

## Aerobic Exercise Enabled with Rehabilitation Technology Improves Mobility and Balance of Patients with Parkinson's Disease: A Quality Assurance Report

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### Abstract

**Background and Purpose:** Evidence supports aerobic exercise for positive health and wellness. Unfortunately, physical and mental impairments can limit aerobic exercise potential by elders and those with neurodegenerative disease. Two Quality Assurance (QA) studies evaluated if rehabilitation technology could enable individuals with mild-moderate PD to exercise aerobically to gain mobility and balance skills without injury or exacerbation of self reported PD signs and symptoms.

**Methods:** Participants volunteered to train aerobically on two body weight supported treadmill systems (AlterGR and GlideTrakTM) (QA I) and/or a recumbent elliptical trainer (NuStep TR5x) with compression and cooling (VasperTM) (QA II). Pre and post training, the 10 Meter Walk, Six Minute Walk, Timed Up and Go (TUG) and Five Times Sit to Stand (FTSTS) were administered while signs/symptoms of PD were self reported before, during and after training.

**Results:** Twenty participants (11 and 9 respectively in QA I and II) completed 200-225 minutes of aerobic training achieving 60%-80% of maximum heart rate. Significant ( $p < 0.05$ ) gains were measured in balance and mobility without exacerbation of PD signs/symptoms. Despite reporting fatigue and discomfort during exercise, improvement in energy, resilience and tremors were self reported. Magnitude of gains differed by technology training group.

**Discussion and Conclusions:** Participants recommend rehabilitation technology for home use and community fitness center integration. The comparative QA findings helped clarify screening criteria, indications, contraindications, red flags and operational procedures for improving the integration of 3 types of technology into wellness and rehabilitation programs within a Physical Therapy Health and Wellness Center. The findings also provided support to create a group, technology enhanced aerobic class for clients with PD.

**Keywords:** Parkinson's disease; Aerobic exercise; Intense exercise; Robotic technology

### Introduction

Parkinson's Disease (PD) and Parkinsonism are commonly diagnosed in elderly patients [1]. PD is characterized by progressive impairments in motor function including resting tremors, rigidity, bradykinesia, micrographia, poor postural righting and reduced speech volume. PD is also associated with non-motor signs and symptoms of inflammation, pain, depression and decreased memory skills [2]. Basic science research is directed towards curing the disease with a focus on genetics, regenerative medicine and new pharmaceuticals. Quality assurance studies are focused on providing patient sensitive, accessible, effective intervention based on current evidence.

The most common medical management for PD is based on dopamine replacement medication [3]. Unfortunately medications often do not improve fine motor skills, dyskinesia, sensory

dysfunction, freezing, tremors, balance or fall risks. Moderate, flexibility, strengthening, balance, coordination, aerobic and intense exercises are recommended to reduce falls, maintain community mobility and maximize independence despite disease related impairments [4-12]. Physical immobility is the leading cause of disability and disease worldwide [13].

Consistent physical exercise can facilitate cardiovascular fitness, mobility, musculoskeletal health and disease prevention. Aerobic exercise may also help maintain dopamine receptors as well as increase endorphins, brain derivative neurotrophic factors (BDNF), growth hormones, up-regulation of dopamine, motor control, postural righting responses, bone density, oxygen delivery and blood flow [14,15]. Recent animal and human studies suggest intense and aerobic exercise may slow down aging (e.g. maintain telomere length, increase brain volume) [16-18], improve memory and prevent Alzheimer's Disease [17,19], as well as contribute to brain reorganization and neuroprotection in the case of PD [14,20-27].

A variety of moderate and aerobic exercise programs exist for patients with PD (e.g. dancing, fast striding, race walking, boxing, cycling, stationary biking, running, hiking or pairing a PD patient with a fit partner on a tandem bike) [26-30]. Unfortunately, PD patients with significant neuromotor control problems have difficulty performing free standing aerobic and intense exercise. Body weight supported training (BWST), either over ground or over a treadmill create another option for aerobic exercise training for patients with PD). Un-weighting decreases ground reaction forces and reduces cardiovascular load while facilitating spinal pattern generators to facilitate walking/running [31-35]. Unloading can be adjusted to counter the increasing forces associated with faster speeds like running and jogging. For example, when jogging fully weighted at @4.5 mph, @800# of force is generated when the foot hits the ground. When un-weighted to approximately 50% of body weight, the ground reaction forces are reduced to @450#. Integrating a reduced biomechanical load, enables individuals to run faster (e.g. up to 15 mph), albeit potentially with a shorter stride and decreased single limb support time [31,35].

Unfortunately, small amounts of un-weighting with a trunk harness (e.g. 20%) can be uncomfortable during walking, jogging or running [35]. Consequently, creative un-weighting systems are being developed to improve the comfort of un-loading at higher levels. For example, lower body positive air pressure support [www.AlterG.com] [36] and pelvic suspension systems [www.GlideCycle.com] have been developed for clinical use [37].

In addition to BWST systems, cooling and compression systems (VasperTM [www.vasper.com](http://www.vasper.com) and NuStep.com) [38,39] are also being integrated into performance training protocols to increase strength, endurance, power, aerobic capacity and positive metabolic change [31-35] (e.g. release of endorphins, upregulation of dopamine and human and brain derived growth factors).

To date, these new exercise technologies for un-weighting and cooling/ compression have primarily been integrated into sports medicine training programs to improve efficiency and effectiveness of exercise training for competitive athletes. Little is known about whether these technologies can effectively be used to improve mobility and balance of patients with neurological impairments that compromise voluntary movement. Before health care delivery systems, rehabilitation centers, community fitness centers or health and wellness facilities can justify the purchase of new exercise technology designed primarily for healthy adults and athletes, it is necessary to confirm patient sensitivity, accessibility, safety and effectiveness when this technology is integrated into exercise programs for individuals with impairments. The first step is to carry out quality assurance studies to clarify methodological issues related to sensitivity, accessibility and initial outcomes of short term intervention. These studies are not focused on contributing to the discovery of new research knowledge [40].

([http://umanitoba.ca/admin/vp\\_admin/media/bulletin79.pdf](http://umanitoba.ca/admin/vp_admin/media/bulletin79.pdf), [www.hreb.ualberta.ca/qa&pe.hTM](http://www.hreb.ualberta.ca/qa&pe.hTM)). The UCSF Physical Therapy Health and Wellness Center is integrated into a community fitness center on an academic health science campus. Rehabilitation technology is commonly placed at this site for increased visibility, assessment for patient care, education of students and need for transitional, integrative clinical research by faculty. Two AlterGR un-weighting systems were placed in the Health and Wellness Center in 2010. The GlideTrakTM was placed in the Center in 2011. The VasperTM system of cooling and compression with Nustep T5XR was

placed in the Center in 2013. The objective of the two quality assurance studies reported here was to determine if :1) the novel technologies (AlterGR, GlideTrakTM and VasperTM could be used to enable individuals with neurological impairments associated with mild to moderate PD to achieve aerobic levels of exercise: 2) short term aerobic training would be associated with measurable change in mobility and balance without exacerbation of qualitative signs and symptoms of PD or adverse events (e.g. equipment related injuries, cardiovascular events or falls; 3) participants would perceive the equipment positively (e.g. utility of use, training challenges and symptom management); 4) participants would recommend the equipment to others; 5) differences in quantitative and qualitative effects would be documented between the different technology assisted aerobic training paradigms; and 6) participants had training preferences relative to the different technology.

## Materials and Methods

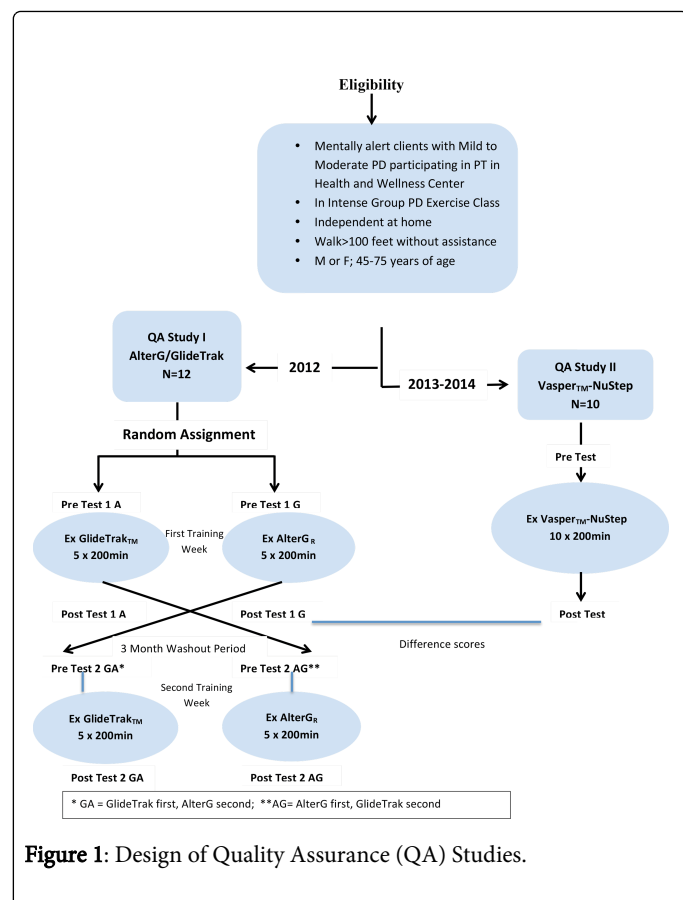
### Quality assurance (QA) study I

Participants: Clients 45-75 years of age with mild to moderate PD, either receiving wellness physical therapy in the UCSF Health and Wellness Center or having completed a previous research study in the Center ,were informed about the opportunity to participate in a QA study. Each client was mentally alert (VA mental status exam>24), [41] independent in the community (CAFÉ 40 Functional Independence >50%), [42] able to walk without an assistive device, with a medical history on file, without other neurological problems except PD, with or without a pacemaker and cleared by a physician to exercise aerobically. Formal consent was not required for this methodological QA study. Participants continued their usual activities during the QA study.

Twelve individuals volunteered to participate. After the baseline assessment, participants were randomly assigned to begin aerobic training with the AlterGR or the GlideTrakTM with a 3 month delayed cross over. Baseline resting was repeated before the second session of aerobic training on the alternate bodyweight support device was initiated (Figure 1).

### Assessment: QA study I

Assessment was performed before and after the exercise intervention series. Mobility (10 meter Walk [43,44], Six Minute Walk [45] and balance (Five times Sit to Stand [46,47] and/or Timed Up and Go [48,49] were considered the primary, quantitative, dependent variables measured with standardized tests [43-49]. Each participant completed non-standardized daily training questionnaire before and after each exercise training session self-reporting, qualitative signs and symptoms of pain, discomfort, fatigue, tremor and freezing using an ordinal visual analog scale (VAS) based on numbers ranging from 0-10 (0= none or mild symptoms to 10= severe symptoms) [50]. After the last training session, the participant completed a non standardized equipment questionnaire using the the VAS ordinal system (0-10) to grade the ease of the training setup, the ability to achieve an intense aerobic workout and comfort/discomfort during training. Each participant listed their likes and dislikes about the equipment. In addition, each participant was asked if he/she would recommend the equipment to others, would like to use the equipment at home and/or would suggest the equipment be integrated into a community fitness centers (yes, no maybe).



## Equipment: QA study I

**O<sub>2</sub>/HR Monitoring:** A blood pressure cuff was used to measure blood pressure and heart rate at the first visit. During exercise, an oximeter was used every 10 minutes to record O<sub>2</sub> and HR. During training, each participant wore a Polar monitor to monitor if target HR was achieved (70-80% of age appropriate maximum). Exertion (> 3/10) was monitored to approximate aerobic levels of exercise for participants with pacemakers or taking cardiac medications to limit HR.

**AlterG Anti-Gravity Treadmill (AlterGR)** (Figure 2). The AlterGR (www.AlterG.com) employs an air distribution system for un-weighting. This technology was developed to study the effects of gravity on bone health and physiology of astronauts in space. The technology was approved by the FDA for fitness and functional rehabilitative training for healthy athletes and those recovering from sports related neuromusculoskeletal injuries.

Before training, the individual dons a pair of neoprene shorts which zip into a pressurized air bag chamber suspended over a treadmill. With the shorts zipped into the pressure chamber, and the individual standing on the treadmill, the machine “calibrates” the weight by generating an upward “lifting” force (140 to 300 pounds). After “weighing” the individual, the air is released and the calibrated weight is used as a reference for selected the degree of un-weighting during exercise (0-80%). There is some air left in the bag which underestimates the weight of the participant by about 6# [50]. The accuracy of un-weighting and re-weighting varies by approximately 5% [50].

The treadmill speed (0.1 to 15 mph) and the slope (1-15%) are controlled by the user or the therapist. The faster the speed, the greater the un-weighting required to minimize ground reaction forces. 31 Un-weighting can be dynamically adjusted based on speed of jogging/running.

The GlideTrak<sup>TM</sup> bodyweight support system blends un-weighting technology and low-impact gait training indoors over a treadmill (www.glidecycle.com) [50,51]. The unit can un-weight an individual up to 100% through pelvis support between a seat and a pelvic pad across the anterior superior iliac spines (ASIS). The unit has a posted seat suspended by two straps in the rear and two in the front. The GlideTrak<sup>TM</sup> is adjusted to each individual with un-weighting created by tightening the straps of the seat on the frame [36]. The amount of un-weighting was estimated by observing the weight change of the subject while standing on a scale during lifting of the seating system. When un-weighted @50% with the seating system, previous researchers reported the knee was flexed 10-20 degrees (Figure 2A-2C) [52].



C. Vasperi<sup>TM</sup> System with NuStep T5XR



**Figure 2: Rehabilitation Technology to Facilitate Aerobic Performance.** A) AlterG Air Distributed Body Un-Weighting Treadmill. B)

The GlideTrak<sup>TM</sup> frame/seating system was placed over a StarTrak treadmill (www.startrak.com). Participants were instructed to “pace walk/glide with the treadmill speed at 3 to 7.5 mph. For stability, the participant held on to the frame of the GlideTrak<sup>TM</sup>, used the trunk harness or simply maintained their balance to facilitate arm swinging. The arms free to swing. The GlideTrak<sup>TM</sup> is approved by the FDA for fitness and rehabilitation.

## Intervention : QA study I

Each subject warmed up over ground for 5 minutes prior to treadmill training (e.g. walking with ankle and arm weights [2-5#],

stepping over objects, integrating large arm swings, high stepping on stairs, rhythmical stepping to music and general stretching). This warm up was matched to participant abilities. Each individual was also asked to stretch the heel cords before and after aerobic training (knee straight and knee flexed). The warm up was supervised by a physical therapist or a trained volunteer.

On the AlterGR, a consistent trained volunteer helped each participant put on the suit, get on/off the treadmill, zip the suit to the air bag, calibrate the equipment and select the amount of un-weighting by pressing a weight control button with LED confirmation. Each participant was un-weighted to approximately 50% of the bodyweight. The slope and speed were adjusted by the assistant and the participant to achieve the target heart rate. The computer LED display of un-weighting, suit size, height of the air bag, running speed and training time were documented each day to facilitate consistency.

A physical therapist helped each participant get on/off the GlideTrakTM and adjusted the un-weighting to approximately 50% of body weight. The speed and the slope of the treadmill were adjusted by the therapist and the participant. The speed of the treadmill, time and suspension strap marker levels were recorded to increase the consistency of adjusTMents from day to day.

The participant warmed up and cooled down by stretching the heel cords and walking slowly for 3-4 minutes. Each participant performed aerobic levels walking/jogging/gliding for 5 consecutive days, 40-45 minutes per session (total of 225 minutes of training) on each BWST system (AlterGR and the GlideTrak TM).

After the first aerobic training week (and the follow up measurements), each participants went into a "wash out" period for 3 months. During that time each participant could continue involvement in usual care. After 3 months, the participant returned for another baseline assessment prior to beginning the second week of aerobic exercise training on the alternate body un-weighting equipment. All of the assessments and training took place at the same time each day while "on" medications.

## Study design and data A=analysis: QA study I

This was a cross over design with random assignment to the first technology assisted training session and a 3 month wash out period. All dependent variables were described by mean (score or percentage score), standard deviation and effect size [53]. The post/pre difference scores on the primary dependent variables were analyzed for

significance of change across and within each aerobic training group using the Paired Wilcoxon test ( $p < 0.05$ ). To analyze the difference scores on mobility and balance between the AlterGR and the GlidetrakTM, post-pre test gain scores were compared using the Two Sample Wilcoxon Test ( $p < 0.05$ ) [54]. Change in secondary dependent variables (self reported signs and symptoms), workout characteristics (amount of un-weighting, maximum HR, exertion) and equipment variables were described, but not analyzed for significance. Given the methodological purpose of this quality assurance study, each of the dependent variables was tested for significance at  $p < 0.05$ .

## Results

### QA Study I

Twelve participants were recruited. One participant dropped out after the first aerobic training session. He could not achieve a comfortable adjusTMent of the seating system for the GlideTrakTM. This led to rubbing of the medial thigh. This was considered a minor adverse event.

Eleven subjects with mild to moderate PD (two females, average age of 69.1 years [ $\pm 2.8$  SD], 4.1 years with PD ( $\pm 3.0$  SD)) completed the study with no adverse events (Table 1). All participants were taking at least one medication to manage symptoms of PD (with a mean of 3.7 medications ( $\pm 1.4$  SD)).

### Quantitative outcomes

With the exception of the two subjects with a pacemaker, all participants were able to jog on the AlterGR and stride on the GlideTrakTM to achieve the targeted age appropriate maximum heart rate (70- 80% of maximum) (Table 1). During training on the AlterGR, participants made significant gains ( $p < 0.05$ ) on the 10 meter walk, the 6-minute walk, FTSTS and TUG. The gains ranged from 11.5% to 17.8% with effect sizes ranging from 0.57 to 1.51 (Table 2). During GlideTrakTM training, the gains ranged from 4.4-14.7% and the effect sizes ranged from 0.38 to 0.71. The gains were not statistically significant post aerobic training on the GlideTrakRM. Participants performed within age related norms on the mobility tests [55,56] as well as the balance tasks [57-59]. The gain scores post AlterGR training were significantly higher than gains achieved following training on the GlideTrakTM ( $p < 0.05$ ) (Table 2).

Participant	Gender	Age (years)	Onset (Years)	PD	Hoehn & Yahr I-III	Pacemaker	Target HR 70-80%	Un- Weighting	Training Speed (mph)
1	M	77.2	6		II	yes	100-104	50%	AG 7.0 GT 6.0
2	M	70	5		II	No	105-124	50%	AG 6.5 GT 5.5
3	M	66.9	10		III	No	107-126	50%	AG 4.8 GT 4.5
4	F	64	8		II	No	104-124	50%	AG 6.0 GT 6.5
5	M	64.1	3		III	No	109-124	50%	AG 4.7 GT 6.8
6	M	66.7	5		III	No	107-122	50%	AG 5.8 GT 7.0
7	F	57.5	2		II	No	113-126	40%	AG 6.0 GT 6.5
8	F	73.1	3		II	No	110-118	50%	AG 5.0 GT 7.0



9	M	61.3	3	II	No	111-128	50%	AG 4.5 GT 5.5
10	M	71.5	3	II	No	104-118	50%	AG 5.5 GT 6.5
11	M	75.6	12	III	yes	108-116	50%	AG 4.5 GT 5.5

**Table 1:** Description of Participants: Quality Assurance Study I. AG=AlterG RGT=GlideTrakTM \* Pace maker limited maximum heart rate, \*\* Target heart rate set at 70-80% of maximum based on age  $[(220-\text{age}) \times 70\% - (220-\text{age}) \times 80\%]$ , \*\*\* Speed of jogging/striding set by participant and therapist to achieve maximum heart rate. Eleven participants completed the quality assurance study I. Seventy three percent of the participants were males. The participants had a mean age of 69.4 years of age with a diagnosis of mild to moderate PD for an average of 4.1 years. All were un-weighted to @ 50% of body weight to enable jogging/striding with reduced ground reaction forces. All but two participants achieved exercise heart rate. The two who did not achieve the desired heart rate were participants with pacemakers.

	Gait Speed (cm/sec)	6-minute walk (m)	TUG* (sec)	FTSTS ** (sec)
<b>TUG* (sec)</b>				
Pre Score Mean (SD)	1.84 (0.23)	419.1 (84.6)	6.86 (1.31)	9.76 (2.05)
Post Score Mean (SD)	2.06 (0.43)	501.3 (85.9)	6.46 (1.52)	8.11 (1.29)
Difference Score	0.22 (0.36)	82.2 (40.95)	-0.39 (1.24)	-1.65 (1.58)
% Difference Score	12.00%	19.80%	-5.70%	-16.90%
Effect Size	0.61	2.01	-0.31	-1.04
Paired Wilcoxon $p < 0.025$ ; Sum of Ranks: < 10 or > 45	Sum of ranks=6 Significant	Sum of ranks= 7 Significant	Sum of ranks= 6 Significant	Sum of ranks= 7 Significant
<b>GlideTrakTM Group</b>				
Pre Score Mean (SD)	1.94 (0.32)	460.2 (87.8)	6.53 (0.93)	9.06 (1.75)
Post Score Mean (SD)	2.08 (0.57)	486.5 (77.5)	6.36 (1.48)	7.94 (1.87)
Difference Score	0.13 (0.44)	26.5 (72.1)	-0.16 (0.82)	1.12 (1.27)
% Difference Score	6.70%	5.70%	-2.50%	-12.30%
Effect Size	0.30%	0.37	-0.2	-0.88
Paired Wilcoxon $p < 0.05$ ; Sum of Ranks: 10 or > 45	Sum of ranks=19 Significant	Sum of ranks=13.5 Significant	Sum of ranks=14 Significant	Sum of ranks= 22 Significant
<b>Alter-G compared to GlideTrakTM</b>				
Mean Difference	0.10 (0.65)	58.4 (80.8)	-0.25 (1.75)	-0.64 (1.75)
Effect Size	0.14	0.72	-0.21	-0.36
Two Sample Wilcoxin (Significant<0.025); sum < 65 >115	Sum= 32.5 significant (AG>GT)	Sum= 43.0 significant (AG>GT)	Sum= 44.5 significant (AG>GT)	Sum= 17 significant (AG>GT)

**Table 2:** Change in Mobility and Balance by BWST Group (AlterGR and GlideTrakTM): Quality Assurance Study I. Effect sizes ranged from small to large (0.2 to 2.01) with significant gains post AlterGR Training (10 meter walk Six minute walk, Timed Up and Go and Five Times Sit to Stand).

## Qualitative outcomes

All participants reported moderate levels of joint pain (back, neck, knee or ankle), fatigue, tremor, freezing and incoordination at beginning of the study. Post aerobic training on each BWST, the participants self rated signs and symptoms in the mild range (e.g. mean scores ranging from 1.5 to 2.6 on an ordinal scale of 0-10). The effect sizes were generally small except for pain and tremor where the effect size was moderate (-0.48 to -0.54) (Table 3).

The participants self reported mild to severe signs and symptoms during training on both BWST systems, with a slight reduction in severity from the first to last session. During training on the AlterGR, moderate to severe pain decreased from 18% to 12%, discomfort from 30% to 25%, fatigue from 46% to 37%, tremor from 10% to 0% and freezing from 29% to 12%. The discomfort was a sense of urinary urgency when un-weighted to 50-60% of bodyweight. On the GlideTrakTM, during training from the first session to the last session, moderate to severe pain decreased from 22% to 12%, discomfort from

80% to 44%, fatigue from 30% to 25% and tremor from 20% to 12%. increased from 0% to 12%. The discomfort on the GlideTrak™ was Moderate to severe freezing during training on the GlideTrak™ related to the adjustment of the pelvic/seat support.

Group	Pain	Pain	Pain	Incoordination	Balance	Fatigue	Tremor	Freezing
	Back	Arms	Legs					
AlterG (AG)		1.2 (2.1)	1.6 (2.3)	2.5 (2.8)	2.4 (3.0)	2.1 (1.4)	1.7 (1.8)	0.9 (1.7)
Pre	1.5 (1.5)	1.1 (1.8)	1.6 (1.9)	2.4 (1.9)	2.5 (2.0)	2.6 (2.1)	1.3 (1.6)	0.9 (1.6)
Post	1.6 (1.5)	-0.4 (0.7)	-0.7 (1.6)	-0.4 (2.5)	0.1 (2.3)	0.45 (1.6)	-0.6 (1.2)	-0.4 (1.3)
Difference	0.7 (2.1)	-0.57	-0.44	-0.16	0.04	0.28	-0.5	-0.31
Effect Size	0.33	0.6 (1.3)	0.5 (0.8)	2.9 (2.7)	3.0 (2.6)	2.2 (1.5)	1.5 (1.5)	0.6 (1.2)
Pre	1.2 (1.5)	0.8 (0.8)	1.3 (1.4)	2.5 (2.5)	2.4 (2.2)	2.7 (2.1)	1.0 (1.3)	0.9 (1.6)
Post	1.2 (1.4)	-0.2 (1.6)	0.14 (1.5)	-0.4 (1.7)	-0.5 (2.1)	0.5 (1.8)	-0.6 (1.1)	0.01 (1.5)
Difference	0.03 (1.1)	-0.13	0.09	-0.24	-0.24	0.28	-0.55	0.01
Effect Size	0.03	1.2 (2.1)	1.6 (2.3)	2.5 (2.8)	2.4 (3.0)	2.1 (1.4)	1.7 (1.8)	0.9 (1.7)

**Table 3:** Change in Signs and Symptoms Pre and Post Training: Study I. The participants reported mild signs and symptoms with minimal change before and after training except for tremor where there was a moderate reduction in both groups and a moderate reduction of arm and leg pain after training on the AlterGR. Difference scores: 0= no problems or no signs and symptoms; 10 = severe signs and symptoms. Negative change is improvement.

On the AlterGR, the participants liked the feeling of a “good workout “without the fear of falling” and particularly enjoyed being able to jog again. The participants disliked putting on the shorts and did not like the feeling of bladder fullness or urgency when un-weighted by 50%. On the GlideTrak™, the participants liked the feeling of standing tall, stretching the legs into a long stride and getting a “good workout” while challenging balance. However, the participants could not achieve a comfortable seat adjustment (Table 4).

In terms of participant opinion about the equipment, compared to the GlideTrak™, the participants rated the AlterGR easier to set up, to use independently, to adjust to comfort and accomplish a better workout. On both BWST systems, participants rated the equipment the same in terms of the ability to strike the heel, achieve a long stride and post exercise soreness. If the participants could purchase the equipment for home use, 64% would choose the AlterGR and 36% the GlideTrak. Forty five percent of the participants would recommend both pieces of equipment be placed in community based fitness centers. If only one BWST system could be purchased, 82% would recommend the AlterGR.

70-80% of maximum). Short term aerobic training with un-weighting (225 minutes) was associated with improvement in mobility and balance

When planning to jog un-weighted with an air pressure system, individuals should empty the bladder before starting training to improve tolerance to the sensation of abdominal and bladder pressure. Un-weighting to @ 50% can be associated with discomfort during training (e.g pelvic discomfort from the seat of the GlideTrak™ and urinary urgency from the AlterGR). If jogging can still be achieved, air un-weighting or pelvic suspension should be adjusted to 30-40%. On the GlideTrak™ it is possible for the therapist to assist with leg movements for walking if necessary. Participants experienced greater improvement in balance and gait stability after training on the AlterGR compared to the GlideTrak™. The AlterGR enables participants with PD to jog/run again while protecting against falling. Participants would recommend the AlterGR and GlideTrak™ to their friends and community fitness centers as well as use at home, with a preference towards the AlterGR (Table 5).

### The main points learned from QA study I

With BWS, individuals with mild to moderate PD were able to achieve aerobic levels of exercise by jogging/running or gliding (HR

Liked	Disliked	General Comments
<b>Alter-G R</b>		
Freedom of running without fear of falling Weightless exercise and comfortable	Cumbersome to get into the equipment but easy to use Feeling like my bladder was full even though I went to the	Easy to maintain balance Good workout Good body support and secure feeling while exercising

Easy to set up and use; easy to get a good workout I like the ability to run with ease while still pushing my limits Gives me a glance back to my days as a runner; something I had lost due Glide Trak™ to PD	restroom before the session Putting on the neoprene shorts	
<b>Glide Trak™</b>		
Feel I could stretch my legs I could stride as if running in a dream Felt I had a more erect posture after the workout	Never achieved anything even close to comfort Back, hips, pelvis, tops of thighs felt a lot of pressure Difficult to set up Pelvic support is uncomfortable	If I could get comfortable, I think this could be a good challenge for my balance as well as a good workout More demanding in terms of balance Have the perception my feet did not have contact with the treadmill as much as the AlterG <sup>R</sup>
Felt I had a more erect posture after the workout	Difficult to set up Pelvic support is uncomfortable	Have the perception my feet did not have contact with the treadmill as much as the AlterGR

**Table 4:** Subjective Comments about the Exercise Technology Post Training: Quality Assurance Study I. All participants had positive comments about both pieces of equipment but still felt some discomfort with the unweighting to 50%.

Characteristics of Work Out	Alter- G <sup>R</sup>	GlideTrak™
Ease of set up	7.8 (2.0)	5.6 (2.7)
Ease of making adjustments	8.5 (1.2)	4.8 (2.2)
Comfort during workout	8.3 (0.9)	4.9 (2.7)
Quality of work out	8.9 (0.9)	7.7 (2.5)
Ability to heel strike	7.9 (1.4)	8.4 (1.2)
Length of stride	8.0 (1.3)	8.3 (1.1)
	8.9 (0.9)	7.7 (1.6)
<b>Preference for Equipment</b>		
Want to purchase for home use	64%	36%
If cost =, preference to Purchase for home	82%	18%
Recommend for a community fitness Center	82%	18%*

**Table 5:** Participant Ratings of Equipment Characteristics and the Work Out: Quality Assurance Study I. Mean score ratings on a Scale of 0 (poor, difficult) to 10 (easy, minimal, excellent). \*45% of the participants wanted to recommend both the Glide Trak™ and AlterG<sup>R</sup>

## Quality assurance (QA) study II

Participants: The eligibility criteria were the same as for QA study I. As in QA study I, formal consent was not required for participation. Participants continued usual activities while participating in QA Study II.

## Assessment: QA study II

Before and after training, without an assistive device, the participants completed the same standardized, quantitative tests on mobility and balance as completed in QA study I. Before and after the aerobic exercise training, the participants completed the following standardized, qualitative, self report questionnaires: sleep [60], fatigue [61], resilience [62] and freezing [63]. After the last exercise session, the participants completed the same equipment evaluation questionnaire included in QA study I with the addition of a section allowing participants to compare the AlterGR and the Vasper™.

## Equipment: QA study II

The Vasper™ cooling and compression unit (Figure 2) 38 utilizes the principles of blood flow restriction (BFR) training with physical cooling to accelerate effects of physical exercise [39,40,64,65]. Liquid cooled compression cuffs are applied to both arms and thighs with adjustable pressures to accommodate personal preferences and comfort. For this QA study, the feet were placed on cool pedals, 50-69 mm hg of pressure was created in both the arm and leg cuffs and a cooling vest was worn on the trunk. The participant elected to be barefoot or continue to wear socks. The participant performed reciprocal arm and leg movements on the NuStepT5XR recumbent cross trainer [38].

## Intervention: QA study II

Each participant warmed up as in QA I. After the warm up, each participant completed a 20 minute aerobic exercise session following an interval training protocol. Out of more than 20 protocols available including the opportunity to design a unique protocol, one of two standard interval training programs was selected for purposes of standardization: "Super Six" or "Hummingbird". Each participant trained at a low level of with the potential to set the resistance levels

within the protocol between 0 and 15 for both the sprinting and interval workouts.

The Super Six Program included a warm up of 9 minutes at resistance level 4, with six sprinting intervals of 30 seconds at a resistance level of 6, followed by interval training for 60 seconds at a resistance level of 4. The Hummingbird Program included a warm up of 7 minutes at a resistance level of 4. This was followed by seven sprints at resistance level 6 (three 30 second sprints and four 15 second sprints) with each sprint followed by 60 seconds of interval training at resistance level 4. The computer LED provided a visual image of the target wattage level for the workout with a floor and a ceiling noted. Each aerobic training session was followed with a 5 minute "recovery" session with the participant in a supine position on a cooling mat. Each participant was scheduled for 10 sessions (2x/week) at the same time of day (when "on" medication). These protocols cumulated to 200 minutes of aerobic exercise.

### Study design and data analysis:QA study II

This was a pre-post test methodological study. The primary dependent variables, the secondary dependent variables and the workout characteristics were summarized and described by mean

(score or percentage score), standard deviation and effect size [54]. The post/pre difference scores on the quantitative primary dependent variables were analyzed for significance using the Paired Wilcoxon test ( $p < 0.025$ ). The differences between the post-pre change scores for the primary dependent variables for the Vasper<sup>TM</sup> and the two BWST training groups from QA I were compared using the Two Sample Wilcoxon Test ( $p < 0.05$ ).

### QA Study II

Ten participants volunteered to participate. One eligible participant was unable to begin the study as a consequence of an acute, painful herniated disc experienced at home. Thus, 9 individuals participated and completed the study (three females, an average of 68.3 years [ $\pm 3.0$  SD], diagnosed with PD for an average of 6.4 years [ $\pm 6.1$  S]) (Table 6). All were taking medications for PD (a mean of 3.4 [ $\pm 0.9$  SD] different medications). The participants in QA study II were not significantly different in age, gender, severity of PD, or PD onset than the participants in QA study I. Eight of the 9 participants had experience training on the AlterGR prior to this quality assurance study. Due to travel, two participants only completed 8 of the 10 training sessions.

Participants	Gender	Age in years	Onset of PD (Years)	Hoehn and Yahr	Peak Watts Beginning/End	Target Aerobic HR 70-80%	Exercise HR	Sprint Level Beginning/End
1	M	65	11	II	295/416	108-124	136	8/6
2	M	71	3	II	159/329	104-120	100	4/6
3	F	73	3	II	159/297	103-118	115	2/5
4	F	68	2	II	433/391	106-122	118	6/6
5	M	67	20	III	200/278	108-122	93	4/6
6	M	71	3	II	269/176	104-122	100	6/6
7	M	65	3	III	119/107	108-124	102	3/4
8	F	70	10	III	81/42	105-120	116	2/4
9	M	65	3	III	132/338	108-124	112	3/4

**Table 6:** The average age of the participants was 68.3 years, diagnosed with PD for an average of 12.4 years. There were 3 females. All of the subjects exercised within 60-80% of maximum heart rate (5 of 9 within 70- 80%) Five of the 9 participants were working out at a higher wattage and 5 were sprinting at a higher resistance level after 10 sessions of aerobic training.

During training, one participant flared an old ankle injury. He was able to get a new orthotic and wear an ankle support as recommended by his primary care physician. He completed the exercise training with no further ankle complaints. This was considered an adverse effect of training. Another participant was jogging to catch a shuttle bus and experienced a tear of the vastus medialis. He was able to complete the exercise training with careful use of the involved leg during reciprocal stepping during the sprint phase on the Vasper<sup>TM</sup>. The vastus medialis injury created a risk for further injury with training but was not considered an adverse event caused by the training.

All participants achieved 60-80% of their maximum heart rate during training on the Vasper<sup>TM</sup>, with 55% achieving the 70-80%

target HR range. Peak wattage and peak sprint energy output did not increase incrementally with each training session. Over time, 66% of participants increased the performance work out and 55% increased the sprint level (Table 6).

### Quantitative data

Following training on the Vasper<sup>TM</sup>, the participants significantly ( $p < 0.05$ ) increased gait speed (1.73 to 2.01 m/sec), endurance (440 to 471 meters ) and balance performance (decreasing task performance time by 3 to 4 seconds and performing within age expected norms). The effect sizes were moderate to large, ranging from 0.29 to 0.82 (Table 7).



	10m Walk Speed (m/s)	6 Minute Walk Distance (m)	Timed Up and Go (s)	5 Times Sit To Stand (s)
<b>VasperTM with NuStep</b>				
Pre Score Mean (SD)	1.73 (0.36)	439.9 (126.3)	14.6 (23.6)	12.5 (8.7)
Post Score Mean (SD)	2.01 (0.40)	470.7 (135.4)	10.4 (13.1)	9.6 (2.8)
Difference Score (SD)	0.28 (0.34)	30.8 (54.4)	-4.1 (10.6)	-2.9 (6.5)
% Difference Score	16.4%	7.0%	-23.0%	-28.3%
Effect Size	0.82	0.57	-0.39	-0.45
Significance <2or>26	Sum of ranks =7 p<0.05 Sign	Sum of ranks =6 p<0.05 Sign	Sum of ranks=6 p<0.05 Sign	Sum of ranks=7 p<0.05 Sign

**Table 7:** Summary of Mobility and Balance Gains Post Aerobic Training on Vasper<sub>TM</sub>: Quality Assurance Study I. There were significant gains on all of the quantitative measures of mobility and balance following aerobic training on the Vasper<sub>TM</sub>.

### Qualitative data

Based on the standardized questionnaires, the severity of the selfreported signs and symptoms were mild-moderate before and after training. Improvement was noted in resilience (effect size 0.55). Pain, freezing and sleep were slightly worse (increase of 4.3%, 8.3% and 11.8% respectively (Table 8). At the beginning of aerobic training on the Vasper<sub>TM</sub>, participants reported moderate to severe pain in the neck, right knee and low back with selfreported pain 11% higher after completing the exercise training (2 of 9 participants). Pain in the left knee and ankles were mild to moderate initially with all subjects selfreporting no pain or mild pain at the end of exercise training. After the last exercise training session, 100% of the participants reported an improvement in energy level, 50% reported reduced muscle tension and 50% reported decreased falling.

	(A) Pain*	(B) Freezing (%)**	(C)Resilience (%)**	(D) Fatigue (%)**	(E) Sleep (%)**
Pre Score Mean (SD)	1.49 (1.35)	30.2 (22.4)	77.2 (12.0)	43.4 (18.8)	70.1 (15.5)
Post Score Mean (SD)	1.61 (1.45)	33.7 (23.4)	85.8 (8.8)	42.8 (18.6)	67.1 (18.2)
Difference Score (SD)	0.12 (1.36)	3.56 (11.6)	8.5 (15.4)	-0.54 (15.1)	3.0 (7.0)
% Difference Score (SD)	8.3%	11.8%	10.9%	-1.2%	-4.3%
Effect Size	0.09	0.31	0.55	-0.04	-0.43

**Table 8:** Change in Self Rated Signs and Symptoms Post Training with Vasper TM: Quality Assurance Study II. \* (A) Pain was recorded on a Visual Analog Scale from 0 (no pain)-10 (severe pain) for six sites (neck, low back, R and L knee, R and L ankle) with a decreased mean score representing improvement. \*\* (B-E) were reported as a Percentage of the maximum score on standardized questionnaires: B) Freezing of Gait Questionnaire (FOG-Q); (C)The 14-Item Resilience Scale (RS-14); D) Fatigue Questionnaire; (E) Parkinson's Disease Sleep Scale. A decrease in the mean % scores on Fatigue and Freezing represented improvement. An increase in the % scores on Resilience and Sleep represented improvement. Self rated resilience was self reported with moderate improvement and there were minimal effects on the other signs and symptoms.

On the equipment survey, the participants liked the self competitive nature of the Vasper<sub>TM</sub> protocol and the intensity of the workout. Only one participant did not sense a level of improvement with the workout (Table 9). Applying the VAS (0-10), the participants rated the Vasper TM high (8.1-8.7) on ease of use, comfort, ability to adapt to the equipment and achieve an intense workout with minimal post exercise soreness and good performance feedback. Seventy five percent of participants would purchase the Vasper<sub>TM</sub> for home use and 100% would recommend the equipment to their friends and to community fitness centers (Table 10).

Liked	Disliked	General Comments
<b>NuStep/VasperTM</b>		
Excellent supplement To Alter G Works all body Pats – forces one to work Hard as intervals promote Working to the maximum Self competition The ability to sprint and use intervals to challenge myself Consistency of high level	No negatives Nothing that I disliked "I did not feel a high level of Improvement as I hear Reported by others" "Foot pedals did not hold For me"	Good exercise w/o impact "Loved it – great workout "I can compete against myself and feel muscle tone in my arms" I have noted improvement Of my leg strength I enjoy the workout and often feel the burn in my muscles

Of training		
<b>AlterGR</b>		
Positive health benefits I can run without fear of falling – lots of sweating. I can run again The weightless feeling Psychological benefit, timed, can do other things simultaneously By controlling weightlessness and speed, [I] can walk at a better pace.	Having to deal with shorts and their leaks. Questions of hygiene. Running on treadmill versus running outside Pain to get in and out of rubber suit. I generally don't enjoy working out on treadmills, even with un---weighting putting on the shorts.	At 50% unweighting, I have A feeling of "really running" Excellent– no fear of falling. I used to be a runner and with the AlterGR I am a runner again. "I was a 3 hour marathoner in the past; having to give up Running has been the biggest loss due to PD" "AlterGR gives me some of the restored running experience."

**Table 9:** Participants Qualitative Comments on the Vasper<sup>TM</sup> and the AlterG<sup>R</sup>: Quality Assurance Study II.

Characteristics of Equipment/Work out*	NuStep/Vasper <sup>TM</sup>	AlterG <sup>R</sup>
Ease of using equipment	8.2 (1.9)	5.8 (3.2)
Comfort during training	8.1 (1.5)	7.3 (2.2)
Ease of making adjustments	7.8 (1.6)	7.9 (1.4)
Getting used to equipment	8.7 (1.0)	7.8 (1.5)
Ability to achieve intense W/O	8.7 (1.6)	7.5 (2.9)
Good challenge to balance	7.0 (1.6)	8.4 (1.5)
Post exercise soreness	8.6 (0.9)	8.1 (1.5)
Receiving feedback re performance	8.4 (1.3)	8.0 (1.4)
Recommendations/Preferences **		
Preference for using Vasper <sup>TM</sup> or AlterG <sup>R</sup>	75%	25%
Would purchase Vasper <sup>TM</sup> or AlterG <sup>R</sup> or home use	75%	25%
If Fitness Center could only purchase one new piece of equipment, which would you recommend ?	63%	37%

**Table 10:** Participant Evaluation of Equipment Characteristics and Workout on the Vasper<sup>TM</sup> Compared to the AlterG<sup>R</sup>: Quality Assurance Study II. On all equipment parameters as well as the workout, based on averages, the participants rated the Vasper<sup>TM</sup> higher than the AlterG<sup>R</sup>. \*Rated on a scale of 0-10 with a 0=difficult, poor and 10= easy, excellent. \*\*Proportion of participants indicating yes. Eight participants in Study II worked on the AlterG<sup>R</sup>. Note. Eight of 9 participants would like to use Vasper<sup>TM</sup> at home, recommend it to their friends and to community fitness centers.

### Comparison of outcomes: Vasper<sup>TM</sup> and AlterG<sup>R</sup>

Quantitatively, the mean gains on mobility and balance were greater after training on Vasper<sup>TM</sup> compared to the Glide Trak<sup>TM</sup>, but only significantly greater ( $p < 0.05$ ) on the 6 Minute Walk and Timed Up and Go. The effect sizes were low to moderate. The gains were generally smaller on the Vasper<sup>TM</sup> than the AlterG<sup>R</sup>, but only significantly different ( $p < 0.05$ ) on the 6 Minute Walk and the FTSTS (Table 11).

Participants self reported greater improvement in both balance and gait safety on the AlterG<sup>R</sup> compared to the Vasper<sup>TM</sup> (75% and 44% respectively) Comparing the change in signs and symptoms post training on the Vasper<sup>TM</sup> and the AlterG<sup>R</sup>, participants self reported greater improvement in energy, ease of equipment set up, adaptation to training and achievement of a good workout on the Vasper<sup>TM</sup>. The AlterG<sup>R</sup> was ranked higher than the Vasper<sup>TM</sup> for challenging balance (8.4 versus 7.0) (Table 10). Seventy five percent of the participants preferred the aerobic workout on the Vasper<sup>TM</sup> compared to the Alter GR. Participants would use the equipment at home, recommend a Vasper<sup>TM</sup> workout to their friends and put Vasper<sup>TM</sup> units in the fitness centers. If participants could only recommend one piece of equipment to the community fitness center, 63% would recommend the Vasper<sup>TM</sup> and 37% the AlterG<sup>R</sup>.

### Summary of key points post Vasper<sup>TM</sup> training in QA II

Participants were able to achieve aerobic training with reciprocal leg and arm training under conditions of cooling and compression. Participants made significant gains in mobility and balance following 10 sessions of aerobic training on the Vasper<sup>TM</sup> Gains in resilience and energy were consistently reported after aerobic exercise training on the Vasper<sup>TM</sup> Participants reported the Vasper<sup>TM</sup> was easier to use, more comfortable and provided a more intense workout than training on the AlterG<sup>R</sup> BWST.

The Vasper<sup>TM</sup> provides a ceiling and floor threshold to guide wattage output by the participant With the legs exposed, the therapist has easy access to help move the legs if a participant had difficulty alternating a limb Participants would purchase the Vasper<sup>TM</sup> for home use, recommend it to friends and community fitness centers with a preference for the Vasper<sup>TM</sup> compared to the AlterG<sup>R</sup>

### Discussion

These quality assurance studies compared three different types of rehabilitation technology assisted aerobic training. Patients with mild to moderate PD trained with technological assistance (AlterG<sup>R</sup>, GlideTrak<sup>TM</sup>, Vasper<sup>TM</sup>) to achieve an aerobic level of exercise without flaring signs and symptom of PD. A short period of technology assisted aerobic training (220-225 minutes) was associated with significant gains in mobility and balance. Quantitative gains in mobility and balance were significantly higher when training on the AlterG<sup>R</sup> compared to the GlideTrak<sup>TM</sup> or the Vasper<sup>TM</sup> and significantly higher on the Vasper<sup>TM</sup> compared to the GlideTrak<sup>TM</sup>. Participants experienced moderate to severe discomfort during aerobic training, particularly when un-weighted 50%. However, despite discomfort during aerobic training, general qualitative self-reported

signs and symptoms (0-10) remained in the mild range before and after aerobic exercise training (average of 1.1-2.6). Vasper TM and the AlterGR technology were easier and more comfortable to use for aggressive aerobic training than the GlideTrakTM. With each of the pieces of technology, the participants wanted to be able to train at home and in the community fitness center. Vasper TM received the highest preference for integration into fitness centers.

### Integration of QA study findings into the clinic

Following these two quality assurance studies, protocols for integrating the three pieces of rehabilitation technology into the PT Health and Wellness Center were more clearly defined. The Medical History form was expanded to include more detail about bladder problems. Instructions were implemented to ask each client to stop at the restroom before exercise training on the AlterGR. Clients with

sensitive bladders or problems with occasional incontinence were asked to purchase their own shorts. Screening criteria were created to select appropriate patients to train on each piece of technology (e.g. VAS pain assessment, need for assistive device, 10 meter walk, 6 minute walk, FTSTS, TUG; and MD clearance if the client has a heart condition, especially if on medications to control HR or has a pacemaker. A list of red flags relative to exercise response were posted for all staff and therapists (e.g. light headedness, confusion, dizziness, fainting, increased pain, excessive rise in HR or BP). Check lists were developed to document exercise activities and physical performance parameters (HR, O<sub>2</sub>) before, during and after exercise. An administrative equipment visit was created to allow capable individuals to train independently to maintain fitness. In addition, a technology assisted group exercise class was initiated for patients with mild to moderate PD.

Comparison By Training Groups	10m Walk Speed (m/s)	6 Minute Walk Distance (m)	Timed Up and Go (s)	5 Times Sit To Stand (s)
NuStepTM-Vasper and AlterGR				
Mean Difference	0.50 (0.66)	-45.8 (62.2)	-4.10 (10.41)	-1.38 (5.62)
Effect Size	0.76	-0.74	-0.39	-0.25
Significance <8 or >37	Sum of ranks= 73; p<0.05 NS	Sum of ranks= 52.5 p<0.05 Sign AG>NV	Sum of ranks= 83; p<0.05 NS	Sum of ranks= 63.5; p<0.05 Sign AG>NV
\NuStepTM-Vasper and GlideTrakTM				
Mean Difference	0.12 (0.51)	8.4 (122.6)	-4.04 (10.29)	-2.28 (6.65)
Effect Size	0.23	0.07	-0.39	-0.34
Significance <65 or >115	Sum of ranks= 70; p<0.05 NS	Sum of ranks= 53; p<0.05 Sign NV>GT	Sum of ranks= 65; p<0.05 NS	Sum of ranks= 62; p<0.05 Sign NV>GT

**Table 11:** Change in Mobility and Balance post Aerobic Training on the Vasper<sub>TM</sub>, AlterG<sup>R</sup> and te GlideTrak<sub>TM</sub>: Quality Assurance Studies I and II. The quantitative gains achieved post training on the AlterG<sup>R</sup> were greater than the gains achieved posttraining on the Vasper<sub>TM</sub>. The gains achieved post training on the Vasper<sub>TM</sub> were significantly greater than the gains achieved post training on them GlideTrak<sub>TM</sub>.

### Unique Aspects of QA Study Participants

The findings from this QA report on the AlterGR, GlideTrakTM, and VasperTM can only be generalized to high functioning patients with mild to moderate PD who are cognitively intact, independent at home and functional community ambulators [55]. The participants walked at the speed expected for those 60-69 years of age without PD (2.05 m/sec for males and 1.87 m/sec for females) [55,56] In terms of endurance, our participants walked about 10% less than age expected norms (e.g. 438- 501 meters on the 6 Minute Walk compared to 572 and 538 meters for males and females 60-69 years or 527 and 471meters for males and females 70-79 years) [57]. Based on available space, the participants in the QA study had to turn every 10 meters instead of the standard 30 meters [58]. This required more steps and more turns. Turns often led to freezing, slowing performance.

In terms of balance, individual participants demonstrated variability in performance on the TUG and FTSTS. In QA study I, the

participants performed similar to young healthy controls (7.36 sec +0.95 sec) [58]. In QA Study II, baseline balance performance was not as good as age expected norms on the TUG or FTSTS. However, after aerobic training, participants significantly improved balance performance, achieving a minimally significant clinical improvement of 2.3 seconds [58], performing the TUG better than the individuals aged an average of 62.7 years (16.8 seconds (+ 6.8). After aerobic training, FTSTS performance also exceeded the norms [59-65].

### Is Aerobic Exercise Enough?

A variety of community exercise programs have been established for patients with PD (comprehensive exercises, dance, boxing, Tai Chi) [66-71]. In some cases the stated objective is to "delay the progression of the disease" [66]. Our QA studies reinforce the benefits of short term technology assisted aerobic exercise to maintain if not improve mobility and balance without exacerbating signs and symptoms. Although a regular aerobic exercise program is core to

positive health and aging [72], nutrition, hydration, stress management, life style changes, cognitive leaning, and counseling for anxiety and depression should be addressed [72-74]. The exercise program should also match patient interests, be reasonable in terms of time, be practical and be fun [19,75-78]. Unfortunately, aerobic exercise is not routinely prescribed for PD clients, particularly if the individual has significant objective neurological impairments. Some individuals with PD may only need encouragement to exercise. Some may dislike exercise as well as dislike the hassle of technology. Others may love the excitement of integrating new technology. It is also possible technology may provide a mechanism to protect against falls and facilitate aerobic exercise performance by PD patients with more severe impairments. This issue was not addressed in this QA report.

## Cost Benefit Issues

Advanced technological fitness equipment is more expensive than established exercise equipment. Rehabilitation technology with robotic assistance is more expensive than technology providing mechanical assistance (e.g. unweighting, cooling, compression). There is wide variation in costs of equipment, including the technology used in this QA study. For example, the GlideTrak TM frame and seat is @ \$6,000. The cost of a treadmill is independent of the frame. The equipment can be easily adapted to home of a fitness center. The AlterGR is @ \$35,000 (which includes the treadmill). The manufacturer recommends purchasing an annual service and maintenance contract (@ \$2,500/year). The AlterGR can also be used at home or in a fitness center. The Vasper TM is @ \$30,000 and the NuStep 5XTR is @ \$6,000. Both could be used at home or in a fitness center, but currently the VasperTM system has limited availability. If the same patient outcomes could be achieved with each technological system, then administrators are likely to purchase the least expensive equipment. On the other hand, the participants in this QA study series had strong preferences (VasperTM over the AlterGR or the GlideTrakTM and AlterGR over the GlideTrakTM). Preference must be factored into a cost benefit analyses, especially when facilitating patient commitment to regular dynamic exercise that must accommodate progressive neurological impairments.

## Study Limitations

There were limitations in these two methodological quality assurance studies that constrain the generalization of findings. A small number of participants were included and the participants had mild to moderate impairments which limits generalization to individuals with severe PD impairments. The training period was short (daily for a week or twice a week for 5 weeks) and there was a short term follow up which limits generalization to long term benefits, especially neuroprotection. Although there were no significant differences in age, gender, PD severity, or PD onset between the participants in QA Study I and II, the participants were not the same, raising some question about interpreting differences in outcomes for QA I and II.

Eight subjects had used the AlterGR prior to participating in QA II. Although familiarity could have influenced the selfreport responses on the equipment questions relative to the AlterGR and the Vasper TM, in fact the participants rated many aspects of aerobic training on the VasperTM higher than the AlterGR. The time involved for interventions was similar in both quality assurance studies, but OA I had a more intense training schedule (daily, 5 days, 45 minutes/session) than OA II (e.g. 5 weeks, 2x/week, 30 minutes/session). This confounds participant preferences since they trained longer on the

VasperTM compared to the AlterGR. A cross over repeated measures study design creates the risk of residual training effects even when the order of training is randomized. However a washout period of 3 months was included and retesting was performed prior to the second training session. The selfreport equipment questionnaire was not standardized making this aspect of the QA study hard to replicate. The exercise training was completed while participants were "on" their medications. Thus, findings cannot be generalized to training when "off" medications. On the other hand, the participants were all on regular medications for PD and change in medication or recommendations to go off medications were not part of the study. Adverse events were interpreted as injuries related to using the equipment (e.g. falls, skin abrasions, light headedness, confusion, musculoskeletal injury, excessive soreness). Training discomfort during aerobic exercise was not considered an adverse event given, reports of discomfort (with or without technology) are not uncommon when performing intense aerobic exercise such as running (e.g. fatigue, joint pains, post exercise stiffness, muscle soreness).

The purpose of the QA studies was to clarify practice procedures in the clinic to assure patient sensitive, high quality, outcome oriented care. This methodological study took place with no extramural funding. This limited the opportunity to administer broad, in-depth objective musculoskeletal, neurophysiological, laboratory and imaging tests. In a short term, intense aerobic training program (200-225 minutes), it would be unusual to be able to document objective changes in neurophysiology even when improved function is measured.

## Summary

This series of quality assurance studies supports the benefit of improving mobility and balance when innovative technology is used to facilitate aerobic levels of exercise in individuals with mild to moderate PD. None of the clients experienced a fall or a serious adverse event. While new rehabilitation technology is more expensive than traditional exercise equipment, fitness centers will need to make a commitment to serve the increasing proportion of community based elderly and those with PD. The participants in this QA study recommend making rehabilitation technology more accessible and available at home and in the community.

A new paradigm of technology assisted aerobic exercise in the community may need to include a physical therapist to assess and screen individuals for ability to use technology, match the technology with client strengths and weaknesses, recommend assistive or supportive devices if needed to manage pain, establish exercise guidelines to assure safe exercise performance, and educate trainers and fitness center staff about how to help clients use the equipment.

Longitudinal, randomized PD exercise intervention studies, including cost benefit analyses with a delayed start to document natural disease progression, are needed to validate long term, potentially neuroprotective benefits of community based, aerobic exercise programs (with or without technology).

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