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

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20 use of the VELIS with patients is to initially carry out a pilot study on healthy subjects. The objective
21 was to evaluate the impact of the customizable settings on physiological parameters and to ensure
22 this prototype's efficiency and safety of use. Twelve healthy participants with various profiles
23 (physical condition, used to cycling or not) were included. They have completed four times a 14km
24 itinerary with various settings of the VELIS. We recorded GPS data, heart rate and perceived exertion.
25 Based on exercise intensity, we confirm that riding an E-bike should be considered as a physical
26 activity. Safety of the participants is ensured by the engine brake. Recordings show that it took
27 between 1 and 3 minutes for the novice to become familiar with the VELIS and to get optimal
28 assistance. The main finding of this pilot study confirms that VELIS is an easy to use and secure tool
29 to make PA approachable, whatever the level of training in healthy subjects.

30

31

32 **Introduction**

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

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

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

46

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

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

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

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

60

61 **Methodology**

62 **Population**

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

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

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

70 **Material**

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

74

75 **VELIS**

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

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

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

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

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

93

94 **The itinerary profile**

95 The course used was 14km long with 350m of positive elevation. The itinerary profile was divided
96 into 3 zones: 1) 6km near flat (average grade 2%) *called in the text "Flat part"*; 2) 2.5km uphill

97 (average grade 7.5%) *called in the text "Ascent";* 3) 5.5km downhill (average grade -7%) *called in the*
98 *text "descent".*

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

101 **Protocol**

102 Participants cycled alone to avoid peer pressure.

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

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

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

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

113 **Follow-up criteria and method of analysis**

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

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

121 **Management of missing data**

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

125

126 **Results**

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

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

133

134 ***Exercise intensity***

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

140 GPS recordings show that the speed seems independent of the physical condition (Table 3) as
141 average speeds are very close and sometimes even faster for the untrained group than for the
142 trained group. We can also observe that the average speed appears to be slightly influenced by the
143 topography. Indeed, between the flat part and the ascent, the road goes from an average grade of
144 2% to 7.5%, yet the recordings show very close speeds.

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

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

152 ***Intuitive adjustment to settings***

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

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

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

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

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

169 ***Safety and optimization of PA time***

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

176

177 **Discussion**

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

181 Then, our results show that VELIS makes cycling approachable to everyone regardless of physical
182 condition and terrain. The VELIS technology allows for a regular effort adapted to the subject on a
183 varied terrain with climbs. This on-board technology, which adapts to the subject's physical
184 condition, can also be used to plan more specific training sessions. Its use is very intuitive as

185 participants need less than 2 minutes to understand and adapt to the optimized pedaling, regardless
186 the terrain.

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

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

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

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

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

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

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

217

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219 *Table 1: Outcome Measures*

| <i>Outcome Measure</i> | <i>Time Frame</i> | <i>Criteria</i> |
|---|---|---|
| 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 |

220

221

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

| | | <i>Trained</i> | <i>Untrained</i> | |
|----------------------------------|------------------|----------------|------------------|-----|
| Number of subjects (Female/Male) | | 5 (2/3) | 7 (3/4) | |
| Age | <i>mean (sd)</i> | 45,6 (15,3) | 50,6 (11,0) | 225 |
| BMI | <i>mean (sd)</i> | 23,3 (2,5) | 26,5 (5,5) | |
| GPAQ total MET.min/week | <i>mean (sd)</i> | 5944 (1263) | 1486 (361) | 226 |
| Level of PA (GPAQ) | | Intense | Moderate / Low | |
| Ruffier Dickson Index | <i>mean (sd)</i> | 5,2 (1,9) | 9,2 (1,9) | 227 |

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

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

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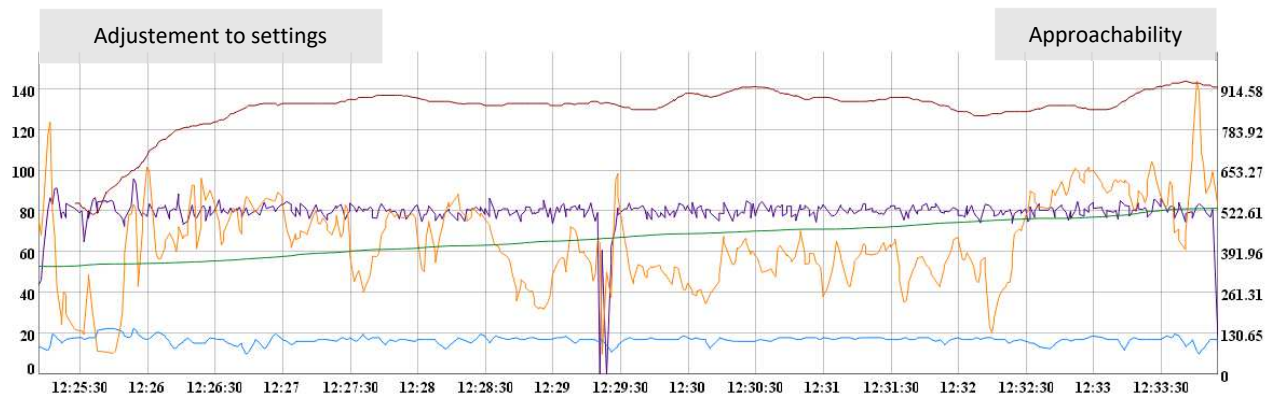


247 *Figure 1: Picture of the VELIS*

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251

252 *Figure 2 : Blind setting to 80rpm. Recording made on the ascent.*

253 *Pedaling cadence (rpm) : min 0 – max 96.1 – mean 79.7 – sd 6.7*

254 *Electric Power (Watt) : min 64.1 – max 940.7 – mean 419.3 – sd 139.5*

255 *Altitude (meters above sea level) : min 345.9 – max 532.3 – mean 435.8 – sd 54.4*

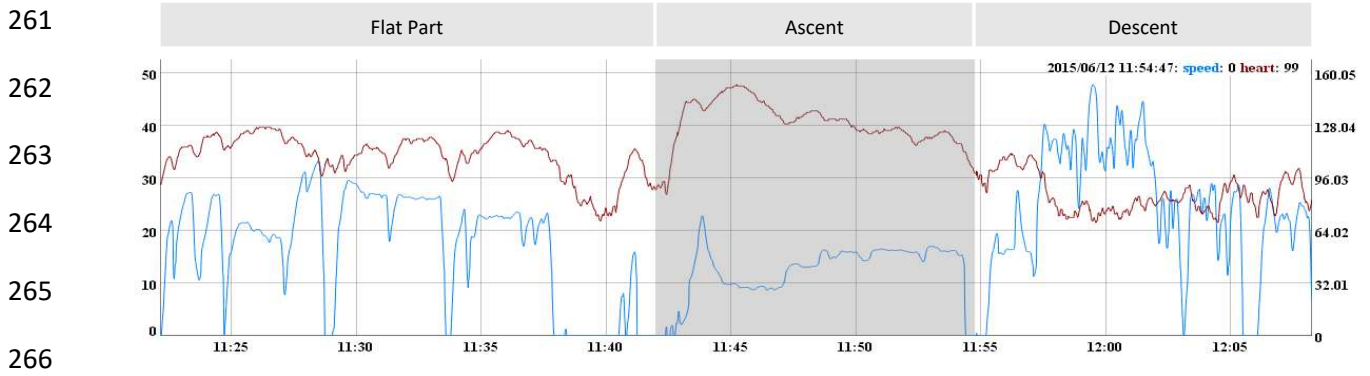
256 *Speed (km/h): min 9.9 – max 22.5 – mean 16.9 – sd 1.8*

257 *Heart rate (bpm): min 78.4 – max 144 – mean 130.2 – sd 12.2*

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

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

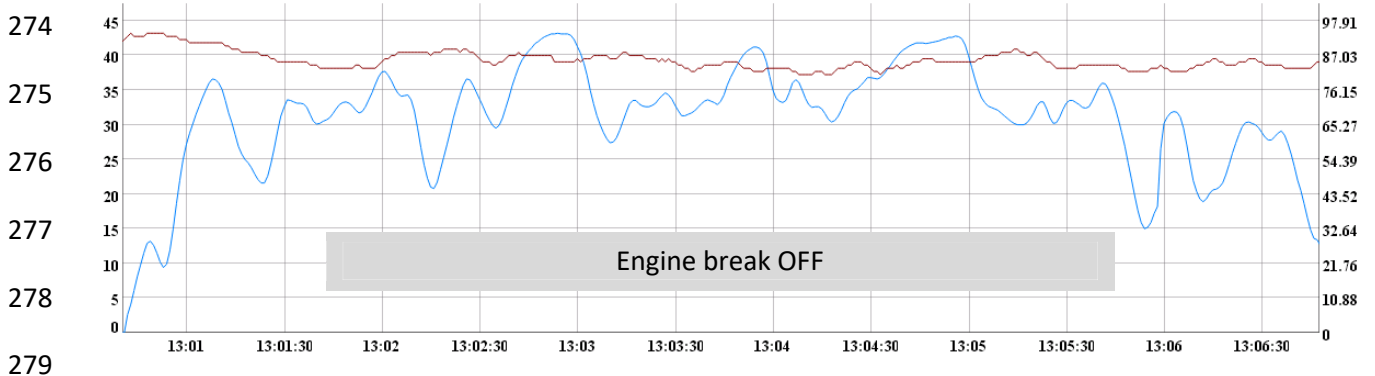
269 *Heart rate (bpm) : min 69 – max 153 – mean 108.2 – sd 20.8*

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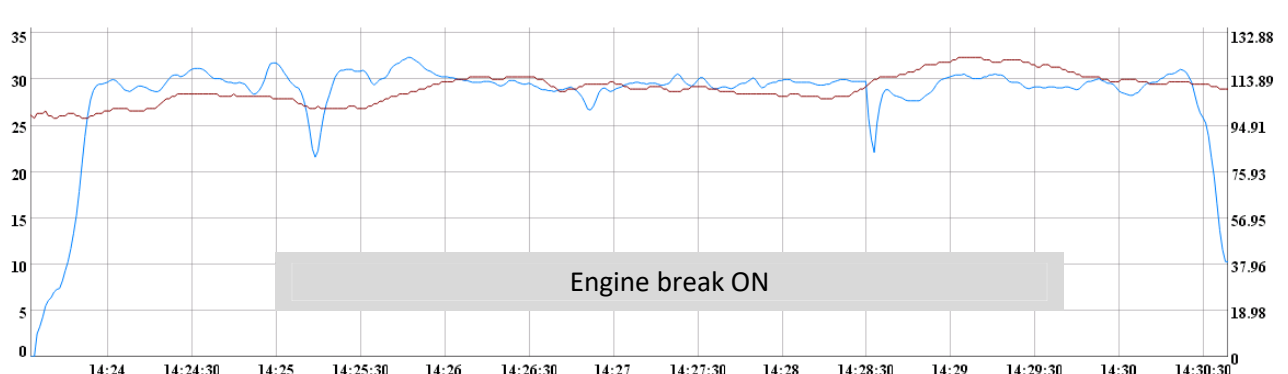
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286 *Figure 4 : Descent without engine brake (above) and with engine brake set at 25km/h (below).*

287 *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*

288 *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*

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292 Competing interests:

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

295

296

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298

299 Ethical approval: Not required

300

301

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