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Paraplegic adaptation to assisted-walking: energy expenditure during wheelchair *versus* orthosis use

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Study Design: To study the energy cost of locomotion during ambulation with different orthoses (HIP Guidance Orthosis Orlau Parawalker (PW), $n=4$; Reciprocating Gait Orthosis (RGO), $n=6$; RGO+FNS, $n=4$).
Objectives: Since high energy costs of locomotion have been proposed as a major reason for early rejection of orthotic use, our aims were (a) to evaluate the impact of functional neuromuscular stimulation (FNS) on energy expenditure during orthosis-assisted ambulation; (b) to study whether energy expenditure data can predict the poor long-term patients' compliance and (c) to assess selection criteria for the assignment of the different types of orthosis.
Setting: The study was completed at the Center of Sports Medicine and Center of Bioengineering, 'don C. Gnocchi' Foundation, IRCCS, Milan, Italy.
Methods: The HR/$\dot{V}O_2$ relationship and the energy cost of locomotion (C) were studied in 14 patients (lesion level C_7-T_{11}) during wheelchair (WHCH) use at various speeds and during locomotion with different orthotic devices. Patients' short- and long-term compliance were assessed by questionnaires evaluating duration of and problems related to orthotic use.
Results: (a) In patients using RGO+FNS the slope difference of HR/$\dot{V}O_2$ curves (Δ_{sl}HR/$\dot{V}O_2$) between WHCH and orthosis was significantly lower than in other groups (-3 beats l^{-1} in RGO+FNS *vs* 43 and 52 beats l^{-1} in RGO and PW, respectively); (b) neither C, nor $\dot{V}O_2$ peak, or Δ_{sl}HR/$\dot{V}O_2$ correlated with orthosis duration of use; (c) in the RGO+FNS group, C was lower at maximal walking speed, which linearly correlated with maximal WHCH speed.
Conclusion: (a) Electrical stimulation seems to improve locomotion, as a consequence of hemodynamic effects, but does not decrease energy expenditure, which remains high; (b) the poor long-term compliance to orthosis use cannot be predicted by the energy expenditure parameters; (c) the subjects who can reach high speeds by WHCH seem to be the most appropriate for RGO+FNS locomotion.
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Introduction

In the last few years many mechanical and, more recently, electromechanical (or hybrid) devices have been developed, to allow paraplegic patients to stand and walk, although at a low speed. Research projects are in progress with the purpose of developing multichannel implanted stimulators, whose main advantages would be a higher muscle selectivity, a better modulation in muscle recruitment and the absence of external wires and electrodes.[1] Orthotic use requires a very high energy expenditure, which leads to exhaustion after a few minutes of walking.[2] As a consequence, orthotic use is frequently abandoned, generally after a short time,[3] and effective benefit for patients is still under debate.[4] In order to improve compliance, the mechanical design of the orthoses[5] has been revised to allow a better adaptation to the specific characteristics of each subject (anthropometric features, lesion level, residual capabilities, etc.). In particular, valuable information was obtained by a comprehensive biomechanical analysis of paraplegic

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assisted-walking patterns, which combines kinematic and kinetic data with EMG activity of supralesional muscles.[6]

Although many studies have been carried out, frequently the patient withdrawals from orthotic use are still difficult to predict by any variable, either clinical or based on the biomechanics of the orthoses.[7] In order to improve tolerability, it is therefore important to evaluate all the causes of low compliance: among these, the cardiovascular response to upright standing and walking are of particular interest.

One of the main problems regarding the cardiovascular adaptation to walking and exercise in spinal men, is the different individual response to physical activity. The spinal cord injury affects in most cases the physiologic determinants of ventricular filling. In particular, blood redistribution is impaired as a consequence of both the loss of sympathetic vasoregulation below the lesion level (splanchnic area and legs vessels), and the inefficiency of leg muscular pump,[8] as well as the decrease of the vascular volume in lower limbs, following muscle atrophy.[9] As a result, the increase of cardiac output during exercise is obtained by raising heart rate, with a negligible increase of stroke volume.[10] This mechanism was demonstrated to limit the maximal aerobic power in subjects with spinal cord injury, as the inadequate blood supply to working muscles in upper limbs causes an early outcome of fatiguability.[8] As a matter of fact, the increase in central blood shift obtained with an anti-G suit, which causes an augmented load on the cardiovascular system, leads to a higher maximal $\dot{V}O_2$ in paraplegic subjects.[11]

The functional neuromuscular stimulation (FNS) was also shown to support central blood redistribution.[12] FNS is widely used to improve paraplegic ambulation with mechanical orthoses. Presumably, FNS acts by increasing O_2 supply to the working muscles and consequently improves patients' compliance by reducing the energetic cost of locomotion and, consequently, fatiguability.[13]

The problem is more complex if one considers that the orthosis ambulation implies an additional challenge for the patient, who has to change from the sitting to the standing position in order to use the orthosis. In the absence of the compensatory mechanisms of splanchnic vasoconstriction and muscular pump, the cardiac load at rest critically depends on the orthostatic pressure level. Thus blood pooling effects are emphasized when patients assume a standing position.[14]

The effect of blood redistribution on muscular exercise can be assessed by analyzing the changes of heart rate (HR) following increases in metabolic rate (oxygen consumption, $\dot{V}O_2$), expressed by the $HR/\dot{V}O_2$ relationship. If the FNS improves central blood redistribution, increasing cardiac output during exercise by increasing stroke volume, then the slope of the $HR/\dot{V}O_2$ relationship should decrease.[15] As far as we know, there are no data addressing how the hemodynamic response to the electrically stimulated ambulation may affect the $HR/\dot{V}O_2$ relationship.

Comparing the cardiovascular response during orthotic ambulation, with and without FNS, and during wheelchair (WCHC) locomotion in the same patient, the bias due to different individual cardiovascular adjustments can be overcome. Moreover, the $HR/\dot{V}O_2$ dependence on each of the two body positions, sitting and standing, can be evaluated. Additionally, the comparison between orthosis and WHCH metabolic and cardiorespiratory adjustments may improve our understanding of some of the hemodynamic determinants of O_2 consumption.

In the present study we addressed all these issues. In particular, we focused on the question of whether the blood flow redistribution obtained while walking with orthosis + FNS may affect the O_2 cost of locomotion, in comparison with non-stimulated devices. We also tried to assess whether the reasons for low compliance to assisted ambulation may be found in the high walking energy expenditure and fatigue, associated with orthotic use. Finally, we searched for selection criteria for the assignment of orthosis type.

Materials and methods

Subjects

Fourteen paraplegic patients participated in the study. Individual anthropometric and clinical data are shown in Table 1. Mean age was 31.4 ± 10.2 years (mean $\pm$ SD), and body weight 71.7 ± 16.2 kg. All subjects were characterized by spinal cord lesions, ranging between C7 and T10. Participants were consensus informed. After a short muscular training aimed at strengthening arm and trunk muscles, patients have been using their orthoses approximately 2 h a day for 4 weeks (5 days a week) under day hospital conditions. Tests were performed after subjects had been using the device for at least 2 months.

Before the beginning of experimental procedures, all subjects underwent a medical and physical examination with ECG and pulmonary function control. None of them showed any cardiorespiratory disease.

Patients were divided into three groups, according to the different type of orthosis: (1) HIP Guidance Orthosis Orlau Parawalker (PW, $n=4$, age = 19 – 34 years, weight = 48 – 78 kg); (2) Reciprocating Gait Orthosis (RGO, $n=6$, age = 24 – 59 years, weight = 54 – 100 kg); (3) RGO assisted by the functional neuromuscular stimulation (RGO + FNS, $n=4$, age = 31 – 43 years, weight = 71 – 86 kg). The electrical stimulation was applied to the quadricep and hamstring by two surface electrodes for each muscle (self-adhesive 38×89 mm carbon-impregnated electrodes PALS, Axelgaard Manif. Co, USA).

Table 1 Physical and clinical characteristics of the subjects, and physiological responses to maximal exercise (peak exercise)

Subject	*Age (years)*	*Sex*	*Weight (kg)*	*Height (cm)*	*Lesion level*	*ASIA Imp. scale*	*Orthosis*	*$\dot{V}O_2p$ WHCH (ml min kg^{-1})*	*HR p WHCH (bpm)*	*$\dot{V}E$ p WHCH (l min^{-1})*
1	21	F	48	160	C7	B	PW	10.2	161	19.5
2	34	M	62	175	T10	A	PW	17.7	143	51.2
3	28	M	78	177	T3-T4	A	PW	24.3	176	91.6
4	19	M	66	175	T6-T8	A	PW	12.1	163	48.7
5	24	M	54	178	T3	A	RGO	13.1	179	50.9
6	28	M	62	180	T3-T4	A	RGO	25.4	156	65.8
7	25	M	94	182	T6-T7	A	RGO	17.3	181	116.6
8	27	M	89	178	T7-T8	A	RGO	20.2	170	38.1
9	59	M	100	182	T11	A	RGO	11.8	97	63.3
10	31	M	57	172	T9	A	RGO	23.5	148	79.1
11	43	M	71	178	C7	B	RGO + FNS	10.9	113	37.2
12	39	M	86	170	T6-T7	A	RGO + FNS	15.6	173	61.6
13	31	M	80	173	T9-T10	A	RGO + FNS	26.6	183	92.7
14	31	M	57	172	T9	A	RGO + FNS	23.5	148	79.1

Electrical stimulation pattern
Muscle electrical stimulation was performed by a 4-channel stimulator (LSU, Louisiana University, USA). Rectangular waves at 20 Hz frequency, 300 μs duration, and 120 mA max amplitude were used.

Orthoses
Constructive principles and mechanical properties descriptions of the three types of orthosis used in this study are reported elsewhere.[16–18] No significant modifications were applied to the different devices.

Measurements and data collection
The following parameters were measured: heart rate (HR, beats min^{-1}) by continuous electrocardiographic recording in V_5 lead (Cardioline Delta 1 Plus, Italy); pulmonary ventilation ($\dot{V}E$, 1 min^{-1}); O_2 and CO_2 concentrations in expired air (% vol) (Oxygen Analyser, Servomex, UK, and Binos C, Fisher Rosemouth, Germany) collected in 150 l Douglas bag[19]; venous lactate concentration (LA, mM) (LKM 140, Dr Lange, Germany). Gas analyzers were calibrated before each experiment.

Oxygen consumption, ($\dot{V}O_2$, 1 min^{-1} and ml kg^{-1} min^{-1}) was determined by open circuit standard method.[19] The cost of locomotion (C, ml kg^{-1} m^{-1}), ie the energy required to cover 1 m per unit of transported mass (body + WHCH or orthosis weight), was finally calculated.

Testing procedure
Patients were studied at rest (both sitting on the WHCH and standing with orthosis) and under different conditions (on different days): (a) during orthosis-assisted ambulation, maintaining two to three different velocities chosen by the subject, including the self-selected optimal speed, for 7 min each. One day later the test was repeated at the maximum speed which could be achieved and maintained by the patient for 5 min; (b) during WHCH locomotion on a wheelchair-adapted rolling ergometer (Ergotronic 4000, Sopur, Germany) at 3–4 incremental speeds (for 7 min each) until muscular exhaustion. During (a) and (b), subjects were required to maintain a constant speed, which was accurately measured. For both (a) and (b) experimental conditions the patient was allowed to rest for about 10 min after each speed.

Respiratory gases were collected at rest for about 5 min and between the 5th and 7th minute of each exercise intensity (steady state conditions). For venous lactate determination blood samples were drawn by glass capillaries from the ear lobe before and 5 min after the heaviest exercise.[19]

Questionnaires
To assess the short and long-term compliance to orthotic use, patients were contacted by telephone 18 months and 4 years after the beginning of the study and were asked to answer a questionnaire, regarding the use of their orthosis (Table 2). Twelve of 14 subjects were successfully reached and agreed to answer the questions.

Statistical analysis
Where not otherwise indicated, statistical descriptions of data were made by means and standard deviation. For the statistical comparisons we used the unpaired Student *t*-test or the one way ANOVA when appropriate. The least square linear regression was applied to the HR/$\dot{V}O_2$ relationship, followed by a fit *F*-test to confirm linearity. The level of statistical significance was set at $P < 0.05$.

Results

Considering all patients, during WHCH ambulation the achieved maximal speeds ranged from 3.1 to 8.5 km h^{-1}, averaging 6.2 ± 2.0, 5.4 ± 1.3 and 5.2 ± 1.6 km h^{-1}, for PW, RGO and RGO+FNS, respectively (P=ns between groups). During orthosis assisted ambulation, maximal speeds were reduced to about 10% of the WHCH velocities: 0.59 ± 0.2; 0.67 ± 0.1 and 0.57 ± 0.3 km h^{-1}, for PW, RGO and RGO+FNS, respectively (P=ns). A strong positive correlation ($r^2 = 0.74$, $P < 0.001$) was observed between the maximal speeds achieved by WHCH and orthosis in each subject (Figure 1).

During WHCH locomotion at maximal speed, HR peak values were 160 ± 16, 155 ± 31, 154 ± 31 b min^{-1} and $\dot{V}O_2$ kg^{-1} peak were 18.0 ± 6.1, 18.5 ± 5.4, 19.1 ± 7.2 l min^{-1} for PW, RGO and RGO+FNS, respectively.

During orthosis-assisted locomotion at maximal speed HR peak values were 150 ± 13, 131 ± 21, 155 ± 23 b min^{-1}, and $\dot{V}O_2$ kg^{-1} peak were 13.4 ± 3.0, 13.8 ± 3.5, 17.2 ± 4.8 for PW, RGO and RGO+FNS, respectively. Neither HR nor $\dot{V}O_2$ kg^{-1} peak showed significant differences between groups and within the same group during different types of locomotion.

Maximal ventilations at $\dot{V}O_2$ peak were 63.8 ± 24.0, 68.9 ± 27.1, 67.6 ± 23.9 l min^{-1} during WHCH ambulation, and 71.8 ± 7.3, 76.5 ± 21.3 and 72.3 ± 12.2 m kg^{-1} min^{-1} during orthosis locomotion for PW, RGO and RGO+FNS, respectively (P=ns between groups and within the same group during different types of locomotion).

Figure 2 shows that, with both WHCH and orthosis (n=76, corresponding to 3–4 $\dot{V}O_2$ values for each subject), $\dot{V}O_2$ and velocity of ambulation were linearly correlated. In Figure 3 the HR/$\dot{V}O_2$ relationships are presented in separate plots for each type of orthosis, together with the corresponding values obtained using

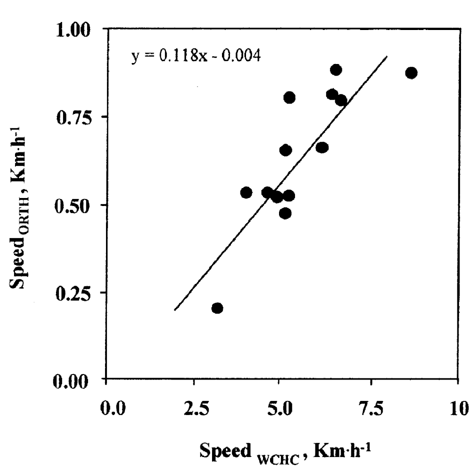

Figure 1 Relationship between maximal speeds achieved by WHCH and by orthotic ambulation in each subject

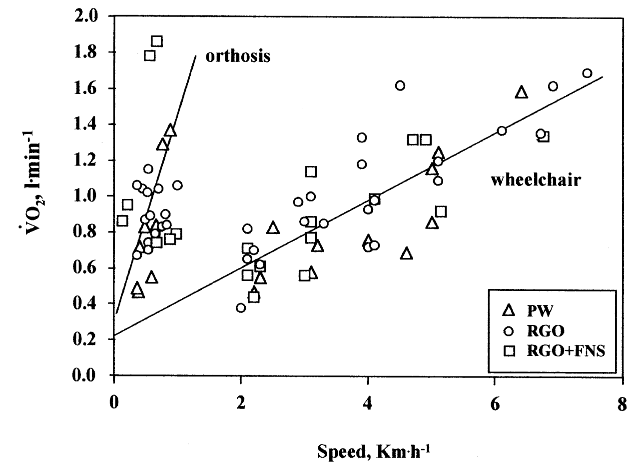

Figure 2 Overall relationship (individual data) between aerobic energy expenditure ($\dot{V}O_2$) and velocity of ambulation using WHCH and orthosis. Triangles, circles and squares correspond to PW, RGO, and RGO+FNS values, respectively. Linear trends were separately plotted for WHCH and orthosis data. Resting $\dot{V}O_2$ data (velocity=0) were removed for clarity

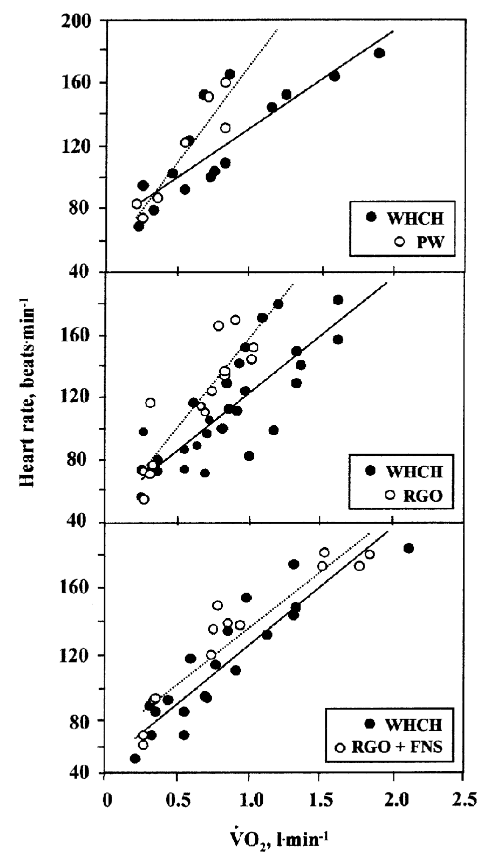

Figure 3 HR/$\dot{V}O_2$ relationship for the three types of orthosis used. Filled circles indicate the values during WHCH locomotion on the roller ergometer (the equations of the linear regressions are reported in Table 3), open circles refer to orthotic use. Linear trends were separately plotted, either for WHCH (continuous lines) and orthotic (dashed lines) use

WHCH. The R^2 slope and the linear regression of each curve were also calculated (Table 3). The slope difference $\Delta_{sl}HR/\dot{V}O_2$ (b l^{-1}) refers to the increase in heart beats for liter of O_2 consumed when changing from WHCH to orthosis use. These differences were significant when comparing PW or RGO to WHCH use ($P<0.05$), but not for RGO + FNS locomotion (P = ns). When normalizing the $\dot{V}O_2$ kg^{-1} of body + WHCH or orthosis weight, $\Delta_{sl}HR/\dot{V}O_2$ did not substantially change (data not shown).

Figure 4 shows the percentage $\dot{V}O_2/\dot{V}O_2$ peak ratio during standing, walking at self-selected speed, and walking at maximal speed in each subject. In seven (50%) out of 14 patients the self-selected speed caused an increase in $\dot{V}O_2$ above 80% of $\dot{V}O_2$ peak.

The cost of locomotion for each type of orthosis was estimated at three different ranks of velocities, arbitrarily chosen to get the median velocity of all subjects in the medium rank, and to maintain an approximate equal number of velocities per rank. Figure 5 shows that, for very low speeds of ambulation, paraplegics using RGO + FNS had a significantly higher C, compared with that of the other groups. At medium velocities, RGO + FNS cost tended to remain higher but not significantly different with respect to other groups, whereas at higher speeds this difference completely disappeared. However, at the most comfortable velocity, spontaneously chosen by the subject, C in RGO + FNS group was 1.99 ± 1.37 at 0.49 km h^{-1}, significantly higher than in other groups (0.81 ± 0.3 at 0.53 km h^{-1} and 0.88 ± 0.01 at 0.50 km h^{-1} in PW e RGO groups, respectively; $P = 0.05$).

Five minutes after the maximal velocities during WHCH locomotion, venous lactate increased in comparison to pre-exercise value (5.3 ± 2.0 *vs* 1.1 ± 0.3 mM, $P<0.05$), with no differences between

Table 3 Variable of the $HR/\dot{V}O_2$ relationships presented in Figure 3

	Slope ($b{\cdot}ml^{-1}$ O_2)	*Intercept (bpm)*	R^2	P	$\Delta slope_{WHCH\text{-}ORTH}$ ($b{\cdot}ml^{-1}$ O_2)
WHCH	68.8	59.0	0.65	<0.001	–
PW	121.0	48.5	0.71	<0.001	52.2
RGO	112.2	43.3	0.76	<0.001	43.4
RGO + FNS	65.5	70.3	0.87	<0.001	−3.3

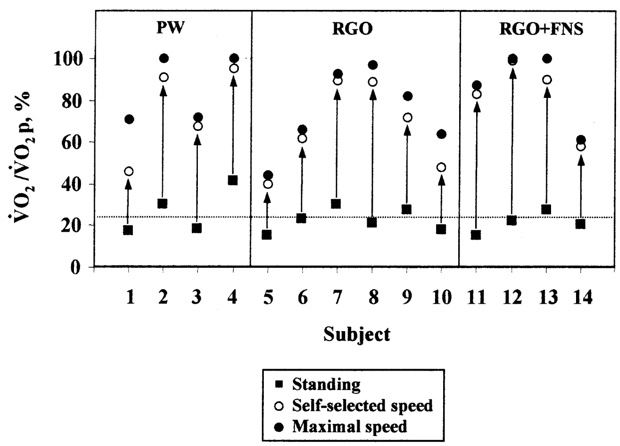

Figure 4 Percentage $\dot{V}O_2/\dot{V}O_2$ peak ratio during standing (filled squares), walking at self-selected speed (open circles), and walking at maximal speed (filled circles) in each subject. Arrows refer to the transition between resting conditions and walking at the self-selected speed. The dotted lines represent the mean resting metabolic rate to maintain the standing position

Table 2 Problems related to orthoses usage and short-term (18 months from the beginning of the study) and long-term (4 years from the beginning of the study) compliance

Subjects	*Orthoses type*	*Short-term follow-up (months of use after training)*	*Long-term follow-up*	*Difficulties in orthotic use*
1	PW	n.a.	n.a.	n.a.
2	PW	4	abandoned	difficult to don/doff
3	PW	2	abandoned	difficult to don/doff
4	PW	2	abandoned	hard work
5	RGO	18	still using	difficult to don/doff
6	RGO	2	abandoned	too bulky
7	RGO	14	still using	too bulky
8	RGO	15	still using	too bulky
9	RGO	4	abandoned	too bulky
10	RGO	n.a.	n.a.	n.a.
11	RGO + FNS	2	continues FNS only	difficult to don/doff
12	RGO + FNS	2	continues FNS only	medical problems
13	RGO + FNS	3	continues FNS only	medical problems
14	RGO + FNS	2	continues FNS only	difficult to don/doff

*n.a. = not available

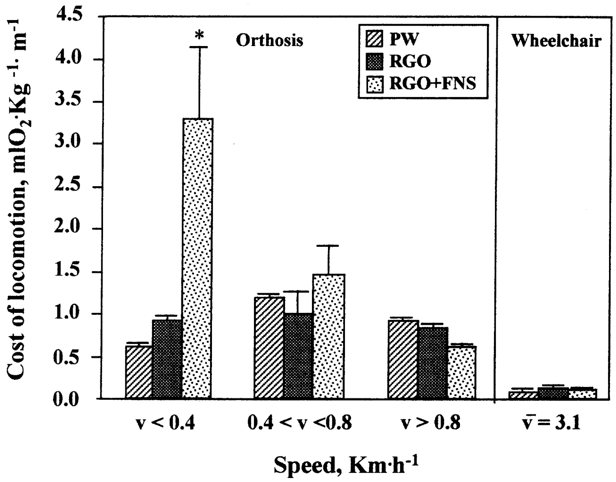

Figure 5 Cost of locomotion for the three types of orthosis, and for WHCH ambulation as a function of different velocities ($* = P < 0.05$ *vs* other groups at the same speed. One-way ANOVA). Lined bars = PW; filled bars = RGO; dotted bars = RGO + FNS

PW, RGO and RGO + FNS groups. A significant increase with respect to the basal value was also observed during orthosis-assisted ambulation (3.1 ± 2.1 *vs* 1.1 ± 0.5 mM, $P < 0.05$), with no differences between groups.

No correlation was observed between venous lactate and maximal velocities during orthosis ambulation, and no significant difference was found between subjects using electrically stimulated devices and patients using other types of orthosis.

Table 2 shows for each patient the short-time duration (months) and the long-term usage of orthosis. Problems related to orthotic use are also reported: these were the main cause of abandonment in those subjects who rejected the orthosis. Moreover, no correlation was found between the duration of orthosis use after training (expressed in months), and $\dot{V}O_2$ max ($R^2 = 0.15$, P = ns), C ($R^2 = 0.16$, P = ns) and $\Delta_{sl}HR/\dot{V}O_2$ ($R^2 = 0.10$, P = ns).

Discussion

The problem of the early withdrawal from orthotic use is well known.[20] Our data confirmed this finding, as indicated in Table 2, which shows that only three out of 12 patients (25%) were still using orthotic devices after 4 years from the beginning of the study (long-term follow-up).

This study compared the cardiorespiratory and metabolic adjustments to WHCH and orthotic ambulation in individual patients, in order to understand some of the physiological changes occurring during assisted locomotion, and to study whether the early abandonment of the orthosis may be attributed to excessive fatiguability.

Gravitational effects during orthotic use

In paraplegic subjects the muscular pump in lower limbs and the vasomotor control in the splanchnic area are impaired, thus leading to an inadequate venous return during exercise.[8] Moreover, when exercise is performed in the standing position, such impairment is overemphasized.[14]

In the present work we studied the effects of blood redistribution on muscular performance during locomotion with WHCH and orthosis, with and without FNS, by comparing the $HR/\dot{V}O_2$ relationships in the two conditions. During orthotic deambulation the gravitational effect decreases stroke volume and thus impairs the blood redistribution to working upper limb muscles. Consequently, at a given $\dot{V}O_2$, HR is higher and the slope of the $HR/\dot{V}O_2$ curve is increased.[9] Thus, such a phenomenon critically limits energy expenditure during near-maximal work.

Standing When a back extrapolation of the $HR/\dot{V}O_2$ relationship to resting $\dot{V}O_2$ was attempted, the ordinate differences observed between WHCH and orthoses were possibly related to the postural component of the two conditions (sitting *vs* standing). The higher the difference, the more the subject is supposed to require a static muscular activity, which increases *per se* HR. Moreover, an abnormally high resting metabolic rate is required, which reaches about 20% to 30% of the maximal oxygen uptake (Figure 4). In healthy subjects the corresponding value is 4% to 8%. The practicality of these observations is that specific training in postural adaptation might be helpful.

Walking with RGO and PW The gravitational effect is particularly evident in RGO and PW patients at maximum effort, since we observed an almost twofold increase in the $HR/\dot{V}O_2$ slope with respect to WHCH in both PW and RGO patients ($P < 0.05$). This indicates that for a given work load the cardiorespiratory involvement is much higher during orthotic use than during WHCH locomotion, and this may accelerate fatigue occurrence. Moreover, the oxygen demand is in most subjects above 50% of the $\dot{V}O_2$ peak, even during locomotion at self-selected speed (Figure 4). Such relative intensity cannot be sustained for long periods of time.

Walking with RGO + FNS On the contrary, the $HR/\dot{V}O_2$ slope did not substantially differ between WHCH and orthotic locomotion in RGO + FNS patients, suggesting that muscle stimulation can improve venous return and stroke volume. Figoni[29] showed a similar effect on cardiac output, by evaluating the cardiovascular response to arm cranking with and without electrically simulated leg cycling. However, as shown in Figure 4, at the comfort velocity spontaneously chosen by each subject, the energy expenditure was substantially higher in RGO + FNS patients as well as in the other groups: in particular, in three out of the four RGO + FNS patients the $\dot{V}O_2/\dot{V}O_2$ p ratio was higher than 80%. This suggests that, despite the improvement in cardiovascular efficiency observed during ambulation with RGO + FNS, the overall energy demand of orthotic use remains extremely high, regardless of the device used.

Marsolais[21] showed an increased HR peak in RGO + FNS patients, and proposed that the stimulation itself can increase HR, directly or by increasing oxygen requirement because of the larger muscular mass at work. Our data did not show any significant increase in HR peak in the RGO + FNS group. However, the $\dot{V}O_2$ peak was 25% higher during orthotic walking than during WHCH locomotion. It seems therefore that electrical stimulation may increase the cardiac preload by acting as an auxiliary muscular pump, thus possibly reducing the need to raise heart rate for a given $\dot{V}O_2$.

Role of thermoregulation and anaerobic metabolism

All experiments were carried out at the same temperture (room temperature), so we can *a priori* exclude that the differences observed in the HR/$\dot{V}O_2$ slope between groups might be related to thermoregulatory adaptations.

Anaerobic metabolism might also account for the observed difference between groups. However, we did not find any significant differences in blood lactate concentration among the three groups using orthoses. Therefore, a similar anaerobic lactacid component can be assumed for all the patients tested.

Cost of locomotion

The energy costs of orthosis-assisted locomotion have been previously reported.[22,23] In this study, C was higher in RGO + FNS subjects, especially at low velocities of ambulation (Figure 5). Such a trend confirms previously reported data.[13] A significant difference between C in RGO + FNS *versus* RGO has also been reported by Petrofsky,[24] although only for certain speeds. One possible explanation may come from the work of Marsolais,[21] who showed that only faster speeds result in lower energy expenditure with RGO + FNS, as a decreased amount of energy is wasted in stance.

When calculated at the velocity spontaneously chosen by our subjects, C values were significantly higher in RGO + FNS patients than in other groups. This suggests that, at similar speeds, the electrical stimulation of extensive muscular masses leads to a higher $\dot{V}O_2$. Nene[13] reported that electrical stimulation, producing a substantial redistribution of muscle working load by the recruitment of large muscles, yields an increased energy cost of locomotion.

The significant correlation between lesion level and C previously reported by Merkel,[25] was not confirmed in our patients ($R^2 = 0.05$), probably because of the low number of cases and of the different fitness level of the patients. Regardless of lesion level, we showed that the energy cost of locomotion is lower for higher velocities of ambulation. Therefore an appropriate training with RGO + FNS can be proposed to those individuals who can ambulate at sufficiently elevated speeds. The strong correlation between maximal WHCH speed, a good index of the subjects' fitness, and maximal speed during orthosis locomotion indicate that such capability may be predicted by a simple WHCH test. Thus, if orthoses prescription will still be encouraged, the WHCH test at different velocities may help to identify those patients who will probably experience the minimum effort in assisted ambulation and will better tolerate the task for longer periods.

Patients' compliance

A large number of patients abandoned the orthotic walking in our work, in agreement with previous data.[20] Unfortunately, either C, $\dot{V}O_2$, or the slope difference in HR/$\dot{V}O_2$ relationship failed to directly predict the duration of orthotic use. Other mechanisms are therefore to be identified to explain the low patients' compliance. The results of our questionnaire about the patients' motivation for orthotic use and abandonment showed that the main drawback may be difficulties of doff and don (Table 2). Moreover, orthoses are cumbersome to use, and do not substantially improve the quality of life. Although only in one case the excessive effort in walking was the cause of the orthosis abandonment, according to the subject's report, it is well known that an energy expenditure exceeding 40% to 80% of the maximal value cannot be tolerated for a long time.[26] Walking in healthy subjects can be tolerated for hours, as it is known to have negligible energy costs. The use of orthotic devices is not convenient at the observed energy requirements. However, if the maximal (or peak) oxygen uptake is much higher, as in paraplegic athletes,[27] then the $\dot{V}O_2$/$\dot{V}O_2$ peak at the self-selected speed should be lower and therefore tolerable. Similar results were obtained by Sykes[20] and Lotta.[7] Nevertheless, some subjects continued to use their orthoses for long periods limited to a few hours daily at home, underlying the possible beneficial effect of exercise on the overall cardiovascular fitness. As largely demonstrated,[28] this practice improves patients' fitness and reduces the risk of cardiorespiratory disabilities.

Conclusions

Our data showed that electrical stimulation can partially improve locomotion, as a consequence of hemodynamic effects, but does not decrease energy expenditure, which remains high. However energy expenditure parameters cannot predict patients' long-term compliance to orthosis use. Nevertheless, the determination of the maximal speed achieved and the corresponding $\dot{V}O_2$ peak during WHCH locomotion, and the comparison between individual WHCH and orthosis HR/$\dot{V}O_2$ curves may represent a useful test to evaluate the hemodynamic determinants of energy expenditure during assisted ambulation with different types of orthosis. Subjects who can reach high speeds by WHCH seem to be the most appropriate for RGO+FNS locomotion. Therefore, an ergometric WHCH test may help to predict the efficiency of the cardiorespiratory system and the tolerability of the device. This may help clinicians to decide which subjects are better candidates for stimulated devices.

Although a large number of patients prefer WHCH locomotion during daily living activity, we believe that training with such devices should be encouraged in spinal men. The advantage of walking are numerous.[26] Further studies are needed to give training personnel more complete information in the setting of a correct training program. This may finally improve the adaptation of the paraplegic to his device, consequently increasing the compliance in use.

Abbreviations

RGO, reciprocating gait orthosis; RGO+FNS, reciprocating gait orthosis+functional neuromuscular stimulation; PW, Para Walker; WHCH, wheelchair; HR, heart rate; $\dot{V}O_2$, oxygen uptake; $\dot{V}O_2p$, peak oxygen uptake; $\dot{V}E$, pulmonary ventilation; C, energy cost of locomotion; LA, lactic acid

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