

Cementless Press-Fit and Fibrous or Bony Ingrowth "Asian Total Hip Prosthesis" Design Using Computed Axial Tomography and Computer Aided Design and Computer Aided Manufacturing (Part 1: Computer Graphics of Femoral Canal for Intramedullary Stem Prosthesis)

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The purpose of this study was to design intramedullary femoral stems that will optimally distribute the stresses to the bone. It was postulated that an ideal distribution of stresses would occur if the femoral stem had the same shape as the canal. However, because of the curved nature of the canal it was not possible to insert a canal replica. To make insertion possible, certain areas on the stem must be removed. Cross-section of the femoral canal at 5 and 10mm intervals, were non-destructively obtained by computer assisted tomography and each outline was stored on computer disk. Close-fit stem shapes were generated by computer aided design. These close-fit hip stem designs significantly improved total and priority region stem-canal contact. Further investigation employing both theoretical analysis and laboratory experimentation will examine the strength of these stems and their stress distribution to the femur.

Key Words: Femoral canal, computer axial tomography, computer aided design, close-fit hip stem.

Loosening of cemented femoral stems can lead to serious bone destruction, during the loosening and removal processes (Blacker and Charnley 1978; Carter *et al.* 1980; Chandler *et al.* 1981; Morscher and Dick 1983; Ring 1983; Salvati and Wilson 1973). Press-fit ingrowth or non-ingrowth stems are an alternative for longterm cases. However, large areas of contact are likely to be necessary to achieve tolerable stresses on the endosteal surface, in the bone as a whole, and to avoid ongoing bone resorption.

If the stem itself is designed to more closely fit

within the canal, there will be a significant decrease of small concentrations of stress in the femur since the force will be transferred over a larger area to the femur. Consequently, the stresses would be more evenly distributed to the femur. Further, this has the potential of leading to a closer simulation of the normal overall stress distribution of an intact femur.

Because of the three-dimensional nature of the canal, a stem cannot totally fill the canal. Therefore, at the principal regions of load transfer, notably the calcar and the lateral stem tip, wide areas of contact between the stem and the femur are necessary. It is hypothesized that by using this criteria, the forces will be distributed over a larger area and the bone will not resorb abnormally, consequently, decreasing prosthetic failure. It is the purpose of this study to design close fitting stems which transmit the stresses to the femur more uniformly.

MATERIALS AND METHODS

To obtain the shape of the femoral canal non-

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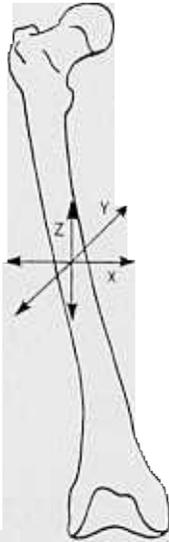


Fig. 1 XYZ reference axis used to orient the femur

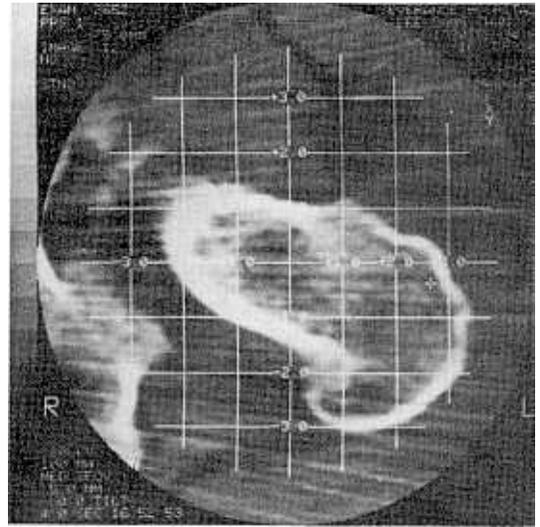


Fig. 2a CAT scan section of the calcaneus region.

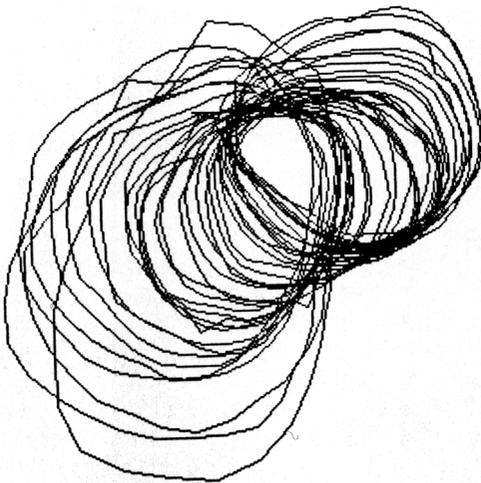


Fig. 3. Computer generated picture looking down the canal.

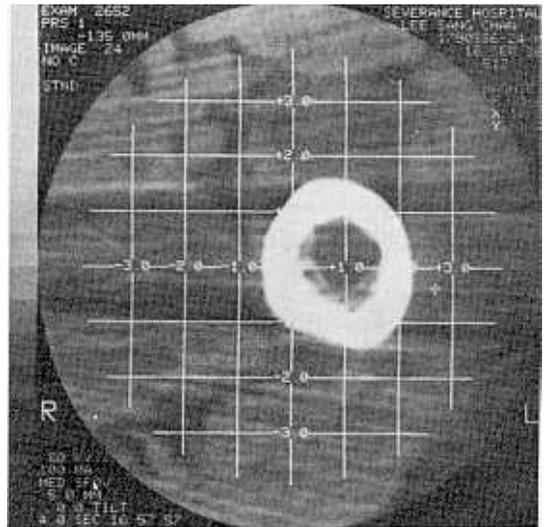


Fig. 2b CAT scan section of the femoral shaft.

destructively, computer tomography was employed in six cadaver femurs. It is necessary to identify the femur's orientation and to standardize its dimensions. For this purpose vascular plastic tube was placed around the femur in three locations. It was placed around the neck where the head would later be resected to give the opening of the canal. The two plastic tubes were along the outer femoral surface to identify the anterior and lateral sites of each level. The flat table on which the femur rested during CAT-scanning, provided the Z-axis for the femur (Fig. 1). On the CAT-scan screen, two orientation points were

placed in a linear line on the outer density of the femoral canal and the distance between them read. This distance was printed on the right hand margin of the frame and was the actual distance of the femur shaft. The distance between the two reference points on the film was then measured with a micrometer. The actual distance divided by the latter measured distance was the magnification ratio. CAT-scanning began at the 25cm below the head and advanced up the femur toward the head at 10mm intervals up to 2cm below the lesser trochanter and 5mm intervals thereafter. Twenty-four levels were obtained (Fig. 2a

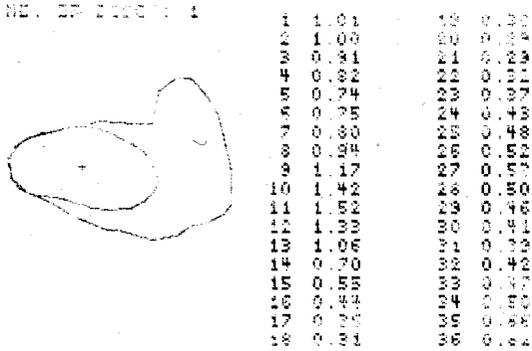


Fig. 4a. In the medial calcar region, the average gap between the stem and the canal is 0.59mm.

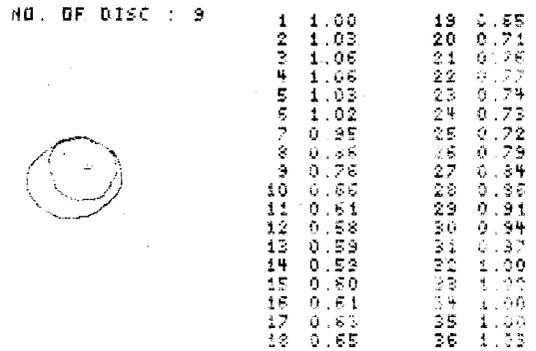


Fig. 4b. In the region of the distal tip, the stem fills 66% of the canal over a 16mm axial distance.

Table 1. Gaps for one calcar region axial slice

Gap(mm)							% Contact	% Fill
0	1	2	3	4	5	6		
57.5	22.5	5.0	7.5	7.5	0.0	0.0	78	93

Table 2. Gaps results for one femur

% Canal contact			% Canal Fill		
Distal	Middle	Proximal	Distal	Middle	Proximal
63	80	76	66	86	85

and 2b).

The actual dimension of each section was determined by magnification using a General Electric 8800 Scanner. Using the HP-9845B Desk-top computer, each tracing was digitized and stored in data files on computer disk. Each frame had a corresponding Z value also inputted into its array to allow for stacking of the section. Looking down the canal of the computer model is presented in Fig. 3.

The available femoral canal shape is defined as follows. Because of the curved nature of the canal it was not possible to insert a stem that entirely filled the canal. However, if the trochanter was resected along the vertical lateral side of the canal shaft, the canal was exposed and a very wide opening was present for insertion of the stem. The stem shape which was a replica of the canal could be inserted without removing much, if any, area along the stem. But if the trochanter was conserved along with as much bone as possible, the path of insertion was curved. For the stem to be inserted now, areas along the stem was removed leaving a stem shape that was close fitting but not completely filling the canal. This defines the upper and lower bounds for the size of the aperture.

In terms of which regions of a completely filling stem may be removed to make insertion possible, the stem must touch in the areas of the proximal medial and the distal lateral surfaces, but can have the medial surface only, lateral surface only, or a combination

of the two areas removed.

To test the accuracy of this method of obtained the canal shape, a plaster model was constructed. Female mold of femoral canal was constructed with polyester followed by making the replica of the plaster mold of femoral stem with polyester. Polyester stem was inserted into the cadaver femur and obtained cross-sectional image of it by CAT-scanning. These CAT-scanning images were superimposed on the original CAT-scanning films of the femur. And then calculated a copy of perimeter line of the femoral canal and stem, absolute coordinate frame and coordinate of Z-axis. X-Y coordinate of the points on the perimeter of the femoral canal and the stem was obtained by executing program "DIGITIZE" with manual digitizing method. The digitizing data was verified by executing program "SECT". Cross-section reduction rate of each image of the femur with the stem was calculated by running program "FEMUR" (Rogers and Adams 1976).

RESULTS

Gaps analysis of the computer models and the actual implanted stems showed that optimally computer designed stems always produced the highest total contact and priority region contact scores (Table 1, 2). In the medial calcar region where the stem was

designed to make close contact, the average gap between the stem and the canal was 0.59mm at the top of the calcar and 0.82mm at the section 5mm lower down. In the region at and just below the lesser trochanter, the stem was found to fill 86% of the canal over a 20mm axial distance. Finally, in the region of the distal tip, the stem filled 66% of the canal over a 16mm axial distance (Fig. 4a and 4b). In regions of stress transfer, the close fit stems contacted the canal over a larger surface area.

DISCUSSION

The General Electric 8800 scanner has a spatial resolution at the 1mm level and that the scanner has very good resistance to artifacts resulting from large contrast changes. These findings are important since that spatial resolution is the main factor limiting perception when high contrast materials such as bone are scanned. Background noise has little effect on the perceptibility of bone since the signal to noise ratio is so large. If artifacts arise from multiple small sources and are small, those may be considered similar to background noise and hence have little effect on quantitative measurements of bone.

The profound influence of CT viewer control settings on anatomic measurement was mentioned previously. Data input by means of digitizing films of CAT scans has three major sources of error; 1) the effect of viewer controls, 2) the distortion of film reproductions and 3) the inaccuracy of digitizing either by manual input or by laser or other scanning devices. A study of cortical thickness measured by CAT scan clearly demonstrates the cumulative effect of all three of these inaccuracies in addition to the effect of large scan thickness. Accuracy is needless lost and time is wasted by this method.

The accuracy of fit between the prototype stem and the femoral canal demonstrates that the fit is quite good in the calcar region. The fact that the stem fills the majority of the canal in the regions that it was designed to is encouraging in light of the fact that portions of the stem had to be removed so that the stem could be inserted. However, the lack of a close-fit between the distal lateral part of the stem and the canal laterally where it was designed to make contact highlights the importance of several sources of error.

The position of insertion of the stem can radically affect the fit between the implant and the bone. This variability can be minimized through further standardization of reaming techniques and the use of a collar and accurate collar cutting guides (Crowninshield *et al*, 1981).

While this process of implant manufacture was demonstrated using a close-fit intramedullary hip stem, most other implant designs are much simpler to design because extensive interference analysis is either simpler or totally unnecessary. Though this demonstration focused on noncemented designs, this process can be applied to any method of implant fixation and is not restricted to implants designed to make contact with cortical bone. Designing an implant with a desired layer thickness of cement, fibrous tissue or bone should be a straight forward extension of this process now that sources of inaccuracy have been identified and corrected.

The use of this computerized three dimensional database of the bone and the implant is an ideal starting point for finite element modelling and this is currently under investigation. While it may be intuitive that close fit intramedullary stems will result in a more even stress distribution than current designs, this hypothesis shall be tested *in vitro* in the laboratory and subsequent adaptation of the femur to the implant shall be studied *in vivo*. One of the great advantages of this technique is that it is well suited to sequential improvement in designs based on experience.

SUMMARY

Computed axial tomography (CAT) and computer aided design (CAD) is an extremely rapid and accurate method of implant production. Computed tomographic pixel density data is used to automatically define the medullary canal and the external surface of each individual scan of a bone or joint and this data is stored as contours. Sequential axial contours are then combined to form a three dimensional image of the joint. This 3-D image serves as a database for the design of an implant. The specific design of an implant can then be used to instruct a computer controlled milling machine to manufacture the implant.

In the case where an intramedullary stem is desirable, extensive interference programming is essential to modify the stem design so that the stem can be inserted and withdrawn while designated critical areas still remain in intimate contact with the cortical cancellous interface. Interference calculations are particularly important in the design of hip intramedullary stems due to the curvature of the proximal femur.

A prototype intramedullary hip stem demonstrates the system's ability to manufacture a stem swiftly and easily, demonstrates that a close-fit in desired regions can be achieved and identifies possi-

ble source of error in need of improvement. While CAT-CAD-CAM is compatible with any method of implant fixation, noncemented implant may be particularly useful in young patients where revision surgery is likely. Cemented implants may be designed with a uniform layer of cement of a desired thickness.

The process of CAT-CAD-CAM may be directly applied to two areas; 1) to improve the current custom implant applications to patients with neoplastic diseases or bony deformities and 2) to possibly improve long term performance of implants in patients where standard implants are used, particularly in situations where standard designs have already proven to be unsatisfactory.

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