

UNIVERSIDADE DE SÃO PAULO  
FACULDADE DE ODONTOLOGIA DE BAURU

JULIANA STUGINSKI BARBOSA

**Diagnostic validity of the use of questionnaires, clinical  
examination and a portable single-channel electromyography  
device for Sleep Bruxism**

**Validação do uso de questionários, exame físico e aparelho portátil  
de eletromiografia para o diagnóstico do Bruxismo do Sono**

BAURU  
2015



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Tese constituída por artigos apresentada a Faculdade de Odontologia de Bauru da Universidade de São Paulo para obtenção do título de Doutor em Ciências no programa de Ciências Odontológicas Aplicadas, área de concentração Reabilitação Oral.

Orientador: Prof. Dr. Paulo César Rodrigues Conti

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*Não sou nada sem vocês.*

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*“A sabedoria é filha da experiência.”*

***Leonardo da Vinci***

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## ABSTRACT

### **Diagnostic validity of the use of questionnaires, clinical examination and a portable single-channel electromyography device for Sleep Bruxism**

The presented study intended to compare two methods for assessing Sleep Bruxism (SB): International Classification of Sleep Disorders diagnostic criteria (ICSD-3) and a portable single-channel electromyography (EMG) device (Grindcare) with gold standard polysomnographic (PSG) examination. The comparison with PSG was used to determine an appropriate cut-off value and the number of nights of sleep with the Grindcare device necessary for a valid/reliable SB diagnosis. Twenty consecutive post-graduate students and staff at Bauru School of Dentistry composed the sample. Each participant underwent interview, clinical assessment, the Grindcare for five consecutive nights and a PSG exam. The discrimination between bruxers and non-bruxers was based only on the PSG analysis. Data about electromyography per hour with Grindcare (EMG/h) and PSG (bursts/h) were scored. The validity of ICSD-3 criteria and the Grindcare device were assessed by using receiver operating characteristics (ROC) curve analysis (AUC), likelihood ratios (LR), the diagnostic odds ratio (DOR) and Bland-Altman analysis. The ICSD-3 diagnostic criteria items for SB had fair to moderate concordance with PSG diagnosis, with AUC ranging from 0.55 to 0.75. The best value of agreement was obtained by the report of SB more than once a week associated with a report of transient morning jaw muscle pain or fatigue with a moderate, but significant agreement with the PSG SB diagnosis (AUC=0.75) with 90% specificity, positive LR=6 and DOR=13.5. When the frequency of self-reported SB increased to more than 4 times per week, the combination of this finding with tooth wear had also high values of agreement with PSG SB diagnosis (AUC= 0.75, LR=6, DOR=13.6). Bland-Altman analysis of the EMG bursts/h showed positive agreement between Grindcare device and PSG exam. The ROC analyses also showed that using a minimum of 18 EMG/h for 3 nights and 19 EMG/h for 5 nights in Grindcare as cut-offs resulted in a 90% specificity and positive LR equal to 5. Since there is considerable heterogeneity in the results, the application of ICSD-3 for SB clinical diagnosis may be limited. Moreover, the Grindcare is able to predict SB diagnosed by PSG with a reasonable accuracy, when used for 3 or 5 consecutive nights, and it may be a valid choice in clinical practice for SB assessment.

Key words: Sleep bruxism. Diagnosis. Polysomnography. Sleep disorders. Tooth Wear. Facial pain.

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## RESUMO

### **Validação do uso de questionários, exame físico e aparelho portátil de eletromiografia para o diagnóstico do Bruxismo do Sono**

O presente trabalho comparou dois métodos de diagnóstico para Bruxismo do Sono (BS): critérios de diagnóstico da Classificação Internacional de Distúrbios do Sono (ICSD-3) e um aparelho portátil com um canal de eletromiografia (EMG) (Grindcare) com o exame padrão ouro, polissonografia (PSG). A comparação com a PSG foi utilizada para determinar valores de corte apropriados e o número de noites necessárias para diagnóstico do BS válido e confiável com o Grindcare. Vinte estudantes da pós graduação e funcionários da Faculdade de Odontologia de Bauru participaram da amostra. Cada participante se submeteu a entrevista, exame físico, uso do Grindcare por cinco noites consecutivas e exame de PSG. A discriminação entre participantes com e sem bruxismo foi baseado somente na análise da PSG. Dados sobre EMG por hora de uso do Grindcare (EMG/h) e PSG (bursts/h) foram anotados. A validade dos critérios ICSD-3 e do Grindcare foram avaliados pela análise da área sob a curva (ASC) ROC (receiver operating characteristics), razão de probabilidade (RP), razão de possibilidade de diagnóstico (RPD) e análise de Bland-Altman. Os itens do ICSD-3 para BS obtiveram pouca a moderada concordância com o diagnóstico por PSG, com ASC de 0,55 até 0,75. O melhor valor de concordância obtido foi o relato de BS mais do que uma vez na semana associado ao relato de dor transitória na musculatura mastigatória ou fadiga pela manhã com moderada, mas significativa concordância, (ASC=0,75) com especificidade de 90, RP positiva=6 e RPD=13,5. Quando a frequência do relato de BS aumentou para 4 vezes na semana, a combinação do relato com desgaste dentário também apresentou valores altos de concordância com o diagnóstico realizado através de PSG (ASC= 0,75, RP=6, RPD=13,6). A análise de Bland-Altman dos EMG bursts/h mostrou uma concordância positiva entre os resultados do Grindcare e PSG. A análise pela curva ROC também mostrou que, se utilizado o mínimo de 18 EMG/h por 3 noites e 19 EMG/h por 5 noites de uso do Grindcare como valores de corte, a especificidade do teste é de 90% e a RP positiva de 5. Como há considerável heterogeneidade nos resultados, a aplicação dos critérios de diagnóstico da ICSD-3 para BS pode estar limitada. Ainda, o aparelho Grindcare está apto a prever BS diagnosticado pela PSG, quando utilizado por 3 ou 5 noites consecutivas, e pode ser um recurso válido para a prática clínica.

Palavras- chave: Bruxismo do sono. Diagnóstico. Polissonografia. Distúrbios do Sono. Desgaste dos dentes. Dor facial.

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# *1 Introduction*

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## **1 INTRODUCTION**

Sleep bruxism (SB) is classified as a sleep-related movement disorder according to the American Academy of Sleep Medicine (AASM)(American Academy of Sleep Medicine 2014) and it is defined as a repetitive jaw-muscle activity characterized by clenching or grinding of the teeth and/or by bracing or thrusting of the mandible during sleep (Lobbezoo et al. 2013).

There has been an increasing attention to SB, as it is thought to be an important aetiological factor, which could cause and/or perpetuate abnormal tooth wear, periodontal disease and Temporomandibular Disorders (TMD).(Koyano et al. 2008; Carra et al. 2012). The assessment of SB continues to represent a challenge in clinical practice since most dentists have difficulty in evaluating whether the patient actually has active SB or not (Koyano et al. 2008).

According to Lavigne et al. (2011), the methods for assessing SB in order of increasing reliability are: patient history, clinical assessment, questionnaires, ambulatory EMG monitoring, and full audio-video PSG recording (Lavigne et al. 2011).

The assessment of SB is often based on self-report or reports of tooth-grinding sounds during sleep and the presence of clinical signs and symptoms (Carra et al. 2012) not only in clinical practice but also in large population studies (Lobbezoo et al. 2013). Physical examination of associated signs like tooth wear, indentated tongue or jaw muscle hypertrophy and questionnaires including the patient, sleeping partner or patient parent's reports of teeth grinding during sleep, and/or symptoms, like morning facial pain, soreness or headache, are often used to characterize SB (Lavigne et al. 2008). All these signs and symptoms, however, do not seem to be a reliable and valid measure of SB (Lobbezoo et al. 2013).

Appropriate questionnaires can be used to investigate SB. Recently, the AASM published the new edition of the classification (ICSD-3) with diagnostic criteria for the full range of sleep disorders, including SB. They included the report of regular or frequent tooth grinding sounds occurring during sleep and the presence of one or more of the following clinical signs and/or symptoms: (I) abnormal tooth wear consistent with reports of tooth grinding during sleep; (II) transient morning jaw muscle pain or fatigue; and/or temporal headache; and/or jaw locking upon awakening consistent with reports of tooth grinding during sleep (American Academy of Sleep Medicine 2014).

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According to Carra et al., the clinical diagnosis of SB should be based on the International Classification of Sleep Disorders (ICSD) criteria proposed by the American Association of Sleep Medicine (AASM) (Carra et al. 2012). These criteria have been used in clinical and population studies (Ommerborn et al. 2007, 2012; Troeltzsch et al. 2011; Fernandes et al. 2012, 2013) as well as in systematic reviews (De Luca Canto et al. 2014). However, until now, this criterion has not been validated for both clinical and research purposes.

To establish a definitive diagnosis of SB, laboratory evaluation is required (Lobbezoo et al. 2013). In clinical and research practice, polysomnography (PSG), with audio and video recordings, is the gold standard for SB diagnosis as it permits a quantitative assessment of oromandibular movements (Lavigne et al. 1996, 2008; Rompré et al. 2007; Lobbezoo et al. 2013). PSG allows full-night of electroencephalogram (EEG), electrooculogram (EOG), electromyography (EMG), leg movements, respiratory effort, airflow, and oxygen saturation. Repetitive and recurrent episodes of rhythmic masticatory muscle activity (RMMA) of the temporalis and masseter muscles are the characteristic EMG pattern that is scored during sleep to make a PSG diagnosis of SB (Lavigne et al. 2008). Audio and video recording increases the specificity and sensitivity in RMMA detection by distinguishing between RMMA episodes and other orofacial movements (Carra et al. 2014).

It has been difficult to obtain accurate estimates of the magnitude of SB in the general population as there are still problems using PSG, especially those related to cost, number of nights, and patient habituation. Indeed, the sleep lab may not be very representative of sleep in a natural milieu, which is a significant problem (Kato et al. 2003; Lavigne et al. 2008).

Based on the above mentioned challenges associated with a PSG examination and on the time-variant nature of SB, it would be desirable to develop and use a more simple and portable device to help classification of SB over long periods of time (multiple nights) in the patients' own home (Koyano et al. 2008; Carra et al. 2012) and to be valuable in the clinical assessment and in large-sample studies (Carra et al. 2012). Portable electromyography (EMG) devices have been used for this purpose, as they can record and analyze masticatory muscle activity during sleep from the temporalis or masseter muscles, depending on the device used. Although less expensive, they still seem to be less reliable, when compared to PSG (Mizumori et al., 2009; Ahlberg et al. 2008; Koyano et al. 2008; Mainieri et al. 2012; Minakuchi et al. 2012; Deregibus et al. 2013).

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A single-channel assembly surface EMG device has been used for measurement of jaw muscle EMG activity, mainly associated with tooth grinding or clenching during sleep (Grindcare, Medotech A/S, Herlev, Denmark) (Jadidi et al. 2008, 2011, 2013; Koyano et al. 2008; Bernhardt et al. 2012; Yachida et al. 2012; Raphael et al. 2013; Conti et al. 2014). This EMG device has two modes of operation: I. measurement – simple monitoring of the EMG activity of the anterior temporalis muscle and II. treatment - emitting a non-painful electrical pulse to the temporal region, when EMG activity exceeds a previously individually determined threshold (Jadidi et al. 2008). Preliminary data with the use of this EMG device have, indeed, indicated a good linear fit between the scoring methods using the single channel EMG and the full PSG data (Haugland et al. 2011). There was no information, however, about the optimal cut-off value for the number of muscle EMG episodes and the number of nights needed for a reliable SB diagnosis with the portable single-channel EMG device (Grindcare), when compared to the gold standard technique (i.e. PSG).

The studies presented here are intended to compare two methods for assessing SB: ICSD-3 clinical assessment (questionnaires and clinical examination) and the Grindcare device with gold standard PSG examination. The comparison with PSG was used to determine an appropriate cut-off value and the number of nights of sleep with the portable single-channel EMG device necessary for a valid/reliable SB diagnosis.

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2 *Articles*

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## 2 ARTICLES

The articles presented in this Thesis were written according to the *Journal of Sleep Research* (Diagnostic validity of the use of a portable single-channel electromyography device for sleep bruxism) and *Journal of Dental Research* (Validation of ICSD-3 criteria for Sleep Bruxism) instructions and guidelines for articles submission.

### 2.1. ARTICLE 1

#### **Diagnostic validity of the use of a portable single-channel electromyography device for sleep bruxism**

##### **Authors:**

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Paulo César Rodrigues Conti, PhD, Professor, Department of Prosthodontics. Bauru School of Dentistry, University of São Paulo, Bauru, Brazil

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## ABSTRACT

To determine an appropriate cut-off value and the number of nights of sleep with the portable single-channel EMG device (Grindcare) necessary for a valid sleep bruxism (SB) diagnosis. Twenty consecutive post-graduate students and staff at Bauru School of Dentistry composed the sample. Each participant underwent the Grindcare for five consecutive nights and the polysomnography (PSG). The discrimination between bruxers and non-bruxers was based only on the PSG analysis. Data about electromyography per hour with Grindcare (EMG/h) and PSG (bursts/h) were scored. There were positive correlations between the two devices for EMG/h and bursts/h in three and five consecutive nights. Bland-Altman analysis of the EMG bursts/h showed positive agreement between the methods. The ROC analyses also showed that using a minimum of 18 EMG/h for three nights and 19 EMG/h for five nights in Grindcare as cut-offs resulted in a 90% specificity and positive likelihood ratio equal to 5. Grindcare is able to predict SB diagnosed by PSG and gold standard criteria with a reasonable accuracy, when used for three or five consecutive nights, and it may be a valid choice in clinical practice for SB assessment.

Key words: Diagnosis. Polysomnography. Sleep bruxism. Sleep disorders.

## Introduction

Sleep bruxism (SB) is classified as a sleep-related movement disorder according to the American Academy of Sleep Medicine (AASM)(American Academy of Sleep Medicine 2014) and defined as a repetitive jaw-muscle activity characterized by clenching or grinding of the teeth and/or by bracing or thrusting of the mandible during sleep.(Lobbezoo et al. 2013)

The assessment of SB continues to represent a challenge in clinical practice. Physical examination of associated signs like tooth wear, indentated tongue or jaw muscle hypertrophy and questionnaires including the patient, sleeping partner or patient parent's reports of teeth grinding during sleep, and/or symptoms, like morning facial pain, soreness or headache, are often used to characterize SB.(Lavigne et al. 2008) All these signs and symptoms, however, do not seem to be a reliable and valid measure of SB.(Lobbezoo et al. 2013)

In clinical and research practice, polysomnography (PSG), with audio and video recordings, is the gold standard for SB diagnosis as it permits a quantitative assessment of

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oromandibular movements. (Lavigne et al. 1996, 2008; Rompré et al. 2007; Lobbezoo et al. 2013) However, there are still problems related especially to high costs, needed number of nights, time-consuming and complex signal analyses, and patient habituation. Indeed, the sleep lab may not be very representative of sleep in a natural milieu, which is a significant problem.(Kato et al. 2003; Lavigne et al. 2008)

Based on the above mentioned challenges associated with a PSG examination and on the time-variant nature of SB, it would be desirable to develop and use a more simple and portable device to help classification of SB over long periods of time (multiple nights) in the patients' own home.(Koyano et al. 2008; Carra et al. 2012) Portable electromyography (EMG) devices have been used for this purpose, as they can record and analyze masticatory muscle activity. Although less expensive, they still seem to be less reliable when compared to PSG.(Mizumori et al., 2009; Ahlberg et al. 2008; Koyano et al. 2008; Mainieri et al. 2012; Minakuchi et al. 2012; Deregibus et al. 2013)

Measurement of jaw muscle EMG activity, mainly associated with tooth grinding or clenching during sleep, may be assessed by a single-channel assembly surface EMG device (Grindcare, Medotech A/S, Herlev, Denmark).(Jadidi et al. 2008, 2011, 2013; Koyano et al. 2008; Bernhardt et al. 2012; Yachida et al. 2012; Raphael et al. 2013; Conti et al. 2014) This EMG device has two modes of operation: I. measurement – simple monitoring of the EMG activity of the anterior temporalis muscle and II. treatment - emitting a non-painful electrical pulse to the temporal region, when EMG activity exceeds a previously individually determined threshold.(Jadidi et al. 2008) Preliminary data with the use of this EMG device have, indeed, indicated a good linear fit between the scoring methods using the single channel EMG and the full PSG data. (Haugland et al. 2011) There was no information, however, about the optimal cut-off value for the number of muscle EMG episodes and the number of nights needed for a reliable SB diagnosis with the portable single-channel EMG device, when compared to the gold standard technique (i.e. PSG).

Based on that, the aim of this study with single-channel EMG and PSG recordings was to determine an appropriate cut-off value and the number of nights of sleep with the portable single-channel EMG device necessary for a valid SB diagnosis.

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## **Methods**

### *Study population*

The project was conducted in accordance with Helsinki guidelines and had been approved by the local ethics committee (number ID 173/2011). Written informed consent was obtained from all participants.

Participants were recruited from post-graduate students and staff at Bauru School of Dentistry, University of Sao Paulo, Brazil. They responded to social media advertisement looking for self-reported SB and healthy volunteers.

Questionnaires and clinical assessment were performed to include participants with a 'possible' SB diagnosis according to the published criteria.(Lobbezoo et al. 2013) All participants had no Temporomandibular Disorders (TMD) signs and/or symptoms, according to Research Diagnostic Criteria for TMD (RDC/TMD) standards.(Dworkin and LeResche 1992) Specifically, SB individuals were considered amongst those who answered, "yes" to RDC/TMD questionnaire 15c ("Have you been told, or do you notice that your grind your teeth or clench your jaw while sleeping at night?").

Exclusion criteria were: current illness or history of neurologic or psychiatric disorders; history of chronic musculoskeletal pain; previous diagnosis or signs and symptoms of others sleep disorders (e.g., snoring, sleep apnea, and periodic limb movement); use of prescription medicine or drugs with possible sleep effects or alterations of motor behavior; presence of gastro esophageal reflux and alimentary disorders; smoking, alcohol abuse, consumption of more to three cups of coffee per day; electrode gel allergy; currently under medical or dental treatment; pregnancy; user of pacemaker or implanted defibrillator; with some dental characteristics like loss of more than two posterior teeth except third molars and wearers of removable partial or full dentures; enlarged tonsils, skeletal class II, and with Mallampati score III or IV for the risk of concomitant sleep apnea.(Carra et al. 2012)

After the initial screening, 23 subjects were eligible and agreed to participate. Two participants withdrew from the study because of difficulties in wearing the ambulatory EMG device, and one did not agree to sleep in the laboratory. After that, 20 individuals (mean age  $\pm$  SD  $27.1 \pm 4.9$  years, 95% single, 5 men and 15 women) composed the final study sample.

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### *Study Design*

On the first day, all participants were asked to complete a Brazilian Portuguese translation of the RDC/TMD questionnaire (<http://www.rdc-tmdinternational.org>) and a questionnaire about general health and sleep behavior.

All participants were properly instructed, and trained in the use of the EMG device. Then they were asked to wear the portable single-channel EMG device (Grindcare, Medotech A/S, Herlev, Denmark) during sleep for at least 5 nights during one week. After at least one week, they spent 2 consecutive nights in a sleep laboratory for PSG recordings. The portable single-channel EMG device was also used during the PSG exam to avoid any differences among sleep nights. Data obtained from the single-channel EMG device during these nights were not included in the study.

### *EMG Analysis*

The Grindcare has a single-channel assembly, with three electrode contacts. The electrode was designed to be placed over the anterior temporalis area, which provides the same EMG information when compared to those obtained from the masseter muscle during sleep.(Koyano et al. 2008) The device analyzes events of EMG activity, according to a Signal Recognition Algorithm (SRA) described by Jadidi et al.(Jadidi et al. 2008) EMG activity is amplified (x 800) and filtered (250 Hz - 610 Hz) in the device, and further analyzed for events of EMG activity.

The SRA is based on a Fast Fourier Transformation analysis and threshold comparison. To determine the individual contraction parameters, every night participants were requested to relax their jaw muscles for 10 seconds, then to clench their teeth around 60% of the maximum voluntary contraction for 10 seconds. The determination of the number of events was done based on the algorithm, considering an event when the EMG activity exceeds the previously adjusted signal level at rest, plus 20% of the maximum EMG level during the 60% contraction.(Jadidi et al. 2008) One EMG event is recorded in the log file when the amplitude of the EMG signal exceeds the threshold for more than 100 ms for up to 1 second. Longer-lasting EMG events are counted as additional events.(Raphael et al. 2013) The SRA has been shown to be able to differentiate, at least to a reasonable extent between clenching, relaxing, and grimacing EMG activity.(Jadidi et al. 2008)

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The total number of EMG events, events per hour (EMG/h) and number of measurement hours were recorded for all nights.

Data were transferred and saved in a computer equipped with commercial software (Grindcare Manager, Medotech A/S, Herlev, Denmark). The log file provided information about the proper use of the EMG by the patient by reporting loss of electrode contact.

For statistical analysis purposes, the obtained data were divided in three periods:

- T1: values from the first night
- T2: mean values from three consecutive nights
- T3: mean values from five consecutive nights

### *PSG recordings*

Laboratory-based PSG studies were conducted at a sleep laboratory in the city of Bauru, under supervision of a physician certified by the Brazilian Association of Sleep Disorders.

Subjects spent two nights in the sleep laboratory. The first night was used for habituation to the environment and for verification of exclusion criteria features. The second night was used to collect experimental data.

PSG recordings were performed in a dark, sound attenuated and temperature-controlled room. The mean time for the start of sleep recording was 10:30 PM, and the finishing time was 6:00 AM or upon the subjects' spontaneous awakening.

An ambulatory PSG system (Alice 5 International, Philips Respironics, United States) was used to perform a full-sleep study. The following channels were recorded: electroencephalography (EEG) (F3M2, F4M1, C3M2, C4M1, O1M2, O2M1); electrooculogram (EOG) (right and left); electrocardiogram (ECG)(three derivations); EMG from chin and masseter muscles (rhythmic masseter muscle activity - RMMA scoring) and from anterior tibialis (bilateral) for periodic limbs movements' diagnosis. Respiratory parameters were assessed by recording abdominal and thoracic respiratory effort, airflow (oronasal cannula), snoring and oxymetry. Sensors were used to capture the sleep position.

Audio-visual recordings were performed simultaneously to distinguish SB episodes from other oromandibular activities.

An experienced sleep technician scored the PSG signals. The scores were confirmed by the certified physician and by one of the authors (JSB). PSG analysis was performed using Alice Sleepware Software (Philips Respironics, United States).

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Using 30-s epochs, all sleep analyses were carried out. Sleep stage was scored according to standard criteria.(Iber et al. 2007)

Masseter EMG bursts were detected based on pre-defined EMG threshold (20% of maximal voluntary tooth clenching task – MVC).(Carra et al. 2012) Right masseter EMG bursts with duration exceeding 0.25 seconds were selected for oromotor activity scoring, according to published criteria.(Lavigne et al. 1996; Carra et al. 2012) Oromotor episodes separated by 3 seconds 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 to 2.0 seconds), tonic (one EMG burst lasting more than 2.0 seconds) or mixed (both burst types) episodes. EMG bursts were considered within the same RMMA episode if the interval between them was shorter than 2 seconds.(Lavigne et al. 1996; Carra et al. 2012)

### *Data Analysis*

For data analysis, the discrimination between bruxers (SB Group) and non-bruxers (Control Group) was based only on the PSG analysis as the gold standard. Subjects received the PSG diagnosis of SB if the RMMA index was greater than 2 episodes per hour of sleep.(Carra et al. 2014)

According to these criteria, 10 participants composed a SB Group ( $28.3 \pm 5.8$  years – 9 women and 1 man) and 10 constituted the Control Group ( $25.9 \pm 3.6$  years – 6 women and 4 men).

The coefficient of variation from the multiple night recordings (CV: SD/mean) was calculated for all individuals in each group to examine the night-to-night variability in EMG activity with values from five consecutive nights from the portable single-channel EMG device.(Yachida et al. 2012)

The bruxism index (the percentage of total sleep time spent with EMG activity greater than 20% MVC was calculated for all individuals in the PSG night.(Van Der Zaag et al. 2008)

### *Statistics*

Data were described as median  $\pm$  interquartile range (IR). The non-parametric Mann-Whitney test was used to analyze differences between groups in PSG and the portable single-channel EMG device measurements. Spearman's rank correlation (Rho) and the Bland

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Altman plot(Bland and Altman 2010) were used to measure the correlation and agreement between EMG activity with Grindcare device (EMG/h) and PSG (EMG burts/h).

For all analysis, the presence or absence of SB diagnosed by the PSG examination was the dichotomous outcome variable.

A receiver operating characteristic (ROC) curve analysis(Zou et al. 2007) was performed to detect diagnostic accuracy (area under the curve – AUC), sensitivity, specificity and likelihood ratios (LR)(Deeks and Altman 2004) of EMG/h in each period of the single-channel EMG device to discriminate between groups. These curves were drawn by plotting the sensitivity against the false-positive rate (1–specificity), for varying cut-off levels of EMG/h. A non-discriminating test would follow the diagonal line of the figure, whereas a 100% accurate test would coincide with the upper left corner of the box.(Zou et al. 2007)

ROC curves were also used to determine the cut-off value for SB diagnosis. For this purpose, a specificity value was set at 90%.(Widmer et al. 1990)

The level of significance was set at  $P < 0.050$ . Data were analyzed using MedCalc (MedCalc Software, Ostend, Belgium).

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## Results

Data from the first PSG night were not used for the statistical analysis, except for data from 2 participants, one in each group, because of technical problems during the second night recordings. All sleep variables recorded with the PSG system are displayed in Table 1.

Table 1- Sleep variables of bruxers and controls.

| Sleep variables                       | All sample<br>(n=20) |       | SB Group<br>(n=10) |       | Control Group<br>(n=10) |      | Mann-Whitney test [p<br>(95%CI)] |
|---------------------------------------|----------------------|-------|--------------------|-------|-------------------------|------|----------------------------------|
|                                       | Median               | IR    | Median             | IR    | Median                  | IR   |                                  |
| Number of RMMA                        | 9.5                  | 15.5  | 17.0               | 10.5  | 2.0                     | 7    | <0.001 (7;13)                    |
| RMMA per hour                         | 1.5                  | 2.7   | 2.7                | 1.8   | 0.3                     | 1    | <0.001 (7;13)                    |
| Number of Bursts                      | 23                   | 74    | 63.5               | 133.8 | 7.0                     | 17.5 | <0.01 (3;12)                     |
| Burst per hour                        | 3.6                  | 9.7   | 8.8                | 19    | 1.1                     | 2.7  | <0.001 (2.9; 12)                 |
| Total time RMMA +<br>Bursts (seconds) | 49.8                 | 133.6 | 127.1              | 138.1 | 7.2                     | 42.2 | 0.005 (2.9;11.9)                 |
| Total time RMMA<br>(seconds)          | 51.7                 | 105.5 | 134.2              | 119.9 | 27.0                    | 31.5 | 0.004 (21.84;155.9)              |
| Total sleep time<br>(minutes)         | 392.3                | 81.5  | 419.8              | 91.5  | 374.5                   | 67.6 | 0.5 (-38.49;66.49)               |
| Bruxism index                         | 0.2                  | 0.51  | 0.5                | 0.4   | 0.0                     | 0.1  | 0.006 (0.14; 0.73)               |
| Sleep onset latency<br>(minutes)      | 61.5                 | 77    | 38.8               | 80.4  | 93.0                    | 91.8 | 0.06 (-88.5; 2.5)                |
| REM-Sleep latency<br>(minutes)        | 76.5                 | 75.6  | 87.3               | 85    | 75.8                    | 55.3 | 0.9 (-28.9; 54.5)                |
| Sleep efficiency (%)                  | 77.9                 | 15.9  | 82.7               | 17.9  | 70.7                    | 15.8 | 0.04(0.1;19)                     |
| Sleep stage N1 (min (%))              | 9.3                  | 5.9   | 9.5                | 7.8   | 9.0                     | 4.8  | 0.85 (-3.5; 4.0)                 |
| Sleep stage N2 (min (%))              | 46.3                 | 8.2   | 47.2               | 9.2   | 45.6                    | 9.7  | 0.85 (-9.1; 4.2)                 |
| Sleep stage N3 (min (%))              | 21.9                 | 9.0   | 22.3               | 10    | 21.3                    | 10.1 | 0.85 (-5.6; 7.2)                 |
| Sleep stage REM (min<br>(%))          | 17.2                 | 9.4   | 17.8               | 10.5  | 17.2                    | 9.9  | 0.79 (-4.9; 6.3)                 |
| Awakening (minutes)                   | 16.8                 | 37    | 16.8               | 39.5  | 25.8                    | 40.8 | 0.67 (-30.5; 24.0)               |
| Micro-arousals                        | 75.5                 | 41.5  | 84.5               | 48    | 73.0                    | 43   | 0.9 (-28.01;36.98)               |
| Micro-arousals per hour               | 13.2                 | 8.0   | 13.4               | 10.7  | 13.2                    | 7.5  | 0.9 (-5.9; 4.7)                  |
| Changes in sleep stage                | 106.0                | 34    | 124.0              | 54    | 102.5                   | 38.3 | 0.21 (-11.9; 45.0)               |
| Apnea events per hour                 | 0.4                  | 1.0   | 0.4                | 0.6   | 0.6                     | 1.4  | 0.65 (-1.0; 0.3)                 |

Legend: IR – interquartile range; CI – confidence interval; RMMA – rhythmic masticatory muscle activity; REM – rapid eye movement

As expected, the SB group had higher values for all masseter EMG variables and for the bruxism index. The numbers of RMMA and EMG bursts were about six times higher in bruxers than in controls ( $P < 0.01$ ).

No differences were found between groups for any other PSG variables, except for sleep efficiency. For this parameter, the control group showed significantly the lowest value. Seventy per cent of all participants had values less than 85% for sleep efficiency.

Data of the portable single-channel EMG device are displayed in Table 2. The EMG variables were significantly higher for the SB group in T1 and T2 periods. There were no differences between groups in terms of hours of measurement and CV values.

Table 2 – Number of electromyography (EMG) events, events per hour (EMG/h) and number of measurement hours for Grindcare use in one, three and five nights.

|                     | <i>All sample</i><br>(n=20) |       | <i>SB Group</i><br>(n=10) |       | <i>Control Group</i><br>(n=10) |       | <i>Mann-Whitney test [p (95%CI)]</i> |
|---------------------|-----------------------------|-------|---------------------------|-------|--------------------------------|-------|--------------------------------------|
|                     | Median                      | IR    | Median                    | IR    | Median                         | IR    |                                      |
| <i>T1</i>           |                             |       |                           |       |                                |       |                                      |
| EMG events          | 83.5                        | 126.8 | 154.0                     | 165   | 65                             | 77    | 0.04 (5; 154)                        |
| EMG per hour        | 13.5                        | 19.1  | 20.6                      | 23.7  | 8.8                            | 11.1  | 0.06 (-0.6; 23.6)                    |
| Measurement minutes | 390.5                       | 198.8 | 421.5                     | 184.5 | 381                            | 195   | 0.27 (-79.9; 155)                    |
|                     |                             |       |                           |       |                                |       |                                      |
| <i>T2</i>           |                             |       |                           |       |                                |       |                                      |
| EMG events          | 75.5                        | 118.3 | 144.5                     | 184   | 45                             | 62.7  | <0.001 (32; 142)                     |
| EMG per hour        | 10.9                        | 15.5  | 17.7                      | 24.6  | 7.8                            | 10.5  | <0.001 (3.2; 17.1)                   |
| Measurement minutes | 413                         | 155   | 434                       | 179.8 | 389.5                          | 153.8 | 0.04 (1.0; 105)                      |
|                     |                             |       |                           |       |                                |       |                                      |
| <i>T3</i>           |                             |       |                           |       |                                |       |                                      |
| EMG events          | 84.0                        | 111.5 | 140.0                     | 168.8 | 63                             | 67    | <0.001 (33; 108)                     |
| EMG per hour        | 12.1                        | 14.8  | 17.7                      | 23.6  | 8.1                            | 10.9  | <0.001 (4; 13.7)                     |
| Measurement minutes | 416                         | 159   | 419.0                     | 187.5 | 409                            | 124   | 0.62 (-34; 48.9)                     |
|                     |                             |       |                           |       |                                |       |                                      |
| CV (%)              | 33.1                        | 32    | 27.2                      | 18.4  | 51.6                           | 38.69 | 0.35 (-33.4; 9.8)                    |

Legend: IR- interquartile range; CI – confidence interval; EMG – electromyography; CV - coefficient of variation; T1 - only the first night; T2 - values from three consecutive nights; T3 - values from five consecutive nights.

When considering the entire sample, the number of EMG/h was positively correlated with EMG bursts/h in T2 ( $\rho=0.493$ ,  $P = 0.03$ ) and T3 h ( $\rho=0.538$ ,  $P = 0.01$ ) (Figure 1). The good agreement between EMG/h and EMG bursts/h is plotted in Figure 1.

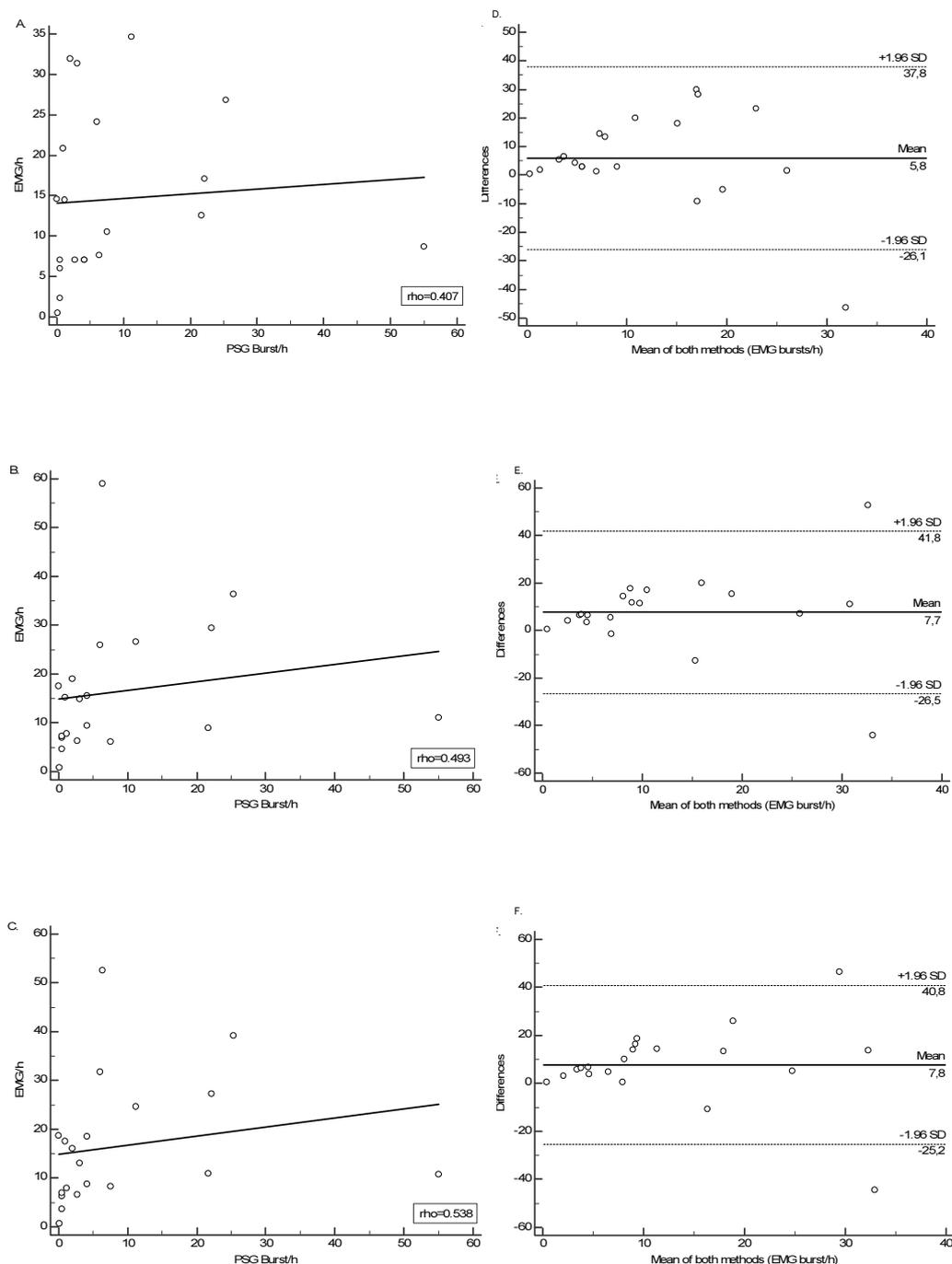


Figure 1- Correlation scatterplots and Bland-Altman analysis. Correlation between bursts per hour from polysomnography (PSG bursts/h) and electromyography events per hour from Grindcare device (EMG/h) in the first night of Grindcare use (A), three consecutive nights (B) and five consecutive nights (C). Bland-Altman plots show mean of against difference between Grindcare device and PSG for the first night (D), three consecutive nights (E) and five consecutive nights (F). Thick black line shows bias (average differences) and dashed lines shows the 95% limits of agreement (average difference  $\pm$  1.96 standard deviation).

The values for sensitivity, specificity and LR for number of EMG/h in each period are described in Table 3.

Table 3- Sensitivity, specificity, and likelihood ratios (LR) for number of EMG events per hour of Grindcare use (EMG/h) in each period.

| EMG/h     | Sensitivity | 95% IC      | Specificity | 95% IC       | +LR  | 95% IC     | -LR  | 95% IC    |
|-----------|-------------|-------------|-------------|--------------|------|------------|------|-----------|
| <i>T1</i> |             |             |             |              |      |            |      |           |
| ≥11       | 60          | 26.2 - 87.8 | 60          | 26.2 - 87.8  | 1.50 | 0.6 - 3.7  | 0.67 | 0.3 - 1.7 |
| ≥20       | 40          | 12.2 - 73.8 | 90          | 55.5 - 99.7  | 4.00 | 0.5 - 29.8 | 0.67 | 0.4 - 1.2 |
| ≥25       | 30          | 6.7 - 65.2  | 90          | 55.5 - 99.7  | 3.00 | 0.4 - 24.2 | 0.78 | 0.5 - 1.2 |
| <i>T2</i> |             |             |             |              |      |            |      |           |
| ≥11       | 60          | 26.2 - 87.8 | 60          | 26.2 - 87.8  | 1.50 | 0.6 - 3.7  | 0.67 | 0.3 - 1.7 |
| ≥18       | 50          | 18.7 - 81.3 | 90          | 55.5 - 99.7  | 5.00 | 0.7 - 35.5 | 0.56 | 0.3 - 1.1 |
| ≥25       | 40          | 12.2 - 73.8 | 100         | 69.2 - 100.0 | NA   |            | 0.60 | 0.4 - 1.0 |
| <i>T3</i> |             |             |             |              |      |            |      |           |
| ≥11       | 70          | 34.8 - 93.3 | 60          | 26.2 - 87.8  | 1.75 | 0.7 - 4.1  | 0.50 | 0.2 - 1.5 |
| ≥19       | 50          | 18.7 - 81.3 | 90          | 55.5 - 99.7  | 5.00 | 0.7 - 35.5 | 0.56 | 0.3 - 1.1 |
| ≥25       | 40          | 12.2 - 73.8 | 100         | 69.2 - 100.0 | NA   |            | 0.60 | 0.4 - 1.0 |

Legend: T1 - only the first night; T2 - values from three consecutive nights; T3 - values from five consecutive nights; NA – not available.

The optimal cut-off values to discriminate SB subjects from non-SB subjects, when a 90% specificity level was adopted, were 18 EMG/h or higher in T2 and 19 EMG/h or higher in T3.

A graphic illustration of the ROC curves for each period is presented in Figure 2. The smallest area was detected in the T1 period, and the AUC was not significant.

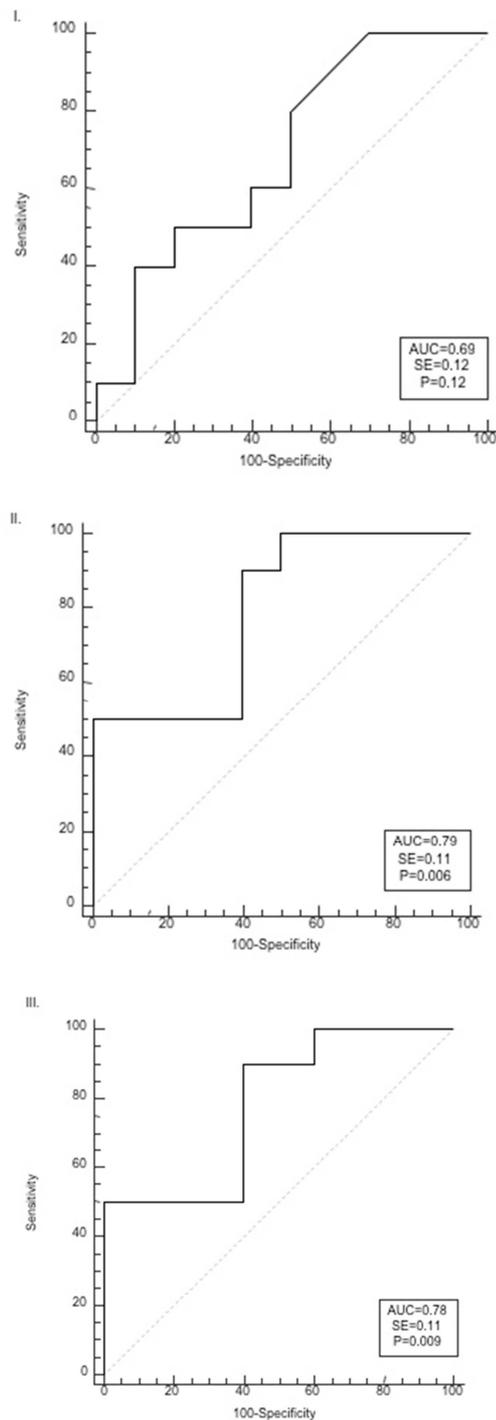


Figure 2- Summary receiver operation characteristic (ROC) curves comparing Grindcare device and polysomnography (PSG) for prediction of sleep bruxism as defined by PSG. I. ROC for the first night of Grindcare use (T1); II. ROC for three consecutive nights of Grindcare use (T2); III. ROC for five nights of Grindcare use (T3).

## Discussion

This study showed that a single-channel EMG device is able to predict SB diagnosed by PSG and gold standard criteria with a reasonable accuracy, when used for three or five nights, as indicated by the ROC AUC equal to 0.790 and 0.780, respectively. The ROC analyses also showed that using a minimum of 18 EMG/h for three nights and 19 EMG/h for five nights as cut-offs resulted in a 90% specificity which is acceptable.(Widmer et al. 1990) These figures, however, had less than 75% of sensitivity.

The ROC AUC is a summary measurement that essentially averages diagnostic accuracy across the spectrum of test values. An AUC greater than 0.5 indicates the test is not worse than chance.(Zou et al. 2007) For a single night recording with the portable single-channel EMG device, the values for EMG bursts/h produced a ROC curve with an AUC equal 0.5. Therefore, for a more reliable SB diagnosis, more than one night recording with the Grindcare device is essential.

The sensitivity of a clinical test refers to the ability of the test to identify correctly those subjects with the disease / disorder and specificity refers to those subjects without the target condition.(Widmer et al. 1990) Sensitivity and specificity are inversely proportional, which means that as the sensitivity increases, the specificity decreases and vice versa.(Akobeng 2007) They are independent of the population of interest, subjected to the test and they differ according to which cut-off point is chosen to define and distinguish e.g. bruxers and controls. The ROC curve allows analyses of the trade-offs between sensitivity and specificity at all possible cut-off points.(Akobeng 2007)

High sensitive tests are particularly important in the diagnosis of illness that might lead to irreversible damage or even death.(Widmer et al. 1990) Low specificity tests carry a risk to produce a false-positive result, which can lead to overtreatment with possible biological, psychological or financial damage to patient. As SB is a time-variant, non-progressive and self-limitation condition,(Lavigne et al. 2008) we propose that a high specificity may be considered more important than a high sensitivity.

In medical sciences, diagnostic tests should have at least 75% sensitivity and 90% specificity.(Widmer et al. 1990) Based on these parameters, in the present study, different cut-off values are recommended for different number of nights using the single-channel EMG device. We set 90% of specificity although, when using this parameter, sensitivity did not reach “ideal” values. As the cut-off values had low sensitivity, more rigorous criteria should

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be applied in the clinical assessment of SB (i.e. frequency of self-report SB, worn dentition, masseter hypertrophy, teeth fracture, etc.) to reduce the chance of false-negative results.

Although the SRA described by Jadidi et al.(Jadidi et al. 2008) could discriminate between different types of jaw motor activities, it has been described that a RMMA event could occur after an episode of sleep apnea.(Lavigne et al. 2008) Sleep breathing disorders such as snoring and airway resistance may, indeed, be concomitant with SB(Carra et al. 2012). In this study, questionnaires were used to rule out patients with signs and symptoms of sleep breathing disorders and others sleep disturbances.

The LR is the probability of a given test result when the condition is present divided by the probability of the same test result when the condition is absent.(Deeks and Altman 2004; Grimes and Schulz 2005) In this study, LR summarized how many times more (or less) likely bruxers were to have a particular test result with the single-channel EMG device than controls. The farther the positive LR from the value 1, the stronger is the evidence for the presence or absence of SB. LRs also convey the point that positive and negative results of the same test often change probability asymmetrically.(Grimes and Schulz 2005) In this sense, when specificity was set at 90%, the best accuracy was acquired with cut-off values equal to or greater than 18 EMG/h for 3 nights (LR= 5) and 19 EMG/h for 5 nights (LR=5) with the single-channel EMG device.

The LR tests allowed the comparison of different EMG/h cut-offs for SB diagnosis, when using the Grindcare device and thus refined clinical judgment, providing insights into the test significance and its limitations. In this study, selected scores for EMG/h cut-offs for 3 and 5 nights with use of the EMG device increased the probability of a correct SB diagnosis by about 30%.(Grimes and Schulz 2005) The LR analysis extends the results of ROC analysis, which shows a clear dose-response increase in LR, when the number of night recordings increase from 1 to 3.

The advantage of the LR approach is that, unlike traditional screening measures such as predictive values, results obtained with this method can be applied to populations with different SB prevalence.(Deeks and Altman 2004; Grimes and Schulz 2005) For example, a recent epidemiologic study in Brazil showed that the SB prevalence was 5.5%.(Maluly et al. 2013) Considering this value, 3 calculations can be performed: convert pretest probability (Ppre) to pretest odds (Opre), using  $Opre = Ppre / (1 - Ppre)$ , then multiply the pretest odds (Opre) by the LR for the finding to derive the posttest odds (i.e.,  $Opost = LR \times Opre$ ), and then convert posttest odds back to posttest probability, using  $Ppost = Opost / (1 + Opost)$ .(Grimes and Schulz 2005) So, the use of these scores for EMG/h cut-off in this study

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sample could increase the probability of SB diagnosis by about 28.2%. Indeed, caution is needed for this result once this prevalence is not particularly associated with our sample characteristics.

Twenty-five bursts per hour of sleep is a score used for SB diagnosis in the PSG recordings as described by Lavigne et al. (Lavigne et al. 1996) This data could be extrapolated as cut-offs for single-channel EMG device, however, the number of nights and the validity of this score were not specific. In the present study, 25 EMG bursts/h has a high specificity, a low sensitivity.

The low cost-effect is a great advantage of home recordings with simple ambulatory EMG devices. (Jadidi et al. 2011) Recording more than 2 nights allowed us to confirm the night-to-night variability of EMG activity of SB participants, when compared to controls, which could be a positive and important point for clinical use. The night-to-night variability in SB measures should be taken more into consideration for SB diagnosis. (Van Der Zaag et al. 2008; Minakuchi et al. 2012) There is a report, based on PSG, that the CV for the number of RMMA per hour of sleep in subjects with SB is 25% (Lavigne et al. 2001) and 37% using ambulatory PSG recordings. (Van Der Zaag et al. 2008) It has also been shown that patients with painful conditions have higher night-to-night variability of EMG activity, when compared to pain-free individuals, using a portable single-channel EMG device. (Yachida et al. 2012) No differences in CV between groups, however, were found in the present investigation. Different measurement strategies and analyses or the young sample without facial pain could be reasons for such differences.

The natural fluctuation of SB also denotes that more than one night of single-channel EMG device use is reasonable for SB diagnosis, even as the ROC test outcomes had been shown in this study.

Two first night PSG recordings were used in this study due to technical problems. Although it could be a limitation, no differences between first and second nights of PSG recordings on SB outcome variables or standard sleep variables have been described in the literature. (Van Der Zaag et al. 2008; van der Zaag et al. 2014)

Poor sleep efficiency could influence the SB behavior. (Camparis et al. 2006; Rossetti et al. 2008) Sleep efficiency corresponds to the sleep time in relation to time in bed and its reduction may occur due to an increased latency or number of micro-arousals. (Camparis et al. 2006) In this study, the control group presented the lowest values for sleep efficiency indicating a poorer sleep; however, it did not influence other sleep parameters, including the number of microarousals.

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The single-channel EMG device has automatic EMG detectors and usually use a unique algorithm for EMG/h for analyses.(Jadidi et al. 2008) The comparison with others studies that tested portable EMG devices for SB diagnosis is not possible, as there are significant different methodological and technical issues. Further studies are necessary to certify the cut-off values obtained in this study and also to compare the reliability between single channel EMG devices in the same sample.

The short-term nature of evaluation, as well as the relatively small number of individuals are limitations of the present investigation and need to be considered when judging the actual findings. Even that, the sample size was sufficient to calculate the cut-off values of the single-channel EMG device for SB diagnosis. Small differences in AUC could become statistically significant with larger samples for the assessment periods.

There are also limitations related to selection bias that are noteworthy. Participants were practically all singles. People who sleep alone or with a sleep partner who is not disturbed by tooth grinding sounds may not be able to provide a reliable report of presence of tooth grinding during sleep (Rompré et al. 2007). Although PSG is the gold standard method for SB diagnosis (Koyano et al. 2008; Carra et al. 2012), the data about self-reported SB and clinical findings were not included, which did not permit to classify participants as “definitive” SB patients, as proposed in a recent publication.(Lobbezoo et al. 2013)

The use of a single-channel EMG device also has some problems. The EMG records from single-channel devices are obviously only able to monitor the EMG activity of a single muscle and they can not be used to gather information on more complex patterns of muscle activity(Manfredini and Lobbezoo 2010) or to differentiate awake from sleeping periods.(Raphael et al. 2013) Moreover, single-channel EMG devices are sensitive to participant compliance including the set-up procedure for EMG recordings, which requires relaxation and clenching.(Bernhardt et al. 2012; Yachida et al. 2012) Difficulties in the calibration of the EMG device could, in part, explain the high interquartile range of EMG/h.(Bernhardt et al. 2012)

Some problems described in literature like lost electrodes, that could prevent EMG measurement, or compliance issues (participants forgot or could not use the EMG device), led us to reduce the number of nights chosen for this study to 5 nights per week. The same problems were reported in previous studies using this device.(Bernhardt et al. 2012; Yachida et al. 2012; Conti et al. 2014) Although EMG electrode placement could vary among all nights, it was reported that no significant difference can be observed in maximal EMG activity.(Arima et al. 2012)

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In conclusion, the use of a single-channel EMG device with proper cut-off values may be a valid choice in clinical practice for SB assessment. The association with others clinical parameters obtained from the history and physical examination may be explored in further studies.

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## 2.2. ARTICLE 2

### Validation of ICSD-3 criteria for Sleep Bruxism

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#### ABSTRACT

The aim of this study was to conduct a validation pilot study to compare the third edition of International Classification of Sleep Disorders (ICSD-3) criteria for Sleep Bruxism (SB) diagnosis with gold standard polysomnography examination results. Twenty consecutive post-graduate students and staff at Bauru School of Dentistry participated. Each participant underwent interview, clinical assessment and a polysomnography (PSG). The discrimination between bruxers and non-bruxers was based only on the PSG analysis. We assessed the validity of ICSD-3 criteria by using receiver operating characteristics (ROC) curve analysis (AUC), likelihood ratios (LR) and diagnostic odds ratio (DOR). The ICSD-3 diagnostic

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criteria items for SB had fair to moderate concordance with PSG diagnosis, with AUC ranging from 0.55 to 0.75. The best value of agreement was obtained by the report of SB more than once a week associated with a report of transient morning jaw muscle pain or fatigue with a moderate, but significant agreement with the PSG SB diagnosis (AUC=0.75) with 90% specificity, positive LR=6 and DOR=13.5. When the frequency of self-reported SB increased to more than 4 times per week, the combination of this finding with tooth wear had also high values of agreement with PSG SB diagnosis (AUC= 0.75, LR=6, DOR=13.6). Since there is considerable heterogeneity in the results, the application of ICSD-3 for SB clinical diagnosis may be limited.

**Key words:** Bruxism, Tooth Wear, Diagnostic Techniques and Procedures, Sleep, Polysomnography, Investigative Techniques

### **Introduction**

Sleep bruxism (SB) is defined as a repetitive jaw-muscle activity characterized by clenching or grinding of the teeth and/or by bracing or thrusting of the mandible during sleep (Lobbezoo et al. 2013). There has been an increasing attention to SB, usually due to the purported associations with considerable dental and periodontal complications (Carra et al. 2012). However, the clinical assessment of SB is still a challenge for both, clinicians and researchers.

Laboratory evaluation is required to establish a definitive diagnosis of SB (Lobbezoo et al. 2013). Polysomnography (PSG) with audio and video recordings is the gold standard for SB diagnosis as it permits a quantitative assessment of oromandibular movements (Lavigne et al. 1996, 2008; Rompré et al. 2007; Svensson et al. 2008; American Academy of Sleep Medicine 2014). It has been difficult to obtain accurate estimates of the magnitude of SB in the general population as there are still problems using PSG, especially those related to cost, number of nights, and patient habituation. Besides, the lab environment it is not very representative of sleep in a natural milieu (Kato et al. 2003; Lavigne et al. 2008).

Due to the PSG limitations, questionnaires and physical evaluation are often used to diagnose SB (Lavigne et al. 2008), not only in clinical practice but also in large population studies (Lobbezoo et al. 2013). Paesani et al. recently reported that several systematic reviews of the literature were performed to describe the etiology and prevalence of SB and the

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common limitation point of those papers was related to the diagnostic accuracy, which could lead to low internal validity (Paesani et al. 2013).

According to Carra et al., the clinical diagnosis of SB should be based on the International Classification of Sleep Disorders (ICSD) criteria proposed by the American Association of Sleep Medicine (AASM) (Carra et al. 2012). These criteria have been used in clinical and population studies (Ommerborn et al. 2007, 2012; Troeltzsch et al. 2011; Fernandes et al. 2012, 2013) as well as in systematic reviews (De Luca Canto et al. 2014).

Recently, the AASM published the new edition of the classification (ICSD-3) with diagnostic criteria for the full range of sleep disorders, including SB. They included the report of regular or frequent tooth grinding sounds occurring during sleep and the presence of one or more of the following clinical signs and/or symptoms: (I) abnormal tooth wear consistent with reports of tooth grinding during sleep; (II) transient morning jaw muscle pain or fatigue; and/or temporal headache; and/or jaw locking upon awakening consistent with reports of tooth grinding during sleep (American Academy of Sleep Medicine 2014).

As can be seen, despite all the efforts, there is still a lack of validated questionnaires and guidelines for assessing ICSD-3 criteria for SB that can be administered by dentists in clinical practice. In order to test the criterion validity of questions about symptoms of SB as well clinical examination, we conducted a validation pilot study to compare directly ICSD-3 clinical assessment of SB with a gold standard PSG examination.

## **Methods**

### *Sample Population*

The study was conducted in accordance with Helsinki guidelines and had been approved by the local ethics committee. Written informed consents were obtained from all participants.

Participants were recruited from post-graduate students and staff at Bauru School of Dentistry, University of Sao Paulo, Brazil. They responded to social media advertisement looking for self-report SB and healthy volunteers.

Questionnaires and clinical assessment were performed to identify SB and exclusion criteria features. Exclusion criteria were: presence of Temporomandibular Disorders (TMD), current illness or history of neurologic or psychiatric disorders; history of chronic musculoskeletal pain; previous diagnosis or signs and symptoms of others sleep disorders (e.g., snoring, sleep apnea, and periodic limb movement); use of prescription medicine or

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drugs with possible sleep effects or alterations of motor behavior; presence of gastroesophageal reflux and alimentary disorders; smoking, alcohol abuse, consumption of more than three cups of coffee per day; electrode gel allergy; currently under medical or dental treatment; pregnancy; user of pacemaker or implanted defibrillator; with some dental characteristics like loss of more than two posterior teeth except for the third molars and wearers of removable partial or full dentures; enlarged tonsils, skeletal class II, and with Mallampati score III or IV for the risk of concomitant sleep apnea.

After the initial screening, 21 subjects were eligible and agreed to participate. One patient withdrew from the study for not agreeing to sleep in the laboratory. After that, 20 individuals (mean age  $\pm$  SD 27.1  $\pm$  4.9 years, 95% single, 5 men and 15 women) composed the final study sample.

#### *Assessment of Sleep Bruxism*

The same trained dentist applied a standardized diagnostic protocol to all patients equally. It consisted of a systematic evaluation of SB signs and symptoms according to the following:

1. The Brazilian Portuguese translation of the RDC/TMD questionnaire (<http://www.rdc-tmdinternational.org>) (Dworkin and LeResche 1992) Self-reported SB individuals answered, “yes” to RDC/TMD questionnaire 15c (“Have you been told, or do you notice that your grind your teeth or clench your jaw while sleeping at night?”).
  2. Evaluation of the frequency of SB with five possible choices: (0) none of the time; (1) < 1 night per month; (2) 1-3 nights per month; (3) 1-3 nights per week; (4) 4-7 nights per week (Markiewicz et al. 2006).
  3. Questionnaire based on the ICSD-3, which included three questions about presence or absence of transient morning jaw muscle pain or fatigue, temporal headache and jaw locking upon awakening (American Academy of Sleep Medicine 2014).
  4. Assessment of occlusal and incisal tooth wear on a 5 point ordinal scale. The examination consisted in the inspection of the last present molar in the fourth dental quadrant (right mandibular dental arch). Tooth wear was scored on a tooth-by-tooth basis with the use of a 5-point ordinal scale: 0 = no wear; 1 = visible wear within the enamel; 2 = visible wear with dentin exposure and loss of clinical crown height of  $\leq 1/3$ ; 3 = loss of crown height  $> 1/3$  but  $< 2/3$ ; and 4 = loss of crown height  $\geq 2/3$  (Lobbezoo and Naeije 2001).
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*PSG recordings*

After the diagnostic protocol examination, all participants then slept in a sleep laboratory for PSG recordings for two consecutive nights. The first night was used for habituation to the environment and for verification of exclusion criteria features. The second night was used to collect experimental data.

An ambulatory PSG system (Alice 5 International, Philips Respironics, United States) was used to perform a full-sleep study. The following channels were recorded: electroencephalography (EEG) (F3M2, F4M1, C3M2, C4M1, O1M2, O2M1); electrooculogram (EOG) (right and left); electrocardiogram (ECG) (three derivations); electromyography (EMG) from chin and masseter muscles (rhythmic masseter muscle activity - RMMA scoring) and from anterior tibialis (bilateral) for scoring of periodic limb movements. Respiratory parameters were assessed by recording abdominal and thoracic respiratory effort, airflow (oronasal cannula), snoring and oxymetry. Movement sensors were used to capture the sleep position.

Audio-visual recordings were performed simultaneously to distinguish SB episodes from other oromandibular activities.

An experienced sleep technician scored the PSG signals. The scores were confirmed by a physician certified by Brazilian Association of Sleep Disorders, and by one of the authors (JSB). PSG analysis was performed using Alice Sleepware Software (Philips Respironics, United States).

*Data Analysis*

Using 30-s epochs, all sleep analyses were carried out. Sleep stage was scored according to standard criteria (Iber et al. 2007). Masseter EMG bursts were detected based on pre-defined EMG threshold (20% of maximal voluntary tooth clenching task) (Carra et al. 2012). Right masseter EMG bursts with duration exceeding 0.25 s were selected for oromotor activity scoring, according to published criteria (Lavigne et al. 1996; Carra et al. 2012). Oromotor episodes separated by 3 seconds intervals were recognized as rhythmic masticatory muscle activity (RMMA) if they corresponded to one of the three following patterns: phasic (three or more EMG bursts, each lasting 0.25 to 2.0 s), tonic (one EMG burst lasting more than 2.0 s) or mixed (both burst types) episodes. EMG bursts were considered within the same RMMA episode if the interval between them was shorter than 2 s (Lavigne et al. 1996; Carra

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et al. 2012). Subjects received the PSG diagnosis of SB if the RMMA index was greater than 2 episodes per hour of sleep (Carra et al. 2014).

For data analysis, the discrimination between bruxers (SB Group) and non-bruxers (Control Group) was based only on the PSG analysis.

The frequency of positive answers in the questionnaire as well as in the clinical examination was assessed for all items, with Fisher's exact test comparison.

A receiver operating characteristic (ROC) curve analysis (Zou et al. 2007) was used to quantify how accurate questions and/or clinical examination used in ICSD-3 criteria verified SB, analyzed by the PSG examination. For this purpose, diagnostic accuracy (area under the curve – AUC), sensitivity, sensibility and likelihood ratios (LR) of questions and variables from clinical examination were calculated (Deeks and Altman 2004).

Diagnostic odds ratio (DOR) was used to indicate the best discriminatory test performance. DOR is the ratio of the odds of positivity in SB group relative to the odds of positivity in the control group. The values of DOR ranges from 0 to infinity, with higher values indicating better discriminatory test performance. A value of 1 means that the test does not discriminate between SB individuals and those without it (Glas et al. 2003).

As in the ICSD-3 diagnostic criteria for SB, a positive self-report of SB was combined with one of these items: tooth wear; transient morning jaw muscle pain or fatigue; temporal headache and jaw locking upon awakening (American Academy of Sleep Medicine 2014). We considered “frequent” or “regular” self-reports of SB when the participant indicated a frequency of at least once per week.

The level of significance was set at  $p < 0.050$ . Data were analyzed using MedCalc (MedCalc Software, Ostend, Belgium) and Microsoft Excel.

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## Results

Based on the PSG criteria, 10 participants qualified for the SB Group ( $28.3 \pm 5.8$  years old – 9 women and 1 man) and 10 for the Control Group ( $25.9 \pm 3.6$  years – 6 women and 4 men).

The frequency of self-reported answers and clinical findings are shown in Table 1.

Table 1- Frequency of positive responses and findings in all items.

|  | Sleep Bruxism Group (n=10) | Control Group (n=10) | Fisher's exact test (p) |
|--|----------------------------|----------------------|-------------------------|
| <i>Self-reported sleep bruxism</i>           |                            |                      |                         |
| At least 1 night per month                   | 90%                        | 50%                  | 0.14                    |
| At least 1 night per week                    | 70%                        | 30%                  | 0.17                    |
| At least 4 nights per week                   | 60%                        | 10%                  | 0.06                    |
| <i>Tooth wear</i>                            |                            |                      |                         |
| At least score 1 in any tooth examined       | 100%                       | 70%                  | 0.21                    |
| At least score 2 in any tooth examined       | 50%                        | 40%                  | 1.0                     |
| At least score 3 in any tooth examined       | 10%                        | 0%                   | 1.0                     |
| <i>Sleep bruxism symptoms</i>                |                            |                      |                         |
| Transient morning jaw muscle pain or fatigue | 70%                        | 30%                  | 0.17                    |
| Morning temporal headache                    | 30%                        | 10%                  | 0.58                    |
| Jaw locking upon awakening                   | 20%                        | 20%                  | 1.0                     |

None of the evaluated teeth showed the maximal score for tooth wear (score 4 = loss of crown height  $\geq 2/3$ ) and only one participant in the SB group had a score of 3 (loss of crown height  $>1/3$  but  $<2/3$ ) in the lower central incisor. The distribution of the tooth wear scores were similar between groups (Figure 1).

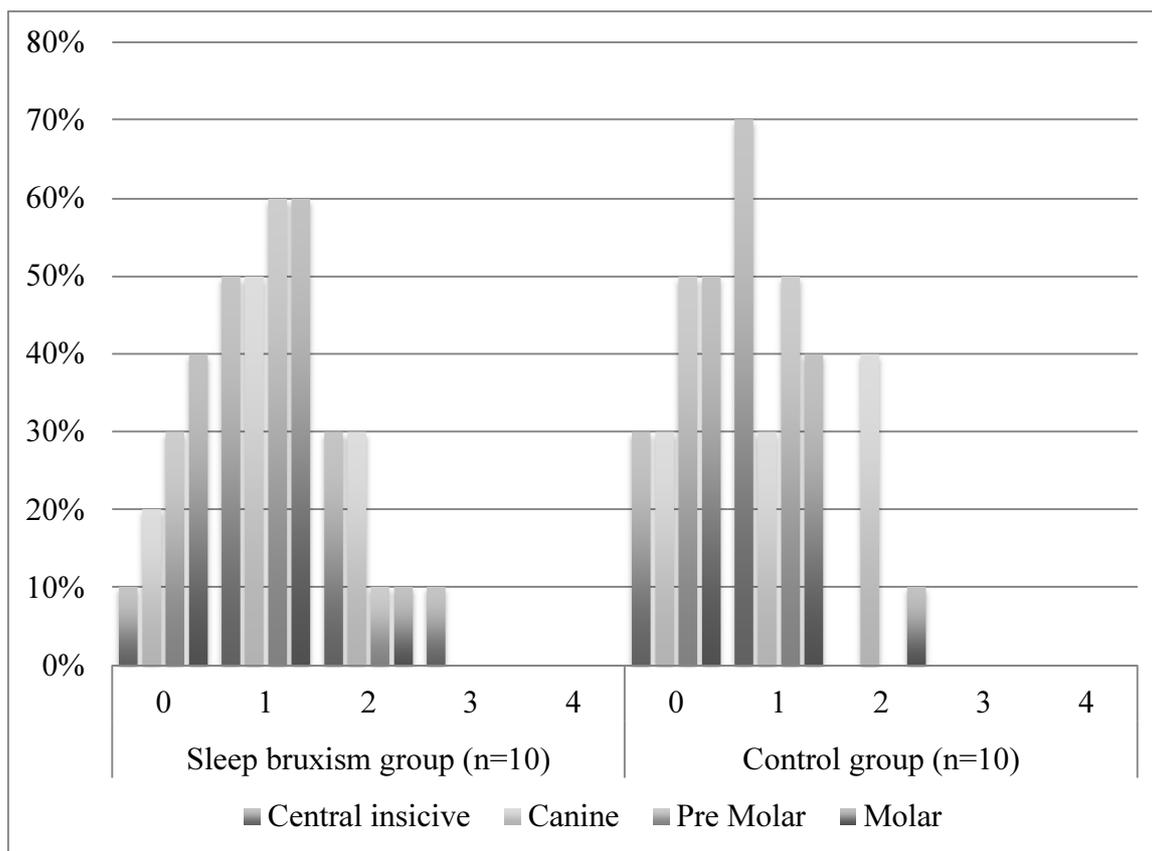


Figure 1 – Distribution (%) of clinical occlusal and incisal tooth wear scores (0-4) per group.

The ICSD-3 diagnostic criteria for SB had fair to moderate concordance with the PSG diagnosis, with AUC ranging from 0.55 to 0.75 (Table 2 and 3). The weekly self-report SB (more than once a week) associated with a report of transient morning jaw muscle pain or fatigue had moderate and significant agreement with PSG SB diagnosis (AUC=0.75) with 90% of specificity, positive LR=6 and DOR=13.5. When the frequency of self-reported SB increased (more than 4 times in a week), the combination of this finding with tooth wear had the best values of agreement with PSG SB diagnosis (AUC= 0.75, LR=6, DOR=13.6). Although the combination with reports of transient morning jaw pain or fatigue was less powerful, it was still significant (Table 3).

Table 2- Frequency of positive responses to the third edition of International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for Sleep Bruxism.

|  | Sleep Bruxism Group<br>(n=10) | Control Group<br>(n=10) | Fisher's exact<br>test (p) |
|--|-------------------------------|-------------------------|----------------------------|
| <i>Self-reported sleep bruxism (at least once in a week) plus</i>      |                               |                         |                            |
| Presence of tooth wear (at least score 1 in any tooth)                 | 70%                           | 30%                     | 0.17                       |
| Presence of tooth wear (at least score 2 in any tooth)                 | 50%                           | 40%                     | 1.0                        |
| Transient morning jaw muscle pain or fatigue                           | 60%                           | 10%                     | 0.06                       |
| Morning temporal headache  | 30%                           | 0%                      | 0.21                       |
| Jaw locking upon awakening   | 20%                           | 20%                     | 1.0                        |
| <i>Self-reported sleep bruxism (at least four days in a week) plus</i> |                               |                         |                            |
| Presence of tooth wear (at least score 1 in any tooth)                 | 60%                           | 10%                     | 0.06                       |
| Presence of tooth wear (at least score 2 in any tooth)                 | 30%                           | 10%                     | 0.58                       |
| Transient morning jaw muscle pain or fatigue                           | 50%                           | 10%                     | 0.54                       |
| Morning temporal headache  | 20%                           | 0%                      | 0.47                       |
| Jaw locking upon awakening   | 20%                           | 10%                     | 1.0                        |

Table 3- Calculation of the sensitivity, specificity, likelihood ratios (LR), area under the curve (AUC) of Receiver Operator Characteristic test (ROC) and Diagnostic Odds Ratio (DOR) for the third edition of International Classification for Sleep Disorders diagnostic criteria for sleep bruxism.

|  | Sens.<br>(%) | Spec.<br>(%) | +LR  | -LR  | AUC  | CI            | p     | DOR  |
|--|--------------|--------------|------|------|------|---------------|-------|------|
| <i>Self-reported sleep bruxism (at least once in a week) plus</i>      |              |              |      |      |      |               |       |      |
| Presence of tooth wear (at least score 1 in any tooth)                 | 70           | 70           | 2.33 | 0.43 | 0.7  | 0.457-0.881   | 0.06  | 5.4  |
| Transient morning jaw muscle pain or fatigue                           | 60           | 90           | 6    | 0.44 | 0.75 | 0.509 - 0.913 | 0.009 | 13.5 |
| Jaw locking upon awakening   | 20           | 90           | 2    | 0.89 | 0.55 | 0.315 - 0.769 | 0.55  | 1.61 |
| Temporal headache  | 30           | 100          | -    | 0.7  | 0.65 | 0.408-0.846   | 0.06  | -    |
| <i>Self-reported sleep bruxism (at least four days in a week) plus</i> |              |              |      |      |      |               |       |      |
| Presence of tooth wear (at least score 1 in any tooth)                 | 60           | 90           | 6    | 0.44 | 0.75 | 0.509-0.913   | 0.009 | 13.6 |
| Transient morning jaw muscle pain or fatigue                           | 50           | 90           | 5    | 0.56 | 0.7  | 0.457-0.881   | 0.04  | 8.92 |
| Jaw locking upon awakening   | 20           | 90           | 2    | 0.89 | 0.55 | 0.315-0.769   | 0.55  | 2.25 |
| Temporal headache  | 20           | 100          | -    | 0.8  | 0.6  | 0.361-0.809   | 0.13  | -    |

Legend: Sens – Sensitivity; Spec – Specificity; LR – Likelihood ratio; AUC – Area under the curve; CI – Confident interval; DOR – Diagnostic odds ratio.

## Discussion

Our findings provide initial evidence regarding the validity of the ICSD-3 diagnostic criteria for SB in comparison with the gold standard PSG tool for SB diagnosis. The AUC values ranged from 0.55 to 0.75 and DOR from 1.1 to 13.6, indicating that only some combinations of ICSD-3 criteria had reasonable accuracy in terms of differential diagnosis between PSG bruxers and non-bruxers.

We used AUC and DOR to evaluate the potential diagnostic value of the ICSD-3 criteria for a clinical SB diagnosis. The results indicated that the presence of transient jaw pain or fatigue associated to frequent weekly self-reports of SB was the most reliable combination for a SB diagnosis (AUC=0.75; DOR=13.5). We also found that if the participants reported bruxism equal or more than 4 times in a week, the combination with the presence of tooth wear could also be considered as accurate for SB diagnosis (AUC=0.75; 13.6). Although DOR is difficult to clinically interpret, it is useful in the assessment of the overall test accuracy (Glas et al. 2003) and, in this study, it permitted the comparison between the combinations. In addition, there was a substantial specificity (0.9) and the LR was equal to 6 with the best combinations.

The LR is the probability of a given test result when the condition is present divided by the probability of the same test result when the condition is absent (Deeks and Altman 2004; Grimes and Schulz 2005). In this study, LR summarized how many times more (or less) likely bruxers were to have a particular result compared to the controls. The farther the positive LR from the value 1, the stronger the evidence is for the presence or absence of SB. LRs also convey the point that positive and negative results of the same test often change probability asymmetrically (Grimes and Schulz 2005).

The new ICSD clinical diagnostic criteria published in 2014 by AASM included the report of regular or frequent tooth grinding sounds occurring during sleep (American Academy of Sleep Medicine 2014). But what is, indeed, regular or frequent? The answer is not described in the diagnostic guidelines. So the weekly (more than once in a week in the last past month) self-reported SB was considered as “frequent” for SB clinical diagnosis in this study and we used two frequencies to produce the combination for ICSD-3 diagnostic criteria.

The need of tooth grinding sounds report is also a limitation of ICSD-3 diagnostic criteria for SB. People who sleep alone or with a sleep partner who is not disturbed by tooth grinding sounds are not able to provide a reliable report of presence of tooth grinding during sleep (Rompré et al. 2007). In our study, almost all participants were single and lived alone,

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which could be a limitation. In this sense, we opted to use the question included in Portuguese version of RDC/TMD questionnaire for SB detection. This question has been used frequently in studies that involved SB diagnosis (Raphael et al. 2012; Yachida et al. 2012).

The report of transient morning facial pain or fatigue was frequent in the SB group and, in combination with self-reported SB, may represent an important symptom combination for SB diagnosis. Others studies have also described that sleep bruxers frequently reported transient or low pain intensity in the jaws upon waking (Bader et al. 1997; Lavigne et al. 1997; Camparis et al. 2006; Rompré et al. 2007). The interesting finding was that when self-report SB frequency increased, the LR, AUC and DOR values for the combination of the report of transient jaw pain or fatigue plus self-report SB decreased. Although we did not evaluate the EMG activity from the PSG results, this finding is consistent with the results from Rompré et al., in which participants with low frequency of SB were more likely to report craniofacial pain than those with more frequent SB (Rompré et al. 2007). The report of jaw muscle pain was associated to 40% less episodes of SB per hour in PSG, which indicated that when a jaw pain report is concomitant with PSG SB, the number of SB episodes tend to decrease (Lavigne et al. 1997). The so-called pain-adaptation model (an inverse relationship between agonist jaw muscle activity and pain intensity) has been hypothesized to explain these findings (Rompré et al. 2007). A recently published paper also questioned a direct association between masticatory muscle activity and facial pain (Conti et al. 2014)

Tooth wear is widely reported as a classic dental sign of SB. In this study, for tooth wear evaluation, we used the scale described by Lobbezoo and Naeije (Lobbezoo and Naeije 2001). As in their study, level 4 of tooth wear score was absent in our sample. We examined the right mandibular arch. As previous reported, there was no effect of dental quadrant and left and right sides have comparable reliabilities (Lobbezoo and Naeije 2001).

Abe et al. demonstrated that no difference in tooth wear grade was found between low and high frequency of muscle contractions in young adults with SB (Abe et al. 2009). It was also reported that more than 90% of dental students had at least one severe attrition facet (Seligman et al. 1988). These findings are in agreement with our results, indicating that tooth wear alone cannot be used as an absolute criterion for SB detection. Tooth wear is a cumulative record of both functional and parafunctional wear and it may be related to others factors like chemical erosion, age, occlusal conditions and dental characteristics (Lobbezoo and Naeije 2001; Koyano et al. 2008; Lavigne et al. 2008; Abe et al. 2009; Carra et al. 2012).(Lobbezoo and Naeije 2001; Koyano et al. 2008; Lavigne et al. 2008; Abe et al. 2009;

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Carra et al. 2012) Also, it neither prove ongoing bruxism activity nor can it indicate if the subject has static tooth clenching (Koyano et al. 2008).

The non-significant AUC and lower values of DOR and positive LR indicated that the diagnostic accuracy of the combinations with temporal headache or jaw locking upon awakening is insufficient for clinical application.

The strength of our study included the use of PSG as a gold standard tool for SB diagnosis. PSG studies for SB are rare because of cost and time investment and limited technological access (Raphael et al. 2012). We included an acclimation night in our study to avoid concerns about sleep behaviors. However, the natural fluctuation of SB also denotes that more than one night of exam must be done (Yachida et al. 2012).

The short-term nature of evaluation, as well as the relatively small number of individuals are also limitations of the present investigation and need to be considered when judging the actual findings. The validity of the items was based on a limited number of cases, thereby limiting comparability.

Analyses of first nights PSG recordings were used for 2 subjects in this study due to technical problems. Although it could be a limitation, no differences between first and second nights of PSG recordings on SB outcome variables or standard sleep variables have been described in the literature (Van Der Zaag et al. 2008; van der Zaag et al. 2014).

The use of questionnaires and clinical examination for SB diagnosis has many advantages like cost and their capacity to gather large amounts of information. This pilot study clarified some items with respect to the use of ICSD-3 SB criteria that could improve the use of these tools. In the diagnostic criteria for SB, the report of regular or frequent SB and the presence of (I) abnormal tooth wear or (II) transient morning jaw muscle pain or fatigue were the best discriminatory items for SB diagnosis. Since there is considerable heterogeneity in the results, the application of ICSD-3 for SB clinical diagnosis may be limited.

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# 3 *Discussion*

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### **3 DISCUSSION**

In clinical practice it is essential to know how a particular test result predicts the risk of abnormalities. Both papers presented in this thesis aimed to evaluate methods for assessing SB compared to gold standard PSG exam. In our knowledge, this is the first study to validate ICSD-3 and Grindcare® for SB diagnosis, as well as to determine the best cut-off values of EMG per hour of device use.

The ROC AUC analysis was used for the diagnostic accuracy. This curve plays a central role in evaluating diagnostic ability of tests to discriminate the true state of individuals, finding the optimal cut-off values, and comparing two alternative diagnostic methods when each method is performed on the same subject (Zou et al. 2007). The AUC driven from this analysis is not affected by decision criterion and it is also independent of prevalence of disease since it is based on sensitivity and specificity (Hajian-Tilaki 2013). The greater the AUC area, the higher the capacity to discriminate bruxers from non-bruxers, and the more useful is the method (Zou et al. 2007).

Ideally, the method that is both highly sensitive and highly specific is desirable although not always possible. When the cut-off point between normal and abnormal is changed to increase either sensitivity or specificity, there is usually a concomitant decrease in the other (Akobeng 2007). High sensitive tests are particularly important in the diagnosis of illness that might lead to death or irreversible damage (Akobeng 2007). So, high specificity methods are desirable to detect SB as it is a time-variant (Van Der Zaag et al. 2008) and non progressive condition (Lavigne and Montplaisir 1994). Low specificity tests could lead to overtreatment, with possible biological, psychological and financial damage to the individual (Akobeng 2007).

In this study, for all the methods tested, the best AUC values ranged from 0.75 to 0.79, with 90% specificity, which is acceptable (Widmer et al. 1990). Only some combinations of ICSD-3 criteria had reasonable accuracy in terms of differential diagnosis between PSG bruxers and non-bruxers: the report of regular or frequent SB and the presence of (I) abnormal tooth wear or (II) transient morning jaw muscle pain or fatigue.

The ROC analyses also determined that the cut-offs values for the single-channel EMG device use were minimum of 18 EMG/h for three nights and 19 EMG/h for five nights. This calculation used the square of distance between the point (0, 1) on the upper left hand

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corner of ROC space and any point on ROC curve. In order to obtain the optimal cut-off point, the square of this distance was minimized (Zou et al. 2007; Hajian-Tilaki 2013).

In order to refine the comparison among methods, this study used the likelihood ratio which, as its name implies, is the likelihood of a given test result in a person with a condition compared with the likelihood of this result in a person without the condition. In this study the likelihood ratio could be described as the percentage of bruxers with a given test result divided by the percentage of non-bruxers with the same result. The implications are clear: bruxers should be much more likely to have an abnormal test result than healthy individuals (Grimes and Schulz 2005).

The advantage of the LR approach is that, unlike traditional screening measures such as predictive values, results obtained with this method can be applied to populations with different SB prevalence (Deeks and Altman 2004; Grimes and Schulz 2005). In the case of SB, the data on prevalence ranged between 2 to 15% (Lavigne and Montplaisir 1994) and it seems to be geographic and age dependent. For example, a recent PSG epidemiologic study in Brazil showed that the SB prevalence was 5.5% (Maluly et al. 2013). Considering this value, 3 calculations can be performed: convert pretest probability ( $P_{pre}$ ) to pretest odds ( $O_{pre}$ ), using  $O_{pre} = P_{pre}/(1 - P_{pre})$ , then multiply the pretest odds ( $O_{pre}$ ) by the LR for the finding to derive the posttest odds (i.e.,  $O_{post} = LR \times O_{pre}$ ), and then convert posttest odds back to posttest probability, using  $P_{post} = O_{post}/(1 + O_{post})$  (Grimes and Schulz 2005). Considering the LR equal to 6, found in this study for the best SB discriminatory methods, the use of one of these methods in this study sample could increase the probability of SB diagnosis by about 28.2%. Indeed, caution is needed for this result, once this prevalence is not particularly associated with our sample characteristics.

ICSD-3 diagnostic criteria provide dichotomous test outcomes. So, in article 2, the DOR was used to indicate the best discriminatory test performance among the questions and clinical findings. In this study, the DOR meant the ratio of the odds of positivity in SB group relative to the odds of positivity in the control group. The values of DOR ranges from 0 to infinity, with higher values indicating better discriminatory test performance. A value of 1 means that the test does not discriminate between SB individuals and those without it (Glas et al. 2003). Caution is required when using only this test, as the DOR of a test is unlikely to be a test-specific constant. Its magnitude likely depends on the spectrum of condition as well as on preselection through the use of other tests (Glas et al. 2003). In this study this test was used as a complementary data.

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The strength of our study included the use of PSG as a gold standard tool for SB diagnosis. PSG studies for SB are rare because of cost and time investment and limited technological access (Raphael et al. 2012). We included an acclimation night in our study to avoid concerns about sleep behaviors. However, the natural fluctuation of SB also denotes that more than one night of exam must be done (Yachida et al. 2012).

### **Clinical diagnosis of Sleep Bruxism**

The AASM has been proposed diagnostic criteria for SB, which consists of anamnestic and clinical indicators (American Academy of Sleep Medicine 2014) and serve as practical descriptors of SB for clinical and population studies (Fernandes et al., 2013; Ommerborn et al. 2007, 2012; Troeltzsch et al. 2011) as well for systematic reviews (De Luca Canto et al. 2014). These criteria are not considered perfect or definitive for SB diagnosis (Koyano et al. 2008; Carra et al. 2012; Lobbezoo et al. 2013) and, until now, its versions have never been compared to gold standard PSG exam.

Recently the AASM published the third version of ICSD that we used in Article 2. The primary symptom of this is the report of regular or frequent tooth grinding sounds occurring during sleep. Although the report of tooth grinding is useful to assess the presence or absence of SB, it has some limitations. First, SB fluctuates substantially over time (Lavigne et al. 2001; Van Der Zaag et al. 2008). Second the occurrence of tooth grinding sounds is also highly variable, as showed in a laboratory study (Lavigne et al. 2001), and most episodes of SB may be unaccompanied by noise (Lavigne et al. 1996). And third, as reports of tooth grinding are usually associated with a sleep partner's complaint of a disturbing grinding noise, single persons could be unable to identify themselves as bruxers (Koyano et al. 2008). Almost all individuals of this study were single persons. In this study we considered as bruxers those individuals that answered, "yes" to RDC/TMD questionnaire 15c ("Have you been told, or do you notice that your grind your teeth or clench your jaw while sleeping at night?") (Dworkin and LeResche 1992). Other complicated fact is the use of the words "regular or frequent". The AASM did not specify the meaning of that. In this study, a frequency established by questionnaire already published in the literature about oral behaviors was used for this purpose (Markiewicz et al. 2006).

We understand that a single question concerning SB added cost-efficiently to large ongoing epidemiologic surveys to provide needed information concerning the prevalence of SB in specific population groups. Furthermore, the RDC/TMD single question should reduce

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translational difficulties associated with multi-item scales, making it useful for comparison of epidemiologic studies. So, the ROC analysis, with SB PSG exam as the response and self-reported SB as the predictor, provided some data that will be use in futures articles and it is exposed in Annexes section in this Thesis. Considering only the positive answer to the RDC/TMD question, the AUC is 0.70, but not significant [ $p=0.06$ ; CI (0.457-0.8810)], indicating that the self-reported SB item did not provide a significant improvement in predicting the response compared with chance (0.5). However, when frequency is considered and based on the ROC curve, the AUC improved [0.881;  $p=0.001$ ; CI 90.575-0.948)]. The frequency on the self-reported ED item that provided a good balance between sensitivity and specificity is the maximum category, i. e., defining as having SB anyone reporting more than 4 days in a week, the associated sensitivity and specificity are 90% and 60%, respectively and positive LR equal to 6 (Annexes II and III).

None of the signs and symptoms attributed to SB constitutes direct evidence of current SB activity (Koyano et al. 2008; Lobbezoo et al. 2013). Tooth wear is historically the most observable clinical sign of the presence of SB (Lobbezoo and Naeije 2001; Carlsson et al. 2003; Koyano et al. 2008). The results of this study showed that the excessive tooth wear alone was not a good criterion for the SB diagnosis.

Although our sample did not present TMD, the transient report of morning facial pain or fatigue were frequent in SB group. This finding is consistent with the pain adaptation model: an inverse relationship between agonist muscle activity and pain intensity (Rompré et al. 2007). Others studies have also described that sleep bruxers frequently report transient or low pain intensity in jaw upon waking (Bader et al. 1997; Camparis et al. 2006; Rompré et al. 2007) and, in combination with self-reported SB, represented an important symptom for SB diagnosis in this sample.

The non-significant AUC and lower values of DOR and positive LR indicated that the diagnostic accuracy of the combinations with temporal headache or jaw locking upon awakening is insufficient for clinical application. Studies have shown that more than 40% of subjects with sleep bruxism report morning headache (Bader et al. 1997; Kampe et al. 1997). Caution is needed when consider temporal headache as a clinical symptom of SB as it could be related to others sleep disorders as sleep apnea (Singh and Sahota 2013; Russell et al. 2014) or even associated to a primary headache. Recently, a study showed that SB was significantly associated to chronic migraine (Fernandes et al. 2013). Few studies have addressed jaw locking upon awakening to sleep bruxism. One of these failed to associated SB

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self-reported to disc displacement with reduction and intermittent locking in adolescents.(Kalaykova et al. 2011)

When this study was planned, the ICSD-3 was not published yet. So, some data about others signs of SB were obtained. Presence or absence of moderate to severe hyperkeratosis of cheeks was defined as a bite-like impression on the internal side of cheek mucosa, and/or tongue scalloping as identify the visualization of indentation on the lateral aspects of the tongue mucosa (Paesani et al. 2013). Examination was performed with standardized lighting conditions. Cheeks and tongue were inspected with a small mirror while the participant reclined in a dental chair (Yachida et al. 2012). In this study, the association between hyperkeratosis in cheeks or tongue indentation and SB could not be achieved [AUC=0.630; p=0.27; CI (0.389-0.831)]. The presence of these signs could be attributed to others factors as swallowing, tongue width at rest, presence of overjet, reduced vertical dimension of occlusion and gender.(Piquero et al. 1999; Yanagisawa et al. 2007; Mizutani et al. 2014) Unfortunately these factors were not addressed in the present investigation.

As for hyperkeratosis and tooth wear, the presence of muscle hypertrophy on voluntary contraction has been observed in this study. With hands on participant's face, the examiner asked him/her to relax and then to clench his/her teeth. Masseter muscle hypertrophy was considered when a 2-3 fold volume increase from rest to maximal voluntary contraction.(Lavigne et al. 2008). Lavigne et al. reported that caution is needed, as the clinical assessment of hypertrophy is not well defined (Lavigne et al. 1996). In fact the results showed that this item could not predict the presence of SB [AUC=0.55; p=0.62; CI (0.315-0.769)]. In a recent study that associated clinical signs and symptoms of SB to RMMA occurrence, the presence of muscle hypertrophy was also not significant (Yoshizawa et al. 2014).

### **Ambulatory EMG monitoring**

Since 1970s, portable EMG measurement systems has been developed to diagnose and measure SB. The advantages of these devices compared with PSG exams are linked to low cost and multiple-night recordings in the patient's home (Koyano et al. 2008; Carra et al. 2012, 2014). The devices differ in degree of complexity, ranging from miniature self-contained EMG detectors to ambulatory PSG systems, that allow monitoring more variables like EEG, EOG, ECG and respiratory features.

In order to reduce costs and facilitate handling by patients at home, compact portable devices were developing with automatic EMG detectors and analyzers. Grindcare is included

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in this category. The device (Grindcare, Medotech A/S) has a single-electrode assembly, with 3 electrode contacts. The electrode was designed to be placed over the anterior temporalis area, which provides the same type of EMG information obtained from the masseter during sleep. The device analyzes events of EMG activity, according to the signal recognition algorithm. To determine the individual contraction parameters, every night patients are requested to relax their jaw muscles for 10 seconds, then to clench their teeth around 60% of the maximum voluntary contraction for 10 seconds. The determination of the number of events was done based on the algorithm, which considered an event to be when the EMG activity exceeded the previously adjusted signal level at rest plus 20% of the maximum EMG level during the 60% contraction (Jadidi et al. 2008).

The disadvantages of the portable EMG devices are linked to technical failures that can lead to data loss and misclassification. The problem of data loss requires repeating of the sleep study, which could reduce the compliance of the patient. Some problems described in literature with Grindcare use, like lost electrodes, that could prevent EMG measurement, or compliance issues (participants forgot or could not use the EMG device) (Bernhardt et al. 2012; Yachida et al. 2012; Conti et al. 2014), led us to reduce the number of nights chosen for this study to 5 nights per week.

Moreover, it has been reported that portable EMG measurement systems tend to overestimate SB-related activity as other orofacial activities, such coughing, sighing or soliloquy (Kato et al. 2003; Lavigne et al. 2008; Carra et al. 2014). Therefore, there could be a risk of false-positive bruxers being included in research studies. Almost 30% of jaw muscle activity measured by these devices is not specific to SB in bruxers (Dutra et al. 2009; Carra et al. 2014). Our findings showed that underestimation is also possible. Using the cut-off values presented (18 EMG/h in three nights and 19 EMG/h in five nights), 5 out of 10 individuals that received PSG diagnosis of SB were enrolled as non-bruxers after Grindcare use. This fact could be explained as the orofacial movements show a time-variant feature (Lavigne et al. 2001; Van Der Zaag et al. 2008). The CV presented in this study was 33% for all the sample. The ideal study design could need more than one night of PSG exam, which was not possible in our study. Our results need to be reproduced and confirmed in larger validation studies for Grindcare. Maybe a bigger sample size study could correct the cut-off values for EMG/h to adjust the Grindcare index and reduce the risk of over or underestimation.

Other studies aimed to compare portable instrumental approaches to SB diagnosis, available for commercial use, with PSG recordings assume as the gold standard (Mainieri et al. 2012). The devices were: BiteStrip and Bruxoff.

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BiteStrip device (Scientific Laboratory Products, Ltd., Tel Aviv, Israel) is a miniature self-contained EMG detector and analyzer. Following activation and attachment to the face, the patient is instructed to perform 2 to 3 MVC to determine the individual bruxing threshold that is set at 30% of MVC. This device counts the number of jaw muscle activity events, which is estimated by simply attaching a recorder to the skin over one masseter muscle. EMG activity is collected over 5 to 6 hours. After use, the clinician can extract a motor activity score (Mainieri et al. 2012).

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. 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. The scoring could also be done manually.

The results of these studies compared with ours regarding the diagnostic accuracy data are contrasted. While in this study, the Grindcare device had 90% of sensitivity with the cut-off values chosen, the Bitestrip device had 59-100% of sensitivity of 71–84.2% (16, 17). The Bruxoff device had the highest accuracy values than Grindcare, showing an excellent agreement with PSG for both manual (AUC=0.98) and automatic scoring options (AUC=0.96). However, these comparisons had severe problems and bias. First, the devices are different not only in the system measurement, but also in the number of electrodes, position in the head or face, algorithms, and tests. The Bruxoff device included ECG, necessary for SB diagnosis. Second, different levels of EMG activity were adopted as cut-off levels in the index (10 to 30% of MVC) (Shochat et al. 2007; Ahlberg et al. 2008; Jadidi et al. 2008, 2011, 2013; Mainieri et al. 2012; Deregibus et al. 2013; Raphael et al. 2013; Castroflorio et al. 2014; Conti et al. 2014). These devices use a unique algorithm for RMMA or bursts activity scoring (Jadidi et al. 2008; Mainieri et al. 2012; Castroflorio et al. 2014). This factor impacts the specificity and sensitivity in detecting RMMA or bursts because they depend on the device use (Carra et al. 2012). Because of all cited above the comparison between the devices is impaired.

As observed by Manfredini et al., the results of the PSG studies, including ours, could not be generalized as these studies were performed in selected samples, without any other medical problem or environmental risk factors, which is different from the patients that could attend in clinical setting (Manfredini et al. 2014).

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This study provided information on two assessment methods, which are available in clinical situations and discusses their effectiveness and usefulness. More clinical studies should examine the questionnaire items and clinical examination in larger sample because they are the easiest to apply in everyday practice and have low cost. Another possible direction is to refine and test the method that can measure actual bruxism activity directly using a device that can take advantage of the mobile sensors, which have opened a new dimension in human-computer interaction.

# 4 *Conclusions*

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## **4 CONCLUSIONS**

Based on the results presented in the present study, it can be concluded that:

1. The single-channel EMG device (Grindcare®) is able to predict SB diagnosed by PSG and gold standard criteria with a reasonable accuracy;
2. The minimum of 18 EMG/h for three nights and 19 EMG/h for five nights of single-channel EMG device (Grindcare®) use are necessary for an accurate SB diagnosis;
3. The report of regular or frequent SB and the presence of (I) abnormal tooth wear or (II) transient morning jaw muscle pain or fatigue were the best discriminatory items for SB diagnosis based in the ICSD-3 diagnostic criteria;
4. Since there is considerable heterogeneity in the results, the application of ICSD-3 for SB clinical diagnosis may be limited.



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# *Annexes*

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I.



**Universidade de São Paulo  
Faculdade de Odontologia de Bauru**

**Comitê de Ética em Pesquisa**



**Processo nº 173/2011**

Bauru, 2 de dezembro de 2011.

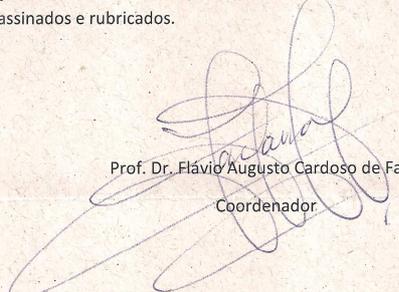
Senhor Professor,

O projeto de pesquisa encaminhado a este Comitê de Ética em Pesquisa em Seres Humanos, denominado "A utilização do dispositivo Grindcare no diagnóstico do bruxismo do sono", de autoria de Juliana Stuginski Barbosa, que será desenvolvido sob sua orientação, foi enviado ao relator para avaliação e apreciado em reunião realizada no dia **30 de novembro de 2011**.

O CEP-FOB/USP considerou o projeto APROVADO lembrando que a condição de aprovação da pesquisa propriamente dita exige o que segue:

- que sejam encaminhados ao CEP-FOB/USP relatórios anuais sobre o andamento da pesquisa (parciais e finais), conforme o cronograma apresentado;
- que sejam notificados ao CEP-FOB/USP, com a devida justificativa, qualquer modificação na metodologia e/ou título e a inclusão ou exclusão de autores;
- na apresentação do relatório final, incluir todos os TCLEs e/ou termos de doação de dentes devidamente assinados e rubricados.

Atenciosamente,

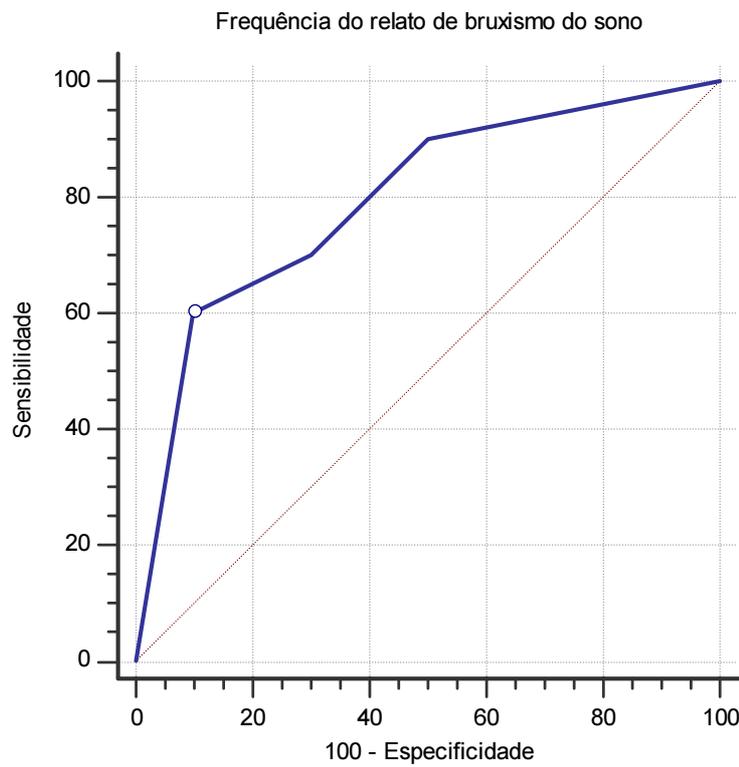
  
Prof. Dr. Flávio Augusto Cardoso de Faria  
Coordenador

**Prof. Dr. Paulo César Rodrigues Conti**  
Docente do Departamento de Prótese

II. Calculation of the sensitivity, specificity, likelihood ratios (LR), positive (PPV) and negative predictive values (NPV) for the self-report sleep bruxism single question.

| “Have you been told, or do you notice that your grind your teeth or clench your jaw while sleeping at night?” | Never               | 1-3 nights per month | 1-3 nights per week | 4-7 nights per week |
|---|---------------------|----------------------|---------------------|---------------------|
| Sensitivity (CI)  | 100% (69,2 - 100,0) | 90% (55,5 - 99,7)    | 70% (34,8 - 93,3)   | 60% (26,2 - 87,8)   |
| Specificity (CI)  | 0% (0,0 - 30,8)     | 50% (18,7 - 81,3)    | 70% (34,8 - 93,3)   | 90% (55,5 - 99,7)   |
| +LR (CI)  | 1,00 (1,0 - 1,0)    | 1,80 (0,9 - 3,5)     | 2,33 (0,8 - 6,5)    | 6,00 (0,9 - 41,2)   |
| -LR (CI)  | -                   | 0,20 (0,03 - 1,4)    | 0,43 (0,2 - 1,2)    | 0,44 (0,2 - 1,0)    |
| PPV (CI)  | 50% (27,2 - 72,8)   | 64,3% (35,1 - 87,2)  | 70% (34,8 - 93,3)   | 85,7% (42,1 - 99,6) |
| NPV (CI)  | 83,3% (35,9 - 99,6) | 70% (34,8 - 93,3)    | 69,2% (38,6 - 90,9) | 50% (27,2 - 72,8)   |

Legend: CI- Confident Interval



Curva resultante do teste Receiver Operator Characteristic (ROC) para o auto relato de bruxismo do sono nos últimos trinta dias de acordo com a frequência do relato para predizer o diagnóstico polissonográfico de bruxismo do sono. Área sobre a curva – 0.795.