Assessment of Treatment Outcomes with Vibro-Tactile Position Therapy

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Introduction:

This study is an initial evaluation of a neck-worn device for the treatment of positional obstructive sleep apnea (OSA).

Methods:

Thirty patients (22 males and 8 females) underwent a baseline polysomnography (PSG), received four-weeks of supine-dependent vibro-tactile feedback, and then completed a follow-up PSG while position therapy was delivered. Inclusion required a pre-enrollment ESS ≥ 5, overall apnea-hypopnea index (AHI) ≥ 10, BMI < 35, and overall/non-supine AHI ratio ≥ 1.5.

The PSG studies were conducted at an AASM accredited facility with the scoring of the apnea-hypopnea index (4% SpO2 desaturation), sleep stages, and arousals based on the AASM criteria. Video editing of body position was used to determine PSG supine time.

Utilization and efficacy data were acquired nightly with the neck-device. Subjective measures were obtained just prior to the baseline and follow-up PSG studies, including the Epworth Sleepiness Score (ESS), Insomnia Severity Index (ISI), Patient Health Questionnaire (PHQ9), and Profile in Moods State (POMS).

Results:

Table 1: Changes in Sleep Patterns at Baseline and with Delivery of Position Avoidance Therapy

Mean ± SD unless noted	Baseline	Follow-up	*p* value
Group Characteristics			
Male sex, % (n)	73% (22)		
Age, years	51 ± 9		
BMI, kg/M^2	28 ± 3.4	28 ± 3.4	N/A
Sleep Disordered Breathing and Snoring			
Overall AHI, events/hr	24.7 ± 14.7	7.5 ± 7.7	< 0.00001
Supine AHI, events/hr	44.9 ± 25.5	4.5 ± 12.7	< 0.00001
Apnea Index events/hr	12.1 ± 11.3	2.3 ± 3.9	< 0.0001
% time SpO2 < 90%	4.2 ± 5.1	1.2 ± 2.1	< 0.01
% time Snoring > 50dB	39.5 ± 28.7	26.4 ± 25.0	0.034
Sleep Architecture			
Stage N1, %	37.3 ± 15.4	23.1 ± 10.9	< 0.0001
Stage N2, %	45.3 ± 11.8	57.4 ± 8.6	< 0.00001
Stage REM, %	11.5 ± 5.5	13.7 ± 5.1	0.057
Sleep Continuity			
Sleep efficiency, %	80.9 ± 11.9	85.1 ± 7.6	0.051
Arousal Index, hr	31.9 ± 15.4	19.7 ± 11.3	< 0.001
Awakenings, hr	5.9 ± 3.2	4.4 ± 1.7	0.015
Sleep Position			
Time supine, %	46.4 ± 12.7	2.2 ± 6.1	< 0.00001
Supine attempts, hr	0.9 ± 0.5	1.2 ± 0.7	0.029

The mean and median reductions in overall AHI were 69% and 79% respectively. Significant changes in sleep disordered breathing and snoring, sleep architecture and continuity, and sleep position were observed (Table 1). Eighty-three percent of subjects achieved a 50% reduction in overall AHI (Table 2).

Table 2: Classification accuracy of loud snoring vs. overall, supine, and non-supine AHI during diagnostic recordings

Values listed: % of total (n)	Mild	Moderate	Severe	
	≥5 AHI <15	≥15 AHI <30	AHI ≥30	Total
Group size, n	11	10	9	30
AHI < 10 and > 50% reduction	81.8 (9)	80.0 (8)	55.6 (5)	73.4 (22)
AHI > 50% reduction	0.0 (0)	0.0 (0)	33.3 (3)	10.0 (3)
AHI > 35% reduction	9.1 (1)	0.0 (0)	11.1 (1)	6.7 (2)
Non-responder	9.1 (1)	20.0 (2)	0.0 (0)	10.0 (3)

Reference: Assessment of neck-based treatment and monitoring device for positional obstructive sleep apnea. Levendowski DJ, Seagraves S, Popovic D et al. J Clin Sleep Med 2014, in press

Results (Continued):

Figure 1 compares the total number of arousals occurring as a result of sleep disordered breathing vs. the number of supine attempts/arousals that resulted from position avoidance feedback.

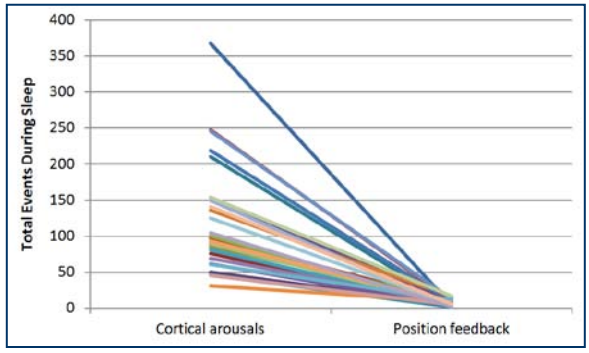

Figure 1: Comparison of total number of cortical arousals vs. positional feedback events during sleep

Table 3 presents mean changes in subjectively reported outcome measures resulting from four-weeks of position therapy. A moderate association was observed between the ESS and depression change scores (r = 0.63, p < 0.001).

Table 3: Changes in subjectively reported outcome measures after four-weeks of position avoidance therapy

All values mean ± SD	Pre-treatment	Post-treatment	*p* value
Daytime Somnolence – ESS	11.3 ± 4.6	9.5 ± 4.6	0.064
Insomnia – ISI	11.0 ± 5.6	8.9 ± 5.4	0.066
Depression – PHQ-9	7.0 ± 5.0	8.9 ± 5.4	0.027
Quality of Life – POMS	57.0 ± 21.6	49.1 ± 18.9	0. 068

Table 4 summarizes median and mean compliance and efficacy metrics across four-weeks of position therapy. No patterns emerged to suggest patients behaviorally trained to avoid the supine position as a result of four-weeks of therapy.

Table 4: Median (mean + SD) and position therapy recordings

Median (mean + SD)	Week 1	Week 2	Week 3	Week 4	*p* value
Average days used	7 (6.9 ± 0.4)	7 (7.0 ± 0.2)	7 (6.8 ± 0.5)	7 (7.0 ± 0.2)	0.240
Average hours used	6.7 (7.2 ± 1.3)	6.9 (7.0 ± 1.4)	7.1 (7.1 ± 1.2)	6.8 (7.0 ± 1.3)	0.934
Average percent time supine	0.8 (1.7 ± 2.0)	0.7 (2.2 ± 4.6)	0.6 (1.8 ± 3.1)	0.6 (1.8 ± 3.5)	0.957
Supine attempts/night	6 (6.9 ± 4.0)	6 (6.7 ± 4.8)	5 (6.3 ± 3.6)	5 (5.7 ± 3.7)	0.684
Average feedback duration (sec)	12 (26 ± 26.5)	12 (22 ± 19.0)	10 (20 ± 29.3)	10 (19 ± 28.4)	0.741
Average % time snoring > 50dB	8.8 (25 ± 29.5)	11.7 (25 ± 26.1)	12.6 (26 ± 27.3)	13.5 (26 ± 26.4)	0.999

Conclusion:

- Supine avoidance therapy was effective in reducing sleep disordered breathing in the vast majority of patients with positional OSA.
- The associated reduction in OSA severity resulted in significant improvements in sleep architecture and sleep continuity. Limited improvements in subjectively reported symptoms were observed.
- The number of OSA associated cortical arousals which occur subsequent to delivery of positional treatment are an order of magnitude greater than the number of arousals attributed to supine avoidance feedback.
- While short term compliance appears promising, additional studies are needed to assess long term compliance with position therapy.

Accuracy of Neck Actigraphy in the Assessment of Behavioral Sleep/Wake

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Introduction:

Wrist actigraphy is conventionally used to provide a behavioral assessment of sleep vs. wake. This study evaluates the accuracy of actigraphy acquired from the back of the neck in patients with obstructive sleep apnea.

Methods:

Thirty-five subjects (26 males and 9 females, BMI 28 ± 3.1 kg/m2, age 50 ± 9.3 years) completed a baseline laboratory polysomnography (PSG) while concurrent measurements were obtained while wearing a neck-device. Approximately four-weeks after the baseline study, 30 subjects completed a follow-up PSG while the neck-device delivered vibro-tactile supine avoidance feedback.

Figure 1: Photograph of neck-device from a) back, and b) front.

For PSG, sleep was manually scored according to the American Academy of Sleep Medicine criteria.

For the neck-device, sleep vs. wake was measured in 30-second epochs using a threshold applied to the median filter output derived from the three X, Y, and Z signals. If any of the three signals had an angle < 50° and exceeded the actigraphy threshold, the epoch was classified as awake. Periods with gross movement extend the wake classification for up to 3 epochs. The initial ten-minutes after the device was turned on were automatically classified as wake. Sleep/wake detection was applied in real-time with the results stored to the device memory.

After alignment, epoch by epoch comparisons were made between the PSG and the neck-device. Individual results for sleep (sensitivity) and wake (specificity) were then averaged across subjects. Bland-Altman plots were used to compare differences in the measurement of total sleep time, sleep efficiency, sleep onset, and wake-after-sleep-onset.

Results:

Table 1 presents the mean sensitivity (sleep) and specificity (wake) of neck actigraphy as compared to PSG. Detection of wake improved during the follow-up PSG, likely due to the reduction in awakenings resulting from significant improvements in sleep disordered breathing severity. Once treated, significant improvements in the overall accuracy across sleep and wake epochs were observed.

Table 1: Classification accuracy of the Neck-Device detection of Sleep vs. Wake vs. PSG

Mean + SD	Baseline	Follow-up	*p* value
Sensitivity – sleep	90.1 ± 8.6	91.2 ± 8.1	0.317
Specificity – wake	55.8 ± 18.7	61.1 ± 16.8	0.132
Overall agreement	82.3 ± 9.3	86.5 ± 6.5	0.025
Overall AHI	24.7 ± 14.7	7.5 ± 7.7	< 0.00001

Results (Continued):

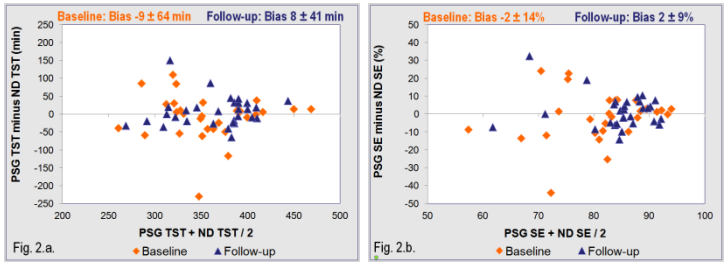

Figure 2: Bland Altman plots comparing PSG vs. ND sleep time for a) Total Sleep Time (TST), and b) Sleep Efficiency (SE).

Figure 2.a. presents differences in total sleep time (TST) from PSG and the neck-device. Eight baseline studies (27%) and three follow-up studies (10%) had ≥ 15% absolute error between the two TST measures (y-axis) relative to their average TST (x-axis). Eight of the 11 gross errors over-reported TST from the neck-device.

Figure 2.b. presents differences in sleep efficiency (SE). Twenty-one baseline studies (70%) and 26 follow-up studies (87%) had an absolute SE error ≤ 10%. Errors were biased toward over-reporting sleep during the baseline and under-reporting sleep during the follow-up studies.

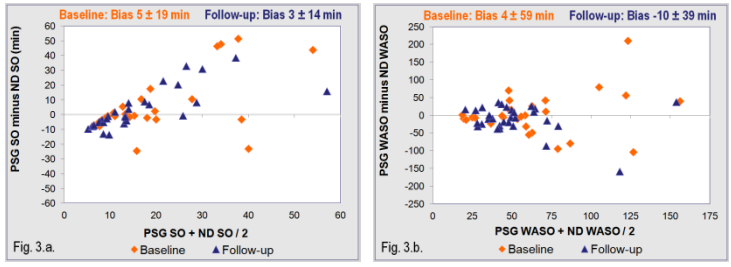

Figure 3: Bland Altman plots comparing PSG vs. ND sleep time for a) Sleep Onset (SO), and b) Wake After Sleep Onset (WASO)

Figure 3.a. presents differences in detected sleep onset (SO) between PSG and the neck-device. Twenty-three baseline studies (77%) and 24 follow-up studies (80%) had an absolute SO error ≤ 15-min. Eleven of the 13 gross errors (85%) were biased toward early detection of SO from the neck-device.

Figure 3.b. presents differences in wake after sleep onset (WASO). Nine baseline studies (30%) and only two follow-up studies (7%) had an absolute WASO error ≥ 45 minutes. Errors were similarly distributed toward under- and over-reporting WASO during the baseline when the preponderance of errors were observed.

Conclusion:

- Neck actigraphy provides reasonable accuracy in behaviorally estimating sleep/wake.
- The percentage of records with gross TST and SE errors were similar in patients with OSA and were superior to the error estimates reported for wrist actigraphy.
- Neck actigraphy was biased toward early detection of SO, similar to wrist actigraphy.
- TST, SE, and WASO accuracies improved substantially when the OSA was treated with positional therapy.

Reference: Assessment of a neck-based treatment and monitoring device for positional obstructive sleep apnea. Levendowski DJ, Seagraves S, Popovic D et al. J Clin Sleep Med 2014, in press.

Capability of a Neck Worn Device to Differentiate Benign Snoring From Obstructive Sleep Apnea

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American Thoracic Society conference preceding, May 2014, San Diego, CA

Introduction:

To evaluate the potential for using loud snoring, measured with an acoustic microphone from the neck, as a simple and objective tool to identify those with a high probability of having obstructive sleep apnea (OSA).

Methods:

Fifty-five subjects were studied during laboratory polysomnography (PSG) with simultaneous recordings using a device worn on the back of the neck. Overall, supine, and non-supine apnea/hypopnea indices were scored according to the American Academy of Sleep Medicine criteria.

Data from two groups were included in the analysis (Table 1). Group 1 included 31 comparisons with 9 recordings obtained during all-night diagnostic studies and 22 recordings obtained from 11 subjects with split-night studies (the diagnostic and CPAP titration periods were analyzed separately). Group 2 included 65 recordings with 35 obtained during diagnostic studies and 30 obtained approximately four-weeks later while vibro-tactile, supine avoidance feedback was delivered. The AHI for Groups 1 and 2 were based on oxyhemoglobin desaturations of 3% and 4%, respectively. Positional OSA was based on a supine AHI two or more times greater that the non-supine AHI.

The neck-device measured snoring with an acoustic microphone and both neck position and sleep/wake with an accelerometer. The percentage of time snoring >50dB was determined for overall, supine, and non-supine epochs characterized as sleep by actigraphy. Snoring indicative of clinically relevant sleep disordered breathing was based on >50dB snoring in >10% of neck-based sleep time

Table 1: Demographic and Anthropomorphic Data	Group 1	Group 2
Sample size (n)	20	35
Males	75%	77%
Age (years ± SD)	46 ± 13.2	50 ± 9.4
BMI (kg/m2 ± SD)	29 ± 4.1	29 ± 3.3
Overall AHI	19 ± 16.0	28 ± 23.1
Supine AHI	23 ± 19.4	43 ± 26.7
Non-Supine AHI	17 ± 24.5	10 ± 14.2
Positional OSA (%) with supine AHI ≥5	62.5%	94.3%

Results:

Table 2 presents the classification accuracies of loud snoring in its capability to characterize obstructive sleep apnea in the diagnostic recordings from Groups 1 and 2 across clinical cutoffs of 5, 10, and 15 events/hr. The results suggest that loud snoring was slightly less sensitive and more specific than the Stop Bang or Berlin Questionnaires in identifying those with a high pre-test probability of having at least mild OSA. Differences in screening accuracy were noted for the supine and non-supine positions.

Table 2: Classification accuracy of loud snoring vs. overall, supine, and non-supine AHI during diagnostic recordings

Dx	Overall			Supine			Non-supine		
	>5	>10	>15	>5	>10	>15	>5	>10	>15
Sensitivity	74.5	81.0	84.8	70.8	100.0	100.0	72.6	84.3	87.2
Specificity	75.0	76.9	59.1	83.3	50.0	45.2	78.6	58.5	50.9
PPV	94.6	91.9	75.7	97.1	39.1	26.1	95.8	71.7	56.7
NPV	33.3	55.6	72.2	26.3	100.0	100.0	29.7	75.0	84.4

Results (Continued):

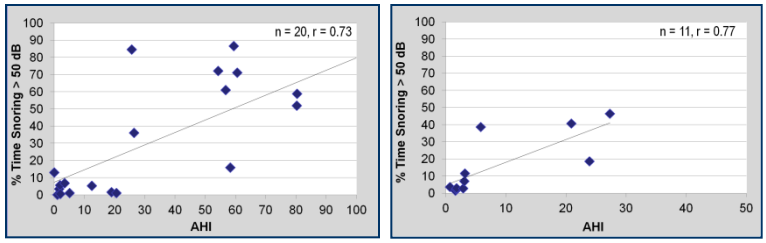

Figure 1: Correlation plot between % time snoring >50 dB and AHI with 3% desaturation during a) diagnostic PSG, and b) CPAP titration.

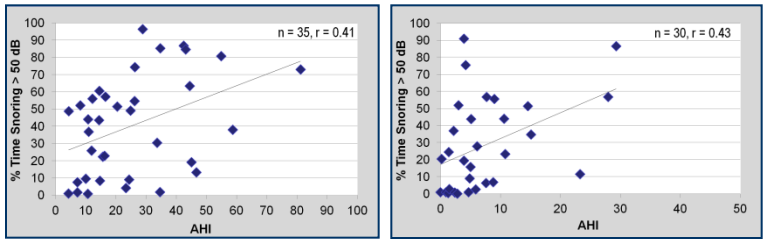

Figure 2: Correlation plot between % time snoring >50 dB and AHI with 4% desaturation during a) diagnostic PSG, and b) position therapy.

Correlations between loud snoring and the AHI are presented in Figure 1 during diagnostic and treatment recordings based on a 3% oxyhemoglobin desaturation, with corresponding results based on a 4% desaturation presented in Figure 2. The associated classification accuracies are presented in Tables 3 and 4.

Table 3: Classification accuracy of loud snoring vs. AHI with 3% desaturation criteria during diagnostic and CPAP titration recordings

AHI based on 3% desat	Dx and Tx Combined			Dx			Tx – CPAP Titration		
	> 5	> 10	> 15	> 5	> 10	> 15	> 5	> 10	> 15
Sensitivity	77.8	87.5	86.7	71.4	76.9	83.3	100.0	100.0	100.0
Specificity	84.6	80.0	81.3	83.3	85.7	87.5	85.7	75.0	75.0
PPV	87.5	82.4	81.3	90.9	90.9	90.9	80.0	60.0	60.0
NPV	73.3	85.7	86.7	55.6	66.7	77.8	100.0	100.0	100.0

Table 4: Classification accuracy of loud snoring vs. AHI with 4% desaturation criteria during diagnostic and position therapy recordings

AHI based on 4% desat	Dx and Tx Combined			Dx			Tx – Position Therapy		
	> 5	> 10	> 15	> 5	> 10	> 15	> 5	> 10	> 15
Sensitivity	76.6	86.1	88.0	75.8	82.8	85.7	78.6	100.0	100.0
Specificity	50.0	51.7	42.5	50.0	66.7	42.9	50.0	47.8	42.3
PPV	80.0	68.9	48.9	96.2	92.3	69.2	57.9	36.8	21.1
NPV	45.0	75.0	85.0	11.1	44.4	66.7	72.7	100.0	100.0

Conclusion:

The capability of loud snoring to accurately estimate important sleep disordered breathing appears to be affected, at least in part, by the SpO2 desaturation criteria used. During the diagnostic studies, the 3% criteria contributed to improved correlations and screening accuracy.

Improved accuracies during the treatment recordings for Group 1 are likely affected by the fact that subjects were being treated with CPAP, and thus less snoring would be expected relative to the AHI.

Based on a 4% desaturation criteria, loud snoring does not appear to be effective in ruling out mild OSA in patients sleeping laterally in conjunction with supine avoidance therapy.

Further studies must be conducted to determine if changes in the percent time snoring correspond with changes in sleep disordered breathing severity.