty).
DISCUSSION

Elastomer femoroplasty of the proximal femur is a new and promising preventive strategy to reduce the increasing demand on healthcare resources of hip fractures and their sequelae. We showed that EF prevents displacement of the fracture according to NSA. Out of the 16 femurs treated with EF only one femur failed and had complete displacement. The fracture in this femur ran through the femur head of both the treated and paired control femur. The elastomer had insufficient grip to prevent displacement in this case.

In addition to the prevention of displacement the results of this study show a positive effect of minimal invasive elastomer femoroplasty on the fracture load, diminishing the possible EF induced fracture risk that we saw in our previous study. In this previous study we drilled a 10 mm diameter entrance in the lateral cortex and found a 10% decrease in fracture load. The major difference with our present study is that we drilled a smaller, 3.5 mm diameter, entrance hole. It is likely that the non-significant reduction in fracture load decrease after EF in our current experiment (3.5%
for the balloon and 6.3% for the drill technique) can be contributed to the smaller diameter of the entrance hole. In vivo this 3.5 mm defect in the lateral cortex would close due to bone formation within a short period of time.

However the results of the fracture loads have to be interpreted cautiously. Since there was a large spread in fracture loads between femur pairs and between treated and control femurs from the same pair a statistical type 2 or beta error could be possible. A possible explanation for this large spread in fracture loads could be the differences in hip geometry between pairs and individual proximal femurs. Previous studies using cadaveric materials also found large standard deviations in the load to fracture [13, 21]. In future experiments with EF this large spread in fracture loads could possibly be decreased by using standardized composite bones.

We used fixed specimens for our experiments. This is a limitation of our study since most biomechanical experiments are done with fresh frozen cadaveric bones. We justified this second choice material because each femur was tested to its native, fixed control. The results from the DXA-scans show that in our experiments the drilling of a hole and excavation of the proximal femur has no significant negative effect on
measured BMD. This suggests that DXA does not accurately assess the cancellous bone
mass. Since the femurs in both control and treated groups did not significantly differ
in fracture load, the role of cancellous bone on proximal femur strength is uncertain in
these fixed cadaver femurs.

Reduction of hip fracture incidence by preventive EF is unlikely since EF does
not increase fracture loads. However hip fracture surgery could be reduced since
EF prevents the displacement of fracture elements according to NSA. Conservative
functional treatment of these undisplaced hip fractures, with early reactivation
and mobilization, can than be administered. This will diminish hip surgery related
complications. Furthermore the mortality rate after conservative functional treatment
as has been described after Garden 1 hip fractures is significantly lower compared to
surgery [22, 23].

The polydimethylsiloxane elastomer we used is not a particularly stiff material
like steel or regular cement. Increasing the strength of the proximal femur to reduce
hip fracture incidence by augmentation or enhancement with injectable cement
(Femoroplasty) has been proposed [21]. However, in case of a fall the energy is passed
on to parts of the hip with no augmentation like the femur shaft or acetabulum. A
fracture in those regions often requires more extensive surgery with subsequent
increased morbidity and mortality [24-26]. On the other hand continuous loading and
unloading in a fractured femur after EF stabilization could cause movement in the
fracture leading to complications like delayed or malunion. In such cases or in the case
of secondary fracture dislocation, osteosynthesis by implantation of a Dynamic Hip
Screw or gamma-nail should not be a problem. Normal drills and instruments can easily
penetrate the EF-treated hip. This is a major advantage over cement.

Although rare, avascular necrosis occurs in the conservatively treated undis-
placed hip fractures in 2-11% [22, 23]. This could be a possible drawback of preventive
EF. We also know that cement augmentation in unstable pertrochanteric fracture does
not cause an increase in avascular necrosis [27]. Future studies should clarify the effect
of EF on the vasculature of the femur head and proximal femur.

The balloon technique created a significantly greater cavity for the elastomer,
however this did not result in significant differences in fracture loads or NSA between
both groups. The quantity of the elastomer in the proximal femur did not significantly
correlate with fracture load in either group. Again future experiments with standardized
composite bones could overcome the difficulty of the large spread in fracture loads.

From our previous experiments we know that displacement forces after EF
tested in a single leg stance configuration are approximately 1500N. Hip-contact
forces with walking in a normal gait pattern are higher, ranging from 1500-2250N in a
75 kg individual [28-30]. However after hip fracture surgery patients start to mobilize
using walking aids and thus only loading with a smaller portion of their body weight.
Moreover, pain after a hip fracture of an EF stabilized hip, will probably also restrict the
patient from full weight bearing. This would reduce the load of force and therefore reduce the risk of secondary displacement of the fracture elements, allowing impaction and consolidation. Future cyclic loading and unloading tests in fractured femurs treated with EF will have to clarify these displacement forces.

We found that EF reduced even complex trochanteric fractures to normal geometry. However in vivo these instable, extra-capsular fractures are more likely to have secondary displacement after load bearing. Therefore, a careful selection of patients who are likely to acquire a transcervical fracture in the future should be made. Since the likelihood of identical fractures in both hips is as high as 75% [11, 31]. High-risk patients with a transcervical hip fracture could be considered for preventive EF in their contralateral hip during primary hip fracture surgery.

In conclusion this study shows that elastomer femoroplasty stabilizes the proximal femur by restoring hip geometry according to NSA after fracture. Furthermore minimal invasive balloon and excentric drill femoroplasty techniques did not reduce fracture force compared to paired control femurs. However these results have to be interpreted cautiously since sample size was small and standard deviations were high. Minimal invasive elastomer femoroplasty could be a promising new strategy to prevent hip fracture surgery. Future experiments should clarify its feasibility in-vivo.
REFERENCES
