Journal of Dental Sciences 19 (2024) 1714–1721

Available online at www.sciencedirect.com

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Effects of vibratory feedback stimuli through an oral appliance on sleep bruxism: A 14-week intervention trial

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Received 23 October 2023; Final revision received 11 November 2023; accepted 12 November 2023
Available online 20 November 2023

KEYWORDS
Biofeedback;
Bite force;
Occlusal splints;
Sleep bruxism

Abstract *Background/purpose:* Various biofeedback stimulation techniques for managing sleep bruxism (SB) have recently emerged; however, the effect of the successive application of vibratory feedback stimulation has not been clarified. This study aimed to elucidate the effect of vibration feedback stimulation via an oral appliance (OA) on SB.
Materials and methods: This prospective, single-arm, open-label intervention study included 20 participants diagnosed with "definite" SB who wore a specially designed OA for 98 nights at home. A force-based SB detection system triggered a vibrator attached to the OA. Vibratory stimulation was withheld during the first 3-week adaptation period (weeks 1–3), applied during the 9-week stimulation period (weeks 4–12), and withheld again during the post-stimulation period (weeks 13–14). The number and duration of SB events per hour of sleep were calculated based on piezoelectric signals recorded with the OA-based vibration feedback device and compared between weeks 3 and 4, 8, 12, and 14 and between weeks 12 and 14 using the Friedman test (post-hoc test with Bonferroni correction).
Results: The duration of SB events significantly decreased after vibratory stimulation (weeks 3 versus 4, 8, and 12: $P < 0.001$, $P = 0.026$, and $P = 0.033$, respectively) and then significantly increased upon cessation of vibratory stimulation after the stimulation period (weeks 12 versus 14: $P < 0.001$).
Conclusion: Contingent vibratory stimulation through an OA-based vibration feedback device may suppress SB-related masticatory muscle activity continuously for 9 weeks and may be an effective alternative for managing SB.

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https://doi.org/10.1016/j.jds.2023.11.003

Introduction

In the third edition of the International Classification of Sleep Disorders, sleep bruxism (SB) is categorized as a sleep-related movement disorder and defined as repetitive jaw-muscle activity characterized by clenching or grinding of the teeth during sleep, which is associated with sleep arousal.[1] SB may lead to serious dental problems, e.g., tooth attrition with dentin exposure,[2] fractures and chipping of dental prostheses or teeth,[3] and exacerbation of periodontal disease and temporomandibular disorders.[4,5] Therefore, various SB management methods have been proposed, including oral appliance (OA) use,[6,7] biofeedback approaches, pharmacological therapy, and cognitive-behavioral treatment. Using OAs can reduce SB-related masticatory muscle activity[8]; however, such effects are transient, and after approximately 2 weeks of use, the SB level is reported to return to that before the splint was applied,[9,10] probably due to the patient's adaptation to the OA. Nevertheless, an OA has clinical significance even after adaptation because it can protect teeth or restorations from the excessive occlusal force of SB. Pharmacological treatments also have SB inhibitory effects,[11] although their efficacy and safety have not been thoroughly established.[6] Biofeedback treatments using auditory, electrical, and vibratory stimulation[12–15] are effective in inhibiting SB. However, auditory stimulation may arouse the patient or his/her sleeping partner through the generated sounds. Electrical stimulation may affect patients with pacemakers.

Vibration stimulation may cause discomfort or sleep disturbances,[16,17] but does not cause significant side effects similar to those of auditory or electrical stimulation, and it has the same level of SB inhibition. The effect of vibration stimulation applied for 4 weeks showed a significant reduction in the number and duration of SB episodes, without subjective or objective sleep disturbance.[16] The SB inhibition effect disappeared immediately after the cessation of vibration stimulation, suggesting that 4 weeks of vibration stimulation feedback had no behavioral learning effect.[16] However, for the clinical application of the method to patients with chronic SB, a long-term evaluation of the effects of vibratory feedback should be conducted. Such studies may also elucidate the existence of behavioral learning effects.

Therefore, this study aimed to evaluate the SB inhibition effect of vibratory feedback stimulation. The null hypothesis of this study was that there was no difference in SB levels between periods with and without stimulation.

Materials and methods

Ethics statements

This clinical trial was approved by the institutional ethics committee (number: S18, CRB3200002) and followed the ethical principles of the Declaration of Helsinki and the Clinical Trials Act (Japan). All participants provided written informed consent. The study protocol was registered with the Japan Registry of Clinical Trials (https://jrct.niph.go.jp/, trial registration number: jRCTs032220401).

Participants

Twenty-four healthy adults were screened on the basis of the clinical diagnostic criteria for SB[18] between October 2022 and July 2023. The inclusion criteria were (1) nocturnal tooth grinding sounds occurring three or more nights in a week during the last 6 months, as reported by the participant's sleep partner, and (2) symptoms of morning masticatory muscle tenderness or fatigue, masseter muscle hypertrophy upon clenching, or clinical findings of tooth wear with exposed dentin on three or more occluding surfaces. The exclusion criteria were as follows: (1) two or more missing molars, except for the third molars; (2) use of a removable denture; (3) active dental treatment, including orthodontic therapy; (4) medication administration with possible effects on motor behavior and sleep; (5) drug or alcohol abuse; (6) major psychiatric or neurological disorders; and (7) sleep disorders.

The participants completed two nights of unattended in-home electromyography (EMG) recordings during sleep using an ambulatory single-channel wearable EMG device (EMG Logger; GC Corp., Tokyo, Japan).[19] To avoid the first-night effect,[20] the second-night EMG data were evaluated to diagnose SB. The participants were provided a confirmed diagnosis of "definite" SB when they exhibited $\geq$7.6 SB episodes per hour of sleep.[19]

Sample size calculation

Based on a previous study,[16] we expected vibration stimulation via the OA to decrease the duration of SB episodes by 22.13 s/h. A sample size of 18 participants was required to detect this change, assuming a risk of 5% ($\alpha = 0.05$) and power of 90% ($\beta = 0.10$). After anticipating a dropout rate of 25%, the adjusted sample size was 24 participants.

Oral appliance-based vibration feedback device (Figs. 1 and 2)

The OA-based vibration feedback device comprised a force-detection OA and vibration control unit (46 × 22 × 13 mm, 12 g; COREFRONT Co., Ltd., Tokyo, Japan). This device was a modified version that had been previously described.[16] Specifically, a 40-μm-thick pressure-sensitive piezoelectric film (Elmech Electronics Industries Co., Ltd., Niigata, Japan) was placed 1 mm below the occlusal surface of the force detection OA, shaped like a maxillary stabilization appliance. The force detection OA was fabricated from a dental milled resin (pure PMMA disc; Quest Co., Ltd., Tokushima, Japan). When the piezoelectric film is deformed by any substantial occlusal force, the piezoelectric sensor generates an electrical signal depending on the degree of mechanical stress applied to the film. The force detection OA includes an amplifier and a threshold detection circuit that produces a signal when the preset threshold is exceeded. The output signal drives the battery-powered vibration control unit. This biofeedback system uses a rechargeable lithium battery built into the vibration control unit, thus making the device wireless. The vibration feedback application configuration (intensity and duration) was set according to a previous study.[16] A single dentist

(K.M.) adjusted the force detection OA to achieve full contact with all the mandibular teeth and maintain the centric position.

Experimental protocol (Fig. 3)

The participants were asked to wear an OA-based vibration feedback device for 98 nights. All recordings were performed at home. The vibration stimulus was not applied during the first 3-week adaptation period (nights 1—21) and during the 2-week post-stimulation period (nights 85—98); however, vibration stimuli were continuously applied during the 9-week stimulation period (nights 22—84).

Sleep bruxism event scoring

As per Aoki et al.'s study,[21] we identified piezoelectric signals $\geq$10% of the signal recorded during maximum voluntary contraction as potential SB events. Any consecutive events with an interval of $\leq$3 s were combined as a single event, whereas those with an interval of $\geq$3 s were counted as separate events. Every event lasting >1 s was considered an SB event. After conditioning, SB variables (the duration of SB events per hour of sleep and the number of SB events per hour of sleep) were calculated for all 98 nights. A dentist (K.M.) with 2 years of analytical experience performed the scoring.

Questionnaire on subjective sleep quality and usability of the device

Regarding the subjective sleep quality and usability of the device, the participants were asked to complete the original questionnaire, the modified Japanese version of the Epworth Sleepiness Scale (JESS),[22] and the modified Japanese version of the Pittsburgh Sleep Questionnaire (PSQI-J)[23] on the day after weeks 3, 4, 8, 12, and 14. The original questionnaire included items on the average number of awakenings perceived during sleep in the previous week and a 100-mm visual analog scale (VAS) related to toothache, jaw pain, body stiffness, difficulty staying asleep, choking sensation, and difficulty turning over while wearing the device. The VAS was anchored with 0 indicating "none" and 100 indicating "the worst imaginable." The modified JESS was used to examine the degree of daytime somnolence in the previous week, whereas the modified PSQI-J was used to assess the subjective sleep quality in the previous week.

Statistical analyses

The data recorded over 5 weeks, including week 3 (baseline) after adaptation to the OA-based device; weeks 4, 8, and 12 with vibration stimulation; and week 14 without vibration stimulation, were analyzed (Fig. 3). Participants who were unable to record at least three nights of data for every recording week were excluded from the analysis. To examine the SB inhibition effect of the vibration stimuli, the differences in the median value of the duration and number of SB events per hour of sleep were tested among the five recording weeks using the Friedman test (post-hoc test with Bonferroni correction; Fig. 3). To evaluate the subjective sleep quality and usability of the device, the number of awakenings perceived and VAS, JESS, and PSQI-J scores were compared between the five recording nights using the Friedman test (post-hoc test in a round-robin manner with Bonferroni correction). The significance level was set at 5% (JMP Pro 16; SAS Institute Inc., Cary, NC, USA and R software; R Project for Statistical Computing, R Foundation, https://www.r-project.org).

Results

Of the 24 participants (10 women and 14 men; average age±standard deviation: 25.8 ± 2.2 years), four could not complete the entire study protocol: one due to a water-damaged circuit caused by wear of the occlusal splint surface and the other three due to insufficient data. Therefore, the data from the remaining 20 participants were analyzed.

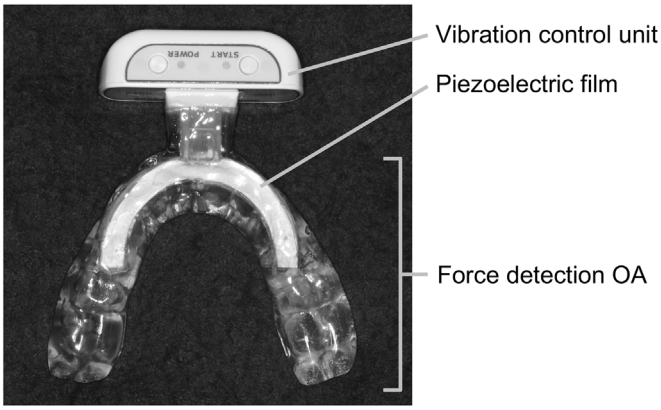

Fig. 1 OA-based vibration feedback device
Occlusal force signals are detected by a piezoelectric film located internally in the OA. The signals are sent to the vibration control unit, which generates and applies vibration stimuli to the force detection OA. The vibration application configuration (intensity and duration) is set in the vibration control unit. OA: oral appliance.

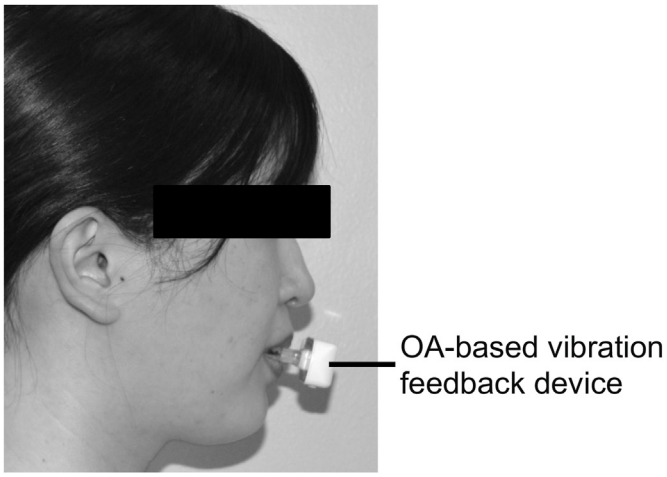

Fig. 2 Participant wearing the OA-based vibration feedback device
Recordings were conducted at the participants' homes for 98 nights. OA: oral appliance.

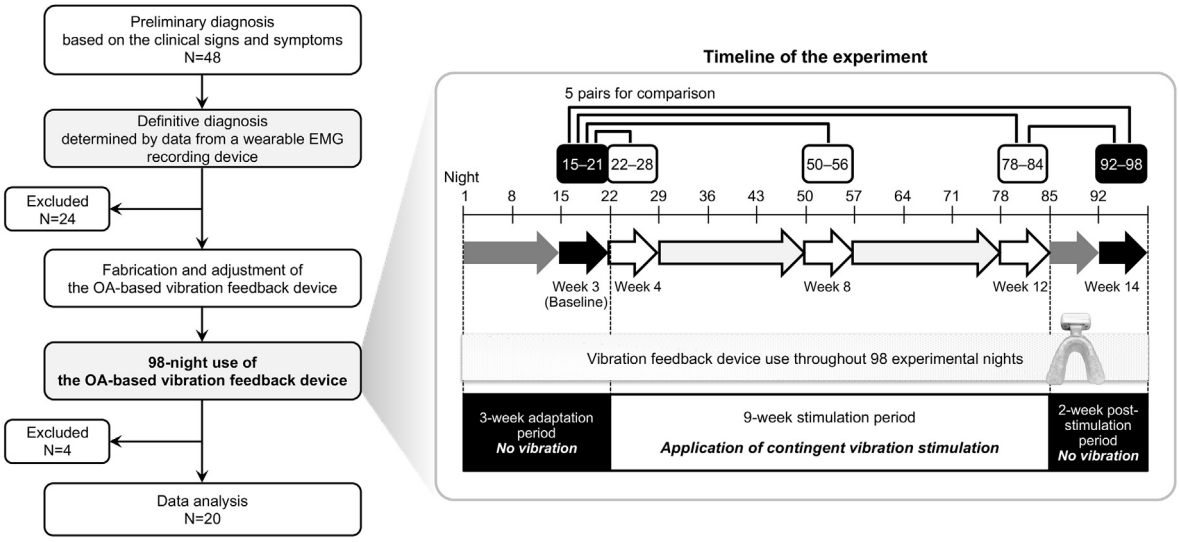

Fig. 3 Patient flow diagram and timeline of the experiment
Recording by the OA-based vibration feedback device alone with no EMG recording throughout the 98-night experiment. EMG: electromyography; OA: oral appliance.

Sleep bruxism inhibition effect by the vibration stimulus

The median value of the duration and number of SB events per hour of sleep recorded for each week and the results of the statistical analyses are summarized in Figs. 4 and 5. The effect of the recording weeks on the duration and number of SB events was significant (Friedman test, both $P < 0.001$). The post-hoc tests revealed that the duration of SB events decreased significantly on weeks 4, 8, and 12 compared with that on week 3 ($P < 0.001$, $P = 0.026$, and $P = 0.033$, respectively), but the number of SB events decreased significantly only on week 4 ($P = 0.002$). Both the duration and number of SB events increased on week 14 compared with that on week 12 (both $P < 0.001$).

Subjective sleep quality and usability of the device

The median values of the number of awakenings perceived, VAS scores for subjective sleep quality and usability of the device, JESS scores, and PSQI-J scores for the 5 weeks are shown in Table 1, along with the results of the statistical analyses.

Discussion

This study evaluated the long-term inhibitory effect of contingent vibration stimulation feedback using nightly recordings after a 3-week adaptation period followed by a 9-week stimulation period. The results showed that both

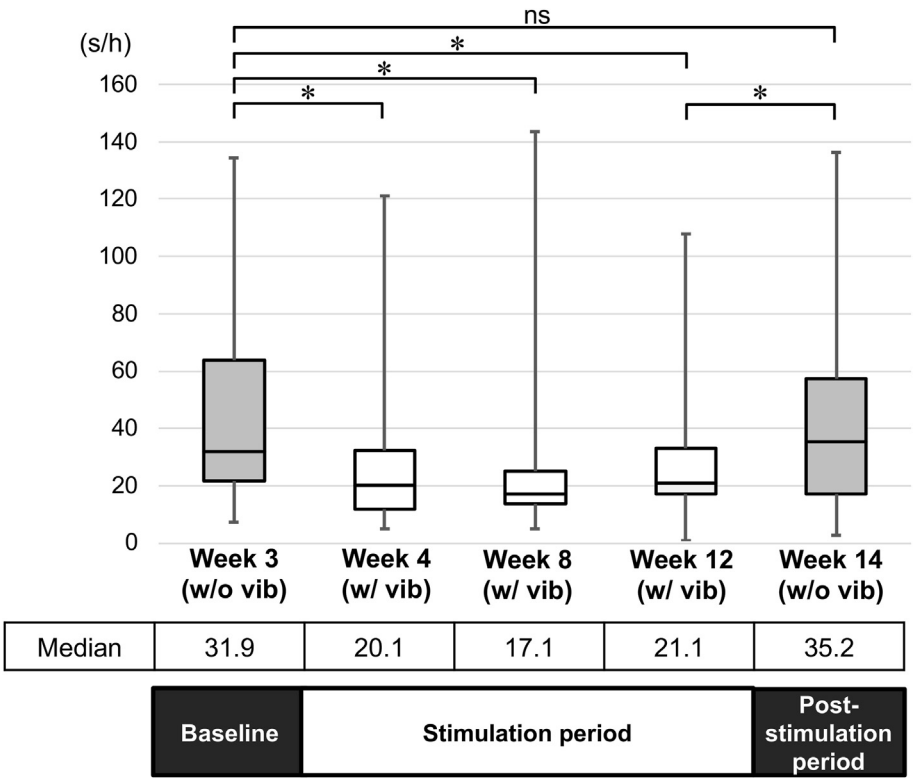

Fig. 4 Comparison of the duration of SB events between the five recording weeks
Comparison of the duration of sleep bruxism episodes between the five experimental weeks. The boxes represent the median and first and third quartiles, respectively. Whiskers represent minimum and maximum values. N = 20. ns: not significant; SB: sleep bruxism; w/o vib: without vibration stimulation; w/vib: with vibration stimulation. *$P < 0.05$.

the number and duration of SB events were continuously inhibited during the 9-week period, thereby rejecting the null hypothesis. The SB inhibition effect remained equivalent throughout the 9-week stimulation period, suggesting that the SB inhibition effect may last for a long time without adaptation to the vibration stimulation itself. Besides, during week 14 without vibration, both the duration and number of SB events returned to baseline levels. Overall, the SB inhibition effect was observed only during the stimulation period, although the SB inhibition effect disappeared when the vibration stimulation ceased, indicating that there was no learning effect from the long-term vibration stimulation. These findings are in line with those of a previous study that investigated the long-term effects of vibration feedback stimulation over 3 months.[24]

During week 4 after the adaptation period, vibration stimulation significantly reduced the duration and number of SB events by 37.0% and 20.1%, respectively, compared with that at baseline. At weeks 8 and 12, compared with baseline, the duration of SB events significantly decreased by 46.3% and 33.7%, respectively; whereas the number of SB events decreased by 27.8% and 21.8%, respectively, which were not significantly different. Previous studies have reported a greater reduction in the duration of SB episodes than in the number of SB episodes,[16,17] suggesting that vibratory stimulus is more effective in reducing the duration of SB events than the number of SB events. As with any type of SB feedback management system that would apply feedback stimuli after the SB event is detected, they are more effective in interrupting the SB events that occurred than in eliminating them.[16]

Significant differences in the number of subjective awakenings, "difficulty in turning over in bed while wearing the device," and PSQI-J score were found among the five recording weeks. Some participants complained of awakening during sleep, discomfort due to vibration stimulation, or even poor sleep quality during the study period; however, we could not find a consistent trend in association with the recording weeks.

Difficulty in staying asleep while wearing the device," as evaluated by the VAS score was also significantly different between the recording weeks. The median VAS score was the highest during week 4 when vibration stimulation started, and it decreased significantly after application of the device for 8 weeks, indicating that participants first experienced a certain degree of discomfort with vibration stimuli and then became accustomed to them.

The gold standard for SB recordings is polysomnography (PSG), with audio-video recordings in a sleep laboratory. However, the main problems associated with this approach are its cost and technical complexity. Additionally, these recordings require manual scoring by a sleep technician.[25] Recently, a single-channel ultraminiature wearable electromyograph[19] as a diagnostic device for SB has been commercially available, allowing easy quantification of masticatory muscle activity levels during sleep, although it cannot monitor sleep state. This study employed a system with a piezoelectric sensor embedded in an occlusal splint[26]

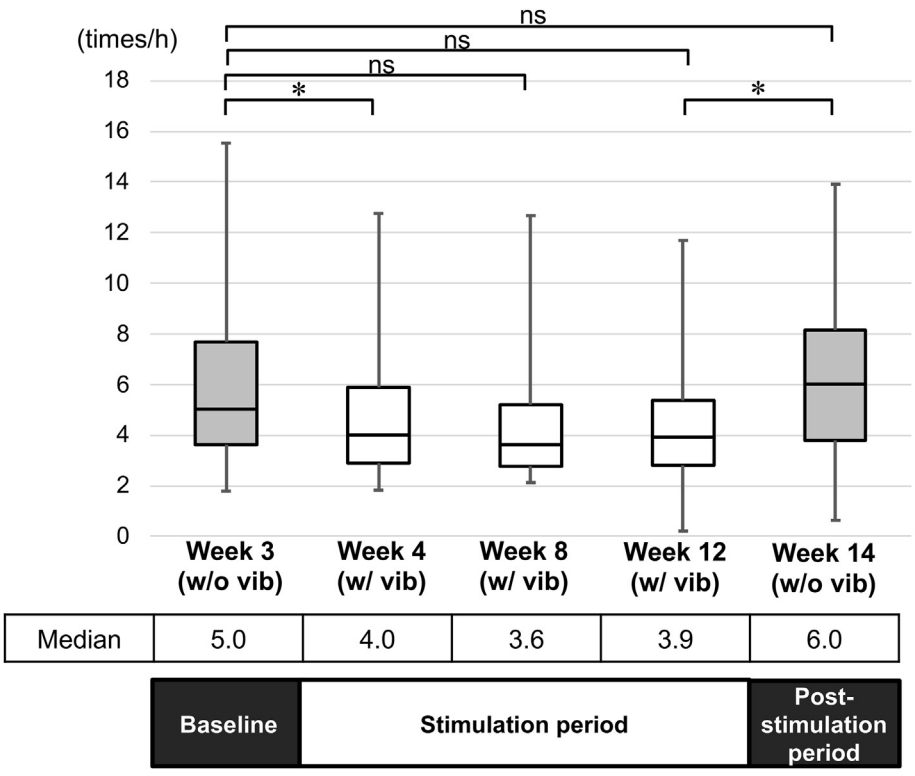

Fig. 5 Comparison of the number of SB events among the five recording weeks
Comparison of the number of SB episodes between the five experimental weeks. The boxes represent the median and first and third quartiles, respectively. Whiskers represent minimum and maximum values. N = 20. ns: not significant; SB: sleep bruxism; w/o vib: without vibration stimulation; w/vib: with vibration stimulation. *$P < 0.05$.

Table 1 Comparison of subjective sleep quality and usability of the device among the five recording weeks.

	Baseline	Stimulation period			Post-stimulation period	*P*-value (Friedman test)
	Week 3 (w/o vib)	Week 4 (w/ vib)	Week 8 (w/ vib)	Week 12 (w/ vib)	Week 14 (w/o vib)	
Number of awakenings during sleep (times)	1 (0–4)	1 (0–5)	0 (0–4)	0 (0–5)	0 (0–3)	0.007[b]
Toothache upon waking[a]	0 (0–47)	0 (0–60)	0 (0–52)	0 (0–85)	0 (0–85)	0.156
Fatigue and pain in the jaw upon waking[a]	0 (0–34)	0 (0–24)	0 (0–16)	0 (0–22)	0 (0–43)	0.140
Headache, stiffness of the body, and stiff shoulders upon waking[a]	0 (0–49)	0 (0–72)	0 (0–78)	0 (0–91)	0 (0–74)	0.284
Difficulty in staying asleep while wearing the device[a]	7 (0–64)	33 (0–71)	0 (0–86)	0 (0–74)	0 (0–63)	<0.001*,**
Choking sensation while wearing the device[a]	0 (0–44)	0 (0–0)	0 (0–0)	0 (0–3)	0 (0–0)	0.406
Difficulty in turning over in bed while wearing the device[a]	0 (0–67)	0 (0–73)	0 (0–89)	0 (0–74)	0 (0–66)	0.007[b]
Japanese version of the Epworth Sleepiness Scale score [0–24]	8.0 (0–16)	7.0 (2–20)	7.0 (1–15)	6.5 (2–17)	6.0 (2–15)	0.389
Japanese version of the Pittsburgh Sleep Quality Index score [0–21]	3.5 (1–7)	3.0 (0–10)	3.0 (0–7)	3.0 (0–9)	3.0 (0–8)	0.006[b]

N = 20. The data are represented as median (minimum to maximum). w/vib: with vibration stimulation; w/o vib: without vibration stimulation. The Friedman test was used to compare medians between weeks 3, 4, 8, 12, and 14. [a] Participants answered the question using a 100-mm visual analog scale, with anchors 0 indicating "none" and 100 indicating "the worst imaginable," respectively. [b] Post-hoc tests with Bonferroni correction showed no significant differences between the weeks. *Significant difference between weeks 4 and 12. **Significant difference between weeks 4 and 14.

to detect SB events, which minimizes problems associated with electromyographs, the complexity of attaching electrodes, reproducibility of electrode placement, and associated effects of skin conditions on the measurement data.[27] Indeed, a previous study that used portable PSG demonstrated that this system has the potential to detect SB episodes more accurately than single-channel EMG.[21]

This study has some limitations. First, the sleep stage was not monitored, and artifacts caused by body movement and other motions could not be eliminated.[28] Single-channel devices overcount the SB events.[19,29,30] These points should be noted when interpreting measurement data. Moreover, it is well known that most SB events tend to occur in relation to recurrent micro-arousal,[6,31,32] defined as an abrupt shift in electroencephalogram frequency without complete awakening.[33] However, monitoring sleep stages using a PSG device was not feasible over an extended period for this study. Future studies are needed to investigate the effects of vibration stimulation on the relationship between sleep stages and SB. Second, the influence of wearing an OA on the measurement data should be noted. The use of an OA induces short-term SB inhibition, although the SB inhibition effect diminishes after 2—4 weeks of continuous use due to adaptation.[9,34] Hence, the effect of the vibration stimulus was evaluated after the adaptation period, although the effect of wearing an OA should be elucidated in more detail in the future. Third, similar to a previous study,[16] our study revealed a certain level of discomfort with the device and vibration stimulus. However, it was suggested that the participants may have become accustomed to wearing the SB inhibition device for a long period and to vibration stimuli. Further, although the intensity and duration of the vibration were optimized[16] in a previous study, these parameters should be adjusted and optimized depending on the patient, taking into consideration both enhancement of SB reducing effect and reduction of discomfort.

In conclusion, this study demonstrated that the OA-based vibration feedback device successfully inhibited the duration and number of SB events continuously for 9 weeks after a 3-week OA-based vibration feedback device adaptation period, and the SB inhibition effect disappeared when vibration stimulation was discontinued. This biofeedback system may be an effective alternative for the long-term management of SB.

Declaration of competing interest

The authors declare no competing interests.

Acknowledgments

This study was supported by the JSPS KAKENHI (grant numbers: 20K10076, 22K17144, and 22K17118). The authors thank Ai Iizumi for assistance with data collection.

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