Evidence Table

Clinical Area: Pillar implants for snoring  

Study Type: Case Series- prospective  
Study Aim: To evaluate the safety and efficacy of pillar implants for treating snoring

Outcomes  
• Primary: Pain, functional parameters, snoring (did not specify primary outcomes).

Design  
• Number of subjects: n=40  
• Method of subject selection (inclusion/exclusion criteria): Included otherwise healthy patients with primary snoring who had soft palate length ≥25 mm. Excluded those with obstructive sleep apnea or upper airway resistance syndrome.  
• Consecutive patients? Not reported.  
• Description of study population: Mean age=42 ± 9 years; mean BMI=25.2 ± 2.5 kg/m²; chronic snoring for a mean of 9.7 ± 7.9 years.  
• Intervention: The first 19 patients received a Anti-Snoring Device and the remainder received the Pillar Palatal Implant System, both by Restore medical, Inc. The implant system includes a delivery tool preloaded with implants. The implants themselves were identical. Each patient received three implants parallel to the soft palate midline under local anesthesia.  
• Source of outcome data (e.g. patient self-report, doctor report, lab results): Sleep studies and SNAP (recording of snoring sounds) at baseline and 90 days; self- and bed-partner report at baseline, 90 180 and 360 days.  
• Length of follow-up: 12 months.  
• Completeness of follow-up: The bed partners of 8 patients did not provide data.

Validity  
• Is the study type appropriate for the question(s) being asked? No, there was no control or comparison group.  
• Were patients similar with respect to baseline characteristics? Appeared to be.  
• Was the intervention and other aspects of patient care similar for all patients (or for all patients in a defined subgroup)? Yes. The implants were the same for all patients, but the delivery tool differed.  
• Was the process of observation likely to affect the outcome? Possibly, outcome assessment was not blinded.  
• Did an objective observer assess outcomes and were outcome measurements consistent? The authors did not report how sleep studies and recordings of snoring were evaluated.

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• **Conclusions regarding validity of methods:**
This was a case series with no control or comparison group. As such, it is subject to selection and observation biases. In addition, the outcome measures were not well described and the authors did not specify primary outcomes. The study was funded in part by Restore Medical, the manufacturer of the pillar implant system.

**Results**

Snoring score*, 0-10 visual analogue scale, bed partner report n=32, 80% of sample

<table>
<thead>
<tr>
<th>Median</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>7.1</td>
</tr>
<tr>
<td>Day 90</td>
<td>4.1</td>
</tr>
<tr>
<td>Day 180</td>
<td>4.2</td>
</tr>
<tr>
<td>Day 360</td>
<td>4.3</td>
</tr>
</tbody>
</table>

There were statistically significant differences in the median score baseline to day 90, baseline to day 180 and baseline to day 360.

* Unclear whether this measures frequency and/or loudness.

Epworth Sleepiness Scale (Daytime sleepiness )

<table>
<thead>
<tr>
<th>Median</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>6.0</td>
</tr>
<tr>
<td>Day 90</td>
<td>3.0</td>
</tr>
<tr>
<td>Day 180</td>
<td>3.0</td>
</tr>
<tr>
<td>Day 360</td>
<td>4.0</td>
</tr>
</tbody>
</table>

There were statistically significant differences in the median score baseline to day 90, baseline to day 180 and baseline to day 360.

SNAP findings (recordings of snoring), n=21, 53% of sample

<table>
<thead>
<tr>
<th>Baseline</th>
<th>Day 90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of snores per hour</td>
<td>273 ± 178</td>
</tr>
<tr>
<td>Maximum relative loudness*</td>
<td>15 ± 7</td>
</tr>
</tbody>
</table>

* Loudness in dB of the loudest 10% of all snoring events.

No significant differences found baseline to day 90.
Adverse effects

- The were no surgical or postoperative complications during the fist 2 weeks
- None of the 120 implants penetrated the soft palate.
- There was no clinically significant speech or swelling disturbances.
- In 10 patients, 13 implants partially extruded after a median of 53 days, causing mild pain or a foreign body sensation.
- After 3 months, 7 implants were partially extruded.

Authors’ Conclusions

“Our data demonstrate a significant decrease in snoring and daytime sleepiness over a period of one year.”

Reviewer’s Conclusions

There was a statistically significant reduction in bed partner reported snoring and self-reported daytime sleepiness a year after treatment compared to baseline. In the 50% of patients who had recordings done of snoring after 3 months, there were no statistically significant changes from baseline. This was a case series and as such there was no comparison with an alternate treatment or no treatment.