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ORIGINAL ARTICLE

Reliability of a portable device for the detection of sleep bruxism

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Abstract
Objectives The aim of the study was to assess the repeatability in detecting sleep bruxism (SB) episodes by combined surface electromyography and heart rate (HR) signals recorded by a compact portable device (Bruxoff®). SB episodes are preceded by a sudden HR change. Thus, HR detection increases the precision of automatic detection of SB.
Materials and methods Ten healthy subjects (five women and five men; 30.2±11.02 years) were selected for the study. Rhythmic masseter muscle activities, constituting the basic pattern of SB, were detected during three nights of recording during three different weeks with the Bruxoff device.
Results The two-way ANOVA was not significant for SB episodes per night, SB episodes per hour, and heart frequency: no significant differences were observed during the three different nights of recording for each of the abovementioned variables ($P>0.05$). The intraclass correlation coefficient showed a good reproducibility for SB episodes per night (69 %), SB per hour (74 %), and heart frequency (82 %). A poor reproducibility was revealed for the number of masseter contractions (53 %). The Pearson analysis showed the absence of a significant correlation between the number of masseter contractions per night and the number of SB episodes per night ($r=-0.02$, $P=0.91$).
Conclusions The Bruxoff device showed a good reproducibility of measurements of sleep bruxism episodes over time.
Clinical relevance These findings are important in the light of the need for simple and reliable portable devices for the diagnosis of SB both in the clinical and research settings.

Keywords Sleep bruxism · Surface electromyography · Masseter muscle · Heart rate · Rhythmic masticatory muscles activity

Introduction

The current widely accepted bruxism definition is the one recently proposed by Lobbezoo et al. [1] of bruxism as a repetitive jaw-muscle activity characterized by clenching or grinding of the teeth and/or by bracing or thrusting of the mandible having two possible circadian manifestation during sleep (sleeping bruxism, SB) and wakefulness (awake bruxism, AB).

Sleep bruxism is a centrally mediated disorder having a multifactorial etiology [2]. Considering that bruxism can seriously affect life quality through dental and orofacial problems, an early diagnosis is essential. Clinical diagnosis of SB is based upon the diagnostic criteria proposed by AASM [3] even if the validation of these diagnostic criteria is still lacking.

While full-night polysomnography (PSG) with audio-video recording remains the gold standard for SB diagnosis [4], several home electromyographic (EMG) recording devices have been introduced in order to detect SB episodes [5–9]. They have the advantage of being much simpler and less expensive than PSG. Moreover, the screening in the natural home environment helps the collection of more representative data than sleep laboratory recording. Due to the simplicity of diagnostic procedure, multiple night recording can be performed. Last but not least, most bruxers do not undergo overnight polysomnographic recordings, leading to underdiagnosed and undertreated state of the disorder [10]. However, the reliability of most portable devices has not been

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validated yet [4], and rhythmic masticatory muscle activity (RMMA), constituting the basic pattern of SB [2], are observed in 60 % of the general adult population as a physiological activity of the masticatory muscles during sleep [11]. Thus, portable devices measuring only the surface electromyography (sEMG) activity tend to overestimate the SB episodes [5].

Recent studies [12] demonstrated that SB is part of an autonomic nervous system activation in which several autonomic manifestations occur before the SB-RMMA; in particular, an increase of the heart frequency immediately precedes the SB episode. Thus, the combined recordings of sEMG activity from the masseter muscle and heart rate signals could represent a good solution to improve the reliability of portable devices for the SB diagnosis [5, 13, Castroflorio et al. (Detection of sleep bruxism: comparison between an electromyographic and electrocardiographic portable holter and polysomnography, in press)].

Bruxoff (Bruxoff ®, Spes Medica, Battipaglia, Italy) is a three-channels portable device used to acquire surface EMG of both masseter muscles and of heart frequency. In previous studies, we have demonstrated the validity of Bruxoff as a screening portable device for subjects referring symptoms of SB [5, Castroflorio et al. (Detection of sleep bruxism: comparison between an electromyographic and electrocardiographic portable holter and polysomnography, in press)]. A recent study in which the Bruxoff measurements were compared to the PSG measurements demonstrated a sensitivity and specificity of 91.6 and 84.6 %, respectively [Castroflorio et al. (Detection of sleep bruxism: comparison between an electromyographic and electrocardiographic portable holter and polysomnography, in press)]. Lavigne et al. [14] investigated the variability in SB oromotor activity over a period of between 2 months and 7.5 years using audio-polysomnographic recording. They found that SB diagnosis remains relatively constant over time in moderate to severe sleep bruxers and that individual variability could be important in some SB patients. However, some methodological features related to the sEMG detection could be associated to the variation of the SB episodes observed in this study [15].

The use of concentric electrodes (Code®, Spes Medica, Battipaglia, Italy) could represent a methodological solution in order to improve the quality of the detected sEMG signals from the masseter muscles with portable devices. The geometry of these electrodes permits an easy application from the patients since they are invariant to rotations and reduces the cross talk phenomena due to their Laplacian design [16].

Considering those previous studies, we tested the validity of Bruxoff device through the assessment of repeatability of surface EMG and heart frequency measurements in a sample of healthy subjects. The following clinical question was thus addressed in this study: is the SB episodes detection obtained with this new device reliable and reproducible?

Material and methods

Subjects

The study was performed on ten subjects (five men and five women, mean age 30.5±11.6 years) selected among patients referring to the Oral Physiology Unit of the Lingotto Dental School of the University of Torino. All the subjects were positive for SB diagnosis according to the clinical diagnostic criteria for SB (AASM, 2005). The positive criteria were (1) awareness of sleep bruxism and (2) fatigue and/or discomfort of the jaw muscles on awakening. Furthermore, all subjects were screened with a comprehensive portable polysomnography (type II device) in order to exclude other sleep disorders [Castroflorio et al. (Detection of sleep bruxism: comparison between an electromyographic and electrocardiographic portable holter and polysomnography, in press)]. Exclusion criteria were (1) presence of prosthodontic rehabilitations, (2) missing teeth, (3) periodontal disease, (4) according to Rompré et al. [17], group II and/or group III TMDs (discal and/or articular TMDs) as a primary complaint to facilitate the clinical selection of candidate bruxer subjects according to the diagnostic criteria for SB, and (5) a medical history of neurological disorders, mental disorders, or sleep disorders (e.g., periodic leg movements, and insomnia). All the subjects were unmedicated at the time of recording and were not under the effect of alcohol, nicotine, or caffeine.

The procedures were approved by the Lingotto Dental School ethic committee (#20120098). All individuals gave their informed consent in accordance with the Helsinki Declaration and understood that they were free to withdraw from the experiment at any time.

Recordings

A portable device (Bruxoff ®, Spes Medica, Battipaglia, Italy) with three channels was used for recording. Two channels were used to acquire sEMG bilaterally from the masseter, and the third channel was used to acquire the heart frequency (HF). The three signals were sampled at 800 Hz with 8 bit resolution. The data were stored on a MicroSD card as a binary file. The surface EMG channels were filtered between 10 and 400 Hz with gain 4,300. The ECG channel was filtered between 15 and 160 Hz with gain 700. Surface EMGs from the masseter muscle of both sides were detected with disposable bipolar concentric electrodes (Code®, Spes Medica, Battipaglia, Italy), with a radius of 16 mm and with detection site made of AgCl (Fig. 1).

The concentric-ring systems of the Code electrodes show higher spatial selectivity with respect to the traditional detection systems and reduce the problem of electrode location since they are invariant to rotations and reducing EMG cross talk [16].

Fig. 1 The Bruxoff® and the CoDe® (Spes Medica, Genova, Italy) electrode used in this study for the detection of myoeletric signals from the masseter muscles. The concentric-ring systems of the Code electrodes show higher spatial selectivity with respect to the traditional detection systems and reduce the problem of electrode location since they are invariant to rotations and reducing EMG cross talk. At the *top*, a schematic representation of the electrode location over the masseter muscle is shown. *Black line* gonial angle-cantus line used as anatomical landmark

The heart frequency was detected with a disposable bipolar electrode located on the left side of the thorax just below the pectoral muscles [Castroflorio et al. (Detection of sleep bruxism: comparison between an electromyographic and electrocardiographic portable holter and polysomnography, in press)]. EMG and HF signals were recorded during three different nights in 3 weeks (at least 4 h of sleep per night). The subjects used the device and mounted the electrodes at their homes without technical assistance after prior training. They were provided with written instructions and a night-time telephone number to call in the event of difficulties.

Masseteric EMG and sleep bruxism scoring

At the beginning of the recording, the subjects were asked to perform three maximum voluntary clenching (MVC) lasting 3 s each and separated by 10 s of rest. The greatest of the MVC measures was used for normalizing the EMG values as a percent of MVC.

Scoring on the Bruxoff recordings was automatically performed by a dedicated software (Bruxmeter ®, OT Biolettonica, Torino, Italy). The software is able to classify a SB episode if the sEMG burst is greater than 10 % MVC and if it immediately follows (1–5 s interval) a heart rate increase of 20 % with respect to the baseline accordingly to the existing PSG literature [4].

Masseter EMG that bursts with duration exceeding 0.25 s was selected for oromotor activity scoring [2].

Cutoff value of amplitude was set at 10 % of the awake MVC. Thus, oromotor episodes separated by 3 s intervals were recognized as RMMA if they corresponded to one of the three following patterns: phasic (three or more EMG bursts each lasting 0.25–2 s), tonic (one EMG burst >2 s), or mixed (both burst types) episodes [2].

Statistical analysis

Data are reported as mean ± standard deviation (SD). Statistical analysis was performed using the software Statistical Package for the Social Sciences (SPSS) 15.0

Table 1 Descriptive statistics of bruxism episodes per night (SB/n), masseter contractions per night (MC/n), and bruxism episodes per hour (SB/h) recorded during the experimental sessions

Subject	Gender	Age	Night	SB/n	MC/n	SB/h	Sleep, min
A	M	24	1	32	75	4.7	430.80
			2	42	98	5.3	482.40
			3	45	108	6.9	452.40
B	F	26	1	47	136	6.3	445.80
			2	66	281	9	444.60
			3	39	249	7.4	444.60
C	M	33	1	12	53	2.1	328.80
			2	11	84	3	267.00
			3	13	110	3.2	252.60
D	M	26	1	25	64	5	306.00
			2	30	84	6.4	322.80
			3	29	80	6.2	330.60
E	M	59	1	6	90	1.3	300.00
			2	14	79	1.9	492.00
			3	20	120	2.6	508.20
F	M	24	1	27	124	3.5	485.40
			2	27	174	4.5	443.40
			3	26	50	3.6	436.80
G	F	23	1	22	202	2.2	600.00
			2	31	251	3.2	573.60
			3	27	305	3.1	512.40
H	F	22	1	51	148	5.9	510.60
			2	37	96	6.3	335.40
			3	21	83	5.4	334.20
I	F	42	1	13	413	2	390.00
			2	21	341	3	426.00
			3	13	713	2.6	312.00
L	F	26	1	34	565	8.1	431.40
			2	28	930	4	424.80
			3	38	161	4.5	420.00
	mean	30.5		28.10	213.51	4.43	414.26
	SD	11.66		13.51	206.25	2.01	88.82

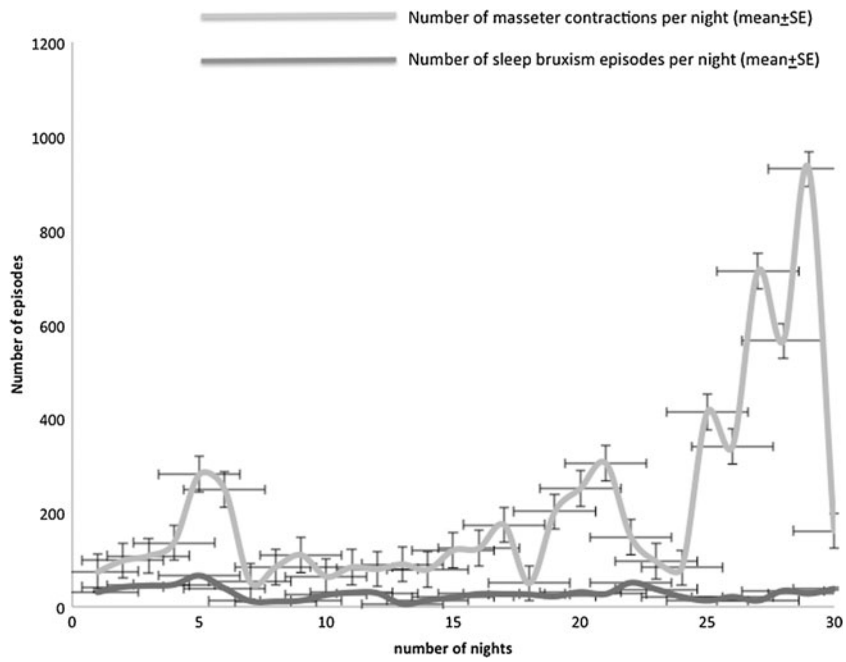

Fig. 2 Number of SB episodes and number of masseter contractions (mean and SE) during the 30 nights considered in the study. A bruxism diagnosis based only on the sEMG analysis tends to overestimate SB

(SPSS Inc., Chicago, IL, USA). The sample passed the Kolmogorov-Smirnov normality test ($P>0.10$). Two-way repeated measures analysis of variance (ANOVA) was applied to test the effect of time on the performed measurements (number of SB episodes per night, number of SB episodes per hour, number of masseter contractions per night, and heart frequency) ($P<0.0001$, CI 95 %), followed by a Bonferroni post hoc test when necessary. The Pearson's correlation coefficient (CI 95 %, α 0,05) was applied in order to test the correlation between the number of masseter contractions and the number of SB episodes to verify the effect of the joint detection of masseter sEMG and heart frequency on the diagnostic ability of the portable devices.

Reproducibility of SB episodes per night, SB episodes per hour, and number of masseter contractions per night was assessed by the intraclass correlation coefficient (ICC). ICC provides the percentage of the total variance of the measures that can be attributed to the variability between subjects. The remaining percentage of variance is due to repeated trials. ICC values higher than 80 % indicate excellent reproducibility, whereas values below 60 % reflect poor reproducibility. ICC between 60 and 80 % is considered good reproducibility [18].

Results

The number of SB episodes per night was on average (mean ± SD) 28.23±13.51, while every night lasted on average 415.54±89.47 min. Thus, the number of SB episodes per hour was on average 4.44±2.01, with a mean heart frequency of 61.93±7.98 bpm. The total number of masseter contractions per night was 208.9±206.25. (Table 1) (Fig. 2).

The two-way ANOVA was not significant for SB episodes per night, SB episodes per hour, and heart frequency; no significant differences were observed during the three different nights of recording for each of the abovementioned variables ($P>0.05$). The ICC showed a good reproducibility for SB episodes per night (69 %) and SB per hour. A poor reproducibility was revealed for the number of masseter contractions (53 %) (Figs. 3, 4, and 5).

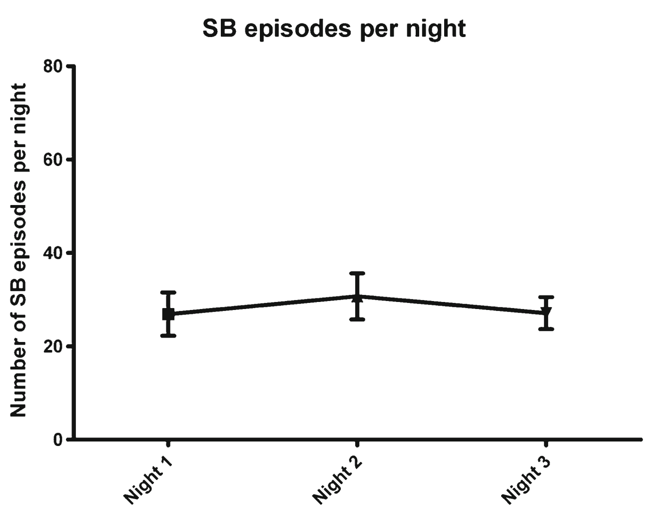

Fig. 3 Mean and SE of the number of SB episodes per each of the three nights recorded. The ANOVA analysis was negative ($P>0.05$). The ICC revealed a good reproducibility of the variable over time (69 %)

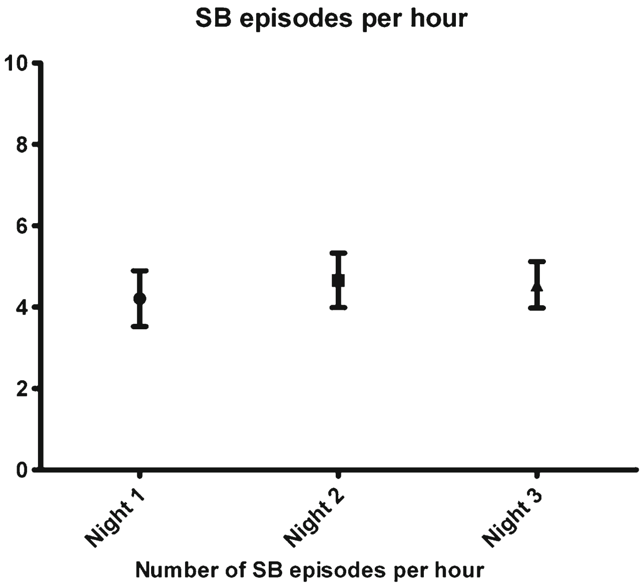

Fig. 4 Mean and SE of the number of SB episodes per hour recorded during the three nights. The ANOVA analysis was negative ($P>0.05$). The ICC revealed a good reproducibility of the variable over time (74 %)

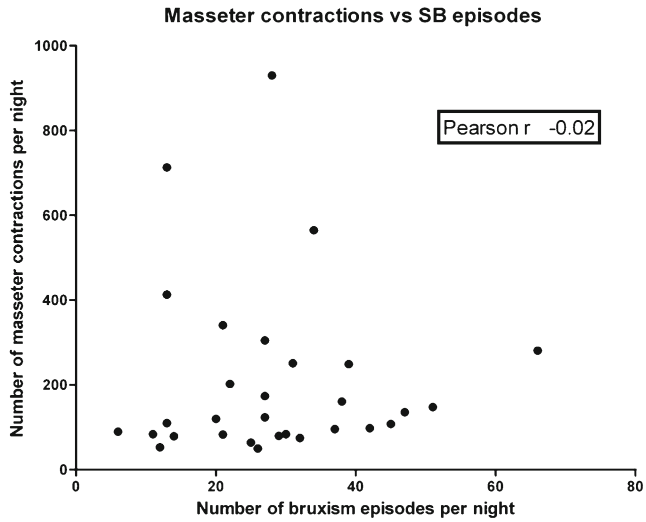

Fig. 6 The Pearson analysis showed the absence of a significant correlation between the number of masseter contractions per night and the number of SB episodes per night ($r=-0.02$, $P=0.91$). A bruxism diagnosis based only on the sEMG analysis tends to overestimate SB

The Pearson analysis showed the absence of a significant correlation between the number of masseter contractions per night and the number of SB episodes per night ($r=-0.02$, $P=0.91$) (Fig. 6). The same result was obtained comparing the number of masseter contraction per hour and the number of SB episodes per hour ($r=-0.33$, $P=0.13$) (Fig. 7).

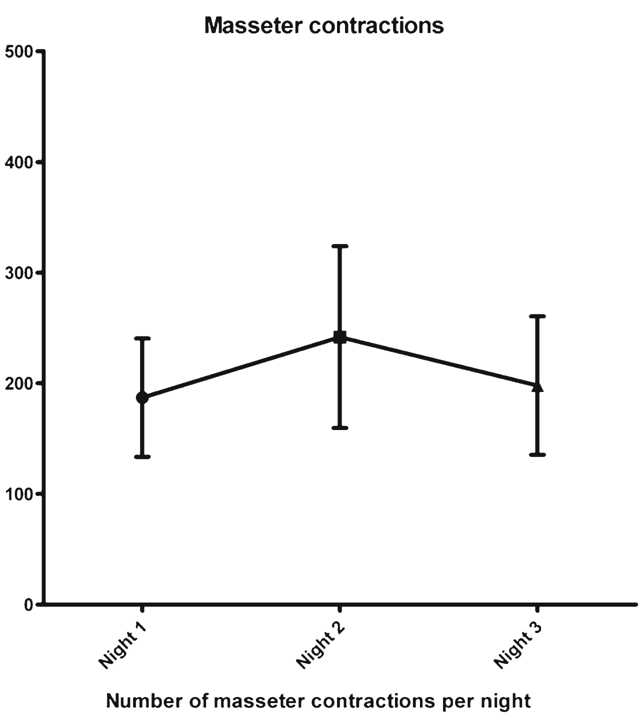

Fig. 5 Mean and SE of the number of masseter contractions recorded during the three nights. Although the ANOVA was negative ($P>0.05$), the ICC revealed a poor reproducibility of the variable over time (53 %)

Discussion

This study demonstrated the good reproducibility of the Bruxoff measurements during three different nights in three different weeks. ICC showed a good reproducibility for the number of SB episodes per night and SB episodes per hour.

Several portable diagnostic tools have been developed to record masseter and/or temporalis EMG activity during sleep in the attempt to overcome PSG high costs and time consumption. However, the reliability of most portable devices has not been validated yet [4]. RMMA are observed in the 60 % of the general adult population as a physiological activity of the masticatory muscles during sleep [11]. Thus, portable devices

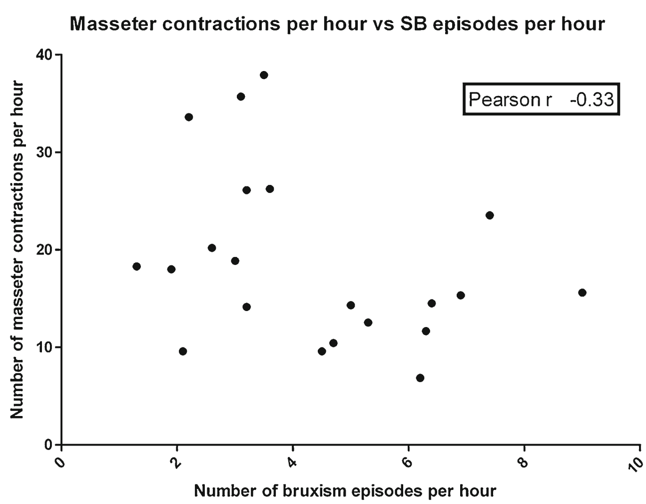

Fig. 7 The Pearson analysis showed the absence of a significant correlation between the number of masseter contraction per hour and the number of SB episodes per hour ($r=-0.33$, $P=0.13$)

measuring only the sEMG activity tend to overestimate the SB episodes diagnosis [5]. Our results support this conclusion: a very poor, and not significant at all, correlation between the number of masseter contractions and the number of SB episodes was observed.

Recent studies reported a sudden shift in autonomic cardiac and respiratory activity as well as specific brain activation immediately before the SB episode [12]. Thus, the joint analysis of sEMG activity from the masseter muscle and heart rate could represent a good solution to improve the reliability of portable devices for SB diagnosis [5, 13, Castroflorio et al. (Detection of sleep bruxism: comparison between an electromyographic and electrocardiographic portable holter and polysomnography, in press)].

The term reliability in the clinical and research settings is properly used when a test measurement or device produces the same results with different investigators, observers, or administration of the test over time. If repeated use of the same measurement tool on the same sample produces the same consistent results, the measurement is considered reliable. Lavigne et al. [14] demonstrated that in moderate to severe SB subject, the SB diagnosis remain constant over time. Thus, the reliability of a portable device designed to support the SB diagnosis could be measured. However, very few studies were conducted in the past on the reliability of the available portable instruments. Rivera-Morales and McCall [19] tested a portable EMG unit modified to be triggered only in correspondence of a clenching activity. Their results revealed a good reproducibility of the device during two different trials in a single session with electrode repositioning. Minakuchi et al. [6] tested a self-contained electromyographic (EMG) detector/analyzer (D/A) device for the detection of jaw muscle activity events above threshold. A substantial night to night variability was clearly observed on ten healthy subjects, confirming the fact that measuring only the sEMG variable to diagnose SB could lead to an overestimation of SB episodes. Our results revealed a poor reproducibility of the number of masseter contractions. This variability should be considered when evaluating the specificity and sensitivity of devices detecting only sEMG signals. The positive predictive value of the Bitestrip device was 59–100 %, with a sensitivity of 71–84.2 % [7, 8] while EMG-telemetry recordings had an unacceptable rate of false-positive findings (76.9 %) counterbalanced by an almost perfect sensitivity (98.8 %) [9]. Those contrasting results are related to the inability of those devices in differentiating RMMA from other oromotor activities. A recent work by Mizumori et al. [13] supported the use of a joint analysis of EMG and ECG signals to improve the diagnostic accuracy of a portable system according to our previous studies [5, Castroflorio et al. (Detection of sleep bruxism: comparison between an electromyographic and electrocardiographic portable holter and polysomnography, in press)]. However, their data were not compared to PSG, and thus, conclusions regarding specificity and sensitivity cannot take in account. Considering the PSG data as the gold standard and thus evaluating the contemporaneity of SB events between PSG and Bruxoff, the sensitivity and specificity of Bruxoff measurements were 91.6 and 84.6 %, respectively [Castroflorio et al. (Detection of sleep bruxism: comparison between an electromyographic and electrocardiographic portable holter and polysomnography, in press)].

In addition, the present study demonstrated that the investigated device is reliable and measurement of SB episodes is reproducible over a limited period of time (3 weeks). In a clinical perspective, considering that the clinical diagnostic criteria for SB have not been validated yet, Bruxoff could enhance the diagnostic performance aiming a more focused treatment and a more precise identification of probable bruxers, especially in those cases in which complex rehabilitations (e.g., implants) have to be planned.

Further studies are necessary on a greater sample and over longer period of time to confirm the excellent results obtained with this study. Notwithstanding that the portable sEMG/ECG device under assessment in this investigation proved to be reliable for measuring what is purported to measure, viz., oromotor activity during sleep. These findings are important in the light of the need for simple and reliable portable devices for the diagnosis of SB both in the clinical and research settings.

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Conflict of interest The authors do not have any financial relation with Spes Medica and/or OTBioelettronica. There is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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