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CLINICAL AND OBJECTIVE GAIT OUTCOMES REMAINED STABLE SEVEN YEARS AFTER TOTAL KNEE ARTHROPLASTY: A PROSPECTIVE LONGITUDINAL STUDY OF 28 PATIENTS

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1. Introduction

The long-term gait recovery of patients who have undergone total knee arthroplasty (TKA) is unknown. Instrumented three-dimensional gait analysis, also known as clinical gait analysis (CGA), can help to quantify functional recovery after surgery [1, 2]. Numerous studies in the scientific literature have focused on the evolution of knee kinematics before and up to a maximum of one year after surgery [3, 4]. Despite improved gait quality, with an increased Knee flexion range in the operated knee and a higher gait velocity, surgery has not been shown to have restored a normal gait pattern one year after TKA [5-7].

To the best of our knowledge, only one study has used CGA to evaluate gait evolution beyond one year after TKA. Spatio-temporal parameters, knee kinematics and knee kinetics during the gait cycle's loading response have been measured up to three years after TKA [8]. Those authors observed a significant improvement in gait parameters between three months and one year after surgery for most outcome measurements (such as spatio-temporal, knee kinematics and kinetics parameters and patient reported outcomes). However, three years after surgery, patients showed no improvement and even some deficits compared with one year after surgery. This lack of improvement was probably related to progressive weakness with ageing. Another study analysed gait evolution before and five years after TKA by comparing fixed-bearing prostheses (26 patients) and mobile-bearing prostheses (29 patients) [9]. Those authors observed that all gait parameters had worsened five years after the surgery. However, their gait analysis was performed using five miniature angular-rate sensors mounted on the trunk (sacrum), both thighs and both calves, but not using 3D analysis systems. Therefore, one should be cautious before interpreting and comparing these results.

No studies to date have addressed the evolution of gait before TKA and beyond five years afterwards. We asked the patients in our cohort, who had undergone two CGAs, at three months and one year after surgery, to undergo a final CGA between six and seven years after their surgery [5].

This longitudinal study's aims were: 1) to observe the evolution of clinical and kinematic outcomes over a long period (i.e. from before TKA (T0) to seven years after surgery (T2)), and 2) to determine whether the surgery's effects on clinical and kinematic outcomes remained stable between one year (T1) and seven years (T2) after surgery.

2. Material and methods

2.1. Participant selection

The 118 patients who had participated in a previous prospective longitudinal study were considered eligible for the present study [5]. Every patient who underwent an initial CGA one week before their TKA was contacted six to seven years later and asked to participate in our study by undergoing a final CGA. Patients with a history of lower limb or back surgery, neurological or orthopaedic disorders that might affect gait or balance, or who used any kind of walking aid were excluded.

Ninety patients were lost to follow-up: two had died, 15 presented with a physical disability preventing their participation, 36 did not want to participate, and 28 were not contactable despite multiple attempts (Figure 1).

Therefore, for the study's first objective, 28 patients were evaluated using CGA seven years after their TKA. Only 20 of those 28 patients could be included for the second objective because of missing data at one year. Thus, the study used a total of three CGAs: the week before TKA (baseline, T0), one year after surgery (T1) and seven years after surgery (T2).

2.2. Surgical procedures

The present cohort had received two different, cemented, posterior-stabilised, fixed-bearing designs: 22 patients had a PFC Sigma® TKA (Depuy Orthopaedics, Inc., Warsaw, IN, USA), and 6 patients had a GMK System® TKA (Medacta, Inc, Castel San Pietro, Switzerland). Routinely, a single-shot antibiotic prophylaxis was given before skin incision. All except two of the TKAs were performed using a medial parapatellar approach; two were performed using a lateral parapatellar approach. All the surgeons routinely used the tibia cut first technique, with independent bone cuts made in 18 patients (measured resection) and a gap balancing technique used in the other 10 patients using a dedicated balancer jig (for both extension and flexion gaps). Patellae were routinely denervated. Resurfacing was done in 19 patients.

After surgery, walking with crutches with full weight-bearing was allowed starting on day one. All patients went through a standard six-week rehabilitation programme. Deep vein thrombosis prophylaxis with low molecular heparin was started on the day of surgery and maintained for six weeks.

2.3. Participants' characteristics

Data on sex, age, preoperative and postoperative Body Mass Index (BMI) and the location of any osteoarthritis were collected from our prospective hospital-based registry (The Geneva Arthroplasty Registry)[10]. The location of knee osteoarthritis (medial tibiofemoral compartment, lateral tibiofemoral compartment or patellofemoral compartment) was assessed using weight-bearing anteroposterior and lateral X-rays, and a skyline view of the patella was made for each patient before TKA. In addition, lower limb alignment was quantified using the hip–knee–ankle angle and operated knees were defined as valgus or varus knees [11] (Supplementary Tables). An experienced orthopaedic surgeon evaluated all these measurements.

2.4. Clinical outcomes

The following clinical outcomes were measured at each visit using several questionnaires: pain level and functional capacity were determined using the modified Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaires[12], quality of life was measured using the Medical Outcomes Study 12-item Short-Form Health Survey (SF-12) [13], and patients' perceived general physical health and mental health were assessed using the SF-12's physical component score.

Patients were also asked to estimate their level of knee pain from 0 to 10 using a visual analogue scale. Scores of 1 to 4 indicate mild pain, scores of 5 and 6 indicate moderate pain and scores of 7 to 10 indicate severe pain [14].

Lastly, patient satisfaction was evaluated using a questionnaire that included 1) overall satisfaction following the TKA, 2) satisfaction regarding pain relief, and 3) satisfaction regarding functional improvement [15]. For each question, patients graded their level of satisfaction on a five-point Likert scale, as follows: very dissatisfied (1), dissatisfied (2), neutral (3), satisfied (4), or very satisfied (5). Levels of satisfaction were evaluated at one year (T1) and seven years (T2) after TKA.

2.5. Kinematic outcomes

CGA was performed under identical conditions at each time point. A 12-camera motion analysis system was used to capture full-body motion during gait (VICON Peak, Oxford, UK, at T0 and T1; Qualisys Oqus 7+, Qualisys, Sweden, at T2). Markers were placed on the lower limbs and pelvis according to the Conventional Gait Model [16]. Patients were asked to walk barefoot at their own pace along a 12-metre walkway. Data for each patient were collected over at least ten gait cycles. Visual 3D (C-Motion, Inc., Germantown MD, USA), the open-source Biomechanical ToolKit package and Matlab R2012b (MathWorks, USA) software were used to compute kinematic data [17]. Only the operated limb was considered. The gait outcomes calculated from the CGAs and used in the statistical analysis were: self-selected gait velocity ($m.s^{-1}$), dimensionless gait velocity (gait velocity ($m.s^{-1}$) divided by the square root of the product of the leg length (m) and the gravitational constant ($m.s^{-2}$), also called the Froude number), and the range of knee flexion (°) and maximal knee flexion (°) during the complete gait cycle [18].

2.6. Statistical Analysis

The patient characteristics recorded were sex, age (years) and BMI (kg/m^2) and the clinical outcomes were patient-reported outcome measures. The gait outcomes measured at baseline were gait velocity ($m.s^{-1}$), dimensionless gait velocity ($m.s^{-1}$), knee flexion range (°) and maximum knee flexion (°). Qualitative parameters were described using frequencies and percentages; quantitative parameters were described using mean and standard deviation (SD). Clinical and gait parameters at baseline, one year and up to seven years after TKA were described using median and inter-quartile range (IQR).

We performed non-parametric analyses using the paired Wilcoxon signed-rank test (p-value < 0.05) to estimate differences between parameters: before and seven years after TKA (T0 vs T2) and one and seven years after TKA (T1 vs T2). Differences in clinical and gait parameters were estimated as the mean difference between measurements at baseline and one year and between measurements at one year and seven years after TKA (T0 vs T1 and T1 vs T2). Statistical analyses were performed using STATA software, version 13.1 (StataCorp LP, College Station, TX, USA).

3. Results

Mean age at T0 was 67.4 years old (9.3); mean time to follow-up at T2 was 7.0 years (0.9); mean age at T2 was 74.0 years old (9.3); 62% of participants were women. Regarding clinical and kinematic outcomes at T0, there were no significant differences between the 90 patients who underwent a CGA at T0 only and the 28 patients who underwent one at T0 and T2 (Supplementary Data, Table 1).

3.1. Comparison before TKA and seven years after TKA

Compared to baseline (T0) measurements, the evolution of clinical outcomes showed a significant improvement up to seven years (T2), except for the SF-12 mental component score (T0: 40.4 (34.7–49.9) vs T2: 46.6 (39.0–50.9), $p = 0.121$). Regarding overall patient satisfaction, the majority of patients (n = 25) were satisfied at T2. Similar results were observed for satisfaction with pain (n = 24) and function (n = 23) (Table 1). Regarding gait outcomes, gait velocity and dimensionless gait velocity were significantly lower after 7 years of evolution (T0: 1.1 $m.s^{-1}$ (0.9–1.2) vs T2: 1.0 $m.s^{-1}$ (0.8–1.1), $p = 0.011$ and T0: 0.37 (0.30–0.41) vs T1: 0.31 (0.28–0.36), $p = 0.013$, respectively). Knee flexion range had significantly improved between T0 and T2 T0: 43.9° (38.1–49.9) vs T2: 48.4° (44.6–54.1), $p < 0.001$).

3.3. Comparison between one and seven years after TKA

No significant evolution in clinical and gait outcomes was observed between T1 and T2, apart from significant decreases in gait velocity (T1: 1.3 $m.s^{-1}$ (1.1–1.4) vs T2: 1.0 $m.s^{-1}$ (0.9–1.1) $p < 0.001$) and dimensionless gait velocity (T1: 0.42 $m.s^{-1}$ (0.37–0.47) vs T2: 0.35 $m.s^{-1}$ (0.29–0.36), $p < 0.001$) (Table 2). In addition, all the patients indicated their overall satisfaction with their surgery at T1 and T2, and the vast majority were satisfied in terms of pain (86%) and function (82%).

3.4. Evolution from pre-TKA to one and seven years after TKA

Comparing knee kinematics during the three CGAs (T0, T1 and T2), we observed an improvement in the range of knee motion at T1 that had remained stable at T2 (Figure 2). Looking at the evolution of gait velocity, improvements in dimensionless gait velocity, range of knee motion during CGA, and reported pain and satisfaction had all improved between T0 and T1. All the parameters had then remained stable to T2, except gait velocity, which had clearly diminished (Figure 3).

4. Discussion

The present study's results indicated that seven years after TKA, patients' self-reported clinical outcomes and most of their knee kinematics outcomes measured using CGA, especially knee flexion range during walking, had improved or remained stable. Their gait velocity, however, had decreased.

Compared to the baseline situation before TKA, the results seven years after surgery showed improvements in knee flexion range during walking and a decrease in knee pain. Moreover, patients perceived improved function, as revealed by better WOMAC pain and function scores and higher scores on the physical component of the quality-of-life questionnaire (SF-12 physical score). These findings were consistent with the literature, including the high percentages of satisfaction regarding pain and function [19, 20]. The only outcomes observed to decrease significantly between the CGAs at T1 and T2 were patients' gait velocity (mean decrease = 0.11 $m.s^{-1}$) and dimensionless gait velocity (mean decrease = 0.6 $m.s^{-1}$). Interestingly, between one and seven years after surgery, patients maintained all their other improvements over time, with no significant changes in terms of clinical outcomes and knee kinematics during CGAs (Table 2 and Figures 2 and 3). Knee ROM remained stable between T1 and T2. Although gait velocity (and dimensionless gait velocity) had improved by an average of 0.2 $m.s^{-1}$ by one year after surgery, as observed in previous studies [5], this gain was not maintained over time. As Ro *et al.* suggested, a decrease in gait velocity may also be associated with a suboptimal improvement in knee biomechanics and with a limited knee ROM after TKA [21]. Decreased gait velocity over time may be due to many factors, such as cognitive decline, depressive symptoms, the progression of arthritis at sites other than the joint arthroplasty, less physical exercise or a higher BMI, but the most likely factor is ageing [22]. Gait velocity decreases naturally with age, and it appears that the mean values observed among our cohort, as a function of their age, were close to the norms for elderly patients [23]. Indeed, Fang *et al*. found mean gait velocities of 1.15 $m.s^{-1}$ for healthy older adults from 60–69 years old and 0.99 $m.s^{-1}$ for healthy older adults from 70–79, giving a statistically significant mean difference of 0.16 $m.s^{-1}$ [24]. Thus, the decrease in gait velocity observed in our longitudinal cohort as a whole does not necessarily seem to be related to a physical problem (with no impact on their knee function), and it could be considered primarily as a natural evolution of their walking and function related to ageing.

Finally, Nakahara *et al*. used questionnaires to investigate the satisfaction and expectations of a cohort of 375 patients; they found responses to their “walking and standing” item were strongly correlated with patient satisfaction after TKA [25]. This result highlighted that patients found maintaining these activities over time to be important. Nevertheless, our patients showed high overall satisfaction at their last follow-up, with 83% satisfied with their gait function outcome. This was perhaps an indication that the significant gait velocity loss measured using CGA had gone unnoticed by those patients [26].

This study had some limitations. Firstly, as with many long-term studies, there was a large number of drop-outs for the last CGA, with a loss of 76% of our patients between pre-surgery and seven-year follow-up (Figure 1). Drop-outs reflect the difficulties in motivating a large group of patients with repetitive, time-demanding sessions. In this high percentage of drop-outs, 28 (35%) patients were lost during the seven years to the follow-up and 19 (24%) refused to participate after their surgery. When looking at their reasons for refusing to participate, some patients were suffering from fatigue and walking difficulties, but many others were in “great shape”, very satisfied with their TKA and, therefore, did not necessarily want to come back to the hospital. This is important because patients dropping out did not necessarily present with poor outcomes, as already pointed out by Joshi *et al*., thus limiting the potential selection bias on such long-term longitudinal studies [27]. Another limitation was that we did not have a control group whose longitudinal data on clinical and kinematic outcomes we could compare. Unfortunately, the literature revealed no long-term prospective studies evaluating these outcomes in a healthy population. The third limitation, which is directly linked to the number of drop-outs, as explained before, is the relatively small sample size. The last limitation was also directly linked with the long follow-up period: seven patients also had a TKA on the contralateral side or a total hip arthroplasty on the homolateral or contralateral side (Supplementary Data, Table 2). To assess whether these surgeries had had an impact on the kinematic outcomes observed in our study, a specific Kruskal–Wallis test was used to compare patients who had undergone secondary surgery (n = 7) and others (n = 20). No significant differences were observed in terms of gait velocity, knee kinematics and clinical outcomes; therefore, it seems that this factor did not influence our results. Despite these limitations, there are no other such long-term studies on the evolution of gait kinematics in the literature. Thus we feel that our study is interesting and relevant as a way to start filling a gap in knowledge.

5. Conclusions

Our observations suggested that, independently of the ageing that may cause a gradual decline in physical activity and functional capacity, improved clinical and gait outcomes were maintained for an extended period. Seven years after TKA, knee function, pain levels, satisfaction levels and patient-reported outcome measures were stable or higher than one year after TKA and before TKA. The only parameter that declined over time was gait velocity. This was very likely related to ageing and went almost unnoticed by patients. These findings are important for clinicians and their patients, as they reinforce evidence of TKA's effectiveness and the positive impact it can have on patients' quality of life and level of function over time.

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Ethics

This study was approved by the canton of Geneva's ethics committee (n. CER 09-307). Written informed consent was obtained from all participants.

Conflict of interest

Hermes Miozzari is an Associate Editor for the "EFORT Open Review" and a board member of "Swiss Orthopaedics". Stéphane Armand is a member of the editorial board for the "EFORT Open Review". There are no conflicts of interest associated with this research.

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Tables:

Table 1: Clinical and gait outcomes comparison for the same group of patients between two clinical gait analysis (CGA): before and seven years after total knee arthroplasty (TKA).

Parameters	***Before TKA*** (n=28)	***Seven years after TKA*** (n=28)	**p-value**	***Delta*** **Mean difference (95%CI)**
Clinical characteristics				
Sex (F/M), n	17/11	17/11		NA
Age (years), median (IQR)	**69 (60-75)**	**75.5 (67-82.5)**	**0.01**	6.6 (1.6-11.5)
BMI (kg/m^2), median (IQR)	29.3 (25.9-37.1)	30.6 (29.3-36.2)	0.80	0.4 (2.9-3.9)
Clinical outcomes Median (IQR)				
WOMAC pain score	**45 (25-50)**	**80 (70-95)**	**<0.001**	36.6 (26.3-46.6)
WOMAC function score	**53.6 (39.3- 62.5)**	**78.6 (60.7- 92.8)**	**<0.001**	23.9 (12.7-35.3)
SF-12 mental score	40.4 (34.7- 49.9)	46.6 (39.0-50.9)	0.121	3.8 (-0.4-7.9)
SF-12 physical score	**34.9 (28.9- 39.7)**	**40.4 (33.7- 48.3)**	**0.027**	5.9 1.4-10.4)
Knee pain (VAS)	**4.8 (1.9-5.8)**	**0 (0-2)**	**<0.001**	2.5 (-3.6- -1.3)
Satisfaction n				
Global				
Unsatisfied/Satisfied	NA	3/25	-	NA
Pain				
Unsatisfied/Satisfied	NA	4/24	-	NA
Functional				
Unsatisfied/Satisfied	NA	5/23	-	NA
Gait outcomes Median (IQR)				
Gait velocity (m.s^{-1})	**1.1 (0-9-1.2)**	**1.0 (0.8-1.1)**	**0.011**	0.11 (0-0.02)
Dimensionless Gait Velocity	**0.37 (0.30-0.41)**	**0.31 (0.28-0.36)**	**0.013**	0.03 (0-0.08)
Flexion range during gait cycle (°)	**43.9 (38.1-49.9)**	**48.4 (44.6- 54.1)**	**0.001**	6.4 (1.3-11.4)
Maximum knee flexion during gait cycle (°)	47.5 (41.7-50.8)	46.3 (40.4-56.1)	0.068	2.5 (2.5-7.5)

BMI: Body Mass Index; SF12: 12-item Short-Form Health Survey; WOMAC: Western Ontario and McMaster Universities Arthritis Index; IQR: Inter Quartil Range. NA: Not Applicable**. In bold: significant difference (p value < 0.05) – Wilcoxon signed rank test**

Table 2: Clinical and gait outcomes comparison for the same group of patients between two clinical gait analysis (CGA): one year and seven years after total knee arthroplasty (TKA).

Parameters	*One year after TKA* (n=20)	*Seven years after TKA* (n=20)	p-value	*Delta* Mean difference (95%CI)
Clinical characteristics				
Sex (F/M), n	13/7	13/7	-	N.A
Age (years), median (IQR)	**69 (61-71)**	**74 (67-77)**	**<0.001**	5.5 (5.1-5.8)
BMI (kg/m²), median (IQR)	28.2 (26.5-36.3)	30.4 (26.2-37.2)	0.501	1.3 (3.5-6.1)
Clinical outcomes median (IQR)				
WOMAC pain score	90.0 (70-90)	80.0 (70.0-95.0)	0.665	-0.3 (-10.1-9.6)
WOMAC function score	80.3 (62.5- 89.3)	78.6 (60.7-92.9)	0.968	- 3.6 (-17.5-10.4)
SF-12 mental score	47.5 (36.3-59.4)	48.4 (39.4-55.6)	0.494	1.6 (-4.4-7.5)
SF-12 physical score	41.3 (33.7-48.4)	42.3 (33.9-52.7)	0.398	2.0 (-4.6-8.7)
Knee pain (VAS)	0 (0-1.4)	0 (0-2)	0.877	0.4 (-1.5-2.2)
Satisfaction n				
Global				
Unsatisfied/Satisfied	0/20	0/20	-	NA
Pain				
Unsatisfied/Satisfied	3/17	2/18	-	NA
Functional				
Unsatisfied/Satisfied	2/18	3/18	-	NA
Gait outcomes Median (IQR)				
Gait velocity ($m.s^{-1}$)	**1.3 (1.1-1.4)**	**1.0 (0.9-1.1)**	**<0.001**	0.23 (0.15- 0.31)
Dimensionless Gait Velocity	**0.42 (0.37-0.47)**	**0.35 (0.29-0.36)**	**<0.001**	0.07 (0.03-0.11)
Flexion range during gait cycle (°)	48.5 (42.7-53.7)	47.5 (44.3-54.3)	0.455	0.61 (-1.19-2.27)
Maximum knee flexion during gait cycle (°)	49.5 (45.3-52.5)	50.5 (45.3-57.2)	0.627	0.53 (-2.25-3.65)

BMI: Body Mass Index; SF12: 12-item Short-Form Health Survey; WOMAC: Western Ontario and McMaster Universities Arthritis Index; IQR: Inter quartile range. NA: Not Applicable. **In bold: significant difference (p value < 0.05) – Wilcoxon signed rank test**

Figure's legend

Figure 1.

Flow diagram of patient enrolment according to our inclusion and exclusion criteria before, one year after and around seven years after Total Knee Arthroplasty (TKA).

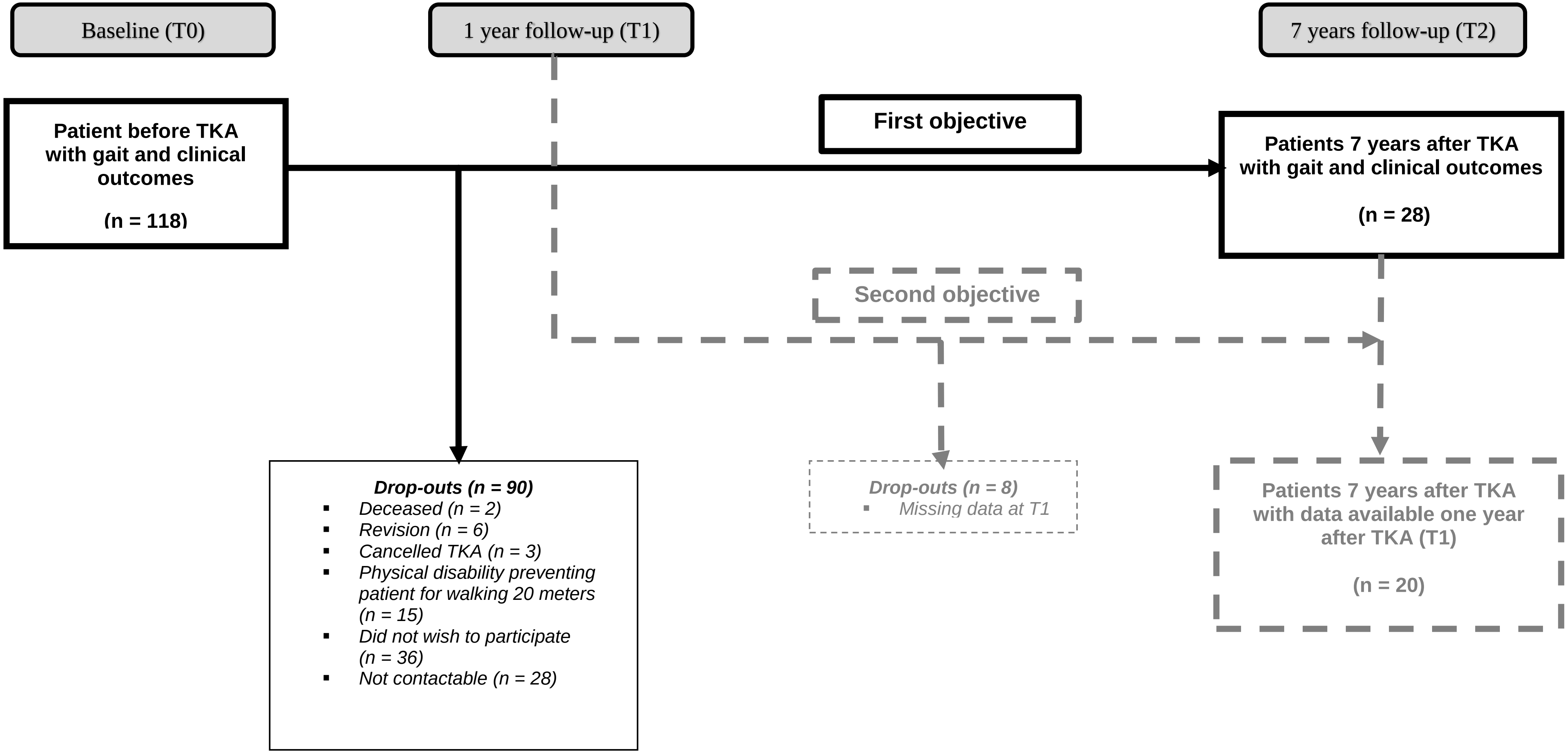
Figure 2.

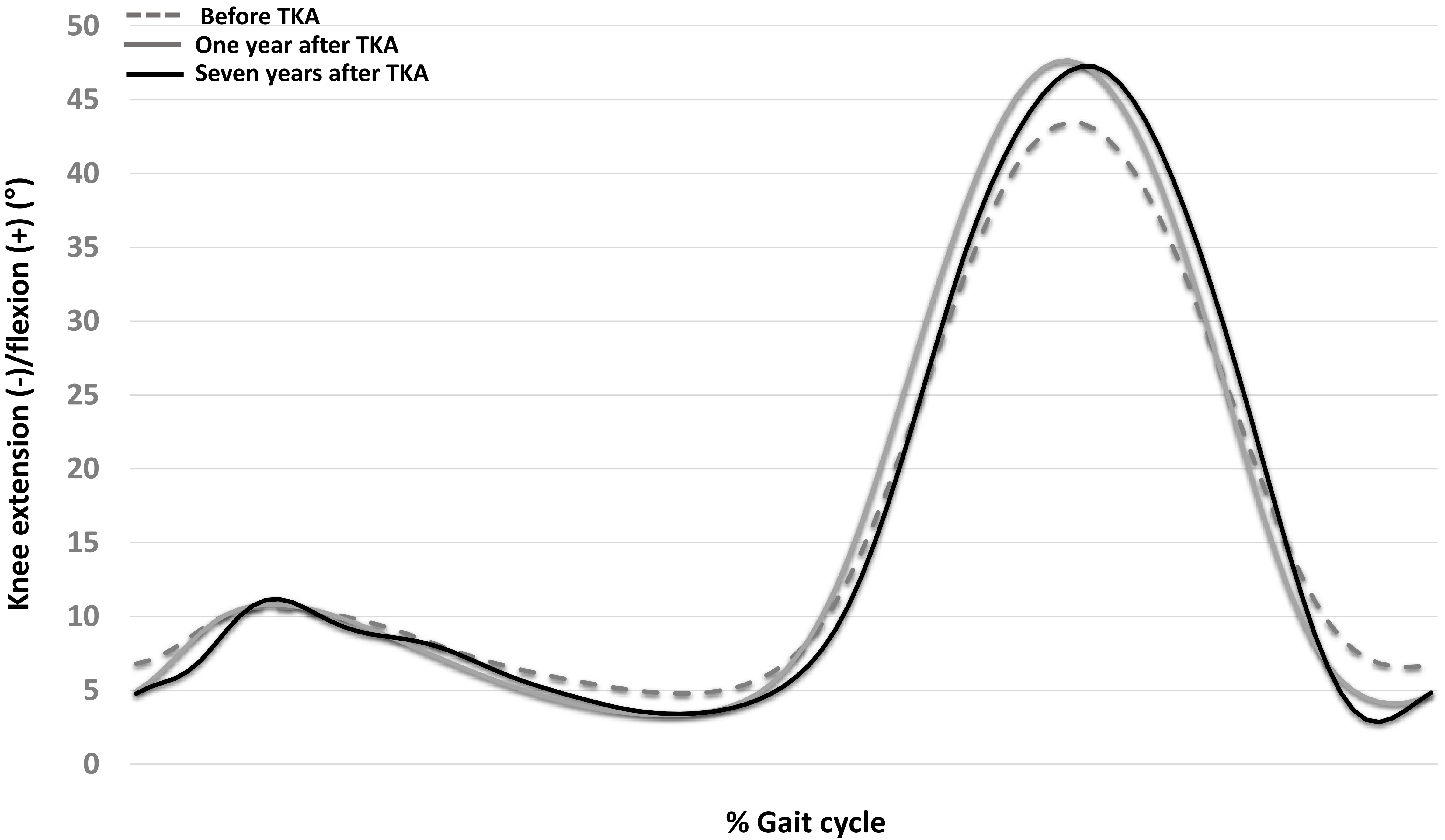
Sagittal plane knee kinematics during the gait cycle (knee flexion/extension in degrees) for the patient group before surgery (T0, dotted grey line), for the patient group one year after surgery (T1, solid grey line) and for the patient group around seven years after surgery (T2, solid black line).

Figure 3.

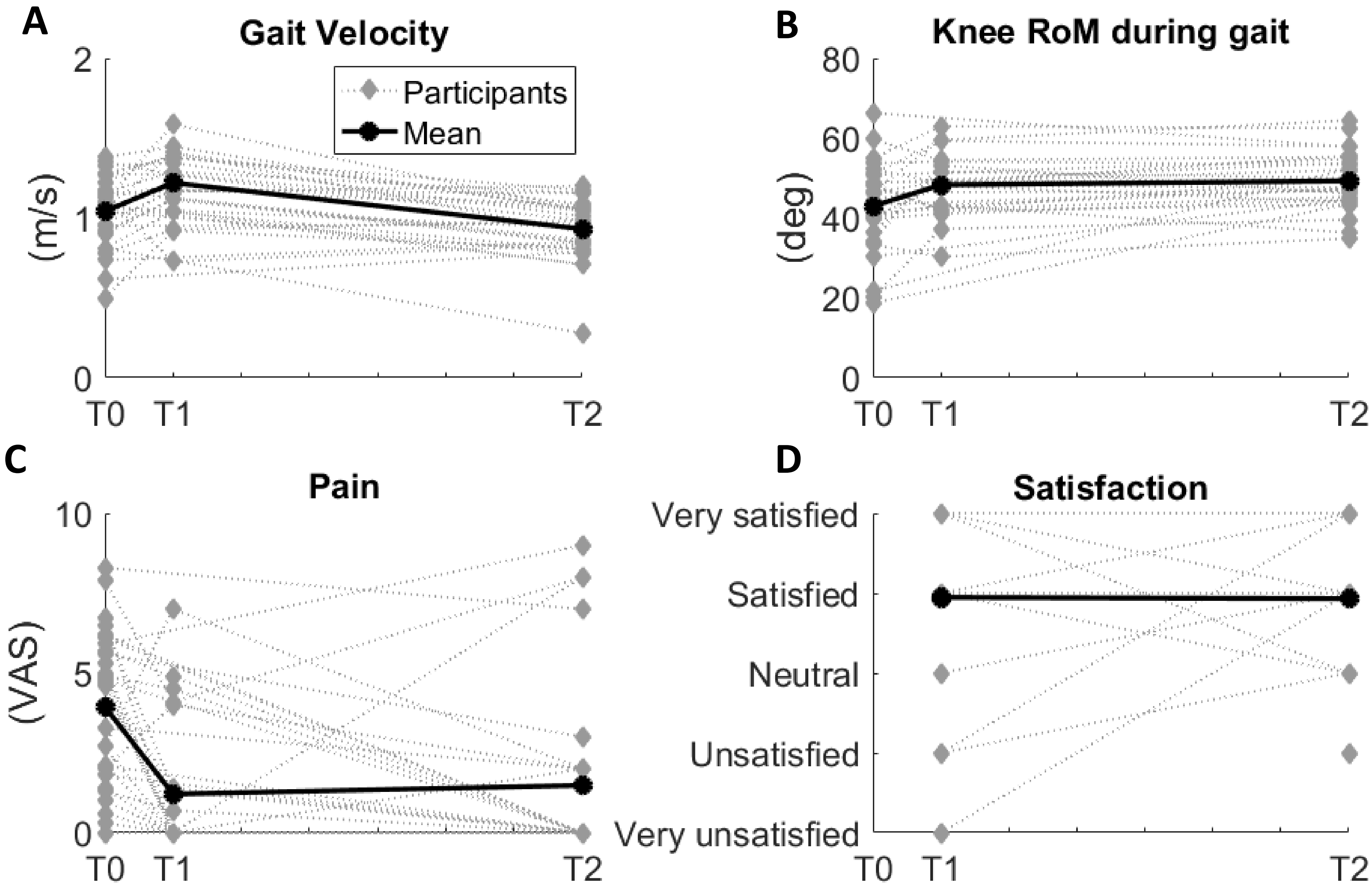
A/ Evolution of gait velocity ($m.s^{-1}$), **B/** Evolution of knee range of motion during gait (degrees), **C/** Evolution of reported pain levels (VAS) and **D/** Evolution of reported satisfaction levels (VAS) for each patient (grey lozenge) included in the study. T0 is before TKA, T1 is one year afterwards, and T2 is around seven years after TKA. In graphs A, B and C, the black line and round dots are the mean values for each CGA.

Figure 1:


Baseline (T0)
1 year follow-up (T1)
7 years follow-up (T2)
Patient before TKA with gait and clinical outcomes
(n = 118)
First objective
Patients 7 years after TKA with gait and clinical outcomes
(n = 28)
Second objective
Drop-outs (n = 90)
Deceased (n = 2)
Revision (n = 6)
Cancelled TKA (n = 3)
Physical disability preventing patient for walking 20 meters (n = 15)
Did not wish to participate (n = 36)
Not contactable (n = 28)
Drop-outs (n = 8)
Missing data at T1
Patients 7 years after TKA with data available one year after TKA (T1)
(n = 20)



Before TKA
One year after TKA
Seven years after TKA
Knee extension (-)/flexion (+) (°)
50
45
40
35
30
25
20
15
10
5
0
% Gait cycle


A
Gait Velocity
Participants
Mean
(m/s)
2
1
0
T0
T1
T2
B
Knee RoM during gait
(deg)
80
60
40
20
0
T0
T1
T2
C
Pain
(VAS)
10
5
0
T0
T1
T2
D
Satisfaction
Very satisfied
Satisfied
Neutral
Unsatisfied
Very unsatisfied
T0
T1
T2