Lathouwers *et al.*
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User accommodation to an active microprocessor-controlled knee in individuals with unilateral transfemoral amputation: a 5-week non-randomized trial

Elke Lathouwers[1,2], Alexandre Maricot[1], Bruno Tassignon[1,3], Sybille Geers[4], Louis Flynn[2,5], Tom Verstraten[2,5] and Kevin De Pauw[1,2*]

Abstract

Background Evaluation studies on active microprocessor-controlled knees (AMPK) in individuals with unilateral transfemoral amputation (TFA) are lacking in the literature. Furthermore, research on user accommodation to AMPK remains to be investigated. Hence, this study aims to conduct a comparison between an AMPK and individual's current prosthesis and assess the accommodation to using an AMPK during daily activities over a 5-week period on functional performance tests.

Methods Participants with TFA completed a protocol comprising L-test, slope walking, level walking (2MWT) and dual-task level walking (dual-2MWT) once a week with their current prosthesis and the AMPK. The outcomes of interest were the distance covered during the 2MWT and dual-2MWT, time required to perform the L-test, accuracy of the serial subtractions during the dual-2MWT, heart rate (HR), rating of perceived exertion, fatigue, comfort and perceived workload. Generalised least-squared models were built to investigate differences in prosthetic conditions over time. Pearson correlations were calculated to determine associations between the performance and subjective outcomes. The level of significance was set at 0.05.

Results Seven participants (age = 53 years ± 14 years) completed the study. Over time, the AMPK participants took longer to complete the L-test than their current prosthesis ($p < 0.001$). They reported higher fatigue ($p = 0.033$), lower comfort ($p = 0.010$), and higher perceived exertion with the AMPK ($p = 0.048$). Slope walking showed no significant walking speed or HR differences except higher HR with the AMPK in session 3 ($p = 0.032$). Dual-task level walking demonstrated lower walking speed with the AMPK ($p = 0.035$) and more responses to serial subtractions in sessions two ($p = 0.043$) and four ($p = 0.023$). No other differences between conditions were found on one of the functional tests. Weak associations ($|r| = 0–0.5$) were observed between performance and subjective measures.

Conclusion Using the AMPK highlights initial challenges in task completion times and subjective comfort and fatigue levels. Our findings indicate that five one-hour sessions are insufficient for achieving user accommodation, and underscore the need for further research with a larger sample, continued prosthetic use and user accommodation to enhance prosthetic functioning and user experiences.

*Correspondence:
Kevin De Pauw
kevin.de.pauw@vub.be
Full list of author information is available at the end of the article

Trial registration: NCT05407545.

Keywords Lower-limb amputation, Prosthesis, Accommodation, Microprocessor-controlled knee

Introduction

Transfemoral amputations, comprising approximately 26% of all lower limb amputations, result from both traumatic (e.g. traffic accident) and non-traumatic causes (e.g. infection) [1]. A transfemoral amputation poses substantial challenges due to the loss of both the knee and ankle joint, significantly impacting the individuals' ability to perform daily activities, such as walking, or their societal participation, ultimately diminishing their quality of life [2, 3]. To address these issues, individuals are fitted with a prosthetic knee and foot combination, followed by rehabilitation. This intervention aims to restore functional capabilities and enhance mobility, and seeks to improve the individual's self-esteem and overall well-being [4–6]. The integration of prosthetic technology with personalized rehabilitation programs is vital for facilitating independence and improving the quality of life for those with transfemoral limb loss [4–6].

Over the past years, the control mechanisms of prosthetic knees have undergone significant advancements, broadening the market beyond predominantly passive devices by introducing passive micro-processor controlled knees (PMPK) and active micro-processor controlled knees (AMPK) offering improved control over lost knee functions and compensating for the muscle loss [7]. Passive prosthetic knees, which manage knee movement using mechanical friction or fluidic flow control, remain the most affordable option for users. However, their functionality could be improved, offering minimal support for climbing stairs, walking on uneven terrains, or performing sit-to-stand movements [7]. In contrast, PMPK employ a microprocessor and intrinsic sensors to continuously and rapidly adjust the knee's resistance, facilitating smoother movements [7]. Despite these advantages, these devices cannot generate power to assist with sit-to-stand movements or stair climbing, relying entirely on the user's strength [7]. AMPK or powered control systems have been developed to overcome these limitations. These systems are capable of providing net positive work, in addition to their energy absorption by means of a motor, minimizing compensatory behaviour and providing constant support during movements easing activities such as stair climbing and slope walking [7–9]. On top, it has been shown that the use of an AMPK lowers the metabolic cost and increases walking speed [7]. However, this advanced functionality comes with an increased weight and cost, which may be drawbacks for some users [7].

It is well established that individuals with lower limb amputations are at significant risk of developing secondary injuries [10–12]. Notably, low back pain and osteoarthritis of the unimpaired limb are frequently reported, often attributed to unequal weight distribution, movement compensations, and muscle use imbalances between the unimpaired and impaired limb [10]. Additionally, secondary injuries such as wounds, phantom pain, and those resulting from tripping and falling are common [11, 12]. PMPK and AMPK have been shown to enhance user safety [13–15]. They bolster stability and promote gait symmetry, thereby reducing the risk of falls and alleviating the added strain on the unimpaired limb in comparison to passive devices [13–19]. However, it is imperative to consider the learning curve inherent in adapting to these technologies beyond the safety advancements associated with such advanced prosthetic devices. From clinical observations, passive knee prostheses offer elementary support and necessitate several weeks to months for proficient mastery. In contrast, PMPK and AMPK tend to involve a more arduous learning process. It is well established that adapting to walk with a prosthesis requires adequate familiarization time. A recent study examined the accommodation process in first-time prosthetic users [20]. Assessments taken every 2 months revealed a performance plateau in level walking after 4 months, suggesting that full adaptation to a prosthesis typically requires up to 3–4 months [20]. However, the literature currently lacks data on how different prosthetic devices compare in terms of the learning curves they present for users and the amount of familiarization required to effectively use them.

Evaluation studies on AMPK in people with transfemoral amputations, particularly those encompassing a more extended intervention period (> 1 to 2 weeks) with adequate user accommodation time, are scarce in the literature [21]. Objective performance metrics and subjective assessments are typically employed to elucidate the immediate benefits and acute challenges of using knee prostheses in comparison to the individuals current prosthetic device [22]. Yet, no consensus exists on a key set of measurements to be used when evaluating a prosthetic device during daily activities such as level walking, slope walking, sit-to-stand movements, dual-task walking, and stair climbing [22, 23].

Given the gap in the literature regarding prosthetic adaptation when transitioning from a passive prosthesis or PMPK to an AMPK, the primary objective of this

study is to investigate the effects of walking with an AMPK over a 5-week period on functional performance. Over this timeframe, participants will use the AMPK for 1 h weekly and undergo functional testing with both objective and subjective measurements. This approach will enable a comprehensive comparative analysis of their current prosthesis and assess user adaptation to the AMPK based on weekly progress. This study should be viewed as an exploratory investigation into the learning curves involved in transitioning from a passive or PMPK prosthesis to an AMPK. We hypothesize that participants will demonstrate superior performance with their current prosthesis during the first and second sessions, but that this difference will diminish over time. The secondary objective is to examine whether objective and subjective measurements are correlated.

Materials & methods

Population & sample size

Participants with a unilateral transfemoral amputation were recruited for this study. Participants were included when aged between 25 and 75 years, completed their rehabilitation and having a Medicare Functional Classification level K3-4. Adults with a bilateral, a trans-articular knee or hip, or additional upper limb amputation, were excluded as well as participants with neurological disorders, with stump pains and wounds or with a uncomfortable fit of the socket. All participants provided their written consent after being written and verbally informed regarding the study protocol. The study was executed in compliance with the Declaration of Helsinki [24] and Ethical approval was obtained from the medical ethics commission of VUB and UZ Brussel (B.U.N. 1432022000136). The study was also registered via ClincalTrials.gov under NCT05407545.

Protocol

We investigated the effect of an active lower limb prosthesis on the performance of daily activities by means of a non-randomized counterbalanced clinical trial. Figure 1 provides a visualization of the workflow of this 5-week experimental trial.

Participants visited the lab 5 times over a period of 5 weeks (i.e. once a week). At baseline (T0) an anamnesis was performed, socket suspension and fit were checked by a prosthetist, and participants performed a familiarisation trial after which they performed the experimental protocol. Then, at T1, T2, T3 and T4 the participants revisited the lab and completed the experimental protocol at each of these visits. The 1-h weekly use over 5 weeks is determined by the resources available for this study.

The experimental protocol entailed an L-test which was performed 3 times, followed by a 2 min of treadmill slope walking at an inclination of 10%, 2 min of treadmill level walking (2MWT) and a dual-task 2MWT [23, 25–27].

The dual-task 2MWT compiled out of conducting a 2MWT while performing a cognitive task, i.e. serial subtractions. Serial subtraction is mental arithmetic task that tests attention and working memory [28–30]. Participants were asked to continually subtract sevens from a random selected 3-digit number as long as the duration of the test [28]. The protocol was completed with both the individuals' current prosthesis and the active prosthesis to enable comparison. Both devices were fitted to the individuals' preference by the same prosthetist. The order in which the devices were tested, was randomized to control for possible order effects.

Measurements and devices

The AMPK utilized in this study was the Power Knee™ (PK), in conjunction with the Pro-Flex XC foot (Össur). The AMPK alignment was each time conducted by the same prosthetist and settings were determined via the corresponding software application in accordance to the manufacturer guidelines. The AMPK was mounted on the individuals' own socket. The individuals' current prostheses are provided in appendix Table 4 and included both passive prostheses as well as PMPKs.

At the beginning of each trial, heart rate measurements were collected. The self-selected walking speeds during the 2 min slope walking, 2MWT and dual-2MWT were captured and the serial subtractions during the dual-2MWT were recorded allowing to determine accuracy and the number of responses. During the L-test, time to complete the test was recorded.

Heart rate (beats per minute) was continuously measured during each task by means of a chest strap (Cyclus2, RBM elektronik-automation GmbH, Germany) and was transmitted in real-time to the VO_2 Master's mobile application (VO2 Master Manager). Rating of perceived exertion (rage 6 = no exertion to 20 = maximal effort) [31], level of comfort and fatigue (i.e. VAS comfort and VAS fatigue, range: 0 = very uncomfortable/no fatigue to 100 = very comfortable/very fatiguing) [32] and NASA-Task Load index (NASA-TLX) assessing perceived workload [33] were determined after each task.

Data processing and statistical analysis

The collected data was exported from Redcap to an Excel file. Meanwhile, the audio files from the dual task were transcribed, and the number of responses and accuracy were added to the previous mentioned Excel file to perform statistical analyses. All statistical analyses were performed using R (version 4.3.1; R Core Team, 2024)

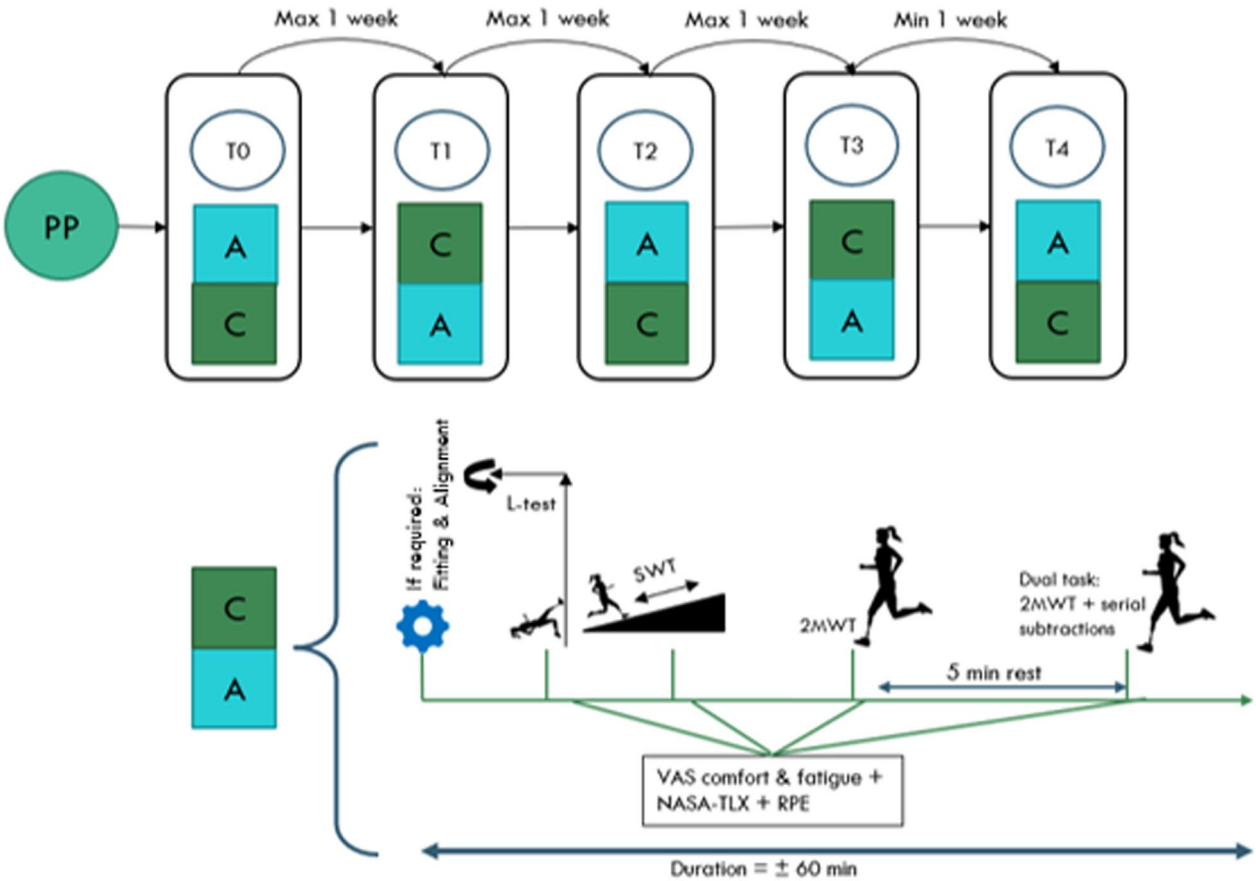

Fig. 1 Flowchart of the 5-week experimental trial. *PP* participant with transfemoral amputation, *T0–T4* measurement moment week 1 to week 5, *C* Test with current prosthetic knee, *A* test with active prosthetic knee, *SWT* 2-min treadmill slope walking test, *2MWT* 2- minutes' treadmill walk test, *VAS* visual analogue scale, *RPE* Rating of Perceived Exertion, *NASA–TLX* NASA–Task Load Index. C and A are altered over week to account for order effects

[34]. The level of significance was set at $\alpha = 0.05$. Descriptive statistics were calculated and tabulated using the Table 1-package (version 1.4.3) [35]. The primary endpoints of this non-randomized counterbalanced clinical trial are the walking speed during the 2MWT and dual-2MWT, time required to perform the L-test and the accuracy of the serial subtractions during the dual-2MWT. Secondary endpoints are heart rate, rate of perceived exertion, fatigue, comfort and perceived workload. To investigate the differences between the individual's current protheses and the PK over time for the primary and secondary endpoints, a linear model was used. Assumptions were checked (i.e. homoscedasticity and normality of the residuals). In order that all assumptions were fulfilled for each outcome, a log transformation was applied to the outcome VAS comfort during slope walking, and a squared transformation was applied to the VAS Fatigue outcome during slope walking, and to the rate of perceived exertion and heart rate outcomes of the dual-2MWT. After applying these transformations, all assumptions were fulfilled and a model per outcome was generated using the generalized least squares function from the nlme package (version 3.1-164) [36, 37] with the prosthetic condition (i.e. AMPK & Current) and sessions (i.e. T0, T1, T2, T3 & T4) included as independent variables and the individual's age and body mass index as covariates. The correlation structure within each level of the variable ID was set at autoregressive. Reported p-values are uncorrected.

To determine possible associations between the performance and subjective outcomes, Pearson correlation values were determined using the corrplot package (version 0.92) [38]. Given the exploratory nature of this correlation analysis, there are no p-values reported in the result section.

Results

Participants' characteristics

Seven participants with a unilateral transfemoral amputation participated and successfully completed the study

Table 1 Descriptives

	Session 1		Session 2		Session 3		Session 4		Session 5	
	Current (N = 7)	**AMPK (N = 7)**	**Current (N = 7)**	**AMPK (N = 7)**	**Current (N = 7)**	**AMPK (N = 7)**	**Current (N = 7)**	**AMPK (N = 7)**	**Current (N = 7)**	**AMPK (N = 7)**
Time L-test (Seconds)										
Mean (SD)	25.8 (5.2)	33.7 (9.1)	23.7 (4.9)	31.0 (7.8)	26.2 (6.7)	33.5 (6.5)	25.6 (6.7)	32.7 (6.8)	26.0 (8.1)	30.3 (8.9)
Median [Min, Max]	26.5 [19.7, 33.2]	33.3 [23.4, 49.8]	24.5 [18.2, 30.0]	32.1 [21.1, 38.9]	25.5 [18.3, 36.6]	34.8 [23.8, 40.1]	25.3 [18.2, 36.1]	36.1 [23.1, 38.8]	25.4 [18.8, 39.4]	31.1 [21.5, 42.6]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
Heart rate L-test (BPM)										
Mean (SD)	102 (12)	107 (14)	84 (20)	107 (19)	93 (13)	101 (8)	106 (16)	99 (24)	99 (11)	98 (8)
Median [Min, Max]	106 [86, 116]	107 [86, 128]	87 [62, 105]	105 [88, 130]	96 [74, 103]	100 [92, 110]	116 [86, 120]	110 [61, 122]	95 [87, 112]	99 [89, 109]
Missing (%)	0	0	28.6	28.6	42.9	42.9	28.6	28.6	28.6	28.6
VAS comfort L-test										
Mean (SD)	69 (32)	47 (17)	77 (11)	37 (22)	69 (19)	44 (15)	78 (15)	59 (27)	65 (11)	55 (16)
Median [Min, Max]	84 [4, 95]	50 [26, 79]	81 [66, 90]	41 [5, 61]	70 [50, 91]	50 [25, 62]	72 [61, 95]	64 [25, 90]	67 [50, 80]	59 [30, 70]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
VAS fatigue L-test										
Mean (SD)	22 (20)	43 (24)	33 (18)	60 (21)	32 (22)	49 (17)	34 (24)	39 (31)	38 (13)	49 (20)
Median [Min, Max]	16 [0, 50]	40 [7, 71]	36 [15, 60]	68 [28, 80]	20 [13, 60]	50 [32, 74]	43 [6, 61]	20 [9, 76]	40 [20, 50]	42 [30, 70]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
RPE L-test										
Mean (SD)	9 (2)	11 (3)	9 (1)	13 (2)	11 (3)	13 (2)	10 (4)	12 (4)	11 (3)	11 (3)
Median [Min, Max]	8 [6, 13]	13 [6, 13]	9 [8, 10]	13 [10, 16]	10 [7, 14]	13 [10, 14]	8 [7, 15]	13 [6, 15]	13 [6, 14]	13 [7, 14]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
Walking speed slope walking (km/h)										
Mean (SD)	2.4 (0.5)	2.1 (0.7)	2.8 (0.9)	2.6 (0.7)	2.4 (0.9)	2.2 (0.8)	2.3 (0.9)	2.1 (0.7)	2.4 (0.8)	2.3 (0.8)
Median [Min, Max]	2.1 [1.8, 3.0]	1.9 [1.4, 3.0]	3.0 [1.5, 4.0]	3.0 [1.5, 3.0]	2.8 [1.0, 3.0]	2.7 [1.0, 3.0]	2.3 [1.0, 3.3]	2.0 [1.1, 3.0]	2.8 [1.0, 3.0]	2.7 [1.0, 3.0]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
Heart rate slope walking (BPM)										
Mean (SD)	119 (20)	118 (19)	127 (25)	128 (25)	109 (14)	123 (20)	118 (28)	117 (26)	114 (20)	114 (14)
Median [Min, Max]	115 [95, 142]	110 [95, 142]	134 [100, 156]	132 [99, 153]	105 [99, 129]	122 [103, 143]	120 [88, 150]	114 [89, 145]	105 [98, 136]	114 [98, 131]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
VAS comfort slope walking										
Mean (SD)	50 (22)	56 (20)	56 (220)	43 (17)	55 (21)	39 (8)	54 (23)	62 (14)	58 (16)	51 (12)
Median [Min, Max]	50 [24, 80]	50 [26, 82]	69 [33, 75]	50 [21, 63]	41 [39, 80]	36 [32, 50]	66 [21, 75]	58 [50, 82]	60 [38, 80]	50 [40, 70]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6

Table 1 (continued)

	Session 1		Session 2		Session 3		Session 4		Session 5	
	Current (N = 7)	**AMPK (N = 7)**	**Current (N = 7)**	**AMPK (N = 7)**	**Current (N = 7)**	**AMPK (N = 7)**	**Current (N = 7)**	**AMPK (N = 7)**	**Current (N = 7)**	**AMPK (N = 7)**
VAS fatigue slope walking										
Mean (SD)	54 (12)	49 (22)	64 (16)	68 (9)	57 (14)	71 (13)	57 (24)	52 (29)	53 (9)	59 (9)
Median [Min, Max]	50 [36, 70]	60 [10, 69]	69 [44, 80]	67 [58, 62]	60 [32, 69]	66 [60, 87]	60 [17, 80]	70 [21, 80]	57 [38, 60]	60 [44, 70]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
RPE slope walking										
Mean (SD)	12 (3)	13 (2)	13 (1)	15 (2)	13 (1)	14 (2)	12 (4)	13 (4)	12 (1)	12 (2)
Median [Min, Max]	12 [8, 16]	13 [11, 17]	13 [12, 15]	15 [12, 17]	13 [12, 14]	13 [12, 16]	13 [7, 16]	14 [7, 16]	12 [11, 14]	12 [9, 14]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
Speed level walking (km/h)										
Mean (SD)	2.9 (0.7)	2.6 (0.8)	3.3 (0.7)	3.0 (0.7)	2.9 (1.3)	2.7 (1.1)	2.8 (1.2)	2.4 (0.9)	2.7 (1.1)	2.5 (1.0)
Median [Min, Max]	3.1 [1.9, 4.0]	2.3 [1.8, 3.7]	3.2 [2.5, 4.0]	3.0 [2.0, 3.8]	3.2 [1.0, 4.1]	3.1 [1.0, 3.8]	2.5 [1.2, 4.0]	2.4 [1.1, 3.5]	3.0 [1.0, 4.0]	3.0 [1.0, 3.3]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
Heart rate level walking (BPM)										
Mean (SD)	110 (20)	110 (19)	115 (23)	121 (26)	108 (18)	114 (22)	109 (25)	108 (24)	105 (19)	103 (13)
Median [Min, Max]	108 [84, 136]	104 [89, 136]	120 [91, 143]	128 [88, 146]	106 [92, 128]	113 [93, 142]	114 [82, 135]	108 [84, 113]	100 [87, 129]	103 [87, 116]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
VAS comfort level walking										
Mean (SD)	76 (17)	65 (16)	65 (21)	55 (18)	67 (18)	62 (19)	81 (14)	65 (22)	63 (20)	63 (11)
Median [Min, Max]	84 [42, 89]	66 [40, 85]	67 [33, 86]	46 [39, 79]	69 [50, 94]	62 [37, 87]	80 [60, 96]	68 [38, 95]	61 [32, 80]	61 [50, 80]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
VAS fatigue level walking										
Mean (SD)	42 (18)	43 (10)	43 (25)	53 (19)	41 (20)	44 (24)	32 (25)	42 (29)	44 (19)	40 (13)
Median [Min, Max]	41 [18, 67]	38 [20, 75]	27 [23, 72]	58 [22, 70]	50 [9, 58]	41 [12, 74]	30 [3, 68]	40 [4, 79]	40 [20, 72]	39 [26, 60]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
RPE level walking										
Mean (SD)	10 (1)	10 (2)	12 (3)	13 (3)	11 (2)	11 (2)	11 (3)	12 (4)	11 (3)	11 (3)
Median [Min, Max]	10 [9, 13]	10 [7, 13]	13 [9, 15]	14 [8, 16]	12 [8, 14]	12 [8, 14]	11 [6, 14]	12 [6, 16]	10 [6, 14]	10 [7, 14]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
Walking speed dual task level walking (km/h)										
Mean (SD)	2.9 (0.7)	2.6 (0.7)	3.2 (0.7)	2.9 (0.5)	2.9 (1.2)	2.4 (0.9)	2.8 (1.3)	2.4 (0.9)	2.6 (1.0)	2.5 (1.0)
Median [Min, Max]	3.0 [1.9, 4.0]	2.5 [1.9, 3.7]	3.0 [2.3, 4.0]	3.0 [2.1, 3.5]	2.8 [1.0, 4.0]	2.7 [1.0, 3.2]	2.5 [1.0, 4.0]	2.4 [1.1, 3.5]	2.8 [1.0, 3.8]	3.0 [1.0, 3.3]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6

Table 1 (continued)

	Session 1		Session 2		Session 3		Session 4		Session 5	
	Current (N = 7)	AMPK (N = 7)	Current (N = 7)	AMPK (N = 7)	Current (N = 7)	AMPK (N = 7)	Current (N = 7)	AMPK (N = 7)	Current (N = 7)	AMPK (N = 7)
Accuracy dual task level walking (%)										
Mean (SD)	91.6 (13.9)	90.6 (15.8)	91.2 (18.6)	90.6 (16.0)	92.8 (14.5)	95.2 (7.8)	93.8 (8.8)	81.4 (10.0)	96.0 (4.5)	98.6 (2.0)
Median [Min, Max]	97.0 [61.0, 100]	98.0 [56.0, 100]	100 [58.0, 100]	98.0 [62.0, 98.2]	100 [67.0, 100]	100 [82.0, 100]	97.0 [79.0, 100]	94.0 [74.0, 98.0]	98.0 [89.0, 100]	100 [96.0, 100]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
Number of responses dual task level walking										
Mean (SD)	47 (13)	41 (13)	46 (9)	49 (14)	45 (11)	44 (12)	47 (19)	52 (15)	55 (9)	54 (7)
Median [Min, Max]	48 [23, 63]	45 [16, 52]	48 [31, 54]	54 [26, 60]	43 [36, 63]	49 [22, 51]	55 [19, 67]	59 [27, 64]	51 [45, 68]	53 [46, 66]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
Heart rate dual task level walking (BPM)										
Mean (SD)	111 (19)	106 (14)	113 (24)	117 (25)	104 (15)	110 (20)	111 (26)	110 (24)	106 (20)	105 (16)
Median [Min, Max]	111 [85, 135]	109 [88, 128]	110 [89, 143]	114 [89, 142]	102 [89, 122]	104 [92, 137]	117 [82, 139]	119 [84, 134]	105 [97, 137]	108 [87, 126]
Missing (%)	0	0	28.6	28.6	42.9	28.6	28.6	28.6	28.6	28.6
VAS comfort dual task level walking										
Mean (SD)	65 (21)	58 (23)	54 (21)	37 (10)	62 (22)	42 (23)	68 (16)	60 (19)	54 (14)	55 (12)
Median [Min, Max]	69 [32, 96]	59 [33, 94]	59 [34, 84]	40 [23, 50]	56 [36, 90]	39 [22, 80]	61 [50, 89]	50 [41, 88]	58 [32, 70]	50 [41, 70]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
VAS fatigue dual task level walking										
Mean (SD)	43 (21)	50 (21)	50 (18)	55 (18)	50 (26)	55 (22)	46 (26)	46 (28)	51 (11)	53 (15)
Median [Min, Max]	37 [14, 67]	59 [14, 75]	58 [18, 60]	60 [26, 73]	61 [17, 80]	65 [18, 71]	58 [3, 69]	50 [2, 70]	50 [40, 64]	60 [35, 70]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6
RPE dual task level walking										
Mean (SD)	11 (3)	10 (3)	14 (1)	14 (2)	12 (2)	13 (1)	12 (3)	11 (4)	12 (2)	11 (4)
Median [Min, Max]	12 [6, 14]	11 [7, 14]	14 [12, 15]	13 [13, 16]	13 [9, 14]	13 [13, 14]	13 [7, 14]	11 [6, 16]	13 [10, 14]	12 [6, 14]
Missing (%)	0	0	28.6	28.6	28.6	28.6	28.6	28.6	28.6	28.6

AMPK Active microprocessor-controlled knee, *SD* Standard Deviation, *Min* Minimum, *Max* Maximum, *VAS* Visual Analogue Scale, *BPM* Beats Per Minute, *RPE* Rating of Perceived Exertion

protocol. The group consisted of one female and six males, and the majority of participants (n = 6) had a left-sided amputation. Trauma was the leading cause of limb loss (n = 4), followed by vascular issues (n = 2) and cancer (n = 1).

The mean age and standard deviation of the participants amounted 53 years ± 14 years (median = 56 years, min = 36 years and max = 74 years), with the average height being 174 cm ± 7 cm (median = 177 cm, min = 163 cm and max = 179 cm), and the mean weight being 77 kg ± 11 kg (median = 7 kg, min = 65 kg and max = 97 kg). Additionally, the mean body mass index of the participants amounted 25.6 kg/m^2 ± 4.0 kg/m^2 (median = 25.4 kg/m^2, min = 20.3 kg/m^2 and max = 32.4 kg/m^2). Detailed individual participant characteristics can be found in Appendix A.1.

Differences between prosthetic conditions over time

Table 1 provides a detailed overview of the descriptives (i.e. mean, standard deviation, median, minimum, maximum and % of missing values) per outcome grouped by sessions and prosthetic condition. Table 2 provides an overview of the statistical modelling outcomes used to analyse between-group and within-group differences in performance and subjective outcomes.

Aim 1: Effect over time of the AMPK on performance outcomes

The outcome parameters for the L-test comprised time to perform the test and heart rate. We found a significant main effect for the prosthetic conditions. Participants required more time to complete the L-test when walking with the AMPK than with the current prosthesis (β = 7.88 s, SE = 1.62, p < 0.001). No significant differences were discerned in heart rate. However, a trend towards significance emerged for an interaction effect, particularly concerning the interplay between session 2 and the use of the AMPK (β = 18.20 bpm, SE = 9.7, p = 0.069). The β estimate represents the average increase in heart rate upon using the PK during session 2.

For the slope walking, the parameters of interest were walking speed and heart rate. Walking speed did not differ between sessions or prosthetic conditions. For the heart rate, a significant interaction effect was found between session 3 and the use of the AMPK (β = 13.00 bpm, SE = 5.86, p = 0.032). The β estimate indicates an increase in average heart rate when walking with the AMPK compared to the current prosthesis at session 3. No other significant differences were present.

The performance outcomes for level walking were walking speed to perform the test and the heart rate. No significant differences were found for either outcome, and no significant effects were indicated over time or between prosthetic conditions.

For dual-task level walking, the outcomes of interest were walking speed, heart rate, accuracy of the serial subtractions, and the number of responses to serial subtractions. We found a significant main walking speed effect for the prosthesis condition, indicating that the walking speed was significantly lower with the AMPK compared to the current prosthesis (β = −0.34 km/h, SE = 0.16, p = 0.035). Heart rate did not differ between sessions or conditions. Regarding accuracy, we found that in session 4, participants performed significantly better than in their first sessions (β = 7.35%, SE = 2.99, p = 0.012). No other differences were found in the accuracy of the outcome. About the number of responses, we detected a significant interaction effect between session 2 (β = 9.46, SE = 4.53, p = 0.043) and the use of the AMPK, and between session 4 and the use of the AMPK (β = 10.40, SE = 4.35, p = 0.023). These two interactions indicate an increase in number of responses upon walking with the AMPK compared to the current prosthesis at sessions 2 and 4.

Aim 2: Effect over time of the AMPK on subjective outcomes

The outcome parameters for the L-test for slope walking, level walking, and dual-task level walking were comfort, fatigue and rating of perceived exertion.

For the L-test, significant differences were present for fatigue and comfort, rating of perceived exertion. Fatigue was significantly higher when walking with the AMPK compared to the current prosthesis (β = 21.29, SE = 9.66, p = 0.033), comfort was rated significantly lower compared to the current prosthesis (β = −56.20, SE = 34.24, p = 0.010) and rating of perceived exertion was significantly higher with the AMPK compared to the current prosthesis (β = 2.64, SE = 1.3, p = 0.048).

Regarding slope walking, level walking, and dual-task level walking, there were no significant differences in comfort, fatigue, or rating of perceived exertion.

Aim 3: Association between performance and subjective outcomes

Table 3 provides an overview of the Pearson correlation coefficients quantifying the associations between the performance and subjective outcome measures. All correlations indicate weak associations between the performance and subjective measures.

Discussion

The present study evaluated the effects of an active microprocessor-controlled knee (AMPK) on the performance of daily activities by means of objective and subjective measurements of individuals with transfemoral

Table 2 Results between-group and within-group differences in performance and subjective outcomes

Outcome parameter of interest	Autoregressive coefficient	Parameter estimates ± SE (p-value)					
	Φ	**Intercept (= Current prosthesis at session 1)**	**Prosthetic Condition (= AMPK)**	**Sessions A = session 2 B = session 3 C = session 4 D = session 5**	**Age**	**BMI**	**Condition:Session A = AMPK at session 2 B = AMPK at session 3 C = AMPK at session 4 D = AMPK at session 5**
L-test							
Time	0.51	−0.15 ± 7.50 (0.984)	7.88 ± 1.62 **(< 0.001)**	A = −0.30 ± 2.26 (0.896) B = −1.00 ± 2.34 (0.669) C = −1.86 ± 2.30 (0.425) D = 1.17 ± 2.35 (0.622)	0.40 ± 0.07 **(< 0.001)**	0.18 ± 0.26 (0.509)	A = −0.88 ± 2.64 (0.750) B = −2.00 ± 2.72 (0.465) C = −0.68 ± 2.54 (0.791) D = −3.56 ± 2.54 (0.170)
Heart rate	0.37	81.27 ± 21.56 **(0.005)**	4.59 ± 5.99 (0.413)	A = −18.11 ± 7.85 **(0.026)** B = −8.36 ± 8.25 (0.317) C = 4.59 ± 7.92 (0.566) D = 2.94 ± 7.99 (0.715)	−0.34 ± 0.21 (0.112)	1.52 ± 0.75 (0.502)	A = 18.20 ± 9.72 (0.068) B = 5.18 ± 10.16 (0.613) C = −11.33 ± 9.41 (0.236) D = −8.37 ± 9.37 (0.377)
VAS comfort	$0.07*10^{-2}$	61.22 ± 50.61 (0.151)	−56.20 ± 34.24 **(0.010)**	A = 19.69 ± 35.94 (0.766) B = −34.78 ± 37.19 (0.387) C = 24.33 ± 35.95 (0.650) D = −33.44 ± 34.24 (0.392)	−3.64 ± 4.90 (0.584)	10.08 ± 9.29 (0.247)	A = −33.62 ± 42.62 (0.537) B = 31.12 ± 44.10 (0.621) C = 30.90 ± 42.62 (0.602) D = 44.52 ± 42.62 (0.282)
VAS fatigue	0.14	28.95 ± 25.24 (0.258)	21.30 ± 9.66 **(0.033)**	A = 13.26 ± 11.41 (0.254) B = 8.60 ± 12.18 (0.484) C = 9.66 ± 11.43 (0.402) D = 13.43 ± 11.43 (0.247)	0.69 ± 0.24 **(0.006)**	−1.71 ± 0.86 (0.055)	A = 5.88 ± 15.34 (0.704) B = −6.04 ± 16.32 (0.713) C = −16.00 ± 15.10 (0.296) D = −9.50 ± 15.04 (0.531)
RPE	0.21	10.68 ± 3.75 **(0.007)**	2.64 ± 1.30 **(0.048)**	A = 0.23 ± 1.59 (0.885) B = 2.81 ± 1.69 (0.104) C = 1.18 ± 1.59 (0.464) D = 1.96 ± 1.60 (0.226)	0.03 ± 0.04 (0.343)	−0.15 ± 0.13 (0.244)	A = 1.91 ± 2.08 (0.363) B = −1.49 ± 2.20 (0.503) C = −0.99 ± 2.03 (0.631) D = −2.11 ± 2.02 (0.302)
Slope walking							
Walking speed	0.52	4.03 ± 0.80 **(< 0.001)**	−0.26 ± 0.17 (0.14)	A = 0.22 ± 0.24 (0.370) B = −0.11 ± 0.25 (0.647) C = 0.31 ± 0.24 (0.208) D = 0.03 ± 0.25 (0.890)	−0.05 ± 0.01 **(< 0.001)**	0.03 ± 0.03 (0.280)	A = 0.10 ± 0.28 (0.726) B = 0.35 ± 0.29 (0.236) C = 0.01 ± 0.27 (0.970) D = 0.14 ± 0.27 (0.595)
Heart rate	0.82	82.19 ± 37.13 **(0.033)**	−-1.27 ± 3.67 (0.732)	A = 5.76 ± 5.78 (0.325) B = −10.46 ± 5.59 (0.069) C = 1.44 ± 5.88 (0.809) D = 3.86 ± 6.35 (0.546)	−0.75 ± 0.38 (0.057)	2.95 ± 1.34 **(0.034)**	A = 1.72 ± 5.86 (0.770) B = 13.00 ± 5.86 (0.032) C = 1.26 ± 5.61 (0.823) D = 0.61 ± 5.79 (0.917)
VAS comfort	0.17	2.90 ± 0.48 **(< 0.001)***	0.14 ± 0.18 (0.425)*	A = 0.21 ± 0.21 (0.320)* B = 0.08 ± 0.23 (0.718)* C = 0.02 ± 0.21 (0.937)* D = 0.24 ± 0.21 (0.270)*	0.01 ± 0.00 (0.104)*	0.02 ± 0.02 (0.235)*	A = −0.41 ± 0.28 (0.151)* B = −0.38 ± 0.30 (0.216)* C = 0.06 ± 0.28 (0.817)* D = −0.24 ± 0.28 (0.396)*

Table 2 (continued)

Outcome parameter of interest	Autoregressive coefficient	Parameter estimates ± SE (p-value)					
	Φ	Intercept (= Current prosthesis at session 1)	Prosthetic Condition (= AMPK)	Sessions A = session 2 B = session 3 C = session 4 D = session 5	Age	BMI	Condition:Session A = AMPK at session 2 B = AMPK at session 3 C = AMPK at session 4 D = AMPK at session 5
VAS fatigue	0.01	5666.18 ± 1895.90 **(0.005)**$^{+}$	−214.13 ± 861.57 (0.805)$^{+}$	A = 1283.19 ± 952.29 (0.185)$^{+}$ B = 684.81 ± 1019.57 (0.506)$^{+}$ C = 697.71 ± 952.95 (0.468)$^{+}$ D = −362.88 ± 952.48 (0.705)$^{+}$	17.96 ± 17.78 (0.319)$^{+}$	−140.08 ± 64.00 **(0.035)**$^{+}$	A = 565.56 ± 1336.61 (0.675)$^{+}$ B = 834.46 ± 1430.49 (0.563)$^{+}$ C = −67.28 ± 1335.48 (0.960)$^{+}$ D = 889.69 ± 1335.11 (0.509)$^{+}$
RPE	0.70	16.05 ± 5.43 **(0.005)**	1.03 ± 0.79 (0.199)	A = 0.18 ± 1.19 (0.876) B = −0.24 ± 1.18 (0.844) C = −0.56 ± 1.21 (0.646) D = −0.41 ± 1.27 (0.751)	−0.02 ± 0.05 (0.767)	−1046.26 ± 1940.09 (0.593)	A = 0.13 ± 1.28 (0.920) B = 0.12 ± 1.29 (0.925) C = -0.21 ± 1.22 (0.862) D = −1.60 ± 1.25 (0.208)
Level walking							
Walking speed	0.60	4.93 ± 0.96 **(< 0.001)**	−0.29 ± 0.17 (0.101)	A = 0.19 ± 0.25 (0.468) B = −0.15 ± 0.26 (0.556) C = 0.31 ± 0.26 (0.230) D = −0.29 ± 0.17 (0.556)	−0.05 ± 0.01 **(< 0.001)**	0.03 ± 0.03 (0.313)	A = −0.02 ± 0.28 (0.955) B = 0.35 ± 0.29 (0.236) C = −0.23 ± 0.27 (0.410) D = 0.03 ± 0.28 (0.909)
Heart rate	0.88	65.75 ± 35.99 (0.075)	−0.22 ± 2.71 (0.935)	A = 3.78 ± 4.36 (0.391) B = −1.24 ± 4.14 (0.767) C = 2.12 ± 4.42 (0.634) D = 4.39 ± 4.84 (0.370)	−0.69 ± 0.37 (0.935)	3.11 ± 1.31 **(0.023)**	A = 5.55 ± 4.28 (0.203) B = 2.59 ± 4.27 (0.547) C = −0.03 ± 4.10 (0.994) D = −2.23 ± 4.26 (0.604)
VAS comfort	0.45	16.15 ± 25.60 (0.532)	−11.16 ± 6.17 (0.078)	A = −8.74 ± 8.40 (0.304) B = −9.58 ± 8.74 (0.280) C = 4.87 ± 8.51 (0.571) D = −9.61 ± 8.64 (0.273)	0.08 ± 0.25 (0.743)	2.13 ± 0.90 **(0.023)**	A = −0.06 ± 10.04 (0.995) B = 9.77 ± 10.41 (0.353) C = −6.66 ± 9.69 (0.496) D = 11.92 ± 9.68 (0.225)
VAS fatigue	0.18	87.56 ± 23.72 **(< 0.001)**	2.48 ± 8.58 (0.774)	A = 1.60 ± 10.35 (0.878) B = 2.39 ± 11.02 (0.829) C = −11.83 ± 10.37 (0.261) D = −1.80 ± 10.38 (0.863)	0.41 ± 0.23 (0.076)	−2.66 ± 0.81 **(0.002)**	A = 7.65 ± 13.71 (0.580) B = −2.68 ± 14.55 (0.855) C = 10.03 ± 13.44 (0.460) D = −6.00 ± 13.38 (0.656)
RPE	0.42	16.80 ± 4.10 **(< 0.001)**	0.30 ± 1.03 (0.776)	A = 1.73 ± 1.39 (0.221) B = 0.89 ± 1.45 (0.545) C = 0.27 ± 1.41 (0.850) D = −0.48 ± 1.43 (0.741)	0.03 ± 0.04 (0.531)	−3030.45 ± 1433.16 **(0.041)**	A = 0.52 ± 1.68 (0.757) B = −0.55 ± 1.75 (0.754) C = 0.80 ± 1.63 (0.628) D = −0.16 ± 1.62 (0.922)
Dual-task level walking							
Walking speed	0.64	4.73 ± 0.94 **(< 0.001)**	−0.34 ± 0.16 **(0.035)**	A = -0.02 ± 0.23 (0.932) B = -0.27 ± 0.23 (0.246) C = 0.15 ± 0.24 (0.532) D = -0.23 ± 0.24 (0.360)	−0.05 ± 0.01 **(< 0.001)**	0.04 ± 0.03 (0.239)	A = 0.05 ± 0.25 (0.859) B = 0.16 ± 0.26 (0.535) C = −0.09 ± 0.24 (0.707) D = 0.15 ± 0.25 (0.561)

Table 2 (continued)

Outcome parameter of interest	Autoregressive coefficient	Parameter estimates ± SE (p-value)					
	Φ	Intercept (= Current prosthesis at session 1)	Prosthetic Condition (= AMPK)	Sessions A = session 2 B = session 3 C = session 4 D = session 5	Age	BMI	Condition:Session A = AMPK at session 2 B = AMPK at session 3 C = AMPK at session 4 D = AMPK at session 5
Heart rate	0.80	3050.11 ± 6978.12 (0.664)$^{+}$	−1105.38 ± 744.13 (0.145)$^{+}$	A = 185.44 ± 1161.19 (0.874)$^{+}$ B = −1126.34 ± 1130.06 (0.325)$^{+}$ C = 558.68 ± 1183.77 (0.640)$^{+}$ D = 748.82 ± 1270.51 (0.559)$^{+}$	−165.95 ± 71.25 **(0.025)**$^{+}$	713.96 ± 251.93 **(0.007)**$^{+}$	A = 1874.27 ± 1189.25 (0.123)$^{+}$ B = 1714.81 ± 1191.12 (0.158)$^{+}$ C = 661.53 ± 1138.73 (0.565)$^{+}$ D = 747.74 ± 1173.90 (0.528)$^{+}$
Accuracy of dual task	0.88	145.66 ± 23.94 **(< 0.001)**	−1.10 ± 1.84 (0.553)	A = 1.68 ± 2.95 (0.573) B = 2.58 ± 2.81 (0.363) C = 7.35 ± 2.99 **(0.018)** D = 1.47 ± 3.27 (0.656)	0.12 ± 0.25 (0.643)	−2.38 ± 0.87 **(0.009)**	A = 0.87 ± 2.90 (0.767) B = 2.75 ± 2.89 (0.348) C = −2.20 ± 2.78 (0.433) D = 3.71 ± 2.89 (0.206)
Number of responses of dual task	0.72	104.08 ± 20.53 **(< 0.001)**	−5.52 ± 2.81 (0.057)	A = -1.45 ± 4.26 (0.735) B = −1.60 ± 4.23 (0.708) C = 1.33 ± 4.35 (0.762) D = 3.04 ± 4.59 (0.511)	−0.25 ± 0.21 (0.227)$^{+}$	−1.68 ± 0.74 **(0.028)**	A = 9.46 ± 5.5. **(0.043)** B = 5.97 ± 4.58 (0.199) C = 10.40 ± 4.35 **(0.022)** D = 5.43 ± 4.44 (0.228)
VAS comfort	0.62	45.75 ± 34.70 (0.195)	−7.11 ± 6.06 (0.247)	A = −5.82 ± 8.83 (0.514) B = −10.59 ± 8.96 (0.244) C = 3.86 ± 9.01 (0.429) D = -4.03 ± 9.34 (0.668)	0.45 ± 0.35 (0.197)	−0.28 ± 1.23 (0.821)	A = −9.23 ± 9.84 (0.354) B = 3.50 ± 10.02 (0.729) C = −0.99 ± 9.45 (0.917) D = 6.75 ± 9.55 (0.483)
VAS fatigue	0.58	60.77 ± 37.92 (0.117)	7.30 ± 7.21 (0.317)	A = 6.06 ± 10.35 (0.561) B = 6.76 ± 10.58 (0.526) C = 6.14 ± 10.55 (0.564) D = −0.53 ± 10.86 (0.962)	0.32 ± 0.38 (0.407)	−1.33 ± 1.34 (0.328)	A = −2.79 ± 11.73 (0.814) B = −1.55 ± 12.01 (0.898) C = −8.38 ± 11.28 (0.462) D = −2.59 ± 11.36 (0.821)
RPE	0.30	224.16 ± 87.99 **(0.015)**$^{+}$	−17.16 ± 27.10 (0.530)$^{+}$	A = 44.54 ± 34.46 (0.204)$^{+}$ B = 17.47 ± 36.44 (0.634)$^{+}$ C = 12.16 ± 34.68 (0.728)$^{+}$ D = 3.47 ± 34.83 (0.921)$^{+}$	−0.40 ± 0.85 (0.645)$^{+}$	−2.59 ± 3.05 (0.401)$^{+}$	A = 33.28 ± 43.78 (0.452)$^{+}$ B = 35.44 ± 46.05 (0.446)$^{+}$ C = 7.31 ± 42.57 (0.865)$^{+}$ D = −2.80 ± 42.34 (0.948)$^{+}$

RPE Rating of Perceived Exertion, *VAS* Visual Analogue Scale, *SE* standard error, *BMI* Body Mass Index, *AMPK* Active microprocessor-controlled knee. Significant p-values (α < 0.05) are in bold

amputations over a 5-week period and assess the level of user accommodation with the AMPK. Furthermore, this study aimed to investigate the objective and subjective measurements associated with each other. Main outcomes were walking speed, time to perform a test, heart rate, scores on the visual analogue scales for fatigue and comfort as well as rate of perceived exertion.

Performance outcomes

Our study found that participants required significantly longer times to complete the L-test when using the AMPK (mean estimated difference = 7.88 s), with no significant improvements observed over the 5 weeks within the AMPK condition. This clinically meaningful difference suggests that despite the advanced capabilities of the AMPK, users initially experience slower task completion times, potentially due to limited user accommodation

Table 3 Association between performance and subjective outcome measures

	VAS Comfort	VAS Fatigue	RPE
L-test			
Time	r = −0.34	r = 0.49	r = 0.32
Heart rate	r = −0.16	r = −0.09	r = 0.00
Slope walking			
Walking speed	r = −0.30	r = −0.09	r = 0.16
Heart rate	r = −0.38	r = 0.10	r = 0.28
Level walking			
Walking speed	r = −0.14	r = −0.16	r = 0.09
Heart rate	r = −0.16	r = −0.16	r = 0.00
Dual-task level walking			
Walking speed	r = −0.40	r = −0.13	r = 0.29
Heart rate	r = −0.36	r = −0.17	r = 0.17
Accuracy of dual task	r = 0.29	r = 0.28	r = 0.06
Number of responses of dual task	r = 0.14	r = 0.06	r = 0.08

VAS Visual Analogue Scale, *RPE* Rating of Perceived Exertion, *r* Pearson correlation coefficient

time to learn to operate the AMPK and higher prosthetic weight (i.e. $\Delta_{\text{AMPK-Current}}$: 690g-1650g), though the knee's motorized design is intended to offset the added weight of the prosthesis [39, 40]. The dual-task 2MWT, which involved both physical (i.e. level walking) and cognitive (i.e. serial subtractions) components, demonstrated a significant reduction in walking speed with the AMPK compared to the current prosthesis ($\beta = -0.34$ km/h). This decrease in walking speed may also potentially be attributable to the user accommodation time and weight difference with the AMPK. However, it should be noted that while using the AMPK, the number of responses to making serial subtractions was systematically higher than the current prosthesis (range β: 5–10).

We would typically expect a decline in performance on both tasks in a dual-task scenario, as dividing attention generally leads to reduced efficiency [29]. However, in our study, only the primary task performance declined, suggesting a cognitive trade-off where participants allocated more cognitive resources to the secondary task [29, 41]. While AMPK enhance gait and mobility, they are thought to increase cognitive load due to their complexity and the user's need to adapt to the technology. However, AMPK are expected to decrease cognitive load over time. Research indicates that passive microprocessor-controlled prostheses may actually improve dual-task performance compared to non-microprocessor-controlled prostheses [42]. As a result, more research is required to check at a longer-term how the use of AMPK influences the dual-task performance. In our study, we employed a dual-task paradigm involving serial sevens, specifically targeting the auditory attention/concentration, mental tracking, and computation of the brain [43]. Future research could expand upon this by incorporating other dual-task methods, such as reaction time tasks, controlled processing tasks, visuospatial tasks, mental tracking tasks, additional working memory tasks, and discrimination tasks [43]. These variations would engage different brain regions, offering a more comprehensive understanding of how various prosthetic devices affect cognitive functions [41].

Subjective outcomes

Subjective measures, including general fatigue, general comfort, and rate of perceived exertion, provided additional insights into the user experience. Participants reported significantly higher levels of fatigue and lower comfort during the L-test when using the AMPK ($\beta = 21$ and -56 respectively), indicating that the AMPK was more physically demanding and less comfortable. This increased demand could be attributed to the limited user accommodation time, and the additional weight and the effort required to control the prosthesis [7, 39]. Differences in average weight between the current knee prosthesis and AMPK ranged between 690 and 1650 g. Research is required to map the consequences of the trade-off between the additional weight and benefits (e.g. the increased assistance) provided by the AMPK, and how this balance affects user performance. On the other hand, no significant differences in comfort, fatigue or rating of perceived exertion were reported on the other functional tests. This suggests that, even with limited user accommodation time, the AMPK performed comparably to the current prosthesis. Moreover, the absence of significant differences could also point to the need for further exploration with a larger sample size to fully assess the benefits of the AMPK.

Correlation between subjective and performance outcomes

The weak correlations observed between performance metrics and subjective outcomes suggest that users' perceived exertion and comfort levels may not directly reflect their functional performance. This disconnect underscores the importance of considering both objective and subjective measures when evaluating prosthetic devices [44]. Future research combining these measures provides complementary insights into the user experience and identifies potential areas for improvement of the prosthetic design [45]. Additionally, given the exploratory nature of the correlation between subjective and performance outcomes, our small sample and missing data, we did not take into account individual variability and repeated measures.

Table 4 Individual characteristics

	Age [Years]	Height [cm]	Weight [kg]	BMI [kg/m^2]	Reason for amputation	Year of amputation	Current knee	Current foot	Δ_{Weight} current knee—AMPK [kg]
Participant 1	45	179	72	22.47	Vascular	2020	Genium	Triton side flex	± 0.690
Participant 2	56	173	97	32.41	Trauma	2015	C-Leg	Pro-flex torsion LP	± 0.925
Participant 3	40	166	70	25.40	Trauma	2011	Genium	Pro-flex align	± 0.690
Participant 4	65	179	65	20.29	Trauma	2015	Rheo	Proprio-foot	± 0.800
Participant 5	60	163	71	26.72	Vascular	2015	C-Leg	Triton	± 0.925
Participant 6	74	177	88	28.09	Trauma	2011	Kenevo	Trias	± 1.190
Participant 7	36	179	76	23.72	Cancer	1998	106 Pro	Trias	± 1.650

BMI Body mass index, *AMPK* Active microprocessor-controlled knee, Δ_{Weight} difference in weight between AMPK and current prosthetic knee

Therefore, future research should include the inclusion of hierarchical models to better account for individual variability and repeated measures, allowing for a more detailed analysis of within-subject effects and their impact on the relationships between subjective and objective measures.

Study limitations and future directions

While the study is novel in documenting the user accommodation involved in walking with an AMPK 1 hour per week over 5 weeks, participants had limited use of the device due to the availability of two AMPK's, which affected our study design and the interpretation of our results. Mahon et al. [20] observed that user accommodation reaches a plateau around 4 months of continuous use after a new passive ankle–foot prosthesis device is fitted, entailing that user accommodation to such prosthesis takes up to 4 months [20]. However, the translatability of our current findings to AMPK remains to be seen. Therefore, future research should dive into mapping the user accommodation process in function of the type of prosthesis. This could be achieved by utilizing both well-designed prospective studies and randomized controlled trials in which a sufficiently large sample of individuals receiving a new prosthesis are monitored at different time intervals (e.g. every month) over a predefined period (e.g. 6 months). To further explore the initial learning process with AMPK, generate more robust results and provide some clinical implications, future studies should involve continuous use of the PK over a predefined period (e.g. 5-weeks). Additionally, extending the evaluation to include a variety of clinical tests representative for daily activities such as stair climbing could provide a more comprehensive assessment of prosthetic functioning and user accommodation [23, 46].

Conclusion

This study assessed the weekly effects of an active microprocessor-controlled knee on daily activity performance among individuals with a transfemoral amputation over a 5-week period, revealing initial challenges in task completion times, dual task performance, and subjective comfort and fatigue levels, largely attributable to the limited prosthetic accommodation with a lack of training to learn to operate with the AMPK. These findings indicate that five one-hour sessions might be insufficient for achieving user accommodation. Consequently, our study underscores the need for further research with continued prosthetic use and user accommodation to optimise prosthetic functioning.

Appendix

See Table 4.

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Author contributions

EL drafted the work. EL, BT, AM, SG, LF, TV, KDP contributed substantially to the conceptualisation and the design of the work. SG contributed substantially to the patient recruitment. EL contributed substantially to the acquisition of the work. EL performed the data analysis and data interpretation of the work. All authors revised the work critically for important intellectual content and gave their final approval of the version to be published.

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Availability of data and materials

The authors declare that the data supporting the findings of this study are available within this article. The dataset supporting the findings of this study is available from the corresponding author, upon reasonable request.

Declarations

Ethics approval and consent to participate

All participants provided their written consent after being written and verbally informed regarding the study protocol. The study was approved by the medical Ethics Committee of the University Hospital of the Vrije Universiteit Brussel (B.U.N. 1432022000136). The study was also registered via ClincalTrials.gov under NCT05407545**.**

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Author details

[1]Human Physiology and Sports Physiotherapy Research Group, Vrije Universiteit Brussel, 1050 Brussels, Belgium. [2]Brussels Human Robotics Research Center (BruBotics), Vrije Universiteit Brussel, 1050 Brussels, Belgium. [3]Faculty of Rehabilitation Sciences, REVAL Rehabilitation Research Center, Hasselt University, Diepenbeek, Belgium. [4]Unit of Physical and Rehabilitation Medicine, Ghent University Hospital, 9000 Ghent, Belgium. [5]Robotics & Multibody Mechanics Research Group, Vrije Universiteit Brussel, 1050 Brussels, Belgium.

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