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Early Evaluation at 6 Months of the Healing of Intrabony Defects Following Treatment with an Enamel Matrix Protein Derivative. A Controlled Clinical Study.

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Introduction

The regenerative potential of enamel matrix protein derivatives (EMD) on human periodontium has been evaluated and validated over the last years in countless histological, clinical controlled studies and meta-analyses. The use in clinical practice, however, has shown a certain delay of the regenerative outcome as demonstrated clinically and on radiographs, which extends up to one year after the surgery, or even more, making this outcome more dependable on the post-treatment maintenance conditions.

Objectives

The purpose of the present study was to compare clinically the treatment of deep intrabony defects with an enamel matrix protein derivative (EMD) to access flap (AF) surgery, in an early evaluation at 6 months after the therapy.

Material and Methods

Twenty-five patients (12 male and 13 female), between 35-56 years old, with moderate to severe periodontitis, light- or non-smokers, and displaying a total of 32 deep intrabony defects, were treated either with EMD (Emdogain®, Straumann, Waldenburg, Switzerland) (test) or with AF alone (control). All patients underwent initial therapy one month prior to surgery. All patients were instructed and motivated to maintain a good oral hygiene level, verified by a reduction of the PI (Silness and Löe) < 1. Before surgery and six months after, the following clinical parameters were registrated: the periodontal pocket depth (PD), the gingival recession (GR) and the clinical attachment level (CAL). All measurements were performed with a rigid periodontal probe (PCP 12, Hu-Friedy), at six sites per tooth (buccal: mesiobuccal, central, distobuccal; oral: mesiooral, central, distooral).
Radiographic examination was performed using the conventional RIO technique. For each patient, the highest measured value was taken into account and the mean PD, GR and CAL were calculated. The Wilcoxon paired-samples test was used to compare the differences between baseline values and the values measured six months after and the Mann-Whitney U independent-samples test was used for comparison between the groups. Surgery was performed under local anesthesia. A full thickness flap was raised after intrasulcular incision, without using release incisions. After removal of the granulation tissue, the exposed roots underwent thorough S/RP, using ultrasonic devices and curettes. No resective surgery was performed, nor any root conditioning. Emdogain® gel was placed into the defects of the test group. The defects of the control group underwent the same surgical protocol, without any grafting procedure. Post surgical care included antibiotherapy for one week (3x500 mg Amoxycillin daily) and 0.2% Chlorhexidin (Dentaton®, Ghimas s.p.a., Casalecchio di Reno, Italy) mouth rinses, twice a day, for the following two weeks, as gentle debridement of the operated area every second week, during two months.

Results

No adverse healing response was observed. No signs of inflammation, infection, allergy or severe pain were present. Pre- and postoperative mean values of the PD, GR and CAL in the two treated groups are displayed in the table No.1 and table No.2.

Table 1. Six months clinical results of treatment of intrabony defects with Emdogain®

Patient Nr.	Tooth Type	Defect Type (walls)	PPD	(mm)	PPD	CAL	(mm)	CAL gain (mm)	GR	(mm)	GR	CEJ BD	BC BD	CEJ BC
			Pre-operative	After 6 months	Diff.	Pre-operative	After 6 months		Pre-operative	After 6 months	Diff.			
1	21	2	6	3	3	7	6	1	1	3	2	11	6	5
2	21	2	7	4	3	9	6	3	2	2	0	11	6	5
3	14	2	8	4	4	8	4	4	0	0	0	9	6	3
4	14	2	6	3	3	6	5	1	0	2	2	9	5	4
5	25	2	8	4	4	8	6	2	0	2	2	9	4	5
6	24	1	11	5	6	11	6	5	0	1	1	12	7	5
7	22	1	7	3	4	7	7	0	0	4	4	9	4	5
8	22	1	10	3	7	10	8	2	0	5	5	10	4	6

9	27	2	8	6	2	8	6	2	0	0	0	10	9	1
10	1.1.m	2	6	3	3	8	6	2	2	3	1	9	2	7
11	1.7.m	1	8	7	1	9	8	1	1	1	0	12	9	3
12	2.5.m	1	11	6	5	11	6	5	0	0	0	11	8	3
13	3.6.m	1	8	4	4	9	6	3	1	2	1	10	7	3
14	4.3.m	2	9	3	6	9	5	4	0	2	2	11	7	4
15	2.6.m	1	7	3	4	9	5	4	2	2	0	10	7	3
16	2.3.m	1	6	3	3	7	4	3	1	1	0	8	5	3
Mean			7,88	4,00	3,88	8,50	5,88	2,63	0,63	1,88	1,25	10,06	6,00	4,06
SD			1,67	1,32	1,54	1,41	1,15	1,50	0,81	1,41	1,53	1,18	1,93	1,48

Table 2. Six months clinical results of treatment of intrabony defects with access flap surgery AF

Patient Nr.	**Tooth Type**	**Defect Type (walls)**	**PPD**	**(mm)**	**PPD**	**CAL**	**(mm)**	**CAL gain (mm)**	**GR**	**(mm)**	**GR**	**CEJ BD**	**BC BD**	**CEJ BC**
			Pre-operative	**After 6 months**	**Diff.**	**Pre-operative**	**After 6 months**		**Pre-operative**	**After 6 months**	**Diff.**			
1	2.3.d	2	6	3	3	7	4	3	1	1	0	9	4	5
2	1.6.m	2	6	4	2	6	5	1	0	1	1	6	4	2
3	4.5.m	2	9	3	6	12	8	4	3	5	2	12	4	8
4	2.7.m	2	6	5	1	6	5	1	0	0	0	8	5	3
5	2.4.m	1	7	4	3	7	8	-1	0	4	4	8	5	3
6	4.8.m	1	8	3	5	8	3	5	0	0	0	9	6	3
7	3.5.m	1	6	1	5	6	1	5	0	0	0	7	4	3
8	1.7.m	circ	8	3	5	10	3	7	2	0	-2	13	7	6
9	2.5.m	2	7	2	5	7	3	4	0	1	1	8	5	3
10	2.3.d	1	7	5	2	8	7	1	1	2	1	8	5	3
11	2.6.m	1	7	7	0	10	9	1	3	2	-1	12	7	5
12	3.3.m	2	7	5	2	11	10	1	4	5	1	13	6	7
13	1.7.m	2	6	4	2	6	4	2	0	0	0	8	5	3
14	1.3.m	2	12	5	7	12	6	6	0	1	1	13	8	5
15	3.7.m	2	9	4	5	9	6	3	0	2	2	9	5	4
16	3.5.d	1	6	3	3	6	4	2	0	1	1	6	4	2
Mean			7,31	3,81	3,50	8,19	5,38	2,81	0,88	1,56	0,69	9,31	5,25	4,06
SD			1,62	1,42	1,97	2,20	2,50	2,20	1,36	1,71	1,35	2,47	1,24	1,77

Table 3. Intraoperative measurements of the Emdogain(R) and access flap groups

Treatment	**CAL (mm)**	**CEJ-BD (mm)**	**CEJ-BC (mm)**	**INTRA (mm)**
AF (n=16)	5,38±2,50	9,31±2,47	4,06±1,77	5,25±1,24
EMD (n=16)	5,88±1,15	10,06±1,18	4,06±1,48	6,00±1,93

Table 4. Clinical parameters at baseline and 6 months for the AF (n=16) and the EMD surgery groups (n=16)

Treatment	**Baseline**	**6 months**	**Difference**	**Significance**
Probing depth				
AF	7,31±1,62	3,81±1,42	3,50±1,97	p=0,001
EMD	7,88±1,67	4,00±1,32	3,88±1,54	p<0,0001
			n.s.	
Gingival recession				
AF	0,88±1,36	1,56±1,71	0,69±1,35	n.s.
EMD	0,63±0,81	1,88±1,41	1,25±1,53	p=0,007
			n.s.	
Clinical attachment level				
AF	8,19±2,20	5,38±2,50	2,81±2,20	p=0,001
EMD	8,50±1,41	5,88±1,15	2,63±1,50	p=0,001
			n.s.	

Table 5. The CAL gain related to the number of the defects in the AF and EMD groups

CAL gain (mm)	**AF**		**EMD**	
	N°	**%**	**N°**	**%**
-1	1	6,25	-	-
	-	-	1	6,25
1	5	31,25	3	18,75
2	2	12,5	4	25
3	2	12,5	3	18,75
4	2	12,5	3	18,75

5	2	12,5	2	12,5
6	1	6,25	-	-
7	1	6,25	-	-

Fig.1 Case A. a) The bone defect exposed

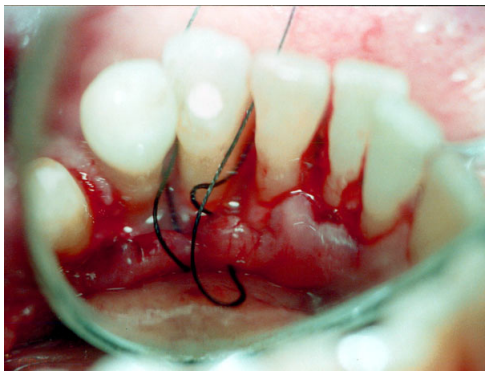


Fig.1 Case A. b) Emdogain® gel in place

Fig.1 Case A. c) Rx image before treatment

Fig.1 Case A. d) Rx image at six months

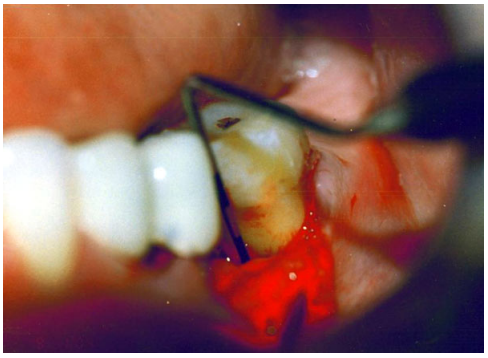
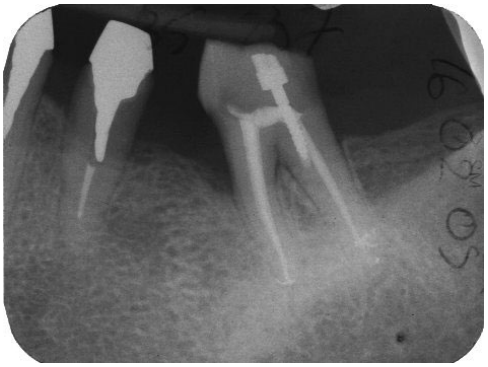


Fig.2 Case B. a) The bone defect exposed



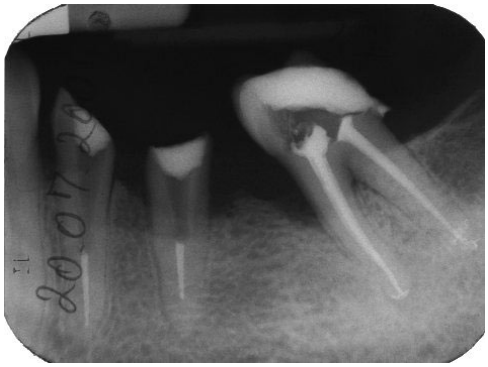


Fig.2 Case B c) Rx image at six months

Fig.2 Case B b) Rx image before treatment

Conclusions

Within the limits of the present study, it can be concluded that: (i) at 6 months after surgery both therapies resulted in significant PD reductions and CAL gains, and (ii) early evaluation (at 6 months) of the treatment with EMD resulted in no higher CAL gains and PD reductions than the treatment with access flap surgery.

Abbreviations

PD - probing depth
CAL - clinical attachment level
EMD - enamel matrix protein derivative
AF - access flap

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Poster Faksimile:

Early Evaluation at 6 Months of the Healing of Intrabony Defects Following Treatment with an Enamel Matrix Protein Derivative. A Controlled Clinical Study.

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ABSTRACT

AIM: The purpose of the present study was to compare clinically the treatment of deep intrabony defects with an enamel matrix protein derivative (EMD) to access flap (AF) surgery, in an early evaluation at 6 months after the therapy.
METHODS: Twenty-five patients suffering from chronic periodontitis, and displaying a total of 32 intrabony defects, were randomly treated either with EMD (test) or with access flap surgery (control). Gingival parameters and soft tissue measurements were made at baseline and at 6 months following therapy.
RESULTS: No differences in any of the investigated parameters were observed at baseline between the two groups. Healing was uneventful in all patients. At 6 months after therapy, the test group showed a reduction in mean probing depth (PD) from 7.88+/-1.67 to 4.00+/-1.32 mm (p=0.0001) and a change in mean clinical attachment level (CAL) from 8.50+/-1.41 to 5.68+/-1.15 mm (p=0.001). In the control group, the mean PD was reduced from 7.31+/-1.62 to 3.81+/-1.42 mm (p=0.001) and the mean CAL changed from 8.19+/-2.20 to 5.38+/-2.50 mm (p=0.001). The test treatment resulted in no statistically slight higher PD reductions and CAL gains than the control one. Both in the test group and in the control group 50% of the sites gained at least 3 mm of CAL. In the control group a CAL gain of 6, respectively 7 mm or more was measured in one defect each (6.25%).
CONCLUSIONS: Within the limits of the present study, it can be concluded that: (i) at 6 months after surgery both therapies resulted in significant PD reductions and CAL gains, and (ii) early evaluation (at 6 months) of the treatment with EMD resulted in no higher CAL gains and PD reductions than the treatment with access flap surgery.

INTRODUCTION

The regenerative potential of enamel matrix protein derivatives (EMD) on human periodontium has been evaluated and validated over the last years in countless histological, clinical controlled studies and meta-analyses. The use in clinical practice, however, has shown a certain delay of the regenerative outcome as demonstrated clinically and on radiographs, which extends up to one year after the surgery, or even more, making this outcome more dependable on the post-treatment maintenance conditions.

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MATERIALS AND METHODS

Twenty-five patients (12 male and 13 female), between 35-56 years old, with moderate to severe periodontitis, light- or non-smokers, and displaying a total of 32 deep intrabony defects, were treated either with EMD (Emdogain®, Straumann, Waldenburg, Switzerland) (test) or with AF alone (control). All patients underwent initial therapy one month prior to surgery. All patients were instructed and motivated to maintain a good oral hygiene level, verified by a reduction of the PI (Silness and Löe) < 1. Before surgery and six months after, the following clinical parameters were registrated: the periodontal pocket depth (PD), the gingival recession (GR) and the clinical attachment level (CAL). All measurements were performed with a rigid periodontal probe (PCP 12, Hu-Friedy), at six sites per tooth (buccal: mesiobuccal, central, distobuccal; oral: mesiooral, central, distooral). Radiographic examination was performed using the conventional RID technique. For each patient, the highest measured value was taken into account and the mean PD, GR and CAL were calculated. The Wilcoxon paired-samples test was used to compare the differences between baseline values and the values measured six months after and the Mann-Whitney U independent-samples test was used for comparison between the groups. Surgery was performed under local anesthesia. A full thickness flap was raised after intrasulcular incision, without using release incisions. After removal of the granulation tissue, the exposed roots underwent thorough S/RP, using ultrasonic devices and curettes. No resective surgery was performed, nor any root conditioning. Emdogain® gel was placed into the defects of the test group. The defects of the control group underwent the same surgical protocol, without any grafting procedure. Post surgical care included antibiotherapy for one week (3x500 mg Amoxycillin daily) and 0.2% Chlorhexidin (Dentaton®, Ghimas s.p.a., Casalecchio di Reno, Italy) mouth rinses, twice a day, for the following two weeks, as gentle debridement of the operated area every second week, during two months.

RESULTS

No adverse healing response was observed. No signs of inflammation, infection, allergy or severe pain were present. Pre- and postoperative mean values of the PD, GR and CAL in the two treated groups are displayed in the table No.1 and table No.2.

Table 1. Six months clinical results of treatment of intrabony defects with Emdogain®

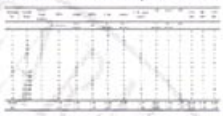
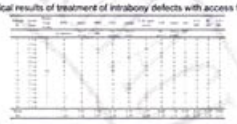


Table 2. Six months clinical results of treatment of intrabony defects with access flap surgery AF



No differences in any of the investigated parameters were observed at baseline between groups (Table 3).

Table 3. Intraoperative measurements of the Emdogain(R) and access flap groups

Healing was uneventful in all patients. At 6 months after therapy, the test group showed a reduction in mean probing depth (PD) from 7.88+/-1.67 to 4.00+/-1.32 mm (p=0.0001) and a change in mean clinical attachment level (CAL) from 8.50+/-1.41 to 5.68+/-1.15 mm (p=0.001). In the control group, the mean PD was reduced from 7.31+/-1.62 to 3.81+/-1.42 mm (p=0.001) and the mean CAL changed from 8.19+/-2.20 to 5.38+/-2.50 mm (p=0.001). The test treatment resulted in no statistically slight higher PD reductions and CAL gains than the control one (Table 4.). Both in the test group and in the control group 50% of the sites gained at least 3 mm of CAL. In the control group a CAL gain of 6, respectively 7 mm or more was measured in one defect each (6.25%) (Table 5). The Emdogain® group displayed a visible, yet incomplete defect fill in 7 out of 16 defects, while access flap surgery group displayed no radiographic defect fill at all (Fig.1, 2).

Table 4. Clinical parameters at baseline and 6 months for the AF (n=16) and the EMD surgery groups (n=16)

Table 5. The CAL gain related to the number of the defects in the AF and EMD groups

Fig.1 Case A.

a) The bone defect exposed | b) Emdogain® gel in place | c) Rx image before treatment | d) Rx image at six months

Fig.2 Case B.

a) The bone defect exposed | b) Rx image before treatment | c) Rx image at six months

CONCLUSIONS

Within the limits of the present study, it can be concluded that: (i) at 6 months after surgery both therapies resulted in significant PD reductions and CAL gains, and (ii) early evaluation (at 6 months) of the treatment with EMD resulted in no higher CAL gains and PD reductions than the treatment with access flap surgery.

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