Beyond Human or Robot Administered Treadmill Training

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Abstract

The demand for rehabilitation services is growing apace with the graying of the population. This situation creates both a need and an opportunity to deploy technologies such as rehabilitation robotics, and in the last two decades many research groups have deployed variations of this technology for gait rehabilitation. While gait robotic technology is elegant and sophisticated, results so far are mixed. We argue here that much of this technology may be misguided in its focus, providing highly repeatable control of rhythmic movement but ultimately overfocusing on this one aspect of gait. Our approach to lower extremity therapeutic robots is guided by our model of dynamic primitives in locomotion, which posits that walking is a composite of three dynamic primitives including oscillations (rhythmic movements), but also submovements (discrete movements), and mechanical impedances (balance). We developed devices based on the principle that the machine should allow the patient to express those dynamic primitives as much as (s)he can, while accommodating a large spectrum of pathological gaits. In the following, we review four innovative solutions for lower extremity (LE) rehabilitation based on this approach: Anklebot, MIT-Skywalker, Soft Exosuit, and Variable-Friction Cadense Shoes.

Keywords

Rehabilitation robotics · Robot-assisted therapy · Robotic therapy · Assistive technology · Lower extremity · Stroke · Cerebral palsy

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31.1 Introduction

In the following, we review four innovative solutions for lower extremity (LE) rehabilitation ranging from rehabilitation robotics to assistive technology for participants with LE impairment: Anklebot [1], MIT-Skywalker [2], Soft Exosuit [3, 4], and Variable-Friction Cadense Shoes [5]. These designs depart from the most common LE robotic therapy, and we highlight here some of the initial results while investigating what might constitute best practice. Our approach to lower extremity therapeutic robots is guided by our model of dynamic primitives in locomotion (see next section); by the principle that the machine should allow the patient to express those dynamic primitives as much as (s)he can (i.e., it should be able to "get out of the way"); and by the need to accommodate a vast spectrum of pathological gaits and impairment levels as defined in [6]. The Anklebot and the MIT-Skywalker exemplify our approach to train at least three independent training modes (rhythmic, discrete, and balance training) that can be added or subtracted depending on the patient's needs as showcased later. The Exosuit expands the training to a wearable technology that can be employed outside the clinical setting and train or assists during walking. Last, but not least, the Variable-Friction Cadence shoes embody the concept behind the MIT-Skywalker on a wearable solution that can also train or assist.

31.2 A Competent Model for Walking

We propose a competent model of human walking (as well as arm movement) based on dynamic primitives [7]. By "competent model" we mean that it may only be a first approximation of a fundamental theory, but it is good enough to improve the design of robots and regimens for both UE and LE therapy. The theory of dynamic motor primitives is succinctly outlined by Hogan and Sternad [8]. To accommodate real-life walking with all its variations, we propose that walking is a composite of three dynamic primitives, specifically submovements (discrete movements) [9], oscillations (rhythmic movements) [10, 11], and mechanical impedances (balance) [12–16]. The three primitives are related via the concept of a virtual trajectory, which in a nutshell operates like a reference trajectory to standard motion controller with no assumption that dynamics are meaningful or fast [8]. To render precision, a discrete movement is defined as one with a clear start and stop posture. Because the term "rhythmic" has numerous confusing variations of meaning, the corresponding dynamic primitive is defined as an almost-periodic oscillation [17]. Mechanical impedance is defined as the operator that determines the force or torque evoked by imposed displacement [18].

These dynamic primitives have different neural substrates. In a functional MRI study, Schaal et al. demonstrated that a discrete wrist movement recruited more regions of the brain than did the same movement performed rhythmically [10]. Perhaps more important, they influence learning in different ways. It has been shown that motor learning of discrete arm movements has a positive transfer to rhythmic movements but not vice-versa [19]. To the extent that recovery after neural injury resembles motor learning, this suggests that discrete training as in pointing with the ankle may be more effective as it appears to have a positive transfer to rhythmic training of locomotion than vice-versa [19]. Discrete locomotor therapy would consist of patients working on self-directed, visually guided, discrete steps to initiate movement or pointing movements to targets with the lower limb [20].

Upright walking requires active balance mechanisms that often include modulating mechanical impedance. The posture or configuration of the limbs profoundly affects the response to perturbations, i.e., mechanical impedance. Challenges to balance commonly evoke changes of lower limb posture, for example, a wider stance. Impaired balance is a common symptom in most neurological injuries such as stroke and cerebral palsy [21–24]. Balance training has been shown to reduce postural asymmetry associated with hemiparesis and was a part of the home-based protocol in the LEAPS study which resulted in walking benefits similar to those achieved with body-weight supported treadmill training BWSTT [25].

A similar combination of dynamic primitives has been proposed to underlie upper extremity actions [26]. This suggests that the differences between upper extremity and lower extremity control may be smaller than previously considered in the literature.

31.2.1 Anklebot

We focused our initial LE robotics development efforts on the ankle because it is critical for propulsion, shock absorption, and balance during walking. Following stroke, "drop foot" is a common impairment. It is caused by a weakness in the dorsiflexor muscles that lift the foot. Two major complications of drop foot are "slapping" of the foot after heel strike in the early stance (foot slap) and dragging of the toe during swing, making it difficult to clear the ground (toe drag). In addition to inadequate dorsiflexion ("toe up"), the paretic ankle also suffers from excessive inversion (sole towards midline). Both begin in the swing phase and result in toe contact (as opposed to heel contact) and lateral instability during stance, a major cause of ankle injuries. Lack of proper control during these phases increases the likelihood of trips and falls. In fact, deficits of swing clearance, propulsion, and balance contribute to more than 70% of stroke survivors sustaining a fall within six months [21], leading to higher risks for hip and wrist fractures in the first year [22–24]. The ankle is also the largest source of mechanical power during terminal stance [27]. The plantarflexors contribute as much as 50% of positive mechanical work in a single stride to enable forward propulsion [28–31]. In pre-swing plantarflexors also act to advance the leg into swing phase while promoting knee flexion at toe-off [32]. Additionally, the ankle helps maintain body-weight support during gait [33–35] and balance. Finally, the ankle musculature helps absorb impact forces during foot strike to enable controlled landing. In summary, given its importance in overground foot-floor swing clearance, propulsion, shock absorption, and balance, we elected to focus first on the ankle. The Anklebot has the potential to address both swing clearance and propulsion, as well as balance problems since it is actuated in both the sagittal and frontal planes [1].

The design, characterization, donning procedure, and safety features of the adult and pediatric version of the Anklebot have been previously described [36, 37]. Here, we will briefly summarize the salient design features and measurement capabilities of the two versions of the robot. It is a portable, tethered wearable exoskeletal ankle robot that allows normal range of motion in all three degrees of freedom of the ankle and shank during walking overground, on a treadmill, or while sitting (25° of dorsiflexion, 45° of plantar flexion, 25° of inversion, 20° of eversion, and 15° of internal or external rotation). It also provides independent assistance or resistance in two of those degrees of freedom (dorsi-plantarflexion and eversion/inversion) via two linear actuators mounted substantially in parallel. Anatomically, internal–external rotation is limited at the ankle, the orientation of the foot in the transverse plane being controlled primarily by rotation of the leg at the hip. Under-actuation, i.e., actuating fewer degrees of freedom than are anatomically present, affords one key advantage: it allows the device to be installed without requiring precise alignment with the patient's joint axes (ankle and subtalar joints). This is actually an important characteristic of all our robotic devices. In this configuration, if both actuators push or pull in the same direction, a dorsi-plantarflexion torque is produced. Similarly, if the two links push or pull in opposite directions, an inversion–eversion torque results.

The Anklebot is a backdriveable robot with low intrinsic mechanical impedance, weighs less than 3.6 kg (2.5 kg for the pediatric version) can deliver a continuous net torque of approximately 23 N m in dorsi-plantarflexion and 15 N m in eversion–inversion (7.21 and 4.38 N m for the pediatric version). The robot can estimate ankle angles with an error less than 1° in both planes of movement over a wide range of movement (60° in dorsi-plantarflexion and 40° in eversion–inversion), and can measure ankle torques with an error less than 1 N m. It has low friction (0.74 N m) and inertia (0.8 kg per actuator for a total of 1.6 kg at the foot) to maximize back-driveability. Of course, the Anklebot torque capability does not allow lifting the weight of a patient. At best, we can cue the subject to use his/her voluntary plantarflexor function by providing supplemental support to the paretic ankle plantarflexors during the stance phase. Our design is aimed at supporting foot clearance during swing phase assisting a controlled landing at foot contact. The torque generated by the Anklebot can compensate for drop foot during early and final stance phases of gait and insufficient muscle activity during push-off. We can also generate torque during the mid-swing phase to evoke concentric activity in the dorsiflexor muscles. In this respect, the Anklebot can provide continuous torques up to ~23 N m in the sagittal plane (~7 N m for the pediatric version), which is higher than required to position the foot in dorsiflexion during mid-swing.

We conclude this description of the salient features of the Anklebot by noting that we showed that unilaterally loading the impaired leg with an unpowered adult or pediatric Anklebot's additional mass had no detrimental effect on the gait pattern of subjects with chronic hemiparesis or children with cerebral palsy [38, 39].

31.2.2 Translating to Practice: Training in Seated Position

Results with stroke survivors with chronic hemiparetic gait and children with cerebral palsy who underwent a 6 week interactive seated anklebot training program were quite promising [1, 20, 36]. Follow-up studies confirmed the potential benefits of paretic ankle training on impairment and that reducing impairment would translate into functional improvement in overground walking speed. We used a visually guided, visually evoked, training paradigm in which the amount of assistance changed and challenged participants to improve performance. In these trials, we trained subjects in a seated position ("open chain") and not in task-specific gait training (see Fig. 31.1). Task difficulty (i.e., target locations on the screen) was initially set proportional to baseline deficit severity (i.e., paretic ankle active range of motion). Training parameters (i.e., target locations, speed) were adjusted every 2 weeks based on individual subject performance and included discrete and rhythmic pointing movements with the ankle.

For example, Chang and colleagues reported a study with participants with chronic stroke (>6 month) and hemiparetic gait (N = 29) who received 18 sessions of isolated robot-assisted motor training of the ankle (3x/week for 6 weeks). All participants had stable clinical baseline scores across three admission measures, and no participant was receiving simultaneous outpatient rehabilitation. Baseline gait speed defined three impairment groups: high, >0.8 m/s; medium, 0.4–0.8 m/s; low, <0.4 m/s. Outcome measures included the Berg Balance Scale, the 6 min Walk Test, and the 10 m Walk Test, and were recorded upon admission, discharge, and 3 months following intervention [40].

Three distinct and significant between-group patterns of recovery emerged for gait speed. The within-group analysis showed that the medium and high group exhibited significant improvements in gait speed and endurance upon discharge, that were maintained at 3 months. Gait speed improvements were clinically significant (>0.16 m/s) for the high function group across all gait speed and endurance measures at discharge and at 3 months. The moderate group also exhibited clinically significant improvements at follow-up on the 10 m Walk Test, fast pace (0.16 m/s), and approached clinical significance for the 10 m Walk comfortable pace (0.12 m/s). The low group had small but significant improvements, at discharge on two of the three gait measures, and these improvements were

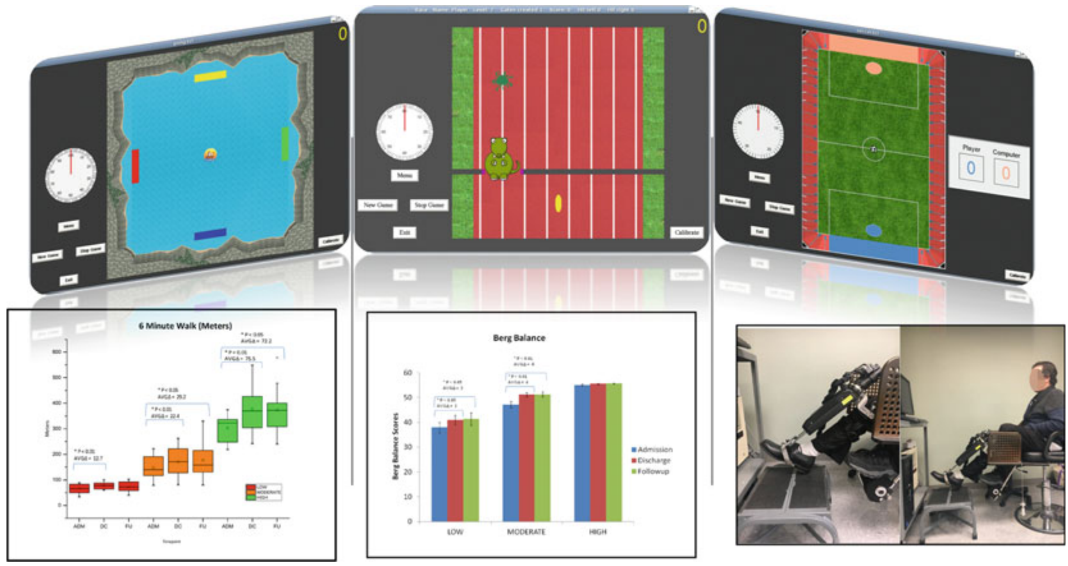


Fig. 31.1 Training in seated position. Top row shows some of the serious games developed for the anklebot. Left bottom row panel shows the endurance test (6 min walk test) in which patients walked continuously for 6 min, and total meters walked were measured. Low, moderate, and high groups showed significant differences at discharge (Low: mean change = 12.7 m, $p < 0.01$. Moderate: mean change = 22.4 m, $p < 0.01$. High: mean change = 75.5 m, $p < 0.01$). At follow-up, low group maintained small but non-significant change (mean change = 6.6 m, $p > 0.05$). Moderate group showed further improvement (mean change = 29.2 m, $p < 0.05$) and high group maintained significant changes (mean change = 72.2 m, $p < 0.05$). Middle bottom panel shows balance scores at admission, discharge, and follow-up (x/56). Higher scores indicate better functioning. Impairment groups: low, moderate, and high were based on average admission gait speed (low, <0.4 m/s; moderate, 0.4–0.8 m/s; high function, >0.8 m/s). Low and moderate groups showed significant changes at discharge (Low: mean change from admission to discharge = 3, $p < 0.05$. Moderate: mean change from admission to discharge = 4, $p < 0.01$) and maintained improvements at follow-up (Low: mean from admission to follow up = 3, $p < 0.05$. Moderate: mean change = 4, $p < 0.01$). High group showed non-significant changes at discharge and follow-up; admission score for high group approached ceiling (mean = 55 out of maximum 56 points) and plateaued at discharge and follow-up. I bars indicate standard error. Right bottom panel shows the side view of patient wearing ankle robot in a seated position (right) and close up of robotic training device (left)

maintained at 3 months. For balance measures, the low and moderate impairment groups had significant improvements at discharge that were robust on follow-up measure. The high function group demonstrated no significant change in balance.

Joint-specific robotic training of the paretic ankle provided the most benefit to individuals with moderate or mild gait speed impairments after stroke. Baseline gait speed function (low, moderate, high) was associated with three distinct recovery profiles. This suggests that severity-specific intervention may be critical to improving efficiency of stroke recovery. Of course, we must take the results in these small studies with the appropriate caveats as the number of subjects is small, the intensities and duration of the interventions are different, the patient populations are distinct, and they are non-controlled studies. However, it is important to highlight that initially we did not expect that training while seated to be successful as load receptor input is essential for a physiological leg muscle activation during stance and gait [41]. Yet our initial and subsequent experimental results told a different story. We speculate that the observed overground changes with training while seated are related to changes of ankle mechanical impedance leading to a more ecological foot landing during gait [12, 42–45].

31.2.3 MIT-Skywalker

The MIT-Skywalker robot is inspired by the concept of passive dynamic walkers [46]. In conventional gait physiotherapy, the therapist pushes or slides the patient's swing leg forward, either on the ground or on a treadmill. In kinematically-based robot-assisted gait therapy, the leg is propelled forward by the robotic orthosis acting on the patient's leg (e.g., in Lokomat or Autoambulator). Instead of lifting the patient's leg manually or mechanically, we achieve forward propulsion during swing in MIT-Skywalker using the concepts of the passive walker by lowering the walking surface at maximum hip extension. This provides swing clearance and takes advantage of gravity and the pendular dynamics of the leg to propel the leg forward, while allowing proper neural inputs due to hip extension near swing onset and ecological heel strike at swing termination. Moreover, since the working principle takes advantage of the natural dynamics of the leg, no mechanism attached to the patient's leg is needed. This maximizes safety by eliminating the possibility of exerting unwanted forces on the leg due to mismatch between the artificial (robot) and natural (human) degrees of freedom. Equally important, it significantly reduces the don and doff time required—a significant consideration for clinically practical designs. Preliminary tests demonstrated its ability to provide therapeutic assistance without restricting the movement to any pre-determined kinematic profile, providing ecological heel strike and hip extension to maximize patient participation during therapy [2]. More details on the hardware architecture and characteristics of MIT-Skywalker can be found elsewhere [2, 47], as well as details of our control algorithm used to track the patient's gait abilities and challenge them to increase participation and improve speed and symmetry [48, 49].

31.2.4 Translating to Practice: MIT-Skywalker

Here we report on our initial feasibility study in which the MIT-Skywalker was employed to deliver three distinct modes of training in line with our model of walking: rhythmic, discrete, and balance.

31.2.4.1 Rhythmic Training Mode

The timing of the track drops is determined by the vision system estimating the position of the heel on the track. When a minimum x-position is found (indicating the onset of patient-directed swing phase), a signal is sent to drop the track. In the interest of a quick but soft drop, the sagittal plane drive was programmed to drop 2.5° (approx. 3.3 cm below the horizontal plane at the mid frontal plane) and back to horizontal in 0.7 s. Acceleration of the initial drop was four times the deceleration at the end of the perturbation, resulting in a soft feel on heel strike. Our initial target of 0.4 s for swing was based on healthy gait at 2 m/s. Training speeds for study participants were mostly done below or at 1 m/s resulting in longer swing times of the paretic limb. The soft feel of the final track movement was comfortable for subjects even if the foot hit the track early. When delivering the rhythmic program, three additional goals were implemented for some participants.

31.2.4.2 Speed Enhancing Programs

On top of the standard rhythmic protocol described above, the speed-enhancing programs focused on raising participant's training speed.

31.2.4.3 Asymmetric Speed Programs

The asymmetric speed programs focused on altering the step-length asymmetry via speed distortion (asymmetric split-belt speeds).

31.2.4.4 Vision Distortion Programs

A visual display presented in front of patients distorted the perceived length of each step while instructing participants to equalize the distorted steps to induce changes in step-length symmetry as seen in [49].

31.2.4.5 Discrete Training Mode

The MIT-Skywalker is the first rehabilitation robot to introduce discrete training for post-stroke lower extremity training. In this mode of training, the treadmill tracks operate in position mode. A random target is projected onto the treadmill track from an overhead projector. The patient is instructed to land the heel on the target. Once the vision system recognizes that the patient's heel has landed, the algorithm compares the x-position of the heel with the x-position of the target to determine if the target was hit. The treadmill track gently moves the heel back to a neutral position underneath the body. A half second later, a new target is displayed. The number of successfully hit targets and the success rate is displayed at the front end of the treadmill and the level of difficulty (target size) and location can be adjusted. Patients considered this simple game very engaging.

31.2.4.6 Balance Training

The MIT-Skywalker system is capable of imposing perturbations in both the frontal and sagittal planes. This is achieved by lowering or raising the walking surface or rotating the whole system in the frontal plane. In this feasibility study, only frontal plane perturbations were used with a stereotyped sinusoidal profile ranging from (0–2.5° 2.5° 0°) in 1.4 s. This is a fairly gentle profile for a healthy subject but challenging for our patients. The initial rotational direction was presented randomly and perturbation timing was randomized between 2 and 4 s. For stroke and cerebral palsy adult participants with a moderate impairment, the frontal plane perturbations were used in concert with the rhythmic program. For our most severe participant, the frontal plane perturbations were used exclusively to develop balance during standing alone. We employed a video game in the form of a surfer to indicate the frontal plane rotation.

Before and after each session, participants in this feasibility study were asked to walk for approximately 30 s to 1 min while the MIT-Skywalker vision system recorded hip and knee kinematics. During training, kinematics and heart rate were also recorded. Clinical Evaluations were performed by a physical therapist before and after the 1 month-long study at least one day removed from therapy. Subjects underwent clinical evaluations that included a 6 min walk test, self-selected and maximum walking velocity tests (measured as the average velocity of the middle 6 m of a 10 m walk test), the Berg balance scale, the Tardieu scale, and sagittal plane kinematic analysis using a 3D Guidance Trak-STAR system (Ascension Technology Co. Milton, VT). Furthermore, we monitored heart rate. We observed an average increase in heart rate between the standing and training periods of 14.7 bpm for rhythmic training sessions. Each training block lasted approximately 5 min and each rest period was between 1 and 5 min depending on the state of the participant (Table 31.1).

This initial study marks the first time the MIT-Skywalker system has been tested with persons with neurological impairments. This initial study demonstrated the feasibility of the three different training routines and showed their promise for the rehabilitation therapy of various disabilities (stroke and cerebral palsy) at three impairment levels. MIT-Skywalker showed its versatility to accommodate each. Further, each participant was able to make substantial gains in one or more of

Table 31.1 Clinical evaluations before and after 1-month training

	Participant 1		Participant 2		Participant 3	
	Initial	Final	Initial	Final	Initial	Final
6 min walk test (m)	478	546	200	209	213	204
SSV (m/s)	0.89	1.17	0.50	0.50	0.24	0.22
MSV (m/s)	1.50	1.65	0.59	0.63	0.26	0.26
Berg balance test	54	55	10	37	52	55

the tested parameters even though the injury onset was more than 5 years in the past (in the case of our CP patients, the injury was over 25 and 56 years prior).

That said, these are just a feasibility study, and proper clinical controlled studies must be performed to better understand how to tailor lower extremity therapy and how move robotics for the lower extremity beyond its "infancy" [50].

31.2.5 From Traditional Anklebots to Soft Exosuits for Restoration of Walking for Individuals Post Stroke

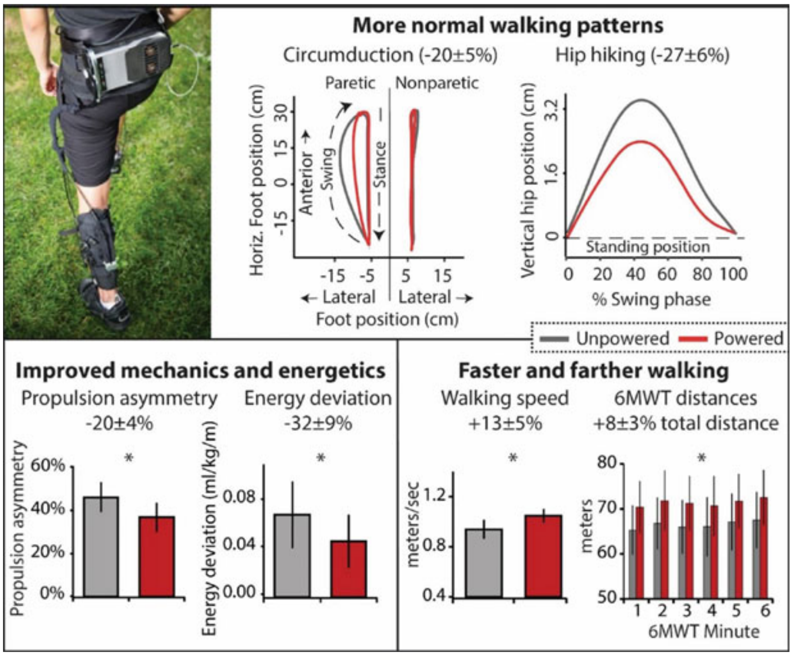
Post-stroke hemiparesis results in asymmetric and slow walking. Unfortunately, the current rehabilitation environment emphasizes the rapid attainment of walking independence over gait restoration. Although walking independence is an important short-term goal for survivors of stroke, independence is often achieved via compensatory mechanisms that limit recovery. Indeed, gait compensations are associated with a reduced fitness reserve, increased risk of falls, reduced endurance, and reduced speed [51, 52]. Although assistive devices such as canes, walkers, and ankle-foot orthoses are highly utilized after stroke, persisting gait deficits (such as impaired paretic propulsion [53, 54] result in a high energy cost of walking and walking disability.

Interventions that can reduce the high energy cost of walking after stroke have the potential to facilitate improved long-distance walking capacity and reduce walking-related disability [55, 56]. Indeed, a high energy cost of walking is a primary contributor to physical inactivity across neurological diagnostic groups. In people post-stroke, recent work has shown that gait interventions that facilitate faster walking only have a positive effect on the energy cost of walking if they concurrently facilitate more symmetric walking [57]. This finding may account for why 76% of individuals in the chronic phase after stroke identify deficits in their ability to walk farther distances as limiting engagement at home and in the community, whereas only 18% identify deficits in walking speed as a limiting factor [58]. That is, walking faster may not be sufficient to improve everyday walking behavior if it is not also economical.

Next-generation soft wearable robots, called exosuits, assist paretic dorsiflexion during swing phase to facilitate ground clearance and paretic plantarflexion during stance phase to enhance propulsion [59]. The development of these systems was guided by a human-in-the-loop approach where iterative development helped uncover user needs and system requirements in conjunction with new concept and technology development [60]. The result was new approaches to attaching and anchoring to the body through the use of functional apparel components that combine extensible (e.g., knits) with inextensible (e.g., woven) textile materials, placed at strategic anatomical locations. Integrated lightweight laminates provide reinforcement and create force transmission paths that distribute pressure and enhance anchoring and enable the possibility of assisting multiple joints with a single actuator through the use of multi-articular textile architectures [61]. An important aspect of their control approach for the ankle and hip is that active assistance is triggered coincidently with key biomechanical events (detected with wearable sensors), thus making it suitable for adapting to different walking speeds or step lengths [62, 63]. Combined with lightweight and efficient actuators, these innovations have enabled the demonstration of lightweight, autonomous wearable systems that can assist the ankle and hip joints for healthy individuals [64, 65].

Preliminary research on exosuits for individuals poststroke that focused on device development [3, 66] (see Fig. 31.2) demonstrated immediate, within-session improvements in both paretic ground clearance and forward propulsion [3], interlimb symmetry, energy cost of walking

Fig. 31.2 Soft robotic exosuit technology that has been shown to improve post-stroke walking patterns, improve the mechanics and energetics of hemiparetic walking, facilitate faster and farther post-stroke walking. See references for primary sources and additional detail



[59], and reduced gait compensations [66]. The level of assistance applied was relatively low (~12% of biological joint torques), yet the exosuit assistance was able to facilitate an immediate 5.33° increase in the paretic ankle's swing phase dorsiflexion and 11% increase in the paretic limb's generation of forward propulsion. These improvements in paretic limb function contributed to a 20% reduction in forward propulsion interlimb asymmetry and a 10% reduction in the energy cost of walking, compared to walking with the exosuit unpowered, which is equivalent to a 32% reduction in the metabolic burden associated with poststroke walking [3]. In [66], it was shown that the same soft exosuit targeting the paretic ankle could reduce common poststroke gait compensations. Specifically, compared to walking with the exosuit unpowered, walking with the exosuit powered resulted in significant reductions in hip hiking (27%) and circumduction (20%). Together, these immediate biomechanical benefits enabled clinically meaningful increases in both short- and long-distance walking speeds [4].

31.2.6 Translating to Practice: The Robotic Exosuit Augmented Locomotion (REAL)

Though promising, the value of exosuits in the context of gait rehabilitation is unknown; the potential for training-related effects that are retained beyond the use of exosuits is not known. Building on our previous findings of immediate improvements in speed and propulsion when walking with a soft robotic exosuit [3, 53], we designed the Robotic Exosuit Augmented Locomotion (REAL) gait training program (Fig. 31.3). REAL training merges the exosuit technology with contemporary motor learning concepts to provide an individualized and progressive gait training protocol designed to therapeutically retrain faster walking by way of increased paretic propulsion. More specifically, REAL training combines (i) paretic propulsion augmentation, (ii) progressive speed training, and (iii) goal-based strategic feedback in an algorithm-based therapeutic program centered on high intensity, task-specific, and progressively

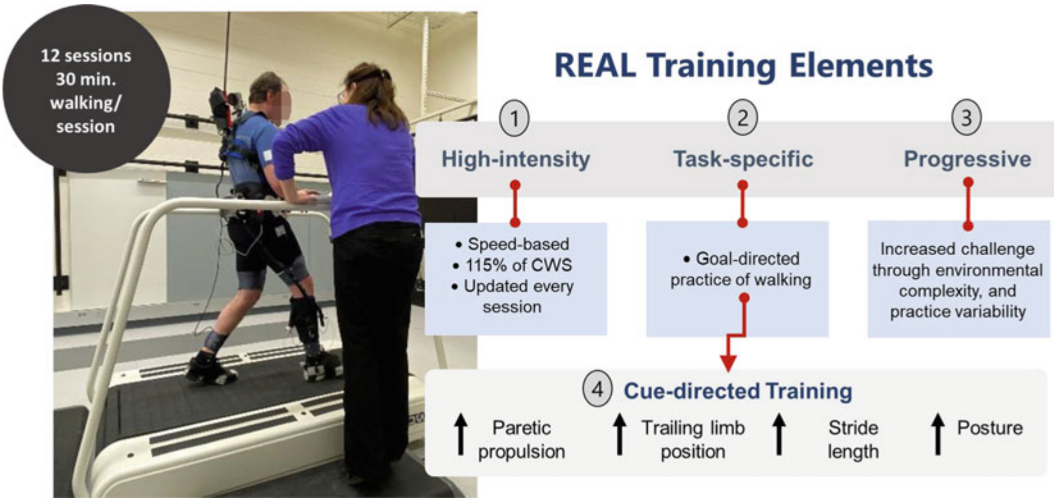


Fig. 31.3 Illustration of participant in REAL protocol and overview of different elements that are part of training. Walking begins on treadmill but transitions to overground [67]

challenging walking practice—principles which are known to be important in motor learning, and relevant for contemporary robot augmented rehabilitation interventions.

The REAL training program is currently undergoing clinical trials. A recent consideration of concept trial with a single stroke survivor demonstrated the feasibility and therapeutic potential of the REAL program [67]. The subject underwent gait training over five daily sessions. Each session consisted of 30 min of total walking practice, divided into five 6 min training bouts. The first two bouts were conducted on the treadmill, followed by three bouts overground. Data from the trial showed that comfortable walking speed was stable at 0.96 m/s prior to training and increased by 0.30 m/s after training. Clinically meaningful increases in maximum walking speed (change of 0.30 m/s) and 6 min walk test distance (change of 59 m) were similarly observed. Improvements in paretic peak propulsion (change of 2.80% BW), propulsive power (change of 0.41 W/kg), and trailing limb angle (change of 6.2°) were observed at comfortable walking speed (p's < 0.05). Likewise, improvements in paretic peak propulsion (change of 4.63% BW) and trailing limb angle (change of 4.30°) were observed at maximum walking speed (p's < 0.05). These results demonstrate that the REAL training program is feasible to implement after stroke and capable of facilitating rapid and meaningful improvements in paretic propulsion, walking speed, and walking distance. This early-stage clinical investigation provides several design considerations and insights that can inform subsequent clinical trials of the soft robotic exosuit technology and next generation robot-assisted gait rehabilitation.

As we consider transitioning the exosuit technology and REAL training paradigms to the community, we can leverage the exosuit sensors for remote monitoring and assessment. In an early proof of concept study, it has been shown that inertial measurements on the feet can capture changes in clinically relevant variables during walking in free-living settings [68]. Moreover, these sensor measurements can facilitate automatic adjustments to the exosuit's assistance profiles to better adapt to the changing needs of the patient across varying task demands and environmental contexts. The vision underlying the application of soft robotic exosuit technology as a long-term neurorehabilitation intervention spanning both clinical and community settings is the gradual reduction of gait asymmetries and undesirable compensatory motions such as hip hiking and circumduction, in favor of more physiological gait mechanics. The exosuit technology has the potential to influence post-stroke rehabilitation from the very early stages of recovery. When combined with adjuvant therapies such as body weight support, the gait-restorative effects of the exosuit can be used even in those who do not have independent ambulatory ability. As patients progress, the exosuit can provide the combined ability to apply gait-restorative forces and provide quantitative feedback during community walking. This will extend the abilities of clinicians to the real world, providing a unique tool to retrain gait through the design and progression of personalized community-based walking rehabilitation programs.

31.3 Extending the MIT-Skywalker to Variable-Friction Cadense Shoes: An Accessible New Technology for Disabled Gait

As discussed earlier, one of the most common impairments following a neurological injury is drop foot which leaves patients with difficulty advancing the foot during the swing phase of gait. A common compensatory strategy is circumduction, which involves moving the leg outward in a circle to advance the foot during the swing phase and is a natural response to the challenge of clearing the floor. Circumduction is energetically inefficient and taxing on hip adductors and flexors, which leads to a decrease in stamina, walking speed, gait symmetry, and rhythmicity.

As discussed earlier the MIT-Skywalker introduced the concept of "removing the floor constraint" during the swing phase of gait. The MIT-Skywalker employs parallel treadmill tracks that independently drop under the foot when the patient initiates swing, thereby restoring rhythmicity and symmetry [69]. The track returns to the horizontal position to meet the foot at heel strike [70]. This work showed promise in a month-long feasibility study [7] and led to the development of the Cadense shoe (Fig. 31.4). The Cadense shoe works by providing a low friction surface between the floor and shoe during swing and a high friction surface between the floor and shoe during stance, thereby reducing the penalty for failure to clear the floor during the swing phase. The shoe is constructed with low friction plastic *pucks* arranged below soft foam. The pucks protrude from the shoe outsole and are tuned to remain exposed under the load of a foot scuff but to depress into the midsole under the weight of stance. When the pucks are depressed, the high friction rubber material is exposed to the floor creating a high friction surface between the shoe and floor.

A small pilot study with the Cadense shoe showed a 9–56% increase in maximum speed and comfortable gait speed in the 10 m walk test with a 41–66% decrease in the frontal plane hip angle for three study participants that otherwise exhibiting exaggerated circumduction [5].

Fig. 31.4 MIT-Skywalker shown with a left track drop and the Cadense shoe

Interestingly, these changes occurred after only two minutes of warming up with the shoe without any instruction. The Cadense shoe extends the concepts incorporated in the MIT-Skywalker and has the potential to provide comparable therapy at a steep cost reduction, improving global accessibility.

31.4 Conclusion

An NIH-sponsored randomized controlled trial (RCT) demonstrated that contrary to expectations of its clinical proponents, body-weight-supported treadmill training administered by 2 or 3 therapists did not lead to superior results when compared with a home program of strength training and balance (LEAPS Study). This is a remarkable and extremely important result, one that must be acknowledged and explored further by roboticists: The goal of rehabilitation robotics is to optimize care and augment the potential of individual recovery. It is not simply to automate current rehabilitation practices, which for the most part lack a sound basis of scientific evidence. This is not a criticism of clinical practitioners, who must provide treatment as best they know how, but is primarily due to a lack of tools suitable to properly assess clinical practices themselves. To move LE robotics beyond its infancy, we have to determine what constitutes "best practice." Here robotics offers tools to carefully and methodically build evidence- and science-based approaches that allow a patient to harness plasticity and recover within only the limitations of biology. In this chapter, we examined two pairs of alternatives: (a) the Anklebot and the Soft Exosuit, and (b) the MIT-Skywalker and Cadense shoes, discussing our working model for gait and locomotion, which suggested the need to engage the supraspinal network explicitly—much like we do in upper extremity robotic therapy and, we suspect, as occurs in usual-care gait training approaches.

Of course, these are only the initial, faltering steps towards our goal. We recognize the present conclusion of the American Heart Association's statement in its guidelines: "… robotics for the lower extremity (LE) still in its infancy…" We still don't know how to tailor therapy for a particular patient's needs. We do not know the optimal dose, or in cost–benefit terms: What is the minimum intensity to promote actual change? Should we deliver impairment-based approaches (as in seated "open-chain" ankle training, i.e., joint-based, non-task specific) or functionally-based approaches (as in the soft exosuit, task specific) and to whom: those who had suffered severe, moderate, mild strokes? How can we predict potential responders versus non-responders based on stratification of impairments and deficit severities? What types of serious games should be designed and which patients' behavioral metrics should be used to drive these games? If impairment-based approaches, should therapy focus on each joint one at a time? If so, should therapy progress proximal to distal restricting all but a few limited degrees of freedom and then expand to additional degrees of freedom? Should we assist-as-needed, resist, or perturb and augment error? Who might be the responders who benefit most from these interventions? How should we integrate the robotic gyms in therapy practices? Should we consider "dual use" technology approaches as the Cadense shoes that are assistive technology in nature but may also promote long-term impairment reduction.

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C. J. Walsh declares that Harvard University has entered into a licensing and collaboration agreement with ReWalk Robotics to commercialization the soft exosuit. C. J. W. is a paid consultant for ReWalk Robotics.

T. Susko holds an equity position in BrainE Labs, the company that manufactures the Cadense Shoe.

L. Awad serves a scientific advisor to ReWalk Robotics and a paid consultant with MedRhythms.

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