

Article

Functional Performance and Patient-Reported Goal Attainment with a Novel Microprocessor-Controlled Knee in Active Transfemoral Amputees: A Multicenter Randomized Crossover Trial

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Abstract

Background/Objectives: Lower-limb amputation significantly impacts autonomy and daily functioning. Microprocessor-controlled prosthetic knees (MPKs) improve mobility, safety, and quality of life compared with non-microprocessor prosthetic knees (nMPKs). Despite general benefits, differences among MPK models remain unclear. The goal of this investigation was to evaluate functional mobility and patient-reported outcomes in active transfemoral amputees using a new MPK (PROTEOR QUATTRO) compared with existing MPKs. **Methods:** In this multicenter cross-over clinical trial, active transfemoral amputees were assessed using patient-specific functional scales (PSFS), standardized locomotor capacity tests (6MWT, 10mWT, HAI, SAI) and satisfaction and quality-of-life questionnaires (PEQ-A, SF-36, ESAT). Biomechanical data collection was performed during walking test, to examine gait symmetry indices. **Results:** The QUATTRO MPK was associated with significantly higher PSFS scores, reflecting higher self-rated ability in performing chosen daily life activities compared with patient's current prosthesis. Standardized locomotor tests revealed comparable performance between devices. Biomechanical analyses showed similar symmetry indices for QUATTRO and other MPKs. Patient-reported outcomes showed an improvement in physical health with QUATTRO, while overall satisfaction remained similar. **Conclusions:** QUATTRO improved patient-perceived ability to perform meaningful daily-life activities while maintaining comparable performance on standardized locomotor tests. These results highlight the importance of patient-centered assessments in identifying functional benefits that may guide individualized prosthetic prescriptions for active transfemoral amputees.

Keywords: transfemoral amputees; microprocessor-controlled knee; gait assessment; functional mobility; patient-reported outcomes; patient-specific goals



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1. Introduction

Lower-limb amputation is a life-changing event that affects an individual's autonomy and ability to perform activities of daily life. After an amputation, prosthetic devices help individuals reintegrate into society and maintain an independent lifestyle [1–3].

For people with above knee amputation (AKA), prosthetic knees and feet are essential for regaining mobility, ensuring stability during the stance phase and safe and efficient movements during the swing phase. Conventional microprocessor-controlled prosthetic knees (MPKs) are commonly prescribed in high-income countries, for active individuals with AKA, offering advantages such as stumble recovery and adaptability to variable walking speeds.

Evidence consistently demonstrates the superiority of MPKs over non-microprocessor knees (nMPKs) in individuals with transfemoral amputation [4]. Using MPKs has been strongly associated with a lower incidence of injurious falls, particularly among amputees with diabetes or vascular etiologies [5]. Furthermore, studies have reported significant improvements in functional mobility and user satisfaction across various clinical performance tests and patient-reported outcome measures [6–9]. MPK users also demonstrate improved motor and physical function, enhanced quality of life, and greater energy efficiency during walking, while typically experiencing lower perceived exertion than users of nMPK [10,11]. Collectively, these findings indicate that MPKs provide meaningful functional and psychosocial benefits compared with nMPK, supporting their clinical relevance in the rehabilitation of active transfemoral amputees.

Despite these overall advantages, differences in functional outcomes and user satisfaction across MPK models remain unclear [4]. A retrospective study including four MPKs (C-Leg (Ottobock, Vienna, Austria), Rheo Knee (Össur, Reykjavík, Iceland), Plié (Freedom Innovations, Irvine (CA, USA) and Orion (Blatchford Group, Basingstoke, UK)) reported no significant differences in overall functional mobility or satisfaction; however, paired comparisons indicated that the C-Leg improved quality of life compared with the Plié, whereas the Rheo Knee was associated with a higher incidence of injurious falls [12]. Comparative analyses of the Rheo Knee XC (Össur) and C-Leg further highlighted model-specific functional advantages: the Rheo Knee XC facilitated small-step swing release, whereas the C-Leg outperformed the Rheo Knee XC in tasks such as backward walking, descending stairs or slopes, and recovering from a stumble during swing extension [13]. Bellmann et al. (2010) conducted a biomechanical comparison of four conventional MPKs (C-Leg (Ottobock), Hybrid Knee (Nabtesco, Kobe, Japan), Rheo Knee (Össur), and Adaptive 2 (Blatchford Group)), revealing that the C-Leg was associated with reduced contralateral side loading during ramp and stair descent, indicating better safety and stability [14]. Differences in metabolic energy consumption between the knees were minimal, suggesting that this parameter may not be sufficient to distinguish between the devices. Stumble recovery tests further confirmed that the risk of falling was lower with the C-Leg [14]. Collectively, these results suggest that different MPK designs offer benefits that depend on the functional context, emphasizing the importance of individualized prosthetic prescription.

The Patient-Specific Functional Scale (PSFS) is a valuable outcome measure in the clinical setting. It enables individuals to identify personally important activities and rate their ability to perform them, thereby quantifying both the limitations they face and their capacity to carry out tasks that are meaningful to them. This patient-centered approach guides care on goals that standardized locomotor tests or questionnaires do not always identify. The PSFS has demonstrated validity and responsiveness in individuals with lower-limb amputation [15] and is recommended by the International Society of Prosthetics and Orthotics (ISPO) as an outcome measure to be used in clinical practice before and after

the care of a person with a lower-limb amputation [16]. Despite this, the PSFS remains underutilized for comparing MPK devices.

Given the variability in patient lifestyles and environmental demands, evaluating multiple conventional MPKs is essential to determine the device that best matches each patient's functional needs and expectations. In this context, it is important to compare the new PROTEOR QUATTRO MPK (PROTEOR USA, Tempe (AZ), USA) with existing marketed options to optimize device prescription. Therefore, this study aimed to compare functional mobility, patient-reported outcomes, and quality of life between QUATTRO and other MPKs, to support more personalized prosthetic prescriptions. We hypothesized that, due to similar technical functions, biomechanical and standardized locomotor tests and questionnaires would show minimal differences across MPKs. However, given the individualized nature of the PSFS, we hypothesized that this patient-reported outcome would reveal differences between QUATTRO and MPKs currently available on the market.

2. Materials and Methods

This multicenter prospective research adhered to the principles of the Declaration of Helsinki and Medical Device Regulation (EU) 2017/745. The study protocol was approved by a national ethics committee (CPP Nord Ouest III, ID-RCB: 2022-A01266-37) and retrospectively registered on ClinicalTrials.gov (NCT06017024). The manuscript was written according to the respective CONSORT guidelines for reporting randomized crossover trials.

2.1. Participants

Participants were included if they:

- Were ≥ 18 years old;
- Had a unilateral or bilateral, above knee amputation or knee disarticulation;
- Had a K3/K4 activity level;
- Were equipped with a MPK reimbursed by French Health System: C-leg, Rheo Knee, Orion, Hybrid Knee;
- Had a suitable socket (Socket Comfort Score ≥ 5) [17].

No limitations were enforced regarding the etiology of the amputation.

Participants were excluded if they:

- Were a protected person;
- Were a pregnant or breast-feeding woman;
- Had any other pathology affecting sensory feedback;
- Used walking aids;
- Weighed more than 136 kg;
- Had insufficient cognitive capacity to charge and take care of the prosthesis.

2.2. Experimental Design

A randomized controlled trial was conducted across five rehabilitation centers in France to compare the performance of the QUATTRO MPK with other marketed MPK solutions. Participants were assigned to one of two intervention sequences using a simple randomization procedure generated in Microsoft Excel® with the ALEA random number generator function. No block or stratified randomization was applied. The allocation sequence was generated prior to participant enrolment. This resulted in 9 participants assigned to sequence 1 (starting assessment with current MPK) and 9 participants assigned to sequence 2 (starting assessment with the QUATTRO). Each participant completed two consecutive four-week intervention periods. Due to the pragmatic multicenter design, no formal allocation concealment procedure was implemented. To minimize confounding

effects, each participant used the same socket, liner, prosthetic foot and shoes across all testing sessions.

2.3. Procedure

Written informed consent of the participant, demographic (sex, body mass, height, age), health information (amputation side, year of amputation, amputation etiology), and the prosthetic components (socket, liner, knee, foot) were collected for each enrolled participant. Participants were randomly assigned to start testing either the QUATTRO or their current MPK during the first visit (Figure 1). After confirming eligibility, each participant defined specific functional goals together with the physician investigator using the PSFS. These goals were then rated by the participant, with the same physician present at each assessment to ensure consistency across study periods.

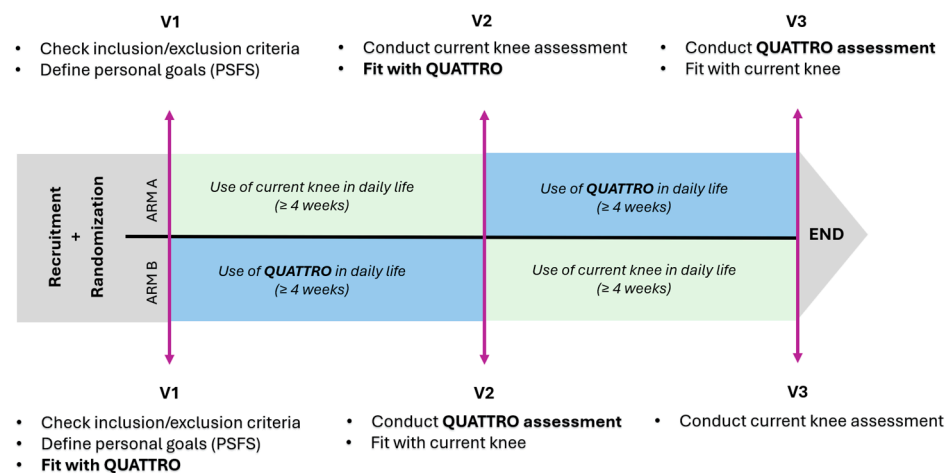


Figure 1. Clinical investigation design.

Each MPK (current and QUATTRO) was used for a minimum of four weeks in daily life before outcome measures were collected. Following this period, participants completed the full assessment session, including functional tests and questionnaires. Functional tests were administered by a physiotherapist at each study site, and responses to questionnaires were recorded using numerical rating scales.

Blinding of participants and assessors was not feasible due to the nature of the intervention, as the prosthetic knees were visibly different and required direct interaction from the user to charge and operate them. Adherence was monitored through participant self-report during follow-up visits. Participants were instructed to use the prosthetic knee as part of their usual daily activities throughout each four-week period, including work-related tasks, walking, cycling, and other routine activities. No washout or de-adaptation period was implemented between intervention periods, as the effects of prosthetic knee use were considered immediate and reversible, with no expected persistent physiological adaptation likely to influence the subsequent period.

Prosthetic knee setup and fitting procedure: The QUATTRO prosthetic knee was delivered with the factory default settings. The primary operating mode used during the study was walking mode; other modes were accessible via a dedicated mobile application at the participant's discretion.

Initial bench alignment was performed in accordance with the manufacturer's recommendations. This was followed by dynamic alignment and fine-tuning when walking on flat ground, then on varied terrain. Parameter settings were adjusted according to manufacturer recommendations and standard clinical practice.

All participants completed a conventional familiarization session including level walking, turning, stair and ramp ascent and descent, and sit-to-stand transitions, in a single formal fitting session. Additional adjustments could be requested during the study period if needed. After the QUATTRO period of use, the “current knee” settings were kept same as original to preserve comparability between periods.

To ensure consistency across sites, all prosthetists were certified clinicians trained by manufacturer certifiers, and a harmonized fitting protocol was implemented across all centers.

Adverse events were prospectively and systematically recorded throughout the study using a dedicated section in the case report form (CRF). All device-related incidents, falls, pain, or participant-reported issues were documented and reviewed at each study visit.

2.4. Outcomes Measures

The primary outcome was the score on the Patient-Specific Functional Scale (PSFS). Secondary outcomes included mobility assessment by 6 Minute Walk Test (6MWT), 10 m Walk Test (10mWT), Hill assessment Index (HAI), Stair Assessment Index (SAI) and satisfaction and Quality of Life (QoL) assessment through three questionnaires (PEQ-A, SF-36, ESAT). Gait performance was assessed by biomechanical parameters calculated with Loadsol© insoles (Software version 1.7.63), validated in individuals with transfemoral amputation [18], and goniometers at knee joint.

2.4.1. Patient-Reported Outcomes

Self-report measure of physical function was assessed using the PSFS, which allowed participants to identify two to three activities limited by their condition and to rate each one from 0 (“unable to perform”) to 10 (“no difficulty”).

Prosthesis-related quality of life was evaluated using the Prosthetic Evaluation Questionnaire and its Addendum (PEQ-A). The Prosthetic Evaluation Questionnaire (PEQ) includes nine validated subscales (utility, residual limb health, appearance, sounds, ambulation, perceived responses, social burden, frustration, and well-being) and additional individual questions [19]. The PEQ-A was created to add 14 supplementary items assessing confidence, concentration, and falls [20].

Health-related quality of life was measured using the 36-Item Short-Form Health Survey (SF-36) [21]. This questionnaire consists of 36 questions divided into 8 subscales: physical functioning, role limitations relating to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations relating to mental health, and health transition. Two component scores can be calculated from those subscales: the physical health component (PHC) and mental health component (MHC). The SF-36 has previously been used for patients with lower limb amputation [15,22].

User satisfaction was assessed using the French adaptation of the Quebec User Evaluation of Satisfaction with Assistive Technology (ESAT) [23,24], used for patients with lower limb amputation [25]. This questionnaire assesses a person’s satisfaction through 12 items, yielding three scores: Device, Services, and total ESAT. Each item was rated from 1 (not at all satisfied) to 5 (very satisfied).

2.4.2. Mobility Assessment

Walking ability was assessed using the 6-Minute Walk Test (6MWT) and 10 m Walk Test (10mWT) [26,27]. The total distance traveled and the total duration of the tests were recorded, respectively. On 10mWT, the participants were instructed as follows: “Walk as fast as you safely can, without running.” The test was performed 3 times and when necessary, recovery was given between trials [27].

To assess gait performance under standardized clinical conditions during the 6MWT, participants wore a wireless electro-goniometer (Biometrics Ltd., Newport, UK) and Loadsol© insoles (Novel GmbH, Munich, Germany) [28]. The insoles, placed in participants' shoes, measured the vertical ground reaction force (vGRF) [18] in real time and transmitted data via Bluetooth to a smartphone. Loadsol insoles have previously been validated on individuals with lower-limb amputation, demonstrating acceptable validity and reliability for quantifying gait asymmetry [18]. Prior to data collection, insoles were calibrated according to the manufacturer's instructions, by alternately loading each limb with full body weight while avoiding upper-limb support.

A single electro-goniometer (M110, Biometrics Ltd., UK) positioned on each leg, recorded knee angles in the sagittal plane at 100 Hz [29]. Calibration was performed with the participant standing with both legs fully extended (0° reference).

To reduce potential inter-operator variability, a single trained operator performed all sensor placement procedures for each participant across both experimental sessions.

Ramp and stair performances were assessed using the Hill Assessment Index (HAI) and Stair Assessment Index (SAI) [30]. The HAI is scored on an ordinal scale from 0 to 11. The HAI indicates that a perfect score of 11 is an even step length without an assistive device visually determined by the examiner. The SAI is scored on an ordinal scale from 0 to 13. The SAI indicates that a perfect score of 13 is a step-over-step pattern without rail and assistive device visually determined by the examiner.

2.5. Sample Size Determination

A study conducted in 11 transfemoral subjects [31] evaluated the PSFS and reported a post-rehabilitation standard deviation $\sigma = 2.8$ points. In addition, another study including 42 lower-limb amputees [15] reported the MDC₉₀ for the PSFS, based on five patient-specific functional goals, and the MDC₉₀ values varied across goals, with a minimum value of 3.1 points. This most conservative threshold was selected for the present study, as it ensures that the sample size is large enough to detect even the smallest detectable change, beyond the measurement error.

The required sample size was calculated using the formula:

$$n = \frac{2 * \sigma^2}{MDC_{90}^2} * (z_{1-\beta} + z_{1-\alpha})^2$$

with a type I error rate set at $\alpha = 5\%$ (two-sided) and a type II error rate set at $\beta = 10\%$ (corresponding to 90% statistical power) [32]. Based on these assumptions, the required sample size is 14 participants.

Although the present study used a crossover design, this formula is based on an independent-groups assumption and was intentionally chosen as a conservative approach. At the time of study design, reliable estimates of within-subject variance and treatment-period correlation were not available for this population and device. Therefore, this simplified approach was used to avoid underestimation of the required sample size.

Considering the projected enrolment capacity for the five investigation sites (each expected to easily recruit 2 to 3 participants), while also accounting for potential participant withdrawals after inclusion, the target sample size was set to 18 participants.

2.6. Data Analysis

Walking speeds (m/s) were calculated by dividing the distance covered in the 10mWT by the time to travel that distance. The average value from the 3 trials was used [27]. For the 6MWT, only the distance is reported.

Data from insoles and goniometers (ASCII format) were processed using MATLAB®. Ground reaction force data were analyzed following the method described by Cutti et al. [33] to compute temporal and loading symmetry. Heel-strike and toe-off were detected when vertical force exceeded or fell below 2% of body weight, respectively. Step and stance durations were calculated for each stride (Figure 1). Symmetry indices were computed as ratios between the sound and prosthetic limbs (e.g., $\text{Step_symmetry} = \text{Step}_{\text{sound}} / \text{Step}_{\text{prosthetic}}$; $\text{Stance_symmetry} = \text{Stance}_{\text{sound}} / \text{Stance}_{\text{prosthetic}}$).

The impulse of the vGRF (Figure 2) over the stance phase was computed ($\text{Impulse_symmetry} = \text{Impulse}_{\text{sound}} / \text{Impulse}_{\text{prosthetic}}$). Then the presence of the first and second peaks of vGRF was verified (0–40% and 60–100% of the gait cycle, respectively) (Figure 1), and first peak symmetry indices were calculated ($\text{Peak1_symmetry}_{\text{peak1}} = \text{Peak1}_{\text{sound}} / \text{Peak1}_{\text{prosthetic}}$).

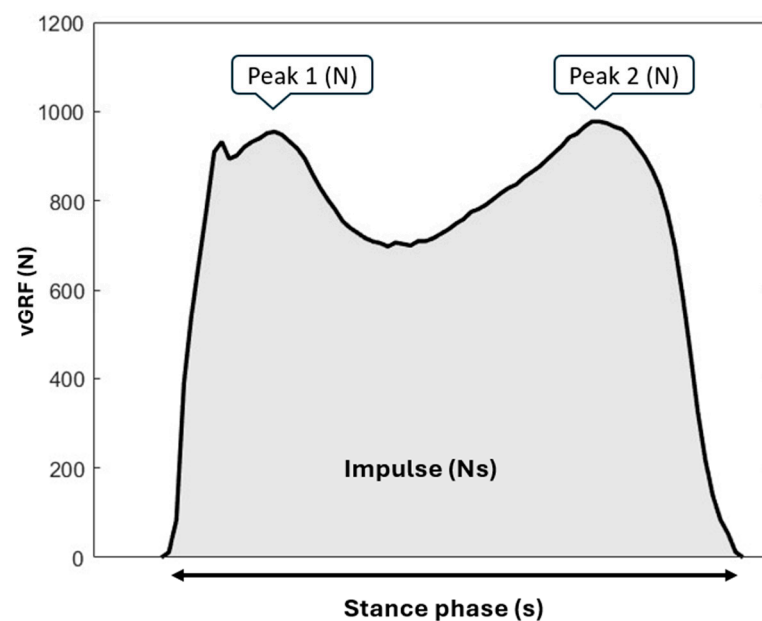


Figure 2. Example of vGRF curve with specific parameters. Peak 1: magnitude of the first peak force (N). Peak 2: magnitude of the second peak force (N). Impulse: force time integral (Ns). Stance phase: time from heel strike to toe off (s).

For goniometer data, gait cycles were segmented using flexion angle thresholds (half of maximal flexion or 35°). The onset of a positive angular velocity marked the beginning of each new cycle. Peak knee flexion was extracted for each cycle, and flexion symmetry was computed as the ratio of the sound limb to the prosthetic limbs ($\text{Angle_symmetry} = \text{Angle}_{\text{sound}} / \text{Angle}_{\text{prosthetic}}$).

For all symmetry indices, a value of 1 represents perfect symmetry.

To process questionnaire data, the following methods were used.

- PSFS: Mean score of specific functional objectives were calculated for each participant. The complete set of personal objectives was also categorized into: (1) activities or daily situation related to standardized locomotor tests and previous tests used in literature to compare MPKs [13,30,34] and (2) activities or daily situation non-related to standardized locomotor tests or previous tests used in literature to compare MPKs, but are frequently used by some patients. Scores were then compared with the corresponding minimal detectable change (MDC) values to identify clinically meaningful changes: MDC = 3.3 for Item 1, MDC = 4.2 for Item 2, and MDC = 3.1 for Item 3 [15].

- SF-36: Scoring was performed using the RAND method [35]. For each scale, z-scores were calculated, from which T-scores were derived to obtain physical health and mental health components [21].
- PEQ-A: Responses were classified according to the validated PEQ scoring rules. Mean subscale scores were computed; addendum items were analyzed separately. Items were either (i) valid responses, or (ii) not applicable when the symptom or activity was not present for the participant.
- ESAT: Mean Device, Service, and Total scores were derived from valid responses.

2.7. Statistical Analysis

The PSFS was the pre-specified primary outcome and the only confirmatory endpoint of this study. Analyses of individual PSFS items were considered exploratory, as the activities varied from participant to participants in terms of content and functional relevance. As pre-specified in the trial registration, we hypothesized that PSFS scores would be higher with QUATTRO compared with the participant's current MPK. The primary analysis was based on the participant-level paired difference between the two conditions and was assessed using a paired *t*-test or Wilcoxon signed-rank test, depending on the distribution of the paired differences.

As a sensitivity analysis, to account for the crossover design and to examine potential treatment, period, and sequence effects, we performed a repeated-measures analysis including treatment (MPK), period, and sequence as fixed effects, with participant included as a repeated factor.

The secondary outcomes of this study were focused on patient mobility, satisfaction and QoL using quantitative data. Our hypothesis was that mobility, satisfaction and QoL would not be affected by the type of MPK. These secondary analyses were considered exploratory and were not adjusted for multiplicity.

Normality of the paired differences between conditions was assessed using the Shapiro–Wilk test. When normality was confirmed ($p > 0.05$), paired *t*-tests were performed; otherwise, Wilcoxon signed-rank tests were used. Effect sizes (Cohen's *r* for non-parametric data and Cohen's *d* for parametric data) were used to express the extent of observed differences. To aid interpretation of *r*, values of 0.5, 0.3, and 0.1 were considered to represent large, medium, and small effect sizes, respectively. Similarly, for *d*, values of 0.8, 0.5, and 0.2 were considered to represent large, medium, and small effect sizes, respectively [36]. These classifications were used to describe statistical magnitude only and were not considered indicators of clinical significance. Clinical relevance was interpreted separately using established outcome-specific thresholds, such as the MDC for the PSFS. For participants with at least one available assessment, missing follow-up data were handled using a last observation carried forward analysis [37]. Participants who withdrew before the first assessment were excluded from the analysis, resulting in a complete-case analysis. All statistical analyses were conducted using MATLAB® (MATLAB R2024b). For each test, the level of statistical significance was established at $p < 0.05$ on a two-tailed test.

3. Results

Participant recruitment occurred between June 2023 and December 2024. Eighteen participants were enrolled in this study. One participant withdrew before the first data collection. One adverse event was reported during the study. This event involved a temporary device malfunction (insufficient extension return), resulting in a temporary loss of confidence in the prosthetic knee without fall or injury. The issue was resolved after recalibration of the device settings. No serious adverse events were reported.

Seventeen participants (age: 49.6 ± 10.8 years; body mass: 77.4 ± 16.9 kg; height: 176.3 ± 8.2 cm) completed the study, with 9 allocated to sequence 1 (starting with current knee) and 8 to sequence 2 (starting with QUATTRO) (Figure 3).

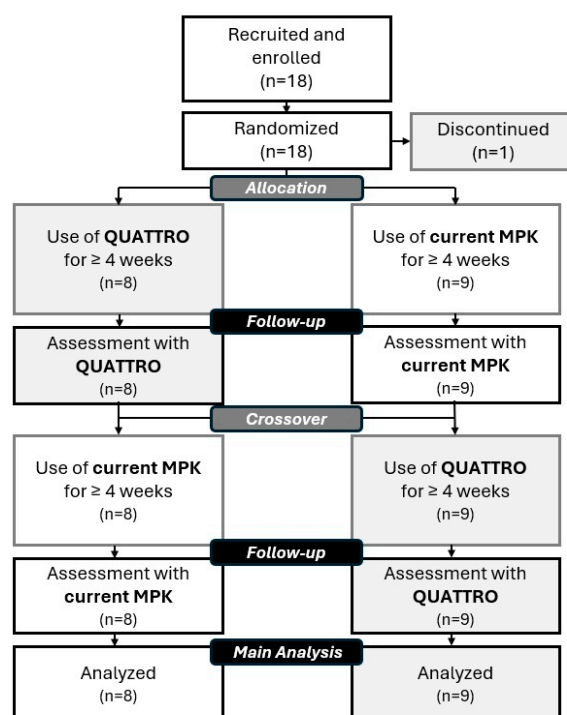


Figure 3. Consolidated Standards of Reporting Trials (CONSORT) diagram.

Demographic characteristics are detailed in Table 1. The primary etiologies of amputation were traumatic in 12 participants (70.6%), vascular in 2 (11.8%), cancer-related in 2 (11.8%), and infection-related in 1 (5.9%). The duration of the period of use was 33.2 ± 6.0 days with the current MPK and 32.6 ± 5.1 days with QUATTRO. The current prosthetic knees used were C-Leg (Ottobock) ($n = 11$), Rheo Knee (Össur) ($n = 5$), and Orion (Blatchford Group) ($n = 1$). Most participants were fitted with an energy-storage-and-return (ESAR) foot.

Table 1. Participants' characteristics.

Subject Number	Gender	Height (m)	Mass (kg)	Age (Years)	Time Since Amputation (Years)	Etiology	RL Side (Left/Right)	Current MPK	Prosthetic Foot
1	M	1.88	83	38	21	cancer	L	Rheo Knee	Össur, Reflex rotate
2	M	1.79	120	35	15	traumatic	L	C-leg	Ottobock, Taleo
3	M	1.78	72	44	2	vascular	L	Orion	Proteor, Dynatrek
4	M	1.85	82	47	24	traumatic	R	C-leg	Proteor, Shockwave
5	M	1.82	89	30	2	traumatic	L	Rheo Knee	Proteor, Shockwave
6	M	1.80	75	69	51	traumatic	R	C-leg	Proteor, Agilix
7	M	1.78	85	46	10	traumatic	L	C-leg	Össur, Proflex XC
8	M	1.77	70	62	36	traumatic	L	C-leg	Proteor, Agilix
9	M	1.70	78	58	41	traumatic	R	Rheo Knee	Proteor, Rush Hipro
10	M	1.74	76	53	24	traumatic	L	C-leg	Össur, Proflex XC
11	M	1.66	64	56	13	traumatic	L	C-leg	Proteor, Dynatrek
12	M	1.82	75	59	5	infection	L	Rheo Knee	Proteor, Kinterra
13	M	1.75	100	51	24	traumatic	L	Rheo Knee	Össur, Proflex XC Torsion
14	F	1.53	51	61	1	traumatic	R	C-leg	Proteor, Pacifica LP
15	F	1.70	50	42	35	cancer	L	C-leg	Ottobock, Taleo
16	M	1.80	83	38	1	vascular	R	C-leg	Proteor, Shockwave
17	M	1.80	62	54	1	traumatic	L	C-leg	Proteor, Agilix

3.1. Patient-Reported Outcomes

3.1.1. Patient-Reported Goals

Among the 17 participants who completed the study, 16 evaluated three functional goals, while one participant evaluated two goals, for a total of 50 assessed goals. The intra-individual general PSFS score shows that 14 participants (82.3%) increased their score with the QUATTRO compared with their current MPK, while one decreased their score (5.9%) and two participants' score did not change between both sessions (11.8%). Exploratory analysis on MDC showed that 5 of 17 participants exceeded the MDC threshold (3.3 points) for item 1; 2 of 17 participants exceeded the MDC threshold (4.2 points) for item 2; and 7 of 16 participants exceeded the MDC threshold (3.1 points) for item 3 [15].

Overall PSFS scores were higher with QUATTRO than with the current MPK ($p = 1.83 \times 10^{-4}$, $r = 1.09$) (Figure 4a). The repeated-measure analysis of variance performed on the PSFS score also showed significant differences between MPKs ($p = 0.016$) and ruled out the presence of a randomization group effect ($p = 0.63$), as well as the interaction effect ($p = 0.34$) (Figure 4b).

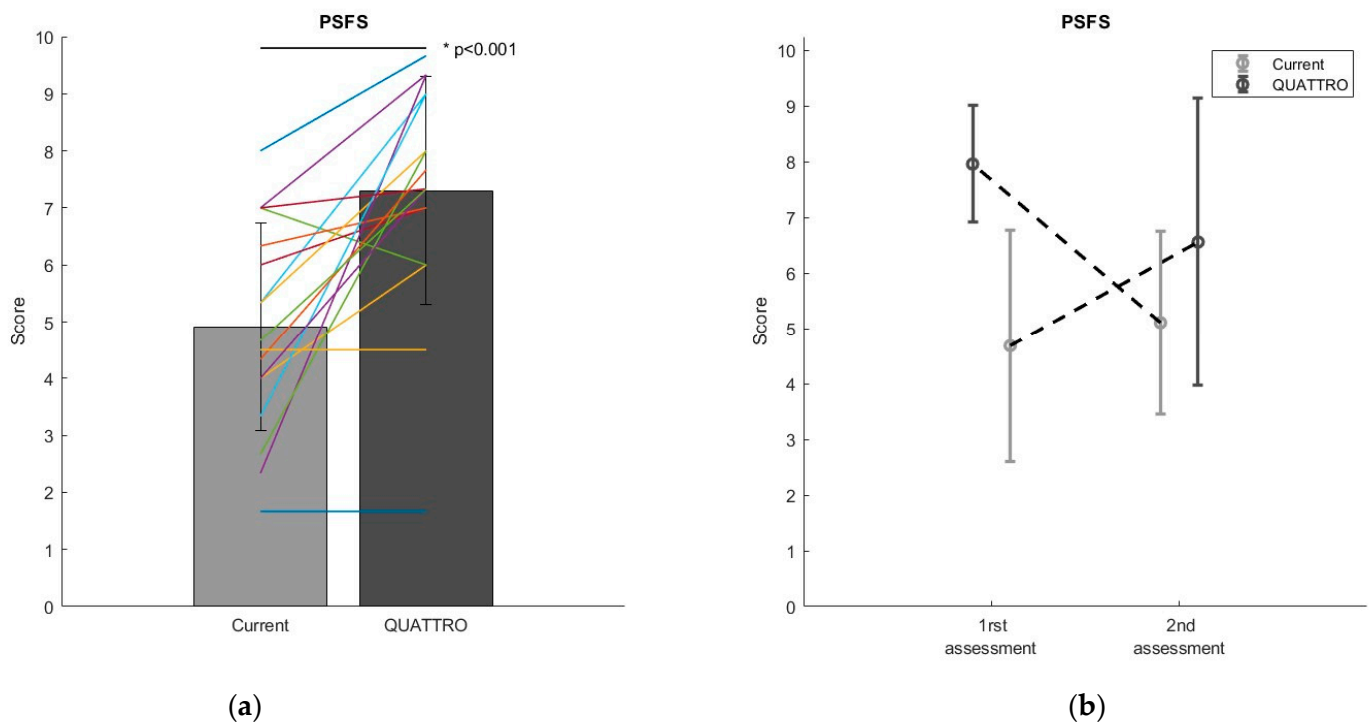


Figure 4. (a) PSFS score obtained with Current MPK and QUATTRO—individual (colored lines) and average/STD (grey columns/black lines) scores. (b) PSFS score $\times$ order interaction visualization (dashed lines); average/STD (circle/solid lines) for Current MPK (grey) vs QUATTRO (black). * indicates here a statistical significance of $p < 0.001$.

On daily activities assimilated to standardized locomotor tests and previous tests used in literature, PSFS scores are higher with QUATTRO than current MPKs (Figure 5). In addition, relating to everyday activities or situations that are unrelated to standardized locomotor tests but are likely to be frequently used in daily life, PSFS scores are higher with QUATTRO than current MPKs (Figure 6).

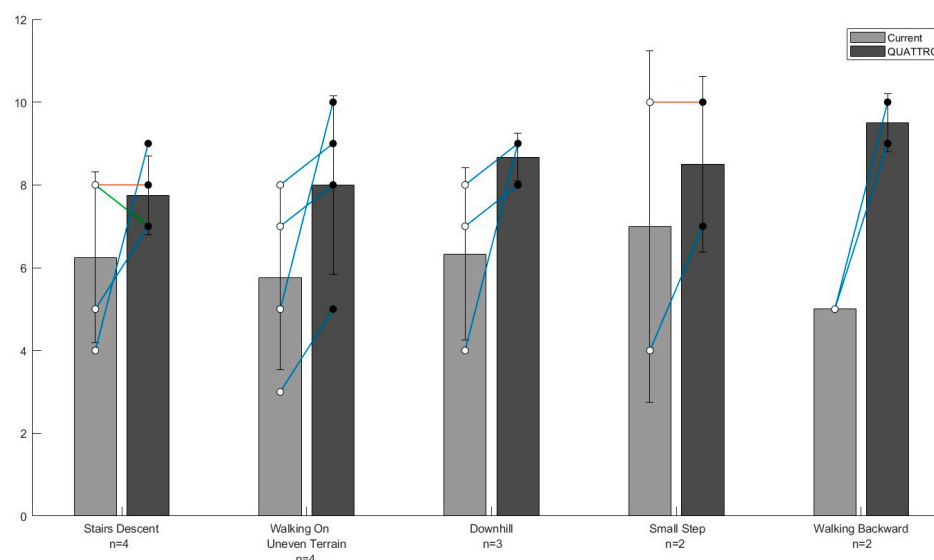


Figure 5. Daily activities from the PSFS reflecting standardized locomotor tests and previously reported tasks used to compare MPKs. *n* represents the number of participants who selected each type of activity. Dots connected by lines represent individual participant scores. Blue denotes improved scores and green denotes lower scores using QUATTRO, and orange denotes participants whose scores remained unchanged between the two prostheses.

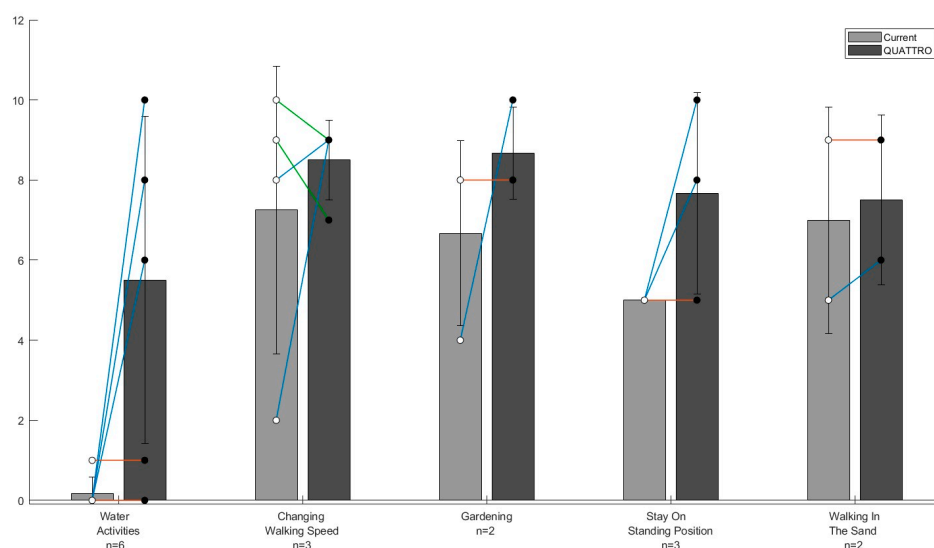


Figure 6. Daily activities from the PSFS that do not reflect standardized locomotor tests and previously reported tasks used to compare MPKs but frequently used by some patients. *n* represents the number of participants who selected each activity. On water activities two participants had the same scores (Current MPK = 0; QUATTRO = 8). Dots connected by lines represent individual participant scores. Blue denotes improved scores and green denotes lower scores using QUATTRO, and orange denotes participants whose scores remained unchanged between the two prostheses.

3.1.2. Satisfaction and QoL Outcomes

For exploratory secondary outcomes, results from PEQ-A indicated that among the validated subscales, QUATTRO was associated with a higher PEQ appearance and PEQ residual limb health subscales, compared with the current MPK ($p = 0.02$, 95% CI: 0.72 to 16.88, $d = 0.56$ and $p = 0.005$, 95% CI: -2.35 to 13.98 , $d = 0.7$, respectively) (Table 2). Regarding the individual questions, transfer ability (car, chair, toilet, and shower) was numerically higher with QUATTRO compared with the current MPK ($p = 0.03$, 95% CI: 0.80 to 16.46, $r = 0.48$) (Table 2). The intensity and bothersome of phantom limb sensations

were lower with the QUATTRO than with participants' current MPK ($p = 0.002$, 95% CI: 7.83 to 28.72, $r = 0.36$ and $p = 0.009$, 95% CI: 2.10 to 17.45, $d = 0.98$, respectively) (Table 2). In addition, the intensity of residual limb pain was lower with QUATTRO than with their current MPK ($p = 0.04$, 95% CI: -1.86 to 37.26, $d = 0.65$). Furthermore, a reduction in the number of uncontrolled falls with QUATTRO was observed ($p = 0.03$, 95% CI: -1.94 to -0.06 , $r = 0.81$), as well as a reduction in the fear of falling frequency ($p = 0.049$, 95% CI: -0.71 to 13.28, $r = 0.51$). The other questions did not show any significant differences between QUATTRO and the current MPK.

Table 2. Outcome measures. For physical performance tests, higher scores indicate better performance (6MWT, 10mWT, HAI, SAI). For symmetry indices, values closer to 1 denote greater symmetry. For self-reported measures, higher scores indicate better perceived outcomes. Boldface scores indicate statistically significant differences ($p < 0.05$). For the normality test (Shapiro–Wilk test, Swtest), a value of 0 indicates a normal distribution, whereas a value of 1 indicates a non-normal distribution.

Outcome Measures	Score Current MPK	Score QUATTRO	Treatment Difference	Paired Observation	IC95%	Swtest	<i>p</i> -Value	Effect Size
Self-reported outcomes								
Score PSFS								
Item 1	4.53 ± 3.54	7.18 ± 3.05	2.64 ± 3.79	17	[0.70; 4.6]	0	0.005	0.70
Item 2	6.29 ± 2.37	7.88 ± 1.22	1.59 ± 2.18	17	[0.47; 2.71]	1	0.008	0.82
Item 3	3.88 ± 2.68	7 ± 2.94	3.13 ± 2.78	16	[1.64; 4.61]	0	0.0002	1.13
Total	4.91 ± 1.82	7.3 ± 2.0	2.39 ± 2.20	17	[1.27; 3.52]	0	1.83 × 10⁻⁴	1.09
Score validated PEQ subscales								
Ambulation	79.9 ± 8.69	83.8 ± 10.0	3.91 ± 0.16	17	[−2.04; 9.85]	0	0.08	0.37
Appearance	75.0 ± 12.6	83.8 ± 14.4	8.8 ± 0.16	17	[0.72; 16.88]	0	0.02	0.56
Frustration	86.6 ± 13.9	86.3 ± 15.9	−0.29 ± 18.1	17	[−9.6; 9.03]	0	0.26	0.16
Perceived Response	78.1 ± 9.8	85.0 ± 12.2	6.88 ± 9.8	17	[1.82; 11.94]	1	0.10	0.38
Residual Limb Health	79.5 ± 12.7	85.3 ± 12.7	5.81 ± 15.9	17	[−2.35; 13.98]	0	0.005	0.7
Social Burden	86.2 ± 20.2	88.1 ± 16.5	1.91 ± 11.7	17	[−4.13; 7.95]	0	0.40	0.07
Sounds	89.7 ± 11.7	90.2 ± 12.7	0.5 ± 8.2	16	[−3.80; 4.90]	1	0.39	0.09
Utility	91.2 ± 11.7	93.8 ± 11.6	2.59 ± 7.63	17	[−1.33; 6.51]	0	0.09	0.34
Well-Being	82.3 ± 19.5	87.0 ± 15.5	4.66 ± 22.0	16	[−7.17; 16.49]	0	0.21	0.21
Score of additional individual questions PEQ								
Satisfaction	81.6 ± 13.1	87.0 ± 10.2	5.42 ± 0.18	17	[−3.82; 14.67]	0	0.12	0.30
Transfer	78.9 ± 12.1	87.6 ± 12.2	8.63 ± 0.15	17	[0.80; 16.46]	1	0.03	0.48
Phantom Limb Sensations Intensity	68.2 ± 21.5	82.5 ± 13.1	18.27 ± 13.59	9	[7.83; 28.72]	1	0.002	0.36
Phantom Limb Sensations Bothersome	77.1 ± 18.3	80.3 ± 18.8	9.78 ± 9.98	9	[2.10; 17.45]	0	0.009	0.98
Residual Limb Pain Intensity	59.3 ± 26.3	74.2 ± 30.0	0.18 ± 0.27	10	[−1.86; 37.26]	0	0.04	0.65
Residual Limb Pain Bothersome	61.9 ± 26.2	67.6 ± 35.9	5.45 ± 0.22	11	[−9.34; 20.24]	0	0.22	0.25
Back Pain Intensity	69.8 ± 26.4	70.2 ± 28.3	7.13 ± 0.34	8	[−21.23; 35.48]	0	0.29	0.21
Back Pain Bothersome	77 ± 17.8	74.2 ± 28.3	−2.67 ± 0.18	9	[−16.79; 11.45]	0	0.66	0.15
Score of PEQ-A, additional questions								
Confidence	87.5 ± 13.9	91.6 ± 12.1	4.10 ± 0.14	17	[−3.27; 11.47]	0	0.13	0.29
Attention load	74.9 ± 26.9	79.8 ± 25.2	5.14 ± 0.18	14	[−5.27; 15.55]	0	0.15	0.29
Stumbled Frequency	68.2 ± 30.4	74.3 ± 27.2	6.09 ± 0.29	13	[−11.70; 23.87]	1	0.48	0.38
Stumbled Count	3.5 ± 4.3	4.5 ± 9.6	1.13 ± 9.08	16	[−3.72; 5.97]	1	0.54	0.18
Uncontrolled Fall Frequency	68.1 ± 37.0	81.1 ± 31.2	0.15 ± 0.25	9	[−4.47; 33.80]	1	0.05	0.53
Uncontrolled Fall Count	1.5 ± 2.6	0.5 ± 1.2	−1 ± 1.84	17	[−1.94; −0.06]	1	0.03	0.81
Semi controlled Fall Frequency	77.2 ± 32.3	81.3 ± 28.7	8.8 ± 0.18	10	[−3.88; 21.48]	1	0.14	0.46
Semi controlled Fall Count	1.7 ± 4.9	1.5 ± 2.4	−0.12 ± 3.69	17	[−2.01; 1.78]	1	0.33	0.16
Dual Task Difficulty	85.5 ± 18.1	89.8 ± 14.0	4.8 ± 0.14	17	[−2.97; 11.53]	1	0.22	0.24
Fear of Falling Frequency	85.8 ± 17.4	92.1 ± 15.3	6.28 ± 0.14	17	[−0.71; 13.28]	1	0.049	0.51
Contrariety After Falling	73.5 ± 37.9	70.9 ± 38.3	2.17 ± 0.32	6	[−30.94; 35.28]	0	0.44	0.07
Embarrassed After Falling	72.8 ± 36.8	77.25 ± 36.3	6.71 ± 0.19	7	[−10.71; 24.14]	1	0.34	0.74
Fear of Falling With Prosthesis	85.9 ± 17.5	89.5 ± 15.8	3.58 ± 0.14	17	[−3.54; 10.71]	1	0.13	0.37
Difficulty Focus on Something Else	86.8 ± 14.6	87.8 ± 14.9	0.99 ± 0.13	17	[−5.71; 7.69]	1	0.77	0.22
Score SF-36								
Mental health component	56.47 ± 6.08	57.41 ± 3.84	0.94 ± 7.17	17	[−2.75; 4.63]	1	0.43	0.05
Physical health component	51.88 ± 5.27	55.35 ± 5.21	3.47 ± 4.2	17	[1.31; 5.63]	0	0.003	0.83
Score ESAT subscales								
Technology	4.27 ± 0.30	4.51 ± 0.41	0.24 ± 0.5	17	[−0.01; 0.5]	0	0.06	0.49
Service	4.57 ± 0.5	4.57 ± 0.48	0.0 ± 0.63	17	[−0.32; 0.32]	0	1	0
Total	4.37 ± 0.25	4.53 ± 0.41	0.16 ± 0.47	17	[−0.08; 0.41]	0	0.17	0.35
Mobility assessment								
Step_symmetry	0.91 ± 0.12	0.88 ± 0.15	−0.03 ± 0.10	17	[−0.08; 0.02]	0	0.88	0.29
Stance_symmetry	1.11 ± 0.1	1.11 ± 0.1	$5.9 \times 10^{-4} \pm 4.2 \times 10^{-2}$	17	[−0.02; 0.02]	0	0.48	0.01
Impulse_symmetry	1.34 ± 0.24	1.33 ± 0.24	$-7.1 \times 10^{-3} \pm 8.4 \times 10^{-2}$	17	[−0.05; 0.04]	0	0.63	0.08
Peak1_symmetry	1.19 ± 0.24	1.17 ± 0.21	−0.02 ± 0.14	17	[−0.09; 0.06]	0	0.70	0.13
Angle_symmetry	1.06 ± 0.21	1.05 ± 0.17	−0.01 ± 0.16	16	[−0.1; 0.07]	0	0.64	0.09
6MWT (m)	495.9 ± 74.3	508.2 ± 87.2	12.29 ± 54.17	17	[−15.56; 40.15]	0	0.36	0.23
10mWT (m.s ⁻¹)	1.82 ± 0.24	1.84 ± 0.28	0.018 ± 0.13	17	[−0.05; 0.09]	0	0.60	0.13
HAI Score	10.1 ± 1.5	10 ± 1.8	−0.059 ± 0.75	17	[−0.44; 0.33]	1	1	0.10
SAI Score	11 ± 2.2	11.4 ± 2.4	0.35 ± 0.79	17	[−0.05; 0.76]	1	0.25	0.93

SF-36 results indicated a higher score in the physical health component with QUATTRO compared with the current MPK ($p = 0.003$, 95% CI: 1.31 to 5.63, $d = 0.83$). Results from the ESAT questionnaire showed a trend towards increased satisfaction with prosthetic technology when using QUATTRO ($p = 0.06$, 95% CI: -0.01 to -0.5 , $d = 0.49$) (Table 2).

3.2. Mobility Assessment

Based on the Loadsol© insole data collected during the 6MWT, similar results were observed between QUATTRO and the current MPK for symmetry parameters (Table 2). Likewise, knee angle symmetry at peak flexion, derived from the electro-goniometer data during the 6MWT, showed no significant difference between the two assessments.

On group analysis, the total distance covered during the 6MWT and the walking speed calculated during the 10mWT did not significantly differ between QUATTRO and current MPKs (Table 2). Similarly, the Stair Assessment Index (SAI) showed no significant effect of QUATTRO on stair descent ability, and the Hill Assessment Index (HAI) revealed no effect on ramp descent performance.

4. Discussion

This multicenter study evaluated the biomechanical and clinical characteristics of a new MPK, QUATTRO, against other MPKs, and its impact on locomotor abilities and patient-reported outcomes in active transfemoral amputees.

4.1. Standardized Questionnaire and Patient-Centered Evaluation

Assessment of personal goals showed that the QUATTRO was associated with higher self-rated ability for the patient-specific daily-life activities selected by participants, with a large effect size indicating a substantial average difference between the conditions. Across PSFS items, participants reported less difficulty performing their selected personal goals with QUATTRO compared with their current MPK, as reflected by higher PSFS scores. This reduction in perceived difficulty suggests that QUATTRO may facilitate the performance of everyday activities and improve functional performance in daily life [38]. Overall, 14 of 50 individual participant-selected goals exceeded their MDC thresholds, indicating changes beyond expected measurement error [39].

While rehabilitation can influence PSFS outcomes [40], participants in this study had already completed a rehabilitation program and did not receive any specific rehabilitation with QUATTRO. All fittings, including device calibration and device-specific instruction, were performed during a single visit under multidisciplinary supervision before the participant returned home. Therefore, the observed differences likely reflect the characteristics of QUATTRO rather than rehabilitation effects.

Consistent with these functional improvements, the QUATTRO also showed higher patient-reported QoL scores compared with other MPK models. Both PEQ-A and SF-36 assessments indicated improvements in physical health domains, including higher Residual Limb Health and higher Physical Health Component scores. While previous studies generally report limited differences in QoL among MPK models [12,41], the present findings demonstrate measurable improvements with QUATTRO. This suggests that its functional advantages could be associated with enhanced patient-perceived QoL as they may support achieving goals related to daily-life activities.

In contrast, subjective evaluation using the PEQ-A and ESAT did not reveal an overall improvement in prosthesis satisfaction in this study, which is consistent with previous literature reporting minimal differences in satisfaction among the various MPK models [41]. While satisfaction scores remained broadly comparable, the improvements in QoL indicate that our initial hypothesis—that satisfaction and QoL would not differ among MPKs—was

partially supported. Satisfaction was consistent with the hypothesis, whereas QoL showed measurable differences favoring the QUATTRO MPK solution.

4.2. Standardized Locomotor Evaluation and Real-Life Sensitivity

Locomotor assessments using the 6MWT and 10mWT indicated comparable functional mobility performances between QUATTRO and participants' current MPK. Biomechanical analysis during the 6MWT showed similar knee angles and symmetry indices across devices. These findings are consistent with previous literature reporting comparable knee flexion angles between prosthetic or sound limbs [13] and no significant differences in self-reported functional mobility (PLUS-M) when comparing MPKs [12]. These results suggest that QUATTRO provides functions similar to those of other MPKs when considering standardized locomotor tests on level ground. Although standardized locomotor tests are useful for distinguishing between different mobility levels [38] and between different knee categories (nMPK and MPK) [42,43], their ability to discriminate within highly active populations and among users of similar MPKs appears limited. It therefore appears necessary to rely on measures that more closely reflect everyday activities in order to highlight the specific benefits of these high-performance devices. The differences observed in scores related to daily activities support this conclusion: walking on uneven terrain, taking small steps, or walking backward are actions made easier by QUATTRO. Evaluating activities specific to daily life thus provides a better understanding of one prosthetic solution's advantages over another.

Stair descent and slope tests also revealed no significant differences. These results are consistent with previous studies that found similar results on HAI and SAI between different types of MPKs [44,45]. These findings suggest that the QUATTRO provides no different functional performance under standardized locomotor tests. However, participants' self-assessment of their personal goals in real downhill situations shows a clear improvement in achieving downhill walking with QUATTRO. This discrepancy highlights that functional progress is better perceived when evaluation takes place in contexts that reflect everyday life and are directly related to users' expectations. Downhill walking, being a less standardized activity influenced by environmental factors (i.e., slope, surface, and context), appears particularly sensitive to the benefits of QUATTRO management. It also addresses aspects such as confidence, perceived safety, and adaptability, which are often better captured through patient-centered measures. Thus, standardized locomotor tests may be insufficiently sensitive to detect subtle differences between advanced prosthetic components, often requiring larger sample sizes to reveal significant effects. Moreover, their ability to assess certain activities commonly performed by patients and useful in daily life is limited. In contrast, patient-specific functional scales, which assess goals and activities most relevant to each individual, appear particularly well suited to capturing meaningful changes at the individual level [46,47] and thus support a more personalized approach to prosthetic prescription. Consistent with this perspective, 59.6% of the activities reported by participants could not be assessed using standardized locomotor tests or questionnaires (i.e., gardening, walking on sand, crossing a river, fishing, etc).

5. Limitations and Future Directions

The sample size was relatively small ($n = 17$), reflecting the limited availability of transfemoral amputees meeting inclusion criteria; however, this is consistent with sample sizes in comparable prosthetic research [13,34,41]. A larger cohort would also allow for paired comparison between each MPK, which was not feasible in this study, and would elucidate the differences among various MPKs. Among the seventeen participants included, only two were women, representing 12% of the study population. In contrast, women

account for approximately 35% of the amputee population [48]. This imbalance suggests that more gender-balanced samples should be considered in future research.

In addition, although MPKs have demonstrated particular benefits in individuals with vascular or diabetic etiologies [5], this subgroup was underrepresented in our cohort. Therefore, the effectiveness of the QUATTRO in this specific population cannot be fully determined based on the present findings. Nevertheless, the distribution of etiologies in our study is consistent with proportions commonly reported in the literature [13,49,50], supporting the generalizability of the results within a typical MPK user population. Also, longer follow-up studies with larger cohorts are warranted to assess durability of perceived improvements and long-term adaptation to the QUATTRO prosthetic solution.

6. Conclusions

In summary, the PROTEOR QUATTRO MPK demonstrated significant advantages in user-perceived function, especially in activities reflecting real-life conditions. No statistically significant between-device differences were detected in the measured locomotor and gait-related outcomes in this study. These findings suggest that patient-defined goals and perceived QoL may capture inter-device differences that are not reflected in the standardized locomotor tests and kinematic parameters. Beyond functional outcomes, improvements in quality of life may also reflect broader psychological benefits, including increased confidence in ambulation, reduced fear of falling, and greater perceived autonomy.

However, it remains essential to monitor biomechanical parameters to ensure that emphasizing subjective outcomes does not compromise gait performance or safety. A patient-centered approach combining clinical, biomechanical, and subjective data is essential to fully capture the benefits of new MPK technologies and to guide prescription practices, ensuring optimal functional performance and long-term satisfaction.

Overall, this study provides a novel integrated perspective on MPK evaluation by combining biomechanical, functional, and patient-reported outcomes in both standardized and ecological conditions.

Supplementary Materials: The following supporting information can be downloaded at <https://www.mdpi.com/article/10.3390/prosthesis8080082/s1>. Individual scores obtained at the PSFS, PEQ subscales, PEQ additional questions, SF-36 (MHC and PHC), ESAT subscales and Mobility assessment.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the national ethics committee CPP Nord Ouest III, (protocol code ID RCB: 2022-A01266-37 and date of approval 14 April 2023). The first participant was enrolled on 7 June 2023; The study was retrospectively registered on ClinicalTrials.gov on 19 July 2023 (NCT06017024). Neither Regulation (EU) 2017/745 nor the ANSM guidance for clinical investigations of medical devices requires prospective registration in ClinicalTrials.gov (or another public trial registry) as a legal prerequisite before enrolment of the first participant. For this reason, our statement that the registration date was later than the study start date because prior registration was not legally required remains accurate.

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

Data Availability Statement: The original contributions presented in this study are included in the Supplementary Material. Further inquiries can be directed to the corresponding authors.

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Conflicts of Interest: At the time of the study V.S., C.D. and L.C. were employed by the sponsor; L.G. became employed by sponsor after completion of the study and at the time of manuscript submission. To minimize potential sponsor influence, questionnaire data were collected digitally using standardized procedures, functional performance tests were assessed by physiotherapists from the rehabilitation centers, and PSFS evaluations were conducted by the physician investigators. Sensor-based data acquisition and analysis, as well as statistical analyses, were conducted according to predefined procedures. Other authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

10mWT	10 m Walk Test
6MWT	6 min Walk Test
AKA	Above Knee Amputation
ISPO	International Society of Prosthetics and Orthotics
MDC	Minimal Detectable Change
MPK	Microprocessor-controlled Prosthetic Knee
nMPK	Non-microprocessor Knee
PEQ-A	Prosthetic Evaluation Questionnaire—Addendum
PSFS	Patient-Specific Functional Scale
QoL	Quality of Life
ESAT	= QUEST Quebec User Evaluation of Satisfaction with assistive Technology
SCS	Socket Comfort Score
vGRF	Vertical Ground Reaction Force

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