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Update on Hypopharyngeal and Base of Tongue Management in OSA

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Disclosures

The following personal financial relationships with commercial interests relevant to this presentation:

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Overview

Why hypopharyngeal surgery?

Evaluation techniques for procedure selection

Hypopharyngeal procedures and outcomes

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Why Hypopharyngeal Surgery?

Effective surgery directed at site(s) of obstruction
- **Nose**
- **Palate**
- **Hypopharynx**

Fujita Classification
- **Type I Palate**
- **Type II Combined**
- **Type III Hypopharynx**

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OSA surgery review (Sher *et al.* Sleep 1996)
- **UPPP "successful" in 41% of all OSA patients**
  - **52% Fujita Type I**
  - **5% Fujita Types II and III**
- **Conclusion: failure to identify site(s) of obstruction is principal factor in poor results for surgery**

Friedman Stage (Friedman OtoHNS 2002)

Success of UPPP/T:	**Stage I**	**81%**
	Stage II	**38%**
	Stage III	**8%**

Unfortunately, few patients Stage I

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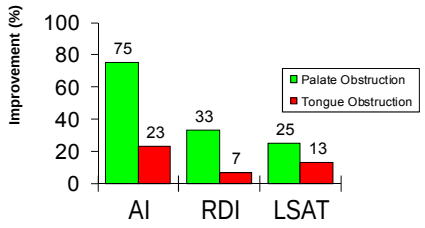
Palate Surgery Outcomes: Palate vs. Tongue Obstruction



Sher et al. SLEEP 1996;19:156-177

Adapted from Table 7

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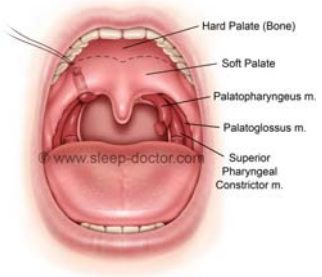
Expansion Sphincter Pharyngoplasty



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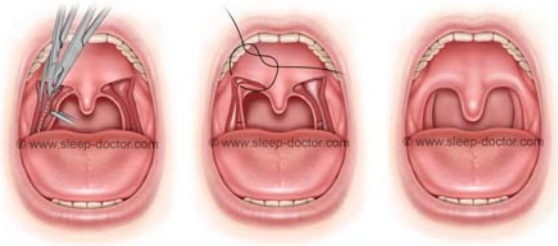
Lateral Pharyngoplasty



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Identifying the Sites: Drug-Induced Sleep Endoscopy

Developed in UK in 1991
Pringle MB, Croft CB. Clin Otolaryngol 1991;16:504-9.

Used in several centers around the world but less commonly in U.S.

Fiberoptic endoscopy of sedated, "sleeping" patient
Goal: reproduce SDB seen on sleep study

VOTE Classification system (Kezirian, Hohenhorst, de Vries Eur Arch Oto 2011)
--some standardization and comparison of findings/outcomes across centers

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Velum/Palate

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Oropharyngeal Lateral Walls

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Tongue

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Epiglottis

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Site of Obstruction and Surgical Options

Current	Future?
Palate/Tonsils	Velum/Palate
Hypopharynx/ Retrolingual	Oro LW
	Tongue
	Epiglottis
Maxillofacial	
	Maxillofacial

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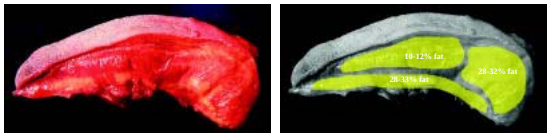
What Is the Link between Obesity and OSA? Why Is Obesity Associated with Worse Outcomes after Most Procedures?

Fat Is Deposited in Tongue in Obese Subjects (Nashi et al, Laryngoscope 117:1467, 2007)



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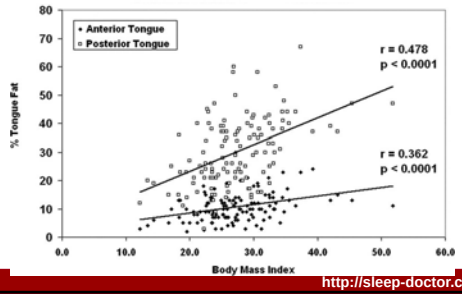
Correlation of Percent Tongue Fat with BMI (Nashi et al, Laryngoscope 117:1467, 2007)



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Factors and Outcomes

Examining case series studies, although some small

Most randomized trials are pilot studies (sample size)

Factors: BMI, preop AHI, cephalogram measures

Outcomes: AHI and "success"

"Success" = 50% reduction in AHI/AI to absolute level no greater than 20/15/5

Major oversimplification

- Goal generally to improve OSA/AHI
- Other outcomes (sleepiness, QOL)

However, AHI reported widely and enables comparison

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Hypopharyngeal Procedures

Genioglossus advancement

Tongue radiofrequency

Tongue stabilization

Midline glossectomy

Hyoid suspension

Partial epiglottectomy

Hypoglossal nerve stimulation

Maxillomandibular advancement

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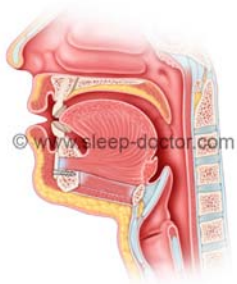
Genioglossus Advancement

Rectangular osteotomy below incisor roots between canines
--GBAT: circular osteotomy

Capture genial tubercle and genioglossus muscle attachments

Advance bone fragment and muscle attachment to place genioglossus on tension

Risks: dental numbness, injury



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	BMI	Pre AHI	Post AHI	Success (AHI)	Factors
Riley 1994				39% (9/23)	
Johnson 1994		59	14*	78% (7/9)	PAS and MP-H (not real statistical analysis)
Lee 1999		53	19*	69% (24/35)	
Miller 2004 (GBAT)	30.5	53	16*	67% (7/11)	AHI (better with <40); BMI and AHI
Liu 2005	28.0	62	30*	52% (23/44)	AI < 20; low BMI (<30) in sample
Emara 2011	27.5 (all < 30)	41	15*	87% (20/23)	All age < 60 years
Kim 2012	26.8			41% (35/85)	Not BMI but lateral cephalogram measures
Hendler 2001 (mortised genioplasty)	32.6	60	29*	48% (16/33)	AHI, BMI <30
dos Santos 2007 (genioplasty)	25.4 (all below 30)	12	4*	70% (7/10)	? BMI (all < 30 in sample)

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Tongue Radiofrequency

Many areas of the body
Heart, prostate, oncology
Turbinates, palate, tonsils, tongue

Energy delivered to create injury, then fibrosis

Multiple technologies
Monopolar (Gyrus/TCRF) vs. Bipolar (ArthroCare and Celon)

Less invasive
Can be done in clinic—titratable, snoring

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Tongue Radiofrequency Outcomes

Most have overweight BMI but not obese (highest mean BMI 32)
Wide range mean baseline AHI

Success rates 20-80% in different series
Randomized, placebo-controlled trial shows modest but real improvements in AHI and FOSQ (QOL)

Factors associated with outcomes
- AHI (not universal)
- BMI 29 or 30
- Friedman Stage (II better than III)

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Tongue Radiofrequency Improves UPPP/T outcomes

FS	UPPP/T Only	UPPP/T + RF Tongue
I	80%	
II	38%	55%
III	8%	33%

Palate surgery alone provides improvement

Addition of tongue RF improves outcomes for patient subgroups that would not be expected to have ideal outcomes after palate surgery

Friedman Oto—HNS 2003
Friedman Oto—HNS 2004

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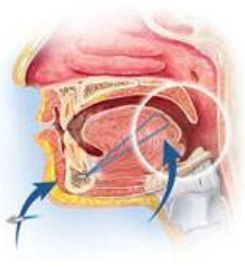
Tongue Stabilization

Marketed as Repose/Airvance system

Technique
Bone screw in mandible
Pre-attached suture passed through tongue base and secured to stabilize tongue base



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Tongue Stabilization Case Series

Most have overweight BMI (highest mean 31)
Wide range mean AHI

Success rates 20-80% in different series

Factors associated with outcomes (limited eval)
- AHI
- BMI 29, graph
- ? Suture tightening

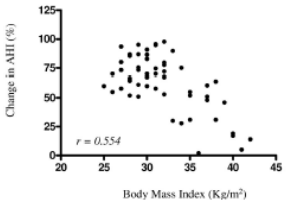

Fig. 2. Relationship between presurgery baseline body mass index and postsurgery change in apnea-hypopnea index after 3 years follow-up. ($r = 0.554$, $P < .001$).

Source: Vicente Laryngoscope 2006 (n=54)

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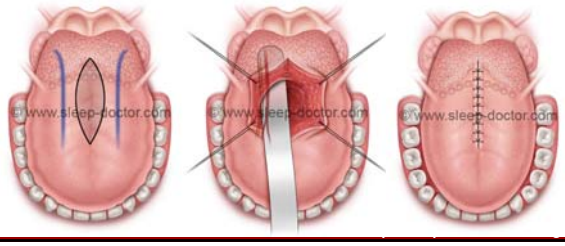
Midline Glossectomy

Morbid procedure with CO2 laser, cautery
Robinson technique: Coblation (not FDA indication)



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Tongue Resection: Midline Glossectomy, SMILE, Hyoepiglottoplasty, and Lingual Tonsillectomy

Most series have mean BMI in obese range (29-36)
Mean baseline AHI wide range but higher than RF/TS

Success rates 25-100% in different series

Factors associated with outcomes
- AHI
- BMI (31 in responders vs. 38 in nonresponders)

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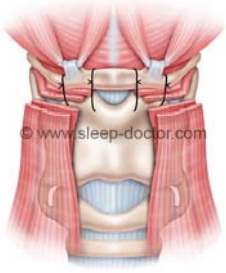
Hyoid Suspension



Rationale: Pharyngeal soft tissues attach to mobile hyoid bone
Advance hyoid, limit mobility

Mandible inferior border with fascia lata or sutures (Repose/Airvance)
--suture breakage?

Superior border of thyroid cartilage

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	Technique	BMI	Pre AHI	Post AHI	Success (AHI)	Factors
Vilaseca 2002	Thyroid	27.8	48.3	29.0*	56% (5/9)	
Neruntarat 2003	Thyroid	29.3	44.5	15.2*	78% (25/32)	
den Herder 2005 (primary)	Thyroid	26.3	33	18*	71% (10/14)	
den Herder 2005 (secondary)	Thyroid	27.7	32	26	35% (6/17)	
Bowden 2005	Thyroid	34.1	36.5	37.6	17% (5/29)	Not AHI or BMI (although high BMI in sample)
Benazzo 2008	Thyroid	28.2	37	19*	62% (67/109)	BMI (29.1 vs. 27.7), AHI (44 vs. 30) lateral pharyngeal collapse only on MM; excluded those with abnormal cephs
Baisch 2006	Thyroid	28.2	38	19*	60% (40/67)	Not BMI (graph)
Gillespie 2011	Mandible (Repose)	32	41	19*	70% (16/23)	Technique (less dissection of hyoid musculature)

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Hyoid Suspension in Combination with Other HP Procedures: Case Series

Wider range of mean BMI
Mean baseline AHI wide range but higher than RF/TS

Success rates 20-80% in different series, for different techniques
Factors associated with outcomes
- AHI
- BMI 30, 32
- SNB angle on lateral cephalogram (normal 80±2 degrees; >78 degrees)
- Age (one study; not examined much as a factor)

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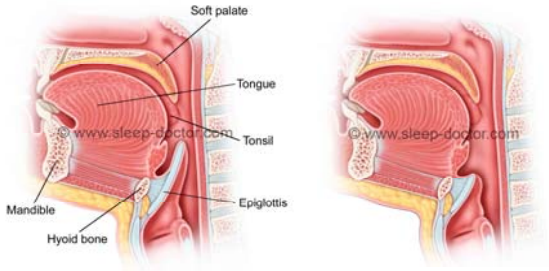
Partial Epiglottidectomy



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Partial Epiglottectomy

Resection of portion of epiglottis
Below: central suprahyoid vs. central above vallecula
Others resect lateral portions

	BMI	Pre AHI	Post AHI	Success (AHI)	
Mickelson 1997 (midline gloss)	*36.0*	*73*	*47**	*25% (3/12)*	
Catalfumo 1998		42	8*		Selection by displacement of epiglottis from tongue base
Golz 2000	23.4	45	14*	78% (21/27)	Selection same as Catalfumo

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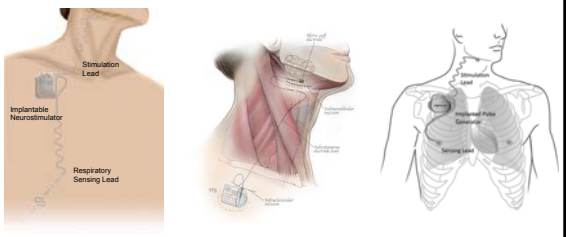
Hypoglossal Nerve Stimulation Technologies

Three companies in this area: Apnex Medical, ImThera, and Inspire Medical Systems.



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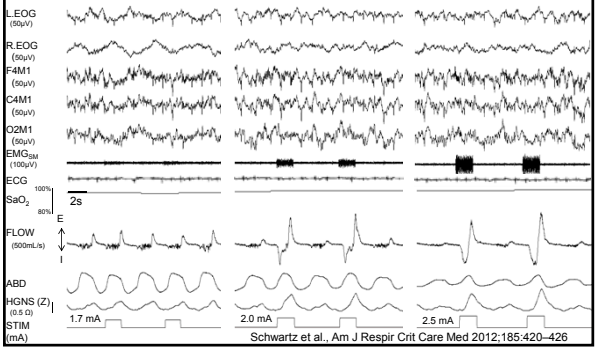
Acute Effects – Sleep Titration PSG (Apnex HGNS®)



Schwartz et al., Am J Respir Crit Care Med 2012;185:420–426

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Inspire Medical Pivotal Trial: Strollo NEJM 2014

- Single arm
- 12 centers: US, Europe
- Safety
- Efficacy
  - AHI
  - ODI
  - FOSQ
  - ESS
  - % sleep O2 <90%
- Key Entry Criteria
  - Failed CPAP
  - AHI 20-50
  - BMI < 32
  - Age: 20 - 70
  - Minimal central/mixed OSA
  - DISE: no CCC palate

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Study Schematic and Timeline

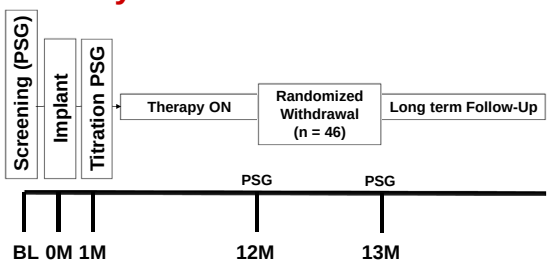

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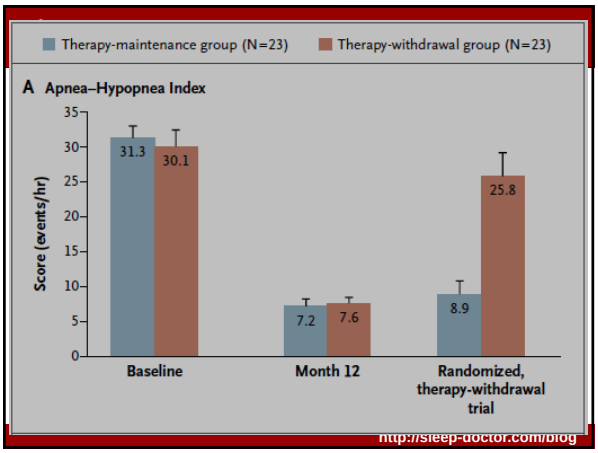
Table 2. Primary and Secondary Outcome Measures.*

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	

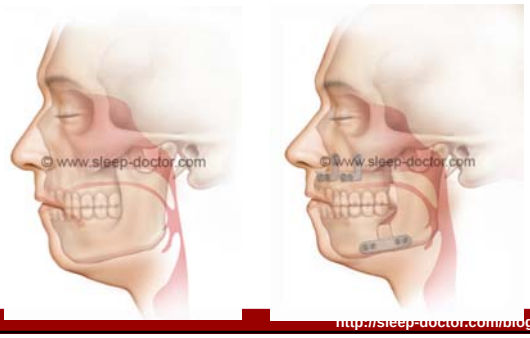


Safety Outcomes (Serious AEs)

Event Descriptions	Outcomes
3 Device Explants • 1 Infection/Hematoma • 2 Elective Explants	• Device explanted without sequelae • Underwent multilevel pharyngeal surgery and subsequently had an explant. Second subject decided to withdraw before system activation and requested explant. Both underwent device explant without sequelae.
2 Cuff Dislodgements	• Occurred early in postoperative period. Surgical revision and re-placement required. Both subjects continued in the study with no further sequelae.

Inspire Medical: one explant for infection
ImThera: device and technical failures early (IPG, leads, external charger); no explants

Maxillomandibular Advancement



Factors Associated with Outcomes

BMI: cutpoint of 30 or 32 kg/m^2

AHI: more important than for palate surgery outcomes

Mandible/SNB: not as thoroughly studied (lack of cephalogram data?) but appears to be important

Structures: VOTE

Age?: very little data, but I believe important

What Do I Do?: Structure-Based Approach

Velum/Palate	UPPP ± tonsillectomy
	Other palate procedures (ESP and LP)
Oro LW	? Hyoid suspension, ESP, LP, MAD/MMA
Tongue	Genioglossus advancement
	Tongue RF
	Tongue stabilization
	Tongue resection (BMI >30/32)
	Hypoglossal nerve stimulation
Epiglottis	Hyoid suspension vs. Partial epiglottectomy
Maxillofacial	MMA

Counseling patients key: BMI, AHI, mandible (SNB), ?age

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Conclusions

Selecting a hypopharyngeal surgery based on:

Procedure technique (mechanism of action)
Patient anatomy (evaluation)
Factors associated with outcomes
Surgeon training and experience
Patient preferences

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Conclusions

Poor outcomes have always been considered a failure of surgical technique/skill

Selection of appropriate procedure(s) may be just as important