Intra-oral and peri-oral electronic devices
An overview of current therapeutic and diagnostic systems

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The functions and organ systems of the human body are, to a significant extent, controlled by electrical signals that travel along the nerves. Electronic medical devices are aimed at controlling biological processes and treat disease by modulating these electrical impulses. These devices may assist in the therapy of conditions that are currently untreatable or resistant to other therapy methods. They may deliver treatment with greater precision and fewer side-effects than conventional pharmaceutical products do.

In the last few decades, a variety of wearable electronic medical devices have been introduced to the market. Examples of such devices include neuro-stimulators, cardiac pacemakers, implantable cardio defibrillators, cochlear implants and retinal implants. These devices are used to address a variety of conditions, such as brain disorders (including epilepsy, Parkinson’s disease, traumatic brain injury, stroke, psychiatric disorders, etc.), chronic pain conditions (addressed through e.g. spinal cord stimulators), incontinence, cardiovascular disorders (including heart failure, angina and peripheral vascular disease), deafness and blindness.

A number of vital structures located in the oral cavity region are controlled by the nervous system, such as the salivary glands and the orofacial musculature. Given the largely proven diagnostic and therapeutic value of electronic devices, it is surprising that only a few intra- and peri-oral electronic medical devices have been released to the market. Moreover, in contrast to electronic devices that involve typically invasive procedures, such as pacemakers and spinal cord stimulators, the placement and even the wearing of devices in the intra- and peri-oral region are not invasive.

Nevertheless, it appears that the US Food and Drug Administration (FDA) has considered for many years that electronic medical devices carry an increased risk if worn in the head and neck area, compared with other body areas, such as the limbs. Thus, electronic medical devices for the head and neck area are generally classified by the FDA as Class III devices, which are the highest risk devices and are, therefore, subject to the highest level of regulatory control. However, recently the FDA has classified a small number of these types of devices as Class II devices, which are lower risk devices than Class III and require less regulatory control to provide reasonable assurance of the device’s safety and effectiveness. Nevertheless, those devices have to meet special controls, which are requirements intended to address the unique concerns of specific types of devices. Some examples are as follows.

- On 13 November 2014, the FDA allowed marketing of an electronic device as a preventative treatment for migraine headaches (Cefaly, CEFALY Technology). The portable, battery-powered prescription device resembles a plastic headband worn across the forehead and atop the ears. The user positions the device in the centre of the forehead, just above the eyes, using a self-adhesive electrode. The device applies an electrical current to the skin and underlying body tissue to stimulate branches of the trigeminal nerve, which has been associated with migraine headaches.

- On 8 July 2014, the FDA issued a final order classifying a transcranial magnetic stimulator for headache into Class II (special controls). The device delivers rapidly alternating, or pulsed, magnetic fields of brief duration that are externally directed at spatially discrete regions of the brain to induce electrical currents for the treatment of headache.

- On 20 November 2013, the FDA issued a final order to reclassify an electrical salivary stimulation system (SaliPen, Saliwell) as a Class II (special controls) device. Previously, it was a Class III device. This intra-oral device (more details later in the article) is restricted to patient use upon prescription of a dental practitioner or physician.

- On 22 January 2016, the FDA announced a proposed administrative order to reclassify cranial electrotherapy stimulator devices intended to treat insomnia and/or anxiety, from Class III to Class II (special controls).

Examples of three electronic intra- and peri-oral devices that are available are covered in the paragraphs that follow.

The TheraMon® system consists of (a) a micro-sensor that measures and stores the temperature readings, that is wearing time data of the removable therapeutic device (Fig. 1), (b) a reading station that reads the memory of the micro-sensor using radio-frequency identification technology and transfers the data to a computer via a USB cable (Fig. 2), and (c) an assessment software that represents the wearing time in a diagram. TheraMon® is a Class I medical product (lowest level of risk) that does not claim any medical therapeutic or diagnostic functionality.

Sensors like TheraMon® can be implemented in mandibular advancement devices (MADs), which are increasingly being prescribed as an alternative to the use of continuous positive airway pressure (CPAP) systems in the treatment of obstructive sleep apnoea. Studies have shown that MADs are preferred by patients and, thus, compliance with treatment may be greater than for CPAP. However, compliance with the treatment can be better measured in the CPAP system, as the built-in processor allows follow-up of the actual hours of use of the mask. In contrast, conventional MADs lack this control system and, thus, objective verification of compliance is not possible. Therefore, a microchip for thermal sensing that is inserted into a MAD can provide this missing ability to measure compliance objectively.

In a blind prospective clinical study of three month’s duration, the safety and feasibility of objective measurement of compliance with MAD wearing was evaluated. A Lirón MAD (Fig. 3) equipped with a temperature micro-sensor was...
A double-blind study, carried out at three medical centres in Europe, tested the device performance with short-term use, using a built-in moisture sensor. As the primary outcome, measured oral dryness changes as a result of 10 minutes of wearing the device were assessed and compared between the usage of the device either switched on or switched off. Twenty-three patients with xerostomia due to different causes (primary Sjögren’s syndrome, radiotherapy, medication-induced, graft-versus-host disease and idiopathic) were evaluated. The decrease in oral dryness (as measured by the moisture sensor) was significantly superior (p < 0.0001) when induced by the device in switched-on mode. No significant side-effects were observed.

In a multi national randomised clinical trial, long term (6 months) intra-oral electrostimulation was tested in a mixed sample of xerostomia patients (Sjögren’s syndrome, radiotherapy, medication-induced, graft-versus-host disease and idiopathic). In Stage I of the study, switched-on versus switched-off devices were compared, for a period of one month in a double-blind design (96 patients). In Stage II, immediately after Stage I, the xerostomia-relieving effects of the switched-on device only, were assessed in an open label study (96 patients).

The results of Stage I show that the patient-reported degree of oral moisture improved by 26 per cent when the device was switched on (with a statistical significance level of p < 0.0001) versus an 18 per cent improvement when switched off. The results of Stage II show that the level of self perceived oral moisture increased by 24 per cent (p < 0.0001) and the amount of collected saliva increased by 25 per cent (p < 0.0001) at rest and by 18 per cent (p < 0.0001) during mastication. No severe or irreversible systemic or local adverse effects were observed at either stage of the trial.

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Parafunctions are movements of known form of oral parafunction. Parafunctions are considered outside or beyond normal function. The prevalence of bruxism in the adult population is estimated at 8 per cent; however, as many individuals may be unaware of this condition, the occurrence is most likely higher.

Bruxism is prevalent during the night, but some people with bruxism unconsciously clench their teeth during the day, often when they feel anxious or tense. In some cases, bruxism is mild and may not even require treatment.

Unfortunately, people with sleep bruxism usually are not aware that they brux; so they are not diagnosed until complications occur. That is why it is important to diagnose sleep bruxism as early as possible and to seek appropriate treatment. Bruxism is usually diagnosed based on clinical examination of the teeth, complaints of jaw and masticatory pain, and reports by the bed partner of grinding noises. Patients suspected of bruxism are not routinely referred to the sleep laboratory due to its high cost. Thus, clinical and experimental data are scarce and there is no widely accepted gold standard for a definitive, objective diagnosis.

BiteStrip (SLP) is a diagnostic tool that can assist the clinician in detecting bruxism and assessing over time the effectiveness of the therapy delivered to treat the disorder. It is a miniature single-use electronic device designed as a screener for bruxism (Fig. 7). It consists of three electromyography (EMG) electrodes and an amplifier to acquire masticatory muscle signals, a central processing unit with real-time software that detects and analyses EMG Patterns, and a display that exhibits the measurements in the morning. All elements are integrated on a single flexible substrate.

At bedtime, patients are instructed to attach the device over the mandible to the cheek, to activate it and to perform a series of maximal strength clenching and grinding activities in order to establish an individual threshold for the night-time monitoring (Fig. 8). The device must be worn for at least 1 hour of sleep. In the morning, patients deactivate the device and wait for approximately 20 minutes for the bruxism index (number of bruxing events per hour of recording) to be displayed.

The BiteStrip device was used in a before-and-after experimental clinical study with the objective of evaluating the effect of a MAD on sleep bruxism and sleep scores.

After a habituation period of one week, sleep bruxism scores were taken at baseline and after use of the MAD for 30 days. Scores were compared using BiteStrip, which registered the number of contractions of the unilateral masseter muscle after a 5-hour period, giving a severity score of 0 to 5 after the registrations. In order to assess sleep, the Sleep Assessment Questionnaire, a screening tool with scores ranging from 0 to 88, was administered before and after use of the MAD.

Twelve-eight subjects (13 women and 15 men; mean age of 49.9 ± 12.0) with a clinical history of sleep bruxism and no spontaneous TMD pain were selected. The clinical diagnosis of either moderate or severe sleep bruxism was further confirmed through use of BiteStrip (score of 2 or 3) at baseline. A 30-day follow-up period was used for evaluation. Both methods were validated against polysomnography. In addition, common signs and symptoms of TMD based on the Research Diagnostic Criteria for Temporomandibular Disorders (WTCoxon signed-rank and Student’s paired t-test; p < 0.05). Concerning the signs and symptoms of TMD, there was a significant reduction in temporal pain sounds, as well as in masticator and temporalis tenderness to palpation. In summary, the improvement measured by BiteStrip was the same as the improvement assessed by other methods.

**Conclusion**

In conclusion, implementation of electronically based intra-oral therapeutic and diagnostic devices creates new possibilities for all kinds of novel applications for which the power of electronics and related technologies (software, wireless communications) is harnessed to provide better and personal medical services at lower costs.