Exploring the Use of Speech Features to Determine Mandibular Position In Oral Appliance Therapy for Dental Sleep Medicine

by

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Abstract

This thesis assessed the use of speech characteristics to determine mandibular position for oral appliance therapy in dental sleep medicine. A review of the literature was completed indicating minimal research into this subject and no clear definition on appropriate use and application of the procedure. A retrospective comparison between patients treated with the anterior protrusive technique and the sibilant phoneme technique for mandibular positioning suggested there may be clinically relevant differences in target mandibular position worthwhile exploring. A questionnaire was created and validated to explore differences in patient experience in oral appliance therapy. An interdisciplinary expert panel was convened which reached a consensus definition for the use of speech characteristics to determine mandibular position in oral appliance therapy. A randomized crossover pilot study was conducted providing initial comparative data between the anterior protrusive and speech positioning techniques as well as initial efficacy data on the speech positioning technique for oral appliance therapy. The creation of the first validated questionnaire to measure patient experience in oral appliance therapy provides a foundational step in evaluating, understanding, and improving patient outcomes in dental sleep medicine. It also provides a roadmap for expanding patient experience research in continuous positive airway pressure. The formal establishment of an interdisciplinary consensus procedure for the use of speech characteristics to determine mandibular position for oral appliance therapy will allow for reproducibility in teaching clinicians and for future research. From the pilot study a crossover randomized controlled trial is feasible. Initial data also suggests patients may have more than one target therapeutic mandibular position in oral appliance therapy, with significantly less mandibular protrusion for the speech positioning technique necessary compared to the anterior protrusive technique. The speech positioning technique is a clinically viable alternative technique with the possibility of increasing the number of patients responsive to oral appliance therapy and for patients with limited mandibular protrusion.

Preface

This thesis is an original work by Enoch Ng. The research projects, of which this thesis is a part, received research ethics approval from the University of Alberta Research Ethics Board, project “comparing classic denture occlusal registration positioning vs standard protrusion style registration positioning”, Pro00088954, March 19, 2020; project “expert consensus on the procedure of using speech for mandibular positioning in dental appliances”, Pro00128767, February 22, 2023; and project “two cohort prospective single blinded patient crossover trial comparing anterior protrusive and sibilant phoneme mandibular positioning techniques for dental sleep appliances”, Pro00097563, January 14, 2020.

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Chapter 1 – Introduction

1.1 Background

Obstructive sleep apnea (OSA) was first described in 1965 by research groups Jung & Kuhlo (1965) and Gastaut et al., (1966). It was initially described as long periods of apneic events with cyanosis and bradycardia followed by deep irregular snoring breaths in patients with Pickwician syndrome (Jung & Huhlo, 1965). Research in sleep and breathing developed throughout the 1970s, with defining OSA parameters described by in 1976 by Guilleminault et al. (1976). OSA is a prevalent medical condition now understood to involve repetitive upper airway obstruction with maintained respiratory effort during sleep with associated cortical arousals and intermittent hypoxia (Bahr et al., 2021; Dewan et al., 2015; Eckert, 2018; Eckert & Younes, 2014; Kapur et al.,2017; Prabhakar et al., 2020). OSA has been correlated with significant health effects, including cardiovascular disease, diabetes, and daytime sleepiness (Anker et al.,2016; Gami et al., 2005; Wang et al., 2013; Young et al., 2008). Other health concerns associated with OSA include Alzheimer's, Parkinson's, periodontal disease, cancer, chronic obstructive pulmonary disease, and asthma (Alkhalil et al., 2009; Andrade et al., 2018; Billings, 2015; Cao et al., 2022; Dixit, 2018; Guay-Gagnon et al., 2022; Latorre et al., 2018; Owens & Malhotra, 2010; Siachpazidou et al., 2020; Tremblay et al., 2017). OSA and related obstructive sleep breathing disorders are estimated to affect 15% of the world population, or an estimate 1 billion people worldwide (Franklin & Lindberg, 2015; Heinzer et al., 2015; Lyons et al., 2020). In terms of dollar value, OSA is estimated to cost the United States of America over $150 billion a year due to direct, indirect, and health related costs (Frost & Sullivan, 2016a; Watson, 2016).

Prior to 1980, the primary treatment for OSA was to bypass upper airway obstruction through tracheostomy surgically (Bahammam, 2011). In 1980, continuous positive airway pressure (CPAP) was introduced as the first non-surgical intervention for OSA (Sullivan et al., 1981). A nasal mask with positive pressure was used on a handful of patients, demonstrating successful management for OSA through a pneumatic splint created by positive pressure airflow to maintain patency of the upper airway. In the 1990s, dentists began fabricating appliances that would position the mandible anteriorly for OSA management (Clark et al., 1993). Maintaining this anterior position during sleep seemed to decrease the collapsibility of the oropharynx and appeared to provide some benefits for patients suffering from OSA. In 1995, the first clinical practice guidelines for the appropriate use of dental appliances for OSA, known as oral appliance therapy (OAT), were published (American Sleep Disorders

Association [ASDA], 1995). While the use of mandibular advancement appliances was not as efficacious as CPAP, they provided an accepted alternative treatment for patients unable to tolerate CPAP. From the 1990s onwards, the field of dental sleep medicine has experienced significant growth and development.

The primary medical treatment for all severities of OSA is positive airway pressure (PAP) therapy. Variations of PAP exist, including continuous PAP (CPAP), bilevel PAP (BiPAP), and auto-titrating PAP (APAP). CPAP provides a single continuous set pressure to maintain upper airway patency, BiPAP provides two levels of pressure with increased pressure for breathing in and decreased pressure for breathing out, and APAP machines have specialized algorithms to provide continuously adjusting pressure throughout sleep depending on individual patient breathing patterns (Freedman, 2020; Johnson, 2022; MedlinePlus, n.d.). Collectively, these forms of PAP therapies are commonly known as CPAP. Despite multiple options of PAP therapies, patient adherence to PAP in general has been found to be lower than 50% (Qiao et al., 2023; Rotenberg et al., 2016).

Recently, the custom fit titratable dental sleep appliance has been considered another first-line treatment option for mild and moderate OSA (Ramar et al., 2015). It is also an accepted treatment for patients with severe OSA who are unable to tolerate CPAP (Ramar et al., 2015). Evidence suggests that dental appliances for OSA are less efficacious but better tolerated than CPAP, with the greater patient compliance in OAT compared to CPAP resulting in similar overall effectiveness (efficacy by time usage) for improved health outcomes (Sutherland et al., 2015). Specifically, dental sleep appliances appear to be more comfortable, less intrusive, more portable, and easier to use compared to CPAP (Almeida et al., 2013; American Academy of Dental Sleep Medicine [AADSM], 2023; Ferguson, 2001; Naismith et al., 2005). Patients who are able to use both treatment options usually prefer dental appliances over CPAP (Ferguson et al., 1996, 1997; Randerath et al., 2002; Tan et al., 2002). These appliances generally protrude the mandible and tongue anteriorly to maintain airway patency (Brown et al., 2013). The amount of protrusion traditionally has been determined at 50-75% of maximum mandibular protrusion, and the parameters for this anterior protrusive positioning have become well established (Aarab et al., 2010; Ippolito et al., 2020; Mayoral et al., 2019; Piskin et al., 2015; Tegelberg et al., 2003; Vroegop et al., 2012). Multiple side effects have been associated with OAT, particularly temporomandibular disorder, masticatory myalgia, and skeletal and dental occlusal changes. The incidence and severity of these side effects are correlated with increased protrusion, with significantly increased risk associated with greater than 50% protrusion. However, recent research suggests alternative approaches may provide for

minimal anterior protrusion of the mandible with similar OSA disease index reduction (Anitua et al., 2017; Viviano et al., 2022). The importance of exploring alternative mandibular positioning techniques with potentially less required protrusion for dental sleep appliances is related to the risks of long-term adverse effects associated with increased protrusion in dental sleep appliances (Perez et al., 2013; Pliska et al., 2014; Sanders et al., 2013; Sheats et al., 2014).

During functional evaluation and management, speech and orofacial myofunctional disorders have been linked to OSA in anatomical regions. Speech signalling patterns have been shown to be a potentially useful predictor for OSA, while orofacial myofunctional therapy (OMT) has been shown to decrease OSA index numbers by up to 50% in adults (de Felicio et al., 2018; Koka et al., 2021; Simply et al., 2020). Mandibular movement and tongue-jaw dissociation are paramount in speech and OMT (Green et al., 2000, 2002; Meyer, 2000; Mogren et al., 2022). Other major components include the tongue and jaw positions at rest and during speech (Alghadir et al., 2015; Hamlet & Stone, 1981; Marshall, 2007, Meyer, 2000; Mogren et al., 2022; Ostry et al., 1994, 1996; Solomon et al., 2016; Van Dyck et al., 2016). Due to their importance in speech therapy and OMT, it would be reasonable to assume that mandibular position during the production of speech sounds may provide indicative factors for a mandibular position to maintain airway patency. While these mandibular positions may be a relevant point for measurement in relation to airway patency, this is generally not discussed within speech and orofacial myofunctional literature. Obtaining these mandibular position measurements during wakefulness may also be a helpful indicator for predictive measurements of airway patency during sleep. This topic has yet to be explored in speech therapy and OMT literature.

Removable prosthodontics has been using speech, specifically sibilant sounds, for denture prosthodontics since the 1970s (Pound, 1977). The use of sibilant sounds for mandibular positioning is known as the sibilant phoneme technique. It can be used to obtain or verify a reproducible mandibular position in three dimensions regardless of dentition (Pound, 1977). This position or zone, known as the phonetic neutral zone, appears to place the mandible in its most natural anterior superior position without causing interferences in speech and function (Pound, 1977; Singh & Olmos, 2007). Preliminary research suggests this zone may also provide a mandibular position that decreases the risk of upper airway collapsibility (Singh & Olmos, 2007). This may be similar to how dentures fabricated with the mandible positioned within the phonetic neutral zone experience denture retention through oropharyngeal muscular stability (Bohnenkamp & Garcia, 2007, 2008; Makzoumé, 2004). However, minimal research has been done on this technique to determine its utility in dental sleep appliances

compared to the currently accepted anterior protrusive technique, though initial research is promising (Viviano et al., 2022). Neither of these initial papers, however, describes a methodology for using speech as a positioning technique for mandibular position, or appropriate modification of the sibilant phoneme technique from denture prosthodontics for dental sleep appliances. Also, there appears to be no expert consensus on the appropriate procedural use of speech as a positioning technique for mandibular position in dental sleep medicine (American Sleep and Breathing Academy [ASBA], 2018; Chan, 2015; Mahony & Lipskis; 2012; Marangos, 2018; Olmos, 2019; Rawson, n.d.).

In summary, using speech sounds may provide an alternative to the current anterior protrusive technique for mandibular positioning, with the initial use of the sibilant phoneme technique in prosthodontics as a potential starting point study. However, insufficient research has been conducted to determine whether speech-based mandibular positioning is a viable alternative to the anterior protrusive technique. Evidence is necessary to establish the parameters of the effectiveness of using speech as an alternative technique for mandibular positioning in dental sleep appliances.

The purpose of this research is to explore the use of speech characteristics in determining a mandibular position for oral appliance therapy in dental sleep medicine. This includes answering multiple questions, including what is the current published literature in relation to the use of speech for mandibular positioning in dental sleep medicine; how do patients previously treated with such a technique compare to patients previously treated with the anterior protrusive technique; how do we measure patient experience between the two mandibular positioning techniques; what is the consensus procedure for the appropriate use of speech characteristics in mandibular positioning; and how does oral appliance therapy for OSA delivered through mandibular positioning obtained through speech characteristics compare with mandibular positioning through the anterior protrusive technique.

1.2 Research Objectives

To explore the use of speech characteristics in determining mandibular position for oral appliance therapy in dental sleep medicine.

1.3 Research Questions

Research Question	Actionable Outcome
1. What is the current published literature in relation to the use of speech for mandibular positioning in dental sleep medicine?	Ng ET, Mayoral P, Hernandez I, Lagravère MO. Comparing a sibilant phoneme denture bite position with an anterior protrusive mandibular positioning device in oral appliance therapy for dental treatment of obstructive sleep apnea: A systematic review. J Dent Sleep Med. 2020;7(4)
2. How do patients previously treated with a speech based mandibular positioning technique compare to patients previously treated with the anterior protrusive technique in oral appliance therapy for obstructive sleep apnea?	Ng ET, Mayoral P, Hernandez IA, Lagravère MO. Comparing anterior protrusive with sibilant phoneme mandibular positioning techniques for dental sleep appliances in managing obstructive sleep apnea: A retrospective study. J Dent Sleep Med. 2021;8(1)
3. How do we measure patient experience between the two mandibular positioning techniques?	Ng ET, Perez-Garcia A, Lagravère-Vich MO. Development and initial validation of a questionnaire to measure patient experience with oral appliance therapy. J Clin Sleep Med. 2023 Aug 1;19(8):1437-1445. doi: 10.5664/jcsm.10562. PMID: 37082817; PMCID: PMC10394373.
4. What is the consensus methodology for the appropriate use of speech characteristics in mandibular positioning?	Manuscript submitted to JDSM
5. How does oral appliance therapy for OSA delivered through mandibular positioning obtained through speech characteristics compare with mandibular positioning through the anterior protrusive technique on a patient and group level?	Manuscript submitted to JDSM

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Chapter 2 – Literature review: Comparing a sibilant phenome denture bite position with an anterior protrusive mandibular positioning in oral appliance therapy for dental treatments of obstructive sleep apnea.

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Ng ET, Mayoral P, Hernandez I, Lagravère MO. Comparing a sibilant phoneme denture bite position with an anterior protrusive mandibular positioning device in oral appliance therapy for dental treatment of obstructive sleep apnea: A systematic review. *J Dent Sleep Med*. 2020;7(4)

2.1 Summary

Objective

The objective of this review is to provide a summary of the published literature related to the use of a sibilant phoneme technique (SPT) for determining mandibular positioning in dental sleep appliances for the management of obstructive sleep apnea (OSA), and to summarize these findings into normative ranges and protocols similar to those already established for anterior protrusive mandibular positioning.

Materials and Methods

A search was performed on five databases: MEDLINE, Embase, Cochrane Library, Scopus, and Web of Science Core Collection. Articles not related to sleep medicine and dentistry were excluded. Only articles with a high likelihood of using a sibilant phoneme/phonetic and/or biomimetic occlusal registration with presleep and postsleep testing were selected. Review of the selected articles did not justify a meta-analysis.

Results

Six articles met the loose inclusion criteria, of which only three articles met strict inclusion criteria. Of these three articles, two included deliberate maxillary expansion precluding the results from comparability with other mandibular positioning techniques. The remaining article was a direct comparison of the number of titrations between a SPT and a George Gauge anterior protrusive technique for mandibular positioning for dental sleep appliances.

Conclusions

Insufficient information exists on the use of the SPT for mandibular positioning in dental sleep appliances for the management of OSA. Because of the potential for a therapeutic outcome with minimal protrusion of the mandible and therefore lower risk of developing the side effects associated with dental sleep appliances, further research should be explored in this area.

Keywords: dental appliance, obstructive sleep apnea, phonetic bite, sibilant phoneme

2.2 Background

Sleep-disordered breathing is a prevalent medical condition believed to affect more than 15% of the global population 9 (Franklin & Lindberg, 2015; Frost & Sullivan, 2016a, 2016b). Of the different types of sleep-disordered breathing, obstructive conditions (specifically, OSA) are of particular interest to dentists. OSA is characterized by repetitive partial or complete obstructions in the upper airway, usually along the pharyngeal segment, while maintaining the thoracic effort of breathing and with associated oxygen desaturations and/or neurologic arousals (Kapur et al., 2017). This collapse along the pharyngeal segment usually occurs due to a loss of muscle tonus during sleep (Eckert, 2018). The oxygen desaturations and neuroarousals from OSA have a cascading effect on health and function, with well-established correlations between OSA and cardiovascular disease, diabetes, and daytime sleepiness, for example (Anker et al., 2016; Gami et al., 2005; Wang et al., 2013; Young et al., 2008).

Though OSA is a medical condition, one of the treatments involves dentists fabricating custom-fit dental sleep appliances (Ramar et al., 2015). This therapy is widely known by several names including oral appliance therapy, mandibular appliance therapy, dental sleep appliance, mandibular repositioning appliance, mandibular repositioning therapy, or mandibular advancement appliance. Though these devices do not have the same efficacy as positive airway pressure for treating OSA in terms of apnea-hypopnea index reduction, their overall treatment effectiveness is similar because of greater patient compliance (Chan & Cistulli, 2009; Sutherland et al., 2016). In this article, these devices will be referred to as “dental sleep appliances” in that they are dental appliances used for the treatment of sleep breathing disorders, specifically for OSA.

There are multiple recommended treatments for OSA in adults. These include weight loss, positional therapy, positive airway pressure machines, dental sleep appliances, and surgical intervention (American Sleep Apnea Association [ASAA], 2019; Caples et al., 2010; Epstein et al., 2009; Patil et al., 2019; Veasey et al., 2006). Although sleep physicians may make diagnoses and direct the treatments for

patients with OSA, usually only licensed dentists are able to fabricate custom-fit dental sleep appliances when they are prescribed due to state and federal regulations and in accordance with American Academy of Sleep Medicine (AASM) and American Academy of Dental Sleep Medicine (AADSM) practice parameters (Gauthier et al., 2012; Gianoni-Capenakas et al., 2020; Kushida et al., 2006). These appliances traditionally have been fabricated to position the mandible and tongue anteriorly to aid in maintaining patency of the pharyngeal airway (Brown et al., 2013). Although there are an assortment of different dental appliances varying in material and form, treatment parameters are generally focused around the position in which the mandible is held rather than the style of the device worn by the patient. Parameters for anterior protrusive positioning have become well established in regard to considerations such as habitual occlusion, retrusion, and protrusion (Ippolito et al., 2019; Mayoral et al., 2019). Vertical positioning has traditionally been primarily determined by material thicknesses required for the devices and/or measuring gauges, as some research indicates increased vertical dimension in appliance treatment does not correspond with increased treatment effectiveness (Piskin et al., 2015; Pitsis et al., 2002; Vroegop et al., 2012). Anterior positioning has traditionally been primarily determined as 50% to 75% of maximum protrusion (Aarab et al., 2010; Tegelberg et al., 2003). However, recent research has indicated minimal anterior protrusion of the mandible may be sufficient to achieve treatment success parameters for some patients (Anitua et al., 2017). The conflicting article conclusions warrant further investigation to bring a consensus within the research in this area.

By necessity, most dental sleep appliances are designed to anchor off of existing dentition, an existing appliance, or dental implants. Reasonable retention may be possible for patients with an edentulous maxilla due to the prosthodontic principles related to postpalatal seal, but secured retention cannot be established on edentulous mandibles without the use of implants. However, the principles related to the fabrication of dental prosthesis may be of particular interest to dentists who provide appliance therapy for OSA. Principles in denture fabrication for the edentulous patient include the use of phonetics in determining mandibular position with the use of sibilant sounds to determine the closest speaking space in three dimensions (including corrections of pitch, roll, and yaw) (Pound, 1977). This closest speaking space is generally considered the most anterior mandibular position beyond which may cause muscular dysfunction at rest, and may provide an alternative to the commonly accepted 50% to 75% maximum protrusion for dental sleep (Singh & Olmos, 2007).

The importance of exploring alternative mandibular positions for dental sleep appliances is vital due to common side effects associated with protrusive positioning used in oral appliance therapy and the

current lack of consensus about the necessary degree of mandibular protrusion. These commonly accepted adverse effects are not all transient, and some of the long-term adverse effects include temporomandibular disorder, long-term changes to the craniofacial structure, dental occlusal changes, and other soft-tissue adverse effects (Perez et al., 2013; Pliska et al., 2014; Sanders et al., 2013; Sheats et al., 2017). Of particular interest is that the greater the mandibular protrusive position, the greater the risks and changes associated with these long-term adverse effects. This, combined with research both for and against the need for significant mandibular protrusion, warrants further investigation into different mandibular positioning techniques (Aarab et al., 2010; Anitua et al., 2017;Tegelberg et al., 2003). An initial mandibular position obtained with a SPT may provide the greatest therapeutic benefit for the management of OSA with the lowest risk of the accepted adverse effects commonly associated with dental sleep appliances.

2.3 Methods

A computer-assisted literature search was done on the medical databases MEDLINE, Embase, Cochrane Library, Scopus, and Web of Science Core Collection. Determination of the appropriate syntax for each database was done with the help of a health sciences librarian. The systematic search was done on December 24, 2019. A combination of “sibilant”, “biomimetic”, “phoneme”, “phonetic bite”, “dentistry”, “denture”, “dental”, “prosthodontic”, “prosthetic”, “airway” “respiratory”, “sleep apnea”, “appliance”, “orthodontic” and their permutations were used with the appropriate syntax inputs for each database. The specific search parameters used for each database are listed in Appendix 2.A.

Exclusion criteria included any articles not related to human subjects or dentistry.

Loose inclusion criteria included any articles related to OSA treatment in adults, probable use of a biomimetic or sibilant-type phoneme technique or device, and pretreatment and posttreatment sleep testing (in accordance with AASM and AADSM guidelines).

Strict inclusion criteria eliminated any articles that did not explicitly state the method of occlusal registration for mandibular positioning used, did not use a custom-fit titratable appliance (in accordance with AASM and AADSM guidelines), or where attempts to contact the authors for clarification on methodology were unsuccessful.

Potential references were first screened to remove all duplicates, then by title, and finally by abstracts to determine relevance. Only articles considered relevant were reviewed in full text. Articles were reviewed independently by two reviewers.

2.4 Results

Our search yielded 1,645 articles and/or abstracts. An electronic search of duplicates in Refworks was conducted and duplicates removed, with 720 references remaining. After sorting through titles, 11 references remained. Of these 11 references, 6 were extended abstracts (such as for conference proceedings) and 5 were journal articles. The titles of the six extended abstracts were used as search terms in Google Scholar, with the first five pages of results reviewed for potentially relevant journal articles that did not appear within our original literature search. Six articles were selected from this Google Scholar search as relevant based on title and abstract. A total of 11 articles were reviewed in full text, and 6 were deemed relevant by loose inclusion criteria. Three of these articles were deemed relevant by strict inclusion criteria. Article selection criteria details are summarized in Table 2.1.

Table 2.1 Article selection criteria

Loose Selection Criteria	Strict Selection Criteria
- OSA in adults - Likely used a biomimetic or sibilant type phoneme technique or device - Pretreatment and posttreatment sleep tests (in accordance with AASM and AADSM guidelines) - Six articles met loose criteria for inclusion in this review (three of these articles met the strict inclusion criteria)	- Explicitly stated or described method of occlusal registration for mandibular positioning - Use of a custom titratable appliance (in accordance with AADSM guidelines) - 3 articles met the strict criteria for inclusion in this review

Descriptive Results

Of the three articles that met the loose inclusion criteria but not the strict inclusion criteria, two were case reports and one was a case series (Heit et al., 2016; Singh et al., 2014, 2019).

Of the three articles that met the strict inclusion criteria, two were case series and one was a retrospective cohort study (Singh et al., 2016; Singh & Cress, 2017; Viviano et al., 2022).

Data Extraction

The collected data did not support a meta-analysis. Qualitative description of the relevant data for each study is provided in Table 2.2 and Table 2.3.

Table 2.2 Articles meeting loose selection criteria (articles meeting strict criteria not included)

Type of Study	Case Report	Case Report	Case Series
Reference	Heit et al. 2016	Singh et al. 2019	Singh et al. 2014
Patient data	27-year-old female	56-year-old male	6 males, 3 females, average age of 54.5 years
Pretreatment AHI (events per hour)	70	16.4	Average of 13.2 $\pm$ 7.2
Posttreatment AHI (events per hour)	< 5	5.3	Average of 4.5 $\pm$ 3.6
Treatment time	9 months	14 months	Average of 8.7 $\pm$ 5.8 months
Occlusal registration technique	Not described	Not described	Corrected for patient specific vertical position

Table 2.3 Articles meeting strict selection criteria

Type of Study	Case Series	Case Series	Retrospective Cohort
Reference	Singh et al. 2016	Singh and Cress 2017	Viviano et al. 2022
Patient data	15 patients older than 21 years	10 patients older than 21 years	20 patients per cohort (2 cohorts) Age and body mass index provided per patient
Pretreatment AHI (events per hour)	Average of 45.9 $\pm$ 10.5	Average of 12.8 $\pm$ 5	AHI provided per patient
Posttreatment AHI (events per hour)	Average of 16.5 $\pm$ 8.8	Average of 6.2 $\pm$ 2.9	AHI provided per patient
Treatment time	Average of 9.7 $\pm$ 1.9 months	Approximately 9 months	Not described
Occlusal registration technique	Sibilant Phoneme	Sibilant phoneme	Sibilant phoneme versus George Gauge
Other notes	Deliberate maxillary	Deliberate	Significantly less titrations and

	expansion as part of treatment	maxillary expansion as part of treatment	mandibular repositioning with sibilant phoneme technique compared to George Gauge anterior protrusive technique No difference in AHI outcomes between techniques

Summary Description

Of the three articles that met the strict inclusion criteria, two were case series and one was a retrospective cohort. Both case series included deliberate maxillary expansion and no direct comparisons with a control group. For the retrospective cohort, a direct comparison was made between the SPT and the APT for mandibular positioning in relation to the number of titrations necessary to reach treatment efficacy (defined as an AHI reduction of 50% and below 10 events per hour). Due to the deliberate maxillary expansion, data extracted from the case series studies could not be used for direct comparison between different mandibular positioning techniques.

Of the three articles that met the loose inclusion criteria but not the strict inclusion criteria, two were case reports and one was a case series. The use of a biomimetic bite registration technique is noted but not described. For all three of these studies, no control group is present.

The retrospective cohort study was the only study to directly compare the SPT and the APT for mandibular positioning for dental sleep appliances. This study appeared to be a pilot study and focused on comparing the number of titrations needed to successfully manage a patient's OSA by AHI numbers, with the results indicated that the SPT required less titration than the APT.

2.5 Discussion

Of the three studies found that specifically noted the use of SPT for mandibular positioning used for dental sleep appliances in the treatment of OSA, two studies involved deliberate permanent orthopedic changes (maxillary expansion). Though it should be noted that there is nothing within the current AASM and AADSM guidelines that would explicitly exclude deliberate orthopedic remodeling (including maxillary expansion), deliberate orthopedic changes to the maxilla were a complicating factor for the study of the sibilant phoneme technique alone. Furthermore, those two studies were not comparative with other techniques due to no control group and were case series in nature. Only one article directly compared the SPT to the APT for mandibular positioning for oral appliance therapy. That study did not include deliberate orthopedic remodeling as a compounding variable of treatment.

Of the two studies that included deliberate maxillary expansion, the Daytime Nighttime Appliance was used (it is a removable appliance now under the brand Vivos Therapeutics). Details on how the expansion was conducted (rate, intervals, recommended force levels, frequency of adjustments, types of adjustments, specialized materials, etc.) were not described. As well, selection criteria and/or criteria for why these particular patients were candidates for this appliance as opposed to more traditional dental sleep appliance therapy was not provided. Because this expansion device is not widely used, the lack of details severely limits the ability for nonaffiliated third-party clinicians and researchers to replicate the results of these studies and could potentially make the results questionable.

Of the cohort study directly comparing the SPT and the APT, no power analysis was provided. The study primarily focused on comparing the number of titrations necessary to reach successful AHI management, with success defined as an AHI reduction of 50% and below 10 events per hour. Although all clinicians were board certified and no statistical differences were found between the two cohorts pre-operatively, without a power calculation it is difficult to determine whether the sample size for this study was sufficient to draw generalized conclusions. Other limitations within this study included no description of the adjustment/titration protocols used, no description of the appliances used, and a lack of specific methodology description or references for the George Gauge protrusive and sibilant phoneme techniques. Although the difference in starting points between the two methods was briefly discussed in general terms, specifics were not described. Based on these limitations, this study appears to be a pilot study. Nevertheless, the primary result that the SPT required less titrations to reach successful AHI management compared to the APT is compelling as this is the only study we could find that provided any direct comparisons between the APT and SPT for dental sleep appliances. From this study, despite its many limitations, one would assume that the SPT would require less mandibular advancement. However, this study did not explicitly investigate this measure.

In all three studies, OSA was diagnosed by sleep specialist physicians. Although patients within the cohort study were treated in accordance with AASM and AADSM guidelines, which emphasize an interdisciplinary collaborative approach, for the case series studies it is unknown whether patients were also evaluated for potential nasal obstructions by qualified personnel (usually otolaryngologists) and whether radiographic imaging studies were properly interpreted by qualified personnel (usually medical or dental radiologists). It is recommended for all dentists that a team approach be taken when providing dental sleep appliance therapy and that communication between the treating dentist, physician, and other clinicians involved in the patient's care occur on a regular basis.

None of these studies describe the differences between the SPT and the APT in practical terms for clinicians. Although the APT generally requires a protrusive gauge, the SPT requires the use of a round bite stick. Although most protrusive gauges have a set thickness, the round bite sticks can be selected at any thickness. In both techniques, an excellent occlusal registration is vital as is recording the details of the technique and bitefork or bitestick used. Reproducing the mandibular position for the SPT requires using the same technique (having the patient repeating the same sibilant sounds) with the same dimension bitestick as originally used. Similarly, reproducing the mandibular position for the APT requires that the same gauge (for example, a George Gauge) be used with the same original technique (% or mm protrusion, based on habitual bite, maximum retrusive, or incisal edge-to-edge). A breakdown of advantages and disadvantages between the two techniques is included in Appendix 2.B.

Although a review of the literature provided some insight on the use of phonetics in determining initial mandibular position for treatment of OSA by dental appliances, the limited number of articles published makes generalized conclusions impossible. Our results are indicative of a field in which minimal research has been done, and therefore a field ripe with opportunities for primary research to be conducted. It seems puzzling that so little information exists regarding the use of this technique, a staple in removable prosthodontics for determining a reproducible mandibular position regardless of tooth position.[75,76] Perhaps most interesting is that the use of a SPT in removable prosthodontics consistently places the mandible in the most anterior and superior position while optimizing oral muscular stability for retention of removable dentures (Pound, 1077). This muscular stability would potentially translate to greater muscular tonus in the oropharynx and, if the oral structures were maintained in such a position, may translate into maintained oropharyngeal muscular tonus during sleep (decreased oropharyngeal muscular collapsibility during sleep)(Singh & Olmos, 2007). This would potentially mean that significantly less mandibular protrusion may be necessary in the use of dental sleep appliances for the management of OSA, thereby decreasing the incidence and severity of adverse effects commonly associated with dental sleep appliances. Primary research into this area of study should be conducted to determine whether a SPT should be considered as an alternative to an APT for determining the initial mandibular position for dental sleep appliances.

2.6 Conclusion

Minimal research exists on the use of a sibilant phoneme technique for mandibular positioning for dental appliances in the treatment of OSA. Furthermore, for this limited number of studies most are confounded by deliberate maxillary expansion as part of the treatment protocols within the study,

making direct comparisons with other mandibular positioning techniques for dental sleep appliances untenable. Because of the potential for a therapeutic outcome with minimal protrusion of the mandible and therefore much lower risk of developing common adverse effects associated with dental sleep appliances, further research should be conducted in this area.

2.7 References

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Chapter 3 – Comparing anterior protrusive vs sibilant phoneme for mandibular positioning for dental sleep appliances in managing obstructive sleep apnea: a two-cohort retrospective study

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Ng ET, Mayoral P, Hernandez IA, Lagravère MO. Comparing anterior protrusive with sibilant phoneme mandibular positioning techniques for dental sleep appliances in managing obstructive sleep apnea: A retrospective study. *J Dent Sleep Med*. 2021;8(1)

3.1 Summary

Title

Comparing Anterior Protrusive Mandibular With Sibilant Phoneme Mandibular Positioning Techniques for Dental Sleep Appliances in Managing Obstructive Sleep Apnea: A Retrospective Study

Objectives

The objective of this study is to compare the differences in mandibular protrusion between anterior protrusive mandibular and sibilant phoneme mandibular positioning techniques for dental sleep appliance therapy.

Methods

Three clinics in the United States and one clinic in Spain provided retrospective data from dental records on patients treated with either the anterior protrusive or sibilant phoneme technique for dental sleep appliances. Only patients with an apnea-hypopnea index (AHI) reduction to fewer than 10 events per hour and greater than 50% were included. Patient data from those treated with the sibilant phoneme technique were assigned to one group, whereas patient data from those treated with the anterior protrusive technique were assigned to another group.

Results

The two groups were statistically different in pretreatment (Pre-Tx) AHI. Because of the number of patients with severe obstructive sleep apnea (OSA) in the anterior protrusive group, subgroup analysis was used to compare only those patients with mild and moderate OSA. The sample size met the minimum requirements by power calculation. Patients treated with the sibilant phoneme technique had

less mandibular protrusion from habitual position compared to those treated with the anterior protrusive technique.

Conclusions

The study results suggest that the use of a sibilant phoneme technique is an alternative to an anterior protrusive technique for determining mandibular position due to decreased protrusion necessary to reach the same reduction in the AHI of patients with OSA.

Keywords: anterior protrusive; dental appliance; obstructive sleep apnea; sibilant phoneme

3.2 Introduction

Obstructive sleep apnea (OSA) is a medical condition characterized by the repetitive loss of upper airway patency via collapse of the pharyngeal segment while maintaining thoracic respiratory effort (Kapur et al., 2017). Although multifactorial, an essential component of this collapsibility revolves around anatomic impairment. Components involved in this impairment include the tongue, soft palate, pharyngeal walls, airway length and shape, craniofacial morphology, and hyoid bone position (Osman et al., 2018). Other factors involved in airway collapse include ineffective upper airway dilator muscles, unstable ventilator control, and low respiratory arousal threshold (Eckert, 2018). For this reason, the American Academy of Sleep Medicine (AASM) advocates for several different treatment options including weight loss, positive airway pressure, pharmacotherapy, dental sleep appliances, and surgical intervention (American Academy of Sleep Medicine [AASM], n.d.).

Although sleep physicians make diagnoses and direct treatment for OSA, dentists play a vital role due to expertise in the fabrication and treatment protocols related to dental sleep appliances (Gianoni-Capenakas et al., 2020; Ramar et al., 2015). These appliances work by advancing the mandible and tongue anteriorly and widening the velopharynx along the lateral walls, thereby working on the pharyngeal anatomic components in OSA (Brown et al., 2018; Burke et al., 2018; Chan et al., 2019; Ferguson et al., 2006; Hoekema et al., 2004; Juge et al., 2018; Ngiam et al., 2013). However, there are a number of generally accepted adverse effects associated with the use of dental sleep appliances and mandibular protrusion. These include dental occlusal changes, temporomandibular disorder, and craniofacial changes (de Almeida et al., 2002; Giannasi et al., 2009; Marklund et al., 2001; Minagi et al., 2018; Ramar et al., 2015; Sheats et al., 2017). The risk and magnitude of these side effects usually increase with increased apnea-hypopnea index (AHI) and increased mandibular protrusion, with protrusion beyond 50% of maximum generally correlating with significantly greater risk of side effects

(de Almeida et al., 2002; Ferguson et al., 2006; Kato et al., 2000; Minagi et al., 2018; Rose et al., 2002; Sheats et al., 2017; Walker-Engström et al., 2003). As well, craniofacial and occlusal changes continue over time with no defined endpoint independent of the type of dental sleep appliance used (Pliska et al., 2014).

Normal mandibular protrusion is, on average, between 9.86 to 13.09 mm with overjet being the primary method of measurement (Koolstra et al., 2001; Mayoral et al., 2019). This would imply that protruding the mandible greater than 4.93 to 6.55 mm would greatly increase the risk of side effects occurring with any dental appliance. For dental sleep appliances, mandibular protrusion is generally accepted to start at 50% to 70% of maximum protrusion, where the higher the value of AHI of the patient, the greater the mandibular advancement/protrusion generally necessary for treatment (Aarab et al., 2010; de Almeida et al., 2002; Gindre et al., 2008; Gupta et al., 2016; Minagi et al., 2018). However, recent research indicates that minimal protrusion may be sufficient for treatment of OSA by dental sleep appliances (Aarab et al., 2010; Anitua et al., 2017, Bartolucci et al., 2016; Nigam et al., 2013).

Phonetics and the sibilant phoneme have been used in prosthodontics for removable dentures since before the 1970s. The sibilant phoneme provides a reproducible position in three dimensions regardless of whether dentition is present or absent (Pound, 1977). This position also happens to be the most anterior superior position beyond which would interfere with speech and function (Pound, 1977; Singh & Olmos, 2007). To date, minimal research has been done to determine whether the sibilant phoneme would provide a meaningfully position for dental sleep appliance therapy.

The purpose of this study is to compare two different mandibular positioning techniques for dental sleep appliance therapy. It was hypothesized that the sibilant phoneme technique will require less mandibular advancement compared with the current anterior protrusive technique, which uses 50% to 70% initial protrusion. The significance of this research involves minimizing the risk of dental sleep appliance side effects to patients including craniofacial changes, TMJ dysfunction, and progressive occlusal changes.

3.3 Materials and Methods

This study was approved by Alberta Research Information Services: Human Research Ethics Board (Pro00088954).

Data Collection

Any patient not treated in accordance with AASM and American Academy of Dental Sleep Medicine (AADSM) guidelines was excluded from the study (Ramar et al., 2015). All patients must have OSA diagnosed by a physician, been treated with a custom and titratable dental sleep appliance and have had pre-treatment (pre-Tx) and posttreatment (post-Tx) sleep studies of level 3 or higher (Collop et al., 2007; Kapur et al., 2017).

For the study the definition of successful treatment for OSA was an AHI reduction of at least 50% and fewer than 10 events per hour (Mogell et al., 2019). Inclusion criteria required successful treatment of the patient's OSA by a dental sleep appliance and pre-Tx and post-Tx overjet and overbite positions or total change in overjet and overbite as measured by the treating clinical team. Other data collected included sex, age, body mass index (BMI), height, weight, ethnicity, other medical conditions, current medications, allergies, and signs and symptoms of pre-existing TMJ dysfunction and any changes to those conditions.

Based on the exclusion criteria and definition of successful treatment three practices providing dental sleep medicine treatment in the United States and one university/hospital research team in Spain agreed to participate. Retrospective data were collected during 2019 for patients previously treated by the clinicians for use in this project.

All clinicians who contributed data were either published researchers or board certified in dental sleep medicine. Detailed discussions with the individual clinicians indicated that all clinicians who provided patient data on the sibilant phoneme mandibular (SPM) technique followed the protocol published by Singh and Olmos whereas all clinicians who provided patient data on the anterior protrusive mandibular (APM) technique followed the protocol published by Mayoral et al. (Mayoral et al., 2019; Singh & Olmos, 2007). Although there were other clinicians who volunteered to provide patient data, their participation was declined due to either inability to confirm specific details on their SPM or APM technique or missing data points required for this project that they did not routinely collect or record into patient charts (including not recording pre-Tx or post-Tx AHI interpreted by a sleep physician (or equivalent) in the patient charts and keeping copies of the sleep reports where appropriate). All clinicians who contributed data to the project were provided with detailed instructions on the specific data points to extract from patient charts and a database into which to input the data points. All data provided were reviewed and patients that did not meet inclusion criteria (specifically, patients that did not have an AHI reduction of at least 50% and fewer than 10 events per hour) were removed. Because of the retrospective nature of

this study, requiring consecutive patient data from the participating clinics was not possible. General inclusion criteria for treatment included any patient that could be treated within AASM and AADSM treatment parameters. Dental measurements within each clinic were taken by a single clinician per clinic.

A total of 19 patients with SPM positioning were collected from the clinical teams in the United States and a total of 44 patients with APM positioning were collected from the research team in Spain that fell within the inclusion criteria. Based on discussions with the clinicians who provided their data for analysis, the APM position was obtained in accordance with previous research done by Mayoral et al. (2019). (Figure 3.1) whereas the SPM position was obtained in accordance with previous research done by Singh and Olmos (2007) (Figure 3.2). From data collected and discussions with the clinicians who provided data for analysis, patients were primarily treated with OrthoApnea (https://www.orthoapnea.com/en/) and Diamond Digital Sleep Orthotic (https://diamondorthoticlab.com/) dental sleep appliances.

Figure 3.1

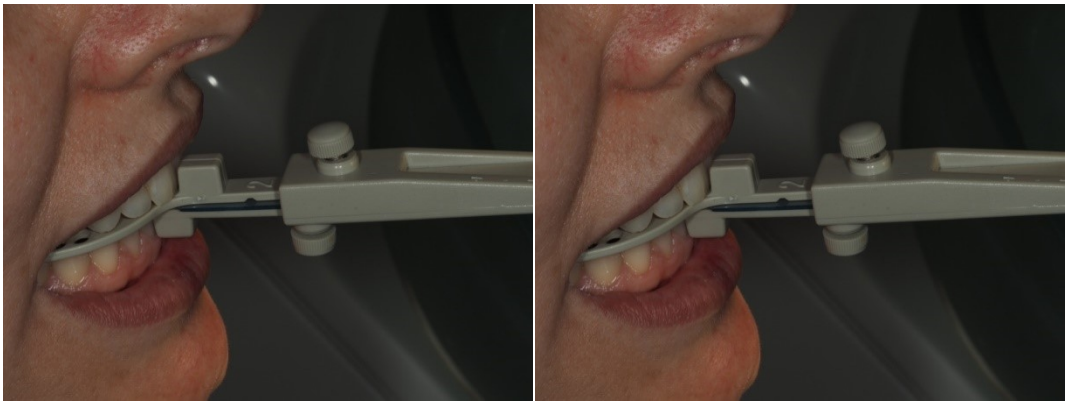


Image showing anterior protrusive mandibular positioning technique with a George Gauge. Reprinted from "Ng ET, Mayoral P, Hernandez IA, Lagravère MO. Comparing anterior protrusive with sibilant phoneme mandibular positioning techniques for dental sleep appliances in managing obstructive sleep apnea: A retrospective study. J Dent Sleep Med. 2021;8(1)" with permission.

Figure 3.2

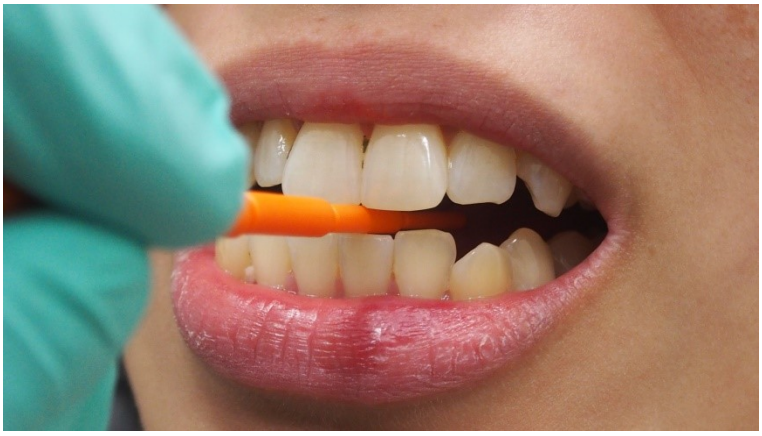


Image showing sibilant phoneme mandibular positioning technique. Reprinted from "Ng ET, Mayoral P, Hernandez IA, Lagravère MO. Comparing anterior protrusive with sibilant phoneme mandibular positioning techniques for dental sleep appliances in managing obstructive sleep apnea: A retrospective study. J Dent Sleep Med. 2021;8(1)" with permission.

Power Calculation

To determine the minimum per group sample size, we used the Massachusetts General Hospital Biostatistics sample size calculator (http://hedwig.mgh.harvard.edu/biostatistics/). The parameters were a quantitative parallel study with a two-tailed significance of 5%, power of 0.8, and difference in means of one standard deviation (Jain et al., 2015). The sample size necessary with these parameters was 34 (17 per group).

Statistical Tests

In analyzing the data, the Spearman correlation was used to test for correlations between continuous variables (for example, AHI and age). The Welch *t*-test was used to compare between groups due to group size differences and the inability to assume equal variances between groups. Descriptive statistics are provided, and subgroup analysis was also performed to separate patients with mild and moderate apnea from those with severe apnea within groups.

3.4 Results

Hypothesis

The primary comparative value in the study was the total change in overjet between the two treatment interventions. Therefore, the null hypothesis was that there would be no difference in total change in overjet between the SPM and APM techniques for mandibular positioning. Total change was understood to be the difference between pre-Tx overjet and post-Tx overjet.

Descriptive Data

Patient demographic information is provided in Table 3.1.

On average, patients were middle aged (45 to 65 years old) and overweight (BMI of 25 to 29 kg/m^2).

Table 3.1 Patient demographic information

	Sibilant Phoneme Cohort	Anterior Protrusive Cohort
Number of Patients (Sample Size)	19	44
Female: Male Participants	12:7	14:30
Average Age (years)	56.26	57.75
Average Height (centimeters)	170.41	172.07
Average Weight (kilograms)	75.47	75.50
Average body mass index	25.51	25.36

SPM Position

From data reported by the clinicians, in no patients did TMJ dysfunction symptoms (joint noises, myalgia/muscle pain) develop, nor were there any post-Tx limitations to mandibular range of motion. No patients found it necessary to temporarily halt treatment for any reason. One patient treated with the sibilant phoneme technique required jaw relaxation exercises (jaw opening exercises to stretch mandibular muscles) (Cunali et al., 2010; Ishiyama et al., 2017). Several patients had increased mandibular range of motion and/or reported reduced facial myalgia post-Tx.

APM Position

From data reported by the clinicians, three patients reported transient temporal myalgia, one patient reported transient masseteric myalgia, and two patients reported transient joint noises during treatment. All of these reported transient symptoms were resolved within 3 months of the start of treatment. In another two patients, prolonged masseteric myalgia developed that did not resolve within 3 months. Six patients reported pre-Tx temporal and/or masseteric myalgia that resolved during their treatment whereas one patient's reported temporal and masseteric myalgia did not resolve during treatment. In no patients did any post-Tx limitations to mandibular range of motion develop. Ten patients treated with the anterior protrusive technique required jaw relaxation exercises. Two patients temporarily halted treatment because of the development of symptoms. Several patients had increased mandibular range of motion and/or reported reduced facial myalgia post-Tx.

Statistical Analytics

Pearson's Correlation analysis was run across all patients to determine if pre-Tx AHI, change in AHI, and post-Tx AHI were significantly associated with age, gender, height, weight, and BMI as well as with pre-, mid-, and post-Tx TMJ dysfunction symptoms. Statistically significant associations were found between pre-Tx AHI and age ($r = 0.25$, $P < 0.05$) and BMI ($r = 0.25$, $P < 0.05$). Statistically significant associations were found between AHI reduction and BMI ($r = 0.26$, $P < 0.05$). No statistically significant associations were found between post-Tx AHI and age, sex, height, weight, BMI, and pre-, mid-, and post-Tx TMJ dysfunction symptoms. All statistically significant Pearson correlations were positive and moderate in value ($0.2 < P < 0.04$).

To determine whether the two samples were comparable, Welch *t*-test was performed to compare pre-Tx and post-Tx AHI between the two cohorts, respectively. Pre-Tx AHI was significantly different ($P < 0.001$), whereas post-Tx AHI was not statistically different ($P > 0.05$).

Review of the cohorts showed that although the SPM group had only two patients with an AHI within the severe criteria, the APM group had 15 patients with an AHI within the severe criteria. In accordance with AASM guidelines, the criterion for determining severe sleep apnea was an AHI > 30 events per hour. Therefore, subgroup analysis was performed excluding all patients with an AHI > 30 events per hour.

Subgroup Differences

Statistically significant differences were found between the two subgroups in pre-Tx TMJ dysfunction symptoms ($0.02 < P < 0.05$) and change in overjet ($P < 0.001$). SPM change in overjet averaged 3.86 mm whereas APM change in overjet averaged 8.41 mm. There were no other statistically significant differences between the two subgroups.

Summary of Statistics

Findings are summarized in Table 3.2. Subgroup findings are summarized in Table 3.3. Figure 3.3 depicts mandibular treatment position between the APM and SPM positioning techniques within the Posselt envelope of motion.

Table 3.2 Cohort statistics summary.[a]

	SPM Positioning	APM Positioning	Statistical Significance
Average age (years)	56.26 ± 15.23	57.75 ± 9.40	$P > 0.05$
Average height (cm)	170.41 ± 9.71	172.07 ± 8.58	$P > 0.05$
Average weight (kg)	75.47 ± 25.05	75.50 ± 14.58	$P > 0.05$
Male:Female ratio	7:12	30:14	$P > 0.05$
Average BMI	25.51 ± 6.12	25.36 ± 3.93	$P > 0.05$
Average Pre-Tx AHI	**17.28 ± 10.92**	**29.73 ± 17.72**	**$P < 0.001$**
Average Post-Tx AHI	3.72 ± 2.56	4.97 ± 2.51	$P > 0.05$
Pre-Tx TMJ dysfunction symptoms			**$0.03 < P < 0.05$**
Mid-Tx TMJ dysfunction symptoms			$P > 0.05$
Post-Tx TMJ dysfunction symptoms			$P > 0.05$
Use of jaw relaxation exercises			**$0.03 < P < 0.05$**

*[a]Statistically significant findings are **bolded**. Essentially, pre-Tx AHI was significantly higher in the anterior protrusive cohort compared to the sibilant phoneme cohort. More patients in the sibilant phoneme cohort reported pre-Tx TMJ dysfunction symptoms. Patients in the anterior protrusive cohort were more likely to use jaw relaxation exercises. SPM and APM positioning data on TMJ dysfunction symptoms and Jaw Relaxation Exercises were collected in binary categorical form (Yes or No) and therefore not included in the table.*

AHI, apnea-hypopnea index; APM, anterior protrusive mandibular; BMI, body mass index; Post-Tx, posttreatment; Pre-Tx, pretreatment; SPM, sibilant phoneme mandibular; TMJ, temporomandibular joint.

Table 3.3 Subgroup statistics summary.[a]

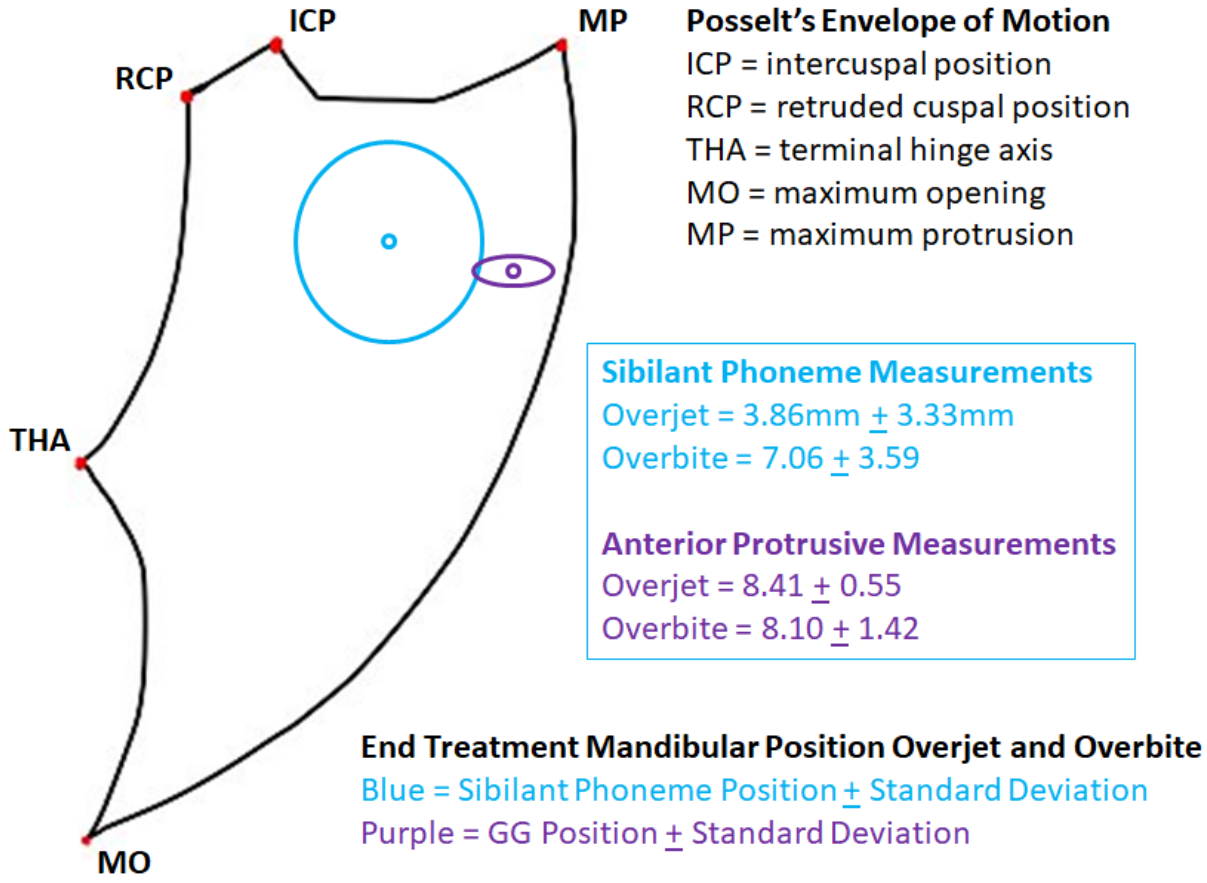
Subgroup statistics summary. [a]

	SPM Positioning	AMP Positioning	Statistical Significance
Average age (years)	54.65 ± 15.30	55.21 ± 9.04	$P > 0.05$
Average height (cm)	171.26 ± 9.73	171.07 ± 9.54	$P > 0.05$
Average weight (kg)	77.78 ± 25.52	71.69 ± 13.99	$P > 0.05$
Male:Female ratio	7:10	18:11	$P > 0.05$
Average BMI	26.03 ± 6.22	24.33 ± 3.50	$P > 0.05$
Average Pre-Tx AHI	14.95 ± 8.78	19.57 ± 3.86	$P > 0.05$
Average Post-Tx AHI	3.38 ± 2.47	4.52 ± 2.38	$P > 0.05$
Pre-Tx TMJ dysfunction symptoms			**$0.02 < P < 0.05$**
Mid-Tx TMJ dysfunction symptoms			$p > 0.05$
Post-Tx TMJ dysfunction symptoms			$p > 0.05$
Use of jaw relaxation exercises			$p > 0.05$
Average Δ overjet (mm)	**3.86 ± 3.33**	**8.41 ± 0.55**	**$p < 0.001$**
Average Δ overbite (mm)	7.06 ± 3.58	8.10 ± 1.42	$p > 0.05$

*[a]Statistically significant findings are **bolded**. Essentially, more patients in the sibilant phoneme subgroup reported pre-Tx TMJ dysfunction symptoms. Patients in the sibilant phoneme subgroup had significantly less changes in overjet compared to the anterior protrusive subgroup. SPM and APM Positioning data on TMJ dysfunction Symptoms and Jaw Relaxation Exercises were collected in binary categorical form (Yes or No) and therefore not included in the table.*

AHI, apnea-hypopnea index; APM, anterior protrusive mandibular; BMI, body mass index; Post-Tx, posttreatment; Pre-Tx, pretreatment; SPM, sibilant phoneme mandibular; TMJ, temporomandibular joint.

Figure 3.3



Pictorial representation of mandibular treatment position between the anterior protrusive and sibilant phoneme positioning techniques. Reprinted from "Ng ET, Mayoral P, Hernandez IA, Lagravère MO. Comparing anterior protrusive with sibilant phoneme mandibular positioning techniques for dental sleep appliances in managing obstructive sleep apnea: A retrospective study. J Dent Sleep Med. 2021;8(1)" with permission.

3.5 Discussion

Although the APM method has been taught and used extensively in dentistry for determining initial mandibular position for dental sleep appliances, recently published literature indicates other methods may provide similar clinical outcomes while potentially decreasing the risk of side effects associated with dental sleep appliances (Anitua et al., 2017; Bartolucci et al., 2016). We designed this study to investigate whether commonly used prosthodontic methods for determining mandibular position by use of an SPM technique would yield results similar to those of the APM method. Specifically, one goal of

the study was to determine whether the SPM technique would provide for a smaller change in overjet and overbite in comparison with the APM technique for mandibular positioning.

Because the two samples were not similar in pre-Tx AHI, likely due to the disparity in the number of patients with severe OSA, subgroup analysis to exclude patients with severe apnea was warranted. The reasoning for subgroup analysis was that previous research has indicated that the more severe the AHI, the greater the protrusion necessary for treatment efficacy using the APM method (Ferguson et al., 2006; Kato et al., 2000; Rose et al., 2002; Walker-Engström, et al., 2003). Therefore, any analyses run with unequal pre-Tx AHI would potentially compromise the purpose of the study.

Review of the subgroup analyses showed no statistical differences between the two subgroups in pre-Tx AHI and biographical data (age, sex, weight, height, BMI) and no difference in post-Tx AHI. This indicated that the subgroups were comparable, and that the two methods did not affect management of the patient's AHI. Furthermore, the sample size for both the cohorts and the subgroups met the minimum threshold as set by the power analysis. Based on this understanding and in review of the data showing a strong statistical difference in total overjet change between subgroups of the two interventions, the null hypothesis that there is no difference in total change in overjet between the SPM and APM techniques for mandibular positioning was rejected. The SPM technique requires less total change in overjet compared to the APM technique.

Other findings indicate minimally significant differences in AHI reduction outcomes between the two subgroups, though the difference between the two subgroups in pre-Tx TMJ dysfunction symptoms may warrant further investigation. The difference in use of jaw relaxation exercises, combined with no difference in post-Tx TMJ dysfunction symptoms, suggests the APM method may lead to greater transient TMJ dysfunction symptoms. However, the lack of difference in midtreatment (mid-Tx) TMJ dysfunction symptoms potentially contradicts this theory. Further research into this area is warranted.

The average post-Tx overjet for the APM method was 8.41 mm, whereas the average post-Tx overjet for the SPM method was 3.86 mm. The difference in final mandibular position between the two methods was, on average, 4.56 mm. Conservatively, the average end of treatment protrusion using the APM method was 64% whereas for the SPM method it was 29%, a difference in protrusive range of 35%. Because protrusion beyond the range of 4.93-6.55 mm (beyond 50% of protrusive range) greatly increases the risk of the development of side effects such as occlusal changes and TMJ dysfunction

symptoms, a difference of 4.56 mm in protrusion should be considered significant for dental sleep appliances. Table 3.4 explains these percentages.

Table 3.4 Summary of protrusion measurements.[a]

	Less Mandibular Protrusive Range	*Middle Mandibular Protrusive Range*	*Greater Mandibular Protrusive Range*
Normal mandibular protrusive range (mm)	9.86 mm	11.475 mm	13.09 mm
50% protrusion risk cutoff (mm)	4.93 mm	5.7375 mm	6.545 mm
Anterior protrusive position (mm)	8.41 mm	8.41 mm	8.41 mm
Anterior protrusive position (% of protrusion)	85.29%	73.29%	64.25%
Sibilant phoneme position (mm)	3.86 mm	3.86 mm	3.86 mm
Sibilant phoneme position (% of protrusion)	39.15%	33.64%	29.49%

[a]*Please refer to Figure 3.2 for reference points on mandibular motion and protrusion*

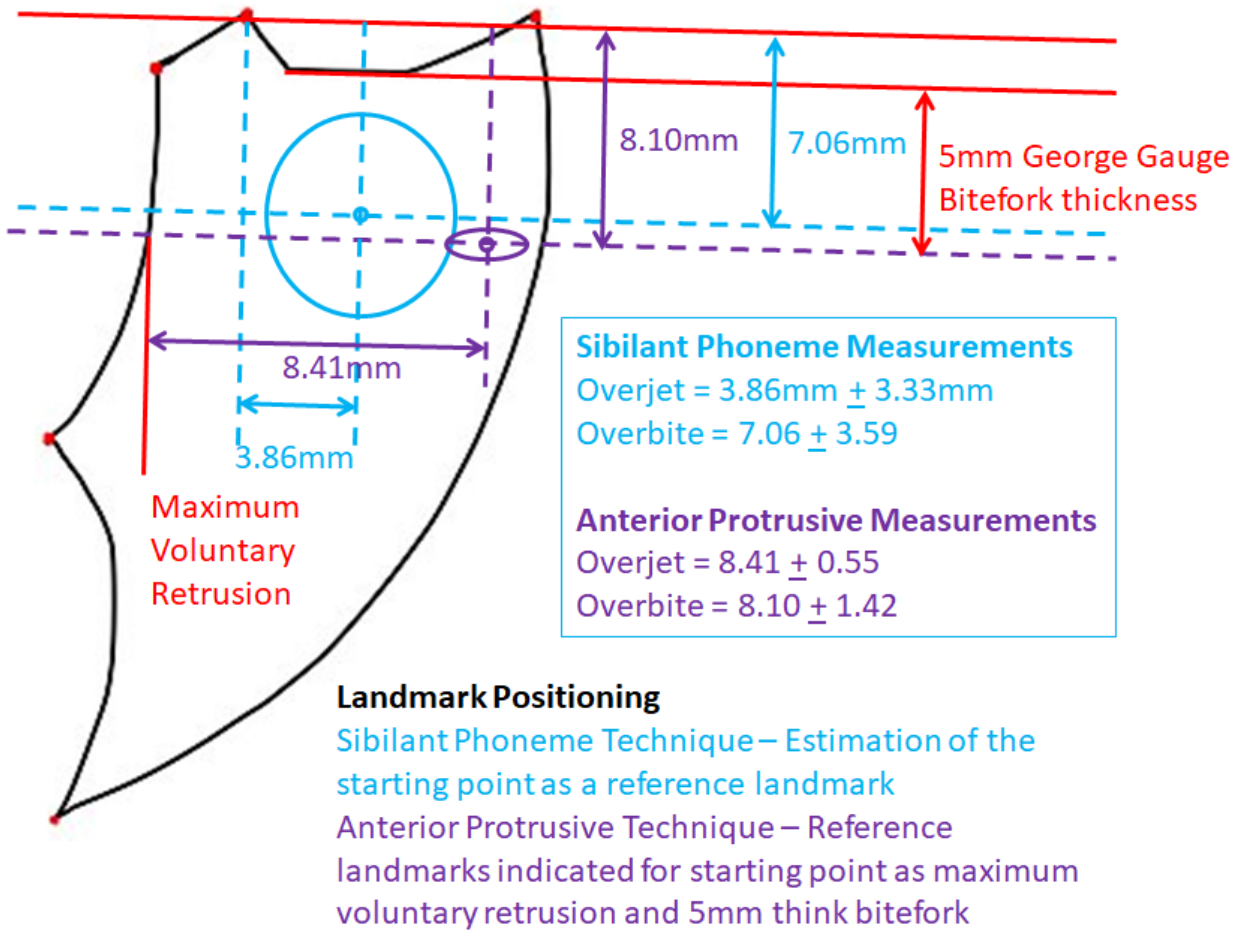
Informational References

- *Normal mandibular protrusive range of motion spans from 9.86 mm to 13.09 mm. (Koolstra et al., 2001; Mayoral et al., 2019). The greater the mandibular protrusion with prolonged use of dental sleep appliances, the greater the risk for side effects including craniofacial changes, temporomandibular disorder, and occlusal changes. Protrusion beyond 50% of maximum greatly increases the risk for side effects (de Almeida et al., 2002; Ferguson et al., 2006; Kato et al., 2000; Minagi et al., 2018; Rose et al., 2002; Sheats et al., 2017; Walker-Engström et al., 2003).*
- *Occlusal changes from the use of dental sleep appliances are progressive in nature with no defined endpoint in treatment (Pliska et al., 2014).*

Such a decrease in overjet could significantly decrease the risk of TMJ dysfunction side effects commonly associated with the use of dental sleep appliances. The study results suggest that the use of a SPM technique compared to the APM technique may be able to achieve similar clinical efficacy in managing the AHI in a patient with OSA while also potentially providing a mandibular position with decreased risk of the development of TMJ dysfunction symptoms and occlusal changes commonly associated with the use of dental sleep appliances.

However, recently published literature also notes that there can be significant variability in overjet measurements when using different landmarks for starting position. A recent study has shown the difference between habitual bite position and maximum voluntary retrusion, as a starting point when assessing mandibular advancement when using the George Gauge, yields an overjet difference of 4.81 $\pm$ 1.75 mm (Ippolito et al., 2020). This may explain discrepancies between the results of previous studies. Another recent study has indicated that the SPM technique uses different landmarks than the habitual bite position or maximum voluntary retrusion used with the APM technique (Viviano et al., 2022). To date, no studies have directly compared the landmarks used for starting points neither between the techniques nor for their corresponding overjet and overbite measurements. Research on the effects of mandibular position and changes in landmarks may provide insight into some of this variability. Although changes in overbite in the study were not statistically significant, overbite with the SPM method was on average 1.04 mm smaller. Changes in mandibular vertical position (overbite) significantly affect landmark position, with a change of 3 mm in vertical position leading to a 2- to 3-mm change in horizontal (overjet) landmark location (Mayoral et al., 2019). An estimation of these effects on position between the two techniques is illustrated in Figure 3.4. This difference in reference landmarks may account for some of the variability found in the technique comparison outcomes. Further investigation is required to determine how much variability between the SPM and APM techniques and measurements may be from differences in landmarks.

Figure 3.4



Pictorial representation of the sibilant phoneme mandibular and anterior protrusive mandibular landmarks overlapped with Posselt envelope of motion. "Ng ET, Mayoral P, Hernandez IA, Lagravère MO. Comparing anterior protrusive with sibilant phoneme mandibular positioning techniques for dental sleep appliances in managing obstructive sleep apnea: A retrospective study. J Dent Sleep Med. 2021;8(1)" with permission

There are significant differences in the effort and materials required between the APM and SPM techniques. Although the APM technique requires a protrusive gauge of some sort, the SPM method requires the use of a round bite stick or similar object (a microbrush, thin round wooden dowel, or tri-syringe/air-water syringe tip are all acceptable). The protrusive gauges necessary for the APM technique have a range of costs, some with an initial cost of $100 and a per-impression cost of $1.00 per bite fork, whereas other gauges are single use and cost approximately $100 each. For the APM technique, most protrusive gauges have set vertical (overbite) dimensions (George Gauge bite forks are 2 mm and 5

mm). For the SPM technique, vertical dimension can be set at whatever bite stick thickness the clinician has on hand. In both techniques, the accuracy of the bite registration is critical to successful treatment. However, the SPM technique has a greater learning curve and is more prone to error for the inexperienced clinician. These differences may explain why the APM method is much more popular and well known among dental practitioners.

The results of the current study should be viewed with caution because of several limitations. One of the primary limitations of the study was the large differences in sample size between the two samples. This difference was addressed as adequately as possible statistically and in subgroup analysis. Another significant limitation was the retrospective nature of the study, meaning no evaluation for both inter-operator and intraoperator primary data point measurement (in reference to overjet and overbite) variability was possible (as previously mentioned, intraoperator self-evaluation for measuring overjet and overbite is not routinely done in clinical private practice; this makes calculating intraoperator kappa impossible for this study). Other limitations include potential interoperator patient inclusion criteria variability, nonsequential nonrandomized patient selection, differences and variability between the sleep physicians who diagnose OSA and the AHI/respiratory disturbance index values, night-to-night variability within patient sleep testing, potential patient selection bias, limited prior published research with which to establish baseline protocols, differences in dental sleep appliances and patient variability and tolerance with different dental sleep appliances, differences in equipment, differences in treatment teams, and potentially the use of only 5-mm bite forks for the George Gauge. Any conclusions drawn from this study should account for these limitations and should be further investigated with future prospective randomized trials. However, the data and results in our study indicate that the sibilant phoneme method for mandibular positioning for dental sleep appliances warrants further study and that the study provides a foundational stepping stone upon which future research can be built. Future studies should investigate this relationship in a prospective fashion and the differences between the APM and SPM methods on total oral volume and on mandibular position using a three-dimensional approach.

3.6 Conclusions

The study results suggest that the use of a sibilant phoneme technique is an alternative to an anterior protrusive technique for determining mandibular position due to decreased protrusion necessary to reach the same reduction in the AHI of patients with OSA. This decreased protrusion necessary for

treatment may decrease the risk of the development of TMJ dysfunction (facial myalgia/muscle pain, joint noises, and joint pain) and occlusal/bite changes, among other side effects, with the use of dental sleep appliances. Further research into the use of the sibilant phoneme technique for dental sleep appliances is warranted.

Acknowledgements

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Figure Legend

Figures are best viewed in color

Figure 3.1 Image showing anterior protrusive mandibular positioning technique with a George Gauge (Mayoral et al., 2019). George gauge maximum retrusion and maximum protrusion is shown. Absolute range of maximal mandibular retrusion (left) and protrusion (right) are measured (in mm) with the George Gauge. Mayoral, P., Lagravère, M. O., Míguez-Contreras, M., & Garcia, M. (2019). Antero-posterior mandibular position at different vertical levels for mandibular advancing device design. *BMC Oral Health*, *19*(1), 85 (Mayoral, et al., 2019).

Figure 3.2 Image showing sibilant phoneme mandibular positioning technique (Singh & Olmos, 2007).

Figure 3.3 Pictorial representation of mandibular treatment position between the anterior protrusive and sibilant phoneme positioning techniques. Posselt envelope of motion with treatment positions and their standard deviations are indicated on the diagram. ICP is where all the teeth bite together comfortably. RCP is the furthest back a person can retrude their bottom jaw without any major effort to open the mouth. MP is the maximum distance a person can push their bottom jaw out and forward. MO is the position the bottom jaw is in when a person opens mouth as wide as possible. THA is the position of the bottom jaw when a person is only rotating their jaw open. Information modified from Koolstra et al., 2001. The three-dimensional active envelope of jaw border movement and its determinants. *J Dent Res*, *80*, 1908–1912 (Koolstra et al., 2001).

Figure 3.4 Pictorial representation of the sibilant phoneme mandibular and anterior protrusive mandibular landmarks overlapped with Posselt envelope of motion. Estimation of the effect of differences in positioning and landmark reference points. Changes in mandibular vertical position (overbite) correlate with increased maximum voluntary retrusion due to posterior rotation of the mandible. The difference of maximum voluntary retrusion between using a 2-mm and 5-mm George Gauge bite fork is 1.2 mm on average (Mayoral, et al., 2019). The anterior protrusive technique for dental sleep appliances is most reliably taken from maximum voluntary retrusion (Ishiyama et al., 2017). There is currently no literature comparing the sibilant phoneme technique starting point to maximum voluntary retrusion. This figure is meant as an illustration explaining the variability in measurements between

the landmarks and starting points for the sibilant phoneme and anterior protrusive techniques and may not be to scale.

Chapter 4 – Development and initial validation of a questionnaire to measure patient experience with oral appliance therapy

 A version of this chapter has been published as https://jcsm.aasm.org/doi/10.5664/jcsm.10562

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4.1 Summary

Study Objectives:

To develop and validate a questionnaire to measure patient experience with oral appliance therapy.

Methods & Results

The AMEE Guide No. 87 was followed in the development and validation of a patient questionnaire to assess patient experience with oral appliance therapy.

Conclusion:

The creation and validation of a questionnaire to assess patient experience with oral appliance therapy may provide new methods for advancing research in the field of dental sleep medicine.

Brief Summary

Understanding patient experience is a vital component of the treatment of any medical condition. Obstructive sleep apnea is a medical condition where one of the primary treatments includes oral appliance therapy. Assessing patient experience in oral appliance therapy for the treatment of obstructive sleep apnea is a relatively overlooked component in patient care. The creation of a validated questionnaire to measure patient experience with oral appliance therapy will allow for advancement in dental sleep medicine patient care. This questionnaire can be used to gain a greater understanding of patient experience with oral appliance therapy with long term improvement to patient care through improved patient adherence to treatment, improved self-management skills, and stronger patient-doctor relationships with resultant more continuous care.

Keywords

Dental Sleep Medicine, Oral Appliance Therapy, Obstructive Sleep Apnea, Patient Experience

4.2 Introduction

Obstructive sleep apnea (OSA) is a medical condition characterized by partial or complete blockage of respiration in the upper airway during sleep. OSA affects approximately 1 billion people globally and is associated with other medical conditions such as hypertension, diabetes, and daytime sleepiness (Anker et al., 2016; Frost & Sullivan, 2016a, 2016b; Wang et al., 2013). Although there are multiple treatments for OSA, the American Academy of Sleep Medicine (AASM) recommends positive airway pressure (PAP) therapy and oral appliance therapy (OAT) as the main treatment options (Patil et al., 2019; Ramar et al., 2015; Veasey et al., 2006). PAP therapy entails the use of positive airway pressure to generate a pneumatic splint within the upper airway, preventing its collapse during inspiration. OAT, however, aims to hold the mandible in a forward position to increase the volume and reduce collapsibility within the upper airway while also helping keep the tongue from falling back into the upper airway. Both PAP therapy and OAT have been shown to improve treatment outcomes such as disease management and quality of life (Chan & Cistulli, 2009; Sutherland et al., 2015).

Prior studies on treatment outcomes of PAP therapy and OAT have been quantitative in nature and have focused on clinical efficacy and patient safety (Cronin et al., 2019; Nordin et al., 2016; Saglam-Aydinatay & Taner, 2018). Patient experience with these therapies, especially for OAT, has been relatively overlooked (Asadi-Lari et al., 2004; Cronin et al., 2019; Nordin et al., 2016; Saglam-Aydinatay & Taner, 2018). This experience is vital to understand the manifestation of a condition, treatment outcomes and characteristics of the care received (e.g., satisfaction with treatment, quality, accessibility to care), and patient engagement in services (e.g., compliance with treatment)(Ahmed et al., 2014). Assessing patient experience is challenging as it includes the experiences of patients with conditions and services, the identification of salient aspects of the service(s) under consideration, and the collection and integration of quantitative and qualitative data to comprehensibly evaluate experience-related outcomes (Beattie et al., 2015; Rand et al., 2019).

The assessment of patient experience with PAP therapy and OAT is particularly challenging because these therapies have several methods of deployment. PAP therapy can be delivered through different pressure settings such as bilevel pressure and autotitrated pressure and across different delivery masks such as nasal masks, oral masks, and oronasal masks. OAT may be customized in terms of fit and form, and different techniques may be used for mandibular positioning and titration/adjustment. Patient experience, quality of life, and satisfaction with services have been fairly studied in the context of

treatments for OSA, especially PAP therapy (Apergis et al., 2021; Choi et al., 2011; Douglas & Engleman, 1998; Hilbert & Yaggi, 2018; Nordin et al., 2016; Otsuka et al., 2020; Saglam-Aydinatay & Taner, 2018; Skalna et al., 2019; Tegelberg et al., 2012; Ulfberg et al., 1999). Prior studies on this therapy, including different pressure and mask delivery modalities, has shown that patient satisfaction and adherence to treatment significantly improves symptom resolution and that nasal masks are preferred over oral masks for treatment delivery (Blanco et al., 2018, 2019; Rowland et al., 2018). Preliminary PAP and OAT studies have reported that numerous treatment-related factors, including perceived efficacy, side effects, outcomes, portability, ease of use, and cost can shape patient experience and treatment choices (O'Beirne, 2017). Particularly, studies in OAT have shown that characteristics of the appliance design, symptom resolution, and technical factors (e.g., titration methods, attachment components) may influence treatment success (e.g., clinical efficacy, perceived effectiveness, patient adherence, absence of side effects); however, there is a lack of universally accepted criteria for treatment success and validated means to examine patient experiences in OAT (Ahrens et al., 2010; Balevi; 2014; Ishiyama et al., 2019).

Prior studies suggest that different techniques and appliances used in OAT may positively affect patient safety and satisfaction by decreasing the risk of developing side effects (e.g., decreased mandibular protrusion) with oral sleep appliances (Sheats et al., 2017; Ng et al., 2021). However, to our knowledge, there has not been any published research assessing patient experience with different methods of delivering OAT. Research on this issue requires the development and validation of tools to measure potential differences in patient experiences across delivery methods. The development of these tools is vital to advancing the field of dental sleep medicine. Greater insight into patients' experiences may help improve patients' acceptance of OAT, satisfaction and compliance with this treatment, and quality of life.

4.3 Objective

To develop and validate a questionnaire to measure patient experience with OAT.

4.4 Materials and Methods

Design

The AMEE Guide No. 87 was followed to develop and validate a questionnaire on patient experience within OAT (Artino et al., 2014). This guide was selected because it incorporates the feedback of patients and experts into the process of developing and validating a questionnaire. This process encompassed

the following phases: literature search, interviews with existing patients, synthesis of information, question development, expert validation, cognitive pretesting, pilot testing, and final expert review.

Literature Search

A computer assisted literature search was done on the databases PubMed, Ovid Medline, and Scopus to identify articles related to patient experience and preference between and within different treatment methods for OAT. Search terms used to identify relevant articles were derived from the relevant literature and included “obstructive sleep apnea”, “patient satisfaction”, “mandibular advancement”, and non-MeSH terms “oral appliance therapy”, “patient experience”, and “protocol”. The search terms and strategy were adapted to each database.

Patient Interviews

Five patients previously treated with OAT were individually interviewed after obtaining their consent. Interview questions elicited patients’ experiences with OAT and the services received to manage their OSA. Examples of interview questions included: “what did you feel was the most important part of your care?”, “what did you like about your care?”, “What didn’t you like about your care?”, “if you could change anything about the care you received, what would it be?”. All interviews were conducted in a conversational manner by EN, a board-certified dental sleep medicine practitioner and diplomate of the American Board of Dental Sleep Medicine. Interviews were conducted by phone and lasted approximately 30 minutes. Note taking was used to collect interview data. This means of data collection was chosen to prevent patients from altering their accounts as a result of being recorded and due to the short duration of the interviews. It was assumed that after receiving treatment, patients may be inclined to positively review the services received especially if being recorded. Interview notes were analyzed using manifest content analysis (Kleinheksel et al., 2020). Relevant data were coded by EN and codes were sorted into categories and sub-categories or aspects of categories.

Synthesis of Information in Construct Definition

Based on the results on the literature search and patient interviews, relevant dimensions and aspects of patient experience within OAT were defined. Dimensions referred to salient components of the construct under consideration that seem to be sufficient to describe, understand, and measure the construct. Aspects were elements of the identified dimensions that further enhance their description, understanding, and measurement.

This construct definition process was conducted to attain content validity. Combining the literature review and feedback from existing patient interviews ensured that the defined construct covered all characteristics of patient experience in relation to OAT to allow for the development of a tool to appropriately measure patient experience in relation to OAT.

Questionnaire Development

Dimensions and aspects of the construct were considered for question development. Questions were generated to collect data on the aspects included in each dimension of patient experience with OAT. Questions were shared with sleep medicine practitioners (subject experts) who were selected based on their clinical expertise. All were board certified with the American Board of Dental Sleep Medicine. These experts were asked to provide feedback on the questions regarding clarity (degree to which each item is understandable and properly worded), sequence (degree to which items are properly organized within the questionnaire), and relevance (degree to which each item is important/necessary to measure the dimension of the construct it is intended to measure).

Expert Validation

A five-person expert panel made up of individuals with expertise in tool development and patient experience was assembled to assess the questionnaire developed in the previous phase and to further ensure content validity regarding patient experience. Panelists were doctors in Educational Psychology, Methodology, Statistics, and Dentistry all with ongoing academic institutional involvement in research and teaching. These panelists were also instructed to provide feedback on clarity and sequence of the developed questions and to rate the relevance of question as follows: “essential”, “useful”, or “not useful”. A standardized tool was used to obtain the panelists’ feedback on the questionnaire (Table 4.1). Disagreements in feedback between members of the panel resulted in rewording and/or alterations of the questionnaire until satisfaction by all panel members was achieved.

Cognitive Pretesting

To ensure appropriate interpretation of the questionnaire by non-experts (response process validity), cognitive pretesting was performed with individuals without advanced dental knowledge, expertise in survey development, or history of treatment with OAT nor medical history positive for OSA. Pre-

determined codes for common errors including requests for clarification, rewording suggestions, and an "other" category were used to classify responses from during cognitive pretesting.

Pilot Testing

The written, self-administered questionnaire was pilot tested with five patients who had successfully completed dental sleep appliance therapy within the last year to test for credibility and dependability validity evidence. All patients had been diagnosed by a sleep specialist with moderate or severe OSA and were treated in Canadian health institutions in accordance with American Academy of Dental Sleep Medicine guidelines. Patients were asked to complete the questionnaire by rating the questions included and to comment on their understanding of the questions. A standardized tool for pilot testing feedback was provided to allow for structured evaluation of the questionnaire (Table 4.2).

Final Expert Panel Review

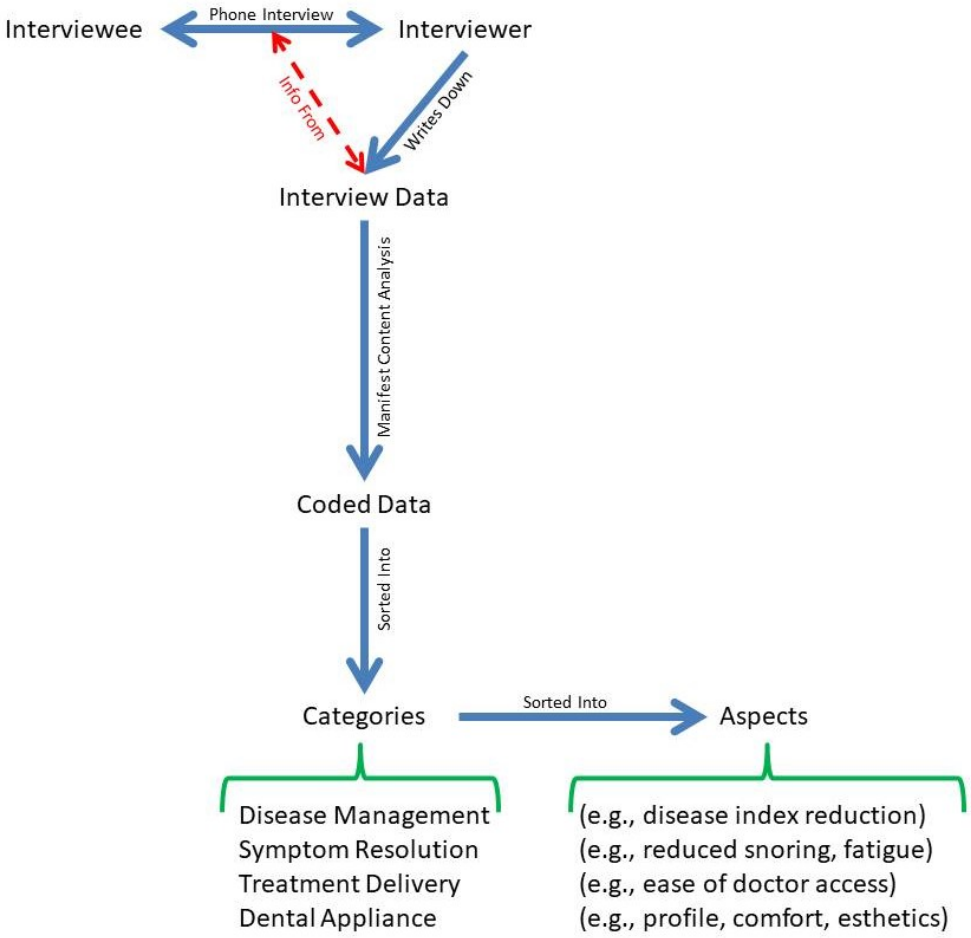
The finalized questionnaire was reviewed by both the dental sleep medicine subject experts and the tool development experts to assess whether the additional changes negatively affected the validity of the questionnaire. These experts were asked to provide general comments on this issue if necessary.

4.5 Results

Our search identified 522 articles on symptom, management, and outcome measures for OSA as well as quality of life of patients living with this condition. Five of these articles described the use and/or validation of questionnaires to measure changes in symptoms and patient reported outcomes in the treatment of OSA. None of these articles reported the use of a validated questionnaire nor provided validity evidence for the questionnaires used to assess patient experiences in dental sleep medicine with OAT.

Five patients participated in the patient interviews. Based on the manifest content analysis of the interview notes, patients' comments were grouped into several categories. These categories were related to disease management, symptom resolution, treatment delivery, and their experience with the specific appliance for OAT (Figure 4.1).

Figure 4.1

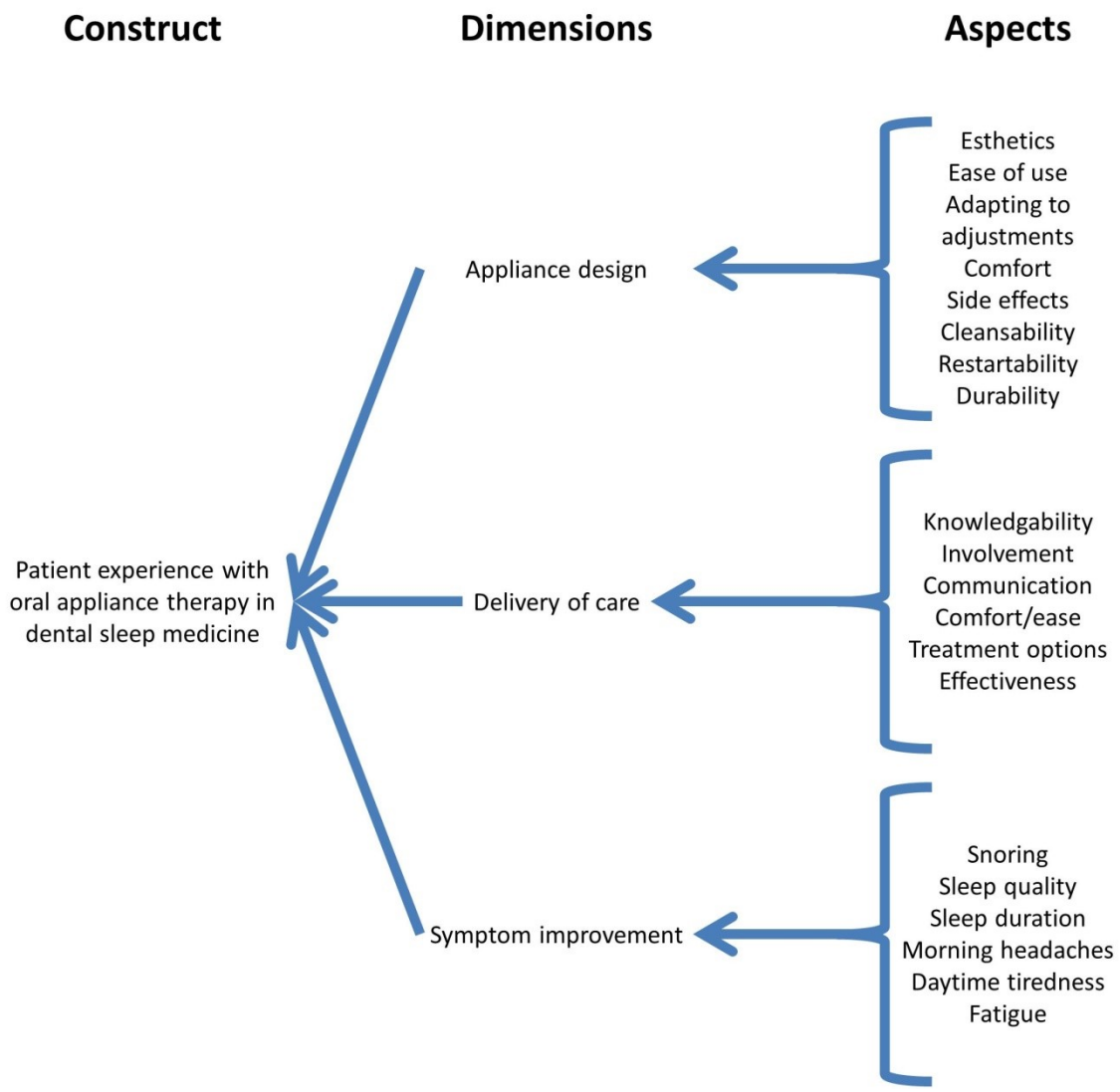


Breakdown of the data gathering and sorting process from interview to categorization. Reprinted from "Ng ET, Perez-Garcia A, Lagravère-Vich MO. Development and initial validation of a questionnaire to measure patient experience with oral appliance therapy [published online ahead of print, 2023 Apr 21]. J Clin Sleep Med. 2023;10.5664/jcsm.10562. doi:10.5664/jcsm.10562" with permission

The construct of patient experience was divided into three dimensions: symptom improvement, appliance design, and delivery of care. Numerous validated tools to measure symptom reduction for OSA were available in the literature (*e.g.,* Epworth Sleepiness Scale for daytime sleepiness, Fatigue Severity Scale for fatigue, Sleep Apnea Quality of Life for quality-of-life improvement). However, the literature search revealed a lack of validated tools for measuring patient experience with appliance

design and care delivery in OAT. No tools for measuring all three dimensions of patient experience synchronously were identified from the literature search and patient interviews (Figure 4.2).

Figure 4.2



Breakdown of dimensions and their associated aspects used in defining the construct of patient experience with oral appliance therapy in dental sleep medicine. Reprinted from "Ng ET, Perez-Garcia A, Lagravère-Vich MO. Development and initial validation of a questionnaire to measure patient experience with oral appliance therapy [published online ahead of print, 2023 Apr 21]. J Clin Sleep Med. 2023;10.5664/jcsm.10562. doi:10.5664/jcsm.10562" with permission

Initial feedback from subject experts noted that questions to objectively assess symptom improvement were unnecessary due to the availability of validated tools (e.g., the Epworth Sleepiness Scale and Fatigue Severity Scale). Similarly, the development of questions to measure disease index reduction was regarded unnecessary as disease index reduction for OSA is measured objectively by sleep testing (e.g., Braebon Medibyte Home Sleep Apnea Test, Remmers Home Sleep Apnea Test, WatchPAT One Home Sleep Apnea Test). However, the development of questions for subjectively measuring symptom improvement was deemed necessary, along with questions to evaluate delivery of care and experiences with the actual dental appliance. Based on the subject experts' feedback, several questions were reworded and/or expanded to ensure complete coverage of all aspects related to the three dimensions related to OAT and to ensure technical accuracy. For example, the question/statement "Discussion of treatment options including alternatives, risks and benefits" was reworded as "The clinician discussed with me alternative dental related treatments, risks, and benefits".

A total of twenty-seven questions were developed. Eleven questions were related to the dimension of appliance design (e.g., Adjustments made to the appliance are easy to adapt to), eight questions were related to the dimension of delivery of care (e.g., The clinician involved me in the decision-making process), and eight questions were related to symptom improvement (e.g., I feel that my sleep quality is better). The questions were grouped by dimension and ordered from specific (e.g., The clinician's communication was clear and understandable) to general (e.g., I am satisfied with the treatment overall). A 10-point numeric scale was included for respondents to rate their experience in relation to each question. This type of scale is commonly used to examine individuals' perceptions and experiences. All questions also had comment boxes to allow respondents to elaborate on their ratings.

Based on expert panel feedback, the general format of the questionnaire was modified (e.g., orientation was changed from portrait to landscape; instructions for respondents were reworded to improve clarity). The ten-point numeric scale for each question was replaced for a five-point Likert scale ranging from "poor" to "excellent" as suggested by these experts. One question within the appliance design ("Adapting to the appliance is easy") dimension was split into two questions ("It is easy adapting to using the appliance" and "Adjustments made to the appliance are easy to adapt to") to ensure that each question referred to only one aspect of patient experience. Several other questions were reworded for clarity and reading level. All questions were also reformatted to be affirmative statements (e.g., "Sleep quality" to "I feel that my sleep quality is now better"). No questions were removed from the

questionnaire. The questionnaire was confirmed to be below a grade 8 reading level through the Flesch-Kincaid Grade Level test.

In the cognitive pretesting, none of the four respondents suggested further modifications to the questions included in the questionnaire. For example, one respondent commented that “the questionnaire was formatted cleanly, clearly, in a user-friendly manner, and that each question was easily understandable”.

Five patients participated in pilot testing. Three patients were female and two were male ranging in age from 33 to 71 years. Patients’ feedback from pilot testing was analyzed to determine whether their understanding of each question matched the dimension and aspect of patient experience it was intended to measure. Based on this feedback, two questions were added to the symptom improvement dimension (“My snoring is less frequent” and “I experience less frequent morning headaches”) and one question was added to the appliance design dimension (“The appliance is easy to keep in throughout the night”) for clarity. Several questions were also reworded to enhance clarity. For instance, “The sleep appliance is esthetically acceptable” was worded as “The sleep appliance is cosmetically acceptable when I look at it”. No questions were removed as no questions were deemed irrelevant through patient feedback.

Final review of the questionnaire by the exert panel yielded no new changes to the improved version of the questionnaire. All reviewers were satisfied with the developed version of the questionnaire. (Figure 4.S1).

4.6 Discussion

This study aimed at developing a validated questionnaire to measure patient experience within OAT following The AMEE Guide No. 87. Understanding patient experience is vital to improve overall patient care, including treatment adherence, quality of life, and health outcomes (Bombard et al., 2018; Doyle et al., 2013; Luxford & Sutton, 2014; Schwartz et al., 2020). Our data suggest that a comprehensive measurement of patients’ experiences with OAT should consider at least three main dimensions: symptom improvement, appliance design, and delivery of care. This represents an important contribution to the literature as patient experiences with different techniques of delivering OAT have been largely neglected.

Patient experience with symptom improvement, which is usually the primary reason for seeking treatment, may influence patients' adherence to OAT (Tallamraju et al., 2021). Symptom improvement may also enhance quality of life through decreased snoring resulting in co-sleeping with a bedpartner, morning headaches resulting in decreased pain and improved concentration, and daytime sleepiness resulting in improved productivity and enjoyment of life. Available questionnaires also include symptom improvement as a relevant dimension of patient experience. These questionnaires are often administered several times to allow for the measurement of changes in symptomology throughout the course of a treatment, including the follow-up phase. For example, the Night Time Sleepiness Evaluation, Epworth Sleepiness Scale and the Berlin Questionnaire include OSA-related symptoms such as nodding off and falling asleep while driving. The STOPBANG and Berlin questionnaire both have questions pertaining to loud snoring. The Sleep Apnea Quality of Life Index has questions specific to the impact of symptoms on quality of life such as "how upset have you been about being told that your snoring was bothersome or irritating?" and "how much concern have you had about the need to make special sleeping arrangements if you were traveling and/or staying with someone?".

Patient experience with appliance design is vital to patient comfort and long term adherence. Patients who are uncomfortable with the use of the appliance are unlikely to use the appliance.[40] Appliances that are difficult to clean may accumulate debris and odor that make a patient uncomfortable with continued use of the appliance over the long term. Appliances that are unaesthetic may hinder patient use if social concerns arise about its cosmetic appearance to potential partners or friends. For example, appliances that have a similar appearance to a night guard may be more acceptable for patients who frequent social gatherings overnight including camping outdoors or traveling to conferences with a roommate. The experiences with clinical procedures and interventions have also been included as a relevant dimension of patient experience in previous questionnaire. For example, Rustemeyer et al.'s post-surgical patient satisfaction questionnaire evaluates patient experience after orthognathic surgery and includes questions such as "How do you feel about the surgical outcome of your operation?" and "how would you assess your chewing function today?" (Rustemeyer et al., 2010). The Post-Operative Quality of Life Questionnaire has also been used to evaluate patient experience with upper airway surgical procedures for OSA. Questions related to this dimension include "How would you assess your post-operative physical OSAS symptoms, if any such as breathing, frequent colds, tiredness etc.). Better than the pre-operative period?" and "How would you assess your post-operative quality of sleep? Better than the pre-operative period?".

Patient experience with delivery of care is vital for patients' understanding of their diseases and long-term adherence to treatment. Patients who understand the direct and long term consequences of their disease are more likely to demonstrate better self-management skills and greater adherence to care.[158] Patients who are able to build relationships with excellent communication and comfort with their healthcare practitioners are less likely to change between healthcare practitioners and therefore maintain more continuous rather than disrupted care. Similarly, patients who are empowered to learn about and choose their own treatment form from multiple treatment options are more likely to adhere to treatment long term (Fortuna et al., 2018; Losi et al., 2021). Existing questionnaires have also included the experience of care delivery as a relevant dimension of patient experience. For example, the self-administered patient experience questionnaire to assess lifestyle services focuses heavily on access, communication, and trust (Brauer et al., 2018). Questions related to this dimension in this questionnaire include "how often did the team members explain things to you in a way that you clearly understood?", "how often did the team members treat you with courtesy and respect?", and "how did you access this service?". Likewise, the PSQ-18 also has questions related to access, communication, and trust (Marshall & Hays, 1994). These questions include "I am able to get medical care whenever I need it", "my doctors treat me in a very friendly and courteous manner", "I think my doctor's office has everything needed to provide complete medical care", and "doctors are good at explaining the reason for medical tests".

Patient self-report is important in gaining information related to patient experience. The use of validated questionnaires allows for appropriate collection of relevant and robust data for the proper measurement of patient experience (Ahmed et al., 2014; Artino et al., 2014; Berkowitz, 2016; Lees, 2011). Despite limitations in universally accepted best practices for survey development (Sullivan, 2011) (e.g., response rates, appropriate response anchors, appropriate target population), comprehensive and transparent survey designs informed by the feedback of content-area experts, methodologists, patients, and other stakeholders (e.g., caregivers, care providers) can provide a clear understanding and validity evidence of the construct of interest (Artino et al., 2014). The lack of existing validated tools to measure patient experience within OAT to address OSA highlights the need for instrument validation in this area.

Despite the rigorous process in the development of this questionnaire, several limitations should be acknowledged. The scoping review was limited specifically to OAT and did not include comprehensive searches for other treatments related to OSA. Patient interviews were not recorded. Due to the limited number of experts available for expert validation calculating a content validity ratio, content validity

index, or factor validity index was not possible. As well, pilot testing was done with a limited number of patients. Large scale pilot testing in future use of this questionnaire may be beneficial in gaining data to assess item score correlations, measure unidimensionality through factor analysis, and evaluate the relationships of specific aspects with tools previously developed to evaluate those specific similar/related aspects of patient experience.

Despite these shortcomings, this questionnaire can be used to evaluate patient experience with OAT for research and clinical purposes. The salient dimensions identified in our study can be measured in isolation or combined for a global measurement. The questionnaire can be used to compare patient experience between different sleep appliances, different dental sleep medicine practitioners, and different mandibular titration techniques.

4.7 Conclusion

This paper described the development and initial validation of a questionnaire to measure patient experiences with OAT using the AMEE Guide No. 87. Based on the validity evidence obtained, the developed questionnaire may reliably measure patient experience with OAT in general and across different methods of delivering OAT in relation to symptom improvement, appliance design, and delivery of care. Research is warranted to provide further and robust validity evidence for this questionnaire.

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Figure Legend

Figure 4.1: Breakdown of the data gathering and sorting process from interview to categorization

Figure 4.2: Breakdown of dimensions and their associated aspects used in defining the construct of patient experience with oral appliance therapy in dental sleep medicine.

Supplemental Figure 4.S1: Graphic representation of the validation workflow in development of the questionnaire

Table 4.1 Questionnaire evaluation form for the expert panel in initial evaluation of the proposed questionnaire.

The draft questionnaire was provided separately.

Numeric Scaled Questions with Comments	**Please circle your response in evaluating this question**			**Suggestions to improve question**
Sleep appliance esthetics	Essential	Useful	Not Necessary	
Your comfort with others seeing you using the appliance	Essential	Useful	Not Necessary	
Ease of putting on the appliance	Essential	Useful	Not Necessary	
Ease of taking off the appliance	Essential	Useful	Not Necessary	
Ease of adapting to using the appliance	Essential	Useful	Not Necessary	

Ease of adapting to adjustments made to the appliance	Essential	Useful	Not Necessary
Comfort when wearing the appliance before falling asleep	Essential	Useful	Not Necessary
Comfort on waking up with the appliance in	Essential	Useful	Not Necessary
Experience with side effects from the appliance	Essential	Useful	Not Necessary

Table 4.2 Questionnaire evaluation form for pilot testing from patients having already previously undergone OAT.

Questionnaire Section for Rating

Appliance Characteristics Dimension

Please indicate (with an x) how much you disagree or agree with the following statements related to the care you received.

Please comment on your reasoning for your rating:

Statement	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree	Comments
The sleep appliance is cosmetically acceptable						
Using the appliance in front of others does not make me feel uncomfortable						
The appliance is easy to put on						
The appliance is easy to take off						

Please rate the question's relevance to your patient experience in the dental treatment of your sleep apnea

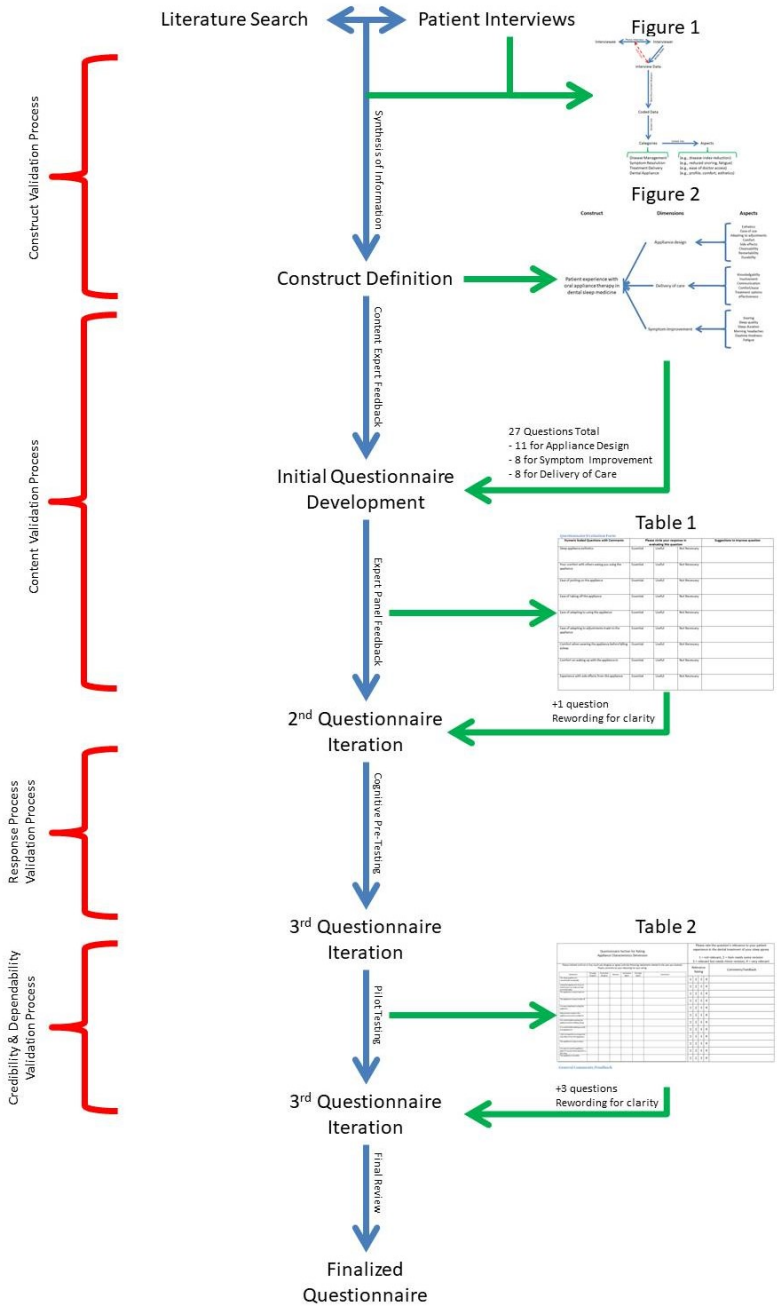
1 = not relevant, 2 = item needs some revision, 3 = relevant but needs minor revision, 4 = very relevant

Relevance Rating	Comments/ Feedback
1 2 3 4	
1 2 3 4	
1 2 3 4	
1 2 3 4	
1 2 3 4	
1 2 3 4	
1 2 3 4	
1 2 3 4	

It is easy adapting to using the appliance	1 2 3 4
Adjustments made to the appliance are easy to adapt to	1 2 3 4
It is comfortable wearing the appliance before falling asleep	
It is comfortable waking up with the appliance in	
I did not experience unexpected side effects from the appliance	1 2 3 4
The appliance is easy to clean	
It is easy to use the appliance again if use was interrupted for a few days	
The appliance is durable	

General Comments/Feedback

Figure 4.S1



Graphic representation of the validation workflow in development of the questionnaire. Reprinted from "Ng ET, Perez-Garcia A, Lagravère-Vich MO. Development and initial validation of a questionnaire to measure patient experience with oral appliance therapy [published online ahead of print, 2023 Apr 21]. *J Clin Sleep Med*. 2023;10.5664/jcsm.10562. doi:10.5664/jcsm.10562" with permission

Chapter 5 – Delphi consensus on the use of speech for mandibular positioning in dental sleep medicine

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Ng ET, Lagravere MO, Perez-Garcia A. Delphi consensus on the use of speech for mandibular positioning in dental sleep medicine. *J Dent Sleep Med.* 2024;10(4).

5.1 Summary

Study Objectives

To develop and describe a protocol for the use of speech to determine mandibular position for applications in dental sleep medicine using a Delphi consensus protocol.

Methods

The Delphi process was chosen as a method to reach expert consensus through structured iterative feedback in relation to defining the procedure of using speech to determine mandibular position in dental sleep medicine.

Results

Eleven experts in the fields of sleep medicine and otolaryngology, dental sleep medicine, speech language pathology and orofacial myofunctional therapy, physiotherapy, and optometry provided feedback through the Delphi process. Multiple rounds of expert feedback were necessary prior to consensus being reached in defining and describing the use of speech to determine mandibular position in dental sleep medicine.

Conclusions

A consensus-based definition for the use of speech in mandibular positioning for dental sleep medicine was achieved. Not only does this provide the foundation and allow for reproducibility in teaching clinicians and for future research; our use of the Delphi process in this manner for the development of a dental protocol may also provide a template for future dental research in dental protocol development.

Brief Summary

Current Knowledge/Study Rationale

Speech has been used in prosthodontics to determine a muscularly stable and reproducible mandibular position. Recently the use of speech to determine mandibular position for oral appliance therapy (OAT) has been advocated by certain pioneers in dental sleep medicine. These experts have provided varying opinions and descriptions for the procedure. The need for a formalized protocol with interdisciplinary input is necessary to allow for appropriate research and standardized clinical training.

Study Impact

The primary adjustment method for OAT involves anterior mandibular titration with resulting risks of muscle pain, temporomandibular disorder, and occlusal changes dependent upon the degree of protrusion. The use of speech for determining mandibular position may provide alternative positioning for OAT that may decrease side effect risk and improve patient response.

Keywords

Speech, orofacial myofunctional therapy, dental sleep medicine, oral appliance therapy

5.2 Introduction

Sleep breathing disorders are a grouping of conditions related to difficulties with breathing during sleep, usually related to upper airway collapse, that affect approximately 15% of the adult population (AASM, n.d.; Franklin & Lindberg, 2015; Frost & Sullivan; 2016a,2016b; Kapur et al., 2017). These conditions range in severity from persistent snoring to obstructive sleep apnea (OSA), with associated health consequences including cardiovascular disease, diabetes, and daytime sleepiness (Anker et al., 2016; Memon & Manganaro, 2023; Wang et al., 2013; Young et al., 2008).

Primary medical treatments for OSA include continuous positive airway pressure (CPAP) machines and dentist fabricated oral appliance therapy (OAT) while secondary treatments range from weight loss to orofacial myofunctional therapy (AASM, n.d.; Eckert, 2018; Gianoni-Capenakas et al., 2020; Ramar et al., 2015). While CPAP is considered first line treatment for all forms of sleep apnea, long term adherence to therapy is poor (Qiao et al., 2023; Rotenberg et al., 2016). OAT is also considered a

first line treatment for mild and moderate OSA and is much better tolerated though its efficacy is not as great as CPAP (Patil et al., 2019; Ramar et al., 2015). The high acceptance and tolerance rate for OAT compared to CPAP is a driving factor in its medical benefit, including for patients with severe OSA who cannot tolerate CPAP as a primary treatment. The portability of OAT is also a great advantage compared to CPAP for patients who travel or enjoy outdoor overnight activities as OAT does not require power or water. Despite the differences in efficacy and adherence, overall effectiveness between CPAP and OAT is generally equivalent due to superior patient adherence to care with OAT (Sutherland et al., 2015).

In OAT, the devices work by holding the mandible in a suitable position to maintain an open airway. Traditionally, mandibular position for OAT has been determined through the anterior protrusion technique (APT) (Ippolityo et al., 2020; Mayoral et al., 2019). The APT works by measuring the most retruded and most protruded position of the mandible (known as the protrusive range) and placing the mandible between 50-70% of the maximum protruded position (Aarab et al., 2010; Mayoral et al., 2019; Tegelberg et al., 2003). The device is then adjusted to titrate the mandible anteriorly until the patient cannot tolerate further mandibular protrusion, the patient's OSA is treated, or further protrusion will not benefit the patient. For the APT, vertical positioning of the mandible is not individualized to the patient but is primarily determined by the required material thickness of the appliance being selected by the dentist for OAT (usually 5mm due to appliances used in OAT being traditionally made of acrylic) (Ng et al., 2020; Ng et al., 2021).

More recently, speech sounds have been used to help in determining mandibular positioning for OAT (Ng et al., 2020; Ng et al., 2021; Viviano et al., 2022). In dentistry, the use of sibilant sounds to determine mandibular position is known as the sibilant phoneme technique (SPT) and was originally used for determining mandibular position and denture teeth positioning in edentulous patients (Bohnenkamp & Garcia, 2007; Bohnenkamp & Garcia, 2008; Makzoumé, 2004; Pound, 1977). It has since been modified and shown to be a potential method for determining mandibular position while minimizing mandibular protrusion for OAT and therefore limiting the potential incidence of side effects commonly associated with OAT including occlusal changes, temporomandibular disorder, and muscle pain (Ghazal et al., 2008; Martins et al., 2018; Ng et al., 2020; Ng et al., 2021; Pantin et al., 1999;). This may occur due to the SPT providing a patient specific vertical mandibular range within which to position the mandible while also maintaining oropharyngeal muscular stability in the phonetic neutral zone (Bohnenkamp & Garcia, 2007; Bohnenkamp & Garcia, 2008; Makzoumé, 2004; Ng et al., 2021; Pound, 1977;Viviano et al., 2022). However, while a definitive protocol has been described for the use of the

SPT for dentures, the modification of the SPT for use in OAT has not been described in detail (Pound, 1977).

While the SPT has been proposed as an alternative to the APT, a validated formal protocol for measuring mandibular position and/or vertical positioning in the use of speech for mandibular positioning for application in dental sleep medicine has not been developed. The APT has been described and studied extensively with protocols for its appropriate use published in peer reviewed literature as well as its limitations and common side effects with its use (Aarab et al., 2010; Ippolito et al., 2020; Mayoral et al., 2019; Piskin et al., 2015; Tegelberg et al., 2003; Vroegop et al., 2012). Comparatively, the SPT has minimal research and no formally described protocol in peer reviewed published literature specific to dental sleep medicine (Ng et al., 2021; Viviano et al., 2022). As previously mentioned, due to the potential for significantly decreased protrusion the SPT may have less risk of undesired side effects compared to the APT including occlusal changes, temporomandibular disorder, and muscle pain (Ghazal et al., 2008; Martins et al., 2018; Ng et al., 2020; Ng et al., 2021; Pantin et al., 1999). There is currently no research within the dental sleep medicine field that would limit using only sibilant sounds in speech to determine mandibular position for OAT and using the SPT as originally intended for denture prosthodontics provides only the closest speaking space, or smallest vertical position at which to position the mandible (Pound, 1977). As this space has minimal inter-incisal distance, this space is insufficient for the fabrication of a dental appliance for OAT due to material thickness. Modification to the SPT to allow for increased inter-incisal distance has been mentioned in peer reviewed published literature, though not described in detail (Viviano et al., 2022). Expert opinions have provided subjective descriptions for the modification of the SPT for use in dental sleep medicine though these may be subject to personal opinions and bias (ASBA, 2018; Chan, 2015; Mahony & Lipskis; 2012, 2015; Marangos, 2018; Olmos, 2010, 2012, 2019; Olmos, S.R., n.d.; Rawson, 2023) .[80-85,172-175] To date there has been no validated protocol for the appropriate use of speech for mandibular positioning in dental sleep medicine.

We propose to establish a protocol for the use of speech to determine mandibular position for applications in dental sleep medicine using a Delphi method. Due to variations in expert opinions and lack of detail within the literature, achieving a consensus definition on how to appropriately use speech for mandibular positioning in dental sleep medicine is a necessary first step to future assessment of its efficacy and, if demonstrated, to develop a standardized clinical protocol for use in clinical practice (ASBA, 2018; Chan, 2015; Mahony & Lipskis; 2012, 2015; Marangos, 2018; Olmos, 2010, 2012, 2019;

Olmos, S.R., n.d.; Rawson, 2023). The Delphi method is a well-established structured technique for reaching expert consensus for research questions that cannot be answered empirically. Through an iterative process with structured feedback, statements are modified and returned to experts for review and this process is repeated until consensus is reached. The Delphi method may be used to appropriately define and describe a protocol for the use of speech to determine mandibular positioning in dental sleep medicine including for OAT to provide a standard methodology for its use and reproducibility in teaching clinicians and for future research.

5.3 Materials and Methods

Ethics approval

This study was approved by Alberta Research Information Services: Human Research Ethics Board (Pro00128767). The Delphi process was chosen as a method to reach expert consensus through structured iterative feedback in relation to defining the procedure of using speech to determine mandibular position in dental sleep medicine. This included a search and review to discover literature related to the procedure and existing knowledge gaps. A steering committee was formed to amalgamate this information, prepare structured feedback forms, predetermine agreement cut-offs for expert consensus, and identify experts to invite to participate within the Delphi process. Experts who responded in agreement to participate were then provided with information structured feedback forms which were evaluated by the steering committee. Based on the feedback, modifications were made to the protocol under question and sent back to panelists for review. This process was repeated until expert consensus was achieved.

Literature search/review

A recently conducted literature review covered this topic (Ng et al., 2020). The literature review search terms were used again to update the articles, which resulted in a single additional article according to the reviews strict inclusion criteria (Ng et al., 2021). In addition, the same search terms were used in google where the first three pages of results were reviewed to not limit results to peer reviewed articles only. An additional six articles were found to be of relevance, two of which appeared to be duplicates (ASBA, 2018; Chan, 2015; Mahony & Lipskis, 2012, 2015; Olmos S.R. n.d.; Rawson, 2023). In addition, four videos were noted demonstrating a methodology on using speech to determine mandibular position (Marangos, 2018; Olmos, 2010, 2012, 2019). These articles and videos provided

expert opinion and description on the use of speech to determine mandibular positioning in dental sleep appliances. Authors and mentions of experts by name were also searched in the PubMed database for peer reviewed articles of relevance. No additional articles specific to the use of speech for mandibular positioning were found.

Steering committee

A steering committee was formed consisting of one board certified orthodontist (ML), one dentist board certified in dental sleep medicine (EN), and one professor of research methodology and qualitative research (APG). The steering committee created a list of experts to invite to participate within the Delphi process as well as determining levels of agreement for acceptable consensus and format for expert feedback. All members of the steering committee were precluded from being considered an expert in providing feedback within the Delphi process.

Based on information gathered from the literature review, the steering committee determined that the fields of speech language pathology, otolaryngology, physiotherapy, optometry, and dental sleep medicine would be of relevance in relation to the use of speech for mandibular positioning in dental sleep medicine.

An agreement level of 66% between Delphi panelists was pre-selected by the steering committee as an acceptable level of consensus.

Based on information gathered from the literature review, the use of speech for mandibular positioning in dental sleep medicine was subdivided into phases and steps for easier evaluation. A formalized template was created by the steering committee for structured feedback from potential panelists.

Formulation of procedure for evaluation

Based on information gathered from the literature search/review, the steering committee aggregated the data and formulated it into phases which described the process of using speech to determine mandibular position. A total of five phases were identified by the steering committee. These phases were then further deconstructed into steps, with a total of nineteen steps identified by the steering committee.

The five phases identified by the steering committee were: 1. recording anatomical landmarks, 2. pre-procedural testing, 3. patient positioning, 4. identifying speech measurement limits, and 5. capturing occlusal relationships for mandibular position. The nineteen steps were then assigned to the appropriate phase by the steering committee. The phases and steps were organized into a list for expert panelist informational reference. The informational document can be found in Appendix 5.A.

A structured template was created by the steering committee for expert panelists to provide their feedback. The template was designed with specific instructions relevant to the evaluation of titles/names, inclusion or exclusion, additional lines, sequencing, and other suggestions. An example of this structured template can be found in Appendix 5.B.

Expert panelists

Eighteen experts in the fields of sleep medicine and otolaryngology, dental sleep medicine, speech language pathology and orofacial myofunctional therapy, physiotherapy, and optometry were invited by formal email to participate. All otolaryngologists were involved in sleep medicine and had a history of collaboration with dentists involved in sleep medicine. All speech language pathologists were also certified orofacial mycologists. All physiotherapists had advanced training in temporomandibular disorder. All optometrists were also registered nurses and involved in the field of orofacial myofunctional therapy. All dentists were board certified in dental sleep medicine with the American Board of Dental Sleep Medicine and had been listed as an author related to the use of speech in mandibular positioning from articles or sources revealed in the literature review. Of the eighteen experts invited six were dentists, five were otolaryngologists, three were physiotherapists, three were speech language pathologists also certified orofacial mycologists, and one was an optometrist.

Eleven of the eighteen invited to participate responded with agreement to participate as experts on the Delphi panel. Four were dentists, two were otolaryngologists, two were physiotherapists, two were speech language pathologists also certified orofacial myologists and one was an optometrist. Both otolaryngologists who elected to participate requested their feedback be limited purely to portions specific to nasal function.

Expert feedback

The Delphi method is a well-established structured technique for reaching expert consensus for research questions that cannot be answered empirically. Through an iterative process with structured feedback

from panelists, statements are modified and returned to experts for review and this process is repeated until consensus is reached. Panelists are generally selected for their expertise in relation to some or all of the questions being researched.

Panelists were asked to provide their expert opinion on the phases related to the use of speech in mandibular positioning and to return their feedback within two weeks. The formalized template was provided with instructions specific to the evaluation of the names of the phases, their importance in inclusion or exclusion, whether additional phases should be included, and the sequencing of the phases. Panelists were provided with a summary of all proposed phases and steps for reference. Panelist feedback was reviewed and incorporated into the phases, which were then sent back to the panelists for review. A summary of changes was included within the feedback template. This process was then repeated for evaluation of the steps within each phase.

5.4 Results

Phases

Nine experts provided feedback in evaluation of the phases related to use of speech for mandibular positioning. Both participating otolaryngologists declined to provide feedback stating a preference to limit their feedback specific to nasal function. Two rounds of expert feedback were necessary to reach consensus threshold. The name of one phase was expanded; *pre-procedural testing* was expanded to *pre-procedural screening and testing*. The order sequencing of the phases did not change from what was originally proposed. No phases were removed and no additional phases were added. While the evaluation of phases was not specific to the steps within each phase, based on panelist feedback steps were added into or updated within phases. These changes are summarized in Appendix 5.C.

Steps

Recording anatomical landmarks

Nine experts provided feedback in evaluation of the steps within the phase of recording anatomical landmarks. Both participating otolaryngologists declined to provide feedback stating a preference to

limit their feedback specific to nasal function. Two rounds of expert feedback were necessary to reach consensus threshold. Two steps were added: *record dental and occlusal relationships (such as overjet, overbite, dental crowding, etc.)* and *recording mandibular ranges of motion (such as maximum opening, protrusion, deflection of opening, etc.)*. The two additional steps were placed in order positions one and two; the order sequencing of the rest of the steps did not change from what was originally proposed. No steps were removed. Consensus threshold was reached by the second round. These changes are summarized in Appendix 5.D.

Pre-Procedural screening and testing

Eleven experts provided feedback in evaluation of the steps within the phase of pre-procedural screening and testing. Two rounds were necessary to reach consensus threshold. The descriptions of multiple steps were expanded. One step was added; *visually screen for nasal obstructions (such as gross nasal deviations and enlarged inferior turbinates)*. The order sequencing of the first three steps was modified from what was originally proposed and the additional step placed after the first step. Consensus threshold was reached by the second round. These changes are summarized in Appendix 5.E.

Patient positioning

Nine experts provided feedback in evaluation of the steps within the phase of patient positioning. Both participating otolaryngologists declined to provide feedback stating a preference to limit their feedback specific to nasal function. Two rounds were necessary to reach consensus threshold. The descriptions of multiple steps were expanded; *measure baseline (habitual) posture and head position* was expanded to *measure baseline (habitual) posture and head position in both standing and sitting position*, *provide interventions to relax the patient's orofacial musculature* was expanded to *provide interventions to relax the patient's orofacial musculature (for example, by massage or cold laser)*, *instruct patient to position arms hanging neutrally without support on either side of their body* was expanded to *instruct patient to position arms hanging neutrally without support on either side of their body (or hands on lap neutrally, if preferred for comfort by patient)*, and *instruct patient to look straight ahead with eyes not focused on any particular object or landmark* was expanded to *instruct patient to look straight ahead with eyes directed towards a blank wall or blank paper and not focused on any particular object or landmark*. No steps were added. The last four steps were amalgamated into a single step. The order sequencing of the steps did not change from what was originally proposed. Consensus threshold was reached by the second round. These changes are summarized in Appendix 5.F.

Identifying speech measurement limits

Nine experts provided feedback in evaluation of the steps within the phase of identifying speech measurement limits. Both participating otolaryngologists declined to provide feedback stating a preference to limit their feedback specific to nasal function. Consensus threshold was met within the first round. The descriptions of two steps were clarified; *instruct patient to count the numbers out loud from sixty to eighty in English at a normal speed* was expanded to *instruct patient to count the numbers out loud from sixty to eighty in English at a normal conversational speed and volume* and the word *lisps* was removed from *note any lateral mandibular movements and any lateral tongue movements/lisps*. No steps were added or removed. The order sequencing of the steps did not change from what was originally proposed. These changes are summarized in Appendix 5.G.

Capturing occlusal relationships for mandibular position

Nine experts provided feedback in evaluation of the steps within the phase of identifying speech measurement limits. Both participating otolaryngologists declined to provide feedback stating a preference to limit their feedback specific to nasal function. Consensus threshold was met within the first round. No descriptions were changed. No steps were added or removed. The order sequencing of the steps did not change from what was originally proposed. These changes are summarized in Appendix 5.H.

Final Review

Once consensus thresholds were reached for all phases and steps, the entire protocol on the use of speech for mandibular positioning was sent for final review to all panelists for open feedback. During the first round, significant feedback was received resulting in changes to Phase 2 and Phase 3, with the first step of Phase 3 added into Phase 2 to ensure an evaluation of head position prior to any of the interventional steps in Phase 2. The two steps in Phase 1 for individually evaluating ankylolabia were combined into a single step. Descriptions for certain steps were expanded and examples included in order to provide guidance for clinical application. Spelling and grammar were corrected. In the second round of feedback there were no additional changes suggested.

The finalized protocol is attached in Appendix 5.I.

5.5 Discussion

OAT is a primary treatment option for OSA, with significantly greater adherence when compared to CPAP therapy. Traditionally, mandibular positioning and titration in OAT uses the APT with a set vertical thickness usually determined by material thickness. Clinically significant side effects are frequently associated with increased anterior titration of the mandible. Recent research has shown that alternative mandibular positioning techniques, such as through the use of speech to determine mandibular position, may be viable in OAT. However, while preliminary research has shown promise, an appropriate definition and protocol for the use of speech in mandibular positioning has not previously been published. As the description of such a procedure is not empirically measurable, the Delphi method was applied to obtain an appropriate definition and description of the procedure of using speech for mandibular positioning in dental sleep medicine.

While a number of clinical experts in the field of dental sleep medicine have provided their personal opinions and instructional videos on how to use speech to determine mandibular position, an appropriately rigorous process has not been undertaken to properly define and describe the procedure. By use of the Delphi process, a consensus based definition including interdisciplinary expert feedback for the use of speech in mandibular positioning for dental sleep medicine was achieved. Multiple rounds of feedback were necessary, with input from different specialties providing insight into different aspects that may have significant impact on mandibular movement in speech. These included aspects not previously described such as nasal patency, eyesight and eye focus, lateral tongue movements and body posture necessitating expertise from the fields of otolaryngology, optometry, speech language pathology, and physiotherapy. All expert feedback was weighted equally, and panelists were blinded to the opinions of their colleagues to prevent any peer pressure in feedback. Pre-defined consensus thresholds determined by the steering committee were strictly adhered to. The final full description of the procedure reached consensus threshold amongst all panelists. While this definition does not predict clinical outcomes, it does provide a standardized methodology for the procedure to allow for its appropriate standardized use in clinical training and for future research.

Aside from the previously mentioned applications for the clinical use of speech in mandibular positioning, the application of the Delphi method for such a complex multi-layered process involving multiple phases and multiple steps within each phase may provide a template for future application in other descriptive research within dentistry and medicine. Traditionally, all steps are evaluated in unison

for each round in the Delphi methodology. In procedures that require steps nested under phases for order sequencing, or with significant number of steps that require order sequencing, it may not be practical or possible to assess all steps at once. Evaluation of phases without steps, and then steps within each phase while also providing panelists with information in all steps and phases, may provide a template for evaluation of complex multi-phase multi-step protocols.

The Delphi process was used due to its strengths in structured feedback, anonymity for unbiased feedback, and flexibility in accepting asynchronous feedback by email reply. However, there are inherent limitations with the use of the Delphi process. These limitations include a lack of open discussion, the time requirement for multiple rounds of feedback, and that the outcomes from feedback are highly expertise dependent. The time commitment was likely a factor in the number of invited experts who did not elect to participate. Despite this, the expert panelists who did participate included representation across all healthcare fields invited. The inclusion of specific areas for open feedback and the diversity of expert panelists were attempts to address these limitations, though there were no methods by which to evaluate the effectiveness of such.

5.6 Conclusion

This project encapsulated the application of the Delphi method to define and describe the use of speech for mandibular positioning in dental sleep medicine. Throughout the process significant feedback from experts in multiple healthcare fields including otolaryngology, physiotherapy, optometry, speech language pathology, and dentistry highlighted the importance and diversity of thought that provided significant insight into the development of this protocol. From this process a consensus based definition for the use of speech in mandibular positioning for dental sleep medicine was achieved. Not only does this provide the foundation and allow for reproducibility in teaching clinicians and for future research; our use of the Delphi process in this manner for the development for a dental protocol may also provide a template for future dental research in dental protocol development.

Disclosure Statement

Conflict of interest: none. Financial Disclosure: none. Non-financial disclosure: none.

Data Availability

No new data were generated or analysed in support of this research.

Author Contributions

E.N.: conceptualization, methodology, investigation, data curation, formal analysis, writing – original draft, writing – review and editing.

M.L.: conceptualization, methodology, investigation, formal analysis, writing – original draft, writing – review and editing

A.P.G.: conceptualization, methodology, investigation, formal analysis, writing – original draft, writing – review and editing

Abbreviations

APT: anterior protrusive technique

CPAP: continuous positive airway pressure

OAT: oral appliance therapy

OSA: obstructive sleep apnea

SPT: sibilant phoneme technique

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Chapter 6 – Comparing anterior protrusive and speech-positioned mandibular positioning techniques for adult dental sleep appliances – a pilot crossover randomized controlled trial

Ng ET, Lagravere MO, Flores-Mir C, Hernandez IA, Mayoral P, Perez-Garcia A. Comparing anterior protrusive and speech-positioned mandibular positioning techniques for adult dental sleep appliances – a pilot crossover randomized controlled trial. *J Dent Sleep Med.* 2024;10(4).

6.1 Summary

Background

Oral appliance therapy (OAT) is a primary treatment for obstructive sleep apnea (OSA), which involves the fabrication and adjustment of custom-fit titratable dental appliances. While the speech positioning technique (SPT), commonly used in denture prosthodontics, has been suggested as an alternative for the anterior protrusive technique (APT) for determining lower jaw position in OAT, its efficacy remains to be elucidated.

Study Objectives

The purpose of this study was to determine the feasibility and potential efficacy of a crossover randomized controlled trial (RCT) comparing the SPT and the APT in OAT.

Methods

A pilot trial was conducted with participants randomly assigned to complete OAT with either the SPT or APT before a washout period and then crossover assignment to complete OAT with the alternative mandibular positioning technique. Feasibility data was collected through administrative tracking and clinician 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 questionnaires.

Results

A total of 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 SPT and APT, one patient was a responder to the SPT but not the APT, and one patient was a responder to the APT but not the SPT. The other five patients were OAT responders to both the SPT and APT. Average mandibular protrusion for the SPT was 48.82% and 63.37% for the APT. Unusual side effects were reported by several patients while in OAT with the APT. There were no significant differences in sleep quality and patient experience reported between the two mandibular positioning techniques.

Conclusion

Conducting a crossover RCT comparing the SPT and the APT appears to be feasible, especially if multiple sites are involved to enhance recruitment. Pilot trial 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. A RCT is necessary to further assess the observed efficacy of the SPT for mandibular position.

Keywords

Obstructive sleep apnea, oral appliance therapy, dental sleep medicine

6.2 Background

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 (Eckert, 2018; Kapur et al., 2017; Osman et al., 2018). It is estimated that over 15% of the global population suffers from OSA (Franklin & Lindberg, 2015). Direct, indirect, and healthcare-related costs exceed $150 billion annually in the United States alone (Frost & Sullivan; 2016a, 2016b). OSA is associated with multiple medical conditions, including cardiovascular disease, cerebrovascular disease, obesity, renal diseases, psychiatric disorders, type 2 diabetes, asthma, COPD, and cancer (Anker et al., 2015; Gami et al., 2005; Memon & Manganaro, 2023; Wang et al., 2013; Young et al., 2008). 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 (Feng et al., 2022; Gu et al., 2022; Jennum et al., 2015; Lavie et al., 2005; Marshall et al., 2008, 2014; Pascual et al., 2018).

The primary treatments for adult obstructive sleep apnea are positive airway pressure therapy (PAP) and oral appliance therapy (OAT) (AASM, n.d.; Ramar et al., 2015). 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 through creation of a pneumatic splint within the upper airway through the entire respiratory cycle (Kakkar & Berry, 2007; MedlinePlus, n.d.; Standford Medicine Health Care, n.d.; Weiss & Kryger, 2016). 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 (Gianoni-Capenakas et al., 2020; Ramar et al., 2015). Many variations of OAT exist with differences primarily in material, manufacture, device design, and adjustment methods. While both treatments are similar in overall effectiveness, greater adherence has been observed in patients treated with oral appliance therapy (Sutherland et al., 2015).

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 (Gianoni-Capenakas et al., 2020; Ramar et al., 2015). Appliances generally anchor 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 (Brown et al., 2018; Burke et al., 2018; Chan et al., 2010; Ferguson et al., 2006; Hoekema et al., 2004; Juge et al., 2018; Ngiam et al., 2013; Sheats et al., 2020). 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 (Aarab et al., 2010; Gindre et al., 2008; Gupta et al., 2016; Ippolito et al., 2020; Mayoral et al., 2019). 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 (Anitua et al., 2017; Anitua et al., 2023). While the anterior protrusive technique parameters have been well-studied and well-documented for adult oral appliance therapy, common side effects include temporomandibular disorder, muscle pain, and occlusal changes (de Almeida et al., 2002; Giannasi et al., 2009; Marklund et al., 2001; Minagi et al., 2018; Pliska et al., 2014; Ramar et al., 2015; Sheats et al., 2017). The risk for and occurrence of these side effects can significantly impact patient experience, quality of life, and treatment adherence (Cronin et al., 2019; Ng et al., 2023; Nordin et al., 2016; Saglam-Aydinatay & Taner, 2018;). 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 (Pound, 1977). 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 (Bohnenkamp & Garcia, 2007; Bohnenkamp & Garcia, 2008; Makzoumé, 2004). 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 (Ng et al., 2020, 2021; Viviano et al., 2022). Previous research appears to support the potential effect of holding the mandibular position to achieve muscular stability in denture retention obtained through the SPT translates on oropharyngeal muscular stability in OAT during sleep (Ng et al., 2021; Viviano et al., 2022). 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 the SPT in dental sleep medicine, including in OAT (Ng et al., 2024).

The purpose of this study is twofold: to explore the feasibility of a full-scale randomized controlled trial (RCT) comparing the APT and the SPT and to gather preliminary data of the efficacy of the 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 a RCT. Gathering preliminary efficacy data will aid in assessing the need for further demonstrating the efficacy of the SPT through a more robust research design.

6.3 Materials and Methods

Study Design

A pilot trial design was selected to assess the feasibility of a RCT with crossover design 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 (Eldridge et al., 2016). 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 a

RCT (Hassan et al., 2006; Equator Network, 2010). The study was approved by Alberta Research Information Services: Human Research Ethics Board (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 minimum space necessary to fit an intraoral scanner head for digital impressions, patients with a maximum mandibular opening 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 (Hu & Liptak, 2018; Sugù et al., 2022).

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.

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 6.1)

Figure 6.1

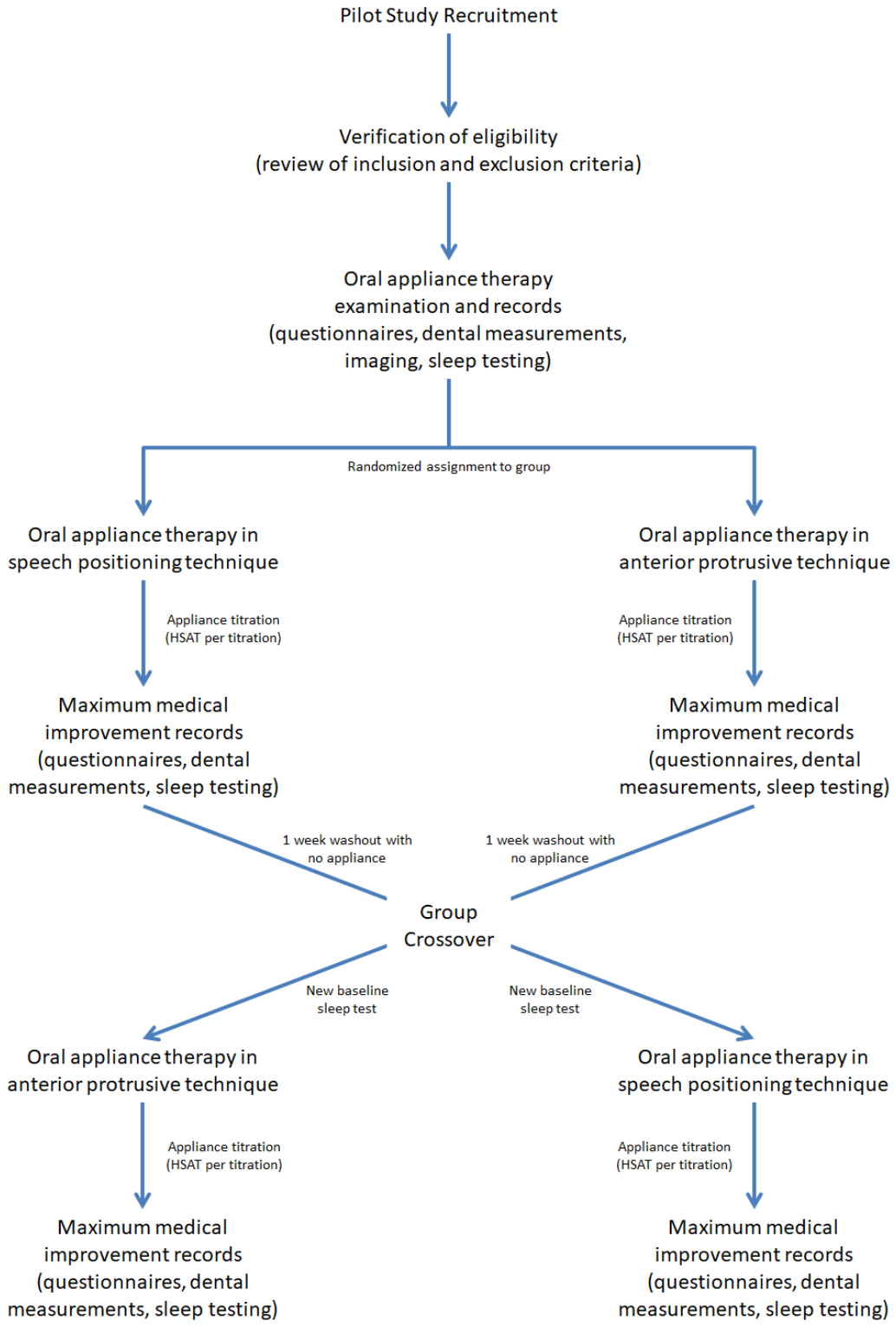


Diagram of patient flow in the pilot trial.

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 as collected through home sleep testing, physical measurements of mandibular position using dental landmarks, occurrence of side effects, and differences in sleep quality and patient experience. These are outlined in Table 6.1. 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 the 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.

Table 6.1 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)
		Number of titrations/adjustments
		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	

Comparative Analyses

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

6.4 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 patients 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 (BMI) 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 6.2.

Table 6.2 Individual pilot patient demographic data. All patients with OSA. Other medical conditions listed by patient report.

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® (Bupropion), 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	Amitriptyline
71	Female	157.5	154	28.16	14	30	Caucasian	Gastroesophageal reflux disease, hypertension, high cholesterol	Rosuvastatin, Irbesartan 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	Caucasian	Attention deficit hyperactivity disorder, heartburn	Vyvanse® (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	

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 significantly 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 6.3.

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 APT but not in the SPT, and one was a responder to OAT in the SPT but not in the APT. 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 6.3. Specific per-patient sleep indices details are provided in Appendix 6.A.

Table 6.3 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.

	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)

Changes in mandibular position (Figure 6.2)

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

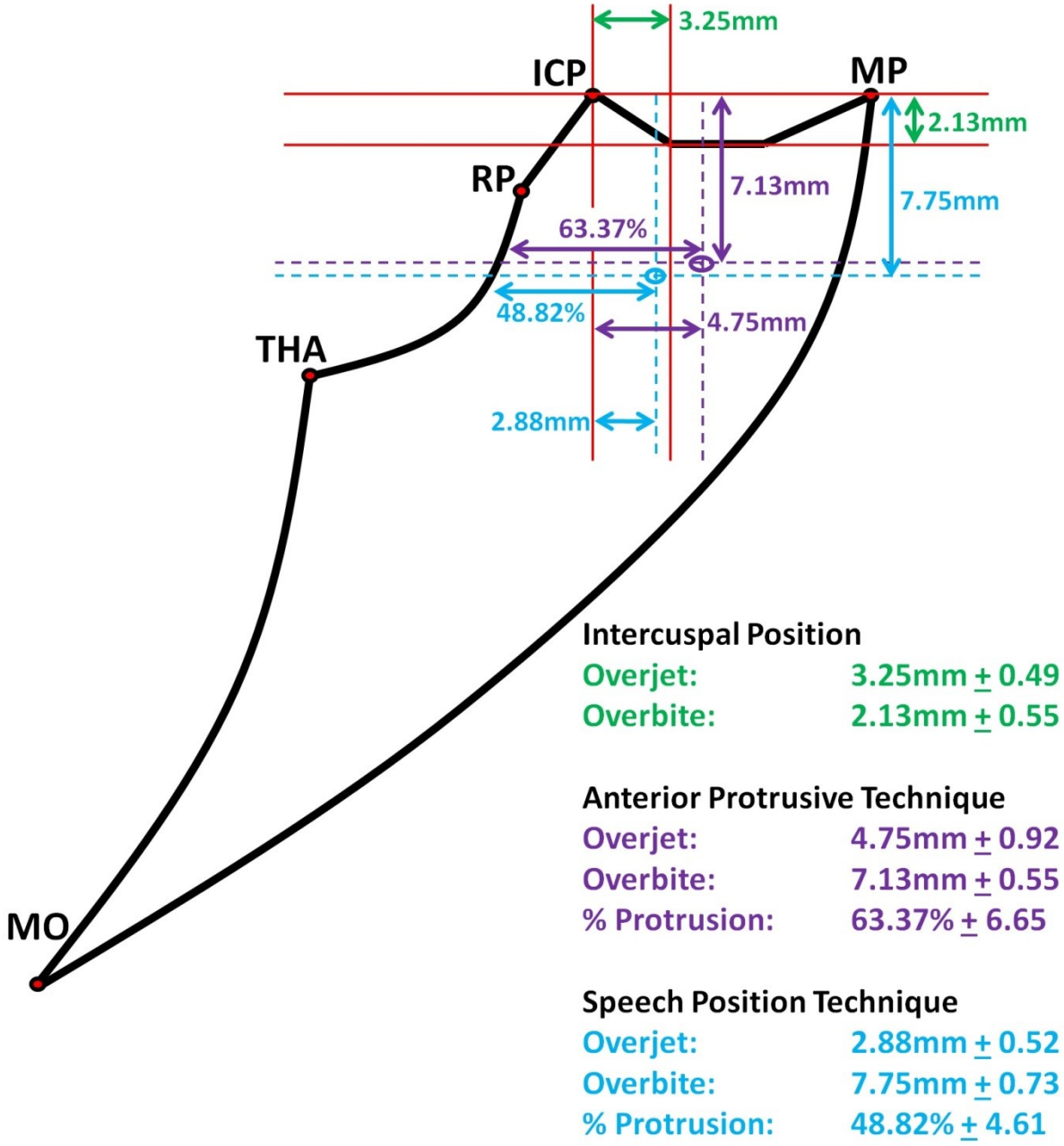
For the SPT, the initial inter-occlusal distance was determined as 4.5mm of inter-incisal space based on the minimum material thickness required for structural integrity for the dental sleep appliances. For the APT, the initial inter-occlusal distance was determined as 5mm of inter-incisal space based 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 6.4. Specific per-patient mandibular position details are provided in Appendix 6.B.

Table 6.4 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.

	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)		

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).

Figure 6.2



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.

Side effects

From the pilot trial data, 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 unusual 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 6.5. Specific per-patient sleep questionnaire details are provided in Appendix 6.C.

Table 6.5 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.

	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)

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 6.6. At the end of trial participation, 3 patients reported no preference for keeping either appliance, three patients reported a preference for keeping the SPT-positioned appliance, and two patients reported a preference for keeping the APT-positioned appliance.

Table 6.6 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".

	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)

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.

6.5 Discussion

The purpose of this pilot trial was to assess the feasibility of a RCT crossover design comparing the SPT and the APT and to generate preliminary efficacy data for the 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 (Al-Nawas et al., 2015; Cooper et al., 2018; Encyclopedia of Adolescence, 2011; Low et al., 1999; Macey et al., 2016; Moerbeek, 2020; Palmer et al., 1997; Patel et al., 2021). 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 of 46 qualified patients in the private practice clinic. The recruitment rate suggests that a dedicated dental sleep medicine clinic may be able to 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 speciality 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.

The gender ratio difference for patients enrolled within the pilot study warrants review as OSA is more prevalent in men rather than women. However, it is well established that women seek medical care more frequently than men. This may account for the 3x number of women to men who participated in the pilot study, but should be a consideration for future research planning (Bertakis, et al., 2000; Thompson et al., 2016).

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 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 (Garnett & Northwood, 2022; Thoma et al., 2010). An increased budget may be necessary as financial incentives for increased clinician involvement and for patient incentives for participation has been shown to be significantly impactful in improving patient recruitment (Abdelazeem et al., 2022; Bickman et al., 2021; Vellinga et al., 2020; Wise, 2023). Ethical considerations in financial incentives for patient recruitment will need to be considered (Velling et al., 2020).

This pilot trial 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 (FAirEST, n.d.; Hingorjo et al., 2012; Yoon et al., 2017; Zaghi et al., 2021), 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 (Camañes-Gonzalvo et al., 2022; Chen et al., 2020; Lee et al., 2022). 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 (Dydyk et al., 2023). 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 the 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 maintenance of appropriate tongue rest posture in the oral cavity (Alghadir et al., 2015; Fukuda et al., 2023; Wang et al., 2018). 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 (Armiji-Olivo et al., 2011; Chan et al., 2024; Choi et al., 2000; Greenland et al., 2010; Herzog et al., 2022; Jan et al., 1994; Takigawa et al., 1995; Walsh et al., 2008).

The pilot 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 was mixed but patient reported preference at end of trial suggested a possible preference for the SPT compared with the APT for OAT. While most patients reported no preference differences consistent with responses to the patient experience questionnaire, at the end of the trial three patients reported a preference for keeping the SPT-positioned appliance, while two reported a preference for keeping the APT-positioned appliance. Both patients who experienced non-traditional side effects in OAT with the APT noted a preference for the SPT-positioned appliance. Two patients noted a preference for the SPT-positioned appliance based on the increased speed of treatment. The patient who was not a complete responder to the SPT noted a preference for the APT-positioned appliance. 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. 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 the SPT in OAT may also be of interest.

6.6 Conclusions

The pilot trial suggests that a 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 trial 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.

The pilot trial data suggests that the clinical application of the 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 interdisciplinary 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.

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Figure Legend

Figure 6.1

Diagram of patient flow in the pilot trial.

Figure 6.2

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.

Supplementary Files

Appendix 6.A: Individual pilot patient sleep indices data.

Appendix 6.B: Individual pilot patient mandibular position data.

Appendix 6.C: Individual pilot sleep quality patient data.

Chapter 7: Overall discussion and conclusion

7.1 Introduction

This chapter discusses the main thesis results and their contributions to the field of dental sleep medicine (DSM). Recommendations for future research are also discussed to further advance the field of DSM. The primary objective of this thesis was to explore the use of speech characteristics in determining mandibular position for oral appliance therapy (OAT) among patients with obstructive sleep apnea (OSA) by answering the following questions:

1. What is the current published literature in relation to the use of speech for mandibular positioning in DSM?
2. How do patients previously treated with the speech based mandibular positioning technique compare to patients previously treated with the anterior protrusive technique in OAT for OSA?
3. How do we measure patient experience between the two mandibular positioning techniques?
4. What is the consensus procedure for the appropriate use of speech characteristics in mandibular positioning?
5. How does OAT for OSA delivered through mandibular positioning obtained through speech characteristics compare with mandibular positioning through the anterior protrusive technique on a patient and group level?

These questions were answered through a literature review that revealed a knowledge gap (question 1), a retrospective trial that suggested a clinically relevant difference between the two mandibular positioning techniques (question 2), the creation and initial validation of a tool to measure patient experience in oral appliance therapy (question 3), the formalization of the procedure to use speech characteristics for mandibular positioning (question 4), and a pilot trial providing initial efficacy data on

the speech positioning technique for oral appliance therapy in patients with obstructive sleep apnea (question 5).

7.2 Discussion

The present thesis provides significant scientific contributions to the field of DSM. While OAT continues to dominate the field regarding adult dental treatment for OSA, recent research (including research that is part of this thesis) has shown that significant mandibular protrusion may not be necessary for successful OAT outcomes. Alternative mandibular positioning techniques can be employed to increase the number of patients who may benefit from OAT for their OSA. These techniques may improve their acceptance and adherence to OAT and decrease the incidence and severity of side effects inherent in OAT for some patients.

In this area, the contributions of this thesis include:

- Supporting further exploration on the use of speech characteristics for mandibular positioning in OAT
- Recognizing that sibilant phoneme techniques used in denture prosthodontics adapted in some form for use in OAT by clinicians provides a potential difference in mandibular target/therapeutic position compared to the commonly accepted anterior protrusive technique
- Acknowledging that sibilant phoneme techniques used in denture prosthodontics adapted in some form for use in OAT by clinicians have variabilities with no formal consensus definition on appropriate application in dental sleep medicine
- Establishing the use of speech for mandibular positioning in oral appliance therapy for the appropriate application of speech characteristics for mandibular positioning in dental sleep medicine based on expert census
- Developing and validating a patient experience questionnaire on oral appliance therapy that can be used to compare differences in patient experience between different appliances, between delivery and/or positioning techniques, and between different clinicians
- Demonstrating the feasibility of a crossover randomized controlled trial comparing the effectiveness of the SPT and the APT in OAT

- Providing preliminary effectiveness data for SPT and APT in clinical setting, with results indicating more than one target/therapeutic mandibular position may be present in patients undergoing OAT
- Outlining initial potential phenotypic characteristics of patients non-responsive to the SPT for OAT
- Describing patient experiences and preferences resulting from their exposure to the SPT and the APT for OAT
- Examining and comparing side effects of the SPT and the APT for OAT

The primary clinical takeaways from this thesis include the following:

- Generation of an expert consensus clinical procedure for using the speech positioning technique to determine mandibular position
- The speech positioning technique can be reasonably applied clinically in OAT for an alternative target mandibular position than the anterior protrusive technique
- The quality, incidence, and severity of side effects may be different between different mandibular positioning techniques
- Patients may have a preference for one mandibular positioning technique over another even when both techniques provide an efficacious outcome measured through OSA disease index reduction
- Interdisciplinary clinician collaboration can provide significant insights in research to improve already established clinical treatments

One of the primary outcomes is creating a standard procedure for utilizing the speech positioning technique in DSM. Prior to this thesis there were multiple opinions on how to use speech to determine mandibular position in OAT. The formal standardization of this procedure allows for appropriate comparison with other mandibular positioning techniques for research, a clear and uniform procedure for clinical training, and the ability for other healthcare practitioners to modify and apply for use within their own fields if necessary. Improving awareness of the speech positioning technique should be continued through research publication, informing DSM field experts of the updated and formalized procedure, and collaborating with DSM clinical and continuing education programs.

While previous research has compared different mandibular positioning techniques between patients, to our knowledge, this is the first paper with definitive results that show that more than one therapeutic

target position may exist for individual patients. The clinical significance is that patients who are not responsive to one target position may be responsive to a different target position; in other words, patients who are non-responsive to one mandibular positioning technique may be responsive to a different mandibular positioning technique. This can significantly broaden the number of patients who can be treated with OAT for OSA. Patients who cannot tolerate PAP therapy and have previously failed OAT in an anterior protrusive technique may benefit from another trial with the speech positioning technique.

Also of clinical significance, the incidence, quality, and severity of side effects appeared to differ between the anterior protrusive and speech positioning techniques. Patients at higher risk for or with pre-existing temporomandibular disorder may benefit from the speech positioning technique in OAT. Patients with limited mouth opening/protrusion may also be treated with the speech positioning technique in OAT. Patients who develop side effects in the anterior protrusive technique may also benefit from a transition to the speech positioning technique in OAT. This may include patients experiencing mild transient side effects where a different positioning technique may improve the patient's experience in treatment thereby prompting better overall adherence to treatment.

This thesis also suggests the importance of interdisciplinary collaboration. While it is commonly understood that otolaryngologists and sleep physicians are important collaborators in OAT, physiotherapists and speech-language pathologists provided significant insight into developing the procedure for using speech for mandibular position. This underlines the importance of open communication and collaboration with fields not traditionally involved in DSM and how their input can positively shape the delivery of care for OAT. Continued interdisciplinary collaboration and research may prove fruitful in further enhancing the field of DSM.

7.3 Recommendations for future research

Future studies are needed to assess the efficacy of the SPT in OAT to determine its equivalency to the APT in terms of disease index reduction. Evaluation of differences in mandibular position, occurrence and quality of adverse side effects, and patient experience between the SPT and APT in OAT is also necessary and may be done in conjunction or independently of evaluation of disease index reduction. Due to the nature of crossover trials, evaluation of side effects may be limited to short term side effects only. Studies comparing long term side effects between the SPT and APT may not be feasible in crossover RCT designed studies but would also be important to research.

Collection of phenotypic markers of response and nonresponse of patients to the SPT for OAT is also imperative. These may include orofacial myofunctional markers such as lip seal strength, tongue tone, tongue jaw dissociation, and tongue range of motion. Additional factors may include nasal patency evaluations and malocclusion/dentition configuration on tongue resting posture.

Future research may also include evaluating the speech positioning technique in languages other than English. This may not be done by direct translation, as the phonetics between languages may be significantly different. Close collaboration with language experts may be indicated.

Another significant area of research may be continued validation of the patient experience questionnaire with other questionnaires to improve external validity. Validation of specific dimensions will depend on the questionnaires chosen for comparison. For example, comparing to the Epworth Sleepiness Scale may only be relevant to the dimension of symptom improvement and the specific aspect of daytime sleepiness; it may not be appropriate to compare the dimension of appliance design to Epworth scores.

Expanding research collaboration between speech-language pathologists and dentists in dental sleep medicine should also be explored. While the importance of orofacial myofunctional therapy in facial growth and development is being continuously studied in collaboration between speech language pathologists and orthodontists, the use of speech resonance, articulation, and phonation to screen for obstructive sleep apnea is a relatively new area of research (Espinoza-Cuadros et al., 2015; Fox et al., 1989; Romero et al., 2022). Collaborative research between speech language pathologists and dentists on the possibility of using speech characteristics to explore patient response to oral appliance therapy should be pursued. As well, research on methods to improve and increase interdisciplinary research within the field of dental sleep medicine should be explored.

7.4 Conclusions

The work presented in this thesis reviewed the research into development and initial validation of the use of speech characteristics to determine mandibular position and its formalization into the speech positioning technique in OAT. The knowledge gained from the results presented includes comparisons between the APT and SPT, potential clinical differences and applications within OAT, and a roadmap for future interdisciplinary collaboration within already well-defined dental treatments for their improvement. The SPT provides an effective alternative method for mandibular positioning in OAT with the possibility of increasing the number of patients with OSA who may benefit from OAT. The SPT may

provide an alternative mandibular position with greater patient adherence and more tolerable side effects for patients averse to or with discomfort in current OAT. Non-traditional multidisciplinary collaboration can yield significant benefits to already well-established therapies.

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Appendices

Appendix 2.A – Search strategy for Ovid MEDLINE (1946 to 2019)

Search strategy for Ovid MEDLINE (1946 to 2019)

1. sibilant* or biomimetic* or phoneme* or (phonetic adj3 bite*)
2. limit 1 to (humans and dentistry journals)
3. exp Dentistry/ or exp Sleep Apnea Syndromes/ or exp Respiratory System/ or exp Prosthodontics/ or (dentistry or dental or denture* or prosthodontic* or prosthetic* or airway or respiratory or sleep apnea or appliance* or orthodontic*).ti,ab,kf.
4. 1 and 3
5. 2 or 4

Search strategy for Embase (1974 to 2019)

1. sibilant* or biomimetic* or phoneme* or (phonetic adj3 bite*)
2. exp dentistry/ or exp sleep disordered breathing/ or exp respiratory system/ or (dentistry or dental or denture* or prosthodontic* or prosthetic* or prosthetic* or airway or respiratory or sleep apnea or appliance* or orthodontic*).ti,ab,jx,kw.
3. 1 and 2

Search strategy for Cochrane Library

sibilant* or biomimetic* or phoneme* or (phonetic near/3 bite*)

AND

dentistry or dental or denture* or prosthodontic* or prosthetic* or prosthetic* or airway or respiratory or "sleep apnea" or appliance* or orthodontic*

Search strategy for Scopus

TITLE-ABS-KEY (sibilant* OR biomimetic* OR phoneme* OR (phonetic pre/3 bite*)) AND TITLE-ABS-KEY (dentistry OR dental OR denture* OR prosthodontic* OR prosthetic* OR prosthetic* OR airway OR respiratory OR "sleep apnea" OR appliance* OR orthodontic*)

Search strategy for Web of Science Core Collection

TS=(sibilant* OR biomimetic* OR phoneme* OR (phonetic near/3 bite*)) AND TS=(dentistry OR dental OR denture* OR prosthodontic* OR prosthetic* OR prosthetic* OR airway OR respiratory OR "sleep apnea" OR appliance* OR orthodontic*)

Appendix 2.B – Table comparison between anterior protrusive and sibilant phoneme mandibular positioning techniques.

	Anterior Protrusive	**Sibilant Phoneme**
Customized vertical	No (Vertical determined by gauge)	Yes
Operator ease	Less technique sensitive	More technique sensitive
Learning curve	Less difficult	More difficult
Potential for operator error	Less likely	More likely
Delegable to staff	Potentially	No
Potential for patient adverse effects	More likely	Less likely
Popularity	Commonly used Commonly taught	Not commonly used
Titration method	Anterior only	Anterior and/or vertical

Cost	$$ (Initial gauge expense; bite fork expenses usually nominal)	$ (No gauge necessary)
Examples of gauges Used	George Gauge Andra Gauge Airway Metrics Gauge	No gauges used

Appendix 5.A – Information table

The following information about potential steps related to the proposed phases of using speech to determine mandibular positioning for dental appliances is provided for information purposes only. Please do not evaluate the potential steps at this time.

Proposed Phase 1: Recording anatomical landmarks

Proposed Steps

- Record the presence, grading, and grading method for maxillary ankylolabia (upper lip tie). Restriction has potential to affect lip seal
- Record the presence, grading, and grading method for mandibular ankylolabia (lower lip tie). Restriction has potential to affect lip seal
- Record the presence, grading, and grading method for ankyloglossia (tongue tie). Restriction has potential to affect speech and mandibular movement

Proposed Phase 2: Pre-Procedural testing

Proposed Steps

- Review CBCT imaging of the upper airway for potential pathology or obstructions
- Perform modified Cottle's maneuver on each patient's nostril to screen for nasal valve compromise
- Instruct patient to use saline nasal rinse for debris removal to screen for improvements to nasal patency from debris removal
- Assess for potential effects of nasal valve patency on the patient's speech and mandibular movement

Proposed Phase 3: Patient positioning

Proposed Steps

- Seat patient in an upright manner on a stool or chair without back support
- Ensure patient's feet are firmly planted flatly and evenly on the floor
- Instruct patient to position arms hanging neutrally without support on either side of their body
- Instruct patient to look straight ahead with eyes not focused on any particular object or landmark

Proposed Phase 4: Identifying speech measurement limits

Proposed Steps

- Instruct patient to count the numbers out loud from sixty to eighty in English at a normal speed. Repeat if needed
- Note the maxillary and mandibular incisal edge positions in an anterior-posterior direction during the production of /s/ as the anterior limit of the mandible
- Note the maxillary and mandibular incisal edge positions in a superior-inferior direction during the production of /s/ as the superior limit of the mandible
- Note the maxillary and mandibular incisal edge positions in a superior-inferior direction during the production of /i/ as the inferior limit of the mandible
- Note the positions of the maxillary and mandibular midlines to one another as the lateral limits of positioning of the mandible

Proposed Phase 5: Capturing occlusal relationships for mandibular position

Proposed Steps:

- If the exact desired vertical dimension is known, capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object of thickness that matches the desired specific vertical dimension and that only allows for point contact in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions and verify position again with the speech measurement limits previously noted
- If a specific vertical range is desired, capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object of thickness that matches the minimum desired specific vertical dimension and that only allows for point contact in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions. Verify position again with the speech measurement limits previously noted. Note the maximum vertical range desired. Do not exceed the absolute maximum vertical range as denoted in the speech measurement limits
- If an unspecified vertical range is desired, capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object of minimal thickness that matches the inter-incisal distance during the production of /s/ sounds and that only allows for point contact in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions. Verify position again with the speech measurement limits previously noted. Note the maximum vertical range as the inter-incisal distance during the production of /i/ sounds and

capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object that matches the inter-incisal distance during the production of /i/ sounds and that only allows for point contact in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions. Verify position again with the speech measurement limits previously noted.

Appendix 5.B – Expert consensus on the procedure of using speech for mandibular positioning in dental appliances

The purpose of this research is to define the procedure of using speech to determine mandibular positioning in dental appliances through expert consensus. You have been identified as an expert in this procedure (or part of it) considering your clinical and/or research experience. As you know, procedures are made up of phases and steps within those phases. In this second round of expert feedback, we would like to know your view about the STEPS of the phase "identifying speech measurement limits". Your answers and comments will not be shared with other experts. In upcoming rounds, you will be asked about steps within other phases. Thank you in advance for your time and support.

Please read the information provided in Table 1 before judging whether the following steps are sufficient and properly sequenced.

Section 2: Identifying speech measurement limits

Please indicate whether the following steps, which were derived from the literature and other sources (e.g., videos), should be part of the steps of the phase of identifying speech measurement limits for the procedure of using speech for mandibular positioning in dental appliances. Feel free to improve the name of the suggested steps if necessary and elaborate on your answer of including/excluding each phase using the comment box.

Table 1.

Steps	**Include this Step**	**Exclude this step**	**Rename this step (if necessary)**	**Comment**
Instruct patient to count the numbers out loud from sixty				

to eighty in English at a normal speed. Repeat if needed

Note any lateral mandibular movements and any lateral tongue movements/lisps

Note the maxillary and mandibular incisal edge positions in an anterior-posterior direction during the production of /s/ as the anterior limit of the mandible

Note the maxillary and mandibular incisal edge positions in a superior-inferior direction during the production of /s/ as the superior limit of the mandible

Note the maxillary and mandibular incisal edge positions in a superior-inferior direction during the production of /i/ as the inferior limit of the mandible

Note the positions of the maxillary and mandibular midlines to one another as the lateral limits of positioning of

the mandible

Section 2: Additional steps

Please suggest additional steps if necessary and elaborate on your suggestion(s) using the comment box. Leave this section blank if no additional step(s) is/are needed.

Suggested additional step **Reasoning for additional step**

Section 3: Steps order

Please order the steps in the sequence they should be performed, including those you may have suggested. If the order does not matter for certain or all steps, please indicate so.

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____

Appendix 5.C – Changes to phases and steps from the first round of expert feedback are shown below in redlined format

Proposed Phase 1: Recording anatomical landmarks

Proposed Steps

- Record dental and occlusal relationships (such as overjet, overbite, dental crowding, etc.)
- Record mandibular ranges of motion (such as maximum opening, protrusion, deflection on opening, etc.)
- Record the presence, grading, and grading method for maxillary ankylolabia (upper lip tie). Restriction has potential to affect lip seal
- Record the presence, grading, and grading method for mandibular ankylolabia (lower lip tie). Restriction has potential to affect lip seal
- Record the presence, grading, and grading method for ankyloglossia (tongue tie). Restriction has potential to affect speech and mandibular movement

Proposed Phase 2: Pre-Procedural screening and testing

Proposed Steps

- Assess orofacial musculature (for example, by palpation)
- Screen for temporomandibular disorder sign and symptoms
- Review ~~CBCT~~ of imaging (for example, CBCT or MRI) of the upper airway for potential pathology or obstructions as well as TMJ position and condition
- Perform modified Cottle's maneuver on each patient's nostril to screen for nasal valve compromise
- Instruct patient to use saline nasal rinse for debris removal to screen for improvements to nasal patency from debris removal
- Assess for potential effects of nasal valve patency on the patient's speech and mandibular movement

Proposed Phase 3: Patient positioning

Proposed Steps

- Measure baseline (habitual) posture and head position
- Provide interventions to relax the patient's orofacial musculature

- Seat patient in an upright manner on a stool or chair without back support with palms facing medially
- Ensure patient's feet are firmly planted flatly and evenly on the floor
- Instruct patient to position arms hanging neutrally without support on either side of their body
- Instruct patient to look straight ahead with eyes not focused on any particular object or landmark

Proposed Phase 4: Identifying speech measurement limits

Proposed Steps

- Instruct patient to count the numbers out loud from sixty to eighty in English at a normal speed. Repeat if needed
- Note the maxillary and mandibular incisal edge positions in an anterior-posterior direction during the production of /s/ as the anterior limit of the mandible
- Note the maxillary and mandibular incisal edge positions in a superior-inferior direction during the production of /s/ as the superior limit of the mandible
- Note the maxillary and mandibular incisal edge positions in a superior-inferior direction during the production of /i/ as the inferior limit of the mandible
- Note the positions of the maxillary and mandibular midlines to one another as the lateral limits of positioning of the mandible

Proposed Phase 5: Capturing occlusal relationships for mandibular position

Proposed Steps:

- If the exact desired vertical dimension is known, capture~~d~~ the relative positions of the mandibular occlusion to the maxillary occlusion using a round object of thickness that matches the desired specific vertical dimension and that only allows for point contact in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions and verify position again the speech measurement limits previously noted
- If a specific vertical range is desired, capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object of thickness that matches the minimum desired specific vertical dimension and that only allows for point contact in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions. Verify position again with the speech measurement limits previously noted. Note the maximum vertical range

desired. Do not exceed the absolute maximum vertical range as denoted in the speech measurement limits

- If an unspecified vertical range is desired, capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object of minimal thickness that matches the inter-incisal distance during the production of /s/ sounds and that only allows for point contact in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions. Verify position again with the speech measurement limits previously noted. Note the maximum vertical range as the inter-incisal distance during the production of /i/ sounds and capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object that matches the inter-incisal distance during the production of /i/ sounds and that only allows for point contact in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions. Verify position again with the speech measurement limits previously noted.
- Perform post-bite registration confirmation and evaluation with additional testing if indicated

Appendix 5.D – Changes to recording anatomical landmarks

Changes to the steps within the phase of "recording anatomical landmarks" from expert feedback are shown below in redlined format

Proposed Phase 1: Recording anatomical landmarks

Proposed Steps

- Record dental and occlusal relationships (such as overjet, overbite, dental crowding, etc)
- Record mandibular ranges of motion (such as maximum opening, protrusion, deflection on opening, etc)
- Record the presence, grading, and grading method for maxillary ankylolabia (upper lip tie). Restriction has potential to affect lip seal
- Record the presence, grading, and grading method for mandibular ankylolabia (lower lip tie). Restriction has potential to affect lip seal
- Record the presence, grading, and grading method for ankyloglossia (tongue tie). Restriction has potential to affect speech and mandibular movement

Appendix 5.E – Changes to pre-procedural screening and testing

Changes to the steps within the phase of "pre-procedural screening and testing" from expert feedback are shown below in redlined format

Proposed Phase 2: Pre-procedural screening and testing

Proposed Steps

- Review of imaging (for example, CBCT or MRI) of the upper airway for potential pathology or obstructions as well as TMJ position and condition
- Visually screen for nasal obstructions (such as gross nasal deviations and enlarged inferior turbinates)
- Screen for temporomandibular disorder signs and symptoms (such as clicking, popping, deviation of mandibular movement, and pain)
- Assess orofacial musculature (for example, by palpation held for 5 seconds to include assessment of potential radiation of symptoms)
- Perform modified Cottle's maneuver on each patient's nostril to screen for nasal valve compromise
- Instruct patient to use saline nasal rinse to screen for improvements to nasal patency from debris removal (such as subjective improvement to airflow and/or breathing and visual decrease of inferior turbinate and septal swell body size). Repeat with nasal decongestant if possible
- Assess for the effects of changes to nasal patency on the patient's speech and mandibular movement

Appendix 5.F – Changes to patient positioning

Changes to the steps within the phase of "patient positioning" from expert feedback are shown below in redlined format

Proposed Phase 3: Patient positioning

Proposed Steps

- Measure baseline (habitual) posture and head position in both standing and sitting positions
- Provide interventions to relax the patient's orofacial musculature (for example, by massage or cold laser)
- Seat patient in an upright manner on a stool or chair without back support with palms facing medially. Ensure patient's feet are firmly planted flatly and evenly on the floor. Instruct patient to position arms hanging neutrally without support on either side of their body (or hands on lap neutrally, if preferred for comfort by patient). Instruct patient to look straight ahead with eyes directed towards a blank wall or blank paper and not focused on any particular object or landmark

Appendix 5.G – Changes to identifying speech measurement limits

Changes to the steps within the phase of "identifying speech measurement limits" from expert feedback are shown below in redlined format

Proposed Steps

- Instruct patient to count the numbers out loud from sixty to eighty in English at a normal conversational speed and volume. Repeat if needed
- Note any lateral mandibular movements and any lateral tongue movements~~/lisps~~
- Note the maxillary and mandibular incisal edge positions in an anterior-posterior direction during the production of /s/ as the anterior limit of the mandible
- Note the maxillary and mandibular incisal edge positions in a superior-inferior direction during the production of /s/ as the superior limit of the mandible
- Note the maxillary and mandibular incisal edge positions in a superior-inferior direction during the production of /i/ as the inferior limit of the mandible
- Note the positions of the maxillary and mandibular midlines to one another as the lateral limits of positioning of the mandible

Appendix 5.H – Changes to capturing occlusal relationships for mandibular position

Changes to the steps within the phase of “capturing occlusal relationships for mandibular position” from expert feedback are shown below in redlined format

Proposed Steps

- If the exact desired vertical dimension is known, capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object of thickness that matches the desired specific vertical dimension and that only allows for point contact in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions and verify position again with the speech measurement limits previously noted
- If a specific vertical range is desired, capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object of thickness that matches the minimum desired specific vertical dimension and that only allows for point contact in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions. Verify position again with the speech measurement limits previously noted. Note the maximum vertical range desired. Do not exceed the absolute maximum vertical range as denoted in the speech measurement limits
- If an unspecified vertical range is desired, capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object of minimal thickness that matches the inter-incisal distance during the production of /s/ sounds and that only allows for point contact in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions. Verify position again with the speech measurement limits previously noted. Note the maximum vertical range as the inter-incisal distance during the production of /i/ sounds and capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object that matches the inter-incisal distance during the production of /i/ sounds and that only allows for point contact in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions. Verify position again with the speech measurement limits previously noted.
- Perform post-bite registration confirmation and evaluation with additional testing if indicated

Appendix 5.I – Protocol on the use of speech for mandibular positioning in dental sleep medicine

Phase 1: Recording anatomical landmarks

Proposed Steps:

1. Evaluate and record dental and occlusal relationships (such as overjet, overbite, teeth and gingival ratios, dental crowding, tooth ratios, skeletal and dental midlines, etc.)
2. Evaluate and record mandibular ranges of motion (such as maximum opening, protrusion, deflection of opening, etc)
3. Evaluate and record the presence, grading, and grading method for maxillary and mandibular ankylolabia (upper and lower lip tie). Restriction has potential to affect lip seal

   Evaluate and record the presence, grading, and grading method for ankyloglossia (tongue tie). Restriction has potential to affect speech and mandibular movement

Phase 2: Pre-Procedural screening and testing

Proposed Steps:

1. Measure baseline (habitual) posture and head position in both standing and sitting position
2. Review imaging (for example, CBCT or MRI) of the upper airway for potential pathology or obstructions as well as TMJ position and condition
3. Visually screen for nasal obstructions (such as gross nasal deviations and enlarged inferior turbinates)
4. Screen for temporomandibular disorder signs and symptoms (such as clicking, popping, deviation of mandibular movement, and pain)
5. Assess orofacial musculature (for example, by palpation held for 5 seconds to include assessment of potential radiation of symptoms)
6. Perform modified Cottle's maneuver on each nostril to screen for nasal valve compromise. If positive, consider use of a nasal dilator (or similar) and referral to otolaryngology for evaluation
7. Instruct patient to use saline nasal rinse to screen for improvements to nasal patency from debris removal (such as subjective improvement to airflow and/or breathing and visual decrease of inferior turbinate and/or septal swell body size). Repeat with nasal decongestant if possible
8. Assess for the effects of changes to nasal patency on the patient's speech and mandibular movement (for example, visually or by validated questionnaires such as the NOSE or SNOT-22 at

baseline and after nasal patency evaluative interventions)

Phase 3: Patient positioning

Proposed Steps:

1. Re-evaluate posture and head position in both standing and sitting position
2. Provide interventions to relax the patient's orofacial musculature (for example, by massage or cold laser)
3. Seat patient in an upright manner on a stool or chair without back support with arm and palms in a neutral position. Ensure patient's feet are firmly planted flatly and evenly on the floor. Instruct patient to position arms hanging neutrally without support on either side of their body (or hands on lap neutrally, if preferred for comfort by patient). Instruct patient look straight ahead with eyes directed towards a blank wall or blank paper and not focused on any particular object or landmark

Phase 4: Identifying speech measurement limits

Proposed Steps:

1. Instruct patient to count the numbers out loud from sixty to eighty in English at a normal conversational speed and volume. Repeat if needed
2. Note any lateral mandibular movements and any lateral tongue movements

   Note the maxillary and mandibular incisal edge positions in an anterior-posterior direction during the production of /s/ as the anterior limit of the mandible

   Note the maxillary and mandibular incisal edge positions in a superior-inferior direction during the production of /s/ as the superior limit of the mandible

   Note the maxillary and mandibular incisal edge positions in a superior-inferior direction during the production of /i/ as the inferior limit of the mandible

   Note the positions of the maxillary and mandibular midlines to one another as the lateral limits of positioning of the mandible

Phase 5: Capturing occlusal relationships for mandibular position

Proposed Steps:

1. If the exact desired vertical dimension is known, capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object of thickness that matches the desired specific vertical dimension and that only allows for point contact of incisal edges in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions and verify both sufficient occlusal clearance and position for the speech measurement limits previously noted (for example, with injection of polyvinyl siloxane bite registration material between the teeth, digital intraoral scanning, or through digital recording of jaw and occlusion tracking)

   If a specific vertical range is desired, capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object of thickness that matches the minimum desired specific vertical dimension and that only allows for point contact of incisal edges in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions and verify both sufficient occlusal clearance and position for the speech measurement limits previously noted (for example, with injection of polyvinyl siloxane bite registration material between the teeth, digital intraoral scanning, or through digital recording of jaw and occlusion tracking). Note the maximum vertical range desired with an absolute maximum as denoted in the speech measurement limits

   If an unspecified vertical range is desired, capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object of minimal thickness that matches the inter-incisal distance during the production of /s/ sounds and that only allows for point contact of incisal edges in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions and verify both sufficient occlusal clearance and position for the speech measurement limits previously noted (for example, with injection of polyvinyl siloxane bite registration material between the teeth, digital intraoral scanning, or through digital recording of jaw and occlusion tracking). Note the maximum vertical range as the inter-incisal distance during the production of /i/ sounds and capture the relative positions of the mandibular occlusion to the maxillary occlusion using a round object that matches the inter-incisal distance during the production of /i/ sounds and that only allows for point contact of incisal edges in order to maintain proper orientation of the occlusal planes relative to each other in three dimensions and verify both sufficient occlusal clearance and position for the speech measurement limits previously noted

2. Perform post-bite registration confirmation and evaluation with additional testing if indicated

Appendix 6.A – Individual pilot patient sleep indices data.

Individual pilot patient sleep indices data. Patients were provided with an oral appliance in both SPT and APT in a randomized crossover design. Home sleep apnea test study results pre and post-treatment with both mandibular positioning techniques are provided.

Abbreviations:

APT – anterior protrusive technique
SPT – speech positioning technique

AHI APT Pre-Op	AHI APT Post-Op	AHI SPT Pre-Op	AHI SPT Post-Op	RDI APT Pre-Op	RDI APT Post-Op	RDI SPT Pre-Op	RDI SPT Post-Op	ODI APT Pre-Op	ODI APT Post-Op	ODI SPT Pre-Op	ODI SPT Post-Op
21.1	8.6	24	9.9	29.1	12.6	31.1	15.4	20.6	8.2	25.1	10.1
24.8	15.7	32.7	7.1	32	19	41.4	10.4	20.6	12.7	35.2	8.1
30.4	8.8	43.7	15.8	37.9	12.2	52.7	23.9	20	9.7	33.9	14.3
25	6.3	25.1	9.4	31.6	12.3	32.9	15.6	12.4	3.9	17.4	4.7
15.6	2.4	15.4	3.6	27.7	11.6	28.4	11.3	14.8	2.6	14.5	4.2
17.9	16.1	24.9	22.5	31.6	27.1	36.1	35.5	14.6	16.1	24.1	21.3
19.6	7.9	15	5.5	26.4	15.4	23.8	14.8	7.1	6.5	11.5	3.4
16.4	5.4	16.2	5.8	24.5	15.5	27.2	15.4	14.3	4.3	10.7	4.5

Appendix 6.B – Individual pilot patient mandibular position data.

Individual pilot patient mandibular position data. Patients were provided with an oral appliance in both SPT and APT in a randomized crossover design. Mandibular position measurements are provided. Positive overjet values indicate mandibular position anterior to incisal edge to edge position, negative overjet values indicate mandibular position posterior to incisal edge to edge position.

Abbreviations:

APT – anterior protrusive technique
SPT – speech positioning technique
OJ – overjet
OB – overbite

Overjet	Overbite	Max Open	APT Protrusion	SPT Protrusion	APT Retrusion	SPT Retrusion	APT Pre-Op OJ	APT Post-Op OJ	APT Pre-Op OB	APT Post-Op OB	APT # Titrations	SPT Pre-Op OJ	SPT Post-Op OJ	SPT Pre-Op OB	SPT Post-Op OB	SPT # Titrations
4	2	48	5	4	5	6	0	3	5	5	3	0	0	4.5	6.5	2
3	3	52	8	8	4	4	0	3	5	5	3	0	0	4.5	5.5	1
5	5	42	5	5	8	8	-1	2	5	5	3	-1	-1	4.5	5.5	1
5	1	30	8	9	2	2	0	2	5	5	2	0	0	4.5	4.5	0
3	2	51	5	5	7	7	-2	-1	5	5	1	-2	-2	4.5	4.5	0
3	1	50	6	5	5	6	0	3	5	5	3	0	0	4.5	8.5	4
1	0	55	8	8	3	3	0	0	5	5	0	0	0	4.5	4.5	0
2	3	61	5	5	7	7	0	0	5	5	0	0	0	4.5	5.5	1

Appendix 6.C – Individual pilot sleep quality patient data.

Patients were provided with an oral appliance in both SPT and APT in a randomized crossover design. Symptomology questionnaire results pre and post-treatment with both mandibular positioning techniques are provided.

ESS APT Pre-Op	ESS APT Post-Op	ESS SPT Pre-Op	ESS SPT Post-Op	NTSE APT Pre-Op	NTSE APT Post-Op	NTSE SPT Pre-Op	NTSE SPT Post-Op	FSS APT Pre-Op	FSS APT Post-Op	FSS SPT Pre-Op	FSS SPT Post-Op
12	9	12	11	18	14	16	12	59	54	54	46
5	2	7	4	4	2	9	0	25	12	41	15
11	2	6	1	7	2	7	4	21	17	20	14
11	6	11	10	5	4	7	2	42	37	24	42
5	5	10	10	6	6	6	6	9	9	12	9
2	3	2	3	7	7	7	7	52	46	50	48
12	6	11	5	0	6	0	0	46	35	41	21
12	12	17	15	11	5	8	11	34	30	45	56