

The Pillar™ System: A New Treatment for Snoring Long-Term Clinical Results

By: Michael D. Bierk
Manager, Medical Affairs
Restore Medical Inc.

Objective:

The Pillar System palatal inserts, a new treatment for habitual snoring, has recently been introduced as a safe, effective, and minimally invasive treatment that is designed to be permanent. This report evaluated the overall long-term safety and treatment success rate of the Pillar System in patients followed for up to one year.

Methods:

The original prospective, non-randomized, multi-center clinical trial was conducted to evaluate the Pillar System in over 100 patients diagnosed as primary snorers. All patients were treated identically, with three inserts placed in the soft palate during a single treatment session. The trial demonstrated safety and effectiveness through pre- and post-treatment comparison of results, using various measurement tools. This report summarizes the results from a subset of those patients from the original study that were followed for one year.

Results:

The results described were obtained from 37 patients who had successfully completed their 12-month follow-up. The mean body mass index (BMI) of the total patient population was 26.0 ± 2.3 ($n=37$). Sleep studies were performed to exclude those patients with clinical evidence of Obstructive Sleep Apnea (OSA). The mean pre- and post-treatment respiratory disturbance indexes (RDI) were 2.27 ± 2.1 and 3.24 ± 4.2 , respectively, and were not considered clinically significant.

The overall treatment success of the Pillar System was evaluated in two ways: 1) by a snoring intensity measurement (un-anchored VAS score), and 2) by patient and bed partner satisfaction. To analyze success by snoring intensity, patients were classified into two groups based on their 90-day results:

Treatment "success"	29/37 (78.4%)
Treatment "non-responders"	8/37 (21.6%)

Within the treatment "success" group, patient and bed partner satisfaction levels were 91.7% and 88.6%, respectively, at 90 days. Both these measures indicate a high treatment success rate with a standardized one-time procedure.

To characterize the long-term results, the treatment "success" group was separated into two groups based on each patient's 360-day results with durable "success" being defined as a continued reduction in snoring intensity from baseline levels:

Durable "success"	26/29 (89.6%)
Treatment "relapse"	3/29 (10.4%)

Nearly 90% of the successful patients (durable "success" group) maintained a lower mean VAS score at 360 days (3.9 ± 2.5). Durable "success" patients also had a 48% drop in their mean Epworth Sleepiness Scale (ESS) scores, from 9.2 ± 4.4 to 4.8 ± 3.2 . Furthermore, among successfully treated patients the reported patient and bed partner satisfaction rates at 360 days (Patient=82.1%; Bed Partner=77.8%) confirm the low relapse rate above.

For all patients, regardless of success outcome, 75% of patients and 73% of bed partners would recommend the procedure at 360 days.

Post-operative pain was reported as mild and of short duration (24-72 hrs.), and was effectively treated with non-narcotic analgesics. There were no significant changes in speech or swallowing, and reported adverse events were considered mild and resolved with little or no medical intervention.

Conclusion:

The Pillar System procedure has been shown to be a minimally invasive, relatively painless procedure. The procedure can be performed in a single brief office visit and provides a lasting effect in reducing snoring intensity in the majority of patients. The results demonstrate that the Pillar System is a safe and effective procedure to treat patients with habitual snoring.

The Pillar™ System: A New Treatment for Snoring Clinical Results (cont.)

Introduction

Habitual snoring, often caused by flutter of the soft palate, affects up to 20% of the adult human population and their partners¹. The affliction can include a number of effects beyond the social aspect, including hypopnea and apnea², fragmented sleep and oxygen desaturation³, and resultant daytime dysfunction⁴. Stiffening the soft palate has been shown to reduce or eliminate chronic snoring. Other procedures to treat snoring stiffen the soft palate by removing and/or scarring tissue. The Pillar™ System, a new treatment for snoring, stiffens the soft palate tissue through: the inherent stiffness of an insert, the fibrotic tissue response and tissue ingrowth. This stiffening of the soft palate results in an alteration of the dynamic response of the tissue to airflow, and substantially reduces the severity of snoring in many patients.

There have been several published studies that assessed the long-term effectiveness of other snoring treatments (such as UPPP, LAUP, and RF Ablation), but there seems to be no consistent method to measure long-term success and determine a relapse rate. These published studies report wide ranges of overall treatment satisfaction and relapse rates (46-75%; 10-47%, respectfully).⁵⁻¹²

The Pillar System has been shown to be safe, effective, minimally invasive, and is performed under local anesthesia. The inserts are intended to be permanent, and are designed to produce a lasting effect in the reduction of a patient's snoring intensity. The purpose of this report is to provide further information regarding the long-term safety and effectiveness of the Pillar System.

Materials and Methods

The original prospective, non-randomized, multi-center trial demonstrated the safety and effectiveness of the Pillar System in over 100 patients diagnosed as primary snorers. As an extension to the original clinical trial, two centers agreed to follow patients up to twelve months. A total of 42 patients from the original study have reached the 360-day follow-up. Five (5) patients were not included in the analysis due to baseline VAS scores, which were already at a non-bothersome level (<4.5). The data are reported from the remaining 37 patients who have completed their twelve-month follow-up.

Bed partners and patients were requested to complete a questionnaire prior to the patients' procedure and at each follow-up interval for comparative purposes. Patients were followed at 24-72 hours, 2 weeks, 30 days, 90 days, 180 days, and at 360 days post-procedure. Follow-up evaluations consisted of assessments for any adverse events, sleep quality and snoring intensity based on responses included in the questionnaires. Visual analog scales (VAS) were used to describe the bed partner's perception of snoring intensity where VAS scores ranged

from 0 (no snoring noise) to 10 (extreme snoring noise). The Epworth Sleepiness Scale (ESS), a validated clinical indicator that quantifies the patient's chance of falling asleep during eight different activities of daily living, was also included as part of the patient questionnaire. Additionally, patients and bed partners were asked whether they would recommend the Pillar System to a friend or family member, based on how they were feeling at the follow-up interval. Sleep studies were performed to rule out patients with clinical evidence of Obstructive Sleep Apnea (OSA).

All patients were prescribed broad-spectrum antibiotics prior to treatment; the procedure was carried out in an outpatient setting and performed under local anesthesia. Patients received three inserts placed into the soft palate (midline, right and left lateral), which involved a single, simple procedure averaging 10 minutes. All inserts were placed as close to the hard and soft palate junction as possible. The lateral inserts were placed approximately five (5) mm or less from the midline insert, to avoid the thin tissue in the lateral areas of the soft palate. The patients were prescribed appropriate broad-spectrum, post-operative antibiotics and non-narcotic analgesics to be taken on an "as needed" (PRN) basis.

All available data was summarized using descriptive statistics for continuous variables (e.g. mean, standard deviation, range) and frequency tables or proportions for discrete variables. Students' t-tests were used to test the difference in follow-up VAS scores versus baseline.

All summary statistics and statistical analysis were done using The SAS System for Windows Version 8 (Copyright © 1999-2000 SAS Institute Inc., Cary, NC, USA).

Results

The treatment results reported here are from those 37 patients from the original study who have completed their twelve-month follow-up. The mean body mass index (BMI) of enrolled patients was 26.1 ± 2.3 (n=42). The mean pre- and post-treatment RDIs were 2.27 ± 2.1 and 3.24 ± 4.2 , respectively.

In order to analyze the overall success rate and the long-term effectiveness of the Pillar System, patients were first classified based on their response to treatment. These patients were placed into two groups as shown below:

<i>Treatment success</i>	29/37 (78.4%)
<i>Non-responders</i>	8/37 (21.6%)

Inclusion Criteria

The inclusion criteria for each of the above patient groups are described as follows:

-For this analysis, **treatment "success"** was measured at 90 days and defined as a reduction of

The Pillar™ System: A New Treatment for Snoring Clinical Results (cont.)

baseline snoring intensity level of two or more points, or a reduction of snoring intensity level to a score of 4.5 or below, as determined on a VAS. The second criterion was used as a measure of “success” as the data demonstrated that the level of 4.5 on the VAS was deemed non-bothersome as determined by a cross tabulation of the snoring verbal description with the snoring intensity (VAS). That is, the bed partners who described the patients’ snoring as non-bothersome (described as “none” or “soft, occasional”) marked a VAS score of 4.5 or less in all cases. These criteria used to measure “success” were similar to that which has been used in previously published studies.⁷

-A “**non-responder**” was used to define those patients who did not meet the inclusion criteria described above at 90 days (i.e. they did not respond to treatment).

- Further, when speaking of the long term effects, **durable “success”** is defined as patients whose bed partners initially reported a successful improvement in their baseline snoring intensity level at the 90-day follow-up and continued to maintain a decrease in the VAS at 360 days when compared to the same measure at baseline.

- Finally, **treatment “relapse”** is defined as patients whose bed partners initially reported a successful improvement at 90 days, but failed to maintain a decrease in the VAS when compared to the level at baseline.

Therefore the patients were placed into two groups based on their long-term results as shown below.

Durable success	26/29 (89.6%)
Treatment relapse	3/29 (10.4%)

As can be seen, the vast majority (~90%) of successful patients have durable long-term results, while only approximately 10% had a treatment relapse.

Safety

Adverse event information was collected at the time of the procedure and at each subsequent follow-up. There were no reported major adverse events associated with the use of the Pillar System, such as infection or aspiration. There were no significant speech and swallowing difficulties observed in patients. There were no significant ongoing throat and mouth pain among patients. The pain VAS score increased from baseline to 2.2±1.6 at the 24-72 hour follow-up, and quickly returned to baseline level shortly thereafter. The data indicates the procedure resulted in

minimal post-procedure pain, and the majority of cases were treated with non-narcotic analgesics.

All of the reported adverse events were minor and those associated with partial implant extrusions and foreign body sensations (described in more detail below on all 42 patients), were considered mild and were resolved with little or no medical interventions.

Insert Partial Extrusions:

Partial extrusions were observed at a per insert incidence rate of 10.3% (13/126) and a per patient incidence rate of 19.0% (8/42). A partial extrusion occurs when the tip of the insert breaks through the surface mucosal tissue and the rest of the insert remains embedded into the soft palate tissue. There were no adverse safety issues associated with the partial extrusions, and inserts were easily removed and replaced. Results from the clinical trial indicate there may be several factors possibly contributing to partial extrusions such as patient selection, placement technique, and placement location.

Foreign Body Sensation (FBS):

Foreign body sensation (FBS) was reported in 16.7% of (7/42) patients. Foreign body sensation is defined as a sensation that something is different in the back of the throat and/or palate, usually felt when swallowing. The majority of incidents were considered mild and transient. The majority (85.7%; 6/7) of foreign body sensation incidents resolved with no additional medical intervention. One patient requested that the insert be removed due to the foreign body sensation.

Effectiveness

Snoring Intensity

The 26 patients that were considered to have **durable success** decreased their VAS scores significantly (8.1±1.4 to 2.9±2.3) at 90 days, and maintained a reduction of over 50% (3.9±2.5) at 360 days. The **relapse** patients (n=3) demonstrated a decrease at 90 days (7.6±0.6 to 3.2±1.2), but this was not maintained at 360 days as the mean score returned to baseline levels (7.9±0.6). Those patients that were classified as **non-responders** remained virtually unchanged at 90 days and 360 days (7.2±1.5, 6.6±1.6 and 7.4±1.5).

Epworth Sleepiness Scale (Daytime Sleepiness)

The Epworth Sleepiness Scale (ESS) was included in the patient questionnaire as a tool to further assess the quality of sleep for each snoring patient throughout the follow-up period. The ESS values for the **durable success** patients at 360 days were significantly lower when compared to baseline values 9.2±4.4 and 4.8±3.2, respectively. The **non-responders** had a slight decrease in their ESS and **relapse** patients remained relatively unchanged.

The Pillar™ System: A New Treatment for Snoring Clinical Results (cont.)

Patient and Bed Partner Recommendations

Patients and bed partners were asked at each follow-up if they would recommend the procedure to other patients seeking treatment for snoring problems. At 90 days 91.7% (n=36) of all patients treated and 86.1% (n=36) of their bed partners were satisfied with the procedure, as evidenced by the recommendation. In following, the 360-day results show that 82.1% (n=28) of patients and 77.8% (n=27) of bed partners from the “treatment success” group above are still satisfied with the procedure.

In the analysis of all patients, regardless of success outcome: 75% of patients (27/36) and 73% of bed partners (24/33) would recommend the procedure at 360 days.

Conclusion

In summary, the Pillar System has been shown to be a minimally invasive, relatively painless procedure, which can be performed in a single brief office visit, and has been shown to produce a lasting effect in reducing snoring intensity in the majority of patients.

The results of the clinical trial and long-term follow-up demonstrate that the Pillar System is a safe and effective treatment for patients with habitual snoring.

References

1. Hoffstein V, Mateika JH, Mateika S. Snoring and sleep architecture. *Am Rev Respir Dis* 1991;143:92-96.
2. Lugaresi, E, Cirignotta F, Geraldini R, et al. Snoring and sleep apnea: natural history of heavy snorers' disease. In: Guilleminault C, Paried M, editors. *Obstructive Sleep Apnea Syndrome: Clinical Research and Treatment*. New York: Raven Press; 1990. p. 25-36.
3. Guilleminault C. Clinical features and evaluation of obstructive sleep apnea. In: Kroger MN, Roth T, Dement WC, editors. *Principles and practice of sleep medicine*. Philadelphia: WB Saunders; 1989. p. 552-8.
4. Hughston V. Snoring. *Chest* 1996;109:210-22.
5. Wareing MJ et al. Laser assisted uvulopalatoplasty: six and eighteen month results, *J Laryngol Otol* 1998 Jul;112(7):639-41.
6. Neruntarat C. Laser-assisted uvulopalatoplasty: short-term and long-term results, *Otolaryngol Head Neck Surg* 2001 Jan;124(1):90-3.
7. Trotter MI et al. Medium-term outcome of palatal surgery for snoring using the Somnus unit, *J Laryngol Otol* 2002 Feb;116(2):116-8.
8. Li KK et al. Radiofrequency volumetric reduction of the palate: An extended follow-up study, *Otolaryngol Head Neck Surg* 2000 Mar;122(3):410-4.
9. Blumen MB et al. Treatment of snoring with controlled temperature radiofrequency: short- and mid-term tolerance and efficacy, *Ann Otolaryngol Chir Cervicofac* 2000 Dec;117(6):349-358.
10. Boot H et al. Long-term results of uvulopalatopharyngoplasty for obstructive sleep apnea syndrome, *Laryngoscope* 2000 Mar;110(3 Pt 1):469-75.
11. Koay CB et al. Short- and long-term outcomes of uvulopalatopharyngoplasty for snoring, *Clin Otolaryngol* 1995 Feb;20(1):45-8.
12. Levin BC et al. Uvulopalatopharyngoplasty for snoring: long-term results, *Laryngoscope* 1994 Sep;104(9):1150-2.

Pillar and Restore Medical are trademarks of Restore Medical Inc.
© 2003 Restore Medical Incorporated
All Rights Reserved. Printed in the USA.
Restore Medical Inc.
St. Paul, MN 55113
www.restoremedical.com