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Upper Airway Stimulation for Treatment of Obstructive Sleep Apnea

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Upper Airway Stimulation for Treatment of OSA

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Introduction:

- What is OSA
  - Consequences of untreated OSA
- CPAP therapy
- Why do we need alternatives to positive airway pressure (PAP) therapy
- How do we evaluate a patient for alternative treatments
- Who is a candidate
- What are the alternatives
Obstructive Sleep Apnea
How we Measure OSA

• Hypopnea:
  • Reduction in airflow of 30% for 10 seconds with corresponding desaturation of 4%
• Apnea:
  • Cessation of breathing for 10 seconds
• RERA:
  • Respiratory event related arousal
• Apnea Hypopnea Index (AHI)
  • Average of apneas and hypopneas per hour
• Respiratory Disturbance Index (RDI)
  • Apneas, hypopneas and RERA on average per hour
Scoring Sleep Studies

- <5 Normal
- >5-15 Mild
- >15-30 Moderate
- >30 Severe
What are the consequences of untreated OSA?

- Cardiovascular
  - Hypertension
  - Heart failure
  - MI
  - Arrhythmia
  - Stroke
- Pulmonary
- Endocrine
  - Diabetes
- Other
  - Reflux
- Functional
Treatment

- Surgical treatments predate medical treatments
  - Tracheotomy
  - UPPP
- CPAP shortly thereafter
Positive Airway Pressure

CPAP = continuous positive airway pressure.
Benefits of CPAP

- Sleep quality
- Reduced snoring
- Alertness
- Reduced GERD
- Depressive symptoms
- Blood pressure control
- Heart function, esp atrial fibrillation
- Mortality rate

Kanathur et al. Therapy in Sleep Medicine, 2012
Adverse Effects of CPAP


Why do we need alternatives?

- Patients who cannot tolerate CPAP
- Non-adherence 46-83%
- Better response with more severe symptoms

Expiratory Positive Airway Pressure (EPAP)

- Theravent®
- Provent®
  - Imposes expiratory resistance
  - Stent open airways
  - 94% compliance

Rosenthal, L. et al. A. JCSM 5(\(^\)) 2009
Provent®

- Well tolerated
- Decrease in AHI by 42.7% (vs 10% sham)
- Further research is required to identify the ideal candidates.

Oral Appliances:

- Useful in primary snoring and OSA
- 2 Types:
  - Tongue retaining
  - Mandibular advancing
Oral Appliances:

- Success in treatment
  - Mild to moderate OSA
  - AHI <10 in 52%
- Treatment adherence 76%

- Adverse events:
  - Tooth movement
  - Changes in occlusion
  - TMJ pain
  - Salivation
  - Gum irritation
  - Tongue pain (tongue retaining devices only)

Body Positioning Devices
What is sleep surgery?

• Surgery to facilitate other modalities of treatment
  • Improve tolerance of CPAP
  • Improve use of oral appliances or EPAP
• Surgery to definitively treat OSA
  • Bariatric surgery
  • Modification of the upper airway
  • Upper airway stimulation (Inspire®)
Who is a candidate?

- Diagnosed OSA by appropriate PSG screening
- BMI (<40)
- Willing to undergo postoperative PSG to objectively assess outcome of alternative treatment
Mueller’s Maneuver
Evaluation: Fujita Classification

Type I
Retropalatal

Type II
Combined

Type III
Retrolingual
Sleep Endoscopy

• Flexible fiberoptic examination of patient with sedation
• Assesses airway under more “true” to sleep circumstances
• Better assessment of site of obstruction
Surgical Management:

- Addressing different sites of obstruction
  - Nose
  - Palate
  - Tongue base / Hypopharyngeal
Surgical Management

Nasal Obstruction Surgery

- <20% successful in mild OSAS with nasal obstruction
- Facilitate CPAP compliance
  - Decreased CPAP pressures
  - Tolerance of different masks

Palatal Procedures

- Laser assisted Uvuloplasty
- Injection snoreplasty
- Cautery Assisted Palatal Stiffening Operation (CAPSO)
- Tonsillectomy
- Pillar implants
- UvuloPalatoPharyngoPlasty (UPPP)
- Anterior Palatoplasty
- ZP3
- Expansion sphincteroplasty
- Palatal advancement
- Lateral pharyngoplasty
Management: Tongue Base

- Radiofrequency reduction
- Laser midline glossectomy
- Laser Lingualplasty
- Lingual tonsillectomy
- SMILE procedure
- TORS

- Hyoid Myotomy and advancement +/-Tongue base suspension
- Genioglossus advancement
- Hypoglossal Nerve Stimulator
Bimaxillary Advancement

- Osteotomies of maxilla and mandible
- Addresses oropharyngeal and hypopharyngeal airway
- Can be used after failed “phase 1” sleep surgery
- 90-95% success
- Limited by patient acceptance
Tracheotomy

- “Gold Standard”
- Temporary adjunct to procedures in severe cases
Upper Airway Stimulation:

- Surgically implanted device
- Does not alter native anatomy of pharynx and tongue base
How Does Inspire Therapy Work?

• Inspire therapy:
  • Is fully implanted
  • Senses breathing
  • Delivers mild stimulation to key airway muscles
  • Turns on and off with a handheld remote
Inspire Therapy
Inspire System

- Stimulation Lead
- Respiratory Sensing Lead
- Patient Sleep Remote
- Implantable Pulse Generator
- Physician Programmer
Adjustability of Device

• Implantable neurostimulation systems are adjustable to optimize therapy

• Inspire is a closed-loop system measuring respiration and providing stimulation

• Titration occurs during an in-lab sleep study
Upper Airway Stimulation Effect

No Stimulation  Stimulation Active
Inspire Therapy affects the airway at multiple levels:

- **Tx OFF - Palate**
- **OFF - Tongue Base**
- **Tx ON - Palate**
- **ON - Tongue Base**
Star Trial: Stimulation for Treatment of Apnea Reduction

Upper-Airway Stimulation for Obstructive Sleep Apnea

Patrick J. Strollo, Jr., M.D., Ryan J. Soose, M.D., Joachim T. Maurer, M.D., Nico de Vries, M.D., Jason Cornelius, M.D., Oleg Froymovich, M.D., Ronald D. Hanson, M.D., Tapan A. Padhya, M.D., David L. Steward, M.D., M. Boyd Gillespie, M.D., B. Tucker Woodson, M.D., Paul H. Van de Heyning, M.D., Ph.D.,

**PRIMARY OUTCOMES**

The scores on the **AHI** and **ODI** (primary outcome measures) were lower (indicating fewer episodes of sleep apnea) at 12 months than at baseline. The median AHI score decreased 68%,

**SECONDARY OUTCOMES**

Scores on the FOSQ and Epworth Sleepiness Scale indicated significant improvement at 12 months, as compared with baseline. The increase in the

N Engl J Med 2014;370:139-49; p 143-4; Figure 3, p 147.
Green underlines added for clarity in text excerpts.
Significant Reduction In OSA Severity

**Apnea-hypopnea Index**
- Baseline: 29.3
- Month-12: 9.0
- **68% reduction**
- **p < 0.001**

**Oxygen Desaturation Index**
- Baseline: 25.4
- Month-12: 7.4
- **70% reduction**
- **p < 0.001**
Significant Improvement In Daytime Functioning

Epworth Sleepiness Scale
Daytime Sleepiness

<table>
<thead>
<tr>
<th>Score (median)</th>
<th>Baseline</th>
<th>Month-12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>11.0</td>
<td>6.0</td>
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</table>

*p < 0.001

Functional Outcomes of Sleep Questionnaire
Daytime Functioning

<table>
<thead>
<tr>
<th>Score (median)</th>
<th>Baseline</th>
<th>Month-12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>14.6</td>
<td>18.2</td>
</tr>
</tbody>
</table>

*p < 0.001

Normal Range
Reduction in Snoring

Source: Inspire STAR pivotal trial
Inspire Therapy Visits

Assessment
- Sleep profile
- Anatomy check

Implant
- Typically outpatient

Follow Up
- Therapy activation
- Therapy optimization
- Routine annual follow up
Who is a candidate for Upper Airway Stimulation

- Moderate to severe OSA with AHI 20 or more
- BMI 32 or less
- No significant central component of apneas
- Appropriate anatomy based on sleep endoscopy
Inspire Therapy Visits

Assessment
- Sleep profile
- Anatomy check

Implant
- Typically outpatient

Follow Up
- Therapy activation
- Therapy optimization
- Routine annual follow up
Surgery:
Hypoglossal Nerve (XII)

Mylohyoid

Hyoglossus
Plunge Point in fresh cadaver

**GGh & GGo ramifying**
Nerve Integrity Monitor

Patient Interface

Electrodes

A. Thumb Switch
B. Cable

ECG Subdermal Electrodes
- Designed to monitor with 2 F needles
- Single needle

EMG Subdermal Electrodes
- Designed to monitor with 12 F needles
- Needle-specific single use

Subdermal Needle Electrodes
- Designed to monitor with 2 F needles
- Needle-specific single use

Electrode Ground (Green with "E")
- Always locate these electrodes in a non-instrumented, electrically neutral area (electrically neutral areas are remote from the surgical areas, the site is clear of the surgical area, and the electrode will not contact muscle tissue).

Medtronic Xomed NIM 3.0

NIM-Response® 3.0
**NIM EMG Electrode Placement**

**NIM Set up**

**EMG Monitoring Electrodes:**

- **Genioglossus:** insert towards mid-inferior section of the tongue along inner molars, underneath the tongue using Prass Paired Electrodes (18 or 12.5 mm)
  - **Goal:** Include m-XII branches for optimal protrusor identification/recruitment

- **Stylo-/Hyoglossus:** insert along ventrolateral aspect, shallow parallel course just beneath the mucosa using Prass Paired Electrodes (12.5 or 18 mm)
  - **Goal:** Exclude l-XII branches for optimal retractor identification/exclusion

**Stimulation:** 0.3 - 0.8 mA

Identify final retractor branch, evaluate challenging branches for inclusion
Respiratory Sensing Lead

Sensing (Sense) Lead

**Location**
- Inferior to 5th rib, and Superior to 6th rib
- 5 cm interfascial tunnel; deep to external, superficial to internal, intercostal muscle
- Anchor to fascia/muscle

**Functions**
- Obtain breathing pressures via sensor membrane
- Convert pressure changes to electrical current waveform
- Deliver waveform to IPG for closed-loop therapy
Lateral view, showing stim cuff electrode include vertebrae and chin

AP view, showing IPG/lead wrap and sensing lead include IPG and sensor lead
Inspire Therapy Visits

Assessment
- Sleep profile
- Anatomy check

Implant
- Typically outpatient

Follow Up
- Therapy activation
- Therapy optimization
- Routine annual follow up
Experience To Date

- 14 implants
- 8 post implant titrations
- First adult Down’s syndrome patient implanted in country
- 1 of 10 centers in the post commercial trial
## Results

<table>
<thead>
<tr>
<th>Patient</th>
<th>AHI Pre</th>
<th>AHI Post</th>
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</thead>
<tbody>
<tr>
<td>Patient 1:</td>
<td>27.2</td>
<td>1</td>
</tr>
<tr>
<td>Patient 2:</td>
<td>23.0</td>
<td>7.7</td>
</tr>
<tr>
<td>Patient 3:</td>
<td>18.4</td>
<td>5.1</td>
</tr>
<tr>
<td>Patient 4:</td>
<td>25</td>
<td>5.7</td>
</tr>
<tr>
<td>Patient 5:</td>
<td>44</td>
<td>5.1</td>
</tr>
<tr>
<td>Patient 6:</td>
<td>26.3</td>
<td>0</td>
</tr>
<tr>
<td>Patient 7:</td>
<td>86.3</td>
<td>7.7</td>
</tr>
<tr>
<td>Patient 8:</td>
<td>50.1</td>
<td>15*</td>
</tr>
</tbody>
</table>

* = Down’s patient with 8 central apneas
• I have but one misgiving. I believe that my characterization of the first generation of this device as a “Model T” was misleading. This really is a Lamborghini, and I am really happy to have one driving my breathing every night. It is making a big difference in my life. In fact, I just now realized as I’m writing this that I have had enough energy in the evening that I’m taking a yoga class that starts at 8 p.m. On January 29, 2015 that would have been impossible because I would have been wiped out before 5:30 p.m. What a gift.
Conclusions

- OSA is a prevalent disease
- Impacts the health of all of our patients
- CPAP remains first line therapy
  - Compliance remains an issue
- Multiple non-PAP therapy options exist and are evolving
  - EPAP
  - Oral appliances
  - Surgery
  - Upper airway stimulation represents one of the most promising therapies for a select group of patients