An Update on Oral Appliances

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Conflict of Interest Disclosure

I, Todd Morgan, hereby declare that the content for this activity, including any presentation of therapeutic options, is well balanced, unbiased, and to the extent possible, evidence-based.

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I own intellectual property in: **Apnea Guard Trial Appliance**

Lecture Goals

- Evidence supporting OAT
- Practice Guidelines
- How do oral appliances work?
- When do they work?
- How can we improve?

Sleep Med Clin. 2016 Jun;11(2):173-87. doi: 10.1016/j.jsmc.2016.03.001.
Novel Approaches to the Management of Sleep-Disordered Breathing.
Morgan TD[1].

A Collaborative Effort: Where does the dentist fit in?

- The MD/DDS relationship
- Treatment options for patients
- When to deploy Oral Appliance Therapy?

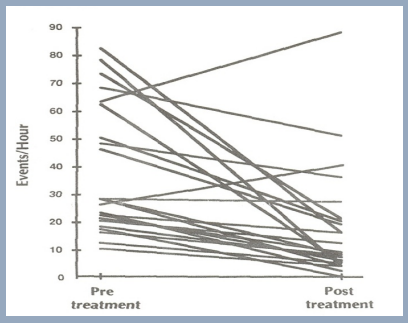
PIONEERS TO SETTLERS

- Research
- Acquiring a better understanding of anatomy and physiology of the sleeping airway
- Using all the tools available to personalize
- Phenotyping models
- Proof of concept

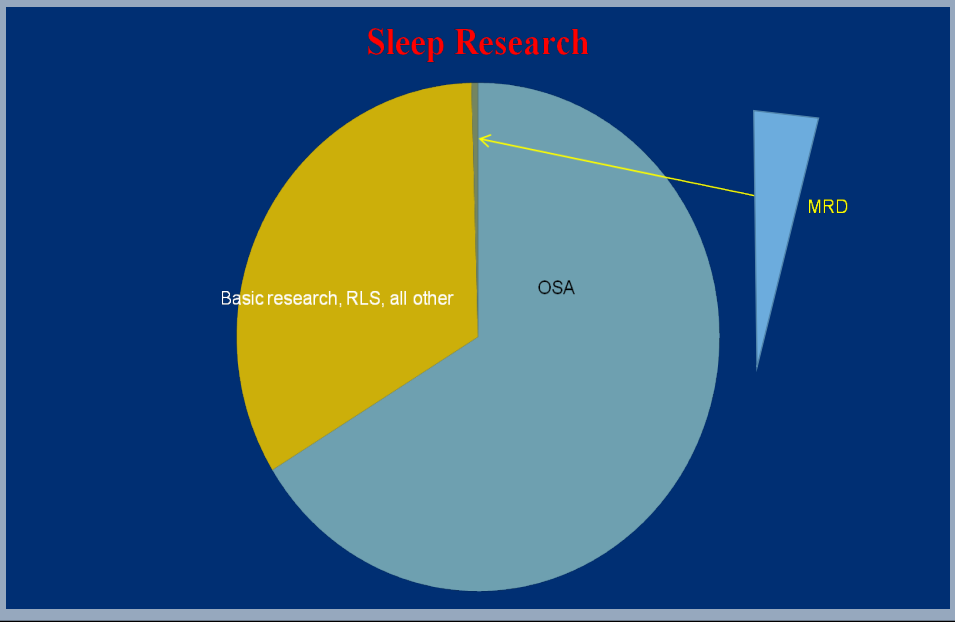
"They want to know if they can have their arrows back."

Early Experience OAT

- Simple single position, customized device
- "ramp" for lower front teeth to maintain jaw protrusion
- Worsened OSA in some?

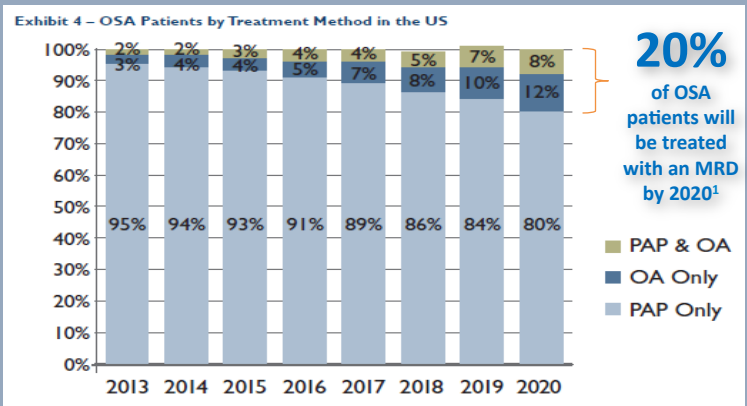


Menn SJ, Loube DI, Morgan TD, Mitler MM, Berger JS, Erman MK. **The mandibular repositioning device: role in the treatment of obstructive sleep apnea.** Sleep. 1996 Dec;19(10):794-800.



Oral Appliance Market Trends

- The oral appliance market is projected to grow exponentially as patient education on product use as well as increased clinician training continues to advance[1]

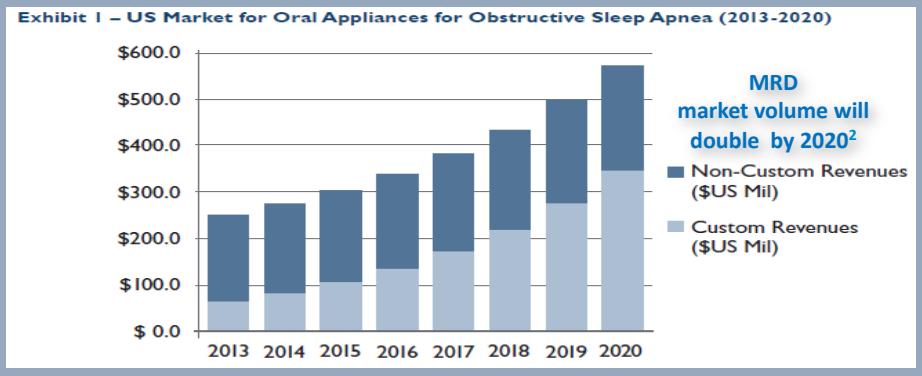


[1] Frost & Sullivan, Vital Signs, The Price of a Good Night's Sleep: Insights into the US Oral Appliance Market, January, 2015

ResMed

Oral Appliance Market Trends

- Over the past decade, the body of scientific evidence addressing the use of oral appliance therapy and associated clinical outcomes has grown considerably[1]
- The U.S. oral appliance market for OSA is projected to double by the year 2020[2]



[1] Ramar, K. et al., *Journal of Clinical Sleep Medicine*, Vol. 11, No. 7, 2015.
[2] Frost & Sullivan, Vital Signs, The Price of a Good Night's Sleep: Insights into the US Oral Appliance Market, January, 2015

ResMed

Oral Appliance Therapy: Clinical Practice Guidelines 2015

- Jointly Commissioned: AASM, AADSM *
- 1995- Case studies only
- 2005- 10 level I studies
- 2015- 51 RCTs

Ramar K, Dort LC, Katz SG, Lettieri CJ, Harrod CG, Thomas SM, Chervin RD. **Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015**. Journal of Dental Sleep Medicine 2015;2(3):71– 125.

Oral Appliance Therapy: *Recommendations* Clinical Practice Guidelines 2015

- MD: Diagnosis and treatment of OSA
- CPAP is first option
- DDS: Select appropriate custom and titrateable device
- Collaborative follow-up is key to success

- Choose One Name PLEASE!

Ramar K, Dort LC, Katz SG, Lettieri CJ, Harrod CG, Thomas SM, Chervin RD. **Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015**. Journal of Dental Sleep Medicine 2015;2(3):71– 125.

What do you call this thing?

- Jaw Advancement Device
- Oral Pharyngeal Dilator
- Mandibular Advancement Splint
- Mandibular Advancement Device
- Mandibular Repositioning Device
- "Bit" -J.S. Poceta

- OAT…

Historical Evidence for MRD Efficacy

- 1982-2006 89 publications on MRD
- 3,027 patients
- Overall success rate 54%
- Criteria: AHI reduced by 50%, or to less than 10
- Side effects are relatively frequent, but minor

- **TMJ complications were rare**

Hoffstein V, **Review of oral appliances for treatment of sleep-disordered breathing.** Sleep Breath. 2007 Mar;11(1):1-22.

Summary or Position Papers on MRDs

What are the common recitals?

Oral Appliances are indicated in mild and moderate OSA

Or, those unwilling to use PAP

A multi-disciplinary approach to care is recommended…

YEAR				CONCLUSION
2006	Lim J, et al	*Oral appliances for OSA – Cochrane Database*	**Royal Surrey County Hospital**	recommend MRD therapy to patients with mild sympathetic OSA, or those unable/unwilling to tolerate CPAP therapy
				Short-term side-effects are common but usually
2005	Kushida CA, Morgenthaler, Littner MR	*Practice parameters for the treatment of snoring and OSA with oral appliances: An update for 2005*	**SLEEP**	MRD's indicated for use in patients with mild to moderate OSA who prefer them to CPAP therapy, or fail treatment attempts with CPAP therapy
2006	Ferguson, Cartwright, Rogers, Schmidt-Nowara			Literatue rev of OA therapy for OSA now provides better evidence for the efficacy of this treatment modality and guidance regarding frequency of adverse effects
2007	Chan AS, et al	*Dental appliance treatment for OSA*	**CHEST**	MRD's less efficacious than CPAP, but generally preferred by patients
2007	Schwarting S, et al	*Position paper on the use of mandibular advancement devices in adults with sleep related breathing disorders*	**DG ZS-German Society Dental Sleep Medicine**	Emphasis on interdisciplinary approach of MRD therapy and suggests treatment under guidance of dentists trained in sleep medicine
2011	Randerath, et al	*European Respiratory Society Task Force on Non-CPAP therapies in sleep apnoea*	**ERJ**	upported otomy seems as efficient as CPPA in patients who refuse conservative tx. UPPP, pillar implants and hyoid suspension should only be considered in selected pts where risk of lg term side effects are considered.

Walter Reed Army Medical Center Sleep Clinic

- **N = 497** patients, mean AHI = 30,
- An adjustable OA was *"ordered"* for patients who are set to deploy, even if they were already using CPAP
- Patients were instructed to self-advance their device (TAP) 0.25 mm each night as tolerated, with the goal of optimizing subjective sleep quality (diary)
- HST was used to check progress during titration
- Following at-home titration protocol a ***FINAL*** OA titration was scheduled (PSG)
- The device was then incrementally advanced by the patient to the final target setting determined by PSG (if different)
- The patients were followed by a Board certified sleep physician

Holley AB, Lettieri CJ, Shah AA **Efficacy of an adjustable oral appliance and comparison with continuous positive airway pressure for the treatment of obstructive sleep apnea syndrome.** Chest. 2011 Dec;140(6):1511-6.

Summary/Conclusions

- **N = 497** patients, mean AHI = 30,
- **MRD reduced AHI < 5** in 70.3% (mild), 47.6% (moderate), and 41.4% (severe)
- Using an AHI 10 as a cutoff: 86% (mild), 75% (moderate), 60% (severe)
- Complications were rare

Why are these outcomes better than previously seen?

Careful titration of OAT, through…

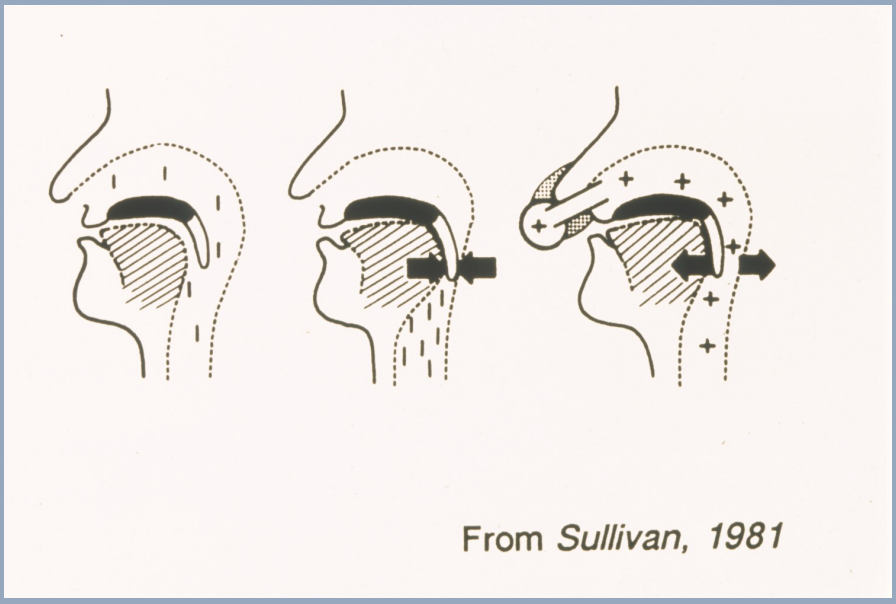
COLABORATION!

Holley AB, Lettieri CJ, Shah AA

Efficacy of an adjustable oral appliance and comparison with continuous positive airway pressure for the treatment of obstructive sleep apnea syndrome. Chest. 2011 Dec;140(6):1511-6.

CPAP is still the reigning champ!

When in doubt… pressurize the snout!



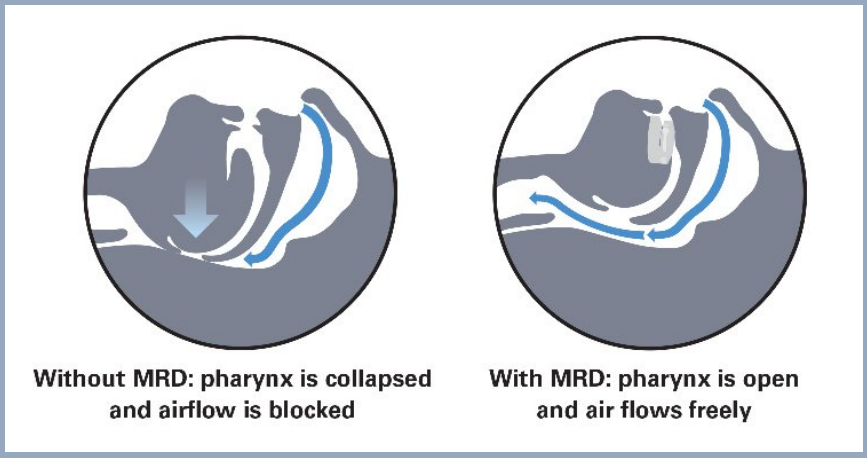
Basics of Airway Collapse: What is the significance of the role of muscles?

ANATOMICAL insufficiency

NEUROMUSCULAR response is inadequate or inappropriate

Surgeons share our frustrations!

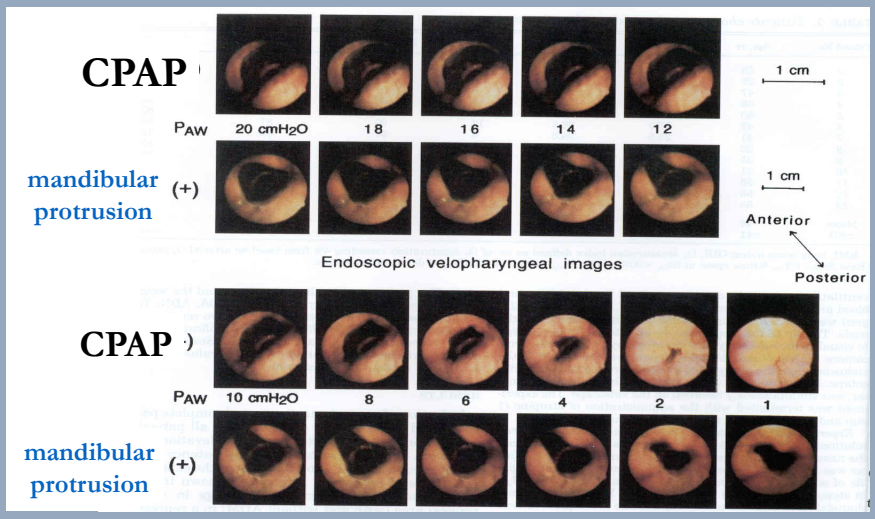
Is it really this simple?

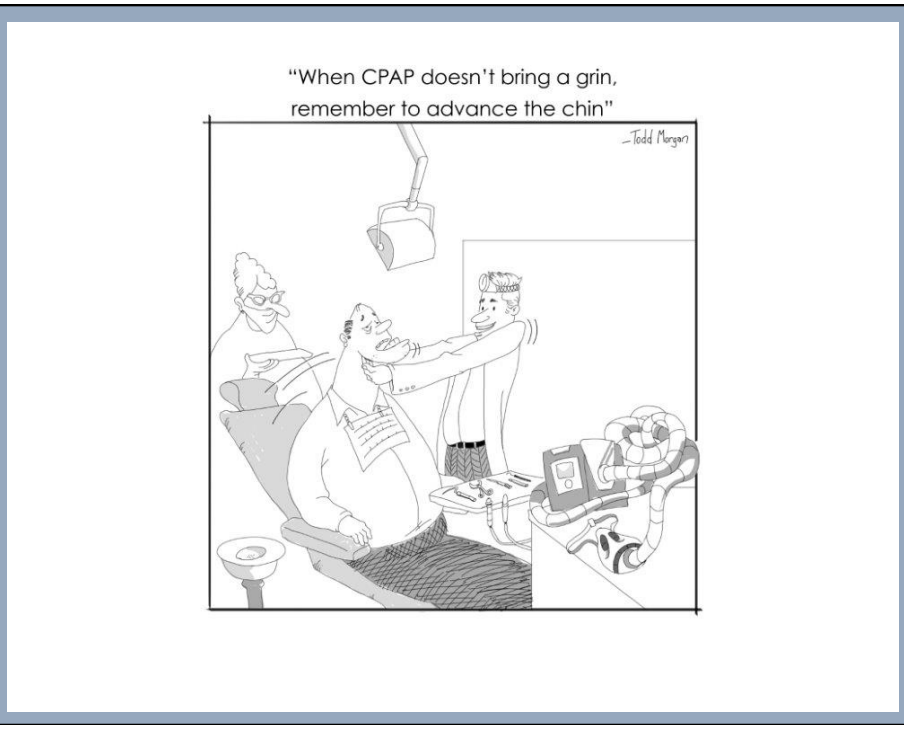


Without MRD: pharynx is collapsed and airflow is blocked

With MRD: pharynx is open and air flows freely

Comparing Effect of PAP to OA General Anesthesia (Isohno, et al)





Compare and Contrast OSA Causality

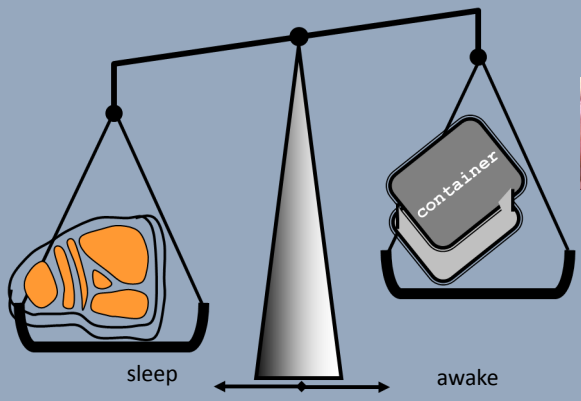
Patient A

- *AHI = 20*
- No snoring
- Obese
- Does not wake up @ nite
- Non-positional
- Epworth = 6
- A/H = 18/2

Patient B

- *AHI = 20*
- Loud snoring
- Lean
- Awakens @ nite
- Epworth = 17
- Nasal Allergies
- AM headache
- A/H = 2/18

Phenotyping Responders to OAT: The Beginnings



Amount of soft tissue

Size of bony enclosure

Neural mechanisms
(Pharyngeal dilator muscle contraction)

Isohno, et al

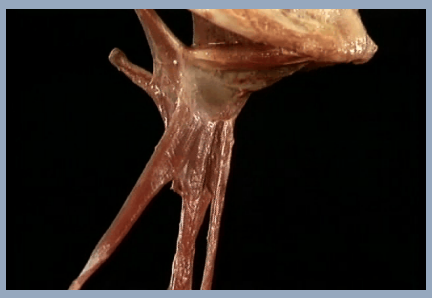
The Key to Identifying Oral Appliance Responders

How do Oral Appliances work?

What are the important anatomical factors?

Anatomical Relationships: Mandibular Advancement

- Insertion of the tongue into the mandible anteriorly (gg),
- Linkage of the soft palate to the tongue by insertion of the palatoglossus muscles into the sides of the tongue,
- Linkage of the palatopharyngeus muscles to the palatoglossus muscles through the palatine aponeurosis,
- Linkage of the superior and middle pharyngeal constrictors to the mandible via their insertion on the pterygomandibular raphe, a fibrous band that extends to the medial surface of the angle of the mandible.



OA Theoretical Mechanism of Action

Summary: Jaw Advancement

- pulls the base of the tongue forward, may increase gg tone
- pulls the soft palate forward and putting the walls of the upper airway under tension,
- keeps the mouth from falling open during sleep

These are primarily passive mechanical effects that may primarily allow decompression, accounting for *lateral expansion*

Cone Beam Imaging

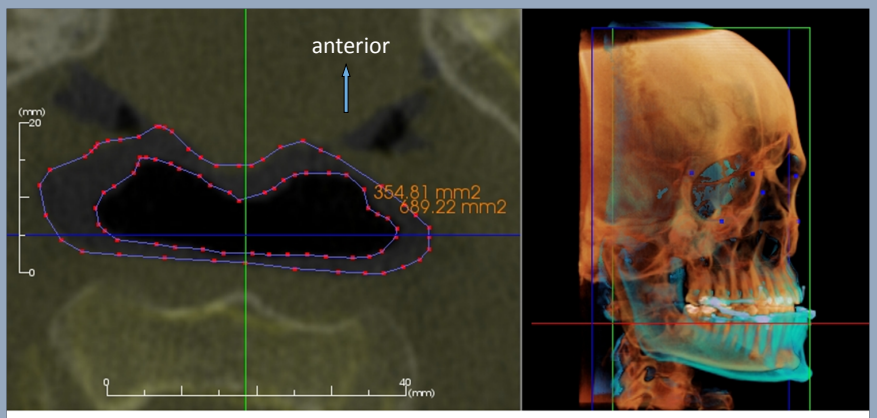
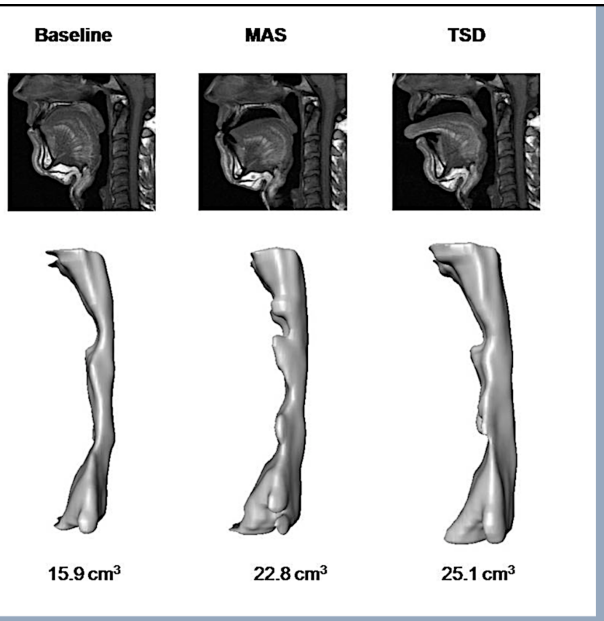


Image by Douglas L. Chenin, DDS. Director of Clinical Affairs, Anatomage. Adjunct Faculty, UOP Dental School Ortho. Dept.

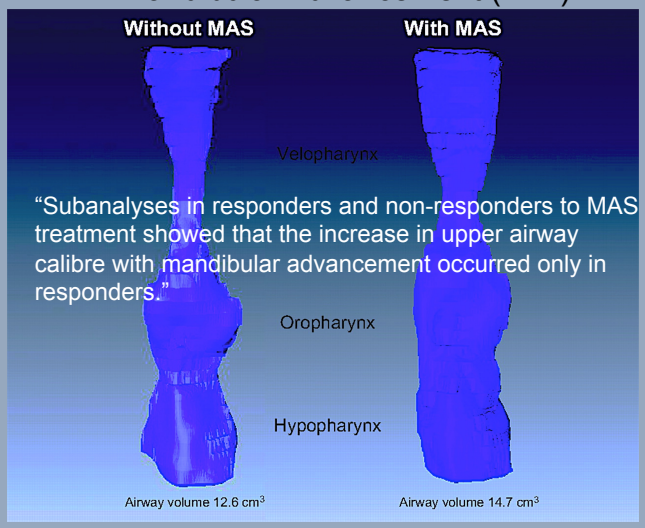


Sutherland et al. Sleep 34: 469-477, 2011

TSD = tongue stabilizing device

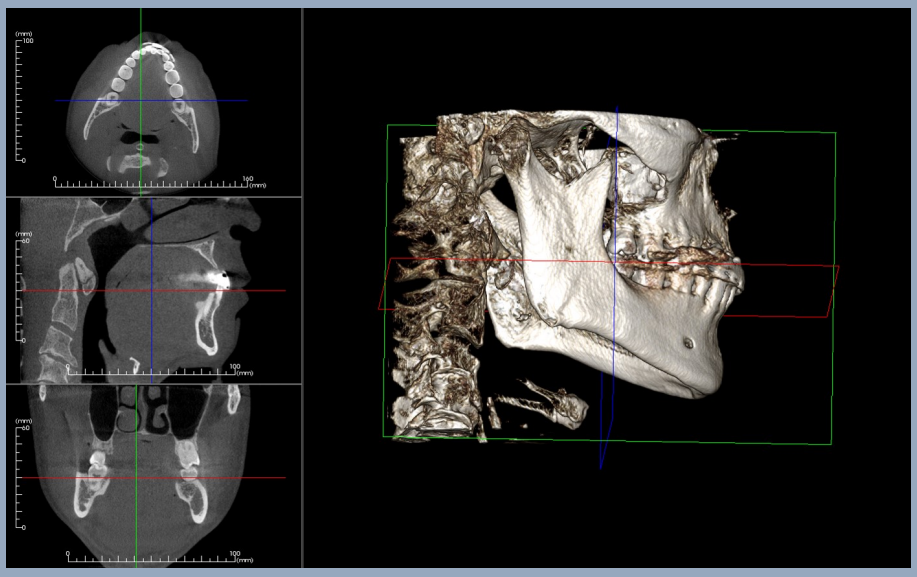
MAS = mandibular advancement splint

Volumetric Reconstructions of the Upper Airway in a Responder Showing the Increase in Caliber of the Upper Airway With Mandibular Advancement (MRI)

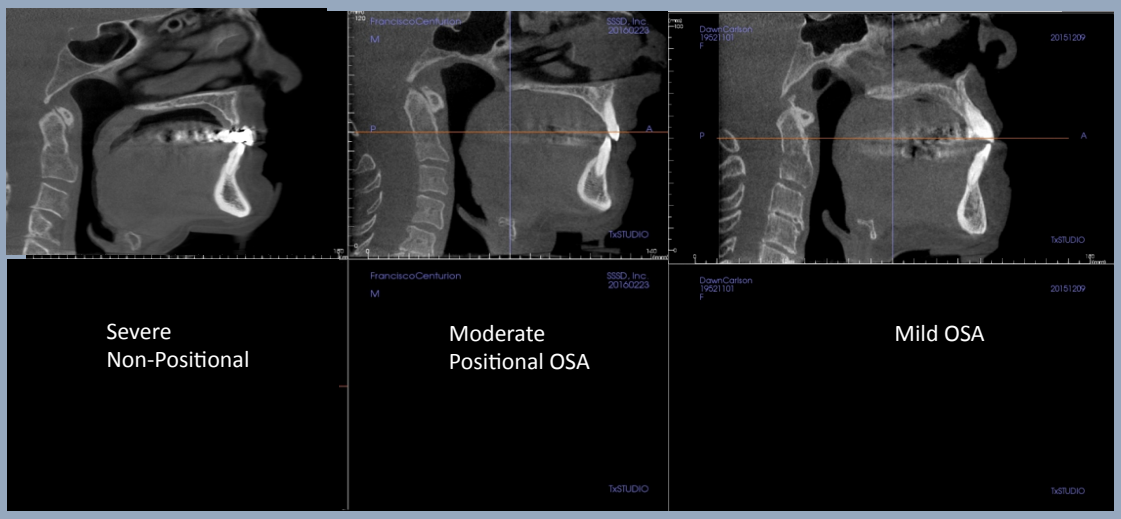


Chan et al. Thorax 2010;65:726-732

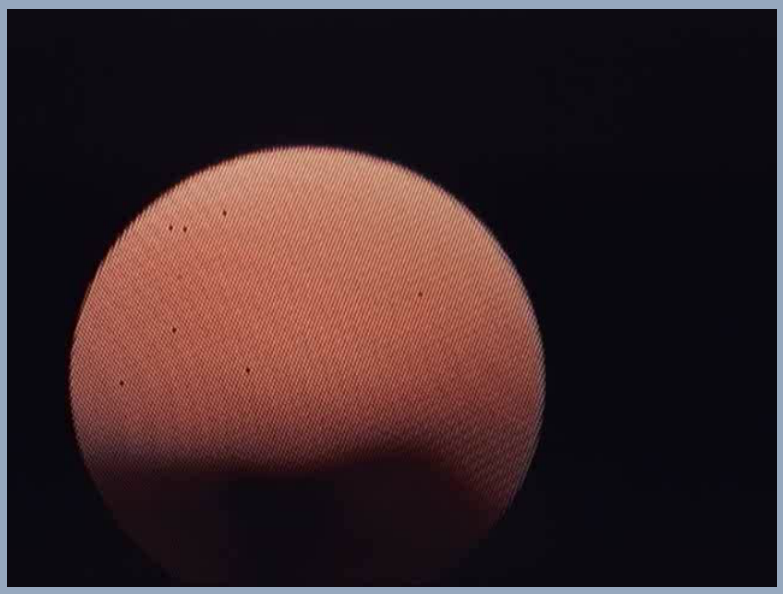
THORAX



CBCT: Hyoid Loses Density with Progression of Disease?



DISE



DISE: Helpful in Identifying Responders?

- N = 65
- Propofol-induced "Sleep" endoscopy
- 35 showed improvement in airway caliber with modest mandibular advancement
- 7 dropped out due to unsuitable dental conditions
- Epworth score improved: 7.35 ± 2.8 to 4.1 ± 2.2 ($p < 0.05$)
- AHI dropped: 21.4 ± 6 to 8.85 ± 6.9 ($p < 0.05$)
- ODI [(18.6 ± 8 events per hour to 7 ± 5.8 ($p < 0.05$)].
- Effective prediction of responders in 71% of candidates

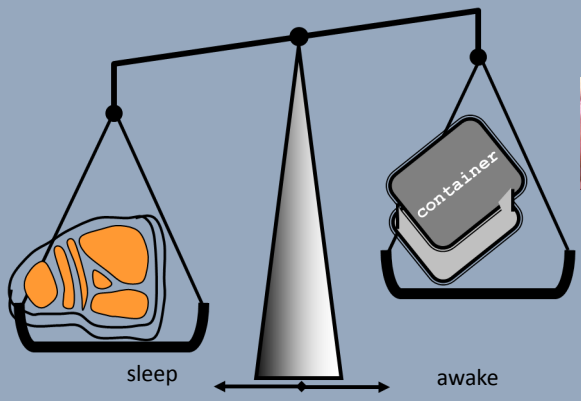
Drug-induced sleep endoscopy as a selection tool for mandibular advancement therapy by oral device in patients with mild to moderate obstructive sleep apnoea. Acta Otorhinolaryngol Ital. De Corso E, Bastanza G, Della Marca G 2015 Dec;35(6):426-32.

The Key to Identifying Oral Appliance Responders

How do Oral Appliances work?

What are the important anatomical factors?

Amount of soft tissue

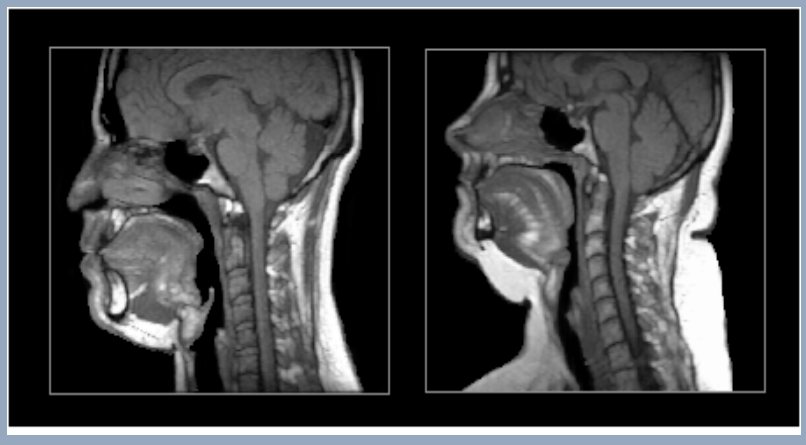


Size of bony enclosure

Neural mechanisms
(Pharyngeal dilator muscle contraction)

Isohno, et al

Obesity: Easy to Understand?

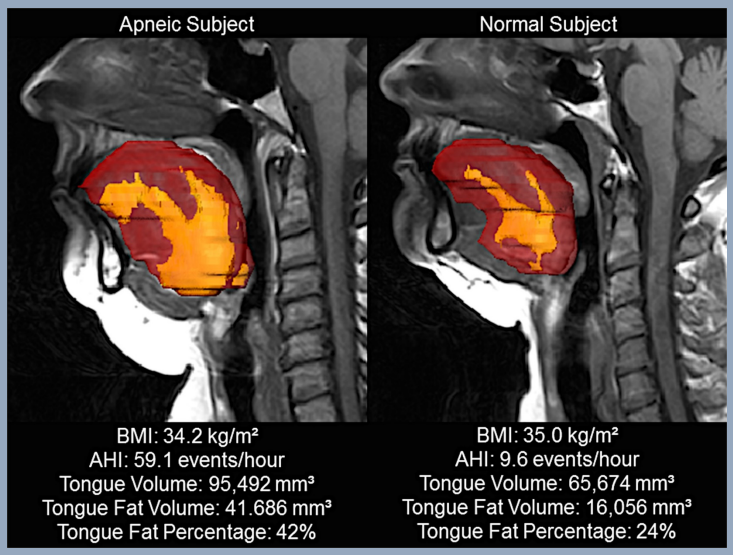


Normal subject

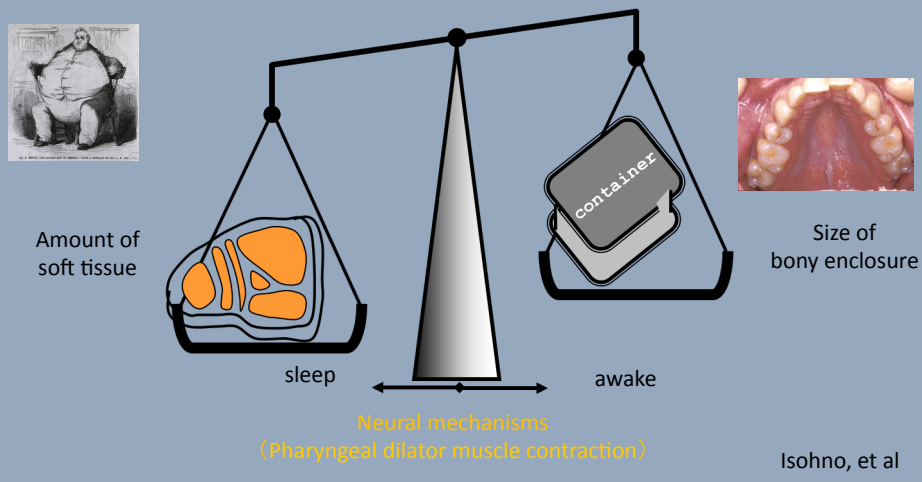
OSA patient

But wait, some obese folks have no OSA!

Schwab, R, et al

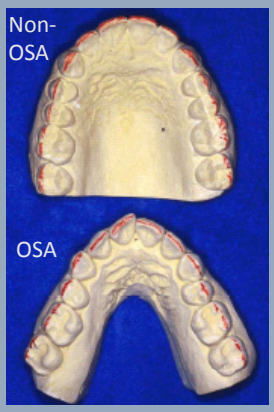


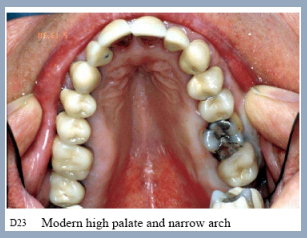
Tongue fat and its relationship to obstructive sleep apnea. Kim AM, Keenan BT, Jackson N, Chan EL, Staley B, Poptani H, Torigian DA, Pack AI, Schwab RJSleep. 2014 Oct 1;37(10):1639-48.



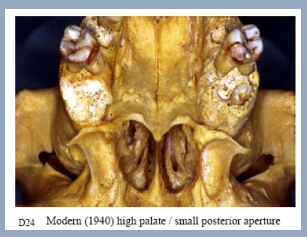
Anatomical Narrowing

10,000y





D23 Modern high palate and narrow arch



D24 Modern (1940) high palate / small posterior aperture

Photos courtesy of Brian Palmer, DDS

Stanford Morphometric Model

$P + (Mx - Mn) = 3 \times OJ + 3x (BMI - 25) \times (NC/BMI)$

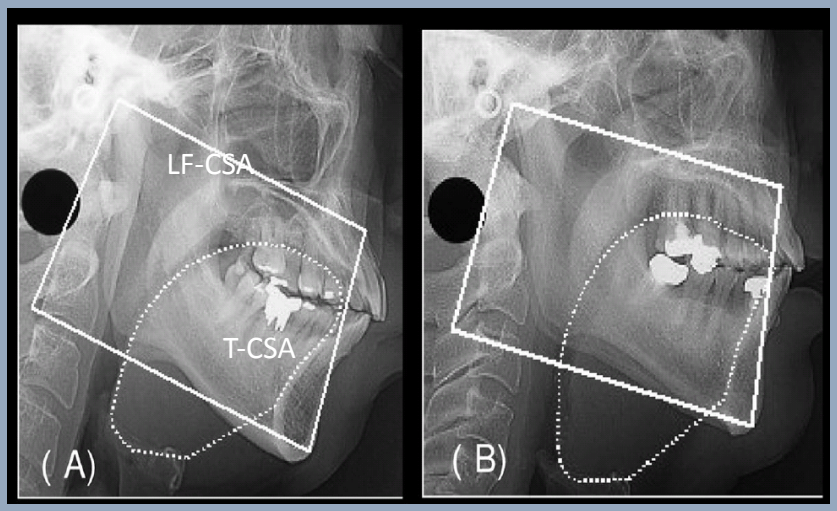
P = palatal height
Mx = maxillary intermolar distance
Mn = mandibular intermolar distance
OJ = overjet
NC = neck circumference
BMI = body mass index

"Model has clinical utility and predictive values for patients with suspected obstructive sleep apnea"

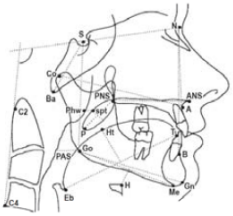
A predictive morphometric model for the obstructive sleep apnea syndrome. Kushida CA[1], Efron B, Guilleminault C. Ann Intern Med. 1997 Oct 15;127(8 Pt 1):581-7.

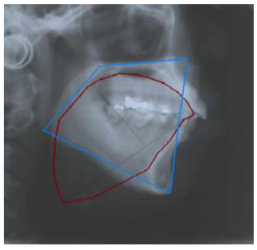
Pharyngeal "Footprint" of the Tongue is increased as the arch narrows

Control *versus* OSA

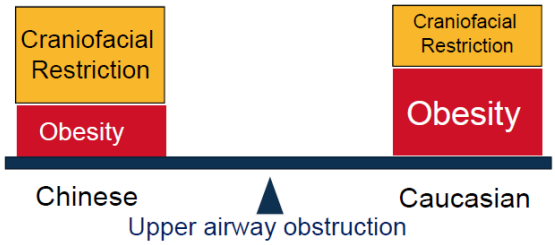


Tsuiki S, Isono S, et al, Anesthesiology, 2008



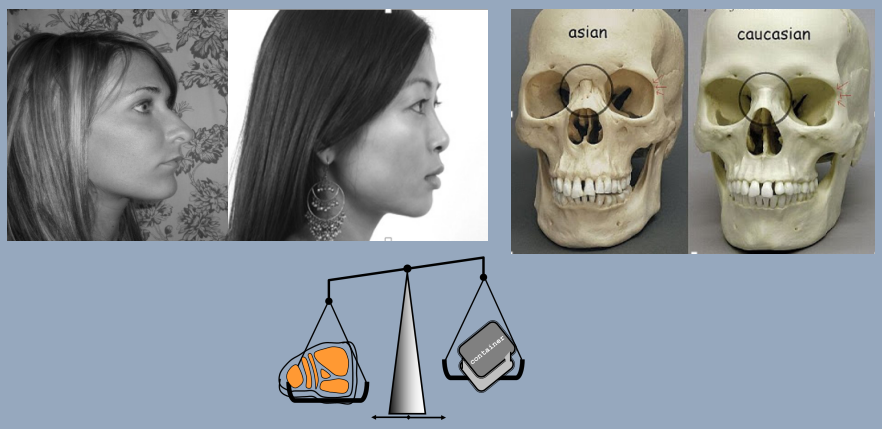


Ethnic differences in OSA risk factors



Lee et al. SLEEP, 2010

Racial Influence Over the Prevalence of OSA



Clinical Tip:
How do you spot a small container?

Clinical Tip: Just say "ahhh"

- Tongue Scalloping (PPV 81%) !!!
- Is it size of tongue?
- Or the container it's in?

2. Weiss TM, Atanasov S, Calhoun KH.
The Association of Tongue Scalloping With Obstructive Sleep Apnea and Related Sleep Pathology *Otolaryngology -- Head and Neck Surgery December 2005*

Modified Mallampati estimates the Anatomical Balance

1 2 3 4

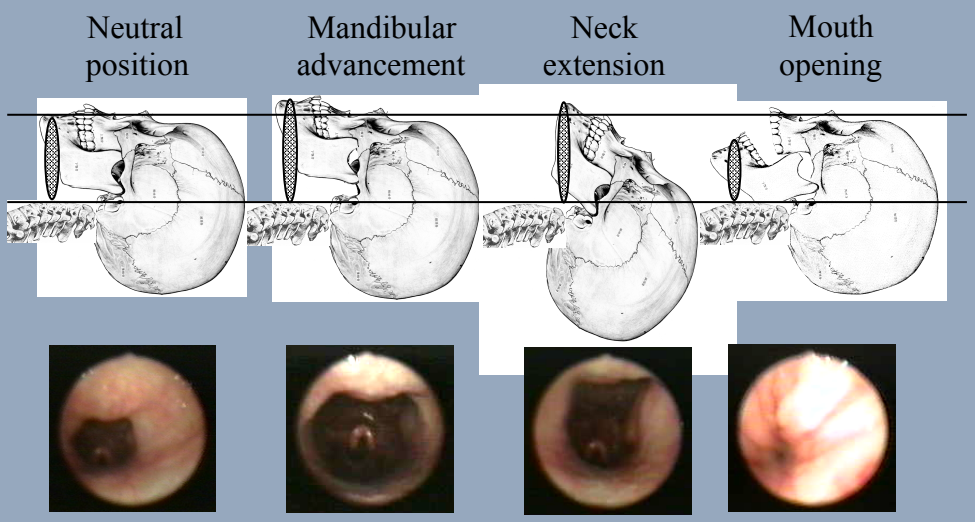
One point increase ➡ OSA risk doubles

Sleep. 2006 Jul;29(7):903-8. **Physical examination: Mallampati score as an independent predictor of obstructive sleep apnea.** Nuckton TJ[1], Glidden DV, Browner WS, Claman DM.

Best Outcomes: Summary

- Patient selection
- Appliance selection
- Determining optimal jaw positioning: Titration and testing

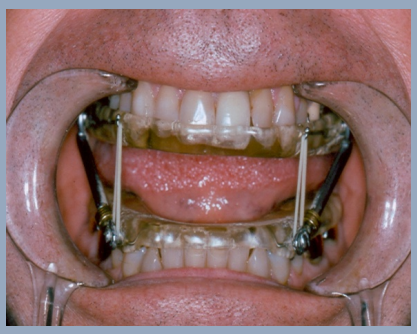
Bony enclosure size changes with changing head and neck position within a subject. Therefore, anatomical balance changes.

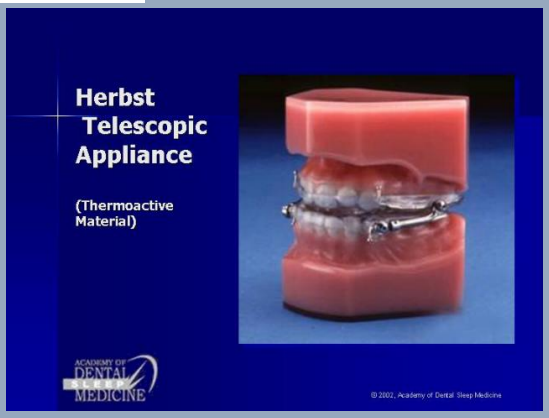


Velopharyngeal airway images

Isono et al., (J Appl Physiol, 2004)

Appliance Selection

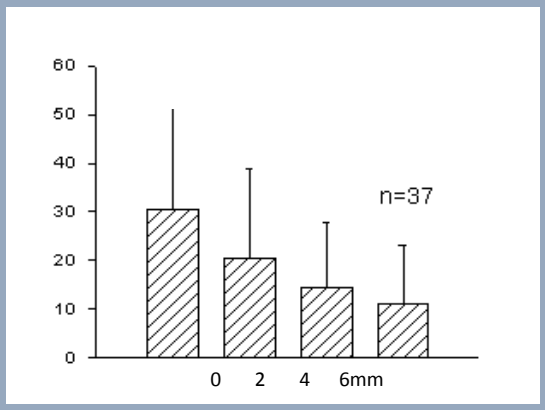




Key points: Oral Appliance Titration

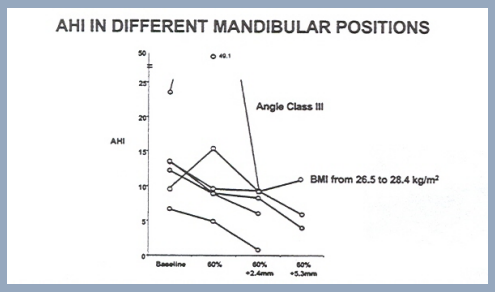
- Subjective vs. objective titration
- Sleep study-guided oral appliance titration
- Overnight OA calibration: HST, Matrix, Trial Oral Appliances

Mandible advancement dose-dependently improves SDB in OSA patients



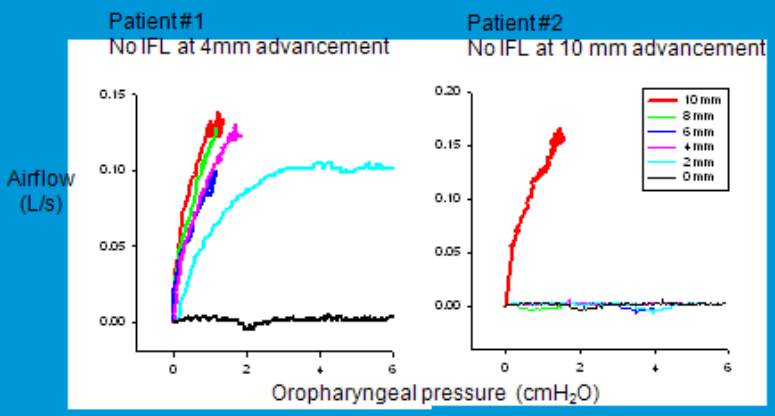
Chest. 2000 Apr;117(4):1065-72. **Dose-dependent effects of mandibular advancement on pharyngeal mechanics and nocturnal oxygenation in patients with sleep-disordered breathing.** Kato J[1], Isono S, Tanaka A, Watanabe T, Araki D, Tanzawa H, Nishino T

Early Experiences: Titration



Am J Orthod Dentofacial Orthop. 2004 May;125(5):548-55. **Effects of an anteriorly titrated mandibular position on awake airway and obstructive sleep apnea severity.** Tsuiki S[1], Lowe AA, Almeida FR, Fleetham JA.

Preliminary results



(unpublished)

courtesy: Shiroh Isono

Use repeated studies to optimize titration aka: "The slow crawl to open airway"

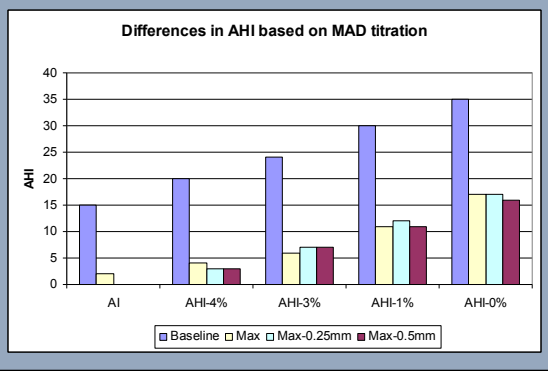
Sixty-two year old male with hypertension and moderate OSA completed four x 2-night studies:

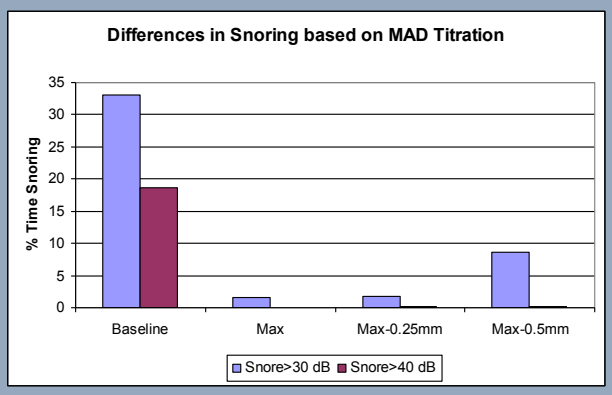
1) prior to treatment,

2) at maximum acceptable jaw protrusion,

3) 0.25 mm less than maximum,

4) 0.5 mm less than maximum.





One quarter of a millimeter!

Prospectively Identifying Responders to OAT

- Technician Directed Jaw Positioning
- Trial Devices + Sleep Study

Matrix® System

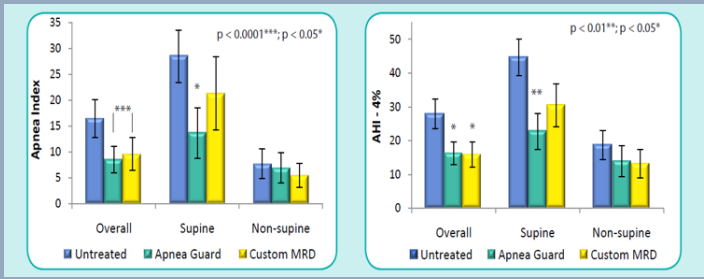
OTC Snore Guards

"Just try one of those ones on the internet"

Apnea Guard® Trial Oral Appliance

- Expandable tray, customized fitting
- Fitted in 10 minutes
- FDA cleared for 30 days
- E0485

Apnea Guard Validation Trial



- N = 15
- Custom device had been optimally titrated using repeated HST
- Trial device set by written protocols to predicted jaw position
- Apnea Guard demonstrated equivalency to custom device and comparably reduced AI and AHI, superior to custom in supine position

Levendowski DL, Morgan T et al. Initial Evaluation of a Titration Appliance for Temporary Treatment of Obstructive Sleep Apnea J *Sleep Disord Ther* 2011

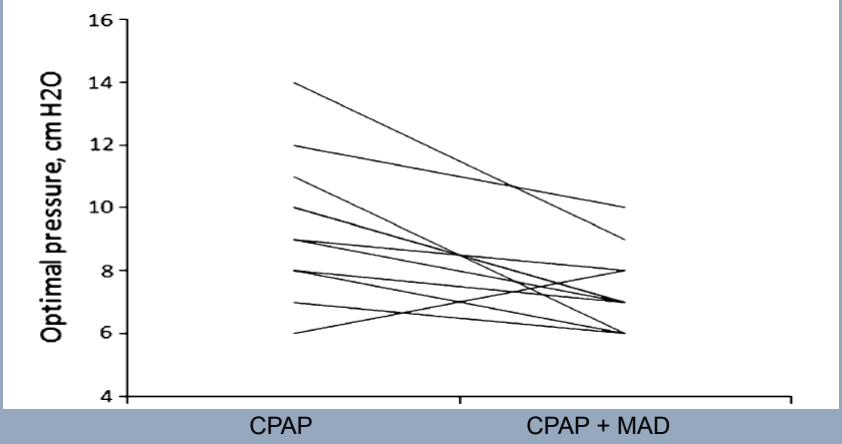
OAT + PAP = COMBO

Combined oral appliance and positive airway pressure therapy for obstructive sleep apnea: a pilot study.

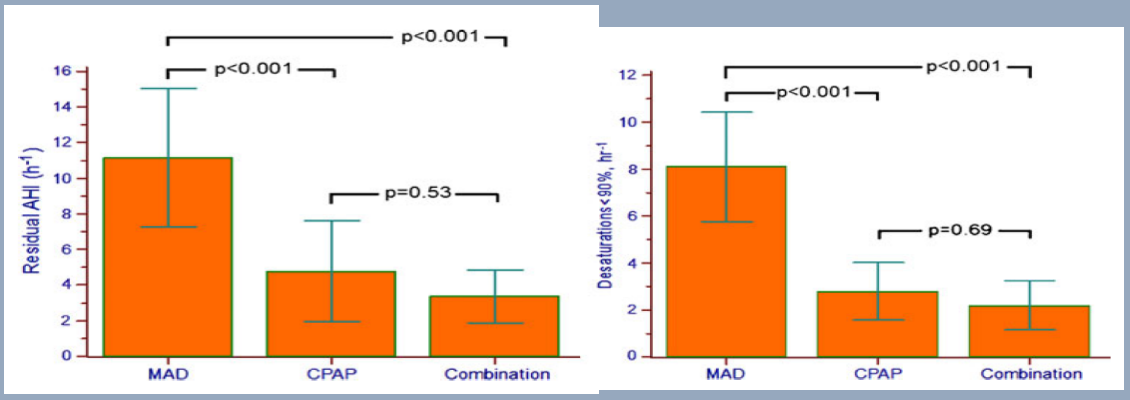
- Case series of 10 patients who were intolerant to CPAP, but had residual apneas/hypopneas on MAD
- Placed on auto-CPAP with MAD for 3 nights after 1 week washout off of MAD
- Overnight oximetry and data downloads obtained for patients combo therapy

El-Solh et al. Sleep Breath. 2011 May;15(2):203-8

Combined oral appliance and positive airway pressure therapy for obstructive sleep apnea: a pilot study.



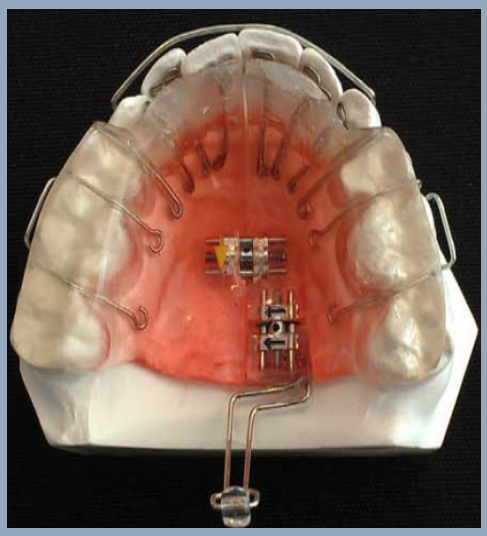
Combined oral appliance and positive airway pressure therapy for obstructive sleep apnea: a pilot study.



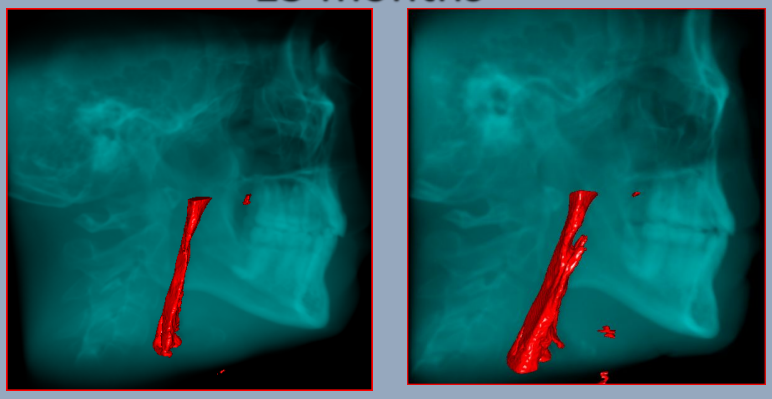
El-Solh et al. Sleep Breath. 2011 May;15(2):203-8

Biomimetic Solutions

- Orthodontic expansion
- No surgery needed?



Change in upper airway after 15 months



Decrease in AHI from 24/hr to 2.8/hr

Singh GD et al. Dent Today 2011

Providing the Physician with Confidence:

What does the right dentist look like?