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Design and Manufacture of Short Stemless Femoral Hip Implant based on CT Images

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This study describes a methodology for designing a short femoral stem, based on CT scan data, for young patients requiring a hip replacement. One advantage of using a short femoral stem is that it reduces the amount of surgery, conserving the greater trochanter and the femoral neck ring. Precise digital data of the internal femoral anatomy are necessary to develop new prosthetic implants using computer-aided design (CAD) techniques. Image processing and CAD Softwares were used to obtain a 3D reconstruction of the cortical bone and canal geometry, implant design, fit evaluation and 2D drawings. A short femoral stem can then be manufactured from this CAD model using computer aided manufacturing (CAM) techniques. The design procedures and rationales are explained. The fit of the stem was tested before clinical application, using virtual stem implantation so that predictable implant-related problems could be rectified. It was concluded that the designed short femoral stem matched the femoral cavities very well. The results indicate that the investigated method of designing a short femoral stem is practicable and very desirable for young patients.

Key words: Femoral stem, proximal stem, CAD, CNC manufacturing

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INTRODUCTION

The concept of the short stemless hip implant design in total hip arthroplasty (THA) is not new now a day, as its fitment based on minimally invasive surgery (MIS) technique (Morrey, 1989). If adequate stability and sufficient load transfer can be obtained with a proximal insert into the femur, the goals of a hip replacement can be achieved without a conventional stem. The benefits of MIS made short stemless hip implants easier to fit, as conventional hip stem cannot be easily inserted with minimally invasive technique. In recent studies, the preservation of bone stock has been another issue for the design of stemless hip implants (Santori *et al*., 2006; Lombardi *et al*., 2009). The first attempts to publish this new stemless design idea to reduce stress shielding effect of conventional THA were made by Munting and Verhelpen (1995). After that, many other researchers try to use similar design idea to make MIS more convenient to surgeons and beneficial to surgery results (Tai *et al*., 2003; Renkawitz *et al*., 2008).

A review of historical hip designs indicated that many researchers advocated neck-sparing features in early hip designs since the 1970's. In retaining the femoral neck, both torsional and axial loads are reduced, along with bending moments on the femoral component (Harrison *et al*., 2010). Following are the advantage of neck retention:

- Provides better blood flow vs. hip resurfacing
- Provides better axial and torsional stability vs. conventional THA (thus a shorter stem)
- Provides for more tissue sparring approaches (both hard and soft tissue)
- Potential for less blood loss
- Potential for quicker rehab

The influence of implant-sizing on mechanical stability was investigated for the new stem, in particular with relation to the bone quality (Westphal *et al*., 2006).

Although substantial progress has been made in the development of cementless total hip arthroplasty (THA) in recent years, a number of limitations remain. To address such limitations, new indigenous low cost high quality THA implant designs with shorter stems have been developed within the Indian context.

MATERIALS AND METHODS

Designing of prosthesis inculcates in itself knowledge and understanding of a number of fields and collaboration between specialists in medicine and manufacturing to come up with an efficient solution. Figure 1 shows work flow diagram for designing a hip prosthesis. This includes data collection from patients, development of prosthesis dimensions based on measured data, biomechanics studies for function and motions (since a natural joint's bones are coupled by ligaments), prototyping to verify the functional aspects and material selection (biocompatible, high strength to weight ratio). Once a simple design of prosthesis is ready, implantability issues (design for ease of implantation) are verified by virtual implantation accompanied with surgeons' feedback. Major design consideration must also be given to revision surgery, since the prosthetic joints may loosen or break inside the body. Manufacturing issues also needs to be considered. Based on the surgeons and manufacturing engineer's comments, the final design will be made and used for testing.

Designed for proximal fit and fill and bone conservation: In spite of the clinical success of total hip replacement

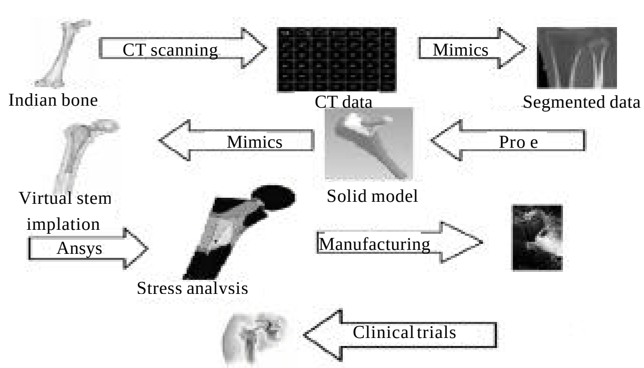

Fig. 1: Work flow diagram for designing Hip prosthesis

(THR), still THR surgeries produce strong limitations to the quality of life on operated individuals. As people live and remains active longer than in the past, the needs of more appropriate techniques in the treatment of dysfunctional joints quickly increased in the last years and it is expected to increase further. Such need pushed the industry and the research in developing new methods for the treatment of dysfunctional hips with particular attention to young and active patients and femoral short stemless implant could be the solution. The short femoral stem implant has been specifically designed to be implanted using a mid neck resection, facilitating a highly bone conserving procedure that retains the femoral neck and leaves the diaphysis intact. The implant is designed such that it follow the medial and lateral natural profile of the medial calcar, three point mechanical stability and rest fit concept as shown in Fig. 2. The geometry of the short femoral stem prosthesis is based on a detailed analysis of high resolution CT scans with the objective of offering a less invasive femoral stem that locates proximally, leaving the diaphysis intact and providing a bone conserving solution for the young patient.

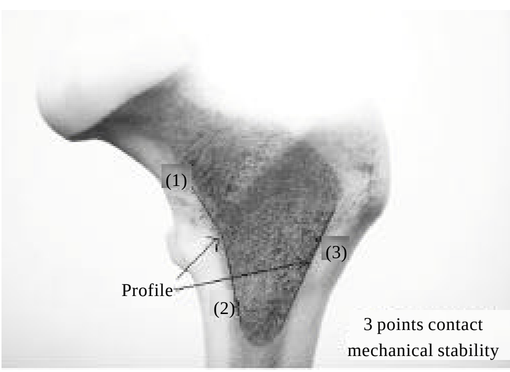

Fig. 2: Concept of designing short femoral stem

Anthropometric measurements: Thirty CT scans obtained from the All India Institute of Medical Sciences (AIIMS) were analyzed. The scans were from 10 female and 20 male subjects. The ages of the subjects ranged from 40 to 55 years with an average of 51.3 years. These images in DICOM format were imported into MIMICS® (Materialize, Inc., Leuven, Belgium) to get a 3D graphic model of each femur. A 3D model was developed by a thresholding and region growing technique, to extract the boundaries of the femur from CT data.

The dimensional measurements of the femurs were divided into 2 groups. In the first group we measured extramedullary parameters like femoral head offset (horizontal offset), head diameter, femoral head position (vertical offset), neck-shaft angle and anteversion angle. In the second group, we measured intramedullary parameters like mediolateral canal width (ML) and anterioposterior canal width (AP) at 3 levels (D, E and F) as shown in Fig. 3a and b.

3D Modelling of short femeoral stem implant: The obtained intramedullary and extramedullary geometrical parameters of the femur make it possible to commence designing a short femoral stem. Based on design assumptions of a close intramedullary fit of stem, the cross-section and shape of the short femoral stem was standardized. One of the most important characteristics of short femoral stem prostheses is their degree of filling the medullary canal at the proximal region. That's why the planner must shape the prosthesis stem such that it would fit the medullary canal as much as possible for best type of fitment.

The implant was designed so that appropriate cross-sectional geometries could be swept along the main trajectories and guided contours of the implant

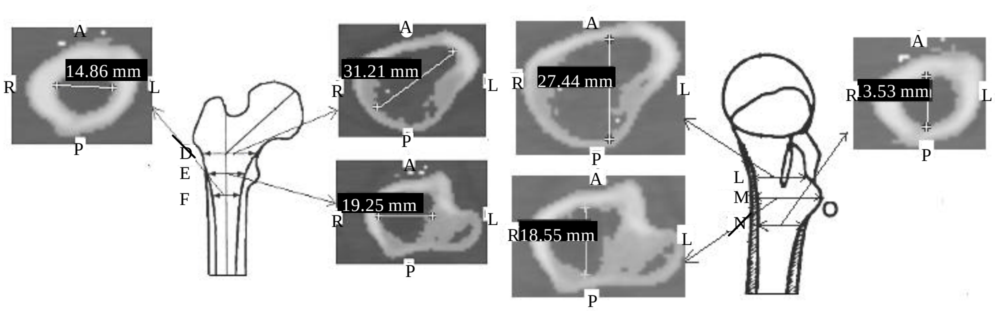

Fig. 3(a-b): (a) Mediolateral measured dimensions and (b) anteroposterior measured dimensions. Where, D: Mediolateral canal width, 20 mm above the lesser trochanter, E: Mediolateral canal width, at the level of the lesser trochanter, F: Mediolateral canal width, 20 mm below the lesser trochanter, L: Anteroposterior Canal width, 20 mm above the lesser trochanter, M: Anteroposterior Canal width, at the level of the lesser trochanter, N: Anteroposterior Canal width, 20 mm below the lesser trochanter

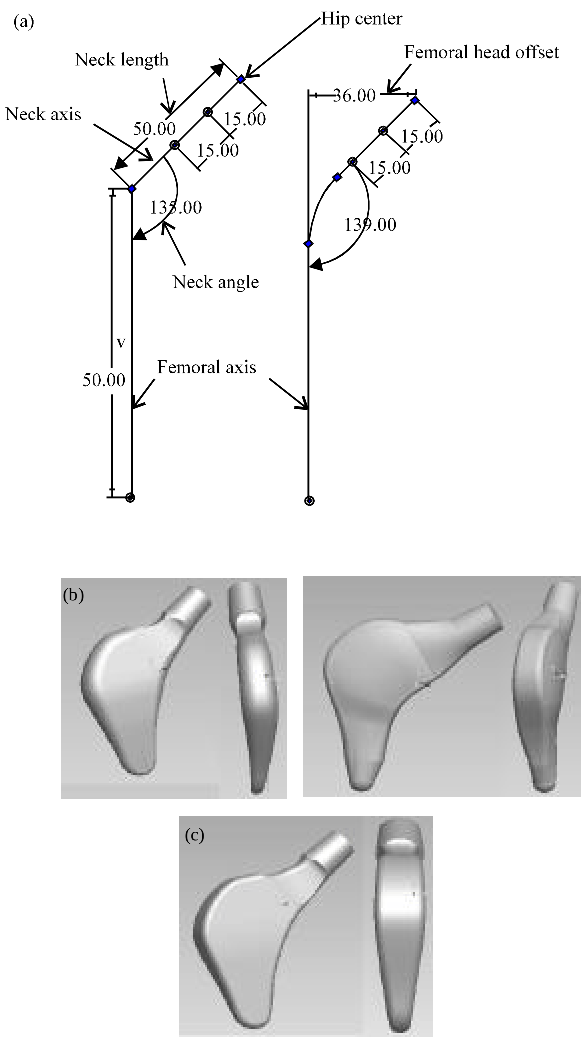

Fig. 4(a-c): Solid models of short femoral stem. (b) Wedge shape with femoral curve (c) Straight wedge shape

(Fig. 4a), also defining the characteristic angular orientation of the prosthesis neck and then the final stage, which is that of building a solid model of the standard prosthesis with femoral curve and without femoral curve (i.e. straight stem) by using ProE software, as shown in (Fig. 4a-c).

Virtual implantation: To check for a close intramedullary fit and impingement of the short hip femoral stem to the femur bone, virtual implantations were performed. The close intramedullary stem fit may decreases the stresses at the proximal implant-bone interface. This fit was tested before actual fabrication and clinical application, so that implant-related problems could be corrected. Virtual implantations of the prototype stem were performed with all digitized femur specimens obtained from CT scans, based on the implantation protocol and the factors to assess the fit of the designed implant shape given by Adam *et al*. (2002) (Fig. 5).

Fig. 5: Virtual implantation of short femoral stem

Designed for physiological loading: Initial and long-term stability of the short femoral stem was achieved through the loading path of the stem. This was validated using FEA testing where a model of the short stem implant was analyzed using a CT-based femur model on Ansys version 11. Relevant material properties and boundary conditions were applied in order to replicate natural conditions. The FEA showed that the load travels along the path of maximum stiffness flowing through the three contact points of the medial calcar, lateral calcar and lateral cortex. Typical stresses found were well below the yield strength of bone 130 MPa as per Bennett and Goswami (2008), indicating no risk of fracture as shown in Fig. 6.

Manufacturing of a short femoral stem hip implant: The machining of the titanium alloy femoral stem generally performed on a 5 or more axis CNC machine but here we did machining of this short femoral stem on a 3 Axis CNC machine. The following is the stepwise process NC sequence of machining of implant, developed in Pro/ENGINEER.

- Step (1) involves the profile milling of 3-axes, which cuts the outer profile of the implant
- Step (2) Involves volume milling of 3-axes, which cuts the material on wedge

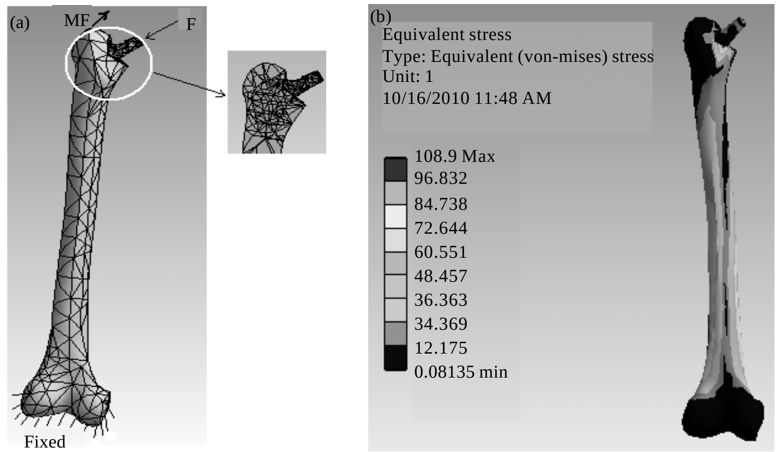

Fig. 6: FEA on short femoral stem implanted into the femur bone. (a) Meshing and Boundary conditions and (b) Contour plots of Von-Mises stresses

- Step (3) Involves surface milling of 3-axes, which finishes wedge portion of Implant
- Step (4) Involves trajectory milling of some portion, for ease of further machining
- Step (5) Involves the finishing cut of 3-axes; finishing the final geometry of the Implant
- Step (6) Turning taper turning) at the upper portion

The same procedures are applied after flipping the work piece and maintaining the mirror imaged reference (datum) co-ordinates on other side. The finished short femoral stem implant is shown in Fig. 7.

RESULTS AND DISCUSSION

There are three key extrafemoral dimensions like leg length (or femoral head position), femoral head offset and anteversion angle which helps restore proper hip kinematics and helps improving overall patient satisfaction. Optimizing these parameters before actual implantation leads to correct leg length, range of motion and joint stability. The intramedullary parameters like mediolateral canal width (ML) and anterioposterior canal width (AP) are responsible for the proper fit and primary stability. These anthropometrically measured parameters are summarized as the mean and standard deviation in Table 1.

The obtained anthropometrically measured data were used to model the anatomical shape of the short femoral stem. It is essential that the stem fills the medullary canal as completely as possible. This fit was tested

Table 1: Mean and standard deviation (SD) values of anthropometrically measured parameters

Parameters	Units	Mean±SD
Femoral head offset	mm	48±4.15
Femoral head diameter	mm	50.4±3.66
Femoral head position	mm	60.33±6.13
Mediolateral canal width, 20 mm above the LT (D)	mm	45.78±3.32
Mediolateral canal width, at the level of the LT(E)	mm	40.22±3.2
Mediolateral canal width, 20 mm below the LT (F)	mm	22.56±2.71
Neck-shaft angle	degree	125±5.49
Anteroposterial canal width, 20 mm above the LT(L)	mm	33.26±4.6
Anteroposterial canal width, at the level of the LT(M)	mm	26.9±3.6
Anteroposterial canal width, 20 mm above the LT(N)	mm	21.36±3.37
Anteversion angle	degree	11.9±4.22

before emoral stem closely fits and matches both medial and lateral profiles of the canal, as shown in Fig. 5.

Finite Element Analysis (FEA) showed that from the point of view of reducing the direct stresses in the stem, therefore increasing the life of hip implant, a significant contribution was made by reducing the stem length of the prosthesis that fits proximally based on the best fit concept. It also concluded that by preserving the femoral neck, the stresses were reduced along with bending moments on the bone-implant system. The use of material with a lower modulus, such as titanium, would be superior to that of stiffer materials such as Co-Cr-Mo. It was also shown typical stresses found were well below the yield strength of bone indicating no risk of fracture (Fig. 6b).

All the machining of titanium was undertaken on a 3 Axis CNC machine for the short femoral stem. First, the machining was done on one side followed by machining on the other side after flipping the work piece and maintaining the same reference (datum) co-ordinates.

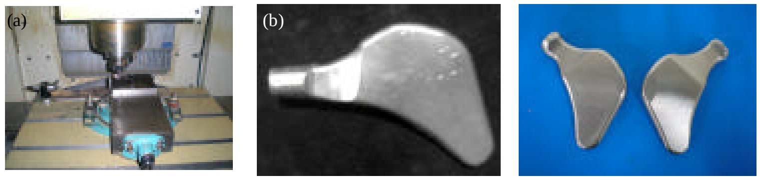

Fig. 7(a-b): (a) Implant machining and (b) photographs of newly designed short femoral stem

CONCLUSIONS

This study introduces a method for designing a short femoral stem hip implant based on CT images. Using image processing software MIMICS, CAD/CAM software Pro/Engineering and FE analysis software ANSYS, the design cycle is shortened. The results of verification indicated that this method of designing a short femoral stem hip implant based on CT images is practicable. The cost of short femoral stem hip implants can be lowered so most patients can accept it, thus helping to improve the quality of life for many patients in India.

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