

# **Validation of the BiteStrip®: A Screener for Sleep Bruxism.**

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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.