

## **Mandibular protrusion during sleep predicts outcome with oral appliance therapy of sleep apnea.**

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### **Rationale**

Treatment of obstructive sleep apnea (OSA) with mandibular protruding oral appliances (MPOAs) is limited by their non-uniform efficaciousness. In order to better select patients for this therapeutic modality, we have developed a remotely controlled, motorized mandibular protruder (MATRx, Zephyr Sleep Technologies Inc.) which enables a protrusive titration test under polysomnographic (PSG) monitoring.

### **Methods**

A prospective, predictive accuracy study was carried out on 65 OSA patients (REI>10, BMI<40). Each received a two night sleep test with a validated portable monitor (Snoresat, Sagatech Electronics Inc.) that yields a respiratory event index (REI) equivalent to a PSG-determined apnea-hypopnea index, followed by a MATRx PSG study. The latter was reviewed by a blinded sleep physician using predetermined criterion for predicting therapeutic outcome with subsequent MPOA therapy. If mandibular protrusion effectively eliminated OSA in REM sleep while supine (1 or less apneas or hypopneas per 5 min), therapeutic success was predicted. Otherwise, therapeutic failure was predicted. If insufficient REM supine was observed, REM lateral was used for subjects who slept predominately on their side in the baseline study. A sleep dentist, blinded to the results of the MATRx study, applied a custom-fitted MPOA (Somnodent, SomnoMed) and adjusted it to a target position, the minimum protrusion to achieve predicted success or a sham value (70% of full protrusion) for predicted failures. Therapeutic outcome was determined by two nights of study with the portable monitor.

### **Results**

At baseline, the mean respiratory event index (REI) was 22.5 in the predicted success group and 26.5 in the predicted failure group. The difference was not statistically significant ( $p > .05$ ). PSG data were inadequate in 10% of studies. Step protrusions in REM caused an arousal in 14% of cases, and in only 3% was this associated with a sleep state change. Using REI<10 as the criterion for therapeutic success while wearing the therapeutic MPOA at target protrusion, MATRx predictions had significant positive predictive value (96%) but non-significant negative predictive value (60%). When subjects with mild OSA (REI: 10-15) were excluded, these values rose to 100% and 80%, respectively. The predictive accuracy of the test using various criteria are summarized in Table 1.

Table 1: Results

	Outcome Criteria		
	REI < 10 (baseline REI > 10)	REI < 10 (baseline REI > 15)	REI < 10 & 50% reduction
Positive Predictive Value	96.1 %*	100 %*	84.6 %*
Negative Predictive Value	60.6 %	80 %*	75.8 %*
Sensitivity	65.8 %	79.1 %*	73.3 %*
Specificity	95.2 %*	100 %*	86.2 %*

\* indicates statistical significance ( $p < 0.05$ )

### **Conclusion**

A blinded, prospective, predictive study indicates that the MATRx test accurately identifies OSA patients who will experience therapeutic success with MPOA therapy. The test has significant negative predictive power when baseline REI is taken into account.

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