Assessing Orthotic Normalization of Pharyngeal Dynamics

John S. Viviano, B.Sc., D.D.S.

ABSTRACT: Airway orthotic therapy, considered mainstream in the treatment of sleep-disordered breathing, has been demonstrated to normalize both structure and function of the pathological airway through manipulation of mandibular posture. Although effective, the literature reports a variable rate of success and no validated candidacy selection protocol. Acoustic reflection has been used to evaluate and document the upper airway and its dynamics with and without an orthotic in place. This paper will discuss the use of acoustic reflection to assess the level of airway normalization resulting from protrusive and vertical repositioning of the mandible and its utility to establish orthotic candidacy, construction, titration, and maintenance parameters. This protocol has potential for use in both medical and dental facilities that treat patients with sleep-disordered breathing.

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Address for reprint requests:
Dr. John S. Viviano
4099 Erin Mills Parkway
Mississauga, Ontario
Canada L5L 3P9
E-mail:
DrJohnViviano@aol.com

Dr. John S. Viviano *obtained his B.Sc. D.D.S credentials from the University of Toronto and has maintained a private practice of general and cosmetic dentistry in Ontario, Canada since 1983. He maintains a special interest in the conservative treatment of sleep-disordered breathing. A member of various sleep organizations, he is credentialed by the certifying board of the Academy of Dental Sleep Medicine and has lectured internationally on the treatment of sleep disordered breathing and the use of acoustic reflection. He has authored articles reviewing acoustic reflection and establishing protocols for its potential utility in assessing airway normalization.*

An airway orthotic (AO) is a tooth retained oral appliance used in the treatment of Sleep-Disordered Breathing (SDB). It has been demonstrated to alter airway structure and function through manipulation of mandibular posture.[1-4] The term AO is derived from the belief that these devices work by manipulating the jaw into the posture that best stabilizes the airway, thus normalizing airway behavior. Officially recommended for the treatment of SDB by the American Academy of Sleep Medicine in 1995,[5] airway orthotics are now considered a mainstream treatment modality.

Depending on outcome criteria, the literature reports that airway orthotics that advance the mandible successfully, treat SDB in approximately 48-69% of cases.[6-7] A recent review of 54 studies conducted from 1982-2002 inclusive demonstrates that orthotics that reposition the mandible have better success rates than tongue retaining devices, and that they successfully reduce the apnea/hypopnea index (AHI) to below ten in 55% of cases.[8] Regarding apnea severity, using a mandibular repositioning AO, Lowe, et al.[9] recently demonstrated an 80% success rate for patients with a moderate level of apnea and a 61% success rate for those patients with severe apnea, which suggests that successful AO outcome is more likely with a lower Respiratory Disturbance Index (RDI).

However, in studies evaluating AO efficacy, some patients achieve a good outcome and some not, regardless of their initial level of RDI. This may suggest that the level of RDI alone is not dependable criterion for determining candidacy. Although the clinical setting is not bound by the *random selection* process used in these studies, to date there has been no research that establishes and validates a candidacy selection protocol for airway orthotic therapy.

Acoustic reflection (AR), first reported in 1977,[10] has been used to evaluate and document the upper airway and its dynamics with and without an AO in place.[11-16] We will discuss it's utility to assess normalization of pathological airway dynamics resulting from mandibular manipulation and it's potential for determination of AO candidacy, construction, titration and maintenance parameters, which could be useful in both medical and dental facilities.

Materials and Methods

Acoustic Reflection

Through acoustic reflection technology, the Eccovision Pharyngometer (E. Benson Hood Labs, Pembroke MA) affords the ability to objectively evaluate and document the pharyngeal airway. This physiological tool consists of a wave tube (1) that houses a loudspeaker which generates a sound pulse directed into the oral cavity propagating caudally through the airway (2), and two microphones that record the resulting incident and reflected sound waves returning from the airway, a CPU (3) that processes the recorded information, a computer monitor (4) that displays in both graphical and text format objective cross-sectional measurements over a given length of airway, and a printer (5) that provides a report for hard copy archiving (**Figure 1**). The manufacturer's manual[17] reviews the technology in general and its use, including a standard operating procedure. The importance of adequate training and adherence to this standard operating procedure cannot be overstated. Rather than repeating this easily accessible information, this article expands on the standard operating procedure and exam technique taking into account our current knowledge of airway dynamics as reported in the literature.

Both accuracy and reproducibility of AR are well documented.[10,18-26] A recently published review demonstrates favorable comparison of measurements afforded by AR to those derived from computerized tomography (CT) and magnetic resonance imaging (MRI).[27] Kamal's[28] investigation of 350 normal airways yielded a coefficient of variation for intra-subject measurements of 5-7% for pharyngeal volume and normative standards for area

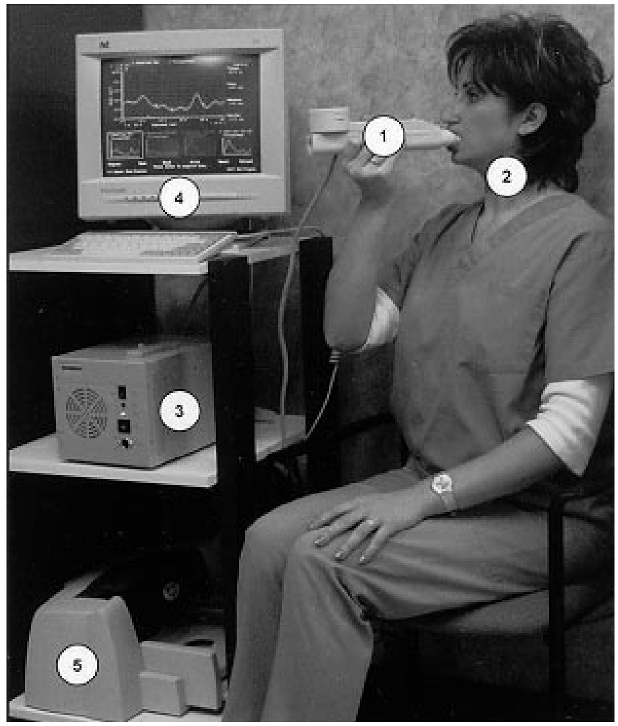

Figure 1
Sound is generated in the wave tube (1), reflected in the airway (2), and recorded by two microphones in the wave tube. The CPU (3) processes the acquired information and displays cross-sectional area of the upper airway from the oral cavity to the glottis, and various other data on the monitor (4). A report is printed by the printer (5) for hard copy archiving.

specific caliber (cross-sectional area). The standard acoustic curve (pharyngogram), he suggests, is useful in evaluating both structure and function of the pre- and post-therapeutic airway (**Figure 2**).

The pharyngogram is a reproducible representation of a cross-sectional area of the pharyngeal airway. Various anatomical landmarks can be demonstrated on the pharyngogram when conducting an acoustic exam. The oropharyngeal junction (OPJ) can be demonstrated by asking the patient to gently breathe through the nose, which results in collapse of the pharyngogram tracing to near zero as the soft palate moves forward off the posterior wall of the pharynx and rests on the dorsum of the tongue. In the event of nasal congestion, the patient may perform a silent "nngg" to produce the same depression. The glottis can be demonstrated by performing a gentle Valsalva or Mueller maneuver (exhale or inhale against a closed glottis), which results in a drop in the cross-sectional area on the pharyngogram tracing at the level of the glottis as it closes. An alternative way to establish the glottis is to have the patient abruptly cease either inhalation or exhalation or to have him/her attempt a silent "oooh" during gentle tidal breathing. Although the glottis can be

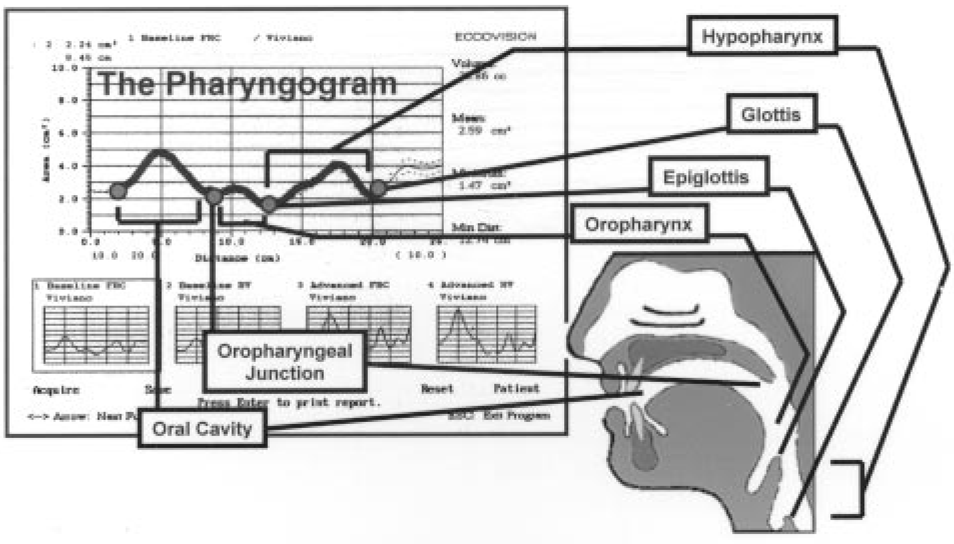

Figure 2
The pharyngogram represents a cross-sectional area (caliber) of the airway from the oral cavity caudal to the glottis. The area under the curve represents volume over a given length of airway, and landmarks along the pharyngogram relate to specific anatomical landmarks.

difficult to establish in some patients, at least one of these methods will work on most patients. If these methods fail, one can elect to establish the local area minimum on the pharyngogram between 15 and 21 cm as the glottis, this variance being due to patient size and gender. The epiglottis can often be established as a local area minimum immediately caudal to the established OPJ on the pharyngogram.

The hypopharynx can be defined as the section of airway between the established glottis and epiglottis landmarks. However, since AR does not provide high resolution of anatomic soft tissue structures, as an approximation, the hypopharynx is often defined as the section of airway 10 cm mouthward of the established glottis (**Figures 3** and **4**).

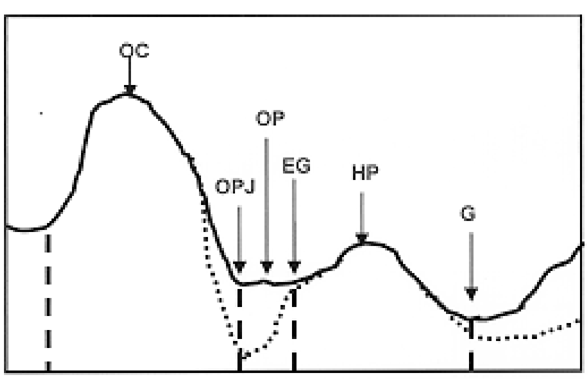

Figure 3
Pharyngogram with landmarks indicated: oral cavity (OC); oropharyngeal junction (OPJ); oropharynx (OP); epiglottis (EG); hypopharynx (HP); glottis (G). Dotted lines represent reduction in airway caliber with nasal breathing and Valsalva or Mueller maneuvers.

Both noninvasive and accurate, AR provides an objective measurement of the oral cavity and pharyngeal airway caudal to the velopharynx down to the glottis.[10,19-21] Other advantages include ease of use and repeatability, inexpensive to perform, and high patient acceptance. Perhaps its two most significant advantages are its ability to repeat readings at 0.2-second intervals, facilitating the dynamic study of airway characteristics such as airway compliance, and its ability to evaluate the airway in three dimensions allowing for documentation of caliber and volume over a given length of airway.[20]

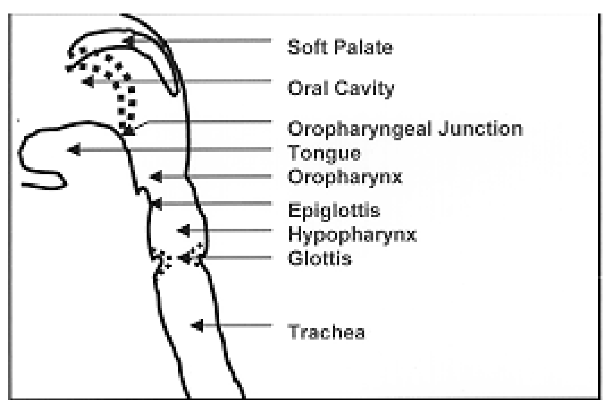

Figure 4
Schematic of a midline sagittal cross-section of the airway. During mouth breathing, the soft palate rests against the posterior wall of the pharynx, closing off the nasopharynx from the rest of the airway. During nasal breathing (**dotted line**), the soft palate moves forward and demonstrates as a local area reduction in cross-sectional caliber when evaluated through AR. Narrowing of the glottis through a Valsalva/Mueller maneuver or an alternative method also results in a local area reduction in cross-sectional caliber when evaluated through AR.

This 3-dimensional capability is of particular importance because increase in airway caliber resulting from mandibular advancement with an AO is greater in the lateral than the anterior posterior (AP) dimension,[3] making evaluation of the airway in three dimensions a requirement in order to accurately document the effect of an AO.

Limitations of this technology include the inability to provide a direct cross-sectional area measurement at the velopharynx, the inability to provide high resolution of anatomic soft tissue structures, and the inability to conduct traditional AR during sleep.

Pharyngeal Dynamics

The discussion of pharyngeal dynamics will revolve around structure (caliber/volume), function (compliance/collapsibility) and site of collapse. These airway characteristics have been evaluated and documented in the literature through various modalities. Airway caliber represents airway cross-sectional area and has been studied at various anatomical regions such as the velopharynx, oropharynx, hypopharynx, and glottis. Airway compliance refers to collapsibility of the airway. Greater compliance indicates an increased tendency to collapse during sleep.

Horner[29] discussed the importance of airway structure (caliber/volume) in his presentation of the *pressure-volume* relationship, whereby decreasing airway volume results in a decrease in the negative pressure required for airway collapse. He concluded that a critical region of airway caliber narrowing (particularly at end-expiration) results in susceptibility to collapse. Evaluation of upper airway closing pressures in snorers lends support to this theory and demonstrates that the smaller caliber of the pathological airway at end-expiration makes it more susceptible to suction collapse upon inspiration. This disposition to collapse becomes more so during REM sleep with further loss of muscle tonus.[30] Multiple imaging studies have demonstrated that obstructive sleep apnea (OSA) patients have a smaller pharyngeal airway caliber than normal subjects during both sleep and wakefulness.[31,32]

Various methods are used to evaluate pharyngeal function (compliance/collapsibility). Stienhart, et al.,[33] using endoscopy to investigate collapsibility at the palatal and tongue-base levels during propofol induced sleep, revealed that patients with OSA demonstrate significantly stronger collapsibility compared with snorers. This is most evident at the tongue base with a strong correlation to higher values of RDI when recorded by standard polysomnography. Ciscar, et al.,[34] using MRI, demonstrated that variation in the velopharyngeal cross-sectional area during the respiratory cycle is greater in apneic patients than in controls, particularly during sleep, suggesting increased compliance. Malhotra, et al.,[35] utilizing various methods of evaluating upper airway collapsibility, demonstrated that apnea patients have significantly greater collapsibility than controls, both while asleep and while awake.

Evaluation of the upper airway through fiber-optic visualization, pressure and resistance measurements, fluoroscopy, CT, and MRI all corroborate that patients with OSA experience structural narrowing/collapse of the upper airway. This narrowing/collapse is usually focal, located at the velopharynx, and extending downward to the oropharynx and hypopharynx in approximately 50% of individuals.[36] Investigation of upper airway pressure measurements in apneics,[37] has demonstrated that the site of airway obstruction varies among consecutive apneas in most patients, and obstruction at lower levels is more likely to be observed during REM sleep.

Pharyngeal Dynamics and Acoustic Reflection

Traditional AR is performed during wakefulness. Although evaluation of the awake airway when investigating sleep disorders has been criticized, many studies involving AR demonstrate a significant relationship between pharyngeal measurements during wakefulness and the dynamics of the airway during sleep.[11-16] The existence of a relationship between the awake and sleeping airway has also been demonstrated using techniques other than AR.[35,37,38] A recent publication evaluating two collapsibility measurement techniques in normal and apneic subjects, during both wakefulness and sleep,[35] concluded that: “Upper-airway collapsibility measured during wakefulness does provide useful physiologic information about pharyngeal mechanics during sleep and demonstrates clear differences between individuals with and without sleep apnea.”

In order to meaningfully evaluate the upper airway through AR, one must first understand the factors that influence pharyngeal dynamics during wakefulness.

Gender differences regarding caliber and compliance have been demonstrated using AR. Studies of normal subjects demonstrate females to have a smaller pharyngeal airway than males.[28,39,40] Recently, a study evaluating obese apneics demonstrated this same relationship.[41] With regard to compliance, several studies corroborate that males have greater pharyngeal collapsibility than females.[39,40,42]

Conflicting findings exist regarding the affect of age on the airway as evaluated through AR. Martin, et al.,[42] demonstrated a decrease in airway caliber with age for both genders. In contrast, Huang, et al.,[40] found no change in caliber for either gender with age. This group did find, however, that males demonstrate an increase in compliance with age, suggesting that airway function may play a role in the increased incidence of OSA in older males.

AR can be performed in both supine and upright postures. However, Martin, et al.,[43] demonstrated that patients with SDB differentiate themselves from controls more so in the seated upright position than in supine position when evaluated through AR. He concluded that these patients defend their upper airways more upon lying down than do snorers or normal subjects while awake. Studies evaluating neuromuscular function support this theory, demonstrating genioglossal tone to be increased in awake apneics while in semi-recumbent and supine positions in comparison to normal subjects.[44,45] Huang, et al.,[40] using AR, provides further support for this theory, demonstrating that gender differences of airway structure and function that are significant in the upright position become less distinguishable when evaluated in the supine position.

Obesity appears to affect the relevance of caliber and compliance in OSA patients. Although obese apneics demonstrate greater compliance than obese controls,[14] non-obese apneics do not[13] when compared to non-obese controls, instead, they differentiate themselves through a difference in caliber.

Acoustic evaluation of the upper airway during wakefulness must take into consideration gender, age, posture, and obesity when developing normative standard, and evaluating both airway pathology and normalization of airway pathology.

Pathological Pharyngeal Dynamics and Acoustic Reflection

AR studies document the pharyngeal airway caliber of apneics to be significantly smaller than controls[11,12] with remarkable correlation between the number of apneas per hour of sleep and pharyngeal cross-sectional area during wakefulness.[12] Compliance of the pharyngeal airway, as studied through AR, is also demonstrated to differentiate the pathological airway from controls.[13,14] However, obesity appears to alter the relative importance of compliance versus caliber. Evaluation of the upper airway of obese, awake apneics demonstrated a smaller caliber and higher compliance when compared to controls.[14] In contrast, although evaluation of non-obese awake apneics also demonstrated a reduced caliber when compared to controls, no significant difference in compliance was observed.[13] That compliance varies independent of caliber in obese apneics was demonstrated in a study evaluating the relationship between pharyngeal area and weight loss. The study documented through AR that the post-weight loss airway became statistically less compliant, but did not change significantly in caliber[15] (**Figures 5** and **6**).

Evaluation of upper airway function in awake OSA patients, pre- and post-weight loss,[15] demonstrated a paradoxical inspiratory narrowing of the glottis in some patients pre-weight loss and remarkable resolution post-weight loss, suggestive that abnormal glottal function during wakefulness may be an indicator of airway pathology during sleep.

AR documents pathological airway dynamics as a decrease in caliber and/or increase in compliance and/or abnormal glottal function.

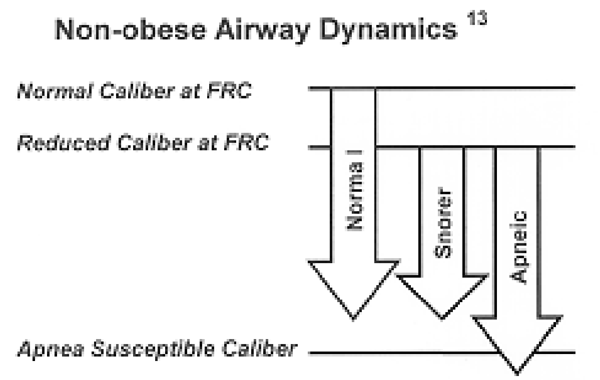

Figure 5
Arrow length represents relative compliance (collapsibility) of the airway. Although non-obese apneics demonstrate similar compliance to non-obese normals, reduced caliber facilitates them reaching the airway caliber susceptible to total collapse. In spite of a reduced airway caliber, non-obese snorers do not reach apnea susceptible caliber due to reduced compliance.

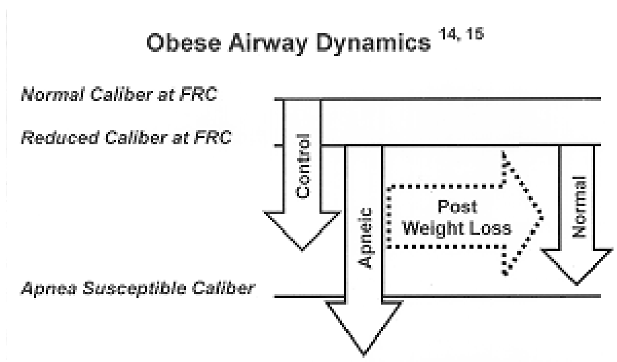

Figure 6
Arrow length represents relative compliance (collapsibility) of the airway. Obese apneics have both a reduced caliber and an increased compliance when compared to controls which facilitates their reaching the airway caliber susceptible to total collapse. However, obese apneics that experience normalized RDI post-weight loss experience a reduction in compliance but no significant increase in caliber. This highlights the significance of airway compliance in obese apneics.

Normalizing Pharyngeal Dynamics

Using various modalities,[31-35] including AR,[11-15] the apneic airway exhibits a reduced caliber and increased compliance. An AO alters mandibular posture by advancing the mandible. Studies demonstrate the effect of mandibular advancement on the airway. CT,[46] MRI[1,3] and video-endoscopy[2,4,47] are all used to demonstrate airway dilation following mandibular advancement with an AO. Endoscopic evaluation of OSA patients experiencing total muscle paralysis through general anesthesia demonstrated widening of the retro-palatal airway as well as at the base of the tongue following mandibular advancement.[2] This evaluation also found that a more negative pressure was required to cause collapse of the airway following mandibular advancement, suggesting a reduction in compliance.[2]

Normalization of pharyngeal dynamics as evaluated through AR during wakefulness demonstrates a remarkable relationship to resolution of RDI during sleep. Rubinstein, et al.,[15] demonstrated a decrease in pharyngeal compliance during wakefulness following the successful treatment of OSA with weight loss. Loube,[16] using AR to evaluate hypopharyngeal changes produced by mandibular advancement during wakefulness, related his findings significantly to improvement or absence of improvement in airway collapse during sleep. Most recently, Metes, et al.,[46] using both CT and AR during wakefulness, demonstrated that the success/failure rate of an AO's ability to resolve RDI is related to anatomic dimensions and pharyngeal airway volume with the AO in place, especially airway cross-section at the oropharynx. Of particular interest, this group also demonstrated that the success/failure rate is not related to the severity of RDI.

Using various modalities of investigation, the literature suggests that patients with OSA and simple snoring have abnormalities of anatomical and physiological features of the pharynx that distinguish them from each other and from normal subjects both, while asleep and awake. AR can evaluate and document both the anatomical factor of caliber/volume and the physiological factor of compliance/collapsibility when evaluating the normalization of pharyngeal dynamics.

Assessing Orthotic Normalization of Pharyngeal Dynamics

Critical Parameters: Horner[29] describes a *pressure-volume* relationship, suggesting a critical airway volume at which collapse occurs during sleep. In a study using AR to evaluate the pharyngeal size of normals, snorers, and apneics during wakefulness, Bradley, et al.[13] describes a continuum regarding pharyngeal size; a critical level of narrowing below which one will snore and another more severe level of narrowing below which the airway will collapse during sleep (**Figure 7**).

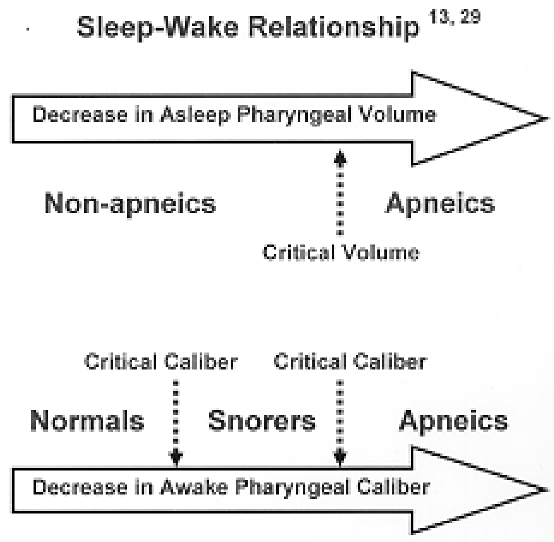

Figure 7
The literature suggests that violation of a critical parameter measured during sleep and/or wakefulness results in loss of airway patency during sleep.

The objective of an AO is to normalize airway dynamics. The literature suggests that airway normalization during wakefulness is indicative of normalization during sleep.[15,16,46,47] Pathological pharyngeal dynamics have been evaluated and documented with and without an AO in place using AR.[10-16,18-21,46] The sleep-wake relationship[35] of airway dynamic characteristics and the sleep-wake relationships[11-16,46] reported in multiple acoustic studies all suggest the existence of a level of compliance and/or caliber during wakefulness that is critical to the maintenance of patency during sleep. Normalization of airway dynamics with an AO as documented through AR during wakefulness provides insight regarding its ability to do so during sleep.

Kamal[28] documented the mean pharyngeal cross-sectional area of normal subjects to be 3.194±0.311 cm^2 for males and 2.814±0.331 cm^2 for females. He also documented the mean cross-sectional glottic areas for these subjects to be 1.06±0.119 cm^2 for males and 0.936±0.108 cm^2 for females. In a recent publication, Kamal[48] documented a reduced mean pharyngeal area in snorers (apneic and nonapneic) from that documented in normal subjects. He also demonstrated a linear relationship between pharyngeal area and Apnea Index (AI), as documented through AR and polysomnography. The apneic snorers had a mean AI of 25.9 and a mean pharyngeal area of 1.589 cm^2, and the nonapneic snorers had a mean AI of

4.0 and a mean pharyngeal area of 2.41 cm^2. Kamal also suggests that careful evaluation of both pharyngeal cross-sectional area and pharyngometry wave forms may provide useful information regarding the site of airway obstruction. This data supports the notion of a spectrum of airway pathology with associated critical parameters that differentiate normals from snorers from apneics. However, when comparing data from your patient's to Kamal's findings, it is important to note that in contrast to the protocol discussed in this article, Kamal used an analysis segment of 0 cm to 20 cm when establishing pharyngeal measurements inclusive of the oral cavity. Evaluation of airway caliber through AR can establish if a subject has a pathologically narrow airway caliber compared to normative standards, and whether mandibular manipulation with a bite-jig normalizes this reduced caliber.

Non-obese apneics demonstrate a similar compliance to controls but differentiate themselves through a reduced caliber,[13] suggesting that normalization of this reduced caliber may be a critical parameter necessary for successful outcome with an orthotic in the non-obese apneic (**Figure 5**).

Obese apneics differentiate themselves from controls through both decreased caliber and increased compliance.[14] However, post-weight loss, obese apneics experience a normalization of compliance, but no significant improvement in caliber,[15] suggesting that normalization of compliance may be a critical parameter necessary for successful outcome with an orthotic in the obese-apneic (**Figure 6**).

Figures 5 and **6** summarize much of our current knowledge base regarding the structural and functional dynamics of the apneic airway as documented through AR. Acoustic evaluation of these dynamics coupled with the use of a bite-jig to vary mandibular posture, thoughtful comparison to Kamal's[28] normative standards, and to literature validated critical parameters[13,14,48] can guide us in assessing the ability of an AO to normalize the pharyngeal dynamics of an apneic's airway.

Acoustic Exam Protocol: The following information is intended to expand upon, validate, and further clarify description of the pharyngometry exam technique found in the manufacturer's manual.[17]

The Mouthpiece: The Free Flow mouthpiece (SensorMedics Corporation, Yorba Linda, CA) currently in use, has a patented restraint bat that gently positions the patient's tongue downward and away from the wave tube opening, virtually eliminating proximal tongue interference. Designed to aide in patient tongue orientation, this tongue bat allows the operator to acquire reproducible data with minimal patient effort. However, in a review of various upper airway imaging modalities, Schwab[49] described how placement of the acoustic mouthpiece has the potential to alter upper airway anatomy, making it difficult to confidently compare acoustic measurements with those of other modalities.

The technique by which an acoustic baseline reading should be taken to minimally influence airway anatomy is open for discussion. Some suggest that this baseline reading should be in centric occlusion (CO), ensuring no vertical increase. However, taking an acoustic reading in CO posture has the potential to alter upper airway anatomy as a result of the increase in muscle tonus that accompanies CO posture.

Ideally, acoustic baseline readings should be performed while the orofacial musculature is relaxed, in balance, and in a state of minimal tonic contraction to minimally influence upper airway anatomy. Mandibular rest, or habitual posture has been described as that assumed while muscles that elevate or depress the mandible are at rest with the subject seated upright or in a standing position. In this resting position, the mandible is held in a muscular sling with the teeth slightly out of contact, creating space between them referred to as freeway space, usually 1-3 mm in the anterior region but as much as 10 mm or more for some patients.[50]

The tongue bat on the Free Flow mouthpiece is attached to the main body by two bite-pads which open the vertical several mm. Any anatomical alteration to the airway resulting from this increase in vertical is patient specific, due to the fact that some individuals experience a vertical increase consistent with their habitual rest posture. This increase can vary greatly among patients. However, in order to minimize or eliminate this variable when taking baseline readings, it is recommended that the bite-pads on the Free Flow mouthpiece be reduced by scalpel to a wafer-thin, compliant pad approximately one mm in thickness. With this reduction, the purpose of this pad is no longer for the teeth to bite down on, but rather a way to retain the tongue positioning restraint bat described previously. This reduced thickness and resulting increased compliance allows the bite-pads to pass through the naturally existing freeway space between the maxillary and mandibular dentition without increasing vertical in most cases. This reduces the likelihood of interference with the assumption of habitual rest posture of the mandible and allows an acoustic reading at true habitual rest posture and evaluation of the upper airway uninfluenced by mouth opening and muscle contraction which are not normally present at true baseline (**Figure 8**).

The Bite-Jig: Evaluation of the airway with varying mandibular postures can be accomplished through use of a chairside fabricated bite-jig. As of the writing of this

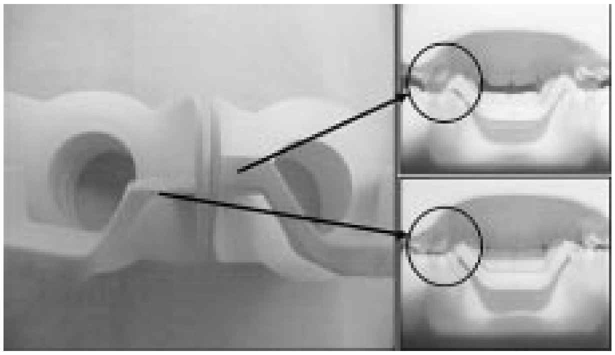

Figure 8
Scalpel reduction of the bite-pads on the Free Flow mouthpiece ensures that baseline acoustic readings are more representative of true baseline, minimizing vertical repositioning.

paper, there is no commercially available bite-jig developed for use with the Acoustic Pharyngometer. However, several groups are active in this area. Presently, our clinic uses the EMA-Trial Appliance (Frantz Design Inc., Austin, TX) which was originally designed to evaluate the effect of mandibular advancement during polysomnography. This appliance allows reproducible evaluation of various protrusive positions in three mm increments. To facilitate the evaluation of varying vertical, snap-on bite-pads were custom fabricated to allow for a vertical increase of three mm (**Figure 9**).

In order to conduct an acoustic exam with an intra-oral appliance such as a bite-jig or an AO in place, it is necessary to cut the bite-pads and tongue restraining bat on the Free Flow mouthpiece out completely (**Figure 10**).

Patient Posture: The issue of patient posture was reviewed in our discussion of pharyngeal dynamics and

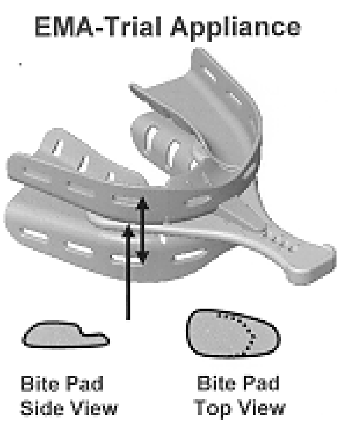

Figure 9
The EMA-Trial Appliance allows advancement in three mm increments. In our clinic, we increase vertical three mm by inserting a custom made bite pad between the upper and lower components.

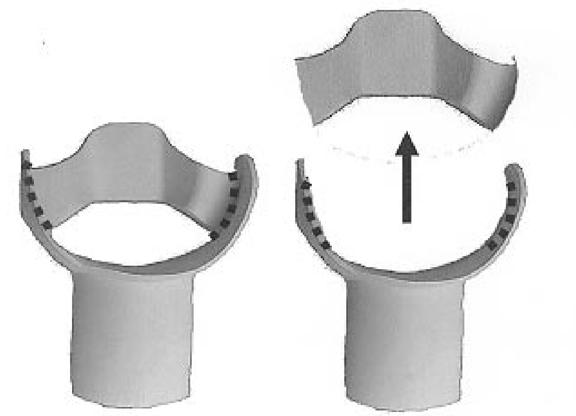

Figure 10
It is necessary to remove the tongue bat as shown (using scissors) in order to use the Free Flow mouthpiece with an intraoral appliance such as a bite-jig or airway orthotic.

acoustic reflection. Although AR can be performed while the patient is supine, to eliminate the confounding effects of the neuromuscular-compensatory mechanism that manifests in the *awake* apneic airway while supine, it is recommended that the AR exam be conducted with the patient seated upright.

Establishing Caliber and Compliance: In order to obtain reproducible results, a consistent protocol must be followed when conducting an acoustic exam. To establish this protocol, the following terms, which refer to specific points of the respiratory cycle, must be defined. Each term is defined as the volume of air in the lungs at a specific point of respiration. Functional residual capacity (FRC) is the volume of air remaining in the lungs at the end of a normal expiration during tidal breathing when all the respiratory muscles are relaxed. Total lung capacity (TLC) is the volume of air in the lungs following maximal inspiration. Residual volume (RV) is the volume of air remaining in the lungs following maximal expiration.

Since airway caliber is related to the respiratory cycle[31] and reduction in caliber predisposes the airway to collapse,[29,30] it is helpful to establish the point of greatest narrowing during respiration (end-expiration just prior to inspiration).[51] To ensure reproducible measurements of airway caliber at its narrowest point, AR readings are consistently taken at FRC (end expiration just prior to inspiration). Once the reading is taken, the last ten acoustic measurements, each automatically taken at 0.2 second intervals, are averaged to establish the pharyngogram tracing, representing airway caliber. The degree with which these averaged measurements differ is visually represented by dashed lines bordering the pharyngogram tracing, representing ±1 standard deviation from the mean. A set of averaged readings with little variance results in a smaller standard of deviation and a more accurate acoustic reading, represented as a pharyngogram tracing with minimal or no dashed lines.

A measure of airway compliance or degree of collapsibility can be derived from a comparison of the caliber established at FRC and the caliber established after a maximal lung-volume change, expiration from "TLC to RV." Since airway caliber is related to the respiratory cycle (changes in lung volume),[31] the greater the difference between the FRC and the "TLC to RV" reading, the greater the measure of compliance/collapsibility (*floppiness*) of the airway. It is important that the patients do not alter their body, head, or neck posture while exhaling from "TLC to RV." Since it is sometimes difficult to establish when the patient has actually reached RV, it is helpful for them to indicate this to you by simply closing their eyes, as any other method is likely to alter the body posture. The measurement is taken when the patient reaches RV (**Figure 11**).

General Protocol: When conducting an acoustic exam, ensure that the wave-tube is at room temperature. Patients sit comfortably upright in a straight-backed chair, their gaze fixed at a point straight ahead and parallel to the floor. Looking into their eyes in a mirror directly in front of them helps to ensure this posture. Maintaining this posture is important, since any flexion or extension of the neck may result in a change in airway anatomy.[52] Head, neck, and shoulder posture were maintained throughout the examination. The patient is asked to breathe exclusively through the mouth, as nasal breathing will cause the soft palate to fall and rest on the dorsum of the tongue, preventing passage of the acoustic wave. Some operators advocate holding the patient's nose to ensure only oral breathing. However, if using this technique, be aware that in some individuals the velum falls forward and downward when you hold the nose, resulting in an altered acoustic reading. For baseline, have the patient assume mandibular habitual rest posture with the mouthpiece in place to avoid any increase in muscle tonus associated with heavy occlusion on the scalpel-reduced bite-pads (take the readings at FRC or RV as described previously). For readings with the bite-jig at various mandibular postures, the same protocol is followed ensuring that the tongue is lying on the floor of the mouth in the posture it would assume if the patient made the sound "oooh".

Establishing Landmarks and Analysis Segment: As described earlier under *Acoustic Reflection*, the pharyngogram is a reproducible representation of the cross-sectional dimension of the airway from the oral cavity caudal to the glottis. The first measurement should be taken at FRC to establish a standard pharyngogram or cross-sectional representation of the pharyngeal airway at the narrowest point of the respiratory cycle during normal tidal breathing. This reading establishes airway caliber.

The second measurement is taken at RV following expiration from TLC. Comparison of this reading to that obtained at FRC will provide you a measure of pharyngeal compliance/collapsibility. Although you will be repeating the FRC and "TLC to RV" tests below, it is helpful to use this opportunity to train the patient as to

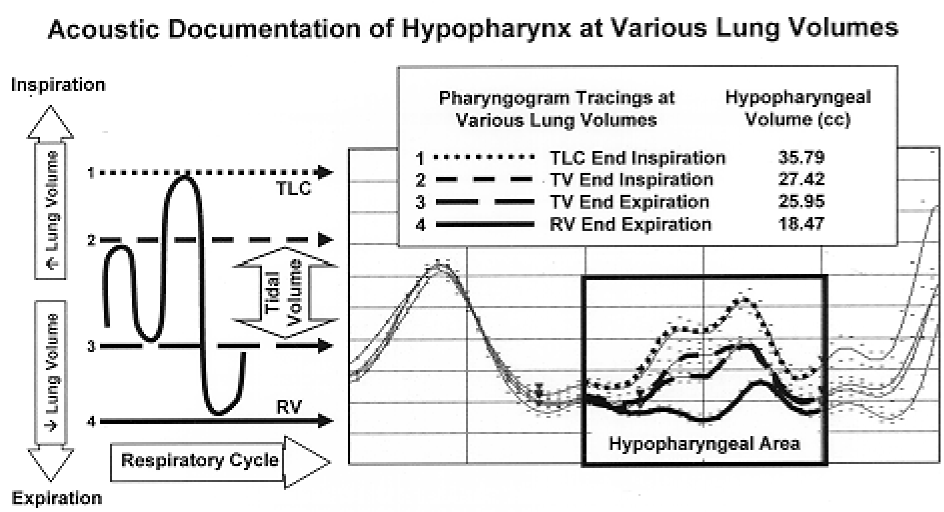

Figure 11
Airway size varies with lung volume throughout the respiratory cycle. In the example, hypopharyngeal volume decreased from 35.79 cc to 27.42 cc, to 25.95 cc, to 18.47 cc when readings were taken at four distinct points of the respiratory cycle: total lung capacity (TLC), tidal volume at end of inspiration (TV), tidal volume at end expiration (FRC), and residual volume following a complete expiration (RV). For reproducible results, acoustic readings should be taken at a consistent point of the respiratory cycle. Airway caliber is measured at FRC, and a measure of airway compliance is obtained by comparing this caliber to that obtained following full exhalation from TLC to RV.

how to conduct these breathing maneuvers, helping you to establish that you can in fact obtain a reproducible pharyngogram curve at both FRC and RV points in the respiratory cycle.

The third measurement is taken while nose breathing to demonstrate collapse of the pharyngogram at the oropharyngeal junction as the soft palate moves forward and rests on the dorsum of the tongue, blocking the acoustic sound pulse entering through the oral cavity. The resulting local area minimum on the pharyngogram establishes the oropharyngeal junction.

The final measurement is taken with the Mueller maneuver (or alternative techniques described in *Acoustic Reflection)* to demonstrate collapse of the pharyngogram at the glottis, thus establishing this landmark.

The analysis segment is located on the x-axis and represents the portion of airway that the Eccovision statistical analysis will apply to (located on the upper right portion of the screen and in the printed reports). As it is user defined, the analysis segment can be set to include the hypopharynx and/or oropharynx as defined by the landmarks you have established. This analysis segment can be customized for each screen, which is sometimes necessary should your choice of bite-jig alter the relative position of the Free Flow mouthpiece or wave-tube (along the x-axis), potentially altering the relative position of the landmarks established at baseline (**Figures 12-14**).

Bit-Jig Protocol: Establish baseline landmarks and set the analysis segment as described in the section, *Establishing Landmarks and Analysis Segment.* Landmarks should be re-established and the analysis segment adjusted, if necessary, once the bite-jig is in place to ensure consistent analysis of the same segment of airway evaluated at baseline.

Baseline caliber and compliance are established by conducting the FRC and "TLC to RV" tests. Repeat these tests with the bite-jig in place to establish caliber and compliance with mandibular repositioning.

As discussed under *Pathological Pharyngeal Dynamics and Acoustic Reflection*, obese apneics demonstrate remarkable compliance with this test; airway caliber measured at RV is found to decrease by over 50% from that measured at FRC. In contrast, this decrease is only 30% in controls[14] which suggests that normalization of compliance to less than 30% may be a critical threshold when evaluating obese apneics. However, non-obese apneics present differently. Although they also have a reduced caliber, their compliance is similar to controls[13] which suggests that normalization of caliber may be a critical threshold for non-obese apneics (**Figures 15** and **16**).

At this point, the preadjusted bite-jig is inserted into the patient's mouth. Using a Free Flow mouthpiece that has had the tongue bat cut out as described under *The Bite-Jig*, re-establish landmarks as described. Once you

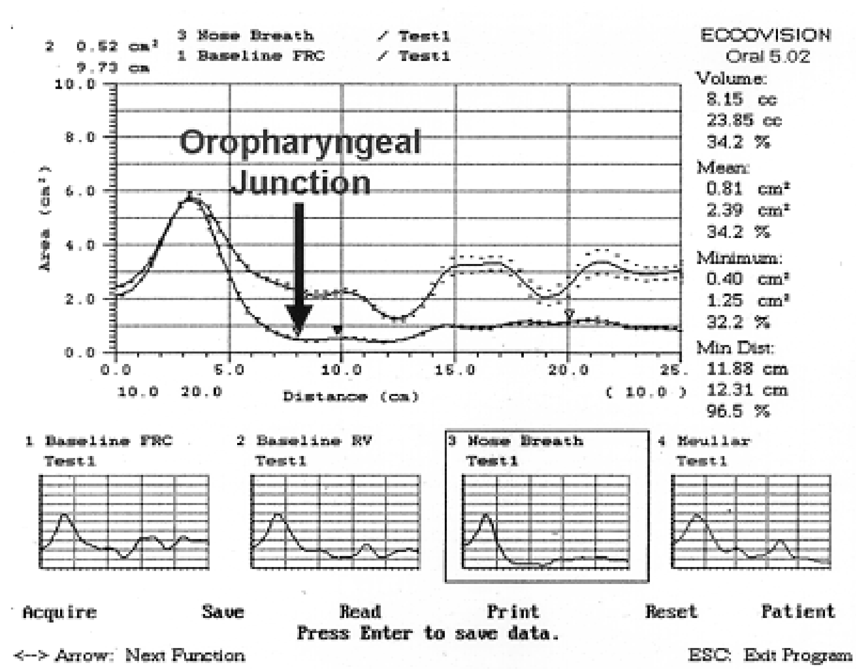

Figure 12
Standard pharyngogram wave form taken at end-expiration of tidal breathing (FRC) and during nose breathing demonstrating a collapse of the pharyngogram at the oropharyngeal junction. The oropharyngeal junction is estimated to be at the eight cm point along the x-axis.

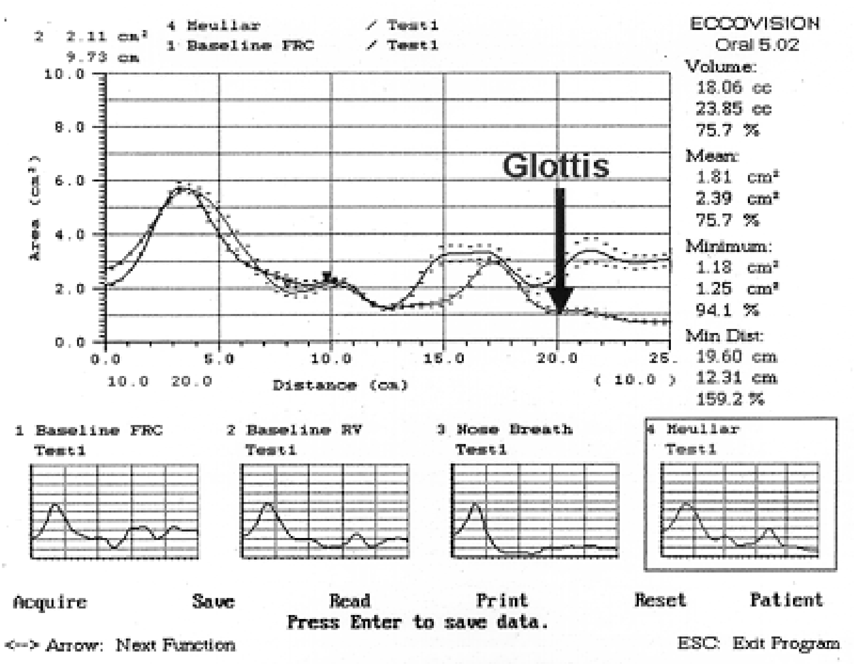

Figure 13
Standard pharyngogram wave form taken at end-expiration of tidal breathing (FRC) and with the Meuller maneuver, demonstrating a collapse of the pharyngogram at the glottis. The glottis is estimated to be at the 20 cm point along the x-axis.

have established that the analysis segment is correctly set, retake the FRC (caliber) and "TLC to RV" (compliance) readings, establishing caliber and compliance with the altered mandibular posture. Comparison of these readings to the baseline readings taken previously will provide an objective evaluation of the degree to which mandibular repositioning has normalized pharyngeal dynamics, both structure and function.

Once the readings are taken, the Eccovision software allows comparison between any two graphs and provides both visual graphic and objective statistical comparison. Pairing up the baseline caliber (FRC) and advanced caliber (FRC) graphs provides insight into the effect of mandibular repositioning on airway caliber. Comparing

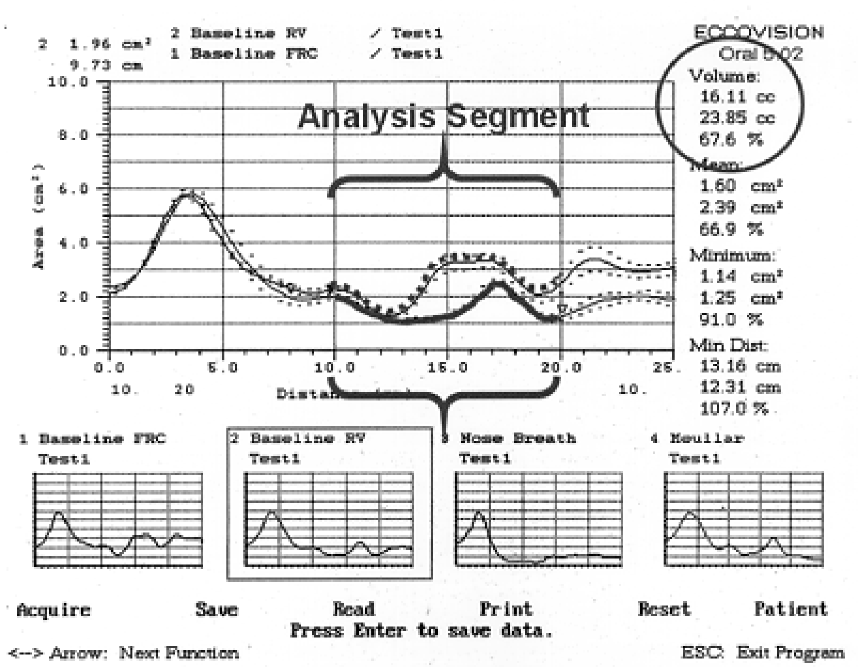

Figure 14
Standard pharyngogram wave form taken at end-expiration of tidal breathing (FRC, dotted line) and with lung-volume change test (TCL to RV, solid line), demonstrating a reduction in hypopharyngeal volume from 23.85 cc to 16.11 cc (32.4% reduction). The analysis segment is set to evaluate the section of airway between 10 cm and 20 cm on the x-axis to represent an approximation of the hypopharyngeal area.

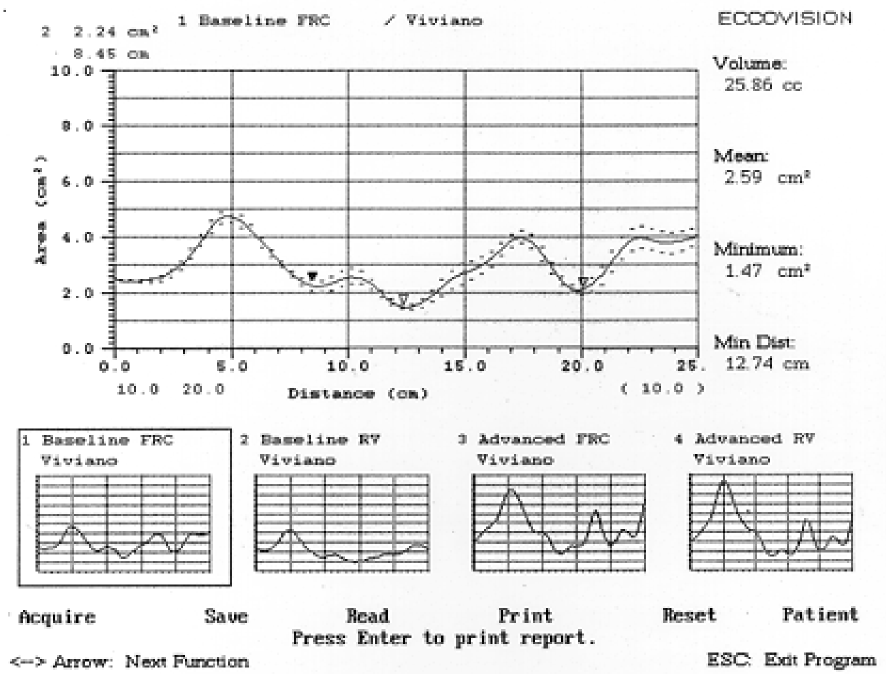

Figure 15
Baseline (FRC) pharyngogram demonstrating a hypopharyngeal (10-20 cm on the x-axis) volume of 25.86.cc.

the baseline compliance (TLC to RV) graph to the advanced compliance (TLC to RV) graph demonstrates the level of airway splinting (stiffening) with mandibular repositioning (**Figure 17** and **18**).

Other useful comparisons include the baseline caliber (FRC) to the advanced compliance (TLC to RV) graph and the advanced caliber (FRC) to the advanced compliance (TLC to RV) graph, both of which provide further insight regarding improvement in compliance with mandibular advancement (**Figures 19** and **20**).

Orthotic Candidacy: Whether an AO stabilizes the pharyngeal airway by increasing caliber or decreasing compliance is difficult to determine. However, the literature provides helpful criteria for establishing orthotic candidacy. Both caliber and compliance have differentiated normals from snorers and apneics.[11-15] A study

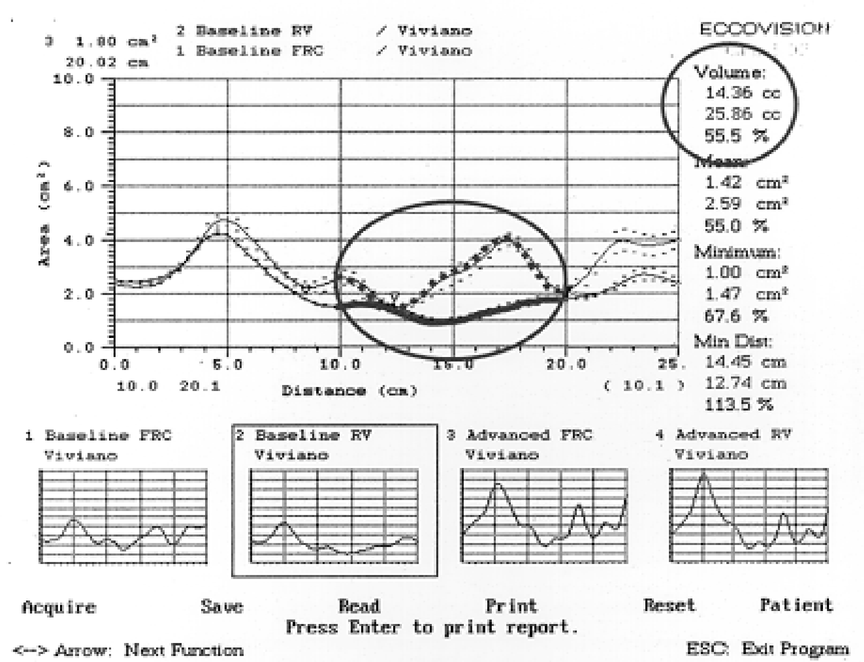

Figure 16
Baseline (FRC, dotted line) and baseline lung-volume change (TLC to RV, solid line) readings demonstrating a reduction in hypopharyngeal volume from 25.86 cc to 14.36 cc (44.5% reduction).

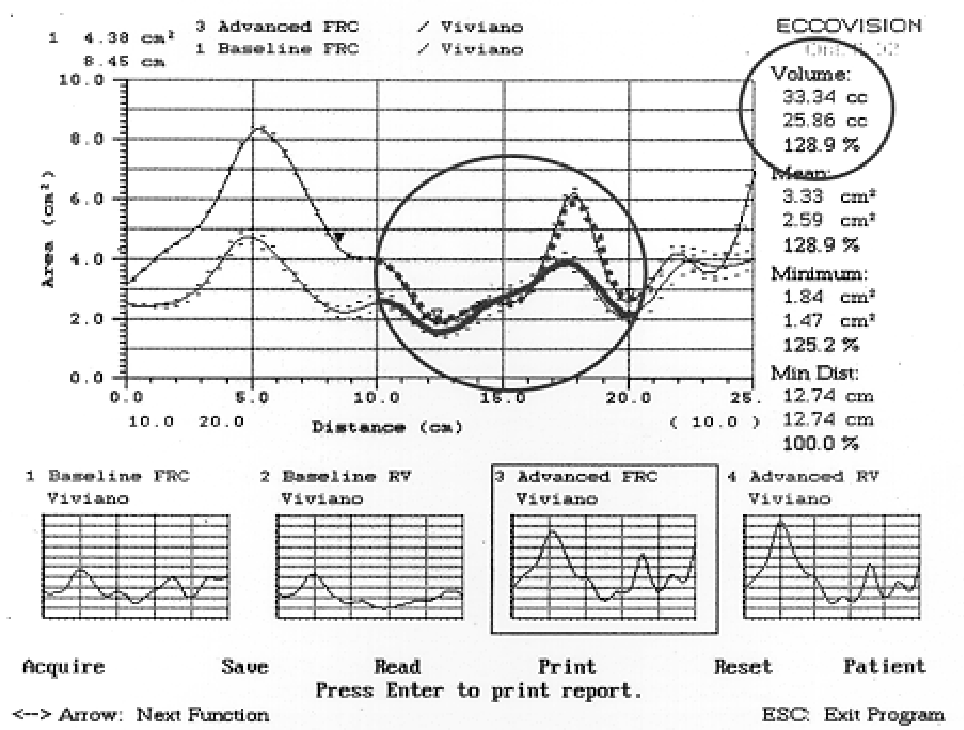

Figure 17
Baseline (FRC, solid line) and advanced (FRC, dotted line) readings showing a 28.9% increase in hypopharyngeal volume post-mandibular advancement.

involving mandibular advancement and propofol induced sleep[53] demonstrates a remarkable relationship between normalization of airway dynamics below the velopharynx and successful treatment outcome. The results of this study suggest that an AO works best when dealing with closure caudal to the velopharynx, regardless of whether there is additional closure at higher levels, indicating that reduced caliber of the hypopharynx may favor AO

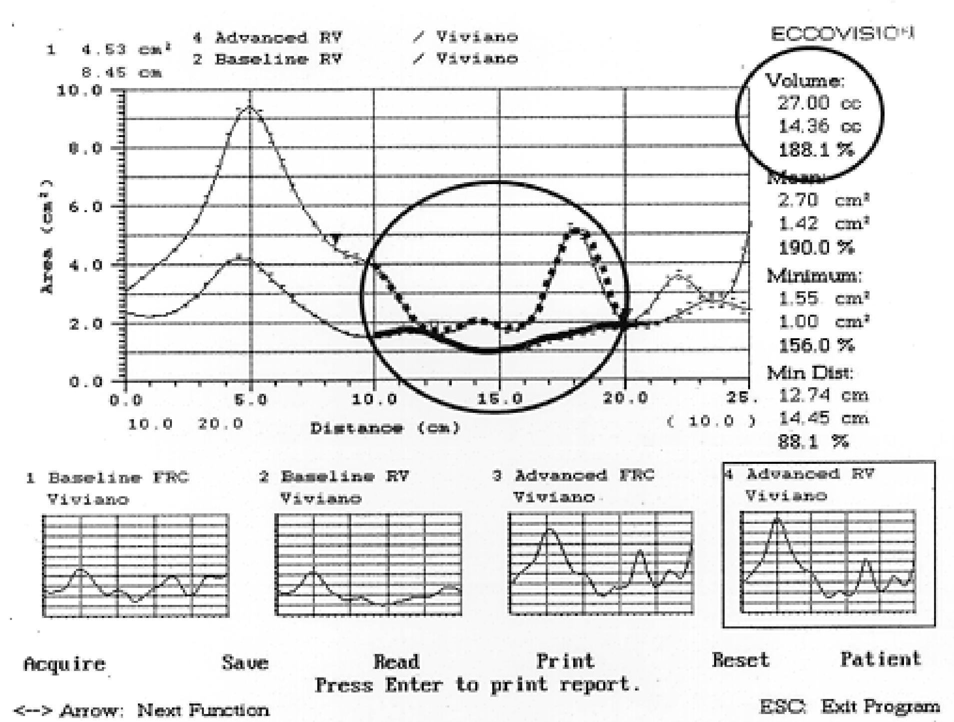

Figure 18
Baseline lung-volume change (TLC to RV, solid line) and advanced lung-volume change (TLC to RV, dotted line) readings showing a remarkable dilation and splinting (stabilization) of the pharyngeal airway with mandibular advancement.

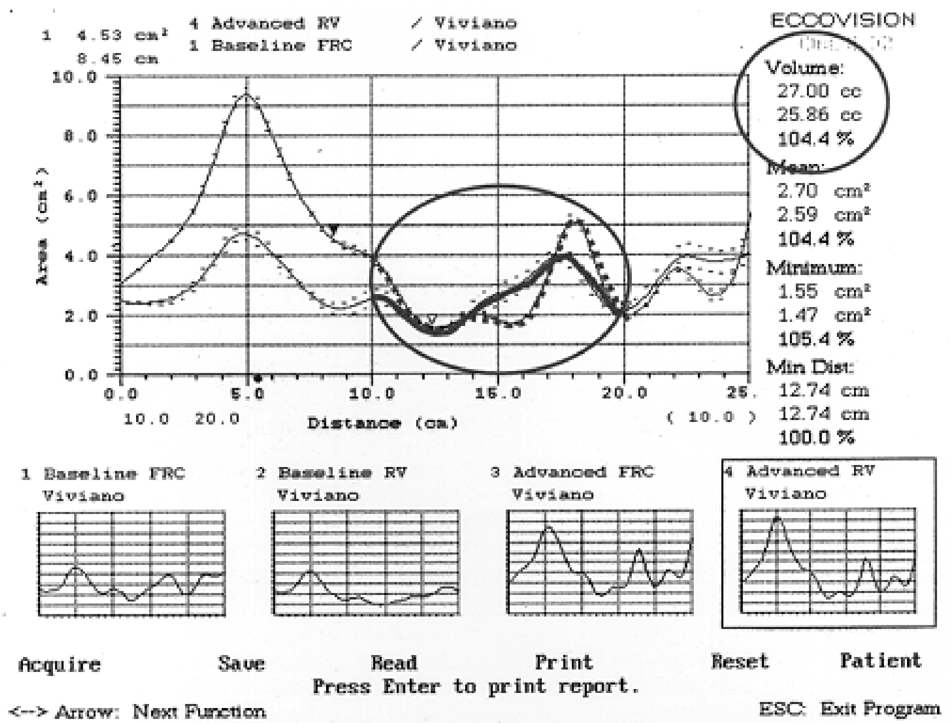

Figure 19
Baseline (FRC, solid line) and advanced lung-volume change (TLC to RV, dotted line) readings showing an increase in hypopharyngeal volume from 25.86 cc to 27.00 cc (4.4% increase) and demonstrating remarkable stabilization of the hypopharyngeal airway during the lung-volume change postmandibular advancement when compared to baseline FRC readings.

therapy regardless of whether narrowness also exists at the velopharynx.

A growing number of studies involving endoscopy,[2,4,47] MRI,[1,3] CT,[46] and AR[16,46] demonstrates increased pharyngeal caliber with mandibular advancement using an AO during wakefulness. Loube[16] used AR to evaluate hypopharyngeal changes of pre- and post-mandibular advancement with an AO and demonstrated that no change in volume was 95% predictive of failure, and that an increase in volume was 60% predictive of a successful treatment

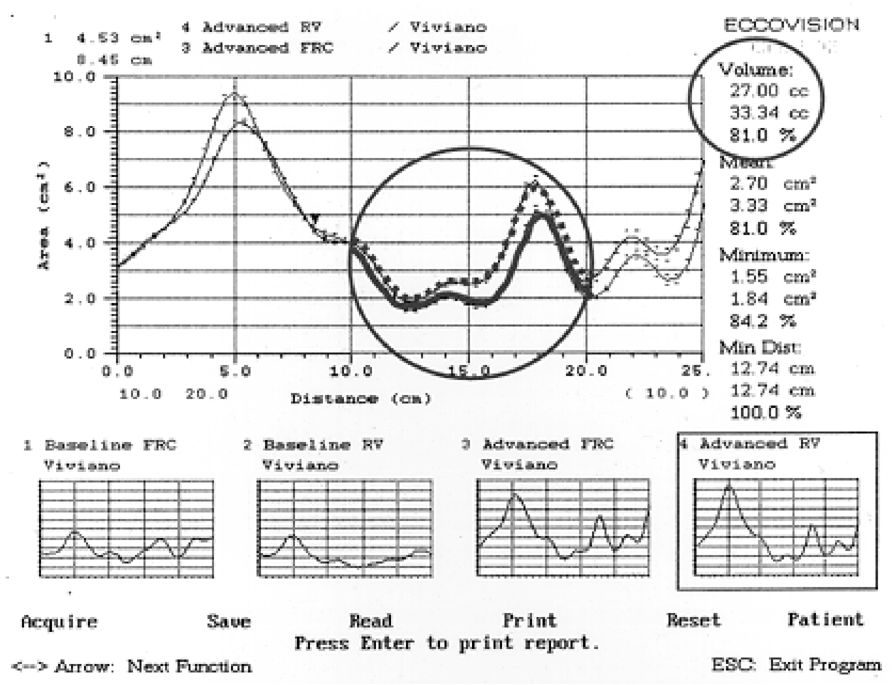

Figure 20
Advanced (FRC, dotted line) and advanced lung-volume change (TLC to RV, solid line) readings showing a reduction in hypopharyngeal volume from 33.34 cc to 27.00 cc (19% reduction). This represents a remarkable splinting of the pharyngeal airway when compared to the same two readings taken at baseline (**Figure 16**).

outcome. The 60% predictive value for success associated with airway dilation indicates that variables other than volume, such as compliance (which was not evaluated), may play a role in determining success. These findings suggest that normalization of both airway structure (caliber/volume) and function (compliance/collapsibility) may influence outcome. The highly predictive value associated with no airway response to mandibular manipulation could help us isolate those individuals who demonstrate no benefit and/or worsen with orthotic therapy.

The potential for airway normalization with an AO can be evaluated through the use of a temporary bite-jig that can guide the mandible through various postures, allowing acoustic evaluation of airway dynamics at each position and helping to establish candidacy for this therapy.

Orthotic Construction Parameters: Although it is popular to minimize vertical opening when constructing an AO, some patients benefit from varying the vertical posture of the mandible beyond that associated with mandibular protrusion.[54] However, this issue remains controversial, since the literature also suggests that the amount of bite opening induced by an orthotic does not impact treatment efficacy.[55] Notwithstanding this controversy, through use of a chair-side constructed bite-jig discussed earlier, the mandible can be manipulated in both the vertical and anterior-posterior (AP) dimensions and can provide an opportunity to evaluate through AR, the level of normalization of airway dynamics at each posture. This in turn can aid in the determination of ideal construction parameters. A bite registration taken at optimum mandibular posture could potentially increase the efficiency and effectiveness with which AO therapy is provided.

Orthotic Titration: Current titration protocol involves mandibular advancement until subjective relief of symptoms is experienced. This is followed by standard polysomnography to objectively verify efficacy. In an effort to establish efficacy, mandibular advancement further than therapeutically necessary sometimes occurs. The resulting hyperextension of the masticatory and cervical muscles can lead to increased discomfort and lower compliance to therapy. Of further concern, it has also been demonstrated that reduction in caliber occurs in some patients with advancement past 75% of full protrusive.[56] This finding is further supported by a study investigating the use of video endoscopy to assist in the titration of an AO,[47] which demonstrates that pharyngeal diameter does not increase linearly to the amount of mandibular protrusion. This group also concluded that evaluation of pharyngeal caliber through video endoscopy during wakefulness is useful for optimizing AO treatment effectiveness.

Nocturnal pulse oximetry, found to be useful in the diagnosis and/or screening of sleep apnea in the general population,[57] is also used to determine end-point orthotic titration. This process involves an overnight study, usually in the patient's home, to determine if the orthotic has normalized oxygen desaturation. In contrast, AR can provide immediate evaluation of the orthotic's ability to normalize pathological airway dynamics at various mandibular postures thus providing real-time feedback regarding ideal titration parameters.

Thinking in terms of seeking *optimum mandibular posture* rather than *optimum mandibular protrusion* is somewhat of a paradigm shift. As discussed previously, the ability to evaluate in *real time* the effect of vertical repositioning on airway dynamics may help to minimize unnecessary or potentially harmful mandibular advancement. Orthotic titration, optimized through acoustic evaluation of the airway's response to mandibular manipulation, minimizes the possibility of inadvertent advancement past the ideal point of effectiveness, possibly into a position that could compromise the airway or the patient's comfort.

Orthotic Maintenance: The regular and frequent intervals at which patients see their dentist ideally positions the dental practitioner to conduct maintenance and follow-up appointments for patients being treated with an AO. The importance of regular follow-up is generally regarded as mandatory whenever ongoing therapy is prescribed. Its value regarding orthotic therapy was highlighted in a recent publication,[58] demonstrating that patients attending regularly for adjustments and follow-up visits experienced a better long-term effect than patients continuing to use their original orthotic. Orthotic effectiveness may be affected by factors such as weight gain, development of allergies, medication use, etc. A yearly examination of the orthotic and dentition along with subjective evaluation through patient consultation is considered standard protocol. An acoustic examination at these visits could objectively substantiate if the orthotic is still optimally titrated to maintain airway patency during sleep.

Discussion

Usual and customary protocol for airway orthotic therapy involves direction from a physician instructing an individual (usually a dentist), trained in the delivery of airway orthotics, to fashion and titrate an orthotic until subjective feedback indicates an improvement of symptoms. The patient is then referred back for a repeat sleep study to determine the orthotic's effectiveness. Although individuals with less severe symptoms appear to be effectively treated more often than those of higher severity,[9] some patients achieve a good outcome and some not, regardless of their initial level of severity.[46,53] This indicates that RDI alone is not dependable for predetermining outcome.

Due to various factors, a patient's subjective feedback is often of limited value. The patient may not have a bed-partner to monitor improvement of symptoms during sleep, and some individuals demonstrate little or no day-time symptoms upon which to base a comparison. In these cases, patients are often advanced as far as they can comfortably tolerate and then referred back for a follow-up sleep study for determination of efficacy. Alternatively, understanding how the dynamics of a pathological airway differ from normative standards, along with the ability to evaluate in *real time* the effect of mandibular repositioning on these dynamics, would facilitate the determination of orthotic candidacy. Acoustic protocols at each subsequent stage of airway orthotic therapy potentially increases the efficiency with which this treatment modality is delivered.

Protocols for the use of AR have been discussed; however, these protocols are being both derived and revised based on a constant flow of newly published data. A very recent publication[59] described the novel use of a topical airway anesthetic to negate the compensatory neural processes that preserve upper airway patency during wakefulness to facilitate the evaluation of true airway compliance. Further studies may establish this to be a useful revision to the discussed protocols. Although the literature currently provides much insight regarding protocols for AR, with continued research and due diligence, these protocols will continue to evolve and to further establish the utility of acoustic derived data.

Although video endoscopy,[2,4,47] CT,[46] and MRI[3] have all been used to assess the effect of mandibular advancement on the airway, the low cost, ease of use and repeatability, and high patient acceptance of AR make it an ideal imaging modality for this purpose. The ability to take measurements in three dimensions and at 0.2 sec intervals allows the *real time* assessment of both structural and functional dynamics and facilitates evaluation of an orthotic's ability to normalize the airway dynamics of a pathological airway.

Conclusion

The use of AR to evaluate the airway dynamics of patients with SDB has potential utility in both medical and dental facilities that provide airway orthotic therapy. Although much evidence has been cited, continued investigation to further validate critical parameters necessary to normalize the awake airway as documented through AR would further substantiate this utility and afford us the ability to establish an increased level of successful AO treatment outcome by facilitating determination of candidacy, construction, titration, and maintenance stages of therapy.

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