July 7, 2011

LOS ANGELES (Reuters) - The number of obese U.S. adults rose in 16 states in the last year, helping to push obesity rates (BMI > 30) above 30 % in 12 states!

"Tongue-Tied" About Sleep Apnea?

Novel Treatment for OSA: The Hypoglossal Nerve Stimulator

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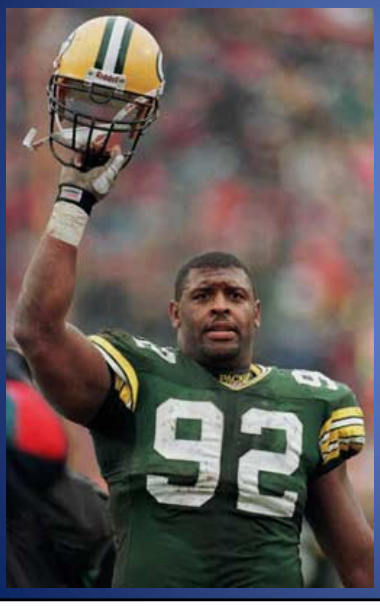
NCSRC Symposium
Concord, NC
September 28, 2012

…resulting in "fatal cardiac arrhythmia," said Dr. Mike Sullivan, the medical examiner for Mecklenburg County….sleep apnea may have been a factor.



Reggie "Minister of Defense" White
age 43 (1961 – 2004)

"It's a 100 percent difference," Harvin said. "I'm not waking up groggy. I'm waking up feeling refreshed and ready to go. So like I said, hopefully that's it."

Harvin said he's no longer taking medication for the migraines.

September, 2010

Increased prevalence of sleep-disordered breathing among professional football players. NEJM. January, 2003.

Disclosures

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- Pulmonary, Critical Care, and Sleep Medicine
- Salem Chest Specialists, Winston-Salem, N.C.
- Southeastern Sleep Disorders Center of SCS – Medical Director

- (+) Financial incentive as local P.I. for Apnex medical, through Piedmont Medical Group clinical research company

- No direct affiliation with Novant Health
- No direct affiliation with DME companies

www.APNEXmedical.com
www.sleepapneatrial.com

Treating Obstructive Sleep Apnea with Hypoglossal Nerve Stimulation

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Introduction

The genioglossus (GG) muscle is a potential therapeutic target for the treatment of obstructive sleep apnea (OSA) as its activation causes tongue protrusion and stiffening and dilation of the pharyngeal airway. This can be achieved via stimulation of its motor nerve, the hypoglossal nerve (HGN).

This study reports the first clinical trial of a new generation implantable HGN stimulation therapy system (HGNS®, Apnex Medical Inc., St. Paul, MN, USA) for patients with OSA.

Interim study results (6 months follow-up) are presented.

Methods

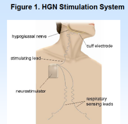
Study Design: Single arm, open label, undertaken at 4 Australian sites.

Study Participants: 21 patients (14 males) with moderate-to-severe OSA who had failed CPAP treatment. Age 53±9 yrs (range 34-68). BMI 33±4 kg/m^2 (range 27-39).

Protocol: HGNS was initiated approx. 30 days post-implant (Figures 1 & 2). In-laboratory sleep studies were performed before and 1, 3 and 6 months after implant. Questionnaires were completed before and 3 and 6 months post-implant and included: Epworth Sleepiness Scale (ESS); Functional Outcomes of Sleep Questionnaire (FOSQ); Calgary Sleep Apnea Quality of Life Index (SAQLI); Pittsburgh Sleep Quality Index (PSQI); and the Beck Depression Inventory (BDI).

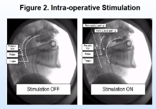
Primary End-points: Mean change from baseline in apnea-hypopnea index (AHI) and FOSQ at 3- and 6-months.

Figure 1. HGN Stimulation System



- Electrical signals were generated by an implanted neurostimulator and delivered to the HGN via an implanted cuff electrode. Respiration was monitored via implanted thoracic impedance leads.
- Stimulation was delivered immediately prior to- and during the inspiratory phase of respiration.

Figure 2. Intra-operative Stimulation

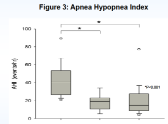


- Correct cuff placement was verified intra-operatively by fluoroscopic assessment of upper airway opening during brief stimulation.

Results

- Patients were followed for 142±42 nights (range 52-226)
- Therapy was used a mean of 89±15% of nights (range 47-100%) for 6±2 hr/night (range 2-8 hrs).
- Two serious device-related adverse events occurred: an infection requiring device removal and a stimulation lead cuff dislodgement requiring replacement.

Figure 3: Apnea Hypopnea Index



- *Severity of OSA decreased at 3 and 6 months* (also see Table 1).
- At 6 months, the AHI in those with a BMI<35 (n=13) was less than those with a BMI>35 (n=6) (14±8 *vs.* 32±24 events/h, respectively, P=0.03).

Table 1: Polysomnography

	Baseline N=21	3 mo N=17	P-value	6 mo N=19	P-value
AHI (events/hr)	43.1 (17.5)	19.0 (10.7)	<0.001	19.5 (16.7)	<0.001
Arousal Index (events/hr)	43.8 (19.5)	23.4 (9.6)	<0.001	23.5 (15.4)	<0.001
ODI4% (events/hr)	16.8 (14.4)	8.0 (7.8)	<0.001	9.1 (16.7)	<0.001
Total sleep time (TST) (min)	340.5 (64.0)	363.0 (65.7)	0.43	349.5 (57.7)	0.88
Sleep efficiency (%)	76.6 (11.3)	82.5 (12.5)	0.04	81.7 (11.6)	0.03
Time in N1 (% TST)	27.4 (10.4)	17.6 (7.5)	0.003	20.8 (11.5)	0.003
Time in N2(% TST)	47.9 (7.2)	49.2 (8.5)	0.96	50.6 (9.6)	0.62
Time in N3 (% TST)	11.2 (7.7)	14.8 (9.5)	0.34	11.6 (9.3)	0.99
Time in REM (% TST)	13.5 (5.5)	18.4 (4.4)	0.006	17.0 (5.6)	0.02

- *The decrease in AHI was accompanied by reduction in arousals and in number and severity of oxygen desaturations.*
- *Sleep architecture was improved.*

Table 2: Symptoms

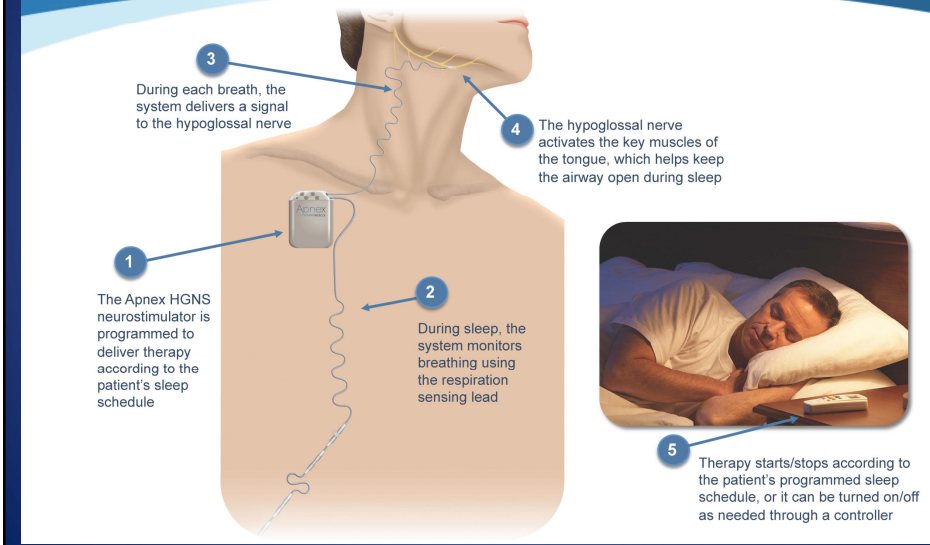
	Baseline	3 mo	P-value	6 mo	P-value
ESS	12.1 (4.7)	7.9 (4.0)	<0.001	8.1 (4.4)	<0.001
FOSQ	14.4 (2.0)	17.0 (2.0)	<0.001	16.7 (2.2)	<0.001
SAQLI	3.2 (1.0)	4.8 (1.3)	<0.001	4.9 (1.3)	<0.001
PSQI	10.1 (2.6)	7.5 (3.8)	0.025	8.7 (3.9)	0.19
BDI	15.8 (9.0)	8.8 (7.5)	<0.001	9.7 (7.6)	<0.001

- *Daytime sleepiness and function improved.*

CONCLUSIONS

- Treatment of OSA with this implantable HGNS system is a safe and effective way to treat individuals with moderate to severe OSA who have failed or do not tolerate positive airway pressure therapy.
- Individuals with a BMI<35 had a better AHI response suggesting that global obesity-related oropharyngeal crowding may be a predictor of poor therapeutic response.
- Compliance with the therapy is high.

About HGNS® Therapy



Outline

- Background
  - OSA basics
  - Hypoglossal nerve stimulation for OSA
- APNEX Trial specifics
- Case examples
- Questions/Discussion

Obstructive Sleep Apnea

- **Complete cessation of airflow x10 seconds…or longer**
- **Continued respiratory effort**
- **Occurs > 5x per hour**

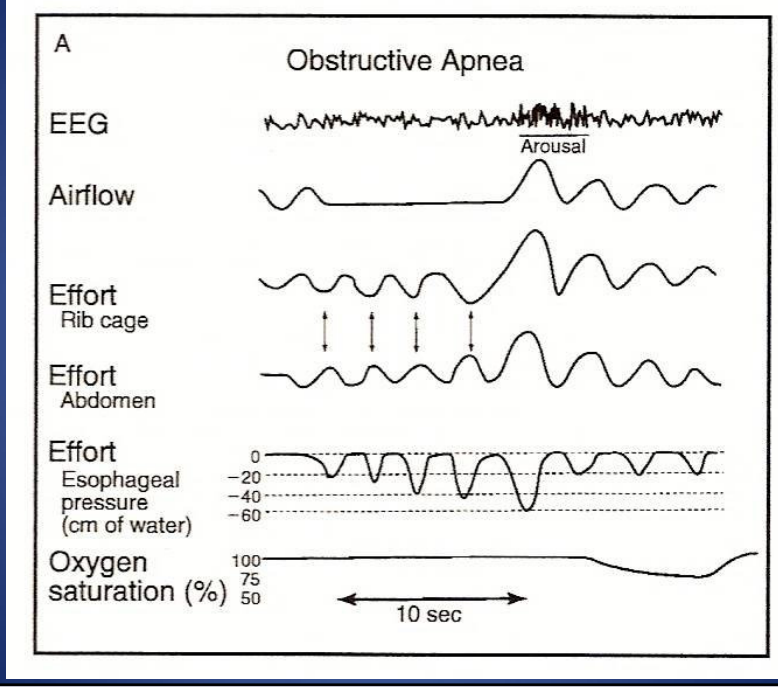
- **Usually a decrease in O_2 Saturation >4%**

Obstructive Sleep Hypopnea

- 30% reduction in airflow x10 seconds
- Continued respiratory effort
- Decrease in O_2 saturation >4% (or >3% if effort reduced by 50%)

- Combined with apneas = Apnea/Hypopnea Index (AHI)
  - <5 = "normal"
  - 5-15 = "mild"
  - 16-30 = "moderate"
  - **>30 = "severe"**

Does NOT take into account O2 desaturation…



OSA and Cardiovascular Risks

General
- 15 million Americans with OSA
- Most do NOT know that they have this…

HTN
- 50% of OSA pts have HTN
- 30% of HTN pts may have OSA
- Pts with more severe OSA, difficult to control BP, and better CPAP compliance do the best

Heart Failure
- 11 – 37% of CHF pts have OSA
- Less often c/o sleepiness
- Men > women
- > 50% if diastolic failure

Stroke
- Difficult to study without bias (survivors)
- Higher incidence immediately afterwards
- AHI > 20 may be higher risk
- 10 yr f/u after stroke shows higher mortality in pts with OSA

Arrythmias
- 50% of OSA pts display some type
- Non-sustained V-Tach, sinus arrest, 2nd degree av-block, frequent PVC's (>2 per min)
- 4x risk for atrial fibrillation
  - 82% of recurrence in 1 year after cardioversion if left untreated
  - Half that % if treated with CPAP
- Increased risk for sudden cardiac death in the early morning hours (NEJM)

Pulmonary HTN
- AHI > 20 = 20%
- Usually mild, rare to have PAP > 35mmHg

End Stage Renal Disease
- Small series, 40-60%

The Epworth Sleepiness Scale

How likely are you to fall asleep in these situations?

Activity	Score
Sitting and reading	0 - 3
Watching TV	0 - 3
Sitting inactive in a public place(e.g. in a theater or mtg)	0 – 3
Sitting quietly after lunch without alcohol	0 – 3
Sitting in a car as a passenger for 1 hour without a break	0 – 3
Lying down to rest in the afternoon when able	0 – 3
Talking to someone	0 – 3
In a car, while stopped for a few minutes in traffic	0 - 3
Total	____ / 24

None = 0
Slight = 1
Mod. = 2
High = 3

"STOP-BANG" Questions

S – snoring
T – tiredness
O – observed apneas (ask sleeping partner)
P – pressure (HTN)

B – body mass index (≥35 kg/m^2)
A – age (> 50 yrs)
N – neck circum. (≥ 16^{II} women; ≥ 17^{II} men)
G – gender (male)

*Sensitivities at AHI cutoffs greater than 5, 15, and 30 = 83.6, 92.9, 100%

Background Research
HGNS Therapy

Background Research – HGNS Therapy

Kezirian, E.J., et al.; Electrical stimulation of the hypoglossal nerve in the treatment of obstructive sleep apnea. SleepMed Rev 14(2010)299-305.

- CPAP is the primary Rx - but 40-50% of patients fail due to compliance issues or refusal
- Upper airway occlusion in OSA has been attributed to decline in pharyngeal neuromuscular activity occurring in a structurally narrow airway
- Surgical treatment focuses on correction of anatomic abnormalities, but potential role exists for activation of upper airway musculature.

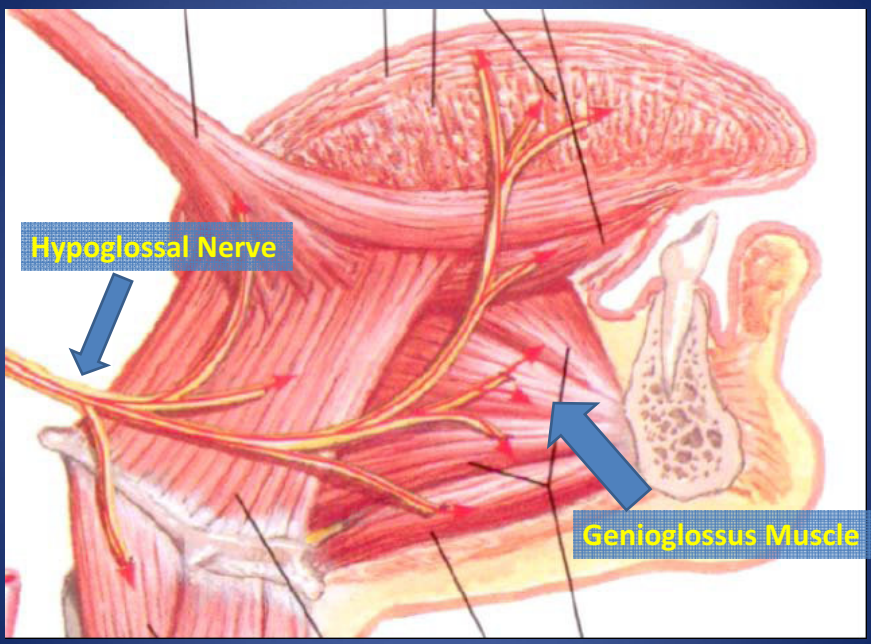
Background Research

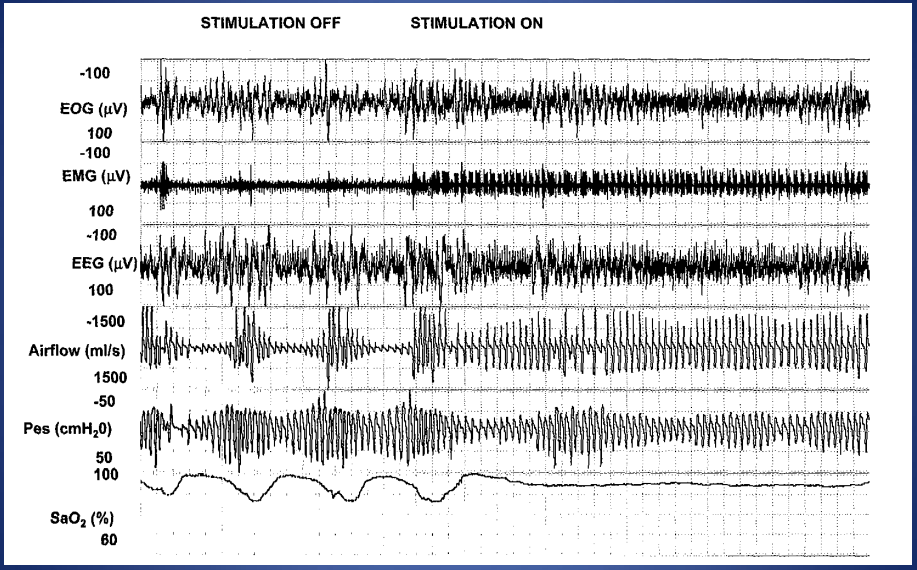
- Animal studies - dogs, cats, rats
- Inserted needle electrodes, and even bilateral HGN cuff electrodes.
- Beagles helped determine the "best" innervation (ie, tongue protrusor muscle = genioglossus)

Background Research

Human Subjects

- began in late 1970's – generally a failure
- late 1980's began to show some promise, with a decrease in AHI but still daytime hypersomnolence
- difficult to reproduce in further studies
- major problem was the arousal associated with placement of the leads on superficial areas (submental/submandibular) areas
- 1990's research helped fine-tune which nerve fibers worked the best, leading to studies done on implantable HGNS by Medtronic, Inspire Medical Systems, and Apnex Medical in the mid-2000's


Hypoglossal Nerve
Genioglossus Muscle


STIMULATION OFF
STIMULATION ON
-100
EOG (μV)
100
-100
EMG (μV)
100
-100
EEG (μV)
100
-1500
Airflow (ml/s)
1500
-50
Pes (cmH2O)
50
100
SaO2 (%)
60

Background Research

- Stim frequency: 50-100Hz to produce tetanic contraction of the genioglossus
- Stim amplitude: 15-40V
- Stim duration: 0.2-1.0ms

- Timing of the stimulation should occur at the beginning of inspiratory effort - for every breath (ie, no hysteresis)

- Prevention of arousal: the hypoglossal nerve is a purely motor nerve, which should selectively recruit the genioglossus muscle and reduce risk for "sensory" arousals.

Background Research

- Patient selection may be key: "coupling effect" of the genioglossus muscle for some patients
  - a non-neural interaction exists between the upper airway segments
    - think: when the tongue moves forward, the soft palate moves upward, and the posterior oropharynx opens wider
  - allows for this type of device to work for patients who have more than just tongue base obstruction

Background Research

- 8 patients in early study: 4 centers, 1996-1997
- 36-57 y/o; BMI 28.4 +/- 4.5kg/m^2; AHI 50
  - followed for 6 months - PSG done at 1, 3, 6 and 12 months
- AHI dropped to 20
- better sleep architecture, with an increase in N3 (deep) sleep, no arousals from the nerve stimulation, and no complaints of tongue pain, atrophy, etc.

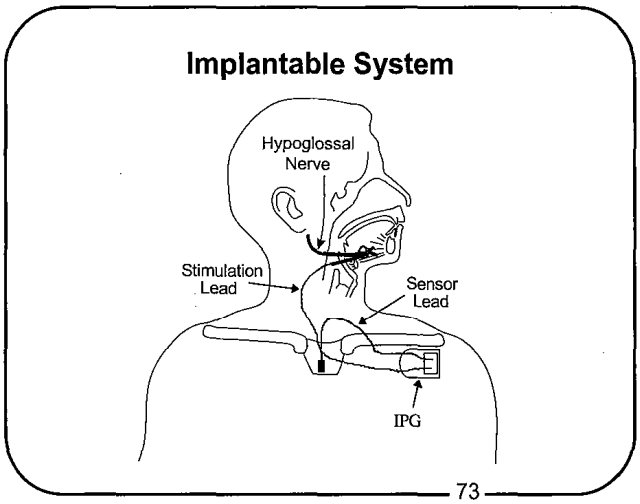


Fig. 1. Schematic representation of the Inspire™ I system for hypoglossal nerve stimulation in OSA patients. The stimulator (implantable pulse generator–IPG) is connected to the respiratory sensor by means of a sensor lead. A stimulation lead connects the stimulator to the half-cuff electrode around the hypoglossal nerve.

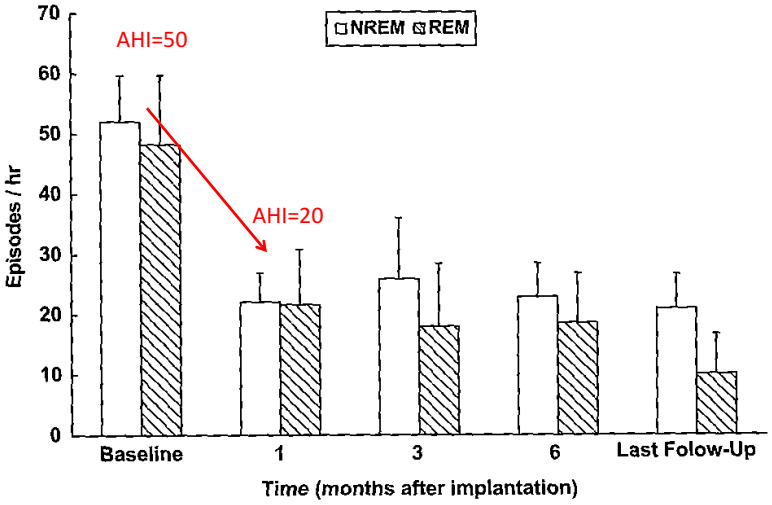


Fig. 3. *Effect of HGN stimulation on AHI. NREM and REM AHI at baseline, 1 month, 3 months and 6 months after implantation and at last follow-up.*

Apnex Ongoing Research Trial

Enrollment Funnel for Clinical Site by Month

100 interested candidates
(Patient Recruitment)

↓

20 (20%) meet initial qualifications

16 (80%) talk to sites

10 (60%) office visit

5 (50%) sign informed consent

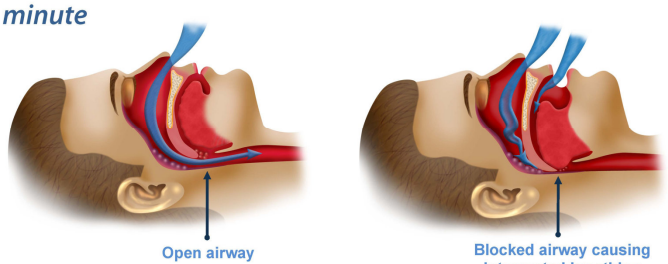
2 (40%) pass Endo, I/E and PSG

↓

2 Enrolled

Obstructive Sleep Apnea (OSA)

- Common sleep disorder in which breathing is ***briefly and repeatedly interrupted*** during sleep
- Occurs when the tongue/surrounding tissues ***block the airway*** during sleep
- OSA can cause breathing to be paused from ***several seconds to over a minute***



OSA Health Risks

- In addition to ***excessive daytime drowsiness and fatigue***, OSA sufferers are at risk for serious health conditions

Condition	Increased Risk of Having Condition with Untreated OSA*
Motor Vehicle Accidents	2 to 6.7
Occupational Accidents	2.2
Coronary Artery Disease	1.2 to 5.4
Stroke	1.6 to 3.1
High Blood Pressure	2.9
Congestive Heart Failure	2.4
Type 2 Diabetes	1.5
Death	3.8

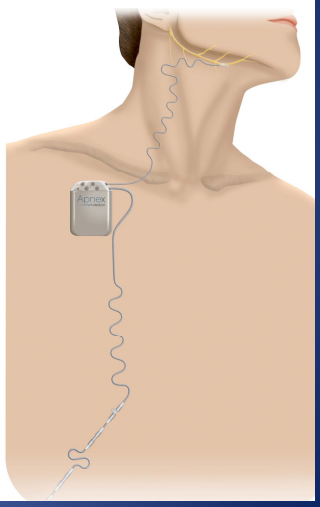
* Compared to Normal Healthy Population

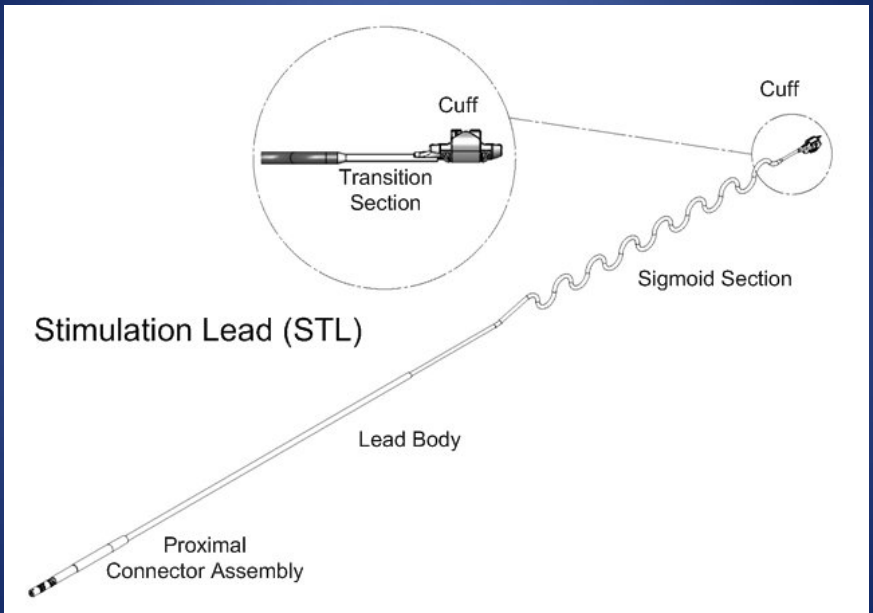
OSA Treatment Options

- Lifestyle changes
- Continuous positive airway pressure devices (e.g. CPAP)
- Oral appliances
- Surgery

Apnex HGNS Surgical Procedure

- The device, which is similar to a pacemaker, is implanted under the skin below the collarbone
- One small wire is connected to the device; is implanted under the skin; and attached to the hypoglossal nerve which is located in the neck area
- Another small wire is connected to the device and has two parts that are implanted under the skin by the ribs





HGNS Programmer System

Apnex HGNS System® – Procedures & Use

IMPLANT
- ENT
- 2-3 hour procedure
- Gen'l anesthesia

Healing Period

TITRATE
- Sleep Physician
- Programmer
- Sleep lab
- Over-night

USE
- Patient at home
- Auto program
- Adjustable with programmer

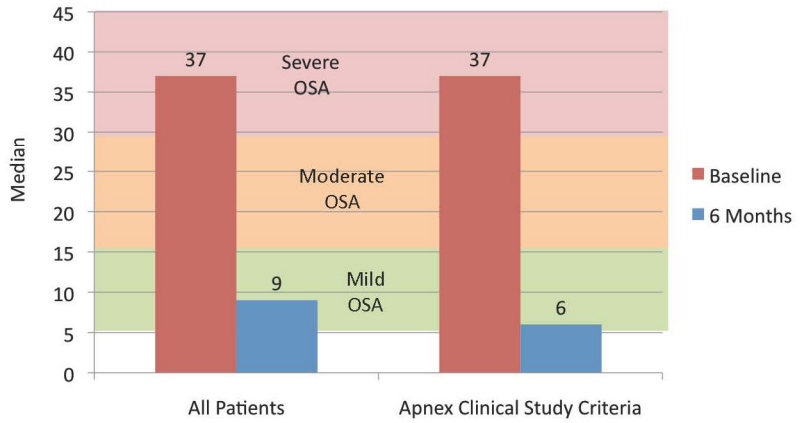
Apnex HGNS Surgical Procedure

- General anesthesia
- The surgical procedure takes about 2 to 4 hours
- Overnight hospital stay required for the study

Apnex Feasibility Study

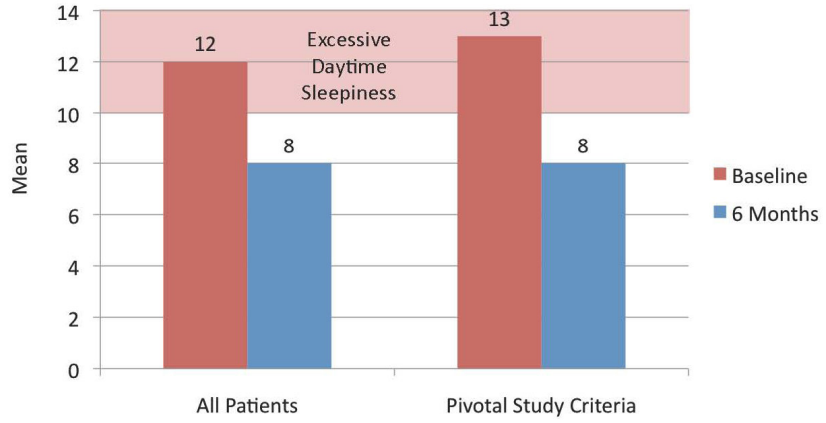
- Conducted in US and Australia
- 32 patients enrolled (29 have completed 6-month follow-up)
- Key eligibility requirements:
  - ✓ AHI between 20 - 100
  - ✓ BMI < 40
- Results shown:
  - ✓ Baseline (prior to HGNS therapy) compared to after 6 months of HGNS therapy
  - ✓ All feasibility study patients and a subgroup of patients that meet the new Apnex Clinical Study criteria

Apnea Hypopnea Index (AHI)
Baseline to 6-months



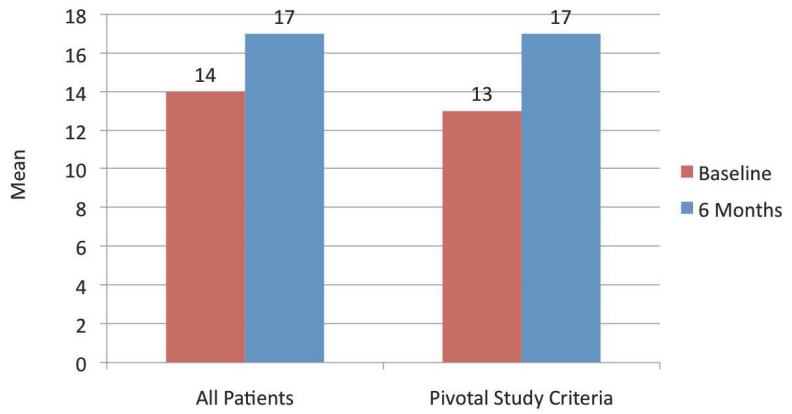
- ***HGNS significantly reduced the number of times sleep was interrupted each hour***

Epworth Sleepiness Scale (ESS)
Baseline to 6-months



- ***HGNS reduced how sleepy patients felt during the day to a near normal level***

Functional Outcomes of Sleep Questionnaire (FOSQ)
Baseline to 6-months



- ***HGNS improved patients' ability to function during they day, with an increase of 2 points being a clinically significant change***

Commonly Reported Complications

- Temporary post-operative nausea and vomiting
- Temporary post-operative pain, or discomfort in the areas of the surgical incisions
- Superficial surgical site wound infections
- Transient tongue irritation or abrasion from tongue rubbing on teeth
- Occasional tongue muscle soreness upon awakening in the morning

The Apnex Clinical Study

- The ***Apnex Clinical Study*** is evaluating whether Apnex HGNS Therapy is safe and effective in treating patients with moderate or severe OSA
- Clinical studies must conform to strict rules set by the ***U.S. Food & Drug Administration (FDA)*** designed to protect the rights and safety of study participants

Qualification Criteria

- To participate in the Apnex Clinical Study, participants must meet certain eligibility requirements, including:
  - ✓ Age 21 - 80
  - ✓ Diagnosis of moderate or severe OSA
  - ✓ Have not benefitted from, or are unable to tolerate, continuous positive airway pressure (CPAP) therapy
  - ✓ Body mass index (BMI) ≤ 35 kg/m^2
- Additional qualifications required for the Apnex Clinical Study will be determined by the study doctor

Study Groups

- If you qualify for the study after the Baseline Visits, you will be assigned to a Study Group
- You will be assigned by chance to one of the following groups:
  - ***Treatment group*** *(2 out of every 3 patients)*
    Patients in this group will have their HGNS® system turned on 1 month after the implant procedure
  - ***Control group*** *(1 out of every 3 patients)*
    Patients in this group will have their HGNS system turned on 7 months after the implant procedure (the system will remain off until then)
- You will be told to which group you were assigned 1-month after your HGNS implant procedure

Study Design

Prospective, randomized, parallel, two-group, controlled multi-center clinical study

- **2:1 Randomization (Treatment : Control)**
- **All subjects receive HGNS System ®**
- **Treatment: On at 1 month, remains on throughout study**
- **Control: Off until the 7 month visit, then turned on for duration of study**
- **Blinding of subjects and investigators is not possible**
  - ✓ **PSG studies will have identifying information removed to minimize bias in the assessment of data contributing to the primary effectiveness endpoints**
  - ✓ **PSG Core Lab will be blinded for scoring of all PSGs**
- **Sample size: Up to 132 subjects enrolled and implanted**
- **Results reported at 12 months of therapy, five year follow-up on all subjects**
- **15 US sites and up to 5 OUS sites**

Endpoints

- **Primary Effectiveness Endpoint #1**
  Proportion of subjects that meet the responder definition.
  It is hypothesized that the responder rate in the Treatment Group will be significantly greater than the responder rate in the Control Group at six months post-implant.
- **Primary Effectiveness Endpoint #2**
  Proportion of subjects in the Treatment Group that meet the definition of a responder at 12 months post-implant.
  It is hypothesized that the observed responder rate in the Treatment Group at 12 months post-implant will be statistically >50%.

A responder is a subject that has:
An apnea-hypopnea index (AHI) < 20*, and ≥ 50% reduction in AHI from baseline AND
A reduction in oxygen desaturation index (ODI 4%) of ≥ 25% or an ODI 4% of less than 5

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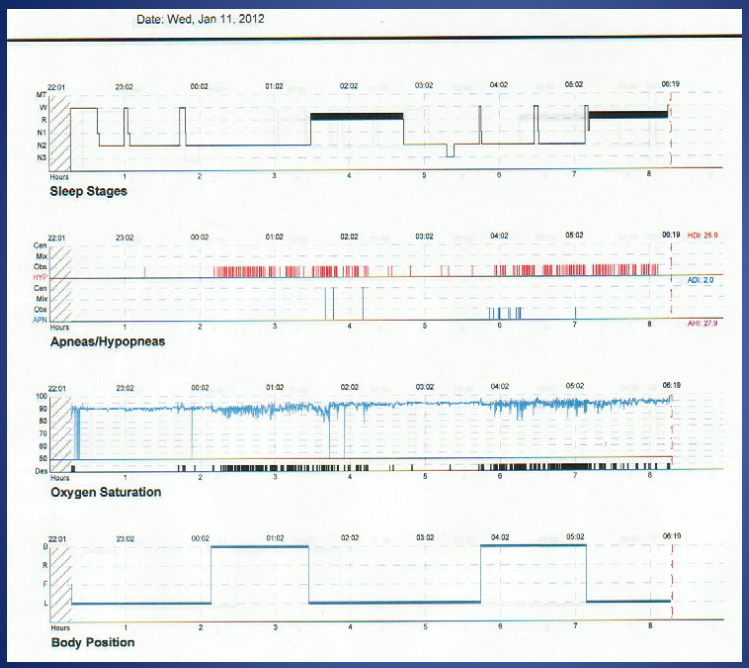
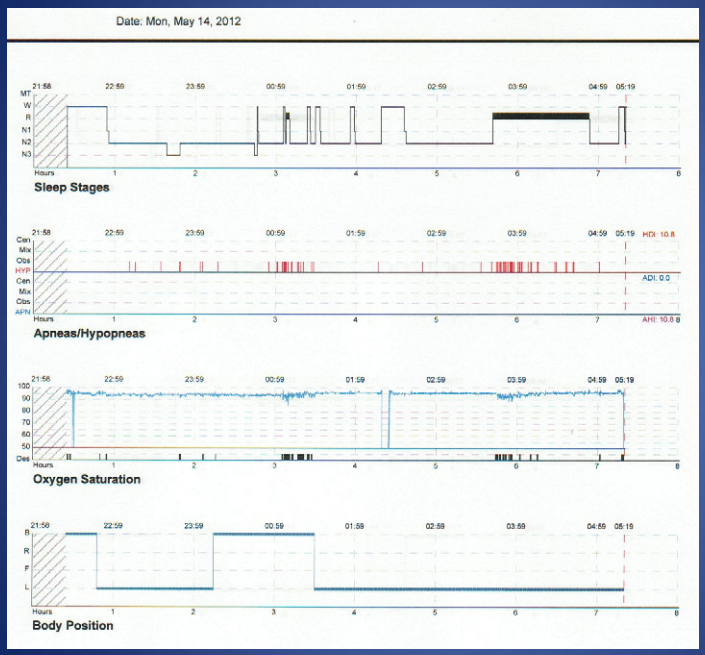
HGNS Therapy
Local case example



Baseline PSG
AHI = 28
Sat = 79%



6 month PSG
AHI = 11
Sat = 89%

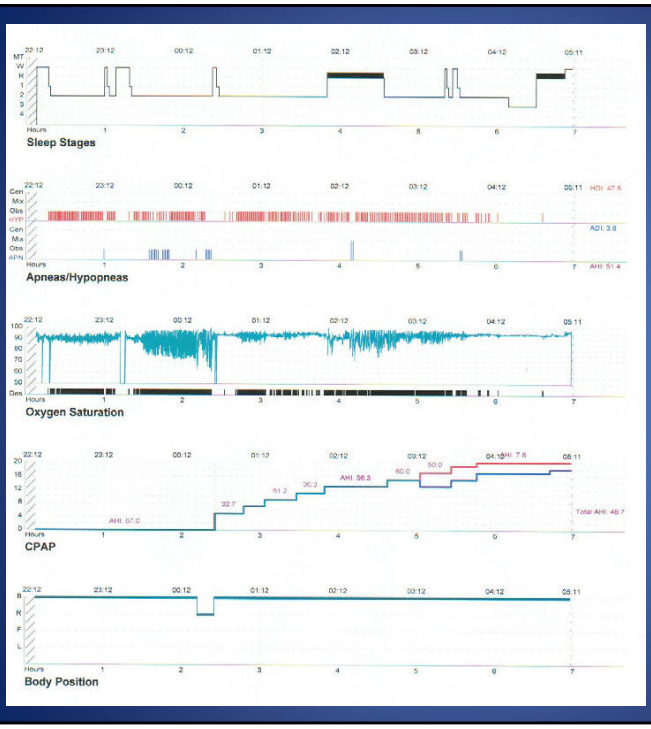
Case 1 = "Howe Special"

64 y/o female

Pre-op left knee replacement

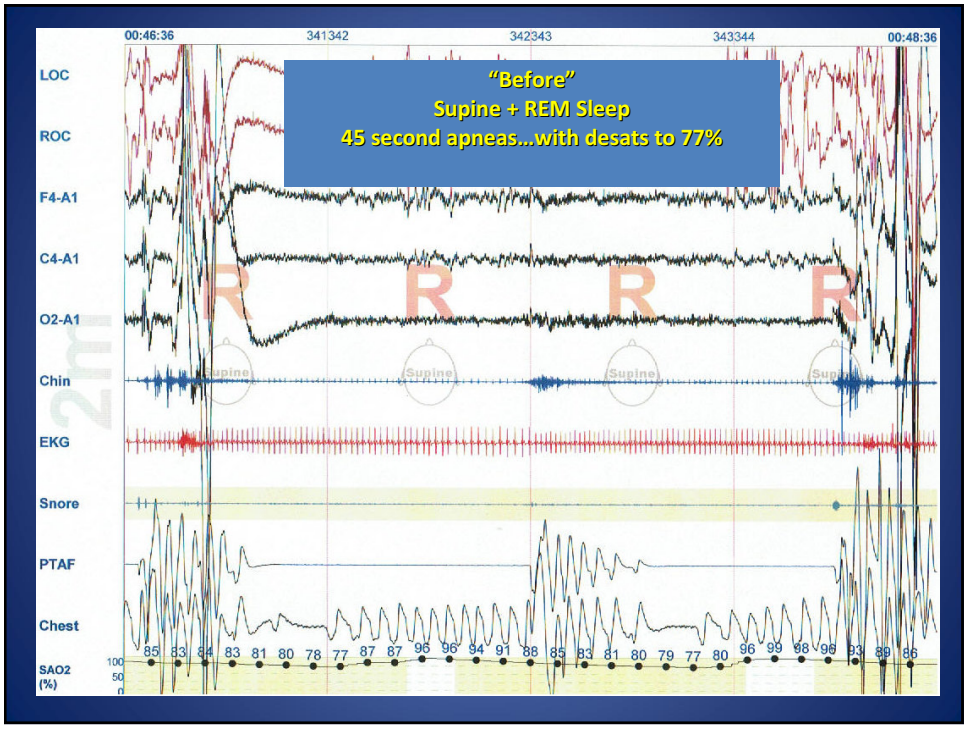
Neck Circ = 18 in
BMI = 54
ESS = 13 / 24

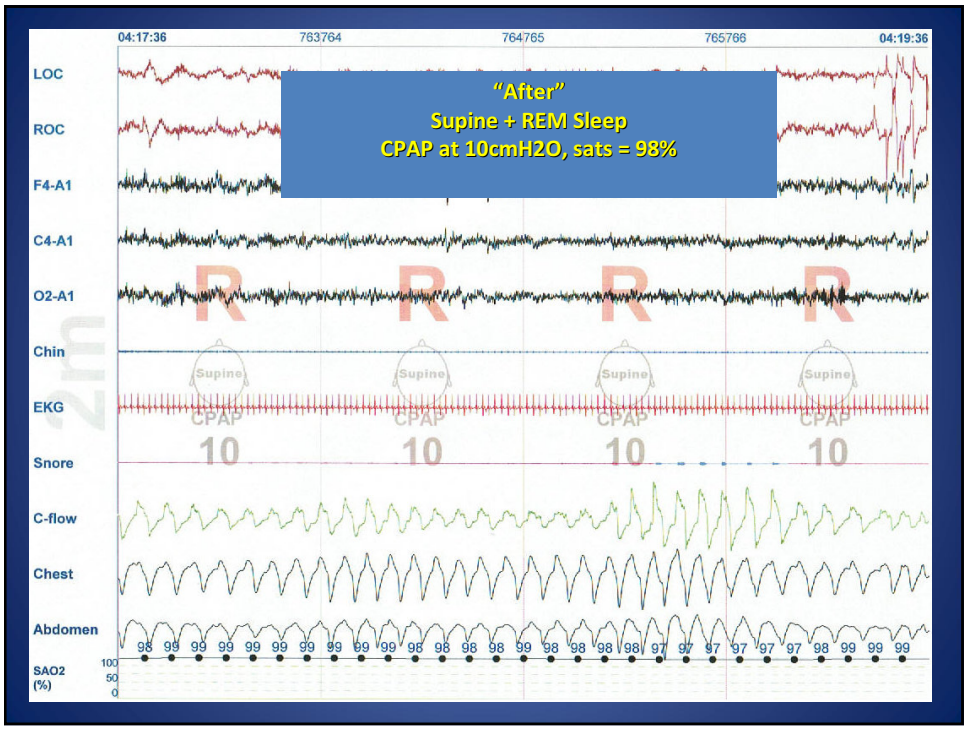
Sxs: <u>4-drug HTN</u>



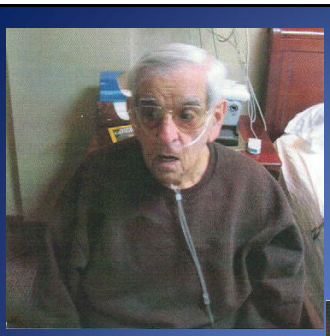
Split-Night Study
AHI = 76
61%

Bi-PAP = 21 / 17cmH2O


00:46:36
341342
342343
343344
00:48:36
"Before"
Supine + REM Sleep
45 second apneas...with desats to 77%
LOC
ROC
F4-A1
C4-A1
O2-A1
Chin
EKG
Snore
PTAF
Chest
SAO2 (%)
2m
R
Supine
85 83 84 83 81 80 78 77 87 87 96 96 94 91 88 85 83 81 80 79 77 80 96 99 98 96 93 89 86

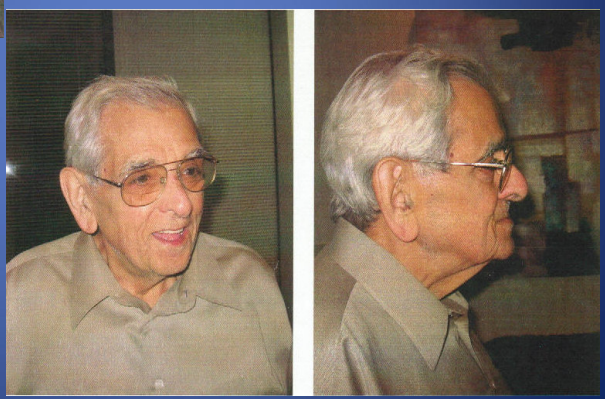

04:17:36
763764
764765
765766
04:19:36
"After"
Supine + REM Sleep
CPAP at 10cmH2O, sats = 98%
LOC
ROC
F4-A1
C4-A1
O2-A1
Chin
EKG
Snore
C-flow
Chest
Abdomen
SAO2 (%)
2m
R
Supine
CPAP
10
98 99 99 99 99 99 99 99 99 99 98 98 98 98 99 98 98 98 98 97 97 97 97 97 97 98 99 99 99

Conclusions

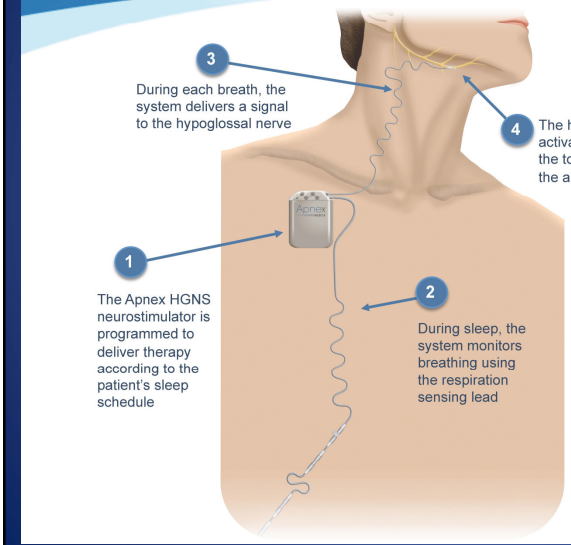


"Before" Picture
Severe OSA and CAD…

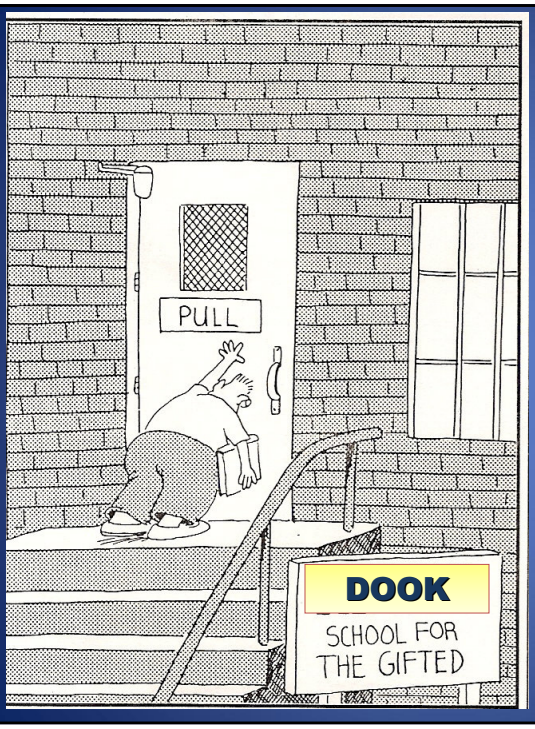
"After" Picture
Using CPAP every night



About HGNS® Therapy



5
Therapy starts/stops according to the patient's programmed sleep schedule, or it can be turned on/off as needed through a controller



Sleep and oxygen are good for you.