



An Auto-Titrating Mandibular Positioner: Accuracy in Predicting Oral Appliance Therapy Outcome and Efficacious Mandibular Protrusion

S. Charkhandeh, DDS^{2,3}, Z. Topor, PhD^{1,2}, J. Grosse, MMath², N. Vranjes, DDS³, S.A. Zareian Jahromi, PhD^{1,2}, J. D'Andrea, PhD², S. Bruehlmann, PhD², J.E. Remmers, MD^{1,2}

¹University of Calgary, ²Zephyr Sleep Technologies, ³Snore Center, Calgary, Alberta, Canada

ABSTRACT

Introduction: We have developed an auto-titrating mandibular positioner for predicting oral appliance therapy (OAT) outcome and efficacious target protrusive position (ETPP) in obstructive sleep apnea (OSA). The present study evaluates the accuracy of the automated titrator when used unattended in the home.

Methods: Study participants (n=124, mean AHI=24.9±13.0hr⁻¹) were derived from 151 patients with OSA, of whom 9 discontinued participation, 14 are currently in progress, and 4 had inconclusive studies. The remaining 124 participants formed our study population. All participants received a two night unattended mandibular titration study at home. The mandibular positioner comprised of temporary dental trays attached to a computer-controlled actuator, and during the titration study, apneas and hypopneas were automatically detected from respiratory airflow and oxyhemoglobin saturation. Study 1 involved continuous interaction between detected respiratory events and mandibular position. In Study 2, the positioner held the mandible at an ETPP predicted by Study 1, and further protruded the mandible when the AHI exceeded 10hr⁻¹. Prospectively established prediction rules applied to the results of each titration study predicted OAT outcome, either predicted success (PS) or predicted failure (PF), and discrepant predictions were resolved by repeating Study 2. Participants classified PS were prospectively assigned a predicted ETPP, and participants classified PF were assigned a sham protrusive target (70% of full protrusion). All participants received a custom dental appliance (G2 Somnomed). Baseline and outcome AHI values were the mean of two nights of home sleep testing, and therapeutic success with OAT was defined as outcome AHI<10hr⁻¹ & 50% of baseline AHI.

Results: The unattended auto-titration studies provided satisfactory results in almost all cases (inconclusive study rate: 3%). The overall therapeutic success rate was 73%. Using prospective prediction rules 83 participants were classified as PS and 41 as PF. Values for sensitivity/specificity and positive/negative predictive (P/NPV) were 0.82/0.76 and 0.90/0.61, respectively, with an overall incorrect prediction rate of 19%. A retrospective, classification decision tree analysis reduced this rate to 11% and provided values for sensitivity/specificity and P/NPV values of 0.93/0.77 and 0.91/0.82, respectively. Of the 75 PS participants who experienced therapeutic success, 71 responded at the predicted ETPP (PPV = 0.95). For the 75, the median relative protrusion at therapeutic success was 75% (range: 9–100%) and in 41% therapeutic success occurred at less than 70% of full protrusion.

Conclusions: The results of this prospective clinical trial show that the auto-titrating mandibular positioner is suitable for use in the home and accurately predicts OAT outcome as well as an ETPP. The system may increase OAT efficacy and efficiency while avoiding excessive mandibular protrusion in some cases.

INTRODUCTION

We have developed a home test for predicting outcome with oral appliance therapy (OAT) and an efficacious mandibular position. The test uses a computer-controlled mandibular positioner, which receives information about the patient's respiratory status and automatically adjusts the degree of mandibular protrusion during the night.

The objective of the study was to evaluate the predictive accuracy of the CCMP in

- selecting patients suitable for oral appliance therapy, and
- establishing target efficacious protrusive position.

METHODS

- A prospective, blinded outcome study was carried out on consecutive patients that met the inclusion criteria (n=149, 13 discontinued participation) recruited from a sleep clinic or a dental practice using broad inclusion criteria (age 21-80; AHI > 10 hr⁻¹, BMI < 40 kg/m²).
- Each subject underwent 2-3 full night tests in the home. The subject independently applied all sensors as well as the mandibular positioner. Oxygen saturation and respiratory airflow were recorded and respiratory events were identified in real time while the subject slept with temporary dental trays in place.
- The results were automatically analyzed and interpreted by pre-established criteria to predict outcome therapeutic success or failure and a target efficacious protrusive position. Test results were inconclusive in 5 participants.
- Each subject was fitted with a custom oral appliance (Somnomed G2) at the target protrusion identified by the CCMP test. Subjects predicted to be a failure were set at a sham position of 70% (range of motion).
- Subjects were adjusted until AHI was less than 10 hr⁻¹ or clinical limits of protrusion were reached.
- Baseline and outcome AHI values were determined by a home sleep test (using 4% reduction).

Patient Baseline Characteristics

Age (yrs)	50.5 ± 11.0
Females/Males	23/113
BMI (kg.m ²)	30.1 ± 4.2
AHI (events.hr ⁻¹)	25.4 ± 13.2
SaO ₂ (%)	92.1 ± 1.4

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Contact Dr. Charkhandeh at shouresh@gmail.com

RESULTS

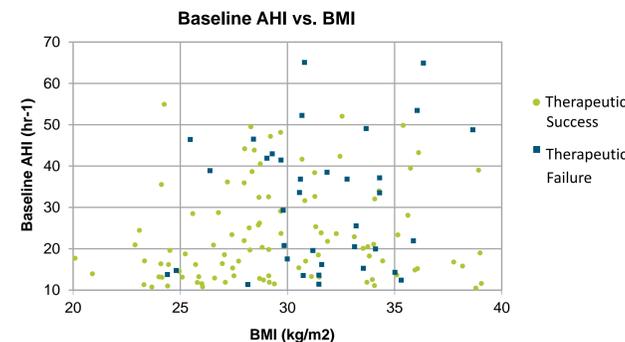


Figure 1. Distribution of baseline AHI and BMI for all participants. Therapeutic success: outcome AHI<10hr⁻¹ & 50% of baseline AHI. Therapeutic success rate was 74%.

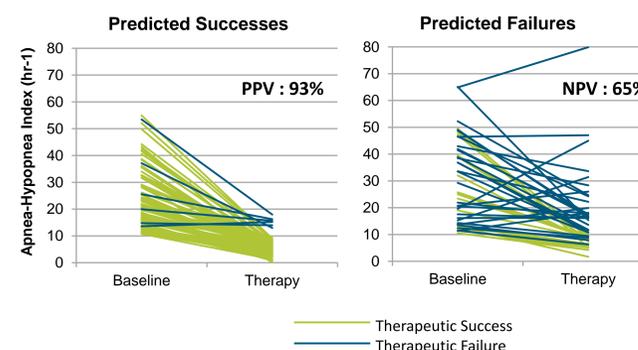


Figure 2. Prospective predictive accuracy. AHI at baseline and final therapeutic position for predicted successes (left panel) and predicted failures (right panel). Overall error rate: 17%; sensitivity: 83%; specificity: 83%.

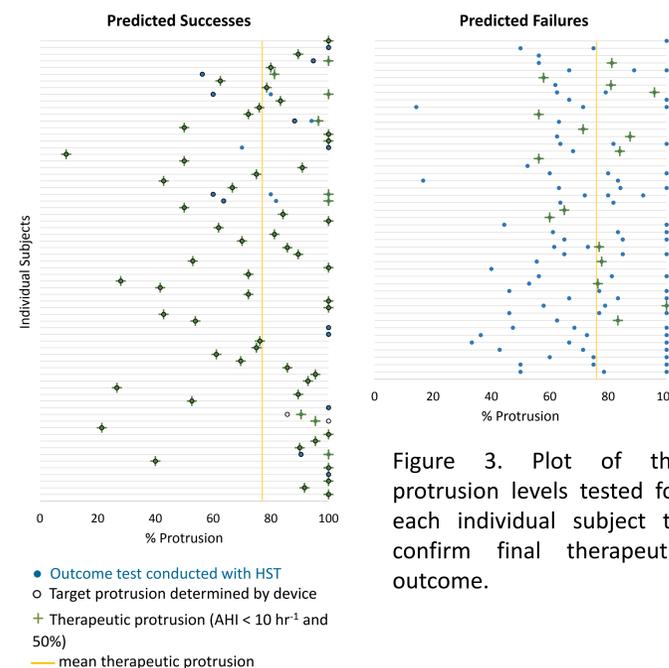


Figure 3. Plot of the protrusion levels tested for each individual subject to confirm final therapeutic outcome.

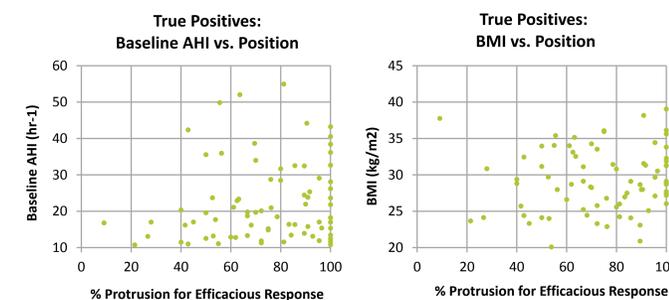


Figure 4. Distribution of baseline AHI and BMI in relation to mandibular position at efficacious response.

A. Therapeutic Outcome @ Target Protrusion		#Subjects (PS group)	B. Target Protrusion	
Therapeutic Success		73	<50%	100%
Therapeutic Failure		6	60-69%	100%
Target Accuracy*		92.4%	70-79%	100%
			80-89%	78%
			90-100%	38%

Table 1. A. Predictive accuracy at target. B. The percentage of predicted success subjects that could be inserted directly at the provided target protrusion. The remaining subjects titrated gradually out to their target protrusion.

Time to Treatment	Predicted Success	Predicted Failure
Median	0 days	87 days
Mean	26.4 days	103.3 days

Table 2. Titration period (treatment, max protrusion or clinical endpoint).

DISCUSSION

Our results show that a computer controlled mandibular positioner can be used in unattended studies to predict OAT outcome and an efficacious mandibular position. The predictive accuracy for outcome using prospectively established criteria was reasonable (PPV: 93%; error rate: 17%). This was improved by using retrospectively determined criteria (error rate: 12%) that now require prospective confirmation (Remmers et. al., ATS 2015). As well, the results of the test accurately predicted an efficacious target for mandibular position (PPV: 92%) that allowed for treatment to be administered in a minimal amount of time (median 0 days).

CONCLUSIONS

- We have developed an auto-adjusting oral appliance titration system suitable for unattended sleep studies.
- A prospective evaluation in home shows good accuracy in identifying favorable candidates for OAT and in identifying an efficacious target protrusive position.
- Use of the device enabled the majority of suitable candidates to be immediately treated with oral appliance therapy.