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Original article

Short-term clinical and radiological comparisons between two medial pivot total knee arthroplasty implants with different geometries

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Abstract. *Background and aim:* Different total knee arthroplasty (TKA) implants were created for the treatment of severe symptomatic gonarthrosis and Medial Pivot TKA (MP TKA) seem to reproduce the normal kinematics of the knee. We compare two different prosthetic designs of MP TKA in order to identify whether there is a difference between the two in terms of degree of patient satisfaction. *Methods:* A total of 89 patients were analyzed. A group of 46 patients who benefited from a TKA with the Evolution® prosthesis and one of 43 patients who received a TKA with the Persona® prosthesis. KSS, OKS, FJS and the ROM were analyzed at follow up. *Results:* The values of KSS and OKS were similar between the two groups (p>0,05). Our statistical analysis revealed a statistically significant increase (p <0.05) in ROM in the Persona® group and in FJS in the Evolution® group. No radiolucent lines were observed in both groups at the radiological final follow-up. *Conclusions:* MP TKA models analysed are a valuable tool to achieve satisfactory clinical outcomes. This study demonstrates that the FJS is an important score for the evaluation of patient's satisfaction: a ROM's limitation can be accepted by the patient in exchange for a more natural perceived knee. (www.actabiomedica.it)

Key words: Total Knee Arthroplasty, Medial Pivot, Ball in socket, J curve, Kinematics

Introduction

Osteoarthritis (OA) of the knee is the most common painful and disabling joint disease affecting about 240 million people worldwide (1,2). The prevalence of knee OA increased significantly over the last decades and continues to rise (3). The gold standard treatment for symptomatic end-staged OA is Total Knee Arthroplasty (TKA), but is also successfully performed in the moderate knee OA. TKA has demonstrated effectiveness with substantive and sustained quality of life improvement (4), pain relief and better knee function including range of motion (ROM) and walking ability (5).

Despite the excellent outcomes achieved by the majority of TKA surgeries, approximately the 20% of the patients are not satisfied (6). One of the main problems reported in literature is the altered kinematics of the replaced knee joint. That's why several manufacturers proposed multiple design innovation of their implants to reproduce the normal knee kinematics and ultimately improve patient outcomes (7). Currently, the most commonly used prosthetic design are cruciate retaining (CR) and posterior stabilizing (PS) TKA. However, it is known that these two different TKA designs are related to two main kinematic problems (8). The first is the "paradoxical motion" that is an anterior translation of the femoral condyles during flexion, instead of the physiological rollback; this leads to a decreased quadricipital strength, inferior ROM because of the earlier posterior impingement, increased

polyethylene wear, sagittal instability and alteration in gait. The second is the "reverse screw-home" that is the extrarotation of the tibia about 15° on the femur during the last 20° of extension and it may cause inferior ROM and patello-femoral instability (9,10). The knee physiologically moves with the medial condyle staying very nearly stable like a ball-in-socket joint while the lateral compartment pivots on the medial one, allowing for a posterior-lateral rollback of the lateral femoral condyle (11–15). To simulate this kinematic model, Medial Pivot Arthroplasty (MPA) was created. Two new generation implants design of MP TKA are used in our analysis: Evolution® (MicroPort Orthopaedics, Arlington, Tennessee, USA) and Persona® (Zimmer Biomet, Warsaw, USA) Medially Congruent TKA design. The first implant is characterized by a femoral component with a medial "ball-in-socket" articulation with sagittal, constant single radius (C- Curve) instead the other design is characterized by an anatomical femoral design with sagittal asymmetrical shape J-curve, variable multi radius, and an adapted "medially-congruent" polyethylene insert (16). This study is meant to compare these two different third-generation medial pivot TKA implants and evaluate the improvement of clinical patient related outcomes at follow-up from the preoperative and the radiological outcome at the final follow up.

Materials and methods

The study was conducted in accordance with the Declaration of Helsinki and was approved by all the participating hospital. The Authors set up the study following the ethical recommendations of National Law Guidelines for Clinical Study. All patients signed a specific informed consensus before surgery and during clinical examination. We collect the data of each patient assigning an ID and then the database was analyzed in an anonymous form protecting the privacy of the participants. No additional procedure or examination were performed on the subjects included in the study. No external funding was received. Ethical Approval: Patient data was retrospectively analyzed and did not change patient care. Ethical Committee approval was therefore deemed unnecessary.

We retrospectively selected from hospital records 118 patients who underwent primary total knee arthroplasty for primary knee osteoarthritis (OA) between January 2018 and March 2020.

Inclusion criteria were primary unilateral knee OA type 3 or 4 according to the Kellgren-Lawrence classification (KL), age > 55 years, neutral alignment or varus deformity less than 20° on the mechanical axis, use of Persona® TKA (Zimmer Biomet, Warsaw, USA) or Evolution® TKA (Microport, Arlington, Tennessee, USA), minimum 2-years clinical and radiological follow-up. Exclusion criteria were preoperative diagnosis of inflammatory and/or traumatic and/or neurogenic OA, valgus knee alignment, previous lower extremity fractures, previous femoral o tibial osteotomy, collagen disorders and/or avascular necrosis, severe bony defects or joint deformity which required augmentation or more constrained polyethylene insert, any loss of musculature or neuromuscular disease that compromises the affected limb, body mass index (BMI) greater than 45. According to inclusion and exclusion criteria and excluding the dropout we recruited 89 patients (Fig. 1).

For each patient were recorded: demographic data, preoperative and postoperative knee range of motion (ROM) using a goniometer, Oxford Knee Score (OKS), Knee Society Score (KSS), and at the final follow up the Forgotten Joint Score (FJS) (Table 1-3).

Radiological evaluation was performed to assess presence and location of radiolucent lines according to the method described by the Knee Society Total Knee Arthroplasty Roentgenographic evaluation and scoring system (17).

These patients were divided into 2 groups based on total knee arthroplasty implant: Persona® TKA group (group 1) or Evolution® TKA group (group 2). In our series, group 2 was predominant 46/89 (51.7%) vs 43/89 (48.3%). Group 1 was composed of 20 females and 23 males; the mean age was 76.9 ± SD 6,77 (range 57-92) and the mean BMI was 25.5 ± SD 3.20 (range 18.7 – 33.8). Group 2 was composed of 25 females and 21 males, and the mean age was 76.3 ± SD 6.28 (range 59-90) and the mean BMI was 26.1 ± SD 3.47 (range 19.5 – 34.9).

Statistical analysis was performed using GraphPad Prism 5.0. Statistical analysis of the data were

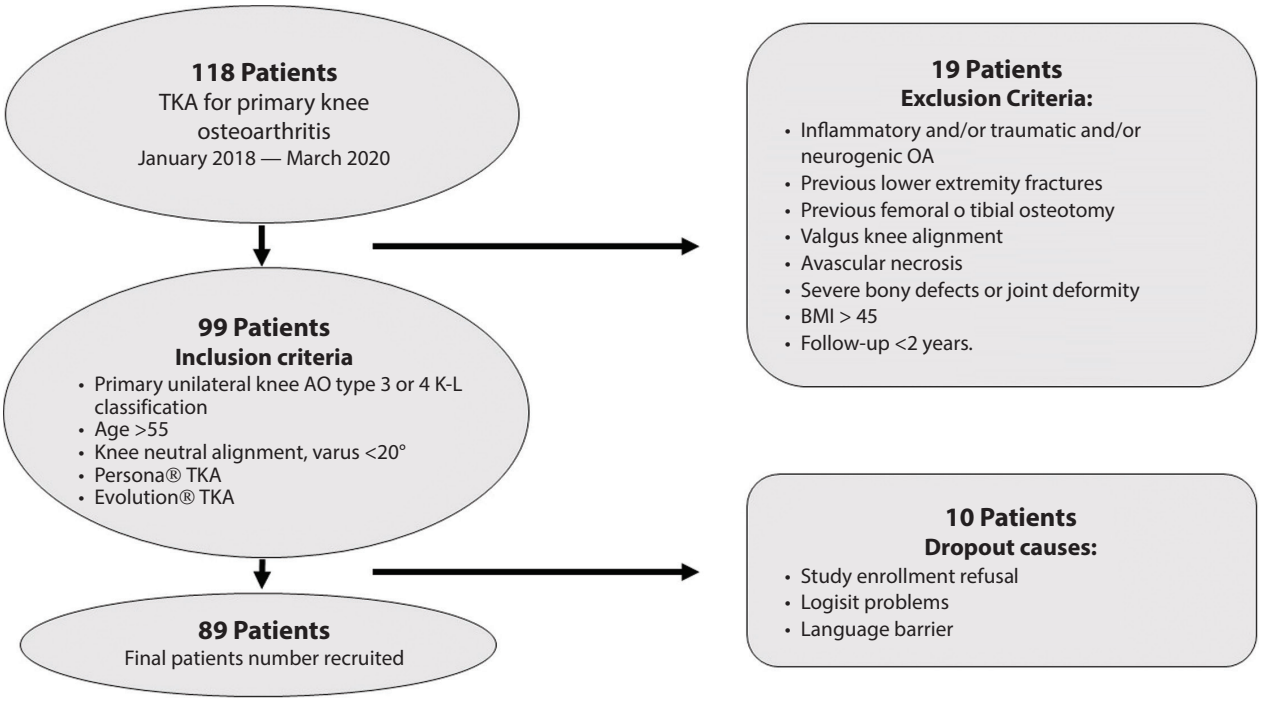

Figure 1. Patients selection with inclusion and exclusion.

Table 1. Demographic data related to patients included in the study.

	PERSONA® TKA		EVOLUTION® TKA		
VARIABLE	***Mean (± DS)***	***Range***	***Mean (± DS)***	***Range***	***p-Value***
Gender	M 20 (47%) / F 23 (53%)	-	M 21 (46%) / F 25 (54%)	-	-
Kellgren-Lawrence	12 (28%) - 31 (72%)	-	14 (30%) - 32 (70%)	-	-
Age	76,9 (± 6,77)	57 - 92	76,3 (± 6,28)	59 -90	n.s
BMI	25,5 (± 3,20)	18,7 – 33,8	26,1 (± 3,47)	19.5 - 34,9	n.s

n.s. not significant, s.s. statistically significant.

Table 2. Persona® TKA preoperative versus final follow-up.

	PERSONA® TKA				
VARIABLE	***Pre-op: Mean (± DS)***	***Pre-op: Range***	***Final follow-up: Mean (± DS)***	***Final follow-up: Range***	***p-Value***
ROM	89,21° (± 13,04)	60° - 110°	119,2° (± 10,17)	95° - 135°	n.s
OKS	21,4 (± 3,24)	17 - 26	41,47 (± 7,55)	22 - 48	n.s
KSS functional	47,37 (± 16,86)	10 - 70	87 (± 21,56)	30 - 100	n.s
KSS clinical	50,95 (± 11,33)	30 - 69	85,94 (± 16,37)	45 - 100	n.s
KSS total	98,32 (± 23,56)	40 - 131	172,53 (± 36,01)	65 - 200	n.s
FJS	-	-	85,71 (± 19,90)	40 - 100	-

n.s. not significant, s.s. statistically significant.

Table 3. Evolution® TKA preoperative versus final follow-up.

	EVOLUTION® TKA				
VARIABLE	***Pre-op: Mean (± DS)***	***Pre-op: Range***	***Final follow-up: Mean (± DS)***	***Final follow-up: Range***	***p-Value***
ROM	93,5° (± 14,79)	70° - 120°	110,8° (± 14,08)	85° - 135°	n.s
OKS	21,4 (± 3,12)	17 - 27	43 (± 5,97)	28 - 48	n.s
KSS functional	49,1 (± 17,26)	10 - 90	84 (± 19,44)	35 - 100	n.s
KSS clinical	46,4 (± 13,91)	30 - 72	86,6 (± 15,48)	43 - 100	n.s
KSS total	95,5 (± 26,04)	40 - 156	170,6 (± 31,91)	78 - 200	n.s
FJS	-	-	96,9 (± 6,42)	73 - 100	-

n.s. not significant, s.s. statistically significant.

performed using the t-Student test for unpaired or paired data to compare each variable for significant differences between the two groups of patients. The level of significance was set at $p < 0.05$.

Surgical technique

All surgeries were performed at a single institution (Borgo Trento Hospital, Verona) by the senior author (EV). The surgical technique was identical for both TKA designs. After a midline skin incision and subcutaneous dissection, a standard medial parapatellar capsulotomy was performed and both cruciate ligaments and menisci were resected. The tibial osteotomy was made using an extramedullary alignment guide placed distally on the anterior tibialis tendon which was considered the center of the ankle: the tibial slope was set at 5° in both the groups. The distal femoral osteotomy was then performed perpendicular to the mechanical axis of the femur using an intramedullary alignment guide. The extension gap was checked using a standard spacer block aiming for a 1–2 mm increased opening on the lateral compartment. The femoral component size and rotational alignment were determined according to the surgical trans-epicondylar axis (TEA): the four-in-one cutting block was placed on the femur and the postero-medial cut was checked first to make the cut very close to the bone-cartilage transitional zone. All the femoral bone osteotomies were completed and attention was paid to the tibial component and its sizing and rotational alignment was determined using the appropriate tibial baseplate trial: the anatomical tibial component was set according to the middle third of the tibial tubercle. In all the patients, patellae's osteophytes were removed, and its tracking was then checked using the "no thumb technique" with the anterior capsule temporarily closed using clamps and with the patella relocated in the femoral groove. At this point, a clinical examination, consisting of varus–valgus stress test at different degrees of flexion, was performed. The surgeons aimed to get a subjective greater lateral opening (1–2 mm) compared to the medial opening during the entire passive ROM stability tests. After the removal of the trial components, the definitive tibial and femoral components were placed and cemented (Cemex, Tecres S.p.A., Sommacampagna, Italy) in all the patient; the polyethylene was than insert.

Results

The average clinical follow-up period was 24.9 months (range 24-29, ± SD 1.22). The clinical outcomes are summarized in table 2 - 4: the OKS, KSS clinical, functional, total and ROM improved in both groups.

The OKS mean value for Persona® TKA group improved from 21.6 (range 17-26 ± SD 3.24) to 41.5 (range 22-48 ± SD 7.55). The median OKS value improved from 21.4 (range 17-27 ± SD 3.12) to 43 (range 28-48 ± SD 5.97) at the final follow-up for the Evolution® TKA group. The KSS total mean value for Persona® TKA group improved from 98.32 (range

Table 4. Results: preoperative versus final follow-up (minimum 24 months).

	EVOLUTION® TKA (C-Curve)		PERSONA® TKA (J-Curve)		
VARIABLE	***Mean Pre-op***	***Mean Post-op F-U***	***Mean Pre-op***	***Mean Post-op F-U***	***p-Value***
OKS	21.4	43	21.4	41.5	n.s.
KSS tot	95.5	170.6	98.3	172.5	n.s.
FJS	-	96.9	-	85.7	s.s.
ROM	93.5°	110.8°	89.2°	119.2°	s.s.

n.s. not significant, s.s. statistically significant.

40-131 ± SD 23.56) to 172.53 (range 65-200 ± SD 36.01) and for the Evolution® TKA group from 95.5 (range 40-156 ± SD 26.04) to 170.6 (range 78-200 ± SD 31.91) at the final follow-up.

The t- Student test for pared data was used to investigate the difference between the clinical scores at T0 and at final follow-up for both groups showing significant differences (p-value < 0.05). The t- Student test for unpaired data was used to investigate the difference between the clinical scores at final follow-up for both groups no significant differences (p > 0.05). The mean ROM for Persona® TKA group improves from 89.21° (range 60°-110° ± SD 13.04) to 119.2° (range 95°-135° ± SD 10.17) and for the Evolution® TKA group from 93.5° (range 70°-120° ± SD 14.79) to 110.8° (range 85°-135° ± SD 14.08) at the final follow-up. The t-Student test for pared data was used to investigate the difference between the preoperative ROM and the ROM at the final follow-up for both groups showing significant differences (p-value < 0.05). We founded a statistically significant different between the two groups in the ROM at final follow-up using the t- Student test for unpaired data (p-value < 0.05). The mean FJS value for the Evolution® TKA group was 96.9 (range 73 - 100 ± SD 6.42) and for Persona® TKA group was 85.71 (range 40- 100 ± SD 19.90) at the final follow-up. Finally, we used the t-Student test for unpaired data to compare FJS values at final follow-up for both groups, finding a statistically significant difference (p-value < 0.05) for Evolution® TKA group.

Radiological assessment was undertaken for all patients at final follow-up. No radiolucent lines were observed in both groups. There were no cases of femoral or tibial component migration in both groups.

Discussion

The scientific community agrees that the success of a prosthetic implant depends largely on the degree of patient satisfaction, the absence of residual pain and the achievement of patient's preoperative expectations. The search for the global satisfaction of each patient undergoing TKA is still being studied. Among the many factors that affect the success of a prosthetic implant and its outcomes, the search for the best prosthetic design, to recreate correct joint biomechanics, is currently debated.

In recent years multiple studies have investigated the kinematics of prosthetic implants comparing it to that of native knees (18–22). The findings in the 2000s by Pinskerova et al. were fundamental because, thanks to their studies based on MRI and anatomical preparations of non-arthritic knees, showed that in the healthy knees there is a pivot movement on the medial femoral condyle and a sliding of the lateral condyle followed by rotation of the tibia during flexion of the knee (12). To simulate this kinematic model, Medial Pivot prostheses were created (13,16,23–25). There have been many efforts by manufacturing companies to try to develop prosthetic implants capable of replicating this medial pivot kinematics with innovative materials and designs in order to improve proprioception, functionality, satisfaction of the patient, stability and durability of the implant. Several authors have reported satisfactory clinical, functional and radiographic outcomes at medium term follow-up in patients undergoing surgery with different techniques and MPA models.In our study we compare a same prosthetic design implant (Medial Pivot TKA) but with two different geometries of femoral component: the first is Persona® prosthesis which is characterized by a J curve geometry of femoral

component with asymmetric and posterior multi radii (MR) on sagittal plane, by an anatomical tibial baseplate and by a polyethylene medial congruent insert which maximalize the contact area on the medial compartment of the knee improving the antero-medial stability and reproducing the medial pivoting kinematics during the entire ROM. The second is Evolution® prosthesis which has a single radius (SR) of curvature in the symmetrical femoral condyles (C curve) and a spherical and fully congruent medial compartment ("ball-in-socket") thanks to an asymmetric polyethylene insert, which is deep dished medially and flat laterally: this design allows for an easier postero-lateral rollback during ROM.

For many authors the femoral component plays a fundamental role in achieving satisfactory functional outcomes and performances: many studies haven't shown significant differences between SR and MR designs in Patient Reported Outcome Measures (PROMs) and our study confirms these findings in the literature (7,26). Furthermore this research observes that ROM improves in both groups at postoperative control compared to preoperative (27,28). However the Persona® group achieves a wider ROM than Evolution® group and this finding is statistically significant. The literature is conflicting in this regard: in fact, a recent work by Luo et al. shows that SR TKA (C curve) guarentees a greater ROM the MR TKA (J curve) in the groups they studied (29). The improvement of ROM is not a decisive variable since its increase or decrease may derive not only from a correct positioning of the components but also from the pre-operative ROM and from the functional recovery carried out after surgery (30,31). According to Baker et al. the pain resolution in a previous arthritic knee are the most incident determinants of joint function in the overall balance of success of surgery and the levels of satisfaction mainly depend on patient's preoperative expectations (32). Although priorities differ between each patient, an increasing number of patients tolerates a certain degree of functional limitations (ROM) instead of residual pain and less naturaless of the prosthetic knee (32). In this way scores such OKS and FJS appear to be more useful than other clinic scores, because they mainly assess pain and awareness of the prosthetic knee. The reasons why the patient does not feel a prosthetic joint as its own can be found in causes like rigidity, pain, muscle weakness, joint instability and in the sensation of a foreign implant inside the body. In the present study the clinical-functional scores of the two groups (OKS and total KSS), compared at preoperative and follow-up, improved statistically significantly in both groups, averaging excellent values for both prosthetic models; there was no significant difference in clinical-functional PROMs between the groups. These results are in line with the recent literature where the prosthetic model, implanted with the same surgical technique by seeking mechanical alignment of the lower limb, does not affect subjective outcomes and objective findings of the clinician in the two cohorts of patients (33). The FJS measures the patients' awareness of his new implant: a prosthetic implant that patient forgets to have implies that the patient is pain-free, allows him to obtain an acceptable range of motion and a degree of stability in all levels of flexion during daily activities. We find that the mean postoperative FJS value between the two group is better and statistically significant for patients in the Evolution® group than those in the Persona® group and these results are in line with those of Samy et al. (34).

Although the results obtained are promising, this study has some limitations: 1. Follow-up is short, therefore a longer follow-up is necessary to confirm the findings obtained; 2. Patient selection may not be representative of the general population, so a larger and more representative sample is needed; 3. The results are mainly based on PROMs, therefore on subjective variables; 4. Despite the exclusion criteria applied, the degree of ROM of the knees at preoperative was variable, not constituting a homogeneous group. Further studies with longer follow-up and higher sample numbers are needed to confirm the validity of the biomechanical concept inherent to the medial pivot design.

Conclusion

This study supports the data already available in the literature about the good clinical and functional outcomes of medial pivot prosthetic designs.

Although the Persona® prosthesis allows better recovery of knee's flexion-extension motion, the

Evolution® prosthesis guarantees, to the patient, greater naturalness in the movement; so a ROM's limitation can be accepted by the patient in exchange for a more natural perceived knee.

In conclusion both the two MP prosthetic models analysed in our study are a valuable tool to achieve satisfactory outcomes, which must be related not only to functionality but also to patient expectation.

Conflicts of Interest: All authors declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

Ethical Approval: Patient data was retrospectively analyzed and did not change patient care. Ethical Committee approval was therefore deemed unnecessary.

Informed Consent: All patients signed a specific informed consensus before surgery and during clinical examination.

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