CLINICAL STUDY REPORT

Title of Study: “Treatment of sleep bruxism with the Luco Hybrid OSA Appliance®”

Principle Investigator: Dr. Ken Luco

Organization: Luco Hybrid OSA Appliance Inc.

REPORT:

The data analysis demonstrated that the Luco Hybrid OSA Appliance® is an effective treatment for the signs and symptoms of sleep bruxism. This was based upon the American Academy of Sleep Medicine’s classification of sleep bruxism[i]. They areas of study were based upon the clinical description of signs and symptoms described in this publication. This included three areas of study, to provide diverse data that would the most reliable results.

The First Area of Study Was Clinical Including an Examination of Each Subject. The Examination consisted of palpation of the TMJ and masticatory, upper shoulder and cervical musculature, and measurement of the subject’s mandibular range of movement (including wide opening, left lateral, right lateral, and protrusive movements).

The Second area of study was utilizing a home sleep recording of the subject’s sleep including an EMG module to record the muscle activity of the masseter and temporalis muscles. These two muscles are the most common and significant muscles involved in sleep bruxism. Also studied was the subject’s heart rate during sleep. Sleep bruxism has been shown to cause an increase in both heart rate and blood pressure with each bruxism event. Two Medibyte Event® 12 channel sleep recorders with EMG modules were used in the study. These units allowed recording of respiration, heart rate, blood oxygen levels, and other variables not used in the study. The EMG module allowed recording in real time of any sleep bruxism events involving the masseter and temporalis muscles.

The third area of study involved a visual analog scale developed for the study. This is filled in by the subjects confidentially and added to the database for analysis. Five questions were asked on the VAS scale:

1. TMJ/ear pain upon waking and later in the day
2. Jaw muscle pain upon waking and later in the day tooth sensitivity
3. tooth sensitivity to temperature extremes
4. tensions/migraine headaches upon waking and later in the day
5. neck and shoulder pain upon waking and later in the day

Results: The First Area of Study:

For Group 1, the data demonstrated an 94.0% reduction in jaw, neck, and shoulder muscle pain at the 14 day milestone. This increased to a 98.0% reduction at the third milestone (completion).

For Group 2, the data demonstrated that the night without the device resulted in a complete relapse of the symptoms for the subjects who had been in treatment for years. At the third milestone there was a 91.9% reduction in jaw, neck, and shoulder muscle pain compared with the night the device is not worn. At the 60 day milestone there was a 97.6% reduction in this muscle pain.

Re regarding the palpation of the TMJ, group 1 demonstrated a 98.1% reduction of lateral pole pain at the 14 day milestone. This increased to 99.7% at the 60 day milestone. Group 1 demonstrated a 99.1%

reduction in pain of the posterior joint space at the 14 day milestone increasing to a 100% reduction by the 60 day milestone.

Group 2 demonstrated a 96.6% reduction when wearing the device as compared to the night without this increased to 99.3% by the 60 day milestone posterior joint space improved by 98.1% compared to the night without the device and improved to 99.4% of the 60 day milestone.

The Luco hybrid OSA appliance is effective in treating jaw neck and shoulder muscle pain as well as lateral pole and posterior joint TMJ pain associated with sleep bruxism.

Group 1 demonstrated at the 14 day milestone an overall increase of mandibular range of motion of 27.8%. This did not change at the 60 day milestone and remained at 27.8%. Group 2 demonstrated a 14.5% increase in range and mandibular motion on the night the device was worn as compared to the night it wasn't. This increased to 18.8% at the 60 day milestone.

The second area of study the home sleep recording of sleep bruxism events demonstrated in group 1 a 94.5% reduction in the number of sleep bruxism events increasing to 97.4% of the 60 day milestone. Group 2 demonstrated a 94.5% reduction in sleep bruxism events in the night the device is worn in comparison tonight device was not. This increased to 97.4% at the 60 day milestone. The duration of the sleep bruxism events similarly improved in group 1 there was an 89.2% reduction at the 14 day milestone increasing to a 91.7% reduction in the generation of length of sleep bruxism events. Group 2 similarly demonstrated a reduction in the length of sleep bruxism events. On the night the device was born there was an 88.6% reduction in event length compared to the night it was not worn. This increased to 92.5% reduction at the 60 day milestone.

Bruxism index relates to the hourly rate of sleep bruxism events. Group 1 demonstrated a 90.0% reduction in the bruxism index at the 14 day milestone increasing to 92.6% at the 60 day milestone. Group 2 demonstrated a 90.6% reduction in the bruxism index comparing the night the device is warranted to the night it wasn't. At the 60 day milestone there was a 95.3% reduction in the bruxism index.

The AASM classification of sleep bruxism states an increase in both heart rate and blood pressure during sleep bruxism events. The pulse oximetry recording demonstrated in Group 1, a pretreatment mean maximum heart rate of 110.6 bpm. At the 14 day milestone this had reduced by 27.9% to a mean of 77.4 bpm. This further reduced at the 60 day milestone 70.7 bpm. Group 2 similarly demonstrated a mean maximum heart rate of 106.9 bpm on the night the device is not worn, reducing to 79.8 bpm on the night it was more. This further reduced to 73.9 bpm at the 60 day milestone.

The final area of study was the visual analog scale, completed confidentially by the subjects at each milestone. The first question on the VAS scale was "TMJ/ear pain on waking and later in the day". Group 1 reported a 91.8% reduction in TMJ ear pain on waking at 14 day milestone. There was no change of the 60 day milestone (91.8%). For group to there was an 80.6% reduction in TMJ ear pain the night the device is worn as compared to light it wasn't this increased to 92.9% by the 60 day milestone.

The second question on the VAS scale was "jaw muscle pain on waking and later in the day". Group 1 reported 81.1% reduction in jaw muscle pain at the 14 day milestone increasing to 91.6% of the 60 day milestone. Group 2 demonstrated an 82.6% reduction in jaw muscle pain the night the device was worn increasing to 93.6% of the 60 day milestone.

The third question on the VAS scale with regarding tooth sensitivity to hot and cold temperature extremes. Group 1 reported a 92.0% reduction in tooth sensitivity at the 14 day milestone increasing to

98.1% of the 60 day milestone. Group 2 similarly demonstrated a 95.6% reduction into sensitivity the night the appliance was worn increasing to 98.1% of the 60 day milestone.

The fourth question on the VAS scale was regarding tension/migraine headaches on waking or later in the day. Group 1 reported a 90.9% reduction in these headaches at the 14 day milestone increasing to 97.6% of the 60 day milestone. Group 2 reported a 92.9% reduction in these headaches on the night the device is worn increasing to 98.1% at the 60 day milestone

The final question on the VAS scale was regarding neck/shoulder pain on waking and later in the day. Group 1 reported an 88.5% reduction in neck shoulder pain at the 14 day milestone increasing to 95.8% at the 60 day milestone. Group 2 reported an 89.0% decrease in neck and shoulder pain the night the device is worn increasing to 96.1% of the 60 day milestone.

To summarize the findings of the study, the Luco Hybrid OSA Appliance® effectively treated all of the variables that were studied. This demonstrated the Luco Hybrid OSA Appliance® is an effective, long-term treatment of sleep bruxism and its associated signs and symptoms. It is also an effective treatment of associated tension/migraine headaches that are common with sleep bruxism.

July 2016, the FDA granted market clearance to the Luco Hybrid OSA Appliance® for the treatment of sleep bruxism and to aid in the treatment of associated tension/migraine type headaches in adults. The

[i] American Academy of Sleep Medicine. International classification of sleep disorders, 3rd ed. Darien, IL: American Academy of Sleep Medicine, 2014.