Poster presented at the APSS 2001- proof of concept

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Introduction: Sleep Bruxism is characterized by the involuntary grinding and clenching of teeth during sleep. Symptoms include tooth wear, temporomandibular joint (TMJ) dysfunction, chewing difficulties, headaches and daytime sleepiness. Based on a large survey, the prevalence of bruxism in the adult population is estimated at 8% (1), however, as many individuals may be unaware of this condition, the prevalence is most likely to be higher. Bruxism is diagnosed based on clinical examination of the teeth, complaints of jaw and masticatory pain, and reports by the bed partner of the grinding noise.
Patients suspected of bruxism are not routinely referred to the sleep laboratory. Thus, clinical and experimental data is scarce, and there is no widely accepted "gold standard" for a definitive, objective diagnosis. We present a novel home monitoring device for the detection of bruxism.

Methods: The BiteStrip is a miniature single-use electronic device designed as a front line screener for bruxism . It is comprised of three EMG electrodes and an amplifier to acquire masticatory muscle signals, a CPU with real time software, which detects and analyses EMG patterns, a permanent chemical display which presents the outcome in the morning, a light emitting diode (LED) and a lithium battery.
All elements are integrated on a single flexible substrate. At bedtime, patients are instructed to attach the device to the cheek over the mandible, to activate it and to perform a series of maximal strength clenching and grinding activities, in order to establish an individual threshold for the nighttime monitoring.
The device must be worn for at least 3 hours of sleep. In the morning, patients deactivate the device, and wait for approximately 20 minutes for the bruxism index (number of bruxing events per hour of recording) to be displayed. We present the preliminary testing of the device with comparison to masticatory muscle EMG recorded concomitantly on either cheek in the sleep laboratory.

Results: Figure 2 displays a segment of the recordings. Output of the BiteStrip is displayed above the masticatory muscle EMG. Note that the BiteStrip detects only those EMG bursts, which exceed the individually predetermined threshold.

Conclusions: The BiteStrip is a viable, promising device for the detection of bruxism. Further testing and validation on a large population of bruxers is underway.

References: Lavigne, G.J. and Montplaisir, J.Y. Restless legs syndrome and sleep bruxism: prevalence and association among Canadians. Sleep 1994; 17(8):739-43.

Poster presented at the ISRS 2002 - preliminary results

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Introduction: Sleep Bruxism (SB) is characterized by involuntary grinding and clenching of teeth during sleep. The movements are rhythmic or tonic contractions of the masseter and other jaw muscles. Patients are usually unaware of the condition, and bed partners or roommates usually complain of the unpleasant noise. Symptoms include abnormal wearing of teeth, temporomandibular joint (TMJ) dysfunction or pain, chewing difficulties, headaches and daytime sleepiness. The prevalence of SB is 8% in the adult population. SB is diagnosed based on clinical examination of the teeth, complaints of jaw and masticatory pain, and subjective reports by the bed partner or family member, of the grinding and clenching noise. Currently there is no "gold standard" for a definitive, objective diagnosis. Due to high costs of PSG in-lab recordings, patients suspected of SB are not routinely referred to the sleep laboratory. In light of the need for an efficient, low cost, automated objective screening device able to monitor bruxism episodes at night, Scientific Laboratory Products (SLP) Ltd. have developed the BiteStrip®. This screener is a small, lightweight device attached to the cheek, over the TMJ. The BiteStrip® consists of two pre-gelled EMG electrodes, real time analysis hardware and software, a miniature display unit and a lithium battery. The device detects the bruxism events, computes their total amount and displays a score (the"Bscore") in the morning. The purpose of this study was to validate the BiteStrip® against polysomnographic recordings with masseter EMG.

Methods: 11 consecutive patients age 18-45 referred to the sleep lab for sleep disorders of any kind participated. Patients underwent full PSG recordings including masseter EMG in the sleep laboratory concomitantly with the use of the BiteStrip® for a single night. Bscores were collected and masseter EMG scored by experienced PSG scorers. Due to the small number of subjects, Spearman rank correlations were computed for the in-lab Bscores against the PSG-determined total number of bruxism events (EMG). Furthermore, to rule out sleep apnea as a third factor causing the EMG signal, correlations were computed between Bscore and the respiratory disturbance index (RDI). Finally, to assess the relations between bruxism and sleep, correlations were computed between the Bscore and sleep efficiency (SE).

Results: One out of 10 subjects did not complete the study, as the BiteStrip® was removed from this subject early in the night. For the remaining 10 subjects (see table 1) the correlation between EMG and Bscore was: $r=0.96$ ($p<0.001$). Insignificant correlations were found between Bscore and RDI ($r=0.44$, $p<0.2$) as well as between Bscore and SE ($r=-0.37$, $p<0.3$).

Table 1: Spearman correlations (r) and p values

	EMG	RDI	SE
Bscore	0.96 ($p<0.001$)	0.44 ($p<0.2$)	-0.37 ($p<0.3$)

Conclusions: Despite the small number of subjects, an excellent correlation was found between traditional PSG derived EMG recordings and the Bscore derived by the BiteStrip®. This was not related to movements caused by sleep apnea. The relationship between bruxism and sleep quality remains unclear, and deserves further investigation. We conclude that the BiteStrip® may be an excellent tool for patients and doctors of patients suspected of Bruxism.

Poster presented at the APSS 2003 - validation of the BiteStrip

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Introduction: The Bitestrip is a miniature single-use electronic screener for sleep bruxism (SB). It is comprised of EMG electrodes and an amplifier to acquire masticatory muscle signals, a CPU with real time software, which detects and analyses EMG patterns, a permanent chemical display which presents the outcome in the morning, a light emitting diode (LED) and a lithium battery. All elements are integrated on a single flexible substrate. At bedtime, it is attached to the cheek over the mandible. Patients are instructed to perform 4-5 maximum voluntary clenches (MVCs) in order to establish an individual threshold for bruxing events. In the morning, after removal of the device, the total number of bruxing events throughout the night is displayed. A good correlation between BiteStrip results and traditional EMG scoring of polysomnographic recordings has been reported previously. In the present study, performance of the BiteStrip is evaluated in unattended home studies.

Methods: Eleven adult subjects with a history of SB based on clinical evaluation participated in the study (BRUX). Six adult subjects with no history of SB based on subjective reports alone participated as controls (NBRUX). All subjects used the BiteStrip for one to three nights. BiteStrips were collected and final scores were averaged across nights per subject. As the BiteStrip final score represents not a single number but rather a range (e.g., 100-124), each subject had 2 scores: an averaged minimum (MINAVG) and an averaged maximum (MAXAVG). Non-parametric Mann-Whitney tests for 2 independent samples were performed between groups for MINAVG and MAXAVG scores.

Results: Altogether, 46 nights were completed. Eight nights were excluded due to battery failure (3), premature removal of the device (3) or unclear display (2). Mean (+/-SD) minimum scores were 130.53(+/-130.41) and 7.67(+/-13.46) and mean maximum scores were 178.30(+/-177.22) and 31.67(+/-13.46) for the BRUX and NBRUX groups respectively. Mann-Whitney U statistics were 2.5 for MINAVG (p=0.001, one tailed) and 3.5 for MAXAVG (p=0.002, one tailed).