Use of a smart electrically assisted bicycle (VELIS) in the health field -Proof of concept-

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Univ. Grenoble Alpes, CNRS, TIMC-IMAG, 38000 Grenoble, France

Key Words

Exercise ; adherence ; E-bike ; electrically assisted bicycle ; connected objects

Acknowledgements :

Thanks to all the people who kindly cycled for this study.

Thanks to Ebikelabs SAS 38000 Grenoble France for the design of the prototype and their cooperation in data collection.

Thanks to the Cycloline company 22 rue Charrel, 38000 Grenoble for the prototype assembly.

Abstract

Physical activity (PA) is highly recommended in the management of most chronic diseases. For these patients, the smart electric bicycle can be effective to improve adherence to this behavior. The E-bike used in this study (called VELIS) has an innovative onboard technology that allows for subject monitoring and the engine power is designed to adapt to the user's abilities. A prerequisite for the use of the VELIS with patients is to initially carry out a pilot study on healthy subjects. The objective was to evaluate the impact of the customizable settings on physiological parameters and to ensure this prototype’s efficiency and safety of use. Twelve healthy participants with various profiles (physical condition, used to cycling or not) were included. They have completed four times a 14km itinerary with various settings of the VELIS. We recorded GPS data, heart rate and perceived exertion. Based on exercise intensity, we confirm that riding an E-bike should be considered as a physical activity. Safety of the participants is ensured by the engine brake. Recordings show that it took between 1 and 3 minutes for the novice to become familiar with the VELIS and to get optimal assistance. The main finding of this pilot study confirms that VELIS is an easy to use and secure tool to make PA approachable, whatever the level of training in healthy subjects.

Introduction

Prescription of physical activity (PA) for the management of patients with chronic disease has been accepted as a standard. These supervised short-term reconditioning programs are effective to improve patients' physical abilities and quality of life, but failed to achieve a real change in patient behavior regarding PA.

Indeed, patients have difficulties maintaining their level of PA after interventions. The ultimate challenge is therefore to promote a long-term adherence to PA, which implies a successful post-rehabilitation transition to definitive adoption of this new health behavior.

Connected objects are being used increasingly and are able to recognize, measure and record physical activity [1]–[3]. Additionally, considering recent publications, connected objects used in telehealth rehabilitation seem to show their effectiveness in improving long term adherence to PA in patients with chronic diseases [4]–[6]. The different types of interventions used, often a combination of motivational and technological support, have the objective of ensuring an autonomous and safe practice.

Cycling is a physical activity highly recommended by the medical community. It is a low-trauma activity for musculoskeletal structures and suitable for active transportation. Unfortunately, biking is not accessible to everyone, depending on physical abilities and topography of the living area. That's why, in recent years, electrically assisted bicycles (E-bike) have become increasingly popular.

E-bikes could be more than just a PA equipment. In fact, connected E-bikes should be appropriate to personalize and to adapt the level of supervision with the ability to improve the relevance of PA adhesion programs.

The smart E- bike (called VELIS) tested in our preliminary study, combines all benefits of an E-bike with an innovative onboard technology that has been designed for an easy and intuitive use. VELIS allows for subject monitoring and the engine power is designed to adapt to the user's abilities.

A prerequisite for the use of the device with patients is to initially carry out a pilot study on healthy subjects to assess the ease of use. We also need to evaluate the impact of the customizable settings on physiological parameters and to ensure this prototype's efficiency and safety of use.

Methodology

Population

Twelve healthy participants (7 males, 5 females), aged 29 to 66 with various profiles (physical condition, used to cycling or not) were included.

Inclusion criteria were to be older than 25, to demonstrate cycling skills and to accept the participation in this pilot study.

We classified the participants into two groups (trained/untrained) according to their level of physical activity (Global Physical Activity Questionnaire - GPAQ) and their physical condition (Ruffier Dickson Index) [7].

Material

For this study we used two E-bikes called VELIS with a frame size M and L to adapt to the size of the participants, a mobile phone with the e-cortex application, and a Polar RC3 heart rate monitor with chest strap. Safety equipment was provided to the participants (bike helmet and yellow vest).

VELIS

The E-bike prototype used in this study (Figure 1) can be considered as smart because it should be able to adapt to the physical condition of the subject and the topography of the terrain. It is also connected since you can schedule an activity and follow its parameters. An electronic board system allows various parameters to be set via the "e-cortex" interface, the configurable elements being the pedaling cadence, the maximum assistance speed, the maximum assistance power, the engine brake release speed, and the acceleration curve at start-up.

The target pedaling cadence can be adjusted according to the subject who uses the bike and the objective of the session. The electric assistance will then be modulated according to the needs of the subject to allow him or her to stabilize on the target pedaling cadence.

Allowing the motor's electrical power to be modulated according to the subjects' needs should allow access to any mountainous terrain.

An engine brake is available on the VELIS that allows the maximum speed to be set in order to guarantee the user's safety. Adding to that, the VELIS complies with the current regulations, since above 25km/h no electrical assistance will be provided.

In order to offer all these options, the VELIS embeds technology such as a direct-drive rear wheel motor (9C RH205), a Grinfineon controller, an eBikeCortex power management unit, a regenerative brake and a Samsung 48V11AhLiMn battery.

The itinerary profile

The course used was 14km long with 350m of positive elevation. The itinerary profile was divided into 3 zones: 1) 6km near flat (average grade 2%) *called in the text* "Flat part"; 2) 2.5km uphill (average grade 7.5%) *called in the text* “Ascent”; 3) 5.5km downhill (average grade -7%) *called in the text “*descent*”.*

We voluntarily prepared a varied course to follow the evolution of all the parameters induced by these significant profile changes.

Protocol

Participants cycled alone to avoid peer pressure.

Twelve participants have done four repetitions of the route with variation of the target cadence preset, expressed in rotation per minute (rpm) (65/55/75/65). The rates of 55 rpm and 75 rpm were randomly assigned to the second or third output. The first and last output were done at a rate of 65 rpm. Subjects were asked to plan the 4 sessions within one week (one per day) though some of them took more time and others have done 2 sessions in one day.

Three participants have done ten repetitions of the ascent part with blinded variation of the cadence to measure the adaptation time to the settings.

One participant has done 2 repetitions of the descent part with and without motor brake to measure the effort intensity.

These two specific experiments were not carried out on all subjects for time and availability reasons.

Follow-up criteria and method of analysis

Table 1 describes when and how data were collected. The participants stopped at the end of the flat part and at the end of ascent to fill-in a notebook measuring pedaling comfort with a visual analog scale and perceived exertion with the Borg scale [8] wich is a subjective measure of exercise intensity correlated with physiological data.

To define the intensity of exercise provided by each participant, we used the percentage of the reserve heart rate (HR reserve = max HR - rest HR) and the classification table of endurance physical activity intensity - relative intensity (US department of Health and Human Services, 1996).

Management of missing data

In case of missing data in the HR record that could be due to transmission problems, and provided that the missing periods do not exceed 10 sec, they will be imputed using the average of the previous and following 10 sec.

Results

The population shows significant variability in all parameters including fitness level based on Ruffier Dickson Index (RDI). This allowed us to determine two subgroups according to their physical training levels (trained / untrained) (Table 2).

The trained group includes 5 participants with an intense PA level according to GPAQ and a good physical condition according to RDI. The untrained group includes 7 participants with a low to moderate AP level according to GPAQ and a low to moderate physical condition according to RDI.

Exercise intensity

During the different sessions, the heart rate (HR) recordings showed that participants were all in a light to intense exercise (25 to 84% of the Reserve HR). No participants were “very light” or “very intense”. In parallel, we evaluated the perceived exertion using the Borg scale, allowing a subjective qualification of the intensity of the effort. Results show fairly low average scores not exceeding the qualification "neither light nor hard" (13/20).

GPS recordings show that the speed seems independent of the physical condition (Table 3) as average speeds are very close and sometimes even faster for the untrained group than for the trained group. We can also observe that the average speed appears to be slightly influenced by the topography. Indeed, between the flat part and the ascent, the road goes from an average grade of 2% to 7.5%, yet the recordings show very close speeds.

In addition, we did not observe significant increase in the exercise intensity provided between the flat part and the ascent, despite the very different terrains. After analysis of the recordings, we noticed that the "trained" group was more likely to increase their heart rate in the ascent (table 3).

Figure 2 shows, at the last minute, a significant increase in the power developed by the motor. Indeed, at the end of the ascent the slope increases quite clearly over a few hundred meters. In parallel, for the participant, no data is modified: the recording shows a constant speed, the cadence remains at 80 rpm and the heart rate rises very little compared to the profile of the road.

Intuitive adjustment to settings

We aimed to evaluate the time required for subjects (n=3) to adapt to blind preset pedaling rates. Indeed, on the VELIS, the assistance mode requires that the cyclist's pedaling cadence corresponds to the preset cadence so that the assistance is optimal.

Three participants have done ten repetitions of the ascent part with blinded variation of the cadence to measure the adaptation time to the settings.

The ten blind recordings showed that it took 1 to 2 minutes for the subjects to adjust to the target pedaling cadence. On the recording (Figure 2), the participant takes about 1 minute to adjust to the preset pedaling cadence blindly determined (80rpm). During the rest of the recording, the cadence does not vary any more. The calculated average pedaling rate was 79.7 rpm.

The recording in Figure 3 was made on the first attempt of a participant, with a pedaling rate of 65 rpm. The shaded area corresponds to the ascent. During this part we observe an increase in HR from the start and during the first 3 minutes then a gradual but significant decrease of about 20 bpm during the rest of the climb despite the 7.5% slope. At the same time, we can observe an increasing speed.

This recording shows that it took about 3 minutes for the novice to become familiar with the bike and to get optimal assistance.

Safety and optimization of PA time

Figure 4 shows the HR of the participant in the 7% average grade descent with and without engine brake. Without engine brake, the speed is high, and the average HR is 85.5(2.9) bpm, a very light intensity for this participant. When the engine brake is set to 25km/h, the participant can then pedal without reaching a dangerous speed and the average HR is then 110(6.1) bpm. This is moderate intensity for this participant and will therefore allow him to work in fundamental endurance while ensuring safety.

Discussion

First of all, our study allows us to conclude, in agreement with many other recent studies [9,10], that E- bike practice should be considered as a physical activity, including for trained people using the appropriate settings to assist the subject only when needed.

Then, our results show that VELIS makes cycling approachable to everyone regardless of physical condition and terrain. The VELIS technology allows for a regular effort adapted to the subject on a varied terrain with climbs. This on-board technology, which adapts to the subject's physical condition, can also be used to plan more specific training sessions. Its use is very intuitive as participants need less than 2 minutes to understand and adapt to the optimized pedaling, regardless the terrain.

In practice, VELIS allows group practice and thus permits greater social interactions. It will also ensure that participants can achieve the objectives set, without risk of failure. The fact that the motor brake can also be configured on the VELIS allows a non-cyclist population to ride a bike safely. All roads are then accessible for everyone and biking can become pleasurable.

This opens up very interesting clinical perspectives, since VELIS meets all requirements to ensure intrinsic motivation, and therefore, promote long-term adhesion to PA (pleasure, social support, set graded tasks, avoid failure, provide feedback on performance, …) [11].

We are aware of the habitual limitations of these pilot studies: a. small sample size; b. training level based on very simple physical score; c. absence of VO2 max evaluation; d. absence of power sensor use. The sample size of this study corresponds to the recommendations of the CONSORT for Feasibility and Pilot Studies [12], which state that in this type of exploratory study, investigators can estimate the appropriate sample size. We had to adapt to both logistical and time limitations, but our sample, even if limited, met our objective of including various profiles in terms of physical condition and cycling habits.

Still, this is, to date, the largest series (12 subjects) comparing two groups of subjects classified by the level of training. To our knowledge, only one other study, from Mayr published in 2018 [13] tested a smart E-bike prototype to demonstrate the ability of this new tool to control the intensity level and avoid overload, while allowing group practice, by adjusting the level of assistance according to needs. However, in that study, only 2 subjects were evaluated.

The prototype development at this stage did not allow a detailed analysis of the power developed by the subject, and did not allow the VO2 to be calculated. This is regrettable because it would enable us to control very accurately the intensity of the effort provided by the subject.

This kind of “on-board physiological platform” should allow us, in clinical research, to have a more accurate vision of subjects’ physiological adaptation and behavioral change dynamics. We still need to further develop this tool, and new studies are commencing with power sensors used to collect more objective data for breast cancer patients (clinical trial ID: NCT03340857), diabetic patients (clinical trial ID: NCT03912623), and fibromyalgia patients (financing acquired).

In conclusion, the main finding of this pilot study confirms that VELIS is an easy to use and secure tool to make PA approachable, whatever the level of training in healthy subjects. This is a necessary prerequisite to consider the use of this device in patients with pathologic conditions.

Table 1: Outcome Measures

Outcome Measure	*Time Frame*	*Criteria*
Level of physical activity	Prior to the tests	GPAQ: Global Physical Activity Questionnaire developed by WHO
Assessment of physical condition	Prior to the tests	Ruffier test to calculate Ruffier Dickson Index (RDI)
Heart rate	During the tests. Continuous recording	Polar heart rate monitor
Speed and Duration	During the tests. Continuous recording	GPS data
Perceived Exertion	During the tests. End of flat part + end of ascent	RPE: Rating of Perceived Exertion
Pedaling comfort	During the tests. End of flat part + end of ascent	Visual analogue scale

Table 2 : Population description n=12. Characteristics of the "trained" - "untrained" subgroups. BMI =Body Mass Index. GPAQ = Global Physical Activity Questionnaire. MET = Metabolic Equivalent Task

		Trained	*Untrained*
Number of subjects (Female/Male)		5 (2/3)	7 (3/4)
Age	*mean (sd)*	45,6 (15,3)	50,6 (11,0)
BMI	*mean (sd)*	23,3 (2,5)	26,5 (5,5)
GPAQ total MET.min/week	*mean (sd)*	5944 (1263)	1486 (361)
Level of PA (GPAQ)		Intense	Moderate / Low
Ruffier Dickson Index	*mean (sd)*	5,2 (1,9)	9,2 (1,9)

Table 3: Recording of duration, average speed, average heart rate in the flat part and the ascent during the 4 tests (n=12)

FLAT PART	*Test1_65*		*Test_55*		*Test_75*		*Test4_65*	
	Trained	Untrained	Trained	Untrained	Trained	Untrained	Trained	Untrained
Duration min: sec	15: 36	16: 42	16: 12	17: 33	13: 06	14: 32	14: 17	15: 10
Average speed km/h	21,0	19,8	20,1	19,1	23,7	21,6	23,0	21,3
Average HR (sd) bpm	115 (10)	108 (19)	113 (9)	112 (17)	113 (14)	108 (17)	109 (18)	103 (16)
ASCENT								
	Trained	Untrained	Trained	Untrained	Trained	Untrained	Trained	Untrained
Duration min: sec	09: 14	08: 12	07: 55	10: 19	06: 39	06: 56	07: 26	08: 38
Average speed km/h	17,1	18,9	19,0	14,9	21,9	21,6	20,4	18
Average HR (sd) bpm	129 (7)	112 (13)	114 (13)	123 (17)	124 (17)	111 (13)	119 (20)	105 (13)

Figure 1: Picture of the VELIS

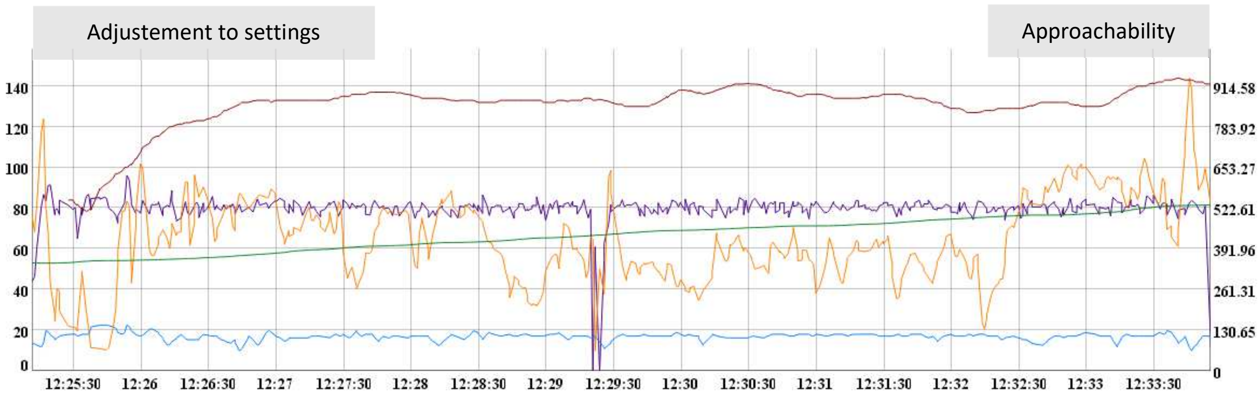

Figure 2 : Blind setting to 80rpm. Recording made on the ascent.
Pedaling cadence (rpm) : min 0 – max 96.1 – mean 79.7 – sd 6.7
Electric Power (Watt) : min 64.1 – max 940.7 – mean 419.3 – sd 139.5
Altitude (meters above sea level) : min 345.9 – max 532.3 – mean 435.8 – sd 54.4
Speed (km/h): min 9.9 – max 22.5 – mean 16.9 – sd 1.8
Heart rate (bpm): min 78.4 – max 144 – mean 130.2 – sd 12.2

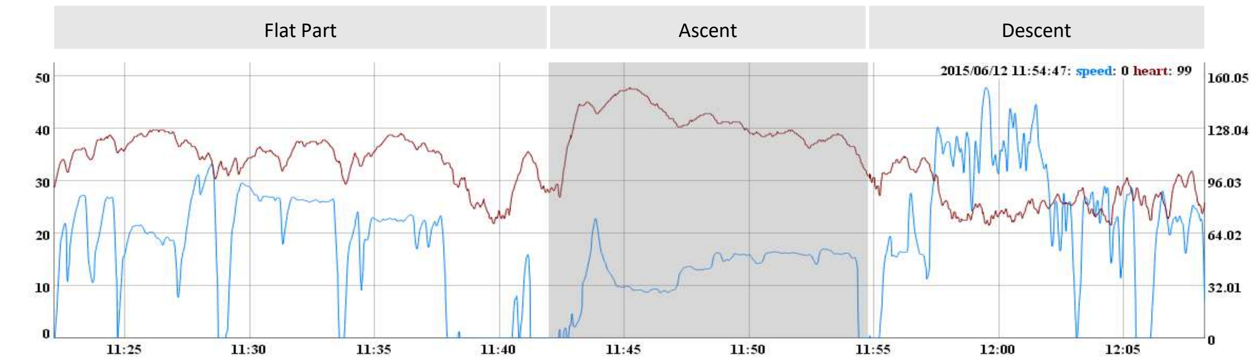

Figure 3: Adjustments to settings - Test 1 cadence 65.

Speed (km/h) : min 0 – max 47.8 – mean 17.8 – sd 10.7

Heart rate (bpm) : min 69 – max 153 – mean 108.2 – sd 20.8

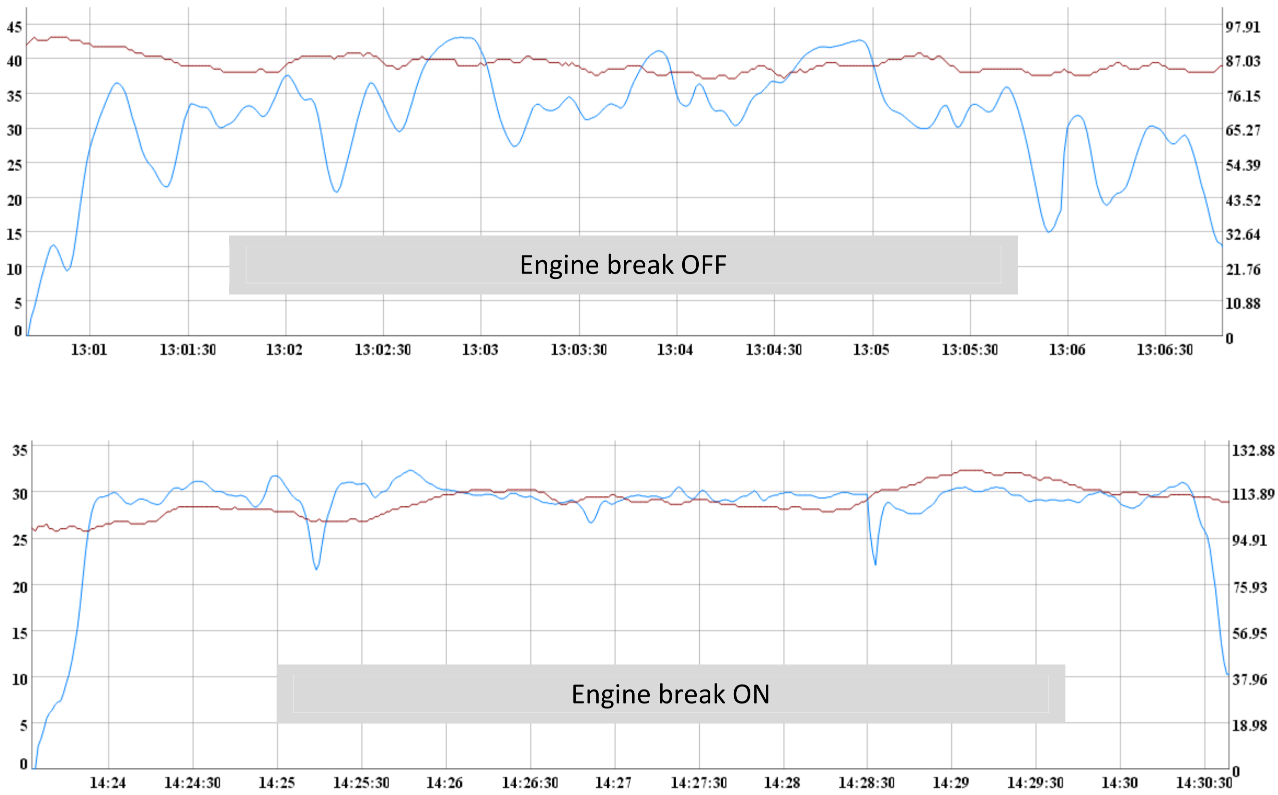

Figure 4 : Descent without engine brake (above) and with engine brake set at 25km/h (below).

Engine brake OFF : Speed (km/h) : min 0 – max 43.2 – mean 31.2 – sd 7.7 Heart rate (bpm) : min 81 – max 94 – mean 85.5 – sd 2.9

Engine brake ON : Speed (km/h) : min 0 – max 32.4 – mean 28.3 – sd 5 Heart rate (bpm) : min 98 – max 123 – mean 110.2 – sd 6.1

Competing interests:

JL Bosson has a shareholding in the company e-bike labs, which developed the electronic controllers used on the bicycles for this research. None for the others authors.

Funding: None

Ethical approval: Not required

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