eXciteOSA Questions & Answers

What are the indications for eXciteOSA®?

eXciteOSA is intended for the reduction of snoring and mild obstructive sleep apnea by strengthening tongue muscles via electrical muscle stimulation.

eXciteOSA is a removable tongue muscle stimulation device that delivers neuromuscular stimulation to the tongue in order to reduce mild obstructive sleep apnea (AHI <15) and snoring for patients that are 18 years or older.

How is eXciteOSA different from other therapies?

eXciteOSA is the first, daytime therapy for mild obstructive sleep apnea and snoring that uses an entirely novel and original method to train the upper airway against collapsing during sleep. Unlike traditional therapies, which are mechanical or pneumatic airway splints to be used during sleep, the device works by improving tongue endurance and responsiveness preventing collapse during sleep. Clinically significant results have been observed, when used for 20 minutes, once a day for 6 weeks. [1-3]

How does eXciteOSA work?

eXciteOSA works by using non-invasive intraoral neuromuscular electrical stimulation (NMES) – an electrical current, to stimulate and improve muscle function of the tongue. The improved responsiveness of these muscles prevents the tongue from collapsing, maintaining upper airway patency. This reduces obstructive events, its associated desaturations, and improves the quality of sleep.[1-3]

How is eXciteOSA worn?

The mouthpiece is connected to the control unit through the USB connector and port. The mouthpiece is then placed into the mouth above and below the tongue. Two flanges of the mouthpiece and associated electrodes sit comfortably above and two sit below – like a glove.

The mouthpiece is designed such that when it is being used, it gently encloses the tongue, without the need for fixation during the therapy period.

How effective is eXciteOSA in clinical studies?

The daytime intraoral neuromuscular stimulation technology has been extensively tested with premier clinical institutions in the UK, Europe, and the USA, some of which have included over one hundred subjects.

The clinical data shows clinically relevant and statistically significant changes in objective and subjective measures (AHI, ODI, objective snoring sound, VAS, ESS, and PSQI).[3]

This data has been presented at the American Thoracic Society 2020 Virtual Conference, and Sleep 2020 Virtual Conference.[4-7]

Please reach out to info@signifiermedical.com for the latest clinical evidence and white paper.

What should my patient expect during therapy?

During the first few therapy sessions, patients will likely experience a slight accumulation of saliva.

Additionally, patients will experience tongue contractions at higher therapy levels. Please note that levels outside of the user's comfort zone will not improve the outcome or speed up results. However, please encourage users to explore higher therapy levels as tolerance levels are likely to go up each week. A reasonable balance of increasing the therapy level while still making sure the user is not experiencing any discomfort will ensure the best possible outcome.

How would I describe the therapy to my patient?

The therapy is similar to endurance training, like a long-distance track athlete. The purpose is not to add more muscle like a bodybuilder, but rather to improve muscle function and endurance in order to reduce upper airway collapse during sleep.

How soon can patients see a result?

Our data suggests that most users noticed an improvement within four weeks of therapy.

Nevertheless, it is recommended to use the device daily for the full 6-weeks with two sessions each week thereafter, to maximize outcomes.

Q&As continued on the next page

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If a person stops using eXcite^{OSA}, will their OSA or snoring return?

Our studies show that after our recommended 20 minutes per day for 6 weeks of therapy, the patient may sustain the results post-therapy for 3 to 6 months. In order to see long-term results, users are encouraged to adhere to the maintenance period, which requires two sessions per week after the initial 6-weeks.

Is eXcite^{OSA} advised for somebody who is already using Continuous Positive Airway Pressure (CPAP)?

eXcite^{OSA} is indicated for the reduction of mild obstructive sleep apnea (AHI <15) and/or snoring for patients that are 18 years or older. Under the controlled supervision of a physician, it may be possible to use eXcite^{OSA} to support CPAP therapy.

Is there a best time of day to recommend the therapy?

There is no specific time of day that has correlated with a better outcome.

We recommend that patients use their own schedule as reference when determining the time of day that will allow for optimal adherence. Routine and consistency are our only recommendations.

Is it as effective with high BMI patients?

Patients with a higher BMI are known to have excessive fat content around the tongue and neck, and additional factors contributing to their OSA.

Our clinical trials did not include patients with a BMI over 35, so it is not known if the eXcite^{OSA} therapy will be effective in patients with a BMI above 35.

Are there any side-effects?

To date, no serious adverse events have been reported and there are no long-term effects that would preclude you from referring eXciteOSA® to a patient.

In the clinical trials, some patients reported transient side effects of excessive salivation (12), tongue discomfort (11), tooth discomfort (7), tingling (7), metallic taste (3), or mouth tightness (1).[3]

All symptoms were transient and experienced only during active stimulation, with no patient having ongoing effects after finishing the 20-minute therapy. Notably, the prevalence of the symptoms reduced dramatically throughout the therapy period.

What are the contraindications?

eXcite^{OSA} is contraindicated if the patient:

- is pregnant or may be pregnant
- has a pacemaker of implanted electrodes
- has dental jewelry in the mouth
- suffers from a mouth ulcer
- has, or is suspected to have, an AHI > 15 as determined by the evaluation by a sleep health professional with a sleep study.

Always refer to the User Guide which contains all safety information.

Where do I find more information?

More information is available from the website (www.eXciteOSA.com), or please contact a Signifier Medical Technologies representative at info@signifiermedical.com.

Learn more

Click here to view a range of webinars available online.

REFERENCES: 1. E.Wessoleck *et al*. Intraoral electrical muscle stimulation in the treatment of snoring. Somnologie (Berl). 2018; 22(Suppl 2): 47–52. **2.** A.Sama *et al*. Daytime Intraoral Neurostimulation with Snoozeal® for treatment of Snoring and Mild Sleep Apnea. CHEST Annual Meeting Notes, 2018. **3.** Clinical study of 115 patients with snoring or mild OSA (Apnea- Hypopnea Index (AHI) <15 n=65) completed the trial. Objective snoring and respiratory parameters were recorded with 2 consecutive WatchPAT® night sleep studies before and after the use of the device. An intra-oral tongue stimulator device was used for 20 mins, once a day for 6-week period. **4.** B. Kotecha et al. A Novel Daytime Intra-Oral Neuromuscular Stimulation Therapy in Simple Snorers: Objective Improvement in Snoring . *Sleep* 43(Supplement_1):A245- A245 **5.** B. Kotecha et al. Daytime Intra-Oral Neuromuscular Stimulation Therapy on Patients with Mild Obstructive Sleep Apnoea. *Sleep* 43(Supplement_1):A245-A246 **6.** B. Kotecha et al. A Novel Daytime Intra-Oral Neuromuscular Stimulation Therapy in Simple Snorers: Objective Improvement in Snoring . *American Journal of Respiratory and Critical Care Medicine* 2020;201: A2445 **7.** B. Kotecha et al. Daytime Intra-Oral Neuromuscular Stimulation Therapy on Patients with Mild Obstructive Sleep Apnoea. *American Journal of Respiratory and Critical Care Medicine* 2020;201: A2444

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