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12-Months Clinical Comparison between Osteoinductal® and Emdogain® for the Treatment of Intrabony Defects

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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.

Objectives

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).

Material and Methods

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 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 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 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 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

Treatment	Baseline	12 months	Difference	Significance
Probing depth				
Osteoinductal®	8.25±1.84	3.69±0.95	4.56±1.97	p=0.001
EMD	7.85±1,95	3.65±1.23	4.20±2.17	p<0.0001
			n.s.	
Gingival recession				
Osteoinductal®	1.31±1.25	1.63±1.82	0.31±1.35	n.s.

EMD	0.50±1.00	1.40±1.14	0.90±0.91 n.s.	p=0.001
Clinical attachment level Osteoinductal® EMD	9.56±1.82 8.35±2,28	5.31±1.78 5.05±1.76	4.25±1.69 3.30±2.54 n.s.	p=0.001 p<0.0001

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

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

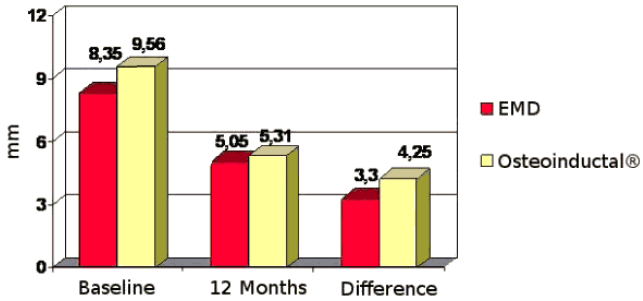
Table 2. The configuration of the defects

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

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

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.



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

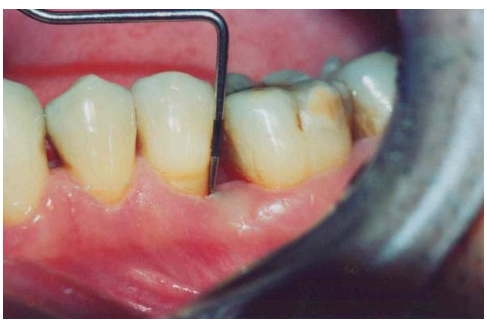


Fig.1 Case A. a) initial clinical measurements

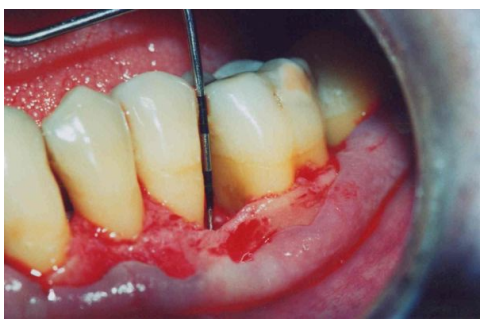


Fig.1 Case A. b) the bone defect exposed

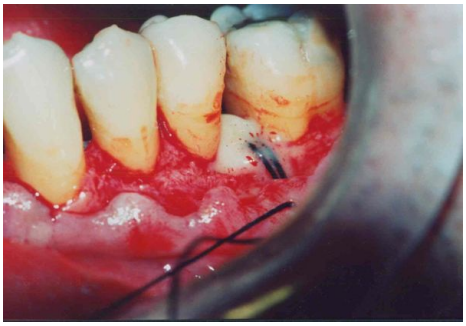


Fig.1 Case A. c) Osteoinductal® in situ

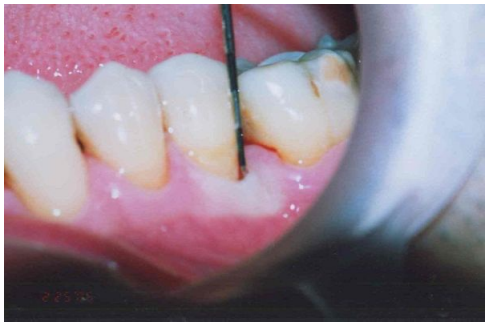


Fig.1 Case A. d) clinical measurements after 12 months

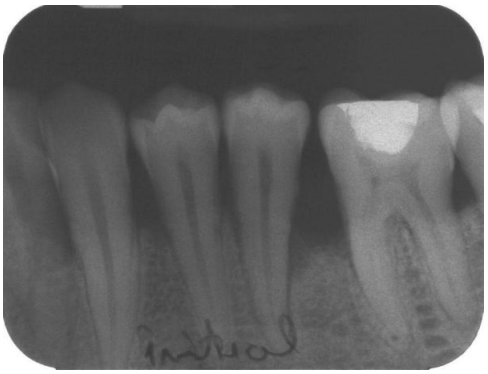


Fig.1 Case A. e) Rx image before treatment

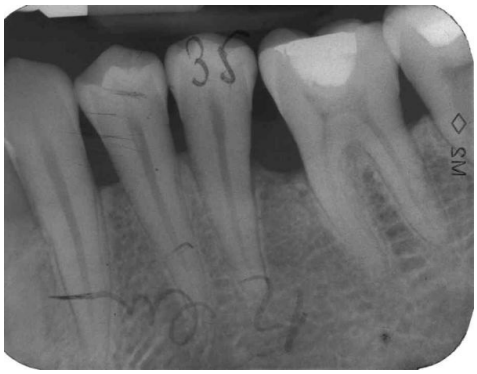


Fig.1 Case A. f) Rx image twelve months after the treatment

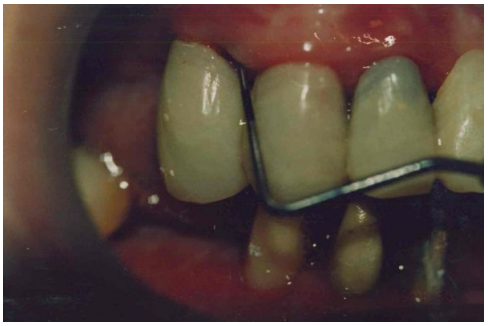


Fig.2 Case B. a) initial clinical measurements

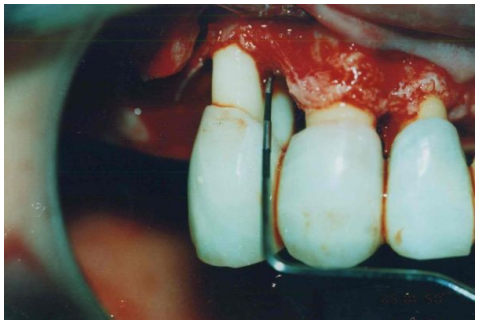


Fig.2 Case B. b) the bone defect exposed

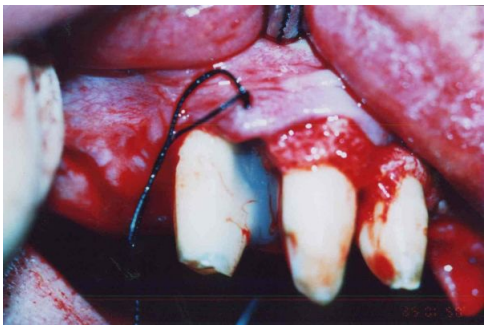


Fig.2 Case B. c) Emdogain® in situ

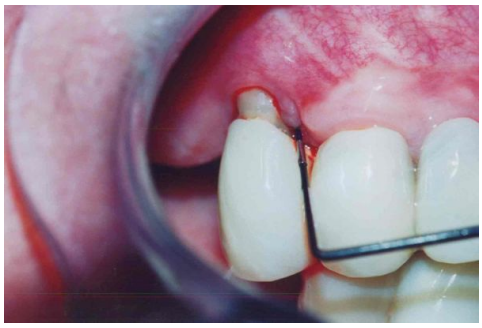


Fig.2 Case B. d) clinical measurements after 12 months

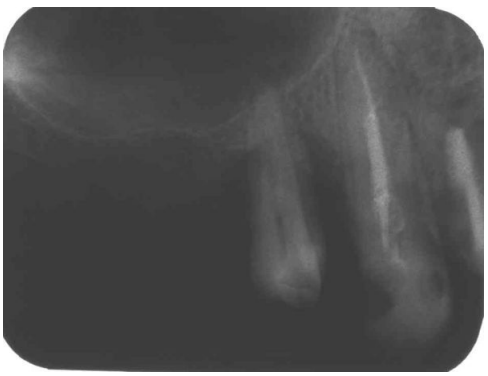


Fig.2 Case B. e) Rx image before treatment

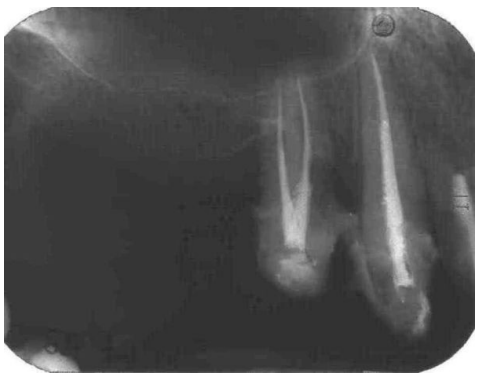


Fig.2 Case B. f) Rx image six months after the treatment

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.

Abbreviations

EMD - matrix protein derivative
OCHS - oily Calcium Hydroxide suspension
CAL - clinical attachment level
PPD - probing pocket depth

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Poster Faksimile:

Clinical Comparison Between a Polylactide-polyglicolide Copolymer (Fisiograft®) and an Enamel Matrix Protein Derivative (Emdogain®) for the Treatment of Intrabony Periodontal Defects in Humans

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ABSTRACT

A polylactide-polyglicolide(PLA-PGL) has been documented clinically to enhance bone regeneration in closed bone defects and to sustain periodontal healing in intrabony defects. So far, there are no controlled clinical studies to compare the effect of the PLA-PGL with the effect of other "biological agents" in treating deep intrabony defects. Aim of the study: to compare treatment of deep intrabony defects with PLA-PGL(Fisiograft® Ghimas,Italy) to an enamel-matrix-protein-derivative(EMD: Emdogain® Straumann AG,Waldenburg,Switzerland). Nineteen patients, displaying 26 intrabony defects, were randomly treated with PLA-PGL (test) or with EMD(control). Soft tissue measurements were made at baseline and 6 months after. No differences in the investigated parameters were observed at baseline between groups. Wilcoxon and Mann-Whitney tests were used for statistics. Alpha-error was set 0.05, the power-of-the-study 0.57. No adverse healing response was observed. Six months after, sites treated with PLA-PGL showed reduction in probing pocket depth (PPD) from 7.77±1.48mm to 3.38±0.77mm (p=0.001) and a change in clinical attachment level(CAL) from 9.08±3.57mm to 4.77±1.09mm (n.s.). In the group treated with EMD, PPD was reduced from 7.54±1.20mm to 3.85±1.28mm (p=0.001).CAL changed from 8.15±1.14mm to 5.85±1.28mm (p=0.016). No or little hard tissue fill was observed radiographically in the defects treated with PLA-PGL. Both treatments resulted in improvements of PPD and CAL. A statistically significant difference between the groups in favor of Fisiograft® group was observed with respect to CAL gain(p=0.029),no statistically significant PPD reduction difference between groups was observed. At six months, both therapies seemed to lead to significant improvements of the investigated clinical parameters.

INTRODUCTION

Polylactides and polyglicolides are known from their pharmaceutical (retard medication supports), surgical (resorbable sutures, screws, microplates, membranes, sinus lift procedures etc.) and TE (bioresorbable supports for cultured cells) applications A polylactide-polyglicolide copolymer (PLA-PGL) has been documented clinically to enhance bone regeneration in closed bone defects (Bucci et al 1999, Pistelli et al. 2000, Pistelli 2003, Serino et al. 2003, Rimondini et al 2005) and to sustain periodontal healing in intrabony defects (Stratul et al. 2004). So far, there are no controlled clinical studies to compare the effect of the PLA-PGL with the effect of other "biological agents" in treating deep intrabony defects

AIM OF THE STUDY

Aim of this clinical controlled study was to compare the treatment of deep intrabony defects with the PLA-PGL copolymer Fisiograft® (Ghimas s. p.a., Casalecchio di Reno, Italy) to the enamel-matrix-protein-derivative EMD Emdogain® (Straumann AG,Waldenburg,Switzerland).

MATERIALS AND METHODS

Nineteen patients (11 male and 8 female), between 32-61 years old, with moderate to severe periodontitis, light- or non-smokers, and displaying a total of 26 deep intrabony defects, were treated either with the combination of flap surgery + Fisiograft® (test) or with FS + EMD (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: mesioral, central, distoral). 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. The alpha-error was set 0.05, and the power of the study 0.57. 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 SRP, using ultrasonic devices and curettes. No resective surgery was performed, nor any root conditioning. Fisiograft® was placed into the defects of the test group. Application form of the product (gel, granules, sponge, gel+granules) was randomly assigned to each defect.The amount of material did not exceed the margins of the defect. The defects of the control group underwent the same surgical protocol, except they were filled with Emdogain® gel. Post surgical care included antibiotherapy for one week (3x500 mg Amoxycilin daily) and 0.2% Chlorhexidin (Dentatonin®, 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 Fisiograft®

Table 2. Six months clinical results of treatment of intrabony defects with Emdogain®

No differences in any of the investigated parameters were observed at baseline between groups (Table 3). Six months after the treatment, the sites treated with PLA-PGL showed a reduction in probing pocket depth(PPD) from 7.77±1.48mm to 3.38±0.77mm (p=0.001) and a change in clinical attachment level(CAL) from 9.08±3.57mm to 4.77±1.09mm (n.s.). In the group treated with EMD, PPD was reduced from 7.54±1.20mm to 3.85±1.28mm (p=0.001), CAL changed from 8.15±1.14mm to 5.85±1.28mm (p=0.016) (Table 4). No or little hard tissue fill was observed radiographically in the defects treated with PLA-PGL.

Table 3 Intraoperative measurements for the Fisiograft(R) and Emdogain(R) groups

Table 4. Clinical parameters at baseline and 6 months for the EMD (n=13) and the fisio surgery groups (n=13)

Fig.1 Case A.

a) The bone defect exposed — b) Fisiograft® in place — c) Rx image before treatment — d) Rx image at six months

Fig.2 Case B.

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

CONCLUSIONS

Both treatments resulted in improvements of PPD and CAL. A statistically significant difference between the groups in favor of Fisiograft® group was observed with respect to CAL gain(p=0.029), no statistically significant PPD reduction difference between groups was observed. At six months, both therapies seemed to lead to significant improvements of the investigated clinical parameters.

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