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Are we compromising on Total Knee Arthroplasty component dimensions ? A prospective study on distal femoral dimensions in Indian patients.

KEYWORDS: Arthroplasty, Total Knee Arthroplasty, Femoral component, ML mismatch

Dr. Melvin J George
Dept. of Orthopaedics, Amrita Institute of Medical Sciences, Kochi, Kerala, India.

Dr. Jai Thilak
Clinical Professor, Division of Arthroplasty and Sports Medicine, Dept. of Orthopaedics, Amrita Institute of Medical Sciences, Kochi, Kerala, India.

ABSTRACT *Mismatch between the components in Total Knee Arthroplasty (TKA) and the anatomical dimen-sions is always a hot topic for discussion. To study the same in our subset of patients, we con-ducted this study. Intra-operatively, the distal femoral dimensions were measured using sterile calipers after removing the osteophytes and compared with the medio-lateral dimensions (ML) of the implants used. We found that APM (AP dimension of medial condyle) and APL (AP dimension of lateral condyle) have positive correlation with ML. Male patients have bigger distal femoral dimensions and more mediolateral mismatch when compared to fe-males. None of the implants used had the perfect match with the anatomical dimension. The medio-lateral mismatch is more in bigger knees than in the smaller knees. Functional scoring was done till 1 year post operative period which did not reveal any statistically significant difference between those with larger and lesser ML mismatch.*

Introduction

Total Knee Arthroplasty (TKA) is a commonly done surgery worldwide. It provides immediate pain relief for patients suffering from Osteoarthritis and rheumatoid arthritis of knee. The success of TKA depends upon various factors, among which correct sizing is an important one. The size of the implants used is based on the measurement obtained intra-operatively. Ideally the sizing should be precise in both anteroposterior and mediolateral dimensions. Antero-posterior (AP) dimension is important to maintain flexion-extension gap and medio-lateral (ML) dimension is important for even stress distribution, soft tissue irritation and adequate bone coverage. The currently used TKA implants worldwide, and those available in Indian subcontinent are based on morphometric measurements obtained from Western / Caucasian population(7). So, the risk of component oversizing is more common in Indian and Asian sub-population, as they are of a smaller built and stature(1,4). This study looks into the distal femoral dimensions of Indian patients undergoing TKA and their correlation with parameters like ML mismatch length, size of the distal femur, gender and BMI of the patient.

Material and method

Aims and Objectives

- To find out the correlation between the distal femur dimensions.
- Evaluation of gender variations in distal femur dimensions.
- Gender-wise correlation of mediolateral dimensions of patient to the used implant size to evaluate the difference in the mismatch.
- System-wise correlation of medio-lateral mismatch dimensions.
- Size-wise correlation of medio-lateral mismatch lengths between smaller or bigger knees
- To assess the relation between BMI and distal femoral dimensions.

Inclusion Criteria

Patients undergoing TKA in our institution during August 2011 - March 2013 period, who has given valid informed consent.

Exclusion Criteria

- Congenital or acquired deformities of the knee.
- Any history of disease or trauma involving the knee joint.
- Gross deformities of >20 degrees valgus / varus deformity.

Sample size

There are not many studies, which clearly mention the correlation of AP and ML distal femur dimensions. From the graphs plotted in them, the ML and AP values seem to have a high positive correlation. Based on this, a sample of 100 patients with 95% confidence and 20% allowable error, assuming a correlation coefficient of 0.8; would be sufficient for the study.

Statistical analysis

Pearson's Correlation Co-efficient between AP and ML dimensions was computed for correlation. It's statistical significance was tested. To test the statistical significance of gender comparison studies, Student's t test was applied; Among the different BMI groups, implant groups and among the AP size groups, Analysis of Variance was applied for correlation. Level of evidence - III (Evidence from case, correlation, and comparative studies).

Intra-operatively, 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) and medial condyle (APM) and medio-lateral (ML) dimension are measured, before the bony cuts were made. The ML dimension is measured as the maximum medio-lateral dimension possible, at the posterior most part when knee is kept in 90 degrees of flexion. APL and APM dimensions are measured at the maximum distant points on lateral and medial condyles of femur respectively along the axis of condyles.

Volume : 6 | Issue : 1 | JANUARY 2016 | ISSN - 2249-555X

Fig. No: 1

Fig. No: 2

In the Table no: 1 showing genderwise correlation of distal femoral dimensions, it is

Table No : 1 - Correlation between gender and distal femur dimensions.

	Gender	n	Mean	Std. Deviation	p-value
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	

concluded that the male patients have larger distal femoral dimensions 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.

In Table No:2 showing genderwise comparison with the ML mismatch, it was found out, the mediolateral mismatch length is much more in males (mean - 12.57) when compared to females (mean – 5.37). So, in our group of patients, gender specific knee

Variable	Male (Mean ± SD)	Female (Mean ±SD)	p-value
Pt 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 length	12.57 ± 5.607	5.37 ± 3.550	<0.001

Intra-operative picture showing the measurement of AP dimension of medial condyle (Fig. No: 1) and lateral condyle (Fig. No: 2)

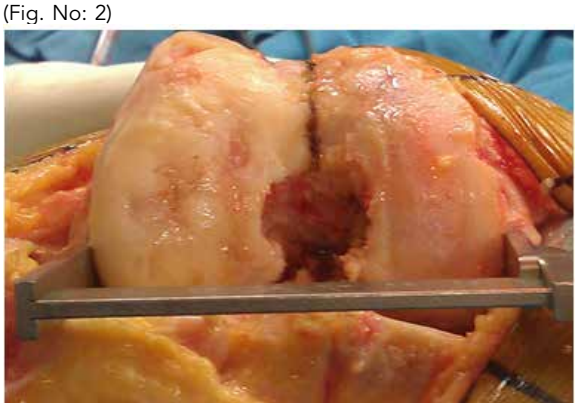

Fig. No: 3 - Intra-operative picture showing measureof Medio-lateral dimension.

The patients those who gave valid informed consent is included in the study. They were counselled regarding the study nature and the purpose of it. Their height and weight were obtained pre-operatively. Correlation between the various distal femoral dimensions obtained from the patients is found out. The AP, ML dimensions of the implant used, is obtained from the respective companies database. The intra-operative measurements obtained from the patient is compared with the measurements of the implant used in the patient and the medio-lateral mismatch length (the difference between the patient's value and implant's value) is found out. The mismatch length is compared with other variables like, size of the femoral condyle (taking APM as index), gender, implant used and BMI. Follow up was done using Knee Society Knee Scoring till 1 year post operative period to evalu-ate for functional limitations in those patients with more ML mismatch.

Results

Since, the correlation between the various distal femoral dimensions is not clearly elucidated in the studies found, our first aim was to identify the correlation between the various distal femoral dimensions. For that, Pearson's correlation co-efficient is used. On evaluation, it was found that APM and APL values seems to have positive correlation with ML dimension with the co-efficient values being 0.484 and 0.621 and the p value less than 0.005; which is statistically significant.

Volume : 6 | Issue : 1 | JANUARY 2016 | ISSN - 2249-555X

Table No: 2 – Genderwise comparison of ML mismatch length designs should be oriented more towards male patients than females, to obtain a better anatomical fit.

In the Table No: 3, to compare the ML mismatch lengths obtained with each implants used, the ML mismatch is least seen in knees replaced with Vanguard (Biomet, Warsaw, IN, United States) implants; followed by Nexgen (Zimmer, Inc. Warsaw, IN, United States), PFC Sigma (DePuy Orthopaedics, Inc. Warsaw, IN, United States) and Genesis II (Smith & Nephew, Adam Street, London, UK) in increasing order. One of the drawbacks for this comparison study is that, the number of knees replaced with PFC Sigma and Vanguard are much less when compared to that of Genesis and Nexgen. So, an evenly distributed variables couldn't be obtained for comparison.

Implant		n	Mean	SD	p value
Pt ML length	Genesis	76	70.42	7.54	
	PFC Sigma	12	68.58	7.45	
	Vanguard	21	68.90	5.30	0.419
	Nexgen	41	68.41	5.59	
Implant ML length	Genesis	76	64.66	4.13	
	PFC Sigma	12	63.00	3.33	
	Vanguard	21	65.67	3.33	0.321
	Nexgen	41	64.22	4.66	
ML Mismatch length	Genesis	76	7.91	5.73	
	PFC Sigma	12	7.00	5.16	
	Vanguard	21	4.29	3.22	<0.001
	Nexgen	41	4.44	2.62	

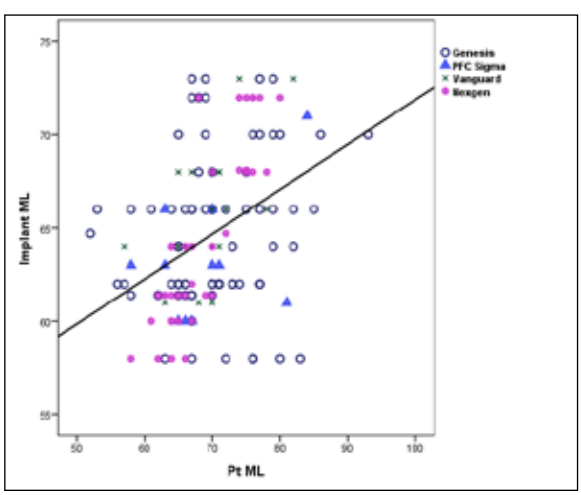

Fig. No: 4 – Scatter diagram showing the ML dimension mismatch with the various implant systems used.

The medial or lateral overhang could result in soft tissue irritation, interfere with the ligament balancing, results in limitation of the range of joint movement and induces pain. So we looked into those knees with ML over hanging.

		n	Mean	Std. Deviation	p-value
Pt ML	Genesis	15	62.20	6.10	
	PFC Sigma	2	60.50	3.54	
	Vanguard	2	61.00	5.66	
	Nexgen	1	68.00		
Implant ML	Genesis	15	67.74	4.20	
	PFC Sigma	2	64.50	2.12	
	Vanguard	2	66.00	2.83	
	Nexgen	1	72.00		
ML mismatch	Genesis	15	-5.81	3.76	0.880
	PFC Sigma	2	-4.00	1.41	
	Vanguard	2	-5.00	2.83	
	Nexgen	1	-4.00		

Table No: 4 - Table showing the correlation study of those patients with ML overhanging with respect to the implants used.

In 150 knees, 20 knees had larger implant ML dimensions when compared to the patient's intra operative value. Out of these 20 patients with ML overhanging, 75% patients had their knees replaced with Genesis, 10% each with Depuy and Biomet and 5% with Zimmer implants. The difference ranges from 13mm to 1mm. Correlation study revealed no significant difference. (p value – 0.880). Multiple comparison (Bonferroni) test between the various implant groups was done, which revealed significant difference in comparison between Genesis and Vanguard (p value – 0.011); and Genesis and Nexgen (p value – 0.001).

To study the correlation of distal femur dimensions with respect to the size of the distal femur, patients were divided into 6 groups depending upon the AP dimension of the medial condyle (from 45mm to 75mm). Groups **- 1** - 45-55mm, **2** - 55-60mm, **3** - 60-65mm, **4** – 65-75mm. Groups 1 and 6 had few number of patients, and hence was clubbed to groups 2 and 5 respectively reducing the total number of groups to 4. Multiple comparison (Bonferroni) test was done, which revealed significant difference in comparison between groups 1,4 (p value – 0.035); 2,3 (p value – 0.043) and 2,4 (p value – 0.001). In the Table No: 5, comparing the mismatch lengths and the femoral condyle size (AP dimension of medial femoral condyle), it was found that with the exception of group 2 (55-60mm); other groups show positive co-relation with the ML mismatch length; ranging from 6.21mm in group 1 to 9.50mm in group 4.

APM Length	n	Mean ML mismatchlength	SD	p-value
1	40	6.21	3.39	
2	40	4.99	4.11	
3	41	7.92	6.09	0.001
4	29	9.50	5.36	

Table No: 5 – Size wise (APM based) comparison of ML mismatch length.

So, the ML mismatch is more in bigger knees when compared to smaller knees. This supports the finding in our study that the male patients have bigger knees and more ML mismatch when compared to their female counterparts.

6. To find the correlation between BMI of the patient and the distal femoral dimensions, patients were divided into 6 groups based on their BMI. Since the groups 4, 5 did not have much patients, they were added to group 3. Those patients who were unable to stand without support and weight could not be measured were included in Group 6 and exempted from the correlation study. This shortened our number of patients for analysis to 101. Multiple comparison (Bonferroni) test was done, which revealed significant difference in average APL length between Group 1 and 2 (p

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value – 0.02) and Group 1 and 3 (p value – 0.03). **BMI groups -** 1 - Normal (18.5 – 25). 2- Over weight (25 - 30). 3- BMI - (> 30)**.** In Table No:6 showing the correlation between BMI of the patient and the femoral dimensions,

Length	BMI class	n	Mean	Std. Deviation	p -value
AP medial condyle	1	19	58.32	3.83	0.175
	2	56	60.98	5.48	
	3	26	60.31	5.91	
AP lateral condyle	1	19	58.89	4.34	0.015
	2	56	61.84	4.86	
	3	26	61.88	4.56	
ML length	1	19	69.32	6.27	0.380
	2	56	70.48	6.75	
	3	26	68.60	6.42	

Table No: 6 – Correlation between BMI and distal femoral dimensions

only the AP dimension of the lateral condyle (APL) shows correlation with BMI of the patient. Linear progression of the APL occurs with increasing BMI, except in severe obese patients.

Discussion

It would have been an ideal scenario if an implant was available which matched the dimensions of the patient's bone. Mismatch regarding the patient's and implant dimensions are always a hot topic of discussion among the surgeons and implant companies. Implant design should focus inter-individual variations in knee joint anatomy(8). The results of the study supports the fact that the distal femoral dimensions of the patients vary based on the race(3,12), gender(3,5,8) and built.

In our study, it was found that AP dimension of the condyles show correlation with ML dimension. Male patients had bigger distal femur dimensions and more ML mismatch with the implant length in the study group. All the four company implants used in this study had ML mismatch in varying proportions. The AP dimension of lateral condyle shows a correlation with the BMI of the patient. The drawbacks of this study is that the AP dimension of the condyles are measured along the axis and not at 90 degrees to ML width. Those patients with more ML length difference need to be followed up for functional limitations. The study with respect to the implants show none of the implants used, are not perfectly designed to match the distal femur dimensions of our group of patients. So, the implant companies need to come up with implants with multiple ML dimensions for a single AP dimension and in our subset of patients ideally a gender specific implant should be provided both for males and females. Probably custom made implants would be the future of Joint replacement surgery.

Conclusion

APM (AP dimension of medial condyle) and APL (AP dimension of lateral condyle) have positive correlation with ML (Mediolateral dimension). Male patients have bigger distal femoral dimensions when compared to females in all the distal femoral dimensions. Males have more mediolateral difference with the implant when compared to females. None of the implants used in the study had the perfect match with the anatomical dimensions. The medio-lateral mismatch is more in bigger knees than in the smaller knees. AP dimension of the lateral condyle (APL) shows positive correlation with BMI of the patient. Follow up scoring done till 1 year post operative period to assess the functional limitations in those patients with more ML mismatch did not reveal any statistically significant result.

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