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Clinical Comparison between an Oily Calcium Hydroxide Suspension (Osteoinductal®) and an Enamel Matrix Protein Derivative (Emdogain®) for the Treatment of Intrabony Periodontal Defects in Humans

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Introduction

Biologic agents as EMPs and growth factors became recently of increasing interest in the periodontal regeneration. 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 predictable healing in closed bone defects and a certain amount of regeneration in periodontal defects. Such results have recently led to attempts to use the oily Calcium Hydroxide suspension alone or under various combinations, in treating periodontal defects. So far, there is no clinical controlled study to compare the effect of the oily Calcium Hydroxide suspension with EMD in treating periodontal intrabony defects.

Objectives

Aim of this study is to compare the treatment of deep intrabony defects using an OCHS to the treatment with an enamel matrix protein derivative (EMD).

Material and Methods

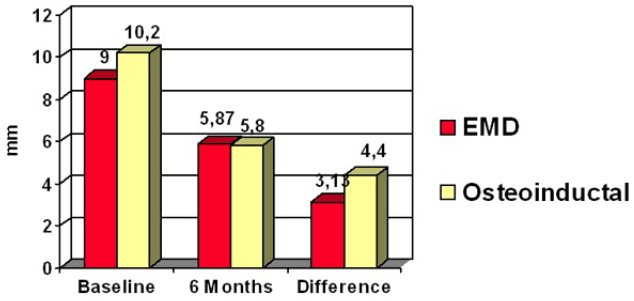
Thirty patients (14 male and 16 female), with moderate to severe periodontitis, light- or non-smokers, each displaying one deep intrabony defect, were treated either with an oily Calcium Hydroxide suspension (Osteoinductal®, Osteoinductal GmbH, Muenchen, Germany) or with EMD (Emdogain®, Straumann AG, 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 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 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 Amoxycilin 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 6 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

Treatment	Baseline	6 months	Difference	Significance
Probing depth				
Osteoinductal ®	8,60 ± 2,06	3,27 ± 1,39	5,33 ± 1,40	p < 0,001
Emdogain ®	8,53 ± 2,17	4,13 ± 1,30	4,40 ± 2,20	p < 0,001
			n.s.	
Gingival recession				
Osteoinductal ®	1,60 ± 1,45	2,60 ± 1,72	1,00 ± 1,00	p = 0,007
Emdogain ®	0,47 ± 0,74	1,73 ± 1,49	1,27 ± 1,58	p = 0,01
			n.s.	
Clinical attachment level				
Osteoinductal ®	10,20 ± 2,08	5,80 ± 2,37	4,40 ± 1,40	p < 0,001
Emdogain ®	9,00 ± 1,96	5,87 ± 1,19	3,13 ± 2,45	p < 0,001
			p =0.033	

Table 1. Clinical parameters at baseline and 6 months for the EMD (n=15) and the Osteoinductal groups (n=15)



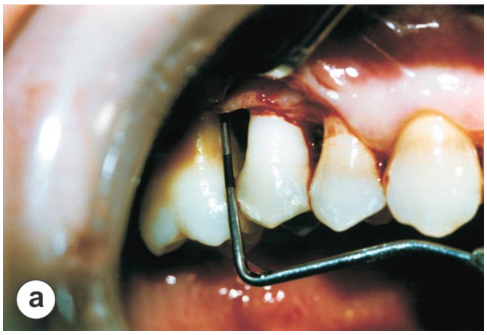
Graph 1: Graphical distribution of the CAL in the experimental groups at baseline and six months after

	Osteoinductal® (n=15)	**Emdogain®** (n=15)
1 wall	6	8
2 walls	6	7
3 walls	3	-

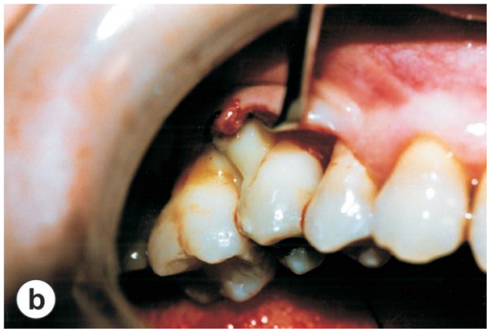
Table 2. The configuration of the defects

CAL gain (mm)	**Osteoinductal®**		**Emdogain®**	
	N°	%	N°	%
0	-	-	1	6,67
1	-	-	3	20,00
2	1	6,67	3	20,00
3	3	20,00	2	13,33
4	5	33,33	3	20,00
5	2	13,33	2	13,33
6	3	20,00	-	-
7	1	6,67	-	-
10	-	-	1	6,67

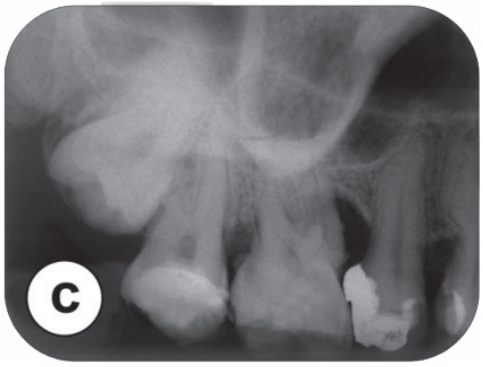
Table 3. The CAL gain in the Osteoinductal® and in the EMD group



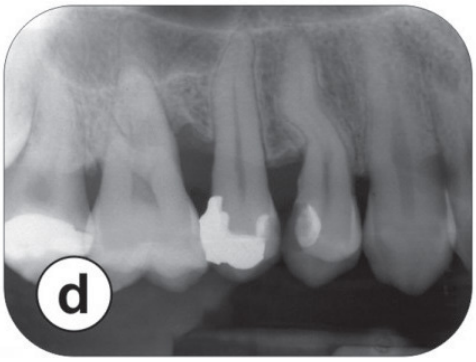
Case A. a) the bone defect exposed



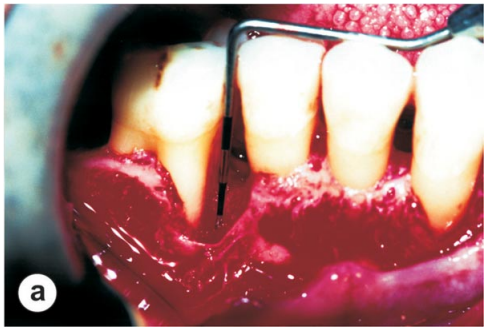
Case A. b) Osteoinductal® in situ



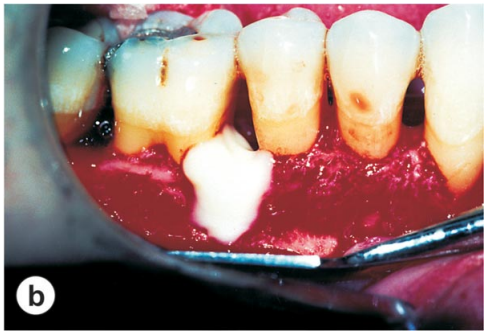
Case A. c) Rx image before treatment



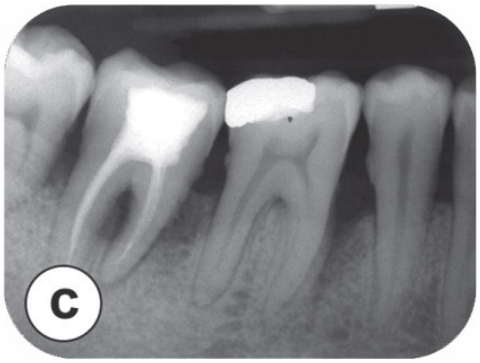
Case A. d) Rx image six months after the treatment



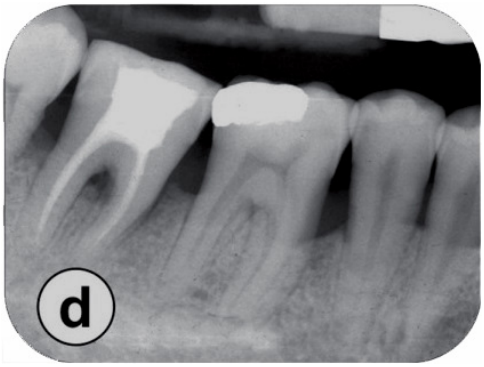
Case B. a) the bone defect exposed



Case B. b) Osteoinductal® in situ

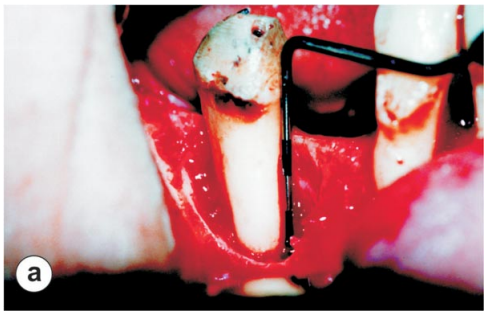


Case B. c) Rx image before treatment

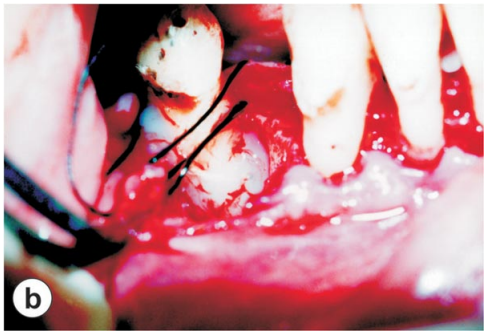


Case B. d) Rx image six months after the treatment

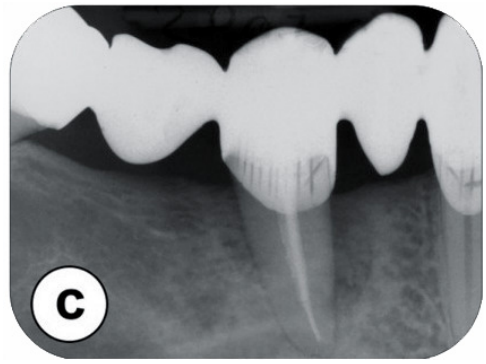
At six months after the therapy, the sites treated with OCHS showed a reduction in probing pocket depth (PPD) from 8.60 ± 2.06 mm to 3.27 ± 1.39 mm and a change in clinical attachment level (CAL) from 10.20 ± 2.08 mm to 5.80 ± 2.37 mm ($p<0.001$). in the group treated with emd, the ppd was reduced from 8.53 ± 2.17 mm to 4.13 ± 1.30 mm and the cal changed from 9.00 ± 1.96 mm to 5.87 ± 1.19 mm ($p<0.001$). 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 significant difference between the two groups in favor of the ochs group was observed with respect to the cal gain ($p=0.033$), whereas no statistically significant ppd reduction difference between the groups was observed.



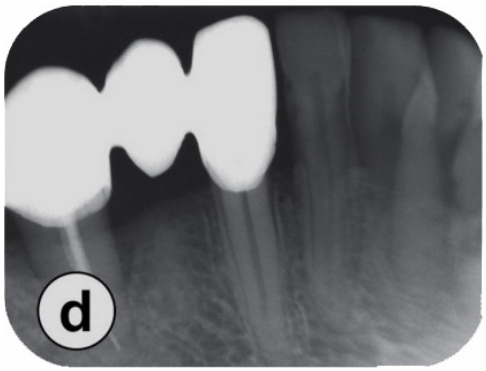
Case C. a) the bone defect exposed



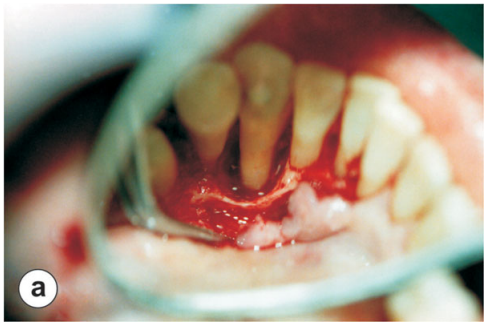
Case C. b) Emdogain® in situ



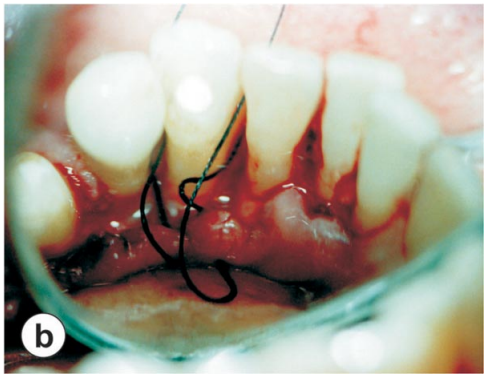
Case C. c) Rx image before treatment



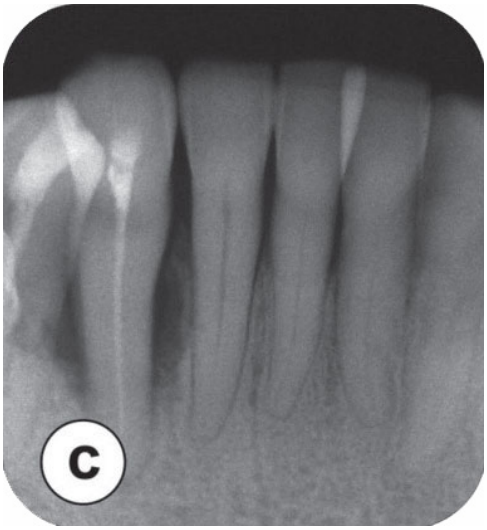
Case C. d) Rx image six months after the treatment

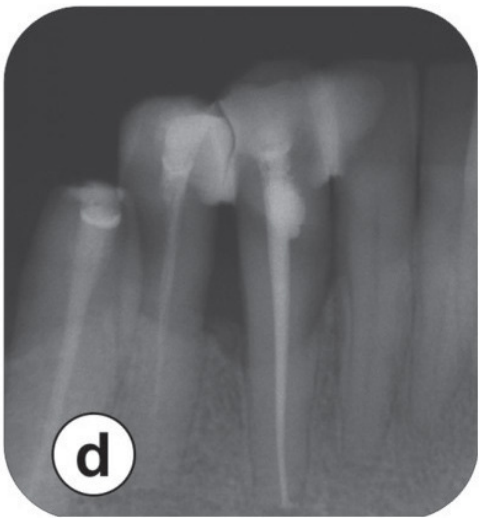


Case D. a) the bone defect exposed



Case D. b) Emdogain® in situ





Case D. c) Rx image before treatment

Case D. d) Rx image six months after the treatment

Conclusions

1. at six months after the surgery, both therapies led to significant improvements of the investigated clinical parameters.
2. the treatment with Osteoinductal® resulted in significantly higher CAL gains than the treatment with EMD.
3. more clinical controlled and histological studies are needed in the future to evaluate the regenerative potential of the oily Calcium Hydroxide suspension Osteoinductal®, when compared to other regenerative approaches.

Abbreviations

OCHS	oily Calcium Hydroxide suspension
EMD	enamel matrix derivative
PPD	periodontal pocket depth
GR	gingival recession
CAL	clinical attachment level

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

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Poster Faksimile:

Clinical Comparison between an Oily Calcium Hydroxide Suspension (Osteoinductal®) and an Enamel Matrix Protein Derivative (Emdogain®) for the Treatment of Intrabony Periodontal Defects in Humans

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ABSTRACT

An oily Calcium Hydroxide suspension (OCHS) 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 are no controlled clinical studies to compare the effect of the OCHS with the effect of other "biological agents" in treating deep intrabony defects.

Aim of the study was to compare the treatment of deep intrabony defects with an OCHS (Osteoinductal®, Osteoinductal GmbH, München, Germany) to an enamel matrix protein derivative (EMD: Emdogain®, Straumann AG, Waldenburg, Switzerland).

Thirty healthy patients, each of whom displayed one intrabony defect, were randomly treated either with the OCHS (test) or with EMD (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 six months after the therapy, the sites treated with OCHS showed a reduction in probing pocket depth (PPD) from 8.60 ± 2.06 mm to 3.27 ± 1.39 mm and a change in clinical attachment level (CAL) from 10.20 ± 2.08 mm to 5.80 ± 2.37 mm (p<0.001). In the group treated with EMD, the PPD was reduced from 8.53 ± 2.17 mm to 4.13 ± 1.30 mm and the CAL changed from 9.00 ± 1.96 mm to 5.87 ± 1.19 mm (p<0.001). 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 significant difference between the two groups in favor of the OCHS group was observed with respect to the CAL gain (p=0.033), whereas no statistically significant PPD reduction difference between the groups was observed.

Within the limitations of this study, it could be concluded that both therapies led to significant improvements of the investigated clinical parameters.

INTRODUCTION

Biologic agents as EMPs and growth factors became recently of increasing interest in the periodontal regeneration. 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 predictable healing in closed bone defects and a certain amount of regeneration in periodontal defects. Such results have recently led to attempts to use the oily Calcium Hydroxide suspension alone or under various combinations, in treating periodontal defects. So far, there is no clinical controlled study to compare the effect of the oily Calcium Hydroxide suspension with EMD in treating periodontal intrabony defects.

OBJECTIVE

Aim of this study is to compare the treatment of deep intrabony defects using an OCHS to the treatment with an enamel matrix protein derivative (EMD).

MATERIALS AND METHODS

Thirty patients (14 male and 16 female), with moderate to severe periodontitis, light- or non-smokers, each displaying one deep intrabony defect, 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 Loe) < 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, distaloral). 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 SRP, using ultrasonic devices and curettes. No resective surgery was performed, nor any root conditioning. Osteoinductal® was placed into the defects of the test group, in direct contact with the rough, vital bone surface. The defects of the control group were treated with EMD, following root conditioning with EDTA (PrefGel®). Post surgical care included antibiotherapy for one week (3x500 mg Amoxycilin 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 6 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.

Table 1. Clinical parameters at baseline and 6 months for the EMD (n=15) and the Osteoinductal groups (n=15)

Treatment	Baseline	6 months	Difference	Significance
Probing depth				
Osteoinductal ®	8,60 ± 2,06	3,27 ± 1,39	5,33 ± 1,40	$p < 0,001$
Emdogain ®	8,53 ± 2,17	4,13 ± 1,30	4,40 ± 2,20	$p < 0,001$
			n.s.	
Gingival recession				
Osteoinductal ®	1,60 ± 1,45	2,60 ± 1,72	1,00 ± 1,00	$p = 0,007$
Emdogain ®	0,47 ± 0,74	1,73 ± 1,49	1,27 ± 1,58	$p = 0,01$
			n.s.	
Clinical attachment level				
Osteoinductal ®	10,20 ± 2,08	5,80 ± 2,37	4,40 ± 1,40	$p < 0,001$
Emdogain ®	9,00 ± 1,96	5,87 ± 1,19	3,13 ± 2,45	$p < 0,001$
			p =0.033	

Table 2. The configuration of the defects

	Osteoinductal® (n=15)	Emdogain® (n=15)
1 wall	6	8
2 walls	6	7
3 walls	3	-

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

CAL gain (mm)	Osteoinductal®		Emdogain®	
	N°	%	N°	%
0	-	-	1	6,67
1	-	-	3	20,00
2	1	6,67	3	20,00
3	3	20,00	2	13,33
4	5	33,33	3	20,00
5	2	13,33	2	13,33
6	3	20,00	-	-
7	1	6,67	-	-
10	-	-	1	6,67

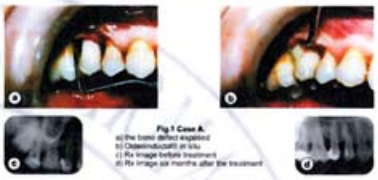

Fig.1 Case A.
a) the bone defect exposed
b) Osteoinductal® in situ
c) Rx image before treatment
d) Rx image six months after the treatment

Fig.2 Case B.
a) the bone defect exposed
b) Osteoinductal® in situ
c) Rx image before treatment
d) Rx image six months after the treatment

At six months after the therapy, the sites treated with OCHS showed a reduction in probing pocket depth (PPD) from 8.60 ± 2.06 mm to 3.27 ± 1.39 mm and a change in clinical attachment level (CAL) from 10.20 ± 2.08 mm to 5.80 ± 2.37 mm (p<0.001). In the group treated with EMD, the PPD was reduced from 8.53 ± 2.17 mm to 4.13 ± 1.30 mm and the CAL changed from 9.00 ± 1.96 mm to 5.87 ± 1.19 mm (p<0.001). 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 significant difference between the two groups in favor of the OCHS group was observed with respect to the CAL gain (p=0.033), whereas no statistically significant PPD reduction difference between the groups was observed.

Fig.3 Case C.
a) the bone defect exposed
b) Emdogain® in situ
c) Rx image before treatment
d) Rx image six months after the treatment

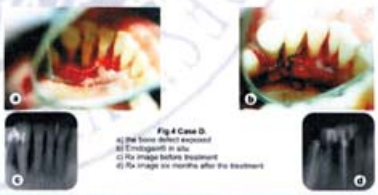

Fig.4 Case D.
a) the bone defect exposed
b) Emdogain® in situ
c) Rx image before treatment
d) Rx image six months after the treatment

CONCLUSIONS

1) at six months after the surgery, both therapies led to significant improvements of the investigated clinical parameters; 2) the treatment with Osteoinductal® resulted in significantly higher CAL gains than the treatment with EMD; 3) more clinical controlled and histological studies are needed in the future to evaluate the regenerative potential of the oily Calcium Hydroxide suspension Osteoinductal®, when compared to other regenerative approaches.

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