A Multi-Centre Evaluation of Oral Pressure Therapy for the Treatment of Obstructive Sleep Apnoea

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Abstract

OBJECTIVES: This study sought to evaluate a new non-invasive oral pressure therapy (OPT) system (Winx(TM), ApniCure) for treatment of obstructive sleep apnoea (OSA). The system is comprised of a bedside console and a soft polymer mouthpiece with tubing. The console contains a pump that creates vacuum drawing the soft palate anteriorly and stabilizing the tongue to reduce obstruction during sleep.

METHODS: Sixty-three eligible subjects at 6 centres, 69.8% male, 53.6+/-8.9 years (mean+/-SD), BMI 32.3+/-4.5 kg/m^2, with mild to severe OSA underwent laboratory polysomnography at baseline (one night with (Tx1) and one without treatment in randomized order) and again following 28 nights of treatment (Tx28). Total apnoea-hypopnea index (AHI(/hr)) and oxygen-desaturation index (>4% events) were scored blindly using AASM criteria. Epworth Sleepiness Scale (ESS) and Clinical Global Impression Severity and Change (CGI-S and CGI-C) were assessed at baseline and Tx28. OPT usage was recorded by the console.

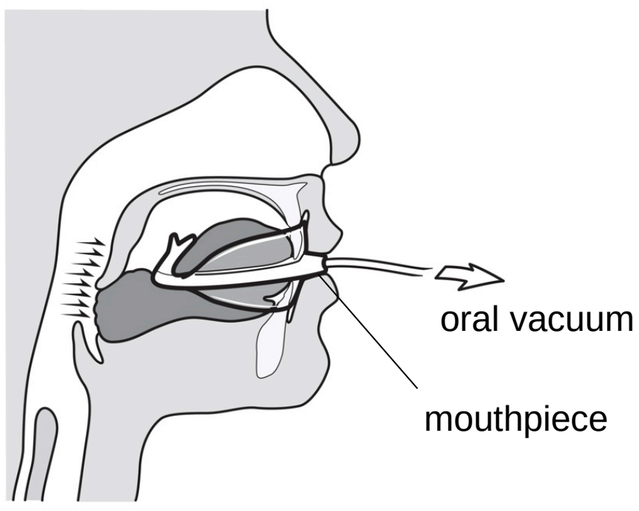
RESULTS: Baseline AHI (35.5+/-24.5, mean+/-SD) was significantly reduced at Tx1 (23.1+/-24.0) and at Tx28 (21.6+/-21.7). Baseline ODI (29.7+/-21.8, mean+/-SD) was significantly reduced at Tx1 (20.7+/-22.4) and at Tx28 (19.6+/-20.6). Clinical success defined a priori as AHI reduction >= 50% and treatment AHI <= 20 at Tx1 was observed in 26/63 subjects (4/15 mild, 10/18 moderate, 12/30 severe). In these 26 subjects, AHI (median (interquartile range)) was reduced from 26.2 (19.8-45.3) to 5.7 (3.6-10.0) while ODI was reduced from 19.2 (14.8-35.4) to 4.7 (2.5-9.0). For 20 subjects, Tx1 AHI was <=10. Median ESS scores were unchanged in subjects who switched directly from CPAP therapy to OPT study participation and were significantly reduced from 13 (8-16) to 8 (4-12) in those untreated for two or more weeks prior to OPT study participation. Average nightly usage across the take-home period was 6.0+/-1.4 hours. On CGI-C, 58% of subjects scored much improved or very much improved. There were no severe or serious device-related adverse events. Six subjects were terminated or withdrawn prior to completion of 28 nights of treatment (three for device intolerability, two for high AHI with inadequate treatment response, one for scheduling).

CONCLUSION: Clinically significant improvements in AHI, ODI, ESS and overall clinical status were achieved in an easily identified sub-group. Oral pressure therapy was safe and well-tolerated and nightly usage was high.

SUPPORT: ApniCure, Inc.

Background and Objectives

- Oral Pressure Therapy (OPT) is a novel approach to treating obstructive sleep apnea (OSA).
- The OPT system (Winx™, ApniCure, Inc., Redwood City, CA) comprises a bedside console, a soft polymer mouthpiece, and a flexible tube connecting the mouthpiece to the console. The console creates vacuum pulling the soft palate anteriorly and stabilizing the tongue to reduce obstruction during sleep.
- This study examined the safety, effectiveness, and tolerability of this system.



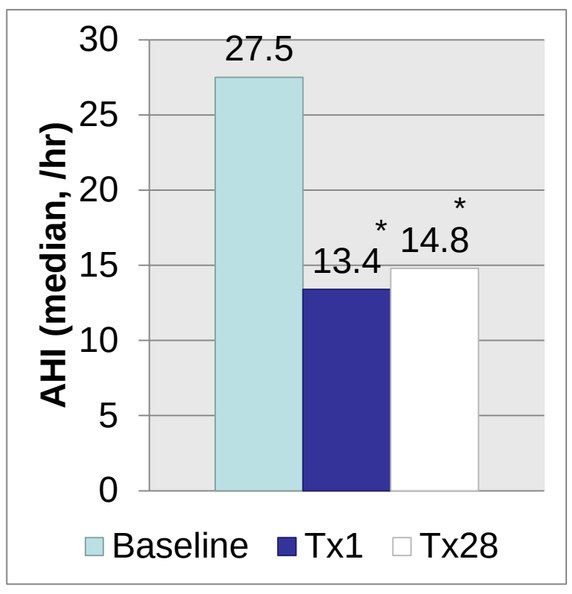
Methods

- Six centers, Good Clinical Practice
- Subjects with mild to severe OSA, with or without prior CPAP use
  - Exclusions: poor nasal patency, OSA surgery history, central sleep apnoea, severe cardiovascular disease, BMI > 40, age <18 years or >80 years, insomnia, inadequate mouthpiece fit
- PSG obtained at baseline (without OSA treatment for at least 2 weeks) and with treatment (Tx1) in random sequence. PSG repeated with treatment (Tx28) after 28 nights of usage.
  - Respiratory inductance plethysmography, nasal airflow cannula, oral airflow thermistor, finger oximeter, video body position
  - PSG scored blindly using AASM recommended criteria by one scorer
- Symptomatic measures: Epworth Sleepiness Scale (ESS) and a modified Functional Outcomes of Sleep Questionnaire (mFOSQ)
  - Sub-analysis by use of prior OSA treatment at time of baseline symptom measurement
- Clinical Global Impression Severity and Change assessed at baseline and Tx28
- Subjects' opinion of therapy scored on Likert scale.
- Usage recorded objectively by console
- Analysis cohort had:
  - total sleep time (TST) ≥ 4 hours at baseline and Tx1
  - AHI ≥ 5 at baseline
- Sub-analysis responder cohort: prospectively defined clinical success criteria of AHI reduction (Tx1 vs baseline) ≥50% and Tx1 AHI ≤20
- Statistics: signed rank test

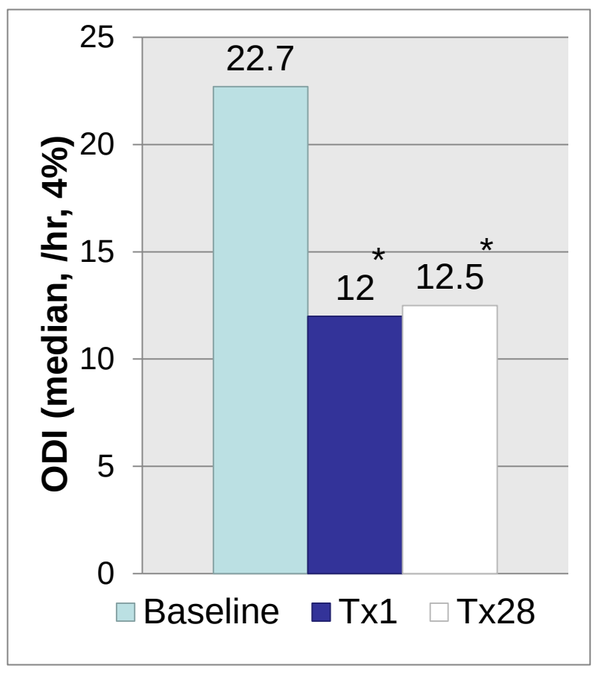
Results: Analysis Cohort (n=63)

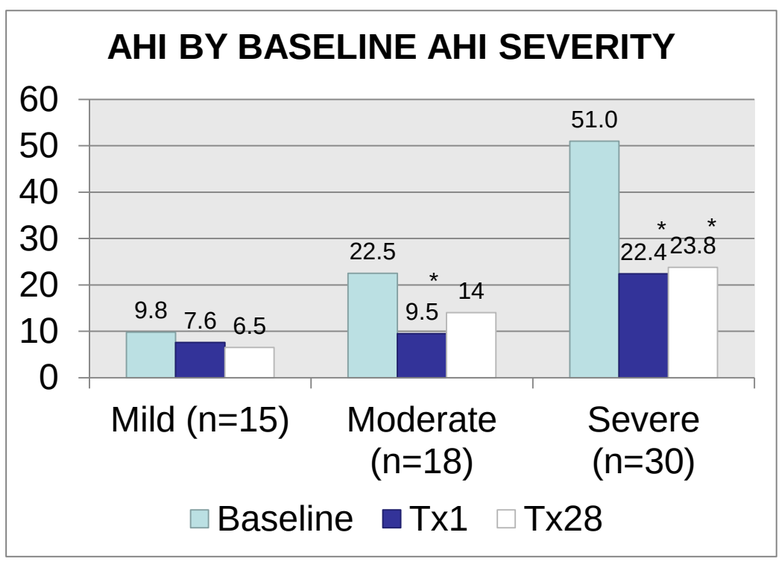
SUBJECTS (analysis cohort)

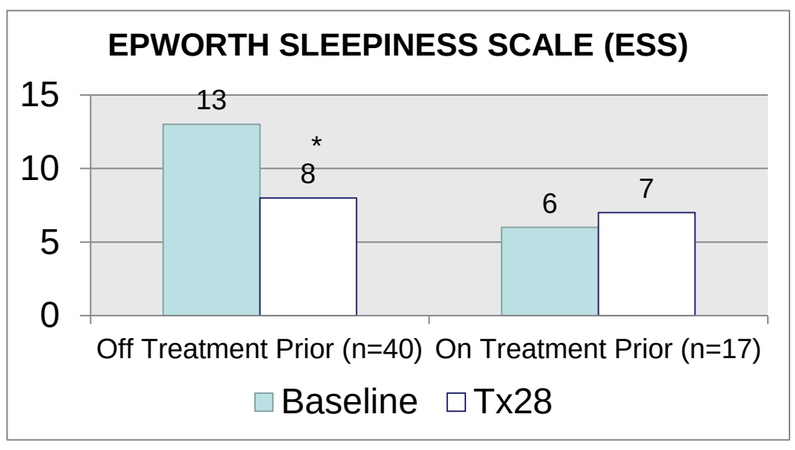
- 63 subjects (44 male)
- BMI 32.3±4.5 kg/m^2 (mean±SD)
- age 53.6±8.9 years (range 32-80)
- OSA treatment history: 33% naïve, 24% CPAP failure, 43% CPAP user

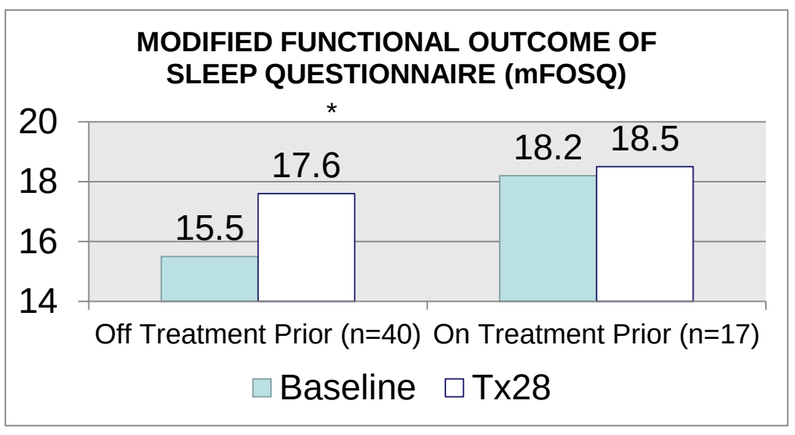


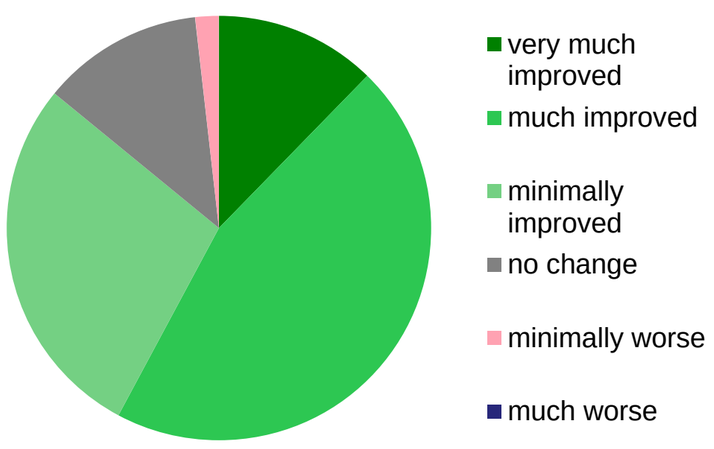
* p<0.05 vs. baseline











COMPLIANCE (analysis cohort)

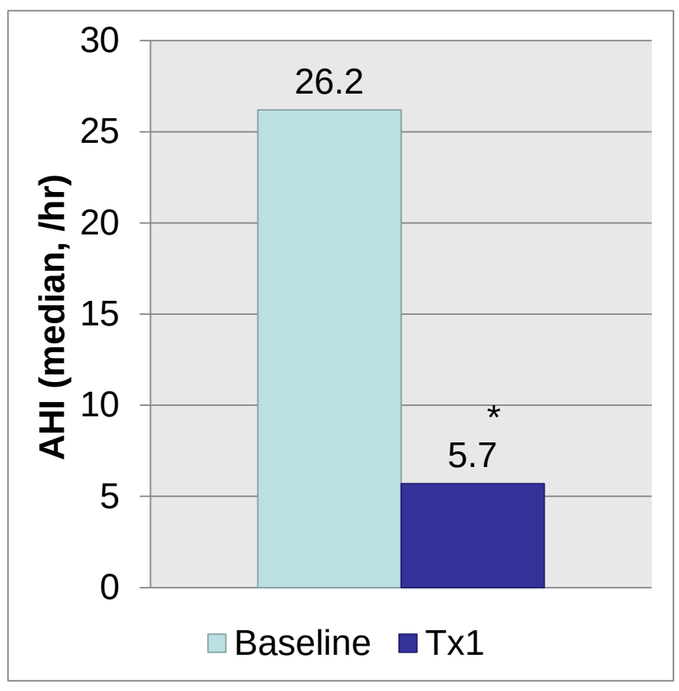
- Median usage per night was 6.0 hours.
- Median % of nights with more than 4 hours of usage was 88.9%.
- 76% of subjects agreed with the statement, "I would use the system to treat my sleep apnea."

SAFETY (analysis cohort)

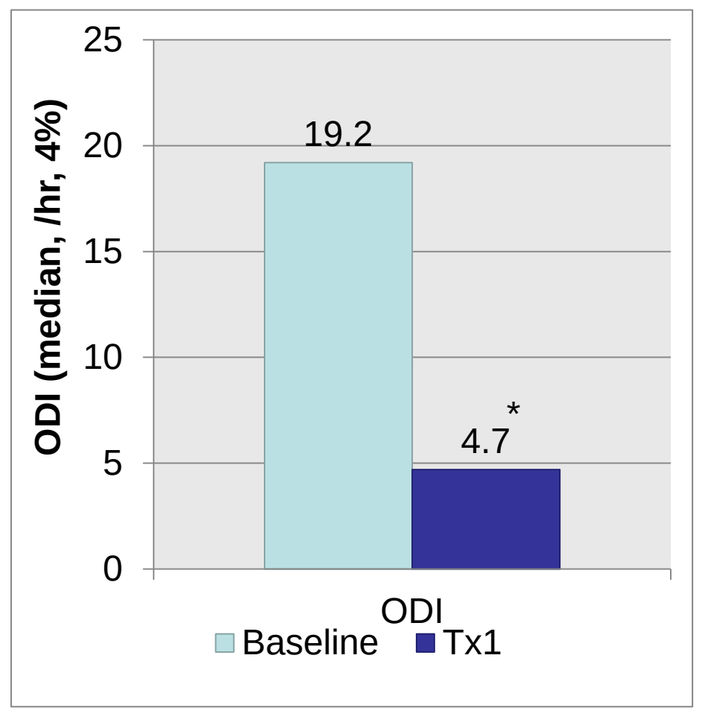
- No serious device-related adverse events or unanticipated adverse device effects
- 5 subjects withdrew before completing 28 nights of treatment
  - 3 due to oral tissue discomfort and irritation
  - 2 due to high AHI with inadequate therapeutic response

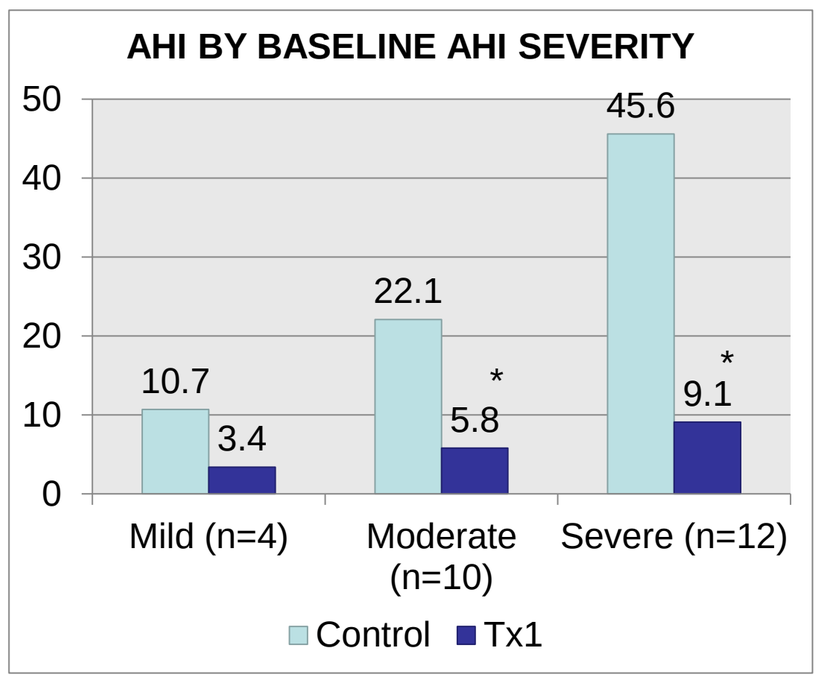
Results: Responder Cohort (n=26)

- 26 of 63 (41.3%) met criteria of AHI reduction (Tx1 vs baseline) ≥50% and Tx1 AHI ≤20
- 20 subjects had Tx1 AHI <10



* p<0.05





Conclusions

AHI, ODI, and symptomatic measures including Epworth Sleepiness Scale, a modified FOSQ, and Clinical Global Impression Severity were significantly improved by OPT. Nightly usage was high in frequency and duration and subjects indicated interest in using OPT to treat their OSA. Response to OPT is easily evaluated in individuals. OPT is a new, safe, well tolerated non-invasive therapy for OSA in appropriate patients.