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Effectiveness of a New Microprocessor-Controlled Knee–Ankle–Foot System for Transfemoral Amputees: A Randomized Controlled Trial

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Abstract: Background: Advances in prosthetic technology, especially microprocessor-controlled knees (MPKs), have helped enhance gait symmetry and reduce fall risks for individuals who have undergone transfemoral amputation. However, challenges remain in walking in constrained situations due to the limitations of passive prosthetic feet, lacking ankle mobility. This study investigates the benefits of SYNSYS®, a new microprocessor-controlled knee–ankle–foot system (MPKA_NEW), designed to synergize knee and ankle movements. Methods: A randomized crossover trial was conducted on 12 male participants who had undergone transfemoral amputation who tested both the MPKA_NEW and their usual MPK prosthesis. Biomechanical parameters were evaluated using quantitative gait analysis in various walking conditions. Participants also completed self-reported questionnaires on their quality of life, locomotor abilities, and prosthesis satisfaction. Results: The MPKA_NEW showed a significant reduction in the risk of slipping and tripping compared to standard MPK prostheses, as evidenced by increased flat-foot time and minimum toe clearance during gait analysis. The MPKA_NEW also improved physical component scores in quality-of-life assessments (Short-Form 36 General Health Questionnaire), suggesting enhanced stability and reduced cognitive load during walking. Conclusions: The MPKA_NEW offers significant improvements in gait safety and quality of life for people who have undergone TFA, particularly in challenging conditions. Further studies are needed to assess the long-term benefits and adaptability across diverse amputee populations.

Keywords: gait; transfemoral amputation; microprocessor-controlled knee–ankle–foot system; synergy; biomechanics

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Citation: Requena, C.; Bascou, J.; Loiret, I.; Bonnet, X.; Thomas-Pohl, M.; Duraffourg, C.; Calistri, L.; Pillet, H. Effectiveness of a New Microprocessor-Controlled Knee–Ankle–Foot System for Transfemoral Amputees: A Randomized Controlled Trial. *Prosthesis* **2024**, *6*, 1591–1606. https://doi.org/10.3390/prosthesis6060115

Academic Editor: Giuseppe Solarino

Received: 12 November 2024
Revised: 3 December 2024
Accepted: 6 December 2024
Published: 18 December 2024

1. Introduction

Over the past two decades, prosthetic design has benefited from emerging technologies such as onboard electronics, composite materials, and hydraulic systems, leading to improved safety and enhanced quality of life for users [1]. In particular, this period saw the development of several microprocessor-controlled knees (MPKs), which usually regulate the flow of a hydraulic unit to vary the resistance of the knee flexion and extension. The microprocessor uses signals from sensors embedded in the device to adjust the behavior in both stance and swing. Studies comparing microprocessor-based knee prostheses and mechanical knees revealed the superiority of MPKs with an increased gait symmetry, improved walking patterns, and a reduced risk of falls [1–3]. Risk and fear of falling remain major limitations in the social participation of people who have undergone transfemoral amputation (TFA) and are associated with an altered quality of life [4–6].

Despite the technological progress, people who have undergone TFA still encounter difficulties, particularly when moving outdoors [7]. Slopes and stairs are challenging and require special attention [8,9]. Typical prosthetic feet used by people who have undergone TFA are passive components. They are made of deformable material, taking advantage of the elasticity to store and release energy during the stance phase. On the contrary, they cannot flex at all during the swing phase. The stiffness of these prosthetic feet is optimized for walking on flat terrain, based on the user's weight and activity level. However, walking on slopes or stairs, for example, requires a greater range of motion in the ankle joint [10,11], and the foot stiffness is no longer adapted [12,13]. Excessive stiffness during the stance phase can cause energy-return feet to not flatten quickly enough, reducing the time they stay flat on the ground [14], which creates an unstable support surface and increases the risk of slipping, particularly on downhill slopes [8]. It can also make some motion impossible, such as descending stairs with the foot on the step. To overcome this, individuals adopt a specific strategy and position the middle of their foot on the edge of each step [15], leading to a very unstable position, particularly perilous for individuals who have undergone TFA who lack direct control of knee flexion velocity [16,17]. Additionally, the absence of mobility during the swing phase is a source of tripping, and studies have shown that incorporating dorsiflexion in the prosthetic ankle during the swing phase can reduce the risk of falls among people who have undergone amputation [18,19].

To address these limitations, new-generation prosthetic foot–ankle systems were developed. These systems incorporate either an electric motor, which can adjust the foot position according to the terrain (slopes, stairs) [20,21], or a unit controlled by a microprocessor, capable of delivering energy to the user during the support phase [22–24]. However, these solutions are generally not favored by individuals who have undergone TFA due to constraints of weight, size, price, etc. In a 2022 study, Ernst et al. demonstrated that the added value of using a microprocessor-controlled ankle–foot system is dependent on the associated prosthetic knee. They suggested that investigating the coordinated use of microprocessor-controlled knees and feet could offer potential improvements in walking on slopes and uneven terrain [11].

Proteor recently developed SYNSYS®, which is a prosthetic limb combining the knee joint and the foot–ankle unit. The originality of the device is in the fact that it is biarticular and allows a synergetic motion by using a unique hydraulic unit controlling both the knee and the ankle. This microprocessor-controlled knee–ankle system (MPKA) is able to reproduce physiological joint mobilities up to 125° flexion–extension at the knee and 42° flexion–extension at the ankle. A state machine was designed to identify gait phases and walking conditions from a minimal set of sensors (ankle moment sensors, a tibial inertial unit, and a hall sensor). The models of adaptation of the damping and the stiffness of the knee and the ankle are modified according to reference values extracted from experimental databases [15]. The design of the device results in an automatic plantar flexion of the ankle at the beginning of the stance. During slope or stair descents, the synergy allows dorsiflexion of the ankle as the knee flexes. Also, the synergetic behavior of the device allows a truly active dorsiflexion of the ankle during swing, which is a unique feature of this device [25–27].

Biomechanical indicators are typically used to evaluate the effectiveness of prosthetic systems, providing quantitative data on how well the prosthesis reproduces natural limb movement. Key performance indicators include joint kinematics, joint kinetics, and muscle activation patterns. Joint kinematics refers to the movement of the joints in terms of angles, velocities, and accelerations. For example, a study by Bellmann et al. (2012) showed that MPKs could achieve more natural knee and ankle kinematics compared to non-microprocessor-controlled knees [28]. This is particularly important for activities like stair descent and slope walking, where coordinated knee and ankle movements are essential for stability and safety. Joint kinetics, which include the forces and moments, can be modulated by microprocessor-controlled systems to reduce the load on the residual limb, thereby improving comfort and reducing the risk of overuse injuries. Research by Kahle et al. (2008) indicated that MPKs could significantly reduce the peak loading forces on the knee joint during various activities, which is beneficial for long-term joint health [29].

Moreover, specific measures related to fall risk such as the time that the foot is flat and ground clearance can also be used. The duration that the foot remains flat on the ground during the stance phase, known as the flat-foot time (FFT), is an important indicator of stability. This FFT represents the time spent with a maximum base of support, so a longer FFT offers a more stable support phase, reducing the risk of slipping, especially on uneven terrain. Since slow flattening of the foot is a risk factor for slipping [14,30], it is important to optimize prosthetic foot designs to extend the flat-foot period, enhancing stability during walking [31]. Minimal toe clearance (MTC), the minimum distance between the foot and the ground during the swing phase, is a good indicator for assessing the risk of trips and falls. Insufficient toe clearance can lead to tripping, especially on uneven surfaces or obstacles. Research has shown that prosthetic designs that enhance dorsiflexion during the swing phase can significantly improve ground clearance and thus reduce the risk of tripping [14,18,19,32–34].

The objective of the study presented here is to assess the benefits for transfemoral amputees of the microprocessor-controlled 'knee–ankle–foot' system SYNSYS®, able to control the knee and ankle articulations in synergy, in comparison to the reference MPKs used by transfemoral amputees. We formulated two hypotheses:

H1: *Slipping risk should be decreased thanks to the better adaptation of the ankle in stance.*

H2: *Tripping risk should be decreased thanks to the mobility of the ankle during swing.*

To check these hypotheses, a clinical investigation was implemented to compare MPKA to classical prosthetic solutions with an MPK, after daily use.

2. Materials and Methods

2.1. Ethical Approval and Trial Registration

This study was approved by a National Ethics Committee (CPP Sud-Est III No. 2018-045B) and registered with "https://www.clinicaltrials.gov/ (accessed on 16 July 2024) (Identifier: NCT06522646). The manuscript was written according to the respective CONSORT guidelines for reporting randomized crossover trials [35].

2.2. Trial Design

The protocol followed a prospective, randomized, crossover design. Participants were randomly assigned to wear either the SYNSYS® prosthesis during the first treatment period, followed by the usual prosthesis during the second treatment period, or the usual prosthesis during the first treatment period, followed by the SYNSYS® prosthesis during the second treatment period. Each treatment period lasted a minimum of 4 weeks.

2.3. Participants

2.3.1. Eligibility Criteria

Only people who had undergone TFA with an activity level of d4602 (International Classification of Function, Disability and Health) or higher and who had worn a stance and swing phase microprocessor-controlled knee, financed by the French national health care service, for at least 3 months were included in this study. The people who had undergone TFA had to have a foot size of 24–30 cm and a knee-to-floor height of 43.5–55 cm.

People who met the following criteria were not included: minors or adults under legal protection, persons with bilateral amputations or other medical conditions that seriously affect walking, persons wearing an active vacuum socket, and pregnant or breastfeeding woman.

Recruited persons were affiliated with the French national health care service.

2.3.2. Consent to Participate

Eligible persons were thoroughly informed about the study according to the Declaration of Helsinki and its amendments; if they agreed to participate, they were included after obtaining written informed consent.

2.4. Setting and Location

Data were collected at the Institution Nationale des Invalides in Paris and the UGECAM—Centre Louis Pierquin in Nancy, both specialized in the care of patients undergoing locomotor rehabilitation.

2.5. Prosthetic System

In this study, each participant used two different prostheses: their prescribed MPK and an energy-storage-and-return (ESR) foot (class II or III, as defined by the French health care system [36], with a fixed ankle attachment), referred to hereafter as MPK_HAB, and the microprocessor-controlled prosthetic knee–ankle–foot system SYNSYS® (Proteor, Dijon, France), referred to hereafter as MPKA_NEW.

A copy of the usual user's socket was made to obtain an independent MPKA_NEW prosthesis. The alignment was optimized by a certified prosthetist based on recommendations from the manufacturer. The participants received a session of dedicated training (walking on level ground, up and down slopes, downstairs, sitting, etc.) supervised by a physiotherapist and the prosthetist to accommodate the MPKA_NEW and its functionality. The goal of this rehabilitation was to educate the patient on the MPKA_NEW's functionality, not to correct pre-existing gait deviation.

2.6. Interventions

People who had undergone TFA were offered a one-week test with the MPKA_NEW prosthesis to confirm the adaptability of the prosthetic system to their daily life and to fine-tune the prosthesis alignment and settings. Then, each participant who consented to participate wore, in a random order, the MPK_HAB and MPKA_NEW for at least 4 consecutive weeks, after validation of the optimal settings by a prosthetist.

At the end of each 4-week period, if the prosthesis was the MPKA_NEW, the values of the embedded sensors were extracted. Then, a quantitative gait analysis (QGA) was performed. QGA was performed for four gait situations (level ground, 12% uphill and downhill, and downstairs), complemented by a functional gait test (a six min walking test) and the completion of self-questionnaires. Each subject was equipped with 54 markers to record kinetics and kinematics with an optoelectronic motion analysis system (VICON, Motion Systems, Oxford Metrics, Oxford, UK), coupled with force plates (AMTI force plates, Watertown, MA, USA) and sampled at 100 Hz. The markers were positioned on specific anatomical landmarks according to the protocol described by Pillet et al. [15]. One static acquisition and a minimum of six dynamic acquisitions were recorded at a comfortable speed for each participant and each walking situation.

Participants completed the Prosthesis Evaluation Questionnaire (PEQ), Short-Form (SF)-36, PPA-LCI, and PLUS-M after each period of prosthetic use. The PEQ consists of 82 questions describing prosthesis function and assessing prosthesis-related quality of life [37]. The questionnaire is divided into nine functional scales, corresponding to four main domains: prosthetic function, mobility, psychosocial experience, and well-being. For a complete analysis, subjects' confidence, concentration, and fear were assessed using an addendum to the PEQ [38]. Participants' quality of life was also assessed using the Short-Form (SF)-36 General Health Questionnaire, which provides scores for physical and mental components [39,40]. Finally, participants' locomotor abilities were assessed by self-assessment questionnaires PPA-LCI and PLUS M, consisting of 13 and 11 questions, respectively, describing different walking situations encountered daily.

Once the QGA and questionnaires were conducted for the first prosthesis, the subject was asked to wear the second one for at least 4 weeks, and QGA and questionnaires were conducted again for the second prosthesis. At the end, each subject had one complete set of QGA and questionnaire results per prosthesis.

2.7. Outcomes

Spatiotemporal parameters and lower-limb joint kinematics and kinetics in the three anatomical planes were computed in each walking situation (level ground, slope ascent and descent, and stairs descent). Data were filtered (4th-order Butterworth low-pass filter with a cut-off frequency of 5 Hz cut) and processed with customized Matlab scripts and functions (MATLAB version: 9.13.0 (R2022b), Natick, MA, USA: The MathWorks Inc.).

To compute flat-foot time (FFT), it is assumed that the foot is flat on the ground at 20% of the gait cycle. The FFT is computed as the time when the foot angle stays within ±1.25° of its value at 20% of the gait cycle, as described in Dauriac, 2018 (Figure 1A). This FFT was calculated as a percentage of the gait cycle to normalize the data between subjects. Start, end, and duration of FFT were extracted.

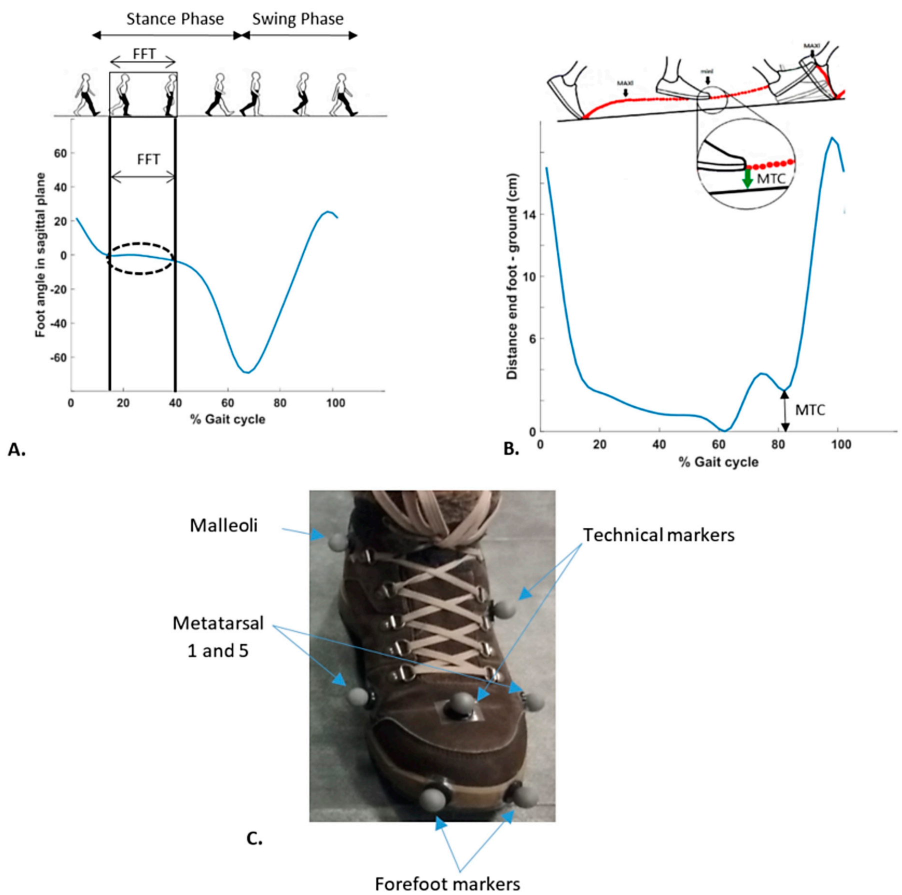


Figure 1. Illustration of FFT (**A**), MTC ((**B**), inspired by Riveras et al. 2020 [33]) calculation methods, and positioning forefoot markers to calculate MTC (**C**), respectively.

Then, the minimum toe clearance (MTC), defined as the minimum distance between the forefoot and the ground during the swing phase, was estimated (Figure 1B). From the static acquisition in the reference position, two markers were placed at the extremity of the forefoot (Figure 1C). The position of the center between these markers was computed in a coordinate system linked to the forefoot built from the other markers positioned on the forefoot (two metatarsal markers and two on the toes). The forefoot markers were removed after the static acquisition (Figure 1C) to avoid disturbing the gait. Its position in the global frame was calculated during the swing phase from the movement of the forefoot coordinate system.

Finally, the questionnaires were analyzed according to their respective scores. For the PEQ, a Kiviat diagram was created to better appreciate the scores of the different subcategories of the questionnaire. Concerning the PPA LCI and the PLUS M, the raw score and T Score were, respectively, calculated for each participant. For the SF-36, the Physical Health Composite (PHC) and the Mental Health Composite (MHC) were computed according to published guidelines [39].

2.8. Sample Size

A preliminary study was conducted to calculate the required number of participants for this study [15]. Given the small cohort size of the preliminary study, we set an effect size objective of 1.25, a Type I error rate (alpha) of 5%, and a power of 85% to account for the risks of missing data and loss to follow-up. These assumptions led to a minimum sample size of 12 patients per group for matched pairs with a correlation of 0.5.

2.9. Randomization

Randomization was conducted using a computer-generated code that assigned participants to groups based on a stratification method (two inclusion sites) and block randomization to ensure balance in the list for every four patients. Screening of participants was realized by a prosthetist, and participant inclusion was performed by the investigating MPR physicians at each investigation center, while randomization was managed by a single engineer throughout the study. The randomization needed to be performed prior to the inclusion visit for logistical reasons, ensuring the availability of devices and human resources at each investigation site. Investigators were not aware of the randomization prior to the inclusion and were informed of it at the time of the inclusion visit.

2.10. Blinding

Due to the visible nature of the tested prostheses, both the investigator and participant were aware (not blind) of the assigned randomization arm throughout the study.

2.11. Statistical Methods

To analyze the data collected from the randomized crossover trial, we employed linear mixed-effects models to account for the repeated-measures design and the hierarchical structure of the data. The primary goal was to assess the fixed effects of the prosthetic type (MPK_HAB vs. MPKA_NEW) and the visit (first vs. second) on various biomechanical and self-reported outcomes.

Linear mixed-effects models (LMMs) were chosen for several reasons in this study. Firstly, LMMs are particularly suited for handling repeated measures, as each participant was measured multiple times under different conditions (two prosthetic devices and across two visits). This data structure induces inherent correlations that LMMs can appropriately model by accounting for within-subject correlations. Additionally, LMMs accommodate individual differences among participants. By including random effects for each participant, LMMs can capture these inter-individual variations, thereby improving the accuracy and reliability of the fixed-effects estimates.

This test also assesses the interaction effects between fixed effects (prosthesis*visit). If this interaction effect is not statistically significant, the linear mixed model is recalculated without considering this interaction effect, in order to test only the fixed effects.

All statistical analyses were performed using R (version 4.3.3), specifically employing the nlme package for fitting linear mixed-effects models. *p*-values were obtained to assess the significance of the fixed effects, and effect sizes $|r|$ (Cohen's d) were calculated for significant differences to quantify the magnitude of the effects. Effects are considered as small for $|r| = 0.2$, medium for $|r| = 0.5$, or large for $|r| \geq 0.8$ [41,42].

3. Results

3.1. Recruitment

Data were collected from November 2018 to April 2023. Figure 2 shows the flowchart of participants enrolled in this study. Of 23 individuals screened and randomized, 11 were allocated to the group B1 (wearing MPK_HAB first, then MPKA_NEW) and 12 to the group B2 (wearing MPKA_NEW first, then MPK_HAB).

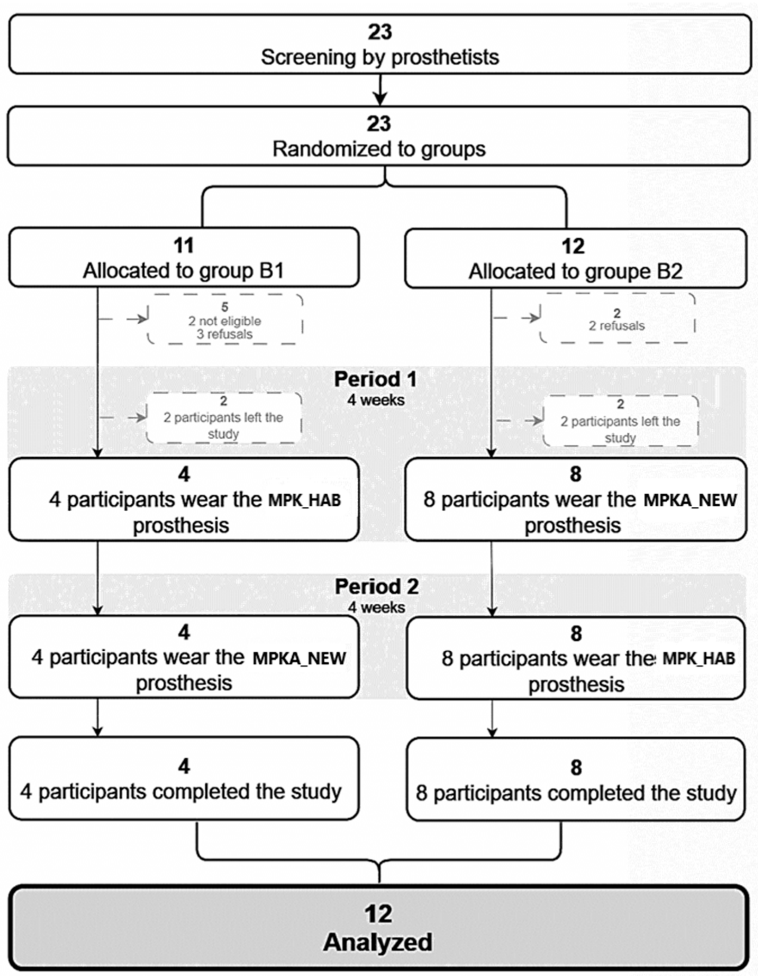


Figure 2. Flowchart of participants. Group B1: wearing MPK_HAB first, then MPKA_NEW. Group B2: wearing MPKA_NEW first, then MPK_HAB.

From 23 potential participants screened, 7 did not participate in the study. Two people were not included following the investigative physician's decision based on the study's inclusion and exclusion criteria. Five eligible participants declined to be included in the study due to personal reasons. From the 16 participants included, 4 participants left the study before completing their inclusion period and before any assessment, either for medical reasons (3) or due to prosthesis malfunction (1). The malfunction was reported to the manufacturer, who corrected the issue, and the malfunction did not reoccur.

Data from 12 participants (4 B1, 8 B2) who completed the study were included in the analyses.

3.2. Population Characteristics

Twelve participants were able to complete the study. The characteristics of each participant are listed in Table 1 Only men participated in this experimental campaign with a mean (SD) age of 45.8 (15.2) years, height of 177.1 (8.4) cm, and weight of 76.9 (10.9) kg.

Table 1. Transfemoral amputee participant characteristics.

	Age (yrs)	Height (cm)	Weight (kg)	Time Since 1st Prosthesis (yrs)	Cause of Amputation	Current Prosthetic Knee	Current Prosthetic Foot
1	65	175	92	40	Traumatic	CLeg 3	Variflex
2	53	184	72	22	Traumatic	CLeg 3	Proflex XC
3	44	178	70	7	Traumatic	CLeg 4	Proflex XC
4	60	163	77	4	Traumatic	Rheoknee	Proflex Rotate
5	39	180	74	9	Traumatic	Rheoknee	Proflex XC
6	48	196	74	1.5	Traumatic	CLeg 4	Proflex XC
7	56	172	68	39	Traumatic	Rheoknee	Variflex
8	67	182	62	3	Traumatic	CLeg 4	Triton
9	30	183	80	2	Traumatic	CLeg 4	HiPro
10	21	167	65	20	Congenital	Rheoknee	Proflex XC
11	25	169	78	20	Congenital	Rheoknee	Proflex XC
12	41	179	87	6	Traumatic	Rheoknee	Proflex XC

3.3. Stance Phase

Flat-foot time systematically began earlier with the MPKA_NEW compared to the MPK_HAB and was closer to the reference values for able-bodied individuals [43] (Figure 3). The results also demonstrated a statistically significant increase ($p < 0.01$) in the duration of flat-foot time with the MPKA_NEW compared to the MPK_HAB in all walking situations, except for uphill walking. No interaction effect was found.

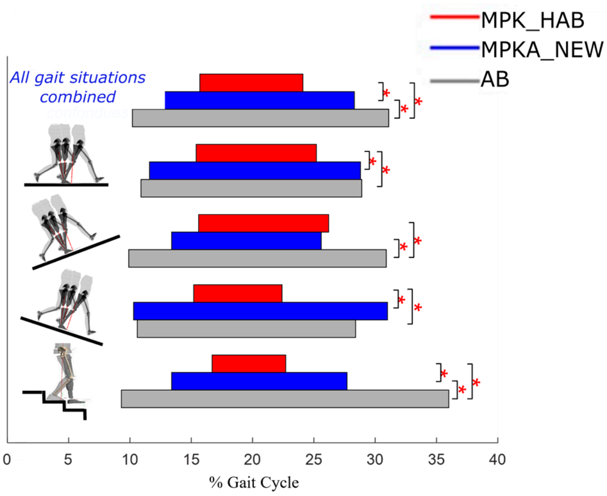


Figure 3. Graphical representation of the start, end, and duration of flat-foot time for each walking situation. The SA data are taken from the preliminary study carried out during Boris Dauriac's thesis [43]. (AB = able-bodied subjects, MPK_HAB = usual prosthesis, MPKA_NEW = SYNSYS prosthesis), * $p < 0.05$.

Various stance-phase parameters were studied for each gait situation, including gait speed, prosthetic and contralateral step lengths, stance-phase durations, and flat-foot times (Table 2). No significant differences were found between the two prostheses in terms of gait speed, prosthetic step length, and contralateral step width.

However, a significant reduction in contralateral step length was observed when walking on slopes ($p = 0.01$ and $p = 0.02$), and a significant increase was noted when descending stairs ($p = 0.03$) with the MPKA_NEW. Additionally, a significant increase in prosthetic step width was observed during uphill walking ($p = 0.03$) and stair descent ($p \leq 0.01$) with the MPKA_NEW. Finally, a significant reduction in stance-phase duration was observed on level ground.

Table 2. Stance-phase parameters for each walking situation.

		MPK_HAB	MPKA_NEW	*p*-Value	Effect Size ∣r∣
WALKING SPEED (M/S)	Level Ground	1.16 (0.1)	1.2 (0.1)	0.28	1.12
	Uphill 12%	1.04 (0.1)	1.01 (0.1)	0.55	0.62
	Downhill 12%	1.05 (0.2)	0.98 (0.2)	0.15	1.58
	Stairs	0.46 (0.1)	0.42 (0.1)	0.07	2.01
STEP LENGTH P (CM)	Level Ground	67.6 (7.8)	68.8 (8.3)	0.49	0.71
	Uphill 12%	67.7 (8.1)	64.8 (9.4)	0.17	1.5
	Downhill 12%	62.1 (5.9)	64 (4.8)	0.44	0.80
	Stairs	39.9 (5.2)	40 (6.7)	0.95	0.06
STEP LENGTH C (CM)	Level Ground	65.4 (4.9)	64.3 (5.4)	0.50	0.70
	Uphill 12%	66.7 (6)	62.9 (6.2)	0.01 *	3.02
	Downhill 12%	58.6 (7.6)	51.4 (10.4)	0.02 *	2.74
	Stairs	24.2 (6.7)	29 (7.2)	0.03 *	2.54
STEP WIDTH P (CM)	Level Ground	20.1 (4.4)	20.9 (4.9)	0.35	0.97
	Uphill 12%	21.4 (4.9)	23.9 (5.8)	0.03 *	2.59
	Downhill 12%	20.3 (4.5)	20.7 (4.6)	0.41	0.85
	Stairs	21.9 (3.3)	23.7 (3.4)	<0.01 *	3.48
STEP WIDTH C (CM)	Level Ground	22.5 (3.9)	23.4 (4.6)	0.30	1.1
	Uphill 12%	22.0 (6.8)	23.3 (5.3)	0.07	1.97
	Downhill 12%	21.8 (4.5)	23.4 (5.7)	0.21	1.32
	Stairs	23.7 (3.1)	22.9 (2.2)	0.52	0.67
STANCE PHASE (% GC)	Level Ground	58.7 (1.1)	57.2 (1.3)	0.03 *	2.69
	Uphill 12%	60.0 (2.1)	59.6 (2.2)	0.43	0.82
	Downhill 12%	56.2 (3.8)	56.3 (3)	0.33	1.02
	Stairs	60.8 (5.4)	63.3 (5.9)	0.17	1.47
FLAT-FOOT TIME (% GC)	Level Ground	9.8 (5.7)	17.2 (6.3)	0.02 *	2.65
	Uphill 12%	10.6 (4.3)	12.2 (4.2)	0.36	0.96
	Downhill 12%	7.2 (3.3)	20.7 (4.7)	<0.01 *	7.66
	Stairs	6 (3.6)	14.3 (6.4)	<0.01 *	5.28

Data are means (SDs). P = prosthetic side, C = contralateral side, GC = gait cycle. * *p*-value < 0.05 comparing MPH_HAB and MPKA_NEW.

3.4. Swing Phase

A significantly greater MTC was observed with the MPKA_NEW compared to the MPK_HAB when walking on level ground (1.8 ± 8 cm with the MPK_HAB vs. 4.6 ± 2.1 cm with the MPKA_NEW, $p < 0.01$, ∣r∣ = 0.7) and when walking up a 12% slope (1.8 ± 6 cm with the MPK_HAB vs. 4.1 ± 1.5 cm with the MPKA_NEW, $p < 0.01$, ∣r∣ = 0.61). Furthermore, a significant variability in this parameter is observed when using the MPK_HAB prosthesis. This variability decreases when using the MPA_NEW, approaching the level observed on the contralateral side (Table 3). No interaction effect was found.

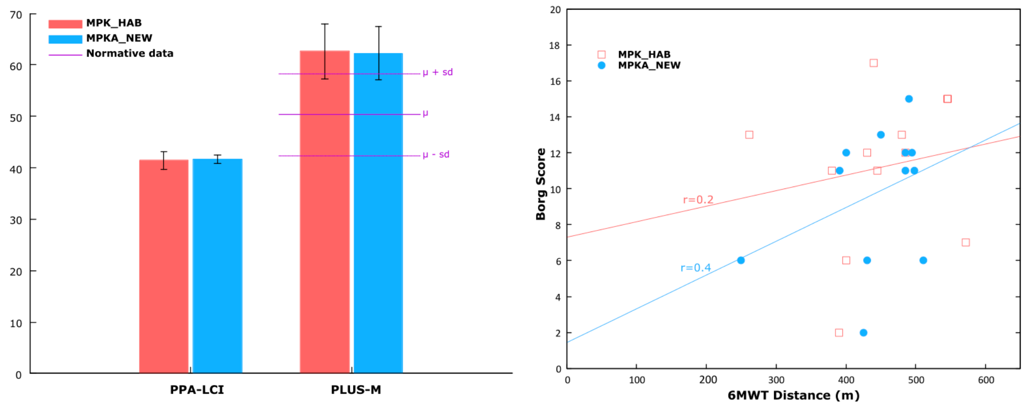
Table 3. Minimum toe clearance (MTC) in cm during level-ground gait and 12% uphill.

	MTC_C	MPK_HAB	MPKA_NEW	*p*-Value	Effect Size ∣r∣
Level ground	2.2 (1.5)	1.8 (8)	4.6 (2.1)	0.01 *	3.08
12% uphill	3 (1.2)	1.8 (6)	4.1 (1.5)	<0.01 *	3.45

Data are means (SDs). MTC_C = contralateral, MPK_HAB = usual prosthesis, MPKA_NEW = SYNSYS prosthesis. * *p*-value < 0.05 comparing MPK_HAB and MPKA_NEW.

3.5. Locomotor Skills and Performances

With regard to locomotor skills, no significant differences were found in the answers to PPA-LCI and PLUS-M self-questionnaires (Figure 4A). A ceiling effect was observed for both questionnaires, regardless of the prosthesis used. However, it is important to note that the results of the PLUS-M questionnaire showed that subjects had locomotor performance way beyond the standard defined by Hafner in 2017 [44].



(**A**) (**B**)

Figure 4. (**A**). PPA LCI and Plus M questionnaire scores for each prosthesis (red: MPK_HAB, blue: MPKA_NEW prosthesis). "Normative data" correspond to data defined by Hafner in 2017 acquired for validation of PLUS-M in adults with lower-limb amputation. (**B**). Relationship for each participant and each prosthesis (red: MPK_HAB, blue: MPKA_NEW prosthesis) between the distance covered in the 6MWT and the effort measured to perform this test.

Moreover, no correlation was found between the distance covered in the 6 min walking test (6-MWT) and the effort required to perform this test (Figure 4B). No significant difference between both prostheses was found when comparing the distance covered during this test. Effort measured following this test (Borg Scale) showed a slightly lower perceived effort with the MPKA_NEW than with the MPK_HAB (11.2/20 with the MPK_HAB vs. 9.8/20 with the MPKA_NEW), but this difference was not statistically significant (p = 0.08).

3.6. Quality of Life

Quality of life was assessed through SF-36 questionnaire scores (Figure 5 and Table 4). There was statistically significant improvement for the physical questionnaire components with the MPKA_NEW (MHC: p = 0.07, $|r|$ = 0.29; PHC: p = 0.04, $|r|$ = 0.36). No interaction effect was found.

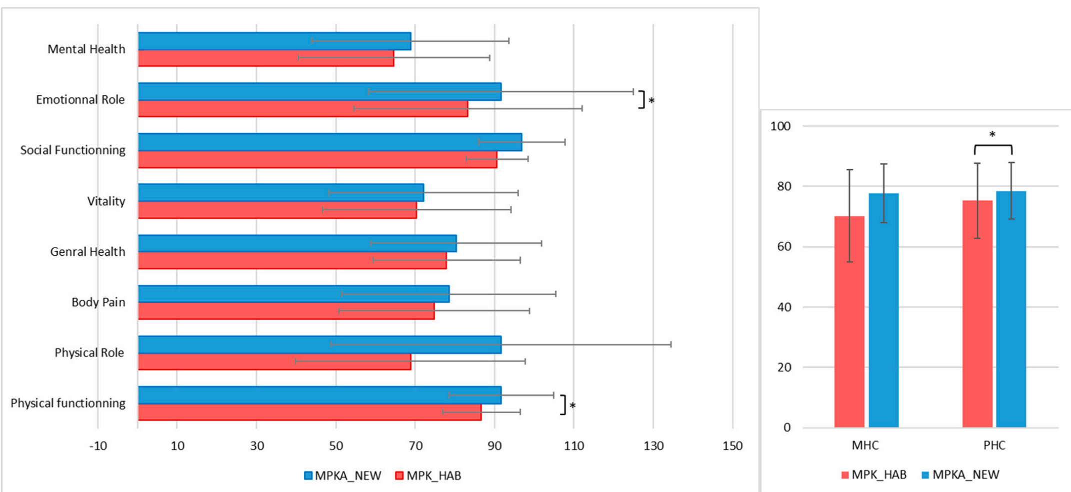


Figure 5. Score obtained on SF-36 questionnaires with both prostheses. Data are means. * $p < 0.05$ comparing MPK_HAB and MPKA_NEW.

Table 4. Scores obtained on SF-36 questionnaire with both prostheses.

	MPK_HAB	MPKA_NEW	*p*-Value	Effect Size ∣r∣
Physical functionning	86.7 (13.2)	91.7 (9.8)	0.04 *	2.43
Role physical	68.8 (42.8)	91.7 (28.9)	0.06	2.09
Body pain	74.8 (27)	78.5 (24)	1.00	3.50
General health	77.9 (21.5)	80.4 (18.6)	0.31	1.08
Vitality	70.4 (23.8)	72.1 (23.8)	0.66	0.45
Social functional	90.6 (10.8)	96.9 (7.8)	0.06	2.10
Role emotional	83.3 (33.3)	91.7 (28.7)	0.04 *	2.33
Mental health	64.6 (24.9)	68.8 (24.1)	0.70	0.39
MHC	70.2 (15.3)	77.7 (9.7)	0.07	2.01
PHC	75.3 (12.4)	78.5 (9.4)	0.04 *	2.36

Data are means (SDs). SF-36: medical outcomes study short-form 36; PHC: Physical Health Composite; MHC: Mental Health Composite; * $p < 0.05$ comparing MPK_HAB and MPKA_NEW.

3.7. Prosthesis Evaluation Questionnaire

The scores for each category of the PEQ are presented using a Kiviat diagram (Figure 6). The score scale ranges from 0 to 100 for each question; the closer the score is to 100, the better the perception. The diagram shows the average satisfaction level of the 12 participants for each category. A score of 0 (zero satisfaction) corresponds to the central point of the graph, and a score of 100 (maximum satisfaction) corresponds to the end of the axes.

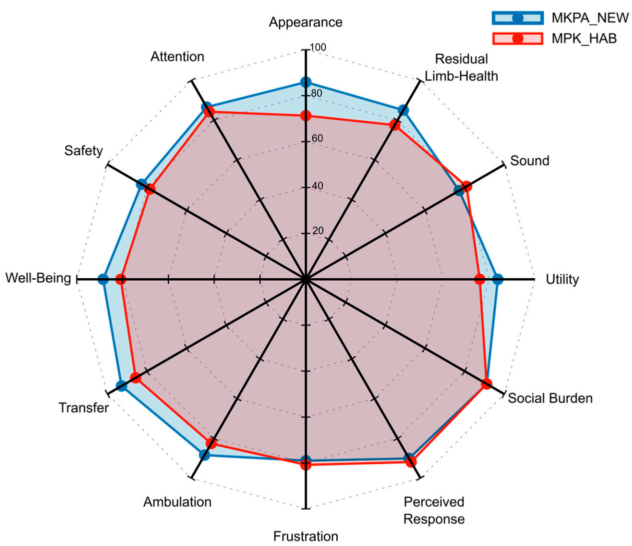


Figure 6. Kiviat diagram showing the scores obtained for each category of the PEQ and for each prosthesis. The closer the score is to 100, the better the feeling.

The MPKA_NEW scored higher for eight out of twelve categories; for six of these categories (appearance, limb health, utility, ambulation, transfer, and well-being), the difference between the two prostheses exceeds the minimum detectable change (MDC) [45], favoring the MPKA_NEW. In addition, a significant difference between the MPK_HAB and MPKA_NEW was observed in the "appearance" ($p = 0.03$, $|r| = 2.44$) and "well-being" ($p = 0.05$, $|r| = 2.24$) categories while positive, but not significant, trends were observed in five scales (limb health, utility, ambulation, transfer, and safety).

4. Discussion

The aim of this study was to evaluate the use of a new microprocessor-controlled knee–ankle prosthesis (SYNSYS® from Proteor), referred to as MPKA_NEW, for people who have undergone transfemoral amputation compared to using a conventional microprocessor-controlled knee prosthesis combined with an energy-restoring foot, referred to as MPK_HAB. The latter corresponds to the standard prosthesis provided by the French health care system to active users able to walk outdoors. To prove the added value of the MPKA_NEW in terms of gait security, we studied two parameters. The main criterion was flat-foot time related to the slipping risk in the stance phase. The secondary criterion was the minimum toe clearance during the swing phase, related to the tripping risk. Complementary results were also reported to quantify the clinical outcomes.

During the stance phase, a wider base of support for the foot improves stability during walking, thereby reducing the risk of falling [46]. The lack of ankle mobility in current prostheses results in a prolonged contact time on the heel before the foot is flat on the ground (particularly when descending a slope), increasing the risk of instability when loading onto the prosthetic limb [22,47]. The automatic plantar flexion of the ankle during heel-to-floor contact enabled by the MPKA_NEW allows the user to reduce this time. This quicker time to foot flattening enables a safer loading. Relative to the stance-phase duration, the significant increase in flat-foot time with the MPKA_NEW shows that this device enables the amputee user to have a maximum contact surface with the ground for a longer period, compared with the MPK_HAB. The reduction in stance-phase duration on level ground with the MPKA_NEW could suggest an improvement in walking efficiency, possibly linked to better dynamic control or an increased perception of stability by the user. This increased contact surface therefore reduces the risk of the prosthetic foot slipping off, also enabling the user to compensate more easily for slight loss of balance and to adjust the foot precisely, while further shifting the center of pressure of the foot's forces on the ground [14,30,43]. These results are in accordance with those found for a specific foot with a great ankle range of motion. Indeed, it has been demonstrated that adding ankle mobility enhances prosthetic adaptation in various situations, particularly during walking on slopes or inclined surfaces. Studies indicate that this enhancement leads to a more natural progression of the center of pressure and an overall improvement in body dynamics, including a lesser reduction in the center of mass velocity and an increase in walking speed [48]. Systems with such mobility also reduce the residual hip moment during slope walking, thereby aligning the gait patterns more closely with those of able-bodied individuals [24,49]. Additionally, the ability to stand more easily on inclined surfaces is significantly improved, especially when ankle mobility is coupled with microprocessor-controlled knee function [50].

As far as stairs are concerned, there are little data on flat-foot time in the literature. This lack of data can be attributed to the fact that no alternative strategies have been studied, as users are often compelled to adopt a compensatory technique of descending stairs by rolling over the edge of the step to compensate for the reduced ankle range of motion [17]. The use of this strategy entails that the foot is almost never flat on the step, which obviously increases the risk of slipping. In this walking situation, the MPKA_NEW knee–ankle synergy facilitates locomotion by providing ankle dorsiflexion as the knee flexes when going down stairs. It is then possible for users to put the foot on the full step, securing the stance phase. This change in strategy is highlighted by the huge effect size ($|r| = 0.83$) associated with the increase in flat-foot time when navigating stairs.

During the swing phase, the main risk is stumbling when the tip of the swinging foot comes into contact with the ground [51]. Elevation of the pelvis on the prosthetic side (hip-hiking) or premature contralateral plantar flexion in the middle of the stance phase (vaulting) are two locomotor compensations commonly used by transfemoral amputees to assist the clearance of the prosthetic step by increasing the distance to the ground [52–55]. In this study, a significant increase in ground clearance (MTC) with the MPKA_NEW was demonstrated, improving safety during the swing phase and reducing the risk of tripping. This is made possible thanks to the active ankle dorsiflexion during the swing phase with the MPKA_NEW, which occurs with the flexion of the knee. Active dorsiflexion is usually specific to advanced microprocessor-controlled ankles, but these components are typically not used by transfemoral amputees because of the important distal weight.

The MPKA_NEW provides transfemoral amputees an active dorsiflexion function while mitigating the drawbacks.

Beyond the biomechanical aspects, which could demonstrate the improvement of gait symmetry, adjustment of gait patterns, and reduction in the risk of falls [2,3,56], it is also crucial to comprehensively assess the impact of this new prosthesis on their daily lives. The evaluation of locomotor abilities and performance using PPA-LCI and PLUS-M questionnaires, as well as the 6 min walk test, suggested that transfemoral amputee participants were able to develop, with the MPKA_NEW, at least as many capabilities and performances as with their conventional prosthesis.

Furthermore, previous studies have indicated that lower-limb amputees experience a lower quality of life compared to the general population [57–59]. This aspect was examined in this study through PEQ and SF-36 questionnaires. The results showed a significant increase in PHC score and an increasing trend in MHC score with the MPKA_NEW, indicating an overall improvement in quality of life. Although a significant difference was not found in the PEQ, the scores trend towards improvement with the MPKA_NEW in the categories of safety, well-being, transfer, and ambulation, supporting the PHC score result. Moreover, a significant difference was found in this questionnaire regarding the "appearance" and "well-being" categories, reinforcing the trend obtained for MHC and emphasizing the psychological impact of the prosthetic component on the person. These improvements could be the results of previously mentioned biomechanical adaptations (FFT, MTC).

The synchronized control of the knee and ankle provided by the MPKA_NEW allows for a smoother transition from heel strike to foot flattening in the stance phase. This feature is particularly evident in scenarios such as stair descent, where the dorsiflexion of the ankle coupled with knee flexion enabled users to place their prosthetic foot fully on the step, thereby enhancing the length of time in a stable position. Furthermore, the active dorsiflexion during the swing phase contributed to a significant reduction in tripping risk by improving ground clearance. These biomechanical advantages not only improved gait efficiency but also reduced the cognitive load required for compensatory strategies, as reflected in self-reported quality-of-life metrics.

Limitations

This study has some weaknesses. Foremost, the study cohort is exclusively male subjects, which limits the generalization of the results to more diverse demographics. Furthermore, the study predominantly involves a cohort of youthful and physically active amputees. This focus aligns with the study's inclusion criteria and the demanding nature of the study protocol, which included a 6 min walk test and gait analysis under challenging conditions such as slopes and stairs. However, this selection does not necessarily reflect the adaptability of the tested MPKA_NEW to other population groups, such as older or less active individuals. Moreover, the majority of participants included in the study underwent traumatic amputations, which, in turn, could restrict the generalizability of the results for other types of amputations.

In this study, only a "technical" rehabilitation aiming at understanding the function of the prosthesis was provided to the patients. The encouraging results of this study suggest that the development of more specific and personalized rehabilitation programs with this prosthesis could be justified. Such programs might, over the long term, reduce the locomotor compensations commonly observed in these patients, potentially leading to a more natural gait pattern and further improvements in quality of life.

5. Conclusions

The MPKA_NEW significantly improved stability and safety in transfemoral amputees during both stance and swing phases. In stance, it increased contact time, reducing the risk of slipping, while in swing, it enhanced ground clearance, mitigating tripping risks. These functional improvements translated into a higher self-reported quality of life, evidenced by a significant increase in the SF-36 PHC score and positive trends in other self-reported metrics.

The functional improvements reported suggest that a reduction in gait defaults could be expected with long-term use of SYNSYS®. Future studies should prioritize larger cohorts and include individuals with more recent amputations or those undergoing their first prosthetic fitting to evaluate safety, cognitive demands, and long-term outcomes. Additionally, assessing the device's effectiveness in individuals with lower activity levels or a shorter history of prosthetic use will help determine its suitability for populations where safety is critical. Finally, a deeper investigation into the evolution of gait compensations and the associated cognitive load will provide valuable insights into the impact of SYNSYS® on users' lives, enabling further refinement of its applications.

Author Contributions: Conceptualization, J.B., I.L., X.B., M.T.-P., L.C. and H.P.; data curation, C.R. and C.D.; formal analysis, C.R., J.B. and C.D.; funding acquisition, J.B., X.B., L.C. and H.P.; investigation, C.R. and C.D.; methodology, J.B., I.L., X.B., M.T.-P., L.C. and H.P.; project administration, H.P.; resources, J.B., I.L., X.B., M.T.-P. and H.P.; software, C.R., J.B., X.B., C.D. and H.P.; supervision, J.B., X.B., L.C. and H.P.; validation, C.R., J.B., I.L., X.B., M.T.-P., C.D., L.C. and H.P.; visualization, C.R., J.B., X.B., M.T.-P., C.D., L.C. and H.P.; writing—original draft, C.R.; writing—review and editing, J.B., C.D., L.C. and H.P. All authors have read and agreed to the published version of the manuscript.

Funding: This research was funded by DGE agreement no. 192906114 RAPID—Projet AAFAPE between the French government and Proteor.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of CPP Sud-Est III (protocol code: 2018-045B; date of approval: 9 July 2018).

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

Data Availability Statement: The data supporting the conclusions of this article will be made available by the authors on request. The data are not publicly available due to privacy and ethical restrictions.

Acknowledgments: We thank all the participants, investigators, and collaborators for their cooperation in this study. We would like to thank the DGE for their financial support in all the projects involved in the end-to-end development of this innovative prosthetic system.

Conflicts of Interest: DGE had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results. C. Duraffourg and L. Calistri are employees at Proteor, and Proteor contributed to the funding.

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