A pilot study to test the validity of a piezoelectric intra-splint force detector for monitoring of sleep bruxism in comparison to portable polysomnography

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Abstract

Purpose: To test the validity of a force-based detection system (ISFD: intra-splint force detector) to record sleep bruxism (SB) in comparison to portable polysomnography (PSG).

Methods: Simultaneous portable PSG recordings with a masseter electromyography (EMG) channel and ISFD with a deformation-sensitive piezoelectric film were performed on six participants with definite SB. First, simulated bruxism behaviors (static clenching, grinding, tapping, and rhythmic clenching) were recorded using both EMG and ISFD. Using these data, interval and duration criteria for ISFD data conditioning were established. Then, portable PSG recordings were conducted with the ISFD during sleep. Using the above criteria, ISFD events were compared with EMG-based SB episodes (the gold standard), and the sensitivity and positive predictive value of ISFD events were calculated. Spearman’s correlation coefficients between true-positive ISFD events and SB episodes were then calculated.

Results: Among the tested conditioning criteria, a 3-s interval combined with a 1-s duration was selected. The median sensitivity and positive predictive value for the ISFD were 0.861 and 0.585, respectively. The duration of true-positive ISFD events was correlated with that of EMG-based SB episodes (rho = 0.658, P < 0.01).

Conclusion: ISFD has validity for SB detection and could be an alternative to single-channel EMG-based recordings.

Keywords: bite force, masseter electromyography, piezoelectric film, sleep bruxism

Introduction

Sleep bruxism (SB) is a sleep-related movement disorder defined in the third edition of The International Classification of Sleep Disorders (ICSD-3) as “repetitive jaw-muscle activity characterized by tooth clenching or grinding and/or bracing or thrusting of the mandible” occurring during sleep [1]. SB may cause abnormal tooth attrition [2-4], fractures of dental prostheses and teeth [5], and exacerbation of periodontal disease and temporomandibular disorders [6,7]. Thus, for SB, accurate diagnosis and appropriate management are needed to maintain the oral health of affected individuals and ensure a good prognosis after dental treatment.

In clinical settings, SB has typically been diagnosed from information obtained through questionnaires, self-reports, and clinical examinations. However, on the basis of clinical signs and symptoms alone, diagnosis is generally restricted to “probable SB” [8], as it is currently impossible to evaluate SB severity quantitatively.

The gold standard for SB recording is polysomnography (PSG) with audio-video recordings in a sleep laboratory. However, the main problems associated with this approach are cost and technical complexity, as participants are required to sleep at a laboratory and to be wired directly to many recording devices. In addition, these recordings require manual scoring by a sleep technician [9].

In natural environments, SB measurements have been performed using electromyography (EMG) to monitor jaw-closing muscle activity using a single-channel portable EMG device [10]. The advantage of SB recording is that it can be performed in the patient’s home environment across multiple nights at minimum expense, allowing a better understanding of the variations and fluctuations in SB. Even for single-channel EMG-based systems, electrode placement can be problematic. It is difficult to require patients to clean their skin and position the electrodes precisely in the same place night after night. It is well documented that electrode relocation and changes in skin impedance levels can cause variation in EMG recordings [11]. Furthermore, single-channel EMG recording data may be contaminated by wire and electrode movements [12].

Considering the limitations of these SB recording methods, Takeuchi and colleagues have developed an easy-to-operate recording device that utilizes an oral appliance (OA) to measure quantitatively the force produced at the teeth [12,13]. This force-detection recording system uses a deformation-sensitive piezoelectric film embedded 1 mm below the occlusal surface of a modified maxillary OA. This so-called “Intra-Splint Force Detector” (ISFD) is free of positioning variability artifacts because it fits to the teeth precisely and stably, and also eliminates motion artifacts due to electrode and wire movements. Furthermore, recordings are obtained as easily as using an OA prescribed for SB.

A pilot study has reported a high correlation between ISFD signals and the masseter EMG during simulated SB behavior [13]. A sleep-laboratory study involving a single SB patient revealed an ISFD sensitivity of 0.89 when compared with audio-video PSG-based masseter EMG activity as the gold standard [12]. Furthermore, multiple-night ISFD recordings from two participant groups (SB and control participants) in their home environment found that the SB group exhibited significantly longer SB events than the control group, thus adding credibility to the ISFD method as a means of recording SB [12]. However, the validity of the ISFD as an SB recording method has not yet been investigated systematically.

Therefore, the present study was performed to first establish the conditioning criteria for ISFD signals for quantitative measurement of SB episodes, and then to evaluate the validity of the ISFD system for SB recording in comparison with portable PSG-based EMG recording as the gold standard.

Materials and Methods

Participants

Between February 2020 and August 2021, six healthy adults aged 24-33 years (5 women and 1 man; mean age ± standard deviation: 26.2 ± 3.1 years) attending the Showa University Dental Hospital were recruited based upon the clinical diagnostic criteria for SB [14]. The inclusion criteria were: (1) ≥2 missing molars, except for the third molars, (2) usage of a removable denture, (3) active dental treatment, including orthodontic therapy, (4) use of medication with possible effects on motor behavior and sleep, (5) drug or alcohol abuse, (6) major psychiatric or neurological disorders, and
(7) sleep disorders (e.g., narcolepsy, sleep apnea, restless legs syndrome).

The participants completed two unattended at-home PSG recordings during sleep using a portable PSG device (Sleep Profiler, Advanced Brain Monitoring Inc., Goleta, CA, USA) [15]. The second PSG dataset was assessed for SB diagnosis to avoid any “first night” effect [16]. Participants were assigned a confirmed diagnosis of “definite” SB [8,17] on the basis of the following criteria: (1) ≥4 SB episodes per hour of sleep, (2) ≥25 SB bursts per hour of sleep, or (3) ≥6 SB bursts per episode. Participants were required to meet ≥1 criteria, representing a modification of the research diagnostic criteria for SB in a laboratory audio-video PSG setting [9,18].

This clinical study was approved by the institutional research ethics committee (Showa University Clinical Research Review Board, No. 20) on February 13, 2020, and followed the ethical principles of the Declaration of Helsinki and the Clinical Trials Act (Japan). All candidates provided written informed consent before participating. The study protocol was registered in JRCT (Japan Registry of Clinical Trials; https://jRCT.niph.go.jp/, trial registration number: jRCTs032190225) on February 27, 2020.

ISFD

The ISFD (Fig. 1, I.T. Engineering Co., Ltd., Tokyo, Japan; 40 × 21 × 13 mm, 10 g) system used a 40-μm-thick pressure-sensitive piezoelectric film (Elmech Electronics Industries Co., Ltd., Niigata, Japan) embedded 1 mm below the occlusal surface of a modified maxillary stabilization appliance composed of 3D-printed resin (Freeprint ortho; Detax GmbH & Co. KG, Ettlingen, Germany) [12,13]. The deformation of the piezoelectric film caused by any substantial occlusal force causes the piezoelectric sensor to generate an electrical signal that varies depending on the degree of mechanical stress applied to the film. These signals are amplified, and every signal exceeding the preset monitoring level is stored in the recording unit [19]. A single dentist (R.A.) adjusted the occlusion of the modified OA to achieve simultaneous multiple contacts at the centric position with full, balanced occlusion during eccentric movements.

Portable PSG recordings

To evaluate SB-related masticatory muscle activity, masseter EMG recordings were obtained using a portable PSG device (Sleep Profiler, Advanced Brain Monitoring Inc., Goleta, CA, USA, Fig. 2). This battery-powered head-mounted device (72 g, 71 × 20 × 48 mm) was modified to record three frontopolar electroencephalograms (EEGs) between AF7-AF8, AF7-Fpz, and AF8-Fpz; quantitative snoring sound; pulse rate; head movement and position; and EMG from the right masseter. The sampling frequency of the EMG was 256 Hz. The low-frequency filter was 0.1 Hz, and the high-frequency filter was 67 Hz.

After nocturnal recordings, total sleep time, sleep efficiency, sleep latency, awakening index, and microarousal index were calculated using the automatic analysis function of the manufacturer’s software.

Measurements of simulated bruxism during wakefulness

The participants were asked to wear a portable PSG and the ISFD to simultaneously record both the EMG and ISFD signals, and were instructed to perform an experiment involving simulated bruxism behavior including four different tasks (static clenching, grinding, tapping, and rhythmic clenching) in a modification of the method reported by Takeuchi et al. [13]. Prior to the four tasks, maximum voluntary clenching was performed for 3 s. Then, the following tasks were carried out: (1) a 5-s static clenching task three times, (2) a 5-s grinding task three times, (3) a 5-s tooth tapping task at a rate of twice per second three times, and (4) a 10-s rhythmic clenching task at a rate of once per second (Fig. 3). The rest period between each task was 20 s. The participants were instructed to perform these tasks at the maximum occlusal force and allowed to practice these tasks before the experiment.

SB measurements

To minimize any short-term inhibitory effects of the OA [20,21] and to allow participants to familiarize themselves with ISFD use, they were asked to wear it for 15 consecutive nights at home. The simultaneous ISFD
and portable PSG recordings were performed on the 14th and 15th nights. Only the 15th-night data were used for analysis to avoid the first-night effect of experimental recordings.

SB episodes were scored using the right masseter muscle EMG. At the beginning of night recording, maximum voluntary clenching was performed for 3 s three times. All EMG amplitudes >10% of the mean maximum voluntary contraction were identified using the manufacturer’s software. Then, an experienced scorer (Y.N.) blinded to the participants visually inspected the EMG signals and excluded episodes occurring in the awake state and those judged to be caused by electrode movements. The remaining episodes were categorized into three types of SB episodes separated by ≥3 s interval of stable background EMG: phasic episodes (≥3 s EMG bursts, each lasting 0.25-2.0 s), tonic episodes (EMG burst >2.0 s) and mixed episodes (combined phasic and tonic episodes) [9]. The number and duration of SB episodes per night were calculated.

**Data analysis**

**Analysis 1: Conditioning of the ISFD signal recorded during simulated bruxism behavior**

EMG signals recorded from the portable PSG device were scored similarly to those recorded during sleep.

First, the raw ISFD signals were rectified and converted into absolute values (Fig. 4). Next, all ISFD signals above a threshold set at 10% [13] were considered potential ISFD events. ISFD events were then determined by ≥3.0 s interval of stable background EMG: phasic episodes (≥3 s EMG bursts, each lasting 0.25-2.0 s), tonic episodes (EMG burst >2.0 s) and mixed episodes (combined phasic and tonic episodes) [9]. The number and duration of SB episodes scored using the four criteria for each task are also summarized in Table 1.

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The sensitivity (true-positive / [true-positive + false-negative]) were calculated. In addition, Spearman’s correlation coefficients between the duration of true-positive events detected by EMG and ISFD were calculated.

Next, these true-positive events were classified into phasic, tonic, or mixed episodes according to the EMG activity pattern. Spearman’s correlation coefficients were calculated for each type of episode. The significance level was set at 0.05 (JMP Pro 16, SAS Institute Inc., Cary, NC, USA).

**Results**

**Analysis 1**

The average duration of EMG events scored using the above criteria for each task and averaged ISFD event durations scored using the four different criteria (1-s and 3-s intervals and 1-s and 2-s durations) are summarized in Table 1.

Correlation coefficients between EMG event duration and ISFD event durations scored using the four criteria for each task are also summarized in Table 1. The correlation coefficients between event durations scored by the two methods recorded during the grinding and tapping tasks were consistently significant, being independent of ISFD conditioning criteria and >0.85. In contrast, those for the rhythmic clenching task were not significant. For the clenching task, the correlation coefficients for a 3-s interval were higher than those for a 1-s interval. In addition, the correlation coefficient for the rhythmic clenching task with a 3-s interval and a 1-s duration was the highest among the four combinations. Therefore, a combination of a 3-s interval and a 1-s duration was selected as the criterion for ISFD conditioning.

**Analysis 2:**

The sleep variables recorded by the portable PSG during sleep as well as the EMG-based SB episodes and the ISFD data conditioned using the 3-s interval and 1-s duration criteria are summarized in Table 2. The sensitivity and PPV for all six participants are shown in Table 3.

Spearman’s correlation coefficients between the duration of true-positive ISFD events and EMG-based SB episodes are shown in Table 4. When SB episodes were classified as phasic, tonic, or mixed, significant correlations with ISFD events were found for phasic episodes (ρ = 0.648, n = 75, P < 0.01) and mixed episodes (ρ = 0.325, n = 40, P = 0.04), but not for tonic episodes (ρ = 0.148, n = 15, P = 0.60).

**Discussion**

Visual assessment of the wakefulness data showed that the ISFD signals during tooth grinding were strong, indicating that grinding behavior is better recorded using the ISFD signal than by using the masseter EMG. This finding was not surprising because the motion during side-to-side grinding behavior is produced by jaw muscles with a more horizontal orientation, not by the masseter muscle, which is vertically oriented [13]. Another visual finding was that the static clenching task was better recorded by EMG than by ISFD (Fig. 4). This was predictable and inherent...
The very nature of piezoelectric sensors. These sensors are best at detecting rapid changes in force, not static force, and therefore the ISFD signal clearly detected the clenching onset and offset points, although the signal intensity was not as strong during the task. These phenomena have been well documented by Takeuchi et al., who compared signals captured by masseter EMG and ISFD during simulated bruxism behavior [13].

This study conditioned the ISFD signal to compensate for the above-mentioned weakness of ISFD detection by applying the interval criteria.
criteria to the ISFD signals and found slightly better reproducibility with the 1-s duration criterion. All recorded sleep variables were within the normal range [24,25], suggesting that the experimental setting did not disturb the participants’ sleep quality. The median sensitivity and PPV of the ISFD system were 0.861 (minimum 0.719 to maximum 0.905) and 0.585 (minimum 0.510 to maximum 0.933), respectively. Specificity could not be calculated because the number of false-negative events was not available. The ISFD event duration detection was significantly correlated with that detected in the EMG-based SB episodes. However, the duration and number of ISFD events were approximately 1.3 times greater than those of the EMG-based SB episodes. In other words, while sensitivity was relatively high, the ISFD tended to overestimate SB episodes with false-positive ISFD events. Because the ISFD was originally developed as a single-channel measurement device for SB with clinical utility, event analyses have been conducted without referring to sleep status information such as EEG. However, when EMG-based SB episodes were analyzed, EMG signals during wakefulness and those judged as artifact signals due to electrode movements were eliminated by referring to the EEG and head movement data of the portable PSG. In fact, all 83 false-positive ISFD events concerned with potential EMG activities, and were not judged as SB episodes because they occurred in a wakeful state (45.8%) or were associated with body movements (21.7%). The authors previous audio-video PSG study involving a single SB patient excluded every ISFD event that was judged as a non-SB episode by referring to PSG-based sleep monitoring data, and consequently demonstrated excellent ISFD PPV (0.90) [12].

The number of SB episodes recorded by a single-channel portable EMG, without sleep status monitoring, was reported to be approximately 1.9 times greater than that recorded by PSG [26]. Furthermore, another PSG study reported that the PPV of single-channel EMG recordings was as low as 0.231, while sensitivity was quite high (0.988) [27]. That study found no significant correlation between SB episode durations recorded with single-channel EMG and with audio-video PSG [27]. Overall, these studies, including the present one, suggest that SB recordings without sleep monitoring tend to overestimate SB. This should be regarded as a limitation of any portable single-channel recording system that monitors such phenomena during sleep. However, the validity of SB detection by the ISFD might be superior to single-channel EMG [12,28].

This study also investigated the effects of SB episode patterns, including phasic, tonic, and mixed events, on the duration of ISFD events. Among 130 true-positive ISFD events, the proportions of phasic, tonic, and mixed events were 57.7%, 11.5%, and 30.1%, respectively. Despite the significant correlations found between the durations detected by the ISFD and EMG for phasic and mixed episodes, no such correlation was found for tonic episodes. Furthermore, most of the 13 false-negative ISFD events (53.8%) were tonic episodes. This finding is inherent to the nature of piezoelectric sensors, which are best at detecting changes in force, and not static force, as explained above. However, there were significant correlations between the two methods for phasic and mixed episodes, accounting for about 85% of all SB episodes, and a significant but moderate (Spearman’s $\rho = 0.658$) correlation was found for all true-positive ISFD events, supporting the validity of the ISFD method. Compared with a single-channel portable EMG device [26,27], ISFD is less likely to be affected by setup errors in a home environment but is as easy to handle as wearing an OA prescribed for SB. A certain number of false-positive ISFD events were observed, but the proportion tended to be lower than that reported previously for single-channel portable EMG [26,27]. These results suggest that the ISFD may be clinically useful for measuring SB levels. In addition, the results obtained by ISFD recording may more accurately reflect the effects of SB-related occlusal force on teeth and dental prostheses than those of EMG, since the ISFD system directly detects occlusal force.

However, there are confounding effects of OA on SB evaluations by ISFD. Several studies have reported decreased SB-related masticatory muscle activity immediately after OA delivery, returning to the baseline level as patients grow accustomed to the OA [20,21]. The target population of the present study were patients with chronic severe SB who accepted daily use of OA to protect their teeth and dental prostheses against the occlusal forces related to SB. Long-term SB monitoring is feasible in such patients by using this system with a minimum OA confounding effect. The OA was designed using computer-aided design software and fabricated with a 3D printer in order to keep the piezoelectric film position in the OA as consistent as possible, independent of the participants. However, it was impossible to fully control the variability of the thickness of the OA above the piezoelectric film and the occlusal contact relationship. It should be noted that these differences may have affected the capacity of the ISFD to detect SB episodes, and this should be considered one of the study limitations.

Moreover, to manage SB in such patients, the authors developed an SB inhibitory system using an ISFD that can apply vibratory feedback stimulation in response to detected SB-related occlusal forces on the OA. Previous studies have already demonstrated that this system can successfully control SB-related masticatory muscle activity [19,24,25]. In these studies, ISFD signals were used to trigger the vibratory stimulation, and not to evaluate the SB level; therefore, to monitor the SB level, the system required an additional SB recording system such as a portable PSG. The present findings show that the ISFD allows nightly SB monitoring and assessment of the therapeutic effects of vibratory feedback stimulation by ISFD alone, thus dramatically improving the clinical utility of the system.

The present study exclusively recruited patients with definite SB. While a previous study reported a significant group difference in SB event durations detected by the ISFD system between the SB and control groups [12], further research on individuals with multiple SB levels is warranted to verify the diagnostic validity of the ISFD. However, such a clinical study could only be performed after reporting the validity of the system in comparison with the gold standard method, as was the case here. Despite the above limitations, the present results suggest that the ISFD has the potential to detect SB episodes more accurately than single-channel EMG recording. Since the system is free of setup errors and easy to handle, it could be an alternative to single-channel EMG-based SB recordings, especially for patients with chronic SB who need long-term recordings.

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Conflict of interest
All authors declare that they have no known competing financial interests or personal relationships that could have potentially influenced the work reported in this paper.

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