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RESEARCH ARTICLE

Improving CPAP Therapy with Superimposed Pressure Oscillation

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ABSTRACT

Background: Continuous positive airway pressure (CPAP) is considered the gold standard therapy for Obstructive Sleep Apnea (OSA); however, many side effects, such as uncomfortable high titration pressure (TP) and mouth dryness, are associated with this treatment. This work proposes using pressure oscillations superimposed on a mean pressure to modulate the upper airways, reduce TP, and stimulate the salivary glands to reduce mouth dryness.

Methods: Two nonconsecutive overnight randomized controlled clinical trials were designed, one with a standard CPAP setup but reduced TP and the other by adding superimposed pressure oscillations (SIPO) to the reduced TP CPAP setup. 33 OSA patients who usually received CPAP treatment with predetermined TP settings participated in the two trials. Complete polysomnography was performed for sleep and patient assessments. However, a spitting technique protocol was used on 15 randomly selected patients from the same group to investigate the effect of SIPO on mouth dryness. These trials are registered under ACTRN12622001518752.

Results: The apnea-hypopnea index (AHI) was significantly reduced from 25.08 ± 2.32 to 17.56 ± 2.11 ($p = 0.020$*) with SIPO, indicating a 29.95% reduction in AHI and a decrease in breathing obstructions during enhanced therapy. Additionally, SIPO significantly decreased the oxygen desaturation index (ODI) ($p = 0.002$), maintaining the blood oxygen level within the normal range during the trials. ODI≥3 decreased significantly by 38.04% with SIPO. Saliva test results demonstrated that SIPO significantly increased saliva volume by 23.13% in non-stimulation and by 39.09% during stimulation compared to the CPAP trial.

Conclusions: This work demonstrates that SIPO reduces the TP to 70% of its standard clinical setting and stimulates salivary secretion to reduce mouth dryness. Further, significant improvements in AHI, respiratory arousal index (RAI), Arousal index (AI), and sleep efficiency (SE) are observed. This work is proof of concept, and further trials should be undertaken to generalize the proposed technique.

Keywords: Obstructive sleep apnea (OSA), Superimposed pressure oscillations (SIPO), Breathing difficulties, Sleep patterns, Mouth dryness, Upper respiratory system

1. Introduction

With almost one billion affected people worldwide and almost 18 million in the American States alone, sleep apnea syndromes pose serious health problems[1]. Among the three known types of sleep apnea (obstructive, central, and mixed), obstructive sleep apnea (OSA) is the most common and is the subject of this research. OSA occurs in the upper airway (UA), where the initial sleep onset reduces UA activities, often leading to partial or full blockage and breathing difficulties[2,3]. Symptoms of OSA include narrowing of the UA, reduced cross-sectional area of the pharynx (especially with large uvula, tongue, and/or tonsil size), and choking during sleep, causing chronic sleep-related breathing disorders at regular intervals. Snoring is a prevalent symptom of OSA[4]. OSA severity is measured by the apnea-hypopnea index (AHI), reflecting the number of choking and sleep interruption events per hour[5]. Higher AHI values indicate more severe OSA, resulting in low oxygen levels, high carbon dioxide levels, dry mouth, and poor sleep quality. OSA can lead to cardiovascular problems, difficulty sleeping, insomnia, drowsiness, poor daytime performance, mood fluctuations, depression, high blood pressure, and an increased risk of diabetes, stroke, fatty liver, and other metabolic diseases[6-8].

To improve current treatment methods for sleep apnea, researchers and medical device, manufacturers have focused on the modulation of the upper airway (UA) tissue vibrations[9]. UA tissue vibration, which generates snoring, aids better air access to the lungs. By tuning these vibrations, it is possible to improve the pneumatic splint, which keeps the pharyngeal airway open during inspiration and expiration. The UA possesses an elasticity and mass that give rise to vibrational characteristics, but controlling its oscillation becomes challenging when the tissue sags. To trigger vibrational characteristics, initial stretching of the tissue is crucial[10]. Applying a mean pressure to stretch the tissue and adding a slight oscillating pressure can initiate a tissue modulation process[11]. This superimposed pressure oscillation (SIPO), aligned with the snoring frequency, assists in opening the UA and preventing choking during sleep[12]. Studies exploring the effects of vibrations on the upper airway have shown that playing the didgeridoo, oropharyngeal exercises with vibration, and vibroacoustic therapy have resulted in significant improvements in various sleep-related parameters, such as daytime sleepiness, apnea-hypopnea index, and oxygen saturation[9-12]. These findings suggest that vibrations benefit the upper airway, leading to improved respiration in individuals with sleep-related breathing disorders.

Extensive research conducted by Ashaat and Al-Jumaily delves into the significance of SIPO on continuous positive airway pressure (CPAP) in reducing titration pressure and maintaining an open airway[9]. They investigated the dynamic characteristics of unhealthy UA models through detailed theoretical and experimental simulations using finite element analysis, computational fluid dynamics, and fluid-structure interaction methods. The study utilized an appropriate silicon rubber model for the tongue and uvula, exhibiting physical properties comparable to human tissue, and validated the effectiveness of SIPO in reducing titration pressure and AHI. Findings revealed that the uvula and tongue models' first and second natural frequencies closely coincide, suggesting simultaneous stimulation at similar frequencies. Additionally, the study noted slightly higher natural frequencies in unhealthy uvula models than in healthy ones.

Furthermore, mechanical fluctuations in the UA can stimulate saliva secretion, making any SIPO applied to the UA trigger increased liquid secretion from the salivary glands[13]. This phenomenon aids in better lubrication of the UA. Previous investigations have reported significant improvements in saliva secretion with SIPO[14].

Overall, by exploring UA modulation and its effects through SIPO, this research contributes to the ongoing advancements in sleep apnea treatment methods, aiming to provide relief and improved quality of life for affected individuals[9].

2. Methodology

The study employed a crossover controlled randomized clinical trial design. Participants with sleep apnea were randomly assigned to receive either continuous positive airway pressure (CPAP) alone or CPAP with SIPO during two separate nights. The order of treatments was randomized, with the reference night being the CPAP treatment. The objective was to compare the effectiveness of CPAP with SIPO in managing sleep apnea symptoms over two nights within the same group of participants.

This study selected participants from the Fisher & Paykel Healthcare clinical trial registry based on BMI, age, and pre-diagnosed apnea-hypopnea index (AHI). Randomization was performed considering gender, age, neck circumference, height, and weight. Participants were informed about the study procedures and provided voluntary consent. The control group underwent two nights of treatment, with CPAP applied on the first night and CPAP with SIPO on the second night, and vice versa.

The study was conducted at night to account for worse respiratory parameters and longer sleep hours. Daytime participation was allowed for night shift workers. A well-trained team of sleep lab technicians facilitated the trial setup, data recording, and participant assistance. Participants received an invitation letter with detailed information about the study, including safety considerations, possible side effects, reimbursement, and participants' rights. A participant information sheet and consent form were provided and discussed in person with the participants. Data were recorded on a separate form called the Case Report Form (CRF) for statistical analysis. Before the actual trials, a training session was conducted, and participants were contacted before each trial night to confirm appointments and assess any upper airway difficulties. The trials were conducted over two nonconsecutive nights for each participant.

The clinical trial administration criteria were established to ensure appropriate participant selection. Inclusion criteria required participants to be aged 18 years or older, have an apnea-hypopnea index (AHI) of more than five events per hour, exclusively use CPAP, demonstrate good tolerance to CPAP (at least four hours per night on average over the last three months), and utilize a full-face mask. Exclusion criteria encompassed conditions such as insomnia or other sleep disorders, previous surgical interventions for obstructive sleep apnea, metallic implants in the upper airways, pacemakers, pregnancy or suspected pregnancy, and use of devices other than CPAP (such as APAP or BiPAP). Withdrawal criteria allowed participants to terminate their involvement if they requested, if continued participation was deemed detrimental to their well-being by the investigator, in case of a severe adverse event, or for other reasons. Comfort features of the CPAP machine, such as humidification and pressure adjustments, were turned off during the trials to maintain the fairness and accuracy of the study. The aim was to conduct fair trials comparing participants' usual CPAP therapy with the novel SIPO device, excluding comfort features, to ensure accuracy without introducing additional risks to the participants.

The study adhered to the American Academy of Sleep Medicine (AASM) guidelines for analyzing polysomnography data, specifically, the AHI scoring. The AHI Chicago rule and recommendations were followed, and the AHI alternative scoring method was used, as it was considered more accurate.

Demographic data collection was an essential step in the study. Participants' height and weight were measured using appropriate scales, with a weight scale capable of measuring up to 136 kg and a specialized scale for participants with severe obesity. Height was measured using a Stadiometer. In addition to height and weight, other demographic information such as age, neck circumference, years of CPAP use, ethnicity, and CPAP's fixed therapeutic pressure were recorded.

During the polysomnography setup, the participants were fitted with Embla S4500 electrodes to measure various signals, including ECG, EEG, EMG, snoring pattern, SPO2, EOG, and abdominal efforts. Electrodes were placed on the head, face (eyes and chin), legs, chest, abdomen, and neck. Additionally, a fingertip oximetry sensor was used.

After attaching the electrodes to the participant's body, they were connected to the corresponding ports on the PSG panel. The correct attachment of electrodes was confirmed by green lights on the PSG device ports, indicating a successful connection. The participants were then fitted with a full-face mask (FFM), and the PSG signals were checked through verbal confirmation. The participants were asked to perform various actions such as looking in different directions, blinking their eyes, making a snoring sound, grinding their teeth, checking for mask air leaks, and breathing normally.

2.1 CLINICAL TRIALS

The clinical trial conducted in this study received ethical approval from the Northern B Health and Disability Ethics Committee, registered under the US Department of Health and Human Services Office for Human Research Protection with the reference number 00008715—the trial aimed to validate two hypotheses and involved two-night trials with different setups.

For the trials, two setups were developed and calibrated. The first setup was a standard CPAP setup equipped with all necessary measurement accessories for sleep analysis and patient assessment using plethysmography. The second-night setup was similar to the first one, with an additional equipment block added to generate the SIPO.

To ensure the safety of the patients, all the equipment used during the trials, including PSG electrodes, CPAP hose, and SIPO hose, were sterilized. This measure was taken to prevent any negative impact on the patient's medical condition.

During the clinical trials, data were collected from 33 participants with OSA over two nonconsecutive nights (Figure 1), and the first night involved CPAP

therapy alone. In contrast, the second night included CPAP therapy along with SIPO. Various demographic data and parameters were recorded for analysis.

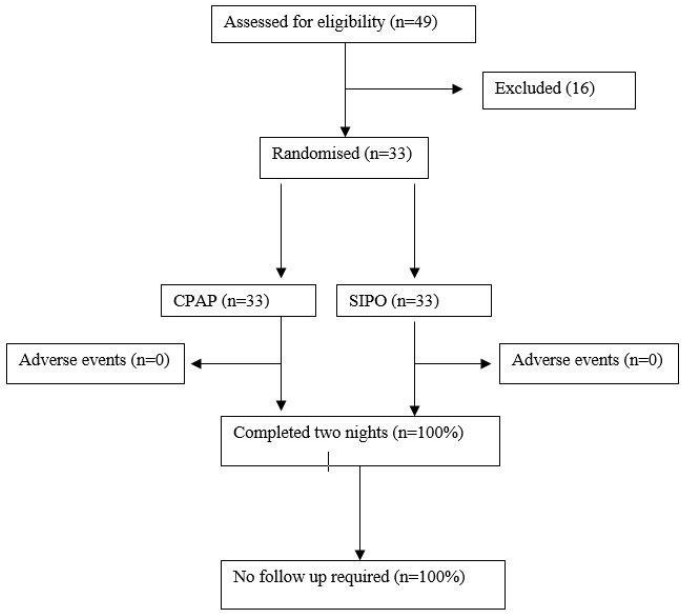

Figure 1 CONSORT flowchart of the participants

The CPAP pressure was calibrated for each patient based on professional health recommendations. The pressure gradually increased until a comfortable range was reached, and the final therapeutic range (TR) was determined. The pressure was then reduced to 70% to induce some apneas during sleep. This specific value was selected after multiple attempts of pressure reduction to initiate mean pressure, which would facilitate necessary tissue pre-stretching and trigger vibrational characteristics.

During both nights, routine polysomnography monitoring was conducted, and PSG electrodes were attached to specific areas of the patient's body to gather sleep-related data, Figure 2.

The clinical trial obtained ethical approval and involved two-night trials with different setups. Data were collected from participants with OSA, and parameters such as CPAP pressure, demographic information, and sleep measurements were recorded for analysis.

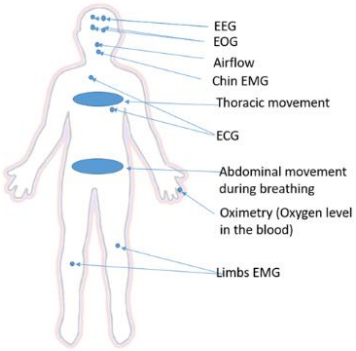

Figure 2 Polysomnography sensors

2.2 POSITIVE AIR PRESSURE THERAPIES

During the first trial night, participants underwent CPAP therapy with the machine set to a new pressure of 70% of the TP. The specific pressure reduction value was determined based on a previous pilot study. The CPAP device was calibrated by a physician prior to the trial night. Polysomnography was conducted simultaneously to monitor the participants' sleep.

On the second trial night, the saliva secretion test was performed, PSG electrodes were attached, and the oscillator hose was connected to the full-face mask. Participants lay down, and the mask pressure was calibrated. The CPAP device was operated at the reduced pressure value, and in the SIPO night, one cmH2O pressure from the oscillator was added to the CPAP pressure. Mask air pressure was monitored, leaks were sealed, and participants were allowed to sleep in a darkened room. Data was recorded until participants woke up.

To maintain the modified CPAP pressure for both nights, participants were instructed to bring their own CPAP devices, which the Fisher & Paykel Healthcare technician team checked. The device setups were confirmed, and the CPAP pressure was reduced by 30% from the original to achieve the trial's new pressure. The same pressure was applied in subsequent trials along with oscillations.

2.3 DATA SCORING

The PSG software was used to measure and record selected parameters; however, its automatic AHI readings were not accurate for obstructive sleep apnea data due to including mixed sleep apnea events. Thus, a manual scoring method was employed to calculate the sleep apnea events. The manually scored AHI was used to calculate other parameters, which were then included in the final individual report. The events were categorized into two indices: the apnea index and the hypopnea index. The apnea index was determined by tracking the reduction of the blood's airflow (CPAP flow) level to 90% for approximately 10 hours per participant. The hypopnea index could be measured by either a decrease in airflow to 30% and a decrease in blood oxygen (O_2) or by observing arousals in the EEG waves, particularly the alpha wave, through the attached EEG electrodes on the head.

2.4 SALIVA COLLECTION TEST METHODOLOGY

Stimulated and unstimulated spitting saliva tests were performed on patients who agreed to participate in the test (n=15) before and after each trial to determine the effect of SIPO on mouth dryness, Figure 3. An unstimulated saliva test was performed within five minutes. Each patient was asked to sit at rest without talking and with eyes open and was then instructed to rinse the mouth a few times, discard the water, wait for one minute, and discard the saliva. Saliva was collected in the mouth and, after five minutes spitting it into a funnel attached to a graduated cylinder (salometer). The stimulated saliva test was done for three minutes. The procedure was performed by asking participants to chew sugar-free gum and discard saliva for the first two minutes. Chewing was continued by spitting each minute for three minutes into a funnel attached to the salometer.

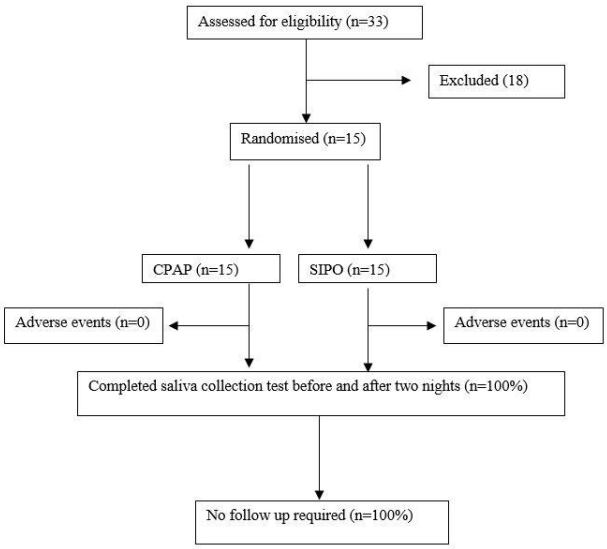

Figure 3: CONSORT flow chart of the saliva collection test

Saliva flow rate and salivary gland stimulation were tested in each trial. CPAP and SIPO nights were analyzed for saliva volume using saliva collection tests. The Statistical Package for the Social Sciences SPSS analysis was used to determine the correlation between saliva secretion and patient demographics. The saliva flow rate was analyzed for both treatments to understand the patients' responses concerning saliva secretion. Statistical analyses were performed using t-tests to analyze the results (Figure 4).

3. Results and Discussion

3.1 SIPO EFFECT ON SLEEP PARAMETERS.

As proposed by the hypothesis of this study, the SIPO technique, along with CPAP, is postulated to improve CPAP performance by reducing TP. This study tested this hypothesis using data collected from the plethysmograph outputs, and the parameters were analyzed using the SPSS-version 20 tool to compare CPAP and SIPO night results for patients from different demographic regions. Independent t-tests and Pearson's correlations were used to analyze the results. The results were analyzed to determine whether demography impacted SIPO use.

UA obstruction is the main problem in OSA; hence, studying UA muscle response helps to understand the patient's response to treatment. Any disruption in the sleep pattern was recorded, and the data were analyzed for sleep efficiency, which was determined using the apnea and hypopnea indices. The breathing parameters analyzed for the two scenarios of CPAP and SIOP-CPAP nights included respiratory arousal index (RAI), arousal index (AI), sleep efficiency (SE), and AHI indexes.

3.1.1 Respiratory Arousal Index (RAI)

RAI is arousal from apnea, hypopnea, and a periodic increase in respiratory effort per hour. Increased values of RAI indicate an increase of sleep events[15]. When comparing RAI values of the CPAP trials (17.38 ± 2.07) with those of the SIPO trials (10.45 ± 1.14), a significant decrease of about 39.89% ($p = 0.005$) was found using the oscillations. This reduction implies a decrease in UA resistance. RAI can also be recorded in association with snoring when UA resistance increases but not due to apnea/hypopnea.[16]

3.1.2 Arousal Index (AI)

Arousal/awakening events occur during sleep. The polysomnography recorded these events per hour.[17] The AI of the CPAP trials slightly decreased compared to that of the SIPO trial by 9.53%, $p = 0.568$). Lin et al. demonstrated a significant decrease in AI but with 24 physical therapy sessions applied to the upper airway of 15 participants.[18] However, the pressure CPAP/SIPO clinical trial included 33 participants, which would provide more accurate results.

3.1.3 Apnea Hypopnea Index (AHI)

To measure the severity of OSA, the apnea-hypopnea index (AHI) can indicate whether the patient has regular, moderate, or severe OSA. AHI can be measured using polysomnography, which measures the oxygen drop in the blood associated with a breathing pause. The CPAP's AHI was 25.08 ± 2.32 and decreased to 17.56 ± 2.11 ($p = 0.020$*) with the SIPO trials. This reduced AHI by 29.95% by applying SIPO therapy, indicating that fewer breathing obstructions occurred with enhanced therapy. Mok et al.[19] compared two trials: one used an invented vibrating device, and the other applied CPAP. No enhancement was found in the participants' sleep. The AHI of their CPAP trial was lower than the vibration device (4.0 ± 3.2 vs 13.0 ± 13.8 events/hour, respectively, $p = 0.001$). The differences between the two results may be attributed to differences in the experimental setup.

3.1.4 Sleep Efficiency

Polysomnography recorded the total sleep time (in minutes) and divided it by the total lying time in bed to obtain sleep efficiency. Data in this study showed a reduction in sleep efficiency of around 10.33% ($p = 0.051$) when using oscillations (70.79± 3.38) in comparison to the CPAP trials (75.87 ± 3.38). This indicates that the SIPO trial nighttime (306.81 ± 17.78) was shorter than the CPAP trial time (336.79 ± 16.87). The reduction in sleeping time may be attributed to the added oscillation device noise in the sleeping room accompanied by CPAP noise, the Y junction adapter being slightly heavy and uncomfortable compared to the CPAP equipment when using the full-face mask, and the difficulty in moving due to the two breathing hoses.

3.1.5 AHI Supine

When the participants slept while lying on their backs with their faces up, polysomnography recorded their AHI in the existing sleep position. A supine sleeping position is considered an exacerbating factor for obstructive sleep apnea and causes more collapses.[20] Decreasing AHI in this position means the airway was open most of the sleeping time. High values indicated an increase in the number of collapse events per hour. The supine sleeping position is considered an exacerbating factor for obstructive sleep apnea and causes further collapse. Comparing the two clinical trials in this study, the AHI supine in the CPAP trial was 46.45 ± 14.09, while that with SIPO was 15.13 ± 3.51. The AHI in the supine position significantly decreased ($p = 0.038$) by 67.42% while applying SIPO therapy compared to CPAP alone. Statistics have shown a strong relationship between the supine sleeping position and high AHI in patients with OSA.[3,9, 20]

3.1.6 AHI Non-Supine

The values of the apnea-hypopnea index were set to record the number of collapses in non-supine positions, such as the left lateral and right lateral positions.[21] A significant increase in the AHI in the

non-supine sleeping position (p = 0.051) was observed when using pressure oscillation therapy (33.78± 4.68) compared with CPAP therapy (20.91± 4.46). AHI non-supine increased by 61.516% after applying SIPO. This may be attributed to many factors, including the uncomfortable SIPO gear in non-supine positions and the air leak and therapy pressure loss.

3.1.7 REM AHI

The apnea-hypopnea events during the rapid eye movement (REM) sleep stage are called "REM-related OSA" [21]. During the rapid eye movement sleep stage, AHI was tracked for all participants, and it was observed to increase (p = 0.017) while using oscillations significantly. AHI REM C increased by 51.65% after applying the SIPO (23.46± 1.99) compared with the CPAP (15.47 ± 2.59). Haba et al.[3] also found an increase in AHI REM while using pressure oscillations, but this was not significant owing to the small number of samples (n = 15).

3.1.8 Non-REM AHI

Non-rapid eye movement is a sleep stage during which apnea-hypopnea events occur frequently.[22] During nonrapid eye movement, the AHI increased non-significantly (17.86%) with oscillations compared to the CPAP trial. Haba et al. found a non-significant decrease in NREM AHI using SIPO in 15 participants with low BMI. Compared to their clinical trials, this might be an indicator that patients with high BMI, and OSA experienced a non-REM AHI increase.

3.1.9 Oxygen desaturation index ODI

The precise oxygen saturation level in the human blood should be approximately 95-100 %.[23] When the oxygen level in the blood is reduced, the blood pressure is lowered, and hypertension occurs. Clinical trial statistics (Table 1) showed that the ODI significantly decreased using SIPO (p = 0.002), which means that the oxygen level in the blood remained in the normal range most of the time during the trials. ODI≥3 decreased significantly by 38.04% when applying the SIPO in this study. Haba et al. also found a decrease in the ODI, but the difference was insignificant (p = 0.583).

Table 1 Clinical parameters during the CPAP and SIPO trials.

Devices group. CPAP	Mean ± SE	Devices group SIPO	Mean ± SE	P-value ≤ 0.05
RAI C	17.38± 2.07	RAI O	10.45± 1.14	.005*
AI C	27.22± 3.50	AI O	24.63± 3.19	.568
SE C	78.94± 2.31	SE O	70.79± 3.38	.051*
AHI C	25.07± 2.32	AHI O	17.56± 2.11	.020*
AHI Supine C	46.45± 14.09	AHI Supine O	15.13± 3.51	.038*
AHI NSupine C	20.91± 4.46	AHI NSupine O	33.78± 4.68	.051*
AHI REM C	15.47± 2.59	AHI REM O	23.4633± 1.99	.017*
AHI NREM C	20.96± 2.71	AHI NREM O	24.70± 2.61	.327
ODI≥3 C	29.30± 3.03	ODI≥3 O	18.16± 1.72	.002*

3.2 SALIVA STIMULATION

Although CPAP helps to treat OSA, its long-term use results in dry UA. As demonstrated above, the SIPO technique has been found to reduce the dryness level of the mouth and has provided good sleep quality to the participants.[24] One of the main objectives of the clinical trials was to estimate the impact of SIPO on sleep patterns and mouth dryness, which is eliminated by the activation of salivary glands, leading to better saliva secretion.

Stimulated and unstimulated saliva collection tests were performed to analyze the dryness levels of OSA participants using the SIPO. A stimulated test was performed when the upper airway muscles were active and unstimulated tests were performed when the upper airway muscles were at rest. The results were compared for cases where participants used CPAP alone and when using SIPO. Saliva samples were clinically analyzed to determine the moisture levels of the respiratory muscles of the human body.[25]

Saliva test results were much better for patients with SIPO, and mouth dryness was resolved using the oscillation technique. The SIPO increased the saliva volume by 23.13% in non-stimulation, Figure 4a). During stimulation, the SIPO increased the saliva volume by 39.09% compared to the CPAP trial, Figure 4b). It is believed that SIPO resolved this problem by sending oscillatory waves that activated the salivary glands and increased the saliva volume and flow rate.[26]

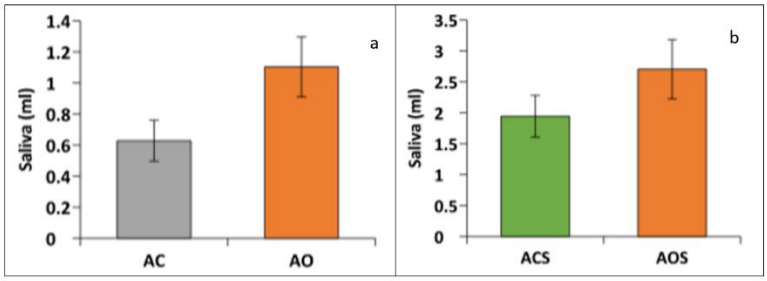

Figure 4: (a) Non-stimulated and (b) Simulated saliva test volumes under CPAP(AC) and SIPO(AOS)

4. Concluding Remarks

The combination of CPAP and superimposed pressure oscillations (SIPO) was found to improve obstructive sleep apnea therapy by reducing titration pressure (TP) and improving saliva secretion.20,21 One potential advantage of SIPO is the ability to lower CPAP pressures, potentially enhancing tolerance and adherence to therapy. While some argue that the low oscillation level may not have a significant effect, the data presented in this study demonstrate a significant reduction of 30% in TP pressure. This reduction not only reduces the risk of high pressure but may also lead to a potential decrease in the size of the blower needed to supply the air. Moreover, the significant reduction in the apnea-hypopnea index (AHI) suggests that better airway opening and improved breathing patterns are achieved. Additionally, the saliva test results indicate an advantage of SIPO in improving upper airway lubrication and reducing dryness, further highlighting the potential benefits of this therapy.

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Ministry of Health-New Zealand Ethics Ref: 18/NTB/35/AM03.

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Conflict of Interest Declaration: The authors declare that they have no affiliations with or involvement in any organization or entity with any financial interest in the subject matter or materials discussed in this manuscript.

Contribution Statement: AMA contributed to the concept, designed the experimental setups, participated in some of the clinical trials, analyzed the results, and wrote the draft and final paper. DA participated in some of the clinical trials, calibrated the setup, conducted statistical analyses, and wrote the draft paper. SA contributed to the analysis of the data. OA provided medical opinions and expertise throughout the clinical trials and contributed to the writing.

Data Access: Row data is available from the contact author.

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