Effects of spinal cord stimulation on heart rate variability in patients with Failed Back Surgery Syndrome: comparison between a 2-lead ECG and a wearable device

Running title: ECG versus wearable device in SCS

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Financial support: The author(s) received no specific funding for this work.

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Writing – review & editing: Lisa Goudman, Raf Brouns, Bengt Linderoth, Maarten Moens.

Conflict of interest: Bengt Linderoth serves as a consultant to Medtronic, St Jude/Abbott, Boston Sci and Elekta AB. Maarten Moens has received speaker fees from Medtonic and Nevro. The authors declare no other conflicts of interests.

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Abstract

Objectives

Heart rate variability recordings have the potential to examine the role of the autonomic nervous system. Several wearable devices are nowadays readily available. Up till now, no studies explored whether a wearable device is able to reliably measure a treatment response in chronic pain patients. Therefore, the aim of this study is to evaluate the reliability of a Polar® V800 wearable device to accurately measure RR-intervals in patients with Failed Back Surgery Syndrome (FBSS) during Spinal Cord Stimulation (SCS), as compared with an eMotion 2-lead ECG recording.

Materials and Methods

Twenty-two patients diagnosed with FBSS and treated with SCS participated in this study. HRV was measured with a 2-lead ECG registration tool and a Polar® V800 during on and off state of SCS. Intraclass correlation coefficients, correlations, limits of agreement, Cronbach’s alpha and effect sizes were calculated.

Results

Analysis based on the recordings from the ECG and wearable device revealed the same HRV parameters (except for the time-frequency domain) to capture the treatment response of SCS. Parameters that are relevant for measuring the SCS treatment response have strong correlations ($r \geq 0.82$), good ICC values (ICC $\geq 0.82$), acceptable consistency ($\alpha \geq 0.9$) and limited bias.

Conclusions

Similar pre-to post treatment changes were revealed between a wearable device and 2-lead ECG with reliable HRV estimates for parameters that are able to capture the treatment changes. This
suggests that a wearable heart rate monitor might be a reliable wearable tool for the detection of pre-to post treatment changes of SCS, in patients with FBSS.

**Keywords:** Heart rate variability; functional neurosurgery; autonomic nervous system; chronic pain
Introduction

Heart rate variability (HRV) is the variability in the interval between successive heart beats \(^1\). HRV recordings have the potential to assess the role of the autonomic nervous system in healthy individuals as well as in patients with chronic pain \(^2\). In healthy subjects, a harmonic balance between the excitatory sympathetic and inhibitory parasympathetic systems can be observed. Dysregulation of the harmonic balance between the sympathetic and parasympathetic system has been suggested in chronic pain patients with an overweight of sympathetic activation \(^3\)–\(^5\). Therefore, diminished parasympathetic modulation is associated with chronic pain \(^1\). Due to the coupling between systems involved in pain modulation and the autonomic control of the heart \(^6\), HRV can serve as a physiological biomarker of reflecting pain intensity \(^7\) and might potentially be used to evaluate treatments \(^8\), \(^9\).

Spinal Cord Stimulation (SCS), a minimally invasive treatment, is considered a valuable treatment option for chronic critical leg ischaemia, Failed Back Surgery Syndrome (FBSS) and refractory angina pectoris, among others \(^10\)–\(^14\). The goal of SCS is making chronic pain tolerable, whereby benefits can be expected on functionality and health-related quality of life \(^15\)–\(^17\). Previous studies already revealed that SCS may influence the autonomic nervous system \(^18\), \(^19\). More specifically, a reduced cardiac sympathetic activity during SCS can be observed \(^20\)–\(^22\). When SCS is switched on, the overweight of the sympathetic system diminishes and the parasympathetic influence becomes stronger \(^21\), \(^23\).

Many measurement instruments are available for registering inter-beat intervals, such as smartphone photo-plethysmography or heart rate monitors, whereby ECG is still considered the gold standard \(^24\). Recently, the market for wearable devices has advanced, as did their potential use for healthcare applications \(^25\). Typically, heart rate monitors, such as the Polar\(^\text{®}\), are worn on the wrist with wireless chest strap electrodes, enabling measuring inter-beat intervals \(^26\). Advantages of the Polar\(^\text{®}\) heart rate monitor are the ability to perform long-term registrations, commercially available, robust technology
and user-friendly software. The Polar® S810 heart rate monitor has previously been validated against ECG devices with reassuring results regarding the agreement between both devices for inter-beat intervals and HRV parameters \(^{27,28}\). The Polar® V800, a more recently released heart rate monitor, has already been validated in rest in healthy volunteers but evaluation of its use to monitor therapeutic effects in a chronic pain population has not yet been performed. Therefore, the aim of this study is to evaluate the reliability of a Polar® V800 wearable device to accurately measure inter-beat intervals in patients with FBSS during on and off states of SCS, as compared to a 2-lead ECG recording.

**Materials and Methods**

**Participants**

FBSS patients (at least 18 years old) who are treated with Spinal Cord Stimulation (SCS) at the department of Neurosurgery of Universitair Ziekenhuis Brussel were invited to participate in this study. Patients were excluded if they had one or more coexisting conditions known to affect HRV analysis (including but not limited to atrial fibrillation, frequent atrial or ventricular extra beats, paced rhythm, left ventricular bundle branch block, cancer, kidney or hepatic failure) \(^{19}\). 

The study protocol was approved by the local ethics committee of Universitair Ziekenhuis Brussel (B.U.N. 1423201837785) and registered on clinicaltrials.gov (NCT03768791). All patients provided written informed consent before participation. The study was conducted according to the revised Declaration of Helsinki (1998).

**Study protocol**

The study consisted of a single outpatient visit. Patients were asked to switch off their SCS 12 hours before the study visit. During the study visit, a 5-minute inter-beat (RR) interval measurement was recorded. Next, patients were asked to provide a pain intensity score for their back and leg pain and
then the neurostimulator was switched on again. After a resting period of 40 minutes, RR intervals were again registered for 5 minutes followed by a rating of pain intensity. RR intervals were simultaneously recorded with a 2-lead ECG device and a Polar® V800 device.

Patients were asked to refrain from alcohol, tobacco, caffeine and drug consumption 24 hours before the study visit. There was no restriction regarding the use of prescribed medication, including analgesics.

Questionnaire

All participants completed a visual analogue scale (VAS) for assessment of the pain intensity. Pain intensity scores were provided separately for back, left leg and right leg pain. The VAS ranged from no pain to maximal pain and is ranging from 0 to 10. Patients completed this pain intensity score twice; once after RR registration when SCS was switched off and once after RR registration when SCS was activated. The VAS pain score is broadly accepted as a reliable and valid tool that is sensitive to change.

HRV registration and analysis

RR recordings were made with a non-invasive 2-lead ECG registration tool (eMotion HRV sensor (MEGA electronics Ltd., Kuopio, Finland)). The eMotion device is validated for individuals without arrhythmia and has previously successfully been implemented in research settings. The ECG signal was measured by two standard surface electrodes, attached to the patient’s chest. The negative electrode was placed in the right infraclavicular fossa and the positive electrode below the pectoral muscle, in the left anterior axillary line. Data was collected at a sampling rate of 1000 Hz and digitally stored on the device. Simultaneous RR recordings were made with a V800 Polar® heart rate monitor with Polar® H10 chest strap. Patients were unable to see the Polar watch, to prevent patients from receiving
biofeedback. Patients were informed that their heart activity would be recorded for 5 minutes. Once patients were comfortably installed in a supine position, the start of the recording on both devices was synchronized. An independent researcher collected all HRV data in all patients.

The ECG signals were saved as text (.txt) files in the eMotion LAB software and a 5 minute segment was selected for off-line analysis using the heart rate variability analysis software (HRVAS) \textsuperscript{35}. The RR-intervals of the Polar\textsuperscript{®} were exported and saved from Polar Flow (https://flow.polar.com/) in text format. Preprocessing of the data consisted of ectopic interval detection with a median filter and ectopic interval correction with a cubic spline interpolation method. For analysis in the frequency and time-frequency domain, detrending (wavelet packet technique) and resampling were performed. After preprocessing, data was visually screened for outliers. Suspicious fragments were tested and removed if they met the predefined criteria of an outlier (more than 3 standard deviations, SD).

HRV analysis was performed in the time, frequency and time-frequency domain. In the time domain mean inter beat interval (IBI), heart rate (HR), standard deviation of normal-to-normal R-R intervals (SDNN) and root-mean-square of successive differences of NN (RMSSD) were calculated. In the frequency domain, spectral power was computed for two frequency bands namely low frequencies (LF) from 0.04 to 0.15 Hz and high frequencies (HF) from 0.15 to 0.4 Hz \textsuperscript{35}. These frequencies are expressed in absolute and normalized (normalized to total power) numbers. Power spectrum was calculated with the Burg method \textsuperscript{36}. The aforementioned analysis yields information about how signal power is distributed in the frequency domain, without insights into the temporal evolution of the spectrum \textsuperscript{35}. Time-frequency analysis provide simultaneous time and frequency information. Time-frequency analysis was performed with a windowed Burg periodogram. Additionally, LF to HF ratio’s (LF/HF) were calculated. Ratio’s > 1 are an estimate of sympathetic dominance while ratio’s <1 are in
favour of parasympathetic pre-eminence \textsuperscript{34, 35}. The authors refer to a previous reporting for more details regarding the preprocessing and analyses of the data \textsuperscript{18}.

Sample size calculation

Sample size calculation to reveal a significant difference in HF HRV when SCS was switched on and off, was performed using G*Power 3.1.3 (Düsseldorf, Germany) based on the HF HRV component of a previously reported study in patients with chronic pain \textsuperscript{19}. Mean HF power components of 70 and 140 msec\textsuperscript{2} were used in the current calculation. The minimal total sample size should reach 24 patients, based on two-tailed testing with alpha = 0.05 and a desired power of 0.95.

Statistical analysis

Normality was evaluated with the Shapiro Wilk test and QQ-plots and equality of variances by Levene’s tests. Descriptive statistics are provided as mean (± SD) or as median (interquartile range). Pain intensity scores between the on and off state of SCS were compared with Wilcoxon tests. HRV data in the four domains between the on and off state was compared with paired t-tests or Wilcoxon tests for both measuring devices. P values of 0.05 or less, were considered statistically significant. Relative reliability was evaluated by intra-class correlation coefficients (ICC) for all parameters between both measurement devices. Correlation coefficients were calculated to evaluate the correlation between ECG and Polar measurements. Intraclass correlation coefficients higher than 0.8 and 0.9 are considered good and excellent relative agreement respectively, whereas coefficients higher than 0.7 are considered sufficiently reproducible \textsuperscript{34, 37}. Internal consistency was evaluated by Chronbach’s alpha. Values of >0.7 indicate acceptable internal consistency reliability \textsuperscript{38}. Absolute reliability was examined by Bland and Altman plots. On these plots, the difference between paired observations on the y-axis (ECG – Polar) are plotted against the mean value on the x-axis ((ECG + Polar)/2) \textsuperscript{39}. Effect sizes, to evaluate the magnitude of the difference, were calculated as the mean difference between both
measurement devices divided by the standard deviation of the difference \[^{40}\]. Differences were considered small if effect size ≤0.2, moderate when effect size ≤0.5 and great when effect size >0.8 \[^{41}\]. All analyses were performed in R Studio version 0.99.903.

Results

Descriptives

Twenty-three of the 40 patients who were contacted to participate in November and December 2018, were included in this study. One patient had not switched off the neurostimulator and was therefore excluded from participation, resulting in a study population of 22 patients.

Six males and 16 females participated in this study with an average age of 55.09 ± 7.63 years. The mean duration that patients were implanted with SCS was 937 ± 648 days. All patients received SCS at level (D8)-D9-D10 and were implanted with either a Senza rechargeable system (Nevro Corp., Redwood City, CA, USA) with 2*8 contacts or a Restore SensorTM SureScan system connected with a SpecifyTM 5-6-5 SureScan MRI surgical lead (IPG RestoreSensor, Medtronic, Inc., Minneapolis, MN, USA). SCS was delivered with a median charge per pulse of 0.105 (0.06-0.7) µC, median charge per seconds of 550 (49.5-750) µC/sec and a median duty cycle of 30 (25-30) %. Twelve patients supplemented their pain treatment with opioid use and 8 patients were also taking beta-blockers.

There was a significant decrease in back pain intensity when SCS was switched on (VAS when SCS off: 6.2 (Q1-Q3: 4.3-7.5); VAS when SCS on: 4.3 (Q1-Q3: 1.4-5.8) (V=203, p=0.0003)). Leg pain intensity at the symptomatic side revealed a significant decrease when SCS was functioning (off: 5.5 (Q1-Q3: 4.3-7.6), on: 4.3 (Q1-Q3: 1.8-5.8) (V=190, p=0.01)) (Figure 1).
Effect of SCS

a) Time domain

There was a significant increase in mean IBI when SCS was switched on (976 ms (854.9-1095.4)) compared to switched off (913.8 ms (852-996.5)) (V=32, p=0.001), when measured with the ECG (Figure 2A). When measuring with the Polar®, a significant increase in mean IBI was observed when SCS was switched on (973 ms (854.8-1089)) compared to switched off (922.7 ms (878.3-1024.1)) (V=52, p=0.015) (Figure 2A). The mean HR was significantly lower when SCS was switched on with the ECG (SCS off: 65.9 beats per minute (bpm) (60.33-70.88); SCS on: 61.55 bpm (55.15-70.33)) (V=222, p=0.001) and the Polar® (SCS off: 64.8 bmp (58.92-70.03); SCS on: 62 bpm (55-70.25)) (V=201, p=0.016) (Figure 2B).

b) Frequency domain

Normalized LF significantly decreased when SCS was switched on (ECG: t(21)=2.52, p=0.02; Polar*: t(21)=2.25, p=0.03) (Figure 2D), yet absolute LF power was not significantly different between both states (ECG: V=140, p=0.40; Polar: V=142, p=0.63). There was a significant increase in normalized HF power (t(21)=2.52, p=0.02) from 0.41 (±0.20) when SCS was switched off to 0.49 (±0.25) when SCS was switched on, when measured with the ECG (Figure 2E). When using the Polar®, a significant increase (t(21)=2.25, p=0.03) in normalized HF power was observed when SCS was switched on (SCS off: 0.39 (±0.18); SCS on: 0.46 (±0.25)) (Figure 2E). Absolute HF power significantly increased when switching on SCS with both measurement devices (ECG: V=49, p=0.01; Polar: V=62, p=0.04) (Figure 2C).

c) Time-frequency domain

Measurements with the ECG revealed that normalized LF significantly decreased when SCS was switched on compared to switched off (t(21)=3.04, p=0.006), while absolute LF did not differ (V=141, p=0.66). Measurements with the Polar® could not reveal a difference in normalized LF (t(21)=1.83, p=0.08), nor in absolute LF (V=157, p=0.34) when switching on SCS. Absolute and normalized HF power
increased when SCS was switched on (aHF: V=46, p=0.007; nHF: t(21)=-3.04, p=0.006) when measuring with the ECG. The Polar® only demonstrated a significant increase (V=61, p=0.03) in absolute HF when SCS was switched on (130.7 ms² (26.69-290.46)), compared to switched off (87.6 ms² (40.57-218.20)) (Figure 2F). The LF/HF was significantly lower when SCS was switched on (1.08 (0.40-1.87)), compared to switched off (1.46 (0.91-3.28)) (V=190, p=0.04) when using the ECG.

The HRV parameters in the three domains can be found in Table 1.

Reliability analysis

Correlation coefficients, ICC, Cronbach’s coefficient α, 95% limits of agreement and effect sizes of all HRV parameters are presented in Table 2. All HRV parameters revealed a significant correlation between recordings from the Polar® and ECG with correlation coefficients varying from 0.44 to 0.97. Parameters that revealed significant effects when SCS was switched on, compared to switched off with both measurement devices, demonstrated good ICC values (ICC ≥0.82) and acceptable internal consistency values (α ≥ 0.9). Bland-Altman plots of those variables are provided in Figure 3. Bias is acceptable for all HRV parameters except for RMSSD and absolute LF power in the frequency and time-frequency domain. All effect sizes are small or moderate.

Discussion

This study evaluates HRV in patients with FBSS treated with SCS using the commercially available wearable device Polar® V800 and to compare this approach with a standardized 2-lead ECG assessment, taking a wide range of key HRV parameters into account.

In the field of chronic pain, research on autonomic disbalance receives ever growing attention, also in the field of chronic pain ¹. The association between peripheral and central systems regulating
cardiovascular function and pain modulatory systems is established by vagal-nociceptive interactions
42, 43. HF oscillations often function as surrogate measures of vagal activity while LF oscillation are
considered as a combination of sympathetic and vagal activity 44. The vagally mediated HF oscillations
serve as output measure of the regulatory ability of the brain to control over the periphery of the body
[22]. High self-regulatory abilities are inversely correlated with self-reported symptoms of pain in
healthy subjects [23]. In various chronic pain disorders, a decrease in parasympathetic activation has
been reported, compared to healthy controls 1. An increase in parasympathetic nervous activity may
indicate pain relief 9, a finding which suggests the use of HRV as more objective measurement of pain
intensity and as a possible biomarker for pain.

The highly standardized acquisition and analysis of HRV parameters represent key strengths of this
report. Inter-beat intervals from both ECG and Polar® were exported as text file and analysed with an
identical software package and preprocessing protocol. Previous studies underlined the primordial
importance of selecting suitable software packages for HRV analysis as parameters derived from
different software packages may not be comparable 26. As mentioned in the study of Giles et al. (2016),
several critical differences between the Polar® V800 and ECG devices exist, among which the use of an
elasticated chest strap versus fixed sensor locations, transmission of the data through Bluetooth signal
in the V800 versus wired electrodes in the ECG and differences in the peak detection algorithms 26. Yet
in spite of these dissimilarities, the obtained HRV parameters, relevant for assessment of therapeutic
response strongly concur. No components of tonic stimulation, due to SCS, were detected in the ECG
data.

Both devices revealed a significant increase in inter-beat intervals and a significant decrease in HR
when SCS was switched on. The reduced HRV and increased HR when SCS was switched off are
comparable to the results found in chronic low back pain patients, where those results were allocated
to an autonomic dysregulation 4. In the frequency domain, absolute and normalized HF power
increased while normalized LF power decreased when SCS was switched on. Use of either device
confirms dominant sympathetic activity when SCS is switched off, with an “under-utilization” of the parasympathetic system. When SCS is switched on, the dominance of the sympathetic system diminishes and the parasympathetic system becomes more influential. The results in the time-frequency domain are similar to those found in the frequency domain when using the ECG, however HRV parameters derived from the Polar® only found a statistically significant treatment response in absolute HF power and not in normalized power. The normalization process to obtain normalized power spectra is performed to reduce individual variability, which is still present when expressing the results of a power spectrum in absolute power. This might suggest that the decision to express the results of a power spectrum calculation in the time-frequency domain as absolute or normalized values is important to be able to evaluate the treatment response of SCS with the Polar®. Nevertheless, there was a trend in normalized LF and normalized HF to reveal the same results with the Polar® as with the ECG (p=0.08). As the name itself explains, time frequency analysis allow the simultaneous assessment of both time and frequency information while frequency analysis purely focus on the periodic oscillations decomposed at different frequencies and amplitudes. As other studies often only report findings from the time, frequency and nonlinear domain, this inconsistency in findings in the time-frequency domain should be further explored in future studies. Combining the results of the three domains, we conclude that the Polar® V800 is able to detect similar therapeutic responses as the 2-lead ECG in patients with FBSS. Caution may be needed when analyzing the less frequently used time-frequency domain.

In the time domain, IBI and HR are important parameters for measuring the treatment response of SCS. Both parameters have an excellent ICC (HRV: 0.9 HR: 0.9), excellent Cronbach’s α (0.95) and small effect size. This result is in line with the excellent ICC of 0.98 that was obtained with Polar® S810 in a previous study. RMSSD and SDNN were not reliable when recorded with a Polar® V800 compared to the ECG. Previously, a sex difference was found for SDNN with good agreement between a Polar® RS800 and an ECG for males, but unacceptable agreement between both devices for females. In this
study, 73% of the participants were females, which could have influenced the results of SDNN. In the more robust frequency domain, good to excellent ICC values and excellent internal consistency were revealed for parameters that may detect a response to SCS. In healthy volunteers, similar positive results were found with a Polar® V800 in supine position 26.

In this study, we evaluate the reliability of a readily commercially available and wearable heart rate monitor in a healthcare setting. Previous studies confirmed the reliability of commercially available wearables for analysis of HRV in healthy persons, but these findings may not be extrapolated to patient populations. We show that the Polar® V800 device can be used to detect pre-to post treatment changes to SCS with similar results as a gold standard. This opens up more opportunities for HRV analysis in various settings, among which for instance ambulatory care. Future expansion of this concept could entail the use of wireless biosensors for continuous remote monitoring such as the VitalPatch® that is able to register RR time series, together with breathing rates, skin temperature and functional positions based on an accelerometer 47. These wireless biosensors could be the next step in monitoring therapeutic responses in chronic pain patients in a home-setting and could perhaps prove to be more reliable parameters for pain intensity than current approaches. Additionally, the use of biosensors in ambulatory or home-settings could also be implemented as therapeutics based on biofeedback, which holds the promise to improve outcome for patients with chronic back pain 48.

**Conclusion**

Similar treatment responses were observed when assessing key HRV parameters registered using the Polar® V800 and the eMotion 2-lead ECG. This indicated that the Polar® V800 heart rate monitor represents a reliable and user-friendly tool for the detection of pre-to post SCS responses in patients with FBSS and will more easily allow long-term registrations in ambulatory settings.
Acknowledgments

The authors thank Ine Van de Weghe, Stefano Aguirre, Rosalia van Zundert, Kenneth De Becker and Kim Voogt for their help with the data collection.

References


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<th>ECG</th>
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<tr>
<td></td>
<td>SCS off</td>
<td>SCS on</td>
<td>Test statistic + P value</td>
<td>SCS off</td>
</tr>
<tr>
<td><strong>Time domain</strong></td>
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<tr>
<td>Mean IBI (ms)</td>
<td>913.8 (852-996.5)</td>
<td>976 (854.9-1095.4)</td>
<td>V=32 P=0.001*</td>
<td>922.7 (878.3-1024.1)</td>
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<tr>
<td>HR (bpm)</td>
<td>65.9 (60.33-70.88)</td>
<td>61.55 (55.15-70.33)</td>
<td>V=222 P=0.001*</td>
<td>64.8 (58.92-70.03)</td>
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<td>SDNN (ms)</td>
<td>41.5 (29.4-63.23)</td>
<td>39.15 (27.12-51.02)</td>
<td>V=137 P=0.75</td>
<td>47.85 (31.5-101.78)</td>
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<td>RMSSD (ms)</td>
<td>27.95 (15.03-47.62)</td>
<td>30.75 (16.88-51)</td>
<td>V=107 P=0.54</td>
<td>45.7 (19.6-89.88)</td>
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<td><strong>Frequency domain</strong></td>
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<tr>
<td>Absolute LF (ms²)</td>
<td>99.39 (62.40-260.76)</td>
<td>98 (54.36-244.21)</td>
<td>V=140 P=0.40</td>
<td>127.59 (48.57-289.17)</td>
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<tr>
<td>Absolute HF (ms²)</td>
<td>66.48 (33.67-163.22)</td>
<td>114.17 (27.5-285.21)</td>
<td>V=49 P=0.01*</td>
<td>85.81 (46.15-194.79)</td>
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<td>Normalized LF (n.u.)</td>
<td>0.60 ± 0.20</td>
<td>0.51 ± 0.25</td>
<td>T=2.5 P=0.02*</td>
<td>0.61 (0.18)</td>
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<td>Normalized HF (n.u.)</td>
<td>0.41 ± 0.20</td>
<td>0.49 ± 0.25</td>
<td>T=2.5 P=0.02*</td>
<td>0.39 (0.18)</td>
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<td>LF/HF</td>
<td>1.48 (1.03-2.59)</td>
<td>1.10 (0.52-2.39)</td>
<td>V=174 P=0.13</td>
<td>1.45 (0.97-2.98)</td>
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<td><strong>Time-frequency domain</strong></td>
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<tr>
<td>Parameter</td>
<td>SCS On (ms²)</td>
<td>SCS Off (ms²)</td>
<td>V</td>
<td>P</td>
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<tr>
<td>Absolute LF ms²</td>
<td>110.84 (53.60-282.58)</td>
<td>120.36 (51.98-215.29)</td>
<td>V=141</td>
<td>P=0.66</td>
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<td>Absolute HF ms²</td>
<td>68.99 (31.86-164.94)</td>
<td>120.43 (26.07-258.32)</td>
<td>V=46</td>
<td>P=0.007*</td>
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<td>Normalized LF n.u.</td>
<td>0.61 ± 0.20</td>
<td>0.52 ± 0.24</td>
<td>T=3.04</td>
<td>P=0.006*</td>
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<tr>
<td>Normalized HF n.u.</td>
<td>0.39 ± 0.20</td>
<td>0.50 ± 0.24</td>
<td>T=-3.04</td>
<td>P=0.006*</td>
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<td>1.46 (0.91-3.28)</td>
<td>1.08 (0.40-1.87)</td>
<td>V=190</td>
<td>P=0.04*</td>
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Table 1. Overview of the HRV parameters during SCS on and off states with recordings from the Polar V800 and ECG. *: significant result. Abbreviations.

<table>
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<tr>
<th></th>
<th>Correlation</th>
<th>ICC (95% CI)</th>
<th>Chronbach’s α</th>
<th>Bias (LOA)</th>
<th>Effect size</th>
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<td><strong>Time domain</strong></td>
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<tr>
<td>Mean IBI (ms)</td>
<td>rs=0.896, p&lt;0.001</td>
<td>0.90 (0.82 to 0.94)</td>
<td>0.95</td>
<td>-9.68 (-151.67;132.32)</td>
<td>0.1 (small)</td>
</tr>
<tr>
<td>HR (bpm)</td>
<td>rs=0.894, p&lt;0.001</td>
<td>0.91 (0.85-0.95)</td>
<td>0.95</td>
<td>0.64 (-10.06;11.35)</td>
<td>0.1 (small)</td>
</tr>
<tr>
<td>SDNN (ms)</td>
<td>rs=0.439, p=0.003</td>
<td>0.04 (-0.25 to 0.33)</td>
<td>0.086</td>
<td>-41.71 (-413.63;330.21)</td>
<td>0.2 (small)</td>
</tr>
<tr>
<td>RMSSD (ms)</td>
<td>rs=0.514, p&lt;0.001</td>
<td>0.06 (-0.24 to 0.34)</td>
<td>0.11</td>
<td>-53.75 (-390.37;282.87)</td>
<td>0.3 (moderate)</td>
</tr>
<tr>
<td><strong>Frequency domain</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absolute LF (ms²)</td>
<td>rs=0.685, p&lt;0.001</td>
<td>0.02 (-0.28 to 0.31)</td>
<td>0.04</td>
<td>-213.89 (-2196.83;1769.05)</td>
<td>0.2 (small)</td>
</tr>
<tr>
<td>Absolute HF (ms²)</td>
<td>rs=0.970, p&lt;0.001</td>
<td>0.98 (0.97 to 0.99)</td>
<td>0.99</td>
<td>-18.86 (-163.81;126.08)</td>
<td>0.2 (small)</td>
</tr>
<tr>
<td>Normalized LF (n.u.)</td>
<td>r=0.824, p&lt;0.001</td>
<td>0.82 (0.7 to 0.9)</td>
<td>0.9</td>
<td>-0.02 (-0.28;0.24)</td>
<td>0.2 (small)</td>
</tr>
<tr>
<td>Normalized HF (n.u.)</td>
<td>r=0.824, p&lt;0.001</td>
<td>0.82 (0.7 to 0.9)</td>
<td>0.9</td>
<td>0.02 (-0.24;0.28)</td>
<td>0.2 (small)</td>
</tr>
<tr>
<td>LF/HF</td>
<td>rs=0.812, p&lt;0.001</td>
<td>0.12 (-0.18 to 0.4)</td>
<td>0.2</td>
<td>0.09 (-16.10;16.28)</td>
<td>0.01 (small)</td>
</tr>
<tr>
<td><strong>Time-frequency domain</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absolute LF (ms²)</td>
<td>rs=0.547, p&lt;0.001</td>
<td>0.00 (-0.29 to 0.29)</td>
<td>-0.028</td>
<td>-657.36 (-8108.67;6793.96)</td>
<td>0.2 (small)</td>
</tr>
<tr>
<td>Parameter</td>
<td>rs</td>
<td>p</td>
<td>Lower CI</td>
<td>Upper CI</td>
<td>Effect Size</td>
</tr>
<tr>
<td>---------------------------</td>
<td>--------</td>
<td>--------</td>
<td>----------</td>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Absolute HF (ms²)</td>
<td>0.968</td>
<td>&lt;0.001</td>
<td>0.99 (0.99 to 1)</td>
<td>1</td>
<td>-10.21 (-86.44;66.01)</td>
</tr>
<tr>
<td>Normalized LF (n.u.)</td>
<td>0.691</td>
<td>&lt;0.001</td>
<td>0.69 (0.5 to 0.82)</td>
<td>0.82</td>
<td>-0.06 (-0.40;0.28)</td>
</tr>
<tr>
<td>Normalized HF (n.u.)</td>
<td>0.691</td>
<td>&lt;0.001</td>
<td>0.69 (0.5 to 0.82)</td>
<td>0.82</td>
<td>0.06 (-0.28;0.40)</td>
</tr>
<tr>
<td>LF/HF</td>
<td>0.711</td>
<td>&lt;0.001</td>
<td>0.00 (-0.29 to 0.29)</td>
<td>-0.096</td>
<td>-1.858 (-77.08;73.36)</td>
</tr>
</tbody>
</table>

**Table 2.** Intra-class correlation coefficients, Cronbach’s alpha, bias and effect sizes in supine position between HRV parameters obtained from the Polar V800 and ECG. Abbreviations. Bpm: beats per minute, HF: high frequency, HR: heart rate, IBI: inter beat interval, LF: low frequency, LF/HF: ratio of LF to HF, n.u.: normalized unit, LOA: limits of agreement, r: Pearson correlation coefficient, RMSSD: root-mean-square of successive differences of normal-to-normal heart beat interval, rs: Spearman correlation coefficient, SDNN: standard deviation of normal-to-normal R-R intervals.
**Figures**

**Figure 1.** VAS scores for back and leg pain during off and on states of SCS. Significant differences were found for both back and leg pain. Abbreviations. VAS: Visual Analogue Scale.

**Figure 2.** Boxplots of HRV parameters during off and on states of SCS for mean heart rate variability (A), heart rate (B), absolute high frequency (C), normalized low frequency (D), normalized high frequency (E) and absolute high frequency from the time-frequency domain (F). Measurements with the ECG are coloured in blue, measurements with the Polar in green.

**Figure 3.** Bland-Altman plots showing the agreement between Polar V800 and ECG for mean heart rate variability (A), heart rate (B), absolute high frequency (C), normalized low frequency (D), normalized high frequency (E) and absolute high frequency from the time-frequency domain (F). The y-axis represents the difference between the HRV parameter from the ECG minus the HRV parameter measured with the Polar. The dotted line in the middle represents the mean difference (bias). The two other dotted lines represents the upper and lower limits of agreement.