Sleep Apnea Therapy-II

Kentucky Sleep Society Spring Course 2016
Robyn Woidtke MSN, RN, RPSGT, CCSH

Objectives

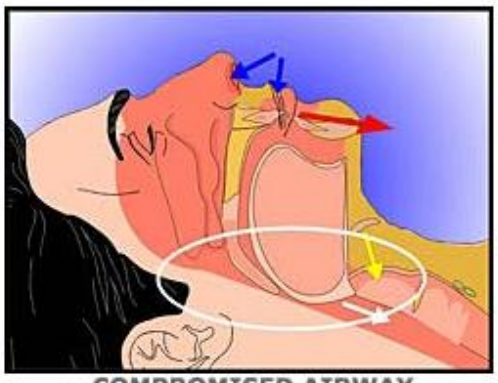
- Explain the various alternatives to PAP therapy
- Assess the literature with regards to outcomes

Goals of Therapy

- Eliminate/reduce
  - apnea and hypopnea
  - desaturations
  - Arousals
- Improve sleep
  - Continuity
  - Quality
  - Quantity
- Alleviate daytime sequela and long term health consequences

Oral Appliances: Mechanism of Action

- Provide
  - Lower jaw re-positioning
  - Stabilize the lower jaw and tongue
  - Increase muscle tone of the lower jaw



Oral Appliances

- Multidisciplinary approach
  - MD and DDS
- Sleep assessment
- Dental suitability
  - Boil and bite
  - Customization

Indications

- Primary snoring or mild SA
- Moderate to severe OSA
  - Initial trial with CPAP
  - Intolerant to CPAP
  - Used in conjunction with CPAP
  - Those who refuse tx with CPAP

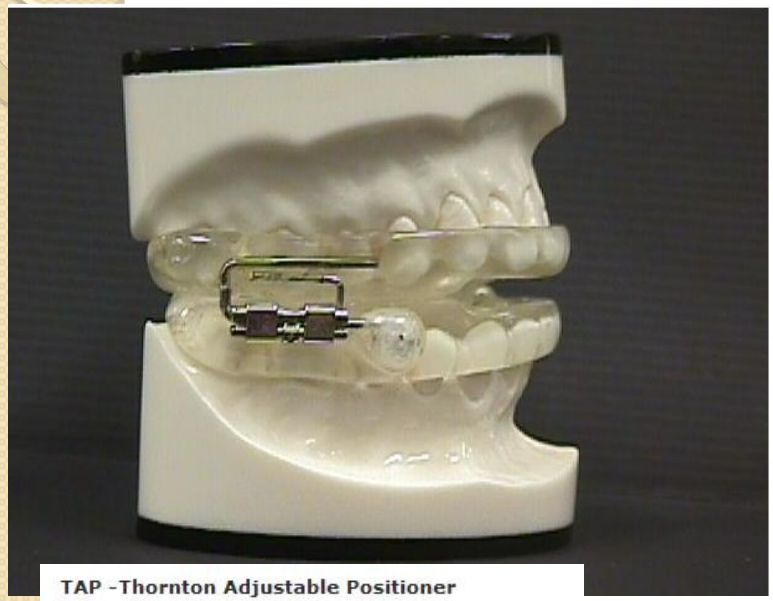
Am Acad of Dental Sleep Med (2009)

Many different options/names

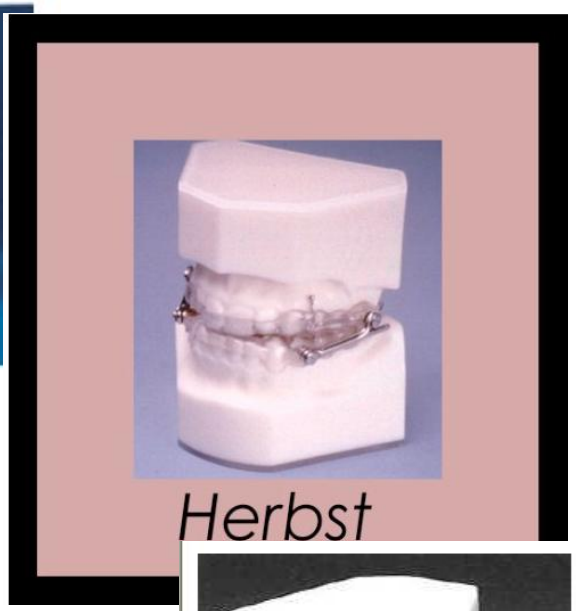
- ~70 different oral appliances
  - Mandibular advancement device (MAD)
  - Mandibular Repositioning Device (MRD)
  - Tongue retaining device (TRD)
  - Oral appliances (OA)

Am Acad of Dental Sleep Med (2009)

Lots and lots…….



TAP -Thornton Adjustable Positioner



Fixed jaw relation snore guard made of elastic silicone ru
(elastomeric appliance)

REVIEW ARTICLES

JCSM
Journal of Clinical Sleep Medicine

http://dx.doi.org/10.5664/jcsm.3460

Oral Appliance Treatment for Obstructive Sleep Apnea: An Update

Kate Sutherland, Ph.D.[1,2]; Olivier M. Vanderveken, M.D., Ph.D.[3,4]; Hiroko Tsuda, Ph.D.[5]; Marie Marklund, Ph.D.[6]; Frederic Gagnadoux, M.D., Ph.D.[7,8,9]; Clete A. Kushida, M.D., Ph.D., F.A.A.S.M.[10]; Peter A. Cistulli, M.D., Ph.D.[1,2]; on behalf of the ORANGE-Registry (Oral Appliance Network on Global Effectiveness)

Table 1—Oral appliances versus CPAP treatment: results from randomized controlled trials

Study	Design	Subjects n (% male) [withdrawals]	Inclusion	Oral appliance	Treatment [washout] duration	Baseline AHI	Treatment AHI		OA vs. CPAP		
							CPAP	OA	AHI	ESS	Patient preference
Aarab 2010[27]	parallel (*placebo group included*)	57 (74%) (20 OA/18 CPAP) [7]	AHI 5-45 + ESS ≥ 10	Customized, Two-piece, set 25, 50, or 75% advancement depending on sleep study results at each level	24 weeks	CPAP: 20.9 ± 9.8 OA: 22.1 ± 10.8	1.4 ± 13.1	5.8 ± 14.9	↔ (p = 0.092)	↔	N/A – parallel groups
Barnes 2004[58]	crossover (*placebo group included*)	80 (79%) [24]	AHI 5-30	Customized, 4 week titration to maximum comfortable advancement	3x12 weeks [2 weeks]	21.5 ± 1.6^	4.8 ± 0.5^	14.0 ± 1.1^	CPAP	↔	CPAP
Engleman 2002[54]	crossover	48 (75%) [3]	AHI ≥ 5/h + ≥ 2 symptoms (including ESS ≥ 8)	Customized, one-piece, 80% maximal protrusion, two deigns a) complete occlusal coverage or b) no occlusal coverage, assigned randomly	2x8 weeks [not reported]	31 ± 26	8 ± 6	15 ± 16	CPAP	CPAP	↔
Ferguson 1996[60]	crossover	25 (89%) [2]	AHI 15-50 + OSA symptoms	Snore-Guard (Hays & Meade Inc), maximum comfortable advancement	2x16 weeks [2 weeks]	24.5 ± 8.8	3.6 ± 1.7	9.7 ± 7.3	CPAP	N/A	OA
Ferguson 1997[59]	crossover	20 (95%) [4]	AHI 15-55 + OSA symptoms	Customized, two-piece appliance, titration starting at 70% maximum advancement over 3 months	2x16 weeks [2 weeks]	26.8 ± 11.9	4.0 ± 2.2	14.2 ± 14.7	CPAP	↔	OA
Gagnadoux 2009[55]	crossover	59 (78%) [3]	AHI 10-60 + ≥ 2 symptoms, BMI ≥ 35 kg/m²	AMC (Artech Medical), two-piece, advancement determined by single-night titration	2x8 weeks, [1 week]	34 ± 13	2 (1-8)#	6 (3-14)#	CPAP	↔	OA
Hoekema 2008[56]	parallel	103 (51 OA/52 CPAP) [4]	AHI ≥ 5	Thornton Adjustable Positioner type 1, titratable	8-12 weeks	CPAP: 40.3 ± 27.6 OA: 39.4 ± 30.8	2.4 ± 4.2	7.8 ± 14.4	CPAP	↔	N/A – parallel groups
Lam 2007[61]	parallel (*placebo group included*)	101 (79%) (34 OA/34 CPAP) [10]	AHI ≥ 5-40 + ESS > 9 if AHI 5-20	Customized, non-adjustable, set to maximum comfortable advancement	10 weeks (83% referred for concurrent weight loss program)	CPAP: 23.8 ± 1.9^ OA: 20.9 ± 1.7^	2.8 ± 1.1^	10.6 ± 1.7^	CPAP	CPAP	N/A – parallel groups
Phillips 2013[57]	crossover	108 (81%) [18]	AHI ≥ 10 + ≥ 2 symptoms	Customized, two-piece appliance (SomnoMed), titrated to maximum comfortable limit in acclimatization period before study	2x4 weeks [2 weeks]	25.6 ± 12.3	4.5 ± 6.6	11.1 ± 12.1	CPAP	↔	OA
Randerath 2002[62]	crossover	20 (80%)	AHI 5-30 + OSA symptoms	IST; Hinz; Herne, Germany, two piece, non-titratable, set to two-thirds of maximum advancement	2x6 weeks [not reported]	17.5 ± 7.7	3.2 ± 2.9	13.8 ± 11.1	CPAP	N/A	N/A
Tan 2002[63]	crossover	21 (83%) [3]	AHI 5-50	One-piece, 75% maximum advancement and Silensor (Erkodent Gmbh) two-piece, titratable	2x8 weeks, [2 weeks]	22.2 ± 9.6	3.1 ± 2.8	8.0 ± 10.9	↔	↔	N/A

↔, equivalent between treatments; AHI, apnea-hypopnea index; N/A, not applicable, not measured in study. Data presented as mean ± SD, unless denoted ^(mean ± SEM) or #(median [interquartile range]).

http://dx.doi.org/10.15331/jdsm.5120

Efficacy versus Effectiveness in the Treatment of Obstructive Sleep Apnea: CPAP and Oral Appliances

Kate Sutherland, PhD[1,2]; Craig L. Phillips, PhD[1,2]; Peter A. Cistulli, MD, PhD[1]

Table 1—Efficacy and effectiveness of oral appliances versus CPAP: AHI and health outcome results from randomized trials.

Study	Study Design	N	Baseline AHI	Treatment AHI		Health Outcomes			
						Daytime Sleepiness		Health-Related Quality of Life	Blood Pressure
				CPAP	OA	Subjective (ESS)	Objective		
Aarab, 2010	parallel	57	20.9 ± 9.8	1.4 ± 13.1	5.8 ± 14.9	↔	N/A	↔	N/A
Barnes, 2004	crossover	80	21.5 ± 1.6	4.8 ± 0.5	14.0 ± 1.1	↔	↔ (MWT)	N/A	↔
Engleman, 2002	crossover	48	31 ± 26	8 ± 6	15 ± 16	CPAP	CPAP (MWT)	CPAP	N/A
Ferguson, 1997	crossover	20	26.8 ± 11.9	4.0 ± 2.2	14.2 ± 14.7	↔	N/A	N/A	N/A
Gagnadoux, 2009	crossover	59	34 ± 13	2 (1–8)#	6 (3–14)#	↔	↔ (OSLER)	OA	N/A
Hoekema, 2008	parallel	103	40.3 ± 27.6	2.4 ± 4.2	7.8 ± 14.4	↔	N/A	↔	N/A
Lam, 2007	parallel	101	23.8 ± 1.9^	2.8 ± 1.1	10.6 ± 1.7	CPAP	N/A	CPAP	↔
Phillips, 2013	crossover	108	25.6 ± 12.3	4.5 ± 6.6	11.1 ± 12.1	↔	N/A	↔	↔
Tan, 2002	crossover	21	22.2 ± 9.6	3.1 ± 2.8	8.0 ± 10.9	↔	N/A	↔	N/A

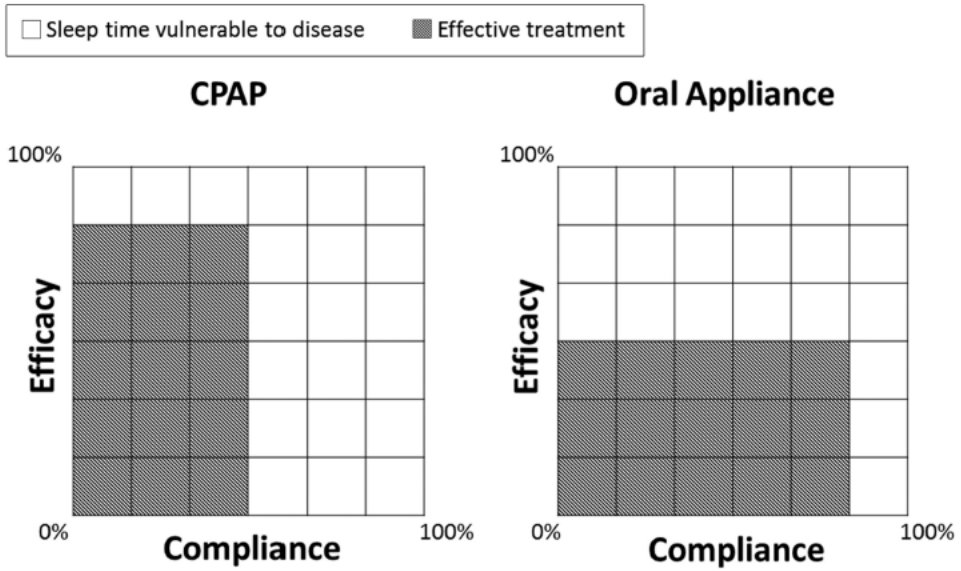
#Median (interquartile range). ^Mean ± standard error. Summary of AHI data with CPAP and oral appliances (OA) in randomized trials comparing treatments. Summary of commonly reported health assessments are presented. "CPAP" or "OA" indicates superior results were found with that treatment, ↔ indicates equivalent findings observed with both treatments. AHI data is mean ± standard deviation, unless otherwise indicated. ESS, Epworth Sleepiness Score; MWT, maintenance of wakefulness test; OSLER, oxford sleep resistance test.

Journal of Dental Sleep Medicine 2015

The SARAH INDEX

$$\text{Sleep Adjusted Residual AHI (SARAH Index)} = \frac{[\text{AHI}_{\text{Treatment}} \times \text{Hours}_{\text{Treatment}}] + [\text{AHI}_{\text{Untreated}} \times \text{Hours}_{\text{Untreated}}]}{\text{Hours}_{\text{Total Sleep Time}}}$$

Figure 1—Comparison of treatment effectiveness profile of CPAP and oral appliances.



Efficacy (y axis) reflects the ability of treatment to prevent obstructive breathing events when it is physically applied. Compliance (x axis) reflects the hours the treatment is applied for over the total sleep time when obstructive events can occur. "Effectiveness" requires both efficacy and compliance and the balance of these likely reflects over health outcomes. This schematic illustrates the scenario of an oral appliance which is only half as efficacious as CPAP but has two-fold greater compliance which results in equivalent effectiveness (shaded area).

Surgical

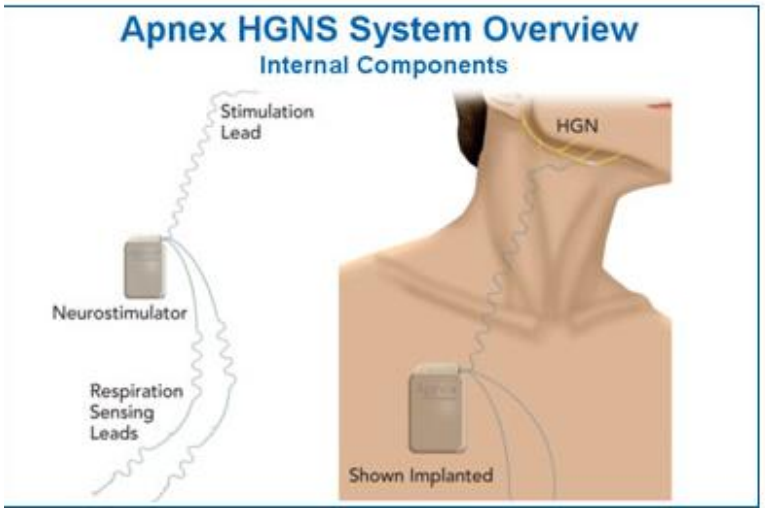
- Adenotonsillectomy
- Nasal Surgery
- Uvulopalatopharyngoplasty
- Genioglossus Advancement
- Hyoid Advancement
- Maxillomandibular Advancement
- Hypoglossal Nerve Stimulation
- Tracheostomy

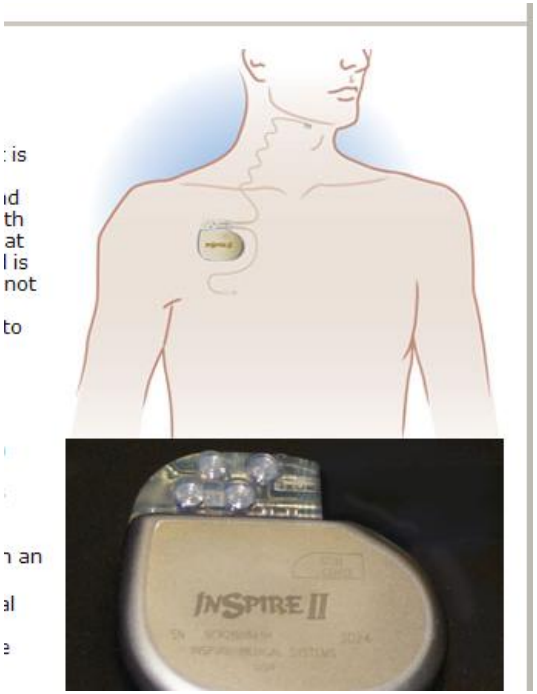
Table 7—Common Surgical Procedures for OSA by Site

Upper Airway Bypass Procedure	Tracheotomy
Nasal Procedures	Septoplasty
	Functional rhinoplasty
	Nasal valve surgery
	Turbinate reduction
	Nasal polypectomy
	Endoscopic procedures
Oral, Oropharyngeal, and Nasopharyngeal Procedures	Uvulopalatopharyngoplasty and variations
	Palatal advancement pharyngoplasty
	Tonsillectomy and/or adenoidectomy
	Excision of tori mandibularis
	Palatal implants
Hypopharyngeal Procedures	Tongue Reduction
	Partial glossectomy
	Tongue ablation
	Lingual tonsillectomy
	Tongue Advancement/Stabilization
	Genioglossus advancement
	Hyoid suspension
	Mandibular advancement
	Tongue suspension
Laryngeal Procedures	Epiglottoplasty
	Hyoid suspension
Global Airway Procedures	Maxillomandibular advancement
	Bariatric surgery

Epstein et al 2009

Hypoglossal Nerve Stimulation





Hypoglossal Nerve Stimulation (Eastwood et al., 2011)

- N=21
- Single arm, prospective, interventional study
- Each participant was CPAP intolerant and had surgical implantation of the device
- The device is able to be controlled by the patient
  - 89% ±15% the device was used
  - 19/21 had baseline and 6 month follow up PSG
  - Significant improvement from baseline in AHI (43.1 ± 17.5 to 19.5 ±16.7, p=<0.05)
  - ESS 12.1 ±4.7 to 8.1 ± 4.4, p=<0.05)
- HGNS demonstrated favorable safety, efficacy and compliance.

Hypoglossal Nerve Stimulation (Kezirian et al, 2014)

HGNS was used on 86±16% of nights for 5·4±1·4 hours per night. There was a significant improvement ($p < 0·001$) from baseline to 12 months in AHI (45.4±17·5 to 25·3±20·6 events/h) and FOSQ score (14·2±2·0 to 17·0±2·4) as well as other polysomnogram and symptom measures. Outcomes were stable compared to 6 months following implantation

Table 1

Polysomnogram Measures

Parameter	Baseline	6 Months	12 Months***
AHI (events/h)	45.4 (17.5)	20.8 (17.6)*	25.3 (20.6)*
Apnea Index (events/h)	4.6 (6.3)	1.5 (2.2)*	3.2 (5.9)**
Hypopnea Index (events/h)	40.8 (15.3)	19.4 (16.6)*	22.1 (17.9)*
Arousal Index (events/h)	44.3 (17.7)	24.4 (13.2)*	27.5 (13.4)*
Respiratory Arousal Index	31.4 (18.4)	11.9 (11.9)*	14.4 (12.4)*
ODI4% Index (events/h)	20.9 (17.3)	10.7 (17.1)*	15.7 (19.6)*
Total Sleep Time (min)	346.4 (71.6)	355.2 (52.9)	362.7 (55.9)
Sleep Efficiency (%)	77.2 (12.6)	82.8 (10.9)**	82.6 (10.2)**
% N1	29.3 (11.2)	20.5 (10.2)*	21.8 (10.3)*
% N2	48.8 (7.9)	52.3 (10.2)	50.6 (8.4)
% N3	9.3 (7.7)	10.9 (8.9)	11.9 (8.9)
% REM	12.6 (6.5)	16.1 (5.7)**	16.4 (5.0)**

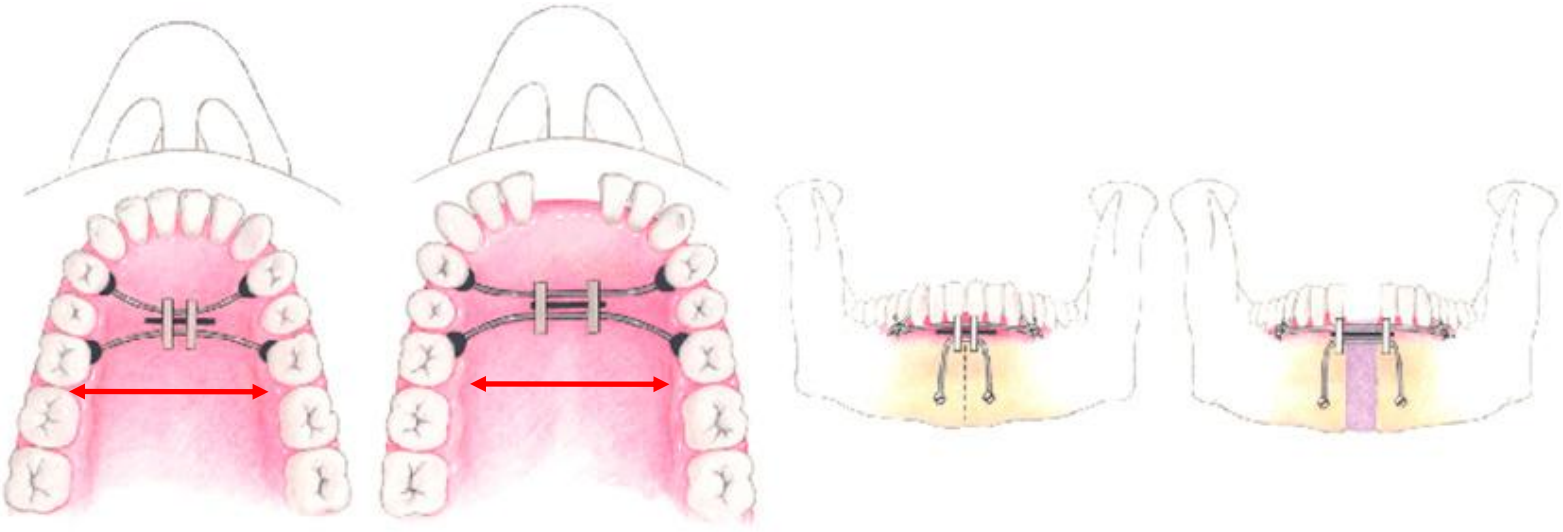
Symptoms and Quality of Life Measures

Scale	Baseline	6 month	12 month***
FOSQ	14.2 (2.0)	16.8 (2.4)*	17.0 (2.4)*
ESS	12.1 (4.6)	8.3 (3.6)*	7.9 (3.8)*
SAQLI	3.1 (1.1)	4.8 (1.4)*	4.9 (1.4)*
PSQI	9.9 (3.2)	8.3 (4.3)	7.8 (4.3)**
BDI	15.7 (9.0)	8.5 (7.8)*	9.1 (8.2)*

Rapid Distraction Osteogenisis

- Rapid maxillary distraction in conjunction with TNA has shown to be successful in treating children with OSA and maxillary contraction (high-arched palate and unilateral or bilateral crossbite)
- Rapid maxillary distraction requires an orthodontic device anchored to two upper molars on each side of the jaw,which applies daily pressure causing each half of the maxilla to grow apart.
- Bone grows into the spaces bordering the midline
- cartilage
- This technique aims to expand the hard palate laterally, raise the soft palate, and widen the nasal passage.

Rapid Distraction Osteogensis



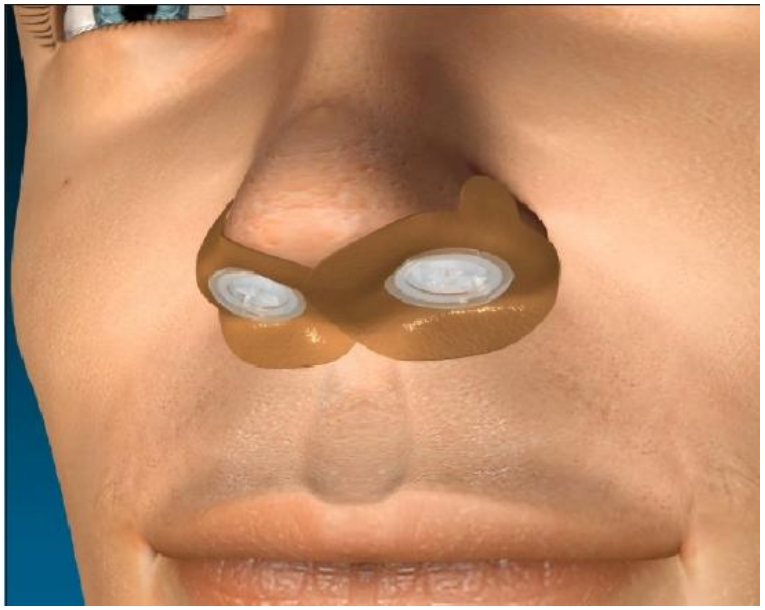
Won et al. (2008) Proc Am Thorac Soc

Oral "pap"

- Provides a negative pressure to the tongue
- Pulls the tongue forward using suction
- Oral like appliance is fit to the patient
- Dual tubing wicks away saliva into container

Provent

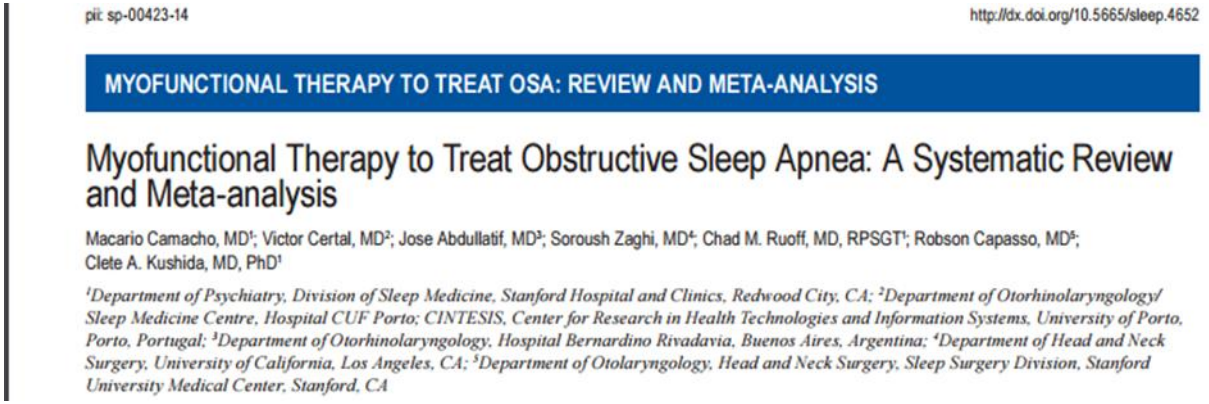
- Provides end expiratory pressure
- Exerts a pull on the trachea causing increased caudal tension : lessens the propensity for collapse
- Data show it works, but not as good as CPAP
- Improved subjective sleepiness (Berry et al, 2011



Problems

- Devices work, but not sure on who they will work the best on
- Lack of reimbursement
- Lack of market penetration
- Small companies lack clinical and ongoing support for clinicians and/or patients

- Myofunctional Therapy
  - Series of isotonic and isometric exercises targeted at the oral and oropharyngeal structures



pii: sp-00423-14 http://dx.doi.org/10.5665/sleep.4652

MYOFUNCTIONAL THERAPY TO TREAT OSA: REVIEW AND META-ANALYSIS

Myofunctional Therapy to Treat Obstructive Sleep Apnea: A Systematic Review and Meta-analysis

Macario Camacho, MD[1]; Victor Certal, MD[2]; Jose Abdullatif, MD[3]; Soroush Zaghi, MD[4]; Chad M. Ruoff, MD, RPSGT[1]; Robson Capasso, MD[5]; Clete A. Kushida, MD, PhD[1]

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Current literature demonstrates that myofunctional therapy decreases apnea-hypopnea index by approximately 50% in adults and 62% in children. Lowest oxygen saturations, snoring, and sleepiness outcomes improve in adults. Myofunctional therapy could serve as an adjunct to other obstructive sleep apnea treatments.

And all sorts of things……

- Didgeridoo

Table 2 Effects of intervention on sleep related outcomes

Outcome	Didgeridoo group	Control group	Raw difference* (95% CI)	Adjusted difference† (95% CI)
Epworth scale				
At 4 months	7.4 (2.3)	9.6 (6.0)		
Change from baseline	–4.4 (3.7)	–1.4 (2.6)	–3.0 (–5.7 to –0.3), P=0.03	–2.8 (–5.4 to –0.2), P=0.04
Pittsburgh quality of sleep index				
At 4 months	4.3 (2.1)	5.6 (2.7)		
Change from baseline	–0.9 (1.6)	–0.2 (1.7)	–0.7 (–2.1 to 0.6), P=0.27	–0.8 (–2.3 to 0.8), P=0.30
Partner rating of sleep disturbance				
At 4 months	2.3 (1.4)	4.8 (2.2)		
Change from baseline	–3.4 (2.4)	–0.6 (1.9)	–2.8 (–4.7 to –0.9), P<0.01	–2.7 (–4.2 to –1.2), P<0.01
Apnoea-hypopnoea index				
At 4 months	11.6 (8.1)	15.4 (9.8)		
Change from baseline	–10.7 (7.7)	–4.5 (6.9)	–6.2 (–12.3 to –0.1), P=0.05	–6.6 (–13.3 to –0.1), P=0.05

What this study adds

Regular playing of a didgeridoo reduces daytime sleepiness and snoring in people with moderate obstructive sleep apnoea syndrome and also improves the sleep quality of partners

Severity of disease, expressed by the apnoea-hypopnoea index, is also substantially reduced after four months of didgeridoo playing

Summary

- Options do exist for the treatment of OSA
- Take a patient centered approach to treatment, be curious and creative
- Assess the patients understanding and provide additional information as needed
- Support suggestions with the evidence