Research Article

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Knee prosthesis sizes in Indian patients undergoing total knee replacement

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ABSTRACT

Background: Various studies have shown the ethnic difference for anthropometric measurements for Asian population compared to western world. The current available knee implants does not address the ethnic differences in the knee sizes. There is a paucity of clinical data published from India.

Methods: This was a retrospective study in 1228 knees underwent total knee replacement between years 2008 to 2012. The parameters analyzed in this study were age and sex wise distribution and mismatch analysis for femoral and tibial component of the implants.

Results: Out of total 1228 knees operated, 477 were in male and 751 in female patients. The most commonly used femoral implant size was 2.5 in males (34.6%, n=165) and size 2.0 in females (47.1%, n=165). The tibial implant Size 3.0 in males (53.3%, n=254) and size 2.0 in females (54.4%, n=409) was used frequently. In mismatch analysis, we found that tibial component was larger than femoral in 49.7% of cases (n=610), equal in 46.3% (n=569) and smaller in 4% (n=49) of cases operated.

Conclusions: Higher aspect ratio and splaying of the lower end femur needs to be considered to meet the knee prosthesis size for of Indian population. This study may give the new insights to the specific implant designs for Indian patients.

Keywords: TKR, Knee prosthesis, Size and mismatch analysis, Aspect ratio, Real world evidence

INTRODUCTION

Total knee replacement (TKR) in some form has been practiced for over 50 years, but the complexities of the knee joint only began to be understood 30 years ago. Significant advances have occurred in the type and quality of the metals, polyethylene, and more recently, ceramics used in the prosthesis manufacturing process, leading to improved longevity and better clinical outcome. Clinical outcome of primary total knee arthroplasty/replacement (TKA/TKR) has improved over the last decade, as a result of better prosthesis design, new materials and optimization/advancement of surgical

techniques. TKA is now a reliable treatment for severe arthritis. As with most techniques in modern medicine, more and more patients are receiving the benefits of arthroplasty.

The success of TKA depends to a large extent on prosthesis selection, accurate sizing and proper placement of the components.^{2,3} The Antero-Posterior (AP) and Medio-Lateral (ML) diameters of femoral component are critical in deciding the implant size. AP diameter is important in maintaining flexion-extension spacing and optimal tension in the quadriceps mechanism,³ whereas the ML diameter determines adequate coverage of the

resected bone surface, allowing even stress distribution tension-free wound closure, and smooth tracking of the patellar component in the trochlear groove during flexion.⁴

The current implants are not designed, considering the ethnic differences across the world. This leads to challenges in selection of proper implant sizes, mainly in Asian population. Previous studies have highlighted the ethnic differentiation within Asian population. The Chinese study in 172 normal knees analyzed the anthropometric measurements of proximal tibia and distal femur and compared with the similar dimensions of five total knee prostheses conventionally used in China. The study showed under sizing of tibial ML dimension mainly in smaller size implants and it overhang in larger size implants, but Femoral ML dimension overhangs in all implant sizes. Consequently, the aspect ratio (ML/AP%) found to be decreased for both tibia and femur.⁵ Another Chinese study also highlighted the need of smaller sized femoral component for Chinese population. 6 The study in 337 knees have compared the aspect ratio in males and females, found that higher aspect ratio for femur and tibia in smaller size knees, mainly in females.7 Mahfouz M et al. has published a three-dimensional morphology data of 1000 knees comparing African Americans, East Asians and Caucasians. The shape differences among the ethnic groups were found, highlighting larger knees in males compared to females in all ethnic groups. They also have noted the smaller aspect ratio in Asian males compared to Caucasian males.⁸ The study conducted by Ewe TW et al. to establish the relationship between morphometry of distal femur and TKR implant design, showed that aspect ratio for femur was smaller to that of implant leads to all four types of implants used were tend to overhang distal end of femur.9

The most relevant Indian study is by Vaidya S et al. They have analyzed 86 osteoarthritis knees for AP and ML diameter of lower end of femur using anthropometric Computed Tomography (CT) scan. The mean AP diameter in male population was higher compared to females. Additionally, the splaying of lower end of femur in ML dimension (>10 mm) was observed.¹⁰

The mismatch analysis between femoral and tibial component of prosthesis and it's correlation with the age and sex, would also give the insights into the requirement of age and gender specific implant sizes. Two studies have reported the mismatch of femoral and tibial components in clinical settings. 9,11 No Indian study has reported the various implant sizes used in patient population and it's correlation with age and sex.

Considering the paucity of data in this domain, the study was undertaken to evaluate various parameters such as implant sizes used and its sex wise distribution, mismatch analysis (femoral to tibial component).

METHODS

This was real world evidence where retrospective analysis was performed on prospectively collected data of 1228 TKR operated between year 2008 to 2012 at Joint Replacement Center in a public sector hospital in Mumbai (India), a referral center from various regions of India. Hence, the data represents the essence of diversity of Indian population. All the implants used were of DePuy (Johnson and Johnson Company).

The demographic and clinical diagnosis information was taken from the patient specific case record form. The information on knee implants such as type of implant, size of the implants (all components) was taken from the same source. The parameters analyzed in this study were sex wise distribution and mismatch analysis for femoral and tibial component of the implants. All the analyses were performed using 10.0 version of SPSS statistical software. Continuous variables were summarized by using summary statistics (number of observations, mean and standard deviation) and categorical values by using frequencies and percentages. For all study cases, descriptive statistics were estimated and presented in tables to know the overall profile.

RESULTS

Out of total 1228 knees operated, 477 were in male and 751 in female patients. The mean age was 63.79 years in males and 62.20 years in females (Table 1).

Table 1: Patient demography.

Patient demography				
No of cases operated	1228			
Males	477 (38.8%)			
Females	751 (61.2)			
Age	62.82 years			
Male	63.79 years			
Females	62.20 years			

In male patients, femoral component of sizes 2.5 (34.6%, n=165) and 3.0 (38.6%, n=184) were used. The femoral implant size of 2.0 was used in 47.1% (n=354) and size 1.5 in 29.8% (n=224) females (Table 2). The tibial implant sizes of 3.0 (53.3%, n=254) and 4.0 (27.9%, n=133) were implanted in males where as in females, sizes of 2.0 (54.4%, n=409) and 2.5 (31.4%, n=236) were most commonly implanted (Table 3).

Table 2: Association between sex and the femoral component of knee implant.

Sex							
Implant sizes	Male (N = 477)			Female (N = 751)		Total (N = 1228)	
	No.	%	No.	%	No.	%	
1.5	013	02.7	224	29.8	237	19.3	

2.0	065	13.6	354	47.1	419	34.1
2.5	165	34.6	134	17.8	299	24.3
3.0	184	38.6	039	05.3	223	18.2
4.0	049	10.3	-	-	049	04.0
5.0	001	00.2	-	-	001	00.1
Total	477	100.0	752	100.0	1229	100.0

Table 3: Association between sex and tibial component of knee implant.

Tibial implant	Sex Male (N = 477)		Female (N = 751)		Total (N = 1228)	
sizes	No.	1 ///	No.	%	No.	%
1.5	001	00.2	065	08.7	066	05.4
2.0	018	03.8	409	54.4	427	34.8
2.5	065	13.6	236	31.4	301	24.5
3.0	254	53.3	039	05.2	293	23.8
4.0	133	27.9	002	00.3	135	11.0
5.0	005	01.0	-	-	005	00.4
8.0	001	00.2	-	-	001	00.1

In mismatch analysis, we found that tibial component was larger than femoral in 49.7% of cases (n=610), equal in 46.3% (n=569) and smaller in 4% (n=49) of cases operated (Table 4).

Table 4: Mismatch analysis between femoral and tibial component of knee implants.

Parameter - Implant component	No. of cases (N = 1228) (%)		
Femur > Tibia	049 (04.0)		
Femur < Tibia	610 (49.7)		
Femur = Tibia	569 (46.3)		

DISCUSSION

It is a first large scale Indian study analyzing the knee implant sizes and its correlation with the age and sex, representing the broader view for Asian population, which have a similar build and the stature. As discussed earlier, the Asian population needs a smaller implant sizes compared western world, 12,13 given the situation of current implants are not designed to meet the requirements for Asian population.

The current retrospective analysis attempts to analyze the actual implant sizes used in Indian patients undergoing TKR. The data correlates well with the anthropometric findings of smaller implant sizes in Indian population. Indian patients need smaller femoral component, especially in females. As per our data, sizes of femoral component was 2.5 to 3.0 for 73.2% of male cases and 1.5 to 2.0 for 76.9% of female cases and tibial tray size was 3.0 to 4.0 for 81.2% of male cases and 2.0 to 2.5 for 85.8% of female cases. The results were similar to other

studies published from Asian countries, showing smaller size of lower end of femur and tibia.

Interestingly when we did a mismatch analysis between the femoral and tibial component, we observed that, almost 49.7% of cases had femoral component smaller than tibial component, and larger in 4% of cases. We compared these results with the western world. The study undertaken by Schai et al. in American population, reported data as equal in 78%, mismatched as femoral component larger than tibial in 17 % and smaller in 5% of patient population studied. 11 This can be attributed to a lower femoral AP dimension compared to the ML of Asian patients in comparison to Western patients. Mahfouz M et al. has documented the higher aspect ratio in Asian patients due to a smaller femoral AP dimension.8 Ewe TW et al. document similar findings in Asian patients where tibial component larger than femoral was observed in more than 50% of study population. As a consequences, splaying of the lower end of femur in ML dimensions is seen in both the sexes with a given femoral sizes, which indicates that the Indian femur has more ML dimensions than AP for a given implant size, as compared to western world.

This study could be gives more insight to need for manufacturing of implants suitable for Indian population. It will also help surgeon in selection of appropriate and accurate implants to minimize the mismatch and for better clinical outcome. Further detailed morphometric analysis would be needed to help in designing the implants as required.

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institutional ethics committee

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