

Feasibility of Hypoglossal Nerve Stimulation Therapy to Treat Obstructive Sleep Apnea

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RATIONALE: Reduced upper airway muscle activity is fundamental to obstructive sleep apnea (OSA) pathogenesis. Prior research has demonstrated that hypoglossal nerve stimulation has the potential to reduce OSA severity without causing arousal from sleep. The objective of this study was to examine the safety and effectiveness of a novel hypoglossal nerve stimulation (HGNS™, Apnex Medical, Inc.) system as a potential treatment alternative for OSA.

METHODS: Eighteen subjects with OSA but unable to tolerate continuous positive airway pressure (CPAP) underwent surgical implantation of the HGNS system in a feasibility study. The HGNS system is designed to stimulate the hypoglossal nerve during sleep, activating the genioglossus muscle synchronous with inspiration, which is sensed by changes in thoracic impedance. Apnea-hypopnea index (AHI) during laboratory polysomnography was used to measure OSA severity pre-implant and three months post-implant, which was two months after therapy initiation. Symptomatic response was assessed using Epworth Sleepiness Scale (ESS), Functional Outcomes of Sleep Questionnaire (FOSQ), Calgary Short Sleep Apnea Quality of Life Index (SAQLI), Pittsburgh Sleep Quality Index (PSQI), and Beck Depression Inventory (BDI). Paired t-tests were used to assess changes from baseline. Mean nightly use (mean hours of use over all patient-nights) was calculated using at-home therapy utilization data stored by the HGNS system. Therapy adherence was defined as percent of subjects with mean nightly use ≥ 4 hours/night.

RESULTS: Clinical data at 3 months post-implant are available in twelve (12) subjects (8 male), age 55.4 ± 10.5 yrs (mean \pm SD); baseline and three-month data are presented in

the table below. Enrollment and follow-up is ongoing. Three months after implant, there was a 56% reduction in mean AHI (49.3/hr to 21.6/hr), with eight subjects (67%) experiencing an AHI reduction of 50% or more (mean AHI 53.6/hr to 16.8/hr). In addition, there was improvement in symptoms based on the ESS, FOSQ, SAQLI, PSQI, and BDI scores. Adherence was 92% (11/12). Excluding the one subject who discontinued HGNS use, mean nightly use of the HGNS system was 6.5±1.1 hours/night over an average of 113±59 nights that therapy was active. One system was explanted due to infection after the three-month visit was completed. There were no device failures and no unanticipated adverse device effects.

Clinical Results Three Months Post Implant			
	Baseline (n=12)	3-Month (n=12)	p-value
AHI (events/hr)	49.3±18.1	21.6±11.7	<0.001
BMI (kg/m ²)	32.4±3.4	32.3±3.5	0.883
ESS	13.3±3.7	7.9±4.6	0.005
FOSQ	14.0±2.0	17.5±2.1	<0.001
SAQLI	2.8±1.0	4.8±1.5	0.001
PSQI	9.4±2.8	7.1±3.6	0.038
BDI	15.1±9.6	6.8±7.7	0.027

CONCLUSIONS: In a substantial majority of patients in which it has been used to date, HGNS therapy significantly decreases OSA severity, measured by AHI, with associated improvement in symptoms. Therapy is well-tolerated with high mean nightly use. Data collection is ongoing.