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PRASAT NEUROLOGICAL INSTITUTE

Role of nerve stimulation in sleep

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JCSM
Journal of Clinical Sleep Medicine

SPECIAL ARTICLES

Treatment of Adult Obstructive Sleep Apnea with Positive Airway Pressure: An American Academy of Sleep Medicine Clinical Practice Guideline

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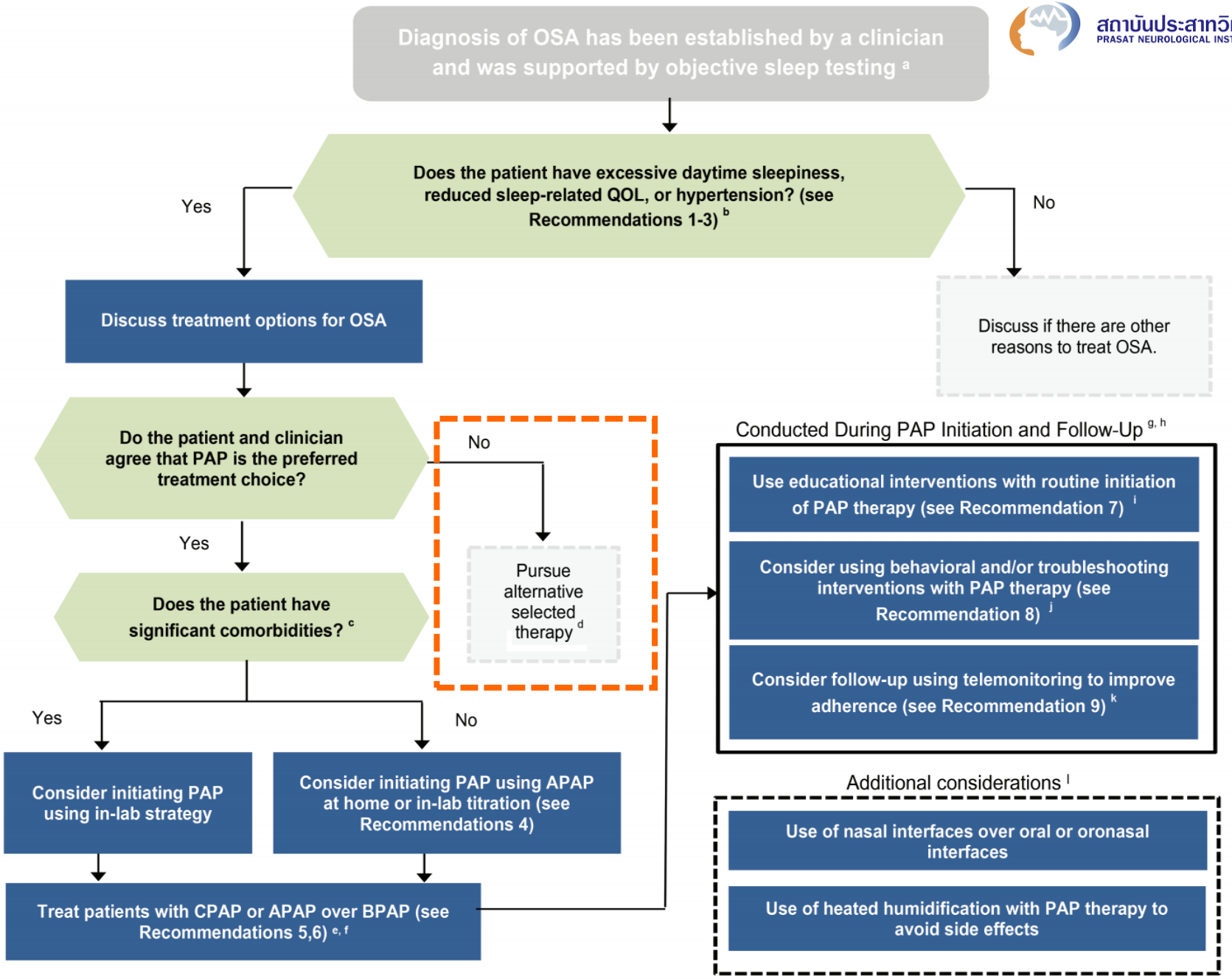


Journal of Clinical Sleep Medicine, Vol. 15, No. 2, February 15, 2019

Alternative selected therapy

- Behavioral
  - Positioning therapy
  - Weight loss
  - Alcohol cessation
- Oral appliance
- Surgical
  - Bypass upper airway
  - Upper airway procedure
- Adjunctive
  - Oxygen
  - Medication
  - Bariatric surgery

Nerve stimulation

Journal of Clinical Sleep Medicine, Vol.5, No. 3, 2009

History and evolution of HGNS concepts

- In 1978, Guilliminault[1] was attempt to improve upper airway patency in humans via transcutaneous submental and intraoral electrical simulation of UA muscle with limited success.

- In 1996, Schwartz et al.[2] report preliminary successful human studies by intramuscular stimulation of the lingual muscle in 9 patients, the frequency of airway collapse decreased without causing sleep arousal

1. Guilleminault C, Hill MW, Simmons FB, Dement WC (1978) Obstructive sleep apnea: electromyographic and fiberoptic studies. Exp Neurol 62(1):48 –67
2. Schwartz AR, Eisele DW, Hari A, Testerman R, Erickson D, Smith PL (1996) Electrical stimulation of the lingual musculature in obstructive sleep apnea. J Appl Physiol 81(2):643 –652

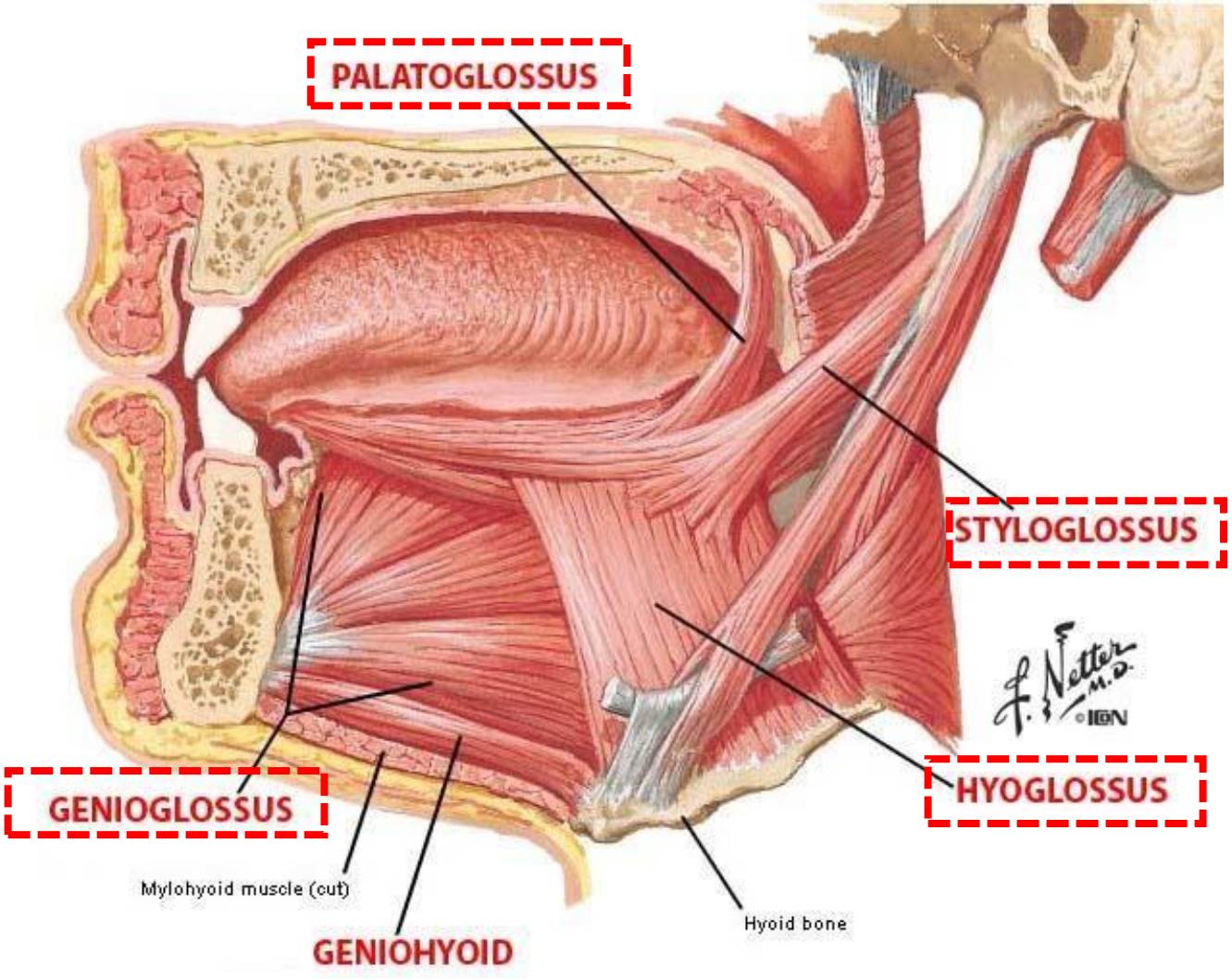
History and evolution of HGNS concepts

- A pilot study[3] in 2001 proposed that unilateral electrical stimulation of the HGN was feasible and potential therapeutic option of OSA

- In 2010, Efficacy of OSA treatment was shown in 7 of 8 HGNS implanted patients (Inspire Medical systems, Maple Grove MN). For 6-month continuation of the study, the results were consistent. They were not successful in the long term due to technical defects that led to device dysfunction[4]

3. Schwartz AR, Bennett ML, Smith PL, De Backer W, Hedner J, Boudewyns A et al (2001) Therapeutic electrical stimulation of the hypoglossal nerve in obstructive sleep apnea. Arch Otolaryngol Head Neck Surg 127(10):1216 –1223
4. Kezirian EJ, Boudewyns A, Eisele DW, Schwartz AR, Smith PL, Van de Heyning PH et al (2010) Electrical stimulation of the hypoglossal nerve in the treatment of obstructive sleep apnea. Sleep Med Rev 14(5):299 –305

Tongue anatomy and physiology



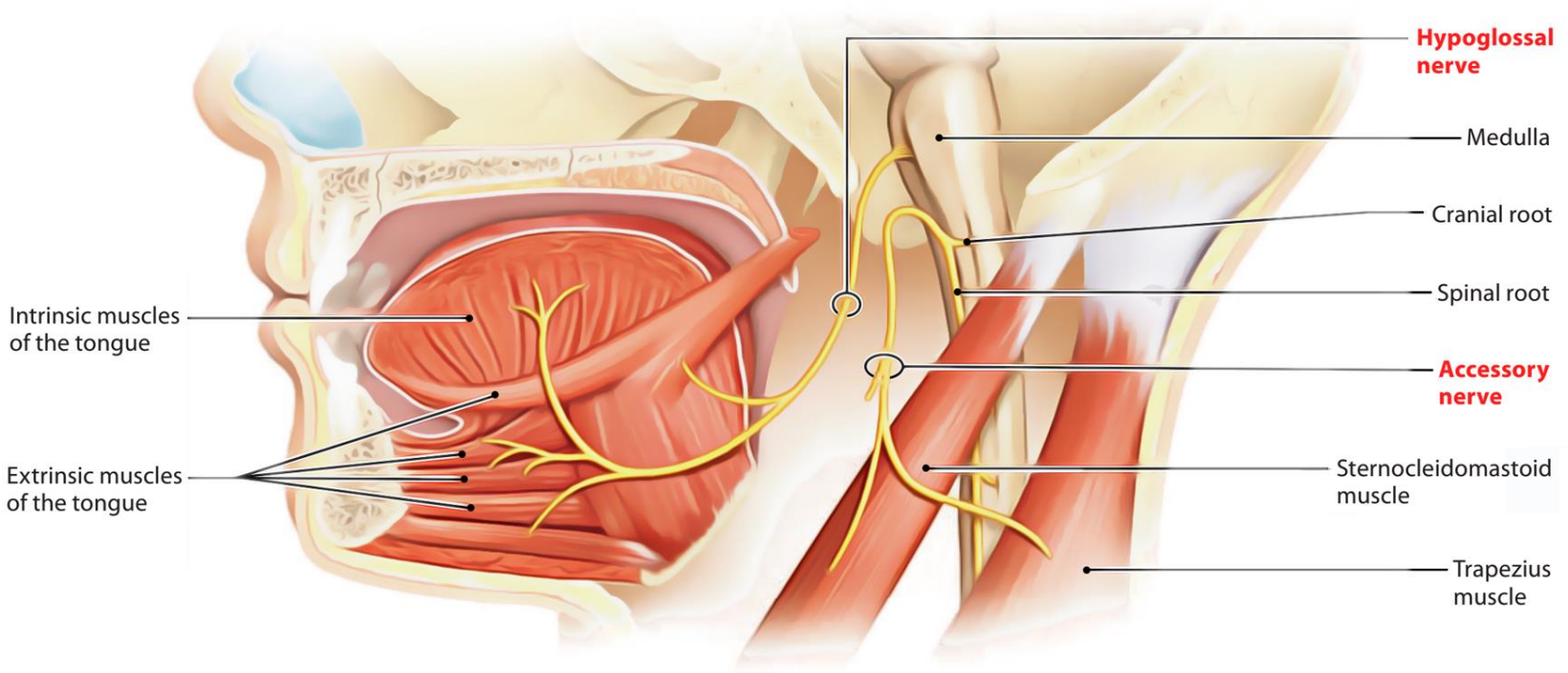
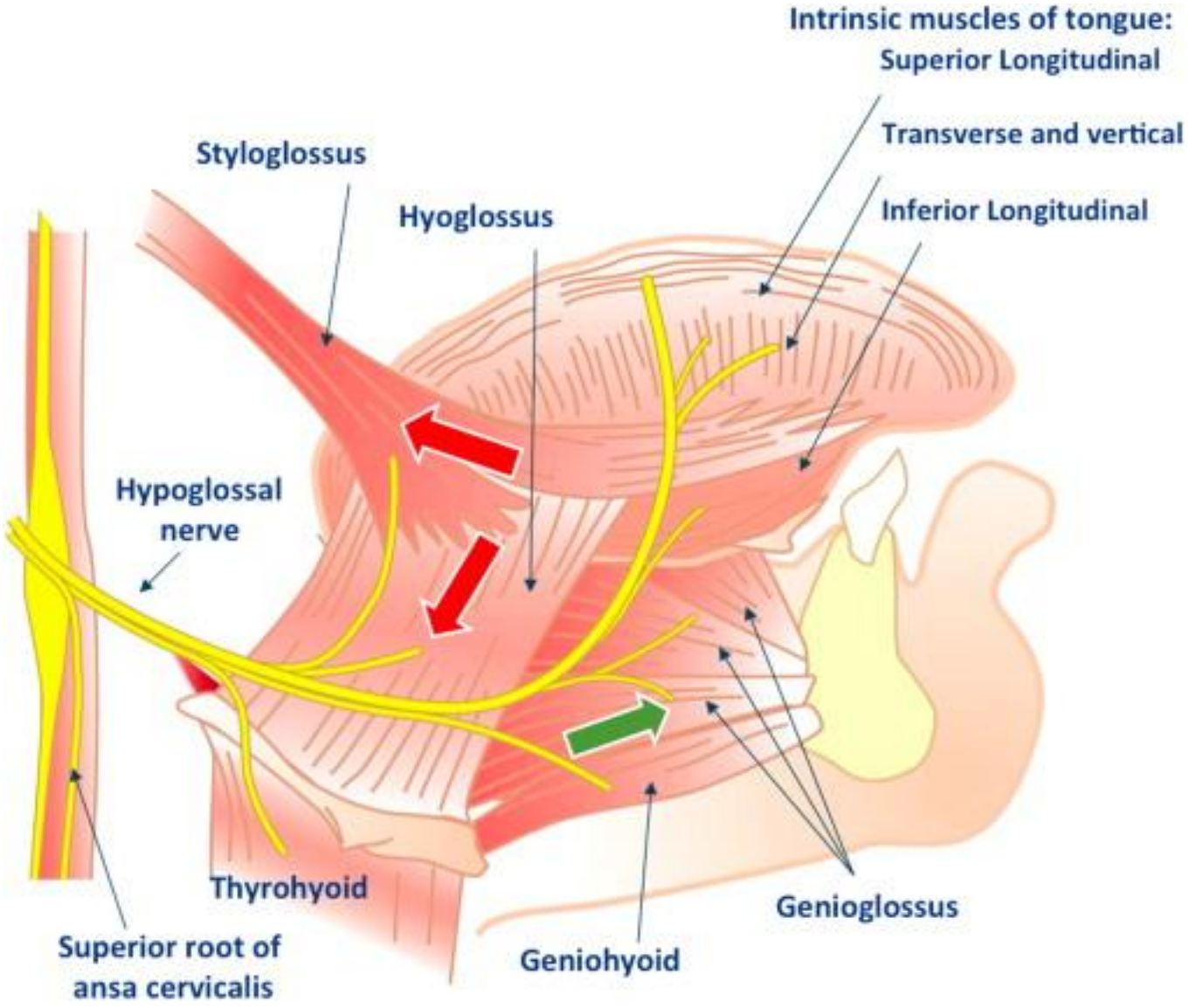
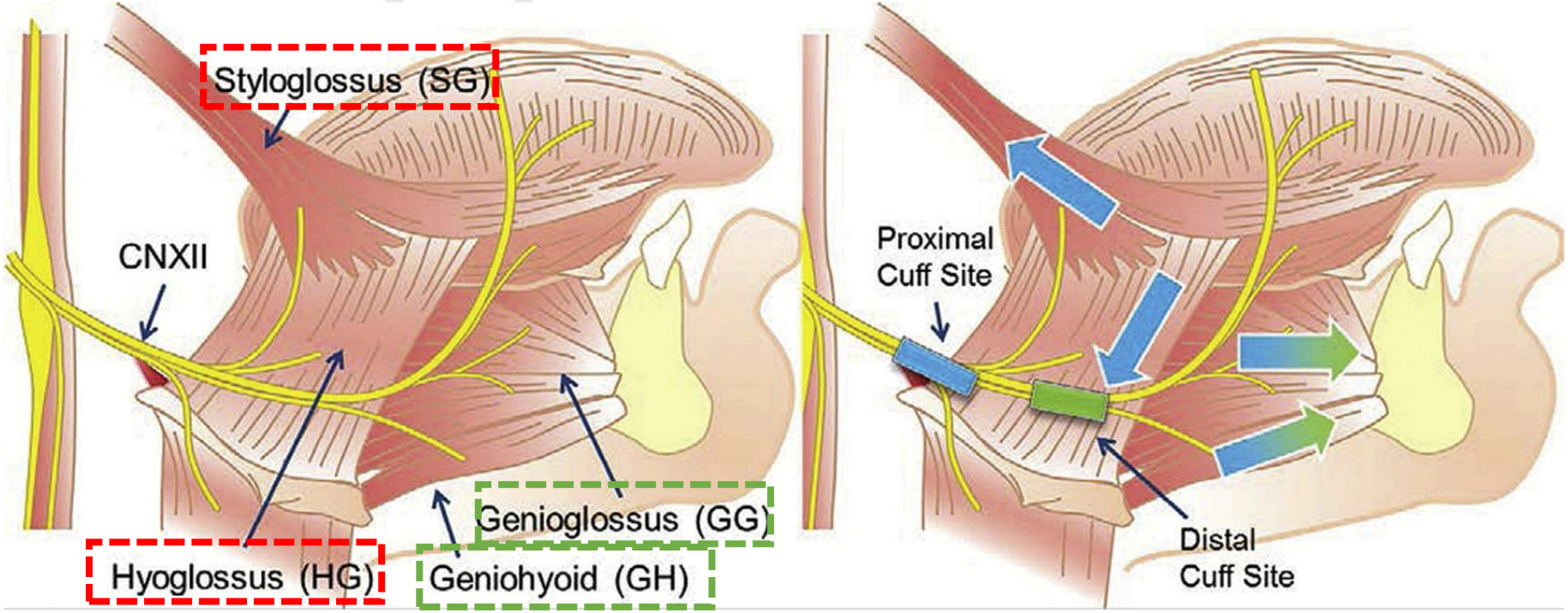


Table 1: Tongue Musculature and Nerve Supply

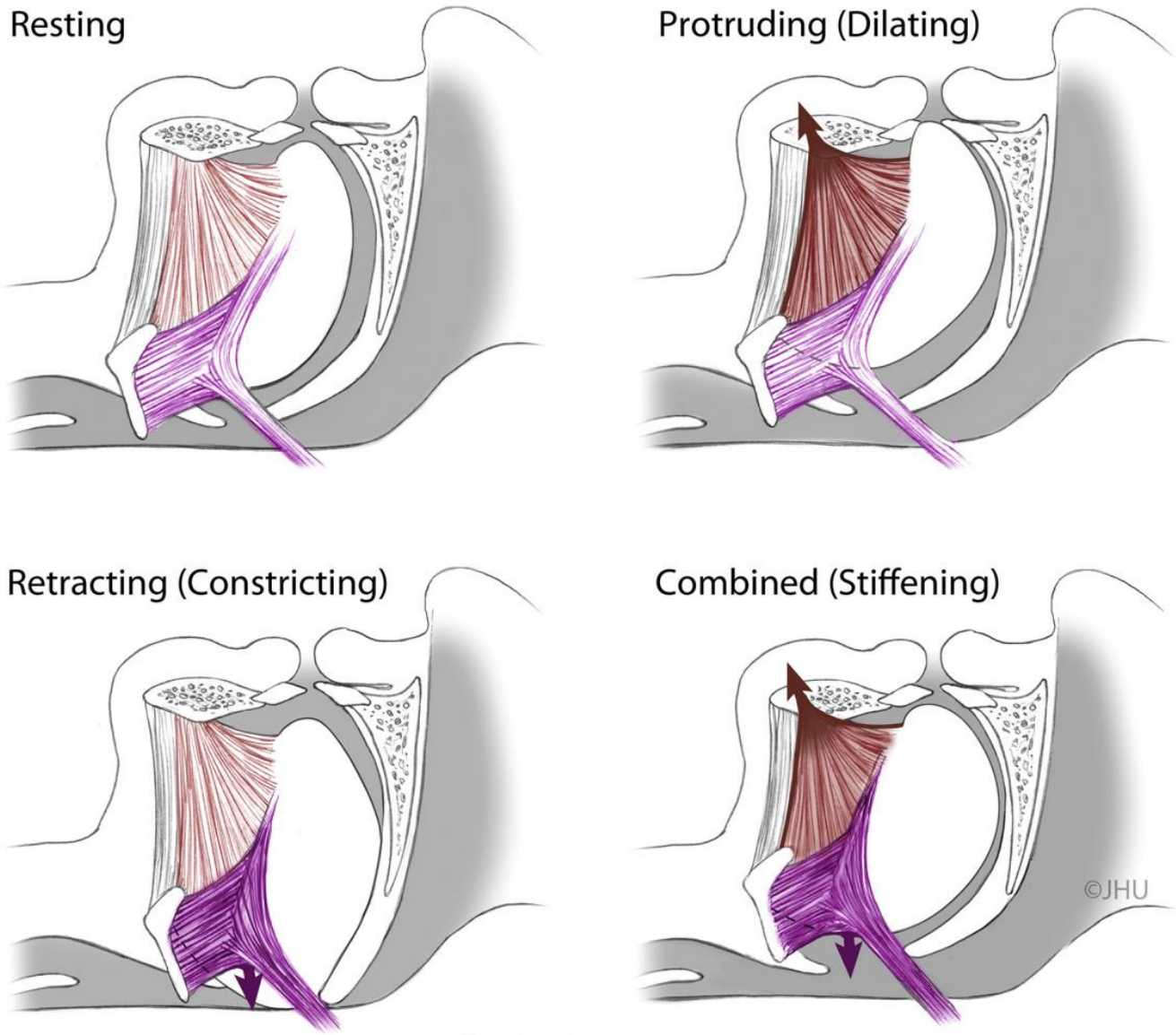
Muscle	Innervation	Function
Genioglossus	Lingual branch of hypoglossal nerve	Posterior fibers: Push tongue root forward and protrude tongue tip Anterior fibers: Depress and retract tongue
Hyoglossus	Lingual branch of hypoglossal nerve	Retract tongue and Depress tongue sides
Styloglossus	Lingual branch of hypoglossal nerve and vagus nerve	Draws tongue upward
Intrinsic Muscles	Lingual branch of hypoglossal nerve	Alters tongue shape; Can cause tongue to shorten, narrow, and curve
Palatoglossus	Vagus nerve	Elevates the back of the tongue


Intrinsic muscles of tongue:
Superior Longitudinal
Transverse and vertical
Inferior Longitudinal
Styloglossus
Hyoglossus
Hypoglossal nerve
Thyrohyoid
Superior root of ansa cervicalis
Geniohyoid
Genioglossus



The anatomy and rationale for cuff placement. Left image shows the hypoglossal nerve and its branches to the retractors (styloglossus and hyoglossus) or protrudors (genioglossus and geniohyoid) muscles. Right image shows the two cuff placement sites, where the proximal site results in both group activations while the distal site selectively activates protrudors. Colors denote this difference (proximal results in all four arrows, distal only green arrows)

DOI: https://doi.org/10.1016/j.chest.2018.08.1070



DOI: https://doi.org/10.1016/j.chest.2018.08.1070

HGNS devices and device concepts

- Apnex (St. Paul, MN, USA)
  - Unilateral inspiratory stimulation to the medial branch of the hypoglossal nerve
  - Double impedance sensor positioned over the lower rib of both hemithoraces.
- Inspire (Maple Grove, MN, USA)
  - Unilateral inspiratory stimulation to the medial branch of the hypoglossal nerve
  - Effort sensor placed between the intercostal muscle
- Aura6000 (ImThera Medical, San Diego, CA, USA)
  - No chest sensing
  - Main trunk and targeted all muscles in the hemi-lateral tongue
- Genio™ system (Nyxoah SA, Mont-Saint-Guibert, Belgium)
  - Bilateral stimulation
  - No any leads

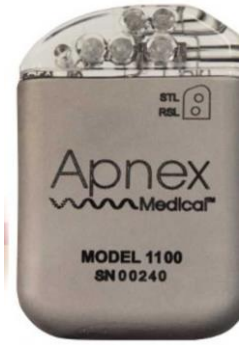
TREATING OSA WITH HYPOGLOSSAL NERVE STIMULATION

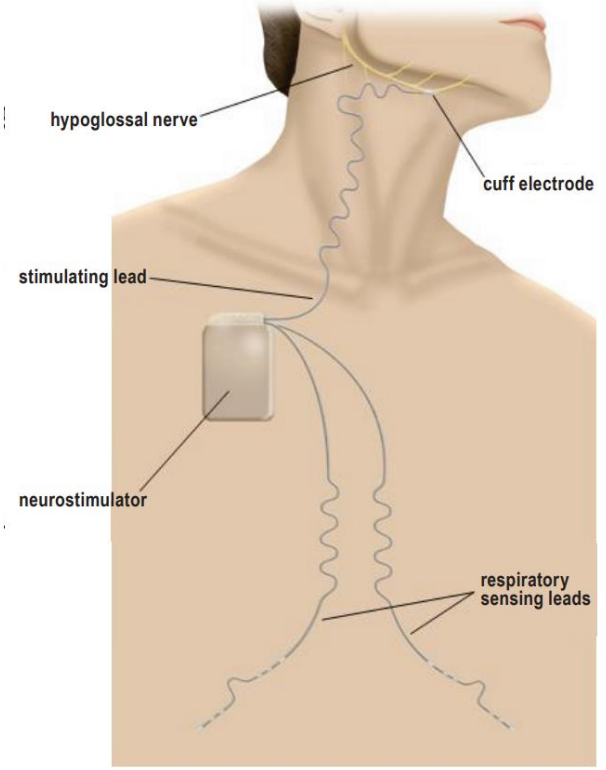
http://dx.doi.org/10.5665/sleep.1380

Treating Obstructive Sleep Apnea with Hypoglossal Nerve Stimulation

Peter R. Eastwood, PhD[1,2]; Maree Barnes, MBBS[3]; Jennifer H. Walsh, PhD[1,2]; Kathleen J. Maddison, BSc[1,2]; Geoffrey Hee, MBBS; Alan R. Schwartz, MD[5]; Philip L. Smith, MD[5]; Atul Malhotra, MD[6]; R. Douglas McEvoy, MBBS[7,11,15]; John R. Wheatley, MBBS, PhD[8]; Fergal J. O'Donoghue, MBBS, PhD[3,4]; Peter D. Rochford, BAppSc, GradDip (Bio Instr)[3,9]; Tom Churchward, RPSGT[3]; Matthew C. Campbell, MBBS[3]; Carsten E. Palme, MBBS[10]; Sam Robinson, MBBS[11]; George S. Goding, MD[12]; Danny J. Eckert, PhD[13]; Amy S. Jordan, PhD[4]; Peter G. Catcheside, PhD[7,11,15]; Louise Tyler, RN, RPSGT[8,14]; Nick A. Antic, MBBS, PhD[7,11,15]; Christopher J. Worsnop, MBBS, PhD[3,4]; Eric J. Kezirian, MD, MPH[16]; David R. Hillman, MBBS[1]

- 21 patients implanted
- AHI between 20 and 100 event/hour (at least 80% hypopnea), BMI < 40 kg/m^2, age between 21 and 70 years
- 6 month follow up yielded successful result with more than 50% reduction in AHI





SLEEP, Vol. 34, No. 11, 2011

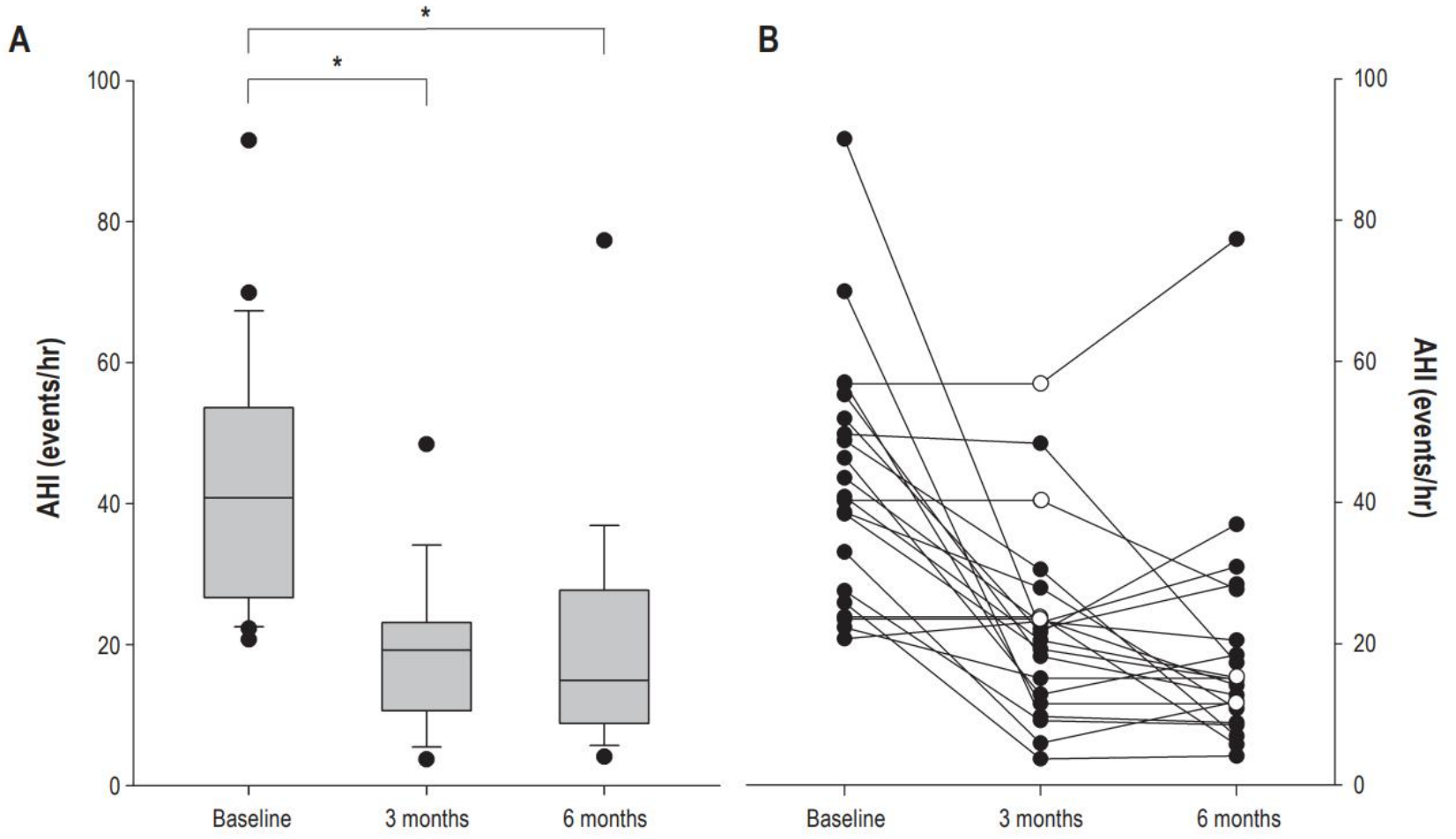
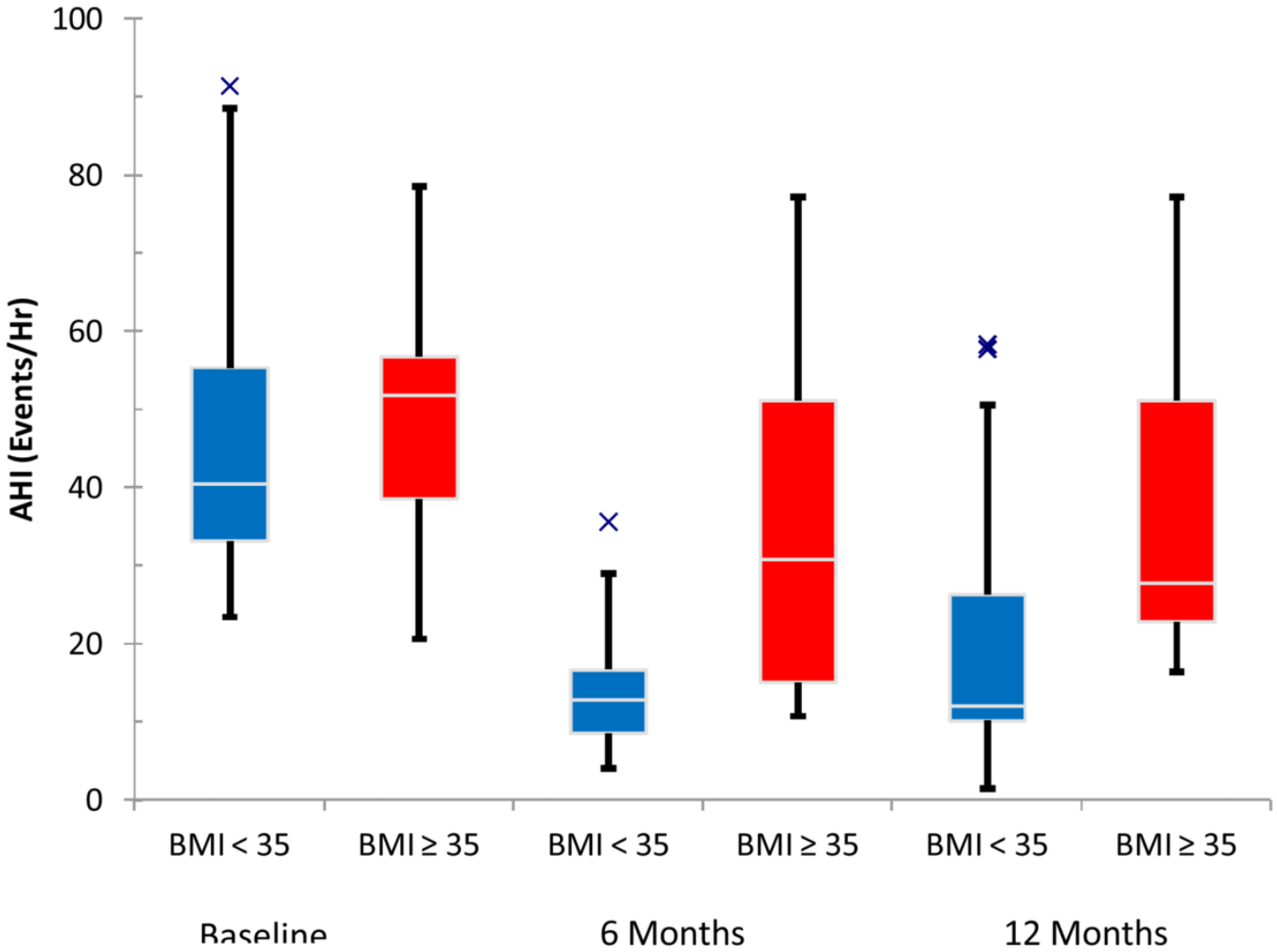


Figure 4—Apnea-hypopnea index (AHI) scores at Baseline and at 3 and 6 months following implant. **(A)** Boxplots of group data showing the median values indicated by the thick horizontal lines, and the 25th and 75th percentiles indicated by the upper and lower margins of the box, respectively at Baseline (n = 21), 3 months (n = 17), and 6 months (n = 19) post-implant. Error bars represent 5th and 95th percentiles. Extreme values are indicated by closed circles, *P < 0.001. **(B)** Line graph showing individual data (n = 21). A missing data point in any given subject was derived using the last value carried forward method and is shown as an open circle.

SLEEP, Vol. 34, No. 11, 2011



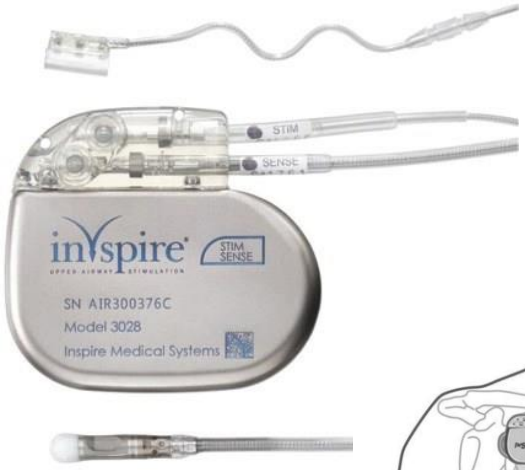
J Sleep Res. 2014 February ; 23(1): 77–83. doi:10.1111/jsr.12079

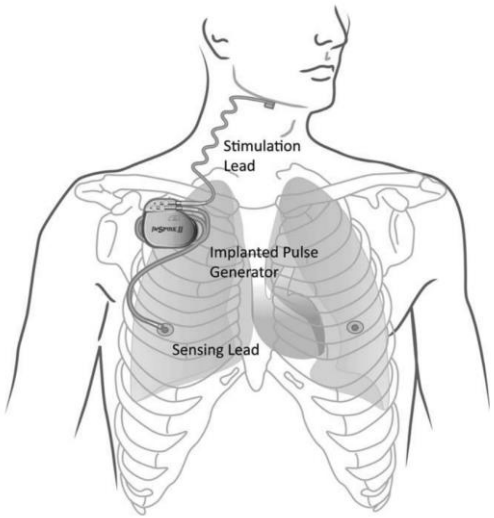
Box and whisker plot of the apnea-hypopnea index at baseline and at 3, 6, and 12 months post implantation, shown separately for BMI ≤ 35 kg/m2 and BMI > 35 kg/m2 . The median values are noted by horizontal white lines, and the boxes represent the intraquartile range. The whiskers represent the 1.5x the intraquartile range (or the minimum or maximum value if < 1.5x the intraquartile range). The Xs represent outlier values.

Implanted Upper Airway Stimulation Device for Obstructive Sleep Apnea

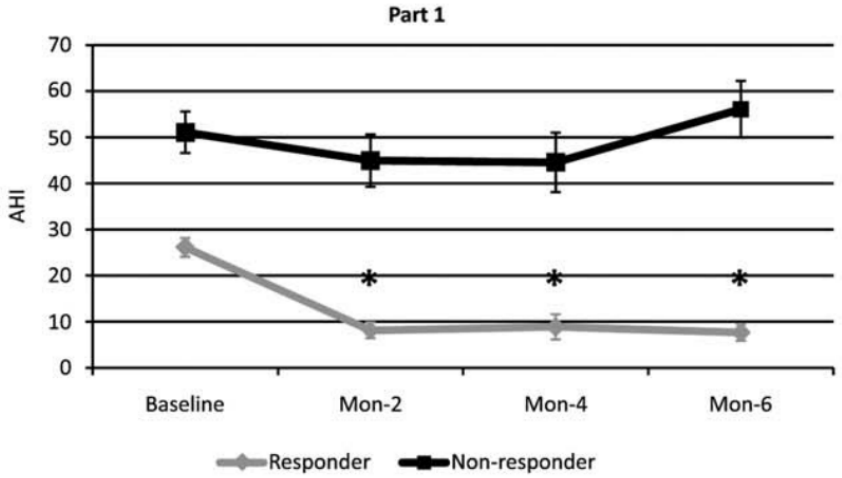
Paul H. Van de Heyning, MD, PhD; M. Safwan Badr, MD; Jonathan Z. Baskin, MD; Michel A. Cramer Bornemann, MD; Wilfried A. De Backer, MD, PhD; Yaniv Dotan, MD; Winfried Hohenhorst, MD; Lennart Knaack, MD; Ho-Sheng Lin, MD; Joachim T. Maurer, MD, PhD; Aviram Netzer, MD; Rick M. Odland, MD; Arie Oliven, MD; Kingman P. Strohl, MD; Olivier M. Vanderveken, MD, PhD; Johan Verbraecken, MD, PhD; B. Tucker Woodson, MD

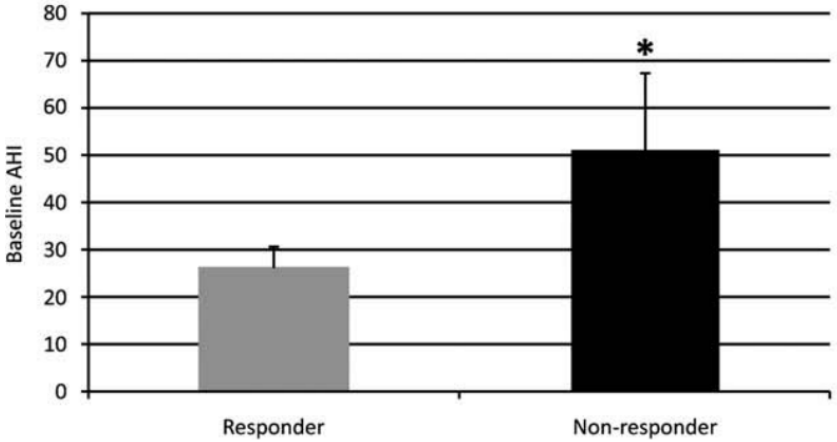
- The result from 6-month clinical trial with the Inspire II device
- First part with wide inclusion
  - 20 patients implanted
  - AHI >25 event/hour, BMI < 35 kg/m^2
  - 14 patients showed the predicted outcome
  - 6 patients showed greater than 50% reduced AHI

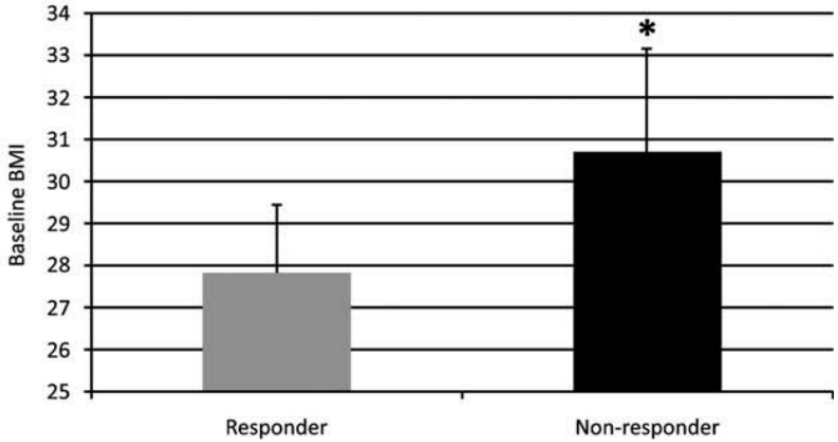




Laryngoscope, 122:1626–1633, 2012







Apnea hypopnea index (AHI) response of part 1 subjects is shown. AHI was reduced significantly in the responder group at 2-, 4-, and 6-month postimplant visits (marked by asterisks) compared with the baseline. The responder group had a significantly lower AHI and body mass index (BMI) than the nonresponder group

Laryngoscope, 122:1626–1633, 2012

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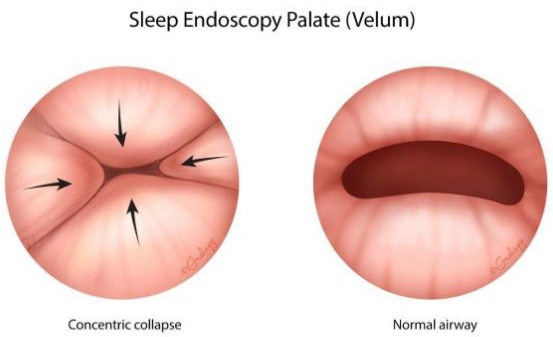
Paul H. Van de Heyning, MD, PhD; M. Safwan Badr, MD; Jonathan Z. Baskin, MD; Michel A. Cramer Bornemann, MD; Wilfried A. De Backer, MD, PhD; Yaniv Dotan, MD; Winfried Hohenhorst, MD; Lennart Knaack, MD; Ho-Sheng Lin, MD; Joachim T. Maurer, MD, PhD; Aviram Netzer, MD; Rick M. Odland, MD; Arie Oliven, MD; Kingman P. Strohl, MD; Olivier M. Vanderveken, MD, PhD; Johan Verbraecken, MD, PhD; B. Tucker Woodson, MD

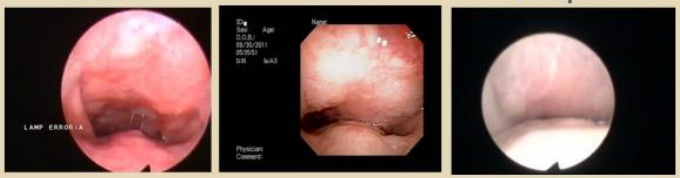
- Second part with narrowed the criteria base on the finding from part one and included drug-induced sleep endoscopy (DISE) as a diagnosis modality
  - AHI between 20 and 50 event/hour
  - BMI < 32 kg/m^2
  - Absence of complete concentric collapse (CCC) of the velum as seen during DISE

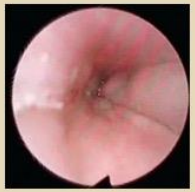


Laryngoscope, 122:1626–1633, 2012

DISE inclusion/exclusion criteria

None | Partial AP | Complete AP





All other velopharynx collapse types
All other oropharyngeal/hypopharyngeal types

~80%

Implant Eligible

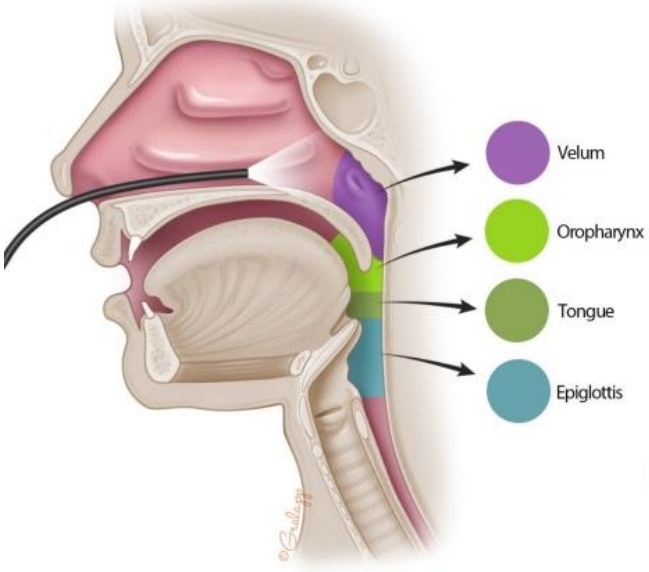
Velopharynx
Complete
Concentric Collapse

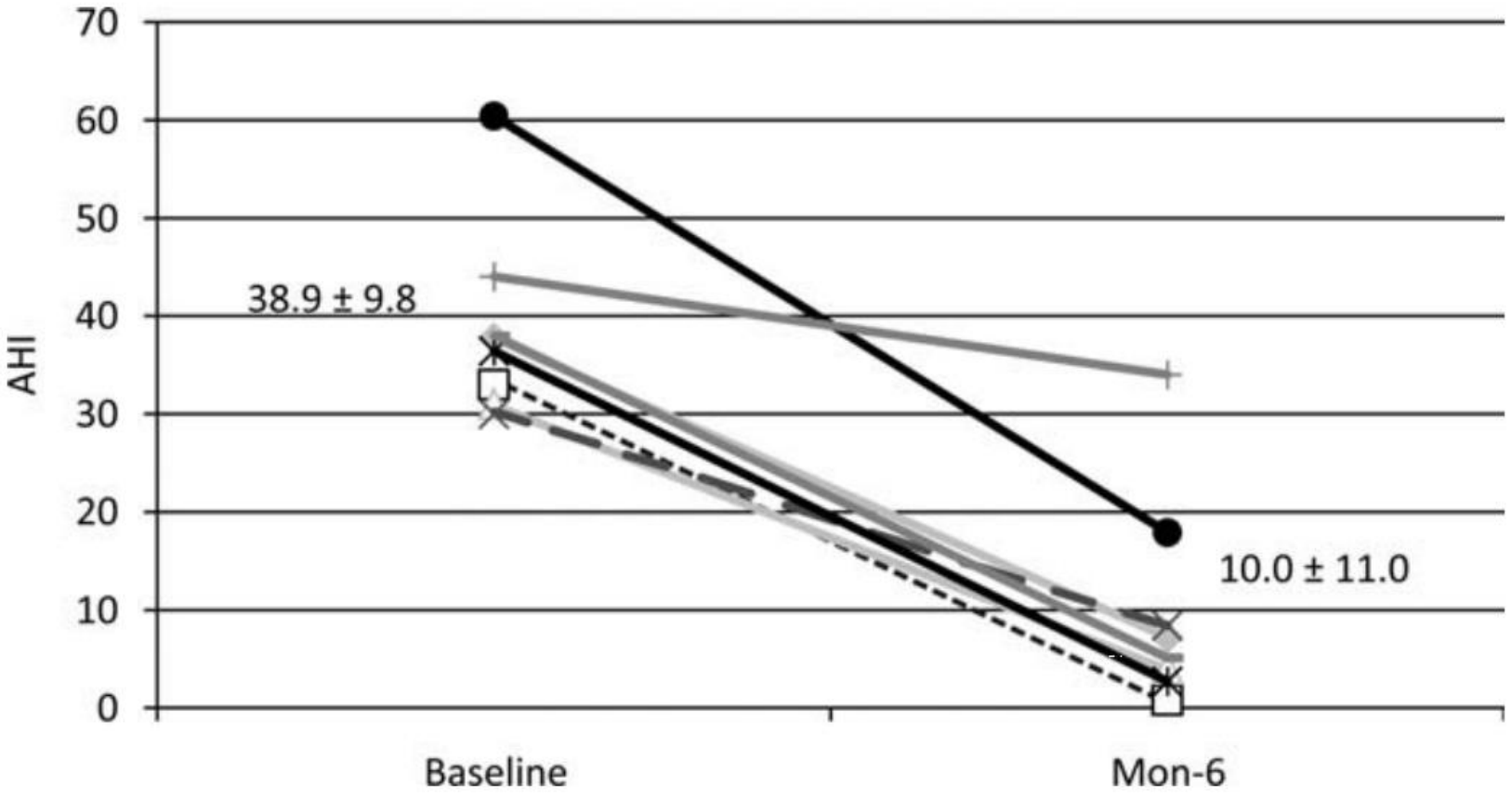
~20%

Contra-indicated

Strollo PJ, Soose RJ, Maurer JT, et al. Upper-airway stimulation for obstructive sleep apnea. *N Engl J Med* 2014; 370:139-49.

Sleep Endoscopy





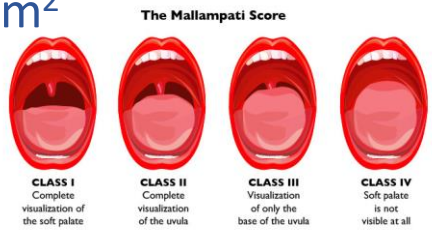
Summary of part 2 subjects' apnea hypopnea index (AHI) at baseline and 6 months postimplant is shown

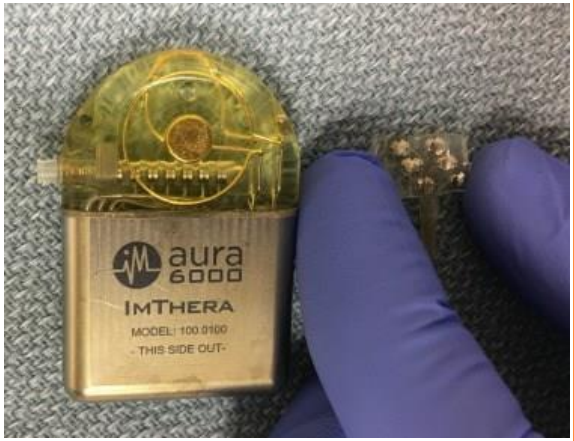
Laryngoscope, 122:1626–1633, 2012

Targeted hypoglossal neurostimulation for obstructive sleep apnoea: a 1-year pilot study

Gimbada B. Mwenge*,#, Philippe Rombaux#,¶, Myriam Dury#, Benoît Lengelé+ and Daniel Rodenstein*,#

- The result from 1-year clinical trial with Aura6000 in 13 implanted patient
- Inclusion criteria
  - BMI between 25 and 40 kg/m^2
  - AHI $\geq$ 20 event/hour
  - Mallampati score 1-3
  - Palatine tonsils grade 0-2

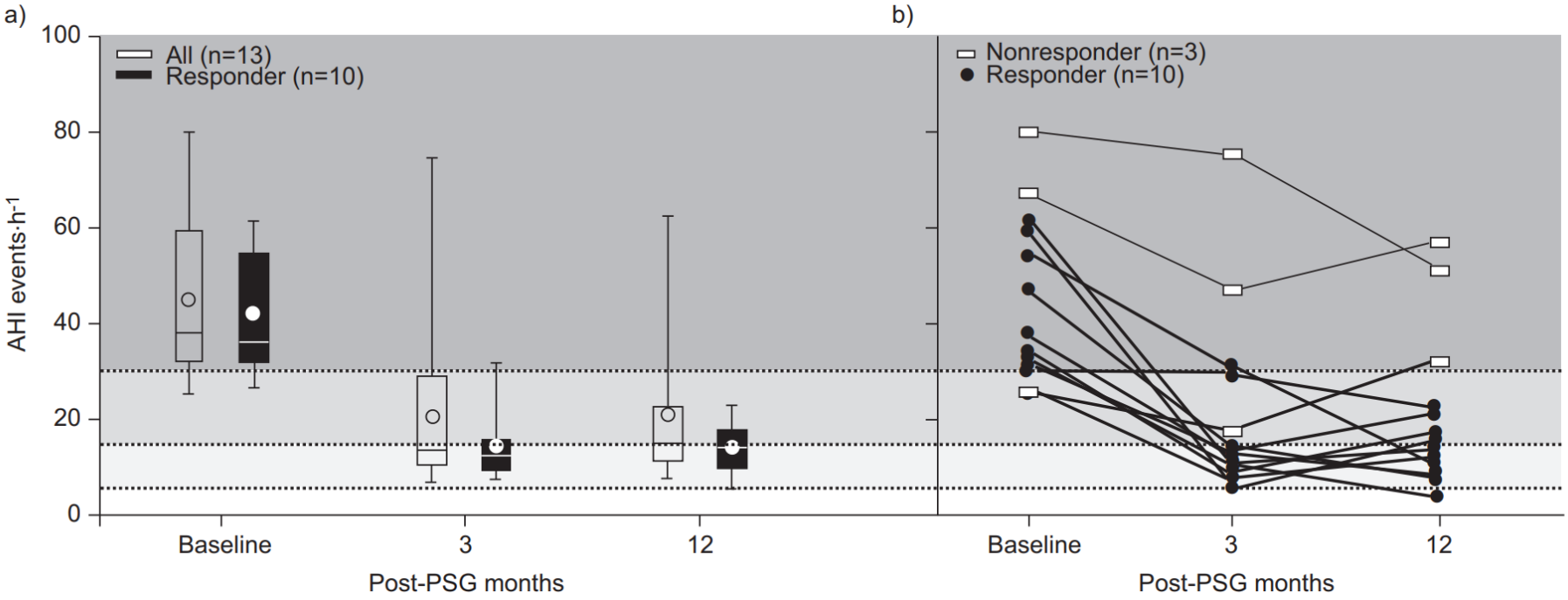




- Primary outcome : mean change in AHI in PSG performed 3 and 12 months relative to presurgical baseline

Eur Respir J 2013; 41: 360–367 DOI: 10.1183/09031936.00042412

Mean AHI decrease from 45.2 to 21 events/hour



Eur Respir J 2013; 41: 360–367 DOI: 10.1183/09031936.00042412

สถาบันประสาทวิทยา
PRASAT NEUROLOGICAL INSTITUTE

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Upper-Airway Stimulation for Obstructive Sleep Apnea

Patrick J. Strollo, Jr., M.D., Ryan J. Soose, M.D., Joachim T. Maurer, M.D., Nico de Vries, M.D., Jason Cornelius, M.D., Oleg Froymovich, M.D., Ronald D. Hanson, M.D., Tapan A. Padhya, M.D., David L. Steward, M.D., M. Boyd Gillespie, M.D., B. Tucker Woodson, M.D., Paul H. Van de Heyning, M.D., Ph.D., Mark G. Goetting, M.D., Olivier M. Vanderveken, M.D., Ph.D., Neil Feldman, M.D., Lennart Knaack, M.D., and Kingman P. Strohl, M.D., for the STAR Trial Group*

N Engl J med 370;2 nejm.org january 9, 2014

STAR trial

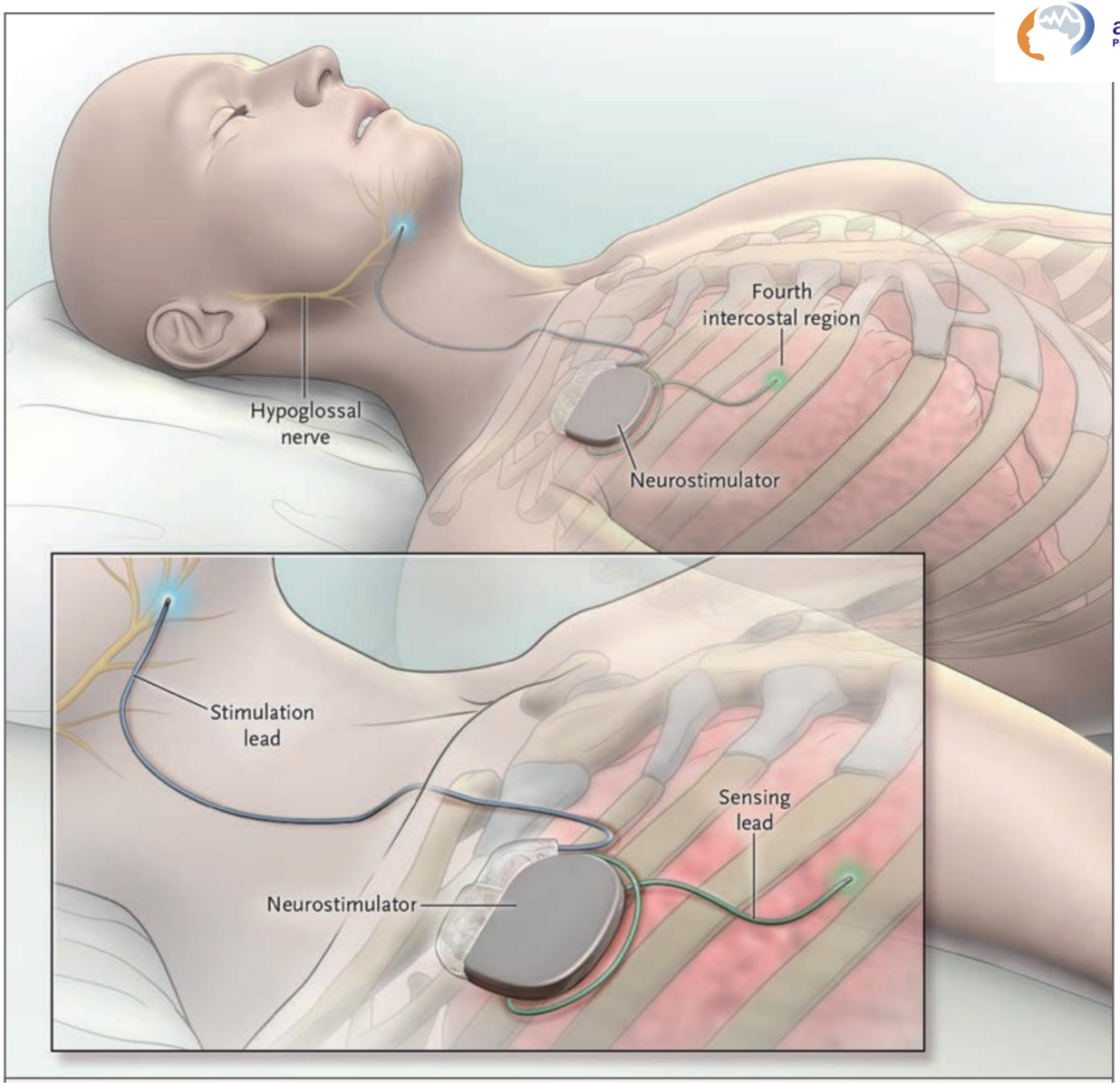
- Inclusion criteria
  - Adult with moderate to severe OSA if they had difficulty accepting or adhering to CPAP treatment
  - BMI < 32 kg/m^2
- Exclusion criteria
  - AHI < 20 or > 50
  - Central /mixed apnea ≥ 25%
  - Non-supine AHI < 10
  - Complete concentric collapse at retropalatal airway by endoscopy during drug induces sleep
  - No neuromuscular disease, hypoglossal nerve palsy, severe restrictive or obstructive pulmonary disease, moderate to severe pulmonary hypertension, sever valvular heart disease, NYH class III or IV heart failure, recent MI or severe cardiac arrythmia (within past 6 month), persistent uncontrolled hypertension, active psychiatric disease

N Engl J med 370;2 nejm.org january 9, 2014

STAR trial

- All case was done in lab PSG and endoscopy during drug induced sleep
- Eligible patient was implant INSPIRE®
  - Excluded patient with tonsil size of 3 or 4
- 1 month after surgery , in lab PSG for secondary baseline and immediately activation of the device
- Follow up at month 2,3,6 and 12

N Engl J med 370;2 nejm.org january 9, 2014



STAR trial

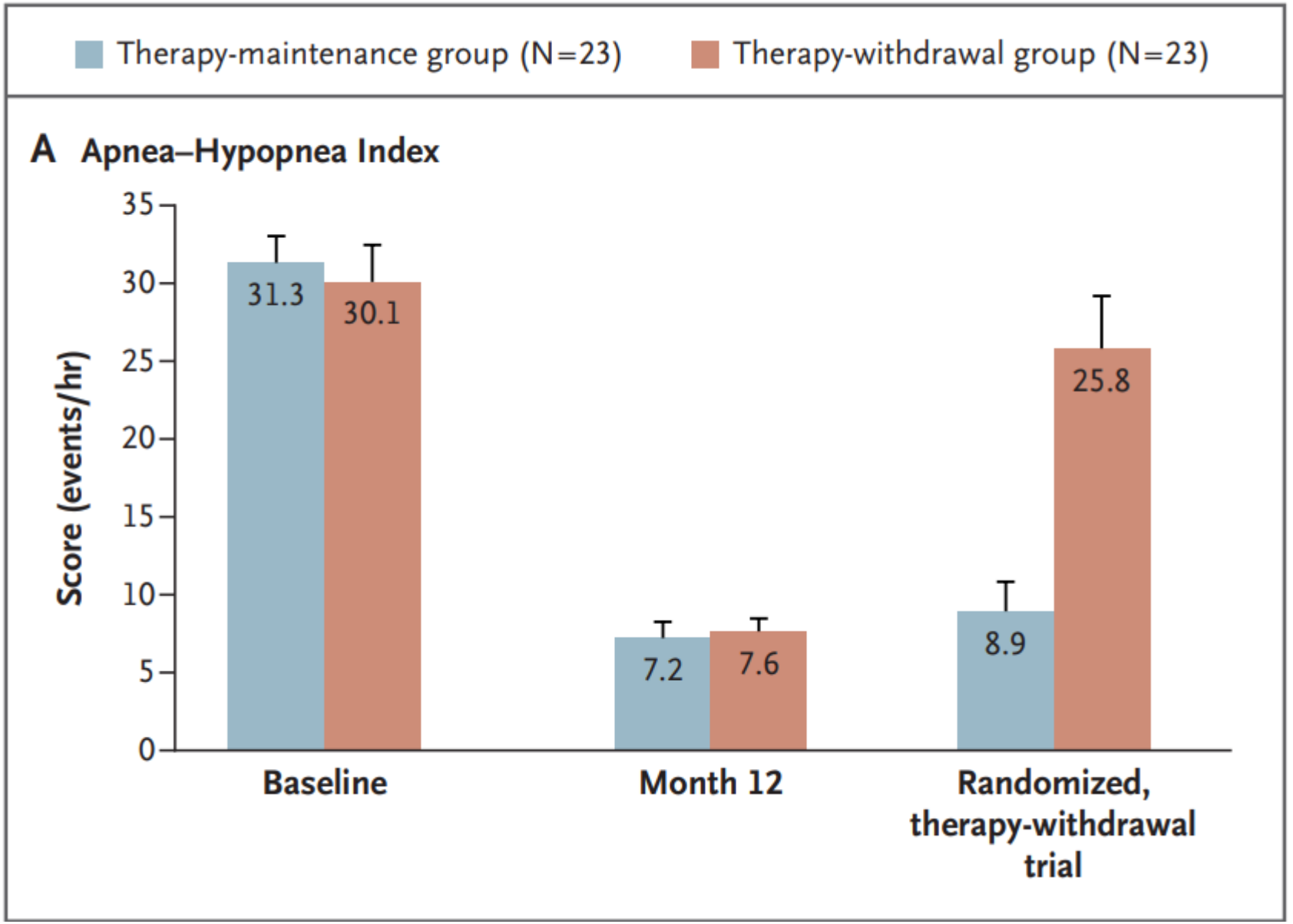
- Primary outcome : change for severity of AHI and ODI
- Secondary outcome : self reported sleepiness and disease-specific quality of life as assessed with the use of the Epworth Sleepiness Scale, Functional Outcomes of Sleep Questionnaire and the percentage of sleep time with the oxygen saturation less than 90%.

N Engl J med 370;2 nejm.org january 9, 2014

STAR trial

- A responder
  - AHI reduction of at least 50% from baseline and AHI score on the 12 months PSG less than 20
  - ODI reduction of at least 25% from baseline
- Participants who did not complete the 12 months visit were considered not to have a response.
- randomized controlled therapy withdrawal trial , AHI was compared between the therapy-maintenance group and therapy-withdrawal group

N Engl J med 370;2 nejm.org january 9, 2014



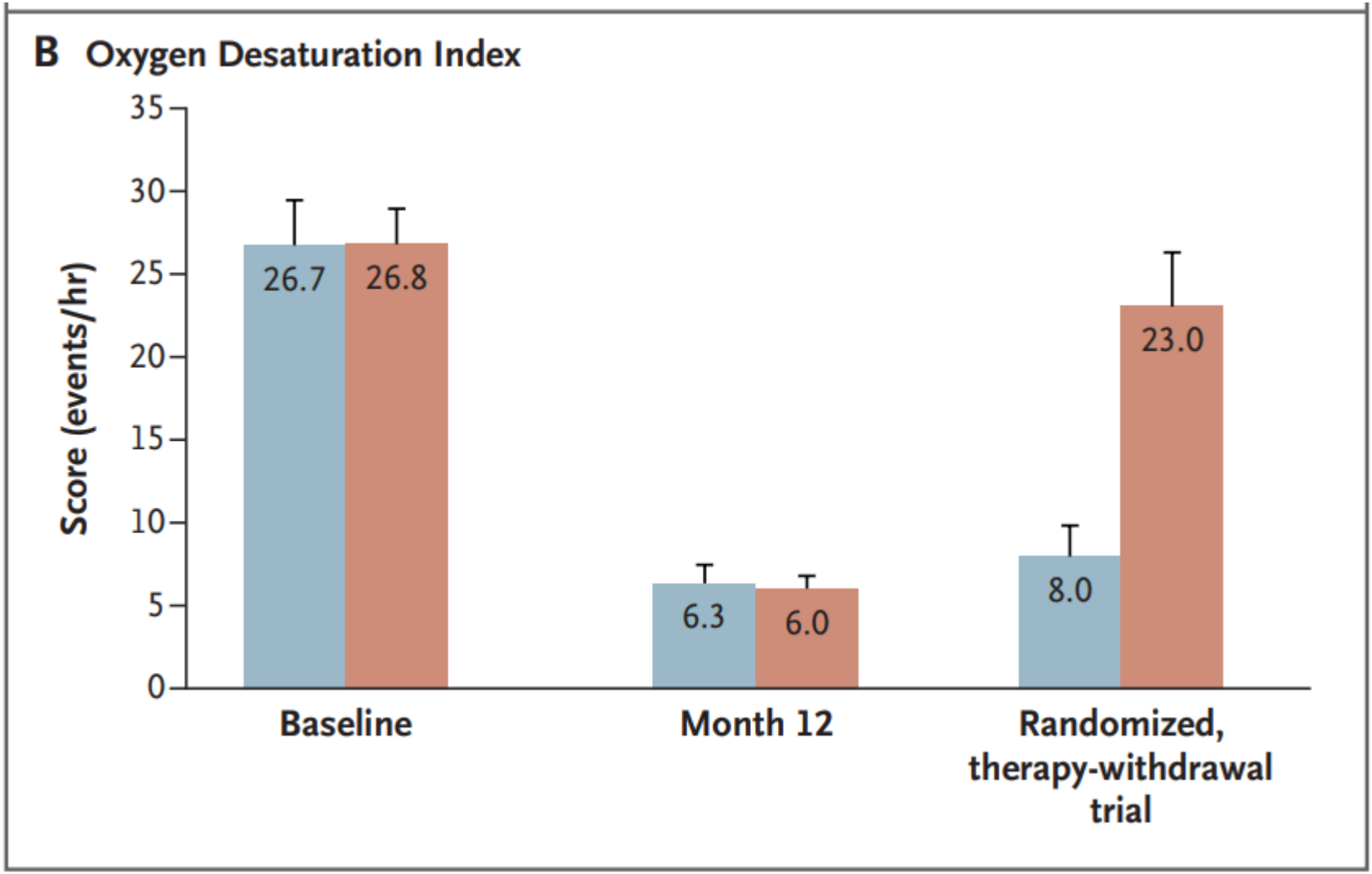

B Oxygen Desaturation Index
Score (events/hr)
35
30
25
20
15
10
5
0
26.7
26.8
6.3
6.0
8.0
23.0
Baseline
Month 12
Randomized, therapy-withdrawal trial

Table 2. Primary and Secondary Outcome Measures.*

Outcome	Baseline	12 Months	Change	P Value
Primary outcomes				
AHI score†	32.0±11.8	15.3±16.1	−16.4±16.7	<0.001
Median	29.3	9.0	−17.3	
Interquartile range	23.7 to 38.6	4.2 to 22.5	−26.4 to −9.3	
ODI score‡	28.9±12.0	13.9±15.7	−14.6±15.8	<0.001
Median	25.4	7.4	−15.7	
Interquartile range	19.5 to 36.6	3.5 to 20.5	−24.0 to −8.6	
Secondary outcomes				
FOSQ score§	14.3±3.2	17.3±2.9	2.9±3.1	<0.001
Median	14.6	18.2	2.4	
Interquartile range	12.1 to 17.1	16.2 to 19.5	0.7 to 4.7	
Epworth Sleepiness Scale score¶	11.6±5.0	7.0±4.2	−4.7±5.0	<0.001
Median	11.0	6.0	−4.0	
Interquartile range	8.0 to 15.0	4.0 to 10.0	−8.0 to −1.0	
Percentage of sleep time with oxygen saturation <90%	8.7±10.2	5.9±12.4	−2.5±11.1	0.01
Median	5.4	0.9	−2.2	
Interquartile range	2.1 to 10.9	0.2 to 5.2	−6.6 to −0.3	

The U.S. Food and Drug Administration (FDA) approved Inspire® Medical Systems' pacemaker-like hypoglossal nerve stimulator for patients with **moderate to severe obstructive sleep apnea (OSA) who *cannot tolerate* continuous positive airway pressure (CPAP)**.

AMERICAN ACADEMY OF
OTOLARYNGOLOGY–
HEAD AND NECK SURGERY
FOUNDATION

Otolaryngology–
Head and Neck Surgery
1–9

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Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes

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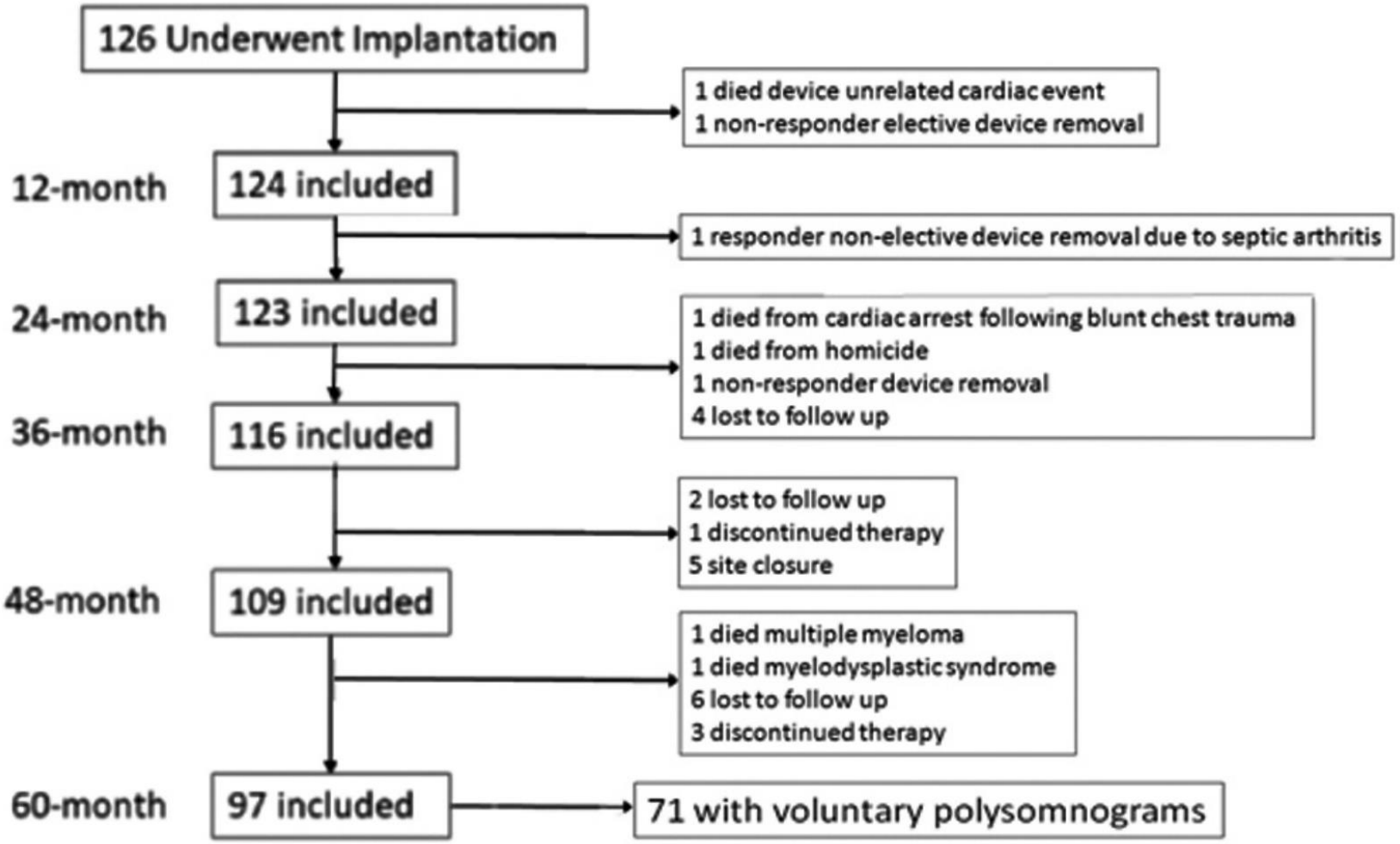
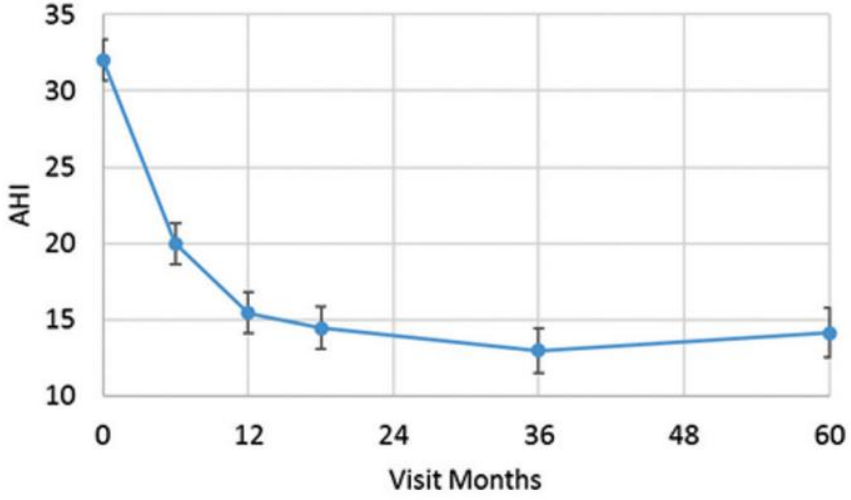
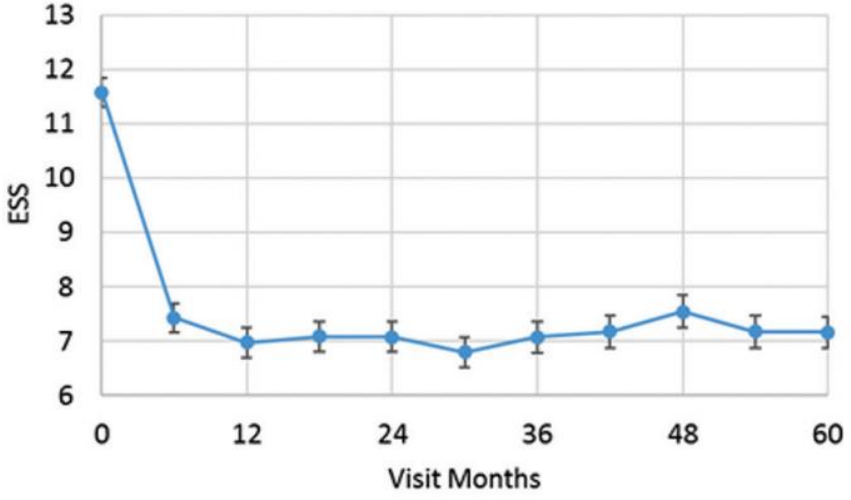
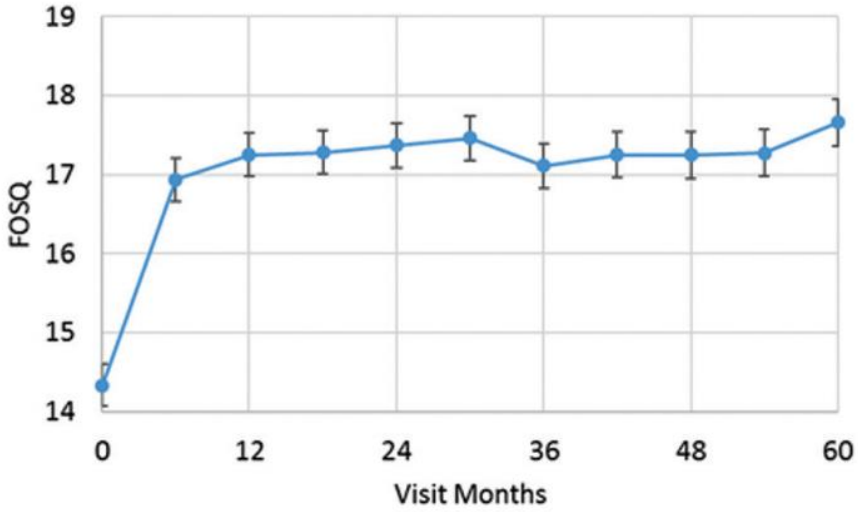
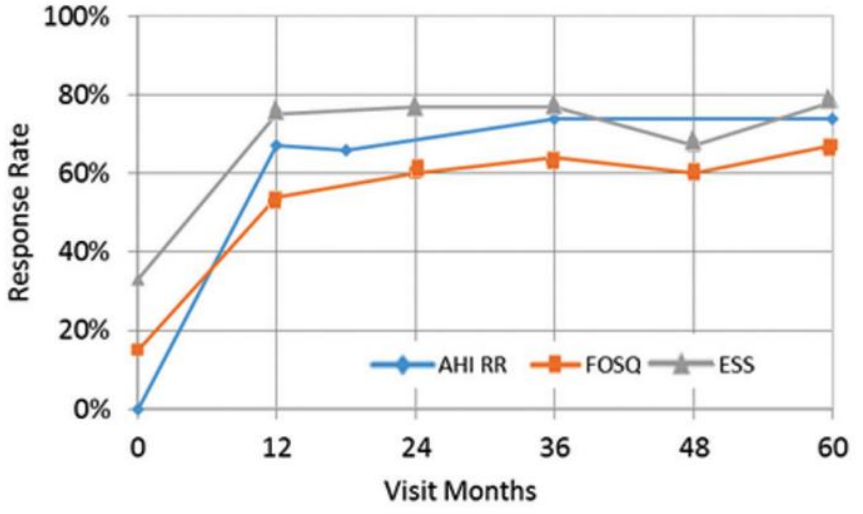

126 Underwent Implantation
1 died device unrelated cardiac event
1 non-responder elective device removal
12-month
124 included
1 responder non-elective device removal due to septic arthritis
24-month
123 included
1 died from cardiac arrest following blunt chest trauma
1 died from homicide
1 non-responder device removal
4 lost to follow up
36-month
116 included
2 lost to follow up
1 discontinued therapy
5 site closure
48-month
109 included
1 died multiple myeloma
1 died myelodysplastic syndrome
6 lost to follow up
3 discontinued therapy
60-month
97 included
71 with voluntary polysomnograms

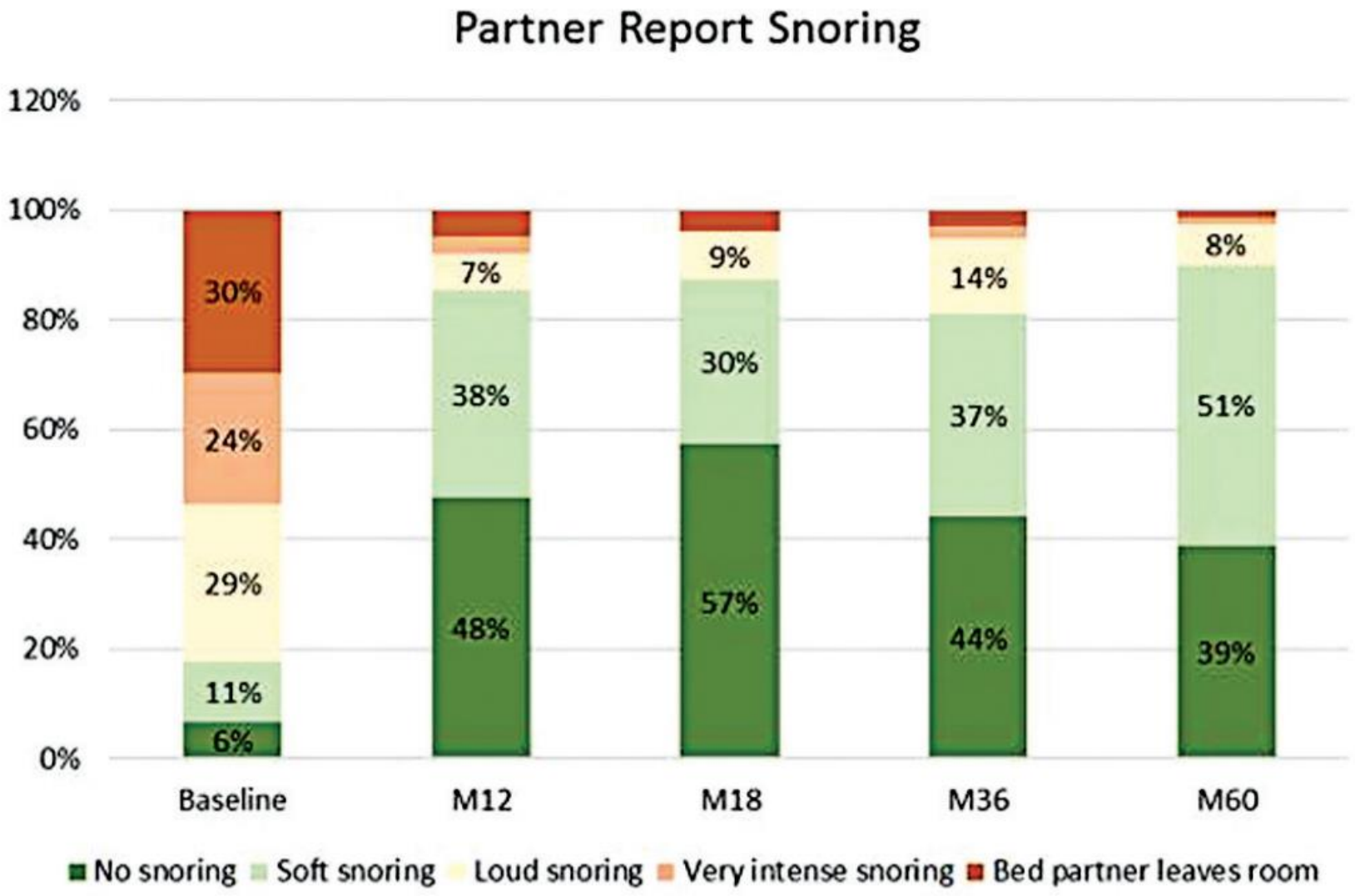








Sixty-month outcome of AHI, sleep quality of life (FOSQ), and daytime sleepiness (ESS). Values are presented as mean 6 SD. Response rates (in percentages) are based on the following parameters: AHI .50% reduction to >20 events/hour, ESS score <10, and FOSQ score .17.9. AHI, apnea hypopnea index; ESS, Epworth Sleepiness Scale; FOSQ, Functional Outcomes of Sleep Questionnaire.



Bed partner report of snoring intensity over time

Table 4. Predictors of 60-Month AHI Responders.

	Month 60, Mean ± SD or % (n)			
Characteristic	Responders (n = 53)	Nonresponders (n = 18)	Odds Ratio	95% Confidence Limits (*P* Value)
Age	56.0 ± 9.3	50.1 ± 10.4	1.07	1.01, 1.13 (.03)
Male	81 (43)	83 (15)	0.86	0.21, 3.55 (.83)
BMI	28.6 ± 2.5	28.8 ± 2.3	0.97	0.77, 1.21 (.76)
Neck size	40.8 ± 3.5	41.5 ± 2.9	0.93	0.79, 1.11 (.43)
AHI	29.3 ± 7.6	33.7 ± 13.1	0.95	0.90, 1.01 (.09)
ODI	25.5 ± 8.5	32.2 ± 12.4	0.94	0.88, 0.99 (.02)
Prior UPPP	32 (17)	6 (1)	0.13	0.02, 1.02 (.052)
FOSQ	14.8 ± 2.7	15.0 ± 2.3	0.96	0.78, 1.19 (.73)
ESS	11.3 ± 4.9	12.7 ± 5.3	0.95	0.85, 1.06 (.32)

Table 5. Nonserious Adverse Events.

Adverse Event	No. of Events						Participants With Event, % (n of 126)
	0-12 mo	12-24 mo	24-36 mo	36-48 mo	>48 mo	Total	
Procedure related							
Postoperative discomfort related to incisions	47	1	2	1	1	52	30.2 (38)
Postoperative discomfort independent of incisions	41	0	1	0	0	42	27.0 (34)
Temporary tongue weakness	34	0	0	0	0	34	18.3 (23)
Intubation effects	18	0	0	0	0	18	11.9 (15)
Headache	8	0	0	0	0	8	6.3 (8)
Other postoperative symptoms	22	0	0	0	0	22	11.1 (14)
Mild infection	1	0	0	0	0	1	0.8 (1)
Device related							
Discomfort due to electrical stimulation	81	23	26	7	5	142	60.3 (76)
Tongue abrasion	28	12	4	3	2	49	27.0 (34)
Dry mouth	10	5	2	0	3	20	15.1 (19)
Mechanical pain associated with presence of the device	7	2	3	1	1	14	11.1 (14)
Temporary internal device usability or functionality complaint	12	8	1	3	1	25	16.7 (21)
Temporary external device usability or functionality complaint	11	11	8	9	6	45	26.2 (33)
Other acute symptoms	21	14	1	2	1	39	24.6 (31)
Mild infection	1	0	0	0	0	1	0.8 (1)

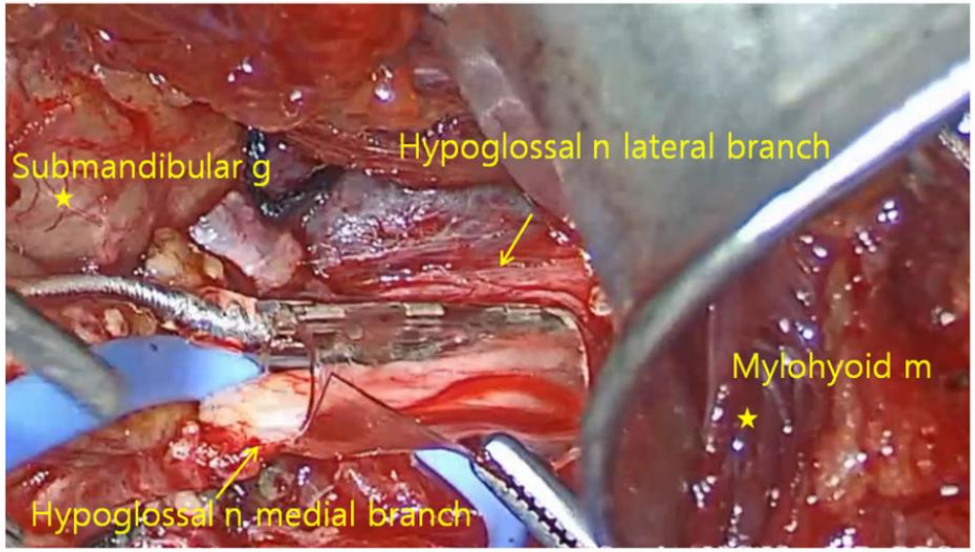


Fig. 1 Cuff electrodes encircling the medial branch of hypoglossal nerve with three stimulation nodes. Note the lateral branch is not included in the cuff. (*n* nerve, *m* muscle, *g* gland)

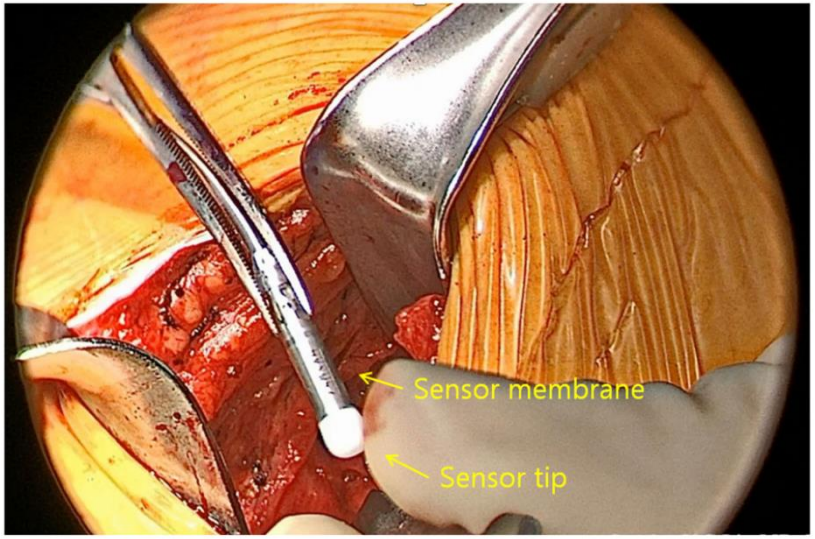


Fig. 2 Pleural pressure sensing lead is placed with the ventilatory sensor facing the pleura

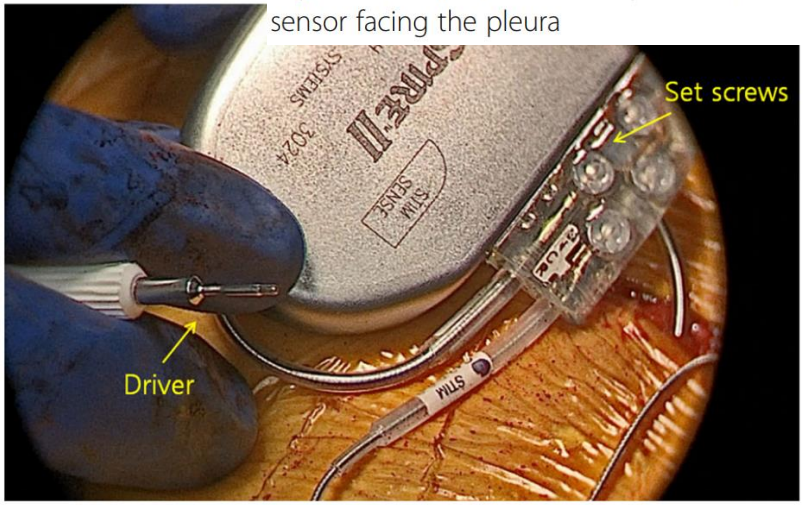


Fig. 3 Implantable pulse generator (IPG) has two 3.2 mm low profile connector ports (STIM port, SENSE port) which house the stimulation and pleural pressure sensing lead connectors. The lead connectors are secured with set screws using a driver

Bilateral hypoglossal nerve stimulation for treatment of adult obstructive sleep apnoea

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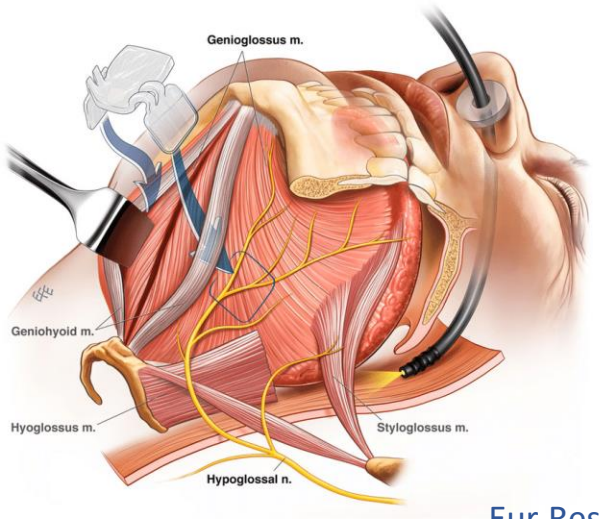

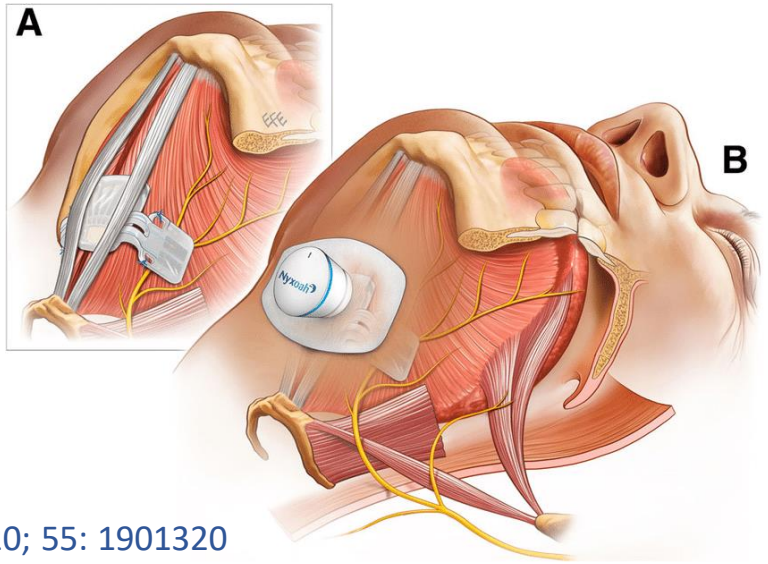

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Bilateral hypoglossal nerve stimulation for treatment of adult obstructive sleep apnoea

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PRASAT NEUROLOGICAL INSTITUTE

- Prospective, open-label, non-randomized, single-arm treatment, ENT department
- 8 centers in three countries (Australia, France and UK)
- Primary outcome
  - Device-related serious adverse events
  - Change in the AHI
- Secondary outcome
  - Change in ODI

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Bilateral hypoglossal nerve stimulation for treatment of adult obstructive sleep apnoea

สถาบันประสาทวิทยา
PRASAT NEUROLOGICAL INSTITUTE

- Inclusion criteria
  - Age 21-75 years
  - BMI $\leq$ 32 kg/m^2
  - AHI 20-60 events/hr (central/mixed AHI < 10)
  - No positional OSA (non-supine AHI<10, supine AHI$\geq$ non supine AHIx2)
  - Absence of soft palate complete concentric collapse (CCC) during drug induced sleep endoscopy
  - Not tolerated or accepted CPAP

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Bilateral hypoglossal nerve stimulation for treatment of adult obstructive sleep apnoea

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- 22 out of 27 implanted participants (63% male, aged 55.9±12.0 years, body mass index (BMI) 27.4 ±3.0 kg·m−2) completed the protocol.

- At 6 months BMI was unchanged (p=0.85); AHI decreased from 23.7 ±12.2 to 12.9±10.1 events·h−1 , a mean change of 10.8 events·h−1 (p5 days per week, and 77% reported use for >5 h per night.

- No device-related serious adverse events occurred during the 6-month post-implantation period

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Bilateral hypoglossal nerve stimulation for treatment of adult obstructive sleep apnoea

TABLE 2 Outcome measures for modified intention-to-treat analyses

	Baseline	6 months	Mean difference (95% CI)	p-value
Subjects n	**22**	**22**		
Sleep disordered breathing				
AHI events·h^{-1}	23.7±12.2	12.9±10.1	10.8 (14.6–7.0)	<0.0001
ODI events·h^{-1}	19.1±11.2	9.8±6.9	9.3 (13.1–5.5)	<0.0001
S_{aO_2} <90% % time	5.0±6.0	2.1±3.0	2.9 (4.6–1.3)	0.0015
Apnoea index events·h^{-1}	10.1±10.2	5.6±8.4	4.8 (9.2–0.4)	0.0334
Hypopnoea index events·h^{-1}	12.5±8.9	7.6±6.2	4.9 (8.1–1.7)	0.0049
Symptoms				
ESS	11.0±5.3$^{\#}$	8.0±5.4	3.0 (5.7–0.8)	0.0113
FOSQ-10	15.3±3.3	17.2±3.0	1.9 (0.4–3.4)	0.0157
Sleep architecture				
Sleep efficiency %	84.0±10.8	87.3±8.9	3.2 (0.01–6.4)	0.0494
NREM stage 1 %	13.1±7.9	8.2±4.0	5.0 (8.3–1.7)	0.0053
NREM stage 2 %	60.9±8.7	67.6±9.5	6.7 (2.2–11.3)	0.0058
NREM stage 3 %	8.2±6.9	3.5±4.3	4.7 (6.6–2.7)	<0.001
REM %	17.8±6.4	20.7±7.3	2.9 (−0.3–6.2)	0.0782
Arousal index events·h^{-1}	28.7±11.5	16.0±8.0	12.7 (16.6–8.9)	<0.0001

Data are presented as mean±SD or mean (95% CI), unless otherwise stated. AHI: apnoea–hypopnoea index; ODI: 4% oxygen desaturation index; S_{aO_2} <90%: proportion of the night spent at an oxygen saturation <90%; ESS: Epworth Sleepiness Scale; FOSQ-10: 10-item Functional Outcomes of Sleep Questionnaire; NREM: non-rapid eye movement; REM: rapid eye movement. $^{\#}$: n=21.

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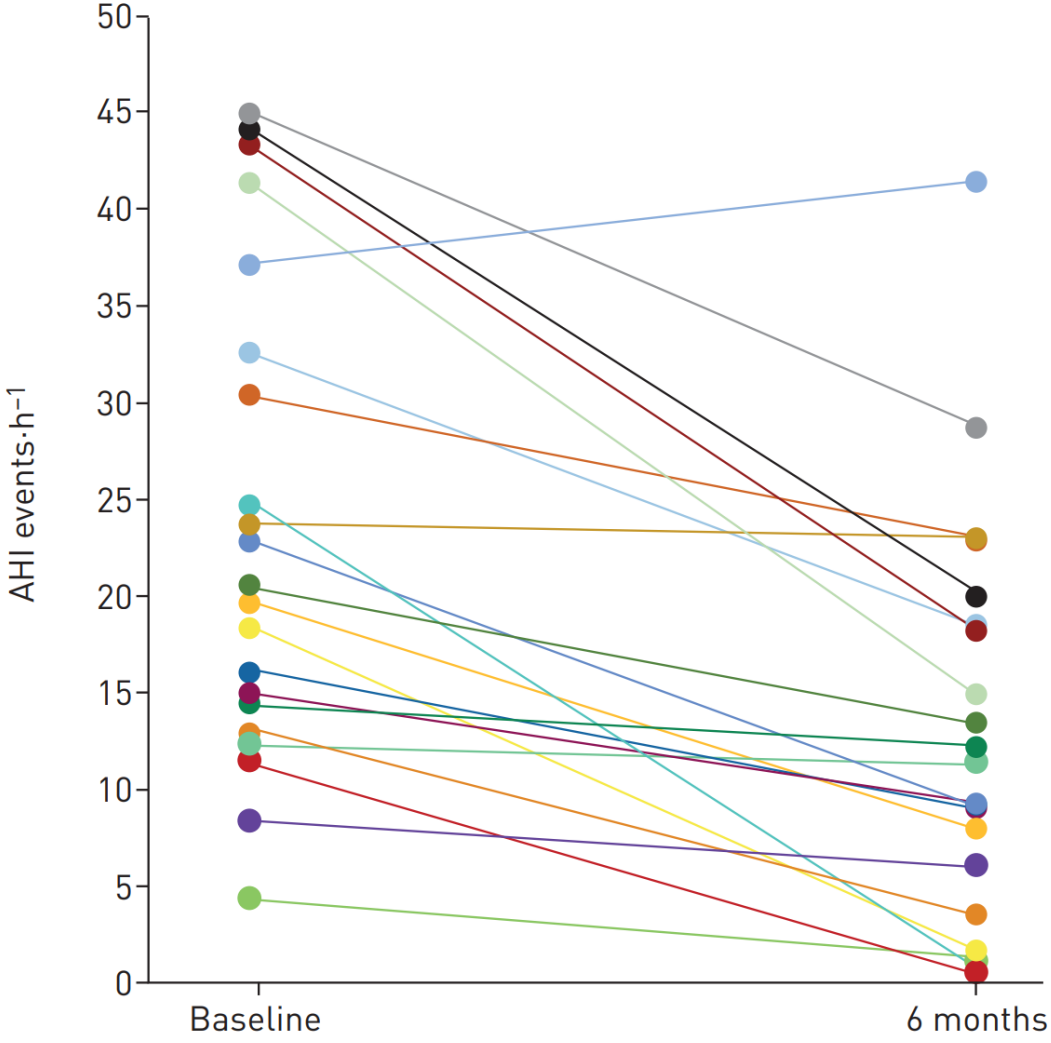

Change in apnoea–hypopnoea index (AHI) for each participant from baseline to 6 months post-implantation. Each line represents an individual participant using modified intention-to-treat analyses (n=22).

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Take home messages

- The Inspire HGNS device remains the only FDA-approved neurostimulation therapy for OSA
- CPAP-non-responders with a BMI <32 kg/m^2, and AHI < 50 and favorable pattern of upper airway collapse on DISE
- HGNS therapy is not currently considered a first-line treatment option.