Use of Thermoforming Ethylene Acetate for an Innovative Device

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Currently, the methods to reconstitute the lost periodontal structures have relied on conventional mechanical, anti-infective modalities, followed by a range of regenerative procedures. An innovative medical device, using thermoforming ethylene acetate base, with an electromagnetic applicator, homologated with CE mark in class 2a, was used in the treatment of second degree teeth mobility. The affected areas were exposed to a precise, totally atraumatic and noninvasive electromagnetic field. The preliminary study on 10 subjects was performed with this medical device, using a standard protocol of 30 exposures of 2 h each, on the affected area. Subjects were both male and female, aged between 20-70 years, in healthy state and having a good oral hygiene status. After 2 months, the results were recorded by testing the mobility of the affected teeth, by measuring the periodontal pockets depth and by comparing the radiographs effectuated before and after the treatment. The results were assessed and proved the appreciable reduction of teeth mobility, the reduction of periodontal pockets depth and bone regeneration in the regions exposed to the electromagnetic applicator. The conclusions of this preliminary study recommend this innovative medical device for the use in the healing of periodontal lesions as noninvasive and atraumatic therapy.

Keywords: periodontal lesions, innovative medical device, healing

Periodontal diseases, caused by the bacterial biofilm, can affect up to 90% of adults worldwide. Severe periodontitis leads to losing connective tissue and bone support and finally losing teeth. The periodontal ligament (PDL) is an important structure that is composed of periodontal tissue, in which PDL cells generate connective tissue fibers that span the gap between the cementum and the alveolar bone to suspend the tooth [1].

Therefore, many researches were conducted on periodontal tissue regeneration for restoring the alveolar support of the teeth. Currently, the methods to reconstitute lost periodontal structures (i.e. alveolar bone, periodontal ligament, and root cementum) have relied on conventional mechanical, anti-infective modalities followed by a range of regenerative procedures such as guided tissue regeneration, the use of bone replacement grafts and exogenous growth factors (GFs), and recently developed tissue engineering technologies. However, all current or emerging paradigms have either been shown to have limited and variable outcomes or have yet to be developed for clinical use [2].

Regenerative medical therapy has been expected to compensate for the therapeutic disadvantages of reconstructive surgery and organ transplantation, as well as create a new therapeutic strategy. The objective of regenerative medical therapy is to induce the regeneration and repair of defective tissues based on the natural healing potential of patients themselves. [3]

To date periodontal regeneration is considered to be biologically possible but clinically unpredictable. Recently, reports have begun to emerge demonstrating that populations of adult stem cells reside in the periodontal ligament of humans and other animals. This opens the way for new cell-based therapies for periodontal regeneration [4].

In dentistry, non metallic materials for appliance manufacturing have a long tradition [5]. Among the achieving technologies of the dentures, can distinguish heat-curing, self-curing, injection, light-curing, casting and microwave use [6].

Vacuum thermoforming is a plastic process that involves forming thermoplastic sheets into three–dimensional shapes through the application of heat and pressure. Basically during vacuum forming processes, plastic material is heated until it becomes pliable, and then it is placed over a mold and drawn in by a vacuum until it takes on the desired shape [7].

Experimental part

Materials and Methods

The innovative medical device, homologated with CE mark in class 2a, was used to treat the regions with bone destruction and second degree mobility of teeth, to a precise electromagnetic field in a totally atraumatic and minimally invasive approach. The device consists of an extraoral (fig. 1) and an intraoral part.

Fig. 1.Presentation mode of the extraoral part of Electronic Doctor medical device

The intraoral component of the device consists of a personalized vacuum thermoformed base, as a positioning support for the electromagnetic applicator. The thermoforming base of innovative device was made in the Erkoform appliance. The aspect of the intraoral component of the device inserted on the teeth, with a vacuum

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Fig. 2. Aspect of the intraoral component of the device, with a vacuum thermoformed base and the electromagnetic applicator, inserted on the teeth

thermoformed base and the electromagnetic applicator, is presented in figure 2.

The medical devices consist of a power generator and a bobbins system, and generate an electromagnetic field, with 7-8 Hz frequency and below 1 mT intensity. The duration of emission and the electromagnetic characteristics of this device are controlled by personalized software, incorporated into the extraoral component of Electronic Doctor device. The power supply, represented by the rechargeable batteries, induces the advantage of easy maneuverability of the device.

The preliminary study was realized on 10 patients.

The distribution of the selected patients was in the age limits 20-70 years, 5 male and 5 female. The age distribution of the selected patients is presented in figure 3.

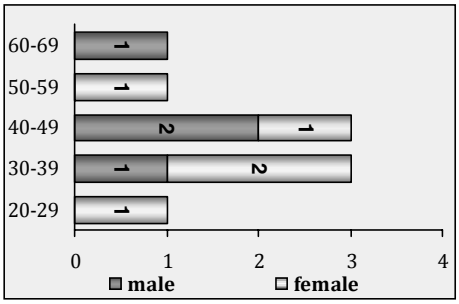

Fig. 3. Age distribution of the patients

All selected patients were in a healthy state, with a good oral hygiene status and presented second degree mobility of the teeth and 2 mm depth of periodontal pockets.

A standard protocol of 30 exposures of 2 h each to the target region was used.

Results were recorded as following:

- by performing two radiographs, at presentation of patients and 1 month after the end of the treatment with the Electronic Doctor medical device;
- by testing the mobility degree of the teeth, at presentation of patients and 1 month after the end of the treatment with this device;
- by measuring the periodontal pockets depth at presentation of patients and 1 month after the end of the treatment with this device;

Results and disscutions

Two months after starting the treatment and one month after the end of the treatment with the medical device, we assessed the results which demonstrated the following:

-reduction in the mobility of the teeth: from grade II to grade I (in 2 patients) or without mobility (in 8 patients);

-reduction of the periodontal pockets depth: from 2 mm, with 0.5 mm (1 subject), with 1.0 mm (2 subjects), respectively without periodontal pockets (7 patients);

-bone regeneration in the treated area: was viewed through the comparative study of radiographs taken before and after the treatment. An increased density of the bone in the regions exposed to the electromagnetic applicator proves cellular densification.

Teeth exhibit limited repair potential in response to damage, and dental pulp stem cells probably provide a source of cells to replace that damage and to facilitate repair. Stem cells in other parts of the tooth, such as the periodontal ligament and growing roots, play more dynamic roles in tooth function and development [8].

For successful tissue regeneration, it is indispensable to provide cells with a local environment which enables them to proliferate and differentiate efficiently, resulting in cell-induced tissue regeneration [1].

Stem cells have been opening a promising future in clinical therapies because of their two remarkable features known as self-renewal and multi-lineage differentiation. [9].

Human mesenchymal stem cells (hMSCs) are a promising cell type for both regenerative medicine and tissue engineering applications by virtue of their capacity for self-renewal and multipotent differentiation. Modulation of osteogenesis in human mesenchymal stem cells by specific pulsed electromagnetic field stimulation is reported [10].

Over the past 30 years, the beneficial therapeutic effects of selected low energy, time varying electromagnetic fields (EMF) have been documented with increasing frequency to treat therapeutically resistant problems of the musculoskeletal system [11].

The reports of Cohen and al, Gurbuz and al, Pirozzoli and al, Rajaei and al, Ruiz Gomez and al, Supino and al , have demonstrated that EMF does not produce genotoxic effects [12-17].

In conformity with the researches of Albulescu and al. [18], the application of low intensity and low frequency electromagnetic fields on the proliferation of stem cells and on the differentiation into adipocytic and osteocytic phenotypes, had a benefic effect, with potential use in regenerative medicine.

Plastics have an important role in the configuration of the new products development [19]. Glycolmodified polyethylene is used in many fields, including medicals [20]. Modified polyethylene terephthalate is a thermoplastic polymer, with an excellent high-impact and chemical resistance, simultaneously with flexural strength. It is obtained from polyethylene terephthalate (PET) by copolymerization and the resulting copolymer has a lower melting temperature and it is a useful material for thermoforming applications which requires complex shapes [21 ,22].

Singh G. considered that, among the advantages of appliances obtained by vacuum-forming technology the enhanced patient comfort, which increases patient compliance providing better chances of retention, the aesthetic, ease of oral hygiene maintenance, easily removed and replaced by patients at will, easy to fabricate, good retention and stability are included [23]. The greatest advantages of vacuum forming are the ease of handling, constant heating temperature regardless of the external influence and power supply, short working time and less parts and therefore more cost effectiveness [24,25].

The management of periodontal tissue defects that result from periodontitis represents a medical and socioeconomic challenge. Concerted efforts have been and still are being made to accelerate and augment periodontal tissue and bone regeneration, including a range of regenerative surgical procedures, the development of a variety of grafting materials, and the use of recombinant growth factors [26].

Conclusions

The use of Electronic Doctor medical device as minimally invasive and atraumatic innovative periodontal therapy is recommended for a better healing compared with the classic treatment techniques.

This preliminary study recommends the use of this medical device for cellular proliferation, including for use in preventive purposes and also for the maintenance of the results.

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