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A NOVEL MYOFUNCTIONAL THERAPY WATER BOTTLE TO REDUCE SNORING AND OBSTRUCTIVE SLEEP APNEA

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ABSTRACT

There is a clear unmet need to provide alternative, first-line solutions for both obstructive sleep apnea and primary snoring. A novel myofunctional therapy nozzle that delivers therapy through drinking water provides a low risk, low burden, and affordable solution that can easily be administered to primary snorers and obstructive sleep apnea patients to reduce the overall harm from these conditions. A prototype myofunctional therapy nozzle and water bottle were developed and used to conduct a product usability study over the summer of 2020 to assess likeability, one-month adherence, and snoring improvement. 37 participants participated in the study and completed one month of device use. 27 participants were included in the snoring analysis and 35 participants in the tiredness analysis.

The one-month assessment has shown 88% adherence, the overall satisfaction of the product was 80% measured by CSAT, 93% have reported subjective improvements in reducing snoring intensity, occurrence, and/or impact, and 34% of participants reported improvements in tiredness. Bedpartner reported median snoring intensity decreased from somewhat loud to soft or quiet, overall snoring occurrence decreased, and median snoring impact reduced from moderately to a little bit after one month of device use. Preliminary results are promising and warrant further investigation.

Keywords: Snoring, Obstructive Sleep Apnea, Myofunctional Therapy, Oropharyngeal Exercises, Wellness Device, Water Bottle

NOMENCLATURE

BPA	Bisphenol A
CPAP	Continuous Positive Air Pressure
CSAT	Consumer Satisfaction Score
MT	Myofunctional Therapy
OSA	Obstructive Sleep Apnea
PLA	Polylactic Acid

1. INTRODUCTION

There is a clear unmet need to provide alternative, first-line solutions for both obstructive sleep apnea (OSA) and primary snoring. Most people suffering from OSA are currently not receiving treatment with estimates of 80% undiagnosed (23 million Americans) and 40% non-adherence to the gold standard treatment, continuous positive air pressure (CPAP), among diagnosed patients. This has serious implications for overall health resulting in increased daytime sleepiness and comorbidities of hypertension, heart disease, diabetes, and depression. The undiagnosed population alone contributes to an estimated cost burden of $30 billion from comorbidities and mental health, $26.2 billion from motor vehicle accidents, $6.5 billion from workplace accidents, and $86.9 billion from lost productivity, with a total cost burden to the US of $149.6 billion each year [1]. Although most people are undiagnosed, indicators such as snoring can be found in up to 94% of OSA patients [2] and habitual snorers (snoring ≥ 3 nights/week) with bed partners often seek out some form of treatment for their snoring. Low risk, low burden, and affordable solutions that are easily administered to primary snorers and OSA patients open new treatment paradigms to reduce the overall harm from these conditions.

Oropharyngeal exercises are a promising therapy for motivated patients and have shown, on average, to reduce snoring by more than 50% and apnea hypopnea index by 14.3 points [3,4]. The efficacy of oropharyngeal exercises for the treatment of sleep related breathing disorders is based on the fact that these disorders are caused by a "double hit" from (i) increased resistive loading of the upper airway by mechanical factors such as obesity, and (ii) absent compensatory neuromuscular responses. Thus, improving neuromuscular responsiveness of these upper airway muscles can compensate for anatomical causes and benefit a majority of snorers and serve as either first-line or adjuvant treatment in up to 36% of patients

with OSA who have altered neuromuscular responses of the upper airway during sleep as the primary cause of their OSA [5]. Current protocols have been developed by researchers at the University of Sao Paulo, Brazil who started with 15 oropharyngeal exercises [6] then simplified down to six exercises [7] but still required a trained myofunctional therapist to teach and monitor the exercises for each participant. Despite their efficacy, all exercise regimens need to be performed regularly, correctly, and in a measurable way, factors that limit their widespread adoption. This creates a demand for a simplified device that can effectively deliver oropharyngeal exercise therapy in less burdensome and more acceptable way.

To address the problem of adoption and adherence, a myofunctional therapy (MT) nozzle was developed that simplifies the oropharyngeal exercise regimen for primary snorers and OSA patients. The MT nozzle was made with food-grade silicone cast in food-safe 3D printed PLA molds. The MT nozzle was designed to attach to an off-the-shelf BPA-free reusable water bottle & straw (Figure 1 & 2). The water bottle was chosen to have a minimalistic design to better understand what is most important to users and what may impact therapy usage. Future product iterations will be designed to meet requirements determined from the study. The therapy nozzle and water bottle delivery system are patent-pending.

FIGURE 1: MYOFUNCTIONAL THERAPY NOZZLE & REUSABLE WATER BOTTLE

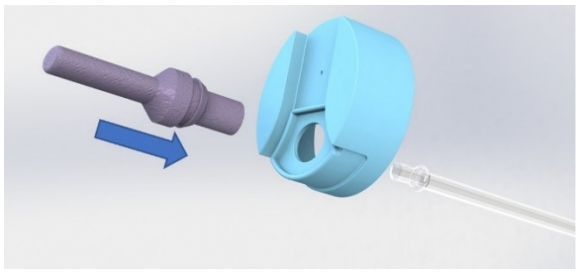

FIGURE 2: MYOFUNCTIONAL THERAPY NOZZLE & REUSABLE WATER BOTTLE ASSEMBLY

The scientific premise of the device is that it simplifies the oropharyngeal exercises into natural tongue suction, tongue compression against palate, and swallowing movements (Figure 3 & 4). These exercises activate most of the muscles targeted with the previously mentioned protocol, reducing the therapy burden by utilizing the biologically driven action of drinking water.

There are three main goals to the therapy.

- Goal 1: Tighten muscles in throat and soft palate to reduce vibration and collapsibility. Increasing the number of swallows per volume of liquid helps tighten these muscles.
- Goal 2: Tighten genioglossus muscle to reduce/prevent tongue from falling back in throat while sleeping. Both the Tongue Suction and Tongue Press exercises help to strengthen tongue muscles.
- Goal 3: Promote tongue placement on roof of mouth with light suction and nasal breathing at rest. Repetition and light resistance help to build muscle memory so that the tongue is in proper position.

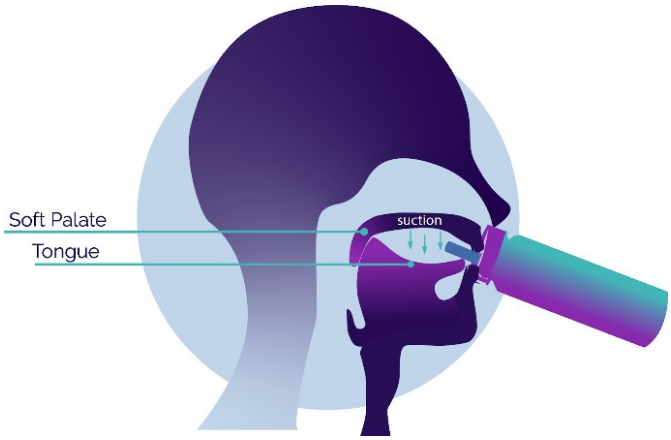

FIGURE 3: DEPICTION OF TONGUE SUCTION WITH THE MYOFUNCTIONAL THERAPY WATER BOTTLE

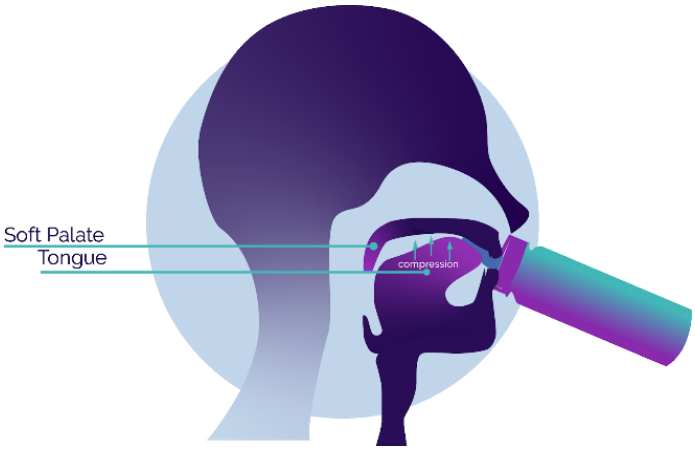

FIGURE 4: DEPICTION OF TONGUE PRESS WITH THE MYOFUNCTIONAL THERAPY WATER BOTTLE

The novel MT nozzle delivers targeted oropharyngeal exercises through daily use of a simple reusable water bottle. It is designed to deliver one day's worth of therapy by drinking one bottle of water making it a simple and effective method to adopt and adhere to oropharyngeal exercises. The innovative MT nozzle allows the user to repeatedly perform the exercise movements while also providing targeted resistance to train and improve tongue, soft palate, and pharyngeal muscle strength and endurance. The nozzle is engineered to utilize natural biomechanical motions of the tongue and prevent improper exercise motions, which makes it easy to use with minimal instruction or attention. The nozzle promotes proper tongue swallowing position and tongue suction resistance during the preparatory and oral phase of the swallow and provides additional resistance as the tongue compresses the nozzle against the hard palate through the transition of the oral and pharyngeal phases of the swallow. The MT nozzle has low risk and low burden and can easily be administered to positively impact the problems of adoption and adherence. This user-centric design and unique connection of the therapy with a biologically driven action of drinking water greatly increases the probability of long-term adherence to the therapy.

The aim of the product usability study over the summer of 2020 was to assess likeability, adherence, and snoring improvement after one month of device use with a prototype MT nozzle and water bottle. Participants were recommended to drink one 880mL bottle of water a day (water amount could be adjusted if was too easy or too difficult) five days a week and keep a daily water recording log. Subjective bed partner reported snoring was collected pre- and post-use of device over one month. Participants had two feedback interviews conducted through virtual video call: initial impressions after a few days of use and feedback after one month of use. The consumer satisfaction score (CSAT) was used to determine likeability of the device and is traditionally used as an indicator of a consumer's likelihood of using a product or service repeatedly. An anonymous survey was provided after one month to measure the CSAT. Tiredness improvement was decided to be analyzed after several participants mentioned tiredness improvement in the one-month interviews.

2. MATERIALS AND METHODS

2.1 Participants

Social media was used to recruit 37 participants to participate in the usability study for the novel snoring exercise water bottle. Recruitment materials consisted of two Facebook posts and one LinkedIn post that were distributed with the REMastered Sleep company pages. The posts showed a picture of the study prototype and messaging that there was recruitment of participants for a consumer product usability study with a novel snoring exercise water bottle. Because this was a usability study for the prototype, there were no inclusion or exclusion criteria other than that the participant had to have the capabilities to attend the virtual assessment meetings and return a signed consent form after reviewing the study materials and having any questions answered during the optional study information session.

Participants consisted of 26 males and 11 females. The age of participants ranged from 24 to 68, with most participants centered around 28 and 60. Body-mass-index had a mean of 28.3 and a standard deviation of 4.4. Although the usability study was advertised on social media as a snoring exercise water bottle, seven participants with diagnosed OSA participated in the study. Participants were asked to continue use of their current devices such as CPAP or oral appliance. Participants were sent the water bottle with minimal instructions for use to assess the usability of the product, and then device use was assessed and corrected if needed in the initial feedback meeting.

A total of 27 participants were included in the snoring analysis and 35 participants were included in the tiredness analysis. Eight participants were excluded from the snoring analysis because they did not have a bed partner that could provide snoring feedback, or they used a device while sleeping that would interfere with the results such as a mouth guard or CPAP. Two participants were excluded from both the snoring and tiredness analysis based on non-compliance using the device (one participant) and using the device to help with jaw clenching (one participant).

2.2 Subjective Bed Partner Survey

A bed partner snoring survey was sent to participants on paper with the water bottle. The survey required the bed partners to choose the best answer from five different levels for intensity, occurrence, and impact (Figure 5). At one month the survey was sent through email along with an additional open-ended question asking the bed partner to describe changes noticed from before device use until the current date.

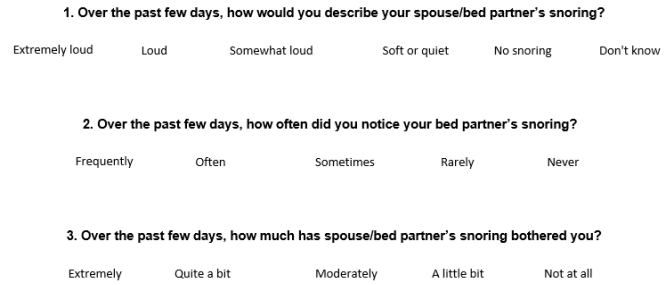

FIGURE 5: BED PARTNER SNORING SURVEY EXAMPLE

2.3 Adherence

A daily water recording log was sent with each device for the participant to record daily water intake with the prototype device. If participants missed recording some days, they were asked to verbally describe the amount of water drank for the missing days to the best of their memory during the one-month virtual video feedback meeting. Adherence was measured by percentage of water drank compared to recommended water amount and proportion of days that the bottle was used relative to the five days a week recommended amount. One bottle of water was recommended each day; however, each person was starting at a different level of strength, so this could be adjusted

to fit each individual person's needs (1/2 bottle, ¾ bottle, 1 bottle, etc.). The first week allowed for ramping up of the therapy.

2.4 Consumer Satisfaction Score (CSAT)

Data was collected by sending out an anonymous survey to participants after one month of device use.

2.5 Tiredness Analysis

At the one-month assessment interview participants were asked, "How well did it work? What changes have you noticed?". Participants that self-reported receiving benefits in tiredness or uninterrupted sleep after one month of device use were considered to receive positive benefits in tiredness.

2.6 Weight Monitoring

At each assessment session, the participant was asked for their weight and this was recorded. Participants without access to a scale were asked to estimate their weight at each session. Weight was monitored as an additional variable that could impact snoring.

3. RESULTS AND DISCUSSION

37 participants completed the one-month study. The feedback interviews revealed participants liked the device, thought it was comfortable to use, the effort to drink was not a problem, it was easy to use it while doing other tasks such as while working or watching tv, and enjoy the concept of doing something during the day (positive biofeedback) that may have lasting effects rather than having to sleep with a device each night. The therapy levels chosen worked for most participants with only some opting to go to lower or higher levels of resistance. Some participants reported additional improvements in swallowing, nasal breathing with tongue on roof of mouth positioning during day that carried over into night, increased tongue strength and endurance, and improvements in hydration. Some participants noted slight tongue irritation or tongue muscle fatigue, but symptoms went away with a reduced therapy intensity. Some participants reported getting water in their air tube when drinking too fast in the first days of use, but this was corrected with instruction of proper form in the initial assessment. No other negative effects were reported.

One-month adherence of the device was calculated to be 88% for the 37 participants. Most daily water usage results were recorded during the one-month interview as the participants explained their device usage for each of the previous weeks since device usage began. Not many participants (only 24%) were compliant with filling out the daily water tracking table for the full one month of device use. Reasons stated were that after the first week there was not much change day to day in their weekly routine, and/or the participant was busy and forgot to fill out the form each day. The consumer satisfaction score (CSAT) was calculated to be 80%, with 27 participants having completed the anonymous survey.

25 of the 27 (93%) participants in the snoring analysis reported improvements in snoring intensity, occurrence, and/or impact. Median snoring intensity decreased from somewhat loud to soft or quiet after one month of device use (Figure 6). Overall snoring occurrence decreased after one month of device use (Figure 7). Median snoring impact decreased from moderately to a little bit after one month of device use (Figure 8).

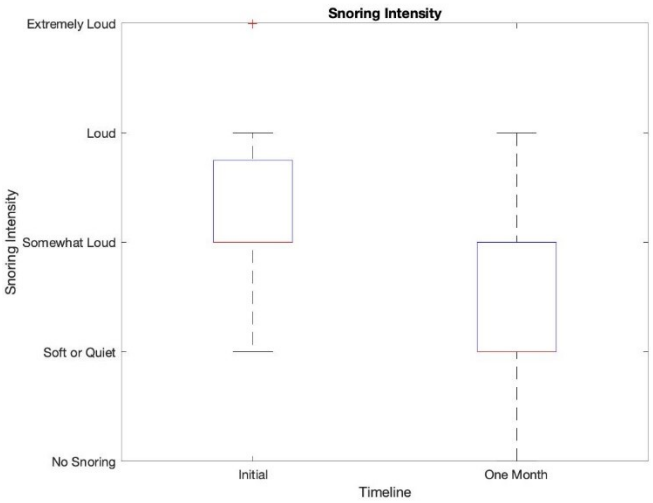

FIGURE 6: BOX PLOT OF BED PARTNER REPORTED SNORING INTENSITY: INITIAL VS. ONE MONTH OF DEVICE USE

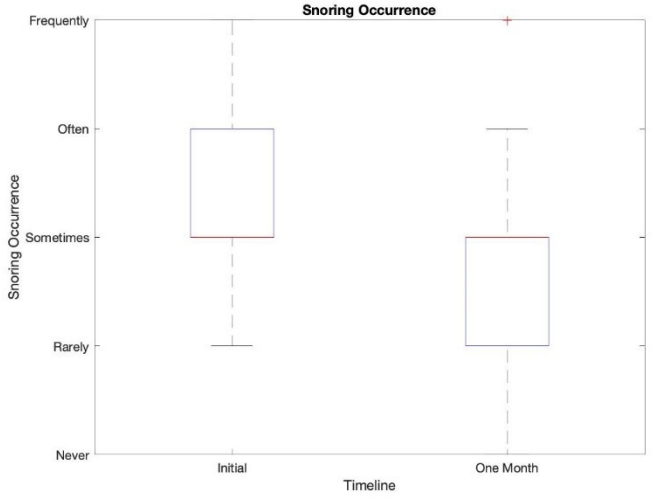

FIGURE 7: BOX PLOT OF BED PARTNER REPORTED SNORING OCCURRENCE: INITIAL VS. ONE MONTH OF DEVICE USE

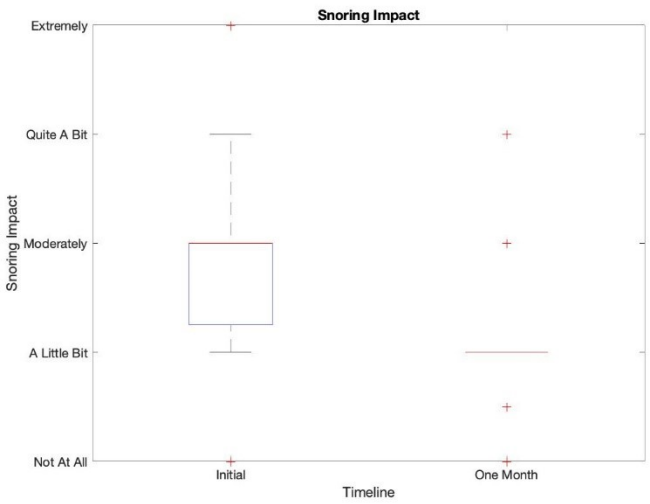

FIGURE 8: BOX PLOT OF BED PARTNER REPORTED SNORING IMPACT: INITIAL VS. ONE MONTH OF DEVICE USE

A graphical approach was chosen to show the results instead of a statistical analysis because the usability study design was not intended to establish statistical significance. The clear downward shift for all metrics to the more desirable outcome suggests that the bed partner's perception is that the device has functioned as intended. Because all data was self-reported and without a control group to compare against, the results are subject to the placebo effect. Future studies should use data collected from alternate sources which cannot be biased and that involve the use of control populations. One potential source is audio recordings of the subjects' snoring. These recordings can be analyzed for intensity, occurrence, and duration based on pre-defined criteria, and the results can be quantified.

Change in weight was monitored and was not a major contributor to these downward shifts. Only 14% participants lost weight from the initial to one month assessment with average weight loss of 3.5lb with a range of 1lb to 5lb. Most participants did not have a change in weight (43%) or gained weight (41%) Average weight gain was 3.5lb with a range of 0.2lb to 10lb. Change in weight was not recorded for the participant who was non-compliant with device use.

Tiredness Results: 12 of the 35 participants (34%) self-reported improvements in tiredness after one month of device use. Participants described feeling better rested or less tired, less headaches, reduced awakenings in the middle of the night, and less fogginess in the morning. Ten of the participants that reported benefit in tiredness have not been diagnosed with OSA. These improvements in tiredness could be a result of improving the symptoms of undiagnosed OSA given the high undiagnosed rate in the general population.

Three of the seven OSA diagnosed participants included in the tiredness analysis were compliant with use of either a CPAP or oral appliance. One severe OSA patient reported further tiredness benefit with use of MT water bottle as adjunct to already compliant CPAP therapy. The other two participants with mild OSA who were compliant with CPAP or an oral appliance did not receive noticeable improvement by combining their existing devices with use of the MT water bottle (Table 2).

Table 2: Self-Reported Changes in Tiredness by OSA Participants Using MT Water Bottle as Adjunct with Existing Therapy

Participant	Self-Reported Changes After One Month of MT Water Bottle Use
Severe OSA + CPAP	"One of the things that seem to change is that I think I am sleeping better. I used to get up every 2 or 3 hours to go to the bathroom. Hard to get back to sleep. I have slept 7 hours without any interruptions. I have been getting the best sleep I have gotten with CPAP the last few weeks."
Mild OSA + CPAP	"I don't know if seen an improvement."
Mild OSA + Oral Appliance	"I guess I haven't noticed any changes if you will."

4. CONCLUSION

Preliminary data suggests that the novel myofunctional therapy water bottle has promise as an alternative, first-line solution to help with snoring and/or daytime tiredness. Future studies are warranted to better determine effectiveness.

ACKNOWLEDGEMENTS

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