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Original Article

A prototype of an adjustable advanced reciprocating gait orthosis (ARGO) for spinal cord injury (SCI)

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Objective: To develop a reciprocating gait orthosis which could be used in different sized patients.
Design: Clinical trial and orthotic development.
Setting: A large rehabilitation hospital in Rome, Italy
Patients and methods: To carry out this project normal reciprocating gait orthosis parts were used. The device was modified to adjust the hip–ankle height, and the hip–hip distance. It was tested, by five patients already walking with standard ARGO, to evaluate the performances of the orthosis. The device has been tested on seven newly injured patients fulfilling specific criteria of different height and weight.
Main outcome measures: Prototype suitability; patients appreciation.
Results: The device can be used for persons between 1.60 m and 1.85 m tall, weighing up to 100 kg. The orthosis allows an upright position without the use of the hands, and walking with a walker or with two canes. The foot orthosis cover sizes 36–40 (British 3–7) and 41–45 (British 7–11). With the exception of donning, doffing and lifting, the walking performances of the prototype and the general appreciation is comparable with those of a standard device. After a short period of training all seven patients were able to walk in the parallel bars. All of them expressed general appreciation for the device; despite this only four patients wanted the orthosis, two refused it and one has not decided yet.
Conclusions: The prototype allows the same standing and walking performances of normal ARGO. It could be used in spinal cord injury patients to let them test the potential of the device and thus be useful in the effort to reduce the percentage of ARGO rejection.
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Keywords: reciprocating gait orthosis; spinal cord injury; compliance

Introduction

Many patients with spinal cord injury spend their life in a 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 become available which provide additional stability. The most common devices are the Reciprocating Gait Orthosis (RGO) and the Advanced Reciprocating Gait Orthosis (ARGO).

There are many reasons why patients should be encouraged to walk with these orthosis:[1,2] it has been suggested that upright mobility might produce improvements in cardio-respiratory function, urological drainage, bowel function, bone density, spasticity and contractures.[3] Despite these potential benefits, it is a common experience that there is a high frequency of drop out in utilisation varying from 15 to 71%.[4,5] In a recent study[6] the features which could allow us to predict the risk of non use, the influence of sex, age, distance from injury, level of lesion, years of education, employment and marital status has been examined, but unfortunately these factors were shown not to be influential in determining non usage of the braces. Furthermore, in the cited study the same difficulties in using and the same lack of autonomy was found for users and non users of the orthosis. The general appreciation of the orthosis was not an indicator for RGO rejection 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.

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The aim of this study is to develop a prototype of an adjustable device that enables a rehabilitation team to try out a reciprocating appliance on probable future users of all sizes, before prescribing, with the subject able to directly test the effort needed and the moving potentials of the device. This study has been partially presented in abstract form.[7]

Design and methods

The ARGO consists of a hip–knee–ankle–foot orthosis which controls hip extension while assisting reciprocal hip flexion.[4,8,9] The device stabilizes the lower limbs and the trunk both in the sagittal and in the frontal plane and provides reciprocal walking on a mechanical basis by means of a single cable between both hip joints.[3]

To carry out the project we used ARGO (Hugh Steeper Ltd®) parts, except for the knee. We then set ourselves the objective of adjusting the foot, the height (distance ground–hip hinge joint) and width (distance between the two hinge joints of the hip). Subsequently, we also made an adjustment of the thoracic height (Figure 1A).

For the foot, we made polypropylene ankle–foot orthoses in two sizes (Figure 1F). They are interchangeable; a metal draw-piece with a 'U' section is fitted on the side and a square-section rod, proximally connected to the hinge joint of the hip, can slide in it. With this system we adjust the height of the leg (design 1).

To adjust the width we sectioned the rear connection pipe and inserted one with a smaller section; by sliding it like a telescope, the width of the pelvis can be adjusted as wished and the system blocked with a clamp. (Figure 1D,E, design 2).

The study consisted in two parts:

(1) To test the performances of the device five patients who already walked with standard ARGOs were asked to use our prototype during a rehabilitation session and express their opinion on the device and some aspects of its use by means of the Visual Analogue Scale;[10] four physical therapists experienced in the rehabilitation of walking by means of ARGO were asked to express their judgement with the same instrument. The results were compared with those of standard ARGOs by means of Student's *t*-test (significance $P<0.05$).
(2) The device and its utility for providing a good test of locomotion with ARGO has been evaluated in seven patients who fulfilled the criteria for device prescription:[11] 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 cardiovascular pathologies. Their performances have been videotaped and evaluated according to WISCI scores.[12] Patients clinical features are shown in Table 1.

Patients were trained for at least 15 days, 1 h/day; during this period patients received from a physician and a psychologist a full explanation of the advantages and disadvantages of standing and walking by means of ARGO. At the end of the training period they were asked to decide whether they preferred to have the device or not.

Results

The device can be used for persons between 1.60 m and 1.85 m tall, weighing up to 100 kg (Figure 1B,C). The foot orthosis cover sizes 36–40 (British 3–7) and 41–45 (British 7–11). The orthosis allows an upright position without the use of the hands, and walking with a walker or with two canes.

It lacks the knee lock and the linkage system between the hip and the knee. This means that patients need to lift the body over the heels during standing instead of pivoting over the knees.

Performances and appreciation

Patients already trained in ARGO use reached the same level of walking with the prototype (WISCI levels) within one rehabilitation session. The results of VAS scores and the comparison with standard ARGOs are shown in Tables 2 and 3. With the exception of donning and doffing time, and difficulties and lifting effort, the walking performances of the prototype and the general appreciation is comparable with those of standard device.

New patients training

At the end of the training period all seven patients were able to walk in the parallel bars, without help, for 10 meters (WISCI level 5). Patients expressed general appreciation for the device and for the possibility to test it before any choice. Despite the difficulties in lifting, donning and doffing, four patients decided they wanted the orthosis, two refused it and one still has to make her decision.

Discussion and conclusion

Reciprocating gait orthoses, was first created to allow children with spina bifida to walk,[14] in the last 15 years it has been used for adults with spinal cord injuries. The first studies of this kind of device were focused on the physiological effects of walking with RGO.[8] More recently, studies on long-term usage have been published[4,5,11] in an attempt to identify reasons of non-usage.

It is a common experience that there is a frequency of non-usage of the braces varying from 15 to 71%.[4,5] Such a high level of non-usage is important for several different reasons.[5] It leads investigators to question their prescription practice, with particular regard to the assessment and selection of patients. It has economic implications: in fact in Italy a reciprocating

gait orthosis of the advanced type costs about 6200 euros or 5500 US dollars, without considering the cost of walking aids, patients' training and repairs. Finally, a low level of compliance may lead to a loss of benefit to the patient. In our experience[6] about 50% of the patients abandoned the ARGO at 1 year follow-up. Thus, a better selection would mean a reduction of the expenses for these orthoses of at least one half.

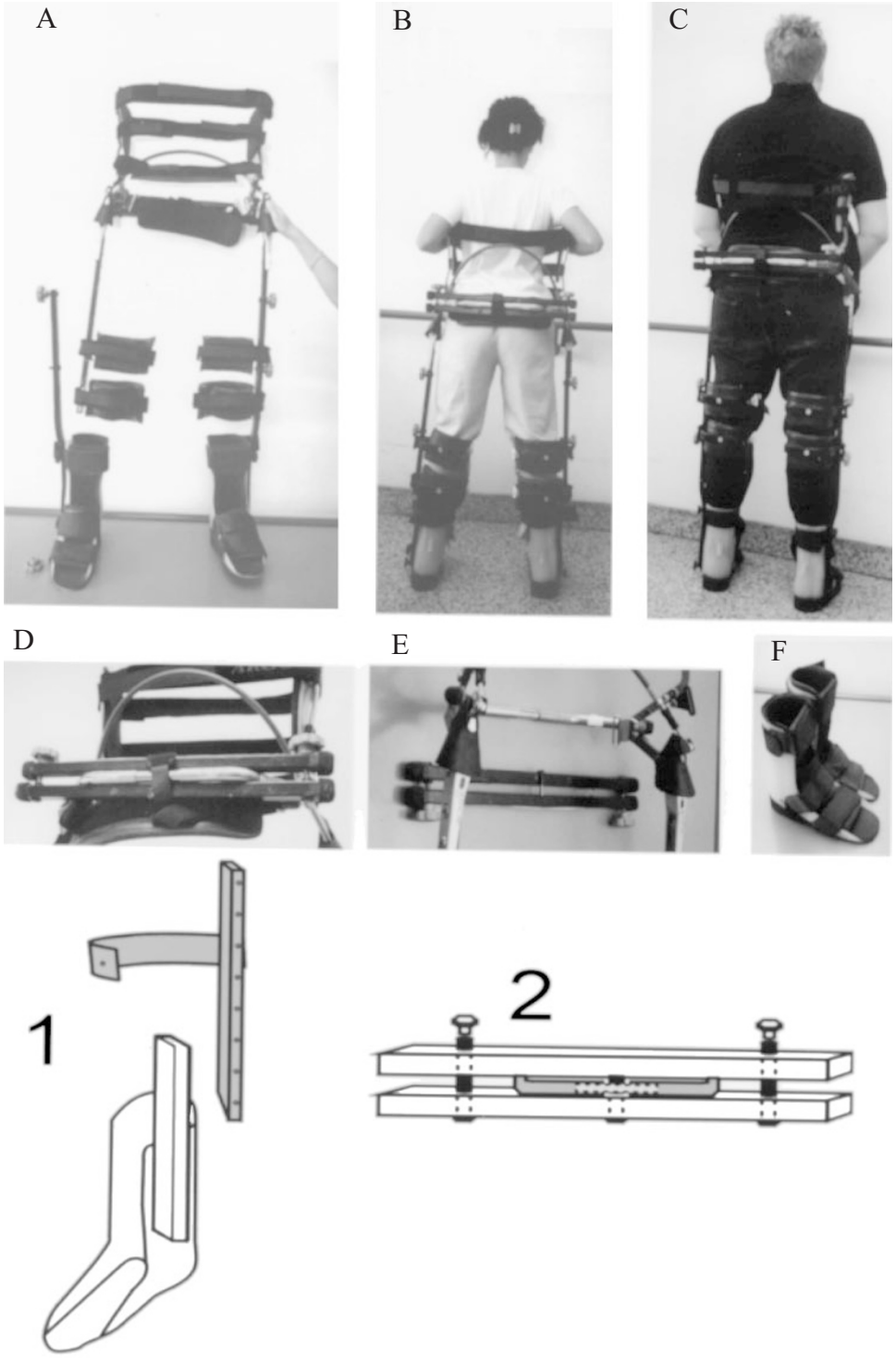

Figure 1 (**A**) Front view of the device with the right foot unlocked. (**B**) M.C. weight 47 kilos, height 160 cm, T7, standing without the use of the hands. (**C**) M.A. weight 98 kilos, height 185 cm, T4 standing without the use of the hands. (**D**) Particular of the back view of the device showing the width adjustment system locked. (**E**) Particular of the front view of the device showing the width adjustment system unlocked. Design 1: schematic of the ankle–foot orthosis. Design 2: schematic of the width system

Table 1 Patients clinical features

Sex	*Age* (years)	*Distance* (months)	*Level**	*Impairment**	*Weight* (kilos)	*Height* (cm)	*Decision*
M	30	14	T4	A	75	185	Accepted
M	25	70	T5	A	75	170	Accepted
F	18	11	T7	A	47	160	Accepted
F	50	12	T10	A	55	160	Accepted
M	35	72	T7	A	60	170	Not taken
M	37	9	T4	A	98	185	Refused
M	26	22	T5	A	60	175	Refused

*According to ASIA standards[13]

Table 2 VAS scores: patients evaluation

Parameters	*Standard*	*Prototype*	P
Walking speed	4.6±0.89	4.8±1.4	0.8
Donning and doffing	2.8±0.83	5±0.7	0.002
Walking aids	6.2±0.4	6.4±1.1	0.72
Stairs climbing	4.2±0.8	4.4±0.5	0.66
Lifting	2.6±0.5	3.6±0.5	0.02
Fatigue	5±0.7	5±1	1
General appreciation	5.8±0.8	5.6±1.5	0.8

Table 3 VAS scores: physical therapists evaluation

Parameters	*Standard*	*Prototype*	P
Walking speed	8±1.15	7.75±0.9	0.75
Donning and doffing	7.25±0.9	3±1.6	0.004
Walking devices	7.5±0.6	7.5±0.6	1
Stairs climbing	6.7±1.5	6±1.8	0.54
Lifting	6.75±0.9	5±2.7	0.27
General appreciation	8±0.8	6.7±0.9	0.09

The main reasons for non-use of the braces are both medial and non-medical: most 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 with transport, to walk outside and to climb stairs. ARGO locomotion requires a high energy expenditure for a speed which is at maximum only 10% of that of a wheelchair[15] locomotion cost seems to be one of the main causes of orthosis rejection, although in the same study no significant correlation between oxygen consumption and cost of locomotion and duration of orthosis use after training was reported.

The present prototype has been developed in an attempt to reduce the percentage of ARGO rejection by allowing direct testing of the device before prescription.

Since the different parameters analyzed failed in predicting the degree of orthosis usage, direct testing might provide an effective way for a more focused prescription. After an appropriate period of training patients should be able to ascertain both positive (physical improvement and psychological benefits) and negative (energy expenditure and lack of autonomy) aspects of ARGO use and thus be able to make an informed decision.

The prototype allows a large range of width, height (25 centimeters) and weight (40 kilos) and thus fits the great majority (90%) of patients, according to Italian population standards.[16]

Because of a technical difficulty in regulating the elastic joint between the hip and the knee joint, our prototype lacks the knee joint. Thus, it obviously makes some functions more difficult: in particular, donning and doffing is more difficult and more prolonged, and assuming the upright position requires more effort than with regular ARGO, but we consider these aspects not critical for experimental and training purposes. Furthermore, it is our experience that patients, with regular ARGO often prefer to start assuming the upright position with the knee lock blocked (i.e. with the legs already extended).

ARGO's and the prototype's performances were evaluated by patients and therapists by means of VAS. Within each group there was no difference between the two orthoses. As a side result, clear differences are present between patients' and therapists' evaluation of both orthoses (with the therapists giving higher scores). These differences might reflect differences in the expectation and knowledge of the real possibilities of the orthosis. This may be considered as a further demonstration that SCI patients are biased in their decision to adopt the walking device by the desire to obtain functional walking.

Although preliminary, the present study indicates that the proposed prototype is useful for a better ARGO prescription. In fact, of the seven patients admitted to ARGO prescription according to published criteria,[11] two (28%) demonstrated lack of motivation when they were allowed to directly test ARGO usage (the main reason for both of them being the high energy cost of walking). Following the results of this pilot study, our next step will be to select patients who fulfil the criteria for a reciprocating orthosis[11] according to their decision; after 1 year follow-up we will know if there is a reduction of orthosis rejection percentage from the 46% we found in a previous study.[6]

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