The efficacy of a motorized lower-limb prosthetic device: a pilot study

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Abstract

BACKGROUND Performing daily activities is challenging for individuals with a transfemoral amputation. Technological advancements in prosthetic prototypes aim at improving functional independence. A state-of-the-art active device, the CYBERLEGs-gamma (CLs-ɣ) prosthesis, consisting of powered ankle and knee joints, has been designed and constructed. The control system combines pressure-sensitive insoles and inertial motor units to synchronize both joints to work together. To date, the novel device has not been clinically evaluated. Therefore, the objective of this study was to investigate the efficacy of the CLs-ɣ prosthesis during daily activities compared to current passive and quasi-passive devices.

METHODS Participants performed a familiarization trial, an experimental trial with the current prosthesis, three adaptation trials and an experimental trial with the CLs-ɣ prosthesis. Participants completed a stair climbing test, a timed-up & go test, a sit to stand test, a two-minute dual task (i.e. the psychomotor vigilance task during treadmill walking) and a six-minute treadmill walk test at normal speed. Nonparametric Wilcoxon-signed rank tests were conducted with critical alpha set at 0.05.

RESULTS Eight individuals with a transfemoral amputation (age: 55 ± 15 years, K-level 3) were included. Stride length significantly increased during walking with the CLs-ɣ prosthesis ($p=0.012$) because of a greater step length of the amputated leg ($p=0.035$). Normal walking speed was significantly slower ($p=0.018$), the net metabolic cost of transport was significantly higher ($p=0.028$) and reaction time significantly worsened ($p=0.012$) when walking with the CLs-ɣ compared to the current prosthesis. When participants took stairs, they adopted a step-over-step strategy with the CLs-ɣ prosthesis in contrast to step-by-step wearing the current prosthesis.

CONCLUSIONS A higher physical effort and cognitive demand were required during activities wearing the novel motorized prosthesis. Although performance outcome measures did not improve, participants had a greater stride length and better simulated able-bodied stair ambulation.

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Keywords

Transfemoral – Amputation – Powered – Prostheses – Ankle – Knee – Clinical evaluation – Daily activities – Robotics

Background

Performing daily activities can be challenging for individuals with a transfemoral amputation (TFA). For example, a higher metabolic cost and reduced physical performance are shown during walking, ramp ambulation, stair climbing and rising from a chair [1–4]. Moreover, task characteristics differ. People with a TFA often ambulate stairs step-by-step, whereas step-over-step is common for able-bodied individuals [3]. During walking, an asymmetrical pattern is observed and additional attentional effort is required due to the lack of information coming from the proprioceptive system and loss of motor control [5, 6]. These challenges and adaptations lead to the development of secondary complications such as lower-back problems, osteoarthritis and discomfort of other joints [7].

The amputation of a limb is the leading cause for the aforementioned deficiencies. Current passive and quasi-passive devices can already restore certain daily functions. However, large improvements are possible through technological advancements. For example, active (powered, motorized) prostheses are already on the market, but are yet under-prescribed and under-utilized [8]. The reasons are the large costs related to the use of an active prosthesis and limited reimbursements by the health companies. Moreover, current active prostheses focus on improving walking abilities [9]. Although walking is a common daily activity, people with an amputation feel reduced functionality during many other daily activities. Therefore, the main goal of a novel prosthesis is to restore the loss of function so that individuals regain an independent lifestyle in society, participate in physical activities and thus improve their quality of life.

Engineers from the Vrije Universiteit Brussel recently designed, developed and constructed the CYBERLEGs-gamma (CLs-γ) prosthesis (Figure 1), the successor of the beta-version[10]. The novel prototype (technology readiness level: 5) consists of an integrated controller in the knee and ankle joints [11]. At the ankle joint, an actuator provides torque by compressing or decompressing series elastic springs, whereas a parallel spring system acts between the shank and the foot to reduce energy consumption by storing potential and kinetic energy during dorsiflexion and releasing it during plantarflexion [12]. At the knee joint, the actuator provides resistance, similar to eccentric muscle power, during the weight acceptance phase and is activated right before heel strike. Afterwards, the controller provides active torque, similar to concentric muscle power, during the stance phase when the knee is extending. The motion is constrained to the sagittal plane, i.e. flexion and extension. The CLs-ɣ prosthesis comprises the control system and electronics in the leg structure and still requires an external power source (battery

pack) to be placed on the pelvis. Electronics of the system are custom made boards to control not only the prosthesis, but also act as interface between the pressure-sensitive insoles that are instrumented in the shoes of both feet and the inertial motor units that are attached to the trunk and lower limbs [13]. A more detailed mechatronic description is available in literature [14].

[Insert figure 1]

Figure 1. The CYBERLEGs-gamma prosthesis. The knee actuator consists of the motor, gearbox and spindle, and the springs in series, acting on the knee joint through metal beams. The wearable apparatus consists of a motor moving the spring in and out of place. The ankle actuator consists of the motor, gearbox, and series and parallel springs acting on the ankle joint. The ankle and knee are clamped together, allowing a change in distance between the joints.

Evaluation of a prosthetic prototype is key in the iterative process of design and development of an innovative medical device. While prototype efficacy could provide valuable information for the engineers, the iterative evaluation process could be optimized by using a holistic approach which includes psychophysiological, biomechanical and physical performance outcome measures [9, 15]. Walking trials are frequently investigated, however, other daily activities, such as rising from a chair, taking turns and stair climbing are also important to improve the ecological validity of the experiment [16].

The aim of this study was to evaluate the CLs-ɣ prosthesis during daily activities. We hypothesized improved physical performance during stair climbing, sit to stand and walking with the CLs-ɣ compared to the current prosthesis. It was also hypothesized that walking with the CLs-ɣ restored a more symmetrical walking pattern (e.g. step length and width, stance and swing phases, and heel pressure), and decreased physical (e.g. metabolic cost, heart rate and rating of perceived exertion) and cognitive (e.g. reaction time) effort compared to the current prosthesis.

Methods

Recruitment

Nine participants with a transfemoral amputation (K-level > 2) were enrolled in the study [17]. The recruitment process was performed by the physiotherapist of an orthopaedic centre (VIGO, Wetteren, Belgium), where

experiments took place. Medicare Functional Classification level was subjectively determined by two independent physiotherapists (JG and PVDV) and in case of disagreement a medical doctor was contacted. The study was approved by the institutional medical ethics committee of UZ Brussel and Vrije Universiteit Brussel (Belgium, B.U.N. 143201732970) and the Federal Agency for Medicines and Health Products (FAMHP reference number: 80M0725). All participants were provided written and verbal information about the experimental protocol, potential risks and benefits before giving informed consent to participate in the study.

Experimental protocol

Each participant visited the laboratory six times for a familiarization session, an experimental trial with their current prosthesis, three adaptation trials and an experimental trial with the CLs-γ prosthesis (Figure 2). The total duration of this experiment (within subject design) was eight months. The environmental humidity, pressure and temperature of the laboratory was set at 48 ± 6 %, 764 ± 8 mmHg and 24.5 ± 1.6 °C; respectively. All appointments took place in the morning at the same hour and at least 24 hours between each session was planned to counteract fatigue. The familiarization trial aimed to accustom participants to the experimental protocol, to get used to the measurement devices and to determine the participants' normal walking speed. Normal walking speed was determined through verbal feedback from the participant. The investigator altered the walking speed until the participant confirmed the speed is consistent with the normal walking speed [18]. The recorded walking speed was kept constant during the experimental treadmill trials to enable comparisons between conditions. Furthermore, a duplicate of the participants' current socket was made to optimise fitting and alignment of the novel prosthesis. Participants were fitted to the novel device by a certified prosthetist and instructed during the different tasks by a physiotherapist.

[Insert Figure 2]

Figure 2. Experimental protocol including a familiarization trial – an experimental trial with the current prosthesis (passive or quasi-passive device) – three adaptation sessions to the novel prosthesis (i.e. the CYBERLEGs-gamma (CLs-γ) prosthesis) – an experimental trial with the CLs-γ prosthesis. The five tasks were a stair climbing test, a timed-up & go test, a sit to stand test, a two-minute dual task and six-minute treadmill walk test.

The main experimental trials with the current and CLs-γ prosthesis consisted of five consecutive tasks with ten minutes of rest between each task: the stair climbing test (SCT), the timed-up & go test (TUG), the sit to stand test

(STS), a two-minute dual task (i.e. the psychomotor vigilance task during treadmill walking) and a six-minute treadmill walk test (6MWT) [16, 19–23]. Description of each task can be found in aforementioned references. The walking tests were carried out at normal walking speed. Remark that during the psychomotor vigilance task participants had to respond by pushing a button with the index finger of their dominant hand. Earplugs were required during the task to reduce distraction related to sound. The visual stimulus, displayed as a red dot, was visualized on a computer screen with a random time interval between 1000 and 10000 ms. The interval stimulus-response onset was set at 500 ms and the distance to the screen was approximately one meter.

Between the experimental trials with the current and CLs-γ prosthesis, participants underwent three adaptation trials. The focus of adaptation differed among each trial: (*i*) socket fit and walking, (*ii*) alignment and SCT, (*iii*) STS and TUG. Participants were fitted and aligned to the novel device by a certified prosthetist and instructed during the different tasks by a physiotherapist. During each adaptation session, participants also performed hallway walking for ten minutes. Participants were free to move at their own pace and if needed crutches were allowed.

Dependent measures

Physical performance determinants were gathered in terms of duration (s) of the SCT and TUG, number of cycles during the STS, reaction time (ms) during the psychomotor vigilance task, normal walking speed ($m.s^{-1}$) and cadence ($steps.min^{-1}$) during the 6MWT. Biomechanical outcome measures (spatiotemporal and kinetics data) were recorded during walking. Cadence ($steps.min^{-1}$), maximum heel pressure ($N.[cm^2]^{-1}$), stance and swing phase (% of gait cycle), step width (cm) and stride length (cm) were reported. Physiological outcome measures (cardiovascular and respiratory) were collected in terms of heart rate (bpm) and session rating of perceived exertion (score between 0-10) after each experimental test. Oxygen uptake ($mL.[min.kg]^{-1}$), ventilation ($L.min^{-1}$) and metabolic equivalents were gathered during the 6MWT. Psychological outcome measures like the visual analogue scale (score on 100) for fatigue were collected after the five tests [24]. The EuroQol-5D (score on 100) was filled in before the test with the CLs-γ and current prosthesis [25]. Other questionnaires were completed during the familiarization, i.e. the prosthetic evaluation questionnaire and the system usability scale.

Measurement devices and data analysis

Spatiotemporal and kinetics data were collected with the Zebris software (Medical GmbH, Isny, Germany). Ground reaction force time-series were automatically reduced to zero-dimensional maxima under the forefoot,

midfoot and heel. Cadence, stance and swing phases, step width, step and stride length were continuously determined. Gait variability, expressed as the coefficient of variation, was calculated for step width, and step and stride length from the standard deviation dividing by the mean [26]. Ergospirometrical data were continuously gathered during the 6MWT using a portable system (Cosmed K5®, Cosmed, Rome, Italy). Preceding each test, a calibration (volume, ambient air and reference gas) was performed after a system warm-up period of thirty minutes. The setting mixing chamber was used, and data was continuously transferred to the program Omnia (Cosmed). The device was mounted on the back of the participant with a harness. The net metabolic cost of transport ($mL.[m.kg]^{-1}$) was calculated from dividing the relative oxygen uptake ($mL.[min.kg]^{-1}$) by the product of the duration of the test (min), the weight (kg) of the participant and the distance (m) covered during the test [27]. Heart rate was measured at the end of each task with an elastic belt strapped around the chest (Polar M400®, H7-sensor, Kempele, Finland). The performance outcome measure of the psychomotor vigilance task was reaction times, measured with E-prime 3.0 (Psychology Software Tools, Sharpsburg, USA).

Statistical analysis

Data are presented as mean (standard deviation). SPSS version 25.0 (International Business Machines Corporation, New York, USA) was used for statistical analyses. Shapiro Wilk normality tests showed that most datasets were not normally distributed. Therefore, nonparametric Wilcoxon-signed rank tests were conducted. The critical alpha for all analyses was set at 0.05. Effect sizes were calculated from dividing the absolute standard test statistics by the square root of the number of observations [28].

Results

One participant withdrew after the first trial for reasons not related to the study. Therefore, data analysis was performed on eight participants (one female and seven males; age: 55 ± 15 years; height: 174 ± 5 cm; weight: 81 ± 11 kg; table 1). An equal number of participants had an amputation of the right or left lower limb. Four participants' current prosthesis was passive, while the other half of the participants wore a quasi-passive device (microprocessor-controlled). Years since amputation varied among participants (22 ± 14 years), but they were all familiar with their current prosthesis for a minimum duration of three months.

Table 1. Participants' characteristics: demographic data, prosthetic components and normal walking speed.

Participant (gender)	Age (yrs)	Body weight (kg)	Body length (cm)	AMP side	Length stump (cm)	Suspension mechanism	Current prosthetic knee and ankle joint	Years since amputation	Speed ($m.s^{-1}$) current	Speed ($m.s^{-1}$) CLs-γ
1 (M)	65	72	172	L	28	Vacuum	Össur Total knee® Össur Flex walk®	41	0.83	0.83
2 (M)	34	76	178	R	36	Liner	Otto Bock C-leg® Otto Bock Taleo®	9	1.25	0.56
3 (M)	35	75	176	L	35	Vacuum	Össur Total Knee® Össur Variflex®	19	0.88	0.56
4 (M)	72	90	172	L	38	Strap	Otto Bock Genium® Otto Bock Taleo®	7	0.83	0.33
5 (M)	63	98	178	R	28	Vacuum	Össur Mauch® Össur Variflex®	29	0.44	0.33
6 (F)	55	83	165	R	30	Strap	Össur Total knee® Össur Flex walk®	34	0.61	0.33
7 (M)	56	90	179	L	35	Vacuum	Otto Bock C-leg® Otto Bock C-walk®	5	0.56	0.56
8 (M)	61	63	170	R	35	Liner	Otto Bock C-leg® Otto Bock C-walk®	30	0.83	0.56

All participants were indicated as Medicare Functional Classification Level K3 ambulators and had their current prosthesis for at least one month. Abbreviations: **AMP** amputated **CLs-γ** CYBERLEGs-gamma, **F** female, **L** left, **M** male, **R** right.

Gait biomechanics

Stride length significantly increased when walking with the CLs-γ compared to the current prosthesis (17 ± 10 %, p = 0.012; Table 2, Figure 3A). The increased stride length was due to a greater step length of the amputated leg (22 ± 20 %, p = 0.035; Table 2, Figure 3B). No significant difference in step length of the non-amputated leg was reported (Figure 3B). Step width did not significantly change while walking with the current and CLs-γ prosthesis. Coefficients of variation did not differ between both prostheses for stride length, step width, and step length of the amputated and non-amputated leg. The percentage duration of stance phases of the amputated and non-amputated leg did not vary between walking with the current and CLs-γ prosthesis. Additionally, swing phase did not differ between both prostheses. Maximum heel pressure of the amputated and non-amputated leg did not change while walking with the current compared to the CLs-γ prosthesis.

Table 2. Dependent variables are presented as mean and standard deviation, their corresponding p-value, absolute standard test value (Z) and effect size.

Variables	Current	CLs-γ	p-value	Z	Effect size	Variables	Current	CLs-γ	p-value	Z	Effect size
Stride length (cm)	84.75 (7.57)	99.38 (10.74)	0.012	2.52	0.63	Ventilation ($L.min^{-1}$)	31.46 (7.83)	29.61 (7.33)	0.398	0.85	0.28
Step length AMP leg (cm)	41.38 (4.60)	50.63 (8.55)	0.035	2.10	0.53	Metabolic equiva-lents	4.15 (1.13)	3.86 (1.20)	0.271	1.10	0.28
Step length N-AMP leg (cm)	43.63 (6.63)	48.75 (7.96)	0.231	1.26	0.32	Net metabolic cost ($mL.[m.kg]^{-1}$)	0.35 (0.13)	0.56 (0.16)	0.028	2.97	0.74
Step width (cm)	16.13 (5.00)	15.75 (3.06)	0.733	0.34	0.09	RPE SCT	2.00 (0.76)	2.50 (1.07)	0.334	0.97	0.42

CV stride length	0.06	0.03	0.075	1.78	0.45
CV step width	0.13	0.09	0.235	1.19	0.30
CV step length AMP leg	0.07	0.06	0.443	0.77	0.19
CV step length N-AMP leg	0.09	0.05	0.674	0.41	0.11
Stance phase AMP leg (%)	63.71 (3.19)	60.81 (9.00)	0.327	0.98	0.25
Stance phase N-AMP leg (%)	73.76 (4.08)	76.88 (7.74)	0.263	1.12	0.28
Swing phase AMP leg (%)	35.26 (5.16)	34.89 (10.50)	0.327	0.98	0.25
Swing phase N-AMP leg (%)	27.26 (2.04)	27.43 (10.10)	0.207	1.26	0.32
Heel pressure AMP leg ($N.cm^2$)	18.99 (4.75)	24.19 (5.41)	0.063	1.86	0.46
Heel pressure N-AMP leg ($N.cm^2$)	19.68 (6.17)	22.04 (3.91)	0.575	0.56	0.14
Heart rate SCT (bpm)	102 (18)	106 (17)	0.611	0.51	0.13
Heart rate TUG (bpm)	100 (16)	100 (17)	0.533	0.59	0.15
Heart rate STS (bpm)	108 (18)	104 (17)	0.204	1.27	0.32
Heart rate 6MWT (bpm)	120 (25)	113 (18)	0.893	0.41	0.10
Oxygen consumption ($mL.[min.kg]^{-1}$)	14.15 (4.01)	14.10 (3.80)	0.499	0.68	0.17
RPE TUG	1.90 (1.00)	1.75 (0.46)	0.739	0.33	0.08
RPE STS	3.00 (0.93)	2.63 (1.19)	0.180	1.34	0.34
RPE 6MWT	3.25 (1.04)	3.38 (1.30)	0.480	0.71	0.18
VAS SCT	2.09 (1.41)	3.48 (2.00)	0.093	1.68	0.42
VAS TUG	2.00 (2.02)	2.03 (1.90)	0.672	0.42	0.11
VAS STS	3.73 (2.15)	3.34 (2.08)	0.553	0.57	0.14
VAS 6MWT	3.48 (3.04)	3.63 (2.36)	0.735	0.34	0.09
EQ-5D	84.38 (9.43)	87.89 (9.05)	0.059	1.89	0.47
Speed ($m.s^{-1}$)	0.77 (0.25)	0.45 (0.12)	0.018	2.37	0.59
Cadence ($steps.min^{-1}$)	71 (13)	60 (9)	0.012	2.52	0.63
Reaction time (msec)	337 (56)	398 (65)	0.012	2.52	0.63
Duration SCT (sec)	16 (8)	36 (13)	0.012	2.52	0.63
Duration TUG (sec)	15 (6)	20 (6)	0.012	2.52	0.63
Number of stands	8.00 (3.00)	7.80 (3.28)	0.671	0.43	0.11

Abbreviations: **AMP** amputated, **CLs-γ** CYBERLEGs-gamma, **CV** coefficient of variation, **EQ-5D** EuroQol-5D, **N-AMP** non-amputated, **RPE** rating of perceived exertion, **SCT** stair climbing test, **STS** sit to stand test, **TUG** timed-up & go test, **VAS** visual analogue scale, **6MWT** six-minute walk test.

[Insert Figure 3]

Figure 3. Mean and standard deviation for stride (A) and- step length (B) are presented while walking with the current compared to the CYBERLEGs-gamma (CLs-γ) prosthesis. Abbreviations: **AMP** amputated leg, **N-AMP** non-amputated leg.

Physiological measures

Heart rate at the end of each task did not change when wearing the current compared to the CLs-γ prosthesis. The amount of oxygen consumption, ventilation and metabolic equivalents did not vary between walking with both prostheses. However, the net metabolic cost of transport significantly increased 61 ± 47 % when wearing the CLs-γ compared to the current prosthesis during the 6MWT ($p = 0.028$; Table 2, Figure 4).

[Insert Figure 4]

Figure 4. Representation of the net metabolic cost per meter during the six-minute treadmill walk test with the current compared to the CYBERLEGs-gamma (CLs-γ) prosthesis.

Subjective workload

No differences in session rating of perceived exertion and the visual analogue scale for fatigue were reported during the different tests between the current and CLs-γ prosthesis. The self-reported scores on the EuroQol-5D did not significantly change between both prostheses.

Task performance

Figure 5 shows that the normal walking speed was significantly lower with the CLs-γ compared to the current prosthesis (42 ± 21 % decrease, p = 0.018; Table 2). Cadence significantly decreased 12 ± 8 % while walking with the CLs-γ compared to the current prosthesis (p = 0.012; Table 2). It took participants significantly longer to respond to the stimulus on the psychomotor vigilance task while walking with the CLs-γ compared to the current prosthesis (19 ± 12 % increase, p = 0.012; Table 2). Participants significantly needed more time to complete the SCT and TUG with the CLs-γ compared to the current prosthesis (125 ± 75 % increase, p = 0.012 and 33 ± 21 % increase, p = 0.012, respectively; Table 2). Number of stands during the STS did not differ between both prostheses.

[Insert Figure 5]

Figure 5. Individual (1-8) and group average (MEAN) normal walking speed (mean and standard deviation) with the current (◊) versus the CYBERLEGs-gamma (CLs-γ) (□) prosthesis are displayed.

Discussion

The aim of this study was to investigate the effectiveness of a novel prosthesis, consisting of powered ankle and knee joints, during daily activities. The main finding was that the CLs-γ prosthesis reduced walking symmetry, and physical and cognitive effort during daily activities compared to current devices. Worth mentioning is that although performance outcome measures were not improved, participants wearing the novel prosthesis were able to conduct the step-over-step during stair climbing instead of the step-by-step strategy with their current prosthesis.

Little is known about powered ankle and knee joints incorporated in one prosthetic device. The approach of configuring both joints working together is a major challenge, which is reflected in the few studies that have already been conducted with other prototypes [29–32]. Previous research did not report improved functioning with the synchronized joints and the impedance or kinematic control-based mechanism. The CLs-γ prosthesis differs from previous prototypes since the finite state controller relies on pressure-sensitive insoles in the shoes and inertial motor units attached to the trunk and lower limbs. These novel mechanisms of the CLs-γ prosthesis showed to partially restore the capacity to exert some tasks that could not be performed with their current prosthesis. The most notable change was observed during stair ascending and descending where participants conducted the step-over-step instead of the step-by-step strategy. This reciprocal stair ambulation shows the possible functional capacity of motorized lower limb prostheses. Moreover, we assume that more able-bodied functioning would reduce the risk of overuse injuries and secondary complications.

Although stride length significantly increased with the novel prosthesis, the greater stride length did not approach values of able-bodied walking (CLs-γ: 99 ± 11 cm vs. able-bodied: 157 ± 5 cm) [33]. Stride length mainly increased as a result from a larger step length of the amputated leg. This exacerbated the asymmetrical walking pattern and did not contribute to a higher symmetry between the amputated and non-amputated leg. Also, gait variability of stride length, a measure for gait symmetry, did not significantly differ between the the CLs-γ and current prosthesis, an asymmetrical walking pattern remains present [26].

Walking with the CLs-γ prosthesis significantly increased oxygen consumption. A weight reduction of the next prototype would most likely decrease the net metabolic cost since it directly influences oxygen uptake. Second, the control system and interface need further development, which apparently affected gait and walking efficiency. This was recently observed in a study wherein the authors outlined that the controller parameters (passive and active loops) could influence the metabolic cost [34]. For example, torque-angle or torque-time optimization would benefit biological measures [35]. This obviously highlights the need of developing more sophisticated and user-specific controllers in future prototype development.

Some studies investigated the reaction time on an auditive stimulus during stepping and standing posture in people with a TFA [36]. In the current study, a longer reaction time on a visual stimulus was observed during treadmill walking when wearing the CLs-γ prosthesis. Therefore, to reduce the cognitive effort during gait, and to cope with

the increased physiological demand, participants' normal walking speed was slower with the CLs-γ compared to the current prosthesis. This means that walking with the novel device interferes with the individual's ability to focus on other tasks [6]. We suppose it may be possible that the increased cognitive demand was driven by lack of adaptation period to the novel device. The duration of an adaptation period varies among different studies, i.e. between a few hours, up to three weeks and even three months [37]. One study reported that after a few hours of adaptation all participants with a TFA were already able to properly perform daily activities with clinically relevant results for further development of the prototype [30]. Therefore, in the current study we implemented three adaptation sessions of in total approximately three hours to prepare them for the experimental trials. We assume it may be possible that the adaption was enough to gather relevant outcomes for the development process, but apparently not sufficient to obtain an automatized gait pattern, and thus participants were unable to conduct an additional task.

A limitation of this study is that the 6MWT was performed on a treadmill, while – according to the standardized procedure – it should be conducted in a hallway [16]. It is been proven though that the treadmill 6MWT showed a high test-retest reliability [23]. The treadmill 6MWT was chosen for safety of the participants, since the CLs-γ prosthesis reached technology readiness level 5, whereas the hallway 6MWT is recommended for more developed prototypes. We also did not record kinematics during walking and the results are only relevant for individuals with a TFA, classified as MFC level K3. A bigger sample size (average 10 [9]) is also recommended in future research since the current study demonstrated for several parameters (maximum heel pressure, step width, stride length, swing phase and step length of the non-amputated side and heart rate during STS) moderate effect. In a next step, it is advised to include an adaptation period of three months at a higher technology readiness level (≥ 6, i.e. 'model or prototype demonstration in a relevant environment') to map long-term adaptation of the novel prosthesis [11].

Conclusion

The CYBERLEGs-gamma prosthesis consists of powered ankle and knee joints meant to replace a human ankle-knee system for various tasks including walking, sit to stand, and stair climbing. A higher physical and cognitive effort were required during walking with the novel prosthesis compared to current devices. Overall, our hypotheses were rejected, meaning that technological advancements in lower limb prosthetics are required to enable synchronized and powered ankle and knee joints. Although performance outcome measures were not improved,

participants wearing the novel prosthesis better simulated able-bodied stair ambulation. All participants were able to conduct stairs with the step-over-step instead of the step-by-step strategy.

List of Abbreviations

AMP amputated

CLs-ɣ CYBERLEGs-gamma

CV coefficient of variation

EQ-5D EuroQol-5D

F female

L left

M male

N-AMP non-amputated leg

R right

RPE rating of perceived exertion

SCT stair climbing test

STS sit to stand test

TFA transfemoral amputation

TUG timed-up & go test

VAS visual analogue scale

6MWT six-minute treadmill walk test

Declarations

Ethics approval and consent to participate

The study was approved by the institutional medical ethics committee of UZ Brussel and Vrije Universiteit Brussel (Belgium, B.U.N. 143201732970) and the Federal Agency for Medicines and Health Products (FAMHP reference number: 80M0725). All participants were provided written and verbal information about the experimental protocol, potential risks and benefits before giving informed consent to participate in the study.

Consent for publication

Consent for publication of results is obtained from all participants.

Availability of data and materials

All data generated or analysed during this study are included in this published article.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

JGH substantially contributed to the conception of the methods used, participant recruitment, data acquisition, interpretation and analysis, and writing the manuscript. JGE and LF made substantial contributions to the conception of the methods used, participant recruitment, and data acquisition, interpretation and analysis. SDB, RG, KDP and BR made substantial contributions to conception, design and writing the manuscript. SC, NV, RM and DL were involved in the conception of the methods used, data interpretation and writing the manuscript. All authors read and approved the final manuscript.

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