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A review of 42 patients of 16 years and over using the ORLAU Parawalker

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Abstract

A 7 year retrospective review of 42 patients of 16 years or over using the ORLAU Parawalker has been conducted to establish the degree of long-term compliance in using the orthosis on a regular basis. Regular use was defined as putting the orthosis on at least once a week.

All subjects had been supplied with an ORLAU Parawalker via the routine supply procedures adopted in Oswestry, and were followed up at regular 6 month intervals as part of the standard treatment regime.

The records from routine follow-up were surveyed for those patients who were continuing to use their orthosis to establish age, length of time since supply of orthosis and cause of lesion. Average period of usage is calculated for those still using their orthosis, and for all patients in the study.

Of the 42 subjects, 32 were myelomeningocele patients with confirmed absence of innervation of hip extensors and abductors, the remainder being paraplegic patients with traumatic or acquired complete thoracic lesions. Compliance figures were extracted from the results, as were the minimum possible average periods of usage. The respective results were:

- of the 32 myelomeningocele patients 59.4% continued usage after an average period of 85.5 months, and
- of the 10 traumatic or acquired lesion patients 60% continued usage after an average period of 24.8 months respectively, which gave a combined compliance of 59.5% after a minimum average 71.1 months of use.

The performance of myelomeningocele patients suggests that their additional deformities do not lead to inferior compliance as adults and that a high proportion to continue to walk after adolescence.

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Introduction

The continuing interest in reciprocal walking for paraplegic patients is reflected in the growing number or orthoses which are becoming routinely available. Well established designs (Butler and Major, 1987; Douglas *et al.*,1983) have been supplemented more recently by new variants (Lissons *et al.*, 1992; Motloch, 1992; Kirtley, 1992) and further fundamental work on Functional Electrical Stimulation (FES) (Bajd *et al.*, 1989; Hermens and Baardman, 1993; Marsolais and Kobetic, 1987) and hybrid systems (Cliquet *et al.*, 1986; Nene and Jennings, 1989; Isakov *et al.*, 1992) is continuing in the search for even greater levels of ease and efficiency of walking.

The evidence of Mazur *et al.* (1989), who showed that non-walkers had five times the number of pressure sores, twice the number of bone fractures, with walkers being almost four times more likely to be independently mobile within the community as teenagers, strongly suggests that the earlier claims of therapeutic benefit and improved independence for heavily handicapped patients who ambulate regularly

(Rose, 1976; Carroll, 1974; Menelaus, 1987) are justified. Nevertheless doubts persist that the long-term patient compliance necessary to realise those benefits can be sufficiently achieved to warrant the costs of both the orthoses and the required monitoring and treatment of patients.

The market environment in which healthcare increasingly takes place demands an appropriate balance between benefits and costs. This requires that where potential benefits are identified they must be shown to occur in a significant number of patients. Prior to the development of effective reciprocal walking system lower limb orthoses were rarely used over sufficiently long periods by thoracic lesion paraplegic patients for the claimed therapeutic benefits to be realised. Many spinal injuries centres have refrained from prescribing knee-ankle-foot orthosis (KAFO) for this group because their experience suggested that less than ten per cent of such patients continue to use them for more than six months. Paraplegic patients with complete lesions between T1 and T6 were reported by Rosman and Spira (1974) not to use their orthoses at all and those with lesions at T7 to T11 for standing purposes only. A review of a range of spinal cord lesion patients of 15 years and older (Mikelberg and Reid, 1981) showed that for 12 of these with complete thoracic lesions (4 T5-T7 and 8 T12-L1) using bilateral KAFOs and 9 incomplete lesions from C7 to cauda eqina (3 of whom had one KAFO and 1 AFO) only 45% continued to use their orthoses. The follow-up period varied from one to six years but distribution of the time span was not reported. Hahn (1974) reviewed 52 patients with complete lesions at L1 or above using fixed ankle KAFOs. Of those reviewed only 35% reported they could walk 'solo' at a follow-up period of approximately two years.

A more recent study (Moore and Stallard, 1991) of adult traumatic lesion patients has shown the use of an effective reciprocal walking orthosis as part of an on-going treatment regime can produce much improved patient compliance. In a review of 50 patients with complete thoracic lesions using the Parawalker, 64% continued to use their orthoses on a regular basis at an average period since supply of 34.4 months. The higher level of compliance was attributed to the ease of walking in the device and the simplicity of putting on and taking off the orthosis. Subsequent comparative reviews of different reciprocal walking systems have confirmed this device as the most efficient and mechanically reliable of those which are currently available (Whittle and Cochrane, 1989; Banta *et al.,* 1991; Bowker *et al.,* 1992; Jefferson and Whittle, 1990; Lotta *et al.,* 1994; Bernardi *et al.,* 1995), and this suggests that the improved compliance should be consistently achieveable.

The mechanical difficulties of providing walking for children are much less pronounced (Stallard *et al.,* 1989) and as a consequence concern about compliance has largely been confined to adult patients. In most healthcare systems paediatric patients are given more regular routine attention and this further enhances the likelihood that they will persist with their walking programme. However, there is a widely acknowledged difficult transition phase at the time when paediatric patients become adolescent and are able to make their own choices. Since the majority of these will have congenital lesions with the associated increased incidence of deformities which mitigate against walking, the problems for these patients as they move into adulthood may be further exacerbated as compared with traumatic lesion adults who have independently elected to ambulate.

Routine supply of the Parawalker has continued in Oswestry since the earlier study of compliance in adult traumatic thoracic lesion patients (Moore and Stallard, 1991). During that period not have only have additional patients in that category been newly supplied, but many of the paediatric patients treated prior to the original study (who as children did not qualify for it) have passed through adolescence into adulthood. A new study incorporating freshly supplied adults and paediatric patients becoming "adult" has therefore become possible which has enabled the influence of the "adolescence transition" to be examined and more light to be shed on the potential for long-term compliance.

Patients and methods

A 7 year retrospective review of patients supplied with the ORLAU Parawalker was conducted on patients who were 16 years and over. At this age many patients lose access to

paediatric physiotherapy services and effectively become adults in terms of clinical provision.

The myelomeningocele patients in the study included all those being routinely followed up in Oswestry who were or had become adult during the 7 year retrospective review and had lesions which had caused them to have lack of control of hip abductors and extensors.

The adult traumatic or acquired lesion paraplegic patients were all over 16 years of age and had complete thoracic lesions at level L1 or above. This study includes all such subjects who had been supplied subsequent to the Moore and Stallard (1991) review.

Each of the patients had been routinely supplied with an ORLAU Parawalker (Butler and Major, 1989) at Oswestry and were following the pattern of six monthly review which is an essential part of the treatment system.

Data was collected by surveying the patients' records held in ORLAU and maintained by physiotherapists during the regular reviews. Although many factors are recorded this study is restricted to:

- age (measured at the end of the 7 year period);
- length of usage at the time of the survey, if the orthosis was still being used at least once a week. The term 'use' is here defined to mean that the subject put the orthosis on to experience some benefit as perceived by them. Thus, as in the Moore and Stallard (1991) review, this may include functional, recreational or walking benefits. Patients who did not attend for review or respond to correspondence were deemed to have discarded their orthosis and ceased complying;
- cause of lesion (traumatic (or acquired) or myelomeningocele).

Records were only available for those patients who were still using their orthosis. For this reason Average Period of Use is calculated for those still using, with a supplementary average for all patients in the survey, assuming immediate cessation after supply for those who had given up, to indicate the worst possible theoretical outcome.

Results were computed as follows:

$$\bar{P}_u = \frac{\sum t}{n_u}$$

$$\bar{P} = \frac{\sum t}{n}$$

$$\bar{A} = \frac{\sum a_u}{n_u}$$

$$C_u = \frac{n_u}{n} \times 100\%$$

where:

$\bar{P}_u$ = average period of time since supply for those still using
$\bar{P}$ = average period of usage for all subjects
$\bar{A}$ = average age of users in the study
C = Ccompliance
t = period of use for each user (assumed 0 for those no longer using)
a_u = age of each subject still using their Parawalker
n = total number of subjects in study
n_u = number of subjects still using their Parawalker

Results

Of the 42 patients in the study 10 had traumatic or acquired lesions and 32 myelomeningocele lesions. Some 25 of all these continued to use their orthosis on a regular basis.

The results are summarised in Table 1. Compliance for the traumatic or acquired lesion patients was 60% with the average time from supply being 41.3 months for those still using their orthosis (or 24.8 months assuming all non-users gave up immediately), whereas the myelomeningocele patients had a compliance of 59.4% with the average time from supply being 144 months for those still using their Parawalker (or 85.5 months assuming all non-users gave up immediately)

Combining the two groups gives an average compliance of 59.5% with an average time since supply of 119.4 months for those still using (or 71.1 months assuming all non-users gave up immediately).

The average age of all patients in the study was 25.0 years, with the paraplegics having an average of 34.8 years and the myelemeningocele patients an average of 21.9 years.

Discussion

As indicated above, those patients who failed to attend for review or answer correspondence

Table 1. Summary of results

	Traumatic subjects	Myelomeningocele subjects	Traumatic and myelomeningocele subjects
Compliance	60%	59.4%	59.5%
Average time since supply for those still using	41.3 months	144.0 months	119.4 months
*Average time of usage for all subjects	24.8 months	85.5 months	71.1 months
Average age of subjects still using	34.8 years	21.9 years	25 years

*This assumes, because information was not available, that the non-users had ceased using their orthosis immediately and therefore represents the worst case possible.

were deemed to have discarded their orthosis. Experience has shown that a small number of patients ignore calls for routine review until they perceive a problem for themselves, despite continued regular orthotic walking activity. Thus the results presented represent the most pessimistic interpretation possible and may mask a better result.

Nevertheless, results which show a compliance of 59.5% with an average period of usage of almost 6 years (assuming an absolute worst case in which those patients who had given up and for which data was not therefore available had ceased using their orthosis immediately) provide further evidence to bolster the confidence of those who consider walking for heavily handicapped patients worthwhile. Taken in the context of the Mazur *et al.* (1989) findings, in which non-ambulatory children had five times the number of pressure sores, it also suggests that there are direct economic benefits in a long-term walking programme. A full cost analysis of providing a Parawalker in ORLAU indicates that a 3 year programme requires total resources of between £2000 to £2300 per annum. This is supported by a similar analysis in a separate clinical centre (Pratt, 1992). Treatment of a pressure sore has been estimated as costing between £1,000 (El Masry, 1995) and £26,000 (McSweeney, 1994). Taking the cost of a walking programme over the 10 years duration of the Mazur *et al.* (1989) study and comparing it with that of treating the additional pressure sores of non-walkers reported by them over the same period suggests that the use of ambulation orthoses could provide a saving of between £4,000 to £8,000 per annum for each ambulatory patient. This more than covers the cost of treating the 40% of patients supplied with an orthosis who then drop out even taking no account of the additional costs of treating fractures. The misery and inconvenience caused by a pressure sore or bone fracture cannot be ascribed a financial cost, but is clearly extremely worthwhile avoiding in social terms.

Results for the paraplegic patients were strikingly similar to those reported by Moore and Stallard (1991) for a similar group. The performance of the myelomeningocele patients compares very favourably with that of the traumatic paraplegic patients within this review and that reported by Moore and Stallard (1991). This suggests that the majority do understand the benefits of a walking programme, and that despite the additional difficulties which their deformities create a significant number continue to ambulate through and beyond adolescence. The myelomeningocele patients were on average very much younger than the paraplegic

patients in both studies. Whilst no immediate significance can be read into this, it is possible that as they get older their compliance may vary more widely from that shown by the paraplegic patients.

The implied higher level of independence in later life made possible by a walking programme is potentially of great significance. In their study of 36 matched pairs of myelomeningocele patients Mazur *et al.* (1989) reported that walkers were almost four times more likely, as teenagers, to be independent in mobility within the community than non-walkers. This outcome has important financial implications for society as well as the individual patient. The burdens on social services and the patient's immediate family are likely to be considerably relieved by a post adolescent ability to take responsibility for independent general mobility. Local anecdotal evidence on adult myelomeningocele patients treated with the Parawalker from an early age suggests that their ability to achieve this is in line with that reported by Mazur *et al.* (1989) for ambulatory patients. However, additional research will be necessary for this to be positively confirmed.

Effective walking programmes demand a very significant commitment by the patient and their family. Additional problems for walking created by deformities commonly found in myelomeningocele patients are not insignificant, and these add to the difficulties of all concerned. The compliance results for the myelomeningocele patients in this study compare favourably with those shown for adult traumatic or acquired paraplegia patients, and this is particularly encouraging. The study of adult traumatic lesion patients by Moore and Stallard (1991) showed a compliance rate of 64% with average follow-up of 34.4 months. That result and its comparison with this review call into question the commonly held view that myelomeningocele patients will have widely divergent outcomes from those of traumatic lesion patients. Experience in Oswestry shows that the prescription of devices which have a high level of mechanical reliability and provide the efficiency and convenience essential to overall independence, used within the context of an integrated treatment system which includes assessment, controlled supply, appropriate orthotic rectification, training and regular routine follow-up, can enable paediatric patients to continue to receive the therapeutic and functional benefits of ambulation through adolescence into their adult lives.

The results reported in this review provide important support for the concept of walking for heavily handicapped patients. In particular it is clear that the effect of a walking programme on independent mobility within the community as patients become mature adults could have very important long-term social and economic implications. Further evidence on the reasons for abandoning ambulation might make it possible to improve the 59.5% compliance rate reported in this study. The present environment in which the delivery of healthcare takes place demands that such issues be given added prominence. It is hoped that this study will justify financial support for a more in-depth research project to establish a wider range of outcomes relative to clinical and health economics issues.

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