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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 nonsmokers, 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®

Patier Nr.	nt 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	3,8	8 8,50	5,88	2,63	0,63	1,88	1,2	5 10,0	6 6,0	0 4,06
SD			1,67	1,32	1,5	4 1,41	1,15	1,50	0,81	1,41	1,5	3 1,18	1,9	3 1,48

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

Patien Nr.	t 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 e 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	5 4,06
SD			1,62	1,42	1,97	2,20	2,50	2,20	1,36	1,71	1,35	5 2,47	1,24	1,77

Table 3. Intraoperative measurements of the $\mathsf{Emdogain}(\mathsf{R})$ 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)

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

AF			EMD				
N٥	%	N٥	%				
1	6,25	-	-				
-	-	1	6,25				
5	31,25	3	18,75				
2	12,5	4	25				
2	12,5	3	18,75				
2	12,5	3	18,75				
	1 - 5 2 2	N° % 1 6,25 - - 5 31,25 2 12,5 2 12,5	N° % 1 6,25 - - - 1 5 31,25 3				

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







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

This Poster was submitted by Assist. Prof. Dr. Dr. Stefan-Ioan Stratul.

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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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	Table 1. Six months clinical results of treatment of intrabony delects with Emdogainth
ABSTRACT	WIZ _ + HE U * * * 217
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demonstrated clinically and on radiographs, which extends up to one year after the surgery, or even more, making this outcome more dependiable on the post treatment maintenance conditions.	Heading was unevential in all patents. At 6 months after therapy, the lest group showed a reduction in mean probing depth (PD) from 75.8-11.87 to 4 0.041.12 emm (prd.0001) and a charge in mean clinical antachment level (CAL) from 8 501-1.41 to 5.681-1.13 mm (prd.001), bit the control group, the mean PD was reduced from 73.141-0.15 to 3.811-1.13 mm (prd.001), bit the control group, the mean PD was reduced from 73.141-0.15 to 3.811-1.13 mm (prd.001), bit the control group, the mean PD was reduced from 73.141-0.15 to 3.811-1.13 mm (prd.001) and the mean CAL, charged from 8.191-2.20
AIM OF THE STUDY	to 5.38+72.50 mm (jm9.001). The test transmost resulted in no statistically slight higher PD reductions and CAL, gains than the controllocer (Table 4). Both in the test group and in the controllocer group SO's of the stest gained at least 3 mm of CAE. In the control group a CAL, gain of 6, respectively 7 mm or more was measured in one divide sets (16.2%). The Endogating group days and with the control incomplete termony and a values and the CAE. In the control group a CAL, gain of 6, respectively 7 mm or more was measured in one divide sets (16.2%). The Endogating group days and a values, exist incomplete termony and the control of the CAE. In the control group a CAL, gain of 6, respectively 7 mm or more was measured in one divide sets (16.2%). The Endogating group days and a values, exist incomplete measured in one divide sets (16.2%). The Endogating group days and the control group days the sets of the control of the test of the control of th
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MATERIALS AND METHODS	
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RESULTS	a) The bone defect exposed b) Emdogain® gel in place c) Rx image d) Rx image before treatment at six month
No adverse healing response was observed. No signs of inflammation, inflation, always or severe pain were present. Pie- and postportraine mean values of the PD, GR and CAL in the two treated provids are displayed in the table No 1 and table No 2.	Fg2 Cave B
Contact the authors	a) The bone defect exposed b) Rx image before treatment c) Rx image at six months

Contact the authors

Dr. Dr. Stefan-Ioan Stratul, DND PhD MDv Medicus Primarus, ResAaado

Within the limits of the present study, it can be concluded that: (i) at 6 months after surgery both the resulted in significant PD reductions and CAL gains, and (i) early evaluation (at 6 months) of the treatment PMD and their is on bitter of CAL sharing and (D) and holes within the treatment with encoded with the treatment for the treatment of the treatmen

CONCLUSIONS