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Evaluating Sleep Quality with Emerging Technologies

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Evaluating the Sleep of an Orthodontic Population Using Emerging Technologies

Sleep disordered breathing is a highly prevalent indication of airflow limitation. Airflow limitations can occur at the level of the nasopharynx, oropharynx, or hypopharynx. Sleep disordered breathing has a multifactorial etiology, including large fat deposits, a large tongue, consumption of alcohol or sedatives, illness, or excessive relaxation of pharyngeal musculature, among others. These airflow limitations can cause daytime sleepiness, a decrease in productivity, increased blood pressure, or automobile accidents.

Severe airflow limitations can be categorized as either apneas or hypopneas. An apnea involves total breathing cessation for over 10 seconds. A hypopnea involves a partial blockage of airflow for over 10 seconds. These events can culminate in arousal from sleep and gasping for air. The Apnea Hypopnea Index (AHI) is the number of events that occur per hour.

A diagnosis of obstructive sleep apnea involves an AHI score of at least 5. Sleep apnea diagnosis is separated into three categories: mild, moderate, or severe. Mild sleep apnea consists of an AHI score of 5-15 events per hour. Moderate sleep apnea consists of an AHI score of 15-30 events per hour. Severe sleep apnea has an AHI score of over 30 events per hour.

Risk factors for sleep disordered breathing include the male sex, age over 50, BMI >35, a large neck circumference, nasal congestion, diabetes, family history of OSA, and smoking.

Obstructive sleep apnea is highly prevalent, as an estimated 29.4 million adults in the United States have obstructive sleep apnea, though 23.5 million are undiagnosed. This points to the importance of accurate screening tools.

Sleep apnea can be treated using Continuous Positive Airway Pressure (CPAP), oral appliances such as mandibular advancement devices, a hypoglossal nerve stimulation device, lifestyle changes, or surgical intervention such as maxillomandibular advancement, removal of palatine tonsils/adenoids, tongue reduction surgery, or septoplasty.

Untreated sleep disordered breathing can cause many negative effects, including weight gain, cognitive impairment, memory loss, and increased daytime sleepiness. It can also lead to an increased risk of comorbidities, including hypertension, atrial fibrillation, heart attack, stroke, Type 2 diabetes, and depression.

The gold standard for diagnosing obstructive sleep apnea is in-lab polysomnography. In-lab polysomnography records body movement, breathing rate, respiratory effort, nasal airflow, oxygen saturation, blood pressure, heart rate, eye movement, and electroencephalography. The results are interpreted by a sleep technician. Although polysomnography is highly accurate, it is also time-consuming, uncomfortable for the participants, and expensive.

An alternative to in-lab polysomnography is the home sleep apnea test (HSAT). A flow-based HSAT device typically consists of a small wearable monitor with leads, a nasal cannula, chest/abdomen belts, and a pulse oximeter. It records breathing rate, respiratory effort, nasal airflow, oxygen

saturation, and heart rate. It generates a sleep report and can be used for the diagnosis of obstructive sleep apnea. It is a convenient option when compared to polysomnography, but it can be uncomfortable and requires participant compliance. Home sleep apnea tests have lower accuracy than in-lab polysomnography and depend on the participant for proper use.

Questionnaires can also be used to identify obstructive sleep apnea risk factors. There are a variety of questionnaires that can be used, including the NOSE Score Questionnaire, Pittsburgh Sleep Quality Index, STOP-Bang Questionnaire, Insomnia Severity Index, PROMIS Sleep Disturbance Questionnaire, and Epworth Sleepiness Scale.

The STOP-Bang Questionnaire provides a score of “low risk,” “intermediate risk,” or “high risk” for the participant’s risk of an Obstructive Sleep Apnea diagnosis. The participant will check either “yes” or “no” as a response to a series of questions. Each positive response will add one point to the participant’s overall score, which is used for the determination of OSA risk. An overall score of 0 – 2 is “low risk,” a score of 3 – 4 is “intermediate risk,” and a score of 5 or greater is “high risk.”

STOP-Bang Questionnaire

Please answer the following questions by checking “yes” or “no” for each one	*Yes*	*No*
Snoring (Do you snore loudly?)	❑	❑
Tiredness (Do you often feel tired, fatigued, or sleepy during the daytime?)	❑	❑
Observed Apnea (Has anyone observed that you stop breathing, or choke or gasp during your sleep?)	❑	❑
High Blood **P**ressure (Do you have or are you being treated for high blood pressure?)	❑	❑
BMI (Is your body mass index more than 35 kg per m^2?)	❑	❑
Age (Are you older than 50 years?)	❑	❑
Neck Circumference (Is your neck circumference greater than 40 cm [15.75 inches]?)	❑	❑
Gender (Are you male?)	❑	❑

Score 1 point for each positive response.

Scoring interpretation: 0 to 2 = low risk, 3 or 4 = intermediate risk, ≥ 5 = high risk.

The NOSE Score Questionnaire involves a series of responses that yield a numerical score representative of the severity of nasal obstruction. The participant provides their responses to a variety of prompts using a ranking system from “Not a problem” (0 points) to “Severe problem” (4 points). The numerical responses are added, then the sum is multiplied by 5, to provide a result of “mild,” “moderate,” “severe,” or “extreme” nasal obstruction.

Over the past one month, how much of a problem were the following conditions for you?

	Not a problem	Very mild problem	Moderate problem	Fairly bad problem	Severe problem
Nasal congestion or stuffiness	0	1	2	3	4
Nasal blockage or obstruction	0	1	2	3	4
Trouble breathing through my nose	0	1	2	3	4
Trouble sleeping	0	1	2	3	4
Unable to get enough air through my nose during exercise or exertion	0	1	2	3	4

NOSE score (multiply your total score x5) ☐

Nasal obstruction severity classification: mild (5-25) | moderate (30-50) | severe (55-75) | extreme (80-100)

The PROMIS Sleep Disturbance Questionnaire evaluates the subject's sleep quality through a series of statements that a subject ranks their agreement from 1 (not at all) through 5 (very much) for the past 7 days. After adding up the numerical values associated with each response, the subject will receive a raw score from 8-40. A conversion chart is used to convert from the raw score to the T Score. A T-Score of <55 is associated with no to slight sleep disturbance, 55.0-59.9 is associated with mild sleep disturbance, 60.0-69.9 is associated with moderate sleep disturbance, and ≥70 is associated with severe sleep disturbance.

LEVEL 2—Sleep Disturbance—Adult*

*PROMIS—Sleep Disturbance—Short Form

Name: _____ **Age:** ____ **Sex:** ❑ Male ❑ Female **Date:**_____

If the measure is being completed by an informant, what is your relationship with the individual receiving care? _____

In a typical week, approximately how much time do you spend with the individual receiving care? _____ hours/week

Instructions to patient: On the DSM-5 Level 1 cross-cutting questionnaire that you just completed, you indicated that *during the past 2 weeks* you (the individual receiving care) have been bothered by "problems with sleep that affected your sleep quality over all" at a mild or greater level of severity. The questions below ask about these feelings in more detail and especially how often you (the individual receiving care) have been bothered by a list of symptoms **during the past 7 days. Please respond to each item by marking (✓ or x) one box per row.**

						Clinician Use
In the past SEVEN (7) DAYS....						
	Not at all	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**	
1. My sleep was restless.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	
2. I was satisfied with my sleep.	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1	
3. My sleep was refreshing.	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1	
4. I had difficulty falling asleep.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	
In the past SEVEN (7) DAYS....						
	Never	**Rarely**	**Sometimes**	**Often**	**Always**	
5. I had trouble staying asleep.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	
6. I had trouble sleeping.	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	
7. I got enough sleep.	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1	
In the past SEVEN (7) DAYS....						
	Very Poor	**Poor**	**Fair**	**Good**	**Very good**	
8. My sleep quality was...	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1	
					Total/Partial Raw Score:	
					Prorated Total Raw Score:	
					T-Score:	

Sleep Disturbance 8b
Short Form Conversion Table

Raw Score	T-score	SE*
8	28.9	4.8
9	33.1	3.7
10	35.9	3.3
11	38.0	3.0
12	39.8	2.9
13	41.4	2.8
14	42.9	2.7
15	44.2	2.7
16	45.5	2.6
17	46.7	2.6
18	47.9	2.6
19	49.0	2.6
20	50.1	2.5
21	51.2	2.5
22	52.2	2.5
23	53.3	2.5
24	54.3	2.5
25	55.3	2.5
26	56.3	2.5
27	57.3	2.5
28	58.3	2.5
29	59.4	2.5
30	60.4	2.5
31	61.5	2.5
32	62.6	2.5
33	63.7	2.6
34	64.9	2.6
35	66.1	2.7
36	67.5	2.8
37	69.0	3.0
38	70.8	3.2
39	73.0	3.5
40	76.5	4.4

*SE = Standard Error on T-score metric

The Epworth Sleepiness Scale determines the participant's level of daytime sleepiness. It asks the participant to rank their likelihood of falling asleep during a variety of common activities on a scale from 0-3, where 0 is "would never doze," and 3 is "high chance of dozing." After adding up the numerical value of all their responses, the result will determine whether the participant exhibits excessive sleepiness.

Epworth Sleepiness Scale scoring system

	Score
1. Sitting and reading	
2. Watching TV	
3. Sitting in a public place(e.g., theatre or a meeting)	
4. Sitting in a car as a passenger without a break	
5. Lying down to rest	
6. Sitting and talking to someone	
7. Sitting quietly after lunch without alcohol	
8. In a car, while stopped for a few minutes in traffic	
Total score	

(0 = would never doze, 1 =slight chance of dozing, 2 = moderate chance of dozing, 3 = high chance of dozing.

Total score >10, suggests presence of excessive sleepiness.)

The Insomnia Severity Index (ISI) asks the subject to respond with their level of agreement to a series of prompts related to their sleep habits. The possible responses are on a scale of 0 – 4, where the lower numerical responses indicate little to no presence of insomnia symptoms. After completing the questionnaire, the numerical responses are summed for interpretation. An overall score of 0-7 indicates “no clinically significant insomnia,” a score of 8-14 indicates “subthreshold insomnia,” a score of 15-21 indicates clinical insomnia of moderate severity, and a score of 22-28 is severe clinical insomnia.

Insomnia Severity Index (ISI)

Name: _____ **Date:** _____

1. Please rate the current (i.e., last 2 weeks) **SEVERITY** of your insomnia problem(s).

	None	Mild	Moderate	Severe	Very
Difficulty falling asleep:	0	1	2	3	4
Difficulty staying asleep:	0	1	2	3	4
Problem waking up too early:	0	1	2	3	4

2. How **SATISFIED**/dissatisfied are you with your current sleep pattern?

Very Satisfied				Very Dissatisfied
0	1	2	3	4

3. To what extent do you consider your sleep problem to **INTERFERE** with your daily functioning (e.g. daytime fatigue, ability to function at work/daily chores, concentration, memory, mood, etc.).

Not at all Interfering	A Little	Somewhat	Much	Very Much Interfering
0	1	2	3	4

4. How **NOTICEABLE** to others do you think your sleeping problem is in terms of impairing the quality of your life?

Not at all Noticeable	Barely	Somewhat	Much	Very Much Noticeable
0	1	2	3	4

5. How **WORRIED**/distressed are you about your current sleep problem?

Not at all	A Little	Somewhat	Much	Very Much
0	1	2	3	4

Guidelines for Scoring/Interpretation:

Add scores for all seven items (1a+1b+1c+ 2+3+4+5) = _____
Total score ranges from 0-28
- 0-7 = No clinically significant insomnia
- 8-14 = Subthreshold insomnia
- 15-21 = Clinical insomnia (moderate severity)
- 22-28 = Clinical insomnia (severe)

Novel wearable technology has been developed that gives information about sleep habits, and some that have the potential to screen for Obstructive Sleep Apnea. Examples of some of these "wearables" include the Oura Smart Ring, Apple Watch, and Belun Ring.

The Belun Ring (formally, Belun Sleep System BLS-100, Belun Technology Co. Ltd., Hong Kong) is a deep learning-facilitated, PPG and accelerometry-based medical-grade wearable, which was recently cleared by the US FDA for the diagnosis of moderate to severe OSA and sleep stage classification in subjects suspicious of OSA (K222579). A recent Belun Ring validation study demonstrated a moderate-to-substantial OSA diagnostic concordance and good overall accuracy in 3-sleep stage classification (REM, non-REM, and wake).[8]

The Belun Ring captures a variety of data points during each night of sleep. One such value is the Respiratory Event Index (REI), which is derived from the total recorded sleep time, heart rate variability, and oxygen saturation changes. The Belun Ring also captures sleep efficiency, which is calculated by dividing the time the participant is asleep by the total time in bed. The Belun Ring's AHI score, "bAHI," has been proven to have a high correlation with a polysomnography-obtained AHI score.[5]

Smart phone apps have also been developed as a new technology used to screen for snoring or sleep apnea. For example, Sleep Cycle, SnoreLab, SleepScore, Drowzle, and Sleep Check Rx are available to the public and produce sleep data after nighttime use for the user's interpretation. The Sleep Cycle app tracks time asleep, stages "Awake, Sleep, and Deep Sleep," sleep regularity, time to bed, time woken up, time in bed, sleep efficiency, heart rate, and time snoring, and also records audio. A score report is generated from each night of sleep, and data are aggregated over time for pattern analysis. Sleep Cycle users also have the ability to add "sleep notes," in which they may record outside factors that may have affected their night of sleep, for example, whether alcohol or caffeine was consumed, if they did a workout that day, if they were feeling sick, etc. Sleep Cycle is available in Apple App Store and Google Play store. The audio recordings are stored in the app, and are automatically deleted after 20 nights.

Objectives

To investigate the sleep of the adult orthodontic patient population at the Case Western Reserve University School of Dental Medicine using the NOSE Questionnaire, STOP-Bang Questionnaire, Epworth Sleepiness Scale, Insomnia Severity Index, PROMIS Sleep Disturbance Questionnaire, Sleep Cycle app, and Belun Ring.

Experimental design

The project will be a descriptive cross-sectional study.

A total of 55 adult participants will be recruited from the Case Western Reserve Orthodontics Clinic, based on the sample size calculation with a power of 80%. Inclusion criteria: current adult patients in the Case Western Reserve Orthodontics Clinic, ages 20-75, willingness to give informed consent

and participate in study, owner of a smartphone, and ability to return the Belun Ring and complete follow-up questionnaire. Exclusion criteria: age <20, currently or with history of taking blood pressure medication, currently undergoing transverse or anterior-posterior orthodontic correction, and currently pregnant or trying to become pregnant.

Participants will provide informed consent and will be instructed on the steps of the study. Demographic information will be collected, including a participant identifier, age of participant, and sex of participant. The use of the Belun Ring will be demonstrated, and they will be instructed on use of the Sleep Cycle app. They will complete the NOSE ScoreQuestionnaire, STOP-Bang Questionnaire, Insomnia Severity Index, PROMIS Sleep Disturbance Questionnaire, and the Epworth Sleepiness Scale (ESS).

Data collected from the STOP-Bang Questionnaire includes positive/negative responses to: snoring, tired, observed, pressure, BMI >35, age over 50, neck size large, male gender, and the resulting OSA risk assessment of low, intermediate, or high.

Data collected from the NOSE Questionnaire includes positive or negative responses to: nasal congestion or stuffiness, nasal blockage or obstruction, trouble breathing through my nose, trouble sleeping, unable to get enough air through my nose during exercise or exertion, and the resulting classification of severity of nasal obstruction (mild, moderate, severe, extreme).

Data collected from the Insomnia Severity Index include difficulty falling or staying asleep, problem with waking up too early, satisfaction level with current sleep pattern, noticeability of subject's sleep problem to others, and amount of distress regarding current sleep habits.

Data collected from the PROMIS Sleep Disturbance Questionnaire includes level of agreement with statements about the subject's ability to fall asleep, quality of sleep, amount of sleep, level of satisfaction with their sleep, ability to stay asleep throughout the night.

The Epworth Sleepiness Scale collects information regarding the subject's likelihood of falling asleep during the following activities: sitting and reading, watching television, sitting in public, sitting in a car, lying down to rest, sitting and talking to someone, sitting quietly after lunch without alcohol, and while sitting in a car stopped in traffic.

The participants are then instructed to wear the Belun Ring for seven nights and simultaneously use the Sleep Cycle app.

Data collected from the Belun Ring includes the Respiratory Event Index (REI) (derived from total sleep time, heart rate variability, and O_2 saturation changes), Sleep Efficiency (time participant is asleep divided by total time in bed), stress level, mean spO2 (%), Sleep Score (bAHI, Belun Ring's version of AHI), REM sleep (percentage), minimum spO2 (%), mean pulse rate (bpm), percent of time below 90% oxygen saturation, and total sleep time (minutes).

The Sleep Cycle app will collect the subject's time asleep, stages "Awake, Sleep, and Deep Sleep," sleep regularity, time to bed, time woken up, time in bed, sleep efficiency, heart rate, and time snoring. It also will record audio while the subject is asleep. During the night, the subject's

smartphone will be placed on their nightstand. The subjects also have the option to add “sleep notes” to give additional information about their night of sleep, for example, if they were feeling sick or if they exercised right before bed.

The subjects will return to the Case Western Reserve Orthodontic Clinic for their next orthodontic adjustment appointment. The subjects will return the Belun Ring to the clinic and we will download the data. The Sleep Cycle Score Report from each night will be collected by either sharing via WhatsApp, an encrypted messaging service, or recording the data points manually into an Excel spreadsheet.

Subjects will then complete a Follow-Up Questionnaire. They will record the dates they used the devices during sleep. Subjects will also indicate whether they had a “normal” night of sleep, or if they were experiencing sickness, allergies, or any other sleep disruptions that may have affected the data collected. They will also indicate whether they have a bed partner.

Participants will be referred for further evaluation, if needed.

Statistical Analysis Design

Out of the seven nights of sleep studied, the five with the longest night of sleep will be used for analysis. The values from those five nights will be averaged for each patient.

Descriptive statistics will be applied to the data, in order to determine reliability and consistency among different data collection methods, since similar variables are collected by different means. Correlation of data collected by different methods will be performed in order to cross examine and further validate results.

We will compare the accuracy of the response to the STOP-Bang question “Do you snore?” to audio data from the Sleep Cycle app. We will also compare the amount of snoring reported to the nasal obstruction score of the NOSE questionnaire. We will compare the distribution of the STOP-Bang questionnaire results (low/medium/high risk of Obstructive Sleep Apnea) to the distribution of results from the sensors. We will compare the agreement in recommendation for follow-up between the STOP-Bang Questionnaire and the sensors. Last, we will collect the percentage of people in the adult orthodontic clinic that should be referred for further evaluation for potential intervention.

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