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Name of Candidate: MAJ Gamal A. Baker
Master of Science Degree
June 11, 2020

All work has been completed to the satisfaction of the research committee.

THESIS/MANUSCRIPT APPROVED: DATE:

[redacted]

Lisa N. Yarbrough, COL, DC
Program Director, AEGD-2 Hawaii
Committee Chairperson

30 Apr 20

[redacted]

Brandon M. Gage, LTC, DC
Assistant Program Director, AEGD-2 Hawaii
Committee Member

30 Apr 20

[redacted]

Catherine F. Uyehara, PhD
Chief, Department of Clinical Investigation, TAMC
Committee Member

14 May 2020

PATIENT-PERCEIVED SUCCESS OF THREE COMMON ORAL APPLIANCES IN ORAL APPLIANCE THERAPY OF OBSTRUCTIVE SLEEP APNEA

A manuscript

Presented to the Faculty of the Advanced Education in General Dentistry, Two-Year Program,

United States Army Dental Health Activity, Schofield Barracks, HI

And the Uniformed Services University of the Health Sciences – Post Graduate Dental College

In Partial Fulfillment of the Requirements for the Degree of

Master of Science in Oral Biology

By

Gamal A. Baker, MAJ, DC, USA

April 2020

DENTAL

Uniformed Services University

DISCLAIMER

By
GAMAL A. BAKER, MAJ, DC, USA
D.D.S, Meharry Medical College School of Dentistry 2012
B.A., College of the Holy Cross, 2006

Mentor Staffing By
BRANDON M GAGE, LTC, DC, USA
M.S., Uniformed Services University of the Health Sciences – Post Graduate Dental College
Certificate, Advanced Education in General Dentistry-Two Year, Fort Hood, TX
D.D.S., Creighton University – School of Dentistry 2006
B.A., Brigham Young University 2002

And

LISA N YARBROUGH, COL, DC, USA
Certificate, Advance Education in General Dentistry-Two Year, Fort Bragg, NC 2005
D.M.D., University of Florida 1998
B.S., Florida State University 1994

Schofield Barracks, HI
April 2020

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DEDICATION

To my wife, Constance, and my daughter, Mackenzie: thank you for your encouragement, support, and love throughout the past two years. I couldn't have done it without you.

The author hereby certifies that the use of any copyrighted material in the thesis manuscript entitled:

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MAJ Gamal A. baker
Comprehensive Dentistry Residency
Uniformed Services University
Date: **04/23/2020**

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Abstract

Patient-perceived success of 3 common oral appliances in oral appliance therapy of obstructive sleep apnea

Presented by: Gamal A. Baker, MAJ, DC,

Baker, GA[1]; Lustik, MB[2]; Gage, B[1]; Yarbrough, L[1]
[1]Pacific Regional Dental Command
Advanced Education General Dentistry Program, Schofield Barracks, HI
[2]Department of Clinic Investigation, Tripler Army Medical Center, HI

Introduction: : Obstructive sleep apnea (OSA) is a highly prevalent sleep-related breathing disorder characterized by periods of recurrent cessation of breathing caused by partial or complete collapse of the upper airway. The dental role in treatment of OSA most commonly involves fabrication of mandibular advancement appliances (MAA).

Objective: To evaluate the relationship between three common obstructive sleep apnea oral appliances and patient-perceived success in the Active Duty Army population. The study attempts to determine if patients observe an improvement in their snoring, OSA, and daytime wakefulness after the initiation of oral appliance therapy and the effect on patient compliance with appliance wear.

Methods: A secured and anonymous, 13-question, web-based survey was fabricated and uploaded to surveymonkey.com available for all Active Duty Army Service Members treated for mild or moderate OSA with oral appliance therapy using a Herbst, TAP3, or Prosomnus appliance. The survey was distributed to subjects via email or during post-insertion appointments by Army dentists at multiple locations.

Results: Kruskal Wallis tests showed significant differences in patient responses between the appliances regarding the questions of "Has reduced how often I snore," "Has reduced how loud I snore," "Is comfortable," and "I am happy with my OSA apnea oral appliance" ($p < 0.001$) with subjects preferring the Prosomnus appliance much more than the other two appliances. Subjects using the Prosomnus appliance wore the appliance most nights or every night of the week 87% of the time ($p < 0.001$), significantly higher than the other two appliances.

Conclusion: In this study, the far more preferred appliance is the Prosomnus appliance. While there is no significant difference in improvement of wakefulness or daytime energy levels amongst the different appliances, if patients are not wearing the appliance then the loss of patient compliance renders the treatment modality unsuccessful.

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Background

Obstructive sleep apnea (OSA) is a highly prevalent sleep-related breathing disorder characterized by periods of recurrent cessation of breathing caused by partial or complete collapse of the upper airway.[i] These breathing interruptions can occur hundreds of times during a single night. Untreated OSA is associated with a host of comorbidities including cardiovascular disorders, cerebrovascular disease, type 2 diabetes and cognitive dysfunction.[ii] It may also lead to poor quality sleep and excessive daytime sleepiness. It is estimated that 1 in 5 Americans have at least mild OSA. The "gold standard treatment" for OSA, especially moderate and severe cases, is continuous positive airway pressure (CPAP) therapy. Its purpose is the prevention of upper airway collapse during sleep using airflow of various intensities administered through a mask or nasal cannula.[iii] Sutherland et al. noted that in the context of OSA, efficacy reflects the ability of treatment to prevent the occurrence of obstructive breath of events per hour of sleep, while effectiveness relies on the OSA severity and total sleep time; wearing the CPAP less than 4 hours per night can allow for reoccurrence of OSA and rebound of symptoms.[iv] Overall effectiveness becomes more important than efficacy if the treatment is not followed adequately. Adherence to CPAP is often poor, limiting its effectiveness; the machine and required facemask are bulky and often uncomfortable for patients to wear throughout the night. Other treatment alternatives include oral appliances (mandibular advancement appliances), various surgeries and/or adjunctive measures such as weight loss. Treatment of OSA is a multidisciplinary problem requiring a multidisciplinary approach; Pulmonology, ENT, OMFS, General Dentistry/Prosthodontics, Sleep Medicine, Psychology, and Dietary Nutrition are all critical players in the management and treatment of OSA.

The dental role in treatment of OSA most commonly involves fabrication of mandibular advancement appliances (MAA). Such devices act by protruding the mandible and increasing the upper airway size.[v] Their use is indicated in patients with mild to moderate OSA, and in individuals who are intolerant to CPAP treatment.[vi] They have been shown to be effective in reducing snoring and obstructive breathing events as well as improving health outcomes in the short-term.[vii] Long-term studies have also reported continuing effectiveness in terms of Apnea-Hypopnea Index (AHI) and Oxygen Desaturation Index (ODI) up to 5 years,[viii] while others have found that AHI increases with time.[ix] Comparative studies show that most patients prefer oral appliances over CPAP.[x] Other oral devices include tongue-retaining devices, splints that hold the tongue in place or anteriorly displace the tongue with suction forces while patients sleep to keep the airway open.[xi] They are less frequently used than MAAs and tend to be used on individuals that sleep on their backs or stomachs.

In the United States Army, many patients are diagnosed with mild or moderate sleep apnea. While some patients are able to tolerate CPAP or Automated Positive Air Pressure (APAP) devices, many are not and are referred to dental for fabrication of oral appliances. In some cases, patients are referred for oral appliances to serve as adjuncts to CPAP therapy when a CPAP cannot be used (limited space, close quarters, during

training exercises, etc). At the discretion of the referring physician, MAAs can also be the first line of treatment for patients with mild OSA and/or primary snoring. The three oral devices most commonly used in Active Duty Army dental clinics are all mandibular advancement devices of varying home titration capabilities: the TAP3® appliance, the Prosomnus® IA/MicrO2 appliances, and the Herbst appliance (see Figures 2, 3, and 5). Another appliance, the dreamTAP® (see Figure 4), is also infrequently prescribed for Active Duty Army Service members and is not included in this study. Of these appliances, the TAP3 and IA/MicrO2 are the most frequently prescribed as their fabrication is the most expedient and they are considered the most comfortable. However, evidence of this is largely anecdotal. The TAP3 and dreamTAP appliances are fabricated by the Army-operated Area Dental Lab (ADL; Fort Gordon, GA). In contrast, the Prosomnus IA/MicrO2 and Herbst-type appliances are outsourced to the Prosomnus® Sleep Technologies lab. Prior to October 2019, Herbst appliances were outsourced to Great Lakes Dental Technologies (Tonawanda, NY). According to ADL production numbers, from December 1, 2017 to March 24, 2020, 3970 MAA appliances were fabricated for the Active Duty population (Prosomnus IA/MicrO2 = 3450, TAP3 = 276, Herbst = 183, dreamTAP = 61).

Most researchers have focused on objective criteria to determine appliance success with particular concentration on pre-treatment and post-treatment changes in the apnea-hypopnea index (AHI). However, there are several studies that compared the effectiveness of different oral appliances. A 2009 study from Ghazal et al. compared a TAP appliance (an earlier model similar to the TAP3 appliance) to the IST appliance (similar to the Herbst appliance). The study compared 103 patients that used either appliance and measured both objective and subjective criteria for treatment success (a total of 44 patients were used at the conclusion of the study). Questionnaires were completed before and after treatment. The authors discovered that, while both appliances improved objective findings (AHI, oxygen saturation, total sleep time, etc.), patients were less likely to use the TAP appliance in the long-term due to appliance discomfort and subjective improvement of sleepiness (Epworth Sleepiness Scale, Pittsburgh Sleep Quality Index, performance ability, energy level, etc).[xii]

Another 2009 study from Gauthier et al. compared two other appliances, the Silencer and the Klearway. Sixteen (16) total patients completed questionnaires on MAA satisfaction (e.g., comfort) and efficacy (e.g., reduction of respiratory noises, headache). Sleep partners were also included in the study. Researchers discovered that the Respiratory Disturbance Index (RDI) was slightly lower with the Silencer, but subjects' preference for comfort was in favor of the Klearway. The Epworth score, respiratory noise and morning headache were also improved following use of both appliances. The authors concluded that, although both appliances decreased RDI and subjective daytime sleepiness in a similar manner, patient choice between various types of MAA needs to be taken into account when considering the benefit of RDI reduction over other criteria.[xiii]

Finally, a 2018 study from Saglam-Aydinatay and Taner evaluated the long-term adherence to MAA therapy and patients' experiences of the treatment in OSA. The researchers evaluated sixty-nine (69) subjects by phone survey to determine the

demographic characteristics of the patients and to assess self-reported adherence to therapy, subjective long-term effectiveness, and patient experiences with the appliance. Only 32% used the appliance regularly with the most common reasons reported by patients for discontinuing use being the inability to adapt to the appliance and pain in the temporomandibular joint. The most common factors associated with continued usage were effectiveness and ease of use.[xiv]

Patients' adherence to an oral appliance therapy (OAT) regimen often revolves around their perception of treatment success; patients are more likely to comply with a treatment protocol when they feel they are being "cured" or, at a minimum, improving. The objective of this study is to evaluate patient-perceived success of three common obstructive sleep apnea oral appliances—the Prosomnus IA/MicrO2, TAP3, and Herbst--in the Active Duty Army population. The study attempts to determine if patients observe an improvement in their snoring, OSA, and daytime wakefulness after the initiation of oral appliance therapy and the effect on patient compliance with appliance wear. "Prosomnus appliance" will refer to IA/MicrO2 appliances and "Herbst appliance" will refer to any Herbst-type appliance fabricated by Prosomnus Technologies or Great Lakes Dental Technologies.

Methods and Materials

A survey consisting of 13-questions was uploaded to a secure and anonymous web-based survey platform (*surveymonkey.com*®) available for all Active Duty Army Service Members treated for mild or moderate OSA with OAT using a Herbst, TAP3, or Prosomnus appliance. Questions included in the survey were a combination of original questions and standardized questions from the Epworth Sleepiness Scale (ESS) and Pittsburgh Sleep Quality Index (PSQI).

Survey Distribution

Army dentists at multiple locations that routinely treat OSA patients were asked to distribute a custom survey flyer (Figure 1) according to the following inclusion criteria: (1) must be diagnosed with mild or moderate OSA and/or snoring by primary care manager (PCM) with referral for OAT, (2) must be treated with Prosomnus device, TAP3 device, or Herbst appliance for OAT of OSA or snoring, and (3) must have completed at least 1 post-insertion follow-up appointment of oral appliance. To maintain anonymity, dentists did not communicate with researchers the name or means of communication with patients to which the survey flyer was distributed. Review of study eligibility criteria was incorporated into the survey instrument. Personally Identifiable Information and Personal Health Information was not recorded.

Data Analysis

Survey responses for each qualifying question were summarized by number and percent for each category of the 5 point Likert scale (see Table 1 Survey responses were excluded if any of the above criteria were not met or surveys were not completed. The survey was made available from November 2019 to February 2020.

Table 1. Survey Questions and Response Options

QUESTION	RESPONSE OPTIONS
Have you been diagnosed with mild or moderate obstructive sleep apnea and/or snoring by a sleep medicine provider or primary care manager (PCM) with a referral for oral appliance therapy (OAT) to the dental clinic?	-Yes -No
Were you treated for OSA with a Herbst appliance, TAP3 appliance, or Prosomnus device by your dental clinic (see photos)?	-Yes -No
Which device did you receive from the dental clinic for treatment of your OSA (keep in mind, the COLOR of the device may be different)?	-Herbst -TAP3 -Prosomnus
After receiving your OSA dental appliance from the dental clinic, did you complete at least one post-delivery follow-up appointment for the device no less than one month after you received it?	-Yes -No
Have you been treated with any other oral device? If yes, what was it?	-Yes, with fill in the blank -No
Do you currently use, or have you ever used a Continuous Positive Airway Pressure (CPAP) machine?	-Currently use a CPAP machine -Do not currently use a CPAP machine, but have used in the past -Have never used a CPAP machine
How long ago, in years and months, were you first diagnosed with OSA/snoring by your PCM or sleep medicine physician?	Fill in __ years and __ months
If you are no longer using your oral appliance for OSA, how long ago, in years and months, did you stop using the device?	Fill in __ years and __ months
How strongly do you agree or disagree with the following statements about your obstructive sleep apnea oral appliance a. Wearing my OSA oral appliance has improved my wakefulness during the day b. Wearing my OSA oral appliance has improved my energy level during the day c. Wearing my OSA oral appliance has reduced how OFTEN I snore d. Wearing my OSA oral appliance has reduced how LOUD I snore e. My OSA oral appliance is comfortable f. I am happy with my OSA oral appliance	-Completely agree -Somewhat agree -Neutral -Somewhat disagree -Completely disagree
In the past week, I wore my obstructive sleep apnea oral appliance throughout the night:	-Every night (7 nights) -Most nights (4-6 nights) -A few nights (1-3 nights) -Not at all (0 nights)
I have stopped wearing my obstructive sleep apnea oral appliance because:	-It is uncomfortable -It does not fit -I don't know how to insert it -I don't know how to remove it -I don't get any improvement with it -N/A -Other (please specify)
My spouse/partner/roommate notices improvement in my snoring since I began using the OSA oral appliance	-Yes -No -N/A (single, lives alone, no longer using device) -I don't know

Figure 1. Survey flyer given to Army dentists and provided for subjects to complete web-based survey

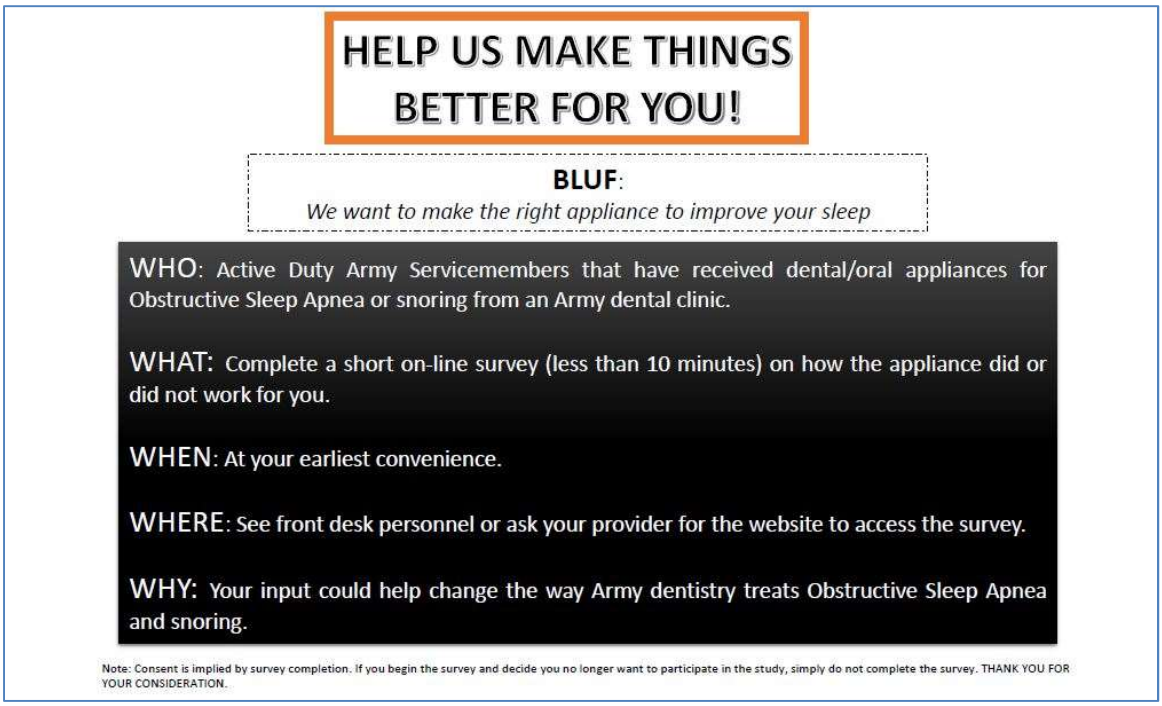

Figure 2. Prosomnus IA/MicrO2 appliance

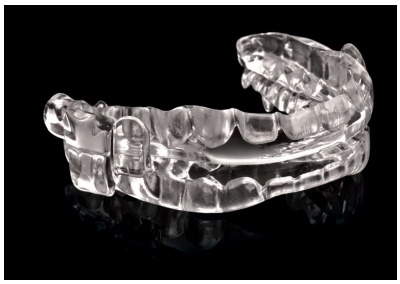

Figure 3. TAP3 appliance

Figure 4. dreamTAP appliance

Figure 5. Herbst appliance

Results

A total of 58 responses were received from subjects (13 Herbst, 12 TAP3, and 30 Prosomnus with 1 Herbst patient previously unsuccessfully treated with a TAP3, and 6 Prosomnus patients previously unsuccessfully treated with a TAP3, Herbst, or dreamTAP. Kruskal Wallis tests showed significant differences in patient responses between the appliances regarding the questions of "Has reduced how often I snore," "Has reduced how loud I snore," "Is comfortable," and "I am happy with my OSA apnea oral appliance" ($p < 0.001$) with subjects preferring the Prosomnus appliances much more than the other two appliances. Most Prosomnus responders were diagnosed with OSA/snoring within a year of completing the survey (n=11, 37%; $p = 0.032$). Most TAP3 responders were diagnosed with OSA/snoring 1-2 years prior to completing the survey (n=7, 58%). Finally, most Herbst responders were diagnosed with OSA/snoring 2-4 years prior to completing the survey (n=9, 69%). Thirty percent of all subjects ceased wearing their appliance for various reasons with the most common reason being discomfort associated with the TAP3 (n=4, 80% of TAP3 patients) and Herbst appliances (n=5, 71% of Herbst patients) ($p < 0.04$). Subjects using the Prosomnus appliances wore the appliance most nights or every night of the week (87%, $p < 0.001$), significantly higher than the other two appliances.

Table 2. ANOVA values for Responses, Part I

	All		Herbst		Prosomnus		TAP 3		
	n	%	n	%	n	%	n	%	p-value
Completed at least one post-op follow-up appt									0.663
Yes	57	98	13	100	30	97	12	100	
No	1	2	0	0	1	3	0	0	
Had been treated with other oral device*									0.190
Yes	7	12	1	8	6	19	0	0	
No	51	88	12	92	25	81	12	100	
CPAP									0.574
Currently use	35	60	10	77	17	55	8	67	
Not currently, but have in past	13	22	2	15	7	23	3	25	
Never used	10	17	1	8	7	23	1	8	
How long ago diagnosed with OSA/snoring (years)									0.032
<=1	15	27	2	15	11	37	2	17	
>1-2	17	30	2	15	8	27	7	58	
>2-4	20	36	9	69	8	27	3	25	
>4	4	7	0	0	3	10	0	0	
How long ago first treated with an oral appliance (months)									0.020
1-9	24	43	1	8	16	53	7	58	
10-18	21	38	7	54	9	30	5	42	
>18	11	20	5	38	5	17	0	0	
In the past week I wore my OSA oral appliance throughout the night									<0.001
Not at all (0 nights)	10	18	3	23	4	13	3	25	
A few nights (1-3)	12	21	9	69	0	0	3	25	
Most nights (4-6)	25	45	1	8	18	60	6	50	
Every night (7)	9	16	0	0	8	27	0	0	
My spouse/partner notices improvement in snoring since I began using the OSA oral appliance									0.079
Yes	47	84	9	69	27	90	10	83	
No	1	2	0	0	1	3	0	0	
N/A (single/live alone/no longer using device)	2	4	0	0	2	7	0	0	
Don't know	6	11	4	31	0	0	2	17	

*Herbst patient was also treated with TAP3;Prosomnus patients (n=6) -- 3 were treated with Herbst, 1 with TAP and Herbst, 1 with TAP3, and 1 with dream tap.

Table 3. ANOVA values for Responses, Part II

	Completely disagree		Somewhat disagree		Neutral		Somewhat agree		Completely agree		Somewhat/ completely	
	n	%	n	%	n	%	n	%	n	%	n	%
Wearing my oral appliance:												
Has improved my wakefulness during the day	0	0	1	8	5	38	7	54	0	0	7	54
Has improved my energy level during the day	0	0	1	8	6	46	6	46	0	0	6	46
Has reduced how often I snore	0	0	0	0	1	8	12	92	0	0	12	92
Has reduced how loud I snore	0	0	0	0	0	0	12	92	1	8	13	100
Is comfortable	2	15	7	54	3	23	1	8	0	0	1	8
I am happy with my OSA apnea oral appliance	2	15	3	23	7	54	1	8	0	0	1	8
Prosomnus												
Wearing my oral appliance:												
Has improved my wakefulness during the day	0	0	1	3	6	20	19	63	4	13	23	77
Has improved my energy level during the day	1	3	0	0	6	20	21	70	2	7	23	77
Has reduced how often I snore	0	0	0	0	2	7	7	23	21	70	28	93
Has reduced how loud I snore	0	0	0	0	1	3	4	13	25	83	29	97
Is comfortable	2	7	1	3	1	3	21	70	5	17	26	87
I am happy with my OSA apnea oral appliance	1	3	2	7	1	3	6	20	20	67	26	87
TAP3												
Wearing my oral appliance:												
Has improved my wakefulness during the day	0	0	0	0	5	42	6	50	1	8	7	58
Has improved my energy level during the day	0	0	0	0	5	42	7	58	0	0	7	58
Has reduced how often I snore	0	0	0	0	0	0	9	75	3	25	12	100
Has reduced how loud I snore	0	0	0	0	0	0	8	67	4	33	12	100
Is comfortable	2	17	4	33	4	33	1	8	1	8	2	17
I am happy with my OSA apnea oral appliance	0	0	2	17	7	58	2	17	1	8	3	25
All												
Wearing my oral appliance:												
Has improved my wakefulness during the day	0	0	2	4	17	30	32	57	5	9	37	66
Has improved my energy level during the day	1	2	1	2	18	32	34	61	2	4	36	64
Has reduced how often I snore	0	0	0	0	3	5	28	50	25	45	53	95
Has reduced how loud I snore	0	0	0	0	1	2	24	43	31	55	55	98
Is comfortable	6	11	12	21	8	14	23	41	7	13	30	54
I am happy with my OSA apnea oral appliance	3	5	7	13	15	27	9	16	22	39	31	55

	Weighted mean				
	All	Herbst	Prosomnus	TAP3	p-value*
Wearing my oral appliance:					
Has improved my wakefulness during the day	3.7	3.5	3.9	3.7	0.178
Has improved my energy level during the day	3.6	3.4	3.8	3.6	0.102
Has reduced how often I snore	4.4	3.9	4.6	4.3	<0.001
Has reduced how loud I snore	4.5	4.1	4.8	4.3	<0.001
Is comfortable	3.2	2.2	3.9	2.6	<0.001
I am happy with my OSA apnea oral appliance	3.7	2.5	4.4	3.2	<0.001

*Kruskal Wallis tests comparing mean ranks among the 3 appliances.
Prosomnus significantly better than Herbst and TAP3 for the 4 highlighted.
TAP3 better than Herbst for snoring less often.

Figure 6. Weighted Mean for wearing oral appliance, combining data for all appliances

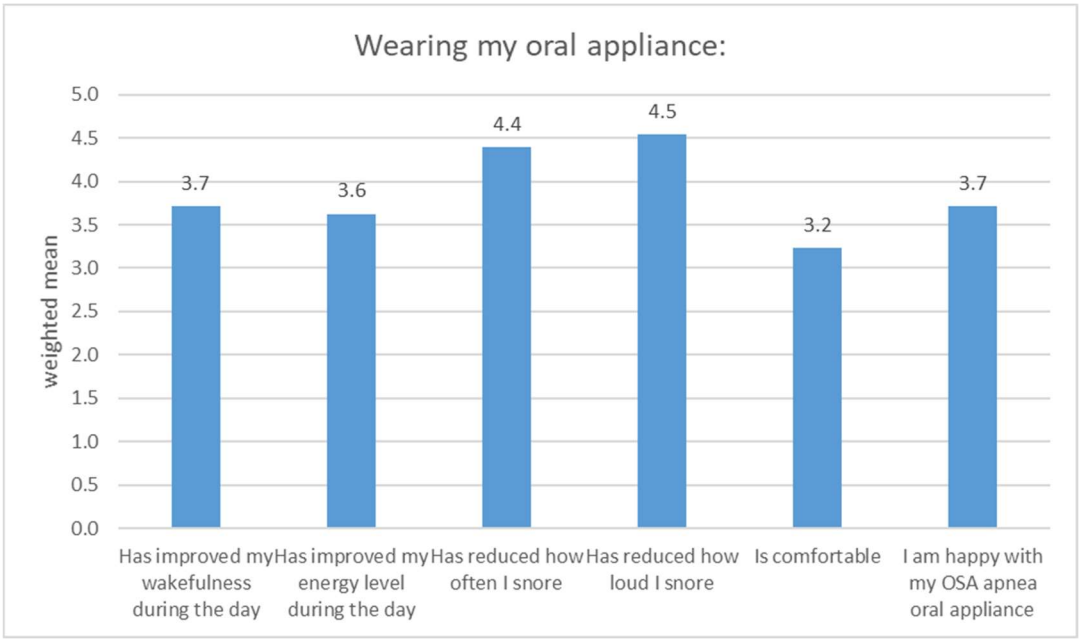

Figure 7. Percentage Charts for Wearing Oral Appliance, combining data for all appliances

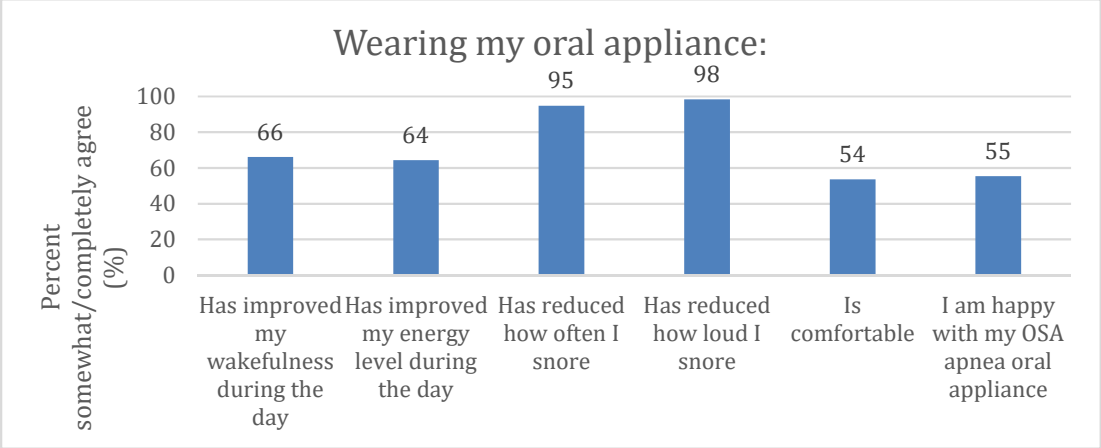

Figure 8. Weighted Mean Graph Comparing Prosomnus, TAP3, and Herbst Appliances

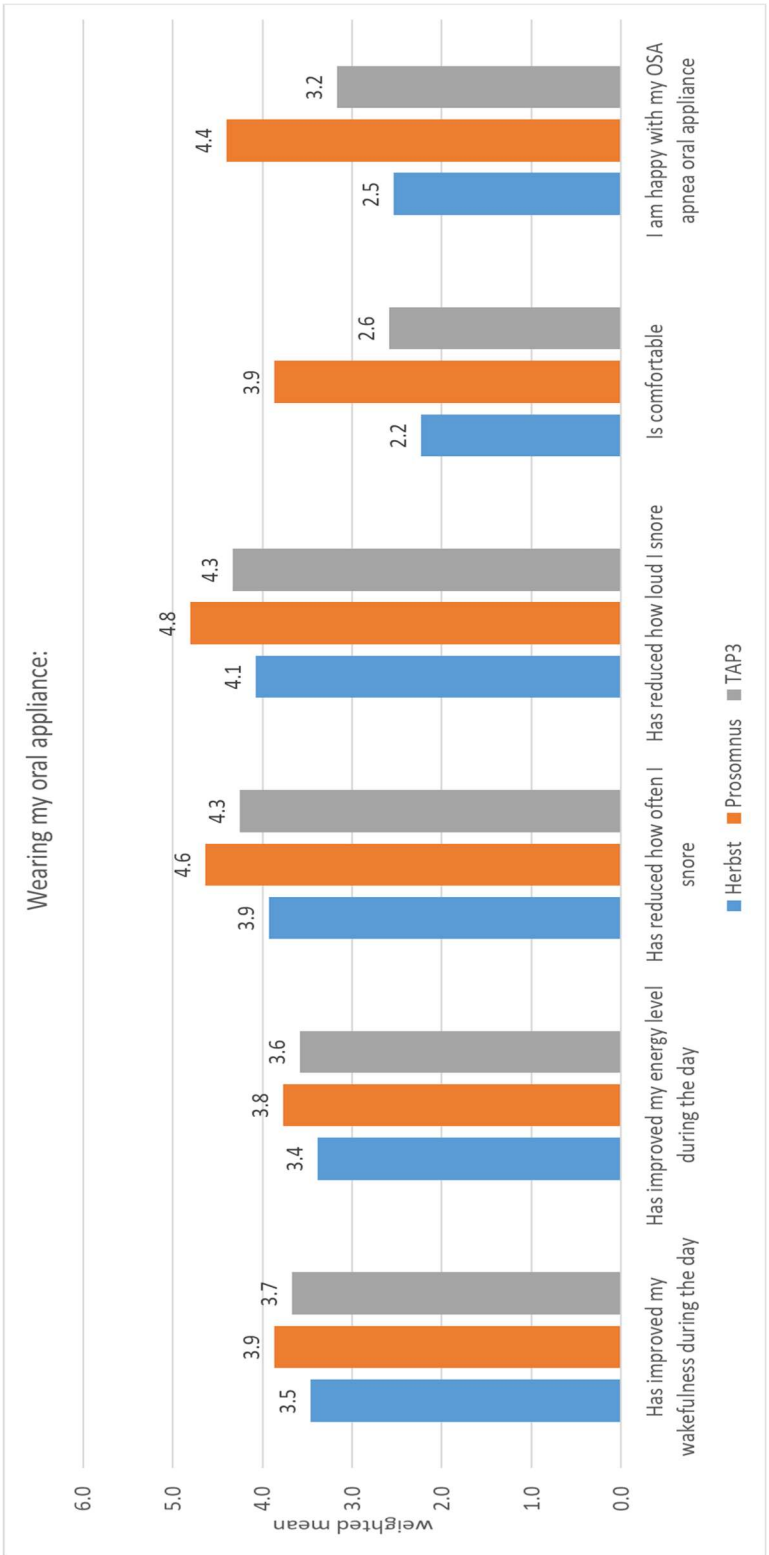

Figure 9. Percentage 'Completely Agree/Somewhat Agree' comparing Prosomnus, TAP3, and Herbst appliances

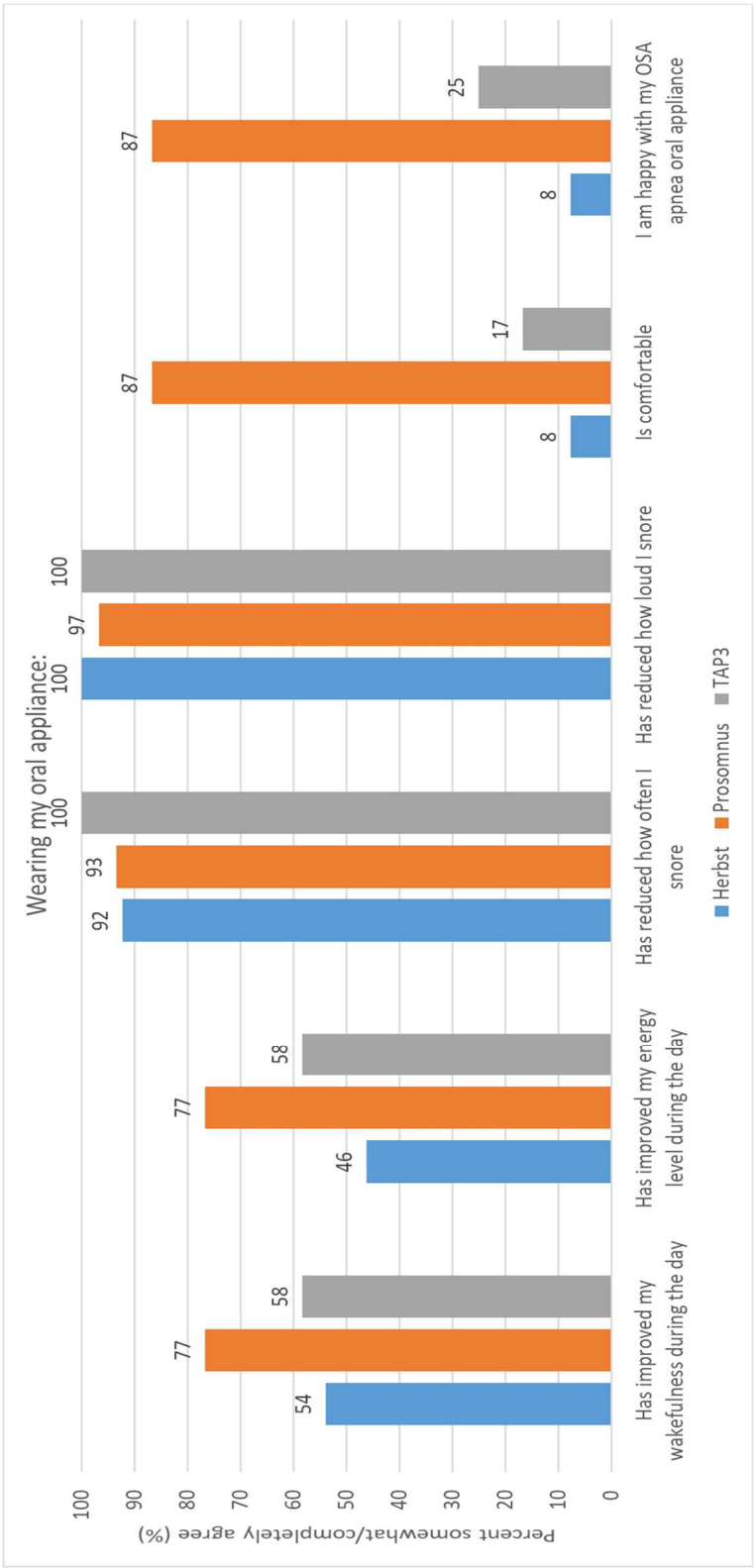

Figure 10. Percentage 'Completely Agree' comparing Prosomnus, TAP3 and Herbst appliances

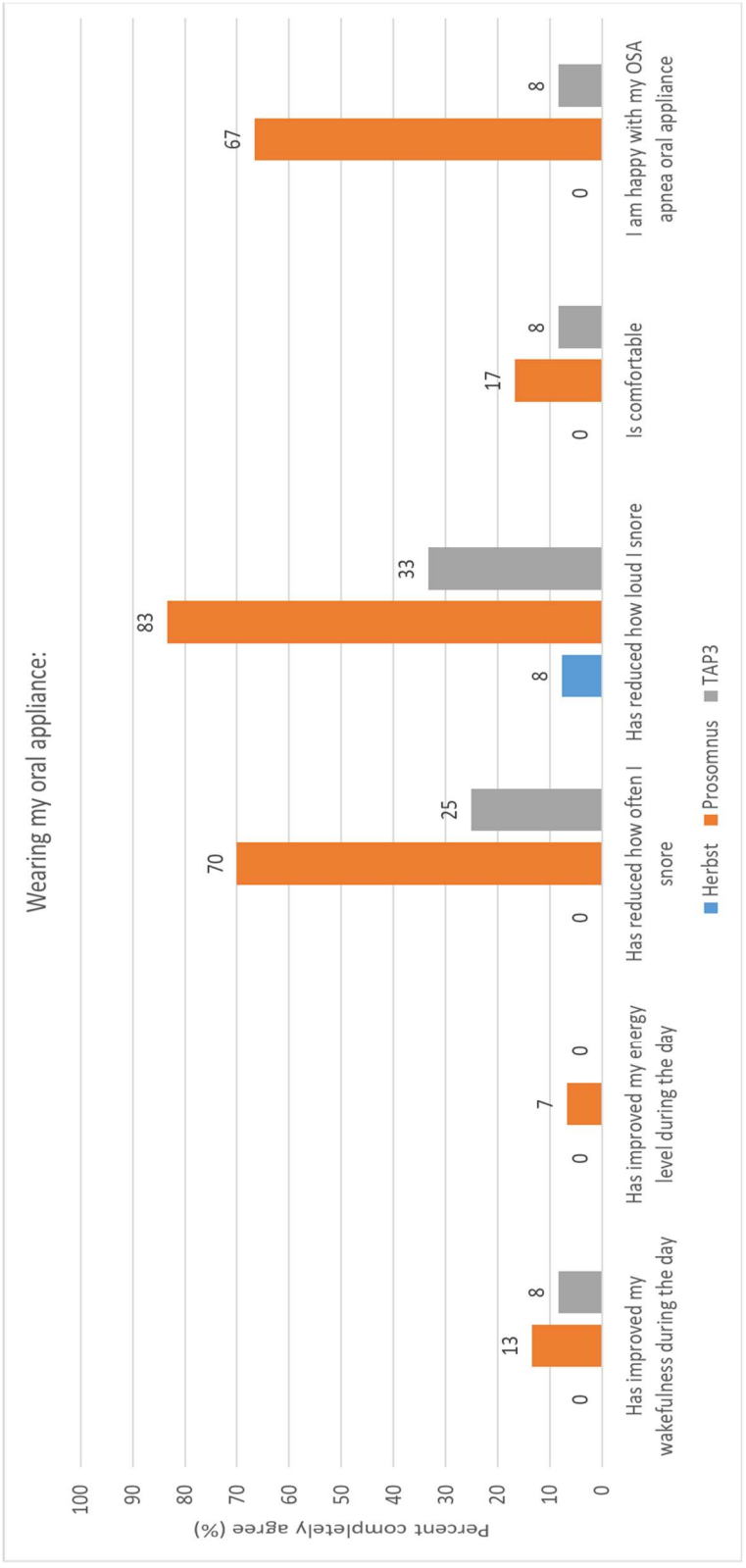

Figure 11. Somewhat Agree versus Completely Agree for 'Has improved my wakefulness during the day'

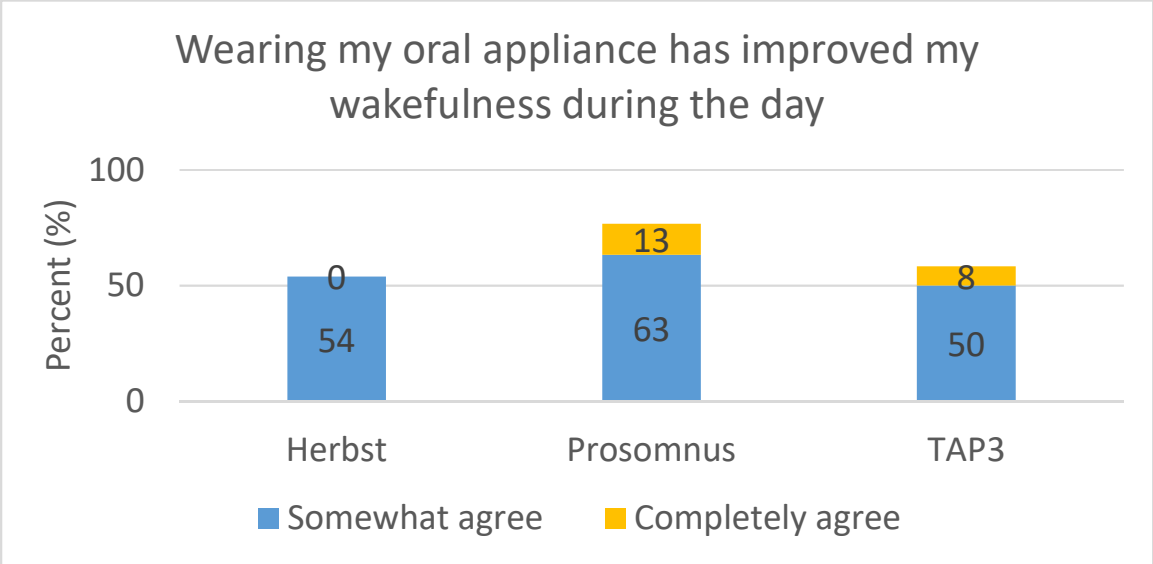

Figure 12. Somewhat agree versus Completely Agree for 'Has improved my energy level during the day'

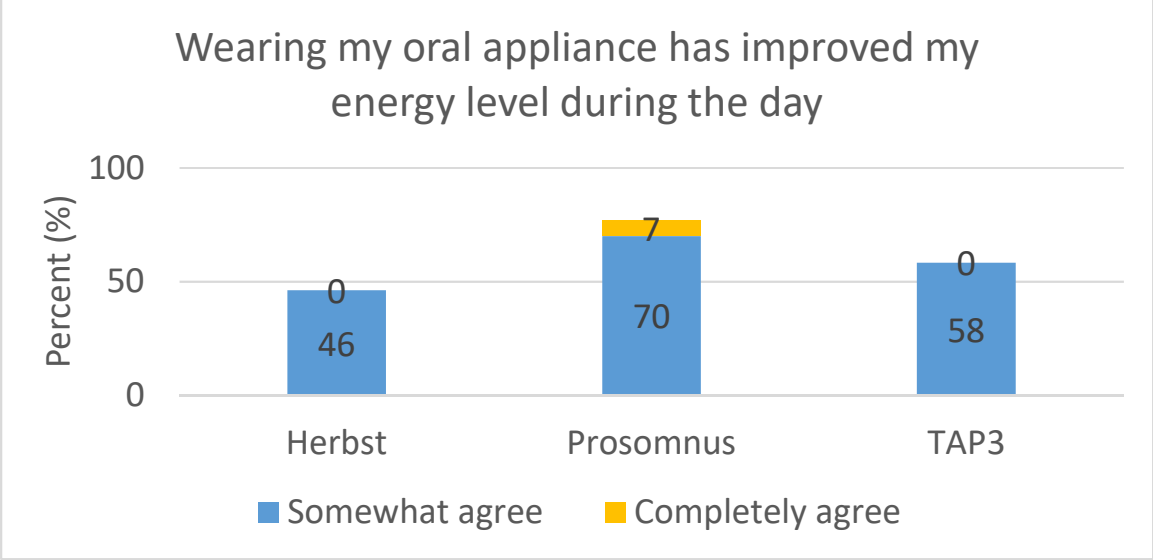

Figure 13. Somewhat Agree versus Completely Agree for 'Has reduced how often I snore'

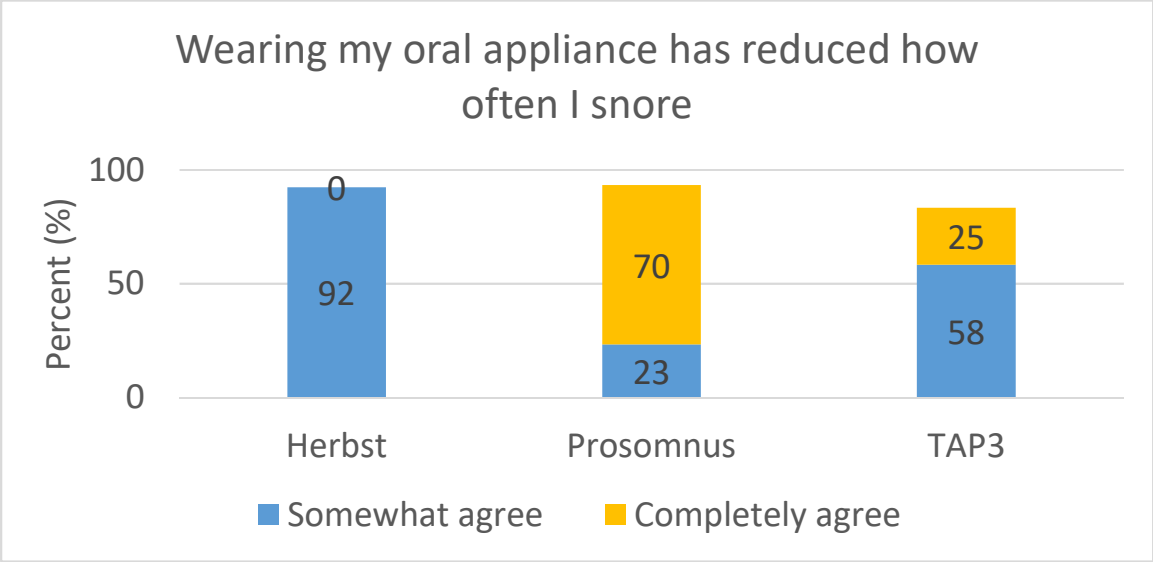

Figure 14. Somewhat Agree versus Completely Agree for 'Has reduced how loud I snore'

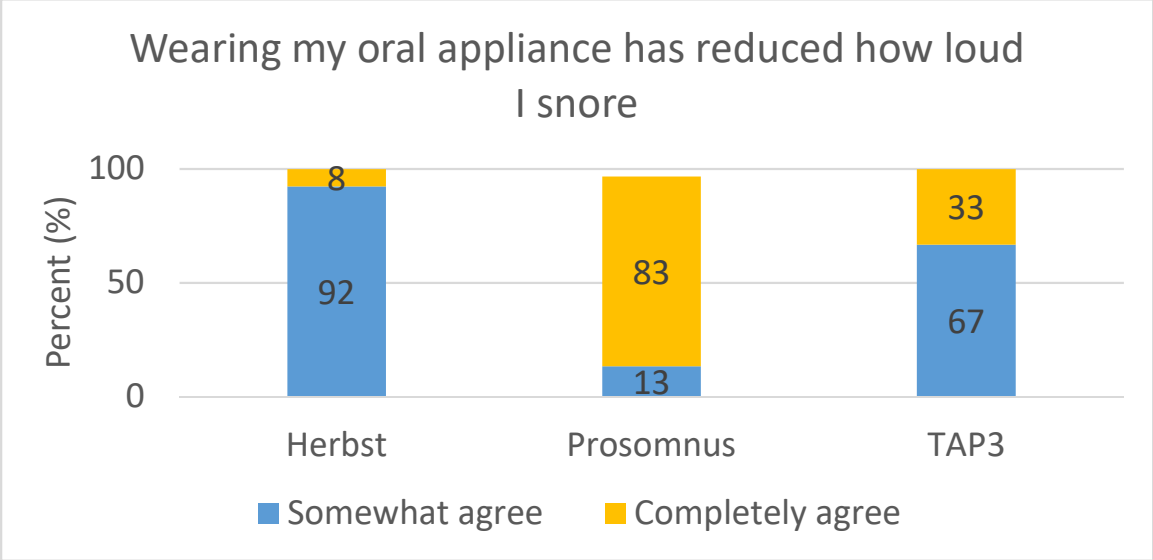

Figure 15. Somewhat Agree versus Completely Agree for 'Wearing my oral appliance is comfortable'

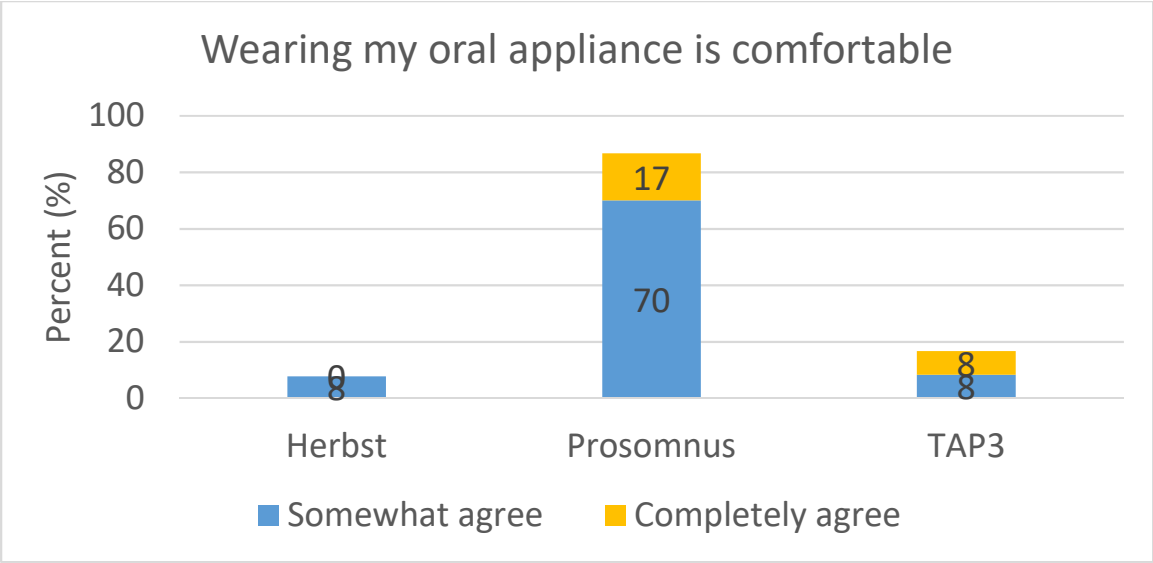

Figure 16. Somewhat Agree versus Completely Agree for 'I am happy with my OSA oral appliance'

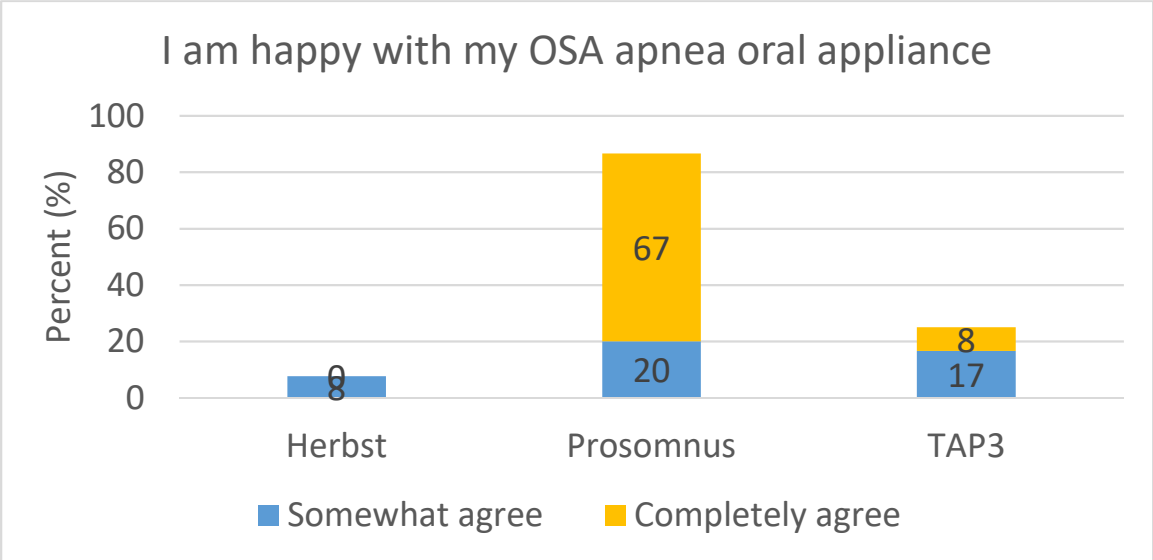

Table 4. ANOVA values for 'Stopped wearing my appliance' with associated reasons for discontinued wear

	All			Herbst		Prosomnus		TAP 3		
	n	patients who don't use	% of all patients	n	patients who don't use	% of all patients	n	patients who don't use	% of all patients	p-value
Stopped wearing because:										
Uncomfortable	11	69	21	5	71	38	2	50	7	4	80	33	0.040
It does not fit	1	6	2	1	14	8	0	0	0	0	0	0	
I don't know how to insert it	0	0	0	0	0	0	0	0	0	0	0	0	
I don't know how to remove it	0	0	0	0	0	0	0	0	0	0	0	0	
I don't get any improvement with it	6	38	11	2	29	15	2	50	7	1	20	8	
Other -- prefer/have CPAP	4	25	8	0	0	0	2	50	7	1	20	8	
Other --broken	2	13	4	2	29	15	0	0	0	0	0	0	
Other --forget and CPAP works fine	1	6	2	1	14	8	0	0	0	0	0	0	
Other -- dentist did not take into consideration overb	1	6	2	0	0	0	1	25	4	0	0	0	
Stopped wearing for any reason	16		30	7		54	4		15	5		42	0.028

Discussion

Untreated OSA is associated with multiple comorbidities. The risk for these comorbidities increases as the severity of respiratory disturbances increase. While OAT is not expected to "cure" OSA, its ability to potentially drop the patient's AHI below 5 may reduce the risk for developing these comorbidities. The dental role in treatment of OSA most commonly involves fabrication of MAAs designed to increase airway size by protruding the mandible. As previously stated, the ADL has fabricated or outsourced 3970 MAAs for the Active Duty population (Prosomnus = 3450, TAP3 = 276, Herbst = 183, DreamTAP = 61) in just the past 2 ½ years with the cost of each appliance being $427 per Prosomnus IA/MicrO2 appliance, $472 for each Herbst-type appliance, and $360 for each TAP3 appliance. This does not include the man-hours required to fabricate each of these devices. In 2019, the United States Army Active Duty population reached approximately 476,000.[xv] Rogers et al. noted that 107,766 cases of OSA of varying degrees were reported between January 2004 and December 2015, comprising 22.6% of the Active Duty population. This follows the national average.[xvi] However, the severity of the disease for each case was not recorded in that study, making it difficult to note how many cases could have potentially been treated with MAAs. It is well understood that OSA not only affects the general health of the Service Member, but also retention of the Service Member in Active Duty Service. Management of this chronic disease, then, becomes of the utmost importance along with streamlined treatment that promotes fiscal responsibility and expedited, idealized multidisciplinary care.

In this study, it is interesting to note that most patients that received Prosomnus appliances were diagnosed with OSA/snoring by their PCM in the past year. This may be due to increased attendance at Dental Sleep courses for Active Duty providers credentialed or attempting to be credentialed to fabricate these appliances, providers gaining the opportunity to try their own custom-fitted appliances at these courses, and anecdotal evidence passed from provider to provider. The growing use of Prosomnus IA/MicrO2 devices and reduced use of Herbst and TAP3 devices could be associated with increased knowledge of the appliances and the techniques needed to fabricate them, the ease of the fabrication process for the Prosomnus IA/MicrO2 appliances (scanned or traditional VPS impressions) as compared to Herbst and TAP3 appliances (traditional VPS impressions only), and post-insertion product support by the Prosomnus company. It is difficult to know if any reasons for increased use of Prosomnus IA/MicrO2 devices is directly associated with patient choice or desire.

There is a significant difference in patient satisfaction with their OSA appliance (2.5 for Herbst, 3.2 for TAP3, 4.4 for Prosomnus) that is likely directly correlated to patient-perceived effect on snoring for each device (weighted mean 3.9 to 4.8 with highest for Prosomnus IA/MicrO2 appliance) and appliance comfort (weighted mean 2.2 for Herbst, 2.6 for TAP3, and 3.9 for Prosomnus); patients place more value in the appliance that they can comfortably wear and, from what they have noticed, reduces snoring. It is interesting to note that no significant difference was noted for improved wakefulness or improved energy levels amongst the three appliances, implying that patients place more

value in reduced snoring and potential improvements in sleep for the partner/spouse than on energy level changes.

Patient compliance with appliance wear is important to treatment effectiveness; a home care oral appliance cannot work if the appliance is not worn. In this study, 87% of patients using the Prosomnus IA/MicrO2 device wore their appliance 4 or more nights per week (60% 4-6 nights per week, 27% every night), significantly higher than the 32% noted by Saglam-Aydinatay et al. in their study of long-term adherence to OAT of OSA and higher than the 50% CPAP compliance noted by Bartlett et al.[xvii] Only 8% of patients using the Herbst appliance and 50% of patients using the TAP3 appliance wore their device 4 or more nights per week, with no patients using either appliance every night. According to the ADL, Prosomnus IA/MicrO2 appliances cost the Army $472 per appliance, the Herbst is $472 per appliance, and the TAP3 is $360 per appliance. With 276 TAP3 appliances fabricated, and only 50% worn effectively, 138 appliances were unsuccessful, resulting in $65,136 in wasted funds. With 183 Herbst appliances fabricated, and only 8% worn effectively, 168 appliances were unsuccessful, resulting in $79,296 in wasted funds. It is important to note that these financial sums do not include time wasted for the patients taken away from their primary military occupation or the time and supplies used in the dental treatment facility. The time and financial benefits of streamlining OAT in Army dental sleep medicine is evident. If patients do not find value in treatment, and they are given the opportunity to discontinue the treatment modality, compliance is likely to falter with both time and money squandered.

Conclusion

Based on the findings of this research, the Prosomnus appliance is the far more preferred appliance compared to the other two, in this study. Not only is the appliance more comfortable to the patient, but it is worn more often and more commonly results in improved snoring. While there is no significant difference in improvement of wakefulness or daytime energy levels amongst the different appliances, if patients are not wearing the appliance then the loss of patient compliance renders the treatment modality unsuccessful. While the United States Army continues to offer all three devices included in this study, removing the TAP3 and Herbst options may reduce the financial liability of their fabrication, saving both money and time to focus these resources on more successful treatment options. If eliminating the TAP3 and Herbst appliances is not feasible, the author of this manuscript proposes standardization of treatment by making the Prosomnus IA/MicrO2 appliance first-line in OAT. Other devices can remain options for those patients that do not respond to therapy using the IA/MicrO2. With Prosomnus offering many different styles of mandibular advancement devices to accommodate an array of unique patient circumstances, fabrication of the TAP3 appliance and outsourcing for the fabrication of the Herbst appliance can be made obsolete. Future studies would benefit from an increased sample size for each device and a prospective design with standardization of appliances, providers, and post-insertion follow-up. This study relies heavily on patient recollection which can be, at times, unreliable over long periods.

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