

Response of Epworth Sleepiness Scale Dimensions to Targeted Hypoglossal Nerve Stimulation (THN)

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Background

- Hypoglossal nerve stimulation (HGNS) improves sleep disordered breathing and quality of life in patients with Obstructive Sleep Apnea (OSA)
- Large improvements in the Epworth Sleepiness Scale (ESS), an inventory of daytime sleepiness, are reported in HGNS trials
- Responsiveness of individual ESS items to HGNS has not been reported
- Individual ESS item response to proximal HGNS in the THN3 randomized, controlled trial and 3-year follow-up is explored in this post-hoc analysis

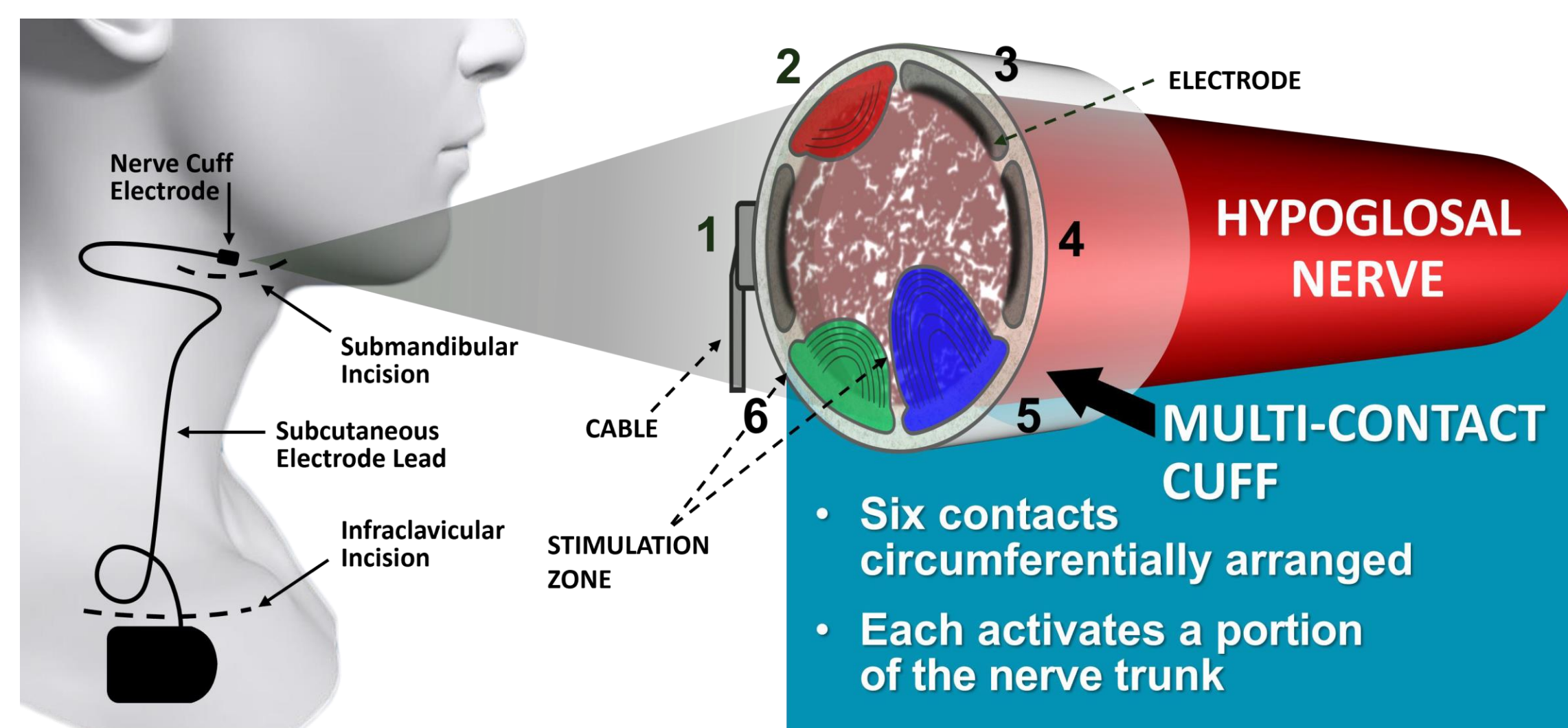
Objectives

- To determine the effect of proximal HGNS on individual ESS items in THN3
 - Treatment vs. Control through 4 months
 - Pooled Treatment and Control vs. Baseline through 3 years
- THN3 enrolled subjects with:
 - Moderate to Severe OSA (AHI 20-65/hr)
 - BMI ≤ 35 kg/m²
 - With or Without Complete Concentric Collapse

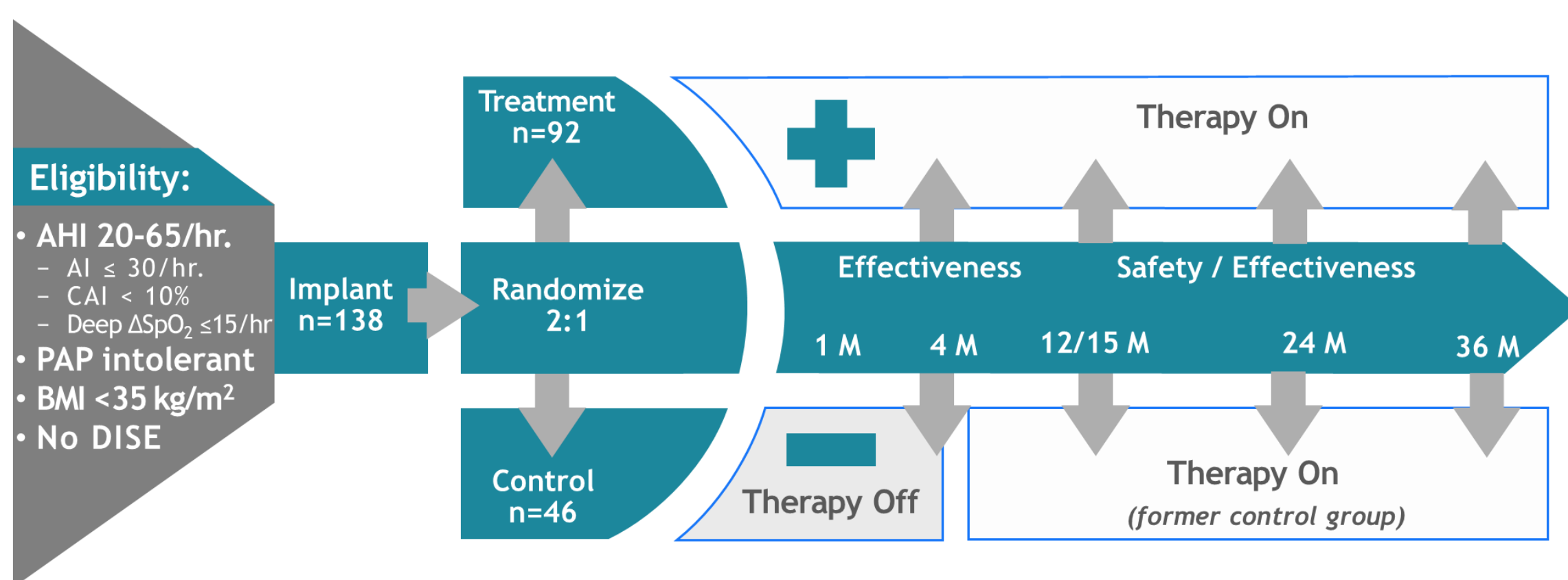
ClinicalTrials.gov



THN System, Placement, Mechanism



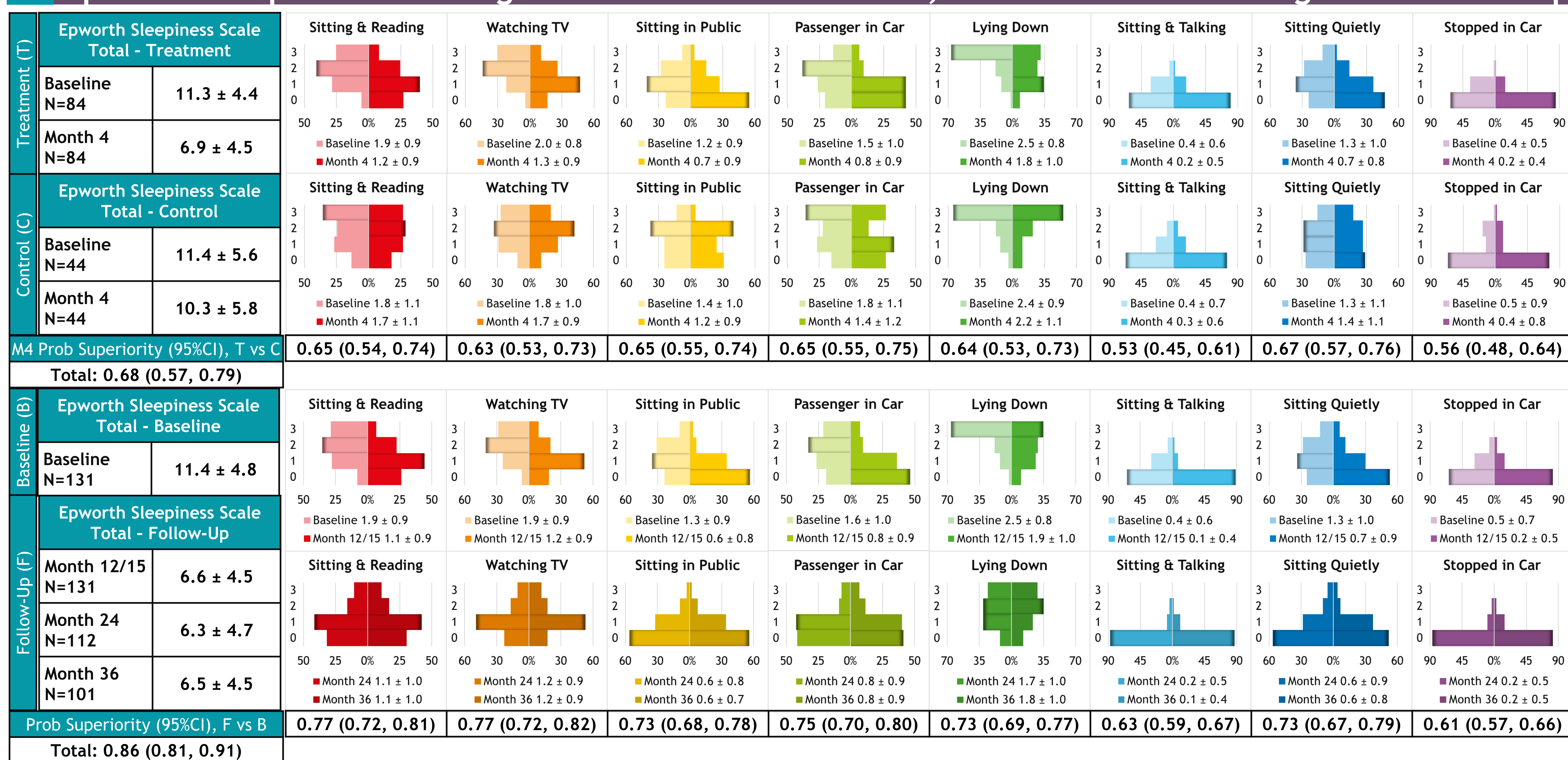
Study Design: Multicenter RCT & Longitudinal Follow-up



Subject Characteristics and Epworth Sleepiness Scale Structure

Baseline Characteristics for Subjects Completing Long-Term Follow-up					ESS Dimension Vignettes and Responses			
Baseline Value (Mean \pm SD)	Baseline (N=138)	Month 12/15 (N=134)	Month 24 (N=114)	Month 36 (N=103)	0 = No chance of dozing 1 = Slight chance of dozing		2 = Moderate chance of dozing 3 = High chance of dozing	
Age, years	55.5 \pm 9.1	55.8 \pm 9.0	55.5 \pm 8.7	55.4 \pm 8.8	V1: Sitting and Reading	V5: Lying down to rest in the afternoon when circumstances permit		
BMI, kg/m ²	29.8 \pm 3.0	29.8 \pm 3.0	29.9 \pm 3.1	29.9 \pm 3.2	V2: Watching TV	V6: Sitting and talking to someone		
AHI, /hr	37.9 \pm 9.8	37.7 \pm 9.8	38.0 \pm 9.6	37.5 \pm 9.6	V3: Sitting inactive in a public place (e.g., a theater or meeting)	V7: Sitting quietly after a lunch without alcohol		
ESS	11.2 \pm 4.8	11.4 \pm 4.8	11.3 \pm 4.7	11.7 \pm 4.7	V4: As a passenger in a car for an hour without a break	V8: In a car, while stopped for a few minutes in traffic		

Epworth Sleepiness Scale Vignettes - THN3 Randomized, Controlled Trial & Long-Term Follow-Up



Conclusions:

- All ESS items improve in response to proximal HGNS, with all distributions migrating from higher to lower chance of dozing
- Sedentary activities without distractions responded best
- ESS with HGNS is normal and has the largest effect size
- THN3 RCT results provide unique insights into ESS dynamics: Follow-up vs. Baseline effect sizes > Treatment vs. Control



THN3 main results at JAMA Otolaryngology (Open Access)

OSPREY TRIAL:

The OSPREY randomized controlled trial is ongoing to confirm the results of THN3 and expand Level 1 evidence for THN in OSA.

Sleep-Apnea-Study.com

