

Executive Summary for Research Projects : October 18, 2004

**Project One: 40 Obese Male Apneics (BMI \geq 30)
(n=20 Acoustic Group, n=20 Control Group)**

**Project Two: 40 Non-Obese Male Apneics (BMI<30)
(n=20 Acoustic Group, n=20 Control Group)**

Purpose: To evaluate Utility of Airway Acoustic Evaluation of Airway Dynamics in Apneic Males

Priori Hypothesis:

Acoustic evaluation of awake airway dynamics has utility in establishing airway orthotic candidacy, construction, titration & maintenance parameters.

Subjects:

Group A : Orthotic titrated by patient "subjective feedback questionnaire" and optimum airway normalization as determined by airway acoustics

Group B: (Control) Orthotic titrated by patient "subjective feedback questionnaire" (Usual and Customary Protocol)

Inclusion Criteria:

Males 40 \leq age $<$ 60, Newly diagnosed apnea, or failed, refused or never tried CPAP with polysomnogram verified 15 \leq RDI \leq 90.

Exclusion Criteria:

Use of alpha blockers, steroids or medications affecting upper airway tone (benzodiazepines, sedatives etc.), unstable medical condition, regular CPAP use within the previous 6 months, clinical evidence for hypothyroidism, TMD, lack of healthy dentition, Restricted Range of Mandibular Motion. Significant weight increase since Baseline Sleep Study.

General:

Groups matched for BMI, RDI, age, and ethnic background. Participants receive consultation, acoustic evaluations, WP100 evaluations, airway orthotic and airway orthotic therapy at no fee; value \$1,500 - \$2,000 CA. In-lab Polysomnograms and physician time covered by OHIP. Patients, Physician and Sleep Technicians will be Blind to which group the patient is in.

Stage	Group A Acoustic Orthotic Protocol n=20	Stage	Group B (Control) Usual & Customary Orthotic Protocol n=20
Stage I	Initial Screening: <ul style="list-style-type: none"> Clinical Oral Examination and Medical History Confirm Candidacy as per Inclusion/Exclusion Criteria Symptom Questionnaire (used to establish end-point) Consent for Therapy and Study Participation Baseline Acoustic Evaluation (Pharyngeal and Nasal) Pharyngeal Acoustic Evaluation at Various Mandibular Postures Baseline WP100 Diagnosis Go to Stage II-a ASAP 	Stage I	Initial Screening: <ul style="list-style-type: none"> Clinical Oral Examination and Medical History Confirm Candidacy as per Inclusion/Exclusion Criteria Symptom Questionnaire (used to establish end-point) Consent for Therapy and Study Participation Baseline Acoustic Evaluation (Pharyngeal and Nasal) Pharyngeal Acoustic Evaluation at Various Mandibular Postures Baseline WP100 Diagnosis Go to Stage II-a ASAP
Stage II-a	Alginate Impressions & Record taking for Orthotic Go to Stage II-b in one week	Stage II-a	Alginate Impressions & Record taking for Orthotic Go to Stage II-b in one week
Stage II-b	Insert Orthotic: Evaluate vertical using acoustics to establish optimum airway response *use Optimum vertical with first advancement position Go to Stage II-c in two weeks	Stage II-b	Insert EMA-2: Evaluate vertical bite pads using acoustics to establish optimum airway response *use Minimum vertical with first advancement position Go to Stage II-c in two weeks
Stage II-c	Symptom questionnaire. Advance orthotic, evaluate vertical using acoustics to establish optimum airway response *use Optimum vertical then go to Stage II-d. If patient cannot accommodate further advancement then go to Stage III ASAP	Stage II-c	Symptom questionnaire. Advance orthotic, evaluate vertical using acoustics to establish optimum airway response *use Minimum vertical then go to Stage II-d. If patient cannot accommodate further advancement then go to Stage III ASAP
Stage II-d	Repeat Stage II-c after 2 weeks of continuous nightly wear	Stage II-d	Repeat Stage II-c after 2 weeks of continuous nightly wear
Stage III-a	Set Orthotic at setting that provides optimum questionnaire results and optimum airway normalization established through acoustics. Pharyngeal acoustic evaluation with orthotic in place, WP100 evaluation, arrange in-lab polysomnogram	Stage III-a	Set orthotic at setting that provides optimum questionnaire results with minimum advancement. Pharyngeal acoustic evaluation with orthotic in place, WP100 evaluation, arrange in-lab polysomnogram
Stage III-b	Failed orthotic outcome: titration protocol switched to that of group B & Acoustics, WP100, Questionnaire & in-lab Sleep Study are repeated.	Stage III-b	Failed orthotic outcome: titration protocol switched to that of group A & Acoustics, WP100, Questionnaire & in-lab Sleep Study are repeated.
Stage IV	3 month and yearly follow-up appointments to document, subjective satisfaction by questionnaire, orthotic compliance, and utility of acoustics and WP100 to establish efficacy. In-lab polysomnogram on a yearly basis	Stage IV	3 month and yearly follow-up appointments to document, subjective satisfaction by questionnaire, orthotic compliance, and utility of acoustics and WP100 to establish efficacy. In-lab polysomnogram on a yearly basis

Patient Flow Schematic

