Pearls and Pitfalls of Hypoglossal Nerve Stimulation

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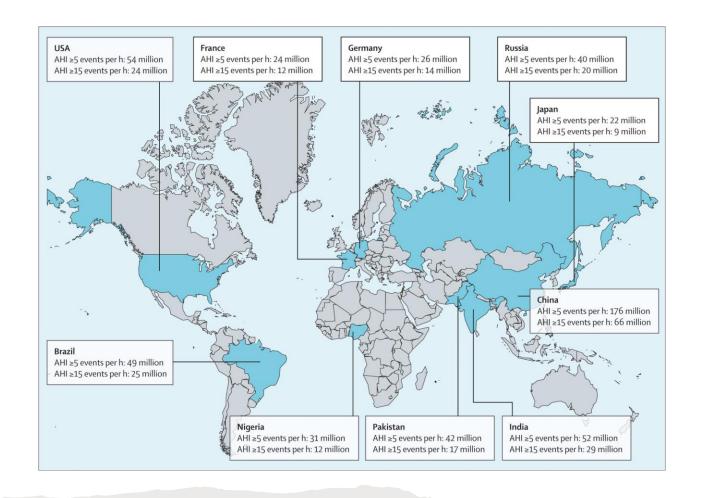
VCU Health

Disclosures

- Inspire Medical Systems Consultant
- Nyxoah Safety monitoring
- Siesta Medical Consultant
- Avivomed Consultant

Topics of Discussion

- Lightning Overview of Hypoglossal Nerve Stimulation
- Patient Selection Pearl DISE Patterns that lead to successful outcomes
- Intraoperative Pearls Nerve anatomy and dissections tips
- Post-operative Pathway Pearls— Programming for comfort and airway opening



Worldwide prevalence of OSA is 1 billion!!

What if CPAP fails?

- 40-60% of patients cannot tolerate or fail CPAP
- No accepted second line treatment for CPAP failures
- What about the other 12.5 million?



HNS Patient Care Pathway

Patient Screening



Endoscopy (DISE) & Inspire Procedure

























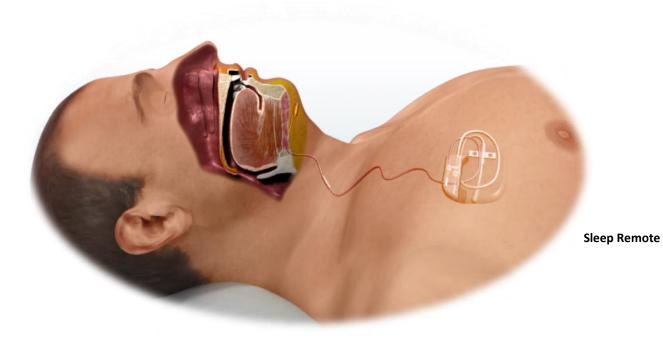
Inspire Programmer



Inspire Cloud

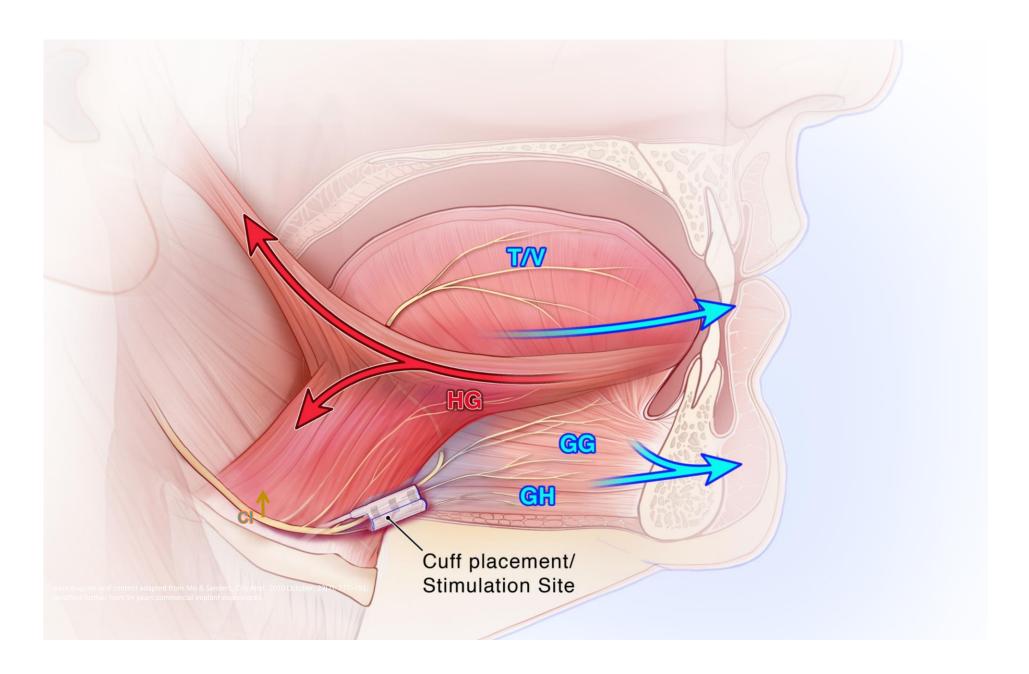
Hypoglossal Nerve Stimulation

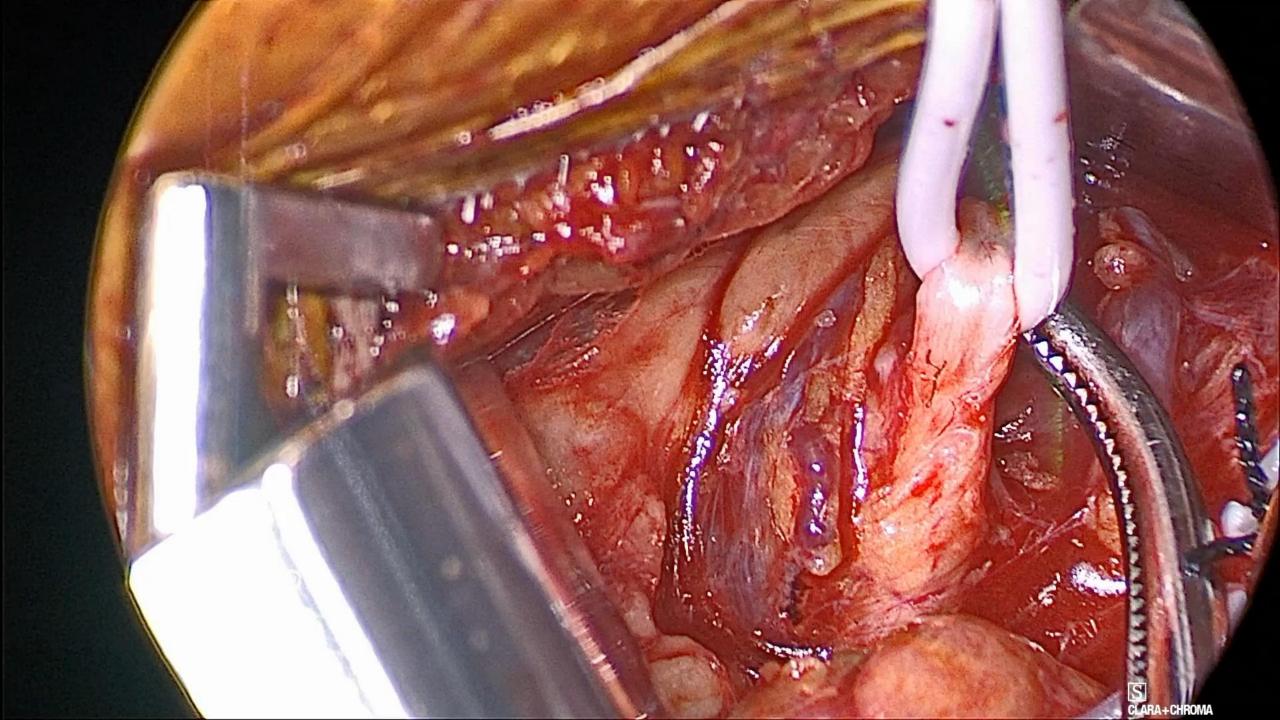
(Adjustable, Titratable, Adherence Monitoring)





- > FDA approved in 2014
- ➤ 2 small incisions
- ➤ 60-90 minute outpatient surgery with minimal downtime





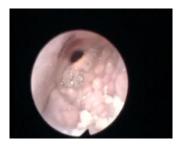


Hypoglossal Nerve Stimulation Effect

No Stimulation



Base of Tongue



Palate

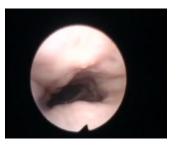
Stimulation On



Base of Tongue



Palate



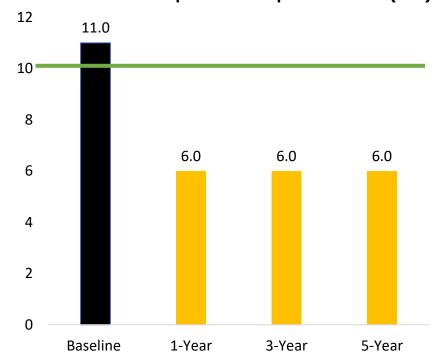


STAR Trial Overview

Apnea Hypopnea Index (AHI)

35.0 29.3 30.0 Median AHI (events/hour) 25.0 20.0 15.0 9.0 10.0 6.0 6.2 5.0 0.0 Baseline 1-Year 3-Year 5-Year

Epworth Sleepiness Scale (ESS)



Strollo et al NEJM 2014; Woodson et al Heise et al ERJ 2019 Pietzsch et Marin; 2018;



ADHERE Registry

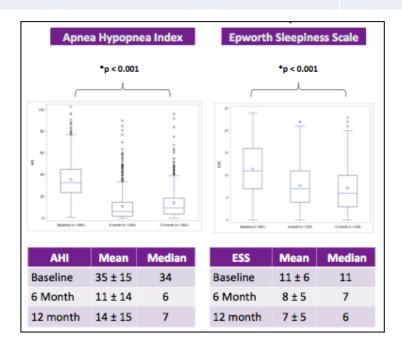
- Age (y): 60 ± 11 (22-86)
- BMI (kg/m2): 29.3 ± 3.9
- Gender: 26% female
- Multivariate analysis: female gender and lower BMI were predictors of therapy success
- Long-term adherence:5.7h/night

Boon M, Huntley C, Steffen A, et al. UAS for OSA: results from the ADHERE registry. *Otolaryngol Head Neck Surg* 2018.

Thaler E, Schwab R, Maurer J, Soose R, et al. Results of the ADHERE UAS registry and predictors of therapy efficacy. *Laryngoscope 2019*

Soose RJ, Boon M, Larsen C, et al. Phenotypic predictors of Long-Term Upper Airway Neurostimulation Responsiveness in the ADHERE International Registry. Abstract AAO-HNS, New Orleans, 2019.

AHI response rate at 12mo		
AHI <5	41%	
AHI <10	65%	
AHI <15	78%	
AHI <20 + >50% reduction	81%	



Hypoglossal Nerve Stimulation is a safe, effective and efficient outpatient procedure to treat OSA BUT who is a good candidate?

Patient Selection — Candidacy Criteria

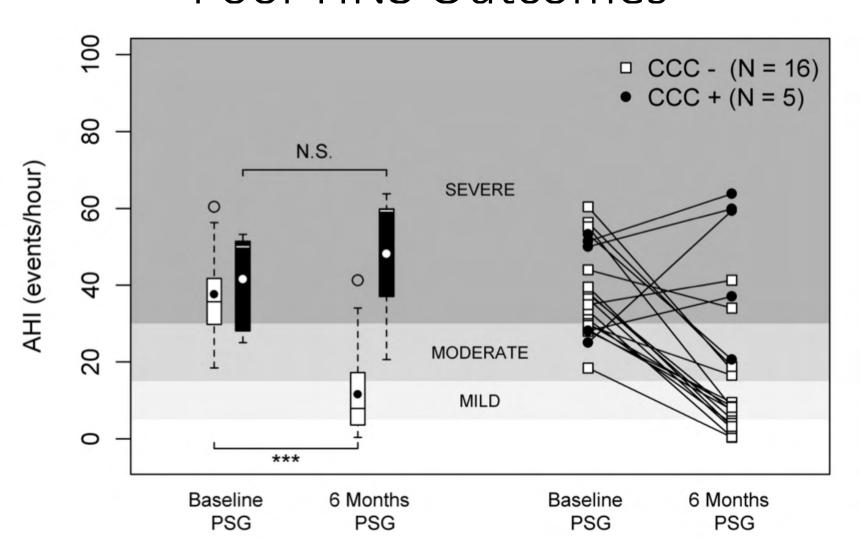
- AHI 15-65 with less than 25% central apneas
- Are unable to use or get consistent benefit from CPAP
- BMI under 32 (up to 35 or even higher possible if medically necessary)
- Age 18+
- No complete concentric collapse on DISE
- UPDATE from the FDA: AHI<100 and BMI<40 BUT payers have not followed suit



Complete Concentric Collapse

Date 16

Complete Concentric Collapse Predicts Poor HNS Outcomes



Vanderveken OM, Maurer JT, Hohenhorst W, et al. Evaluation of drug-induced sleep endoscopy as a patient selection tool for implanted upper airway stimulation for obstructive sleep apnea. J Clin Sleep Med. 2013;9(5):433-438.





Drug-Induced Sleep Endoscopy and Hypoglossal Nerve Stimulation Outcomes: A Multicenter Cohort Study

Phillip Huyett, MD ; David T. Kent, MD; Mark A. D'Agostino, MD ; Katherine K. Green, MD, MS; Ryan J. Soose, MD; Thomas M. Kaffenberger, MD ; B Tucker Woodson, MD ; Colin Huntley, MD ; Maurits S. Boon, MD; Clemens Heiser, MD ; Amelie Birk, MD; Maria V. Suurna, MD ; Ho-Sheng Lin, MD; Jonathan A. Waxman, MD, PhD ; Eric J. Kezirian, MD, MPH ;

TABLE VI.
Surgical Response (≥50% Decrease in Apnea-Hypopnea Index to <15 Events/Hour) on tPSG and Association With DISE Findings.

None vs. partial vs. complete Complete vs. partial/none	19 (79.2%) vs. 116 (68.6%) vs. 114 (76.0%)	.29
Complete vs. partial/none		.23
	114 (76.0%) vs. 135 (69.9%)	.22
Complete vs. partial*	114 (76.0%) vs. 116 (68.6%)	.17
Any vs. none	230 (72.1%) vs. 19 (79.2%)	.64
Complete vs. none	114 (78.0%) vs. 19 (79.2%)	1.00
Complete concentric collapse: presence vs. absence	8 (57.6%) vs. 241 (73.0%)	.22
None vs. partial vs. complete	163 (74.1%) vs. 67 (74.4%) vs. 19 (57.6%)	.13
Complete vs. partial/none	19 (57.8%) vs. 230 (74.2%	.042
Any vs. none	86 (69.9%) vs. 163 (74.1%)	.41
Complete vs. none	19 (57.8%) vs. 163 (74.1%)	.049
None vs. partial vs. complete	48 (64.9%) vs. 86 (70.5%) vs. 115 (78.2%)	.09
Complete vs. partial/none	115 (78.2%) vs. 134 (68.4%)	.043
Any vs. none	201 (74.7%) vs. 48 (64.9%)	.09
Complete vs. none	115 (78.2%) vs. 48 (64.9%)	.033
None vs. partial vs. complete	216 (73.5%) vs. 24 (72.7%) vs. 9 (56.3%)	.32
Complete vs. partial/none	9 (56.3%) vs. 240 (73.4%)	.13
Any vs. none	33 (67.3%) vs. 216 (73.5%)	.37
Complete vs. none	9 (56.3%) vs. 216 (73.5%)	.13
	Any vs. none Complete vs. none Complete concentric collapse: presence vs. absence None vs. partial vs. complete Complete vs. partial/none Any vs. none Complete vs. none None vs. partial vs. complete Complete vs. partial/none Any vs. none Complete vs. partial/none Any vs. none Complete vs. none None vs. partial vs. complete Complete vs. partial/none Any vs. none	Any vs. none 230 (72.1%) vs. 19 (79.2%) Complete vs. none 114 (78.0%) vs. 19 (79.2%) Complete concentric collapse: presence vs. absence 8 (57.6%) vs. 241 (73.0%) None vs. partial vs. complete 163 (74.1%) vs. 67 (74.4%) vs. 19 (57.6%) Complete vs. partial/none 19 (57.8%) vs. 230 (74.2%) Any vs. none 86 (69.9%) vs. 163 (74.1%) Complete vs. none 19 (57.8%) vs. 163 (74.1%) None vs. partial vs. complete 48 (64.9%) vs. 86 (70.5%) vs. 115 (78.2%) Complete vs. partial/none 115 (78.2%) vs. 134 (68.4%) Any vs. none 201 (74.7%) vs. 48 (64.9%) Complete vs. none 115 (78.2%) vs. 48 (64.9%) Complete vs. partial vs. complete 216 (73.5%) vs. 24 (72.7%) vs. 9 (56.3%) Complete vs. partial/none 9 (56.3%) vs. 240 (73.4%) Any vs. none 33 (67.3%) vs. 216 (73.5%)

Should lateral wall collapse be a contraindication for hypoglossal nerve stimulation?**,**

Ryan S. Nord a,*, Thomas Fitzpatrick IV a, Graham Pingree b, Albina Islam a, Andrew Chafin b

Table 2Treatment response.

Lateral wall	Overall	Complete	Partial	None	
collapse					
Post-Op AHI	10.44 \pm	12.06 \pm	8.51 \pm	10.03 \pm	
	12.82	13.86	9.38	13.99	
Post-Op ESS	6.3 ± 4.7	6.6 ± 4.8	$\textbf{7.3} \pm \textbf{5.0}$	$\textbf{5.2} \pm \textbf{4.1}$	
Voltage (V)	1.85 ± 0.65	1.88 ± 0.73	1.89 \pm	1.78 ± 0.62	
			0.57		
Alt configuration	22.52 %	17.78 % (8)	23.33 % (7)	27.78 %	
	(25)			(10)	
Awake endoscopy	32.53 %	40.00 % (18)	20.00 % (6)	30.56 %	
	(35)			(11)	
Adherence (h)	$\textbf{6.42} \pm \textbf{2.07}$	6.30 ± 2.04	6.71 \pm	6.32 ± 2.30	
			1.82		
Surgical success	77.47 %	66.67 % (30)	90.00 %	80.56 %	
	(86)		(27)	(29)	

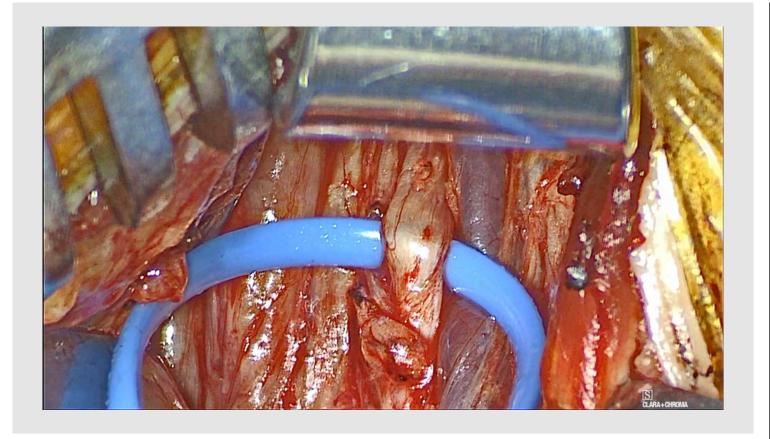
PEARL: Patients with tongue base collapse and without complete lateral wall collapse do best

Nord RS, Fitzpatrick T, Pingree G, Islam A, Chafin A. Should lateral wall collapse be a contraindication for hypoglossal nerve stimulation? Am J Otolaryngol. 2023;45(1):104053.

A pre-operative DISE exam is essential to rule out CCC however, complete lateral wall collapse is also an important factor.

5 Pearls to Optimize Nerve Dissection

- 1. Avoid the nerve to the mylohyoid and the lingual nerve
- 2. Efficient dissection by using venous landmarks
- 3. Divide crossing venous branches
- 4. Locate the free edge of the hyoglossus
- 5. Test tongue motion using bipolar and unipolar settings



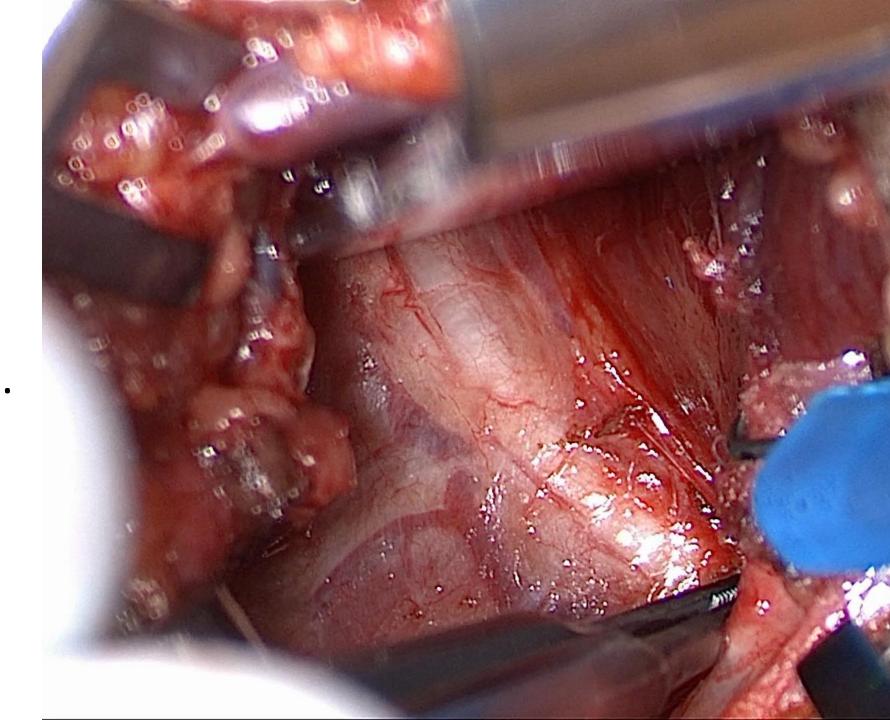
- May be ptotic in older individuals
- No stim on NIM

Lingual Nerve



Breakpoint

 Before doing any dissection, try to estimate location of the breakpoint.

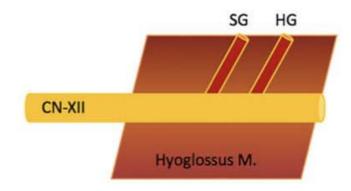


Crossing branch of the Ranine Vein

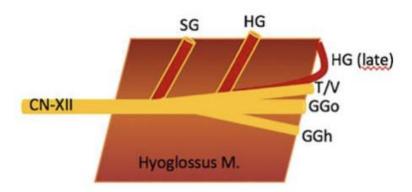


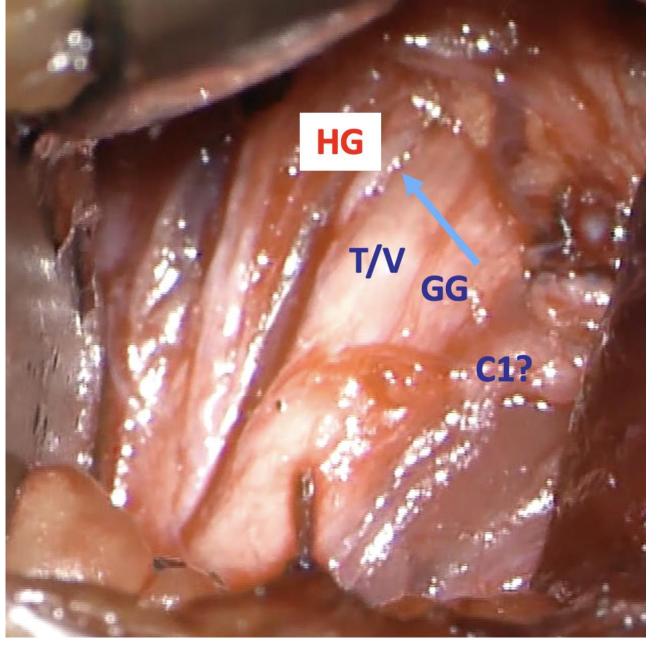
 Ligate any branch of the Ranine vein that crosses the nerve to improve visualization and confidence in dissection

type 1: 33%

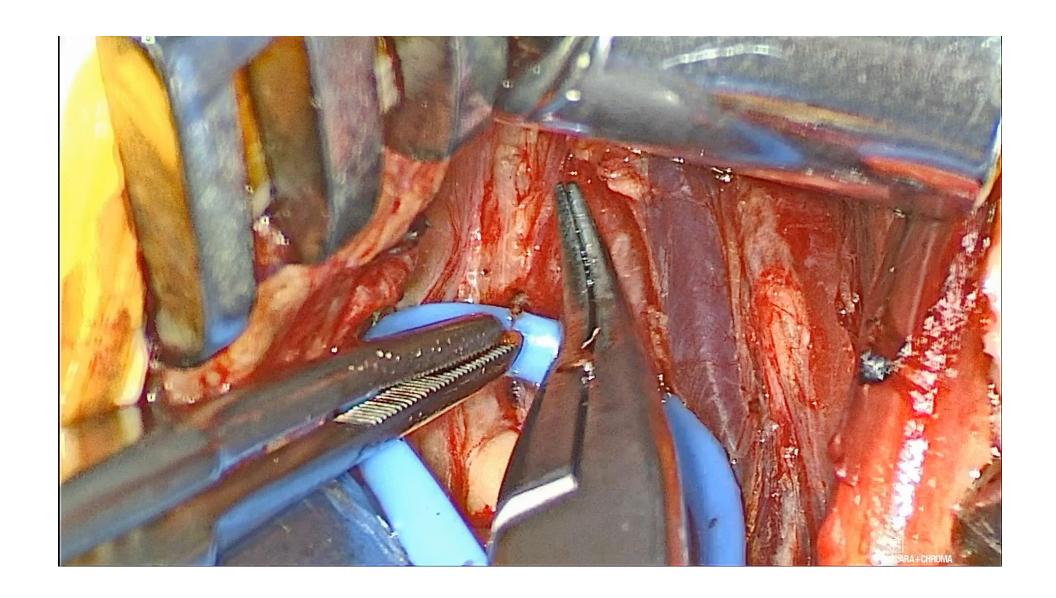


type 2: 67%

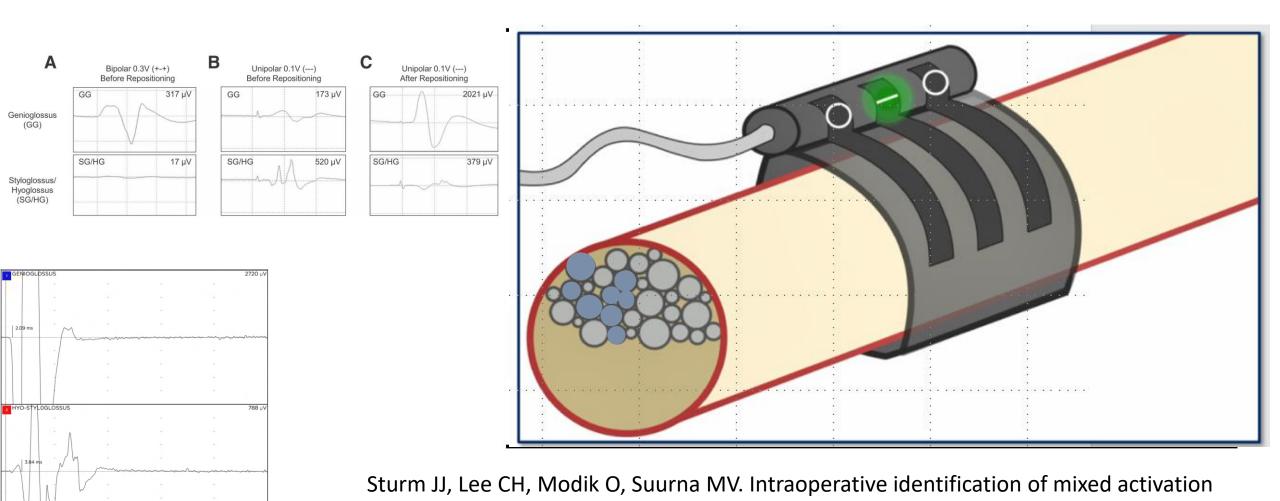




Heiser C, Knopf A, Hofauer B. Surgical anatomy of the hypoglossal nerve: A new classification system for selective upper airway stimulation. *Head Neck*. 2017;39(12):2371-2380.



Check bipolar AND unipolar settings



profiles during hypoglossal nerve stimulation. J Clin Sleep Med. 2020;16(10):1769-1774.

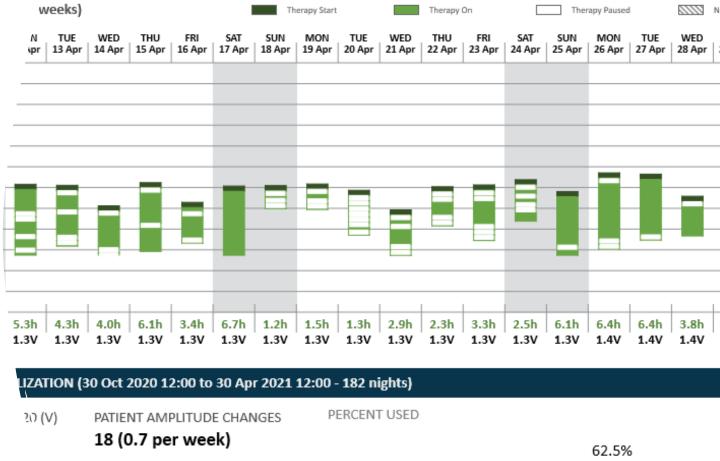
Achieve Success in the Care Pathway

- Achieve comfort
- Find the best tongue motion
- Find the best palate motion

3.2 hours

Case #1

 Patient has advanced to level 10 but finds stimulation wakes him up at night and is uncomfortable



INCOMING PATIENT CONTROL (V) 1.1 - 2.0

13.7% 12.4%

< 1.3 AMPLITUDE (V)



Improved tolerance with decreased voltage

UTILIZATION SUMMARY (30 Apr 2021 12:00 to 19 May 2021 12:00 - 19 nights)

NIGHTS USED

HOURS PER NIGHT USED

THERAPY PAUSES

18 of 19 (95%)

5.8 hours

1.2 per night

NIGHTS USED >= 4 HOURS

16 of 19 (84%)



PATIENT AMPLITUDE UTILIZATION (30 Apr 2021 12:00 to 19 May 2021 12:00 - 19 nights)

AMPLITUDE ON 30 Apr 2021 (V)

1.5

4 (1.5 per week)

INCOMING AMPLITUDE (V)

1.0

PATIENT AMPLITUDE CHANGES

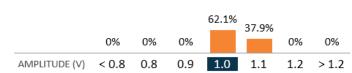
4 (1.5 per week)

PERCENT USED

AMPLITUDE (V)

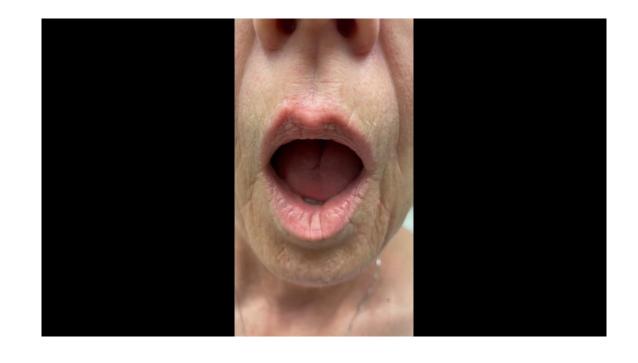
AMPLITUDE (V)

AMPLITUDE (V)



Patient returns after nontherapeutic study

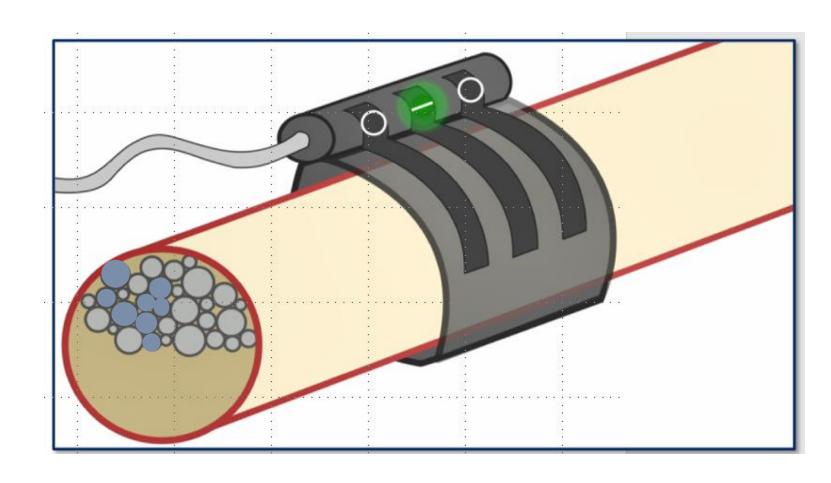
Bipolar (+-+)



AHI 20.8

Changing the Electrode Configuration can improve comfort and efficacy

• Changing the electrode configuration can result in improved tongue motion.



Tongue Motion with Electrode Change



Unipolar (o-o)

AHI 2.5

Retraction on all settings

- 60 y/o man comes from outside physician as a consult to help troubleshoot his inspire device.
- Underwent uncomplicated implant approximately 1 year ago and despite multiple setting changes and awake endoscopy, an acceptable tongue motion phenotype was unable to be identified on any setting.



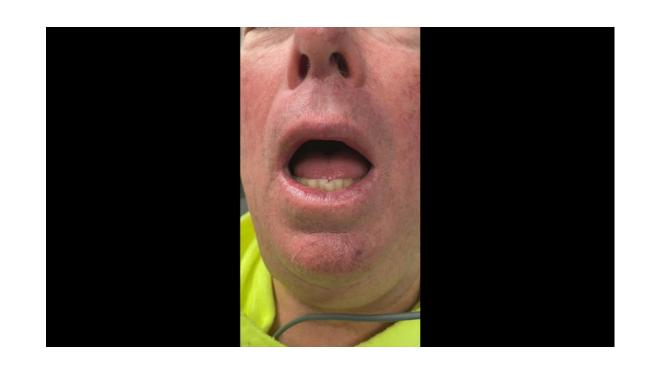
Revision

- Place loop under cuff and remove cuff
- Divided two branches or Ranine vein as I worked more distally on the nerve
- Found clear exclusion branch



Pre-op: AHI 46.5

Post-op: AHI 1.7 (full night)



Awake Endoscopy to find the best palate opening

- If the tongue motion does not provide an answer, look at the palate.
- Cycle through voltages, electrode configurations, neck positions etc to find the optimal settings.



Conclusions

- Hypoglossal nerve stimulation is an effective treatment for moderate to severe OSA after CPAP failure or intolerance
- Patient selection is key to success tongue base collapse without complete lateral wall collapse
- Knowledge of the relevant nerve anatomy allows a successful outcome
- Simple office-based adjustments can often help the struggling patient

Thank you! 404-434-0257 / ryan.nord@vcuhealth.org



