Sleep Trials

A comprehensive sleep study was conducted to test the efficacy of the designed and manufactured ergonomic sleep system. The sleep studies were conducted at Melbourne University's Sleep and Respiratory Laboratory which is partially funded by Swinburne and is a joint facility. Polysomnography (PSG), which is the gold standard in diagnosing OSA and sleep quality, was the basis for testing the efficacy of the ergonomic sleep system. These trials were conducted in three stages, which included stage one without the pillow for screening and determining the current level of apnoea hypo-apnoea index (AHI); stage two, which occurred after 15 days of using the therapeutic pillow and then, stage three was performed after 30 days of using the ergonomic sleep system. A clinical type 1 study was conducted using the gold standard PSG test and the results proved significant improvement to subject's sleep quality and AHI index. A benchmarking study was conducted to contrast the results of the ergonomic sleep system with the current gold standard CPAP, oral appliances and other PT based treatments.

Phase 1: Baseline study

The first phase of the sleep trials was a full night sleep study conducted to determine baseline readings at Melbourne University sleep laboratory. The participant underwent a type 1 PSG screening under normal regular sleeping conditions (i.e., without a sleep aid). Standard type 1 PSG data was collected including readings of EMG, EOG, ECG, and EEG, limb movement, airflow, heart rate, oxygen saturation, phases of sleep and sleeping position (Chai-Coetzer, Douglas et al. 2014). The data collected from the studies after being scored determines the AHI value, thereby determining the baseline value. AHI value is the major indicator of progress in this study. This result functioned as the baseline from which the final phase (using the ergonomic system) results were compared. Participants were provided with a SnoreBeGone® pillow on completion of the first night's study. The participants were requested to use the pillow for the next thirty nights.

Phase 2: Home based Therapy

The participants used the ergonomic sleep system for the 30 nights following the baseline study. The ergonomic sleep system is uniquely shaped for the upper body, and therefore, the participants had to get used to sleeping in this particular position. This positional therapy helps the participants get used to sleeping in the left or right lateral sleeping position. A 30-day period was allowed for therapeutic customisation to the ergonomic sleep system.

Phase 3: Ergonomic sleep system study

Now that the participants were used to sleeping on the ergonomic sleep system, a second type 1 PSG was conducted on the participants at University of Melbourne sleep lab. The same PSG parameters measured in the first phase were measured in this phase including readings of EMG, EOG, ECG, and EEG, limb movement, airflow, heart rate, oxygen saturation, phases of sleep and sleeping position. The data collected from the studies after being scored determines the AHI value, thereby determining the post treatment value which was then compared with the first night's study.

Overnight investigative sleep study procedure

The purpose of the overnight study was to measure several physiological variables that may influence OSA severity and may change as a result supine and non-supine sleep position as to determine the OSA severity. Sleep studies were conducted at the Sleep Laboratory in the University of Melbourne. The overnight diagnostic sleep study was performed using continuous PSG based on a computerised system in order to monitor sleep and breathing. This provided a comprehensive assessment of both respiratory and sleep state variables. Each overnight sleep study involved physiological measurements, in addition to the standard polysomnographic measurements. Studies were considered adequate provided they contain at least 180 minutes of sleep. The apparatus and procedures are outlined below. Two investigators were present throughout each study night.

Participants were asked to attend the University of Melbourne sleep laboratory three hours prior to their normal bedtime. Upon arrival, the participant was given approximately an hour to complete the Epworth Sleepiness Score wellbeing and SnoreBeGone® questionnaires. Once the questionnaires were complete, the participant was prepared for their overnight study. While in a standing position, the participant's height, waist and neck circumference were measured and recorded. Each participant was weighed on a digital scale, then asked to change into comfortable sleeping clothes.

Once the participant was dressed for bed and had completed their pre-bedtime routines, the polysomnographic apparatus was applied. The electrodes to record EMG, EOG, and EEG were applied using Elefix® conductive paste, gauze and tape as per standard clinical protocol. To record EEG information, two scalp electrodes, positioned at O2 and C4 (from the 10-20 electrode placement system), were used with an opposing mastoid reference (M1). The EOG recordings were measured using bilateral electrode placement 1cm lateral, and 1cm inferior, to the eye's outer canthus, coupled with a centrally located reference electrode that was placed centrally in the glabella. Electrodes were also applied bilaterally 1cm lateral and 1cm inferior to the corners of the mouth to obtain chin EMG recordings. The electrodes to record electrocardiography (ECG) were applied to the chest as per standard clinical protocol, with one electrode at the lateral border of the right clavicle and the second electrode on the mid-axillary line on the lower left ribcage between ribs 8-10. A nasal cannula was placed in the nostrils to order to measure airflow. Once all the equipment was in place the patient was asked to perform certain activities in order to calibrate the equipment. This included swallows, deep breaths, left and
right and up and down eye movement, limb movements, and tongue protrusions against the top teeth. The patient was asked to relax in a supine position, with their eyes open, and breathe normally through waking baseline measurements.

Following five minutes of wakefulness recordings, the lights were turned off and the participant was allowed to sleep. The placement of leads and wires permitted normal positional changes during the night and both sleep and wake times were determined by the patient. Positional changes were recorded from a position sensor and also observed through an infrared camera placed next to the bed and manually recorded. Upon waking in the morning, the equipment was removed, and the participant was free to go home.

Patient demographics

Twenty adults ranging in age from 25 to 75 were recruited for this study. There were three female participants with a mean age of 65 and patients ranged in OSA severity from mild to severe and were not currently receiving treatment for their OSA. Three participants were prescribed a CPAP machine, but they discontinued use for more than six months.

The following analysis involves data obtained for the remaining 14 participants for whom there was sufficient data. The subjective questionnaire data for the active patient that failed to achieve sufficient sleep at the follow-up study night was complete, and therefore included in the analyses of subjective outcomes.

Data analysis procedure

OSA Severity Measures

The main severity measures of OSA are the AHI, arousal index (AI) and ODI 3% (SpO2). Respiratory disturbances were recognised by an event lasting more than 10 seconds and greater than 90% decrease in airflow and identified by at least 3% decrease in oxygen saturation (Berry, Budhiraja et al. 2012). The arousal index AI refers to the number of arousal events in an hour of sleep and was also measured. This was measured in accordance with the AASM manual. The ODI indicating the count of oxygen desaturation events where oxygen saturation is decreased by 3% or more from the baseline. According to the AASM scoring criteria, ODI is defined as the count of desaturations multiplied by 60 and divided by the total sleep time in minutes (Berry, Brooks et al. 2017).

Sleep measures

Standard sleep measures from the PSG included sleep efficiency (SE), sleep onset latency (SOL), and analysis of sleep architecture which comprised of staging sleep and considering time spent in each stage of sleep.

Subjective measures

The Epworth Sleepiness Scale (ESS) was used as to assess the subjective measures of sleep. This questionnaire lists eight activities which are part of normal day to day living. Respondents were asked to rate from 0 to 3 the likelihood of them dozing off during these activities. A higher the score indicated the severity of sleepiness was higher (Johns 1991).

Results and data analysis of sleep trials

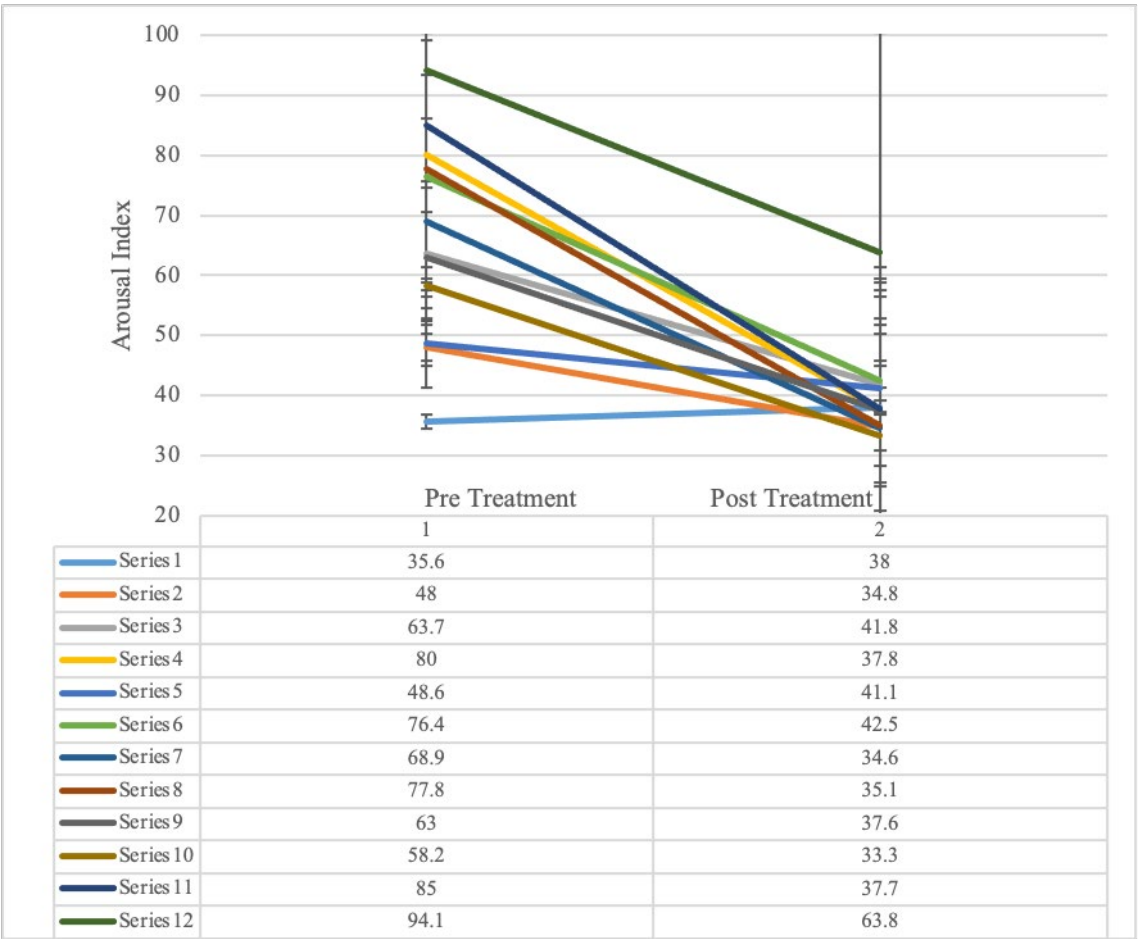
There were thirteen participants (12 males and 1 female) who completed the study from start to finish. The compliance rate for the ergonomic sleep system or SnoreBeGone pillow was 100 % with a median use of approximately 6 hours per night within the 30-day period of trial. The polysomnographic and clinical characteristics of participants during the baseline and after 1 month of using the SnoreBeGone pillow and Ergonomic sleep system are shown in *Table 1-1*. As the results indicate, there is a decrease in total AHI, more importantly, there is a great decline in AHI in the participants sleeping in the supine position.

Table 1-1: Average polysomnographic tests comparing baseline and ergonomic sleep system

	Baseline Average	Ergonomic Sleep System Average
AHI/h	40.23	16.72
Supine AHI/h	46.73	19.36
Non-Supine AHI/h	5.21	5.95
REM AHI	30.10	28.45
NREM AHI	31.86	15.00
RDI/h	53.48	23.79
Arousal Index	63.15	42.28
Total sleep Time, min	273.04	282.67
Sleep Onset Latency, min	14.00	9.42
Stage 1 sleep	29.90	18.24
Stage 2 sleep	59.00	53.99
Stage 3 sleep	17.86	16.95
REM sleep/total sleep time	14.68	10.82
sleep efficiency %	67.72	78.78
Percentage supine position	90.08	33.75
Percentage non-supine position	9.92	65.83

Table 1-2: Individual apnoea–hypopnoea index values and percentage of supine position

	AHI		
No	Baseline	After using Ergonomic Sleep System	% change in AHI
1	36.4	16.8	53.85
2	38.9	0.6	98.46
3	24.5	13.3	45.71
4	41.3	25.3	38.74
5	43.6	17.3	60.32
6	34.9	12.3	64.76
7	35	7.7	78.00
8	58	19.8	65.86
9	39.3	30.1	23.41
10	56.1	3.5	93.76
11	13.3	1.8	86.47
12	61.5	52.1	15.28



	1	2
Series 1	35.6	38
Series 2	48	34.8
Series 3	63.7	41.8
Series 4	80	37.8
Series 5	48.6	41.1
Series 6	76.4	42.5
Series 7	68.9	34.6
Series 8	77.8	35.1
Series 9	63	37.6
Series 10	58.2	33.3
Series 11	85	37.7
Series 12	94.1	63.8

Figure 1 - Arousal Index

- The sleep study indicated that there was a decrease in AHI in 100% of the participants. There was a significant decrease in OSA in most of the participants, with 10 out of 12 cases have their OSA reduced to moderate levels and in 3 cases OSA reduced to none, meaning 3 participants did not have OSA after using the sleep system. The AHI levels in the three participants reduced to 0.6, 1.8 and 3.5, which proved to be the best results of the developed ergonomic sleep system. The second indicator, which is the arousal index, decreased down to the range of 32-42, indicating that there were far less arousals when sleeping on the ergonomic sleep system.

- A survey was conducted with seven of the participants who had used or were currently using the CPAP machine. This survey compared the CPAP and ergonomic sleep system ergonomics, ease of use and adherence. Results indicated that the participants preferred the ergonomic sleep system for its comfort, aesthetics, low maintenance, ease of use, and they were more likely to adhere to using the ergonomic sleep system over the CPAP machine.

09/04/2021

RE: To whom it may concern

This letter summaries key findings for development of worldwide patent no # 2014903889 entitled "Bed and bed insert with postural support", as well as patents US2011/0056503 and US9980574B2.

The Obstructive Sleep Apnoea (OSA) effects on individuals in their day-to-day activities and is a socio-economic burden. The Swinburne University of Technology, U-Sleepwell and SleepCorp Australia, developed a novel ergonomic sleep systems. Over the last 10 years a mutual collaboration has yielded multiple intellectual properties and patents (US2011/0056503 and US9980574B2), products developed and commercialized (e.g.: pillow). The collaboration also conducted high end research for efficacy of sleep system variants with completion of sleep trials, a PhD thesis, and related publications.

The study initially conducted a computational analysis of pharyngeal airway modelling based on cephalometric analysis of the Upper Airway (UA) passages. The results validated the lateral sleep position effectiveness for Apnoea/ Hypopnoea Index (AHI) and thus alleviates OSA with improved sleep quality.

Further, sleep trials were conducted in Melbourne University, in the Sleep and Respiratory Laboratory which is joint facility between both Universities' from Dec 2016 – Apr 2018 to establish efficacy of the ergonomic sleep system in accordance to ethics reference R/2016/259 - Design, development and validation of a sleep system for Obstructive Sleep Apnoea.

This involved Polysomnography (PSG) based sleep studies with twelve participants. The compliance rate for the ergonomic sleep system or SnoreBeGone pillow was 100% with a median use of approximately 6 hours per night within the 30-day trial period. The sleep study indicated that there was a decrease in AHI in 100% of the participants. In addition, significant decrease in OSA was observed with 10 out of 12 participants. Also, OSA reduced to moderate levels in most case and in 3 it was alleviated after using the sleep system (e.g.: AHI levels in the three participants reduced to 0.6, 1.8 and 3.5). The second dominant finding was the arousal index, decreased down to the range of 32-42, indicating that there were far less arousals when sleeping on the ergonomic sleep system. The study also had a significant improvement in scoring on the subjective Epworth sleepiness scale (ESS). The mean scores between participants decreased significantly from 15 to 6, indicating efficacy of the ergonomic sleep system. These results indicate the effectiveness of the developed sleep systems in reducing OSA.

Please do contact me if you need any further clarifications in this regard.

Dr Ambarish Kulkarni
Swinburne University of Technology
John Street, Hawthorn, Victoria 3122 Australia
ambarishkulkarni@swin.edu.au
+61 3 9214 8097