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Enhancing Walking Performance With a Bilateral Hip Exoskeleton Assistance in Individuals With Above-Knee Amputation

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***Abstract*— Transfemoral amputation is a debilitating condition that leads to long-term mobility restriction and secondary disorders that negatively affect the quality of life of millions of individuals worldwide. Currently available prostheses are not able to restore energetically efficient and functional gait, thus, recently, the alternative strategy to inject energy at the residual hip has been proposed to compensate for the lack of energy of the missing leg. Here, we show that a portable and powered hip exoskeleton assisting both the residual and intact limb induced a reduction of walking energy expenditure in four individuals with above-knee amputation. The reduction of the energy expenditure, quantified using the Physiological Cost Index, was in the range [−10, −17]% for all study participants compared to walking without assistance, and between [−2, −24]% in three out of four study participants compared to walking without the device. Additionally, all study participants were able to walk comfortably and confidently with the hip exoskeleton overground at both their self-selected comfortable and fast speed without any observable alterations in gait stability. The study findings confirm that injecting energy at the hip level is a promising approach for individuals with above-knee amputation. By reducing the energy expenditure of walking and facilitating gait, a hip exoskeleton may extend mobility and improve locomotor training of individuals with above-knee amputation, with several positive implications for their quality of life.**

***Index Terms*— Exoskeletons, transfemoral amputation, wearable robots, gait assistance.**

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This work involved human subjects or animals in its research. Approval of all ethical and experimental procedures and protocols was granted by the Local Ethics Committee, namely the Comitato Area Vasta Centro Toscana under Protocol ID: CLs++ 2ndCS and Approval No. 16454_spe.

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I. Introduction

TRANSFEMORAL amputation is a debilitating condition that leads to long-term mobility restriction and secondary disorders that negatively affect the quality of life of millions of individuals worldwide [1]. Individuals with above-knee amputation exhibit altered kinematic patterns, asymmetric, slower, and inefficient gait, as they typically walk only for short distances, with a 30% reduced speed and consuming 30-60% more energy compared to non-disabled individuals, [2], [3], [4]. Commonly prescribed prostheses are passive devices that are not able to emulate the biomechanical functions of the missing biological limb since they cannot actively produce net positive mechanical work during locomotion. As a result, to compensate for the lack of net positive energy of the missing ankle joint, individuals with above-knee amputation overload the intact and the residual limb muscles for generating body propulsion, leg advancement, support, and balance during gait [5].

Powered prostheses have the potential for restoring physiological gait, by injecting energy at the proper time of the gait cycle through motors that replicate the functionality of the missing joints. Unfortunately, adding battery and motors increases the weight of the device and currently most of the available powered prostheses have still considerable weight. The weight is particularly critical due to the distal location of the prosthesis that is suspended on the residual limb. Indeed, the penalty on walking performance in energy expenditure, stability and gait asymmetry is higher when a mass is added far from the center of the body mass [6], [7],

[8], [9], [10], [11]. Successful design optimizations have been proposed for prostheses weight reduction. However, so far these devices have not shown consistent improvement in the walking economy in individuals with above-knee amputation.

The hip and ankle joints are the major producers of positive energy during walking [12]. Thus, recent studies investigated the effect of assisting the hip via powered exoskeletons to compensate for the lack of energy at the ankle in transfemoral amputees [10], [13]. The mass of a powered hip exoskeleton is closer to the body's center of mass, as a consequence the metabolic penalty of carrying the added mass is reduced [6]. Preliminary results showed that powered hip exoskeletons can improve walking economy and biomechanical patterns [10], [13], [14], [15]. Specifically, in [13] authors report that a unilateral hip exoskeleton improved the metabolic cost of walking by 15.6% in six individuals with above-knee amputation by injecting energy at the residual hip joint. However, considering that people with transfemoral amputation overexert not only the residual hip but also the hip and ankle joints of the intact limb [2], bilateral hip assistance might be a valuable strategy for assisting gait in this population. Indeed, previous biomechanical studies have shown that individuals with limb amputation exhibit increased work from the ankle plantar flexors and hip extensors on the unaffected side compared to biomechanical work measured in nonamputee individuals. This increased activity is likely a compensatory mechanism to counterbalance the diminished push-off power from the amputated limb [2].

Here, supported by a pilot experiment [14], we explored the effects of bilateral hip assistance on walking performance in individuals with above-knee amputation by comparing walking with and without a portable Active Pelvis Orthosis (APO). The study aimed to investigate whether bilateral hip assistance could elicit improvement in walking performances, including walking energy expenditure, speed, and kinematics. Firstly, the experiment was devoted to tuning the bilateral hip assistive profile for reducing walking energy expenditure. Secondly, the selected hip assistive profile was tested to verify (i) gait efficiency and kinematics during treadmill-based walking and (ii) functional outcomes (gait speed and symmetry) during overground walking. Both on the treadmill and overground, the assessment was performed by comparing the following three walking conditions within a single session: (i) natural walking (i.e., walking without the hip exoskeleton, NoAPO), (ii) walking with the hip exoskeleton controlled in *transparent*mode (TM), i.e., providing zero output torque and (iii) walking with the hip exoskeleton in *assistive* mode (AM), i.e., providing flexion-extension hip torque.

II. Study Participants

The study participants were individuals with unilateral transfemoral amputation, exhibiting mild-to-moderate gait deviations and capable of independent gait. Participants were recruited among individuals with above-knee amputation, aged between 30 and 80 years old, who had completed post-amputation rehabilitation and had a residual mobility level equal to or lower than K3 (Medicare Functional Classification Levels) [16]. Exclusion criteria included: (1) relevant comorbidities (e.g. hemiplegia, degenerative nervous system diseases, hip or knee replacement, chronic heart failure, chronic obstructive pulmonary disease, severe sensory deficits, etc.); (2) stump pain or issues with socket fitting; (3) inability to walk on a treadmill; (4) poor cognitive skills (Mini-Mental State Examination < 24 [17]); (5) severe anxiety or depression (State-Trait Anxiety Inventory-Y > 60 [18] and Beck Depression Inventory-II > 29 [19], respectively); (6) implantable cardiac devices, such as pacemakers or automatic defibrillators, (7) physician disapproval of participation.

In total, four subjects were enrolled for this study (mean age: 52 ± 16 years old; all men; time since amputation in the range [1-39] years; two subjects exhibited left-side amputation).

The study included participants with various prosthesis types and prior experience using the APO. A detailed description of the four participants is reported in Table I. All participants were informed about the purpose of the study, procedures, and data treatment and signed an informed consent before starting the experiment.

III. The Active Pelvis Orthosis

The Active Pelvis Orthosis is a bilateral powered hip exoskeleton designed to assist hip flexion-extension movements by providing smooth assistive torque at the hip level and automatically adapting to natural gait variations. The APO can provide support to individuals with mild-to-moderate gait impairments, capable of independent gait.

The APO system used for this study was based on the same mechatronic architecture as previously reported prototypes [20], [34], [35], with additional design optimizations for portability and weight reduction to 5.7 kg (5.2 kg without the battery).

The APO can deliver the desired torque pattern through a hierarchical control algorithm relying on accurate gait phase recognition for synchronization of the assistive action with the movement of the user. The gait phase is estimated by continuously tracking the hip joint angles through a pool of Adaptive Oscillators and using a wavelet-based initial contact detection method for cyclic smooth reset of the gait phase, in accordance with the methodology proposed in [21].

The relatively low output impedance of the APO combined with the reliable real-time estimation of the gait phase allows to control the APO in two different operational modes, namely Transparent mode (TM) and Assistive mode (AM). In TM, the controller sets the desired torque to 0 N·m and the APO is transparent to the user's residual movement ability, i.e., the user can walk, and the APO provides minimal-to-null resistance to the user. In AM, the APO provides phase-locked torque profiles. The torque profile can be independently designed for each hip joint, as the sum of two Gaussian functions [14]. For each Gaussian function, the experimenter can tune the following parameters: (i) the position of the center, i.e., the timing of the torque peak (% of the gait phase), (ii) the height of the peak, i.e., the amplitude (N·m) of

TABLE I
CHARACTERISTICS OF STUDY PARTICIPANTS

		ID1	*ID2*	*ID3*	*ID4*
Personal data	**Age**	73	34	54	48
	Sex	M	M	M	M
	Height [m]	1.80	1.74	1.66	1.62
	Weight [kg]	67	104	78	98
	Medicare Functional Level	K3	K2	K3	K3
	Experience using APO	Yes	No	Yes	No
Prosthesis	**Knee**	*MPK*	*MPK*	*Mech*	*Mech*
	Foot	ESAR	Rigid	ESAR	ESAR

Legend: ESAR: Energy storing and return, Mech: Mechanical knee joint, MPK: Microprocessor controlled prosthetic knee

the torque peak [positive/negative to deliver flexion/extension assistance respectively] and (iii) the width of the curve, i.e., the duration of the assistance (% of the gait phase).

IV. Study Design

The study was carried out at the clinical center IRCCS Fondazione Don Carlo Gnocchi of Florence (Italy) and lasted approximately ten months. The experimental protocol was approved by the local Ethics Committee, namely the Comitato Area Vasta Centro Toscana (Protocol ID CLs++ 2ndCS, approval numbers 16454_spe).

The primary outcome of the study was the gait efficiency of individuals with above-knee amputation, assessed through the physiological cost index (PCI) during treadmill walking under different conditions (i.e., NoAPO, TM, AM). Secondary outcomes included gait symmetry and kinematics during treadmill walking and gait speed and symmetry during overground walking.

For each participant, the protocol included 7 sessions conducted on different days over 2 weeks: one enrollment session, three tuning and familiarization sessions followed by a test session on the treadmill, and one familiarization session followed by a test session overground (Fig. 1).

In the *Enrollment* session, clinicians verified the inclusion/exclusion criteria. Then, the participant donned a heart rate sensor and walked on the treadmill to select a comfortable treadmill speed. After two minutes of treadmill walking at a comfortable speed, a physical therapist adjusted the treadmill speed, so the participant's heart rate (HR) remained in the range of 55-65% of the HR_{max} [22], named HR_{ref}. The selected speed was used in the following sessions on the treadmill. This criterion allowed sustained and comparable exercise intensity across participants.

After the *Enrollment* session, three sessions (session #2-3-4) were devoted to the tuning of the assistive profile and to familiarization with the hip assistance on the treadmill.

At the beginning of each session, participants donned the heart rate sensor and the APO. Experimenters adjusted the APO passive regulations and straps to ensure a proper fit for the participants. Afterwards, the assistance tuning procedure started. The tuning procedure was dedicated to finding the appropriate set of assistive parameters for improving the gait efficiency of the participant during treadmill walking. The assistive parameters were manually tuned by experimenters with a cascade approach. The tuning procedure started with a bilateral biomimetic assistance, i.e., a flexion/extension assistive profile imitating the physiological hip moment. Torque timing and duration were set as in the pilot experiments [14]. The torque amplitude was gradually increased bilaterally both in the flexion and extension phase to reach ~0.1 N·m/kg; and when movements of the socket or an abnormal gait pattern were noticed, the assistance amplitude was slightly reduced. The walking cadence of the participants with the selected assistance was recorded and used to set a metronome. The metronome was used to keep a fixed cadence. This criterion was employed to have a comparable number of strides across walking conditions (NoAPO, AM, TM), and to prevent a potential bias in the assessment of the energy expenditure. After a brief familiarization (about 5 minutes) with the initial hip assistance, its effect on the energy expenditure was assessed by comparing alternate 3- to 4-minute bouts of walking on the treadmill with and without the assistance (AM, TM). If the HR of the participant was not reduced when walking in AM compared to TM, different assistance parameters were explored. These adjustments in the assistive profile, such as fine-tuning the torque timing or amplitude, were assessed using the same procedure: a 5-minute familiarization period followed by alternating 3- to 4-minute bouts of walking on the treadmill with and without assistance (AM, TM).

After the tuning and familiarization sessions, the test session (*TRM – Test session*) was devoted to the assessment of the APO in terms of gait efficiency and gait biomechanics during treadmill walking. At the beginning of the experiment, participants sat for 4 minutes to record the HR during resting, considered as the baseline. Next, the participants walked on the treadmill in TM, AM and without the APO, at the cadence and speed fixed during the *Enrollment session*. The different walking conditions were alternated using a symmetrical design (see Fig. 1), which was adopted to avoid the bias introduced

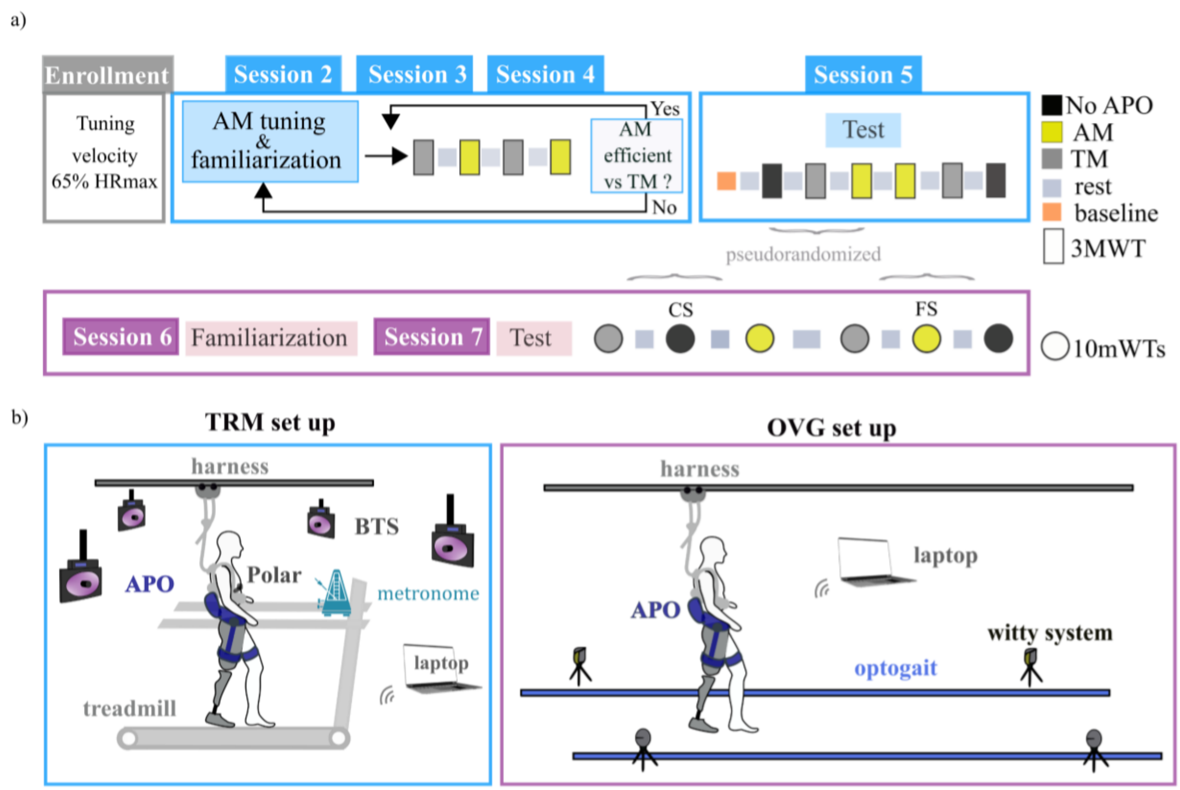

Fig. 1. **Schematic of the experimental protocol and setup.** a) The experimental protocol consisted of 7 sessions. The first (Enrollment) session included the evaluation of the study participants' eligibility. Following the Enrollment (day1) participants performed four sessions walking on the treadmill (TRM) and two sessions overground (OVG). Gait performance were evaluated at different walking conditions: (i) without the APO (black, NoAPO) (ii) with the APO in transparent mode (grey, TM), (iii) with the APO in assistive mode (yellow, AM). During overground sessions 10 meter walking tests (10mWTs) were performed at self-selected comfortable (CS) and fast speed (FS). b) The experimental setup for the TRM sessions consisted of a treadmill, a metronome, the Polar system to measure the participant's heart rate. In addtion, in session#5 the BTS system was used to record the gait kinematics. The experimental setup for the OVG test session consisted of the Witty and the Optogait system to assess gait speed and spatiotemporal parameters. In both the setup, a body harness was used to ensure participant's safety and a laptop to control the APO.

by the sequential order, and to mitigate any potential familiarization or fatigue effect. Participants were allowed to touch the handrails during walking, if needed, and were required to maintain this choice across sessions and walking conditions. All study participants opted to walk by holding both hands on the handrails during all the treadmill walking trials. Between each walking condition, the participants rested for a short duration of between 3 and 6 minutes, until the HR returned to the baseline value. To ensure accurate and reliable HR measurements and minimize external influences, multiple precautions were implemented throughout the experiments. These precautions included control of environmental conditions, such as temperature, acoustic noise, and the number of people in the experimental room, and limiting undesired acoustic and visual stimuli for the participant. Additionally, considerable attention was placed on establishing a baseline measure characterized by a low standard deviation and ensuring consistent participant behaviour during walking trials.

At the end of the *TRM – Test session*, the participant was asked to perform a two-minute walking test under the three conditions (NoAPO, TM, AM) and the gait kinematics was recorded during the last minute of each condition.

After the *TRM-Test session*, two sessions (session #6,7) were devoted to investigating the effect of the same hip assistance on the gait speed during overground walking. Session #6 was dedicated to warming up and familiarization with the APO overground, and session #7 was devoted to the assessment (*OVG – Test session*). During the familiarization, participants walked on a 23-meter walkway at their self-selected comfortable (SS) and fast speed (FS). During the test session, participants walked on the same walkway under the three different conditions (NoAPO, TM, AM), three times per condition. The walking speed was measured over a 10-meter segment placed in the middle of the walkway.

Both in the *TRM – Test session* and in the *OVG – Test session*, the order of the test conditions was randomized between APO and NoAPO firstly and between TM and AM secondly, to avoid the sequential bias and minimize the procedure of donning/doffing the APO.

V. Data Collection and Data Analysis

The PCI was computed according to the following equation:

$$PCI\left(\frac{beats}{meter}\right) = \frac{\overline{HR}_{walking} - \overline{HR}_{baseline}(bpm)}{gaitspeed(meter/min)}$$

where $\overline{HR}_{walking}$ and $\overline{HR}_{baseline}$ are the average values of HR computed, respectively, during the last 2 minutes of the walking condition and of the baseline in sitting position (measured in beats per minute, bpm) [23], [24]. The HR was measured through a chest heart rate sensor system (Polar H10). The PCI values of the first and second bout of walking in the same condition (AM, TM, NoAPO) were averaged and these average values were used to compute the percentage change across conditions.

Gait spatiotemporal parameters (e.g., cadence, stride time, stance time and step length) were measured from the instrumented treadmill (C-Mill, MOTEK, the Netherlands) in the *TRM*sessions and from an optoelectronic walkway (Optogait, Microgate, Bolzano, Italy) during the *OVG*sessions. Spatial and temporal gait symmetry was computed using the Symmetry Ratio, as follows [25]:

$$SymmetryRatio\,(-) = \frac{V_{prosthesis}}{V_{sound}}$$

where V_V is the step length (cm) for the spatial symmetry and the stance time (% of the gait cycle) for the temporal symmetry.

The overground walking speed was measured by means of two photocells (Witty, Microgate S.r.l., Italy) placed 10 m from each other, in the middle of the corridor.

Gait biomechanics was measured using a stereophotogrammetric motion capture system (Smart-DX, BTS Bioengineering, Milano, Italy). Twenty-two reflective optical markers were placed on anatomical landmarks, following the Davis protocol [26]. In the case of gait analysis with the APO, the marker on the sacrum and the markers on the left and right greater trochanter were masked by the APO and they were moved from the anatomical landmark to the robotic frame. Trajectories of optical markers were collected and processed through the BTS Smart software (Smart-DX, BTS Bioengineering, Milano, Italy). Mean and standard deviation values of the lower-limb kinematic profiles were computed. Range of Motion (RoM) on the sagittal plane of hip, knee and ankle joints was computed as difference between maximum flexion and extension joint angle.

The APO data (including hip angle and torque) were acquired and analysed offline in Matlab (Mathworks Inc, Natick, USA). From the hip angle, we estimated the hip joint velocity and the delivered assistive power. Hip angle, torque, and power signals were then segmented into single strides using the initial foot contact estimated online by the method reported in [21].

VI. Results

A. Treadmill Test: Gait Efficiency and Kinematics

Fig. 2a reports the PCI values of the assessment test of each study participant. The APO in AM reduced the PCI relatively to the NoAPO condition in three out of four participants, respectively by -7.7%, -1.9% and -24.0% for ID1, ID2 and ID4, whereas it increased the PCI by 8.2% in ID3. All study participants showed lower PCIs in AM compared to TM, with reductions equal to -12.0% (ID1), -9.7% (ID2), -9.6% (ID3), and -16.5% (ID4).

In terms of gait symmetry, two out of four participants improved both the spatial and temporal symmetry walking with the APO in AM compared to walking without the APO respectively by 8.8% (ID2), 4.4% (ID4) and 1.0% (ID2) and 4.3% (ID4). Comparing walking with the APO in AM versus TM, two subjects improved their spatial symmetry ratio by 10.1% (ID2) and 9.3% (ID4), and their temporal symmetry ratio by 1.0% (ID2) and 3.9% (ID4). The other two study participants, ID1 and ID3, did not change their gait symmetry under the different walking conditions (Fig. 2b). Three out of four participants were able to follow the metronome, by maintaining the same cadence in all the different walking conditions [respectively of 44 steps/min (ID1) and 45 steps/min (ID2 and ID3)]. ID4 slightly changed the walking cadence under the different walking conditions, walking, on average, with a cadence of 42.4 steps/min in TM, 41.2 steps/min in AM, and 42.7 steps/min in the NoAPO condition (Fig. 2b).

In terms of kinematics, the RoM of the hip and the ankle of the intact limb were larger with the APO in AM than without the APO 13% (6.8°) and 9% (2.6°), respectively for the hip and ankle joints). No relevant differences were observed in the RoM of other joints. On the prosthesis side, a slight increment of the residual hip RoM was observed for all participants (2.1° in AM, 3.8 in TM), whereas a reduction of 17.3° of the ankle RoM was observed only in the participant with the rigid prosthetic foot (Fig. 3).

B. Overground Test: Gait Speed and Symmetry

Fig. 4 reports the results of the 10mWTs performed at comfortable and fast self-selected walking speeds under different conditions (NoAPO, TM, AM). Three out of four participants walked slightly faster with the APO in AM compared to NoAPO condition at their fast speed [+1.4% (ID1), -3.1% (ID2), +0.7% (ID3), +16.1% (ID4)] and two out of three participants also at the comfortable walking speed [-5.8% (ID2), +3.9% (ID3), +8.6% (ID4)]. ID1 did not perform the test at the comfortable speed.

All study participants walked slower with the APO in TM compared to AM, on average by 4.23% at fast speed and by 4.6% at comfortable speed. In addition to the speed, Fig. 4 reports spatial and temporal gait symmetry measured during overground walking under different conditions (NoAPO, TM, AM). At the fast self-selected speed, when comparing walking with the APO in AM and without the APO, only minor variations of approximately 1% were observed in terms of spatial symmetry and temporal symmetry. At the comfortable self-selected walking speed, comparing walking with the APO in AM and without the APO, all participants slightly improved their temporal gait symmetry on average by 1.75%. Regarding spatial symmetry, two participants experienced slight improvements, while one participant exhibited a minor deterioration. In both cases, these changes were of small magnitude.

VII. Discussion

The use of wearable assistive technologies, such as powered hip exoskeletons, which can either reduce the energy expenditure necessary for walking at a certain gait speed or enable faster walking, holds the potential to amplify mobility and ease

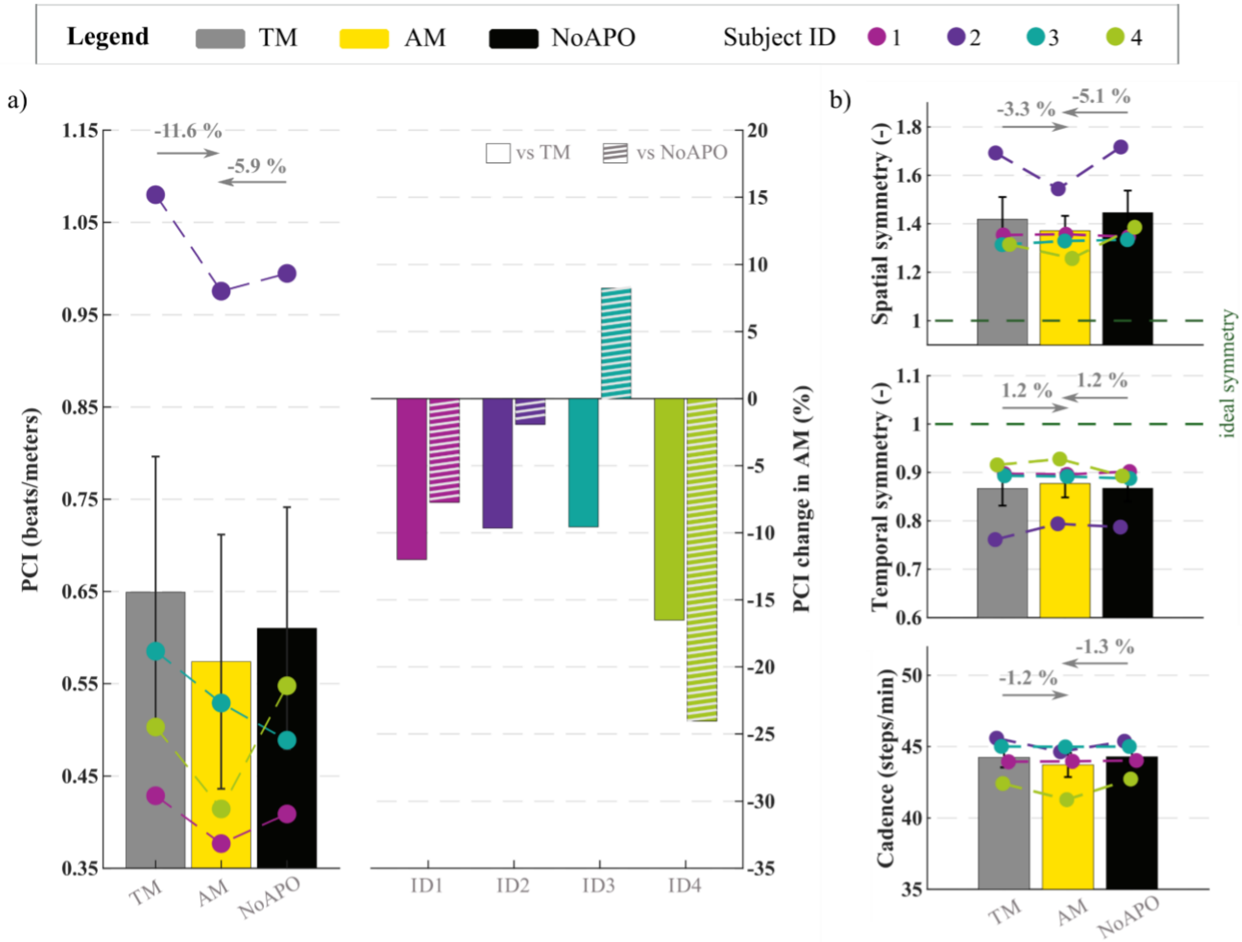

Fig. 2. **Results of the treadmill test: gait efficiency and spatiotemporal parameters.** a) Physiological cost index (PCI) during treadmill walking under different conditions, i.e., without the APO (NoAPO, black), with the APO in assistive mode (AM, yellow), with the APO in transparent mode (TM, grey). On the left, bar plots represent the PCI (beats/meters) averaged across all participants (n=4), error bars show the standard error of the mean (s.e.m.). Colored circles represent individual study participants. On the right, for each participant colored bars represent the percentage change in the PCI of walking with the APO in AM compared to walking with the APO in TM (no pattern) and without the APO (pattern line). b) From top to bottom, spatial symmetry ratio, temporal symmetry ratio and cadence (steps/min) averaged across all study participants (mean, s.e.m.). Full spatial and temporal symmetry is indicated with dashed horizontal lines (green).

locomotor training for individuals with transfemoral amputations. These advancements may have profound implications for improving their overall quality of life [27]. The results of this study on four individuals with above-knee amputation showed that the use of the APO providing bilateral hip flexion/extension torque during treadmill walking led, on average, to higher gait efficiency (i.e., reduced the PCI) compared to walking without it. All study participants were able to walk overground with the APO at both their comfortable and fast self-selected speed, including starting and stopping, without any observable alterations in gait stability and quality. A single study participant also showed a considerable increase in comfortable and fast self-selected speed when walking with the APO in AM compared to TM and NoAPO conditions (ID4).

To date, only a few studies have shown a marked reduction in energy expenditure during walking in individuals with above-knee amputation due to the use of powered assistive technologies, namely powered prostheses, or exoskeletons [10], [13], [28], [29]. Some studies have shown metabolic reductions in the range of 5-6.5% when walking with microprocessor-controlled prostheses compared to walking with passive prostheses [28], [29], while a recent study investigated the effect of using a unilateral hip exoskeleton in individuals with above-knee amputation and found an average reduction of 15.6% in metabolic cost compared to walking without it [10], [13]. The unilateral exoskeleton was designed to provide hip flexor-extensor assistance on the users' prosthetic side, and it was controlled to exert up to 0.1 N·m/kg. Interestingly, the unilateral hip exoskeleton was used in combination with the users' own (passive) prostheses, suggesting that assisting the hip joint is a valuable alternative to microprocessor-controlled prostheses to improve gait functions of individuals with lower-limb amputation.

In this framework, the goal of the present study was to investigate the effect of bilateral hip assistance in individuals with above-knee amputation, as this may have positive implications to reduce the overexertion that individuals with above-knee amputation typically experience on their sound and residual hips. The torque amplitude was set to 0.1 N·m/kg on both

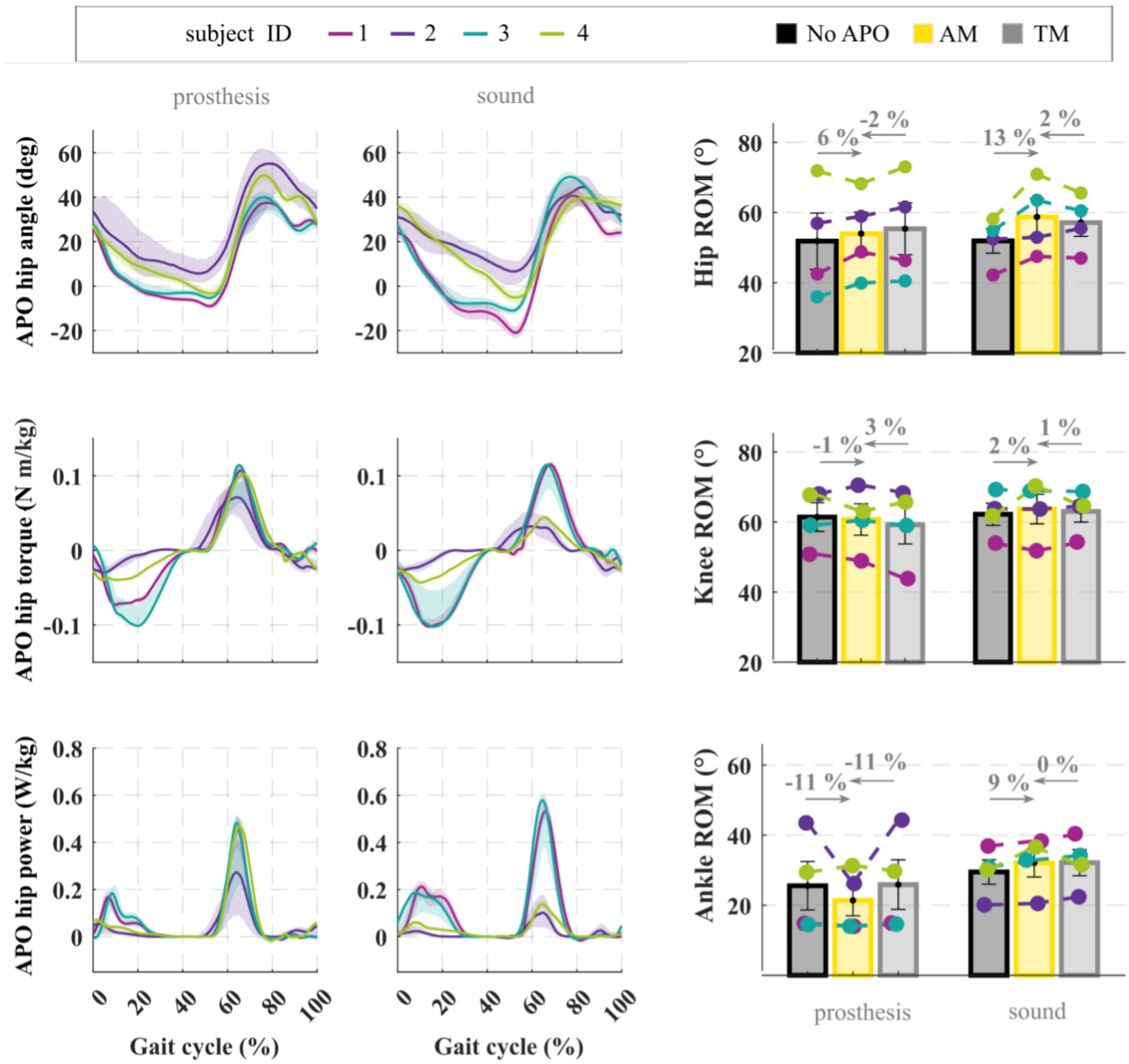

Fig. 3. **Lower limb kinetics and kinematics measured during treadmill walking.** On the right hip angular profiles, APO output torque and power in AM measured by APO onboard sensors of the prosthesis and sound side for each participant. On the left, range of motion of the prosthesis and sound side during treadmill-based walking (i) without the APO (NoAPO, black), (ii) with the APO in assistive mode (AM, yellow), (iii) with the APO in transparent mode (TM, grey). Range of motion (ROM) on the sagittal plane for the hip, the knee and the ankle joints, averaged across participants, is shown as means ± s.e.m. Individual range of motion for each participants is reported as a circle in the corresponding color.

the prosthetic and the sound sides, similarly to the previous study with unilateral assistance. In line with such previous research, this preliminary study indicates that injecting energy at the hip level could improve the gait efficiency of individuals with transfemoral amputations, as three out of four subjects reduced their metabolic consumption during walking between -2% and -24% compared to walking without the device. Notably, the benefit induced by the bilateral hip assistance in this study was, on average, lower than the one observed with unilateral hip assistance in previous research [13]. Among all possible factors that may have contributed to the different result, the differences in the experimental protocol and types of measurement, the characteristics of the study participants, and the weight of the device might have played a crucial role [6]. Such methodological differences prevent us from a direct comparison of the outcomes and therefore, from drawing conclusions about which approach is more effective.

The differences in the experimental protocol should be considered for a more thorough interpretation of the results and comparison with other studies. The first consideration regards the gait speed and cadence of walking trials. Biomechanical studies have shown that the hip joint provides higher positive mechanical work during walking at higher cadence and speeds than at self-selected comfortable walking speed [30], [31]. Requião et al., observed that the muscular utilization ratio (also called “mechanical demand”) in healthy subjects increased from 21% to 50% and from 15% to 43%, respectively for hip flexors and extensors, when the cadence increases from 60 to 120 steps/min [31]. Therefore, it can be hypothesized that adding flexion-extension positive energy throughout the gait

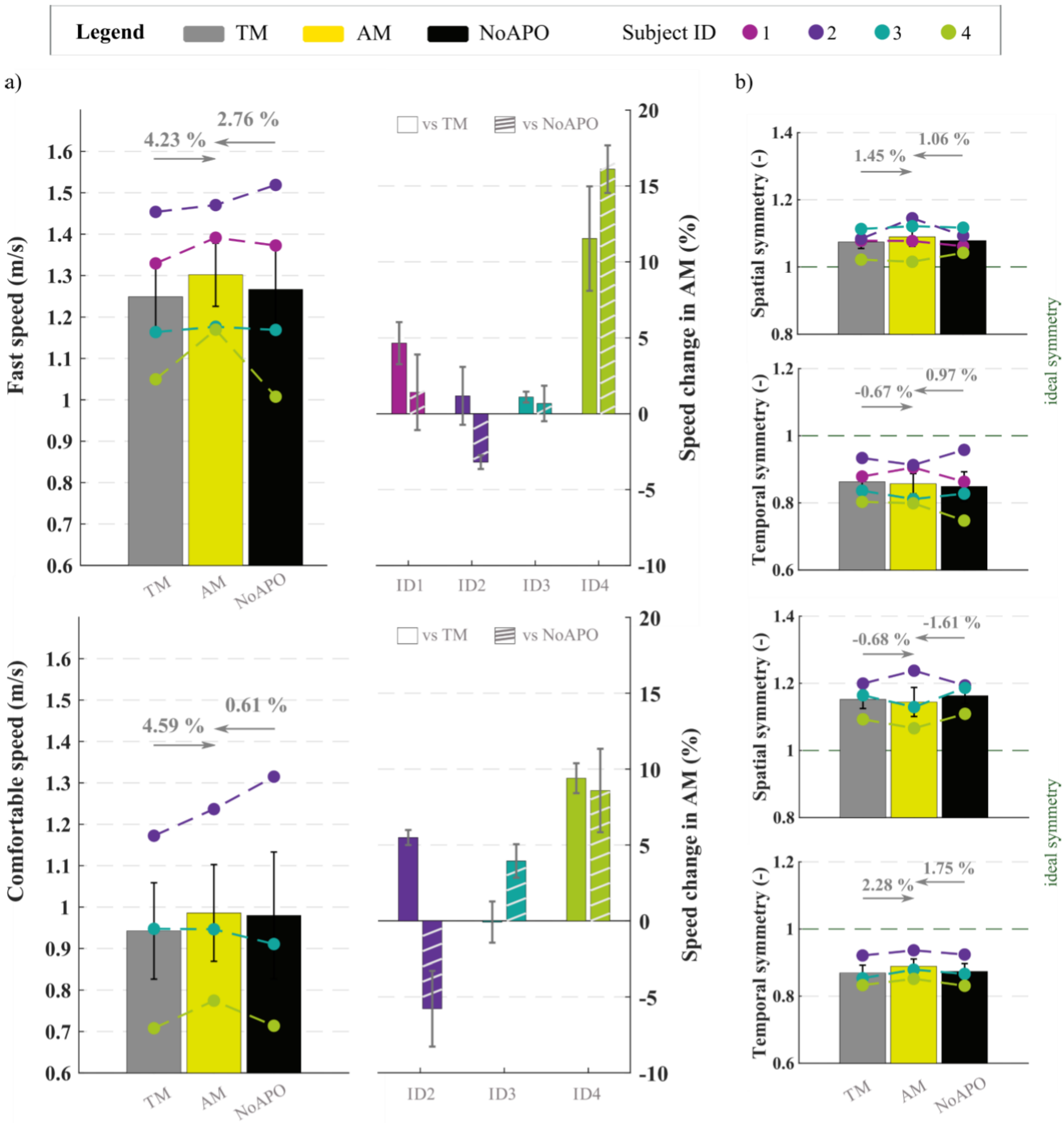

Fig. 4. **Results of the overground test: gait speed and symmetry.** 10mWTs performed at the fast speed (top) and at the self-selected gait speed (bottom) under different conditions, i.e., without the APO (NoAPO, black), with the APO in assistive mode (AM, yellow), with the APO in transparent mode (TM, grey). a) On the right, bar plots represent the gait speed (m/s) averaged across all participants, error bars show the standard error mean (s.e.m.), the arrows above the bars indicate the percentage change across participants. Colored circles represent individual study participants. On the left, colored bars represent the percentage change in the PCI of walking with the APO in AM compared to walking with the APO in TM (no pattern) and without the APO (pattern bar), for each participant. b) From top to bottom, spatial and temporal symmetry averaged across all study participants are reported as means and s.e.m. The ideal spatial and temporal symmetry is indicated with dashed horizontal lines (green).

cycle yields more pronounced effects when walking at relatively high gait speed and cadence, when muscles need significantly more energy. If this hypothesis is correct, the reduced energy consumption observed in this study may have been more substantial with experimental conditions entailing higher speed and cadence. In line with this, other studies using hip exoskeletons at treadmill speeds comparable to this study, also reported similar metabolic reductions [32], [33].

Regarding the gait speed overground, among all, only one participant (ID2) showed a reduction in walking with the APO in AM compared to NoAPO. This participant (ID2) also exhibited markedly higher energy expenditure across walking conditions compared to other study participants. Interestingly, ID2 was the only participant using a prosthetic rigid foot rather than an ESAR foot and classified as K2 instead of K3. It is possible to hypothesize that there is a correlation between the effect of the hip assistance and the type of prosthetic foot used by the participants. Indeed, while in physiological gait, the proper coordination between the hip extensors and ankle plantar flexors is relevant for efficient energy transfer during the mid-stance and push-off phases, in the case of transfemoral amputation, such hip-ankle coordination may be dependent upon the type of ankle-foot prosthesis. In particular, the hip extension torque provided by the exoskeleton during the stance phase may have enhanced the energy storage of the ESAR feet, whereas these effects may have vanished with rigid ankle-foot prostheses due to the prosthesis mechanical constraints.

Another relevant consideration for the interpretation of the results pertains to the choice of assessment metrics, specifically the use of the PCI instead of the metabolic cost based on Brockway's equation. Due to Covid-19 restrictions, we were unable to directly measure oxygen and carbon dioxide exchanges to estimate metabolic cost. Instead, we computed the PCI using HR measurements. Prior studies have shown significant correlation between PCI and oxygen uptake in a group of individuals with unilateral transfemoral amputation [24], indicating the reliability of PCI as an indicator for assessing exercise load in walking. Nevertheless, other studies have highlighted potential variability between these two types of measurements [34], which could account for part of the difference between the findings of the present study and previous research.

In a broader analysis, as highlighted in a prior study, three key factors namely, adaptation, training, and customization of the exoskeleton assistance, were identified as having a notable impact on the metabolic benefits of walking with an exoskeleton [35]. Concerning the adaptation period, prior research has indicated that healthy subjects require approximately 18 minutes of continuous walking with an exoskeleton to achieve metabolic adaptation [36], and in [13] individuals with above-knee amputation have experienced the unilateral hip assistance for 18 minutes before testing it. In our study, individuals with above-knee amputation had a shorter adaptation time with the selected assistance (i.e., about 5 minutes during the test sessions), as they were not capable of walking for prolonged time. The experimental protocol was thus specifically designed to have short walking trials, and testing trials were executed after a relatively short adaptation period to avoid fatigue. In addition to this aspect, we designed the protocol to include multiple test and re-test trials within a single session, thereby to minimize the impact of measurements variability [37]. Regarding the training, a previous study has shown that 109 minutes of assisted walking has increased the metabolic reduction from 10% to 31% in healthy subjects walking with an ankle exoskeleton [35]. Similarly, transtibial amputees required 20 days of training with a powered prosthesis to achieve significant metabolic benefits, with the initial small/null improvements gradually accumulating over time [38]. This suggests that the improvements observed in this study could translate into a larger benefit after longer (e.g., multiple days) training. The potential for greater benefits with longer-term training underscores the importance of further research to optimize training protocols and identify the most effective means of exoskeleton-assisted gait. Finally, regarding the assistance customization, it is worth noting that in this pilot study, the process of tuning the exoskeleton assistance was manually performed by experimenters. The tuning procedure consisted of the following steps: first a bilateral hip torque profile matching the shape of the biological torque profile was set with amplitude equal to $\sim$0.1 N·m/kg in both flexion and extension; then, experimenters fine-tuned the amplitude and timing of the assistive profiles to ensure a visible reduction in the PCI for each participant. Noteworthy, for the two study participants with prior experience using the APO (ID#1, ID#3) a higher torque magnitude was selected for both the extension phase on the prosthetic side and the flexion and extension on the sound side. This preliminary observation, in line with previous research [39], may suggest that individuals with prior exoskeleton knowledge are more adept at leveraging high exoskeleton assistance compared to naïve users. However, the manual nature of the tuning procedure and the limited time dedicated to it may have limited the possibility to achieve even higher energy reductions for each participant. Automatic assistance optimization methods have shown a potential for metabolic cost reduction but typically require prolonged continuous walking sessions (ranging from 30 to 60 minutes) [40], [41]), which may be overly demanding for individuals with lower-limb amputations. Alternatively, it could be useful to develop guidelines that facilitate the identification of appropriate subject-specific assistance based on gait impairments or other individual characteristics. Further studies involving multiple training sessions and a larger participant pool could help in designing these guidelines or simplifying the automatic assistance optimization techniques.

As an additional consideration for the interpretation of the results, it is important to highlight that in the present study the exoskeleton's weight was 5.7 kg, and that reducing the weight of the device may enhance the effectiveness of the assistance by reducing the "loading effect" on the user. Higher assistance levels may offset the effect of additional weight, However, we observed uncomfortable socket movements and unstable human-robot interaction dynamics at higher assistance levels, as reported in [13]. Therefore, from a design perspective, future investigations should be focused on reducing weight, by re-designing the transmission means, with a new single-axis SEA collocated with the biological flexion axis, and the backpack, with more compact electronics based on smaller processing unit and customized battery pack. Additionally, improvements in the human-robot coupling (e.g., with auto-alignment mechanisms) are essential, so that the exoskeleton can provide higher assistance while preserving the user comfort and interfaces stability.

This study showed that the APO assistance had little to no effects on both spatiotemporal gait symmetry parameters and joint kinematics. The little changes that were measured for a few subjects could be attributed to natural gait variations rather than to a clinically significant modification of the walking pattern, with slightly more evident benefits in treadmill walking than overground. However, the short adaptation and training were likely not sufficient to induce modifications in the gait scheme of patients, as suggested by previous research [42], [43]. The only notable variation was the increase in the hip RoM observed in both AM and TM compared to the NoAPO condition. This increase may be attributed to the loading effect of the robot on the individual, inducing a slight backward imbalance and consequently increasing the hip range of motion to maintain a consistent cadence and speed.

Delving into the role of hip and ankle joints, previous research suggests that individuals with above-knee amputations experience the high energetic cost during walking due to the inability to exploit the spring-like function of the Achilles tendon. To compensate for the lack of net positive energy at the ankle, they redistribute the workload to the less efficient hip joints and to the ankle joint of the intact limb [44]. To restore a more efficient gait in transfemoral amputees, different approaches may be appropriate. As a first option, it would be possible to assist the ankle joint of the intact limb, providing the additional power that is required; however, it should be noted that this solution may have practical limitations, due to the need to counterbalance the detrimental effect of the distal mass on the user's ankle. The second option is to assist the hip joints bilaterally. Considering the physiological architecture of hip and ankle muscles, assisting the hip joint may be more effective from an energetic standpoint [44], also considering that the additional weight is closer to the user's center of mass. Interestingly, these two alternative solutions have never been compared through rigorous studies, thus future investigations may focus on this topic.

This study contributes to showing that powered hip exoskeletons hold potential for assisting gait in individuals with transfemoral amputations. However, the small sample size and the heterogeneity of the participants (in terms of age, prosthetic device, previous experience with the APO, and time since amputation) constitute a limitation on the generalizability of the results. Future research will consider including assessments such as electromyographic and kinetics to provide a mechanistic explanation of any observed metabolic benefit. Additionally, future experiments will focus on a more comprehensive evaluation of the effect of different assistive profiles. Exploring an assistive strategy delivering purely extensor torque could be interesting, as this assistance may alleviate the excessive effort that people with transfemoral amputations often exert during stance for compensating the decreased push-off on the prosthetic side [2], [45]. Furthermore, a structured investigation into costs and benefits of both unilateral and bilateral assistance could yield valuable insights and drive the development of the next generation of exoskeletons for individuals with transfemoral amputation.

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N. Vitiello and S. Crea share the senior authorship. N. Vitiello, S. Crea, and F. Giovacchini have commercial interests in IUVO S.r.l., Pontedera, Italy. The APO technology has been exclusively licensed to IUVO S.r.l. for commercial exploitation. Össur is a shareholder of IUVO S.r.l. The other authors declare no competing interests.

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