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Novel Porous Oral Patches for Patients with Mild Obstructive Sleep Apnea and Mouth Breathing: A Pilot Study

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Abstract

Objectives. Habitual open-mouth breathing (OMB) during sleep can cause snoring and obstructive sleep apnea (OSA). This study used a porous oral patch (POP) to treat patients with mild OSA and OMB during sleep. The subjective and objective outcomes were evaluated.

Study Design. Prospective study.

Setting. Tertiary referral center.

Subjects and Methods. Patients with ≥5 events hourly but <15 hourly on the apnea-hypopnea index (AHI) were enrolled. All patients slept with their mouths closed by using the POP, which is a porous skin pad consisting of 3 layers: silicone sheet, polyurethane foam, and polyurethane film. Before treatment and during treatment, subjective outcomes were assessed using the Epworth Sleepiness Scale (ESS) and visual analog scale (VAS) of snoring. Objective outcomes were assessed using polysomnography and cephalometry.

Results. Thirty patients were enrolled in this study. All patients slept with their mouths closed while using a POP. The ESS and VAS of snoring scores were 8.1 ± 1.5 and 7.5 ± 2.0 before the POP, respectively, in contrast to 5.2 ± 1.6 and 2.4 ± 1.4 while using a POP, respectively ($P < .05$). The median AHI score was significantly decreased by using a POP from 12.0 per hour before treatment to 7.8 per hour during treatment ($P < .01$). The snoring intensity and median snoring index were 49.1 ± 10.8 dB and 146.7 per hour before the POP, respectively, which decreased to 41.1 ± 7.8 dB and 40.0 per hour while using a POP, respectively ($P < .01$). Cephalometry revealed that the retropalatal space and retrolingual space were 7.4 ± 1.6 mm and 6.8 ± 2.5 mm before the POP, respectively, compared with 8.6 ± 1.2 mm and 10.2 ± 1.8 mm during treatment, respectively ($P < .01$).

Conclusion. The POP is a useful device to treat patients with mild OSA and habitual OMB.

Keywords

snoring, obstructive sleep apnea, open-mouth breathing, porous oral patches, device

Snoring and obstructive sleep apnea (OSA) consist of a continuum from partial airway collapse with vibration of the upper airway to total airway obstruction. Among the numerous contributing factors to snoring and OSA, mouth opening during sleep can affect upper airway collapsibility and resistance.[1-3] Open-mouth breathing (OMB) involves the growth of the orofacial structures, including narrowing of the maxilla, reduced development of the mandible, malocclusion, and mouth dryness.[4] In patients with OSA, the mouth is opened during sleep and is associated with inferior movement of the mandible that decreases the pharyngeal diameter.[5,6] Mouth opening during sleep is also accompanied by a reduction in the length of upper airway dilator muscles that lie between the mandible and the hyoid bone,[7] which exacerbates snoring and OSA.

Relief from severe nasal obstruction during sleep is related to a significant normalization of mouth breathing, enhancement of the sleep-stage architecture, and a modest reduction in the severity of OSA.[8] However, many snoring individuals and patients with OSA are accustomed to opening their mouths during sleep in spite of the patent nasal pathway. In these patients, the symptoms of snoring and OSA may persist despite undergoing nasal or oropharyngeal surgery. Therefore, close-mouth breathing must be maintained during sleep to reduce snoring and OSA for these patients. Conventional dental appliances may stabilize the upper airway by preventing the mouth from falling open during sleep. However, the dental appliance may cause

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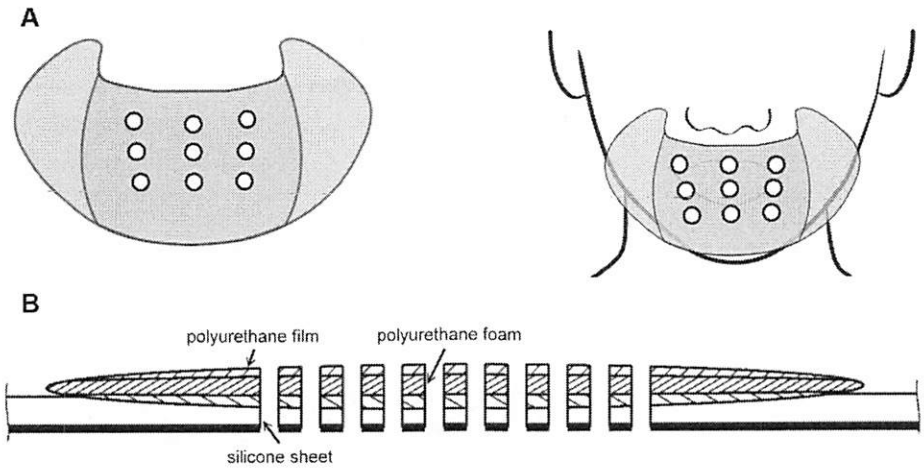

Figure 1. Diagrams of the structures of porous oral patches (A). Longitudinal section (B).

excessive salivation, temporomandibular joint discomfort, and changes in occlusive alignment.[9] This study used a porous oral patch (POP) to treat patients with mild OSA and OMB during sleep. The subjective and objective outcomes were evaluated.

Patients and Methods

Inclusion Criteria

A prospective study was conducted on patients who complained of snoring and habitual mouth opening during sleep, as observed by the bed partner. Each patient underwent a complete workup, including a thorough medical history review, physical examination, overnight polysomnography, and fiberoptic nasopharyngolaryngoscopy with the Müller maneuver. Patients with $\geq$5 events hourly but <15 hourly on the apnea-hypopnea index (AHI) were enrolled in this study. Palate position and tonsil size were graded according to the Friedman classification.[10] The uvula size was also graded.[11] Patients with a Friedman palate position of grade 3 or 4 and a tonsil size of grade 3 or 4 were excluded in this study. Patients with an uvula size greater than grade 2 were also excluded. Patients with allergic rhinitis, chronic rhinitis, nasal septal deviation, sinonasal disease, and facial hair were excluded as well. Patients with a body mass index exceeding 30 kg/m^2 were also excluded. This study was approved by an institutional review board of Far Eastern Memorial Hospital.

Porous Oral Patches

The POP was a porous skin pad consisting of 3 layers: silicone sheet, polyurethane foam, and polyurethane film (**Figure 1**). The silicone sheet is placed and sealed over the mouth during sleep. The polyurethane film is the outermost protective layer. The polyurethane foam is a water absorption layer and can help to reduce snoring noise.

Subjective Evaluation

Patients slept with their mouths closed by using a POP for 3 nights. This study investigated subjective outcomes using the Epworth Sleepiness Scale (ESS)[12] and visual analog scale (VAS) of snoring before and during treatment. The bed partners of all subjects were requested to participate in helping to establish this snoring scale. A score of 0 represented no snoring at all. A score of 10 indicated when the bed partner had moved out of the bedroom because of irritating sounds or avoided sleeping near the patient.[13] The reduction in dry mouth, as well as tolerability and side effects (rash, drooling, dyspnea) was evaluated.

Objective Evaluation

Overnight polysomnography was performed on each patient before and during treatment. Sleep study variables included the AHI score, snoring index, and minimal oxygen saturation (MOS). The AHI score referred to the total number of obstructive apnea and hypopnea episodes per hour of sleep. Apnea referred to the cessation of airflow for at least 10 seconds. Hypopnea referred to a $\geq$50% reduction in the baseline ventilatory value for more than 10 seconds associated with a more than 4% decrement in oxygen saturation. The intensity of snoring was measured during polysomnography by using a digital sound meter with a miniature microphone above the suprasternal notch. The maximum decibel level recorded on the sound meter during each 30-second period of the polysomnogram was identified, and the mean value of this measurement (mean maximum decibel level) was used to determine the snoring intensity. The snoring index referred to the total number of snores with intensity greater than 50 dB per hour of sleep time.

Cephalometric Evaluation

Cephalometric radiography was performed in the supine position during wakefulness before and during treatment to evaluate the retropalatal space (RPS) and retrolingual space (RLS). The RLS is determined by drawing a line connecting the supramental point and gonion with the posterior wall of the pharynx and measuring the distance between the tongue base and the posterior wall of the pharynx. The RPS is

Table 1. Basic Demographic Information.

	All Subjects (n = 30)
Sex (male/female), n	26/4
Mean age, y	46 ± 10
Mean body mass index, kg/m^2	26.8 ± 3.2
Palate position (grade 1/2), n	12/18
Tonsil size (grade 1/2), n	19/11
Uvula size (grade 1/2), n	3/27

defined as the minimum distance from the posterior border of the uvula to the posterior nasopharyngeal wall.

Statistical Analysis

Statistical analysis was performed using SPSS software (SPSS Inc, Chicago, Illinois). A comparative analysis of the results was then performed by the Student t test. Next, nonparametrically distributed variables were compared using the Wilcoxon signed-rank test. $P < .05$ indicates a statistically significant difference.

Results

Thirty patients (26 men and 4 women; age range, 32-65 years; mean age, 46 years) were enrolled in this study. **Figure 1** shows the structure of a POP. **Table 1** presents the demographic information. Every individual was able to sleep while wearing a POP and did not appear to have removed it. The ESS and VAS of snoring scores were 8.1 ± 1.5 and 7.5 ± 2.0 before the POP, respectively, in contrast to 5.2 ± 1.6 and 2.4 ± 1.4 while using a POP, respectively ($P < .05$).

The median AHI score was significantly decreased by using a POP from 12.0 per hour before treatment to 7.8 per hour during treatment ($P < .01$, Wilcoxon signed-rank test). The MOS was slightly increased from 86.7% ± 4.4% to 88.4% ± 4.9% during treatment ($P > .05$). The snoring intensity and median snoring index were 49.1 ± 10.8 dB and 146.7 per hour before the POP, respectively, which decreased to 41.1 ± 7.8 dB and 40.0 per hour while using a POP, respectively ($P < .01$) (**Figure 2**).

Cephalometric radiography revealed that the RPS and RLS were 7.4 ± 1.6 mm and 6.8 ± 2.5 mm before the POP, respectively, whereas they were 8.6 ± 1.2 mm and 10.2 ± 1.8 mm after the POP, respectively, exhibiting a significant difference ($P < .05$) (**Figure 3**). Before treatment, 83% (25/30) of patients had a dry mouth when awaking, and 53% (16/30) of patients drooled during sleep. During treatment, no one had a dry mouth or drooled during sleep ($P < .01$ for both). No one had a skin rash while wearing a POP. Moreover, all patients tolerated this device well, and no one had dyspnea during sleep when using a POP.

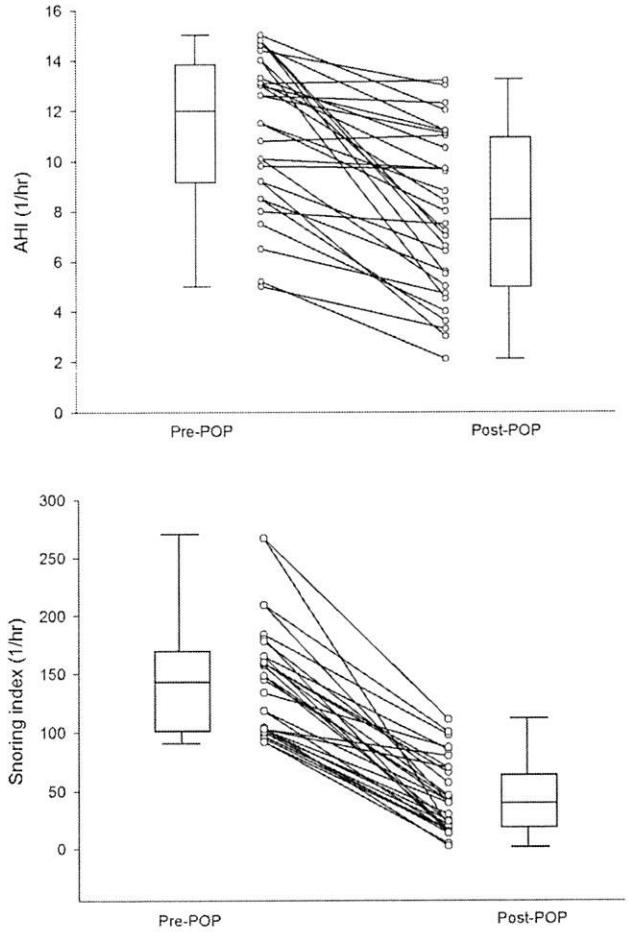

Figure 2. Individual patient response for the apnea-hypopnea index and snoring index before and while using a porous oral patch. Box plot = all patients; open circles and solid lines = individual patients.

Discussion

Nasal breathing plays a major physiological role in controlling the humidity and temperature of the nasal cavity and protecting it from the environment. If obstructions are found in the nasal or nasopharyngeal pathways, the nasal breathing pattern may change to a mouth breathing pattern to compensate for the decreased nasal flow and allow for adequate respiration.[14] However, approximately 12% of the subjects were assumed to be habitual open-mouth breathers, although they had an adequate nasal airway.[15] The study evaluated the efficacy of a POP in treating patients with mild OSA and habitual OMB during sleep by enrolling only patients without nasal obstructions. According to these results, no patient using a POP complained of dyspnea during sleep. Moreover, the AHI score after the POP improved, and MOS increased slightly while using a POP. This finding is due to the fact that all patients have an adequate nasal airway; they can switch to nasal breathing and enlarge airway dimensions while their mouths are closed by a POP during sleep.

In patients with a single site of obstruction, the site of obstruction is the velopharynx in over 90% of patients, whereas over 40% of patients have an obstruction in multiple sites, including the RPS and RLS.[16,17] A previous study has demonstrated that mouth opening, even in the absence

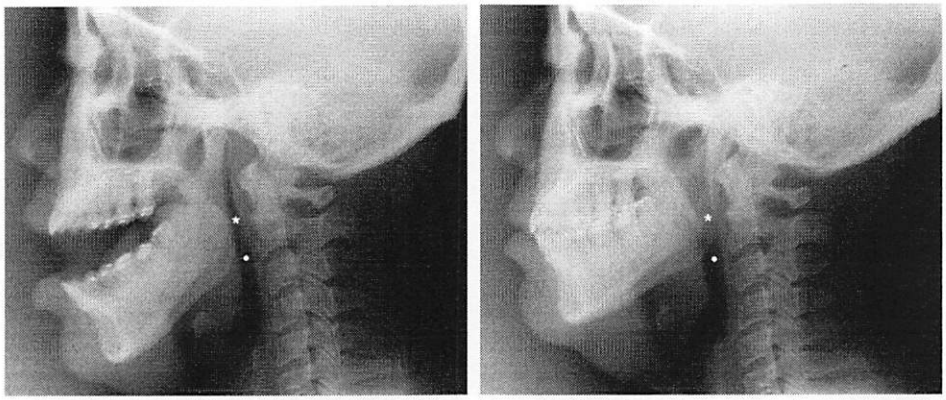

Figure 3. Cephalometric radiography with open mouth (A) and closed mouth (B). Enlarged retropalatal space (asterisk) and retrolingual space (circle) are observed when the mouth is closed.

of oral airflow, increases the propensity to upper airway collapse.[7] The retropalatal distance is significantly narrowing while the mouth is open (**Figure 3**). This finding is caused by posterior displacement of the soft palate, which is in contact with the posteriorly displaced tongue base when the mouth is open. Additionally, the retropalatal distance is reduced by posterior movement of the soft palate against the posterior pharyngeal wall to close the nasopharyngeal airway and breathe by the oral route. Posteroinferior movements of the mandible and tongue reduce the retroglossal distance (**Figure 3**). Analytical results thus demonstrate that the AHI and snoring index significantly improve in patients with mild OSA and OMB while using a POP.

Physiological mechanisms also contribute to the improvement of snoring and OSA. Recent studies have suggested that receptors in the nasopharynx control muscle tone in the oropharynx.[18] Nasal airflow decreases in mouth snorers during sleep, although they do not have nasal obstructions. Reduced nasal airflow decreases the activation of nasal receptors while subsequently inhibiting muscle tone, breathing frequency, and minute lung ventilation.[19] Moreover, decreased nasal flow reduces lung nitric oxide, which contributes to the maintenance of upper airway patency by functioning as an aerotransmitter between the nose, pharyngeal musculature, and lung.[20] Therefore, OMB during sleep compromises upper airway muscle tone.

Habitual OMB during sleep normally causes a dry mouth and drooling. The POP is composed of 3 layers: silicone sheet, polyurethane foam, and polyurethane film (**Figure 1**). Silicone gel is nontoxic, is resistant to water, and is used frequently for medical purposes such as in the healing of wounds. Therefore, the silicone sheet is placed and sealed over the mouth during sleep. The silicone sheet allows for easy removal, washing, and reapplication of the POP. The polyurethane film is the outermost protective layer, while the thicker polyurethane foam contains the lotus root-like porous structures that provide the integrality of the POP. The polyurethane foam is a water absorption layer and can help to reduce snoring noise. Therefore, while a POP was used during sleep, the snoring intensity and snoring index decreased, and no patient had a dry mouth or drooled. Clinically, chin straps have a similar function for mouth snorers. However, compared with the POP, chin straps are made of fabric, and they go under the chin and around the top of the head.[21]

A limitation of the study is the small sample size. This study is a pilot study to determine the feasibility of the use of the POP device in treating OSA. Although patients, on average, improve with treatment, the study does not define the safety or efficacy due to a small single-institution case series without a control group. Further large studies with multi-institution and control groups can be conducted to assess the efficacy and safety of the POP device.

Conclusion

This prospective study demonstrates that the POP is a useful device to decrease snoring severity and has a modest effect on the AHI in patients with mild OSA and habitual OMB without an elevated body mass index.

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Author Contributions

Tsung-Wei Huang, study design, acquisition and interpretation of data, drafting of the article, final approval of the version to be published, accountability for all aspects of the work; **Tai-Horng Young**, study design and revision of the article, acquisition and interpretation of data, final approval of the version to be published, accountability for all aspects of the work.

Disclosures

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References

1. Fitzpatrick MF, McLean H, Urton AM, Tan A, O'Donnell D, Driver HS. Effect of nasal or oral breathing route on upper airway resistance during sleep. *Eur Respir J.* 2003;22:827-832.

2. Meurice JC, Marc I, Carrier G, Series F. Effects of mouth opening on upper airway collapsibility in normal sleeping subjects. *Am J Respir Crit Care Med.* 1996;153:255-259.
3. Isono S, Tanaka A, Tagaito Y, Ishikawa T, Nishino T. Influences of head positions and bite opening on collapsibility of the passive pharynx. *J Appl Physiol.* 2004;97:339-346.
4. Bresolin D, Shapiro PA, Shapiro GG, Chapko MK, Dassel S. Mouth breathing in allergic children: its relationship to dentofacial development. *Am J Orthod.* 1983;83:334-340.
5. Suratt PM, Dee P, Atkinson RL, Armstrong P, Wilhoit SC. Fluoroscopic and computed tomographic features of the pharyngeal airway in obstructive sleep apnea. *Am Rev Respir Dis.* 1983;127:487-492.
6. Kuna ST, Remmers JE. Neural and anatomic factors related to upper airway occlusion during sleep. *Med Clin North Am.* 1985;69:1221-1242.
7. Meurice J-C, Marc I, Carrier G, Series F. Effect of mouth opening on upper airway collapsibility in normal sleeping subjects. *Am J Respir Crit Care Med.* 1996;153:255-259.
8. McLean HA, Urton AM, Driver HS, et al. Effect of treating severe nasal obstruction on the severity of obstructive sleep apnoea. *Eur Respir J.* 2005;25:521-527.
9. Ferguson KA, Cartwright R, Rogers R, Schmidt-Nowara W. Oral appliances for snoring and obstructive sleep apnea: a review. *Sleep.* 2006;29:244-262.
10. Friedman M, Tanyeri H, La Rosa M, et al. Clinical predictors of obstructive sleep apnea. *Laryngoscope.* 1999;109:1901-1907.
11. Herzog M, Kühnel T, Bremert T, Herzog B, Hosemann W, Kaftan H. The upper airway in sleep-disordered breathing: a clinical prediction model. *Laryngoscope.* 2009;119:765-773.
12. Johns MW. A new method for measuring daytime sleepiness: the Epworth Sleepiness Scale. *Sleep.* 1991;14:540-545.
13. Powell N, Riley R, Guilleminault C, Troell R. A reversible uvulopalatal flap for snoring and sleep apnea syndrome. *Sleep.* 1996;19:593-599.
14. Harvold EP, Tomer BS, Vargervik K, Chierici G. Primate experiments on oral respiration. *Am J Orthod.* 1981;79:359-372.
15. Warren DW, Hairfield WM, Seaton D, Morr KE, Smith LR. The relationship between nasal airway size and nasal-oral breathing. *Am J Orthod Dentofacial Orthop.* 1988;93:289-293.
16. Rama AN, Tekwani SH, Kushida CA. Sites of obstruction in obstructive sleep apnea. *Chest.* 2002;122:1139-1147.
17. Moriwaki H, Inoue Y, Namba K, Suto Y, Chiba S, Moriyama H. Clinical significance of upper airway obstruction pattern during apneic episodes on ultrafast dynamic magnetic resonance imaging. *Auris Nasus Larynx.* 2009;36:187-191.
18. White DP, Cadieux RJ, Lombard RM, et al. The effects of nasal anesthesia on breathing during sleep. *Am Rev Respir Dis.* 1985;132:972-975.
19. McNicholas WT, Coffey M, Boyle T. Effects of nasal airflow on breathing during sleep in normal humans. *Am Rev Respir Dis.* 1993;147:620-623.
20. Lundberg JO. Airborne nitric oxide: inflammatory marker and aerocrine messenger in man. *Acta Physiol Scand Suppl.* 1996; 633:1-27.
21. Fairbanks DN. Snoring: a general overview with historical perspectives. In: Fairbanks DN, Mickelson SA, Woodson T, eds. *Snoring and Obstructive Sleep Apnea.* 3rd ed.Philadelphia: Lippincott Williams & Wilkins; 2003:1-2.