

Treatment of Intrabony Periodontal Defects with Emdogain-TS[®] - a Report of 26 Cases

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The aim of the present study was to present results after six months following the treatment of intrabony defects with Emdogain-TS[®].

Twenty-six intrabony defects were treated with enamel matrix proteins (EMD) and PerioGlas[®] (Emdogain-TS[®], Institut Straumann AG, Waldenburg, Switzerland) (EMD-TS[®]). The following clinical parameters were evaluated at Baseline and at six months after treatment: plaque index (PI), gingival index (GI), bleeding on probing (BOP), probing depth (PD), gingival recession (GR) and clinical attachment level (CAL).

The primary outcome variable was CAL. The sites treated with EMD-TS[®] demonstrated mean CAL changes from 9.0 ± 2.0 mm to 5.9 ± 1.4 mm ($p < 0.001$) at six months. At six months, the mean PD was reduced from 7.5 ± 1.6 mm to 3.7 ± 1.0 mm ($p < 0.001$), and the mean GR increased from 1.5 ± 1.2 mm to 2.2 ± 0.9 mm ($p < 0.001$).

It can be concluded that the treatment of intrabony defects with EMD-TS[®] results in significant improvements of the investigated clinical parameters.

Key words: regenerative periodontal therapy, enamel matrix proteins, intrabony periodontal defects, PerioGlas[®], Emdogain-TS[®]

INTRODUCTION

According to the current definition of Karring et al (1997) periodontal regeneration includes the formation of a new connective tissue attachment - i.e. new cementum with inserting collagen fibers - at the diseased root surfaces, and the regrowth of a new alveolar bone.

The root cementum plays a fundamental role in the maintenance of the teeth (Bosshardt and Schroeder, 1996). In the 1970s Slavkin and Boyde proposed that enamel related proteins from epithelial root sheath were involved in the formation of acellular cementum (Slavkin and Boyde, 1975; Slavkin, 1976).

Based on these experimental studies, further clinical studies were initiated (Heijl, 1997a; Schwartz et al, 2000; Van der Pauw et al, 2000; Sculean et al, 2000). The results of the available studies of an enamel matrix derivative (EMD) (Emdogain[®],

Institut Straumann AG, Waldenburg, Switzerland) showed that EMD may lead to significant probing depth reduction and gain of CAL (Zetterström et al, 1997; Heijl et al, 1997b; Sculean et al, 1999b; Heden et al, 1999; Sculean et al, 1999a; Okuda et al, 2000). Emdogain[®] is a product that consists of a resorbable, implantable material composed of amelogenin and related proteins. The product has been commercially available in Europe since late 1995. These proteins play a fundamental role in the development of periodontal ligament, alveolar bone and acellular cementum. The main advantages of alloplastic materials are unlimited quantity and the lack of disease transmission. PerioGlas[®] (US Biomaterials, Alachua, FL, USA) is a bioactive glass that has osteoinductive and hemostatic properties. Bioactive glass consists of silicon dioxide (46%), sodium oxide (24.4%), calcium oxide (26.9%) and phosphorus oxide (2.6%). Perioglas[®] has a particle size of

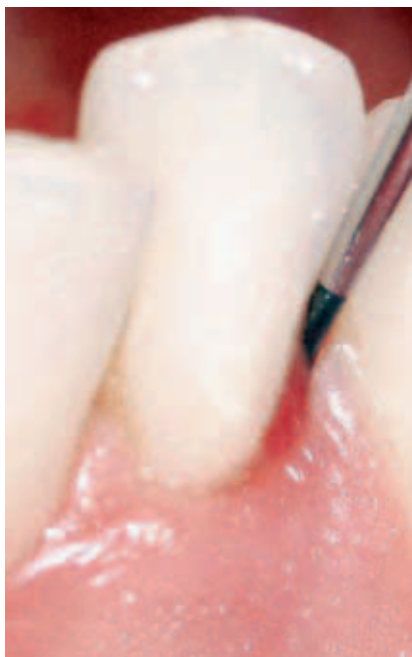


Fig. 1 Pre-operative probing depth of 10 mm.



Fig. 2 Post-operative probing depth of 4 mm at six monthly recall visit.



Fig. 3 Pre-operative radiograph of a defect treated with EMD-TS. A 10 mm probing depth was measured.

90–710 μm . In addition, it plays an inhibitory role in epithelial downgrowth (Fetner et al, 1994; Karatzas et al, 1999). Conversely, Nevins et al (2000) showed that bioactive glass had only limited regenerative potential. From the clinical point of view, PerioGlas® supports soft tissues of the periodontium during the regenerative period. Clinical studies (Zamet et al, 1997; Shapoff et al, 1997; Lovalence et al, 1998; Froum et al, 1998) showed reduction of probing depth and gain of CAL.

The idea behind Emdogain-TS® (Institut Straumann AG, Waldenburg, Switzerland) was to combine the best properties from enamel matrix proteins and PerioGlas®. Emdogain-TS® has been commercially available since September 2001 and is indicated for wide 2-3 wall intrabony defects. It is easy to handle, does not migrate from the surgical site and adapts well to the defect. Hitherto, little clinical data exist (Sculean et al, 2002) evaluating the outcomes following this treatment approach. Therefore, the aim of the present study was to present the results after treatment of intrabony defects with EMD-TS®.

STUDY DESIGN

Ten patients (6 females and 4 males) aged between 21 and 67 years (mean 44.7 ± 13.7) with a total number of 26 periodontal intrabony defects took part in this study. Inclusion criteria were: 1) no systemic diseases; 2) a good level of oral hygiene (Plaque index <1); 3) Probing pocket depth ≤ 6 mm and intrabony defect depth of ≥ 3 mm; 4) 2-3 wall intrabony defects; 5) non-smokers; 6) no use of antibiotics during the previous six months; 7) no periodontal treatment during the last 2 years.

Clinical parameters were evaluated prior to Baseline and six months after the surgical treatment with the same periodontal probe with a tip diameter of 0.5 mm (PCP 12, Hu-Friedy, Chicago, IL, USA) for the following:

1. Plaque index (PI) according Sillnes and Löe 1964
2. Gingiva index (GI) according Sillnes and Löe 1967
3. Bleeding on probing (BoP)
4. Probing depth (PD)
5. Clinical attachment level (CAL)
6. The distance between the gingival margin and the cemento-enamel junction (CEJ) was measured to determine gingival recession (GR). In



Fig. 4 Radiograph taken six months post-surgical treatment; a 3 mm probing depth was measured.



Fig. 5 Pre-operative probing depth of 9 mm.



Fig. 6 Six months post-operative; probing depth was 3 mm.



Fig. 7 Pre-operative radiograph of a defect treated with EMD-TS. Pre-operatively, a probing depth of 10 mm was measured.



Fig. 8 The view of tooth 36 during surgery.

cases where the CEJ was not visible, a restoration margin was used for these measurements. The measurements were made at 6 sites per tooth: mesiobuccal (mv), buccal (v), distobuccal (db), mesiolingual (ml), lingual (l), and distolingual (dl). The cemento-enamel junction (CEJ) was used as reference point. In case the CEJ was not visible, a restoration margin was used for these measurements.

Periapical radiographs were taken with the long cone parallel technique prior to Baseline and at six months after surgery. In this study only the data for the deepest point of the selected defects were reported. Four clinical cases are shown in Figures 1–9.



Fig. 9 Radiograph taken six months post surgery. A probing depth of 3 mm was measured.

Surgical Procedures

All surgical procedures were performed under local anesthesia and by the same operator (AM). Following intracrevicular incisions, full-thickness mucoperiosteal flaps were raised buccally and lingually. All granulation tissue was removed from the defects and the root surfaces were scaled and planed using hand and ultrasonic instruments. The root surfaces were conditioned for 2 min with 24% EDTA gel (pH 6.7) to remove the smear layer. Subsequently, the defects were thoroughly rinsed with sterile saline to remove all EDTA residues.

Following root conditioning, EMD was applied onto the root surfaces and into the defects with a sterile syringe. The remaining EMD was mixed with PerioGlas® and the defects were completely filled with the mixture of EMD and PerioGlas®. The alveolar crest served as limit in order to avoid overfilling of the defects. Finally, the flaps were repositioned coronally and closed with vertical or horizontal mattress sutures (Figs. 10-15).

Post-operative Care

The patients were advised to rinse twice daily for 4 weeks with 0.2% chlorhexidine digluconate. Tooth brushing was only allowed in the treated areas after this 4-week rinsing regimen. Sutures were removed 14 days after surgical treatment. Recall appointments were scheduled every 2 weeks during the first two months, and once a month for the next four months.

Statistical Analysis

The statistical analysis was performed using a commercially available software program. (SPSS for Windows 95, SPSS Inc., Chicago, IL, USA). The deepest defect per tooth was included in the calculations. The paired t-test was used for the statistical evaluations of the changes from Baseline to six months.

RESULTS

No complications such as allergic reactions, supuration or abscesses were observed both post-operatively, and during the complete study period. Table 1 illustrates the mean PD, CAL, and GR at Baseline and six months. Pre-operative probing depth varied between 6 and 11 mm.

The sites treated with EMD-TS® demonstrated mean CAL changes from 9.0 ± 2.0 mm to 5.9 ± 1.4 mm at six months. The CAL improved significantly compared to Baseline ($p < 0.001$). The mean PD was reduced from 7.5 ± 1.6 mm to 3.7 ± 1.0 mm at six months. The PD decrease significantly compared to the Baseline ($p < 0.001$). At six months the mean GR increased from 1.5 ± 1.2 mm to 2.2 ± 0.9 mm. The increase in GR was statistically significant ($p < 0.001$). The Mean Plaque and Gingival Scores at Baseline and six months are shown in Table 2.

DISCUSSION

The results of the present study indicate that treatment of intra-bony periodontal defects with EMD-TS® results in clinical and statistically significant reduction of PD and gain of CAL.

No allergic reactions against the alloplastic PerioGlas® or Emdogain® grafts were observed. The clinical safety of Emdogain® was proved by Zetterström et al (1997). Only 2-3 wall defects were included in the present study, since these defects have the highest potential for regeneration as shown previously (Heijl et al, 1997; Lovelance et al, 1998). It is also well known that the effect of smoking has a negative influence on the regenerative process (Cortellini et al, 1996); therefore, smokers were excluded from this study. The results from previously controlled clinical studies also reveal that the stability of clinical attachment follow-



Fig. 10 Pre-operative probing depth of 10 mm at the mesial aspect of the right maxillary first premolar.



Fig. 11 View of tooth 14 during surgery after palatal flap mobilization.



Fig. 12 Situation after application of EMD-TS.



Fig. 13 Vertical or horizontal mattress sutures (buccal aspect).



Fig. 14 Vertical or horizontal mattress sutures (palatal aspect).



Fig. 15 Six months post-operative, 3 mm probing depth.

Table 1 Mean PD, CAL and GR at Baseline and six months after treatment with Emdogain-TS®

	PD	CAL	GR
Baseline	7.5±1.6mm	9.0±2.0mm	1.5±1.2mm
6 months	3.7±1.0mm	5.0±1.4mm	2.2±0.9mm

Table 2 Mean Plaque and Gingival Scores at Baseline and six months after treatment with Emdogain-TS®

	Emdogain-TS®
Plaque index score	
Baseline	0.13 ± 0.11
6 months	0.35 ± 0.41
Gingival index score	
Baseline	0.51 ± 0.53
6 months	0.17 ± 0.11

ing regenerative therapy depends on perfect oral hygiene and compliance with a recall program (Cortellini et al, 1996). In the present study plaque index scores of the patients were close to zero. Thus, we had the best conditions to obtain reduction of PD (3.8 mm) and gain of CAL (3.1 mm). There are some data on treatment of intrabony defects using Perioglas® alone without Emdogain® (Zamet et al, 1997; Shapoff et al, 1997; Lovalence et al, 1998; Froum et al, 1998; Nevins et al, 2000). The sites treated with bioactive glass revealed a PD reduction from 4.00 mm to 4.26 mm at the six and twelve months post-operative recall, respectively (Froum et al, 1998). Another study revealed a mean PD reduction of 2.7 mm six months after surgical treatment (Nevins et al, 2000). These findings are in accordance with a further report that showed a mean PD reduction of 3.07 ± 0.80 mm after six months post-operatively (Lovalence et al, 1998). The results of these previous studies are in agreement with the

reduction of probing depth observed in our present study using Emdogain-TS®.

The use of Emdogain® alone is also well documented (Zetterström et al, 1997; Heijl et al, 1997b; Sculean et al, 1999b; Heden et al, 1999; Sculean et al, 1999a; Okuda et al, 2000). The sites treated with EMD revealed a reduction of PD from 3.3 mm to 3.1 mm at the eight and thirty-six months post-operative recall, respectively (Heijl et al, 1997).

These results corroborate those reported by Okuda et al (2000). Reduction of mean PD of 3.00 ± 0.97 mm has been shown twelve months post-operatively. In a multi-center study, Zetterström et al (1997) reported the clinical outcome after EMD or access flap surgery at eight months and three years post-operatively. At eight months, a mean CAL gain of 3.1 mm was reported.

Furthermore, the study from Sculean et al (1999b) confirmed the previous data. They reported a mean CAL gain of 3.0 mm eight months after the treatment with EMD. On the other hand, PD reduction of 5.2 mm was reported twelve months post-operatively by Heden et al (1999).

Comparison of results from the cited studies with the data of the present study indicates that the treatment of intrabony defects with Emdogain® alone results in similar outcome as treatment with Emdogain-TS® (at the six months post-operative recall). Thus, the combination of bioactive glass (PerioGlas®) and enamel matrix proteins (Emdogain®) apparently has no additive effect on the reduction of probing depth and gain of CAL when treating intrabony defects.

CONCLUSIONS

It can be concluded that the treatment of intrabony defects with EMD-TS® results in significant improvements of the investigated clinical parameters. The Emdogain-TS® did not improve the clinical outcome compared to enamel matrix proteins (Emdogain®) or bioactive glass (PerioGlas®) alone. However, further clinical studies are necessary to investigate in more detail the treatment of intrabony defects with EMD-TS®.

To the best of our knowledge, there is only one clinical study, reporting the outcome of EMD and PerioGlas® treatment after one year (Sculean et al, 2002). The present six months results corroborate those obtained by Sculean et al (2002) after twelve months, who reported a mean CAL gain of 3.2 mm and a PD reduction of 4.15 mm at twelve months.

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