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Evaluation of the Polylactide-Polyglycolide Copolymer Fisiograft® in Treatment of Deep Intrabony Defects

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Introduction

Resorbable synthetic polymers have been developed by the biomedical research over the last decades. Among them, the Polylactic and the Polyglycolic acids and their copolymers under various proportions, were extensively used in manufacturing surgical devices destined to the oral, maxillo-facial and orthopaedic surgery (Pihlajamaki et al. 1998, Waris et al. 2003). Experimental studies have demonstrated that the degradation period of the commonly used polymeric surgical devices (osteosynthesis plates, screws, sutures or membranes) is correlated with local factors and with the specific density, which further depends on the polymerization degree/the molecular weight of the material (Heidemann et al. 2003). A low-density polylactide-polyglycolide copolymer (Fisiograft®, Ghimas S.p.A., Casalecchio di Reno, Italy) was recently used as a space filler in dentistry to treat closed bone defects and in implantology for sinus floor augmentations. The material is currently manufactured as gel, granules or sponge, displays a good handling during the surgery; degradation occurs through "bulk erosion" by hydrolysis in a period between 3-6 months, depending on the tissular conditions, leaving instead a high percentage of bone (Piatelli 2003). So far, there are no clinical studies to evaluate the effect of the polylactide-polyglycolide copolymer Fisograft® in the treatment of deep periodontal intrabony defects.

Objectives

Objective of this clinical controlled study was to compare clinically the treatment of deep intrabony defects using the combination of flap surgery (FS)+ polylactide-polyglycolide Fisiograft® to the FS alone.

Material and Methods

Thirteen patients (10 male and 3 female), between 33-57 years old, with moderate to severe periodontitis, light- or non-smokers, and displaying a total of 24 deep intrabony defects, were treated either with the combination of FS + Fisiograft® (test) or with FS 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. 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, without any grafting procedure. Post surgical care included antibiotherapy for one week (3x500 mg Amoxycilin 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

The healing phase progressed uneventful. 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.

Patient Nr.	Tooth Type	Defect Type (walls)	PPD	(mm)	PPD	GR	(mm)	GR	CAL	(mm)	CAL gain (mm)	CEJ BD	BC BD	CEJ BC
			Pre-operative	After 6 months	Diff.	Pre-operative	After 6 months	Diff.	Pre-operative	After 6 months				
1	43	2	5	3	2	1	1	0	6	4	2	8	4	4
2	46	3	7	6	1	1	0	-1	8	6	2	10	4	6
3	33	2	7	3	4	0	0	0	7	3	4	8	6	2
4	36	1	7	4	3	0	0	0	7	4	3	8	5	3
5	48	2	10	5	5	0	1	1	10	6	4	11	8	3
6	46	2	9	3	6	1	3	2	10	6	4	11	8	3
7	17	1	9	4	5	1	2	1	10	6	4	11	6	5
8	14	1	8	3	5	0	1	1	8	4	4	9	7	2
9	17	1	7	4	3	0	0	0	7	4	3	8	6	2
10	11	1	6	2	4	2	6	4	8	8	0	9	4	5
11	17	c	12	6	6	0	3	3	12	9	3	16	9	7
12	46	1	8	3	5	2	3	1	10	6	4	10	6	4
Mean			7.92	3.83	4.08	0.67	1.67	1.00	8.58	5.50	3.08	9.92	6.08	3.83
SD			1.88	1.27	1.56	0.78	1.83	1.41	1.78	1.78	1.24	2.27	1.68	1.64

Tab. 1: Six months clinical results of treatment of intrabony defects with FS + Fisiograft®

Patient Nr.	Tooth Type	Defect Type (walls)	PPD	(mm)	PPD	GR	(mm)	GR	CAL	(mm)	CAL gain (mm)	CEJ BD	BC BD	CEJ BC
			Pre-operative	After 6 months	Diff.	Pre-operative	After 6 months	Diff.	Pre-operative	After 6 months				
1	27	2	6	5	1	0	0	0	6	5	1	7	5	2
2	34	2	7	3	4	0	1	1	7	4	3	8	4	4
3	24	1	7	4	3	0	4	4	7	8	-1	8	5	3
4	16	1	6	3	3	2	6	4	8	9	-1	9	4	5
5	21	2	6	4	2	3	5	2	9	9	0	12	3	9
6	23	2	6	3	3	1	1	0	7	4	3	9	4	5
7	24	2	8	4	4	0	1	1	8	5	3	9	3	6
8	16	2	7	4	3	1	3	2	8	6	2	9	4	5
9	46	1	9	8	1	1	2	1	10	10	0	12	4	8
10	33	1	9	5	4	1	3	2	10	8	2	12	4	8
11	23	2	7	4	3	2	3	1	9	7	2	10	5	5
12	34	1	7	6	1	2	3	1	7	9	-2	8	4	4
Mean			7.08	4.42	2.67	1.08	2.67	1.58	8.00	7.00	1.00	9.42	4.08	5.33
SD			1.08	1.44	1.15	1.00	1.78	1.31	1.28	2.13	1.76	1.73	0.67	2.10

Tab. 2: Six months clinical results of treatment of intrabony defects with flap surgery (FS) alone

No differences in any of the investigated parameters were observed at baseline between groups. The clinical measurements six months after treatment revealed in the group of defects treated with the combination of FS + Fisiograft® (Table 1) a reduction of the probing pocket depth (PD) from 7.92 ± 1.88 mm to 3.83 ± 1.27 mm (p=0.002), and a change of the mean clinical attachment level (CAL) from 8.58 ± 1.78 mm to 5.50 ± 1.78 mm (p=0.003). In the control group, the mean PD was reduced from 7.08 ± 1.08 mm to 4.42 ± 1.44 (p=0.002) and the mean CAL changed from 8.00 ± 1.28 mm to 7.00 ± 2.13 (ns) (Table 2). The test treatment resulted in statistically higher PD reductions (p=0.024) and CAL gains (p=0.02) than the control group (Table 3). In both groups, a minute or no radiographic defect fill was observed at six months after treatment.

Treatment	Baseline	6 months	Difference	Significance
Probing depth				
Fisiograft	7.92±1.88	3.83±1.27	4.08±1.56	p=0.002
Acces flap	7.08±1.08	4.42±1.44	2.67±1.15	p=0.002
			p<0.024	
Gingival recession				
Fisiograft	0.67±0.78	1.67±1.83	1.00±1.41	p=0.031
Acces flap	1.08±1.00	2.67±1.78	1.58±1.31	p=0.004
			n.s.	
Clinical attachment level				

Fisiograft	8.58±1.78	5.50±1.78	3.08±1.24	p=0.030
Acces flap	8.00±1.28	7.00±2.13	1.00±1.76	p=0.063
			p=0.002	

Tab. 3: Clinical parameters at baseline and 6 months for the Fisiograft and the flap surgery groups (n=12 for each group)

Case A

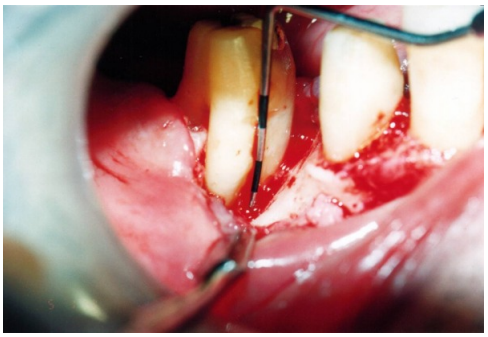


Fig. 1a: The bone defect exposed

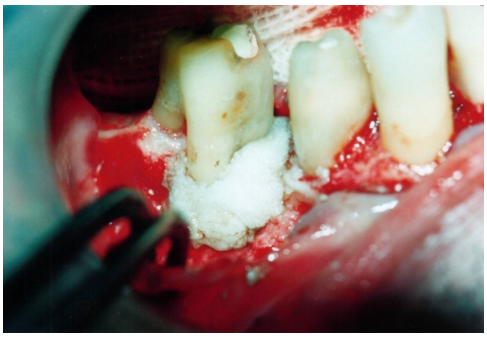


Fig. 1b: Fisiograft® in place

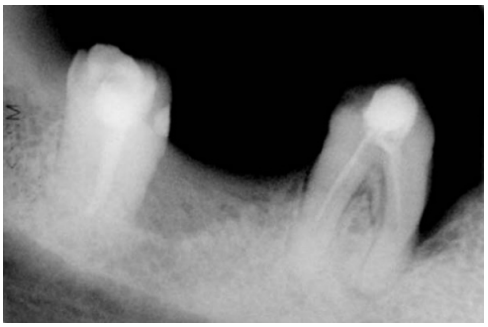


Fig. 1c: Rx image before treatment

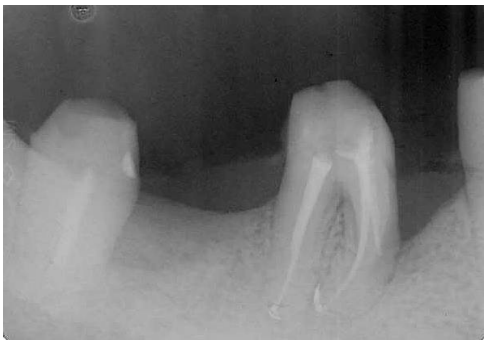


Fig. 1d: Rx image at six months

Case B

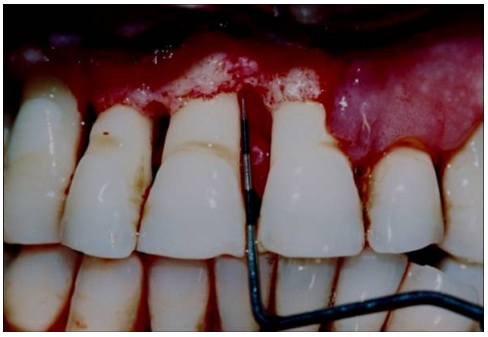


Fig. 2a: The bone defect exposed

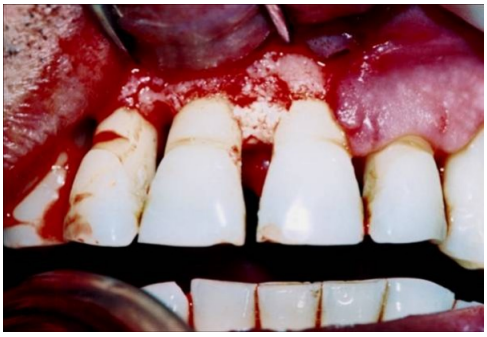
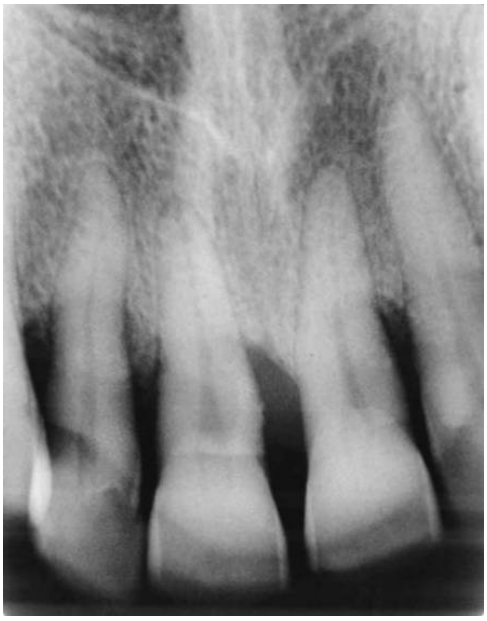


Fig. 2b: Fisiograft® in place



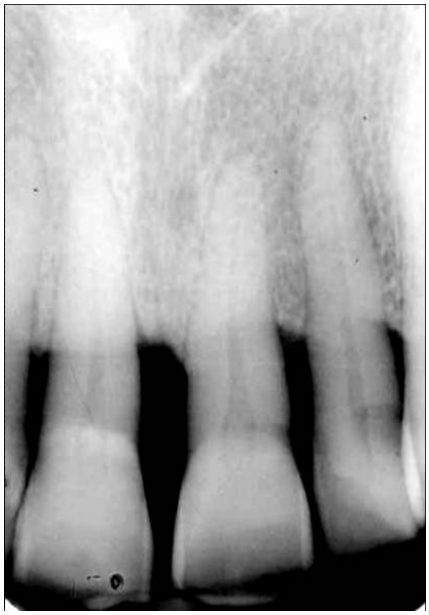


Fig. 2c: Rx image before treatment

Fig. 2d: Rx image at six months

Conclusion

1. At six months after the surgery both therapies resulted in PD reductions and CAL gains.
2. Treatment with flap surgery + Fisiograft® resulted in significantly higher CAL gains and PD reductions than treatment with FS alone.
3. More controlled clinical studies are needed in order to evaluate the regenerative potential of the polylactide-polyglycolides, the most suitable delivery form of Fisiograft®, and its most effective combinations with other regenerative materials.

Abbreviations

PD - probing depth
CAL - clinical attachment level
GR - gingival recession

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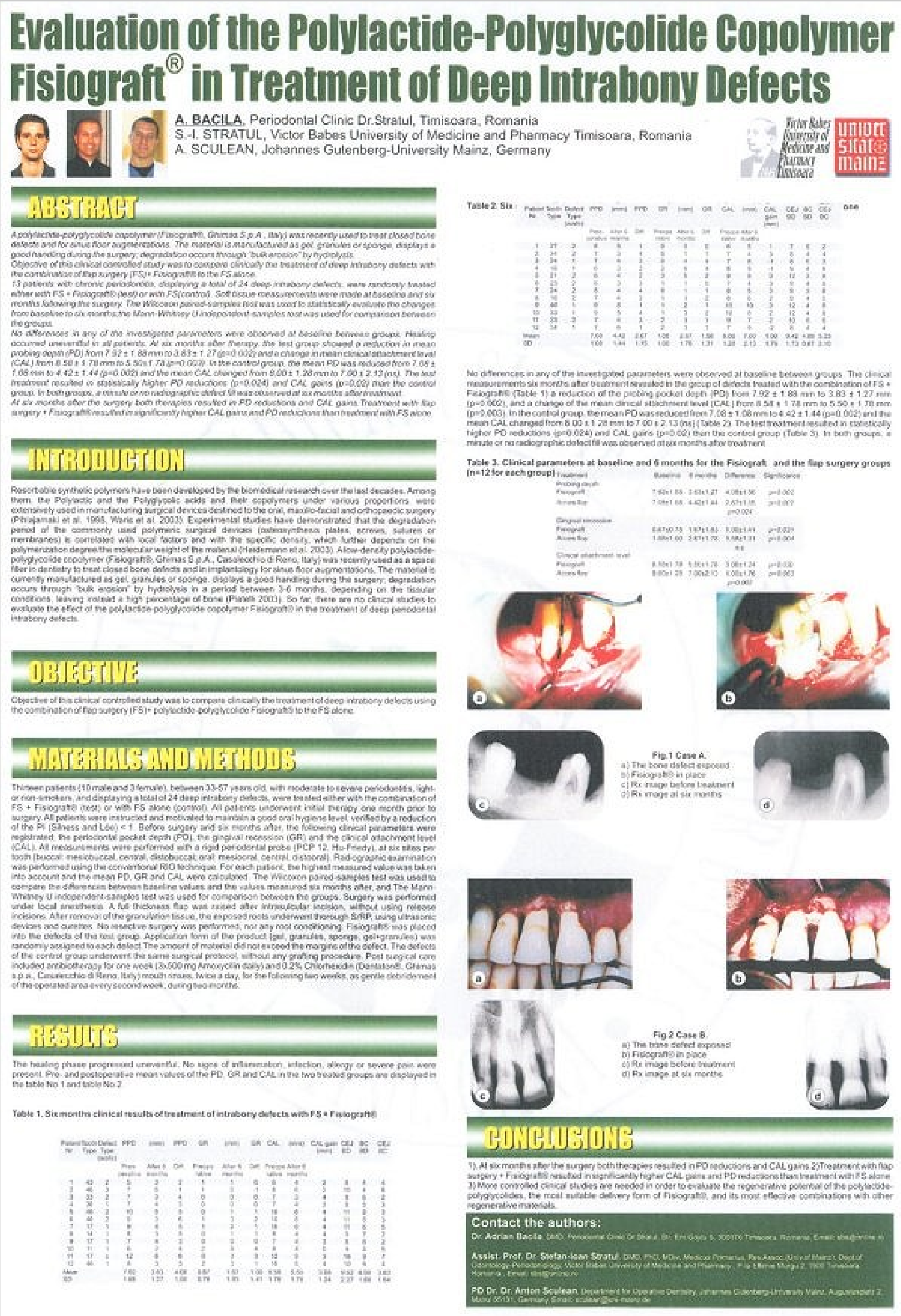

Evaluation of the Polylactide-Polyglycolide Copolymer Fisiograft® in Treatment of Deep Intrabony Defects

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ABSTRACT

A polylactide-polyglycolide copolymer (Fisiograft®, Ghimas S.p.A., Italy) was recently used to treat closed bone defects and for sinus floor augmentations. The material is manufactured as gel, granules or sponge, displays a good handling during the surgery; degradation occurs through "bulk erosion" by hydrolysis.
Objective of this clinical controlled study was to compare clinically the treatment of deep intrabony defects with the combination of flap surgery (FS)+ Fisiograft® to the FS alone.
13 patients with chronic periodontitis, displaying a total of 24 deep intrabony defects, were randomly treated either with FS + Fisiograft® (test) or with FS(control). Soft tissue measurements were made at baseline and six months following the surgery. The Wilcoxon paired-samples test was used to statistically evaluate the changes from baseline to six months;the Mann-Whitney U independent-samples test was used for comparison between the groups.
No differences in any of the investigated parameters were observed at baseline between groups. Healing occurred uneventful in all patients. At six months after therapy, the test group showed a reduction in mean probing depth (PD) from 7.92 ± 1.88 mm to 3.83 ± 1.27 (p=0.002) and a change in mean clinical attachment level (CAL) from 8.58 ± 1.78 mm to 5.50±1.78 (p=0.003). In the control group, the mean PD was reduced from 7.08 ± 1.08 mm to 4.42 ± 1.44 (p=0.002) and the mean CAL changed from 8.00 ± 1.28 mm to 7.00 ± 2.13 (ns). The test treatment resulted in statistically higher PD reductions (p=0.024) and CAL gains (p=0.02) than the control group. In both groups, a minute or no radiographic defect fill was observed at six months after treatment.
At six months after the surgery both therapies resulted in PD reductions and CAL gains Treatment with flap surgery + Fisiograft® resulted in significantly higher CAL gains and PD reductions than treatment with FS alone.

INTRODUCTION

Resorbable synthetic polymers have been developed by the biomedical research over the last decades. Among them, the Polylactic and the Polyglycolic acids and their copolymers under various proportions were extensively used in manufacturing surgical devices destined to the oral, maxillo-facial and orthopaedic surgery (Pihlajamaki et al. 1998, Waris et al. 2003). Experimental studies have demonstrated that the degradation period of the commonly used polymeric surgical devices (osteosynthesis plates, screws, sutures or membranes) is correlated with local factors and with the specific density, which further depends on the polymerization degree/the molecular weight of the material (Heidemann et al. 2003). A low-density polylactide-polyglycolide copolymer (Fisiograft®, Ghimas S.p.A., Casalecchio di Reno, Italy) was recently used as a space filler in dentistry to treat closed bone defects and in implantology for sinus floor augmentations. The material is currently manufactured as gel, granules or sponge, displays a good handling during the surgery; degradation occurs through "bulk erosion" by hydrolysis in a period between 3-6 months, depending on the tissular conditions, leaving instead a high percentage of bone (Pistelli 2001). So far, there are no clinical studies to evaluate the effect of the polylactide-polyglycolide copolymer Fisiograft® in the treatment of deep periodontal intrabony defects.

OBJECTIVE

Objective of this clinical controlled study was to compare clinically the treatment of deep intrabony defects using the combination of flap surgery (FS)+ polylactide-polyglycolide Fisiograft® to the FS alone.

MATERIALS AND METHODS

Thirteen patients (10 male and 3 female), between 33-57 years old, with moderate to severe periodontitis, light- or non-smokers, and displaying a total of 24 deep intrabony defects, were treated either with the combination of FS + Fisiograft® (test) or with FS 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. 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, without any grafting procedure. Post surgical care included antibiotherapy for one week (3x500 mg Amoxycilin daily) and 0.2% Chlorhexidin (Dentatone®, 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

The healing phase progressed uneventful. 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 FS + Fisiograft®

Patient Nr	Tooth Type	Defect Type (walls)	PPD Preoperative	PPD After 6 months	PPD Diff	GR Preoperative	GR After 6 months	GR Diff	CAL Preoperative	CAL After 6 months	CAL gain (mm)	CEJ BD	BC BD	CEJ BC
1	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
2	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
3	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
4	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
5	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
6	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
7	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
8	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
9	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
10	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
11	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
12	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Mean			[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
SD			[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Table 2. Six ... **one**

Patient Nr	Tooth Type	Defect Type (walls)	PPD Preoperative	PPD After 6 months	PPD Diff	GR Preoperative	GR After 6 months	GR Diff	CAL Preoperative	CAL After 6 months	CAL gain (mm)	CEJ BD	BC BD	CEJ BC
1	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
2	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
3	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
4	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
5	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
6	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
7	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
8	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
9	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
10	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
11	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
12	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Mean			7.08	4.42	2.67	1.08	2.67	1.58	8.00	7.00	1.00	9.42	4.08	5.33
SD			1.08	1.44	1.15	1.08	1.78	1.31	1.28	2.13	1.76	1.73	0.81	2.10

No differences in any of the investigated parameters were observed at baseline between groups. The clinical measurements six months after treatment revealed in the group of defects treated with the combination of FS + Fisiograft® (Table 1) a reduction of the probing pocket depth (PD) from 7.92 ± 1.88 mm to 3.83 ± 1.27 mm (p=0.002), and a change of the mean clinical attachment level (CAL) from 8.58 ± 1.78 mm to 5.50 ± 1.78 mm (p=0.003). In the control group, the mean PD was reduced from 7.08 ± 1.08 mm to 4.42 ± 1.44 (p=0.002) and the mean CAL changed from 8.00 ± 1.28 mm to 7.00 ± 2.13 (ns) (Table 2). The test treatment resulted in statistically higher PD reductions (p=0.024) and CAL gains (p=0.02) than the control group (Table 3). In both groups, a minute or no radiographic defect fill was observed at six months after treatment.

Table 3. Clinical parameters at baseline and 6 months for the Fisiograft and the flap surgery groups (n=12 for each group)

Treatment	Baseline	6 months	Difference	Significance
Probing depth				
Fisiograft	7.92±1.88	3.83±1.27	4.08±1.56	p=0.002
Access flap	7.08±1.08	4.42±1.44	2.67±1.15 p=0.024	p=0.002
Gingival recession				
Fisiograft	0.67±0.78	1.67±1.83	1.00±1.41	p=0.031
Access flap	1.08±1.00	2.67±1.78	1.58±1.31 ns	p=0.004
Clinical attachment level				
Fisiograft	8.58±1.78	5.50±1.78	3.08±1.24	p=0.030
Access flap	8.00±1.28	7.00±2.13	1.00±1.76 p=0.007	p=0.063

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) Fisiograft® in place
c) Rx image before treatment
d) Rx image at six months

CONCLUSIONS

1). At six months after the surgery both therapies resulted in PD reductions and CAL gains 2)Treatment with flap surgery + Fisiograft® resulted in significantly higher CAL gains and PD reductions than treatment with FS alone 3) More controlled clinical studies are needed in order to evaluate the regenerative potential of the polylactide-polyglycolides, the most suitable delivery form of Fisiograft®, and its most effective combinations with other regenerative materials.

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