Study Title: Midline traction versus bilateral thrust oral appliances: A randomized controlled trial to determine superiority for improving upper airway function and sleep quality.

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Texas A&M University College of Dentistry
Dallas, Texas

Informed Consent to Participate in a Research Study

Study Title: Midline traction versus bilateral thrust oral appliances: A randomized controlled trial to determine superiority for improving upper airway function and sleep quality.

Short Title: A study on oral appliances to improve breathing during sleep

Principal Investigator: Emet Schneiderman, PhD emet@tamhsc.edu, 214-828-8377
Co-Principal Investigator: Steven Bender, DDS bender@tamhsc.edu, 214-828-8432
Co-investigators: Jason Hui, DDS; Ann McCann RDH, PhD; Preetam Schramm, PhD; P. Duane Wilson, DDS, Pollyana Moura, DDS, MS

Research Coordinator & Emergency Contact: Zohre German, MS, german@tamhsc.edu 214-828-8291.

Funded by: Baylor Oral Health Foundation

To Participants:

This is an investigator-initiated research study. Please read the following document as a part of the informed consent process. The informed consent process is to advise you of the risks and benefits involved in the study so you can make a free decision whether or not to participate. Informed consent includes having the study fully explained to you, an opportunity to ask questions, your questions answered to your satisfaction and a written informed consent to read and sign.

Description of Study:

You are being asked to participate in this research study by the Principle Investigators: Emet Schneiderman PhD, and Steven Bender, DDS at Texas A&M College of Dentistry. It will take place in the 7th floor clinic, Room 725 at 3302 Gaston Avenue, Dallas TX 75246.

This is an interventional study to assess by objective sleep quality measures the response to two of the leading oral appliance designs used in treating obstructive sleep apnea. Subjects with moderate or severe obstructive sleep apnea previously diagnosed by polysomnography (PSG) or home sleep testing, who have been prescribed Continuous Positive Airway Pressure (CPAP) therapy, will be recruited and selected to enter the study. Each patient is expected to participate in the study for **nine** (9) **consecutive weeks**. The first 4-weeks involve using one of the oral appliances followed by 1-week washout period (use your CPAP therapy during this week), then 4-weeks using the second oral appliance. Home sleep recordings will be collected at four time points: T1- first oral appliance start; T2 - end first oral appliance; T3 - second oral appliance start; T4 -end second oral appliance (see Figures 1 and 2).

If you have been diagnosed with moderate or severe obstructive sleep apnea, have been prescribed a CPAP machine, but have found this therapy to be unsatisfactory, you may qualify to participate in this study.

Justification for the trial: Why is this study being done?

The purpose of this study is to evaluate the response to and determine superiority between two of the most prominent oral appliances used in treating moderate or severe obstructive sleep apnea. Both oral appliances will be custom made for you free of charge after a dentist obtains an impression of your teeth. The oral appliances being evaluated are comprised of two plastic plates that cover upper and lower teeth. Both oral appliances act by moving your lower jaw forward to increase the space in the back of your mouth (throat). The increased space is expected to reduce the number of apnea events and snoring.

The study will evaluate oral appliance A and B by comparing nights: (see Figures 1 and 2)

1. With your overnight sleep study and CPAP
2. Between oral appliance A and B

The purpose of collecting sleep data with an oral appliance is to determine its success in promoting stable sleep and reducing snoring.

Both sleep recorders are Food and Drug Administration (FDA) cleared medical devices. Both oral appliances are currently marketed as a medical device to treat obstructive sleep apnea and are FDA cleared.

Figure 1. Midline traction oral appliance

Figure 2. Bilateral thrust oral appliance

Why am I being asked to participate in this study?

You are being asked to participate in this study because you have been diagnosed with obstructive sleep apnea by a physician who recommended you use CPAP therapy to treat the breathing disorder.

How long will the study take?

Approximately nine (9) weeks in total (4-weeks with oral appliance A; 1-week on CPAP; 4-weeks with oral appliance B; are required for you to experience both oral appliances.

How many people are participating in this study?

You will be one of approximately 64 subjects involved in this research project.

Procedures you will be asked to follow:

Selected study participants will be required to visit at Texas A&M College of Dentistry approximately nine (9) times.

Table 1. The number and purpose of visits to the research study center at Texas A&M College of Dentistry.

	Visit 1	Visit 2 T1	Visit 3	Visit 4 T2	Visit 5	Visit 6 T3	Visit 7	Visit 8 T4	Visit 9
Time (minutes)	120 (2 hrs)	60 (1 hr)	15	15	15	15	15	15	15
Purpose	Study orientation & dental impressions	Pick up oral appliance and sleep recorders; daily sleep log	Drop off sleep recorders to Texas A&M College of Dentistry	Pick up sleep recorders	Drop off sleep recorders to Texas A&M College of Dentistry	Pick up oral appliance and sleep recorders	Drop off sleep recorders to Texas A&M College of Dentistry	Pick up sleep recorders	Drop off sleep recorders to Texas A&M College of Dentistry

Table 2. Visit 1 - your requirements and check list

Item no.	**Visit 1 - Processing and Your Requirements**	**Check List**
1	Informed consent	
2	Medical / Dental history	
3	Medication(s) currently taken	
4	Sleep Study report	
5	CPAP Sleep Study report	
6	Complete questionnaires	

During the approximate 2-hour Visit 1, you will first be given an oral exam by one of the team dentists to insure that your teeth, gums, jaw joints and jaw muscles are sufficiently healthy and stable for your safe participation in the study. If determined to be adequate, you will then be fully enrolled in the study and your tasks will be explained to you in detail. Dental impressions of your teeth will be obtained to serve as a model for your custom oral appliances.

At Visit 2 (T1) you will receive one of the oral appliances plus the sleep recorders. A dentist will complete the custom fitting of both oral appliances and you will receive instructions on using the sleep recorders.

If you agree to participate in this study, you will have to wear the oral appliances (OA) during your night's sleep and apply the sleep recorders (sensors on your chest and face) at night before going to bed. You will remove the OA and sleep recorders when getting up the following morning. The sleep recorders may take up to 20 minutes to place and 5 minutes to remove. Each morning you will fill in a daily sleep log. The OA plus sleep recorders are required to be used simultaneously for at least one (1) night on four (4) different days during the nine weeks. Each oral appliance is to be used every night for four (4) continuous weeks during sleep for more than five (5) hours each night or as tolerated. Up to 4 additional nights of sleep recordings may be required if any of the 4 designated nights of recording fail. You will also fill out 3 short questionnaires concerned with sleepiness, snoring and quality of life at three of the visits. During the two 4-week periods that you will be using the oral appliances every night, you will not be using CPAP.

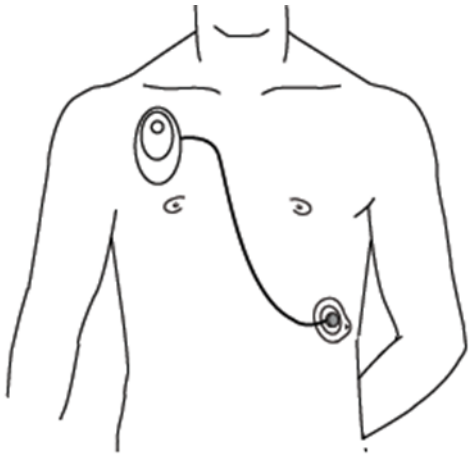

Figure 3: SleepImage sleep device in recording position.

1. At bedtime, position and attach the SleepImage recorder as shown in Figure 3 at night **under** your pajama or T-shirt.
2. At bedtime, position and attach the Medibyte recorder and its sensors **over** your pajama or T-shirt as in Figure 4.

Figure 4: Home Sleep Test Medibyte device in recording position.

1. Hold down the button on the SleepImage recorder for 5 seconds to start recording.
2. Turn on the Medibyte recorder.
3. Collect a minimum of 5 hours of sleep data.
4. Stop recording by removing the device from your body upon awakening the following morning and discard the adhesive electrodes. Replace the SleepImage device in its carrying case and return it to the study coordinator.
5. Stop Medibyte recording by removing all sensors and wires; turn off the device and replace all items into its carrying case. Return it to the study coordinator.

Risks

The minor physical risk associated with the sleep-monitoring aspects of this study are no more than those involved with standards test of bodily (physiological) functions, for example wearing a heart monitor. The oral appliances (OAs) are FDA cleared and are in wide use by dental patients throughout the US. The OAs may cause pain in the jaw joint and teeth, and difficulty in opening or closing the jaw; these conditions are usually temporary. In the long term, the OAs may cause changes in tooth position and in the bite (occlusion), as well as damage to the teeth and gums. The only aspects of this experience that make it "experimental" (i.e., research) rather than "routine clinical care" is that (1) you will be randomly assigned to one OA or the other during the two active phases of the study, and (2) additional physiological measurements will be made beyond what are typically gathered during standard clinical practice. All of these tests are noninvasive.

We do not anticipate any significant physical risk from participating in this study. Though not impossible, we do not expect the adhesive hypoallergenic electrodes of the Medibyte or the SleepImage devices to cause itching or rashes. The pulse oximeter may cause some minor irritation of the finger or finger nail. By wearing an OA, a subject may experience some discomfort and/or reduced function of the jaw joint (temporomandibular joint) and muscles of the jaw (chewing muscles) and of the face during and after treatment. Subjects may also experience some reduction in sleep quality due to discomfort while getting used to wearing the OA (adaptation). Other minor risks include temporary irritation of the mouth and oral cavity due to contact with the OA, and excessive salivation or dry mouth from mouth breathing. Repositioning of the lower jaw and tooth movement may also occur, but are typically minor and reversible. Also highly unlikely, a subject could swallow or aspirate part of an OA should it break. Participants will be carefully monitored for all of these risks by one or more of the study dentists.

The potential benefits of taking part in this study are:

1. Two customized oral appliances at no charge
2. An effective device not requiring electricity to operate
3. Reduced apnea and snoring
4. Improved sleep quality and continuity
5. An effective treatment for obstructive sleep apnea that does not require wearing a face mask
6. No pressurized air blowing through your nose
7. Receiving information on your sleep quality

The researchers or study coordinator will discuss with you possible options that might be of benefit to you if a sleep issue is discovered.

Alternative Treatments:

No alternative treatment options are directly part of this study. If you decide that either oral appliance therapy is not suitable for you, the alternative is for you to continue to use your prescribed CPAP therapy.

Voluntary Participation or Withdrawal: Is my participation voluntary?

Instead of being in this study, you have the option to not participate. Participation in this study is voluntary. You have the right to choose to:

1. Participate
2. Not participate

3. Stop at any time without giving reasons

Can I participate in another study during this Study?

No, by signing this Consent Form, you confirm that you will not participate in another study during the term of this study that includes the final visit.

Confidentiality: What happens with my data?

Efforts will be made to keep your personal information private and confidential. Absolute confidentiality cannot be guaranteed. If information from this study is presented, you will not be identifiable. You will be assigned a coded number. The identifiable information from your recordings will be maintained within Texas A&M College of Dentistry. We will protect your records so that your name and any identifying information will be kept private. The chance that this information will be given out to someone else is very small. Anonymous and coded summarized data might be shared. No identifiers linking you to this study will be included in any sort of report that might be published or presented without your explicit permission. A description of this clinical trial will be made available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. This consent form will be filed securely in an official area. People who have access to your information include the Principal Investigator and research study personnel. Representatives of regulatory agencies such as the Office of Human Research Protections (OHRP) or the Food and Drug Administration (FDA) and entities such as the Texas A&M University Human Subjects Protection Program may access your records to make sure the study is being run correctly and that information is collected properly. If there are any reports about this study, your name or other identifiable information will not be in them. Information about you and related to this study will be kept confidential to the extent permitted or required by applicable state and federal laws.

Cost/Compensation:

There are no costs to you if you participate in this study. No financial compensation will be provided to you, but the two customized oral appliances are yours to keep upon completion of the study. Participants are required to return the home sleep study kits as required by the protocol to the research coordinator.

Clinical care, discomforts and injuries related to this study will be carefully monitored and managed by the dentists on the research team. You will not be responsible for the cost of treatment directly related to the research procedures during the study period.

What if New Findings Occur During the Study?

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study.

If new information is provided to you, your consent to continue participating will be re-obtained.

Investigator Payment:

The investigators conducting this study are compensated only for their time to do the study and will not get any payment for specific results of the study.

Participant Rights:

Your participation in this research study is voluntary. You may choose not to join or may leave the study at any time. If you choose not to be in this study or stop being in the study, there will be no effect on your dental or medical care, employment, evaluation, student status or relationship with Texas A&M University College of Dentistry. This decision will also not involve penalties or loss of benefits to which you are otherwise entitled.

If the investigator decides that participating in this study is not in your best interest (for instance, if you become ill), your participation in the study will be stopped. The principal investigator also has the option to terminate the participation of subjects who are uncooperative or otherwise affect the integrity or conduct of the research. Participation in this study does not guarantee that you will be able to obtain care at Texas A&M University College of Dentistry beyond the scope of this study. After the study, if you wish to become a regular patient of the College, you will need to go through the standard screening process to determine eligibility. This will involve additional cost to you.

For questions about this research study contact: Emet Schneiderman, PhD emet@tamhsc.edu, (214)-828-8377. If you experience a research-related injury that is not serious, call (214)-828-8291; if serious or an emergency, call 911.

For questions about your rights as a research participant or if you have questions, complaints, or concerns about the research, you may call the Texas A&M University Human Subjects Protection Program office at (979) 458-4067 or send an email to the office: irb@tamu.edu.

I agree to participate in this study. I have read all of the above, or have heard it read to me. I have had the opportunity to ask questions about this study, and my questions have been answered to my satisfaction. I consent to release my records to the research staff.

1. I clearly understand that this is a research study.	( ) Yes ( ) No
2. I clearly understand the risks associated with participation in this study.	( ) Yes ( ) No
3. I clearly understand the length of time during which I will be participating in this study.	( ) Yes ( ) No
4. I clearly understand the purpose and anticipated outcomes of this study.	( ) Yes ( ) No
5. I clearly understand that my participation in this study is voluntary.	( ) Yes ( ) No
6. I clearly understand that my participation in this study does not affect my legal rights.	( ) Yes ( ) No
7. I certify that I am 18 years of age or older.	( ) Yes ( ) No

_____	_____
Subject's Name	Date of Birth
_____	_____
Subject's Signature	Date
_____	_____
Name of Person Obtaining Consent (Print)	Date
_____	_____
Principal Investigator's Signature	Date

IRB NUMBER: 2017-0390-CD-FB
IRB APPROVAL DATE: 07/26/2018

YOU WILL BE GIVEN A SIGNED COPY OF THIS CONSENT DOCUMENT TO KEEP