



Original Article

Long-term results of palatal implantation for severe obstructive sleep apnea patients with prominent retropalatal collapse

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Abstract

Background: Most previous reports on palatal implantation for patients with severe obstructive sleep apnea have been anecdotal. Our objective in this study was to assess the long-term outcomes of palatal implantations from objective as well as subjective perspectives when applied to patients with severe obstructive sleep apnea and prominent retropalatal collapse.

Methods: This retrospective review was conducted in a single institution using subjective data (Epworth Sleepiness Scale and visual analog scales of snoring sounds and sleep quality) and objective data (respiratory disturbance index, minimum O₂ saturation, sleep efficiency, and snoring index using a polysomnograph) before and after surgery. A total of ten patients were enrolled in this study. The median time between pre-operative sleep-related tests and the operation date was 1.0 months and the median time between operation date and post-operative sleep-related tests was 33.0 months.

Results: Significant improvements were observed in the visual analog scale scores of snoring ($p = 0.004$), visual analog scale scores of sleep quality ($p = 0.005$), and Epworth Sleepiness Scale ($p = 0.012$). Eight of the ten patients reported a reduction of at least 50% on the visual analog scale of snoring sounds, which was the criterion of subjective surgical success. We also observed significant improvements in the respiratory disturbance index ($p = 0.009$) and minimum O₂ saturation ($p = 0.033$). Two of the ten patients presented a reduction in respiratory disturbance index of $\geq 50\%$ and a subsequent respiratory disturbance index of < 20 , which were the criteria of objective surgical success. A percentage change in respiratory disturbance index was negatively associated with prominent retrolingual collapse and the length of the soft palate.

Conclusion: Patients with severe obstructive sleep apnea and prominent retropalatal collapse may benefit from palatal implantation from a subjective perspective. Palatal implantation could be considered an alternate form of treatment for some cases of severe obstructive sleep apnea, due to the likelihood of improvement in clinical symptoms and the normalization of sleep quality.

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Keywords: Obstructive sleep apnea; Palatal implantation; Sleep surgery; Snoring

Conflicts of interest: The authors declare that they have no conflicts of interest related to the subject matter or materials discussed in this article.

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1. Introduction

Obstructive sleep apnea (OSA) is a syndrome with multiple systemic involvement. Sequelae include life-threatening adverse cardiovascular, neurocognitive, and metabolic outcomes.¹ Continuous positive airway pressure therapy (CPAP) is the first-line treatment for OSA^{2,3}; however, many patients with limited tolerance for CPAP seek alternative treatments, such as oral appliances or surgical procedures.^{2,3} A variety of surgical procedures have been developed to treat patients with OSA. Aggressive surgical treatments, such as uvulopalatopharyngoplasty and maxillomandibular advancement, are generally recommended for cases of severe OSA.² Nonetheless, many patients with severe OSA are ill-suited to the risks inherent in aggressive surgical procedures.

Palatal implantation was developed in 2003 as an office-based procedure performed under local anesthesia with minimal morbidity.⁴ This procedure is aimed to reduce snoring by enhancing the stiffness of the soft palate to resist vibration. It can also help prevent soft palate collapse, which can obstruct the upper airway and cause sleep apnea. Several clinical studies have demonstrated the effectiveness of palatal implantation for patients with mild to moderate OSA.^{3–10} Satisfactory outcomes have been achieved in the treatment of patients with severe OSA using palatal implantation as part of multi-level or stepwise surgery.¹¹ However, there has been relatively little research on using palatal implants alone for the treatment of severe OSA.

OSA is regarded as a multilevel disease, and anatomic findings have proven more substantive than severity in cases of OSA.¹² In this study, we hypothesized that patients with severe OSA presenting prominent retropalatal collapse could be treated successfully using office-based palatal implantation. In this series, palatal implantation was only administered after a comprehensive explanation of the potential benefits and risks for patients with severe OSA and prominent retropalatal collapse who are ill-suited to CPAP treatment. We investigated the effectiveness of the procedure and sought to identify the factors that could influence the outcomes.

2. Methods

2.1. Sleep apnea evaluation

Patients who snored and had daytime somnolence were asked to provide a detailed history of their medical condition as well as a complete physical examination including a full head and neck examination. The patients completed the baseline Epworth Sleepiness Scale (ESS) questionnaire (total score ranging from 0 to 24) to determine the extent of daytime somnolence¹³ and filled out a visual analog scale (VAS) characterizing their sleep quality with a score ranging from 0 (worst sleep quality) to 10 (best sleep quality). Their bed partners completed a VAS of snoring sounds ranging from 0 (no snoring at all) to 10 (severe, disruptive snoring) to characterize the snoring intensity. Polysomnography (PSG) was used to document the sleep parameters of each patient, and all respiratory

events were scored using standard criteria.¹⁴ We adopted the respiratory disturbance index (RDI) to evaluate the severity of OSA, wherein a value greater than 30/hour was defined as severe OSA.¹⁵ In cases of severe OSA, CPAP therapy was recommended as the first-line treatment in conjunction with weight loss, adjusting sleeping position, and avoiding alcohol and tobacco.¹⁵ Patients who were unable to tolerate CPAP therapy were counseled about the benefits and risks of surgical procedures.

2.2. Palatal implantation

Palatal implantation was recommended for patients with prominent retropalatal collapse during Müller's maneuver (>75% reduction in the cross-sectional area) who were strongly opposed to undergoing major sleep surgery or for whom the procedure was deemed high risk. Patients with hypertrophic tonsils (tonsil size grade III or IV) or significant nasal obstruction were excluded. Patients who agreed to undergo the procedure did so under local anesthesia at our office. The site of implantation was in front of the hard palate-soft palate junction. Each patient who underwent the procedure received three implants (Pillar System; Medtronic-Xomed, Jacksonville, FL, US) placed in the standard fashion (midline and 3 mm on either side of the midline).⁴

2.3. Outcome measures

Subjective treatment outcomes were assessed by comparing the values on the VAS of snoring sounds, VAS of sleep quality, and ESS scores before the procedure, and at least 24 months postoperatively. Subjective treatment success was defined as a $\geq 50\%$ reduction in the VAS of snoring scores.^{8,16} We also compared objective data, including RDI, minimum O₂ saturation (minSaO₂), sleep efficiency, and snoring index, as obtained by PSG. Objective treatment success was defined as a $\geq 50\%$ reduction in RDI and a subsequent RDI of < 20 .^{17–19} The extent of the decrease in mean postoperative RDI was assessed by the percentage change in RDI, as calculated using the following formula: $\Delta RDI = \frac{(\text{preop RDI} - \text{postop RDI})}{\text{preop RDI}} * 100\%$.⁴ We analyzed relationships between changes in outcome values with BMI, neck circumference, soft palate length, uvula length, Friedman tongue position (FTP) grade,²⁰ tonsil size, and prominent retrolingual collapse during Müller's maneuver (>75% reduction in the cross-sectional area). All cases presenting a significant change in BMI during follow-up were excluded from the study. This study was approved by the Institutional Ethics and Research Committee of the Cheng Hsin General Hospital.

2.4. Statistical methods

All statistical analysis was performed using SPSS version 18.0.0 (SPSS, Inc., Chicago, IL, US). We adopted nonparametric statistics due to the small number of cases. The Wilcoxon signed rank test was used for paired nonparametric data and the Mann–Whitney U test was used for unpaired

nonparametric data. Spearman rank correlation was used to test for associations between changes in outcome values and demographic data. Continuous data were presented as median and interquartile range (IQR). Statistical significance was accepted when $p < 0.05$.

3. Results

Between March 2011 and March 2014, a total of ten patients were enrolled in this study. All of the patients were male, ranging in age from 30 to 62 years old (median age 54 years, IQR: 45–59 years). The BMI ranged from 24.8 to 32.7 kg/m² (median 26.0 kg/m², IQR: 25.2–28.5 kg/m²) and the neck circumference ranged from 37.0 to 44.0 cm (median 39.7 cm, IQR: 38.0–42.5 cm). The length of the soft palate ranged from 30.0 to 40.0 mm (median 40.0 mm, IQR: 33.8–40.0 mm) and the length of the uvula ranged from 5.0 to 15.0 mm (median 8.0 mm, IQR: 5.0–11.25 mm). Eight of the ten patients had grade I tonsils and two patients had grade II tonsils. One of the ten patients had FTP grade I, seven patients had grade III, and two patients had grade IV. Four of the ten patients presented significant retrolingual collapse, as determined using Müller's maneuver under videolaryngoscope assistance (Table 1).

The median time between pre-operative sleep-related tests and the operation date was 1.0 months (IQR: 1.0–1.8 months), and the median time between the operation date and post-operative sleep-related tests was 33.0 months (IQR: 30.0–36.0 months). Eight of the ten patients (80%) had a statistically significant reduction in snoring intensity ($\geq 50\%$), based on the VAS of snoring sounds (median pre-operative score 8.0, IQR: 7.8–9.3 vs. median post-operative score 4.0, IQR: 3.5–4.5, $p = 0.004$). The median pre-operative VAS of sleep quality was 3.5, IQR: 2.0–5.3 compared to 8.0, IQR: 6.0–9.0 post-operatively and the improvement was statistically significant ($p = 0.005$). We also observed a statistically significant difference in ESS scores (median pre-operative scores 9.0, IQR: 4.0–11.0 vs. median post-operative scores 5.5, IQR: 0.8–8.0, $p = 0.012$). Two of the ten patients (20%)

presented a $\geq 50\%$ reduction in RDI and subsequent RDI of < 20 . The median pre-operative RDI was 45.1, IQR: 40.9–69.0 and the median post-operative RDI was 38.5, IQR: 23.5–48.8 ($p = 0.009$). There was a statistically significant difference between median pre- and post-operative minSaO₂ (71%, IQR: 62.0–78.3% vs. 76.5, IQR: 69.8–82.0%, $p = 0.033$). No significant difference was observed between the snore index score and sleep efficiency (Table 2). Δ RDI was negatively associated with prominent retrolingual collapse during Müller's maneuver ($p = 0.019$) and soft palate length ($p = 0.014$). The values of Δ RDI showed normal distribution in the Kolmogorov–Smirnov test ($p = 0.54$). None of the remaining outcomes were obviously related to BMI, neck circumference, uvula length, FTP grade, or tonsil size. Subsequent CPAP treatment or major sleep surgery was recommended for patients who did not achieve objective surgical success. Only one patient received CPAP thereafter and the remaining patients opted for lifestyle modification.

No cases of implant extrusion were noted. Some of the patients complained of mild sore throat, mild speech disturbance, slight trouble swallowing, and/or a mild foreign body sensation. All of these side effects resolved within one month.

4. Discussion

At present, CPAP therapy is the preferred first-line treatment for OSA in adults^{2,3,15}; however, its efficacy is highly variable and depends on patient adherence to therapy, with reported adherence rates ranging from 30% to 70%.^{17,21} Furthermore, many patients who are unable to tolerate CPAP remain opposed to surgery under general anesthesia as a second-line treatment, putting physicians in a difficult position.²² As an office-based procedure using local anesthesia, palatal implantation, has proven highly acceptable in such patients, resulting in less pain and morbidity and necessitating fewer office visits than is required of other minimally invasive office-based techniques, such as laser-assisted uvulopalatoplasty or radiofrequency thermal ablation therapy.²³ In our series, we observed no major complications. Six of the ten

Table 1
Demographic data of patients.

	Median (IQR)
Age	54 (45–59)
BMI	26.0 (25.2–28.5)
NC, cm	39.7 (38.0–42.5)
SPL, mm	30.0 (30.0–40.0)
UL, mm	8.0 (5.0–11.25)
Tonsil grade	Grade I: 70% Grade II: 30%
FTP	Grade I: 10% Grade III: 70% Grade IV: 20%
RLC	Significant: 40% Non-significant: 60%

IQR = interquartile range; BMI = body mass index; NC = neck circumference; SPL = soft palate length; UL = uvula length; FTP = Friedman tongue position; RLC = retrolingual collapse.

Table 2
Outcomes after palatal implantation.

	Pre-op Median (IQR)	Post-op Median (IQR)	<i>p</i>
Subjective outcomes			
VAS of snoring sounds	8.0 (7.8–9.3)	4.0 (3.5–4.5)	0.004*
VAS of sleep quality	3.5 (2.0–5.3)	8.0 (6.0–9.0)	0.005*
ESS	9.0 (4.0–11.0)	5.5 (0.8–8.0)	0.012*
Objective outcomes			
RDI	45.1 (40.9–69.0)	38.5 (23.5–48.8)	0.009*
%minSaO ₂	71.0 (62.0–78.3)	76.5 (69.8–82.0)	0.033*
Snore index	378.4 (133.2–574.7)	178.7 (112.0–401.3)	0.203
Sleep efficiency	57.3 (52.7–64.8)	56.3 (49.3–73.5)	0.878

VAS = visual analog scale; ESS = Epworth Sleepiness Scale; RDI = respiratory disturbance index; %minSaO₂ = minimum O₂ saturation; IQR = interquartile range.

*Statistical significance was set at $p < 0.05$.

patients complained of sore throat after surgery; however, these were easily controlled using local topical regimens.²⁴ No patients experienced partial extrusion of the implant, despite a reported incidence of partial extrusion of 2%–25%.^{4–8,10,16,25}

Palatal implantation has proven moderately efficacious for patients with mild to moderate OSA,⁵ whereas most clinical studies on the treatment of severe OSA have been anecdotal. Evcimik et al. reported significant improvements in apnea-hypopnea index (AHI) among patients with severe OSA at 8 months post-op; however, the number of patients was small (n = 8).²⁶ Furthermore, the long-term (12–48 months) outcomes of palatal implant among patients suffering from simple snoring and mild to moderate OSA have presented fair results.^{6,23,25} Note that our series is the first to examine the long-term outcomes of palatal implantation in patients with severe OSA.

The prognosis of subjective outcomes, particularly snoring intensity, was quite impressive in this series. Eight of the ten patients (80%) presented a reduction in snoring intensity of at least 50%, based on VAS of snoring sounds. In previous studies, the reported success rate had only been 50%–68%.^{8,16} The sound of snoring is created by the vibration of structures in the upper airway, particularly the soft palate.^{5,6,23} Snoring can cause social embarrassment and marital disharmony,²⁵ and may even result in sleepiness during the day.²⁷ Palatal implantation is meant to increase the rigidity of the soft palate, particularly the uvular muscle, thereby confining palatal flutter.²⁸ It is reasonable to expect the soft palate procedure to significantly improve snoring, even in patients with severe OSA. The deterioration of these effects over time due to the long-term resolution of scar tissue has been reported; however, the stiffening effects of scarring can be reinforced by performing subsequent procedures.²³ ESS is used to quantify daytime sleepiness using subjective evaluations of states of tiredness, sleepiness, or fatigue.²⁹ It has proven effective in measuring average sleep propensity and the scores generally increase linearly with the severity of OSA¹³; therefore, it stands to reason that well-performed sleep surgery should lead to a significant improvement in ESS scores, the VAS of sleep quality, and RDI/AHI, as noted in this study.

All of the subjective parameters in this study presented significant improvements; however, some of the patients were likely influenced by a placebo effect.⁵ The ESS questionnaire and VAS of sleep quality were completed by the patient, whereas the VAS of snoring was completed by the bed partner (i.e., the main victim of snoring). Significant improvements noted by patients as well as their bed partners are indicative of more credible subjective outcomes.

As for objective measures, we observed significant improvements in RDI (Δ RDI: 32%) and minSaO₂ in this series, which have been respectively identified as independent predictors of all-cause mortality and sudden cardiac death.^{30,31} Furthermore, Δ RDI was negatively associated with soft palate length and retrolingual collapse. A longer soft palate undermining the prognosis after palatal implantation has previously been reported.⁴ Cases of retrolingual collapse during Müller's

maneuver are an obvious indication of obstruction over tongue base level, predisposing patients to worse outcomes when undergoing single-level surgery.³²

Nevertheless, only 20% of patients in this study achieved objective surgical success following palatal implantation, despite the fact that the success rates for patients with mild to moderate OSA ranged from 24.1% to 44.8%.^{4,7,8} Indeed, the effectiveness of palatal implantation in reducing RDI/AHI was not as pronounced as CPAP or major sleep surgery. According to a statement by the American Academy of Sleep Medicine, the desired outcome of treatment includes resolution of the clinical signs and symptoms of OSA, and normalization of sleep quality, RDI/AHI, and oxyhemoglobin saturation.² RDI/AHI has been used to classify disease severity; however, it does not encompass all dimensions of OSA.^{2,22} We are not suggesting that palatal implantation could displace CPAP or major sleep surgery as first-line treatment for severe OSA. Nonetheless, many patients who have failed/rejected CPAP and major surgery could achieve good results from palatal implantation in terms of improved patient-reported symptom scores.

This study has a number of limitations. First, this study was limited by a small number of patients and the lack of control groups. Larger studies will be required to validate our findings. Second, accurate diagnosis of the sites of obstruction and the appropriate selection of procedures are crucial to the success of sleep surgery.³³ Videolaryngoscope-assisted Müller's maneuver tends to be subjective and many patients are unable to produce a full inspiratory force.²⁰ Drug-induced sleep endoscopy may be preferable to awake Müller's maneuver to determine the level of obstruction.³² We excluded patients who presented severe nasal obstruction in physical examinations although rhinomanometry may have been a better choice for objective measurements.^{34,35}

In conclusion, this is the first study to report on the long-term prognosis of palatal implantation for the treatment of severe OSA. We found that patients with severe OSA and prominent retropalatal collapse may benefit from palatal implantation, in terms of subjective improvements, whereas objectively verifiable improvements were somewhat limited. We consider palatal implantation a viable alternative treatment for severe OSA due to the potential for reducing the symptoms of OSA and the normalization of sleep quality.

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