Managing Disturbing Snoring With Palatal Implants

A Pilot Study

Wai-kuen Ho, FRCSEd; William I. Wei, FRCS; Ka-fai Chung, MRCPsych

Objective: To evaluate the safety and efficacy of polyethylene terephthalate implants in the soft palate to modify disturbing snoring.

Design: Interventional study, before-after trial.

Setting: Referral center, institutional practice, hospitalized care.

Patients: Twelve consecutive patients with disturbing snoring and an apnea-hypopnea index less than 15 per hour and a body mass index of 30 or less were recruited. One patient with no adverse effects was lost to follow-up. Extrusion of implants occurred in 2 patients. Complete data in 9 patients were available for analysis.

Intervention: Polyethylene terephthalate implants were inserted in the soft palate.

Main Outcome Measures: Safety of the procedure and evaluation of the loudness of snoring by bed partners using a visual analog scale.

Results: There were no complications of infection or bleeding. Extrusion of implants occurred in 2 patients with no clinical sequelae. The mean (SD) loudness of snoring at baseline, as assessed by bed partners using a visual analog scale of 0 to 100, was 79 (17.2). This significantly decreased to 48 (20.4) at 3 months (Wilcoxon signed rank test, \( P = .008 \)). Daytime sleepiness as measured with the Epworth Sleepiness Scale also decreased from an average score of 8.9 at baseline to 5.7 at 3 months (\( P = .007 \)). There were no significant changes in the apnea-hypopnea index and body mass index from baseline to 3 months' follow-up.

Conclusions: Polyethylene terephthalate implants in the soft palate are safe. Snoring decreased significantly at 3 months after surgery. Polyethylene terephthalate implants in the soft palate should be further explored as a treatment for snoring.

Arch Otolaryngol Head Neck Surg. 2004;130:753-758

In the past decade, both the public and the medical profession are increasingly concerned with the morbidities associated with sleep-related breathing disorders.1,2 The spectrum of the problem ranges from simple snoring, to upper airway resistance syndrome, to obstructive sleep apnea syndrome of varying severities. Although disturbing snoring alone without complete upper airway obstruction is associated with minimal health hazards, the loud snoring sound is frequently the cause of marital disharmony and social embarrassment. For example, it is not uncommon that heavy snorers are hesitant to travel to avoid the embarrassment and complaints from roommates or fellow passengers. Thus, although simple snoring, unlike obstructive sleep apnea syndrome (OSAS), carries minimal risk to general physical health, its impact on the social life of the snorer is an issue that cannot be ignored.

Airway collapse on inspiration during sleep is the basic mechanism in sleep-related breathing disorders. Partial narrowing of the upper airway results in airflow turbulence. The resultant vibration of soft tissue in the upper airway produces the snoring sound. Vibration of soft tissues can occur at the palatal level (the velopharynx) or at the tongue base. Collapse and vibration at the velopharynx is found in most patients with sleep-related breathing disorders.3,4 Various treatment strategies have been used to counteract upper airway collapse in sleep-disordered breathing. Most patients found nasal continuous positive airway pressure too cumbersome for nonapneic snoring alone. Aggressive operative procedures such as uvulopalatopharyngoplasty5 or even laser-assisted uvuloplasty (LAUP)6 are consid-
In this study, we evaluated the safety and the efficacy of inserting polyethylene terephthalate (PET) implants into the soft palate to treat disturbing snoring. The principle is to increase the stiffness of the soft palate so that its vibration during turbulent airflow with inspiration could be reduced during sleep. In comparing with RFTA or sclerotherapy, we postulated that solid implants in the soft palate would have an immediate and predictable effect. The safety of the procedure and the efficacy of the implants in relieving snoring were the foci of the study.

**METHODS**

Patients who presented to the Division of Otorhinolaryngology–Head & Neck Surgery, Department of Surgery, and the Department of Psychiatry, University of Hong Kong Medical Centre, Queen Mary Hospital, with disturbing snoring as the chief complaint were recruited. These patients had to have an apnea-hypopnea index (AHI) of less than 15 per hour and a body mass index (BMI; calculated as weight in kilograms divided by the square of height in meters) of 30 or less. Patients with known cardiovascular diseases, previous history of pharyngeal surgery, or history of swallowing or speech disorders were excluded. Approval from the Queen Mary Hospital Institutional Review Board, University of Hong Kong Medical Centre, was obtained before the commencement of the study. Informed consent to participate in the study was obtained from all individuals in an interview with the operating surgeons.

Anthropometric parameters of age, height, and weight of each patient were recorded. A thorough examination of the upper airway was performed to exclude pathologic conditions causing upper airway obstruction during sleep. The patients’ bed partners were required to complete a questionnaire on their observation of the sleep pattern of the patients. The bed partners’ assessment of the loudness of the patients’ snoring sound was measured with a 0- to 100-mm visual analog scale (VAS). Zero was taken as no snoring and 100 as snoring of maximal loudness so much so that the bed partners had to leave the room. In order to assess the disturbance of the snoring sound to the bed partners/household, spouse’s response to 2 questions were recorded: (1) the effect of the patient’s snoring on the sleep of family members (options: no snoring, mild snoring only, affect spouse only, affect whole family, heard outside house); (2) number of nights per week that the spouse has to leave the room because of the loud snoring of the patient (options: 0, 1-2 nights, 3-4 nights, 5-6 nights, 7 nights in a week). The last 5 patients who were recruited also had the loudness of their snoring sound measured objectively with the SNAP sonographic system

In this study, we evaluated the safety and the efficacy of inserting polyethylene terephthalate (PET) implants into the soft palate to treat disturbing snoring. The principle is to increase the stiffness of the soft palate so that its vibration during turbulent airflow with inspiration could be reduced during sleep. In comparing with RFTA or sclerotherapy, we postulated that solid implants in the soft palate would have an immediate and predictable effect. The safety of the procedure and the efficacy of the implants in relieving snoring were the foci of the study.
median positions of the soft palate at a distance of 5 mm apart in a sagittal plane (Figure 3). Two implants were placed in each of the first 2 patients. Three implants were used for the remaining 10 patients. Fiberoptic nasopharyngoscopy was performed immediately to ensure against full-thickness puncture of the soft palate or the exposure of the ASD implant on the nasal aspect of the soft palate. Oral antibiotic treatment with cefuroxime, 0.5 g/d in 2 divided doses, and metronidazole, 1.2 g/d in 3 divided doses, was given for 1 week. Patients were reassessed at 1 week after operation for any intermediate postoperative complication.

The patient’s final outcome was assessed at 3 months. Subjective assessment by patients and the bed partners were repeated. Evaluation using the BMI, the ESS, polysomnographic assessment, and SNAP were also repeated. Patients’ and bed partners’ recommendation on the procedure were recorded at 3 months.

Statistical analysis was carried out with the Statistical Package for Social Science computer program (version 11; SPSS Inc, Chicago, Ill). The nonparametric 2-tailed Wilcoxon signed rank test was used to analyze paired data from each individual.

RESULTS

Twelve patients (11 men and 1 woman) were recruited for the ASD implantation. Two patients had extrusion of implants. Another patient was lost to follow-up. There was no known complication in this patient as contacted in the second week. Data obtained from 9 men were thus available for analysis. The mean age was 38 years (range, 29-53 years). The BMI on presentation was 25.1 (range, 21-29.6; SD, 2.9).

Assessment of the loudness by the bed partners using a 0-100-mm VAS showed a mean value of 79 (range, 50-100; SD, 17.2) at baseline (Table 1). The subjective assessment of daytime sleepiness using the ESS showed a mean (SD) score of 8.9 (SD, 5.6) out of 24. The preoperative mean (SD) AHI was 4.8/h (5.7/h). The average length of the soft palate as measured from the soft-hard palate junction to the base of the uvula at the midline was 33 mm (range, 24-38 mm; SD, 3.8). The mean width of the base of the uvula was 13 mm (range, 11-18; SD, 2.6).

All patients, including the 10 patients operated on under local anesthesia, tolerated the procedure well. Bleeding was minimal, and all patients were able to start oral feeding immediately and subsequently discharged on the same day. Paracetamol, 500 mg every 6 hours, on an on-demand basis was prescribed. There was no delayed postoperative bleeding or wound infection.

One patient had 1 implant extruded and 1 patient had 2 implants extruded from the oral side of the soft palate on follow-up. Overall, this happened in 16.7% of 12 patients and 8.8% of the 34 implants deployed. The first patient with 1 implant extruded was a 31-year-old woman who had extrusion of the implant at 4½ months after surgery. A relapse of the loud snoring sound occurred following the extrusion and the patient requested a reimplantation. The length of the soft palate in this patient was 24 mm, which was the shortest among the 12 patients (patient 1, Table 2). The width of the base of her uvula was 14 mm. The second patient was a 33-year-old man with a first implant extruded at 3 months and a second implant extruded at 4 months (patient 11, Table 2). The length of the soft palate in this patient was 34 mm, while the width of the base of the uvula was 16 mm. Both patients had no evidence of infection before extrusion of the implants. Neither patient experienced any clinical sequelae as a result of the extrusion but both reported a relapse of significant snoring after extrusion.

The mean (SD) loudness of snoring VAS assessment by the bed partners of the remaining 9 patients was 48 (20.4) (range, 7-100) at 3 months after implantation.

### Table 1. Sleep-Disordered Breathing Parameters at Baseline and 3 Months After Antisnoring Device Implantation (n = 9)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>3 mo After Implantation</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loudness of snoring (VAS, 0-100)</td>
<td>79 (17.2)</td>
<td>48 (20.4)</td>
<td>.008</td>
</tr>
<tr>
<td>Apnea-hypopnea index</td>
<td>4.8 (5.7)</td>
<td>8.3 (11.5)</td>
<td>.33</td>
</tr>
<tr>
<td>BMI</td>
<td>25.1 (2.9)</td>
<td>25.5 (2.2)</td>
<td>.61</td>
</tr>
<tr>
<td>Epworth Sleepiness Scale score</td>
<td>8.9 (5.6)</td>
<td>5.7 (5.6)</td>
<td>.007</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by square of height in meters); VAS, visual analog scale.

*Wilcoxon signed rank test, 2-tailed.

### Table 2. Dimensions of the Soft Palate and the Width of the Uvula in 12 Patients

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Length of Soft Palate, mm*</th>
<th>Width of Uvula, mm†</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>24</td>
<td>14</td>
</tr>
<tr>
<td>2</td>
<td>38</td>
<td>18</td>
</tr>
<tr>
<td>3</td>
<td>34</td>
<td>11</td>
</tr>
<tr>
<td>4</td>
<td>35</td>
<td>13</td>
</tr>
<tr>
<td>5</td>
<td>27</td>
<td>14</td>
</tr>
<tr>
<td>6</td>
<td>36</td>
<td>11</td>
</tr>
<tr>
<td>7</td>
<td>32</td>
<td>17</td>
</tr>
<tr>
<td>8</td>
<td>30</td>
<td>12</td>
</tr>
<tr>
<td>9</td>
<td>34</td>
<td>12</td>
</tr>
<tr>
<td>10</td>
<td>25</td>
<td>14</td>
</tr>
<tr>
<td>11</td>
<td>34</td>
<td>16</td>
</tr>
<tr>
<td>12</td>
<td>32</td>
<td>11</td>
</tr>
</tbody>
</table>

*The length of the soft palate was measured from the soft-hard palatal junction to the base of the uvula at the midline.
†The width of the uvula was measured at the base at its junction with the soft palate proper.
3 months were not significant (Table 1) and there were no significant decreases at 3 months.

In 3 of the 5 patients tested (patients 7, 8, and 10), both the maximum relative loudness and the average relative loudness of the snoring sound decreased at 3 months. Changes in the AHI or the BMI between baseline and 3 months were not significant (Table 1). This was a significant decrease (61% of the original loudness) compared with the preoperative mean of 79 (Wilcoxon signed rank test, 2-tailed, P = .008).

The results of the bed partners’ response to the 2 questions on the disturbance of the snoring sound to the bed partners/household at baseline and 3 months are displayed in Figure 4 and Figure 5. There were trends of shifting toward less disturbance of sleep of family members (Figure 4) and fewer number of nights per week that the spouse needed to leave the room (Figure 5) at 3 months.

Data from the SNAP system on measuring loudness of snoring were available from the last 5 patients. These are displayed in Table 3 with the corresponding snoring loudness VAS assessment and spouse recommendations. No uniform pattern of change in the snoring index was found. In 3 of the 5 patients tested (patients 7, 8, and 10), both the maximum relative loudness and the average relative loudness of the snoring sound decreased at 3 months.

Changes in the AHI or the BMI between baseline and 3 months were not significant (Table 1). The change in daytime sleepiness from a mean of 8.9 to 5.7 as measured with the ESS was significant (P = .007).

At 3 months, all patients except 1 (89%) said that they would recommend ASD implant for the treatment of disturbing snoring. The bed partners of 6 (67%) of 9 patients also said that they would recommend ASD implant as a treatment of snoring.
Table 3. SNAP Results, Loudness Assessment, and Bed Partner Recommendations in 5 Patients

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Snoring Index</th>
<th>Maximum Relative Loudness, dB</th>
<th>Average Relative Loudness, dB</th>
<th>Loudness (VAS, 0-100)</th>
<th>Recommendation*</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>639/576</td>
<td>21/16</td>
<td>14/12</td>
<td>73/31</td>
<td>No</td>
</tr>
<tr>
<td>8</td>
<td>177/328</td>
<td>18/12</td>
<td>14/4</td>
<td>50/21</td>
<td>Yes</td>
</tr>
<tr>
<td>9</td>
<td>545/805</td>
<td>25/26</td>
<td>23/22</td>
<td>100/35</td>
<td>Yes</td>
</tr>
<tr>
<td>10</td>
<td>254/289</td>
<td>27/15</td>
<td>16/8</td>
<td>97/63</td>
<td>Yes</td>
</tr>
<tr>
<td>12</td>
<td>266/373</td>
<td>16/17</td>
<td>10/16</td>
<td>77/50</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Abbreviations: SNAP, a sonographic device that records oronasal respiration; VAS, visual analog scale.

*Recommendation for the procedure from bed partners at 3 months.

as mucosal sloughing and abscess formation, which can occur after RFTA, as were absent in our study. Extrusion of the implant occurred in 16.7% of patients and 8.8% of implants. One implant extruded in the only female patient recruited to this study, which might be related to her short soft palate. The other patient who had 2 implants extruded, however, had an average soft palate dimension. Further studies are worthwhile to verify that a short palatal length may be a risk for implant extrusion. Because of the small number of patients, identification of other predictors for extrusion of implants was not possible. The extrusions in these 2 patients did not result in any clinical sequelae. The evidence that both patients experienced relapse of loud snoring after extrusion occurred and requested reimplantation could indicate indirectly the efficacy of the procedure. Overall, the procedure with the implants was considered safe and well tolerated.

Success of surgery for the treatment of snoring is difficult to define. This may be a complete cessation of snoring or a decrease in the loudness of snoring to a predetermined acceptable level, or may be defined as patient satisfaction after the operation. Said and Strome recently reported that 72% of 39 patients had a decrease of 4 points in a 10-point scale for the loudness of snoring after RFTA on the soft palate. Brietzke and Mair reported a 92% success rate on injection snoreplasty in 27 patients. The success reported was defined as “snoring is gone” or “no longer a problem,” which was a subjective and not well-defined criterion. In this group of patients who underwent ASD implantation, the loudness of snoring assessed by their bed partners was on average 61% of the original value. Using a similar VAS scale to that of our study, Blumen et al reported a 79.5% reduction of snoring at 6 to 8 weeks in 15 patients undergoing RFTA and a 66.2% reduction in 15 patients undergoing LAUP. Although our results would appear inferior to those reported by Blumen et al, our patients were spared the inconvenience of multistaged surgery and the risk of potential untoward events. With the proven safety of the PET implants, further studies are warranted to ascertain the optimal size, shape, and the number of implants required for an effective palatal implant procedure.

To improve the objectivity of assessing the loudness of snoring in addition to that by bed partners, the SNAP system was introduced when it was available for the last 5 patients in this study. These objective measures of loudness of the snores in the small number of patients did not reveal any consistent changes (Table 3). For the 3 patients with improvement, both the maximal and average loudness of snoring improved. For spouse recommendations, no relationship can be observed between spouse recommendation and baseline, final, or changes in objective assessment (SNAP), or between spouse recommendation and baseline, final, or changes in subjective VAS score in these 5 patients. This may suggest that spouse recommendation and satisfaction is affected by factors other than the sound level alone.

Results of postoperative polysomnographic studies showed that increasing the stiffness of the soft palate with the current design of the implant did not increase airway collapse as demonstrated by the stable postoperative AHI. The change of mean AHI from 4.8 at baseline to 8.3 at 3 months was not significant and probably a result of internight variability due to variation in sleep continuity between nights (Table 1).

Patients had improvement in daytime hypersomnia, as reflected by a significant decrease in the ESS scores, at 3 months after surgery (P = .007) (Table 1). Improved ESS scores was also reported by Newman et al in patients following upper airway surgery for upper airway resistance syndrome. This was attributed to a postoperative decrease in the resistance in their upper airway. Implants in the soft palate probably also reduced upper airway collapsibility during sleep and improved the sleep quality as well. As a result, daytime hypersomnia in our patients decreased. However, without esophageal pressure measurement, which is invasive and still mostly a laboratory assessment, this remains a speculation.

We agree with Sharp and Mitchell that “the partners’ opinion is the best subjective measurement of success.” The good acceptance of the ASD procedure could be reflected by 89% of patients and 67% of bed partners recommending ASD implantation to others as a treatment for loud snoring. Furthermore, this was also evidenced by the 2 patients requesting reimplantation when their implants extruded with relapse of severe snoring. Sharp and Mitchell, in their study on the results of LAUP for snoring in 53 patients, reported that 55% (29) of the spouses/sleeping partners were “happy with the result of operation” at 18 to 24 months following surgery. In another study on the efficacy of RFTA vs LAUP for snoring in 30 patients, Blumen et al reported that bed partners were satisfied in 86.6% of patients undergoing RFTA and 66.6% for LAUP at 6 to 8 weeks after treatment. Our
result of 67% recommendation rate would thus lie between that for LAUP and RFTA. However, recommendation from bed partners would be similar to but might be more than just satisfaction. The degree of acceptance observed for ASD probably related to the procedure being simple, quick, and single-staged. The association with minimal pain and discomfort and the absence of serious complications also contributed to this recommendation rate.

The main limitation of the present study was the small number of patients evaluated. Documentation of the loudness of snoring with a subjective VAS score by bed partners might also be biased since any assessment given would very much depend on the mental state of the bed partners during the night. In addition, the placebo effect was an element that could not be ignored. We considered that an assessment by a third party, the bed partner, would have reduced the degree of the placebo effect.

CONCLUSIONS

We reported a preliminary report on 12 patients undergoing PET ASD implants in their soft palate to relieve severe snoring. The procedure was safe and well accepted by both the patients and their bed partners. The average loudness of snoring as assessed by the bed partners decreased to 61% of the original value at 3 months after implantation. The ASD implant with a 1-stage procedure represents a possible direction to relieve snoring with minimal discomfort and risk.

Submitted for publication June 10, 2003; final revision received October 22, 2003; accepted October 23, 2003.

This study was approved by the Queen Mary Hospital Institutional Review Board, University of Hong Kong Medical Centre (Study No. IRB 01-07 RC/B/208). The ASDs and the deployment devices were manufactured by Restore Medical Inc, St Paul, Minn, which was also the sponsor for the study. This study was also supported by a grant from the German Academic Exchange Service and the Research Grant Council of the Hong Kong Joint Research Scheme (Project No. G_HKU 022/02).

Swana W. S. Cheung, RN, is acknowledged for her effort as study coordinator of the project.

Corresponding author and reprints: William I. Wei, FRCS, Division of Otorhinolaryngology—Head & Neck Surgery, Department of Surgery, 2/F Professorial Block, University of Hong Kong Medical Centre, Queen Mary Hospital, Pokfulam, Hong Kong SAR (e-mail: hrmswwi@hkucc.hku.hk).

REFERENCES


