TITLE: Patient Preference Between the ProSomnus IA and TAP 3 Mandibular Advancement Devices in Patients Who Brux

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ABSTRACT

Study Objectives:

This qualitative analysis compared patient preference between a modified ProSomnus IA and TAP 3 appliances in patients diagnosed with obstructive sleep apnea (OSA) and bruxism.

Methods:

A ProSomnus IA modified with the wings extended laterally 2 mm and a TAP 3 MAD were prescribed to 13 patients with bruxism and OSA. One MAD was delivered and used for one month. After one month the patient returned to the clinic and received the second MAD. At the final appointment the patient was asked which device was preferred for long-term treatment.

Results:

Eight of 13 patients enrolled in this study preferred the ProSomnus IA for treatment of OSA over the TAP 3. One patient was not able to tolerate either device and two dropped out of the study. The two patients who preferred the TAP 3 also used a CPAP simultaneously.

Conclusion:

The modified ProSomnus IA was the preferred device for patients with OSA and bruxism. Patients who used the CPAP and a MAD preferred the TAP 3 initially however those two patients later switched back to the ProSomnus IA due to issues with their TAP 3.

Practical Implications:

Choosing the preferred device first will allow the patient to potentially receive successful treatment for OSA and bruxism in a timelier manner, increasing compliance, saving valuable clinic time and preventing costly remakes.

KEYWORDS:
Obstructive sleep apnea, mandibular advancement device, bruxism, sleep medicine

INTRODUCTION

Obstructive sleep apnea (OSA) is a major systemic health condition that is associated with other medical comorbidities such as stroke, hypertension, diabetes, cognitive functions, depression, and excessive daytime sleepiness.[1] It is estimated that 3-7% of men and 2-5% of women have obstructive sleep apnea.[2] OSA risk increases with age and is more common in men. It is estimated that 80-90% of those with obstructive sleep apnea remain undiagnosed.[2] OSA and its associated comorbidities decrease readiness of the individual Soldier and the overall readiness of the military. According to a 2022 study by Haynes et al, the prevalence of OSA among military members is highest within the Army at 12.15%, followed by the Air Force at 9.96%, and then the Navy with 9.06%.[3] According to a study by Moore et al. in 2021, between 2005 and 2019, OSA incidence in the US military increased dramatically from 11 per 10,000 to 333 per

10,000, an increase of over 2900% Service members in the US Army tend to be diagnosed with OSA at higher rates than the US Air Force and Navy.[4]

The gold standard for treatment of obstructive sleep apnea is continuous positive airway pressure (CPAP), however several issues are of particular importance concerning the use of CPAP in the military.[5] First, CPAP usage has poor compliance with less than 50% of users reporting compliance, defined as at least 4 hours per night for at least 5 nights a week of using CPAP.[5] Secondly, CPAP requires an electrical source, or at least a battery, to function, which is not ideal for a field environment, such as training exercises**,** deployment to a war zone**,** or humanitarian missions in rustic regions**.** Due to the poor compliance and intolerance by some patients, and challenges with CPAP in certain situations such as austere conditions, the flexible usage of mandibular advancement devices (MADs) have emerged as a viable alternative treatment option.[6]

Mandibular advancement devices come in a variety of designs and can be classified as prefabricated or customized. Customized MADs can be adjustable or nonadjustable.[7] MADs can be further classified according to their coupling mechanism of being attached or unattached. Attached devices include midline traction, bilateral traction (bilateral pull), and bilateral compression (bilateral push) MADs.[7] Unattached devices include interlocking devices. Each type of device has specific indications, advantages, and disadvantage that clinicians need to consider when choosing the most appropriate design for each patient.[7] The following factors will help determine what MAD should be selected for specific patients: size of mouth, shape of arch, existence of parafunctional habits such as bruxism, defective/vulnerable restorations and teeth, vertical dimension concerns such as a deep bite, retentive elements of the dentition, the need for an anterior airway, patient dexterity, the ability to titrate, and ease of titration for the patient.[8,9.10]

When a patient presents with parafunctional habits such as nocturnal bruxism the device design is critical to allow for lateral movement of the mandible.[8,9,10]

As a large organization, the US Army spends a significant amount of money on treatment of obstructive sleep apnea.[11] The US Army Dental Laboratory (Fort Eisenhower, Georgia, USA) sent out 2,221 mandibular advancement devices in the fiscal year of 2022 totaling over six million dollars in patient treatment received.[11] The Army currently uses five different MADs for treatment of OSA. These include the ADL fabricated TAP 3, the DreamTAP, the ProSomnus IA, Evo, and Herbst appliances (Pleasanton, California, USA). The TAP 3 allows for some lateral movement and the ProSomnus IA must be modified to allow lateral movement. Lateral movement of the device is important in patients who brux. A comparison of the TAP 3 and ProSomnus IA device with modified wings will provide the military, medical, and dental community an opportunity to see if one of these two devices is preferred in OSA patients who brux. If a preference is determined, dental providers could use the preferred device to initiate treatment of patients with OSA who also brux. Furthermore, the dental provider will have increased confidence that they are choosing a device 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 Soldier. Providing 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.

METHODS

This qualitative analysis underwent an institutional review board and all participants provided informed consent to participate in the study. A G 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. There was one main objective for this study: to see if there was a preference between a modified ProSomnus IA and TAP 3 mandibular advancement devices in patients who have OSA and brux. The ProSomnus IA was modified to have the wings extended laterally 2mm to give the patient the ability for lateral movements of the mandible, as the TAP 3 also allows for such movement.

Patients were referred to a prosthodontics clinic for treatment of OSA with mandibular advancement devices, were then screened for bruxism by 1 or a combination of the following 3 methods: signs of bruxism based on an intraoral exam, patients stated his/her bed partner says he/she grinds teeth while sleeping, or confirmation of bruxism on the polysomnogram (PSG). Once screened and bruxism was confirmed, the patient was treated for OSA by receiving the following two devices: the TAP 3 or the ProSomnus IA MAD with wings modified to extend laterally 2mm. 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 lab 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 ProSomnus appliance first (randomization was done to account for potential recency and primacy bias). Once the first device was delivered, adjustments were made to ensure it fit correctly and was

comfortable for the patient. After all adjustments were made, the patient used the first device for at least one month and then returned to the clinic. Titrations to the protrusive position of the device were made as needed based on subjective symptoms of the patient's quality of sleep. After a month, the second device was delivered to the patient, adjusting for clinical acceptance and comfort and was titrated as necessary. After at least one month of using the second device the patient returned to the clinic.

At the final appointment, the patient was asked what 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. The patients then were referred back to sleep medicine or their primary care physician for follow up care and an efficacy PSG.

STUDY RESULTS

In total 13 patients were enrolled in the study and 13 patients received care under the study. Eleven patients completed the study. One patient dropped out after receiving the ProSomnus IA due to being transferred overseas and not being able to return to the clinic before moving. A second patient dropped out of the study after receiving the IA and using it for a week . Eight of the patients preferred the ProSomnus IA with the wings modified to extend laterally 2mm over the TAP 3 appliance. One patient could not tolerate the TAP 3 nor ProSomnus IA and was given a ProSomnus Evo appliance for treatment of OSA. Two patients chose the TAP 3 appliance to treat their obstructive sleep apnea.

The following were reasons provided by the patients as to why they chose the ProSomnus IA appliance or why they did not choose the TAP 3:

- The material of the IA was smoother and felt sturdier.

- The IA was more comfortable.
- The IA allowed the patient to move their jaw side to side.
- The IA felt like it would last a while.
- The IA did not prevent the patient from opening their mouth during sleep.
- The TAP 3 was hard to connect and the IA was easier to place in the mouth.

The following were reasons provided by the patients as to why they chose the TAP 3 appliance or why they did not choose the IA:

- Wearing the IA with a CPAP caused discomfort on the cheeks from the mask pushing against the wings.

The following were reasons provided by the patients on why they chose to go back to the ProSomnus IA after the research after they initially chose the TAP 3:

- The metal on the TAP 3 began to corrode.
- The screw kept loosening and the patient would lose the protrusive position.
- Patient would like to not use CPAP anymore and only use the MAD.

One patient dropped out of the study after receiving the ProSomnus IA MAD. The patient called the clinic and stated he no longer wanted to participate in the study. The patient was given the opportunity to come into to the clinic for an evaluation and to correct any issues related to the MAD, however the patient refused to continue treatment. The same patient also was non-compliant with CPAP after utilizing a full-face mask and a nasal mask. That patient was referred back to the sleep clinic for long term care.

DISCUSSION

While CPAP is accepted as the standard treatment for obstructive sleep apnea, 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 intervention for sleep apnea may be suitable for some patients but this option is best for those with intolerances to CPAP or MAD, anatomical abnormalities resulting in a narrowed airway, and/or facial features that impair an appropriate mask fit.[14] Mandibular advancement devices have greater compliance than CPAP and have less risk than surgical interventions, however, the efficacy of treatment for MADs is lower in patients with severe sleep apnea (AHI >30).[15,16]

Bruxism is a condition in which a person grinds their teeth and can occur whether the person is awake or asleep (nocturnal bruxism). The Glossary of Prosthodontic Terms defines bruxism as "the parafunctional grinding of teeth; an oral habit consisting of involuntary rhythmic or spasmodic nonfunctional gnashing, grinding, or clenching of teeth in other than chewing movements of the mandible which may lead to occlusal trauma." [17] Bruxism is caused by a variety of factors to include stress, depression, genetics, medications.[18,19] 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.[20] It can also cause TMD symptoms, myofascial pain, and headaches.[21] 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.[22] When a patient presents with obstructive sleep apnea and bruxism, dentists can treat OSA and bruxism simultaneously, preventing further damage from bruxism.[23] By allowing for lateral movement when selecting which MAD to use, there may be improved compliance of wearing the prosthesis for a patient diagnosed with OSA and bruxism. The additional benefit of being able to use a prosthesis in any kind of environment regardless of 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 with wings extended laterally 2 mm over the TAP 3 MAD. Patients provided many reasons 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. If the wrong appliance is chosen, patient comfort and thus compliance can be affected. 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 play a role in the preference of the MAD. 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.

The TAP 3 showed significant concerns unrelated to the research including the loosening of the anterior midline traction screw and corrosion of the metal pieces on the TAP 3. The TAP 3 also exhibited increased esthetic concerns because of discoloration of the bilaminate material after a few months, when the ProSomnus IA maintained an esthetically pleasing look. Patients stated their dissatisfaction with the need to add a different material to fill the interocclusal space to achieve a tripod on the TAP 3, due to poor esthetics, and the concern that over time that material would delaminate from the TAP 3 appliance.

Adjustments made to the IA appliance included reducing the extension of the borders and minor occlusal adjustments. Alterations to the TAP 3 were more common and include adjustments to the borders, adjustments to the intaglio to get 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.

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 bruxers. 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 who brux.

CONCLUSION

In this research the majority of patients, who required a mandibular advancement device for treatment of OSA and bruxism, preferred the ProSomnus IA with wings modified laterally 2 mm over the TAP 3 MAD. When CPAP was also used, the patient preferred the TAP 3 MAD. Patients who have OSA and brux appear to prefer a bilateral push milled appliance such as the ProSomnus IA over a midline anterior traction MAD like the TAP 3. When utilizing a bilateral push appliance like the ProSomnus IA, it might be important to modify the design of the MAD to allow for lateral movements. If the patient utilizes a CPAP and MAD simultaneously, choosing a MAD that would decrease irritation of the buccal mucosa is advisable. Other changes such as type of mask and mode of delivery from CPAP might be indicated.

PRACTICAL IMPLICATIONS

This project compared the preference between the Prosomnus IA and TAP3 appliance in patients that are diagnosed with obstructive sleep apnea and bruxism, potentially improving the decision making for clinicians when treating a patient with OSA and bruxism. Choosing the preferred device first will allow the patient to potentially receive successful treatment for OSA and bruxism in a timelier manner, increasing compliance, saving valuable clinic time, and preventing costly remakes. Although every practice might not use the two devices looked at in this study, clinicians can apply what was learned to their practice and the appliances they prescribe.

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