Docket #: S21-149

Intraoral device for obstructive sleep apnea (OSA) treatment for infants, children, and adults

Continuous positive airway pressure (CPAP) therapy is currently the first line non-surgical treatment when a patient is diagnosed with obstructive sleep apnea (OSA). It provides pneumatic stenting of the upper airway and prevents the airway from collapsing during inspiratory phase of breaths. It is very effective when it is worn. However, the compliance to CPAP therapy is very low due to discomfort related to the ill-fitting mask adaptation, high inspiratory and expiratory pressures, and bulkiness of the device. Alternatively, oral mandibular advancement devices (MAD) are available. They are retained by the full upper and lower dentitions and protrude the lower jaw to enlarge the pharyngeal airway by bringing the tongue forward with the protruded lower jaw. While the compliance rate with MAD is much higher, the efficacy of MAD is less than that of CPAP. MAD often results in moderate to severe side effects of temporomandibular joint discomfort and occlusal changes.

Dr. HyeRan Choo at Stanford has developed a device to enlarge and secure the pharyngeal airway while a patient is asleep by controlling the tongue on multiple mechanisms without involving surgeries. First, the device elevates the tongue position, which subsequently elevates the hyoid bone and enlarges the hypopharyngeal space. Second, it lets the tongue comfortably rest on the acrylic pads on the floor of the mouth, which induces intrusive force on the lower molars, counterclockwise rotation of the lower jaw, and lets the lower jaw to naturally advance forward. Third, it provides a mechanical barrier behind the base of the tongue when the tongue falls backward while asleep. The design of the invention secures a continued airway patency. Most importantly, the device can immediately sense the event of airway obstruction with a pressure sensor behind the tongue base and rapidly trigger necessary stimulations to activate the major pharyngeal dilator muscles before the obstructive event occurs. Not only does the invention prevent disruption of the temporomandibular joints, it also secures a patent upper

airway at all times without requiring CPAP masks or uncomfortable air pressure.

Applications

- Obstructive sleep apnea
- Wearable device
- Airway obstruction

Advantages

- Provides multi-level resolution to tongue-based obstruction as described above: mechanical, neuro-electrical, physiological: None of the currently available solutions does that.
- Does not require a mask or attached machine to operate
- Minimally bulky, with no soreness to the temporomandibular joints and no bite change
- Requires no surgery to stimulate the hypoglossal nerve as needed and provides mechanical barriers in addition to electrostimulation in eliminating the tongue obstruction
- Stimulator on device can stimulate the hypoglossal nerve more effectively with minimal strong electrical pulses

Patents

- Published Application: WO2022240774
- Published Application: 20240066291

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