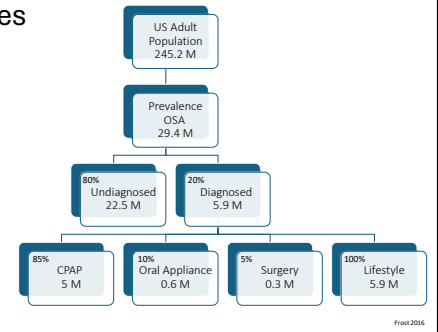


## Combination Therapy for OSA: Surgical Hypoglossal Nerve Stimulation and Mandibular Advancement Device

1

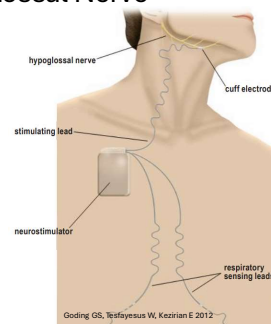
## PAP Alternatives



2

## Overview of Surgical Hypoglossal Nerve Stimulation

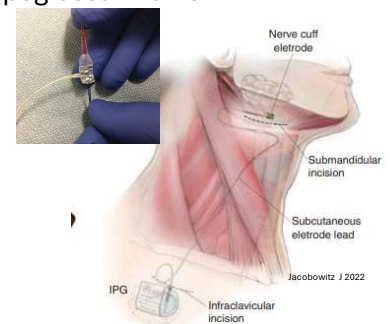
- Unilateral stimulation of hypoglossal nerve actively opens the airway during sleep
- Indications are for moderate to severe OSA with non-circumferential collapse and BMI < 40



3

## Other Surgical Hypoglossal Nerve Stimulations

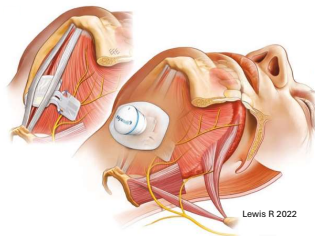
- Livanova



4

## Other Surgical Hypoglossal Nerve Stimulations

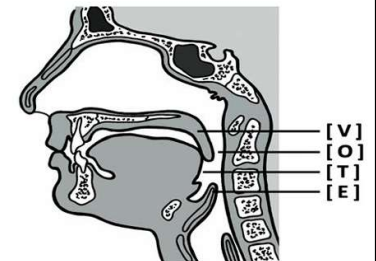
- Nyxoah



5

## Overview of HGNS – VOTE Classification

Velum  
Oropharyngeal  
Tongue base  
Epiglottis



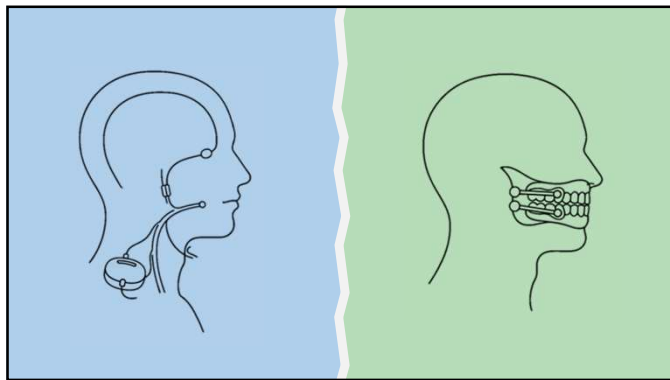
Qian K, Janott G, Pandit V, Zhang Z, Heiser C, Herzog M, Hermert W, Schuller B 2017

6

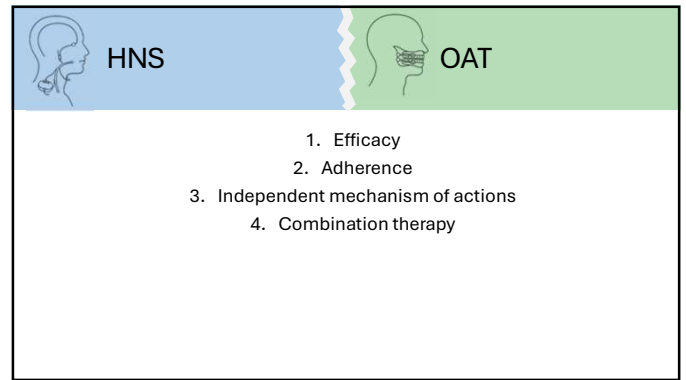
© 2020 Healthwise

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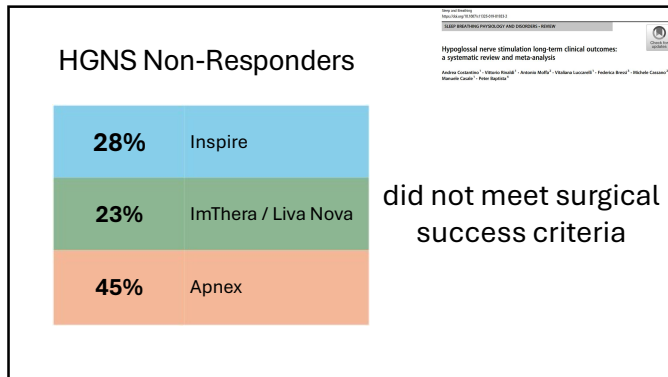


11

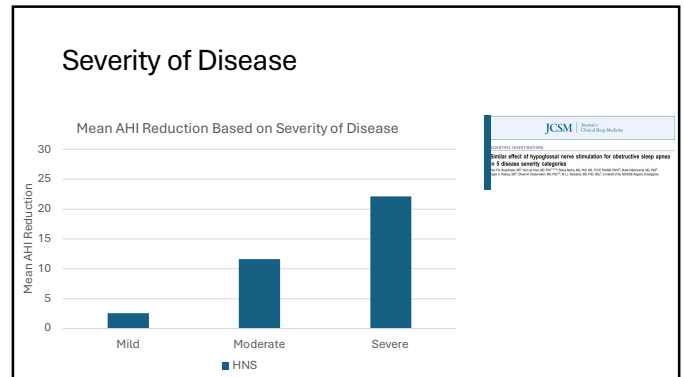
|            |                                                                                                                 |                                                                                                                   |
|------------|-----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Efficacy:  | <ul style="list-style-type: none"> <li>At least 50% reduction AND AHI less than 20/h (Sher criteria)</li> </ul> | <ul style="list-style-type: none"> <li>AHI less than 5/h</li> </ul>                                               |
| Adherence: | <ul style="list-style-type: none"> <li>≥4 hours per night on 70% nights within the month (30 day)</li> </ul>    | <ul style="list-style-type: none"> <li>PAP: ≥4 hours per night on 70% nights within the month (30 day)</li> </ul> |

12

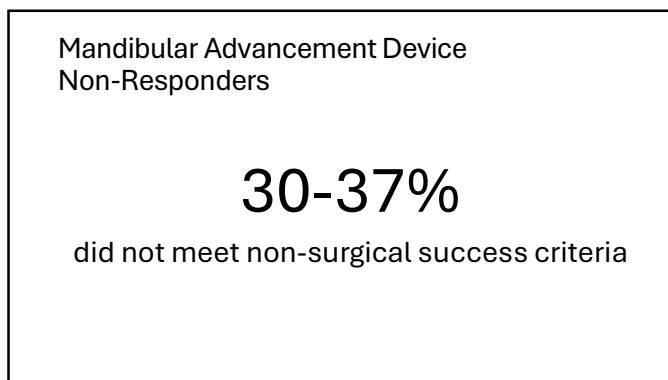
\*Inspire Medical Systems



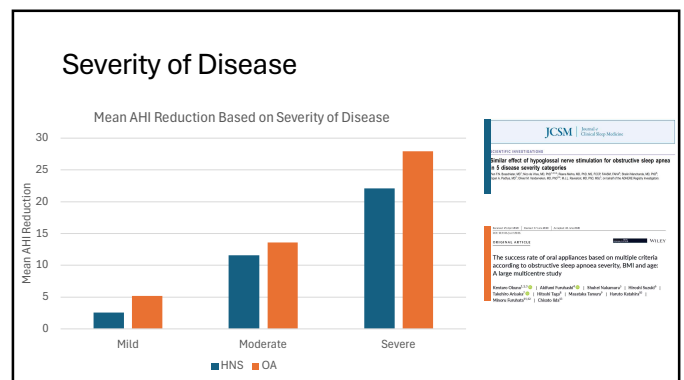
13



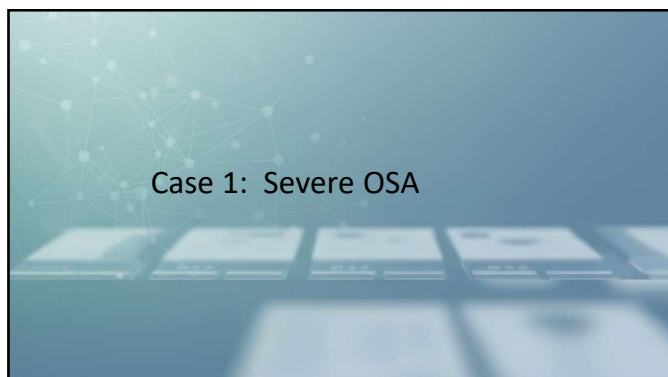
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### Case 1: History

35 year old obese man with a history of OSA diagnosed 12 years ago. He presented with the classic combination of excessive daytime sleepiness and snoring.

- Originally, the sleep apnea was mild, but he was unable to tolerate CPAP at all due to claustrophobia. His most recent PSG, 2020, revealed severe sleep apnea with an overall AHI of - 116.3. He was severely hyper somnolent, which interferes with his life significantly.

**Current medical history:**

- Acid reflux.
- PTSD/ Depression.
- Difficulty sleeping.
- Tinnitus

**Current medications:**

- Cholecalciferol 1000 unit tab take 2 tabs by mouth once daily.
- Escitalopram oxalate 20 mg tab take 1 tab by mouth once daily.
- Loperamide HCL 2 mg take 2 caps by mouth after first bout of diarrhea and then 1 cap every 2 hours.
- Mirtazapine 30 mg: Take 2 tabs by mouth at bedtime

**Past surgical Hx:**

- Tonsillectomy.

**Allergies:**

- Lunesta and Ambien (sleep walking).

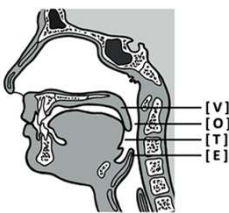
18

| Diagnostic-PSG July 2019                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Diagnostic- HSAT May 2019                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Total sleep time:</b> 401.5 min<br><b>Apnea hypopnea index (AHI):</b> 116.3/ hr<br><b>Total number of respiratory events:</b> 776<br><b>#of obstructive apneas:</b> 118<br><b>#of mixed apneas:</b> 22<br><b>#of central apneas:</b> 68<br><b>#of hypopneas:</b> 570<br><b>Supine AHI:</b> 141.4/ hr<br><b>Duration spent in supine sleep (%):</b> 45<br><b>Non-supine AHI:</b> 95.4/hr<br><b>REM AHI:</b> 73/ hr (11.5% of TST)<br><b>Baseline SpO2 (awake):</b> 92-94%<br><b>Time &lt;89%:</b> 188 min<br><b>SpO2 min:</b> 74%<br><b>Baseline TCO2 (awake):</b> 41-42 mmHg<br><b>Baseline TCO2 (asleep):</b> 44-47 mmHg<br><b>TCO2max:</b> 49 mm Hg<br><b>Total time above 50 mmHg:</b> 0 min | <b>Analysis Time (min):</b> 558.4<br><b>Respiratory Event Index (REI):</b> 86/ hr<br><b>Total number of respiratory events:</b> 800<br><b>#of obstructive apneas:</b> 539<br><b>#of mixed apneas:</b> 11<br><b>#of central apneas:</b> 15<br><b>#of hypopneas:</b> 235<br><b>Supine REI (/hr):</b> 97.7<br><b>Duration spent in supine sleep (%):</b> 83<br><b>Mean SpO2 (%):</b> 88.8<br><b>Minimum SpO2 (%):</b> 66<br><b>SpO2 &lt;=88% (min):</b> 227.4<br><b>Oxygen Desaturation Index (ODI):</b> 88.4 |

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### RESULTS OF DISE

>The patient was referred to the Multidisciplinary Sleep Clinic.  
 >His management plan was DISE to help determine the best treatment option/ options.



|                                           |
|-------------------------------------------|
| Velum: partial AP collapse                |
| Oropharynx: No collapse                   |
| Tongue Base: partial tongue base collapse |
| Epiglottis: complete collapse             |
| Narrowing of lateral hypopharyngeal wall  |

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### Treatment Options



**UA Surgery**

Modified UPPP + hyoid suspension with possible lingual tonsillectomy

**Surgical Options**

MMA and Tracheostomy NOT acceptable to patient

**Non-Surgical Options**

Patient preferring to begin with a less intrusive therapy.  
Patient understood that OAT alone is not likely to adequately resolve his sleep apnea.

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### Treatment Options



**UA Surgery**

Modified UPPP + hyoid suspension with possible lingual tonsillectomy

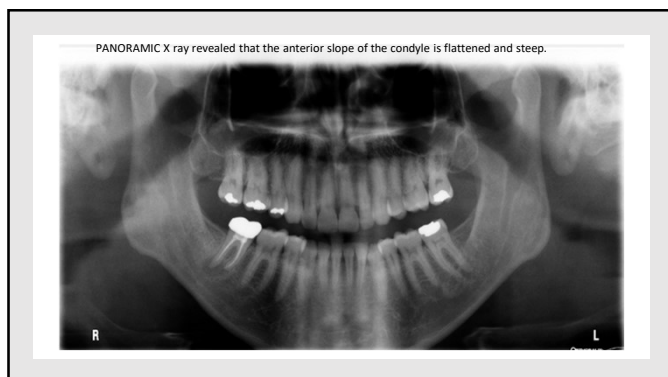
**Surgical Options**

MMA and Tracheostomy NOT acceptable to patient

**Non-Surgical Options**

Patient preferring to begin with a less intrusive therapy.  
Patient understood that OAT alone is not likely to adequately resolve his sleep apnea.

22



23

- BMI 35
- Neck 17inches
- Friedman III
- Mallampati IV
- The uvula was edematous. The soft palate long and has redundant pharyngeal tissue. The turbinates were within normal limits. The maxilla was moderately vaulted.



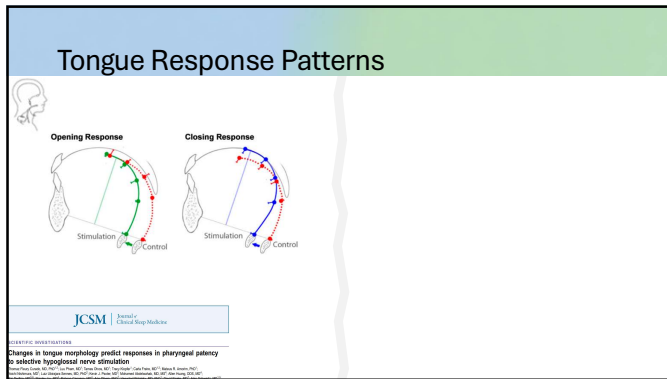

**Oral examination**  
Adequate number of teeth to support oral device, no caries, an overbite of 5 mm, an overjet of 2.5 mm and a healthy periodontium.  
no caries, self-cleansable  
Attrition-canine incisal wear  
The patient presented with a Class I (normal) dental relationship.

**Mandibular range of motion**  
maximum interincisal opening of 48 mm, maximum protrusive of 6 mm, left lateral excursion of 9 mm, right lateral excursion of 9 mm, deviation to left of 1 mm and normal maxillary midline.

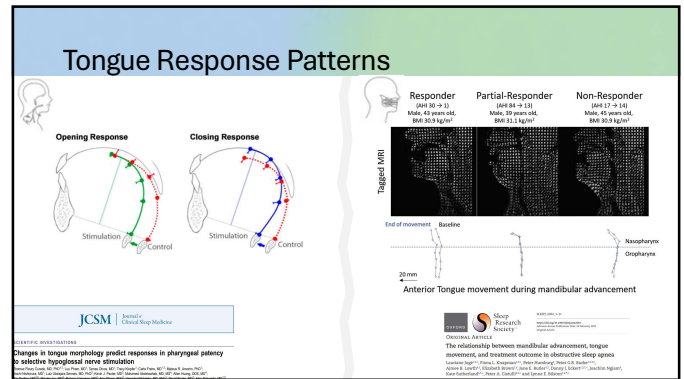
**TMJ/Extraoral Exam:**  
No pain or tenderness was observed upon instructed jaw movements. No pain on palpation of the lateral poles and retrodiscal tissues of the TMJs, or upon palpation of the submandibular, cervical, temporalis or masseter musculature.

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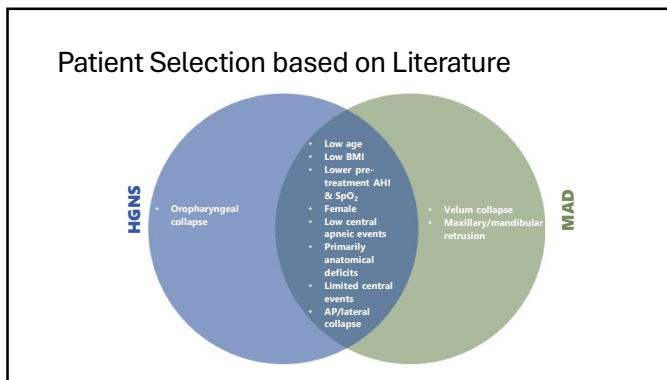




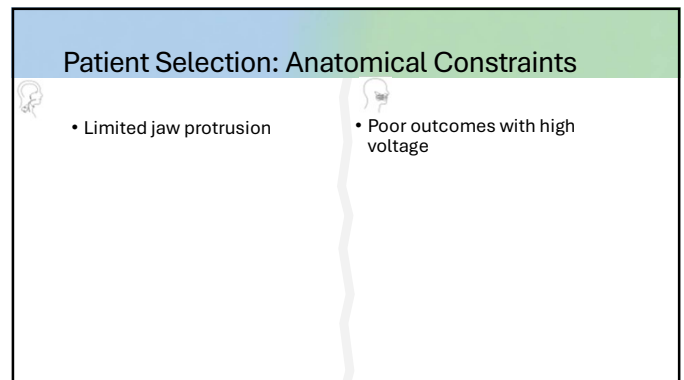
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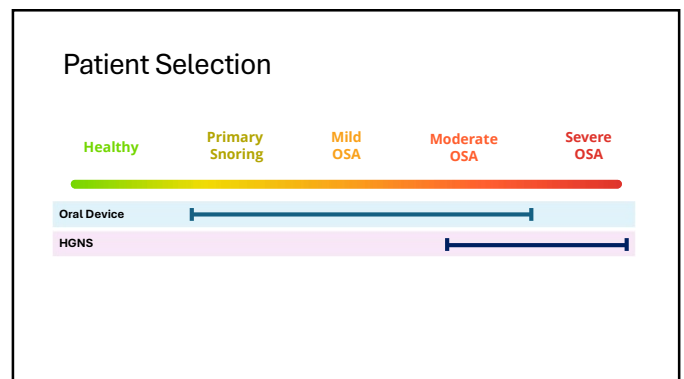
### Patient Selection\*

|                       | HGNS                                             | OAT                                       |
|-----------------------|--------------------------------------------------|-------------------------------------------|
| <b>Age</b>            | 18 years or older<br>Down syndrome starting 13yo | 18 years or older<br>Some starting at 6yo |
| <b>PAP experience</b> | Required                                         | Sometimes required for severe OSA         |
| <b>AHI</b>            | 15-100                                           | 5-30 without PAP experience*              |
| <b>BMI</b>            | Up to 40kg/m²                                    | None                                      |

No tongue malformations, low tonsil size

\*Based on general information, insurance guidelines, AASM/AADSM joint guidelines

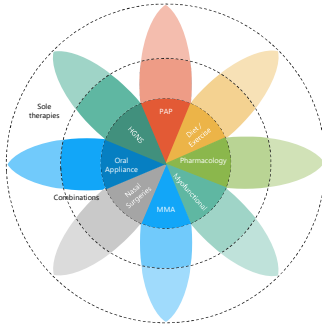
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## Summary

- Why combine therapies?
- Does the combination improve outcomes?

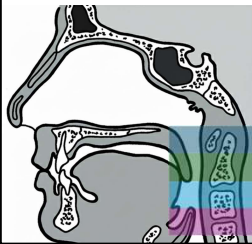


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## Case 2: Combination Therapy

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### Case 2: Combination HNS +OA

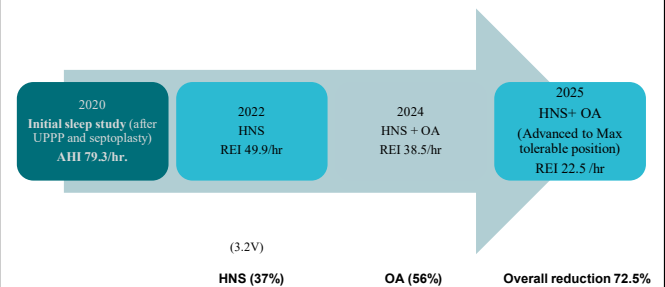


- A case study reviewing one OSA patient in Virginia Commonwealth University Dental Care Faculty Practice. Initial consultation revealed failed CPAP therapy and only partial response to HNS.
- Prior to HNS placement on 10/27/20, the patient underwent UPPP and septoplasty but was diagnosed with severe OSA. Discharge was performed on 9/22/20.
- HNS (3.2V) combined with a chin-strap was also attempted and showed no improvement beyond HNS use alone (AHI 49.9 from baseline 79.3).
- Therefore, a combination treatment was prescribed using a novel distal extension design to achieve HNS+OA therapy.

|            |                             |
|------------|-----------------------------|
| Velum      | Partial lateral collapse    |
| Oropharynx | No collapse                 |
| Tongue     | Anterior-posterior collapse |
| Epiglottis | No independent collapse     |

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### Combination: HNS +OA



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## Case 3: Combination Therapy

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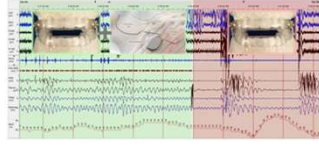
### Case 3

- 62 yo male
- Maxillary edentulous case
- Inspire reduced AHI from 50 to 11.
- Complaints of snoring and bruxism
- Combination Inspire + OAT reduced AHI from 11 to 2 with management of snoring and bruxism.

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### Case 4: Combination Therapy (Literature)

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**CASE REPORTS**  
**Severe Obstructive Sleep Apnea Treated with Combination Hypoglossal Nerve Stimulation and Oral Appliance Therapy**  
 Jang J, Lee, MD, Nanda Sahu, MD, Robert Rogers, DMD, DABDENT, Ryan J, Doherty, MD  
 University of Pittsburgh School of Medicine, Pittsburgh, PA, UPMC Department of Otolaryngology, Pittsburgh, PA, Pittsburgh Dental Sleep Medicine, Westbury, PA

**Case 4**

- 75 yo male
- Inspire reduced AHI from 43.7 to 11.6.
- 1 year follow up and snoring is persistent and bothersome
- Combination therapy reduced to 3.5 AHI and subsequently reduced Inspire amplitude (1.3V to 0.8V)

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### Case 5: Combination Therapy (Case Series)

45

#### Patient Selection – HNS + OAT Combination Case Series

Singh S, Richardson SE, Glick 2024

| PATIENT | AGE | AHI | CPAP  | REASON FOR ORAL APPLIANCE                       | ORAL CAVITY FINDINGS                                                                         | VELUM | OROPHARYNX, LATERAL WALLS | TONGUE BASE | EPIGLOTTIS | SUCCESS WITH COMBINATION THERAPY (AHI)      |
|---------|-----|-----|-------|-------------------------------------------------|----------------------------------------------------------------------------------------------|-------|---------------------------|-------------|------------|---------------------------------------------|
| 1       | 59  | 30  | 14    | Snoring still, Residual AHI, abrasion of tongue | No broken teeth, crowns/fillings present, tori, occlusal wear                                | AP    |                           | AP          | AP         | Resolved snoring, Residual AHI of 6         |
| 2       | 55  | 16  | 15-20 | Abrasion of tongue                              | Anterior broken tooth, crowns/fillings present, occlusal wear                                | AP    |                           | AP          |            | P fine tune study, AHI 5                    |
| 3       | 64  | 45  | 15-20 | Snoring still                                   | No tori, no broken teeth, no crowns, restoration present, evidence of wear on anterior teeth | AP    |                           | AP          |            | Improved snoring with a residual AHI of 6   |
| 4       | 58  | 40  | 12    | Snoring still                                   | Anterior broken teeth, no tori, occlusal wear                                                | AP    |                           | AP          |            | Resolution of snoring and residual AHI of 8 |

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#### Take Home Messages About Combination Therapy

🏠 **Oral appliance therapy device design**

✓ **Stimulation amplitude**

👥 **Workflow for interdisciplinary teams**

👤 **Chief compliant management**

🧰 **Other adjunctive therapies**

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### Case 5: Combination Therapy (OAT Design)

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## Case 5 - Oral appliance therapy device design



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## Considerations with Combination Therapy

- Oral appliance therapy device design
- Stimulation amplitude
- Workflow for interdisciplinary teams
- Chief complaint management
- Other adjunctive therapies

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**?Conclusions:**

-Optimal management of OSA aims to achieve complete disease resolution with minimal side effects and ideally a single treatment modality.



-However, cases involving recalcitrant apnea and hypopnea events, despite initial monodisciplinary treatments, highlight the need to develop techniques and protocols for additional solutions.



-The reported cases suggests combination therapies may be an important avenue for further research toward eliminating clinical symptoms and airway collapse.

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