THE LVI SomnoDent

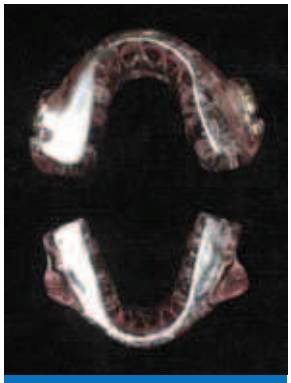
The long awaited FDA approval for the LVI SomnoDent appliance has finally arrived. Actually, by FDA standards it was really fast. As you would expect, the approval process of anything through the FDA is an expensive and time consuming ordeal in outlasting bureaucratic roadblocks. Perhaps a necessary evil as it is designed to protect the patients from instances where things designed to be good actually aren't. Knowing that, it was fully anticipated that this approval process might take longer. The reason it wasn't is that the change in the appliance does not change the basic function of the mandibular advancement device (MAD).

Sleep Apnea is a highly prevalent disease leading to many co-morbidity factors that contribute to poor health including early death. Since the diagnosis of this disease is on the rise, health practitioners are beginning to increasingly offer treatment for this condition. It is a disease that is not always cured but rather, managed. The gold standard treatment modality is with the use of CPAP (continuous positive air pressure). More recently, the use of oral appliances has gained significant ground with a statement by the American Academy of Sleep Medicine, in 2006, endorsing appropriate mandibular advancement devices as the first line of treatment for patients suffering from mild to moderate sleep apnea.

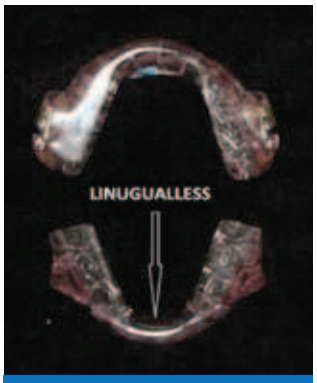
The difference in the LVI SomnoDent is that the lingual flange has been removed from the maxillary and mandibular appliance to allow for more tongue room. What we found at LVI was those that were given the LVI "lingual-less" appliance found them to be more comfortable and preferred them over the regular model. So let's look at the advantages of the LVI SomnoDent over the regular SomnoDent.

Obviously as Neuromuscular dentists we can see the common-sense differences between the traditional SomonDent and the lingual-less. Although I can't imagine it ever being an issue, for your physician colleagues it may be important to let them know that relative to the conventional SomnoDent, the "lingual-less" appliance serves the same advantages and is supported by the long track record of success and research in the appliance design. Although I doubt the sleep physicians even know that the regular SomnoDent HAS a lingual flange.

More tongue room. Common sense will tell you that if you remove thick plastic from the oral cavity, there will be more room for the tongue. More room for the tongue would theoretically mean less mandibular advancement necessary to adequately open the airway. In a study done at LVI, organized by Dr. Sam Kherani, he found that the regular SomnoDent required a 5.6 mm farther advancement of the mandible than the LVI "lingual-less" SomnoDent. This 5.6 mm further advancement with the standard SomnoDent leads to significantly increased discomfort in the TMJ as this was subjective feedback that we also received. Although this study may not be an adequate study to reach that conclusion as fact, as a pilot study it was interesting to see that was shown.



Regular SomnoDent



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Patient comfort. As stated in the opening, patients given the LVI SomnoDent preferred them to the regular SomnoDent. Also, a survey was taken of those that participated in Dr. Kherani's study and were asked which appliance they preferred to wear, and 15 out of 15 preferred the LVI SomnoDent. Not only was this believed to be due to the greater tongue space, the wearing of the Lingual-less SomnoDent lead to less necessary protrusion of the mandible in this pilot study and the participants were able to get their back teeth together much easier after the wearing of the appliance all night.

The study in this paper was conducted using 2 (two) different mandibular advancement device types (with a lingual flange vs. without a lingual flange) and 2 (two) different bite techniques (arbitrary protrusive vs. Neuromuscular) to capture the relationship between the maxilla and the mandible. The resultant sleep metrics (AHI, RDI, ODI, Light Sleep, Deep Sleep, REM, Snoring, Body position) were documented and analyzed leading to the outcome discussed below.

The Lingual-less design has a significant positive impact on the sleep metrics and airway volume as it minimally impinges on the precious tongue room. The Lingual-less design produced sleep metrics very close to those produced by the Protrusive SomnoDent but required the mandible to be protruded 5.6 mm less on average than the Protrusive SomnoDent. The NM design also reduces NeuroMechanical load on the patient and hence a better sympathetic tone helping to keep the airway open during sleep.

We based our results on sleep studies using the Watch-Pat 200 that were performed 10 different times on each participant. Most studies just report subjective reports from patients. Although this author feels that subjective results are not to be taken lightly, the forward advancement was determined by the home sleep studies.

Worst case in using the LVI appliance is that you end up using it exactly the same as the regular SomnoDent appliance, since there is no difference in mandibular advancement. The benefit is that compliance might be better because it's more comfortable for the patient. Not a bad downside.

It is not uncommon for dentists to apply denture pressure paste to the lingual of the flange and adjust the marks away to help the situation when the lingual flange is a noticeable irritation to the patient. Obviously it's really not necessary for it to be there in the first place as it is not important to the function of the appliance or the FDA would not have approved it so fast. In fact, again, common sense would indicate just the opposite. Since we are trying to give the tongue more space by moving the mandible forward, why not help the cause out by eliminating any artificial interference in the oral cavity, like the lingual flange?

LVI SomnoDent

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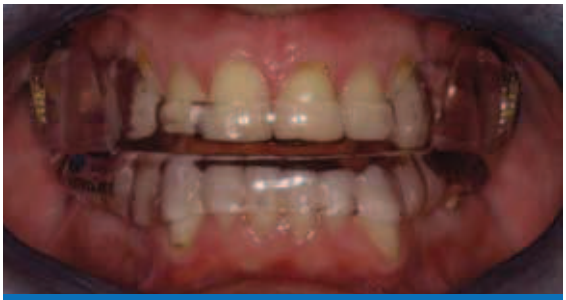
Some may be worried about the appliance being not as strong. Of the 15 appliances placed in the study, not one of them has broken in the last 1.5 years. If there is a patient that has a breakage issue, then prescribe them the regular appliance. But why worry about something until it becomes an issue? Besides, think about why that strength is needed in the first place. The vast majority of the profession is under the mistaken notion that bruxism is incurable. The arbitrary protocols of early MAD therapy established where the bite was taken and how the appliance was designed to minimize breakage. For the Neuromuscular doctor who can eliminate bruxism, the incidence of appliance fracture will be considerably less.

Removing the lingual flange from the regular SomnoMed is similar to why I developed the LVI "fixed" Neuromuscular Orthotic and had the labs remove the lingual flange from the removable NM orthotics. What we found was that the regular orthotics would often cause an elevated EMG's of the digastrics. Often pain would not be alleviated in the patient until we switched to a lingual-less or a LVI "fixed" orthotic which only covers the tops of the teeth. We saw the same thing when our bite registration would encroach on the intra oral cavity



LVI SomnoDent in mouth.
Notice anterior placement of tongue.

and touch the tongue; the digastrics would elevate. When we trimmed away the excess, the digastrics calmed down. It doesn't take much material applied to the lingual surface or your teeth to actually feel the difference and for it to be annoying. I'm sure many of you have experienced a patient complain about a crown feeling too thick when it looked to be a normal size. Try slightly reducing the lingual surface and you'll find that their "issue" goes away.

So for all you sleep doctors out there, I would encourage you to use the LVI SomnoDent for your next MAD. You may be surprised at the patient's reaction and compliance as well as the reduced advancement necessary. What do you have to lose?