Archives of Orthopaedic and Trauma Surgery (2022) 142:2057–2064
https://doi.org/10.1007/s00402-021-04121-6

KNEE ARTHROPLASTY

Comparison of postoperative knee flexion and patient satisfaction between newly and conventionally designed medial pivot total knee arthroplasty: a 5-year follow-up matched cohort study

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Received: 17 August 2020 / Accepted: 9 August 2021 / Published online: 14 August 2021

Abstract

Introduction The medial pivot total knee arthroplasty (TKA) has good patients' satisfaction; however, there is likely the restriction of postoperative knee flexion. The 2nd generation medial pivot TKA prosthesis was designed to improve postoperative knee flexion. This study aimed to compare the clinical outcomes and patient satisfaction between the 2nd generation and 1st generation medial pivot TKA prostheses.

Materials and methods We conducted a retrospective study of 472 consecutive TKAs, performed using either the 2nd generation (EVOLUTION™), having smaller posterior femoral condyle and asymmetrical tibial tray, or 1st generation (ADVANCE™) prosthesis. The use of each system was historically determined. Patient age, sex and body mass index were matched between the two groups, with 157 cases ultimately included in each group. Measured clinical outcomes included: knee range of motion, the Knee Society Score, the rate of re-operation, and radiological parameters. Patient satisfaction was evaluated using the 12-item Forgotten Joint Score (FJS-12).

Results The average follow-up period was 5.0 (3.7–6.3) years for the 2nd generation group and 8.7 (6.1–12.8) years for the 1st generation group ($p < 0.01$). The postoperative knee flexion range was 127° (80°–140°) for the 2nd generation and 118° (90°–135°) for the 1st generation at final follow-up ($p < 0.01$). On multivariate regression analysis, use of the 2nd generation prosthesis predicted greater postoperative knee flexion. The average FJS-12 score was 64 (0–100) for the 2nd generation and mean 57 (0–100) for the 1st generation ($p < 0.01$). Other clinical outcomes were similar between the two groups.

Conclusions Compared to the 1st generation, the 2nd generation medial pivot prosthesis provides greater postoperative knee flexion and patient satisfaction.

Keywords Medial pivot · TKA · ROM · Flexion · Patient satisfaction · Forgotten joint score

Introduction

Total knee arthroplasty (TKA) is commonly performed to treat degenerative knee disease, with the longevity of the components and *good* postoperative functional outcomes having been reported [1, 2]. However, patient satisfaction after TKA has not necessarily been favorable [3, 4]. The unnatural kinematics of the TKA, such as a "paradoxical" anterior femoral slide in the mid-flexion range may contribute to patients' dissatisfaction after TKA [5, 6].

The medial pivot TKA was developed to mimic the natural knee kinematics, having a single radius curvature, high conformity of the medial compartment, and an unrestricted lateral compartment [7]. These features reproduce the natural rollback of the femur during flexion and achieve good antero-posterior knee stability [8]. This medial pivot design has good longevity and good patient satisfaction after TKA [1, 9]. The medial pivot TKA prosthesis was introduced widely in the 1990s like the Medial Rotation Knee™ (MatOrtho Ltd, Surrey, UK) and the Advance Medial Pivot Knee™ (MicroPort Orthopedics Inc., Arlington, TN, USA).

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Furthermore, the developed medial pivot theme, next-generated prostheses was introduced in the 2000s like Evolution™ Medial Pivot Knee (MicroPort Orthopedics Inc., Arlington, TN, USA), SAIPH Knee System™ (MatOrtho Ltd, Surrey, UK), and GMK Sphere™ (Medacta, Castel San Pietro, Switzerland). The former is described as the 1st generation and the latter as the 2nd generation medial pivot prostheses [10]. Postoperative knee flexion was reported to be worse for the 1st generation medial pivot design prosthesis, ADVANCE Medial Pivot™, than other prosthesis designs [11]. As restriction in postoperative knee range of motion (ROM) affects functional outcomes and patient satisfaction, improving postoperative knee flexion is an important design feature to solve in medial pivot TKAs [12].

A newly designed 2nd generation medial pivot prosthesis, the EVOLUTION Medial Pivot Knee System™, includes two specific features to address the restriction in knee flexion with the conventional design—the range of single radius of the femoral component is enlarged and the overhang of the posterior condyle decreased (Fig. 1). Moreover, the tibial tray was changed to an asymmetrical shape in the 2nd generation. These design changes could, in theory, improve postoperative knee flexion [13]. However, clinical results and patients' satisfaction after TKA between the 2nd generation and the 1st generation medial pivot TKA have not been directly compared. Therefore, this retrospective cohort study aimed to compare the postoperative clinical results, including a range of knee flexion, and patient satisfaction after TKA for the 2nd generation and the 1st generation medial pivot prostheses. We hypothesized that the 2nd generation medial pivot prosthesis would improve postoperative knee flexion, with good patient satisfaction.

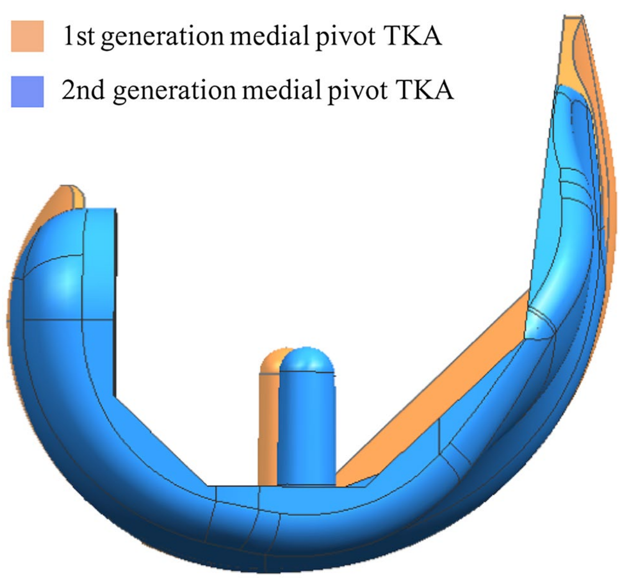

Fig. 1 Differences of the femoral component between the 1st generation and the 2nd generation medial pivot total knee prostheses. Superposition of the 1st generation (orange) and the 2nd generation (blue) medial pivot total knee protheses, showing a decrease in the overhang of the posterior condyle in the new design, which could reduce the gap tension in the position of full knee flexion. *TKA* total knee arthroplasty

Materials and methods

Patient identification

All consecutive patients who underwent TKAs using a medial pivot prosthesis (ADVANCE Medial Pivot™ or EVOLUTION Medial Pivot Knee System™) at our hospital between January 2006 and June 2015 were eligible for this study. We included patients who underwent TKA for knee joint osteoarthritis (OA), with a varus deformity and could answer a questionnaire as part of their outpatient follow-up. Excluded were patients who had a valgus deformity of the knee, rheumatoid arthritis (RA), osteonecrosis of the knee, and secondary OA of the knee.

A possible 472 TKAs, contributed by 344 patients, were identified for observation of the study. Of these 144 TKAs were excluded for the following reasons: 70 used other prostheses, 21 did not adequately complete the questionnaire, 21 had knee joint RA or osteonecrosis, 12 had a valgus deformity of the knee, six were treated for secondary knee OA, and 14 underwent unicompartmental knee arthroplasty. After screening for exclusion criteria, patients in the two groups were matched, one-to-one, on age, sex, body mass index (BMI), and preoperative knee ROM; this information was obtained from patients' records. After matching, 306 TKAs, contributed by 234 patients, were included in the analysis, 153 in each of the two groups.

Prosthetic assignment and surgical technique

The 2nd generation medial pivot prosthesis was introduced in Japan in November 2012. Therefore, the 1st generation medial pivot prosthesis (1st generation group) was used from January 2006 to October 2012, and the 2nd generation medial pivot prosthesis (2nd generation group) from November 2012 to June 2015. A condylar-stabilizing (CS) type insert was used for TKAs. All surgeries were performed by a single expert surgeon (NK), using the same operative technique. Briefly, a medial parapatellar approach was used, with resection of the anterior and posterior cruciate ligaments. An intramedullary rod for the femoral component and an extramedullary rod for the tibial component were used for bone resections, and prostheses were fixed using bone cement. The bone resection was performed using the measured resection technique, and the aim of prosthetic alignment was perpendicular to mechanical alignment [14].

Table 1 Patient characteristics and preoperative parameters

Variables	2nd generation group $N = 153$	1st generation group $N = 153$	p value
Patient characteristics			
Age (year)	76 (SD 6.5; 55 to 88)	77 (SD 5.3; 57 to 89)	0.77
Sex (male: female)	23:130	18:135	0.50
BMI (kg/m^2)	24 (SD 3.2; 18 to 32)	23 (SD 2.5; 18 to 33)	0.16
Follow-up periods (months)	60 (SD 8.3; 44 to 75)	107 (SD 25; 77 to 154)	< 0.01
Preoperative parameters			
Knee extension (°)	− 5.4 (SD 6.0; -20 to 0)	− 5.0 (SD 5.4 -20 to 0)	0.59
Knee flexion (°)	114 (SD 14; 70 to 145)	114 (SD 13; 90 to 140)	0.85
KSS knee score (point)	39 (SD 7.5; 28 to 55)	41 (SD 5.3; 28 to 50)	0.18
KSS function score (point)	42 (SD 7.0; 30 to 55)	43 (SD 5.0; 35 to 55)	0.54
Femorotibial angle (°)	183 (SD 3.2; 178 to 194)	183 (SD 3.1; 173 to 193)	0.90

Mean, standard deviation, and range are provided

BMI body mass index, *KSS* knee society score, *SD* standard deviation

Data collection

The knee ROM and Knee Society Score (KSS) were evaluated at the preoperative, at 1 and 2 years after the operation, and final follow-up time points [15]. The knee joint angles were measured with a standard clinical goniometer based on the previous method [16]. The 12-item Forgotten Joint Score (FJS-12) was used to measure patient satisfaction at the final follow-up [17]. The raw FJS-12 score was transformed to a linearly scaled score from 0 to 100, using following formula: final total score = 100 − ([sum{item 1st to item 12th} − 12]/48 × 100) [9].

Alignment of the prosthesis was measured from standing short film radiographs of the knee, preoperatively and at the final postoperative follow-up, using the KSS classification (α, β, γ, δ) and the femorotibial angle (FTA), as previously described methods [18, 19]. Radiolucent line (RLL) around were evaluated following a previous report [18]. The presence of 2 mm or more of RLL, migration of prosthesis, or prosthetic alignment change were defined as loosening [1]. The operative time, complications and rate of reoperation were collected from patients' records. Postoperative complications and the definition of reoperation were determined by the surgeon, based on physical and laboratory findings. All data were collected by a physician (HU) who was not involved in treating patients included in our study.

Statement of ethics

This study was approved by our Institutional Review Board (Approved number is 00022018). Informed consent was obtained from all participants of this study.

Statistical analysis

Univariate analyses were performed to evaluate differences between the two groups, using Student's t-test for continuous variables and the chi-squared test for categorical variables. Between-group differences for each item of the FJS-12 were evaluated using the Mann–Whitney *U* test, as appropriate for an ordinal dependent variable. Multivariate linear regression analysis was performed to identify which factors (age, sex, BMI, operative time, follow-up period, preoperative knee ROM, preoperative FTA, and prosthetic design) influenced postoperative knee flexion [20]. A previous study reported the correlation between pre- and postoperative knee ROM [20]. Considering the multicollinearity between these two measures, only the postoperative knee ROM was included in the multivariate linear regression analysis to identify factors influencing the total FJS-12 score. Our choice is also consistent with that of a previous study which identified postoperative ROM as a more suitable predictor of patient satisfaction [12]. The prosthesis survival rate was analyzed using the Kaplan–Meier method, with a log-rank test during the follow-up period between two groups.

A power analysis was performed to determine the number of knees needed to detect a difference of 5 degrees, with a standard deviation (SD) of 15 on the ROM or a difference of 13 points, with a SD of 30 on the total FJS-12, based on previous literatures [9, 21]. A total of 142 knees or more per group for ROM and 84 knees or more per group for FJS-12 were determined to achieve a statistical power of 80%, with the two-sided alpha set at 0.05. Therefore, the 153 TKAs in this study was considered sufficient. Statistical significance was defined as a p-value < 0.05. Statistical analyses were performed using the R software package (version 3.1.1) [22].

Table 2 Postoperative parameters

Variables	2nd generation group $N=153$	1st generation group $N=153$	*p* value
Knee Extension(°)			
at 1 year after operation	− 1.0(SD 2.1; − 10 to 0)	− 1.1(SD 1.6; − 10 to 0)	0.86
at 2 years after operation	− 0.6(SD 2.1; − 10 to 5)	− 0.6(SD 1.6; − 10 to 5)	0.76
at final follow-up	− 0.3(SD 1.8; − 10 to 5)	− 0.3(SD 1.4; − 10 to 5)	0.92
Knee Flexion(°)			
at 1 year after operation	117(SD 17; 80 to 130)	110(SD 15; 75 to 125)	0.03
at 2 years after operation	122(SD 17; 80 to 140)	117(SD 11; 80 to 130)	0.01
at final follow-up	127(SD 9.7; 80 to 140)	118(SD 10; 90 to 135)	<0.01
KSS knee score(point)			
at 1 year after operation	78(SD 6.8; 50 to 85)	79(SD 7.2; 60 to 85)	0.82
at 2 years after operation	84(SD 8.2; 60 to 95)	83(SD 5.8; 65 to 90)	0.71
at final follow-up	87(SD 7.5; 65 to 95)	88(SD 5.5; 70 to 100)	0.20
KSS function score(point)			
at 1 year after operation	86(SD 8.5; 45 to 90)	86(SD 7.6; 65 to 95)	0.59
at 2 years after operation	89(SD 6.8; 50 to 100)	88(SD 5.9; 65 to 95)	0.43
at final follow-up	90(SD 7.5; 50 to 100)	91(SD 5.5; 75 to 100)	0.46
Femorotibial angle(°)	177(SD 1.4; 174 to 180)	176(SD 1.2; 173 to 179)	0.15
Thickness of polyethylene insert			
10 mm	115(75%)	110(72%)	0.75
12 mm	33(22%)	39(25%)	
14 mm	5(3.3%)	4(2.6%)	
Prosthetic alignment(°)			
α	94(SD 1.4; 90 to 97)	94(SD 1.4; 90 to 99)	0.15
β	91(SD 2.0; 82 to 95)	91(SD 2.0; 81 to 95)	0.11
γ	2.3(SD 1.6; − 2.3 to 6.7)	2.2(SD 1.7; − 2.0 to 6.3)	0.72
δ	2.4(SD 3.6; − 0.4 to 4.5)	2.6(SD 4.0; − 1.0 to 4.6)	0.61
Radiolucent line(case, %)	5(3.3%)	13(8.5%)	0.09
Survival rate(%)	98.0	96.7	0.75
Reasons of reoperations(case, %)			
Hyperextension	2(1.3%)	2(1.3%)	0.99
Periprosthetic fracture	1(0.7%)	2(1.3%)	0.99
SSI	0(0%)	1(0.7%)	0.99

Mean, standard deviation, and range are provided. Reoperation for any reasons was the end-point for determining the survival rate during follow-up period

BMI body mass index, *SSI* surgical site infection, *SD* standard deviation

Results

The 2nd generation group included 153 TKAs, contributed by 116 patients, and the 1st generation group 153 TKAs, contributed by 118 patients. Patient characteristics are presented in Table 1 and were not statistically significant between the two groups, except for the length of the follow-up period. This difference in length of follow-up is natural because the two groups were assigned historically.

Postoperatively, the average knee flexion angle was 127° (80°–140) in the 2nd generation group, compared to 118° (90°–135°) in the 1st generation group at the final follow-up ($p<0.01$). The knee flexion angle was statistically greater in the 2nd generation group than in the 1st generation group at 1 and 2 years postoperatively (Table 2). Other measured postoperative parameters (knee extension range KSS knee score, KSS function score, FTA, prosthetic alignment, and RLL) were similar between the two groups. There was no aseptic loosening in all cases. Intraoperative complications, such as periprosthetic fracture, were not identified in our case series. There were three cases of reoperation in the 2nd generation group (2.0%) and five in the 1st generation group (3.3%), which was not different. As well, the prosthesis survival rate was not different between the two groups ($p=0.75$; Fig. 2). The details of reoperation are reported in Table 2, and included: exchange of the polyethylene insert,

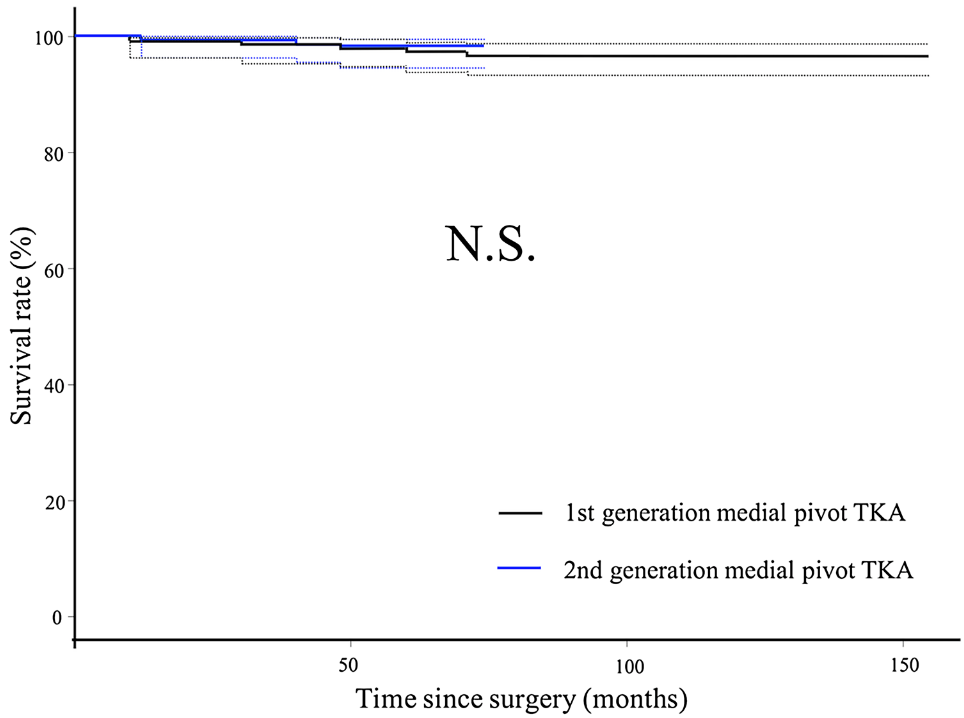

Fig. 2 The Kaplan–Meier survival curve for the 1st generation and the 2nd generation medial pivot total knee prostheses. The survival curves are not significantly different between the two types of prostheses (log-rank test), with the end-point of observation defined as reoperation due to any reason. Dashed lines represent the 95% confidence intervals. *N.S.* not significant

Table 3 Details of the FJS-12 score

Question: are you aware of your artificial joint when?	2nd generation group $N = 153$	1st generation group $N = 153$	*p* value
Total score	66(SD 20; 0–100)	60(SD 21; 0–100)	0.01
Q1. In bed at night	1.8(1–2)	1.8(1–3)	0.70
Q2. Sitting in chair > 1 h	1.8(1–2)	1.8(1–3)	0.79
Q3. Walking for > 15 min	2.1(1–3)	2.3(2–4)	0.11
Q4. Taking a bath/shower	2.0(1–2)	2.0(2–3)	0.99
Q5. Traveling in a car	1.8(1–2)	1.9(2–3)	0.89
Q6. Climbing stairs	2.6(2–4)	2.6(2–4)	0.98
Q7. Walking on uneven ground	2.3(2–3)	2.7(2–5)	0.04
Q8. Standing up from a low-sitting position	2.7(2–4)	3.1(2–5)	< 0.01
Q9. Standing for long periods of time	2.6(2–4)	2.5(2–4)	0.52
Q10. Doing housework/gardening	2.5(2–3)	2.4(2–3)	0.85
Q11. Taking a walk/hike	2.4(2–3)	2.5(2–4)	0.39
Q12.Doing your favorite sport	2.2(2–3)	2.1(2–3)	0.25

Mean, standard deviation, and range are provided for the total FJS-12 score; with the mean and quartile (25% to 75%) provided for each item. The range of each question is 1 (never aware) to 5 (mostly aware)

FJS forgotten joint score, *Q* question, *h* hour, *min* minute

due to hyperextension, in four knees; open reduction and internal fixation for treatment of a periprosthetic fracture in three knees; and irrigation and debridement due to a SSI in one case.

The total FJS-12 scores were better for the 2nd generation than the 1st generation group ($p < 0.01$). The total score and individual item FJS-12 scores are reported in Table 3. Scores on item 7 (walking on uneven ground) and 8 (standing up from a low-sitting position) were also better for the 2nd generation than the 1st generation group ($p = 0.04$ and $p < 0.01$).

On multivariate analysis, preoperative knee flexion and the type of implant were predictive of postoperative knee flexion (Table 4). In addition, postoperative knee flexion predicted the total FJS-12 score (Table 5).

Table 4 Multiple linear regression model for postoperative knee flexion

Independent variables	Unstandardized coefficient (95% CI)	β	*p* value
Intercept	89.8(64.4 to 115)		
Age	0.01(− 0.20 to 0.21)	0.04	0.97
Sex (male = 0, female = 1)	0.66(− 3.46 to 4.78)	0.32	0.88
BMI	− 0.03(− 0.43 to 0.37)	− 0.16	0.87
Follow-up period	− 0.01(− 0.08 to 0.06)	− 0.29	0.77
Implant (1st generation = 0, 2nd generation = 1)	9.37(5.38 to 13.3)	4.63	< 0.01
Preoperative knee extension	0.14(− 0.07 to 0.35)	1.29	0.20
Preoperative knee flexion	0.26(0.17 to 0.36)	5.80	< 0.01

The fit parameters of the model are as follows: R^2 0.31, and adjusted R^2 0.29. The model included 260 estimates

BMI body mass index, *CI* indicates confidence interval, *β* standardized coefficient

Overall, compared to patients who underwent TKA using the 1st generation prosthesis, patients in whom the 2nd generation prosthesis was used showed better knee flexion and total FJS-12 scores at the end of their follow-up period.

Discussion

The newly designed 2nd generation medial pivot prosthesis improved postoperative knee flexion and patient satisfaction. To our knowledge, this is the first study with adequate follow-up to clarify improvement in postoperative knee flexion with the 2nd generation medial pivot prosthesis, compared to the 1st generation medial pivot prosthesis.

Our study design offers two specific advantages for comparing the 2nd generation to the 1st generation medial pivot prostheses. First, all TKAs were performed by the same surgeon, using the same operative technique, at one institution. As such, the pre-, peri- and postoperative care was comparable for all patients. Second, the measured outcomes were obtained by one independent observer who was not involved in the care of patients included in the study group. These advantages of our study design allowed us to compare the effects of the prosthesis design specifically, excluding bias related to the surgery and care, to the extent possible. We also matched cases one-to-one between the groups to control for patient-related factors, to the extent possible.

Preoperative knee flexion is widely recognized as one of the factors which influence postoperative knee flexion [20]. Therefore, the preoperative knee ROM in the patients' background was matched before assessment of clinical outcomes in this study. Postoperative knee flexion angles were assessed at 1 and 2 years postoperatively in the two groups. The knee flexion angles were significantly greater in the 2nd generation prosthesis at both time points. Moreover, on multivariate analysis, which controls for confounding factors, such as preoperative knee flexion or follow-up periods, prosthesis selection was identified as the predictor for final postoperative knee flexion, confirming the advantage of the design features of the 2nd generation medial pivot prosthesis in increasing postoperative knee flexion.

The tension of the knee joint gap in the full flexion position is one of the predictors of postoperative knee flexion [13]. The decrease in the overhang of the posterior condyle in the 2nd generation medial pivot prosthesis would reduce this tension at the end range of knee flexion. In fact, the postoperative range of flexion achieved with the 2nd generation medial pivot prosthesis was comparable to the range obtained using a posterior stabilized-TKA, which is recognized for providing good postoperative knee flexion [23, 24]. A previous report also showed that asymmetrical tibial

Table 5 Multiple linear regression model for the total FJS-12 score

Independent variables	Unstandardized coefficient (95%CI)	β	*p* value
Intercept	28.7 (− 26.9 to 84.2)		
Age	− 0.02 (− 0.45 to 0.42)	− 0.07	0.95
Sex (male = 0, female = 1)	− 4.54 (− 13.9 to 4.27)	− 1.53	0.13
BMI	− 0.53 (− 1.40 to 0.33)	− 1.23	0.22
Follow-up periods	0.03 (− 0.13 to 0.17)	0.32	0.75
Implant (1st generation = 0, 2nd generation = 1)	4.70 (− 4.56 to 13.9)	4.71	0.32
Postoperative knee extension	− 0.09 (− 1.77 to 1.57)	− 0.11	0.91
Postoperative knee flexion	0.37 (0.11 to 0.63)	2.79	< 0.01

The fit parameters of the model are as follows: R^2 0.10, and adjusted R^2 0.08. The model included 240 estimates

BMI body mass index, *CI* indicates confidence interval, *β* standardized coefficient tray improved coverage and rotational alignment in medial pivot prosthesis [25]. Malrotation of the tibial tray has been reported to result in knee ROM restriction [26]; therefore, the prosthetic design change into an asymmetrical tibial tray could improve knee ROM.

The total FJS-12 score was significantly better in 2nd generation than 1st generation medial pivot prostheses, with postoperative knee flexion being the only factor retained on multivariate analysis to predict the FJS-12 score. This means that patients in whom the 2nd generation medial pivot prosthesis was used for TKA were more satisfied with their TKA as greater knee flexion was recovered after surgery then the range after TKA using the 1st generation medial pivot prosthesis.

The risk of failure needs to be considered with the introduction of a new prosthesis design or materials. As such, an adequate follow-up focused on clinical results, compared to a proven prosthesis, is important to determine the benefits of a new prosthesis to patients. Our study included a relatively large cohort of 157 patients in each group, followed for 5 years, which is reasonable for evaluating the early phase of clinical results after surgery [27]. No previous study evaluating the EVOLUTION™ prosthesis has had sufficient follow-up [9, 28]. Our study indicated that patient satisfaction with this 2nd generation medial pivot prosthesis was good at a mean of 5-years after surgery, with no critical failure noted over this period of follow-up.

There are some limitations to our study that should be noted. First, this is a retrospective cohort study. We included safeguards to control for bias: having all surgeries performed by one surgeon, using the same operative technique, with both prosthesis types fabricated by the same manufacturer, using an independent observer to quantify outcomes, one-to-one matching of patients on factors known to influence outcomes, and ensuring identical postoperative care between the two groups. Therefore, we have tried to minimize biases associated with a retrospective design. Second, the assignment of the type of prosthesis used for TKA was historical and the length of follow-up was different between the two groups. We used a multivariate regression analysis to further control the effects of confounding factors, including the period of follow-up. Third, the detailed longitudinal changes regarding FJS-12 were not measured in this study. Future research focused on these issues is desirable. Moreover, the minimal clinically important difference for FJS-12 has been reported to be 14 points in patients who underwent TKA [29]. Although the result of FJS-12 in this study was statistically significant, a further study is warranted to determine a clinical significance. Fourth, a long lower-leg X-ray was not taken in this study to minimize radiation exposure. Therefore, the alignment of a long lower extremity was not measured using a long lower-leg X-ray.

Conclusion

Our 5-year follow-up study provided evidence of the advantages of the 2nd generation medial pivot prosthesis over the 1st generation medial pivot prosthesis in improving postoperative knee flexion and patient satisfaction.

Acknowledgements We appreciate the contributions from all group members in the medical stuff of Osaka City University and Tanabe Central Hospital.

Funding This study was not supported by any funding agencies in the public, commercial, or not-for-profit sectors.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

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