

Efficacy of TheraSnore in the Treatment of Sleep Apnea

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Introduction

A mandible prosthesis is one of the recent non-surgical treatments for sleep apnea. A prosthesis is to prevent air way obstruction during sleep by locking both the maxilla and the mandible. The mandible prosthesis is usually fabricated by a dentist, however, TheraSnore which was invented by Dr. Meade (Albuquerque, NM), can be easily fabricated by physicians and has big possibilities for clinical use. We have investigated efficacy of TheraSnore in the treatment of sleep apnea.

Subject and Test Method

TheraSnore is prepared for 19 cases of breathing difficulties during sleep and 11 cases were evaluated for the oxygen saturation (SaO_2) during night and daytime (10 cases) and/or polysomnography (8 cases) before and after installation. The subjects consisted of 10 men and 1 woman (average age: 53.7 years) whose mean apnea + hypopnea (AHI) index was 47.3/hr (lying on the back), and mean body mass index 26.8kg/m^2 .

The Criticare pulse oxymeter (504P) was used for the evaluation of oxygen saturation during night and daytime. Recording started at 21:00 ~ 22:00 and ended at 5:00 ~ 6:00 of the following day. The polysomnography was performed from 11:00 to 16:00 after 7.5 mg of Zopicron oral administration which is reported to be less hazardous for breathing. ECG during sleep ($\text{C}_3\text{-A}_1$, $\text{C}_4\text{-A}_1$, $\text{O}_1\text{-A}_2$, $\text{O}_2\text{-A}_1$), eye movement (vertical and horizontal), electro-myogram of jaw, SaO_2 , chest/stomach movement by using a strain gauge, air flow formation at nose/mouth by a thermister, snoring noise level, and continuous intratracheal pressure by a multiple pressure sensor were measured along with the polysomnography. Silicon covered 4-channel pressure sensor (2.3mm outer diameter, by Gaeltec Inc.) was inserted through a nose, then each sensor was placed at upper pharynx, middle pharynx (lower uvula), lower pharynx (lower part of the root of the tongue), and the lower esophagus, then confirmed the each location by taking side-view X-ray while laying on the back. The obstruction in the soft palate was judged by the difference between Pepi (upper pharynx) and Pmeso (middle pharynx), and the obstruction in the root of the tongue was judged by the comparison of Pmeso and Phypo (lower pharynx) pressures.

Improvement in subjective symptoms after installation was collected by out patient questionnaires and categorized into "improvement", "light- improvement", "unchanged", and "worse". Improvement in objective symptoms was categorized "improved" if the lowest SaO₂ was increased by 10%, or if apnea +AHI (or intraesophageal pressure) was decreased by 50% or to the normal level. The increase in the lowest SaO₂ by 5~10% or decrease in apnea +AHI (or intraesophageal pressure) by 20~50% is "light improvement".

For the statistic analysis, the t-examination method was utilized.

Fabrication of TheraSnore :

As shown in Fig. 1, TheraSnore consists of soft plastic placed on both sides (top and bottom) of the arch-shaped acrylic plate. Place this device into the cup filled with water and heat it with a 500W microwave oven for four minutes, or boil it in water. When the plastic is soft enough, place the top plastic portion against the maxilla with slightly strong force (Fig.2). Then ask the patient to protrude mandible slightly forward (Fig. 3-B) and bite the lower soft plastic with strong force. After one minute, plastic will be cured with a clean impression of upper and lower jaw then remove it. By using a cutting bar, grind the area where gum, lips and tongue touches, then finish it with a gas burner to form a smooth surface. It takes about 20 minutes to fabricate TheraSnore. The original TheraSnore was designed not to lock the mandible, however, the locking type was used in this investigation.

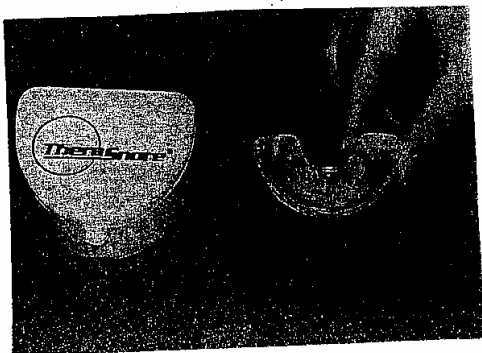


Fig. 1 Before fabrication
TheraSnore consists of the soft plastic glued to both sides of the teeth-shaped acrylic plate.



Fig.2 Fabrication of TheraSnore
Heat TheraSnore for 4 minutes.
When the plastic is soft enough, place the top plastic against the upper teeth.



Fig. 3 A: Before installation B: After installation
 TheraSnore locks the mandible slightly protruded forward as shown in picture (B).

Results

TheraSnore wearing condition:

TheraSnore was used for 3~9 months (Aver. 6.1 month). Five out of 11 cases used it everyday. Five cases used it 2~3 times/week and one used only when sleeping away from home. Problems observed are shown in Table 1. The biggest problem was a tight feeling in the anterior teeth. However, this tight feeling diminished within 10 minutes after removal and was not a serious complication.

Table 1 Problem with TheraSnore installation (multiple choice N=11)

Maxilla and mandible toothache/tight feeling	45%
Stiffness at temporomandibular joint when waking up	27%
Fell out while wearing	18%
No problem	27%

Improvement in subjective symptoms with TheraSnore:

Table 2 shows the improvement in sleeping pattern. The best result was the improvement in snoring (82%) followed by refreshed feeling and feeling of sound sleep after waking up (55%). Therefore, "considerably improved" was 7 out of 11 cases (64%), "improved" is 3 cases (27%), and "unchanged" is one (9%).

Table 3 Breathing pattern of before/after installation of TheraSnore

Case	age/sex/body mass index (kg/m ²)	lowest SaO ₂ (%)	apnea +AHI (/hour)	Intraesophageal pressure (cmH ₂ O)
1	57/male/28.1	48 → 83	40 → 35	48 → 50
2	48/male/31.8	84 → 92	14 → 21	22 → 33
3	56/male/31.2	60 → 75	55 → 46	100 → 78
4	53/male/24.6	81 → 86	65 → 55	120 → 64
5	57/male/26.2	87 → 89	68 → 52	62 → 36
6	55/male/30.5	70 → 83	64 → 18	95 → 30
7	40/male/27.2	73 → 76	40 → 15	54 → 38
8	54/female/22.4	- -	50 → 14	44 → 38
9	69/male/19.1	87 → 93	20	27
10	48/male/25.2	80 → 84	66	58
11	54/male/28.6	74 → 88	38	74
Aver.	53.7/ /26.8 (N=11)	74.4 → 84.9 (N=10)	49.5 → 32.0 (N=8)	68.1 → 45.9 (N=8)

Change in obstruction by TheraSnore:

The examination before TheraSnore use revealed four out of 10 had an obstruction at their soft palate (40%), two had at their soft palate + the root of tongue (20%).

TheraSnore changed two out of eight cases of "obstruction at soft palate + root of tongue" to "obstruction only at root of tongue" but the other six cases remained the same.

Conclusion

As a treatment of sleep apnea, CPAP (continuous pressure application procedure) is adopted by internal medicine, or UPPP (upper pharynx palate forming procedure) for surgical operation. However, a mandible prosthesis is becoming to be the common treatment for its convenience.

The merit of the mandible prosthesis is low cost compare to the surgical procedure, nor risky. One possible problem would be TMJ by protruding the mandible for a long time. Another problem is how long and how often the patient will use the prosthesis. In this investigation, the problem with wearing prosthesis was a tight feeling and light pain at the anterior teeth (total 42%). Other than 11 subject cases, 8 patients got the prosthesis (total 19 cases) and only one out of 19 had to terminate the use because of the pain. This investigation was too short to discuss the long term application which will be the future inquiry.

Reports of efficacy of mandible prosthesis show that the reduction in apnea or apnea + AHI by prosthesis is aver. 58% (33%~72%)²⁾⁻⁶⁾. TheraSnore is originally designed to lock the maxilla alone. However, in this investigation, TheraSnore was designed to lock both jaws. This is because this locking-type prosthesis should be compared to the conventional mandible prosthesis fabricated by a dentist. Also, locking-type TheraSnore can be easily fabricated by a physician. The results show that the improvement in

objective symptoms is satisfactory but the reduction in apnea + AHI is low compared to the other reports. This may be not enough protrusion of the mandible. Normally the mandible is locked at 20% backward from the maximum protrude. During this investigation, patients were ordered to protrude their mandible slightly for the fear of TMJ. In addition, we assumed that even without protrude of mandible, locking anterior might be sufficient to prevent breathing disorder. However, the result suggests that the level of mandible protrusion may affect improvement in apnea.

At the last, we conclude that TheraSnore which can be fabricated by a physician (not by a dentist) is effective for safe application for sleep apnea without TMJ.

Summary

- 1) TheraSnore showed significant improvement in the lowest SaO₂ (from 74.4% to 84.9%). Also, apnea + pypopnea (AHI) is reduced by 36% and the intraesophageal pressure by 33%.
- 2) Improvement in objective symptom was 65% and light improvement was 25%. Improvement in breathing difficulties was 65%, and lightly improvement was 45%.
- 3) Problems of wearing TheraSnore were not serious but a tight feeling in the anterior teeth and coming off during use have been reported.
- 4) TheraSnore which is low cost and easy to fabricate, would be an effective treatment for sleep apnea without surgical operation.

Reference

(Translation is not required.)

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