Benefits of 1-Yr Home Training With Functional Electrical Stimulation Cycling in Paraplegia During COVID-19 Crisis

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Abstract: The purpose of this observational study was to report the experience of a 1-yr home training with functional electrical stimulation cycling of a person with T4 American Impairment Scale A paraplegia for 9 yrs, homebound due to the COVID-19 health crisis. The 40-yr-old participant had a three-phase training: V1, isometric stimulation; V2, functional electrical stimulation cycling for 3 sessions/wk; and V3, functional electrical stimulation cycling for 2–4 sessions/wk. Data on general and physical tolerance, health impact, and performance were collected. Borg Scale score relating to fatigue was 10.1 before training and 11.8 after training. The average score for satisfaction at the end of sessions was 8.7. Lean leg mass increased more than 29%, although total bone mineral density dropped by 1.6%. The ventilatory thresholds increased from 19.5 to 29% and the maximum ventilatory peak increased by 9.5%. Rosenberg's Self-esteem Scale score returned to its highest level by the end of training. For the only track event on a competition bike, the pilot covered a distance of 1607.8 m in 17 mins 49 secs. When functional electrical stimulation cycling training is based on a clear and structured protocol, it offers the person with paraplegia the opportunity to practice this activity recreationally and athletically. In times of crisis, this training has proven to be very relevant.

Key Words: FES Cycling, Paraplegia, COVID-19, Case Report

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People with paraplegia experience the effects of immobility and a sedentary lifestyle and thus are often in need of devices and training techniques that can both provide pleasure and compensate the lack of lower limb motor activity. With the COVID-19 health crisis, able-bodied people have been able to use home exercise bikes for training and physical activity that are easily integrated into daily living. For people with paraplegia, functional electrical stimulation (FES) cycling[1] can take varied forms (cycle ergometer, tricycle on a home trainer) and can be easily integrated within an ecological home environment.[2,3] Functional electrical stimulation is based on the adjustment of the stimulation parameters for the quadriceps, hamstrings, and sometimes glutei muscles to trigger the stimulation channels associated with the crankset position. The intensity of the stimulation applied to these muscles determines the moments of force and the rate of rotation produced on the crankset. The stimulation pattern is predetermined so that the best muscle synergies can be implemented. Studies have suggested the significant and promising benefits of FES cycling[4] especially when training begins early,[5] is regular[6] (at least 3 times/wk), lasts a sufficiently long time (at least 6 mos),[7] and is performed at a sufficiently high intensity.[8]

The main objective of this report was to demonstrate the feasibility and the acceptability of a long and codified FES cycling training regimen at home during the COVID-19 pandemic. In this specific context, the secondary objectives were to assess the impact on the quality of life, the self-esteem, as well on cardiovascular adaptation and body composition.

METHODS

The participant's anamnestic and clinical characteristics at his inclusion V0 are presented in the Supplemental Digital Content 1, http://links.lww.com/PHM/B405. The 3 phases V1 and V2–V3 home training are detailed in the Supplemental Digital Content 2, http://links.lww.com/PHM/B406, and in the Supplemental Digital Content 3, http://links.lww.com/PHM/B407, respectively. Once the participant was familiar with the use of the Cephar stimulator, phase V1 was initiated. During the training, the current intensity was adjusted manually by the participant. In the first session, under clinical supervision, the initial current intensity was determined to produce a strong muscle contraction of a least 4/5 on the Medical Research Council Scale. Phases V2 and V3 were devoted to training on an ergometer bike to which the participant's wheelchair was docked. The stimulation pattern was the original one provided by the BerkelBike cycling software. An evaluation was performed at the end of each week to determine the appropriate resistance level for the following week. At the evaluation, the participant was instructed to gradually increase the resistance against the wheel of the ergocycle (adjustment of a dial graduated from 1 to 8, with 8 being the strongest resistance) every minute until autonomous cycling was no longer possible. During phase V2, which lasted 3 mos, a regular training routine of 3 training sessions per week was established

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CF and CA-C did the concept/idea/research design. CF, MS, RLG, and BR did the data collection. CF, MS, and CA-C did the data analysis. CF, MS, CA-C, RLG, AF, and RC did the interpretation of data and writing. BR did the providing participants. CF, MS, CA-C, and RLG did the consultation (including review of manuscript before submitting).

The study was approved by the ethics committee (CPP SUD-EST IV) on July 9, 2019 (n° ID RCB: 2019-A00808-49). The participant provided written informed consent before enrolment.

Supporting data are available upon request.

The protocol has been declared in the ClinicalTrials registry (Ref: NCT04412447).

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while respecting a maximum pedaling time of 30 mins. During phase V3, which lasted 7 mos, he was invited to adjust both the pedaling duration and the resistance level, depending on his fatigue, motivation, or any medical or personal events. The instruction to never lower the pedaling speed below a certain threshold was never given, as the objective was to have the participant pedal autonomously (without the assistance of his arms) as long as possible.

Tolerance, impact, and performance indicators were collected repeatedly and standardized at various frequencies, as shown in the Supplemental Digital Content 4, http://links.lww.com/PHM/B408.

- ClinicalTrials registry ref: NCT04412447.

RESULTS

The entire training lasted 12 mos: (*a*) in isometric mode (V1: week 40 [W40] to W47, 2019), (*b*) in dynamic mode on the cycle ergometer in phase V2 (W47, 2019, to W11, 2020) and phase V3 (W12–W45, 2020)—109 sessions in total. No medical events marked the training course. The subject also took time off from training for family reasons or vacation. Most notably, he experienced the consequences of the COVID-19 health crisis in that the collective Cybathlon competition of May 2020 in Zurich was canceled. The perception of fatigue as assessed by the Borg Scale score was on average 10.1 ± 1.5 (R = 7–15) before training and 11.8 ± 1.4 (R = 9–17) after training. Satisfaction at the end of each session was on average 8.7 ± 1.3 (R = 3–10). Body composition showed a decrease in the ratio of fat mass to total mass in the left and right legs by 15.3% and 12.6%, respectively, and an increase in lean leg mass of more than 29%. Although the total bone mineral density only decreased by 1.6%, it appeared to be very markedly reduced at the left hip (−24%) at 8 mos of training. The T score went from −2.4 to −3.5 over the same period (Supplemental Digital Content 5, http://links.lww.com/PHM/B409). Regarding the cardiorespiratory parameters, for a power of 100 W, the maximal oxygen uptake (VO_{2max}) remained stable at 1.51 l/min before and during training. The maximum heart rate (HR) was the same as the theoretical maximum HR in both cases. On the other hand, before training, the first ventilatory threshold was crossed at 51.7 W and the second at 76.7 W, but after a few months of training, threshold 1 was crossed at 66.7 W (↑ + 29%) and threshold 2 at 91.7 W (↑ + 19.5%). The maximum ventilatory peak was measured respectively at 56.8 and 62.2 l (↑ + 9.5%; Supplemental Digital Content 6, http://links.lww.com/PHM/B410). The Rosenberg's Self-esteem Scale score, at its highest before training (36 of 40), was blunted thereafter, around (31 of 40), and collapsed at W30 (29 of 40) before bouncing back to its highest level at the end of training (35 of 40; Supplemental Digital Content 7, http://links.lww.com/PHM/B411). Quality of life as assessed by the World Health Organization–Quality of Life Scale remained at a good level (average scores of 3.3 before the start of training until its end). A slight decline in the mean scores (estimated at 3.1) was observed at W5, 2020.

The curve of the training progression is illustrated in Figure 1. In the first 2 mos (W47, 2019, to W11, 2020), pedaling performance on the cycle ergometer was kept stable in terms of pedaling time, as this was defined by the protocol. However, progress in this same period was indicated by the pilot's no longer needing to use his hands to operate the crankset and the increase in resistance measured during the evaluation sessions (Fig. 2). The pilot then showed regular progress in his performances over the following 6 mos by modulating the duration of pedaling according to his level of general fatigue or medical events. At times, the support team stepped in to recommend that he not continue pedaling beyond a certain amount of time. The average pedaling time was 59 mins and 57 secs and the maximum time was 2 hrs and 10 mins. At the halfway point (W30, July 22, 2020), the participant covered a distance of 1607.8 m in 17 mins 49 seconds (on a strictly flat outdoor track) on a CATrike 700 competition bike (Big Cat HPV LLC, Orlando, FL).

DISCUSSION

This brief report focused on the training of a single subject but offers very detailed and weekly results over a 12-mo period, thus providing credible data. Although the physiological monitoring stopped at 8 mos, the monitoring of the pilot's clinical and psychological condition, as well as the evaluation of his FES cycling performance, continued through the 12th month. These sufficiently long durations suggest strong trends that can be compared with the literature data.[3,7,9]

Even if the performance (in particular the speed) was lower than those produced by some pilots during the 2016 Cybathlon,[10] it was in line with the desire to focus on distance rather than speed. Functional electrical stimulation cycle training seems to be an appropriate way to achieve an honorable track performance. The cycle ergometer can be used autonomously at home in combination with the participant's personal wheelchair and occasional outings can be made to experience the pleasure of cycling outdoors using one's own legs to pedal. Some of the obstacles to resuming physical activity can be bypassed, although motivation is required, because the training is not time consuming, discovering that the one's legs can be used for pedaling is positive, the activity does not depend on the weather, it does not require one to leave home, the cost of the cycle is reasonable, and the risk of injury can be controlled. Not least, the training seems adaptable to the individual's motivation and availability.

Toward the end of training, the ratings of perceived exertion never exceeded a differential more than 2 points on the Borg Scale and were almost always scored less than 12 (corresponding to an exertion felt as moderate). The impact on performance was real and compelling. At the participant's request and in the middle of the near-total confinement due to the COVID-19 crisis, training continued beyond the track assessment in July. Electrical stimulation was only delivered to the quadriceps and hamstrings. The glutei muscles were deliberately excluded from the stimulation pattern to spare the subject from the difficult process of applying the electrodes to the buttocks and to demonstrate that cycling could be achieved without these muscles. The single performance on the track exceeded expectations.

Bone mineral content of the whole body increased by 8.3%. Although the total bone mineral density dropped by only 1.6% (not a significant change given the margin of error), the hip showed a significant bone loss of 24%. This finding is consistent with the recommendation never to underestimate the risk of fracture when a person is cycling under electrostimulation.[11]

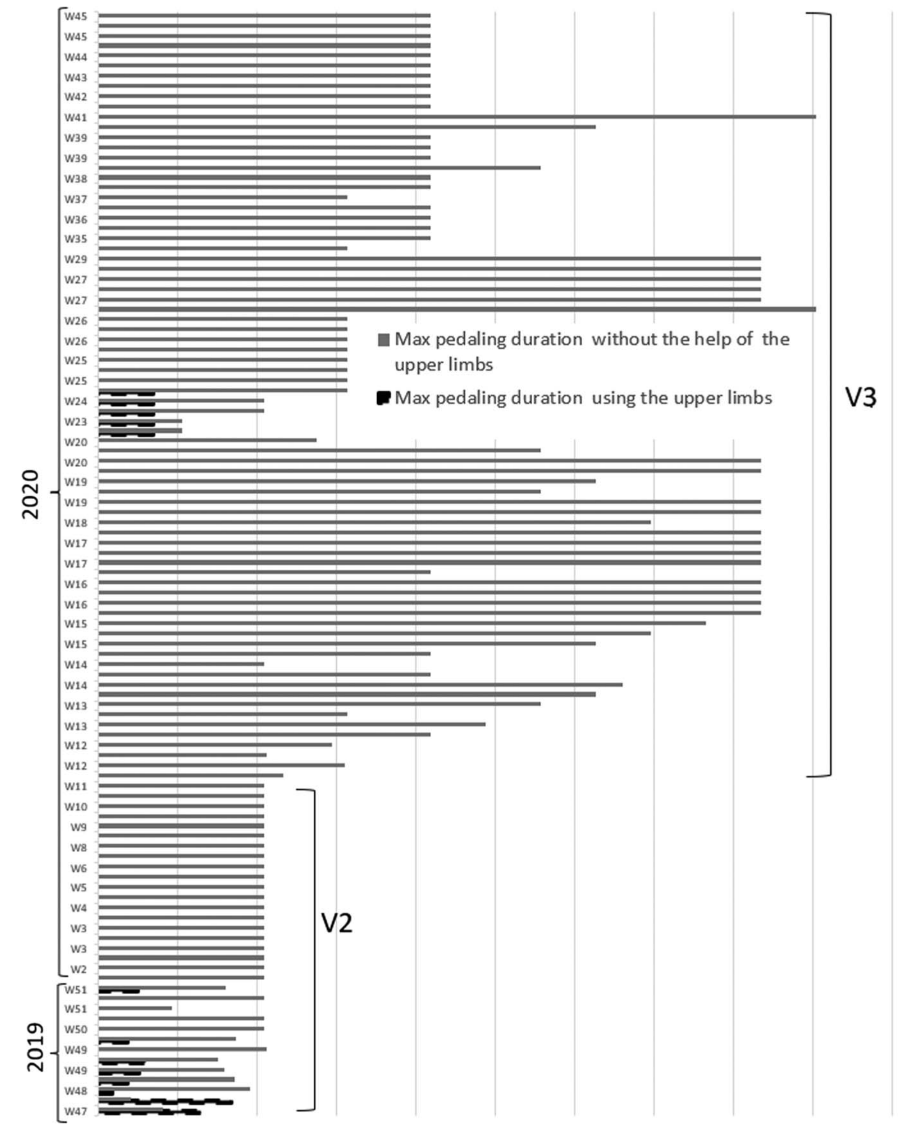

FIGURE 1. Performances in duration of pedaling at each training session (with and without the help of the upper limbs).

On the other hand, body composition showed a strong benefit from this training, with an increase in the lean mass of the legs significantly greater than that reported in the literature, more than 29% in this report versus 11% in people with AIS grade C paraplegia[7] and 4.1% in those with AIS grade A paraplegia.[9] As the pilot's weight did not change, our finding suggests that a phenomenon of reversibility and transformation of fat mass into lean mass occurred, as reported in the literature.[12] The significant impact on body composition can be associated with the expectation of improved carbohydrate metabolism and insulin levels, as previously demonstrated.[13] With regard to cardiorespiratory adaptations, the stress test and the measurement of VO_2 indicated real gains with increases in the ventilatory thresholds, that is, the thresholds for switching from aerobic to anaerobic mode.

The psychosocial impact was reflected by the Rosenberg score, which indicated enthusiasm before the start of training, only to drop below 30 of 40 during the first confinement in response to COVID-19 and the disappointment of learning that the Cybathlon competition was canceled. The score bounced back by the end of the study to its highest level, suggesting that the participant was exhilarated by having successfully met this challenge. Studies on the impact of FES cycling training on quality of life and self-esteem are very rare. Dolbow et al.[2] underlined the impact of this home-based activity carried out under the same experimental conditions on physical and environmental quality-of-life scores. These increased significantly over a 12-mo period. Although subjective and subject to bias by many factors, quality-of-life assessment is essential to validate the value added of such an activity.

A very recent review of the literature highlighted the short duration of the training periods reported in the publications (on average 16 wks), the scarcity of home-based training experiences (18 of 92 studies), the insufficient consideration of quality-of-life indicators, and a methodological insufficiency to conclusively validate the physiological, functional, and psychological effects of FES cycling over time.[1] Randomized controlled trials over long periods are difficult to implement. Only home training protocols could address this difficulty while providing a longitudinal

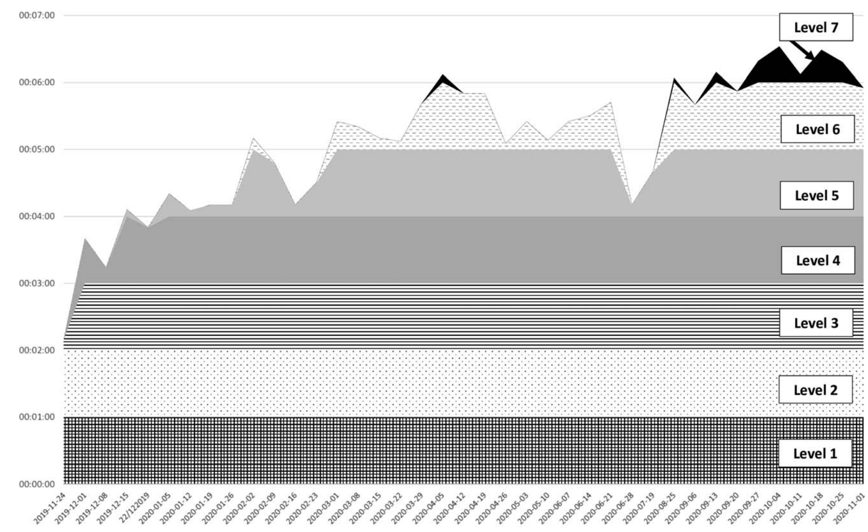

FIGURE 2. Increase in resistance against the wheel from level 1 to level 8 during the phases V2 and V3. The participant was instructed to gradually increase the resistance of the ergocycle (adjustment of a dial graduated from 1 to 8, with 8 being the strongest resistance) every minute until autonomous cycling was no longer possible. The highest level at which a full minute of cycling was achieved was used as starting resistance for the following training sessions.

approach to regularly monitor physiological, physical, functional, and psychological parameters. This would mean a focus on home-based FES training "combined with enhanced user education and specific goal setting between a practitioner and a person with spinal cord injury (SCI)."[1,6]

LIMITATIONS

The findings of this pilot study on a case documented over a long period of 1 yr can in no way be generalized to the general population of patients with SCI. They only offer the basis for a future open study without control group where each patient is his own control or better a randomized controlled study. It highlights the need to enrich the evaluation with a measure of the subject's perceptual health, mood, social participation, and sense of commitment that such a home-based activity may induce.

CONCLUSIONS

As the primary objective of this observation was to determine whether motivation and improvement in training performance are maintained over time, regardless of the difficulties of daily life and despite the COVID-19 crisis, we focused on the most promising indicators suggested by the literature. It seemed that the acceptability and ability of the participant to perform training at home have offered promise for expanding the protocol to a larger number of patients. Priority was given to cardiorespiratory adaptation, cardiovascular risk, and improvement in self-esteem and quality of life. The COVID-19 health crisis has revealed how much confinement affects the morale and especially the physical condition of the most vulnerable people. The participant's training took place in the midst of the crisis. He was able to find a sense of well-being and pleasure, which, along with the physical effort being made, must be considered in the rehabilitation of paraplegic people. For engaging more people in such a long-term home training, the training itself needs to be rewarding and empowering. This study shows that this type of training—self-managed by an individual with a high-level spinal cord injury that occurred several years ago, supervised by a physical therapist, and followed by a physician—is likely to be well accepted over time. It is based on a clear and structured protocol that offers the promise of generalization to other paraplegic individuals so that they can engage in an activity that is both recreational and athletic and that offers the opportunity for progress in both endurance and speed.

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