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**ORIGINAL ARTICLE**

# Effect of contingent electrical stimulation on jaw muscle activity during sleep: A pilot study with a randomized controlled trial design

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**Abstract**

***Objective.*** To determine the effect of contingent electrical stimulation (CES) on jaw muscle activity during sleep in a double-blinded randomized controlled trial (RCT). ***Materials and methods.*** Eleven patients with myofascial TMD (mean age 37 years) and with a clinical diagnosis of bruxism were included. EMG activity (Grindcare®) was recorded from the anterior temporalis muscle during sleep and analyzed online. Jaw muscle activity related to clenching or grinding triggered an electrical square-wave pulse train (450 ms) adjusted to a clear, but non-painful intensity. TMD patients were randomized into two groups: active treatment with CES or no CES (placebo). Number of EMG episodes/hour sleep was the primary outcome parameter. The following variables were assessed as secondary outcome parameters; number of painful muscles, maximum pain-free jaw opening, characteristic pain intensity, depression scores and Oral Health Impact Profile scores. Numerical Rating Scale scores for self-reported pain and muscle tension were registered for at least 4 nights per week during the experiment. ***Results.*** The number of EMG episodes/hour sleep was significantly reduced (52 ± 12%) in the CES group during the sessions with CES (ANOVA: $p = 0.021$) compared to baseline. There were no significant differences in the secondary outcome parameters (ANOVA: $p > 0.513$) or pain or muscle tension scores between groups ($p = 0.645$). The average duration of sleep hours during the nights with and without CES was not significantly different ($p = 0.646$). ***Conclusions.*** These results demonstrate a significant inhibitory effect of CES on jaw muscle EMG activity during sleep in a RCT, but with no effects on self-reported pain.

**Key Words:** *bruxism, contingent electrical stimulation, EMG, myofascial TMD*

## Introduction

According to the American Academy of Sleep Medicine (AASM), sleep bruxism (SB) is a sleep-related movement disorder characterized by grinding or clenching of the teeth during sleep, usually associated with sleep arousal [1]. This parafunctional disorder may cause attrition of tooth substance [2–4] and it is widely believed that bruxism plays an important role in the development of craniofacial pain, including temporomandibular disorders (TMD) [5,6]. However, human biological systems are much more complex and, therefore, it is not a surprise that the relationship between bruxism and craniofacial pain is far from being simple or even linear [5]. Indeed, there are unexplained factors, which complicate the establishment of adequate explanatory models. Part of the reason is the complexity of the bruxism in itself, which presents significant challenges related to creation of operationalized criteria and diagnostic tools and underlying pathophysiology issues [5].

The etiology and neural mechanisms behind SB are not well understood. During the past decade, a number of studies have demonstrated the major role played by central nervous system factors in the development of SB, which, in part, is associated with the phenomenon of arousal reactions during sleep [7–13]. The diagnosis of SB is not easy. Self-reporting by the patient or the patient's spouse may be biased and studying dental wear intra-orally or on dental casts

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cannot trace when the wear occurred, nor discriminate between excessive wear and normal aging [14]. The use of electromyography (EMG) is limited because it does not allow discrimination between clenching and grinding and cannot exclude other usual orofacial activities such as cuffing, swallowing, speaking and tics, unless combined with video and audio recording in the environment of a sleep laboratory [15]. In a sleep laboratory setting, rhythmic masticatory muscle activities (RMMAs, characterized by lower EMG activity than in bruxism and excluding tooth grinding) has been observed in 56% of the study population [15], which inspired the hypothesis that bruxism may represent basically normal orofacial motor behavior in which certain factors may increase the activity and push it into the pathological range of jaw-muscle activity [15]. Consequently, the following polysomnographic (PSG) cut-off criteria were proposed: (1) more than four bruxism episodes per hour, (2) more than six bruxism bursts per episode and/or 25 bruxism bursts per hour of sleep and (3) at least two episodes with grinding sounds [16]. With the use of these criteria, the clinically established presence or absence of bruxism was correctly predicted in 81.3% of the controls and 83.3% of the patients with SB [16].

As sleep recordings may be made in a home setting with an ambulatory system or in a sleep laboratory with either a standard or an ambulatory system (e.g. EMG recording with dedicated software for data acquisition and analysis), the major challenge is to discriminate the oromandibular activity of interest from other motor behaviors. The use of audio and video recordings together with sleep PSG recordings remains the standard mode of assessing sleep movement disorders because it permits a more valid and reliable quantitative assessment of oromandibular activities [10]. However, laboratory recordings are expensive, time consuming in terms of data analysis and it is not very representative of sleep in the natural environment.

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 [17], occlusal adjustment [18], night-guard [19], physiotherapy and muscle relaxation exercises [20], acupuncture [21] and biofeedback [22,23]. The most common treatment of SB involves protection of the teeth by occlusal splints (OS) [24]. Yet, although OS minimizes damage to the teeth, it does not actually prevent or cure bruxism [24]. A study reported that OS reduced muscle activity associated with SB [25], but this effect may only be temporary [26]. Thus, there is a general consensus that OS may prevent further wear of tooth substance but is unable to modify the propensity to brux [27]. Biofeedback techniques appear to be promising treatment options for patients with sleep bruxism. For example, EMG-activated alarms have been tested but with significant interferences with sleep stage and quality [28]. Watanabe et al. [29] reported results from a single subject who used contingent vibratory stimulation delivered to the maxillary teeth via an OS splint. The subject also exhibited a significant decrease in the number of events/hour (25% reduction) and the duration of each event (44% reduction). One potentially stronger form of afferent biofeedback is low-level electrical stimulation of the trigeminal region. Application of electrical stimuli to the trigeminal area is known to elicit an inhibitory reflex response in contracting jaw-closing muscles [30,31]. This principle can be used for contingent stimulation when the jaw muscles become active during bruxism behaviors. Our previous proof-of-concept study [32] reported that the effect of conditioning electrical stimulation (CES) during sleep was a significant change in the EMG events/hour sleep, with a reduction of ~ 53% (compared with baseline) in sessions with stimulation followed by a lesser decrease in EMG activity of ~ 31% in a follow-up session without stimulation.

The present pilot study aimed to determine the effect of CES on jaw muscle activity during sleep derived from measurement of EMG activity predominately associated with tooth-grinding or clenching during sleep in a double-blinded randomized controlled trial (RCT) design. The secondary aims were (i) to obtain preliminary insight into the clinical consequences of the CES on jaw symptoms and other patient-related variables and (ii) to assess the long-term effect of CES on EMG activity.

## Materials and methods

The present study followed good clinical practice (GCP) guidelines and regular monitoring visits to the study centre were made by a research co-ordinator. The co-ordinator evaluated patients records according to the study protocol and insured that the required information/questionnaires were collected and all patients followed at the appropriate time intervals. This study was conducted in accordance with the World Medical Association Declaration of Helsinki. The project was reviewed and approved by the regional ethical committee (approval number: 20070051). According to the ethical rules of the institution, patients were free to interrupt their participation at any time. All participants were informed about the purpose of the study in a standardized way and provided written informed consent prior to study participation.

### *Patients*

Eleven patients (Mean age: 37 ± 3 years; nine women, two men) were included among 35 patients referred

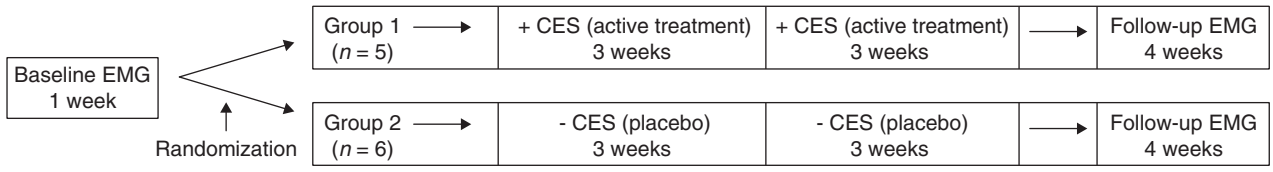


Figure 1. Overview of the design of the clinical experiment. + CES, with Contingent Electrical Stimulation; – CES, without Contingent Electrical Stimulation.

to the Section of Clinical Oral Physiology, Department of Dentistry, Aarhus University, Denmark. The potential study patients were contacted by the investigator who administered a questionnaire to determine their eligibility. All participants provided informed consent prior to the first clinical examination. A thorough patient history and a clinical examination using the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) was performed and patients were included if they fulfilled the following criteria in accordance with [33,34]: (a) a history of tooth grinding occurring at least 3 nights per week for the preceding 6 months, as confirmed by a sleep partner, (b) tooth wear and/or shiny spots on dental restorations, (c) frequent reports of stiffness, fatigue or discomfort in the jaw muscles upon awakening and (d) an RDC/TMD diagnosis of myofascial TMD pain (group 1a or 1b) [35].

### *Study design*

The study was designed as single centre, randomized, double blind, placebo-controlled clinical trial. The patients were randomized into two groups all using a portable EMG device (Grindcare® version 2) during four sessions according to Figure 1, to receive either placebo or active treatment with CES. After inclusion and randomization, the patients filled out a Sleep/Tiredness/Snoring questionnaire, a Danish version of the McGill Pain Questionnaire (MPQ) [36] and the Oral Health Impact Profile (OHIP) [37].

### *Self-reported and clinical measures*

The RDC/TMD questionnaire and clinical examination were performed as described by Dworkin and LeResche [35], which reflects the complex interaction between the physical and psychological dimensions of chronic pain (Table I).

The MPQ was used to assess the sensory, affective and evaluative aspects of pain at four time-points throughout the study (Table I).

The OHIP questionnaire [38] consists of 49 questions which patients answered during the sessions according to Table I. The purpose of the OHIP was to provide a comprehensive measure of the social impact of oral dysfunction, discomfort and disability arising from oral conditions.

The Sleep/Tiredness/Snoring questionnaire consists of 20 questions modified from Clark et al. [39] and Fransson et al. [40] to estimate the frequency of the patients' snoring, daytime tiredness and improving quality of night sleep, which patients answered during the sessions according to Table I. The questions measuring frequencies had six predefined reply alternatives such as 'never', 'once or twice a month', 'once a week', 'several times a week', 'every day/night' or 'don't know'. The answers were intended to help describe the patients' quality of sleep.

To assess pain systematically in the home setting we asked the patients to record their own pain and muscle tension by means of diaries. In the diaries the patients assessed their pain and muscle tension intensity 3-times each day (morning, afternoon, evening/night) in their homes using two separate 0–10 Numerical Rating Scales (NRS), where 0 represents 'no pain' and 'no muscle tension' and 10 'most imaginable pain' and 'most imaginable muscle tension'. In addition to self-monitoring of pain and muscle tension, patients were asked to record what pain medication they had taken during the day. All patients were asked to report any side-effects/adverse events during the experiment.

The questionnaires were handed out to the patients together with the diaries so they could be completed at home, but at the most 2 days prior to scheduled session.

### *Medication and adverse events*

Use of concomitant pain medication (types and amounts) and any adverse events were recorded in the diaries. However, regular medication taken for the treatment of other chronic illnesses was notified at the screening session. Patients were excluded from the study if she/he used daily ingestion of pain relief medication, such as preventive medication against chronic tension headache and migraine.

### *Visit schedule*

The visit schedule for the patients based on the study design was as follows (Table I): Visit 1: screening visit/baseline (day 0), during this visit the experiment was explained to each patient, RDC/TMD clinical examination was performed by a dentist and the patient was included if he/she fulfilled the inclusion criteria. If

Table I. General overview of the collected questionnaires and the planned process during each session and the visit schedule for each patient based on the study design ($n$ = 11).

| | Baseline | | | | |
|---|---|---|---|---|---|
| Session<br>Procedures/visit schedule | Visit 1, Day 0 | Visit 2, Day 7 ± 2 days | Active/placebo,<br>Visit 3, Day 21 ± 2 days | Active/placebo,<br>Visit 4, Day 49 ± 3 days | Follow-up, Visit 5,<br>Day 77 ± 3 days |
| Informed consent | X | | | | |
| Exclusion/inclusion criteria | X | X | | | |
| Medical history | X | | | | |
| RDC/TMD questionnaire[a] | X | | | X | X |
| RDC/TMD clinical examination | X | X | | X | X |
| OHIP questionnaire[a] | X | | | X | X |
| MPQ questionnaire[a] | X | X | | X | X |
| Sleep/tiredness/snoring questionnaire[a] | X | X | | X | X |
| Review of pain and tension diaries | | X | X | X | X |
| Handover of the Grindcare device for measuring EMG activity | X | | | X | |
| Return of the Grindcare device for measuring EMG activity | | X | | | X |
| Handover of coded Grindcare device | | X | | | |
| Return of coded Grindcare device | | | | X | |
| Transfer of patient data from Grindcare device to a PC (every day during the experiment) | | X | X | X | X |
| Randomization | | X | | | |
| Recording of adverse events | | X | X | X | X |
| Recording of simultaneous medication | X | X | X | X | X |

[a] All questionnaires were handed over on the day of the visit. Trial patients completed the questionnaires at the most 2 days prior to the visit.

included, the patient filled out the questionnaires according to visit 1 shown in Table I. A non-coded Grindcare device for recording of baseline data was delivered to the patients and the appropriate and comprehensive training in the use of the device was ensured; Visit 2: randomization visit (day 7 ± 2 days), the patient questionnaires and RDC/TMD clinical examination were performed according to visit 2 shown in Table I, data from Grindcare was transferred to a PC using the software Grindcare Manager (Medotech A/S, DK) and the quality of the data was examined to make sure that the patient had used the device correctly. The patient then received a Grindcare device corresponding to the group number to which he/she had been randomized; Visit 3: treatment/placebo visit (day 21 ± 2 days), the patient questionnaires were completed according to visit 3 in Table I, data from Grindcare was transferred to a PC using Grindcare Manager software and the quality of the data was examined to make sure that the patient had used the device correctly; Visit 4: treatment/placebo visit (day 49 ± 3 days), the patient questionnaires and the RDC/TMD clinical examination were performed according to visit 4 in Table I, the patients returned the Grindcare devices which they had been using for the last 6 weeks, a new Grindcare device just for monitoring of the EMG activity was delivered to each patient; Visit 5: follow-up visit (day 77 ± 3 days), the patient questionnaires and the RDC/TMD clinical examination were completed according to visit 5 shown in Table I, the patients returned the Grindcare devices which they had been using for the last 4 weeks.

*Blinding procedures*

Active and placebo Grindcare devices were identical but differed in their internal software configurations, where the stimulation mechanism was not activated in the placebo devices. Such modification was not visible to the patients or to the investigator. The patients were not aware of the device being active or inactive because CES was triggered during the first 20 min in both conditions in an attempt to 'blind' the patient. In contrast to the placebo devices, the active Grindcare devices delivered CES each time the device detected EMG activity associated with tooth-clenching or tooth-grinding throughout the full sleep period and not just the initial 20 min. Both the patient and the dentist/investigator were blinded to which treatment group (placebo or active) the patient was randomized.

*Randomization*

The patients were randomized in blocks using computer generated random number combinations to receive (in equal numbers) either active or placebo treatment. Opaque sealed envelopes bearing sequential ID numbers were prepared, containing the randomly allocated treatment code letters. Each code letter specified which group each patient was randomly assigned to: group 1 or group 2 (Figure 1). The person performing the randomization procedure was not involved in the experiment process at all.

*Feedback device and EMG analysis*

The basic principle of the device (Grindcare® version 2, Medotech, DK) 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 [32]. The device handles the following tasks: (a) online recording of EMG activity; (b) online processing of EMG signals in order to detect a particular activity (tooth-grinding/tooth-clenching); and (c) 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 5 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. Furthermore, the device comprised the combined EMG and stimulation electrodes, which are in close proximity to the skin and placed at the anterior part of the temporalis muscle, headband for carrying the apparatus around the forehead, pushbuttons for operating the device and display for user interface. 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. This connector could be connected to a PC for setting up the apparatus or for transmitting data to the PC, through which the measurements taken were saved on the patient's computer using Grindcare Manager software (Medotech A/S, DK) (pre-installed by the investigator on the patient's PC) and sent to the investigator via email for subsequent analysis. The quality of the data was carefully examined with a view to ensuring that the trial patients have used the device correctly. All patients received in-depth instruction in how to operate the device and manage the data.

The analog EMG signals were filtered (20–600 Hz), rectified and sampled with a sampling frequency of 2 kHz. Furthermore, the electrodes were used to monitor the EMG signals and to provide the CES signals using the same electrodes. The EMG

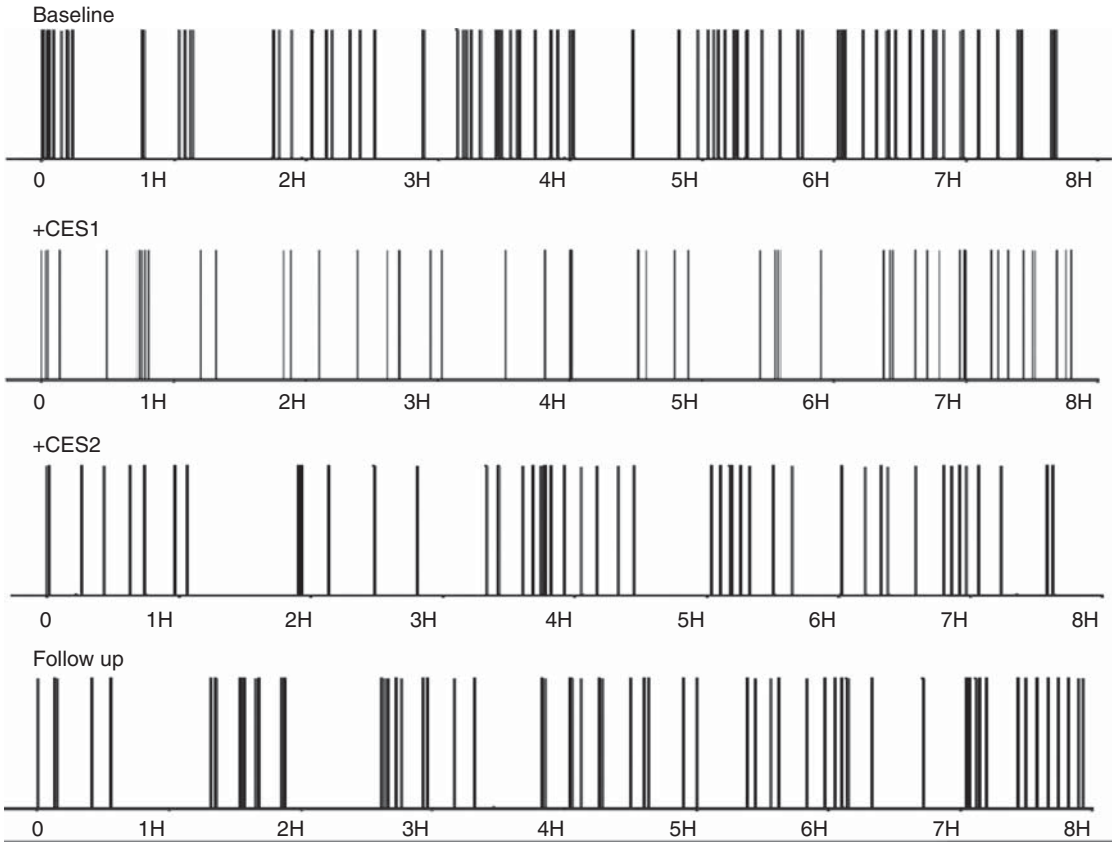


Figure 2. A graphical representation of the report of the activity detected by the portable EMG device (Grindcare®) using SRA analyses. The figure shows 8 h of the activity detected during a representative single night of recordings during the four different phases of the study in the group with active CES: baseline, +CES1, +CES2 and follow-up. Notice the difference in the EMG activity between the different phases.

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 kΩ. The conductance is shown on the display as a connectivity indicator bar. The patients were asked to adjust the position of the electrodes if the impedance was > 10 kΩ.

The CES 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 (450 ms), which was adjusted to a clear, but

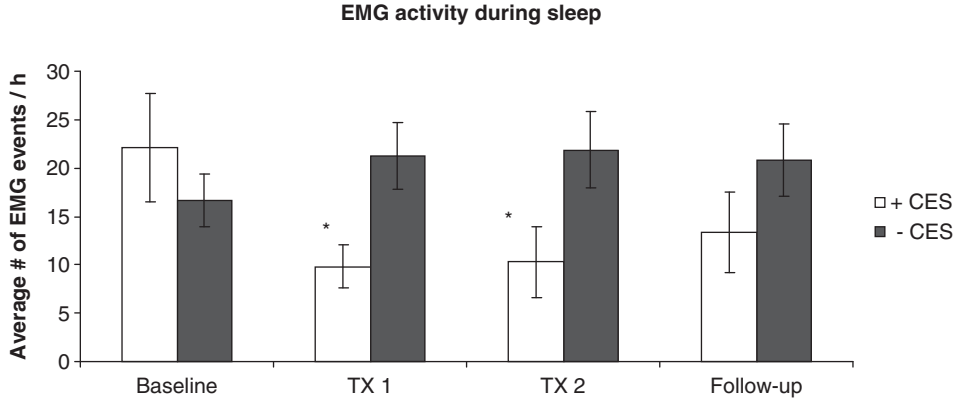


Figure 3. Bar chart showing the average EMG episodes/hour sleep (events) during each session in both active and placebo groups, mean values ± SEM ($n$ = 5 and $n$ = 6, respectively). BL, baseline (1 week), + CES, with contingent electrical stimuli (3 weeks, in two sessions; TX1 and TX2, in a total of 6 weeks), − CES, without contingent electrical stimuli (3 weeks, in two sessions in a total of 6 weeks), Follow-up session (4 weeks, EMG recording without CES). * indicates significant difference ($p < 0.05$) from the baseline.

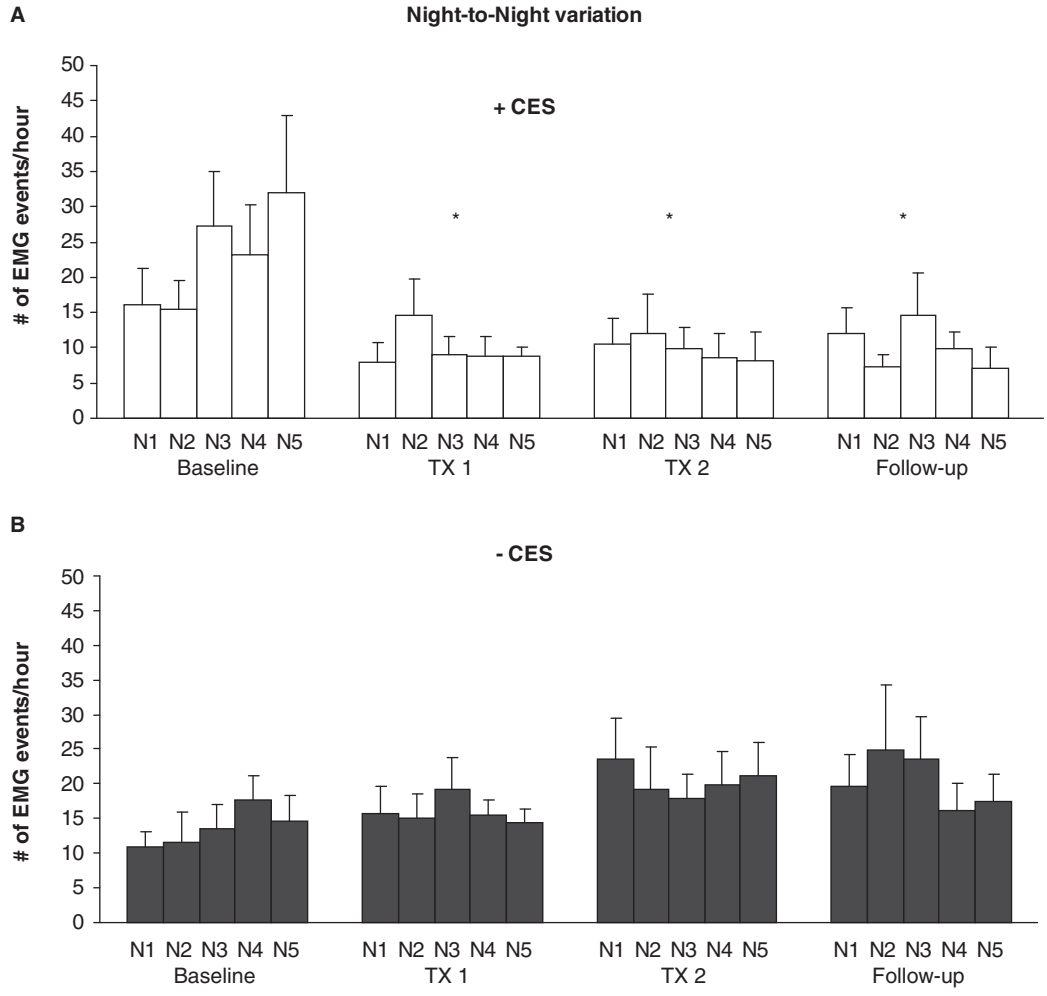


Figure 4. Bar chart showing the average EMG episodes/hour sleep (events) during the first 5 nights of each session in the experiment. (A) Active group, received the following sessions; BL, baseline (1 week), + CES, with contingent electrical stimuli (3 weeks, in two sessions; TX1 and TX2, in a total of 6 weeks), Follow-up session (4 weeks, EMG recording without CES). Mean values ± SEM ($n = 5$). (B) Placebo group, received the following sessions; BL, baseline (1 week), − CES, without contingent electrical stimuli (3 weeks, in two sessions in a total of 6 weeks), Follow-up session (4 weeks, EMG recording without CES). Mean values ± SEM ($n = 6$). * indicates significantly different ($p < 0.05$) from the baseline.

non-painful intensity (range 1–9 mA) was applied through the EMG electrodes.

In order to distinguish between jaw muscle activity associated with sleep bruxism events and other jaw or facial muscle activity, e.g. during chewing, talking, grimacing, etc., the following set-up procedure was performed and registered in Grindcare: the patients were asked to clench their teeth as hard as possible for 2–5 s in order 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 [32].

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 [32]. Grimaces, swallowing and artifacts due to bad 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 accuracy of the SRA templates established in the set-up procedure has previously been documented [32].

Moreover, in order to identify the night-to-night variability in EMG activity, we investigated the night-to-night effect of CES during the first 5 nights of the sessions in each group.

### *Outcome measures*

The primary outcome parameter was the number of EMG events/hour sleep based on the SRA analysis and not as previously on EMG activity exceeding a 10% or 20% MVC threshold [41]. The long-term effect of EMG activity after terminating CES treatment was evaluated from the data collected by

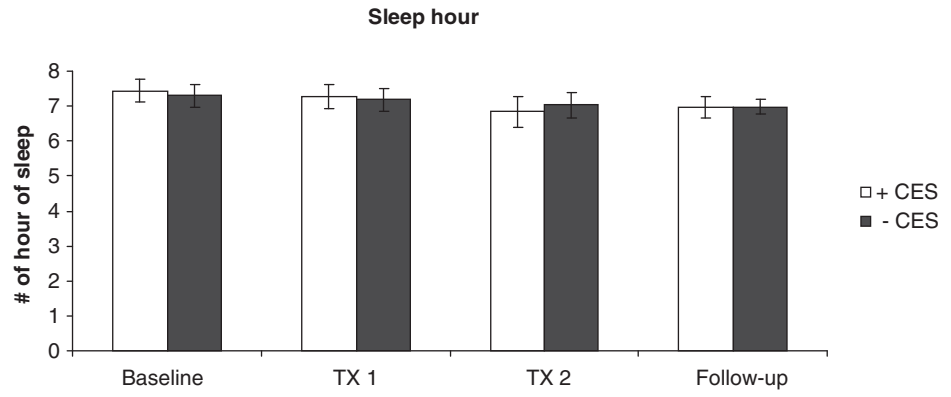


Figure 5. Bar chart showing the average duration of sleep hours during the baseline (1 week), nights with and without Contingent Electrical Stimulation (CES) (3 weeks, in two sessions; TX1 and TX2, in a total of 6 weeks) and follow-up sessions (4 weeks, EMG recording without CES) in the both active and placebo groups, mean values ± SEM ($n = 5$ and $n = 6$, respectively). BL, baseline; + CES, with contingent electrical stimuli; − CES, without contingent electrical stimuli; Follow-up.

Grindcare® for the last 4 weeks of the trial period (follow-up session).

The secondary outcome parameters included the following RDC/TMD measures: number of painful muscles on palpation, maximum pain-free jaw opening, CPI (characteristic pain intensity) and depression scores from the SCL-90-revised (symptom checklist 90) [35]. Number of painful muscles is the total number of muscles that are painful on palpation and can vary from 0–20. 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, worst 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 [35].

Other secondary outcome parameters were analyzed from: self-reported levels of muscle pain and tension; the Sleep/Tiredness/Snoring questionnaire; MPQ [36] and OHIP [38].

*Statistics*

Mean values and standard errors of the mean (SEM) are given in the text and figures. The processed EMG data (number of events/hour sleep) were averaged for each of the sessions (session 1, 2, 3 and 4) and during the first 5 nights of the sessions in each group. For statistical analyses, data were evaluated with the use of analysis of variance (2-way repeated measurements ANOVAs with the following factors: group (placebo and active) and time (sessions)). When appropriate, this was followed by post-hoc Tukey HSD tests including adjustment for multiple pair-wise comparisons. Secondary outcome parameters (number of painful muscles on palpation, maximum pain-free jaw-opening, CPI, depression score derived from the RDC/TMD, OHIP, sleep quality and MPQ scores) were analyzed with similar ANOVA models. Self-reported levels of pain and muscle tension were also measured and analyzed in the same way; $p < 0.05$ was considered significant.

## Results

The results collected from each night from the Grindcare® (Figure 2) were placed together and a two-way ANOVA analysis revealed no significant main effects of group (ANOVA: $p = 0.373$) or session (ANOVA: $p = 0.127$), but there was a significant interaction between group and session for temporalis EMG activity (ANOVA: $p = 0.012$). The post-hoc analysis of this interaction showed a significant reduction of EMG episodes/hour sleep (52 ± 12%) in the active group during the sessions with CES (ANOVA: $p < 0.035$) compared to baseline. The placebo group showed no significant differences in the number of EMG episodes/hour sleep during the placebo sessions compared to baseline (ANOVA: $p > 0.927$) (Figure 3).

Furthermore, additional ANOVA including only the first 5 nights of the sessions showed significant main effects of group (ANOVA: $p = 0.001$; no session effects, ANOVA: $p = 0.104$) and there was also a significant interaction in night-to-night effects between group and session for temporalis EMG activity (ANOVA: $p = 0.000$). The post-hoc analysis of this interaction showed a significant reduction of EMG episodes/hour sleep during the first 5 nights of sessions with CES compared to baseline in the active group (ANOVA: $p < 0.001$) (Figure 4A). Interestingly, there was also a significant reduction of EMG episodes/hour sleep during the first 5 nights of the follow-up session without CES compared to baseline in the active group (ANOVA: $p = 0.001$). However, the post-hoc analysis of this interaction showed no significant night-to-night effects in the number of EMG episodes/hour sleep during the

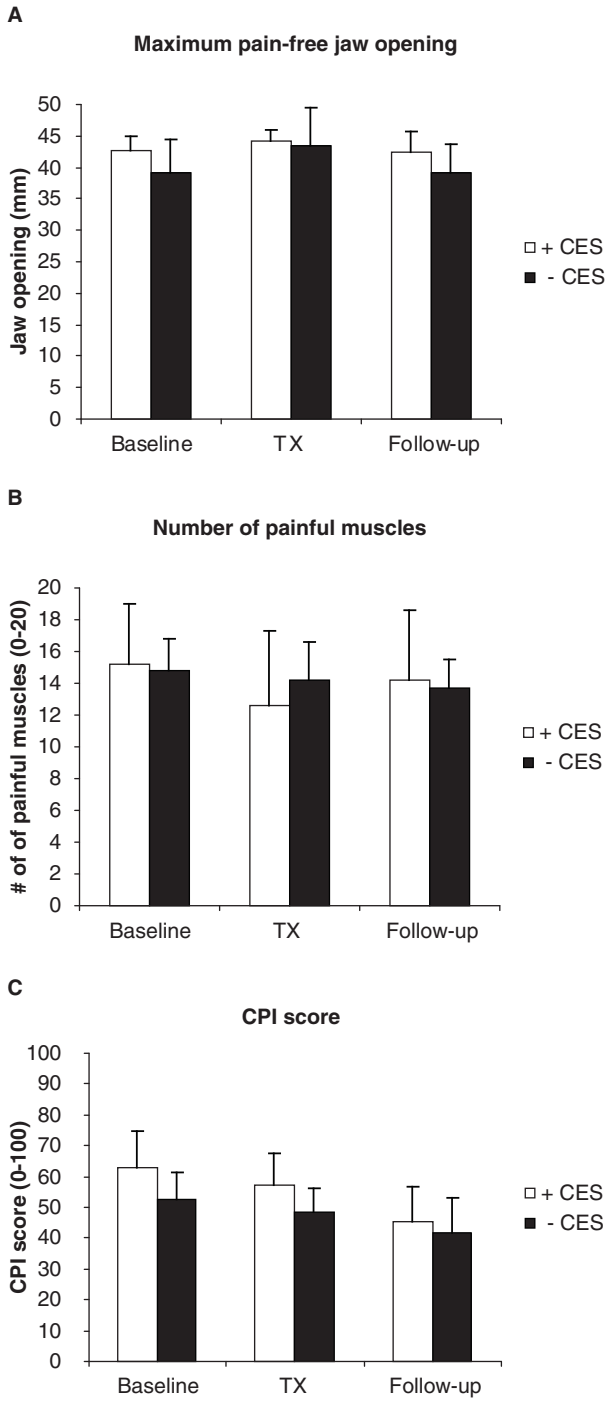


Figure 6. Bar charts showing the scores obtained from the RDC/TMD clinical examinations and questionnaires before and during treatment in the both active and placebo groups, mean values ± SEM ($n = 5$ and $n = 6$, respectively). BL, baseline (1 week); + CES, with contingent electrical stimuli (TX, 6 weeks); – CES, without contingent electrical stimuli (TX, 6 weeks); Follow-up session (4 weeks, EMG recording without CES). (A) Maximum pain free jaw opening, (B) Number of painful muscles, (C) CPI score.

placebo sessions compared to baseline (ANOVA: $p > 0.110$) (Figure 4B)

The average duration of sleep hours during the nights with and without CES showed no significant main effects of group or session (ANOVA: $p = 0.646$ and $p = 0.354$, respectively) and no significant interaction between these two factors was observed (ANOVA: $p = 0.704$). There were 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 contingent stimulation (Figure 5).

The results of the two-way ANOVA did not show any significant main effects of group or session in maximum pain-free jaw-opening (ANOVA: $p = 0.653$ and $p = 0.499$, respectively; no interaction effect, ANOVA: $p = 0.528$) (Figure 6A), number of painful muscles (ANOVA: $p = 0.907$ and $p = 0.183$, respectively; no interaction effect, ANOVA: $p = 0.944$) (Figure 6B), Characteristic Pain Intensity (ANOVA: $p = 0.642$ and $p = 0.085$, respectively; no interaction effect, ANOVA: $p = 0.736$) (Figure 6C), MPQ scores (ANOVA: $p = 0.381$ and $p = 0.753$, respectively; no interaction effect, ANOVA: $p = 0.078$) (Figure 7A), depression scores (ANOVA: $p = 0.891$ and $p = 0.483$, respectively; no interaction effect, ANOVA: $p = 0.308$) (Figure 7B) or OHIP scores (ANOVA: $p = 0.649$ and $p = 0.252$, respectively; no interaction effect, ANOVA: $p = 0.870$) (Figure 7C). A two-way ANOVA showed no significant effects in the Sleep/Tiredness/Snoring questionnaire score between the groups or sessions (ANOVA: $p = 0.440$ and $p = 0.200$, respectively; no interaction effect, ANOVA: $p = 0.582$) (Figure 7D).

There was no significant main effects of group or session in the scores of the TMD pain diaries (ANOVA: $p = 0.841$ and $p = 0.729$, respectively; no interaction effect, ANOVA: $p = 0.340$) and muscle tension diaries (ANOVA: $p = 0.765$ and $p = 0.828$, respectively; no interaction effect, ANOVA: $p = 0.118$) (Figure 8).

## Discussion

The present study showed that EMG triggered CES during sleep is associated with a significant reduction in number of detected EMG events in the temporalis muscle using the SRA technique (Figure 2). In this patient population, the decrease in temporalis EMG activity was not associated with a reduction of symptoms or signs of TMD problems.

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 CES or by wearing the device during sleep. This finding was also confirmed and supported by our recent PSG study [42], which showed that CES was not associated with any significant perturbation of PSG or self-reported data on sleep and sleep quality.

The effect of CES during sleep showed a significant change in the EMG events/hour sleep with a reduction of 48–51% in sessions with CES in contrast to a smaller decrease in EMG activity of ~ 36% in the follow-up session without CES in the active group.

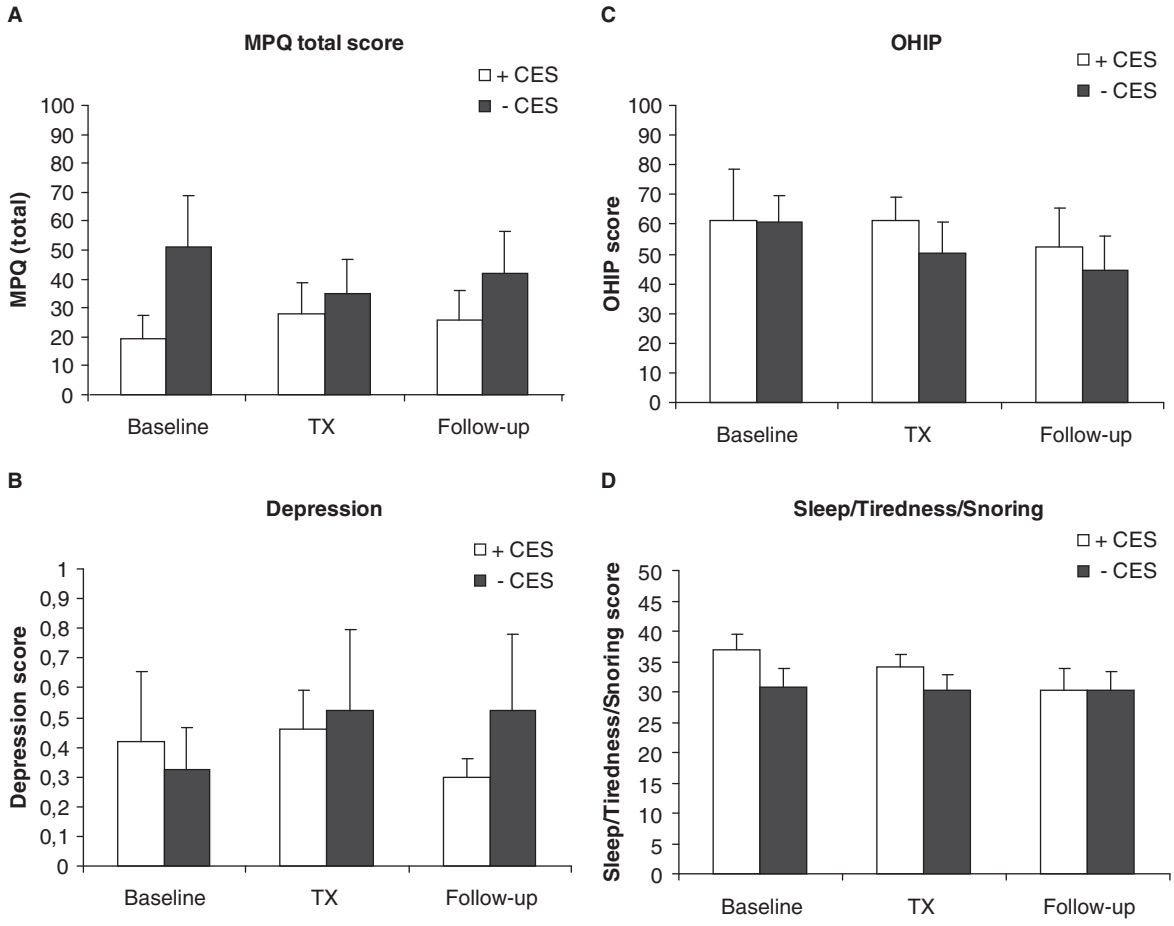


Figure 7. Bar charts showing the scores obtained from the questionnaires during each session in both active and placebo groups, mean values ± SEM ($n = 5$ and $n = 6$, respectively). BL, baseline (1 week); + CES, with contingent electrical stimuli (TX, 6 weeks); − CES, without contingent electrical stimuli (TX, 6 weeks); Follow-up session (4 weeks, EMG recording without CES). (A) McGill Pain Questionnaire (MPQ) score, (B) Depression score, (C) OHIP (Oral Health Impact Profile) score, (D) Sleep/Tiredness/Snoring score.

This finding is in accordance with our previous study, which showed a significant change in the temporalis EMG events/hour sleep with a reduction of 54–55% in sessions with stimulation [32]. However, the reduction in the EMG events/hour sleep in the present study during the last session without CES was not significant, but there was a significant night-to-night reduction in the temporalis EMG events/hour sleep in the first 5 nights of the follow-up session compared to baseline in the active group (Figure 4A). This raises the question of whether the inhibitory EMG effect is only temporary and how long treatment with CES must continue until a long-term or even learning effect is achieved, if possible. There are studies in which the reduction in EMG activity remained low for a period of at least 2 weeks after treatment [43]. However, to determine any possible learning effects of CES on patients with SB will require further studies with a large sample size and a longer period of the treatment with CES and follow-up sessions.

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, MPQ scores or OHIP) showed any significant change over time. Several factors may explain this. First, lack of statistical power because of the low number of studied patients and the SEM values indicate substantial inter-individual variation. Second, a dissociation between levels of muscle activity and craniofacial pain seems very feasible, thus a decrease in EMG activity during sleep is not necessarily associated with a decrease in pain reports [44]. Finally, it is possible 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 in order to change the clinical outcome parameters.

The use of the diaries was an attempt to systematically assess changes in pain and muscle tension intensities during the experiment. Feedback from patients concerning pain and muscle tension intensity is the backbone of appropriate pain assessment. In the clinic, patients can easily be asked about their pain intensity. In the home situation, however, it is more difficult to assess patients' pain and muscle tension intensity and the degree to which they have

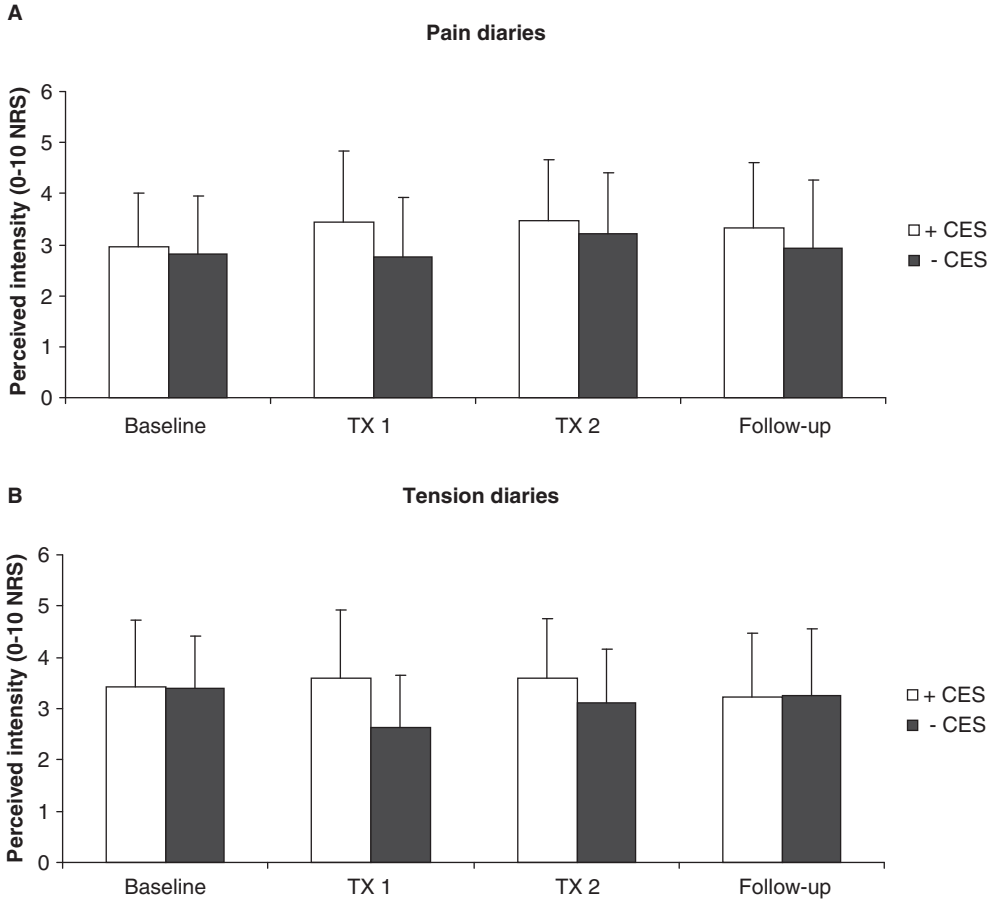


Figure 8. Bar charts showing the scores obtained from the (A) pain and (B) tension diaries on a 0–10 Numerical Rating Scale (NRS), where 0 represents 'no pain/tension' and 10 'worst possible pain/tension' during each session in both active and placebo groups, mean values ± SEM ($n$ = 5 and $n$ = 6, respectively). BL, baseline (1 week); + CES, with contingent electrical stimuli (3 weeks, in two sessions in a total of 6 weeks); − CES, without contingent electrical stimuli (3 weeks, in two sessions; TX1 and TX2, in a total of 6 weeks); Follow-up session (4 weeks, EMG recording without CES).

changed due to the therapy. A scale that uses 'no pain' and 'most imaginable pain' as anchors does not allow for discrimination of sensory and affective components of pain. The use of both NRS pain and muscle tension rating for a detailed description of pain allows for differentiation that may have important clinical and experimental implications. However, no statistically significant effects were observed in the scores of the TMD pain and muscle tension diaries between the sessions in either group. Although, during each session, patients reported that through the pain and muscle tension diary they gained insight into their pain complaints; this may give patients a sense of control over their pain and discomfort. As a consequence, patients' self-care may be influenced positively [45]. The advantage of using a pain diary is that it is more sensitive to daily changes in pain intensity than measures obtained by patient interview and reduces the possible distorting effects of memory on pain [46]. However, only when pain intensity scores differ remarkably from one day to another is self-monitoring of pain in a pain diary useful. For patients with a stable pain pattern who report little fluctuation in pain level from one day to another, use of a pain diary may not be beneficial [45,47]. From a clinical perspective, the pain diary is a valuable instrument for not only diagnostic evaluation, but also to assess treatment effects and the extent to which patients are actively involved in the pain treatment.

All patients in this study fulfilled the RDC/TMD diagnosis of myofascial TMD pain; however, the intensity of pain was low and it was decided to stop the study and revise the inclusion criteria to include a cut-off threshold of NRS pain scores > 3. The revised study design is now pending in several studies.

In conclusion, the present study suggests that the SRA can be applied to ambulatory EMG data and minimize the EMG activity originated from facial muscles. Furthermore, the present results indicate that CES at non-painful intensity does not cause disruption in sleep and is associated with pronounced reduction in temporalis EMG activity during sleep. Further studies with a longer intervention period will

be needed to establish the usefulness of CES for management of sleep bruxism.

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