



BREATHE WELL SLEEP SOLUTIONS

INFORMED CONSENT FOR ORAL APPLIANCE THERAPY

The following consent form has been created to advise you on options you and your child may have should any of the treatment modalities below be applicable to your case. You or your child has been diagnosed with dentofacial abnormalities or mild-to-moderate obstructive sleep apnea (OSA). There are several options to treat your condition(s), including no treatment, treatment, or consultation with a specialist in orthodontics or various types of surgical procedures.

What is oral appliance therapy?

Oral appliance therapy is a relatively new therapy not practiced by all dentists. An oral appliance can be a non-invasive alternative treatment to other modalities in treating dentofacial abnormalities and/or mild-to-moderate OSA and snoring in adults. Oral appliance therapy has been used to effectively treat many patients, but the full effect of oral appliance therapy is still being determined.

There are no guarantees that oral appliance therapy will be effective for you, as everyone is different, and there are many factors influencing the development of the maxilla and jaw position. It is important to recognize that even when therapy is effective, there may be a period before the oral appliance will give you maximum relief of symptoms. Just as your problem took a long time to fully develop, this technique can take a long time to resolve your problem.

The standard treatment period for development is approximately 18 months but is directly affected by the severity of an individual patient's problem and your compliance with your treatment protocol. Your therapy may be augmented by myofunctional therapy and soft-tissue releases. If you have been using a CPAP device, CPAP therapy may be continued during the early stages of your treatment. Oral appliance therapy in no way directly replaces a CPAP although positive outcomes have resulted with additional consultation from a sleep physician.

Side Effects and Potential Complications of Oral Appliance Therapy

Published studies show that short-term side effects of oral appliance use in general may include excessive salivation, difficulty swallowing (with the appliance in place), sore jaws, sore teeth, jaw joint pain, dry mouth, gum pain, loosening or flaring of teeth and changes in the bite. There are also reports of dislodgement of ill-fitting dental restorations. Most of these side effects are minor and resolve quickly on their own or with minor adjustment of the appliance.

Any oral appliance may restrict oral breathing. While the appliance is designed to minimize this risk, should you experience any difficulties in breathing, immediately remove the device and contact your dentist. Long-term complications include changes in the bite that may be permanent, resulting from tooth movement or jaw joint repositioning (which is the desired effect with appliance therapy). These complications may or may not be fully reversible once appliance therapy is discontinued.

If your desired outcome is not fully achieved, restorative dental treatment, orthodontic intervention (including, but not limited to, braces) or other treatments, such as aligners, may be required, for which you will be responsible.

Alternative Treatment Modalities

Other possible modalities for treating dentofacial abnormalities and/or mild to moderate OSA and snoring in adults are:

- Standard orthodontic treatment to reposition the jaw and align the teeth;
- A continuous positive airway pressure (CPAP) machine to treat obstructive sleep apnea. This device is worn during sleep to force air into the lungs. Many patients have difficulty adjusting to a device placed over their nose and mouth and the associated noise that is produced by the device;
- Over-the-counter treatment options like nasal strips;
- Surgery to further open the airway and perhaps remove the tonsils and adenoids; and/or
- Mandibular Advancement Devices (MAD) that move the jaw forward to open the airway.

Follow-Up Visits and Testing

Follow-up visits are required every few weeks or months in our office to adjust the device, to ensure proper fit, and to assure a healthy condition, as well as the maximum, timely development of your mouth and jaw. Every six (6) months, and at the conclusion of your treatment protocol, scans and images are taken along with photographic evidence. You may be asked to fill out a patient questionnaire or participate in a home sleep study. From this point, depending on the amount of development, we will re- assess your case and may consider alternative treatment modalities or extending your treatment time.

Damaged Appliances

There will be a fee charged to you for broken and/or damaged appliances. The fee will be dependent upon the scope of damage. In some cases, a new appliance may be indicated with an associated fee for fabrication.

Patient Compliance

It is your decision to choose oral appliance therapy to treat your condition(s), and you are aware that it may not be completely effective for you. The oral appliance will not work if you do not wear it as prescribed. It is your responsibility to report any occurrence of side effects immediately and to address any questions to your dentist or healthcare professional. If you are using a cleared device for OSA, (mRNA, mmRNA) failure to treat your condition may result in obstructive sleep apnea and/or worsening obstructive sleep apnea. This is also true of alternative modalities such as orthodontics, MADs, and CPAP devices.

Research

This office participates in on-going research to improve patient treatment. Your treatment data (but not your name or any other personal identifiers) may be combined with that of other patients' data to analyze the safety and effectiveness of different treatment modalities.

Do not sign this before you have read and understood it. You are entitled to an exact copy of the paper you sign.

I hereby affirm that I have read and fully acknowledge, accept, and understand any and all risks, known and unknown, involving the wearing of an oral appliance, and I agree to all the terms of this Informed Consent Agreement.

Print Name of Patient _____

Print Name of Parent/Guardian _____

Signature of Parent/Guardian _____

Date _____

Signature of Witness _____

Date _____