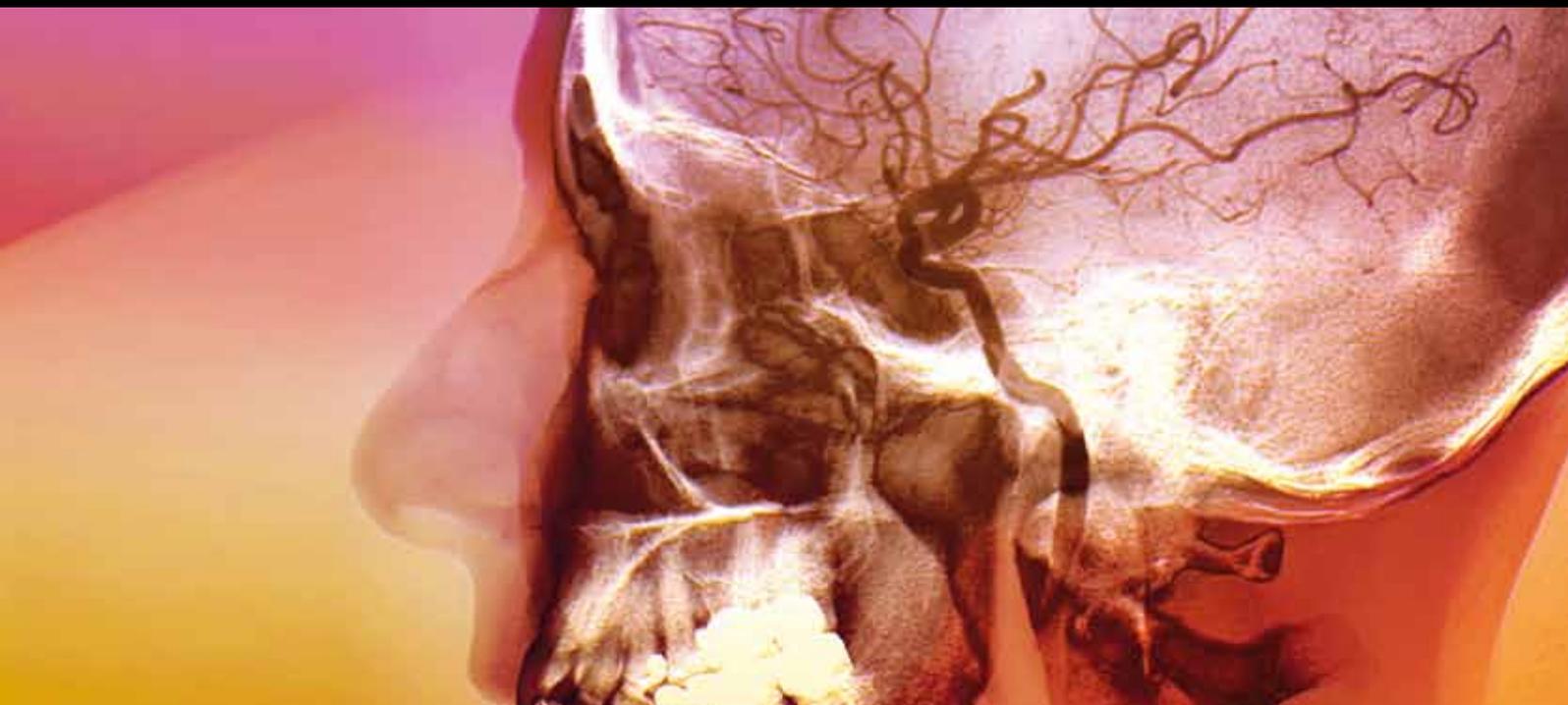


New Technologies for Stroke Rehabilitation

Guest Editors: Marco Iosa, Stefan Hesse, Antonio Oliviero, and Stefano Paolucci





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Stroke Research and Treatment

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Editorial

New Technologies for Stroke Rehabilitation

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“Real progress happens only when advantages of a new technology become available to everybody” said Henry Ford; we would add “or to the most disadvantaged people.”

Stroke is the leading cause of disability in all industrialized countries. Common rehabilitation usually allows about 50% of patients with stroke to recover walking, leaving the others not independent in walking and other activities of daily living [1]. For these reasons, an increasing number of researches are pursuing the use of new technologies to improve the efficacy of rehabilitation. For example, over the last decade, many devices for robotic-assisted training have been developed to allow patients to perform early, intensive, and task-oriented exercises [2, 3], and wearable devices for an objective assessment of human movements have been developed for substituting in clinical settings the expensive and difficulty to use stereophotogrammetric systems of research gait laboratories [4]. Moreover, invasive and noninvasive techniques allowing the manipulation of brain excitability and plasticity appeared in the last decades. If their promises will be confirmed in the next future, these techniques associated to rehabilitation may boost the recovery of stroke patients.

Differently from other fields of engineering, studies about the effectiveness of these technologies often occur after their development and their insertion in the rehabilitation settings. A number of studies showed the efficacy of these new technological approaches, whereas some others did not show any improvement in respect of conventional therapies. This uncertainty about efficacy, together with high purchase cost for some of these devices, some difficulties in their

use by untrained staff, the absence of clear guidelines about better dosage and parameter values to select, and a somewhat diffuse scepticism by some members of the rehabilitation teams may limit the transfer of these new technologies from research laboratories to clinical settings, where patients are waiting to benefit from them.

This special issue aimed to provide an overview on the use of new technologies for the rehabilitation of people with stroke. It contains two reviews and seven original researches. There is a generic review of M. Iosa and colleagues about seven promising technologies for stroke rehabilitation: robots, brain computer interfaces, noninvasive brain stimulators, neuroprostheses, virtual reality, wearable devices, and tablet-pcs. A more specific review is that of E. Q. van Delden and colleagues about twenty different devices for bilateral upper limb training. Upper limb rehabilitation was also the object of the study of G. Thielman and P. Bonsall, reporting the combined use of different technologies such as a unilateral robotic device used for interacting with a virtual task on a monitor, together with an auditory biofeedback for improving the trunk control. Also the study of P. Sale et al. was focused on the use of robotic rehabilitation of upper limb, in their case using a unilateral device designed for hand rehabilitation. Positive outcomes were found in all these studies, suggesting that robotic devices may provide a useful extension of currently available forms of therapy, as also stated in the paper by E. Q. van Delden and colleagues. But this special issue was not only focused on robotic devices. A. R. Bowers and colleagues investigated the on-road detection performance by drivers with hemianopia using oblique

peripheral prisms. The study of G. Morone and colleagues showed the potentiality of using a neuroprosthesis not only for correcting the foot drop in chronic phase, but also for improving the sensorimotor relearning during rehabilitation in subacute phase of stroke, facilitating the gait recovery. P. J. Manns and R. G. Haennel investigated the use of a wearable device for assessing walking capacity in people after stroke in terms of energy expenditure and step measurement, concluding that this device is not enough accurate as step counter. So not all technologies can be used also in stroke population, and not in a nonspecific manner. The study of A. Fusco and colleagues, in fact, analysed three different montages of the electrodes of transcranial direct current stimulation, suggesting different effects among anodal montage acting on manual dexterity, cathodal montage improving manual force, and bilateral montage, the less effective. Also, G. Thielman and P. Bonsall suggested that the degree of changes varied per protocol and may be due to the appropriateness of the technique chosen, as well as based on patients impairments.

These observations result in line with the proposal to change the research question from “is this specific technology effective?” into “how may I use this technology in an effective way?” as suggested by M. Iosa et al. [5] and “which patients is this technology effective for?” as suggested by G. Morone et al. [6]. Robotic devices, for example, were shown to be more effective for severely affected patients, whereas rehabilitative outcomes after robotic training resulted similar to those of conventional manual therapy for moderately affected patients [6, 7].

This special issue would contribute to provide clear results on the potential benefits of the use of new technologies for patients with stroke, avoiding overstatements of results, and, at the same time, reducing the scepticism of those who say “With machines they would perform miracles. What sort of miracles?” as asked by the Inquisitor in the drama of Bertolt Brecht *Life of Galileo*.

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Clinical Study

The ABC of tDCS: Effects of Anodal, Bilateral and Cathodal Montages of Transcranial Direct Current Stimulation in Patients with Stroke—A Pilot Study

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Transcranial direct current stimulation (tDCS) is a noninvasive technique that is emerging as a prospective therapy for different neurologic disorders. Previous studies have demonstrated that anodal and cathodal stimulation can improve motor performance in terms of dexterity and manual force. The objective of this study was to determine whether different electrodes' setups (anodal, cathodal, and simultaneous bilateral tDCS) provide different motor performance and which montage was more effective. As secondary outcome, we have asked to the patients about their satisfaction, and to determine if the bilateral tDCS was more uncomfortable than unilateral tDCS. Nine patients with stroke in subacute phase were enrolled in this study and randomly divided in three groups. Our results showed that tDCS was an effective treatment if compared to Sham stimulation ($P = 0.022$). In particular, anodal stimulation provided the higher improvement in terms of manual dexterity. Cathodal stimulation seemed to have a little effect in terms of force improvement, not observed with other setups. Bipolar stimulation seemed to be the less effective. No significant differences have been noted for the different set-ups for patients' judgment. These results highlight the potential efficacy of tDCS for patients with stroke in subacute phase.

1. Introduction

People with stroke results in several neurological impairments, affecting around 1 million subjects in Europe. Hence, stroke effects are the leading cause of long-term disability in industrialized societies [1, 2]. Rehabilitation's outcomes often conclude in incomplete motor recovery and over 60% of patients cannot use their paretic hands in functional activities. Furthermore, presence of severe paresis after four weeks is considered a negative predictive factor for the motor recovery [2], indicating for these patients serious difficulties in the activities of daily living in their future.

To facilitate recovery of upper limb function, many different rehabilitative treatments are still proposing. Among them, researchers are focusing their attention on non-invasive brain stimulations (NIBS), worldwide. Tools of NIBS are the

repetitive transcranial magnetic stimulation (rTMS) and the transcranial direct current stimulation (tDCS).

Use of tDCS is increasing in patients with stroke for its modulatory effects on cognitive and motor functions [3–5]. In particular for the motor domain, the cortical target of tDCS application has been showed to enhance execution and skills [6], producing interest for the improvement of rehabilitative stroke's course. Moreover, respect than rTMS, it is less expensive, more mobile, and, therefore, more comfortable, making its use easier in clinical settings.

This technique applies electrical current directly on the scalp and modulates the membrane potential dependently by type of electrode's application. In fact, anode is able to facilitate the depolarization of neurons, while, on the contrary, cathode hyperpolarizes the resting membrane potential, reducing the neuronal firing [7]. Application in

TABLE 1: Demographic and clinical characteristics of participants.

	Patient (number-initial of surname)									Mean & S.D.
	1-A.	2-R.	3-A.	4-S.	5-B.	6-D.M.	7-O.	8-R.	9-V.	
Age	36	27	57	67	82	33	65	37	78	53.5 ± 20.7
Gender (male/female)	F	F	M	M	M	F	M	F	M	
Handedness (right/left)	R	R	R	R	R	R	R	R	R	
Type of lesion (hemorrhagic/ischaemic)	I	I	I	I	I	I	I	I	H	
Time after stroke (days)	29	36	47	21	32	22	32	10	26	28.3 ± 10.4
Site of hemiparesis (right/left)	R	R	L	R	L	L	R	L	R	
Type of tDCS (anodal/bipolar/cathodal)	B	A	A	A	B	C	B	C	C	
Sequence of stimulation (tDCS/Sham)	T-S	T-S	T-S	S-T	S-T	S-T	T-S	T-S	S-T	

Mean ± standard deviation of demographic characteristics and clinical features are reported. Abbreviations in the table above: M: male; F: female; R: right; L: left; H: hemorrhagic stroke; I: ischaemic stroke; A: Anodal; B: Bipolar; C: Cathodal; T: tDCS stimulation; S: sham stimulation; S.D.: standard deviation.

motor domain for subjects with stroke has been showed to be effective in enhancing the performance of functional tasks and muscle force [4, 8, 9].

At the same time, a recent meta-analysis has underlined as small sample size, different setups, and a large effect size in studies concerning motor recovery on patients with stroke may reduce the clinical meanings of this preliminary evidence.

The aim of this study was to evaluate the effects on manual dexterity and pinch and grip force of a tDCS single stimulation, compared to Sham stimulation, and if this improvement was different among the three possible electrodes' montages (anodal, cathodal, or bipolar). Secondary outcome was to evaluate the satisfaction of patients in using this advanced rehabilitative technology.

2. Material and Methods

This is a single-blind, crossover, sham-controlled study. Patients were admitted for an inpatient rehabilitation with a diagnosis of stroke to our hospital. The inclusion criteria to participate to this study were selected as follows: first-ever stroke; cortical or cortical-subcortical lesion, confirmed by diagnostic imaging (CT or MRI scans); mild to moderate hemiparesis with presence of minimal hand movement (proved by possibility to perform grip or pinch test). The following exclusion criteria were considered: presence of a history of chronic disabling pathologies of upper limb; spasticity; presence of pacemaker or severe cardiovascular conditions; a history of tumor, prior neurosurgical brain intervention, or severe cardiovascular conditions, including the presence of a pacemaker; a diagnosis of epilepsy or major psychiatric disorders. Demographic and clinical characteristics of the nine patients undergone the experimental procedure are summarized in Table 1.

The protocol was approved by the local independent ethics committee, and all participants gave written informed consent.

2.1. Transcranial Direct Current Stimulation. Stimulation was delivered for 15 minutes, both in real and sham condition, in two consecutive days, randomized for sham/tDCS

and anodal/bipolar/cathodal stimulations. In both sessions, the stimulation was preceded by 60 seconds where the current was gradually increased until intensity of 1.5 mA, eliciting transient sensations that disappeared over seconds, consistently with previous reports [9, 10]. The stimulator (Eldith DC Stimulator, NeuroConn, Germany) provided the direct current using two gel-sponge electrodes with a surface area of 35 cm² (5 × 7 cm for each electrode) embedded in a saline-soaked solution.

Positioning of active electrode varied according to randomized different montage: for anodal stimulation, the active electrode was placed on the projection of the hand knob area of the primary motor cortex of the affected hemisphere; for cathodal stimulation, the electrode was placed on unaffected hemisphere in an analogue position of the anodal stimulation. For these electrodes' setup, referent electrode was positioned on the skin overlying the contralateral supra-orbital region. In bilateral montage, cathode and anode were positioned as active electrode in the same way described above. In the context of electrical stimulation, anode indicates the relative positive terminal where current flows into the body, while cathode indicates the relative negative terminal where the current exits from the body [11].

2.2. Test Protocol. Patients were asked to perform the 9-hole peg test (9HPT) before- and after-tDCS or Sham. This test consists of a squared board with 3 rows of 3 holes. Participants were asked to fill the 9-holes with pegs as fast as possible. Researchers recorded the time spent to execute the task with a stopwatch starting when the subject touched the first peg and stopping it when the subject filled the last hole or when time was longer than 50 s, as previous researches reported [12, 13].

Velocity of execution was computed in terms of holes filled per second (number of filled holes/time). 9HPT-index, as an index of manual dexterity, was obtained. To perform a data normalization among subjects, the 9HPT-index was computed as follows: 9HPT-index = velocity LS/velocity HS * 100. The percentage improvement between pre and post treatment of 9HPT-index was computed as (9HPT-index_{post} - 9HPT-index_{pre})/9HPT-index_{pre} * 100.

As other outcome's measure, for each participant, the maximum pinch force and the maximum grasp force were

TABLE 2: Data of 9HPT-index and manual force recorded for each patient.

Type of stimulation	Type of setup stimulation	Prestimulation			Poststimulation		
		9HPT-index (%)	Pinch (kg)	Grasp (kg)	9HPT-index (%)	Pinch (kg)	Grasp (kg)
tDCS	Anodal	26.7	3.5	14	28.0	3.5	12
tDCS	Anodal	25.6	3.5	10	29.6	3.5	9
tDCS	Anodal	19.6	6	18	24.0	6	18
tDCS	Cathodal	44.7	4.5	14	48.3	6	12
tDCS	Cathodal	88.9	5.5	16	75.0	6	22
tDCS	Cathodal	81.1	2.5	14	100.0	4.5	14
tDCS	Bilateral	88.9	6	24	75.0	5	15
tDCS	Bilateral	77.3	9.5	34	88.9	11	36
tDCS	Bilateral	57.1	5	18	75.0	2.5	16
Sham	Anodal	35.1	4	10	21.3	4	10
Sham	Anodal	20.4	2	8	26.7	2	10
Sham	Anodal	22.2	5	14	25.3	5	16
Sham	Cathodal	30.2	3	15	32.0	3	14
Sham	Cathodal	70.6	6	22	61.1	6	20
Sham	Cathodal	106.3	4	18	96.6	4	20
Sham	Bilateral	125.0	6	16	94.4	6	18
Sham	Bilateral	93.3	9	36	77.8	10	38
Sham	Bilateral	133.3	4.5	20	125.0	3.5	20

measured by means of specific dynamometers. Both hands were evaluated with the patients seated, the elbow at 90° of flexion and a neutral position of the wrist. Grip force was determined according to Jamar method, with the arm as more stretched as possible and handlebars fixed to 5 cm, the most appropriate distance to develop the maximal force [14]. The maximum forces recorded between two trials were analyzed. Each participant performed these tests before- and after-tDCS or Sham.

Finally, four questions were asked about the satisfaction with the tool from patients' perspective. Inspired by QUEST (Quebec User Evaluation of Satisfaction with Assistive Technology) questionnaire [15], items were concerned on dimension and utility of the device, modality of application, comfort in the using. Answers were graded on the Likert-type scale, the most widely used approach to scaling responses in survey research, from "not satisfied at all" to "very satisfied."

2.3. Statistical Analysis. All measurements are reported in terms of mean \pm standard deviation. A repeated measure analysis of variance was performed on the 9HPT-index using as within-subjects factors pre versus post treatment and tDCS versus Sham, whereas as between-subjects factor the type of setup (A, B, or C). Post hoc analyses had been performed using Tukey correction for the inflation or type I error for multiple comparisons. Similarly, same analyses were performed on the pinch and grasp forces recorded for the affected limb of subjects. For verifying the applicability of analysis of variance, we previously performed the Levene's test of equality of error variances for verifying the homogeneity of data of the 3 recorded variables (9HPT-index, pinch

and grasp forces) for both the stimulations (tDCS versus Sham), before and after-stimulation. SPSS 17.0 was used and significant threshold was set at 0.05.

3. Results

Table 2 reports the experimental data of all nine selected patients.

Before applying analysis of variance, the data homogeneity was verified with Levene's test of equality of error variances, of the 3 recorded variables (9HPT-index, pinch and grasp forces) for both stimulations (tDCS versus Sham), before and after-stimulation. Eleven of 12 datasets resulted homogenous ($P > 0.05$), with a significant reduction of homogeneity observed just for grasping after sham stimulation ($P = 0.039$). According to these results, we applied repeated measure analysis of variance.

The improvements recorded after tDCS treatment were significantly higher with respect to the changes observed after Sham treatment, as shown in Figure 1 and Table 3 ($P = 0.022$ of interaction Pre versus Post * tDCS versus Sham). Despite the high data variability, anodal and cathodal showed the higher improvements, but the differences between setups were significant only as main factor ($P = 0.008$), but not for the interaction Pre versus Post * tDCS versus Sham * ABC ($P = 0.212$). Post hoc analyses revealed that the A group had a lower 9HPT-index already before treatment ($P = 0.017$, analysis of variance, factor group).

In terms of manual force, the interaction among factors (Pre versus Post * tDCS versus Sham * ABC) significantly

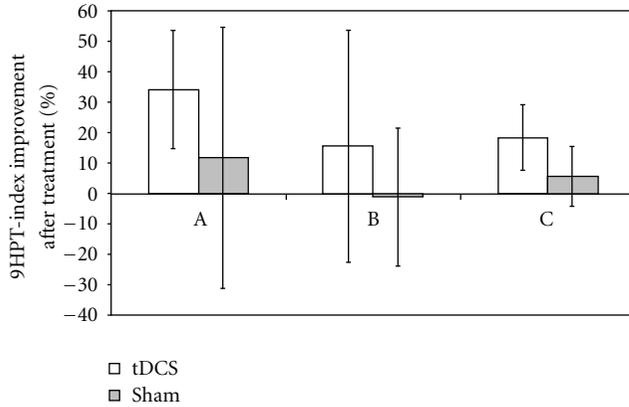


FIGURE 1: Percentual of improvement in the manual dexterity, measured as 9HPT index, for the real and sham stimulation in the three different electrodes' montages. Abbreviations for the stimulation: A: anodal; B: bilateral; C: cathodal.

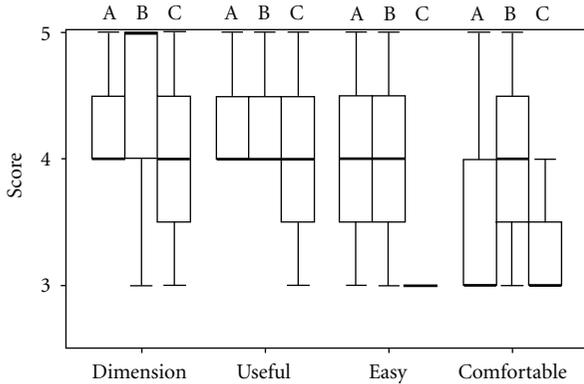


FIGURE 2: 4-item user satisfaction questions, based on a Likert scoring, for the three electrodes' setups (A: anodic, B: bilateral, C: cathodic montage). Box (thin lines: first and third quartiles, wide line: median) and whiskers (minimum and maximum values) plot for patients' judgments about dimension, utility, easiness of use, and comfort.

affected the pinch force of the affected limb ($F(2, 6) = 5.60$, $P = 0.042$). Main factor ABC did not affect significantly the pinch force ($F(2, 6) = 1.22$, $P = 0.360$). We found a significant improvement of $+13.1 \pm 7.5\%$ after cathodal stimulation, a reduction of force of $-6.5 \pm 19.8\%$ after bipolar stimulation and no changes (0% in mean) after anodic stimulation or Sham stimulation. Grasping forces were not altered, with just a slight but not significant effect of tDCS versus Sham * ABC interaction ($F(2,6) = 4.00$, $P = 0.079$), again with higher improvement after cathodal stimulation.

Finally, regarding the user evaluation, overall satisfaction with the device was very good. Results of the short survey was reported in Table 4.

No statistically significant changes were found among anodal, bilateral, and cathodal montages in terms of patients' judgment assessed by means of user satisfaction scale in terms of dimension ($P = 0.848$, Kruskal-Wallis analysis), perceived utility ($P = 0.846$), perceived easiness to use ($P = 0.230$),

TABLE 3: Repeated measure ANOVA results.

Factors and interactions	df	F	P
Pre versus Post	1	0.475	0.516
Pre versus Post * ABC	2	0.404	0.685
tDCS versus Sham	1	1.457	0.273
tDCS versus Sham * ABC	2	3.167	0.115
Pre versus Post * tDCS versus Sham	1	9.507	0.022
Pre versus Post * tDCS versus Sham * ABC	2	2.030	0.212
ABC	2	11.808	0.008

df: degrees of freedom (df of error = 6), F and P values (in bold if statistically significant).

and comfort during treatment ($P = 0.656$) (Figure 2). Just a little surprising trend was observed indicating that bipolar montage was perceived as less invasive, despite the presence of two electrodes on the head and being more comfortable.

4. Discussion

The purpose of this study was to determine the effects of a single transcranial direct current stimulation (real versus sham) on dexterity and manual force in patients with stroke, performing the stimulation through three different electrodes' setups, and determining if the montage was perceived by the patients as satisfactory. Our results suggest that tDCS treatment was more effective than Sham treatment on manual dexterity, while no significant differences were recorded in terms of manual force, even if a slight improvement was noted after the cathodal stimulation. Furthermore, no difficulties in performing treatment were complained by the patients.

Recently, many studies have been focused on devices to facilitate the motor recovery. The tDCS is emerging as one of the most interesting device to apply in stroke rehabilitation, both for the cognitive and motor impairments. Treatments with tDCS can be supplied up to 30 minutes, similarly to the timing of rehabilitative session, before or in synchrony with it, enhancing the rehabilitation outcomes [9, 10]. Moreover, compared to other forms of NIBS, tDCS is more comfortable, more mobile, and cheaper, and no major adverse effects have been reported. Common side effects include mild headache, itching, and erythema at the electrode site [16].

In spite of these advantages, use of this technique in rehabilitation is counteracted due to still too preliminary evidence. In fact, studies vary widely in terms of phase of stroke, functional impairments, targeting of the outcomes, stimulation set-ups, and rehabilitative integration. Hence, in a recent meta-analysis, Bastani and Jaberzadeh concluded that tDCS (in that case, as anodal stimulation) seems to produce significant effects in subjects with stroke but any conclusion should be considered cautiously [3]. At the same, they also noted its potential role as add-on technique to improve motor function and corticomotor excitability.

In our study, we have focused our attention on different electrodes' montages, being an increasing interest on type of stimulation. Our results show as anodal stimulation provided the higher improvement in terms of manual dexterity. These findings are consistent with previous reports [8, 17–19].

TABLE 4: 4-item satisfaction of the user and the 5-point scale used to rate each item.

	Patient (number-initial of surname)									Mean & S.D.
	1-A.	2-R.	3-A.	4-S.	5-B.	6-D.M.	7-O.	8-R.	9-V.	
Dimension	5	5	4	4	3	5	5	4	3	4.2 ± 0.8
Utility	4	5	4	4	4	5	5	4	3	4.2 ± 0.6
Application	4	5	3	4	3	3	5	3	3	3.6 ± 0.9
Comfort	4	5	3	3	3	4	5	3	3	3.6 ± 0.9

1: not satisfied at all, 2: not very satisfied, 3: more or less satisfied, 4: quite satisfied, and 5: very satisfied. Abbreviations in the table above: S.D.: standard deviation.

In such cases, effects can last up to 2 weeks after the treatment [17]. Most of these studies are concerning a chronic phase of the stroke, while only Kim and colleagues have showed a stimulation effect on patients in a subacute phase. Noteworthy, a recent report has observed that tDCS does not seem to be effective in an acute phase [20].

The tasks utilized to measure the manual dexterity, including the Jebsen-Taylor test, the Box and Block test, and the 9HPT, need a complex sensory information and sensorimotor integration for accurate performance. Moreover, the successful performance requires a complex pattern of activation of muscles and joints as well as the use of targets and tools [9, 21]; hence, the role of enhancer of motor rehabilitation should be more appropriate for the anodal stimulation of tDCS.

In fact, also the stimulation with cathode of the unaffected hemisphere seems to be effective in motor function improvement, but reports are not always concordant [17, 19]. On the contrary, our results showed that cathodal tDCS seemed to be a little effect in terms of force, differently by other setups.

In our study, bipolar stimulation seemed to be the less effective. In a previous study, it was reported as simultaneous application of anodal tDCS over the motor cortex and cathodal tDCS over the contralateral motor cortex induced an increase in cortical excitability [22]. Our study supports these findings in terms of dexterity, suggesting a global effect of treatments based on electrical stimulation respect than sham conditions, also for the bipolar montage of electrodes.

Finally, the overall satisfaction by the patient was maintained during a brief protocol treatment, confirming the facility of using this device [10].

The main limitation of our study was the reduced sample size. Although the number of subjects involved in this study was in line with other studies on tDCS [4, 8–10, 17–19], it suggests cautions in data interpretation. On the other hand, from a statistical point of view, the significant effects found in our study ($P = 0.022$ for interaction Pre versus Post * tDCS versus Sham for 9HPT-index and $P = 0.042$ for interaction Pre versus Post * tDCS versus Sham * ABC for pinch force) obtained on a small sample were potentially larger than equivalent results obtained with larger samples, supporting the importance of our results. Anyway, further researches on wider samples are needed. Moreover, the group of anodal stimulation had a generally lower manual dexterity (but not force) that could limit the interpretation of our results. Further research on larger samples is hence needed.

In conclusion, the present study contributes to the panel of evidence that strengthen the role of tDCS inside the rehabilitative stroke's course, in particular for the more complex activities of daily living as add-on technique. More studies are needed to define the better montage set-ups, targeting more specific outcome measures.

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Clinical Study

Hand Robotics Rehabilitation: Feasibility and Preliminary Results of a Robotic Treatment in Patients with Hemiparesis

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Background. No strongly clinical evidence about the use of hand robot-assisted therapy in stroke patients was demonstrated. This preliminary observer study was aimed at evaluating the efficacy of intensive robot-assisted therapy in hand function recovery, in the early phase after a stroke onset. **Methods.** Seven acute ischemic stroke patients at their first-ever stroke were enrolled. Treatment was performed using Amadeo robotic system (Tyromotion GmbH Graz, Austria). Each participant received, in addition to inpatients standard rehabilitative treatment, 20 sessions of robotic treatment for 4 consecutive weeks (5 days/week). Each session lasted for 40 minutes. The exercises were carried out as follows: passive modality (5 minutes), passive/plus modality (5 minutes), assisted therapy (10 minutes), and balloon (10 minutes). The following impairment and functional evaluations, Fugl-Meyer Scale (FM), Medical Research Council Scale for Muscle Strength (hand flexor and extensor muscles) (MRC), Motricity Index (MI), and modified Ashworth Scale for wrist and hand muscles (AS), were performed at the beginning (T0), after 10 sessions (T1), and at the end of the treatment (T2). The strength hand flexion and extension performed by Robot were assessed at T0 and T2. The Barthel Index and COMP (performance and satisfaction subscale) were assessed at T0 and T2. **Results.** Clinical improvements were found in all patients. No dropouts were recorded during the treatment and all subjects fulfilled the protocol. Evidence of a significant improvement was demonstrated by the Friedman test for the MRC ($P < 0.0123$). Evidence of an improvement was demonstrated for AS, FM, and MI. **Conclusions.** This original rehabilitation treatment could contribute to increase the hand motor recovery in acute stroke patients. The simplicity of the treatment, the lack of side effects, and the first positive results in acute stroke patients support the recommendations to extend the clinical trial of this treatment, in association with physiotherapy and/or occupational therapy.

1. Introduction

Hand plays a critical role in upper limb function [1], with various cortical and subcortical structures which are devoted to its sensorimotor control and a wide representation of hand in homunculus. Loss of hand dexterity is a common consequence of a cortical lesion due to cerebrovascular disease [2]. The most important motor deficit, after stroke, is the paresis of the affected side, contralateral to vascular lesion in the brain. The recovery of upper limb, after stroke injuries, is complex and requires multidisciplinary and multifactorial approaches [3, 4]. Currently, functional recovery of the affected arm can be predicted by means of clinical evaluation at the bedside; in particular, active finger extension has been demonstrated to be a strong early predictor of short-, medium- and long-term poststroke upper limb recovery

[5]. The robotics rehabilitation devices are tools specifically developed to assist and to perform exercises for recovering lost functions [6–8]. Various systems have been carried out, in the last 15 years, to treat the upper limb. A high number of devices have been made to administer the therapy for the proximal section of the upper extremity, in particular the shoulder and the elbow segments. Besides, there has been a steady increase in the number of devices that assist and train distal upper extremity movements, such as wrist and/or finger movement, during the last five years. Since 1997, more than 60 clinical trials reported the use of two dozens of different robots for neurorehabilitation of shoulder and elbow segment, with a large number of pilot studies that did not materialize into deeper studies [9]. In particular, from the kinematics point of view, each human finger has three joints and four degrees of freedom (DOFs), which

give 20 DOFs in total. Each finger joint position determines the position of a centre point of rotation (CPoR) for each joint, hence with a great impact on the rehabilitation system architecture, and the consequent difficulty to make a robot. The Amadeo robotic system (Tyromotion GmbH Graz, Austria) can be considered as an external manipulator with end-effector workspace suitable to cover the human hand fingers workspace. The robot performs an intensive training, with a high frequency of gripping movements combined with visual feedback. The exercises may therefore be accompanied by a goal-oriented rehabilitation games, whose difficulty is based upon the progress of rehabilitation and level of success rate in games. Only one preliminary study investigated the effect of a treatment with Amadeo robot on motor and functional recovery in patients with stroke [1]; therefore, there are no studies that considered the effect of this robotic training on ADL and quality of life (QoL). Stein and colleagues tested an Amadeo robotic device for hand rehabilitation in chronic stroke survivors. A total of 12 individuals, with chronic moderate hemiparesis after stroke, were enrolled in this study and all participants underwent a 6-week training programme using a hand robotic device. The results showed an improvement in multiple measures of motor performance, and all subjects tolerated the treatment well, with no complications. The aims of our preliminary study are to evaluate, in acute stroke patients, the efficacy of high-intensity robot-assisted training treatment, to improve hand function and/or sensorimotor hand recovery, and to assess whether the achieved improvements can reduce disability in ADLs and ameliorate patients QoL.

2. Material and Methods

Seven eligible voluntaries, who met the inclusion criteria and signed a consent form, were assigned to an experimental group according to tailored schedules. The study included acute stroke patients at their first-ever stroke exclusively, enrolled after the event onset, with ischemic lesions forms only. The diagnoses were confirmed by means of CT scan and/or MRI exam. The inclusion criteria were first ischemic stroke, at least 26 ± 10 days from the event, unilateral paresis, Mini Mental State Examination higher than 20, muscle strength in finger flexion, and extension higher than 2 (movement without gravity) evaluated with Medical Research Council (MRC), absence of sensory impairment evaluated by neurological test.

The exclusion criteria were as follows: patients aged less than 18 or more than 75, previous cerebrovascular disease or TBI, botulinum toxin injection within the previous 15 days from enrolment, cognitive disorders such as neglect (more than 2 errors after Albert Test score), upper limb apraxia (evaluated by De Renzi Test), and bilateral upper limb impairment.

2.1. Evaluation Procedures and Materials. The patients were evaluated before (T0), after 10 robotic treatments (T1), and at the end of the treatment (T2). Evaluation protocols involved two trained professionals physicians and occupational therapy (OT) not involved in the research treatment,

who were responsible for clinical scales and robotic test administration, respectively. They were blind to the type of rehabilitative protocol administered to the participants. Clinical outcomes were assessed using valid and reliable tools for stroke, that included all levels of the International Classification of Functioning, Disability, and Health. The evaluation scales were as follows: Fugl-Meyer Scale (FM) [10], Medical Research Council Scale for Muscle Strength (hand flexor and extensor muscles) (MRC) [11], Motricity Index (MI) [12], modified Ashworth Scale for wrist and hand muscles (AS) [13], Barthel Index, Functional Independence Measure scales FIM, and Canadian Occupational Performance Measure (COPM) (performance and satisfaction subscales). All the previous scales are validated. The strength flexion and extension were assessed by Robot.

2.2. Robot Device. The Amadeo Robot has got 5 DOFs and provides the motion of one or all five fingers, thanks to a passive rotational joint placed between fingertip and an entity moving laterally; (the thumb has got two passive rotational joints). All five translational DOFs are independent and provide large coverage of the fingers workspace (but not all of it is covered). The interface between human hand and the machine is realized thanks to elastic bands or plasters, and the wrist is restrained from the movements by a velcro strap.

2.3. Treatment Procedures. All subjects underwent an inpatient rehabilitation treatment, consisting in at least a daily 3-hour physiotherapy session, including both dexterity and gait training, according to individually tailored exercise scheduling. In addition to standard rehabilitation, eligible patients also received one daily session of at least 40 minutes of robot experimental treatment (EG).

2.4. Robot Experimental Treatment (EG). Treatments involved two OT. Each participant received 20 treatment sessions for 4 consecutive weeks (5 days/week). Each session lasted for 40 minutes (30 minutes of hand training and 10 minutes of passive upper limbs mobilization). Treatments were performed using Amadeo. According to our previous experience, the exercises were carried out as follows: (1) CPM therapy (the hand is stimulated in continuous passive motion therapy modality for 5 minutes); (2) assisted therapy (the hand motion is assisted by robot and adjusted to the individual limit of function and performance of each patients for 10 minutes); and (3) balloon (active training in a virtual environment by carrying out various target-oriented tasks, 10 minutes). Passive movement speeds were selected according to patient's skill. The difficulty of each exercise was increased day by day, according to the hand motor improvements of the single patient. In particular, the therapist may select from a number of different modules, according to the progress made during the therapy and may also choose between completely passive, assisted, or active variations. Resting time (1 minute) within intersession exercise was allowed according to the individual needs. The strength hand flexion and extension were performed by

Robot at the end of the treatment and during assessment session. The limit of the movement can be set for each individual finger; single fingers can be excluded altogether or limited. In this way, the therapist can react optimally to each and every restriction a patient has. The patient's therapist designs a therapy process for each individual. Every missed session was retrieved. Subjects who did not retrieve sessions and interrupted treatment for more than 3 consecutive days were excluded from the study.

2.5. Data Analysis. A preliminary descriptive analysis was performed to check the normal distribution of patients' clinical and instrumental data using Shapiro-Wilk test. Unless collected variables showed a normal distribution, we used parametric statistic tests. A repeated measure analysis of variance model (ANOVA) was carried out by using time as a within-group factor in order to evaluate within-group changes over time. The Friedman test was used to analyze ordinal data in the different evaluation sessions within each patient group. In the presence of significant main effects, the Wilcoxon signed-ranks test was performed to determine the location of any significant differences between time points. The alpha level for significance was set at $P < 0.05$ for first level of analysis.

3. Result

From March to August 2012, we screened 50 voluntary patients, 7 of whom satisfied the inclusion criteria and were assigned to the robot-assisted therapy (EG). No dropouts were recorded during the treatment and all subjects fulfilled the protocol (compliant subjects: $N = 7$). Table 1 summarizes the observed mean \pm standard deviation and other statistical results for all tests, as they were measured on the compliant subjects at T0 ($N = 7$), T1 ($n = 7$), and T2 ($N = 7$) (Table 1). Clinical improvements were found in all patients that fulfilled the protocol. The Fugl-Meyer scores were as follows: T0 47.4 ± 22.77 , T1 51.4 ± 32.67 , and T2 52.6 ± 32.22 . The MRC flexion values of 1.2 ± 1.64 at T0, of 2.2 ± 1.79 at T1 and 2.4 ± 1.67 at T2 were found. The MRC extension values of 1.2 ± 1.64 at T0, of 2.00 ± 2.00 at T1, and 2.0 ± 1.74 at T2 were found. The HAND AS scores were T0 2 ± 1 , T1 1.4 ± 1.14 , and T2 1.6 ± 0.9 . The WRIST AS scores were T0 1 ± 0.7 T1 1 ± 0.7 , and T2 1 ± 0.7 . The MI value of 19.8 ± 23.27 at T0, of 32 ± 41.24 at T1, and 32 ± 41.24 at T2 were found. The Barthel Index of 30.6 ± 10.99 at T0 and 55.6 ± 23.9 at T2, and the FIM of 57.4 ± 18.6 at T0 and 83 ± 21.35 were found. The statistical analysis using the Friedman test showed statistically significant improvements for the MRC wrist ($P = 0.0085$) and MRC hand ($P = 0.0239$). No statistically significant improvements on Fugl-Meyer Scale (FM), Medical Research Council Scale for Muscle Strength (MRC), Motricity Index (MI), and modified Ashworth Scale for Hand (AS) were found (Table 2).

4. Discussion

Paralysis following neurological disorders can disconnect the brain from the body, eliminating the ability to perform

TABLE 1: Distribution of the study participants by age, gender, etiology, lesion side, and other clinical characteristics.

	Experimental group (EG) ($n = 7$)
	n (%)
Dropouts	0 (0%)
Complains	7 (100%)
Gender	
Female	4 (57%)
Male	3 (43%)
Etiology	
Hemorrhagic	0 (0%)
Ischemic	7 (100%)
Lesion side	
Right	0 (0%)
Left	7 (100%)
	Mean \pm SD
Age (years)	67.0 ± 12.4
Time since stroke (days)	28.8 ± 8.10

volitional movements [14]. A majority of studies examine repetitive task practice, facilitated by robots, for the treatment of upper extremity paresis, with particular attention to the elbow, the shoulder and the wrist segment, using standardized protocols applied to large groups. The use of robotic systems in stroke rehabilitation has witnessed 25 years of development. However, no clinical trials were conducted with a robotic device made for the hand rehabilitation. The robotics systems have already been demonstrated in upper limb motor rehabilitation training, providing safe and intensive treatment to subjects with motor impairments due to a neurological injury. Several studies showed the advantages of robotic therapy on chronic poststroke patients, even if no consistent influence on functional abilities was found, together with evidence of better results after intensive treatments, both robotic and conventional rehabilitative techniques. Furthermore, it has been demonstrated that it is difficult to ascertain the effectiveness of rehabilitative interventions on conditions leading to long-term disability, such as stroke, because the outcome depends on many interacting factors. Many studies, though, underline the importance of brain plasticity and its therapeutic potential in neurological disorders. Accredited theories of cortical reorganization after brain lesion endorse the use of early, intensive, repetitive, and context-related exercise as optimal strategies to promote motor relearning and minimize motor deficit. Currently, in order to improve the motor function, the paradigm of stroke rehabilitation strategies is focused on high-intensity, repetitive finalized, and task-specific training [15], even if there is no widely accepted protocol for hand rehabilitation after stroke, and the treatment varies in duration, intensity, and frequency. The evaluation of outcomes is also a key factor in the robotic rehabilitation treatment, having direct consequences on the patient's amount and time of recovery. A large number of instruments are available, but they are

TABLE 2: Results of observed means \pm standard deviation of all tests and significant P value.

	T0	T1	T2	Statistical significance
	Mean \pm SD	Mean \pm SD	Mean \pm SD	
MMSE	25.1 \pm 2.138			
FM	47.4 \pm 22.77	51.4 \pm 32.67	52.6 \pm 32.22	
MRC flexion	1.2 \pm 1.64	2.2 \pm 1.79	2.4 \pm 1.67	*($P = 0.0085$)
MRC extension	1.2 \pm 1.64	2 \pm 2	2 \pm 1.73	*($P = 0.0239$)
AS HAND	2 \pm 1	1.4 \pm 1.14	1.6 \pm 0.9	
AS WRIST	1 \pm 0.7	1 \pm 0.7	1 \pm 0.7	
MI	19.8 \pm 23.27	32 \pm 41.24	32 \pm 41.24	
Barthel Index	30.6 \pm 10.99		55.6 \pm 23.9	
FIM	57.4 \pm 18.6		83 \pm 21.35	
COPM performance	3.17 \pm 1.563		3.97 \pm 1.321	
COPM satisfaction	2.79 \pm 1.329		4.51 \pm 2.294	
Strength hand flexion	6.06 \pm 6.882		9.5 \pm 10.4	
Strength hand extension	1.4 \pm 3.13		2.56 \pm 5.391	

FM: Fugl-Meyer Scale, MRC: Medical Research Council Scale for Muscle Strength (hand flexor and extensor muscles), MI: Motricity Index, AS: modified Ashworth Scale for wrist and hand muscles, FIM: Functional Independence Measure scales, COPM: Canadian Occupational Performance Measure performance and satisfaction subscales.

poorly validated [16]. Till now, a shared consensus on specific clinical outcome examinations that should be used to assess the effects of robot-assisted therapy is lacking [17]. Mehrholz and colleagues assessed the effectiveness of robot-assisted arm training in improving ADL independence and arm function in stroke patients [18]. They identified 11 trials and the result showed that, in general, a robotic device for the upper limb resulted safe with no side effects, with improvements in arm function and motor strength, but without improvements in ADL independence. These results were confirmed by Kwakkel and collaborators [19]. A recent meta-analysis, for patients after stroke, conducted by Mehrholz and colleagues, focused on electromechanical and robot-assisted arm training for recovery of arm function, with other rehabilitation or placebo interventions—or no treatment at all—, showed that patients who received electromechanical and robot-assisted arm training after stroke are more likely to improve their generic activities of daily living, with an improvement of the paretic arm function, but not the arm muscle strength. In the 19 trials, involving a total of 666 participants, that have been examined, the most important issue was the total absence of the robotic device for the hand. The authors suggested that the results must be interpreted with caution because there were variations between the trials in the duration and amount of training, type of treatment, and in the patient characteristics [20]. Our result shows that an intensive robot-assisted treatment in stroke patient may achieve a significant decrease of motor impairment in the paretic hand [17]. The present study represents the first one carried out, so far, to test the effects of a robot-assisted hand treatment systematically, using the robotic technology as neurorehabilitation therapy in acute patients who experienced a first stroke. The protocol is easy and reproducible and allows the treatment of patients

with moderate to severe upper limb paresis. The intensive training, with a high frequency of gripping movements, especially encourages this rethinking process. During the task-oriented training, the demands on the motor functions could be increased continually. The device supports the intensity, which is needed for the patient to exercise at their individual limit of performance, exactly. This characteristic could be the neurophysiological basis of our result. In particular, the results of statistical analysis of MRC, which demonstrate a positive effect of the robot-assisted approach in early phase on recovery the muscle strength, and the scores of AS suggested that the management of the spasticity is more effective if the rehabilitative treatment starts during the acute phase. The spasticity can develop days to weeks after an acute stroke and, although it may improve or resolve in some individuals, eventually, it may be a permanent sequel in others [21]. Moreover, the management of the spasticity in the first phase of recovery must interfere with the ability and it can be painful or predispose to the development of ulcers and contractures [22]. Furthermore, a gain of FM score, that is related to a reduction of sensorimotor impairment, and a gain of MI scale score, that measures the muscle force with a good recovery on quality of life detected by Barthel Index scale, were also found. The use of robotic platforms to administer the rehabilitation therapy must be crucial, for this reason, because the physical therapies based on robotic platforms assure that each patient, in the same testing group, is treated in the same repeatable way, eliminating the intrinsic subject-dependent variability that affects traditional therapies. Moreover, the robotic platforms, in conjunction with EEG and EMG recordings, could be used to assess the effects of the rehabilitative treatments in a quantitative, measurable way, providing reliable and objective methods for measuring functional recovery after stroke.

5. Study Limitations

The very small sample size, the absence of control group, and the absence of power calculation did not allow to have a high significance in the clinical scales score. Moreover, the lack of control group did not give the possibility to verify if this treatment is valid in terms of effectiveness, but the improvement of all scales could encourage to design a large RCT.

6. Conclusions

The focus on the very early phase of stroke recovery represents a further innovative characteristic of this study, which makes this research useful to clinical practice. The lack of side effect and the good participation, with an absence of the dropout, may suggest a large clinical use. Future positive results of the robotic treatment could be relevant for the advancement of knowledge in hand rehabilitation field and for the development of new clinical guidelines about hand rehabilitation in subjects with stroke.

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Clinical Study

Walking Training with Foot Drop Stimulator Controlled by a Tilt Sensor to Improve Walking Outcomes: A Randomized Controlled Pilot Study in Patients with Stroke in Subacute Phase

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Foot drop is a quite common problem in nervous system disorders. Neuromuscular electrical stimulation (NMES) has showed to be an alternative approach to correct foot drop improving walking ability in patients with stroke. In this study, twenty patients with stroke in subacute phase were enrolled and randomly divided in two groups: one group performing the NMES (i.e. Walkaide Group, WG) and the Control Group (CG) performing conventional neuromotor rehabilitation. Both groups underwent the same amount of treatment time. Significant improvements of walking speed were recorded for WG ($168 \pm 39\%$) than for CG ($129 \pm 29\%$, $P = 0.032$) as well as in terms of locomotion (Functional Ambulation Classification score: $P = 0.023$). In terms of mobility and force, ameliorations were recorded, even if not significant (Rivermead Mobility Index: $P = 0.057$; Manual Muscle Test: $P = 0.059$). Similar changes between groups were observed for independence in activities of daily living, neurological assessments, and spasticity reduction. These results highlight the potential efficacy for patients affected by a droop foot of a walking training performed with a neurostimulator in subacute phase.

1. Introduction

Foot drop is a common sign of many nervous system diseases, characterized by a patient's inability to dorsiflex the ankle, raising the foot. Conventionally, physicians use Ankle-Foot Orthosis (AFO) to correct foot drop during walking. An AFO is typically a polyethylene brace, supporting the ankle in a fixed position in order to help foot in swing phase avoiding forefoot contact with the floor.

Neuromuscular functional electrical stimulation (NMES) may be an alternative approach. It refers to stimulation of lower motor neurons to assist the muscle contraction, and to favour functional tasks as standing, ambulation, or activities of daily living (ADL) [1]. Functional electrical stimulation devices are also referred to as neuroprostheses.

Clinical applications of NMES may take place in stroke rehabilitation, providing both therapeutic and functional

benefits. In particular, treatments with NMES enhance function but do not directly provide function. The NMES can be timed with the swing phase of the gait cycle to stimulate the ankle dorsiflexor muscles. Only foot drop resulting from central nervous system diseases can be treated, because it needs nerve integrity [2]. Stimulating the Common Peroneal Nerve (CPN), NMES operates actively in the ankle dorsiflexion, strengthening the muscle and correcting foot drop. Everaet and colleagues showed that the use of neuromuscular stimulations lasting 3 months increased the maximum voluntary contraction and motor evoked potentials [3]. NMES-mediated repetitive movement therapy may also facilitate motor relearning [4], that is defined as the capacity of recovery of previously learned motor skills that have been lost following localized damage to the central nervous system [5]. Moreover, NMESs have been shown to provide physiologic changes in the brain

including activation of sensory and motor areas, reducing the intracortical inhibition, and increasing amplitude of motor-evoked potentials [6, 7].

In patients with hemiparesis due to stroke, NMES can be used for those that have not sufficient residual movement to perform active repetitive movement treatments. Necessary prerequisites for NMES-mediated motor relearning include high repetition, novelty of activity, capacity to effort, and high functional content [8].

A recent meta-analysis concluded that the use of functional electric stimulation is effective in improving gait speed in patients with stroke, suggesting a positive orthotic effect [9, 10].

However, it is still unclear whether NMES improves overall mobility function [4]. Furthermore, it has been also demonstrated as hemiplegic patients treated with AFO may obtain comparable results to that of those treated with peroneal nerve stimulator in terms of gait improvement [3, 11]. In fact, a multicenter trial demonstrated that both efficacy and acceptance of the stimulator were good in a population of subjects with chronic foot drop improving gait velocity and number of steps taken per day [3]. Finally, no studies have been conducted to compare different approaches of NMES (cyclic NMES, EMG-mediated NMES, and neuroprostheses).

In our study we investigated the use of a commercial stimulator using a tilt sensor (WalkAide, Innovative Neurotronics, Austin, TX, USA), which measures the orientation of the shank, controlling when turning the stimulator on and off.

The principal aim of the study was to evaluate the efficacy of the device in terms of walking speed in patients with stroke in a subacute phase. The secondary aim was to verify the effects on walking capacity, mobility and spasticity.

2. Material and Methods

2.1. Participants. Patients included in the study were affected by first stroke in subacute phase, aged between 18 and 80 years, with an inadequate ankle dorsiflexion during the swing phase of gait, resulting in inadequate limb clearance. Participants needed an adequate cognitive and communication function to give informed consent and understand the training instructions (MMSE > 24). The involved patients were able to ambulate with or without aid of one person with assistive device if needed (FAC 2, 3, or 4), at least 10 meters.

Patients were excluded with severe cardiac disease such as myocardial infarction, congestive heart failure, or a demand pacemaker; Patients were excluded if they had a severe cardiac disease such as myocardial infarction, congestive heart failure, or a pacemaker; if it was present a ankle contractures of at least 5 degrees of plantar flexion when knee is extended; if they had orthopaedics or other neurological conditions different from stroke affecting ambulation (e.g. parkinsonism, previous limb fracture, etc.). Twenty patients were enrolled (mean age: 57 ± 16 years) and randomized in two groups: one group performing therapy with WalkAide (WG) and a control group (CG) performing conventional neuromotor rehabilitation as reported in the following section.

Local ethical committee approved the study and all patients signed informed consent before starting the protocol.

2.2. Therapy. Study was designed as a randomized controlled with two groups of patients. After the enrolment, patients were evaluated by a blind physician and randomly assigned to treatment or control group. Raters were unaware to the group allocation. The intervention group performed 20 session, 40 minute, 5/time per week of walking training with Walkaide, whereas control group performed the same amount of walking training with an AFO.

For WG, a set-up phase was necessary in which a manual controller and a heel sensor pressure data were collected and connected to the other electronic components both by a telemetry link. Analyzing data obtained in the set-up phase and matching them with the rehabilitative purpose, it was necessary as preliminary phase to choose useful tilt parameters to correct foot drop.

Both groups undertook 40 minutes with a physiotherapy dedicated to improve activity of daily living and/or exercise for hand recovery. When needed, patients underwent also speech therapy or therapy for dysphagia.

2.3. Outcome Measures. All the outcome measures have been assessed before the beginning of walking training (T0) and at the end of this training (T1), about 1 month later.

The primary outcome measure was the time spent to walk for 10 m, that is, the time spent to complete the 10 m walking test (10 mWT). The walking speed (WS) during this test has been computed as the ratio between distance (10 m) and the time spent to cover it. Percentage increment of WS has been computed as the difference between WSs at T1 and T0 divided by that at T0 and multiplied for 100.

The secondary outcome measures were the scores obtained by the following clinical scales: Functional Ambulation Classification (FAC) [12] to assess the walking ability, Barthel Index (BI) [13] to assess the independency in activities of daily living, Rivermead Mobility Index (RMI) [14] to assess the mobility, Medical Research Council (MRC) [15] scale manually assessing the muscle strength, Canadian Neurological Scale (CNS) [16] to assess the neurological status of patients, and ashworth scale (AS) [17] to assess the spasticity of the lower limb.

The effectiveness of treatment in terms of scale scores was computed as the proportion of potential improvement that was achieved during treatment, calculated as $[(\text{final score} - \text{initial score}) / (\text{maximum score} - \text{initial score})] \times 100$. The advantages of using effectiveness was that if a patient achieved the highest possible score after rehabilitation, the effectiveness was 100%, and this measure is continued [18].

2.4. Statistical Analysis. Data are reported in terms of mean \pm standard deviation for continuous measurements and median (interquartile range) for scale scores. An analysis of variance was performed on the primary outcome measure using as main factor the group (WG versus CG, between subjects factor) and treatment (T0 versus T1, within subjects

factor), including in the general linear model also the interaction between these two factors. The percentage increments of WS have been compared between the two groups using unpaired t -test and mean difference, 95% confidence interval (CI_{95%}), and power analysis (with alpha error level set at 5%) were also computed and reported.

Nonparametric statistics was performed on ordinal measures such as clinical scale scores: FAC-score, BI-score, RMI-score, MRC-score, CNS-score, and AS-score, all assessed by means of Wilcoxon Signed Rank Test to assess the significance of changes in each group.

3. Results

The two groups resulted matched for age ($P = 0.267$) and for time from stroke ($P = 0.226$), although the WG was quite older (53.3 ± 14.6 versus 61.2 ± 16.2), but at admission their time from stroke event was quite longer than control group (27 ± 27 versus 13 ± 7 days). The duration of specific treatment for walking was not statistically different between the two groups (WG: 34.6 ± 11.2 days versus CG: 34.7 ± 7.6 , $P = 0.980$).

The primary outcome measure, that is, the time spent to walk for 10 meters, resulted is significantly affected by the interaction between group and treatment ($F_{df=1,18} = 5.419$; $P = 0.032$). As shown in Table 1, this revealed a higher improvement in terms of walking speed in WG ($168 \pm 39\%$) in respect of that of CG ($129 \pm 29\%$, $P = 0.021$, t -test). This mean difference (39% , CI_{95%} = 6; 72%) had a statistical power of 81.4%. The factor group did not mainly affected the time to complete the 10mWT ($F_{df=1,18} = 0.205$; $P = 0.656$), whereas the treatment did it ($F_{df=1,18} = 23.375$; $P < 0.001$). However, as shown in Figure 1, these results were mainly due to an initial difference of the performance of the two groups, more than to a difference after treatment. In fact, the subjects of WG before the treatment with Walkaide walked slower than CG, whereas they walked quite faster of CG at the end of treatment.

All these measures, but Ashworth-score, were significantly improved after treatment in both the groups, as detailed in Table 1. Between-group analysis showed that the effectiveness resulted higher in WG than in CG for all the five secondary outcome measures (Figure 2). These differences were statistically significant for FAC-score, and close to the significant threshold for RMI- and MRC-scores.

4. Discussion

Our results showed a significant improvement in both groups of subjects, with a higher proportion for WG than for CG, especially for the parameters related to walking. However, it should be noted that the initial values of the two groups, for their reduced sample size and for the effects of the randomization, were slightly different, although these differences were not statistically significant. WG was in fact younger and more affected, two factors that could be compensated each other, but also potentially inflating the improvements.

TABLE 1: Primary outcome measure walking speed (WS): mean (standard deviation) and P values of paired post hoc tests. Secondary outcome measures: median (interquartile range) of the scores, and P values of Wilcoxon signed rank test.

Outcome measures		WG	CG
Walking speed (m/s)	T0	0.31 (0.15)	0.38 (0.20)
	T1	0.50 (0.20)	0.49 (0.24)
	P	0.001	0.013
FAC-score	T0	2 (0)	2 (2)
	T1	4 (1)	3 (1)
	P	0.004	0.008
BI-score	T0	70 (16)	67 (16)
	T1	88 (7)	85 (9)
	P	0.005	0.012
RMI-score	T0	6 (4)	7 (4)
	T1	10 (2)	10 (2)
	P	0.005	0.007
MRC-score	T0	19 (9)	21 (11)
	T1	25 (11)	23 (12)
	P	0.005	0.010
CNS-score	T0	6 (3)	8 (3)
	T1	8 (3)	9 (4)
	P	0.011	0.015
AS-score	T0	2 (5)	2 (4)
	T1	3 (5)	3 (5)
	P	0.564	0.480

Nevertheless, the increase in walking speed was clearly higher in WG, and also the use of external aids for walking (assessed by FAC-score) was more limited at T1 in WG than in CG, suggesting a potential benefit by the use of NMES.

This is the first randomized controlled trial demonstrating the efficacy in patients affected by a droop foot of a walking training performed with a neurostimulator in subacute stroke phase.

In fact, a previous study had showed efficacy and good acceptance, but in a chronic population [3]. Similar effects were found when chronic stroke patients were stimulated during walking in the community [19].

In a subacute phase of stroke, Yan and colleagues have reported that the use of cyclic NMES reduces spasticity, strengthens ankle dorsiflexors, improves mobility, and increases home discharge rate inpatient stroke rehabilitation [20]. On the contrary, our results did not find significant changes in terms of Ashworth Score. Also Bogataj and colleagues have highlighted that the improvement in gait performance was maintained during time in respect to those treated with conventional therapy [21]. Different from cyclic NMES, NMES performed during walking on floor may give more benefits to improve walking because its practice is close to real condition and is more focused on improving an ability (walking) more than a function (dorsiflexion). Functional electrical stimulation has been proved to be efficacy in

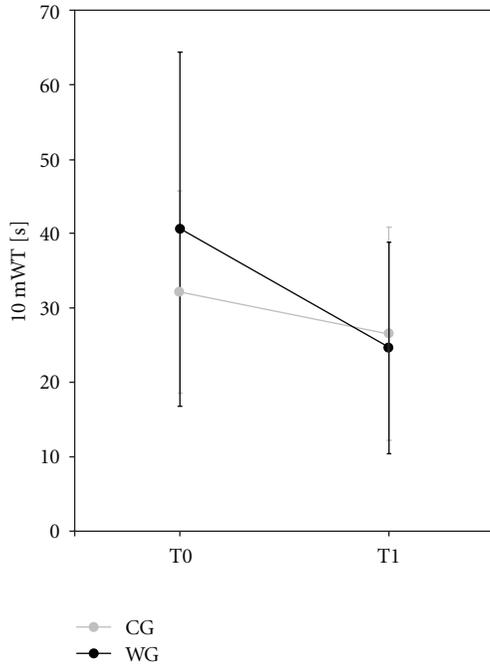


FIGURE 1: Mean and standard deviation of the time spent to walk for 10 m by Walkaide group (WG, black) and control group (CG, grey).

increasing walking speed in chronic stroke even if performed by implantable 2-channel peroneal nerve stimulator for correction of their drop foot [22].

As recently demonstrated, foot drop stimulator increases in the maximum voluntary contraction and motor-evoked potentials suggesting an activation of motor cortical areas and their residual descending connections, which may explain the therapeutic effect on walking speed [3].

A possible explanation of the positive effect on walking recovery in patients affected by a foot drop is that stimulating the peroneal nerve actively dorsiflexes the ankle and strengthens the muscles. At high levels, common peroneal nerve stimulation can produce hip and knee flexion and it has also been claimed to reduce or counteract spasticity [23–25]. This may lead to a global improving of walking function and, maybe, a lower cost in terms of oxygen consumption. Thus, patients during therapy may walk more and better, performing a more amount of steps with less overexertion. This hypothesis might be confirmed by further studies.

Despite these preliminary results of effectiveness, surface peroneal nerve stimulation is not common in the rehabilitative use. This is possibly due to difficulty with electrode placement, discomfort and inconsistent reliability of surface stimulation, insufficient medial-lateral control during stance phase, and lack of technical support. Moreover, NMES induces neuromuscular fatigue but the modification of the electrical stimulation parameters (i.e., frequency, pulse width, modulation of pulses, amplitude, electrode placement, and the use of variable frequency) can reduce fatigue [26, 27].

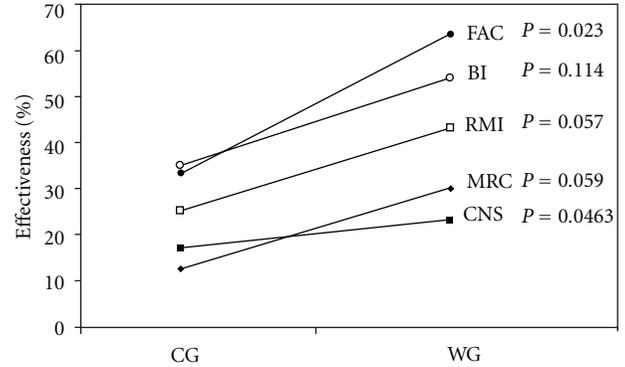


FIGURE 2: Effectiveness for control group (CG) and Walkaide group (WG) in terms of FAC (filled circles), BI (empty circles), RMI (empty squares), MRC (filled rhombus), and CNS (filled squares) scores with the relevant P values of comparison between groups.

The strength AFO is that it is easy to dress and the users can have it custom-molded; the limit of AFO is that it corrects foot-drop through a passive mechanism not involving neuromuscular, spinal, and brain circuits.

Further research on NMES should highlight top-down approach during subacute rehabilitation program transforming the actual human machine interaction [28] in online brain/human machine interaction by mean EEG signals [29].

Some limitations of this study deserve mentioning. Future investigations should be addressed on clinical outcomes at the level of activity limitation and quality of life. Moreover, a peculiar attention should be paid to the long-term outcomes to define the rehabilitative impact of the NMES use. Future studies should also determine the optimal dose and prescriptive parameters, tracking a line for a common use of clinicians and therapists.

In order to better define the role of motor relearning, systems should be addressed towards a neurocognitive use, combining also principle of basic science [30]. Moreover, neuroprostheses should be developed to provide goal-oriented, repetitive movement therapy in the context of functional and meaningful tasks, providing a clear functional, cost-effective benefit in patients with stroke [31].

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Clinical Study

A Pilot Evaluation of On-Road Detection Performance by Drivers with Hemianopia Using Oblique Peripheral Prisms

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Aims. Homonymous hemianopia (HH), a severe visual consequence of stroke, causes difficulties in detecting obstacles on the nonseeing (blind) side. We conducted a pilot study to evaluate the effects of oblique peripheral prisms, a novel development in optical treatments for HH, on detection of unexpected hazards when driving. **Methods.** Twelve people with complete HH (median 49 years, range 29–68) completed road tests with sham oblique prism glasses (SP) and real oblique prism glasses (RP). A masked evaluator rated driving performance along the 25 km routes on busy streets in Ghent, Belgium. **Results.** The proportion of satisfactory responses to unexpected hazards on the blind side was higher in the RP than the SP drive (80% versus 30%; $P = 0.001$), but similar for unexpected hazards on the seeing side. **Conclusions.** These pilot data suggest that oblique peripheral prisms may improve responses of people with HH to blindside hazards when driving and provide the basis for a future, larger-sample clinical trial. Testing responses to unexpected hazards in areas of heavy vehicle and pedestrian traffic appears promising as a real-world outcome measure for future evaluations of HH rehabilitation interventions aimed at improving detection when driving.

1. Introduction

Driving is the primary mode of transportation in the USA. Cessation of driving decreases independence and employment opportunities and increases the risk of depression [1, 2]. Thus, returning to driving following a stroke is an important rehabilitation goal. However, since stroke may cause a number of visual, perceptual, cognitive, and motor impairments that could adversely affect driving skills, post-stroke driving rehabilitation is not straightforward [3–5]. In this paper we focus on rehabilitation of people with homonymous hemianopia (HH), the loss of the same half of the visual field in each eye due to postchiasmal lesions, a severe visual consequence of stroke. People with spatial neglect or other significant cognitive impairments were not included, as our goal was to address the effects of the sensory visual loss without other confounding perceptual or cognitive impairments.

In 2010, there were about 6.2 million stroke survivors in the USA [6] with at least 50% having partial or complete HH

in the acute stage immediately following the stroke [7, 8]. Spontaneous recovery, either complete or partial, may occur within the first three months after the injury [8–11], but improvement after six months is rare [9]. About 30% of stroke patients still have chronic HH after nine months [12]. Chronic HH causes difficulties in detecting objects on the nonseeing (blind) side that may compromise safe walking (bumping into obstacles and falls [13, 14]), compromise safe driving (failure to see potential blindside hazards [15–17]), limit independence, and reduce quality of life [18–20].

In Europe [23], Australia [24], and 22 states of the USA [25], persons with HH do not meet the minimum visual field requirements for licensure (e.g., 120° horizontal field in Massachusetts). However, there are some states where they do meet the field requirements (e.g., New Hampshire has no field requirement) and may legally drive. Furthermore, in some countries (e.g., Belgium, Netherlands, Switzerland, UK, and Canada), persons with stable vision loss (but less than 120° horizontal field) may be licensed after taking a specialized on-road test [23, 26, 27]. Even when persons with

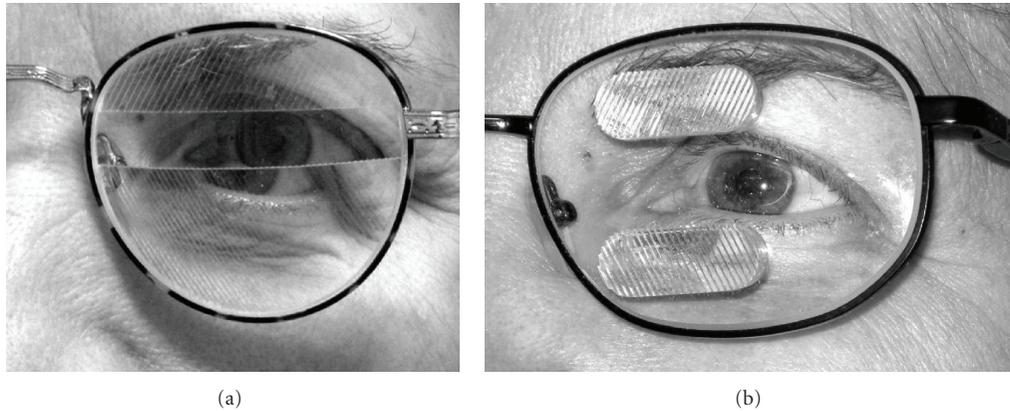


FIGURE 1: (a) Press-on 40Δ Fresnel peripheral prism segments in the oblique configuration on the left spectacle lens as fitted for the study to a patient with left HH. The upper prism is base out and base down, and the lower prism is base out and base up, shown with 9 mm interprism separation, providing expansion in the central area of the visual field used when driving (Figure 2(b)). The effect of the lower prism is notable by the apparent shift of the centrally located lower lid margin, iris, and sclera (imaged by the prism segment). The wearer has an uninterrupted binocular view through the central prism-free area of the lens. (b) Higher-power, 57Δ permanent prism glasses in the oblique configuration with 12 mm interprism separation (not used in this study, but now available from Chadwick Optical Inc., White River Junction, VT, USA).

HH are not legally permitted to drive, some do continue to drive to maintain independence and quality of life; 50% of participants with complete HH in a driving simulator study were still driving despite not meeting the 120° field requirement of the state in which the study was conducted [15]. Pass rates of drivers with HH in on-road studies have varied from 17% [28] to 73% [29], suggesting that some people with HH may be considered fit to drive [27, 30]. Nevertheless, there is a strong evidence that HH adversely affects both vehicle control (steering and lane position [28, 29, 31–33]) and detection of potential blindside hazards [15–17].

Prism glasses are a commonly-applied rehabilitation treatment for HH that optically shift images of objects located in the blind field into regions of the seeing field so that they can be seen [34]. Potentially they could be used to ameliorate blind-side deficits of HH drivers, but there are only very limited data addressing their effects on driving-related skills [35]. Here we report a pilot evaluation of the effects of a new type of prism glasses—oblique peripheral prisms—on detection of unexpected hazards while driving.

Peripheral prisms are a recent development in optical treatments for HH [36]. High-powered prism segments placed above and below the primary line of sight on the spectacle lens on the side of the field loss (Figure 1) provide visual field expansion (enlargement of the visual field; Figure 2), which is helpful for obstacle detection when walking [21, 36, 37]. When permanent peripheral prism glasses incorporating 57Δ embedded prism segments are worn (Figure 1(b)), the expansion can extend as much as 30° into the blind hemifield (equivalent to the width of about 6 to 7 lanes of traffic at 50 m). The latest innovation is the oblique design [38] that provides expansion in paracentral areas of the field, in regions used when looking through a car windshield [22] (Figure 2(b)). By comparison, the original “horizontal”

design provided expansion only in areas outside the central regions of the field (Figure 2(c)). With the oblique design, although the expansion is in paracentral areas, the prism images fall on more peripheral retina; therefore, central diplopia (double vision) does not occur. Users are taught to always look through the central, prism-free area of the lens and to eye scan as they would do habitually; the visual field expansion is effective at all lateral positions of gaze.

With the use of the oblique peripheral prisms, it is possible that people with HH could meet the visual field requirements for licensure in many states and countries (e.g., 90° horizontal visual field extent plus 20° to 30° field expansion, depending on the power and design of the prisms). Indeed, a few persons with HH have already been licensed to drive with these prisms in the USA and Canada. However, use of these prisms does not necessarily mean that the wearer would be safe to drive and, as yet, there had been no evaluation of their effects on detection performance when driving. We therefore conducted a pilot, open-road trial comparing driving performance when real and sham oblique peripheral prisms were worn. Response to unexpected blindside events was selected as the primary measure of the effects of the prism glasses for two reasons. Firstly, reactions to potential pedestrian hazards in driving simulator studies had proven to be a sensitive measure of the effects of a variety of types of visual field loss [15, 16, 39]. Secondly, data from two on-road studies of drivers with peripheral field loss due to glaucoma had demonstrated the possibility of using reactions to unexpected hazards as an outcome measure in open-road evaluations. In the first study [40], drivers with more restricted visual fields had poorer responses to unexpected events than drivers with less restricted fields, while in the second [41] drivers with glaucoma were 6 times more likely to have a critical intervention (driving examiner took control of the vehicle) than drivers with normal vision. Importantly,

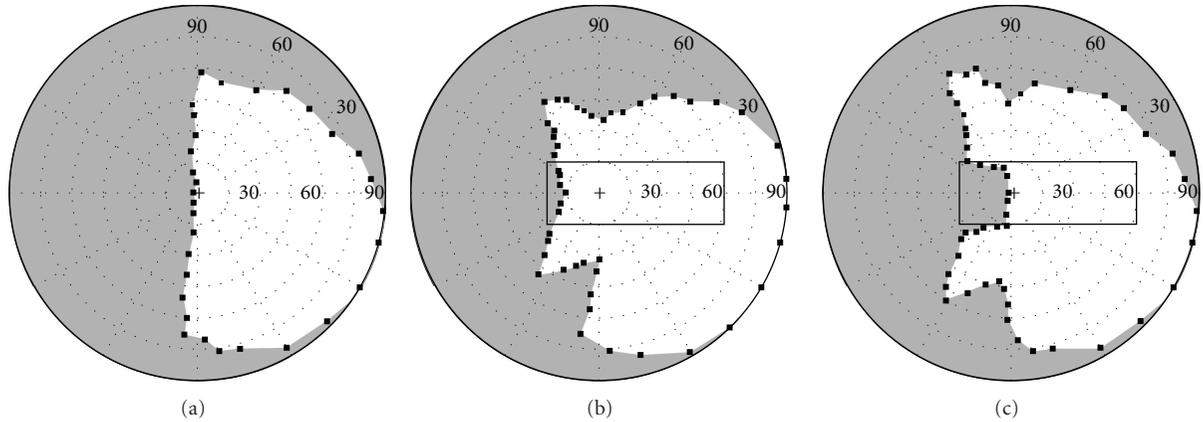


FIGURE 2: Binocular visual field (Goldmann V4e) of a patient with left HH (a) without peripheral prisms, (b) with 40 Δ oblique peripheral prisms as fitted for this study with no vertical separation between the expansion areas (9 mm interprism separation and 30° angle of tilt), and (c) with the original horizontal design of 40 Δ peripheral prisms for walking [21] (12 mm interprism separation). The oblique design provides about 20° of lateral expansion into central areas of the blind hemifield in the region used when looking through a car windshield (rectangle represents the field of view through a typical car windshield for driving on the right [22]); the horizontal design does not provide expansion within this area. Small black squares are the individual points mapped during the perimetry.

the critical interventions were primarily due to detection failures, mostly failing to notice pedestrians.

The main aim of the study was not to conduct fitness-to-drive tests in order to provide driving licenses for study participants. Rather, our goal was to conduct a pilot study to evaluate the effects of oblique peripheral prisms on detection of unexpected hazards when driving in order to acquire the necessary preliminary data to design a larger sample, future clinical trial of the device.

2. Methods

The study was conducted in accordance with the tenets of the Declaration of Helsinki and was approved by the Ethics Committees of the University Hospital of Ghent and Schepens Eye Research Institute. All participants gave their written consent before entering the study.

2.1. Participants. Four current and eight noncurrent HH drivers (with previous driving experience), representative of people with HH who might be driving or wish to resume driving, were recruited from individuals with visual field defects who had applied to CARA (a department of the Belgian Road Safety Institute) for a fitness-to-drive evaluation or annual reevaluation. Screening tests to determine eligibility were conducted by study investigators. The primary inclusion criteria were complete HH (no more than 5° of residual vision on the hemianopic side of the vertical meridian within 30° above and below fixation assessed with a Goldmann V4e target [37]), and no visual neglect (Bells test [42] and Schenkenberg Line Bisection test [43]). In addition, participants had visual acuity of 6/12 (20/40) or better in each eye with their habitual correction, and no significant cognitive decline (Minimal State Examination test, MMSE \geq 24 [44]). Previous studies [15, 17] have reported no significant differences in blindside detection rates between

right and left HH for participants without neglect; therefore, ensuring equal numbers of right HH and left HH was not a recruitment goal. Thus, our sample was homogeneous for visual and perceptual factors that might impact detection, but heterogeneous for other factors that normally vary within the HH population who are likely to want to apply for a driving license (Table 1).

Eleven participants had driven for at least 15 years before the onset of the HH, including eight who had not driven since the onset (range 0.3–11.3 years; Table 1), and three who were currently active licensed drivers and were applying for reevaluation. The twelfth was in the process of obtaining a driving license but had been driving vehicles on private land for many years and had completed 10 hours of driving lessons prior to enrolment. Current drivers ($n = 4$) tended to be younger and to have had HH for longer than noncurrent drivers (Table 1; $P = 0.13$). For noncurrent drivers ($n = 8$), the etiologies were stroke (5), tumors (2), and traumatic brain injury (1). For current drivers the etiologies were stroke (3) and brain surgery for epilepsy (1). None of the participants had motor impairments that affected their ability to operate a car. For the three participants with hemiplegia (Table 1), the test vehicle was adapted to their needs, including selecting automatic gearshift and attaching steering knobs. There was no evidence that the hemiplegia adversely affected their driving performance.

2.2. Peripheral Prisms. An orthoptist at the University Hospital of Ghent, Belgium, (Universitair Ziekenhuis Gent) fitted and trained participants in the use of the prism glasses following procedures based on those successfully implemented in previous studies in which the prisms were evaluated for walking [21, 37]. The only difference was that the “oblique” prism configuration was used [38]. Upper and lower 40 Δ press-on Fresnel prism segments (3M Health Care, St Paul, MN, USA) were fitted to the back surface of one

TABLE 1: Characteristics of the participants with HH.

	All participants ($n = 12$)	Current drivers ($n = 4$)	Noncurrent drivers ($n = 8$)
Male, n (%)	9 (75)	3 (75)	6 (75)
Age, years	49	44	53
Median, range	29 to 68	29 to 60	43 to 68
Binocular VA	6/6	6/6	6/6
Median, range	6/4.5 to 6/7.5	6/4.5 to 6/6	6/5 to 6/7.5
Left hemianopia, n (%)	8 (67)	2 (50)	6 (75)
Time since onset HH, years	2.3	6.1	0.8
Median, range	0.3 to 11.3	1.9 to 11.3	0.3 to 10.3
Stroke caused HH, n (%)	8 (67)	3 (75)	5 (63)
Hemiplegia, n (%)	3 (25)	1 (25)	2 (25)
MMSE score	28	28	29
Median, range	26 to 29	26 to 29	27 to 29

lens (on the side of the field loss) of participants' spectacles primarily used for distance vision. The upper prism was placed base out and base down and the lower prism was placed base out and base up, with the base-apex line at an angle of tilt of 30° to the horizontal (Figure 1(a)). The interprism separation was adjusted so that there was little ($2\text{-}3^\circ$) or no vertical separation between the visual field expansion areas (mapped with V4e target in a Goldmann perimeter), ensuring that the expansion covered as much as possible of the central visual field likely to be used when driving (Figure 2(b)). Participants were taught to always look through the central, prism-free area of the lens and were told to eye scan as they would do habitually.

2.3. Supervised Driving with Prisms. After four weeks of using the prism glasses for walking and as a front-seat car passenger (but not driving), all participants drove for two hours in locations of their choice, wearing and using their prisms under the supervision of a CARA driving evaluator. The primary role of the evaluator was to ensure safety; no scoring was conducted. The supervised practice ensured that all participants had some experience of using the prisms while driving before undertaking the driving evaluation with the prism glasses.

2.4. Driving Evaluations with Real and Sham Prisms. About two weeks after the supervised driving practice with the prisms, participants completed two test drives. In one, the participant was fitted with the prescribed 40Δ prisms (real prisms; RP). In the other, the participant also wore press-on Fresnel prisms, but of a very low power (5Δ ; sham prisms; SP), which provided no useful field expansion (2°), essentially equivalent to not wearing prisms. The prisms were fitted and changed in between test drives by a third person (a clinician at the hospital). To the evaluators conducting the test drives, the RP and SP glasses appeared identical (both were of the oblique design). Thus the evaluators were masked as to whether the participant was wearing real or sham prisms. However, the participants and clinicians were not masked. The two test drives were conducted on the same

day by the same evaluators with an hour break in between; the order of the RP and SP drives was counterbalanced across participants.

2.5. Route and Evaluation Procedures. To ensure that route familiarity did not affect driving performance, different routes of comparable difficulty (each about 25 km in the city of Ghent, Belgium) were used for the RP and SP drives. The route used for each drive was counterbalanced across participants. The route designs were based on those implemented in a previous on-road study [40] and were representative of routes used in standard fitness-to-drive evaluations conducted by CARA. Each route included a similar number of maneuvers and road types (residential and nonresidential, city center, and highway (120 km/h) or expressway (divided road at 90 or 120 km/h)). The traffic was dense, especially in the city and residential areas, including many pedestrians, bicycles, trams, and other vehicles. The high traffic density (including pedestrians and bicyclists) provided ideal conditions for evaluating the impact of the prisms on detection of potential blindside hazards.

The driving evaluations were conducted by CARA evaluators in dual-control cars. The procedures were similar to standard CARA practice for official fitness-to-drive tests, differing only in the scoring system employed and the use of predetermined routes. The CARA evaluator sat in the front seat and had access to the dual controls. The driving evaluations were scheduled as part of the daily CARA routine; therefore, based on their availability, four experienced CARA evaluators participated. Their role was to ensure safety and provide navigational instructions. Detailed scoring [40] of driving was conducted by a rater in the back seat; it was the same rater for all participants (a specialist in fitness-to-drive evaluations of visually impaired people).

At the start of the driving evaluation, a number of basic maneuvers were performed in a parking lot to familiarize the participant with the car and its controls. All driving tests took place in the prevailing weather conditions (unless unsafe because of snow) and between 8:30 AM and 3:00 PM to avoid rush hour traffic in the city. Each test drive took about 40 minutes.

TABLE 2: Summary of interventions that occurred in each condition and on each side for current ($n = 4$) and noncurrent ($n = 8$) drivers.

Intervention	Condition				Total for each intervention
	SP drive		RP drive		
	Current	Noncurrent	Current	Noncurrent	
Brake	1 (0; 1; 0) [†]	9 (3; 5; 1)	0	5 (3; 2; 0)	15
Steering correction	0	6 (1; 0; 5)	1 (0; 0; 1)	1 (0; 0; 1)	8
Verbal advice	1 (0; 1; 0)	4 (2; 0; 2)	0	0	5
Accelerator	0	1 (0; 0; 1)	0	0	1
Total for each drive	2 (0; 2; 0)	20 (6; 5; 9)	1 (0; 0; 1)	6 (3; 2; 1)	
Overall total		22 (6; 7; 9)		7 (3; 2; 2)	29

[†]Numbers in brackets provide the breakdown of interventions by side (seeing side; blind side; no side). Cells with italics are significantly different, as are cells with bold (see Figure 3).

2.6. Driving Measures. Two main aspects of driving were evaluated: responses to unexpected hazards and driving skills (including vehicle control) for specific maneuvers. We evaluated these skills to ensure that there were no negative effects of using the prism glasses (e.g., lane position might be affected by areas of the blind hemifield being made visible by the visual field expansion).

Whenever an unexpected hazard occurred, the backseat rater scored the response of the driver as either satisfactory (safe) or unsatisfactory (unsafe; either without or with an intervention by the CARA evaluator). He also noted details of the hazard, including what the hazard was and whether it was on the left or the right of the car (subsequently recoded into the blind or seeing side for analyses). Interventions were made whenever the CARA evaluator judged that driving was becoming dangerous and there was no option other than to intervene to prevent accidents or collisions. Steering corrections were easily seen from the back seat, while use of the second brake or gas pedal was accompanied by a mechanical sound as well as a light to indicate their use to the backseat rater. Interventions are a direct measure of driving safety, while responses to unexpected hazards that did not require an intervention represent a proxy measure of driving safety.

Detailed scoring [40] of driving skills (lane position, steering, speed, gap judgment, and scanning) was conducted for a range of maneuvers (turning and crossing at intersections, curve taking, merging, changing lanes, and overtaking) by the backseat rater at predetermined locations along the route. Skills were scored as either satisfactory (safe), inadequate (but not unsafe), or unsatisfactory (unsafe; either without or with an intervention). For each driving skill, the proportion of satisfactory scores was computed for each participant as the number of satisfactory scores divided by the total number of times that a skill was assessed (including data from all maneuvers in which the skill was scored).

2.7. Data Analyses. The effect of the prisms was tested by comparing performance in the RP and SP drives. For measures with sufficient data, the effect of driving status (current or noncurrent driver) was also examined. Primary measures included the proportion of satisfactory responses to unexpected hazards on the blind and seeing sides, and the proportion of satisfactory scores for each driving skill.

3. Results

3.1. Responses to Unexpected Hazards. During the 24 drives, there were 80 unexpected hazards. Ten participants had unexpected hazards in both RP and SP drives; two had unexpected hazards in only one of the drives. Unexpected hazards were mainly pedestrians, vehicles, and bicycles at intersections. Responses were rated as unsatisfactory for 41 events (29 with an intervention and 12 without an intervention) and satisfactory for the remaining 39.

Braking was the most common intervention (Table 2) and was primarily due to failures to notice a traffic event (vehicles, pedestrians, traffic lights). By comparison, steering interventions were less common (Table 2) and were mainly a result of taking a lane position too far to the right or the left, or weaving; only 1 of 8 was a result of failing to notice a traffic event. For noncurrent drivers, there were significantly fewer interventions in the RP than the SP drives (Wilcoxon signed ranks test, $z = 2.22$, $P = 0.01$; Table 2 and Figure 3), and they had significantly more interventions than current drivers in the SP, but not the RP drives (Mann-Whitney U test, $z = 1.84$, $P = 0.04$ and $z = 0.51$, $P = 0.34$, resp.; Figure 3).

Of the 80 unexpected hazards, 68 could be attributed to an event on either the blind (9 with and 34 without an intervention) or seeing side (9 with and 16 without an intervention). On the blind side, although the total number of events was similar for the RP and SP drives, the proportion of satisfactory responses was significantly higher in the RP drive (80% versus 30%; $z = 3.25$, $P = 0.001$; Figure 4); the same was true when only the participants with stroke were included (93% versus 32%; $z = 3.52$, $P < 0.001$). These analyses were for data pooled across participants, irrespective of whether or not there was an unexpected hazardous event on the blind side in both the RP and SP drives. When data for only those participants with blindside events in both the SP and RP drives ($n = 8$) were considered, the proportion of satisfactory responses for data pooled across participants was still significantly higher in the RP drive (78% versus 32%; $z = 2.90$, $P = 0.002$) and the proportion of satisfactory responses *per* participant was also significantly higher in the RP drive (Wilcoxon signed ranks test, $z = 1.88$, $P = 0.03$; Figure 5). Taken together, these results indicate a beneficial effect of the RP glasses on detection of blindside hazards. By comparison,

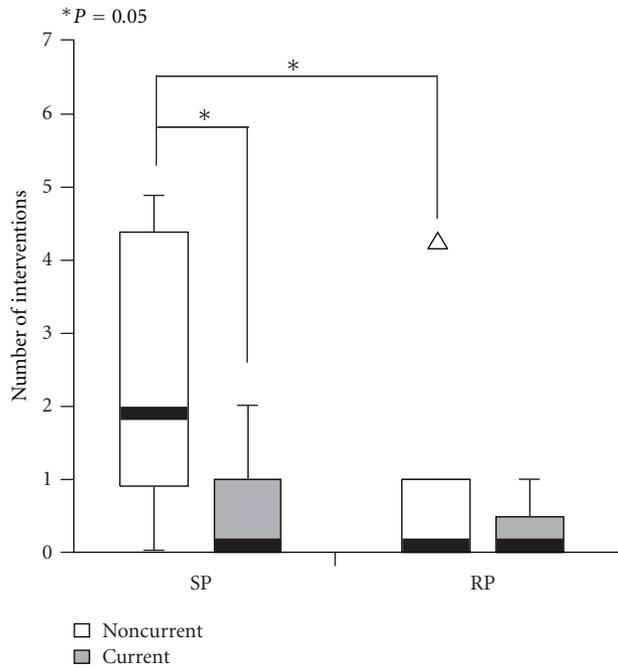


FIGURE 3: Number (median and interquartile range) of interventions in each drive for individual participants. Noncurrent drivers had fewer interventions in the real prism (RP) than the sham prism (SP) drives, and more interventions than current drivers in the SP but not the RP drives. The thick horizontal line within each box is the median; the vertical extent of the box is the interquartile range (IQR); vertical lines at box ends represent the largest nonoutlier data points within $1.5 \times$ IQR. Open triangle is a far outlier ($>3 \times$ IQR).

on the seeing side, there were no significant differences in the proportion of satisfactory responses for the RP and SP drives (64% and 57%, resp.; data pooled across all participants; $z = 0.33$, $P = 0.371$; Figure 4).

There were enough blindside hazards (but not seeing-side hazards) to evaluate prism effects separately for current and noncurrent drivers. For these analyses, data were pooled across all participants within each group. The proportion of satisfactory responses to blindside hazards was significantly higher in the RP than the SP drives for both current and noncurrent drivers, again indicating a beneficial effect of the RP glasses ($z = 2.49$, $P = 0.006$; $z = 2.26$, $P = 0.012$, resp.; Figure 6).

3.2. Ratings of Skills during Specific Maneuvers. The majority of ratings for skills during specific maneuvers were satisfactory (Table 3). There were no significant differences (Wilcoxon signed ranks test, $P > 0.1$) in the proportion of satisfactory scores between the SP and RP drives for any of the skills, suggesting no adverse effects of the RP glasses. The few ratings that were not satisfactory were mainly inadequate, but not unsafe; only 4 out of a total of 3232 ratings (data pooled across all skills and maneuvers) were considered unsafe but did not require an intervention. Inadequate scores were mostly for driving too slowly, taking

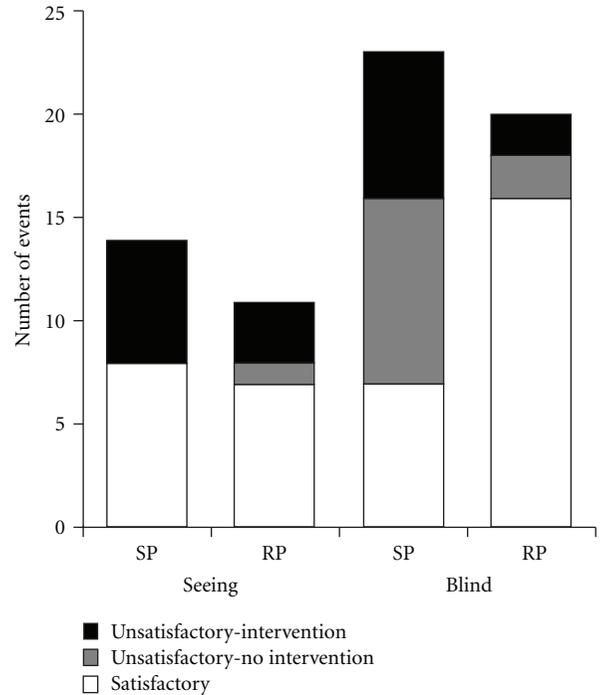


FIGURE 4: Total numbers of unsatisfactory and satisfactory responses to hazardous events on the seeing and blind sides for the 12 participants. The proportion of satisfactory responses to blindside hazards was significantly higher with real prisms (RP) than sham prisms (SP).

a path that was either too wide or too tight on left turns, unstable steering, and poor gap judgment (hesitating) at intersections (Table 3).

3.3. Participants' Experiences of Using the Prism Glasses. The majority (75%) of participants reported that the RP glasses were helpful when driving, in particular, for providing warning and seeing traffic on the blind side (Table 4). A minority (25%) reported initial difficulties in learning how to interpret the prism images of traffic (Table 4). At the end of the study, the clinical decision for 10 of the 12 participants (including seven with stroke) was to continue using the RP glasses for walking and driving (Table 4).

4. Discussion

In this study, the majority (62%) of interventions occurred as a result of a failure to notice a traffic event, suggesting that many participants (all with complete HH and without neglect) had significant detection deficits. If the examiner had not intervened, a collision would most likely have happened. These real-world data are in agreement with recent reports of detection deficits of people with HH in virtual driving and walking tasks [15–17, 45] and are consistent with the report of critical interventions for detection failures by drivers with restricted peripheral fields in another on-road study [41].

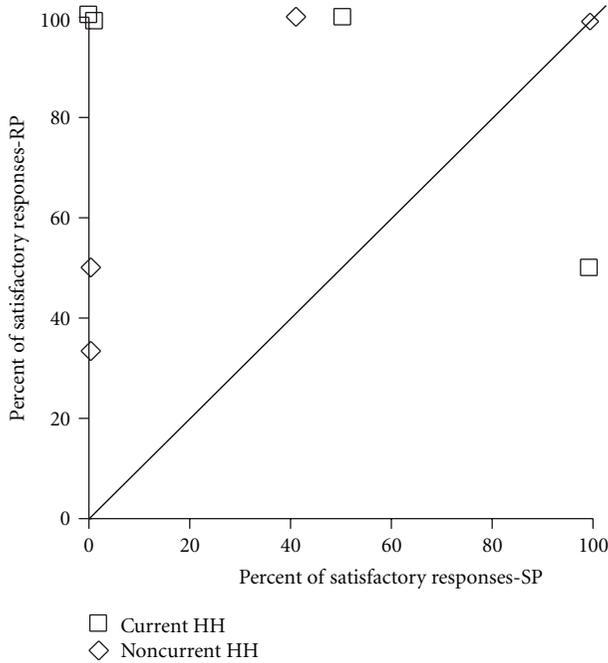


FIGURE 5: Percent of satisfactory responses to unexpected hazardous events on the *blind side* in the sham prism (SP) and real prism (RP) drives for the eight participants with blindside events in both drives. The diagonal line represents identical performance in the two drives. Six drivers (three current and three noncurrent) had a higher proportion of satisfactory responses in the RP than the SP drive (data points above the diagonal; $P = 0.03$).

TABLE 3: Percent (median and range) of satisfactory scores for ratings of skills during specific maneuvers.

Skill	SP drive	RP drive
Speed	98 77 to 100	100 88 to 100
Path	96 83 to 100	100 91 to 100
Steering steadiness	100 90 to 100	100 88 to 100
Gap judgment	100 89 to 100	100 88 to 100
Lane position	100 90 to 100	100 98 to 100
Scanning	100 95 to 100	100 93 to 100

Nevertheless, our findings may seem at odds with some on-road studies of drivers with HH in which there were no reports of interventions for detection failures and the main problems were with lane position and steering control [28, 29]. It is possible that the routes in these studies did not include sufficient density of traffic and pedestrians (and bicycles, a feature of city-driving in Ghent, Belgium) to provide enough opportunities for evaluating responses to potentially hazardous events. It is worth noting that our

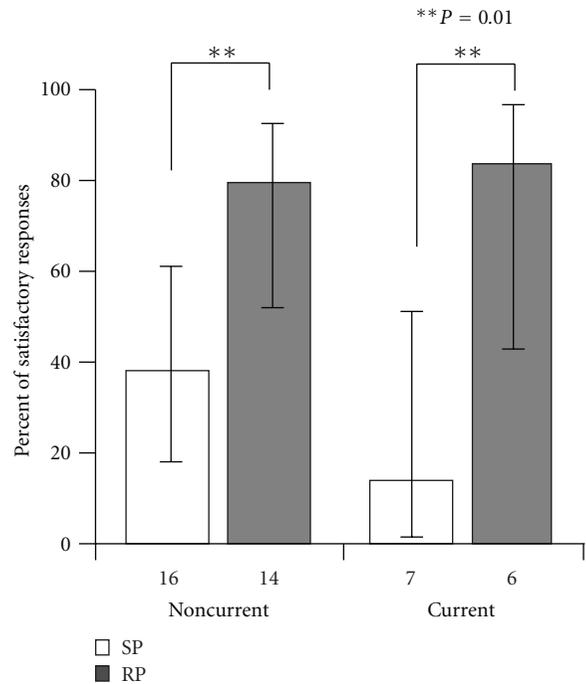


FIGURE 6: Percent of satisfactory responses to unexpected blindside hazards for current and noncurrent drivers. Both current and noncurrent drivers had better responses in the real prism (RP) than the sham prism (SP) condition, suggesting that the use of the peripheral prisms improved detection of blindside hazards for current drivers as well as noncurrent drivers. Numbers under each bar are the total number of hazards in each condition. Error bars represent 95% confidence limits.

cohort of HH drivers did have problems with steering: 24% of interventions were steering corrections (not in response to detection failures).

Not everybody with HH has poor detection. A common characteristic of prior studies [15, 17, 45] has been the wide between-subject variation in detection performance. Thus some patients with HH may compensate effectively using head and/or eye scanning, while others do not, and may need rehabilitation interventions such as prism glasses or scanning training. In order to evaluate the effects of such interventions, it is important to measure detection performance using tasks representative of real-world situations [46]. The results of this exploratory study suggest that responses to naturally-occurring blindside hazards in an open-road driving course has potential as an outcome measure for future studies of interventions aimed at improving detection while driving, provided they are conducted in an environment rich with potential hazards. In particular, despite a small sample size, we were able to measure differences in performance between drives with sham prism (SP) and real prism (RP) glasses. The data suggest that the RP glasses improved responses to blindside hazards for both current and noncurrent drivers as the proportion of satisfactory (safe) responses was higher with the RP than the SP glasses.

While responses to naturally occurring blindside hazards provide an outcome measure with maximum “real-world”

TABLE 4: Participants' experiences of using real prism glasses and clinical decision.

Hours per day, median (range)	4.5 (1–12)
Moderately or very helpful for obstacle avoidance when walking, % (<i>n</i>)	58 (7/12)
Moderately or very helpful for driving, % (<i>n</i>)	75 (9/12)
Main ways in which helpful when driving, % (<i>n</i>) [†]	
Seeing blindside traffic	30 (8/27)
Provided warning	22 (6/27)
Merging/intersections	15 (4/27)
More confident	7 (2/27)
Other	19 (5/27)
Unable to explain	7 (2/27)
Difficulties using prisms when driving, % (<i>n</i>)	
None	50 (6/12)
Initially (learn to use and interpret images)	25 (3/12)
Busy places, rotaries	17 (2/12)
No response	8 (1/12)
Clinical decision % (<i>n</i>)	
Continue walking and driving	83 (10/12)
Continue walking only	8 (1/12)
Discontinue use	8 (1/12)

[†] *n* > 12 as participants made more than one response (open-ended question).

validity, there are a number of challenges and limitations that have to be considered, not least the lack of control over whether or when an unexpected hazard might occur. Our approach was to select routes with a relatively high density of pedestrians, bicycles, and vehicular traffic, which were nevertheless representative of the test routes used in standard fitness-to-drive evaluations conducted by the Belgian Road Safety Institute. A standardized test in a driving simulator including detection of potential approaching hazards [16, 39] may be a useful adjunct, providing controlled, repeatable conditions with many opportunities to evaluate blind and seeing side detection performance. If detection performance in such a test could be validated against responses to unexpected hazards during a road test, it could be used as a replacement for the more dangerous and less well controlled road test.

In addition to prism glasses, compensatory strategies such as eye/head scanning [28, 47, 48] may ameliorate blind-side detection deficits. In a recent on-road study, HH drivers rated as safe made more head movements into their blind field than HH drivers rated as unsafe [33]. Unlike explorative scanning, where the driver with HH has to remember to scan to the blind side, the peripheral prism visual field expansion is always present at all lateral gaze positions and provides a constant stimulus (as does normal peripheral vision) to initiate eye and/or head movements to the blind side to foveate potential hazards. However, the oblique prism glasses do not provide a total solution to the visual difficulties experienced by drivers with HH (they only ameliorate the detection problem) and do not address other driving deficits (such as poor steering control or driving too slowly).

Our sample was heterogeneous with respect to the etiology of the HH, which could be seen as a limitation of the study; however, we suggest otherwise. The main analyses were within-subjects comparisons of performance with RP and SP glasses; therefore, any effects of between-subject variability on performance (e.g., due to differences in etiology) were minimized. Furthermore, our primary interest was in the effect of HH, a sensory visual loss, on detection of hazards when driving and whether peripheral prism glasses could improve performance. Thus our participants were screened to ensure they did not have other comorbidities commonly associated with stroke including major cognitive deficits (MMSE scores ≥ 26 ; Table 1), spatial neglect (a perceptual impairment) and motor impairments that would have prevented them from operating a car (even with modifications such as a steering knob). The main findings were unchanged when only participants with stroke were included in analyses.

Our results add to the growing body of evidence that some people with HH following a stroke (or other forms of brain injury) are fit to drive, while others are not. There is no scientific evidence for the minimum field extent requirements for driving that automatically preclude people with HH from driving in many jurisdictions and countries [49]. Furthermore, conventional methods of assessing visual fields (in which eye movements are not permitted) do not provide any assessment of the ability of the person with HH to compensate by scanning. Thus, we suggest that it seems only fair to permit people with HH following a stroke an opportunity to demonstrate their competency to drive and compensate for their hemifield loss, for example, in a specialized road test [23, 26, 27]. A recent report suggests that this approach works well in Quebec, Canada [27]. However, there is generally a need for the development of standardized evaluation protocols and poststroke driving rehabilitation programs [3].

5. Conclusions

The results of this exploratory study suggest that oblique peripheral prism glasses may improve responses to blindside hazards for drivers with HH (due to stroke or other conditions) while not adversely impacting other aspects of driving (such as vehicle control). These preliminary data represent a first step in addressing the paucity of evidence about the efficacy of prismatic interventions for patients with visual field defects following stroke [46, 50] and provide the basis for a future, larger-sample clinical trial that is needed before firm conclusions can be drawn. Furthermore, our findings suggest that responses to naturally occurring, unexpected hazards may provide a useful real-world outcome measure for future evaluations of rehabilitation interventions that aim to improve detection performance of drivers with HH.

Conflict of Interests

E. Peli has a financial interest in a patent related to the oblique peripheral prism glasses (assigned to Schepens Eye

Research Institute). A. R. Bowers and M. Tant have no conflict of interests.

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Review Article

Seven Capital Devices for the Future of Stroke Rehabilitation

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Stroke is the leading cause of long-term disability for adults in industrialized societies. Rehabilitation's efforts are tended to avoid long-term impairments, but, actually, the rehabilitative outcomes are still poor. Novel tools based on new technologies have been developed to improve the motor recovery. In this paper, we have taken into account seven promising technologies that can improve rehabilitation of patients with stroke in the early future: (1) robotic devices for lower and upper limb recovery, (2) brain computer interfaces, (3) noninvasive brain stimulators, (4) neuroprostheses, (5) wearable devices for quantitative human movement analysis, (6) virtual reality, and (7) tablet-pc used for neurorehabilitation.

1. Introduction

In the last decade, the manual conventional therapy for people affected by stroke has been often integrated with the use of technological devices specifically developed for increasing rehabilitative outcomes. Does the manual therapy really need this support? A study of 2008 showed that at dismissal from a hospital of rehabilitation, about half of patients with stroke are on wheelchair, whereas less than 15% are able to walk inside without aids, less than 10% are able to walk outside, and less than 5% are able in stair climbing [1]. Recovery of upper limb motor functions is even poorer, leading to suppose that upper limb recovery could be mainly intrinsic and slightly improved by therapy [2–4]. Furthermore, the need of more therapies performed in a more adequate and appropriate manner has been claimed [5]. In fact, the recovery has been shown to depend on the intensity of therapy, repetition of specified skilled movements directed towards the motor deficits and rewarded with performance-dependent feedback [6–8].

These are the main reasons for purposing the use of technological devices in order to increase intensity, repetitions, specificity, and feedback during rehabilitation. Many

reviews have already summarised the results of previous studies on the efficacy of these technologically supported treatments (for a recent one see Belda-Lois et al. [5]). In this paper, we provided our point of view on seven specific technological devices designed for supporting motor recovery after stroke. These technologies for rehabilitation of people affected by stroke are robots, brain computer interfaces, neuroprosthesis, noninvasive brain stimulators, wearable devices, virtual reality, and tablet-pc.

2. Robot

The English word robot was derived from the Czech word “robota”, meaning literally “serf labor” and figuratively “forced workers”; it is also used with the general meaning of “workers” in Russian and other Slavic languages [9]. The Robot Institute of America defined a robot as “a programmable, multi-functional manipulator designed to move material, parts or specialized devices through variable programmed motions for the performance of a variety of tasks” [9]. Three Ds were defined for identifying the most common tasks a robot is usually designed to perform: dull,

dirty, and dangerous [10]. These three Ds match neurorehabilitation in regards of the need of repetitive movements suggested as fundamental for sensorimotor relearning [11]. This task can be seen as dull and dangerous, for example, when a therapist is asked to support patient's weight during gait rehabilitation. Most recent approaches suggested that robots may also provide movement controllability and measurement reliability, two aspects that make robots ideal instruments to help medical doctors and therapists to address the challenges facing neurorehabilitation [12].

Robots for neurorehabilitation can be mainly divided in terms of the body functioning that they aim to rehabilitate or in terms of their design. In fact, the first division is primarily between robots for upper limbs and those for lower limbs, with a subdivision between bilateral and unilateral robots (especially for those aiming to upper limb recovery, whereas those for lower limb rehabilitation are usually bilateral because they focused on gait recovery). The second classification usually divided robots in exoskeletons and controller of endpoint trajectories. Typical examples of these robots are Lokomat as exoskeleton for lower limbs, Gait Trainer (or Gang Trainer) as end effector for lower limbs, ARMin III as exoskeleton for upper limb, and MIT-Manus as an end effector for upper limb, but many other commercial robots or specific prototypes exist.

Electromechanical devices, such as treadmill with body weight support or the above-cited Gait Trainer, are often referred to robot family in an improper manner. Furthermore, outcomes of rehabilitation supported with these devices are often analysed together with those of trainings conducted with robots. The adaptability allowed by the presence of "intelligent" sensors is the key point differentiating robots from electromechanical devices. However, in neurorehabilitation, this differentiation sounds picky, although the absence of an intelligent control may expose patients to some potential risks. It usually implies the continuous presence of a therapist during electromechanical trainings and limits the use of electromechanical devices. For example, for the Gait Trainer, the exclusion criteria include the presence of muscular contracture or presence of not healed bone fractures because of the absence of torque sensors able to assess the eventual joint resistance torque.

Are robots and electromechanical devices effective in stroke rehabilitation? An updated Cochrane review found that robotic-assisted gait training (Lokomat and Gait Trainer) in combination with conventional physiotherapy increased the odds of becoming independent in walking [13]. However, gait speed and walking capacity was not found significantly different between patients who received robotic versus conventional therapy alone. This Cochrane review included nonambulatory and ambulatory patients, those with subacute and those with chronic stroke, treated with Lokomat or Gait Trainer. More recently, Morone and colleagues suggested changing the question "Is robotic-assisted training effective?" into "Who may benefit from robotic training?" [14, 15]. The authors found that severely affected patients with subacute stroke are the ideal candidates for an increase of outcomes when conventional rehabilitation is accompanied by robotic training. Conversely, conventional

therapy alone and that supported by robotic training were found equivalent in less affected patients [14]. These differences were maintained also 2 years after dismissal [15].

However, we can paraphrase Clark when in 1997 he wrote: "Where are the artificial minds promised by 1950s science fiction and 1960s science journalism?" [16]: "Where are the robots promised by scientific literature able to restore motor functions after stroke?"

The high purchase cost, the confusion among robots and electromechanical devices, the still uncertainty about their efficacy, the absence of clear guidelines to achieve effective results, the need of trained therapists, and the scepticism by some members of the rehabilitation team are certainly contributing to limit the use of robots during inpatient care [14]. In fact, in this scenario, it still lacks a unified approach for integrating these devices into rehabilitation programs. Furthermore, the effectiveness of these devices therefore still depends heavily on the ability of the rehabilitation team to most effectively tailor the selection of motor parameters to each patient's needs and abilities [17].

Another issue recently raised up is the need to modify the "bottom-up" approach typical of many robots (and even more of electromechanical devices), based on the idea that moving passively the limbs of patients may enhance the recovery of limb functions. It is recently suggested to redesign or use robots on the basis of a top-down approach, for increasing the active participation of the patients during robotic training [5]. The other possible modification that may enhance the efficacy of robotic neurorehabilitation in the next years is the use of ambulatory exoskeletons. At the moment the most common robots are nonambulatory, even when based on motorized exoskeletons (as the Lokomat). Ambulatory exoskeletons may allow for more physiological trainings and allow patients to move in an environment similar to that they will find at their home returning.

3. Brain Computer Interfaces

Brain computer interfaces (BCIs) are a family of various devices aiming to translate measurements of brain activity into commands or messages. So, a BCI is a system directly measuring brain activity associated with the user's intent and translates by means of a computer the recorded brain activity into corresponding control signals for applications [18]. BCI could be used to provide the patient with real-time feedback, to allow for passive monitoring (assessing motor intention without providing real-time feedback), and to allow for active control of a computer and hence of many devices, by means of a computer. When the information is derived from the peripheral nervous system measuring neural activity, these devices are classified as Brain-Neural Computer Interface.

Limiting to brain activity, it is usually measured using electroencephalography (EEG) [18]. More recently, new noninvasive brain imaging techniques, such as functional near infrared spectroscopy (fNIRS), have been suggested to be used instead of EEG as a brain monitoring technique [19]. While EEG measures electrical activity, fNIRS measures

blood oxygenation levels in the brain, providing a different and complementary source of information about brain function [20].

In the last years, BCI devices have been designed as aids for patients, more than for the motor recovery. More recently, BCI systems are becoming more common in the context of neurorehabilitation. They can be used in combination with robotics-based therapy for enhancing the active participation of patients during their rehabilitation [5, 21–23].

In fact, a major problem with existing stroke robotic therapy is the low compliance and the typical bottom-up approach [5, 24]. On the contrary, active participation has been identified as an enhancer of rehabilitative outcomes, especially in the early phase of rehabilitative training [25]. People may find certain aspects of robotic therapy frustrating, exhausting, or boring or can be simply afraid or alienated by electromechanical devices. The use of BCI may hence contribute to increase directly rehabilitation effectiveness by means of the provided real-time feedback.

A new field in which BCI is used in neurorehabilitation is for supporting training based on motor imagery [26]. Recently, BCI has been combined with rehabilitative approaches based on motor imagery for stimulating the brain plasticity [27]. A study performed on 54 patients with stroke reported an accuracy of BCI systems on patients with stroke similarly to that of healthy subjects, despite the brain injury [27]. But the main problem is that effects of BCI devices are usually tested on few subjects, and further researches including large cohorts of patients are needed for proving its effectiveness. Moreover, our experience suggests that a good compliance of patient is required for using brain computer interface for the need of EEG and of a period of familiarization that could be sometimes too long, exhausting, and disaffecting for people with stroke.

4. Noninvasive Brain Stimulators

The activity of brain can be also enhanced or inhibited, not only monitored or used to control external devices. The use of electrical currents or magnetic fields can modify the functional activities of the brain, and it is known by almost two centuries, but in the last decade this approach, known as noninvasive brain stimulation (NIBS), has rapidly gathered a worldwide interest in therapeutic field.

The NIBS consists principally of two techniques: repetitive Transcranial Magnetic Stimulation (rTMS) and transcranial Direct Current Stimulation (tDCS). Globally concerning, NIBS aims to modulate motor cortical function, enhancing the brain plasticity by means of activation of long-term potentiation and long-term depression phenomena, even if definitive evidences in this sense are still lacking [28, 29]. However, both these techniques have showed potential benefits as adjunctive treatment of several psychiatric and neurological disorders, and now researchers are attempting new applications in other patient categories.

Because tDCS varies the spontaneous neuronal firing rates without producing action potentials, acting below the threshold of activation of potentials, it should be considered

as a neuromodulatory intervention rather than a stimulation [30]. This activity is dependent on the polarization of the electrodes. It is assumed that tDCS modulates the brain favoring the depolarization (and hence the activation by anodic stimulation) or hyperpolarizing (and hence the inhibition by cathodic stimulation) the resting membrane potential of neurons [31, 32].

If the application of electrical currents has been initially used to investigate the cortical functions, adding information about neuroanatomy and behavior, afterwards tDCS has gathered a role in the therapy. Used to treat depressive disorders in the 1960s and 1970s, the electrical stimulations are now proposed as treatment of many different diseases. Not only stroke, Alzheimer's and Parkinson's diseases and brain and spinal cord injuries, but also fibromyalgia, low back pain, and other chronic pain syndromes have been studied as possible target of treatment [33].

In stroke rehabilitation, the use of tDCS has regarded the recovery of motor and cognitive impairments. The preferential cortical target has been the primary motor cortex, the brain area in motor execution, memory formation, and consolidation of motor skills [34], enhancing the conviction that tDCS favors the brain plasticity through the strengthening of the synaptic connections, a mechanism similar to long-term potentiation [35]. Many studies have reported improvements in performance of complex ADL-like tasks with the paretic hand in patients with stroke after anodal tDCS [36]. It has been hypothesized that this mechanism involves an extensive network of brain regions. In fact, tDCS might be involved not only in the stimulation of the intended area, but also for adjacent cortical areas, due to the use of large electrode size [37].

There are no published studies reported seizure as adverse effect; on the contrary, pilot studies have attempted to use cathodal tDCS for the treatment of focal epileptic syndromes [38]. Only minor side effects, seldom occurring and not always perceived, may be mild headache, itching and erythema at the electrode site, fatigue, and nausea [32]. Therefore, this technique appears a safe treatment.

The treatment with tDCS can assist both the pharmacological and the rehabilitative treatments, preceding or following them. Sessions can last up to 30 min [39], close to the duration of a session of rehabilitative treatment, and can be administered in synchrony with motor rehabilitative protocols, strengthening the effects of motor rehabilitation [40].

However, some other studies reported that neither anodal nor cathodal transcranial direct current stimulation enhanced the effect of rehabilitation [41, 42]. Hence, although tDCS may appear one of the most potential technologies for the future improvement of therapies in the clinical setting, at the same time, many questions have still to be made to clarify certain aspects still not clear about its efficacy in enhancing motor rehabilitation, especially for patients with stroke in subacute phase. In fact, even if tDCS is widely used, research in this field is relatively young and in its early stages, with reduced sample sizes. The abiding efficacy of tDCS in the followup, the best patients' selection, and how the variation of parameters and a more accurate

focality (intensity, duration, and polarization) can influence a stable motor improvement need to be deeply studied. Nevertheless, the perspectives that widespread use of tDCS opens are very relevant, as the possibility of a continuous home-based therapy. In the clinical practice, advantages of tDCS in respect of rTMS or other technological devices are related especially to the fact that the stimulator is cheap, reduced in size, portable, simple to use, and painless.

Similar to the tDCS, rTMS has showed to be effective in the treatment of many neurological and psychiatric conditions, despite a major variability. Differently by the direct current, rTMS operates on neurons via brief pulses of high-intensity magnetic field by an inductive coil. Use of repetitive stimulations entails a persistent modulation of neural excitability. The induced current is able to depolarize neurons both directly at the axon hillock or indirectly via depolarization of interneurons. Classic use of rTMS implies trains of pulses at specific frequencies. Stimulator consists of a large electrical capacitance that is attached to a coil of several turns of copper wire. This implies a modulation of cortical excitability as well as of other physiological, metabolic, and behavioral measures [43]. Although rTMS has been studied much more than tDCS, also for rTMS it is not well clear how it delivers the immediate clinical benefit, even if the association of neuromodulators and growth factors release is supposed to be over the above-cited mechanism of neuroplasticity [29]. Differently from tDCS, rTMS entails a wider intersubject and intersession variability [44], conditioning the effect because of the broad variety of experimental procedures and parameters utilized. In fact, several different protocols have been proved, but no definitive evidence has been established.

In neurorehabilitation, clinicians have tested rTMS, in order to drive the adaptive plasticity and to facilitate the process of recovery. Several small investigations have shown functional improvements. Most of the results have been obtained by inhibitory approaches, both for motor (performances) and cognitive (speech) impairments [45, 46].

In conclusion, despite some encouraging studies, the use of NIBS is promising but needs to be delved deeper. Protocols should be standardized worldwide and multicenter-controlled clinical trials should be set up to provide definitive evidence in neurorehabilitation. In addition, studies about the economic benefits from a continuous use of these techniques should be taken into consideration (i.e., cost-effective home therapy versus inpatient rehabilitation). At the same time, many therapeutic opportunities based on NIBS are open for researchers worldwide.

5. Neuroprosthesis

Neuroprosthesis (or neural prosthesis) is a general term referring to devices that cannot only receive output from the nervous system (such as BCI), but can also provide input, with the possibility to interact with the peripheral and central nervous systems [18]. Furthermore, neuroprosthesis is a device that substitutes, completely or in part, a motoneural

function at peripheral level. Cochlear and retinal implants are examples of neuroprosthesis [18].

In neurorehabilitation field, electronic devices may directly stimulate muscles or nerves that should in turn stimulate muscles (this second possibility needs the integrity of peripheral nerves).

Some neuroprostheses are based on the principle of functional electrical stimulation (FES), and in the recent years it has been used in stroke rehabilitation. For example, during locomotion, FES can be timed with the swing phase of the gait cycle to stimulate the ankle dorsiflexor muscles, usually weaker in patients with stroke. Recently it has been shown that the use of FES for 3 months increases the maximum voluntary contraction and the motor-evoked potentials [47].

FES has been used as surface or as implanted stimulation. A possible example of gait FES is based on a tilt sensor which measures the orientation of the shank, controlling when to turn the stimulator of tibialis anterior on and off [48]. Another example is based on the use of a pressure attached below the foot, allowing to know if the heel is in contact with the ground or not for controlling ankle joint movements [49].

Regarding FES efficacy recent findings showed that FES may improve active movements and strengthen muscles, improving gait velocity and endurance, preventing falls [50], reducing spasticity, and providing better functional recovery [51–53]. So, in the field of gait rehabilitation, neuroprosthesis may provide more potential benefits than common orthoses, as reported by rehabilitative outcomes [54] and patients' comments [48, 55].

6. Virtual Reality

Similar to the use of the term robot, also the expression virtual reality is sometimes used improperly in neurorehabilitation. In many studies a computer-based technology providing visual stimuli on a monitor is generally called virtual reality. But with the expression virtual reality (VR) we should refer to a high-end user-computer interface involving real-time stimulation and interactions of an embedded subject through multiple sensorial channels (visual and auditory, sometimes haptic, smell and taste if possible), based on a synthetic environment in which the subject feels his presence [56]. Similar to the three Ds of robotic works, VR is based on three Is defining its features: immersion, interaction, and imagination [56]. So, a computer videogame should not be considered as VR because of the absence of immersion in a virtual environment. However, with the more wide use of tridimensional visual stimuli also in video games, this difference is going to be reduced in the early future.

Both VR and computer-based stimulation are supposed to have the potential to greatly increase the ways in which people are trained during rehabilitation. There are many advantages provided by VR at the basis of this idea: the synthetic environment is easily changeable, allowing for designing an optimal individualized therapy, VR can provide functional, rich stimuli and motivating context, increasing

the active participation of the subject in his rehabilitation (a fundamental aspect to increase the rehabilitative outcomes [25]), and then the data can be collected for monitoring and evaluating rehabilitation progress.

In the last few years there have been an increase in the application of virtual reality and computer-interface-based systems to the rehabilitation of a variety of deficits resulting from lesions of the nervous system [57, 58]. The main area is probably the rehabilitation of patients with stroke, in particular with respect to the function of the upper extremities.

Several virtual reality systems for upper limb rehabilitation have been developed and tested worldwide following different methods and therapeutic concepts including systems used to train reaching movements through imitation of a virtual instructor [59, 60]; systems based on haptic devices [61]; systems for training individual hand and finger properties such as range of motion and strength by means of intense practice of skilled movements [62, 63]; systems to train general upper limb movements by mental rehearsal and the imitation of movements of the nonparetic arm [64].

It has been shown that, after VR training, there is a cortical reorganization due to neuroplasticity in which cortical activation was reorganized from contralesional (before VR) to ipsilesional (after VR) activation; that is, there is a shift in cortical organization of the affected limb from the ipsilateral hemisphere to the contralateral hemisphere after the VR intervention. It is probably due to the fact that VR may have motivated and promoted practice-dependent reorganization resulting from the increased amount of use of the affected limb in relevant motor tasks [65].

A recent Cochrane review analysed 19 studies involving 565 patients with stroke, putting together the use of VR with video-gaming therapy for stroke rehabilitation [66]. Positive results were found in terms of recovery of arm function and increase in independence in activities of daily living, and few and mild adverse effects were sporadically reported, whereas no evidence was found for improvements in global functions, grip strength, or gait speed. However, this Cochrane review suggested caution in interpretation of results because studies on VR effects in rehabilitation generally enrolled a small sample of subjects, and interventions and outcome measures varied, limiting the comparisons among studies. Then, because the intervention approaches in the included studies were predominantly designed to improve motor function rather than cognitive function or activity performance, there was no evidence for cognitive improvement after VR training. Finally, the majority of participants in VR rehabilitation were young people with chronic stroke, relatively active (in many researches they should be able to move a joystick), then the positive effects were found soon after the end of the treatment, and it is not clear whether the effects are long-lasting.

Although further trials involving larger numbers of participants and longer-term followup are required, VR and video-gaming therapy could be further developed on the basis of the recent development and the progressive cost reduction of 3D televisions, combined with markerless system for movement analysis [67] or accelerometric devices

for controlling video games [68]. These technologies could bring at home of patients new rehabilitative tools in the early future.

7. Wearable Devices

The instrumented movement analysis is a systematic manner to investigate motor abilities of a subject, involving measurements, descriptions, and assessments of quantities characterizing human biomechanics and locomotor control [69, 70]. It is a fundamental tool for assessing pathological conditions and compensatory motor strategies and for evaluating the improvements during rehabilitation, in a more sensible and objective manner than ordinal scores of clinical scales [71].

Through instrumented movement analysis, the kinematic and kinetic parameters of human movements can be determined, and musculoskeletal functions can be quantitatively evaluated. As a result, instrumented movement analysis has been employed in sports, rehabilitation, and health diagnostics. It is sometimes called “gait analysis” because most of these studies are related to human locomotion.

Research on instrumented movement analysis has been conducted since the late 19th century, and its widespread application in biomedical engineering began with the availability of video camera systems [72–74]. A standard laboratory of gait analysis is formed by a multicamera motion capture system and force platforms with the capability of measuring ground-reaction forces [75]. However, this standard gait analysis requires specialized laboratories, expensive equipment, and lengthy setup and postprocessing times, with limitations in terms of the moving area and gait cycles.

In the last decade, an alternative gait analysis method was developed based on wearable sensors. Some of the potential benefits of using wearable device to assess movements in clinical settings could include the low cost compared with more commonly used gait analysis equipment, the small dimensions and light weight, and no limitation of the testing environment to a laboratory, enabling subjects to walk relatively unrestricted [76, 77].

Wearable devices for motion sensing can be accelerometers [76, 77], force sensors [78, 79], goniometers [80], inclinometers [81], gyrosensors, and strain gauges, and they can be worn or attached to various parts of the body [82].

Particular interest has been devoted to the use of accelerometers for assessing human locomotion [76]. In fact, the ability of a subject to maintain balance during walking can be properly assessed by measuring upper-body accelerations [83, 84]. A large and growing body of the literature has investigated the use of this technique in healthy subjects [85–88], patients with stroke [77, 89], children with cerebral palsy [90], people with low-back pain [91], and those with cognitive impairments [92].

With the development of motion-sensing technology, an increasing number of wearable sensors will be developed for gait analysis in the future, increasing the use of wearable sensors in the clinical field [82]. Even clothes formed by fibers

and yarns made in conducting and piezoresistive materials able to record vital signals have been developed as a really wearable device [93].

The development of wireless wearable sensors has also been facilitating the development of wearable ambulatory robotic exoskeletons. More of them are still in prototypal version, such as those developed in projects financed by the European Community as, for example, Tremor (extended title: An ambulatory BCI-driven tremor suppression system based on functional electrical stimulation) [94] and Better Projects (extended title: BNCI-driven robotic physical therapies in stroke rehabilitation of gait disorders) [5]. However, some commercial products have recently been delivered, such as EKSO (Ekso Bionics, Richmond, CA, USA) and ReWalk (Argo Medical Technologies Inc., Marlborough, MA, USA) exoskeletons. These devices are primarily developed as orthoses especially for subjects with spinal cord injury [95], but it is arising the idea to use ambulatory exoskeletons also during stroke rehabilitation [5, 96].

8. Tablet-PC

The last but not the least technology that merits a mention in this paper is a new technology that is changing our life, modifying the way we interact and communicate: the multi-touching tablets. This is evident through the widespread use of smartphones and tablet-pc. The ease of downloading and using applications (apps), many of them free, is changing our life style, allowing to do many things in new forms, from reading newspaper, playing, communicating with friends, getting weather updates, to finding the closest supermarket. It is hence clear that this technology can have potential benefits also in healthcare and rehabilitation fields [97]. Particularly tablet-pc, with its many apps, seems to have potentialities for enhancing therapy, offering speech to text options, handwriting enhancements, and options for motor skill development, and so forth. First of all, tablet may increase the possibilities of augmentative and alternative communication interventions [98]. Then, it could be helpful for assessing deficits of fine movements at hand level and hence for assessing rehabilitation outcomes [99]. Finally, specific rehabilitative programs for upper limb rehabilitation can be developed on this simple tool, with all the advantages above reported for the video-game-based therapy.

When returning home, people with stroke may use these tablets for improving their hand abilities. This opportunity is offered by the multitouching technology. Furthermore, tablets, similar to virtual reality and video-game-based therapies, may allow to collect data of patients' improvements. It is also possible to imagine that these data can be shared in real time via internet with therapists, medical doctors, and other members of rehabilitative staff. So, although at the moment the evidence that tablets can be effective for enhancing stroke rehabilitation is still lacking, and only few studies investigate this aspect, the potentiality of this tool and its wide diffusion suggest that tablet will enter soon in neurorehabilitation [98, 99].

9. Conclusions

At the lights of the above researches, the seven technologies reported in this paper seem to have potentialities to increase the effectiveness of rehabilitation in patients with stroke. However, according to Morone and colleagues [14, 15], the question about their efficacy on rehabilitation should be changed into which patients may benefit more from the use of these devices. Robotic therapy seems to be more effective when used in severely affected patients, whereas virtual reality video-game-based therapy is probably more effective in less affected patients. We expect similar target patients for Tablet-pc. Also other aspects, such as compliance and psychological features, should be taken into account for defining the best target population. The last potentiality of these new technologies is their possible combination. For example, brain stimulation was performed during robotic training in patients with stroke in subacute [41, 100] and chronic [101] phases. Accelerometric assessment was performed during sessions of electromechanical training to obtain online information about the patients' recovery and the goodness of parameter selection [17]. As reported above, the use of wireless wearable devices could be combined with robotic technologies for the development of ambulatory exoskeletons [93, 94]. Also brain computer interface could be combined with robotic training for a top-down approach [5].

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Review Article

A Systematic Review of Bilateral Upper Limb Training Devices for Poststroke Rehabilitation

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Introduction. In stroke rehabilitation, bilateral upper limb training is gaining ground. As a result, a growing number of mechanical and robotic bilateral upper limb training devices have been proposed. *Objective.* To provide an overview and qualitative evaluation of the clinical applicability of bilateral upper limb training devices. *Methods.* Potentially relevant literature was searched in the PubMed, Web of Science, and Google Scholar databases from 1990 onwards. Devices were categorized as mechanical or robotic (according to the PubMed MeSH term of robotics). *Results.* In total, 6 mechanical and 14 robotic bilateral upper limb training devices were evaluated in terms of mechanical and electromechanical characteristics, supported movement patterns, targeted part and active involvement of the upper limb, training protocols, outcomes of clinical trials, and commercial availability. *Conclusion.* Initial clinical results are not yet of such caliber that the devices in question and the concepts on which they are based are firmly established. However, the clinical outcomes do not rule out the possibility that the concept of bilateral training and the accompanied devices may provide a useful extension of currently available forms of therapy. To actually demonstrate their (surplus) value, more research with adequate experimental, dose-matched designs, and sufficient statistical power are required.

1. Introduction

As technology advances, a growing number of mechanical and robotic training devices (i.e., mechanical devices with electronic, computerized control systems) for upper limb training have been proposed for stroke rehabilitation. Compared to conventional therapies, these training devices have the advantage that they allow a self-controlled increase in training intensity and frequency as well as the opportunity to train independently [1–4]. In recent years, a substantial number of these training devices have been designed specifically for bilateral upper limb training, but an integral overview and evaluation have thus far been lacking. The present study seeks to fill this lacuna.

Bilateral upper limb training is by no means a new form of stroke rehabilitation. Since days long past, therapists have been creative in using appliances, such as pulleys, to

move the most impaired upper limb simultaneously with the less impaired upper limb [5]. Nevertheless, the current upsurge in the interest in bilateral upper limb training has a relatively short history and arose partly serendipitously [6, 7] and partly from insights gleaned from the motor control literature. In this literature, coupling (or interaction) effects between the two upper limbs have been investigated extensively in rhythmic interlimb-coordination studies involving healthy subjects [8–12]. It is well established that healthy subjects show a basic tendency towards inphase (i.e., symmetrical movements) or anti-phase (i.e., alternating movements) coordination, with a prevalent 1:1 frequency-locking mode for upper limb bilateral movements [12]. These tendencies reflect the coupling between the upper limbs. Based on the assumption that this coupling facilitates the functional recovery of the paretic arm, it is exploited in bilateral upper limb training, usually by moving both arms

and/or hands in either in-phase or anti-phase coordination. However, whether one pattern is to be preferred over the other is currently not evident.

Recent systematic reviews produced mixed results on the superiority or inferiority of bilateral upper limb training over other interventions in poststroke rehabilitation. Two such reviews found strong evidence in support of bilateral upper limb training after stroke [13, 14]. Another review was more reticent in its conclusions than the previous two [15], and three systematic reviews concluded that bilateral training is at best similarly effective as other treatments but certainly not better [16–18]. These mixed results may be related to the heterogeneity of types of bilateral upper limb training and the devices used in clinical trials. Therefore, an overview and evaluation of clinical applicability of bilateral upper limb training devices may be helpful in directing future research in this regard.

The present systematic review evaluates bilateral training devices designed for poststroke upper limb training in terms of (1) mechanical and electromechanical characteristics, (2) supported movement patterns, (3) targeted part and active involvement of the upper limb, (4) training protocols, (5) outcomes of clinical trials, and (6) commercial availability. The aim of the paper is to evaluate these aspects in a qualitative manner because not sufficient randomized clinical trials are available on the devices in question to evaluate or compare clinical outcomes statistically. We therefore aim at comparing and integrating concepts, findings, and insights from largely qualitative studies, culminating in an overview of training devices for poststroke rehabilitation, an assessment of their clinical applicability, and some general conclusions and recommendations for future developments and research.

2. Methods

Bilateral upper limb training device was defined as a device developed for upper limb rehabilitation that is either specifically designed for bilateral training or at least supports bilateral training as one of the prominent training modes, where both upper limbs perform simultaneous movements with one limb moving actively and the other limb moving actively, passively, or with assistance.

Relevant literature was identified through computerized and manual searches in the following electronic databases: PubMed, Web of Science, and Google Scholar. These databases were searched using the following MeSH headings and key words:

- (i) cerebrovascular disorder\$, cerebrovascular accident, CVA, stroke, hemiparetic stroke, paresis, hemiparesis, hemiplegia,
- (ii) upper extremity\$, upper limb\$, arm\$, forearm\$, wrist\$, hand\$, finger\$,
- (iii) bilat\$, bimanual\$
- (iv) robot\$, mechan\$, device.

Bibliographies of review articles, empirical articles, and abstracts published in conference proceedings were also

examined. In further iterations, references from retrieved articles were examined to identify additional relevant articles. In light of the recent interest in bilateral upper limb training in stroke rehabilitation literature [6, 19], only articles published from 1990 onwards were searched.

Devices were selected for discussion if they met with the aforementioned definition of a device for bilateral upper limb training. Devices were categorized as robotic devices when they met the description of the PubMed MeSH term of robotics. All other devices were categorized as mechanical devices. Both categories are discussed in separate paragraphs.

3. Results

The search resulted in 311 single citations of which 70 reported on 20 different bilateral training devices. Of these, 6 were mechanical and 14 were robotic devices.

3.1. Mechanical Devices

3.1.1. BATRAC (Tailwind). Bilateral arm training with rhythmic auditory cueing (BATRAC) was introduced in 2000 [20], together with a custom-made bilateral arm trainer. The device consists of two independent T-bar handles mounted on nearly frictionless tracks that can move in the transverse plane perpendicular to the user. The handles have to be pushed forward and pulled back, either with both upper limbs simultaneously (in-phase) or alternately (anti-phase), at a frequency paced by a metronome providing auditory cues. If a patient is unable to hold the handle with the hand of the most impaired upper limb, the hand is strapped onto it. The original BATRAC protocol focuses expressly on shoulder and elbow function. A modified version of the original BATRAC protocol focuses on distal upper limb function [21]. For the purpose of the latter protocol, a device was developed consisting of two manipulanda with handgrip that can be mounted on the distal ends of a chair's arm rests (see Figure 1(a)). The manipulanda allow flexion and extension movements of the wrist in the horizontal plane and have to be moved rhythmically in pace with an auditory metronome in either a mirror-symmetrical (in-phase) or an alternating (anti-phase) fashion. Visual feedback is provided in the form of a Lissajous display, left and right hand movement amplitudes, and the relative phase (and its variability) between both hands (see Figure 1(b)).

The original BATRAC protocol was first used in a pilot effect study involving a single group of patients with chronic stroke (i.e., more than 6 months after stroke onset) [20]. Fourteen patients received 6 weeks of BATRAC, three times a week, four times 5 minutes per session. Posttreatment assessment revealed improvements in Fugl-Meyer Assessment (FMA), Wolf Motor Function Test (WMFT), University of Maryland Arm Questionnaire for Stroke measuring daily use of the most impaired upper limb, as well as strength measures and range of motion measures for the most and less impaired upper limb. Most of these benefits sustained at 8-week followup.

Another study [22] examined the efficacy of a modified version of the BATRAC protocol. In this study,

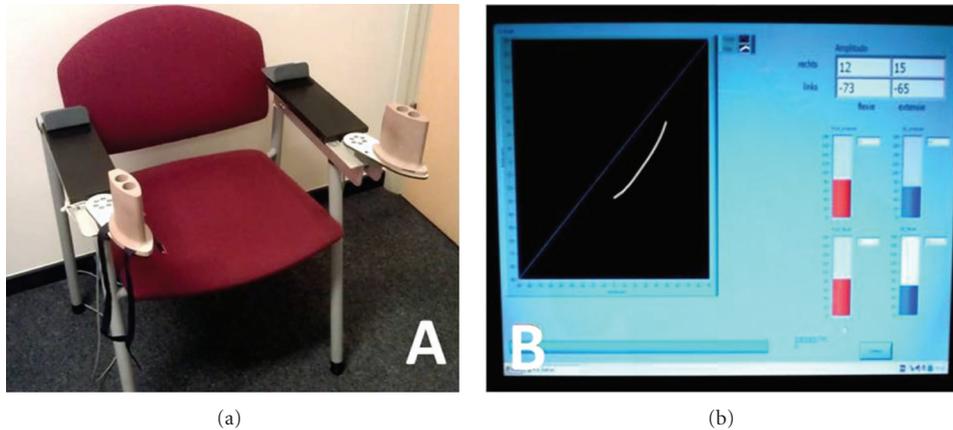


FIGURE 1: Modified BATRAC apparatus. (a) Manipulanda with handgrips. (b) Feedback, with Lissajous plane on the left (movements of left hand plotted against those of the right hand) and feedback regarding amplitudes and relative phase (and its variability) on the right. Reprinted with permission.

14 patients with chronic stroke participated in four 2-hour-plus BATRAC sessions per week for 2 weeks. Although no significant changes in FMA or WMFT were found as a result of this intervention, patients reported an increase in daily use of the most impaired upper limb as evidenced by a significant change on the Motor Activity Log (MAL).

In a large RCT with patients with chronic stroke, BATRAC was compared with dose-matched therapeutic exercises [23]. A total of 111 patients were randomized over both intervention groups and received 6 weeks long 3 training sessions per week. The improvements in upper limb function were comparable between both groups post-treatment and retained after 4 months. There were however greater adaptations in brain activation after BATRAC than after the control treatment, suggesting that both treatments referred to different underlying neural mechanisms.

Currently, an RCT with 60 patients in the subacute phase after stroke (1–6 months) is being conducted [21]. In this RCT the BATRAC device for distal upper limb movements (Figure 1) is used and compared to constrained-induced movement therapy and conventional physical therapy. This RCT will be completed by the end of this year and will be reported in 2013/2014.

A commercial version of BATRAC, called Tailwind (see Figure 2), is produced and sold by Encore Path, Inc. Baltimore, MD, USA and is also available at Anatomical Concepts UK Ltd., Clydeland, Scotland. This device is produced for home-based training and differs from the original device, as the Tailwind also allows upward and outward movements. The BATRAC device for movements about the wrist is not commercially available.

3.1.2. Reha-Slide Duo and Reha-Slide (Nudelholz). The Reha-Slide Duo (see Figure 3) consists of a board with two sledges running on parallel tracks [24]. Two handles on the sledges can be moved forward and backward separately, similar to the Tailwind used for BATRAC. The board on which the tracks are placed can be inclined up to 20° for



FIGURE 2: Tailwind. Reprinted with permission (<http://www.tailwindtherapy.com/>).



FIGURE 3: Reha-Slide Duo. Reprinted with permission (<http://www.reha-stim.de/>).

upward movements, and friction for forward and backward movements can be adjusted for both handles separately via adjustable rubber brake elements in a range from 5 N to 80 N (with the board horizontal).

The Reha-Slide Duo was incorporated in an arm-studio for upper limb rehabilitation [24]. However, no clinical results have been reported to date specifically for the Reha-Slide Duo.



FIGURE 4: Reha-Slide (Nudelholz). Reprinted with permission (<http://www.reha-stim.de/>).

The Reha-Slide (Nudelholz, see Figure 4) consists of the same inclinable board with parallel tracks and sledges as the Reha-Slide Duo; however, an additional rod connects the two handles 75 cm apart from each other on either side, similar to a rolling pin [25]. The rod can be moved forward and backward by 30 cm (elbow extension and flexion), sideways in both directions by 15 cm (shoulder abduction and adduction), and it can be rotated by 360° (wrist flexion and extension). The handles are yoked, so that the less impaired upper limb can drive the most impaired upper limb during training. The board on which the tracks are placed can be inclined up to 20° for upward movements, and friction for forward and backward movements can be adjusted via adjustable rubber brake elements in a range from 5 N to 80 N (with the board horizontal). A wireless computer mouse can be centrally fixed to the rod for interaction with computer software (games and biofeedback).

The Reha-Slide was first tested with 2 patients 5 and 6 weeks after stroke [25]. Both patients trained for 20–30 minutes every workday for 6 weeks using the Reha-Slide in addition to a 10 week in-patient rehabilitation program of 4 times per week 45 minutes of physiotherapy and 3 times per week 45 minutes of occupational therapy following principles of neurodevelopmental therapy (NDT). Reha-Slide treatment included training of the forward-backward movement cycles and drawing a square clockwise and counter-clockwise, while rotating the wrists. These exercises were repeated with the board inclined such that the patient moved his or her hands to shoulder level. The total number of movement cycles practiced was about 400. Both patients showed improvements in muscle strength and FMA scores.

In an RCT the effects of treatment with the Reha-Slide were compared with electrical stimulation of wrist extensors [26]. Fifty-four in-patients 4–8 weeks after stroke were randomized over two groups. The Reha-Slide group received the same protocol as described above [25]; however, the degree of inclination was always set in such a way that the handles reached the shoulder level, and forward-backward friction level was increased over the weeks of the training. A metronome helped to pace movements, and at the end of each session, patients played a computer game of their choice for 5 minutes. The electrical stimulation group practiced 60–80 wrist extension repetitions per 30-minute



FIGURE 5: The Rocker for APBT. Reprinted with permission.

session. All patients also participated in an 8–10 week in-patient rehabilitation program based on NDT principles, including 5 45-minute sessions of physiotherapy and 4 30-minute sessions of occupational therapy per week. FMA score and muscle strength improvement did not differ significantly between groups, both after treatment and at 3-month followup. Posttreatment improvement in the Box and Block Test (BBT) was greater in the Reha-Slide group, but this difference disappeared at 3-month followup. Muscle tone (measured with the MAS) differed significantly over the groups at 3-month followup, with an increase in tone in the electrical stimulation group.

The Reha-Slide and Reha-Slide Duo are commercially available at Reha-Stim, Berlin, Germany.

3.1.3. APBT (the Rocker). The device used for active-passive bimanual movement therapy (APBT, see Figure 5) is a custom-built system of connected crankshafts located in the body of a unit that couples two manipulanda [27]. It supports mirror symmetrical or near-symmetrical (a phase lag of 60°) coordination of wrist flexion and extension movements in the horizontal plane. With this system an actively moving less impaired upper limb can passively move the most impaired upper limb in either a synchronous or (60° phase lag) asynchronous fashion.

For a pilot study, 9 patients with stroke (onsets ranging from 2–84 months before recruitment) participated in six 10-minute sessions of APBT per day, for 4 weeks [27]. The intervention was rhythmically practiced at a self-paced movement rate (approximately 1.2 Hz). Five patients practiced synchronous movements and four patients practiced asynchronous movements. Patients were instructed to maintain their most impaired upper limb muscles at rest. After treatment, five of the nine patients (from both groups) had increased their FMA scores by more than 10%. These improvers also showed a decrease in affected cortical map volume. There was no follow-up assessment.

In an RCT, 32 patients with chronic stroke were randomized over two groups [28]. Patients in the control group received a set of wooden blocks and were instructed to perform two self-directed, home-based tasks (transporting and manipulating the wooden blocks) with their most impaired upper limb for 10 minutes, 3 times per day, for

4 weeks. Patients in the APBT group received the same set of wooden blocks and the same instructions, but had also access to the APBT device. They were instructed to use the APBT device for mirror-symmetric movements of the wrists for 10–15 minutes prior to the exercises with the blocks. Attention first had to be focused on the less impaired upper limb at the beginning of each session, followed by a gradual shift towards the most impaired upper limb. In the third week, they were instructed to imagine they were actively producing the movements of their most impaired wrist, with progression towards bilaterally active movements in the fourth week. At 1-month follow-up FMA change scores were significantly greater in the APBT group than in the control group. This difference was not present at the immediate posttreatment assessment. There were no significant differences in grip strength and National Institutes of Health Stroke Scale scores at any posttreatment assessment. The APBT group exhibited significant increases in ipsilesional M1 excitability, transcallosal inhibition from ipsilesional to contralesional M1, and intracortical inhibition within contralesional M1, both immediately posttreatment and at 1-month follow-up. These changes were absent in the control group at both assessment times. Note that the interventions were not dose-matched: the APBT group spent more time training.

The effects of additional APBT were also assessed in a single case series study with two matched pairs in the subacute phase after stroke [29]. In addition to usual standard care treatment consisting of daily occupational therapy and physical therapy, all patients received 20–30 minutes of motor practice 1 or 2 times per day, 5 days per week, for 1–3 weeks. Motor practice included tasks that were designed to improve joint stability, mobility, and strength, as well as reaching, and grasp and release exercises. On top of that, patients receiving additional APBT practiced mirror-symmetrical wrist flexion and extension movements for 10 minutes prior to motor practice. The magnitudes of improvements on the FMA and Action Research Arm Test (ARAT) at posttreatment as well as 1-month follow-up assessments were greater in patients who received additional APBT. Again the interventions were not dose-matched.

The APBT device (the Rocker) is not commercially available.

3.1.4. Able-X. Recently, a movement-based game controller (the CyWee Z) has been incorporated into a custom-built handlebar (Able-X, see Figure 6) in order to render it suitable for bilateral use [30]. With the CyWee Z positioned in the handlebar, rotations in the transverse plane produce horizontal mouse cursor translations on a computer screen, while rotations in the sagittal plane produce vertical mouse cursor translations. Using a suite of games a graduated series of physical challenges can be provided with the CyWee Z.

Fourteen patients with chronic stroke participated in a study aimed to determine the effectiveness of a bilateral, self-supported upper limb rehabilitation intervention using the handlebar with CyWee Z [30]. All patients received a control treatment, followed by a washout period, and finally the intervention. During the initial control period, patients played four simple mouse-based computer games



FIGURE 6: Able-X with CyWee Z. Reprinted with permission.

on a personal computer (PC) with their less impaired upper limb. The training was provided in group sessions, with three participants playing on three PCs under supervision of one or two therapists, during a 2.5 week period encompassing 8 to 10 sessions, each lasting between 45 and 60 minutes. Then followed a period of 2-3 weeks during which no intervention was provided. Finally, patients received the intervention comprised of playing games on a PC using the custom-built CyWee Z handlebar. As in the control treatment, three participants played on three PCs supervised by one or two therapists, that is, the same amount of therapist interaction was provided for the two types of treatment. The intervention lasted for 8–10 sessions of 45–60 minutes over a period of 2.5 weeks. During each session, the participants made an estimated minimum of 500 repetitions and possibly up to 800 repetitions. One repetition could be an up-down movement, a left-right movement, or (in most cases) a combination of both (e.g., moving cursor from center to top-right corner of screen). Scores on the FMA improved significantly after intervention. Scores on the WMFT and Disabilities of Arm, Shoulder and Hand (DASH) did not improve.

The Able-X handlebar (including CyWee Z) is commercially available at <http://www.im-able.com/>.

3.2. Robotic Devices

3.2.1. H-O-H. The Hand-Object-Hand (H-O-H) system (see Figure 7) was one of the first bilateral training devices to be introduced in stroke rehabilitation [19]. This particular robotic training device was presented as an introduction to the design of more complex robotic assistance devices for poststroke upper limb rehabilitation. In the H-O-H system both hands are placed in two rigid handles that constrain the patient's movements to flexions and extensions about the wrists, that is, to a single degree of freedom (DOF) per hand, which have to be coordinated. A 17.5 cm long

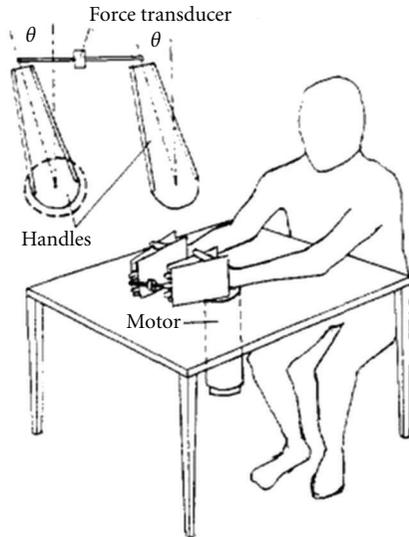


FIGURE 7: H-O-H. Inset: top-view of the force transducer between the distal parts of the handles. Reprinted with permission.

pencil-like object consisting of two machine screws attached to both sides of a force transducer is placed between the distal parts of the handles. The robotic aid consists of a computer-controlled motor mounted underneath one of the handles. The system is capable of partially or fully substituting for one hand in two tasks: rhythmically moving the object from left to right and vice versa (i.e., parallel movements for the hands) and squeezing.

Even though the H-O-H system has been advocated for poststroke upper limb training, no clinical results have been reported to date, nor is the system commercially available.

3.2.2. The Bimanual Lifting Rehabilitator. The Bimanual Lifting Rehabilitator (see Figure 8) is a 2-DOFs linkage that captures the dynamics of bimanual lifting [31]. One of the two links consists of the object to be lifted with two handles, while the other link provides both measurement of the object's vertical position and assistance when the force of one arm is inadequate or insufficient. The computer-controlled motor, positioned near the elbow and attached to the link alongside the forearm of the most impaired side, adjusts the lifting force of the most impaired upper limb by applying torque to the controlled link when the link to be lifted is tilted. Tilt is measured with a potentiometer positioned near the bearing between the two links. The Bimanual Lifting Rehabilitator is capable of partially or fully substituting the force of one upper limb, for example when lifting a cafeteria tray carrying a cup of coffee.

Like the H-O-H system, no reports of clinical tests of the Bimanual Lifting Rehabilitator are available, nor is the device commercially available.

3.2.3. MIME. The Mirror Image Movement Enhancer (MIME, [32]) is a 6-DOFs robot manipulator (PUMA 560, Stäubli Inc.), equipped with actuators to apply forces in goal-directed movements (see Figure 9). The MIME system

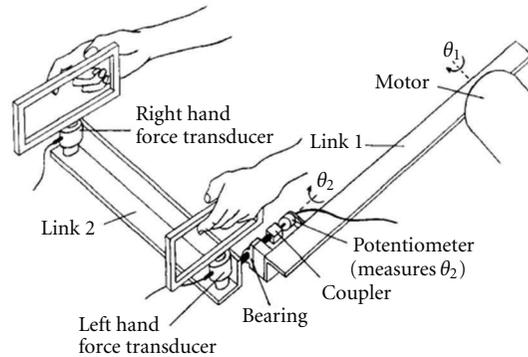


FIGURE 8: The Bimanual Lifting Rehabilitator. Reprinted with permission.

focuses on shoulder and elbow function. The most affected forearm and hand are strapped in a customized splint, which restricts wrist and hand movement and is attached to the end effector. The less affected upper limb is strapped in a similar splint attached to a position digitizer. The robot's 6 DOFs allow the forearm to be positioned in a large range of positions enabling the patient to practice quite complex 3D movement patterns. A 6-axis sensor measures the forces and torque between the most affected upper limb and the robot. MIME supports four modes of robot-assisted movement. In the bimanual mode the patient is instructed to perform bimanual mirror-image movements while the robot assists the most affected upper limb by continuously moving the most affected upper limb to the contralateral forearm's mirror-image orientation and position. The passive, active-assisted, and active-resisted modes are unilateral training modes.

The MIME system has been used in three randomized clinical trials (RCTs). In the first RCT [33], the effects of the MIME system were compared with NDT targeting the upper limb in patients with chronic stroke. In total 27 patients received 24 1-hour sessions of therapy over 2 months. A therapist blinded to group assignment evaluated outcomes on the FMA, Functional Independence Measure (FIM), and biomechanical measures of strength and reaching kinematics. After 2 months of training the group receiving treatment with the MIME system had larger improvements in the proximal movement portion of the FMA, larger gains in proximal strength, and larger increases in reach extent than the group receiving NDT. The FMA difference between groups disappeared at 6-month followup. However, the MIME system group showed larger improvements in the FIM at 6-month followup; a difference that was not present directly after treatment. In this RCT all four modes of robot-assisted movement were used, which means that the group receiving treatment with the MIME system spent approximately 12 minutes of each session in the bilateral mode and 25 minutes in unilateral modes. Hence, it is unclear which type of training (bilateral or unilateral) contributed most to the observed improvements.

In a second RCT [34], patients with stroke in the subacute phase were recruited and divided over four groups.



(a)



(b)

FIGURE 9: MIME. (a) Unilateral mode. (b) Bilateral mode. Reprinted with permission (funding: US Department of Veterans Affairs Rehabilitation Research and Development Program).

One group received NDT targeting the proximal upper limb ($n = 6$) and three groups received robot-assisted treatment: bilateral ($n = 5$), unilateral ($n = 9$) or combined unilateral and bilateral ($n = 10$). All groups received 15 1-hour treatment sessions over 4 weeks. Compared to the NDT group, only the combined unilateral and bilateral (robot-assisted) group showed greater gains in the proximal FMA and the synergy scale of the Motor Status Score after treatment. However, this difference disappeared after 6 months. At the 6-month followup all gains in all treatment groups were equivalent, except that the unilateral group showed greater improvement in the distal FMA than the combined unilateral and bilateral group.

Results of a third RCT, involving patients between 7 to 21 days after stroke, were reported last year [35]. Fifty-four patients were randomized over three groups receiving treatment for 3 weeks. The low-dose robot-assisted group received up to 15 hours and the high-dose robot-assisted group up to 30 hours of training with the MIME system in all four modes. The third group received up to 15 hours of conventional upper limb training. After treatment the high-dose robot-assisted group showed larger gains in FIM scores than the conventional training group. At the 6-month followup this difference was no longer present. There was however a significant difference between the high-dose and low-dose robot-assisted groups on the Modified Ashworth Scale (MAS), with the former having larger increase in



FIGURE 10: ARCMIME. Reprinted with permission (funding: US Department of Veterans Affairs Rehabilitation Research and Development Program and National Institutes of Health Phase I Small Business Innovative Research).

muscle tone than the latter; a difference that was not present immediately after treatment.

The MIME system is not commercially available.

3.2.4. ARCMIME. The ARCMIME (see Figure 10) was designed in an attempt to develop a clinically viable, commercial device with similar clinical outcomes as the MIME system [36]. The ARCMIME structure consists of aluminum extrusions and linear slides on which arm splints are mounted. The system was designed such that it could be manually adjusted and reconfigured. The pitch angle can be adjusted 85° from horizontal and the two arms with the linear slides can be rotated 345° around their individual pivot points. Unlike the MIME system, which allows movements in 3D, the ARCMIME only allows movements along the linear slides.

Four patients with stroke and two healthy subjects performed tasks with the ARCMIME as well as the MIME system to compare the operation of both systems [36]. Ten trials of each of the four modes were performed at each of two movement trajectories. When movement patterns were matched, the force directed towards the targets by the paretic limb were not significantly different for the two systems. From these results it was concluded that the clinical gains seen with the MIME system may be reproducible with the ARCMIME system.

The ARCMIME system is not commercially available.

3.2.5. Braccio Di Ferro. The Braccio di Ferro (see Figure 11) is a planar manipulandum with 2 DOFs operated by two motors [37]. The operational plane can be changed from horizontal to vertical. The Braccio di Ferro can generate four types of forces: an assistive field, a resistive elastic field, a rigid "wall," and a viscous field. This haptic robot was designed primarily for unilateral use. However, by substituting the handle with a length-adjustable bar that can rotate freely, the Braccio di Ferro can also be used for bilateral training. Bar rotations are measured with a potentiometer.

Bilateral training with the Braccio di Ferro was tested with patients with chronic stroke. In two feasibility studies

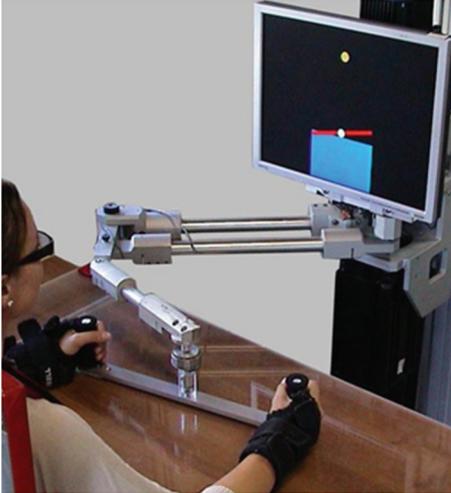


FIGURE 11: Braccio di Ferro. Reprinted with permission (<http://www.iit.it/>).

[38, 39] patients performed forward and backward movements in the Braccio di Ferro generating the four types of forces described above. The training cycle consisted of five sessions over 2 to 3 weeks, each session lasting no more than 45 minutes. All patients improved their performance: movements became faster, smoother, more precise, and required decreasing levels of assistive force. However, no clinical outcomes have been reported for the device.

The Braccio di Ferro is not commercially available.

3.2.6. Bimanual Handlebar. The bimanual handlebar [40] has two active DOFs (see Figure 12) allowing forward and backward translational movements as well as rotational movements of the end-effector around an axis perpendicular to the direction of the translation. The bimanual handlebar is made of two parts, which are both mounted on the end-effector and independently measure forces generated by each upper limb using two 6-DOFs force and torque sensors. The complete handlebar turns like a steering wheel and can actively resist the subject's movements. An LCD screen is mounted on the top of the handlebar to enable visual representation of a virtual task. The subject's task is to track a reference object on the screen by moving the robot end-effector, which is also displayed on the screen with a tracker object. In the bilateral mode, the subject holds the handlebar with both hands and must coordinate them to keep the tracker object's orientation constant.

No clinical tests have been reported to date for this device and it is not commercially available.

3.2.7. Bi-Manu-Track. The research group that developed the Reha-Slide also developed the Bi-Manu-Track [41]. The Bi-Manu-Track is a computerized motor-driven arm trainer that allows bilateral training of two movement patterns: forearm pro- and supination and wrist flexion and extension (see Figure 13). To switch between movement patterns the device can be tilted by 90°. The Bi-Manu-Track supports



FIGURE 12: Bimanual handlebar. Reprinted with permission.



FIGURE 13: Bi-Manu-Track. Reprinted with permission (<http://www.reha-stim.de/>).

three computer-controlled modes of practice. In the passive-passive mode the robot controls both arms. In the active-passive mode the less impaired upper limb actively moves the handle while the robot guides the most impaired upper limb. In the active-active mode both arms perform actively by overcoming an initial isometric resistance. Movements can be either mirror-symmetric (in-phase) or parallel (anti-phase). Amplitude, speed, and resistances can be set individually.

The Bi-Manu-Track was tested first in 12 patients with chronic stroke [41]. On top of an ongoing comprehensive rehabilitation program patients received daily upper limb training of 15 minutes in all three modes of the Bi-Manu-Track on weekdays, for 3 weeks. After treatment MAS scores revealed significant muscle tone reduction in wrist and fingers. However, scores returned to pretreatment values at 3-month followup. Other scores, such as the Rivermead Motor Assessment, did not change significantly.

In an RCT the effects of treatment with the Bi-Manu-Track were compared with electrical stimulation treatment of the wrist extensor in patients with severe hemiparesis [42]. In total 44 patients 4 to 8 weeks after stroke were randomized over both groups. All patients trained for 20 minutes every workday for 6 weeks. The Bi-Manu-Track

group performed 800 repetitions per session: 200 wrist cycles in the passive-passive mode and 200 in the active-passive mode, 200 forearm cycles in the passive-passive mode and 200 in the active-passive mode. These patients were also allowed to practice 25 to 50 repetitions in the active-active mode. The electrical stimulation group practiced 60–80 wrist extension repetitions per session. Upper limb muscle power and FMA scores increased significantly more in the Bi-Manu-Track group than in the electrical stimulation group posttreatment and at 3-month followup.

In another RCT the Bi-Manu-Track was used to test the effect of bilateral robot-assisted training with transcranial direct current stimulation (tDCS) [43]. In this study, 96 patients with severe upper limb impairment 3–8 weeks after stroke were randomized over three groups. For 6 weeks, one group received anodal stimulation of the lesioned hemisphere and one group received cathodal stimulation of the contralesional hemisphere for 20 minutes. The third group received sham stimulation. During stimulation patients practiced 400 repetitions of two different bilateral movements with the Bi-Manu-Track. The passive-passive and active-passive modes were used during training. Bi-Manu-Track training and tDCS were additional to an ongoing comprehensive rehabilitation program consisting of daily ergometer training, a daily 45 minutes of physiotherapy, and 4 times per week 30 minutes of occupational therapy. All patients improved on the FMA and BBT, but there were no differences between groups posttreatment and at 3-month followup.

A third RCT compared the effects of Bi-Manu-Track training with dose-matched active control therapy [44]. Two groups of 10 patients with chronic stroke each received 90–105 minutes of training each workday for 4 weeks. The Bi-Manu-Track group practiced 300–400 forearm repetitions in the passive-passive mode, 300–400 in the active-passive mode, 150–200 forearm repetitions, and 150–200 wrist repetitions in the active-active mode within one session. For patients with active forearm pro- and supination or active wrist flexion and extension a fourth mode (passive-active) was introduced with the most impaired upper limb actively executing the training cycles. A computer software program was added to the Bi-Manu-Track training so that patients received immediate visual feedback about the actions or force they exerted during training. Following robot-assisted training patients practiced various functional activities for 15 minutes. The control group received a dose-matched training protocol, including NDT, with emphasis on functional task training. The Bi-Manu-Track group significantly increased FMA scores, upper limb activity ratio (assessed with accelerometers), the amount and quality of upper limb use (assessed with the MAL), and bimanual ability (assessed with the ABILHAND questionnaire). There were no differences on the FIM and no follow-up assessment is reported.

In a pilot study, examining 21 patients in the chronic phase after stroke, unilateral and bilateral robot-assisted training with the Bi-Manu-Track were compared with each other and with standard upper limb rehabilitation [45]. The bilateral Bi-Manu-Track group received training similar to

that described above [44]. The unilateral Bi-Manu-Track group received a modified protocol and only trained the most impaired upper limb. In the active-active mode, the most impaired upper limb had to move the handle against a resistance (set by a therapist) through the whole movement (in contrast to only overcoming an initial resistance). The control group received dose-matched treatment with activities involving weight bearing, stretching, strengthening, and unilateral and bilateral coordination, and fine motor tasks. The unilateral Bi-Manu-Track group improved more on the FMA overall score, proximal subscore, and distal muscle power than did the bilateral Bi-Manu-Track and control groups. However, the bilateral Bi-Manu-Track group had greater gains in proximal muscle power than the unilateral Bi-Manu-Track and control groups. There were no differences on the MAS and no follow-up assessment is reported.

The same research group carried out an RCT with patients with chronic stroke, comparing Bi-Manu-Track bilateral upper limb training with therapist-based bilateral upper limb training and a control treatment [46]. All groups received treatment for 90–105 minutes per session, 5 sessions per week, for 4 weeks. The bilateral Bi-Manu-Track group received training similar to that described above [44]. The therapist-based bilateral upper limb training group practiced a variety of bilateral functional tasks under one-on-one supervision of therapists. Treatment for the control group involved conventional therapeutic activities for the upper limb, unilateral and bilateral fine motor tasks, and compensatory practice on functional tasks. On the FMA, the therapist-based bilateral upper limb training group showed higher distal part scores than the control group. On the Stroke Impact Scale (SIS), the Bi-Manu-Track group showed better strength subscale, physical function domain, and total scores than the control group. In addition, kinematic variables differed between the three groups. The therapist-based bilateral upper limb training group demonstrated significantly better temporal efficiency and smoothness, straighter trunk motion, and less trunk compensation compared with the Bi-Manu-Track and control groups. The Bi-Manu-Track group had increased shoulder flexion compared with the therapist-based bilateral upper limb training and control groups.

Currently, an RCT with patients in the chronic phase after stroke (6–24 months) is in operation (<http://www.clinicaltrials.gov/>, NCT01525979). In this 5-arms RCT treatment with the Bi-Manu-Track used in a unilateral and bilateral fashion is compared with unilateral, bilateral, or combined task-related upper limb training.

The Bi-Manu-Track is commercially available at Reha-Stim, Berlin, Germany.

3.2.8. Hand Robotic Rehabilitation Device. In 2009, Rashedi et al. [47] reported the design and development of another hand robotic rehabilitation device (see Figure 14). Like the Bi-Manu-Track, it enables bilateral training of two movement patterns: forearm pro- and supination and wrist flexion and extension movements. Three different modes were programmed for the device: a passive mode in which

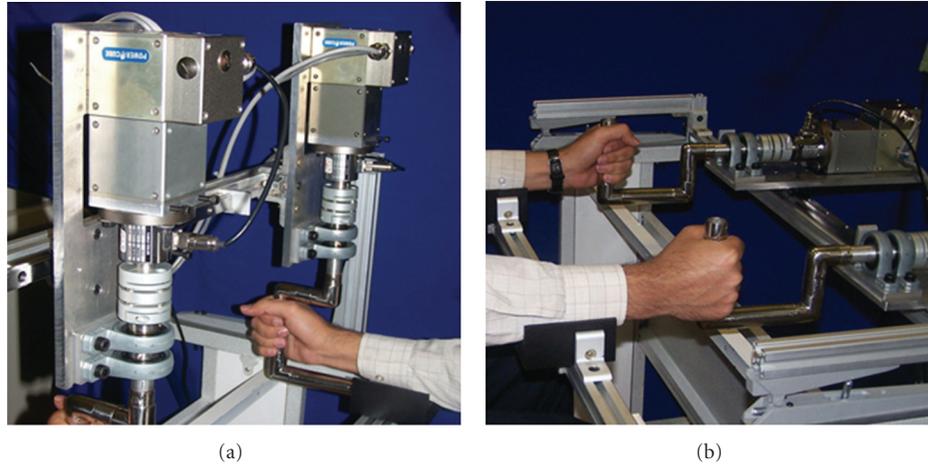


FIGURE 14: Hand robotic rehabilitation device. (a) Wrist flexion and extension. (b) Forearm pro- and supination. Reprinted with permission.



FIGURE 15: BFIAMT. Reprinted with permission (<http://www.bmes.org.tw/>).

the velocity and range of motion can be controlled separately, an active bimanual mode in which the less impaired upper limb moves the most impaired upper limb in a mirror-image motion pattern, and an active mode in which each side could move independently against an adjustable resistance.

No clinical tests have been reported for this device and it is not commercially available.

3.2.9. BFIAMT. The bilateral force-induced isokinetic arm movement trainer (BFIAMT, see Figure 15) is a robot-aided device with 2 servomotors, 2 parallel roller guides, 2 handles, 2 forearm troughs, 2 load cells, and a control panel [48]. The BFIAMT resembles the earlier described Reha-Slide (the handles can be moved forward and backward over parallel tracks), although with the BFIAMT the servomotors can provide aid or resistance during movement, and the load cells detect pull and push forces. The device supports four different treatment modes: bilateral passive, bilateral active-passive, bilateral reciprocal, and bilateral symmetric upper limb movement.

The BFIAMT was used in a single cohort study with patients with chronic stroke [48]. Patients followed a training program consisting of 40 minutes of training 3 sessions per week for 8 weeks. Treatment sessions consisted of two parts.

In Part 1 (30 minutes) patients completed 3 consecutive sets of 20 repetitions of bilateral symmetric arm push and pull movements with the BFIAMT. A subject's isometric maximal arm push and pull strength in both the less and most impaired upper limbs were identified before treatment. The preset demanded forces for the 3 sets were 10%, 20%, and 10% of maximal push and pull forces of the affected and unaffected arms. In addition, subjects were instructed to perform bilateral symmetric push and pull movements at a comfortable cycling pace; the most preferred cycling frequency was 0.1 Hz. During training bilateral push and pull forces were shown in real time to the patient as visual feedback. Generally, the subjects had to keep exerting the demanded forces bilaterally for 10 seconds to complete a smooth push and pull movement. In Part 2 of the treatment (10 minutes), patients received a conventional rehabilitation program focused on treatment that did not provide symmetric bilateral movement and resistance training to the upper limbs. This program included range of motion exercise, muscle tone normalization, compensatory activity of daily living training, postural control training, and gait correction. At posttreatment and 8-week follow-up assessments upper limb function (assessed with FMA, MAS, and Frenchay Arm Test) had improved significantly, as well as grip, push and pull strengths, and reaching kinematics.

The BFIAMT is not commercially available.

3.2.10. Bimanual-Coordinated Training System. The bimanual-coordinated training system is a master-slave system configured with two identical terminals, one for each limb [49]. Two length-adjustable handles for elbow flexion-extension movements are connected with the terminals and two torque transducers and a torque signal amplifier are applied to measure terminal torques and to verify the torque relationship between the two terminals. Furthermore, the system is configured with two identical motors and gearboxes. The working states of the two motors are determined by the forces exerted by the upper limbs on the two terminals. The terminal receiving the larger



FIGURE 16: Driver's SEAT. Reprinted with permission (funding: US Department of Veterans Affairs Rehabilitation Research and Development Program).

force serves to generate state and behaves as the master terminal, while the other terminal works in electromotive state and behaves as the slave terminal. The system supports three training modes: (i) passive-driven mode with the less impaired upper limb driving the most impaired upper limb (which moves passively), (ii) active-assisted mode with the less impaired upper limb assisting the most impaired upper limb to complete desired movements, and (iii) active-resisted mode with the less impaired upper limb resisting the movement of the most impaired upper limb (here the motor operated by the most impaired upper limb behaves as the master, while the motor controlled by the less impaired upper limb behaves as the slave).

No clinical tests have been reported for this device and it is not commercially available.

3.2.11. Driver's SEAT. The Driver's Simulation Environment for Arm Therapy (Driver's SEAT; see Figure 16) was developed as a prototypical rehabilitation device [50]. Driver's SEAT is a 1-DOF robotic device with a servomotor and an adjustable-tilt split-steering wheel which measures position and force related performance. The split-steering wheel interfaces with driving simulator hardware that generates realistic graphical road scenes and collects data associated with steering dynamics. The steering wheel configuration measures the forces generated with each arm independently. The device allows three modes of operation: passive movement, active steering, and normal steering. In the passive movement mode the less impaired upper limb does the steering while the most impaired upper limb is moved passively with the help of the servomechanism. In the active steering mode subjects are instructed to steer with the most impaired upper limb while relaxing the contralateral upper limb. In this mode the servomechanism serves to encourage steering with the most impaired upper limb while involvement of the less impaired upper limb is actively discouraged through



FIGURE 17: Adaptive Bimanual Robotic Training. Reprinted with permission.

a partial restraint. This restraint is invoked using corrective force cues defined as the stiffening of the wheel in proportion to the less impaired upper limb's tangential force on the wheel rim. In the normal steering mode subjects are encouraged to practice coordinated driving and improve their force symmetry by actively steering with both upper limbs.

In an experiment involving 8 patients with chronic stroke and 8 healthy subjects the effects of steering with (active steering mode) and without (normal steering) force cues were compared [51]. In patients with stroke, force cues significantly increased productive torque activity in steering directions up and against gravity with the most impaired upper limb.

The Driver's SEAT is not commercially available.

3.2.12. Adaptive Bimanual Robotic Training. Trlep et al. developed another robotic system designed for steering tasks [52]. This system uses the HapticMASTER robot system (FCS Control Systems, The Netherlands). The existing 3 DOFs of the HapticMASTER are expanded with an extra active joint at the end of the robot to allow the simulation of an active steering wheel. Bimanual handlebars mounted on the end-effector of the robot independently measure the forces generated by each arm. The handlebars turn like a steering wheel and can actively resist the subject's steering (see Figure 17). With both upper limbs supported by a passive gravity compensation mechanism, subjects can perform tasks in a virtual flight simulator environment. The robot is programmed to constrain the motion of the handlebars to the trajectory of three exercise modes: (i) vertical movement with active shoulder flexion with the elbow extended, (ii) horizontal movement with active elbow extension and shoulder protraction, and (iii) isolated active elbow extension. During exercise subjects are stimulated to use the most impaired upper limb against resistance produced by the robot. If the most impaired upper limb is

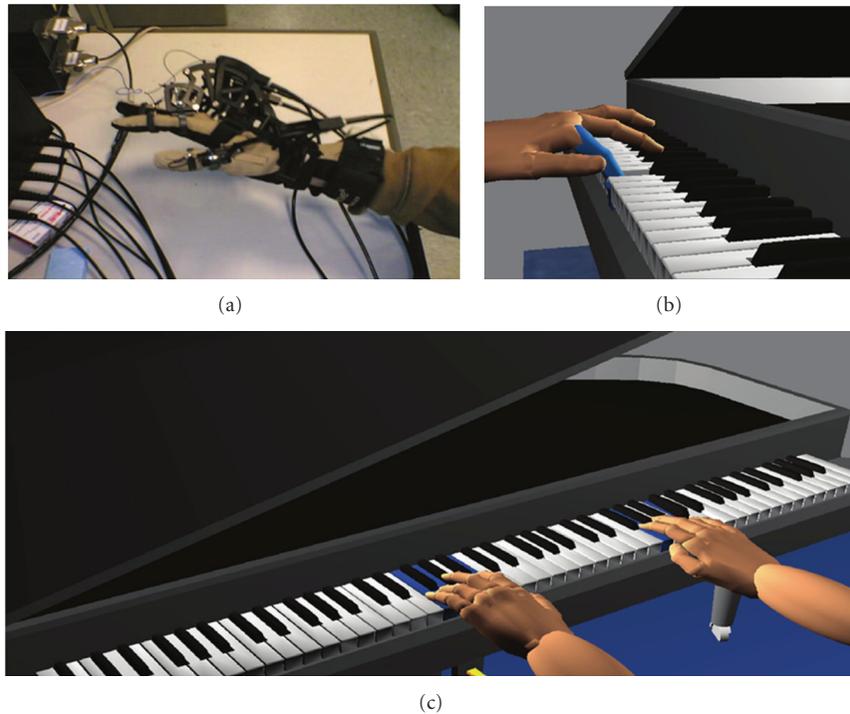


FIGURE 18: Virtual Reality Piano. (a) CyberGrasp worn over a CyberGlove. (b) A virtual key press. (c) Piano simulation with hands shown in a first-person perspective. Reprinted with permission.

not able to perform as required, the forces applied by the less impaired upper limb are scaled down using an adaptive gain to stimulate use of the most impaired upper limb.

The adaptive bimanual robotic training system was tested in 4 patients with chronic stroke [52]. All patients received 8 training sessions; 2 training sessions a week for a period of 4 weeks. Each training session consisted of the three exercises described earlier. Each exercise was first performed unilaterally using the less impaired upper limb, subsequently in the bilateral mode and finally as a unilateral exercise of the most impaired upper limb. Ten stimulated movements were performed in each training mode. Training of the three exercise modes resulted in improvements of task performance in bilateral and unilateral tasks of orientation and position tracking. No clinical test results were reported.

The adaptive bimanual robotic training system is not commercially available.

3.2.13. Virtual Reality Piano. The Virtual Reality Piano (see Figure 18) is a robotic/virtual environment system designed for upper limb training in patients with stroke [53]. The Virtual Reality Piano presents visual, auditory, and tactile feedback comparable to an actual piano by using a force reflecting exoskeleton (CyberGrasp). Upper limb tracking (with the CyberGlove) allows patients to train both the arm and hand as a coordinated unit. The Virtual Reality Piano includes songs and scales that can be performed with one or both upper limbs. Adaptable haptic assistance is available for more involved patients, and an algorithm adjusts task difficulty in proportion to patient performance.



FIGURE 19: EXO-UL7. Reprinted with permission.

The Virtual Reality Piano was tested with four patients with chronic stroke [53]. All patients improved in performance time and key press accuracy, and 3 patients showed improvements in their ability to move each finger individually after 8-9 days of training for 90 minutes. Two patients improved on the Jebsen Test of Hand Function and 3 of the 4 patients improved on the WMFT.

The Virtual Reality Piano is not commercially available. The CyberGrasp is available at VRLOGIC GmbH, Dieburg, Germany and CyberGlove Systems LLC, San Jose, CA, USA.

3.2.14. EXO-UL7. The EXO-UL7 is a two-arm exoskeleton robot with 7 DOFs for each arm (see Figure 19). The seven single-axis revolute joints are responsible for shoulder abduction-adduction, flexion-extension and internal-external rotation, elbow flexion-extension, and wrist

TABLE 1: Summary of mechanical bilateral upper limb training devices.

Name of device	Movement of most impaired upper limb	Targeted part of the upper limb	Device clinical investigation (patients in phase post-stroke: acute, subacute, or chronic)	Commercially available
BATRAC (Tailwind)	Active	Proximal (shoulder and elbow)	Yes 2 single group studies (chronic) [20, 22] 1 RCT (chronic) [23]	Yes
BATRAC (modified)	Active	Distal (wrist)	1 RCT in progress (subacute) [21]	
Reha-Slide Duo	Active	Proximal (shoulder and elbow)	No	Yes
Reha-Slide (Nudelholz)	Passive, assisted, and active	Proximal and distal (shoulder, elbow, and wrist)	1 case series (subacute) [25] 1 RCT (subacute) [26]	Yes
APBT (the Rocker)	Passive	Distal (wrist)	1 case series (subacute) [29] 1 single group study (subacute and chronic) [27] 1 RCT (chronic) [28]	No
Able-X	Active	Proximal and distal (shoulder, Elbow, and wrist)	1 single group study (chronic) [30]	Yes

BATRAC: bilateral arm training with rhythmic auditory cueing; APBT: active-passive bimanual movement therapy; RCT: randomized clinical trial.

pronation-supination, flexion-extension, and radio-ulnar deviation [55]. Four six-axis force/torque sensors are attached to the upper arm, lower arm, the hand, and the tip of the exoskeleton for the human-machine interaction. Together with a control PC and a game PC, patients can manipulate virtual objects in video games while receiving haptic feedback [54]. The robot can be used for unilateral and bilateral training. In the unilateral mode the most impaired upper limb is supported with a weak assistive force toward the target. In the bilateral mode the desired joint angles are mirror symmetrically transmitted from the less impaired upper limb (master) to the most impaired upper limb (slave).

In a small RCT, 15 patients with chronic stroke were randomized over three groups: a unilateral robotic training group, a bilateral robotic training group, and a usual care group [54]. Only the results of both robotic training groups were reported. Both robotic training groups received two 90-minute sessions of training a week, for 6 weeks. Each session a different combination of eight video games that interacted with the EXO-UL7 were played. The results showed no significant difference between the two robotic training groups in FMA score improvements. However, there was a significant difference in kinematic variables in favor of bilateral robotic training.

The EXO-UL7 is not commercially available.

A summary of the review for the mechanical bilateral upper limb training devices is provided in Table 1, while the robotic devices are summarized in Table 2.

4. Discussion

In the foregoing, we reviewed the main characteristics of the bilateral upper limb training devices that have been proposed in the literature as well as their potential for

clinical applications as a function of the currently available clinical evidence and commercial availability. Although the devices discussed in this paper are unlikely to represent the complete spectrum of bilateral upper limb training devices for poststroke rehabilitation, the paper is representative in that it covers the most prominent devices and provides an accurate, state-of-the-art overview of the potential of, and the difficulties involved in, the integration of mechanical and robotic devices in poststroke rehabilitation, including their availability.

Although the discussed devices have in common that they were all developed specifically for bilateral upper limb training or at least support bilateral upper limb training as one of the prominent training modes, they differ considerably in terms of their mechanical and electromechanical complexity. While the mechanical characteristics of some devices, like BATRAC (Tailwind), Reha-Slide and Reha-Slide Duo, are relatively simple, others involve complex forms of robotic control and sophisticated engineering solutions. The simpler devices are obviously easier to implement in rehabilitation, since they are relatively simple to operate and come at lower costs than the devices that use a lot of technical equipment for more precise measurement and movement control. Importantly, to the extent that solid clinical results are available for devices for bilateral upper arm training, no indications or trends are evident that the more intricate devices would have greater clinical efficacy than the simpler, less costly solutions.

As can be appreciated from Tables 1 and 2, the available evidence for the clinical efficacy of the bilateral upper arm training devices in poststroke rehabilitation is rather limited. No clinical results have been presented for 9 of the 20 devices discussed. Moreover, the evidence status of the clinical outcome measures reported for the other 8 devices is limited due to design limitations and other methodological

TABLE 2: Summary of robotic bilateral upper limb training devices.

Name of device	Movement of most impaired upper limb	Targeted part of the upper limb	Device clinical investigation (patients in phase post-stroke: acute, subacute, or chronic)	Commercially available
H-O-H	Passive and assisted	Distal (wrist)	No	No
Bimanual Lifting Rehabilitator	Passive and assisted	Proximal (shoulder and elbow)	No	No
MIME	Assisted (in bilateral mode)	Proximal (shoulder and elbow)	1 RCT (acute) [35] 1 RCT (subacute) [34] 1 RCT (chronic) [33]	No
ARCMIME	Assisted (in bilateral mode)	Proximal (shoulder and elbow)	No	No
Braccio di Ferro	Assisted and active	Proximal (shoulder and elbow)	No	No
Bimanual Handlebar	Active	Proximal (shoulder and elbow)	No	No
Bi-Manu Track	Passive, assisted, and active	Distal (elbow/forearm and wrist)	2 RCTs (subacute) [42, 43] 3 RCTs (chronic) [44–46] 1 RCT in progress (chronic) (http://www.clinicaltrials.gov/ , NCT01525979)	Yes
Hand Robotic Rehabilitation Device	Passive, assisted, and active	Distal (elbow/forearm and wrist)	No	No
BFIAMT	Passive, assisted, and active	Proximal (shoulder and elbow)	1 single group study (chronic) [48]	No
Bimanual Coordinate Training System	Passive, assisted, and active	Proximal (elbow)	No	No
Driver's SEAT	Passive, assisted, and active	Proximal (shoulder and elbow)	No	No
Adaptive Bimanual Robotic Training	Active (with passive gravity compensation)	Proximal (shoulder and elbow)	No	No
Virtual Reality Piano	Assisted and active	Distal (wrist and fingers)	1 single group study (chronic) [53]	Virtual Reality Piano: no CyberGrasp: yes
EXO-UL7	Assisted	Proximal and distal (shoulder, elbow, Forearm, and wrist)	1 RCT (chronic) [54]	No

H-O-H: hand-object-hand; MIME: Mirror Image Movement Enabler; ARCMIME: Applied Resources Corp. Mirror Image Movement Enabler; BFIAMT: bilateral force-induced isokinetic arm movement Trainer; RCT: randomized clinical trial.

shortcomings. Among these are the following. First of all, only some RCTs have been conducted to test the efficacy of the discussed devices. According to the commonly accepted hierarchy of evidence, the most reliable evidence comes from meta-analyses in systematic reviews, followed by evidence from RCTs, cohort studies, and then case studies. Positive results from the case studies and cohort studies discussed in this paper only provide an indication that a particular device may be beneficial in rehabilitation. In many cases, a comparison with other relevant forms of treatment is lacking so that it is impossible to make any statements about the relative superiority or inferiority of training on a particular device relative to other interventions. Second, some of the reported RCTs may be biased because they did not control for the amount of training. For example, the amount of time spent in training by the APBT group was larger than by the control group [28], and the number of repetitions of

wrist movements in the Bi-Manu-Track group far exceeded the number of repetitions in the electrical stimulation group [41]. Of course, admittedly, this discrepancy between the groups is tied to one of the advantages offered by mechanical or robotic training devices, namely that the number of movement repetitions can be considerably increased compared to conventional treatment programs. Third, in several studies in which positive clinical outcomes were found, it is impossible to ascribe the observed effects to bilateral training per se, as the training protocols also involved unilateral training. Likewise, it is impossible to tell whether the effects were due to practicing proximal or more distal parts of the most affected arm, to active, passive, or assisted training of the most impaired limb, or to performing in-phase or anti-phase coordination patterns, because none of these aspects were systematically controlled for in the design of the studies in question.

Based on the discussed clinical results and results from prior meta-analyses [13–18], bilateral upper limb training (with or without training devices) appears to be at least as effective as alternative forms of treatment, with the added advantage that training devices allow an increase in training intensity and frequency as well as the opportunity to train independently [1–4]. However, much more research is needed than has been conducted thus far in order to tailor treatments to the specific needs and characteristics of individual patients. First, there is a definite need for RCT's aimed specifically and systematically at testing various aspects of bilateral training: bimanual versus unimanual, proximal versus distal, active versus passive or assisted movement, and their efficacy in patients with (sub)acute versus chronic stroke. Second, it is even more important to know exactly what it is that patients learn from bilateral upper limb training and what mechanisms are underlying this learning process. This means that measuring changes in clinical outcomes is not sufficient, but that measures of neural reorganization (see also [23]), kinematics, and timing also have to be incorporated, as, for example, in the ULTRA-stroke trial [21]. As it stands, there is very little we can conclude vis-à-vis these aspects from the existing literature.

In conclusion, one may conclude that the principle of bilateral training, and the promise it holds for the rehabilitation of the motor function of the upper limbs, has sparked not only theoretically motivated research in this area, but also various promising innovations in mechanical and robotic devices aimed specifically, or at least partially, at accommodating bilateral training of the upper limbs. However, initial clinical results are not yet of such caliber that the devices in question and the concepts on which they are based are firmly established. It is rather the case that the initial clinical outcomes do not rule out the possibility that concept of bilateral training and the accompanied mechanical and robotic devices may provide a useful extension of currently available forms of therapy. However, to actually demonstrate their value, more research with adequate experimental, dose-matched designs and sufficient statistical power is required. As it stands, one should avoid the proliferation of technological devices that are not sufficiently evidence based and insure that technological advances become and stay aligned with conceptual and empirical developments.

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Clinical Study

SenseWear Armband and Stroke: Validity of Energy Expenditure and Step Count Measurement during Walking

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The purpose of this study was to test the validity of the SenseWear Pro Armband (SWA) for the measurement of energy expenditure (EE) and step count against a criterion in persons with stroke. Twelve participants with chronic stroke (mean age 64.2 ± 10.4 years; mean gait speed 0.67 ± 0.25 m/sec) completed two trials of a six-minute walk test, while wearing a SenseWear Armband (SWA) on each arm and being continuously monitored using a portable metabolic cart. Agreement between estimates of energy expenditure from the SWA and the metabolic cart was fair for the armband on the hemiplegic arm (intraclass correlation coefficient (ICC) = 0.586) and good for the armband on the unaffected arm (ICC = 0.702). Agreement between the SWA estimate of step count, and step count as measured by the Step Activity Monitor was poor (ICC < 0.352), with significant underestimation by the SWA. Our results show that, for these moderately impaired persons with stroke, the SWA should be used with caution for the measurement of energy expenditure and should not be used to measure step count.

1. Introduction

Higher levels of physical activity energy expenditure (EE) are associated with reduced mortality and improvement in risks factors for chronic diseases such as heart disease or diabetes [1]. Maintenance of a 150 minutes/week of moderate intensity physical activity EE in older adults is associated with better functional outcomes [2]. In persons with stroke, exercise interventions show that coronary disease risk factors such as blood pressure and total cholesterol can be reduced with exercise training [3, 4], but that functional gains are lost without maintenance of activity [5]. Those with stroke are 2.6 times less likely to expend 1000 kcals per week than someone without a chronic condition [6]. Few meet activity guidelines, and time spent sedentary is greater than 80% of the day [7], which is significantly greater than sedentary time of their peers [8, 9]. Low levels of physical activity and fitness after discharge back to the community [10] have increased recognition of the need for community physical activity programming for persons with stroke [11, 12].

Accurate measuring devices for both physical activity EE and step count are important as a means to provide feedback about physical activity outcomes, before, during, and after a community based physical activity intervention. Additionally, persons with stroke expend more energy than their peers for everyday activities such as walking [13] and a device that can measure EE accurately may potentially be used to determine if exercise and activity programs lead to beneficial reductions in EE for functional activities. The SenseWear Pro ArmBand (SWA) (Body Media, Pittsburgh, PA, USA) uses multiple sensors including heat flux (heat dissipated from body), galvanic skin response (estimate of skin conductivity), skin temperature, and a two-axis accelerometer to provide estimates of EE and posture (lying or not lying) [14]. Information from the accelerometers about body position helps to predict user context (e.g., standing, walking, biking) which reportedly improves the accuracy of EE algorithms [15]. The use of information from multiple sensors makes the SWA a potentially more accurate measurement tool for assessing EE than accelerometry alone.

Energy expenditure studies testing the SWA show that they provide valid estimates of activity EE in comparison with doubly labeled water [16, 17]. A recent study with healthy individuals showed that agreement between the SenseWear Pro3 Armband and the SenseWear Mini with doubly labeled water was good (ICC = 0.80 and 0.85 resp.) [17]. The SWA appears to be sensitive to changes in EE [18, 19], but at higher EE the device generally underestimates EE [17, 18, 20]. The validity of the SWA has been tested with clinical populations including individuals with coronary heart disease, chronic obstructive pulmonary disease, cystic fibrosis, and arthritis [18, 19, 21, 22]. In two studies with individuals with chronic obstructive pulmonary disease, agreement between the SWA and the metabolic cart was found to be fair [19] or good [18] but use of a walker increased error variability and reduced agreement [19]. In cardiac patients, correlations between the metabolic cart EE and the SWA (version 2.2) ranged from 0.67 to 0.90 for arm and rowing ergometry, treadmill, and stepper [21]. Correlations between the metabolic cart EE estimates and the SWA improved with the use of cardiac-specific equations [21].

Few investigations have tested the validity of the measurement of step count by the SWA. At normal walking speeds, the SWA may provide a reasonably accurate estimation of step count [18, 19], though one research group found that the SWA underestimated steps at all speeds during treadmill walking [22]. However, measurement of step count was limited to three minutes [22], and it wasn't clear if participants achieved normal arm swing during treadmill walking, which may impact the accuracy of the SWA-derived step count. Studies with individuals with cystic fibrosis and chronic obstructive pulmonary disease show that step count from the SWA was significantly less than the criterion at slower speeds [18, 19, 22].

No study has reported the validity of the SWA for the measurement of EE or step count in individuals who have had a stroke. Thus, the primary purpose of this study was to test the validity of the SWA for the measurement of EE and steps against a criterion in a sample of individuals with stroke. We hypothesized that the SWA would underestimate EE and step count during walking in persons with stroke. Secondly, we determined if EE and step counts were significantly different between the SWA worn on the nonhemiplegic and hemiplegic arm.

2. Materials and Methods

2.1. Study Participants and Recruitment. Participants with stroke were consecutively recruited from exercise and rehabilitation centres in Edmonton, AB, Canada. Inclusion criteria for recruitment were as follows: (1) able to ambulate with/without an assistive aid; (2) at least six months post-stroke; (3) observable asymmetric gait; (4) medically stable; (5) ability to tolerate walking for at least a block or five minutes. The study was approved by the University of Alberta health research ethics board and participants signed written informed consent prior to participation.

2.2. Measurements Participant Characteristics. Baseline information including body weight, height, resting heart rate, gait speed, and blood pressure were measured. Impairment from stroke was measured by a physical therapist using the Chedoke-McMaster Stroke Assessment (CMSA) [23]. A score out of seven was determined for the hemiplegic arm, foot and leg. A score of one on the CMSA indicates no movement, a score of four indicates that the participant is able to complete some movements out of synergy, whereas seven is indicative of normal movement [23]. Because we hypothesized that active arm function may impact the accuracy of the SWA during walking, participants with scores of three or less on the CMSA arm scale were classified as having a nonfunctional hemiplegic arm. Balance was measured using the Berg Balance Scale, a 14 item observational test that provides information about standing balance and fall risk [24].

Instruments. The SWA (Body Media, Pittsburgh, PA, USA; software version 6.1) was used as the experimental method for estimating EE and step count. Utilizing proprietary equations developed by the manufacturer, EE is estimated by integrating acquired sensor data with participant's demographic characteristics including gender, age, smoking habit, handedness, height, and body weight [15]. Energy expenditure is estimated for each minute of data using complex pattern recognition algorithms that detect user context (i.e., walking, running) [17]. Each context or activity class has a linear regression model associated with it, estimating EE from the motion data and the physiological sensors [17]. Algorithms have been developed and refined through testing primarily young or middle aged adults and nondisabled reference groups, though more recent algorithms have incorporated data from clinical populations such as obesity and heart disease [14]. Step count is derived by the proprietary software from the raw accelerometer data.

The Oxycon Mobile metabolic cart (CareFusion Respiratory Care, Yorba Linda, CA, USA) was used to measure oxygen uptake continuously. Prior to testing, the metabolic cart was calibrated against known gases. The Oxycon Mobile provides valid estimates of oxygen uptake at a variety of different workloads [25]. It uses a breath by breath measurement method and continuously monitors the participants' respiratory rate, minute-by-minute oxygen uptake (VO_2), carbon dioxide production, and respiratory exchange ratio (RER). Energy expenditure (kcal/min) was then determined by multiplying the caloric equivalent based on RER with oxygen uptake data (L/min) [26].

For step count, the StepWatch Activity Monitor (SAM) (Orthocare Innovations, Oklahoma City, OK, USA) was used as the criterion measure. This monitor is valid for the measurement of ambulatory activity (in steps per minute) in people with stroke when walking on level surfaces, uneven surfaces, outdoors, and on stairs, as long as the monitor is positioned on the nonparetic leg [27]. The SAM uses a uniaxial accelerometer and the software allows programming according to the participant's gait speed and gait quality (e.g., shuffling). The monitor is 98% accurate at a variety of gait speeds and across various surfaces with individuals with stroke [27].

2.3. Procedures. Data collection took place in one 90 minute laboratory visit. After signing informed consent, baseline information about participant characteristics was collected prior to the walking trials.

2.3.1. Participant Preparation. Participants were asked to abstain from coffee or food in the two hours prior to the test and not to exercise in the 24 hours prior to the test. The two SWA devices, worn posteriorly on each triceps, were set up by entering the participant's age, gender, height, weight, dominant handedness, and smoking history into the software. The guidelines defined by manufacturer state that the arm band should be worn on the right arm. Bilateral tests were conducted with two armbands (one on each arm) finding good repeatability of accelerometric and galvanic skin response sensor values (correlation coefficient >0.80) [15]. However, because of the asymmetrical placement of sensors (i.e., unilateral heat flux sensor), right arm placement is recommended. We placed one SWA on each of the hemiplegic and nonhemiplegic arms to allow investigation of potential differences in accuracy that may be related to hemiplegia. The monitors were worn for 15 minutes prior to data collection, as per the manufacturer's instructions. The SAM was programmed according to gait speed and then positioned over the lateral malleolus of the non-paretic leg.

Participants were oriented to the metabolic cart including the vest worn, as well as the face mask. The face mask was fitted over the participants' mouth and nose. Once the face-mask was properly fitted (i.e., no leaks), the metabolic cart was started and participants rested quietly for 10 minutes in a seated position prior to starting the walking trials. Heart rate (HR) was derived from continuous monitoring with a pulse oximeter affixed to the participants' ear lobe. After application of all equipment, and the acclimation period, the walking trials were started.

2.3.2. Walking Trials. Each participant completed two six-minute walk tests over a 25 m course (walking in a straight line, and around pylons at each end). They used their own walking aid, as required, and a safety belt was worn during all walking testing, in the event that assistance with balance was required. The protocol from the American Thoracic Society [28] was used, and standard instructions were provided. Because there was no ability to time stamp the SAM to indicate the beginning and end of the walking trial, participants were transported to the start of the six-minute walk test in a wheelchair. They stood immediately prior to starting the walk test and began to walk once the investigators simultaneously started the metabolic cart and time-stamped the SWAs. After the participant walked for six-minutes, they were instructed to stop walking and stand. Simultaneously, investigators time-stamped the SWAs and the metabolic cart to indicate the end of the walk.

After the first six-minute walk test, the participant rested in the seated position for 15-minutes during which time their HR and blood pressure were recorded. During the rest

period, the metabolic cart mask was removed for comfort. After the 15-minute rest break, the mask was reapplied, and the second six-minute walk test was completed. At the end of the second trial, the participant was monitored (e.g., HR and blood pressure) for 10 minutes. After the walking trials were complete, participants rested as needed prior to administering the Berg Balance Scale and the CMSA.

2.4. Statistical Analyses. All statistical analyses were performed using SPSS software (version 19.0; IBM, Markham, ON, Canada). The EE data from the metabolic cart and the SWA were grouped into one minute intervals and exported into a Microsoft Excel spreadsheet and synchronized for further analysis. Step count information in steps/min was downloaded from the SWA and the SAM at the same time as the EE download. The primary outcomes were mean EE in kcal/min and total steps and for both outcomes the full six-minutes of data from each walk test were used in the analysis. Means and standard deviations were calculated for physiological, energy expenditure, and walking data. Paired *t*-tests were used to determine if there were significant differences between outcomes on the two trials of the six-minute walk test.

For the two primary outcomes (mean EE and total steps) agreement between (1) the SWA on the hemiplegic and the nonhemiplegic arm and (2) the SWAs and the respective criterion measures (metabolic cart or SAM) was assessed using intraclass correlation (ICC) analyses (Model 2,1) [29]. The ICC analysis for EE was repeated: (1) after splitting the sample by nonfunctional and functional arm use and (2) using only the SWA information from the armband on the right arm. An ICC < 0.40 was considered to indicate poor agreement between outcomes for the devices, ICC between 0.41 and 0.60 fair agreement, ICC between 0.61 and 0.80 moderate agreement, and ICC > 0.80 substantial agreement [29]. Standard error of measurement, an estimate of the difference between observed values and the true value, was calculated using the formula $SD \times \sqrt{1 - r}$, where SD is the standard deviation of the difference scores and *r* is the calculated ICC value [30]. Absolute percent differences were calculated as the difference between the criterion and the value from the SWA divided by the criterion, multiplied by 100.

For EE and steps, agreement between methods was presented graphically with the criterion on the *x*-axis and the difference between the criterion and the SWA values on the *y*-axis. Use of the criterion value instead of the mean of the two measurement methods on the *x*-axis is different than a traditional Bland Altman plot [31], but we deemed this to be more appropriate especially for step count where the difference between the methods was large. Finally, scatter plots were diagrammed to explore the associations between gait speed and error in EE and step measurement (i.e., percent difference between criterion and SWA). Data are expressed as mean \pm standard deviation (SD) and significance was set at the $P < 0.05$ level.

TABLE 1: Participant characteristics.

Age (years)	64.2 (10.4)
Gender, <i>n</i> male/ <i>n</i> female	7/5
Body mass index	29.4 (4.6)
Time after stroke (years)	6.6 (4.3)
Gait speed (m/sec)	0.67 (0.25)
Range	0.29–1.10
Berg balance scale (out of 56)	40.7 (12.5)
CMSA Arm score (out of 7)	3.5 (2.1)
Range	1–7
Number who scored 1–3	7
CMSA Leg score (out of 7)	4.4 (1.2)
Range	2–6
Number who scored 1–3	3
Use of walking aid	
No aids, <i>n</i>	2
Cane, <i>n</i>	10
Use of lower extremity orthosis	
Yes, <i>n</i>	8
No, <i>n</i>	4

Data are expressed at mean (SD); *n*: number; CMSA refers to Chedoke-McMaster Stroke Assessment. Baseline gait speed reported is from 10 m walk test.

3. Results

The characteristics of the twelve individuals with stroke who participated are displayed in Table 1. The majority had left hemiplegia (10 of 12) and eight of 12 had an average gait speed ≤ 0.8 m/sec indicating that they were not community ambulators [32]. One participant required stand-by assist to walk but all others walked independently. Most used a cane and an ankle foot orthosis to walk. Seven of 12 participants scored three or less on the Chedoke-McMaster Stroke Assessment (arm) indicating that they did not use their hemiplegic arm for functional activities.

Raw scores for the outcomes (physiological responses, EE, and steps) are presented in Table 2. Heart rate and oxygen uptake were slightly but significantly greater during the second six-minute walk test, as was the estimated EE from the metabolic cart. Estimated total steps during the six-minute walks were not different between the two walking trials for either device. Participants walked on average 10 m further on the 2nd six-minute walk but this difference was not statistically significant.

3.1. EE Agreement. Values from the two six-minute walks (for EE and steps) were combined for testing agreement, thus the sample size was 22 and 24 for tests utilizing the SWA on the hemiplegic arm and the nonhemiplegic arm respectively. For one participant, the SWA malfunctioned on the hemiplegic arm (i.e., no values were recorded). On average, the SWA reported greater EE during walking (Figure 1, Table 2), compared to the metabolic cart, and agreement was slightly better with the nonhemiplegic arm compared to the hemiplegic arm (Table 3). Agreement

between the SWA on the hemiplegic arm versus the non-hemiplegic arm was moderate. Agreement between EE values from the SWA on the right arm (placement as per the manufacturer’s instructions) and the MC was good and is similar to agreement between the EE values from SWA on the non-hemiplegic arm and the MC (ICC = 0.715, and 0.702 resp.). This should not be surprising as the right arm and the non-hemiplegic arm were one and the same for all but two individuals. Absolute percent difference in EE was 17.9% for the hemiplegic arm and 18.4% for the non-hemiplegic arm with only about one third of values falling within $\pm 10\%$ difference. Graphically (Figure 1), average overestimation by the SWA was 0.33 kcal/min. There does not appear to be better or worse agreement related to the average EE as measured by the criterion.

Agreement between the SWAs and the criteria was also tested by grouping values for those with ($n = 5$) and without ($n = 7$) functional use of their hemiplegic arm. Agreement between the SWA on the hemiplegic arm and the metabolic cart generally did not differ between the group with functional use of the arm (ICC = 0.577), as compared to those without functional arm use (ICC = 0.619). However, agreement between the SWA on the non-hemiplegic arm and the metabolic cart was better in the group that had functional arm use (ICC = 0.893), as compared to those without (ICC = 0.390).

3.2. Total Steps Agreement. Agreement between the two devices when measuring total steps was poor as evidenced by the ICCs and absolute percent differences between measures (Table 3). The SWA consistently underestimated steps by a mean of 193 steps over the six-minute walk (Figure 2). In spite of generally large underestimation, there were also two participants for whom the SWA overestimated steps (on both trials). Agreement between the devices does not appear to improve as the number of total steps increases. Limits of agreement were large (see Figure 2).

3.3. Associations with Gait Speed. Association between gait speed and error in the measurement of EE or steps were explored. Figure 3 suggests that higher and lower gait speeds are associated with greater error in the measurement of EE. Slower gait speed appears to be associated with greater underestimation of step count by the SWA, but underestimation of step count occurs at all gait speeds (Figure 4).

4. Discussion

This study is the first to test the validity of the SWA for the measurement of EE and step count in individuals with stroke. We found that agreement between SWA EE estimates and the criterion was fair with the SWA on the hemiplegic arm and moderate with the SWA on the non-hemiplegic arm. This finding suggests that, similar to other activity monitors used for people with stroke [27], they work best when placed on the nonaffected side. And though the ICC values did reach the threshold for good agreement on the non-hemiplegic arm, the mean absolute percent difference was high ($\sim 18\%$),

TABLE 2: Physiological, energy expenditure, and walking data from six-minute walks.

	Six-minute walk one	Six-minute walk two	<i>P</i>
Physiological data			
Heart rate (beats/min)	92.9 (13.3)	95.1 (14.0)	0.019
Oxygen uptake (mL/kg/min)	10.9 (2.0)	11.4 (2.2)	0.013
Respiratory exchange ratio	0.88 (0.08)	0.86 (0.05)	0.125
Energy expenditure data			
EE SWA (hemiplegic arm), kcal/min	4.7 (1.4)	4.7 (1.3)	0.845
EE SWA (nonhemiplegic arm), kcal/min	4.8 (1.6)	4.9 (1.3)	0.432
EE metabolic cart, kcal/min	4.3 (1.0)	4.5 (1.0)	0.013
Walking data			
Steps from SWA (hemiplegic arm)	296.9 (196.7)	330.5 (197.6)	0.062
Steps from SWA (nonhemiplegic arm)	335.3 (229.0)	305.3 (231.3)	0.21
Steps from StepWatch Activity Monitor	505.5 (98.0)	515.8 (105.2)	0.171
Distance walked (m)	215.2 (80.5)	225.2 (86.4)	0.084
Walking speed (m/sec)	0.60 (0.22)	0.63 (0.24)	0.084

All values are mean (SD). EE: energy expenditure; SWA: SenseWear ArmBand.

TABLE 3: Agreement, standard error of measurement, and absolute percent difference by condition.

Variable, condition	ICC	SEM	Absolute percent difference
EE, SWA hemi versus SWA non-hemi	0.620	0.73	NC
EE, SWA hemi versus metabolic cart	0.586	0.68	17.9 (15.3)
EE, SWA non-hemi versus metabolic cart	0.702	0.48	18.4 (13.3)
Steps, SWA hemi versus SWA non-hemi	0.682	97.92	NC
Steps, SWA hemi versus SAM	0.220	151.5	39.3 (40.4)
Steps, SWA non-hemi versus SAM	0.352	132.34	41.7 (38.0)

EE: energy expenditure; SWA: SenseWear Armband. SEM: standard error of measurement, units are kcal/min for EE, and steps for the steps variable. Values for absolute percent difference are mean (SD). NC: not calculated.

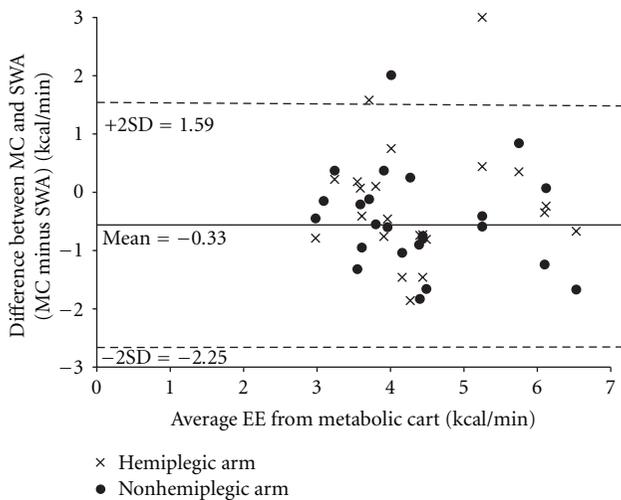


FIGURE 1: Graphical plot of average EE versus the difference between the two measurement methods.

suggesting caution when using the SWA to estimate EE in individuals with stroke. For this group of individuals with

stroke, who walked slowly, the SWA does not measure step count accurately.

Our results with respect to EE estimation and step count can be compared, in particular, to the findings from three clinical studies [18, 19, 22]. Hill and colleagues tested the measurement properties of the SWA in individuals with chronic obstructive pulmonary disease. They reported fair agreement, characterized by limits of agreement of 1.3 METS and an overall difference of 0.2 METS between estimates of EE by the SWA and EE as measured by indirect calorimetry [19]. Using our data, the difference between EE from the SWA on the hemiplegic arm and EE from the metabolic cart (0.4 kcal/min) roughly calculates to a 0.28 METS difference, similar to results from the Hill study. A study with individuals with cystic fibrosis reported strong correlations ($r > 0.85$) between EE as estimated with the SWA and indirect calorimetry [18]. Though not ICCs, these correlations are higher than our correlations and may be explained to some extent by the normal walking speed of participants with cystic fibrosis [18]. Our results related to step count are in line with other studies that found that slow walking or use of a rollator walker resulted in underestimation of step count by the SWA [19, 22]. A gait speed threshold of 50 m/min (0.83 m/sec) has been suggested

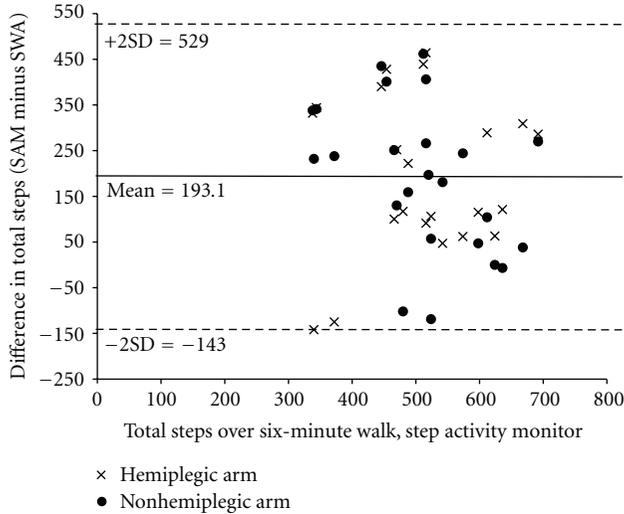


FIGURE 2: Graphical plot of average step count as measured by the Step Activity Monitor versus the difference between the two measurement methods.

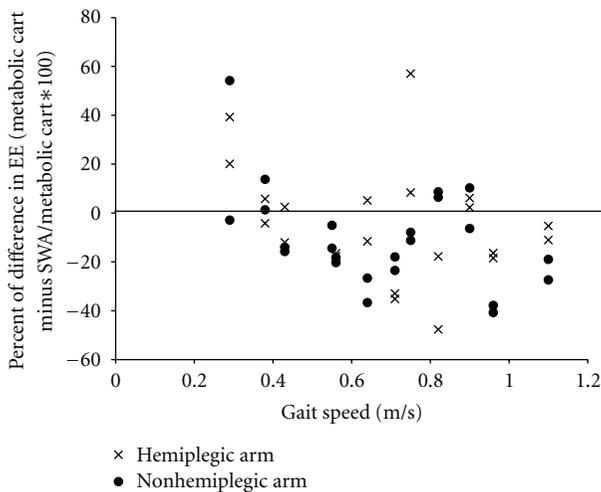


FIGURE 3: Scatterplot between gait speed and percent difference of energy expenditure (EE) for the SenseWear Armband (SWA) and metabolic cart. Percent differences less than zero indicate overestimation by the SWA. Each participant has four data points (one for each arm for each 6-minute walk test), viewed in a vertical line from the gait speed value. Note: there are only two data points for the participant for whom the SWA malfunctioned on the hemiplegic arm.

(i.e., if a person walks more slowly than 50 m/min the SWA will not count steps accurately) [19, 33]. A threshold cannot be determined from our results; however, our average gait speed was well below the suggested threshold, and only three of our participants walked faster than 50 m/min.

Possible explanations of our findings may be related to step count information, difference between arms in terms of vascularity and arm swing, or gait speed. We put these explanations forward for discussion, but more work is required to fully understand the factors that may affect the

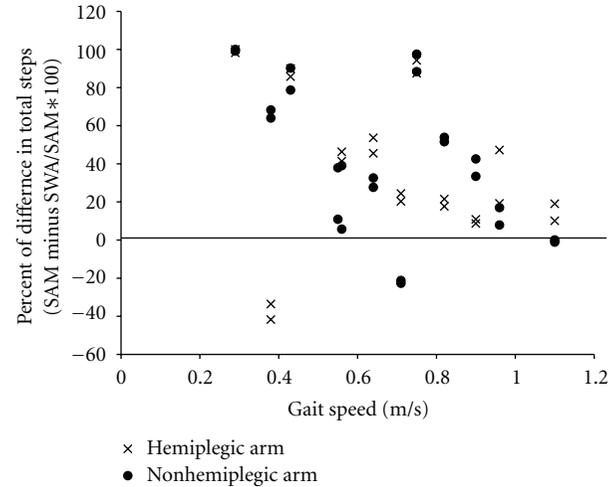


FIGURE 4: Scatterplot between gait speed and percent difference of step count as measured by the Step Activity Monitor (SAM) and the SenseWear Armband (SWA). Percent differences less than zero indicate overestimation by the SWA. Each participant has four data points (one for each arm for each 6-minute walk test), viewed in a vertical line from the gait speed value. Note: there are only two data points for the participant for whom the SWA malfunctioned on the hemiplegic arm.

accuracy of the SWA in the stroke population. The SWA, regardless of which arm it was worn on, did not provide a valid estimate of step count in this sample of stroke survivors. Estimates of step count are presumably derived exclusively from the raw accelerometer data. However, because the algorithms used by Body Media are proprietary, it was not possible to determine how much that incorrect information from the accelerometer during a walking activity contributed to inaccuracies in the EE estimates. Others have suggested that the accelerometer contributes relatively less to EE estimates [19, 34] than the other sensors and our findings support this view as in spite of lower accelerometer readings, the SWA generally overestimated EE.

Vascular differences from arm to arm may account for the difference observed in our stroke survivors. Many people with hemiplegia perceive their hemiplegic arm to be cold, and this sensation is associated with reduced arm and hand temperature as compared to the non-hemiplegic arm [35]. A small sample of people with stroke who perceived their arm to be cold had 35% less blood flow to the hemiplegic hand [35]. This compromised circulation could affect values for the temperature sensors and the sweat rate sensors of the SWA. However, we did not measure arm temperature or sweating so we can only speculate.

Arm swing may have also influenced our results. We found that when using the SWA on the non-hemiplegic arm, agreement between the SWA and the EE criterion was better generally, but especially in those with functional arm use, which suggests that more normal arm swing is associated with better accuracy. This result may be deceiving as those with arm function classified by the CMSA as functional, also had higher gait speed (0.82 m/sec versus

0.57 m/sec). We know from previous studies that slower gait speeds are associated with step count underestimation by the SWA [18, 19]. However, the effect of slow gait speed on EE estimation with the SWA is unknown. Our findings suggest that gait speed has little effect on EE measurement (Figure 3). Moreover, in spite of the classification of a functional hemiplegic arm, arm swing on the hemiplegic side often remained minimal during gait. Use of CMSA as a surrogate of arm swing is an imperfect measure and a better measure may have been calculations of arm swing amplitude from video recordings. Future studies may also consider standardizing arm swing (or lack thereof) by asking participants to wear a unilateral sling.

Though vascular changes and lack of arm swing are different in this group of stroke survivors, as compared to other samples, it would be expected that those differences might lead to underestimation of EE by the SWA. This was the case for a minority of participants (Figure 1) but overestimation by the SWA was more common and is challenging to explain. However, the galvanic skin response sensor does pick up on physiological stress [15], and it is possible that walking in a new environment (including wearing the metabolic cart vest) might increase readings to that sensor and help to explain overestimation. Vascular and arm swing differences between participants likely contributed to the large variability we observed in the EE measure but without knowing more about the algorithm used in the SWA software to calculate EE, and it is difficult to make sense of these findings. In future studies, measurement of vascular changes in the arms, as well as better measures of arm swing may help to explain the findings.

One of the challenges of testing a device like the SWA in people with mobility disability, and a limitation of this study, is the heterogeneity of samples, or representation of only part of a group of individuals with stroke. Our group of participants was small and at least moderately impaired with an average gait speed well below what would be expected in a similar age group without disability. A group of stroke survivors who walked faster, regardless of how much arm swing they had, would create more acceleration and perhaps the device would provide less variable and more accurate results for EE. Further studies with larger samples and more functionally varied groups are required to more fully understand the potential to use the SWA to measure EE in individuals with stroke. Also, because our sample almost exclusively had left hemiplegia, the SWA on the right arm (the arm on which the manufacturer recommends placement) was also the non-hemiplegic arm. More individuals with right hemiplegia should be tested.

5. Conclusions

Our results suggest caution when considering use of the SWA for measurement of EE in stroke survivors who walk slowly. Further studies are required to better understand the effects of hemiplegia on SWA accuracy. Use of the SWA to estimate step count in individuals with stroke who walk slowly is not recommended.

Acknowledgment

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Research Article

Rehabilitation of the Upper Extremity after Stroke: A Case Series Evaluating REO Therapy and an Auditory Sensor Feedback for Trunk Control

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Background and Purpose. Training in the virtual environment in post stroke rehab is being established as a new approach for neurorehabilitation, specifically, ReoTherapy (REO) a robot-assisted virtual training device. Trunk stabilization strapping has been part of the concept with this device, and literature is lacking to support this for long-term functional changes with individuals after stroke. The purpose of this case series was to measure the feasibility of auditory trunk sensor feedback during REO therapy, in moderate to severely impaired individuals after stroke. *Case Description.* Using an open label crossover comparison design, 3 chronic stroke subjects were trained for 12 sessions over six weeks on either the REO or the control condition of task related training (TRT); after a washout period of 4 weeks; the alternative therapy was given. *Outcomes.* With both interventions, clinically relevant improvements were found for measures of body function and structure, as well as for activity, for two participants. Providing auditory feedback during REO training for trunk control was found to be feasible. *Discussion.* The degree of changes evident varied per protocol and may be due to the appropriateness of the technique chosen, as well as based on patients impaired arm motor control.

1. Background and Purpose

Stroke is the leading cause of long-term disability in the United States, as there are estimated 6.4 million Americans that have survived a stroke and are now living with minor-to-severe activity limitations [1]. Activity limitations are often associated with persistent impairment of the upper limb. Specific impairments in this group can range from loss of range of motion, to impaired force generation, to decreased reaction times. These impairments can all lead to loss of arm function and further deficits in motor control, severely affecting a person's ability to live independently [2].

Training utilizing repetitive task practice strategies in poststroke rehab is an evolving method of treatment with a variety of treatment regimens possible. Recently, the application of various robotic systems to incorporate repetitive task practice and facilitate real-world tasks in stroke rehabilitation

has been investigated [3–6]. However, since this groundbreaking form of treatment is so new, protocols are not well established and the differences between the robotic devices being used have led to difficulty in establishing specificity within protocols.

In 2 recent reviews evaluating the effect of robotic therapy on the upper limb of individuals after stroke, the high variability of all the work completed to date limited the determination of the effectiveness of this type of therapy [3, 4]. One report indicated that even with robotic training, compensatory movement strategies were still a confluence and needed to be controlled [3]. According to prior robotic therapy investigations in this realm, the ideal candidates are those individuals who are quite impaired in their movement and are unable to perform the forward reaching movement without having the arm supported from the elbow to the hand [3–6]. However, individuals after stroke in the acute

phase [5] as well as in the chronic phase [5] with mild-to-moderately severe impairments, have been shown to benefit from robotic therapy through various measures.

One delving question in poststroke rehabilitation is what is beneficial with individuals who are quite impaired and how great is the level of impairment where one can still benefit from the therapy [6]? One investigation that attempted to answer this question trained individuals at least 6 months after stroke onset, who were considered moderate to severe (average upper extremity Fugl Meyer {FMA} 9/66) and utilized passive supported therapy in a gravity-eliminated position [7]. The results for that investigation revealed impairment and disability level changes (functional changes were not assessed). One multicenter, randomized controlled trial evaluating the effectiveness of robotics in long-term upper-limb impairment led to no improvement in motor function immediately after training, but did show improved outcomes 9 months after therapy was complete (as compared to usual care with nondescript therapy) [8]. There was a third comparative group in that investigation that led to similar changes as the robotic group. Thus, more intense analysis of robotic therapy is necessary to help us understand how these results can translate into regularly used training protocols.

The robot-aided device REO has had only one pilot investigation and one feasibility study completed to date [9, 10]. This REO system involves the patient being securely constrained to a device that can facilitate passive, active assisted, and active movement while avoiding compensatory trunk movement. Similar to the robotic devices discussed previously, the REO provides visual and auditory feedback as a means to enhance motor learning. In addition, this device forces the restriction of the trunk movement by use of a strap across the shoulder connected to the chair. The one pilot investigation mentioned did result in changes for a variety of patient levels on various outcome measures (FMA, strength, spasticity, and pain); however, no control condition was utilized [9]. The feasibility investigation noted that moderately impaired individuals after stroke (FMA 35/66) that were in inpatient rehab were accepting of the device and demonstrated significant changes on the FMA, but again there was no control condition [10].

Several investigations that have controlled the compensatory strategies of individuals after stroke onset have been undertaken recently [11–13]. A review paper [11] and a proof of concept paper [12] evaluated how controlling compensatory movements through feedback was incorporated into upper-limb recovery. The limited randomized controlled investigations that were found in that review, suggested that individuals who have had a stroke benefit from performance feedback in the physical environment (such as motor control deficits involving the controlling of trunk movement) to preserve motor learning abilities [11]. In other words, if the individuals can learn to control their trunk movements, motor recovery of the upper limb as evidenced by kinematic changes, can be made. The proof of concept paper noted clinical improvements on the FMA in more severely impaired poststroke individuals, when given proprioceptive feedback about the involved arm [12]. Thus, incorporating controlling trunk and/or arm movements has

been shown to be an effective training method for individuals at various levels of impairment after stroke.

Systematic reviews of task-specific training have indicated that intensity and task specificity are primary indicators of effective treatment for individuals after stroke [3, 14]. Upper-limb training investigations for individuals who have suffered a stroke have shown improved arm movement ability after completing the task-related training (TRT) with the impaired upper limb [15–17]. One particular method investigated showed that restricting trunk use, as is also used with the REO, has some short-term functional benefits as well as benefits to recovery of the impaired arm (interjoint coordination via reorganization of the arm versus trunk degrees of freedom), but no functional benefits [15, 18]. The concern reported is that the trunk stabilizer becomes a dependent force on which the patient relies to achieve greater arm movement. Additionally, the present protocols using the REO, as mentioned previously, have not been adapted to the recent findings addressing the minimal functional effects of training with the trunk strapped down. Lastly, the appropriate level of patient to most benefit from unrestrained TRT has previously been defined in the literature as moderately impaired on the FMA (scoring between 20 and 40), and TRT has been well tested out in terms of trunk stabilization feedback, thus making for a solid control condition [15, 17].

The present case series utilized TRT as a control condition in a crossover comparison design, to obtain preliminary data for establishing a REO protocol for the upper limb. The purpose of this case series was to measure changes that can be made by incorporating a novel form of feedback to control trunk movements and auditory trunk sensor feedback during robot assisted arm therapy in moderate to severely impaired individuals after stroke. It was expected that all subjects would exhibit having learned to reach with greater use of their arm/less use of their trunk, exhibiting less dependency than with the stabilizer feedback.

2. Case Descriptions

Individuals with the following were excluded: receptive aphasia, apraxia, or other significant cognitive deficits (determined by the primary investigator during interview question and answer, as well as during command following during the screening sessions). Additional exclusions were (a) sensory/perceptual or orthopedic problems that limit one's ability to reach at the table without sliding the arm on the tabletop (discerned during initial physical exam screening using the Motor Assessment Scale {MAS} [19], a simple classification of arm and hand movements using the involved upper extremity) and (b) any cardiac or pulmonary conditions that limited exercise (physician clearance). The MAS cutoff was at level 4 for upper arm and 1 for hand, allowing for scapular stability/mobility and some grasping activity.

Inclusion criteria: demonstrating severe and moderately severe arm movement impairments, defined between 20 and 44 on the upper-arm subsection of the FMA (a series of

functional multitask arm/hand movements, out of a possible score of 66) [20]. Individuals scoring below this range have previously been determined to be unable to participate in unrestrained TRT, receiving no benefit from the training [17] and individuals scoring greater than 50 have been considered only mildly impaired [21]. Written approval was obtained from the subject's physician after individual's consent; prior to actual participation and after subjects signed the informed consent the patient's primary physician was sent a letter describing the investigation, their patient's involvement, and asking for medical clearance via a waiver.

Three individuals after stroke voluntarily chose to be evaluated for the investigation, were ultimately included, and were randomized as to which protocol was given initially. All 3 individuals had a goal to be able to use their impaired arm for activities of daily living (ADLs). Subject (1): 63-year-old male, 3 years after onset of left-sided cerebrovascular accident (parietal lobe/basal ganglia), right side (dominant) sensorimotor deficits; subject (2): 68-year-old male 18 months after left-sided parietal lobe CVA that led to right side (dominant) sensorimotor deficits, subject (3): 56-year-old male 16 months after onset of right-sided parietal lobe CVA led to left-sided (nondominant) sensorimotor weakness.

2.1. Design. The institutional review boards at both the University of the Sciences and Magee Rehabilitation Hospital approved the study. Using a crossover design, four weeks of real-world TRT was first completed for 2 subjects, and then 4 weeks of REO therapy was completed after a 3-4-week washout period where no training was performed. The reverse sequence was utilized for the third subject; REO followed by a 3-4-week washout and 4-week real-world TRT. This clinical trial is registered with the NIH clinical trials registry as NCT000844870.

2.2. Testing. Several standardized outcome measures were collected no longer than five days before the start of each training and within five days after completion of each training period. Due to the proximity of the testing in between the crossover period/washout period the initial postesting data was utilized as the subsequent pretesting data. Subjects were advised to continue to use their "new found" movement as much as possible, just as they had been advised during the training timeframe. The rehabilitative effects were measured according to the International Classification of Functioning, Disability and Health model (ICF) [22]. Body structure and function typically include motor impairment, while activity is measured by daily task performance, and participation measured by life situations.

The FMA [20] as well as the Reaching Performance Scale (RPS—measure of trunk movement used in reaching) [21], were used to determine body function and structure changes of the arm and trunk, respectively. Clinical measures of elbow and shoulder active range of motion (AROM) were assessed using a goniometer [23] (shoulder flexion was measured in sitting against gravity, while elbow extension was measured with gravity eliminated; the patients participating were not all able to complete elbow motion against gravity), and

grip strength was measured using a dynamometer [24]. The average or 3 trials were used for all clinical measures. The MAS [19], used in pretest screening, was again collected at posttest as an additional body function and structure measure. Wolf Motor Function Test (WMFT—total time score to complete a number of tasks with impaired upper extremity) [25] was used as an activity measure, as well as the Motor Activity Log (MAL—patient's perception of function related to certain arm activities) [26]. Lastly, cognitive changes via the minimal status exam (MMSE—23 or lower is indicative of cognitive impairment, with a max score of 30) were collected [27].

2.3. Intervention. The rehabilitative sessions lasted 40–45 minutes, 2-3 days a week for up to 6 weeks (12 sessions). Subjects were seated with trunk-motion free. Both protocols were arranged to train with a wireless sensor pad draped across the back of the chair, cueing the subjects to keep their back against the pad whenever the back came off of the chair (see Figure 1). Figure 1 displays the individual with their back off of the sensor pad, initiating the auditory signal. Intermittent feedback for both groups was arranged by use of a faded feedback protocol in which the first third of the training trials were without the feedback 20% of the time, the second third of trials were without feedback for 40% of the time, and the final third was without feedback for 60% of the time [28]. This feedback protocol has previously been utilized in a TRT investigation [17].

REO allowed patients to perform robot-assisted activities, which involved continuous reaching with the arm placed in the device (see Figure 2). Visual feedback from the video monitor yielded the perceived best path to complete each motion. This marked path was overlaid by the subject's actual path taken. Verbal and some tactile feedback by the therapist was given during initial REO training, as the auditory sensor device proved to add a higher dimension of concentration for controlling trunk movement. Although the REO device has a shoulder restraint to control trunk movement, the goal was to not utilize this restraint. The goal was to complete motions while avoiding compensatory trunk movement, during passive, active-assisted, and active movement.

Variable practice TRT involved reaching to contact or grasp objects variably placed on the workspace, requiring arm movements of different amplitudes across all quadrants of the tabletop [15–17]. Common objects were used that varied in size, shape, and weight (e.g., cups, mugs, writing and eating utensils). Training activities included, sliding the arm across the tabletop with objects in hand and reaching to grasp/transport objects. As training progressed, subjects were encouraged to increase speed. Subjects received an auditory signal for feedback when the back came off of the pad. Instructions given were to move at preferred speed, and as training progressed subjects were encouraged to increase speed. If a session lasted less than 45 min, subsequent sessions employed more complex tasks. As REO incorporated some active-assisted and some passive movements the time spent in therapy was the best way to equate the sessions and therefore, REO required 10–20% more training trials per session. During each session, 180–220 movements



FIGURE 1: TRT workstation with sensor pad placed on anterior surface of chair back.



FIGURE 2: REO therapy training device (with trunk strap attached).

were performed for the TRT group, and 240–260 robotic movements (recording only movements reaching out away from the body in each protocol) were performed for the REO group, using the hemiparetic arm. Equivalent training time and feedback were controlled for with both protocols.

2.4. Analysis. Posttests taken after each training bout, on each method, were completed and compared to pretraining scores. Significant changes were evident by relative change scores of 30% or greater. Based off of findings from other stroke investigations where minimal clinically important differences (MCID) after stroke revealed a 16% to 30% change as being meaningful for a number of the ICF measures we tested [29, 30], we conservatively used 30% for our results. A recent systematic review of outcome measures used for the evaluation of robot-assisted upper-limb exercise in stroke [31] has further details regarding the MCID for the FMA, grip strength, and WMFT, indicating a MCID of 7 for the FMA, 2.9 Kg for grip strength, and 12 for the WMFT. We were only able to use the FMA and the grip strength

since the WMFT score in their calculations was a calculated mean rate of performance score (functional ability scale), not the performance times as we used. We used the MAL as an equivalent measure to their mean rate of performance score.

3. Results

3.1. REO Performance. Subject 1 performed approximately the same amount of time on guided (passive) and initiated (active assisted) movement (40% each), with only 20% on the most difficult step-initiated (active) movement. Subject 2 performed about 30% of the time on the guided movement and 45% of the time on the initiated movement, and then 25% of the time on the most difficult step initiated activities. Subject 3 followed the same pattern as subject 1 for guided and initiated movement, but the percentages were 45% each therefore, leaving only 10% of the training on the most difficult step-initiated movement. The rationale for determining each of the programs and progress is a clinical decision based on biomechanics of the joint, capsular tightness, movement smoothness, and the ability to appropriately recruit the needed muscle pattern throughout the normal reaching pattern with no excessive compensatory mechanisms observed. The program progression is always to push the individual to the edges of their movement in which he or she is still able to maintain good reaching mechanics.

3.2. Outcome Measures. REO and TRT led to changes for all 3 participants (see Table 1). Table 1 notes the training order on the x -axis and the particular outcome measure on the y -axis, which are arranged according to ICF classification. Particular significant MCID training changes are highlighted for each subject.

Subject 1 displayed body function and structure level changes only after TRT for the MAS hand (65% improvement), with no improvement apparent after the REO. Further body function and structure changes were indicated by the RPS (far and near), yielding 30% improvement after REO, and this was maintained after TRT. Following this body function and structure level trend were elbow extension and grip strength (30% improvement for each), both maintained after REO and TRT. Lastly, activity measure changes after REO were noted by the WMFT at 45% improvement, again maintained after TRT.

Subject 2 displayed activity level changes that were only apparent after TRT, indicated by the WMFT (45% improvement). Subject 3 yielded body function and structure level changes after TRT that were maintained after REO (30% improvement on RPS near and far). Additionally, subject 3 presented with activity level changes indicated by the WMFT, evident after TRT (35% improvement) and maintained after REO. All other changes were below 30% and were not considered to be as relevant as the findings reported here.

Observationally, the one initial body function and structure impairment that was limiting to a subject was the poor scapular stability, and capsular tightness/impingement of subject 3, exhibited by limited amount of shoulder flex and elbow extension; this permitted much less active

TABLE 1: Outcome tests.

	Subject 1 (REO first)	Subject 2 (TRT first)	Subject 3 (TRT first)
Impairments pre-MAS-	Upper Arm = 5/6	Upper Arm = 5/6	Upper Arm = 5/6
	Hand = 1/6	Hand = 1/6	Hand = 6/6
<i>Posttraining 1/pretraining 2</i>	5/6, 2/6	5/6, 1/6	5/6, 6/6
<i>Posttraining 2</i>	5/6, 5/6 (after TRT only)*	5/6, 1/6	5/6, 6/6
Impairment pre-RPS(close)	8/18	8/18	11/18
<i>Posttraining 1/pretraining 2</i>	13/18 (after each)*	9/18	17/18 (after each)*
<i>Posttraining 2</i>	13/18 (after each)*	9/18	16/18 (after each)*
Impairments pre-RPS (far)	8/18	9/18	11/18
<i>Posttraining 1/pretraining 2</i>	13/18 (after each)*	8/18	17/18 (after each)*
<i>Posttraining 2</i>	13/18 (after each)*	10/18	15/18 (after each)*
Impairments pre-FMA	30/66	26/66	37/66
<i>Posttraining 1/pretraining 2</i>	27/66	26/66	36/66
<i>Posttraining 2</i>	27/66	25/66	40/66
Impairment pre-shld. Flex	98 deg	106 deg	83 deg
<i>Posttraining 1/pretraining 2</i>	104 deg	133 deg	89 deg
<i>Posttraining 2</i>	97 deg	114 deg	90 deg
Impairment pre-elbow ext	40 deg	66 deg	57 deg
<i>Posttraining 1/pretraining 2</i>	69 deg (after each)*	63 deg	66 deg
<i>Posttraining 2</i>	71 deg (after each)*	70 deg	64 deg
Impairment pre-grip str.	12 lbs.	5 lbs.	10 lbs.
<i>Posttraining 1/pretraining 2</i>	20 lbs. (after each)*	5 lbs.	12 lbs.
<i>Posttraining 2</i>	21 lbs. (after each)*	2 lbs.	10 lbs.
Activity pre-WMFT-	216.94 sec	300.33 sec	179.24 sec
<i>Posttraining 1/pretraining 2</i>	112.97 sec (after each)*	164.38 sec (after TRT only)	53.18 sec (after each)*
<i>Posttraining 2</i>	128.61 sec (after each)*	403.10 sec	49.76 (after each)*
Activity pre-MAL	5/70	7/70	18/70
<i>Posttraining 1/pretraining 2</i>	7/70	16/70	30/70
<i>Posttraining 2</i>	11/70	14/70	39/70
Cognition pre-MMSE	28/30	29/30	27/30
<i>Posttraining 1/pretraining 2</i>	29/30	29/30	27/30
<i>Posttraining 2</i>	29/30	29/30	28/30

MAS: Motor Assessment Scale, RPS: Reaching Performance Scale, FMA: Fugl Meyer Assessment, WMFT: Wolf Motor Function Test, MMSE: Minimental Status Exam, MAL: Motor Activity Log.

Asterisk after parentheses indicate at least 30% change, after the particular therapy.

movement training (step initiated), as compared to the other 2 subjects. Conversely, subject 1 was especially able to utilize the REO for active movement, as his general scapular stability permitted extensive step-initiated movement.

4. Discussion

Both protocols used environmental feedback as a means to enhance motor learning. However, it became apparent during initial training that using the sensor to limit trunk movement during REO therapy was sensory overload for the subjects, and thus verbal and some tactile feedback from the therapist was necessary (at first) to control shoulder movement/compensatory movements of the trunk while completing the movement path outlined on the computer screen. The traditional method of forcibly restricting the trunk during REO has limited long-term functional use due

to the poor carryover of trunk control once the restraint is removed, detracting from the ultimate goal of these protocols [16, 18, 32, 33]. Conversely, using the REO with the trunk restraint can be very advantageous, allowing independent interaction with the REO, when clinicians are working on repetitive task practice and treating more than one patient at a time [34]. However, as the training therapist discovered during initial controlled training sessions, the modification in the training movement set by the REO device can also be used to limit the motion to a safe distance that does not cause any substitution.

Two out of three participants with moderate levels of body function and structure motor impairment were able to utilize a robotic therapy device, with these training modifications, to benefit the impaired upper limb. Particular REO performance guidelines can be gathered from this case series as all 3 subjects were trained with general training progression patterns, demonstrating that a moderately impaired

patient would be able to perform at least 200 training movements reaching out away from one's body during the course of a typical training session. It was apparent that 10–20% more arm movements per session with robotic therapy allowed for equivalent training session time, compared to more established TRT.

All 3 subjects made activity level changes as indicated by the WMFT, with subjects 1 and 3 maintaining these changes after each of the protocols. Subjects 1 and 3 also displayed body function and structure changes (RPS near and far), that were maintained after each of the protocols. Subject 2 made the least amount of changes, while no subject made changes on the other activity level measure (MAL), perhaps not being as sensitive as the WMFT.

As all 3 subjects did yield WMFT activity level changes, this is perhaps the best indicator of the benefits of these additional structured activities engaging their impaired arm in training. The RPS level changes for subjects 1 and 3 that were maintained for either therapy are a credit to the generalized focus of both types of therapy assisting in controlling arm versus trunk disassociation of movement. The focus of improving the problem of arm control in this population is clearly indicated with these impairments and addressable with the REO. Conversely, subject 2 made no changes as a result of the REO activities; in fact, the gains made on the WMFT and shoulder flexion were back to baseline after the completion of the training on the REO. The treating therapist felt that this was due to scapular immobility and capsular tightness. Thus, despite meeting the minimal criteria to be included in the investigation, the compensatory abilities may have initially masked the poor function of the scapula. Furthermore, subject 2 made no changes on the MAS hand score or with elbow extension. Thus, in comparison to the changes made by subjects 1 and 3 on these measures and in conjunction with the trunk control changes (RPS), we were able to confirm that compensatory trunk movement is used to assist arm reach, as well as hand orientation for grasping.

Clinically, the activity level change (MAL) represents a strong indicator of the patient's belief that they are benefiting from therapy, and with no subject perceiving this benefit, it may be a limitation of the measure. However, there were no changes on the FMA, which is often cited as a measure of motoric change and notably, both other published reports that utilized the REO demonstrated positive findings on the FMA as well as a high level of patient satisfaction [8, 9]. Evaluating the changes that subject 1 made on the MAS hand section that were not seen on the FMA score is perhaps due to the fact that the body function and structure changes made were at the elbow, arm control (RPS), and grip strength, not on some of the finer hand and wrist activities tested out by the FMA.

The result that this auditory feedback training modification is not just possible with TRT but also with REO for this level of patient is promising and warrants further investigative evaluation. The benefits that are carried over from the initial training protocol to the next can be seen as a limitation, as it is unknown with such a short washout period if the overall benefit is the cumulative effect of additional

therapy or the true effect of the actual therapy just received. Conversely, the progression of REO to TRT as a training protocol may be the ideal protocol for a patient with the level of impairments as subject 1, as this was the most number of changes evidenced.

The use of Kinematic analysis in future investigations should lead to a differentiation of upper arm, lower arm movement, and trunk control as well as assist in determining control strategies that are developed as a result of training. A randomized controlled investigation with a population of subjects with similar deficits and perhaps similar time after stroke (as well as subsequent similar baseline measurements) would better clarify what impairments are better trained with REO, what impairments are better trained with more established protocols such as TRT, and the appropriate length of training of each.

Conflict of Interests

The authors declare there are no competing interests in this paper.

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