A biomechanical evaluation of orthopaedic implants for hip fractures by finite element analysis and in-vitro tests

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Abstract: The aim of this study was to test the hypothesis that a reinforced gamma nail for the fixation of subtrochanteric fractures would experience less stress during loading compared with a common gamma nail. The issue of whether the use of the stronger implant would result in more stress shielding in the surrounding bone was also addressed.

A finite element analysis (FEA) of a synthetic bone was employed to calculate the stress distribution in implant and bone for two fracture types (AO 31-A3.1 and AO 31-A3.3). The FEA was validated by mechanical tests on six synthetic femurs. To test the hypothesis in vitro, mechanical tests on six pairs of fresh-frozen human femurs were conducted. The femurs were supplied with a common or a reinforced gamma nail in a cross-over study design. Strains were measured on the nail shaft to quantify the loading of the nail.

The FEA resulted in 3–51 per cent lower stresses for the reinforced gamma nail. No increase in stress shielding could be observed. In the in-vitro tests, the reinforced gamma nail experienced less strain during loading ($p < 0.016$). The study demonstrated the benefit of a reinforced gamma nail in subtrochanteric fractures. It experienced less stress but did not result in more stress shielding.

Keywords: finite element analysis, standardized femur, osteosynthesis, intramedullary implant, hip fracture, in-vitro test, biomechanics, gamma nail

1 INTRODUCTION

Hip fractures are considered one of the major health problems of ageing societies [1]. These fractures are correlated with an increased disability and mortality and a decreased quality of life [2, 3]. Early mobilization of patients with these fractures is essential to improve fracture healing, minimize immediate post-surgical morbidity, and reduce health care costs. One essential prerequisite for early mobilization is mechanically stable fracture fixation [4].

Nowadays, most hip fractures are treated by extra- or intramedullary implants, which allow a stable fixation in the majority of cases [5]. Approximately 5–10 per cent of all hip fractures have a subtrochanteric location [6]. These fractures are considered highly unstable and pose a significant challenge to the fixation method [7]. Different types of implant, e.g. dynamic hip screws, intramedullary nails, or sliding plates, are available for the fixation of subtrochanteric fractures, without significant differences in clinical outcome [8–11]. However, fixation by long gamma nails may be preferable to plate fixation in highly unstable subtrochanteric fractures or subtrochanteric non-unions [11, 12]. The reason is possibly that the choice of implant, particularly with reference to proximal nail dimensions and implant materials, determines the amount of fracture site motion in unstable subtrochanteric fractures [13].

Despite the good clinical results with osteosyntheses, there is still a significant number of post-operative complications, such as delayed union, non-union, or even implant failure [14, 15]. This is particularly true for subtrochanteric, pathologic, or
other highly unstable fractures [10, 16, 17] and for fractures with delayed or absent healing [8, 18, 19]. Reinforcement and strengthening of implants could possibly prevent failure and improve fracture stability and also fracture healing. 

However, when patients with unstable fractures and expected delay of fracture healing are supplied with stronger and stiffer implants, stress shielding can be an issue [20–24]. Stress shielding is the effect when the load transfer to the bone decreases, and the load on the implant increases, because of the high stiffness of the implant [22, 25]. Less load transferred to the bone could possibly slow down fracture healing and increase post-traumatic bone loss [26–28]. Furthermore, reinforcement of some parts of the implant could shift the mode of failure to other parts of the implant construct. Reinforcing a plate could threaten the screws, or reinforcing an intramedullary nail could threaten the lag screw or locking screws [29].

This study was performed to test the hypothesis that a stronger intramedullary nail for the fixation of unstable subtrochanteric fractures would experience less mechanical stress during loading. The potential consequences of decreased implant stress would be changes in the loading of bone and fracture. Therefore, the study specifically addressed whether (1) the use of a stronger implant would result in more stress shielding in the surrounding bone, and (2) an increase in fracture severity would increase the stress on the implant. Because of the complexity of these specific aims, a previously developed numerical model of the human femur was employed to test the hypothesis.

2 MATERIALS AND METHODS

The biomechanical performance of two intramedullary implants with diverse proximal diameters was evaluated by two different approaches. First, finite element analyses (FEAs) of the implants in a synthetic bone model were conducted and validated subsequently by analogue mechanical tests. Second, the implants were tested mechanically in human cadaver specimens.

2.1 FEA of synthetic femur model

The FEAs of the implants within synthetic bones were conducted to determine strains and stresses within implant and bone and the system stiffness of the osteosynthesis during loading. A previously developed finite element (FE) model of a synthetic femur was used to conduct the FEA [30]. Briefly, the FE model was able to predict valid strains on intramedullary implants that fixated hip fractures of synthetic femurs with a good accuracy. The validation of this previous model was accomplished by comparing strains on the implant and the osteosynthesis stiffness, which were calculated by the FE model, with strains and stiffness values that were determined in analogue mechanical experiments. In addition, the influence of the coefficients of friction between the fracture fragments and in the bone–implant interface was investigated. The model and its mechanical and numerical assumptions were therefore applicable to determine the difference in biomechanical performance between the two implants that were investigated in this study.

The FE models in the current study simulated two different cephalomedullary nails (Stryker Osteosynthesis, Schoenkirchen/Kiel, Germany) in femurs of synthetic bone (Fig. 1). One nail was a Gamma3 Long R2.0 (left, length 420 mm), which is a current
standard treatment for subtrochanteric fractures [8, 16] (Figs 1(a) and 2(a)). The other nail was a prototype similar in design to a Gamma3 Trochanteric Nail 180, but with a larger diameter of the proximal shaft and thicker walls in this region (Figs 1(b) and 2(b)). Two subtrochanteric fractures were investigated: a two-part reverse fracture (AO 31-A3.1, Fig. 1(a)) and a three-part reverse fracture without support of the lesser trochanter (AO 31-A3.3, Fig. 1(b)) [31].

The FE models were computed for two load cases. Both load cases were calculated for the maximum load on the hip during walking for an 80 kg person. The chosen scenario is the most common load case during the recovery of total hip patients [32]. Load case A simulated a single hip joint force on the centre of the femoral head (Fig. 1(a)). The acting force amounted to 1866 N, following Bergmann et al. [33]. For load case B, a resultant force composed of the forces by the tractus iliotibialis and the muscles attached to the major trochanter was added to the loading scenario (Fig. 1(b)). For this load case, the hip joint force amounted to 2007 N, and the added muscle force amounted to 574 N, according to the proposed load case by Heller et al. [34]. The vector product of hip joint force and added muscle force was equal to the hip joint force used in the load case A. For the load case A, the angles between the load direction and the diaphyseal axis were calculated to be 13° in the frontal, and 8° in the sagittal, plane [33]. For the load case B, the angles between the load direction and the diaphyseal axis were calculated to be 28.5° in the frontal, and 17° in the sagittal, plane [34].

The material properties for the synthetic femur were assigned according to the manufacturer’s specifications (model 3406, Sawbones AB, Malmö, Sweden). The Young’s modulus for cortical bone amounted to 16.0 GPa and to 155 MPa for cancellous bone. The Poisson’s ratio was set to 0.3 for both materials. The material properties of Ti6Al4V were used for the implants. The Young’s modulus was set to 113.8 GPa, and the Poisson’s ratio to 0.34. All materials were assumed to be homogeneous, isotropic, and linear elastic.

The FE models considered all contacts between fracture fragments and implant. All contacts were considered as frictional except the interfaces between the threaded parts of the implant and the bone. These interfaces were considered bonded, as the screw connections did not allow axial or shear movement, and the detailed stress distribution within the threads was not of interest. The coefficient of friction for the frictional contacts was 0.46 between bony parts (determined in own experiments, unpublished), 0.23 between implant components (determined in own experiments, unpublished), and 0.3 for the interface between bone and implant [35]. All contacts were calculated with an augmented Lagrange algorithm, which allowed coulomb friction behaviour.

The FE models consisted of 53 000–67 000 elements and 103 000–127 000 nodes and were built with ANSYS® Academic Research, v.11.0 WorkbenchTM (ANSYS Inc., Canonsburg, PA). Higher-order (quadratic ansatz) structural solids with hexahedral or tetrahedral shapes were used for meshing. Convergence tests were performed on all models to ensure a fine enough element discretization for stress and strain analysis.

To investigate the difference between the two implants for a wider range of bone qualities, the mechanical properties of the FE models were altered to simulate osteoporotic bone. The Young’s modulus was changed from 16.0 GPa to 12.4 GPa for the cortical bone and from 155 MPa to 77 MPa for the cancellous bone [36].

The stiffness of the osteosynthesis was determined by dividing the maximum load by the maximum displacement of the centre of the femoral head in the load direction. The von Mises stress distribution within the implant was examined to identify spots of maximum stress in areas of high tensile strain in the axial direction of the nail. These stress points are usually the locations where cracks start and failure occurs in the case of repetitive loading. The maximum principal stress distribution was calculated for the cortical bone to determine the loading of the bone. The normal strain on the nail in the direction

![Fig. 2](image-url)
of its longitudinal axis was examined to locate spots of high local strain. By doing so, locations could be identified where strain gauges (SGs) could measure high signals of strain in the later cadaver tests.

2.2 Experimental validation of FE models

Mechanical tests were conducted to validate the FE models of the implants in synthetic femurs regarding the load on the implants. Six composite bones (left femur, model 3406, Sawbones AB, Malmö, Sweden) were osteotomized and fixated with a Gamma3 Long R2.0. Strains on the implants and the system stiffness were measured for validation. The implants were fitted with three uniaxial strain gauges prior to implantation to measure strains on the proximal and the middle part of the nail shaft. Three of the six bones had an AO 31-A3.1 fracture; the other three had an AO 31-A3.3 fracture. The specimens were loaded with the load case A. For further details on the methods of this validation, the authors refer to a previous study [30]. To evaluate the quality of the numerical models, a linear regression analysis between the experimental and the numerical results was performed. The quality of the numerical results was expressed by the coefficient of linear regression $R^2$, and by the slope and the intercept of the regression curve, as described by Taddel et al. [37].

2.3 In-vitro human cadaveric tests

In addition to the FEA and the mechanical tests on the synthetic femurs, cadaver tests were conducted with the same set-up as the FE models to test the stated hypotheses in vitro and to verify the results of the FEA. Strains on the implants and the system stiffness were measured to determine the difference in biomechanical performance between the two implants. Eight pairs of fresh-frozen human femurs (four female, four male, age 67 ± 7 yrs) were osteotomized and fixated with the two implants used in the FEA in a randomized paired crossover design. By doing so, four left-side femurs and four right-side femurs were supplied with a Gamma3 prototype. All other femurs were supplied with a Gamma3 Long R2.0 (right or left, length 360–420 mm, depending on side and length of femur).

The implants were fitted with two uniaxial strain gauges prior to implantation to measure strains on the proximal nail shaft. The strain gauges (KFG-1-120-C1-11L3M3R, Kyowa Electronic Instruments Co., Ltd, Tokyo, Japan) were fixed anteriorly and posteriorly of the hole for the lag screw. These are the spots of maximum strain on the nail in subtrochanteric fractures [30]. The axes of the strain gauges were in line with the longitudinal axis of the nail shaft. The strain gauges were linked to the data acquisition system Spider 8 (Hottinger Baldwin Messtechnik GmbH, Darmstadt, Germany), which was connected to a personal computer to record the data with the software Catman easy (Hottinger Baldwin Messtechnik GmbH, Darmstadt, Germany).

The bones were thawed for 12 h at a temperature of +4 °C prior to the implantation procedure. The thawed bones were embedded in casting resin (RENCAST FC53, Huntsman Advanced Materials GmbH, Bergkamen, Germany). The distal end was embedded in a block, and the femoral head was embedded in a hemisphere of casting resin, which was concentric to the hemispherical adaptor of the test set-up (Figs 3(a) and (b)). The concentricity of adaptor, casting, and the femoral head introduced the force to the centre of the femoral head.

The surgeries were performed by a trained surgeon according to the usual operative technique for Gamma3 trochanteric nails, as given by the manufacturer’s manual. To prevent any damage of the nail during the drilling of the hole for the lag screw, an identical dummy nail was inserted first. The lag screw was positioned centrally in the femoral head, with a distance of 6–10 mm to the medial cortex. On all implants, the option for dynamic proximal locking by the setscrew and static distal locking by cortical screws was applied, following clinical practice. The fractures (AO 31-A3.1 and AO 31-A3.3) were introduced by means of osteotomy with a surgical bone saw (Figs 3(c) and (d)). There was no interfragmentary gap size left.

The embedded and operated bones were mounted into an axial load test set-up of a servo-electric testing machine (Zwick 010, Zwick GmbH & Co. KG, Ulm, Germany). The force by the testing machine was introduced to the femoral head by a ball-joint-like support (Figs 3(a) and (b)). A universal joint with two axes supported the distal end. The angles between the machine force and the diaphyseal axis were identical to the set-up of the FEA. The proximal load offset to the diaphyseal axis depended on the anatomical properties of the human femurs. The distal load offset to the diaphyseal axis in the frontal plane amounted to 23 mm.

Static tests similar to the set-up in the FEA and the mechanical tests of the synthetic bones were carried out, with elastic deformation of the specimens. The tests were conducted with a crosshead speed of
10 mm/min. The testing incorporated two load cycles of preconditioning at 600 N and 1200 N for load case A (Fig. 3(a)), with a final load cycle of 1866 N, and one load cycle for load case B (Fig. 3(b)) up to a maximum force of 1053 N. The load levels were controlled via a load cell (Serie K, GTM Gassmann Testing and Metrology GmbH, Germany). The additional muscle force in the load case B amounted to 574 N and was applied by a steel cable to the lateral part of the proximal femur (Fig. 3(b)). A lever tensioned the cable. This lever converted the compressive force of the load cell into a tensile force within the cable. The pivot of this lever was the proximal embedding of the femur at the femoral head (Fig. 3(a)). The muscle force was controlled by a load cell applied to the steel cable (Typ K-25, ATP Messtechnik GmbH, Etttenheim, Germany). A holding time of 5 s per load cycle was used to gather the data.

The workflow was the same for all specimens. The specimens first obtained the 31-A3.1 (Fig. 3(c)) fracture and were tested in load case B and then in load case A. Afterwards, the 31-A3.1 fracture was transformed into a 31-A3.3 fracture by removal of the lesser trochanter (Fig. 3(d)). The specimens were then tested in load case A, followed by load case B.

The system stiffness of the tested specimens was determined by recording the load versus deformation curve for the full load range and for all test cycles. The strains on the nails measured by the strain gauges were recorded for the implantation procedure, for the full load range, and for all test cycles. Only the strains recorded at the maximum load and at the end of the holding time were used for the later statistical analyses. The difference in the means of the strain and stiffness values between the two investigated implants was tested for statistical significance ($p < 0.05$) by an unpaired t-test. The difference in the mean values of strain and stiffness between the two fracture types was tested for statistical significance ($p < 0.05$) by a paired t-test.

3 RESULTS

3.1 FEA of synthetic femur model

The Gamma3 prototype resulted in 3–51 per cent lower stresses at the nail shaft compared with the Gamma3 Long R2.0, depending on the load case and the type of fracture (Table 1). The Gamma3 prototype resulted in from 17 per cent higher to 67 per cent lower stresses at the lag screw compared with the Gamma3 Long R2.0, depending on the load case and the type of fracture (Table 1). For all load cases and types of fracture, the spot of maximum stress was at the contact zone of the fracture fragments in all cases.

Fig. 3 (a) Experimental set-up for the load case A and (b) experimental set-up for the load case B, with a steel cable to apply a simulated muscle force to the femur. (c) Cadaver specimen with an AO 31-A3.1 fracture and (d) cadaver specimen with the less stable AO 31-A3.3 fracture
The fracture severity had a considerable impact on the stress within the implants. Regardless of the load case and the type of implant, the stress on the nail shaft increased by 166 per cent, and the stress on the lag screw increased by 162 per cent from the 31-A3.1 fracture to the more severe 31-A3.3 fracture.

No shift of the spot of maximum stress from the nail shaft to the lag screw could be observed for the Gamma3 prototype (Table 1). Independent of the fracture and the load case, the stress within the lag screw was never higher than 50 per cent of the stress within the nail shaft. Changing the material properties of the bone to simulate osteoporotic behaviour increased the stress on the implant only slightly. This result can be expected, on the basis that the implant is subjected to imposed loads. The stress on the nail shaft increased by 5 per cent, and the stress on the lag screw increased by 8 per cent, averaged over both load cases and fractures.

### Table 1 Stress and stiffness determined by the FEA for the two load cases, the two fracture types, and the two implants. The stress values depict the maximum stress found within the implant or the cortical bone

<table>
<thead>
<tr>
<th>Load case</th>
<th>Fracture</th>
<th>Implant</th>
<th>Von Mises stress, nail shaft (MPa)</th>
<th>Von Mises stress, lag screw (MPa)</th>
<th>Main principal stress, cortex (MPa)</th>
<th>Stiffness (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>31-A3.1</td>
<td>Gamma3 prototype</td>
<td>565</td>
<td>213</td>
<td>112</td>
<td>520</td>
</tr>
<tr>
<td></td>
<td>31-A3.3</td>
<td>Gamma3 Long R2.0</td>
<td>582</td>
<td>210</td>
<td>89</td>
<td>619</td>
</tr>
<tr>
<td>B</td>
<td>31-A3.1</td>
<td>Gamma3 prototype</td>
<td>1119</td>
<td>330</td>
<td>134</td>
<td>323</td>
</tr>
<tr>
<td></td>
<td>31-A3.3</td>
<td>Gamma3 Long R2.0</td>
<td>2065</td>
<td>991</td>
<td>132</td>
<td>288</td>
</tr>
<tr>
<td></td>
<td>31-A3.3</td>
<td>Gamma3 Long R2.0</td>
<td>749</td>
<td>275</td>
<td>94</td>
<td>579</td>
</tr>
</tbody>
</table>

**3.2 Experimental validation of finite element models**

The linear regression curve between the experimental and the numerical strain and stiffness values had a slope of $m = 0.8268$, an intercept of $t = 38.882$, and a linear regression coefficient of $R^2 = 0.8035$. The mean deviation between FEA and experiment for the three strain gauges amounted to 21 per cent (Fig. 5). The mean deviation for stiffness was 36 per cent (Fig. 5). For most measurements, the numerical result was between the maximum and the minimum experimental value (Fig. 5).

**3.3 In-vitro human cadaveric tests**

The stronger Gamma3 prototype experienced less strain during loading. Independent of load case and fracture type, the strains on the Gamma3 prototype
were significantly lower (−26 per cent with \( p = 0.016 \) in SG anterior, −58 per cent with \( p < 0.001 \) in SG posterior) than on the Gamma3 Long R2.0. No significant difference (\( p = 0.447 \)) in stiffness was found between the two implants, averaged over both fractures and load cases, although the Gamma3 prototype achieved a somewhat higher stiffness of +16 per cent (Fig. 6).

The fracture severity had an impact on the loading of the implants for the cadaver tests as well. Regardless of the load cases and implants, the strains on the implants were significantly higher (+66 per cent with \( p < 0.001 \) in SG anterior, +69 per cent with \( p = 0.001 \) in SG posterior) for the 31-A3.3 fracture than for the 31-A3.1 fracture. The stiffness of the specimens was significantly lower (−44 per cent

Fig. 5  Strains and stiffness determined for three long gamma nails in three synthetic femurs for the validation of the FE model. The experimental (EXP) values are given as means, with error bars that depict the maximum (max) and the minimum (min) value of the three tested specimens.

Fig. 6  Strains and stiffness measured in the cadaver tests. The testing groups are split up into load case (A or B), fracture type (31-A3.1 or 31-A3.3), and implant (Gamma3 prototype or Gamma3 Long R2.0). All values are based on six specimens and given as means with standard deviation (sd).
with \( p = 0.008 \) for the 31-A3.3 fracture than for the 31-A3.1 fracture (Fig. 6).

As an unanticipated result, the additional muscle loading of the load case B had no significant effect on the loading of the implant. No significant difference \( (p = 0.107 \) in SG anterior, \( p = 0.238 \) in SG posterior) in strains on the implant was found between the two load cases, averaged over both fractures and implants.

4 DISCUSSION

This study evaluated the biomechanical performance of two cephalocondylic intramedullary nails with dissimilar stiffness and strength to test the hypothesis that the stronger implant would experience less stress during loading. Because of the potential consequences of a decreased implant stress on the loading of the bone and the fracture, two specific questions were investigated:

1. Does the use of a stronger implant result in more stress shielding in the surrounding bone?
2. Does reduced fracture stability increase the stress on the implant?

The FEA confirmed the hypothesis and showed that the stronger implant experiences less stress at the nail shaft, which is the part of most interest regarding fatigue failure [38]. Therefore, the stronger implant would endure longer periods of delayed healing. This effect was more pronounced in the less stable fracture. The cadaver study confirmed the results of the FEA. The stronger implant experienced 26–58 per cent \( (p < 0.016) \) less strain during the mechanical tests. However, the reduced stress within the stronger intramedullary nail did not result in more stress shielding in the surrounding bone tissue. The FEA resulted in similar stresses within the cortical bone for the two different implants.

The fracture stability had a large effect on the implant stress in the FEA and the cadaver tests. The FEA showed a difference of about 160 per cent in implant stress between the two different subtrochanteric fractures, with the higher stresses observed in the less stable fracture type. This effect was backed up by statistically significant results of the cadaver tests. The strains measured on the nail shaft were higher in the less stable 31-A3.3 fracture by an average of almost 70 per cent \( (p \leq 0.001) \).

As known from the literature, different implant designs result in different stress distributions within the implant [39]. This is important to know when unstable subtrochanteric fractures have to be fixated, because the implant is heavily stressed in these fractures [30]. The results of the FEA and the cadaver tests underline the benefit of a stronger and stiffer intramedullary nail in unstable subtrochanteric fractures. The nail experienced less stress/strain and is therefore less susceptible to failure. The reduced stress within the stronger implant has been confirmed for the nail shaft and partly for the lag screw. There would be no risk of failure for the lag screw, because the stresses in the nail shaft were higher in all cases.

Previous studies on the topic of differences in implant stiffness and its impact on stress shielding focused on joint replacements. These studies showed coherence between the implant stiffness and the amount of stress shielding [40, 41]. An increase in implant stiffness correlated with a decrease in stress within the surrounding bone. The current study did not confirm this effect for the use of a stiffer osteosynthesis. When looking at each of the four different testing conditions in the FEA, there was no clear effect of stress shielding for the stronger implant. Depending on the fracture and the load case, the stronger implant resulted in between 26 per cent more stress and 21 per cent less stress in the cortex of the proximal femur.

The findings for the relation between fracture severity and implant stress are consistent with the current literature. The maximum stress within an implant increases with the fracture severity [30], whereas the load on the bone decreases [20]. Therefore, the type of implant and its fatigue strength are important in unstable fractures [13, 42]. This is reflected by the clinical situation, where implant-related problems occur mostly in complex fracture scenarios with a low initial stability [43–45].

The mechanical tests with the composite bones showed fair corroboration with the FE models. The validation of the FE model resulted in a mean deviation of 22 per cent for all measurements, which is good and comparable with other computational studies on the standardized femur [46, 47]. However, the strains at the proximal part of the nail calculated by the FEA and measured in the mechanical tests on the cadaver bones showed large deviations (Fig. 7). In addition, the stiffness of the FE models was almost twice the stiffness measured for the cadaver specimens (Fig. 7). Although the material properties of the FE model were changed to simulate osteoporotic bone, the large deviations between the standardized femur and the human femurs remained almost constant (Fig. 7). The reason for the
deviations is probably the very different geometry of the human cadaver femurs and the standardized femur, which represents a young population. Furthermore, the typical cortical thinning in aged long bones was not realized in the FE models [48].

The main strength of this study is the use of an already validated model of a standardized femur with an intramedullary nail. Differences between implants are easier to evaluate using a standardized bone. Although the model and its assumptions were already validated for a slightly different implant, the model was validated again for one of the two tested implants. Two fractures were tested in two different loading scenarios to investigate the stated hypothesis and research questions not only in one model. One of the two loading scenarios included an additional muscle force to simulate a physiological loading of the femur. The constraints of the proximal and the distal ends of the femurs in the FEA and in the mechanical tests were physiologically according to Speirs et al. [49]. By changing the material properties in the FE model of the standardized femur to simulate an osteoporotic behaviour, the influence of the implant stiffness has been assessed for a wider range of bone qualities.

In addition, the results of the FEA were checked by mechanical tests of human cadaver femurs. Within these tests, strains were measured on the intramedullary nail inside the cadaver bone. The additional muscle loading was realized by a special test set-up.

A limitation of this study is definitely the comparison of a long intramedullary nail with a short one, which is usually not indicated for subtrochanteric fractures. However, during the tests, no long version of the tested prototype was available. Furthermore, the moment that is introduced by the force on the femoral head to the proximal part of the nail is the same for a short and a long nail. Therefore, the stress distribution in the proximal part of the nail, which is the part of most interest in terms of failure, should not depend so much on the length of the nail.

Another limitation is the low number of strain gauges on the implants used for validation of the FE models. This was due to the restricted space between the nails and the intramedullary canal. A further validation of the standardized femur with strain gauges on the bone surface was not taken into consideration because of its known validity from other studies [47, 50]. The number of specimens limits the cadaver study. Only six pairs of human femurs were tested, despite the large deviations in bone mineral density and strength in human specimens [51].

The amount of stress shielding was evaluated by calculating the principal stress in the FE model of the standardized femur. This model had homogeneous and isotropic material behaviour compared with the inhomogeneous and anisotropic material behaviour of real human bones. Therefore, the calculated stresses might deviate from the stress...
distribution *in vivo*. In addition, it is possible that the short prototype nail tilted more over the fracture and therefore increased the load on the bone.

The load cases used were not fully physiological with a complete set of muscles, as proposed by Heller *et al.* [34]. However, load case B incorporated a resultant force that represented the muscles acting on the lateral side of the trochanter. For future evaluations of implants, it is planned to include a full set of muscles in the validated FE model of the standardized femur.

5 CONCLUSIONS

This study demonstrated the benefit of a stronger intramedullary implant in unstable subtrochanteric fractures. It experienced less stress/strain under loading and would therefore have a lower risk of fatigue failure. However, the use of the stronger and stiffer implant did not result in more stress shielding in the surrounding bone. Thus, obese patients or patients with expected delays of fracture healing may potentially benefit from the application of stronger implants. Furthermore, the amount of stress within the implant was related to the instability of the fracture type.

Regarding the methods, the FEA of the synthetic femur generated valid results compared with the analogue mechanical tests with synthetic bones. Nevertheless, the strains calculated by the synthetic femur FE model were not comparable with the strains measured in the cadaver tests. The cadaver tests were not meant to validate the FE models, but to see how the FEA of a synthetic femur compares with the *in-vitro* situation. However, even with 'osteoporotic' material behaviour, the calculated and the measured strains were still dissimilar. Therefore, the evaluation of implants in synthetic bones has to be examined with caution, because of a possible lack of transferability to *in-vitro* or *in-vivo* scenarios.

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