

A review of reciprocal walking systems for paraplegic patients: factors affecting choice and economic justification

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Abstract

The prescription of treatment systems which include orthoses to enable patients with high level thoracic spinal lesions to walk reciprocally is now widely practised. It remains a clinical option for which the efficacy is frequently called into question. A broad range of experience has now been accumulated with orthoses of this type, and this is reflected in the literature. The indications for prescription and outcomes of treatment have, as a result of the reported research, become clearer. However, the length of time over which the relevant work has been published and the variety of journals in which it has appeared makes it difficult to perceive a coherent message.

This review analyses the published work in order to identify the degree to which the therapeutic benefits which can accrue from ambulatory activity produce an economically justified outcome. Provided appropriate supply procedures are observed so that good patient compliance with the treatment is achieved, there is strong evidence that fewer pressure sores and improved independence will occur at a level where real overall cost savings can be made.

Factors which affect patient compliance and on which research findings have been published are identified. Comparisons are made between different orthoses with regard to these, so that more informed choice, taking into account preferences of individual patients, can be made by clinicians.

Introduction

Reciprocal walking for patients who have no control of their lower limbs as a result of

traumatic, acquired or congenital paraplegia at level L1 or above, as proposed by Rose (1979), has now been routinely available since 1983 (Douglas *et al.*, 1983; Butler *et al.*, 1984). The objectives of such treatment systems are to provide therapeutic benefit and improvements in independence. When achieved these have important long-term financial and social implications, as well as enabling paraplegic patients who were previously unable to do so to walk in a manner which is acceptably close to normal.

There are several orthoses available to fulfil this role but confusion surrounds the justification, cost and clinical viability of these. At present the choice is most strongly influenced by the familiarity of clinicians with just one system. They are frequently overwhelmed by other clinical work and this prevents them from undertaking detailed comparisons of the efficiency of available systems. It is therefore very difficult for them to make a fully informed decision on the most suitable orthotic management of patients in their care who wish to ambulate. The increasing influence of managers within market oriented healthcare systems suggests that they should have a role in identifying the relevant health economics factors relative to walking for paraplegics, so that they can advise clinicians on the most appropriate action in the best interests of the patient, healthcare provider and purchaser.

The systems and their objectives

There are two basic types of reciprocal walking device which are routinely available:

1. Cross-linked hip joint orthoses
 - (a) Reciprocating Gait Orthosis (RGO) (Beckmann, 1987).

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- (b) Advanced Reciprocating Gait Orthosis (ARGO) (Lissons, 1992) (Fig. 1(a));

2. Freely hinged hip joint orthoses

- (a) Hip Guidance Orthosis (HGO)
 (b) Parawalker (Butler and Major, 1987) (Fig. 1 (b)).

In the first group the emphasis is on close conformity of the orthosis to the patient and assuring that the hip joints are controlled to move in a fixed reciprocal pattern, whereas in the second type there is greater concentration on convenience of doffing and donning and ease of clearing the swing-leg for reciprocal walking.

Major and Butler (1995) show that it is not realistic to expect that any of the systems will achieve an efficiency of locomotion which approaches that of a wheelchair on flat surfaces. Their use therefore requires that the objectives be clearly identified. Anecdotal clinical experience of Carroll (1974), Rose *et al.* (1983) and Menelaus (1987) has long suggested that there are two achievable objectives from walking heavily handicapped patients:

therapeutic benefit;
 improved independence.

More recently properly validated evidence to support the previous anecdotal experience has been established. Mazur *et al.* (1989) undertook a 10 year follow-up study of 36 matched pairs of paralysed spina bifida patients. One group was treated with a vigorous walking programme from the age of 2 years and the second group used only wheelchairs for mobility. From the point of view of therapeutic benefit the non-walkers had twice as many bone fractures and five times the number of pressure sores. Taking independence into account the study showed that significantly greater numbers of walkers could achieve each of a number of activities of daily living and that as teenagers 22% of the walkers were able to move about the community using cars or public transport, whereas only 6% of the non-walkers could do so.

These overall findings are further supported by the observations of Sykes *et al.* (1995). They reported that patients who used a reciprocal walking system had significantly greater feelings of well-being than those who did not.



(a)



(b)

Fig. 1 (a) RGO (b) Parawalker (Fig. 1(a) is reproduced with the kind permission of Steepers, Roehampton, UK)

The basis of choice

The anecdotal and clearly validated evidence which now exists for the benefits of walking to paralysed patients creates a more easily justifiable demand for orthotic walking systems. However, if the benefits are to be achieved patients must elect to use their expensive appliances on a regular basis. The factors which determine the degree to which this will occur are:

- ease of walking (i.e. efficiency);
- convenience of application (i.e. doffing and donning time);
- additional walking aids required (crutches or walking frames);
- reliability (lack of mechanical failures);
- cosmesis.

Overlaying those factors will be the costs of providing the treatment system, and these must be clearly understood if any form of economic analysis is to be undertaken.

Without the data necessary to make comparisons between the available systems neither clinicians nor managers can make a rational decision on choice. When these systems first became available the lack of data on performance led to inconsistencies in prescription patterns. The frequently high profile created by media attention on paraplegic patients walking with one system or another led to a broadening of interest in this area by scientific workers. As a consequence there is now much published work which addresses the individual factors identified as influencing the performance of patients and their ongoing use of walking devices.

Financial implications

There is a temptation to take a very simplistic view of the financial implications of the supply of walking orthoses and to look only at the purchase price. However, this ignores the more significant factors of:

- (a) the orthosis being only one essential element of an overall treatment system which also includes assessment, patient training, on-going routine monitoring, repair and replacement;
- (b) the long-term benefits to the patient in terms of reduced pressure sores and bone fractures, and the increase of independence in adolescence and adulthood.

As regards the cost of supply the most realistic approach is to recognise the "treatment system" concept so as to ensure that all financial implications are taken into account. Overall costings of a typical system (Parawalker) have been calculated for an average 3 year replacement cycle. On that basis the real costs are approximately five times that of the orthosis for the complete cycle. This includes the initial cost of the orthosis, additional walking aids and patient training; routine monitoring of the patient and orthosis at six monthly intervals; any repairs and the cost of any replacement parts during the 3 year period. An independent calculation by a different clinical supply centre produced figures which were very close to this (Pratt, 1991). Currently that figure amounts to approximately £8000 (GBP).

There is insufficient published data on different systems to make a direct comparison of cost. However, the training time will be a key element of any financial analysis. Lotta *et al.* (1994) did compare training times for the RGO, ARGO and Parawalker. The average times they identified are shown in Figure 2. From this it can be seen that there does appear to be some variability between the systems with the Parawalker having the lowest patient training times (or numbers of training sessions).

The benefits of a vigorous walking programme are much more difficult to assess. However, it is known that there is a high risk of pressure sores in paraplegic patients and that the cost of treating these is extremely high. McSweeney (1994) identified that there is no agreed model for assessing cost and estimates consequently do vary. Figures between £15,000 (GBP) (El Masri, 1995) and £26,000 (GBP)

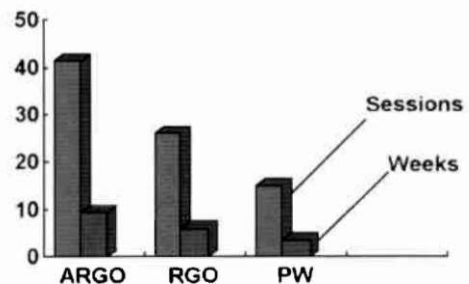


Fig. 2. Patient training times in the use of reciprocal walking orthoses (Lotta *et al.*, 1994).

(McSweeney, 1994; Dealey *et al.*, 1997) have been quoted as the average cost for each pressure sore, and Harding (1992) indicates that sores cost the UK National Health Service an estimated £600m (GBP) per annum.

If the results reported by Mazur *et al.* (1989) on the increased number of pressure sores experienced by non-walkers, the average cost of pressure sore treatment and the cost of providing ambulation with, for example, a Parawalker are taken into account then walking has the potential to make savings in the order of £50,000 (GBP) per patient over a 10 year period. These savings are large enough for the possible differences in cost between different systems not to significantly change the overall financial balance. The financial benefits of greater independence are much less easy to define. Between three and four times the number of walkers achieve independent mobility within the community as compared with non-walkers (Mazur *et al.*, 1989) and that is clearly very advantageous to those who have been given the opportunity and have elected to ambulate. Whilst such an outcome will not be directly reflected in individual healthcare departmental budgets there can be no doubt that there are potentially significant financial and social benefits to the patient and community as a whole.

The potential savings on patients who persist with their walking treatment are offset by the costs incurred on those who have been provided with an orthosis but have poor compliance. A rate of 50% of patients continuing to use their orthosis regularly still leaves scope for overall savings for the health service provider.

Performance comparisons

1. Absolute energy cost of walking

Reciprocal walking systems have been devised to reduce the energy cost of walking as compared with previously used knee-ankle-foot orthosis (KAFO) systems. Three studies of thoracic lesion patients using KAFOs have been published (Clinkingbeard *et al.*, 1964; Huang *et al.*, 1979; Merkel *et al.*, 1984). Between them these authors monitored a total of six patients with complete thoracic lesions, the average energy cost being 30.3J/kg/m. In a similar study of thoracic lesion patients using a reciprocal walking orthosis Nene and Patrick (1989) reported a significantly lower average energy cost of 16J/kg/m. These results

give a clear indication that the use of reciprocal walking systems produces a much higher level of efficiency in ambulation than that achieved in KAFO devices. This is further emphasised by the comparisons by Stallard *et al.* (1991) of the results of their study of patients using reciprocal walking orthoses with that of a similar group of patients using "conventional orthoses (KAFOs)" by Asher and Olsen (1983), on the basis of the Hoffer *et al.* (1973) classification of handicapped gait. Patients who used reciprocal walking orthoses were on average more than one category better than those using conventional orthoses. Guidera *et al.* (1993) reported that 19% of children using the RGO were community walkers and Stallard *et al.* (1991) 34% of those in the Parawalker, both considerably higher than the Asher and Olsen patients using conventional KAFOs.

Three studies of the absolute energy cost of reciprocal walking orthoses have been undertaken (Bernardi *et al.*, 1995; Hirokawa *et al.* 1990; Nene and Patrick, 1989). There is close agreement between Bernardi *et al.* and Hirokawa *et al.* on the RGO average cost at 20 and 21 J/kg/m respectively. Nene and Patrick (as reported above) show that the Parawalker has an average cost of 16 J/kg/m, slightly lower but within the same comparative range.

2. Comparable energy cost of walking

Three studies have made direct comparisons of relative energy cost between the RGO and the Parawalker (or HGO) on individual patients. Banta *et al.* (1991) used oxygen uptake techniques, Bowker *et al.* (1992) examined physiological cost index (PCI) and Whittle and Cochrane (1989) studied the peak walking aid forces required for the HGO. There is remarkable similarity of comparison in these parameters (as shown in Fig. 3), with the

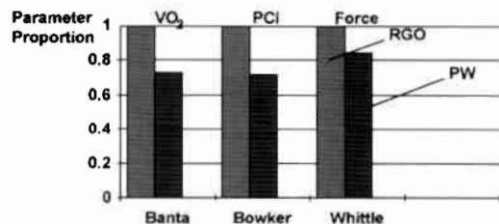


Fig. 3. Comparative energy costs in the use of the RGO and Parawalker (Banta *et al.*, 1991; Bowker *et al.*, 1992; Whittle *et al.*, 1989).

Parawalker or HGO requiring less energy in each case.

Phillips *et al.* (1995) and Jefferson and Whittle (1990) made anecdotal observations regarding ease of ambulation in comparing the HGO and the RGO, and the HGO, RGO and ARGO respectively. In the first case it was reported that heavier children with spina bifida "felt more secure in the less flexible HGO and were better able to concentrate their efforts on ambulation rather than on staying upright", and in the second it was concluded that "on the basis of the smaller pelvic movement in the HGO it would be expected that the energy cost of walking in this orthosis would be less than in either of the other two devices". Phillips *et al.* use the RGO for younger patients "because components for the HGO are not available for children under about five years of age".

3. Convenience of use

Whittle and Cochrane (1989) measured the difference in time required to independently put on and take off the RGO and the Parawalker. They showed that the Parawalker was on average 59% quicker in this respect.

Jefferson and Whittle (1990) identified that "the inclusion of a compression mechanism in the Steeper's orthosis (ARGO) made sitting and standing much easier with corresponding advantages to the patient both socially and in terms of energy expenditure at the beginning and ending of a walk", but did not provide quantitative data in this regard on differences between the three orthoses they reviewed.

4. Additional walking aids required

All of the available walking systems require additional walking aids to enable the upper limbs to generate the propulsion forces. There are two main options:

- walking frames (rollators etc);
- crutches.

The choice will affect convenience – walking frames being more cumbersome and less cosmetic. However, a walking frame does provide more inherent stability and is therefore easier to use. Orthosis design does influence the choice, though the patient will make the final decision.

Whittle and Cochrane (1989) in a cross-over trial of 22 patients using RGO and the Parawalker showed that 6% of RGO patients

used crutches whereas 69% of Parawalker patients chose to do this.

Lotta *et al.* (1994) in a review of three types of walking orthosis showed that 100% of Parawalker patients used crutches, 81.8% of ARGO patients did and 15.4% of RGO patients elected to do so.

5. Mechanical reliability

In their comparison of the RGO and HGO Whittle and Cochrane (1989) reported a repair rate of 11% for the RGO with no repairs for the HGO (i.e. 0%).

The Lotta *et al.* (1994) review of RGO, ARGO and Parawalker also reported on the numbers of repairs required on each and Fig. 4 summarises their findings in this respect. It will be seen they reported the ARGO as requiring most repairs and the Parawalker the fewest. Guidera *et al.* (1993) reported an average of three repairs per year for the RGO.

6. Cosmesis

There are two main aspects of cosmesis:

- (i) the style of walking;
 - (ii) the degree to which the orthosis can be disguised under clothing when required.
- (i) Style of walking

An objective of reciprocal walking orthoses is to mimic able bodied gait as closely as possible. Normal ambulation consists of a free flowing forward progression of the body. The more closely the patient's movements can resemble this activity the more likely is it that the ambulation style will be considered "cosmetic". Whittle and Cochrane (1989) undertook kinematic studies as part of their comparison of RGO and HGO and showed that the latter provided smooth forward translation of the trunk whereas the RGO had periods in the cycle where there was little forward

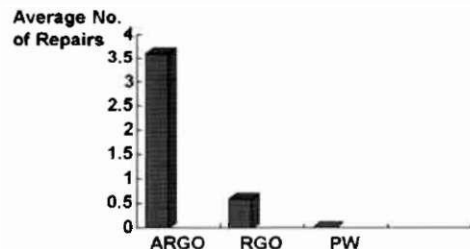


Fig. 4. Mechanical reliability of reciprocal walking orthoses (Lotta *et al.*, 1994).

translation. This difference between cross-linked and free hip hinge reciprocal walking orthoses was confirmed in a further study of three orthoses by Jefferson and Whittle (1990).

(ii) Cosmesis of the orthosis

The Whittle and Cochrane (1989) study elicited a response from patients in this regard and 75% of patients preferred the RGO to the HGO. Whilst there does not appear to be any published data on patient opinions of the ARGO, the appearance is similar enough to the RGO to suggest it would also be considered preferable to the Parawalker in this respect.

7. Weight of the orthosis

The weight of the orthosis will, theoretically, have little or no influence on patient walking performance since they are not required to lift the complete device from the ground during reciprocal walking. However, it is a factor of convenience when not being worn. The heavier the orthosis the more difficult it will be to carry and stow for transportation.

A comparison of the weight of RGO and HGO was made by Whittle and Cochrane (1989) and they reported that the RGO was on average 23% lighter.

Although no formal comparisons which include the ARGO have been published, superficial examination of the design suggests that it falls somewhere between the other two.

8. Overall comparison

Not surprisingly no orthosis is pre-eminent in all areas. As with any device or system the users have to weigh up the attributes and make a choice based on their particular needs. Sufficient information on the various elements affecting overall performance now exists for an intelligent choice to be made.

In healthcare there is an added complication in that the customer may be considered as:

- the patient;
- the clinician;
- the provider;
- the purchaser.

Within the environment it is important for managers to understand the comparisons so that they can quite properly ensure that a rational selection of treatment is made within the context of the purchaser/provider relationship and the priorities of the responsible authority.

The realisation of potential benefits

All the available evidence suggests that walking for paraplegic patients is justified. The existence of competing systems provides choice, but there is a wide divergence of experience. Wide ranging reviews of available systems have now provided data which should reduce confusion and enable choice to be more rationally decided.

A view is still expressed that it is not worth bothering to supply children because they will give it up after a short while – the implication being that the therapeutic benefits will not therefore accrue. The degree to which this happens must depend largely on the effectiveness of the treatment system and the orthosis provided. In the final analysis patient compliance will be the key to long-term benefit.

There have now been three patient compliance studies for the Parawalker (Moore and Stallard, 1991; Major *et al.*, 1997; Stallard *et al.*, 1995). In the first two studies adult traumatic patients had average compliance rates of 64% and 60% with patient's usage being approximately 3 years, whereas the third study of adult spina bifida patients showed a similar compliance rate with patient usage being 7 to 12 years. Sykes *et al.* (1995) reported compliance of children using the RGO as 29% with a mean follow-up period of 5.5 years and Guidera *et al.* (1993) as 48% for an indeterminate follow-up period which was between 0 and 6 years.

These results are greatly superior to other studies of compliance for conventional (e.g. KAFO) paraplegic walking devices (Hahn, 1974; Mikelberg and Reid, 1981; Rosman and Spira, 1974). It would be reasonable to expect a correlation between efficiency of the system, compliance and subsequent long-term benefit.

Unfortunately data on compliance of reciprocal walking systems does not appear to have been made in a coherent and directly comparable manner. However, conclusions on their likely levels could probably be inferred from comparisons of performance data. Since reciprocal walking orthoses are generically superior in walking efficiency to KAFO devices they could all be expected to have improved patient compliance. Nevertheless managers might wish to request data on individual reciprocal walking orthoses so that they can make the appropriate relevant judgements in an independent manner.

Conclusion

Great progress has been made in providing walking for the heavily disabled person since Lorber (1971) reported the disappointing outcome in which 41 spina bifida patients who had undergone 333 orthopaedic procedures were all chairbound. The prime therapeutic purpose of the extensive effort which has been made in this area has now been vindicated and there is clear evidence that provided such systems are supplied by an experienced clinic team with all the necessary resources then the compliance required to achieve those objectives can be forthcoming.

The challenge now for the healthcare managers is to reconcile the more obviously recognised costs of walking systems with the long-term and therefore less clearly defined financial savings of ambulation for high lesion paraplegic patients. To ensure they do this effectively they need to evaluate all systems so that they can promote the one which best meets the criteria of all parties – patient, clinician and finance managers.

There is no doubt that there have been disappointments and that scepticism still exists about the true value of walking systems. This is understandable when many have been provided in unsuitable clinical settings which have led to an approach in which the device is supplied without proper initial assessment and the long-term follow-up which is crucial for success. It is for managers to understand this and to ensure that appropriate arrangements for supply exist within their area of control.

Research and development will continue. In the medium term it is likely that the need for further development of purely mechanical orthoses (Stallard and Major, 1995) will lead to the evolution of better, more efficient orthotic structures. More sophisticated approaches involving electrical stimulation of paralysed muscles (Petrovsky *et al.*, 1985; Andrews, 1986; McClland *et al.*, 1987; Hermans, 1992) may produce further benefits but will demand greater investment in research and more time.

The financial implications of walking for the heavily handicapped have now become much more clearly defined. Managers need to recognise the necessity of proper professional assessment of patients, careful selection of treatment, provision of training and routine follow-up. When all that is done the published

results show that the outcome is worthwhile. Clinicians and managers alike can now provide walking for future social benefit and can do so in the knowledge that there is both therapeutic and financial justification for this. Reconciling the long-term benefits and short-term costs is therefore considerably less of a problem than once it was.

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