

Effect of an intra-oral nasal dilation appliance on 3-D nasal airway morphology in adults

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Abstract To determine the effects of a nasal dilation appliance on 3-D nasopharyngeal airway patency. The sample comprised 187 adults (98 males, 89 females) with a history of sleep-disordered breathing. Acoustic rhinometry readings were taken from all patients before and after the intra-oral placement of a nasal dilation appliance (OASYS®). The mean left and right nasopharyngeal airways were reconstructed in 3-D, and the data from the right and left nostrils were subjected to principal components analysis (PCA) and finite-element scaling analysis (FESA). Comparing the pre- and post-treatment 3-D mean, left nasopharyngeal airways using PCA, the first two eigenvalues accounted for 96% of the total shape change, and statistical differences were found ($p < 0.01$). Similarly, for the right side, significant differences were detected between the mean pre- and post-treatment 3-D nasopharyngeal airways ($p < 0.01$) using PCA. Using FESA to quantify and localize changes after the placement of the nasal dilation appliance, the 3-D mean, normalized, left nasopharyngeal

airway was found to be 14% wider in the anterior nasal valve region and 28% wider in the distal regions, while the 3-D mean, normalized, right nasopharyngeal airway was 13% wider in the anterior nasal valve region and 27% wider further distally. The use of an intra-oral nasal dilation appliance may be useful in the management of nasopharyngeal conditions, such as snoring, upper airway resistance syndrome, sleep-disordered breathing, and obstructive sleep apnea, especially in cases where nasal obstruction is demonstrable.

Keywords 3-D airway · Acoustic rhinometry · Nasal valve

Introduction

External nasal morphology does not always correlate well with the nasopharyngeal airway anatomy, and traditional methods used to assess airway size are unreliable [1]. Cheng et al. [2] reconstructed a nasal airway model from an in vivo magnetic resonance imaging (MRI) scan of an adult male to determine nasal airway response to pharmaceutical agents, as it is thought that patients with chronic airway issues may present with airflow obstruction due to long-term inflammatory processes. In this respect, Nuhoglu et al. [3] investigated changes in the nasopharynx in children with asthma using computerized tomography (CT) and reported that sinus mucosa thickening, concha hypertrophy, and septal deviation were present inter alia. Similarly, Filho et al. [4] evaluated cephalometric radiography and nasopharyngeal video-endoscopy for the diagnosis of nasopharyngeal airway obstruction. They reported that cephalometric diagnoses of hypertrophy of the middle and inferior turbinates exhibited high sensitivity but low specificity when compared to nasopharyngeal endoscopy.

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In contrast, acoustic rhinometry (AR) seems to be a reliable method of assessment of the nasopharyngeal airway in children [5]. As well, Zambetti et al. [6] employed AR in normal adult subjects to determine areas within the nasal cavity that influence the dynamics of nasal airflow. However, when Tarhan et al. [7] compared AR data to CT data, they reported that AR nasal cavity measurements in healthy adults remain accurate to the level of the paranasal sinus ostia, but further posteriorly AR tends to overestimate cross-sectional areas. Nevertheless, AR is useful for diagnosis, and it is also a reliable method to show the dimensional changes of the nasal cavity before and after a given treatment such as turbinate surgery, septo- and rhinoplasty, orthognathic surgery, and paranasal sinus surgery [8]. Therefore, AR is a tool that can aid in the assessment of nasal obstruction and can also be used to document the effect of surgery on nasal airway obstruction [9].

Although nasal airway function may be a component of sleep-disordered breathing (SDB) in some patients, the relationship between nasal airway function, SDB, and upper airway resistance syndrome (UARS) remains unclear. However, it is thought that correction of nasal obstruction can improve night-time breathing in some patients [10]. Furthermore, the majority of patients undergoing rhytidectomy reported improvement of nasal breathing and demonstrated an increase in the nasal valve cross-sectional area as measured with AR, possibly as a post-rhytidectomy melonasal consequence [11]. Thus, clinical protocols that enhance the dimension of the nasal airway at the nasal valve or nasal isthmus may have beneficial effects for patients with SDB or UARS.

The OASYS[®] system (Fig. 1a) is a custom-made dental device for the treatment of sleep apnea. It has nasal dilator buttons that extend from the upper flange and are positioned under the upper lip. The lips can close together by stretching around the buttons, but there may be concurrent effects on the nasal airway. Therefore, the aim of this study is to test the effect of an intra-oral nasal dilation appliance (OASYS[®],

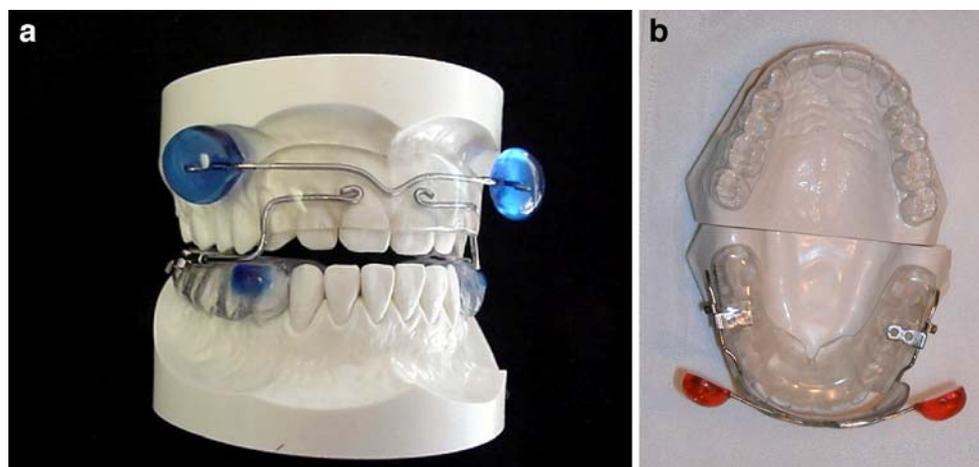
Fig. 1b) on 3-D nasal airway morphology in adults. The null hypothesis to be tested is that an intra-oral nasal dilation appliance has no effect on the nasal airway. Rejection of the null hypothesis will be based on quantification and localization of any changes detected and will provide preliminary evidence for the use of a non-surgical approach to enhance nasal airway function, which may be a component of SDB and/or UARS in some patients.

Materials and methods

This retrospective study was based on clinical assessments made as part of clinical treatment for SDB, after obtaining each patient's consent. All identities were kept anonymous throughout the study. The sample comprised 187 consecutive adults (98 males, 89 females) with a history of SDB/UARS diagnosed with a sleep laboratory polysomnograph (PSG) before treatment. The mean age of the patients was 53.2 ± 13 years, with a mean body mass index (BMI) of 28.2 ± 5.8 and a mean respiratory disturbance index (RDI) of 31 ± 19.5 , as determined from the sleep laboratory PSG. Dental impressions were taken from each patient's upper and lower dental arches by one clinician (MA) using standard dental impression materials, such as alginate or polyvinyl silicone, with careful attention to extend the impression to capture the vestibule anterior to the maxilla. A positional bite registration was also taken at 70–80% of maximum protrusion with 3–4 mm inter-incisal opening. Dental casts were made from the impressions, and the casts along with the bite registration were sent to a laboratory to manufacture the OASYS[®] device.

The laboratory constructed the main body of the OASYS[®] with a separate upper splint to distribute the forces and protect the upper teeth (Fig. 1). This upper splint was seated on the upper dental arch and checked for fit and comfort. The main body of the OASYS[®] fits onto the lower posterior teeth. It is constructed of a thermo-sensitive base

Fig. 1 **a** Intra-oral nasal dilation appliance (OASYS[®]) with blue nasal dilator buttons. **b** The main body of the OASYS[®] has red nasal dilator buttons and a separate upper splint to distribute the forces and protect the upper teeth



material that is warmed to soften it, making the fit over the lower posterior teeth easier. It was seated onto the dental arch, and each patient was instructed to move their mandible forward and position the upper segment in front of the upper anterior teeth so that the mandible was held forward. The nasal dilator buttons were adjusted to position them approximately centered between the lower border of the nose and the commissure of the lips. In this position, the buttons were located just lateral to the nasal-labial folds and anterior to the maxilla, to generate a stretch of the upper lip. Each patient was then instructed to breath through the nose for a period of 5 min.

At the delivery appointment, following the recommendations of Hilberg and Pedersen [12], AR readings were taken from all patients before and after the intra-oral placement of a nasal dilation appliance. The same protocol was used for quality control and optimal application of the AR by a trained operator (MA), who followed the same operating procedure under similar environmental conditions. Figure 2 shows an AR reading being taken. Attention was given to the nosepiece and the coupling between the equipment and the nose to obtain a correct position and sufficient seal without disturbing the nasal anatomy. All readings were taken after following the manufacturer's instructions on calibration procedures. From the readings, the mean, minimum cross-sectional areas (MCA) and mean nasal volume measurements were calculated and subjected to paired, two-tail *t* tests.

Using appropriate software, the mean left and right nasopharyngeal airways were also reconstructed in 3-D, and the data from the right and left nostrils were subjected to principal components analysis (PCA) and finite-element scaling analysis (FESA). A PCA can be used to compare different groups of patients with specific characteristics [13]. Normally, a few modes (the principal components) are sufficient to describe all of the shapes approximately. Importantly, the points representing the shapes in the mode space are grouped according to their main characteristics. Thus, PCA is the determination of axes that account for the maximal variance. If PCA is applied, the two most significant modes can be used for classification/diagnostic purposes [14].

Similarly, FESA can be used to depict clinical changes in terms of allometry (size-related shape change). Initially, Procrustes superimposition is used to rotate, translate, and scale the configurations to equivalent size. Using FESA, the change in form between a reference configuration and target configuration can then be viewed as a continuous deformation, which can be quantified based on major and minor strains (principal strains). If the two strains are equal, the form change is characterized by a simple increase or decrease in size. However, if one of the principal strains changes in a greater proportion transformation occurs in both size and shape. The product of the strains indicates a



Fig. 2 Head position was standardized while AR readings were taken in a dental chair with the patient looking straight ahead with the Frankfurt plane approximately parallel to the floor. Once in the correct position, attention was given to the nosepiece and the coupling between the equipment and the nose to obtain a sufficient seal without disturbing the nasal anatomy. All readings were taken after following the manufacturer's instructions on calibration procedures

change in size if the result is not equal to 1. For example, a product >1 represents an increase in size equal to the remainder; 1.09 indicates a 9% increase. Similarly, a product of 0.85 indicates a 15% decrease. The products and ratios can be resolved for individual landmarks within the configuration, and these can be linearized using a log-linear scale. For ease of interpretation, a pseudo-color-coded scale can be deployed to provide a graphic display of size change [14].

Results

Using conventional measurements, the MCA at 2–4 cm of the analysis segment without the appliance was $0.67 \pm 0.27 \text{ cm}^2$. After insertion of the nasal dilation appliance, the MCA increased to $0.91 \pm 0.35 \text{ cm}^2$ ($p=0.00016$). Similarly, the mean nasal volume at that location was $3.18 \pm 1.8 \text{ cm}^3$ before treatment. After insertion of the nasal dilation appliance, the mean nasal volume increased to $3.27 \pm 1.67 \text{ cm}^3$, but this increase failed to reach statistical significance ($p=0.64$). Therefore, geometric morphometrics were used to localize and quantify any changes using normalized data.

Using PCA to compare the left and right nasopharyngeal airways before treatment, no significant differences were

found ($p=0.59$). However, using PCA to compare the left nasal cavities before and after the insertion of the nasal dilation appliance, a significant difference was detected ($p=0.0012$), with the first two principal components accounting for some 96% of the total shape change (Fig. 3). Similarly, using PCA to compare the right nasopharyngeal airways before and after the insertion of the nasal dilation appliance, a significant difference was detected ($p=0.0002$), with the first two principal components accounting for about 95% of the total shape change (Fig. 4).

Figure 5 shows the pre-treatment 3-D mean, left nasopharyngeal airway (colored purple) superimposed on the post-treatment 3-D mean, left nasopharyngeal airway (colored pink) with the nasal dilation appliance in situ. It is apparent that the post-treatment 3-D mean, left nasopharyngeal airway (colored pink) is wider.

Using pseudo-colored FESA to quantify these local changes, Fig. 6 shows the effect of the nasal dilation appliance on the 3-D mean right nasopharyngeal airway. Using the vertical pseudo-color scale, the orange color demonstrates that the right nasopharyngeal airway is 13% relatively wider in the anterior nasal valve region and about 27% wider further distally (red coloration). Similarly, for the post-treatment 3-D mean left nasopharyngeal airway, the orange region indicates a relative 14% airway enhancement in the anterior nasal valve region and a 28% improvement in the distal regions of the nasal airway (red coloration, Fig. 7).

Discussion

Recent literature has established AR as a valid instrument for objectively documenting nasal patency [15]. For

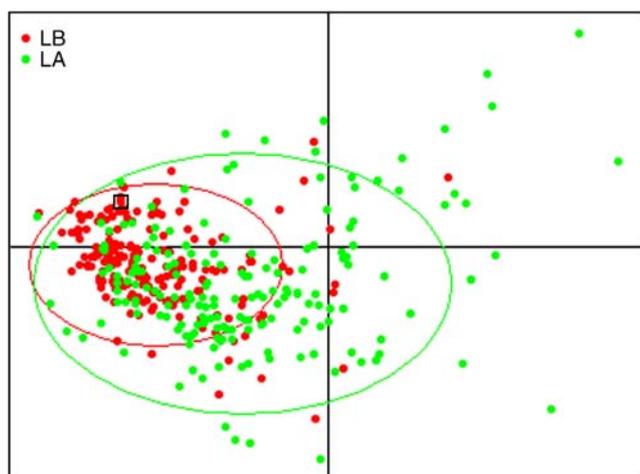


Fig. 3 Principal components analysis comparing the left nasopharyngeal airways (LB, red dots) before and after the insertion of the nasal dilation appliance (LA, green dots). Using the first two principal components, which account for 96% of the total shape change, a significant difference was detected ($p=0.0012$)

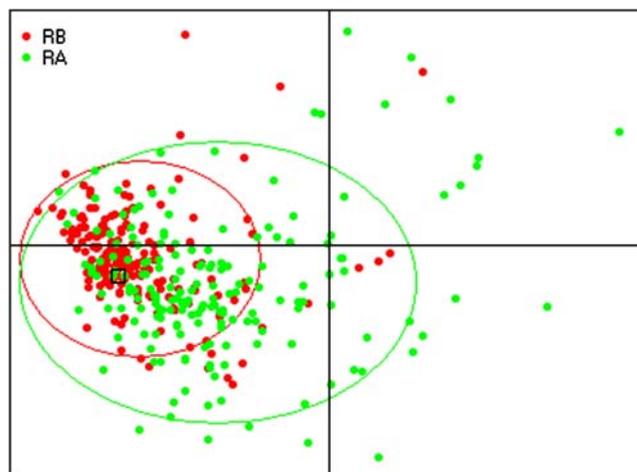


Fig. 4 Principal components analysis comparing the right nasopharyngeal airways (RB, red dots) before and after the insertion of the nasal dilation appliance (RA, green dots). Using the first two principal components, which account 95% of the total shape change, a significant difference was detected ($p=0.0002$)

example, Mamikoglu et al. [16] found that the diagnosis of nasal septal deviation can be supported by AR. The nasal dilation appliance investigated in this study (OASYS®, Fig. 1) stretches the upper lip using intra-oral nasal dilator buttons that extend from the upper flange and are positioned inside the upper vestibule. Although no quantitative data was collected in this particular study for compliance, we found that patient tolerance was high, and

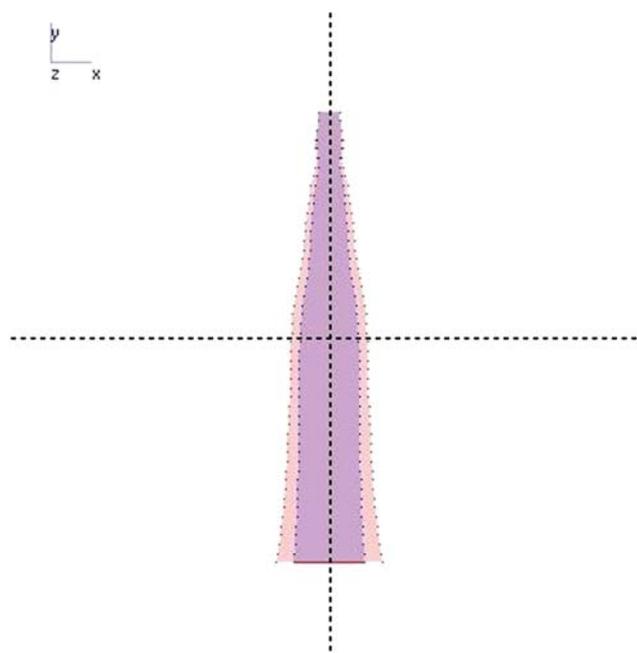


Fig. 5 The pre-treatment 3-D mean, left nasopharyngeal airway (purple) superimposed on the post-treatment 3-D mean, left nasopharyngeal airway (pink) with the nasal dilation appliance in situ. It is apparent that the post-treatment 3-D mean, left nasopharyngeal airway (pink) is wider

side-effects were limited to mild, mucosal irritation. In one case, the nasal buttons were temporarily removed and the device used as a repositioning appliance until patient tolerance improved. Nevertheless, while wearing the device, there may be concomitant effects on the nasal airway, and therefore, it may be useful for the treatment of sleep apnea where nasal obstruction is suspected. However, the effectiveness of this appliance depends on its ability to maintain nasal patency in the supine position while asleep. While these conditions remain outside the scope of the present study, with the appliance in situ, a $\approx 25\%$ increase in the mean MCA ($p < 0.001$) was found in the erect sitting position during wakefulness. In addition, the average increase in nasal cavity anatomy was $\approx 0.05\text{cm}^3$, but this failed to reach statistical significance because inherent size variation of the sample masked the small volume increase. In addition, while $\approx 83\%$ of patients showed an increase in nasal cavity volume, the remainder showed a decrease, using non-scaled data. Thus, the clinical benefits observed

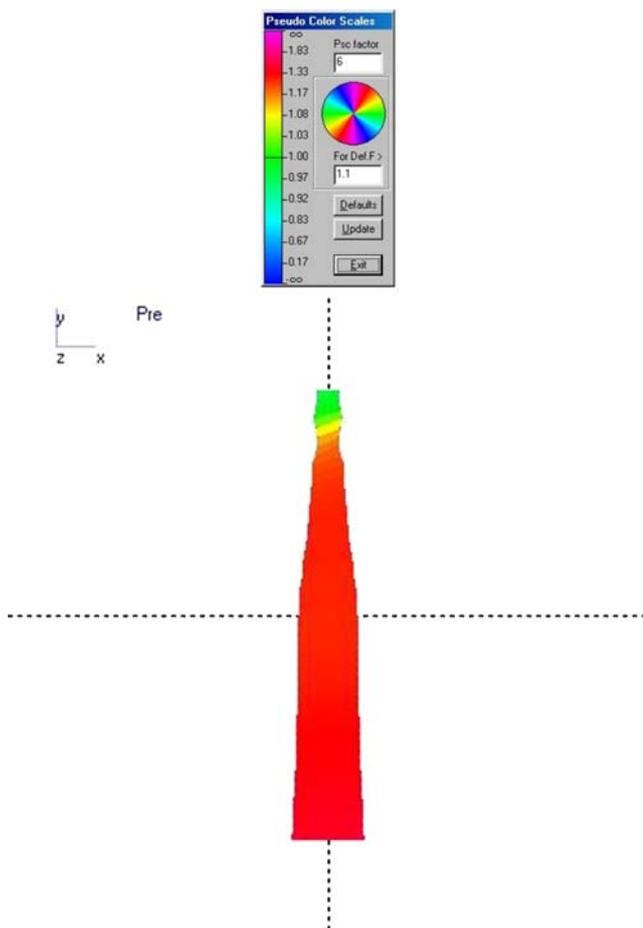


Fig. 6 Pseudo-colored finite-element analysis to show the results of the nasal dilation appliance on the 3-D mean right nasopharyngeal airway. The vertical pseudo-color scale indicates that the right nasopharyngeal airway is 13% wider in the anterior nasal valve region (*orange*) and about 27% wider further distally (*red*)

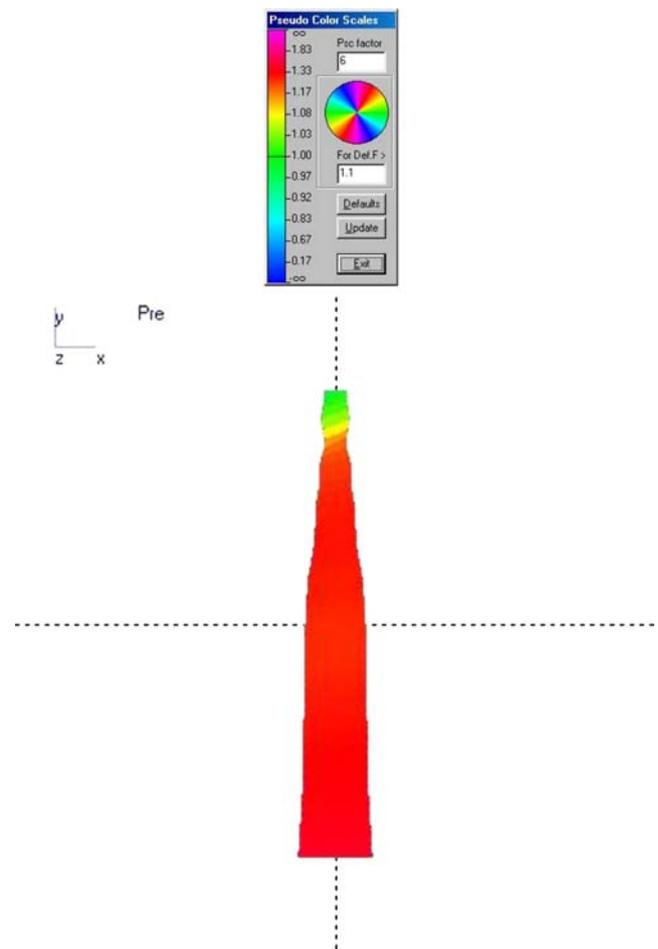


Fig. 7 Pseudo-colored finite-element analysis to show the results of the nasal dilation appliance on the 3-D mean left nasopharyngeal airway. The vertical pseudo-color scale indicates that the right nasopharyngeal airway is 14% wider in the anterior nasal valve region (*orange*) and about 28% wider further distally (*red*)

in this preliminary were supported by conventional measurements, but it remains important to corroborate the current findings with other assessments of functional outcome, such as quantification of nasal resistance, subjective nasal symptoms, etc., before any claims of clinical benefits can be made. Therefore, the above investigations remain as a premise for future studies.

In this present study, mean 3-D nasal cavities were also reconstructed using a novel technique [14]. Earlier, Terheyden et al. [17] processed CT data, and a virtual 3-D model of each nasal cavity was constructed. The measuring accuracy, using CT as the gold standard, revealed a mean error at the nasal valve of 5% and at the nasal isthmus of 2%. Beyond 6 cm, the correlation decreased and overestimation of the true area occurred. Similarly, Djupesland and Rotnes [18] replicated a nasal airway using stereolithography from a 3-D magnetic resonance imaging (MRI) scan. The influence of the maxillary sinuses depended on the size of the ostia, and sound leakage represented an important source of error

reducing the accuracy of posterior measurements. Therefore, for the purposes of this current study, only readings within 6 cm of the anterior nares will be considered pertinent for discussion. In addition, male and female patients were analyzed together, as no statistical difference with regard to gender distribution has been demonstrated [19]. Accordingly, the analytical results obtained for the left and right nostrils in this current study were similar, reflecting the notions of Kalmovich et al. [19]. In addition, it should be noted that measurement errors of AR are a function of positional variation during data acquisition [20]. Therefore, all AR was performed in the erect position in all cases at all times with the patient sitting in the same dental chair. The same dental chair was used by the same operator (MA) with patients sitting in it with a similar head position (Fig. 2).

Nasal resistance depends on the geometric and morphologic features of the nasal airway and on the airflow. In this study, we employed geometric morphometrics to demonstrate size and shape changes in the critical nasal valve (isthmus) region because, according to Poisseuille's equation, resistance to airflow is inversely proportional to the radius of the cylinder to the fourth power. This means that even a small size or shape change at this site will have large repercussions. Using PCA on normalized data, the results indicated that the appliance had a positive effect on nasal cavity morphology. In addition, the change in MCA in this region (between 2–4 cm) indicated an increase of about 25% using non-scaled data. Furthermore, the distribution of cross-sectional areas in the nasal cavity obtained using AR was reconstructed in 3-D [14] and quantified this increase localized at the critical nasal valve. Zheng et al. [21] demonstrated that AR can provide information on nasal physiology, pathophysiology, and diagnosis in adults, as well as for the assessment of therapeutic effectiveness. However, it is thought that the areas of the nasal airway cavity with highest resistance are located in an anterior position, where the differential nasal resistances are higher [22]. Moreover, Cakmak et al. [23] reported that AR is a valuable method for measuring changes in the nasal valve area. The results of the present study show that the use of an intra-oral nasal dilation appliance enhances the narrowest part of the nasopharyngeal airway by 13–14%. Given that resistance to flow is proportional to the radius to the fourth power, this enhancement likely represents a substantial improvement for the patient. However, while most of the patients volunteered a clinical improvement in symptoms, no subjective data was collected in the present study, and this observation remains as a premise for a further study in the future.

Nonetheless, while AR is a useful, objective tool, which correlates well with nasal obstruction, it is important to note that when the minimum cross-sectional area is $<0.2 \text{ cm}^2$, measurements beyond this site need to be considered with caution [24]. Indeed, Cankurtaran et al. [25] simulated nasal valve

morphology and suggested that AR does not provide reliable information posterior to a significant constriction, such as narrowing in the nasal valve area. Therefore, our results are taken from within 6 cm of the anterior nares, as Numminen et al. [26] suggest that the reliability of AR is very good in the anterior and middle parts of the nasal cavities, while evaluations based on the posterior regions are less accurate. Despite these constraints, we found a 27–28% improvement in the middle region of the nasal airway bilaterally with the use of a non-surgical, intra-oral, nasal dilation appliance. Nevertheless, it is important to note that the 3-D reconstructions represent mathematical modeling and not anatomical reconstructions, such as those obtained from CT scans.

Despite its limitations, AR is useful in the evaluation of nasal patency. For example, Yang et al. [27] used this technique to investigate patients with deviated nasal septum and surmised that AR can be used to determine reference sites for nasal surgery. Similarly, Ahmad and Gendeh [28] examined patients with nasal obstruction pre- and postoperatively where sinonasal surgery was indicated for correction of the abnormality and for post-operative evaluation. Indeed, several techniques are also available to determine the level of obstruction in snoring and obstructive sleep apnea (OSA) syndrome, including AR [29]. According to Morris et al. [10], the best candidates for nasal surgery for SDB may be non-overweight patients with nasal obstruction. Nevertheless, while the role of nasal obstruction in OSA is controversial [30], our current study provides evidence that the nasal obstruction associated with a spectrum of SDB, including moderate to severe OSA may be ameliorated using a non-surgical, intra-oral, nasal dilation appliance. The physiologic mechanisms of this improvement are not fully understood but may involve stretch receptors that induce some form of neuromuscular reflex. The response may also be due in part to nasal decongestion and/or vascular drainage. However, the changes reported represent only short-term observations, and it is not inconceivable that these may not be sustained in the long term. Therefore, future studies will investigate PSG outcomes with the use of the OASYS® device and evaluate the long-term consequences, if any, of the appliance.

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