

John S Viviano, BSc, DDS, obtained his degrees from the University of Toronto and has maintained a private practice of General, Family and Cosmetic Dentistry in Ontario, Canada since 1983.

He is credentialed by the certifying board of the Academy of Dental Sleep Medicine and maintains a special interest in the conservative treatment of sleep-disordered breathing. Dr. Viviano lectures internationally on the treatment of sleep disordered breathing and the use of Airway Acoustics. He has authored articles reviewing Airway Acoustics and establishing protocols for its use in assessing airway normalization.

Giora Pillar, MD, PhD., is a sleep researcher and physician in the sleep lab at Rambam Medical Center, and senior lecturer at the Faculty of Medicine, Technion-Israel Institute of Technology, Haifa, Israel. He obtained his medical and scientific degree from the Technion, and thereafter completed a fellowship at the Sleep Medicine, Endocrinology and Circadian Rhythm Department, Brigham & Women Hospital and Harvard Medical School, Boston, USA. He has the American Board of Sleep Medicine examinations certification, and has 15-year experience in diagnosing and treating patients with sleep disorders.

Dr. Pillar's many research projects include the study of structure and function of the apneic airway, state dependant characteristics, and gender influence. He lectures internationally on sleep medicine and is the author of a book entitled "Sleep Disorders: Diagnosis, Management, and Treatment. A Handbook for Clinicians". Dr. Pillar is the recipient of several awards for his work in the field of sleep.



Dr. John S Viviano & Associates

Patient Referral Slip

Patient Name: _____

Patient Phone: _____

Referred By: Dr. _____

Comments: _____

Please evaluate candidacy for Airway Acoustic research project involving Airway Orthotic Therapy.

Please fabricate an Airway Orthotic to treat Sleep Apnea.

Doctor's Signature: _____

Please fax prior to consultation appointment:

- This Signed Document
- Complete Baseline Sleep Study
- Sleep Study Reporting Letter

Provide this slip to patient for office directions

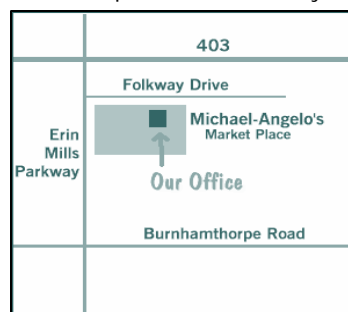
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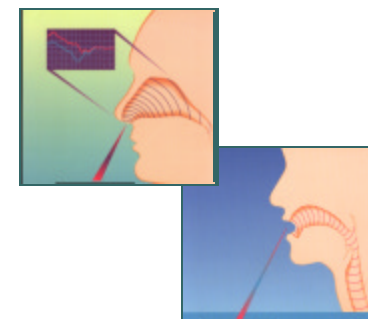


Airway Orthotics

*Conservative Treatment
for
Snoring & Sleep Apnea*

Airway Acoustic Research Project

*Dr. John S Viviano
Dr. Giora Pillar*



Airway Acoustic Research Project:

*To evaluate the utility of acoustic
assessment of the airway in patients
that elect to use an airway orthotic to
treat Sleep Apnea*

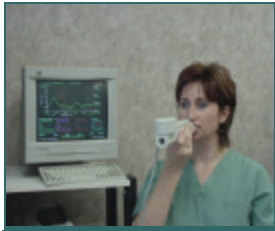
Airway Acoustic Research Project: for Airway Orthotic Therapy

Airway Orthotics

Airway Orthotics are a very effective therapy for both simple Snoring and Sleep Apnea^{7,8,9}. By altering jaw posture, these oral devices dilate and stiffen a narrow or floppy airway and are "indicated for use in patients with primary snoring or mild Sleep Apnea who do not respond to or are not appropriate candidates for treatment with behavioral measures such as weight loss or sleep position change and for patients with moderate to severe Sleep Apnea who are intolerant to or refuse nCPAP treatment"⁹.

Airway Acoustics

Airway Acoustics is a simple, non-invasive, procedure that uses reflected sound waves to assess and document upper airway structure and function; known to be related to Sleep Apnea^{1,2,3}. This tool provides an objective measurement of the amount of dilation and stiffening provided by an Airway Orthotic^{4,5,6}. **Designed to establish the clinical usefulness of airway acoustics in patients that elect Airway Orthotic Therapy, this study has specific inclusion and exclusion criteria.**



Acoustic Exam Documents
Airway Structure & Function

Patient Benefits

You have been diagnosed by your physician as requiring treatment for Sleep Apnea. Untreated, his condition may pose serious health risks since it disrupts normal sleep patterns and can reduce normal blood oxygen levels and stress your cardiovascular system; which in turn may result in the following: excessive daytime sleepiness, irregular heartbeats, high blood pressure, heart attack or stroke.



Silencer Orthotic



EMA-2 Orthotic

Airway Orthotic Therapy is a conservative and completely reversible treatment for Snoring and Sleep Apnea. Side effects are usually short lived and are rarely a problem. It is preferred over nCPAP by 10 out of 11 patients as a long term treatment¹⁰ and demonstrates excellent long term compliance¹¹.

Qualifying patients agreeing to participate will be offered this therapy at no charge. The customary fee of \$1,500—\$2,000 will be waved if the participating patient completes the agreed to study requirements.

Inclusion Criteria

Males 40 ≤ age ≤ 60
Newly diagnosed Sleep Apnea with Sleep Study verified 15 ≤ RDI ≤ 90
Failed, refused or have never tried nCPAP
Baseline Sleep Study within previous year

Exclusion Criteria

Use of alpha blockers, steroids or medications affecting upper airway tone
Unstable medical condition
Regular nCPAP use within previous 6 months
Clinical evidence for hypothyroidism
Temporo-mandibular dysfunction
Lack of healthy dentition
Restricted Range of Mandibular Motion
Significant weight gain since baseline Sleep Study

Bibliography:

1. *Chest*. 1991; 100(1):81-85
2. *Am Rev Respir Dis*. 1990; 141(5pt1):1228-1231
3. *Am Rev Respir Dis*. 1984; 130: 175-178
4. *Cranio*. 1996;14(4):332-343
5. *Clin Pulm Med*. 1998; 5(2):124-128
6. *Chest*; 10/1/2000; ABSTRACT
7. *Chest*. 1999; 116:1511-1518
8. *Sleep*. 2000; 23: 172-178
9. *Sleep* 1995; 18:511-513
10. *Chest* 1996; 109:1477-1483
11. *Cranio*: 2000:18:2