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

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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 titrator when used unattended in the home.

Methods: Study participants (n=124, mean AHI=24.9±13.0/hr) were derived from 151 patients with OSA, of whom 5 discontinued participation. 14 are currently in progress, and 4 had inconclusive studies. The remaining 124 participants formed our study population. All participants received a night and 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, apnoeas and hypopnoeas 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 10/hr. Prospectively established prediction rules applied to the results of each titration study predicted OAT outcome, either predicted success (PS) or predicted failure (PF), and discriminated predictions were resolved by repeating the test. 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 final therapeutic success with OAT was defined as outcome AHI<10/hr & 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 71%. 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 0.91/0.82, respectively. Of the 75 participants, each 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.

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 self-selected position (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).

RESULTS

Figure 1. Distribution of baseline AHI and BMI for all participants. Therapeutic success: outcome AHI<10/hr & 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.

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.