Original Article

Patient - implant dimension mismatch in total knee arthroplasty: Is it worth worrying? An Indian scenario

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Abstract

Background: The correct sizing of the components in both anteroposterior and mediolateral (ML) dimensions is crucial for the success of a total knee arthroplasty (TKA). The size of the implants selected is based on the intraoperative measurements. The currently used TKA implants available to us are based on morphometric measurements obtained from a Western/Caucasian population. Hence, the risk of component ML mismatch is more common in Asian sub-population, as they are of a smaller built and stature. This study aims to look into the following aspects - magnitude of the ML mismatch between the femoral component and the patient's anatomical dimension, evaluation of gender variations in distal femur dimensions, and gender-wise and implant-wise correlation of ML mismatch.
Materials and Methods: Intraoperatively, the distal femoral dimensions were measured using sterile calipers after removing the osteophytes and compared with the ML dimension of the implant used. ML mismatch length thus obtained is correlated with the various parameters.
Results: Males showed larger distal femoral dimensions when compared to females. Males had larger ML mismatch. None of the implants used perfectly matched the patient's anatomical dimensions. Patients with larger mismatch had lower scorings at 2 years postoperative followup.
Conclusion: Implant manufacturers need to design more options of femoral implants for a better fit in our subset of patients. The exact magnitude of mismatch which can cause functional implications need to be made out. The mismatch being one of the important factors for the success of the surgery, we should focus more on this aspect.

Key words: Distal femoral dimensions, femoral component, gender specific knee, mediolateral mismatch, total knee arthroplasty
MeSH terms: Orthopaedic equipment, arthroplasty, replacement, knee, osteoarthritis

Introduction

Ideally, component sizing in total knee arthroplasty (TKA) should precisely match anatomical anteroposterior (AP) and mediolateral (ML) dimensions. The current TKA implants available are designed based on morphometric measurements obtained from a Western/Caucasian population. As many other studies but few in India[1,2] show the risk of component oversizing is more common in Asians, as they are of smaller built and stature.[3-5] This study looks into the intraoperative measurements of distal femoral dimensions of patients undergoing TKA in our institute, the ML mismatch, gender variations, correlation of ML mismatch with gender, and the type of implant used.

Materials and Methods

One hundred and fifty patients undergoing TKA in our institution between August 2011 and March 2013 were included in the study. Among these, 129 patients had osteoarthritis and 21 patients had rheumatoid arthritis. 117 patients were females and 33 were males. Twenty one of them had a valgus deformity, 129 had varus deformity; either of them not exceeding 20°. Forty one were left side, and 109 were right side. Those patients with congenital or

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Access this article online	
Quick Response Code:	Website: www.ijoonline.com
	DOI: 10.4103/0019-5413.189618

How to cite this article: Thilak J, George MJ. Patient - implant dimension mismatch in total knee arthroplasty: Is it worth worrying? An Indian scenario. Indian J Orthop 2016;50:512-7.

acquired deformities of the knee, any history of disease or trauma involving the knee joint, those with femoral bone defects, and gross deformities with >20° of valgus or varus deformity were excluded. To test the statistical significance of gender comparison studies, Student's t-test was applied. Among the different implant analysis of variance was applied for correlation. The four implants used in this study were Vanguard (21) (Biomet, Warsaw, IN, USA), Nexgen (41) (Zimmer, Inc., Warsaw, IN, USA), PFC Sigma (12) (DePuy Orthopaedics, Inc., Warsaw, IN, USA), and Genesis II (76) (Smith and Nephew, Adam Street, London, UK). Our hospital has cleared four implants systems for total knee replacement surgeries, and these four implants were regularly used in our patients. These implants are the most common ones available for use from these companies in India. The surgeon has the experience of using these implants and does about 150 joint replacements per year for the past 12 years. Regardless of the implant, the sizing was decided purely on intraoperative findings. The distal femur was sized with the company provided sizer which was anterior referencing technique in Nexgen and PFC Sigma implants and posterior referencing in Vanguard and Genesis. The design of the implant, whether cruciate retaining (CR) or posterior stabilizing (PS), was decided intraoperatively. We had 98 of them replaced with PS design and 52 with CR design [Table 1].

Intraoperatively, all visible osteophytes were removed, and measurements were all taken by a single surgeon to reduce random error. All dimensions were measured using a sterile caliper. The anterior–posterior lengths of the lateral condyle (APL), medial condyle (APM) and medio-lateral dimension (ML) were measured before the bony cuts were made. APL and APM dimensions are measured at the maximum distant points on lateral and medial condyles of femur, respectively, along the axis of condyles. The ML dimension is measured as the maximum ML dimension possible, at the distal posterior most part when the knee is kept in 90° of flexion [Figures 1-3].

The patients those who gave valid informed consent were included in the study. They were counseled regarding the study nature and the purpose of it. The AP, ML dimensions of the implant used, was obtained from the respective

Table 1: The distribution of demographic data

Varaiable	*n*
Male	33
Female	117
Osteoarthritic	129
Rheumatoid	21
Left side	41
Right side	109
Cruciate retaining	52
Posterior stabilizing	98
Varus deformity	129
Valgus deformity	21

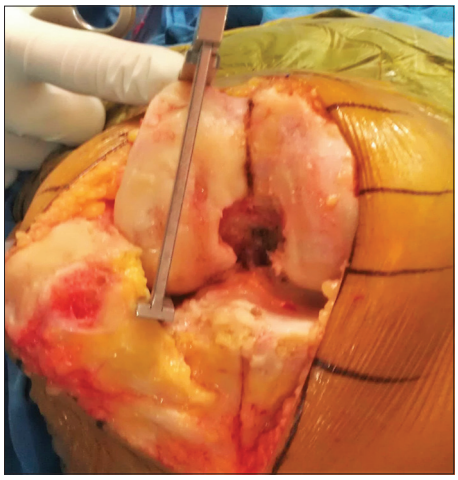

Figure 1: Intraoperative photograph showing measurement of anteroposterior dimension of lateral femoral condyle

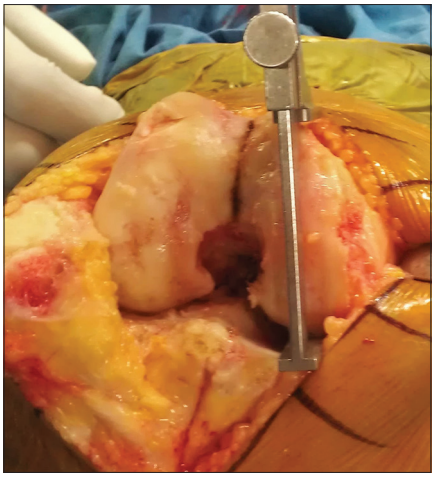

Figure 2: Intraoperative photograph showing measurement of anteroposterior dimension of medial femoral condyle

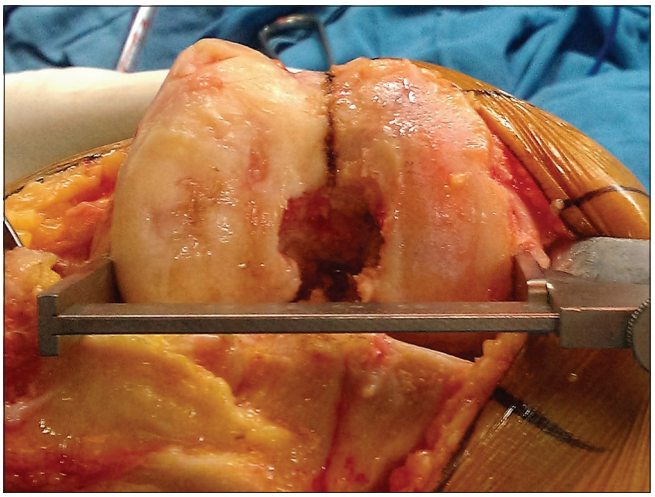

Figure 3: Intraoperative photograph showing measurement of mediolateral dimension

companies' database. The intraoperative measurements obtained from the patient were compared with the measurements of the implant used in the patient, and the ML mismatch length (the difference between the patient's value and implant's value) was found. The mismatch lengthwas compared with other variables like gender and the type of implant used. Scoring done using Knee Society Knee Scoring at the intervals of 6 weeks, 3 months, 6 months, 1 year, and yearly thereafter.

The study was cleared by the ethical and scientific committee of the institution. The nature of the study was well explained to each patient before obtaining the informed consent and patient's right to privacy was maintained. (The graphs plotted on them, the ML and AP values seem to have a high positive correlation).[6-9] Based on this, a sample of 100 patients with 95% confidence and 20% allowable error, assuming a correlation coefficient of 0.8, was sufficient for the study.

Results

All the patients were followed up and scoring was done until 2 years postoperatively. The male patients have larger distal femoral dimensions (APM, APL, and ML) when compared to females. The difference is found to be maximum in ML dimension, and all the correlation studies are found to be statistically significant [Table 2].

It was found that the ML mismatch length is much more in males (mean 12.57) when compared to females (mean 5.37). The results were statistically significant with $P < 0.001$ [Table 3].

In the comparison study obtained, it was observed that in 86.67% of patients, the ML length of the patients is bigger than that of the respective implants used. With the followup scorings, we have done over a period of 2 years postoperative, the comparison study between the patients with larger undersizing and those with near anatomical fit does not show much difference. The pain score and function score at 1 year averaged 92 and 60, respectively, and that at 2 years averaged 92 and 90, respectively.

97.33% patients reported full satisfaction after the procedure at 2 years postoperative followup. This included the patients with larger ML dimension mismatch as well.

No implants were found to have perfect match anatomically with the dimensions of our subset of patients [Figure 4, Table 4].

In 150 patients, twenty patients had larger implant ML dimensions when compared to the patient's intraoperative value (negative ML mismatch). The mean femur overhanging lengths obtained [Table 5] are charted against the implant used.

Discussion

Mismatch regarding the patients and implant dimensions is always a hot topic of discussion among the surgeons and implant companies. Implant design should focus interindividual variations in knee joint anatomy. The results of the study support the fact that the distal femoral dimensions of the patients vary based on the race,[10] gender,[11-13] and built. It would have been an ideal scenario if an implant was available which matched exactly the dimensions of the patient's bone. That is how the concept of patient-specific technology and patient-specific instrumentation (PSI) was introduced which claimed to obtain a customized implant fit quickly and with greater accuracy with shorter rehabilitation, lesser blood loss,

Table 2: Correlation between gender and distal femoral dimensions

	Gender	*n*	Mean±SD	*P*
ML length	Male	33	78.55±4.764	<0.001
	Female	117	66.88±4.716	
APM length	Male	33	65.58±4.250	<0.001
	Female	117	58.55±5.184	
APL length	Male	33	66.91±3.311	<0.001
	Female	117	59.38±4.068	

ML=Mediolateral, SD=Standard deviation, APL=Anteroposterior dimension of lateral femoral condyle, APM=Anteroposterior dimension of medial femoral condyle

Table 3: Gender-wise comparison of mediolateral mismatch length

Variable	Mean±SD		*P*
	Male	Female	
Patient ML length	78.55±4.764	66.88±4.716	<0.001
Implant ML length	66.27±4.765	63.91±3.905	0.004
Difference in ML length	12.57±5.607	5.37±3.550	<0.001

ML=Mediolateral, SD=Standard deviation

Table 4: Implant-wise comparison of mediolateral mismatch lengths (implants coded to conceal the identity)

Variable	Implant code	*n*	Mean±SD	*P*
Patient ML length	"A"	76	70.42±7.54	
	"B"	12	68.58±7.45	
	"C"	21	68.90±5.30	
	"D"	41	68.41±5.59	
Implant ML length	"A"	76	64.66±4.13	
	"B"	12	63.00±3.33	
	"C"	21	65.67±3.33	
	"D"	41	64.22±4.66	
ML mismatch length	"A"	76	7.91±5.73	<0.001
	"B"	12	7.00±5.16	
	"C"	21	4.29±3.22	
	"D"	41	4.44±2.62	

ML=Mediolateral, SD=Standard deviation

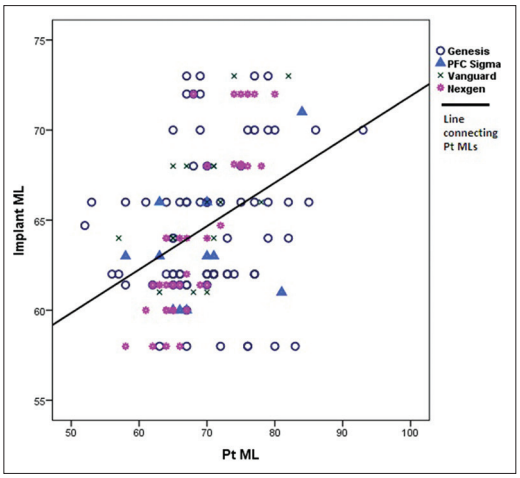

Figure 4: Scatter diagram showing the correlation between implant dimension and anatomical dimension

Table 5: The magnitude of mediolateral overhanging (patient's value - implant value) obtained with respect to each implants

Implant	*n*	Mean ML mismatch	SD
A	15	−5.81	3.76
B	2	−4.00	1.41
C	2	−5.00	2.83
D	1	−4.00	

ML=Mediolateral, SD=Standard deviation

and an overall reduction in costs.[14] But recent studies comparing the conventional TKAs and PSI TKAs failed to bring out the claimed advantages.[15,16] Thus, the researchers concluded that even sex-specific or custom implants will not replace the need for meticulous surgical skill. Surgeons can take steps to ensure proper sizing of the individual TKA to match the efficiency of PSI TKA. Customizing the surgery can be done effectively without the inventory or cost associated with patient-specific implants.[17] Current generation of implants such as Attune (Depuy) and Persona knee (Zimmer) are expensive; the reason being they come with morphologic knee implants, comprehensive sizing, integrated instruments, and specific precise instrumentation to match the AP and ML dimensions of the knee as anatomical as possible.[18]

Even though the accurate alignment of the components and correct sizing can influence the implant life and functional recovery status of the patient, the acceptable range of the implant size mismatch which can be well tolerated by the patients is not elucidated. Our study with respect to the implants shows none of the implants used are perfectly designed to match the distal femur dimensions of our group of patients, and they have varying mismatch magnitude. Our study supports the existing literature which stress upon the fact that implant - patient mismatch do exist and the patients with larger mismatch lengths are being followed up for long term with Knee Injury and Osteoarthritis Outcome Score, Lysholm Score, and Knee Society Knee Score as the parameters of postoperative functional recovery to assess the relationship of ML mismatch and postoperative functional status. After reviewing the existing literature, considering the fact that on an average only around 80% of patients are fully satisfied with TKA[11] twenty patients out of 150 patients (13.33%) are definitely a worrying ratio. Though there are multiple reasons for the dissatisfied 20% of TKA patients, we are not sure of a study, where these patients showed ML implant overhanging. It would be worthwhile a study to look into this cross-section of dissatisfied patients and critically look into the ML mismatch which can be a contributory cause. Moreover, studies among the Asian population show that the satisfaction rate is much less among the Indian population.[13] Among these patients with implant overhanging, 17 were females and three were males. Hence, in our subset of patients, females tend to overhang more than males, even though the ML mismatch in general is more in males. Hence, in our group of patients, gender specific knee designs should be oriented more toward male patients than females to obtain a better anatomical fit. Gender differences in pain and functional status after TKA have also been extensively studied previously. Women achieve at least the same degree of functional improvement as men and may have similar or even greater improvement in pain after arthroplasty than men but still have final pain scores that are less favorable.[19]

The variations in demographics, preoperative status and subsequent postoperative outcomes between the races should be considered when comparing TKA outcome studies in the Asian populations.[20] In the Asian population, according to the literature reviewed, ML mismatch occur more commonly in females, and it is most often overhanging. The mismatch is more in larger femurs too.[6] There are studies quoting interracial variations in distal femur dimensions and ML mismatch with different conclusions. In our subset of population, we observed that the mismatch is larger in males, who in general have bigger knees than their female counterparts. But, the ML overhanging is more in females than males. Ideally, the ML length of the femoral component should perfectly match the anatomical ML dimension for the best surgical outcome. The medial or lateral overhang could result in soft tissue irritation, interfere with the ligament balancing, results in a limitation of the range of joint movement, and induces pain. Since our study involved only one group of patients (Indian population), we cannot comment on the fact that reason of implant overhanging in our 13.33% of TKA patients is due to the differences of AP/ML correlation between Caucasian/Western population and Indian population. But according to the results of our study, we conclude that definitely there

is AP/ML divergences among our subset of the Indian population which can lead to implant overhanging and functional limitations in future.

It is a well-known fact that dimension mismatch do occur in TKAs. Total knee replacement itself is only a choice of compromises, and the success of surgery depends on striking the right balance between the various compromises one make to get the knee work. Hence, though ML sizing is important, we really do not know how big a role it plays in the success of the final outcome. But, the magnitude of mismatch beyond a limit can have an implication in the outcome of the surgery. Our followup scoring done until 2 years postoperative period definitely shows less satisfying results with the patients with more ML overhanging. The exact magnitude above which patients can have functional implications cannot be made out with this study. We had the patient with the maximum of 9.57 mm ML overhanging. His functional scoring was much lower than those with near anatomical match. Many other factors might have added to the low scoring of these patients with a larger mismatch. The data we obtained were of significance, both clinically and statistically. We need to cut down the incidence of overhanging to improve the functional status and the success rate of TKA surgeries.

The limitations of this study would be the unequal number of each implant used for comparison and the possible error in obtaining the measurements. There is no current evidence in the literature which suggests the magnitude of ML mismatch causing functional limitations. Those patients with more ML length difference need to be followed up for functional limitations for a longer period to comment on this aspect.

Conclusion

Male patients have bigger distal femoral dimensions when compared to females in all the distal femoral dimensions. Males have more ML mismatch length with the implant when compared to females, and it is most often undersizing of the component. Females tend to overhang more than males. All the implants used in the study showed some amount of mismatch with that of the patient's dimensions. But from the scorings we have done until 2 years postoperative period, we tempt to conclude that the patient - implant mismatch does exist in routine TKAs and appear to impact upon long term results. Those patients with larger ML mismatch scored lesser at 2 years postoperative followup when compared with those with lesser ML mismatch.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Shah DS, Ghyar R, Ravi B, Hegde C, Shetty V. Morphological measurements of knee joints in Indian population: Comparison to current knee prostheses. Open J Rheumatol Autoimmune Dis 2014;4:75-85.
2. Vaidya SV, Ranawat CS, Aroojis A, Laud NS. Anthropometric measurements to design total knee prostheses for the Indian population. J Arthroplasty 2000;15:79-85.
3. Chaichankul C, Tanavalee A, Itiravivong P. Anthropometric measurements of knee joints in Thai population: Correlation to the sizing of current knee prostheses. Knee 2011;18:5-10.
4. Chin KR, Dalury DF, Zurakowski D, Scott RD. Intraoperative measurements of male and female distal femurs during primary total knee arthroplasty. J Knee Surg 2002;15:213-7.
5. Chin PL, Tey TT, Ibrahim MY, Chia SL, Yeo SJ, Lo NN. Intraoperative morphometric study of gender differences in Asian femurs. J Arthroplasty 2011;26:984-8.
6. Celik T, Yuksel D, Kosker M, Kasim R, Simsek S. Vascularization of coralline versus synthetic hydroxyapatite orbital implants assessed by gadolinium enhanced magnetic resonance imaging. Curr Eye Res 2015;40:346-53.
7. Ewe TW, Ang HL, Chee EK, Ng WM. An analysis of the relationship between the morphometry of the distal femur, and total knee arthroplasty implant design. Malays Orthop J 2009;3:24-8.
8. Kwak DS, Han S, Han CW, Han SH. Resected femoral anthropometry for design of the femoral component of the total knee prosthesis in a Korean population. Anat Cell Biol 2010;43:252-9.
9. Ha CW, Na SE. The correctness of fit of current total knee prostheses compared with intra-operative anthropometric measurements in Korean knees. J Bone Joint Surg Br 2012;94:638-41.
10. Rosenstein AD, Veazey B, Shephard D, Xu KT. Gender differences in the distal femur dimensions and variation patterns in relation to TKA component sizing. Orthopedics 2008;31:652.
11. Guy SP, Farndon MA, Sidhom S, Al-Lami M, Bennett C, London NJ. Gender differences in distal femoral morphology and the role of gender specific implants in total knee replacement: A prospective clinical study. Knee 2012;19:28-31.
12. Vundelinckx BJ, Bruckers L, De Mulder K, De Schepper J, Van Esbroeck G. Functional and radiographic short-term outcome evaluation of the Visionaire system, a patient-matched instrumentation system for total knee arthroplasty. J Arthroplasty 2013;28:964-70.
13. Ho WP, Cheng CK, Liau JJ. Morphometrical measurements of resected surface of femurs in Chinese knees: Correlation to the sizing of current femoral implants. Knee 2006;13:12-4.
14. Hitt K, Shurman JR 2nd, Greene K, McCarthy J, Moskal J, Hoeman T, *et al*. Anthropometric measurements of the human knee: Correlation to the sizing of current knee arthroplasty systems. J Bone Joint Surg Am 2003;85-A Suppl 4:115-22.

15. Davis JJ, Bono JV, Lindeque BG. Surgical strategies to achieve a custom-fit TKA with standard implanttechnique. Orthopedics 2010;33:569-76.
16. Maniar RN, Singhi T. Patient specific implants: Scope for the future. Curr Rev Musculoskelet Med 2014;7:125-30.
17. Lonner JH, Jasko JG, Thomas BS. Anthropomorphic differences between the distal femora of men and women. Clin Orthop Relat Res 2008;466:2724-9.
18. Tait R. Redefining Joint Replacement; Today's Medical Developments; 5 August, 2013.
19. O'Connor MI. Implant survival, knee function, and pain relief after TKA: Are there differences between men and women? Clin Orthop Relat Res 2011;469:1846-51.
20. Siow WM, Chin PL, Chia SL, Lo NN, Yeo SJ. Comparative demographics, ROM, and function after TKA in Chinese, Malays, and Indians. Clin Orthop Relat Res 2013;471:1451-7.