

Obstructive Sleep Apnea and Snoring - A New Treatment Approach

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Please note – this study has been translated from the original Danish

Summary

Study of subjects with obstructive sleep apnea syndrome (OSAS) and/or severe snoring, treated with a new anti-snoring mouthpiece called the SnoreMender.

The mouthpiece consists of a double ring-like structure of soft plastic material. When closed together in the mouth, the lower jaw is pulled forward in relation to the maxilla, thereby creating enough space in the pharynx to clear the obstruction of the airway.

Use of this new mouthpiece has changed the life for the majority of the patients, increasing their working capabilities, social accommodation and libido.

X-ray cephalometric studies of the subjects with identical head posture, both with and without the mouthpiece in situ, showed increase in the free airway space in the pharynx.

Background

Obstructive sleep apnea is a severe problem for the people concerned. Annoying noise, daytime sleepiness, poor quality of sleep, morning headache, choking fits, decrease in the libido, and drowsiness are some of the problems which they face all too frequently (from 30% - 95%), (1, 2, 3, 4.) and their families often experience disturbances in their otherwise normal sleeping rhythm.

Due to the above mentioned problems many of these patients are unable to concentrate and they are unable to stay alert. This might among other things cause an increase in work related accidents: Survey material from Israel relates 52% of the work related accidents to persons with apnea conditions, and in a survey from Virginia (USA) a 7 times higher risk for traffic-related accidents could be noted in the group of patients compared to persons without the apnea condition (7).

Further, Wiemann et al (8) have conducted surveys of survival rates with or without treatment with nCPAP equipment of persons who suffer from the sleep apnea syndrome, and shown an excess mortality of 35% within a decade in the group that was not receiving treatment!

The assumption "once a snorer - always a snorer" compared with the development of the sleep apnea syndrome, makes the intense research in this area quite understandable.

Figure 1 shows the anatomy in the area for snoring and obstruction. It is primarily the oropharynx and the hypopharynx. In horizontal position the mandible with its heavy, adjoining palatal curves and soft palate falls back in the pharynx and causes an obstruction. If only the soft palate with uvula falls back, a snoring will occur, but hardly any obstruction.

Figure 1 (a) - Obstructed Airway

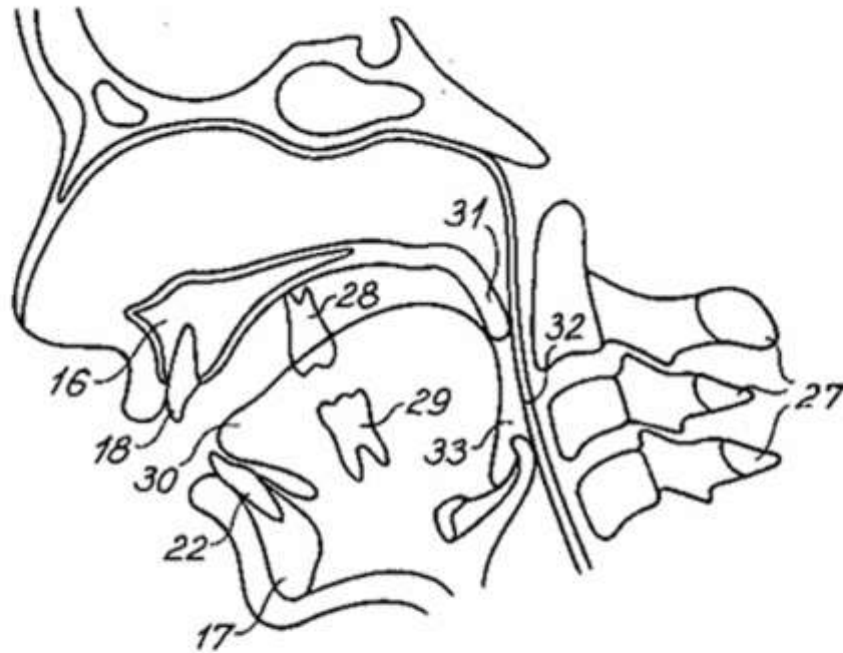
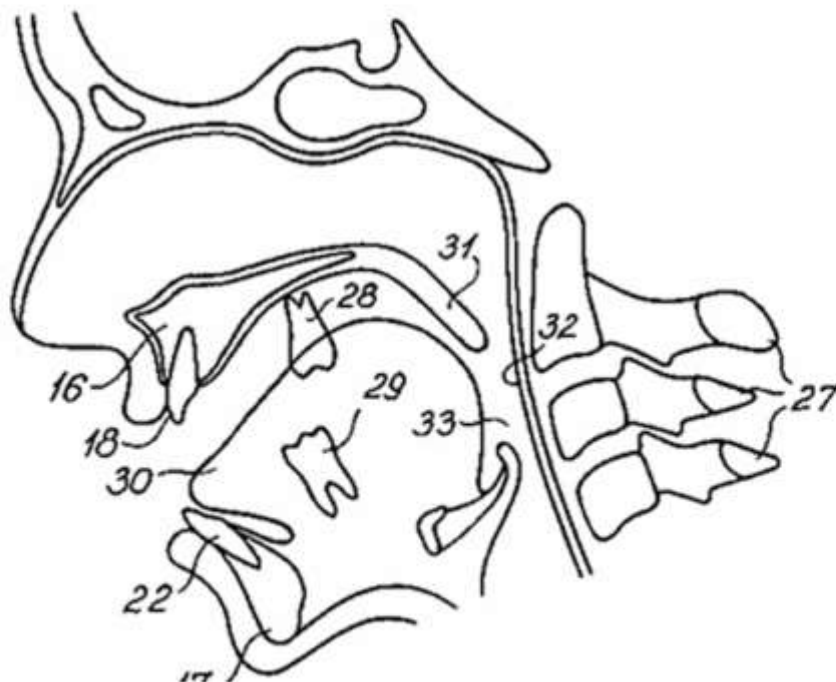


Figure 1 (b) - Clear Airway



Several more or less invasive forms of treatment have been suggested and used, and of these the below mentioned still seem to be in widespread use.

Novozent® is an apparatus of the non-invasive type which supposedly increases the airway if inserted in antrum nostril. It is correct that the airway in this region is improved, but to assume that it should result in a termination of the sleep apnea syndrome is unlikely, since the problem, as described above, is situated deeper in the pharynx.

Different kinds of lubricating materials (for example Asonor®) have been introduced - without any remarkable results.

Acupuncture in especially CV23 (Conception Vessel) have been tried on some patients with limited results.

Different kinds of surgery have been (and are still) in use. There are different kinds of UPPP (Uvulo-palato-pharyngo-plastic) (9), partial glossectomy (10) and maxillofacial osteotomy (sagittal split of mandible and LeFort I-osteomy with an advance of the mandible as well as maxilla) (11)

Extraoral/cranial apparatus for securing a constant overpressure that will prevent the airway from collapsing has been developed in at least two variants: nCPAP (nasal continous positive airway pressure) (12) and BiPAP (with a kind of physiological respiration possibility) (13).

Viewing these methods one unfortunately has to ascertain that the effect of the various treatments is either too small, the frequency of secondary effects that are close to handicaps is too big, or that the apparatus is socially unacceptable. The present device is developed on this background; based on a wish for a non-invasive solution, without any irreversible structure changes, and with a social acceptance as high as possible.

Epidemiology

Obstructive sleep apnea is stated to occur with a frequency of 1.6% of the total population or 20% of all people over 40, which in the United States of America and Europe with the population sizes of 325 million and 213 million respectively means that 5.2 million and 3.4 million people respectively suffer from the sleep apnea syndrome!

In Denmark a relative frequency is noted (by spot checks done by specialized doctors). Every week 2 patients see a doctor specialized in ear-, nose-, and throat-problems with the problem that they snore so heavily that they want a treatment. There are in Denmark 400 G.P.s specialized in ear-, nose- and throat-problems, which means that 2 persons x 47 working weeks x 400 G.P.s = 37,600 persons who seek treatment. That is about one half (47%) of the illness-ridden group!

Apart from this it is assumed that a far bigger percentage of the population is snoring more or less frequently, and this is by some seen as being incipient sleep apnea syndrome. The idea to begin the prophylactic treatment at this early state is obvious because in this way many of the mentioned symptoms can be eliminated. Seen this way the need for treatment will probably approach 3% of the total population.

Material and Method

The present study was conducted as a prospective multicenter study. 6 doctors specialized in ear-, nose- and throat-problems participated in the study which geographically spread from north to south in Denmark. Each of the centers received 10 sets of questionnaires and the SnoreMender plastic anti-snoring device (Appendix 1 and 2).

The first form was handed out to the patient who together with his/her spouse gave a subjective description of the situation before, during, and after the treatment, while the second form was used by the doctor to note the objective examination of the patient before and after the treatment.

A description of several physiological parameters was requested since during the various treatments, and especially during the use of the nCPAP equipment, changes (normalisation) of among other things, HDL, Cortisol etc. have occurred and also cessation of snoring or obstructive apnea have been noted.

Inclusion criteria

- a. All sorts of snoring (with or without obstructive apnea)
- b. All adult individuals

Exclusion criteria

- a. Subjects with dentures (uni- or bimaxillar)
- b. Children
- c. Mental diseases
- d. Pronounced parodontosis

X-ray technique

Lateral cranial shots of the cervical spine with facial and calvarie skeleton were conducted.

Focus - film distance was constantly 190 cm. The distance between the centersagittal plan to the film was approximately 10 cm; the enlargement of the centersagittal plan was therefore 5.6% and earlier produced control groups can hence be used directly (Solow, 14).

When the above mentioned conditions could not be met, it was noted which technique had been used instead.

The patient took up a horizontal and relaxed position. Two exposures were made: one without and one with the SnoreMender anti-snoring device in situ. The position of the head was not changed between the two exposures.

Figure 2 - X-ray of the patient without the SnoreMender



Figure 3 with the SnoreMender in situ.



Craniofacial points and lines

NCV4iaT: The tangent from the nasion to the most inferior anterior point on the fourth cervical vertebrae
hy: The most anterior point on the ossis hyoideum

ep: The most posterior point of epiglottis

ep': The point on the frontal wall of the pharynx determined by the insertion between the perpendicular line to the NCV4iaT on level with the epiglottis point

Craniofacial variables measured

OPH1: Oropharyngeal distance 1. The vertical distance from the NCV4iaT line on a level with the most anterior prominence of atlas from the tongue's posterior limit to the back wall of the pharynx

OPH2: Oropharyngeal distance 2. The vertical distance measured 15 mm caudally for anterior atlas prominence from the tongue's posterior limit to the back wall of pharynx

OPH3: Hypopharyngeal distance 1. The vertical distance measured 30 mm caudally for anterior atlas prominence from the tongue's posterior limit to the back wall of pharynx

HPH1: Hypopharyngeal distance 2. The vertical distance measured 45 mm caudally for anterior atlas prominence from the tongue's posterior limit to the back wall of pharynx

hy-NCV4iaT: Right-angled distance from hyoideum to NCV4iaT

ep-ep': Distance from epiglottis to epiglottis'

Procedure

1. Selection of patients
2. The patient is informed about the idea and the analysis (orally and in writing) (Appendix 3)
3. Pre-treatment conditions are noted in the forms I and II
4. The SnoreMender, an anti-snoring device is handed out
5. Post-treatment conditions are noted in the forms I and II
6. The horizontal X-ray with and without the anti-snoring device
7. Collection of the forms for further analysis

Results

In the present study 25 men and one woman were examined.

Anthropological Data

From the anthropological data it can be seen that basically all patients are snoring all night (22/24) and that most of them have been snoring for several years (23/24). Approximately 32% (7/22) are experiencing so violent disturbances in their sleep that they actually suffer from narcolepsy (a disposition to fall asleep at the wrong time and place), and that 1/4 directly express that they are having trouble with their concentration!

There was no correlation between weight, height, use of tobacco or alcohol and the severity of the different symptoms.

All test subjects used the anti-snoring device over a period of time ranging from one month to three months. Except for one subject who used it only a couple of times per month, all the others used the device every night, or at least a couple of nights per week.

To the question of acceptance of the device more than one half (14/24) answered that they had gotten used to it within a couple of days, while the rest of them expressed that they had not accepted the device, in spite of the fact that they still used it at least a couple of times per week.

The snoring pattern had changed remarkably after the period of acclimatisation; thus, only 2 persons had not felt any difference while 3 had reduced their snoring by 50%, 11 had only few snoring periods after the period acclimatisation and 7 had totally stopped snoring. Muscular soreness, as well as a soreness in joints and teeth were reported by 2/3 of the subjects, who moreover explained that the symptoms disappeared after a couple of days.

None of the participants in the study found the discomfort in teeth, joints or muscles so strongly that they wanted to stop using the device which, as mentioned, was used at least a couple of times per week by 95% of the group. Further, 75% of the group was so enthusiastic about the SnoreMender that they immediately wanted to recommend it to others!

The question of changes in the quality of life after the use of the SnoreMender was answered affirmatively by 37% of the subjects.

X-ray cephalometry

The x-ray cephalometric data ascertains that the variables OPH1, OPH2, OPH3 and HPH1 (pharynx measure) showed a significant increase in the linear dimensions, i.e. more free airway space. This agrees with the anthropological results mentioned above. Moreover it should be mentioned that the attempt has been made to make an equal gradient between calvarie and cervical spine at both exposures.

Results for differences with and without the SnoreMender

Table 1. X-ray cephalometric variables

Variable	Average	Disperssion	t-value	p-value Wilcoxon's one sample test
OPH1	2.9729	3.7348	3.90**	0.00065***
OPH2	2.0146	4.4729	2.21*	0.01457**
OPH3	2.5354	5.0487	2.46*	0.00378**
HPH1	4.425	7.234	2.87**	0.00003***
NSL/SVT	-0.8708	3.4208	-1.25	0.26176
OPH1+OPH2+OPH3	7.5229	10.253	3.59***	0.00112***

In the group as a whole an average linear increase of the pharyngeal space over the four variables could be ascertained to be no less than 11.93 mm.

In the case of the other variables a significant difference from situations with or without the SnoreMender in situ could not be demonstrated.

Discussion

As mentioned under the results one patient did not accept the device, solely because he had a distinct underhung jaw with an already protruding mandible. Also, several mentioned a discomfort in their muscles, joints or (especially) teeth of longer or shorter duration.

A lot of people have some sort of dental deviation, that be a too close packing of the teeth, facial- or lingual deviating single teeth, rotations etc. etc. that might lead to immediate discomfort after using the SnoreMender. To solve these problems the device is produced in a material that can easily be formed according to individual needs.

At about 70°C the material is easy to form, and it can be pulled, squeezed or twisted where it is necessary for the sake of the teeth which deviate from the standard/normal dental structure.

The individual adjustment of form can be done in the mouth of the patient or on a model made by the dentist to match the patient's dental structure.

In the present study, however, no-one had any special adjustments done, and yet 91% of the group succeeded in reducing their snoring by 50% and 78% of the group terminated their snoring completely!

The one patient whom the SnoreMender did not affect could for purely psychological reasons simply not accept a foreign object in his mouth for long.

In the case of contraindications it must be presumed that a notable parodontosis with loose teeth should not without any preceding treatment be exposed to the pressure of the SnoreMender.

Further it must be ascertained that the patient does not suffer from any narrowing of the nasal part of the pharynx (this is only the case for a minor part of the total population of persons snoring or suffering from sleep apnea). If this is the case the problems should probably be treated before experimenting with the SnoreMender.

Conclusion

The present study has shown a considerable effect of the treatment using the new product called the SnoreMender treating obstructive sleep apnea and snoring documented by a questionnaire survey and an x-ray cephalometric analysis.

Thus, probably far more people than earlier have the possibility to seek treatment for their snoring and obstructive sleep apnea in a very easy, quick, inexpensive and non-invasive way without any irreversible changes of anatomy in the pharynx being done.

The SnoreMender is therefore recommended as a "drug of first choice", which might later be supplemented with more extensive treatments, if necessary. Its use might be able to save considerable time and resources for those in the medical profession that deal with snoring problems.

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Appendix 1 – Patient Questionnaire

Project anti-snoring

(Pilot study on the effect of mouth-inserted anti-snoring-device)

Doctor's name (stamp):

Patient's name and address:

Male / Female:

Age:

Please mark the proper answer with a circle or underlining; it is in some questions possible to go into detail, and further comments can be given at the bottom.

Questions:

1. How often do you snore?
2. All night Several times Few times A couple of times
3. per night per nights per week
4. Do you snore when taking a nap? Yes No Don't know
5. How long have you been snoring?
6. 1 week 1 month 3 months ½ year Several years All life
7. Do you share the bedroom with your spouse/partner? Yes No No spouse/partner
8. If No, for how long have you been sleeping alone? 1 month ½ year 1 year Several years
9. Do you suddenly fall asleep during the day? Yes No Don't know
10. Are you having problems concentrating? Yes No Don't know
11. What is the worst thing about snoring?
12. Describe in your own words:
13. How big is your consumption of tobacco? (amount and kind)
14. How big is your consumption of alcohol? (amount and kind)
15. How big is your consumption of medicine? (amount and kind)

Results and Experiences:

1. How often did you use the device?
 - a. Every night
 - b. A couple of times a week
 - c. A couple of times a month
 - d. Never
2. How long was your period of acclimatisation?
 - a. Immediate habituation
 - b. A couple of hours
 - c. One night
 - d. Several days (please estimate number of days)
3. How has your pattern of snoring been since the period of acclimatisation?
 - a. I have not noticed any difference

- b. I have reduced snoring
 - c. I have very little snoring
 - d. I have stopped snoring
4. Has the usage changed your life / quality of life?
- a. Yes
 - b. No
 - c. Don't know
5. If you answered Yes to 4, please answer the following
- a. Do you feel more refreshed in the daytime
 - i. Yes
 - ii. No
 - iii. Don't know
6. Has your family/friends noticed any difference?
- a. Yes
 - b. No
 - c. Don't know
7. Has your general health been improved?
- a. Yes
 - b. No
 - c. Don't know
8. Have you noticed any changes in your dental system such as sore teeth, muscles or joints?
- a. Yes
 - b. No
 - c. Don't know
9. Have you noticed any positive changes concerning the use of the device?
- a. Yes
 - b. No
 - c. Don't know
10. If you answered Yes to 9, please describe these positive changes in your own words
11. Have you noticed any negative changes concerning the use of the device?
- a. Yes
 - b. No
 - c. Don't know
12. If you answered Yes to 11, please describe these negative changes in your own words
13. What should the device cost in your opinion?
- a. Less than 100 kr
 - b. 100-300 kr
 - c. 300-500 kr
 - d. 500-800 kr
 - e. more than 800 kr
14. Would you recommend this device to other people?
- a. Yes
 - b. No
 - c. Don't know
15. Other comments:

Appendix 2 – Doctors Examination

OBJECTIVE EXAMINATION:

Patient's name:

Physicians Stamp

Height:

Weight:

Blood pressure (S/D):

What treatment would you normally offer the patient?

Apnea index (if known)L:

Oropharyngeal condition (Fibrosophy):

Enlarged uvula

Slack palatal curves

Enlarged tongue

Mandibular prognathy

Other conditons you find relevant for judging the patient's positive / negative success:

RESULT after the use of the device:

Changes in the oropharyngeal conditon? (Describe:)

Bloodpressure after the period of treatment:

Systolic

Diastolic

Thank you for your cooperation.

Sincerely yours

Natashia Ingemarsson-Matzen

Appendix 3 – Patient Instructions

Written information for the patient

2 copies are handed out. One is signed by the patient and returned in order to document that the patient has received information on the idea and analysis! At the same time the patient is orally informed by the doctor who is giving the treatment about the free choice of his/her participation and furthermore the possibility to resign at any time should he/she wish to do so.

Tests have shown that snoring and the attached sleep apnea illness, which can be recognized by interruptions in the sleep because of breathing difficulties, can be treated with various techniques.

The purpose of this study is to test a new approach to the treatment of snoring and the sleep apnea illness. Your answers and the results of the examination are of course anonymous.

The new technique consists of a double ringlike structure made of a soft material which you insert in your mouth before going to sleep. The ringlike anti-snoring device is folded so that it resembles a horseshoe. It is inserted in your mouth so that the lower jaw is pulled forward as an underhung jaw. The jaws have free mobility and you can breathe through the mouth or nose according to your own choice. By holding the lower jaw in an "underhung-jaw-position" improved airways are created in the pharynx. In this way both the noise caused by snoring and the typical respiration difficulties are avoided.

Before the anti-snoring device is handed out, we ask you to fill out the front page of your questionnaire, and your doctor will conduct an examination of your nose/pharynx area. The use of the device is harmless, but if you suffer from parodontosis you should not participate in this survey before you have received treatment for your parodontosis. Please be aware that this is a new device that requires habituation. It is only natural that you may experience discomfort or pain in your joints, muscles and teeth. The discomfort will usually disappear after a couple of days' use, and you will find it a natural part of yourself, even during a brief nap.

An x-ray examination is to be taken of the position of the jaws in order to make a comparison to the cranium and neck; one examination will be made with the device inserted and one without. The x-ray examination is harmless in so far that special amplifiers will be used to illuminate the x-ray picture; this way the radiation is reduced to the same amount as when a normal x-ray picture at the dentist's is taken.

After 2 or 3 weeks we ask you to describe your results and experiences with the device by filling out the other side of the questionnaire.

This study can be important for a subsequent recognition of the product and for the treatment of sleep apnea (the troubled respiration during sleep) and snoring, and therefore it is essential that as many people as possible should participate.

Participation is voluntary and you are of course free to stop your participation at any time.

I have received information, understood, read and received a copy of this document:

Please Sign and Date here: