Original article

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Clinical and functional results of Optetrack™ Total Knee Arthroplasty after 6 to 13 years: findings from a retrospective study

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Abstract

Introduction: Total Knee Arthroplasty (TKA) is considered the gold standard in the treatment of knee osteoarthritis and post-traumatic knee deformities. The aim of the study was to report the functional results of a group of Optetrack™ TKA patients over a period between 6 and 13 years after surgery.

Material and methods: A group of 47 TKA prostheses applied to 39 patients (32 women) were analysed retrospectively. All patients received the same type of TKA and the same rehabilitation program. Patients were assessed before surgery and 3, 6 and 12 months after surgery; follow-ups were performed annually. Assessment was based on Knee Range of Motion (ROM) and a Knee Rating Score (IKS) composed of two partial scores: Knee Score (KS) and Functional Score (FS). The variables influencing the IKS score were identified using a Generalized Linear Model.

Results: The mean follow-up was 9.95 years (range 6–13). Mean age was 81.2 years (range 62–95). At the last follow-up, the mean IKS score increased from 78.6 (range 15–155) to 145.2 (range 58–200). Mean KS increased from 40.5 (range 0–96) to 85.7 (range 50–100); mean FS increased from 38.9 (range 0–75) to 60.9 (range 0–100). Mean knee ROM increased from 87.6° to 108.4° (range 50°–130°). Preoperative IKS score, male sex and age at surgery were positively correlated to the IKS score at follow-up.

Conclusions: TKA improved pain score, while the functional score decreased over time. Good preoperative IKS score and male sex were considered good outcome predictors; old preoperative age was considered as unfavourable.

Keywords: arthroplasty management, knee rating score, physical therapy, rehabilitation, TKA rehabilitation

Introduction

Total Knee Arthroplasty (TKA) is considered the gold standard in the treatment of knee osteoarthritis (OA) [1], and all traumatic or pathological cases resulting in severe functional limitation with significant disabling pain not responsive to conservative therapy [2]. It is one of the most commonly-performed orthopaedic surgical procedures worldwide [3], with a constantly growing demand [4]. In Italy, statistics showed 14969 interventions in 2020, with a 2:1 female to male ratio, and the highest prevalence between 65 and 74 years [5].

Over the years, many types of TKA have been developed to achieve even better functional results, e.g. condylar-resurfacing, cruciate retaining, posterior stabilised, constrained, high-flexion and gender-specific prostheses [6]. The TKA procedure aims to reduce pain, recover functionality and improve quality of life [7–9].

In order to achieve a good functional outcome, post-surgery rehabilitation is of primary importance [10–13]. A multidisciplinary and early inpatient rehabilitation intervention reduces the time needed for functional recovery [14,15], as well as the length of stay and overall hospitalisation costs [16,17]. Consequently, it is of fundamental importance to monitor the functional results of patients undergoing TKA implantation [5]. Numerous studies have been conducted over the years to observe the clinical and functional performance of this type of TKA [18–23] with the aim of developing better and more durable prostheses over time and planning more appropriate rehabilitation interventions to achieve better functional recovery [13]. In Italy, a previous retrospective observational study assessed the clinical and functional results of 63 patients who underwent the same type of TKA Optetrack™ between 1999 and 2004 [24]; however, in this study, the maximum observation period was limited to five years. Moreover, the authors did not analyse any factors that could influence the clinical and functional outcomes. Therefore, the primary purpose of this retrospective study was to extend the observation period of the original study [24], reporting the clinical and functional results of the same cohort of patients. In addition, the second objective was to identify which factors (e.g., Body Mass Index, age, gender, general patient' conditions) could be considered predictors of a good post-operative functional outcome.

Materials and methods

Study design

An observational retrospective study was performed, and reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline [25].

Setting and ethics

This study was conducted in a university hospital in Verona (Italy) according to the principles of the Declaration of Helsinki [26]. Ethical approval was not required for the present study due to its retrospective nature, without any direct involvement of the subjects, and the fact that it was based on anonymous data from medical records [27]. The data was entirely and irreversibly anonymised by generalising the critical variable (e.g. by replacing the patient's name with a random number) [28]. The datasets used and analysed during the current study are available from the corresponding author for reasonable reasons.

Participants

No age, sex or pathology criteria were applied when including TKA patients; however, all patients received the same Optetrak TKA, surgical method and rehabilitation process. Optetrak™ TKA (Exactech, Gainesville, FL, USA) represents an evolution of the Insall-Burnstein II Posterior Stabilized prosthesis (Zimmer, Warsaw, Ind) [18,20–22,29,30].

All subjects in whom the Optetrak TKA was not used, and those in whom the Optetrak TKA was explanted and/or replaced with another type, were excluded.

Surgical method

All the prostheses had been implanted by the same team of orthopaedic surgeons using the same surgical method (cemented, with patella prosthesis and posterior stabilization with the sacrifice of the posterior cruciate ligament). All subjects underwent the same antibiotic prophylaxis before and after surgery and the same pharmacological and mechanical treatment for the deep vein thrombosis prophylaxis (Appendix 1).

Rehabilitation protocol

All patients had been transferred to the same rehabilitation centre between the third and sixth postoperative days, following the same stretching-based rehabilitation protocol based on ROM recovery and quadriceps strengthening [9] (Appendix 1). The protocol consisted of four different phases: [phase 1] – Partial Range of Motion (ROM) recovery and 3-phase gait; [phase 2] – ROM improvement, crossed gait, muscle strengthening; [phase 3] – ROM improvement; [phase 4] – ROM improvement, crossed gait, muscle strengthening. Each phase lasts a minimum of one week. The passage to the next phase was subordinated to achieving specific objectives. When the results were not achieved, the patient repeated the same phase a maximum of two times; if the patients did not reach the planned results, they were referred to an orthopaedic specialist [24]. The patients with the best results followed a home exercise program as early as the second week (days 8-15) (see Appendix 1). All subjects who did not follow the planned rehabilitation process in all its phases or who did not regularly show up for check-ups were excluded.

Outcome measures

For the clinical assessment, the original version of the Knee Rating Score (IKS) was used [31,32]. Although this score has demonstrated limitations in terms

of validity and responsiveness [33,34], it has been widely used in the clinical setting to measure performance after total knee replacement [35]. Recently the IKS was deeply revised and updated [35]; however, the patients in our study were originally assessed with the old score version [24].

The total IKS score ranged from 0 (worst value) to 200 (best value). The score itself was obtained by the sum of two partial scores: the Knee Score (KS), which reflects pain, knee stability and range of motion, and the Functional Score (FS), based on the maximum distance travelled while walking, the ability to climb stairs and the use of walking aids. Both subscales ranged from 0 (worst value) to 100 (best value). Senior trained clinicians performed the Range of Motion (ROM) measurement using a manual goniometer [36,37] with the patient in the prone position and with the joint at the edge of the table. A manual goniometer has been proven to be a valid and reliable method to measure knee ROM; the intraclass correlation coefficients (ICCs) were 0.99 for intratester reliability and 0.90 for intertester reliability [38].

Data sources and measurement

The clinical and functional data of the prostheses were obtained from the anonymous evaluation forms included in the medical records without the direct involvement of the patients. Patients were assessed by expert clinicians immediately before surgery and three, six and twelve months after surgery; subsequently, follow-up examinations were administered periodically [24].

In some cases, additional information was collected regarding the patients' functional limitations. For example, it was recorded if a patient was unable to climb the stairs due to pain or other reasons, or if crutches or a cane were used due to the presence of pain, fear of falling or out of habit prior to the TKA.

Quantitative variables

The patient's age, sex, Body Mass Index (BMI), operated side, FS and KS scores and ROM were collected and inserted into a structured datasheet. IKS scores were calculated by adding the FS and KS scores. Any missing values between the different follow-ups were imputed for each patient by linear regression.

According to the Knee Rating Score, patients were also classified into three categories: Category A (Unilateral or bilateral with opposite knee successfully replaced), Category B (Unilateral, other knees symptomatic) and Category C (Multiple arthritis or medical infirmity) [31,33].

Statistical methods

Pre-surgery values were compared with the last mean follow-up values and with the those measured during all the scheduled periodic checks. In all comparisons, the significance level was set to $p < 0.05$; Bonferroni's correction was applied for multiple comparisons. Data with a normal distribution was compared with the Student's T-Test, and data with non-normal distribution was compared with the Mann-Whitney U-test (between groups comparisons) or Wilcoxon's test (within-group comparisons). Data on the 24 patients (26 prostheses) was lost to follow-up, and these were excluded from the analysis.

The Akaike Information Criterion (AIC) stepwise variable selection model building approach was used to estimate the best Generalized Linear Model (GLM) to identify any potential association between variables that could influence the IKS score measured at the mean follow-up (e.g., preoperative BMI, preoperative IKS, preoperative age). In addition, the Shapiro-Wilk test was used to analyse the residual distribution of the regression model (normal Q-Q plot). All calculations were performed using R-studio software [39].

Results

Participants

A total of 73 arthroplasties were included in the study. All were performed between 1999 and 2006. In total, this included 63 subjects (57 female) with a mean age of 72.8 years (range 56-87). All patients underwent the same type of TKA; no age, sex or pathology restrictions were placed on inclusion [24]. Patients underwent the joint replacement surgery for different reasons: knee OA (61 cases, 81%), Paget's disease (three cases, 4%), Rheumatoid Arthritis (three cases, 4%), post-traumatic OA (four cases, 5.4%) and congenital deformity (two cases, 2.7%). Over the entire observation period, 24 subjects dropped out (36.5%) for a total of 26 prostheses (33.7%): three subjects had refused to attend the planned visit (but reported that the TKA was still implanted and functioning), seven had died of causes not related to the surgery, and 14 were unreachable. To avoid overestimation of the results, all patients who did not follow the planned rehabilitation process in all its phases or who did not regularly attend the subsequent controls were excluded.

Therefore, in total, the study assessed the clinical and functional results of 47 arthroplasties distributed across 39 subjects (32 women; 82%) (Fig. 1.).

Descriptive data

The mean age of the subjects at mean follow-up was 81.2 years (range 62-95); no significant differences in age, BMI, and mean pre-intervention IKS were noted between men and women ($p > 0.05$). The mean passive

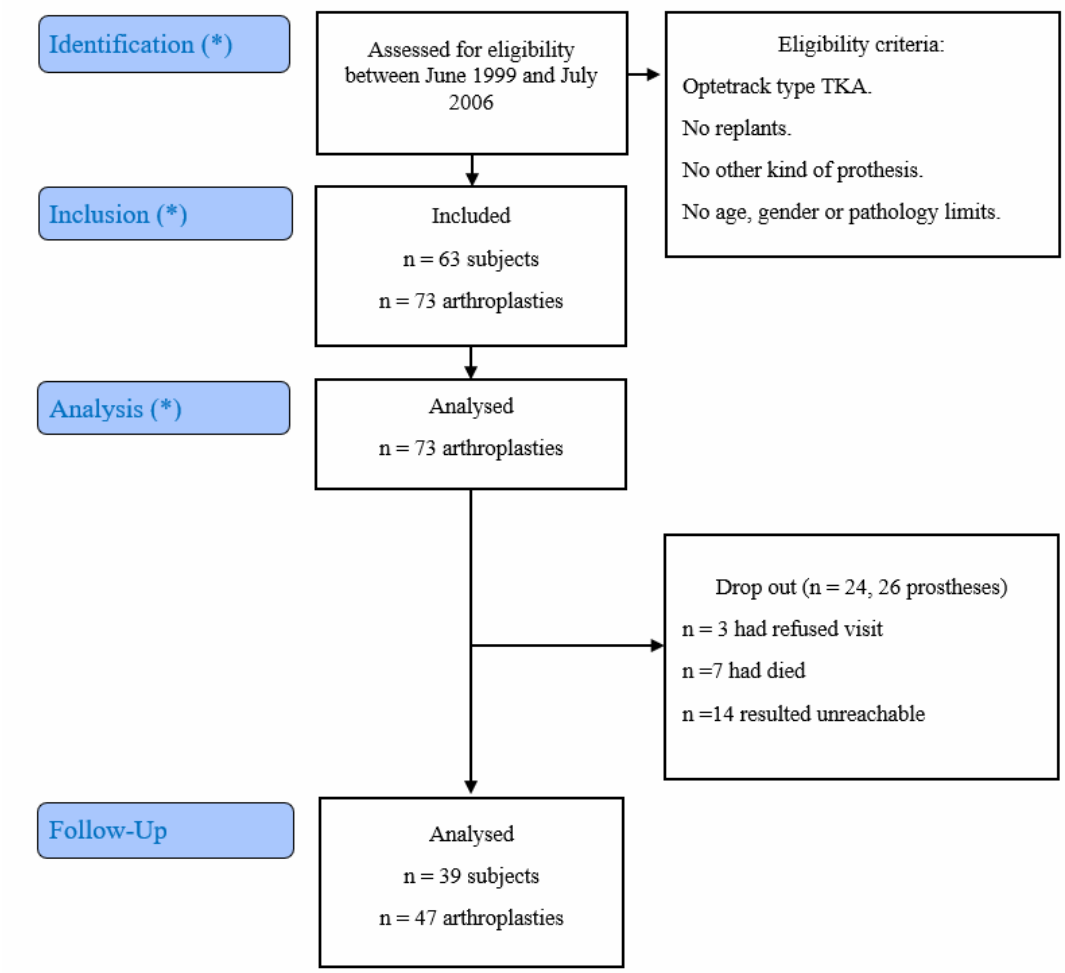

Fig. 1. STROBE Flow Diagram [24]

Note: (*) This phase was performed in the original study [25].

Tab. 1. Characteristics of the sample before the surgery (baseline) and at the mean follow-up of 9.95 years

	Total N = 39 Mean (range)		Mean difference Δ (p Value) (Baseline vs Follow/up)	Male (M): N = 7 Mean (range)	Female (F): N = 32 Mean (range)	Mean difference Δ (p Value) (Male vs Female)
	Baseline	Mean Follow/up		Mean Follow/up	Mean Follow/up	
Age	72.0 (56–87)	81.2 (62–95)	+ 9.14 ($p < 0.01$)	82.7 (75–91)	80.6 (62–95)	+2.13 ($p = 0.5$) ns
BMI	30.2 (21–37)	29.9 (21–44)	–0.26 ($p = 0.5$) ns	30.0 (27–36)	29.9 (21–44)	+0.08 ($p = 0.8$) ns
IKS	78.6 (15–155)	145.2 (58–200)	+65.3 ($p < 0.01$)	170.7 (88–200)	138.4 (58–189)	+32.4 ($p < 0.01$)
KS	40.5 (0–95)	85.7 (50–100)	+45.4 ($p < 0.01$)	92.2 (53–100)	83.9 (50–100)	+8.3 ($p < 0.01$)
FS	38.9 (0–75)	60.9 (0–100)	+20.5 ($p < 0.01$)	78.5 (35–100)	56.1 (0–100)	+22.4 ($p = 0.05$)

BMI− Body Mass Index, FS− Mean Functional Score, IKS− Mean Insall Knee Score, KS− Mean Knee Score, ns− statistically not significant.

articular ROM was 108.4° (range 50°–130°), with a statistically significant difference observed between men and women (120° M vs 105.6° F, $p < 0.01$) (Tab. 1).

Concerning the functional categories, 16 subjects were classified as category A (10F, 63%), 10 as category B (10F, 100%) and 13 as category C (12F, 92%).

Clinical and functional results

The mean follow-up was 9.95 years (range 6–13). For 43 prostheses (91.5% of total), the final control was performed in year 6; the number of prostheses assessed fell with the period of observation, with only six prostheses evaluated in the year 13 (12.8%) (Tab. 2).

Tab. 2. Arthroplasty evaluated for each year of follow-up

Follow-up	Prostheses		
	Total	Evaluated	Percentage
Mean (9.95 years)	47	47	100 %
Year 6	47	43	91.5%
Year 7	47	45	95.7%
Year 8	47	43	91.5%
Year 9	47	32	68.1%
Year 10	47	25	53.2%
Year 11	47	23	48.9%
Year 12	47	15	31.9%
Year 13	47	6	12.8%

At the final follow-up, significant improvements in mean IKS score were noted in both groups compared to preoperative values ($p < 0.05$) (Fig. 2 a-b). The female patients always obtained significantly worse scored than the male patients (Fig. 2 c).

A significant reduction in IKS score was noted in year 13 compared to year 1 (–17.9; $p = 0.02$); however, this value was still significantly better than the preoperative values (+65.3; $p < 0.01$) (Fig. 3).

Correlation between preoperative variables and outcome

The variance explained by the regression model for the available data was 50%; the Normal Q-Q plot showed that the residuals had a normal distribution (Shapiro Wilk Test $p = 0.346$) even if outliers were present; the mean of the errors was zero (T-Test $p = 1$). Preoperative IKS score, IKS score after one year and male gender were positively correlated with the mean IKS score measured at the follow-up; however, the correlation between patient age and the outcome was negative. None of the other variables (BMI, Insall functional classes, underlying pathology or operated side) were correlated.

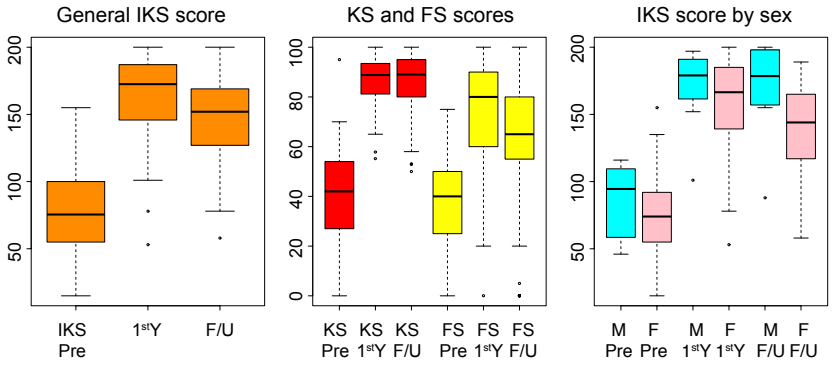

Fig. 2. (a-c) IKS (general), KS (pain-related) and FS (functional) score comparisons: values measured before surgery, after one year and at the mean follow-up of 9.95 years

1stY – first-year follow-up, F – female, FU – last mean Follow-up, M – male, Pre – preoperative.

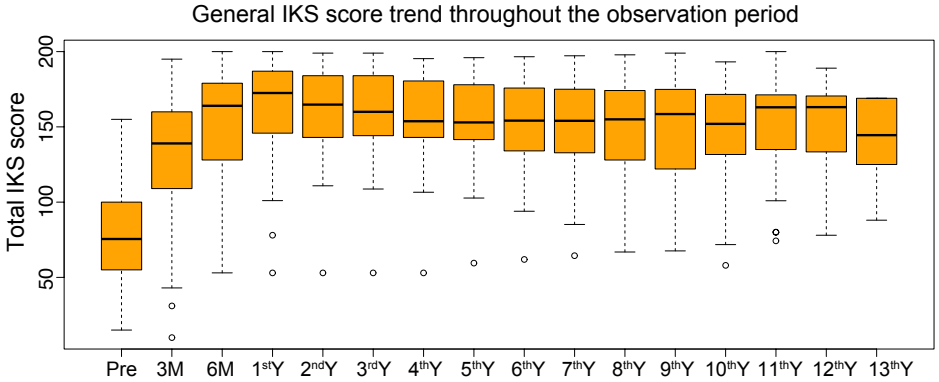

Fig. 3. IKS (general) score trend throughout the observation period

Discussion

Although total knee replacement is a widespread practice in Italy [5], our understanding of the procedure is hampered by a lack of good quality observational studies. Given the high heterogeneity of surgical methods and rehabilitation protocols, there is a need for longitudinal follow-up studies aimed at acquiring knowledge regarding the performance of the prostheses and potentially improving their associated rehabilitation programs.

The present study examined the results of 47 arthroplasties implanted in 39 patients over a period of 6 to 13 years. The rehabilitation approach based on stretching and pain control was effective, and the results were maintained even in the long term. The IKS score progressively improved until the first year, stabilizing until year 3 but showing a slight and progressive decrease in the following years. After eight years, the IKS score was still significantly better than the preoperative value, but worsened by 13.1 points compared to the first year ($p < 0.05$) due to a decrease of 10.1 points of FS ($p = 0.07$); however, KS remained almost unchanged. At the last follow-up, all the scores were still significantly better than the preoperative values and higher than those measured in the third and sixth months.

These values were in line with some studies [19,21] but slightly lower than others [18,22,40]. Those apparently negative results could be due to the fact that the observation period of our sample was much more extended than the mean length of the previous works (9.95 vs 6.8 years) [18,22,40]. In addition, the mean age of our sample was significantly higher than in similar studies [18,19,21,22,40] (81.0 vs 70.0 years). Indeed, age has been found to have a negative influence on functional score [41]. In our case, the IKS score of older patients was negatively influenced by poor FS score; these were apparent in seven patients who used to use a handrail or crutches (justified by patients with "a sense of lack of security") and in five women who received an FS=0 because walking was impossible due to severe motor and cognitive deficits related to old age and not to TKA. However, using a handrail to climb the stairs or using walking aids is a common practice in older patients linked to a sense of security; these habits lowered the FS score but were not indicative of an arthroplasty problem [33].

None previous study focused on this type of TKA had analysed the results of men and women separately [18,19,21,22,40]. The female patients in our sample always obtained lower IKS scores, mainly due to lower FS scores, and these negative results remained even when the five worst cases with FS=0 were excluded. This difference became statistically significant starting from year 3, and was maintained until year 11 ($p < 0.05$). The gender difference in prosthetic surgery could influence post-surgical complications [42] and results. According to some authors, female sex could be predictive of longer postoperative hospital length of stay [43,44], worse functional outcomes [45] and lower expectations after TKA [46]. In contrast, other authors found no significant differences in clinical and functional results [47–49]. Nandi et al. [50] report that the differences after TKA between men and women were equal six weeks after the operation. Interestingly, although men reported lower preoperative levels of emotional distress than women, preoperative anxiety and depression scores were better predictors of severe postoperative pain among men than women, underlying the importance of considering sex, psychosocial factors and their interaction in understanding postoperative pain course [50].

The correlation between high preoperative IKS scores and good functional outcome is still under debate [18,41,45,51]. According to some authors [18,45,51], preoperative scores could negatively influence outcomes, while Razak et al. [41] stated that a low preoperative score predicted a better result. In our study, subjects with low preoperative IKS (<80) obtained worse results than patients with higher preoperative IKS scores (> 80), and the difference between the groups remained statistically significant in all observations ($p < 0.05$).

The influence of BMI on functional outcomes in patients who undergo TKA is controversial [18,41,51–53]. Our sample showed a higher frequency of patients with BMI between 20 and 30 before surgery, and the worst postoperative results were obtained from the group of patients with BMI > 30, which would support the idea that obesity could be a negative prognostic factor for complete functional recovery, as confirmed by Robinson et al. [18]. In a meta-analysis conducted on 28 trials that included 20988 TKA, Si et al. [54] concluded that patients with BMI > 30 were subject to worse functional results and to a more significant number of complications or revision interventions that also determined an increase in hospital management costs [55]. Although the results of the influence of BMI on the functional outcome are not yet entirely in agreement, what is evident is that obesity remains the most important risk factor for developing osteoarthritis and consequently the need for a prosthesis [56,57]; even if a high BMI is not a contraindication to the intervention, it is good that patients are educated in the preoperative phase to lose weight to reach better results and enjoy a better quality of life.

Lastly, the good results obtained by the subjects belonging to Insall category A support the idea that the presence of another well-functioning hip or knee arthroplasty did not adversely affect the functional capacity of the subjects. On the other hand, the low scores obtained by patients in group B suggest that having a pathological and symptomatic contralateral knee negatively affected functional performance, according to the predictors identified by Chew et al. [51].

Limitations and strengths

The main limitation of this study was the low number of subjects. On the other hand, this is the first Italian study conducted with a long observation period of up to 13 years. Furthermore, methodological rigor was ensured thanks to reporting developed following the STROBE guidelines [25].

The present study was conducted in a single public hospital in one Italian region; this may make it difficult to generalize our findings to other contexts (e.g., private systems). Despite this, our results aligned with other studies conducted in other countries and with a small sample size [23]. Therefore, further research should include prospective and multicentre studies with adequate methodological rigor and larger samples to confirm and/or generalize the results.

Nevertheless, the fact that the study analysed the same type of TKA represents a key strength because this approach eliminated any confounders linked to the variability of prostheses and rehabilitation protocols. In addition, this is the first study to differentiate the functional results by sex.

Conclusions

From a clinical point of view, this study presents some important insights. (a) The analysis of the different outcomes provides an insight into the clinical and functional progress of the prostheses over time, and allows clinicians (e.g., physiotherapists) to give an overview of the post-operative period to patients who often want to know how recovery will go. In addition, it can be seen that (b) patients will show an improvement trend up to one year after the operation, against an average shorter rehabilitation period; this information can also represent a positive reinforcement strategy for patients undergoing knee replacement and related rehabilitation, leading to a better relationship between patients and practitioner. Finally, (c) our results underline the importance and usefulness of adopting early rehabilitation after knee arthroplasty surgery, obtaining results that are maintained over time.

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