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Original Article

Effects of a novel oral appliance on snoring in adults: A pilot study

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AbstractBackground/purpose: Oral appliances (OAs) have been recommended as alternatives for adult patients with obstructive sleep apnea who are intolerant of continuous positive airway pressure therapy. The aim of this study was to explore the effect on snoring rates among adult patients through use of a novel OA termed the Lin OA (LOA, airflow-interference-type nasal congestion relieving and snore-ceasing oral appliance).
Materials and methods: The LOA consist of two parts: dental braces and a fixed tongue compressor. The compressor lengths range from 0.5 cm to 3.5 cm across versions. Patients used the LOA during sleep and the SnoreClock smartphone application recorded their snoring rates.
Results: A total of 4920 recordings (4239 recordings from 34 men, 681 recordings from 8 women) were used for the analysis. The recordings were sorted in accordance with the applied length of the LOA tongue compressor (0.5—3.5 cm, LOA-0.5, LOA-1 and LOA-3.5), and participants not using the LOA were denoted as the LOA-0 group. The women had higher snoring rates in the LOA-0, LOA-0.5 to LOA-2 groups, but lower snoring rates in the LOA-3 group than men by the univariate analysis. The snoring rates were significantly reduced by a mean of 5.04% with every 1 cm increase in tongue compressor length. Continuous LOA use resulted in

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snoring rate reductions of 0.02% per day by the random intercept model of the linear regression.

Conclusion: Use of this novel LOA may significantly reduce snoring rates by 5.04% with each 1 cm increase in tongue compressor length.

1. Introduction

Sleep-disordered breathing is defined as breathing abnormalities during sleep resulting from increased collapsibility of the upper airway tissues. It encompasses four sections: obstructive sleep apnea (OSA, which involves partial or complete airway obstruction), central sleep apnea syndromes, sleep-related hypoventilation disorders, and sleep-related hypoxemia disorders.[1] Habitual snoring involves varying degrees of gas exchange abnormalities with sleep fragmentation.[2] One study reported that snorers' risk of carotid stenosis is twice that of the non-snorers'.[3] Snoring is associated with hypertension, diabetes, and heart disease in elderly patients.[4] Most research has noted an increasing trend of snoring among younger generations (aged 30—50 years) as well as older ones (aged >65 years).[5–7]

Snoring affects approximately 30% of middle-aged men and 20% of middle-aged women, respectively.[8] It is essentially an abnormal respiratory sound occurring during sleep and is the earliest and most consistent sign of upper airway dysfunction. In addition, snoring can occur alone (e.g., primary snoring) or in association with OSA.[9,10] Moreover, anatomical variations in cranial base morphology had also been demonstrated between snorers with or without apneic features.[11] Therefore, early detection of snoring through surveillance and further management would benefit affected individuals.

The treatments selected for snorers are primarily based on the results of comprehensive evaluations by their referring physicians, whether they incorporate conservative managements (sleeping position adjustment, application of mandibular advancement devices) or surgical managements (uvulopalatopharyngoplasty, palatal implants).[12] The gold standard treatment for OSA is continuous positive airway pressure, yet the compliance for which has been relatively low.[13] As a result, oral appliances (OAs) are currently recommended for patients with primary snoring and for patients with OSA who cannot tolerate continuous positive airway pressure therapy or prefer alternatives.[14] Compared with continuous positive airway pressure, OAs are a better tolerated option for patients with OSA of varying severity, but mainly those with less severe OSA.[15] The mechanisms behind involve holding the mandible forward to increase upper airway volume and reduce pharyngeal collapsibility.[16] Traditional OAs are designed to optimize upper airway function and prevent its collapse through altering neutral positions of the jaw during sleep. This is achieved by holding the mandible in a more anterior position. These traditional appliances are variably termed "mandibular advancement devices", "mandibular advancement splints", or "mandibular repositioning appliances",[17] with customized OAs being fabricated from digital or physical impressions of patients' distinct oral structures.[18] Studies have reported that customized, titratable OAs could reduce scores for the apnea-hypopnea index, visual analog scale, and Epworth Sleepiness Scale as well as reduce arousal and oxygen desaturation and increase oxygen saturation to a greater extent than non-customized, titratable OAs.[13,14] Titratable OAs function under a mechanism that allows mandibular advancement in increments of ≤1 mm but limits it by a protrusive length of at least 5 mm.

OAs have been reported to reduce both the frequency and intensity of snoring, thereby improving individuals' quality of life.[14] To the best of our knowledge, our current study is the first to evaluate the effect of a tongue-compressed oral appliance among snorers. There are scarce models regarding the tongue-compressed oral appliances under current clinical practice. According to the inventor's conception, Lin tongue-compressing OA (LOA, airflow-interference-type nasal congestion relieving and snore-ceasing oral appliance) is a customized, tongue-compressed oral appliance where the length of the tongue-compressor part varies between versions (Fig. 1). Subjects could incrementally titrate to the longer tongue-compressed version of LOA upon their tolerance/adaptation where better effect of snoring rate reduction is expected from a longer tongue-compressed LOA version. In this study, we validated the effect of this novel LOA among snorers with the use of the SnoreClock smartphone application to determine snoring rates.

2. Materials and methods

This observational study was conducted to explore the effect on snoring rates among adult patients through use of a novel OA termed the Lin OA. The study protocol was reviewed and approved by the Research Ethics Committee of the Buddhist Dalin Tzu Chi General Hospital in Chiayi, Taiwan (No. B10703013).

Forty-seven patients with snoring problems were recruited from a dental clinic in Taiwan. Each patient was provided with a LOA (patent number: I602555 [Taiwan], ZL 2013 1 0753192.9 [China]).[19] The LOA comprises two parts: customized dental braces and a fixed tongue compressor, the length (0.5, 1, 1.5, 2, 2.5, 3, and 3.5 cm) of which varied by version (configurations of the LOA versions shown

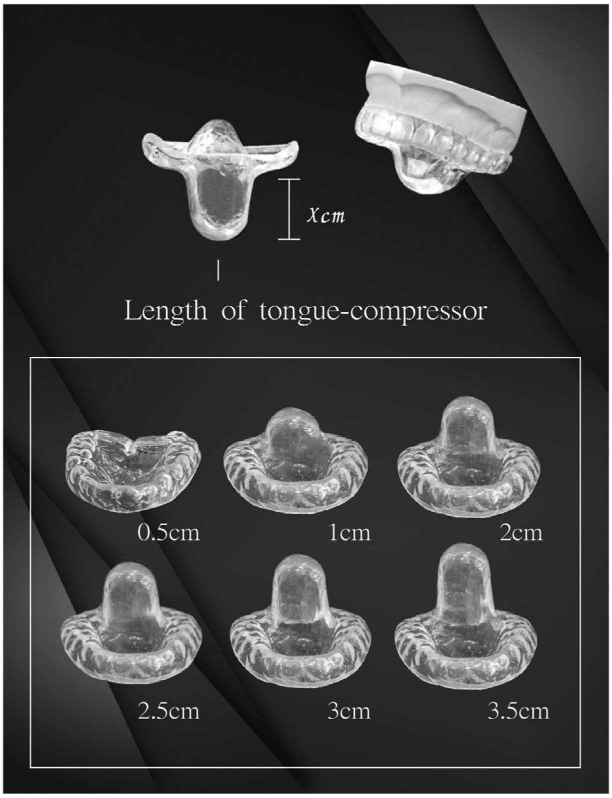

Figure 1 Different lengths of the tongue-compressor parts of Lin oral appliance (LOA).

by Fig. 1). In addition, the tongue-compressor part of LOA is 0.5 cm in thickness, which does not occupy significant pharyngeal space.

The patients had been voluntary and signed informed consent forms before their enrollment to this study program. During interviews by our research assistants, demographic characteristics including age, sex, body mass index and past medical histories were obtained from the patients. Detailed programs regarding proper LOA usage had been delivered to all the participants as well. The education programs addressed the use of LOA: patients could switch from a LOA with shorter tongue compressors to those with longer ones based on their adaptation to the appliances. Alongside, the benefits of different versions were explained to potentially reduce snoring rates. Furthermore, we ensured that all the patients understood how to use the LOA by their on-site demonstration before their participation.

Since our previous study had validated the SnoreClock smartphone application's accuracy upon detecting snoring rates at home along with its accessibility and user friendliness,[20] it had been implemented for recording the snoring rates in this current study. All patients were instructed to place their smartphones within 30 cm of the head end of their body. However, no specific restrictions on phone placement (e.g., on the bed or on a bedside table) were given. The patients returned their smartphones to our researchers for analysis after completing the necessary recordings every single night during their whole-night-sleeps which followed our approved study protocol.

The software R version 4.0.3 (R Foundation for statistical computing, Vienna, Australia) was used for all statistical analyses. Statistical significance was set at $p < 0.05$, and all tests were two-tailed. Categorical variables are presented as frequencies and percentages, and continuous variables are presented as means $\pm$ standard deviations. The t test or the Wilcoxon test was applied to compare the continuous variables between two groups (male and female). Multilevel models were used to estimate the variance disparity of within-subject and between-subject snoring rates. Additionally, random intercept models of the linear regressions were built to determine the factors significantly associated with snoring rates.

3. Results

After we excluded the patients wearing fewer than three versions of the LOA ($n = 3$) and those whose maximal snoring rates were less than 10% ($n = 2$), a total of 4920 recordings from 42 patients (4239 records from 34 men, 681 records from 8 women) were enrolled for analysis. The mean age was 43.1 $\pm$ 10.5 (years), the mean body mass index (BMI) was 25.7 $\pm$ 5.1 (kg/m^2), and the mean recording time was 6.7 $\pm$ 2.6 (hours). The mean "baseline snoring rates" for this current study population was 32.6 $\pm$ 32.0%. No statistical significance with regard to "baseline snoring rates" had been reached between genders (43.0 $\pm$ 29.5% for females and 30.2 $\pm$ 25.0% for males, $p = 0.210$). Besides, no patients had a history of smoking or alcohol abuse. Furthermore, age ($p = 0.104$), BMI ($p = 0.995$) and mean numbers of recordings ($p = 0.991$) per person were not significantly different between genders.

The patients wore LOAs with tongue compressor lengths between 0.5 and 3.5 cm (LOA-0.5 to LOA-3.5). Notably, no patients switched between LOA versions within the same day of record. No use of LOA over the entire sleep duration was denoted as LOA-0. Females in the LOA-0, LOA-0.5, LOA-1 and LOA-2 groups had significantly higher snoring rates than males. On the contrary, in the LOA-3 group, females had significantly lower snoring rates than males (6.5 $\pm$ 5.4% vs. 8.8 $\pm$ 10.4%, $p < 0.001$). From our current study, females did not use the LOA-1.5 or LOA-2.5 version and ever since they had self-reported satisfactory outcomes with the LOA-3.5, no data was attained thereafter. By contrast, the male patients opted to use longer versions, such as LOA-2.5, LOA-3, and LOA-3.5, in order to achieve better outcomes (Table 1). The mean adaptation time for the participants to adjust to LOA-0.5 was 6.87 days, and lesser adaption time was concurred with LOA-1 or greater version. We also plotted the mean snoring rates of our enrolled patients under different LOA tongue compressor length usage (Fig. 2). To have a better understanding of the effect upon snoring rate reduction by applying different LOA versions, we had plotted the snoring rates of the enrolled subjects by different LOA versions shown by mean $\pm$ standard error (Fig. 3).

The simple linear regression was performed to search the significant factors associated with snoring rates (Table 2). On account of significant between-subject variance in snoring rates ($p < 0.001$), random intercept model of linear

Table 1 Demographics and characteristics of the subjects enrolled.

Variable	Total	Female	Male	*p* value
Subjects (n)	42	8	34	–
Age (years)	43.1 ± 10.5	48.5 ± 10.7	41.7 ± 10.1	0.104
Body mass index (kg/m^2)	25.7 ± 5.1	25.8 ± 7.1	25.7 ± 3.4	0.995
Baseline snoring rates %	32.6 ± 32.0	43.0 ± 29.5	30.2 ± 25.0	0.210
Total records (n)	4920	681	4239	
Total recording duration of LOA				
Mean numbers of records per person (n)	117.1 ± 118.6	85.1 ± 51.3	124.7 ± 128.9	0.911
Mean recording time, hour(s)	6.7 ± 2.6	6.5 ± 1.1	6.7 ± 1.3	<0.001
Mean snoring rates (n of records)				
Total, snores %	19.0 ± 32.9	27.7 ± 22.5	17.5 ± 17.1	<0.001
LOA-0*, snores % (n)	28.2 ± 32.2 (496)	36.2 ± 23.3 (99)	26.3 ± 23.1 (397)	<0.001
LOA**-0.5, snores % (n)	29.9 ± 32.1 (442)	40.5 ± 27.1 (94)	27.1 ± 21.7 (348)	<0.001
LOA-1, snores % (n)	25.0 ± 29.1 (1220)	31.5 ± 23.6 (228)	23.4 ± 17.0 (992)	<0.001
LOA-1.5, snores % (n)	33.6 ± 24.4 (99)	–	33.6 ± 24.4 (99)	–
LOA-2, snores % (n)	14.1 ± 22.0 (1706)	17.6 ± 12.4 (236)	13.5 ± 12.4 (1470)	<0.001
LOA-2.5, snores % (n),	9.3 ± 22.9 (210)	–	9.3 ± 22.9 (210)	–
LOA-3, snores % (n)	8.8 ± 21.6 (636)	6.5 ± 5.4 (24)	8.8 ± 10.4 (612)	<0.001
LOA-3.5, snores % (n)	6.7 ± 12.8 (111)	–	6.7 ± 12.8 (111)	–

LOA, Lin oral appliance.
* LOA-0: patients not using the LOA.
** LOA-x: different lengths of the tongue-compressor parts of the LOA (the length included 0.5 cm, 1.0 cm, 1.5 cm, 2.0 cm, 2.5 cm, 3.0 cm, and 3.5 cm).

regression was favored and applied to determine the associated factors. With each 1 cm increase in tongue compressor length, snoring rates significantly decreased by a mean of 5.04%. As for each 0.5 cm increase in tongue compressor length, a 2.52% means of snoring rate reduction was met. As a result, the longer length of the LOA version would associate with better effects upon snoring rate reduction. Besides, a daily snoring rate reduction of 0.02% was observed in all groups (except the LOA-0 group) with continuous use. Notably, better snoring rate reduction could be reached when significant variables in the fixed effect of Table 3 had also been met. Though older age was associated with higher snoring rates, this association was not significant (Table 3).

4. Discussion

From our current study, we had demonstrated both the LOA's time-dependent (snoring rate reduction by 0.02% per day upon continual use) and the tongue compressor's length effect (snoring rate reduction by 5.04% with each 1 cm increase in the LOA tongue compressor length) in Table 3. Together with advancement in the length of tongue compressor part and the consecutive days used, it would be promising that this LOA had a bulk effect upon snoring reduction. For example, if a participant wears the LOA-3 for the next 2 months, then his/her snoring rates might be reduced by 16.32% ($5.04^{*}3 + 0.02*60$). To verify these results, further studies involving more subjects and a comparison with other types of OAs are warranted.

A review study had ever reported a mean 45% of reduction in snoring for patients who used OAs.[21] However, most of these OAs were mandibular adjustment appliances, and the objective measurements of snoring were not adequately examined.[21] By contrast, our methodology—LOA and the smartphone application (SnoreClock) usage for recording snoring rates had allowed for the objective measurement. Alongside, the SnoreClock smartphone application is of high value upon identifying snoring, and had been validated in the previous study.[20]

Although OAs are recommended for patients with primary snoring and some patients with OSA,[14] their use remains underused,[21] partially due to the lack of qualified dentists working in this area and in part to reimbursement policies.[21] A study reported that OAs are less efficacious than continuous positive airway pressure in reducing apnea-hypopnea index but are regarded as a preferable modality and been used more widely.[22] For patients using OAs for treatment of snoring or OSA, good adherence (median use within the first year was 77% of sleep time) led to increased comfort and achieved the desired efficacy.[21] In addition, the potential side effects (discomfort and excessive salivation) are minor and temporary which do not affect usage.[22]

Numerous types of OA are available on the market. They can be divided into three major categories: mandibular advancement devices, soft palatal lift appliances, and tongue-stabilizing devices.[23] Mandibular advancement devices include mandibular advancement splints and mandibular repositioning devices.[21] The possible mechanism behind mandibular advancement devices for reducing snoring and treating OSA was that the overjet, mandibular intercanine distance, and the lower arch crowding were variably decreased.[24] Additionally, a clinical trial with application of mandibular advancement devices on snorers had validated its effect on reducing palatal flutter and tongue base snoring.[25] Yet, most investigations of OA functions have been limited by small sample sizes. Besides, the use of

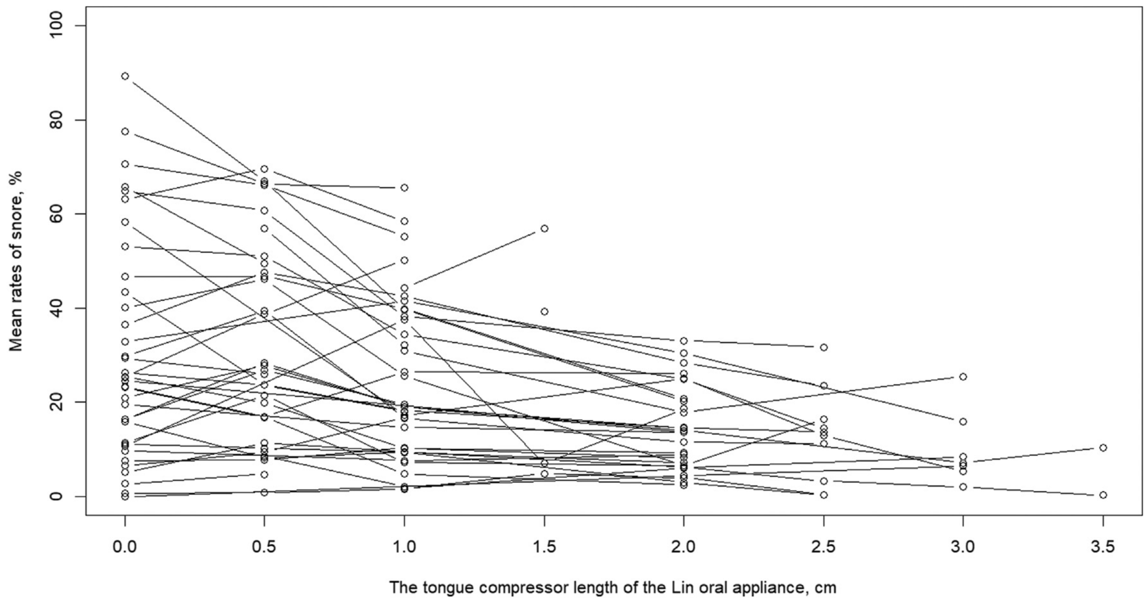

Figure 2 Mean rates of snoring of the enrolled subjects by applying different versions of Lin oral appliance (LOA).

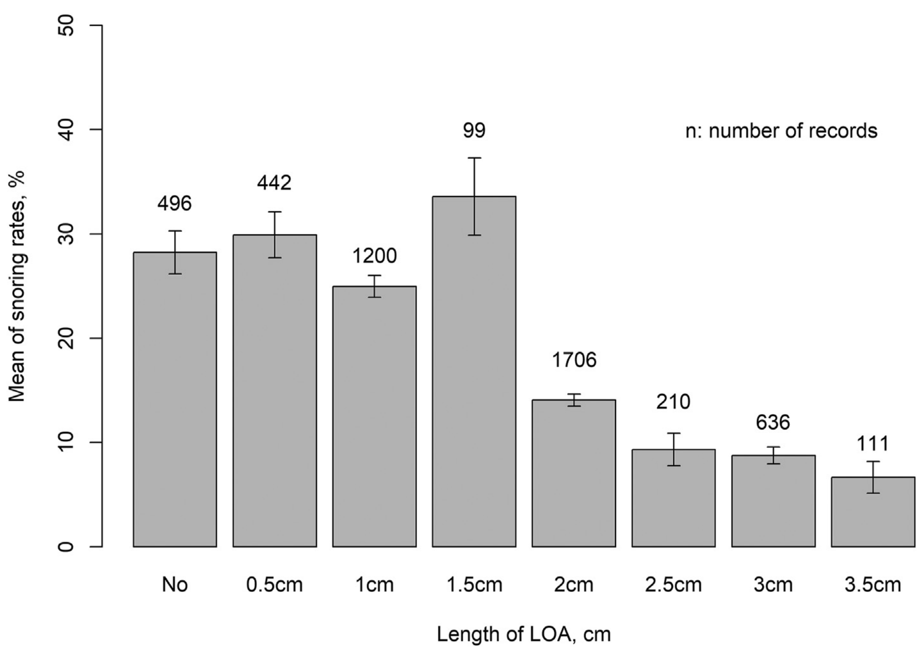

Figure 3 Snoring rates of the enrolled subjects by applying different versions of Lin oral appliance (LOA) shown by mean $\pm$ standard error.

participants was primarily in upright position or being awake, which might not reflect the real-world sleep status.[18]

The LOA in our current study is a novel OA, which had implemented three possible mechanisms to reduce individuals' snoring rates. First, by different versions of the LOA, variable lengths of the tongue compressor parts are to maintain a patent upper airway and expand the oro-laryngopharyngeal volume during sleep in the supine position. Second, surface tension of oropharyngeal would be increased by the tongue compressor's support, thereby, reducing oropharyngeal vibration and snoring rates. Third, with the tongue compressor's support, the harmonized fascial system which interpenetrates and surrounds organs, muscles, and other structures, would provide an environment that enables the whole-body system to operate in an integrated manner.[26] To be more specific, the deeper fascia that stretches from the tongue to the caudal respiratory muscles would be stabilized by the tongue compressors during breathing in sleep; therefore, reduce snoring at the same time. Further studies are necessary to investigate the

Table 2 The factors associated with snoring rates (%) by the linear regression.

Variable	Estimate	*t* value	*p* value
Age, per year	0.08	3.53	<0.001
LOA length*, per 1 cm	−7.65	−27.97	<0.001
Days of the same LOA version**	−0.04	−8.28	<0.001
Intercept	29.04		<0.001

LOA, Lin oral appliance.
* Lengths of the tongue-compressor parts of the Lin oral appliance.
** The continuous days of wearing the same version of LOA.

Table 3 The factors associated with snoring rates (%) by the random intercept model of the linear regression.

Variable	Estimate	*t* value	*p* value
Fixed effects			
Age, per year	0.33	1.27	0.214
LOA length*, per 1 cm	−5.04	−17.97	<0.001
Days within the same version**	−0.02	−4.79	<0.001
Intercept	16.64	0.271	
Random intercept effects			
S.D. across subjects	16.73		<0.001
Residual S.D.	11.37		

LOA, Lin oral appliance; S.D., standard deviation.
* Lengths of the tongue-compressed parts of the Lin oral appliance.
** The continuous days of wearing the same version of LOA.

differences in snoring reduction effectiveness between LOA and mandibular advancement devices in order to validate the genuine effect behind.

Studies have reported that male, elderly, and having a higher BMI are common risk factors associated with snoring.[27,28] As we have conducted our current study in Taiwan, the motivation or intention for the females to seek medical attention for snoring would somehow be stigmatized by the traditional Chinese culture. Studies in the past had demonstrated similar results where females were significantly underrepresented with or underestimated in the loudness of their snoring and delayed their visits to physicians on account of the perception: "unfeminine".[29,30] While the female counterpart ($n = 8$) was far less than the male counterpart ($n = 34$) in our current study, it might be a factor contributing to the significant differences of snoring rates manifested between genders. Though higher BMI has been deemed as a risk factor associated with snoring, the BMI between genders in our study population showed no significant differences. Nonetheless, still other factors (neck circumference, obesity) have been validated to be associated with sleep-disordered breathing from other studies where there may be contributors as well.[31] As a result, the summed effect of multiple factors would be the explanations to the differences of the manifested snoring rates between genders in our study population.

Nonetheless, it may require adaptation for individuals to adjust to this tongue-compressed oral appliance in our current study. Besides, the self-adaptive mechanism of each individual to the LOA may possibly cause a transient rise of snoring rate. It is worth discussing that the possible mechanisms may arise from the alteration of the cooperative fascia tension overlying the respiratory tract, yet the genuine underlying mechanisms were beyond the scope of our current study. Most importantly, as the LOA-0.5 being the initial oral appliance version applied by most of the individuals, they may need to adapt to this tongue-compressed oral appliance.

Therefore, the individuals' self-adaptative mechanism to the LOA may cause a transient rise of snoring rates where escalations from LOA-0 to LOA-0.5 were observed. Alongside, de-escalation of snoring rates had been seen from LOA-1 to LOA-3.5 version except LOA-1.5 version (Fig. 3). The explanation behind might be the apparent differences of *n* number in the LOA-1.5 group from other LOA groups.

This study has some limitations. First, the sample size was relatively small; only 42 participants (including 34 males and 8 females) were enrolled for analysis. Second, the LOA has only been registered in Taiwan and China; registration in other countries would expand its applicability and verify the effect on snoring rate reduction between ethnics. Third, other important parameters with regard to the quality of sleep (e.g., apnea-hypopnea index, oxygen desaturation index, respiratory effort, etc.) may be investigated through the overnight's examination with polysomnography in another independent study. Finally, the side effects along with adherences to LOA use require further investigation.

In conclusion, this novel LOA significantly reduce snoring rates by 5.04% with each 1 cm increase in the use of tongue compressor length. Additionally, snoring rates could be reduced by 0.02% per day with continual usage. It would be promising that further studies with larger sample sizes along with investigation of other types of OAs are the necessities of confirming the effects of the LOA in comparison with other OAs.

Declaration of competing interest

The authors declare no conflict of interest.

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