



One year follow up of spinal cord injury patients using a reciprocating gait orthosis: Preliminary report

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Objective: To examine the influence of social, physical and psychological factors in determining the usage/non usage of reciprocating gait orthosis (RGO) in spinal cord injury (SCI) patients.

Design: Prospective clinical trial.

Setting: A large rehabilitation hospital in Rome, Italy.

Participants: Twenty four SCI patients of traumatic aetiology (all fulfilling the criteria to prescribe the device).

Methods: Social, physical and neurological examination according to ASIA standards; psychological enquiry by means of the Eysenck Personality Questionnaire (EPQ) and the scale for self rating anxiety and depression of the Cognitive Behavioural Assessment.

Results: After 1 year follow up 11 (46%) of our patients no longer used the RGO. There was no statistically significant difference between patients who used the RGO and those who rejected the orthosis with regard to social and physical data. There was a significant difference ($P=0.005$ at the end of training and $P=0.003$ at 1 year follow up) with regard to functional ambulation level. With regard to psychological enquiry RGO-non users showed a higher frequency of values over the mean in the E scale (extroversion) of the EPQ than RGO-users ($P=0.05$).

Conclusions: None of the identified parameters were useful to predict the use/rejection of the orthosis. Although they need to be confirmed, our psychological data suggest that extensive psychological testing could be useful to sharpen the ability to predict.

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Introduction

Patients with spinal cord injury are usually confined to a life in the wheelchair. However, during the past four decades several orthotic devices have been developed to allow some patients to stand and walk with the use of walking aids.^{1,2} More recently, orthoses have been developed which provide additional stability. The most common devices are the Reciprocating Gait Orthosis (RGO) and the Advanced Reciprocating Gait Orthosis (ARGO) both consisting of a hip-knee-ankle-foot orthosis which controls hip extension while assisting reciprocal hip flexion.^{3–5} These devices stabilise the lower limbs and the trunk both in the sagittal and in the frontal plane and provide reciprocal walking on a mechanical basis by means of, respectively, a double or a single cable between both hip joints.³

There are many physical reasons why these patients should be encouraged to walk with these orthoses;^{1,2} it is believed, although not demonstrated, that upright mobility can produce improvements in cardio-respiratory

function, urological drainage, bowel function, bone density, spasticity and contractures.⁶

Despite these benefits, it is a common experience that there is a frequency of non usage of the braces varying from 15 to 71%.^{3,7}

The aim of this study is to establish the frequency of non usage and to study the influence of several physical, social and psychological factors on this choice.

Patients and methods

We studied a group of 24 patients (19 males and five females) with motor complete (ASIA A)⁸ SCI of traumatic aetiology, all of thoracic level: mean age was 33.6 ± 3.2 years, mean distance from injury was 5.3 ± 2.1 years. All of them fulfilled the criteria for an orthosis of RGO type: complete motor lesion of traumatic aetiology, lesion level between T1 and T12, age between 15 and 50 years, motivation to walk with this kind of device, absence of severe spasticity, para-osteoarthropathies, pressure sores and severe respiratory and

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cardiovascular pathologies.⁹ None of the patients had a history of major psychiatric or cognitive disorders. All the patients were braced with an RGO orthosis.

The patients underwent a complete neurological and physical examination and social history at the beginning of the study.

At the end of the training period with the braces, and at 1 year follow-up, the following parameters were recorded: usage/non usage, number of sessions of training, time required for donning and doffing, need of an aid for donning and doffing, gait speed, ability to climb up and down the stairs, usage of walker or crutches, functional ambulation level according to the Garrett Scale (Table 1),¹⁰ episodes of troubles affecting the device.

Patients were submitted to psychological investigation which included a personality questionnaire and questionnaires to examine anxiety and depression. We used the Eysenck Personality Questionnaire (EPQ)¹¹ which is made up of three scales that study three aspects: the N scale is the scale of neuroticism; the P scale is the scale of psychoticism; the E scale is the scale of extroversion (Table 2); the first two are not signs of a psychopathology (neurosis and psychosis), but only aspects of the personality that could predispose patients to the development of psychopathology. To evaluate anxiety and depression we used the CBA (Cognitive Behavioural Assessment),¹² schedule 3 (for self-rating anxiety) and schedule 8 (for self-rating depression) (Table 2). As utilised in other studies,¹³ we chose the 'cut-off' score equivalent to one standard deviation above the mean of the norms. Patients were then defined as 'anxious' and 'depressed' when their scores on the two scales were higher than the mean of uninjured subjects plus one standard deviation. The results were evaluated by means of chi-square test and Student's *t*-test; statistical significance was assumed if $P < 0.05$.

Results

After 1 year follow up 11 (46%) of our patients no longer used the RGO. Thus we have been able to define two groups of patients: RGO-users (Group A) and RGO-non users (Group B) (Table 3). The main reasons for non-use were either medical (one patient with fractured femur) or non medical (patients found the orthosis uncomfortable or too difficult to don or doff, or too slow or too hard to use or poor fitting).

Table 1 Classification of level of walking according to Garrett¹⁰

1.	Hospital ambulation
2.	Home ambulation with limitations
3.	Home ambulation
4.	Community ambulation with severe limitations
5.	Community ambulation with moderate limitations
6.	Community ambulation with no limitations

There was no statistically significant difference between the two groups with regard to sex ratio, distance from injury, level of injury, instruction degree, marital status and employment (Table 3).

There was no statistically significant difference with regard to donning and doffing time, the need of aid to don and doff, walking speed, walking aids, and the capacity of ascending and descending stairs, neither at the end of training, nor at 1 year follow-up (Table 4).

There was a significant difference ($P = 0.005$ at the end of training and $P = 0.003$ at 1 year follow up) with regard to functional ambulation level both at the end of training and at 1 year follow-up with the users achieving a higher functional capacity than non-users. RGO users had a functional level between home ambulation with limitations and home ambulation, while RGO non users had a functional level between hospital ambulation and home ambulation with limitations (Table 4).

Psychological examination: comparing the frequency of scores over the mean values by means of chi-square test we found that patients in Group B showed a high frequency of values over the mean in the E scale (extroversion) of the EPQ in respect to Group A (7/11 vs 3/13, $P = 0.05$). There was no significant difference in the frequency of anxiety (1/13 in Group A and 2/11 in Group B) and depression (1/13 in Group A and 1/11 in Group B).

Discussion

Reciprocating gait orthoses, first created to allow children with spina bifida to walk,¹⁴ in the last 15 years have been used in adults with spinal cord injuries.

Table 2 Internal consistency and test-retest reliability

	Alpha coefficient	Test-retest <i>r.</i> 7 days	Test-retest <i>r.</i> 30 days
State anxiety scale	0.92	0.68	0.59
Depression scale	0.86	0.88	0.72
N scale	0.82	0.77	0.72
P scale	0.58	0.72	0.69
E scale	0.78	0.85	0.80

Table 3 Clinical and demographic features

	Group A	Group B	<i>P</i>
Age	32 ± 1.8 years	34 ± 3	n.s.
Distance from injury	5 ± 2.2 years	5.4 ± 2.6	n.s.
Male/female ratio	9/2	8/3	n.s.
Lesion level:	4/9	5/6	n.s.
over/below T6			
Years of school	10.38 ± 3.4	10.33 ± 3.7	n.s.
Employment: yes/no	2/11	3/8	n.s.
Marital status:	3/10	4/7	n.s.
married/non married			

n.s. = not significant

Table 4 RGO using features

	<i>At the end of training period</i>		
	<i>Group A</i>	<i>Group B</i>	<i>P</i>
Training sessions	58.3 ± 27.6	40.5 ± 24.2	n.s.
Walking speed	13.7 ± 6.3 m/min	10.2 ± 5.4	n.s.
Garrett score	2.33 ± 0.5	1.55 ± 0.5	0.005
Time for donning	8.9 ± 4.4 min	8 ± 4	n.s.
Aid/no aid for donning	7/6	7/4	n.s.
Time for doffing	4.6 ± 2.4 min	3.7 ± 1.5	n.s.
Aid/no aid for doffing	7/6	7/4	n.s.
Walker/crutches	13/0	10/1	n.s.
Ability to climb the stairs: yes/no	13/0	2/9	n.s.

	<i>At 1 year follow up</i>		
	<i>Group A</i>	<i>Group B</i>	<i>P</i>
Walking speed	16 ± 9.1 m/min	10.2 ± 5.4	n.s.
Garrett score	2.4 ± 0.5	1.55 ± 0.5	0.003
Time for donning	8.9 ± 4.4 min	8 ± 4	n.s.
Aid/no aid for donning	7/6	7/4	n.s.
Time for doffing	4.6 ± 2.4 min	3.7 ± 1.5	n.s.
Aid/no aid for doffing	7/7	7/4	n.s.
Walker/crutches	13/0	11/0	n.s.
Ability to climb the stairs: yes/no	13/0	11/0	n.s.

n.s. = not significant

The first studies on this kind of device have been focused on the physiological effects of walking with the RGO.⁴ Only more recently have studies on long-term usage been published^{3,7,9} in the attempt to identify reasons for non usage.

The well known level of non usage is important for several different reasons:^{3,7} it leads investigators to question their prescription practice, with particular regard to the assessment and selection of patients. It has economic implications: in Italy a reciprocating gait orthosis of the advanced type costs 10 million Italian Lire (about 5700 US dollars) without considering the cost of walking aids, patient training and repairs. Finally a low level of compliance may lead to a loss of benefit to the patient.

The first aim of our study was to examine the frequency in which devices were no longer used. Our results showed that at 1 year follow up 46% of the patients gave up using the device, a frequency which is higher than the data of Jaspers (15%)³ and McCall (22%).¹⁵ This rejection of the orthosis continues because it is well known that there is a tendency to further increase this number after the first year.¹⁶

The main reasons for non-use of the orthosis were medical (one patient with fractured femur) and non medical: all the patients who abandoned the device reported that the device was uncomfortable, too difficult to don or doff, too slow compared to the wheelchair, too hard to use or poor fitting; furthermore, most of them needed aid to don and doff and complained of difficulty to get in and out of the car, to walk outside and to climb the stairs. The same

difficulties and lack of autonomy however were reported by the patients who continued to use the RGO. The general appreciation of the orthosis was not an indicator for abandoning the RGO because patients who abandoned it were pleased with positive aspects of RGO and frequently reported the psychological benefit due to the possibility of assuming the upright position and talking to others at the same level.

Both at the end of training and at 1 year follow up the features of use of the device were not significantly different in patients who abandoned the RGO and in those who kept using it with the exception of the functional ambulation level (Table 4). The RGO users had a functional level between home ambulation with limitations and home ambulation, while RGO non-users had a functional level between hospital ambulation and home ambulation with limitations. None of our patients reached a 'social' level of ambulation.

Based on these results, identification of factors which could act as predictors of non-use of the RGO are raised. Unfortunately none of the physical and social parameters that we could identify in SCI patients before the prescription of the RGO were useful (Table 3). In fact, patients in the two groups did not show any significant demographic and clinical difference: age, sex, distance from trauma, level of the lesion, educational level, employment, marital status, etc. There were two non-significant differences that probably need further examination. First in the group of non users, mean body weight was higher than in the other group and there were more patients overweight and second, in the group of RGO users there were more patients who, although confined at home, used the device to work (for example architects or engineers who needed to stand up to design).

The different functional ambulation score in the two groups could not be used as a predicting factor in that the orthosis is customised for each patient and can not be determined before fitting and training.

Psychological problems are known to play an important role in determining the prognosis of Spinal Cord Injury patients particularly in regard to social and vocational adjustment.^{17,18} Tate and co-workers¹⁹ demonstrated that patients with SCI and depression spend more time in bed and less time outside their houses, need more nursing and medical therapy. Psychological problems seem to influence the choice of orthosis and other appliances too.

Anxiety and depression are part of the psychological reaction to spinal cord injury, and occur when adjustment to the handicap is poor.^{13,20-22} Probably because of the long mean distance from injury the two groups of patients did not show any significant difference in the frequency of anxiety and depression and thus RGO rejection could not be ascribed to these pathologies. With regard to personality profile, however, RGO non-users showed a significantly higher frequency of values over the mean in the E scale (extroversion) of the EPQ in respect to RGO users.

We suggest that the difference concerning the E scores between Group A and Group B could influence the use of the RGO. Patients with this kind of personality are sociable and like keeping company; they are optimistic, more able to accept changed conditions and more impulsive in their choices. Introverted persons are quiet and reserved; they are used to planning before acting, without following their instincts and arriving at a more reasoned choice. Furthermore it seems that introverted persons are able to learn more quickly and completely than the others.¹¹ The abandonment of the orthosis could be due to a non-reasoned choice, dictated by impulsiveness; when the patients, after a period of enthusiasm, meet the initial difficulties, tend to give up using the orthosis. On the other hand patients who persist in use of the RGO, meet the same difficulties as the others, probably made a more reasoned, less impulsive choice and they are less prone to change their mind. Moreover these patients are able to learn better: this could mean that they understand the advantages of using the orthosis and they also understand the 'therapeutic' more than 'social' use of the RGO.

Conclusions

Our results raise the question of the cost/benefits ratio of a high cost device which does not allow complete autonomy, whose use is limited, and whose benefits are still to be demonstrated.

Unfortunately none of the physical and demographic parameters of SCI patients were demonstrated to be useful as predictors of the non-use of the orthosis.

Our psychological data are only preliminary; thus, we are reluctant to conclude that the RGO should not be prescribed to patients with a high score in the extroversion scale, but we are sure that these patients should be informed of the greater therapeutic more than social advantages of the device.

It could be useful to produce a universal training RGO to let the patients prove the orthosis, before prescribing the customized orthosis.

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