The use of an advanced reciprocating gait orthosis by paraplegic individuals: a follow-up study

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This article describes the results of a follow-up study of 14 paraplegic individuals who were fitted with the ARGO (Advanced Reciprocating Gait Orthosis – STEEPER*) at least 1 year previously. It was found that 85% were still using the apparatus on a regular basis. The general satisfaction of the users was high, although the functional use was limited. Therapeutic reasons appeared to be the main reason for wearing the ARGO. The points that were most appreciated were the psychological and physiological benefits of standing and walking. Discussion with the users who were paraplegic provided valuable information concerning possible technical improvements to the ARGO.

Keywords: paraplegic; SCI; gait orthoses; standing; walking; functional electrical stimulation

Introduction

During the past four decades, several mechanical systems have been developed to restore the standing and walking function of those who are paraplegic. In the '50s and '60s, primarily Long Leg Braces (LLB) have been prescribed but their use was found to be rather limited.^{1,2} These braces seemed to be effective only for persons with a level of lesion below T11. More than 50% of the patients fitted with these braces did not use them after a short initial period of time.

More recently, orthoses have become available which provide additional stability at the hip, such as the Hip Guidance Orthosis (HGO), the Reciprocating Gait Orthosis (RGO) and the Advanced Reciprocating Gait Orthosis (ARGO). A follow-up study of the HGO revealed that 64% of the users continued to use the device on a regular basis.^{3,4} The RGO and ARGO provide reciprocal walking on a mechanical basis by means of, respectively, a double or a single cable linkage between both hip joints. The ultimate goal is walking with these orthoses in a four-point gait, resulting in lower energy consumption as compared to the swing-through or swing-to gait with the LLB.⁵

A completely different method to restore gait in those with paraplegia is the use of Functional Electrical Stimulation (FES). Several systems exist, ranging from four channel appliances with surface electrodes,^{6,7} to complex systems with 48 channels and percutaneous electrodes.⁸ There is at this time, as far

as we know, no follow-up study published on the use of FES.

Recently, a substantial amount of research has been directed towards the combination of a mechanical gait orthosis with FES,^{9–13} in an attempt to improve the energy efficiency of the paraplegic gait. We are currently involved in the development of such a hybrid ARGO-FES system.^{12,13}

Such further technological developments should take into account the experience obtained with the previously used systems. Therefore, investigation of the functional outcome of ARGO use, in patients fitted for more than 1 year, was taken as the objective for the present study.

The first question was whether the ARGO was still being used by the patients and if so, in which situations? Secondly, if its use was abandoned, what were the specific reasons for this rejection? Thirdly, what were the problems encountered in using the ARGO, and what aspects of the apparatus could be improved according to user opinion?

Methodology

From 1989 to 1994, 23 paraplegic individuals were fitted and trained in the use of an ARGO at the Centre for Evaluation and Rehabilitation of Motor Functions (CERM) of the University Hospitals Leuven. For the follow-up study, only 14 out of these 23 patients could be questioned due to various reasons: six had moved or changed address without notice, one was deceased, and two were still in rehabilitation at the time of the interview, so that

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they could not provide relevant information for this study.

All 14 patients were interviewed over the phone by an independent researcher using a standardised questionnaire (Table 1). This researcher was unknown to the patients, was not a member of the clinical staff and did not participate in rehabilitation. The major reason to interview the patients over the phone and not by mailing the questionnaire, was the rather technical nature of a significant part in the questionnaire. Since many patients do not know how to describe technical problems accurately, a better clarification could be acquired in a personal conversation.

All the patients were informed about the purpose of this study. The interview took half an hour on average. The complete questionnaire is included in Table 1.

Table 1 The Questionnaire

General patient information:
Age
Sex
Employment
Level of lesion
Time since supply of the ARGO
Preferred walking aid (crutches, walker,...)
Previous orthosis
What was the motivation for buying an ARGO?
Are you disappointed in your expectations?
Is the ARGO still in use?
A. If so:
A1 How frequently do you use it?
A2 How long on each occasion?
A3 For which activities?
A4 Do you also walk outside the house?
A5 Do you make the transfer inside a car?
A6 Do you need assistance with:
-donning
-rising
-walking
-sitting down
-doffing
A7 For which activities would you like to use the ARGO if it were possible and why can't you?
A8 Which technical problems have you faced yet?
A9 In which areas should the ARGO be improved?
A10 Have you ever had medical complaints due to the use of an ARGO?
A11 Do you mind the outlook of the ARGO or the appearance of walking with it?
A12 What is your general appreciation of the appliance?
B. If not:
B1 Why did you abandon the apparatus?
B2 Was there a specific reason to stop?
B3 For how long have you been using the ARGO?
B4 Could you use the ARGO fully independently or did you need assistance?
B5 Did you have problems with the cosmesis of the ARGO or the appearance of walking with it?
B6 What is your general appreciation of the appliance?

Patient information

Personal patient information is given in Table 2. Fourteen patients were interviewed, 12 males and two females (Table 1). Age ranged from 16 to 57 years (mean 33.6). The levels of lesion were mid-thoracic to L1, except two high levels C7 lesions. Four patients were in employment (two full- and two part-time) and three were still studying. Twelve patients used the ARGO in combination with a walker and two preferred crutches. Four patients used LLBs previously.

All patients had used the ARGO for at least 1 year and most of them for more than 3 years. Prior to the prescription of the ARGO, the patients received information on what to expect from their new walking aid. They were subjected to a standardised selection procedure focused on patient motivation, general condition, upper limb muscular strength, body weight, spasticity, occurrence of muscle contractures and bone mineral content of selected areas. The patients were then trained 4 weeks prior to fitting, followed by a 4 to 6 weeks training period with the appliance, which was usually continued at home under the supervision of a private physiotherapist.

Results

The main answers given by the patients on the phone are summarised in Table 3.

General

Among the 14 patients interviewed, 12 were still using the ARGO on a regular basis. One of the patients who had stopped, was planning to resume ARGO use. As principal reasons for abandoning ARGO use patients mentioned were mechanical problems with the ARGO and lack of time due to employment or preoccupation because of various interests.

The four patients who used long leg braces previously had all discontinued use of these braces. The main motivation for starting with the ARGO was therapeutic. All patients stated that they had been well informed about the possibilities of walking with the ARGO prior to fitting and only two said they were disappointed in their expectations.

In a general appreciation by the twelve active ARGO-users, two found it 'very good' and six 'good'. Three patients gave no appreciation at all and one found it 'bad'. Among the two non-users, one was satisfied ('good') and one gave no appreciation.

Frequency of use

The frequency of using the ARGO ranged from daily to twice a month, with an average of three times a week. On each occasion, the ARGO was used for 1 to 2 hours.

Table 2 Personal patient information

<i>Patient</i>	<i>Age</i>	<i>Sex</i>	<i>Level of lesion</i>	<i>Follow-up period years (y) months (m)</i>	<i>Preferred walking aid</i>	<i>Previous orthosis</i>	<i>Employment</i>
1	16	M	T8	2 y	walker	none	student
2	55	M	T8	3 y 4 m	walker	none	none
3	36	M	T12	3 y 5 m	crutches	LLB	part-time
4	36	M	C7	3 y 7 m	walker	none	none
5	23	M	T12	1 y 7 m	walker	none	none
6	41	M	C7	3 y 3 m	walker	none	none
7	29	F	T7	3 y 3 m	walker	none	none
8	36	M	T6	4 y 8 m	walker	none	none
9	18	F	T5	3 y 2 m	walker	none	student
10	21	M	T10	2 y 6 m	crutches	LLB	student
11	36	M	L1	4 y 3 m	walker	LLB	part-time
12	57	M	T10	3 y 4 m	walker	none	full-time
13	36	M	T6	3 y 1 m	walker	LLB	none
14	42	M	T5	4 y	walker	none	full-time

Table 3 Summary of main answers

<i>Patient</i>	<i>ARGO in use</i>	<i>Frequency of use (/week)</i>	<i>Assistance needed</i>	<i>Outdoor use</i>	<i>Transfer into car</i>	<i>Cosmetic problems</i>	<i>Final assessment</i>
1	yes	5 ×	none	garden	not tried	no	good
2	yes	3 ×	donning	no	no	no	good
3	yes	3 ×	rising	no	no	no	no opinion
4	yes	2 ×	donning	no	not tried	no	good
5	yes	2 ×	none	no	not tried	no	bad
6	yes	7 ×	rising	no	not tried	no	very good
7	yes	3 ×	none	garden	yes	no	good
8	yes	1 ×	none	no	yes	no	good
9	yes	4 ×	none	garden	no	no	good
10	yes	3 ×	none	no	yes	yes	very good
11	yes	0.5 ×	donning + rising	garden	no	no	no opinion
12	yes	1 ×	rising	no	no	no	no opinion
13	no	n/a	rising	n/a	n/a	no	no opinion
14	no	n/a	none	n/a	n/a	no	good

Functional use

All patients used the ARGO mainly for therapeutic reasons, ie to stand and walk without a real functional goal. A few patients tried to use it at work but did not continue because they considered the ARGO to be too heavy and cumbersome for use in a really functional way. They also found the walking speed to be too low. When asked for functional applications of the ARGO, patients mentioned a few specific activities: one used it to play 'petanque' and another liked to stand when he had visitors at home. Some patients also used it in the kitchen when taking something out of a cupboard, etc.

Only one user managed to make the transfer into a car (a Range Rover) without much difficulty. Two others were able to do so but found it too difficult to perform on a regular basis. The others had never tried it.

Indoor-Outdoor use

The ARGO application was mainly limited to indoor use. Four patients mentioned walking in the garden as outdoor activity. Nobody was using the ARGO for walking in the street.

Independent use

Half of the regular users could use the ARGO fully independently. The others preferred some help in donning (especially the shoes are problematic) and in rising. Four needed some assistance to rise with crutches or with a walking frame. One of them though could rise independently if he had one fixed grip (eg a table) and one crutch. On the other hand, rising between parallel bars was not problematic for any of them.

Complaints and complications

In general, there were no complications of a physiological nature eg pressure sores. Two patients had however fallen, but without serious injury.

Most complaints were of a technical nature and were related to the functioning of the knee-locking cables and the knee-locking mechanism when rising and sitting down. Cable length tuning is indeed delicate: when the cables are too loose, knee unlocking will not occur at the start of rising, while cables that are too tight prevent locking of the knee joint at the end of the rising procedure.

Moreover, the knees had to be in full extension in order to lock the knee joints. Even with the gas spring at the knee, full knee extension is not always achieved. This led to very uncomfortable situations for the patient who, at the end of a substantial effort, found himself in a position where he could not stand on his feet, and neither could he sit down.

Further frequently mentioned complaints about the ARGO were its weight, the fact that it was too big to use in an active wheelchair, and the discomfort whilst sitting due to the back tube.

Cosmesis

Of the 12 regular users, only one reported problems with the cosmesis of the ARGO or with the appearance of gait. Although the ARGO can be worn under the clothing, none of the users did so.

Discussion

The first objective of this study was to get a better insight into the potential use of the ARGO and, if used, in which situations? About 85% used the ARGO regularly. This high score is comparable to the first follow-up study on the HGO.¹⁴ In that article, the remark was made that this number was probably so high because these users were highly motivated 'pioneers'. Indeed, in a second follow-up study at the same centre,⁴ the number had dropped to 64%. The authors concluded from this that the results could be biased by the early selection of very motivated and more involved patients. The same remark applies here: the results of 85% in this study may also be influenced by patient selection.

Moreover, this result may be biased by the fact that we only questioned the users themselves. This source of information may not always be objective as enthusiastic people tend to overestimate the number of times they practise and they minimise the problems they encounter. Further investigation with an interview of the relatives and assessment of the apparatus after several years of use is ongoing.

The ARGO was mainly used for therapeutic reasons. Patient rehabilitation programs and follow-up studies make those who are paraplegic more aware of the negative effects of the lack of movement, such as the development of osteoporosis and cardiovascular

problems, and they therefore wish to enhance their general health and condition.

The limited functional use can be due to the fact that the life and environment of most paraplegic patients is adapted to a large extent for wheelchair use so that there is no real need for rising and standing at home or at work. This is illustrated by the reaction of a patient who intended to use the ARGO in the kitchen when preparing a meal and cleaning the dishes. Unfortunately, this appeared to be impractical since the cooking plates and the cupboards, which were perfectly accessible for a wheelchair user, were too low for an ARGO-user.

Psychological well-being is also frequently mentioned as an important aspect in using the ARGO: people are glad to be 'back on their feet' or able to talk to visitors at the same 'level'. Although one patient used a standing chair for functional tasks because it gave more stability, he still used the ARGO for standing and when walking inside the house because a standing chair did not permit full upright standing and gave the sensation of sitting in a wheelchair.

Outdoor use of the ARGO is also rather limited: five patients walked with the appliance in the garden. Nobody used the ARGO when in the community. The speed of walking was too low compared with a wheelchair and it was not easy to carry a bag, etc. The limited outdoor use could not be explained by concerns about the cosmesis of the ARGO or the appearance of gait, since only one person expressed dissatisfaction with it. This low number should however be interpreted carefully. Nobody really walked outside the house and of course, inside the house cosmesis could be considered less of a problem. Consequently, the actual number of patients with problems concerning cosmesis could, in fact, be higher.

Those subjects who did try using the ARGO in conjunction with a car, found it very difficult to make the transfer into the vehicle. The stiff connection between the back tube and the legs made it very difficult to pull the legs into the car, especially when doors are narrow as in most four-door cars.

The second objective of this study concerned the abandoning of the ARGO and the factors that influenced this decision. Only two persons abandoned the ARGO altogether; one mentioned that there were so many mechanical problems that he became discouraged; and the other was fully employed and had very little spare time for upright exercise. In addition, he had many other interests and means of training besides the ARGO.

General appreciation of the ARGO was not an indicator for abandoning it or not. Indeed, 66% were pleased or even very pleased with it, and only one person disliked it. However, the latter person was still using the ARGO. Of the two non-users, one was satisfied ('good') and one gave no appreciation.

The fact of whether or not the ARGO was abandoned was also not influenced by the ease of

donning and doffing, nor by the level of lesion. Several patients could not don and doff independently or preferred help, but they still used it. The two patients with a lesion at C7 were still using it and one of them was even particularly pleased with it. On the other hand, one user who abandoned the device, was a fully independent user with a lesion below T6.

Two factors could be considered very important to minimise the failure rate: carefully selecting and informing the patients. The screening of the patients, based on a complete medical and psychological examination by experienced medical staff, helps of course to eliminate possible disappointments. Also, most of the patients seem to have been well informed in advance, even on the rather limited functional possibilities, since only two patients expressed some disappointment relative to their expectations.

This follow-up study was further interesting from an engineering point of view. The third aim was to determine possible improvements to the ARGO according to the user's opinion.

A first mechanical improvement could be made on the hip mechanism. The rigid structure made it difficult to put on shoes and to make the transfer into a car. Furthermore, the back tube caused discomfort while sitting in the wheelchair. One possible solution would be to construct the hip joint in such a way that the upper part can be removed while sitting.

Secondly, rising was considered to be difficult by many of the patients, as is described in the section on complaints. It required a considerable effort and sometimes knee locking in the standing position was difficult to achieve. The unlocking cables were mentioned several times as a point requiring further improvement. These cables could be completely omitted by the construction of an electronic unlocking mechanism at the knee joint.¹² The substantial effort necessary for rising could be diminished to a reasonable level by combining the ARGO with FES, as stimulation of the quadriceps assists in extending the knees.

This brings us to the question whether the combined use of ARGO and FES could be a means of enhancing outdoor walking and functional use because of its lower energy requirements and slightly increased walking speed. This question remains to be answered.

In conclusion, the results of this follow-up study on the use of the ARGO after at least 1 year following the fitting of the apparatus are positive: 85% were still

using the ARGO and although the functional use was rather limited, the users seemed to appreciate the apparatus.

Several possible improvements have been recognised, and we will address them in our future research, in the hope that they will further improve the patient satisfaction and stimulate a more functional use of the ARGO.

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