

Effect of conditioning electrical stimuli on temporalis electromyographic activity during sleep

F. JADIDI*, E. CASTRILLON* & P. SVENSSON*^{†,‡} *Department of Clinical Oral Physiology, School of Dentistry, University of Aarhus, [†]Department of Oral Maxillofacial Surgery, Aarhus University Hospital, Aarhus and [‡]Orofacial Pain Laboratory, Center for Sensory-Motor Interaction, Aalborg University, Aalborg, Denmark

SUMMARY Inhibitory reflexes during voluntary contractions are well described; however, few studies have attempted to use such reflex-mechanisms to modulate electromyographic (EMG) activity in jaw-closing muscles during sleep. The aim was to apply a new intelligent biofeedback device (Grindcare®) using electrical pulses to inhibit EMG activity in the temporalis muscle during sleep. Fourteen volunteers participated who were aware of jaw-clenching activity as indicated by complaints from sleep partner, soreness or pain in the jaw-muscle upon awakening and tooth wear facets. The EMG activity was recorded from the temporalis muscle, online analysed and the frequency content determined using a signal recognition algorithm. Based on specific individual parameters for pattern recognition, an electrical square-wave pulse train, which was adjusted to a clear, but non-painful intensity (range 1–7 mA) was applied through the EMG electrodes, if jaw-clenching activity was detected. All volunteers

had baseline EMG recordings for five to seven consecutive nights, followed by 3-weeks EMG recordings with the feedback turned on, 2 weeks without the feedback and finally 3 weeks with the biofeedback on. There were no session effects on the average duration of sleep hours ($P = 0.626$). The number of EMG episodes/hour sleep was significantly reduced during the two sessions with biofeedback ($54 \pm 14\%$; $55 \pm 17\%$, $P < 0.001$) compared with baseline EMG activity and the session without biofeedback. The present study suggests that biofeedback with electrical pulses does not cause major disruption in sleep and is associated with pronounced reduction in temporalis EMG activity during sleep.

KEYWORDS: bruxism, electromyography, electrical stimulation, biofeedback, signal recognition algorithm, sleep disorder

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Introduction

According to the International Classification of Sleep Disorders, sleep bruxism (SB) is a sleep-related movement disorder mainly characterized by rhythmic masticatory muscle activity at a frequency of 1 Hz and by occasional tooth grinding (1). SB is probably an extreme manifestation of a masticatory muscle activity occurring during sleep in most individuals. Bruxism can in the time domain be divided into chronic and acute conditions. Acute episodes with bruxism can happen to all and there is some evidence that psycho-physiological factors such as stress, anxiety, fear and frustra-

tion may play a major role in the aetiology of this type of bruxism (2, 3). Chronic bruxism can be divided into nocturnal and diurnal bruxism (sleep and wakeful bruxism) (4). Diurnal bruxism is characterized by clenching of the upper and lower jaws and grinding of the teeth, although dominated by the latter. When it occurs during sleep, it belongs to the family of sleep disorders (5) and will be referred to here as SB (1).

The patho-physiology of SB is becoming clearer, and there is good evidence outlining some of the underlying neurophysiology and neurochemistry of rhythmic jaw movements in relation to chewing, swallowing and breathing (6). Bruxism may cause dental damages such

as attrition, wear and fractures of oral restorations, fatigue/soreness in the jaw muscles upon awakening and implant failure (7). Furthermore, bruxism has often been associated with pain in the back of the head and chronic headache (4). It may take years for the first visible signs of worn teeth to appear; yet, often it is the attrition that leads to a suggestion of past or present bruxism. Available estimates of the prevalence of bruxism range from 5% to 100%, but current estimates for the US population often settle on the 5–20% range (4).

A common clinical observation among bruxers is that daytime stress and anxiety seem to increase their nocturnal bruxing activities. Clark (1980) reported a significant correlation between increase urinary catecholamines as a physiological index of stress and increased nocturnal electromyographic (EMG) levels (8). As bruxism often is unconscious it may normally only be perceived by the housemates as an unpleasant squeaky noise and over 80% of all bruxers may be unaware of the activity (9). This form of the affliction can be relieved relatively easy by drawing the attention of the person to the bruxism. With regard to SB, the problem is more complex as it is difficult to distinguish between bruxism events and other muscle activity, e.g., during chewing, talking, grimacing etc. This will require polysomnographic recordings including video and sound registrations. It is noted, though, that the muscle activity of the bruxing episodes is observed to range between three and 66 s with an average of 9 s (10).

A clinical goal will often be to modify or decrease the level of bruxism. Indeed, the control of bruxism itself is exceedingly difficult and many techniques have been used including hypnosis (11), occlusal adjustment (12), night-guard (13), physiotherapy and muscle relaxation exercises (14), acupuncture (15) and biofeedback (16, 17). The most common treatment of SB involves protection of the teeth by occlusal splints (OS) (18). Yet, although OS minimizes damage to the teeth, it does not actually prevent or cure bruxism (18). A recent study reported that OS reduced muscle activity associated with SB (19) but this effect may only be temporary (20). Thus, there is generally consensus that OS may prevent further wear of the tooth substances but is unable to modify the propensity to brux (4). Alternative techniques have attempted to use auditory feedback based on registration of EMG activity during sleep but with significant interferences with sleep stage

and quality (21). Recently, a study reported the use of contingent electrical stimulation of the perioral region in seven subjects and showed a decrease in the EMG activity by 37% over five nights (17). This approach could therefore represent an attractive alternative to current conventional treatments.

The present study aimed to determine the effect of electrical stimulation based on a novel feedback device derived from the measurement of EMG activity predominantly associated with tooth-grinding or clenching during sleep. A secondary aim was to obtain preliminary insight into the clinical consequences of the biofeedback on jaw symptoms and other patient-related variables.

Materials and methods

Patients

A total of 14 patients (six men, eight women, age: 24–60 years) who were aware of a tooth-grinding activity and who fulfilled the following criteria in accordance with (22): (i) sound associated with tooth-grinding or tooth-clenching reported by a bed partner; (ii) tooth wear and/or shiny spots on dental restorations; (iii) frequent reports of stiffness, fatigue, or discomfort in the jaw muscles upon awakening. The subjects were recruited amongst patients referred to the Department of Clinical Oral Physiology, School of Dentistry, University of Aarhus, Denmark. The project was conducted in accordance with Helsinki guidelines and had been approved by the local ethics committee.

Study design

The study was designed as a randomized, single-blinded cross-over trial. The patients were randomized into two groups to use a portable EMG device (*) in five sessions alternating the active and inactive sessions with biofeedback (Fig. 1). The patients were not aware of the device being active or inactive because electrical stimuli were triggered during the first 20 min in both conditions in an attempt to 'blind' the patient. After inclusion and randomization, the patients were examined by a dentist using the research diagnostic criteria for temporomandibular disorders (RDC/TMD) (23), attrition scores (24), a Danish version of the McGill Pain

*Grindcare®; Medotech, Aarhus, Denmark.

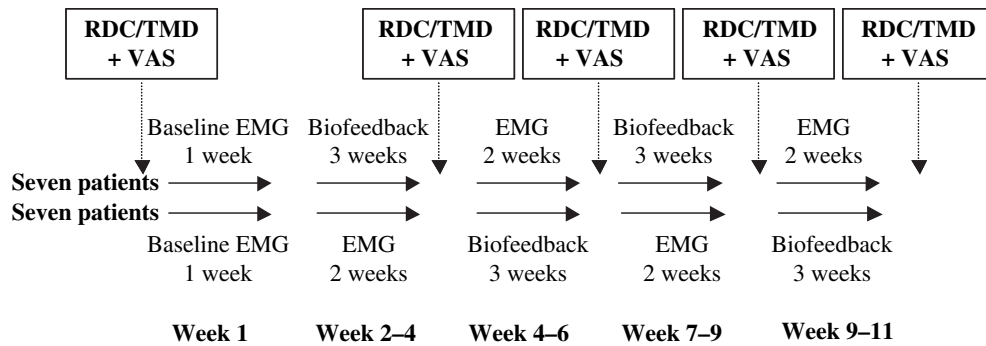


Fig. 1. Overview of the design of the clinical experiment.

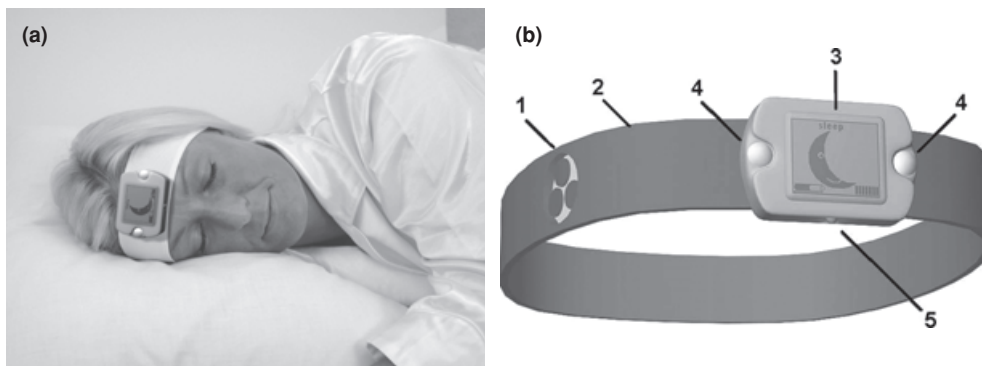


Fig. 2. (a) The Biofeedback device (*Grindcare®) placed at the forehead. (b) The device consists of (1) combined electromyographic and stimulation electrodes, which are in close proximity to the skin and placed at the anterior part of the temporalis muscle, (2) strap for carrying the apparatus around the forehead (3) display for user interface, (4) pushbuttons for operating the device (set-up procedure and selection of the level of stimuli) and (5) a three-colour LED indicator. Furthermore, the apparatus comprise an USB-connector placed in the back of the device for data connection to a PC and/or to a battery charger (not shown in Fig. 2b).

Questionnaire (MPQ) (25), and the Oral Health Impact Profile (OHIP) (26). During the first week, all patients used the device during sleep without biofeedback to record the pre-treatment baseline level (recordings for five to seven consecutive nights). All patients received comprehensive training in the use of the device (see below).

The baseline session was followed in group A by three weeks of EMG recordings with the biofeedback turned on (biofeedback, W1), 2 weeks of EMG without the biofeedback (WO1), 3 weeks of EMG with the biofeedback (W2) and finally 2 weeks of EMG without the biofeedback (WO2). In group B, the sequence was reversed so the baseline was followed by no biofeedback (WO1), then biofeedback on (W1), no biofeedback (WO2) and finally biofeedback on (W2). The patients were given the explanation that 2–3 weeks were required to see an effect.

Feedback device and EMG analysis

The basic principle of the device (*Grindcare®) is a portable EMG apparatus, which is placed around the forehead (above the eyes) with three integrated electrodes in close connection with the anterior part of the temporalis muscle (Fig. 2a). The device handles the following tasks: (i) online recording of EMG activity; (ii) online processing of EMG signals to detect a particular activity (tooth-grinding/tooth-clenching); (iii) providing a battery-powered electrical stimulation based on individual parameters. These individual parameters are used as reference values and to determine threshold values and criteria for triggering the biofeedback (conditioning) signals to the anterior part of the temporalis muscle. The patients were able to adjust and set the intensity of the electrical biofeedback stimulus to a level that was suitable to the user, e.g., a level that was not

uncomfortable to the patient but which clearly could be perceived.

All patients used the device during sleep for at least five nights per week. The EMG apparatus contained parts such as the microprocessor (sampling rate: 2 kHz, stored in 500 ms bins) for processing signals, storing settings and data and transmission of biofeedback signals (Fig. 2b). Furthermore, the device comprised the main display (Fig. 2b-3), visual indicator in the form of LED (Fig. 2b-5), two push buttons or keys (Fig. 2b-4) and a plug-in USB connector (placed on the back of the device and is not illustrated in Fig. 2b). This connector could be connected to a PC for setting up the apparatus or for transmitting data to the PC, from which it may be transmitted to the investigator. All data, which was stored in the memory was transferred to a PC for a further analysis of each single patients EMG data. The memory capacity was 4 mega bits and it was chosen to store continuously sampled EMG data for about 20 h with a frequency of 2 Hz. The analogue EMG signals were filtered (20–600 Hz), rectified and sampled with a sampling frequency of 2 kHz. The device could store EMG data with a frequency range of 1–100 Hz and it was possible to change the frequency of data collection and storage through a computer program via the USB port.

Furthermore, Fig. 2b shows a strap, which was equipped with three 10-mm electrodes (Fig. 2b-1). The electrodes were used to monitor the EMG signals and to provide the biofeedback signals using the same electrodes. The EMG apparatus also automatically monitored the conductance between the electrodes and the skin which assured that the patients had placed the electrodes in such a manner that the resistance to the skin was below 10 k Ω . The conductance is shown on the connectivity indicator (Fig. 2b-3). The patients were asked to adjust the position of the EMG apparatus if the conductance was >10 k Ω . In case of poor connectivity between the electrode and skin during sleep, the EMG recordings with errors were identified and labelled by the software and that data was not used for further analysis.

The biofeedback circuit was controlled by a microprocessor, where it was possible to adjust and set the intensity of the electrical stimulus. An electrical square-wave pulse train (500 ms), which was adjusted to a clear, but non-painful intensity (range 1–7 mA) was applied through the EMG electrodes.

The following set-up procedure of the device was applied: The patients were asked to clench their teeth as

hard as possible for 2–5 s to establish the maximum voluntary contraction (MVC). Then the patients performed grimaces and swallowing movements for 2–5 s. Finally, the threshold value for the intensity of the electrical stimulus was adjusted. The set-up was used to determine the individual parameters and differed between patients. The patients performed the set-up procedure every night to record the personal parameters in the device. The individual parameters were defined as follows: (i) electrode connectivity to the skin (ii) the stimulation intensity level (iii) signal characteristic of the grimaces (iv) the MVC.

The patients used the device every night (5–7 nights per week) during the test period and the EMG activity data was extracted every day and sent to the investigators for continuous quality control and further analysis. Neither the patients nor the dentist knew which session (i.e., biofeedback active or not) the patient was in.

The online analysis of the EMG activity was based on a signal recognition algorithm (SRA) of the frequency domain specifically associated with the tooth-grinding/tooth-clenching EMG activity determined in the set-up procedure. Grimaces, swallowing and artefacts due to poor connections between the electrodes and the skin were intended not to be included in the analysis because the defined SRA templates excluded EMG activity associated with these particular conditions. The specific SRA technology is based on a fast fourier transform analysis, which was used for pattern recognition of the EMG activities during the signal processing. To characterize the behaviour of EMG activity, we essentially analysed the frequency components of the output waveform, which was generated by the temporalis muscle. Typically, the SRA was driven by a reference signal at a defined window frequency (usual bandwidth frequency range, 100–400 Hz) and the amplitudes of the harmonic frequencies in the EMG output waveform, whereby the time-dependent output waveform of the EMG was transformed into a frequency-domain function.

The device measured both the amplitude and frequency content of the EMG signals from the temporalis muscle. The method was a stochastic signal processing, where the patient should first perform the set-up procedure to establish the individual parameters. The device monitored the frequency content, when the patients were asked to grind his/her teeth during the set-up procedure. When these patterns were

determined, they were collected in a table and stored in a memory, which was accessible for the microprocessor.

To determine an EMG event associated with bruxism, a correlation was ascertained between the frequency content of the EMG signal from the continuous measurements and the recorded EMG signals, which was already stored in the table. The EMG activity was recognized during sleep when the window frequencies matched the frequencies content of the EMG signals from the stored table and the SRA was subsequently used to insure that the biofeedback was only triggered by EMG events linked to bruxism.

The main outcome parameter was the number of EMG events/hour sleep based on the SRA analysis and not as previously on EMG activity exceeding 10% or 20% MVC threshold (27).

Methodological study

A novel aspect in the present study was to use the SRA to detect EMG activity specifically associated with tooth-clenching and tooth-grinding and to eliminate EMG activity related to grimaces, swallowing etc. The accuracy of the SRA templates established in the set-up procedure was therefore tested prior to the clinical study in eight healthy subjects (age: 26–55 years). The SRA templates were based on the above-mentioned steps in the set-up procedure, whereby values and/or parameters corresponding to individual muscle activities were measured and stored in the device. The device was used to record the maximal level of grinding activities as well as normally occurring muscle activities (grimaces, swallowing etc.) during the set-up procedure. This was used to establish criteria for triggering the biofeedback to the user in such a manner, that the normally occurring activities could not trigger a biofeedback.

During the methodological study the subjects were asked to perform three different tasks: relax, grimace and clench. These tasks were explained to the subjects and were also practiced by the subject to assure correct performance. The three tasks were carried out in the following sequence which was repeated three times: (i) relax – the subjects were instructed to relax and avoid any contact between the teeth in the upper and lower jaw for a total of 30 s; (ii) grimace – the subjects closed his/her eyes tightly for 10 s and then relaxed for 5 s without any tooth contacts for a total of 55 s; (iii) clench – the subjects had to simulate a tooth-clenching by pressing the teeth firmly together for 1 s

every 5 s. This procedure was performed continuously for 50 s. The device was programmed to have a pause time of 500 ms when an event was detected by the SRA to insure correct initial conditions when the stimulation was initially applied. This condition is always valid even when the stimulation is not active. This allows the SRA to detect a maximum of two events per s of clenching. Between the clenches the subject had to relax the jaw muscles. The EMG data were stored with a frequency of 50 Hz (sampling rate: 2 kHz) to achieve a higher time resolution than in the continuous measurements, which were performed during the clinical experiment.

The number of EMG events during the different tasks was detected using the SRA analyses. A custom-made programme* was in addition used to analyse the EMG activity exceeding a 10% and 20% MVC value in accordance with another study (27) which provided the number of EMG events per unit of time. The number of EMG events for each of the different tasks was subsequently compared between the two analysis techniques.

The EMG analysis programme could generate a graph of raw EMG data for each recorded EMG file. The programme used the % MVC calculation on the raw amplitude data. This was used to compare the outcome of the % MVC method with the SRA technique. Furthermore, it was possible to calculate the number, area and duration of EMG events and print reports. The graphical presentation of the EMG data was a useful tool to see the correlation between the raw EMG data and the EMG activity to confirm if the electrode remained correctly positioned during sleep.

Patient-related variables

The research diagnostic criteria for temporomandibular disorders was used to characterize the patients before inclusion and after each session (Fig.1) (23). The RDC/TMD contains items related to (i) clinical physical examination and (ii) Biobehavioural Questionnaires. In this study four variables from the RDC/TMD were chosen as secondary outcome parameters; number of painful muscles and maximum pain-free jaw opening, CPI (characteristic pain intensity) and depression score from the SCL-90-revised (symptom checklist 90).

Number of painful muscles is the total number of muscles that are painful on palpation and can vary from 0 to 20. Maximum pain-free jaw opening is a combination of the maximum unassisted opening without pain and

the vertical incisor overlap. CPI is calculated from three questions related to the intensity of pain on 0–100 scales (present pain, worse pain and average pain). In this study, average pain was defined as the average pain in the past 2 weeks. The depression score was calculated from the SCL-90 and taken as a general indication of the impact of pain and functional disturbances on the patient.

Furthermore, the MPQ was used to determine the quality of pain in each patient. From the MPQ the pain rating index (PRI) of the sensory, affective, evaluative and miscellaneous dimension of pain was calculated (Melzack 1975). In the present study only the total PRI was used.

Finally, the OHIP was used to register the quality of life in relation to the orofacial region. The OHIP contains 49 questions that the patient answered before and after the study. Seven different domains can be derived from the questionnaire but only the overall scores were used in the present study (28).

Statistics

Mean values and standard errors of the mean (s.e.m.) are given in the text and tables. The processed EMG data (number of events/hour sleep) were averaged for each of the sessions (baseline, W1, WO1, W2, WO2). A mixed analysis of variance (ANOVA) model for repeated measures was used taking into account the two different groups (sequence effects). Secondary outcome parameters (number of painful muscles on palpation, maximum pain-free jaw-opening, CPI, depression score derived from the RDC/TMD, OHIP and MPQ scores) were analysed with similar ANOVA models. Tukey tests were used for *post hoc* comparison when appropriate. $P < 0.05$ was considered significant.

Results

Methodological study

The subjects successfully performed the three tasks with an average duration of 30 ± 1 s for relaxation; 55 ± 1 s for grimacing and 50 ± 1 s for clenching.

The average number of EMG events detected with the SRA method during the three tasks was different (ANOVA: $P < 0.001$) with significantly higher values during clenching compared with relaxation (Tukey: $P < 0.001$) and grimacing tasks (Tukey: $P < 0.001$) and

Table 1. Average number of EMG events detected during three different tasks in the methodological experiment

| | Relax | Grimace | Clenching |
|---------|------------------------|--------------------------|--------------------------|
| SRA | 0.1 ± 0.0 | 0.1 ± 0.0 | 20.8 ± 2.1* |
| 10% MVC | 2.2 ± 0.6 [†] | 256 ± 126.4 [†] | 64.0 ± 11.2 [†] |
| 20% MVC | 0.8 ± 0.2 | 142 ± 85.1 | 36.9 ± 8.3 [‡] |

Mean values ± s.e.m., $n = 8$

SRA, signal recognition algorithm; MVC, maximum voluntary contraction.

*Significant different from Relax and Grimace (Tukey: $P < 0.05$).

[†]Significant different from SRA (Tukey: $P < 0.05$).

[‡]Significant different from 10% MVC (Tukey: $P < 0.05$).

no differences between the relaxation and grimacing tasks (Tukey: $P = 0.998$) (Table 1).

There were also significant differences between the number of EMG events detected with the 10% MVC and SRA analysis techniques for all the three tasks (ANOVA: $P < 0.045$). There were no significant differences between the number of EMG events detected with the 20% MVC and SRA methods (Tukey: $P = 0.227$). As expected, the 20% MVC threshold was associated with smaller numbers of EMG events than the 10% MVC threshold (Tukey: $P < 0.039$); however, the SRA method virtually detected no EMG events associated with the relaxation (one event in one subject) and grimacing (one event in one subject) tasks.

Figure 3a shows a typical example of the rectified EMG data from the methodological study (one control subject) and Fig. 3b–d show the number of detected EMG events using SRA, 10% MVC and the 20% MVC methods respectively. Note that there were no detected EMG events with the use of the SRA technique in the relaxation and grimacing tasks (Fig. 3b) whereas multiple EMG events were detected with both the 10% MVC and the 20% MVC methods. The number of detected EMG events in this particular subject during the clenching task was smaller for the SRA technique (11 events) than the 10% MVC (29 events) and the 20% MVC (27 events) in line with the average values in the group ($n = 8$) (Table 1).

Clinical study

The scatter plots in Fig. 4 shows a correlation between the number of EMG events detected with the use of the SRA model and the 10% MVC analysis ($R^2 = 0.817$) (Fig. 4a) and the 20% MVC method ($R^2 = 0.656$)

Fig. 3. Examples from the methodological study showing the number of detected electromyographic (EMG) events with the use of the signal recognition algorithm (SRA) in one control subject who performed three tasks: relax, grimace and clench. (a) The rectified EMG activity detected by the device during the tasks. (b) The vertical lines represent a detected EMG event based on a SRA. (c) Detected EMG events using 10% MVC from the same patient and same time period for comparison. (d) Detected EMG events using the 20% MVC.

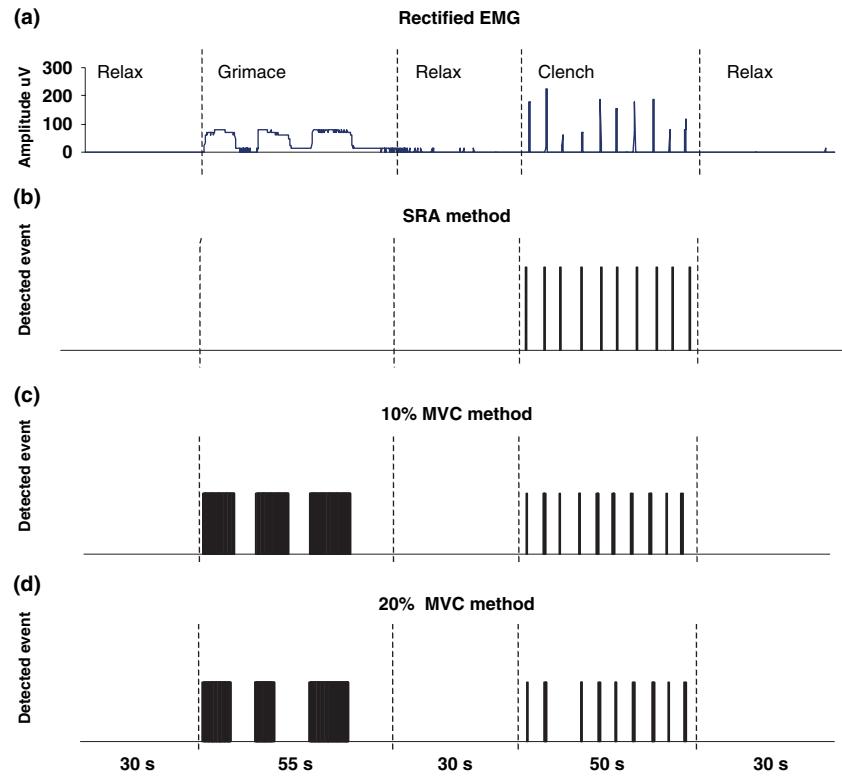
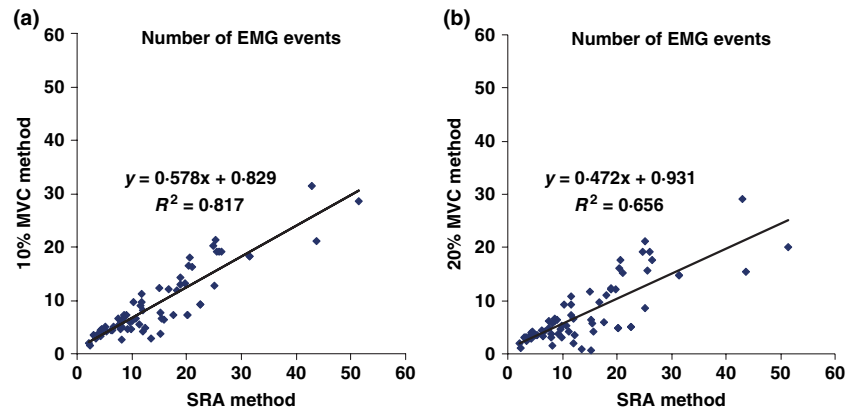


Fig. 4. Correlations in electromyography (EMG) detected events between the signal recognition algorithm model and (a) the 10% and (b) the 20% MVC derived from the clinical study. Each point represents the average EMG events/hour for a total of 14 patients with five sessions each. The solid line represents the best-fitted regression line that characterizes the data.



(Fig. 4b). The values plotted in Fig. 4 represent the average EMG events/hour for each patient in the clinical experiment, which gives a total of (14 subjects with five sessions) 70 values.

There were no differences in the total number of hours of sleep in the five different sessions of the clinical study (7.2 ± 0.1 h) (ANOVA: $P = 0.626$) and no systematic complaints related to the use of the device, which indicated that the sleep quality of the patients was not significantly affected by the biofeedback stimulation. The average number of EMG epi-

sodes/hour sleep per session detected with the SRA method was significantly different (ANOVA: $P < 0.001$), but not influenced by the sequence (ANOVA: $P = 0.452$).

There was a significant reduction of the EMG activities in the two sessions with biofeedback (W1 and W2) compared with the baseline (BL) (Tukey: $P < 0.001$) (Fig. 5). There was also a significant reduction in the last session without biofeedback (WO2) ($31 \pm 25\%$) compared with the baseline EMG session (Tukey $P = 0.003$). No significant difference was found

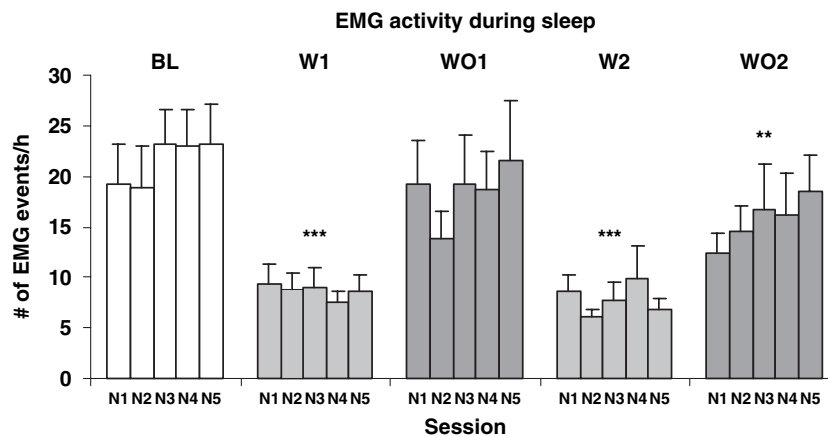


Fig. 5. Bar chart showing the average electromyographic episodes/hour sleep (events) during the first five nights of each session (n1–n5) in the experiment (mean values \pm s.e.m., $n = 14$). **indicates significantly different ($P < 0.01$) and *** $P < 0.001$ from the baseline. The black bars are periods without biofeedback and the white bars are with biofeedback. BL, baseline; W1, with biofeedback first time; WO1, without biofeedback first time; W2, with biofeedback second time; WO2, without biofeedback second time.

between the baseline and the first session without biofeedback (WO1) (Tukey: $P = 0.332$).

Additional ANOVA during the first five nights of the sessions did not show any significant night-to-night changes from any of the sessions (ANOVA: $P > 0.568$) (Fig. 5).

The raw EMG activity detected by the device from one patient in each of the five sessions is shown in Fig. 6a–e.

There were no significant changes in maximum pain-free jaw-opening (ANOVA: $P = 0.612$) (Fig. 7a), number of painful muscles (ANOVA: $P = 0.368$) (Fig. 7b), CPI (ANOVA: $P = 0.587$) (Fig. 7c), MPQ scores (ANOVA: $P = 0.835$) (Fig. 8a) or depression scores (ANOVA: $P = 0.474$) (Fig. 8b). OHIP scores (Fig. 8c) showed a significant reduction from the first session to the last session (ANOVA: $P < 0.001$).

Discussion

The present study demonstrated that the SRA technique can be applied to ambulatory EMG data and minimizes the contribution from facial EMG activity. Furthermore, an EMG triggered electrical stimulus during sleep is associated with a significant reduction in number of detected EMG events in the temporalis muscle using the SRA technique. In this patient population, there were no correlations between the decrease in temporalis EMG activity and symptoms or signs of TMD problems.

Methodological study

The methodological study indicated that the novel SRA analysis is a useful method to detect EMG activity related to jaw clenching because the EMG activity associated with grimacing and other facial movements virtually can be avoided. Previously it has been shown that a similar SRA technique can be applied to jaw muscle EMG activity with high sensitivity, specificity and reliability (29, 30).

In the present study the average time between the detected EMG events during the clench task was 5 s, which was in accordance with the instruction to the subjects. Importantly, the number of detected EMG events with the use of the SRA technique for the grimacing task was very low, in fact only one single event was detected in all the subjects which could be due a false positive event or the subject incidentally clenched his/her teeth during the recording.

The ANOVA test showed that there were significant differences between the number of EMG events detected with the SRA and the 10% MVC methods, but no significant difference between the SRA and the 20% MVC. A possible reason could be due to the small sample size in the methodological study, which was not enough to show a significant difference.

There is also a risk for detecting grimaces or different artefacts (like poor connection between the electrodes and the skin) as clenches for including false positive EMG activities. For example, in Fig. 3a there are some

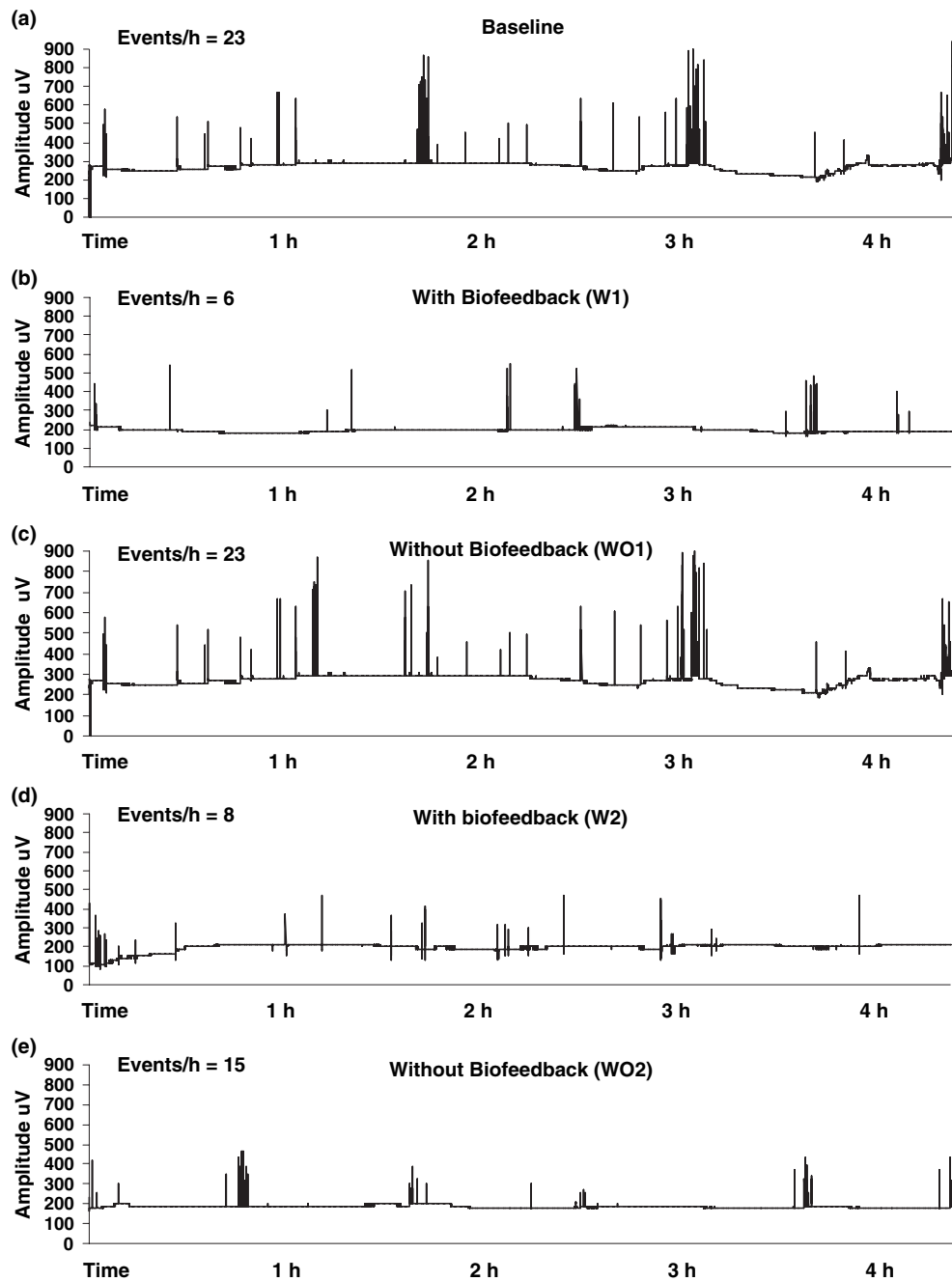


Fig. 6. Typical electromyographic data from one patient in each of the five sessions. (a) Baseline, (b) with biofeedback (W1), (c) without biofeedback first time (WO1), (d) with biofeedback second time (W2) and (e) without biofeedback second time (WO2). Due to the large amount of data there are only shown data from the first 4 h and 10 min of sleep (30 000 data samples).

EMG bursts during the grimacing task which all are above the 10% MVC threshold and even the 20% MVC threshold and therefore would have been detected as 'true positive' clench events in a normal 10% or 20% MVC analysis, but with SRA analysis these spikes are not detected because the technique is less sensitive to

external disturbances compared with the MVC methods. Thus, we suggest that the SRA method has some major advantages over the 10% and 20% MVC methods when ambulatory EMG recordings are analysed from the temporalis muscle, which may have a low signal to noise ratio and be sensitive to different

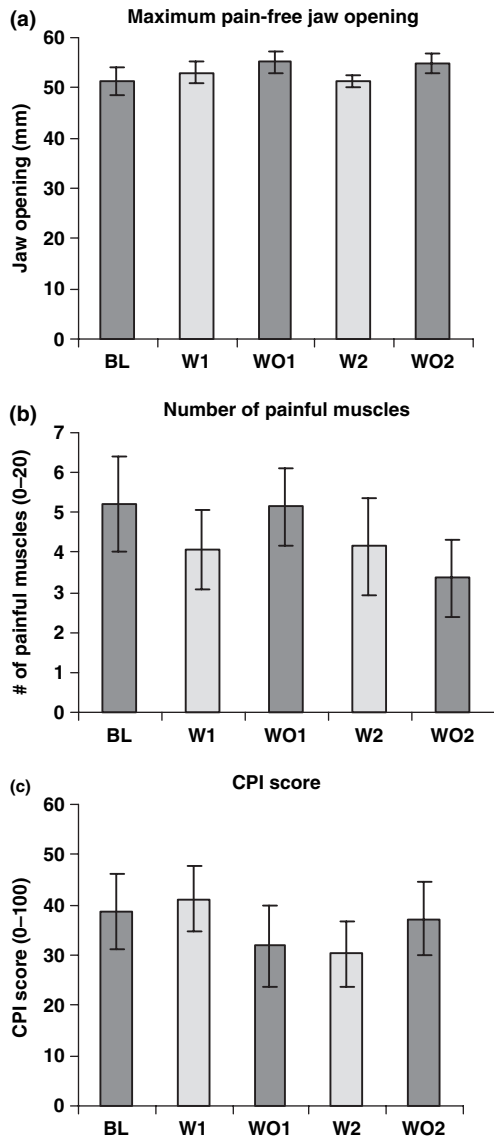


Fig. 7. Bar charts showing the mean scores (\pm s.e.m., $n = 14$) obtained from the RDC examinations and questionnaires before and during treatment. BL, baseline; W1, with biofeedback first time; WO1, without biofeedback first time; W2, with biofeedback second time; WO2, without biofeedback second time. (a) Maximum pain free jaw opening, (b) number of painful muscles, (c) CPI score.

artefacts such as movements of the electrodes, external electrical noise etc.

Clinical study

The correlation analysis between the SRA and the 10% MVC methods indicated that there is, indeed, a strong relationship between the two methods. The slopes in

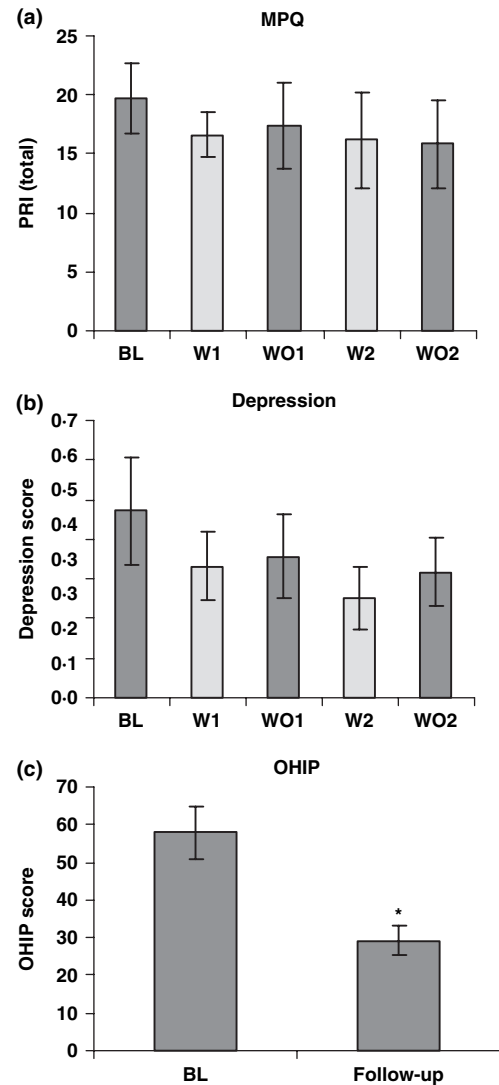


Fig. 8. Bar charts showing the mean scores (\pm s.e.m., $n = 14$) obtained from the questionnaires before and during treatment. BL, baseline; W1, with biofeedback first time; WO1, without biofeedback first time; W2, with biofeedback second time; WO2, without biofeedback second time. (a) MPQ score, (b) Depression score, (c) Oral Health Impact Profile shows a significant difference between BL and the last session ($P < 0.001$).

Fig. 4 suggests that during sleep recordings the SRA technique detects about twice as many events than the 10% MVC technique despite the fact that in the methodological study a smaller number of EMG events were detected during clenching. However, this can be explained by the way the SRA works and the differences between the time resolution and data storage (2 Hz for the clinical study and 50 Hz for the

methodological study). The SRA analysis is designed to look for patterns in the signal whereas the 10% MVC only looks at the amplitude of the signal. The amplitude of the signal over a period of time might not change as much as the patterns in the signal. A regression analysis between the 10% and 20% MVC methods applied on the raw data from the clinical study shows a very high correlation ($R^2 = 0.955$) and that the 20% MVC detects about 7.2% less EMG events than the 10% MVC and only about half the number of EMG events detected with the use of the SRA. It has been previously reported that when the threshold criteria were increased from 3% to 10% and 20% MVC, the total number of detected EMG events decreased from 3339 to 2601 and 1706 respectively (31). In most of the recent studies a threshold of 10% or 20% MVC have been used (32, 33), however, based on the present study there seems to be a risk for underestimation of the number of EMG events (clench events) per time unit, when the amplitude of the events are below the 10% or 20% MVC.

In the present study, there was no change in the overall amount of time the patients slept during the study period, which indicates that the patients were not disturbed by the biofeedback or by wearing the device. However, from the present study it cannot be determined if the microstructure or relationship between sleep stages had been affected as this would have required a polysomnographic recording. Tactile and painful stimuli have both been shown to modify the sleep pattern (34), and the additive influence on arousal responses can be interpreted in several ways because arousal responses might depend on the nature of the sensory stimulation (e.g. intensity, modality) and on the behavioural state during sleep (35–37).

So, it is indeed likely that changes in the electroencephalography activity could have been detected in the present study with moderate intense electrical stimuli. Nevertheless, none of the patients complained about awakenings using the device.

The effect of conditional electrical stimulation during sleep showed a significant change in the EMG events/hour sleep with a reduction of 54–55% in sessions with stimulation in contrast to a minor decrease in EMG activity of about 31% in the last session without stimulation. These results raise the question if learning or conditioning has taken place during the last session without biofeedback in

treatment with repetitive electrical stimulation. There are studies in which the reduction in EMG activity remained low for a period of at least 2 weeks after treatment (38). However, to determine the long-term effect and any possible learning effects of biofeedback on patients with SB will require further studies.

It was a striking finding that none of the patient-related variables (maximum pain-free jaw-opening, number of painful muscles on palpation, CPI, depression scores or MPQ scores) showed any significant change over time. Several factors may explain this. First, the patients were not selected based on the presence of painful TMDs and all the scores indicated only mild or moderate manifestations of TMD. Therefore, it might be difficult to detect any significant effects of an intervention due to a 'floor-effect'. Secondly, the sample size was small and the SEM values indicate substantial interindividual variation. However, the study was designed as a paired-study where the patients were their own controls and therefore reducing the variation. Furthermore, the sample size was sufficient to demonstrate a significant decrease in EMG episodes during the electrical stimulation. One possibility could be that the EMG activity is more responsive to short-term interventions than TMD signs and symptoms and that a longer treatment period would have been needed to change the clinical outcome parameters. The findings in this study regarding the reduction in OHIP scores may reflect that the patients had an improved life quality after getting conditional electrical stimulation during sleep or alternatively a more generalized effect of being included in a study where both active and inactive treatments were alternating. It is therefore impossible to relate the decrease in OHIP scores to a particular phase of the intervention and the study was not designed for this purpose but rather to demonstrate the effect of conditional electrical stimulation on EMG activity.

In conclusion, the present study suggests that the SRA can be applied to ambulatory EMG data and minimize the EMG activity originating from facial muscles. Furthermore, the present results indicate that biofeedback with electrical pulses does not cause major disruption in sleep and is associated with pronounced reduction in temporalis EMG activity during sleep. Further studies will be needed to establish the usefulness of this novel technique for the management of SB.

Disclaimer

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Correspondence: Faramarz Jadidi, Department of Clinical Oral Physiology, School of Dentistry, University of Aarhus, Vennelyst Boulevard 9, 8000 Aarhus C, Denmark.
E-mail: fjadidi@odont.au.dk