Vertical dimension in dental sleep medicine oral appliance therapy

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The objective of this pilot study was to evaluate the effect of a multidimensional approach to occlusal registration, including vertical dimension as assessed using pharyngometry, on the success of oral appliance therapy. Successful medical improvements resulting from therapy were determined by secondary polysomnographic studies. Thirty patients were enrolled in this pilot study. Their initial apnea-hypopnea index (AHI) scores ranged from 6.0 (mild obstructive sleep apnea) to 81.6 (severe obstructive sleep apnea). Occlusal registrations were taken using pharyngometer readings to establish vertical and anteroposterior (AP) positions for each patient and compared to the AP-only position in the same patient, determined using a George Gauge at 70% protrusion. All follow-up sleep tests occurred 31-45 days after the delivery of oral appliances set at the multidimensional vertical and AP positions determined by pharyngometry. No appliance titration was required. In the 26 patients who completed the study, the mean AHI before therapy was 20.7, and the mean AHI after therapy was 7.8, a 62.3% decrease. Within the limitations of this study, the pharyngometer-established occlusal position was effective in lowering AHI without the need for appliance titration procedures, which are typically required when the 70% protrusive George Gauge occlusal registration method is used. Additionally, the position determined with the 70% George Gauge was, on average, 5.0 mm more protrusive than the pharyngometer registration.

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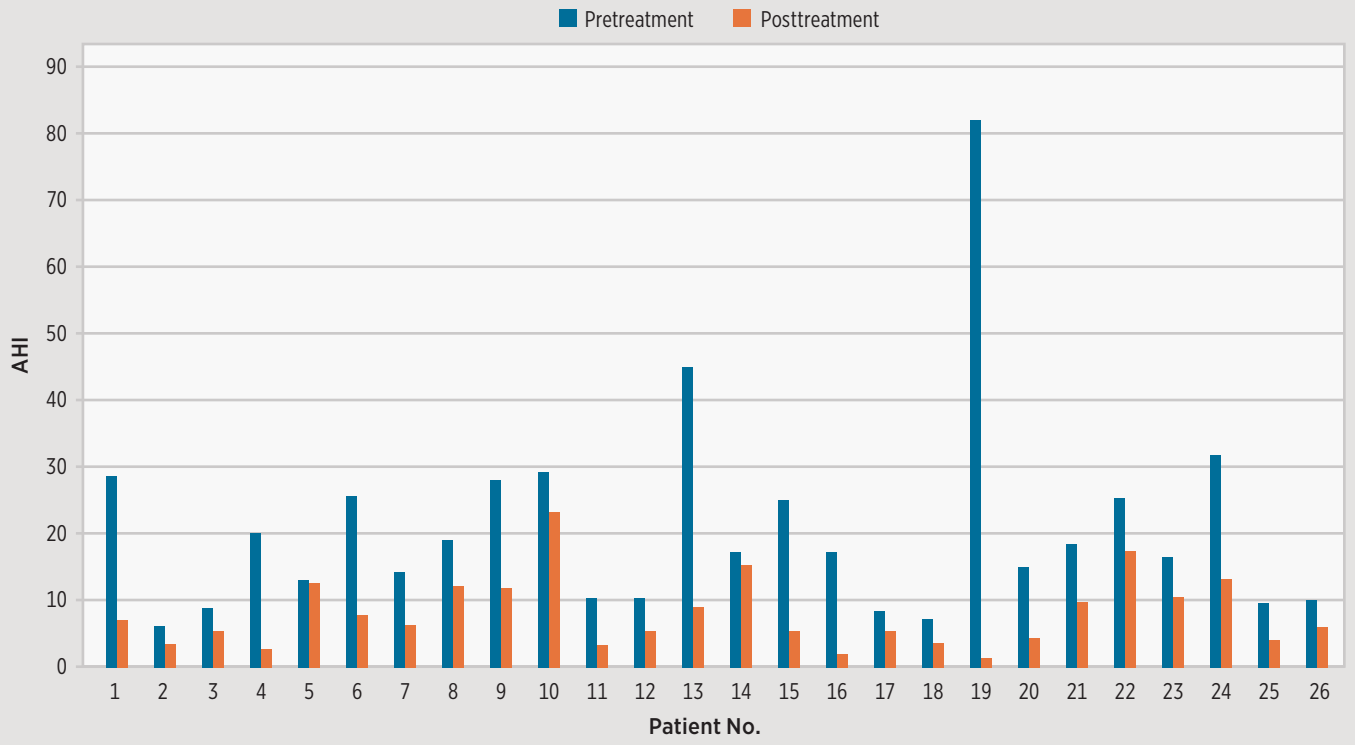
The highest level of care in dental sleep medicine would respect the phenotypic diversity of the human population, providing treatment based on the individual patient's unique anatomy and airway. It is undeniable that there is more than a single dimension to a patient's occlusion and airway. However, few studies address this issue. Most dental sleep medicine studies, to date, reach conclusions and make broad recommendations based on the response to oral appliances that were designed solely using the anteroposterior (AP) dimension.[1-3] A recent retrospective pilot study addressed vertical dimension in oral appliance therapy (OAT); however, there were limitations concerning the target therapeutic position, which involved incremental titration based on the patient's comfort.[4] The study lacked equipment and materials for the measurement of the vertical dimension.

Obtaining occlusal records at 70% protrusion (70% George Gauge, Great Lakes Dental Technologies) has been a standard in OAT fabrication, although 75% protrusion has also been used.[1-3] The subjectivity and variability of this AP dimension can lead to challenges in reliably achieving a therapeutic target position.

The use of pharyngometry may be a solution to establishing a therapeutic occlusal position for patients in need of OAT. Using the pharyngometer, a clinician can determine the changes in acoustic reflection on a cross section of a patient's airway, identifying excess or inadequate vertical dimension as well as jaw protrusion in millimeter increments.[5-9] Moreover, this therapeutic position can be repeated and retested in the patient to confirm the precise degree of vertical opening and protrusion.[5] The size of the airway measured on the pharyngometer changes with any change in occlusal position.[5-7,9-12] The instrument determines a precise target position unique to each patient, eliminating the need for oral appliance titration.

This pilot study aimed to evaluate the effect of using acoustic pharyngometry to add the vertical dimension to AP measurements for fabrication of oral appliances. The analysis was carried out as a consecutive case series and considered 2 relevant questions: (1) Would adding the vertical dimension to the target occlusal position change the definition of a "responder" to OAT compared to when the AP range is used alone?[13-15] (2) Would adding the vertical dimension allow for a less protruded position than the 70% George Gauge, and would that in turn lead to a faster endpoint by decreasing the number of appliance titration appointments? To answer these questions, patients' apnea-hypopnea index (AHI) and oxygen saturation (Spo_2 levels) were measured before and after OAT with appliances designed using both the vertical and AP dimensions, and these findings were compared to results reported in the literature for appliances designed using AP dimensions alone.

Chart 1. Apnea-hypopnea index (AHI) in patients treated with occlusal appliance therapy.



Materials and methods

A total of 30 patients scheduled in sequential order were enrolled in this study, and 26 (16 male and 10 female) were followed to the completion of the study, which evaluated AHI and Spo_2 levels before and after treatment with an OAT. The study excluded patients aged 65 years and older, and the enrolled patients ranged in age from 29-64 years. The body mass index of the patients ranged from 23.0 to 43.0.

The severity of obstructive sleep apnea (OSA) in the patient sample included mild, moderate, and severe forms. The OSA category is determined by the AHI, which is the total number of apnea-hypopnea events per number of hours sleeping, as determined by a sleep study. The present study used the following categories: AHI 5-15, mild OSA; AHI 15-30, moderate OSA; and AHI >30, severe OSA. Study participants in the severe OSA category had all previously demonstrated intolerance to continuous positive airway pressure therapy, and their board-certified sleep physician provided a prescription for them to have oral appliance therapy as an alternative therapeutic measure.

Each patient underwent the same type of sleep study pretreatment and posttreatment. That is, 24 patients who had a pretreatment at-home sleep study (Alice NightOne HST, Philips) had the same test for the follow-up study. Two patients underwent pretherapy and posttherapy nocturnal polysomnography in a sleep laboratory.

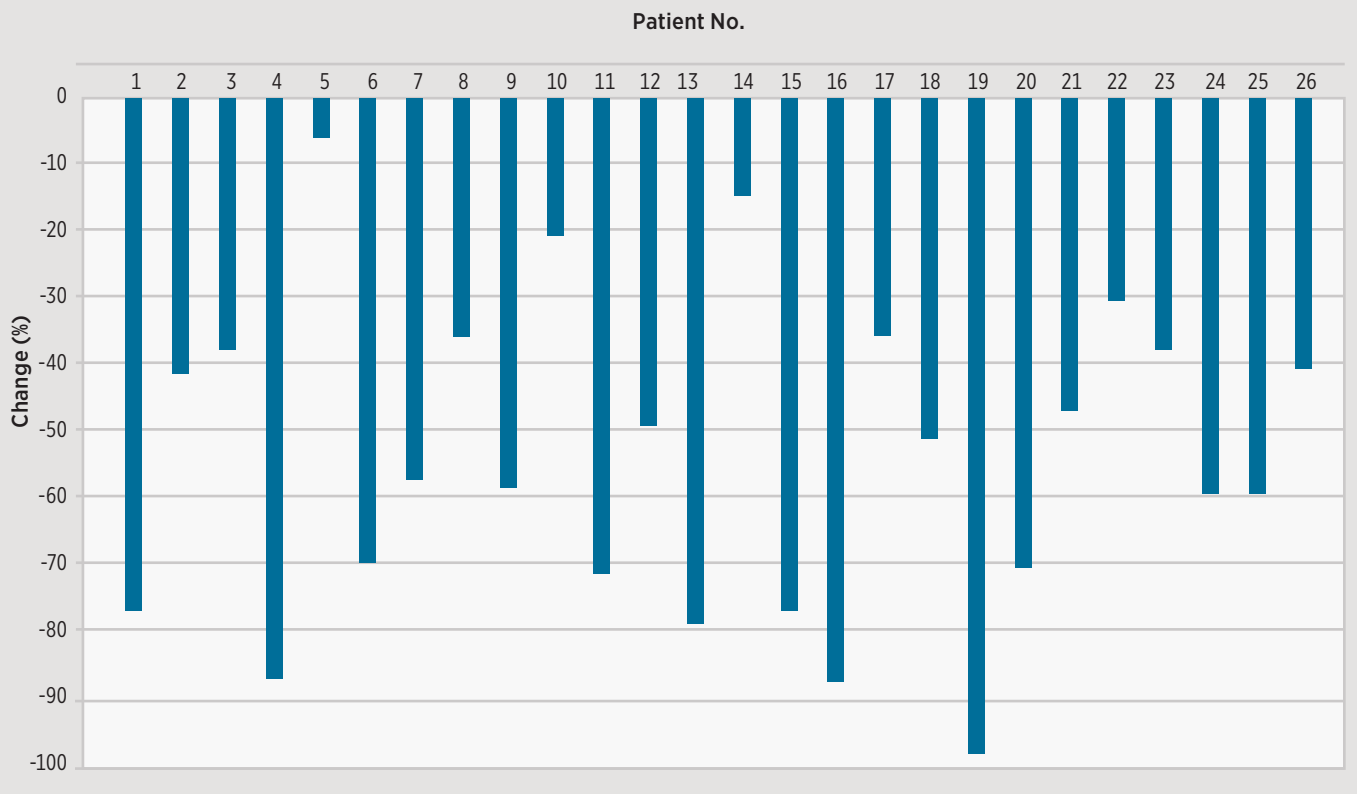
For the fabrication of oral appliances, the occlusal registration procedures followed a digital workflow.[2,16] The 3Shape Trios digital scanning system (Henry Schein) was used in this study. The occlusal registration process included pharyngometry (ECCOVISION, Sleep Group Solutions), the results of which were compared to the George Gauge occlusal registration method at 70% protrusion.[17,18]

George Gauge measurements at 70% of maximum protrusion were taken before pharyngometry. The George Gauge registration was performed with a 4-mm gray fork because this dimension has been identified as a commonly used tool.[19]

Several patients had a wide AP range of motion. From the most retruded position, the 70% position of the AP range was given a reference point, and that point was then recorded in millimeters, starting from the edge-to-edge position. If the actual 70% George Gauge measurement were used, that number would be higher than the number recorded for this study, because no patients in this study had an edge-to-edge (or even more anterior position) as their most retruded position. No patients with a Class III malocclusion or anterior crossbite were enrolled in this study. Therefore, the edge-to-edge position in these patients already included some degree of protrusion from their most retruded position.

All of the patients' pharyngometric occlusal registrations followed the same protocol. The optimal vertical position was found first, and then the AP position was determined. As the initial step, the patient's cross-sectional airway area in square centimeters was calculated from normal baseline breathing captured on the pharyngometer. The patient was then asked to perform a modified Mueller maneuver (inhale with nostrils plugged and mouth closed) to obtain the minimal and mean cross-sectional areas of the airway for comparison.[20,21] Airway Metrics vertical titration keys (Kettenbach) were then used to open the patient's mouth

Chart 2. Percentage change in apnea-hypopnea index from pretreatment to posttreatment.



vertically in millimeter increments, beginning with 4 mm; the same modified Mueller maneuver was performed, and the difference in the cross-sectional areas was compared. Every patient had an improvement of more than 100% in the minimal cross-sectional area after insertion of the Airway Metrics key.

The operator continued to increase the patient's vertical dimension via the use of vertical titration keys until there was no further improvement in the cross-sectional area. In other words, if a 10-mm vertical dimension provided a cross-sectional area that was the same as or less than that resulting from an 8-mm opening, the 8-mm measurement was used. The minimal vertical opening needed to achieve the optimal increase in cross-sectional airway area was identified as the final vertical position. After determination of the optimal vertical position, the operator attained the final AP position in the same manner, via assessment of the cross-sectional area at different protrusive positions, while maintaining the final vertical position on the keys.

Patients reported their subjective tolerance and comfort with the different positions obtained by using the pharyngometer and the George Gauge at 70% protrusion position. The patients had to report comfort and tolerance at their preferred position before the laboratory prescription was written and used for oral appliance fabrication.

All patients received the same type of controlled-cure polymethylmethacrylate milled oral appliance to reduce variability. A minimal 4-mm vertical thickness was used for the fabrication of all oral appliances to ensure creation of a stable, durable device. During delivery of the oral appliance, patients were once again asked to provide a subjective response to the same questions of tolerance and comfort. All patients in the study accepted the occlusal positions found with the pharyngometer. No patients required a change in the vertical or protrusive dimensions of the appliance, and no patients needed appliance titration.

All follow-up sleep tests occurred 31-45 days after delivery of the oral appliance. The resulting data were recorded and compared to pretreatment results. The oxygen saturation data were statistically analyzed with a binomial distribution model using a 2-tailed *P* value.

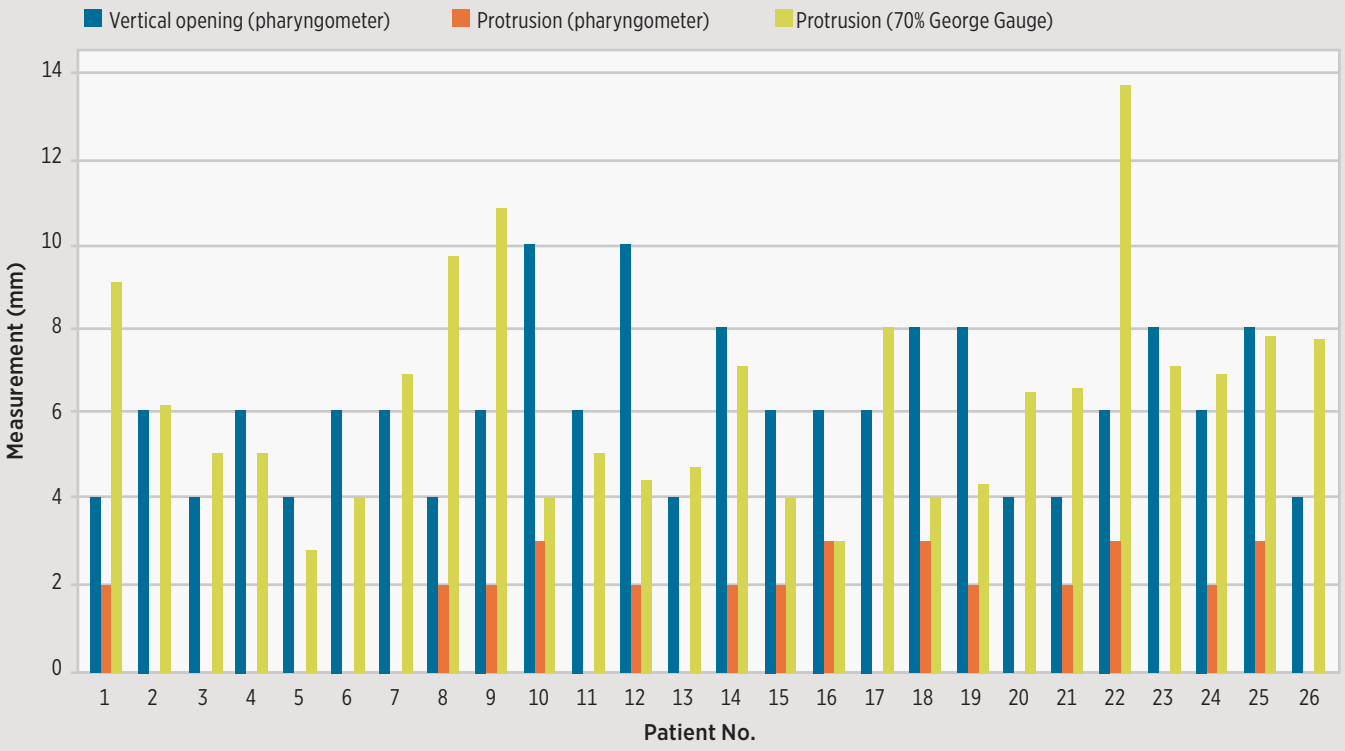
Results

The pretreatment AHI scores ranged from 6.0 (mild OSA) to 81.6 (severe OSA). Overall, 58% of patients had a diagnosis of at least moderate OSA. Seventy-seven percent of patients had a pretreatment AHI greater than 10. Chart 1 compares the pretreatment and posttreatment AHIs of every patient in the study. The mean pretreatment AHI was 20.7 (SD 15.2; range 6.0-81.6), and the mean posttreatment AHI was 7.8 (SD 5.1; range 1.0-22.8). That difference represented a 62.3% drop in mean AHI level after OAT. The results also showed that 30.8% of the patients had a posttreatment AHI of less than 5, and 69.2% had a posttreatment AHI of less than 10.

The percentage reduction in AHI in the patients ranged from 6.1% to 98.8% (Chart 2). The mean reduction in AHI was 54.2% (SD 23.3%).

The pharyngometer registrations indicated that the vertical opening of the 26 patients ranged from 4.0 to 10.0 mm. The

Chart 3. Comparison of protrusion recorded with the pharyngometer (in conjunction with vertical opening) vs 70% George Gauge.



Missing protrusion bars represent 0.0 mm of protrusion (anteroposterior position at the incisal edge).

mean vertical opening was 6.1 mm (SD 1.8 mm). Protrusions were measured from the incisal edge-to-edge position and not from the most retruded position; measurements from the latter position would be greater. When the pharyngometer was used for AP registration, the protrusion from beyond edge-to-edge position ranged from 0.0 to 3.0 mm (Chart 3). The protrusion recorded with the 70% George Gauge ranged from 2.8 to 13.4 mm beyond the edge-to-edge position.

For every patient, the AP position determined with the 70% George Gauge was greater than that determined with pharyngometer. For example, for patient 1, the target AP protrusion beyond the incisal edge was 8.9 mm according to the 70% George Gauge but only 2.0 mm according to the pharyngometer. For patient 2, the AP dimension protruded 6.1 mm beyond edge-to-edge position according to the 70% George Gauge but was exactly at the incisal edge according to the pharyngometer.

It is important to note that the 13.4-mm beyond edge-to-edge data point was recorded in a large man with substantial protrusive capability beyond 20.0 mm from edge to edge. The mean protrusion beyond the incisal edge was 1.3 mm (SD 1.3 mm) when occlusal registration was performed with the pharyngometer. When the George Gauge was used, the mean AP position was 6.3 mm (SD 2.4 mm) beyond the edge-to-edge position (in protrusion). Therefore, the target occlusal position of the 26 patients would have been protruded, on average, an extra 5.0 mm.

When vertical was the same on the George Gauge and pharyngometer bite, as with patient 13, the vertical was 4 mm on the pharyngometer bite which was also 4 mm on the George Gauge bite. For patient 13, occlusal registration with the pharyngometer provided a therapeutic target position that was substantially less protruded (0.0 mm, at the incisal edge) than that obtained with the George Gauge method (4.7 mm beyond edge-to-edge position).

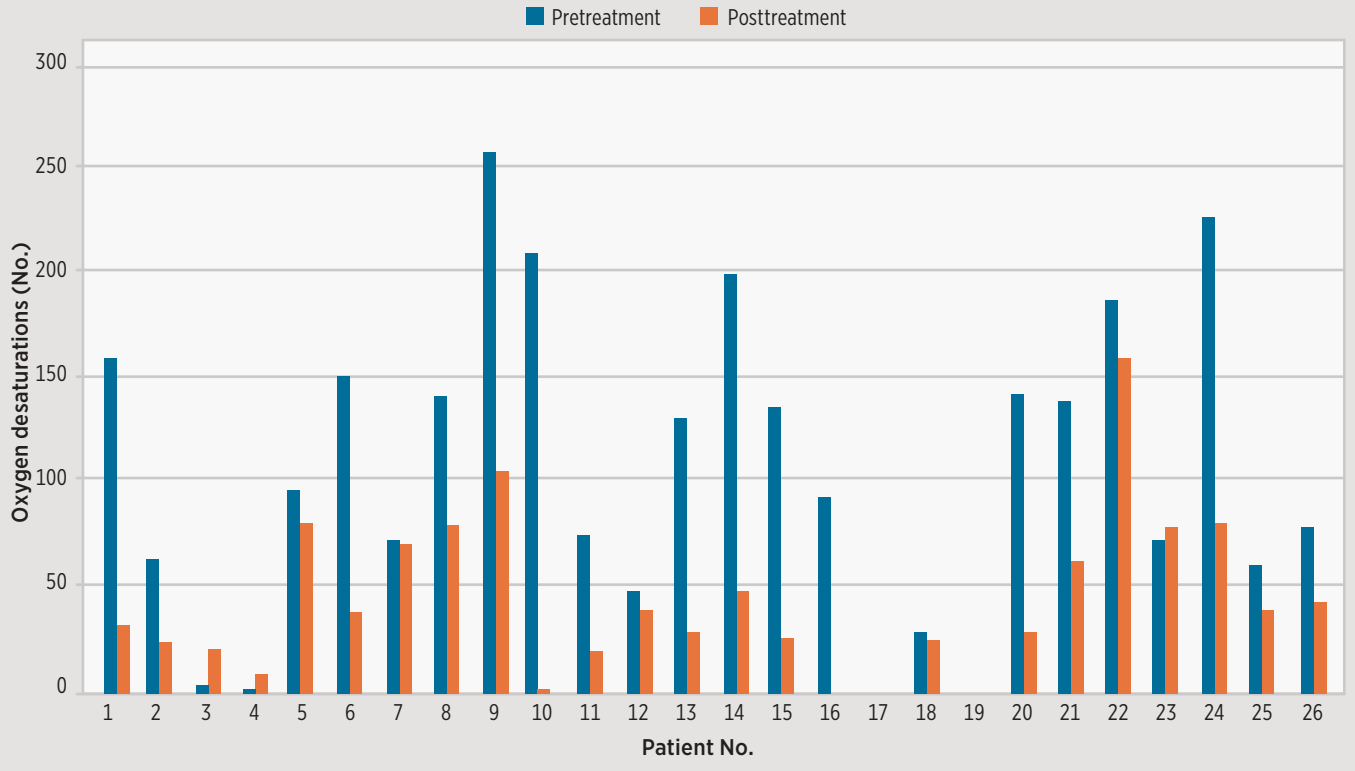
The pharyngometric AP positions established for patients in this study were an average of 36.7% (SD 14.4%) of their maximum protrusion, with a range of 17.0%-70.0%. Only 1 patient was at 70.0%. The majority of patients fell within a range of 20.0%-45.0% of their maximum protrusion when the vertical dimension was taken into consideration during pharyngometric occlusal registration.

The total number of desaturations during the entire night of the sleep test decreased when patients wore their OAT with the pharyngometer-established occlusal position (Chart 4). Two patients (17 and 19) experienced no oxygen desaturation episodes pretreatment, and that remained unchanged after OAT. In patient 16, oxygen desaturations decreased from 92 pretreatment to 0 posttreatment. Notably, in patient 10, the number of desaturations decreased from 206 pretreatment to 1 after OAT, but the improvement in AHI was minor (decrease from 28.8 to 22.8).

The mean number of pretreatment desaturations (decreases in Spo_2 levels from baseline) was 105.3 (SD 70.7), and the mean number of posttreatment desaturations was 43.6 (SD 36.2). This represented a 58.6% mean reduction of the number of desaturations in the 26 patients studied.

Analysis of the mean Spo_2 levels showed that there was no statistically significant difference ($P < 0.002$) in pretreatment and posttreatment values (Chart 5).

Chart 4. Number of overnight oxygen desaturations (decreases in Spo_2 levels from baseline).



Discussion

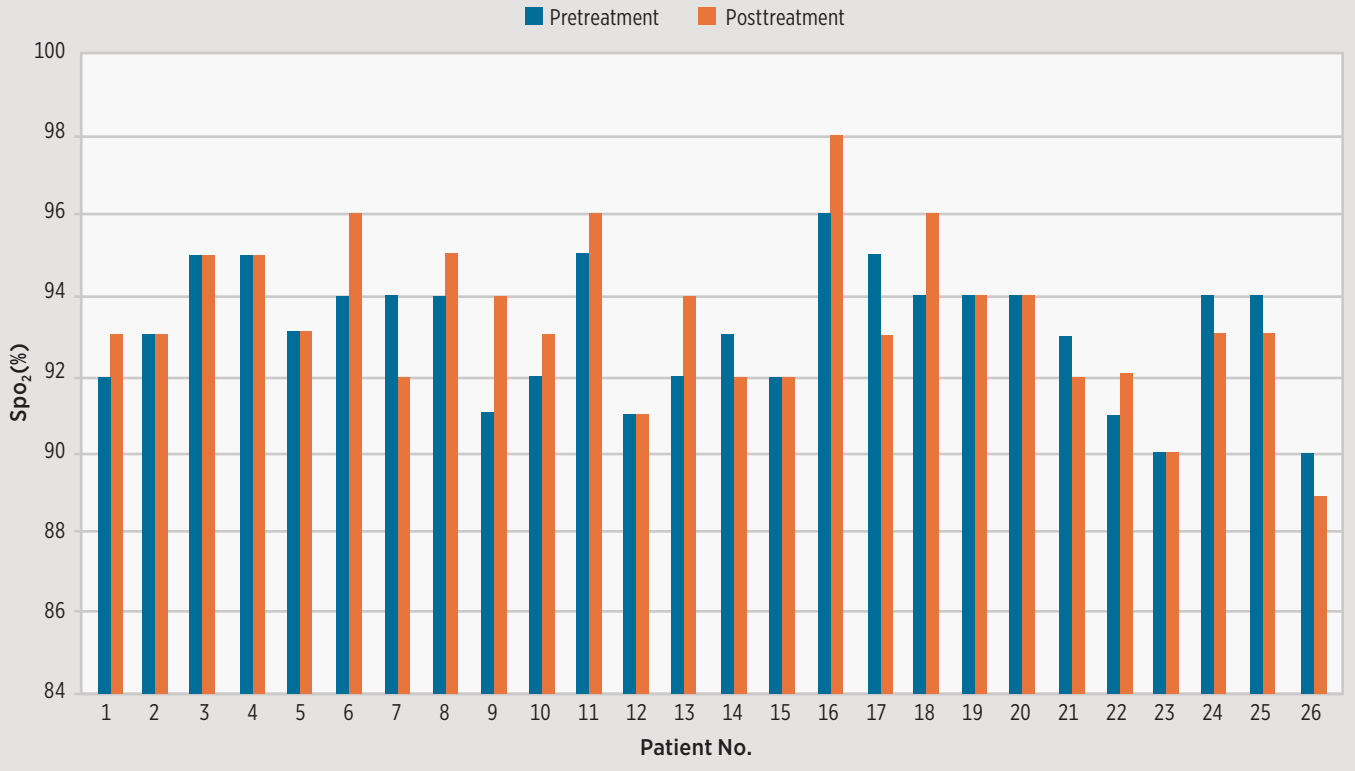
Pharyngometry uses sonar/acoustic technology to establish a cross section of the airway from the oral cavity to the hypopharynx.[5-7,22] Although the patient is not sleeping or in the supine position when this method is used to find an individualized occlusal position, the instrumentation effectively measures cross-sectional space in different positions of the upper airway. In an effort to simulate the collapsibility of the airway during sleep and while an apnea event takes place, the patient is asked to perform a modified Mueller maneuver during the occlusal targeting process.[20,21] Because the patient has a natural defense mechanism to protect the airway while awake, in the present study the Mueller maneuver was modified so that the patient was sitting upright and not in a supine position.[23-25]

The aim of this study was to shed more light into the role of vertical dimension in determining a therapeutic occlusal position in OAT for the treatment of obstructive sleep apnea. Current literature on the topic is limited. A review of oral appliance treatment methods for OSA cited some studies involving the vertical dimension.[26-28] Although these studies contributed to an understanding of the vertical dimension, they had limitations. For example, 1 study only used 2 arbitrary fixed vertical positions, 4 and 14 mm, to gauge the overall effectiveness of occlusal position in OAT.[28] The study raised several questions, such as why and how the 4- and 14-mm vertical openings were selected; whether a vertical opening of 14 mm is too great or 4 mm is too small; and whether the use of instrumentation such as a pharyngometer would provide a more precise ability to measure the collapsibility of a patient's airway at incremental vertical settings to compare potential efficacy and response.

In the present study, repeat sleep studies carried out after OAT revealed that patients had substantially lower AHIs after using an appliance designed using pharyngometric data. These posttreatment test results were obtained without titration of any of the oral appliances. The final positioning for each device was determined via the pharyngometric analysis. The mean reduction in AHI was similar to that achieved in studies where appliances were designed using a George Gauge.[1-3,23-25,29,30] However, in the earlier studies, multiple titrations of the oral appliance were required to achieve therapeutic success. Furthermore, the patients' long-term response to and tolerance for appliances titrated to 80%-100% of protrusion were not studied. Future studies aimed at determining long-term compliance and success are needed to determine the overall efficacy of these appliances.

The data from the present study suggest that using the pharyngometer to establish occlusal position is as effective in lowering AHI as using the George Gauge.[1-3,19,23-25,29,30] However, in the present study, all of the patients' bite registrations using the pharyngometer were taken with the same protocol: The optimal vertical position was found first and then the AP position was determined. The reverse order was not tested; thus, it is unknown if finding the optimal AP position before the optimal vertical position would change the final target occlusal position. Furthermore, since the optimal vertical position was found first, vertical positions greater or less than optimal were not tested in AP range increments.

Chart 5. Mean oxygen saturation levels (Spo_2) of each patient during sleep studies.



Recently, Bamagoos et al concluded, "Mandibular advancement reduces pharyngeal collapsibility in a dose-dependent manner… This indicates that the primary mode of [mandibular advancement splint] therapy is via improvement of passive pharyngeal anatomy."[31] Since the present study suggested that degree of protrusion needed to achieve a desirable outcome can be modified by incorporating the vertical dimension, this approach has the potential to reduce adverse effects associated with a higher degree of protrusion.[16,24,25,32] For patient 13, occlusal registration with the pharyngometer provided a therapeutic target position that was substantially less protruded (0.0 mm) than that obtained with the George Gauge method (4.7 mm). This unnecessary protrusion of 4.7 mm beyond the edge-to-edge position could place the patient at a higher risk for side effects and discomfort.[17] Fransson et al found that the George Gauge overestimates patients' maximum range of protrusion.[33]

Further studies using the same oral appliance designed at 2 different protrusions are needed to compare the outcomes of different occlusal positions. All the patients in the present study were asked if the pharyngometric occlusal position was comfortable; they all affirmed that they were able to accept that position comfortably. More studies must be undertaken to determine if fewer appointments are required when this occlusal registration method is used. In addition, studies are needed to gauge if fewer appointments equate to more confidence in and compliance with OAT from the patient's perspective.[1,24,25]

With pharyngometer-derived OAT, the patients did not experience a statistically significant difference in mean overnight Spo_2 levels. However, the number of desaturations was substantially different, and the number of hypopneas and microarousals (AHIs) decreased substantially.

Knowledge of occlusion and dental gnathology dictates that there are at least 6 dimensions to an individual's bite and trajectory: AP, lateral, vertical, pitch, roll, and yaw. There is no consensus in dental sleep medicine on clinical protocols centered around these factors, let alone their impact on OAT and therapeutic outcomes. Milano et al used elastics to limit vertical opening and found that the technique had a positive influence on treatment success of OAT for positional OSA.[1] However, this approach does not respect the notion that there is a precise target position unique to a patient's anatomy and soft tissues that will provide an optimal outcome achieved without appliance titration.

A specified vertical position related to proper airflow optimization is essential and should be maintained. In a recent study, Martinot et al discussed the importance of the absence of variable vertical movements during sleep.[17] They concluded that "the reduction of vertical respiratory mandibular movements estimated by [vertical mandibular movement respiratory effort index] and sleep respiratory effort duration accompanied the decrease in obstructive hypopneas, apneas, and [oxygen desaturation index]…."[17] These studies indicate that using elastics to maintain a targeted vertical position during sleep have benefits for the patient.[4,17] By extrapolation, it seems that using a pharyngometer and Airway Metrics keys to find a therapeutic occlusal position that provides the optimal improvement in the cross-sectional size of the airway—and then having the patient stabilize the position with elastics during use—could provide substantial treatment benefits.

Doff et al documented that 2 years' use of an adjustable oral appliance to treat OSA caused small, statistically significant dental changes.[32] They noted that a decrease in overbite was significantly associated with the mean mandibular protrusion, suggesting that this type of tooth movement could be minimized by decreasing the amount of advancement.[16,24,25,32]

It is possible that more protrusion leads to greater adverse effects, including muscle strain and temporomandibular joint discomfort.[24,25,32] The long-term compliance of patients, or lack thereof, may also be related to adverse effects of extended protrusion in OAT. On the other hand, insufficient initial protrusion creates the need for successive appliance titrations and multiple appointments to obtain efficacious opening of the airway. Achieving a targeted therapeutic endpoint with the minimum number of appointments may not only build the patient's confidence in treatment but also create better compliance and comfort by lowering the number of potential adverse effects.[24,25]

The definition of a nonresponder to OAT is not clear. Is it related to having at least a 50% reduction of AHI or solely an AHI under 10? Moreover, will that definition change if vertical opening is taken into account? Will adding the vertical dimension allow for a less protruded position, reducing the need for appliance titration?[19,24,25,31,32] Could those identified as nonresponders when a single dimension (AP) is studied become responders when additional dimensions, such as vertical opening, are assessed?[13-15]

The data obtained from the patients in the present study can be used to answer the initial research questions. First, would adding the vertical dimension to the target occlusal position change the definition of a responder to OAT compared to when the AP range is used alone?[13-15] The data indicate that this can occur, but further studies are needed. Second, would adding the vertical dimension allow for a less protruded position than the 70% George Gauge and would that, in turn, lead to a faster endpoint by decreasing the number of appliance titration appointments? For the patients in this study, adding the vertical opening to the occlusal appliance resulted in substantially smaller AP protrusion than was recommended by the George Gauge measurements, and a therapeutic endpoint was achieved without the need for any titration appointments. Long-term follow-up is needed to confirm the efficacy of this approach.

Conclusion

Within the limitations of this study, the results suggest that using the pharyngometer instrumentation and evaluating the optimal vertical dimension during occlusal registration allows for a less protruded position and leads to fewer titration appointments than measurement of 70% protrusion on the George Gauge. They also suggest that there is a benefit to adding vertical dimension assessments in the creation of oral sleep appliances. The occlusal appliances designed utilizing the pharyngometer resulted in improved medical outcomes without the need for titration in any patient in this study.

The use of the pharyngometer was essential in addressing the patient's unique anatomy, physiology, and airway characteristics and rendered unique treatment for each patient. Using the pharyngometer instrumentation can aid in the search for targeted therapeutic occlusal position for every patient. Among the patients in this study, the mean protrusion from the most retruded position was 36.7% when assessed with the pharyngometer in both the AP and vertical dimensions, almost half of the protrusion calculated with the 70% George Gauge. Future studies are needed to determine if the addition of vertical assessments is correlated to a decrease in adverse effects, an increase in compliance, and a long-term increase in successful treatment outcomes.

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Disclosures

Dr Hu is an instructor for Sleep Group Solutions and Modern Dental Group and has received honoraria for lectures from both organizations. He is an integrated clinical advisor for Vivos Therapeutics and has received honoraria from the company. He has also lectured for ProSomnus Sleep Technologies without receiving honoraria. Dr Comisi is an instructor for Sleep Group Solutions and has received honoraria for presentations. Neither author received any financial support of any kind for this study from any company.

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