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ORIGINAL PAPER

Does the medial pivot knee improve the clinical and radiographic outcome of total knee arthroplasty? A single centre study on two hundred and ninety seven patients

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Abstract

Purpose Total knee arthroplasty (TKA) is a cost-effective surgery with a survival rate higher than 90% after 15 years. Nevertheless, patients are unsatisfied in more than 15% of cases. Medial pivot (MP) prosthetic designs were introduced in late 90's with the aim to reproduce natural knee kinematics. The purpose of this study is to evaluate the survivorship and clinical outcomes of a novel design of MP knee with a minimum follow-up of five years.

Methods This is a retrospective review of all patients who underwent primary TKA using the K-Mod dynamic congruence implant (Gruppo Bioimpianti, Peschiera Borromeo, Milan, Italy) between 2012 and 2013 at a single institution. A total of 339 patients (351 knees) were included with a mean age of 74 years (range 41–89). The Knee Society score, the global range of movement, the Western Ontario and McMaster Universities Osteoarthritis score, Forgotten Joint score, and the short-term form 12 health survey were collected. FJS and SF-12 were collected only post-operatively. Radiographic outcomes were evaluated according to the Knee Society's roentgenographic evaluation system. Kaplan-Meyer (KM) curves were performed to evaluate implant survivorship. A two-tailed paired *t* test was performed to evaluate the differences between pre-operative and post-operative score.

Results A total 297 patients (315 knees) were available for clinical and radiographic analysis, and the mean follow-up was 66.4 months. A total of 17 patients (17 knees 5.4%) experienced a post-operative complication, and a reoperation was performed in five patients (5 knees 1.6%). Four patients had a periprosthetic joint infection, and two patients had a post-traumatic periprosthetic femoral fracture. The KM survivorship at five years was 98.2% (95% CI 0.96 to 0.99) for revision for any reason. There was a statistically significant improvement ($p < 0.05$) in all the objective and subjective outcomes measured.

Conclusion The K-Mod dynamic congruence design has shown an excellent clinical, radiographic, and patient-reported outcome in primary TKAs.

Keywords Total knee arthroplasty · Medial pivot · K-mod · Dynamic congruence · Knee kinematic

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Introduction

Total knee arthroplasty (TKA) is one of the most frequent orthopedic surgical procedure, with more than 600,000 surgeries performed each year in the USA [1]. Different non-surgical interventions are available for the treatment of moderate to severe knee osteoarthritis, as medication and physical therapy [2, 3]. Improvements in surgical technique, materials, and implant design led to a reported survivorship greater than 90% after 15 years [4], at the same time patients reported a post-operative satisfaction ranging between 80 and 85% [5–7]. Many factors, as prosthesis design, body mass index, and level of patient educations, are associated with post-operative dissatisfaction and post-operative pain [8, 9].

Post-operative satisfaction may be obtained by reproducing the natural knee kinematics. Many prosthetic designs, as posterior-stabilized (PS) knee, failed to reproduce it. PS designs achieve stability during deep flexion by preventing the posterior translation of the tibia on the femur, thanks to a post and cam, allowing a non-natural anterior shift of the tibia known as "paradoxical movement" [10]. Normally, the medial femoral condyle acts as a pivot, and the tibial surface mainly rotating on its axis prevents the anterior rollback of the tibia through the femur, while the lateral condyle leans on a less congruent tibial contact area, permitting either rotation or antero-posterior shift [11, 12]. The design rationale of medial pivot-TKA (MP-TKA) was to restore the natural knee kinematic by avoiding the post-operative paradoxical movement. The theoretical advantages of this prosthetic design are to provide better knee stability, improve knee function, restore deep post-operative flexion, raise patient's satisfaction, and reduce polyethylene particles wear debris [13].

K-Mod dynamic congruence (Gruppo Bioimpianti, Peschiera Borromeo, Milan, Italy) is a fixed bearing MP-TKA system developed to reproduce the physiological motion of the knee. The dynamic congruence (DC) insert was designed to restore the normal joint kinematics maintaining stability (Fig. 1). The medial side of the liner has a concave surface that allows the medial femoral condyle to act as a pivot; on the other hand, the lateral side of the insert is designed to permit the anteroposterior shift of the lateral femoral condyle. Furthermore, the femoral groove was designed with a 6° angulation on the longitudinal axis of TKA, to optimize the patella-femoral tracking reducing the extensor apparatus stress [14, 15]. Currently, no studies were published using this specific implant yet. The purpose of this study is to determine the medium term clinical and radiological outcomes of the K-Mod MP in primary TKA at a minimum follow-up of five years.

Materials and methods

After obtaining institutional review board approval [16], we retrospectively analyzed data from 339 patients (351 knees) who underwent primary TKA using K-Mod DC (Gruppo Bioimpianti, Peschiera Borromeo, Milan, Italy) at a single

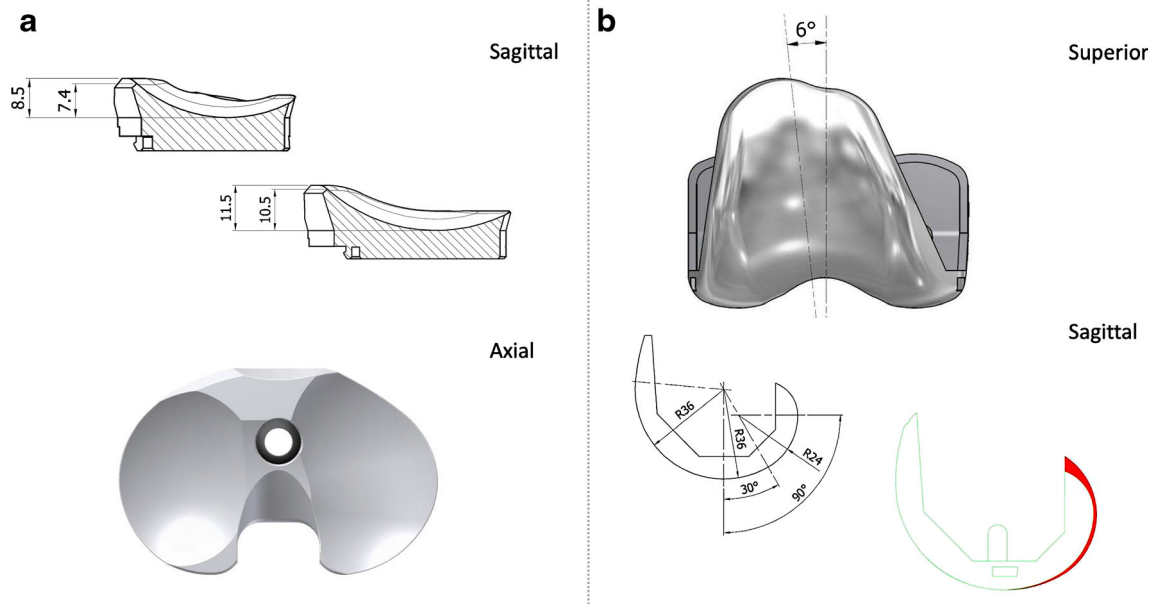

Fig. 1 **a** Sagittal and axial view of the dynamic congruence insert. The insert is in ultra-high-molecular-weight-polyethylene in which the medial side is characterized by an ultra-congruent design that allows only rotation of the medial condyle on its perpendicular axis. The lateral condyle is characterized by an elongated and less congruent shape. **b** Superior and sagittal view of the femoral component. The femoral component is characterized by a double radius of circumference, with a 9 mm thickness in both flexion and extension to correct ligaments tension. The posterior radius of closure was designed to restore the natural femur morphology. In addition, an anatomic trochlear path of 6° of slope was designed to reduce stress on the patellar ligament

institution from January 2012 to August 2013. During the study period, 546 primary TKAs were performed at the same center, 351 with a MP knee design (64.3%), and 195 with a PS knee (35.7%). There were no differences in indications for the TKA-design choice. All the surgeries were performed with MP-TKA by the same experienced surgeon. Indications for TKA were primary or secondary grade III or IV Kellgren-Lawrence knee osteoarthritis. There were 225 women (66.3%) and 114 men (33.6%) with a mean age of 74.3 years (range 41 to 89 years) at the time of surgery. Additional informations are listed in Table 1.

The same surgical approach was performed for all patients (midline incision and medial parapatellar arthrotomy). K-Mod DC TKA was implanted in all patients. The prosthesis fixation was obtained by a complete one stage cementing technique, using two packs of 40 g of low-viscosity bone cement (Exolent, Tecres, Verona, Italy) [17]. Tibial cut on the coronal plane was performed perpendicular to the tibial anatomical axis, using an extramedullary guide. On the sagittal plane, we aimed to restore the native posterior slope according to the pre-operative radiographic measurement. The tibial slope cut ranged from 3 to 7°. The distal femoral cut was performed with a valgus angle of 3 up to 7°on the femoral anatomical axis. The femoral component was 3° externally rotated concerning the posterior condylar angle [18].

Patients were evaluated radiographically and clinically pre-operatively, and then at three, six, and 12 months, and yearly after the first year until a minimum of five-years follow-up. The Knee Society score [19], the global range of movement (ROM), the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) score [20], Forgotten Joint score (FJS) [21], and the short-term form 12 health survey (SF-12) [22] were collected. FJS and SF-12 were collected only post-operatively. The radiographic review was performed by a fellowship trained arthroplasty surgeon. Weight-bearing lower limb, anteroposterior, and lateral radiographs of the knee were evaluated in accordance with the Knee Society's roentgenographic evaluation system by Ewald [23]. Component alignment, radiolucent lines (RLLs), subsidence, and loosening were assessed. RLLs > 2 mm, new RLLs, or progressive RLLs were considered signs of loosening (Fig. 2).

Statistical analysis was performed using Prism 6.0 (GraphPad, La Jolla, San Diego, California, Unites States of America). Kaplan-Meier (KM) survival analysis was performed to generate survivorship curves with 95 confidence intervals (CIs), with the endpoints of re-operations for any reason. Besides, a worst-case KM curve was also performed, where all patients lost to follow-up were considered as a failure [24]. A two-tailed paired *t* test was performed to evaluate the differences between pre-operative and post-operative (last follow-up) Knee Society score, ROM, WOMAC, and OKS. A p value < 0.05 was considered statistically significant.

Results

A total of thirteen patients (thirteen knees) died before the five-year follow-up, due to causes not related to the surgery or to the implant and were excluded from the study; twenty-one patients (twenty-three knees) were lost to follow-up before the minimum period of five-year and were excluded from the study. All the prosthesis were clinically and radiographically stable at the latest follow-up (Fig. 3 Lastly, 297 patients (315 knees) were available for clinical and radiographic analysis (87.6%). The mean follow-up was 66.4 months (range 60 to 73 months).

Complications and reoperations

A post-operative complication was recorded in seventeen patients (seventeen knees, 5.4%). Three patients had a deep infection (0.95%) that developed at eight, 12, and 19 months post-operatively. All three patients underwent two-stage revision in which an articulating spacer was used. One patient developed

Table 1 Summary of demographic data and indications for surgery

Category	Variable	Mean value
Demographic *(n = 339)*		
	Age at the time of surgery	74.5 years (SD ± 8.8 years)
	Gender: female	225 (66.3%)
	Side: right	114 (33.6%)
	Mean BMI at the time of surgery	28.8 Kg/m^2
	Mean follow-up	66.4 m (range 60 to 73 m)
Indications (351 knees)		
	Osteoarthritis	311 (88.6%)
	Rheumatoid arthritis	21 (6%)
	Avascular necrosis	19 (5.5%)

BMI body mass index

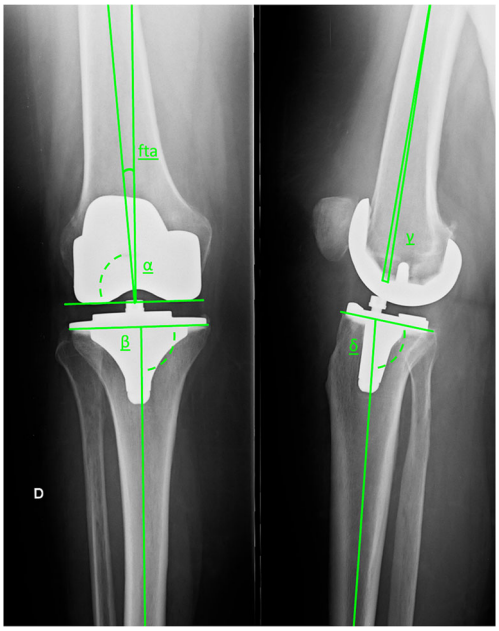

Fig. 2 The Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System by Ewald [20]. The femorotibial angle (or FTA) is the angle between the femoral and tibial anatomic axes; the alfa angle is the angle of the coronal femoral component alignment; the beta angle is the angle of the coronal tibial alignment; the gamma angle is the angle of the sagittal femoral component alignment; the delta angle is the angle of the sagittal tibial component alignment

an acute infection (positive culture for *S. epidermidis*, sensible to Gentamicin) after 20 days from the index arthroplasty and was treated with irrigation and debridement. Two-patients (0.63%) experienced a post-traumatic periprosthetic fracture. In both cases, the implant was stable (type 2 Su and associates), and the fractures were fixed by open reduction and internal fixation. The other complications included superficial wound infection in six patients (1.9%). In all of them, the infection was eradicated by intravenous antibiotics administration. None of these patients showed infection's recurrences at the further clinical examinations. At last, five patients (1.59%) experienced symptomatic deep vein thrombosis. In no cases were observed re-operations due to aseptical loosening of the implant, anterior knee pain, or knee instability.

Survivorship

The Kaplan-Meier estimated survivorship at five years was 98.2% (95% CI 0.96 to 0.99, number at risk at 5 years 309) for re-operations for any reason as an endpoint (Table 2 and Fig. 4) and was 91.6% (95% CI 0.88 to 9.94, number at risk at 5 years 309) in the worst case scenario, when all patients lost to follow-up were considered as a failure (Table 3).

Clinical outcomes

There was a statistically significant improvement ($p < 0.05$) in all the objective and subjective outcomes measured (Knee Society score, ROM, WOMAC, and OKS). FJS and SF-12 were not collected pre-operatively, and the post-operative mean values are listed in Table 3.

Radiographic outcomes

The alignment of the implant was evaluated by the mean alfa angle 96.5° (range 92.4 to 99.5°), the mean beta angle 88.4° (range 83.6 to 95.6°), the mean gamma angle 1.6° (range – 2.5 to 4.3°), and the mean delta angle 88.7° (range 82.3 to 93.8). The implant was considered satisfactory aligned in the coronal plane, between 0° and ± 3°, in 227 knees (72.1%). RLLs were present in 33 knees (10.4%), the width was of < 2 mm, and in no cases, RLLs were progressive (Table 3).

Discussion

An important increase in the demand for primary TKAs is estimated to occur in the next decades [1], but despite the improvement in implant longevity, a number of patients

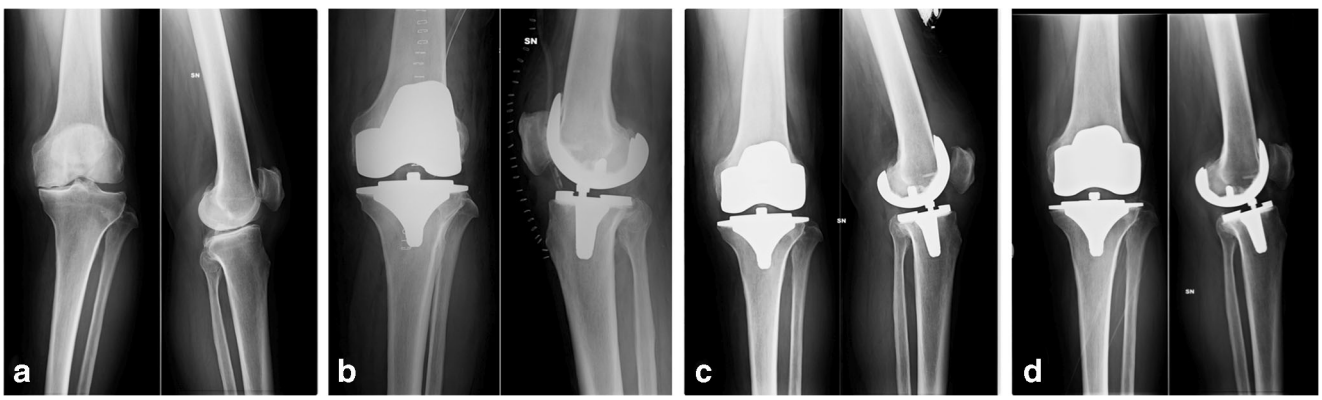

Fig. 3 **a** Pre-operative radiograph of a 67 year old woman with a third degree Kellgren-Lawrence Knee osteoarthritis. **b** The immediate post-operative showed the correct positioning of both components, no RLs were present. **c** 1 year post-operative control. **d** 5 years post-operative control

Table 2 Kaplan-Meier at 5 years, considering patients with reoperations for any cause as failure. The mean survivorship time was 59.4 months (standard deviation 0.3 months, CI 95% 58.7–59.98)

Time (years)	Knees at risk	Died	Lost to follow-up	Reoperations
0	351	0	0	0
1	351	3	7	3
2	338	3	6	1
3	328	4	6	1
4	317	3	4	1
5	309	0	0	0

remain unsatisfied by the outcome of their primary TKA. Post-operative dissatisfaction may be caused by different factors. Kahlemberg et al. [30], in their systematic review, identified a series of predictors for post-operative satisfaction (higher post-operative function, greater post-operative improvement in function, decrease pain, and fulfillment of expectation) and dissatisfaction (persistent pain, anxiety, depression, and poorer mental health). In another systematic review of the literature, Gunaratne et al. [5] identified a series of intra-operative factors that may cause post-operative dissatisfaction, as prosthesis design, fixation methods, and component alignment. In the last decades, MP designs were introduced into the market with the aim to restore the natural knee movements and potentially reduce the number of dissatisfied patients [11, 13].

The aim of our study was to evaluate the post-operative outcomes of patients that underwent primary TKA using a specific MP design. In our cohort of 315 knees (297 patients) with a minimum follow-up of five years, there were six reoperations representing an overall survivorship of 98.2% (95% CI 0.96 to 0.99, number at risk at 5 years 309). Our results strengthen previous reports with similar mid-term follow-up on MP-TKAs [13, 26, 31]. These study present the outcome of 1167 MP-TKAs with five-years follow-up and report only very few cases of aseptical loosening of the prosthetic components (Table 4). With this specific manufacturer MP-TKA, we reported a 0% re-operation rate due to aseptical loosening, progressive radiolucent lines, osteolysis, or knee instability [27]. Our medium-term results are in line to previously published results described by Fitch et al. [28], in a systematic review of the literature on the outcome of 1147 advanced MP-TKAs (MicroPort Scientific Corporation). Moreover, a similar survivorship was observed also with the reported survivor rate of the National Joint Registry of England, Wales and Northern Ireland (NJREWNI) [29]. The NJREWNI reported a one-year revision rate of 0.41% and a five-year revision rate of 2.19% considering all types of implants, fixation, and wearing surface, while they reported a 1-year revision rate of 0.47% and a five-year revision rate of 2.54% considering PS-fixed bearing only. In addition, our results were similar to the TKAs revision rate reported by the Australian Orthopedic Association National Joint Replacement Registry at five years (3.6% considering all type of implant, and 3.5 considering MP-TKAs only) [4].

In addition, we decided to administer the FJS. This "novel" PROM was introduced in early 2012 [21] to assess patient's awareness of their prosthetic-knee joint during activities of daily living, with the ambitious aim to discriminate between patients from good to excellent joint function [32]. It was tested for validity, reliability, and reproducibility in different international large-cohort studies [33, 34]. The mean FJS after five years from the index surgery was 69.2 ± 7.4 in the present study. At the moment, only two studies reported post-operative FJS when MP-TKAs were used. A study by Samy et al. [35], compared two groups of patients, one undergoing TKAs with MP-TKAs and one undergoing PS-TKAs, founding that MP-TKAs scored better results for FJS (59.72 in the MP group and 44.77 in PS group). The study by

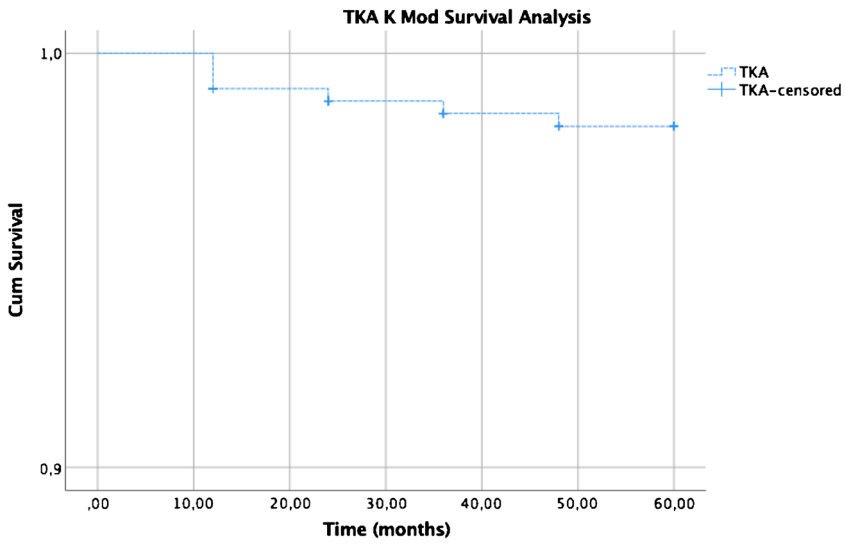

Fig. 4 Kaplan-Meier survivorship curve, with re-operation for any reason as the endpoint

Table 3 Objective scores, subjective scores, and radiographic results of the 353 K-Mod TKAs

Category	Variable	Pre-operative	Post-operative	*p* value
Objective scores				
	Knee Society score	33.4	90.6	< 0.05
	Function score	39.6	81.7	< 0.05
	Range of motion (°)	98.8°	118.8°	< 0.05
Subjective scores				
	WOMAC	48.9	12.2	< 0.05
	OKS	46.3	24.2	< 0.05
	FJS	nr	67.3	/
	SF-12	25.5	45.8	/
Radiographic results				
	Alfa	/	96.5°	
	Beta	/	88.4°	
	Gamma	/	1.6°	
	Delta	/	88.7°	
	Femorotibial angle	Valgus 4.5°	Varus 2.8°	
	Tibial RL	/	43 (12.2%)	
	Femoral RL	/	33 (9.2%)	

WOMAC Western Ontario and Mc Master Universities, *OKS* Oxford Knee Score, *FJS* Forgotten Joint Score, *SF-12* short form health status instrument [13, 25–29]

Katchky et al. [26], in a case series of 92 patients using the SAIPH MP knee system (MatOrtho, Surrey, UK), reported a mean post-operative FJS of 75.3. The mean FJS reported in the present study is similar, or slightly higher when compared with results obtained using different prosthetic designs. A study by Kamenaga et al. [36] reported a mean FJS-12 score of 52.2 at one year using a cruciate-retaining implant (Persona CR, Zimmer Biomet Inc., Warsaw, IN, USA). A study by Thienpont and Zorman [37] documented a better FJS in patients that underwent fixed bearing TKA than patients that underwent mobile-bearing TKAs, 71 and 56.5 points, respectively.

One of the theoretical advantages of the MP-TKA design is the high congruency between the femoral and tibial component, thanks to the morphology of the polyethylene insert (Fig. 1) that guarantee stability in full extension and at different degrees of flexion [11, 12]. Some patients with PS and CR TKAs continue to experience pain and discomfort despite of the components that are correctly balanced in flexion and extension. In particular, discomfort during ascending or descending stairs or getting up from a sitting could be caused by the mid-flexion instability. The term "mid-flexion instability" was introduced in 1990 with a laboratory investigation of the effect of the joint line on TKA stability by Martin and Whiteside [38, 39]. The authors documented that the proximal migration of the joint line reduces the flexion stability, in particular between 30 and 60° [38]. Biomechanical studies have demonstrated that knee joint acts as ball-and-socket joint with the medial condyle which rotates on its axis with a very restricted anteroposterior translation, while the lateral condyle both translate and turn at the different degree of knee flexion. Both CR and PS knee prosthesis designs failed to reproduce the "natural" knee kinematic, characterized by the posterior femoral rollback and external tibial rotation [11, 12, 25, 40]. In addition to the restoration of normal kinematics, MP prosthesis demonstrated to have other advantages. Knee stability, evaluated by in vivo studies, seems to be greater when MP design knee prostheses are used [31, 40]. In particular, MP design is not characterized by the presence of paradoxical anterior shift of the femur during knee flexion. A study by Shimmin et al. [41] confirmed with a fluoroscopic motion study that MP-TKA during activities as kneeling, pivoting, and squatting is characterized by the posterior translation of the lateral femoral condyle and tibial external rotation, while the medial condyle remains stable avoiding the paradoxical anterior femoral shift. A study by Schimdt et al. [31] compared the tibiofemoral rotation under fluoroscopy during normal gait in patients with MP and with two different CR prosthesis designs. They found that patients with MP showed a minimal motion of the medial condyle, while the two groups of patients with CR designs showed the paradoxical tibial roll forward and a great medial condyle translation. Another theoretical advantage of MP prosthesis is a reduced polyethylene wear debris caused by the large contact area of the medial aspect of the articulation. A study by Minoda et al. [42] has analyzed the synovial fluid of patients that underwent MP or PS knee arthroplasty, looking for polyethylene wear particles with

Table 4 Mean follow-up, number of patients, survival rate, revision due to aseptical loosening, and objective and subjective scores of studies performed using a MP-TKA with similar follow-up period

	Follow-up (years)	Number of patients	Survival rate (%)	Revision due to aspetic loosening (%)	Objective scores			Subjective score			
					KSS (pre/post)	FS (pre/post)	ROM° (pre/post)	WOMAC	OKS	SF-12	FJS
Anderson [43]	5	238	97.2	0.42	33/90	nr	107/121	nr	nr	nr	nr
Fan [44]	5.3	59	100	0	30.5/91.1	36.7/82.3	103.5/115.4	nr	nr	nr	nr
Schmidt [31]	5	365	96.6	0.55	67.1/95.5	nr	115/119	nr	nr	nr	nr
Macheras [13]	5	347	100	0	32.5/92.2	42.8/82.1	nr	30.8/79.3	44.6/22	25.3/47.7	nr
Choi [25]	5	58	100	0	40.6/89.4	54.8/88.8	114.1/121.1	55.2/12.7	nr	nr	nr
Katchky [26]	5	100	98	0	nr	nr	nr/124	44.6/6.5	nr	nr	nr/75.3
Present study	5	315	98.3	0	33.4/90.6	39.6/81.7	98.8/118.5	48.9/12.2	46.3/24.2	25.5/45.8	nr/67.3

a standardized technique. They founded that in MP group, particles were smaller and rounded, but the difference did not reach the statistical significance.

This study has some limitations. First, this is a retrospective study design with a low (level IV) level of evidence, based on our internal arthroplasty registry. We can only determine the incidence of complications and the subjective and objective scores obtained with the K-Mod DC TKA. To avoid the risk of selection bias, we enrolled a series of consecutive patients. Recall bias was limited, and only few patients were lost to follow-up within five years (23 over 251 knees, 6.5%). Second, there was no control group. The presence of a control group with a different prosthetic design would raise the statistical weight of our results. Third, all the surgeries were performed by a high-volume surgeon that performs more than 300 total joint replacement (> 200 knees and > 150 hips per year), and the findings may be not reproducible by a low-volume surgeon. Fourth, the follow-up length was relatively short, but considering that this is the first study with this specific implant, it is essential to evaluate the absence of frequent early failures. Lastly, FJS and SF-12 were collected post-operatively only.

In conclusion, in the present study, we reported the excellent clinical, radiographic, and patient-reported outcome of patients that underwent primary TKA with K-Mod DC design. We observed fived-year cumulative implant survivorship of 98.3% that is in line with similar studies with other MP-TKA brand and with arthroplasty registries report. No patients required revision due to implant-related failure (as aseptic loosening, instability, wear debris, or persistent post-operative knee pain). Besides, clinical outcome and PROMs showed a statistically significant improvement, and their mean values were equal or higher when compared with other similar studies. Our results were optimal especially for the FJS (mean value 67.3) and WOMAC score (mean post-operative value 12.2). Therefore, the use of a MP knee may help to fill the gap between clinical outcome and PROMs that is observed with other implant designs, thanks to the restoration of a natural knee kinematics.

Compliance with ethical standards

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

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