New Technologies for Treatment of Snoring and Sleep Apnea

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“It is time for the surgeon to bring a breath of fresh air to our patients that is not from a CPAP device.”

Nelson Powell, 2005

What Is New ???

- Emphasis on Surgical Treatments and Methods to Diagnose Site (s) of Obstruction
- Adults
- Somewhat Arbitrary
  What is “New” to Some
  May be “Old” to Others
A Major Problem in Evaluating Surgical Treatment For Snoring and Sleep Apnea is How to Define a “Cure”

Will Not Discuss Today

- Pillar® Implant System
- Repose® Suspension of Hyoid
- Coblation® to Tongue

Common Definition of Surgical Success

AHI Reduction $\geq 50\%$

Final AHI of $\leq 20$

Probably too Low a Fence
Other

- $O_2$ Saturation
- E.S.S.
- SF-36v2 Quality of Life Questionnaire
- Snoring
  Visual Analog Scale

Powell-Riley Criteria For “Cure” of OSA with Surgery

1. Equivalent to CPAP
   or
2. AHI < 20 and/or at Least a 50% Reduction For All AHI < 20
3. $O_2$ Saturation > 90%
4. Normalization of Sleep Architecture
5. Resolution of EDS

Conventional UPPP Appears to be too Conservative a Procedure to Completely Correct Obstruction at the Palate Level
Pharyngeal Pressure Measurements During Sleep Following UPPP Show Persistent Collapse at the Palate Level in About Half the Cases. A More Aggressive Approach May be Needed in Cases Where We Know the Palate is the Site.

"Aggressive" Palate Level Procedures

1. Transpalatal Advancement Pharyngoplasty
2. Z - Palatoplasty

Transpalatal Advancement
Pharyngoplasty
Woodson, 2005

Z-Palatoplasty
Friedman, 2003
“Cure” in UPPP Failures
- RDI Decrease of 50% or More and to Below 20
- Z-Palatoplasty – 67.7%
- TAP – 67%
- Pillar® Implants -21.7%
  Friedman et al
  Laryngoscope 116:1956, 2006

One Limitation in Discussing “New” Technology to Treat OSA is that the Early Data is Proprietary and Unavailable to be Presented.
Magnetic Airway Implants
Nelson, LM et al
Otolaryngol Head and Neck Surg
133:945-960, 2005

- Study in 10 Dogs
- Repelling Magnets in Tongue Base and Pharynx Prevented Collapse of Pharynx with Negative Pressures (-33cm H2O)
- Equivalent to 10-12 cm H2O CPAP
- Longer Term Evaluation (6 months)
- No Effect on Swallowing
- 1/10 Extrusion

Tongue Support System
AspireMedical.com

A Corsage of Biocompatible Hooks that Lie in the Tongue Base and Attach to the Anterior Mandible by a Wire. Insertion is Via a Needle.

Cross-sectional view. Implant exposed for simulation purposes only.


High Energy Single Session Radiofrequency Tongue Treatment in Obstructive Sleep Apnea
Nelson, L, MD
Barrera, JE, MD, 2007
Study Design

- A retrospective single clinical site, non-randomized case series of consecutive adult patients (n=176) who clinically presented with Fujita type II obstruction. IRB approval was obtained.
- The purpose of the study was to investigate the safety, outcomes, and added patient morbidity of a single stage high energy RF tongue base treatment in multi-level soft tissue surgery of the airway.

Mean BMI was 28 and mean age 42.
- Fourteen Lesions at 750 J each were delivered using the Gyrus Somnoplasty® dual-tongue probe. The range of impedance was 105 – 130 ohms.
- Average operative time for tongue base treatment was 24 min, range 19-35 min.

Pattern Schema

<table>
<thead>
<tr>
<th>Measure</th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESS</td>
<td>11.2 ± 4.9</td>
<td>5.9 ± 4.5</td>
<td>p&lt;.00001</td>
</tr>
<tr>
<td>AHI (events/hr)</td>
<td>35.4 ± 23.9</td>
<td>24.3 ± 21.5</td>
<td>p&lt;.00001</td>
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<td>Supine AHI (events/hr)</td>
<td>52.9 ± 32.3</td>
<td>26.3 ± 23.3</td>
<td><strong>P&lt;.00001</strong></td>
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<td>AI (events/hr)</td>
<td>20.9 ± 23.9</td>
<td>8.3 ± 13.9</td>
<td><strong>P&lt;.00001</strong></td>
</tr>
<tr>
<td>LSAT (%)</td>
<td>83.3 ± 8.7</td>
<td>84.6 ± 6.7</td>
<td><strong>P&lt;.05</strong></td>
</tr>
<tr>
<td>RAI</td>
<td>41.6 ± 22.9</td>
<td>29.0 ± 20.9</td>
<td><strong>P=.0001</strong></td>
</tr>
<tr>
<td>REM (%)</td>
<td>12.7 ± 7.8</td>
<td>18.5 ± 10.5</td>
<td><strong>P&lt;.00001</strong></td>
</tr>
</tbody>
</table>
Complications of TBRF of Tongue

- Of 176 patients, 8 presented with complications (4.5%). 5 Superficial base of tongue ulcers (2.8%), 3 taste disturbances (1.7%) present at 6 mo.
- Abscess, change in tongue mobility or sensation, or airway complications were not seen. Post-op discomfort and time to oral intake similar as multi stage RF.
- Clinical tongue flattening was noted on exam.

Conclusion

- We believe that a 10,500 J threshold of RF can be delivered safely as a single treatment.
- The single stage approach provides an alternative that we believe is more convenient, efficient and cost effective to both patient and physician, and could alleviate the patient compliance issues of returning for multiple treatment procedures.

Newer Methods to Diagnose the Site (s) of Obstruction

- During Sleep
- Reasonable Cost
- Accurate

Commercially Available PSG Machine that Also Measures Nasal and Pharyngeal Pressures During Sleep?
Yes, the Apnea Graph
- Available in UK and Europe
  MRA – Medical LTD, Gloucester, UK
- Not in the U.S. as Yet
- Accuracy ?
- Comfort ?

Plasma Radiofrequency Preceded by Pressure Recording Enhances Success for Treating Sleep-Related Breathing Disorders
Tvinnereim, M. et al
Laryngoscope 117: 731, 2007

- 40 Pts, 9 Month Follow-up
- Snoring, Mild OSA
- Site at Palate
- Coblation® to Palate, one Time
- Snoring, ↓ ≥ 3 on VAS
- AHI 9.86 → 4.18
  62% Below 5
- ESS 10.5 → 4.58
- No Follow-up Pressures Reported

Cine-MRI and Watch-Pat
Detail Site of Obstruction in OSA Patients
- Cine-MRI is utilized as an adjunct diagnostic modality in identifying site of obstruction in OSA patients.
- Real time measures of the PAS and tongue volume are compared to laryngoscopy, cephalometric, and watch-pat data points.
Cine-MRI and Watch-Pat
Detail Site of Obstruction in
OSA Patients

THANK YOU !