Comparison of Biomechanical Gait Parameters and Patient-Reported Outcome in Patients After Total Knee Arthroplasty With the Use of Fixed-Bearing Medial Pivot and Multi-radius Design Implants—Retrospective Matched-Cohort Study

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A B S T R A C T

Background: Total knee arthroplasty (TKA) is considered to be highly successful in treatment of end-stage osteoarthritis. There are multiple implant designs available on the market, and it is difficult to point which one is the best. The aim of this study was to compare the clinical and functional outcomes and gait pattern after TKA with the use of fixed-bearing medial pivot (K-Mod) vs multi-radius design (NexGen) implants and to compare them to norms for healthy patients with no osteoarthritis or arthroplasty procedure in anamnesis.

Methods: A group of 30 patients who received the medial pivot (MP) TKA and 33 patients who received the posterior-stabilized (PS) TKA between May and August of 2018 were included. All surgeries were performed in the level III academic hospital by a single surgeon. Every patient was asked to fulfill the The Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire preoperatively and 2 years postoperatively. Standard X-ray, biomechanical gait analysis using a motion capture system, and statistical analysis were performed at 2 years postoperatively.

Results: A total of 28 patients from either MP cohort (93%) or PS (85%) matched-control cohort completed the whole assessment at the final follow-up. There were statistically significant differences in a few gait parameters such as shorter mean step length both in operated and healthy limb, lower mean gait velocity, and lower mean walking cadence than the norm in both MP and PS groups. As to the WOMAC score, there was statistically significant improvement in both groups comparing preoperative and postoperative outcomes. Nevertheless, in the MP group, there was a significantly higher score, indicating worse outcomes, in the stiffness part of the WOMAC score than in the PS group. No significant differences were found between groups during radiological evaluation.

Conclusions: There were satisfying and promising clinical, radiographic, and patient-reported outcomes in both MP and PS groups with very little difference in relation to norm values. However, both implants failed in fully restoring gait patterns similar to the healthy limb of the same patient.

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the United States only, more than 700,000 such procedures are carried out [3,4]. Even though these huge numbers should be connected with high satisfaction among patients, about 20% of them are unsatisfied with the outcome of the surgery while the average satisfaction after another arthroplasty procedure, hip replacement rate reaches 93% [5–7].

Kinematic studies show that a healthy knee is partially a ball and socket type joint, with a more mobile lateral compartment [12–14]. The fluoroscopic study by Dennis et al. proved that the medial compartment is more stable and more congruent than the lateral one, which causes “medial pivot” (MP) motion during flexion, while tibia movement is caused by body weight and stopped by intact posterior cruciate ligament (PCL) [15]. PS TKA design does not reproduce this physiological movement as it allows paradoxical sliding and rolling in both compartments. Postoperative satisfaction may be obtained by reproducing knee kinematics as close to natural as possible [16].

It was proved that in case of insufficient PCL, the posterior-stabilized (PS) design achieves better stability during flexion by stopping the posterior translation of the tibia with the “post and cam” mechanism. It results in a “paradoxical movement”—an unnatural anterior shift of the tibia as a consequence of preventing the posterior translation of the tibia on the femur [17].

Because the TKA concept of more congruent and less mobile medial compartment is considered as more anatomic and physiological, it is gaining popularity nowadays.

In one systematic review and one meta-analysis [18,19], no superiority of any design was proved; however, in the systematic review by Longo et al. [18], some significant differences were observed in range of motion in favor of PS design in comparison to a standard CR design. The design of MP TKA with the cruciate-retaining technique was aimed to restore native knee kinematics by avoiding any paradoxical movement. Thanks to such design, it was believed that patients will have not only better functional results but also better gait pattern and lower risk of polyethylene wear. However, in several studies [20–28] no superiority of this design was observed in comparison to the PS one in terms of patients’ satisfaction or improvement in range of motion. Only one study [21] reported a significantly better outcome of MP design in terms of Forgotten Joint Score.

K-mod dynamic congruence (Gruppo Bioimplaneti, Peschiera Borromeo, Milan, Italy) is a fixed bearing MP design of TKA, the rationale of which is to reproduce native biomechanics of the knee. It contains dynamic congruence insert which is believed to provide knee stability in knee motion. The MP-TKA system was developed to reproduce the physiological motion of the knee [22–24].

In the study by Cacciola et al. Authors proved that this design has shown excellent clinical, radiographic and patient-reported outcomes (PROs) in primary TKA [24].

Even though there are many studies concerning gait pattern after TKA [25–27], it is estimated that only one-third of patients show a biphasic pattern of sagittal plane moments which is considered physiological [28]. However, to our best knowledge, there is no study analyzing gait parameters of the knee after TKA with the use of MP knee design, and there are only two randomized-controlled trials, where authors compared gait patterns between two designs of TKA implants [29,30].

One of them analyzed the use of the MP design in comparison to the single radius design [28]. Forty-five patients were randomized, and no statistically significant differences were found in terms of functional outcome and gait parameters with slightly superior results for the single radius design group. The second one was the randomized-controlled study comparing gait analysis between patients who underwent TKR with the use of fixed-bearing or mobile-bearing implants [30].

The primary aim of this study was to assess whether the use of the fixed-bearing MP design could help restore the gait pattern of the operated knee to similar parameters as for a healthy person.

The secondary aim was to compare gait parameters restoration and PROs of the MP knee system to one of the most commonly used TKA knee systems, the NexGen (PS) implant (Zimmer, Warsaw, IN) [3]. Given the potentially better knee kinematics offered by the MP system, the hypothesis of this study is that, even though PROs might not differ, gait pattern might better correspond with the healthy native one with the use of the MP design.

**Material and methods**

A consecutive series of patients who received a cemented MP TKA between May 2018 and August 2018 was identified. Patients included in the study were (1) older than 60 years, (2) had BMI (kg/m²) < 40, (3) were able to walk for 10 meters, (4) had leg length discrepancy < 5 mm, (5) knee flexion angle < 90 degrees, (6) hip extension angle > 90 degrees, (7) TKA was a postoperative closed suction drainage left for at least 12 hours. All patients fulfilled the WOMAC questionnaire at the day of the admission to the hospital to assess his knee joint function.

All surgeries were performed in the level III academic hospital with the use of tourniquet (average time of 80 minutes) and postoperative closed suction drainage left for at least 12 hours. All operations were performed by the senior author, who is a highly trained total joint replacement surgeon and performed more than 3000 of such surgeries in his professional career. All patients were qualified for TKA using an MP implant. During surgery, the PCL was assessed for being intact. If PCL was insufficient, a decision to change the type of prosthesis from MP to PS (NexGen LPS) was made. All surgeries were performed using a standard midline incision and medial parapatellar arthrotomy. Tibial cuts were performed first using extradural alignment jigs. These were made perpendicular to the long axis of the tibia with a posterior slope between 0° and 7°. The femur was prepared using intramedullary alignment with a valgus angle between 5° and 7° and external rotation with posterior condylar axis perpendicular to the transepicondylar line. Femoral bone cuts were made in the sequence as recommended by the surgical protocol of the MP knee system and PS system. After removal of posterior and peripheral osteophytes, soft-tissue balance was assessed using the tibial insert trial. Flexion and extension gaps were balanced. No patella resurfacing was performed because of mild patellofemoral joint disease. In every case, patella was denervated. All components were implanted with
the use of cement. The postoperative protocol included chemical and mechanical thromboprophylaxis unless specifically contra-

indicated. All patients received one dose of parenteral antibiotics at the induction of anesthesia and two further doses postoperatively.

Flexion and extension exercises of the ankle and isometric quadriceps contraction exercises were started on the first post-

operative day, with full weight-bearing with pain tolerance. The duration of the exercises was 40 minutes to 1 hour 3 times per day. All exercises were performed bedside without using additional tools. The aim of mobilization with a physiotherapist was to obtain flexion of the knee of 90°. Other methods of mobilization included using a walker or walking with crutches by the third day post-

operatively. The average length of stay in the hospital was 3.3 days (3-4). PRO and gait pattern analysis from the MP K-Mod study cohort were compared to those of a 1:1 matched-control cohort of patients treated with the NexGen PS knee system.

From May until August 2018, 33 patients underwent TKA using the PS knee system at our institution. For these patients, as well as the MP cohort, a propensity score based on age, sex, BMI, and WOMAC score was generated. PS patients were matched to MP patients using a 0.1 propensity score threshold with priority given to exact matches.

Patient-reported outcome

All participants were asked to fulfill the WOMAC questionnaire [32] at the day of admission to the hospital preoperatively and immediately before gait analysis.

Radiographic evaluation

Anteroposterior radiographs were used to assess overhanging of the tibial component. For the assessment of overall alignment, the hip-knee angle (HKA) was determined from long-leg views [33]. Lateral radiographs were used in the assessment of notching or overhanging of the femoral component as well as slope and overhanging of the tibial component [34] (Figs. 1-3). The radiographs were measured and reviewed by two experienced ortho-
pedic surgeons, who did not take part in the surgery or further research. Any disagreement between them was solved by the senior author of this study.

Gait analysis

Patients were asked to undergo three-dimensional gait analysis with the use of a BTS SMART device (BTS Bioengineering, Quincy, MA) in the academic biomechanical laboratory, located in the same hospital. A two-year time period was chosen as authors of this article assumed that a proper rehabilitation protocol improves the function of the operated knee after such a period. This device uses passive markers technology and registers the movement with six cameras. To perform a full gait analysis, several data concerning patients’ anthropometry were collected (lower limb length, knee and ankle joint width, width and depth of the pelvis). All measurements and analysis were performed according to the

Figure 1. Radiographic measurement tibial component overhanging (AP).

Figure 2. Radiographic measurement of the HKA angle. The green line is drawn from the center of the femoral head to the femoral intercondylar notch, while the orange line from the tibial interspinous point to the tibial mid-plafond. The angle between these lines (marked yellow) is the HKA angle (hip-knee-ankle angle).
A statistical analysis of the results for both operated and healthy limbs was performed. All comparisons were performed between continuous variables in unpaired groups. Therefore, after examination, in accordance with the normality of distribution using Shapiro-Wilk test, either t-student test for unpaired groups or U Mann-Whitney test were used. Distribution normality was examined using the Shapiro-Wilk test. Significance level was set at $P$ value below 0.05.

**Results**

A total of 28 patients from either MP cohort (93%) or PS (85%) matched-control cohort completed the whole assessment at the final follow-up (Table 1). Two patients from the MP group were excluded from the final assessment because of hepatocellular carcinoma and undergoing total hip arthroplasty in the same limb as TKA was performed. Four patients from the PS group were excluded as one of them underwent an additional knee surgery because of the knee stiffness, associated with malrotation of the femoral component, and another one suffered from femoral neck fracture, treated with total hip arthroplasty on the contralateral limb. Another two were excluded because of the transient ischemic attack and trimalleolar fracture of the non-operated limb. The mean follow-up duration was 24 months (range: 20-26).

**Gait analysis**

When compared with norms for healthy knees, both in MP and PS groups, the only outcomes to differ significantly from norms were mean step length both in operated (norm = 0.73 m vs...
MP = .43 m, P = .012; vs PS = .50 m, P = .02) and healthy limb (norm = .73 m vs MP = .54 m, P = .021; vs PS = .60 m, P = .019), mean gait velocity (norm = 1.39 m/s vs MP = .62 m/s, P = .008; vs PS = .70 m/s, P = .007), and mean walking cadence (norm = 113.80 steps/minute vs MP = 85.40 steps/minute, P = .01; vs PS = 87.30 steps/minute, P = .003). There were no statistically significant differences between norms for healthy knees and both MP and PS groups for the rest of the analyzed parameters (Table 2).

What is more, comparing gait parameters between MP and PS groups did not reveal any significant differences (Table 3).

Patient-reported outcome

There was statistically significant improvement in PRO in WOMAC score in both groups comparing preoperative score to the final follow-up (P < .05). As to subjective outcomes, the only significant difference between MP and PS groups at the final follow-up was the mean stiffness part of WOMAC score (3.0 vs 1.13, P = .049). There were no significant differences in mean WOMAC score as a whole and other subscales (Table 4).

Radiological evaluation

In the MP group, the HKA was varus in 92.9% of knees within 2.0\(^\circ\)–9.0\(^\circ\) range (median 4.6\(^\circ\) valgus), while in the NexGen PS group, HKA was varus in 96.4% of knees within 2.0\(^\circ\)–9.0\(^\circ\) (median 4.8\(^\circ\)). A total of 96.4% of the femoral components were within 3.0\(^\circ\)–7.0\(^\circ\) varus (median 5.2\(^\circ\) varus) in the coronal plane in the MP group and 96.4% within 3.0\(^\circ\)–7.0\(^\circ\) in PS group (median 5.0\(^\circ\) varus). Flexion in the sagittal plane was measured within 0.0\(^\circ\)–3.0\(^\circ\) (median 1.0\(^\circ\) flexion) in 96.4% of knees in both groups. Similarly, 89.3% of the tibial components in the MP group were within 0.0\(^\circ\) to 3.0\(^\circ\) varus (median 1.8\(^\circ\) varus), while 92.9% in the PS. The tibial slope was within 3.0\(^\circ\)–7.0\(^\circ\) range for 96.4% of patients (median 4.8\(^\circ\)) in MP group and 100% in the PS. No patients had overhang of the tibial component in the anteroposterior or mediolateral directions greater than 2.0 mm. Femoral component notching or oversizing was observed in 3.6% of patients in both groups. No significant differences in comparison between the groups were found (Table 5).

Table 1
Characteristics of participants in the MP (K-Mod) group and matched PS (NexGen) LPS cohort.

| Clinical characteristics of patients included in the study | PS | MP | P value |
|------------------------------------------------------------|----|----|---------|
| BMI (body mass index, kg/m\(^2\))                           | 31.97 (SD = 5.17) | 32.76 (SD = 5.07) | .55 |
| Age (years)                                                | 68.0 (SD = 6.5) | 71.0 (SD = 5.0) | .18 |
| Male/female                                               | 21:7 | 19:9 | .55 |
| Right/left                                                | 17:10 | 17:10 | 1 |

Table 2
Comparison of gait parameters between MP and PS groups.

| Gait analysis parameter | Norm          | MP            | Norm vs MP, P value | PS          | Norm vs PS, P value |
|-------------------------|---------------|---------------|---------------------|-------------|---------------------|
| Mean step length (m)    | 0.73          | 0.43, SD = 0.09 | 0.012               | 0.50, SD = 0.11 | 0.020               |
| Mean gait velocity (m/s)| 1.36          | 0.62, SD = 0.24 | 0.008               | 0.70, SD = 0.23 | 0.007               |
| Mean walking cadence (steps/min) | 113.80 | 85.40, SD = 23.10 | 0.010               | 87.30, SD = 21.45 | 0.003               |
| Mean double stance phase (%) | 13.00 | 15.40, SD = 3.66 | 0.550               | 16.40, SD = 3.16 | 0.071               |
| Mean single stance phase (%) | OL 61.00 | 66.30, SD = 5.73 | 0.076               | 64.10, SD = 5.49 | 0.080               |
| Mean swing phase (%)    | OL 39.00      | 34.20, SD = 5.16 | 0.059               | 35.90, SD = 5.60 | 0.068               |

Discussion

Despite the ongoing development of newer and possibly more biomechanically close to the native knee joint implants, the percentage of unsatisfied patients remains constant. There were several studies, which identified risk factors for dissatisfaction concerning patient-related, surgical technique-related, and implant-related issues [5,37]. In recent years, MP design of knee implant was introduced to the market with high hopes to increase the number of satisfied patients undergoing TKA [22,38].

The aim of this study was to compare the clinical and functional outcomes and gait pattern after TKA with the use of fixed-bearing MP or multi-radius design implants. The most important findings of this study were that the MP knee system demonstrated excellent clinical and radiological outcome in 2-year follow-up comparable to the one of the most widely used knee implants—NexGen LPS. The only aspect in which the PS design significantly overrode the MP was the stiffness subscale of WOMAC questionnaire. However, in terms of gait analysis, both knee implants failed to fully reproduce lower limb gait parameters to levels indicated by norms, with no significant differences between implants. Difference in WOMAC stiffness subscale might result from the fact that PS designs are reported to provide better postoperative ROM than CR [19].

PRO of the MP implant is similar to other studies analyzing this knee design. In the study by Cacciola et al., authors have followed up almost 300 patients for 5 years with 98.2% survivorship of the same implant. However, in this study, no comparison to other implant designs was performed, which makes the study less reliable. Results of our study show similarly satisfying outcomes of the use of this prosthesis, even though follow-up and number of participants were less representative.

There were a few other studies reporting very good PROs in WOMAC score with the use of other implants of MP design. Two of
them report results from 5-year follow-up [39,40], while in the study by Macheras et al. [38], authors demonstrated excellent long-term clinical outcome and survivorship with the use of such design in 15.2 years of follow-up. However, none of these studies compared the clinical outcome of the MP design to that of the PS knee design.

So far, only a few studies compared MP knee design with posterior-stabilized implants [41–43]. In the study by Vikas Kulshrestha et al., authors followed up for 2 years 80 patients randomly allocated to receive a MP design total knee implant ADVANCE MP Knee System in comparison to NexGen LPS. There were no statistically significant differences in terms of Forgotten Joint Score and KSS. However, patients with PS implant had significantly better post-operative ROM. In this study, nonsignificant differences were found in terms of many biomechanical parameters such as timed up and go, stair climb test, and self-paced walk test, all favoring the MP design. Those results might indicate that MP design restores more native knee biomechanics, sacrificing postoperative knee flexion [41].

Observations from this study only partially correspond to our results. The authors stated the mean degree of deformity was lower in the MP group, but the difference was not statistically significant ($P < .068$). When it comes to the severity of deformity in the PS group, 13 (32.5%) had mild, 10 (25%) had moderate, and 17 (42.5%) had severe deformity. The main strengths were the use of validated PROs, the detailed radiographic assessment with the use of long-leg views, and the matched-pair PRO and gait analysis comparison to the NexGen knee system. What is more, in this study, a gait pattern analysis was used to compare the data to age-related norms acquired by Oberg et al. in his study of 233 healthy subjects [36].

Conclusions

In conclusion, in the present study, we reported the excellent clinical, radiographic, and PROs of patients who underwent primary TKA with MP design, comparable to one of the most widely used knee design systems—NexGen LPS. However, both implants failed to reproduce gait patterns similar to norms for healthy patients. Besides, clinical outcome and PROMs showed a statistically significant improvement, and their mean values were comparable with other studies analyzing results of MP design. Therefore, the use of an MP knee gives hopes for achieving good knee kinematics in patients qualified for CR arthroplasty without deterioration in PROMs.

Future studies comparing other designs of implants, as well as proper rehabilitation protocol, should be performed to improve outcome of the surgery and patients’ satisfaction and allow for a gait restoration more similar to the pre-osteoarthritic level. Further research concentrating on improving or developing new designs of total knee implants must be conducted to get closer to the native knee biomechanics. Even though total knee arthroplasty has gone a long way since its beginnings, it still rather resembles a run-on tire of a car than a real tire substitute.

Conflicts of interest

The authors declare there are no conflicts of interest.

References

[1] Bourne RB, McCalden RW, MacDonald SJ, Mokete L, Guerin J. Influence of patient factors on TKA outcomes at 5 to 11 years follow up. Clin Orthop Relat Res 2007:464:27.
[2] Bourne RB, Chesworth BM, Davis AM, Mahomed NN, Charron KD. Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? Clin Orthop Relat Res 2010:468:57.
