Pilot Study Testing the Concept of Intraoral Nasal Dilation

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Abstract
Resistance to nasal airflow at the nares approximates half the airflow resistance of the entire respiratory system. Nasal dilation at the nares prevents collapsibility via the Bernoulli Principle. Acoustic rhinometry was used to test a system of ½ inch diameter acrylic discoid pads placed distal to the cuspids at the height of the maxillary labial vestibule. They were intended to stretch the lip and distend the nares. The intraoral discoid pads were anchored by orthodontic wire to a maxillary advancement device (MAD).

MADs are successfully used by dentists to treat obstructive sleep apnea (OSA) and snoring. The MAD with the acrylic discoid pads was compared to an identical control device without the pads and also compared to a gold standard, external nasal dilator strips (ENDS). The objective measurement device was an acoustic rhinometer.

Subjects in this study were patients in a clinical dental practice diagnosed with OSA by a boarded sleep specialist and determined as appropriate candidates for treatment with a MAD.

This study demonstrated that the intraoral discoid pads placed high in the maxillary labial vestibule distal to the cuspid did not result in nasal dilation on a clinically or statistically significant basis. They increased nasal dilation at the nares only slightly more than they decreased it. The external dilator nasal strips however do significantly increase cross-sectional dimensions at the nares.

Introduction
Human beings have a collapsible, flexible oropharyngeal airway. This characteristic is a necessity for the articulation of speech. Periodic complete collapse of the tongue on the airway is the cause of Obstructive Sleep Apnea (OSA) and hypopnea. The nose is an incredible organ for olfaction, filtration, warming and humidification of inspired air. As the air is drawn into the lungs in inhalation, excessive turbulence of the airflow and a greater demand by the diaphragm than the nasal airway can deliver creates negative pressure, facilitating airway collapse. Humans are obligate nasal breathers. The mouth is merely a back up airway in cases of nasal obstruction. Nasal valve incompetence, swollen allergic nasal membranes, enlarged turbinates and septal deviation are conditions that can impede nasal breathing.

The Nasal valve is a nozzle. Its cross-sectional area is stabilized by inspiratory isometric contractions of the alar dilator muscles. The major portion of nasal resistance to inspiratory air flow has been localized to the nasal valve. Resistance to respiratory air flow at the valve approximates half the airflow resistance of the entire respiratory system. Nasal dilators work against nasal collapsibility via the Bernoulli Principle and decrease nasal air flow resistance via alar muscle dilation. The effectiveness of both external nasal dilators and intranasal mechanical dilators has been demonstrated. The question being tested is whether intraoral nasal dilators compare favorably to a gold standard, external nasal dilator strips (ENDS). The intraoral nasal dilators are discoid acrylic pads placed intraorally in the labial vestibule distal to the nares. They stretch the lip and thus distend the nares. Breathe Right Nasal Strips® are the ENDS being utilized in this study.

The intraoral discoid shaped acrylic pads are affixed to a Mandibular Advancement Device (MAD). MADs are successfully used to treat Obstructive Sleep Apnea (OSA), hypopnea, Upper Airway Resistance Syndrome (UARS) and snoring. MADs support the tongue in a position more anterior than normal, thus preventing collapse of the tongue on the airway. The acrylic discoid pads, ⅜ inch in diameter and ¼ inch thick are embedded stainless steel wires extending from the buccal flanges on each side of the MAD. The dilator pads are positioned in the height of the labial vestibule directly under the cuspid and slightly distal to the nares. The discoid dilator pads are adjustable by bending the wires in or out and can be shortened by grinding on the acrylic.

Method
This clinical study was designed to compare the efficacy of the ENDS vs ½ inch diameter acrylic discoid pads placed in the maxillary vestibule over the cuspids and slightly distal to the nares to stretch the lips and dilate the nostrils resulting in increased nasal airflow. The objective measurement test device is an acoustic rhinometer (the ECCOVISION Acoustic Rhinometer designed by Hood Laboratories in Pembroke, Massachusetts). The apparatus graphs and quantifies the patency of the nasal airway by means of acoustic reflection; both site and degree of airway obstruction can be determined by the simple, noninvasive diagnostic procedure.

Acoustic rhinometry is used primarily by otorhinolaryngologists, allergists, dentists and plastic surgeons to accurately assess the geometry of the nasal cavity. By coupling a reflection tube to the nose and administering a series of clicks controlled by the program, the computer-based system is able to plot the timing and amplitudes of the reflected signal into a graph of the nasal airway. Applications of the technique include assessing airway patency, the site/degree of airway obstruction and airway responsiveness to therapeutic intervention such as MADs. The technique provides more information than traditional rhinomanometry which does not provide clinical data.
3. Fit the control appliance – MAD without the dilators Acoustic Rhinometer reading with control appliance.
4. Fit the MAD with the dilator. Adjust nasal dilators using interim readings with acoustic rhinometer.
5. Acoustic Rhinometer reading with discoid pads on maximally adjusted MAD.
6. Place Breathe Right on nose of patient.
7. Acoustic Rhinometer reading – Breathe Right and no appliance.

Precautions to eliminate errors:
1. Uniformly place nasal adaptor parallel to dorsum of the nose.
2. Neutral electrocardiogram gel was used between nasal adaptor and nostril to assure adequate sealing.
3. Avoid undue pressure on the nostril to avoid deforming nostril and nasal valve.
4. Glasses removed from the nose during testing.
5. Maintain head in a stable position, parallel to the ground.
6. Subjects asked to close mouth, hold their breath and not swallow during testing.
7. Analysis done on the average of three technically acceptable curves.
8. All measurements done in same room.
9. Maximum noise level in room was monitored and never exceeded 60 dB.

Both the MAD with the nasal dilators and the control device were made out of identical material, to the same specifications. Any differences were unintended and based on individual characteristics of the laboratory technician. What is being tested is the value of the acrylic discoid dilators. To establish a relative standard of effectiveness they are being compared to an external dilator, Breathe Right Nasal Strips™. Breathe Right Nasal Strips™ are harmless non-invasive band-aid like devices on which a leaf spring is attached. When placed on the nose the leaf spring wants to straighten out, pulling on the tape and comfortably expanding the nares. The effect of dilating the nares is to decrease nasal resistance and make airflow through the nose easier.

The minimal cross sectional area of the nasal cavity usually occurs at the nasal valve. Eccovision acoustic rhinometry measures the cross sectional airway at the nasal valves and turbinates. It can measure volume of the nose but it does not measure airflow. In fact during testing, the patient is holding their breath. The appropriate measure for nasal dilation is comparing the cross sectional area at the nares. Cross sectional area of the nares with no appliance is compared to cross sectional area at the nares with control appliance, “nasal dilator” appliance and with a Breathe Right and no appliance.

It cannot be reasonably expected nor is there a scientific basis for claims that decreased nasal resistance beyond the nares is a result of an intraoral nasal dilator. In fact, users of Eccovision acoustic rhinometry are cautioned in the manual that a serious constriction of the nasal airway at the nares will result in inaccurate measurement of the airway volume beyond the constriction. There is no scientific basis for a claim that increased volume of the nasal airway beyond the nares is a result of intraoral nasal dilation. Based on the manufacturer’s cautionary statement, such findings would probably be artifact.
**Conclusion**

The intraoral discoid shaped pads placed high in the maxillary vestibule and distal to the cuspids did not result in nasal dilation on a clinically or statistically significant basis. They increased nasal dilation at the nares only slightly more often than they decreased it. The external nasal dilators however, do significantly increase the cross-sectional dimensions at the nares.

Resistance to airflow is a condition that predisposes and/or causes sleep disturbed breathing. A decrease in resistance to airflow in the upper airway is a desirable clinical result. Use of a MAD is a recognized treatment modality for OSA. MADs by virtue of genioglossus advancement have been shown to effectively reduce the AHI and thus may reduce upper airway resistance. Scientific studies have shown MADs to be most successful on patients whose collapse is in the oropharyngeal area. A MAD can sometimes decrease the AHI without a decrease in resistance to airflow as noted on the PSG study using a pressure transducer in the oral/nasal cannula. Despite the significant increase in cross-sectional area at the nares using external nasal dilator strips, the dilator strips used alone have not been shown to be effective in controlling OSA, and limited success reported with snoring. A promising area for future study would appear to be measurement of the combined effect of ENDS used with MADs.

**References**