

Article

Medial Ball-in-Socket Posterior Cruciate-Sacrificing Total Knee Arthroplasty: Clinical, Functional and Radiographic Evaluation of 100 Consecutive Implants

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Abstract: The number of performed total knee arthroplasty (TKA) operations is constantly growing. This study proposes an evaluation of a series of patients undergoing medial pivot (MP) TKA surgery from a subjective, clinical and biomechanical point of view. A consecutive series of 100 TKAs implanted in a single centre, by the same surgeon, with a medial parapatellar approach with the sacrifice of the posterior cruciate ligament and cemented components were evaluated. All patients underwent standardized radiographic and functional clinical evaluation, with standing antero-posterior, lateral and patellar axial views; pre-operatively and post-operatively at 1, 3, 6 and 12 months; and then annually. Results were evaluated using three different patient-related outcome measurement scores (PROMs): the Knee Osteoarthritis Outcome Score (KOOS), the new Knee Society Score (nKSS) and the Short Form Health Survey 36 (SF-36). Excellent results in all treated knees were documented using the PROMs: the mean nKSS was 199.8, the mean KOOS was good to excellent in every subscale, and the mean was SF-36 82%. There were no cases of septic or aseptic loosening, vascular damage, neurological damage, or revision surgery for any reason. According to the experience gained, MP implants demonstrated excellent results, being clinically functional in both objective and subjective terms as well as radiographic evaluations, thus resulting in a winning strategy for obtaining a TKA that makes the patient satisfied and able to perform their daily life activities.

Keywords: total knee arthroplasty; medial pivot; ball-in-socket; outcomes; knee osteoarthritis



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1. Introduction

The average age of the global population is constantly increasing, and at the same time, there is a growth in chronic degenerative pathologies. One of the most common pathologies is knee osteoarthritis (OA). At present, the treatment of choice for advanced knee OA is prosthetic replacement [1]. Due to the ability of this procedure to improve the patient's quality of life, reducing pain symptoms and allowing the recovery of joint functionality [2], the number of total knee arthroplasties (TKAs) is destined to significantly grow in the next few years [3]. In the literature, survival rates of prosthetic implants have been reported as higher than 95% after more than 10 years [4,5]. However, not all patients can obtain the desired satisfaction due to residual pain or the non-optimal functionality of the prosthetic joint. Some studies report dissatisfaction rates as high as 20% [6,7].

Many variables can be involved in patient dissatisfaction: suboptimal indication and/or surgical timing, body mass index (BMI), patient compliance and the quality of the post-operative rehabilitation process, and pseudo-patella baja [8]. Prosthetic design is

one of the factors [9,10] most involved in the success of the procedure in terms of patient satisfaction since it affects the kinematics of the joint. Traditional implants such as cruciate-retaining or posterior-stabilized (PS) designs can cause a series of problems such as impaired antero-posterior translation, mid-flexion instability, and impaired roll-back [11,12].

Some implants have been designed to reproduce the native kinematics of the knee joint using a medial-stabilized design. Characterized by the so-called “ball-in-socket” philosophy, medial pivot (MP) implants have a highly congruent medial compartment and a relatively flat lateral compartment, which allows the medial condyle to pivot on the tibial plateau, while the lateral one translates posteriorly starting from 45° of flexion [13–17]. There are different designs, and these can be employed by retaining or sacrificing the posterior cruciate ligament.

The present study aimed to evaluate whether the theoretical advantages of MP prostheses were confirmed in a series of 100 consecutive TKAs, performed at the Orthopedic Clinic of the of Siena University Hospital (Siena, Italy) and evaluated from a subjective, objective, clinical, and biomechanical point of view.

2. Materials and Methods

Study design. This is a retrospective single-centre, single-surgeon study, analysing 100 consecutive TKAs performed over a period between January 2019 and April 2022. All surgeries were performed by the senior author, using the same surgical technique and the same prosthesis. At our institution, no Ethical Committee nor Institutional Review Board approval is necessary for retrospective studies, and all patients gave their informed consent to the collection and anonymous use of their data for scientific and teaching purposes. This study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Surgical procedure. For all patients, pre-operative planning was based on adequate radiographs performed in a standing position. Surgery was performed under spinal or general anaesthesia, depending on the patient’s general condition and comorbidities. Pre-operative antibiotic and post-operative anti-thromboembolic prophylaxes were administered. Patients were positioned in the supine position, and a pneumatic tourniquet was inflated during the procedure. The medial parapatellar approach was used in all cases. After articular exposure, the femur was prepared using intramedullary alignment jigs, with the aim of achieving a neutral mechanical angle (anatomical valgus angle between 5° and 7°, as measured in the pre-operative radiographs) and an external rotation of the femoral component of 3° in varus knees and 5° in valgus knees, with respect to the posterior condylar axis. The meticulous removal of the osteophytes from the posterior distal femur and posterior capsular release was performed after bone resections when needed. The tibial cut was performed using an extramedullary guide, aiming to achieve a neutral mechanical axis (mechanical alignment) with a posterior inclination between 0° and 3°. Frontal plane soft tissue balance and flexion–extension gaps were evaluated. An Evolution[®] MP cemented prosthesis (Microport Orthopedics Inc., Arlington, TN, USA), with the sacrifice of the posterior cruciate ligament, was implanted in all patients. To control bleeding, in the absence of contraindications, tranexamic acid was administered both intravenously and locally, as previously described [18]. A drain was then inserted and left in place for one day post-operatively. All patients followed the same standardized rehabilitation protocol, including weight-bearing ambulation from post-operative day 1.

Follow-up. All patients underwent a standardized clinical, functional, and radiographic evaluation. Follow-up included clinical and radiological examinations at 1, 3, 6 and 12 months and then annually. The active and passive range of motion (ROM) values were recorded, antero-posterior and varus-valgus stress tests were performed and patellar tracking and points of tenderness were evaluated. Three patient-related outcome measurement scores (PROMs) were also administered at every follow-up visit: the Knee Osteoarthritis Outcome Score (KOOS), the new Knee Society Score (nKSS) and the Short Form Health Survey 36 (SF-36). The KOOS is an outcome analysis tool defined as patient-reported since

it is compiled by the patient. This score was used because there are many references to values in population sub-categories in the literature and it represents a highly repeatable and replicable index [19–26]. The nKSS was presented in 2011 to meet the need for a more patient-related tool, with the aim of associating an objective clinical evaluation with a subjective functional assessment, and it appears to be a reliable and validated outcome indicator [27]. The SF-36 is a self-administered questionnaire that aims to quantify the state of the global health of the patient and to measure health-related quality of life [28–30].

Additionally, radiological evaluation was performed with a standing antero-posterior view, a 30° of flexion lateral view and a Merchant axial view of the patella at each visit. The demographic parameters for each patient and the 3 scores were evaluated, and their trends over time were studied. Additionally, the presence of post-operative complications that would require revision surgery and influence mortality was evaluated.

Statistical analysis. Statistical analysis was performed using the Wilcoxon signed-rank test to identify any statistical differences between nKSS, KOOS, and SF-36 score values assessed before and after surgery. The significance level was set at $p < 0.05$. All data were analysed using XlsStat 2020 software (Addinsoft, New York, NY, USA) for MS Excel (Microsoft, Seattle, WA, USA).

3. Results

Patients undergoing TKA performed at the Orthopedic Clinic of Siena University Hospital (Siena, Italy), with a medial parapatellar surgical approach and Evolution® MP cemented prosthesis with the sacrifice of the posterior cruciate ligament, were included in the study. According to these criteria, 100 implants were selected for the study. Of these 100 prostheses, 46 were performed on male patients and 54 on female patients. In total, 18 bilateral TKAs and surgeries on 34 right knees and 30 left knees were performed. The patella was resurfaced in all cases except nine. At the time of surgery, the mean age was 71.1 ± 7.9 (range 51–88) years, the mean BMI was 24.4 ± 2.1 kg/m² (range 19.8–30.0) and mean follow-up was 22.4 ± 16.9 (range 12–48) months. All data from the three PROMs chosen for the clinical and functional evaluations were analysed. The total pre- and post-operative mean values of the various scores and the values for each of the follow-up intervals were calculated, making each subscale of the various scores explicit. The results are shown in Tables 1–4.

Post-operative radiographs showed a femoral–tibial and patellofemoral alignment that was congruous and consistent with the planned surgery. Furthermore, they did not show any progressive radiolucent line nor any radiologically loosened component (Figure 1). There were no cases of septic or aseptic loosening, nor vascular or neurological damage, for which a new prosthetic revision surgery was necessary.

Table 1. Scores for clinical and functional evaluation. The nKSS ranges from 0 to a maximum of 255 points, KOOS ranges from 0 to a maximum of 100 points and SF-36 is expressed as a percentage (100% maximum).

SCORE	pre-op	1 Month	3 Months	6 Months	12 Months	24 Months	36 Months	48 Months
nKSS (points)	138.0 ± 13.1	183.6 ± 7.3	194.5 ± 9.2	197.2 ± 13.2	198.1 ± 10.6	201.3 ± 11.5	206.6 ± 12.8	206.4 ± 13.3
KOOS (points)	38.4 ± 12.9	83.0 ± 6.7	89.9 ± 3.3	85.5 ± 12.4	88.3 ± 7.8	89.4 ± 7.6	91.5 ± 7.7	89.1 ± 12.3
SF-36 (%)	51 ± 19.4	79.2 ± 14.0	80.3 ± 15.0	81.4 ± 14.0	79.3 ± 8.0	83.6 ± 10.0	83.7 ± 17.0	83.8 ± 12.0

Table 2. Pre- and post-operative mean values of the nKSS. Values are expressed as points (0 to a maximum of 255; mean \pm SD).

nKSS (Points)	pre-op	1 Month	3 Months	6 Months	12 Months	24 Months	36 Months	48 Months
Objective Knee Score	48.3 \pm 14.8	66.2 \pm 1.8	67.5 \pm 0.6	67.6 \pm 0.5	67.7 \pm 0.5	67.2 \pm 1.6	67.9 \pm 0.3	67 \pm 2.2
Patient Expectations Score	13.8 \pm 1.9	11.2 \pm 0.8	12 \pm 1.8	12.7 \pm 0.9	13 \pm 1.0	12.4 \pm 1.4	13.3 \pm 0.9	12.8 \pm 0.8
Patient Satisfaction Score	30.3 \pm 14	33.2 \pm 3.6	35 \pm 6.2	36.2 \pm 4.4	35.3 \pm 4.2	36.6 \pm 3.9	38.2 \pm 3.4	38.3 \pm 3.3
Functional Score	37.2 \pm 17.9	73 \pm 6.7	80 \pm 8.2	80.7 \pm 11.7	82.2 \pm 11.8	85 \pm 10.3	87.2 \pm 10.2	88.5 \pm 12.9

Table 3. Pre- and post-operative mean values of the KOOS. ADL: Activities of Daily Living. Sport/Rec: Sport and Recreation Function. QOL: Quality of Life. Values are expressed as points (0 to a maximum of 100; mean \pm SD).

KOOS (Points)	pre-op	1 Month	3 Months	6 Months	12 Months	24 Months	36 Months	48 Months
Symptoms	46.9 \pm 15.0	91.4 \pm 6.0	96.8 \pm 3.0	91.8 \pm 11.8	94.5 \pm 11.6	96.0 \pm 6.0	96.4 \pm 5.0	94.6 \pm 11.0
Pain	48.8 \pm 14.9	97.2 \pm 4.8	98.1 \pm 3.0	98.4 \pm 2.1	97.5 \pm 4.0	98.2 \pm 2.5	98.8 \pm 2.0	94.7 \pm 10.7
ADL	48.3 \pm 16.9	96.2 \pm 10.8	99.3 \pm 10.7	97.3 \pm 4.8	98.2 \pm 2.9	96.5 \pm 9.8	97.4 \pm 5.0	96.2 \pm 7.4
Sport/Rec	11.5 \pm 14.6	43.0 \pm 23.0	61.3 \pm 14.4	55.2 \pm 30.0	58.3 \pm 22.5	63.4 \pm 19.1	69.0 \pm 26.0	68.8 \pm 25.9
QOL	21.6 \pm 14.5	87.5 \pm 11.2	94.3 \pm 6.5	87.5 \pm 17.3	92.9 \pm 11.8	92.8 \pm 13.6	96.2 \pm 6.2	91.3 \pm 15.4

Table 4. Pre- and post-operative mean values of the SF-36. Values are expressed as percentages (mean \pm SD).

SF-36 (%)	pre-op	1 Month	3 Months	6 Months	12 Months	24 Months	36 Months	48 Months
Physical functioning	50 \pm 15	70 \pm 23	79 \pm 5	77 \pm 20	81 \pm 8	79 \pm 14	84 \pm 11	77 \pm 27
Role limitations due to physical health	25 \pm 19	78 \pm 22	92 \pm 10	87 \pm 11	74 \pm 35	81 \pm 14	85 \pm 32	77 \pm 28
Role limitations due to emotional problems	94 \pm 18	93 \pm 15	81 \pm 32	87 \pm 26	91 \pm 18	82 \pm 33	86 \pm 34	94 \pm 13
Energy/fatigue	25 \pm 15	76 \pm 17	75 \pm 44	79 \pm 27	74 \pm 29	81 \pm 15	84 \pm 21	90 \pm 9
Emotional well-being	54 \pm 18	76 \pm 16	69 \pm 41	79 \pm 29	75 \pm 28	93 \pm 6	84 \pm 22	88 \pm 9
Social functioning	50 \pm 15	94 \pm 9	91 \pm 19	87 \pm 20	97 \pm 10	95 \pm 7	91 \pm 17	84 \pm 26

Table 4. *Cont.*

SF-36 (%)	pre-op	1 Month	3 Months	6 Months	12 Months	24 Months	36 Months	48 Months
Pain	41 ± 14	90 ± 11	87 ± 10	84 ± 18	90 ± 11	94 ± 11	89 ± 13	90 ± 19
General Health	59 ± 14	70 ± 14	84 ± 8	80 ± 12	79 ± 15	82 ± 10	79 ± 16	88 ± 9
Health change	57 ± 21	66 ± 29	66 ± 20	70 ± 29	52 ± 32	65 ± 31	72 ± 19	66 ± 20



Figure 1. Post-operative radiographic and clinical evaluation of a male patient 48 months after a TKA was performed for post-traumatic OA of the right knee.

When studying the trend of individual scores from pre-operative to post-operative periods, followed by follow-up intervals, the greatest improvement occurs between pre- and post-surgery periods ($p < 0.05$), compared to the entire post-operative time course. Trends of the total value and of all the subscales of the nKSS, KOOS and SF-36 are reported in Figures 2–8.

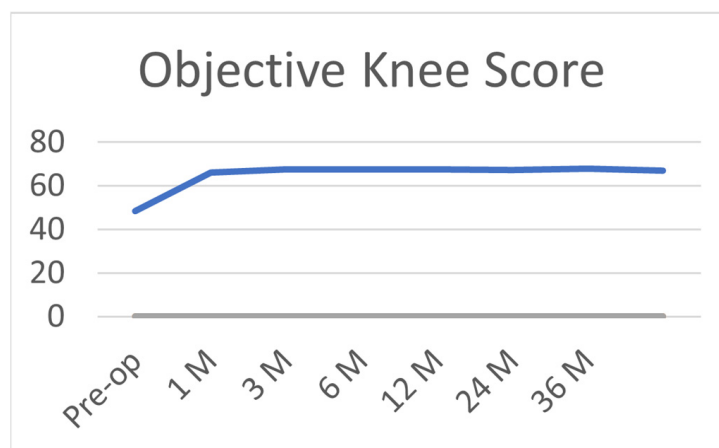


Figure 2. Objective nKSS time course.

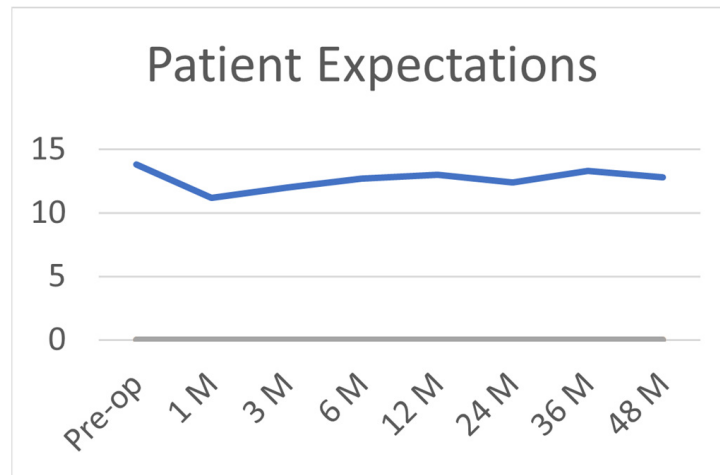


Figure 3. Time course of the item “Patient expectations” in the nKSS.

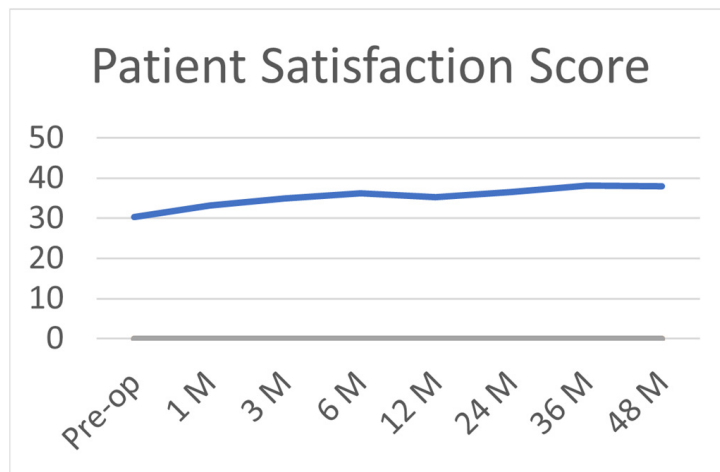


Figure 4. Time course of the item “Patient Satisfaction” in the nKSS.

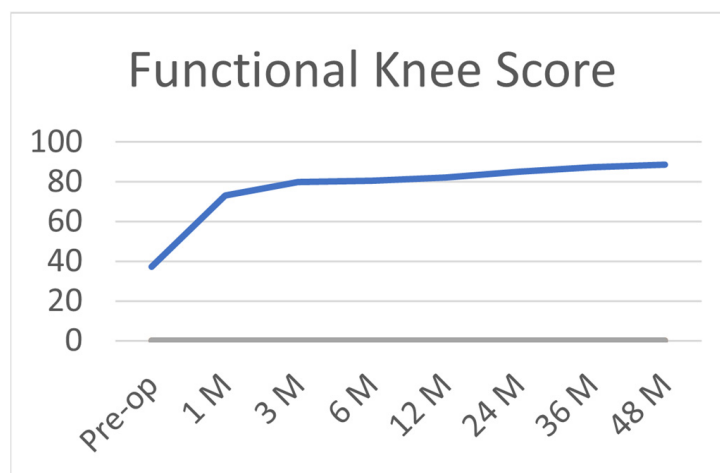


Figure 5. Functional nKSS time course.

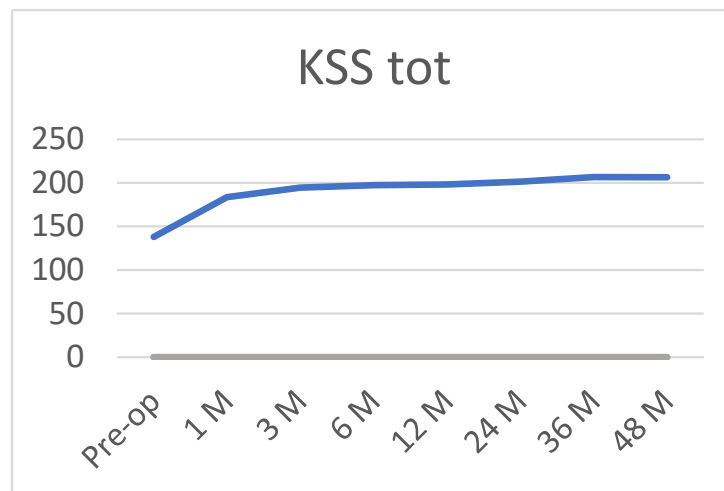


Figure 6. Total nKSS time course.

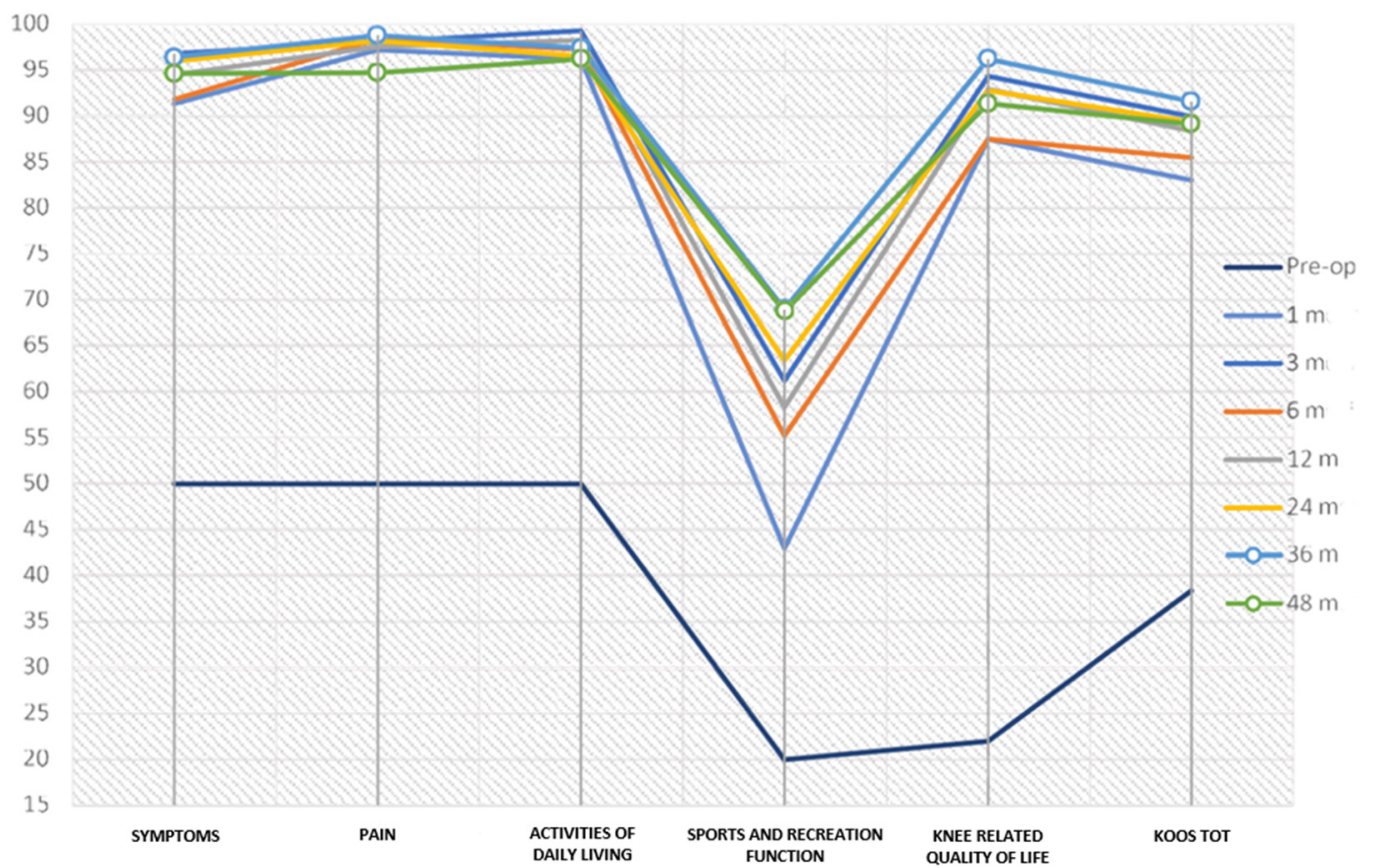


Figure 7. KOOS time course.

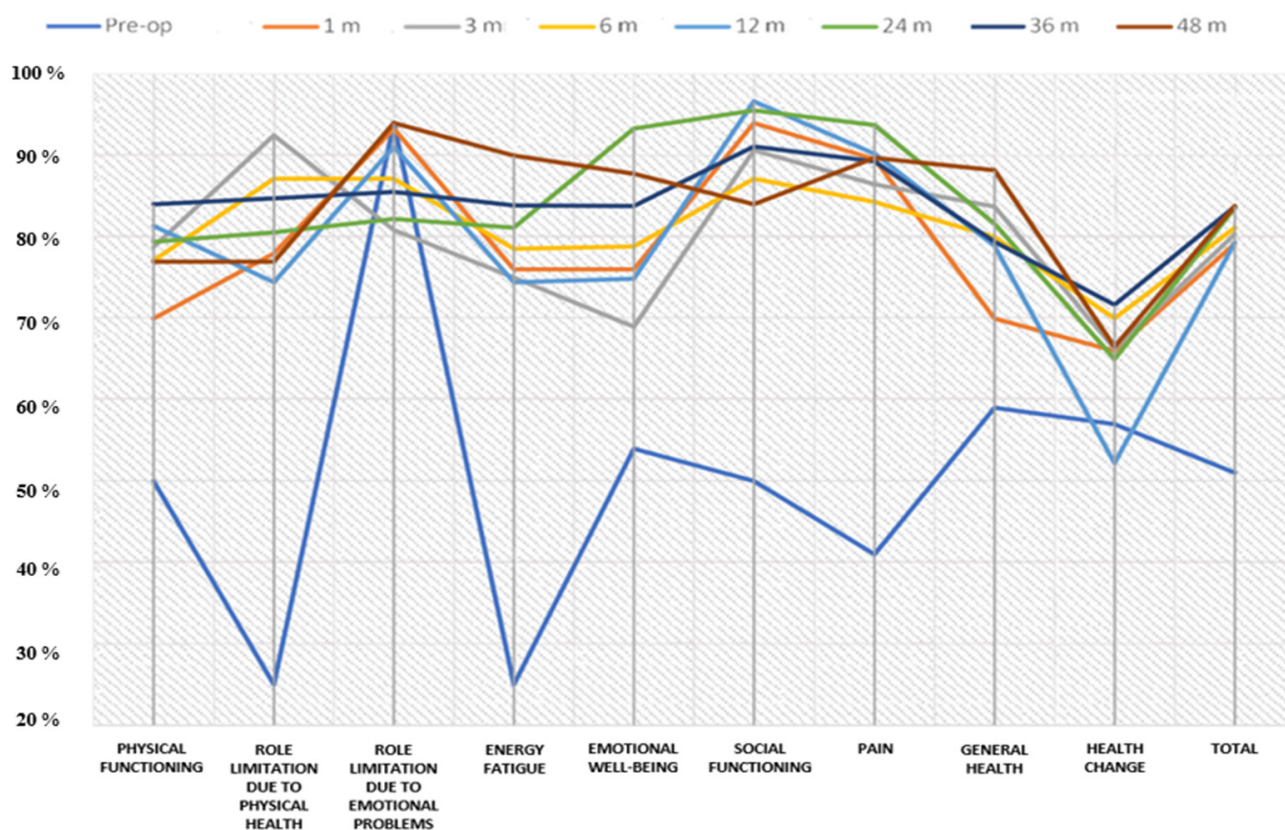


Figure 8. SF-36 time course.

4. Discussion

By studying the nKSS data, it is possible to appreciate the very positive improvements in all the subscales that are used to investigate the patient's clinical condition (objective nKSS, functional nKSS); however, in the subscale that investigates patient expectations and satisfaction, the trend is not as clear. The trend of the "Patient Expectations" decreased from 13.8 ± 1.9 (range 13–15) to 11.2 ± 0.8 (range 10–12) points ($p < 0.05$) in the transition from the pre-operative to post-operative period, most likely because the patient optimistically thinks that the situation will return to normal in the immediate post-operative period, or she/he puts too much trust in the TKA operation. However, with subsequent follow-up intervals, a gradual increase that came very close to pre-operative expectations was observed between 12 and 36 months after the operation. This is also due to the type of MP prosthesis, which from an arthrokinematic point of view is very close to physiological biomechanics. Excellent results were obtained in the nKSS, with no values below 180 and a minimum average value of 183.6 ± 7.3 obtained after 1 month of follow-up, an expected situation that is in line with a picture of the gradual recovery of joint mobility and muscle strength.

When studying the time trend of KOOS, the most significant aspect is the considerable improvement in all the subscales, and thus the total score, from pre-operative to post-operative conditions. The second aspect that can be observed from the graph is a much more gradual improvement in the "Sport and Recreation Function" subscale compared to the other subscales, where a very considerable improvement is observed right from the start at the first follow-up interval (1 month). This could be because patient safety and the patient's ability to perform complex motor activities are aspects that tend to improve more gradually than all other issues, e.g., pain, symptoms and the ability to perform daily activities.

By analysing the results of the SF-36 questionnaire, it is possible to appreciate the significant improvement in the total values of the pre-operative and post-operative scores

(around 30%), but the significant improvements in the activity limitation component due to physical problems and in the general tiredness component is peculiar. However, the improvements, which are minor in absolute terms but certainly present in the components of emotional state, social functioning and pain, should not be underestimated. The use of this type of score in our study had precisely the rationale of investigating the patient's global condition, while not neglecting emotional and social aspects. As expected, knee OA has a major impact on the patient from a socio-emotional point of view due to painful symptoms and limitations of daily activities. In most cases, the TKA with an MP design prosthesis improves painful symptoms and allows one to return to daily activities, resulting in an increase in the general health of patients on both social and emotional level. The high rate of patients who underwent bilateral TKA surgery represents an indirect sign of satisfaction, as the patient returns to the same centre and the same surgeon.

The use of MP prostheses in TKA involves numerous advantages, not least the possibility of the surgeon's choice between a mechanical or kinematic alignment with promising results [31,32]. From a biomechanical point of view, an MP implant mimics physiological joint kinematics, resulting in a natural feeling for the patient [33–35]. Due to their design, antero-posterior and varus–valgus stability was observed along all ROM, which provides a natural movement sensation. This MP prosthetic geometry allows for the excellent functionality of the quadriceps, which implements proprioception, further increasing the sensation of naturalness [36].

Finally, although this kind of prosthesis has been associated with greater wear over time, some studies have shown reduced wear over time [37]. A medial “ball-in-socket” design improves painful symptoms and allows patients to return to daily activities, resulting in an improvement in the general health of the patients both from a physical and psychological point of view. Medial-pivot prostheses demonstrated excellent clinical and functional results in objective and subjective terms (highlighted by the scores used), as well as in the radiographic evaluation.

This is in line with the literature, for example, studies by Nishio et al. [38], Macheras et al. [39], Sabatini et al. [40] and Bianchi et al. [41], in which clinical outcomes and PROMs were found to be better in MP implants than in other designs. Bianchi et al. compared MP and PS designs from a subjective, clinical and biomechanical point of view. Regarding the subjective results, the authors opted for the use of the Forgotten Joint Score Questionnaire. Clinical evaluation included ROM and stability. Furthermore, all the subjects underwent a gait analysis with the use of treadmills with plates for measuring strength and video-recording devices. Data such as walking speed, cadence and stride length, and stance time were recorded. This study certainly demonstrated an improvement in ROM in line with the literature, but the most significant finding was that TKAs with an MP design guarantee better stability in mid-flexion and a better perception of the implant than those with a PS design. An MP design is perceived as very similar to the native knee, guaranteeing a sensation of “natural feeling”. As a matter of fact, the question in which the greatest difference was noted between the two groups of patients (MP vs. PS) was “Do you feel like you have a TKA with artificial knee sensation when you get up from your chair?”. It has been recognized that knee instability in mid-flexion is one of the main causes of discomfort, and it can lead to revision surgery. During the activity of getting up from a chair, a high degree of stability in medium dynamic flexion is required. It is also an action that patients perform many times during their daily lives, and thus it is an excellent index for measuring how patients perceive prosthetic implants [41]. However, other studies show overlapping or non-unique results between MP and different prosthetic designs, as highlighted by Fitch et al. [42] and Young et al. [43]. In their systematic review, the latter authors found statistically significantly better results for the nKSS in the subgroup “not medial stabilized” implants, while a better Western Ontario and McMaster Universities Osteoarthritis Index was found for the “medial stabilized” group. Nevertheless, retrospective comparative [35,44] and non-comparative studies [45,46] have shown better results in medial stabilized implants than other types of prostheses.

Although there is no consensus in the literature regarding the correlation between the pattern of MP arthrokinematics and clinical improvements after a TKA, MP designs currently represent one of the best options for a prosthetic replacement of the knee. This prosthetic geometry allows for a better extensor mechanism by avoiding paradoxical translational movements present in other designs. Furthermore, it allows for better patient satisfaction concerning carrying out normal daily activities, and thus also leads to a better quality of life, as demonstrated by the present study.

5. Conclusions

Medial ball-in-socket posterior cruciate-sacrificing implants, associated with the surgical technique presented in this study, is a winning strategy for obtaining a TKA that makes the patient satisfied and able to perform daily life activities in the best possible way.

Author Contributions: Conceptualization, N.M. and S.G.; methodology, N.C.O.; data curation, E.T., M.C. and T.G. (Tiziano Giacché); writing—original draft preparation, N.C.O.; writing—review and editing, N.C.O., N.M., T.G. (Tommaso Greco) and C.P.; visualization, N.M. and C.P.; supervision, N.M. and S.G. All authors have read and agreed to the published version of the manuscript.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study. Written informed consent has been obtained from the patient(s) to publish this paper.

Data Availability Statement: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest: The authors declare no conflict of interest.

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