Diagnosis and Management of OSA: CPAP and Beyond

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Snoring

A sign of upper airway resistance

A multibillion dollar industry

Obstructive Sleep Apnea (OSA) Syndrome

- High Prevalence
  - 9-38% percent of general population (AHI>5)
    - 6-17% of general population (AHI>15)
  - 50-70 percent of adults > 65 years of age
- Associated with numerous dramatic physiological challenges
  - Intermittent recurrent hypoxia, hypercapnia, wide swings in intrathoracic pressure, etc.
- Chronic disorder

Therapies for OSA

- Background
- CPAP Therapy
- Medical Therapies
- Oral Appliances
- Surgical Therapies
- Comprehensive Approach

Therapies for OSA

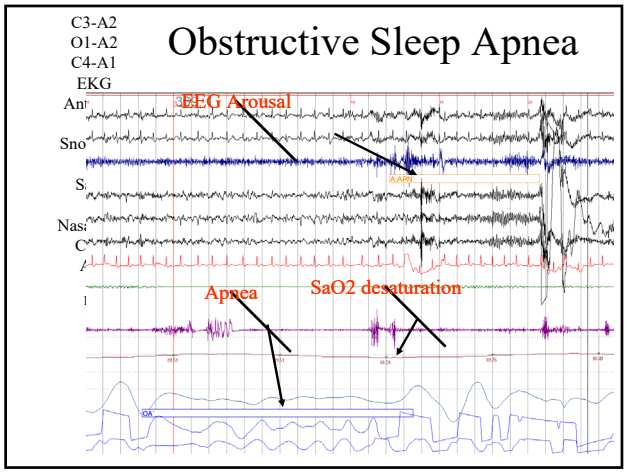
Background

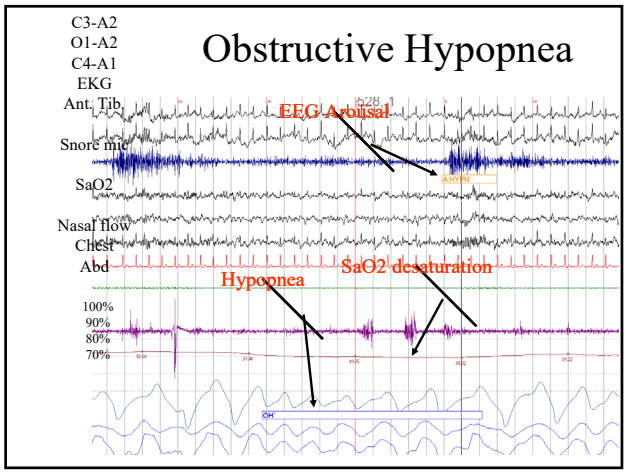
Apneas and Hypopneas

- Apneas
  - Absence of airflow for at least 10 seconds in duration
  - Obstructive, central and mixed (both obstructive and central components)
- Hypopneas
  - Decrease in airflow by ≈50% below baseline for at least 10 seconds in duration
  - Resumption of normal breathing leads to EEG arousal
- Apnea + Hypopnea Index (A+HI) = number of events per hour of sleep
  - Normal < 5, Mild OSA 5-15, Mod OSA 15-30, Severe OSA >30

Testing

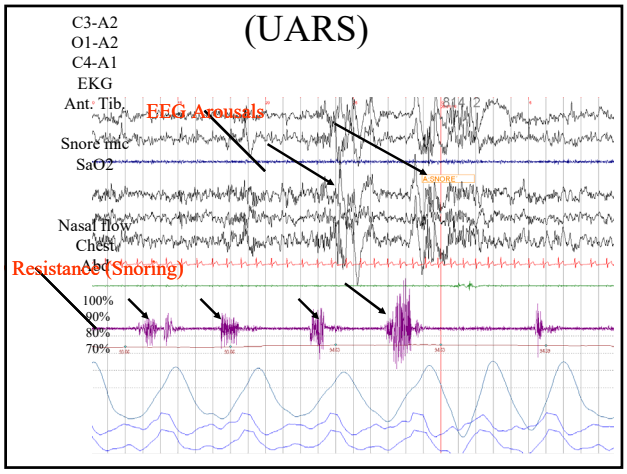
- HST vs. In-laboratory Polysomnography
- HST Pros and Cons
- Pros - easy/at home/less sensors/cost? etc
- Cons- not standardized equipment (20-30% false negative rate)

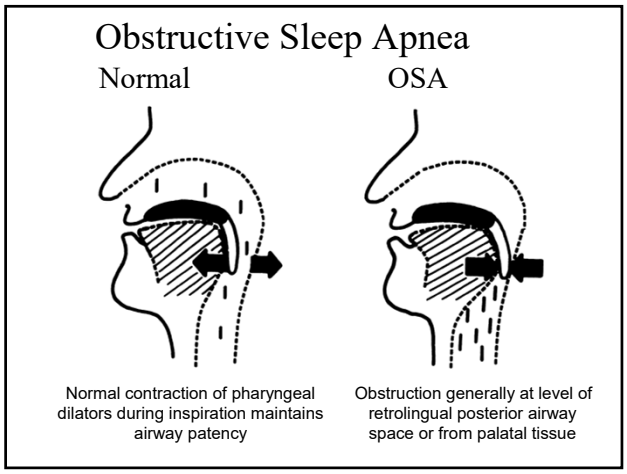




Upper Airway Resistance Syndrome (UARS)

- Apnea + hypopnea index <10 usually less than 5.
- Frequent inspiratory, snore arousals
- More often chronic fatigue or EDS complaints.
- May present as insomnia.
- SaO2 levels are consistently normal, usually above 90% and only mild desaturations (pulse oximetry or HST not helpful tools).

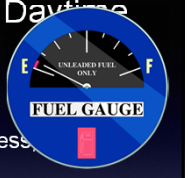




OSA Clinical Symptoms

- Excessive daytime sleepiness (EDS) from increased fragmentation of sleep.
- Snoring (usually, but not always present).
- Morning headaches- dry mouth – night sweats.
- Gasping/choking out of sleep.
- Restless sleep.
- Irritability and decreased short-term memory.
- Non-refreshing sleep.
- GERD.

Summary of Impact from Daytime Sleepiness



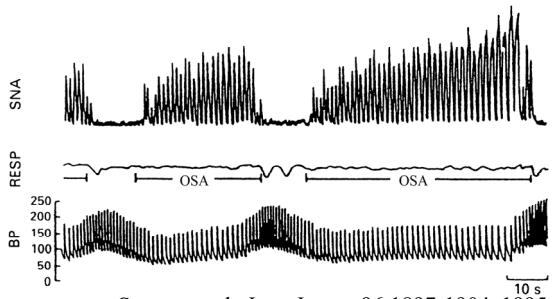
- **Mood:** Irritability and depression
- **Behavioral problems:** Aggressiveness, hyperactivity, poor impulse control.
- **Neurocognitive deficits:** Decreased attention, memory, executive functions
- **Performance deficits:** academic, social, work and driving-related (longer reaction time, judgement, and increased microsleeps), most affected on prolonged cognitive tasks.
- **Other:** disruption to interpersonal relationships and family.

Consequences of OSA

Autonomic Dysfunction

- Increase in sympathetic tone
- Disruption of parasympathetic control

Sympathetic Nerve Activity and REM-Related Apneas



Somers et al. *J. Clin. Invest*. 96:1897-1904, 1995

Clinical Consequences of Increased Sympathetic Drive

- Hypertension
  - Present in 40-60% of OSA patients (>90% if on 3 or more drugs to treat OSA)
  - OSA independent risk factor for developing HTN.
    - Prospective ***Wisconsin Sleep Cohort study*** (N Engl J Med, 342:1378, 2000).
    - Retrospective ***Sleep Heart Health Study*** (JAMA. 283:1829, 2000).
- Myocardial infarction
- Cardiac arrhythmias (i.e. atrial fibrillation)
- CHF
- Stroke/TIA
- Erectile dysfunction
  - Present in approximately 45% of OSA patients.

Obstructive Sleep Apnea

- Predisposing factors
  - Obesity
  - Micrognathia
  - Adenotonsillar hypertrophy
  - Hypothyroidism
- Treatment
  - Nasal CPAP is primary treatment
  - Other therapies…

Therapies for OSA

- Background
- **CPAP Therapy**
- Medical Therapies
- Oral Appliances
- Surgical Therapies
- Comprehensive Approach

Nasal Continuous Positive Airway Pressure (CPAP)

CPAP device

Heated Humidifier (Water reservoir)

Full Face Mask

Traditional Masks

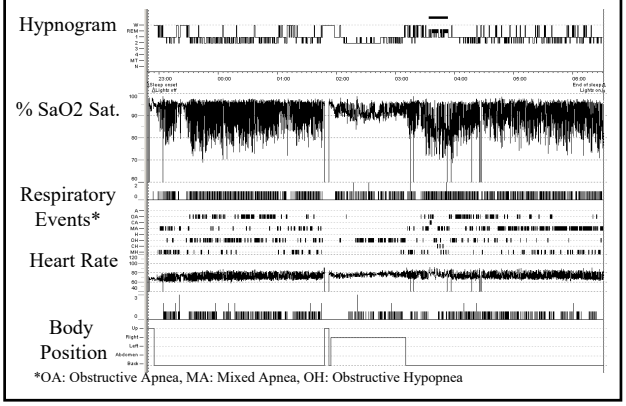
Nasal Pillow Masks

Nasal CPAP Therapy

- Involves comprehensive polysomnogram for titration of pressure.
  - Titrate to effect vs APAP (??pressure)
- Standard of care for moderate to severe OSA.

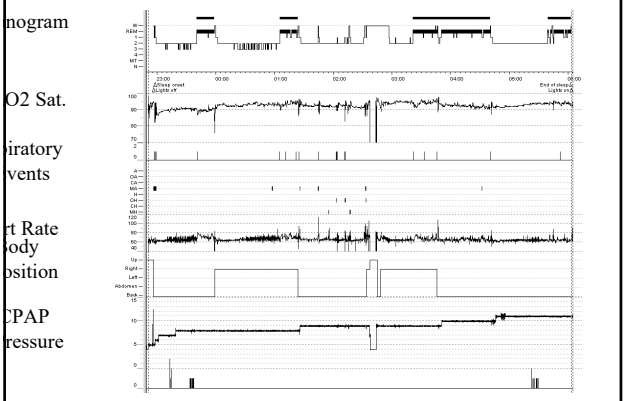
Severe OSA

A+HI=84.2



*OA: Obstructive Apnea, MA: Mixed Apnea, OH: Obstructive Hypopnea

CPAP Therapy



Effects of CPAP Treatment

- Improves daytime sleepiness
- Eliminates hypoxic episodes
- Improves hypertension
- Reduces sympathetic activity
- Normalizes morning blood viscosity
- Normalizes of morning fibrinogen levels

What is CPAP "Failure"?

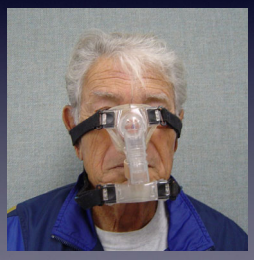
- Inappropriate pressure
- Lack of education
- Inadequate humidification
- Inappropriate mask
- Incorrect mask fitting
- Claustrophobia

➡ Lack of follow-up

"Good night and good luck!"

Problems with Mask Placement

Incorrect Placement



Correct Placement

Therapies for OSA

- Background
- CPAP Therapy
- **Medical Therapies**
- Oral Appliances
- Surgical Therapies
- Comprehensive Approach (Breathewell Protocol)

Medical Therapy for OSA

SLEEP 2006; 29:1036-1044

Medical Therapy for Obstructive Sleep Apnea: A Review by the Medical Therapy for Obstructive Sleep Apnea Task Force of the Standards of Practice Committee of the American Academy of Sleep Medicine

Sigrid C. Veasey, MD[1]; Christian Guilleminault, MD[2]; Kingman P. Strohl, MD[3]; Mark H. Sanders, MD[4]; Robert D. Ballard, MD[5]; Ulysses J. Magalang, MD[6]

[1]University of Pennsylvania, Philadelphia, PA; [2]Standford University Medical Center, Standford, CA; [3]Veterans Administration Medical Center, Cleveland, OH; [4]University of Pittsburgh Medical Center, Pittsburgh, PA; [5]Sleep Health Centers at National Jewish, Denver, CO; [6]The Ohio State University, Columbus, OH

SLEEP APNEA

SLEEP 2006; 29:1031-1035

Practice Parameters for the Medical Therapy of Obstructive Sleep Apnea

Standards of Practice Committee of the American Academy of Sleep Medicine

Timothy I. Morgenthaler, MD[1]; Sheldon Kapen, MD[2]; Teofilo Lee-Chiong, MD[3]; Cathy Alessi, MD[4]; Brian Boehlecke, MD[5]; Terry Brown, DO[6]; Jack Coleman, MD[7]; Leah Friedman, MA, PhD[8]; Vishesh Kapur, MD[9]; Judith Owens, MD[10]; Jeffrey Pancer, DDS[11]; Todd Swick, MD[12]

[1]Mayo Clinic, Rochester, MN; [2]Detroit VA Medical Center, Detroit, MI; [3]National Jewish Medical and Research Center, Denver, CO; [4]UCLA/Greater Los Angeles VA Healthcare System, Sepulveda, CA; [5]University of North Carolina, Chapel Hill, NC; [6]St. Joseph Memorial Hospital, Murphysboro, IL; [7]Murfreesboro, TN; [8]Stanford University, Stanford, CA; [9]University of Washington, Seattle, WA; [10]Rhode Island Hospital, Providence, RI; [11]Toronto, Ontario, Canada; [12]Houston Sleep Center, Houston, TX

Medical Therapy

- Weight Reduction
  - Bariatric surgery
- Pharmacologic Agents
  - Protriptyline
  - Atomoxetine and Oxybutynin
  - Other: Modafinil, SSRI's, estrogen, etc.
- Positional Therapies

- Supplemental Oxygen
  - Improves Oxygen saturation nadir
  - Not recommended as primary therapy for OSA
- Improving Nasal Patency
  - Nasal corticosteroids may improve A+HI, but insufficient as sole therapy

Bariatric Surgery

- Magnitude of weight reduction following bariatric surgery far exceeds that reported following medical intervention.
- OSA may markedly improve or resolve.

Bariatric Surgery

- Concerns:
  - Lack of studies to date with control groups or randomized design.
  - Reports of recurrence of OSA even without regaining weight. Pillar et al. *Chest*, 106:1702, 1994 (7 year F/U).
  - Up to 10% may have post-surgical complications (wound healing, anastomotic leaks, pneumonia, CHF, infection, etc.)

Pharmacotherapy for Mild OSA/UARS

- Protriptyline (Vivactil)
  - Tricyclic antidepressant, but a secondary amine and thus alerting (unlike sedating tertiary amines).
  - Serotonin and Norepinephrine reuptake inhibitor.
  - Metabolized to nortriptyline.

Protriptyline

- 4 double blind, placebo controlled, crossover design studies.
- Sample sizes small (5-12 subjects)
- Studies done in severe OSA (A+HI>45).
- REM sleep time reduced 50%.
- Daytime sleepiness also consistently improved.
- NREM A+HI reduced
  - 74 to 53, $p<0.05$ (Smith et al., *Am. Rev. Resp. Dis.* 127:8-13, 1983).
  - 57 to 33, $p<0.05$ (Hanzel et al. *Chest* 100: 416-421, 1991).
- Oxygen saturation significantly improved with Protriptyline in 7/8 studies.
  - NREM O2 saturation also improves (Stepanski et al., 1988).

Protriptyline

- Practice Parameters (Morgenthaler et al. *Sleep*, 2006).
  - "Protriptyline is not recommended as a primary treatment for OSA"
  - Designated as a "Guideline"
    - Reflects only a moderate degree of clinical certainty
- What is the role for protriptyline in UARS or mild OSA (A+HI<10-15)?
  - Minimal published data currently.
  - Improves snoring (Series and Marc. *Chest*, 104:14-18, 1993).
- Anticholinergic side effects can be limiting factor for use in some patients.
  - Dry mouth, constipation, blurred vision, urinary retention.

Protriptyline: Possible Mechanism of Action

- Increase pharyngeal muscle tone VS increase respiratory drive.
- Bonora et al. *Am. Rev. Respir. Dis.*, 131:41-45, 1985.
  - 23 adult anesthetized cats studied.
  - Protriptyline consistently increased hypoglossal nerve firing during inspiration.
  - Diazepam induced a reduction of hypoglossal nerve activity during inspiration.
  - Conclusion: Systemic protriptyline likely improves genioglossal tone during inspiration.

The Combination of Atomoxetine and Oxybutynin Greatly Reduces Obstructive Sleep Apnea Severity. A Randomized, Placebo-controlled, Double-Blind Crossover Trial
Luigi Taranto-Montemurro , Ludovico Messineo , Scott A. Sands , Ali Azarbarzin , Melania Marques , Bradley A. Edwards , Danny J. Eckert , David P. White , and Andrew Wellman

- **N=20**
- **80mg of atomoxetine and 5mg of oxybutynin**
- **Average age 53, BMI = 24.8, lowered AHI by 63% from 28.5 to 7.5**
- **Neither effective alone**

Preventive Measures

- Weight loss (avoid weight gain)
- Avoid alcohol within 3-5 hours of bedtime
- Avoid supine sleep if patient unable to use CPAP.
  - Is positional therapy an option as a prima treatment for OSA?

Supine Position Only

male, hx of stroke and s/p pacemaker

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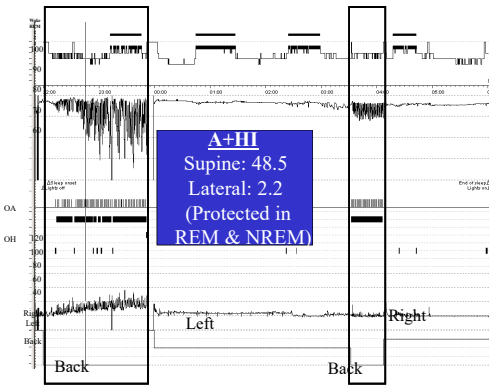

A Supine Exacerbation

r old female with HTN and RLS

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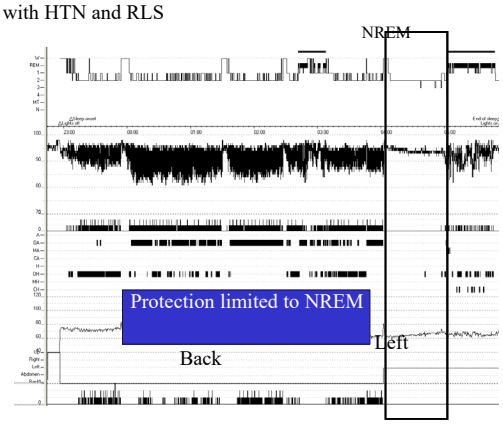

Therapies for OSA

- Background
- CPAP Therapy
- Medical Therapies
- **Oral Appliances**
- Surgical Therapies
- Comprehensive Approach (Breathewell Protocol)

Guidelines for use of Oral Appliances in Sleep Medicine

REVIEW

Oral Appliances for Snoring and Obstructive Sleep Apnea: A Review

Kathleen A. Ferguson, MD[1]; Rosalind Cartwright, PhD[2]; Robert Rogers, DMD[3]; Wolfgang Schmidt-Nowara, MD[4]

[1]Division of Respirology, University of Western Ontario, London, Ontario, Canada, [2]Department of Behavioral Sciences, Rush University Medical Center, Chicago, IL, [3]Department of Dental Medicine, St. Barnabas Medical Center, Gibsonia, PA, [4]University of Texas Southwestern, Sleep Medicine Associates of Texas, Dallas, TX

PRACTICE PARAMETERS

Practice Parameters for the Treatment of Snoring and Obstructive Sleep Apnea with Oral Appliances: An Update for 2005

An American Academy of Sleep Medicine Report

Clete A. Kushida, MD, PhD[1]; Timothy I. Morgenthaler, MD[2]; Michael R. Littner, MD[3]; Cathy A. Alessi, MD[4]; Dennis Bailey, DDS[5]; Jack Coleman, Jr., MD[6]; Leah Friedman, PhD[7]; Max Hirshkowitz, PhD[8]; Sheldon Kapen, MD[9]; Milton Kramer, MD[10]; Teofilo Lee-Chiong, MD[11]; Judith Owens, MD[12]; Jeffrey P. Pancer, DDS[13]

[1]Stanford University Center of Excellence for Sleep Disorders, Stanford, CA; [2]Mayo Sleep Disorders Center, Mayo Clinic, Rochester, MN; [3]VA Greater Los Angeles Healthcare System and David Geffen School of Medicine at UCLA, Sepulveda, CA; [4]UCLA/Greater Los Angeles Healthcare System, Sepulveda, CA; [5]Englewood, Colorado; [6]Middle Tennessee ENT, Murfreesboro, TN; [7]Stanford University School of Medicine, Stanford, CA; [8]Baylor College of Medicine and VA Medical Center, Houston, TX; [9]VA Medical Center and Wayne State University, Detroit, MI; [10]Maimonides Medical Center, Psychiatry Department, Brooklyn, NY and New York University School of Medicine, New York, NY; [11]National Jewish Medical and Research Center, Sleep Clinic, Denver, CO; [12]Department of Pediatrics, Rhode Island Hospital, Providence, RI; [13]Toronto, Ontario, CN

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510(k) | Registration | Listing | Adverse Events | PMA | Classification | CLIA
CFR Title 21 | Advisory Committees | Assemblies | Recalls | Guidance | Standards

Product code: LQZ (Jaw Repositioning)

19 records meeting your search criteria returned - **ProductCode:** *LQZ*

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Device	Applicant	510(k)	Decision Date
Full Breath Sleep Ap	Bryan Keropian Dds	K053065	01/03/2006
Full Breath Sleep Ap	Bryan Keropian Dds	K052862	12/30/2005
Snorenti	James P Boyd	K032410	02/28/2005
Myohealth Clenching	Mci-Myohealth System	K040315	08/27/2004
Dr. Hays Bite Guard	Inventive Resources,	K014079	02/22/2002
Nti Tension Suppress	Nti-Tss, Inc.	K010876	06/20/2001
Accu-Bite Home Kit D	Jerome M. Simon	K980953	10/07/1998
Nti Clenching Suppre	Heraeus Kulzer, Inc.	K981546	07/15/1998
Snorex	Snorex (Nz) Ltd.	K971818	12/18/1997
Osap	Snorefree, Inc.	K960673	05/09/1996
Adjustable Pm Positi	Jonathan A. Parker,	K955503	02/08/1996
Pm Positioner	Jonathan A. Parker,	K953293	09/15/1995
Despa	D.S.R.A., Inc.	K945820	06/15/1995
Elastomeric Sleep Ap	Village Park Orthodo	K946112	06/14/1995
Snoremaster Snore Re	The Snoremaster Co.	K932932	02/10/1995
Snore-No-More	Great Lakes Orthodon	K922818	02/09/1994
Napa	G-Ortho Lab	K902790	09/19/1990
Snoar(Tm) Open Airwa	Kent J. Toone, D.D.S.	K880956	05/11/1988
The Equalizer Airway	Sleep Renewal, Inc.	K870501	03/04/1987

FDA Approved Devices

Product code: LRK (Anti-Snoring)

47 records meeting your search criteria returned - **ProductCode:** *LRK*

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Device	Applicant	510(k)	Decision Date
Silent Partner Serie	Dreamwrx Dental Labo	K051014	08/09/2005
Somnomed Mas Rxa	Somnomed Ltd	K050592	07/12/2005
Nti Tension Suppress	Nti-Tss, Inc.	K041184	05/03/2005
Anti-Snoring/Sleep A	Rj & Vk Bird Pty Ltd	K042161	10/27/2004
Pillar Palatal Impla	Restore Medical Inc.	K040417	07/28/2004
Restful Nights, Ltd.	Ottawa Dental Labora	K021569	03/15/2004
Respironics Custom I	Respironics, Inc.	K033822	02/06/2004
Respironics Custom I	Respironics, Inc.	K033823	02/06/2004
Casys-Oral Airway Sy	Mark Abramson, D.D.S.	K030440	08/26/2003
The Suad Device	Strong Dental Inc.	K023836	07/08/2003
The Breathe Ez Anti-	D&S Redhage	K022891	02/19/2003
Anti-Snoring Device	Pi Medical	K011723	12/18/2002
Snore-Aid Max	Dental Imagineers, L	K022284	12/10/2002
Nose Breathe Mouthpi	Steven K. Sue	K013687	05/28/2002
Norad Nocturnal Oral	Dennis R. Bailey, Dd	K020893	05/28/2002
Sleepbite	Dental Imagineers, L	K013808	01/30/2002
Norad, Nocturnal Ora	Dennis R. Bailey, Dd	K013049	11/29/2001
The Quiet Sleeper	Precision Dental Lab	K012142	10/04/2001
Tongue Stabilizer De	University Of Otago	K993381	12/21/1999
Oral Sleep Disorder	Perl-Rad Sleep Disor	K991209	09/22/1999
Dr. B's Mouthpiece,	Snore - Ezzer	K991948	09/02/1999
Repose Bone Screw Sy	Influence, Inc.	K981677	08/27/1999
Snore-Aid Plus	Dental Imagineers, L	K991449	07/22/1999
The Snore Peace	The Snore Peace Grou	K981923	08/24/1998
Snore-Cure Anti-Snor	Ortho-Tain, Inc.	K980952	06/01/1998

Thorton Adjustable Positioner (TAP)

SomnoMed Mandibular Advancement Splint (MAS)

SUAD

AASM Practice Parameters

- Diagnosis-Standard
  - "The presence or absence of OSA must be determined before initiating treatment with oral appliances to identify those patients at risk due to complications of sleep apnea and to provide a baseline to establish the effectiveness of subsequent treatment".

American Academy of Sleep Medicine (AASM) Practice Parameters. Kushida et al. Sleep. 29:24-243, 2006

AASM Practice Parameters

- Treatment Objective for OSA-Standard
  - "For patients with OSA, the desired outcome of treatment includes the resolution of the clinical signs and symptoms of OSA and normalization of the apnea-hypopnea index and oxyhemoglobin saturation."

American Academy of Sleep Medicine (AASM) Practice Parameters. Kushida et al. Sleep. 29:24-243, 2006

AASM Practice Parameters

- Treatment Objective for Snoring- Standard
  - "For patients with primary snoring without features of OSA or upper-airway resistance syndrome, the treatment objective is to reduce the snoring to a subjectively acceptable level."

American Academy of Sleep Medicine (AASM) Practice Parameters.
Kushida et al. Sleep. 29:24-243, 2006

AASM Practice Parameters

- Indication for Oral Appliances- Guideline
  - "Although not as efficacious as CPAP, oral appliances are indicated for use in patients with mild to moderate OSA who prefer oral appliances, or who do not respond to CPAP, and are not appropriate candidates for CPAP, or who fail treatment attempts with CPAP."
    - "Oral appliances are particularly more likely to succeed when OSA is positional and with lower BMI."

American Academy of Sleep Medicine (AASM) Practice Parameters.
Kushida et al. Sleep. 29:24-243, 2006

AASM Practice Parameters

- Follow-up for OSA: Guideline
  - "To ensure satisfactory therapeutic benefit from oral appliances, patients with OSA should undergo polysomnography or a home sleep study with the oral appliance in place after final adjustments."

American Academy of Sleep Medicine (AASM) Practice Parameters.
Kushida et al. Sleep. 29:24-243, 2006

AASM Practice Parameters

- Follow-up for Snoring: Guideline
  - "Follow-up sleep testing is not indicated for patients with primary snoring."

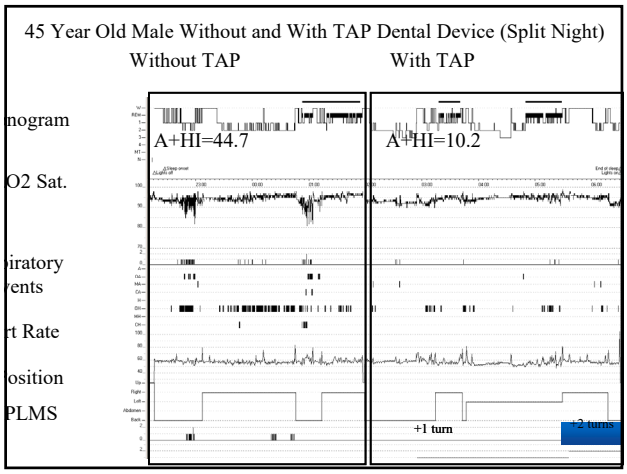
American Academy of Sleep Medicine (AASM) Practice Parameters.
Kushida et al. Sleep. 29:24-243, 2006

AASM Practice Parameters

- Options
  - Cephalometric X-Rays
  - Long-term follow-up with dentist
    - Every 6 months for first year
    - Annually thereafter
  - Long-term follow-up with sleep specialist
    - Assess clinical signs and symptoms of worsening OSA.

American Academy of Sleep Medicine (AASM) Practice Parameters.
Kushida et al. Sleep. 29:24-243, 2006

45 Year Old Male Without and With TAP Dental Device (Split Night)



Same Patient with CPAP Instead of TAP Dental Device

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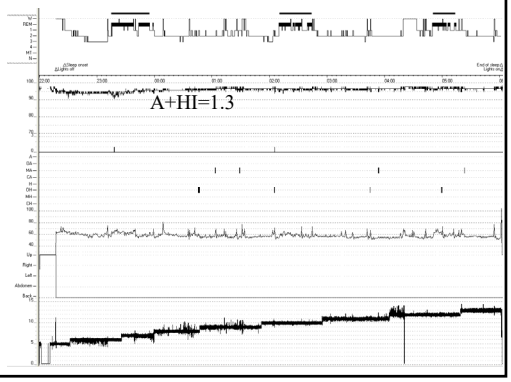

Split Night with TAP Dental Device

TAP Dental Device

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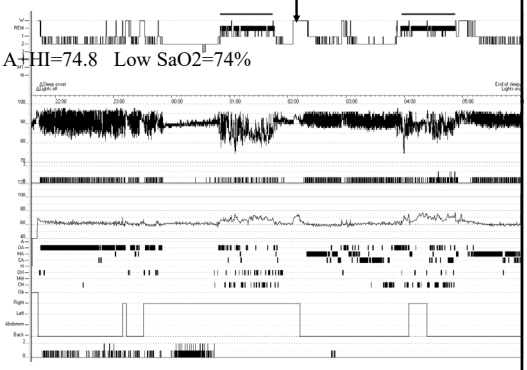


Matrx/Matrx Plus

Therapies for OSA

- Background
- CPAP Therapy
- Medical Therapies
- Oral Appliances
- **Surgical Therapies**
- Comprehensive Approach (OSMI Protocol)

OSA

What are the surgical options?

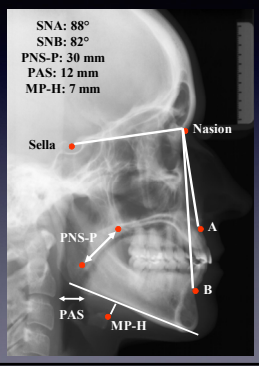
Answer:
Depends on the craniofacial anatomy and the OSA severity.

Level of Airway Obstruction

What is the anatomic level of airway obstruction?

- **Type I** Airway: Obstruction to the airway is at level of soft palate or nasal passages.
- **Type II** Airway: Obstruction to airway involves both soft palate and retrolingual posterior airway space (PAS)
- **Type III** Airway: Obstruction to airway isolated to retrolingual PAS (often seen in Class II).

Cephalometric X-Rays



SNA: Angle from sella to nasion to maxilla (82°)
SNB: Angle from sella to nasion to mandible (80°)
PNS-P: Length of the velum of the soft palate (<35-40 mm)
PAS: Posterior airway space (>11mm)
MP-H: Distance between mandibular plane and hyoid (<15mm)

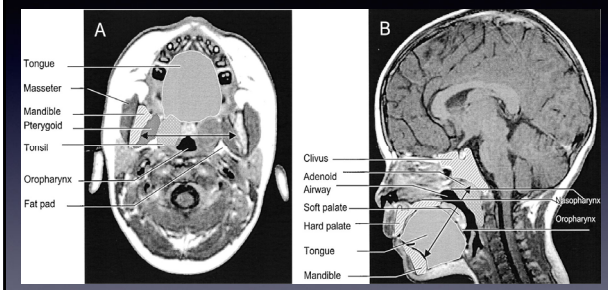
Tonsillar Hypertrophy

•Leading cause of OSA in the pediatric population
•Causes Type I airway obstruction (level of soft palate)

Tonsil size is graded from 0 to 4

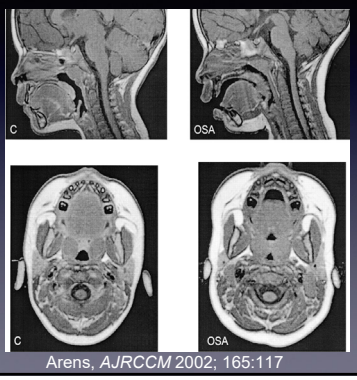
0	1	2	3	4
Surgically Removed	Tonsils hidden Within pillars	Tonsils extend to the pillars	Tonsils extending beyond the pillars	Tonsils extend to midline

Upper Airway MRI



Arens, *AJRCCM* 2002; 165:117

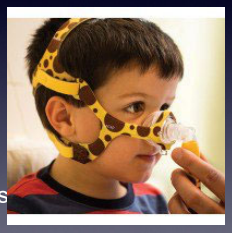
Upper Airway MRI of Control vs OSA Patient



Arens, *AJRCCM* 2002; 165:117

Management of Pediatric OSA

- T&A
- CPAP
- Weight loss
- Tracheostomy
- Future directions
  - Orthodontic procedures
  - Medications



CPAP

Surgical Options for OSA

Type I Obstruction

- Nose
  - Septoplasty
  - Turbinate reduction
- Soft Palate
  - Uvulopalatopharyngoplasty vs Pharyngoplasty
  - Pillar Palatal Implant
  - Other: Somnoplasty, Laser-Assisted Uvulopalatoplasty (LAUP)

Type III Obstruction

- Tongue
  - Genioglossus Advancement (GA) & Hyoid Myotomy/advancement
  - Radiofrequency tongue base reduction
- Mandible or Maxilla
  - Maxillomandibular osteotomy (MMO) with advancement
  - Maxillomandibular Expansion (Palatal expander)

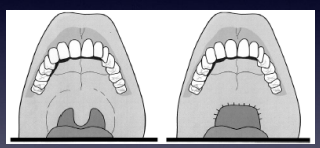
Nasal Reconstruction

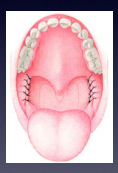
- Septoplasty and Turbinate Reduction
  - Most common nasal surgical procedures
    - Septoplasty for deviated nasal septum
  - Limitation: Only slight improvements in A+HI
  - Usefulness in patients with marked nasal obstruction as isolated anatomical airway limitation in mild sleep-disordered breathing.
  - Potential to improve CPAP compliance in patients with chronic nasal congestion.
    - Potentially may decrease CPAP pressure requirements in some patients.

Uvulopalatopharyngoplasty (UPPP)

- Most common surgical procedure for OSA, however has phased out in favor of pharyngoplasty
- Enlarges retropalatal airway
- Best outcomes in patients with Type I airway.
  - Apnea Index (AI) reduced 75% for Type I airway, versus 23% for Type II or III airways.
- Limitation:
  - A+HI reduced by only 33% for Type I airway.
  - A+HI reduced only 7% for Type II & III.
- Surgical complications
  - Velopharyngeal insufficiency (VPI), postoperative bleeding, voice change, dry throat.

UPPP vs Pharyngoplasty





DISE

- Reliability[1]
- Staging systems (ie VOTE)[2]
- Changes surgical plan (62%)[3]
- European position paper[4]

[1]Vroegop AV et al. Observer variation in DISE: experienced vs non-experienced ENT surgeons. *Sleep* 2013: *36:947-53.*

[2]Kezirian et al. Drug-induced sleep endoscopy: the VOTE classification. *Eur Arch Otorhinolaryngol Head Neck Surg* 2011; 268:1233-6.

[3]Gillespie et al. A trial of drug-induced sleep endoscopy in the surgical management of sleep-disordered breathing. *Laryngoscope* 2012.

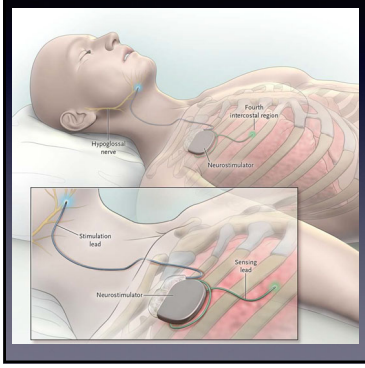
Methods of DISE

VOTE classification

	DIRECTION		
LEVEL	A-P	LATERAL	CONCENTRIC
Velum			
Oropharynx			
Tongue Base			
Epiglottis			

Kezirian EJ, Hohenhorst W, de Vries N. Drug-induced sleep endoscopy: the VOTE classification. Eur Arch Otorhinolaryngol 2011Aug;268(8):1233-6. Epub 2011 May 26.
Hohenhorst W, Eeversdorf MJL, Kezirian EJ, de Vries N. Drug-Induced Sleep Endoscopy in adults with Sleep Disordered Breathing. Technique and the VOTE Classification System. Operative Techniques in Otolaryngology-Head and Neck Surgery. Epub 2012 23;3-10

Implantable hypoglossal nerve stimulation system



Upper Airway Stimulation Therapy Indications*

- Adults 22 years of age and older
- Diagnosed OSA with an AHI range of 15-65 per hour
- CPAP failure or inability to tolerate CPAP treatment:
  - PAP failure is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage)
  - PAP intolerance is defined as inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night)
  - Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it)
- Appropriate airway anatomy

* Indications initially approved by the United States Food & Drug Administration April 2014

Pre-op Anatomical Assessment
Drug Induced Sleep Endoscopy (DISE) Examples

Complete AP Collapse at Palate

Good Candidate

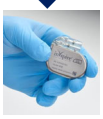
Complete Concentric Collapse at Palate

Not a good candidate

Upper Airway Stimulation Therapy Care Pathway

Patient Screening

Endoscopy (DISE) & Inspire Procedure



Activation: Daytime Clinic Visit

Inspire Sleep Remote

Titration: Nighttime Lab Visit/PSG

Inspire Programmer

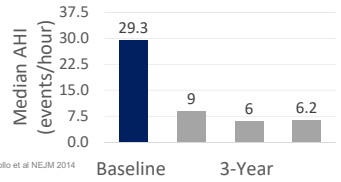
Long-Term Care Management

Inspire Cloud

STAR Trial Overview – 5 Year Follow-Up Complete

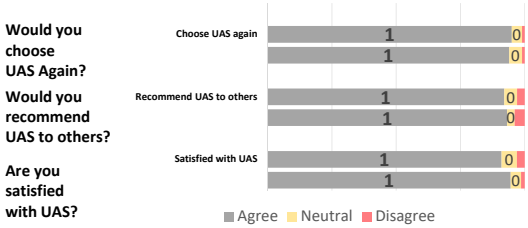
- STAR Trial Design
  - Multi-center prospective
  - 126 patients at 22 centers
  - Randomized Control Therapy Withdrawal ARM

12 month STAR results published in the *New England Journal of Medicine, 2014*

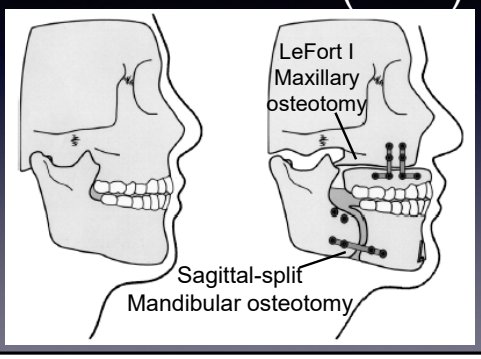


Strollo et al NEJM 2014

Patients Report High Overall Therapy Satisfaction

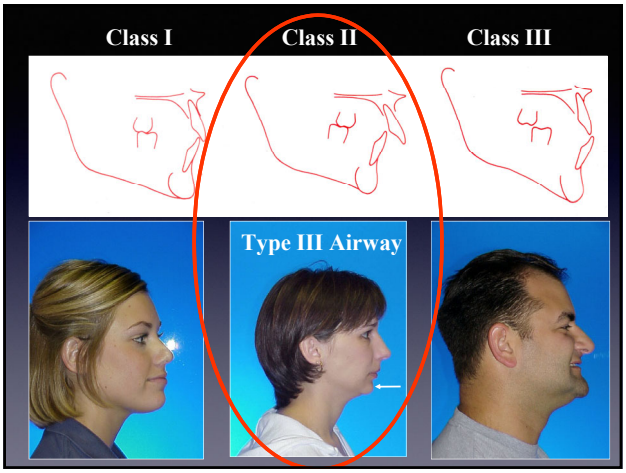


Maxillary and Mandibular Advancement (MMA)



MMA

- Provides maximal enlargement of the retrolingual airway and some enlargement of retropalatal airway.
  - Type III benefit > Type I.
- Maxilla and mandible are advanced simultaneously.
  - Maxillary advancement allows for greater mandibular advancement.
- Often performed as a “phase II” procedure after unsuccessful UPPP or GAHM.
  - Stanford Protocol.



MMA: Outcomes

- Provides best success in treating OSA when compared to all other surgical procedures.
- Controversial if should be done with or without additional adjunctive surgical procedure, i.e., UPPP, GAHM, etc.

MMA

- Preserves “functional integrity” of pharyngeal tissues.
- ↓ surgical risk due to minimal edema within airway and pharynx.
- Skeleton is rigidly fixated limiting motion during swallowing etc., therefore pain is ↓.

MMA Advantages

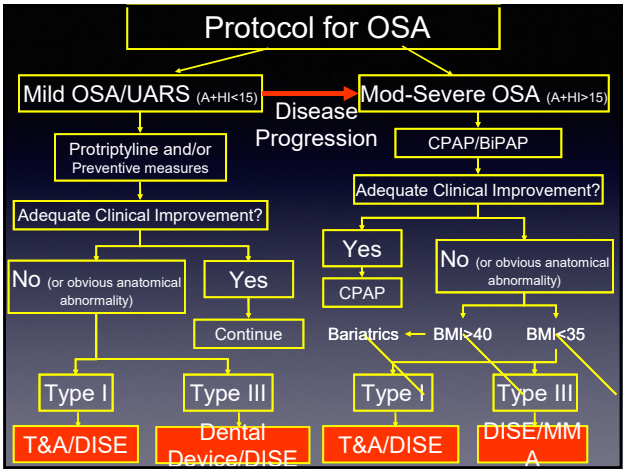
- Treats entire velopharyngeal complex.
- However, does not operate within the VOP complex.
- One time cost ↓ multiple surgical interventions.
- MMO at early age will ↓ OSA related health risks.

MMA Quality of Life

- Short hospital stay
- Minimal discomfort (short term or long term).
- Generally no need for post-op CPAP.
- MMO improves facial esthetics.
- Most return to full-time work in 2 weeks.
- Immediate improvement in OSA symptoms.

Therapies for OSA

- Background
- CPAP Therapy
- Medical Therapies
- Oral Appliances
- Surgical Therapies
- **Comprehensive Approach (OSMI Protocol)**



Future Directions

- Pediatric OSA
  - Palatal Expander
  - Herbst Appliance
- Other….

Rapid Maxillary Expansion (Palatal Expander) in Children with OSA

- 31 children with mean age of 8.7 years participated in study.
- Mean A+HI was 12.2 at baseline.
- Palatal expander worn for 4 months and increased expansion of maxilla by 4.3±0.7 mm and improved nasal airflow.
- A+HI improved to less than 1 for all children at four month follow-up per PSG.
  - Pirelli, Saponara and Guilleminault. *SLEEP*. 27:761-766, 2004.

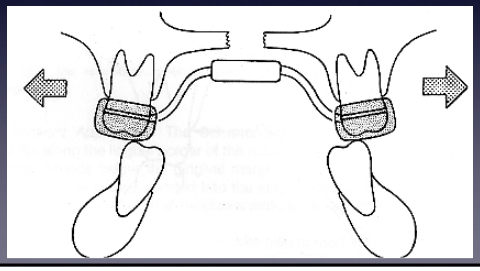
Palatal Expansion


Pre-Expansion (AM.S)


Post-Expansion (AM.S)

Palatal Expansion in Children with OSA

Expansion of midline suture in upper jaw using a palatal expander



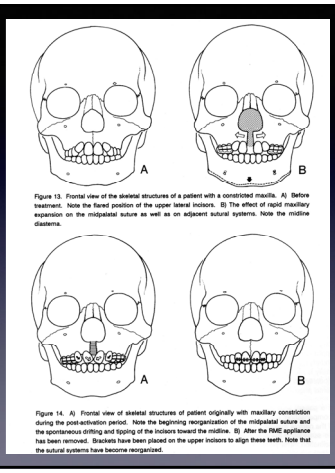


Figure 13. Frontal view of the skeletal structures of a patient with a constricted maxilla. A) Before treatment. Note the flared position of the upper lateral incisors. B) The effect of rapid maxillary expansion on the midpalatal suture as well as on adjacent sutural systems. Note the midline diastema.

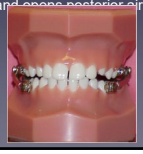
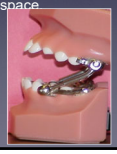
Figure 14. A) Frontal view of skeletal structures of patient originally with maxillary constriction during the post-activation period. Note the beginning reorganization of the midpalatal suture and the spontaneous drifting and tipping of the incisors toward the midline. B) After the RME appliance has been removed. Brackets have been placed on the upper incisors to align these teeth. Note that the sutural systems have become reorganized.

Palatal Expansion

↑ for teeth
↑ width upper jaw
Improves nasal air flow
↑ Space for tongue

Herbst Appliance


- Wo
  - F
- Pos ard
  - R mandible during
  - Moves tongue forward and opens posterior airway space

Didgeridoo Playing as Alternative Treatment for OSA

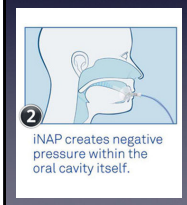
Puhan et al. *BMJ*, 2005.

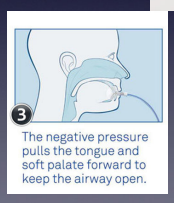
- Randomized controlled trial.
- 25 patients with A+HI 15-30.
- Didgeridoo Group

Lessons and daily practice at home for 4 months for at least 20 minutes per day.

- Control group did not learn to play the didgeridoo.
- A+HI significantly improved in the didgeridoo group.
- Conclusion: Didgeridoo playing decreases upper airway collapsibility by improving upper airway muscle tone.

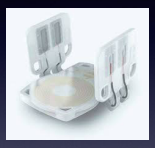
iNAP

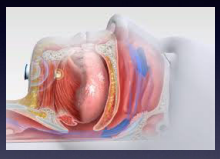




Not FDA approved

Nyxoah (not FDA approved)





Summary

- OSA has serious long-term consequences.
- CPAP therapy is gold standard.
  - Be skeptical of “CPAP failure.”
- Alternatives to CPAP must be specific to patient’s needs.
- Dental devices are an option, but require close co-operation with Sleep Medicine specialist.
  - Need sleep physician with understanding of alternatives to CPAP to coordinate best treatment approach for the patient.