SURGICAL MANAGEMENT OF OSA

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DISCLOSURES

- OSUWMC is a participating center in ADHERE registry
- I am a consultant for Inspire medical
  - Physician advisory council
  - Key opinion leader
  - Creating educational content for physicians
  - Creating clinical practice guidelines
  - Assisting in Japan launch

OBJECTIVES

- To understand the implications of untreated OSA
- To understand the role of traditional surgical options
- To understand the role of hypoglossal nerve stimulation

The posthumous papers of the Pickwick club

Joe the “fat boy”

Pickwickian syndrome

- Described in 1956 by Dr Burwell
- Case report
  - “Extreme obesity associated with alveolar hypoventilation: a Pickwickian Syndrome”
- AKA obesity hypoventilation syndrome

- 1965- OSA described independently by French and German scientists
- 1972- Landmark symposium organized by Sadoul and Lugaresi
- 1972- PSG developed at Stanford using cardiac and respiratory sensors
- 1975 American Sleep Disorders Association founded developing and regulating sleep centers
- 1980s- Fujita and Simmons describe UPPP. First CPAP created by Simmons

OSAHS

- Estimated to affect 2-4% of Americans (~10-15 million)
- >2:1 Male:Female ratio
  - 1:1 after menopause
- Progressive disorder that can worsen over time

“SILENT KILLLER”

- 80-90% with moderate to severe OSA are unaware
- Can be associated with the following
  - DM
  - HTN
  - CVA
  - CHF
  - CAD

obesity

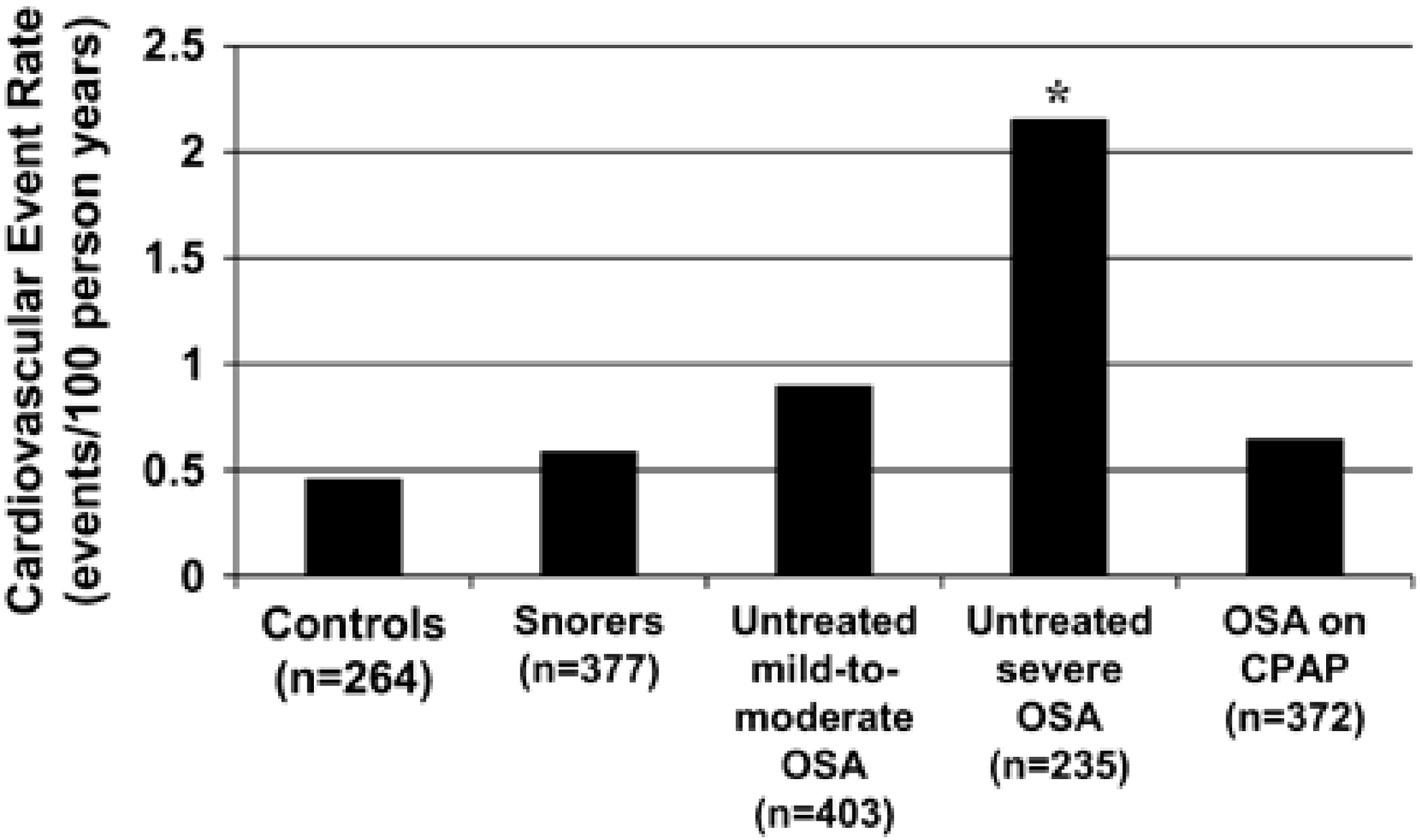
depression

sudden death

increased MVA

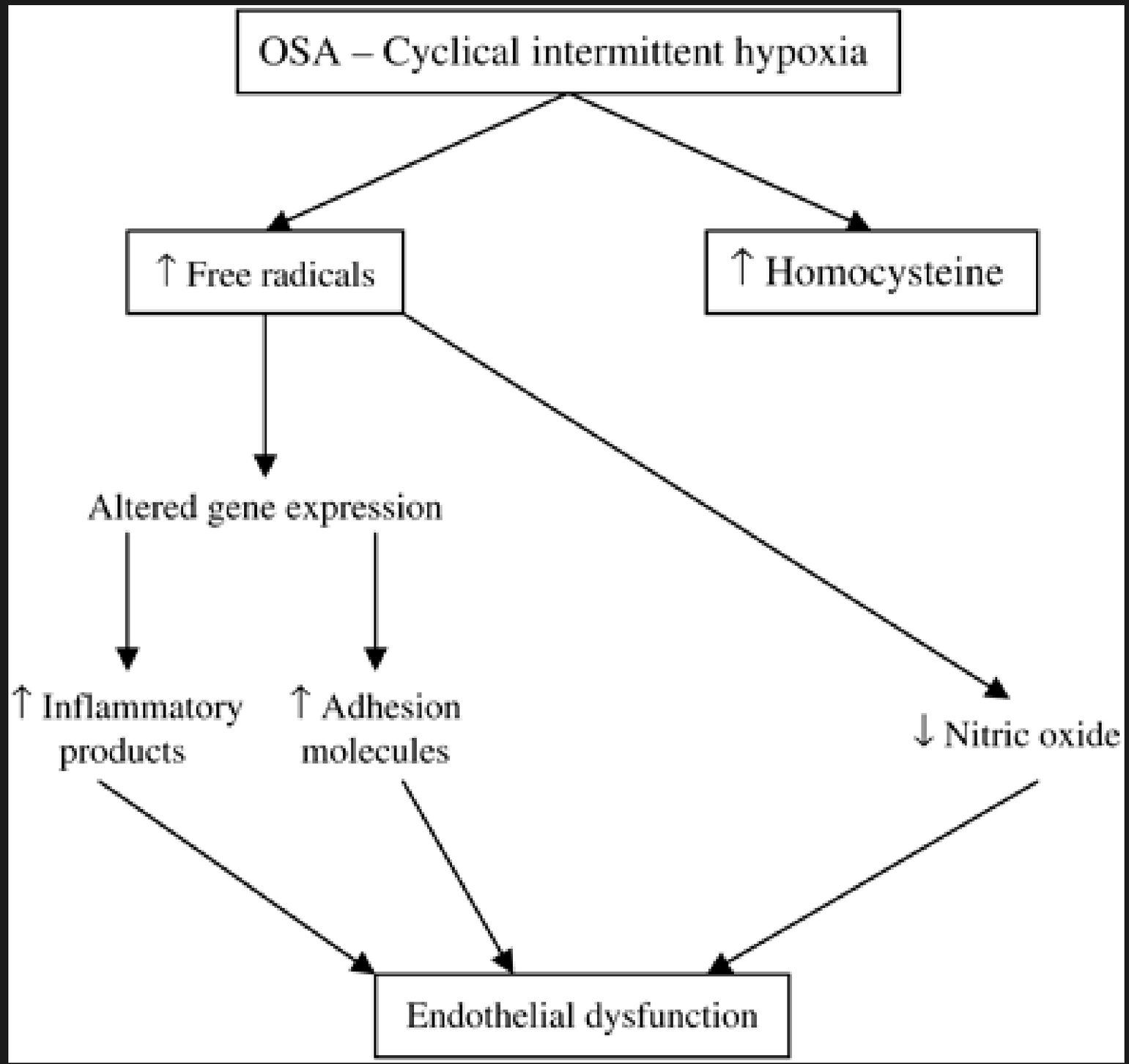
decreased QOL

CV RISKS IN OSA



Pack, AI. Am J Respir Crit Care Med. 2006

CV DAMAGE IN OSA



TREATMENT OPTIONS

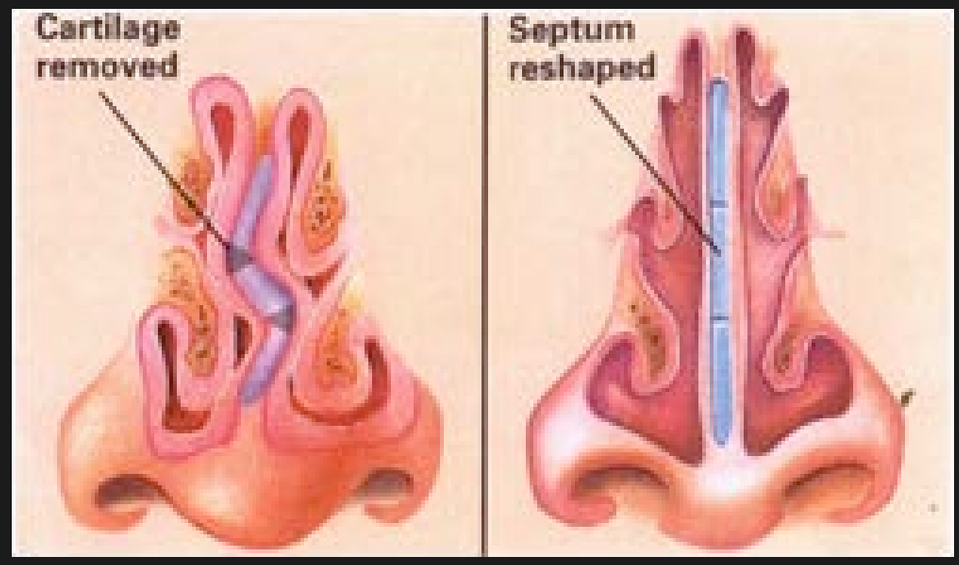
- Positive airway pressure
  - CPAP or BiPAP still considered gold standard
  - Compliance can be a problem
    - 50-60% compliance
- Oral appliance therapy (OAT, MAD)
  - Allows mandible to be positioned in an anterior location
  - Prevents prolapse of tongue and hypopharyngeal airway
  - May not be a good option for TMJ issues or if edentulous

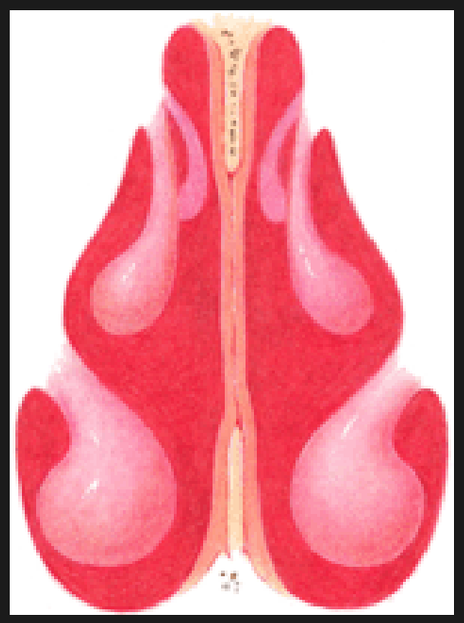
CPAP

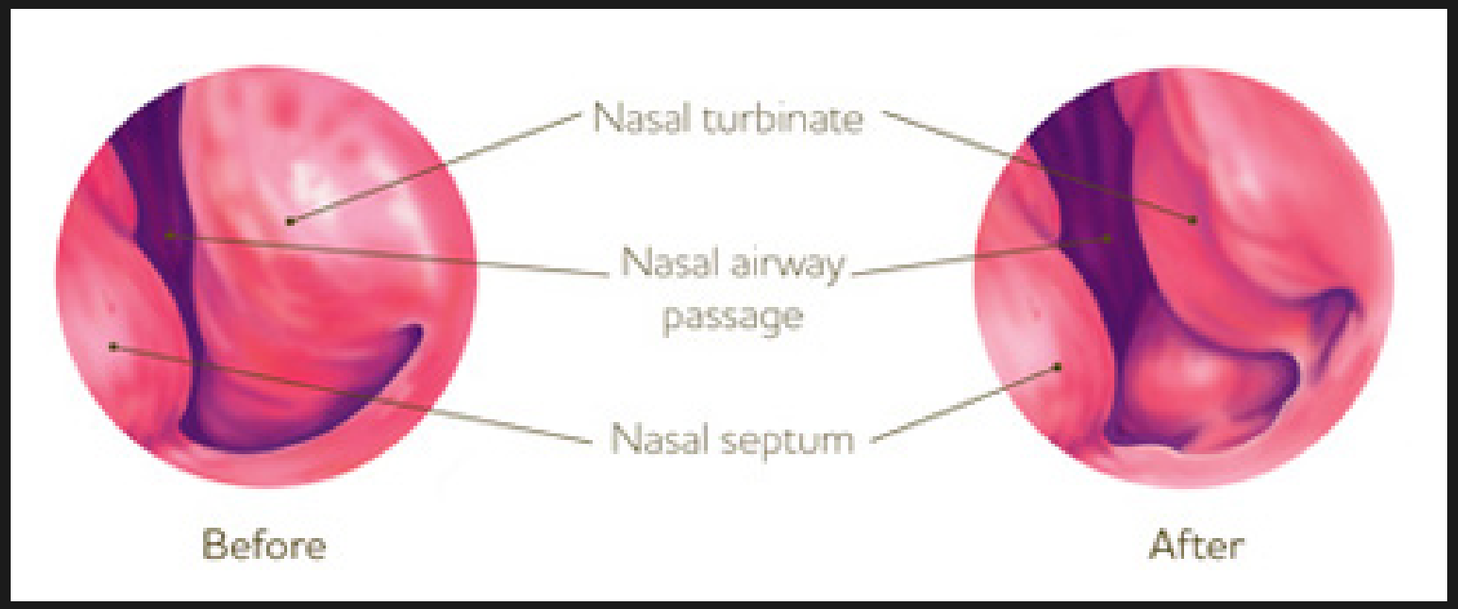
- Surgery to improve CPAP
  - septoplasty, turbinate reduction, adenotonsillectomy
- Upper airway surgery (aka traditional surgical options)
  - nasal, palate, and/or hypopharyngeal surgery
  - “removing or moving tissue”
- Upper airway stimulation (UAS) or hypoglossal nerve stimulation (HNS)
- Maxillomandibular advancement (MMA)
- Non-upper airway surgeries
  - Bariatric surgery
  - Tracheostomy

NASAL SURGERY

- Septoplasty
- Inferior turbinate reduction

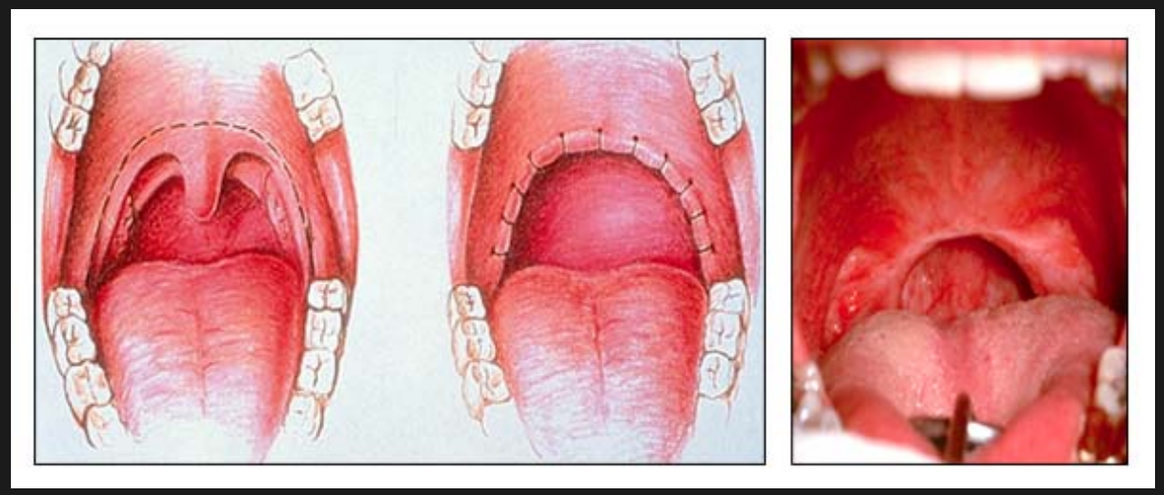


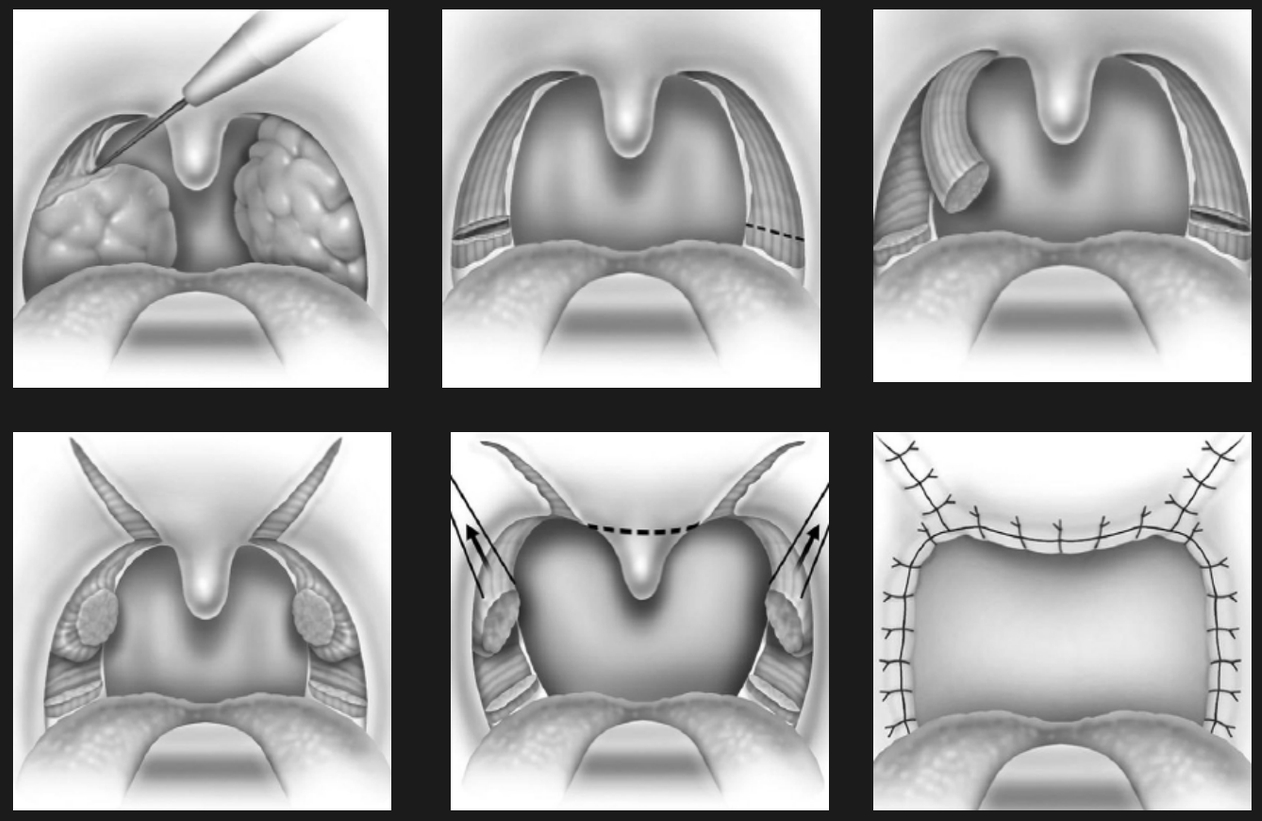




PALATAL SURGERY

- Uvulopalatopharyngoplasty (UPPP or UP3)
- Expansion Sphincter Pharyngoplasty (ESP)

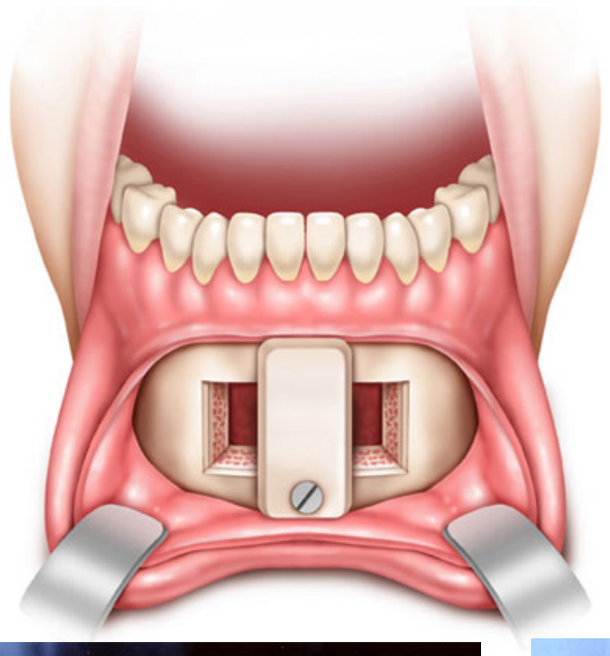


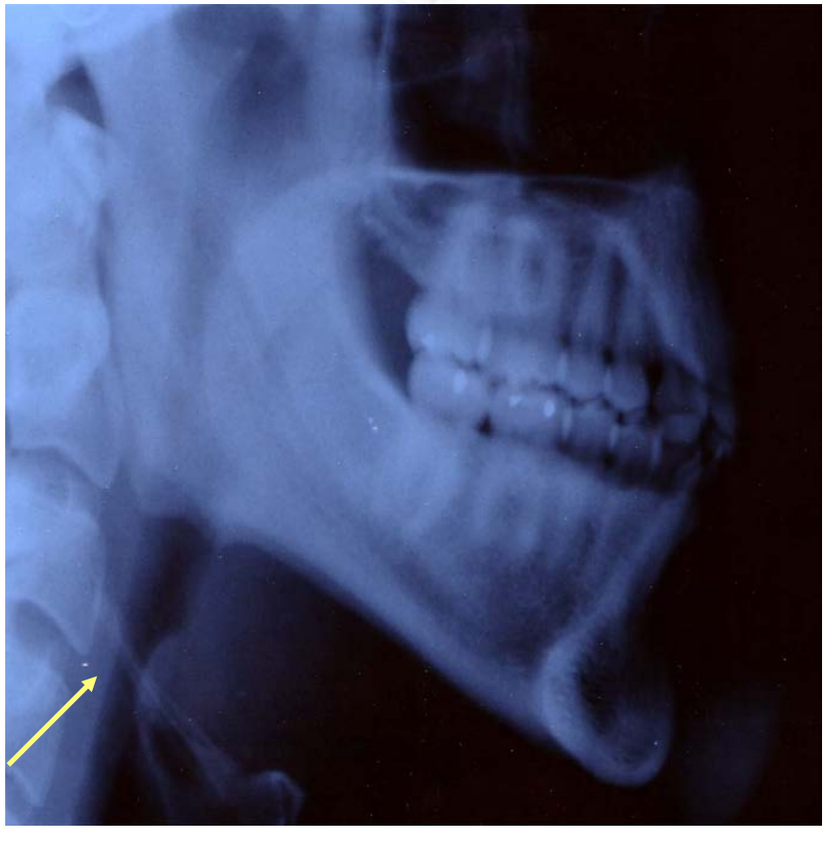


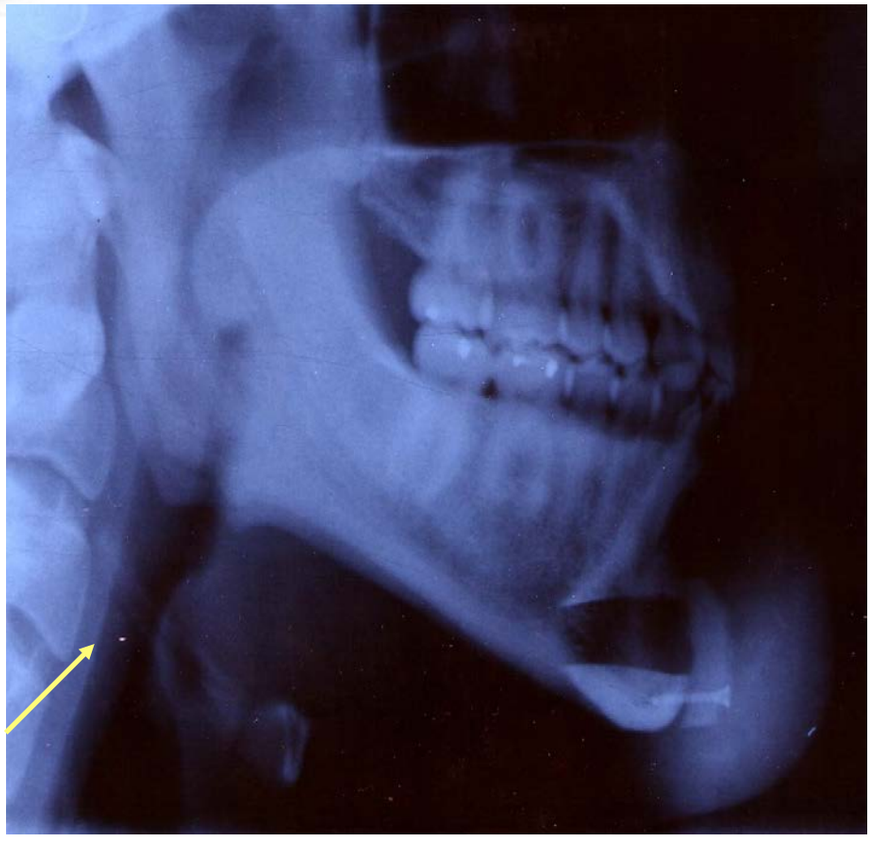
HYPOPHARYNGEAL SURGERIES

- Repositioning Tissue
  - Genioglossal advancement
  - Hyoid and/or tongue base suspension
- Removing/reducing Tissue
  - Radiofrequency ablation
  - Lingual tonsillectomy
  - Midline partial glossectomy

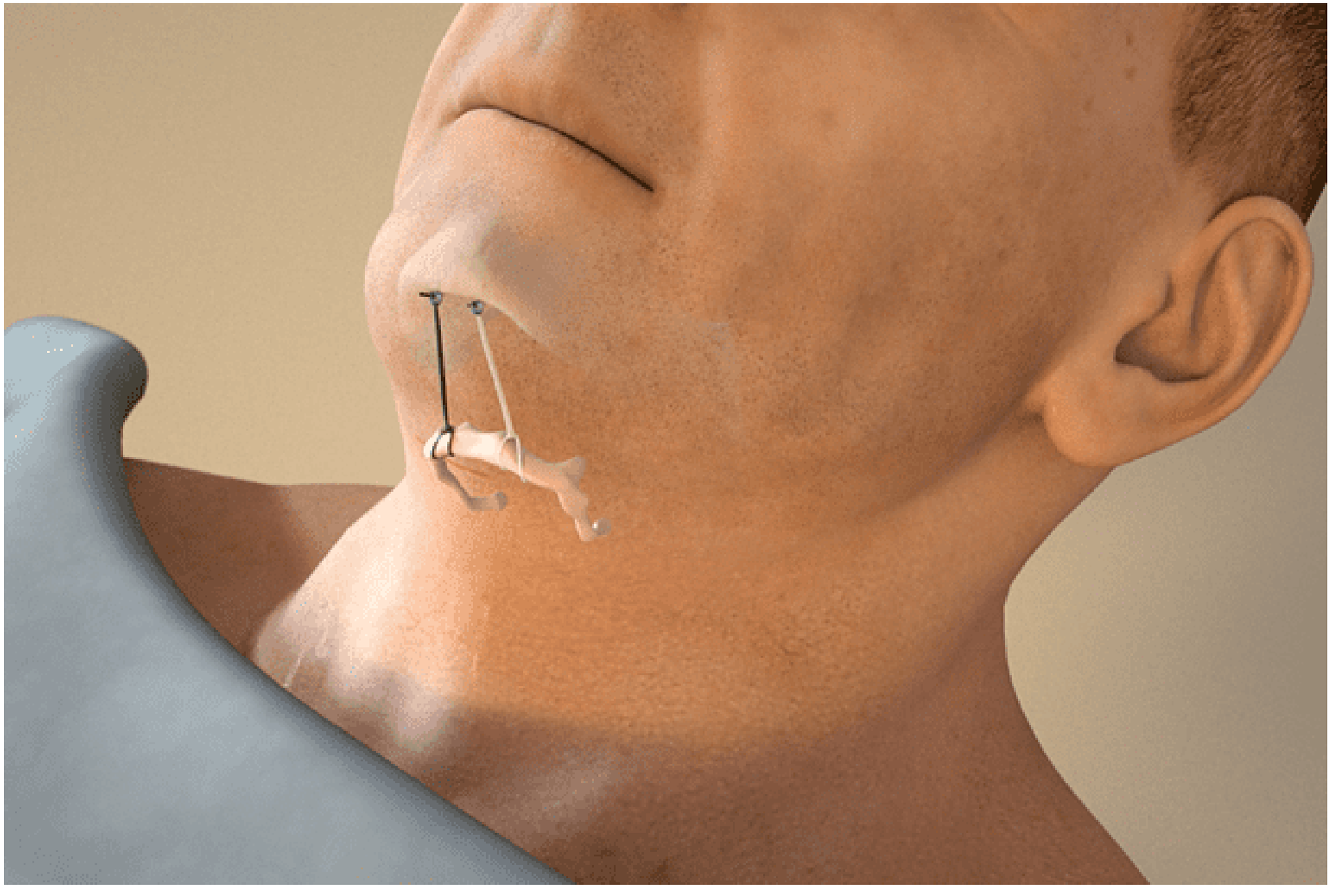
GENIOGLOSSAL ADVANCEMENT







HYOID SUSPENSION



MULTI LEVEL SURGERY

- Meta analysis
- 79 studies for multilevel surgery
- 1978 subjects, mean age 46.2, mean time to post op PSG 7.3mo
- Success rate of 66.4% (Sher criteria)
  - 59.2% after excluding papers on MMA

Lin HC et al. The efficacy of multilevel surgery of the upper airway in adults with obstructive sleep apnea/ hypopnea syndrome. Laryngoscope. 118. May 2008

DISCUSSION

- Multilevel obstruction noted in approx 75%-87%
- Milder disease severity is not necessarily easier to treat
  - 40% success with UPPP alone, despite disease severity
  - 56.5% vs 69.3% surgical success for mild/moderate OSA vs severe OSA

DISCUSSION

- 13.2% (AHI<40) and 6.9% (AHI >40) had worse post op AHI
- Most studies only had short term results <6mo with success rates of 0-100%
- Longest follow up showed 56% improvement at both 1 and 8.5yrs in 16 pts
- Multilevel approach is clearly better than single level surgery in selected pts.

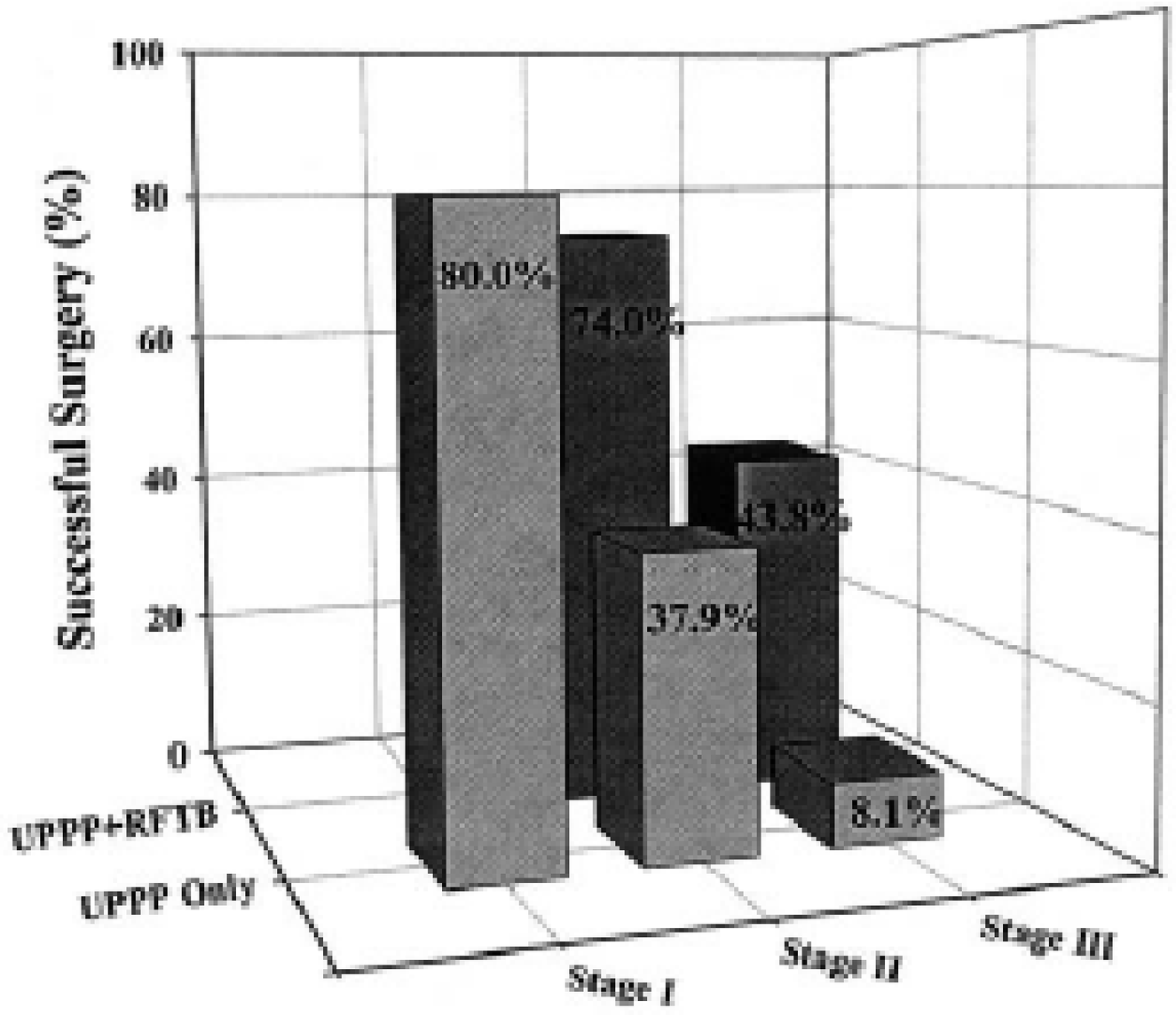
FRIEDMAN CLASSIFICATION

TABLE I.
Modified Friedman Staging System for Patients with Obstructive Sleep Apnea/Hypopnea Syndrome.

	Friedman Palate Position	Tonsil Size	BMI
Stage I	1	3, 4	<40
	2	3, 4	<40
Stage II	1, 2	1, 2	<40
	3, 4	3, 4	<40
Stage III	3	0, 1, 2	<40
	4	0, 1, 2	<40
Stage IV	1, 2, 3, 4	0, 1, 2, 3, 4	>40

All patients with significant craniofacial or other anatomic deformities.

FRIEDMAN CLASSIFICATION



UPPER-AIRWAY STIMULATION OF OBSTRUCTIVE SLEEP APNEA

- Landmark paper, NEJM, Jan 2014
- 126 pts enrolled
- Primary outcomes measures: AHI and ODI

OUTCOME

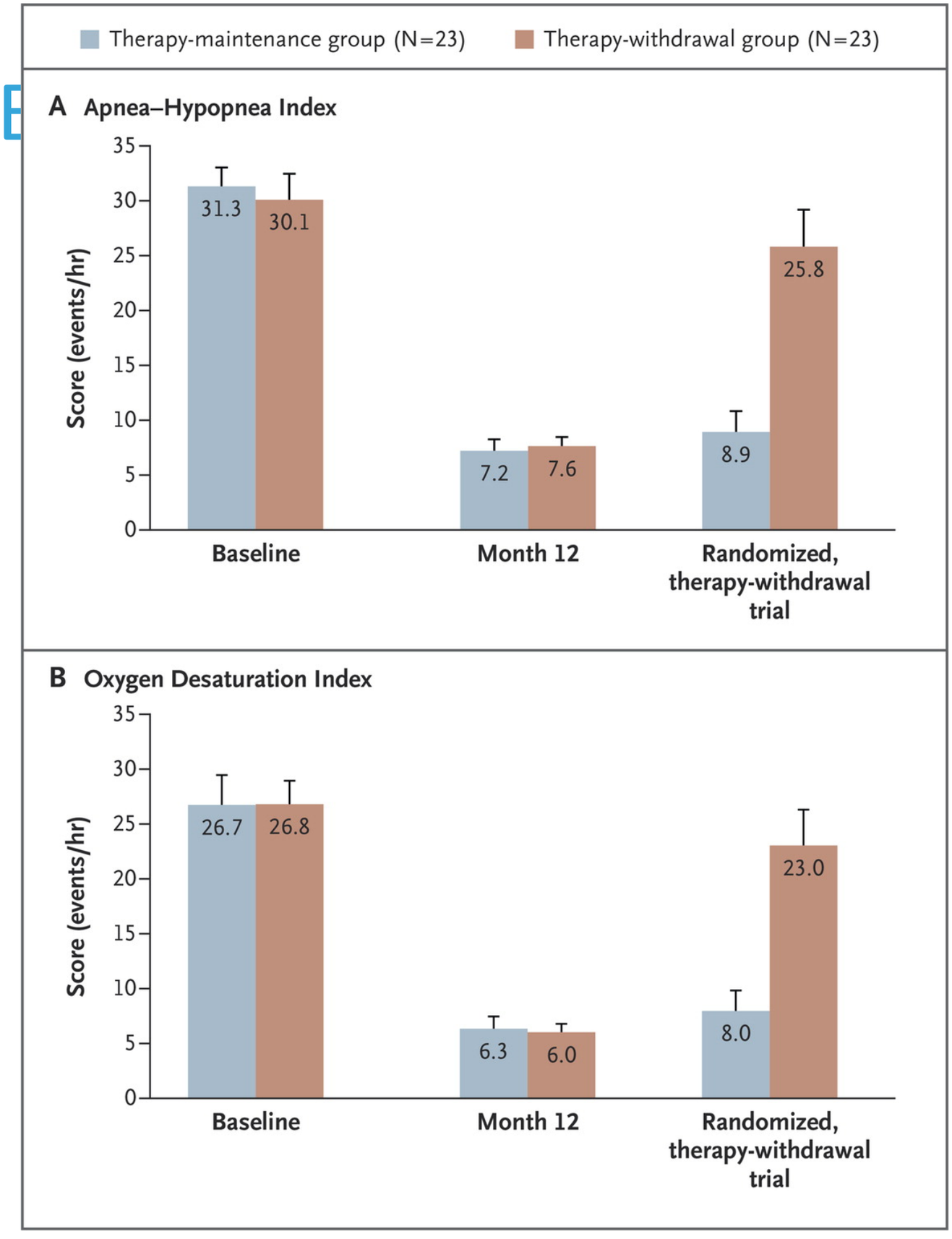

Therapy-maintenance group (N=23)
Therapy-withdrawal group (N=23)
A Apnea–Hypopnea Index
Score (events/hr)
35
30
25
20
15
10
5
0
31.3
30.1
7.2
7.6
8.9
25.8
Baseline
Month 12
Randomized, therapy-withdrawal trial
B Oxygen Desaturation Index
Score (events/hr)
35
30
25
20
15
10
5
0
26.7
26.8
6.3
6.0
8.0
23.0
Baseline
Month 12
Randomized, therapy-withdrawal trial

Table 2. Primary and Secondary Outcome Measures.*

Outcome	Baseline	12 Months	Change	P Value
Primary outcomes				
AHI score†	32.0±11.8	15.3±16.1	−16.4±16.7	<0.001
Median	29.3	9.0	−17.3	
Interquartile range	23.7 to 38.6	4.2 to 22.5	−26.4 to −9.3	
ODI score‡	28.9±12.0	13.9±15.7	−14.6±15.8	<0.001
Median	25.4	7.4	−15.7	
Interquartile range	19.5 to 36.6	3.5 to 20.5	−24.0 to −8.6	
Secondary outcomes				
FOSQ score§	14.3±3.2	17.3±2.9	2.9±3.1	<0.001
Median	14.6	18.2	2.4	
Interquartile range	12.1 to 17.1	16.2 to 19.5	0.7 to 4.7	
Epworth Sleepiness Scale score¶	11.6±5.0	7.0±4.2	−4.7±5.0	<0.001
Median	11.0	6.0	−4.0	
Interquartile range	8.0 to 15.0	4.0 to 10.0	−8.0 to −1.0	
Percentage of sleep time with oxygen saturation <90%	8.7±10.2	5.9±12.4	−2.5±11.1	0.01
Median	5.4	0.9	−2.2	
Interquartile range	2.1 to 10.9	0.2 to 5.2	−6.6 to −0.3	

4 MAIN INCLUSION CRITERIA

- Moderate to severe OSA (AHI 15-65)
- Intolerant of CPAP
- BMI <32kg/m2
- Lack of complete circumferential collapse (CCC) on drug induced sleep endoscopy (DISE)

DISE

- Awake endoscopy/ Mueller maneuver may not be the most accurate way to determine a patient's pattern of collapse during sleep
- DISE is done under propofol sedation to recreate sleep-like conditions
- We want to see apneas/hypopneas develop to determine the area/degree of airway collapse
- Sedation level should be closely titrated as to not artificially induce apneas

VOTE CLASSIFICATION

- V- velopharyngeal collapse
- O- oropharyngeal collapse
- T- tongue base collapse
- E- epiglottis

STRUCTURE	DEGREE OF OBSTRUCTION[a]	CONFIGURATION[c]		
		A-P	LATERAL	CONCENTRIC
Velum				
Oropharynx lateral walls[b]		■		■
Tongue Base			■	■
Epiglottis				■

A-P COLLAPSE VS CCC

- With therapy on there is a protrusion of the tongue base
- Just as important is the palatoglossal coupling effect, leading to dilation of the velopharyngeal airway as well

THERAPY ON VS OFF

No Stimulation

Base of Tongue

Palate

Gentle Stimulation

Base of Tongue

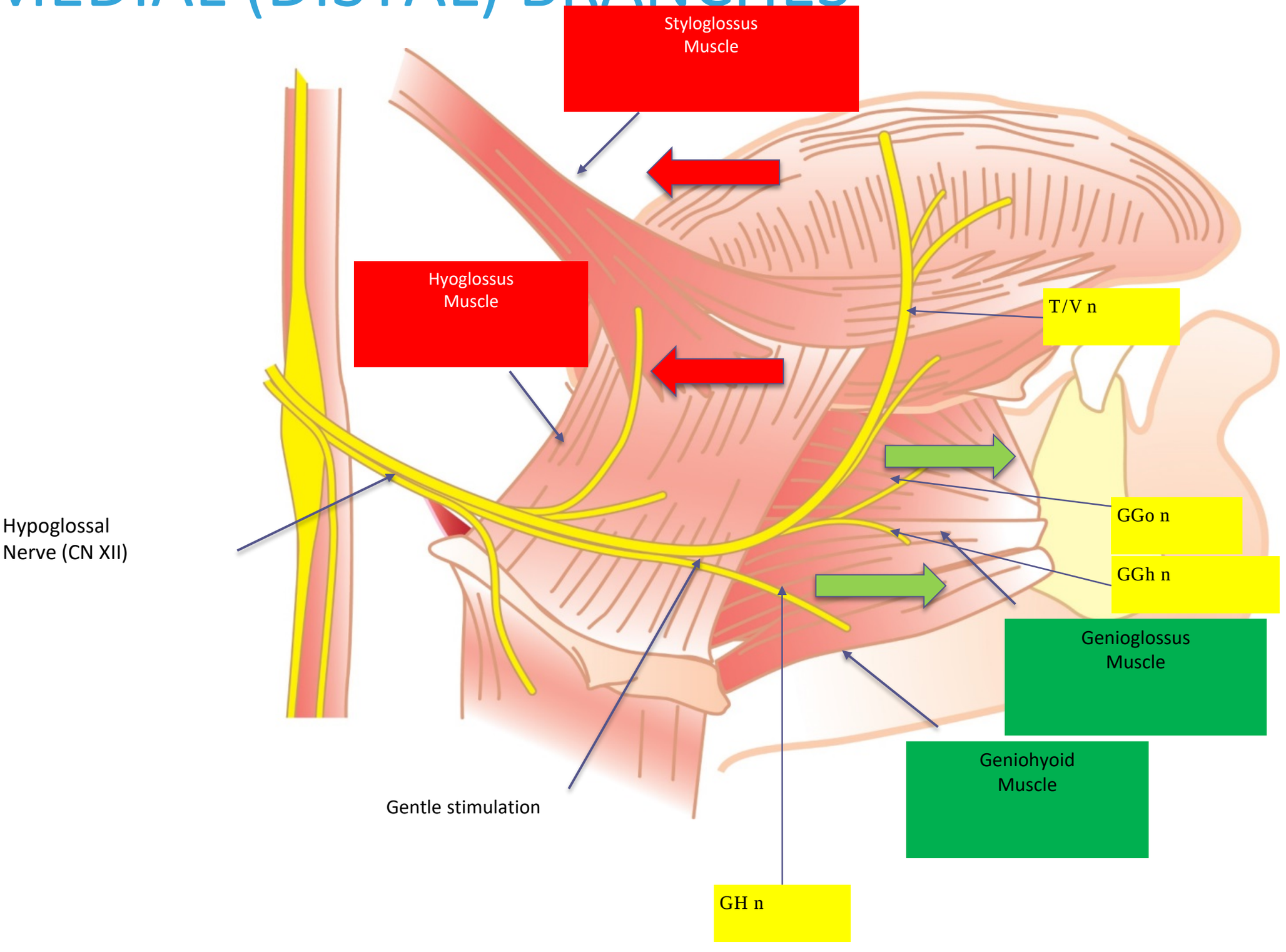
Palate

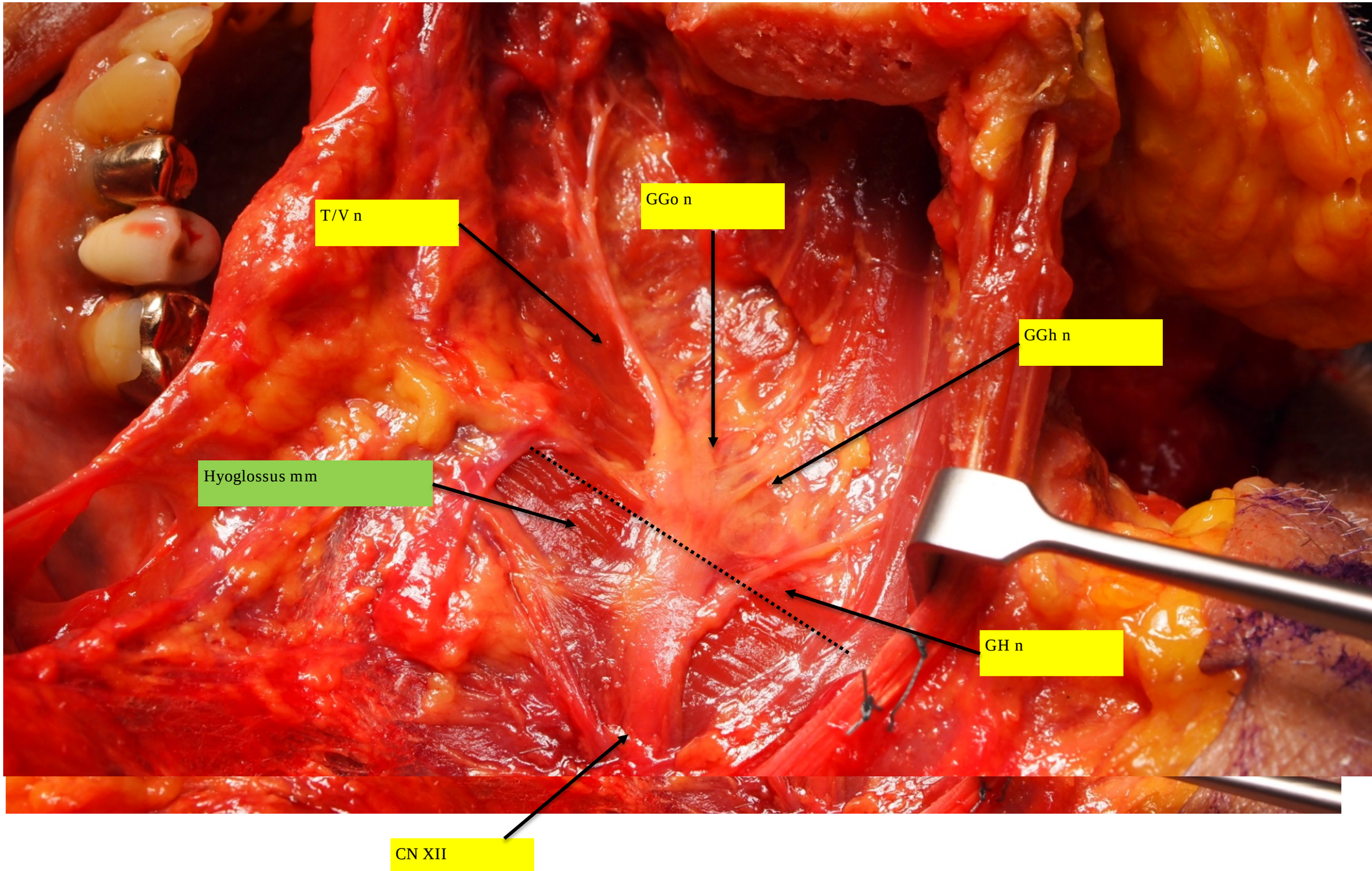
2 INCISIONS

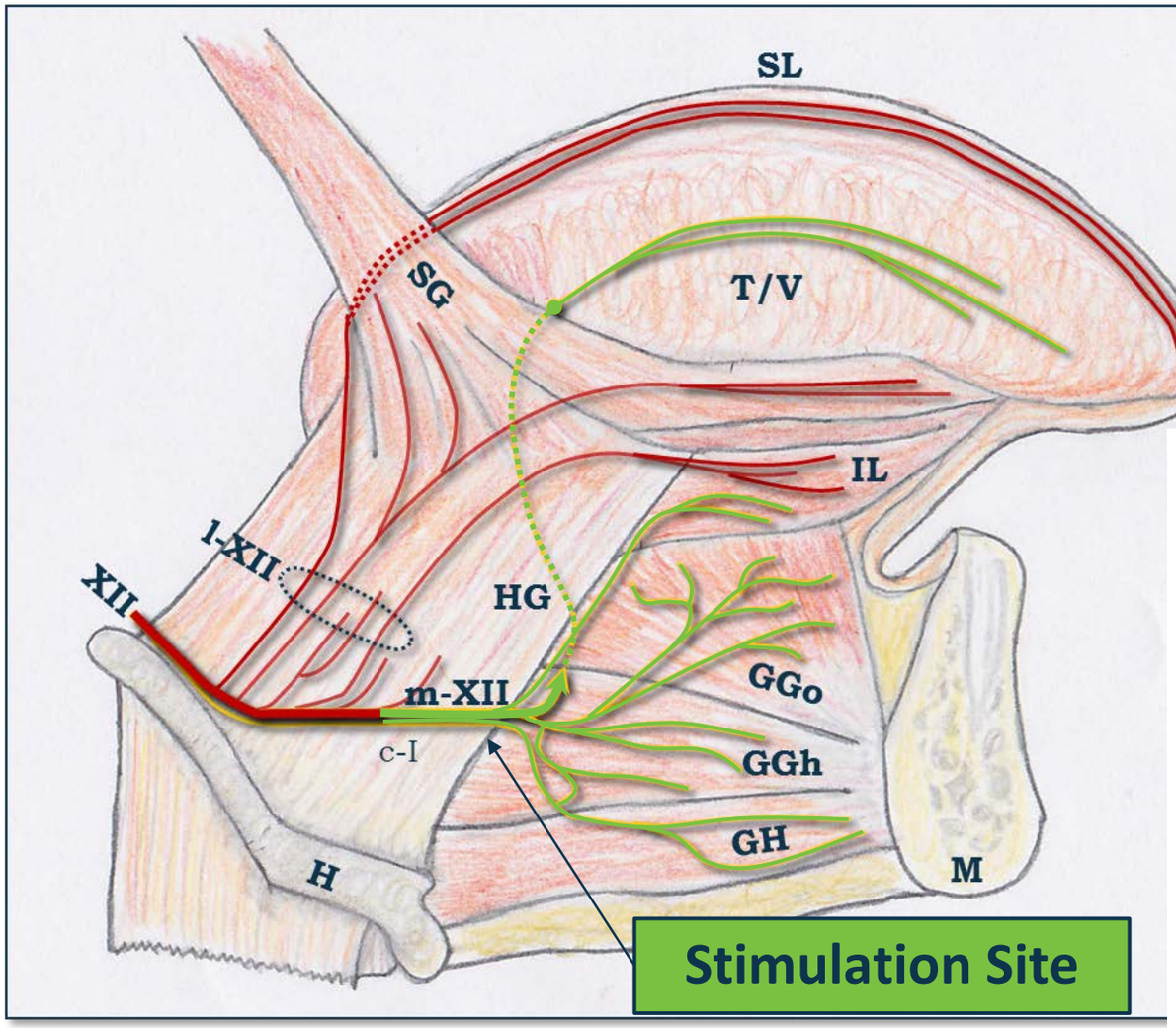
Incision on neck
for stimulation lead

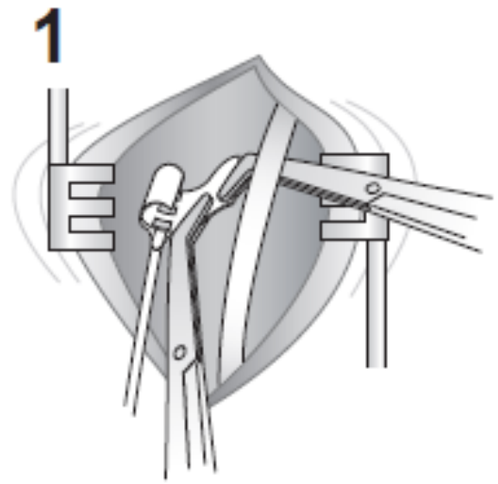
Incision and device under collarbone

“MEDIAL (DISTAL) BRANCHES”




T/V n
GGo n
GGh n
Hyoglossus mm
GH n
CN XII


SL
SG
T/V
IL
1-XII
XII
HG
m-XII
c-I
GGo
GGh
GH
H
M
Stimulation Site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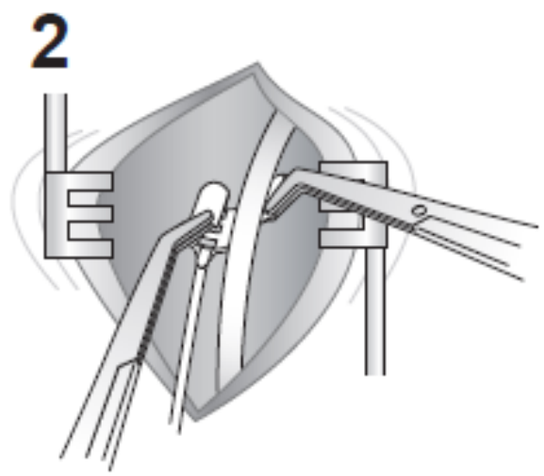
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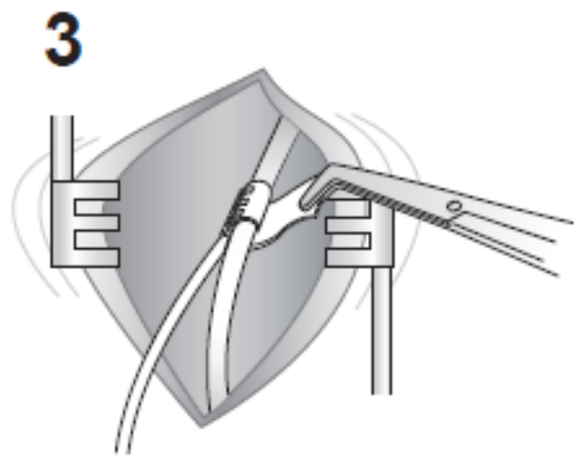
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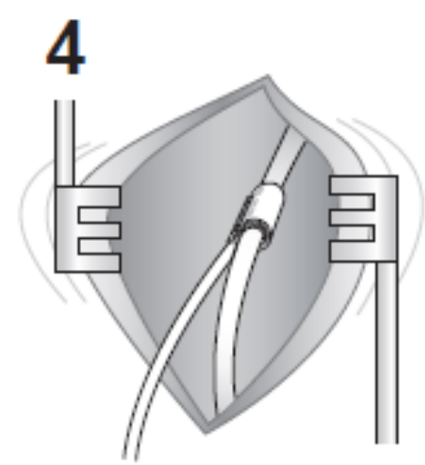
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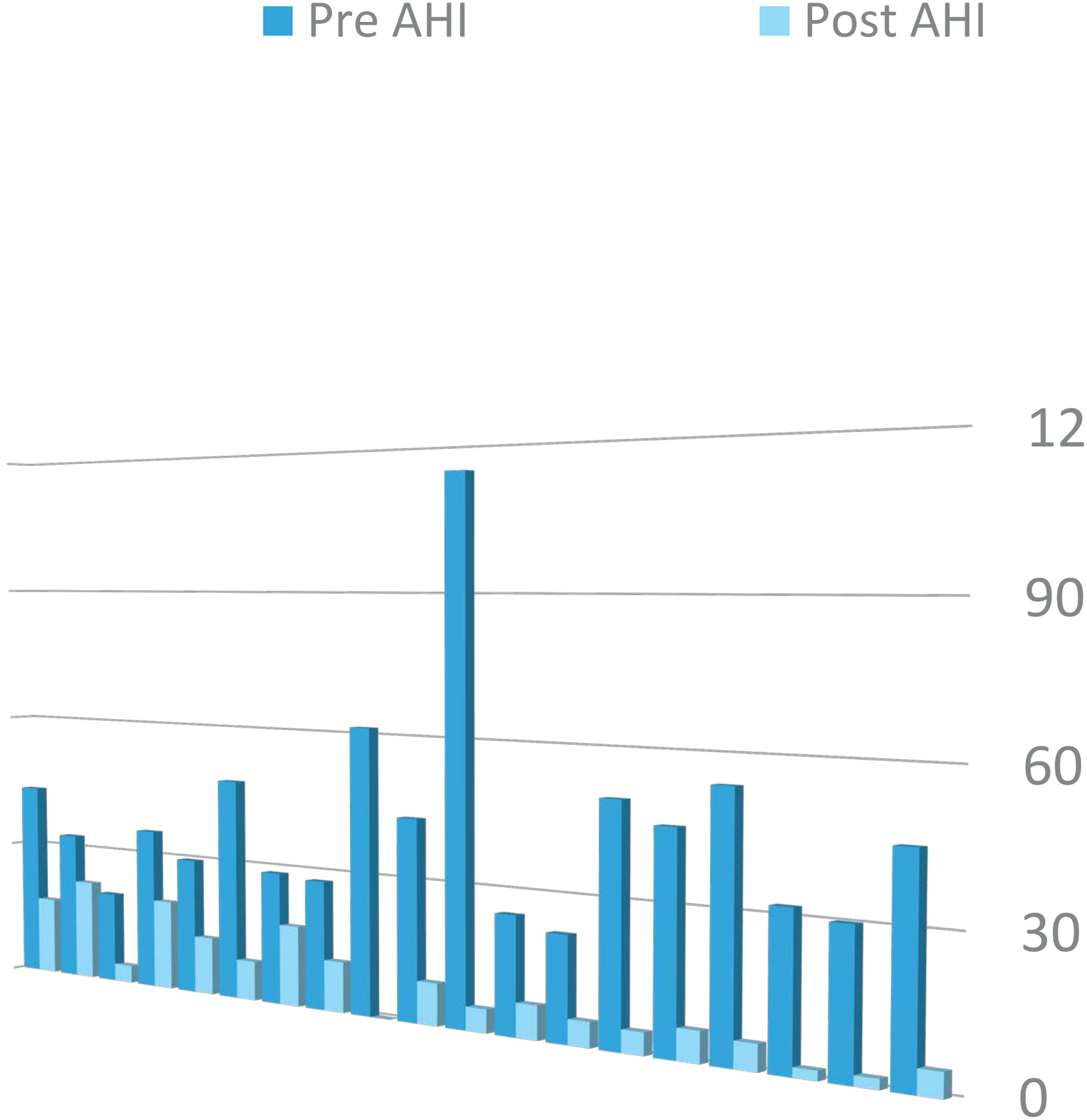
OSUWMC EXPERIENCE

- Started implanting in Apr 2015
- To date we've implanted ~400 pts
  - OSUWMC is #1 implant center in the world since 2018
- Activation 1-2mo post op
- Titration PSG ~2-3mo post activation
  - final titration
  - possible electrode reconfiguration

DEMOGRAPHICS OF FIRST 100

- M~80%, F~20%
- Age range 34-75, Ave 61
- AHI range 19.9-115, Ave 39
- ESS range 3-24, Ave 13.8

RESULTS



AHI REDUCTION

- Range 32.5-100% reduction, Ave 71.8% AHI reduction
- Ave ESS reduction from 15 to 6.2
- Remarkably similar to STAR results!
- Several pts requiring advance electrode configuration/retitration
  - About 10% of pts may benefit from advanced programming
  - Default setting is a bipolar setting (+ - +)

INITIAL CHALLENGES

- Marketing
  - Radio, social media, internal marketing, regional marketing
- Insurance approval
  - most commercial insurance approving
  - CMS approving

CHALLENGES

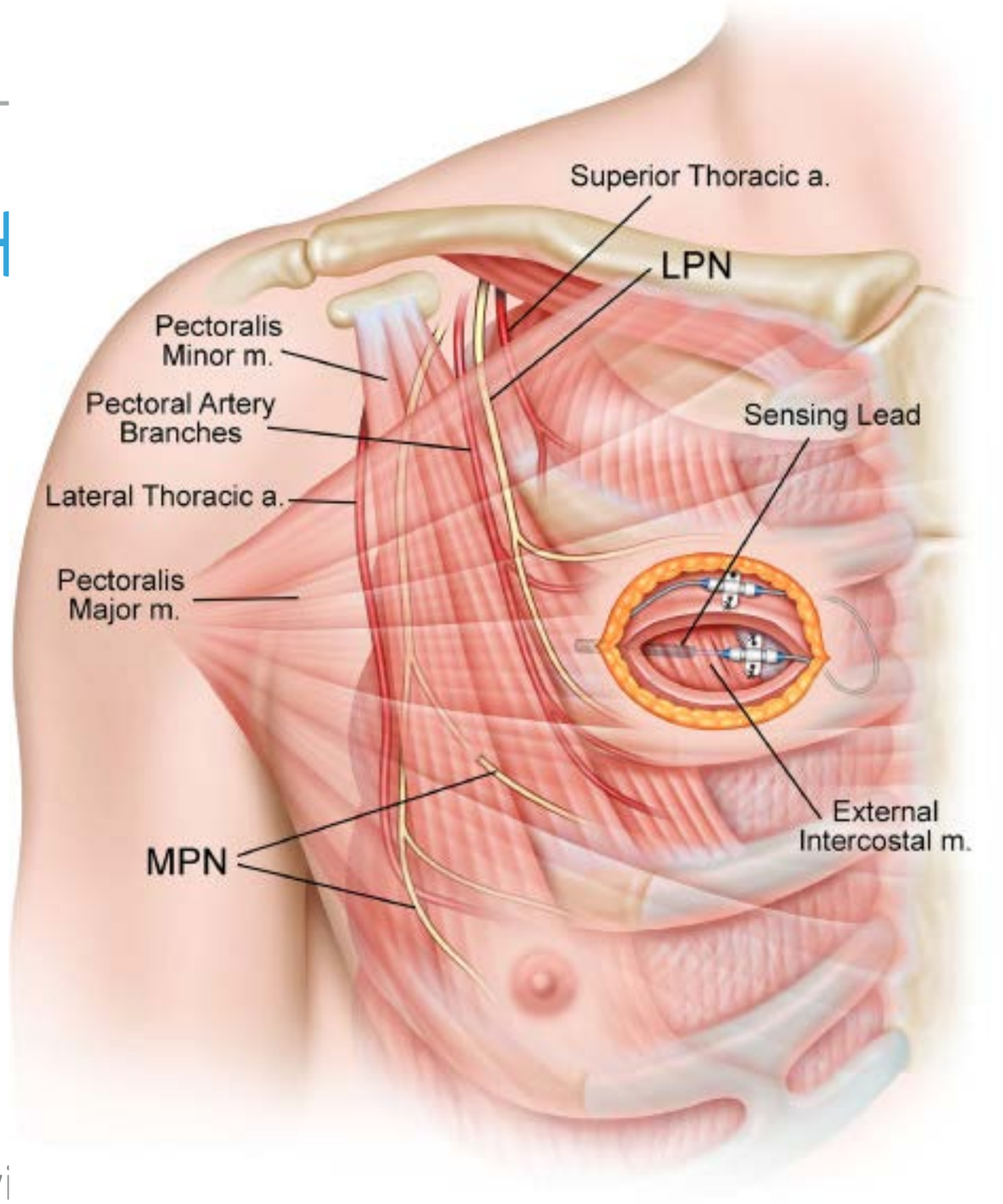
- MRI compatibility
  - current IPG is head/neck/extremity MRI compatible
  - still relative contraindication for thoracic MRI
- Battery life
  - current version is predicted to last 10-12 yrs

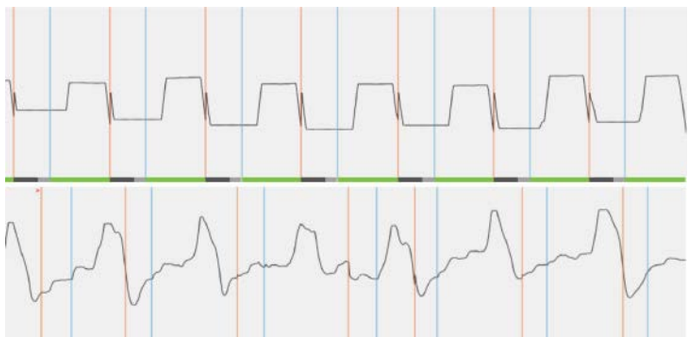
5 YEAR DATA

- Significant reduction in OSA severity
- Significant improvement in sleep-related QOL
- Statistically significant improvement in snoring
- 80% pts use device nightly
- Inspire announces launch of ADHERE registry (2017) to evaluate 5000 therapy pts in the US and Europe

2 INCISION APPROACH

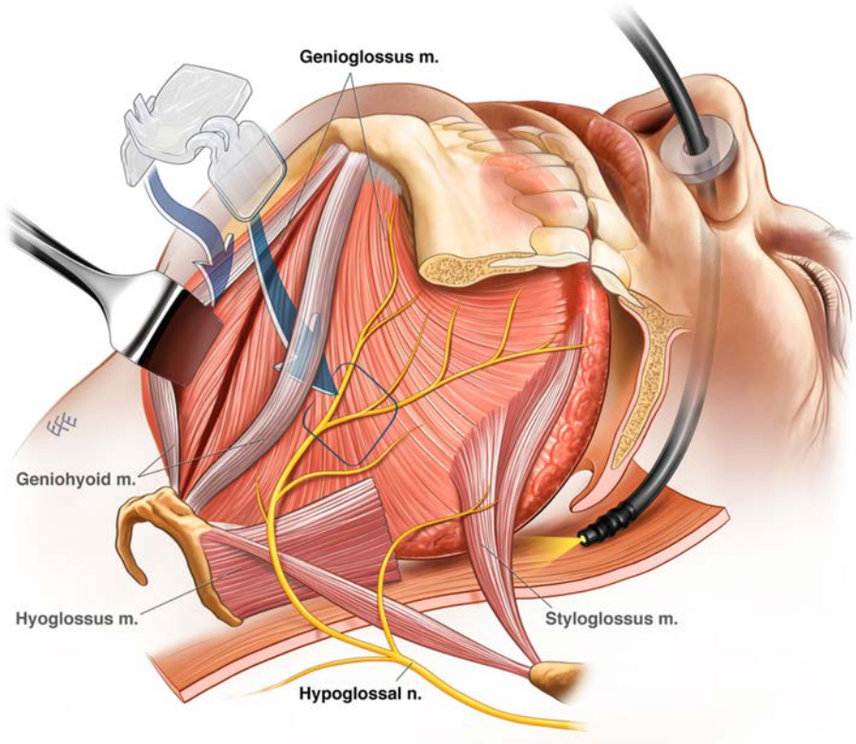
- Started in Jan 2020
- Around 175 done to date
- Official FDA approved method
- Elimination of a third incision
  - faster surgery (70 v 96min)
  - one less tunnel
  - minimizes infection risk
  - quicker recovery/fewer restrictions wi
  - very strong sense waveform





NYXOAH

- Genio
  - Bilateral CNXII stimulator
  - No respiratory sensor
- External power supply



CLINICAL TRIALS (AU, FR, UK)

- 22/27 pts completed protocol
- 6mo AHI drops from 23.7->12.9
- 6mo ODI drops 19.1->9.8
- significant improvements in ESS and FOSQ
- OSU/OSMI participating in US trials

SUMMARY

- OSA is a ubiquitous issue that is untreated by many
- CPAP is still considered the gold standard of treatment
- Traditional surgical options still exist and can be an option for selected candidates
- HNS is an excellent option for the ideal candidate who cannot tolerate traditional therapy options

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

QUESTION