# Efficacy of the Pillar® Palatal Implant System: First Results in OSA Patients

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## Introduction

Currently, the primary treatment options for obstructive sleep apnea (OSA) are surgery or continuous positive airway pressure (CPAP). However, both options are not without issues. Surgical options such as UPPP tend to be costly and associated with significant morbidity[1]. CPAP is a very viable therapy, but it has significantly low patient compliance[2]. The new Pillar® Palatal Implant System (shown in Figure 1) has the potential to be a low cost minimally invasive treatment option for mild to moderate OSA. Palatal implants have previously shown to be very effective in the treatment of primary snoring[3,4,5,6].

## Purpose of Study

This study was designed to study the safety and effectiveness of palatal implants with respect to those patients suffering from mild to moderate OSA.

## Material & Methods

This study was a prospective, non-randomized trial conducted at the University Hospital in Mannheim. Patients were screened according to the inclusion/exclusion criteria (major items listed in table 1). The verification of mild to moderate OSA was conducted using a polysomnography recording. Sixteen (16) patients who met the criteria were chosen for implantation on an "intent to treat" basis. There were 2 females and 14 males enrolled in the study with a mean age of 51 years (range of 34-64) and a body mass index of 26.6 kg/m$^2$ (range of 21.5-30.0). Objective (AHI) and subjective data (excessive daytime sleepiness, snoring, pain, speech and taste) were measured at baseline and 90 days post-operatively. One patient was retested because of technical difficulties during the polysomnography. Three (3) implants were placed in the patient's soft palate under local anesthesia.

## Results & Discussion

The AHI was reduced in 13 of 16 patients (81.3%) with a 53.4% mean decrease for those 13 patients, 16.3 ± 4.5 to 7.6 ± 4.6 ($p<0.001$). Table 2 lists all patients with AHI decreases at baseline and 90 days. Six (6) of the 13 patients (46.2%) experienced an AHI decrease of greater than 50% along with a 90 day AHI of less than 10. Ten of the 13 patients (76.9%) decreased to an AHI less than 10. Snoring intensity was significantly reduced on the visual analogue scale (VAS) from 8.2 ± 1.8 to 4.8 ± 2.4 ($p=0.001$) and the ESS also improved slightly from 6.5 ± 3.8 to 5.0 ± 3.3 ($p<0.03$). As shown in Figure 2 not only did the majority of patients experience a decrease in AHI, but there was also a significant reduction in OSA related symptoms such as snoring and daytime sleepiness.

There were 3 patients (Table 3) that did not experience a decrease in AHI. However, further analysis of those patients revealed that 2 of 3 patients did experience significant decreases in snoring intensity and daytime sleepiness. These two patients had AHI increases of 8.1% (22.2 to 24.0) and 7.7% (13.0 to 14.0) which is considered clinically unchanged. One patient experienced a considerable increase in AHI, which may be attributable to such factors as first-night effect, additional airway obstructions or alcohol consumption.

No significant complications were observed during the procedure or at the 90 day follow-up period. One patient did complain of a scratchy throat, but resolved without treatment within one week.

Figure 3 shows the levels of swallowing, speech, and pain for the study period as indicated by the patient on a VAS. Pain and swallowing had only slight increases at 24-72 hours, but the values quickly returned to baseline levels at the 2 week follow-up. While speech and taste remained unchanged.

## Conclusion

The new Pillar® Palatal Implant System is a viable minimally-invasive treatment option that is associated with very low morbidity for patients suffering from mild to moderate OSA.

## Acknowledgments

This reserach was supported by a grant from Restore Medical, Inc.

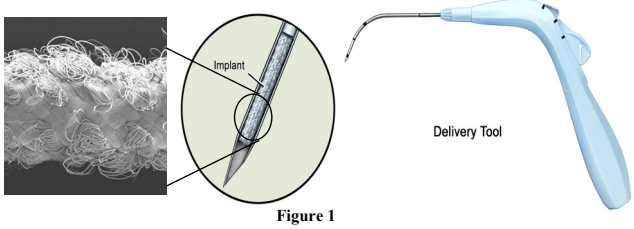



**Figure 1**

**Table 1 – Inclusion/Exclusion Criteria**

Patients were included if:

- Age > 18 years
- Apnea-hypopnea index (AHI) 10-30 episodes/hour
- Body mass index (BMI) ≤ 30 kg/m$^2$
- Soft palate length > 25 mm
- Tonsil size < 50% of the airway
- No significant nasal stenosis
- No previous history of pharyngeal surgery

**Table 2 – Patients with a decrease in AHI**

| Patient | Baseline | 90 Days | % Change |
|---|---|---|---|
| 1 | 13.0 | 4.2 | -67.7 % |
| 2 | 24.0 | 16.0 | -33.3 % |
| 3 | 15.0 | 7.7 | -48.7 % |
| 4 | 17.0 | 9.6 | -43.5 % |
| 5 | 20.0 | 3.9 | -80.5 % |
| 6 | 23.4 | 15.0 | -35.9 % |
| 7 | 20.0 | 5.4 | -73.0 % |
| 8 | 11.1 | 10.3* | -7.2 % |
| 9 | 18.5 | 5.9 | -68.1 % |
| 10 | 11.0 | 0.3 | -97.3 % |
| 11 | 12.0 | 2.3 | -80.8 % |
| 12 | 13.0 | 9.6 | -26.2% |
| 13 | 13.4 | 8.7 | -35.1% |
| Mean | 16.3 | 7.6 | -53.4%** |

* Patient was retested.

**p<0.001

**Figure 2 - Daytime Sleepiness and Snoring Intensity (Patients with an AHI decrease)**

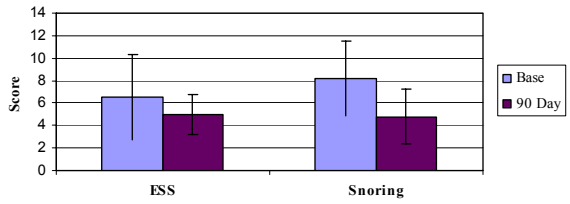
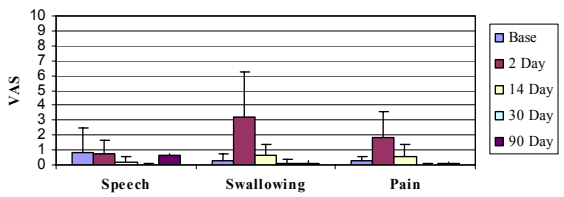



**Table 3 – Patients with an increase in AHI**

| Patient | Baseline | 90 Days | % Change |
|---|---|---|---|
| 1 | 22.2 | 24.0 | 8.1 |
| 2 | 13.0 | 14.0 | 7.7 |
| 3 | 17.8 | 42.5 | 138.8 |

**Figure 3 - Mean Speech, Swallowing and Pain Values (All Patients)**

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