Paraplegia **32** (1994) 608–615

Restoration of gait with orthoses in thoracic paraplegia: a multicentric investigation

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Twenty-eight patients with complete T3–12 traumatic paraplegia were fitted with hip guidance orthosis (HGO, four cases), reciprocating gait orthosis (RGO, 13 cases) or advanced reciprocating gait orthosis (ARGO, 11 cases). Patients were enrolled for 2 months–6 years (median 5 months) in six Italian rehabilitation centres engaged in a common prospective protocol, including a 6 month follow up. After 12–84 (median 20) rehabilitation sessions over a 3–16 week (median 7) period of specific training all of the patients could perform don–doff manoeuvres autonomously in 2.5–15 min (median 6.4), and could walk at least 30 m with a walker (15 cases) or forearm crutches (13 cases) at 10–50 cm/s (median 16.6). HGO patients tended to walk more slowly than the others. None of them could walk upstairs, while three out of 13 RGO patients and seven out of 11 ARGO patients could. Six months later, 21 patients still used the orthosis for 0.5–3 h daily (median 2). Only four patients used the orthosis to walk outdoors. As a median they could still attain the speed recorded at discharge. Six patients had decided to abandon the device, while one was wheelchair bound due to a recent spinal intervention. Neither clinical, demographic or locomotor variables, nor centre and type of orthosis appeared to be predictive of abandonment of the device. During either the training or the follow up periods, six out of 13 RGO and seven out of 11 ARGO had to be repaired by the orthotist 1–10 times (median 3). Thus, in our sample of paraplegics, walking with these orthoses appeared to be a promising form of exercise rather than an alternative to wheelchair locomotion.

Keywords: thoracic paraplegia; gait; orthoses.

Introduction

In recent years gait has been made possible also for thoracic paraplegics, thanks to orthoses in which hip–knee–ankle orthosis are hinged at the hip level with a rigid thoracic corset. These devices stabilise the lower limbs either in the sagittal or in the frontal plane (hip guidance orthosis, HGO, or parawalker).[1] Through forearm crutches, the upper limbs provide the forces needed to propel the body forwards. They also permit the trunk to lean sidewards and rotate towards the supporting lower limb, thus allowing for both clearing and forward swing of the other lower limb. The trunk extensor muscles may be more effectively called into play with the reciprocating gait orthosis (RGO)[2] in which trunk extension on the supporting hip entails hip flexion of the swinging limb, thus facilitating alternate

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gait. A more recent version (advanced RGO, ARGO)[3] also allows the patient to unlock the knee joint during sit-to-stand manoeuvres. Air pistons located on either side of the knees may store energy during sitting, and release it during subsequent standing up.

We ran a multicentre trial in order to gather enough cases to draw some reasonable conclusions on long term results attainable with such orthoses. This work is in line with other studies.[4]

Methods

Centres

In early 1992 six Italian rehabilitation centres appointed two physiatrists each to set up a common protocol of observation of paraplegic patients fitted with HGO, RGO or ARGO. All of the centres had years of experience with rehabilitation of paraplegics and followed either in- or outpatients. Three (Villanova, Vicenza, Torino) were free-standing spinal units, whereas the other three (Milano, Ferrara, Trevi) were departments of rehabilitation within a general hospital.

Protocol

The major points of common protocol were:

Inclusion criteria

1 Paraplegia with complete motor loss (Frankel Scale[5] A or B) due to spinal cord lesion between T1 and T12.
2 Full independence in managing wheelchair driving and transfers.
3 Declared motivation to walk with the proposed device.

Exclusion criteria

1 Lower limb flexor spasms and/or contractures.
2 Pressure sores.
3 Contraindications to cardiovascular stress (e.g. heart ischaemic pathologies, hypertension).

Each centre was allowed to adopt the orthosis and the training regimen it preferred for each individual case. Before agreeing to take part in the trial, patients were given thorough information on the device and the training regimen. Whenever possible they were put in touch with patients previously fitted with the same device. Alternatively, they were shown videotapes illustrating the attainable transfer and gait performances.

Either of the two physiatrists enrolled by each centre could select the patients or perform observations and measurements.

Demographic and clinical information were recorded. The following variables were analysed:

Training period

1 Time lag between onset of paraplegia and onset of training related to the appliance of orthosis (e.g. upper limb strengthening, standing and walking exercises).
2 Duration of training (weeks) and number of sessions.
3 Time (min) required for either donning or doffing autonomous manouevres (median of three observations).
4 Ability to walk level with walker or crutches for at least 30 m.
5 Gait speed over a 15 m level path (median of four runs).
6 Ability to climb up and down a flight of 12 stairs with one handrail.
7 Functional ambulation level, on the Garrett Scale: 1 = hospital ambulation; 2 = home ambulation, with limitations; 3 = home ambulation; 4–6: community ambulation, with severe, moderate or no limitations.[6]
8 Episodes of troubles affecting the device, requiring the orthotist's intervention for substitution and/or repair.

Six month follow up

1 Use or abandonment of the device.
2 Functional ambulation level (Garrett score).
3 Hours of daily use for gait.
4 Distance travelled daily. Data were collapsed into three levels only: up to 0.1, 1, and 5 km.
5 Average speed over a 15 m level path (median of four runs).
6 Number of repairs of the device.

In narrative form we also recorded patients' opinions on the pros and cons of the devices.

The protocol also included subprotocols on other aspects of gait such as metabolic cost, EMG–mechanical correlations, impact on overall disability etc. These aspects are now being studied. The full protocol can be obtained from the coordinating centre (Trevi).

Subjects and orthoses

Twenty-four men and four women, age 15–48, were enrolled over a period of 6 months. All reported a complete traumatic motor paraplegia at level T3–6 or T7–12 in 19 and 9 cases respectively. They were enrolled 1–4 months, 5–12 months and 1–6 years after trauma in 2, 14 and 12 cases respectively. All of them were wheelchair bound. They were fitted with a HGO, RGO or ARGO in 4, 13 and 11 cases respectively.

Statistics

Given the relative paucity of the data only univariate analyses were performed.

In consideration of data skewness, medians rather than means were taken as summary statistics of variables. Wilcoxon sign rank and rank sum tests were adopted to test differences across time or categories, respectively.

Contingency data were analysed through the χ^2 test.

Intercentre comparisons was biased by the Villanova Centre accounting for 13 out

Table I Demographic and clinical features of the 28 paraplegics fitted with locomotor orthoses (HGO, RGO, ARGO) in six Italian centres. All of the subjects presented with motor-sensory complete paraplegia (Frankel A), except subjects 7 and 11 with sensory incomplete paraplegia (Frankel B).

Patient	Age (years)	Sex	Level	Frankel grade	Centre	Orthosis	Trauma wks before
1	24	M	D12	A	Villanova	RGO	32
2	20	F	D3	A	Villanova	RGO	30
3	23	M	D8	A	Villanova	RGO	41
4	29	F	D12	A	Villanova	RGO	34
5	19	M	D11	A	Villanova	RGO	13
6	35	F	D12	A	Villanova	RGO	28
7	15	M	D6	B	Villanova	ARGO	22
8	36	M	D11	A	Villanova	ARGO	54
9	29	M	D5	A	Villanova	RGO	24
10	29	M	D5	A	Villanova	HGO	26
11	23	M	D5	B	Villanova	HGO	26
12	23	M	D5	A	Villanova	HGO	43
13	20	M	D7	A	Villanova	HGO	47
14	23	M	D7	A	Vicenza	ARGO	108
15	27	M	D5	A	Vicenza	ARGO	12
16	18	M	D5	A	Vicenza	ARGO	84
17	18	M	D10	A	Milano	ARGO	38
18	24	M	D3	A	Milano	ARGO	13
19	23	F	D6	A	Milano	ARGO	312
20	26	M	D3	A	Torino	RGO	46
21	18	M	D6	A	Torino	RGO	29
22	48	M	D2	A	Torino	RGO	80
23	18	M	D9	A	Torino	RGO	38
24	27	M	D3	A	Ferrara	ARGO	17
25	22	M	D5	A	Ferrara	RGO	8
26	18	M	D4	A	Ferrara	RGO	52
27	27	M	D6	A	Trevi	ARGO	72
28	21	M	D5	A	Trevi	ARGO	70

of 28 cases, the other five centres accounting for only 2–4 cases each. Thus, data from the latter five centres were collapsed for comparisons among centres.

Significance was always set at $p < 0.05$.

Results

Training period

The training period ranged from 3 to 16 weeks (median 7). In the various centres, 3.5–6 sessions per week (overall median 4.6) were conducted, with no significant difference between Villanova and other centres. The median number of sessions was 24 (range 12–84) and it was unrelated to either the time elapsed from trauma, the level of lesion of the spine (T6 or above, vs below T6), the gait speed eventually attained by the patients or the type of orthosis adopted.

Mechanical troubles affected some of the devices. The most common problems consisted of episodes of frame distortion or rupture at hinge points and/or of failure of the knee-unlocking gears (ARGO only). These problems required repair by the orthotist and interruption of the training programme 11 times in three out of 13 RGO and 27 times in seven out of the 11 ARGO.

After training all of the patients could perform both donning/doffing and dressing manoeuvres autonomously. As a median, donning required 4.5 min (range 1.5–10) vs 2 min (0.8–5) for doffing ($p < 0.001$). Taken together, the two manoeuvres required 6.5 min (2.5–15) (Fig 1).

All of the patients became able to walk level for at least 30 m with either walker (15 cases) or forearm crutches (13 cases, RGO and ARGO only). Functional ambulation level scored 1 ('exercise' ambulation only), 2–3 ('home') or 4–5 ('community') in 8, 17 and 3 cases respectively. Median gait speed was 16.6 cm/s (10–50).

The Garrett scores appeared to be unrelated to the centre, lesion level, sex, time from trauma or number of sessions.

Some differences emerged among orthoses and among centres.

Comparing the orthoses. Figure 1 shows that total donning/doffing time was longer for RGO (median 7 min, range 4.3–15) compared to either HGO (3 min, range 2.5–6.6) or ARGO (median 5, range 3.1–9.3) ($p = 0.009$ and 0.019 respectively). On the contrary, the difference between HGO and ARGO did not reach statistical significance.

Three out of the 13 patients fitted with RGO and seven out of the 11 fitted with ARGO were able to climb up and down a flight of 12 stairs (with one crutch and one handrail), whereas HGO patients were not. Among the 24 patients fitted with RGO or ARGO, neither the level of spinal lesion (T6 or above vs below T6) nor the Garrett score (up to 3 vs 4–5) were related to the ability to climb stairs.

Figure 2 shows that HGO patients walked more slowly (median 11.6 cm/s, range 10.7–13.6) than those fitted with either RGO (16.6 cm/s, range 11.1–50) or ARGO (24 cm/s, range 10–30) ($p = 0.029$ and 0.022 respectively). In the sample of patients fitted with RGO or ARGO the level of lesion was not related to the speed attained.

The HGO patients could only walk with a walker, whereas 13 out of the 24 RGO/ARGO patients walked with crutches. In these 24, however, median speed appeared unrelated to the walking aid (walker vs crutches), to the orthosis (RGO vs ARGO) or to the level of spinal lesion.

Comparing the centres. The median of the levels of spinal lesions was T7 (range T3–12) in Villanova (13 cases), vs T5 (range T2–10) for the other five centres taken together (15 cases, $p = 0.0042$). In Villanova patients attended fewer sessions: 20 (14–25) vs 40 (12–84) in the other centres, ($p < 0.001$), in a shorter training period (4 weeks, range 3–8, vs 8 weeks, range 3–16, $p < 0.001$). HGO, allowing a lower gait speed (see above), were only prescribed in Villanova. However, even when HGO data were ignored there remained a difference between the patients' gait speed at the different centres. Median speed was 15 cm/s, range 10–30, in Villanova vs 25.6 cm/s, range 10–30, in the other centres ($p = 0.046$).

Table II Training period, number of training sessions, repairs to the orthoses, and results obtained in the 28 paraplegics fitted with HGO, RGO or ARGO.

Patient	Orthosis	Centre	Training weeks, sessions	Repairs	Don–doff time, min	Crutches walker	Garrett score	Speed: cm/s	Stairs: Y/N
1	RGO	Villanova	4 20		5.5 1.5	W	1	13.6	N
2	RGO	Villanova	6 30		3 1	C	3	15.9	Y
3	RGO	Villanova	7 20	2	3.3 1	C	4	18.7	Y
4	RGO	Villanova	4 15		5 2	W	1	12.5	N
5	RGO	Villanova	6 25		4.3 1.5	W	1	11.1	N
6	RGO	Villanova	4 20		4.5 1.7	W	1	16.1	N
7	ARGO	Villanova	6 20	2	5 2.5	C	4	18.7	Y
8	ARGO	Villanova	5 20	1	3.5 1.5	C	3	15	Y
9	RGO	Villanova	4 20		5 2	W	1	11.1	N
10	HGO	Villanova	3 15		1.5 1	C	2	10.7	N
11	HGO	Villanova	3 15		1.7 5	C	3	13.6	N
12	HGO	Villanova	4 15		1.5 1.3	C	1	10.7	N
13	HGO	Villanova	3 15		1.8 1.3	C	1	12.5	N
14	ARGO	Vicenza	8 35		3 1.5	C	1	10	N
15	ARGO	Vicenza	10 46		2.7 0.8	C	3	27.3	Y
16	ARGO	Vicenza	7 43		3 1.4	C	2	13.6	N
17	ARGO	Milano	8 28	5	2 1.1	C	3	39	Y
18	ARGO	Milano	9 32	3	3 2	C	3	37.5	Y
19	ARGO	Milano	16 32	3	2.7 2	C	3	30	Y
20	RGO	Torino	3 15		5.4 2.1	W	3	23	N
21	RGO	Torino	6 12	2	5 5	W	3	18.7	N
22	RGO	Torino	10 40	3	6 5	W	3	11	N
23	RGO	Torino	4 16		5.1 4	W	3	23	N
24	ARGO	Ferrara	8 40	1	5 3	W	3	21.4	N
25	RGO	Ferrara	10 50		8 5	W	3	50	N
26	RGO	Ferrara	12 60		10 5	W	2	16.6	N
27	ARGO	Trevi	14 84	10	5.5 3.8	C	3	24	Y
28	ARGO	Trevi	13 78	4	4 2.2	C	5	31	Y

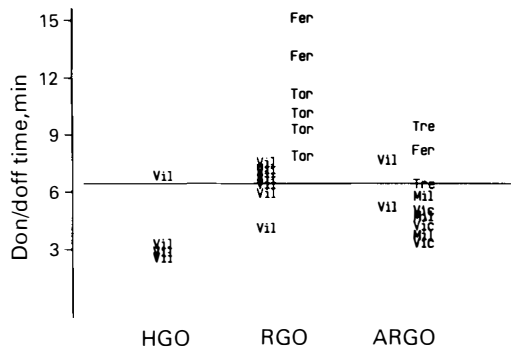

Figure 1 Time (min, on the ordinate) required at the end of the training period both donning and doffing manoeuvres in 28 paraplegic patients fitted with locomotory orthoses (HGO, RGO, ARGO, on the abscissa) in each of the six Italian centres enrolled (Vil = Villanova, Vic = Vicenza, Mil = Milano, Tor = Torino, Fer = Ferrara, Tre = Trevi). Horizontal line: general median time.

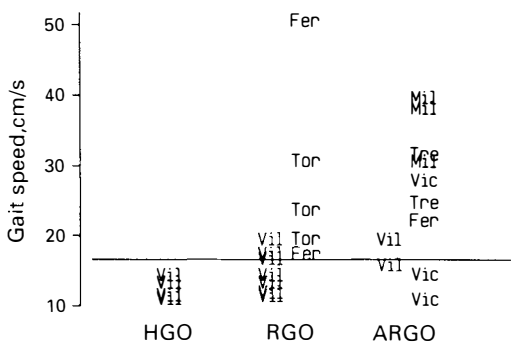

Figure 2 Gait speed (cm/s, on the ordinate) reached by the 28 patients fitted by locomotory orthoses (on the abscissa), in each of the six Italian centres enrolled (see Fig 1). Horizontal line: overall median speed.

Follow up

All of the patients were reexamined 6–7 months after discharge. Major troubles requiring repair by the orthotist affected five RGO (nine episodes) and three ARGO devices (three episodes). If the training and the follow up periods were pooled, repair was requested for six out of 13 RGO and seven out of 11 ARGO (p = ns).

One patient (male, T9 lesion, fitted with RGO in Torino) underwent spinal surgery and was warned against further use of the device. Six out of the other 27 abandoned their orthoses spontaneously. Their decision could not be predicted on the basis of either orthosis or centre. These six subjects had been fitted with HGO and RGO (one case each in Villanova) and with ARGO (one case in Vicenza, two in Milan, one in Turin).

One of these patients reported that she had rejected the orthosis for cosmetic reasons. She was a 23 year old woman, T6 lesion 6 years previously, fitted with ARGO in Milan. At discharge, she required 4.7 min for donning/doffing manoeuvres. The training programme had been rather successful. She walked with forearm crutches at 30 cm/s and was also able to climb up and down stairs and to ambulate in a domestic environment (Garrett score 3). She had taken part in a 16-week training programme regularly.

The other five nonusers reported that they could not find any functional advantage in wearing the orthosis. Again, their final decision could hardly be predicted.

These five men, 20–29 years old, with T3–9 lesion level, enrolled in the study for 13 weeks–2 years (median 11 months) after trauma. None of these features, nor discharge data such as the number of sessions, the length of training period, the donning/doffing time and the gait speed differed significantly from the corresponding data recorded in the 21 subjects who still used the orthosis at follow up. Two of these five could climb up and down stairs. Three of them had scored 3 in the Garrettt scale (home ambulation), whereas two had scored 1.

In the remaining 21 cases, functional ambulation levels did not differ significantly from discharge (Garrett score was unchanged, decreased and increased in 14, 1 and 6 cases respectively). Only four out of these 21 patients used the device to walk outdoors. As a median, patients from either Villanova or the other five centres had not modified their gait speed significantly.

Patients reported walking 0.2–1, 1–2, 2–3 h daily in 9, 9 and 3 cases respectively. They walked daily over distances of up to 0.1, 1 and 5 km in 7, 12 and 2 cases

Table III Orthoses repairs and clinical results recorded in the 28 paraplegics fitted with locomotory orthoses in a 6 month follow up.

Patient	Orthosis	Follow up Garrett	Follow up speed (cm/s)	Follow up hrs use	Follow up km/day	Follow up repairs
1	RGO	1	16	2	1	
2	RGO	3	25	3	2	
3	RGO	5	30	2	3	1
4	RGO	1	16.6	1	1	
5	RGO	4	18.7	1.5	2	
6	RGO	2	20	1.5	2	1
7	ARGO	5	25.8	2	3	
8	ARGO	3	18	3	2	
9	RGO	Abandon				
10	HGO	3	18.7	2	1	
11	HGO	3	20.2	3	1	
12	HGO	1	20	1	1	
13	HGO	Abandon				
14	ARGO	Abandon				
15	ARGO	3	29.4	1	2	
16	ARGO	2	16.6	2	2	
17	ARGO	1	30	1	1	
18	ARGO	Abandon				
19	ARGO	Abandon				
20	RGO	3	27	2	2	2
21	RGO	3	18	0.50	1	1
22	RGO	Operated				
23	RGO	Abandon				
24	ARGO	3	15	2.5	2	1
25	RGO	3	38	2	2	3
26	RGO	3	16	1.5	2	1
27	ARGO	3	22.2	1	2	1
28	ARGO	5	30	2	2	1

respectively. All of them said they considered orthotic walking to be a useful form of exercise, rather than a substitute for the wheelchair.

Discussion

Our results should be interpreted with caution, because of the relative paucity of the data and the number of variables which might have influenced the final outcome. Nevertheless, they suggest a warning against an overenthusiastic prescription of these devices as an effective substitute for the wheelchair.

These orthoses may indeed allow thoracic paraplegic patients to walk, but mainly in a domestic environment. In the long run, compliance is far from being satisfactory. Already after 6 months only two thirds of our patients still used their orthoses for standing or walking, and this for a median of only 2 h daily. The wheelchair was still preferred for most locomotor tasks.

The orthosis itself costs about 5.000 US$, with little variation among the models. To achieve independent gait we needed a median of 24 training sessions. The direct costs of the treatment, therefore, are far from being irrelevant.

The many variations warned against generalisation in our conclusions. Individual cases differed greatly not only in their clinical picture but, also, in the orthosis adopted, the managing centre, the time elapsed from trauma and the duration of training. Furthermore, we are well aware that the exercise regimen probably differed

greatly among centres. On the other hand, we preferred to allow each centre to do 'its own best', since an optimal exercise protocol (hopefully, to be defined in the near future) has not yet been established.

This notwithstanding, the functional results did not differ as greatly between subjects and centres as we had expected. All of the patients achieved independence in donning/doffing manoeuvres and could walk independently, albeit slowly. Only some of them, however, could climb up and down stairs. Such an ability, however, did not prevent some patients from rejecting the device.

Minor differences in the outcome seemed to depend on the device adopted. HGO did not allow stair climbing and allowed a lower gait speed, compared to either RGO or ARGO. On the other hand, it never required repairs, unlike its competitors, and required the shortest don/doff time.

The most experienced centre, Villanova, seemed to accept a lower gait speed from its patients, compared to the other less experienced centres. Possibly, this reflected in part shorter training programmes and perhaps was a more realistic and efficient policy. Despite a lower gait speed, patients' functional ambulation scores (reflecting the ability to walk outdoors rather than in the home) were not lower compared to faster subjects.

We were unable to reveal factors predictive of patients' compliance. Possibly, a multivariate analysis on a wider population might help to clarify this point. Variables encompassing motivation and social factors (e.g. urban vs country living arrangement) might add predictivity to the model.

Technical improvements of the devices might lead to more efficient, normal-looking and eventually more appealing gait. Research is moving along these lines, by experiments in the coupling of orthotic devices with functional electrical stimulation.[7]

In our opinion, as they now stand these devices seem to provide a useful form of exercise rather than an alternative to wheelchair locomotion. It is acknowledged that standing is beneficial for the general health of paraplegics[8] and, even more emphatically, the same claim might be made for orthotic locomotion. Thus, research on non-locomotor benefits (e.g. prevention of bone loss, renal failure, and heart deconditioning) is to be recommended.

These orthoses seems to be justified, provided prescription, appliance, training and monitoring are performed by specialised teams.

Acknowledgement

The Trevi Centre was supported by Regione Umbria, ricerca finalizzata.

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