

Anthropometric measurements to design best-fit femoral stem for the Indian population

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Abstract

Background: The standard commercially available marketed prostheses sometimes may not be the best fit to Indian patients because of the large anatomic variation. Orthopedic surgeons always stress the need for a proper implant–patient match in hip joint replacements, in particular, for a cementless femoral stem. The complications of mismatch are aseptic loosening, improper load distribution, and discomfort. The present study was undertaken to compare the differences in dimensions between femurs of elderly Indians and those of populations from other regions in order to solve the problem of a possible geometric mismatch between a selected implant and the hip joint as far as Indian patients are concerned.

Materials and Methods: Measurements were made using computer aided design techniques on computed tomography (CT) scanned images of 98 femurs (56 left and 42 right). The software used to convert the CT images into solid models was MIMICS[®] (Materialize, Inc., Leuven, Belgium). The geometrical parameters, viz., the femoral head offset, femoral head center (HC), femoral head diameter, femoral head relative position, position of shaft isthmus, neck-shaft angle, bow angle, femoral neck length, canal flare index, femoral length, and canal width at various locations, were chosen to design best-fit standard femoral stems for cementless insertion. These data were compared with the published data of other countries.

Results: A difference of 16.8% was found in the femoral head offset between Indian and Swiss populations, which can affect soft tissue tension and range of motion. At a distance of 20 mm above the lesser trochanter (LT), the anteroposterior (AP) canal width was found to differ by 45.4%, when compared with a French population which can affect the mechanical stability of femoral stem. Femoral dimensions of Indian male and female subjects have also been compared and differences evaluated. At the LT, the aspect ratio (ratio of mediolateral canal width and AP canal width) in case of males (1.198) is approximately13% higher than that of females (1.059).

Conclusions: This study indicates a need for redesign of femoral stems. The obtained anthropometric femoral dimensions can be used to design and develop indigenous hip joint prosthesis in India. The results of this study can also be used in forensic anthropometric studies.

Key words: Cementless femoral stem, implant design, implant-patient match, Indian population

INTRODUCTION

The most common cause of hip joint failure is

osteoarthritis. This hip joint failure is due to the

damage of hip joint mechanism which affects

xpage of motion and objlitute been weight on the joint osteoarthritis. This hip joint failure is due to the range of motion and ability to bear weight on the joint. Other conditions that lead to hip replacement surgery are rheumatoid arthritis, osteonecrosis, trauma and bone

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tumors.1 The most common method of treating a hip joint failure is total hip arthroplasty (THA). The prosthetic components used in THA are made of metals, polymers or ceramics, leading to improved mobility and relief of pain.2 Over 800,000 artificial hip joint replacements are done annually worldwide.3

It is vital to match the dimensions of the implant closely with those of the femur, 4 as some of the complications resulting from mismatch could be aseptic loosening, improper load distribution and discomfort. Secondary biologic fixation of a hip implant depends to a large extent on the quality of its primary stability.⁵⁻⁷ A mismatch in dimensions between the femur bone and prosthesis leads to micromotion of the implanted stem during the early days of post surgery, which hinders the ingrowth of trabeculae bone. It is also vital to design a prosthesis through which adequate loads can be transferred to the bone, preventing stress shielding.⁸ The geometry of the proximal femur is determined by genetic and environmental factors such as age, race, sex and lifestyle.9,10 A population based study was carried out by

Nurzenski *et al*. who found that lifestyle factors influence geometric indices of bone strength in the proximal femur.¹¹

Siwach *et al*. 12 compared the parameters of the femurs of Indian cadavers with those of Western, and Hong Kong Chinese populations. They observed that the implants were oversized, and their angles and orientations were also having a mismatch which can presumably lead to complications like splintering and fractures. Reddy *et al*. 13 highlighted that a mismatch between femoral bone and stem definitely results in micromotion. These micromotions eventually lead to thigh pain, osteolysis and aseptic loosening.13 Leung *et al*. 14-16 were prompted to modify the gamma nail (used for fixing a femoral neck) to suit the Asian population. Some researchers also investigated the differences in femoral bone parameters between male and female femurs.17,18

There has long been a belief among Indian and Asia-Pacific arthroplasty surgeons that the prosthetic components currently available on the market do not fulfill the requirements of these anthropometrically smaller ethnic groups, especially in the smaller sizes.19 If the implant is too large, the femur can fracture as it is driven down inside the bone, so the tendency is to undersize for safety. But if the implant is highly undersized, the bone may fail to bond to it. So, the correct implant size is very important.²⁰ A similar study was carried out by Khang *et al*. ²¹ to investigate the anatomic geometric differences between femurs from Korean subjects and those of American and Japanese subjects, and they suggested to design a new hip prosthesis system for Korean, Japanese, and other Asian patients.

Comparisons of skeletal geometric features that confer hip implant fitment between race and ethnic groups may yield insights about the mechanisms of hip implant fitment that could contribute to design a best fit hip implant among older Indians. The present study was undertaken to compare the differences in dimensions between femurs of elderly Indian as measured on CT scan images and those of populations of other region, as separate templates and design may be required for different regions.

Materials and Methods

Patients and scan details

Patients were enrolled irrespective of age, sex, and region. All patients had some or other problems related to hip joint, like osteoarthritis, pain, fracture, etc. Patients who had problems in areas other than the hip joint were not selected for CT scan.

which belonged to 29 female and 31 male subjects (both femurs of a few patients [n=28] and a single femur of the remaining patients $[n=42]$). The mean age of the total population was 61.3 years (range 40-81 years). This sample population included patients from different regions of India. CT scanned images were obtained in Digital Imaging and Communications in Medicine (DICOM) format. The slice thickness of the scans was 1.25 mm. The patients were scanned for CT in a supine position with neutral rotation of the lower limb. The scanner in use was an LX Horizon high-resolution model (GE, Milwaukee, WI, USA). As a prerequisite, consent of patients was obtained for taking CT scan for study as per the guidelines of the ethics committee.

Measurements of various anthropometric parameters of an Indian population were obtained from computed tomography (CT) scanned images, using computeraided design (CAD) techniques. It has been found that measurement from 3D images obtained through CT scans are more accurate and easier to obtain than from other methods such as 2D radiographs and direct measurement of cadaveric bones.22,23 These Indian femur bone values were compared with the published values of Swiss,²² French, 5 Thai 24 and Caucasian 25 populations. A statistical analysis was conducted to determine significant differences in parametric values between the Indian population and that of other regions. These anthropometric differences, along with the required range of motion related to the Indian lifestyle (e.g. the squatting position), call for the development of a modified hip joint prosthesis for the Indian population.

Measurement of studied parameters

The CT scan data were imported into a 3D *imaging software* to obtain a 3D graphic model by using region growing and thresholding techniques. After geometrical simplification of the 3D model of the femur, the dimensions of studied parameters were measured in true 2D and 3D models. Most of the measurements in this study were based on an advanced method of using CT images combined with 3D reverse engineering, and CAD techniques. A graphic model of each femur was obtained by thresholding and region growing techniques. This methodology has been outlined in a reference by Mahasavairiya *et al*. 24

The following parameters of the femur were chosen to be extracted for understanding the anthropometry and eventually designing a best-fit standard femoral stem for cementless insertion, as shown in Figures 1 and 2:

- Femoral head offset (A)
- Femoral head center (HC) and femoral head diameter (B)
- Femoral head relative position (C)
- Position of shaft isthmus (I)

Dimensions were extracted from 56 left and 42 right femurs

- Neck-shaft angle (J) and bow angle (K)
- Femoral neck length (P)
- Canal flare index (Q) and Anteversion angle (R) , methodology has been outlined in the reference²⁵
- Femoral length (S), methodology has been outlined in the reference.²⁶
- Canal width $(D, E, F, G, H, and L, M, N, O)$

Canal width

The snapshot of extracted mediolateral (ML) measured dimensions and anteroposterior (AP) measured dimensions of an average elderly Indian femur are shown in Figure 3a and b. Sample values have been indicated there upon.

- • D: ML canal width, 20 mm above the lesser trochanter (LT)
- • E: ML canal width at the level of the LT
- • F: ML canal width, 20 mm below the LT
- G: ML canal width at the isthmus
- • H: Periosteal (cortex + canal width) width of femur at the isthmus
- • L: AP canal width, 20 mm above the LT
- M: AP canal width at the level of the LT
- N: AP canal width, 20 mm below the LT
- O: AP canal width at the isthmus

Relative positions at 20 mm above and below the level of LT were chosen as this is a standard practice for measuring hip anthropometric data and then these data were relatively compared with other studies $5,22,25-29$ for each geometrical dimension which might affect the design of a femoral stem.

Statistical analysis

In the statistical analysis, the data of various measured parameters were tabulated with the mean, standard deviation, and range of observations. The data analysis was performed by using the *t*-test (paired) for normal distributions. A *P* value of less than 0.05 was considered to be significant.

Table 1 compares the extracted anthropometric data of

Figure 1: Femur model in polylines showing neck and femoral axes

Figure 2: Measurement of femoral head offset (A), femoral head diameter (B), and femoral head position (C), isthmus position (I), neckshaft angle (J), bow angle (K), femoral neck length (P) and femoral lengths (S)

Figure 3: (a) Mediolateral measured dimensions; (b) anteroposterior measured dimensions

mm = Millimeter, Deg = Degree

this study with the corresponding published values of other regions of the world (Swiss, French, Thai and Caucasian) and Table 2 shows the mean values of femoral parameters for male and female subjects separately.

AP and ML dimensions were measured, and AP/ML ratios were obtained and plotted. Figure 4 illustrates the variation of the ML canal width with the AP canal width, at specific positions along the femurs, for different categories of subjects. The graph in Figure 5 illustrates the aspect ratio for different sample categories, at different positions along the femur. The AP and ML dimensions of the femur decide the optimal AP and ML coverage of bone surface for best fit, and variations in AP and ML dimensions decide the proper size of the femoral stem.

The graph in Figure 6 indicates the variation of the femoral head position relative to the LT, with the femoral head offset, based on gender. This variation in femoral head position with the femoral head offset indicates the correct location of hip center (HC) and HC helps to maintain proper leverage for the soft tissues.

Discussion

Proper sizing and placement of the prosthetic components are crucial to the success and long-term survival of a total hip arthroplasty (THA).²⁸ Indians and Chinese, as a part of the Asian subpopulation, have a smaller build and stature as compared with the Western population.29 Due to the large variability of the anthropometry of different populations of the world, ethnic groups having a smaller build, such as Indians, are likely to develop technical errors in THA with most of the commercially available prostheses because of the nonavailability of smaller and proper sized implants. Studies on anthropometric measurements of the proximal femur of the average Indian population by CT scan may appear to support this argument.

Table 1 compares the extracted anthropometric data of Indian population with the corresponding published values of other regions of the world. The methods used in such studies were radiographic for the French 5 and Caucasian 27 populations. For the Thai 24 and Swiss 22 populations, CT scans were used. Rubin *et al*. 22 also obtained the measurements using radiographic and direct methods and found that the mean difference obtained using radiography compared to direct measurements was 2.4 ± 1.4 mm (mean \pm SD), while the difference obtained using CT scans was 0.8 ± 0.7 mm (mean \pm SD). The magnitude of these errors was much lower than the measured readings. Therefore, the compared values from this study and other studies (involving radiographic measurements) can still convey a fairly accurate idea regarding the anthropometric

*= where the difference in males and females exist, mm = Millimeter, Deg = Degree.

Figure 4: Average ML canal width versus AP canal width at different positions as indicated

differences. The difference in femoral head offset between Indian and Swiss populations²² was found to be 16.8% which indicates that this can cause greater tension in soft tissues of the joint and can also increase the chances of dislocation post surgery. The ML canal width 20 mm above the LT was found to have a difference of 40% compared to the Caucasian population 27 indicating the oversize of stem for the Indians. The AP canal width 20 mm above the LT

Figure 5: Comparison of mean aspect ratio at different positions

was found to have a maximum difference of 45.4% when compared with the French population⁵ and this can impact the close fitting of stem in proximal part of femur, which can result in micromotion and instability. The bow angle showed a maximum difference of 10.4% compared to that of the Thai population, while the canal flare index showed a maximum percentage difference of 11% when compared with that of the Swiss population indicating a deviation in the use of cementless femoral stems for cementless type fixation. The anterior bow of the midportion of the femur is well recognized and has even been built into some current prostheses. The posterior bow of the proximal femur is just

Figure 6: Graph showing variation of the femoral head center (HC) for male and female subjects

as constant as the midportion anterior bow, but it seems to have been unrecognized or is considered of no importance by most designers of femoral stems. Excessive distal femoral bowing in a lateral plane has an impact on the use of a stemmed femoral prosthesis. The cementless stem with a long bowed, distally flexible stem may be associated with greater implant stability than a more rigid, long bowed stem that requires over-reaming to avoid fracture.³⁰ Canal flare index for Indian population is 4.23 (mean), which is above 3 and below 5, and indicates the standard cementless femoral stem as the best choice as per Fessy *et al.*31 algorithm for the choice of femoral implant.

The above differences in dimensions are mostly in the superior and proximal regions of the femora. These can, therefore, significantly affect the performance of a standard size femoral stem for cementless fixation, as pointed out by Hua and Walker.³² Micromotion hinders bone ingrowth, thereby effecting secondary stability over a period of time. Also, the load distribution would not be well distributed, leading to early fatigue failure and possible breakage of the stem which has been echoed by Ducheyne *et al.*33 in 2004.

Table 2 shows the mean values of femoral dimensions for the male and female subjects separately. Mean values for male subjects were found to be higher for all the data except the anteversion angle (R). This could be attributed to the hip size and load distribution differences between the males and females. The neck of the femur forms a shallower angle with the long axis of the femur bone in a female. Forensic anthropologists have also found differences in the measurements of the transverse width and length of the head of the femur between the sexes and have postulated this application in identifying sex of dismembered murder victims; however, there are significant differences between races also.⁹

At the isthmus, values for both males and females are the lowest, with the AP value being larger than the ML value [Figure 4]. The values for all the categories are almost equal at this position. From the isthmus, in the proximal direction of the femur, the ML and AP canal width values increase almost linearly. It is also observed that corresponding values for different categories have mean differences of 9.5% in the proximal position. The design of a stem must provide an initial or primary stability and it should be taken into account during the design evolution stage itself.³⁴

At the isthmus and 20 mm below the LT, there is not much variation in the aspect ratio among different categories [Figure 5]. At the LT, the aspect ratio (ML/AP) in case of males (1.198) is approximately 13% higher than that of females (1.059). At 20 mm above the LT, the aspect ratio for females is higher (1.458) as compared to males (1.355) by approximately 8%. This might make the matching of a standard commercially available cementless femoral stem in proximal area of femur both in male and female patients more difficult.

There are three key extramedullary dimensions, viz., leg length (or femoral head position), femoral offset, and anteversion angle, which help in maintaining proper hip kinematics and improving overall patient satisfaction post surgery of THA.^{35,36} Optimizing these parameters before actual implantation can lead to correct leg length, range of motion, and joint stability. From Figure 6 it is observed that the female femoral HC lies inferiorly (related to the LT), as

Table 3: Proposed dimension of the cementless femoral stem (in mm) for the Indian population

FHO (A) – Femoral head offset; FHP (C) – Femoral head position; NSA (J) – Neck-shaft angle; ML (E) – Mediolateral canal width at the level of the LT; ML (G) – Mediolateral canal width at the isthmus; AP (M) – Anteroposterior canal width at the level of the LT; AP (O) – Anteroposterior canal width at the isthmus

compared to the male femoral HC. The range of femoral head offset for females of the Indian population is found to be smaller by 37% as compared to males of the same population. The linear fit to the male and female data is approximately 10 mm apart. These data reveal that there should be relative degree of difficulty in fixing the same femoral stem to a male and female patient during THA to restore the natural mechanics of the joint by considering both extramedullary and intramedullary parameters of the femur.

The findings of this study show higher values for some major femoral dimensions when compared with international published literature.5,22-24 However, these values are found to be very close when compared with the other Indian studies.12,37,38 The above findings indicate marked differences in the observed dimensions of the femoral canal and femoral head position between males and females. This information is vital to a mechanical/biomedical designer for creating a better design of femoral stems for cementless hip joint prostheses. These differences also influence the fit of the stems to the patient of a particular geographic region. Therefore, for best-fit cementless femoral stem design, the study suggests ML, AP and some extrafemoral dimensions as the criteria to design gender specific proper stems suitable for most of the Indian population. To illustrate this better, three groups were created based on the femoral head offset, neck-shaft angle, canal ML and AP dimensions; the smallest 25%, the middle 50%, and the largest 25% for each gender, respectively. Based on the data, we have proposed a design of three groups of femoral stem for male and female, respectively [Table 3].

CONCLUSIONS

The results of this study indicate that marked differences do exist in the dimensions between the femur of the Indian population and that of the populations of other regions of the world. Canal flare index for the Indian population indicates the standard cementless femoral stem as the best choice.

There are significant differences in dimensions between male and female femora within the Indian population, indicating that a range of femoral stem designs are required to reduce the inventory and narrow down the best fit options for a surgeon. These ranges of evolved femoral stem geometries would eventually improve the clinical outcomes, reduce the cost to the patient, and eliminate the possibility of a revision surgery.

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