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Influence of Femoral Component Design Variations on Early Functional Outcomes in TKA

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ABSTRACT

OBJECTIVE: A large variety of femoral component designs are used in TKA surgery. Femoral component axial rotation is known to significantly influence the kinematics and balance of the replaced knee. What is the impact of any deviation from native distal femoral anatomy due to femoral component design enforced variations? In our study we compared one such design variation comparing prosthesis with fixed inbuilt 3 degrees external rotation femoral component TKA prosthesis (Genesis II) to another prosthesis (PFC Sigma) which has an option of per operative adjustment of the femoral component external rotation which can be matched to native distal femoral axial anatomy. Aim of the study was to ascertain the impact on functional outcomes due to design enforced deviation from the native distal femoral axial rotation.

RESULTS: There was no statistically significant difference in functional outcomes measured by the WOMAC scores between the two groups in the study up to 01 year.

CONCLUSION:

We conclude that the deviation from the native distal femoral external rotation imposed due to implantation of fixed inbuilt 3^0 external rotation femoral components did not have a significant impact on functional outcomes after TKA.

Keywords: Femoral component axial rotation; Total Knee Arthroplasty(TKA); TEA; PCA; WOMAC.

INTRODUCTION

Total knee arthroplasty (TKA) is a common surgical procedure done worldwide; the number of primary TKA procedures is projected to grow by 85% (1.26 million procedures) by 2030 [1]. Over the years many design rationales have been tried and tested in the practice of total knee arthroplasty. Theoretically a design that closely mimics the native knee alignment, biomechanics and ligament balance should have the best outcomes, and long-term survival. A well-functioning total knee replacement has to be well aligned along the sagittal and coronal mechanical axis and placed in the correct axial and rotational planes. Different techniques to determine the final alignment and rotation of the femoral and tibial components at the time of surgery influencing the final outcome in the operated patients have been reported in the literature [2, 3]. Suboptimal alignment and component positioning leads to high dissatisfaction and failure rates due to pain, patella-femoral problems, instability, early wear, premature aseptic loosening of the components is resulting in overall poor outcomes [4, 5, 6]. Femoral component axial rotation is specifically implicated in patella-femoral joint mal-alignment, anterior knee pain and reduced knee flexion [7, 8, 9]. It is well reported in the literatures that about 10-15 % of patients are

unhappy after TKA due to unexplained knee pain, discomfort, instability and decreased range of motion [10, 11, 12]. It is at times difficult for the surgeon to truly ascertain the exact cause of the unhappy knees in the absence of overt clinical signs and symptoms especially in the early postoperative period.

A large variety of TKA prosthesis design rationales with differing femoral component implant designs are available in market. We chose to compare two different fixed bearing PS designs Genesis II (Fixed inbuilt 3 degree of external rotation in axial plane) and PFC Sigma (option of variation of femoral component axial external rotation angle), both are well established implant designs for last 20 yrs., with success rate of over 90 % and survival rate of 15 yrs. [13,14,15].

MATERIALS AND METHODS

The study was designed to compare the impact on early functional outcomes of a specific femoral component design variation enforced by the design rationale wherein the femoral component is placed in a fixed 3 degrees of external rotation compared to when the femoral component is placed in an external rotation in axial plane as per the native distal femoral anatomy in the axial external rotation**.** ***Inclusion criterion*****:** primary osteoarthritis, varus deformity, no previous deformity of thigh and leg, no limb length discrepancy, varus deformities less than 20 degrees, flexion deformity less than 30 degrees. ***Exclusion criterion:*** BMI more than 35 kg/m2, ASA Grade III or above, neurological problems, valgus deformities, collateral ligamentous laxity.

The study was carried out between Sept 2018 and Jan 2020 on fifty patients (n=50) divided into two equal groups matched in baseline demographics, gender and age. The patients presenting with primary osteoarthritis knee meeting the criterion laid down for the study were admitted to a tertiary care hospital under the Orthopaedic Department. All patients were explained in detail about the study and informed consent to participate in study was taken. All the necessary clinical details were recorded in pro-forma prepared for this study. Demographic data for patients, like age, gender, BMI, preoperative deformity in sagittal and coronal plane, patello-femoral movement, ROM of knee and quadriceps power were recorded for all patients.

Patients included in the study underwent total knee arthroplasty of which 25 patients in Group A were implanted with Genesis II (Smith & Nephew Inc., Memphis, TN, USA) and the other 25 patients in Group B were simplanted with PFC Sigma (DePuy Orthopaedics Inc., Warsaw, United States). Baseline weight bearing antero-posterior, lateral and skyline view radiograph of the knee were taken pre-operatively. Both groups were followed up post operatively at 06 weeks, 06 months and 12 months in the out-patients department. There was no patient lost to follow up.

Patients were assessed during their visit to the OPD at 06 weeks, 06 month and 12 months postoperatively. On each follow up visits WOMAC score was calculated.

RESULTS

All the collected data was entered into an MS Excel master sheet . The master sheet contained no identifiable records. Each patient had given a unique identifiable number by which they could be traced if necessary. Data analysis was conducted on an intention to treat basis. Statistical analysis was done using SPSS windows software. Distributions of the age, gender, side of knee were assessed using SPSS windows software. WOMAC score was assessed using paired t-test for both groups of patients.

The present randomized prospective study compares WOMAC Score in both group of patients undergoing total knee replacement with two different implant designs (Genesis II and PFC sigma). The comparative basic demographic data, operative details, postoperative complications and outcome measures in each Implant design group are summarized below.

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	Group A Genesis II	Group B PFC Sigma	Total patients
No. of patients	25	25	50
Mean Age (Std Dev)	65.04 (7.133)	63.52 (5.796)	64.28 (4.978)
Male	09	10	19
Female	16	15	31
Right	15	14	29
Left	14	11	21

Table 1.1: Patients age and side of surgery

In Genesis II 25 patients were operated (**mean age-65.04**) and in PFC Sigma Class 25 patients were operated (**mean age -63.52**). In Genesis II implant design class, among 25 patients 09 were male and 16 were female and out of 25 patients in PFC Sigma design class 10 were male and 15 were female. In Genesis II implant design class, 15 patients were with right knee and 10 with left knee. In PFC Sigma implant design class, 14 Patient were with right knee and 11 with left knee (**Table 1.1)**.

Group	Number of Patients	Mean desired FCAR	Std. Deviation	p value #
Group A (Genesis II)	**25**	**3**	**.000**	**0.0011**
Group B (PFC Sigma)	**25**	**3.88**	**1.01325**	**0.4888**
p value determined by Independent t test * - Significant (<0.05),** - highly Significant (0.001),# - Not Significant (>0.05)				

Table 1.2:- Comparison of External Rotation at time of surgery in two implant designs (Genesis II and PFC Sigma)

The femoral component external rotation at the time of implantation in Genesis II implant is fixed at 3 deg and cannot be changed due to the inbuilt design hence the average femoral component axial external rotation was 3 degrees, this we assume can result in the design enforced variation from the native distal femoral axial anatomy ,while in the case of PFC sigma the femoral component axial external rotation can variate to 3, 5 nd 7 deg as per the surgeons assessment per operatively ,the average femoral component external rotation was 3.88±1.01325 (**Table 1.2)** .

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Time	Group A Genesis II) (n=25)		Group B (PFC Sigma) (n=25)		p value (Independent t test)
	Mean	SD	Mean	SD	
Baseline	60.96	6.27	60.12	5.85	0.433
6 weeks	34.36	4.43	34.82	3.98	0.912
06 Months	31.44	3.513	30.28	3.021	0.2167
01 year	28.00	3.633	26.6	2.5	0.119
p value determined by Independent t test * - Significant (<0.05),** - highly Significant (0.001),# - Not Significant (>0.05)					

Table 1.3: WOMAC scores at follow up upto 01 yr.

The WOMAC scores for both the groups did not show a major variation upto 01 yr. The baseline mean WOMAC scores for Group A (60.96 ±6.27) and Group B (60.12 ±5.85) were comparable prior to surgery. On each follow up visit the patients WOMAC scores were evaluated first done at 06 weeks when there is full extension of the leg achieved. At 06 weeks the men scores were 34.36 ±4.43 in Group A (GenesisII) and 34.82±3.98 in Group B(PFC Sigma) and statistically not significant. The **p value** determined by independent T test for distribution of WOMAC Score at 06 months in Genesis II and PFC Sigma is 0.2167 and at 01 yr. in Genesis II and PFC Sigma is 0.119 which is **not significant** (more than 0.05) (**Table 1.3)**.

DISCUSSION

Various studies in the literature mention 10 – 15 % of the patients are not satisfied after TKA even though the clinical outcomes may be good or satisfactory [8]. The presence of anterior knee pain and discomfort following primary total knee replacement is negatively correlated with patient satisfaction and quality of life. According to the literature, the satisfaction rates after total knee arthroplasty vary between 78 and 90%.[3,5,7,10,11,12].Within the first five years after primary implantation, the revision rate is 2.8% and the rate of reoperations without exchange of components is 4.3 [16]. Many aspects of component alignment, knee kinematics, patella-femoral joint reaction forces and ligament imbalance have been considered as the usual causes for an unhappy knee [17-19].

Rotational alignment of total knee components is difficult to discern radio graphically, making the assessment of rotation primarily an intraoperative assessment by the surgeon. The rotation of the femoral component has effects not only on the flexion space but also on patella-femoral joint kinematics. The fact that the proximal tibial cut is made perpendicular to the mechanical axis of the limb instead of in the anatomically correct 3 degrees of varus, rotation of the femoral component also must be altered from its anatomical position to create a symmetrical flexion space. To create this rectangular flexion space, with equal tension on the medial and lateral collateral ligaments, the femoral component is externally rotated on an average of 3 degrees relative to the posterior condylar axis (PCA). Inaccuracy in the per operative assessment of PCA can take place when the posterior aspect of the native femoral condyle has significant wear, or when the lateral femoral condyle is hypo plastic, as is frequently seen in knees with valgus deformity. In these instances, the surgeon can use the trans-epicondylar axis or the antero-posterior axis popularized by Whitesides. PCA in most cases coincides with the trans-epicondylar axis (TEA) which corresponds to the native axis of knee flexion in the entire range of movement. There is increasing evidence in the literature that the PCA and the TEA also not corresponding and are variable [20]. Each of these

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techniques of determining femoral component axial rotation is primarily based on the geometry of the axial anatomy of the distal femur, with graduated effect of subsequent ligamentous releases to create symmetrical flexion and extension gaps.

The native femoral anatomy in axial plane demonstrates a large variation as per the sex, race and local factors [21-23]. Major deviation from the native distal femoral axial rotation causes flexion gap asymmetry and alters the patella-femoral kinematics and may cause tracking errors [24,25].

Fixed inbuilt external rotation femoral components in the case of our study the implant used (Genesis II,) has a 3 degree fixed inbuilt external rotation of the femoral component and the system does not cater for an option to increase or decrease the femoral component axial rotatation as per the native anatomy of the patient. It is reasonable to assume that this variation from the native distal femoral anatomy enforced due to the design of the femoral component can cause patella femoral mal-alignment and flexion gap imbalance which in turn can affect outcomes. Many other systems cater for variations in the distal femoral anatomy and imbalances at the time of surgery by provisioning for option of changing the femoral component rotation at the time of surgery to balance the flexion gap and restore patello-femoral kinematics. Literature lacks the firm evidence on what is the impact on the functional outcome after Total knee Arthroplasty of a fixed inbuilt external rotation of femoral component in which there is a design enforced variation from the native distal femoral external rotation and its contribution toward unhappy knees after surgery.The aim of the study was to measure the impact of this femoral component design enforced variation in the femoral axial rotation on outcomes.

Berger RA, Crossett LS, Jacobs JJ, Rubash HE [4] did a study in which thirty patients with isolated patella-femoral complications after total knee arthroplasty were compared with 20 patients with well-functioning total knee replacements without patella-femoral complications. The epicondylar axis and tibial tubercle were used as references on computed tomography scans to measure quantitatively rotational alignment of the femoral and tibial components. The group with patella-femoral complications had excessive combined (tibial plus femoral) internal component rotation. This excessive combined internal rotation was directly proportional to the severity of the patella-femoral complication. Small amounts of combined internal rotation (1 degree-4 degrees) correlated with lateral tracking and patellar tilting. Moderate combined internal rotation (3 degrees-8 degrees) correlated with patellar subluxation. Large amounts of combined internal rotational (7 degrees-17 degrees) correlated with early patellar dislocation or late patellar prosthesis failure. The control group was in combined external rotation (10 degrees-0 degree). The direct correlation of combined (femoral and tibial) internal component rotation to the severity of the patella-femoral complication suggests that internal component rotation may be the predominant cause of patella-femoral complications in patients with normal axial alignment.

Results of our study showed that statistically there is no significant difference in functional outcome of both implant designs as measured by WOMAC Score at 03 months, 06 months and 12 months. (p value determined by independent T test for distribution of WOMAC Score at 06 months for both Implant design is 0.2167 and at 12 months follow up is 0.119). Similar results were published by Choi YJ, Lee KW et al where they compared the functional outcomes in Genesis II with Nexgen LPS and found no difference in the outcomes due to the design variation [26] and by Kong CG, Park SW on comparing Genesis II with vanguard prosthesis [27]. Our study indicates that the deviation from the native distal femoral external rotation imposed due to implantation of fixed inbuilt 3^0 external rotation femoral components which was different from the native distal femoral axial external rotation in one group did not have a significant impact on early outcomes after TKA surgery. The outcomes were comparable when the femoral component prosthesis was implanted in the same axial rotation as the native distal femoral axial rotation.

CONCLUSION

The study has not shown any statistically significant difference in terms of influence of external rotation variation of femoral component enforced due to design of the femoral component on functional outcome of the patient when measured by WOMAC Score. This study has some limitations like it was not

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a randomized controlled blinded trial, sample size was small, and follow up period was short.

Conflict of Interest

CS and AD declare that they have no conflicts of interest.

Ethics statement

The study was performed in a manner to conform to the Helsinki Declaration of 1975, as revised in 2000 and 2008 concerning Human and Animal Rights and the authors followed the policy concerning Informed Consent as shown on Springer.com.

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