A Mandibular Positioning Home Sleep Test Prospectively Predicts Outcome of Oral Appliance Therapy for OSA Using Retrospectively Derived Decision Criteria

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ABSTRACT

Rationale: Oral appliance therapy (OAT) resolves sleep apnea in only 50-60% of cases, pointing to the need to prospectively identify therapeutic responders. We sought to assess the accuracy of an auto-titrating mandibular positioner (AMP) with machine learning to predict therapeutic outcome and an efficacious mandibular position.

Methods: Two independent populations (Phase 1: n=149; Phase 2: n=53) of participants with obstructive sleep apnea (OSA) participated in a prospective, blinded clinical trial. Data from Phase 1 were used to develop the predictive method, and data from Phase 2 were used to evaluate its accuracy. Each participant underwent two full-night AMP studies in the home while using a temporary dental appliance, and each was treated with a custom oral appliance. Predictive efficacious (target) position was derived from the AMP study. Therapeutic outcome sleep tests were performed after full clinical adjustment. Prediction of therapeutic outcome was derived from the analysis of a machine learning method (Random Forest).

Results: Using oxygen desaturation index (ODI) of less than 10 hr^{-1} at outcome as the criterion of therapeutic success, predictive accuracy was as follows for Phase 2: sensitivity: 85%; specificity: 93%; positive predictive value: 97%; negative predictive value: 72%; and accuracy: 88%. Of participants correctly predicted to respond to OAT, the predicted mandibular position proved to be an efficacious position in 86% of cases.

Conclusions: Data from an unattended, in-home sleep study with an auto-titrating mandibular positioner, analyzed by a machine learning method, accurately identifies OSA patients who will respond to OAT. The study also provides a therapeutic target protrusive position that is efficacious in the majority of OAT responders.

INTRODUCTION

We have developed an auto-titrating mandibular positioner (AMP) home test for predicting outcome with oral appliance therapy (OAT) in individuals with obstructive sleep apnea (OSA). The AMP home test is comprised of 2 unattended nights of study during which apneas and hypopneas are detected in real time via oxyhemoglobin saturation and respiratory airflow feedback signals.

METHODS

- Prospective, blinded (physician and dentist), controlled study involving two sequential, independent populations (Phase 1: n=149; Phase 2: n=53)
- Between the two study phases, 8 (4%) participants were unable to collect sufficient AMP data (inconclusive) and 15 were lost to follow-up, leaving a final study population of 179 participants (n=131 for Phase 1; n=48 for Phase 2)
- Broad inclusion criteria (ODI > 10 hr^{-1}, BMI < 45 kg/m^2)
- 2-3 full night tests with an AMP in the home with automated provisional prediction of therapeutic outcome and efficacious mandibular position (target)
- All participants received an oral appliance (Phase 1: G2, SomnoMed; Phase 2: MicrO$_2$, MicroDental Laboratories) set to target protrusion (default position of 70% for predicted non-responders)
- Participants were tested at target, then further protruded in 1-2mm increments until therapeutic success (ODI <10 hr^{-1}) or until clinical limits of protrusion were reached
- Machine learning (Random Forest) was used to predict outcome
  - Phase 1 data were used to train the Random Forest; Phase 2 data were used to evaluate the Random Forest machine accuracy
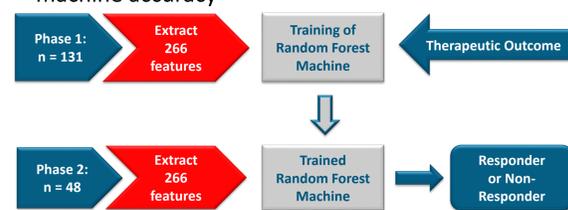

Figure 1. The two-phase approach used to first train and then validate the predictive model.

Participant Baseline Characteristics

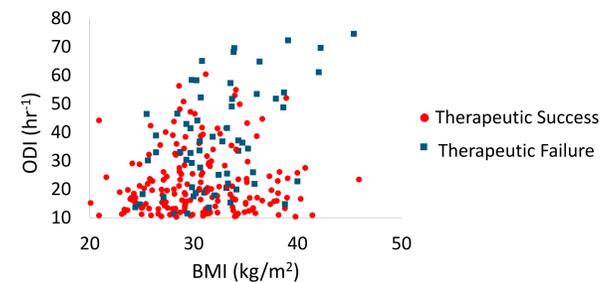|	Phase 1 (n=149)	Phase 2 (n=53)
Age (years)	50.2±10.8	48.8±10.8
Females/Males	25/124	8/45
BMI (kg•m^2)	30.1±4.2	33.1±5.4
ODI (events•hr^{-1})	26.2±14.0	30.1±16.5
SaO$_2$ (%)	92.0±1.5	91.7±2.0

RESULTS

Figure 2. Distribution of baseline ODI and BMI for Phase 1 and Phase 2 study participants (n=179).
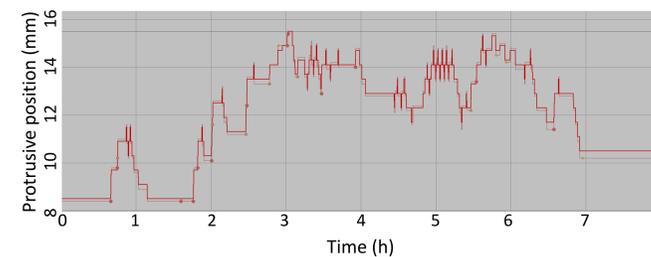

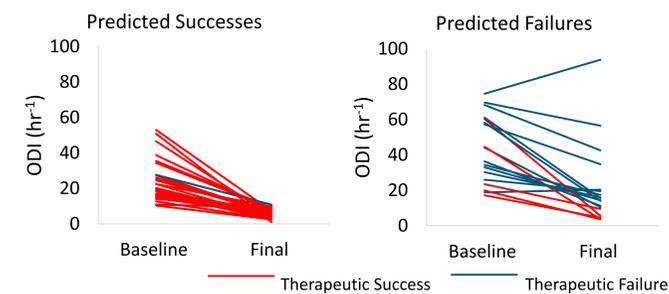Figure 3. AMP study data for true positive. Respiratory events are denoted by circles.

Figure 4. ODI at baseline and final therapeutic position for predicted successes (left panel) and predicted failures (right panel) for Phase 2 study participants (n=48).
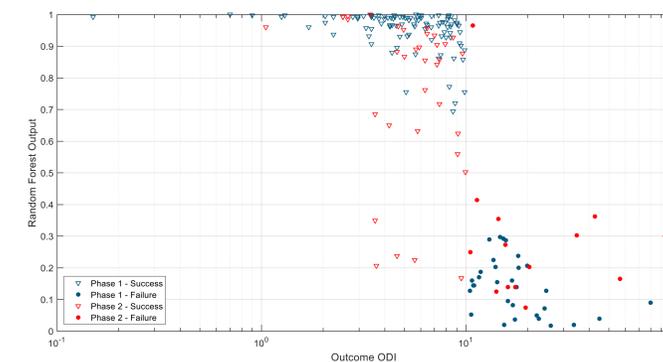

Figure 5. Random Forest output versus outcome ODI. The Random Forest (400 trees) was trained on Phase 1 data (blue data points) then applied to Phase 2 data (red data points). In this figure, Random Forest output is the proportion of trees that predicted success for a given participant.

	Predicted Success	Predicted Failure		
Therapeutic Success	29	5	Sensitivity	85%
Therapeutic Failure	1	13	Specificity	93%
	PPV	NPV		
	97%	72%		

Figure 6. Positive and negative predictive values, sensitivity, and specificity of Phase 2 data (n=48). The overall accuracy was 88%.
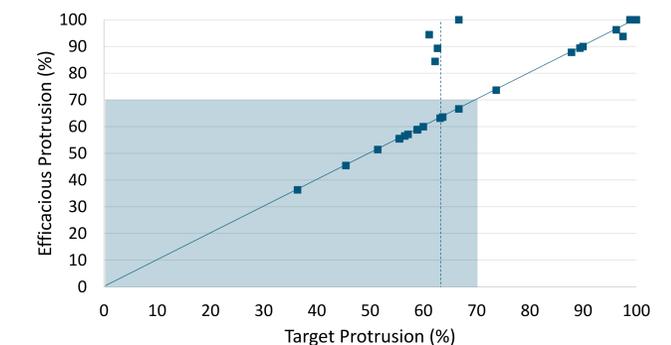

Figure 7. Target position vs. efficacious protrusion. Of Phase 2 participants who were true positives, the overall target accuracy was 86%. The median target position was 63.4% (dashed line).

Distribution and Acceptance of Target Position

Target Protrusive Position	<70%	n=34
	>70%	n=14
OA Placement at Target Position	Target <70%	97% able to accept target without OA adjustment
	Target >70%	38% able to accept target without OA adjustment

DISCUSSION

Our results show that an AMP can be used in unattended studies to predict OAT outcome and an efficacious mandibular position. Data from 179 participants (2-3 study nights per participant) showed that the AMP home studies were feasible, well-tolerated, and safe. Random Forest machine learning analysis trained on Phase 1 data and applied to Phase 2 data resulted in a predictive accuracy of 88% and a positive predictive value of 97%. 86% of Phase 2 study participants were successfully treated at target.

CONCLUSIONS

- We have developed an AMP system suitable for unattended sleep studies
- A predictive method derived from 131 participants and applied prospectively to 48 participants showed good predictive accuracy in identifying favorable candidates for oral appliance therapy

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