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

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ARTICLE INFO

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.

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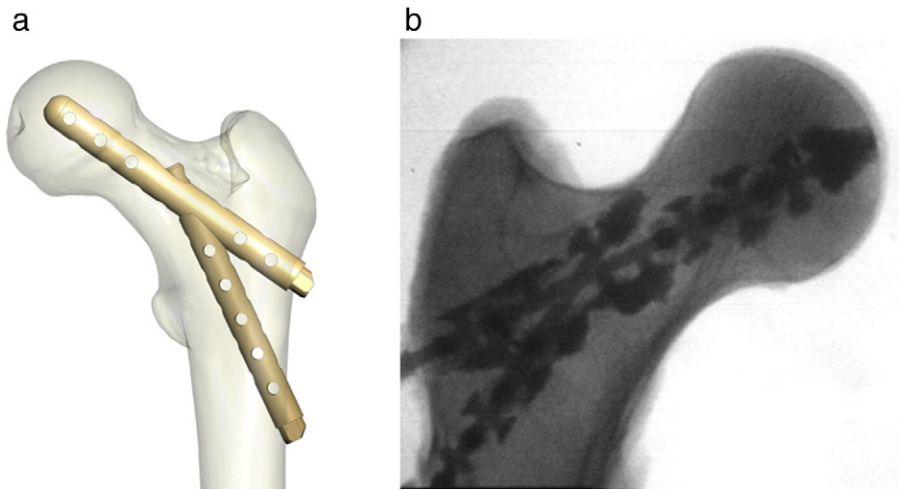
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Fig. 1. Views of the device – (a) Numerical model – (b) X-ray view.

amount of PMMA cement (28 to 40 ml), the occurrence of sub-trochanteric 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
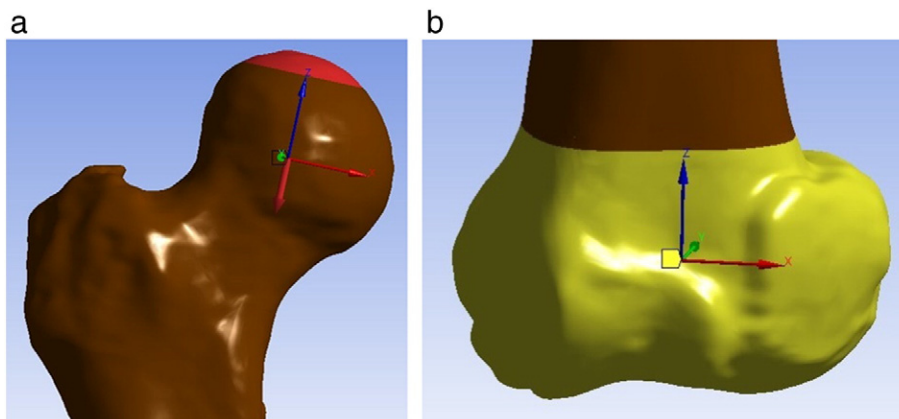

Fig. 2. (a) Load case 1 with a force acting on the femoral head (red area). (b) At the distal end the yellow area had locked translatory DOF (x, y, z) and a locked rotatory DOF (z) with respect to the center of the coordinate system (COS).

convergence analysis, and appropriate loading was verified by calculating reaction forces at the boundary conditions. The FE model of the investigated intact specimen was validated by mechanical experiments in a previous study (Eberle et al., 2011) (Institute of Biomechanics, Trauma Center Murnau, Germany). Axial stiffness, surface strains and local deformations were used for validation (compare to methods of Trabelsi et al. (2011)). The inhomogeneous elastic properties of the bone were applied by a custom written code, which was developed, verified, and validated by experiments at the Institute of Biomechanics.

Two tests were performed: a test in monopodal stance (walking simulation) – Case 1, and a loading test on the trochanter (sideways fall simulation) – Case 2.

• **Case 1**. Monopodal load

The first computed load case simulated a single stance loading scenario or walking (Bergmann et al., 2001) — Fig. 2. This loading scenario was realized by axial compression with physiological boundary conditions according to Speirs et al. (2007). The angle between the force vector and the femoral shaft was set at 15° in the coronal plane, in compliance with similar tests in the literature (Heini et al., 2004; Sutter et al., 2010). The load was set to 2103 N. This load was determined as the maximum failure load of the used specimen in an axial compression test within a previous study performed by Eberle et al. The failure load was typical for osteoporotic femur specimens (Kukla et al., 2001).

• **Case 2**. Sideways fall

The second computed load case simulated a sideways falling scenario (Fig. 3). The load was applied at 15° in internal rotation (anteversion angle) on the greater trochanter, with a support at the femoral head. An angle of 10° was chosen between the horizontal plane and the axis of the femoral shaft for lateral drop tests, as currently performed in the literature (Pinilla et al., 1996; Beckmann et al., 2007; De Bakker et al., 2009). Loading and boundary conditions were realized comparable to Grassi et al. (2011) and Wakao et al. (2009). No experimental data was available for that load case. Therefore, the load was set to 2103 N as well, to achieve a certain comparability to the axial load case.

For each loading case, the femur was tested for two different positions of the implant: in the center or in the upper third of the femoral neck (Fig. 4). The cavities for the cement and the implant were introduced to the bone by Boolean operations. The contacts between cement and bone, and implant and cement were modeled as bonded contacts. Bonded contacts transfer axial and shear forces and were therefore suitable to represent the glue-like behavior of cement. 9.3 ml of cement were used in the model.

Two failure criteria were chosen based on maximum principle strain or stress within the bone (Schileo et al., 2008); through the study of the convergence behavior of the computed risk factors, the degree of discretization that resulted in the highest risk factor was used for all computations. Since biological values as the maximum strength of a bone vary a lot, we have chosen to use risk factors between 1 and 2 as probable failure.

2.3. Specimen preparation

A total of 7 pairs of femurs were harvested from cadavers, provided by Science Care Inc. through its program of voluntary corpse donation to science. For each pair, one femur was randomly assigned for implantation of the device, and the contralateral served as control. Dual energy X-Ray Absorptiometry (DXA) scans (Haut Lévêque Hospital — CHU Bordeaux, Pessac, France) were performed on 5 samples to measure the
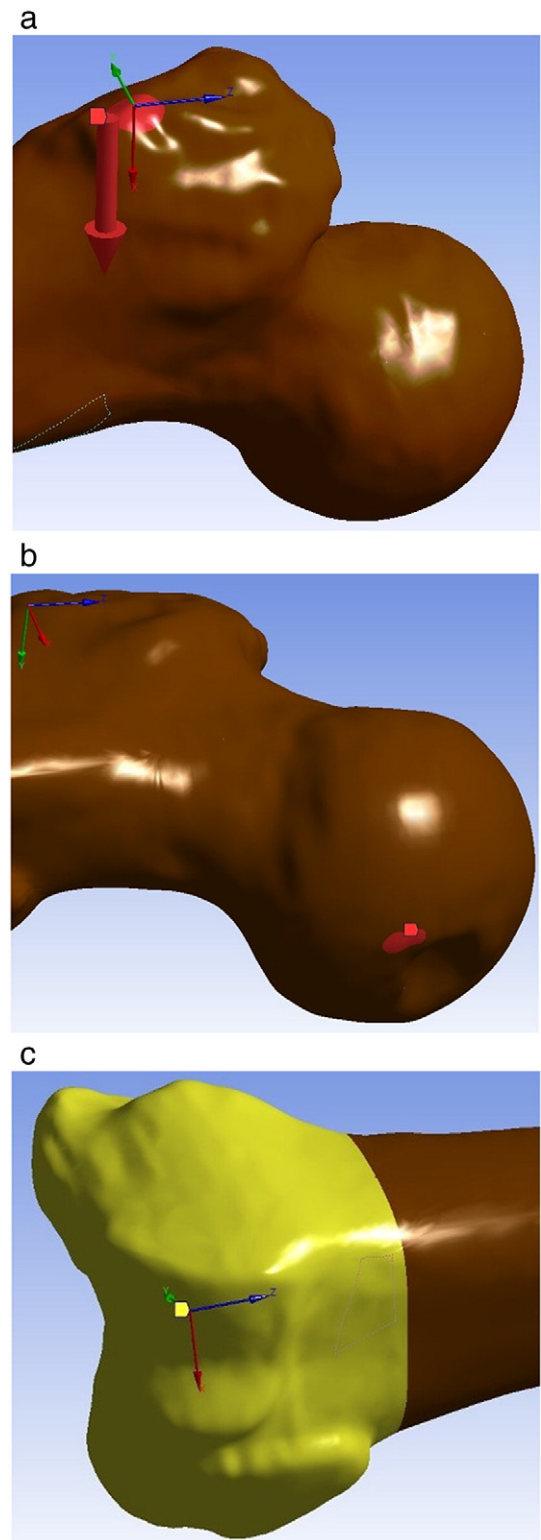

Fig. 3. (a) Load case 2 with a force acting laterally on the trochanter (red area). The area of load application had locked translatory DOF orthogonal to the load vector with respect to the shown COS. (b) The femoral head was supported in a small area by locked displacement in load direction (red area). (c) At the distal end the yellow area had locked translatory DOF (x, y, z) and locked rotatory DOF (x, z) with respect to the center of the COS.

areal bone mineral density (aBMD), and to evaluate measurement equivalence between the femurs of a same pair using a statistical Student test (t-test for paired data, confidence level of 95%).
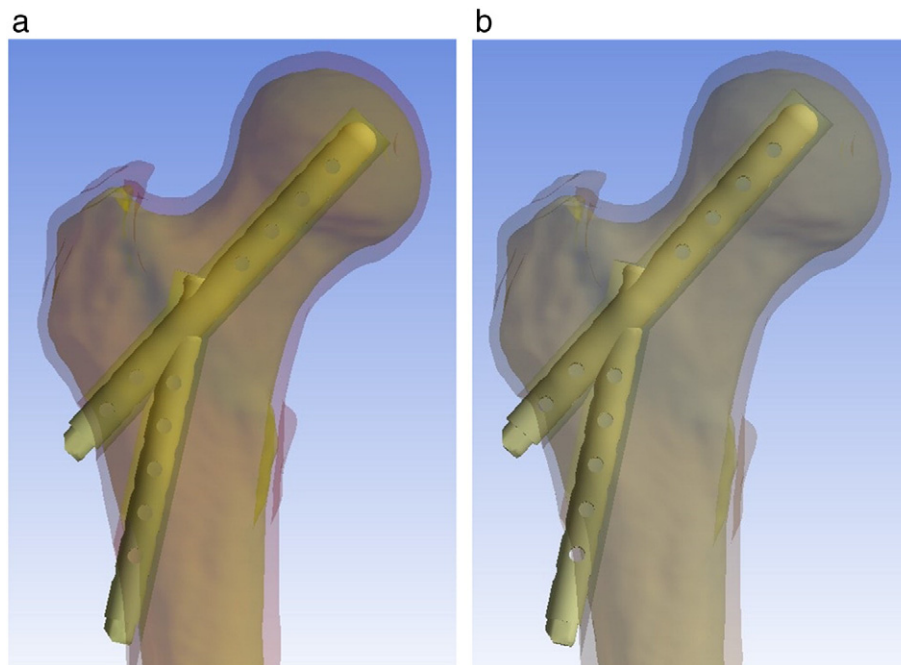
Fig. 4. (a) Central position of the implant in the femoral neck. (b) Upper-third position of the implant in the femoral neck.

2.4. Biomechanical testing

The biomechanical side-impact testing was performed on 6 pairs of female human femurs (3 fresh and 3 embalmed), from donors with a mean age of 90 years old. One femur from each pair was randomly assigned for implantation; the contralateral femur served as an intraindividual control. Implant insertions were performed by a team of two orthopedic surgeons (four-handed surgery), and included a post-insertion PMMA cement augmentation (Cortoss®, Stryker). The mean cement volume injected per femur was 7.8 ml (SD 0.4). The implantation was documented by X-ray. The mechanical testing set-up simulated an impact on the trochanter, and was derived from Pinilla, with an anteversion angle of 15° and a femoral shaft angle of 10° between the horizontal plane and the axis of the femoral shaft (Fig. 5). These set-up characteristics have been mostly used in the fall on the greater trochanter simulations performed by the previous mentioned studies. The specimens were loaded with a constant speed of 100 mm/s to be representative of a low-energy fall, as explained by De Bakker. Paired t-tests were performed to assess the differences between the implanted and control groups, for ultimate load and energy to fracture. Significant difference was defined by a value of $P < 0.05$ (paired t-test, confidence level of 95%).

2.5. Fatigue testing

A fatigue testing was performed on a pair of fresh human femurs obtained from a 61-year-old Caucasian female subject, who was osteopenic (T-Score of −1.9), with a total bone mineral density of 0.816 g/cm^2 and 0.752 g/cm^2 at the femoral neck. One femur of the pair was assigned for implantation. The mechanical testing set-up used was the same as the one used for the biomechanical test described above. According to the technical characteristics of the testing machine, the loading speed for this test was set to 2 mm/s, as done by Beckmann. The non-implanted femur was loaded until fracture. Subsequently, the implanted femur was loaded from 0 to the load that fractured the contralateral femur, at the same constant speed of 2 mm/s. Loading was repeated cyclically for 30 cycles; According to Lord et al. (2001), the frequency of falls increases with age and can reach 3 times per year; 30 cycles corresponding to 30 falls in a period of 10 (3 falls per year) to 30 years (1 fall per year). After the cyclic testing, the femur was loaded until failure.
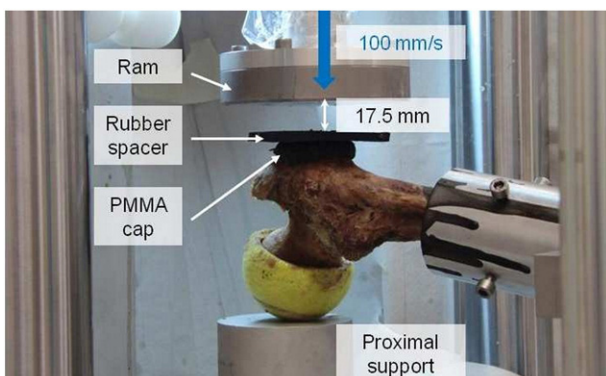
3. Results

3.1. Finite element analysis

The fracture risks were assessed in the two load simulations: monopodal stance and lateral fall.

In the case of an axial compressive load, Y-STRUT® reduced the risk of femoral neck fracture from 25% to 28% (depending on the failure criterion i.e. stress based RF or strain based RF) when it was implanted in the upper third of the femoral head. No significant decrease was observed when the device was implanted in a central position.

In the case of a trochanteric load (sideways fall simulation), Y-STRUT® reduced the risk of trochanteric fracture up to 17% if it was placed at the center, and 52% in the upper third part, whatever the failure criterion considered (Fig. 6).
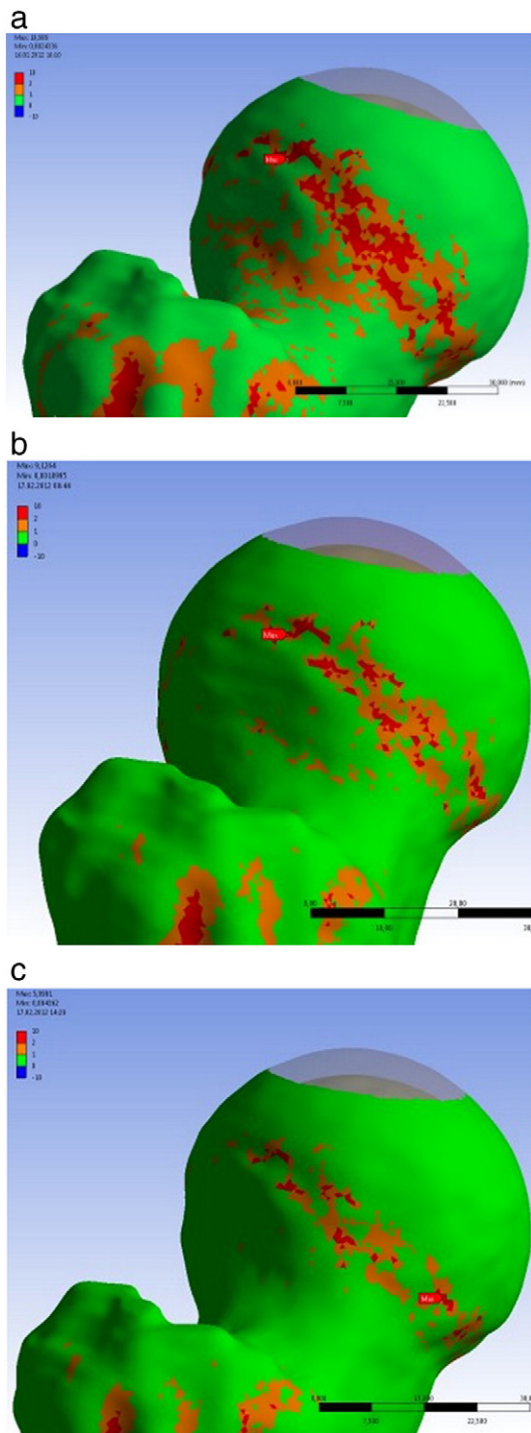

Fig. 5. Set-up for mechanical testing.

Fig. 6. Fracture risk factors. The fracture risk factors are defined by three levels of risk, represented by three colors: RF < 1 (green) = no risk for fracture. 1 < RF < 2 (orange) = bone will probably fail. RF > 2 (red) = bone will fail. Results for the sideways fall simulation. Shown are the maximum value of the strain based failure criterion (RFe) at surface. (a) Intact bone (RFe = 10.9). (b) Y-STRUT®-Center (RFe = 9.1). (c) Y-STRUT® − Upper third (RFe = 5.9).

These simulations have shown that the best placement for the implant is in the upper third of the proximal part of the femur because it leads to a strong decrease in the risk of femoral neck fracture (−28%) and trochanteric fracture (−52%). This placement was used for the implantations for the biomechanical tests.

3.2. Tomography

The results indicated that aBMD values were statistically identical for femurs of a same pair. For both the femoral neck and the entire proximal part, there was no significant difference between aBMD measured on the right and on the left femurs ($P > 0.5$). The areal bone mineral densities being equivalent for the femurs of a same pair, biomechanical tests can be performed on pairs of femurs, femur of each pair being instrumented with the studied device and the contralateral, non-instrumented, serving as control for comparison of results.

All values of T-Score were always lower than −1.0, confirming that the femurs came from osteopenic (−1.0 < T-score < −2.5) or osteoporotic donors (T-score < −2.5).

3.3. Biomechanical testing

All pairs of femurs had a low bone mineral density as defined by a total femur T-score lower than −2.0. Mean aBMD value was 0.678 g/cm² (SD 0.049). The measurements showed that the insertion of the implant increased significantly ($P < 0.05$) the fracture load of the implanted femurs in comparison with intraindividual controls (3606 N (SD 485) to 4261 N (SD 442), +18%). We have also observed an energy to fracture increasing significantly ($P < 0.05$) from 19.3 J (SD 5.6) to 25.5 J (SD 5.4) (+32%), for instrumented femurs versus non-instrumented femurs.

The failure modes observed showed that the type of fracture is unchanged between the specimens with and without implant, showing the reinforcement of the proximal part without having weakened the femur at the insertion holes of the implant (Table 1).

3.4. Fatigue testing

Results are presented in Fig. 7. The control ultimate load and energy to fracture were 3230 N and 25.8 J respectively. The instrumented femur survived the 30 loading cycles without any fracture. The total energy accumulated during cycles was 8.35 J. Further to the fatigue testing, the instrumented femur was loaded to fracture: the ultimate load and energy to fracture observed were 3947 N and 32.8 J respectively, with a crack appearing at the inferior femoral neck. Thus, the instrumented femur resisted the implementation of the non-instrumented femur fracture load for 30 cycles and, at the end of the cyclic loading, it kept his performance with a gain of 22.2% of the fracture load compared to non-instrumented femur.

Table 1
Biomechanical testing results.

| Femurs	Implanted (Y/N)	Fracture load (SD) [N]	Energy to fracture (SD) [J]	Fracture type
1	Control	3371	16	Neck
	Implanted	4102	29	Neck
2	Control	3727	26	Neck
	Implanted	4596	30	Neck
3	Control	3340	13	Neck
	Implanted	4470	22	Shearing at support (due to no limited displacement of impactor)
4	Control	3750	21	Neck
	Implanted	4008	17	Neck
5	Control	4515	25	Neck
	Implanted	4847	31	Pertrochanteric
6	Control	3056	15	Pertrochanteric
	Implanted	3671	24	Femoral shaft, at the level of the support
Total				
n = 6	Control	3606 (485)	19.3 (5.6)	
n = 6	Implanted	4261 (442)	25.5 (5.4)	
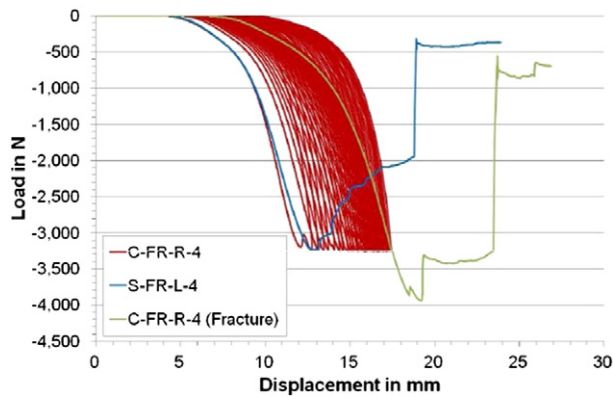
Fig. 7. Fatigue test results. S-FR-L-4 is the load curve of a control femur, until fracture. C-FR-R-4 is the curve of cyclic loading (30 cycles) of the instrumented femur, at the fracture load of the non-instrumented femur previously determined. C-FR-R-4 (Fracture) is the load curve of the instrumented femur, until fracture.

4. Discussion

Results support the hypothesis that Y-STRUT® improves the biomechanical resistance to fracture of the femur. Finite element analysis allowed to identify the best location for the device, showing a high potential decrease in the risk of femoral neck fracture (−28%) and trochanteric fracture (−52%) when the device was placed in the upper third of femoral head. This result could be explained by the bone structure. The lower part of the femoral neck has a strong dense trabecular structure, and osteosynthesis systems are placed in this part to ensure the fracture fixation. Y-STRUT® aims to reinforce the biomechanical performance of the proximal femur before fracture. Therefore, it is relevant to preserve the strong part and place the implant in the weakest part of the bone.

Biomechanical tests with the device were similar to those performed by Beckmann, whose technique was almost identical, because of the size of the perforation (diameter 9 mm and 8 mm respectively) and of the use of cement Cortoss® in similar amounts (7.8 ml for Y-STRUT® and 9–18 ml for Beckmann's injections, respectively). However, Beckmann's study donors were quite young (mean age 66 years old vs 90 years old for Y-STRUT® testing).

The biomechanical tests have demonstrated:

- A significant increase of fracture load (+18%) similar to the results of Beckmann (+23% and +35%)
- A significant increase in the energy to fracture (+32%). This value was lower than that shown by Beckmann, but the tested femurs were harvested on older – especially elderly – patients.

Otherwise, Keaveny et al. (2010) indicated a bone strength loss of 60 N per year. We showed a benefit of resistance of 655 N with the preventive device.

The repeated falls test highlighted that a femur instrumented with Y-STRUT® could withstand the breaking load of the non-instrumented femur cyclically (30 cycles) without losing its performance increase at the end of the cycles. Implant insertion is relevant to support multiple falls to prevent a contralateral femoral fracture in elderly patients.

The femoroplasty techniques have presented several drawbacks, especially because of the use of a large amount of cement. The exothermic polymerization process may cause a necrosis of the surrounding bone cells, weakening the bone even more. This risk is presumably reduced by using a minimal volume of cement with Y-STRUT®. Moreover, revision in femoroplasty is complicated by the difficulty to remove such an amount of cement and of the need to place a fixation system or total hip prosthesis, which seems very difficult to manage, contrary to Y-STRUT® and cement removals allowing osteosynthesis or total joint replacement if a fracture was still to occur.

During the biomechanical tests, we also noted the occurrence of the same type of anatomical fractures with or without the device. Reinforcement of the biomechanical performance was observed for neck and pertrochanteric fractures, showing the potential ability of the device to prevent both types of fracture in a sideways fall configuration. Finally, no fracture was observed for the implant, which remained intact in its housing. Besides, the observed failure modes have not shown brittleness at the anchoring points of the implant. As the Van der Steenhoven's tests with silicone gum, the implant acts to avoid bone dislocation.

5. Conclusions

This study demonstrates the potential of Y-STRUT® to improve the biomechanical performance of the proximal femur. Implant insertion seems to be relevant to support multiple falls and thus, to prevent a second hip fracture in elderly patients. A clinical trial is ongoing to assess the feasibility and the safety of the surgical procedure.

Conflict of interest

Acknowledgments

References

Beckmann, J., Ferguson, S.J., Gebauer, M., Luering, C., Gasser, B., Heini, P., 2007. Femoroplasty – augmentation of the proximal femur with a composite bone cement – feasibility, biomechanical properties and osteosynthesis potential. Med. Eng. Phys. 29 (7), 755–764 (Sep).

Beckmann, J., Springorum, R., Vettorazzi, E., Bachmeier, S., Lüring, C., Tingart, M., Püschel, K., Stark, O., Grifka, J., Gehrke, T., Amling, M., Gebauer, M., 2011. Fracture prevention by femoroplasty — Cement augmentation of the proximal femur. J. Orthop. Res. 29 (11), 1753–1758 (Nov).

Bergmann, G., Deuretzbacher, G., Heller, M., Graichen, F., Rohlmann, A., Strauss, J., Duda, G.N., 2001. Hip contact forces and gait patterns from routine activities. J. Biomech. 34, 859–871.

Cooper, C., Campion, G., Melton III, L.J., 1992. Hip fractures in the elderly: a world-wide projection. Osteoporos. Int. 2 (6), 285–289 (Nov).

De Bakker, P.M., Manske, S.L., Ebacher, V., Oxland, T.R., Cripton, P.A., Guy, P., 2009. During sideways falls proximal femur fractures initiate in the superolateral cortex: Evidence from high-speed video of simulated fractures. J. Biomech. 42 (12), 1917–1925 (Aug 25).

Eberle, S., Wutte, C., Bauer, C., von Oldenburg, G., Panzer, S., Augat, P., 2011. Evaluation of risk for secondary fracture after removal of a new femoral neck plate for intracapsular hip fractures. J. Orthop. Trauma 25, 721–725.

Grassi, L., Schileo, E., Taddei, F., Zani, L., Juszczyk, M., Cristofolini, L., Viceconti, M., 2011. Accuracy of finite element predictions in sideways load configurations for the proximal human femur. J. Biomech. 1–6.

Heini, P.F., Franz, T., Fankhauser, C., Gasser, B., Ganz, R., 2004. Femoroplasty-augmentation of mechanical properties in the osteoporotic proximal femur: a biomechanical investigation of PMMA reinforcement in cadaver bones. Clin. Biomech. 19 (5), 506–512 (Jun).

Keaveny, T.M., Kopperdahl, D.L., Melton III, L.J., Hoffmann, P.F., Amin, S., Riggs, B.L., Khosla, S., 2010. Age-dependence of femoral strength in white women and men. J. Bone Miner. Res. 25 (5), 994–1001 (May).

Kukla, C., Pichl, W., Prokesch, R., Jacyniak, W., Heinze, G., Gatterer, R., Heinz, T., 2001. Femoral neck fracture after removal of the standard gamma interlocking nail: a cadaveric study to determine factors influencing the biomechanical properties of the proximal femur. J. Orthop. Traumatol. 34, 1519–1526.

Lord, S.R., Sherrington, C., Menz, H.B., 2001. Falls in older people — risk factors and strategies for prevention. Cambridge University Press.

Pinilla, T.P., Boardman, K.C., Bouxsein, M.L., Myers, E.R., Hayes, W.C., 1996. Impact direction from a fall influences the failure load of the proximal femur as much as age-related bone loss. Calcif. Tissue Int. 58 (4), 231–235 (Apr).

Ryg, J., Rejnmark, L., Overgaard, S., Brixen, K., Vestergaard, P., 2009. Hip fracture patient at risk of second hip fracture: a nationwide population-based cohort study of 169 145 cases during 1977–2001. J. Bone Miner. Res. 24 (7), 1299–1307 (Jul).

Schileo, E., Taddei, F., Cristofolini, L., Viceconti, M., 2008. Subject-specific finite element models implementing a maximum principal strain criterion are able to estimate failure risk and fracture location on human femurs tested in vitro. J. Biomech. 356–367.

Speirs, A.D., Heller, M.O., Duda, G.N., Taylor, W.R., 2007. Physiologically based boundary conditions in finite element modelling. J. Biomech. 40, 2318–2323.

Sutter, E.G., Moars, S.C., Belkoff, S.M., 2010. A biomechanical evaluation of femoroplasty under simulated fall conditions. J. Orthop. Trauma 24 (2), 95–99 (Feb).

Trabelsi, N., Yosibash, Z., Wutte, C., Augat, P., Eberle, S., 2011. Patient-specific finite element analysis of the human femur—a double-blinded biomechanical validation. J. Biomech. 44, 1666–1672.

Van der Steenhoven, T.J., Schaasberg, W., de Vries, A.C., Valstar, E.R., Nelissen, R.G., 2009. Augmentation with silicone stabilizes proximal femur fractures: an in-vitro biomechanical study. Clin. Biomech. 24 (3), 286–290 (Mar).

Wakao, N., Harada, A., Matsui, Y., Takemura, M., Shimokata, H., Mizuno, M., Ito, M., Matsuyama, Y., Ishiguro, N., 2009. The effect of impact direction on the fracture load of osteoporotic proximal femurs. Med. Eng. Phys. 31, 1134–1139.