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Comparison between PFC Sigma Rotating Platform (standard design) and Buechel Pappas High-Flexion Total Knee Arthroplasties (A Randomized Controlled Study)

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Abstract: ***The purpose of the present study was to compare the short term clinical and functional outcomes of PFC Sigma Rotating-Platform (standard design) with those of Buechel Pappas High- Flexion total knee replacements using Knee Society knee score and Functional knee score .120 knees were randomly allocated to receive either a PFC Sigma Rotating-Platform (n=60) or Buechel Pappas High- Flexion (n=60) total knee prosthesis between January 2010 to December 2011, and were followed for an average mean period of 42.3 months. At the time of the latest follow-up, the average range of motion was 96.85^0 (range, 75^0 to 120^0) in the knees with a PFC Sigma Rotating–Platform prosthesis and 102.75^0 (range, 85^0 to 120^0) in the knees with a Buechell Pappas High-Flexion prosthesis. With a margin of 6^0 improvement in range of motion in Buechel Pappas High-Flexion knee replacements group, difference was statistically significant (p = 0.003).***

Keywords: Knee arthroplasty, High flexion, PFC Sigma RP, Buechel Pappas High Flex knee,

1. Introduction

The PFC Sigma Rotating-Platform (standard design) prosthesis was introduced in 2000. This design was introduced to improve the kinematics of the LCS RP prosthesis by employment of a post and cam mechanism that would lead to consistent posterior roll back, which in turn would lead to better knee range of motion, reduce polyethylene wear at the articular surface and provide better stabilization of the tibial insert [1]. However, the system was not designed for deeper knee flexion, which may be required by some patients, especially in Asian/Indian population for most of their routine habits and customs while squatting, kneeling, or sitting cross-legged [2,3] have driven the development of knee prosthesis designed to accommodate better and even facilitate higher degree of flexion[4.5]. Current Buechel-Pappas (B-P) high flex knee system (3rd generation New Jersey device) is a refinement of the original LCS design. The B-P High-Flex knee design uses a generating curve around a series of parallel axes producing two spherical regions in the principal load bearing segment, which provides for 162 degree of flexion and medial-lateral stability since the bony structures naturally providing this stability are resected. The dimensions of the articulating surfaces of the B-P knee are such that fully congruent contact exists to about 50 degree of flexion, providing a greater degree of congruity in the most highly loaded phases of walking and stair climbing, and significantly reduces contact stresses compared to earlier generation LCS designs that provide quasi-congruent or area contact to about 35 degree flexion. Full line contact occurs with the B-P knee at greater flexion angles while the LCS has quasi-line contact at these flexion angles. The primary load bearing segment arc of the B-P femoral component is greater by 19 degree, thereby increasing the degree of congruent contact during flexion. The B-P tibial platform is anatomically shaped and contains a stop pin to limit bearing rotation and reduce the potential for spin-out and provides 45 degree axial rotation [6].

Debate is still going on whether high flex designs have any advantage over standard designs.To our knowledge, no study to date has compared the clinical results of PFC Sigma Rotating-Platform total knee replacements with those of Buechel Pappas High- Flexion total knee replacements. However, PFC Sigma Rotating–Platform prosthesis has good functional short term results; the purpose of the present study was to compare the short term clinical and functional outcomes of these two designs. We hypothesized that the results would be better for knees treated with the Buechel Pappas High- Flexion prosthesis.

2. Materials and Methods

Between January 2010 to December 2011, 120 knees with primary osteoarthritis (Ahlback grade III, IV, or V) [7], age > 60 years and BMI < 30, were randomly allocated to receive either a PFC Sigma Rotating-Platform (group 1) or Buechel Pappas High- Flexion (group 2) total knee prosthesis. Computer-generated block randomization was utilized to allocate prosthesis equally (n = 20) to the two groups. The study protocol and consent forms were approved by the institutional review board. A detailed informed consent form was signed by each patient, and all

information was kept confidential. One patient died due to myocardial infarction in the immediate postoperative period, leaving 119 cases in the study. Patients were followed up post operatively for a period of minimum 36 months for evaluation of clinical and functional outcomes at 2 weeks, 6 weeks, 3 months, and 6 months and yearly thereafter with use of Knee Society Knee (KSKS) and Functional Score (KSFS) [8]. The mean follow-up period was 42.3 months (range, 36 to 52 months). Surgery was performed by the same surgical and anaesthetic team by using the same pre-op and post–op protocol. According to the protocol, a complete routine pre anaesthetic check-up was carried out. Patients were operated under Combine spinal epidural block (CSEB) with tourniquet inflation to 350 mm Hg. With knee in 90^0 of flexion an anterior midline skin incision (10 to 12 cm in length) was made, followed by a medial parapatellar capsular incision. Appropriate soft tissue and ligamentous releases were performed prior to bone cuts. Tibial preparation was performed first in all cases. Ten millimetres of tibial bone was resected, referenced from the least-involved tibial plateau, to achieve a surface perpendicular to the axis of the tibia in the coronal plane. A 0^0 slope was prepared for the knees in the group 1 and a 5^0 posterior slope was prepared in the sagittal plane for the knees in the group 2. Anterior cortical reference was used for the anterior-posterior cut of the distal part of the femur. Femoral component rotation was determined with use of three reference axes: (1) the transepicondylar axis, (2) the Whiteside [9] line and (3) 3^0 of external rotation relative to the posterior aspect of the condyles. Symmetrical and rectangular extension was obtained. All patellae were denervated circumferentially using the cautery. All implants were cemented after pulsed lavage irrigation, drying, and pressurization of cement. Preoperative antibiotics were started intravenously 12 hours prior to the surgery. A shot of antibiotics was given 20 minutes prior to the application of tourniquet. The Cephalosporin were used to give prophylaxis against gram-positive and Amikacin was used to give cover against gram-negative bacterial infection. The intra-venous antibiotics were discontinued within 24 hours of the end of surgery. LMW heparin used for 1^{st} fourteen post operative days. Patients were made to exercise under supervision of trained doctors and nurses for first 7 post-operative days. Patient is made to learn all the post-operative active exercises and handed over with a pamphlet including diagrammatic representation of those exercises.

The active arc of motion of each knee with the patient in the supine position was measured with use of a standard goniometer preoperatively and at each follow-up. Anteroposterior hip-to-ankle radiographs (with the patient standing), supine anteroposterior and lateral radiographs, and skyline patellar radiographs were made preoperatively and at each follow-up. The radiographs were evaluated to determine the anatomic axis of the limb, the alignment of the components, the presence and location of radiolucent lines at the bone-cement or cement-implant interface, and patellar tilt or dislocation.

3. Statistical Analysis

There were 20 cases in each group and all bilateral knees were considered as two cases separately. The comparative. Statistical testing was conducted with the statistical package for social for the social science system version SPSS 17.0. continuos variables are presented as mean±SD, and categorical variables are presented as absolute numbers and percentage. The comparison of normally distributed continuous variables between the groups was performed using Student's t test. Nominal categorical data between the groups were compared using Chi-squared test or Fischer's exact test as appropriate. $P<0.05$ was considered statistically significant.

4. Results

There were 60 cases in each group and all bilateral knees were considered as two cases separately. The comparative demographic data of the both groups is as below. (Table 1)

Table 1 Comparison of Demographic Parameters of Both Treatment Groups

Parameters	*PFC Sigma RP (Group 1)*	*B-P High Flex (Group 2)*
Diagnosis	OA (100%)	OA (100%)
Mean Age (yrs)	63	67.5
BMI	24.09	24.92
Sex (M : F)	36 :24	27 : 33
Side (R : L)	35 : 25	30 : 30
Unilateral : Bilateral	36 : 12	26 :17

BMI Body mass index, *OA* Osteoarthritis

The mean preoperative Knee Society Score was 14.45 (SD ± 7.824) in group 1 and 15.55 (SD ± 7.294) in group 2. The mean postoperative Knee Society Score at final follow up was 88.68 (SD ±11.879) in group 1 and 92.90 (SD± 4.077) in group 2. The mean preoperative and one year postoperative Knee Functional Scores were 30.5 (SD ± 19.256) and 91.84 (SD ± 13.765) in group1, whereas in group2, Knee Functional Scores were 31.25 (SD ± 20.576) and 89.25 (SD ± 15.917) respectively. It showed no significant difference between the two groups either preoperatively or postoperatively ($p = 0.906$ and $p = 0.591$, respectively). However there was significant improvement in the Knee Society Score and Knee Functional Scores within each group ($p< 0.001$).

Table 2: Comparison of KSKS, KSFS and ROM between Both Treatment Groups

Parameters		*PFC Sigma-RP Group1 (n = 60)*	*B-P High Flexion Group2 (n =60)*	*P value*
KSFS	Pre-op	30.50 ± 18.93	31.25 ± 20.22	0.834
	Final follow up	91.84 ± 13.29	89.25 ± 15.64	0.344
KSKS	Pre-op	14.45 ± 7.69	15.55 ± 7.17	0.419
	Final follow up	88.68 ± 11.52	92.90 ± 4.01	0.014
ROM	Pre-op	72.50 ± 3.46	74 ± 2.92	0.202
	Final follow up	96.85 ± 2.43	102.75 ± 1.61	0.003
Extension Lag	Pre-op	4.50 ± 1.51	5.00 ± 0	0.013
	Final follow up	3.05 ± 2.46	2.50 ± 2.52	0.23
Flexion Contracture	Pre-op	2.90 ± 2.11	2.95 ± 1.58	0.883
	Final follow up	0.41 ± 0.81	0.10 ± 0.44	0.012

KSFS Knee society functional score, *KSKS* Knee society knee score, *ROM* Range of motion

The mean preoperative range of motion (ROM) was 72.5^0 (range, 75^0 to 100^0) in the PFC Sigma Rotating–Platform group and 74^0 (range, 50^0 to 100^0) in the Buechell Pappas High-Flexion group. At the time of the latest follow-up, the average range of motion was 96.85^0 (range, 75^0 to 120^0) in group1 and 102.75^0 (range, 85^0 to 120^0) in group2.With a margin of 6^0 improvement in range of motion in group2, this difference was significant ($p = 0.003$). The mean preoperative and final postoperative range of motion in group2 were 57^0 and 95^0 degrees for the stiff knees, 98.33^0 and 110^0 for the flexible knees, compared to 51.66^0 and 95 degrees for stiff, 100^0 and 115^0 for flexible knees in group1.stiff knee was defined as having flexion contracture of 10 or more degrees with or without less than 90 degrees arc of motion. However flexion contracture decreased and ROM significantly increased within the each group postoperatively ($p < 0.001$).

Table 3 Comparison of Pain score, Flexion contracture, Extensor lag and Stairs use between both Treatment Groups

Parameters			*PFC Sigma-RP (Group1)*	*B-P High Flex (Group2)*	*P value*
Pain Score	None	Preop	0	0	-
		Final	56	60	0.119
	Mild	Preop	0	0	-
		Final	0	0	-
	Moderate	Preop	12	21	0.066
		Final	3	0	0.244
	Severe	Preop	47	39	0.066
		Final	0	0	-
Flexion Contracture	None	Preop	3	3	1.000
		Final	47	57	0.004*
	5 to 10 degree	Preop	42	36	0.001*
		Final	12	3	0.025*
	10 to 20 degree	Preop	14	21	0.232
		Final	0	0	-
	>20 degree	Preop	0	0	-
		Final	0	0	-
Extension Lag	None	Preop	2	0	0.500
		Final	32	39	0.097
	< 10 degree	Preop	54	60	0.027*
		Final	27	21	0.264
	>10 degree	Preop	3	0	-
		Final	0	0	-
Walking Distance	Unable	Preop	0	0	-
		Final	0	0	-
	Housebound	Preop	32	33	1.000
		Final	0	0	-
	< 5 blocks	Preop	27	27	1.000
		Final	1	2	1.000
	5-10 blocks	Preop	0	0	-
		Final	2	4	0.027*
	> 10 blocks	Pre-op	0	0	-
		Final	2	6	
	unlimited	Pre-op	0	0	-
		Final	54	48	0.125
Stairs	Normal	Pre-op	0	0	-
		Final	36	33	0.580
	With Support	Pre-op	39	39	1.000
		Final	23	27	0.264
	Unable	Pre-op	20	21	1.000
		Final	0	0	-

The mean pain score was 2 and 4 points in the group1 and group2, respectively. At the final follow up, mean pain score was 47.89 points, moderate pain was present in 3 (5.3%) patient and remaining 54 (94.7%) patients had no pain in the group1. In the group2, mean pain score was 50 points and all 60 (100%) patients had no pain, after 6 month of surgery, according to the knee society score.

Preoperatively, no patient had flexion contracture of more than 20 degrees in each group. Forty two knees (70%) in the group1 and 36 knees (60%) in the group2 had 5-10 degrees of flexion contracture ($p = 0.001$). Flexion contracture of 10-20 degrees was present in 14 knees (20%) and 21 knees (35%) patients in the group1 and group2 respectively ($p = 0.232$). Three knees in each group had no flexion contracture. Most of the patients had no flexion contractures at final follow up; 45 knees (78.9%) in the group1 and 57 knees (95%) in the group2 ($p = 0.004$). Twelve knees (23.7%) in the group1 and three knee (5%) in the group2 had 5-10 degrees of flexion contracture at final follow up ($p = 0.025$).

29 knees (49%) in the group1, 21 knees (35%) in the group2 had extension lag of $< 10^0$ and 30 knees (52.70%) in group1, 39 knees (65%) in the group2 had no extension lag at final follow up. No statically significant differences were evident between the two groups ($p = 0.264$, 0.097 respectively). Extension lag in the group2 improved significantly at 6 weeks ($p = 0.047$) and 6 months ($p < 0.001$) as compared to group1 patients. This difference in extension lag was due to insufficient postoperative rehabilitation exercises.

In our study there was no case of aseptic loosening of implants, deep infections, migration/subsidence, particulate synovitis, instability, extensive osteolysis and subluxation or dislocation of mobile bearing, till the latest follow up.

5. Discussion

Patient satisfaction surveys following TKR suggest that the ability to crouch and kneel influences a patient's view of the outcome [10, 11]. However despite successful pain relief and improvement in functional outcome with mobile bearing prostheses the increased desire among patients to pursue activities like squatting (130°-full hip flexion and 111°-165° (or full) knee flexion), kneeling, or sitting cross-legged (90°-100° hip flexion and 111°-165° (or full) knee flexion and crouching are essential for their routine habits, cultural and religious purposes in Asian/Indian population as compared to western people[2,3] have driven the development of knee prostheses designed to accommodate better and even facilitate higher degree of flexion[4,5].

This new Buechel Pappas High-Flexion design incorporate subtle changes (extended posterior femoral condyle, reduction of the femoral condyles radii in the mid- and high-flexion ranges, modified cam/post mechanism) in the geometry of the components to allow improved contact mechanics in the high-flexion ranges compared to the traditional designs[5]. Clinical studies on the effectiveness of designs intended to provide high flexion following TKR have produced conflicting results. Gupta et al.[12] (P.F.C. Sigma RP-F versus PFC sigma RP) reported a significant

improvement in the post-operative range of movement using a high flexion rotating platform design when compared with a standard design of rotating-platform TKR. Similarly, studies by Bin and Nam [13], Laskin [14], Weeden and Schmidt [15] showed significantly improved flexion or ROM with the high-flexion compared with the standard design. Dennis et al. [16] showed small, but borderline significant improvements in non weight bearing passive flexion and weight bearing single leg active flexion (SLAF) for the knees receiving the high flex device compared to standard device, 12 month postoperatively. Superiority in flexion was more pronounced in a subgroup of subjects with less than 120 degrees of preoperative flexion in both knees, suggesting the ideal candidate for a high flex TKR may be one with lesser preoperative flexion. In contrast Boese, Gallo Plantikow [17] (PFC-Sigma RP high-flex knee versus traditional PFC-Sigma RP knee.), Mehin, Brunett and Brasher [18], Murphy, Journeaux and Russell [19], Kim, Sohn and Kim [20] (NexGen LPS-Flex versus standard NexGen LPS implant) were unable to show a significant improvement in knee flexion in high flex knee group as compared to standard posterior stabilised knee.

In our study, all the patients had an improvement in knee function as assessed by the Knee Society and Knee functional function score. There was no significant difference in Total Knee score (P = 0.014) and Knee Functional Score (P = 0.344) between the two groups. However, better functional scores in the both groups can be attributed to improved mobility as a result of pain relief, rather than to a gain in movement. From their preoperative examination to the time of latest follow-up, the matched group1 and group2 subjects both gained ROM, 24.35^0 and 26.50^0 on average, respectively. This finding suggests that the difference in the designs of the prostheses may have a limited impact on short-term outcome measures after total knee arthroplasty.

In our study the over-all improvement in ROM was greater in knees with poor preoperative ROM because elimination of Flexion contracture contributed to the ROM. Harvey et al. [21] observed that less mobile knees gained movement, but the more mobile knees lost mobility. McAuley, Harrer and Ammeen [22] assessed 21 patients with 27 stiff knees (< 50 degree ROM), out of which, 18 showed improved quality of life after total knee arthroplasty, as depicted by the increased walking tolerance, increased functional abilities, and decrease in pain. Mullen [23] in their study found little difference between the final post op ROM in comparing the stiff and the flexible knee groups with probable reason being small sample size and stiff knee being defined as < 90 degrees. Similarly in our study though there was difference in the final ROM achieved between the two groups, but the mean ROM in stiff knees was adequate for the patient to carry out most of the activities of daily living and hence improved the quality of living.

Decrease in the pain was seen in all the patients irrespective of pre operative ROM and deformity. However there was no statistically significant difference between the group1 and group2. In our patients we found an increase in flexion limits and a decrease in the extensor lag in the first one year of follow up, contributing to the over-all increase in the final ROM. Higher frequency of flexion contractures in PFC Sigma-RP patients compared to Buechell Pappas High flex knees was due to lack of postoperative exercise regime.

There was one death in early post-operative period in our data (group1) due to acute myocardial infarction. In contrast to study by SooHoo F et al. [24] that showed a higher rate of 41/10,000 for pulmonary embolism in first ninety days after surgery, we did not find any case of postoperative DVT which was probably due to early DVT prophylactic measures taken by us such as LMW heparin and early mobilization of patient out of the bed.

In our study there was no case of aseptic loosening of implants, deep infections, migration/subsidence, particulate synovitis, instability, extensive osteolysis and subluxation or dislocation of mobile bearing, till the latest follow up.

The strengths of this study are that it is a match paired study in term of age, sex distribution, side distribution, BMI and preoperative axial alignment. Secondarily, evaluating patients were treated by a single surgeon at a single centre, means that there was consistency in surgical technique and implant use in the study.

Our study had limitations. First, the knee scoring systems are prone to inter-observer variability and we have no inter-observer variability to ensure reliability. A second possible limitation is that we measured the knee range of motion with the patients in the supine position, rather than under weight-bearing conditions. Dennis et al. [16] reported that weight-bearing ranges of motion differed significantly between two implants with similar passive non-weight-bearing ranges of motion. Hence, the ranges of motion with weight-bearing may have differed between the standard and high-flexion groups in our study. Nevertheless, the patients' abilities to perform activities that required weight-bearing knee flexion, such as kneeling, squatting, and rising after sitting on the floor, were similar in the two groups. Third, accuracy of measurement of ROM of the knee with a clinical goniometer would be less than that compared with using an electro-goniometer or fluoroscopic guided radiographic measurement [25]. Fourth, it is frequently difficult for a patient who has undergone bilateral total knee arthroplasty to distinguish the function of one knee from that of the other. Fifth, hence it is a short term study; so long term survival of implants can not be commented. Other limitations in the study were low sample size and short duration of follow up.

In this study, we hypothesized that the results would be better for knees treated with the Buechell Pappas High-Flexion prosthesis and results have been consistent with our hypothesis.

6. Conclusion

Although Total Knee replacement is a very gratifying procedure with good results, the debate for choice of ideal implant still continues. This study revealed a statistically significant improvement in range of motion among knee's using Buechell Pappas high-flexion total knee prosthesis as compared to PFC sigma RP, both implants were

compareable in terms of clinical or functional outcomes. However, long term studies are required to uncertain long-term survivorship of the Buechell Pappas high flex knee prosthesis.

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