AUGMENTED MOTION BIOFEEDBACK FOR FUNCTIONAL REHABILITATION OF LOWER LIMBS IN PATIENTS AFTER INCOMPLETE SPINAL CORD INJURY: PRELIMINARY RESULTS USING THE LEGTUTOR™ SYSTEM

NADGRAJENA GIBALNA POVRATNA ZVEZA ZA IZBOLJŠANJE FUNKCIJE SPODNJIH UDOV PRI PACIENTIH PO NEPOPOLNI POŠKODBI HRBTENJAČE: ZAČETNI REZULTATI S SISTEMOM LEGTUTOR™

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Abstract

Introduction:

The LegTutor device provides visual goniometric feedback of knee flexion and extension. A computerised game incites patients with lower limb impairments to enhance precision of their movement.

Methods:

Ten patients (9 males; age range 15-70 years) from 5 month to 3 years after incomplete spinal cord injury (C3 to L3; 7 of traumatic cause) were involved in the study. The treatment consisted of 16 LegTutor™ sessions lasting 45 minutes each, 2 treatments per week for a total of 8 consecutive weeks. The task was to keep a moving target on track. Assessment of motor control (LegTutor™ task score), muscle spasticity (Modified Ashworth Scale), muscle strength (MRC scale) and walking independence

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Izvleček

Izhodišče:

Naprava LegTutor nudi povratno informacijo o kotu fleksije oziroma ekstenzije kolena. Računalniška igra spodbuja pacienta z okvaro spodnjega uda, da izboljša natančnost svojega gibanja.

Metode:

V študiji je sodelovalo deset pacientov (9 moških; starosti 15 do 70 let), ki so bili od pet mesecev do tri leta po nepopolni poškodbi hrbtenjače (višine C3 to L3; 7 zaradi nezgode). Terapijo je sestavljalo 16 enot po 45 minut vadbe z napravo LegTutor™, dve enoti vadbe na teden v skupnem trajanju osem zaporednih tednov. Naloga pacienta je bila obdržati premično tarčo znotraj proge. Ocenili smo sposobnost oziroma učinkovitost nadzora gibanja (dosežek, ki ga izmeri sistem LegTutor™), spastičnost mišic (s Spremenjeno Ashworthovo lestvico), mišično moč (z lestvico Medical Research Council) in samostojnost pri hoji (z

(WISCI II) was performed before the beginning and after the end of the treatment.

Results:
Based on the minimal-real-difference criterion, all the patients improved in the trained task; 5 patients improved by at least 1 raw score point regarding muscle spasticity, 3 regarding muscle strength and 2 regarding walking. The improvement in the task score at each side was correlated with reduced spasticity of the lower limb at the same side ($p < 0.05$ for Pearson r, Somers' d and Cohen's kappa).

Conclusion:
The LegTutor™ treatment appears to increase the ability to voluntarily control the affected lower limb as evidenced by a reduction of spasticity. It could thus be a viable complement to the rehabilitation programs for patients after incomplete spinal cord injury.

Key words:
spinal cord injury, rehabilitation, lower limbs, augmented feedback training

lestvico Walking Index for Spinal Cord Injury Version II) pred začetkom in po zaključku vadbe.

Rezultati:
Ob upoštevanju kriterija najmanjše dejanske razlike so po terapiji vsi pacienti izboljšali svoj dosežek pri izvedbi naloge, ki so jo vadili; pet pacientov je izboljšalo rezultat vsaj za eno točko na lestvici spastičnosti, tri točke na lestvici mišične moči in dve točki na lestvici hoje. Izboljšanje dosežka pri nalogi, ki so jo vadili, na vsaki od strani je bilo povezano z zmanjšanjem spastičnosti spodnjega uda na isti strani ($p < 0,05$ za Pearsonov r, Somersov d in Cohenov koeficient κ).

Zaključek:
Zdi se, da terapija s sistemom LegTutor™ poveča zmožnost hotenega nadzora gibanja okvarjenega spodnjega uda, na kar kaže zmanjšanje spastičnosti. Zato bi lahko bila koristno dopolnilo rehabilitacijskim programom za paciente po nepopolni poškodbi hrbtenjače.

Ključne besede:
poškodba hrbtenjače, rehabilitacija, spodnji udi, vadba z nadgrajeno povratno zvezo

INTRODUCTION

Spinal cord injury (SCI) is particularly frequent in young adults. In general, eight out of ten patients with spinal cord injury are less than 40 years old, whereby the ratio of men to women is about 4 to 1 (1). In more than half of the cases the injury occurs in the cervical region of the spine (1). The incidence rate varies considerably between countries – from 12.7 and 13.4 new cases per million inhabitants per year in France and Switzerland, respectively, to 27.1 and 55.0 new cases per million inhabitants per year in Japan and the USA, respectively (1). It has been estimated that during the last 30 years the incidence and prevalence of SCI have not changed (2).

However, the proportion of complete SCI and tetraplegia is presently on the rise (2). No accurate and comprehensive data is available in Italy, but it has been estimated (3-5) that the incidence rate of SCI in Italy is between 20 and 25 new cases per million inhabitants per year, whereby paraplegia (present in about 57 % of the cases) is more frequent than tetraplegia although the proportion of the latter is on the rise. In patients with paraplegia, complete spinal cord lesions are more frequent than the incomplete ones; conversely, among the patients with tetraplegia, incomplete lesions are more frequent (4).

SCI leads to a complex motor, sensory and visceral syndrome, to say nothing of the psychological and social correlates. This article only addresses motor impairment of the lower limbs in incomplete SCI.

Incomplete spinal cord injuries – grades B to D within the A-E range on the ASIA-ISCoS impairment scale (6) – may present with various functional conditions, depending on the level and the intra-cord distribution of the lesion (for example, in "central" cervical spinal cord lesions the upper, but not the lower, limbs may be affected). In motor-incomplete patients (grades C and D) some voluntary control or the lower limbs is maintained, although not necessarily to an extent allowing autonomous walking. Whatever the acute presentation of the syndrome, after 3 to 6 months the partial loss of supraspinal control invariably manifests itself with so-called negative and positive motor signs (7).

The most prominent negative signs are weakness (paresis) and ataxia (i.e., precision loss) in voluntary motions; the most frequent positive counterparts are enhanced tendon reflexes, the Babinski sign, and spasticity. This is a term encompassing both the increased resistance of muscles to passive stretch and the involuntary agonist-antagonist co-activation. Oversimplifying the issue, it can be said that the brain (a) can no longer properly recruit the spinal motoneurons below the lesion and does no longer receive proper information from the body periphery (hence the weakness-ataxia negative signs), and (b) it can no longer properly inhibit when needed the neural circuitries below the lesion; these tend to respond on their own to peripheral stimuli ultimately causing unwilled movements and, in the long run, anatomical shortening (contracture) of the over-activated muscles. In short, the disruption of the brain-spine connection entails a loss of both facilitation and inhibition, which are the two sides of the same coin (see (7) for a classic text on human spinal physiology).

Rehabilitation may aim at both an "adaptive" recovery (e.g., steering a wheelchair) or to "intrinsic" recovery of the impaired functions (e.g., recovery of muscle strength) (8). Within the intrinsic strategy, the main goal of rehabilitation is contrasting weakness and ataxia while decreasing the positive signs. Treatments may target both peripheral and central mechanisms of impairment. On the peripheral side, for example, slow muscle stretching and muscle relaxant drugs may attenuate spasticity, and electrical stimulation may contrast muscle atrophy (9). Central approaches consist of various techniques requiring mental efforts to provide stronger and more precise willed movements (9). This approach assumes that the brain "has forgotten" some latent capacity and/or that it can learn to use more efficiently the surviving neural circuitry. There are several lines of evidence that the assumption holds. The learned non-use phenomenon (a form of disuse atrophy affecting central sensory and/or motor circuitries) is now well-established in various areas of neuro-pathology ranging from strabismus (9) to stroke (10). There is also evidence that the injured spinal cord undergoes slow progressive anatomical atrophy (11) while the areas of cortical representation of the sublesional regions are "invaded" by an enlarged representation of the neighbouring supralesional regions (11). Hence, there is a rationale for exercises requiring skilled voluntary control of the movements of the paretic lower limbs after incomplete SCI.

In this paper, a form of **bio-feedback** (BFB) treatment is studied. BFB encases a large family of techniques, sharing the goal of providing the subject with information about a body function of which he/she cannot be aware of (13). Sweating, heart rate and muscle electrical activations are all examples of variables that can be brought under conscious control by providing the subject with the proper information arising from the activity under scrutiny (feedback), which usually requires some electronic equipment. The feedback can be represented by any signal that can be managed consciously: for example a sound, a skin pressure or any visual signal of which some parameters are related to the "amount" of the tracked biological variable. BFB is probably underutilised in motor rehabilitation. In the early years of electronics it was originally conceived as a highly demanding form of cognitive exercise requiring a good cognitive status and full collaboration, and it was limited to a single body segment (e.g., cervical spine in headache). Thanks to the progresses in electronics, it can nowadays be applied also to high-order variables, thus going beyond the activity of single body segments. Such examples are the motion of the body centre of gravity during standing (14) and walking (15), and the latency of recruitment of an agonist and a postural muscle during voluntary tasks (16). The **augmented feedback** (AFB) approach is a variant of the BFB in that it provides a type of information which is physiologically conscious, yet for some reasons it is weakened or distorted. This is the case of joint position when the expected and the actual joint excursions do not match due to a paresis and/or due to a loss of proprioception.

The approach tested in this study, the LegTutor™, provides the subject with AFB on knee joint flexion and extension. Hence, the aim of this study was to perform a preliminary evaluation of the effectiveness of the LegTutor™ system in the rehabilitation of patients after incomplete spinal cord injury. More specifically, the evidence that the exercise may be associated with improvement in performing a specific LegTutor™ task would support the hypothesis that it can help functional improvements in terms of motor control.

METHODS

Subjects

Ten patients with incomplete motor SCI since at least three months who were able to voluntarily extend the knee against gravity for at least 30° (MRC force level 3) were enrolled. They had to be free from cognitive, orthopaedic or neurologic impairments other than sequelae of SCI. The tests were performed at the Niguarda Ca' Grande Hospital in Milan, Italy, under the supervision of the Chief of the Spinal Injury Unit. All the patients gave informed consent to participate in the study. The study was approved by the hospital's ethics committee.

Instrument and task: the LegTutor™ system

The LegTutor™ system (by MediTouch® technology – www.meditouch.co.il) is one of a series of devices based on wearable motion-capture devices coupled with rehabilitation-oriented software, suitable for various body segments. Through a goniometric transducer, the LegTutor™ enables the patients to perform voluntary flexion-extension movements of the knee, following a thin "track" curved up and down presented on a PC screen. The leg motion is represented by a moving target on the screen. The task is to complete the track, which remains visible for 10 seconds, while remaining within its boundaries (Figure 1).

The subject lies supine, with the knee flexed by some 50° while supported by a curved pillow. The task requested was to remain "on track" during the test. In this posture, this equals to asking for control of the knee extensors only, which also control flexion against gravity. The patients completed the first track for habituation and, after 10-30 seconds, they

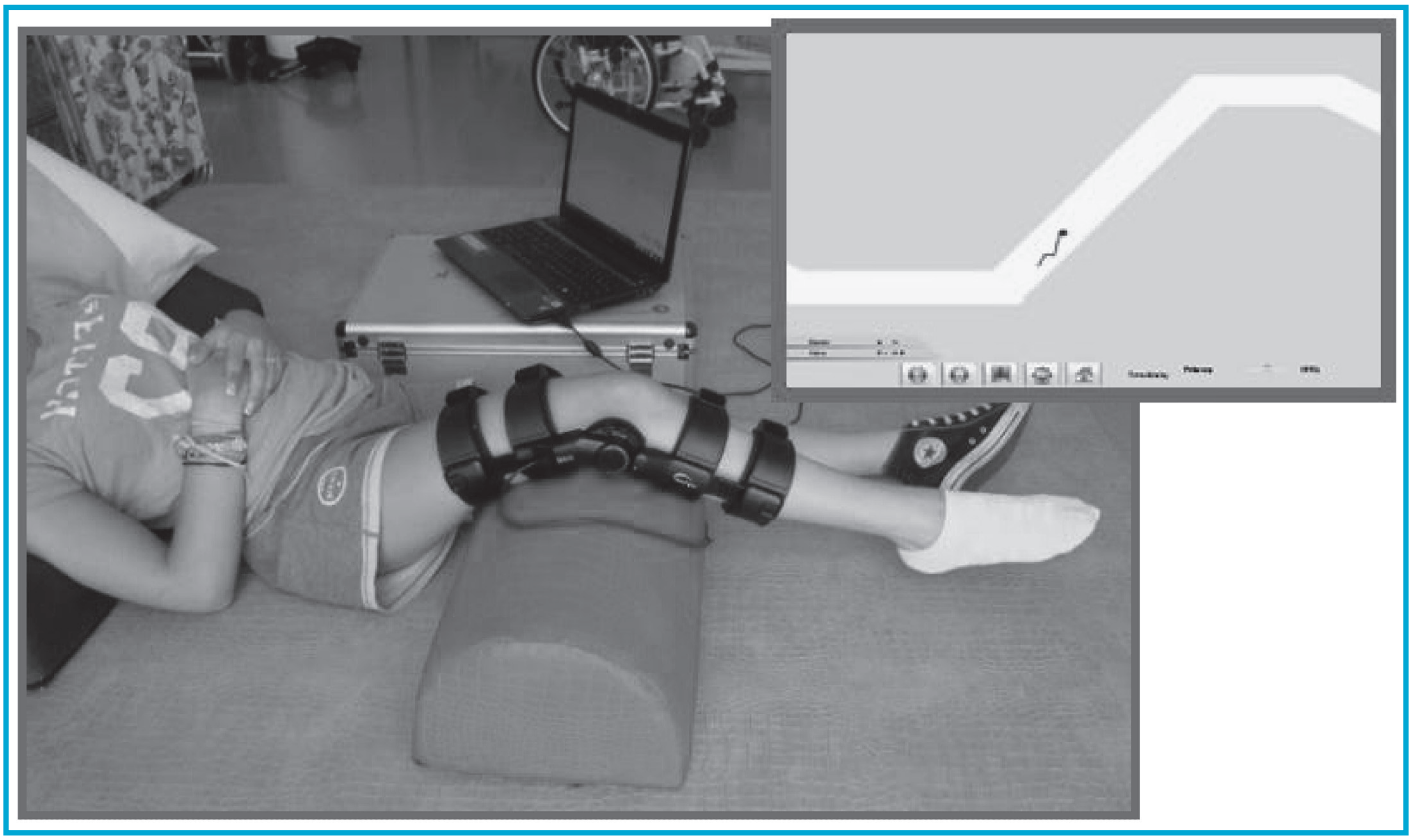

Figure 1: *The LegTutor™ system (photo) and a screenshot of the Track a Target task (upper right corner).*

faced the test track. Both lower limbs were tested, in random order across subjects. The treatments were performed twice a week for 8 consecutive weeks (weekday and day time were kept constant within subjects). The patients were requested to complete the track for 8-10 subsequent times on each leg (the sequence was randomised within each patient). None of the patients found difficulties understanding the task. No drop-out was recorded.

Study design and statistical analysis

Treatment and assessment were performed by the same observer (MS). Four assessments were performed before the beginning and after the end of the treatment:

- Motor control was assessed using the standardised LegTutor™ task score (ranging from 0 to 100, 0 indicating that the target was never on track and 100 indicating that it never went out of the track's boundaries).
- Muscle spasticity was assessed using the Modified Ashworth Scale (17) (ranging from 0 to 4);
- Muscle strength was assessed using the Medical Research Council (MRC) scale (18) (ranging from 0 to 5);
- Walking assessed using the Walking Index for Spinal Cord Injury Version II (WISCI II) (19).

For the LegTutor™ task, a preliminary study had been conducted on 10 healthy controls (results not reported) in order to define the minimal real difference (MRD, also called the minimum significant change) at $p < 0.05$ (20) in a 1-week test-retest study. The estimated MRD amounted to 11 points. For the modified Ashworth scale, the MRC scale and the WISCI II, the minimum detectable change was 1 discrete ordinal unit, and it was assumed to be also the MRD for these tests.

"Improvement" or "worsening" of the patient was declared when at least one of the two lower limbs showed a change of 1 MRD or more in the applied measures. Association between the improvement (i.e., difference score) in the task score and improvement (i.e., difference score) on the other three outcome measures was analysed under three different assumptions and hence using three different approaches:

- assuming both outcome measures in each analysed pair to be at least at the interval measurement level – using the Pearson r coefficient;
- assuming both outcome measures to be at the ordinal measurement level – using the Goodman-Kruskal (G-K) coefficient γ;
- dichotomising both measures (improvement by at least one MRD achieved or not) – using the Cohen κ coefficient.

RESULTS

One woman and 9 men, aged 15 to 70 years, with incomplete SCI (at the C3 to L3 level) who had remaining voluntary motor activity of the lower limbs participated in the study. The time since injury ranged from 5 months to 3 years. Table 1 summarises their demographic and clinical characteristics. Figure 2 gives representative instrumental findings from a tetraparetic subject (patient no. 5 in Tables 1 and 2).

The results of the individual patients are listed in Table 2 and summarised in terms of achieving improvement of at least one MRD in Table 3. All the patients improved in the LegTutor™ task at least on one side, 5 patients improved regarding muscle spasticity (all on the same side where improvement in LegTutor™ task was achieved), 3 regarding muscle strength (all at the same side where improvement in LegTutor™ task was achieved) and 2 regarding walking (one who improved regarding all the three other outcome measures and one who did not improve regarding force). Walking worsened in one patient.

The associations between the improvement in the task score and improvement (i.e., difference score) on the other three outcome measures are summarised numerically in Table 4 (only same-side values are provided for the ordinal- and binary-level coefficients). All the three statistical approaches confirm that improvement in the LegTutor™ task score on a given side tended to be associated with reduction of spasticity on the same side, while no statistically significant association of improvement in the task score either with muscular force (as measured by the MRC scale) or walking ability (as measured by WISCI II) was observed.

Table 1: *demographic and clinical characteristics of the patients.*

Patient No.	Gender	Age (years)	Aetiology	ASIA	Plegia	Level	Time since injury
1	male	32	non-traumatic	C	para	D4	5 months
2	female	58	non-traumatic (suspect viral myelitis)	D	para	D12-L1	11 months
3	male	15	traumatic	C	tetra	C6	6 months
4	male	21	traumatic	C	tetra	C4-C6	2 years 9 months
5	male	64	non-traumatic (surgical removal of ependimoma)	C	tetra	C3	1 year 7 months
6	male	43	traumatic	B	para	L2-L3	8 months
7	male	38	traumatic	D	tetra	C3-C4	5 months
8	male	28	traumatic	C	para	D8	1 year
9	male	45	traumatic	C	tetra	C5-C6	3 years
10	male	70	traumatic	C	tetra	C4-C6	2 years 9 months

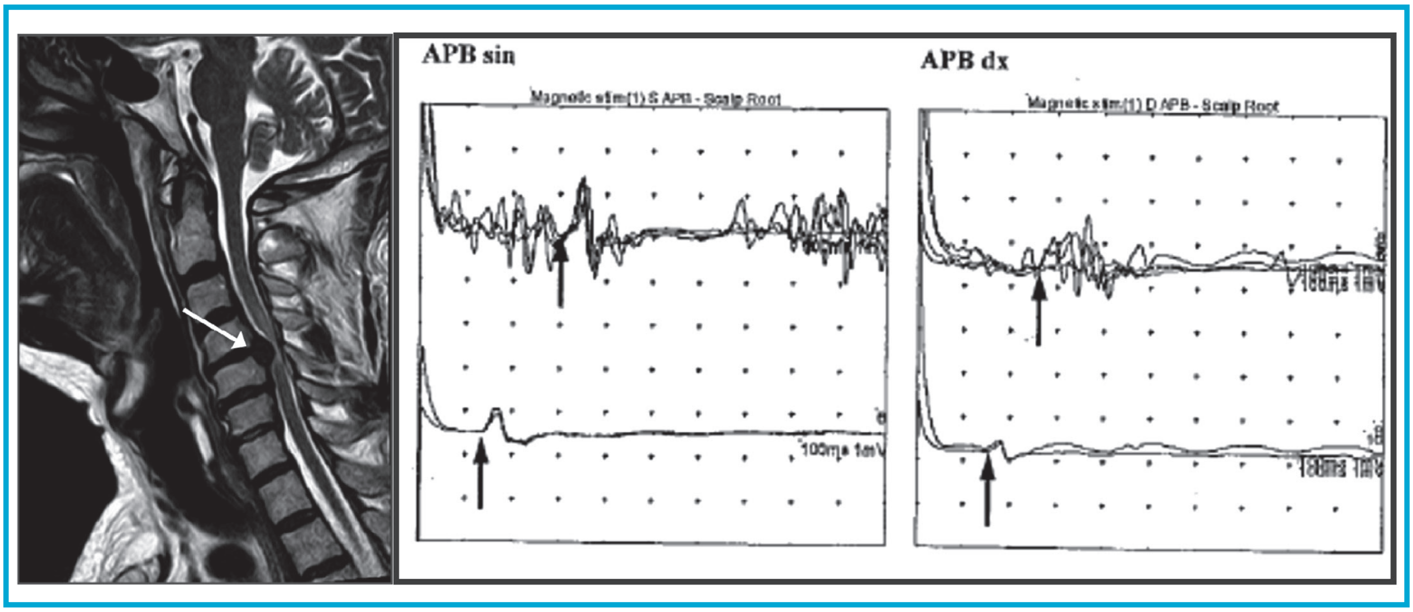

Figure 2: *Patient no. 5 in Tables 1 and 2: left panel – T2-weighted cervical MRI showing severe compression of the spinal cord at C4-C5 level due to an extruded disc herniation; right panel – motor evoked potentials (MEPs, obtained through transcranial magnetic stimulation) from the pre-activated Abductor pollicis brevis (APB).*

Table 2: *Raw scores of the individual patients (bef. – before the treatment program, aft. – after the treatment program).*

Patient No.	LegTutorTM task				Modified Ashworth Scale				MRC				WISCI II	
	left		right		left		right		left		right			
	bef.	aft.	bef.	aft.	bef.	aft.	bef.	aft.	bef.	aft.	bef.	aft.	bef.	aft.
1	48	92	50	81	2	0	1	1	3	5	3	5	0	8
2	82	99	60	98	1	0	1	0	4	5	2	4	13	12
3	50	64	53	86	3	3	2	1	1	3	3	4	0	0
4	74	96	67	92	1	1	2	1	3	3	3	3	1	2
5	80	96	52	82	2	1	3	2	3	3	3	3	13	13
6	79	94	91	95	0	0	0	0	4	4	4	4	9	9
7	83	99	96	98	0	0	0	0	4	4	5	5	2	2
8	80	97	92	98	0	0	0	0	4	4	5	5	12	12
9	76	97	79	97	3	3	3	3	3	3	3	3	13	13
10	62	80	63	76	2	2	2	2	4	4	3	3	0	0

Table 3: *Summary of results of the individual patients in terms of achieving improvement of at least one minimal real difference (MRD) after the LegTutor™ exercise program. The "+" and "–" symbols indicate improvement or worsening, respectively, by 1 MRD or more after treatment as compared to the baseline; blank cells indicate no change beyond the MRD threshold. All the improvements on the Modified Ashworth Scale and the MRC scale occurred on the same side where the LegTutor™ score improved.*

Patient No.	LegTutorTM task (on at least one side)	Modified Ashworth Scale	MRC	WISCI II
1	+	+	+	+
2	+	+	+	–
3	+	+	+	
4	+	+		+
5	+	+		
6	+			
7	+			
8	+			
9	+			
10	+			

Table 4: *Association between improvement in the task score after the treatment and improvement regarding spasticity, muscle force and walking ability (only same-side values are provided for the ordinal- and binary-level coefficients).*

Improvement in		vs. improv. in	Modif. Ashworth scale		MRC		WISCI II
			Left	Right	Left	Right	
LegTutor™ task score	Left	Pearson r	0.756	-0.080	0.495	0.469	0.021
		(p)	(0.011)	(0.827)	(0.145)	(0.171)	(0.955)
	Right	Pearson r	0.602	0.750	0.095	0.417	-0.423
		(p)	(0.066)	(0.013)	(0.794)	(0.231)	(0.224)
LegTutor™ task score	Left	G-K γ	0.789		0.100		0.037
		(p)	(0.083)		(0.871)		(0.948)
	Right	G-K γ		1.000		0.478	-0.500
		(p)		(0.024)		(0.250)	(0.176)
LegTutor™ task score	Left	Cohen κ	0.444		-0.154		-0.154
		(p)	(0.200)		(1.000)		(1.000)
	Right	Cohen κ		0.444		0.074	-0.296
		(p)		(0.200)		(1.000)	(1.000)

DISCUSSION

This was a short case-series study. The design was non-experimental (coincidence of therapist and rater, no control treatment, no adjustments for baseline characteristics etc.), so that inferences on the causal role of treatment on any improvement cannot be supported. However, the study follows a simple proof-of-principle approach: its goal is detecting a potential association between treatment and motor changes, and fostering the estimation of sample size for future experimental studies.

Within these limitations, the results seem to indicate that the studied form of exercise helps improving the voluntary control of the paretic lower limbs. It has an obvious practice effect because all patients improved significantly in the specific task performed. Some generalisation to other motor activities can be surmised due to the positive effect on spasticity. This fits with the expectation of an improved supraspinal drive, leading to inhibition of reflexes and reduction of unwilled co-activations. The effects on force and walking are virtually absent, which speaks in favour of a rather unbiased assessment and simply suggests that an improvement in the supraspinal drive, if any, was not dramatic (expecting which would have been unreasonable). A more comprehensive future within-subject study might confirm the central mechanism of effect on spasticity, for example by combining behavioural measures, motor evoked potentials from transcranic magnetic stimulation and results from H-reflex studies.

Within the taxonomy of BFB (21), the performed exercise belongs to the “knowledge of results” type (here, the rotation of the knee joint) rather than to the “knowledge of performance” type (which would entail, e.g., the providing the subjects with information on the EMG from the extensor muscles). The former type is more intuitive and motivating compared to the latter, but it can lead to “maladaptive” compensatory movements – ultimately fulfilling the task demands – rather than to recovery of the impaired ones. This appears to be improbable, however, given that knee extension and flexion are only governed by the leg extensor muscles.

It should be stressed that our study eschews explicitly addressing the issue whether all (or any) of the changes in the LegTutor™ task score exceeding the estimated MRD were important in the clinical sense. The reason is that MRD alone cannot be used to for such a judgment (see (20) for a thorough review of MRD, including a list of its limitations). As stressed in both methodological (22) and clinical literature (23), detecting a “real” difference (in the sense of exceeding random error beyond reasonable doubt) is namely a necessary condition for detecting a clinically useful difference, but not a sufficient one. Clinical significance entails explicitly “anchoring” the judgment to an external criterion, which is precisely why our study was conducted (whereby the study suggests that spasticity appears to be a reasonable candidate for such an anchor). However, as emphasised at the beginning of the discussion, future studies will have to provide a more definite answer regarding clinical significance of a successful LegTutor™ training.

CONCLUSION

Given the simplicity of the task and the absence of any side effect, and the preliminary results coming from this non-experimental study, the LegTutor™ system seems to be a reasonable candidate for complementing current rehabilitation exercises in incomplete SCI patients.

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