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Feasibility of osteosynthesis of fractured cadaveric hips following preventive elastomer femoroplasty

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ABSTRACT

Background: In vitro cadaveric studies showed that elastomer femoroplasty prevents displacement of fracture parts after proximal hip fracture allowing for conservative treatment. In the event that secondary displacement does occur, the purpose of this present study was to determine the feasibility of performing osteosynthesis of a fractured hip after preventive treatment with elastomer femoroplasty.
Methods: Ten pairs of human cadaveric femurs were fractured in a simulated fall configuration. From each pair, one femur was randomly selected for elastomer femoroplasty prior to fracture generation and the contralateral femur was used as control. Following hip fracture generation, osteosynthesis was performed in all femurs. The operative time per case, technical difficulties during the procedure, and postoperative energy-to-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 elastomer femoroplasty-group ($P = 0.69$). During osteosynthesis of the fractured hip in the elastomer femoroplasty-group, no difficulties including the need for additional instruments to remove elastomer from the proximal femur were recorded. Postoperative energy-to-failure load was similar in the control-group and the elastomer femoroplasty-group.
Conclusion: Fixation with routine osteosynthesis of displaced cadaveric hip fractures is not hindered by the presence of previously injected elastomer.

1. 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 (Berry et al., 2007; Kaper and Mayor, 2001). The risk of a second hip fracture increases with age (Berry et al., 2007; Kaper and Mayor, 2001), weakened cognitive and motor function (Yamanashi et al., 2005), respiratory disease (Mitani et al., 2010) and solitary life (Kim et al., 2012). Recent literature suggests that the outcome of surgery for a second, contralateral fracture may be worse than that of a first hip fracture (Holt et al., 2012; Pearse et al., 2003; Rodaro et al., 2004) in terms of early postoperative complications, discharge institutionalization, independent mobility and survival (Holt et al., 2012).

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 (Black et al., 1996; Lyles et al., 2007; Reginster et al., 2008), external mechanical protection with hip protectors (Kannus et al., 2000), and cement augmentation of osteoporotic bone (Beckmann et al., 2007; Sutter et al., 2010). 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 (Heini et al., 2004). 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 (Boner et al., 2009; Dunne and Orr, 2002). 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 (Beckmann et al., 2007).

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 (van der Steenhoven et al., 2009; van der Steenhoven et al., 2011; van der Steenhoven et al., 2012a). 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 (van der Steenhoven et al., 2009). Rather, EF has been shown to

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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 (Raaymakers and Marti, 1991), 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 (van der Steenhoven et al., 2011; van der Steenhoven et al., 2012a). 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).

2. Methods

2.1. 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 an injection of an embalming fluid into the femoral artery. The embalming fluid consisted of 36% formaldehyde (CH_2O) with a mixture of ethanol (C_2H_5OH), glycerin ($C_3H_5(OH)_3$), phenol (C_6H_5OH), potassium sulfate (K_2SO_4), sodium sulfate (Na_2SO_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, UK). 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).

2.2. 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 ($\pm$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 ($\pm$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 ($\pm$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 (van der Steenhoven et al., 2009). 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 excentric drill. Finally, a 15 mm excentric 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 which initially has a low viscosity, cures without exothermic heat and without the formation of by-products as it hardens in an aqueous environment (Ignjatovic et al., 2003; Khorasani et al., 2005). 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.

2.3. Hip fracture generation

Biomechanical testing was done using an LR5K*Plus* 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 (Courtney et al., 1995). 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° internally rotated (Fig. 1). The load was applied using a silicone-coated cup attached to the crosshead of the testing machine. The crosshead moved with 2 mm/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°. The type of generated fracture was classified according to the AO-classification.

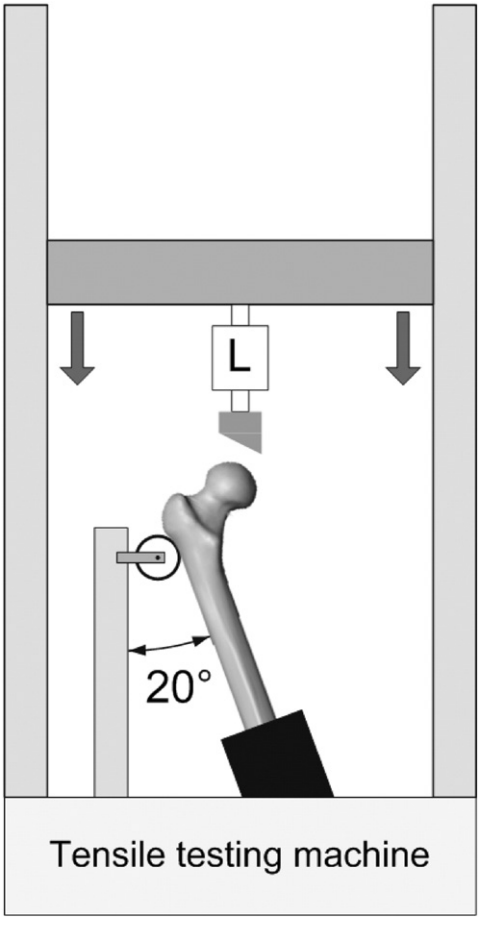

Fig. 1. Graphic display of the single leg stance configuration, with the femur fixed upright at a 20° angle from the vertical plane and 15° endorotation. The 'L' marks the load cell.

2.4. 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 200 mm) following AO guidelines. The column screws of both the DHS and the PFNA were placed with a maximum tip apex distance of 25 mm, as noted in the study of Baumgaertner and Solberg (Baumgaertner and Solberg, 1997). During the osteosynthesis procedures, the operative time (min) and any technical difficulties during the procedure were recorded.

2.5. 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 Fig. 2.

2.6. Statistical analysis

Statistical analysis was done using SPSS (SPSS 16.0, SPSS Inc., Chicago, IL, USA). Within the control and EF-groups, 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.

3. 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 ($\pm$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.

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.

Femur	Control-group		EF-group		Unpaired student *t*-test
	Implant	Min	Implant	Min	$P = 0.8852$
#1	DHS	14	DHS	16	
#2	DHS	13	DHS	13	
#3	DHS	18	DHS	17	
#4	DHS	14	DHS	13	
#5	DHS	13	DHS	12	
Mean (SD)		14 (2)		14 (2)	
#6	PFNA	28	PFNA	23	
#7	PFNA	22	PFNA	24	
#8	PFNA	28	PFNA	19	
#9	PFNA	29	PFNA	22	
#10	PFNA	20	PFNA	27	
Mean (SD)		25 (4)		23 (3)	$P = 0.3171$

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

4. Discussion

The feasibility of performing standard osteosynthesis of a fractured proximal femur after preventive elastomer femoroplasty was evaluated in an in-vitro biomechanical study. We found no statistically significant differences in either operative time to perform osteosynthesis or post-operative energy-to-failure load between fractured human cadaveric femurs that were beforehand treated with elastomer femoroplasty 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 elastomer femoroplasty 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 (Heini et al., 2004; Sutter et al., 2010). Heini et al. injected cement into osteoporotic cadaveric proximal femurs (Heini et al., 2004). By doing so, peak fracture load for a simulated fall on the hip was increased by 82%, with a corresponding increase in energy

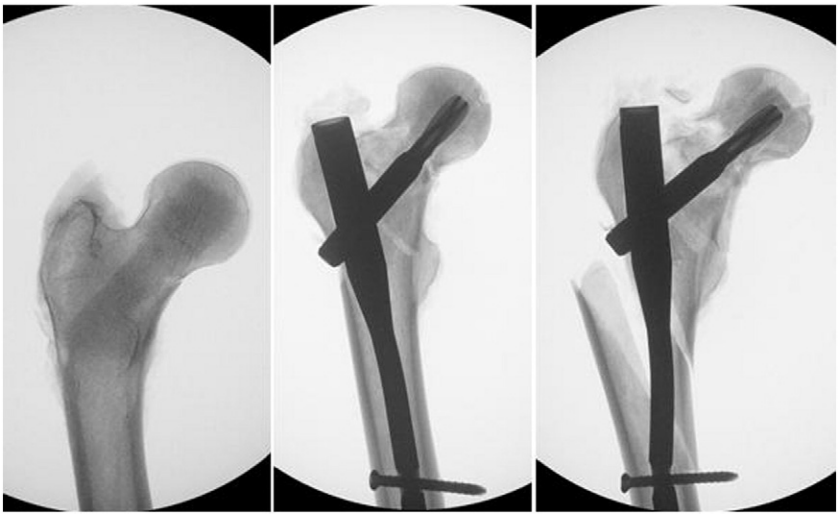

Fig. 2. X-rays of the cadaveric femurs with (from left to right) fracture after EF; osteosynthesis after EF with fracture; after failure of osteosynthesis.

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).

Femur	Control-group		EF-group		Unpaired student *t*-test
	Implant	Failure load (N)	Implant	Failure load (N)	
#1	DHS	4510	DHS	3050	
#2	DHS	3750	DHS	2450	
#3	DHS	3200	DHS	5000	
#4	DHS	3930	DHS	2670	
#5	DHS	3200	DHS	3560	
Mean (SD)		3718 (550)		3346 (1016)	$P = 0.4920$
#6	PFNA	3200	PFNA	4050	
#7	PFNA	3680	PFNA	3940	
#8	PFNA	4740	PFNA	2900	
#9	PFNA	3820	PFNA	3640	
#10	PFNA	3800	PFNA	3460	
Mean (SD)		3848 (558)		3598 (455)	$P = 0.5717$

absorption of up to + 188%, compared to noninjected femurs, indicating that cement augmentation might prevent hip fractures in elderly patients. Unfortunately, cement augmentation was associated with significant heat generation due to polymethyl-methacrylate polymerization. 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 (Beckmann et al., 2007).

As an alternative to bone cement to reinforce the proximal femur, we introduced femoroplasty using polydimethylsiloxane (van der Steenhoven et al., 2009), an elastomer which cures without exothermic heat (Ignjatovic et al., 2003; Khorasani et al., 2005). 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 (van der Steenhoven et al., 2009). Dislocation according to neck shaft angle was significantly reduced in the EF group (van der Steenhoven et al., 2009; van der Steenhoven et al., 2011). Furthermore, during subsequent cyclic loading, the failure load of fractured femurs stabilized by elastomer femoroplasty was 2709 N (van der Steenhoven et al., 2012a) — well exceeding the peak loads of approximately 1500–2025 N during normal gait in a 75 kg individual (Bergmann et al., 2001; Kotzar et al., 1991). 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 (Kheir et al., 1998; Spiller et al., 2007; van der Steenhoven et al., 2012b). 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 2). 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 (Heini et al., 2004; van der Steenhoven et al., 2009). 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.

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