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The effect of intermittent use of occlusal splint devices on sleep bruxism: a 4-week observation with a portable electromyographic recording device

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SUMMARY This randomised controlled study investigated the effect of intermittent use of occlusal splints on sleep bruxism compared with that of continuous use by measuring masseter muscle electromyographic activity using a portable electromyographic recording system. were randomly allocated continuous group and intermittent group. Subjects in the continuous group wore stabilisation splints during sleep for 29 nights continuously, whereas those in the intermittent group wore splints during sleep every other week, that is they used splints on the 1st-7th, 15th-21st and 29th nights. Electromyographic activity of the masseter muscle during sleep was recorded for the following six time points: before (baseline), immediately after, and 1, 2, 3 and 4 weeks after the insertion of a stabilisation splint. The number of nocturnal masseter electromyographic events, duration and the total activity of sleep bruxism were analysed. In the continuous group, nocturnal masseter

electromyographic significantly events were reduced immediately and 1 week after the insertion of the stabilisation splint, and duration was reduced immediately after the insertion (P < 0.05, Dunnett's test), but no reduction was observed at 2, 3 and 4 weeks after insertion. In the intermittent group, nocturnal masseter electromyographic events and duration were significantly reduced immediately after and also 4 weeks after insertion of the stabilisation splint (P < 0.05, Dunnett's test). The obtained results of the present exploratory trial indicate that the intermittent use of stabilisation splints may reduce sleep bruxism activity for a longer period compared with that of continuous use.

KEYWORDS: sleep bruxism, stabilisation splint, electromyography, randomised controlled trial, masseter muscle

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Introduction

Sleep bruxism (SB) is considered as one of the major risk factors which may cause dental problems such as tooth wear, progression of periodontal disease, damage or failure of dental restorations or implants (1–3), and musculoskeletal problems such as masticatory muscle hypertrophy and temporomandibular disorders (TMD) (4, 5). Although the aetiology and neurological mechanisms which generate SB are not well understood, researches including a systematic review

have proven that central factors, especially sleep-related aetiological factors, play a major role in the development of SB (6–9). Wearing occlusal splints during sleep is the most commonly accepted modality among the treatments for SB to date (10–15).

Stabilisation splints have been reported to decrease masseter muscle activity in more than 50% of bruxism patients (16–18). Specifically, the short-term use of stabilisation splints reduced SB-related events in a recent randomised controlled experimental study (12). However, there are clinical reports that splints

did not diminish SB activity with long-term observation (19, 20), and SB activity returns to baseline levels in 2 weeks although it decreased immediately after wearing splints (11). The result of systematic reviews indicated that the effect of splints on SB was controversial because of the lack of strong scientific evidence (21, 22), although positive short-term effects have been shown in recent studies (11, 12, 23).

Splint devices were commonly used in a continuous manner, that is, they were used during sleep every night without discontinuation in most previous studies (14, 16, 19, 24). Several studies such as crossover trials with a wash-out period (2 weeks to 2 months) to minimise the carry-over effect of previously used devices (10, 11). If this wash-out period is short enough to maintain a carry-over effect and the following intervention could affect SB, it might be possible to reduce SB activity for a longer period.

Therefore, the present randomised clinical trial (RCT) aimed to examine the effect of intermittent use of stabilisation splints on SB compared with that of continuous use by measuring masseter muscle electromyographic (EMG) activity using a portable EMG recording system. Two types of use of splints, that is, wearing stabilisation splints every night continuously versus wearing stabilisation splints intermittently (every other week), were employed in this exploratory trial study. The null hypothesis tested in this study was that there is no difference in the effect on SB between the continuous and intermittent use of stabilisation splints in terms of masseter muscle EMG activity.

Materials and methods

Subjects

Twenty bruxers (9 men and 11 women with a mean age of 28-9 years old; range, 24–37 years old) were recruited from the students and staff of Kyushu University. Inclusion criteria were (i) fulfilling the diagnostic criteria of SB from the American Academy of Sleep Medicine (AASM): reporting tooth-grinding or clenching in combination with at least one of the following conditions: abnormal tooth wear; sounds associated with bruxism; and jaw muscle discomfort (25), and (ii) in good general health. Exclusion criteria were as follows: (i) more than two missing posterior teeth excluding third molars; (ii) use of a removable

prosthesis; (iii) existence of TMD problems according to the research diagnostic criteria for TMD (RDC/TMD) (26); (iv) use of medication with possible effects on sleep or motor behaviour; (v) alcohol or drug abuse; (vi) ongoing physical or dental therapy including orthodontic treatment; (vii) major neurological or psychiatric disorders; and (viii) sleep disorders.

Informed consent was given to each subject prior to the interventional procedure. This study was approved by the ethics committee of Kyushu University.

Splint device

Stabilisation splints, which covered the occlusal surfaces of the maxillary dental arch, were used. Splints were made on a maxillary plaster cast mounted on an articulator with the mandibular cast mounted in intercuspal position. They were made of light cured acrylic resin (Splint-Resin LC*). The splint had a smooth surface with 1- to 2-mm thickness in second molar regions, and occlusal contacts with mandibular buccal cusps with cuspid guidance. A splint was made for every subject by the same operator (H.M.).

Masseter EMG recording

EMG activity on one side of the masseter muscle was recorded with a portable EMG recording unit (Pro-Comp INFINITI[†]) and disposable Ag/AgCl surface electrodes (T3402M - TriodeTM electrode[†], Fig. 1). All recordings were performed in the subject's natural environment, that is one's own bedroom. The sampling frequency for EMG signals was 2048 Hz. Bipolar electrodes were set on the masseter muscle in parallel to muscle fibres with an interelectrode distance of 20 mm after cleaning the skin with ethanol. Blood volume pulse (BVP) sensor was also set in a fingertip to monitor the heart rate. These procedures were performed by the subject after careful instruction by the same operator (H.M.). The subjects were instructed to place electrodes in the same sites in the same manner using an instruction brochure in which the step-bystep procedure was visually indicated. The recording

^{*}GC Corporation, Tokyo, Japan.

[†]Thought Technology, Montreal, QC, Canada.

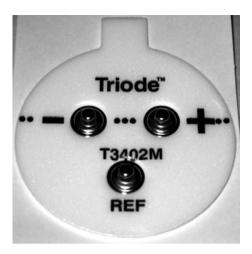


Fig. 1. Disposable Ag/AgCl surface electrodes; T3402M − Triode^{∞} electrode^{\dagger}.

was commenced after the subject's skill for electrode application was confirmed.

Subjects were instructed to perform maximal clenching for 3 s for three times after the commencement of recording. The mean EMG activity from these three maximal clenching tasks was used as a maximal voluntary contraction (MVC) for the data analysis. Subjects were also instructed to perform maximal clenching when they awoke, which was recognised as the end of data recording. The beginning of the sleep period was defined at 20 min after the first maximal clenching session or subsequent stable EMG signals and heart rate were observed. The time when EMG signals and heart rate exhibited an unstable pattern before waking up was regarded as the end of sleep. The reliability of EMG data was confirmed by monitoring raw signals.

Experimental procedures

This study was designed as a RCT. Subjects were randomly assigned to either the continuous group (C group) or intermittent group (I group). A randomisation list was prepared according to a permuted block design by software to create a random number prior to the commencement of this study. A code envelope was opened by the dentist in charge to allocate the subject to either the C group or I group after the installation and adjustment of the splint. The installation and adjustment of the splint were performed by the dentists in charge, who had sufficient experience in splint therapy. Screening, clinical examination,

data acquisition and data analysis were conducted by one investigator (H.M.), who was blinded to the subject's status, that is C group or I group.

Subjects in the C group used splints continuously during sleep for 29 nights, whereas those in the I group used splints every other week, that is, at the 1st to 7th, 15th to 21st and 9th nights (Fig. 2). Careful instructions regarding the usage of splints were given to the subjects to reduce the deviation from the experimental protocol. Subjects were then interviewed regarding the usage of splints at follow-up visits.

Recordings of masseter EMG were conducted at baseline, immediately after, and 1, 2, 3 and 4 weeks after wearing splints (Fig. 2). Subjects were instructed to record masseter EMG data for two consecutive nights at each time point. At the first visit, subjects were instructed how to use the portable EMG recording unit and took it home. Masseter EMG data were verified at the second visit (baseline). When technical problems were detected or reported, adequate instruction was provided and additional recordings were performed. This procedure was also conducted at the visits for 1, 2, 3 and 4 weeks.

Data analysis

The EMG data were averaged at 16 Hz and saved on a memory card Compact Flash (SDCFH-002G-U46[‡]) and transferred to a personal computer. The data were analysed with a software program (Biograph infiniti version $5.1.2^{\dagger}$). The nocturnal masseter EMG events was defined as: (i) EMG elevations above 10% MVC; (ii) two consecutive events with an interval of <5 s were linked; and (iii) events with a duration shorter than 3 s were excluded (27). The number of nocturnal masseter EMG events per hour of sleep (EVENT), total duration expressed as the percentage against the duration of sleep (DURATION) and total EMG activity (AREA) were calculated for each night. Data were obtained for the following six time points: baseline, immediately after (0 weeks), and 1 (1 week), 2 (2 weeks), 3 (3 weeks) and 4 (4 weeks) after wearing splints. Regarding the baseline, the second-night data were used to avoid the first-night effect. The firstnight data were used for other time points in

[‡]SanDISK, Milpitas, CA, USA.

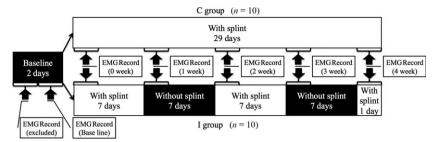


Fig. 2. Study design. C group: subjects who used a stabilisation splint continuously; I group: subjects who used a stabilisation splint intermittently.

principle, and the second-night data were used when technical errors were detected in the first night.

Statistical analysis

Baseline EMG activity was compared between the C group and I group by Student's t-test. The effect of a splint on masseter EMG immediately after insertion was verified by a paired t-test. The effect of intermittent use of splints on masseter EMG was compared with that of continuous use by two-way repeated-measures anova. One-way repeated-measures anova followed by Dunnett's multiple comparison test were performed to evaluate the treatment effect of each usage of splints. A value of P < 0.05 was considered statistically significant. All statistical analyses were performed by IBM SPSS Statistics 19 for windows§).

Results

All participants, that is 20 subjects, completed the experiment without complaint such as pain in the jaw and/or headache in the morning. The C group consisted of 2 men and 8 women with a mean age of 28·6 years (24–37), and the I group consisted of 7 men and 3 women with a mean age of 29·1 years (26–35), respectively. No evident deviation from the experimental protocol regarding the usage of splints was confirmed through the interview with participants at designated visits.

The duration of sleep was 5.0 ± 1.1 and 5.1 ± 0.9 h in the C group and I group, respectively, with no significant difference between the two groups (P = 0.419, Student's t-test). Mean values (\pm standard deviation) of EVENT, DURATION and AREA at six

time points are presented in Table 1. There was no significant difference in baseline EMG activity between the two groups (P > 0.05, Student's t-test; Table 2). There was a significant reduction in masseter EMG activity in 20 subjects (pooled) at 0 weeks in EVENT, DURATION and AREA (P < 0.05, paired t-test; Table 3).

There were significant differences for the observation period in EVENT, DURATION and AREA (P < 0.05) without an interaction (P > 0.05), but there was no significant difference in EMG activity in any of the three EMG variables between the C and I groups (P > 0.05, two-way repeated-measures ANOVA; Table 4).

One-way repeated-measures ANOVA revealed that there were significant differences for the observation period without an interaction in EVENT, DURATION and AREA for the C group and I group (Table 5).

There was a significant reduction in masseter EMG activity at 0 and 1 week in EVENT and at 0 weeks in DURATION for the C group, whereas a significant reduction in masseter EMG activity was observed at 0 weeks and 4 weeks in EVENT and DURATION for the I group (P < 0.05, Dunnett's multiple comparison; Table 1).

Discussion

The present exploratory trial study is the first RCT in which the effect of intermittent use of stabilisation splints was compared with that of continuous use. A unique feature of this study is that the difference in the usage of stabilisation splints was focused. Consequently, the null hypothesis that 'there is no difference in the effect of SB between continuous and intermittent use of stabilisation splints in terms of masseter muscle EMG activity' was rejected according to the obtained results.

[§]International Business Machines Corp., New York, NY, USA.

Table 1. Mean values and results of Dunnett's multiple comparison test of EVENT, DURATION and AREA

	Event		Duration		Area	
	times h ⁻¹	P-value	%	<i>P</i> -value	10 ⁻² area score	P-value
C group $(N = 1)$	0)					
Base line	6.6 ± 2.6		1.02 ± 0.50		0.16 ± 0.08	
0 week	3.5 ± 2.3	0.001	0.56 ± 0.50	0.007	0.10 ± 0.12	0.261
1 week	$4\cdot 3 \pm 2\cdot 3$	0.020	0.73 ± 0.48	0.155	0.13 ± 0.10	0.777
2 week	4.9 ± 2.4	0.135	0.70 ± 0.37	0.097	0.09 ± 0.04	0.074
3 week	5.3 ± 2.4	0.342	0.84 ± 0.66	0.574	0.15 ± 0.09	0.998
4 week	4.9 ± 2.1	0.130	0.68 ± 0.31	0.074	0.08 ± 0.04	0.063
I group $(N = 10)$	0)					
Base line	5.9 ± 2.2		0.86 ± 0.64		0.13 ± 0.14	
0 week	2.6 ± 1.7	0.000	0.35 ± 0.39	0.001	0.04 ± 0.06	0.062
1 week	6.3 ± 3.2	0.954	0.87 ± 0.62	1.000	0.15 ± 0.14	0.898
2 week	4.8 ± 2.5	0.373	0.64 ± 0.46	0.310	0.09 ± 0.09	0.691
3 week	6.1 ± 3.1	0.996	0.78 ± 0.63	0.961	0.13 ± 0.17	1.000
4 week	3.9 ± 2.4	0.026	0.41 ± 0.35	0.005	0.04 ± 0.04	0.061

Values given are mean \pm standard deviation.

P-values represent the results of Dunnett's multiple comparison test versus corresponding baseline data.

C group: subjects who used stabilisation splint continuously, I group: subjects who used stabilisation splint intermittently.

EVENT: The number of nocturnal masseter EMG events per hour of sleep, DURATION: total duration expressed as the percentage against the duration of sleep, AREA: total EMG activity.

Table 2. Comparison of masseter EMG activity at baseline

	C group (N = 10)	I group (N = 10)	<i>P</i> -value
EVENT (times h ⁻¹)	6·6 ± 2·6	5.9 ± 2.2	0.520
DURATION (%)	1.02 ± 0.50	0.86 ± 0.64	0.542
AREA	0.16 ± 0.08	0.13 ± 0.14	0.476
$(10^{-2} \text{ area score})$			

Values given are mean \pm standard deviation.

P-values represent the results of Student's t-test.

C group: subjects who used stabilisation splint continuously, I group: subjects who used stabilisation splint intermittently.

EVENT: The number of nocturnal masseter EMG events per hour of sleep, DURATION: total duration expressed as the percentage against the duration of sleep, AREA: total EMG activity.

The diagnostic criteria of SB from AASM (25) were used for the selection of subjects in the present study. Although the clinical criteria of the AASM have limitations, it is one of the most commonly used diagnostic indicators of SB in both clinical and research situations (11, 14, 15). The current study found that the frequency of nocturnal masseter EMG events at baseline in 20 subjects who were selected with AASM criteria was $6.4 \pm 2.4 \ h^{-1}$. The frequency of nocturnal masseter EMG events at baseline showed no sig-

Table 3. Comparison of masseter EMG activity between baseline and immediately after the insertion of splints

	Baseline	Immediately after	<i>P</i> -value
EVENT (times h ⁻¹)	6.2 ± 2.4	3.1 ± 2.0	0.000
DURATION (%)	0.94 ± 0.57	0.46 ± 0.45	0.000
AREA (10 ⁻² area score)	0.15 ± 0.11	0.07 ± 0.09	0.008

Values given are mean \pm standard deviation.

P-values represent the results of Paired *t*-test. N = 20.

EVENT: The number of nocturnal masseter EMG events per hour of sleep, DURATION: total duration expressed as the percentage against the duration of sleep, AREA: total EMG activity.

nificant difference between the C group and I group, indicating that an appropriate random allocation was obtained.

The duration of sleep in the present study was relatively short. Most of the oromotor activity related to SB is observed in lighter sleep stages, which is dominantly observed in the last third or fourth of total sleep (28). It was considered that many recordings in this study lacked the third or fourth sleep cycle.

A portable EMG recording device was used in this study to evaluate the effect of a stabilisation splint on

Table 4. Results of two-way repeated-measures ANOVA

	EVENT		DURAT	ΓΙΟΝ	AREA	
	F- value	P- value	F- value	P- value	F- value	P- value
Main effect						
Usage	0.091	0.766	1.142	0.340	0.349	0.562
Time	10.369	0.000	7.309	0.000	5.682	0.002
Interaction Usage×Time	2.118	0.070	0.296	0.593	1.040	0.383

F-values and *P*-values represent the results of two-way repeated-measures anova. N = 20.

Usage represents between-subjects effects: between C group and I group, Time represents within-subject effects, that is observation period.

C group: subjects who used stabilisation splint continuously, I group: subjects who used stabilisation splint intermittently.

EVENT: The number of nocturnal masseter EMG events per hour of sleep, DURATION: total duration expressed as the percentage against the duration of sleep, AREA: total EMG activity.

Table 5. Results of one-way repeated-measures ANOVA

	EVENT		DURATION		AREA	
	F- value	<i>P</i> -value	F- value	<i>P-</i> value	F- value	P- value
C group I group	3·717 9·007	0·021 0·000	2·627 6·051	0·036 0·008	2·665 3·874	0·034 0·048

F-values and P-values represent the results of one-way repeated-measures anova. N=20.

C group: subjects who used stabilisation splint continuously, I group: subjects who used stabilisation splint intermittently.

EVENT: The number of nocturnal masseter EMG events per hour of sleep, DURATION: total duration expressed as the percentage against the duration of sleep, AREA: total EMG activity.

SB for a longer period at multiple time points. The major benefits of using a portable EMG recording device include multiple-night recording in the natural environment for the subject, which can be conducted with minimum expense (29, 30). Even though every possible measure to prevent recording failure was taken, some error was anticipated in recording masseter EMG activity, because of mechanical problems, inadequate recording procedures by subjects, or other reasons. Therefore, masseter EMG activity was recorded for two consecutive nights at each time point. When errors were found in data from a predetermined night, those from the other night were used for data analysis. Accordingly, there were no missing

values for masseter EMG activity data in the present study.

A threshold level of 10% MVC was used to minimise the masseter EMG bursts, which were related to other oro-facial activities such as swallowing, in this study. Among various EMG threshold levels to detect SB activity in previous studies (24, 27, 31, 32), the 10% MVC threshold level has been reported in recent controlled studies that evaluated the effects of splints on SB from different laboratories (24, 31, 33-35). This 10% MVC threshold level could be considered as the standard for evaluating SB. Events shorter than 3 s were excluded to exclude most artifacts and to include most nocturnal masseter EMG events (26). Although most artefacts and activities other than bruxism can be excluded by investigating raw EMG signals, some confounding biological activities such as swallowing, talking and head rotation, and the presence of concomitant sleep disorders such as periodic limb movement and sleep breathing disorders, cannot be completely differentiated from SB activity in the absence of simultaneous audio-video recording. Accordingly, there is a possibility that the actual obtained SB activity can be overestimated (28), even though the increase in heart rate using BVP signals helped for determining nocturnal masseter EMG events more precisely (27).

In the present study, stabilisation splints significantly reduced masseter EMG activity at 0 and 1 weeks and there was no significant reduction at 2, 3 and 4 weeks in the C group (one-way repeatedmeasures ANOVA). These results agree with those in the previous study, in which oral devices significantly reduced masseter EMG activity during sleep immediately after insertion, but no reduction was observed at 2, 4 and 6 weeks after insertion (11). A possible effect from peripheral sensory input might have affected masseter EMG activity, even though central mechanisms are considered to be predominant. Several other studies also revealed that changes in the input feedback of peripheral oral receptors temporarily diminish but do not stop SB (6, 17). Interestingly, the I group had a significant reduction in masseter EMG activity at 4 weeks as well as at 0 weeks (one-way repeated-measures anova). When the ancova was performed, the previously observed trends seen with the ANOVA were retained without substantial changes. These results indicate that the intermittent use of stabilisation splints may reduce SB activity for a longer period compared with that in continuous use.

Regarding the results of statistical analyses, careful interpretation must be carried out since the sample size in this exploratory trial study is small. It should be recognised that a type II error (false negative) is possible at 2 and 3 weeks for both groups and that a type I error (false positive) is possible at 4 weeks for the I group with this small sample size. Even though there are limitations to the present study, the immediate reduction in masseter EMG activity was reconfirmed. Moreover, the obtained results indicated the possibility that the intermittent use of stabilisation splint could reduce SB activity for a longer period compared with the continuous use. However, our results should be carefully interpreted until these findings have been confirmed in future studies. Finally, the future direction should address a comparison of the effect of intermittent use of stabilisation splints on SB activity in subtypes of bruxers (phasic, tonic and mixed) (31) and control subjects.

Conclusions

This study has demonstrated that the intermittent use of stabilisation splints may reduce SB activity for a longer period compared with that of continuous use.

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