Choice of biomaterials - do soft occlusal splints influence jaw-muscle activity during sleep? A preliminary report

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Highlights

- Tested if choice of biomaterials for occlusal splints influences biological outcome such as jaw-muscle activity during sleep
- Jaw-muscle activity during sleep was decreased by wearing hard-material occlusal splint
- Jaw-muscle activity during sleep was not influenced by wearing soft-material occlusal splint
- This specific choice of biomaterials may have impact on the neurobiological regulation of jaw-muscle activity during sleep

> Test if the choice of biomaterials for occlusal splints influences biological outcome. > Investigated the effect of a soft-material occlusal splint as well as to hard-type occlusal splint in terms of changes in jaw-muscle activity during sleep. > Jaw-muscle activity during sleep was significantly decreased during the hard-type occlusal splint but not during the soft-material occlusal splint when compared to baseline values. > These findings suggest that the specific choice of biomaterials for occlusal splints may have, at least a short-term impact on the neurobiological regulation of jaw-muscle activity during sleep.

Abstract

Aim: The choice of biomaterials for occlusal splints may significantly influence biological outcome. In dentistry, hard acrylic occlusal splints (OS) have been shown to have a temporary and inhibitory effect on jaw-muscle activity, such as tooth clenching and grinding during sleep, i.e., sleep bruxism (SB). Traditionally, this inhibitory effect has been explained by changes in the intraoral condition rather than the specific effects of changes in occlusion. The aim of this preliminary study was to investigate the effect of another type of occlusal surface, such as a soft-material OS in addition to a hard-type OS in terms of changes in jaw-muscle activity during sleep. **Materials and Methods:** Seven healthy subjects (mean ± SD, six men and one woman: 28.9 ± 2.7 year old), participated in this study. A soft-material OS (ethylene vinyl acetate copolymer) was fabricated for each subject and the subjects used the OS for five continuous nights. The EMG activity during sleep was compared to baseline (no OS). Furthermore, the EMG activity during the use of a hard-type OS (Michigan-type OS, acrylic resin), and hard-type OS combined with contingent electrical stimulation (CES) was compared to baseline values. Each session was separated by at least two weeks (washout). Jaw-muscle activity during sleep was recorded with single-channel ambulatory devices (GrindCare, MedoTech, Herlev, Denmark) in all sessions for five nights. **Results:** Jaw-muscle activity during sleep was 46.6 ± 29.8 EMG events / hour at baseline and significantly decreased during the hard-type OS (17.4 ± 10.5, P = 0.007) and the hard-type OS + CES (10.8 ± 7.1, P = 0.002), but not soft-material OS (36.3 ± 24.5, P = 0.055). Interestingly, the soft-material OS (coefficient of variance = 98.6 ± 35.3 %) was associated with greater night-to-night variations than baseline (39.0 ± 11.8%) and the hard-type OS + CES (53.3 ± 13.7%, P < 0.013). **Conclusion:** The present pilot study in small sample showed that a soft-material occlusal splint does not seem to inhibit jaw-muscle activity during sleep. Within the limitation of the study, it appears that the choice of biomaterials for occlusal splints may have a significant impact on the neurobiological regulation of jaw-muscle activity during sleep.

Introduction

Sleep bruxism (SB) is defined as a sleep-related movement disorder characterized by grinding and/or clenching of the teeth during sleep and associated with excessive arousal responses [1]. Evidence from recent controlled studies suggests that most SB episodes are secondary to a cascade of physiological events related to sleep arousals [2-4]. SB is believed to be linked to problems such as; tooth wear and fractures of dental restorations, osteohypertrophy, muscle hypertrophy, temporomandibular joint and muscle pain, jaw locking, temporal headaches, and cheek-biting [5-7] although the evidence is scares for some of the proposed effects. The prevalence of SB is 8% in the normal adult population, decreases from 14% in childhood to 3% in the elderly and does not have gender differences [8-11].

In order to manage SB, occlusal splint (OS) therapy, information/counseling, pharmacology, and biofeedback treatment such as contingent electrical stimulation (CES) has been proposed [12]. Recently, a feedback system based on the CES principle was introduced and have shown a significant inhibitory effect on jaw muscle activity during sleep [12]. However, OS therapy remains so far the first option for the management of SB because the treatment is reversible and can be performed with lesser costs [13]. Previous studies have investigated the effect of an OS on SB activity compared to a control OS which does not change the occlusion - a so called “palatal control device” [14, 15]. These authors reported that the use of a hard-type OS as well as the palatal control device had an inhibitory effect on SB activity and suggested that the change in occlusal contacts between the maxillary and mandibular dental arches due to the OS might not be the primary factor for a reduction of SB and EMG activity. No information is available if the choice of biomaterial will influence the regulation SB, i.e., it could be hypothesized that a soft-material OS [16] would have a different effect on SB.

We, therefore in this preliminary study, investigated the effect of material differences of OS, which was fabricated by a soft material and may have different effects on occlusion from the effects attributed to a hard-type OS. The specific hypothesis was that the soft-material OS-has an inhibitory effect on jaw muscle activity during sleep. This would be in agreement with previous studies that OS with or without direct effects on the occlusion have temporal inhibitory effects on SB [14, 15]. Furthermore, we tested if contingent electrical stimulation (CES) in combination with the hard-type OS would have a larger inhibitory effect on jaw muscle activity during sleep than a hard-type OS.

Materials and Methods

Subjects

Six healthy men and a woman (mean ± SD, 28.9 ± 2.7 year old) participated in this study. All subjects were generally healthy, more than 20 years old, and had full dentition (28 teeth). They were recruited among students and staff at Hokkaido University, Sapporo, Japan. Exclusion criteria were current illness; history of neurologic or psychiatric disorders; sleep disorders (e.g. sleep apnea and periodic limb movement); use of prescription medicine or drugs; smoking, alcohol abuse and addiction to coffee; electrode gel allergy; simultaneous participation in another trial with medicine or in trials of medical devices; and user of pace maker. The absence of Temporomandibular Disorders were ascertained following standardized diagnostic criteria, RDC/TMD (Research Diagnostic Criteria for Temporomandibular Disorders) [17]. Informed consent was obtained from each subject and the experimental protocol was approved by the local ethics committee.

Study design

All subjects participated in a four session experiment (Fig. 1). Each session consisted of five continuous nights recordings per week (Mondays to Fridays). During the first session, the subjects slept without any OS (baseline, Fig. 1). This was followed by no recording for two weeks (washout). Then, the second session was performed with one out of the following two conditions in randomized order: Hard-type OS or hard-type OS + CES (contingent electrical stimulation). After each session, subjects had a washout period. Finally, in the last session a soft-material OS was tested.

Jaw-muscle activity during sleep was recorded with the use of a single-channel portable electromyographic (EMG) device during all four sessions. The number of jaw-muscle EMG event per hour of sleep was compared between sessions.

Occlusal splints

Both hard-type and soft-material OS were made on a set of maxilla-mandibular study casts (New-Plastone, GC, Tokyo, Japan) which were obtained from each subject by using irreversible hydrocolloid impressions. The casts were mounted in centric relation on a mean value articulator. The detailed design of both hard-type and soft-material OS is described below. All adjustments of the splints were performed with the subjects in a supine position.

Hard-type OS

This OS is a conventional flat, full-arch maxillary stabilization splint. The splint was waxed up with canine guidance (Paraffin Wax, GC, Tokyo, Japan) in an articulator and fabricated according to standard procedures in heat-cured hard acrylic. The thickness of occlusal table was approximately 2-mm in the first molar region.

Soft-material OS

The soft-material OS was made of a ethylene vinyl acetate copolymer sheet (ERKOFLEX®, ERKODENT, Pfalzgrafenweiler, Germany) that was pressed on the maxillary study casts by a vacuum adapter (ERKOFORM-3D®, ERKODENT, Pfalzgrafenweiler, Germany). After curing, the sheet was curved to ordinary usage of sports mouth guard. The thickness of occlusal table was approximately 2.5-mm between the upper and lower first molars and comparable to the hard-type OS.

EMG recordings and contingent electrical stimulation

EMG activity during sleep was simultaneously recorded from the one side of anterior temporalis muscle (Grindcare®, MedoTech, Herlev, Denmark). The belly of the temporalis muscle was determined by manual palpation during voluntary tooth contraction. This EMG device has been developed for feedback to reduce jaw muscle activity during sleep [19]. It is based on the principle of CES, where the electrical stimulus applied through the recording electrode evokes an inhibitory response in the active jaw muscle. The device continuously records and analyses the EMG activity and only when the EMG activity exceeds an individually determined threshold, the feedback system will trigger the electrical stimulation [12, 18, 19].

Statistics

Parametric statistics (mean ± SD) and 2-way analysis of variance (2-ANOVA) with repeated measures followed by Student-Newman-Keuls (SNK) post-hoc tests were used to describe the data. The repeated measure was "session" (4 levels: baseline, hard-type OS, hard-type OS + CES, soft-material OS) and “night” (5 levels) and the outcome variable the total number of EMG events per hour sleep. The data for the duration of sleep are reported as median with interquartile ranges. The level of significance was set at $P < 0.050$.

Results

The median duration of sleep in each session was, baseline: 4.9 h [IQR 3.9 - 5.7 h], hard-type OS: 4.8 h [IQR 4.1 - 5.7 h], hard-type OS + CES: 4.8 h [IQR 4.0 - 5.8 h], and soft-type OS: 5.2 h [IQR 4.2 - 6.7 h] ($P > 0.05$).

There was a significant main effect of session (ANOVA: $P = 0.002$), but not night (ANOVA: $P = 0.18$) and no interaction between session and night (ANOVA: = P = 0.314). The jaw-muscle activity during sleep was 46.6 ± 29.8 EMG events / hour at baseline and significantly decreased during the hard-type OS (17.4 ± 10.5, SNK: $P = 0.007$) and the hard-type OS + CES (10.8 ± 7.1, SNK: $P = 0.002$, Fig. 2). However, the soft-type OS was not associated with a significant change in jaw muscle activity when compared to baseline values (36.3 ± 24.5, SNK: $P = 0.055$). The post-hoc tests could not identify statistical differences between the hard-type OS sessions and the soft-material OS.

Although there were no significant differences for the EMG events / hour sleep between the repeated nights, the soft-type OS (coefficient of variance = 98.6 ± 35.3 %) was associated with significantly greater night-to-night variations than baseline (39.0 ± 11.8%) and the hard-type OS + CES (53.3 ± 13.7%, $P < 0.013$) but only marginally more than the hard-type OS (67.1 ± 24.9, $P = 0.077$).

Discussion

The specific choice of biomaterials in dentistry is often based on tradition rather than scientific evidence. In this preliminary study, we attempted to address the question of effects of soft versus hard occlusal splints (OS) on jaw muscle activity during sleep. Hard-type OS are still the first choice in management of adverse effects associated with sleep bruxism (SB), but no systematic studies are available to answer the clinical relevant question: can a soft-type OS be used instead of a hard-type OS. The results showed that the hard-type OS had a significant effect in terms of reducing the number of EMG events per hour sleep whereas the soft-material OS did not inhibit the jaw muscle activity when compared to baseline values. Interestingly, we also demonstrated that the inhibitory effect of the hard-type OS was more pronounced when combined with a novel feedback device, i.e., contingent electrical stimulation (CES). This temporary (short-term) inhibitory effect on temporalis muscle activity during sleep is in agreement with previous studies [12, 14, 15]. Another important finding from this study was the observation that the soft-material OS seemed to be associated with higher night-to-night variation in jaw-muscle activity when compared to baseline values. The greater fluctuation in the regulation of jaw muscles during sleep could be due to a dampening effect of the soft-material OS on the periodontal afferent input during teeth contacts, although the variation not was significantly different (P = 0.077) compared to the hard-type OS.

The current study has several limitations. We acknowledge that a single channel EMG device not can make a definite diagnosis of sleep bruxism and therefore used the term jaw-muscle activity during sleep. In contrast, studies using polysomnographic recordings may allow the use of “sleep bruxism” in particular if additional video and audio recordings are performed. The compliance of the participant could not directly be assessed but probably the included patients were highly motivated because they were also requested to use the ambulatory EMG device for multiple nights. The shape of the soft- and hard- type OS were not completely the same. The OS covers both hard (teeth) and soft (palatal and lingual and buccal) tissues in order to retain in the mouth. It was not possible to duplicate with hard materials (acrylic resin) fitting to both paratal and lingual and buccal tissues due to the undercuts. However, the thickness was quite the same around 2-2½ mm. Moreover, the sample size of the current study was small and, therefore, this study is only a preliminary report, but warrants further studies into the possible impact of surface materials on jaw muscle activity during sleep. Perhaps larger sample sizes will be needed to show a significant inhibitory effects of a soft-material OS, but this present findings suggest that hard-type OS provides a more robust decrease in jaw muscle activity during sleep. Future studies also need to consider potential gender-related effects and to apply a true randomization of the interventions. However, we believe that it is unlikely that the lack of inhibitory effects associated with the use of the soft-material OS should only be explained by a sequence effect because there is no systematic trend in the night-to-night variations (Fig. 2).

Within the limitation of this study, we suggest that a soft-material occlusal splint does not cause robust inhibition of the jaw muscle activity during sleep whereas a conventional hard-type occlusal splint is associated with a significant inhibition of jaw muscle activity. The combination of contingent electrical stimulation and a hard-type occlusal splint is feasible and seems to have a more pronounced inhibitory effect than a hard-type occlusal splint alone. Overall, the choice of biomaterials for occlusal splints may have an impact on the neurobiological regulation of jaw-muscle activity during sleep.

Figure legend

Fig. 1: Time course of the pilot study. Baseline (control), hard-type OS (Michigan-type occlusal splint), and hard-type OS + CES (contingent electrical stimulation) sessions were followed by at least two-weeks washout (no OS). The order of hard-type OS and hard-type OS + CES was randomized in each subject. Finally, soft-material OS was tested.

Fig. 2: The effect of OS (occlusal splint) on temporalis EMG (electromyographic) activity (EMG events per hour sleep). 2-way analysis of variance (2-ANOVA) with repeated measures followed by Student-Newman-Keuls (SNK) post-hoc tests were used. The asterisks “*” show the significant differences from baseline values. The level of significance was set at $P < 0.050$.

Fig. 1

Study design

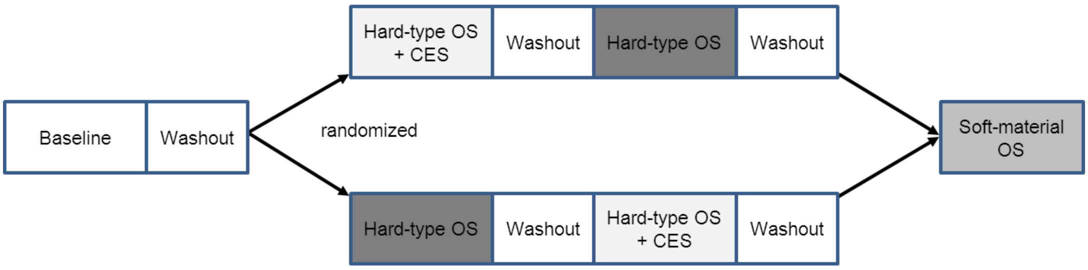
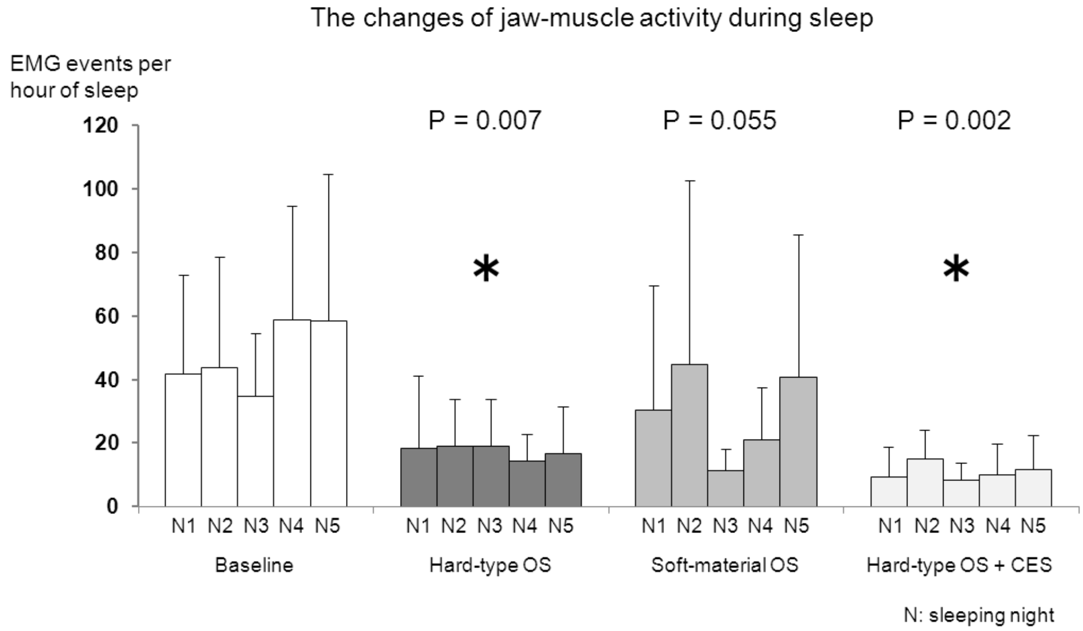


Fig. 2


The changes of jaw-muscle activity during sleep
EMG events per hour of sleep
120
100
80
60
40
20
0
P = 0.007
P = 0.055
P = 0.002
*
*
N1 N2 N3 N4 N5
Baseline
Hard-type OS
Soft-material OS
Hard-type OS + CES
N: sleeping night

References

[1] A.A.o.S. Medicine, Diagnostic and coding manual, 2nd ed., American Academy of Sleep Medicine, Westchester, IL, 2005.

[2] G.M. Macaluso, P. Guerra, G. Di Giovanni, M. Boselli, L. Parrino, M.G. Terzano, Sleep bruxism is a disorder related to periodic arousals during sleep, J Dent Res, 77 (1998) 565-573.

[3] T. Kato, J.Y. Montplaisir, F. Guitard, B.J. Sessle, J.P. Lund, G.J. Lavigne, Evidence that experimentally induced sleep bruxism is a consequence of transient arousal, J Dent Res, 82 (2003) 284-288.

[4] T. Kato, P. Rompre, J.Y. Montplaisir, B.J. Sessle, G.J. Lavigne, Sleep bruxism: an oromotor activity secondary to micro-arousal, J Dent Res, 80 (2001) 1940-1944.

[5] G.J. Lavigne, Manzini, C., Kato, T., Sleep Bruxism, Elsevier Saunders, Philadelphia, 2005.

[6] G. Bader, G. Lavigne, Sleep bruxism; an overview of an oromandibular sleep movement disorder. REVIEW ARTICLE, Sleep Med Rev, 4 (2000) 27-43.

[7] J.D. Rugh, R. Ohrbach, N.D. Mohl, G.E. Zarb, G.E. Carlsson, Occlusal parafunction, in: A textbook of occlusion, Quintessence, Chicago, 1988, pp. 249-261.

[8] L. Laberge, R.E. Tremblay, F. Vitaro, J. Montplaisir, Development of parasomnias from childhood to early adolescence, Pediatrics, 106 (2000) 67-74.

[9] G.J. Lavigne, J.Y. Montplaisir, Restless legs syndrome and sleep bruxism: prevalence and association among Canadians, Sleep, 17 (1994) 739-743.

[10] M.M. Ohayon, K.K. Li, C. Guilleminault, Risk factors for sleep bruxism in the general population, Chest, 119 (2001) 53-61.

[11] D.K. Ng, K.L. Kwok, J.M. Cheung, S.Y. Leung, P.Y. Chow, W.H. Wong, C.H. Chan, J.C. Ho, Prevalence of sleep problems in Hong Kong primary school children: a community-based telephone survey, Chest, 128 (2005) 1315-1323.

[12] F. Jadidi, E. Castrillon, P. Svensson, Effect of conditioning electrical stimuli on temporalis electromyographic activity during sleep, J Oral Rehabil, 35 (2008) 171-183.

[13] A.M. Leib, The occlusal bite splint--a noninvasive therapy for occlusal habits and temporomandibular disorders, Compend Contin Educ Dent, 17 (1996) 1081-1084, 1086, 1088 passim.

[14] T. Harada, R. Ichiki, Y. Tsukiyama, K. Koyano, The effect of oral splint devices on sleep bruxism: a 6-week observation with an ambulatory electromyographic recording device, J Oral Rehabil, 33 (2006) 482-488.

[15] C. Dube, P.H. Rompre, C. Manzini, F. Guitard, P. de Grandmont, G.J. Lavigne, Quantitative polygraphic controlled study on efficacy and safety of oral splint devices in

tooth-grinding subjects, J Dent Res, 83 (2004) 398-403.
[16] E. Lindfors, T. Magnusson, A. Tegelberg, Interocclusal appliances--indications and clinical routines in general dental practice in Sweden, Swed Dent J, 30 (2006) 123-134.
[17] S.F. Dworkin, L. LeResche, Research diagnostic criteria for temporomandibular disorders: review, criteria, examinations and specifications, critique, J Craniomandib Disord Facial Oral Pain, 6 (1992) 301-355.
[18] F. Jadidi, O. Norregaard, L. Baad-Hansen, L. Arendt-Nielsen, P. Svensson, Assessment of sleep parameters during contingent electrical stimulation in subjects with jaw muscle activity during sleep: a polysomnographic study, Eur J Oral Sci, 119 (2011) 211-218.
[19] F. Jadidi, K. Wang, L. Arendt-Nielsen, P. Svensson, Effect of stimulus parameters and contraction level on inhibitory responses in human jaw-closing muscles: Implications for contingent stimulation, Arch Oral Biol, 54 (2009) 1075-1082.