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The influence of the reciprocal cable linkage in the advanced reciprocating gait orthosis on paraplegic gait performance

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Abstract

A wide variety of mechanical orthoses is available to provide ambulation to paraplegic patients. Evaluation of energy cost during walking in each of these devices has been acknowledged as an important topic in this field of research. In order to investigate the benefits of a ballistic swing on gait performance in the Advanced Reciprocating Gait Orthosis (ARGO) a study was conducted in which the ARGO was compared with an orthosis with freely swinging legs. This Non Reciprocally linked Orthosis (NRO) was obtained by removing the reciprocal linkage in the subjects' own ARGOs. Subsequently, flexion/extension limits were mounted to permit adjustment of stride length. Six male paraplegic subjects with lesions ranging from T4 to T12 were included in the study. A single case experimental design (B-A-B-A) was conducted in order to improve internal validity. Biomechanical and physiological parameters were assessed and the subjects' preference for either ARGO or NRO was determined.

It was found that large inter-individual differences produced insufficient evidence in this study to draw general conclusions about difference in energy expenditure between both orthoses. However, individual analysis of the results showed a reduction of oxygen cost (range: 4%-14%) in the NRO in T9 and T12 lesions, while oxygen cost in subjects with T4 lesions increased markedly (22% and 40%). It is concluded that patients with low level lesions could benefit in terms of oxygen lost from removing the reciprocal cable linkage in the ARGO. However, only one subject preferred the NRO for walking, whereas none of the subject chose the NRO for use in daily living activities. Removal of the reciprocal cable linkage in the ARGO may not be desirable for these patients.

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Introduction

To date, several options are available to provide ambulation to paraplegic patients. A commonly accepted classification of walking systems is that of mechanical orthoses, functional electrical stimulation and a combination of both, the so called hybrid systems (Hirokawa *et al,* 1990; Nene *et al.,* 1996). The use of mechanical orthosis has been described extensively by different authors. Well known systems are long leg braces (Huang *et al,* 1979) and various types of Hip-Knee-Ankle-Foot Orthoses (HKAFOs) including the Louisiana State University Reciprocating Gait Orthosis (RGO) (Douglas *et al,* 1983; Hirokawa *et al,* 1990), Parawalker or Hip Guidance Orthosis (HGO) (Nene and Major, 1987; Rose, 1979; Stallard and Major, 1993) and Steeper Advanced Reciprocating Gait Orthosis (ARGO) (Jefferson and Whittle, 1990).

Researchers of new walking systems have acknowledged that reducing energy expenditure during walking and improving user friendliness, e.g. with respect to donning and doffing, are important targets (Marsolais *et al,* 1988;

Bataweel and Edwards, 1995; Hirokawa *et al,* 1990). By decreasing energy expenditure one may improve the accessibility to walking systems for a larger part of the paraplegic population. Especially high level paraplegics may benefit from reduced energy cost because of their disturbed cardiovascular regulation (Glaser *et al,* 1985). Furthermore, decrease of upper body loading during walking may be worthwhile because of the high prevalence and risk of wrist and shoulder pathology (Aljure *et al.,* 1985; Gellman *et al*., 1988).

In order to decrease energy expenditure during walking in HKAFOs, several possibilities have been described in the literature. It has been suggested to develop a system which allows knee lexion during swing phase (Bataweel and Edwards, 1995; IJzerman *et al.,* 1996). A high lateral stiffness has been described to prevent collapsing of the orthosis (Stallard and Major, 1993). Frontal alignment has been suggested in the HGO Parawalker to obtain a more efficient foot clearance with less displacements of the centre of mass of the body (Rose, 1979; IJzerman[b] *et al,* 1996). The use of a reciprocal linkage in an HKAFO was recommended for decreasing energy cost (Douglas *et al,* 1983).

Theoretical advantages of the reciprocal coupling include the transfer of energy from trunk and hip extension to contralateral hip flexion (Bowker, *et al,* 1992; Stallard and Major, 1993). Because the reciprocal linkage prevents bilateral hip flexion and extension, stance stability is improved (Douglas *et al.*, 1983). If the orthosis is well aligned, subjects are able to stand upright without using their crutches.

Disadvantage of the reciprocal cable linkage in the ARGO and RGO is the 1:1 transmission ratio between stance leg extension and contralateral hip flexion (Andrews, 1993; Yang *et al,* 1996). This 1:1 ratio imposes an unnatural walking pattern and may reduce energy efficiency during gait (Andrews, 1993). Because of the linkage, swing leg acceleration is dependent on the ability of the patient to extend the trunk rapidly. Thus, the momentum of the trunk is transferred to the swing leg.

Walking with freely swinging legs, the so-called ballistic swing, is expected to be more efficient because the movement of the leg is not limited in its natural biomechanical characteristics (Tashman *et al,* 1992). Furthermore, in order to achieve a sufficiently large stride length in the ARGO, i.e. hip flexion, the trunk has to be extended. The consecutive displacement of the centre of mass of the body to the new stance leg results in a walking pattern with alternating acceleration and deceleration of the trunk (Tashman *et al,* 1995).

In order to counter some of the above problems, Yang *et al.* (1996), developed an HKAFO allowing a 2:1 flexion/extension coupling ratio (FECR). By using a 2:1 FECR they achieved sufficient hip flexion with less contralateral hip and trunk extension in comparison with a 1:1 FECR. They compared the 1:1 with the 2:1 ratio and found lower values for the Physiological Cost Index (PCI): heart $rate_{rest}$-heart $rate_{walking}$/speed (McGregor, 1981) for the latter. Winchester *et al.* (1993) investigated the Isocentric® RGO in which a more efficient coupling of both legs was obtained. The Isocentric® RGO mainly prevents unwanted cable movement and friction, but still applies a 1:1 transmission ratio. A significant decrease in PCI was found compared with the RGO.

The present study was conducted in order to determine the influence of the reciprocal cable in the ARGO on performance of paraplegic gait. Interpretation of differences between commonly known orthoses with and without reciprocal cable linkages, e.g. (A)RGO and HGO, is difficult because of the large differences in alignment and stiffness between both devices. To investigate the influence of the cable linkage on its own, it was decided to use the ARGO both as reference as well as experimental Non Reciprocally linked Orthosis (NRO).

Physiological and biomechanical properties were assessed to analyse subjects' gait performance in both orthoses. Crutch forces during gait were measured to determine upper body load. Oxygen uptake measurements were performed to estimate energy requirements. Subjects' preference was determined as well, because of its importance with regard to future design considerations.

Methods

Subject selection

Subjects included in the study were experienced ARGO walkers, motivated to participate in a 4 week training programme followed by an 8 week measurement period. Only paraplegic subjects with complete thoracic lesions were included, in order to obtain a homogeneous population. All subjects read and signed consent forms. The study was approved by the local ethical committee.

Study design

Single case experimental methodology was chosen in order to guarantee internal validity of the study (Barlow and Hersel, 1984). A withdrawal design (B-A-B-A) was used comprising two NRO (NRO_1 and NRO_2) and two ARGO ($ARGO_1$ and $ARGO_2$) measurements.

Single case methodology has been used to study longitudinal change when applying a specific treatment (Campbell, 1988; Hacker, 1980). The walking performance in a specific orthosis is usually a stable situation, which only requires control for measurement errors and random errors due to patient performance. Therefore, the design in this project comprised only one assessment in each phase, assuming that period effects were cancelled out.

A two week interval was used between two consecutive assessments in order to make patients accustomed to the orthosis to be measured next. Differences in patient performance due to test effects were thought unlikely to occur since all subjects had participated in previous studies and were familiar with the test procedures. An extensive training period was conducted prior to the measurement period in order to prevent bias due to training effects.

Training

The reciprocal cable in the ARGO was removed at the subjects' first visit to the unit. Subsequently, flexion/extension limits were mounted to the hip joints to permit adjustment of stride length. A 4 week training programme in the NRO was conducted in order to optimise stride length and walking technique in the NRO and to improve physical aerobic capacity. The criterion for starting the measurements was the ability to walk independently with a smooth and regular walking pattern for at least 15 minutes. Use of walking aids and crutch height were standardised for the ARGO as well as the NRO.

Measurements

The measurement protocol comprised physiological and biomechanical assessments, followed by a questionnaire. Repeated measurements of the subject took place on the same time of the day with a similar measurement sequence. Each assessment took place at the end of the two week interval between the measurements.

Physiological assessments

Subjects were asked to refrain from coffee or food for at least 2 hours prior to arrival at the unit. All subjects were non-smokers.

Breath-by-breath measurement of inspired and expired gases was conducted by using the OXYCON-alpha system (Jaeger, The Netherlands). The system was put on a trolley to be able to measure continuously during walking. Subjects were provided with a heart rate belt (Sport Tester, PE3000, Polar Electro, Finland) and a facemask with a flexible gas-tube. Measurement of rest metabolism was performed during 5 minutes, while the patient sat quietly. Subsequently, subjects were helped to stand up and when the heart rate approached a stable level, subjects were instructed to walk at a comfortable, self-selected speed during 10 minutes along a circular 125 metre pathway. The assessment ended with the analysis of the recovery period during 10 minutes (Fig. 1).

Heart rate, oxygen cost V02 ($ml.min^{-1}kg^{-1}$), carbon dioxide VCO_2 ($ml.min^{-1}kg^{-1}$), Respiratory Exchange Ratio (RER), tidal volume (1), breathing frequency (min^{-1}) and expiratory volume ($l.min^{-1}$) were monitored. VO_2 and VCO_2 were expressed in relation to lean body mass (kg LBM).

A delayed steady state was expected since substantial anaerobic energy contribution during walking was found in other studies (Huang *et al.*, 1979). Therefore, oxygen cost (E02) and PCI (McGregor, 1981) were calculated by averaging over the last 5 minute interval according to:

EO_2 ($ml.min^{-1}.kg^{-1}$) = VO_2/walking speed

PCI ($beats.m^{-1}$) = (heart rate$_{steady\ state}$ - heart rate)/v,

where v = walking speed during steady state.

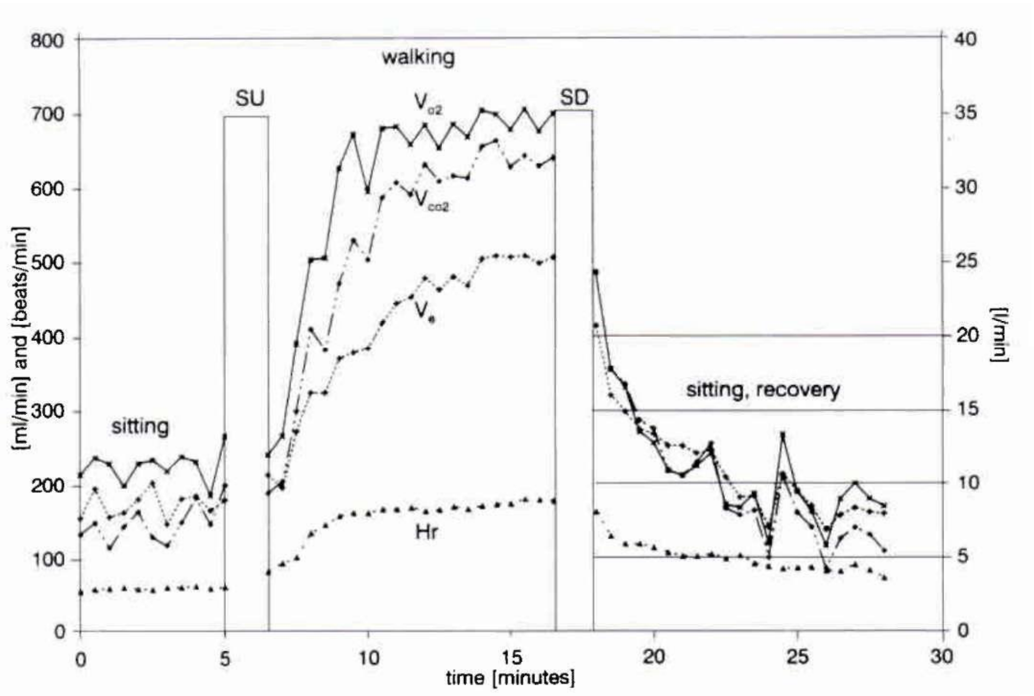

Fig. 1. Physiological measurement of one subject in ARGO. Oxygen uptake (Vo_2), carbon-dioxide (Vco_2), heart rate (Hr) and expiratory volume (V_e, right y-axis) are presented The total elapsed time is presented on the x-axis. The protocol comprises sitting, standing up (SU), walking, sitting down (SD) and sitting recovery. A delayed steady state exercise level was reached after approximately 6 minutes.

Biomechanical assessments

Kinetic and kinematic assessments were performed in the gait lab using a 5 camera 3D motion analysis system (VICON 370, Oxford Metrics, Oxford, UK). Each assessment consisted of 10 trials along a 10 metre gait lane to ensure approximately 20-30 strides for averaging. Marker positions of both ankles were sampled at a frequency of 50 Hz. Crutch forces and heel contacts were recorded simultaneously at 200 Hz using strain gauges and foot switches respectively. All data were filtered (linear phase 2nd order Butterworth, F_{-3dB} = 5 Hz) and split into gait cycle intervals using the heel strike data.

Stride length (m) and cadence (strides.min^{-1}) were calculated from the ankle marker data. Crutch Force Time Integral (CFTI) and crutch peak force (CPF) were calculated and normalised for body mass.

Questionnaire

Two questions were used to determine subjects' preferences regarding walking and general use of ARGO as well as NRO:

1. Did you like this orthosis for general use in in your home situation?
2. Did you like this orthosis to walk with?

Subjects were asked to give their opinion at each measurement day independent from the investigators. Subjects were not asked to compare the devices, since these comparisons may be subject to information bias (Sackett, 1979). Both items were scored on a 10 point scale as well as on a Visual Analogue Scale (VAS) (Price *et al,* 1983), ranging from dislike to excellent orthosis. The scores were averaged in order to obtain one general opinion about general use and about walking.

Data analysis

Box-plots, presenting median, 25% and 75% percentiles and range, were made to determine the distribution of each variable. Natural log transformations were applied to unskew the variable if necessary. Non-parametric tests were used if unskewing did not succeed.

Despite the real difference between ARGO and NRO, a difference between ARGO and NRO can be a result of a period effect (Pocock, 1983). Period effects were separated into training effects due to improvement of walking performance in time and tests effects due to differences in measurement situation, e.g. heart rate measurement can be subject to test effects.

Training effects were tested statistically by means of a paired t-test for the difference between first and second NRO measurements (NRO_1 and NRO_2). Systematic measurement errors and test effects were examined by comparing first and second ARGO measurements ($ARGO_1$ and $ARGO_2$).

The difference between both orthoses was estimated by calculating 95% confidence intervals for the averaged ARGO minus the averaged NRO measurements using paired t-tests. All confidence intervals are presented as relative increase or decrease with respect to the baseline ARGO. Differences in outcome on the questionnaire and in oxygen cost of more than 20% were considered clinically relevant. If the upper and lower limit of the confidence interval for the difference crossed the 20% level, it was concluded that there was insufficient evidence to draw conclusions in hypothesis testing. A p-level of 0.05 was considered significant. All analysis were done using SPSS.

Results

Six male subjects were included in the study. Two subjects had T4, three subjects T9 and one subject a T12 complete lesion (Table 1).

Cadence, oxygen cost, PCI and expiratory volume had skewed distributions. Natural log transformations yielded a log normal distributed parameter. CFT1 was negatively skewed distributed, but the natural log of (1-CFTI) appeared adequate to obtain a log normal distributed variable. Using (1-CFTI) is justified because of the expected asymptotic value of crutch force measurements.

No significant differences between $ARGO_1$ and $ARGO_2$ were found, indicating that tests effects were avoided. No significant differences in biomechanical data between NRO_1 and NRO_2 were found, indicating absence of a training effect.

The physiological reaction of walking performance was analysed in order to determine steady state exercise performance. Figure 1 shows a typical result of one subject walking in the ARGO.

Expiratory volume increased during the first six minutes of walking. VO_2 and VCO_2 were at a stable level after 4-5 minutes. Heart rate rapidly increased up to 160 $beats.min^{-1}$ in the fourth minute.

Oxygen cost and PCI were not significantly different in the ARGO compared to NRO (Fig. 2). VO_2 and RER were not significantly higher in ARGO ($p>0.13$ and $p<0.12$ respectively) (Fig. 2). No significant differences were found in expiratory volume and heart rate. Stride length was not significantly lower in the NRO ($p<0.07$) (Fig. 3). CFTI was not significantly higher in the ARGO ($p<0.08$) (Fig. 3). No

Table 1. Subjects included in the study Weight is expressed in kilogram (kg) and kilogram lean body weight (kg LBW). Mean and standard deviation are calculated.

subject	sex/age	mass (kg/kgLBM)	lesion	walking speed ($m.s^{-1}$)	training in NRO (hours)
1	m/34	66/50	T12	0.41	16
2	m/40	67/53	T9	0.29	16
3	m/57	80/50	T9	0.09	20
4	m/44	90/67	T9	0/20	20
5	m/28	73/57	T4	0.20	14
6	m/29	79/64	T4	0.21	16
x±σ	38.7±10.9	75.8±9.0 56.8±7.3		0.23±0.10	17.0±2.4

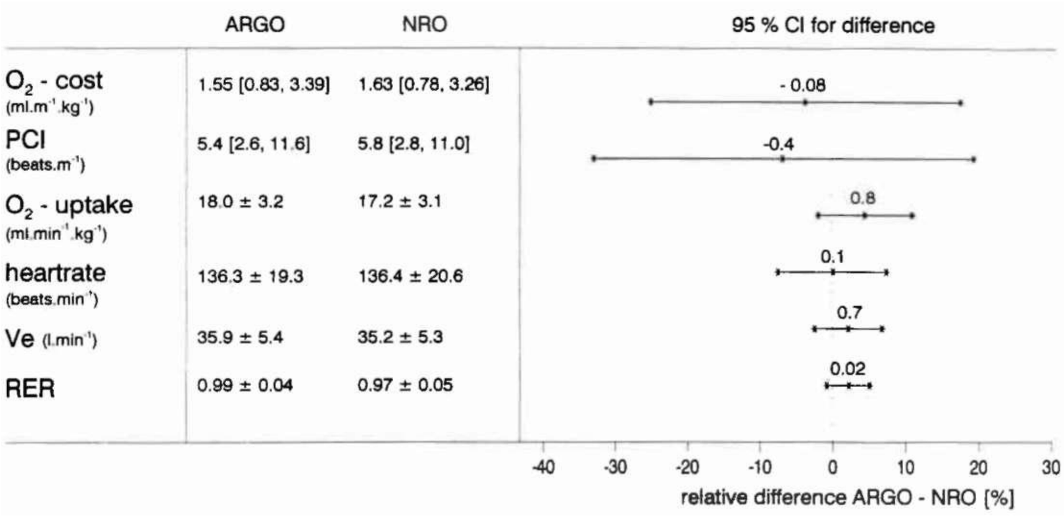

Fig. 2. Confidence intervals (95%) for estimated difference between ARGO and NRO. Mean and standard deviation of each parameter is presented for ARGO as well as NRO. The mean difference between ARGO and NRO is presented on top of the interval. The upper and lower limits of the intervals are presented as relative difference with respect to the baseline ARGO measurements. Negative value of O_2-cost and PCI indicate lower energy requirements during walking in the NRO.

differences in walking speed, cadence and CPF were found.

The scores of subjects on the VAS as well as on the 10 point scale appeared to be consistent. Analysis of the questionnaire showed that subjects preferred the ARGO for use in daily living (Fig 4). No significant difference was found with respect to walking in either the ARGO or NRO.

The large standard deviation for the differences of clinically important effect measures suggests the existence of large inter-individual differences in outcome. Subjects with T9 and T12 lesions showed consistently lower oxygen cost in the NRO (Fig. 5). Both subjects with T4 lesions showed a clinically relevant increase of oxygen cost in the NRO. Although oxygen cost was lower in the NRO in T9 and T12 subjects, only two were satisfied with walking in the NRO. Three subjects with low level lesions ultimately preferred the ARGO.

Discussion

One major concern in comparing different

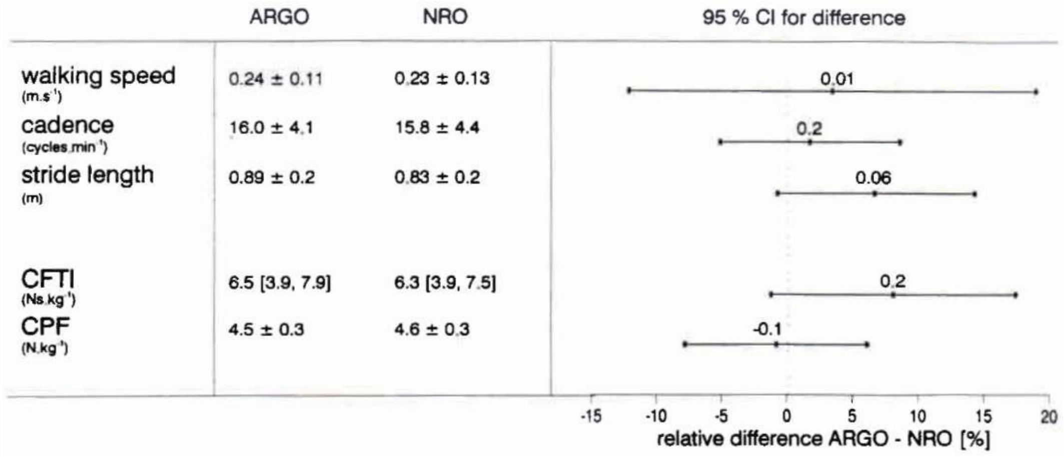

Fig. 3. Confidence interval for relative difference of biomechanical measurements. For explanation of figure see caption Figure 2.

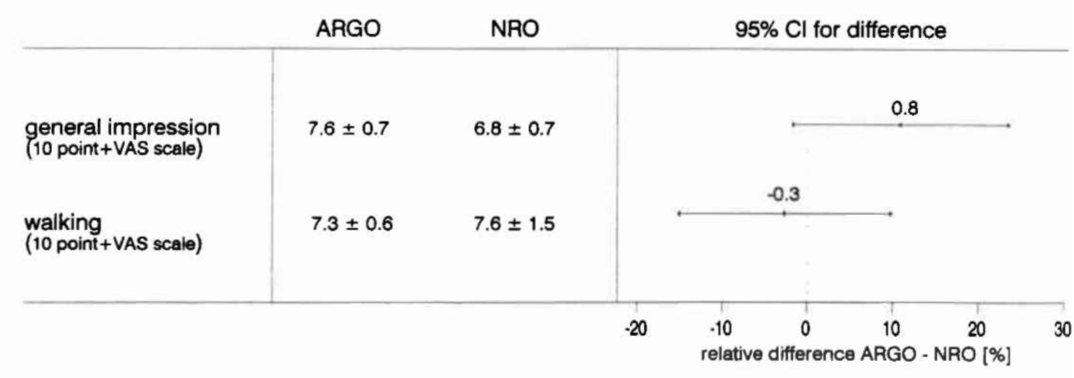

Fig. 4. Subjects' preference for either ARGO or NRO regarding general use in ADL and walking. For explanation of figure see caption Figure 2.

types of orthoses is the prescription and execution of an adequate and sufficient training programme, especially when a specific walking technique has to be learned. Whittle and Cochrane (1989) found that gait training for the Parawalker, which is a system similar to the NRO took 14.4 hours over 5 days, on average. Subjects in the study of Winchester *et al.* (1993), underwent gait training of 12 hours in the Isocentric RGO. In the current study subjects were trained in the NRO for 17.0±2.4 hours. This was thought to be sufficient in order to eliminate training effects. Comparisons of biomechanical data of both NRO measurements underline this assumption.

In the current study it was found that subjects preferred the ARGO for use in daily living. It appeared that they experienced an uncomfortable standing posture in the NRO, leaning in the flexion limit. On average,

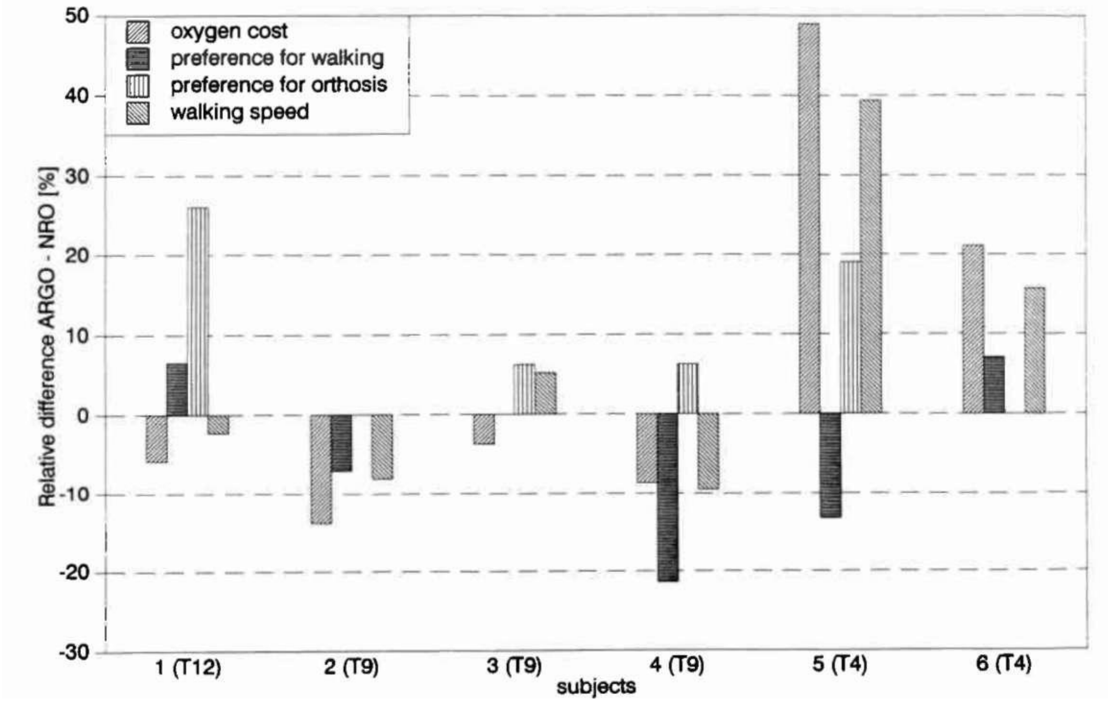

Fig. 5. Display of relative changes in oxygen cost, walking speed and subjects' opinion with respect to general use and walking in both orthoses. Positive differences indicate higher value of parameter in ARGO.

subjects did not prefer the NRO for walking (Fig. **4).** Some remarks can be made with respect to assessment of user aspects by means of a questionnaire. Whittle and Cochrane (1989) have extensively reviewed clinical and user aspects of the RGO and HGO. They noticed that there may be bias in favour of the orthoses which were assessed second in their cross-over trial. Subjects' opinions with respect to a new device may also be subject to recall bias (Sackett, 1979). The new orthosis probably gets more attention from the researchers than the baseline system, i.e. ARGO, and the recall of subjects with respect to ARGO and NRO may differ in volume and accuracy. On the other hand, subjects in the current trial may grade the NRO with respect to a well known standard with which they are very familiar. This may also lead to bias in favour of the well known standard, i.e. ARGO.

From the above, it maybe concluded that comparison of orthoses by means of patients' grading is not free of bias. Discussions with the subjects after the trials showed that their opinion was in agreement with their score on the questionnaire. The conclusion therefore can be supported that removing the reciprocal linkage in ARGO affected standing posture and did not improve the walking experiences of the subjects.

Measurement of oxygen uptake is the most reliable and valid method for estimating energy cost of walking, although several other possibilities have been used, including PCI and CFTI (Winchester *et al,* 1993; Stallard and Major, 1993; Yang, *et al,* 1996). Disadvantages of using oxygen uptake measurements have been reported, but the flexible and user friendly facemask, the small and lightweight gas-tube without valves in the device used prevented interference with the subjects' walking pattern.

Oxygen cost and PCI were calculated after the subjects had walked at least five minutes. This appeared to be a good approach, since steady state was found to be delayed. The high heart rate and respiratory exchange ratio during walking possibly indicates anaerobic energy supply during the 10 minutes walk. Therefore, calculation of energy cost from oxygen cost data was not performed, since this may underestimate energy requirements (Wasserman *et al,* 1987).

No significant difference in oxygen cost was found between the orthoses. The mean difference in oxygen cost could vary between 25% higher in NRO to 17% lower in NRO (Fig. 2). It is concluded that there is inadequate evidence to draw general conclusions for the whole group of subjects. The difference could imply a clinically relevant improvement for either the ARGO or the NRO. However, large differences between subjects were found (Fig 5). Energy requirements of both T4 lesions are up to 40% higher in NRO, whilst oxygen cost in subjects with low lesions was lower in NRO (Fig 5).

The difference in outcome between low and high level paraplegics may be explained by differences in walking speed, since walking speed in high level pearaplegics decreased (Fig. 5). Walking speed in high level paraplegics may be decreased in the NRO either because of the reduced stride length (Fig. 3) or because of a reduced cadence due to the increased effort necessary to maintain a stable posture during double stance. Stride length was reduced by means of flexion-extension limits during the training phase in order to prevent extreme step lengths. Removal of the reciprocal linkage in the ARGO resulted in an increase of flexion/extension range, which is undesirable because the subjects are not able to move the centre of gravity to the new stance leg.

Hirokawa *et al.* (1990), found that oxygen cost was lower in the HGO Parawalker than in the RGO at higher walking speeds. In an orthosis with freely swinging legs more effort is required for stabilisation during double stance. Since the double stance phase is shorter at higher walking speeds, this may explain the lower energy requirements in an orthosis with freely swinging legs.

It is assumed that high level paraplegics are not able to achieve high walking speeds, because of the irregularity of their walking pattern. Furthermore, in order to maintain stability during double stance and to prepare the next step it is expected that they need to put more effort into decelerating the body.

Oxygen cost in low level paraplegics was found to be 4% to 14% lower in NRO (Fig. 5). The observed differences in oxygen cost in the low level lesions were very small and not sufficient to consider them clinically relevant.

Furthermore, only two subjects (2 and 4) with low level lesions, preferred the NRO for walking. Three subjects with low lesions ultimately preferred the ARGO for use in activities of daily living (Fig. 5).

As in the high level paraplegics, the authors expected the reduced stride length to cause a less efficient gait pattern. Due to removal of the reciprocal cable linkage, subjects were standing in a flexed position, leaning in the flexion limits. This flexed position of the trunk and the adjusted flexion limit prevented a full hip flexion of the swing leg. The swing leg is stopped abruptly, during swing phase, when the highest velocities of the leg are attained (Tashman *et al.*, 1995). This may result in loss of energy available for propulsion. Furthermore, the body has to be decelerated to prevent balance disturbances. Additional training of the subjects may be required to optimise the impulse given to the swing leg at toe-off.

In conclusion, it was found that large inter-individual differences with respect to oxygen cost and PCI provide insufficient evidence in this study to draw general conclusions.

However, individual analysis of the results showed that there are differences between low and high level paraplegics. Patients with low level lesions may benefit from removing the reciprocal cable linkage in ARGO, since oxygen cost was lower. However, only one subject preferred the NRO for walking, whereas none of the subjects chose the NRO for use in daily living. It is expected that the uncomfortable standing position, leaning in the flexion limits, was the major cause of this opinion.

Analysis of the results in both T4 lesions showed that oxygen cost was higher in the NRO. It is expected that high level lesions are not able to achieve a walking speed at which they can use the higher swing leg accelerations for propulsion, because of an irregular walking pattern. Removal of the reciprocal cable linkage in the ARGO may not be desirable for these patients.

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