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The influence of orthosis stiffness on paraplegic ambulation and its implications for functional electrical stimulation (FES) walking systems

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Abstract

This study examines the evidence which supports the importance of maintaining relative abduction for effective reciprocal walking in high level paraplegic patients. In comparisons of orthoses, where this can only be achieved mechanically, those with higher lateral rigidity consistently showed greater levels of walking efficiency. The influence on hybrid systems of functional electrical stimulation (FES) of the gluteal muscles, where the primary function is to maintain abduction, also showed reductions in overall energy cost, reductions in upper limb effort, or both.

Examination of the effect of increasing lateral rigidity of a purely mechanical orthosis by 10% showed that significant energy cost reductions were achieved (30% reduction in Physiological Cost Index) for patients with thoracic lesions experienced in reciprocal walking.

A review of FES research suggested that for the modern healthcare sector the cost effectiveness of purely mechanical systems make them an attractive means of routinely providing the functional and therapeutic benefits of walking for high level paraplegic patients. In the prevailing climate of strict budgetry control a case is made for concentrating more research resources on improving still further walking efficiency, and resolving the outstanding problems of functionality and cosmesis in such systems for reciprocal walking.

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Introduction

A widely held view that walking for paraplegic patients is worthwhile (Carroll, 1974; Rose, 1976; Menelaus, 1987) has led to steady improvements in performance of standard mechanical orthoses (Douglas *et al.*, 1983; Butler and Major, 1987; Campbell, 1989; Kirtley, 1992; Motloch, 1992; Lissens *et al.*, 1993). The social and economic value of these developments has been underpinned by research which shows that ambulatory paraplegic patients have half the number of bone fractures and one fifth the number of pressure sores (Mazur *et al.*, 1989). It has been demonstrated that when an orthosis is supplied in a fully controlled clinical environment the majority of patients with thoracic lesions will continue to use the device on a long term basis (Moore and Stallard, 1991). Nevertheless there remains concern that the physical effort involved in walking and the cumbersome nature of the devices required for this purpose deter many patients who could potentially benefit from this activity.

Ambitions to achieve further improvement are manifested in research and development in the separate areas of FES, mechanical orthoses, and also in combinations of these in what are termed hybrid devices.

Each of these approaches appears to have advantages and disadvantages, and all of them require appropriate compromises within the context of paraplegic ambulation (Stallard *et al.*, 1989). However, as research progresses some of the features essential to effective ambulation have become clearer. Lateral stiffness of a mechanical orthosis to enable swing leg clearance to occur easily is amongst the most

important of these. The research and clinical experience of this feature has important lessons not only for future mechanical developments but also for FES research.

Lateral rigidity in orthotic reciprocal walking

A requirement of effective reciprocal ambulation is that relative abduction of the hips is maintained (Rose, 1979; Stallard *et al.*, 1986). The ORLAU ParaWalker (Butler and Major, 1987) has been designed to achieve this by providing a high degree of lateral rigidity to permit easy clearance of the swing leg so that patients with complete thoracic lesions can walk with crutches.

To establish the effectiveness of this mechanical approach patient reviews and energy cost studies have been undertaken on the ORLAU ParaWalker system (Fig. 1), as supplied through clinical teams appropriately trained in the relevant techniques (Stallard *et al.*, 1991; Nene, 1993). These, together with other independent studies (Jefferson and Whittle, 1990; Banta et al., 1991; Bowker *et al.*, 1992; Philips *et al.*, 1995) have shown it to be an efficient device relative to other orthoses in the context of current routine practice.

Fig. 1. Patient with mid-thoracic lesion walking reciprocally with crutches in the ORLAU ParaWalker.

Straightforward mechanical analysis of an orthotic structure shows that it can be up to sixteen times more difficult to maintain abduction in adult patients than it is with children (Stallard and Major, 1993). This indicates the potential, even with the most rigid orthotic structures, for either improving mechanical stiffness or supplementing it with functional electrical stimulation of appropriate muscles to provide additional musculo-skeletal support within the structure.

Functional electrical stimulation (FES) walking

FES has been used successfully by paraplegic patients with complete thoracic lesions in controlled environments (Kralj and Grobelnik 1973; Marsolais and Kobetic, 1987; Frech, 1987; Kralj and Badj, 1989). However, concern about the safety of such systems with their present degree of control, the energy requirement and the need to use walking frames rather than crutches has led to the development of hybrid systems in which FES has been used to supplement the function of mechanical orthoses (Petrofsky *et al.*, 1985; Andrews, 1986; McClelland *et al.*, 1987; Vorsteveld *et al.*, 1992).

A common approach has been to base a hybrid system on one of the mechanical orthoses now in routine service which enable paraplegic patients to walk reciprocally, using either a walking frame or crutches. The ORLAU ParaWalker was utilised as the basis of a hybrid system for development purposes. Results of research on that system have enabled comparisons to be made with similar hybrid approaches to walking and lead to some generalised conclusions which have important implications for further work on FES walking.

ORLAU hybrid system research

Experimental work on six patients has been undertaken in ORLAU to establish the degree to which stimulation of the glutei on the stance side can compensate for the decreasing rigidity of the ParaWalker for adult patients.

The system consisted of a standard

ParaWalker in which the patient had been trained to walk reciprocally with crutches (Stallard *et al.*, 1986). Twin channel stimulation which delivered 60 to 100V at 20 Hz was also applied following a period of training of the glutei and quadriceps by means of a stimulator with similar specification. Training was carried out for a minimum period of 3 months on a daily basis until adequate muscle bulk had been developed (Patrick and McClelland, 1985). Patients were then fitted and trained with the hybrid system in the laboratory.

Monitoring the effect of the ORLAU hybrid system

Once patients had become proficient with the new system and could adequately control the timing of gluteal stimulation on the stance side via crutch handle mounted switches, two separate performance parameters were monitored and field trials were conducted.

Crutch impulse

The vertical ground reaction force applied through the crutches was measured. A Kistler force platform was used to record amplitude against time, as described by McClelland *et al.* (1987). The integral of force/time is known as impulse and is directly related to the effort required of the upper limb to ambulate in a reciprocal walking device. Each patient had impulse measured using the ParaWalker alone and then, after a suitable period, in the ParaWalker supplemented by the gluteal stimulation system.

In a study of six patients (Stallard and Major, 1993) it was shown that five had reductions in impulse when stimulation of the gluteal muscles on the stance side was used, and that one patient had a marginal increase (Fig. 2). The average reduction in upper limb effort required to walk when stimulation was applied, as indicated by impulse measurements, was 18.7% (including the patient in whom a small increase was recorded).

Energy cost

Five patients had their overall energy cost of walking monitored using oxygen uptake (Nene and Patrick, 1990). In four out of the five a decrease in energy cost of between 6% and 9% was recorded when patient controlled stimulation of the gluteal muscles on the stance side was used. The fifth patient recorded no change in energy cost. The patient in which no change occurred was the one where a marginal increase in crutch impulse was noted when FES was used.

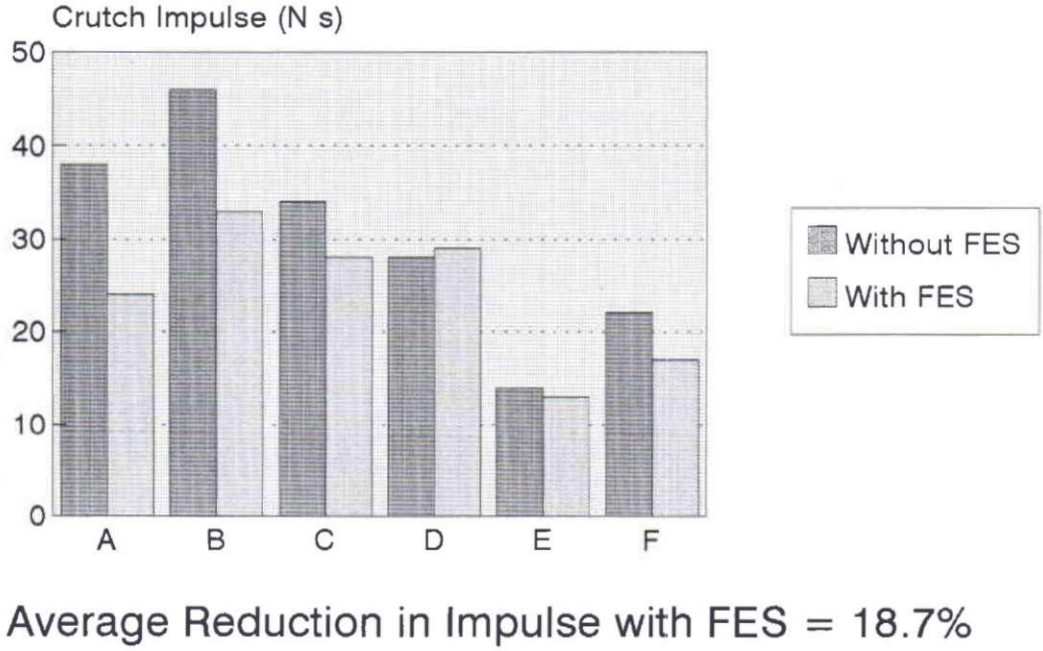

Fig. 2. Crutch impulse for six thoracic lesion patients using the ORLAU Standard and Hybrid ParaWalker systems.

Field trials

Following laboratory trials with the hybrid system patients were invited to try it at home and to comment on its effectiveness in general use. A common series of problems was reported by patients. These were:

1. difficulty of accurate electrode placement;
2. inconsistent stimulation;
3. the extra time it took to apply the system;
4. cross-stimulation of abdominal wall muscles when stimulation amplitude was high enough to be effective in the field environment.

All patients eventually elected not to use the option FES system and went on to use the purely mechanical ParaWalker system with what they considered adequate effectiveness.

Measuring the effect of lateral stiffness

Whilst the circumstantial evidence supports the importance of lateral stiffness in walking orthoses for paraplegic patients, a number of difficulties have previously prevented direct comparisons of the effect of increasing orthotic stiffness on walking efficiency. The introduction of a modified ORLAU ParaWalker '89 hip joint which has 70% greater lateral rigidity (Stallard and Major, 1992) provided an opportunity to monitor changes in patients for whom a replacement orthosis was required. Measurements of orthosis rigidity showed that the new, stiffer hip joint provided an overall increase in lateral orthosis stiffness of 10% (Stallard and Major, 1993).

Patients

The ORLAU ParaWalker '89 was supplied to patients for whom a new orthosis was required after a period of several years in the original ParaWalker design and where circumstances also permitted pre and post supply energy cost monitoring. Details of the three patients are shown in Table 1.

Method

Relative energy cost was measured using Physiological Cost Index (PCI) (Butler *et al.*, 1984). This represents the difference in heart rate between resting and walking divided by speed to give units of heart beats per metre walked i.e.

Table 1. Patient details

Patient	Sex	Age	Level of Lesion
A	M	28	T8/9 Comp.
B	M	31	T12/L1 Comp.
C	M	30	T11 Comp.

$$\text{PCI(bts/m)} = \frac{\text{walking heart rate} - \text{resting heart rate}}{\text{walking speed}}$$

This means of monitoring relative energy cost has been validated in a variety of studies (Rose *et al.*, 1991; Nene, 1993). The precise methodology of monitoring the three patients is that adopted by Nene and Jennings (1989) who established PCI for paraplegic patients using the ORLAU ParaWalker. Telemetered ECG was processed to give patient heart rates whilst resting and then walking over five timed 6.1m runs with one minute rest between each. The PCI for each of the five runs was then averaged to give overall PCI.

Results

Figure 3 shows a histogram of the results for the three patients. From this it can be seen that PCI was significantly reduced in each case when using the ParaWalker '89 device and that the average PCI was changed from 1.4 to 0.98, a reduction of 0.42, or 30%.

Discussion

The evidence that maintaining relative abduction in the lower limbs is one of the most crucial elements of ensuring effective reciprocal walking for high lesion paraplegic patients is becoming ever more irrefutable.

Results reported in this paper of relative energy comparisons in patients who used both the original ParaWalker and the ParaWalker '89 (which is 10% stiffer) provide direct confirmation of the importance of lateral rigidity in walking orthoses for paraplegic patients. Although, because of the mechanical reliability of the ParaWalker together with ethical, logistical and practical difficulties this was done on only three subjects, it confirmed previous compelling circumstantial evidence

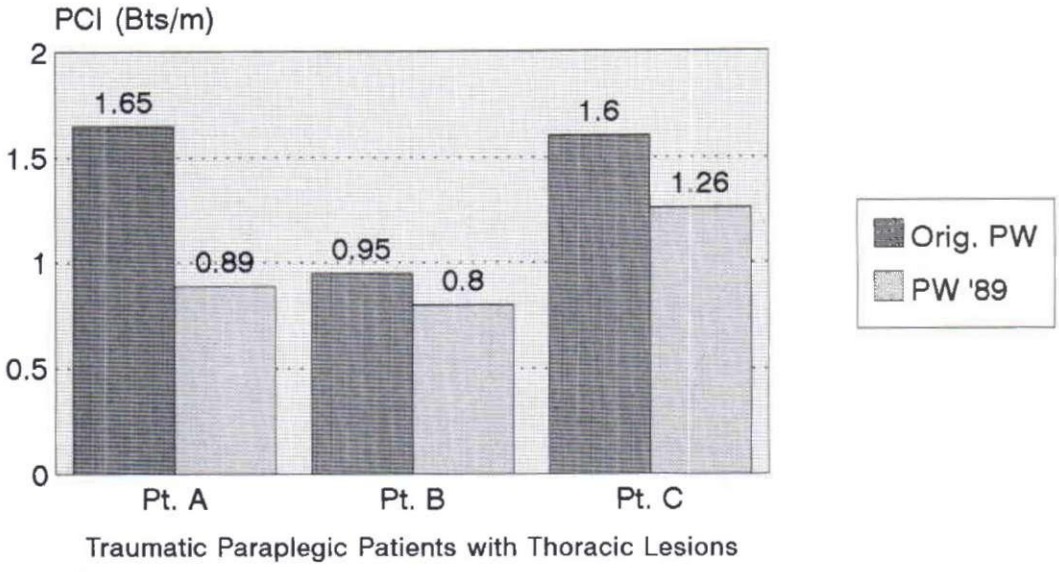

Fig. 3. PCI of three thoracic lesion patients using the Original and '89 ParaWalkers.

supporting the need to maintain relative hip abduction in walking for high lesion paraplegics.

An analysis of the results of research on the ORLAU Hybrid (FES/ParaWalker) System (McClelland *et al.*, 1987; Stallard and Major, 1993) shows that the major contribution of the gluteal stimulation is to ease swing leg clearance by increasing overall lateral rigidity in the patient/orthosis complex, thereby reducing upper limb effort. This results in reductions in overall energy cost (Nene and Patrick, 1990). The added burden of applying the additional FES apparatus led to all of the patients in the trial discarding this element for routine walking in their normal environment.

A study by Alfieri and Marchetti (1993) on a system for paraplegic patients incorporating the Louisiana University Reciprocating Gait Orthosis and FES produced an outcome in which upper limb effort was reduced, but overall energy cost stayed the same. Whilst fatigue in the arms was reduced, this system did not produce the overall energy cost savings seen in the ORLAU system. However, patients tended to retain FES for separate use to relieve spasticity, whilst discarding it for walking.

The common features of these experiences suggest that whilst FES via surface electrodes can be used to supplement mechanical orthoses and effectively reduce upper limb effort, the overall savings in energy cost are either small or non-existent. It is to be expected that energy cost savings will not match the reduction in upper limb effort since the metabolic costs of the stimulated muscle must be taken into account. Patients' unwillingness to tolerate the additional inconvenience of applying electrodes and carrying additional electronic apparatus mirrors the experience of Rushton (1992) in this regard. Healthcare purchasers question the additional cost of hybrid systems and are reluctant in many cases to sanction the necessary expenditure. Performance results suggest that this reluctance has some justification.

A single patient study involving the ORLAU ParaWalker and an implanted FES system (Nene and Jennings, 1989) produced similar patient performance results but greatly

increased the cost and initial inconvenience because of the need for implantation surgery. Further patients have not been tempted by that option.

The use of FES to supplement mechanical orthoses has served to emphasise the importance of maintaining hip abduction if effective walking is to be achieved by paraplegic patients. Whilst the clinical experience suggests that the inconveniences of supplementary FES for walking generally outweigh the advantages of improved performance, there are important lessons to be learned from research in this area:

1. implanted systems will be necessary for FES to be acceptable;
2. for the additional costs and inconvenience of hybrid systems to be justified, greater improvements in performance than those so far achieved will be necessary;
3. pure FES systems will need to address the problem of producing powerful and sustained hip abduction via the gluteal muscles if they are to permit effective and acceptable walking with crutches for patients with complete thoracic spinal lesions.

Unless these problems are addressed it seems likely that FES systems will require to use walking frames for the majority of patients, rather than the more acceptable and practical option of crutches which the most effective mechanical orthotic systems permit.

For hybrid FES systems there would appear to be a case for continuing to control abduction mechanically so as to release the FES system to improve gait in other ways – for example by providing knee flexion in swing phase (Vosterveld *et al.*, 1992).

The new evidence in this paper linking orthosis stiffness directly to walking efficiency emphasises still further the importance of structural properties in mechanical ambulation devices. It is clear that pure mechanical orthoses will remain the most cost effective solution to walking for thoracic lesion patients into the foreseeable future. In a situation where cost benefit analyses will have increasing importance in the health care sector this would strongly suggest that further research and development of mechanical solutions to permit increased walking efficiency, cosmesis and convenience in doffing and donning is now more justified than ever.

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