Central States Occupational and Environmental Medicine Association

A Component Society of American College of Occupational and Environmental Medicine

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Clayton Sleep Institute

St. Louis University School of Medicine

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FMCSA Risk Model

Focus on society's concerns and risk avoidance – licensing more restrictive

Focus on Right to earn living in chosen occupation - licensing less restrictive

Societal Concerns

Drivers' Rights

Ellison H. Wittels, MD; FACP
Senior Medical Consultant
Federal Motor Carrier Safety Administration

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How Much Risk Should There Be

- Safest
  - Prohibit if possible safety risk
- But
  - Tightening regulations beyond what is necessary can increase illegal driving and cause societal problems
  - Eliminating all risk from disease not attainable
    - Especially difficult if disease is continuum
  - Reduce risk as much as reasonably possible
    - FMCSA “As Safe or Safer”

Who Decides Risk

- FMCSA Standards

  Identify individuals who represent an unreasonable and avoidable safety risk if allowed to drive

- Carrier decision
- Medical decision
- Societal decision

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How to Diagnosis OSA

- In lab study

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In-Laboratory Polysomnography

- Advantages
  - Complete measure of physiological parameters during sleep
  - Allows diagnosis of the variety of sleep disorders
  - Technologist monitors study
    - Can assist patient
    - Can troubleshoot to insure high quality signals
- Disadvantages
  - Patient must come in to sleep laboratory
  - Time and labor intensive

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How to Diagnosis OSA

- In lab study
- Home sleep study or Limited Channel Testing (LCT)

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Limited Channel Tests (LCTs)

- Advantages
  - Don't require stay in sleep laboratory
  - Accurate for moderate to severe OSA
  - May cost less
- Disadvantages
  - For OSA only, can't detect other sleep disorders
  - Reliability unknown in patients with other medical comorbidities
  - Higher failure rate
  - Accuracy questionable for mild to moderate OSA
  - Some patients are stressed by responsibility of self testing
  - Don't know who takes the test with most devices

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Chain of Custody

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Manipulation of HSAT

- Since most HSAT devices do not record sleep, it possible for driver to stay up all night and have low AHI.
- If high suspicion and negative results consider retest with PSG in lab study

Capturing sleep at home

- Some devices capture sleep indicator of sleep or even sleep brain waves themselves

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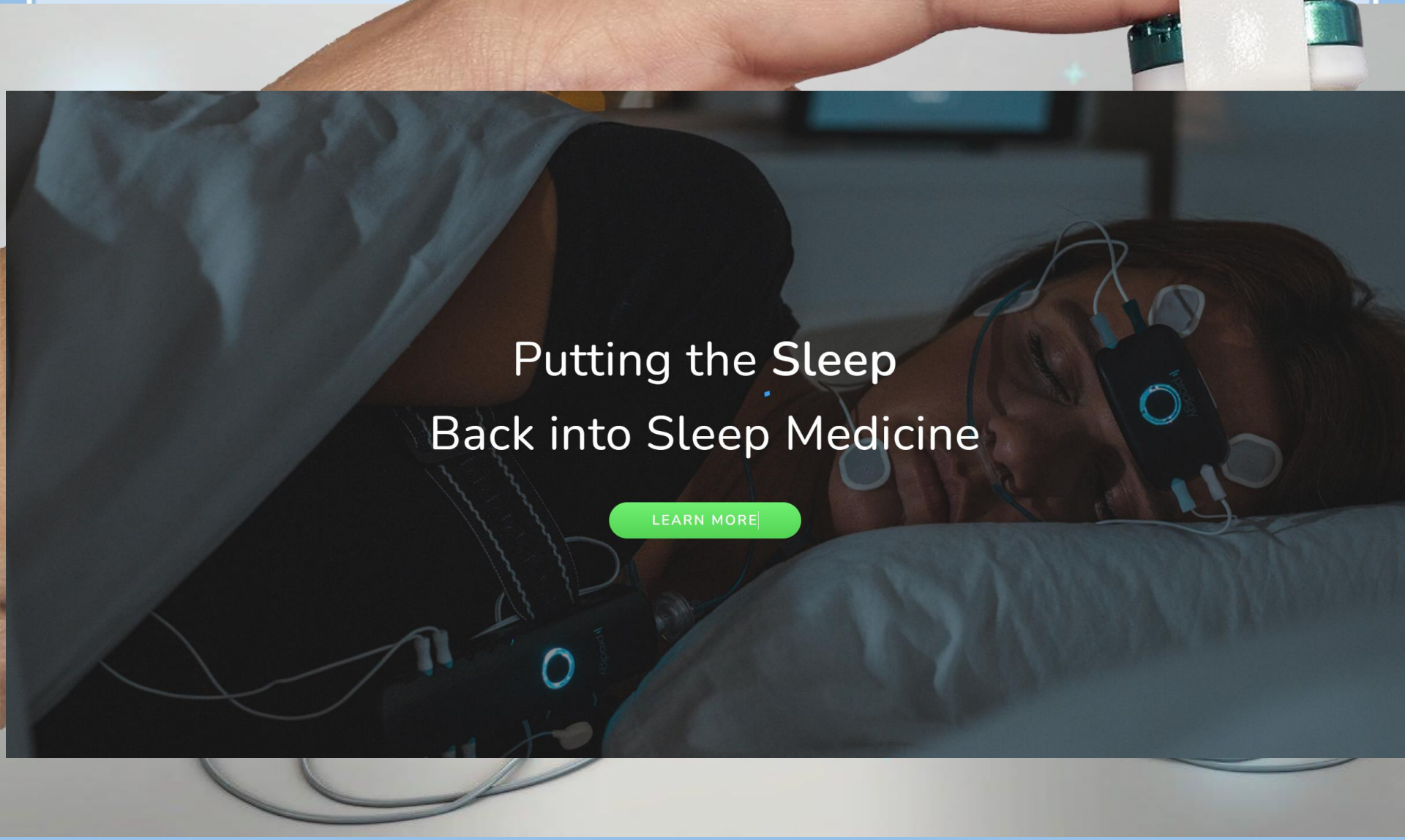
Capturing sleep and home



When to treat guidelines

- Any card holder with fatigue related incident
- Any card holder with an AHI >20 events per hour regardless of symptoms
- >5/hr but less than 20/hr
  - Treat if symptomatic
    - Uncontrolled HTN, daytime sleepiness etc
      - Use caution when assessing daytime sleepiness some data has ESS inversely related to true sleepiness in drivers
    - If asymptomatic offer a trial with treatment
      - Adherence is not required
      - May discontinue therapy without penalty

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Treatments for OSA

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Treatments

- Positive Airway Pressure
  - Continuous Positive Airway Pressure (CPAP)
  - BiLevel
- Surgical Intervention
- Dental Appliance
- Positional Therapy
- Weight Loss

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What is CPAP?

- Little machine sits on side of bed and blows air into airway to prevent throat from collapsing
- Amount of air is custom set for each patient

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The ‘New’ Face of PAP

- Better technology
  - Smaller, quieter machines
  - Bluetooth
  - Better humidifiers
- Many mask options

LIFE

CPAP recall leaves truck drivers with sleep apnea between a rock and a hard place

- FDA Class I recall on June 14, 2021
- 3 Main CPAP manufacturers in world
  - Shortage of PAPs on market
  - Months delays
  - Philips is prioritizing individuals with occupational risks
- How to advise drivers currently on Philip

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Dental Appliance

- Project the mandible forward
- Tongue Retaining Device
- Types
  - ~70 different types
- Compliance
  - 77% nightly for a year

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Dental Appliance

- Side effects
  - Excessive salivation
  - Changes to occlusion
  - Minor complications of jaw, mouth and tooth pain
    - Temporomandibular joint (TMJ)
- Advantages
  - Noninvasive
  - Reversible
  - Portable
  - Not obtrusive to bed partner

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AASM Indications

- Snoring
  - Pt do not respond or not candidates for positional therapy or weight loss
- Obstructive Sleep Apnea Syndrome
  - First line treatment for
    - Mild to Moderate OSA who prefer Oral Appliance compared to CPAP
  - Moderate to Severe
    - CPAP non-responders
    - Failed CPAP
    - Pts should have initial trial with CPAP

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MRB-MRSAC Recommendations

- Moderate to severe OSA should try PAP first
- Requires repeat sleep study documenting effectiveness of oral appliance
- Cleared by treating physician
- No report of EDS

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Table 1. OA therapy efficacy variation.

Treatment Response Definitions		All OSA	OSA Severity		
			Mild	Moderate	Severe
'Complete response'	Treatment AHI < 5/h	36.5%	52.2%	38.3%	23.6%
'Near-complete response'	Treatment AHI < 10/h + ≥ 50% AHI reduction	52.2%	52.2%	59.6%	42.1%
'Partial response'	≥50% AHI reduction	63.8%	52.2%	64.8%	70.0%

These representative data of OA efficacy variation regard a sample of 425 OSA patients treated with a two-piece customised device set to the maximum comfortable protrusive limit [23]. These data represent an individual-level analysis of research participants in studies from a single research centre. No upper limits for apnoea–hypopnea index (AHI) or body mass index (BMI) were set as entry criteria for the studies. Proportions of responders are shown for three commonly used definitions based on changes in the AHI. OA: oral appliances; OSA: obstructive sleep apnoea.

Sutherland and Cistulli, 2019

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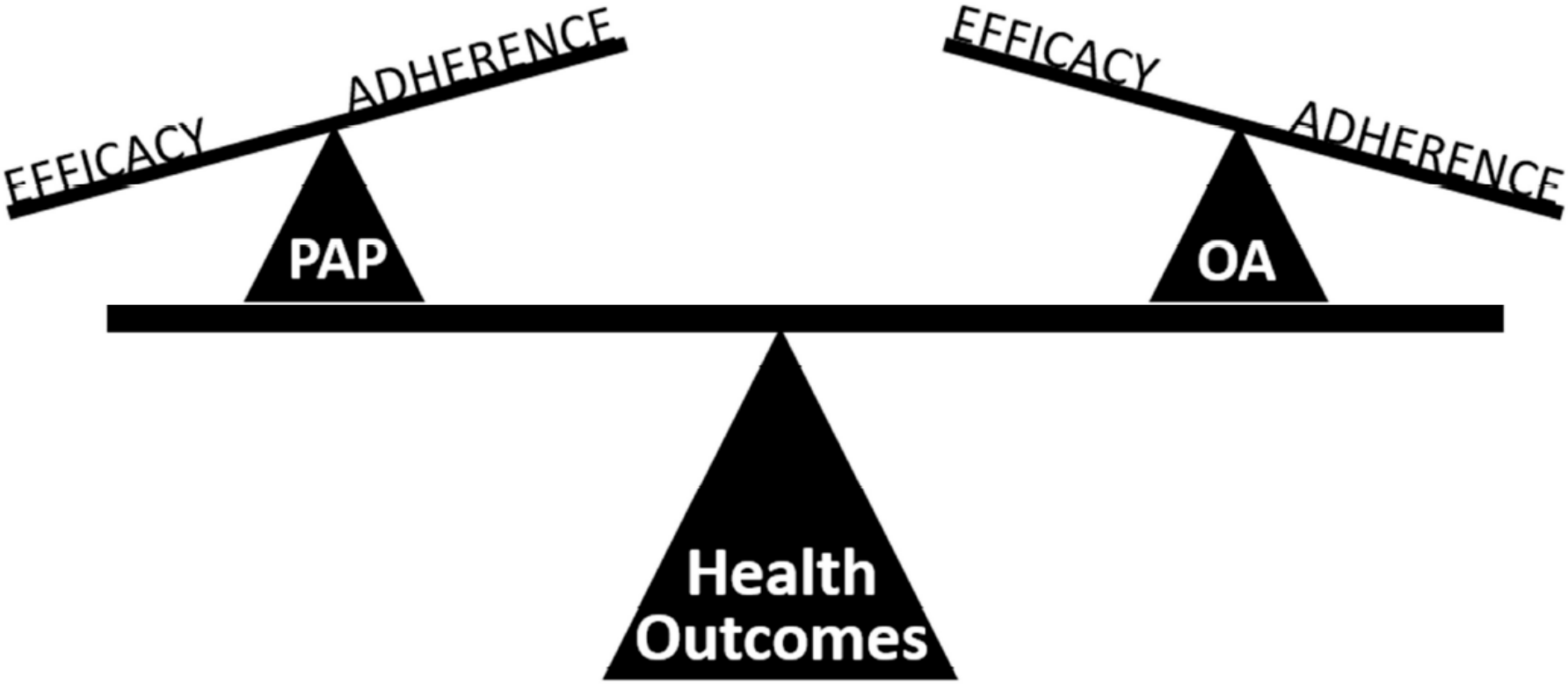


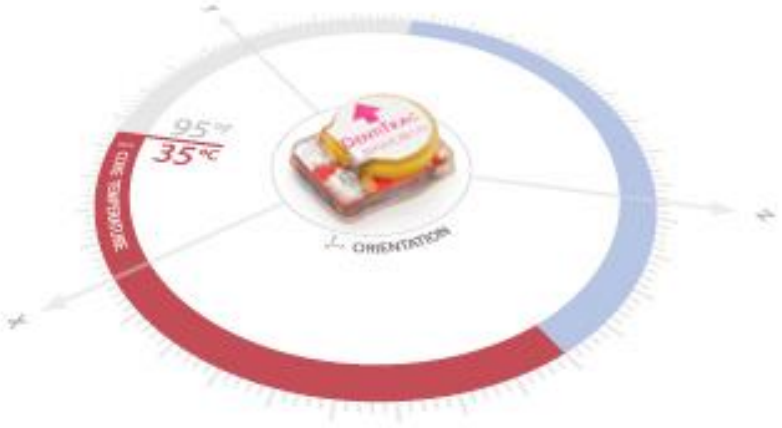
Figure 2. Treatment effectiveness and treatment profiles of OA, and standard PAP therapy. There is evidence that at least the short-term health outcomes of OA and PAP are similar, despite mild residual sleep apnoea with OA treatment. Although PAP is highly efficacious, adherence to it outside of the sleep laboratory is often suboptimal. Treatment effectiveness, in terms of health benefits, is a composite of efficacy and adherence. OA and PAP have different profiles of efficacy and adherence. However, the end result in terms of treatment effectiveness may be the same.

Sutherland and Cistulli, 2019


DENTITRAC
BRAEBON

Accuracy without compromise

Measuring a wide range of metrics, from temperature to three dimensional rotation, enables sophisticated algorithms to determine accurate wearing times. This power comes without compromising the micro-recorder's long lifespan.



- MAD adherence better than CPAP
  - 40 patients 12 months randomized to CPAP or MAD
    - MAD users consistently over estimated through adherence
    - CPAP users underestimated theirs
    - No Significant difference between groups objective adherence
      - 3 months=7.4 and 6.8
      - 12 months=6.9 and 6.8

Vries et al, 2019

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Delay to effective

- Fabricating oral appliance
  - May take 1 to 3 weeks for impression and fabrication of oral appliance
    - Chip shortage averaging 6 weeks for chipped
  - Appliance should then be adjusted for therapeutic benefit
    - 2 weeks to 6 months
  - Repeat sleep study to verify efficacy

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Importance of Post PSG

- Fleury et al, 2004 (34 subjects)
  - 80% protrusion 9% responders
  - Further titration 63.6% responders
- Almeida et al, 2009 (23 subjects)
  - At the final PSG, 65.2% of patients had an AHI ≤ 10 associated with at least a 50% reduction in AHI.
  - After further titration 95.6%.

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Pt follow up Questions

- Are you able to sleep with the appliance?
  - Is it Comfortable?
- Was any gasping or choking observed?
- Did you wake up as often?
- Do you feel more refreshed in the morning?
- How do you feel the rest of the day?
- Does your jaw hurt ? When? For how long?
- Did your partner hear you snore ? Was it as loud as usual?

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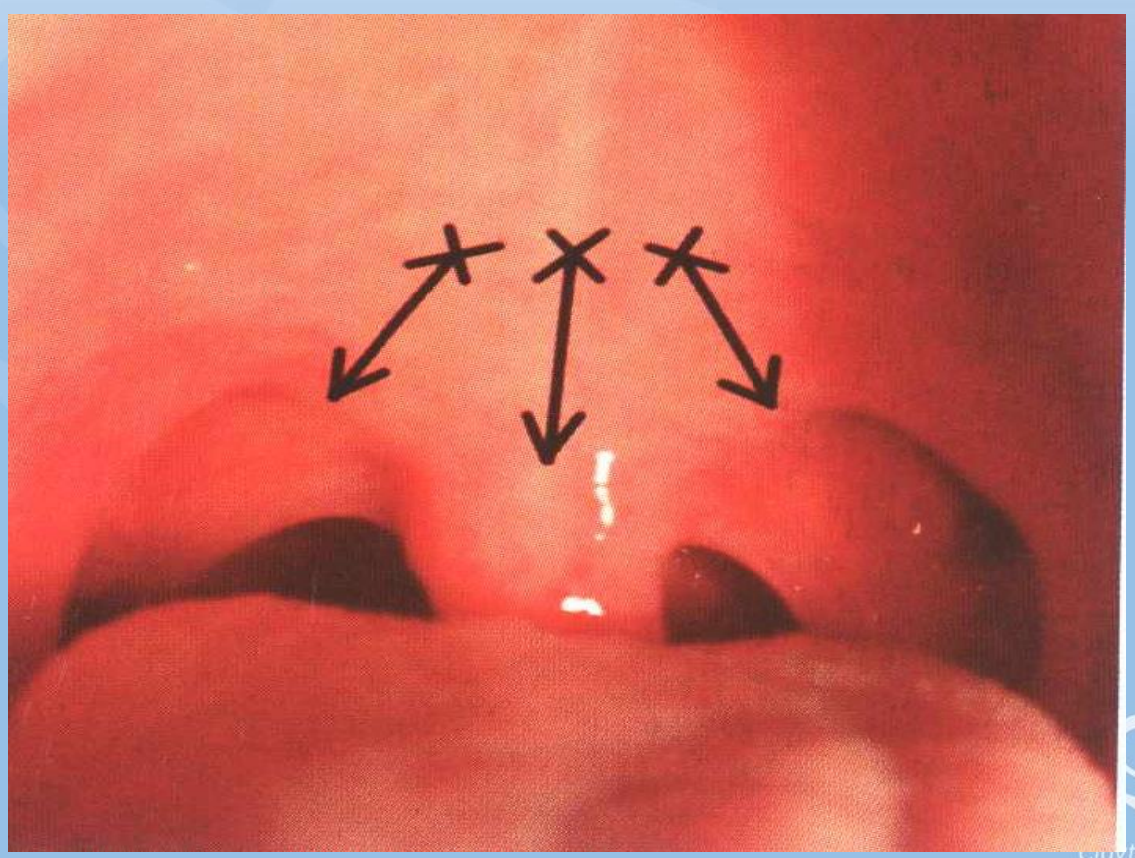
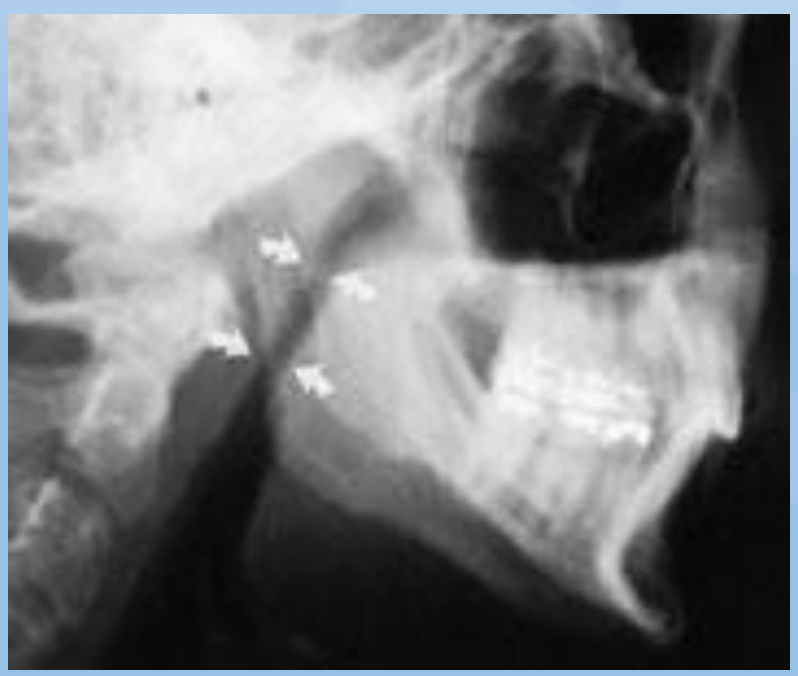
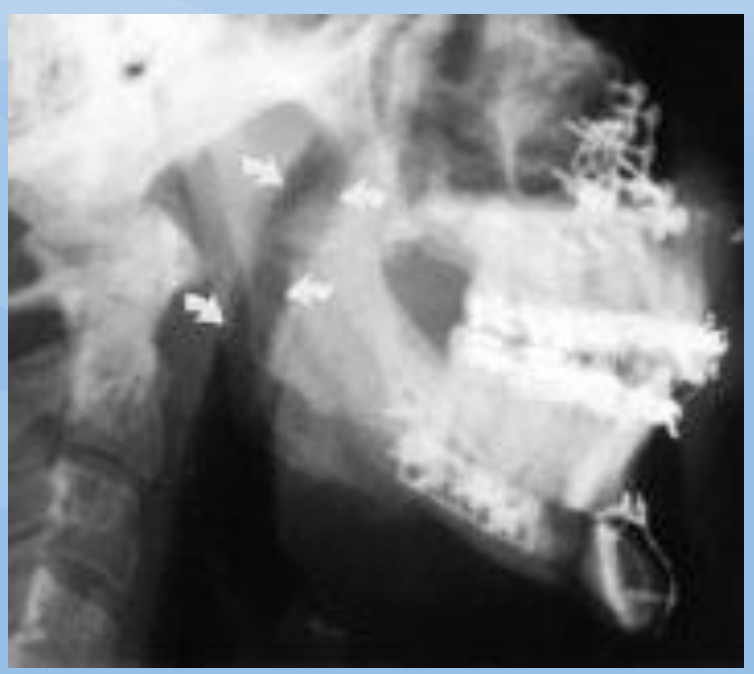
Treatments

- Surgical Intervention



Maxillomandibular Advancement





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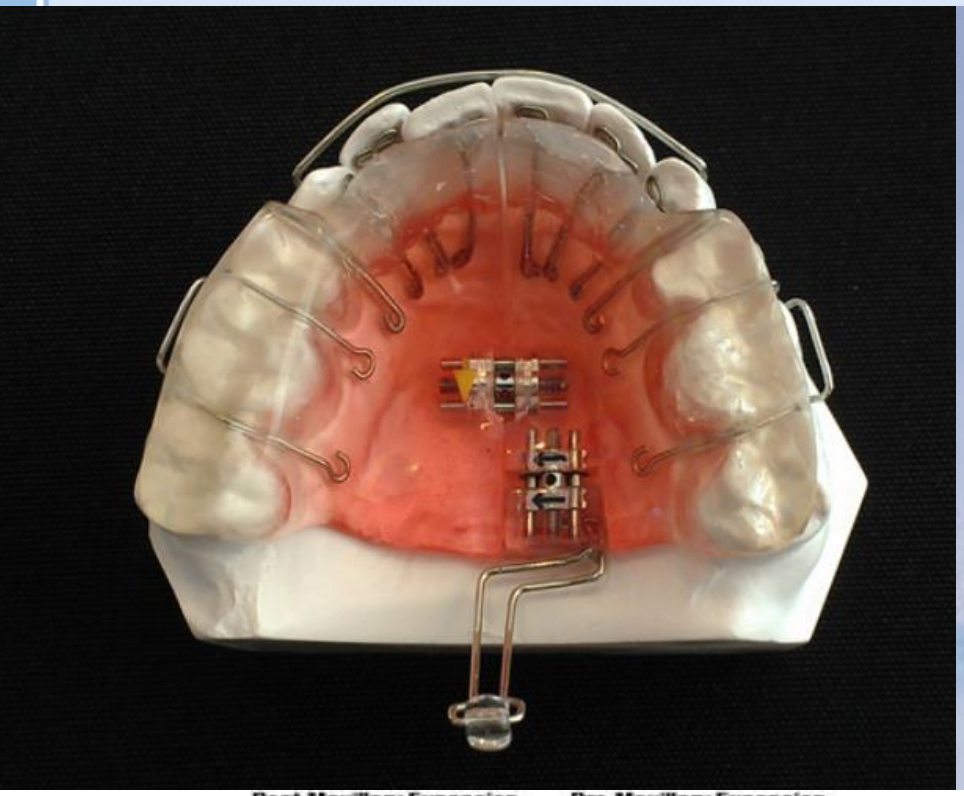
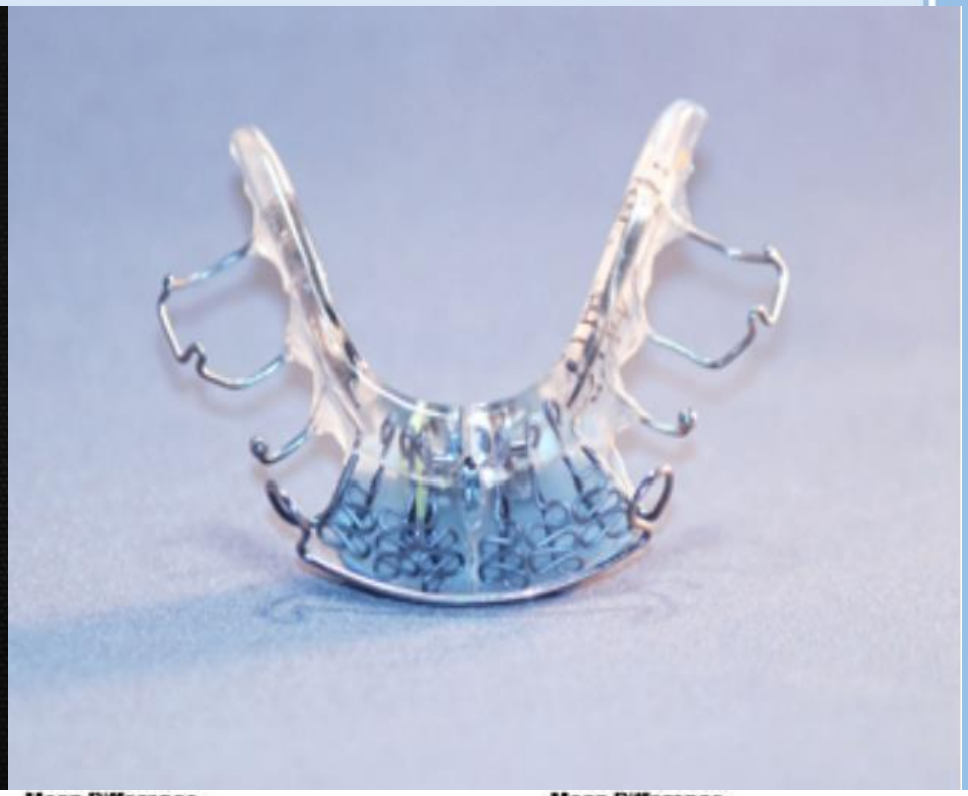
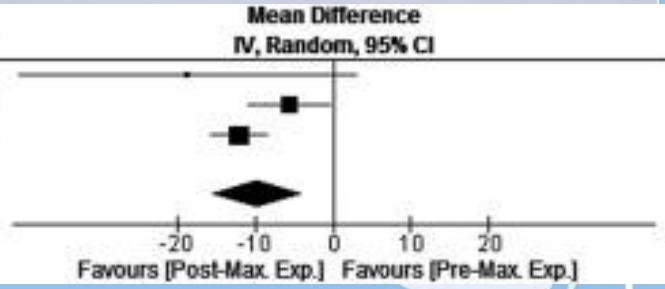
Palatal Expander





Study or Subgroup	Post-Maxillary Expansion Mean	SD	Total	Pre-Maxillary Expansion Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Year
Vinha 2015	14.5	19.4	16	33.2	39.5	16	6.3%	-18.70 [-40.26, 2.86]	2015
Bach 2013	5.7	5.4	7	11.2	4.6	7	41.7%	-5.50 [-10.75, -0.25]	2013
Cistulli 1998	7	4	10	19	4	10	52.0%	-12.00 [-15.51, -8.49]	1998
Total (95% CI)			**33**			**33**	**100.0%**	**-9.71 [-15.41, -4.01]**	

Heterogeneity: Tau² = 13.06; Chi² = 4.68, df = 2 (P = 0.10); I² = 57%
Test for overall effect: Z = 3.34 (P = 0.0008)



Abdullatif, et al 2016

Weight Loss

- Very effective “cure” for OSA in some patients
- Disadvantages
  - Takes time
  - Discipline
  - Difficult to accomplish when sleep deprived
  - No guarantees of effectiveness

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Positional Therapy

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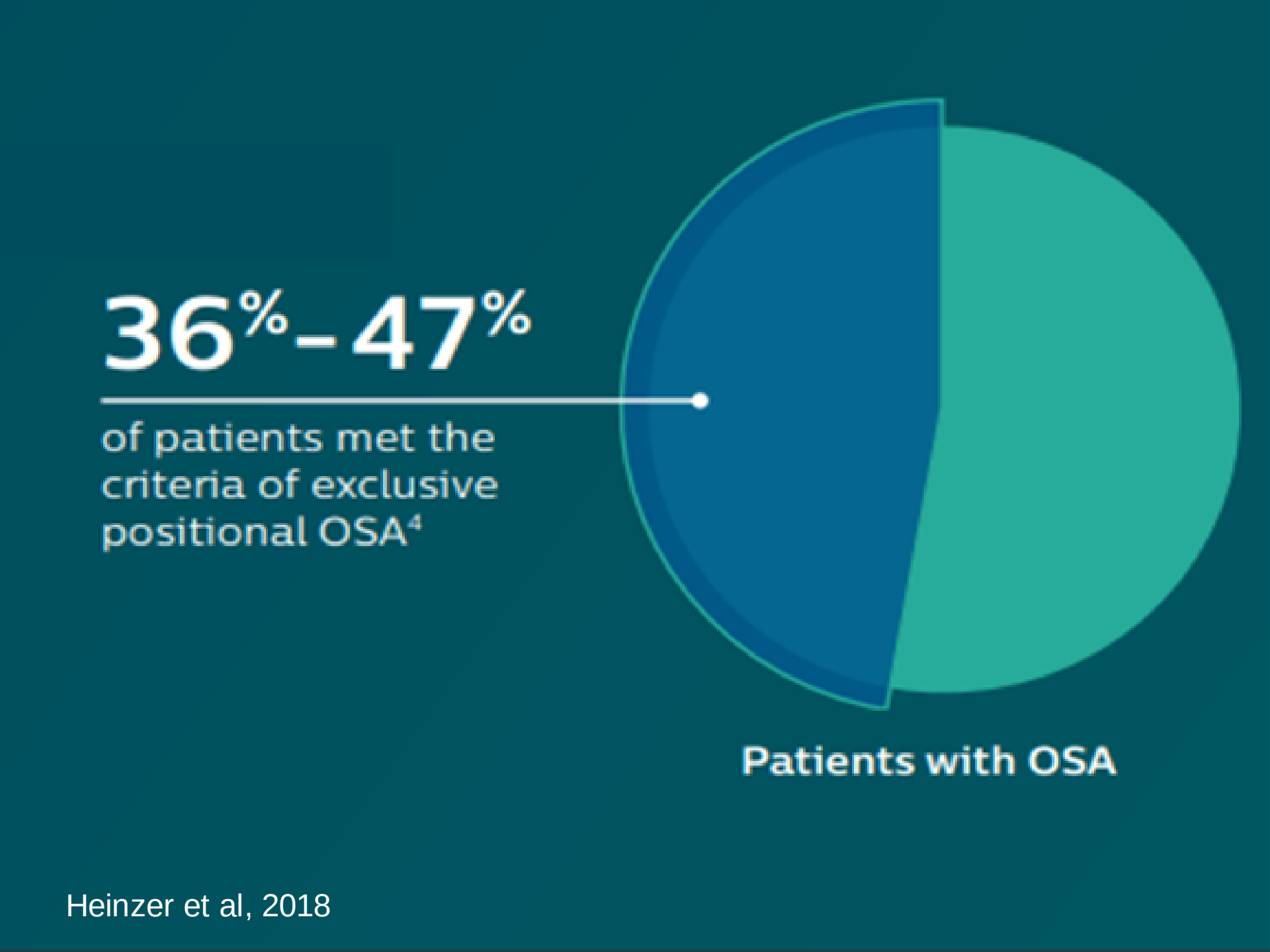
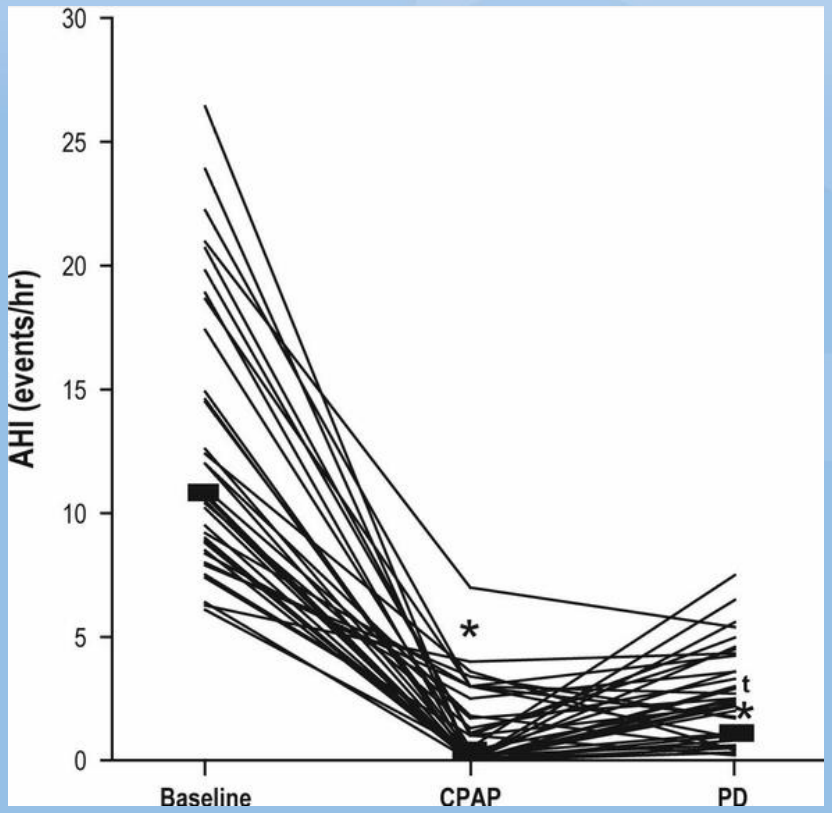
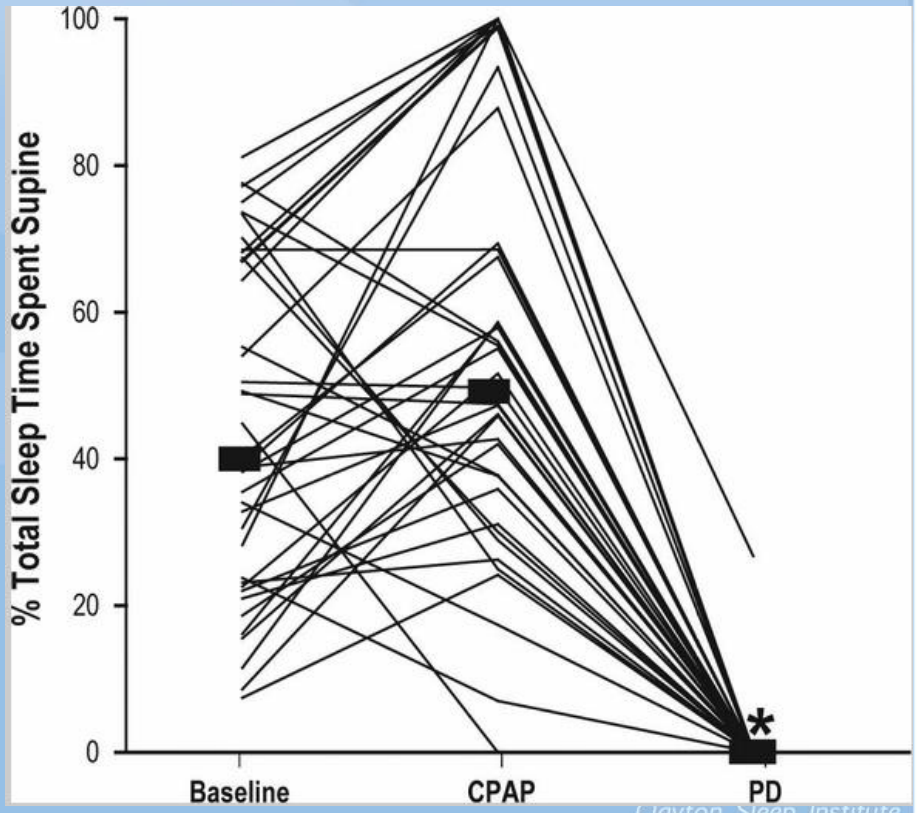


Heinzer et al, 2018

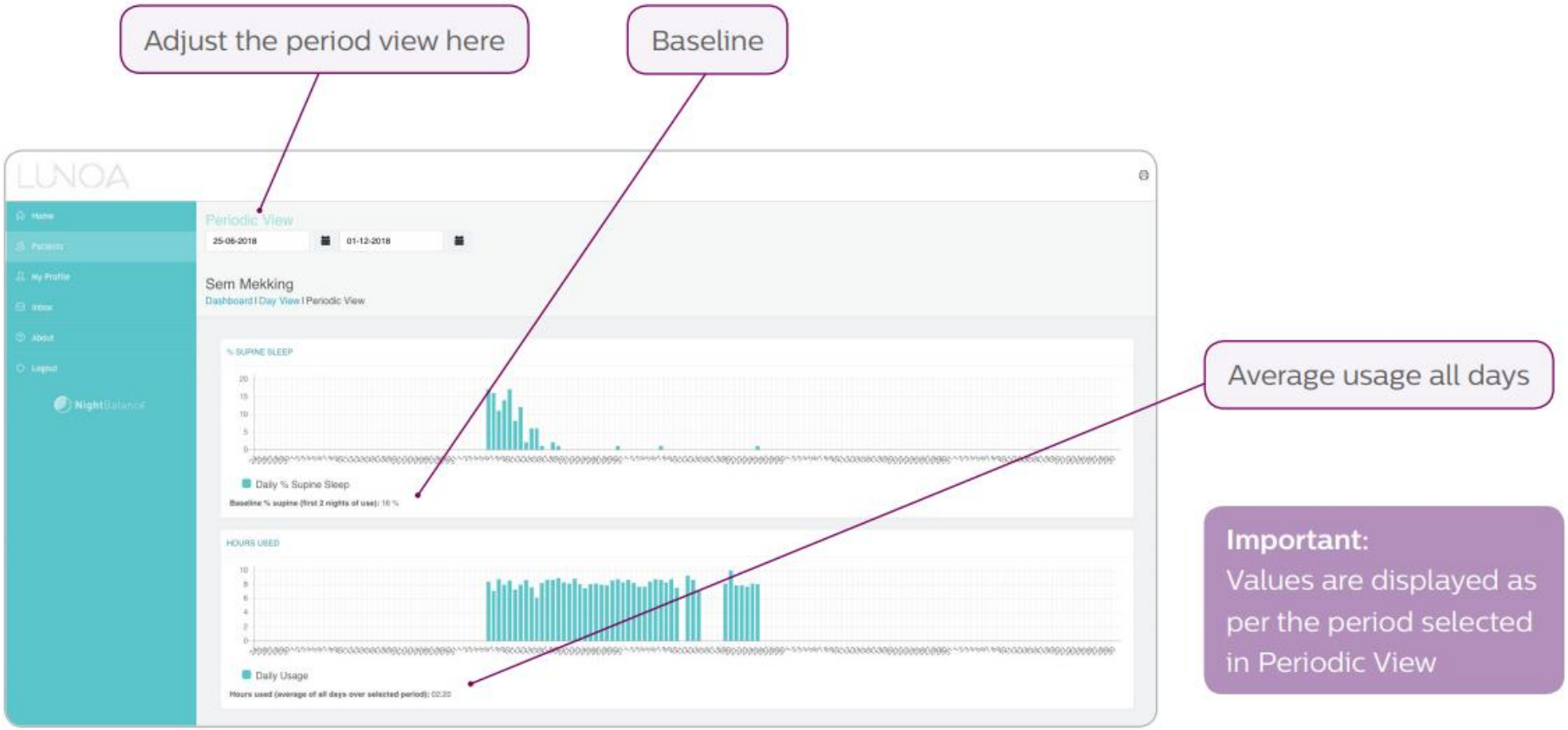
Permut et al, 2010

- 38 subjects, Positional belt compared to CPAP
- AHI reduced to <5/hr in 92% positional and 97% CPAP





Nightbalance download



eXciteOSA


Using eXciteOSA®
20
minutes
a session
1
time
each day
6
weeks
eXciteOSA
Simple and comfortable to use, the daytime therapy requires
only 20 minutes of NMES each day to increase responsiveness
Signifier

eXciteOSA

- 70 patients
  - 95% reduction in snoring
  - AHI reduced from 9.8 to 4.7/hr
  - ESS reduced from 9 to 5.1

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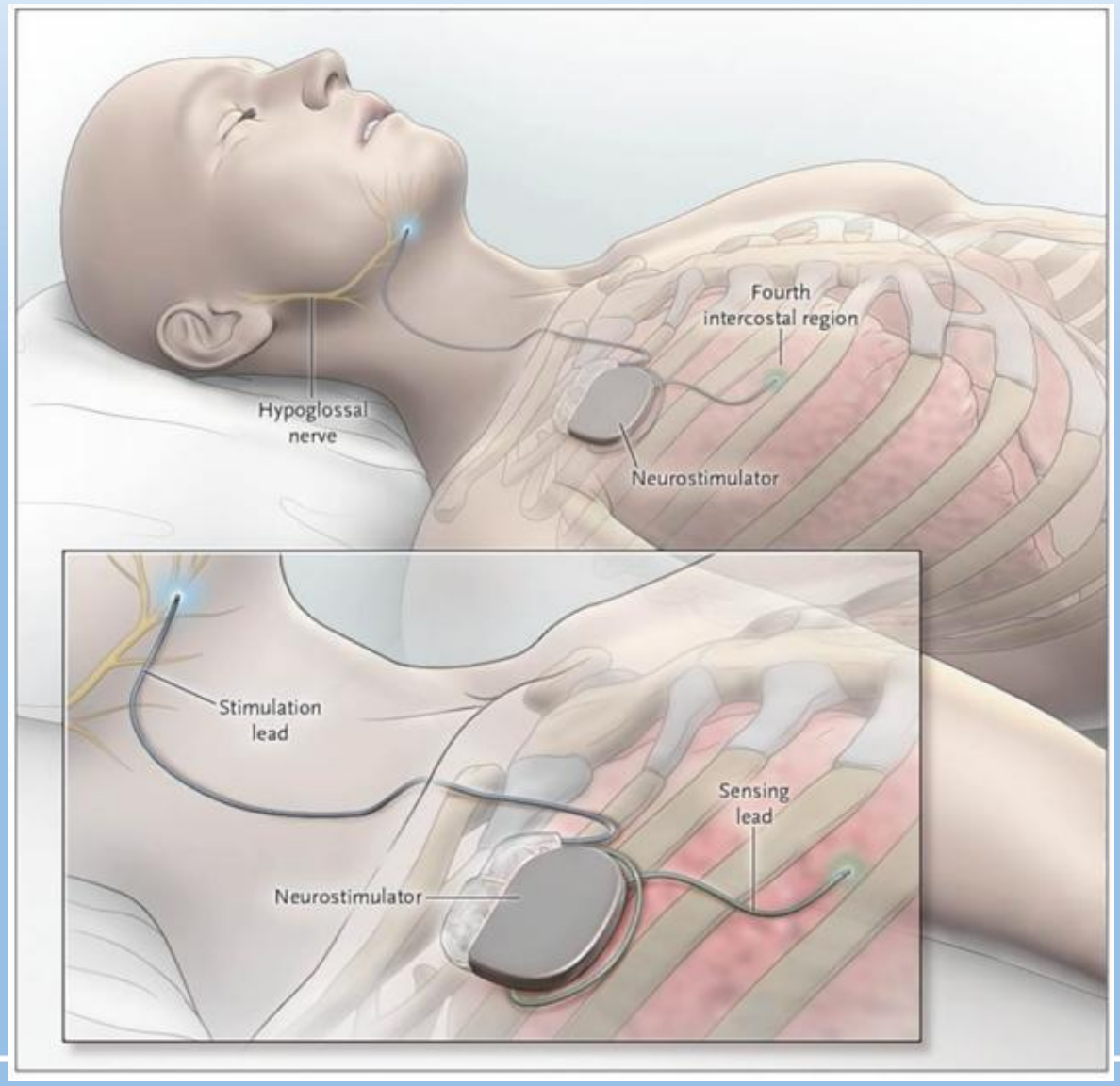
Kotecha et al, 2021

Hypoglossal Nerve Stimulator



Indications

- 22 years of age or older
- AHI= 15-65/hr with less than 25% CSA
- Failed trial with CPAP
- Free of concentric collapse at the palate
- BMI less than 33

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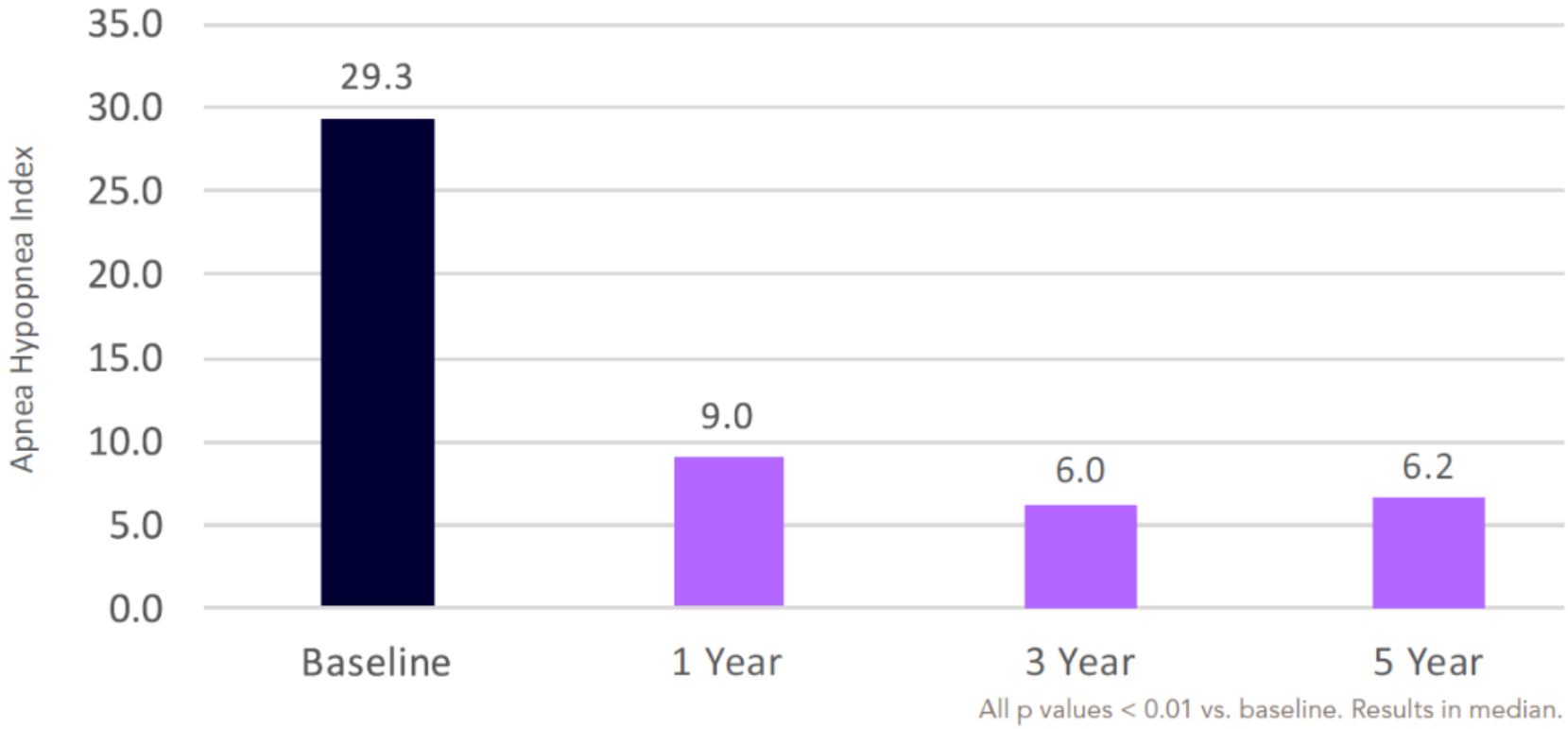
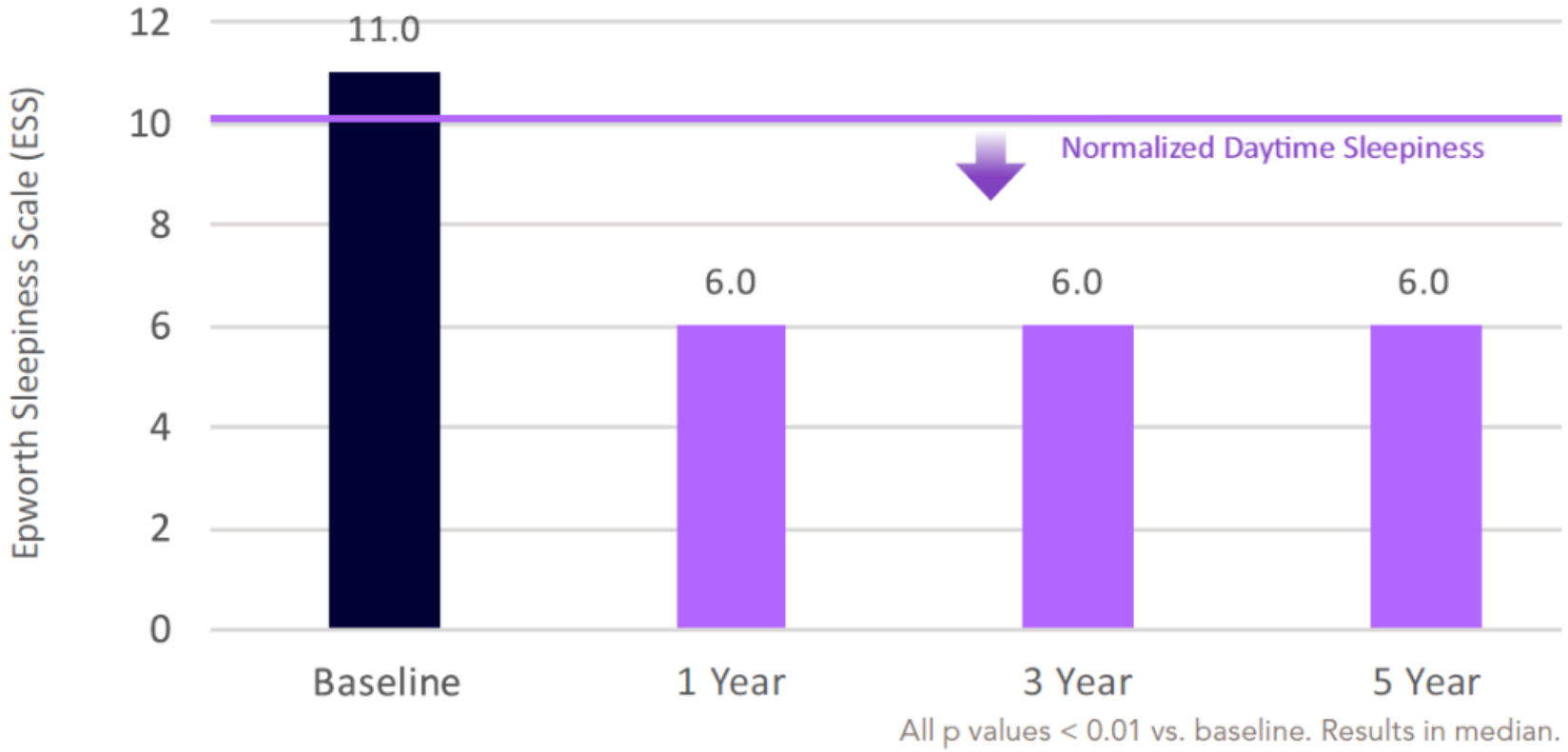
Woodson et al, 2018

Figure 1: Significant Reduction in Apnea-Hypopnea Events



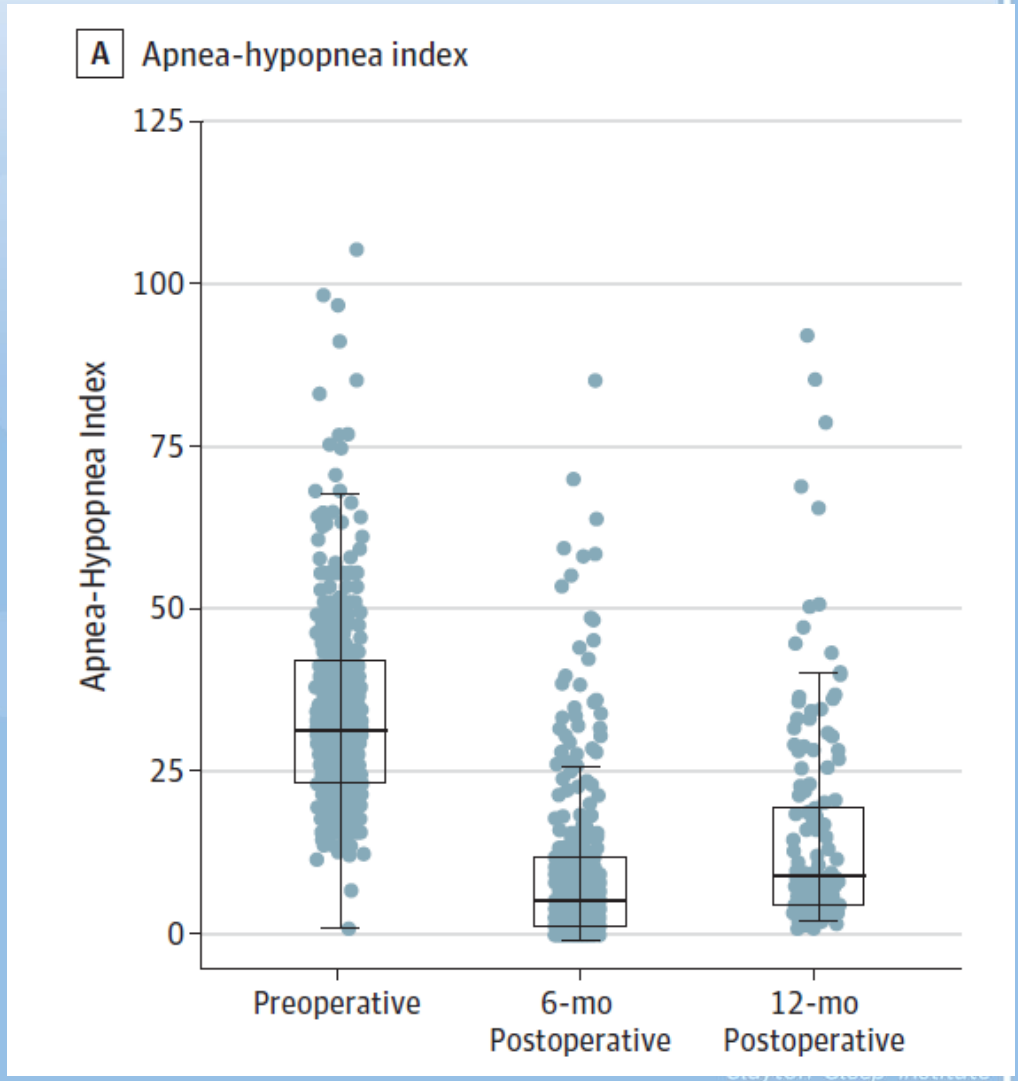
Woodson et al, 2018

Figure 3: Significant Reductions in Daytime Sleepiness



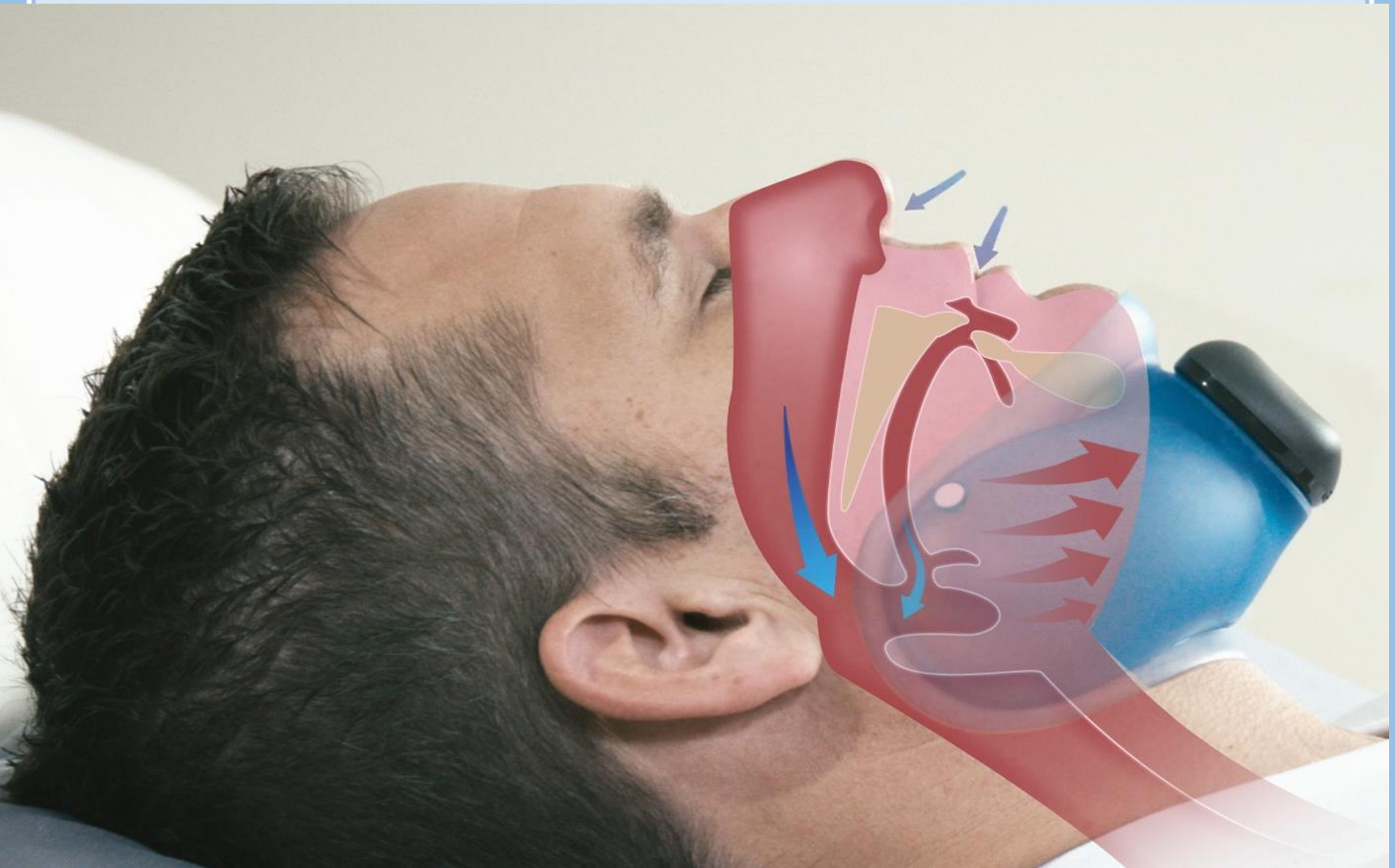
Kent et al, 2019

- Pooled data across 4 cohorts
- 584 subjects
- AHI ↓25.2/hr at 6 months
- AHI ↓16.5/hr at 12 months



Sommetric

Sommetric



- 74% reduction in AHI
- 70% of patients thought acceptable treatment of their OSA
- 88% preferred over other treatments
- 82% thought their sleep was better

Is Inspire DOT Compliant

Inspire
Sleep Apnea Innovation

Testimonials Am I Eligible? FAQ Events Find a Doctor

Is Inspire DOT approved?

- Like CPAP, an Inspire doctor can print out a usage record of Inspire to show the medical examiner that you are using your prescribed sleep apnea treatment
- By proving compliance, there should be no issues renewing your commercial driver's license

Telemedicine

- Telemedicine has been incorporated in sleep
  - Remote monitoring of Adherence
  - Remote therapy setting adjustments
- COVID-19 changes
- Telemedicine most effective for follow up
- High patient satisfaction

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Pharmacological Therapy

- Combo Therapy[1]
  - Targets the Geniogolossus muscle
  - Norepinephrine reuptake inhibitor (Atomoxetine) NREM
  - Muscarinic blocker (Oxybutynin) REM
  - 20 patients single night cross over
    - 28.5 to 7.5/hr, 63%, $p<.001$
- Cannabinoids
  - Dronabinol (synthetic THC)

[1]Taranto-Montemurro et al, 2019

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Prasad et al, 2013

- 17 subjects
- 2.5 mg 5mg and 10 mg
- 32% improvement at 3 weeks
- Side effects included sleepiness in 29 to 50% of patients

JCSM
Journal of Clinical Sleep Medicine

SPECIAL ARTICLES

Medical Cannabis and the Treatment of Obstructive Sleep Apnea:

CONCLUSIONS

Based on the available evidence, it is the position of the AASM that medical cannabis should not be used for the treatment of OSA. The AASM also advises state legislators, regulators and health departments that OSA should not be included as an indication for their medical cannabis programs. Further research is needed to better understand the mechanistic actions of medical cannabis and its synthetic extracts, the long-term role of these synthetic extracts on OSA treatment, and the harms and benefits

Follow up

- Regardless of treatment modality
  - MUST have follow up study documenting efficacy of therapy.
  - MUST have method of documenting compliance with therapy
    - 30 verses 90 day temporary card
  - Annual follow up documenting efficacy and compliance
  - Best to remind minimum of 30 to 60 days prior to annual apointment

Summary

- CPAP best overall treatment option for DOT
- Dental appliances can be effective and compliance monitored but may have prolonged time to effective treatment
- Other alternatives
  - Positional
  - eXciteOSA
  - Sommetrics
  - Hypoglossal Nerve Stimulation

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