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Soldier Preference in Mandibular Advancement Devices in Patients Who Brux

Andrew S Ryser[*,1], Jennifer Sabol[2], Steven Handel[3], Patricia Walworth[4], Walter Dimalanta[5], Sloan McLaughlin[6], Thomas Stark[7], Maddie E Ryser[8] and Kyung Kim[9]

[1]Prosthodontic Resident, CPT, Department of Prosthodontics, Army Postgraduate Dental School, Postgraduate Dental College, Uniformed Services University, Fort Eisenhower, GA, USA

[2]Program Director, COL, Department of Prosthodontics, Army Postgraduate Dental School, Postgraduate Dental College, Uniformed Services University, Fort Eisenhower, GA, USA

[3]Assistant Program Director, LTC, Department of Prosthodontics, Army Postgraduate Dental School, Postgraduate Dental College, Uniformed Services University, Fort Eisenhower, GA, USA

[4]Prosthodontist, MAJ, US Army, Fort Sam Houston, Texas

[5]Prosthodontist, COL, US Army, Fort Bliss, Texas

[6]Assistant Program Director, LTC, Department of Prosthodontics, Army Postgraduate Dental School, Postgraduate Dental College, Uniformed Services University, Fort Eisenhower, GA, USA

[7]Chief, COL, Graduate Dental Education Dean, Army Postgraduate Dental School, Joint Base San Antonio, TX 78234

[8]Private Practice, Georgia

[9]Assistant Program Director, COL, Department of Prosthodontics, Army Postgraduate Dental School, Postgraduate Dental College, Uniformed Services University, Fort Eisenhower, GA, USA

[*]**Corresponding author:** Andrew S Ryser, Prosthodontic Resident, CPT, Department of Prosthodontics, Army Postgraduate Dental School, Postgraduate Dental College, Uniformed Services University, Fort Eisenhower, GA, USA

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Abstract

This pilot study compared military service member's preference between the modified ProSomnus IA™ and TAP 3™ appliances for the treatment of obstructive sleep apnea (OSA) and sleep bruxism. Thirteen patients diagnosed with OSA and bruxism were referred for fabrication of a mandibular advancement device (MAD). Using a random allocation process, patients were treated for one month with either the modified ProSomnus IA TM or the TAP 3 TM MAD. After one month, the patients received the other appliance. By the end of the study, all patients were treated with both devices for a one-month period. During the final appointment, the patients were asked which device was preferred for long-term treatment of OSA and sleep bruxism. Eight of 13 patients enrolled in this study preferred the modified ProSomnus IA TM over the TAP 3 TM MAD for the treatment of OSA. One patient was unable to tolerate either device; two dropped out of the study. The two patients who preferred the TAP 3 TM also used a CPAP simultaneously. The modified ProSomnus IA TM was the preferred

device for most patients with OSA and sleep bruxism. Patients who used a CPAP with the MAD preferred the TAP 3 TM over the modified ProSomnus IA TM during the 2-month study period.

Keywords: Obstructive Sleep Apnea, Mandibular Advancement Device, Bruxism, Sleep Medicine

Abbreviations: OSA: Obstructive Sleep Apnea, MAD: Mandibular Advancement Device, CPAP: Continuous Positive Airway Pressure, ADL: Army Dental Laboratory, PSG: Polysomnogram, STL: Standard Tessellation Language

Introduction

Obstructive sleep apnea (OSA) is an emerging health concern for the military population associated with medical and behavioral comorbidities including stroke, hypertension, diabetes, cognitive dysfunction, and depression **[1]**. The risk of developing OSA increases with age and the condition is more common in men than women. An estimated 3-7% of men and 2-5% of women suffer from OSA **[2]**. Untreated OSA is a growing public health issue as an estimated 80-90% of those with OSA remain undiagnosed **[2]**. A recent study found the prevalence of OSA among military members is highest within the Army at 12.15%, followed by the Air Force at 9.96%, and the Navy with 9.06% **[3]**. Between 2005 and 2019, OSA incidence in the U.S. military increased from 11 per 10,000 to 333 per 10,000, an increase of over 2900% **[4]**. Although the gold standard for OSA treatment is continuous positive airway pressure (CPAP), its use can be challenging in military populations **[5]**. Long-term adherence to CPAP therapy is often poor. According to a recent study, CPAP compliance, defined as a minimum of 4 hours per night for at least 5 nights a week, was less than 50% in patients with mild OSA **[5]**. Additionally, CPAP use is not ideal for a field environment because an electrical source or battery is required to power the device. Service members may be required to spend extended periods of time in an austere environment, therefore a treatment alternative that doesn't require a reliable power source is desperately needed**.** Due to poor CPAP compliance and intolerance by some patients, and unique challenges associated with military deployments, the mandibular advancement device (MAD) has emerged as a favorable treatment option for OSA in service members **[6,7]**. During the fiscal year of 2022, the US Army Dental Laboratory (ADL) (Fort Eisenhower, Georgia, USA) distributed 2,221 mandibular advancement devices to dentists in the military health care system totaling over six million dollars in patient treatment received **[8]**. Assuming a patient has a sufficient number of teeth to support a MAD, the following factors assist with device selection: mouth size, arch shape, of, integrity of restorations and teeth, occlusal conditions (e.g. deep bite, open bite) retentive elements of the dentition, customizability, titratability, patient dexterity and patient comfort **[9,10,11]**. When significant sleep bruxism is present, modification of the device design allows for lateral movement of the mandible and avoids damaging the appliance **[9,10,11]**.

The US Army currently uses five different MADs for treatment of OSA including the TAP 3 ™, DreamTAP ™, ProSomnus IA ™, ProSomnus Evo ™, and ProSomnus Herbst appliances (Pleasanton, California, USA). The TAP 3 ™ allows for some lateral excursion while the ProSomnus IA requires modification to allow for lateral excursion. To date, no published studies evaluate patient preferences regarding the type of MAD used to treat OSA in the military setting. Moreover, no studies in a military population demonstrate the preference of one MAD over another for the management of sleep bruxism. If a preference is determined, therapy could be targeted towards simultaneous treatment of OSA and sleep bruxism. Furthermore, practitioners will have increased confidence when recommending devices that will most likely be preferred, thus avoiding costly remakes, not only in terms of finances and lost lab/clinical time, but also avoiding lost time for the provider and service member. Fabricating a MAD, the patient prefers will increase compliance, decrease the comorbidities associated with OSA, and may decrease accident, injuries, or even deaths caused by the effects of OSA. In the military, increasing effective treatment of OSA will improve readiness and improve the service members' ability to complete the mission.

The purpose of this study is to determine whether service members prefer one type of MAD over another for the management of OSA and sleep bruxism. A second aim of the study is to determine the factors related to the patient's

decision-making process.

Methods

This pilot study underwent an institutional review board and all participants provided informed consent to participate in the study. A power analysis was completed to estimate sample size, and was determined to be 10, with a significance criterion of .05 and a power of 80%. The primary objective of this study was to determine if there was a preference between a modified ProSomnus IA ™ and TAP 3 ™ devices in patients who have OSA and sleep bruxism. The ProSomnus IA ™ was modified with wings extending 2 millimeters (mm) laterally to permit lateral excursions of the mandible, as the TAP 3 ™ also allows for such movements.

Active-duty military patients were referred to Tingay Dental Clinic Prosthodontics Department (Fort Eisenhower, Georgia, USA) for treatment of mild to moderate OSA with oral appliance therapy. Patients were then screened by a single examiner for sleep bruxism by the presence of the following: intraoral signs of bruxism (e.g. dental wear) and patient reporting waking up with a headache or sore/tight jaw muscles, patients stated his/her bed partner says he/she grinds teeth while sleeping, or confirmation of bruxism on the polysomnogram (PSG).

Once sleep bruxism was confirmed, the patient was accepted into the study and treated for OSA by receiving the following two devices: the TAP 3 ™ or the modified ProSomnus IA ™ MAD. Digital impressions utilizing the CEREC Primescan (Dentsply Sirona, Charlotte, North Carolina, USA) were made of the maxillary and mandibular arches as well as the protrusive position determined by use of a George Gauge (Great Lakes Dental Technologies, Buffalo, New York, USA) and vinyl polysiloxane bite registration material. Scanned standard tessellation language (STL) files were sent to the US Army Dental Laboratory for fabrication of the two devices.

In order to randomly select who received which device, a die was rolled and patients with odd numbers received the TAP 3 ™ appliance first and those that rolled even numbers received the modified ProSomnus IA ™ appliance first. Once the initial device was delivered, adjustments were made to ensure the device fit correctly and was comfortable for the patient. After all adjustments were made, the patient used the designated device for at least one month and then returned to the clinic. At two weeks post-delivery, a phone consultation was completed to address tolerability, compliance, and schedule return appointments for adjustments. Appliances were advanced, if necessary, based on subjective symptoms of the patient's sleep quality. After one month, the second device was delivered to the patient. At two weeks post-delivery, a phone consultation was completed using the same protocol to access appliance tolerability, compliance, and efficacy and provide titration instructions as needed. After at least one month with the second device, the patient returned to the clinic.

During the final appointment, the patient was asked which device he or she preferred and would like to go home with for long-term treatment. Whichever device the patient preferred was the device the patient was advised to use for treatment of OSA. Following the appointment, the patients were referred to the sleep medicine clinic at Dwight D. Eisenhower Army Medical Center (Fort Eisenhower, Georgia, USA) or the Veterans Administration primary care physician for follow up care to include a post-delivery PSG.

Study Results

In total, 13 patients were enrolled in the study and 13 patients received care under the study. Eleven patients were diagnosed with mild OSA, and two were diagnosed with moderate OSA with an AHI less than 20. Eleven patients completed the study. One patient dropped out after receiving the ProSomnus IA ™ due to being transferred overseas and unable to return to the clinic before moving.

A second patient dropped out of the study after receiving the ProSomnus IA ™ and discontinuing use after one week. A third patient could not tolerate the TAP 3 ™ or ProSomnus IA ™ and was provided a ProSomnus Evo appliance for treatment of OSA. Only two patients favored the TAP 3 ™ appliance while eight patients preferred the modified ProSomnus IA ™

The following were reasons provided by the patients as to why they chose the ProSomnus IA ™ appliance:

- "smoother and sturdier material"
- more comfortable"
- "I could move my jaw side to side"

- "felt like it would last a while"
- "did not prevent me from opening my mouth during sleep"
- "other device was hard to connect"
- "easier to place in the mouth"

The following were reasons provided by the patients as to why they chose the TAP 3 ™:

- "When using my CPAP, other device caused discomfort on the cheeks"

Discussion

While CPAP is accepted as the standard treatment for OSA, compliance remains an issue for continuous long-term management. Compliance for the use of CPAP is considered 4 hours per night for 70% of nights for 30 consecutive days **[5]**. Patel et al. reported CPAP adherence is between 17-71%, while Rotenberg, Muraiu and Pang noted an average non-adherence rate of 34.1% **[12,13]**. Surgical interventions for OSA may be suitable for some patients with anatomical abnormalities resulting in a narrowed airway (e.g. adenotonsillary hyperthrophy, mandibular retrognathia), and/or facial features that impair CPAP mask fit **[14]**. While surgical treatment may initially cure OSA, relapse may occur requiring patients to return to CPAP or MAD use **[15]**. Both MAD and CPAP carry less risk than surgical interventions. Although compliance is greater with MAD than CPAP, treatment efficacy of CPAP is superior to MAD use for patients with severe sleep apnea (AHI >30) **[16,17]**.

Bruxism is a condition in which a person grinds their teeth and can occur whether the person is awake or asleep. The Glossary of Prosthodontic Terms defines bruxism as "repetitive jaw-muscle activity characterized by clenching or grinding of the teeth and/or bracing or thrusting of the mandible; it has two distinct circadian manifestations elating to whether it occurs during sleep (sleep bruxism) or during wakefulness (awake bruxism)." **[18]**. Bruxism is caused by a variety of factors to include stress, depression, genetics, medications **[19,20]**. If bruxism is mild, the patient may not require treatment and symptoms may not be present. However, if the bruxism is severe or causes obvious signs or symptoms, treatment may be warranted. Bruxism can cause accelerated attrition of teeth leading to pain or sensitivity and might require restoration of the teeth **[21]**. It can also cause TMD symptoms, myofascial pain, and headaches **[22]**. Unfortunately, treatment of bruxism often occurs once attrition of the teeth becomes severe or symptoms become intolerable for the patient. Other treatment options include orthotic devices to prevent wear of the dentition, behavioral management to reduce stress and depression, relaxation techniques, limiting the use of caffeine, medications, and Botox® **[23]**. When a patient presents with OSA and sleep bruxism, dentists can treat the conditions simultaneously **[24]**. For patients with comorbid OSA and sleep bruxism, compliance may be improved by selecting a MAD that allows lateral movements. The additional benefit of being able to use a prosthesis in any kind of environment without the need for a power source gives MAD the flexibility that travelers require without the inconvenience of a CPAP machine.

The majority of patients included in this study preferred the modified ProSomnus IA ™ over the TAP 3 ™ MAD. Patients provided reasons previously listed such as the ability to open their mouth and appliance comfort for why they chose the ProSomnus IA ™, while those who chose the TAP 3 ™ did so due to simultaneous use of a CPAP. The reasons for choosing the TAP 3 ™ while also using CPAP was that the wings on the IA would irritate the buccal mucosa because of pressure from the CPAP face mask. Patients who did choose the TAP 3 ™ preferred the ProSomnus IA ™ over the TAP 3 ™ if the CPAP was also not utilized at night. Use of a CPAP plays a critical role in what MAD the dentist chooses to treat OSA. Appliance choice can influence patient comfort and compliance. Other factors such as nocturnal bruxism also must be taken into consideration to choose the correct MAD design.

The manufacturing process and material of the MAD appeared to influence appliance preference. The ProSomnus IA ™ is a milled PMMA interlocking mandibular advancement device. The TAP 3 ™ is an anterior midline traction device that is made from a prefabricated bilaminate resin that utilizes suction and heat for fabrication on stone or printed models. The ProSomnus is delivered to the patient smooth and glossy with a flat occlusal plane. The TAP 3 ™ is delivered to the patient and the occlusion is finalized by adding clear acrylic to the occlusal portion of the mandibular

device in order to achieve a tripod effect instead of all occlusal force being placed at the anterior hook. When considering which MAD to prescribe to a patient, a demonstration of the available MADs with a discussion on the material, mechanism of action, and ability to titrate is crucial to allow the patient and clinician to choose the appropriate MAD.

Adjustments made to the IA appliance included reducing the extension of the borders and minor occlusal adjustments for patient comfort and improved fit. Alterations to the TAP 3 ™ were more common and include adjustments to the borders, adjustments to the intaglio to allow complete seating of the device, and addition of acrylic to form a tripod after the final titration position was located. The TAP 3 ™ also required adjustments to prevent the screw from loosening in the patients who used the MAD in combination with a CPAP.

The TAP 3 ™ has significant concerns unrelated to this pilot study including the potential for loosening of the anterior midline traction screw and corrosion of the metal pieces. Additional concerns related to the TAP 3 ™ include the need to add acrylic to fill the interocclusal space to achieve occlusal stability and the potential for delamination of the lining from the TAP 3 ™ appliance. The TAP 3 ™ also exhibits esthetic concerns because of discoloration of the bilaminate material after a few months, while the ProSomnus IA ™ maintains an esthetically pleasing look over time.

The Prosomnus IA ™ is made of brittle, hard material that can be easily broken if dropped on a hard surface. The wings of the IA can be a source of discomfort on the buccal mucosa, especially if a patient also utilizes a CPAP. Unlike the TAP 3 ™ MAD, the Prosomnus IA ™ has multiple trays that need to be adjusted if further adjustment to the protrusion of the mandible is going to be made.

Although this study indicated a patient preference when treating OSA and bruxism with a mandibular advancement device, only two types of appliances were tested. The ProSomnus IA ™ and TAP 3 ™ MAD may not be the preferred devices used in all dental practices and were chosen due to limitations of what MAD is available in the US Army. Further research is needed to test all types of MADs in patients with sleep bruxism and OSA. Modification of the ProSomnus IA ™ to extend wings laterally is a factor the clinician should consider and request in the prescription to the company. Without doing so, the ProSomnus IA ™ would not allow for any lateral movement in bruxers. ProSomnus has also introduced a newer version of the IA ™ called the EVO ™ and further studies using that appliance should be completed to determine if there is a preference towards the unattached bilateral push MAD is persistent in patients with OSA and bruxism. The TAP 3 ™ appliance appeared to have manufacturing defects in this study with corrosion and the screw loosening in the anterior midline traction device. However, with a small sample size, conclusions cannot be made, and further research is needed to examine this concern. More research is also needed to determine how much lateral movement is preferred in MADs for patients with OSA and sleep bruxism. Additionally, there are other methods of accurately diagnosing sleep bruxism which include: a PSG with EMG recording of masticatory muscle activity, and the Standardized Tool for the Assessment of Bruxism recently release by Manfredini et al. in 2023 **[25,26]**.

Clinicians should evaluate the entire picture when treating OSA and can use this study to modify MADs for treatment of bruxism or think about the design of the MAD when the patient also utilizes a CPAP. If a specific MAD design is not compatible with a full mask CPAP, perhaps the clinician can work with the sleep doctor to see if a nasal hood would be appropriate thus allowing the patient to not only successfully utilize a CPAP, but to also use the MAD the patient prefers also.

Conclusion

The majority of patients in this pilot study preferred the modified ProSomnus IA ™ over the TAP 3 ™ MAD for treatment of OSA and sleep bruxism. When CPAP was also used, the patients preferred the TAP 3 ™ MAD. Although the number of participants in this study was small, it offers the dental community a chance to consider larger clinical trials evaluating patient preference for MAD design in the presence of sleep bruxism or with concurrent CPAP use.

Data Availability

The authors confirm that the data supporting the findings of this study are available within the article. The data that support the findings of this study are available from the

corresponding author, Andrew Ryser, upon reasonable request.

Disclaimer

The views expressed in this manuscript are those of the authors and do not necessarily reflect the official policy of the United States Government, the Department of Defense, the Defense Health Agency, or Uniformed Services University of the Health Sciences.

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