Early Patellofemoral Function of Unilateral TKA with Medial Pivot Prostheses is Superior than with Conventional Posterior-Stabilized Prostheses

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Abstract

Purpose
The purpose of this study was to provide a systematic evaluation of the patellofemoral joint design of Medial Pivot Prosthesis, which incorporates a variety of “Patella-friendly” design features, by comparing clinical and radiographic results with another prosthesis.

Methods
Early clinical and radiographic results of patients who underwent unilateral TKA with Medial Pivot Prosthesis (The study group, including 126 cases) and conventional Posterior-Stabilized Prosthesis (The control group) were retrospectively compared. Postoperative complications, including anterior knee pain, maltracking, patellar clunk or crepitus (PCC), were evaluated.

Results
The postoperative Kujala score and its improvement from baseline in the study group (Group A) were significantly higher than those in the control group (Group B). The range of motion (ROM) in group A, including the improvement in ROM, was significantly inferior to group B. In the 90-degree Merchant view, the patellar tilt in group A was smaller than that in group B. Two cases of PCC and 3 cases of anterior knee pain were noted in group A, and 9 cases and 6 cases, respectively, were observed in group B. The incidence of PCC was significantly lower in group A. There were no significant between-group differences in the patella tilt angle at 30 or 60° or in the postoperative patellar translation at 30, 60 or 90°. No between-group difference in posterior condyles angle (PCA) was observed. The KSS scores and WOMAC scores between the two groups were similar.

Conclusion
The medial pivot prosthesis could achieve satisfactory outcomes with superior patellofemoral performance attributed to its “patella-friendly” design characteristics compared to the conventional posterior-stabilized prosthesis.

Introduction
Historically, patellofemoral complications have accounted for 50% of revision surgeries[1]. With the development of contemporary designs and improvements in surgical techniques, complication rates
have decreased but remain the most challenging problem after TKA[2]. The incompatible patellofemoral joint design may result in multiple postoperative complications, including patellar anterior knee pain, maltracking, patellar clunk syndrome (PCC) and avascular necrosis[3]. Several in vitro studies have found that patellofemoral kinematics were altered after TKA and that patellofemoral joint pressure was increased compared with the natural knee[4, 5]. The use of a knee prosthesis capable of reconstructing normal patellofemoral joint movement and with low patellofemoral joint pressure might be beneficial in reducing postoperative patellofemoral joint complications [6].

The medial pivot femoral prosthesis incorporates a variety of design features that facilitate the reconstruction of natural patellofemoral joint relationships. The femoral prosthesis design features that affect patella function include the shape and depth of the trochlear groove, the thickness of the anterolateral condylar, and the sagittal curve[7-10]. “Patella-friendly” design features of the medial pivot femoral component include a sagittal plane with a single radius of curvature, extending posteriorly and deepening to the natural depth of the trochlear groove, and an elevated lateral edge. Based on these theoretical advantages, the design features of the medial pivot prosthesis may decrease the risk of patellofemoral joint problems[11, 12]. Several studies have reported clinical satisfaction and survival analysis of TKA for this prosthesis[13-16], however, the comparison of clinical and radiographic results of this prosthetic patellofemoral joint with another prosthesis was rare[11].

The total condylar knee prosthesis, based on the concept of the “four-bar link model”, was designed in 1973. This classic knee prosthesis is widely used in the treatment of knee osteoarthritis due to excellent clinical and radiological results after surgery[17]. The prototype design used today is considered the gold standard for clinical outcome evaluation after TKA [18]. The conventional posterior stabilized knee prosthesis (cruciate-substituting), one of the classic knee prostheses, is currently widely used in clinical applications. The NexGen LPS-Flex prosthesis is the most representative of this kind of prosthesis. The variable sagittal curvature of the femoral prosthesis results in the motion curve being "frame-like", increasing the risk of poor patella tracking and
intraoperatively releasing the lateral retinaculum[19].

This study retrospectively compared the clinical and radiographic results of TKA using the medial pivot prosthesis with conventional posterior-stabilized prosthesis by a matched pair analysis. The hypothesis of the study was that early clinical and radiological results of the medial pivot prosthesis would be comparable or better than those of conventional posterior-stabilized prosthesis, especially in aspects related to patellofemoral function.

Methods

After obtaining the approval of the institutional review board of our hospital and of our patient, all consecutive patients who underwent a unilateral TKA with a medial pivot implant (Advance® Medial Pivot, Wright) between September 2016 and April 2018 were enrolled in this retrospective study.

Inclusion criteria: (1) Diagnosed knee osteoarthritis according to the latest diagnostic criteria of the American Rheumatic Society; (2) Unilateral TKA; and (3) Agreement to follow up for at least one year.

Exclusion criteria: (1) Previous patellectomy and high tibial osteotomy; (2) A history of septic arthritis and rheumatoid arthritis; (3) Valgus deformity more than 15 degrees or varus deformity more than 20 degrees; (4) Flexion angle less than 90 degrees, flexion contracture more than 20 degrees. During this period, a total of 130 patients were included in the study group (group A). According to patients’ clinical and demographic characteristics, including age, gender, side, body mass index (BMI), and range of motion (ROM), we matched a control patient who received a posterior-stabilized prosthesis (NexGen LPS-Flex, Zimmer, Warsaw, IN) during study period for each patient in group A.

A total of 4 patients were excluded because of loss of follow-up in group A, leaving 126 for analysis. The preoperative demographic and clinical results of the remaining patients are summarized in Table 1. Group A was composed of 102 females and 24 males. The average age was 66.9 years (range, 54–78 years). The right knee was involved in 54 cases, and the left knee was involved in 72 cases. The mean body mass index (BMI) was 27.7 kg/m2 (range, 19.3-38.7 kg/m2). Correspondingly, the control group (group B) was composed of 104 females and 22 males. The average age was 67.1 years (range, 52–79 years). The right knee was involved in 57 cases, and the left knee was involved in 69 cases. The mean BMI was 27.9 kg/m2 (range, 19.7-36.9 kg/m2). There were no significant differences in the
demographics or clinical characteristics between the two groups.

All TKAs were implanted by the same surgeon (YZW) who had performed more than 500 cases annually. The surgical principles and postoperative rehabilitation protocol were similar between groups A and B. Briefly, under tourniquet control, knees were exposed through a midvastus approach. Osteotomy was performed by measurement. The femoral prosthesis was implanted at 3° external rotation relative to the posterior condylar axis and 5° valgus relative to the coronal femoral mechanical axis. The rotation of the tibial prosthesis was aligned with reference to the medial one-third of the tibial tubercle. The proximal tibial osteotomy was located 10 mm below the highest point of the articular cartilage on the lateral tibial plateau, perpendicular to the long axis of the tibial coronal plane, with a 3° posterior slope in the sagittal plane. All patellae were unresurfaced and de-nerved with electrocautery. No lateral retinacular release was performed. Patients initiated passive ROM exercise with CPM machine and partial weight-bearing walking training on postoperative day 2.

The clinical results were assessed at the preoperative and final follow-up periods according to the Knee Society’s KSS and the WOMAC Index. Clinical results related to patellofemoral joint symptoms were evaluated using the Kujala scoring system, which is widely used to assess subjective symptoms and functional limitations in patellofemoral disorders[20]. At pre-operation and at the last follow-up, Merchant views were taken with the knee flexion at 30, 60, and 90° to measure patella shift and tilt (Fig. 1)[21]. Patella tilt was formed by the angle between the transverse axis of the patella and the anterior intercondylar line. A positive value of patella tilt indicated that the transverse axis of the patella was tilted outward relative to the anterior intercondylar line[21]. Patella shift was defined as the distance between the intercondylar sulcus and the median ridge of the patella. When the median ridge of the patella was on the lateral side relative to the intercondylar sulcus, we define the shift as a positive value; otherwise, it was considered a negative value[21]. Since the measurement of the patella tilt was based on the anterior intercondylar line, the femoral prosthesis rotation was the main factor influencing the position of the anterior intercondylar line. In addition, rotational deviation of the femoral prosthesis was one of the factors affecting the function of and complications associated with the patellofemoral joint[22]. It is necessary to determine whether there was a significant difference in
the external rotation between the two groups. The measurement of the posterior condylar angle (PCA) was taken at pre-operation and at the last follow-up (Fig. 2). A standard GE Medical Systems CT scanner was used to evaluate the PCA of each knee. The fully extended knee joint was scanned from the distal metaphysis to the tibial tubercle.

To reduce measurement bias, radiographic results were obtained and analysed by the same independent orthopaedic surgeons preoperatively and at the final follow-up. Imaging results were measured three times, then averaged to obtain the final measurements. Images were read on a PACS General Electric, Chicago, IL, USA monitor and measured with a mouse pointer and automatic computer calculations.

The clinical scores, ROM and radiographic measurements at the last follow-up were compared (Student’s t test). The preoperative/postoperative improvement of the above indicators between the two groups was also compared. The difference in the incidence of postoperative complications between the two groups was compared (χ² test). SPSS (IBM Corporation, USA) version 20.0 was used for the statistical analysis. P <0.05 was defined as statistically significant.

Results

Clinical Results

Postoperative clinical results and changes in the results are summarized in Table 2. No statistically significant difference was identified in the KSS total score, including knee score and function score, or in the WOMAC score between the two groups after the operation. No statistically significant difference was identified in the preoperative/postoperative improvements of the above clinical scores. However, we found statistically significant differences in the postoperative Kujala scores and the ROMs between the two groups. The mean Kujala score in group A was better than in group B, while the ROM in group B was significantly higher than in group A. Simultaneously, the preoperative/postoperative Kujala score improvement in group A was observed to be significantly larger than in group B, but the average ROM improvement was significantly different in favour of group B.

Radiographic Results

The imaging measurement data are summarized in Table 3. Postoperative PCA did not show
significant differences between the two groups. No significant between-group difference was observed in the Merchant view at 30 or 60° of patella tilt; however, at the 90° position, the mean patella tilt of group A was statistically smaller than that of group B. There were no statistically significant differences in the patella shift between the two groups at 30, 60 and 90°.

**Complications**

At the last follow-up, 3 cases of anterior knee pain and 2 cases of PCC in group A and 6 cases and 9 cases, respectively, in group B were observed. Compared with group B, the incidence of PCC was significantly lower in group A. There were no periprosthetic infections, loosenings, or incidences of patellar maltracking.

**Discussion**

This study illustrates that the medial pivot prosthesis could achieve satisfactory early clinical outcomes with superior patellofemoral performance compared to the conventional posterior-stabilized prosthesis. In the early development of total knee prostheses, the tibiofemoral joint design was considered most important, with little attention paid to the design of the patellofemoral joint. Cases of revision due to patellofemoral joint complications had been as high as 50% of the total revision rate[1]. With the continuous improvement in and development of prosthetic design and surgical techniques, there are significantly fewer patellofemoral joint complications than before; however, patellofemoral joint problems are still a common complication after TKA. Compared with the natural knee joint, the kinematics of the patellofemoral joint are changed and the pressure of the patellofemoral joint are increased after TKA[4, 5, 28]. It has been reported that using a knee prosthesis that could reconstruct the natural patellofemoral joint movement and achieve low patellofemoral pressure would be beneficial in improving patellofemoral function[6]. Despite claims of a theoretical advantage in the “patella-friendly” design characteristics of the medial pivot prosthesis, no previous prospective clinical study focused on comparing the patellofemoral joint of this prosthesis with other total knee prostheses.

The femoral component of the MP prosthesis incorporates a variety of design features that facilitate the reconstruction of natural patellofemoral joint relationships. The femoral component has a single
radius of curvature in the sagittal plane from fully extended to 90 degrees, which is closer to the anatomy of the natural knee[29]. The depth of the natural trochlear groove is restored, so “overfilling” could be effectively avoided in front of the knee, which would be beneficial for extension devices to function normally[7, 9]. The anterior lateral edge is 3 mm-4 mm higher than the bottom of the trochlear groove, which is an essential feature for maintaining the patella track in early knee flexion [30]. In addition, the trochlear groove extends backwards so that the patella could also fully contact the femoral prosthesis in deep knee flexion[31].

In this study, the Kujala score, which is widely used to assess functional limitations and subjective symptoms in patellofemoral disorders and TKAs, was 77.16±3.80 in group A, which was significantly better than the 75.97±4.06 in group B. We also evaluated differences in the postoperative improvement of the Kujala scores from the preoperative baseline, with group A predominating. In the 90-degree Merchant view, the patella tilt in group A was smaller than in group B. It has been reported that the incidence of patellar clunk increases by 1.27 for each degree raise in patellar tilt[32]. We believed that group A was also superior to group B in terms of imaging performance. The advantage was attributed to the use of a prosthesis with “patella-friendly” properties and the characteristics of the reconstructed natural patellofemoral joint.

PCC is presumably attributed to fibrous nodule impingement after TKA[33], especially the overgrowth of fibrous tissue where the extensor mechanism is attached to the upper pole of the patella[34, 35]. Several surgeons recommended surgical intervention, such as arthroscopic excision of the nodule [23, 36, 37], as a treatment option for disabled patients with persistent, painful PCC after nonoperative management. In this study, 2 cases of patellar clunk syndrome were noted in group A, and the incidence was significantly lower compared to the 9 cases in group B and previous studies( Table 4) [23-27]. We had 2 cases in group B with painful PCC, which did not reach the point where surgery was needed and were treated with nonoperative management including anti-inflammatory medication and physical therapy for pain relief. It has been reported that some femoral prosthesis designs for total knee prosthesis systems are associated with a high incidence of PCC, the most notable of which was the posterior stabilized knee prosthesis[34, 38, 39]. The fibrous tissue impinges on the intercondylar
box of the femoral component when the knee flexes more than 90°[40]. Fukunaga K. et al. [23] indicated that when the length ratio of the intercondylar box/anteroposterior femoral components of the femoral prosthesis are less than 0.7, the incidence of PCC is significantly reduced. The posterior extension of the MP femoral prosthetic trochlear groove reduces the ratio of the intercondylar box, making the patella trajectory more natural[31].

Mihalko, W. et al. [41] reported that knee mobility is associated with "overfilling" of the patellofemoral joints; each 4 mm thick increase in the front of the femoral prosthesis will result in a reduction in knee flexion by 4°. The advance MP femoral prosthetic groove is deepened to the natural anatomical level, which could minimize the "overfilling" of the patellofemoral joint and improve knee joint mobility. Hossain et al.[42] conducted a randomized controlled trial with a greater improvement in MP prosthesis mobility 1 and 2 years after surgery compared with PS prostheses. In the present study, group B performed superior to group A in terms of postoperative activity improvement, while the improvement in the Kujala score in group A was better than in group B; however, similar KSS and WOMAC scores were recorded in the two groups. There are two hypotheses for this similarity between the groups: one, knee mobility may be taken into account in the KSS and WOMAC scores, compensating for the deficiency in the Kujala score in group B; two, the KSS and WOMAC clinical scoring systems may have been subjected to a ceiling effect[43], resulting in the scoring systems not being sensitive enough to determine between-group differences.

Patellofemoral complications after TKA can reduce patient satisfaction and even lead to revision surgery. Increasing evidence has shown that proper surgical techniques[44-46] and optimizing prosthesis design[8, 47] could reduce the incidence of patellofemoral complications. In addition to optimized surgical skills, it is equally important to choose a prosthesis that is beneficial to the patellofemoral joint, especially for patients with a preoperative risk of patellofemoral complications, such as dysplastic trochlea, subluxation of the patella or malrotation of the distal femur[32]. The prosthesis with “patella-friendly” design features used in this study would be an optimal option, which could achieve excellent patellofemoral performance while resulting in a clinical evaluation similar to that with conventional PS prosthesis.
This study has limitations in the loss of follow-up and the rather short time of follow-up. Long-term follow-up is needed to obtain patellofemoral clinical scores, especially for the incidence of patellofemoral complications. Another limitation was the evaluation of patella tracking by X-ray; the evaluation of patellofemoral tracking includes static and dynamic factors, and CT or MRI might be a more sensitive and accurate method for assessing the position of the patella[48]. However, compared to the previous clinical study, we evaluated the patella tilt and shift more comprehensively from three different angles[11]. Furthermore, we excluded PCA factors that may have had an impact on patella tilt.

Conclusion
In summary, unilateral TKA with a medial pivot prosthesis can yield satisfactory outcomes with superior patellofemoral performance attributed to the prosthesis’ “patella-friendly” design characteristics compared with a conventional posterior-stabilized prosthesis. The theoretical advantages of medial pivot prosthesis, combining multiple characteristics to optimize patellofemoral function, were clinically proven.

Abbreviations
BMI: body mass index
KSS: Knee Society Score
WOMAC: Western Ontario McMaster Universities Osteoarthritis Index
ROM: range of motion
PCA: posterior condyles angle
PCC: patellar clunk or crepitus
MP: Medial Pivot
PS: Posterior Stabilized
TKA: total knee arthroplasty

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Declarations

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Availability of data

The full dataset is available from the first and corresponding authors upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

All participants agree to the publication of this paper.

Ethics approval and consent to participate

This study was approved by the Institutional Review Board of the affiliated hospital of Qingdao University. Written informed consent was obtained from all patients enrolled in the investigation.
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**Authors’ contributions**

HX designed the study and critically revised the manuscript. ZW carried out the data analyses, and drafted the manuscript. YQZ and CRD contributed in revising the manuscript. XYC and LG were responsible for the data collection and measurement of radiographic data. YZW performed all the surgeries. All authors read and approved the final manuscript.

**Tables**

Table 1. Preoperative demographic and clinical results
|               | Group A (MP) | Group B (PS) | t or χ² | p-Value |
|---------------|--------------|--------------|---------|---------|
| No. of cases  | 126          | 126          |         |         |
| Age (y)       | 66.92±5.60   | 67.15±6.01   | -0.31   | 0.75    |
| Gender(male/female) | 24/102     | 22/104       | 0.11    | 0.74    |
| Side (right/left) | 54/72       | 57/69        | 0.15    | 0.70    |
| BMI          | 27.74±4.63   | 27.90±4.39   | -0.28   | 0.78    |
| KSS          | 113.56±16.99 | 114.05±17.91| -0.22   | 0.82    |
| Knee score   | 55.36±12.48  | 54.41±13.89  | 0.57    | 0.57    |
| Function score | 58.20±10.19 | 59.63±9.84   | -1.14   | 0.26    |
| WOMAC score  | 53.55±11.34  | 52.26±15.06  | 0.76    | 0.45    |
| Kujala score | 49.34±5.13   | 49.80±5.40   | -0.69   | 0.49    |
| ROM          | 96.30±11.47  | 94.85±12.08  | -0.98   | 0.32    |
| PCA          | 5.29±1.56    | 5.54±1.39    | -1.32   | 0.19    |
| Patellar tilt 30° | 3.42±2.88  | 3.21±3.41    | 0.52    | 0.60    |
| Patellar tilt 60° | 6.12±2.53  | 5.84±2.43    | 0.89    | 0.38    |
| Patellar tilt 90° | 8.04±2.31  | 7.98±2.23    | 0.23    | 0.82    |
| Patellar shift 30° | 0.14±2.92 | 0.36±2.76    | -0.61   | 0.54    |
| Patellar shift 60° | 1.61±3.28  | 1.76±3.02    | -0.39   | 0.70    |
| Patellar shift 90° | 3.36±3.48  | 3.63±2.87    | -0.66   | 0.51    |
| Follow-up periods (y) | 1.64±0.29 | 1.65±0.27    | -0.20   | 0.84    |

*BMI* Body mass index, *KSS* Knee Society Score, *WOMAC* Western Ontario McMaster Universities Osteoarthritis Index, *ROM* range of motion, *PCA* posterior condyles angle

*P* < 0.05 was defined as statistically significant
| Group          |                            | Group A (MP)     | Group B (PS)     | t or χ²  | p-Value |
|---------------|----------------------------|------------------|------------------|----------|---------|
| Postoperative | KSS                        | 175.43±8.89      | 174.25±6.75      | -1.18    | 0.24    |
|               | Knee score                 | 86.89±4.45       | 86.31±4.04       | 1.07     | 0.29    |
|               | Function score             | 88.54±6.21       | 87.93±5.53       | 0.82     | 0.42    |
|               | WOMAC score                | 14.65±7.32       | 13.65±10.04      | 0.91     | 0.36    |
|               | Kujala score               | 77.16±3.80       | 75.97±4.06       | 2.40     | 0.017   |
|               | ROM                        | 118.27±4.38      | 119.75±6.04      | 2.24     | 0.026   |
| Changes       | KSS                        | 61.87±15.79      | 60.20±17.80      | 0.79     | 0.43    |
|               | Knee score                 | 31.90±11.20      | 31.85±14.07      | -0.23    | 0.82    |
|               | Function score             | 30.34±11.95      | 28.30±10.18      | 1.46     | 0.15    |
|               | WOMAC score                | 38.89±12.96      | 38.61±17.63      | 0.14     | 0.89    |
|               | Kujala score               | 27.82±5.31       | 26.17±4.89       | 2.57     | 0.011   |
|               | ROM                        | 21.97±9.75       | 24.90±9.29       | 2.46     | 0.014   |
| Complication  | anterior knee pain         | 3                | 6                | 1.04     | 0.31    |
|               | PCC                        | 2                | 9                | 4.66     | 0.03    |
|               | subluxation                | 0                | 0                | -        | -       |

**KSS** Knee Society Score, **WOMAC** Western Ontario McMaster Universities Osteoarthritis Index, **ROM** range of motion, **PCC** patellar clunk or crepitus

P < 0.05 was defined as statistically significant

Table 3. Postoperative radiographic results and tilt changes
| Group                  | Group A (MP)  | Group B (PS)  | t   | p-Value |
|-----------------------|---------------|---------------|-----|---------|
| Postoperative PCA     | 3.06±1.53     | 2.90±1.49     | 0.82| 0.42    |
| Patellar tilt 30°     | 1.22±1.90     | 1.10±2.07     | 0.47| 0.64    |
| Patellar tilt 60°     | 2.66±1.68     | 2.70±1.89     | -0.20| 0.84 |
| Patellar tilt 90°     | 4.21±1.62     | 4.74±1.95     | -2.38| 0.018 |
| Patellar shift 30°    | -0.83±1.38    | -0.48±1.69    | -1.82| 0.70 |
| Patellar shift 60°    | 0.63±1.63     | 1.02±1.85     | -1.79| 0.08 |
| Patellar shift 90°    | 2.12±1.81     | 2.31±1.94     | 0.82| 0.41 |
| Changes               | Patellar tilt 30° | -2.19±1.73 | -2.10±1.92 | -0.39| 0.70 |
| Patellar tilt 60°     | -3.45±1.60    | -3.13±1.59    | -1.61| 0.11 |
| Patellar tilt 90°     | -3.84±1.43    | -3.23±1.33    | -3.47| 0.001 |

PCA posterior condyles angle

P < 0.05 was defined as statistically significant

Table 4. The incidence of PCC reported in previous studies

| Study                 | year | Number of knees | Prostheses                      | Incidence (%) |
|-----------------------|------|-----------------|---------------------------------|---------------|
| Fukunaga et al.[23]   | 2009 | 113             | Press-Fit Condylar® Sigma®      | 13.3          |
| Frye et al.[24]       | 2012 | 108             | Press-Fit Condylar® Sigma®      | 12.0          |
| Choi et al.[25]       | 2013 | 113             | Press-Fit Condylar® Sigma®      | 9.7           |
| Gholson et al.[26]    | 2017 | 1488            | Press-Fit Condylar® Sigma®      | 3.1           |
| Bae et al.[27]        | 2017 | 100             | Press-Fit Condylar® Sigma®      | 18.0          |
|                       |      | 100             | Vanguard®                       | 4.0           |
| Current study         | 2019 | 126             | NexGen LPS-Flex                 | 7.1           |
|                       |      | 126             | Advance® Medial - Pivot         | 1.6           |
PCC patellar clunk or crepitus

Figures

Figure 1

Patella tilt was defined as angle between the transverse axis of the patella (P) and the anterior intercondylar line (F). Patella shift was defined as the distances between the lowest point of the trochlea(F’) relative to the anterior intercondylar line and the deepest point of the patella(P’) relative to the transverse axis of the patella.

Figure 2

Posterior condyles angle (PCA). PCA was defined as the angle between the transepicondylar axes (TEA) and posterior condyles axes (PCA).
