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Research Article

Oral Appliance Therapy - Cracking the Code

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Abstract

The objectives of the study were to test the hypotheses that during routine examination of a patient is it possible to prospectively determine the effective maxillo-mandibular position (EMP) at which to fabricate a custom fitted mandibular advancement device (MAD).

A series of subjects underwent oral appliance therapy with mandibular advancement device, first using the control method with the initial position being maxillo-mandibular incisal edge-to-edge and interincisal opening of 5 mm's (IMPC) and additional titration was performed on a weekly basis until subjects reported successful OAT. Each subject then underwent an oral appliance efficacy sleep study in the effective mandibular position (EMPC). Each subject then used a new MAD in the experimental IMP (IMPE) determined by the patient specific, multi-variable adaptive quantitative data analytic algorithm (MAD-FIT) and additional titration were performed on a weekly basis until subjects reported successful OAT. Each subject then underwent an oral appliance efficacy sleep study, with the MAD's set in the last titration maxillo-mandibular position (EMPE). Therapeutic outcomes of IMPC, IMPE, EMPC and EMPE were then compared.

MAD-FIT successfully predicted the optimal maxillo-mandibular position in 88% of subjects and under predicted IMPE in 12% of the subjects. In comparison 9% of the control group reported treatment efficacy and under predicted EMPC in 91% of the subjects at IMPC.

In conclusion MAD-FIT demonstrated a statistically significant association with successful oral appliance therapy outcome at the initiation of treatment compared to the control method.

Obstructive sleep apnea; mandibular repositioning device; serial titration; oral appliance therapy; sleep disordered breathing; snoring.

Keywords: Oral Appliance Therapy; Effective Maxillo-Mandibular Position (EMP); Mandibular Advancement Device (MAD)

Abbreviations

OSA: Obstructive Sleep Apnea; OAT: Oral Appliance Therapy; MAD: Mandibular Advancement Device; CPAP: Continuous Positive Airway Pressure; EMP: Effective Maxillo-Mandibular Position; IMP: Initial Maxillo-Mandibular Position; QOL: Quality of Life; ROS: Review of Symptoms; ESS: Epworth Sleepiness Scale; AHI: Apnea-Hypopnea Index; IMPC: Control Initial Maxillo-Mandibular Position; T: Titration; EMPC: Control Effective Maxillo-Mandibular Treatment Position; IMPE: Experimental Initial Maxillo-Mandibular Position; EMPE: Experimental Effective Maxillo-Mandibular Treatment Position; MAD-FIT: Patient Specific Multi-Variable, Adaptive, Quantitative Data Analytic Algorithm

Introduction

Sleep apnea is a potentially serious sleep disorder in which breathing repeatedly stops for 10 seconds or longer and then resumes and that occurs several times an hour, through the night. Obstructive sleep apnea (OSA) is the more common form and occurs

when the muscles in the back of the throat relax. These muscles support the soft palate, the triangular piece of tissue hanging from the soft palate (uvula), the tonsils, the side walls of the throat and the tongue.

When the throat muscles relax, the airway narrows or closes as one breathe in and as a result can't get an adequate breath in. This lowers the level of oxygen in the blood and negatively affecting the rest of the body, specially the brain. This repeat and prolonged oxygen deprivation makes for poor and disturbed sleep and results in daytime sleepiness, inability to concentrate, mood swings and irritability are among some of the symptoms. More serious complications as a result of untreated OSA are decreased lifespan (untimely death), daytime fatigue, high blood pressure and heart disease, increased risk of strokes, type 2 diabetes, metabolic syndrome, lack of libido and incontinence, increased risk of alcohol and substance abuse, Alzheimer's and dementia and not to mention sleep- deprived partners [1].

According to recent studies, OSA affects up to 24% of adult men and 9% of women [2] and is associated with significant morbidity and mortality [3]. Continuous positive airway pressure (CPAP) (Figure 1) delivers air pressure through a mask placed over your nose and the air pressure is greater than that of the surrounding air and is just enough to keep the upper airway passages open, preventing apnea and snoring.

Figure 1: CPAP.

Although CPAP is the most common and reliable method of treating sleep apnea, most people find it cumbersome and uncomfortable and its effectiveness is impacted by adherence [4]. Oral appliance therapy (OAT) with mandibular advancement device (MAD) (Figure 2) has been shown to be easier to use, an effective and suitable alternative to CPAP, particularly in patients with mild and moderate severity of obstructive sleep apnea (OSA) and recommended as alternative for patients with severe OSA who are CPAP noncompliant [5].

Figure 2: Mandibular Advancement Device (MAD).

MAD's keep the throat open by bringing the lower jaw (mandible) forward and keeping the tongue from falling back as seen in lateral cephalometric radiograph of the maxillo-mandibular complex (Figure 3) and relieve snoring and OSA.

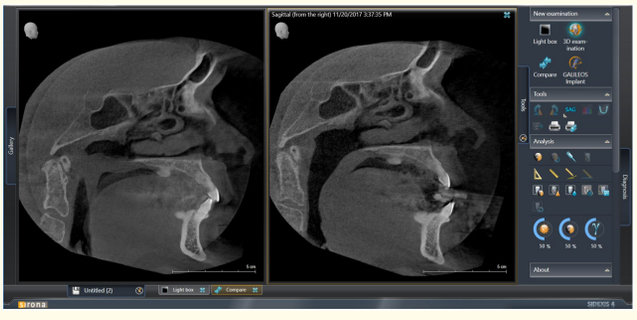

Figure 3: Lateral cephalometric radiograph of the maxillo-mandibular complex.

While the optimal titration of CPAP can be determined in an overnight titration study in a sleep laboratory, a similar method for determining the effective mandibular position (EMP) of a MAD for OAT is currently not part of standard practice. For that reason, there is a need for an objective method of prospectively determining EMP, bypassing the commonly practiced method of subjective and arbitrary determination of the initial maxillo-mandibular position (IMP) for start of OAT with MAD, followed by trial and error and time-consuming titration of developing EMP for effective OAT. Doing so will improve patients sleep resulting in symptomatic relief and improved quality of life, and optimal therapeutic result quicker which improves adherence to therapy and saving the

treating doctor and patient frustration and valuable time otherwise spent titrating.

Methods

75 Consecutive patients, ages 20 - 85 who were referred for oral appliance therapy with symptoms and diagnosis of OSA (AHI > 5/hr.) were recruited from dental practice.

We analyzed pre and post OAT sleep studies and patients survey data including but not limited to report of snoring, Epworth sleepiness scale (ESS), review of symptoms (ROS) and quality of life (QOL) of 75 consecutive patients referred for OAT after a diagnosis of obstructive sleep apnea (OSA).

Each patient was treated twice with MAD's and each time the same design and laboratory were used.

All participants were treated with a MAD and compliance was defined as use > 4 hr./night for > 4 nights/week, and effective therapeutic outcome was defined as subjective reporting of reduction in snoring, improvement in quality of life (QOL), improvement > 50% in daytime symptoms reported in Epworth sleepiness scale (ESS) and objectively by reduction of apnea-hypopnea index (AHI) > 50% at the effective maxillo-mandibular position (EMP). Subjects first underwent treatment with MAD, the way it's most commonly practiced, defining the initial maxillo-mandibular position (IMP) set at incisal edge-to-edge and interincisal distance using 5mm George Gauge fork (Figure 4) (IMPC), followed by weekly titration (T) in 1 mm increments in antero-posterior direction until the patient didn't report any additional change in symptoms and that maxillo-mandibular position was defined as effective treatment position of the control method (EMPC) and control OAT efficacy sleep studies were performed. Each subject then used a new MAD (same design and laboratory as the control MAD) made in the experimental IMP (IMPE) determined by the patient specific multivariable adaptive quantitative data analytic algorithm (MAD-FIT) and that maxillo-mandibular position registered using a 3 Dimensionally adjustable Andra Gauge (Figure 5) (Cosmo Technologies, Salt Lake City, UT) and followed by weekly titration (T) in 1 mm increments in antero-posterior direction until the patient didn't report any additional change in symptoms and that maxillo-mandibular position was defined as effective treatment position of the experimental method (EMPE) and experimental OAT efficacy sleep studies were performed either at home or overnight in a polysomnography laboratory with the MAD set in EMPE. Therapeutic outcomes of IMPC, IMPE, EMPC, and EMPE were then compared.

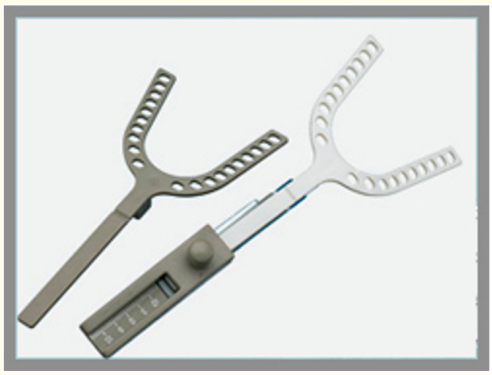

Figure 4: George gauge.

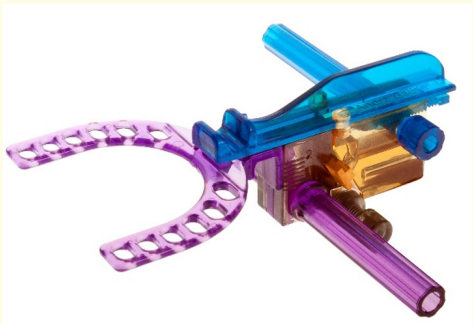

Figure 5: Andra gauge.

Results

Patients (mean age 52 years; 74% male, mean AHI = 26) who underwent OAT using MAD-FIT were more likely to be satisfied with their OAT experience than patients who underwent the control method (88% vs 9%; $p < 0.05$). Further, the 91% diminished satisfaction in patients undergoing the control method improved after adjustment for potential non-responders. Greater sleep apnea symptom relief and satisfaction with OAT were associated with greater compliance. Effect modifications of IMP and ST as study triggers were also detected.

At IMPC, standard predictive parameters (sensitivity, specificity, positive and negative predictive values) showed statistical predictive accuracy ($P < 0.05$) of 8%. The patient specific multi-variable adaptive quantitative data analytic algorithm MAD-FIT determinant of IMPE provided an efficacious mandibular position in 88% of participants predicted to be therapeutically successful MAD

therapy ($P < 0.05$). 75% of the control group underwent up to 5 additional titrations (TC1 n = 8, TC2 n = 16, TC3 n = 20, TC4 n = 8, TC5 n = 4) and 17% were non-adherents, and 8% of the experimental group underwent up to 2 additional titrations (TE1 n = 4, TE2 n = 3) until reported therapeutic outcome. 17% of the control and 3% of the experimental group were non-adherents to OAT (Figure 6). MAD-FIT successfully predicted the optimal maxillo-mandibular position in 88% of subjects and under predicted IMPE in 12% of the subjects. In comparison 9% of the control group reported treatment efficacy and under predicted EMPC in 91% of the subjects at IMPC (Figure 7).

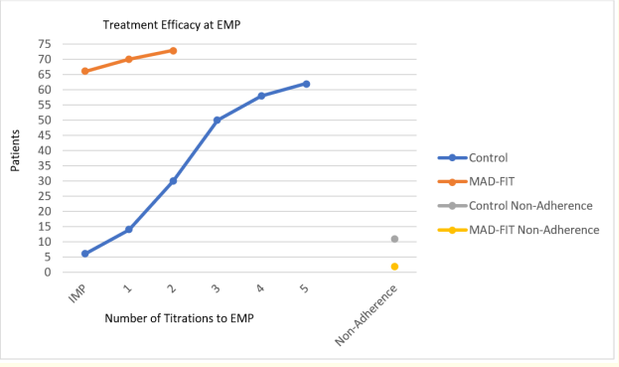

Figure 6: Number of titrations performed to achieve treatment efficacy at effective mandibular position (EMP).

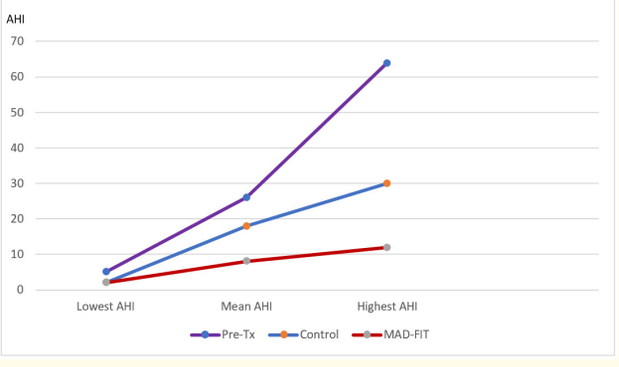

Figure 7: Apnea-hypopnea index at pretreatment, effective mandibular position (EMP) of control and MAD-FIT method.

Patients (mean age 52 years; 74% male, mean AHI = 26) who underwent OAT using MAD-FIT were more likely to be satisfied with their OAT experience than the control method (88% vs 9%; $p < 0.05$). Further, the 91% diminished satisfaction in patients undergoing the control method improved after adjustment for potential non-responders. Greater sleep apnea symptom relief and satisfaction with OAT were associated with greater compliance. Effect modifications of IMP and ST as study triggers were also detected.

Discussion and Conclusion

Using previously established rules for therapeutic outcome and development of EMP, the patient specific multi-variable adaptive quantitative data analytic algorithm (MAD-FIT) predicted therapeutic success of OAT with significantly more accuracy and with fewer titrations and better OAT adherence, compared with the commonly practiced method of subjective determination of the initial maxillo-mandibular position followed by hit or miss, trial and error method of titrating a MAD which resulted in delayed, unpredictable therapeutic outcome and poor OAT adherence. From experience and other research, we know that how quickly a patient feels better from therapy has a direct correlation to adherence and this study reaffirmed that.

In conclusion MAD-FIT demonstrated a statistically significant association with successful OAT outcome at the initiation of treatment compared to the commonly practiced arbitrary and subjective determination of the initial maxillo-mandibular interincisal position followed by trial and error method of titration until patient reporting of improvement of symptoms. The predictive IMP determined by MAD-FIT was more efficient in determining the EMP compared to the control method of subjective determination of IMP of MAD followed by serial titration to develop the EMP for successful OAT.

Patients reported a better overall experience and greater satisfaction with MAD-FIT method than with the control method. Our findings, based on data from current "real-world" settings, suggest that a patient specific multi-variable, adaptive, quantitative data analytic algorithmic determination of the initial maxillo-mandibular relationship provided greater treatment efficacy and there was a decreased need for further titrations, leading to quicker and more effective patient treatment and assumptions about the subjective and arbitrary determination of the initial position of the mandible and the 1 dimensional, bi-directional change can effectively, consistently and predictively influence a 3 dimensional, concentric collapse of the airway paradigms need to revisited.

Brief Summary

Mandibular advancement devices are a recognized treatment for snoring and mild to moderate OSA and an alternative therapy for CPAP noncompliance severe OSA. While the optimal titration of CPAP can be determined in an overnight titration study in a sleep laboratory, a similar method for mandibular advancement device is currently not part of standard dental practice. There needs to be an

objective method that prospectively defines the effective mandibular position for successful therapy with a mandibular advancement device.

Doing so will achieve optimal therapeutic outcome predictably and faster and improve their sleep resulting in improvement of their daytime symptoms, quality of life, which improves adherence to therapy and saving the doctor frustration and valuable time otherwise spent titrating.

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Authors Statement

We all have read the manuscript and approve it for submission.

Declarations

- We did not receive any financial compensation or support for the study from any oral appliance therapy or device manufacturers and no referring physicians and patients were not compensated either.
- We don't perceive there to be any conflicts of interest as the lead investigator was an employee of the dental practice Arch Dental Associates where the patients were treated, and the co-investigators were unpaid research assistants.
- The lead investigator does however disclose his position at APP-NEA, LLC a biotechnology firm that provides cloud-based practice support to dentists and physicians, but the study was unrelated to any products offered by the firm.

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