Available online at www.sciencedirect.com

ScienceDirect

Journal of the Chinese Medical Association 81 (2018) 837−841

www.jcma-online.com

Original Article

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

Hao-Chun Hu [a,b,c,d], Chin-Lung Kuo [e,f], Tao-Hsin Tung [g,h], Szu-Chi Chen [b,i], Lieber Po-Hung LI [b,f,*]

[a] *Department of Otorhinolaryngology-Head and Neck Surgery, Fu Jen Catholic University Hospital, New Taipei City, Taiwan, ROC*
[b] *Department of Otolaryngology, Cheng Hsin General Hospital, Taipei, Taiwan, ROC*
[c] *Institute of Clinical Medicine, National Yang-Ming University, Taipei, Taiwan, ROC*
[d] *School of Medicine, College of Medicine, Fu Jen Catholic University, New Taipei City, Taiwan, ROC*
[e] *Department of Otolaryngology, Taoyuan Armed Force Hospital, Taoyuan, Taiwan, ROC*
[f] *Faculty of Medicine, School of Medicine, National Yang-Ming University, Taipei, Taiwan, ROC*
[g] *Department of Medical Research and Education, Cheng Hsin General Hospital, Taipei, Taiwan, ROC*
[h] *Department of Public Health, College of Medicine, Fu Jen Catholic University, New Taipei City, Taiwan, ROC*
[i] *Institute of Medical Sciences, Tzu Chi University, Hualien, Taiwan, ROC*

Received April 13, 2016; accepted January 3, 2018

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 O_2 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 O_2 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.

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.

* Corresponding author. Dr. Lieber Po-Hung Li, Department of Otolaryngology, Cheng Hsin General Hospital, 45, Cheng Hsin Street, Taipei 112, Taiwan, ROC.
E-mail address: lieber.chgh@gmail.com (L.P.-H. LI).

https://doi.org/10.1016/j.jcma.2018.01.012

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 somnolence[13] 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 ≥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 ≥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: $\Delta\text{RDI} = \frac{(\text{preop RDI} - \text{postop RDI})}{\text{preop RDI}} * 100\%$.[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