# Speed Dependence of Crutch Force and Oxygen Uptake: Implications for Design of Comparative Trials on Orthoses for People With Paraplegia 

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#### Abstract

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Objective: To determine speed dependence of crutch force and oxygen uptake, and to discuss the implications of differences in self-selected walking speed between orthoses in a comparative trial. Design: Cross-sectional comparison. Setting: Treadmill experiments and gait laboratory experiments were performed at five and three different imposed walking speeds, respectively. Patients: Five paraplegic subjects with lesions between T9 and T12 were included. All subjects had experience with ambulation using the advanced reciprocating gait orthosis (ARGO) as well as walking on a treadmill. Main Outcome Measures: Crutch force time integral (CFTI), crutch peak force on stance and swing side $\left(\mathrm{CPF}_{\text {stance }}\right.$ and $\mathrm{CPF}_{\text {swing }}$ ), oxygen uptake ( $\mathrm{VO}_{2}$ ), oxygen cost $\left(\mathrm{EO}_{2}\right)$. Results: $\mathrm{V}_{\mathrm{O}_{2}}, \mathrm{EO}_{2}$, and CFTI were strongly dependent on walking speed. $\mathrm{CPF}_{\text {stance }}$ and $\mathrm{CPF}_{\text {swing }}$ were less dependent. However, depending on the clinically relevant difference that should be detected in a comparative trial, the peak forces can still be confounded by walking speed.

Conclusion: CFTI, $\mathrm{CPF}_{\text {swing }}, \mathrm{Vo}_{2}$, and $\mathrm{EO}_{2}$ should be adjusted for walking speed if differences in walking speed between orthoses are found, but this correction is relevant only if there is no effect modification. Such modification (different slopes between orthoses) cannot be excluded for the studied outcome measures. In addition, because determination of effect modification is difficult in small studies, standardization of walking speed, by means of a three-point design, is recommended. © 1998 by the American Congress of Rehabilitation Medicine and the American Academy of Physical Medicine and Rehabilitation


MEASUREMENT OF oxygen uptake during walking is frequently performed in comparative trials on effectiveness of walking systems for patients with paraplegia. ${ }^{1-6}$ Usually,

[^0]oxygen uptake is expressed either per unit time (oxygen consumption $\left[\dot{V}_{\mathrm{O}_{2}}\right]$ ) or per unit distance (oxygen cost $\left[\mathrm{EO}_{2}\right]$ ). ${ }^{1.7 .8}$ The latter is considered an energy efficiency measure because it relates oxygen uptake to a performance. Beside $\mathrm{VO}_{2}$ and $\mathrm{EO}_{2}$, crutch forces are frequently measured to assess upper body load during walking. ${ }^{6,9.10}$ Typical outcome variables are the crutch force time integral (CFTI) and crutch peak force (CPF). ${ }^{6,9.11}$ Use of crutch force measurements is also valuable in comparisons of walking systems because the high loads on the upper limbs are expected to be more closely related to the occurrence of wrist and shoulder complaints. ${ }^{12}$
Literature on measurement of oxygen uptake and crutch force during paraplegic ambulation shows that most comparisons are performed at self-selected walking speeds. ${ }^{1-3.5 .6}$ Control of walking speed, for instance by using a treadmill, has several disadvantages for the physically handicapped. Patients may feel insecure on a treadmill, which is reflected in the oxygen uptake; treadmills are often too narrow for use with crutches or ambulators and the subjects' usual gait pattern can not be duplicated. ${ }^{5.13}$
Notwithstanding the importance of the self-selected speed as separate outcome measure, a disadvantage for the interpretation of other outcome measures is that patients' self-selected speeds may be different in the various orthoses to be compared in the trial. For instance, in a study on the influence of frontal alignment in the advanced reciprocating gait orthosis (ARGO) it appeared that the self-selected walking speed was increased by about $13 \%$ if the orthosis was aligned in abduction. ${ }^{6}$ Differences in walking speed between two orthoses were found in several other comparative trials. Katz and coworkers ${ }^{8}$ compared the reciprocating gait orthosis (RGO) with a conventional hip-knee-ankle-foot orthosis (HKAFO) in children with thoracolumbar lesions and found that self-selected walking speed in RGO was twice that of the conventional orthosis. ${ }^{8}$ Sykes and coworkers ${ }^{5}$ compared the RGO with a hybrid RGO and found an increase in walking speed of approximately $10 \%$ in the hybrid system. ${ }^{5}$

Differences in self-selected walking speed between orthoses prevent a proper determination of the true differences in other outcome measures, ie, the difference in crutch force and oxygen uptake can be biased because the self-selected walking speeds are different. Such bias by walking speed may result in either confounding, effect modification, or both. ${ }^{14-19}$ Confounding is the condition where adjustment for walking speed leads to another difference (compared with the crude difference) between orthoses. The crude difference can thus either be underestimated or overestimated. Effect modification is present if the adjusted difference varies with the level of walking speed. ${ }^{15}$

For instance, Hirokawa and coworkers ${ }^{4}$ concluded that the RGO with functional electrical stimulation (RGO+FES) was more energy efficient (oxygen cost) than the RGO and that the efficiency in RGO + FES equaled that of the RGO at speeds of
$>.35 \mathrm{~m} / \mathrm{sec}$. Although they did not report it as such, it can be considered as an example of effect modification.
Other than Hirokawa and colleagues, ${ }^{4}$ only a few authors have recognized the influence of walking speed as biasing or extraneous variable. Marsolais and coworkers ${ }^{3}$ compared $\mathrm{VO}_{2}$ of their functional neuromuscular stimulation (FNS) system with long leg braces (LLB) with reference to walking speed. However, they neither presented walking speed-adjusted differences between FNS and LLBs nor performed statistical testing. IJzerman and coworkers ${ }^{6}$ used analysis of covariance to adjust the differences in crutch force for walking speed.
In general, appearance of walking speed as either confounder or effect modifier depends on several factors. ${ }^{16,18,19}$ First, self-selected walking speed should be different between the orthoses to be compared. This requirement is evident when observing the results of various studies where a change in walking speed was reported. ${ }^{5,6,8}$ Second, there should be a (sufficiently strong) relation between walking speed and the outcome measure, ie, either crutch force or oxygen uptake. If one of these two associations is absent, no confounding will be present in the data. ${ }^{16}$
The main purpose of this study was to determine whether a relation between walking speed and relevant outcome measures exists at all and whether it should be accounted for in a comparative trial. In the second instance, we discuss the implications of this speed dependence on study design with regard to the manifestation of either effect modification or confounding in comparative trials on the effectiveness of orthoses.

## METHODS

## Subjects

Five paraplegic subjects were included in the study. Selection criteria were (1) complete paraplegia with lesion between T9 and T12, (2) being experienced with walking in the ARGO, (3) being able to walk at different walking speeds, and (4) no fear of participating in a treadmill experiment. Table 1 summarizes relevant subject information including the range of attainable walking speeds and the self-selected walking speed. A full consent of patients was obtained before inclusion in the experiments. The study was approved by the local medical ethics committee.

## Oxygen Uptake Measurements

Equipment. Breath-by-breath measurement of oxygen uptake was conducted by means of a system for ergospirometry. ${ }^{\text {a }}$ Heart rate (HR; beats $/ \mathrm{min}$ ), $\mathrm{VO}_{2}$, and $\mathrm{VCO}_{2}$ (both $\mathrm{mL} / \mathrm{min} / \mathrm{kg}$ ), respiratory exchange ratio (RER), and expiratory volume ( $\mathrm{V}_{\mathrm{e}}$; $\mathrm{L} / \mathrm{min}$ ) were measured at a sample frequency of 200 Hz .

Table 1: Relevant Subject Information ( $n=5$ )

| Age | Weight (kg) | Level | $\mathrm{V}_{\text {ss }}(\mathrm{m} / \mathrm{sec})$ | $\mathrm{V}_{\text {(range) }}$ <br> Treadmill | $\mathrm{v}_{\text {(range) }}$ <br> Gait <br> Laboratory |
| :---: | :---: | :---: | :---: | :---: | :---: |
| $(1) 35$ | 66.0 | T12 | .43 | $(.19, .59)$ | $(.18, .58)$ |
| (2) 43 | 90.0 | T9 | .29 | $(.14, .42)$ | $(.19, .45)$ |
| (3) 41 | 60.0 | T9 | .32 | $\left(.14, .37^{*}\right)$ | $(.15, .47)$ |
| $(4) 43$ | 86.0 | T12 | .25 | $(.10, .42)$ | $(.11, .49)$ |
| (5) 36 | 53.0 | T9 | .23 | $\left(.11, .21^{*}\right)$ | $(.13, .30)$ |

Data show self-selected walking speeds ( $\mathrm{v}_{\text {ss }}$ ) and range of attainable speeds during gait laboratory and treadmill experiments.

* Subjects could not maintain the high walking speed on the treadmill.

Subjects were walking on a treadmill between parallel bars which had been adjusted to crutch height.

Procedure. Before the measurements were taken, subjects were allowed to practice on the treadmill and their maximal attainable walking speeds were determined. Then, subjects were each provided with a facemask containing a flexible and light weight gas-tube that did not interfere with their walking patterns. The measurements started with determining rest metabolism during 5 minutes of quiet standing between the parallel bars of the treadmill. After 5 minutes, walking speed was set at $.15 \mathrm{~m} / \mathrm{sec}$. Subjects were instructed to concentrate on the treadmill and the regularity of their walking pattern only. Walking speed was increased, with $20 \%$ of maximum walking speed, if a steady state oxygen uptake had been achieved. The actual walking speed was measured in each phase because it appeared that subjects could impede the treadmill at low walking speeds.

Criteria for stopping the treadmill experiment were (1) completion of the measurement protocol, ie, attaining maximum walking speed, (2) inability of the subject to attain the walking speed, and (3) other observations that could have led to unsafe situations. After completing the highest walking speed, subjects were asked to walk for another 5 minutes at approximately $.15 \mathrm{~m} / \mathrm{sec}$ to prevent fainting after a (sub)maximal exercise.

It was decided to conduct one trial with increasing walking speeds, rather than measure each walking speed in separate trials with an interleaving resting period. A practical reason for this protocol is that it is hardly possible for paraplegic subjects to enter a high (maximal) walking speed on a treadmill without increasing walking speed gradually from zero.

Off-line data analysis. Mean and standard deviation (SD) of $\mathrm{VO}_{2}, \mathrm{VCO}_{2}, \mathrm{~V}_{\mathrm{e}}, \mathrm{HR}$, and RER were calculated during the last minute of each phase. $\mathrm{EO}_{2}$ was calculated for each phase according to

$$
\mathrm{EO}_{2}=\frac{\dot{\mathrm{V}} \mathrm{O}_{2}}{\mathrm{v}} \quad[\mathrm{~mL} / \mathrm{m} / \mathrm{kg}]
$$

where: v is walking speed ( $\mathrm{m} / \mathrm{min}$ ) in each phase. All data were expressed per unit of lean body mass (LBM).

## Crutch Force Measurements

Equipment. Biomechanical measurements were performed in the gait laboratory on a $7.5-\mathrm{m}$ walking lane. Approximately 3 m of free space was available before entering the measurement traject, to allow subjects to walk with a well chosen and regular walking speed. The measurement was initiated by means of a light reflecting switch across the walking pathway. Miniature load cells ${ }^{\mathrm{b}}$, integrated in the lower tube of both crutches, were used to measure the axial crutch forces. Foot switches were mounted on the heel of subjects' shoes to determine stride time. All data were sampled at 200 Hz .

Procedure. Four trials were performed to determine the self-selected walking speed. Subsequently, subjects were asked to walk at five different walking speeds, ie, two grades above and two below the self-selected walking speed. However, it appeared that they were able to control their walking speed to the extent that we could only discriminate three different speed categories. At least two trials were performed at each walking speed. Subjects were asked to increase their speed gradually, thus giving them a reference walking speed, instead of randomly assigning walking speeds.

Off-line data analysis. Force data were filtered using a linear phase second-order Butterworth filter, $\mathrm{F}_{-3 \mathrm{~dB}}=5 \mathrm{~Hz}$. All data were split into single strides, representing a right-left step

Table 2: Mean (SD) of Crutch Force Parameters Determined During the Gait Laboratory Experiments

|  | Slow <br> $(0 \%, 90 \%)$ | $\mathrm{v}_{\text {ss }}$ <br> $(90 \%, 110 \%)$ | Fast <br> $(110 \%, 200 \%)$ |
| :--- | :---: | ---: | :---: |
| $\mathrm{v}(\mathrm{m} / \mathrm{sec})^{*}$ | $.16(.04)$ | $.29(.09)$ | $.44(.10)$ |
| $\mathrm{v}[\%]^{*}$ | $54.2(11.7)$ | $96.0(4.7)$ | $148.4(22.9)$ |
| $\mathrm{CFTI}^{*}(\mathrm{sec})^{*}$ | $.756(.15)$ | $.535(.11)$ | $.458(.01)$ |
| $\mathrm{CPF}_{\text {stance }}$ | $.385(.08)$ | $.368(.07)$ | $.410(.08)$ |
| $\mathrm{CPF}_{\text {swing }}{ }^{\dagger}$ | $.370(.03)$ | $.384(.04)$ | $.439(.05)$ |
| Stride length $(\mathrm{m})^{*}$ | $.83(.04)$ | $94(.08)$ | $1.07(.09)$ |
| Step frequency $(/ \mathrm{min})^{*}$ | $12.4(1.9)$ | $18.1(3.6)$ | $24.6(3.8)$ |

Walking speed is classified as three categories with respect to $\mathrm{v}_{\mathrm{ss}}$.

* $P<.01$ (ANOVA)
${ }^{+} P<.05$ (ANOVA).
sequence. CFTI over the stride, CPF on stance and swing side $\left(\mathrm{CPF}_{\text {stance }}, \mathrm{CPF}_{\text {swing }}\right.$ ), and walking speed ( $\mathrm{m} / \mathrm{sec}$ ) were calculated for each trial. CFTI, $\mathrm{CPF}_{\text {stance }}$, and $\mathrm{CPF}_{\text {swing }}$ of left and right crutches were averaged and normalized for body weight. CPF is thus dimensionless and represents the relative body weight through the crutches, whereas CFTI is expressed in seconds.


## Data and Statistical Analysis

Plots were made of $\dot{V}_{2}, \mathrm{EO}_{2}, \mathrm{CFTI}, \mathrm{CPF}_{\text {stance }}$, and $\mathrm{CPF}_{\text {swing }}$ against the relative walking speed ( $\mathrm{v}_{\text {relative }}$ ) in each phase, where $\mathrm{v}_{\text {self-selected }}=100 \%$. Means and SDs over the five subjects were calculated for each of the speed categories (five categories for the treadmill and three for the gait laboratory experiment). Analysis of variance (ANOVA) was used to statistically test differences in $\mathrm{VO}_{2}, \mathrm{EO}_{2}, \mathrm{CFTI}, \mathrm{CPF}_{\text {stance }}, \mathrm{CPF}_{\text {swing }}$, and walking speed between speed categories. Linear regression analysis was used to estimate the slope of the relation between relative walking speed and either stride length, step frequency, $\mathrm{Vo}_{2}$, $\mathrm{EO}_{2}, \mathrm{CPF}_{\text {stance }}, \mathrm{CPF}_{\text {swing }}$, or CFTI. A $p<.05$ was considered significant in hypothesis testing. All analyses were performed with SPSS. ${ }^{\text {c }}$

Table 3: Mean (SD) of Physiologic Parameters Determined During the Treadmill Experiment

|  | Very Slow <br> $(0 \%, 55 \%)$ <br> $(n=5)$ | Slow <br> $(55 \%, 90 \%)$ <br> $(n=5)$ | V <br> $(90 \%, 110 \%)$ <br> $(n=5)$ | Fast <br> $(110 \%, 125 \%)$ <br> $(n=4)$ | Very Fast <br> $(125 \%, 200 \%)$ <br> $(n=3)$ |
| :--- | :---: | ---: | ---: | ---: | :---: |
| $\vee(\mathrm{m} / \mathrm{sec})$ | $.13(.03)$ | $.21(.05)$ | $.28(.06)$ | $.38(.06)$ | $.48(.09)$ |
| $\vee(\%)$ | $-55.3(3.8)$ | $-30.2(4.1)$ | $-4.43(5.7)$ | $18.9(7.4)$ | $49.2(14.5)$ |
| $\dot{\mathrm{V}} \mathrm{O}_{2}$ | $12.1(2.6)$ | $14.0(2.3)$ | $16.1(3.1)$ | $19.7(5.0)$ | $21.0(4.4)$ |
| $\dot{\mathrm{V}} \mathrm{CO}_{2}$ | $10.4(2.4)$ | $12.7(2.2)$ | $15.8(2.7)$ | $19.8(5.0)$ | $22.2(3.3)$ |
| HR | $128(25)$ | $135(22)$ | $141(18)$ | $144(16)$ | $156(16)$ |
| RER | $.85(.05)$ | $.90(.06)$ | $.98(.09)$ | $1.01(.05)$ | $1.06(.08)$ |
| $\mathrm{V}_{\mathrm{e}}$ | $21.8(4.0)$ | $25.9(4.3)$ | $33.1(5.6)$ | $43.7(9.5)$ | $51.3(14.6)$ |
| $\mathrm{EO}_{2}$ | $1.39(.28)$ | $1.05(.22)$ | $.89(.18)$ | $.87(.24)$ | $.75(.23)$ |

Walking speed is classified in five categories. All parameters were significantly different ( $p<.01$ ).

## RESULTS

All measurements were performed satisfactorily, except the maximum walking speed of subjects 3 and 5 during the treadmill experiment. It appeared that subject 3 was not able to increase his walking speed above $.37 \mathrm{~m} / \mathrm{sec}$ because of wrist pain. Wrist pain was a major complaint from all five subjects during walking at higher speeds. The self-selected walking speed of subject 5 probably represented her $\mathrm{Vo}_{2}$ max; we did not further increase her walking speed.
Both stride length and step frequency increased significantly at higher walking speeds (two-way ANOVA, $p<.01$, table 2 ). Stride length and step frequency increased both linearly with respect to the relative walking speed (fig 1).
A summary of relevant physiologic parameters at increasing walking speed of all subjects is given in table 3. All parameters were significantly different for the different walking speeds imposed on the treadmill (two-way ANOVA). Mean HR in rest was high because subjects were asked to stand during this measurement phase. Mean RER approached 1.0 at the selfselected walking speed and increased at walking speeds higher than the self-selected.
The $\mathrm{VO}_{2}$ at the self-selected speed differed among the


Fig 1. Step frequency (left axis, lower part of figure) and stride length (upper part) against walking speed. Walking speed is expressed as relative with respect to the self-selected walking speed ( $\mathbf{v}_{\text {self-selected }}=$ $100 \%$ ). Linear regression has been used to estimate the slope of the relations for each subject separately (using two trials at each walking speed [solid lines]) as well as the slope of the relation for all subjects (dashed line).

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Fig 2. Individual display of $\dot{\mathrm{V}}_{\mathbf{2}}$ against relative walking speed for five subjects. Linear regression analysis has been used to estimate the slope of the relation for all subjects (dashed line).
subjects, ranging from approximately 12 to $21 \mathrm{~mL} / \mathrm{min} / \mathrm{kg}$ (fig 2). $\mathrm{EO}_{2}$ exhibited a nonlinear inverse relation with a relative fast decay up to the self-selected walking speed and a slower decay above self-selected walking speed. In two subjects ( 2 and 3 ) we found a minimum for $\mathrm{EO}_{2}$ being roughly associated with the self-selected speed in only one subject (fig 3).
$\mathrm{CPF}_{\text {stancc }}$ during walking increased from $38.5 \%$ at an average relative speed of $54.2 \%$ to $41 \%$ of body weight at $v_{\text {relative }}$ of $148.4 \%$ (two-way ANOVA, $p<.10$; fig 4). CPF $_{\text {swing }}$ increased from $37.0 \%$ at $v_{\text {relative }}$ of $54.2 \%$ to $43.9 \%$ of body weight at $\mathrm{v}_{\text {relative }}$ of $148.4 \%$ (two-way ANOVA, $p<.05$; fig 5 ). There is much more diversity between subjects in $\mathrm{CPF}_{\text {stance }}$ than in $\mathrm{CPF}_{\text {swing: }}$ : the coefficient of variation ( $\mathrm{CV}=\mathrm{SD} /$ mean $\times 100 \%$ ) of $\mathrm{CPF}_{\text {stance }}$ for all speeds is twice that of $\mathrm{CPF}_{\text {swing }}$ (table 2). In
contrast to $\mathrm{CPF}_{\text {stance }}$ and $\mathrm{CPF}_{\text {swing }}$, CFTI decreased significantly from .756 sec to .458 sec (two-way ANOVA, $p<.01$; fig 6 ).

## DISCUSSION

Speed dependence of oxygen uptake and oxygen cost during paraplegic walking has been reported several times by different authors. ${ }^{3,4,7,8,20,21}$ Oxygen uptake increased with speed according to a first- or second-order relation, while oxygen cost exhibited a nonlinear inverse relation with walking speed. $3,4,7,8,20,21$ Whereas the relation between oxygen uptake and walking speed is often determined across different subjects, this study was aimed at obtaining more insight into the additive effect of walking speed on the outcome in individual subjects. But also here, the data show first-order linearity as well as a

Fig 3. Individual display of $\mathrm{EO}_{2}$ against relative walking speed for five subjects. Linear regression analysis has been used to estimate the slope of the relation for all subjects (dashed line).


Fig 4. Plot of CPF $_{\text {stance }}$ against relative walking speed. CPF $_{\text {stance }}$ is significantly decreasing at higher walking speeds. Linear regression has been used to estimate the slope of the relations for each subject separately (using two trials at each walking speed [solid lines]) as well as the slope of the relation for all subjects (dashed line).
nonlinear inverse relation for oxygen uptake and oxygen cost, respectively.
In contrast to oxygen uptake, the speed dependence of crutch force had not yet been clearly assessed. First indications, however, of such dependence were found in a study on frontal alignment, where walking speed adjusted differences in CFTI were larger as compared with the crude data. ${ }^{6}$ The conspicuous and significant decrease in CFTI ( $56 \%$ between lowest and highest relative walking speed) found in this study indicates that CFTI is strongly dependent on walking speed. This could have been expected because CFTI incorporates a multiplicative stride time component, which reduces at increasing walking speeds. In addition, because differences in CPFs were small
between high and low speeds, it is expected that the speed component dominates the CFTI behavior.

If walking speed is considered as a confounder in a trial comparing different walking systems, its influence is primarily dependent on the slope of the relation between the relevant outcome measure and walking speed (second prerequisite as mentioned in introduction). It will then be found that CFTI will be relatively strong affected by a small difference in walking speed, whereas CPFs will be less so. Because this slope is the most important issue in the assessment of confounding, statistical testing of differences in walking speed between orthoses can not be decisive. Relying on statistics in this case would imply that a strong confounding factor, acting on small differences in

Fig 5. Plot of CPF $_{\text {swing }}$ against relative walking speed. CPF $_{\text {swing }}$ is significantly decreasing at higher walking speeds. Linear regression has been used to estimate the slope of the relations for each subject separately (using two trials at each walking speed [solid lines]) as well as the slope of the relation for all subjects (dashed line).

speed, can be missed in a study with a small sample size. ${ }^{14,16,17,19}$ To determine the magnitude and implications of confounding, the difference between crude and adjusted differences should thus be appreciated. ${ }^{14-17}$ This implies that the experimenter's decision of what is clinically relevant determines the relevance of confounding bias. For instance, the small differences between lowest and highest speed in $\mathrm{CPF}_{\text {stance }}$ of $\pm 7 \%$ (with respect to the value at self-selected speed) will be no major issue in studies that consider clinically relevant differences at $20 \%$. In contrast, the difference of $.69( \pm 18 \%)$ for $\mathrm{CPF}_{\text {swing }}$ between the lowest and highest speed might be large enough to weigh its influence in such a study.
By convention, adjustment for confounding leads to one uniform difference in the relevant outcome measure for all levels of walking speed. Therefore, if adjustment for confounding (for instance through multivariate modeling) is considered, one has to ascertain that the slopes of the relations between walking speed and outcome measure are equal for either orthosis. However, it might be well possible that there is a difference in slopes between the orthoses. Such effect modification should have been assessed before considering any correction, because otherwise it would be useless to calculate an adjusted mean difference between the walking systems. ${ }^{14,15,17}$

As far as oxygen uptake is concerned, the same concepts as discussed for crutch forces, of confounding and effect modification, are applicable. Correction for walking. speed is only worthwhile if the slope of the relation between $\mathrm{V}_{2}$ and walking speed is equal for both orthoses. One difference with respect to crutch forces is that a nonzero intercept (basal metabolic rate [BMR]) with the $\mathrm{VO}_{2}$ axis is expected, which is approximately $6.5 \mathrm{~mL} / \mathrm{min} / \mathrm{kg}$ in this study. The implication is that effect modification should also be expected if $\mathrm{VO}_{2}$ between orthoses is different at equal walking speeds; ie, the intercept for both relations is the same, thus the slopes are different.

Oxygen cost has been used as an outcome measure in several studies. ${ }^{1,35.6,222.23}$ Although used very often, the biological concept behind it is only poorly discussed. One argument could be that $\mathrm{EO}_{2}=\mathrm{VO}_{2} / \mathrm{v}$ is calculated only to express the required energy per meter walked. However, although normalized for
walking speed, $\mathrm{EO}_{2}$ still shows a nonlinear inverse relation and is thus speed-dependent. This speed dependence could have been expected after observation of the linear relation of $\dot{\mathrm{V}}_{2}$ against walking speed. Normalization of the firstorder relation yields

$$
E O_{2}=\frac{\dot{\mathrm{V}} \mathrm{O}_{2}}{\mathrm{v}}=\frac{\mathrm{a} \times \mathrm{v}+\mathrm{BMR}}{\mathrm{v}}=\mathrm{a}+\frac{\mathrm{BMR}}{\mathrm{v}}
$$

because in first instance, BMR is equal in a within-subject comparative trial (all patients are measured in two or more orthoses, and the BMR should be the same for the orthoses). The constant a will then be a term that expresses the vertical shift of the relation and thus the difference between orthoses. In addition, because the term BMR/v will be equal for both orthoses at the same speed, no effect modification can be present.

Consequently, correction for walking speed will then become relatively straightforward, because either adding or subtracting $\mathrm{BMR} / \delta \mathrm{v}$ ( $\delta \mathrm{v}=$ difference in speed between the orthoses) from one of the data points would be sufficient. However, it is theoretically simpler to subtract the BMR even before $\mathrm{EO}_{2}$ is calculated. It then only yields the speed-independent constant a , which expresses the difference in slopes between the orthoses of the relation $\mathrm{V}_{2}$ and walking speed.

Surprisingly, subtracting rest HR from the steady state HR is the usual practice when calculating the so-called physiological cost index (PCI) ${ }^{24}$ :


PCI is thus considered to yield a speed-independent value of the difference between the orthoses if the relation between HR and walking speed is linear. A disadvantage of rest HR, compared with rest $\mathrm{VO}_{2}$, is that it is more influenced by autonomous nerve activity and thus fluctuates between measurement occasions.

Hirokawa and coworkers ${ }^{4}$ have concluded that the difference between RGO and RGO+FES narrows at higher walking
speeds. ${ }^{4}$ In addition, they found linear relations between walking speed and $\dot{V}_{2}$ with equal slopes but a different BMR (BMR is approximately .044kcal in RGO + FES and approximately . 052 kcal in RGO). However, while interpreting their figure, it is expected that the higher BMR in the RGO is only obtained by extrapolating the slope to zero. If the BMR is equal in RGO and RGO+FES, which is expected, it is not likely that effect modification exists.
Sykes and coworkers ${ }^{5}$ performed a study on the influence of electrical stimulation in the RGO on energy expenditure and they anticipated that effectiveness of the hybrid RGO compared with the RGO could be shown by either (1) reduced oxygen cost at equal speed or (2) equal (or lower) oxygen cost at higher speeds. ${ }^{5}$ However, only with respect to their first statement can we conclude that the difference in $\mathrm{EO}_{2}$ between RGO and RGO + FES is unbiased. Two remarks can be made with respect to their second statement. First, an equal $\mathrm{EO}_{2}$ at a higher walking speed in the hybrid RGO implies that the relation between $\mathrm{EO}_{2}$ and walking speed is shifted horizontally. It is concluded that effect modification will then be present and that a single correction for walking speed, though possible, is not worthwhile.

Second, and more importantly, is that their second statement cannot be justified. Because $\mathrm{EO}_{2}$ is found to decrease at higher walking speeds (negative relation), any increase in walking speed in the same orthosis results in a reduced $\mathrm{EO}_{2}$. In addition, because $\mathrm{EO}_{2}$ has a nonlinear inverse relation with walking speed, a difference in walking speed between orthoses of $5 \%$ has more implications for $\mathrm{EO}_{2}$ at low compared with high speeds. It is thus concluded that if a second orthosis is expected to be more energy efficient, the reduction in $\mathrm{EO}_{2}$ should exceed the reduction that was expected because of this speed dependence. An equal $\mathrm{EO}_{2}$ even when walking speed is increased can never yield the conclusion that this orthosis is more energy efficient.

## CONCLUSIONS

This study found that CFTI exhibited a strong relation with walking speed, $\mathrm{CPF}_{\text {swing }}$, was less dependent, and $\mathrm{CPF}_{\text {stance }}$ is probably not worth noting when confounding is suspected. All relations were linear, but it is unknown how the slopes of these relations will be for other orthoses. Such differences in slopes, representing effect modification, are a potential drawback if correction for confounding is considered. In addition, whereas correction for walking speed is relatively straightforward, correction for effect modification is not relevant. Because it is difficult to assess effect modification in small sample sizes, a correction for walking speed can thus always be misleading. It would therefore be more accurate to prevent effect modification by standardizing walking speed, for instance, using a threepoint design. It will then be possible to calculate mean differences across patients at each of the three levels (very slow, normal, and very fast) of walking speed. It is beyond the scope of this report to discuss all details with respect to the selection of outcome measures to assess oxygen uptake and oxygen cost, but it is expected that an altered calculation of oxygen cost may contribute to an interpretation that is less speed-dependent

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## Suppliers

a. Oxycon Alfa; Erich Jaeger Benelux b.v., Medische electronica en dataverwerking, Nikkelstraat 2, 4823 AB Breda, The Netherlands.
b. Miniature load cells, LM-100KA; Kyowa Electronic Instruments, Ltd., Tokyo, Japan.
c. SPSS, 444 North Michigan Avenue, Chicago, IL 60611.


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