Numerical assessment of the mechanical properties of a new proximal femoral fracture implant in comparison with TGN and DHS.

R. Billard\textsuperscript{a,*}, P. Vacher\textsuperscript{a}, E. Vittecoq\textsuperscript{b}, F. Toussaint\textsuperscript{a}, L. Devun\textsuperscript{c}, C. Bonjour\textsuperscript{d}, Y. Arlettaz\textsuperscript{e}

\textsuperscript{a}Laboratoire Symme, Polytech Annecy-Chambéry, Université de Savoie, BP 80439, 74944 Annecy le Vieux Cedex, France
\textsuperscript{b}HES.SO, hepia, rue de la Prairie 4, CH-1202, Genève, Suisse
\textsuperscript{c}Tural, 520 avenue de l’Industrie, 74970 Marignier, France
\textsuperscript{d}Chirmat, 57 route du Chili, 1870 Monthey, Suisse
\textsuperscript{e}Hôpital du Valais, 27 avenue de la Fusion, 1920 Martigny, Suisse

\textbf{Abstract}

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\section{1. Introduction.}

Proximal femoral fractures are a major complication of osteoporosis in terms of mortality and morbidity in the elderly. The total number of hip fractures in the world, estimated at 1.26 million in 1990 is expected to double by 2025 (1). This increase is due in large part to the aging of the world population. Proximal femoral fractures can be of different natures. Reverse obliquity fractures are present in about 5\% of cases, with the remaining 95\% as either cervical or intertrochanteric fractures (2) (Figure 1). From a biomechanical point of view, reverse obliquity fractures differ from cervical and intertrochanteric fractures since the main fracture line runs from distal-lateral to proximal-medial. These fractures are called unstable because forces tend to separate fragments. Some intertrochanteric fractures are unstable when

*Corresponding author. Tel. +33 (0)450 096 510; fax: +33 (0)450 096 543
\textit{Email address:} Remi.Billard@univ-savoie.fr (R. Billard)
\textit{URL:} www.symme.univ-savoie.fr (R. Billard)
the lesser trochanter is broken off. Current implants can treat most stable fractures, but there are still difficulties for the care of unstable fractures.

![Image](a) (b) (c)
lesser trochanter detachment proximal lateral distal medial distal lateral proximal medial

Figure 1: (a) Stable and (b) unstable intertrochanteric fracture, (c) unstable reverse obliquity fracture.

The treatment of proximal femoral fractures requires surgery. Current surgical techniques, such as osteosynthesis, include the use of devices to bring and hold fragments together. The most extensive question is the choice between flexible or rigid fixation. Surgeons use two main types of implants, one is called intramedullary, the other one is called extramedullary. Both implants allow bone healing by compression fracture: the use of a dynamic cephalic screw positioned through the femoral neck, in a sliding connection with a nail (intramedullary system) (Figure 2 (a)) or a plate (extramedullary system) (Figure 2 (b)), may enable the compression of fragments. In the case of extramedullary system, an additional compression screw coupled with the cephalic screw can preload fragments.

Reverse obliquity fractures of the femur are challenging to treat, regardless of whatever implant is used. Complications such as collapse of the fracture, cut-out of the cephalic screw, or medial translation of the shaft are possible (3).

Successful treatment depends on several factors. The most dominant are the choice of implant, made by the surgeon during a preoperative evaluation. The choice seems often based on his usual practices. From one or more x-rays, the size of implant is determined according to the patient’s anatomy based on the neck/shaft angle $\beta$. The latter generally varies from about $113^\circ \leq \beta \leq 133^\circ$ (4). The length of the cephalic screw $L$ is measured. Usually, $L$ varies from about $80 \leq L(\text{mm}) \leq 120$. To cover all anatomies en-
countered, hospitals have a relatively large number of implant sizes (cephalic screws included).

TGN and DHS have been studied from different points of view such as experimental or numerical approaches:

Many researchers have conducted experimental studies (5) (6) (7). For example, Curtis et al. have assessed the rigidity and strength of the fixation provided by intramedullary and extramedullary devices for proximal femoral fractures. Rosenblum et al. have examined the effect of the TGN on strain distribution in the proximal femur. Harrington et al. have compared an intramedullary hip screw and a sliding hip screw for unstable intertrochanteric femoral fractures in the elderly.

A number of research papers have discussed implants using Finite Element analysis (8),(9),(10),(11),(12). For example, biomechanical analysis of the ideal placement of new intramedullary implants was conducted by Helwig et al. Other authors, such as Sowmianarayanan et al., have discussed intramedullary nails and extramedullary plates using FE analysis. They compare three implants in terms of deflection, stress, and strains.

The use of FE numerical simulation of biomechanical models can serve as an alternative to experimenting on ex vivo femurs (13).
In this paper, a new concept of implant for fitting intertrochanteric and reverse obliquity fractures, adaptable to the morphology of each patient, is presented. The study focuses on the mechanical behaviour of this implant. In section 2, a technical description of the implant is made. Section 3 offers a presentation of a numerical investigation carried out around TGN, DHS, and the new implant. In section 4, the results of the numerical study are described. Finally, a conclusion is made in section 5.

2. New implant.

2.1. Technical description.

The new implant, called Clovis implant, has been designed (i) to fit intertrochanteric and reverse obliquity fractures, and (ii) to be adaptable to a large majority of patients. It is made of two stainless steel metal parts, one cephalic dynamic screw and two distal screws. The two parts are connected by a deformable blade (Figure 3). One side of the implant has an elongated shape inserted into the medullary canal. The second is a plate fitted on the lateral side of the femur.

![Figure 3: (a) CAD of the new implant protected by patent n° 2012CH-00725, and (b) X-rays of the Clovis implant (postmortem test).](image)

An external device (ancillary equipment) allows the adjustment of the relative position of intra and extramedullary parts leading to a possible adjustment of the angular orientation of the cephalic screw (Figure 4). Angu-
lar adjustment of the dynamic cephalic screw is possible. Both openings for crossing of the cephalic screw through metal parts have a biconic shape. The implant allows adjustment of the $\beta$ neck angle ranging from $115^\circ$ to $135^\circ$. The cephalic screw is free to slide and allows compression of the fracture to favor bone healing. Two distal screws are used to lock the implant on the diaphysis. These two screws support the implant by two sets of cylindrical holes and slots.

Figure 4: CAD of the ancillary equipment.

2.2. Improvements over current implants.

A post mortem implantation test showed that the device is minimally invasive. A first incision allows to insert the implant at the greater trochanter. A second incision allows to insert the dynamic cephalic screw and the two distal screws. From a point of view of the mechanical strength of the implant, the support points of the cephalic screw on the two rigid parts are spaced apart, thereby limiting stress in the implant. The blade partially protects the greater trochanter and maintains the gluteus medius muscles.
3. Numerical investigation.

3.1. Finite element models.

FE models were created using ABAQUS software. A digital model of femur (Digital 3D Femur, ref. 3908), corresponding to the medium left composite Sawbone, is used in this study. The geometry of the femur was split by idealized fracture planes. Intertrochanteric and reverse obliquity fractures were modeled. The solid model is discretized into ten-noded tetrahedral elements (C3D10M). The average size of elements in the femur is of the order of 3 mm corresponding to a total of 86951 elements. For implants (TGN and DHS), the dimensional characteristics are summarized in Table 1. Implant sizes have been selected on the advice of an expert in orthopedics and traumatology. With the Clovis implant, the cephalic screw is positioned on an intermediate setting. The average size of elements in implants is of the order of 1.5 mm. The two types of FE models of the fractured femur with Clovis implant are shown in Figure 5.

<table>
<thead>
<tr>
<th>Item</th>
<th>Neck/shaft angle</th>
<th>Ceph. screw diam. (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TGN</td>
<td>130°</td>
<td>11.9</td>
</tr>
<tr>
<td>DHS</td>
<td>135°</td>
<td>8</td>
</tr>
<tr>
<td>Clovis</td>
<td>125°</td>
<td>10</td>
</tr>
</tbody>
</table>

Table 1: Dimensional characteristics of TGN, DHS and Clovis implants.

3.2. Material properties and boundary conditions.

Elastic behaviour laws are implemented for cortical bone, trabecular bone and stainless steel implants. Values are given in Table 2. A friction coefficient of 0.1 is used between metal parts, and 0.3 for bone-bone and bone-steel contacts.

The distal end of the femur model is articulated. A 3 kN load is applied to the femoral head through a ball joint. Distal screws and cephalic screw are respectively coupled with the femoral shaft and the femoral head.
Figure 5: FE models of the femur with Clovis implant. (a) The two fracture planes are presented as well as the boundary conditions used. (b) A part of the mesh used for the calculations is shown.

<table>
<thead>
<tr>
<th>Item</th>
<th>Young modulus E (MPa)</th>
<th>Poisson’s ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>cortical</td>
<td>16 350</td>
<td>0.26</td>
</tr>
<tr>
<td>trabecular</td>
<td>155</td>
<td>0.3</td>
</tr>
<tr>
<td>implants</td>
<td>200 000</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Table 2: Material properties assigned to femurs and implants.

4. Results and discussions.

Numerical results provide stiffness, stress distribution in femurs and implants (TGN, DHS, and Clovis) for intertrochanteric and reverse obliquity fractures. The interfragmentary motions are also highlighted. The main goals of this study are (i) to check if implants are able to support a 3 kN load and (ii) to estimate the movements of the lips of the cracks.

4.1. Stiffness.

A comparison of the stiffness for all the femur/implant models (TGN, DHS, and Clovis) is shown in Figures 6 and 7. The overall stiffness $K$ is a function of material properties of the bone, but also the stiffness of the implant, which controls movements of the fractured surfaces. $K$ is expressed
as the ratio of the load on the deflection of the femur. The use of the Clovis implant allows to observe a stiffness closer to that of a healthy femur in cases of intertrochanteric and reverse obliquity fractures. The use of DHS in the event of reverse obliquity fracture shows a medial translation of the shaft: two stiffnesses are shown in 7. The cephalic screw slides in the plate screwed, and the proximal part of the femur slides on the shaft. Stiffness increases only after contact between the proximal part of the femur and the plate screwed.

Figure 6: FE models stiffness of the femur with TGN, DHS, and Clovis implant in the case of an intertrochanteric fracture.

Figure 7: FE models stiffness of the femur with TGN, DHS, and Clovis implant in the case of a reverse obliquity fracture.
4.2. Stress distribution.

The comparison between the stress state of (i) a healthy femur and (ii) fractured femurs fitted with implants, allow to estimate the ability of bone to regenerate. Bone is a living material which remodels in response to the mechanical demands placed upon it (Wolff’s theory states that bone adapt to the loads under which it is placed (14)). In tension, the tensile strength of the cortical bone is typically around 100 MPa. In compression, breaking stress varies from 125 MPa to 250 MPa, according to the authors (15). An objective is to observe a state of stress in the bone sufficient for bone remodeling. However, the state of stress must be less than 100 MPa to avoid a new fracture. Concerning implants, the elastic limit of the stainless steel is of the order of 800 MPa. Unlike the case of bone, the objective for the metal parts is a minimization of stress. The implant should not present a state of stress greater than 800 MPa to prevent an irreversible deformation of the material. Figure 8 shows magnitude and stress distribution in a healthy femur. Figure 9 shows results for all implants (TGN, DHS, and Clovis) and bones, in cases of intertrochanteric and reverse obliquity fractures.
Figure 9: Magnitude and stress distribution in implants and bone in cases of intertrochanteric and reverse obliquity fractures, under 3kN load. (a) TGN, (b) DHS and (c) Clovis implants.

- **Stress in femur - intertrochanteric fracture.**

  The use of TGN shows a relatively low stress state in the femur. This can be explained in part by the diameter of the cephalic screw used with the nail. The implant largely supports the load applied to the femoral head. A low stress state in bone doesn’t necessary favor bone remodeling. Concerning DHS and Clovis, these implants allow to observe a stress state closer to that of a healthy bone. It appears to be interesting for the natural bone development.

- **Stress in implants - intertrochanteric fracture.**

  Stresses in TGN are strong. They are above 800 MPa at the cephalic screw-nail connection. The experiments have shown that TGN is plasticised under 3 kN. Concerning DHS, stresses are also above 800 MPa. The cephalic screw of DHS is very inclined and receives a strong normal force. Stresses due to bending are great at the upper part of the
plate. For the Clovis implant, stresses in the entire device are less than 800 MPa. In this study, the new implant presents a greater safety factor than TGN and DHS.

- **Stress in femur - reverse obliquity fracture.**

  The common point to the three simulations is the strong stress concentration at the internal console of the femur. Excessive stress in this area can cause a fracture of the lesser trochanter. The loss of internal console can cause instability of the entire fracture. A medial translation of the shaft is observed when DHS is used. According to this numerical study, DHS seems unsuitable for the care of reverse obliquity fractures. The two other implants appear to be more adapted to the care of reverse obliquity fracture.

- **Stress in implants - reverse obliquity fracture.**

  In this type of fracture, the loads are largely supported by the internal console of the bone. Therefore implants are less stressed (<600 MPa).

4.3. Movements of the fractured surfaces.

Relative movements of the lips of the cracks are presented in Figure 10. The normal and tangential displacements \( U_n \) and \( U_t \), of the extreme points of the cracks are extracted for the two types of cracks. \( P \) corresponds to the point linked to the shaft, \( P' \) corresponds to the point linked to the proximal part of the femur. Displacements are calculated by the following equations:

\[
U_n = P' \cdot \vec{n} - P \cdot \vec{n}
\]

\[
U_t = P' \cdot \vec{t} - P \cdot \vec{t}
\]

\[
U = \sqrt{U_n^2 + U_t^2}
\]

The displacement norm is plotted as a function of load for both type of fractures (Figures 11 and 12). The additional compression screw of DHS coupled with the cephalic screw has not been modeled in this study. The compression screw may improve the behaviour of the implant in the case of an intertrochanteric fracture. However it doesn’t play an important role in the case of reverse obliquity fractures. The study clearly confirms that the use of an extramedullary fixation is unsuitable with reverse obliquity fractures. Indeed movements are very large for the care of a fracture. Data shows lower relative movement for fractured femurs equiped with the new implant.
Figure 10: Relative movements of the lips of the cracks in case of (a) intertrochanteric and (b) reverse obliquity fractures.

Figure 11: $P'_1$ displacements. Relative movements of the lips of the cracks in case of intertrochanteric fractures.

5. Conclusion.

A new concept of implant has been designed and manufactured to meet a criterion of universality of fracture fixation in terms of adaptation to different morphologies of patients. The implant is able to heal stable fractures but also unstable fractures, such as reverse obliquity fractures. A comparative numerical study of three implants for fixing stable and unstable fractures has been presented. For each of these implants, a Finite Element model was built to calculate the stress states and the associated displacement fields.

Results obtained allowed us to highlight:
Figure 12: $P_2$ displacements. Relative movements of the lips of the cracks in case of reverse obliquity fractures.

- The stress state of a femur fitted with a TGN or a Clovis implants is relatively close to the state of stress calculated for a healthy bone.
- Stresses within the Clovis implant are systematically lower than 800 MPa, unlike the other two implants, which suggests a better holding for intertrochanteric and reverse obliquity fractures.
- The analysis of relative movements of the lips of the cracks shows that the calculated displacements are predominantly smaller than those observed with current implants.

These results will soon be corroborated by post mortem experimental approaches, employing stereo image correlation techniques using high-speed cameras for walkcycle simulations, and high-resolution cameras for quasi-static tests.

ACKNOWLEDGMENTS.

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