

*A Pilot Research Study:*

# Orthodontic Dental Device for Sleep Apnic Children



**PURPOSE:** To determine the effectiveness of a removable dental device in managing diagnosed obstructive sleep apnea in the 9 to 16-year-old age group. Oral devices approved for snoring and/or obstructive sleep apnea are not approved by the FDA for patients under the age of 18.

Lower jaw repositioning devices in adults have been determined by the American Academy of Sleep Medicine to be as effective in managing mild to moderate obstructive sleep apnea as CPAP in people over the age of 18. They also have been shown to be appropriate in patients who have failed CPAP/BIPAP therapy or patients who do not desire or are not candidates for positive airway pressure.

The overall goal of this pilot project is demonstrating this device and mandibular repositioning is effective in the treatment of obstructive sleep apnea in children. We believe that since these devices are effective in patients 18 years and older, they will be equally effective in children.

The device utilized is a Dorsal Accu-Fit (K103076). It has been approved for use in patients 18 years or older for snoring and obstructive sleep apnea by the FDA. Devices with similar design have been used for decades as an orthodontic device in the under 18-year-old age group for correction of overbites.

**COMPENSATION:** A \$75 reimbursement and parking for each clinic visit will be given. There are no charges for the examination, treatment or follow up.

## Department of Sleep Medicine Investigators:

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Don't hesitate to ask any questions!



Dorsal Accu-Fit

# A Pilot Research Study: Orthodontic Dental Device for Sleep Apnic Children

**PARTICIPANTS QUALIFICATIONS:** Children will be selected by Miriam Weiss, RN, Gustavo Nino, MD, and Jenny Lew, MD, to participate. These are children with sleep apnea who have failed or are not candidates for traditional treatments such removal of tonsils and adenoids or CPAP. You will be given a written detailed overview of this study and a consent form. Once you, the parents or guardian, agree the lead investigator, Dr. Sylvan Mintz will contact you by phone. Dr. Mintz was a pediatric dentist and currently limits his practice to dental sleep medicine. He is a consultant at Children's National Hospital Sleep Center. His bio is available upon request.

**WHAT TO EXPECT:** If amenable to this protocol, a Monday afternoon appointment will be made at the Children's National Hospital Dental Clinic. **The first visit** may last as long as 90 minutes. At that appointment, any further questions will be answered, and various consent forms will be signed. That visit will include a thorough dental examination, a panoramic and cephalometric X-rays. These are the same images taken for orthodontic treatment. Also, on this visit records will be obtained which include upper and lower dental impressions and measurements for the dental device.

**The second appointment**, approximately a month later, will be fitting of the device for comfort and instructions in the care and home adjustment of the Dorsal Accufit. This device has a soft inner lining that is warmed to mold to your child's teeth on that appointment by Dr. Mintz.

Between this visit and a follow up dental clinic visit, approximately a month later, will be a series of phone consultations. The device has a mechanism to slowly advance the lower jaw forward depending on clinical symptoms such as a decrease in snoring, less nighttime awakenings and daytime sleepiness. You will be taught how to do these simple adjustments. The phone visit will include your child's ability to wear the device and lessening of these clinical symptoms. Should there be any problems such as tooth, gum or jaw irritation, the patient will be instructed to stop wearing the device and another Children's National Dental Clinic visit will be made to correct any problems.

**The third follow-up visit** will be an examination of the patient's mouth and device. If Dr. Mintz feels your child has been successful in the use of the dental device, we schedule an overnight sleep study where the device will be used. If the sleep apnea is not resolved during the overnight sleep study, further advancement will take place that night. If the desired apnea score is not reached, the child may be awakened one to three times per Dr. Mintz' protocol. If the sleep technician on duty that night does not know how to advance the device, you will be asked to do so.

**No later than six months** after completion of wearing the device through the night on a consistent basis and follow up sleep study, a final dental visit will be made for an oral examination and again molds of the teeth at that time. If the parent or guardian wants to continue with this treatment, then an orthodontist or pediatric dentist must consent to take over this therapy. Otherwise, the device will be returned to the clinic.

The device is only worn during sleep. It is maintained with brushing in the morning and/ or denture cleaning tablets (Polident or Efferdent). Because the jaw is stretched sometimes there will be stiffness to the jaw muscles in the morning. Dr. Mintz will give a simple 30-second exercise to relieve this stiffness.

The main disadvantage of this treatment is a bite change. Generally, the morning exercises prevent this from happening. Although this can happen in 10-15% of patients, it is usually minor and self-correcting once treatment is stopped. Many times, if there is a bite change, it can be beneficial such as correcting an overbite. As outlined in the consent, other problems can occur.