Superior patient satisfaction in medial pivot as compared to posterior stabilized total knee arthroplasty: a prospective randomized study

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Compliance with Ethical Standards:

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Institutional Review Board Letter

ETHICAL CLEARANCE LETTER

INSTITUTE ETHICS COMMITTEE FOR POST GRADUATE RESERACH
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
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Dated. 27.02.2015

Dr. Sahil Batra
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Ref. No. IESC/T-49/25.02.2015
Thesis Guide: Dr. R. Molhotra,
Sub: - "A Prospective Randomized Trial to compare clinical, Radiological and Fluoroscopic outcome Between Advance Medial Pivot Knee (Wright Medical) And Posterior Stabilised Knee (Gcnisis Ii-Smith And Nephew)"

Dear Dr. Batra
The above mentioned protocol was discussed and reviewed in the Ethics Committee for Post Graduates Research meeting held on 25,02.2015 at 3.00 PM in the Ethics Committee Room, AIIMS. The following comments of the Ethics Committee are brought to your notice.

Ref. No.	Title of Study	Name/Department of Investigator	Original Objection	Remarks of Ethics Committee
RT-49/25.02.2015	"A Prospective Randomized Trial to compare clinical. Radiological and Fluoroscopic outcome Between Advance Medial Pivot Knee (Wright Medical) And Postenor Stabilished Knee (Gemsis Ii-Smith And Nephew)	Dr. Sahil Batra, Junior Resident, Department of Orthopedics, AIIMS, New Delhi-110029. Guide: Dr. R. Malhotra, Professor, Department of Orthopedics, AIIMS, New Delhi-110029	1. The chief guide has to present the case 2. This is not true randomization please remove randomization from bile. 3. Please attach permission to use the questionnaire. 4. PIS have to be in direct patient language. 5. Company name should be removed from the title 6. Please confirm from E.C.	The Protocol has been approved from ethical angle w.e.f. 25.02.2015

With best regards,
Yours truly,

Sanjeev Sinha

Dr. Sanjaev Sinha
Member-Secretary
Ethics Committee for Post Graduates Research

Authors Contribution

SB drafted the manuscript and performed all the measurements. RM conceived the study and performed all the surgeries. VK participated in the design of study. DN carried out measurement of radiological and kinematic data independently. HP and DB shaped the final version of manuscript. All the authors read and approved the manuscript.

Both HP and DB are senior and equal authors

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ABSTRACT

Purpose: Medial Pivot (MP) total knee arthroplasty (TKA) aims to restore native knee kinematics due to highly conforming medial tibio-femoral articulation with survival comparable to contemporary knee designs. Posterior Stabilized (PS) TKAs use cam-post mechanism to restore native femoral roll-back.However, there is conflicting evidence regarding the reported patient satisfaction with MP TKA designs when compared to PS TKAs. The primary aim of this study is to compare the patient satisfaction between MP and PS TKA and the secondary aim is to establish potential reasons behind any differences in the outcomes noted between these two design philosophies.

Methods: In this IRB approved single surgeon, single centre prospective RCT, 53 patients (mean age: 62 years, 42 women) with comparable bilateral end stage knee arthritis undergoing simultaneous bilateral TKA were randomized to receive MP TKA in one knee and PS TKA in the contralateral knee. At 4 years post-surgery, all patients were assessed using Knee Society Score (KSS)-Satisfaction and Expectation scores, Oxford Knee Score (OKS). In addition, all the patients underwent standardized radiological and in-vivo kinematic assessment.

Results: Patients were more satisfied with the MP TKA as compared to PS TKA: mean KSS Satisfaction [34.5±3.05 in MP and 31.7±3.16 in PS TKAs ($p < 0.0001$)] and mean KSS Expectation scores [12.5±1.39 in MP TKAs and 11.2±1.41 in PS TKAs (p

<0.0001)].Nosignificant difference was noted in any other clinical outcomes.The in-vivo kinematics of MP TKAs was significantly better than those of PS TKAs.

Conclusion: MP TKAs provide superior patient satisfaction and patient expectations as compared to PS TKA. This may be related to better replication of natural knee kinematics with MP TKA.

Level of Evidence: Level 1

Keywords: Kinematics; Medial Pivot; Posterior Stabilized; Patient Satisfaction; Patient Expectations; Total Knee Arthroplasty

Introduction

Total knee arthroplasty (TKA) usually provides good pain relief and improved function for patients with end-stage symptomatic arthritis, however a significant proportion remain dissatisfied with the outcome [5]. The failure of traditional TKA designs to reproduce physiologic knee kinematics may contribute to patient dissatisfaction [10]**.** Since the introduction of the modern bicondylar TKA concept, designs have focused on the recreation of tibial-femoral roll-back and stability in the sagittal plane by using dished bearing surfaces or cam-post mechanisms [8, 15, 43]. Posterior Stabilized (PS) TKA utilizes cam-post mechanism to improve femoral roll back and simultaneously provide anterior-posterior stability [6, 16, 33]. Medial Pivot (MP) TKA is fixed bearing asymmetric pivoting design prosthesis with a highly congruent medial side and a less conforming lateral compartment to limit anterior-posterior translation in the medial compartment while allowing femoral roll back in the lateral compartment [13]. However the evidence is scarce to suggest its superiority in terms of patient satisfaction with regard to its kinematic behavior. Till date, there are only three prospective studies comparing MP TKA and PS TKA in the same patient and the results are equivocal [18, 20, 32]. Out of them, only one study performed simultaneous bilateral TKA [18] while the other two performed staged bilateral TKA [20, 32]. No study has assessed in vivo kinematics in patients undergoing simultaneous bilateral TKA using two different TKA design philosophies.

The primary aim of this prospective RCT is to compare the patient satisfaction between MP and PS TKAs and the secondary aim is to establish potential reasons behind any differences in the outcomes noted between these two design philosophies.

Material and Methods

This single surgeon, single centre, prospective, randomized, controlled, double-blinded trial (patient and assessor were blinded to the allocation) recruited adult patients with comparable bilateral end-stage knee arthritis (Kellgren Lawrence Grade 4) with American Society of Anesthesiologists (ASA) physical status classification 1 and 2 over a period of six months in a University Teaching Hospital. Patients were excluded if they had a history of patellectomy, high tibial osteotomy, BMI > 40, those undergoing simultaneous hip and knee arthroplasty and/or those who refused to give consent. After obtaining institute's ethics committee clearance, sixty patients (120 knees) were identified for the study. Seven patients were excluded because they either declined to participate (Five) or did not fill the inclusion criteria (Two), leaving fifty-three patients (106 knees) available for study (Figure 1). The study was registered with the Clinical Trials Registry India (ctri.nic.in CTRI/2016/07/011753).

A randomization sequence was generated using validated software to randomly allocate the left knee for MP (ADVANCE® Medial Pivot, Micro Port Orthopedics, Arlington, TN, USA) or PS (Genesis II, Smith and Nephew, Memphis, USA) TKA.Patient received other TKA type for the contralateral TKA. Using the enrollment numbers, opaque and sealed envelopes containing the treatment allocation were prepared. Envelopes were opened in the operation theatre just before the start of surgery after determining eligibility and obtaining written informed consent.

All TKAs were performed by the same surgeon (R.M.). Both knees were replaced sequentially during the same surgery under the same anaesthesia using medial parapatellar arthrotomy. All patients received prophylactic antibiotic (Cefuroxime 1.5 grams) 30-45 minutes prior to skin incision. All patients received IV tranexamic acid (15 mg/kg) 10 minutes prior to tourniquet deflation. PCL was sacrificed in all the cases and implants were fixed with a single mix of Palacos® bone cement. Patella was resurfaced in all cases using all-poly patella components. Peri-operative management including surgical protocol and postoperative mobilization was standardized as per well-established protocols.

The primary outcome measure for this study was Knee Society Score (KSS) patient satisfaction score. The secondary outcome measures were KSS patient expectation score, Oxford Knee Score (OKS), in-vivo sagittal plane knee kinematics and radiological assessments. All patients were assessed by an independent blinded observer. Range of Motion (ROM) was measured using goniometer and flexion deformity if any was recorded.

Fluoroscopic evaluation was conducted post-operatively at 6 months by an independent radiologist. Subjects were assigned to perform a single step up and a weight bearing deep knee bend exercise. The examined limb was placed on an adjustable support around 250 mm in such a way to replicate 80^0 of knee flexion in the desired limb while the other foot was placed on the ground [10, 11, 24, 28]. For step up exercise, patients were asked to stand as if rising up a step of stairs. In deep knee bend exercise, patients lower themselves towards floor producing a flexion of 110^0. Images were recorded and sampled at 25 frames per second. A parallel calibration object was placed and its image was taken. This allowed image to be corrected for distortion using a global correction method [2, 9]. For each frame, the femoral and tibial axes, the tibial tubercle, and the distal pole of the patella were determined using a graphical user interface [12, 35]. Knee Flexion Angle (KFA) was measured between femoral and tibial long axis. Patellar Tendon Angle (PTA) was measured using the line defined between the tibial tubercle and the distal pole of the patella, and, tibial axis. PTA was measured at increment of 10° KFA throughout the flexion arc. The association between PTA and KFA was assessed using MATLAB (MathWorks, Natick, MA), version 7.10.0.499 (R2010a).

Serial pre-operative and post-operative radiographs at baseline and at latest follow-up times were evaluated by the independent radiologist as per protocol defined by the Knee Society Radiographic Evaluation System [23]. The parameters assessed were Tibio-Femoral Angle, Posterior Condylar Offset, Joint Line position and orientation angle, Patellar Tilt and Patellar Translation. The Joint line position was determined as the distance between tip of the fibular head and the distal margin of the lateral femoral condyle preoperatively and post operatively as the distance between the tip of fibula and distal margin of the lateral femoral component. Joint line orientation angle was measured postoperatively as described by Victor [41]. A complete radiolucent line more than 2 mm in width, a visible fracture of the cement around the components, or a change in component position was considered loosening of TKA.

The intra-class correlation coefficient was good (0.87) for fluoroscopic evaluation and excellent (0.93) for radiographic evaluation [19].

Statistical Analysis

Baseline characteristics were described for each patient using mean ± standard deviation or Median (range) or frequencies/percentages as appropriate. KSS Satisfaction and Expectation and OKS were compared using generalized estimating equation (GEE) because the observations were correlated pre-operatively and post-operatively. Between-group comparison, student's t-test was used for independent samples and paired t-test/ Wilcoxon rank-sum test (Mann-Whitney U test) as applicable was used for within the group analysis. Correlation between two continuous variables was analyzed using Pearson correlation coefficients. All analyses were performed using Stata 12.0 (Stata Corp LLC, Texas, and USA). A p value <0.05 was considered statistically significant.

Sample Size: With study power of 0.80 (Type II error) and an alpha =0.01 (Type 1 error), to detect a standardized difference of 1 between both groups using KSS-satisfaction as a primary outcome, a minimum paired sample size of 48 was required [3].

Results

Demographic data is summarized in Table 1. The two groups were well matched for all relevant pre-operative parameters. The data at various follow up periods is presented in Table 2.At 3 months follow-up, patients reported significantly higher mean KSS Satisfaction for the MP knee as compared to the PS knee whereas there was no significant difference in KSS Expectation score. The mean KSS-Satisfaction scores were 32.6±3.41 (24-38) in MP and 29.5±3.26 (22-36) in PS knees ($p < 0.0001$) respectively, and the mean KSS-Expectation scores were 11.9±1.37 (8-14) in MP and 11.1±1.24 (8-15) in PS knees ($p < 0.001$) at 6 months follow up. The mean KSS-Satisfaction scores were 34.5±3.05 (26-38) in MP and 31.7±3.16 (24-38) in PS knees ($p < 0.0001$) respectively, and the mean KSS-Expectation scores were 12.5 ±1.39 (10-15) in MP and 11.2 ±1.41 (8-15) in PS knees ($p < 0.0001$) at the final follow up. The mean OKS scores were 44.3 ±2.17 (40-48) in MP and 44.0 ±2.31 (3947) in PS knees; the difference was not significant. There was no significant difference in the preoperative and post-operative range of motion and flexion deformity between the two types of prostheses (Table 3). There was no significant difference in the tourniquet time, surgical time and drain output between the two types of prostheses.

There was linear decrease in the value of PTA with increasing knee flexion in both step up and deep knee bend exercise. MP group PTA was higher than that in the PS group throughout range of motion and the difference was significant ($p<0.05$) during step up as well as deep knee bend exercises (Figure 2).

No significant differences were observed with respect to the component alignment, leg alignment, posterior condylar offset, joint line position and orientation angle, patellar tilt and patellar shift in both the groups preoperatively and at final follow up. No radiolucent lines were seen either in the MP or the PS prostheses (Table 4).

Complications

None of the patients were lost to follow up or died due to surgery-related or unrelated causes. None of the patients needed reoperation or manipulation under anaesthesia or revision surgery. Two patients in the MP TKA group reported minor giving way symptoms in the immediate post-operative period which was possibly related to overzealous MCL release. They were managed with a knee brace (for six weeks) in initial post-operative period. Both were managed with knee brace for 6 weeks and neither showed any signs / symptoms of instability during subsequent follow ups.

Discussion

The most important findings of the study were significantly better patient satisfaction and expectations in the MP group as compared to the PS group throughout the follow up period. Although no other clinical or radiological outcomes showed any significant difference between the MP and PS TKAs, in-vivo kinematics was significantly better for MP TKAs. This kinematic advantage may manifest as better patient satisfaction and better met- expectations for MP TKAs. Long term survivorship of MP TKA is well documented but little evidence exists about its kinematic advantage translating into clinical outcome, particularly in terms of patient satisfaction [4, 17].

Previous studies have reported conflicting results comparing MP and PS TKAs. Lee et al. have shown that there is no difference in patient preference between MP and PS knee at the end of one year in a prospective study in staged bilateral TKA whereas Samy et al. have shown better Forgotten Joint Score-12 in MP knee as compared to PS knee in a retrospective cohort [20, 37]. Similarly, Pritchett had showed that 76% patients preferred MP over 9% patients with PS at 2 years in a prospective study of staged bilateral TKA whereas Kim et al. had shown poorer results with MP design as compared to mobile bearing PFC Sigma at 2 years in a prospective study of simultaneous bilateral TKA [18, 32]. The methodology of present study is similar to Kim [18] with longer follow up as compared to previous studies but results are contrary; moreover, study by Kim was stopped due to high incidence of infection in MP group and its methodology has been criticized by various authors[18, 31, 39]. None of the above study had analyzed kinematic behavior of the prostheses.

The current study demonstrated superior sagittal knee kinematics in MP knee as compared to PS knee. The knee kinematic activity represent both the tibio-femoral and the patella-femoral joint and it involves standing from a sitting position; a routine daily activity which requires reasonable amount of mid flexion stability [28-30, 34]. In the MP-TKA design the femoral component has a single radius curvature and the insert has an anterior lip that acts like a post which helps increase anterior-posterior stability and kinematics is close to normal knee joint due to the lack of lateral constraint [10]. Increased stability and relative anterior position of femur on tibia (as evident by higher PTA) can enhance quadriceps efficiency [38]. Warth [42] and Nishio [26] reported superior satisfaction score in TKA with MP kinematic pattern using intraoperative sensor and CT-based navigation system respectively.Previously, researchers have attributed the mid-flexion instability in PS TKAs to the cam-post mechanism i.e. impingement of the box cut onto the anterior aspect of the PS post and postcam mechanism of PS knee generating very high contact stress [14, 22, 25, 37].

In the current study, there was no difference in the baseline range of motion pre-operatively and at latest follow up between the two groups. Out of 106 knees, 46 knees (25 MP & 21 PS) exhibited preoperative range of motion of less than 90 degrees; all of them showed significant improvement which seems contrary to what is reported in literature [7, 36]. It is well known that Indian patients retain their range of motion in spite of extensive osteoarthritic changes which may be possible due to the cultural habits such as sitting cross-legged and/or squatting. Shakespeare et al. reported similar results with no difference in the post-operative flexion attained in 261 knees replaced with MP and 288 replaced with a PS knee after 12 months of surgery (109° for MP and 111° for PS, $p=0.11$) [40]. Kim et al. showed that there was statistically significant difference between the final range of motion achieved between the MP knee and the mobile bearing PS knee (115° for MP and 127 ° for PS, $p<0.001$) but were not able to provide any scientific reason for the same [18]. This study reported no significant difference in pre-operative and post-operative radiological parameters between MP and PS knees, similar to the findings of other studies [1, 18, 32].

There are many strengths and certain limitations for the present study. Patient reported outcome measures (PROMs) as well as kinematic analysis were used to detect any meaningful difference between the two prostheses. Each patient served as his/her own control. Thus, it eliminated the bias which can occur due to differences in age, sex, comorbidities and functional status. It is advantageous to compare the benefits of two different treatments in the same patient but it also creates a problem when trying to distinguish between the function of each knee, especially when assessing the overall function. Another limitation of the present study is minimal clinical important difference (MCID) was not considered for KSS. Lee et al. have described MCID for KSS as 5.3 to 5.9 but it was described for KSS-Objective score [21]. MCID for satisfaction and expectation component has not been validated for English version of KSS-2011. Nishitani et al. had described MCID of 2.2 for KSS-Satisfaction in the Japanese version of KSS [27]. The present study recorded a difference of 2.8 in KSS-satisfaction which is more than above reported MCID. Although statistically significant differences were found between the two groups for KSS satisfaction and KSS expectations, whether the noted difference is clinically relevant or not is difficult to establish. Patients seem to favor MP TKA (as compared to PS TKA), although do not report any significant differences in their Oxford knee Scores. No difference in Oxford Knee Score is probably because questionnaire involved the activities which depend upon function of both the knees making it difficult for patients to report the function for a knee in isolation. In addition, OKS primarily assesses pain and function whilst patient expectations and satisfaction is multi-factorial and indeed is determined by various other factors rather than just pain relief and improved function. As per the criteria set by Nishitani et al (re MCID for KSS-satisfaction), the present study results (a difference of 2.8 between the two groups) confirm clinically relevant difference although this seems to be marginal at the best [27].

CONCLUSIONS

In summary, this study found that in patients with end stage knee arthritis, MP design provides better patient satisfaction and expectation as compared to PS design and is associated with improved quadriceps efficiency. This may be related to better replication of natural knee kinematics with MP TKA. Therefore, salient differences in the design features may improve PROMs, which is an indirect measure of patient satisfaction. Further studies are recommended with multi-centre participation and longer follow up.

Conflict of Interest: SB, RM, VK and DN have no conflict of interest. DB reports personal fees from Microport Orthopedics and chairs editorial board office at Journal of Arthroplasty, Clinical Orthopaedics and Related Research and held shares in Intelijoint Surgical outside the submitted work. HP reports personal fees from Zimmer Biomet, Medacta, Depuy Synthes, Meril Life, and grants from Zimmer Biomet, Depuy Synthes, and GSK outside the submitted work.

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FIGURES CAPTIONS

Figure 1: CONSORT 2010 flow diagram (Consolidated Standards of Reporting Trial)

Figure 2: Comparative analysis of PTA/KFA graph between MP and PS TKA in step up and deep knee bend exercise

TABLE LEGENDS

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Table 3: Descriptive statistics of range of motion and flexion deformity preoperatively and at the Latest follow up.

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Figure

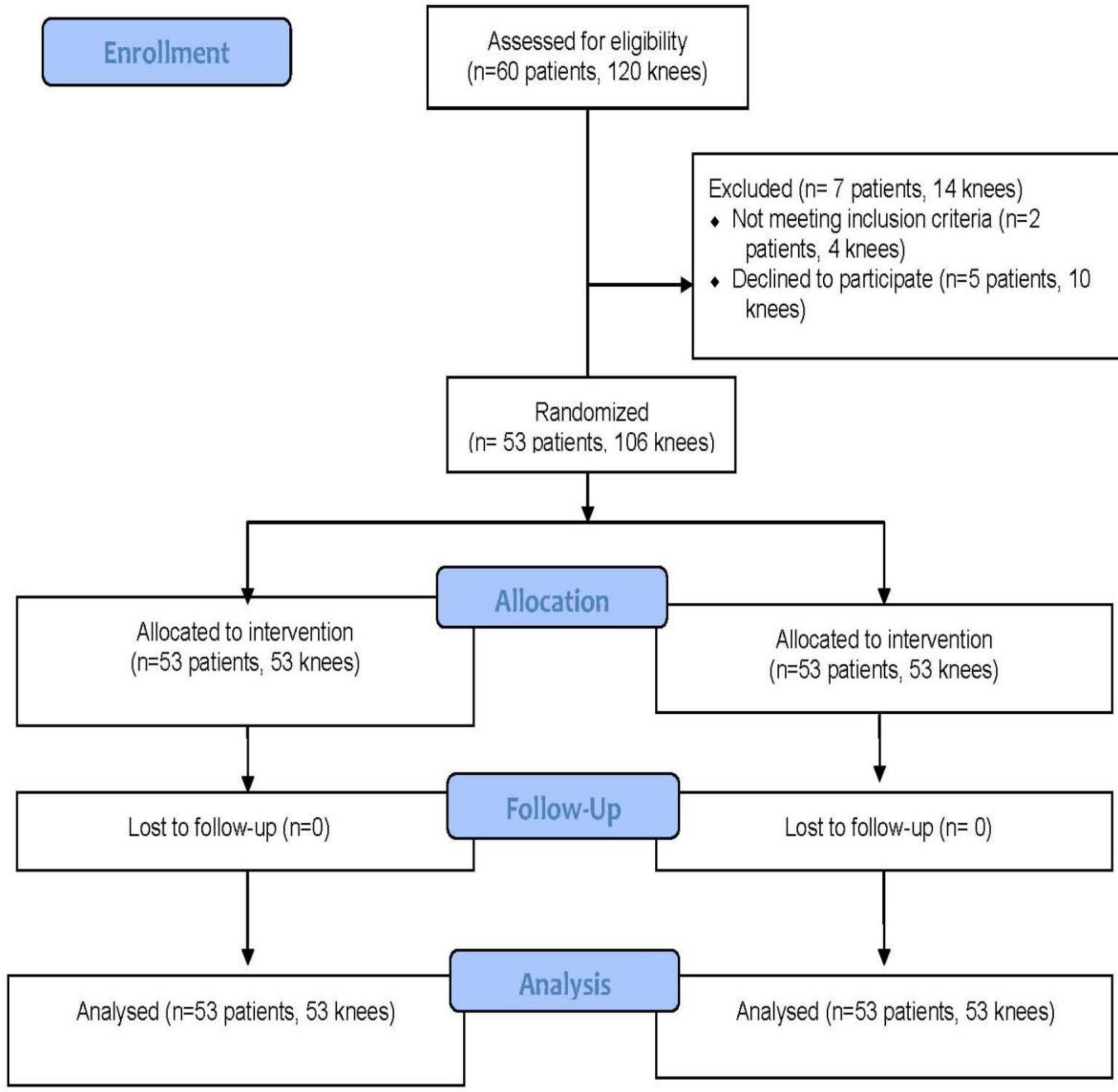

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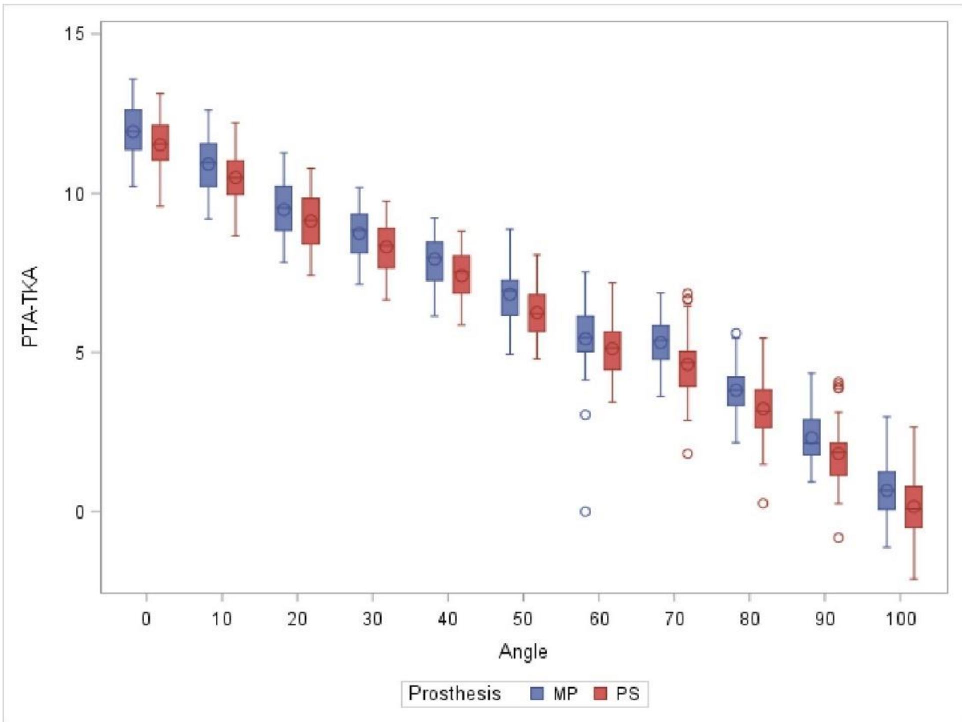
Figure 1



15
10
5
0
PTA-TKA
0
10
20
30
40
50
60
70
80
90
100
Angle
Prosthesis
MP
PS

Figure 2

Table

Table 1: Patient Demographic Data

Parameter	Value
Female/Male^{n}	79.2 (42)/20.8(11)
Age(Years)*	61.7±6.88
BMI(Kg/m^2)*	28.3±3.4
OA/RA^{n}	86.8(46)/13.2(7)
^{n}The values are given as percentage with number of patients in parenthesis, *Data are presented as mean and standard deviation. OA: Osteoarthritis RA: Rheumatoid Arthritis	

Table 2: Descriptive statistics of KSS-Satisfaction and Expectation and Oxford Knee score preoperatively and postoperatively.

Knee society score (satisfaction)				
	Preoperative	**3 months**	**6 months**	**Latest follow up**
MP (n=53)	4.3 ±1.76	30.3±3.63	32.6 ±3.41	34.5±3.05
PS(n=53)	4.3±2.44	27.1±3.41	29.5 ±3.26	31.7±3.16
p value	n.s	**0.0001**	**0.0001**	**0.0001**
Knee society score (expectation)				
MP(n=53)	11.6 ±1.78	11.3 ±1.69	11.9±1.37	12.5 ±1.39
PS(n=53)	11.6 ±1.78	10.8 ±1.50	11.1 ±1.24	11.2 ±1.41
p value	n.s	n.s	**0.001**	**0.0001**
Oxford knee score				
MP(n=53)	9.2 ±2.79	39.4±2.86	41.3±2.6	44.3 ±2.17
PS(n=53)	9.3±3.03	39.3 ±2.86	41.3 ±2.8	44.0.±2.31
p value	n.s	n.s	n.s	n.s
Data are presented as mean ±standard deviation.				

Table 3: Descriptive statistics of range of motion and flexion deformity preoperatively and at the Latest follow up.

	MP(n=53)	**PS(n=53)**	**p value**
Range of motion(°)*			
Preoperative	96±13.6	99 ±11.5	n.s
Latest follow up	118 ±8.6	116 ±9.3	n.s
Change	22 ±11.7	17±13.4	n.s
Flexion deformity(°)			
Preoperative[¥]	10(0-40)	10(0-30)	n.s
Latest follow up[¥]	0(0-10)	0(0-10)	n.s
Change*	-7.6±7.4	-7.2±6.1	n.s

[¥]Data are presented as median (min-max)

*Data are presented as mean ±standard deviation,

Table 4: Descriptive analysis of radiological outcomes

	MP(n=53)	PS(n=53)	p value
Tibio-femoral angle(°)*			
Preoperative	4.4±3	4.3±3.06	n.s
Latest follow up	-4.1±0.77	-4.1±0.67	n.s
Posterior condylar offset(mm)*			
Preoperative	17.7± 0.64	17.7±0.64	n.s
Latest follow up	17.9 ± 0.62	17.8±0.6	n.s
Patellar tilt(°)*			
Preoperative	4.5±2.67	4.3±2.67	n.s
Latest follow up	4.4±1.88	4.2±1.79	n.s
Patellar translation(mm)¥			
Preoperative	2.6 (-3.6 to 5.8)	2.7 (-3.7 to 5.9)	n.s
Latest follow up	3.5 (-3.3 to 7.9)	3.2 (-2.8 to 7.1)	n.s
Joint line position (mm) •			
Preoperative	13.7±0.86	13.7±0.9	n.s
Latest follow up	13.3±0.9	13.3±0.92	n.s
Joint line orientation ()¥			
Latest follow up	0.8 (-2 -2.7)	0.7 (-2.5-2.3)	n.s
Position of implants(°)^			
Coronal femoral angle	94.9±0.46	95±0.04	n.s
Coronal tibial angle	90.2±1.32	90.3±1.21	n.s
Sagittal femoral angle	2.5±0.7	2.6±0.68	n.s
Sagittal tibial angle	86±0.83	86 ±0.8	n.s

• Data are presented as mean and standard deviation,

¥Data are presented as median (min-max), suggests valgus