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The Effect of Technology for the Delivery of Myofunctional Exercises in OSA patients

By

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Submitted in partial fulfillment of the requirements for the degree of Master of Science in Dentistry

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Abstract

Introduction: To assess the influence of technology on the administration and compliance of myofunctional therapy (MFT) in individuals diagnosed with obstructive sleep apnea (OSA). This study compared the results and compliance of a smartphone app-based program to a classic analog (paper-based) exercise method. **Materials and Methods:** The Case Western Reserve University Department of Orthodontics conducted a randomized, prospective clinical trial after receiving IRB approval (STUDY20231615). Twenty-five adults with mild to moderate obstructive sleep apnea (14 app, 11 analog) participated and underwent three months of daily myofunctional therapy focusing on the tongue, buccinator, and soft palate muscles. Participants attended appointments once a month. The visits in months 1 and 2 were just for placebo check-ins and did not involve collecting any data for evaluation. Data that could be measured were only collected at the first (T1) and last (T2) visits. The Belun Ring and SnoreLab app were used to measure sleep quality for three nights in a row between sessions, without any other sleep-aid gadgets. The Iowa Oral Performance Instrument (IOPI) was used to test muscle strength. At T1 and T2, validated questionnaires were given out, such as the STOP-BANG, the Epworth Sleepiness Scale, the PROMIS Sleep Disturbance, and the NOSE Scale. Self-reported 30-day diaries (for the analog group) or app-based activity logs within Airway Gym (for the digital group) were used to keep track of compliance. Each participant received a $100 payment for finishing the study. Statistical analyses comprised paired and independent t-tests or Mann–Whitney U tests ($\alpha = 0.05$). **Results**: There were significant improvements in the anterior ($p = 0.0128$), posterior ($p = 0.00075$), and left buccinator ($p = 0.0155$) IOPI values within groups, which means that the orofacial muscles got stronger following therapy. There was also a significant improvement within the group for Snore Score ($p = 0.0448$), Snore Duration ($p = 0.0081$), minimum SpO (p = 0.0104), Epworth Sleepiness Scale ($p = 0.0054$), and PROMIS Sleep Disturbance ($p = 0.0026$). Comparisons between groups showed only one statistically significant variable, minimal SpO ($p = 0.0007$), which was better for the analog group. There were no significant changes between the delivery modalities for any of the other outcome variables, such as AHI, mean SpO , sleep efficiency, STOP-BANG, NOSE, or snore % ($p > 0.05$). The analog group had a greater overall compliance rate than the app group. **Conclusion:** Myofunctional therapy for three months made the orofacial muscles stronger and improved patients' subjective sleep measures who had OSA. Both administration techniques worked, however the analog format got higher overall compliance and a little better oxygenation. Instruction using apps was an organized, easy-to-use option, but it didn't lead to better results. These results indicate that the efficacy of myofunctional therapy is more contingent upon patient compliance than the method of administration.

Background

Sleep-related breathing disorders (SRBDs) encompass problems that interfere with normal respiratory patterns during sleep, including persistent snoring and more severe manifestations like sleep apnea. While certain types have negligible health impacts, others can profoundly affect overall well being by disrupting sleep quality and altering the equilibrium of oxygen and carbon dioxide in the body. This category of disorders includes primary snoring, upper airway resistance syndrome, obstructive sleep apnea (OSA), and other forms such as central sleep apnea or sleep-related hypoventilation.

Obstructive sleep apnea (OSA) occurs when the upper airway becomes overly collapsible during sleep (Behrents 2019). The heightened collapsibility is largely attributable to diminished neuromuscular tone in the airway muscles. As the airway constricts, the body responds by compensating respiratory effort to maintain airflow. Behrents and colleagues observed that this compensatory response increases carbon dioxide levels and decreases oxygen saturation in the blood. The increased respiratory exertion often induces transient awakenings during sleep, along with elevations in heart rate, blood pressure, and occasionally cardiac arrhythmias. These arousals momentarily reestablish airway patency but generate a cyclical pattern of airway obstruction, awakening, and resumption of sleep. This frequently occurs multiple times per hour.

The etiology of OSA is multifactorial. OSA encompasses a blend of neuromuscular, anatomical, and systemic factors. Fluctuations in muscle tone can modify craniofacial features over time, while elements such as instability in central respiratory control (loop gain), hormonal fluctuations, obesity, rostral fluid shifts, and genetic susceptibility also facilitate airway constriction. Craniofacial characteristics commonly associated with

OSA include mandibular retrognathia, elongated facial morphology, high arched palates, steep mandibular plane angles, anterior open bites, midface deficits, and a low lying hyoid bone.

Clinically, obstructive sleep apnea (Rueda 2020) is defined by recurring episodes of apnea, the complete cessation of airflow, or hypopnea, a partial reduction in respiratory activity during sleep. Untreated OSA can lead to extensive systemic repercussions and significantly reduce quality of life. It is linked to increased risks of occupational and vehicular accidents, metabolic illnesses, cardiovascular diseases, and overall mortality. Complications encompass insulin resistance, coronary artery disease, heart failure, myocardial infarction, hypertension, stroke, arrhythmias, and sudden cardiac death. Neurocognitive impairments resulting from disturbed sleep cause diminished concentration, memory, and job performance. Chronic oxygen desaturation, sympathetic hyperactivity, endothelial damage, and inflammation contribute to metabolic dysregulation and gradual organ impairment.

OSA affects around 14% of men and 5% of women, with these rates likely higher in persons with risk factors. The true frequency of OSA is underestimated due to frequent underdiagnosis and lack of recognition by patients. Obesity remains a significant risk factor for OSA in both adult and pediatric populations (Carneiro 2018; Andersen 2019). Research indicates that over 70% of patients with OSA are overweight, and over 45% of obese adults have varying degrees of OSA. Socioeconomic status may influence illness risk, since reduced income and restricted access to healthcare, often correlated with elevated obesity rates, have been associated with higher OSA prevalence among specific ethnic minority populations (Guglielmi 2019).

Individuals with OSA frequently exhibit symptoms including loud snoring, gasping for air, choking sensations, or interruptions in breathing during sleep, which are often noted by a partner. The hallmark characteristics of OSA (snoring, non-restorative sleep, and excessive daytime sleepiness) are more commonly observed in males. Conversely, women often have less specific symptoms, including fatigue, insomnia, and morning headaches. Other frequently reported symptoms include difficulties with attention and concentration, mood fluctuations, and inadequate control of related medical conditions such as diabetes, hypertension, and obesity.

Treatments Available

OSA shows marked variation in severity, which complicates both monitoring and the achievement of stable treatment outcomes. The Apnea-Hypopnea Index (AHI) and Respiratory Disturbance Index (RDI) are commonly used to quantify OSA severity. The AHI counts the number of apneas and hypopneas per hour of sleep, whereas the RDI also includes respiratory effort-related arousals. An AHI or RDI of less than five events per hour is considered normal in adults. Five to fifteen events per hour is categorized as mild OSA, fifteen to thirty as moderate OSA, and more than thirty as severe OSA.

The treatment of OSA usually includes a combination of behavioral changes, weight loss, continuous positive airway pressure (CPAP) therapy, oral appliances, medications, or surgery. Chang (2019) describes behavioral adjustment as an essential first step aimed at reducing risk factors that contribute to airway obstruction. Patients are especially advised to avoid alcohol and sedatives, as both may worsen airway collapse during sleep. Weight loss has been shown to improve airway stability, reduce snoring, and minimize the number of apneic events. Additionally, avoiding sleeping in a supine

position can further reduce the frequency of events.

Continuous positive airway pressure (CPAP) therapy is the most common treatment for OSA. It maintains upper airway patency by delivering a constant positive pressure throughout sleep. Numerous studies in patients with moderate to severe OSA have shown that regular CPAP use reduces daytime sleepiness and improves overall quality of life. Patil et al. (2019) indicate that average compliance with CPAP therapy is around 67%. Handan (2019) noted that non-adherence is a persistent problem, with adherence which is defined as using the device for at least four hours per night on 75% of nights, ranging from 46 to 83%. Because of these limitations in long term compliance, the field has increasingly explored alternative therapeutic options.

Oral appliances (OAs) are a common treatment for patients with OSA. Ferguson et al. (1997) found that CPAP generally produces superior polysomnographic outcomes compared with OAs, particularly in lowering the AHI, but both treatments lead to comparable improvements in overall clinical complaints. Based on these findings, CPAP is considered more effective in relieving sleep-disordered breathing objectively, whereas OAs can provide similar benefits in patient-reported outcomes. Kushida et al. (2006) suggested that OA therapy is a suitable alternative for those who are unable to tolerate or adequately respond to CPAP.

Despite their advantages, oral appliances have drawbacks. Araie et al. (2018) observed that prolonged utilization of OAs can result in dental alterations, including changes in the inclination of mandibular incisors, which may reduce overjet and overbite in some patients. The authors contend that these adverse effects are generally outweighed by

therapeutic benefits, but clinicians should counsel patients on potential long-term changes prior to initiating OA therapy.

Camacho et al. (2017) stated that rapid maxillary expansion (RME) may be an effective treatment for children with OSA who present with maxillary constriction. This technique widens the maxillary arch, enlarges the nasal cavity, and improves airflow through the upper airway. However, additional aspects must be considered when using RME. As patients approach skeletal maturity, expansion tends to produce more dental tipping and undesirable tooth movements. Studies in the American Journal of Orthodontics and Dentofacial Orthopedics, including Ghoneima et al. (2011), indicate that RME is most effective in enlarging the anterior and inferior segments of the maxilla, while its effects are limited in the posterior and superior regions due to denser ossification at the maxillary-sphenoid junction.

In older patients, conventional expansion often requires surgical assistance due to increased skeletal resistance with age. Surgically assisted expansion procedures, while effective, carry higher morbidity and cost. Mini-implant assisted rapid maxillary expansion (MARPE) has emerged as a minimally invasive alternative for adolescents and adults who have reached skeletal maturity. Recent studies by Kim et al. (2018) and Storto et al. (2019) demonstrated that MARPE can achieve stable and predictable skeletal expansion in older individuals. In addition to correcting transverse maxillary deficiencies, MARPE has been shown to increase upper airway dimensions and reduce airflow resistance, suggesting its potential as an adjunctive therapy for adults with OSA.

Evidence is still insufficient to determine the overall effectiveness of maxillary skeletal

expansion for treating OSA in larger adult populations. However, because MARPE is less expensive and less invasive than traditional surgically assisted expansion, it represents a promising strategy. It offers a means for nonsurgical orthopedic maxillary expansion and a minimally invasive option in the management of OSA.

Surgical treatment is usually reserved for patients with severe OSA or those who have failed conservative therapies. Uvulopalatopharyngoplasty (UPPP) is one of the most frequently performed procedures and involves removal of the tonsils, uvula, and a segment of the soft palate. Aurora et al. (2010) reported that UPPP alone does not consistently normalize the AHI. The American Academy of Sleep Medicine does not recommend UPPP as a standalone therapy for individuals with moderate to severe OSA. A meta-analysis by Choi et al. (2016) demonstrated the best surgical outcomes in Friedman stage I patients, characterized by large tonsils and a relatively normal palatal position, with the most significant improvements in OSA severity observed in this group.

Maxillomandibular advancement (MMA) is the most consistently effective surgical intervention for OSA, with reported success rates ranging from 75 to 100% (Riley et al. 1993). The procedure typically involves a Le Fort I osteotomy of the maxilla and a bilateral sagittal split osteotomy of the mandible to advance both jaws. This forward repositioning of the maxillomandibular complex displaces the tongue and soft palate anteriorly, enlarging the upper airway and improving airflow during sleep. Individuals with persistently elevated AHI who do not respond to other treatments may show substantial improvement following MMA. Walte et al. (1995) described MMA as the gold standard for surgical orthodontic management of OSA. Hsieh et al. (2013) demonstrated that MMA increases airway dimensions in both anteroposterior and lateral

directions while elevating the hyoid bone, thereby enhancing airway stability.

Tracheostomy is considered a last-resort operation for patients with severe OSA who fail other therapies or cannot undergo procedures such as MMA. The surgery creates a direct opening into the trachea, bypassing upper airway obstruction and markedly improving sleep quality and oxygenation. Because the operation is highly invasive and can negatively impact quality of life, it is reserved for selected cases. Guilleminault and colleagues reported that tracheostomy was the main surgical treatment for OSA from the late 1960s to the early 1980s, prior to the development of more targeted therapies.

Currently, surgical intervention for OSA may be staged based on the pattern and level of upper airway collapse. Common sites of obstruction include the soft palate, lateral pharyngeal walls, tongue base, and hypopharynx. Li et al. (1999) proposed a phase-based approach in which the first stage of surgery is guided by presurgical assessment to identify the predominant level of obstruction. Phase I procedures may involve UPPP for oropharyngeal obstruction or genioglossus advancement with hyoid myotomy or suspension for tongue base collapse. A repeat polysomnography is typically obtained six months after the initial procedure to evaluate treatment success. Patients who do not meet predefined success criteria are considered for phase II surgery, usually MMA osteotomies.

More recently, neurostimulation of the hypoglossal nerve has emerged as an innovative surgical option for OSA. The U.S. Food and Drug Administration approved this therapy in 2014. It involves implantation of a device that stimulates the hypoglossal nerve during sleep to increase tongue muscle tone and maintain airway patency. This strategy has

gained popularity among patients struggling with CPAP adherence. Hypoglossal nerve stimulation is a minimally invasive yet effective option for carefully selected patients. Wray et al. (2016) found that the highest success rates occur in those with lower body mass index, AHI below 50, and an anteroposterior pattern of palatal collapse.

Myofunctional Therapy

Myofunctional therapy has recently become one of the most discussed noninvasive approaches for sleep disordered breathing. This method uses targeted exercises for the tongue and oropharyngeal muscles to correct dysfunctional swallowing patterns and encourage nasal breathing. Myofunctional therapy was first developed to support normal craniofacial and dental growth in children, but has since gained attention for its potential role in treating OSA. The central concept is that strengthening the upper airway musculature can improve muscle tone and reduce the likelihood of airway collapse during sleep. Habit correction exercises are typically prescribed several times per day for at least three months. Improved muscle tone is thought to stabilize the pharyngeal walls, reducing obstruction and OSA severity.

Tongue and facial muscle training to influence mandibular growth and promote nasal breathing has been described since the early 1900s. A landmark study by Puhan et al. (2005) generated substantial interest in upper airway muscle training when didgeridoo playing was shown to reduce OSA severity and related symptoms. The investigators reported that patients who practiced regularly experienced significant decreases in daytime sleepiness and AHI, while their partners noted fewer nocturnal disturbances compared with controls.

Myofunctional therapy for OSA usually consists of a structured, multi-component regimen of oropharyngeal exercises. Patients are typically instructed to perform these exercises three times daily for at least three months, with regular follow-up visits to a trained myofunctional therapist to ensure proper technique and adherence. Despite its potential benefits, adherence in routine practice is often poor. Protocols also vary widely between practitioners with respect to program length, exercise intensity, and mode of delivery.

Therapeutic programs often incorporate both isotonic and isometric movements targeting the tongue, lips, cheeks, and pharyngeal dilator muscles. These may include controlled breathing, speech tasks, blowing and sucking exercises, chewing drills, and swallowing practice. Because the upper airway dilator muscles are critical for maintaining patency, many researchers have examined exercise regimens aimed at improving their tone and coordination as a noninvasive means to reduce obstruction. Rueda (2020) emphasized that the main goal of myofunctional therapy is to enhance the function of these dilator muscles by increasing their strength, endurance, and mobility so that the airway is less prone to collapse. These activities may also reduce parapharyngeal fat deposits, such as tongue fat, which tend to be larger in individuals with OSA.

Given that many current treatments for snoring and OSA are invasive, involve surgery, or require external devices, there is substantial interest in therapies that avoid these drawbacks. Myofunctional approaches aimed at strengthening the tongue and oropharyngeal muscles have shown meaningful improvements in OSA symptoms in both pediatric and adult populations.

Guimaraes et al. (2009) conducted one of the most influential randomized clinical trials evaluating myofunctional therapy in patients with moderate OSA. Participants performed a series of exercises targeting the soft palate, tongue, and facial muscles for approximately 30 minutes per day. The exercises were also intended to improve broader stomatognathic functions such as breathing, chewing, and swallowing.

Soft palate exercises included repeated vowel phonation for isometric activation and partial-range movements for isotonic training. Tongue tasks involved tracing the upper and lateral surfaces of the teeth, pressing the tip of the tongue against the anterior hard palate, pressing the whole tongue against the hard and soft palate, and pressing the tongue against the floor of the mouth. Facial exercises focused on contraction and relaxation of the orbicularis oris, sucking maneuvers to engage the buccinator muscles, and placing digital pressure on the cheeks from inside the mouth. Jaw exercises emphasized controlled lateral mandibular excursions.

Additional training addressed functional behaviors such as nasal inhalation with oral exhalation, with and without balloon inflation. Patients were instructed to practice proper chewing and swallowing during meals and in three daily sessions. They were told to maintain light tooth contact, keep the tongue resting against the palate, avoid perioral muscular contraction, and alternate chewing sides.

Before and after the intervention, participants underwent anthropometric assessment, snoring evaluation (frequency and intensity), Epworth Sleepiness Scale (ESS) and Pittsburgh Sleep Quality Index (PSQI) questionnaires, and full polysomnography. The investigators reported significant improvements in neck circumference, snoring

frequency and intensity, daytime sleepiness, sleep quality, and AHI among patients who adhered to the exercise regimen. For example, neck circumference decreased from 39.6 ± 3.6 cm to 38.5 ± 4.0 cm, snoring frequency from 4 [4–4] to 3 [1.5–3.5], snoring intensity from 3 [3–4] to 1 [1–2], ESS scores from 14 ± 5 to 8 ± 6, PSQI scores from 10.2 ± 3.7 to 6.9 ± 2.5, and AHI from 22.4 ± 4.8 to 13.7 ± 8.5 events/hour. Reductions in neck circumference correlated inversely with AHI reduction. Guimaraes et al. concluded that regular oropharyngeal exercises significantly reduce OSA severity and related symptoms and support myofunctional therapy as a viable noninvasive option for patients with moderate OSA.

Camacho et al. (2015) performed a comprehensive systematic review and meta-analysis including nine adult and two pediatric studies that evaluated myofunctional therapy in OSA. They reported five major findings. First, myofunctional therapy produced large reductions in AHI: approximately 50% in adults and 62% in children. In adults, mean AHI decreased from 24.5 events per hour pre-therapy to 12.3 events per hour post-therapy. Among children, AHI decreased from 4.87 to 1.84 events per hour. Control groups showed little or no improvement, underscoring the specific effect of the exercises. Minimum oxygen saturation increased by roughly 3 to 4 percentage points after therapy.

Second, the review showed that myofunctional therapy effectively reduced snoring, both subjectively and objectively. Post-treatment polysomnography demonstrated a 72.4% reduction in the proportion of time spent snoring, from 14.05% to 3.87%. Patients and bed partners also reported reductions in snoring loudness and a shift toward normal breathing sounds.

Third, subjective daytime sleepiness improved substantially. In studies using the ESS, average scores decreased from 14.8 to 8.2, bringing participants below the threshold for excessive sleepiness.

Fourth, despite substantial variability in exercise type, intensity, and duration across studies, both objective sleep parameters and subjective symptoms improved overall. Protocols ranged from five minutes per session twice daily four days per week for two months to ten minutes per session three to five times daily for three months. The longest follow-up reported in adult OSA patients undergoing myofunctional therapy was six months, as in the trial by Guimaraes et al.

Finally, Camacho et al. (2015) emphasized that further research is needed to clarify the mechanisms by which myofunctional therapy works and to standardize protocols. They proposed that improvements in OSA severity may be related to increased muscular tone in oral and oropharyngeal structures and possibly a reduction in tongue fat, but these hypotheses remain unproven. Because protocols often combined many exercises, it was difficult to identify which specific movements most contributed to clinical improvement.

Building on these earlier reviews, Saba et al. (2024) published an updated systematic review and meta-analysis focusing exclusively on randomized controlled trials of orofacial myofunctional therapy (OMT) as monotherapy for OSA. They identified seven RCTs including 310 patients, six in adults and one in children. In adults, OMT produced statistically and clinically significant improvements in multiple outcomes compared with sham therapy or no treatment, including a mean reduction in AHI of about 10 events per

hour, a decrease in ESS scores of approximately 5 to 6 points, a 3 point improvement in PSQI scores, and a roughly 3% increase in minimum oxygen saturation. In contrast, pediatric patients showed poor adherence (less than 50% completing treatment), and no significant improvements in AHI, minimum oxygen saturation, or snoring frequency were observed. Saba et al. concluded that OMT represents a reasonable alternative for adults with OSA who cannot tolerate CPAP or other established therapies, whereas benefits in children may be limited by adherence challenges.

Rueda et al. (2020) conducted a Cochrane review that examined nine RCTs comparing myofunctional therapy with various control conditions, including sham therapy, no intervention, CPAP, and other active or combination therapies. They found that myofunctional therapy likely leads to meaningful reductions in AHI and improvements in daytime alertness and sleep quality compared with sham or no therapy. When directly compared with sham exercises, myofunctional therapy produced little to no change in snoring frequency but modest improvements in perceived snoring severity; however, the certainty of evidence for snoring outcomes was low. In several trials, benefits of myofunctional therapy were similar in magnitude to those of CPAP for outcomes such as ESS and quality of life, although CPAP remains the standard of care for OSA.

When compared with nasal breathing exercises supplemented by nasal dilator strips, myofunctional therapy showed mixed results. Differences in daytime sleepiness were small, improvements in sleep quality were modest, and changes in AHI were limited. In pediatric patients, adding myofunctional therapy to conventional management appeared to produce minimal to no change in AHI.

Rueda et al. highlighted several limitations of the available evidence, including small sample sizes, short intervention and follow-up periods (often fewer than four months), and heterogeneous protocols. As a result, it remains unclear whether the benefits of myofunctional therapy are sustained over the medium and long term and whether patients continue exercises after the end of formal programs.

Exercise and its Effect on Muscle Hypertrophy and Tonicity

It is well established that consistent resistance training leads to substantial improvements in muscle strength and hypertrophy in individuals of all ages and both sexes. Zou et al. (2011) described mechanotransduction as a key process linking mechanical loading to muscular adaptation. During mechanotransduction, mechanosensitive structures on the sarcolemma, such as integrins and focal adhesions, convert mechanical stimuli into biochemical signals that regulate anabolic and catabolic pathways within muscle cells. Mechanical overload activates these signaling cascades, increasing protein synthesis and resulting in muscle fiber growth and strength gains.

Schoenfeld et al. (2017) performed a meta-analysis comparing low-load and high-load resistance training on skeletal muscle outcomes. Traditional guidelines suggested that loads exceeding 70% of one repetition maximum were necessary to optimize hypertrophy and strength, whereas lower loads, typically less than 60% of one repetition maximum, were believed to be insufficient to recruit higher threshold motor units. This debate is particularly relevant for calisthenic or bodyweight based approaches such as myofunctional therapy, which rely on low external loads.

Schoenfeld and colleagues found that both high and low load training significantly

improved muscle strength. Lower-load protocols increased one repetition maximum strength by roughly 28%, with isotonic strength improving more than isometric strength (which increased by approximately 20.5%). Low-load training also promoted hypertrophy, with an average increase in muscle cross-sectional area of about 7%, not significantly different from high-load training. These findings support the concept that low load, high repetition exercise if performed with sufficient effort and frequency can meaningfully increase muscle strength and size, a principle that underpins many myofunctional therapy protocols.

The Impact of Smartphones and Digital Tools on Healthcare Compliance

Smartphone applications are increasingly used in healthcare to support treatment adherence and behavior change. Growing evidence suggests that mobile technologies can influence patient behavior and improve outcomes through real-time prompts, feedback, and self-monitoring.

Carter et al. (2013) conducted a clinical trial comparing adherence to a smartphone based weight loss application with a web-based program and a paper diary. Participants found the smartphone app feasible and acceptable, and adherence was higher in the app group than in the other two groups. Engagement declined across all groups over time, but at six months, 16% of smartphone users were still actively using the app, whereas no participants in the web or paper-diary groups remained engaged.

Similarly, Stephens et al. (2013) performed a systematic review on the effectiveness of smartphone apps in promoting physical activity and weight loss. Most apps were well received by participants and were associated with favorable changes in health

behaviors, including reduced consumption of sugar-sweetened beverages, less screen time, and healthier dietary choices. Users of smartphone apps showed reductions in body weight, body mass index (BMI), waist circumference, and total fat mass.

Montes et al. (2012) executed a randomized controlled trial evaluating smartphone based reminders to enhance adherence to self administered oral medications. Daily reminders significantly improved medication adherence, including among patients with a history of poor compliance, and this benefit persisted for at least six months after the intervention. Smartphone reminders also improved patients' attitudes toward their treatment regimen, although they did not meaningfully change disease specific knowledge or adherence among individuals already strongly resistant to taking medication.

Advances in artificial intelligence have further increased the diagnostic capabilities of digital health tools. Domingues et al. (2024) developed a neural network model using oximetry, accelerometry, and snoring-sensor data from a portable sleep monitor to classify sleep wake states, achieving high sensitivity and an area under the curve (AUC) of 0.90 compared with standard oximetry. Attia et al. (2025) validated an AI-based platform that combines photoplethysmography and oximetry to automatically estimate AHI and sleep stages; the system achieved strong correlations and intraclass correlation coefficients relative to polysomnography, supporting its use for multi-night home testing.

Smartphone only diagnostic tools are receiving increasing attention. Frija et al. (2025) evaluated Apneal®, a smartphone application that uses acoustic, accelerometer, and

gyroscope data to estimate AHI. Both manual and automated analyses correlated strongly with AHI from polysomnography, with intraclass correlation coefficients up to 0.89, demonstrating the feasibility of sensor-free detection based solely on smartphone hardware. Brown et al. (2025) showed that SleepWatch's AI-driven snore-detection system exceeded 95% accuracy in real-world noise environments, underscoring the reliability of acoustic monitoring for large-scale, low-cost OSA screening.

Hoang and Liang (2025) synthesized results from 31 AI-based oximetry investigations and emphasized the need for standardized preprocessing pipelines, diverse training datasets, and transparent algorithm development to ensure generalizable diagnostic performance. Collectively, these advances support a shift toward intelligent, user-friendly digital diagnostics that complement traditional sleep laboratory testing.

O'Connor-Reina et al. (2020) specifically examined the use of a smartphone application (Airway Gym) to deliver myofunctional therapy and reported substantially higher adherence rates than historically reported for traditional, paper-based programs. The app's interactive features helped maintain patient engagement. Average adherence was approximately 64%, compared with an estimated national adherence of about 10% for conventional myofunctional therapy, highlighting the potential of app based delivery to improve adherence in this domain.

Relevant Materials Pertinent to the Present Study

O'Connor-Reina et al. (2020) conducted a pilot randomized trial to evaluate the Airway Gym smartphone application in patients with severe OSA (baseline AHI > 30). The study compared app based myofunctional therapy with usual care, examining changes

in AHI, oxygen desaturation index, upper airway muscle strength (measured with the Iowa Oral Performance Instrument, IOPI), and subjective sleep outcomes assessed with the ESS and PSQI. Patients in the app-based therapy group demonstrated significant improvements in AHI and in oropharyngeal muscle tone measured by IOPI, whereas neck circumference did not change significantly. This finding suggests that improvements in AHI were more likely attributable to enhanced muscle function rather than changes in body composition, contrasting with hypotheses from earlier work, such as that of Guimaraes et al. Monthly IOPI assessments provided objective feedback on progress and likely contributed to the higher adherence observed.

One of the main limitations of traditional myofunctional therapy has been poor adherence and the lack of objective feedback. The Airway Gym study addressed these issues by providing immediate visual and auditory feedback after each exercise and maintaining regular communication between patients and clinicians. The authors noted that myofunctional therapy may be less effective in individuals with restricted tongue mobility, deviated nasal septum, or temporomandibular joint disorders.

Recent technological developments have also expanded digital architectures beyond therapy delivery to include sound- and motion-based screening tools. For example, Apneal® and SleepWatch provide smartphone-based respiratory and snoring assessments, and the Belun Ring offers a wearable oximetry platform supported by a neural network-based cloud algorithm. These systems illustrate a broader move toward integrated digital ecosystems that can both monitor OSA and track response to interventions such as myofunctional therapy.

Iowa Oral Performance Instrument

Franciotti et al. (2022) performed a meta-analysis to evaluate the Iowa Oral Performance Instrument (IOPI) as a quantitative measure of swallowing function. They examined its ability to distinguish healthy individuals from those with swallowing disorders across the lifespan and to detect changes following conventional treatment or tongue-strengthening exercises. The analysis showed that maximal tongue pressure measured by IOPI is consistently higher in healthy participants than in those with pathology, supporting its use as a diagnostic and monitoring tool. However, tongue endurance measures were less reliable, with substantial variability and limited discriminatory power.

Age-related differences also emerged. Children had higher maximal tongue pressure values than adults, but children with disorders demonstrated more pronounced weakness relative to their healthy peers than adults did. This suggests that disease-related deficits may be more evident in pediatric populations. Intervention studies showed that patients with lower baseline tongue pressures experienced the greatest improvements following targeted tongue-training programs.

Suzuki et al. (2020) further reported that myofunctional therapy in OSA patients increased tongue pressures measured by IOPI and was associated with reductions in AHI, reinforcing the idea that oropharyngeal muscle training can have measurable physiological and clinical effects in this population.

STOP-Bang Questionnaire

The STOP-Bang Questionnaire, introduced in 2008, is a brief, widely used screening

tool for self-reported OSA risk. It includes four symptom-based questions: Snoring, Tiredness, Observed apneas, and high blood Pressure (STOP) as well as four demographic or anthropometric items: BMI, Age, Neck circumference, and Gender (Bang). Scores range from 0 to 8, with 0 to 2 indicating low risk, 3 to 4 intermediate risk, and 5 to 8 high risk. The instrument is particularly effective at identifying moderate to severe OSA but is less sensitive for mild disease.

Nagappa et al. (2015) conducted a meta-analysis validating STOP-Bang across diverse patient populations. A threshold score of three or more showed high sensitivity for detecting moderate to severe OSA, identifying 94% of cases in sleep clinic cohorts and 91% of cases among surgical patients. Chung et al. (2008) highlighted that STOP-Bang is quick to administer (one to two minutes), has excellent response rates (90–100%), and offers a high negative predictive value, such that a low score reliably excludes moderate to severe OSA. Together, these findings support STOP-Bang as a practical and efficient tool for identifying individuals at high risk for OSA who require further diagnostic evaluation.

NOSE Scale Questionnaire

Stewart et al. (2004) developed and validated the Nasal Obstruction Symptom Evaluation (NOSE) scale as a concise quality-of-life instrument for quantifying nasal obstruction severity. The scale includes five items rated from 0 to 4; the sum is multiplied by five to yield a total score from 0 to 100, where 0 represents no obstruction and 100 indicates the most severe obstruction.

The NOSE scale was designed to be easy to use, quick to complete, and minimally

burdensome for patients. Stewart et al. reported strong reliability and validity: scores remained stable when nasal status did not change, correlated with clinical severity, and improved in response to successful treatment. As a result, the NOSE scale is widely used to assess nasal obstruction and monitor outcomes of medical and surgical interventions.

Epworth Sleepiness Scale

Sleepiness is defined as an individual's tendency to doze off or fall asleep in a given situation. The Epworth Sleepiness Scale (ESS) is a brief, self-administered questionnaire commonly used in sleep medicine to measure this construct. Kendzerska et al. (2014) and Lapin et al. (2018) have both examined its psychometric properties.

Kendzerska et al. (2014) reviewed the ESS literature and concluded that, although the tool is widely used, its overall measurement properties are only moderate, and high-quality evidence for accuracy is limited. They recommended that ESS be used primarily for group-level comparisons rather than individual diagnosis. While ESS scores correlate reasonably well with other measures of daytime sleepiness, they are less strongly associated with general health status and OSA presence or severity. Thus, ESS can help characterize symptoms related to OSA but should not be used alone to establish the diagnosis.

PROMIS Sleep Disturbance and Sleep-Related Impairment Forms

The PROMIS Sleep Disturbance and Sleep-Related Impairment instruments were developed to improve patient-reported assessment of sleep–wake function in adults. Buysse et al. (2010) defined sleep as a reversible, recurrent state marked by reduced

awareness and responsiveness to the environment, whereas wakefulness denotes active engagement with the surroundings.

The PROMIS Sleep Disturbance questionnaire measures perceived sleep quality, depth, and restorative value over the prior seven days, including difficulties initiating or maintaining sleep and overall satisfaction with sleep. The PROMIS Sleep-Related Impairment questionnaire assesses difficulties with alertness, fatigue, daytime sleepiness, and functional consequences of poor sleep during the same period. Higher scores on either instrument indicate greater disturbance or impairment.

Buysse et al. showed that individuals reporting sleep problems had significantly higher PROMIS scores than controls, and treated patients showed better scores than untreated ones, supporting the scales' reliability and validity. However, PROMIS measures are not specific for individual sleep disorders; they can distinguish patient and control groups and quantify overall severity, but they do not reliably differentiate conditions such as chronic insomnia versus OSA. Lin et al. (2024) extended the use of such self-report tools into digital monitoring, incorporating app-based PROMIS-type surveys with objective mobile data to track changes in sleep quality during behavioral interventions outside laboratory settings.

Belun Ring

Gu et al. (2020) validated the Belun Ring Platform, a novel home sleep apnea testing system that integrates a ring-shaped pulse oximeter with a proprietary cloud-based neural network algorithm. The device records oxygen saturation, photoplethysmography, and accelerometer signals. Total sleep time is estimated from

features extracted from accelerometry and oximetry, while a respiratory event index is derived from heart rate variability and oxygen desaturation patterns. In a simultaneous in-lab polysomnography study of 50 adults without significant cardiopulmonary or neuromuscular disease, the Belun respiratory event index correlated strongly with PSG-derived AHI ($r \approx 0.89$). Sensitivity and specificity for classifying AHI ≥ 15 events/hour were 0.85 and 0.87, respectively, with positive and negative predictive values of 0.88 and 0.83. Total sleep time estimates also correlated well with PSG ($r \approx 0.95$). Although the device tended to overestimate AHI in mild OSA and underestimate AHI in more severe cases, the authors concluded that the Belun Ring provides reasonably accurate estimates of AHI and total sleep time and may serve as a practical alternative to in-lab testing for many patients.

SnoreLab Smartphone Application

Smartphone applications are increasingly used as adjunctive tools for monitoring snoring and sleep-disordered breathing. Among these, SnoreLab has emerged as a validated platform capable of providing clinically relevant information for ongoing monitoring by both patients and clinicians. Shiao et al. (2024) confirmed that SnoreLab reliably detects snoring activity and provides metrics such as “Snore Score” and “Time Snoring,” which quantify snoring loudness and duration. These measures correlate positively with AHI, particularly in individuals with moderate to severe OSA, suggesting that snoring severity can be a useful proxy for underlying sleep-disordered breathing in this subgroup. Hoang and Liang (2025) noted that AI-driven oximetry and acoustic-

analysis systems such as SnoreLab show promise as patient-friendly alternatives to traditional laboratory-based monitoring when adequately validated.

Recent adaptations of myofunctional therapy exercises into smartphone applications aim to improve adherence and potentially yield superior outcomes compared with conventional paper-based programs. Because MFT has shown favorable effects on several clinical and physiological outcomes in patients with OSA, continued research is needed to identify the most effective strategies for delivering and prescribing these exercises. To date, no randomized studies have directly compared app-based myofunctional therapy with traditional analog delivery, highlighting an important gap that the present study seeks to address.

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STATEMENT OF THESIS:

Objective

The purposes of this study are:

1. To compare changes in airway strength and sleep-related metrics between patients performing myofunctional exercises using a smartphone application and those using a printed manual calendar over a three-month period.
2. To evaluate whether the mode of therapy delivery (app-based vs. analog) influences patient compliance and subjective sleep quality, as measured by validated instruments including the Epworth Sleepiness Scale and PROMIS Sleep Disturbance forms.

H0: There is no statistically significant difference in treatment effects or compliance between app-based and analog delivery methods for myofunctional therapy in patients diagnosed with OSA after three months of intervention.

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H1: There are statistically significant differences in treatment effects and compliance between app-based and analog delivery methods for myofunctional therapy in patients diagnosed with OSA after three months of intervention.

H1: There is statistically significant difference in compliance between app-based and analog delivery methods for myofunctional therapy in patients diagnosed with OSA after three months of intervention.

THE IMPACT OF TECHNOLOGY IN THE MYOFUNCTIONAL THERAPY TREATMENT OF OBSTRUCTIVE SLEEP APNEA SYNDROME

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Introduction

Obstructive sleep apnea (OSA) is characterized by recurrent episodes of upper airway collapse during sleep, resulting in partial or complete airflow obstruction and periodic oxygen desaturation [1]. The failure of the upper airway mostly arises from diminished neuromuscular tone in the oropharyngeal muscles that uphold airway patency [2]. When the body makes extra effort to inhale, the levels of oxygen and carbon dioxide vary. This can regularly rouse someone from drowsiness. These events may raise heart rate and blood pressure, hence augmenting the risk of cardiac arrhythmias in individuals. Consequently, persons with obstructive sleep apnea have disruptions in sleep, compromised sleep architecture, and heightened sympathetic nervous system activity.

The etiology of obstructive sleep apnea (OSA) is complex, involving anatomical and physiological variables such as craniofacial morphology, obesity, neuromuscular tone, and central respiratory control (loop gain) [3]. Epidemiological studies indicate that obstructive sleep apnea (OSA) impacts roughly 14% of males and 5% of females within the general adult population, with significantly elevated prevalence in high-risk cohorts [4,5]. Nonetheless, the disease continues to be underdiagnosed, partially owing to insufficient public awareness and erroneous reporting.

The standard treatments for obstructive sleep apnea (OSA) are continuous positive airway pressure (CPAP), lifestyle changes, weight loss, oral appliance therapy, pharmacological medications, and surgical options [6,10]. CPAP is the preferred choice as it successfully preserves airway patency; however, compliance is a considerable challenge for several individuals. Researchers are therefore investigating alternative

therapies to assist patients in adhering to their treatment regimens and enhancing their quality of life.

Myofunctional therapy (MFT) is recognized as a noninvasive intervention for sleep-disordered breathing [11]. MFT employs daily oropharyngeal exercises to fortify the intrinsic and extrinsic muscles of the tongue (genioglossus, hyoglossus, styloglossus, and palatoglossus), in addition to the pharyngeal and face muscles. Obstructive Sleep Apnea (OSA) generally begins with reduced muscle tone in the upper airway. Patients are typically instructed to perform exercises multiple times daily and to attend regular appointments with a myofunctional therapist for assessment and guidance on their approaches [12].

MFT has considerable promise; nevertheless, its sporadic use is due to individuals' lack of dedication and the lack of objective feedback systems. Historically, just 10% of the population in the country complied with the regulations [13]. Digital health solutions, such as smartphone applications, have been deployed to tackle these difficulties, improve participation, deliver prompt feedback, and assure increased uniformity.

Smartphone therapies have demonstrated efficacy across multiple healthcare domains. In weight control research, smartphone applications have shown significantly greater adherence than web-based or paper diary methods [14]. A thorough investigation confirmed their acceptability and effectiveness in promoting healthy behaviors, such as increased physical activity, reduced screen time, and improved nutritional practices [15]. Mobile applications offering medication reminders have enhanced adherence to prescribed regimens, especially for patients who have historically faced challenges with

compliance.

MFT applications have been updated for compatibility with mobile phones. These programs employ software to aid patients in complying with their treatment protocols and to objectively track their success. This study aims to evaluate whether app-based therapy can offer advantages comparable to or above those of conventional analog training, considering that MFT has successfully mitigated sleep-related symptoms and physiological metrics in OSA. This randomized controlled trial evaluates the efficacy and adherence rates of myofunctional exercises delivered via a smartphone application compared to a self-directed manual method in individuals with obstructive sleep apnea (OSA). The outcomes of this study may improve understanding of how digital technologies might boost accessibility, adherence, and treatment efficacy for patients seeking noninvasive alternatives to conventional OSA care.

Materials and Methods

Study Design

This research was a prospective, randomized, controlled clinical trial conducted in the Orthodontics department at Case Western Reserve University School of Dental Medicine. The study was unsponsored and received approval from the Institutional Review Board (IRB study20231615). All participants provided informed consent prior to involvement. The author accepts all accountability for the precision and thoroughness of all presented data.

The experiment was a multi-visit, non-blinded, two-tailed study designed to assess the

effects of myofunctional therapy (MFT) administered by a smartphone application vs an analog technique. Participants were monitored over a three-month duration with appointments arranged usually every 30 days. The principal outcomes were adherence to the exercises and alterations in quantifiable sleep and muscle performance metrics.

Participant Selection

Patients diagnosed with obstructive sleep apnea (OSA) within 12 months were recruited in person through the Case Western Reserve Orthodontic Clinic as well as sleep centers around the Cleveland, Ohio area. Diagnosis was confirmed by a physician-interpreted polysomnography. Eligible participants met all inclusion criteria summarized in Table 1. Exclusion criteria were defined as the opposite of the inclusion criteria. A total of 25 subjects were enrolled: 11 in the analog group and 14 in the smartphone group. The first 6 analog and 7 app participants were drawn from a pilot cohort conducted under the same protocol but expanded in this study with additional baseline Belun Ring measurements as well as an analysis of the SnoreLab data.

Randomization

Participants were randomly allocated to one of two groups by block randomization to maintain about equal sample sizes:

Smartphone Application Group: myofunctional therapy administered via the Airway Gym application.

Analog Group: myofunctional therapy administered by printed guidelines and monitored

manually on a calendar.

Participants were allocated in chronological order based on their registration date.

Intervention Protocol

Both groups performed the same set of nine standardized myofunctional exercises, designed to strengthen the intrinsic and extrinsic tongue muscles (genioglossus, hyoglossus, styloglossus, and palatoglossus) and oropharyngeal muscles (pharyngeal constrictors and stylopharyngeus).

Smartphone Application Group: Participants downloaded the Airway Gym app on their personal smartphones. Participants added me to their account as the trainer so I am able to access/assess their progress. Each exercise was demonstrated via animation and video prior to performance. After completion, participants received visual, auditory, and tactile feedback on execution accuracy. Progress was automatically saved to a secure cloud platform, allowing remote assess adherence and performance for the study.

Analog Group: Participants received printed exercise instructions identical to those in the Airway Gym protocol. They were instructed to complete the routine once per day and record completion on a 30-day adherence calendar. The compliance was reviewed and collected the diary at each monthly follow-up visit.

Sleep parameters were recorded using the Belun Ring, a validated home sleep apnea testing device that measures oxygen saturation, heart rate, and movement to estimate Apnea–Hypopnea Index (AHI), SpO mean, SpO minimum, T<90%, and sleep

efficiency. Participants were directed to refrain from utilizing any supplementary airway equipment (such as CPAP or oral appliances) during Belun Ring recordings to guarantee that the data accurately represented their natural airway physiology. The ring was worn on the index finger overnight, and data was uploaded to the secure Belun Cloud platform for automated evaluation and analysis for our research.

Subjects also recorded snoring data using the SnoreLab app the same nights the Belun ring was used, which generated Snore Score and snore duration measurements. These data were reviewed and exported at each follow-up visit.

Follow Up Visits

At each 30-day follow-up, the following were performed:

- Upload of Belun Ring and SnoreLab data.
- IOPI measurements (anterior, posterior, right, and left).
- ESS, PROMIS, and NOSE questionnaires.
- Review of adherence logs (digital or paper)

At the first and final visit (Month 3), the STOP-BANG questionnaire, height, weight, BMI, neck circumference, and waist circumference were reassessed.

A priori power analysis suggested that around nine individuals per group (analog and digital) would be enough to identify a substantial effect size (Cohen's d = 1.16) at a significance level (α) of 0.05 and a power of 0.80, employing a two-sample, two-

tailed t-test. The assessment of sample size was predicated on expected disparities in primary outcome measures between groups, including adherence to myofunctional therapy and alterations in the apnea-hypopnea index (AHI) during the three-month treatment duration.

Data was compiled and consolidated via Microsoft Excel. The recorded data included Snore Score, Snore Duration, AHI4, mean SpO2, minimum SpO2, Mean Pulse Rate, Sleep Efficiency, IOPI anterior, IOPI posterior, IOPI right, IOPI left, STOP BANG, NOSE, Epworth Sleepiness Scale, PROMIS Sleep Disturbance, and compliance.

The normality of the data distribution was evaluated using the Shapiro–Wilk and Kolmogorov–Smirnov tests. Normally distributed variables were examined using two-tailed paired t-tests for within-group comparisons and independent two-sample t-tests for between-group comparisons. Data that did not follow a normal distribution were evaluated utilizing the Mann–Whitney U test. A p-value below 0.05 was deemed statistically significant. Descriptive analysis of compliance data from the Airway Gym application and analog diaries was conducted, with comparisons made between groups to assess adherence patterns. All statistical results were analyzed within the framework of a feasibility trial, highlighting clinical significance and directional trends instead of rigorous hypothesis testing due to the constrained sample size.

Results

Patients

A total of 40 participants were recruited and randomized into two study arms: 16 patients were assigned to the analog exercise group and 24 patients to the app-based myofunctional therapy group. Voluntary withdrawal or loss to follow-up occurred in both groups over the course of the study. 11 patients in the analog group and 14 patients in the app group completed all study requirements and were included in the final analysis.

Muscle Strength (IOPI)

Within-group analysis demonstrated statistically significant enhancements in anterior tongue strength ($p = 0.0128$), posterior tongue strength ($p = 0.00075$), and left buccinator strength ($p = 0.0155$) from baseline to the final assessment. The strength of the right buccinator exhibited no statistically significant difference ($p = 0.106$). Comparisons across groups revealed no statistically significant differences in any of the IOPI measures, suggesting that both administration strategies (app-based and analog) were equally successful in enhancing oral muscular strength over time.

Sleep Metrics (Belun Ring Data)

Apnea–Hypopnea Index (AHI) – All Participants

Across all participants (n = 23), both groups demonstrated a reduction in AHI from baseline to final measurement. The analog group decreased from 11.47 ± 7.16 to 9.39 ± 8.32 events/hour ($\Delta = -2.08$), and the app group decreased from 10.06 ± 9.67 to 7.80 ±

6.77 events/hour (Δ = –2.26).

Although both groups showed improvement, the intra-group reductions were not statistically significant (analog p = 0.2078; app p = 0.1591).

The overall group comparison approached significance (p = 0.0510), but did not meet the threshold for statistical significance.

AHI in Participants With Baseline AHI > 5

A subset analysis (n = 15) was performed on participants with an initial AHI greater than 5. The analog group reduced from 15.03 ± 5.19 to 11.52 ± 9.21 events/hour (Δ = –3.52; p = 0.1121), which did not reach significance. The app group showed a larger reduction, decreasing from 14.25 ± 10.33 to 9.51 ± 7.76 events/hour (Δ = –4.74), achieving statistical significance (p = 0.0353). Across all participants with baseline AHI > 5, AHI decreased significantly (Δ = –4.17; p = 0.0056). This indicates that clinically meaningful improvements were primarily concentrated among individuals beginning with elevated disease severity.

Minimum Oxygen Saturation (SpO Minimum)

Minimum oxygen saturation remained stable across groups. The analog group decreased slightly from 80.76 ± 6.08 to 80.26 ± 4.67 (Δ = –0.50; p = 0.6707). The app group increased modestly from 80.20 ± 6.09 to 81.00 ± 6.46 (Δ = +0.80; p = 0.6961). No significant differences were detected either within or between groups (overall p = 0.8381).

Mean Oxygen Saturation (SpO Mean)

The analog group exhibited a statistically significant decline in mean oxygen saturation, decreasing from 93.88 ± 1.94 to 92.78 ± 1.78 (Δ = –1.10; p = 0.0067). The app group maintained stable oxygenation (93.62 ± 2.83 to 93.98 ± 2.25; Δ = +0.35; p = 0.6498). Between-group comparison at completion did not reach significance (overall p = 0.6674). While changes were small in magnitude, the analog group showed a measurable reduction in mean saturation.

Pulse Rate

Mean pulse rate remained consistent over time in both groups. The analog group changed from 64.31 ± 5.81 to 64.16 ± 5.03 (Δ = –0.15; p = 0.8964), and the app group from 67.70 ± 7.99 to 66.85 ± 6.31 (Δ = –0.85; p = 0.5274). No significant differences were observed between groups (overall p = 0.5392). Pulse rate variability appeared minimal, suggesting stable autonomic activation during sleep.

Sleep Efficiency

Sleep efficiency was initially higher in the app group (87.45 ± 8.69) compared with the analog group (78.21 ± 12.61). Both groups maintained their sleep efficiency levels throughout the study. The analog group showed a small increase from 78.21 ± 12.61 to 81.43 ± 11.64 (Δ = +3.22; p = 0.4137), while the app group showed a negligible change (87.45 ± 8.69 to 87.64 ± 8.67; Δ = +0.20; p = 0.9499). No significant within-group or between-group changes were identified (overall p = 0.5413).

Results of the Questionnaire

Epworth Sleepiness Scale (ESS)

Both groups demonstrated reductions in daytime sleepiness following the 3-month intervention. The analog group showed a significant decrease in ESS scores, improving from 10.09 ± 5.20 at baseline to 7.27 ± 5.18 at final assessment (Δ = –2.82; p = 0.0096). The app group also showed a reduction (9.43 ± 4.52 to 8.36 ± 3.82; Δ = –1.07), although this change did not reach statistical significance (p = 0.1969). Across all participants, ESS scores decreased significantly (Δ = –1.84; p = 0.0054), indicating an overall improvement in daytime sleepiness associated with daily myofunctional exercises.

PROMIS Sleep Disturbance

Sleep disturbance scores mirrored the pattern observed in ESS outcomes. The analog group demonstrated a significant reduction from 10.09 ± 5.20 at baseline to 7.27 ± 5.18 post-intervention (Δ = –2.82; p = 0.0096). The app group showed a modest improvement (9.43 ± 4.52 to 8.36 ± 3.82; Δ = –1.07), which did not reach statistical significance (p = 0.1969). When analyzed collectively, participants experienced a significant overall improvement in sleep disturbance (Δ = –1.84; p = 0.0054). These findings suggest that both delivery methods result in measurable improvements in perceived sleep quality, with stronger effects observed in the analog group.

SnoreLab

An analysis within the group showed that snoring-related factors got a lot better. Both snore score ($p = 0.0448$) and snore duration ($p = 0.0081$) showed substantial reductions from baseline to end measures. The differences between groups for these measures were not statistically significant, indicating similar decreases in snoring in both intervention groups.

Compliance

Compliance rates, assessed through analog exercise logs and app-tracked performance data, were significantly higher in the analog group compared with the smartphone application group (64.4% vs 42.9%, $p = 0.0121$); however, both cohorts demonstrated satisfactory adherence, indicating that digital delivery did not hinder engagement over the 3-month intervention. The higher adherence observed in the analog group may partially account for their greater improvement in minimum oxygen saturation, underscoring the role of consistent practice in achieving physiological gains. Despite this difference, both delivery methods successfully supported regular participation, reinforcing that myofunctional therapy can be feasibly administered through either traditional paper-based guidance or a smartphone app, with both formats contributing to improved muscle strength, reduced daytime sleepiness, enhanced subjective sleep quality, and decreased snoring metrics.

Discussion

This randomized controlled study evaluated the efficacy of myofunctional therapy (MFT) delivered via a smartphone application versus a conventional analog method, expanding on previous pilot work by incorporating both Belun Ring physiological data and SnoreLab acoustic analysis. Our baseline and post-treatment IOPI values (46 → 51 kPa) fell within the expected range reported in the literature for mild-to-moderate hypotonicity (35–60 kPa; Navarro 2025, Rodríguez-Alcalá 2022, Li 2025) and were comparable to those seen in other OSA cohorts before and after MFT intervention. Because untreated OSA patients typically exhibit tongue pressures lower than healthy adults (~30–60 kPa vs 65–70 kPa; Clark 2012; Adams 2013), the post-intervention values in our cohort (~51 kPa) approximate levels described in compensated or non-hypotonic phenotypes. The magnitude of improvement (~4–5 kPa) is consistent with gains reported in other clinical trials (Rodríguez-Alcalá 2022; Li 2025; Navarro 2025), supporting the reproducibility of oropharyngeal strengthening across studies. Although not all individual IOPI outcomes reached statistical significance, the direction of change was uniform, reaffirming existing evidence that MFT reliably increases tongue and orofacial muscle strength. These increases likely reflect enhanced activation of the genioglossus and related airway dilator muscles, contributing to improved airway tone. Even modest increases in peak pressure (≈5 kPa) have been associated with meaningful improvements in airway stability and AHI reduction in prior literature, which

aligns with patterns seen in our results.

The Belun Ring provided detailed physiologic insight into how MFT influences sleep-related respiratory parameters. Consistent with O'Connor-Reina et al. (2024), Li et al. (2025), Rodríguez-Alcalá et al. (2022), and Guimarães et al. (2009), our findings demonstrated a downward trend in AHI for both groups, confirming that MFT can reduce the frequency of airway obstruction events even when differences do not reach statistical significance. SpO mean and minimum values remained stable across groups, a pattern also noted by Li et al. (2025), who observed improvements in breathing events without marked desaturation changes. Pulse rate remained unchanged, indicating no increase in sympathetic drive or sleep fragmentation, and sleep efficiency showed stability similar to findings by Bui-Diem et al. (2023) and Goswami et al. (2019), where patients reported better perceived sleep quality despite unchanged objective efficiency. Together, these results suggest that MFT improves respiratory stability during sleep not necessarily by altering total sleep time but by reducing arousals and improving upper-airway control.

SnoreLab findings provided additional objective evidence of improvement. Our study demonstrated an average decrease in snore duration of 12 minutes, consistent with O'Connor-Reina et al. (2024), who reported 16 minutes, and Rodríguez-Alcalá et al. (2022), who reported 14 minutes. These results confirm that reductions in snoring time are reproducible across delivery formats. Because reduced snoring is mechanistically linked to improved tone of the tongue base and oropharyngeal musculature, these acoustic improvements support the observed gains in posterior IOPI strength. Both the

analog and app groups trended downward in snore duration, indicating that the exercise protocol itself—rather than the delivery mode—is the primary factor driving improvement. These findings align with Li et al. (2025) and O'Connor-Reina (2024), who reported that strengthened airway muscle endurance reduces tissue vibration and improves perceived sleep quality.

Subjective outcomes followed similar trends. PROMIS Sleep Disturbance scores demonstrated a mean reduction of approximately 1.8 points, paralleling improvements documented in larger MFT cohorts (Rodríguez-Alcalá 2022; Navarro 2025) and sleep-focused behavioral programs (Buysse 2010; Roth 2018). ESS scores exhibited significant within-group improvements, indicating reduced daytime sleepiness following daily MFT practice. The parallel improvement in objective parameters (AHI, IOPI, snoring acoustics) and subjective measures (ESS, PROMIS) reinforces the notion that neuromuscular improvements and perceived sleep benefits occur concurrently, a pattern also reported by Li et al. (2025) and O'Connor-Reina et al. (2024). NOSE and STOP-BANG scores did not change significantly, likely reflecting the short intervention duration or the limited sensitivity of these tools to detect subtle neuromuscular improvements.

Compliance played a key role in treatment response. Consistent with earlier pilot work, adherence was higher in the analog group compared with the app group. Although the Airway Gym app provides interactive features intended to increase engagement, some participants noted difficulty integrating app use into daily routines or navigating its interface. Despite these challenges, compliance in both groups far exceeded historical averages for unsupervised MFT (~10%; Guimarães 2009), demonstrating that

structured guidance—regardless of format—substantially enhances adherence. The comparable physiologic improvements between groups indicate that when exercises are completed consistently, app-based delivery performs equivalently to traditional analog instructions.

Taken together, these findings demonstrate that MFT—whether administered digitally or through traditional instruction—produces meaningful short-term improvements in upper-airway muscle strength, nocturnal oxygenation patterns, snoring behavior, and subjective sleep quality in adults with mild to moderate OSA. The integration of digital home-monitoring tools such as the Belun Ring and SnoreLab represents a significant methodological advancement, enabling precise, repeated physiologic tracking in natural sleep environments. Nonetheless, several limitations must be acknowledged, including modest sample size, recruitment from limited geographic areas, and differing methods of adherence tracking between groups. Because OSA is multifactorial, involving craniofacial structure, neuromuscular tone, body weight, and ventilatory regulation, MFT alone cannot address all contributing factors. Future research would benefit from larger multicenter cohorts, standardized pre-treatment digital data collection, extended follow-up to evaluate long-term muscular adaptation, and continued refinement of app interfaces to facilitate user engagement. Overall, this study contributes to the growing body of evidence supporting MFT as an accessible, cost-effective, and physiologically grounded adjunctive treatment for OSA, with both analog and digital delivery formats demonstrating clinically meaningful benefits.

Conclusion

Both analog and app-based myofunctional therapy produced measurable improvements in upper-airway muscle tone and sleep-related outcomes. Posterior tongue strength, assessed through the Iowa Oral Performance Instrument, showed significant within-group gains, supporting the effectiveness of structured orofacial exercise across delivery formats. When both groups were analyzed together, reductions in AHI, snore duration, Epworth Sleepiness Scale scores, and PROMIS Sleep Disturbance scores reached statistical significance, indicating broad improvements in both physiological and subjective sleep parameters.

The analog group demonstrated higher overall compliance, which may have contributed to the magnitude of improvement observed in this cohort. The Belun Ring provided reliable, noninvasive physiologic data that supported the observed treatment effects and demonstrated the utility of home-based digital monitoring in assessing airway therapy outcomes. These findings align with prior literature showing that strengthening orofacial musculature can meaningfully enhance airway stability and reduce sleep-disordered breathing events.

Overall, the results of this study support myofunctional therapy as a feasible, accessible, and clinically valuable adjunctive treatment for individuals with mild to

moderate obstructive sleep apnea. Both traditional and smartphone-based delivery methods offer practical pathways for implementing daily exercises, making MFT a flexible option for diverse patient populations.

Appendix

Table 1: Inclusion Criteria

1.	Age range: from 18 to 75
2.	Recent PSG available
3.	BMI < 40
4.	No history of alcohol or drug abuse
5.	No history of A-fib, pacemaker, CHF, and or strokes
6.	No history of neuromuscular disease
7.	No chronic use of hypnotics
8.	No restrictions in tongue movement that would prevent the subject to touch the roof of their mouth at any amount of mouth opening
9.	No blockage in nasal passage
10.	No diagnosed temporomandibular joint disorder
11.	Must be able to present for follow up at all directed time points as per the protocol
12.	No excessive changes (>= 5%) in body weight during the duration of the study

Ta

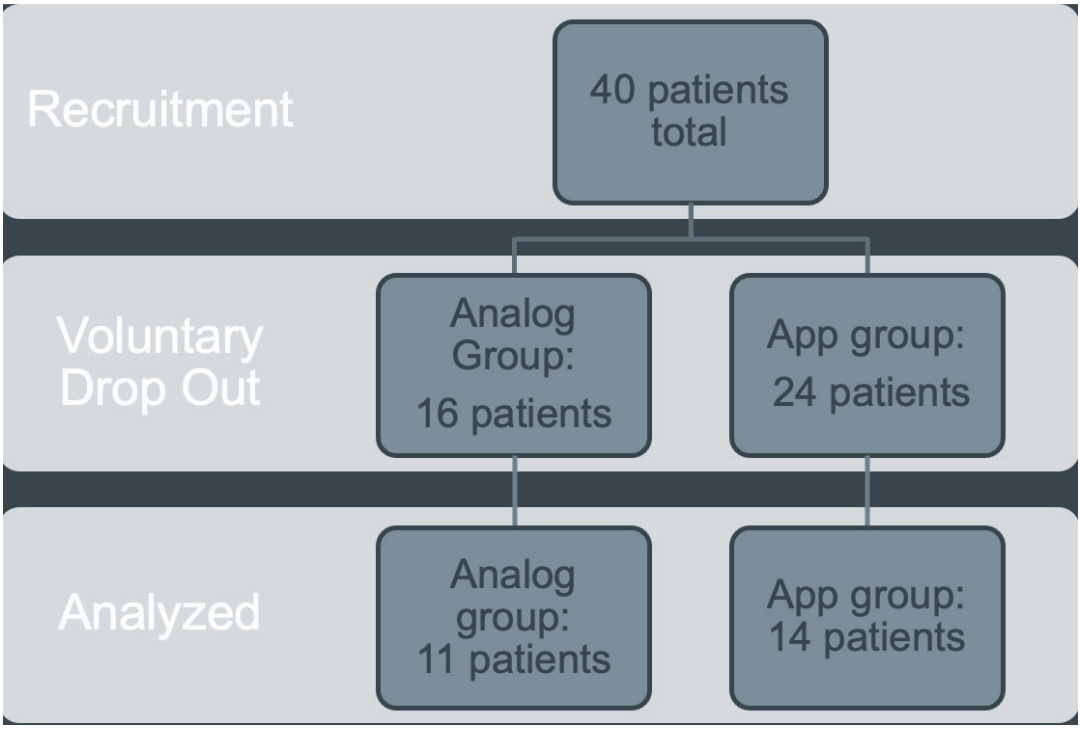
Table 2: Variables collected with corresponding methodology listed

Variable	Collected via:
Age	Self-reported
Sex	Self-reported
Height	Measured On-Site
Weight	Measured On-Site
Neck Size	Measured On-Site
Waist	Measured On-Site
BMI	Calculated with Height and Weight
Tongue Protrusion Strength	IOPI device
Posterior Tongue Elevation Strength	IOPI device
Lip Strength	IOPI device
OSA Risk Assessment	STOP-Bang Questionnaire
Nasal Breathing Efficiency	NOSE Questionnaire
Sleep Quality	PROMIS Sleep Disturbance Short Form 8b
Daytime Sleepiness	Epworth Sleepiness Scale Questionnaire
AHI	Belun Ring Platform
Oxygen Desaturation	Belun Ring Platform

Table 3: Demographics

Variable	Analog (n=11)		Airway Gym (n=14)		P value
	Mean	STDEV	Mean	STDEV	
Age (yr), median (IQR)	62.50	9.62	54.80	14.06	0.13
Male	7		6		0.30
Female	4		8		
Mild Sleep Apnea	7		10		0.51
Moderate Sleep Apnea	3		2		
Severe Sleep Apnea	0		1		
Neck Circumference (in.), median(IQR)	16.01	1.76	15.48	1.45	0.42
Waist Circumference (in.), median (IQR)	43.41	3.71	41.84	6.45	0.48
BMI, median	32.82	7.12	31.55	8.48	0.70

Table 4: Research Flow Chart



Picture 1: Epworth Sleepiness Scale

Epworth Sleepiness Scale[11]

How likely are you to nod off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times.

Even if you haven't done some of these things recently, try to work out how they would have affected you. It is important that you answer each question as best you can.

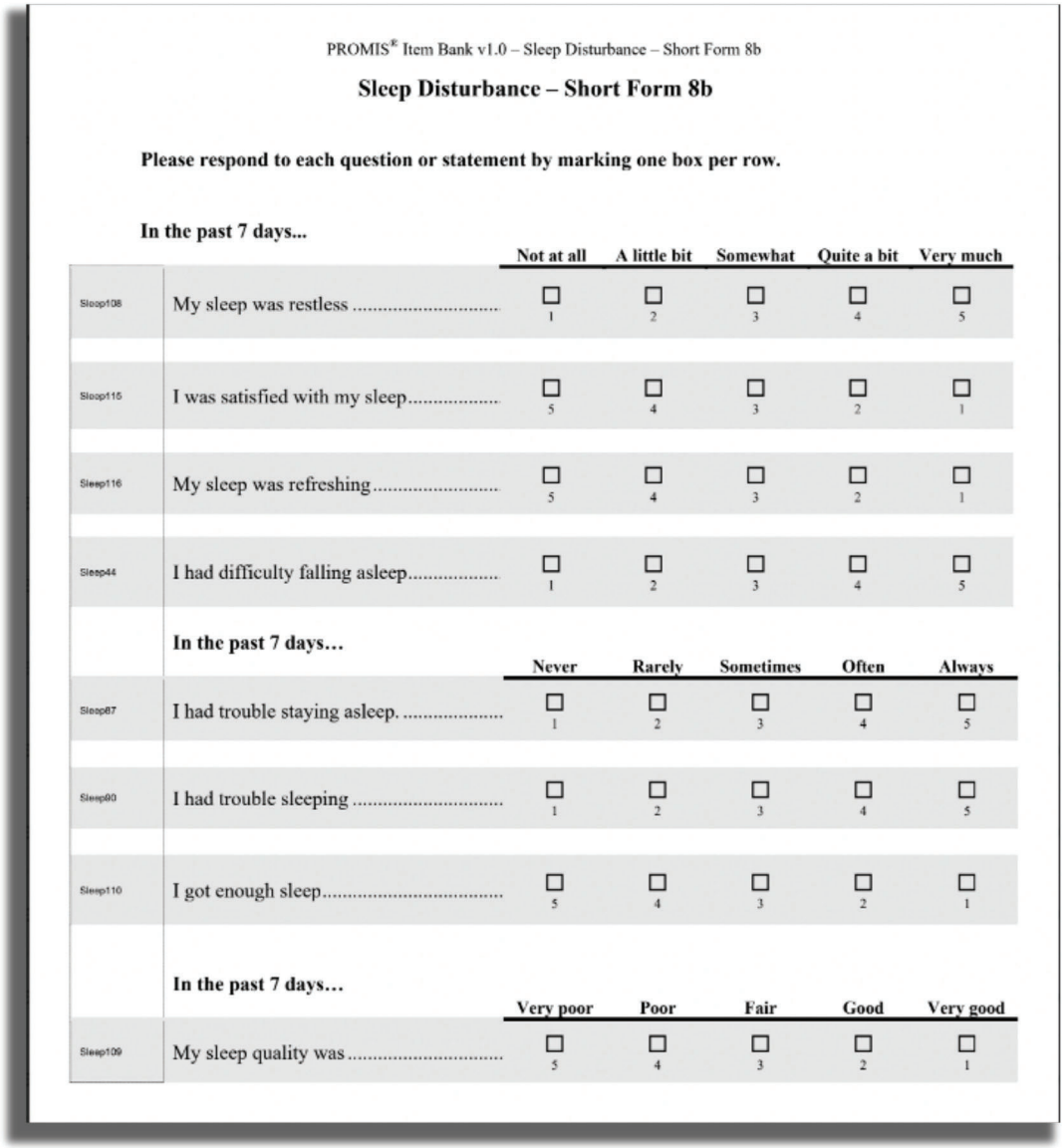
Use the following scale to choose the most appropriate number for each situation.

	Would never nod off 0	Slight chance of nodding off 1	Moderate chance of nodding off 2	High chance of nodding off 3
Sitting and reading				
Watching TV				
Sitting, inactive, in a public place (e.g., in a meeting, theater, or dinner event)				
As a passenger in a car for an hour or more without stopping for a break				
Lying down to rest when circumstances permit				
Sitting and talking to someone				
Sitting quietly after a meal without alcohol				
In a car, while stopped for a few minutes in traffic or at a light				

Add up your points to get your total score. A score of 10 or greater raises concern: you may need to get more sleep, improve your sleep practices, or seek medical attention to determine why you are sleepy.

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Picture 2: Sleep Disturbance Questionnaire



PROMIS® Item Bank v1.0 – Sleep Disturbance – Short Form 8b

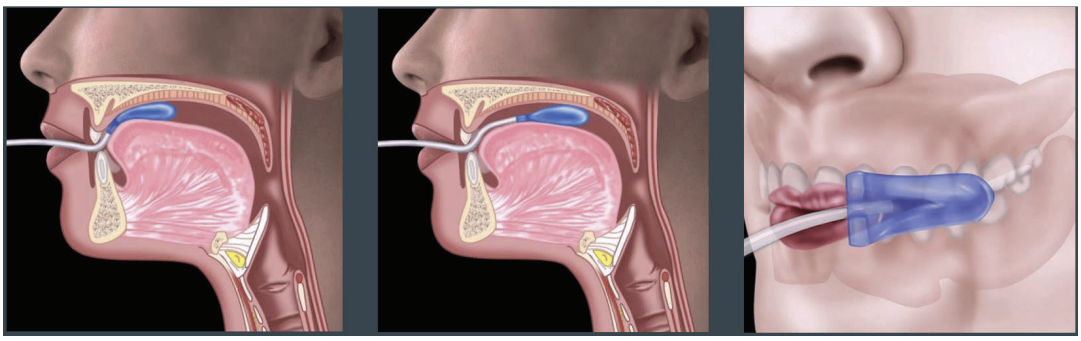
Sleep Disturbance – Short Form 8b

Please respond to each question or statement by marking one box per row.

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep108	My sleep was restless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep115	I was satisfied with my sleep	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep116	My sleep was refreshing	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep44	I had difficulty falling asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	In the past 7 days…	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
Sleep87	I had trouble staying asleep.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep90	I had trouble sleeping	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep110	I got enough sleep	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	In the past 7 days…	**Very poor**	**Poor**	**Fair**	**Good**	**Very good**
Sleep109	My sleep quality was	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Picture 3: IOPI Measurements



Graph 1: Tongue Protrusion

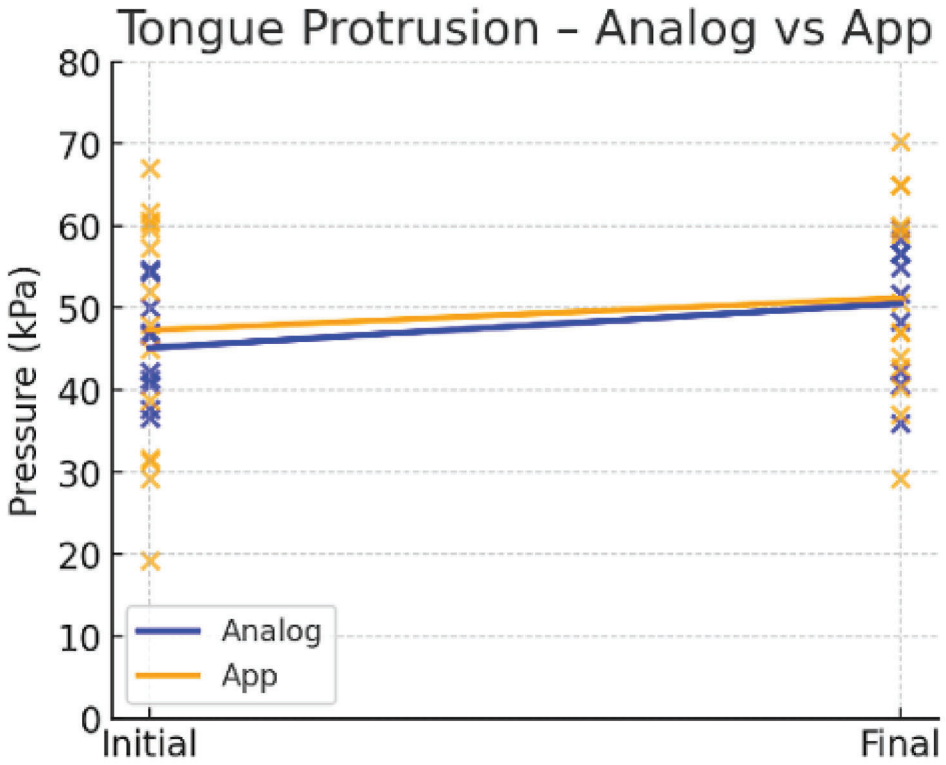


Table 1: Tongue Protrusion

Group	N	Mean T1	SD T1	Range T1	Mean T2	SD T2	Range T2	Mean Δ	SD Δ	Range Δ	P value	Significance
Analog (n=10)	10	45.14	6.45	36.7 – 54.7	50.54	8.32	36.0 – 59.7	5.40	7.56	-4.7 – 20.6	0.0504	NS
App (n=14)	14	47.29	14.95	19.3 – 67.0	51.21	12.14	29.3 – 70.3	3.93	8.93	-7.0 – 21.0	0.1236	NS
All (n=24)	24	46.39	11.99	19.3 – 67.0	50.93	10.51	29.3 – 70.3	4.54	8.25	-7.0 – 21.0	0.0128	Significant

Graph 2: Tongue Elevation

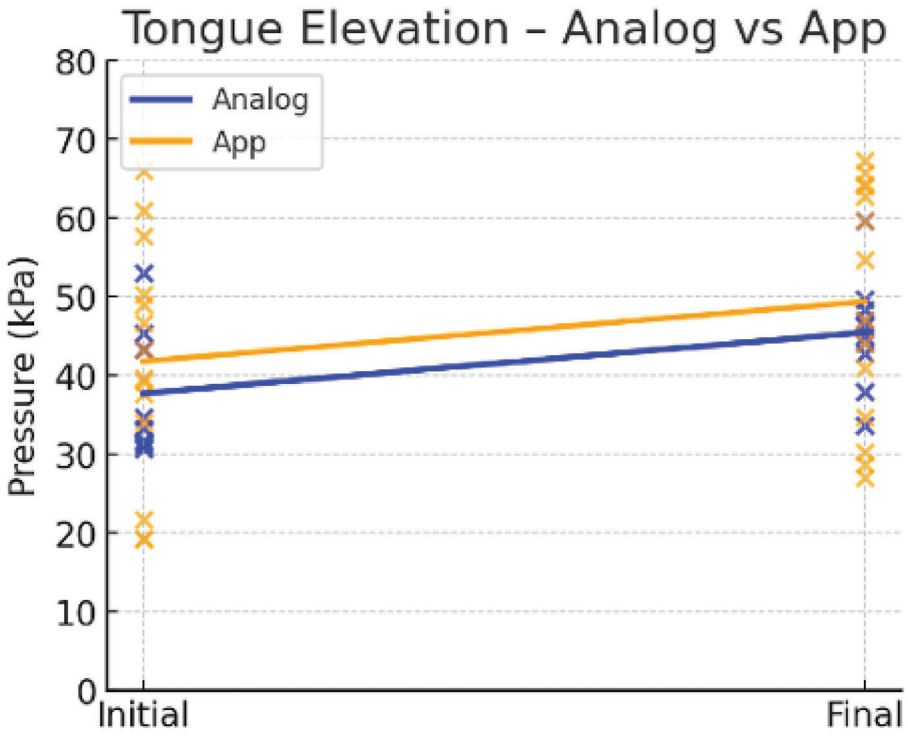


Table 2: Tongue Elevation

Group	N	Mean T1	SD T1	Range T1	Mean T2	SD T2	Range T2	Mean Δ	SD Δ	Range Δ	P value	Significance
Analog (n=10)	10	37.76	7.84	30.7 – 53.0	45.44	6.96	33.7 – 59.7	7.68	9.94	-4.7 – 28.0	0.0372	Significant
App (n=14)	14	41.79	14.84	19.3 – 66.0	49.36	15.06	27.0 – 67.3	7.58	9.75	-8.0 – 27.6	0.0122	Significant
All (n=24)	24	40.11	12.35	19.3 – 66.0	47.73	12.29	27.0 – 67.3	7.62	9.62	-8.0 – 28.0	0.0008	Significant

Graph 3: Right Buccinator

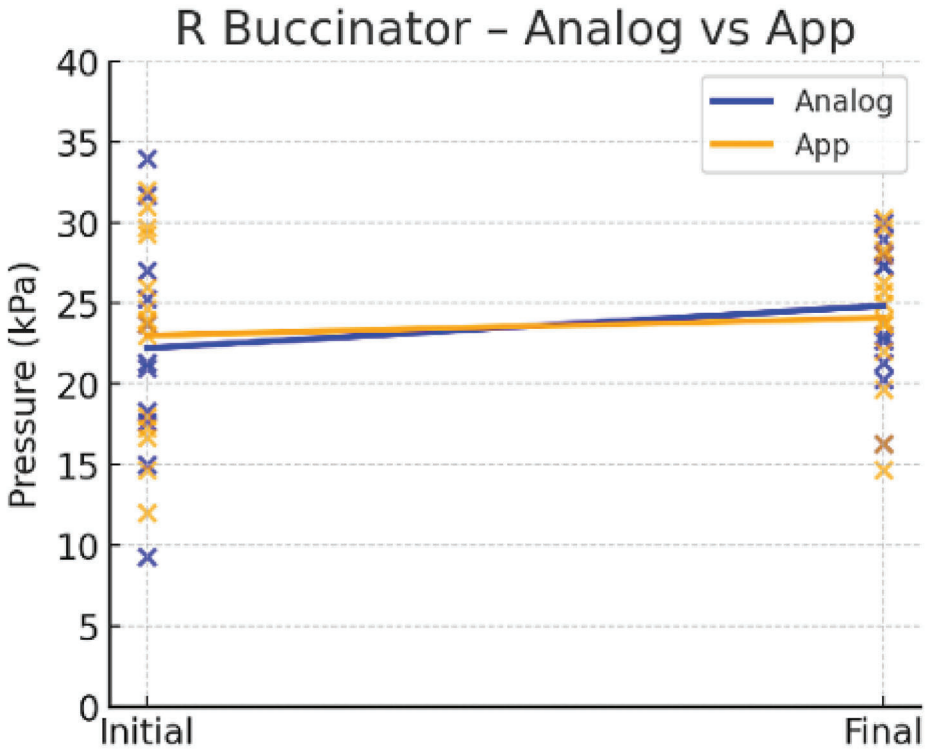


Table 3: Right Buccinator

Group	Mean T1	SD T1	Range T1	Mean T2	SD T2	Range T2	Mean Δ	SD Δ	Range Δ	P value	Significance
Analog (n=11)	22.21	7.21	9.3 – 34.0	24.84	4.36	16.3 – 30.0	2.63	4.55	-4.4 – 8.0	0.0839	NS
App (n=14)	23.01	6.39	12.0 – 32.0	24.10	4.68	14.7 – 30.3	1.09	5.84	-10.0 – 11.0	0.4958	NS
All (n=25)	22.66	6.63	9.3 – 34.0	24.43	4.46	14.7 – 30.3	1.77	5.26	-10.0 – 11.0	0.1055	NS

Graph 4: Left Buccinator

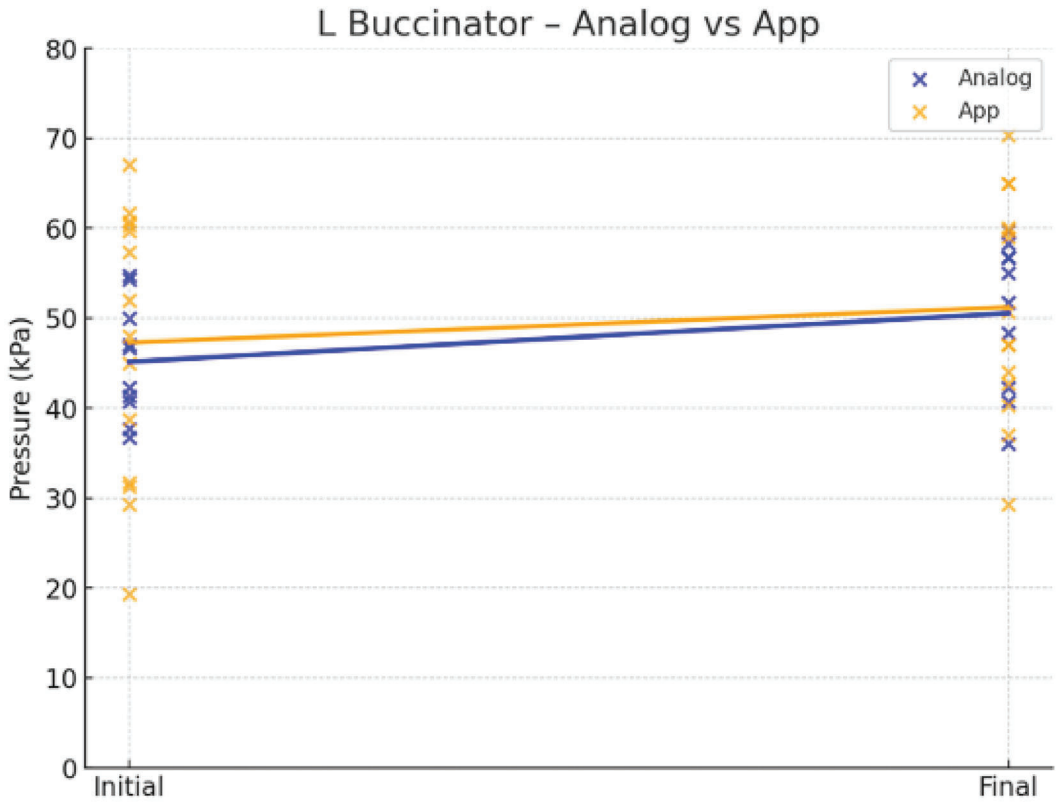


Table 4: Left Buccinator

Group	Mean T1	SD T1	Range T1	Mean T2	SD T2	Range T2	Mean Δ	SD Δ	Range Δ	P value	Significance
Analog (n=11)	22.91	5.15	14.7 – 31.3	25.30	5.48	15.7 – 32.0	2.39	4.95	-5.6 – 10.6	0.1395	NS
App (n=14)	22.19	6.56	12.3 – 36.7	24.84	5.94	15.0 – 33.7	2.65	4.99	-5.0 – 9.7	0.0685	NS
All (n=25)	22.51	5.95	12.3 – 36.7	25.05	5.76	15.0 – 33.7	2.54	4.87	-5.6 – 10.6	0.0155	Significant

Table 5: Inter-rater Reliability

Measure Type	Raters (n)	ICC (A,1)	ICC (A,k)	Interpretation
Combined T1 & T2 Averages (All Categories)	3	0.997	0.999	Excellent

Graph 5: Epworth

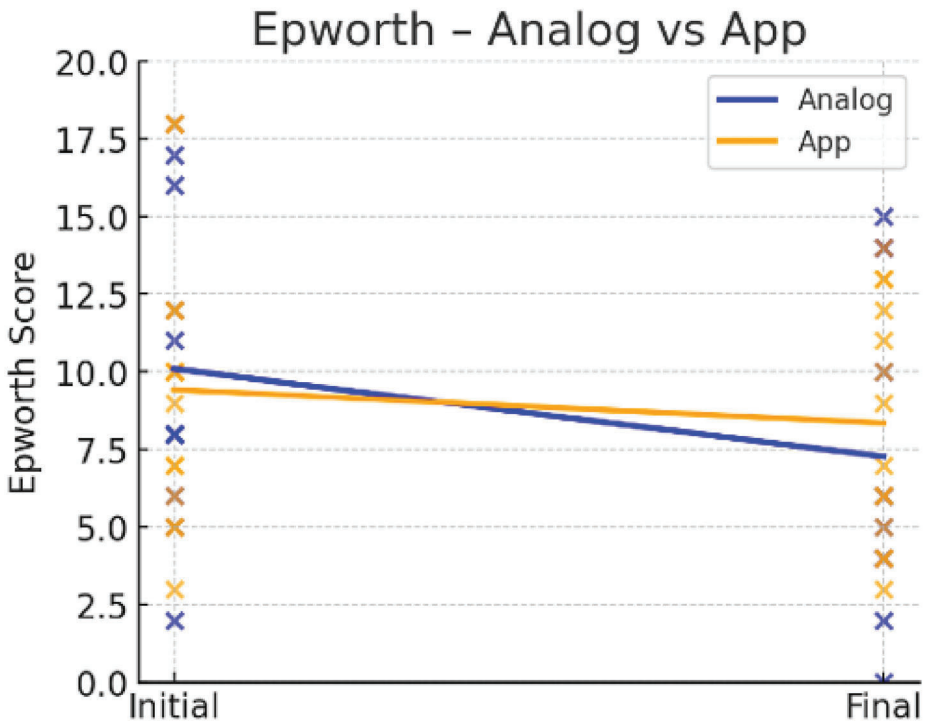


Table 6: Epworth

Group	Mean T1	SD T1	Range T1	Mean T2	SD T2	Range T2	Mean Δ	SD Δ	Range Δ	P value	Significance
Analog (n=11)	10.09	5.20	2.0 – 18.0	7.27	5.18	0.0 – 15.0	-2.82	2.93	-7.0 – 3.0	0.0096	Significant
App (n=14)	9.43	4.52	3.0 – 18.0	8.36	3.82	3.0 – 14.0	-1.07	2.95	-6.0 – 3.0	0.1969	NS
All (n=25)	9.72	4.74	2.0 – 18.0	7.88	4.40	0.0 – 15.0	-1.84	3.01	-7.0 – 3.0	0.0054	Significant

Graph 7: Sleep Disturbance

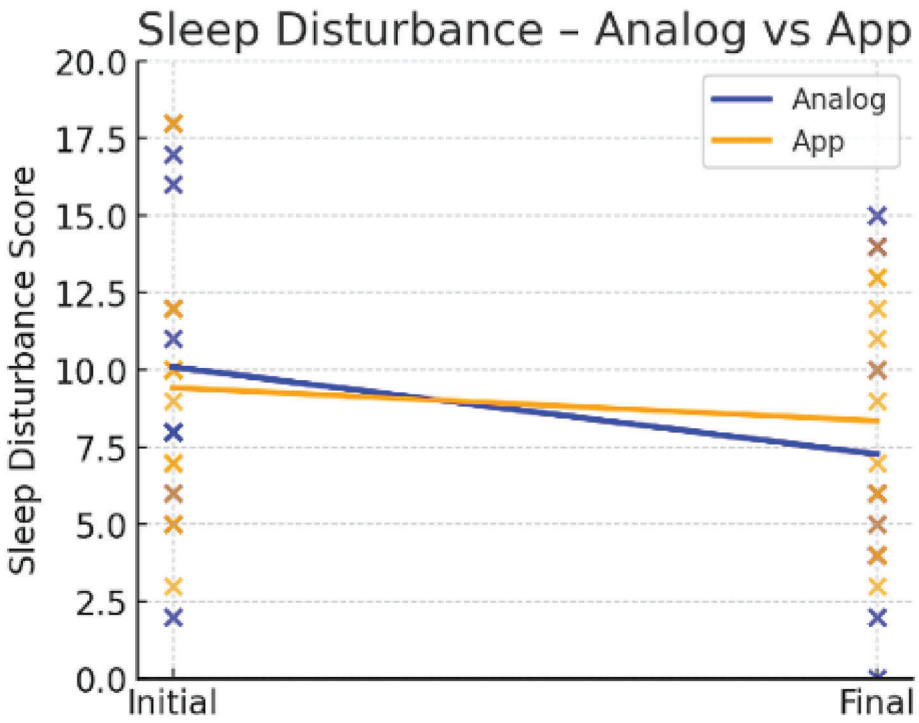


Table 7: Sleep Disturbance

Group	Mean T1	SD T1	Range T1	Mean T2	SD T2	Range T2	Mean Δ	SD Δ	Range Δ	P value	Significance
Analog (n=11)	10.09	5.20	2.0 – 18.0	7.27	5.18	0.0 – 15.0	-2.82	2.93	-7.0 – 3.0	0.0096	Significant
App (n=14)	9.43	4.52	3.0 – 18.0	8.36	3.82	3.0 – 14.0	-1.07	2.95	-6.0 – 3.0	0.1969	NS
All (n=25)	9.72	4.74	2.0 – 18.0	7.88	4.40	0.0 – 15.0	-1.84	3.01	-7.0 – 3.0	0.0054	Significant

Graph 8: AHI greater than 5 Initial

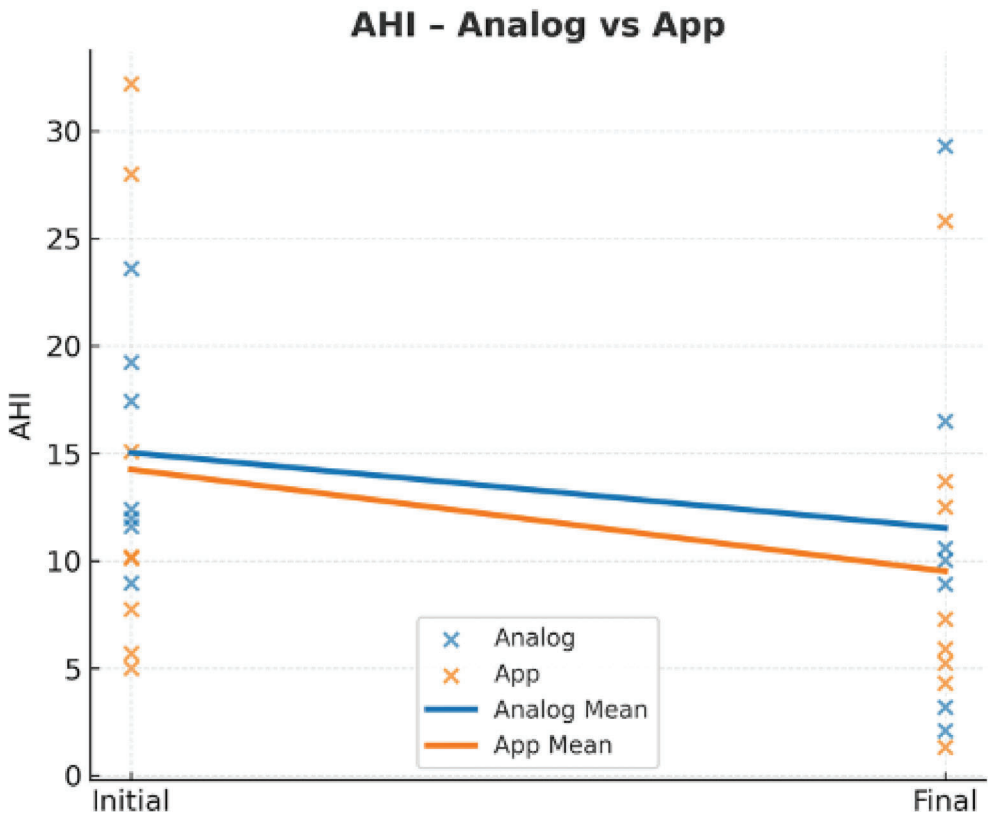


Table 8: AHI Greater than 5 Initial

Group	Mean T1	SD T1	Range T1	Mean T2	SD T2	Range T2	Mean Δ	SD Δ	Range Δ	P value	Significance
Analog (n = 7)	15.03	5.19	9.0 – 23.6	11.52	9.21	2.1 – 29.3	-3.52	5.00	-9.9 – 5.7	0.1121	NS
App (n = 8)	14.25	10.33	5.0 – 32.2	9.51	7.76	1.3 – 25.8	-4.74	5.15	-14.3 – 2.4	0.0353	Significant
All (n = 15)	14.62	8.07	5.0 – 32.2	10.45	8.22	1.3 – 29.3	-4.17	4.94	-14.3 – 5.7	0.0056	Significant

Graph 9: SpO2 Minimum

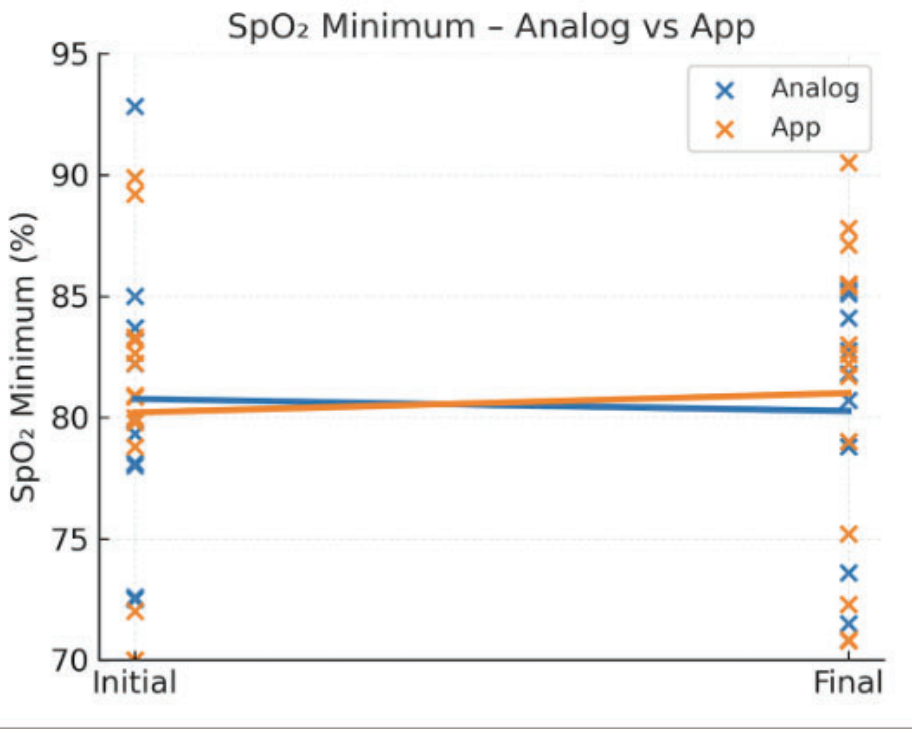


Table 9: SpO2 Minimum

Group	Mean T1	SD T1	Range T1	Mean T2	SD T2	Range T2	Mean Δ	SD Δ	Range Δ	P value	Significance
Analog (n=10)	80.76	6.08	72.5–92.8	80.26	4.67	71.5–85.3	-0.50	3.60	-8.7–4.6	0.6707	NS
App (n=14)	80.20	6.09	70.0–89.9	81.00	6.46	70.8–90.5	+0.80	7.47	-8.6–20.5	0.6961	NS
All (n=24)	80.43	5.96	70.0–92.8	80.69	5.68	70.8–90.5	+0.26	6.08	-8.7–20.5	0.8381	NS

Graph 10: SpO2 Mean

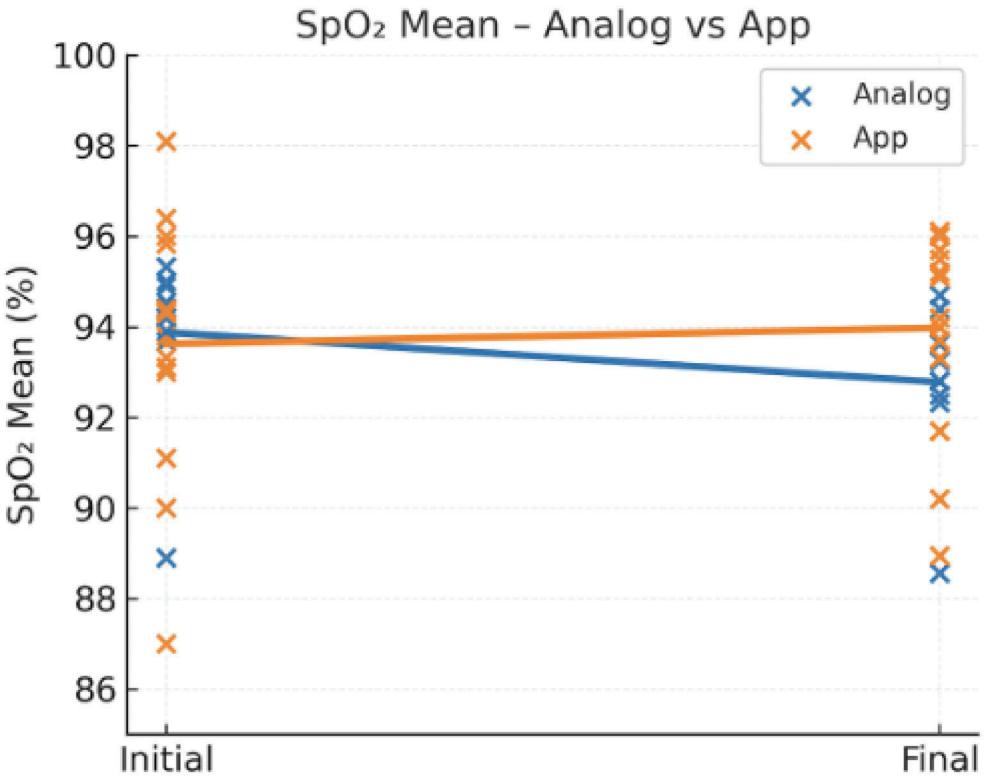


Table 10: SpO2 Mean

Group	Mean T1	SD T1	Range T1	Mean T2	SD T2	Range T2	Mean Δ	SD Δ	Range Δ	P value	Significance
Analog (n=9)	93.88	1.94	88.9–95.33	92.78	1.78	88.57–94.7	-1.1	0.91	-2.53–0.2	0.0067	Significant
App (n=14)	93.62	2.83	87.0–98.1	93.98	2.25	88.95–96.1	0.35	2.85	-4.05–6.1	0.6498	NS
All (n=23)	93.72	2.47	87.0–98.1	93.51	2.12	88.57–96.1	-0.22	2.37	-4.05–6.1	0.6674	NS

Graph 11: Pulse Rate

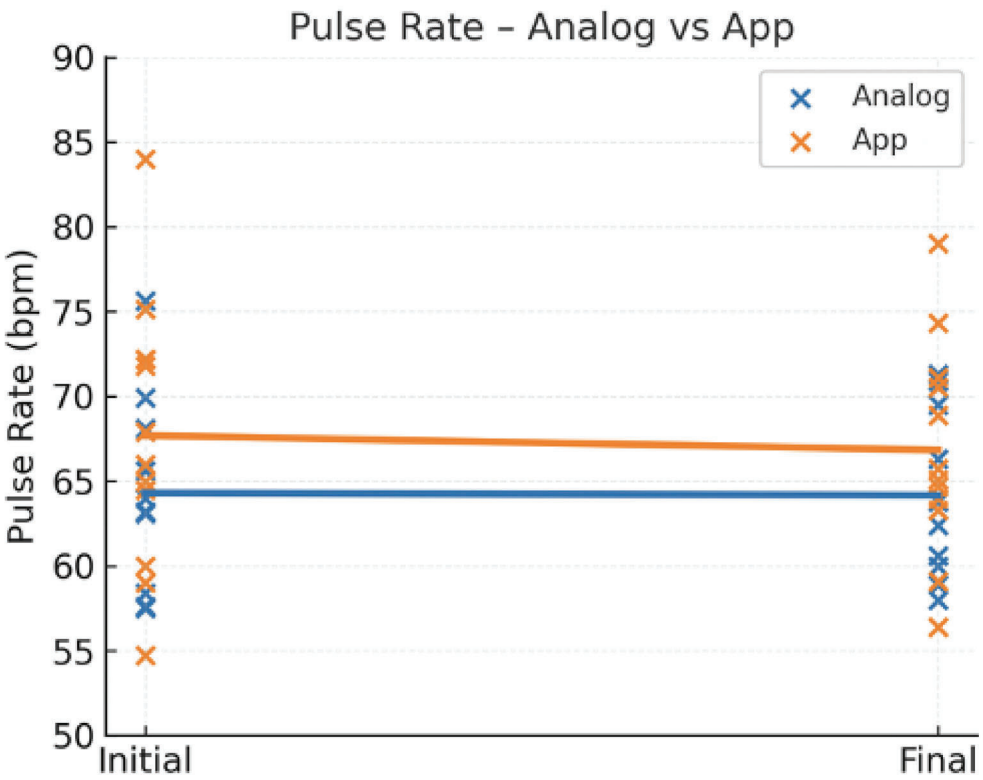


Table 11: Pulse Rate

Group	Mean T1	SD T1	Range T1	Mean T2	SD T2	Range T2	Mean Δ	SD Δ	Range Δ	P value	Significance
Analog (n=10)	64.31	5.81	57.51–75.63	64.16	5.03	58.0–71.3	-0.15	3.45	-6.13–4.75	0.8964	NS
App (n=12)	67.7	7.99	54.72–84.0	66.85	6.31	56.4–79.0	-0.85	4.53	-8.9–6.13	0.5274	NS
All (n=22)	66.16	7.13	54.72–84.0	65.63	5.79	56.4–79.0	-0.53	4.0	-8.9–6.13	0.5392	NS

Graph 12: Sleep Efficiency

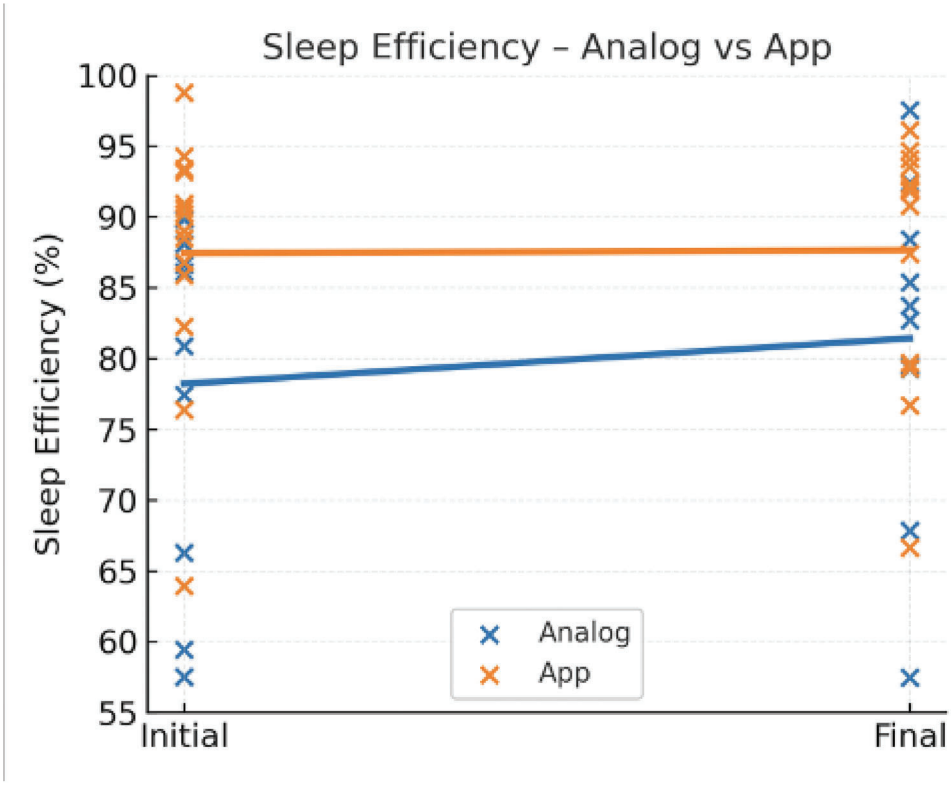


Table 12: Sleep Efficiency

Group	Mean T1	SD T1	Range T1	Mean T2	SD T2	Range T2	Mean Δ	SD Δ	Range Δ	P value	Significance
Analog (n=10)	78.21	12.61	57.51–89.87	81.43	11.64	57.47–97.55	3.22	11.89	-8.83–30.91	0.4137	NS
App (n=14)	87.45	8.69	63.93–98.8	87.64	8.67	66.66–96.1	0.2	11.51	-13.55–32.17	0.9499	NS
All (n=24)	83.6	11.25	57.51–98.8	85.06	10.26	57.47–97.55	1.46	11.51	-13.55–32.17	0.5413	NS

Graph 13: Snore Score

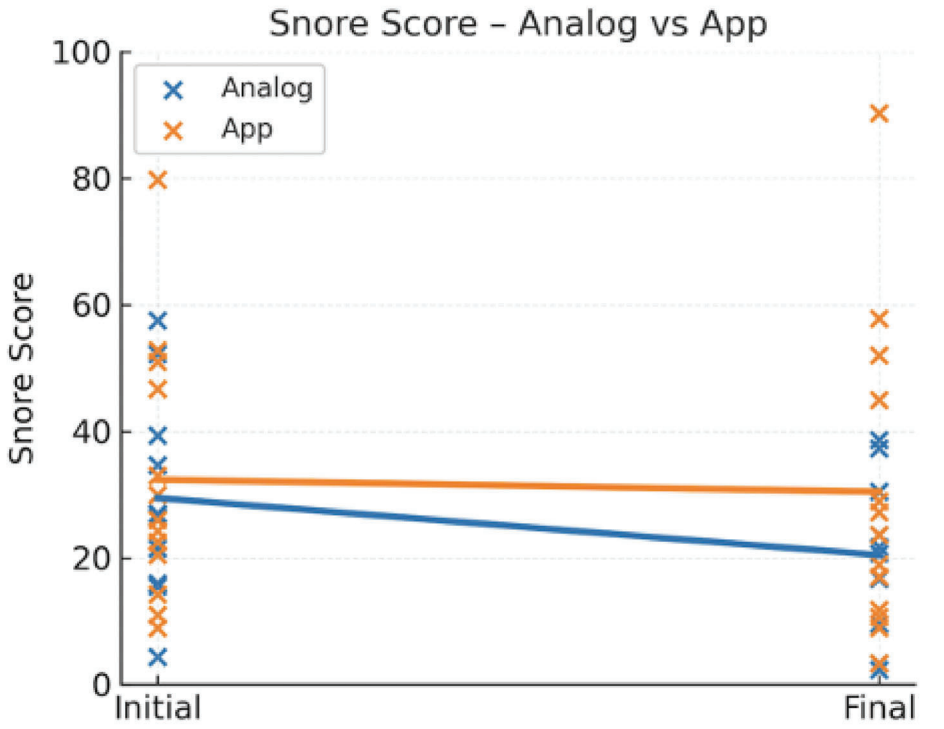


Table 13: Snore Score

Group	Mean T1	SD T1	Range T1	Mean T2	SD T2	Range T2	Mean Δ	SD Δ	Range Δ	P value	Significance
Analog (n=10)	29.45	16.71	4.33–57.51	20.45	12.85	2.29–38.68	-9.0	10.78	-35.76–3.5	0.0269	Significant
App (n=13)	32.37	20.19	9.0–79.76	30.45	24.68	3.39–90.3	-1.93	11.06	-27.71–15.0	0.5415	NS
All (n=23)	31.1	18.41	4.33–79.76	26.1	20.63	2.29–90.3	-5.0	11.27	-35.76–15.0	0.0448	Significant

Graph 14: Snore Duration

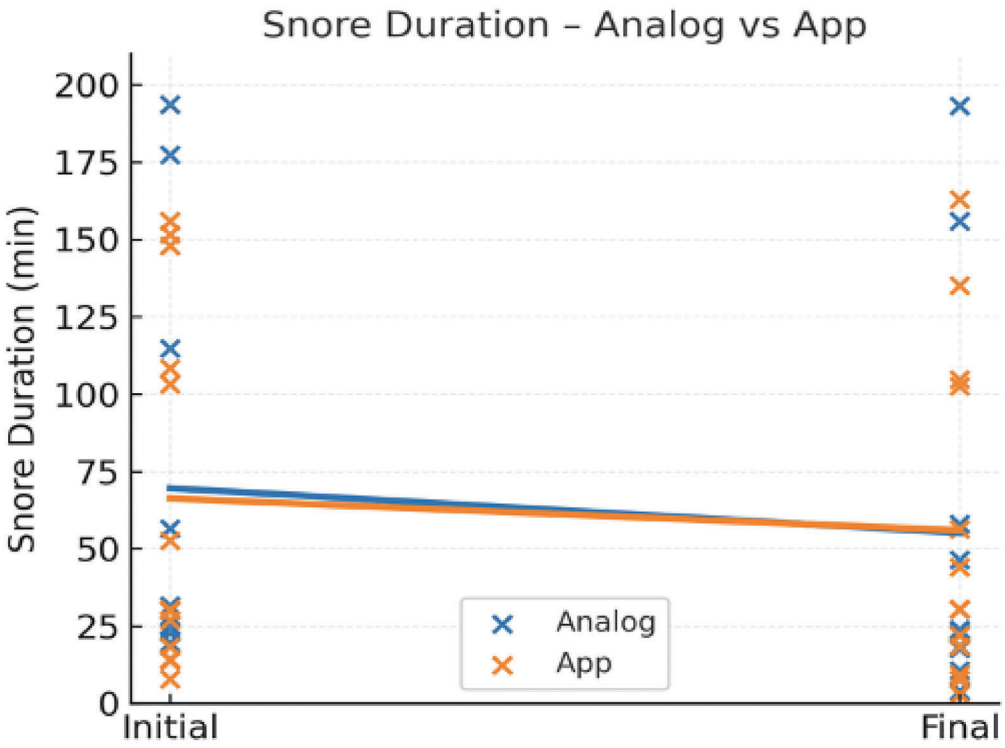


Table 14: Snore Duration

Group	Mean T1	SD T1	Range T1	Mean T2	SD T2	Range T2	Mean Δ	SD Δ	Range Δ	P value	Significance
Analog (n=10)	69.6	67.44	19.67–193.67	55.17	65.52	4.0–193.25	-14.43	20.58	-56.78–15.92	0.0538	NS
App (n=13)	66.28	58.14	8.0–155.86	55.96	52.89	3.0–163.0	-10.33	20.41	-53.36–11.41	0.093	NS
All (n=23)	67.72	60.89	8.0–193.67	55.61	57.29	3.0–193.25	-12.11	20.12	-56.78–15.92	0.0085	Significant

Graph 15: Compliance

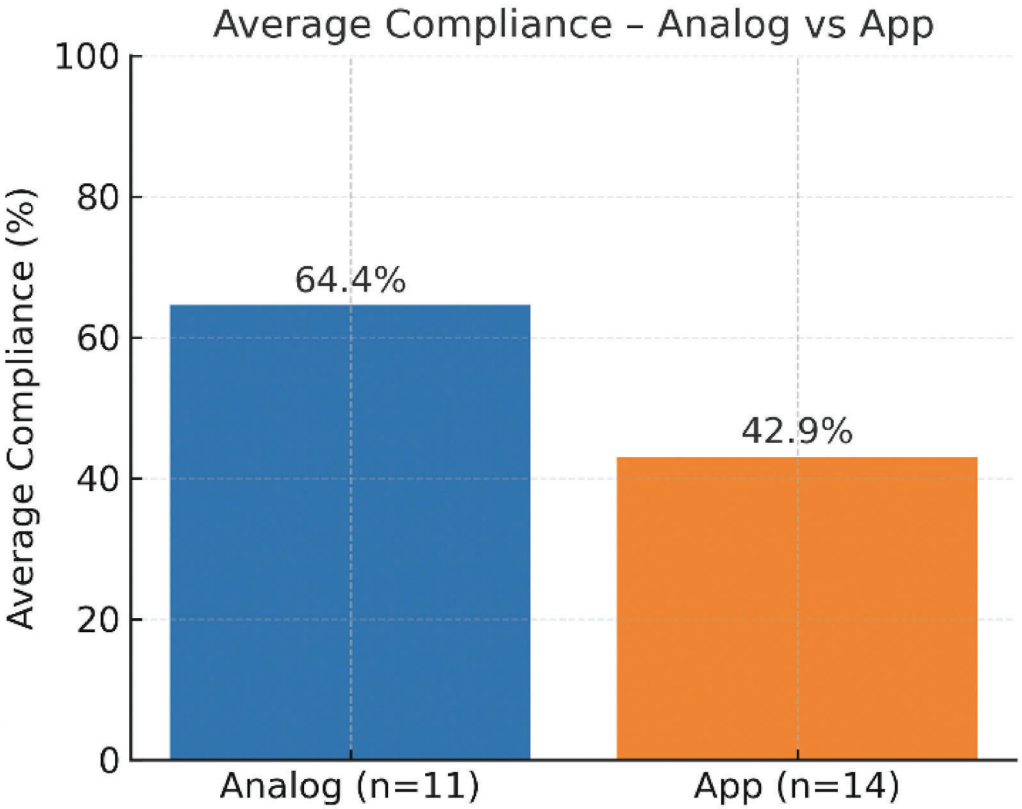


Table 15: Compliance

Group	Mean (%)	SD (%)	Range (%)	P value (Analog vs App)	Significance
Analog	64.4	17.1	39–88		
App	42.9	22.4	9–79		
All	52.3	22.6	9–88	0.0121	S

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INITIAL APPROVAL

Principal Investigator:	Juan Palomo
Title:	The impact of technology in the myofunctional therapy treatment of Obstructive Sleep Apnea Syndrome
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Approval Date:	5/10/2024
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Type of Submission:	Initial Study
Type of Review:	Expedited
Documents Reviewed:	• CWRU Biomedical irb-consent - 7.1.24.pdf, Category: Consent Form; • Airway Gym App Screenshots.pdf, Category: Other; • Study Advertisement.pdf, Category: Other; • Study Advertisement - 5.16.24.pdf, Category: Recruitment Materials; • PSQI Questionnaire, Category: Other; • Myofunctional Exercise Routine.pdf, Category: Other; • StopBang Questionnaire, Category: Other; • IOPI Description.pdf, Category: Other; • Belun_ Ring - Belun Technology.pdf, Category: Other; • AAO Demographic Questionnaire.pdf, Category: Other; • Thesis Protocol - 6.29.24.pdf, Category: IRB Protocol; • sample-written-recruitment-script.pdf, Category: Recruitment Materials; • IOPI Diagram.pdf, Category: Other; • Myofunctional Therapeutic Exercises Compliance Form.pdf, Category: Other;

The IRB has reviewed this submission.

- Per Federal regulation, changes MAY NOT be made to any element of the current research without prior IRB approval, except to eliminate an immediate and apparent hazard to subjects enrolled in the study.

The UH IRB operates under HHS Federalwide Assurance (FWA) number 00003937 and IRB registration numbers 00000684, 00001691 and 00008600. The CWRU IRB operates under DHHS FWA00004428 and IRB registration number 00000683.