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Original article

Mobility and satisfaction with a microprocessor-controlled knee in moderately active amputees: A multi-centric randomized crossover trial

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ABSTRACT

Objective: Microprocessor-controlled knees are generally prescribed and reimbursed for active amputees. Recent studies suggested that this technology could be useful for amputees with moderate activity level. We compared the efficiency of a microprocessor-controlled knee (MPK, Kenevo, Otto Bock) and non-MPKs (NMPKs) in these indications.

Methods: A multi-centric randomized crossover trial was conducted in 16 hospitals from 3 European countries. Participants were randomized to an MPK-NMPK sequence, testing the MPK for 3 months and the NMPK for 1 month, or to an NMPK-MPK sequence, testing the NMPK for 1 month and the MPK for 3 months. Dynamic balance, the main criteria, was assessed with the Timed-Up and Go test (TUG), functional mobility with the Locomotor Capability Index (LCI-5), quality of life with the Medical Outcomes Study Short Form 36 v2 (SF-36v2) and satisfaction with the Quebec User Evaluation of Satisfaction with Assistive Technology 2.0. The occurrence of falls was monitored during the last month of trial. Analysis was by intent-to-treat and per-protocol (PP).

Results: We recruited 35 individuals with transfemoral amputation or knee disarticulation (27 males; mean age 65.6 years [SD 10.1]). On PP analysis, dynamic balance and functional mobility were improved with the MPK, as shown by a reduced median TUG time (from 21.4 s [Q1–Q3 19.3–26.6] to 17.9 s [15.4–22.7], $P = 0.001$) and higher mean global LCI-5 (from 40.4 [SD 7.6] to 42.8 [6.2], $P = 0.02$). Median global satisfaction score increased (from 3.9 [Q1–Q3 3.8–4.4] to 4.7 [4.1–4.9], $P = 0.001$) and quality of life was improved for the mental component summary of the SF-36v2 (median score from 53.3 [Q1–Q3 47.8–60.7] to 60.2 [51.6–62.6], $P = 0.03$) and physical component summary but not significantly (mean score from 44.1 [SD 6.3] to 46.3 [7.0], $P = 0.08$). Monitoring of adverse events including falls revealed no differences between both assessed devices.

Conclusion: This study enhances the level of evidence to argue equal opportunity for all individuals with transfemoral amputation or knee disarticulation, regardless of their mobility grade, to be provided with appropriate prostheses.

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1. Introduction

The worldwide incidence of major lower-limb amputations is high and varies globally from 3.6 to 68.4/100,000 people. Vascular disease and diabetes dominate the amputation etiology in the older population. The incidence ranges from 5.6 to 600/100,000 people in this group [1]. About 30% of lower-limb amputations are at the transfemoral level [2]. For this population, the execution of activities of daily living is often specifically challenging. Transfemoral amputation is associated with limited mobility, reduced societal participation, and increased risk of falling, Additional risk factors for older amputees are chronic diseases, impaired balance and stability. Decreased vision at this age may further diminish ambulation abilities [2].

Exo-prosthetic knee components can be broadly categorized as mechanical, that is, non-microprocessor–controlled knees (NMPKs) and microprocessor-controlled knees (MPKs). In advanced MPKs, the microprocessor controls stance- and swing-phase resistance based on sensor information integrated in the prosthesis. Potentially dangerous situations are detected, and stumble and fall protection is activated. These advanced devices have preferentially been given to more active prosthetic users so that they may better utilize the functional benefits. For instance, in France, the prescription of MPK for active users is based on a walking speed $>$ 1.1 m/s (Haute Autorité de santé, avis HAS C-Leg, 2004). Amputees with lower mobility (often associated with advanced age and more severe comorbidities) are fitted with the more basic NMPKs. In recent years, an increasing number of investigations suggested that the benefits of MPKs may also be appropriate for amputees with lower mobility grades [3–7].

Recently, an innovative MKP has been developed (Kenevo, Otto Bock) with sensors and algorithms specifically addressing the needs of individuals with lower mobility grades, thereby supporting sitting-down and standing-up function, dynamic balance control and more sensitive stumble recovery. The primary objective of this study was to evaluate the effect of this innovative technology on dynamic balance. Secondary objectives were the effect of the technology on mobility, satisfaction and quality of life.

2. Methods

2.1. Study design

A multinational, multi-centric, randomized crossover trial was conducted. The study was designed and reported according to the CONSORT Statement for Randomized Trials of Nonpharmacologic Treatment. The protocol was approved by a scientific advisory board independent of the sponsor, including a methodologist and clinicians specialized in amputee rehabilitation. The study took place in 16 research centres: Austria (1 centre), France (14 centres), and Germany (1 centre). A crossover design was preferred so as to assess the same participant with the prosthesis, with only the knee, NMPK or MPK changed by the ortho-prosthetist. A crossover design has the advantage of reducing the effect of confounding covariates because participants serve as their own control. This design is also statistically efficient and adapted for studies on populations with low incidence because it requires fewer participants than with a non-crossover design.

The study design is described in Fig. 1. Participants randomized to the first arm, the sequence NMPK-MPK, continued using the NMPK prosthesis that they typically used, and after a 30-day follow-up, were assessed with their NMPK. Then they were fitted with the MPK prosthesis and assessed after a 90-day trial. At the end of the study, they were fitted again with their own NMPK prosthesis. Participants randomized to the second arm, the sequence MPK-NMPK, were fitted with the MPK prosthesis and assessed after a 90-day trial. Then they were refitted with their own NMPK prosthesis for a 10-day wash-out period and were assessed after a 30-day follow-up. A 1-month trial period with NMPK prosthesis was sufficient because it was the prosthesis of the participant; however, 1 month was needed to monitor adverse events including falls. The 3-month trial period with the MPK prosthesis was needed for participants to learn how to use the new functions of the MPK prosthesis.

A 10-day wash-out period was needed in the second arm, when switching from the "more secure" device, MPK, to the NMPK, to avoid taking into account possible falls with the NMPK in a transition period. In the sequence NMPK-MPK, the 10-day wash-out period was not needed because falls were monitored only in the last month of the 90-day trial. Defining the duration of the wash-out period was based on the experience of clinicians with the MPK. Although some weeks or months are necessary for participants to adapt to a completely new prosthesis, here 10 days was sufficient because they had to readapt to their own prosthesis, whereas only the knee joint was changed during the trial.

The study protocol was approved by the French National Agency for Medicines and Health Products Safety (ANSM) and ethics committees in respective countries (Comité de Protection des Personnes Île-de-France 3, Ethikkommission Burgenland in Austria, Ethik-Kommission der Universitätsmedizin Göttingen in Germany). A statement of compliance (no. 1782052v0) to the reference methodology MR01 was issued at the National Commission for Computing and Freedoms in France (CNIL). The

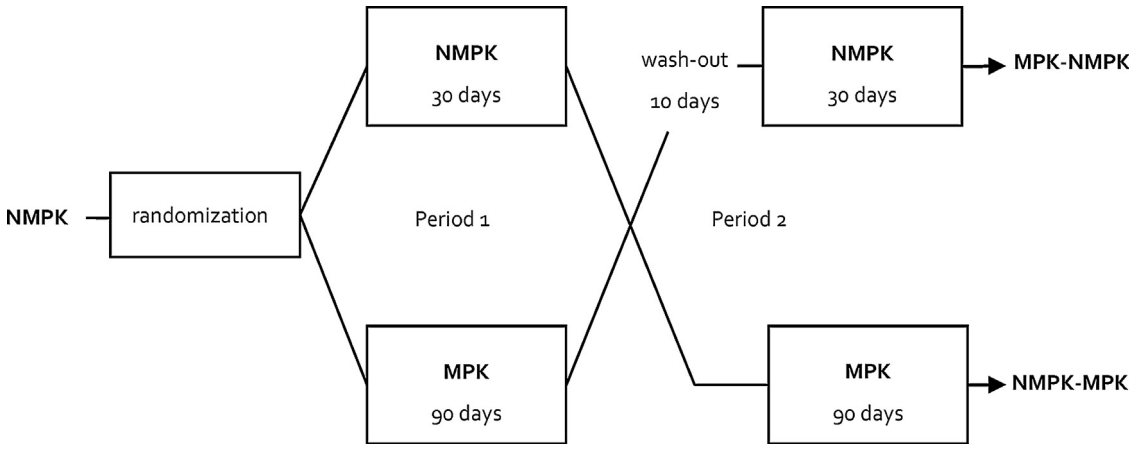

Fig. 1. Study design. MPK: microprocessor-controlled knee (Kenevo, Otto Bock); NMPK, non-MPK.

protocol was registered at ClinicalTrials.gov (NCT02382991). The study was in full compliance with ISO 14155 (GCP).

2.2. Participants

The study aimed to enroll individuals with moderate activity level, able to properly use their current mechanical prosthesis to allow for comparison with the MPK. Inclusion criteria were based on the International Classification of Functioning (ICF), that is, participants with mobility grade d4601 (moving around within buildings other than home) or d4602 (moving around outside the home and other buildings). To verify the moderate activity level of participants, the investigator questioned the participants about activities of daily life to verify whether they had a minimum daily walking distance of 300 m in addition to the mobility grade defined by the ICF (d4601 and d4602). Defining the minimum walking distance was based on the experience of investigators and inspired from the minimal walking distance of 500 m required in France for prescription of a prosthesis equipped with an MPK for more active amputees. In this research, focused on moderately active individuals, the required walking distance had to be reduced accordingly. To exclude active amputees, a score $>$ 19 s on the Timed Get Up and Go Test (TUG) was required. Dite et al. suggested that a cut-off of 19 s can distinguish transtibial amputees with high and low risk of falling [8]. At the moment, no cut-off is defined for the TUG for transfemoral amputation, and considering that functional status is higher with more distal amputation [9–11], we could not extrapolate this cut-off to transfemoral amputees. However, a minimal TUG value was needed to avoid including active amputees, and a 19-s score was consistent with the mean value of 24.5 s reported by Burnfield et al. with similar research [3]. To insure a proper and similar use of both devices, a stabilized residual limb and the use of a mechanical prosthesis were required. No minimal time since the amputation was defined because of the large variation in stabilization time among participants; the requirement was a stabilized residual limb, meaning a stabilized volume and complete healing.

Exclusion criteria were body weight $>$ 125 kg according to manufacturer indications, pregnancy, age $<$ 18 years, not able to provide consent including in an emergency situation, and not able to follow the entire study protocol. Users of underarm crutches were excluded because the limited load on the prosthesis does not allow the proper use of the prosthesis and the assessment of the impact of the knee joint. Walker users were excluded because of the duration of the trial period, estimated as too short by clinicians to modify the gait pattern of these individuals and walk with the MPK without a walker that would limit the proper use and benefits of the MPK. Bilateral amputation, associated injuries or comorbidities were not considered exclusion criteria in order to represent the most vulnerable subjects and those with greater need of balance assistance. All participants included in the trial signed the informed consent form.

2.3. Procedures

In contrast to NMPK, with the stance phase controlled by the wearer, who has to concentrate on each step and ensure the full extension of the knee during the stance phase, the MPK provides a secure flexion and extension of the knee during the stance and swing phase. A minimum of 5 rehabilitation sessions was performed with the MPK to learn how to load, trust and use the prosthesis properly during sitting, standing up, standing, turning, walking on flat and uneven surfaces, walking down and up ramps and walking down stairs by alternating steps. At the beginning of the trial with the NMPK, only one rehabilitation session was required to check the proper use of the device because the participants already had the experience of using their own prosthesis.

Each ortho-prosthetist received a 1-day training from the manufacturer regarding the procedures to integrate the articulation in the prosthesis and adjust settings with the software according to the participant's profile. For each trial, only the knee joint of the prosthesis was changed by the ortho-prosthetist in charge of the participant.

2.4. Outcomes

The TUG was used to investigate the primary objective, dynamic balance. It is validated for assessing functional mobility and dynamic balance in community-dwelling older people [12–15] and in lower-limb amputation [16,17]. Reduced time to perform the TUG suggests functional enhancement. The TUG was considered the more relevant outcome measure in assessing the benefits of the MPK prosthesis because it involves critical tasks in daily life of community-dwelling amputees including walking, turning and transfers.

Secondary outcome measures included the Locomotor Capability Index (LCI-5), the use of walking aids, the Quebec User Evaluation of Satisfaction with Assistive Technology 2.0 questionnaire (QUEST 2.0; French: ESAT) and the Medical Outcomes Study Short Form 36 v2 (SF-36v2) globally reported in 2 sub-scores, the mental component summary (MCS) and physical component summary (PCS), according to the authors recommendations. The LCI-5 is a self-administered questionnaire of 14 items, validated for amputees [18] and consisting of questions regarding basic and advanced activities concerning gait and ambulation on various terrains and in different everyday situations. The final basic, advanced and global scores range from 0 to 56. Higher scores suggest higher locomotor capabilities of the person assessed. The type of walking aid used with each prosthesis was noted and compared. The number and circumstances of falls during the last month of the trial were prospectively noted by the study participants in a diary. QUEST 2.0 was used to assess satisfaction. The questionnaire is specifically dedicated to evaluating assistive technology [19,20]. The SF-36v2 was used to assess quality of life of participants. The SF-36v2 is a self-administered questionnaire, validated for various assistive devices [21] and, using 8 scales, explores diverse dimensions of quality of life. The score for each scale ranges from 0 to 100. A higher score indicates higher level of functioning or higher level of well-being. Finally, all adverse events were recorded and reported if they were unexpected or serious and likely caused by the prosthesis.

2.5. Statistical analysis

The sample size was calculated based on the minimal detectable change with a 90% confidence interval (MDC_{90}) and the difference expected on the TUG measured with NMPK and MPK. The MDC reported by Resnik et al. for lower limb amputees was 3.6 s [17]. Burnfield et al. reported an improvement of 6.8 s with the MPK technology in a similar population but with a non-randomized design [3]. With an expected difference of 5 s and SD of 8 s, the required sample size was estimated at 27 individuals. Taking into account a potential dropout rate of 25%, we planned to enroll 40 individuals.

The Mann Whitney U test or t-test for independent samples was used as appropriate. If the effect was significant, only the first period was analyzed by using one-factor ANOVA (prosthesis). If the effect of the prosthesis was not significant, the effect was analyzed with an adjustment considering the period effect. If the hypotheses

of normality and equality of variances were not confirmed, the non-parametric analysis for a crossover design proposed by Tudor and Koch [32] was planned. In case of missing data, data for participants were excluded from the analysis of the criteria with missing data. The statistical analysis involved using IBM SPSS Statistics 20.0 under the Microsoft Windows 10 environment. $P < 0.05$ was considered statistically significant. All tests were bilateral. Data are presented as mean (SD) or median (Q1–Q3).

2.6. Role of the funding source

The sponsor had no role in the design of this study, defined by an independent scientific advisory board, and no role in data collection, data treatment and data analysis conducted by a contract research organization (Evamed) independent from the sponsor. The sponsor provided MPK devices for the study, training sessions for ortho-prosthetists and rehabilitation teams, and support to monitor the multi-centric study according to the planning defined in the protocol. Participants were not paid to participate in this research.

3. Results

We enrolled 35 participants from 12 investigating centers in France ($n = 27$, 77.1%), one in Austria ($n = 4$, 11·4%) and one in Germany ($n = 4$, 11.4%). Two other French centers could not include participants in the given enrolment period. Demographic data and information about prosthetic use at enrolment are in Table 1. Among the 35 participants enrolled and randomized, 2 decided not to continue the study before the first assessment, and 3 did not qualify for the first assessment due to adverse events (Fig. 2). Data for the remaining 30 participants were analyzed by intent-to-treat analysis. Among those participants, one had a depressive episode while she wore the MPK, which negatively affected the use of the prosthesis. Another participant experienced severe pain in the residual limb and hence was not able to use the MPK properly. One participant used a walker after the inclusion visit. These 3 participants were excluded from the per-protocol analysis, which involved 27 participants.

3.1. Mobility

The TUG time was shorter with the MPK than the NMPK ($P = 0.001$) (Table 2). The global and basic LCI-5 scores were significantly improved with the MPK versus the NMPK (both $P = 0.02$), whereas the advanced score did not differ significantly ($P = 0.16$). The use of walking aids did not differ with the two devices.

3.2. Satisfaction and quality of life

The level of satisfaction was significantly improved with the MPK versus the NMPK globally ($P = 0.001$), regarding services ($P = 0.006$) over the first period, and regarding technology (0.001) (Table 3). After the trial with the NMPK, the 3 criteria the most important for users were safety ($n = 20$), comfort ($n = 14$), and weight ($n = 9$). After the trial with the MPK, the 3 criteria the most important for users were safety ($n = 22$), comfort ($n = 16$), and efficiency ($n = 11$). Quality of life was better with the MPK than NMPK, with an improvement in the MCS of the SF-36v2 ($P = 0·03$) and the PCS, although not significantly ($P = 0.08$).

3.3. Adverse events

During the NMPK trials, one participant reported 1 non-serious fall, another reported 3 non-serious falls, and one was hospitalized for reasons not related to the knee and discontinued the study. During the MPK trials, 2 non-serious falls were related to the knee, 3 non-serious falls were potentially related to the knee and 5 adverse events not related to the knee were recorded. Over the

Table 1
Demographic data by intent-to treat (ITT) and per-protocol (PP) analysis for amputees testing the microprocessor-controlled knee.

	ITT ($n = 35$)	PP ($n = 27$)
Sex (male)	77.1%	81.5%
Age, years, mean (SD) [range]	65.6 (10.1) [48–85]	64.5 (9.7) [48–80]
Weight, kg, mean (SD) [range]	76.6 (16.0) [50–118]	77.6 (16) [50–118]
Height, cm, mean (SD) [range]	171.3 (8.6) [154–192]	172.6 (9.0) [155–192]
Amputation causes	57.1% vascular; 11.4% vascular diabetic; 22.9% traumatic; 11.4% tumor; 8.6 infectious	51.8% vascular; 11.1% vascular diabetic; 22.2% traumatic; 7.4% tumor; 7.4% infectious
Amputation level	94.3% transfemoral 5.7% knee disarticulation	96.3% transfemoral 3.7% knee disarticulation
Time since amputation, months, mean (SD)	61.4 (85.5) [4–324]	61.4 (85.5) [4–324]
ICF mobility grade	91.4% mobility grade ICF d4602 (to move around outside the home and other buildings) 8.6% mobility grade ICF d4601 (to move around within buildings other than one's residence)	88.9% mobility grade ICF d4602 (to move around outside the home and other buildings) 11.1% mobility grade ICF d4601 (to move around within buildings other than one's residence)
Additional disabilities	8.6% trans-tibial amputation of the contralateral lower limb 2.9% forefoot amputation on the contralateral side 5.7% handicap of the upper limbs 2.9% traumatism of the contralateral lower limb 2.9% hemiplegia consecutive to a stroke	11.1% trans-tibial amputation of the contralateral lower limb 7.4% handicap of the upper limbs 3.1% hemiplegia consecutive to a stroke
Residential area	31.4% urban, 68.6% rural	33.3% urban, 66.7% rural
Work status	5.7% had a professional activity, 22.9% without activity and 71.4% retired	7.4% had a professional activity, 22.2% without activity and 70.4% retired
Previous prosthesis	34.3% locked knee, 17.1% brake knee, 11.4% pneumatic knee, 31.4% hydraulic knee, 5.7% free knee	33.3% locked knee, 18.5% brake knee, 14.8% pneumatic knee, 29.6% hydraulic knee, 3.7% free knee
Socket type	2.9% quadrangular, 88.6% with ischial containment, 5.7% for knee disarticulation	3.7% quadrangular, 88.9% with ischial containment, 3.7% for knee disarticulation
Prosthetic foot	45.7% dynamic with carbon, 25.7% dynamic without carbon, 17.1% articulated, 11.4% SACH	51.9% dynamic with carbon, 14.8% dynamic without carbon, 18.5% articulated, 14.8% SACH

ICF: International Classification of Functioning.

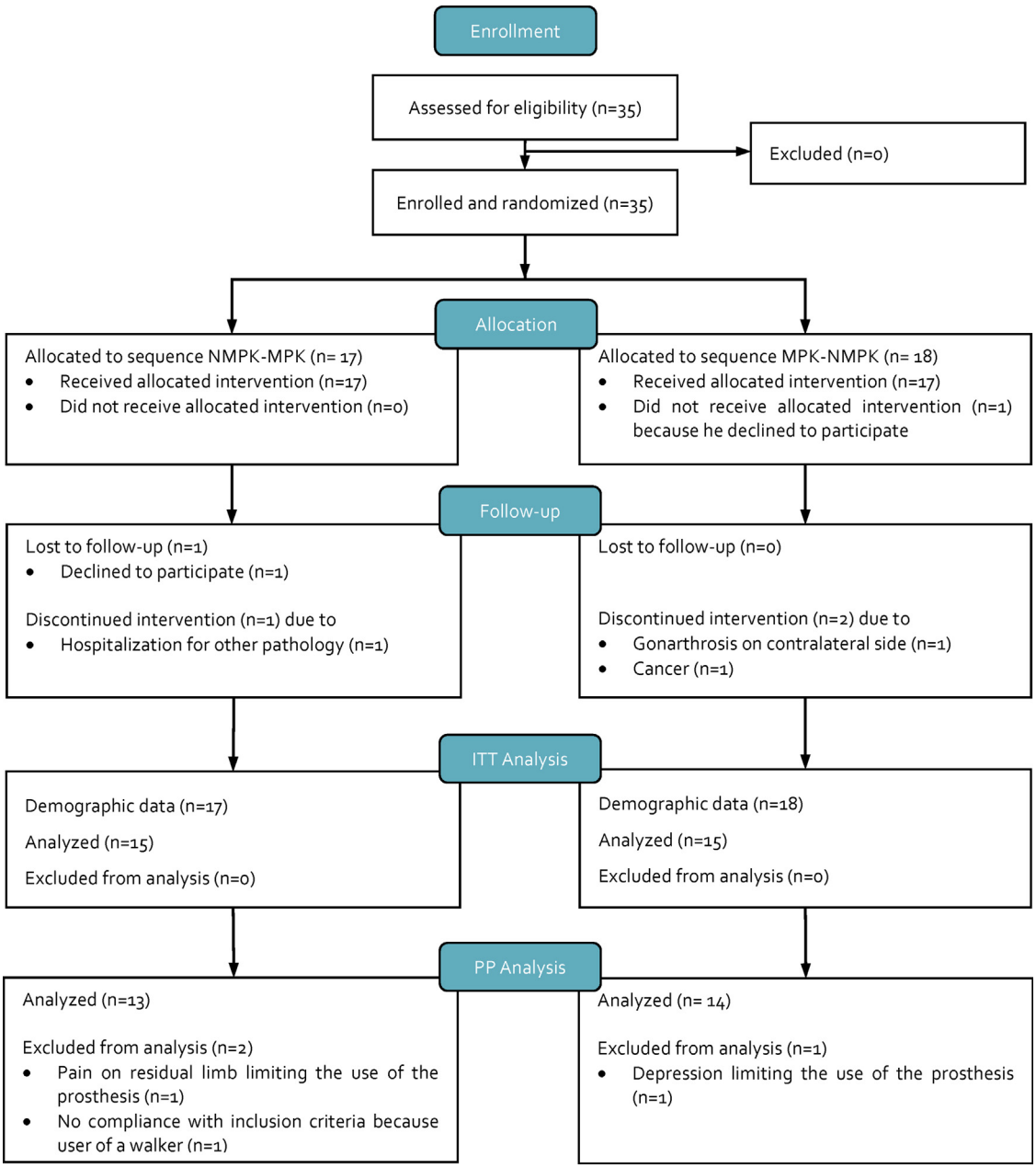

Fig. 2. Flow of participants in the trial.

last month of the trial, a limited number of falls was noted, with no significant difference between the MPK and NMPK (Table 4).

4. Discussion

Recent studies suggested that MPKs could be useful for amputees with moderate activity level. We compared the efficiency of a MPK (Kenevo, Otto Bock) and NMPKs for these individuals in a multi-centric randomized crossover study, which provided a high level of evidence. Dynamic balance and functional mobility were improved with the MPK, as were satisfaction and quality of life on the MCS of the SF-36v2. The incidence of falls did not differ with use of the 2 devices. Thus, all individuals with transfemoral amputation or knee disarticulation, regardless of their mobility grade, can be provided with appropriate prostheses.

Our study has some limitations. The participants presented different causes of amputation and additional injuries (n = 7; 20%) and the NMPK articulations as compared with MPK articulations were of different types (locked knees, brake knees, hydraulic or pneumatic knees). Therefore, even though inclusion and exclusion criteria participated in reducing the heterogeneity of the group in terms of mobility, the population presented different functional capabilities. NMPKs were of different types, but they all provided a mechanical stance-phase control requiring permanent attention and the intervention of the user at each step to prevent falls, in contrast to the MPK. Most amputees had limited mobility due to the amputation but also due to additional pathologies such as comorbidities, cardiovascular or neurological diseases, sensory impairments, orthopaedic injuries, and bilateral amputation. The exclusion of these individuals was not possible because of their large representation in the moderately active amputee population.

Table 2
Timed-Get-Up and Go (TUG), Locomotor Capability Index (LCI-5) and walking aids tests with and without the microprocessor-controlled knee (NMPK and MPK).

	ITT enrollment (n = 35)			PP (n = 27)		
	MPK (n = 30)	NMPK (n = 30)	P-value	MPK (n = 27)	NMPK (n = 27)	P-value
TUG time, s						
Median (Q1–Q3)	18.2 (16.2–25.2)	21.8 (19.5–28.4)	0.001	17.9 (15.4–22.7)	21.4 (19.3–26.6)	0.001
Min–max	12.6–51.9	15.6–49.3		12.6–30·7	15.6–36.6	
Mean (SD)	21.6 (9.0)	24.8 (8.3)		19.4 (5.1)	23.1 (5.4)	
LCI-5						
Global mean (SD)	41.7 (7.3)	38.6 (9.5)	0.006	42.8 (6.2)	40.4 (7.6)	0.02
Basic mean (SD)	21.9 (3.8)	20.1 (4.8)	0.008	22.2 (3.8)	20.8 (4.1)	0.02
Advanced mean (SD)	19.8 (5.0)	18.5 (5.5)	0.09	20.5 (3.8)	19.6 (4.5)	0.16
Walking aids, no. of patients (%)						
None	7 (23.3)	7 (23.3)		7 (25.9)	6 (22.2)	
1 cane	7 (23.3)	7 (23.3)		7 (25.9)	7 (25.9)	
1 crutch	5 (16.7)	3 (10)	0.9	4 (14.8)	3 (11.1)	0.97
2 canes	3 (10)	3 (10)		3 (11.1)	3 (11.1)	
2 crutches	8 (26.6)	9 (30)		6 (22.2)	8 (29.6)	
Walker	0 (0)	1 (3.3)		0 (0)	0 (0)	

Table 3
Satisfaction (QUEST 2.0) and quality of life (SF-36) with and without the microprocessor-controlled knee (NMPK and MPK).

	ITT enrollment (n = 35)			PP (n = 27)		
	MPK (n = 30)	NMPK (n = 30)	P-value	MPK (n = 27)	NMPK (n = 27)	P-value
QUEST 2.0						
Global median (Q1–Q2)	4.6 (4.0–4.9)	3.9 (3.7–4.3)	0.002	4.7 (4.1–4.9)	3.9 (3.8–4.4)	0.001
Technology median (Q1–Q2)	4.5 (3.9–4.9)	3.8 (3.5–4.3)	$<$0.002	4.5 (3.9–4.9)	3.9 (3.5–4.3)	0.001
Services median (Q1–Q2)	4.9 (4.0–5.0)	4.5 (3.8–5.0)	0.009	5.0 (4.5–5.0)	4.8 (4.0–5.0)	0.006
SF-36						
PCS mean (SD)	45.0 (8.4)	43.1 (6.7)	0.14	46.3 (7.0)	44.1 (6.3)	0.08
MCS median (Q1–Q2)	59.4 (51.5–62.4)	52.7 (45.8–60.3)	0.01	60.2 (51.8–62.6)	53.3 (47.8–60.7)	0.03
PF mean (SD)	56.3 (23.0)	48.3 (19.4)	0.04	59.1 (21.2)	51.7 (17.1)	0.07
RP median (Q1–Q2)	87.5 (56.3–100)	56.3 (37.5–81.3)	0.005	93.8 (59.4–100)	62.5 (37.5–81.3)	0.002
BP median (Q1–Q2)	61.5 (41.0–84.0)	61.5 (51.3–81.5)	0.9	62.0 (46.5–92.0)	62.0 (52.0–84.0)	0.72
GH median (Q1–Q2)	78.5 (67.0–85.8)	72.0 (57.0–87.0)	0.31	82.0 (71.0–87.0)	74.5 (63.3–87.0)	0.26
SF median (Q1–Q2)	100 (75–100)	87.5 (75–100)	0.16	100 (75.0–100)	87.5 (75–100)	0.20
MH median (Q1–Q2)	87.5 (70.0–95.0)	72.5 (61.3–88.8)	0.009	90.0 (72.5–95.0)	75.0 (65.0–90.0)	0.007
RE median (Q1–Q2)	100 (62.5–100)	75.0 (50–97.9)	0.04	100 (66.7–100)	75.0 (54.2–100)	0.12
VT median (Q1–Q2)	62.5 (56.3–79.7)	62.5 (56.3–75.0)	0.02	62.5 (56.3–84.4)	62.5 (56.3–75.0)	0.03

PCS: physical component score; MCS: mental component score; PF: physical activity; RP: limitations related to physical health; BP: bodily pain; GH: general health; SF: social well-being; MH: mental health; RE: limitations related to mental health; VT: vitality.

Table 4
Number of falls in the last month of the trial with and without the microprocessor-controlled knee (NMPK and MPK).

Falls	ITT enrollment (n = 35)			PP, (n = 27)		
	MPK (n = 30)	NMPK (n = 30)	P-value	MPK (n = 27)	NMPK (n = 27)	P-value
Number of falls	1	6	0.35	1	3	0.61
Falls related to the knee	0	4		0	2	
Number of patients	1	4		1	3	

However, biases from the role of these additional pathologies were reduced by the choice of a crossover design and by the short duration of trial periods, which prevented significant evolution of pathologies during the study.

Gait speed was not explored in this research, even though it is a common outcome measure to assess the functional status of amputees and has been used in France since 2004 to prescribe an MPK for more active individuals, walking faster than 1.1 m/s. Indeed, in contrast to MPKs dedicated to active amputees, the Kenevo does not provide a swing-phase regulation because the studied population did not require significant walking speed changes. Hence, gait speed was not considered a relevant outcome measurement in this study.

Owing to the complexity to implement biomechanical research with specific equipment and qualified teams in such a multicentric study, we used no objective methods to quantitatively explore the impact of MPK on gait pattern and postural equilibrium. However, several studies reported biomechanical improvements with use of the MPK in active wearers and further studies should investigate the impact on moderately active amputees.

Our findings agree with results from Burnfield et al., who used the TUG with 10 transfemoral amputees with lower activity grade transitioning from a mechanical knee to an MPK (C-Leg Compact; the predecessor of the Kenevo) [3]. The investigators found a significant reduction (P = 0.018) in the time needed to perform the TUG. The present study confirms these results with a larger study population and with increased significance. The minimal detectable change of 3.6 s in TUG was proposed for a mixed population of transtibial, knee disarticulated, and transfemoral amputees [17]. This value was exceeded after fitting the Kenevo in the per-protocol analysis (3.7 s) and was nearly reached in the intent-to-treat analysis (3.2 s). We observed a minimum TUG score of 15.6 s measured with the mechanical knee joint even though our

criterion was to enroll individuals with a TUG score > 19 s. The concerned participant was actually randomized to the MPK group first, and therefore, whether the trial with the Kenevo, including rehabilitation sessions, could improve the performance of some participants refitted with their mechanical knee joint is unknown. Further research is necessary to assess the impact of rehabilitation sessions with the MPK prosthesis on NMPK users.

The reduction in TUG time we observed was not associated with a significant reduction in falls (Table 4). A correlation of TUG time and risk of falls was described in several publications and revealed a limited ability of the TUG to predict future falls owing to the multi-factorial nature of falls [22–26]. The use of the TUG to discriminate between individuals with high or low fall risk is also limited and not recommended for older individuals [25] and not applicable in transfemoral amputation because a cut-off score is not defined. Several factors, not considered in this study, could also increase the risk of falls, such as other comorbidities, neurological diseases, sensory impairments, drugs, and environmental factors. Therefore, the TUG results should not be considered alone to assess the risk of falls and should be associated with a multi-factorial screening of fall risk. Here, falls were monitored among adverse events to ensure that falls did not increase when mobility is improved. Previous studies showed that the use of an MPK can positively influence the falls experienced by amputees with lower mobility grade [5,27]. A long-term study of a large number of amputees with moderate activity will be necessary to investigate the impact of MPK on number of falls.

A secondary focus of this trial was to analyse the effect of the MPK on locomotor abilities of the prosthetic users. The results indicate a significant improvement with the Kenevo in the LCI-5 global score as well as the basic score but not advanced score. Great improvement in basic activities is not surprising because new device features support many of the 7 questions contributing to the basic activities score, including 4 concerning the ability to ambulate stairs and curbs and 1 concerning the ability to get up from a chair.

As compared with the general population, for lower-limb amputees, the quality of life is generally diminished [28]. One study investigating the effect of MPKs in active amputees found an increased score as compared with the norms of people with a limitation in the use of the arm or leg [29]. Seelen et al. compared the MPK and NMPK in terms of the SF-36v2 score [30]. All sub-scores were significantly higher with the MPK, except for the social functioning sub-score and general health sub-score. Former quality of life assessments in amputees using the EQ5D [30] and the Prosthesis Evaluation Questionnaire [3,5,6], showing improvements in terms of ambulation, residual limb health, utility of the prosthesis, satisfaction and preference [1,31], are also in agreement with our findings.

In conclusion, MPKs explicitly tailored to the specific needs of this vulnerable population should be considered a viable therapeutic option to increase mobility and participation. Once other MPKs dedicated to moderately active persons are available on the market, comparisons with the Kenevo will be necessary for clinicians and health authorities to provide accurate recommendations and guidelines in the choice of the device.

Disclosure of interest

The authors declare that they have no competing interest.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.rehab.2018.04.003.

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