Evaluation of robotic-assisted locomotor training outcomes at a rehabilitation centre in Singapore

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ABSTRACT

Introduction: The aim of this study was to determine whether robotic-assisted locomotor training, a new clinical service introduced at the Tan Tock Seng Hospital (TTSH) Rehabilitation Centre, Singapore is effective at improving the ability to transfer and the ambulatory status of patients with an acquired brain injury.

Methods: This was a retrospective review of data collected from patients with an acquired brain injury, before and after robotic-assisted locomotor training from September 2008 to May 2009. The primary outcome measures used were the functional independence measure (FIM) for transfer and ambulation, and the Rivermead Motor Assessment (RMA) gross function subscale. The secondary outcome measures used were the Motricity Index (MI) and Modified Ashworth Scale of the lower limb. Statistical analysis was performed on this data to evaluate whether robotic-assisted locomotor training was effective at improving the functional mobility of these patients.

<u>Results</u>: Significant improvement was observed in the scores of FIM transfer (p is less than 0.05), FIM ambulation (p is less than 0.05) and RMA (p is less than 0.05) after robotic-assisted locomotor training. Significant improvements in the MI of hip flexion (p is less than 0.05), knee extension (p is less than 0.05) and ankle dorsiflexion (p is less than 0.05) post training have also been noted.

<u>Conclusion</u>: Robotic-assisted locomotor training was found to be effective at improving the transfer, ambulation and functional mobility of patients with an acquired brain injury.

Keywords: acquired brain injury, locomotion, robotic, training, transfer

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INTRODUCTION

In recent years, there has been a growing trend toward the use of technology in the field of physical rehabilitation. Robotic-assisted locomotion is one of the evolving technologies in modern rehabilitation centres. The aim of robotic-assisted locomotion is to mimic the hands of therapists to guide the patients' lower limbs through a normal gait pattern while walking on a treadmill. This is achieved through the use of an exoskeletal orthotic device. With this device, patients are able to walk with a normal gait pattern without having to employ any compensatory strategies.(1) In addition, patients are supported with an adjustable body weight support system via a harness during the locomotion training. This allows them to experience reduced but symmetrical weight bearing during the training. It stabilises the patients' pelvis, prevents their knees from buckling and aids in foot clearance during walking.(2) It also gives them a sense of security so that they can practice walking without much fear. It is particularly useful for patients who are unable to bear their full body weight during walking.(1) For therapists, robotic-assisted locomotor training helps to reduce the physical demands imposed on them during locomotor training. In this way, the patients' training is not constrained by the physical limitations of the therapists. This enables patients to walk for a longer distance and duration during training, thus allowing them to relearn the normal gait pattern through progressive and repetitive practice.(2)

Recent research has shown that robotic-assisted locomotor training improves the ability to walk and increases the walking speed of patients with stroke. (4.5) Among patients with acute stroke (< 6 months post stroke), robotic-assisted locomotor training appears to have achieved more significant gains in walking speed and endurance when compared with conventional therapy. (2) Similarly, Husemann et al found a comparable increase of 0.06 m/s in the walking speed of patients with acute stroke who had undergone robotic-assisted locomotor training. (4) In addition, patients who had undergone robotic-assisted locomotor training exhibited an average of 0.3 seconds longer duration of

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Fig 1. Photograph shows a patient undergoing robotic-assisted locomotor training.

the stance phase on the affected lower limb compared to patients who had undergone conventional therapy. In a study by Westlake et al, a comparison was made between patients with chronic stroke (> 6 months post stroke) who had undergone robotic-assisted locomotor training and those who had undergone manual assisted body-weight supported treadmill training. The study results revealed that patients in the robotic-assisted locomotor training group improved significantly in their self-selected walking speed, balance score, the affected lower limb step ratio, step length and Fugl-Meyer score, while patients in the manual treadmill group showed significant improvement only in their balance scores. (5)

In August 2008, Tan Tock Seng Hospital (TTSH) Rehabilitation Centre became the first hospital in Singapore to acquire a robotic-assisted locomotor device, Lokomat. Robotic-assisted locomotor training for patients with an acquired brain injury commenced in September 2008, after six senior physiotherapists had undergone training provided by Hocoma. The aim of this study was to evaluate the effectiveness of robotic-assisted locomotor training for patients with an acquired brain injury, based on the data collected between September 2008 and May 2009.

METHODS

This was a retrospective review of the data collected from

both inpatients and outpatients with mobility problems secondary to an acquired brain injury (traumatic and non-traumatic) pre- and post robotic-assisted locomotor training at the TTSH Rehabilitation Centre from September 2008 to May 2009. Patients > 21 years of age who demonstrated potential for improvement with repetitive gait cycle practice, and who were able to tolerate more than 20 minutes of standing as well as participate in the training were included in the study. Patients with contraindications, including pressure sores in the groin and sacral regions, orthostatic hypotension, unstable cardiovascular status, severe osteoporosis, lower limb joint fractures, and deformities that would hinder normal kinematics for locomotion, were excluded from the training.

The patients in our training programme walked on a treadmill with the assistance of a roboticdriven exoskeleton orthosis (Lokomat, Hocoma Ag, Industriestrasse, Volketswil, Switzerland) (Fig. 1). The main purpose of the exoskeleton orthosis was to guide the patients' lower limbs through a repetitive normal physiological gait pattern. Individual adjustments of the hip and knee control could be made by the physiotherapist in charge in order to achieve a normal gait pattern. Each patient's body weight was supported via the Lokomat body weight support system (Fig. 1). For the first training session, approximately 50% of the patient's body weight was supported via the system. For the subsequent training sessions, body weight support was adjusted downward to an extent that was tolerable to the individual patient. Similarly, the speed of the treadmill was adjusted upward and the torque of the exoskeleton orthosis was adjusted downward, as tolerated by each patient.

The duration of the first training session was approximately 15–20 minutes, while that of subsequent training sessions was gradually increased to 30–45 minutes. The progression of the training was guided by the patient's tolerance. Each training program consisted of a maximum of 15 sessions. For inpatients, the frequency of training was daily (i.e. five times per week), while for outpatients, the frequency was three times per week. The training schedules were arranged at the beginning of the training programme. Changes were made if the patient was unwell and hence, unfit for training for that day. All the patients were not undergoing any conventional physiotherapy or overground gait training during the period of the robotic-assisted locomotor training.

Assessments were conducted before and after the robotic-assisted locomotor training. The primary outcome measures were: (1) Functional independence measures (FIM), including FIM transfer and FIM ambulation items, which were selected out of 13 items for the total FIM motor score, in order to assess the patients' transfer and ambulation ability. (6) Each item had a sevenpoint scale that designated major graduations from dependence (score 0 = total assistance) to independence (score 7 = total independence);⁽⁶⁾ (2) Rivermead Motor Assessment (RMA) gross function subscale, which was used to assess the functional mobility of the patient. (7) The scale includes 13 items that are related to functional mobility. Examples of these items include sitting unsupported, transfer from wheelchair to chair, and walking 10 m indoors with or without aid. The score for each item was provided based on whether the patient could or could not perform each item independently (i.e. unable = 0; able = 1). $^{(7)}$

The secondary outcome measures were: (1) Motricity Index (MI), which was used to assess the motor power of the affected lower limb.(8) The movements assessed were hip flexion, knee extension and ankle dorsiflexion. Each movement was rated according to six grades (i.e. ranging from no movement (score = 0) to normal power (score = 33);⁽⁸⁾ (2) Modified Ashworth Scale (MAS), which was used to assess the muscle tone (i.e. resistance to movement) of the affected lower limb. (9) The three muscles assessed were the quadriceps, hamstrings and calf muscles. Each muscle was rated according to a six-point scale. The minimum score was 0, which indicated no increase of resistance to passive movement, and the maximum score was 5, which indicated maximal resistance to passive movement; (9) (3) Six-minutes walk test (6MWT), during which each patient was instructed to walk at a comfortable speed to cover as much ground as possible along the hospital corridors in six minutes. (10) The hospital corridors surrounded a courtyard with a total circumference of 130 m; (4) Gait parameters, including velocity, step length symmetry and base of support (BOS), were analysed using the GaitRite System (CIR Systems Inc 2007, Havertown, PA, USA). Each patient was instructed to walk along a 6 m long walkway mat, with an additional 0.5 m at each end to allow for acceleration and deceleration, and to "walk comfortably like how you would normally walk" three times. The average gait parameters of the three trials were included for analysis.

Lokomat training parameters, which included body weight support, the speed of the treadmill, exoskeleton orthosis guidance force, distance and the duration of the first and last training sessions, were recorded and

Table I. Demographics of the patients included in the study (n = 23).

Demographic	No. of patients
Mean age ± SD; range	51 ± 13; 26–68
Gender	
Male	15
Female	8
Duration of post injury onset	
≤ 6 months	13
> 6 months	10
Side of hemiplegia	
Right	11
Left	9
Bilateral	3
Diagnosis	
Ischaemic stroke	6
Haemorrhagic stroke	8
Arterio-venous malformation	2
Traumatic brain injury	5
Brain tumour	2
Mean no. of treatments	13

SD: standard deviation

used for analysis. Other data collected were patient demographics, diagnosis, side of hemiplegia, and the number of months elapsed following the acquired brain injury event. Any adverse events, side effects or discomfort during the training were also recorded.

All statistical comparisons were performed using the Statistical Package for the Social Sciences version 14.0 for Windows (SPSS Inc, Chicago, IL, USA). A descriptive analysis was conducted on the patient demographics. Wilcoxon signed-rank test was performed to assess whether there were any significant changes in measurement between pre- and post robotic locomotor training. The level of significance was set at p < 0.05.

RESULTS

A total of 29 patients participated in the robotic-assisted locomotor training programme during the study period. Six (21%) patients discontinued their training after 2–5 training sessions. Two patients cited cost as the reason for discontinuing; one patient developed unstable blood pressure and was advised by the doctor to discontinue the training; another developed knee pain; one patient developed bruises on her lower limb which were possibly caused by pressure from the cuffs of the exoskeletal orthotic device; and one patient developed a fear of the entire Lokomat system. Of the 23 patients who completed the programme, 56.5% completed 15 treatment sessions and 30.4% completed ten or more sessions. Of the remaining two (13.1%) patients, one completed five sessions while the

Table II. Motor performance of the patients as described by FIM, RMA, MI and MAS pre- and post robotic-assisted locomotor training.

Outcome measure	Media	p-value	
-	Pre-training	Post-training	
Primary			
FIM			
Transfer	l (1,4)	4 (3, 4)	0.001*
Ambulation	l (1,3)	3 (2, 4)	0.000*
RMA	I (0, 3)	3 (1,4)	0.002*
Secondary MI			
Ankle dorsiflexion	9 (0, 19)	14 (0, 25)	0.027*
Knee extension	14 (0, 19)	14 (14, 25)	0.005*
Hip flexion	9 (0, 19)	14 (9, 25)	0.001*
MAS	. ,	` ,	
Quadriceps	0 (0, 1)	0 (0, 2)	0.305
Hamstrings	0 (0, 1)	I (0, 2)	0.627
Calf	I (0, 2)	I (0, 2)	0.763

^{*}p-value < 0.05

IQR: interquartile range; FIM: functional independence measures; RMA: Rivermead Motor Assessment gross function subscale; MI: Motricity Index; MAS: Modified Ashworth Scale

other completed seven. These two patients completed less than ten sessions because they were discharged from the hospital and returned to their home countries (i.e. overseas) upon discharge. The training results of the 23 patients were included in this study for analysis. The patients' demographics are shown in Table I.

Body weight support was reduced significantly from $50.3\% \pm 18.6\%$ to $16.1\% \pm 10.9\%$ (p < 0.0001) during the course of the training programme. The speed of the treadmill was increased significantly from 0.49 \pm 0.07 to 0.66 \pm 0.08 m/s (p < 0.0001). The guidance force provided by the Lokomat on the affected lower limb was at $98\% \pm 4\%$ during the first session, and was significantly reduced to $62\% \pm 21\%$ in the last session (p < 0.0001). The patients' walking distance on the treadmill increased from 619 ± 189 to 1062 ± 307 m (p < 0.0001) during the training programme, while the duration of training increased significantly from 21 ± 6 to 31 ± 8 minutes (p < 0.0001).

The primary and secondary outcome measures are summarised in Table II. The baseline medians for FIM transfer, FIM ambulation and RMA for all the patients were at Level 1, indicating that most of the patients were at a low level of functional mobility before the robotic-assisted locomotor training. Statistically significant differences (p < 0.05) between pre- and post training performance were observed in FIM transfer, FIM ambulation, RMA, MI of hip flexion, knee extension and ankle dorsiflexion.

The results of patients with an acute acquired brain injury (≤ 6 months post onset) and those with a chronic

Table III. Motor performance of patients with an acute acquired brain injury as described by FIM, RMA, MI and MAS pre- and post robotic-assisted locomotor training.

Outcome measure	Medi	p-value	
_	Pre-training	Post-training	
Primary			
FIM			
Transfer	I (1, 2.5)	4 (3, 4)	0.006*
Ambulation	I (I, I.5)	3 (2, 4)	0.002*
RMA	0 (0, 0.5)	2 (1,4)	0.005*
Secondary			
MI			
Ankle dorsiflexion	0 (0, 9)	0 (0, 14)	0.109
Knee extension	0 (0, 11.5)	14 (9, 16.5)	0.007*
Hip flexion	0 (0, 9)	14 (9, 14)	0.005*
MAS			
Quadriceps	0 (0,0)	I (0, I.5)	0.020*
Hamstrings	0 (0,0)	I (0, I.5)	0.058
Calf	0 (0, 1.5)	I (0, I.5)	0.257

*p-value < 0.05

IQR: interquartile range; FIM: functional independence measures; RMA: Rivermead Motor Assessment gross function subscale; MI: motricity index; MAS: Modified Ashworth Scale

acquired brain injury (> 6 months post onset) were analysed separately, as differential gains were observed between these two groups of patients. The outcome measures of the patients with an acute acquired brain injury are shown in Table III. Statistically significant differences (p < 0.05) between pre- and post training performance were observed in FIM transfer, FIM ambulation, RMA, MI of knee extension and hip flexion, and MAS of quadriceps. The outcome measures of the patients with a chronic acquired brain injury are shown in Table IV. Statistically significant differences (p < 0.05) between pre- and post training performance were observed only in FIM ambulation and MAS of calf muscles.

Values of gait parameters (i.e. velocity, step length symmetry and BOS) and 6MWT were not obtained for comparison for patients with an acute acquired brain injury, as all these patients required total assistance in their ambulation (median: FIM ambulation Level 1); hence, it was difficult to obtain accurate values of gait parameters and 6MWT. Only four patients with a chronic acquired brain injury completed the GaitRite assessment and 6MWT pre- and post robotic-assisted locomotor training successfully. No statistically significant differences were detected in the velocity (pre mean = 26.4 m/s; post mean = 32.13 m/s), step length symmetry (pre mean = 0.61; post mean = 0.73), BOS (pre mean = 19.7 cm; post mean = 23.1 cm) and 6MWT (pre mean = 107.6 m; post mean = 111.63 m).

No severe adverse events were recorded during the training. A few patients experienced discomfort and developed redness in their groin area during the training. Skin redness normally subsided after one day of rest. These

Table IV. Motor performance of patients with a chronic acquired brain injury as described by FIM, RMA, MI, and MAS pre- and post robotic-assisted locomotion training.

Outcome measure	Mediar	p-value	
_	Pre-training	Post-training	
Primary			
FIM			
Transfer	3 (1,5)	4 (2.75, 5)	0.066
Ambulation	2.5 (1, 4.25)	4 (1,5)	0.038*
RMA	3 (1, 6.25)	4 (1,7)	0.180
Secondary			
MI			
Ankle dorsiflexion	19 (10.5, 25)	25 (10.5, 25)	0.102
Knee extension	22 (14, 25)	25 (14, 25)	0.317
Hip flexion	19 (12.75, 25)	25 (12.75, 25)	0.083
MAS			
Quadriceps	I (0, 2.25)	0 (0, 2.25)	0.180
Hamstrings	I (0, 2.25)	0.5 (0, 2)	0.102
Calf	1.5 (0.75, 3)	1.5 (0, 2.25)	0.046*

^{*}p-value < 0.05

IQR: interquartile range; FIM: functional independence measures; RMA: Rivermead Motor Assessment gross function subscale; MI: motricity index; MAS: Modified Ashworth Scale

patients continued with the robotic-assisted locomotor training after the skin redness had subsided. Three (11.5%) patients developed skin abrasions from the cuffs of the exoskeleton; one patient developed a skin abrasion on the upper calf laterally, another, on the shin and the third, on an old ankle anterior scar. These patients continued with their training after the skin abrasions had healed completely. One patient experienced giddiness, which subsided after taking a rest.

DISCUSSION

The robotic-assisted locomotor training intensity of our study is relatively similar to that of previous studies. (1,3,5) Each training session, during which the patient was walking on the treadmill, lasted 20–30 minutes in our study. In other studies, each training session lasted 30 minutes. (1,2,4,5) The total number of training sessions in other studies varied from 12 to 30 sessions. (1-5) This was comparable to our study, in which an average of 13 sessions were conducted.

For body weight support, the patients in our study started higher at 50% (recommended by Hocoma) in the first treatment session, while the body weight support of the participants in other studies started at 30%–40% in the first treatment session. (1-3,5) The decrease in body weight support throughout the training was about 30%–40% in our study, which was comparable to that reported in previous studies. (1-2,5) The patients in our study did not achieve as fast a walking speed on the treadmill as

patients in previous studies, in which a walking speed of up to 0.83 m/s on the treadmill was achieved by the end of the training programme. (1-3.5) Our patients were only able to achieve an average speed of 0.66 m/s at the end of the training programme. Based on clinical observations, the patients who had attempted to walk at a faster speed (i.e. 0.83 m/s) were unable to achieve the desirable gait pattern.

The results of our study indicate that as a group, significant improvements were noted in the FIM transfer, FIM ambulation, RMA and MI scores. However, when the results were analysed separately, statistically significant improvements in FIM transfer, RMA and MI (hip flexion and knee extension) were observed only in patients with an acute acquired brain injury, but not in those with a chronic acquired brain injury. On the other hand, improvements in FIM ambulation were significant in both groups of patients, even though the extent of improvement was greater in the acute brain injury group.

It is important to note that most of the patients in our study had severe mobility problems. Therefore, the results of our study could only indicate that robotic-assisted locomotor training was effective for those patients with severe mobility problems. However, in essence, this has only shown that the training was useful at achieving what it was designed for. The main purpose of robotic-assisted locomotor training was to enable patients who are mobility-dependent to experience the practice of normal walking without being limited by their own physical limitations or the limitations of their therapists.^(1,2)

The element of practice was an important factor in optimising neurological recovery. It has been found that gains in walking efficiency are correlated with the stepping dosage during therapy sessions. (11) However, it has also been observed that during a normal therapy session, the average number of steps achieved is less than 400 steps, (12) which is far less than the number of steps achieved by a sedentary elderly person per day (5,000 to 6,000 steps). (11) With robotic-assisted locomotor training, it was possible to achieve approximately 1,000 steps for a 30-minute session (random treadmill speed 0.47–0.69 m/s), which is 2.8 times more than what could be achieved during a normal therapy session.

Although the effectiveness of robotic-assisted locomotor training for patients with mildly and moderately severe mobility problems was not reflected in our study, a look at previous studies has shown that robotic-assisted locomotor training was able to assist patients with these levels of mobility problems in making further improvements.^(1-3,5) This indicates that it

has the potential to improve the mobility of patients at a variety of severity levels.

It is also interesting to note that patients with an acute acquired brain injury appeared to benefit more from robotic-assisted locomotor training than those with a chronic acquired brain injury. During the acute phase of recovery, the practice of normal kinetics of locomotion during robotic-assisted locomotor training might have enhanced the spontaneous recovery of these patients, thus improving their mobility. However, for patients with a chronic acquired brain injury, the role of spontaneous recovery was limited. In addition, patients with a chronic acquired brain injury in our study started with a higher functional mobility level in comparison with patients with an acute acquired brain injury. Therefore, it would be more difficult for the former group of patients to experience further gains. This was compounded by the properties of the FIM scale used in our study. Since the FIM scale is not a continuous one, it would be more difficult to gain a one level increment from a higher level (i.e. Level 3 to 5) than to improve from a lower level (i.e. Level 1 to 3). However, it was encouraging that, despite this, patients with a chronic acquired brain injury in our study did manage to achieve a statistically significant 1.5 level increase in median FIM ambulation. This shows that robotic-assisted locomotor training could still play a role in improving the mobility of this group of patients.

From the sample of patients (21%) who discontinued the training program for various reasons, it can be seen that not all patients are suitable for robotic-assisted locomotion training in spite of its benefits. Therefore, careful selection of appropriate patients is essential in order for the program to be successful, and for the patients to achieve optimal results and benefits.

The limitation of our study is its retrospective nature. Hence, we were unable to compare the efficacy of robotic-assisted locomotor training and conventional physiotherapy. The current literature has shown different results when comparing the effects of robotic-assisted locomotor training with conventional physiotherapy for patients with an acute acquired brain injury. Mayr et al and Huseman et al reported that robotic-assisted locomotor training achieved more gains than conventional physiotherapy, (2.4) while a study by Hidler et al found that patients in the conventional physiotherapy group showed more improvement than those in the robotic-assisted locomotor training group. (3)

For patients with a chronic acquired brain injury,

only comparisons between robotic-assisted locomotor training and therapist-assisted manual treadmill training have been made. (1,5) In the study by Hornby et al, patients who underwent therapist-assisted manual treadmill training showed more improvement than those who underwent robotic-assisted locomotor training,(1) whereas Westlake et al observed opposite results in these two groups. (5) The differing results may be due to the different levels of severity of the patients involved in these studies. In one study, most of the patients involved were mobility dependent, (4) while in other studies, the patients involved had moderately severe(1,2) to mildly severe(3,5) mobility problems. Since the effects of robotic-assisted locomotor training varied among patients with different mobility levels, it is difficult to compare between these studies. As such, a comparison of the efficacy of robotic-assisted locomotor training with conventional physiotherapy is even more difficult. However, this comparison is an important clinical question that needs to be addressed. Robotic-assisted locomotor training is an expensive treatment programme due to the high cost of the equipment; it is hence important to determine if it is superior to conventional physiotherapy, and more cost-effective.

The results of our study have shown that robotic-assisted locomotor training aids patients with an acquired brain injury with low levels of transfer ability, locomotion and functional mobility to improve to a significantly higher level. More research with larger randomised controlled trials to establish the efficacy of this technique over conventional physiotherapy, in addition to research that looks into the cost-effectiveness and long-term effects of robotic-assisted locomotor training, is required in the future. These studies will enable clinicians to make good clinical decisions in consideration of their patients.

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