The Laryngoscope

Concurrent Palatal Implants and Uvulopalatal Flap: Safe and Effective Office-Based Procedure for Selected Patients with Snoring and Obstructive Sleep Apnea Syndrome

Tsung-Wei Huang, MD, PhD; Po-Wen Cheng, MD, PhD; Kai-Min Fang, MD

Objectives/Hypothesis: An outpatient surgical procedure for snoring and obstructive sleep apnea syndrome (OSAS) should not only stiffen the soft palate, but also widen the opening of retropalatal space. This study presents a concurrent palatal implants (PI) and uvulopalatal flap (UPF) in the outpatient setting under local anesthesia for OSAS patients.

Study Design: Prospective study.

Methods: Patients with snoring and more than or an equivalent of 5 events hourly but less than 20 hourly on the apnea–hypopnea index (AHI) were enrolled. Three office-based procedures were performed, that is, PI, UPF, and PI concurrent with UPF (PI-UPF). Postoperative pain was evaluated using a visual analog scale. Before surgery and after surgery, subjective outcomes were assessed using the snoring scale, and objective outcomes were assessed using overnight polysomnography.

Results: Sixty-three patients underwent office-based procedures for OSAS. Among them, 21 underwent PI, 20 underwent UPF, and 22 underwent PI-UPF. PI attained the lowest postoperative pain scores. At 6 months after surgery, the mean snoring scale in PI, UPF, and PI-UPF group were 3.7 $\pm$ 0.7, 3.2 $\pm$ 0.8, and 1.8 $\pm$ 0.6, respectively ($P < .05$). The mean AHI scores in group PI, UPF, and PI-UPF were 9.0 $\pm$ 4.6, 8.8 $\pm$ 4.0, and 6.1 $\pm$ 2.5 events per hour, respectively ($P < .05$). The mean snoring index in group PI, UPF, and PI-UPF were 120.6 $\pm$ 79.5, 115.7 $\pm$ 86.3, and 71.8 $\pm$ 41.7 events per hour, respectively ($P < .05$).

Conclusions: Concurrent PI and UPF is a safe and effective office-based procedure for selected patients with OSAS and snoring.

Key Words: Obstructive sleep apnea syndrome, snoring, pillar implant system, palatal implants, uvulopalatal flap.

Level of Evidence: 1b.

***Laryngoscope,* 121:2038–2042, 2011**

INTRODUCTION

Snoring and obstructive sleep apnea syndrome (OSAS) consist of a continuum from partial airway collapse with vibration of the upper airway to complete airway obstruction. Airway collapse in OSAS can occur under various conditions, whereas most vibration of the soft tissues in snoring is assumed to occur at the soft palate.[1] Uvulopalatopharyngoplasty (UPPP), as first described by Fujita et al.,[2] has become the mainstay of surgical treatment in patients with snoring or OSAS. Although an excellent modality for treating specific anatomic obstructions at the palatal level, UPPP has several limitations, for example, general anesthesia requirement and significant postoperative pain and morbidity.[3] Therefore, various outpatient surgical procedures developed to make the procedure more effective, easier to perform, and with a reduced risk of postoperative complications, including laser-assisted uvulopalatopharyngoplasty, radiofrequency volumetric reduction, and cautery-assisted uvulopalatoplasty.[4,5] However, several drawbacks are still encountered such as severe postoperative pain, worsened apnea, multiple treatment sessions, and a poor long-term surgical success rate.[6–8]

As an alternative treatment for socially disruptive snoring and mild to moderate OSAS, the Pillar palatal implant system (Xomed, Jacksonville, FL) can be performed simply and effectively without hospitalization. Nevertheless, many patients still fail to improve after palatal implantation over some time period.[9] This failure may be owing to that palatal implants (PI) stiffen the soft palate to prevent collapse of the retropalatal space without correcting oropharyngeal anatomic abnormalities such as uvular elongation or redundant soft palate webs.

Therefore, in addition to stiffening the soft palate, an outpatient surgical procedure under local anesthesia for snoring and OSAS should correct oropharyngeal anatomy to enlarge the retropalatal space and reduce palatal flutter. This study presents a concurrent PI and uvulopalatal flap (UPF) in the outpatient setting under local anesthesia for OSAS patients. The efficacy and safety of PI concurrent with UPF are also evaluated

From the Department of Otolaryngology, Far Eastern Memorial Hospital, Taipei, Taiwan.

Editor's Note: This Manuscript was accepted for publication May 23, 2011.

Supported by the Far Eastern Memorial Hospital, Taipei, Taiwan, under Contract No. FEMH-2011-C-001.

The authors have no conflicts of interest to declare.

Send correspondence to Dr. Tsung-Wei Huang, Department of Otolaryngology, Far Eastern Memorial Hospital, 21, Section 2, Nan-Ya South Road, Pan Chiao 220 Taipei, Taiwan. E-mail: huangtw28@gmail.com

DOI: 10.1002/lary.22129

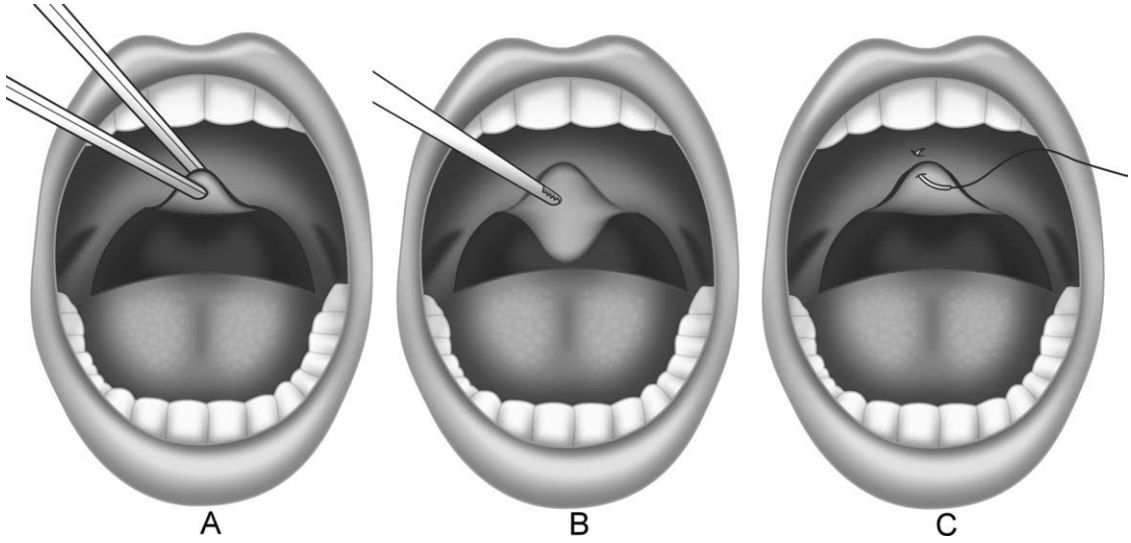

Fig. 1. Diagrams of uvulopalatal flap. After traction of the uvular tip with forceps (A), a microdebrider was used to debride the mucosa, submucosa, and fat of the uvula and soft palate (B). The uvula was fixated with multiple sutures (C).

based on objective and subjective outcomes in selected patients with OSAS.

PATIENTS AND METHODS

Inclusion Criteria

A prospective and nonrandomized trial study was performed at Far Eastern Memorial Hospital, which received approval from the institutional review board of the hospital. OSAS patients who had undergone office-based procedures were assessed for eligibility. Each patient had a complete workup, including a thorough medical history review, physical examination, overnight polysomnography, and fiberoptic nasopharyngolaryngoscopy with Müller maneuver. The study enrolled patients with more than or an equivalent of 5 events hourly but less than 20 hourly on the apnea–hypopnea index (AHI). Palate position and tonsil size were graded according to the Friedman classification.[10] The uvula size was also graded.[11] The study excluded patients with a Friedman palate position of grade 3 or 4 and a tonsil size of grade 3 or 4. Patients with a uvular size greater than grade 2 were excluded. Patients with a body mass index (BMI) exceeding 30 were also omitted. Three office-based procedures were performed, that is, PI, UPF, and PI concurrent with UPF (PI-UPF). After a complete explanation of the benefits and risks of each surgical intervention, the patients selected individually one of the three treatments.

Surgical Procedures

PI. Details of the operative procedure can be found elsewhere.[12] Briefly, a topical lidocaine spray was applied, followed by an injection with lidocaine hydrochloride (10 mg/mL) in epinephrine acid tartrate (concentration, 1:100,000) into each palate site. The mucosa of the soft palate was perforated approximately 5 mm distal to the trailing edge of the hard palate. Three palatal implants were placed into the soft palate of each patient.

UPF. The patients were placed in supine position under local anesthesia on an outpatient basis. Areas for surgical removal were injected with a local anesthetic mixture. The mucosa, submucosa, and fat on the lingual surface of the uvula and soft palate were removed with microdebrider (Xomed).[13] The uvular tip was amputated, and bleeding was controlled with bipolar electrocoagulation. The uvula was reflected back toward the soft palate and fixated into its new position with multiple sutures of 4-0 Monocryl[14] (Fig. 1).

Subjective Evaluation

Postoperative pain intensity was evaluated using a visual analog scale (VAS) (score range, 0–10). The degree of snoring before surgery and 1 month, 3 months, and 6 months after surgery was estimated based on a snoring scale ranging from 0 to 10. The bed partners of all subjects were requested to participate in helping to establish this 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 or had avoided sleeping near the patient.

Objective Evaluation

Overnight polysomnography was performed in each patient before surgery and at 6 months after surgery. Sleep study variables included the AHI score, snoring index, and minimal oxygen saturation (MOS). The AHI score refers to the total number of apnea and hypopnea episodes per hour of sleep. Apnea refers to as cessation of airflow for at least 10 seconds. Hypopnea refers to a 50% or greater reduction in the baseline ventilatory value for more than 10 seconds associated with a

TABLE I.
Summary of Demographic and Baseline Data.

	PI	UPF	PI-UPF	*P*-Value
n	21	20	22	
Gender (male/female)	17/4	16/4	16/6	>.05*
Age (years)	43.2 ± 9.4	43.1 ± 10.1	42.0 ± 10.8	>.05†
BMI (kg/m^2)	27.2 ± 1.5	27.4 ± 1.6	27.6 ± 1.5	>.05†

*Chi-square analysis.
†ANOVA.
Data were expressed as mean ± standard deviation.
BMI = body mass index.

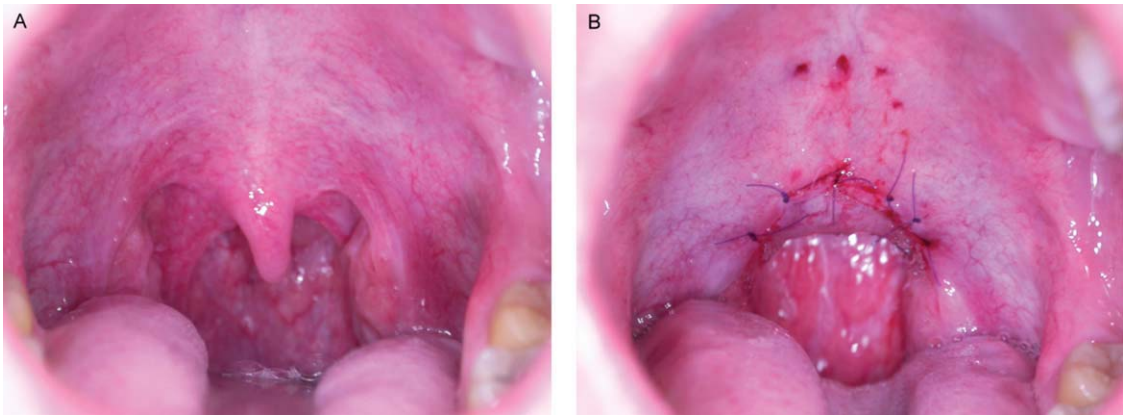

Fig. 2. Oropharyngeal photographs before (A) and after palatal implants concurrent with uvulopalatal flap (B). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

more than 4% decrement in oxygen saturation. The snoring index score refers to the total number of snores per hour of sleep time.

Statistical Analysis

Statistical analysis was performed using SPSS software (SPSS Inc, Chicago, IL). A comparative analysis of the results was performed by analysis of variance (ANOVA) with Tukey-Kramer test and chi-square analysis as appropriate. A value of $P < .05$ indicated a statistically significant difference.

RESULTS

A total of 63 patients (49 men, 14 women) underwent office-based procedures for OSAS. Among them, 21 underwent PI, 20 underwent UPF, and 22 underwent PI concurrent with UPF. Table I presents the demographic and baseline characteristics. Figure 2 shows the preoperative and postoperative oropharyngeal photographs in group PI-UPF. The mean pain scores in PI, UPF, and PI-UPF group were 3.4 ± 1.1, 5.2 ± 0.7, and 5.3 ± 0.9 on the first postoperative day, respectively, indicating a significant difference ($P < .05$). On the third postoperative day, the mean pain scores in the PI, UPF, and PI-UPF groups were 0.9 ± 0.3, 3.1 ± 0.7, and 3.0 ± 0.8, indicating a significant difference ($P < .05$).

Figure 3 shows the preoperative and postoperative snoring scales. At 1 month after surgery, the mean snoring scale in the PI, UPF, and PI-UPF groups were 7.2 ± 0.9, 4.2 ± 1.1, and 2.6 ± 0.9, respectively, indicating a significant difference ($P < .05$). At 6 months after surgery, the mean snoring scale in PI, UPF, and PI-UPF group were 3.7 ± 0.7, 3.2 ± 0.8, and 1.8 ± 0.6, respectively, revealing a significant difference ($P < .05$). The snoring scales in group PI-UPF were lower than those in groups PI or UPF. Notably, in group PI alone, the postoperative snoring scales did not differ significantly from the preoperative ones until 3 months after surgery (Fig. 3).

Table II summarizes the preoperative and postoperative polysomnographic results. Before surgery, each group did not significantly differ in AHI, snoring index, and MOS. Six months after surgery, the mean AHI scores in group PI, UPF, and PI-UPF were 9.0 ± 4.6, 8.8 ± 4.0, and 6.1 ± 2.5 events per hour, respectively, which were statistically different ($P < .05$). Also statistically significantly different were the mean snoring index in

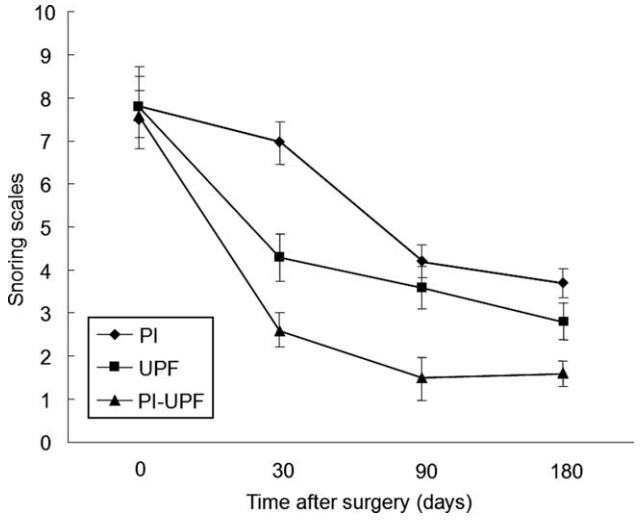

Fig. 3. The snoring scales in each group before and at 1, 3, and 6 months after surgery.

TABLE II.
Preoperative and Postoperative Polysomnographic Results.

	PI (n = 21)	UPF (n = 20)	PI-UPF (n = 22)	*P*-Value
Preoperative				
AHI	14.1 ± 5.1	14.2 ± 5.2	14.1 ± 5.9	>.05
Snore index	226.2 ± 178.1	296.5 ± 185.1	265.6 ± 176.9	>.05
MOS (%)	86.2 ± 5.7	91.0 ± 5.4	89.1 ± 5.8	>.05
Postoperative				
AHI	9.0 ± 4.6	8.8 ± 4.0	6.1 ± 2.5*	<.05
Snore index	120.6 ± 79.5	115.7 ± 86.3	71.8 ± 41.7†	<.05
MOS (%)	90.0 ± 3.1	92.0 ± 4.1	91.1 ± 3.2	>.05

Data were expressed as mean ± standard deviation.
*,†$P < .05$, ANOVA with Tukey-Kramer test.
AHI = apnea-hypopnea index; MOS = minimal oxygen saturation.

groups PI, UPF, and PI-UPF, which were 120.6 ± 79.5, 115.7 ± 86.3, and 71.8 ± 41.7 events per hour, respectively ($P < .05$).

Two patients (10%) in group UPF and two patients (9%) in group PI-UPF reported nasal regurgitation of liquids on swallowing during the first week after surgery; however, the symptoms disappeared within 1 month. Two patients (10%) in group UPF and 3 patients (14%) in group PI-UPF had abnormal pharyngeal sensation lasting more than 3 months. No patients complained of nasal regurgitation or abnormal pharyngeal sensation in group PI. Additionally, our results found no postoperative bleeding or long-term velopharyngeal insufficiency in any patient. The partial implant extrusion rate was 5% (1/20) in group PI and 4.5% (1/22) in group PI-UPF at 6 months after surgery.

DISCUSSION

Palatal flutter caused by narrow retropalatal space is the predominant cause of snoring.[15] Poor muscle tone in the pharynx and palate contributes to retropalatal space narrowing during sleep, possibly leading to failure to maintain airway patency and ultimately partial pharyngeal collapse. Another contributing factor is the anatomic abnormality, that is, a long uvula and redundant soft palate that narrows the opening of retropalatal space and vibrates during respiration. Therefore, an effective surgical intervention for snoring and OSAS must maintain the airway stiffiness and correct anatomic abnormalities.

The PI mechanism reduces snoring through placement of permanent implants, causing fibrosis and submucosal scarring in a single procedure. The implant itself is a segment of braided polyethylene terephthalate (PET). PET has a long history of human implantation, incurring a well-characterized fibrotic response with a fibrous capsule formation typically complete by 4 weeks.[16] Thus, the gradual reduction of snoring for up to 3 months postoperatively corresponds to the time observed for PET-induced fibrosis to occur (Fig. 3). However, PI alone is less effective than PI-UPF at 6 months after surgery, owing to that palatal implants alone can not correct anatomic abnormality to expand the opening of retropalatal space.

As an office-based procedure, UPF attempts to shorten and tighten the soft palate in order to increase the retropalatal upper airway patency.[17] Repositioning and stabilization of the uvula on the soft palate are responsible for the wide opening of the retropatatal airway space. However, the ability to stiffen the soft palate in UPF is not as effective as that in palatal implants. A previous study has demonstrated that palatal implant is an effective means of improving subjectively recurrent or persistent symptoms of snoring, daytime sleepiness, and overall quality-of-life perception in post-UPPP patients.[18] Therefore, PI concurrent with UPF can create a large retropalatal space by not only stiffening the soft palate, but also by widening the opening of retropatatal space. This study demonstrates that PI-UPF attains the highest improvement rate of AHI and snoring at 6 months after surgery.

Another benefit of concurrent PI and UPF is that the procedure is performed as a one-stage surgery under local anesthesia on an outpatient setting. Such a procedure does not put the airway at risk with general anesthesia or sedation. All patients tolerate the procedure well, with the latter performed in an average of 20 minutes. VAS reveals that the postoperative pain in group PI-UPF is lower than those found in the literature for traditional UPPP.[19] This difference may be due to the application of a microdebrider and absence of tonsillar fossa exposure. Microdebrider provides real-time suction and precise tissue resection without thermal damage or injury incurred to the neighboring muscles.[13] Therefore, no postoperative bleeding occurs and the postoperative pain is reduced, possibly owing to a lack of deeper musculature cutting.

The partial implant extrusion rate is 4.5% (1/22) in the PI-UPF group, which resembles findings in the literature. Notably, the partial extrusion occurred in the right implant over the nasal surface of soft palate. The imbrication of uvulopalatal flap may predispose the extrusion of the lateral implants. Therefore, particular attention should be paid to the position of lateral implants when performing the subsequent UPF.

CONCLUSIONS

This prospective study demonstrates a favorable snoring scale and polysomnography outcomes in selected patients with OSAS undergoing concurrent PI and UPF. We believe that concurrent PI and UPF is a safe and effective office-based procedure for selected patients with OSAS and snoring.

BIBLIOGRAPHY

1. Croft CB, Pringle M. Sleep nasoendoscopy: a technique of assessment in snoring and obstructive sleep apnea. *Clin Otolaryngol* 1991;16:504–509.
2. Fujita S, Conway W, Zorick F, Roth T. Surgical correction of anatomic abnormalities in obstructive sleep apnea syndrome: uvulopalatopharyngoplasty. *Otolaryngol Head Neck Surg* 1981;89:923–934.
3. Esclamado RM, Glenn MG, McCulloch TM, Cummings CW. Perioperative complications and risk factors in the surgical treatment of obstructive sleep apnea syndrome. *Laryngoscope* 1989;99:1125–1129.
4. Littner M, Kushida CA, Hartse K, et al. Practice parameters for the use of laser-assisted uvulopalatopharyngoplasty: an update for 2000. *Sleep* 2001;24:603–619.
5. Emery BE, Flexon PB. Radiofrequency volumetric tissue reduction of the soft palate: a new treatment for snoring. *Laryngoscope* 2000;100: 1092–1098.
6. Carenfelt C, Haraldsson PO. Frequency of complications after uvulopalatopharyngoplasty. *Lancet* 1993;341:437.
7. Troell RJ, Powell NB, Riley RW, et al. Comparison of postoperative pain between laser-assisted uvulopalatoplasty, uvulopalatopharyngoplasty, and radiofrequency volumetric tissue reduction of the palate. *Otolaryngol Head Neck Surg* 2000;122:402–409.
8. Finkelstein Y, Stein G, Ophir D, et al. Laser-assisted uvulopalatoplasty for the management of obstructive sleep apnea. Myths and facts. *Arch Otolaryngol Head Neck Surg* 2002;128:429–434.
9. Maurer JT, Hein G, Verse T, Hörmann K, Stuck BA. Long-term results of palatal implants for primary snoring. *Otolaryngol Head Neck Surg* 2005;133:573–578.
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. Romanow JH, Catalano PJ. Initial U.S. pilot study: palatal implants for the treatment of snoring. *Otolaryngol Head Neck Surg* 2006;134: 551–557.
13. Huang TW, Cheng PW. Microdebrider-assisted extended uvulopalatoplasty: an effective and safe technique for selected patients with obstructive

sleep apnea syndrome. *Arch Otolaryngol Head Neck Surg* 2008;134: 141–145.
14. Huang TW, Cheng PW, Chan YH, Wang CT, Fang KM, Young TH. Clinical and biomechanical analyses to select a suture material for uvulopalatopharyngeal surgery. *Otolaryngol Head Neck Surg* 2010;143:655–661.
15. Quinn SJ, Daly N, Ellis PD. Observation of the mechanism of snoring using sleep nasendoscopy. *Clin Otolaryngol Allied Sci* 1995;20:360–364.
16. Nordgård S, Stene BK, Skjøstad KW, et al. Palatal implants for the treatment of snoring: long-term results. *Otolaryngol Head Neck Surg* 2006; 134:558–564.
17. Huntley TC. The uvulopalatal flap. *Op Tech Otolaryngol Head Neck Surg* 2000;11:30–35.
18. Friedman M, Schalch P, Joseph NJ. Palatal stiffening after failed uvulopalatopharyngoplasty with the Pillar Implant System. *Laryngoscope* 2006; 116:1956–1961.
19. Troell RJ, Powell NB, Riley RW, Li KK, Guilleminault C. Comparison of postoperative pain between laser-assisted uvulopalatoplasty, uvulopalatopharyngoplasty, and radiofrequency volumetric tissue reduction of the palate. *Otolaryngol Head Neck Surg* 2000;122: 402–409.