

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

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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.

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