A Comparative Study of 3 Portable Oxygen Concentrators During a 6-Minute Walk Test in Patients With Chronic Lung Disease

Carole J LeBlanc RRT, Lyne G Lavallée PT, Judy A King PhD PT, Rebecca E Taylor-Sussex, Andrew Woolnough MSc, and Douglas A McKim MD

BACKGROUND: The purpose of this study was to compare the ability of 3 portable oxygen concentrators (POCs) to maintain $S_{pO_2} \geq 90\%$ during exercise in patients with chronic lung disease. METHODS: Twenty-one subjects with chronic lung disease (18 with COPD, 3 with pulmonary fibrosis) and documented room air exertional $S_{pO_2} \leq 85\%$ performed four 6-min walk tests: a control walk using the subject's current oxygen system and prescribed exertional flow rate, and 1 walk with each of the 3 POCs (Eclipse 3, EverGo, and iGo) at their maximum pulse-dose setting. RESULTS: S_{pO_2} was significantly higher pre-walk and post-walk with the Eclipse 3, compared to the other POCs (all $P < .01$). The subjects also walked farther and maintained a mean $S_{pO_2} \geq 90\%$ with the Eclipse 3 (both $P < .01$), which delivers the largest oxygen bolus. The subjects indicated that they preferred the EverGo's physical characteristics, but that the Eclipse 3 responded best to their breathing. The iGo was rated less favorably than Eclipse 3 or EverGo. CONCLUSIONS: The Eclipse 3 was best at meeting the subjects' clinical needs. POC users should be appropriately tested during all activities of daily living, to ensure adequate oxygenation. The healthcare provider should provide information and help to direct the subject toward the most clinically appropriate oxygen system, while being mindful of the patient's preferences and lifestyle. (Clinicaltrials.gov NCT01653730). *Key words: COPD; oxygen; instrumentation; pulmonary fibrosis; exercise test; ambulatory care; walking.* [Respir Care 2013;58(10):1598–1605. © 2013 Daedalus Enterprises]

Introduction

Long-term oxygen therapy (LTOT) is indicated for patients with chronic lung disease, and is universally accepted for its effect on mortality in patients with COPD and persistent hypoxemia.[1,2] Supplemental oxygen improves exercise performance, enhances exercise training, and reduces dyspnea.[3,4]

Patients with chronic lung disease using LTOT benefit from an active lifestyle, and portable oxygen systems are of particular interest to this patient population. The challenge for clinicians is in selecting the most appropriate portable oxygen system and meeting the patients' current and future clinical and physical needs.[5-13] The 6th LTOT consensus conference recommended that physicians, patients, and home-medical-equipment providers effectively collaborate to ensure LTOT users have access to the most

Ms LeBlanc, Ms Lavallée, and Dr McKim are affiliated with the Ottawa Hospital Rehabilitation Centre; Ms Lavallée, Dr King and Dr McKim are affiliated with the University of Ottawa; and Ms Taylor-Sussex and Mr Woolnough are affiliated with the Ottawa Hospital Research Institute, Ottawa, Ontario, Canada.

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Correspondence: Carole J LeBlanc RRT CRE, Ottawa Hospital Rehabilitation Centre, 1201-505 Smyth Road, Ottawa, Ontario K1H 8M2, Canada. E-mail: cleblanc@ottawahospital.on.ca.

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appropriate technologies for their clinical and lifestyle needs.[14]

Portable oxygen concentrators (POCs), whose only daily requirement for maintenance is access to electricity to recharge the batteries, present an attractive option when compared to compressed gas and liquid oxygen systems. However, studies have shown that POCs do not always maintain adequate oxygenation during exercise,[5,7,13] and bench studies have shown decreases in F_{IO_2} in POCs as breathing frequency increases.[9,12] These studies give reason for concern, since evidence suggests that maintaining $S_{pO_2} \geq 90\%$ offers a survival advantage.[15]

A small number of studies have examined how variations in the technical specifications between POCs affect clinical outcomes in exercising patients. Subramaniam et al[10] compared 3 POCs during a 10 min treadmill test and found no statistical differences in S_{pO_2} or walking distance. However, a second group did find a difference between 3 POCs during a treadmill test, concluding that higher oxygen delivery capacity was associated with improved exercise outcomes and oxygenation.[5,13]

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In an attempt to reconcile the disparity in these results and to determine if POCs are capable of meeting patients' oxygen needs during exercise ($S_{pO_2} \geq 90\%$), we chose to evaluate 3 POCs using a standardized 6-min walk test (6MWT) in patients with chronic lung disease with severe exertional oxygen desaturation. We also measured patients' personal POC preferences.

Methods

This study was approved by the Ottawa Hospital Research Ethics Board (2009845-01H). All subjects gave written informed consent before their screening assessment.

Study Design and Setting

A within-subject, repeated-measures design was used to compare 3 POCs during an exercise test. The subjects attended 2 sessions at the Respiratory Services, CANVent Program of the Ottawa Hospital Rehabilitation Centre. During the initial screening session, clinical characteristics were measured to determine the patient's eligibility for the study. Eligible patients then returned for a second session, where they completed 4 6MWTs: 1 with their usual portable oxygen source, and 1 with each of the 3 POCs.

QUICK LOOK

Current knowledge

Supplemental oxygen during exercise reduces dyspnea and improves exercise performance in patients with hypoxemia due to chronic lung disease. Portable oxygen concentrators promote mobility, but their ability to reverse exercise-related hypoxemia is suspect.

What this paper contributes to our knowledge

The portable oxygen concentrator with the largest oxygen pulse-dose volume was best at meeting subjects' clinical needs. Home oxygen patients should be tested during all activities of daily living, including exercise, to ensure adequate oxygenation. Patients should be directed toward the most clinically appropriate portable oxygen system, but also consider patient preferences and lifestyle.

6-Min Walk Test

The 6MWT is a reproducible, self paced, walk test, reflective of activities of daily living.[16] A physiotherapist and a respiratory therapist conducted all of the walks using the American Thoracic Society 6MWT standards and script.[17]

Subjects

Oxygen dependent patients with an existing diagnosis of COPD or pulmonary fibrosis who had completed the pulmonary rehabilitation program at the Ottawa Hospital Rehabilitation Centre between January 30, 2008, and March 31, 2011, were invited to participate in the study. While the pathophysiology of pulmonary fibrosis is different than COPD, and the ability of POCs to maintain oxygenation during exercise may differ, this patient population also benefits from and partakes in an active lifestyle. They therefore need access to and/or guidance on the appropriateness of portable oxygen systems. For these reasons patients with pulmonary fibrosis were included in the study.

During the screening session, patients completed a 6MWT on room air to determine their eligibility for the remainder of the study. Patients who maintained $S_{pO_2} > 85\%$ during the walk were excluded (Fig. 1).

Equipment

We selected the 3 POCs with the highest oxygen production capabilities (mL/min) that were available in our

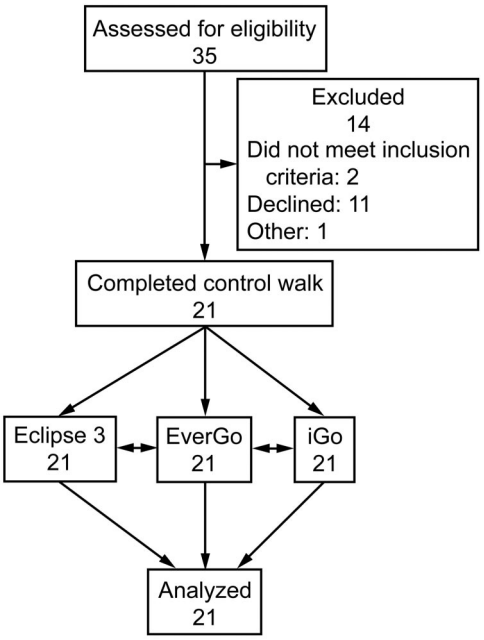

Fig. 1. Flow chart.

region: EverGo (Respironics, Murrysville, Pennsylvania), iGo (DeVilbiss Healthcare, Summerset, Pennsylvania), and Eclipse 3 (Caire Medical, Ball Ground, Georgia). Technical specifications can be found in Table 1. We tested these POCs' ability to meet the subjects' oxygenation needs. Since POC pulse-dose settings are most frequently used by patients on LTOT, to conserve battery power, each unit was set at its maximum pulse-dose setting. For the control walk the subjects used their personal portable oxygen device, on the setting prescribed for paced exercise (Table 2).

Screening Session

On the day of the screening assessment the subject's medical history was obtained and FEV_1 and FVC were measured (CPFS/D, Medical Graphics, St Paul, Minnesota). The subject then performed a qualifying room air 6MWT while S_{pO_2} was monitored.

POC Testing Session

Qualifying subjects returned to the clinic within 3 weeks for a second session. These subjects each performed 4 separate 6MWTs during this second session. Two walks were completed in the morning, followed by a minimum 2-hour lunch break, and then 2 walks in the afternoon. The first 6MWT was a control walk in which the subject used his or her usual oxygen system set at the prescribed exertional oxygen flow (maximum 4 L/min). The subject then performed a 6MWT with each of the 3 POCs, set at the unit's maximum pulse-dose setting. The Eclipse 3 was the only device with adjustable rise time and triggering sensitivity features. For all the subjects the sensitivity was set at "1" (most sensitive) and rise time set at "Fast."

The order in which POCs were used was randomly assigned for each subject, using a sequence generator to minimize order effects. Subjects completed the walk using their usual mode of ambulation (eg, walker with basket). Each 6MWT was separated by a minimum 20-min rest period to allow their S_{pO_2} to return to baseline, during which the subject used his or her own oxygen system at the prescribed resting setting. Subjects were placed on the assigned POC 10 min prior to the next walk. The therapist terminated a walk if the subject's S_{pO_2} reached $\leq 85\%$ for any length of time. Subjects also had the option to terminate a walk at any time, based on their own judgment of perceived exhaustion.

Outcome Measures

S_{pO_2} was measured continuously during the walk, using a forehead probe (OxiMax Max-Fast, Covidien, Mansfield, Massachusetts) with headband, and an oximeter (OxiMax N-600 or N600x, Covidien, Mansfield, Massachusetts). Heart rate was monitored during the walk to ensure probe connectivity and to ensure subject safety, but is not reported. After each walk, oximetry data were downloaded to a computer (Profox Oximetry Software, Profox Associates, Escondido, California). S_{pO_2} and dyspnea (as measured by the 10-point Borg dyspnea scale)[18] were manually recorded before the start (pre-walk) and at the end (post-walk). Total distance walked and time spent with $S_{pO_2} \geq 90\%$ was recorded. Post-walk the subjects completed a self-administered questionnaire designed by the researchers to allow them to rate the POCs (Fig. 2).

Statistical Analysis

Pre-walk and post-walk S_{pO_2} saturations and Borg scores were analyzed using repeated-measures analysis of variance with time point (pre-walk vs post-walk) and POC type as within-subject repeated factors. Pairwise post hoc comparisons applying Bonferonni corrections for multiple comparisons were done to further examine significant effects. A second repeated-measures analysis of variance was completed for outcomes measured only once (walk distance, time with $S_{pO_2} \geq 90\%$) with POC type as the within-subject repeated factor. Questionnaire data were examined with descriptive analyses. All analyses were completed with statistics software (SPSS 18 or 19, SPSS, Chicago, Illinois).

Table 1. Technical Specifications of the Tested Portable Oxygen Concentrators

	iGo 306D S-A	Eclipse 3	EverGo
Maximum O_2 delivery, mL/min	3,000	3,000	1,050
O_2 pulse-dose bolus volume, mL	14–84	16–192	12–70
Purity of O_2, %	91 ± 3	90 ± 3	89 ± 3
Pulse-dose setting	1–6	1–6	1–6
Trigger sensitivity, cm H_2O	−0.05 to −0.12	−0.15 to −0.45	−0.2
O_2 delivery method	Continuous up to 3 L/min Pulse-dose maximum setting 6	Continuous up to 3 L/min Pulse-dose maximum setting 6	Pulse-dose maximum setting 6
FDA clearance status	Approved up to 4,000 mL/min	Approved up to 4,000 mL/min	Approved up to 2,450 mL/min
Noise level, dBa	40 at pulse-dose setting 3	< 49	< 50
Weight, kg	8.6 with one battery	8.4 with one battery	4.5 with two batteries
Dimensions, cm	49.0 H × 31.2 W × 18.0 D	49.0 H × 31.2 W × 18.0 D	21.6 H × 15.25 W × 30.5 D
Battery duration, h	3.0 at pulse-dose setting 6 (bolus 84 mL) and breathing frequency 20 breaths/min	3.5 at pulse-dose setting 6 (bolus 96 mL) and breathing frequency 12 breaths/min	4.0 with pulse-dose of 6 (bolus 70 mL) and breathing frequency 20/min
Battery recharge time, h	3/battery	2–3/battery	2–3/battery

dBa = decibels measured on the a-weighted scale

Table 2. Oxygen Systems, Pulse-Dose Settings, and Oxygen Flows by Number of Subjects

Device Type	Used Pulse-Dose Oxygen no. subjects	Pulse-Dose Setting (or Range)	Used Continuous Flow Oxygen no. subjects	Continuous Flow Setting (or Range) L/min
Compressed gas oxygen cylinder (E or D size)	4	1–5	1	3
Liquid oxygen	1	1.5	9	1–4
EverGo	3	2–2.5	0	0
Eclipse 3	1	4	1	2
Inogen	1	4	0	0

Results

Subject Demographics and Baseline Characteristics

Of the 35 patients who completed the rehabilitation program and were oxygen dependent, 24 agreed to participate, 2 of whom failed to meet the S_{pO_2} criteria during the screening room air 6MWT, and another was excluded due to poor S_{pO_2} tracking, leaving 21 subjects in the analyses (12 females). The subjects had a mean ± SD age of 66.57 ± 8.36 y (range 53–82 y). Eighteen subjects were diagnosed with COPD, and 3 with pulmonary fibrosis. The mean percent-of-predicted FEV_1 was 32.22 ± 11.67% in the subjects with COPD, and 61.0 ± 7.94% in the subjects with pulmonary fibrosis. The mean FEV_1/FVC was 42.22 ± 16.35% in the subjects with COPD, and 85.67 ± 4.04% in the subjects with pulmonary fibrosis.

Fifteen subjects used a wheeled walker to carry the POCs, and 6 used the manufacturer provided POC wheeling device.

6-Min Walk Test Results

The 6MWT results and reasons for walk termination are presented in Table 3. Eighty-six percent of the subjects walked for the full 6 min using the Eclipse 3, as compared to 52% using either the iGo or the EverGo. One walk was terminated by the subject, during an EverGo trial; all other terminations were initiated by the therapist, due to oxygen desaturation.

There was a significant interaction between POC type and the pre-walk versus post-walk S_{pO_2} measurements ($P = .006$). Post hoc tests showed that S_{pO_2} was higher pre-walk ($P < .001$) and was highest with the Eclipse 3 ($P < .001$ for all comparisons of Eclipse 3 to iGo and EverGo). The Eclipse 3 had higher mean S_{pO_2} both pre-walk and post-walk, and the S_{pO_2} decrease between pre-walk and post-walk was the smallest with Eclipse 3 (Fig. 3).

The during-walk S_{pO_2} of the 3 subjects with pulmonary fibrosis were within the distribution of all the subjects.

Portable Oxygen Concentrators Questionnaire

Participant No. _____ ❑ iGo ❑ Eclipse 3 ❑ EverGo

Please circle the most appropriate answer

1. Have you ever used this apparatus in the past?
   Yes No
2. This equipment was easy to use while walking.
   Strongly 5 4 3 2 1 Strongly
   Agree Disagree
3. This equipment responded well to my breathing while walking.
   Strongly 5 4 3 2 1 Strongly
   Agree Disagree
4. The weight of the equipment was acceptable.
   Strongly 5 4 3 2 1 Strongly
   Agree Disagree
5. The size of the equipment was acceptable.
   Strongly 5 4 3 2 1 Strongly
   Agree Disagree
6. I would consider this device for daily use.
   Strongly 5 4 3 2 1 Strongly
   Agree Disagree
7. I feel comfortable with this device.
   Strongly 5 4 3 2 1 Strongly
   Agree Disagree

Please add comments concerning number 7 above:

_____

Please add any other comments: _____

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Fig. 2. Self-administered questionnaire about portable oxygen concentrators.

With the Eclipse 3, 2 of the 3 subjects with pulmonary fibrosis maintained $S_{pO_2} \geq 90\%$ for the duration of the walk, and the 3rd subject maintained $S_{pO_2} > 85\%$. The subjects with pulmonary fibrosis did not maintain $S_{pO_2} > 85\%$, nor did 7 of the 18 subjects with COPD, with the iGo or EverGo.

While the mean Borg score was significantly higher post-walk than pre-walk ($P < .001$), there was no significant Borg score difference between the POCs ($P = .20$).

There was a significant difference between the POCs for time spent with $S_{pO_2} \geq 90\%$ ($P < .001$) and total distance walked ($P = .001$). Post hoc analyses indicated that the subjects walked farther with the Eclipse 3 (control $P = .01$, EverGo $P = .009$, iGo $P = .008$) and spent more time with $S_{pO_2} \geq 90\%$ (control $P < .001$, EverGo $P < .001$, iGo $P = .001$). The Eclipse 3 was the only POC to maintain a mean $S_{pO_2} \geq 90\%$ for the duration of the walk.

Questionnaire Responses

The subjects consistently gave neutral (3) or disagree (1 or 2) questionnaire responses for the iGo. The subjects rated the EverGo most favorably for the questions about the device's physical characteristics (86% of subjects rated EverGo 4 or 5 for each statement), whereas the Eclipse 3 received the most favorable response regarding the device's ability to respond to breathing (95% of subjects gave a rating of 4 or 5). The EverGo and the Eclipse 3 received comparable responses to the remaining statements, with ratings of 4 or 5 in 81% and 76% of the subjects for "easy to use while walking," 50% and 48% for "felt comfortable with device," and 52% and 43% for "would consider for future use" (Table 4).

Discussion

This study compared the ability of 3 POCs to maintain adequate oxygenation during a 6MWT in a well defined group of subjects with chronic lung disease. Despite using the maximum pulse-dose setting for each device, the Eclipse 3 was the only POC to maintain a mean $S_{pO_2} \geq 90\%$ for the duration of the 6MWT, and showed significantly better performance on all outcome measures. The difference in walk distance between the Eclipse 3 and the other 2 POCs was also clinically important.[19] Furthermore, the subjects rated the Eclipse 3 as the best to respond to their own spontaneous breathing patterns during exercise.

Although the Eclipse 3 and the iGo have the same high oxygen production capability (3,000 mL/min), they did not demonstrate equivalent performance. This is in contrast with the results found by McCoy et al,[5,13] who concluded that having a POC with a greater oxygen production capacity improved S_{pO_2} and exercise outcomes. Instead, we found that post-walk S_{pO_2} and walk distance were more similar between the EverGo and the iGo than the Eclipse 3, despite the fact that the EverGo has a published oxygen production capability about one third that of the other 2 POCs (1,050 mL/min). Based on these POCs' technical specifications, we speculate that the most probable characteristic contributing to the performance differences was the O_2 pulse-dose bolus volume. While the bolus volume ranges of the iGo and EverGo are similar, the Eclipse 3 is much larger (see Table 1). In line with results reported by Chatburn and Williams,[9] we suggest that the larger O_2 pulse bolus volume of the Eclipse 3 was an important contributing factor enabling it to better meet the subjects' oxygen needs during exercise.

Table 3. 6-Min Walk Test Results, and Reasons for Walk Termination

	Control	EverGo	Eclipse 3	iGo
S_{pO_2}, %				
Pre	96.14 ± 2.48	95.90 ± 2.98	98.62 ± 1.69*	96.19 ± 2.80
Post	86.67 ± 3.60	87.24 ± 3.96	92.19 ± 5.20*	86.86 ± 4.49
Borg dyspnea score				
Pre	0.21 ± 0.49	0.26 ± 0.49	0.24 ± 0.49	0.24 ± 0.52
Post	3.14 ± 1.73	3.55 ± 2.02	3.14 ± 1.82	3.50 ± 1.58
Time with $S_{pO_2} \geq 90\%$, min:s	2:39 ± 1:43	2:38 ± 2:05	5:16 ± 1:33*	3:11 ± 2:16
Distance, mean ± SD m	262.62 ± 107.54	237.43 ± 116.04	315.52 ± 93.45*	227.62 ± 118.81
Completed walk, %	62	52	86	52
Subject decided to stop walk, %	0	5	0	0
Asked to stop by therapist, %	38	43	14	48

± values are mean ± SD.
* Significant ($P < .01$) difference, compared to all the other portable oxygen concentrator trials.

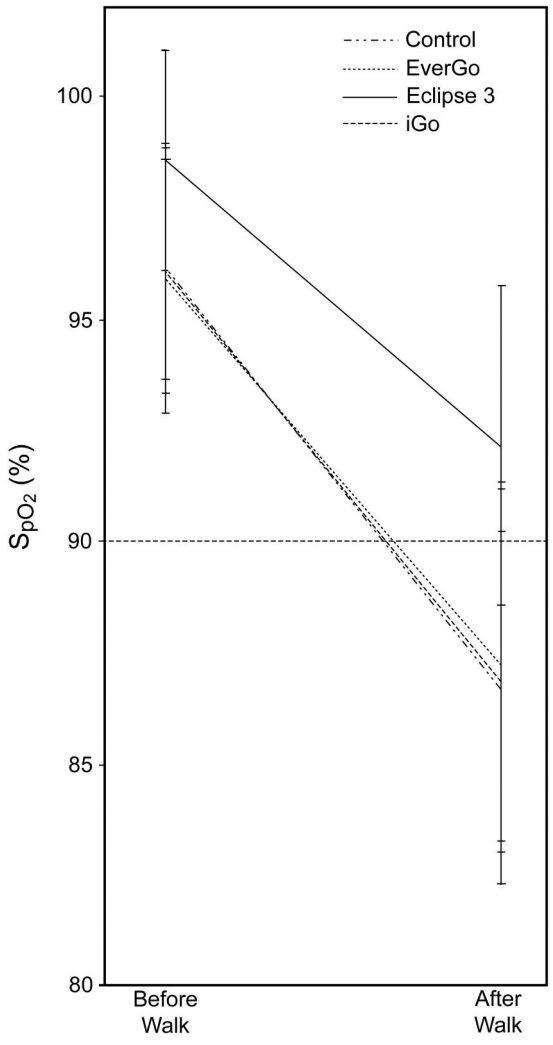

Fig. 3. S_{pO_2} before and after four 6-min walk tests: control (subject's usual portable oxygen system), with the iGo POC, with the Eclipse 3 POC, and with the EverGo POC. * Significant S_{pO_2} difference between Eclipse 3 and EverGo or iGo.

In spite of the Eclipse 3's superior performance for meeting clinical needs, subjects rated the EverGo and the Eclipse 3 similarly when asked if they would use the device in the future. Clearly, the physical characteristics of the EverGo, as the lightest and smallest POC, were important to subjects. Clinicians should educate patients that the goal of supplementary oxygen is to satisfy blood oxyhemoglobin needs and that this should be the first consideration in selecting a POC. The current study tested 3 specific POC models, and, although the technology will change, the recommendations and principles for determining the best POC for patients will remain. It is important to consider not only production capability but also bolus volume when helping patients choose the right POC.

During the control 6MWT most of the subjects desaturated to unacceptable levels. It is clear that subjects' usual paced walking prescription and oxygen device were unable to meet the oxygen requirements of strenuous exercise. During rehabilitation, patients are instructed in how to pace themselves during exercise, in order to minimize oxygen desaturation. Clinicians should ensure that patients are aware of the limitations of their devices and have appropriate oxygen prescriptions for all activity levels. This study should raise awareness of POC variability and that clinicians should focus on clinical outcomes under conditions as close as possible to real life. Clinicians and patients should test any potential new device to ensure it meets their clinical needs during activities of daily living. Patients' preferences (ie, for lighter, smaller, or more convenient devices) should only be considered once potential devices have been demonstrated to meet their oxygen needs.

Limitations

We did not test whether these POCs met their advertised product specifications. Our interpretation therefore assumes

Table 4. Summary of Questionnaire Data

Question	Percent of Subjects Who Selected This Response			
	Response*	iGo	Eclipse 3	EverGo
Have you ever used this apparatus in the past?	Yes	0	19	14
	No	100	81	86
The equipment was easy to use while walking.	1	10	0	10
	2	10	0	0
	3	38	24	10
	4	14	33	24
	5	29	43	57
The equipment responded well to my breathing while walking.	1	5	0	24
	2	19	5	24
	3	29	0	19
	4	24	38	5
	5	24	57	29
The weight of the equipment was acceptable.	1	33	25	5
	2	29	20	0
	3	24	30	10
	4	5	15	29
	5	10	10	57
The size of the equipment was acceptable.	1	33	5	5
	2	33	19	0
	3	14	43	10
	4	10	10	38
	5	10	24	48
I would consider this device for daily use.	1	43	24	19
	2	38	19	10
	3	5	14	19
	4	5	19	19
	5	10	24	33
I feel comfortable with this device.	1	24	0	10
	2	29	10	20
	3	29	43	20
	4	10	29	20
	5	10	19	30

Response number range: 1 = strongly disagree, 5 = strongly agree.

that no product defects or anomalies were present. Further, although subjects with COPD and pulmonary fibrosis were included in the sample, there was an insufficient number of subjects with pulmonary fibrosis to do group analyses. Despite this, visual inspection of the data suggests that the subjects with pulmonary fibrosis had patterns of performance on the different POCs similar to the subjects with COPD. Future studies should aim to recruit more subjects with pulmonary fibrosis, to determine if their needs are different from subjects with COPD. Additionally, due to methodological constraints we did not measure breathing frequency, which might have affected these POCs' ability to meet subjects' oxygen needs. Future studies should measure breathing frequency during ambulation.

Inhaled medication use was also not specifically monitored. Although none of the subjects was observed taking rescue inhaled medication, the subjects were not always visible to the therapists conducting the testing, in particular during lunch breaks and between walks. Nevertheless, since the measurements were made within subjects, and the order in which the POCs were used was randomly assigned, it is unlikely that there would be an effect of bronchodilator use that would have affected any one POC more than another.

Finally, it should be recalled that this study involves selected subjects who desaturated to below 85% during a room air walk test, so our results do not preclude the possibility that any of the POC devices tested could provide adequate oxygenation for subjects who have lesser degrees of desaturation.

Conclusions

These findings suggest that subjects with chronic lung disease exhibit considerable improvement in their ability to maintain S_{pO_2} when exercising with the Eclipse 3. We have shown that bolus size can be an important factor in determining the effectiveness of a POC, and healthcare professionals should be mindful of patients' current and future oxygen needs at all activity levels when guiding them in the selection of their own POC.

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