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Oily Calcium Hydroxide suspension vs. flap surgery in treating deep 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 seems to rely on many factors, as the deposit action of the Calcium Hydroxide, which sustains the bone metabolism in a constant, long-lasting mild alkalic environment, the stimulation of the angiogenetic bone growth with concentration of the growth factors next to the defect wall, and the reduction of the inflammation in the operated site, which enhances the wound healing. Histological and radiological analysis, both in animals and humans seem to indicate a predictable regeneration of closed bone 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 evaluate the effect of the pure oily Calcium Hydroxide suspension in treating periodontal intrabony defects.

Objectives

The aim of this study is to evaluate the effect of the oily Calcium Hydroxide suspension Osteoinductal® alone in the treatment of deep intrabony defects, when compared to access flap (AF) surgery alone.

Material and Methods

Thirty patients (20 male and 10 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 AF surgery alone. 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, 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. Osteoinductal® was placed into the defects of the first group, in direct contact with the rough, vital bone surface. Due to the low consistence of the product, care was taken to avoid, as much as possible, the collapse of the flaps.The amount of material did not exceed the margins of the defect. The defects of the second group underwent access flap surgery alone. Post surgical care included antibiotherapy for one week (3x500 mg Amoxycilin daily) and 0.2% Chlorhexidin (Plak-Out®, Santa Balanos, Greece) 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 flap surgery 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				
Test	8.6±2.06	3.27±1.39	5.33±1.40	p = 0.001
Control	7.20±1.01	4.13±1.41	3.07±1.33	p = 0.001

			p<0.0001	
Gingival recession				
Test	1.60±1.45	2.60±1.72	1.00±1.0	p = 0.007
Control	1.47±1.55	2.80±1.97	1.33±1.40	p = 0.005
			n.s.	
Clinical attachment level				
Test	10.20±2.08	5.80±2.37	4.40±1.40	p=0.001
Control	8.60±1.96	6.87±2.23	1.73±2.25	p=0.001
			p<0.001	

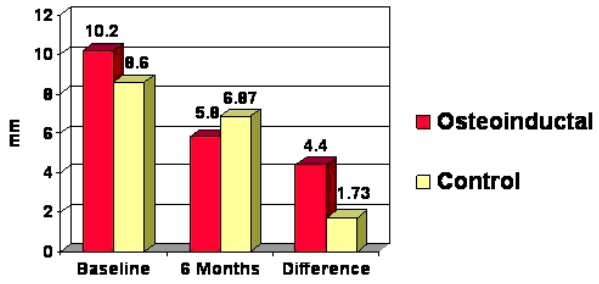
Tab. 1: The clinical parameters at baseline and at 6 months for the Osteoinductal® and the flap surgery groups (n = 15 for each group)

	Test (n=15)	**Control (n=15)**
1 wall	5	7
2 walls	7	8
circular	3	0

Tab. 2: The configuration of the defects

CAL gain (mm)	**Test**		**Control**	
	N°	**%**	**N°**	**%**
-2	-	-	1	6.7
-1	-	-	2	13.3
0	-	-	2	13.3
1	-	-	1	6.7
2	1	6.7	3	20.0
3	3	20.0	4	26.7
4	5	33.3	-	-
5	2	13.3	1	6.7
6	3	20.0	1	6.7
7	1	6.7	-	-

Tab. 3: The CAL gain in the test and in the control group



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

At six months, measurements revealed in the test group a reduction in mean PD from 8.60 ± 2.06 mm to 3.27 ± 1.39 (p<0.001) and a change in mean CAL from 10.20 ± 2.08 mm to 5.80 ± 2.37 (p<0.01). In the control group, mean PD was reduced from 7.20 ± 1.01 mm to 4.13 ± 1.41 (p<0.001) and mean CAL changed from 8.60 ± 1.96 mm to 6.87 ± 2.23 (p<0.01). The test treatment resulted in statistically higher PD reductions (p<0.0001) and CAL gains (p<0.001) than the control one. In the test group 93% of the sites (14 out of 15) gained at least 3 mm of CAL, in the control group, only 26% (4 out of 15) gained the same amount of CAL.

Case A

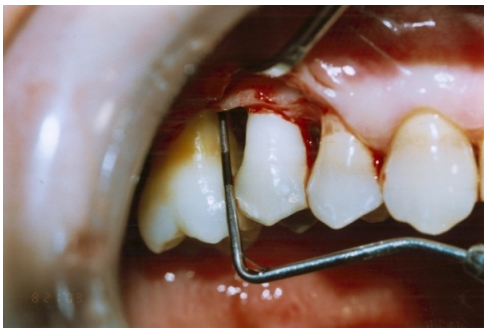


Fig. 1a: The bone defect exposed

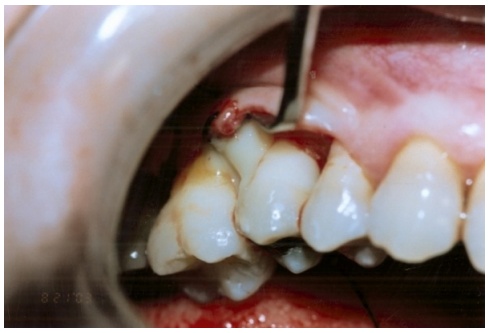


Fig. 1b: Osteoninductal® in situ

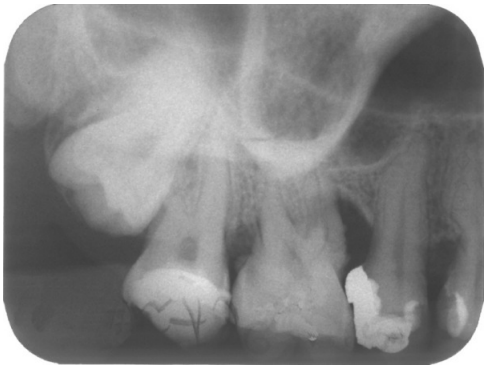


Fig. 1c: Rx image before treatment

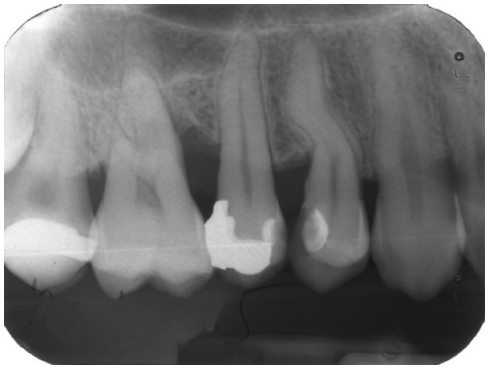


Fig. 1d: Rx image six months after the treatment

Case B

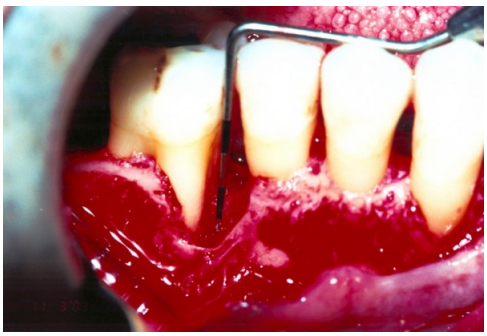


Fig. 2a: the bone defect exposed

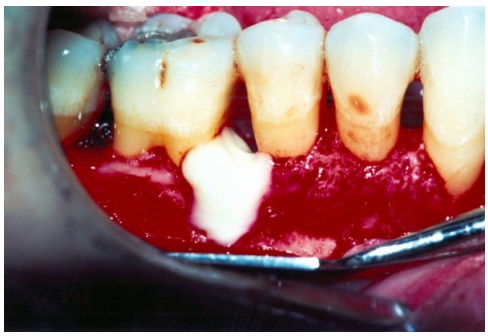


Fig. 2b: Osteoninductal® in situ

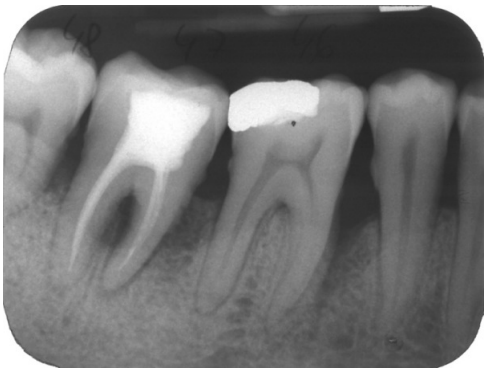


Fig. 2c: Rx image before treatment

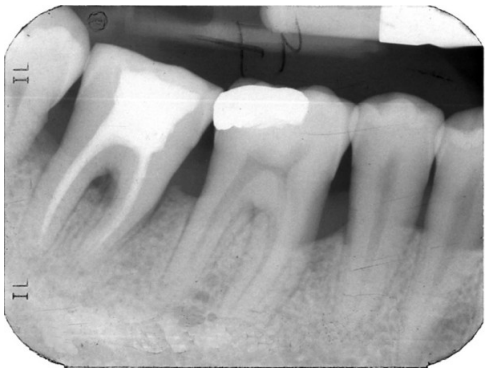


Fig. 2d: Rx image six months after the treatment

Case C

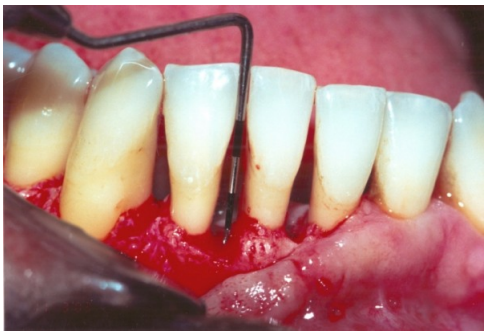


Fig. 3a: the bone defect exposed

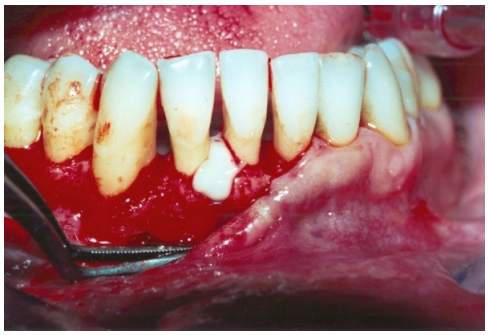


Fig. 3b: Osteoninductal® in situ

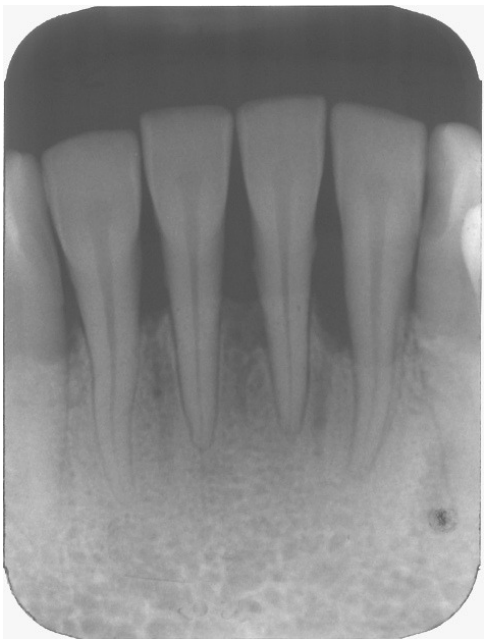


Fig. 3c: Rx image before treatment

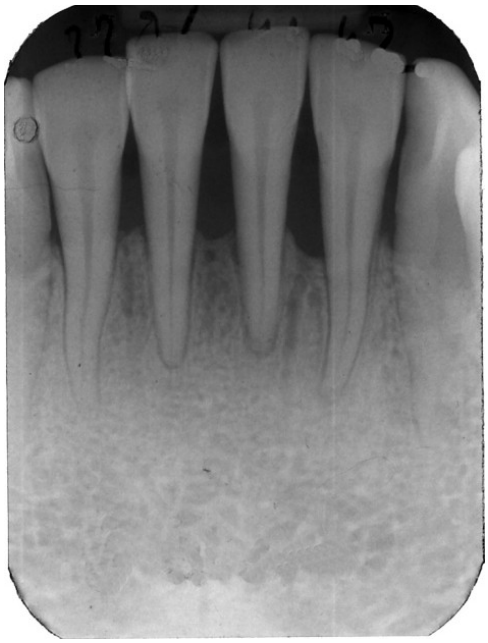


Fig. 3d: Rx image six months after the treatment

Conclusion

1. At six months after the surgery both therapies resulted in significant PD reductions and CAL gains.
2. The treatment with Osteoinductal® resulted in significantly higher CAL gains and PD reductions than treatment with AF surgery.
3. More clinical controlled and histological studies are needed in the future to evaluate the regenerative potential of the oily Calcium Hydroxide suspension Osteoinductal®.

Abbreviations

PD - probing depth
CAL - clinical attachment level
GR - gingival recession
AF-acces flap
PI-plaque index (Silness, Loe, 1963)
BOP-bleeding on probing

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Poster Faksimile:

Oily Calcium Hydroxide Suspension vs. Flap Surgery in Treating Deep Intrabony Defects

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B. WILLERSHAUSEN, Zentrum fur Zahn, Mund, und Kieferheilkunde, Johannes Gutenberg-University, Mainz, Germany

ABSTRACT

An oily Calcium Hydroxyde suspension (Osteoinductal®, Osteoinductal GmbH., München, Germany) was documented to induce bone regeneration in closed defects. Combined with a bone replacement material, the suspension produced statistically significant changes of the PD and CAL.
The aim of this study is to evaluate the effect of Osteoinductal® alone in the treatment of deep intrabony defects, when compared to access flap (AF) surgery alone.
30 patients with one intrabony defect each were randomly treated with either AF+Osteoinductal® (test) or AF alone (control). The parameters evaluated at baseline and six months after surgery were: PI, BOP, PD, GR, CAL. Postsurgical care - administration of antibiotics (Amoxicillin 3x500 mg/die one week, 0.2% Chlorhexidine rinses twice daily for two weeks. Statistical analysis - the Wilcoxon paired test for evaluation of the changes from baseline to six months, and the Mann-Whitney U independent test for comparisons between the groups.
At six months, measurements revealed in the test group a reduction in mean PD from 8.60 ± 2.06 mm to 3.27 ± 1.39 (p<0.001) and a change in mean CAL from 10.20 ± 2.08 mm to 5.80 ± 2.37 (p<0.01). In the control group, mean PD was reduced from 7.20 ± 1.01 mm to 4.13 ± 1.41 (p<0.001) and mean CAL changed from 8.60 ± 1.96 mm to 6.87 ± 2.23 (p<0.01). The test treatment resulted in statistically higher PD reductions (p<0.0001) and CAL gains (p<0.001) than the control one. In the test group 93% of the sites (14 of 15) gained at least 3 mm of CAL, in the control group, only 26% (4 out of 15) gained the same amount of CAL.
The results demonstrate: 1) at six months after the surgery, both therapies resulted in significant PD reductions and CAL gains, and 2) the treatment with Osteoinductal® resulted in significantly higher CAL gains and PD reductions than treatment with AF surgery.

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 seems to rely on many factors, as the deposit action of the Calcium Hydroxide, which sustains the bone metabolism in a constant, long-lasting mild alkasic environment, the stimulation of the angiogenetic bone growth with concentration of the growth factors next to the defect wall, and the reduction of the inflammation in the operated site, which enhances the wound healing. Histological and radiological analysis, both in animals and humans seem to indicate a predictable regeneration of closed bone 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 evaluate the effect of the pure oily Calcium Hydroxide suspension in treating periodontal intrabony defects.

OBJECTIVE

The aim of this study is to evaluate the effect of the oily Calcium Hydroxide suspension Osteoinductal® alone in the treatment of deep intrabony defects, when compared to access flap (AF) surgery alone.

MATERIALS AND METHODS

Thirty patients (20 male and 10 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 AF surgery alone. 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, 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. Osteoinductal® was placed into the defects of the first group, in direct contact with the rough, vital bone surface. Due to the low consistence of the product, care was taken to avoid, as much as possible, the collapse of the flaps. The amount of material did not exceed the margins of the defect. The defects of the second group underwent access flap surgery alone. Post surgical care included antibiotherapy for one week (3x500 mg Amoxycilin daily) and 0.2% Chlorhexidin (Plak-Out®, Santa Balance, Greece) 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 flap surgery 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. The clinical parameters at baseline and at 6 months for the Osteoinductal® and the flap surgery groups (n = 15 for each group)

Treatment	Baseline	6 months	Difference	Significance
Probing depth				
Test	8.6±2.06	3.27±1.39	5.33±1.40	$p = 0.001$
Control	7.20±1.01	4.13±1.41	3.07±1.33	$p = 0.001$
			$p<0.0001$	
Gingival recession				
Test	1.60±1.45	2.60±1.72	1.00±1.0	$p = 0.007$
Control	1.47±1.55	2.80±1.97	1.33±1.40	$p = 0.005$
			n.s.	
Clinical attachment level				
Test	10.20±2.08	5.80±2.37	4.40±1.40	$p<0.001$
Control	8.60±1.96	6.87±2.23	1.73±2.25	$p<0.001$
			$p<0.001$	

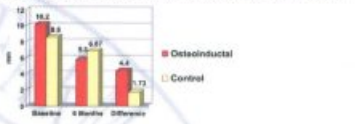
Table 2. The configuration of the defects

	Test (n=15)	Control (n=15)
1 wall	5	7
2 walls	7	8
circular	3	0

Table 3. The CAL gain in the test and in the control group

CAL gain (mm)	Test		Control	
	N°	%	N°	%
-2	-	-	1	6.7
-1	-	-	2	13.3
0	-	-	2	13.3
1	-	-	1	6.7
2	1	6.7	3	20.0
3	3	20.0	4	26.7
4	5	33.3	-	-
5	2	13.3	1	6.7
6	3	20.0	1	6.7
7	1	6.7	-	-

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



At six months, measurements revealed in the test group a reduction in mean PD from 8.60 ± 2.06 mm to 3.27 ± 1.39 (p<0.001) and a change in mean CAL from 10.20 ± 2.08 mm to 5.80 ± 2.37 (p<0.01). In the control group, mean PD was reduced from 7.20 ± 1.01 mm to 4.13 ± 1.41 (p<0.001) and mean CAL changed from 8.60 ± 1.96 mm to 6.87 ± 2.23 (p<0.01). The test treatment resulted in statistically higher PD reductions (p<0.0001) and CAL gains (p<0.001) than the control one. In the test group 93% of the sites (14 out of 15) gained at least 3 mm of CAL, in the control group, only 26% (4 out of 15) gained the same amount of CAL.

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

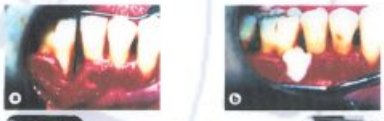


Fig.2 Case B.
a) the bone defect exposed
b) Osteoinductal® in situ
c) Rx image before treatment
d) Rx image six months after the treatment

Fig.3 Case C.
a) the bone defect exposed
b) Osteoinductal® 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 resulted in significant PD reductions and CAL gains, 2) the treatment with Osteoinductal® resulted in significantly higher CAL gains and PD reductions than treatment with AF surgery, 3) more clinical controlled and histological studies are needed in the future to evaluate the regenerative potential of the oily Calcium Hydroxide suspension Osteoinductal®.

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