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 oral 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 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 11 March 2014**, the FDA approved 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 11 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 2015**, 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 months’ duration, the safety and feasibility of objective measurement of compliance with MAD wearing was evaluated.1 A Linón MAD (Fig. 3) equipped with a temperature micro-sensor was

Fig. 1: The TheraMon® microsensor and a removable device to which it will be attached.—Fig. 2: TheraMon® reading station and microsensor, with a removable intraoral device.—Fig. 3: Linón MAD.
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 was significantly improved by 25 per cent (p < 0.001) versus an 18 per cent improvement when switched off (with a statistical significance level of p = 0.002) when the device was switched on. The results of Stage II show that the level of self-perceived oral moisture increased by 24 per cent (p < 0.001) at rest and by 28 per cent (p < 0.001) during mastication. No severe or irreversible systemic or local adverse effects were observed at either stage of the trial.
Bruxism is the most well-known form of oral parafunction. Parafunctions are movements of the masticatory system that 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.

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 5 hours 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. 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 hours period, giving a severity score of 0 to 3 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.

Twenty-eight subjects (13 women and 15 men; mean age of 45.9 ± 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 were evaluated before and after use to assess the side-effects of the MAD. The results showed a statistically significant improvement in both sleep bruxism and sleep scores based on BiteStrip and the Sleep Assessment Questionnaire (Wilcoxon signed-rank and Student’s paired t test, p<0.05). Concerning the signs and symptoms of TMD, there was a significant reduction in temporomandibular joint 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- and peri-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.