

Computational Assessment for Total Hip Arthroplasty Surgery (THA): Gait Analysis, 3-D Modeling and Fracture Risk Evaluation

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Title:

Computational Assessment for Total Hip Arthroplasty Surgery (THA): Gait Analysis, 3-D Modeling and Fracture Risk Evaluation

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Abstract

Total hip arthroplasty (THA) is performed with or without the use of bone cement. Facing the lack of reliable clincical guidelines on decision making whether a patient should receive THA with or without bone cement, a joint clinical and engineering approach is proposed here with the following objectives: 1. Assess patient recovery developing monitoring techniques based on gait analysis, measurements of bone mineral density and structural and functional changes of quadriceps muscles. 2. Validate computational processes based on 3-D modeling and Finite Element Methods (FEM)

We conducted a clinical trial where 36 volunteer patients undergo THA surgery for the first time: 18 receiving cemented implant and 18 receiving non-cemented implant. The patients are scanned with Computer Tomographic (CT) modality prior-, immediately- and 12 months post-surgery. The CT data are further processed to segment muscles and bones and to create 3D-models for the simulation and for calculating bone mineral density (BMD) and fracture risk index (FRI). Quadriceps muscle density Hounsfield (HU) based value is calculated from the segmented file on healthy and operated leg before and after one year from THA surgery.

The risk for structural failure during THA surgery is estimated by calculating femoral bone fracture risk index (FRI) as a ratio between compressive stress during surgery and estimated failure stress on bone. The correlations with the BMD observations during the clinical trial will assess and validate this potential predictor tool.

Furthermore clinical assessment is performed using gait analysis technologies such as a sensing carpet, LED markers and video. Patients undergo these measurements prior-, immediately after - and 12 months post-surgery.

The preliminary results indicate computational tools and methods that are able to quantitatively analyse patient's condition pre and post-surgery: The spatial parameters such as step length and stride length increase 6 weeks post op in the patient group receiving cemented implant while the angle in the toe in/out parameter decrease in both patient groups. The BMD measurement and the Fracture risk analysis display a potential method for eligibility to receive non-cemented implant; the preliminary results show that also elderly that according with current clinical evaluation receives a cemented implant are suitable for the non-cemented type.

Key Words: 3-D modeling, Orthopaedic, Gait Analysis, Bone Mineral Density, Finite Element Analysis, Total Hip Replacement.

Introduction

For the treatment of advanced damages of hip joints THA is well proven surgical technique. The replacement of the hip joint with an artificial prosthesis has been one of the most effective and successful orthopedic interventions for many decades as it reproducibly restores function and reduces pain in formerly pathologic hip joints. It is applied for several pathologies, mainly in arthrosis, but also as a very beneficial treatment in osteonecrosis of the femoral head and femoral neck fractures. Due to the different mechanical properties of the prosthesis material and the bone tissue, a partial unloading of the periprosthetic bone occurs [1].

Currently there are two methodological options for THA - cemented or uncemented. The bone cement may cause reduction in bone density as a result of removal of normal stress from the bone, leading to weakening of the bone in that area and the

fracture risk increases [2]. Bone loss is identified as one of the main reasons for loosening of the stem. Otherwise, thanks to the press-fit of the non-cemented stem achieved by surgery, the bone layers immediately adjacent to the stem are preloaded and encouraged to grow and getting stronger [3]. The non-cemented stem would be the better choice for most patients, but the question remains if the femur can handle the press-fitting and compressive stress during surgery.

Controversy exists regarding the optimal method; large studies have shown different outcomes differentiating between cemented and uncemented methods [4]. Uncemented stems have to be more often revised due to periprosthetic fracture during the first 2 postoperative years than cemented stems. There is no noticeable difference in risk of infection between the outcomes of cemented vs. uncemented THA. In the decision making process between uncemented and cemented THA for the individual patient, bone and muscle quality is regularly included, when e.g. the biological age of the patient is estimated. Preoperative measurements of bone and muscle quality are not a standard today, although it is commonly accepted, that they can have decisive influence on the outcome. Individuals with low bone and muscle quality are good candidates for cemented THA due to the reduced risk for periprosthetic fractures during surgery and the first two postoperative years.

Although age is one indicator for bone and muscle quality, individual differences due to life style and genetics are wide providing a broad range of bone density and muscle quality [5], which should be taken into consideration when deciding whether to implant a THA cemented or uncemented. Measuring both bone and muscle quality will potentially contribute to the decision making between cemented and uncemented THA.

Clinical assessment for THA surgery can be performed using Gait Analysis techniques. Different technologies have been employed to evaluate walking speed, energy consumption, range of motion (ROM), muscle function and different phases in the gait cycle. Pathological process in the hip causes changes in gait secondary to pain and reduced ROM in the hip. The total gait pattern is affected with reduced ROM, changes in muscle function, step length, walking speed, symmetry of the gait etc. After THR the gait improves but usually it is slight asymmetrical even after full recovery [6]. This can be because of leg length discrepancy, type of prosthesis, surgical approach, pain in other joints etc. Pain in the operated leg around the mid-thigh has been documented in patients with uncemented prosthesis possibly due to osteopenia [7].

In summary although many techniques are available to assess THA surgery there are no guidelines, gold standard or clear clinical recommendations currently in practice on the choice of a cemented or an uncemented THA. The present work describes a novel approach using computational tools combining measurements of bone and muscle density, gait analysis, 3-D modeling and simulation for supporting decision making in THA and selecting the optimal surgical procedure.

Material and Methods

Clinical trial: Gait Analysis and Spiral CT

36 voluntary patients (20 females and 16 males) are enrolled into the clinical trial, 18 receiving a cemented - and 18 receiving an uncemented implant. The implant type is decided according to the surgeons evaluation mostly based on patient age, gender and general clinical conditions. All patients had THA surgery for the first time. The

average age at the moment of surgery is 56 for the males and 62 for the females; the youngest patient is 22 and the oldest 77 years. Patients are scanned (64 CT Philip Brilliance) before and immediately after surgery and at 52 weeks post-surgery. The scanning region starts from the iliac crest bone and ends at the middle of the femur; slices thickness is 1mm, slice increment is 0.5mm and tube intensity is set to 120KV. This data allows a precise 3-D reconstruction of the regions of interest.

All patients had a Gait Analysis assessment the day before surgery and at 6 and 52 weeks post-surgery. Patients walk on a sensing carpet called "*GAITrite walk way system*" [8] at the same time a synchronised video and EMG are taken using the wireless "*Kine Measurement System*" (*KMS*), which measures Electromyography (EMG), and digital video [9]. The GAITRite system automates measuring spatial and temporal parameters via a 14-foot electronic walkway, containing 16128 pressure switches embedded between two sheets of vinyl. The KMS data are processed with *"KinePro"* [9] which is a video-based motion analysis system used to observe motion and synchronized EMG patterns during gait. LED markers are placed on the ankles, knees and hips to allow data collection on hip, knee and ankle ROM during a gait cycle. We focus on looking specifically at clinically important gait variables such as step length, gait symmetry, single and double support, and others parameters as seen in Figure 1A.

3-D Modeling for Bone analysis

The medical images coming from the CT scanner consist of grayscale information. All of these are presented in DICOM standard images imported in the *"Mimics* platform" [10] where femur bone and muscle are segmented from the other tissue with point- and region-based methods. The point-based method uses only the attributes of

an image element for its segmentation. Thresholding is a point-based approach to image segmentation and was the technique of choice for this project. Femoral bone thresholding and segmentation is performed according to the process described in [11], 3-D Masks of femurs are created from the pre surgery CT data while 3-D Masks of prosthesis and operated femur are made from the post-surgery scan (Fig 1B). Directly from the mask properties key parameters such as volume and HU density are calcualted from the segmented objects.

BMD is calculated from the proximal femur in the region between femur head and lesser trochanter, along the intertrochanteric line as decipted in Figure 1C. To determine an accurate relationship between HU and BMD values, the CT scan device was calibrated with QUASAR phantom [12]. We use the linear relationship:

BMD = a *HU + b, where *a* and *b* are calibration coefficients, which were calculated from the phantom data along with the corresponding statistical descriptors [13].Voxel values of the preoperative scans concerning healthy and operated femur were converted from Hounsfield units to BMD values by using equation:

 $BMD [mg/cm^3] = 0,40 HU + 24,36$

(1)

The relation respects modality of acquisition for the scans we use in the project: 64-SCT Philips Brilliance, 120 KeV with a correlation of $R^2 \approx 0.99$.

Simulation and FRI calculation

The FE models are created in the following manner: CT datasets are segmented using Mimics and a corresponding 3-D object is created and meshed using the *Mimics FEA* module [10]. There is a direct association between material density (HU values) of the scanned object and the gray value assigned to each pixel in the image data; we assign the material properties with a modified version of the material mapping method

introduced by [14]. For the FE analysis we use post-operative CT data, developing the 3-D masks from trabecular femur, cortical femur, prosthesis stem, polyethylene liner and titanium cup. From our empirical measurements we found the relationship between ash density (BMD) and HU units, then we the equation introduced by [14].

$$E[MPa] = 10500 * \rho a s h^{2,29}$$
⁽²⁾

We use this formula to model both soft (trabecular/cancellous bone) and the compact/cortical bones. The ash density and Young's modulus for the implant stem is founded in literature [15]. 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:

 $FRI\% = \Box max/\Box yield * 100\%$

(3)

Where \Box max is the value of the strain at a given point and \Box yield is the yield strain value which is considered a catastrophic failure of the bone. A value of \Box yield = 0,9% was assumed in the present study[16].

We use *Ansys Workbench 13* [17] to implement the simulation. The input force that we consider for the strain test is the simulated force needed to insert the uncemented stem. We chose an applied force of 1000N to emulate the cumulative damage that would occur from the 30-50 strikes traditionally needed.

The forces have been applied along the femur socket in correspondence of the area around the stem insertion where the highest stress is expected, the objective is to simulate the elongation of the elastic bone tissue when the stem is pushed into the femur (Fig 2-A).

The "*Von Mises elastic strain distribution*" is performed on four patients along the proximal femur; 2 receiving non cemented implant (Fig 2 B-C) and 2 receiving the cemented implant (Fig 2 E-D).

Results

The Gait Analysis technologies employed in the project allow the collection of many parameters as in Figure 1, the comparison of these parameters pre and 6 weeks post THA shows some clear indications. Spatial parameters such as *step length* and *stride length* increase in most of the cases after 6 weeks in the patient group receiving cemented implant (Fig 3 A-B). For both patient groups we measure an angle decrease in the *toe in/out* parameter (formed by the line connecting heel strike and toe-off plantar surface centres of pressure and the forward progression line) 6 weeks after THA as depicted in Figure 3 C.

The pre-operative BMD measurements on the leg receiving the implant show a tendency of decreasing with the patient age as normally expected (Fig 4 A). Indeed according to the current implant policy, older patients receive cement implant because the bones here are generally weaker. Figure 4 A shows that this isn't always true, in fact BMD is, in several cases, above the trend line and higher compared with younger, non-cemented patients.

The simulation process introduced in this paper calculate the fracture risk on different anatomical areas on the proximal femur as effect of the press fit force applied during a theoretical non-cemented surgery. The FE analysis is made on 4 patients: 2 receiving cement and 2 receiving non cemented implant. The Von Mises stress distribution in Figure 2 B-E, show a maximum stress on the proximal femoral socket where the stem is press fitted into the cavity. No remarkable differences are measured between the patients in Figure 2-B, C and E although there is a huge difference in age; patients are

respectively 20, 47 and 76 years hold. The fracture risk is directly calculated from the local strain values (3) on different anatomical regions of interest: Greater Trochanter, Calcar femorale, Anterior side, Intertrochanteric line, Posterior side and Intertrochanteric crest. Maximum FRI is always on the calcar femorale region (figure 4 B). In spite of what we would expect the minimum FRI is measured on a 67 years old patient (undergoing cemented implant), here the FRI on the calcar area is 2,2% while in the other patients is between 16-18% (Fig 4B).

Discussion

Despite the plethora of techniques and parameters available to assess outcome of THA surgery, we are still missing proven guidelines and clear clinical recommendations to securely choose between a cemented and an uncemented THA for our patients.

The latest clinical studies have shown uncemented stems to be more often revised due to periprosthetic fractures during the first 2 postoperative years than cemented stems, but there is no noticeable difference in risk of infection [4]. The bone cement may cause reduction in bone density as a result of removal of normal stress from the bone, leading to weakening of the bone in that area and the fracture risk increases [2]. The non-cemented stem would therefore be the better choice for most patients, but the question remains if the femur can handle the press-fitting and compressive stress during surgery. The present work therefore describes results of our novel approach to find computational tools to support decision making in selecting the optimal surgical procedure in THA.

Preoperative measurements of bone and muscle quality are not a standard today, although it is commonly accepted that old individuals with low bone and muscle

Artificial Organs

quality are good candidates for cemented THA. Our results confirmed the tendency of decreasing BMD with patient age as expected with the exception in several cases, where BMD was above the trend line and higher compared with young, non-cemented patients. In the gait analysis, gait improves usually after THA but can be slight asymmetrical even after full recovery [6]. Our results showed spatial parameters such as step length and stride length increase in most of the cases in the cemented implant group after 6 weeks and for both patient groups, we measured an angle decrease in the toe in/out parameter after 6 weeks.

Most important though were the results from the 3-D modeling and simulation processes. The simulation process introduced here calculated the fracture risk on different anatomical areas of the proximal femur as effect of the press fit force applied during a theoretical non-cemented surgery on 3-D models. Although the FE analysis is made on only 4 patients (2 cement and 2 non cemented), the Von Mises stress distribution showed a maximum stress on the proximal femoral socket where the stem is press fitted into the cavity. Also there were no remarkable differences measured between patients despite a huge difference in age (20, 47 and 76y). Maximum FRI was always on the calcar femorale region and in spite of what we would expect; the minimum FRI was measured on a 67 years old patient undergoing cemented implant.

Our preliminary results based on various computational process that are able to quantitatively analyse THA patient's condition pre- and post-surgery are actually indicating very innovative methods and tools for the more correct selection of patients to cemented vs. non-cement type of surgery.

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PARAMETER DESCRIPTION	Total/Left	Right
Step Count	76	
Distance	3761,4	
Ambulation Time	46,16	
Velocity	81,5	
Cadence	98,8	
Step Time Differential	0,02	
Step Length Differential	2,757	
Cycle Time Differential	0,001	
Step Time(sec)	0,617	0,597
Step Length(cm)	48,15	50,907
Cycle Time(sec)	1,215	1,214
Stride Length(cm)	99,401	99,966
HH Base Support(cm)	14,431	14,453
Swing Time(sec)	0,454	0,399
Stance Time(sec)	0,761	0,815
Single Supp. Time(sec)	0,399	0,454
Double Supp. Time(sec)	0,361	0,366
Swing % of Cycle	37,4	32,9
Stance % of Cycle	62,6	67,1
Single Supp % Cycle	32,8	37,4
Double Supp % Cycle	29,7	30,1
Toe In / Out	-8,6	-4
Hee l OffOn Time	0,057	0,065
HeelOffOn Perc	4,7	5,4
Double Supp Load Time	0,163	0,163
Double Supp Load %GC	16,5	13,4
Double Supp Unload Time	0,16	0,203
Double Supp Unload %GC	13,2	16,7
Stride Velocity	81,973	82,54
Step Len Std Dev	3,038	2,948
Step Time Std Dev	0,025	0,028
Stride Length Std Dev	5,291	4,539
Stride Time Std Dev	0,042	0,048
Swing Time Std Dev	0,02	0,021
Stance Time Std Dev	0,038	0,038
Stride Velocity Std Dev	6,151	5,697
Single Supp Time Std Dev	0,021	0,02
Double Supp Time Std Dev	0,031	0,033
Heel Off On Std Dev	1,124	1,322
Supp Base On Std Dev	2,799	2,363
Foot Length	22,7	23,6
	Δ,-	20,0

Figure 1: Gait analysis parameters measured during the clinical trial (A). Segmentation results from postsurgery data in cement and non-cemented patients (B). The region of interest where the BMD is calculated (C).



Figure 2: Applied forces on the proximal femur (A). Von Mises strain distribution for 2 non cemented patients B-C and 2 cemented patients D-E (cemented patient). 319x227mm (96 x 96 DPI)





Figure 3: Gait parameters pre and 6 weeks post-surgery. Non cemented patients on the left, cemented on the right. Step length (A), Stride length (B) and Toe in Out (C).





Figure 4: BMD (gr/cm3) sorted by implant technique and ordered by patient age (A). FRI (%) for 4 patients calculated on different anatomical regions on the proximal femur ordered by patient age (B).

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