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Introduction

Soon after the recognition and understanding of sleep apnea, Colin Sullivan and co-workers discovered a miraculous therapy, nasal continuous positive airway pressure (CPAP). This uniformly efficacious and benign intervention allowed effective management of life-threatening disease. Unfortunately, the sleep-disturbing features of a competent facial interface, a tethering hose and air pressure distending the upper airway have proved distressing for many obstructive sleep apnea (OSA) patients, and poor adherence to therapy has limited the overall effectiveness of CPAP. One of the most important challenges presently facing the field of sleep medicine is finding satisfactory alternative therapies for OSA, which is now recognized to be one of the most prevalent diseases in industrialized countries.

Oral appliances that reposition the mandible constitute one of the most promising of known treatment alternatives for OSA. Protrusion of the mandible enlarges both the oropharynx and velopharynx by passive mechanisms (i.e. stretching soft tissues that attach to the pharyngeal walls). This mandibular movement can be readily accomplished by a dental appliance that applies a ventral force to the lower teeth and a dorsal force to the upper teeth, and such appliances have been found to successfully treat OSA. Lacking the cumbersome aspects of a CPAP apparatus and internally applied air pressure, oral appliances are often preferred by patients over nasal CPAP therapy, and adherence does not appear to be a major obstacle to therapeutic effectiveness.

Despite these advantages, oral appliance therapy (OAT) has not received widespread acceptance in sleep medicine and this can be attributed in large part to the uncertainty regarding efficaciousness in any particular patient (i.e. OAT reduces the apnea hypopnea index, AHI, to normal values in approximately 50 percent of cases). Apparently, the stretching of buccal and pharyngeal soft tissues does not always develop enough force on the pharyngeal walls to overcome the anatomical problem causing the obstruction. Clinical features (e.g. apnea hypopnea index, body mass index, airway anatomy by acoustic reflectance) and bony imaging (e.g. cephalometrics or CT scan) have not been shown to accurately predict success with OAT. Presumably, this is because these methods do not assess the underlying pharyngeal anatomic problem that causes the obstruction during sleep. This lack of uniform efficacy, from both a therapeutic and diagnostic perspective, highlights the need for a viable method to identify OSA patients who will be successfully treated by an appliance that protrudes the mandible. MATRx is a product that is designed to do exactly this; MATRx will, for the first time, allow sleep physicians to reliably predict the efficacy of mandibular advancement therapy in OSA patients and will provide a target protrusive position for this therapy.

John E. Remmers, MD
Chief Medical Officer
Zephyr Sleep Technologies Inc.

Dr. Remmers is a world renowned expert in the field of snoring and sleep apnea, being the first researcher to elucidate the pathogenesis of sleep apnea and to demonstrate that sleep apnea is caused by an anatomical narrowing of the pharynx.

Dr. Remmers is a pulmonologist and clinical professor of internal medicine at the University of Calgary. Dr. Remmers also has an active sleep practice in the sleep lab at the Foothills Medical Centre in Calgary, Alberta which he founded in 1984.

As a recognized pioneer and innovator in sleep medicine, Dr. Remmers has invented products ranging from portable diagnostic sleep monitors to auto-titrating CPAP devices. Most notably, Dr. Remmers invented the first electronically controlled CPAP device, which was licensed to Healthdyne prior to its acquisition by Phillips Respironics in 1997. In addition, Dr. Remmers’ long-standing relationship with Phillips Respironics led to the development of many commercialized CPAP technologies, in particular the REMstar® Auto CPAP device, which uses a proactive algorithm to automatically adjust CPAP pressure based on patient need.

Dr. Remmers served two terms as the Editor-in-Chief of the Journal of Applied Physiology and has presented honorary research lectures to the American Thoracic Society, the American Physiological Society and American College of Chest Physicians. His research interests relate to the neurobiology of respiratory rhythmogenesis, chemoreception, and the pathophysiology of the control of breathing. Dr. Remmers has published over one hundred peer reviewed publications in the area of respiratory physiology.
Acknowledgements

The MATRx system is available for use due to the collaborative efforts of Zephyr Sleep Technologies Inc., SomnoMed Limited and the University of Calgary.

Zephyr Sleep Technologies Inc. would like to acknowledge the following individuals for the time they have contributed to the creation of this guide. We thank this professional team for their commitment to research and education and for their clinical expertise as it relates to the use and application of MATRx in the field of sleep medicine.

- Laree Fordyce  RPSGT, RST, CCRP, Product & Education Coordinator
- Brenda Pettigrew  RRT, Product & Education Coordinator
- John Remmers  MD, Chief Medical Officer
- Peter Santosham  MBA, Director Sales, Marketing & Distribution
Predicting Success with Oral Appliance Therapy

The MATRx system is used by the sleep tech, in a polysomnographic setting, to reposition the mandible while the patient sleeps in response to observed apneas and hypopneas. This, in turn, enables a prospective prediction of whether or not the patient will experience therapeutic success with a custom-fitted oral appliance and provides a target protrusive position for the dentist to facilitate efficacious OAT. In addition, the MATRx test provides considerable information that can be useful in facilitating clinical management, such as, the possible importance of positional therapy or the impact of mandibular protrusion on emergent central sleep apnea.

Given the high predictive accuracy of a MATRx study, as well as patient preference and the number of patients who are non-compliant to CPAP therapy, this dental titration study may become an important addition to the repertoire of diagnostic and assessment procedures provided by sleep labs.
OATRx™ – The Technology Behind MATRx

During a MATRx study, the control panel is used by the sleep tech to titrate mandibular position in response to apneas and hypopneas.

Figure 1: The OATRx TS (titration software) control panel.

Figure 2: The OATRx scale of the MATRx titration trays. The OATRx scale is used by the sleep dentist to determine the mandibular measurements needed to conduct a MATRx study (i.e. habitual bite position, maximal voluntary protrusion, full retrusion).

The OATRx technology, pioneered and developed by Dr. John Remmers, is the result of countless hours of research and experience in the field of sleep medicine. Two previous prospective studies5,6 were the first papers to demonstrate that mandibular advancement titration during sleep accurately predicts the efficacy of OAT, similar to that of CPAP titration. The knowledge gained from these studies was invaluable in the refinement and improvement of the OATRx technology.

OATRx is based on a deep understanding of mandibular advancement and its impact on sleep architecture during both REM and NREM sleep. This know-how is integrated into the OATRx scale of the MATRx titration trays, the OATRx titration software and the study output known as the OATRx number, which defines the target protrusive position for effective OAT. Together these components form the core of the OATRx technology powering the MATRx system.

The MATRx Advantage

The MATRx dental titration study offers many features that are comparable to and commensurate with the traditional CPAP titration study. In fact, the two studies work hand-in-hand to optimize OSA management.

For Sleep Physicians
• Identification of patients suitable for OAT
• Determination of a target protrusive position that will result in successful OAT
• Optimized OSA management
• Intuitive PSG scoring and interpretation
• Evidence-based guidelines to aid evaluation and management

For Sleep Labs
• Seamless integration with polysomnographic systems and workflow
• Minimal adjustments and interventions; simple, intuitive and convenient
• No disruption of sleep architecture when repositioning the mandible
• Expansion of services without major investment or training

For Sleep Dentists
• Prompt initiation of effective treatment
• Reduced number of patient visits
• Avoidance of under and over titration
• Confidence in therapeutic outcome

For Patients
• Confidence that oral appliances will work for them
• An effective alternative to CPAP therapy
The MATRx™ System
The MATRx System

"Look and Feel"

Figure 3: MATRx titration study using Sandman PSG software.

The PSG montage has been edited to include the MATRx channel which records and displays mandibular position. During this period of REM sleep in the lateral position, the patient is effectively treated with a mandibular protrusive position between 14.2 and 14.4mm.

The "look and feel" of the MATRx dental titration study resembles that of a CPAP titration, except the sleep tech monitors and manipulates mandibular position rather than CPAP pressure and mask fit. The goal of the MATRx study is to progressively increase the intensity of the therapeutic intervention (i.e. mandibular protrusion), until the patient’s apneas and hypopneas are eliminated.

At the end of the study, the sleep physician will be able to identify which patients responded well to mandibular advancement therapy as well as determine the target protrusive position (i.e. OATRx number) that will result in efficacious OAT.
Workflow

1. Patient Selection and Referral
   The sleep physician selects an OSA patient that may be a suitable candidate for OAT and refers the patient to the sleep dentist for assessment.

2. Dental Assessment and MATRx Tray Fitting
   The sleep dentist performs an oral exam to determine if the patient is a suitable oral appliance candidate. If judged to be a candidate, the dentist takes impressions, prepares customized titration trays and records the mandibular measurements needed to conduct the patient’s MATRx study.

3. MATRx Study Set-up
   The sleep tech inserts the patient’s customized titration trays and calibrates the MATRx device to the PSG system, in preparation for the patient’s MATRx study.

4. MATRx Study Titration and Scoring
   The sleep tech titrates the patient’s mandibular position, in response to apneas and hypopneas, with a goal to eliminate these events during REM sleep in the supine position.

5. MATRx Study Interpretation
   The sleep physician evaluates the MATRx study results. If the patient is predicted to be a success, the sleep physician refers the patient back to the sleep dentist with a prescription for OAT, which includes the patient’s target protrusive position (i.e. OATRx number).

6. Oral Appliance Prescription
   The sleep dentist uses the patient’s OATRx number to fabricate and set the patient’s oral appliance to the target protrusive position that will result in successful therapy.
**Hardware Configuration**

External DC Box (i.e. DC Expansion Box) located in the Control Room

![Schematic diagram of the MATRx configuration for a PSG system with an external DC box (e.g. Sandman).](image)

**Amplifier/Headbox, with DC Inputs, located in the Patient Room**

![Schematic diagram of the MATRx configuration for a PSG system with DC inputs in the amplifier/headbox (e.g. Alice).](image)

**NOTE:** We recommend connecting the 3.5mm mono cable (i.e. DC cable) to the DC inputs of the system’s amplifier rather than the DC inputs of the headbox.

Refer to the Installation Manual for specific information on MATRx hardware and software installation.

**Integration**

The MATRx system integrates easily with any sleep lab’s polysomnographic equipment, allowing the sleep tech to monitor the patient and reposition the mandible remotely, without disturbing the patient’s sleep. The MATRx hardware is connected directly to the PSG system using an external DC box or the DC inputs of an amplifier. The OATRx software is installed on the PSG computer’s operating system following standard software installation procedures.

![MATRx PSG initialization (i.e. calibration) with Sandman SD32+ PSG software.](image)

![MATRx PSG initialization (i.e. calibration) with Alice 5 PSG software.](image)
The MATRx™ Study
Titration Considerations

Conducting a MATRx titration study is very similar to a CPAP titration. The objective of the MATRx study is to determine the impact of mandibular protrusion on airway patency. As with CPAP titration, there are important technical and clinical factors to consider.

Starting Position

In a MATRx study, this is known as the *Lower Limit*. However, the patient’s ability to comfortably fall asleep should be the primary consideration when determining the patient’s starting position. In most cases, the lower limit is defined by the sleep dentist during the patient assessment and is usually the patient’s habitual bite position minus 1mm. In some cases, it may be appropriate to begin the MATRx study at a lower limit that is greater (i.e. more protrusive) than the habitual bite position to ensure there is adequate study time to reach the patient’s target protrusive position during REM sleep.

Degree of Mandibular Movement

In a MATRx study, this is known as the *Step Size*. This is the amount of mandibular movement that will occur with each commanded intervention (i.e. step) and is analogous to a change in CPAP pressure during a CPAP titration study. The OATRx software automatically imposes a five second delay between each step because large mandibular movements over a short period of time can cause arousals in some patients. To minimize the risk of arousal, we recommend restricting the step size to 0.2mm and limiting each sequence of mandibular movements to three consecutive 0.2mm steps, for a total of 0.6mm. We also recommend waiting two minutes for equilibration after completing each 0.6mm step. In some cases, a more aggressive step titration procedure may be necessary to ensure there is adequate study time to observe the patient in REM sleep.

Tagging a Study

During a MATRx study, it is important to create both a numeric and a note “CPAP tag” with each change in mandibular position (i.e. commanded step). This information is needed for the MATRx study interpretation.

Optimizing Titration

The mandibular position where apneas and hypopneas are reduced or eliminated, as per the MATRx Interpretive Criteria, is referred to as the patient’s target protrusive position and recorded as the OATRx number (e.g. 16mm). Once the patient’s target protrusive position has been reached, we recommend continuing step titration to further optimize this therapeutic mandibular position.
**Set-up Procedures**

- Edit existing montage (create OATRx channel)
- MP — Mandibular Positioner
- HB — Initial Bite Position
- Max Prot — Maximum Protrusion
- 1. Turn MATRx controller ON
   - Enter Upper Limit (Max Prot)
   - Enter Lower Limit (e.g., HB = 13)
   - Press Validate

- In OATRx Set-up Panel:
  - Enter Upper Limit (Max Prot)
  - Enter Lower Limit (e.g., HB = 13)
  - Press Validate
  - Go to Calibration Check Panel

- NOT ACCEPTABLE
  - (Consult User Manual)
- ACCEPTABLE

- Re-adjust entries

- Attach MATRx titration trays to MP
- Fully extend MP’s manually adjustable lower rod

- Move to each test position by pressing buttons
  - A
  - B
  - C
  - and enter the OATRx scale readings

- Press Calibrate and check result
  - MP should be adjusted
  - MP should be replaced
  - No adjustment necessary

- Manually adjust MP’s lower rod until OATRx scale reading on trays agrees with displayed Actual Position (± 0.5mm)

- Load OATRx montage

- NO AGREEMENT
  - Move to Upper Limit
  - Confirm OATRx scale readings on trays and adjust if necessary
  - Simple high value for PSG channel

- Move to Lower Limit
  - Confirm OATRx scale readings on trays and adjust if necessary
  - Simple low value for PSG channel

- Move between Upper and Lower Limits
  - Ensure displayed Actual Position and PSG channel agree (± 0.5mm)

- Move to Lower Limit
  - Press Start Titration

**Titration Procedures**

- Confirm OATRx scale readings provided by the Dentist
  - Press Next

- Place MATRx titration trays in patient’s mouth
  - Monitor patient’s sleep behavior
  - Monitor...wait...observe

- For obstructive apneas and/or hypopneas
  - Observe for central events
  - No REM

- REM-Observations
  - Goal: To Determine if the Patient Meets Interpretive Criteria
  - If patient remains lateral, use judgment/experience to have patient move to supine position
  - If patient cannot be treated successfully in REM supine, use judgment/experience to have patient move to lateral position

- REM Supine
  - Inconclusive Study
  - Physician to determine if OAT is appropriate

- Predicted Success
  - Predicted Failure
  - Mandibular retrusion may be necessary

- Is patient at Upper Limit? (Max Protusion)
- Move to Upper Limit
  - Press Start Titration

- Predicted Success with positional therapy
  - REM supine has not been observed and patient is a confirmed side sleeper

- Record the OATRx number
  - (i.e., target protrusive position) in patient’s chart
  - Continue titration if time permits

**Notes**

- * Lower Limit Position — Refer to the MATRx Clinical Applications Guide
- ** Interpretive Criteria — Refer to the MATRx Clinical Applications Guide

Section: The MATRx Study | Titration Considerations
Scoring Guidelines

Score the MATRx titration study following the AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications.

Recommended Rule for Hypopnea Scoring

Based on MATRx clinical studies, we strongly recommend using Rule 4-A for scoring, as opposed to 4-B, since 4-A scoring has proven to be a more accurate method for predicting OAT success and failure.

Score a hypopnea if ALL of the following criteria are met:
1. The nasal pressure signal drops by \(\geq 30\%\) of baseline.
2. The duration of this drop occurs for at least 10 seconds.
3. There is a \(\geq 4\%\) desaturation from the pre-event baseline.
4. At least 90\% of the event’s duration meets the amplitude reduction criteria for hypopnea.

Staging and Scoring the MATRx Study

Since a MATRx prediction of success, as stated in the MATRx Interpretive Criteria, relies on the reduction or elimination of apneas and/or hypopneas in REM sleep, the following guidelines are recommended when staging and scoring a MATRx study:
1. Stage the REM periods FIRST.
2. Consider staging the rest of the study as “wake” to enable the REM calculations on the CPAP Titration Chart (see Figure 9).
3. Score the apneas and hypopneas in REM using Rule 4-A.
4. Stage the entire study and score the apneas and hypopneas using Rule 4-A.
5. Do not score respiratory effort related arousals (RERAs) or inspiratory flow limitation (IFL).

Figure 8: RERA event observed during a MATRx study.

NOTE: When conducting a MATRx study, the patient’s mandibular position will not be titrated in response to observed RERAs or IFL. These events are also not scored.

Recommended Output Reports

To assist the sleep physician with interpretation of the MATRx study, we recommend generating two output reports.

1. REM Report: This report will be generated first, after the REM periods are staged and the associated apneas and hypopneas scored.
2. Complete Report: This report will be generated after the entire study has been staged and the associated apneas and hypopneas scored.

Ensure the CPAP Titration Chart (Figure 9) is included in each report. Each commanded step (i.e. change in the patient’s mandibular position) during the titration procedure is captured as a “CPAP tag” and itemized in this chart.

Figure 9: CPAP Titration Chart (relabeled OATRx Titration Chart) generated from a MATRx study conducted with Sandman PSG software. Columns 1, “Treatment Level”, itemizes the “CPAP tags” created at each change in mandibular position during the MATRx study (e.g. CPAP 9.9 = a mandibular protrusion of 9.9mm). Columns 3 and 4, “REM and Non-REM”, itemize the periods of time the patient was observed in each of these sleep states. The red highlighted areas indicate a period of ineffective protrusion in REM sleep. During this period, the patient’s mandibular position is increased from 12.7mm to 12.9mm with a reduction in AHI from 27.2 to 9.5. The minimum SpO2 during this period was 88%. The green highlighted areas indicate a period of effective protrusion in REM sleep. During this period, the patient’s mandibular position has only been advanced a little less than 2mm from the period of ineffective protrusion. With a mandibular position between 13.7mm and 14.4mm, the patient’s AHI is now within normal limits. In addition, the minimum SpO2 was maintained above 92%.

NOTE: This CPAP Titration Chart is generated from the MATRx study conducted on Case 2 in the Case Studies section of this guide; pages 44–45.
Clinical Applications
Based on previous investigations 5,6 and the most recent clinical study 8 we are confident that MATRx can accurately identify patients suitable for OAT.

The following section outlines the MATRx Interpretive Criteria and discusses the importance of sleep state and body position in predicting successful OAT candidates.

**Interpretive Criteria #1**

To predict OAT success, the following criteria must be met during a MATRx study:

- Less than or equal to 1 apnea or hypopnea, over a 5 minute period during a single REM cycle, in the supine position

**Interpretive Criteria #2**

If a single 5 minute REM cycle, in the supine position, is not observed during a MATRx study AND the patient is a confirmed side sleeper, the following criteria can be used to predict OAT success:

- Less than or equal to 1 apnea or hypopnea, over a 5 minute period during a single REM cycle, in the lateral position

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**Predicted Success**

A MATRx study is considered to be a predicted success when:

- Protrusion of the patient’s mandible, during REM sleep, results in the reduction or elimination of apneas and/or hypopneas, as specified in the MATRx Interpretive Criteria

**Predicted Failure**

A MATRx study is considered to be a predicted failure when:

- The patient’s upper limit (i.e. maximum protrusion) has been reached and apneas and/or hypopneas continue at a rate greater than specified in the MATRx Interpretive Criteria
- Central events are observed and continue despite mandibular retrusion
Clinical Considerations

When a supine position is coupled with a passive pharynx, as observed in REM sleep, the combination of REM supine represents the worst case scenario for maintaining patency of the upper airway and achieving a successful outcome with OAT. Therefore, observations made in the supine position during REM sleep are key considerations of the MATRx Interpretive Criteria because they reflect a period of sleep when the upper airway is most susceptible to collapse.

REM Sleep State

Sleep depth modifies skeletal muscle tone and also has an effect on upper airway muscles. Previous studies suggest that the collapsibility of the upper airway during REM sleep is higher than during slow wave sleep and this collapsibility varies from breath to breath. Therefore, during mandibular protrusion with an oral appliance in REM sleep, we can only rely on the elastic properties of the soft tissue to maintain airway patency as opposed to the force generated by contraction of the surrounding musculature.

It is important to note that the inclusion of REM sleep in the MATRx Interpretive Criteria may be limited by the patient’s ability to achieve REM within a sleep lab environment. In cases where insufficient REM sleep has been observed, a full analysis of the patient’s airway response to mandibular protrusion in NREM sleep may be warranted.

Body Position

The effects of gravity on the pharyngeal soft tissues and importance of body position in the pathogenesis of OSA has been pointed out in several studies. In addition, the effects on lung volume may also be important. For OSA patients known to be side sleepers, or patients who are willing to adjust their sleep habits to include postural therapy, periods of REM sleep in the lateral position can, in some cases, be used to apply the MATRx Interpretive Criteria. In these cases, postural therapy in combination with OAT can result in successful outcomes.

Inconclusive Studies

Significant clinical information can be derived from inconclusive MATRx study data as discussed below. In these situations, the sleep physician will need to review the patient’s history and study data to determine if OAT is appropriate.

In some cases, an inconclusive study may warrant retesting. However, prior to determining if a repeat MATRx study is required, it may be helpful to review the patient’s airway response to mandibular protrusion in both REM and NREM sleep. Failure to see any reduction in AHI during lateral sleep, in both REM and NREM, may be indicative of a poor response to OAT.

A MATRx study is considered to be inconclusive when the MATRx Interpretive Criteria cannot be applied as follows:

• The patient’s REM cycles are less than 5 minutes OR REM sleep has not been observed

In situations where an insufficient REM cycle is observed, it may be helpful to evaluate the AHI over the whole night, or over a period when the patient’s mandibular protrusion exceeds 50-75% of maximum.

• The patient’s upper limit (i.e. maximum protrusion) has not been reached during a REM cycle and apneas and/or hypopneas continue at a rate greater than stated in the MATRx Interpretive Criteria

Inconclusive studies can occur when there is insufficient time to titrate to the patient’s upper limit. In such cases, it may be appropriate to begin the MATRx study at a lower limit position that is more intrusive. In addition, it may be necessary to follow a more aggressive titration procedure, being careful not to cause arousals or awakenings.
Determining the OATRx Number

To determine the OATRx number (i.e. target protrusive position) from the MATRx study data, the sleep physician should review the full night of study data and evaluate the patient’s response to mandibular titration during REM and NREM sleep and in both the supine and lateral positions. This is similar to the review performed when determining a patient’s CPAP prescription following a CPAP titration.

In general, the OATRx number is the minimum protrusive position at which the sleep physician feels confident the patient will receive efficacious OAT based on application of the MATRx Interpretive Criteria.

Follow-up testing for successful oral appliance patients

When follow-up testing is determined to be appropriate, a polysomnographic study is the gold standard. When a polysomnographic study is not available, a portable sleep recorder can be used. In these situations, we recommend using an AASM compliant sleep recorder with the oxygen desaturation settings adjusted to 4% to ensure consistency with MATRx study scoring using Hypopnea Rule 4-A.

Figure 11: Hypnogram generated from a MATRx study.
The red highlighted area displays the mandibular titration performed during the MATRx study. The study output is known as the OATRx number and generated from the OATRx TS titration software.
Case Studies

The cases presented in this section represent a typical OSA demographic (i.e. mild to severe OSA with a wide range of BMIs). Each case review includes the following:

- Patient Profile
- Dental Assessment
- MATRx Study Analysis
- Mandibular Titration Summary
- MATRx Study Interpretation
- Therapeutic Outcome

Each case demonstrates the clinical utility of the MATRx study and confirms that the clinical features traditionally used to predict OAT success or failure (i.e. low BMI, high AHI, airway anatomy) may not always be reliable indicators.

The cases also demonstrate application of the MATRx Interpretive Criteria considering the patient's sleep state and body position.

Hypnogram Legend

Each case study hypnogram is marked with a variety of color-coded windows to clearly identify and differentiate periods of time, during the MATRx titration study, when the patient’s degree of mandibular protrusion is effective or ineffective in reducing or eliminating apneas and/or hypopneas. In addition, each color-coded window also identifies the patient’s sleep state and body position during this same period.

The following colors and textures build the components of the hypnogram legend:

- Sleep state—REM (green) or NREM (orange)
- Body position—supine (solid texture) or lateral (hatched texture)
- Mandibular protrusion—effective (green border) or ineffective (red border)
A MATRx study is considered to be a predicted success when:

- Protrusion of the patient’s mandible, during REM sleep, results in the reduction or elimination of apneas and/or hypopneas, as specified in the MATRx Interpretive Criteria.
**Case 1 - Underweight Patient with Severe OSA**

This case reveals that some patients with severe sleep apnea can be successfully treated with OAT, in combination with postural therapy, and that only modest mandibular protrusion may be required.

**Patient Profile**
- 56 year old female
- Pre-study AHI = 34.4
- BMI = 18.3
- Confirmed side sleeper

**MADRx Study Analysis**
During the study, the patient slept reasonably well (sleep efficiency = 77.5%) but displayed little REM sleep (5.2%). No REM supine was sampled despite sleeping supine most of the night. Two REM cycles were observed in the lateral position. The arousal index was 22.4. Arterial oxyhemoglobin saturation was normal throughout the study, except for periods of mild desaturation during REM sleep. No periodic limb movements were observed. Effective mandibular protrusion was observed in both REM lateral periods (Intervals 2 and 4) and the NREM supine period (Interval 3).

**Mandibular Titration Summary**

| Interval 1 | NREM cycle; 30 minutes | SUPINE position | Ineffective protrusion | mandibular position 11.8–12.2mm |
| Interval 2 | REM cycle; 12.5 minutes | LATERAL position | Effective protrusion | mandibular position 12.2–12.6mm |
| Interval 3 | NREM cycle; 50 minutes | SUPINE position | Effective protrusion | mandibular position 14.4–15.2mm |
| Interval 4 | REM cycle; 3 minutes | LATERAL position | Effective protrusion | mandibular position 15.6mm |

**MATRx Study Interpretation**
- Prediction: Patient is a predicted success in the lateral position
- MATRx Interpretive Criteria Applied: Interpretive Criteria #2
  - This criteria was applied to the 12.5 minute period of REM lateral (Interval 2)
- OATRx Number (Target Protrusive Position): 15.0mm

**Therapeutic Outcome**
The patient was fitted with a SomnoDent® oral appliance adjusted to the target protrusive position. A therapeutic outcome study, with the appliance set at this position, revealed a decrease in the AHI to 7.8.
Case 2 - Obese Patient with Severe OSA

This case reveals that in the presence of both obesity and severe sleep apnea, each thought to impede the response to mandibular protrusion, some patients can achieve an excellent response to a mandibular advancement device. Moreover, such a response can occur well short of the patient’s upper limit for mandibular protrusion.

Patient Profile
- 42 year old female
- Pre-study AHI = 41.4
- BMI = 32.3

MATRx Study Analysis
During the study, the patient slept reasonably well (sleep efficiency = 82%) and displayed fairly normal sleep architecture with three REM cycles observed; two in the supine position. The arousal index was 20.3. Arterial oxyhemoglobin saturation was normal throughout the study. One 40 minute episode of periodic limb movements was observed. Effective mandibular protrusion was observed in the NREM lateral period (Interval 1) and both REM supine periods (Intervals 3 and 4).

Mandibular Titration Summary

<table>
<thead>
<tr>
<th>Interval</th>
<th>Description</th>
<th>Position</th>
<th>Mandibular Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interval 1</td>
<td>NREM cycle; 30 minutes LATERAL position</td>
<td>Effective protrusion</td>
<td>11.0–12.0mm</td>
</tr>
<tr>
<td>Interval 2</td>
<td>REM cycle; 5 minutes LATERAL position</td>
<td>Ineffective protrusion</td>
<td>12.4mm</td>
</tr>
<tr>
<td>Interval 3</td>
<td>REM cycle; 25 minutes SUPINE position</td>
<td>Effective protrusion</td>
<td>13.9–14.2mm</td>
</tr>
<tr>
<td>Interval 4</td>
<td>REM cycle; 25 minutes SUPINE position</td>
<td>Effective protrusion</td>
<td>13.7–14.5mm</td>
</tr>
</tbody>
</table>

MATRx Study Interpretation
- Prediction: Patient is a predicted success in the supine position
- MATRx Interpretive Criteria Applied: Interpretive Criteria #1
  - This criteria was applied to both 25 minute periods of REM supine (Intervals 3 and 4)
- OATRx Number (Target Protrusive Position): 14.5mm

Therapeutic Outcome
The patient was fitted with a SomnoDent® oral appliance adjusted to the target protrusive position. A therapeutic outcome study, with the appliance set at this position, revealed a decrease of the AHI to a normal value of 4.0.
Case 3 - Obese Patient with Moderate OSA

This case reveals that in some OSA patients, sleeping in the supine position can dramatically increase airway collapsibility and the occurrence of apneas and hypopneas. In addition, this case demonstrates the utility of the OATRx number in confirming that minimal mandibular protrusion can result in efficacious OAT. This patient was successfully treated by simply stabilizing the mandible at a position 2mm greater than (i.e. more protrusive) than the patient’s habitual bite. Without this knowledge, OAT may have been initiated at a position that resulted in overprotrusion.

Patient Profile
- 74 year old female
- Pre-study AHI = 23.5
- BMI = 34.3
- Confirmed side sleeper

MATRx Study Analysis
During the study, the patient slept predominately in the lateral position. She slept reasonably well (sleep efficiency = 76.9%) and displayed a somewhat disordered sleep architecture with two REM cycles observed. One full REM cycle was observed near the end of the study; no REM supine was observed. Arterial oxyhemoglobin saturation was normal throughout the study, except for periods of mild desaturation during REM sleep. The arousal index was 15.0. A two hour period of periodic limb movements was observed during the first half of the night. Effective mandibular protrusion was observed in the NREM lateral period (Interval 1) and the REM lateral period (Interval 2). In Interval 3, we can clearly see the effect of body position on airway collapsibility, despite titrating to the patient’s upper limit (i.e. maximum protrusion).

Mandibular Titration Summary

<table>
<thead>
<tr>
<th>Interval 1</th>
<th>NREM cycle; 50 minutes</th>
<th>LATERAL position</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Effective protrusion</td>
<td>mandibular position 15.0mm (Lower Limit)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Interval 2</th>
<th>REM cycle; 20 minutes</th>
<th>LATERAL position</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Effective protrusion</td>
<td>mandibular position 16.6–17.2mm</td>
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</table>

<table>
<thead>
<tr>
<th>Interval 3</th>
<th>NREM cycle; 45 minutes</th>
<th>SUPINE position</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ineffective protrusion</td>
<td>mandibular position 17.2–21.0mm (Upper Limit)</td>
</tr>
</tbody>
</table>

MATRx Study Interpretation
- **Prediction:** Patient is a predicted success in the lateral position with minimal protrusion
- **MATRx Interpretive Criteria Applied:** Interpretive Criteria #2
  - This criteria was applied to the 20 minute period of REM lateral (Interval 2)
- **OATRx Number (Target Protrusive Position):** 17.0mm

Therapeutic Outcome
The patient was fitted with a SomnoDent® oral appliance adjusted to the target protrusive position. A therapeutic outcome study, with the appliance set at this position, revealed a decrease in the AHI to 5.2.
Predicted Failures
Predicted Failure

A MATRx study is considered to be a predicted failure when:

- The patient’s upper limit (i.e. maximum protrusion) has been reached and apneas and/or hypopneas continue at a rate greater than specified in the MATRx Interpretive Criteria
- Central events are observed and continue despite mandibular retrusion
Case 4 - Obese Patient with Moderate OSA

This case reveals that some patients with moderate sleep apnea can fail to experience an efficacious response to OAT, despite protruding the mandible to the patient’s upper limit (i.e. maximum protrusion).

Patient Profile
• 76 year old male
• Pre-study AHI = 17.9
• BMI = 32.0

Dental Assessment
(OATRx scale readings for titration study)
• Lower Limit (Habitual Bite – 1mm) = 12.0mm
• Upper Limit (Maximum Protrusion) = 19.0mm

MATRx Study Analysis
During the study, the patient slept reasonably well (sleep efficiency = 83.8%) but had a high arousal index (48.1). Three REM cycles were observed; one in the supine position. Arterial oxyhemoglobin saturation was normal throughout the study, except for periods of mild desaturation during REM sleep. Numerous periodic limb movements were recorded during the night, including during REM sleep. Effective mandibular protrusion was not achieved in REM supine (Interval 3), despite titrating to the patient’s upper limit (i.e. maximum protrusion). Effective mandibular protrusion was only observed in NREM periods in the supine position (Interval 2) and the lateral position (Interval 4).

Mandibular Titration Summary

Interval 1
REM cycle; 30 minutes
LATERAL position
Ineffective protrusion
• mandibular position 12.4–15.0mm

Interval 2
NREM cycle; 30 minutes
SUPINE position
Effective protrusion
• mandibular position 19.0mm (Upper Limit)

Interval 3
REM cycle; 30 minutes
SUPINE position
Ineffective protrusion
• mandibular position 19.0mm (Upper Limit)

Interval 4
NREM cycle; 30 minutes
LATERAL position
Effective protrusion
• mandibular position 14.9mm–16.5mm

Interval 5
REM cycle; 45 minutes
LATERAL position
Ineffective protrusion
• mandibular position 16.5–19.0mm (Upper Limit)

MATRx Study Interpretation
• Prediction: Patient is a predicted failure

Therapeutic Outcome
The patient was fitted with a SomnoDent® oral appliance adjusted to 70% of the patient’s full protrusive position. A therapeutic outcome study, with the appliance set at this position, revealed an increase in AHI to 20.8 compared to a pre-study AHI of 17.9. A repeat therapeutic outcome study, at maximum protrusion failed to further reduce the patient’s AHI.
Case 5 - Overweight Patient with Moderate OSA

This case reveals that some patients with moderate sleep apnea, who are known supine sleepers, can fail to experience an efficacious response to OAT despite protruding the mandible to the patient’s upper limit (i.e. maximum protrusion). In this case, the patient was unwilling to sleep in the lateral position and slept supine all night.

**Patient Profile**
- 55 year old male
- Pre-study AHI = 17.2
- BMI = 27.1

**Dental Assessment**
(OATRx scale readings for titration study)
- Lower Limit (Habitual Bite – 1mm) = 10.0mm
- Upper Limit (Maximum Protrusion) = 18.0mm

**MATRx Study Analysis**
During the study, the patient slept well (sleep efficiency = 87.2%), but had a somewhat elevated arousal index (30.0). The patient slept in the supine position all night with only two REM cycles observed. Arterial oxyhemoglobin saturation was normal throughout the study, except for periods of mild desaturation during REM sleep. No periodic limb movements were recorded. Effective mandibular protrusion was not achieved in either period of REM supine (Intervals 1 and 2), despite titrating to the patient’s upper limit (i.e. maximum protrusion).

**Mandibular Titration Summary**
- **Interval 1**
  - REM cycle; 23 minutes
  - SUPINE position
  - Ineffective protrusion
    - mandibular position 13.9mm–16.1mm

- **Interval 2**
  - REM cycle; 13 minutes
  - SUPINE position
  - Ineffective protrusion
    - mandibular position 16.0mm–18.0mm (Upper Limit)

**MATRx Study Interpretation**
- Prediction: Patient is a predicted failure

**Therapeutic Outcome**
The patient was fitted with a SomnoDent® oral appliance adjusted to 70% of the patient’s full protrusive position. A therapeutic outcome study, with the appliance set at this position, revealed a reduction of the AHI to 14.6. A repeat therapeutic outcome study, at maximum protrusion failed to reduce the patient’s AHI significantly.
Case 6 - Obese Patient with Mild OSA

This case reveals that in some OSA patients, mandibular protrusion may paradoxically increase airway collapsibility and promote the occurrence of apneas and hypopneas. In this patient with mild sleep apnea, titration to maximum protrusion resulted in an increased number of observed apneas and hypopneas.

Patient Profile
- 57 year old female
- Pre-study AHI = 11.5
- BMI = 30.5

Dental Assessment (OATRx scale readings for titration study)
- Lower Limit (Habitual Bite – 1mm) = 8.0mm
- Upper Limit (Maximum Protrusion) = 12.0mm

MATRx Study Analysis
During the study, the patient slept reasonably well (sleep efficiency = 70.8%), but had an elevated arousal index (37.3). Three REM cycles were observed; two occurring near the end of the study in the supine position. Arterial oxyhemoglobin saturation was normal throughout the study, except for periods of mild desaturation during REM sleep. No periodic limb movements were recorded. Effective mandibular protrusion was not achieved in REM supine (Interval 3), despite titrating to the patient’s upper limit (maximum protrusion). Effective mandibular protrusion was only observed in a period of NREM lateral (Interval 1) and in a brief period of REM lateral (Interval 2).

Mandibular Titration Summary

<table>
<thead>
<tr>
<th>Interval 1</th>
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<tbody>
<tr>
<td>NREM cycle; 30 minutes</td>
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<tr>
<td>LATERAL position</td>
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<tr>
<td>Effective protrusion</td>
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<tr>
<td>mandibular position 9.8–10.5mm</td>
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<th>Interval 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>REM cycle; 14 minutes</td>
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<tr>
<td>LATERAL position</td>
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<tr>
<td>Effective protrusion</td>
</tr>
<tr>
<td>mandibular position 11.1–11.4mm</td>
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<th>Interval 3</th>
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<tbody>
<tr>
<td>REM cycle; 32 minutes</td>
</tr>
<tr>
<td>SUPINE position</td>
</tr>
<tr>
<td>Ineffective protrusion</td>
</tr>
<tr>
<td>mandibular position 12.0mm (Upper Limit)</td>
</tr>
</tbody>
</table>

MATRx Study Interpretation
Prediction: Patient is a predicted failure

Therapeutic Outcome
The patient was fitted with a SomnoDent® oral appliance adjusted to 70% of the patient’s full protrusive position. A therapeutic outcome study, with the appliance set at this position, revealed an increase in AHI to 24 compared to a pre-study AHI of 11.5.

**Abstract:** Five patients with severe obstructive sleep apnoea were treated with continuous positive airway pressure (CPAP) applied via a comfortable nose mask through the nares. Low levels of pressure (range 4.5-10 cm H$_2$O) completely prevented upper airway occlusion during sleep in each patient and allowed an entire night of uninterrupted sleep. Continuous positive airway pressure applied in this manner provides a pneumatic splint for the nasopharyngeal airway and is a safe, simple treatment for the obstructive sleep apnoea syndrome.


**Abstract:** Patients with the sleep apnea/hypopnea syndrome (SAHS) treated by nasal continuous positive airway pressure (CPAP) need to use CPAP long-term to prevent recurrence of symptoms. It is thus important to clarify the level of long-term CPAP use and the factors influencing long-term use. We examined determinants of objective CPAP use in 1,211 consecutive patients with SAHS who were prescribed a CPAP trial between 1986 and 1997. Prospective CPAP use data were available in 1,155 (95.4%), with a median follow-up of 22 mo (interquartile range [IQR], 12 to 36 mo). Fifty-two (4.5%) patients refused CPAP treatment (these were more often female and current smokers); 1,103 patients took CPAP home, and during follow-up 20% stopped treatment, primarily because of a lack of benefit. Methods of survival analysis showed that 68% of patients continued treatment at 5 yr. Independent predictors of long-term CPAP use were snoring history, apnea/hypopnea index (AHI), and Epworth score; 86% of patients with Epworth > 10 and an AHI ≥ 30 were still using CPAP at 3 yr. Average nightly CPAP use within the first 3 mo was strongly predictive of long-term use. We conclude that long-term CPAP use is related to disease severity and subjective sleepiness and can be predicted within 3 mo.


**Abstract:** The velopharynx is the most common site of obstruction in patients with obstructive sleep apnea (OSA). Advancement of the mandible effectively reverses the pharyngeal obstruction. Accordingly, we hypothesized that mandibular advancement increases cross-sectional area of several segments of the upper airway, including the velopharynx and the oropharynx. We examined the pressure-area properties of the pharyngeal airway in 13 patients with OSA. Under general anesthesia and total muscle paralysis, the pharynx was visualized with an endoscope connected to a video-recording system. During an experimentally induced apnea, we manipulated the nasal pressure from 20 cm H$_2$O to the point of total closure at the velopharynx. The procedure was repeated after maximal forward displacement of the mandible. Measurements of the cross-sectional area at different levels of nasal pressure allowed construction of a static pressure-area relationship of the "passive pharynx," where active neuromuscular factors are suppressed. In 12 of 13 patients with OSA, advancement of the mandible stabilized the airway by reducing the closing pressure and increasing the area at any airway pressure. Thus the maneuver shifted the static pressure-area curve of the velopharynx and the oropharynx upward in these patients. We conclude that anterior movement of the mandible widens the retropalatal airway as well as that at the base of the tongue in the passive pharynx of OSA patients.

Abstract: We conducted an evidence-based review of literature regarding use of oral appliances (OAs) in the treatment of snoring and obstructive sleep apnea syndrome (OSA) from 1995 until the present. Our structured search revealed 141 articles for systematic scrutiny, of which 87 were suitable for inclusion in the evidence base, including 15 Level I to II randomized controlled trials and 5 of these trials with placebo-controlled treatment. The efficacy of OAs was established for controlling OSA in some but not all patients with success (defined as no more than 10 apneas or hypopneas per hour of sleep) achieved in an average of 52% of treated patients. Effects on sleepiness and quality of life were also demonstrated, but improvements in other neurocognitive outcomes were not consistent. The mechanism of OA therapy is related to opening of the upper airway as demonstrated by imaging and physiologic monitoring. Treatment adherence is variable with patients reporting using the appliance a median of 77% of nights at 1 year. Minor adverse effects were frequent whereas major adverse effects were uncommon. Minor tooth movement and small changes in the occlusion developed in some patients after prolonged use, but the long-term dental significance of this is uncertain. In comparison to continuous positive airway pressure (CPAP), OAs are less efficacious in reducing the apnea hypopnea index (AHI), but OAs appear to be used more (at least by self report), and in many studies were preferred over CPAP when the treatments were compared. OAs have also been compared favorably to surgical modification of the upper airway (uvulopalatopharyngoplasty, UPPP). Comparisons between OAs of different designs have produced variable findings. The literature of OA therapy for OSA now provides better evidence for the efficacy of this treatment modality and considerable guidance regarding the frequency of adverse effects and the indications for use in comparison to CPAP and UPPP.

5. Tsai WH, Vazquez JC, Oshima T, Dort L, Roycroft B, Lowe AA, Hadjuk E, Remmers JE. Remotely desaturation during an RCMP overnight study would predict AMP efficacy, as defined by an absolute We hypothesized that the elimination of respiratory events and significant nocturnal oxygen (RCMP), a temporary oral appliance that can advance or retract the mandible in a process analogous to CPAP pressure is needed during lateral positions compared to supine positions. 

Abstract: Anterior mandibular positioners (AMPs) have become increasingly popular as alternatives to continuous positive airway pressure for the treatment of obstructive sleep apnea. However, widespread acceptance of AMP is limited by an efficacy rate of 50–80% and an inability to predict which patients will respond to therapy. We evaluated 23 patients with obstructive sleep apnea (respiratory disturbance index (RDI) > 15 h⁻¹) with a remotely controlled mandibular positioner (RCMP), a temporary oral appliance that can advance or retract the mandible in a process analogous to changing the mask pressure during a continuous positive airway pressure trial study. We hypothesized that the elimination of respiratory events and significant nocturnal oxygen desaturation during an RCMP overnight study would predict AMP efficacy, as defined by an absolute reduction in RDI to less than 15 h⁻¹, a relative reduction in RDI of more than 30% from baseline, and a subjective improvement in symptoms. AMP compliance was 82%, and therapeutic efficacy was 53%. Among compliant patients, the positive and negative predictive value of an RCMP study in predicting AMP treatment success was 90% and 89%, respectively. An overnight RCMP study is highly predictive of AMP response.


Abstract: The objectives of the study were to test the hypotheses that it is possible, during routine polysomnography (PSG), to prospectively identify favourable candidates for mandibular repositioning appliance (MRA) therapy in the treatment of obstructive sleep apnoea (OSA) and to accurately estimate an optimal protrusive distance at which to fabricate the MRA. A series of subjects underwent a remotely controlled mandibular positioner (RCMP) test during PSG monitoring. The ability of the RCMP test to eliminate OSA and the target protrusion at which that occurred was compared with the success of a custom oral MRA in the 33 subjects who completed the protocol. The RCMP test was a success in 15 subjects and a failure in 18 subjects. Appliance therapy was initiated in 16 patients and completed in 33. MRA therapy was successful at target protrusion in 80% of patients who had a successful RCMP test and failed in 78% of those who failed the RCMP test. In conclusion the remotely controlled mandibular positioner test outcome demonstrated a statistically significant association with mandibular repositioning appliance outcome. The target protrusion determined during the remotely controlled mandibular positioner test was the effective therapeutic protrusion in subjects with a successful remotely controlled mandibular positioner test.


Abstract: The collapsibility of the upper airways has been identified as an important pathogenic factor in obstructive sleep apnea (OSA). Objective measures of collapsibility are pharyngeal critical pressure (Pcrit) and resistance of the upstream segment (Rus). To systematically determine the effects of sleep stage and body position we investigated 16 male subjects suffering from OSA. We compared the measures in light sleep, slow-wave sleep, REM sleep, and supine- vs. lateral positions. The pressure-flow relationship of the upper airways has been evaluated by simultaneous readings of maximal inspiratory air flow (Vmax) and nasal pressure (p-nCPAP). With two-factor repeated measures ANOVA on those 7 patients which had all 6 situations we found a significant influence of body position on Pcrit (p<0.05) whereas there was no significant influence of sleep stage and no significant interaction between body position and sleep stage. When comparing the body positions Pcrit was higher in the supine than in the lateral positions. During light sleep Pcrit decreased from 0.6 ± 0.8 cm H2O (supine) to –2.2 ± 3.6 cm H2O (lateral) (p<0.01), during slow-wave sleep Pcrit decreased from 0.8 ± 1.4 cm H2O (supine) to –1.7 ± 2.6 cm H2O (p<0.05) and during REM sleep it decreased from 1.2 ± 1.6 cm H2O to –2.6 ± 2.4 cm H2O (p<0.05). Changes in Pcrit revealed no body position nor sleep-stage dependence. Comparing the different body positions Rus was only significantly higher in the lateral position during REM sleep (p<0.05). The results indicate that collapsibility of the upper airways is not mediated by sleep stages but is strongly influenced by body position. As a consequence lower nCPAP pressure is needed during lateral positions compared to supine positions.

Customer Support

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