

## **Bone Mineral Density and Fracture risk assessment for patients undergoing total hip arthroplasty as support for decision making**

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### **Abstract**

#### ***Background and propose***

*Bone quality is a crucial parameter on which orthopedic surgeons should base the choice between cemented and cementless THA, a novel method is introduced here to quantitatively estimate BMD and fracture risk (FRI) before surgery. This work is a part of a larger study which objective is to establish a clinical evaluation score systems for total Hip replacement planning and for post-operative assessment.*

#### ***Material and Methods***

*Changes in bone density during THA recovery are monitored to assess specific implant effectiveness. A clinical trial was carried out including 36 volunteer patients which underwent unilateral THA surgery (50% cemented, 50% uncemented). CT scans were acquired before surgery, immediately after and after 12 months. Finite Element methods are used to predict the outcome of bone remodelling around THA implants and calculate the fracture risk index at the patient's proximal femur as effect of the press fit force applied during a simulated cementless surgery.*

#### ***Results and Interpretation***

*The preoperative CT-data demonstrate decrease with age of BMD but with significant differences between patients. Preliminary results show that BMD 1 year post-op at the lesser-trochanter decreases in 90% of the cases in cementless THA and in 50% of the cases in cemented THA. The simulation process that mimicks the press fitting procedure employed during cementless prosthesis shows higher FRI at the calcar while it is lower at the interthrocateric line with significant overlap between age groups.*

### **Introduction**

Total hip arthroplasty (THA) is performed with or without the use of bone cement. The benefit of the cemented procedure is a faster achievement of implant stability compared to an uncemented procedure

where the primary implant stability is secured by geometrical interlocking, press fit forces and friction between bone and implant, whilst the secondary stability is additionally secured by bone ingrowth into the surface texture of the femoral component. In the first years post-operatively, uncemented stems are more frequently revised than cemented stems due to periprosthetic fracture. Managing these fractures may create a real challenge for the surgeons because of the poor quality of the surrounding bone [1]. On the other hand the revision surgery for uncemented implants has a higher success rate and generally results in fewer complications than revision surgeries for cemented implants [2 to 5]. The drawback of cemented procedures is also related to the risk of cement cracking due to fatigue. Overall though the survival rate of uncemented THA is still slightly inferior to that of cemented THA according to the Swedish Hip Registry [6]. Presently clinicians are faced with the lack of reliable guidelines when choosing between cemented or uncemented procedures. In general cemented arthroplasties are more frequently used for older, less active people and people with weak bones, while uncemented replacements are more frequently used for younger and more active people. This can be attributed to the probability of revision surgery being age dependent with higher probability of revision surgery for patients receiving an implant early in life, which favors uncemented THA; and the risk of intra-operative fracture under press fit due to poor bone quality [7,8], which favors cemented THA. Although age is an indicator for bone quality on a population level, individual differences due to life style and genetics are large but [9] should ideally be taken into consideration in the pre-operative planning. For evaluating the risk of intra operative fracture, which essentially is a mechanical problem, surgeons rely on their experience without having any quantitative metrics for guiding their decision. To this end it would seem that subject specific Finite Element Analysis (FEA) could potentially be the ideal tool for providing such quantitative metrics.

At our clinical center orthopedic surgeons chose between the cemented and uncemented THA based on age, sex and general health conditions, however, quantitative preoperative measurements of bone quality have not yet been included in current clinical guidelines. This means that in general patients over 65 years receive cemented implants while the younger and healthy receive uncemented prosthesis. With the aim of improving our healthcare, reducing future costs and developing more thorough clinical guidelines to aid decision making, we have launched a clinical trial at our healthcare center where patients undergoing THA are systematically monitored for this purpose. In the present paper we report preliminary results from this project. The specific aims of this part of the study are:

- To quantify femoral bone quality at two different time points for patients already enrolled in the trial.
- To compare the risk of bone fracture due to press fit under surgery as estimated per subject specific FEA.

We hypothesize that bone density, a major predictor of intraoperative and postoperative fractures, is not solely age and gender related i.e. there is a significant overlap concerning bone density between age groups.

## **Material and Methods**

### **Study Group**

Data were obtained from 36 voluntary patients (20 females and 16 males) undergoing THA surgery for the first time, 18 patients received a cemented - and 18 received a cementless implant. The implant type was decided according to surgeons' evaluation that was mainly based on patient's age, gender and general clinical conditions. The average age at the moment of surgery is 56 for the males and 62 for the females; the youngest patient was 22 and the oldest 77. The patients are scanned with a *64-slices spiral CT Philips Brilliance* three times in one year: before, immediately after surgery and finally at 52 weeks post-surgery. The CT scanning region starts from the iliac crest and ends at the middle of the femur; slices thickness is

1mm, slice increment is 0.5mm and tube voltage was set to 120KVp. This CT dataset allows a precise 3D reconstruction of the regions of interest.

### **Bone Mineral Density Estimation from CT data**

We use the software MIMICS [10] to reconstruct and segment the femur during the clinical trial. The segmentation was performed on the pre-surgery and post-op CT datasets and it was mainly based on opportune thresholds of the CT-HU (Hounsfield Unit). According to previous studies [11-13], HU interval for cortical bone was set to 601-1988 HU while the trabecular bone set to 250-600 HU. Physical factors such as kilovoltage, phantom orientation and position in scan aperture influence remarkably the HU value [14], therefore the CT scan device was pre-calibrated with QUASAR phantom [15] before the pre-operative scans and 1 year later, before the post-op scans using the same Ct protocol adopted for the patients (Fig 1-A). Comparing the curves we notice minimum changes; the lower values (HU<0) vary less than 1,5% over 1 year span, while higher values (HU>0) vary 4,13%.

The conversion HU-BMD held in this study is based on the experimental relationship between HU and BMD that we found through the calibration process. Interpolating the conversion curves from figure 1-A, we obtain the graph in figure 2-B which relate BMD and HU in the formula  $BMD [mg/cm^3] = a \times HU^2 + b \times HU + c$ , where  $a, b, c$  are calibration coefficients, which were computed from the phantom CT data. The correlation coefficient for this calibration resulted  $R^2 \approx 0.99$ .

To estimate the pre-op bone quality, BMD was calculated from the proximal femur volume in the region between femur head and lesser trochanter, along the intertrochanteric line (Fig 2-A). The comparison between pre-op and 1 year post-op BMD cannot be done using the same volume of interest of figure 2-A, indeed the artifacts generated by the metal implant dramatically increases the surrounding HU values (of 500- 600%), thus we assess the BMD changes only on the lesser trochanter which HU values are minimally influenced (of 5-10 %) by the metal implant artifacts (Fig 2-B). Moreover to minimize further the artifact effect on the data, we scan again the patient 24 hours after THA surgery in order to gather bone and prosthesis data from beginning and compare them 1 year later.

### **FE Simulation and FRI calculation**

The Finite Element (FE) simulation aims to compute a fracture risk index at the patient's proximal femur as effect of the press fit force applied during a simulated cementless surgery. The FE models were generated starting by meshing the segmented femur using the *MIMICS FEA* module [10]. A direct association between material density and the HU value assigned to each CT voxel was considered. The material properties were assigned with a modified version of the material mapping method introduced by [11,16]. For the FE analysis we use post-operative CT data, meshing from 3D masks trabecular femur, cortical femur, prosthesis stem, polyethylene liner and titanium cup. Using the above mentioned BMD and HU relationship, the Young's modulus of each element was obtained by using the following equation [16].

$$E[MPa] = 10500 \times \rho \text{ ash}^{2,29} \quad (1)$$

We use this formula to model both cancellous (trabecular) bone and the cortical (compact) bone. Values of the ash density and Young's modulus for the implant stem were set according to literature [17].

The bone fracture risk index (FRI) expresses the risk for structural failure as a ratio of compressive stress (load per unit area) to estimated failure stress:

$$FRI\% = \varepsilon_{max} / \varepsilon_{yield} 100\% \quad (2)$$

Where  $\varepsilon_{max}$  is the value of the strain at a given point and  $\varepsilon_{yield}$  is the yield strain value which is considered a catastrophic failure of the bone. A value of  $\varepsilon_{yield} = 0.9\%$  was assumed in the present study [18].

*Ansys Workbench 13* [19] was used to perform the FE simulation. The input forces considered a strain test designed to resemble the actual stress involved during surgery while inserting a cementless stem into a femur. Two opposite forces of 1000N each were considered to take into account the cumulative stress produced by the 30-50 strikes to fix the stem into the femur during a typical surgery. The forces were applied along the femur socket in correspondence of the area around the stem insertion to resemble the real case, the fixed support placed at approximately 2 cm below the lesser trochanter (Fig 3A). Finally figure 3-B show the simulation results computed at the proximal femur using the Von Mises elastic strain distribution, the FRI is easily calculated on specific areas using the relationship (2).

## Results

All the CT data were of sufficient image quality for the 3D reconstruction, image segmentation and BMD assessment. BMD generally decrease with age, figure 4 show the results from the pre-op CT data where bone mineral density is measured on the volume indicated in figure 2A. Comparing both legs we can see (Fig. 4-A) that the bone density is lower on the side to be operated as we obviously expected; in addition by sorting BMD by gender we see from figure 4-B that BMD decline with the age is smoother with female patients, meaning that males undergoing THA have lower BMD compared to female in same age group. Moreover it is noticeable that some older patients showed a bone density comparable or even higher than the younger.

The preliminary results from the bone density assessment on the lesser trochanter 1 year after surgery are shown in Figure 5. The BMD is calculated on the operated side 24 hours and 1 year post surgery from the operated femur. In non cemented patients the BMD generally decreases after one year; indeed only in one case out of 10 BMD increases after 1 year while for the cemented patients 4 out of 8 increases BMD after 1 year.

The FE analysis is based on the pre-op CT scans and was carried out on all patients, simulating the press fit force employed during cementless THA with a steady force applied on the femur socket as seen in figure 3A. The Von Mises strain distribution display its maximum stress located around the proximal femoral socket where the stem is press fitted into the cavity (Fig 3B). The fracture risk index (FRI) was directly calculated from the local strain values (see equation 2) and average values were computed in the following anatomic regions: Greater Trochanter, Calcar femorale, Anterior side, Intertrochanteric line, Posterior side and Intertrochanteric crest. Results were presented in Figure 6. The maximum FRI was always found in correspondence of the calcar femorale region for all patients. Moreover the fracture risk seem not to be related to patient age, indeed we can see many cases were FRI is higher in young subjects.

## Discussion

The preliminary results shown here demonstrate that gender, age and general clinical condition aren't, alone sufficient for providing optimal decision on the implant technology be employed.

The results support the observation / theory that bone density, as major predictor of intraoperative and post surgery fractures is not solely age and gender related, i.e. there is a significant overlap concerning bone density between age groups. Therefor decision making based on the notion of age related bone density is hardly justifiable [20].

Despite the fact that our FE simulation is still to be improved and that the 'index of fracture is an underestimation of the real risk is possible to note the differences between the various patients beyond their age and gender.

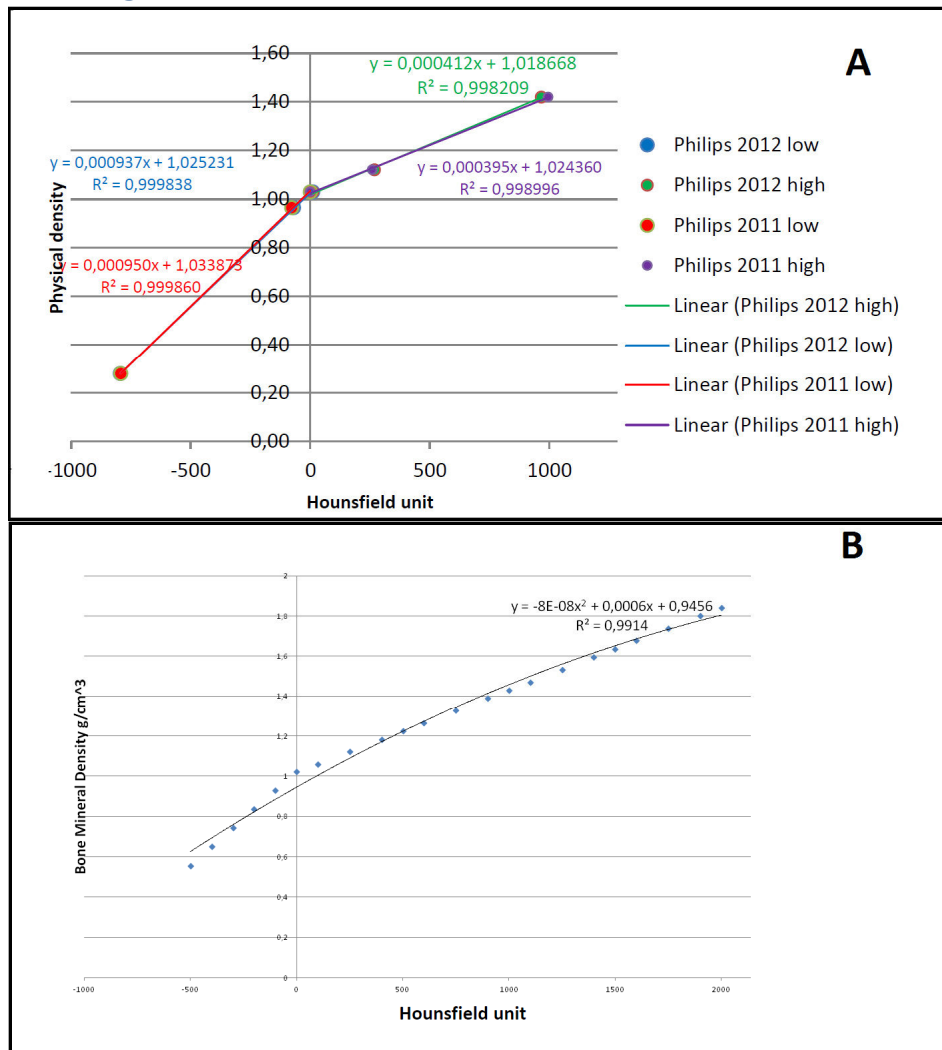
It remains unclear, whether uncemented hip arthroplasties really are the second best option for people with a bone density below a certain degree. It might be that only very low bone density bone is unsuitable for uncemented hip arthroplasty surgery due to significantly increased fracture risk.

Other criteria for decision making, such as gait patterns [21], muscle quality [22], and activation and other co-morbidity could play an even more important role for the long-term success of implanted THAs.

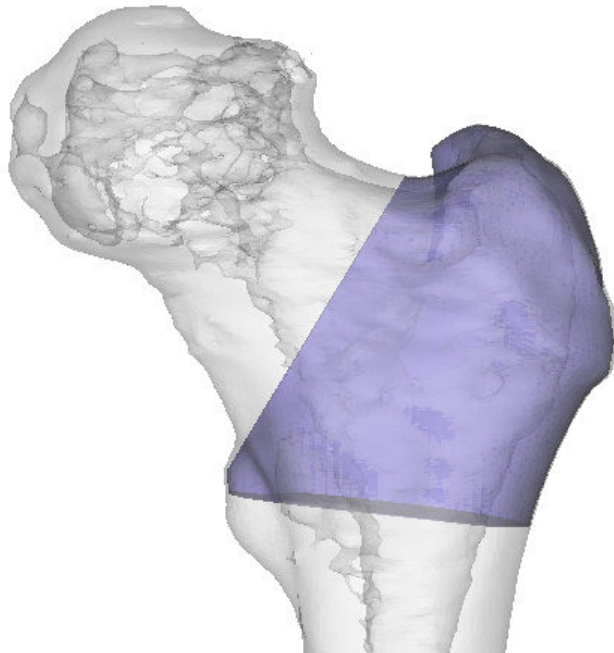
### Acknowledgments

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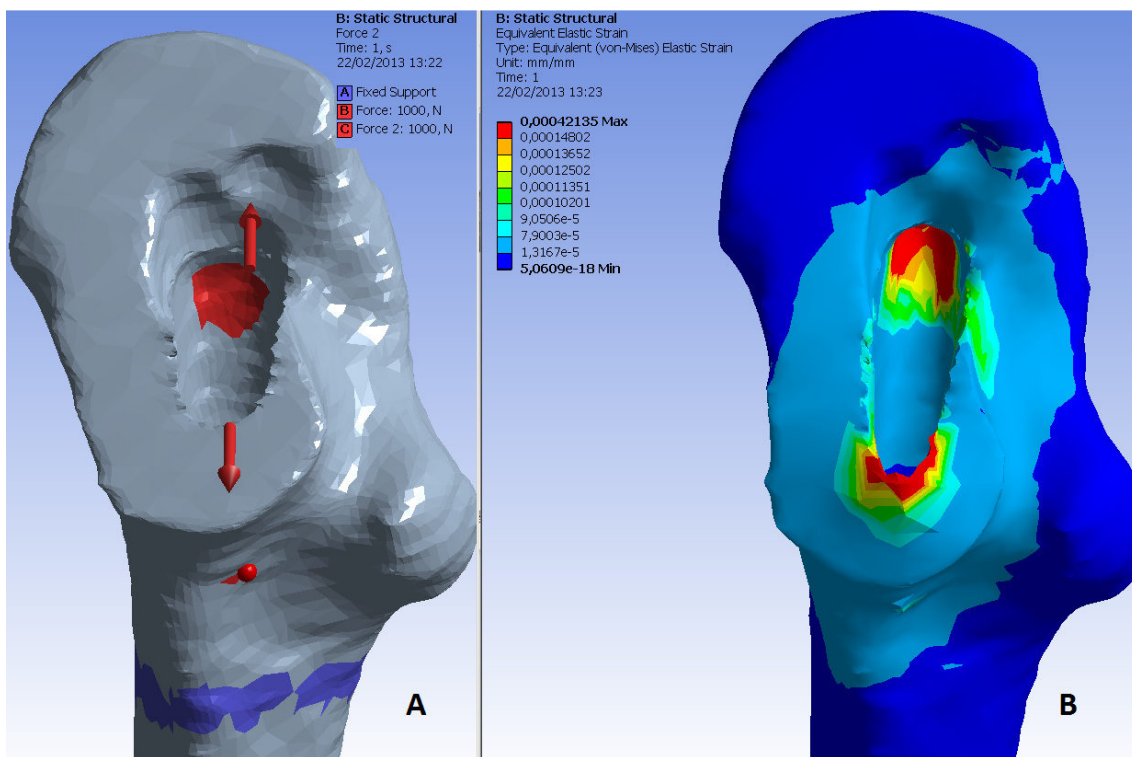
### List of Figures



**Figure 1:** A) Mass density calibration curve of the 64-slices spiral CT Philips Brilliance at Landspítali University Hospital. The equation of each linear regression curve is displayed as well as the corresponding correlation coefficient. B) Interpolation of the linear regression curves which is used to convert HU values to BMD.

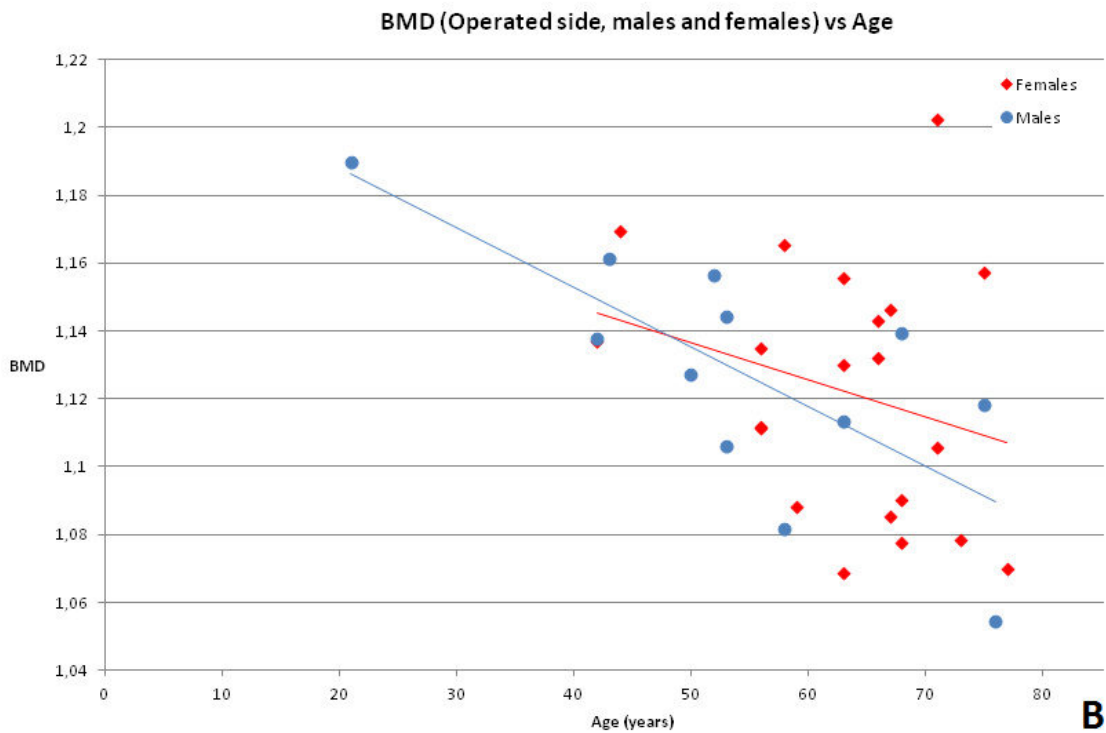
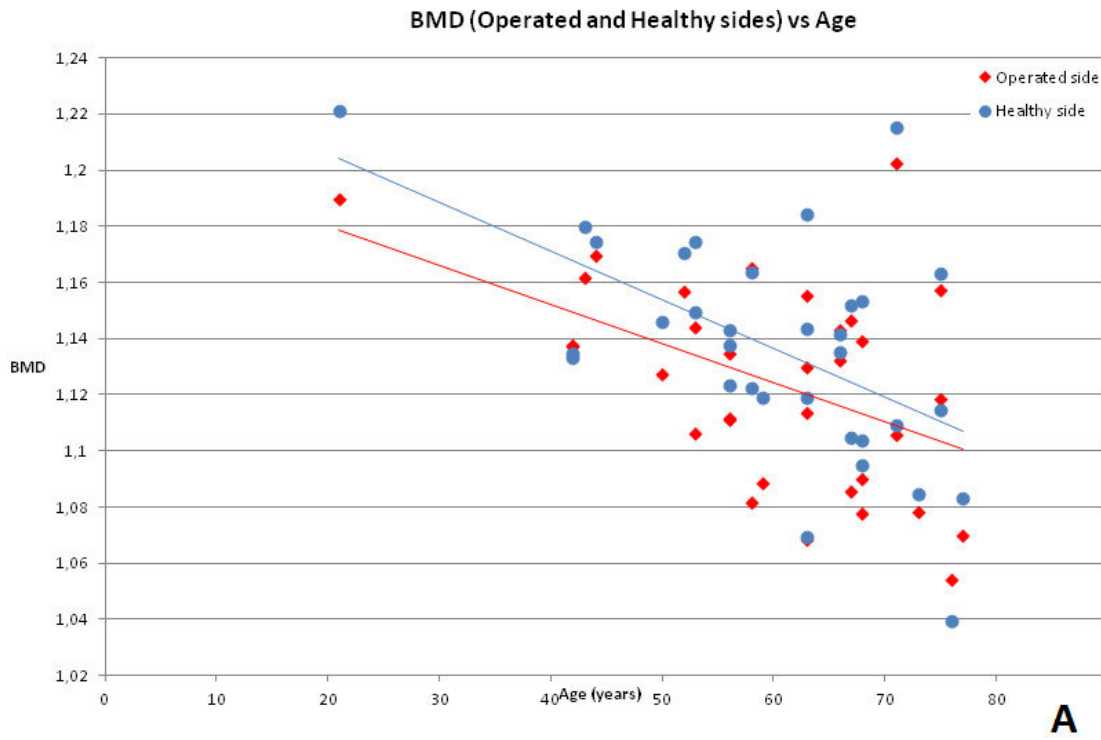


**Figure 2:** A) The region of interest where the pre-op BMD is computed.

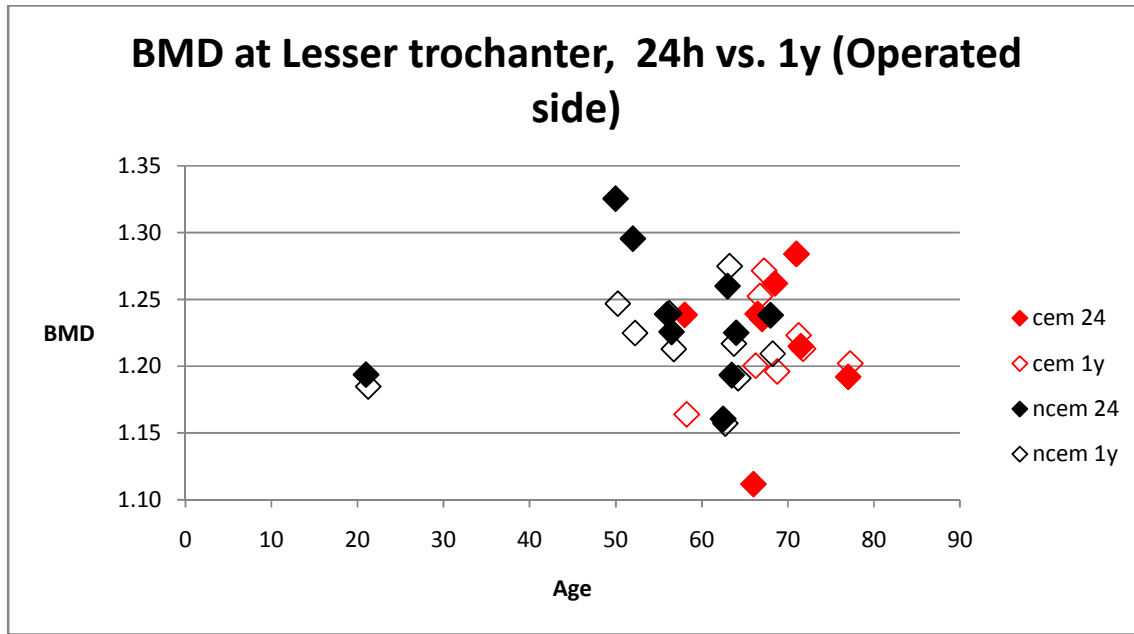


**Figure 3:** Cementless simulation. A) Applied forces at the proximal femur socket. B) Von Mises strain distribution

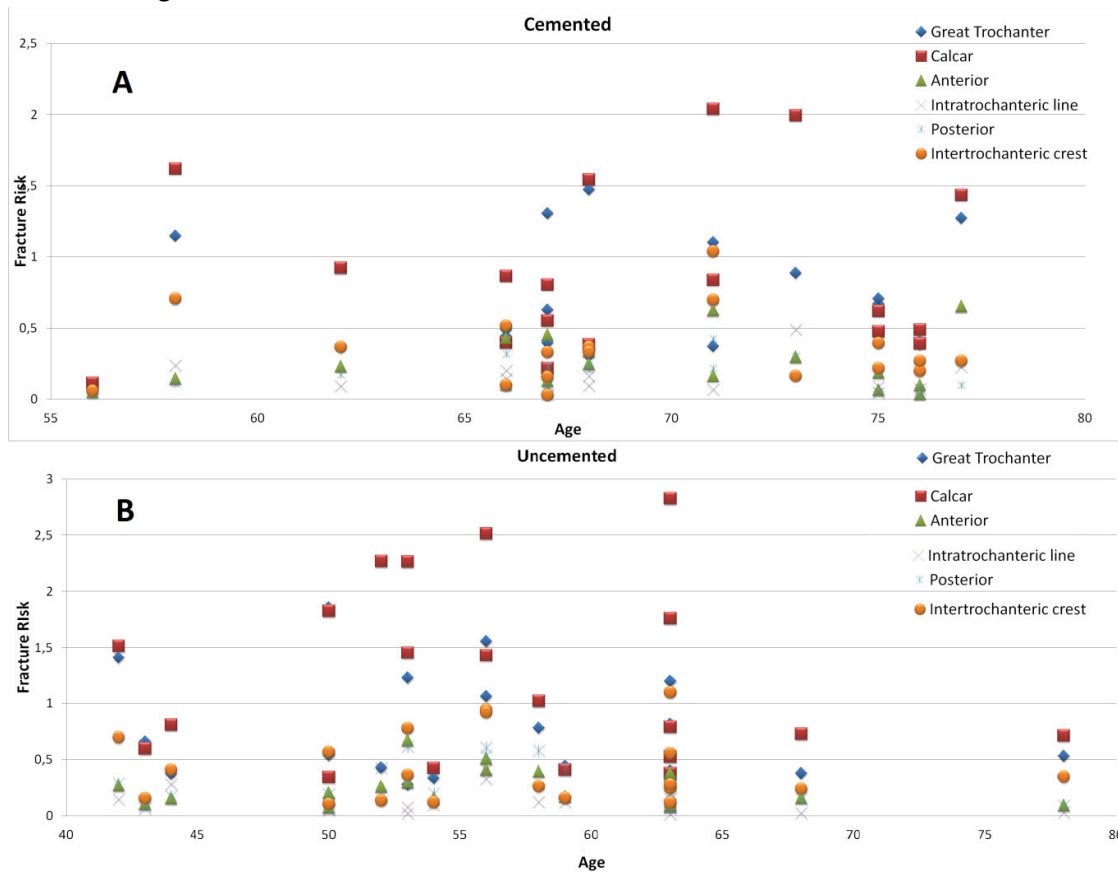




**Figure 4:** Pre-op bone mineral density (gram/cm<sup>3</sup>) vs. age in the region of interest displayed in figure 2 A) Comparison of the femur receiving the implant with the healthy one. B) Comparison of females and males patients.



**Figure 5:** Post-op 24 hours compared with Post-op 1year bone mineral density (gram/cm<sup>3</sup>) vs. Age at lesser trochanter region.



**Figure 6:** Fracture risk indexes (%) calculated on different anatomical regions around the proximal femur socket from patients undergoing cement (A) and cementless prosthesis (B).



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