Title

Comparing anterior protrusive and speech-positioned mandibular positioning techniques for adult dental sleep appliances – a pilot crossover randomized controlled trial

Authors:

Enoch T Ng DDS[1]*; Manuel O Lagravère DDS, MSc, PhD[1]; Carlos Flores-Mir MSc, PhD[1]; Ivonne A Hernandez MSc[1]; Dr. Pedro Mayoral MSc, PhD[2]; Arnaldo Perez-Garcia MSc, PhD[1]

[1] School of Dentistry, Faculty of Medicine and Dentistry, University of Alberta, 11405-87 Avenue, Edmonton, Alberta, Canada T6G 1C9.

[2] University Católica de Murcia UCAM, Faculty of Medicine and Dentistry, School of Dentistry, Madrid, Spain

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Abstract

Objective

This study aimed to determine the feasibility and potential efficacy of the speech positioning technique (SPT) vs the anterior protrusive technique (APT) in oral appliance therapy (OAT) in a crossover randomized controlled trial (RCT).

Methods

A pilot trial was conducted with participants randomized to complete OAT with either the SPT or APT before a washout period then crossover assignment to complete OAT with the alternative mandibular positioning technique. Feasibility data was collected through administrative tracking, patient and clinicians' feedback. Efficacy data was collected through home sleep testing, measurements of mandibular position using dental landmarks, reported occurrence of side effects, differences in sleep quality and patient experience measured through validated questionnaires.

Results

Eight patients participated in this pilot trial. Recruitment rate was 23.91% and attrition rate was 27.27%. One patient was a non-responder to OAT with both techniques, one was a responder to the SPT but not the APT, and one was a responder to the APT but not the SPT. Average mandibular protrusion for the SPT was 48.82% and 63.37% for the APT. Side effects were reported by several patients in OAT with the positioning techniques. No significant differences in sleep quality and patient experience were reported between the APT and SPT.

Conclusion

Conducting a crossover RCT comparing SPT and APT is feasible. Pilot trial data suggests the SPT may provide an alternative therapeutic position to the APT for mandibular positioning in OAT. A properly

sampled RCT is necessary to further assess the observed efficacy of the SPT in mandibular target position.

Clinical Implication

The use of a speech positioning technique to determine mandibular position in oral appliance therapy for patients with obstructive sleep apnea may provide patients with an alternative target mandibular position for therapeutic benefit with less mandibular protrusion and decreased risk of side effects.

Keywords

Oral appliance therapy, obstructive sleep apnea, dental sleep medicine

Introduction

Obstructive sleep apnea (OSA) is a medical condition defined by upper airway obstruction during sleep, resulting in oxygen desaturation and cortical arousal disruption to normal sleep architecture.[1-3] It is estimated that over 15% of the global population suffers from OSA.[4] Direct, indirect, and healthcare-related costs exceed $150 billion annually in the United States alone.[5,6] OSA is associated with multiple medical conditions, including cardiovascular disease, cerebrovascular disease, obesity, renal diseases, psychiatric disorders, type 2 diabetes, asthma, COPD, and cancer.[7-11] Specific to males, OSA is well correlated with an increased risk for erectile dysfunction and an increased risk for all-cause mortality, especially within the middle age range of 40-65 years of age.[12-18]

The primary treatments for adult obstructive sleep apnea are positive airway pressure therapy (PAP) and oral appliance therapy (OAT).[19,20] PAP therapy consists of a machine delivering positive air pressure from a mask connected to the machine through a hose to maintain upper airway patency by creating a pneumatic splint within the upper airway through the entire respiratory cycle.[21-24] OAT devices consist of custom-fit upper and lower dental appliances that can be adjusted to each other and that anchor off the patient's teeth.[19,25] Many variations of the OAT exist with differences primarily in material, manufacture, device design, and adjustment methods. While both treatments have similar effectiveness, greater adherence has been observed in patients treated with oral appliance therapy.[26]

Oral appliance therapy involves the fabrication, delivery, adjustment, and regular patient follow-up for a custom-fit adjustable dental appliance designed to hold the mandible in a specific position to the maxillary complex to improve and maintain a patient's airway patency.[19,25] Appliances are generally anchored to teeth on both the maxilla and mandible with adjustments to mandibular position available through different coupling mechanisms. Adjustments are primarily made to improve patient airway patency with the goal of reaching a therapeutic position, a mandibular position where OSA is fully managed for the individual patient.[27-34] The predominant mandibular positioning and titration method in

OAT is through the anterior protrusive technique. The mandible is placed in a protrusive position relative to its maximum anterior and posterior positional range, with mandibular position traditionally determined as between 50-75% of maximum mandibular protrusion.[35-39] If necessary, titration adjustments are done to protrude the mandible further. Recent research, however, has shown that this degree of mandibular protrusion may not be necessary and as little as 25% protrusion may be sufficient for select patients.[40,41] While the anterior protrusive technique parameters have been well-studied and well-documented for adult oral appliance therapy, common side effects include temporomandibular dysfunction, muscle pain, and occlusal changes.[19,42-47] The risk for and occurrence of these side effects can significantly impact patient experience, quality of life, and treatment adherence.[48-51] Exploring and testing alternative mandibular positioning techniques for oral appliance therapy is necessary to explore the potential for alternative therapeutic positions, improve position accuracy, reduce side effects, and enhance patient adherence.

Since the 1970s, dentistry has used phonetics to obtain and verify a muscularly stable and reproducible mandibular position.[52] This technique is known as the sibilant phoneme or speech positioning technique (SPT). In denture prosthodontics, the SPT is used to identify and verify the phonetic neutral zone, a zone in which the placement of denture teeth allows for oropharyngeal muscular stability and, thereby, denture retention and functional stability.[53-55] More recently, the SPT has been advocated as an alternative technique for mandibular positioning compared to the anterior protrusive technique, which predominates within oral appliance therapy.[56-58] Previous research supports the potential effect of holding the mandibular position to achieve muscular stability in denture retention obtained through the SPT, which translates to oropharyngeal muscular stability in OAT during sleep.[56,57] However, until recently, significant variations existed between experts and their opinions on appropriately adapting the SPT for use in OAT. A recent manuscript has laid out a consensus-based process for using SPT in dental sleep medicine, including in OAT.[59]

The purpose of this study is twofold: to explore the feasibility of a full-scale crossover randomized controlled trial (RCT) comparing APT and SPT and to gather preliminary data on the efficacy of SPT as an alternative mandibular positioning technique to the APT in adult OAT in a clinical setting. Assessing feasibility would be instrumental in determining the logistical details for running an RCT. Gathering preliminary efficacy data will aid in assessing the need to further demonstrate the efficacy of SPT through a more robust research design.

Materials and Methods

Study Design

A pilot trial design was selected to assess the feasibility of a crossover RCT and to generate preliminary efficacy data for SPT. This design is useful for assessing the feasibility of a planned RCT and the potential efficacy of the exposure of interest by conducting the future study, or part of it, on a smaller scale.[60] Factors of interest in pilot studies can include patient recruitment date, patient attrition rate, patient response to specific measurements or data collection processes (such as surveys and questionnaires), and additional data points of interest that can be measured in an RCT.[61,62] Alberta Research Information Services: Human Research Ethics Board approved the study (Pro00097563).

Patient Recruitment Criteria

Patients were eligible for the pilot trial if they were diagnosed with moderate or severe obstructive sleep apnea by a physician and qualified as a candidate for oral appliance therapy based on the American Academy of Sleep Medicine (AASM) and American Academy of Dental Sleep Medicine (AADSM) treatment guidelines. All patients were screened for obstructive sleep apnea and tested with a level 3 ambulatory polysomnography (Medibyte Home Sleep Test, Braebon Medical Corp.). Sleep tests were sent to a sleep specialist physician for formal interpretation and diagnosis. Participants were recruited from a single private practice dental clinic in Edmonton. Patients with active temporomandibular degenerative joint disease, known craniofacial, syndromic, or neuromuscular

disorders, or uncontrolled/untreated co-morbid conditions such as cardiovascular, cerebrovascular, metabolic, and renal diseases were excluded from the pilot trial. Due to technical factors such as the minimum space necessary to fit an intraoral scanner head for digital impressions, patients with a maximum mandibular opening of less than 20mm were also excluded from participating in the pilot trial. A sample size of N=8 was estimated based on previously published dental sleep medicine pilot studies of similar interventional style.[63,64]

Research Protocol

This protocol applies to both the pilot trial and the planned cross-over RCT, as the pilot replicates the actual trial on a smaller scale. Following AASM and AADSM treatment guidelines, patients were given custom-fit titratable dental sleep appliances. For the study, the definition of successful treatment for OSA was an apnea-hypopnea index (AHI) reduction of at least 50% and fewer than 10 events per hour. All appliances were of the same make and model type, manufactured by the same lab, and patients were blinded to which appliance treatment (anterior protrusive or speech positioning technique) they received.

Participants were assigned to either the SPT first or APT first group based on computer-generated randomization for an equal distribution of 8 patients between the two groups. Allocation concealment was achieved with enrolled participants assigned to their group before the treating clinician was made aware of which appliance to provide the patient with. Dropout replacements were enrolled after all original 8 randomizations were assigned.

All appliances were printed nylon-based bilateral traction appliances fabricated by Diamond Orthotic Laboratory. Appliances were titratable in 1mm increments both for anterior and vertical adjustments. All patients started at the same overjet position based on the initial overjet obtained from the SPT occlusal registration. This was to provide a personalized initial mandibular protrusion percentage for

each patient, similar to the protrusion percentage for the patient in SPT, rather than a set percentage equivalent across all patients. This would then allow for a more accurate intra-patient comparison of mandibular protrusion percentages between the two techniques. Vertical opening for APT appliances was set at 5mm based on the 5mm George Gauge bite fork used for APT occlusal registration. The vertical opening for SPT appliances was determined to be 4.5mm based on the minimum material thickness necessary for nylon-printed appliances. (Figure 1)

Patients underwent treatment according to standard AADSM treatment recommendations, with the clinician tracking progress and management of the patient's OSA, including with home sleep apnea testing, until resolution or failure following AASM treatment parameters within a maximum time of 3 months. After treatment, post-treatment records included a repeat of the pre-treatment questionnaires, confirmation efficacy home sleep apnea testing, patient musculature (masseter, temporalis, TMJ lateral capsule, TMJ posterior joint space, and sternocleidomastoid) by palpation evaluation, and measurement of the patient's percentage of mandibular protrusion to maximum mandibular protrusion and retrusion. Patients then underwent a one-week washout period, wearing no appliance before repeating the process, starting with new pre-treatment records (excluding cone beam computed tomography based on radiation exposure guidelines). After completion of new pre-treatment records, patients were then crossed over to treatment with the other appliance (patients provided with the appliance for adjustments with the APT first were provided with the appliance for adjustments with the SPT, while patients provided with the appliance for adjustments with the SPT first were provided with the appliance for adjustments with the APT). Treatment was again repeated similarly under the same criteria. (Figure 1)

Data Collection

Feasibility involved an assessment of the practicality and viability of conducting the full-scale RCT with crossover design. Indicators of this feasibility included participant recruitment, participant retention,

intervention delivery, and duration of data collection. Data on these indicators were collected through research administrative tracking and clinician feedback. Attrition (dropout) data was collected according to the standard clinical protocol for patient care; administrators contacted the patient to reschedule canceled appointments and recorded the reasoning for the patients not rescheduling their appointments. The initial efficacy data for the pilot trial included reductions in disease index as assessed through home sleep testing, measurements of mandibular position using dental landmarks, the occurrence of side effects, and differences in sleep quality and patient experience.

Initial efficacy data for the pilot trial included disease index reduction data collected through home sleep testing, physician measurements of mandibular position using dental landmarks, occurrence of side effects, and differences in sleep quality and patient experience. These are outlined in Table 1. Aside from ambulatory polysomnographic data (AHI, RDI, ODI, etc.) and general dental sleep appliance data (amount of titration, appliance adjustments, signs and symptoms of pre-existing TMJ dysfunction and any changes to those conditions, etc.), other data collected included demographic data (age, ethnicity, sex), medical history (including current medications, allergies, supplements, herbals, and complementary medicine therapies), large field of view cone-beam computed tomography (Rayscan S CBCT, Rayscan Canada Ltd.), digital dental impressions (CS3800, Carestream Health Onex Corp.), and questionnaires on sleep quality and quality of life including Sleep Apnea Quality of Life questionnaire, Epworth Sleep Scale, Berlin Questionnaire, STOPBANG questionnaire, and patient experience with oral appliance therapy. Questionnaires were provided for patients to complete remotely prior to attending clinic appointment times. All patients were provided with the oral appliance therapy patient experience questionnaire after completion of each round of treatment.

Comparative Analyses

Pilot crossover RCT trial data was analyzed using descriptive statistics to generate averages, maximums, minimums, standard deviation, and standard error and to describe differences in patient responses. A

paired t-test assuming unequal variances was used to compare groups due to the inability to assume equal variances between groups (for example, between SPT and APT mandibular positioning variables). As a pilot trial, all statistical results were for descriptive purposes and not for statistical significance due to limitations in sample size.

Results

Patient demographics

Eight patients between the ages of 34 and 71, with an average age of 57 (SE +/- 4.92), completed the study. Patients were recruited between March of 2021 and April of 2023. Two patients were male, and six were female. Half were of Asian ethnicity, and half were of Caucasian ethnicity based on last name and physical appearance. Three patients had previously trialed PAP and were PAP intolerant; the other five were PAP averse. Medical conditions of participants included anxiety, depression, attention deficit hyperactivity disorder, type 2 diabetes, hypertension, high cholesterol, thyroid dysfunction, insomnia, migraines, headaches, fibromyalgia, chronic pain, gastroesophageal reflux disease, and eczema. No patient reported changes to their medical conditions or medications throughout the pilot trial. The weight of participants ranged from 100 lbs to 280 lbs, with an average weight of 163 lbs (SE +/- 19.28). Participants' body mass index ranged from 19.53 to 39.05, with an average BMI of 27.64 (SE +/- 2.59). Specific per-patient demographic data details are provided in Table 2.

Study feasibility data

A total of 46 patients were eligible to participate in the study. A total of 11 patients were recruited to participate in the study for a recruitment rate of 23.91%. Reasons for non-participation included no direct benefit to the patient, extended time of treatment as a research participant, and travel distance to the clinic. A total of 8 patients completed participation in the study for an attrition rate of 27.27%. The reasons for dropping out were illness for two patients and travel distance for one patient.

Patient examination and records for data collection were not longer than non-research data collection clinical time. Normal clinical time allotted for examination and records was 2 hours; no research patient required more than an additional 15 minutes for data collection. Adjustments of appliances in both the SPT and APT took less than 5 minutes.

Changes in sleep indices measurements

Pre-treatment AHI was 21.35 (SE +/- of 1.79) for the APT group and 24.63 (SE +/- 3.48) for the SPT group. Post-treatment AHI was 8.90 (SE +/- 1.69) for the APT group and 9.95 (SE +/- 2.23) for the SPT group. Change in AHI was 12.45 (SE +/- 2.12) for the APT group and 14.68 (SE +/- 2.99) for the SPT group. Results for RDI and ODI were similar to AHI in terms of reduction between groups. Details of sleep indices measurements are summarized in Table 3.

Of the eight patients, one was a non-responder to OAT, and six were complete responders to both mandibular positioning techniques. One patient was a responder to OAT in the AP technique but not in the SP technique, and one was a responder to OAT in the SP technique but not in the AP technique. Statistically, there were no significant inter-group differences between pre-treatment, post-treatment, or change in disease index numbers. Both groups noted significant changes between their intra-group pre-treatment and post-treatment disease index numbers, with significantly lower disease index numbers noted post-treatment than pre-treatment. Details of sleep disease indices are summarized in Table 3.

Changes in mandibular position (Figure 2)

All patient average habitual occlusion overjet was 3.25 (SE +/- 0.49). The average habitual occlusion overbite was 2.13 (SE +/- 0.55).

For the speech positioning technique, the initial inter-occlusal distance was determined as 4.5mm of inter-incisal space based on the minimum material thickness required for structural integrity for the dental sleep appliances. For the anterior protrusive technique, the initial inter-occlusal distance was

determined as 5mm of inter-incisal space based on the 5mm height of the George Gauge bite fork. The average initial overjet for the SPT was 0.4mm (SE +/- 0.74). The initial overjet position for the SPT was used as the initial overjet position for the APT on a per-patient basis to ensure similar starting protrusion for appropriate comparison. Between the two techniques, the SPT averaged 0.75 fewer titrations, 1.87mm less protrusion, and 14.55% less protrusion. Details of the mandibular position are summarized in Table 4.

Exploratory statistics for the pilot sample (N=8) noted significant differences between groups in end overjet position ($p < 0.05$). However, no significant differences in change in overjet, % protrusion, between end overbite position, change in an overbite, or number of adjustments/titrations were noted ($p > 0.05$). These statistical differences did not change in subgroup analysis, having removed the single non-responder patient to both positioning techniques (N=7).

Side effects

The pilot crossover RCT data showed that no patients free from TMJ symptoms before OAT developed TMJ symptoms during OAT. Three patients reported discomfort/pain to palpation of orofacial musculature pre-treatment. All three patients with pre-existing TMJ symptoms (myalgia, limitations of mandibular range of motion) did not fare significantly differently between both mandibular titration techniques. One patient with pre-existing bilateral wrist pain reported worsening wrist pain with the appliance in APT while reporting resolution of wrist pain with the appliance in SPT. The same patient also reported increased jaw clicking when using either dental sleep appliance. One patient experienced changes to occlusion during OAT under both mandibular positioning techniques, which was verified as a change in resting mandibular position as opposed to tooth movement from intraoral scan image overlays. One patient experienced an exacerbation of her tinnitus during OAT with the APT for mandibular positioning and no difference to her tinnitus during OAT with the SPT for mandibular positioning. Two patients reported generally requiring time to adapt to the dental sleep appliance. One

patient reported discomfort on inserting and removing the appliance but no concerns with appliance fit. Side effects were generally transient and were primarily dealt with through morning exercises and manual therapy (self-administered massage). Both patients who reported symptomology with one appliance over the other self-selected long-term use of the other appliance after completion of their participation in the pilot trial.

Sleep quality

Across all patients, the average pre-treatment Epworth Sleepiness Scale (ESS) score was 9.13 (SE +/- 1.04), the average Fatigue Severity Scale (FSS) score was 35.94 (SE +/- 3.89), and the average NTSE score was 7.38 (SE +/- 1.18). Exploratory statistics noted no significant differences between groups and before and after treatment for both groups. Details of sleep questionnaires are summarized in Table 5.

Patient experience

Five patients completed the patient experience questionnaires. Two patients declined to complete the patient experience questionnaire. Patients did not provide reasoning for non-completion. One patient partially completed the questionnaire and declined to complete it on prompting. The reasoning provided was the questionnaire was redundant. Four patients reported no preference differences between the two titration techniques, with one patient reporting a preference for the appliance positioned and adjusted in SPT. The reason for preference was due to fewer office visits (a single adjustment was necessary for the APT, while no adjustments were necessary for the SPT for this patient). There were no significant differences in the other dimensions of care delivery or symptom improvement. Patient experience data is summarized in Table 6.

Additional select patient information

Additional information post-treatment was collected on three patients: the patient who was a complete non-responder to OAT for both the APT and SPT and both patients who were responsive to OAT in one of the APT or SPT but not the other.

In an examination of the patient with complete non-response to OAT, a posterior tongue tie (Grade 3 TRMR), lip seal strength of less than 4 lbs, and a first maxillary molar intermolar distance of 34mm were noted. From previously gathered data the patient had a neck circumference of 16.5 inches, a waist circumference of 39 inches, and a BMI of 31.09.

In examination of the patient who was responsive to OAT in APT but non-responsive to OAT in SPT, a normal range of tongue movement (Grade 2 TRMR), lip seal strength of less than 3lbs, and a first maxillary molar intermolar distance of 32mm were noted. From previously gathered data, the patient had a neck circumference of 14 inches, a waist circumference of 30 inches, and a BMI of 28.16.

In examination of the patient who was responsive to OAT in SPT but non-responsive to OAT in APT a normal range of tongue movement (Grade 2 TRMR), lip seal strength of less than 4lbs, and a first maxillary molar intermolar distance of 31mm were noted. From previously gathered data, the patient had a neck circumference of 14.5 inches, a waist circumference of 39.5 inches, and a BMI of 36.33.

Discussion

This pilot trial aimed to assess the feasibility of a crossover RCT design comparing SPT and APT and to generate preliminary efficacy data for SPT. This pilot trial suggests that the planned RCT is feasible, with a dropout rate less than generally accepted attrition rates of up to 35% in dental clinical trials.[65-72] While the recruitment time for the pilot trial was approximately two years, the patient recruitment rate was 23.91%, with a total of 11 patients recruited out of 46 qualified patients in the private practice clinic. The recruitment rate suggests that a dedicated dental sleep medicine clinic can recruit patients within a smaller time window. However, this should be viewed with some caution due to potential differences between patient-clinician relationships in private practice general dental clinics and dental sleep medicine specialty clinics. The attrition rate in the pilot trial may be attributed to the challenges associated with the specific population being studied, public health guidelines related to COVID-19 and

other respiratory infections in the local geographic area (Edmonton, Alberta), and the difficulties with randomized crossover trials for exploring novel techniques/interventions. Preliminary efficacy data suggest more positive outcomes of SPT compared to APT regarding mandibular position and side effects, which may be of clinical relevance. Altogether, these findings suggest that a crossover RCT comparing the SPT and APT is warranted.

Based on the recruitment rate, attrition rate, and time necessary to recruit sufficient pilot trial participants, strategies to improve recruitment should be considered for a future adequately sampled crossover RCT. These strategies may include increased advertising of the research project, involvement of multiple investigator sites, especially high patient volume dental sleep medicine clinics, and patient incentives for research participation.[73,74] An increased budget may be necessary as financial incentives for increased clinician involvement and patient incentives for participation have been shown to be significantly impactful in improving patient recruitment.[75-78] Ethical considerations in financial incentives for patient recruitment will need to be considered.[75]

This pilot crossover RCT suggests that adult patients with OSA being treated through OAT may not have a single target mandibular position for effective treatment. A range of positions may provide therapeutic benefits for OSA in OAT, with the possibility that a patient with a non-response or incomplete response to a single mandibular positioning technique may benefit from an alternative mandibular positioning technique. As one patient was a responder to the APT but not the SPT, and one was a responder to the SPT but not the APT, the pilot data suggests that patients in OAT who are not responsive at a specific target position may be responsive at a different target position using different mandibular positioning techniques.

Consistent with previous studies,[79-82] the patient with complete non-response to OAT had a large neck circumference, large waist circumference, a BMI indicating obesity, limited tongue mobility, acceptable

lip seal strength, and lower than average maxillary intermolar width. These factors suggest that the patient was a phenotypically poor candidate for OAT.[83-85] Additional factors (e.g., poor tongue tone and poor tongue jaw dissociation) suggest that the patient also had poor myofunctional coordination of the orofacial musculature and insufficient palatal space for appropriate tongue rest posture.[86] The combination of these factors may explain why the patient was non-responsive to both mandibular positioning techniques in OAT.

Interestingly, the patient who was responsive to OAT in APT but non-responsive to OAT in SPT had a large neck circumference, a normal waist circumference, a BMI indicating overweight, average tongue mobility, limited lip seal strength, and lower than average maxillary intermolar width. Additionally, this patient lost lip seal after the second adjustment in SPT, with significantly worsening disease indices on follow-up sleep testing. The patient did not report losing lip seal with OAT in APT. This may suggest that patients with poor lip seal strength may not be good candidates for OAT in SPT due to increased vertical dimension titration.

The patient, who was responsive to OAT in SPT but non-responsive to OAT in APT, had a large neck circumference, a large waist circumference, a BMI indicating obesity, average tongue mobility, acceptable lip seal strength, and lower than average maxillary intermolar width. While the patient had the typical phenotypic presentation suggestive of poor response to OAT, it may be possible that the use of a SPT in OAT provided a patient-specific mandibular position allowing for myofunctionally neutral tongue resting posture. As the patient had adequate lip seal strength and average tongue range of motion, maintaining the mandible in the SPT positional range may have aided in maintaining appropriate tongue rest posture in the oral cavity.[87-89] Additionally, maintaining the mandible in the SPT orientation may have induced changes in cervical alignment that may have improved airway patency or

some other unexplained factors that are not present within a purely mandibular protrusive positioning technique.[90-97]

The pilot crossover RCT data supports prior research that the SPT allows for less absolute mandibular protrusion than APT, while inter-occlusal space does not appear to be significantly different.[56,57] However, there were no significant differences between the two mandibular positioning techniques regarding protrusion percentage. This may suggest that the greater vertical dimension, as measured by incisal edge overbite in the SPT, may position the mandible less anteriorly to the most retruded mandibular position than the APT. A therapeutic position achieved with the SPT may require less mandibular protrusion than one achieved with the APT. A pictorial representation of this can be seen in Figure 2. The clinical significance of these similarities and differences warrants further investigation.

The pilot crossover RCT data suggests that patients in OAT may be at lesser risk of side effects if treated with the SPT than with the APT. However, the experienced side effects were non-traditional and not commonly associated with OAT. Further research into the occurrence and degree of side effects between different mandibular positioning techniques in OAT is warranted.

Early patient experience data suggested a possible preference for the SPT compared with the APT for OAT. While most patients reported no preference differences, three patients reported a preference for the SPT-positioned appliance, while two reported a preference for the APT-positioned appliance. Both patients who experienced non-traditional side effects in OAT with the APT noted a preference for the SPT. Two patients noted a preference for the SPT based on the increased speed of treatment. The patient, who was not a complete responder to the SPT, noted a preference for the APT. One patient noted a preference for the APT based on “comfort” but did not define what that entailed. The decreased completion of patient experience questionnaires suggests greater clinician emphasis on patient experience may be necessary during future studies.

All results from this pilot trial should be viewed with caution. The limited sample size and the nature of pilot studies in design, scope, and limitations bear consideration for any potential insights from the study data. While limited statistical analyses were provided, these were for descriptive purposes and should not be interpreted as statistically significant.

Future research should evaluate for equivalency in OSA disease indices reduction and sleep quality, differences in therapeutic position, and differences in patient experience between the SPT and APT. An additional collection of data related to lip seal strength, tongue tone, tongue jaw dissociation, and full measurements of tongue range of motion, along with potentially other orofacial myofunctional markers may be prudent in phenotyping responders to the SPT for OAT. Other studies investigating the effects of changing lip seal strength on vertical range in the SPT, maxillary dentition configuration on tongue resting posture, the adaptation of the SPT to non-English speakers, and the effects of altering nasal patency on patient response to SPT in OAT may also be of interest.

Conclusion

The pilot crossover RCT data suggests that the clinical application of SPT in a dental sleep medicine practice for OAT is feasible. There were no complications or difficulties in implementing the entirety of the recently published multidisciplinary consensus protocol for the use of speech in mandibular positioning for dental sleep medicine. From a practical perspective, the clinical application did not take greater clinical time in application compared to the APT.

The pilot trial suggests that an RCT with crossover design to compare the SPT and APT is feasible. However, researchers are encouraged to use several recruitment strategies to increase sample size. Further, pilot crossover RCT data suggests that the SPT may provide an alternative therapeutic position to the APT for mandibular positioning in oral appliance therapy in patients with OSA.

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Figure Legend

Figure 1

Diagram of patient flow in the pilot trial.

Figure 2

Pictorial representation of the speech positioning mandibular and anterior protrusive mandibular landmarks overlapped with the Posselt envelope of motion. Estimation of the effect of differences in positioning and landmark reference points. This figure is meant as an illustration explaining the variability in measurements between the landmarks and starting points for the speech positioning and anterior protrusive techniques and may not be to scale.

Table 1

Outline of pilot trial objectives.

Abbreviations:

APT – anterior protrusive technique
SPT – speech positioning technique
OAT – oral appliance therapy
OSA – obstructive sleep apnea

Primary Objective	Determine the feasibility of conducting a randomized controlled trial comparing the SPT and APT in OAT for adults diagnosed with moderate or severe OSA
Secondary Objectives	Explore differences in disease indices reduction in OAT delivered through the SPT or APT
	Explore differences in mandibular position by: Absolute mandibular position (overjet and overbite)
	Explore differences in mandibular position by: Number of titrations/adjustments
	Explore differences in mandibular position by: Percentage of mandibular protrusion by total mandibular range
	Explore differences in side effect type and side effect occurrence
	Explore differences in sleep quality
	Explore differences in patient experience

Table 2

Age	Gender	Height (cm)	Weight (lbs)	BMI	Neck Circ. (inches)	Waist Circ. (inches)	Ethnicity	Medical Conditions	Medications
65	Female	180.34	280	39.05	16	40	Caucasian	depression, diabetes, thyroid disorder, hypertension, cholesterol	Proscar® (Finasteride), Wellbutrin® (Buproprion), Effexor® (Venlafaxine), Lipitor® (Atorvastatin), Glucophage® (Metformin), Methyldopa, Verapamil
54	Female	152.4	186	36.33	14.5	39.5	Caucasian	chronic pain, fibromyalgia, myofascial pain, anxiety, chronic fatigue, depression, insomnia, migraines	Amitryptyline
71	Female	157.5	154	28.16	14	30	Caucasian	Gastroesophageal reflux disease, hypertension, high cholesterol	Rosuvastatin, Ibesartan Hydrochlorothiazide, Pantoprazole
68	Female	152.4	100	19.53	13	27	Asian	migraines, fatigue	
64	Male	168	155	24.91	13.5	36	Asian	Hypertension	Perindopril
62	Female	157.48	170	31.09	16.5	39	Caucasion	Attention deficit hyperactivity disorder, heartburn	Vyvance® (Lisdexamfetamine), Pantoprazole
34	Female	160.02	120	21.26	14	31	Asian	None	
38	Male	173	139	21.07	15.5	31.5	Asian	eczema	

Individual pilot patient demographic data. All patients with OSA. Other medical conditions listed by patient report.

Table 3

	APT PreTx	APT PostTx	APT Δ in Tx	SPT PreTx	SPT PostTx	SPT Δ in Tx
AHI	21.35 (SE +/- 1.79)	8.90 (SE +/- 1.69)	12.45 (SE +/- 2.12)	24.63 (SE +/- 3.48)	9.95 (SE +/- 2.23)	14.68 (SE +/- 2.99)
RDI	30.10 (SE +/- 1.47)	15.71 (SE +/- 1.85)	14.39 (SE +/- 2.31)	34.20 (SE +/- 3.27)	17.79 (SE +/- 2.91)	16.41 (SE +/- 3.52)
ODI	15.55 (SE +/- 1.66)	8.00 (SE +/- 1.65)	7.55 (SE +/- 1.84)	21.55 (SE +/- 3.39)	8.83 (SE +/- 2.21)	12.73 (SE +/- 2.76)

Summary table listing average disease indices measurements before and after treatment as well as change in disease indices measurements for the APT and SPT groups. Disease indices measurements between APT and SPT groups were not statistically significantly different.

Table 4

	N = 8	OJ (Protrusion)	OB (Interocclusal Space)	Titrations to MMI	% Protrusion at MMI
	PreTx	0.4mm (SE +/- 0.74)	5.0mm		
APT	**PostTx**	1.50mm (SE +/- 0.57)	5.0mm	1.88 (SE +/- 0.48)	63.37% (SE +/- 6.65)
	PostTx Δ from MIP	4.75mm (0.92)	7.13mm (SE +/- 0.55)		

	N = 8	OJ (Protrusion)	OB (Interocclusal Space)	Titrations to MMI	% Protrusion at MMI
	PreTx	0.4mm (SE +/- 0.74)	4.5mm		
SPT	**PostTx**	0.4mm (SE +/- 0.74)	5.63mm (SE +/- 0.48)	1.13 (SE +/- 0.48)	48.82% (SE +/- 4.61)
	PostTx Δ from MIP	2.88mm (SE +/- 0.52)	7.75mm (SE +/- 0.73)		

Summary table listing average changes to mandibular position before and after treatment for the APT and SPT groups as well as number of titrations in treatment and % of protrusion post-treatment.

Table 5

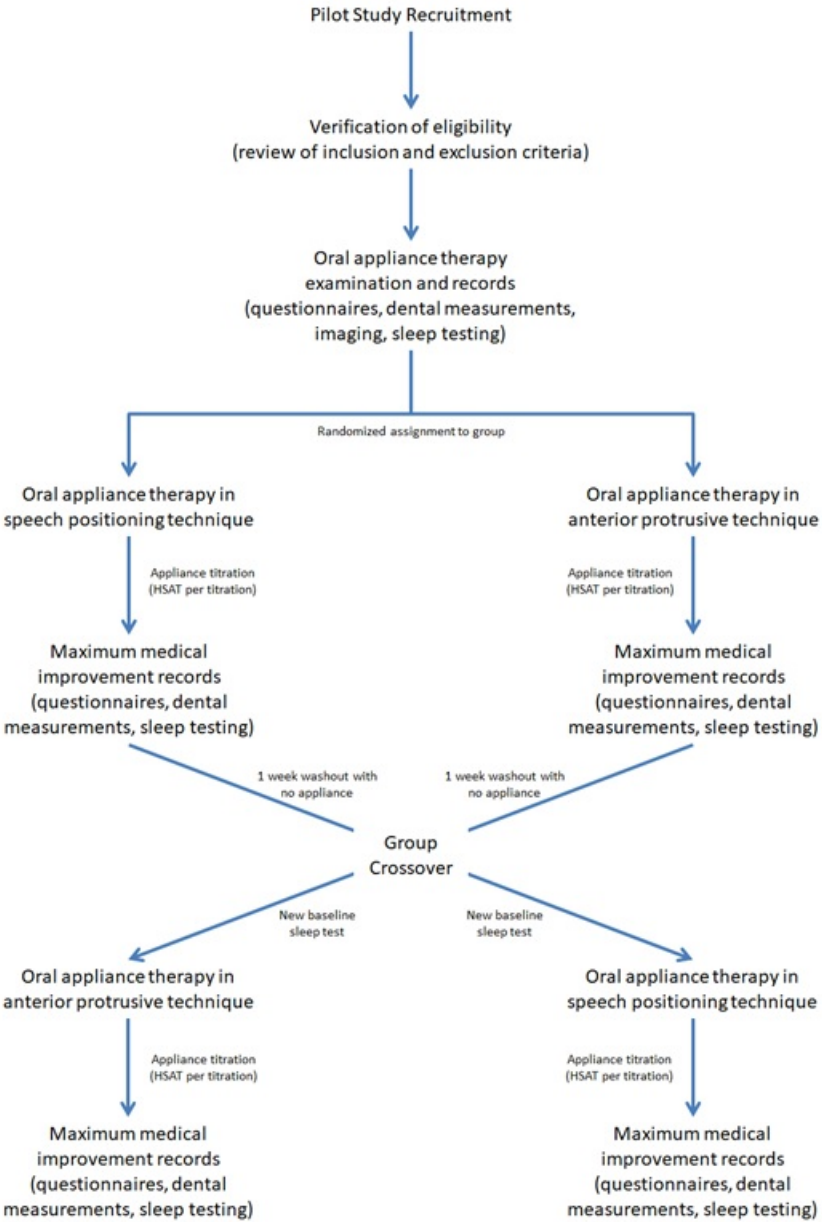
	APT PreTx	APT PostTx	APT Δ in Tx	SPT PreTx	SPT PostTx	SPT Δ in Tx
ESS	8.75 (SE +/- 1.44)	5.63 (SE +/- 1.24)	3.13 (SE +/- 1.22)	9.50 (SE +/- 1.59)	7.38 (SE +/- 1.70)	2.13 (SE +/- 0.85)
FSS	36.00 (SE +/- 5.98)	30.00 (SE +/- 5.73)	6.00 (SE +/- 1.46)	35.88 (SE +/- 5.39)	30.38 (SE +/- 6.05)	5.50 (SE +/- 4.78)
NTSE	7.25 (SE +/- 1.89)	5.75 (SE +/- 1.35)	1.50 (SE +/- 1.34)	7.50 (SE +/- 1.55)	5.25 (SE +/- 1.63)	2.25 (SE +/- 1.33)

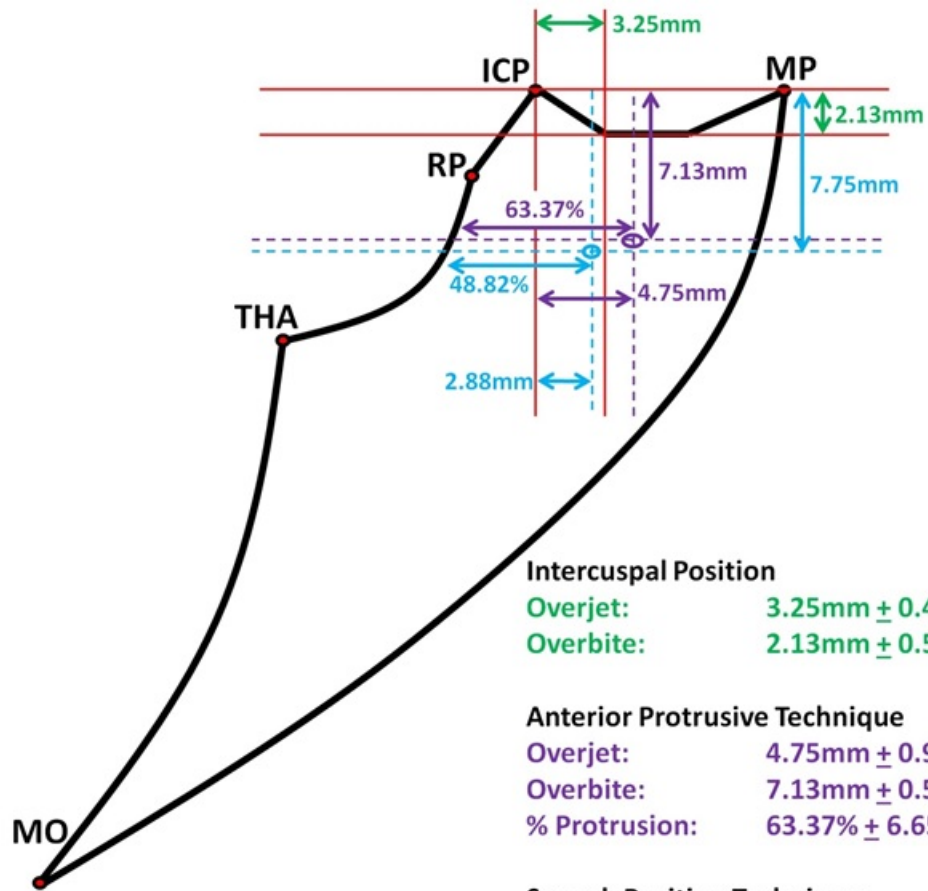
Summary table listing average sleep quality scores from the ESS, FFS, and NTSE before and after treatment as well as change in sleep quality scores for the APT and SPT groups. Sleep quality scores between APT and SPT groups were not statistically significantly different, nor were the sleep quality scores significantly different before and after treatment.

Table 6

	SPT	APT
Overall Rating	87.25% (SE +/- 3.02)	88.63% (SE +/- 2.51)
Appliance Characteristics	89.54% (SE +/- 2.85)	89.54% (SE +/- 2.73)
Delivery of Care	93.50% (SE +/- 2.03)	92.50% (SE +/- 4.40)
Symptom Improvement	78.70% (SE +/-7.34)	81.90% (SE +/- 4.46)

Summary table listing patient experience scores between the APT and SPT groups. Percentages overall and per dimension are provided; the three dimensions of patient experience measured were “appliance design”, “delivery of care”, and “symptom improvement”.


Pilot Study Recruitment
Verification of eligibility
(review of inclusion and exclusion criteria)
Oral appliance therapy
examination and records
(questionnaires, dental measurements,
imaging, sleep testing)
Randomized assignment to group
Oral appliance therapy in
speech positioning technique
Appliance titration
(HSAT per titration)
Maximum medical
improvement records
(questionnaires, dental
measurements, sleep testing)
Oral appliance therapy in
anterior protrusive technique
Appliance titration
(HSAT per titration)
Maximum medical
improvement records
(questionnaires, dental
measurements, sleep testing)
1 week washout with
no appliance
1 week washout with
no appliance
Group
Crossover
New baseline
sleep test
New baseline
sleep test
Oral appliance therapy in
anterior protrusive technique
Appliance titration
(HSAT per titration)
Maximum medical
improvement records
(questionnaires, dental
measurements, sleep testing)
Oral appliance therapy in
speech positioning technique
Appliance titration
(HSAT per titration)
Maximum medical
improvement records
(questionnaires, dental
measurements, sleep testing)



Intercuspal Position

Overjet:	3.25mm ± 0.49
Overbite:	2.13mm ± 0.55

Anterior Protrusive Technique

Overjet:	4.75mm ± 0.92
Overbite:	7.13mm ± 0.55
% Protrusion:	63.37% ± 6.65

Speech Position Technique

Overjet:	2.88mm ± 0.52
Overbite:	7.75mm ± 0.73
% Protrusion:	48.82% ± 4.61