

12 months clinical comparison between Osteoinductal® and Emdogain® for the treatment of intrabony defects

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ABSTRACT

The oily Calcium Hydroxide suspension Osteoinductal® has been documented clinically and histologically to enhance the bone regeneration in closed bone defects and to stimulate the periodontal regeneration in intrabony defects. So far, there is only one controlled clinical study to compare the effect of Osteoinductal® with the effect of the enamel matrix protein derivative Emdogain® in treating deep intrabony defects, at six months after the surgery.

Aim of the study was to compare at 12 months after the surgery the treatment of deep intrabony defects with Osteoinductal®, (Osteoinductal GmbH, München, Germany) to the treatment with the enamel matrix protein derivative Emdogain® (Straumann AG, Waldenburg, Switzerland).

Seventeen healthy patients, displaying a total of thirty-six intrabony defects, were randomly treated either with Osteoinductal® (test) or with Emdogain®(control). Soft tissue measurements were made at baseline and 6 months following the therapy. No differences in any of the investigated parameters were observed at baseline between the two groups.

No adverse healing response was observed in any of the patients. At 12 months after the therapy, the sites treated with Osteoinductal® showed a reduction in probing pocket depth (PPD) from 8.25 ± 1.84 mm to 3.69 ± 0.95 mm and a change in clinical attachment level (CAL) from 9.56 ± 1.82 mm to 5.31 ± 1.78 mm ($p=0.001$). In the group treated with Emdogain®, the PPD was reduced from 7.85 ± 1.95 mm to 3.65 ± 1.23 mm and the CAL changed from 8.35 ± 2.28 mm to 5.05 ± 1.76 mm ($p<0.0001$). Relatively more hard tissue fill was observed radiographically in the defects treated with EMD. Both treatments resulted in significant improvements of PPD and CAL. A statistically not-significant difference between the two groups in favor of the Osteoinductal® group was observed with respect both to the CAL gain and PPD reduction. Within the limitations of this study, it could be concluded that, at 12 months after the therapy, both therapies led to significant improvements of the investigated clinical parameters.

INTRODUCTION

Results of basic research, animal experiments as clinical studies have suggested the influence of an oily Calcium Hydroxide suspension on bone regeneration in closed defects. Its osteostimulative effect, which can be characterized as biologic, seems to rely on factors as the deposit action of the Calcium Hydroxide (sustaining the bone metabolism in a constant, long-lasting mild alkalic environment), the stimulation of the angiogenetic bone growth and, possibly, the concentration of the growth factors next to the defect wall. OCHS have been also proven to reduce the inflammation in the operated site, thus enhancing the wound healing. Histological and radiological analysis, both in animals and humans, suggest a certain amount of regeneration in periodontal defects. So far, there is only one clinical controlled study to compare at six months the effect of the oily Calcium Hydroxide suspension with EMD in periodontal intrabony defects.

OBJECTIVE

Aim of the study was to compare at 12 months after the surgery the treatment of deep intrabony defects with Osteoinductal®, (Osteoinductal GmbH, München, Germany) to the treatment with the enamel matrix protein derivative Emdogain® (Straumann AG, Waldenburg, Switzerland).

MATERIALS AND METHOD

Seventeen patients (6 male and 11 female), with moderate to severe periodontitis, light- or non-smokers, displaying 36 deep intrabony defects in total, were treated either with an oily Calcium Hydroxide suspension (Osteoinductal®, Osteoinductal GmbH, Muenchen, Germany) or with EMD (Emdogain®, Straumann AG, Waldenburg, Switzerland). 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 Løe) < 1. Before surgery and six months after, the following clinical parameters were registered: 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 15, 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 test was used to compare the differences between baseline values and the values measured six months after, and the Mann-Whitney U independent test was used for the comparisons between the groups. Surgery was performed under local anesthesia. A full thickness flap was raised after intrasulcular incision, using release incisions where necessary. 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. Osteoinductal® was placed into the defects of the first group, in direct contact with the rough, vital bone surface. The defects of the second group were treated with EMD, following root conditioning with EDTA (PrefGel®). Post surgical care included antibiotherapy for one week (3x500 mg Amoxicillin daily) and 0.2% Chlorhexidin (Dentaton®, Ghimas, 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

The healing phase progressed uneventful. No signs of inflammation, infection, allergy or severe pain were present. The clinical parameters at baseline and at 12 months for the Osteoinductal® and the EMD groups, the configuration of the defects and the CAL gain are displayed in the tables No.1, 2, 3 and in the graph No.1

Table 1. Clinical parameters at baseline and 12 months for the EMD (n=20) and the Osteoinductal surgery groups (n=16)

Treatment	Baseline	12 months	Difference	Significance
Probing depth				
O	8.25±1.84	3.69±0.95	4.56±1.97	<i>p=0.001</i>
EMD	7.85±1,95	3.65±1.23	4.20±2.17	<i>p<0.0001</i>
			<i>n.s.</i>	
Gingival recession				
O	1.31±1.25	1.63±1.82	0.31±1.35	<i>n.s.</i>
EMD	0.50±1.00	1.40±1.14	0.90±0.91	<i>p=0.001</i>
			<i>n.s.</i>	
Clinical attachment level				
O	9.56±1.82	5.31±1.78	4.25±1.69	<i>p=0.001</i>
EMD	8.35±2,28	5.05±1.76	3.30±2.54	<i>p<0.0001</i>
			<i>n.s.</i>	

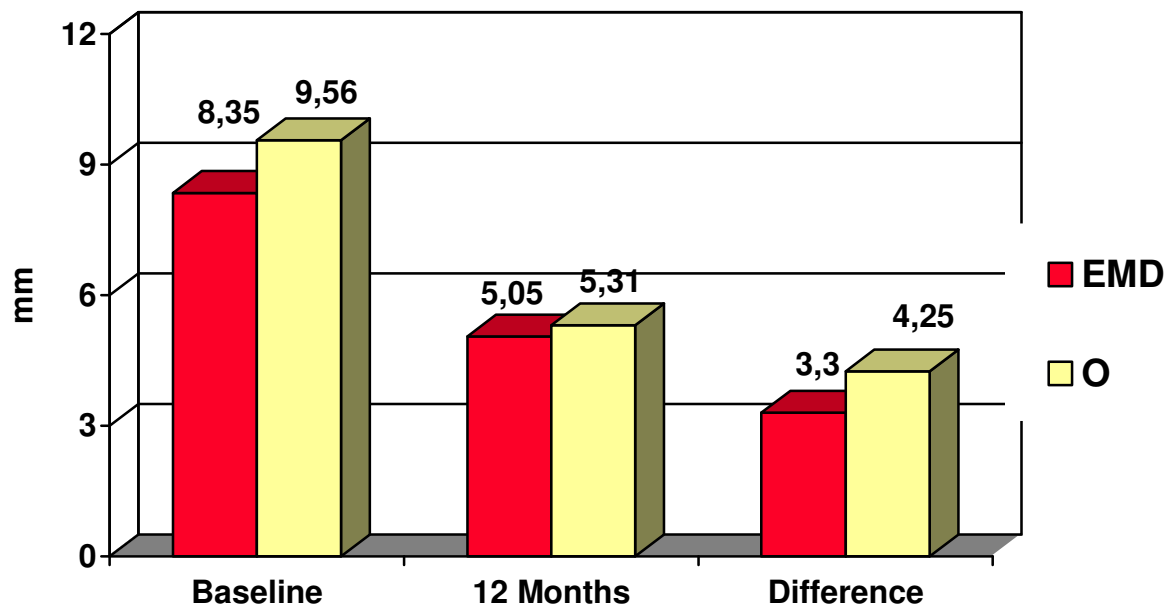
Table 2. The configuration of the defects

	O (n=16)	EMD (n=20)
1 wall	7	10
2 walls	7	7
3 walls	1	1
circular	1	2

Table 3. The CAL gain in the Osteoinductal® and in the EMD group

CAL gain (mm)	Osteoinductal®		EMD	
	N°	%	N°	%
-2	-	-	1	5
-1	-	-	1	5
0	1	6.25	-	-
1	-	-	2	10
2	1	6.25	2	10
3	2	12.5	5	25
4	4	25	4	20
5	5	31.25	2	10
6	2	12.5	1	5
7	1	6.25	1	5
9	-	-	1	5

Graph 1. Graphical distribution of the CAL in the experimental groups at baseline and twelve months after



At twelve months after the therapy, the sites treated with OCHS showed a reduction in probing pocket depth (PPD) from 8.25 ± 1.84 mm to 3.69 ± 0.95 mm and a change in clinical attachment level (CAL) from 9.56 ± 1.82 mm to 5.31 ± 1.78 mm ($p=0.001$). In the group treated with EMD, the PPD was reduced from 7.85 ± 1.95 mm to 3.65 ± 1.23 mm and the CAL changed from 8.35 ± 2.28 mm to 5.05 ± 1.76 mm ($p<0.0001$). Relatively more hard tissue fill was observed radiographically in the defects treated with EMD. Both treatments resulted in significant improvements of PPD and CAL. A statistically not-significant difference between the two groups in favor of the OCHS group was observed with respect to the CAL gain, whereas no statistically significant PPD reduction difference between the groups was observed.

- Fig.1 Case A. a) initial clinical measurements
 b) the bone defect exposed
 c) Osteoinductal® in situ
 d) clinical measurements after 12 months
 e) Rx image before treatment
 f) Rx image twelve months after the treatment

- Fig.2 Case B. a) initial clinical measurements
 b) the bone defect exposed

- c) Emdogain® in situ
- d) clinical measurements after 12 months
- e) Rx image before treatment
- f) Rx image six months after the treatment

CONCLUSIONS

Both treatments resulted in significant improvements of PPD and CAL. A statistically not-significant difference between the two groups in favor of the Osteoinductal® group was observed with respect both to the CAL gain and PPD reduction. Within the limitations of this study, it could be concluded that, at 12 months after the therapy, both therapies led to significant improvements of the investigated clinical parameters.

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