Palatal implants for the treatment of snoring and obstructive sleep apnea/hypopnea syndrome

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OBJECTIVE: Randomized, double-blinded, placebo-controlled, clinical trial to determine the effectiveness of palatal implants for treatment of mild/moderate obstructive sleep apnea/hypopnea syndrome (OSAHS).

STUDY DESIGN AND SETTING: Sixty-two non-obese adults with history of snoring, daytime sleepiness, and mild/moderate OSAHS, were randomized to receive palatal implants (n = 31) or placebo procedure (n = 31). Complete follow-up including quality of life (QOL, SF-36), snoring visual analog scale (VAS), and Epworth Sleepiness Scale (ESS) data were obtained in 62 patients. Seven patients refused follow-up polysomnography for a total of 55 patients (29 implant and 26 placebo).

RESULTS: The treatment group (change in score of −7.9 ± 7.7) was significantly improved compared with the placebo group (change in score of 0.9 ± 4.3) for apnea/hypopnea index (AHI) (P < 0.0001), QOL, SF-36 (P < 0.0001), snoring VAS (P < 0.0001), and ESS (P = 0.0002).

CONCLUSIONS: Palatal implants improve AHI, QOL, snoring intensity, and daytime sleepiness for selected patients with mild/moderate OSAHS.

The Pillar Palatal Implant System is a simple, office-based procedure with minimal morbidity that is designed to stiffen the palate for the treatment of mild to moderate obstructive sleep apnea/hypopnea syndrome (OSAHS) and socially disruptive snoring.

The effectiveness of palatal implants for the treatment of mild to moderate OSAHS and/or snoring has been reported in a number of clinical studies. Without level 1 evidence, however, results from any treatment option remain subject to speculation about potential placebo effects, selection bias, and other factors that may be not a direct result of the treatment.

This randomized, placebo-controlled, double-blinded trial was designed to provide objective, unbiased evidence of the true benefits of palatal implants. We describe the objective and subjective outcomes of the palatal implant patients and compare them to a placebo control group who received an identical surgical treatment procedure without palatal implants.

MATERIAL AND METHODS

Study Design

A prospective, randomized, double-blinded, placebo-controlled study of patients who presented with snoring and daytime sleepiness was conducted to investigate the hypothesis that the palatal implant procedure is more effective than a placebo procedure for treatment of mild to moderate OSAHS. The study was conducted at one site between January 2005 and April 2006 and was reviewed and approved by the local institutional review board. The study was not registered with any other agency because it was not a requirement. Informed consent was obtained from each subject. Patients willing to participate underwent a detailed history and physical examination, including full otolaryngologic examination with fiberoptic nasopharyngoscopy. Demographics were recorded at the initial visit for each patient. Patients filled out a baseline quality of life questionnaire (QOL, SF-36 v2). Bed partners completed a visual analog scale (VAS) to determine preoperative snoring intensity, and patients completed an Epworth Sleepiness Scale (ESS) to determine the extent of daytime somnolence. Candidates were selected based on inclusion and exclusion criteria (see below) and were scheduled to undergo a baseline polysomnogram (PSG) that determined their eligibility.

Eligible patients were randomly assigned to either a treatment or a placebo surgical control group. Block randomization (blocks of 6) was performed by the manufacturer, and patients were assigned to groups before the procedure by sequential sealed envelopes with device lot numbers to be used for each patient. The lot numbers that corresponded to group assignments were not revealed until after the study was completed.

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All patients underwent the palatal implant procedure as previously described. Post-treatment data (PSG, QOL, SF-36 v2, snoring VAS, and ESS) were collected after three months. Upon completion of the 3-month follow-up PSG and data collection, group assignments were revealed and placebo procedure patients were offered the conventional palatal implant procedure.

**Patient Selection**

*Inclusion criteria.* Patients were selected to participate in the study if they had a history of OSAHS and/or symptoms of OSAHS, mainly significant snoring and excessive daytime sleepiness; Friedman tongue position (FTP) I, II, or III based on the previously described staging system; diagnosis of mild or moderate OSAHS (apnea/hypopnea index (AHI) ≥ 5 and <40) on the baseline PSG; a soft palate ≥ 2 cm, but less than 3.5 cm; BMI <32 kg/m².

*Exclusion criteria.* Patients were not selected for this study if they had clinical presentation of severe OSAHS (ESS >20, frequent choking and gasping during sleep, etc); were unwilling to be randomly assigned to the placebo group; had FTP IV; had tonsil size 3 or 4; were classified as stage IV of the Friedman staging system; were diagnosed with severe OSAHS (AHI ≥40) based on PSG. (Some patients with FTP III were considered close to a FTP IV and therefore also were excluded.)

**Polysomnography**

All-night attended, 16-channel comprehensive diagnostic sleep studies were performed pre- and post-treatment. Apnea was defined as the cessation of breathing for at least 10 seconds. Hypopnea was defined as a decrease in nasal/oral airflow (by thermistor), at least 30% less than the baseline, and with a decrease in SaO₂ of at least 4% lasting at least 10 seconds. All PSGs were scored and read by a diplomate of the American Academy of Sleep Medicine, (board-certified physician) who was unaware of the patient’s group assignment.

**Quality of Life Questionnaires, Snoring Intensity, and Daytime Sleepiness Assessment**

Quality of Life (QOL) was assessed with the SF-36 v2 Health Survey (QualityMetric, Inc, Lincoln, RI), a 36-item, validated instrument, extensively used in medical literature. Snoring intensity was evaluated by means of a VAS ranging from 0 to 10 (0 representing no snoring at all; 10 representing severe, disruptive snoring), as determined by the patient’s bed partner. Excessive daytime sleepiness symptoms were evaluated on the ESS, which ranges from 0 to 24. Subjective treatment success was measured with changes in QOL (SF-36 v2), snoring intensity VAS, and daytime sleepiness (ESS) for the treatment group compared with the placebo group. Objective treatment “success” for OSAHS was defined as an AHI reduction of ≥50% and a subsequent AHI of <20. Subjective treatment success was measured with changes in QOL (SF-36 v2), snoring intensity VAS, and daytime sleepiness (ESS) for the treatment group compared with the placebo group. Successful reduction in snoring intensity was defined as a reduction in snoring intensity of at least 50%, based on VAS scores.

**Surgical Technique**

The surgical technique for the palatal implant placement procedure (Restore Medical Inc, St Paul, MN) was performed according to the previously published method. The palatal implant insertion tools provided by the manufacturer for the placebo control group did not include the palatal implants, but they were in all other aspects identical to the implant insertion tools used in the treatment group receiving the implant. Group assignment associated with insertion tools was not distinguishable by study participants and investigators because the implants are deployed from within the hollow needle of a delivery tool. The devices were all identified by a lot number before distribution. All patients underwent a preoperative mouth rinse with chlorhexidine and received a 5-day postoperative course of prophylactic antibiotics.

**Postoperative Follow-up**

Patients were seen in the office two weeks after the procedure, at which point postoperative pain levels and complications were documented. Patients underwent a repeat PSG, and SF-36 v2 questionnaires, repeat snoring levels, and ESS were obtained both from the patients and bed partners during their follow-up 3-month office visit.

**Outcome Measures**

Primary outcomes for this study included AHI; secondary outcomes included SF-36 scores, snoring intensity VAS, and ESS. AHI treatment effect was defined as a statistically significant improvement in the change in AHI from pre-procedure to post-procedure for the treatment group compared with the change in AHI for the placebo group. Objective treatment “success” for OSAHS was defined as an AHI reduction of ≥50% and a subsequent AHI of <20. Subjective treatment success was measured with changes in QOL (SF-36 v2), snoring intensity VAS, and daytime sleepiness (ESS) for the treatment group compared with the placebo group. Successful reduction in snoring intensity was defined as a reduction in snoring intensity of at least 50%, based on VAS scores.

**Statistical Analysis**

Statistical analyses were performed with the SPSS version 11.0.1 (SPSS, Inc, Chicago, IL) and JMP version 6 (SAS Institute Inc, Cary, NC). Continuous data are displayed as mean ± standard deviation (SD). Statistical significance was accepted when $P < 0.05$.

The sample size calculation was based on the primary outcome AHI with results of our previous implant studies for an estimation of experimental response. Setting alpha = .05, 80% power, difference in means of 4, and standard deviation of 5, while considering a 10% dropout rate, a projected enrollment of 60 patients (30 treatment, 30 placebo) was considered an adequate sample size to detect a significant change in the primary outcome with the assumption of no change for the placebo group.
An intention-to-treat analysis was used, and patients were analyzed according to their randomized groups. The Levine’s Test for Equality of Variances was used to determine statistically significant variances. Two-sample $t$ tests (2-tailed) were used as the most conservative method to compare the treatment group to the placebo group via change scores (each patient’s difference from preoperative to postoperative) and to reject the null hypothesis. The paired Student’s $t$ test (2-tailed) was used to compare preoperative versus postoperative mean values within each group and to reject the null hypothesis. Fisher’s exact test was used to test the association between other categorical variables.

**RESULTS**

Sixty-two patients were evaluated, met inclusion criteria, underwent a baseline PSG, were randomized to treatment, and initiated the study. Of those, seven patients did not have a post-treatment PSG available for analysis; however, all other data were available for all 62 patients. Therefore, a total of 55 patients completed the study by undergoing repeat PSG and having postoperative data available for analysis. The median follow-up time in treatment and placebo groups was 96 ± 17 and 94 ± 5 days, respectively.

Table 1 shows the demographics of the study patients ($N = 62$) in each group. The two groups differed only in mean age. The palatal implant patients were slightly older compared with placebo patients (48.1 ± 11.2 vs 39.0 ± 9.9 years, $P = 0.0034$). In all other respects, the groups were similar.

An intent-to-treat analysis looking at objective surgical success was performed on all 62 patients who received initial study treatment (31 patients in each group). The seven patients who were lost to follow-up were considered treatment failures and analyzed accordingly. Table 2 displays the results of this analysis and shows that the implant treatment group demonstrates a statistically significant benefit over the placebo group (Fisher’s exact test, $P < 0.001$). A comparison of the demographics of seven patients without follow-up PSG data to the rest of the study patients showed that the groups were similar in all categories except that the patients without follow-up PSG data had longer palates ($P = 0.0015$). Because of this difference, a worst-case scenario sensitivity analysis was conducted that treated those with missing PSG data in the treatment group as failures ($N = 2$) and those in

| Table 1
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<tr>
<td>Demographic data of 62 patients with obstructive sleep apnea/hypopnea syndrome who underwent palatal implantation or a placebo control procedure.</td>
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<td>Age (yrs)</td>
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<td>Males</td>
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<td>Females</td>
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<td>Friedman Tongue Position (FTP)</td>
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<td>BMI (kg/m²)</td>
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<td>Palate length (cm)</td>
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<td>Neck Circumference (inch)</td>
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<td>Uvula length (cm)</td>
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All values calculated with $N = 31$ for each group except for age which had $N = 26$ for each group.

Data listed as counts or mean ± standard deviation.

*Denotes statistically significant difference between the treatment (palatal implant) and placebo control groups. Statistical significance accepted when $P < 0.05$.

| Table 2
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<tr>
<td>Intent-to-Treat Analysis: Classic successful surgical treatment of OSAHS compared by randomized groups</td>
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<td>Treatment %</td>
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<td>Placebo count</td>
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<tr>
<td>Placebo %</td>
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<td>Total</td>
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Fisher’s exact test, $P$ value < 0.001 (2-tailed).

Data listed as counts or mean ± standard deviation.

*Denotes statistically significant difference between the treatment (palatal implant) and placebo control groups. Statistical significance accepted when $P < .05$. 


the placebo group as successes ($N = 5$). Even under these highly unlikely conditions, the treatment group is still statistically superior ($P = 0.049$) on the endpoint of classical treatment success, and the seven patients without follow-up PSG data do not bias the overall study results. Therefore, all PSG results are reported on the 55 patients (29 palatal implants and 26 placebo procedure) for which complete data were available, and all secondary data are reported on 62 patients. Figure 1 displays a flow diagram of patient progress through this trial.

**OBJECTIVE SURGICAL SUCCESS**

Change scores for AHI for both treatment groups can be seen in Tables 3 and 4, respectively. The AHI change score for the treatment group compared with the placebo group was significantly improved ($P < 0.0001$) (Table 4). Palatal implant patients had a significant decrease in change score when postoperative AHI and preoperative AHI ($7.9 \pm 7.7; P < 0.0001$) scores are compared, whereas the mean AHI change score for placebo patients increased slightly

<table>
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<th>Table 3</th>
<th>Comparison of preoperative versus postoperative PSG data and subjective measures of snoring and daytime sleepiness</th>
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<tr>
<td></td>
<td>Preoperative</td>
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<td>% δ sleep</td>
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<td>Palatal implants</td>
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<td>Placebo controls</td>
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<td>SD</td>
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$A_I$, apnea index; $A_HI$, apnea/hypopnea index; $Min min SaO_2$, minimum saturation of oxygen; $ESS$, Epworth sleepiness scale; $SD$, standard deviation.
(+0.9 ± 4.3). In addition, 23 (79.3%) of 29 treatment patients had a reduction in AHI compared with 12 (46.2%) of 26 placebo patients. Although six (20.7%) treatment patients had an increase in AHI during the study, the mean increase for these patients was minimal (2.8 ± 2.0). By comparison, 14 (53.8%) placebo patients had an increase in AHI during the study, and the mean increase for these patients was 4.1 ± 2.3.

Based on the classic definition for successful surgical treatment of OSAHS, the outcomes in the treatment group differed significantly compared with the placebo group ($P < 0.001$) (Table 5). Palatal implantation resulted in the successful treatment of 13 (44.8%) of 29 treatment patients (including four treatment patients with a preoperative AHI under 20). In contrast, none (0%) of the 26 patients treated as placebo subjects (including nine patients with a preoperative AHI under 20) showed improvement in PSG parameters that resulted in successful treatment.

**SF-36 v2 Quality of Life Survey**

Table 6 displays the preoperative versus postoperative change scores for treatment and placebo groups for each of the eight domains, along with change scores for the average of the eight domains (Avg QOL). A principal component analysis was performed to determine that the Avg QOL was significantly improved in the treatment group compared with the placebo group ($P < 0.0001$), which is consistent with a highly significant change for six of the eight individual domains. The only domains that were not significantly improved by palatal implants compared with placebo treatment were Physical Functioning and Bodily Pain (BP).

**Subjective Symptom Elimination**

Preoperative, postoperative, and change scores for snoring VAS and ESS for all patients can be seen in Tables 3 and 4, respectively. Snoring VAS change score for the treatment group ($-4.7 ± 2.1$) compared with the placebo group ($-0.71 ± 0.9$) was significantly improved ($P < 0.0001$) (Table 4). A comparison of postoperative values with preoperative values demonstrated that snoring VAS significantly improved within both groups ($P < 0.001$). We defined successful improvement of the patient’s symptoms with strict criteria that required a ≥50% decrease in snoring intensity postoperatively. Twenty-one (67.7%) of 31 patients who received palatal implants met these criteria whereas 0 (0%) of 26 of the placebo treatment patients had such an improvement at the 3-month follow-up.

The ESS change score for the treatment group ($-2.2 ± 2.2$) compared with the placebo group ($-0.5 ± 1.5$) was significantly improved ($P = 0.0002$) (Table 4). A comparison of postoperative to preoperative ESS also revealed significant improvement within the palatal implant group ($P < 0.001$), whereas the placebo-treated group did not significantly change.

**Complications and Long-Term Morbidity**

All patients were evaluated for postoperative complications, including implant partial extrusion and infection. Two patients had a partial extrusion of an implant that was addressed by removing the extruded implant and inserting a
new implant two weeks after removal. One patient had classical success with symptomatic improvement, and the other patient had neither symptomatic improvement nor PSG improvement. Patients managed postoperative pain with over-the-counter oral analgesics for up to 48 hours in all cases. All patients were able to immediately resume normal levels of activity and a regular diet.

**DISCUSSION**

Existing publications that support the effectiveness of various forms of surgical treatment for snoring and OSAHS have been criticized for lack of control groups and potential placebo effects. There are few studies in otolaryngologic literature that provide level 1 evidence of treatment effectiveness for snoring and OSAHS.\(^1\)\(^2\)\(^3\) This randomized, double-blinded, placebo-controlled study addresses previous criticism in that it meets the EBM paradigm of level 1 evidence and has demonstrated that palatal implants improve mild to moderate OSAHS and snoring.

The insertion of polyethylene terephthalate implants in the soft palate generates an inflammatory reaction that leads to the formation of a fibrous encapsulation of the implants. The structural support of the palatal implants works together with the fibrotic reaction to stiffen the soft palate and decrease palatal fluttering.\(^4\) Due to this increased rigidity of the palate, apneas and hypopneas are decreased, thus improving OSAHS.\(^5\) In addition, palatal implants preserve the palate’s soft-tissue framework, instead of altering it. Surgical alteration of soft palate tissue can also inhibit the successful use of CPAP in some cases.\(^6\) Four prospective studies have been published that look at long-term patient follow-up for one year or greater in which sustained effectiveness was demonstrated for both snoring\(^7\)\(^8\) and OSAHS.\(^9\)\(^10\)

These results objectively demonstrate a clinically significant decrease in AHI after treatment with palatal implants that is not present in the placebo control group. The effectiveness of palatal implants in achieving a reduction in AHI has been previously reported to range from 24% to 37.5%.\(^1\)\(^1\)\(^5\) In this study, classical “objective treatment success” was achieved in 44.8% (versus 0% in placebo) of the patients who received palatal implants (Table 5). The variation in results across studies is not unexpected and is seen with all therapies for OSAHS. It is speculated to result from variation in night to night PSGs, inability to diagnose and treat the location of obstruction, differences in patient demographics (eg, mean AHI, age, etc), and surgical techniques. Because palatal implants can only treat the palatal component of OSAHS, the degree of success can only be as good as the degree of palatal contribution in the patients selected to participate in a study. In one study reported in the literature,\(^9\) the authors chose to do a combination treatment approach (ie, soft palate and tongue) because they did not believe they could identify the area of obstruction a priori. The authors confirmed this belief by comparing post-study results to pretreatment evaluations.

Seventy-nine percent of implant patients versus 46% of placebo patients had an overall decrease in AHI. At first glance, this difference does not appear to be clinically significant; however, when one looks at the mean change for each group (\(-7.9 \pm 7.7\) vs \(+0.9 \pm 4.3\)), one can better appreciate the overall impact of palatal implants on AHI results. Conversely, 21% of the implant patients had an observed increase in AHI versus 54% of the placebo patients. The mean increase for the implant and placebo group was 2.8 \(\pm 2.0\) and 4.1 \(\pm 2.3\), respectively. These increases over a 90-day evaluation period are more likely due to the variability in the measurement tool as opposed to true worsening of the patient’s OSAHS. Nevertheless, implant patients had both a much smaller occurrence and degree of worsening than did the placebo patients.

Several authors\(^6\)\(^16\)\(^17\) have reported improvements in snoring for palatal implants that range from 67% to 100%, as determined by bed partner satisfaction questionnaires. We did not collect bed partner satisfaction data but did utilize a VAS

### Table 6

<table>
<thead>
<tr>
<th>Measure</th>
<th>Change score (Mean ± SD)</th>
<th>Difference (control – treatment)</th>
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<tr>
<td></td>
<td>N Treatment</td>
<td>N Placebo</td>
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<tr>
<td>Avg. QOL</td>
<td>31 10.3 ± 8.6</td>
<td>31 −1.5 ± 4.8</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>31 5.5 ± 13.9</td>
<td>31 0.4 ± 2.7</td>
</tr>
<tr>
<td>Role limitations—physical health</td>
<td>31 7.7 ± 11.4</td>
<td>31 −0.4 ± 8.2</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>31 1.8 ± 5.6</td>
<td>31 0.1 ± 7.0</td>
</tr>
<tr>
<td>General health perceptions</td>
<td>31 9.7 ± 11.0</td>
<td>31 −2.6 ± 6.9</td>
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<tr>
<td>Vitality</td>
<td>31 23.6 ± 19.3</td>
<td>31 −3.8 ± 13.2</td>
</tr>
<tr>
<td>Social functioning</td>
<td>31 4.0 ± 6.7</td>
<td>31 −3.2 ± 7.2</td>
</tr>
<tr>
<td>Role limitations—emotional</td>
<td>31 11.8 ± 14.4</td>
<td>31 −2.4 ± 6.9</td>
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<tr>
<td>problems</td>
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<tr>
<td>Mental health</td>
<td>31 18.7 ± 15.4</td>
<td>31 −0.16 ± 7.7</td>
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*SD, standard deviation; Avg QOL, average of the 8 domains of SF-36 v2.*
snoring intensity scale that has been utilized previously in clinical studies of palatal implants with reported improvements of 39% to 88%.

In this study, we did not consider anything less than a 50% reduction in VAS as being significant. Although many studies on snoring consider any decrease in VAS as “successful,” many bed partners would probably disagree. In spite of our relatively rigid criteria, 67.7% of the patients with palatal implants met those snoring improvement “success criteria” as compared to 0% of patients in the placebo group. Improvement in snoring is an important assessment because this is the one symptom that most frequently prompts patients to seek treatment.

One of the limitations of this study is the relatively short follow-up period; however, this short follow-up period provided placebo patients with deferred treatment as an incentive to remain in the study until completion. Two articles have assessed long-term follow-up outcomes after soft palate implant placement. One indicates that both PSG and snoring parameters remain stable with only a slight tendency toward relapse after one year. The other article demonstrates an improvement in postprocedure PSG with classical success criteria from 31% at 90 days to 50% at one year, whereas snoring results remained stable.

Group assignment was prematurely revealed for two patients who experienced partial extrusions, but this did not affect the collection or interpretation of objective PSG data by an impartial sleep medicine physician who was not aware of group assignment or partial extrusions.

The major limitation to the study is the potential challenge in generalizing the results that come from a limited study population of nonobese mild to moderate OSAHS patients with specific oral physical characteristics (FTP I, II, and III and tonsil size 1 or 2) where half of the patients evaluated did not qualify for this study. This study attempted to enroll patients with predominate palatal obstruction to demonstrate the specific effects of implants on the soft palate as an isolated procedure; however, the ability to accurately and consistently diagnose and treat the location of airway obstruction is lacking. The use of palatal implants to treat the soft palate component of airway obstruction in patients with multiple points of airway obstruction that require combination therapy may still be indicated as was demonstrated in our previous published data where the best results were obtained when palatal implants were combined with multiple treatments.

Although the inclusion criteria were designed to have a maximum BMI of 30, 15 patients (eight placebo and seven implant) with a BMI between 30 and 32 were included in the study. This was an error in the execution of the study but does not affect the results of the study.

CONCLUSION

Patients treated with palatal implants demonstrate a significant improvement when compared with a placebo surgical control group in OSAHS and snoring. This study provides level 1 evidence that the palatal implant procedure can result in a significant decrease in AHI. Almost half (44.8%) of the mild to moderate OSAHS patients in this study achieved a decrease in AHI >50% to an AHI <20. This study also provides level 1 evidence that the palatal implant procedure provides improvement in QOL, is effective in reducing snoring intensity (67.7% of patients), and demonstrates a statistically significant decrease in the level of daytime sleepiness. Considering the significant improvements seen in this prospective, randomized, placebo-controlled study, the palatal implant procedure provides a low morbidity, simple to use palatal treatment option for mild to moderate OSAHS and snoring. Palatal implants should be considered in combination with other treatments for the nasal airway and hypopharynx in those patients who suffer from multilevel obstruction of the upper airway.

AUTHOR INFORMATION

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AUTHOR CONTRIBUTION

Michael Friedman, primary investigator, data collection, manuscript preparation; Paul Schalch, study coordinator, clinical coordinator, data analysis; Hsin-Ching Lin, study coordinator, clinical coordinator, data analysis; Kedar A Kakodkar, data analysis, literature review, review and analysis; Ninos J. Joseph, study design, study coordinator, statistician, manuscript writer/editor; Narges Mazloom, manuscript preparation, writer/editor, literature analysis.

FINANCIAL DISCLOSURE

This study was financially supported in part by Restore Medical, Inc. who provided implants, randomization, and covered the cost of pre- and post-treatment polysomnography for all patients. Sham implant devices were provided by Restore Medical, Inc. Professional services for the implantation were not paid for and were provided by the investigators. Patient incentives included free implants for all patients who had received sham procedure. These implants were also provided by Restore Medical, Inc. Professional services for these patients, as well, were provided without cost by investigators. All other costs and data analysis were provided by the study investigators or patients’ insurance.
Michael Friedman has received honoraria from Restore Medical, Inc. for presentations. Restore Medical, Inc. has also supported CME programs run by Dr Friedman with unrestricted educational grants.

REFERENCES