Clinical Biomechanics 30 (2015) 713–719

Contents lists available at ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech

# A new approach to prevent contralateral hip fracture: Evaluation of the effectiveness of a fracture preventing implant

Marek Szpalski [a], Robert Gunzburg [b], Max Aebi [c], Charlène Delimoge [d], Nicolas Graf [e], Sebastian Eberle [f], Cécile Vienney [d,*]

[a] Hôpitaux Iris Sud, Department of Orthopedic and Trauma Surgery, Brussels, Belgium
[b] Edith Cavell Clinic, Orthopedic Department, Brussels, Belgium
[c] Salem Spital, Orthopedic Department, Bern, Switzerland
[d] Hyprevention, Clinical Research, Pessac, France
[e] SpineServ GmbH & Co. KG, Ulm, Germany
[f] Institute of Biomechanics, Trauma Center Murnau, Murnau, Germany

ARTICLE INFO

*Article history:*
Received 5 January 2015
Accepted 7 May 2015

*Keywords:*
Hip fracture
Osteoporosis
Fracture prevention
Prophylactic
Proximal femur reinforcement
Biomechanical

ABSTRACT

*Background:* Among the millions of people suffering from a hip fracture each year, 20% may sustain a contralateral hip fracture within 5 years with an associated mortality risk increase reaching 64% in the 5 following years. In this context, we performed a biomechanical study to assess the performance of a hip fracture preventing implant.

*Methods:* The implant consists of two interlocking peek rods unified with surgical cement. Numerical and biomechanical tests were performed to simulate single stance load or lateral fall. Seven pairs of femurs were selected from elderly subjects suffering from osteoporosis or osteopenia, and tested ex-vivo after implantation of the device on one side.

*Findings:* The best position for the implant was identified by numerical simulations. The loadings until failure showed that the insertion of the implant increased significantly ($P < 0.05$) both fracture load (+18%) and energy to fracture (+32%) of the implanted femurs in comparison with the intraindividual controls. The instrumented femur resisted the implementation of the non-instrumented femur fracture load for 30 cycles and kept its performance at the end of the cyclic loading.

*Interpretation:* Implantation of the fracture preventing device improved both fracture load and energy to fracture when compared with intraindividual controls. This is consistent with previous biomechanical side-impact testing on pairs of femur using the same methodology. Implant insertion seems to be relevant to support multiple falls and thus, to prevent a second hip fracture in elderly patients.



## 1. Introduction

The number of hip fractures, representing about 2 million in 2010, will increase by 215% to reach 6.3 million in 2050 (Cooper et al., 1992) if the fracture rate remains stable. This increase reflects the aging of the population, and the prevalence of osteoporosis. Indeed, hip fracture is often the result of a reduction in bone mineral density (BMD), and occurs after low-energy falls.

In this context of bone fragility, a first hip fracture is a warning signal. Among the 2 million people suffering from a hip fracture each year, 20% will sustain a contralateral hip fracture at 5 years. This event often leads to a radical worsening in the way of life (dependency), and these patients, highly weakened physically, see their mortality risk increase to reach 64% during the 5 following years (Ryg et al., 2009).

Therefore, prevention of a contralateral hip fracture is a global public health issue. Preventive treatments mainly consist of drug therapies to reduce the rate of bone loss for people suffering from osteoporosis. However, their efficiency is put in doubt, especially as considering the lack of adherence of the patients to these long-term treatments. Moreover, their side effects are more and more criticized. Efficacy of techniques such as external hip protectors has not been proven too, and they are rarely used.

Several scientific studies have evaluated the biomechanical performance of different preventive measures (mostly femoroplasty) for strengthening the proximal femur to avoid fracture due to a fall. Two previous studies proposed by Heini et al. (2004) and Sutter et al. (2010) with a filling of the femoral head with 40 ml of PMMA cement showed very good results with an increase of the fracture load of +82% and +37% respectively. These tests also demonstrated a significant increase in the energy to fracture (+188% and +154% respectively). Despite the good performance measured, these solutions have significant disadvantages: the rise in temperature due to the use of a very large

* Corresponding author.

http://dx.doi.org/10.1016/j.clinbiomech.2015.05.001
0268-0033/© 2015 Elsevier Ltd. All rights reserved.

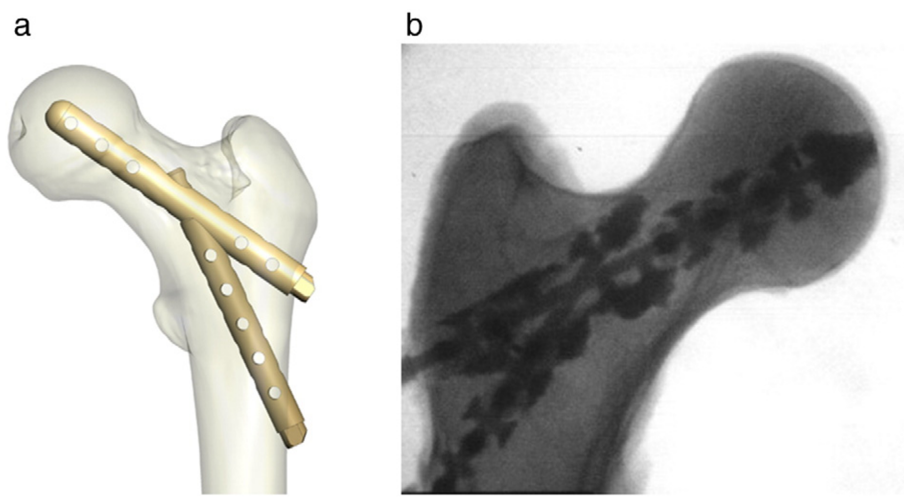


**Fig. 1.** Views of the device – (a) Numerical model – (b) X-ray view.

amount of PMMA cement (28 to 40 ml), the occurrence of subtrochanteric fractures and especially the occurrence of atypical fractures involving the femoral shaft, making very complex necessary revision. Tests with silicone gum by Van der Steenhoven et al. (2009) led to a weakening of the femoral head strength, but this type of filling prevents the dislocation of the bone in case of fracture, making the fracture fixation easier. Another concept, developed by Beckmann et al. (2011), consists of making a central or centro-dorsal perforation (diameter 8 mm) and injecting 8–18 ml of PMMA cement. This amount of cement, significantly lower than used by Heini and Sutter (40 ml), showed rather good results: +23% to 35% for the fracture load, and +160% for the energy to fracture, for femurs from 66-year-old donors.

We studied a new medical device, dedicated to the prevention of hip fracture. We assessed its efficiency to improve the biomechanical performance of the proximal femur.

## 2. Methods

### *2.1. Hip fracture preventive device*

The device (Y-STRUT®, Hyprevention®, Pessac, France) consists of two interlocking rods. The rods have multiple perforations enabling the extrusion of injected bone cement (Fig. 1). The implants are made of PEEK Optima® (Invibio). The cement used is a standard PMMA bone cement (Cortoss®, Stryker®, Kalamazoo, USA), with a threefold function:

– It ensures the connection of the two components of the implant.
– It increases the contact surface with the surrounding bone by seeping through the multiple perforations in order to reduce the stresses applied to the weakened bone.
– In the case of a bioactive PMMA cement use, it promotes the osseointegration of the construction.

### *2.2. Finite element analysis*

To determine the best position of the implant in the femoral neck (i.e. the position associated to the lowest fracture risk), a subject-specific FEA was performed using ANSYS Workbench® (ANSYS® Academic Research, Release 14.5, ANSYS, Inc., Canonsburg, USA).

A CAD-model was first generated from the qCT-data (LightspeedVCT, GE Healthcare, Waukesha, WI, USA) of a femur harvested on a 59-year-old female Caucasian donor, with a low bone mineral density (global BMD of 218; SD 277 g/cm$^3$). Based on the CAD-model, a subject-specific FE-model of the intact femur was developed. The degree of discretization was determined by mesh

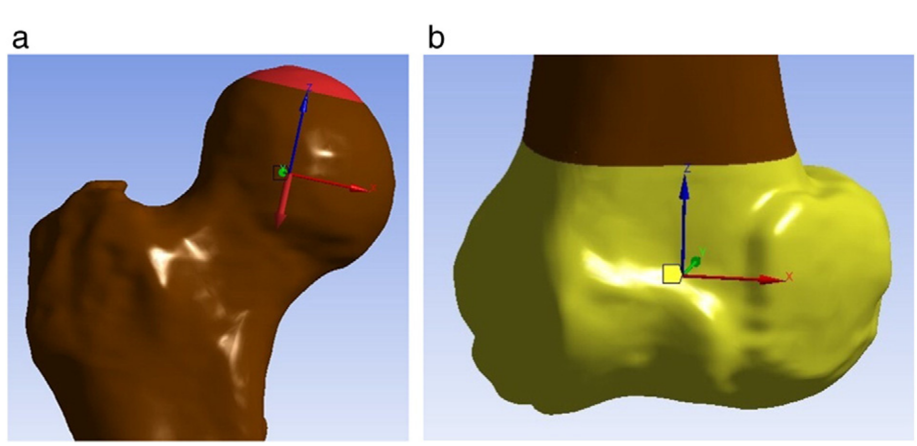


**Fig. 2.** (a) Load case 1 with a force acting on the femoral head (red area). (b) At the distal end the yellow area had locked translatory DOF (x, y, z) and a locked rotatory DOF (z) with respect to the center of the coordinate system (COS).