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CLINICAL AND HISTOLOGICAL OUTCOMES AFTER REGENERATIVE PERIODONTAL THERAPY WITH EMDOGAIN

Gabriela Beresescu University of Medicine, Pharmacy, Science and Technology of Targu-Mureş, 38 Gh Marinescu, Romania

Alina Baldean* Clinical Hospital Targu-Mureş, 43 Gh Marinescu, Romania *Corresponding Author

Emanuela Tegla University of Medicine, Pharmacy, Science and Technology of Targu-Mureş, 38 Gh Marinescu, Romania

ABSTRACT The aim of this study is to evaluate the histological and clinical outcomes of intrabony defects treatment using regenerative periodontal therapy with enamel matrix proteins (Emdogain, EMD). Twenty patients with chronic periodontitis were included in this randomized, controlled clinical study. Two groups received conservative periodontal therapy. In the test group, different teeth received regenerative treatment with EMD. In the control group only conservative periodontal therapy was performed. The following parameters were recorded at baseline and after 8 months: pocket probing depth (PD) and histological examinations. Both groups showed a significant reduction of PD. The teeth treated with EMD showed a significant attachment gain. Within the test group, the radiographic examination of the teeth treated with EMD showed no significant change, whereas the teeth in the control group showed significant bone reduction.Treatment of intrabony defects with EMD may lead to substantially higher gains in clinical attachment and defect filling. The use of EMD in dental practice can prevent further bone loss.

KEYWORDS : fixed orthodontic appliances, gingivitis, histopathology, oral hygiene methods

INTRODUCTION

Periodontal diseases represent the most frequent conditions of the human body, affecting it irrespective of sex, age or geographical area. Periodontal diseases are induced by determinant factors such as microbes associated with local factors (scale, caries, edentations, dental-maxillary abnormalities, parafunctions, smoking, iatrogenic, etc) and general factors (diabetes, cardiovascular, haematological and hepatical conditions, immune dysfunctions, nutrition deficiencies, endocrine dysfunctions, nervous system related diseases).

Periodontitis is an infectious disease which, left untreated, results in progressive attachment and bone loss and ultimately leads to dental loss. Periodontitis seriously affects various aspects of the quality of life in many individuals. The conservative periodontal therapy can lead to predictable pocket reduction and stop further disease progression. However, the therapy is usually followed by an increase in soft tissue and bone loss. Conventional periodontal treatments such as scaling and root planing are generally followed by periodontal repair, thus implying healing without restoration of the tooth attachment apparatus, and are often associated with the formation of a long junctional epithelium [1,2].

Regeneration is defined as a reconstruction of a lost or injured part of the body in such way that the structure and function of the injured tissue are completed restored. However, regenerative periodontal therapy can only restore a fraction of the original tissue. In many clinical situations, where regenerative techniques have been used, significant probing depth reduction in clinical attachment are gained, yet residual defects may still remain [3].

More than ten years have passed since Emdogain was introduced as an adjunctive to periodontal surgery. Emdogain was developed to promote regeneration of the periodontal tissue by mimicking the normal development of these tissues [1].

The aim of this study is to evaluate the histological and clinical outcomes of intrabony defects treatment using regenerative periodontal therapy with enamel matrix proteins (Emdogain, EMD).

MATERIALS AND METHODS

Subjects. In this clinical study, twenty patients (twelve females, eight males) aged between 25-55, with chronic periodontitis were included. The subjects were selected from Department of Odontology and Oral Patology of Faculty of Dentistry, University of Medicine and Pharmacy Tirgu Mures, Romania. The patients were distributed in 2 groups according to the following inclusion criteria: chronic periodontitis, presence of ≥ 16 teeth periodontally affected, periodontal pocket with probing depth (PD) ≥ 6mm, no smoking, good general condition. The study protocol had 77 been approved by Ethical Committee of University of Medicine and Pharmacy Tirgu 78 Mures, Romania. All the patients recruited for the study signed an informed consent.

Conservative periodontal therapy. After recording the patients' periodontal condition, conservative periodontal therapy was performed in both groups. This conservative periodontal treatment consisted of hygiene instructions, full mouth scaling and root planing. In the test group, different teeth received regenerative treatment with EMD after scaling and root planing. The control group received only conservative periodontal therapy.

Informed consent was obtained from each patient. Regenerative therapy with EMD wasperformed using the papilla preservation technique as described by Cortellini [4,5]. The principles of the surgical procedure are the following: a vertical incision is performed on the buccal aspect of the involved teeth. The sites are conditioned with 24% EDTA for 2 minutes to remove the smear layer. After carefully rinsing with sterile saline, EMD is applied with a syringe starting at the most apical level. The mucoperiosteal flaps are replaced and sutured so that a primary closure and wound stability is achieved. Patients are instructed for postsurgery maintenance care.

Patients were seen weekly postsurgery for professional tooth cleaning. After that, the patients were recalled monthly for maintenance, oral hygiene control, and reinstruction in oral hygiene.

The following parameters were recorded at baseline and after 8 months: bone reduction
based on x-rays, bleeding on probing by using a probe, and probing depths (PD). Tooth mobility was recorded using Miller's index. The presence or absence of plaque was evaluated with plaque index (O'Leary et al.1972) [6]. Gingival inflammation was assessed with gingival index (Loe and Silness, 1963) [7].

Histological examination. The histologically evaluation was performed on two volunteer within the test group. After 8 months, the bipsy were harvested for histological evaluation. The sections were stained with Hematoxylin-Eosin and examined microscopically (Leitz DM - RBE 123 Microscope, Leica Wetzlar Germany) at different magnifications (X6.3, X10, X25).

Teeth	Upper teeth	Lower teeth
Frontal teeth	12	9
Premolars	6	7
Molars	6	6

Statistical analysis. The Statistical Package for Social Sciences (SPSS) was used for data processing. The statistical analysis was carried out using t-test and chi-square. The level of significance was set at $p<0.05$.

RESULTS AND DISCUSSIONS

The groups consisted of twenty patients (twelve females, eight males). The average age in the test group was 41.347±10.891, the mean age in the control group was 43.965±11.008. The average observation period was 7.26±0.97 months (test group) and 7.42±0.35 months (control group).

In the test group, 106 teeth were treated with scaling and root planning; later 46 thereof with EMD. In the control group 129 teeth were treated with scaling and root planning.

Table 1 shows the distribution of the teeth received regenerative treatment with EMD after scaling and root planing (Table 1).

Table 1. Distribution of Emdogain treated teeth

In both groups a significant reduction in PD was found: in the test group 1.6mm and in the control group 0.9mm ($p=0.000$) (Fig.1 a, b). The difference between the two groups was significant ($p<0.0001$). The teeth treated with EMD showed a significant attachment gain with a mean of 1.84±0.2mm ($p<0.001$).

The difference between the two groups was significant ($p<0.0001$). The teeth treated with EMD showed a significant attachment gain with a mean of 1.84±0.2mm ($p<0.001$) (Fig. 2, Fig. 3).

A statistically significant increase in mean PD was observed at 8 months in test group ($p<0.0001$). Mean PD reduction in the recorded sites at 8 months was 5.1±0.5mm (Fig. 2). The reduction was maintained during the 1 year observation period, with no significantly change.

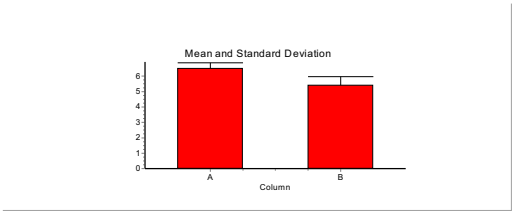

Fig. 1 Changes of PD in test group (a) and control group (b) at baseline (A, B) and after 8 months (C, D

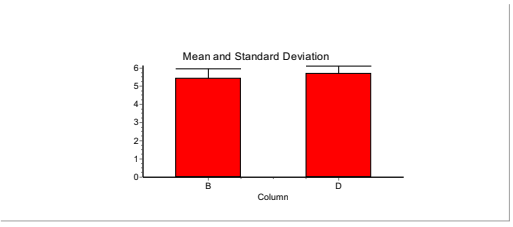

Figure 2. Changes of PD in test group (B) and control (D) after 8 months

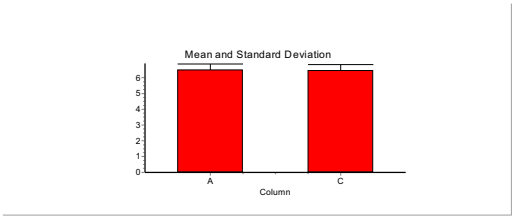

Figure 3. Changes of PD in test group (A) and control group (C) at baseline

No significant correlation was found the baseline PD between the control group and the test group (Fig. 3).

There was no significant change in tooth mobility after 8 months. Minimal significant changes were evidenced radiographically in the test group over the observation period, while the control group showed no changes whatsoever.

The microscopic evaluation revealed a new layer cementum, the formation of an accelular extrinsic cementum. We found that the new cementum was thin, with inserting collagen fibers. New alveolar bone attached was also presented.

This finding sustained the treatment of intrabony periodontal defects with EMD has the potential for a predictable regeneration.

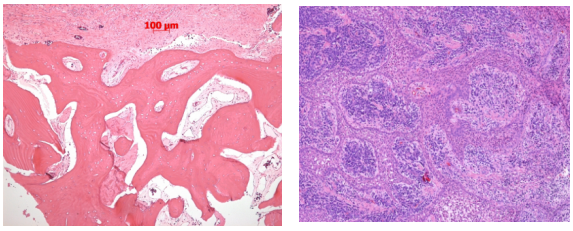

Figure 5. Human biosy of a healing of a intrabony defect after treatment with EMD (original magnification x20)

In the present study, regenerative periodontal therapy with Emdogain resulted in significant PD reduction and CAL gains. Wound healing following EMD application appeared to be favourable. EMD may influence soft tissue healing, in addition to its capability of promoting periodontal regeneration. Our results reported in the present study are consistent with the outcomes published by other authors.

Several studies have been published concerning degree of clinical success, possibilities for combining Emdogain with other agents, or means to promote periodontal regeneration, as well as cellular effects and mechanism of action [8]. The introduction of Emdogain as an adjunct to periodontal surgery therapy has stimulated a great number of research projects concerning its effects and efficacy.

The majority of these publications show that Emdogain is able to significantly regenerate cementum, periodontal ligament and alveolar bone when it is used to treat deep intrabony defects, as was originally indicated [9].

In the first controlled clinical trial, Heijl was to compare the effectiveness of EMD treatment as an adjunct to periodontal flap surgery with that of surgery alone in intrabony defects. The clinical endpoints used were radiographic bone level and clinical attachment level. At the 3-year follow-up examination, the mean radiographic bone gain in the EMD-treated sites had increased from 2.2mm to 2.6mm. The bone level at the control sites was more or less unchanged after three years.

The results showed clinically relevant difference especially since almost half of the patients were smokers [10].

In a controlled clinical study, it was demonstrated that treatment with EMD was superior to open flap debridement (OFD) at 12 months postsurgery [11]. In addition, it was demonstrated that the percentage defect fill after adjusting for crestal bone resorption was more than three times greater for EMD than for OFD alone [11,12].

In a multicentric study, Tonetti et al. reported a mean CAL gain of 3.1mm at one year [13]. Saito et al. evaluated the long-term clinical outcomes of treatment with EMD in a private practice setting [14]. The mean CAL gain at six months was 3.6mm which was significantly greater.

Sculean et al. reported the formation of new attachment at six months following EMD treatment of advanced intrabony lesions. Their results showed bone regeneration after formation of new attachment was not always followed by bone regeneration, although the newly formed cementum was predominantly of a cellular character [15]. Ozcelik et al. reported that patient perceptions on the postsurgery period were significantly better in the non-surgery and surgery with EMD groups when compared with the surgery group [14,15]. On the other hand, Zetterström et al. and Hagenaars et al. reported no differences in post-

surgical healing and patient perceptions, between surgeries with EMD and flap operations [16,17]. Saito et al. in a study regarding the treatment of periodontal defects with enamel matrix derivative, showed after three to six months that periodontal surgery with EMD results in a clinically relevant reduction in probing depth and a gain in clinical attachment [18].

Several studies demonstrated that the use of EMD appear to stimulate the formation of a new attachemtn characterized by the presence of new acellular cementum and new alveolar bone [19, 20]. Alveolar bone formation following the use of EMD has sometimes been reported to be minimal despite the presence of significant amounts of new cementum [12, 15].

Our results are in agreement with those of others authors, but further research need to be performed in order to identify the concept of regeneration.

CONCLUSIONS

Under the limitations of the study, the results shown that the treatment of intrabony defects with EMD may lead to substantially higher gains in clinical attachment and defect filling. EMD has shown stable and predictable regeneration in intrabony defects. The use of EMD in dental practice can prevent further bone loss.

However, these results need to be confirmed on a larger scale in multicenter controlled clinical trial with interesting new developments that will accelerate a regenerative treatment modality, such as the EMD concept or new biodegradeable vehicles.

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