ORIGINAL ARTICLE

Clinical Results Before and After Implementation of a Fast - Track Protocol For 507 Patients Who Underwent Total Knee Arthroplasty Surgery: A Retrospective, Observational Study

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ABSTRACT

Background: Total knee arthroplasty (TKA) is a common surgical procedure for patients with advanced osteoarthritis. This study aimed to assess the effects of using versus not using a fast-track protocol, including a new mobilization device called Flexet.

Methods: This is a retrospective comparative study. Two groups were formed with a total of 507 TKA patients. 283 were treated in 2010 with a standard program (S group) and 224 with a fast-track protocol (FT group) in 2016. The variables studied were active knee flexion and extension, length of stay, and time to autonomous gait.

Results: Study groups were comparable. The mean time from surgery to autonomous gait was shorter for the FT group (4.43 hours, SD = 2.11) than for the S group (59.95 hours, SD = 16.59) ($p < 0.001$). Mean stay for the FT group was 2.36 nights (SD = 1.81) and 6.20 nights (SD = 1.52) for the S group ($p < 0.001$). Mean active flexion at hospital discharge was 89.33º (SD = 7.45) in the FT group versus 84.10º (SD = 9.01) in the S group. The mean active extension was: -5.37º (SD = 2.49) in the FT group versus -8.60º (SD = 3.98) in the S group, ($p<0.001$).

Conclusion: Patients in the FT group showed more significant improvements (i.e., shorter length of stay, shorter time to autonomous gait, and larger active ROM in flexion and extension). However, the exact role of the Flexet device is still to be determined.

Keywords: Total Knee Arthroplasty, Fast-Track, Rapid-Recovery, ROM, early mobilization, active physiotherapy.

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BACKGROUND

Osteoarthritis is the most frequent degenerative condition in the knee joint among older adults. Total knee arthroplasties (TKA) are common surgical procedures that aim to improve the quality of life in patients who suffer from knee osteoarthritis and have increased pain and loss of function. Hospitals have experienced an increasing demand for this surgery due to the aging of the population. The main objectives in the immediate postoperative period are patient mobilization and increasing ROM [1]. The latter is considered one of the key indicators of a successful surgery [2]. Consequently, physical therapy in the postoperative TKA deals with restoring knee range, muscle strength, and returning to daily activities [3].

New post-surgical rehabilitation programs have been developed in the last two decades, which have proven safer and more efficient than standard treatment [4]. These programs are known as "Fast-track Surgery" or "Enhanced Recovery after Surgery" (ERAS) or "Fast-Track" (FT). They use a multidisciplinary approach that encompasses all stages within a TKA: preoperative assessment and patient orientation, anesthetic and intraoperative analgesic procedures, surgical techniques, postoperative treatment of pain, management of fluids, postoperative rehabilitation techniques, and hospital discharge [5]. In addition, fast-track specializes patient education, pain management, and early mobilization. In addition, it highlights close cooperation between surgeons, anaesthesiologists, physical therapists, and nursing specialists within a patient-centered model [6] .

Compared to standard recovery protocols, those described above have proven to reduce hospital length of stay [6–8] without increases in readmission, complications, or revision, thus allowing for improved functional results within the first seven days after a TKA [8] .

Clinicians and researchers have often used Continuous Passive Movement (CPM) devices to restore ROM and promote rehabilitation immediately after knee surgery [9] . Nevertheless, no relevant clinical effects have been established for pain reduction, function restoration, or quality of life, so standard use remained unjustified [10] . In 2011, the Knee Unit Team in our hospital aimed to replace the use of CPMs by developing the Flexet, a simple, inexpensive, and easy-to-use implement for active physical therapy.

The present study aimed to compare key parameters after TKA in patients who underwent two differentiated programs: standard vs. fast-track. Additionally, the traits of this new active mobilization device (Flexet) for ROM improvement are presented.

MATERIALS AND METHODS

This is a retrospective, comparative study included data extracted from the hospital's clinical records. Its Research protocol was identified (code: HCB/2019/0310) and approved by the Hospital's Ethics Committee. The studied variables included active flexion and active extension ROM, length of hospital stay, and time until the first autonomous gait, aided by crutches.

The sample consisted of 507 individuals who underwent TKA surgery in a university hospital and belonged to two different cohorts: the S group, with 283 patients who followed the standard program in the last semester of the year 2010; and the FT group, with 224 patients who followed a fast-track program during the last semester of the year 2016. Each cohort included all the patients who had received TKA during that given semester, except those who were medically unable to follow standard post-surgical protocols due to intraoperative complications. However, all patients were able to follow and complete their at-hospital rehabilitation.

ROM Evaluation

Measurements were performed by two different physical therapists (PT), upon the patient's hospital discharge and by means of a standard goniometer. The lateral femoral condyle was used as a landmark for the point of axis; the fixed arm was placed along the mid-longitudinal line of the thigh, directed towards the greater trochanter; the moving arm was aligned with the mid-longitudinal line of the leg towards the lateral malleolus [11]. Measurements were systematically performed with the patient seated for active flexion and supine for the active extension. For calculation purposes, a full extension has been reflected as 0º of flexion; lack of extension is shown as a negative value.

Time from surgery to first autonomous gait, aided by crutches and length of stay

"Time to the first autonomous gait" measures the length of time from the time surgery is over until the patient performs ten autonomous steps with the aid of crutches.

Length of stay was calculated as the number of nights spent from the time of surgery until hospital discharge. Requirements for discharge included well-managed pain, flexion over 80 degrees, at least -10 degrees of extension, autonomous crutch-aided gait, and the ability to climb up and down a set of stairs.

Following is a detailed description of each of the assistance programs. A comparison of both can be found in Table 1.

S GROUP: standard program, *2010*	FT GROUP: *Fast-Track program, 2016*
Admission the day before surgery	Same day admission
Compression boots pump, 24h post surgery.	No compression boots pump.
Blood drain system up to 48 hours post-surgery.	No blood drain system.
Urinary catheter: Female 48h, Male 24h	No urinary catheter.
Elastomere patient-controlled analgesia (PCA) pump 48h.	Local Infiltrative Analgesia
Famis diet 24h pre-surgery.	Drinking allowed up to 2 hours before surgery.
Famis diet 6-20h post-surgery.	Eating allowed as soon as back in room.
Personal hygiene performed in bed <48hours post-surgery.	Supervised shower 24h post-surgery.

Post-surgery: serum therapy (STP) until able to eat, intravenous analgesia 48 h.	No STP post-surgery, oral analgesia.
Sitting allowed after 24h, null weight bearing, 2 assistants needed. CPM after 48h. Physiotherapy exercises after 24h. Same exercises for home setting. Stair climbing prior to discharge.	Supervised sitting, no assistance needed. Physiotherapy exercises at 2-4 hours. Autonomous use of Flexet device 2x/day. Stair climbing after 24h. Update of exercise protocol upon discharge.

Table 1: Comparison of interventions: S group *vs* FT group

S Group. 2010 Standard program

The standard program for TKA in 2010 adhered to the contemporary scientific recommendations on quality clinical practice and patient service.

Patients who were candidates for TKA were hospitalized one day before surgery. The latter was performed under intradural anesthesia. To help manage postoperative pain, a femoral block with 0.2% ropivacaine with a 10 ml bolus and a 5 ml/h perfusion for two days was performed, as well as a sciatic nerve block with 10 ml 0.25% bupivacaine. Patients received intravenous drug administration with alternating 1g paracetamol and 50 mg dexketoprofen, every 8 hours. In addition, they had access to rescue medication -subcutaneous methadone or 50 mg intravenous tramadol every 8 hours maximum. After recovery, patients were moved to their hospitalization room with a urinary catheter and post-surgical drains, kept in place until 48h after surgery. Intake of liquids began some 6-20 hours post-surgery progressively.

Regarding their post-surgical physical therapy, patients were first assisted to sitting 24h post-surgery while keeping their affected leg straight. Then, the PT taught them five exercises in bed: ankle plantar and dorsal flexion for the activation of blood flow, isometric quadriceps contraction, isometric co-contraction of the anterior and posterior muscle chains, isometric contraction of the gluteus maximus, and diaphragmatic breathing accompanied by flexion and extension of the shoulders. Ten repetitions of each exercise were performed once a day, under the supervision of a PT, until discharge.

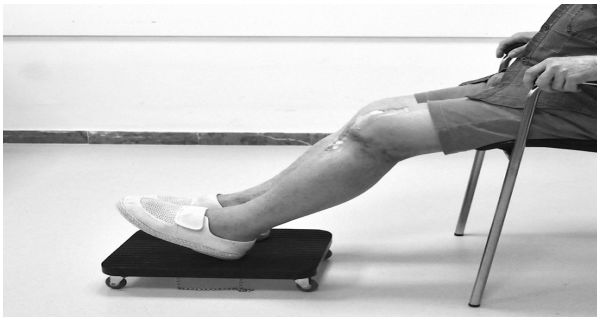
48 hours after surgery, they additionally began passive flexion and extension mobilization with a CPM device (one 30 to 45-minute session in the morning) and supervised walker-aided gait once daily. On discharge day, patients were taught 3-point gait crutch walking and climbing up/down stairs. In the S group, patients required extensive working force since they were assisted with in-bed washing, then helped to get up, put their shoes on, and get dressed.

FT Group. 2016 Fast-track program

The fast-track program continued to use existing clinical guidelines for state-of-the-art working protocols and continuous improvement [12]. Once a patient was considered eligible for TKA, they were invited to participate in an educational workshop with a relative. This typically took place 2-3 weeks prior to surgery and aimed to provide accurate information and prepare individuals for all matters related to their surgery [13]. The goal was to achieve more active participation of patients in their rehabilitation and self-care [14]. A PT and a nurse delivered the educational workshop. It was performed in groups of 5 people and lasted approximately 2 hours. Patients received information about the process and were taught how to do the exercises. They practiced 4-step walking using self-provided crutches and were taught to transfer. They were invited to do the exercises/mobilization at their homes until surgery day. A handout with relevant information and exercise descriptions was provided. Patients were also invited to call the PT for handout-related questions. They were instructed to perform the exercises while lying supine, twice in the morning and twice in the afternoon/evening.

In seeking a more active involvement of the patient, an active knee mobilization device was developed, which we named Flexet. It consists of a rectangular rolling board, with four unidirectional wheels attached to its base, at the corners (Fig.1). To use it, patients first sat on a chair and placed their feet, hip-width distance apart, on the board. It is an active system where not only the affected leg but also the contralateral one is involved (Fig. 2). Patients self-administered its use and the progression of movement in their knee. The device is inexpensive, durable, and easy to store and transport. The Flexet was presented to patients during educational workshops, preoperatively, where they also learned how to put one together themselves. Patients practiced with the Flexet before surgery at their homes. The combination of education plus active-assisted exercises aimed to achieve functional improvements, reduction of pain, greater autonomy, and decreased surgery-derived complications [15]. They also practiced their exercises immediately after surgery and when they got back home after discharge. Time was usually 30 minutes in the morning and 30 minutes in the afternoon/evening.

Figure 1: Image of the Flexet (note: the picture below have been edited with a black line for peer-review blinding purposes).



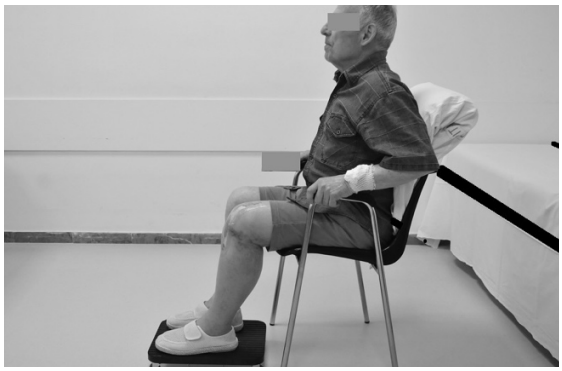


Figure 2-3: Patient at Hospital (note: hospital name has been blinded for peer-review blinding purposes) while performing active-assisted knee flexion-extension exercises two days post-surgery (2016).

Patients in the FT group were admitted to the hospital for their operation. The delivered anesthesia was intradural during surgery, just as in the S group. Still, instead of receiving a femoral block, participants in the FT group received a series of local infiltrative analgesia (LIA), consisting of several injections to the joint capsule with 100 ml of 0.2% ropivacaine and 1mg adrenalin. They also received 50 ml of 0.2% subcutaneous ropivacaine, intravenous methylprednisolone for inflammation and edema control, and tranexamic acid to prevent associated blood loss. Patients were additionally given oral medication, 25 mg dexketoprofen, and 1g paracetamol, in an 8-h alternating manner and rescue medication (50 mg tramadol, every 8 hours) when needed. In the FT group, urinary catheters and post-surgical drains were not used. Like patients in the S group, FT group participants were transferred to the recovery room immediately after surgery and to the hospitalization room later. There, they were offered juice to test for tolerance. They were allowed to make a light, solid intake if the latter was good. Later, they were moved into their rooms.

Patients stood for the first time once they regained sensitivity in their lower limbs, which typically happens 3-4 hours post-surgery. They did so while supervised by a PT and then sat down with their knees in their maximum comfortable flexion. As a part of the FT protocol, patients took an active role in their health and did as much as possible: they put their shoes on, picked up their crutches, and started walking following a four-point walking pattern. Most of the time, they did this without difficulty since they had experience from having practiced at home. Typically, the walked distance was 10-15 meters to help them comprehend that they could manage to move autonomously and with controlled levels of pain. During their first attempt, patients were helped by a PT. If their gait pattern was correct and the first walk was successful, patients were then encouraged to walk accompanied several times on that and the following days.

After their first autonomous walk, patients were encouraged by the PT to continue to do the routine exercises they had been doing since they attended the educational workshop (same program twice in the morning and twice in the afternoon/evening, ten repetitions of each exercise). This included their exercises with the Flexet, 30 minutes in the morning and 30 minutes in the afternoon.

On their day of hospital discharge, patients were taught a new set of exercises and adjusted to their current state. They were instructed to perform ten repetitions of each exercise, twice in the morning and the afternoon/evening. And they should continue to do their Flexet program. A handout containing the description of the exercises, plus some other recommendations and a PT contact phone for inquiries, was given to all participants.

Statistical Analysis

Descriptive analysis indicated absolute and relative frequencies for categorical variables and mean and standard deviation (SD) for quantitative variables. The Kolmogorov Smirnov test determined that our data did not follow a normal distribution. The Pearson's chi-square and Mann-Whitney tests were used to compare groups at baseline for qualitative variables (i.e., gender and laterality) and quantitative variables, respectively. Mann-Whitney test was also utilized for bivariate analysis considering a confidence level of 95%. STATA software, v.14.0, was used for the statistical analysis.

RESULTS

A total of 507 patients were assessed; 283 were in the S group and 224 in the FT group. Table 2 shows the descriptive characteristics of the participating individuals.

	2010 S Group n=283 Mean (SD)	2016 FT Group n=224 Mean (SD)	*p* value
AGE (years)	72.19 (7.74)	71.03 (8.63)	0.361
BMI (Kg/m^2)	30.09 (4.68)	30.23 (5.24)	0.918
	2010 S Group n=283 %	2016 FT Group n=224 %	*p* value
GENDER	Masc=27.2% Fem=72.8%	Masc=29.9% Fem=70.1%	0.284
LATERALITY	Right=50.5% Left=49.5%	Right=54.5% Left=45.5%	0.214

Table 2: Descriptive characteristics of individuals in both study groups.

No statistically significant between-group differences were found for age, BMI, gender, or laterality. The results of both groups were considered, consequently, comparable.

The average time to first autonomous gait was 59.95 hours (SD 16.59) for the S group and 4.43 (SD 2.11) for the FT group. This difference was statistically significant ($p < 0.001$).

Active flexion was 89.33 (SD 7.45) degrees in the FT group *versus* 84.10 (SD 9.01) in the S group. This 5.23 degree difference was statistically significant ($p < 0.001$). The active extension was -5,37 (SD 2.49) degrees in the FT group *versus* -8.60 (SD 3.98) in the S group. The difference (3.23 degrees) was statistically significant ($p < 0.001$).

The average hospital stay for patients in the S group was 6.20 (SD 1.52) nights *versus* 2.36 (SD 1.81) nights in the

FT group. Results were statistically significant ($p < 0.001$).

	2010 S Group n=283 Mean (SD)	2016 FT Group n=224 Mean (SD)	*p* Value
Active Flexion ROM	84.1(9.01)	89.33 (7.45)	<0.001
Active Extension ROM	- 8.6 (3.98)	- 5.37 (2.49)	<0.001
Time from surgery to 1st gait (hours)	59.95 (16.59)	4.43 (2.11)	<0.001
Length of Stay (nights)	6.19 (1.52)	2.36 (1.81)	<0.001

Table 3: Comparison of results for the standard treatment *vs.* the fast-track treatment groups.

DISCUSSION

The objective of this comparative, retrospective study was to present the differences in the functional improvement experienced by patients who had undergone TKA surgery, with (2016) or without (2010) a fast-track program. The specific years were chosen as they both constitute a time when their respective programs were established, thus eliminating a potential bias for a learning curve. Our team introduced the FT in September 2011, hoping to achieve maximum patient autonomy through preoperative therapeutic education, pain management, and early mobilization, reducing hospital length of stay [16].

Our results support that active mobilization immediately after surgery improves functional status at discharge. However, the improvements shown in the present study cannot be solely attributed to active mobilization or the Flexet device but instead were a consequence of the overall FT strategy, from the use of LIA to the absence of drains and urinary catheters. Within this same context, we believe the rehabilitation of patients and their participation in physical therapy tasks before surgery played a key role in improving results.

Following the introduction of the ERAS (Enhanced Recovery After Surgery) concept by H. Kehlet in 1990, many studies have shown that the fast track seems superior to standard treatment, in terms of safety and efficacy, during the perioperative period (4) and that it can significantly lower general expenditure. In our study, the average number of nights spent in the hospital was 2.37 for patients in the FT group and 6.20 for patients in the S group. These results are in line with those of other researchers and confirm that fast-track reduces mean stays, with no associated risk of the increased number of readmissions, complications, or revisions [16,17].

There is moderate evidence showing that rehabilitation initiated on the same day as TKA surgery *versus* the day after reduces pain and improves function [18] . For example, a study published in 2015 showed that multimodal analgesia in patients receiving TKA fast-track surgery allowed for active mobilization immediately after surgery, with pain levels of 2.74 - 2.99 on the visual analogue scale (VAS), following a physical therapy session 24 - 48 hours post-surgery, respectively. Another recent (12) study with 125 patients showed that VAS stayed below two at 24 - 48 hours from surgery. This also matches the results from [19] , who showed an average of 1.47 on VAS at 36 hours from surgery. These studies show that multimodal analgesia used by FT programs enables patients to do their physical therapy exercises immediately after surgery and successfully implement early active mobilization.

In achieving greater patient autonomy immediately after surgery, one of the most important factors seems to be using non-opioid, oral, multimodal [20] medication. The FT group used this type of non-opioid oral analgesia; neither urinary catheters [21] nor post-surgical drains [22] were protocolized. Our findings show superior results for the FT group, which, in line with previous evidence, seems to suggest that as-early-as-possible post-surgical rehabilitation is advantageous [23]. Early mobilization renders several benefits, as suggested by already-existing evidence [24], e.g., a decrease in deep venous thrombosis, increased patient satisfaction, pain management, reduction of length of hospital stay [6] , and rapid return to independent daily life activities. In addition, our study is in line with previous evidence that patients in the FT group first walked 4.43 hours post-surgery, in contrast to those in the S group, who did so on day 3.

Another distinctive trait of the protocol used in the FT group is prehabilitation. It included a presurgical educational workshop, similar to that routinely delivered in hospitals that follow ERAS programs, but with some variations. Including an educational workshop has been advised [25] and constitutes a crucial factor in fast-track programs. Benefits derived from them include patients taking increased responsibility, achieving higher functional status, diminishing pain levels, greater autonomy, and reduced incidence of surgical-derived complications [15,26](2 already showed that surgery patients were mentally better prepared and felt safer towards early mobilizing when they had received educational material [26]. Moreover, attending preoperative workshops has decreased the mental stress associated with surgery [27].

Restoring ROM to functional levels is a key goal of any TKA. Failing to achieve this, is the most frequent complication and the leading cause of patient dissatisfaction [28]. Acquiring sufficient flexion and avoiding flexion contractures (a.k.a. negative extension) is therefore highly relevant. Our study showed that patients in the S group had achieved 84.12 degrees of active flexion and -8.60 of active extension by the time of hospital discharge. These results are very close to those by [29], who studied 84 patients (99 knees) treated by TKA and found mean flexion values of 70 degrees on day 3, 85 degrees on day 5, and 95 degrees on day 14. Our FT group showed statistically significant improvements in active flexion (89.33º) and active extension (-5.37º).

Apart from a physical therapy exercise protocol, the FT group utilized a novel variable: an active-assisted exercise device called the Flexet. The improvements in ROM could be partially attributable to this variable, as well as to others. When we first implemented FT in 2011, one of our goals

was for patients to be able to return to daily activities as soon as possible, which led to the conception of the Flexet. Until then, to restore ROM, we had been using CPM machines, which required patients to be in a lying position and working passively. The Flexet was extremely simple and allowed the patient to work actively while seated. Mau-Moeller et al. [30] studied 127 patients after TKA. They compared an active work device used in supine versus CP use and obtained positive results in the short term for knee flexion ROM, apart from additional benefits such as the process is less complicated or costly [30,31] also recommended using active therapy movement as soon as possible following surgery and pointed at benefits in quality of life, pain, and function [31]if the benefits of controlled active motion (CAM. All of the above supports the type of active therapy enabled by the Flexet. On top of that, the contralateral leg can also take part, positively affecting ROM, strength, or proprioception.

The Flexet adjusts to the recommended empowerment model: patients decide when they will do their session, their progression, and their pace without needing a PT [32]. They can also build their device for an approximate total cost of 20 euros. It is easy to store and transport, durable and can be used unsupervised. Patients can have it at home, become familiar with it before surgery, and possibly improve their presurgical function. The patient's involvement in putting the Flexet together will likely bring empowerment one step further. This device allegedly provided the type of active work needed in our FT program. How and to what extent the Flexet influences recovery must still be assessed. Likewise, it would be interesting to do some further research to determine if it could be effective in improving ROM for other types of rehabilitation programs (e.g., revision TKA, ligament, and meniscal repairs, patellar or tibial plateau fractures, periprosthetic fracture) of the knee or other joints (e.g., hip, ankle). It would be equally interesting to determine its effects on the cardiovascular and muscular systems.

It could be argued that based on the way the Flexet was used in this piece of research, it could have been easily substituted by the use of a towel or a skateboard, or the patient could have just flexed and extended the knee to tolerance. So, we acknowledge these thoughts, but our clinical practice leads us to believe that working with the Flexet offers a better progression for the movement in the joint and that having the patient build it renders additional positive results.

Our study presents data on large sample size (n = 507) but does so in a retrospective manner. Therefore, no data was collected after discharge, and it was impossible to study medium and long-term effects. This constitutes one of the research limitations.

Another limitation has to do with the fact that the FT group not only benefited from the use of the Flexet but also was subject to novel post-surgical analgesic techniques. Therefore, additional randomized trials are required to establish the efficacy and efficiency of introducing this new device for rehabilitation.

CONCLUSION

The fast-track group showed significantly better short-term results than the standard group. Fast-track protocols allow for shorter hospital length of stay, better active knee flexion and extension at discharge, decreased time to first autonomous gait, and reduced length of hospital stay. These elements are key to the individual's return to autonomous daily living.

Our department has included a novel device called the Flexet into the FT rehabilitation program for TKA. We believe this could be a determining factor for the improvement of the active range. However, randomized clinical trials are needed before this device's exact role can be determined within the frame of a rapid recovery program.

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CONFLICT OF INTEREST

This research, the manuscript, nor any abstracts in any form have been submitted, nor is there any financial gain on the part of the authors or conflict of interest.

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