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

Language: English

Authors:
Assist. Prof. Dr. Dr. Stefan-Ioan Stratul, Victor Babes University of Medicine, Romania,
Dr. Darian Rusu, Dr. Adrian Bacila, Periodontal Clinic Dr. Stratul, Timisoara, Romania,
Dr. Anca Benta, Johannes Gutenberg University Mainz, Germany

Date/Event/Venue:
14-15 May 2005
10th Congress of the Balkanic Society of Stomatology BaSS
Belgrade, Republic of Serbia

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, Piatelli et al. 2000, Piatelli 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.

Objectives

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).

Material 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: 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. 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 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, except they were filled with Emdogain® gel. 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

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.

Patient Nr.	Tooth Type	Defect Type(walls)	PPD (mm) Pre-operative	(mm) After 6 months	PPD Diff.	CAL (mm) Pre-operative	(mm) After 6 months	CAL gain(mm)	GR (mm) Pre-operative	(mm) After 6 months	GR Diff.	CEJ BD	BC BD	CEJ BC
1	1.2.d	1	8	3	5	8	4	4	0	1	1	10	6	4
2	1.4.d	2	10	3	7	20	4	16	10	1	-9	20	12	8
3	4.3.m	2	5	3	2	6	4	2	1	1	0	8	4	4
4	3.3.d	2	7	3	4	7	3	4	0	0	0	8	6	2
5	3.6.m	1	7	4	3	7	4	3	0	0	0	8	5	3

Patient Nr.	Tooth Type	Defect Type(walls)	PPD Pre-operative	PPD After 6 months	PPD Diff.	CAL Pre-operative	CAL After 6 months	CAL gain(mm)	GR Pre-operative	GR After 6 months	GR Diff.	CEJ BD	BC BD	CEJ BC
6	4.8.m	2	10	5	5	10	6	4	0	1	1	11	8	3
7	4.6.m	2	9	3	6	10	6	4	1	3	2	11	8	3
8	1.4.m	1	8	3	5	8	4	4	0	1	1	9	7	2
9	1.7.m	1	7	4	3	7	4	3	0	0	0	8	6	2
10	1.1.m	1	6	2	4	8	6	2	2	4	2	9	4	5
11	3.4.m	1	7	4	3	7	5	2	0	1	1	7	5	2
12	4.6.m	1	8	3	5	10	6	4	2	3	1	11	4	7
13	1.7.d	2	9	4	5	10	6	4	1	2	1	11	6	5
Mean			7,77	3,38	4,38	9,08	4,77	4,31	1,31	1,38	0,08	10,08	6,23	3,85
SD			1,48	0,77	1,39	3,57	1,09	3,61	2,72	1,26	2,81	3,30	2,20	1,95

Table 1. Six months clinical results of treatment of intrabony defects with Fisiograft®

Patient Nr.	Tooth Type	Defect Type(walls)	PPD (mm) Pre-operative	PPD (mm) After 6 months	PPD Diff.	CAL (mm) Pre-operative	CAL (mm) After 6 months	CAL gain(mm)	GR (mm) Pre-operative	GR (mm) After 6 months	GR Diff.	CEJ BD	BC BD	CEJ BC
1	2.6.m	1	7	3	4	9	5	4	2	2	0	10	7	3
2	21	2	6	3	3	7	6	1	1	3	2	11	6	5
3	21	2	7	4	3	9	6	3	2	2	0	11	6	5
4	14	2	8	4	4	8	4	4	0	0	0	9	6	3
5	14	2	6	3	3	6	5	1	0	2	2	9	5	4
6	25	2	8	4	4	8	6	2	0	2	2	9	4	5
7	22	1	7	3	4	7	7	0	0	4	4	9	4	5
8	22	1	10	3	7	10	8	2	0	5	5	10	4	6
9	27	2	8	6	2	8	6	2	0	0	0	10	9	1
10	1.7.m	1	8	7	1	9	8	1	1	1	0	12	9	3
11	3.6.m	1	8	4	4	9	6	3	1	2	1	10	7	3
12	4.3.m	2	9	3	6	9	5	4	0	2	2	11	7	4
13	2.3.m	1	6	3	3	7	4	3	1	1	0	8	5	3
Mean			7,54	3,85	3,69	8,15	5,85	2,31	0,62	2,00	1,38	9,92	6,08	3,85
SD			1,20	1,28	1,55	1,14	1,28	1,32	0,77	1,41	1,66	1,12	1,71	1,34

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.

Treatment	CAL (mm)	CEJ-BD (mm)	CEJ-BC (mm)	INTRA (mm)
EMD (n=13)	5,85±1,28	9,92±1,12	3,85±1,34	6,08±1,71
Fisio (n=13)	4,77±1,09	10,08±3,30	3,85±1,95	6,23±2,20

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

Treatment	Baseline	6 months	Difference	Significance
Probing depth				
EMD	7,54±1,20	3,85±1,28	3,69±1,55	p=0,001
Fisio	7,77±1,48	3,38±0,77	4,38±1,39	p=0,001
			n.s.	
Gingival recession				
EMD	0,62±0,77	2,00±1,41	1,38±1,66	p=0,002
Fisio	1,31±2,72	1,38±1,26	0,08±2,81	p=0,001
			n.s.	
Clinical attachment level				
EMD	8,15±1,14	5,85±1,28	2,31±1,32	p=0,016
Fisio	9,08±3,57	4,77±1,09	4,31±3,61	n.s.
			p=0,029	

Table 4. Clinical parameters at baseline and 6 months for the EMD (n=13) and the fisio surgery groups (n=13)
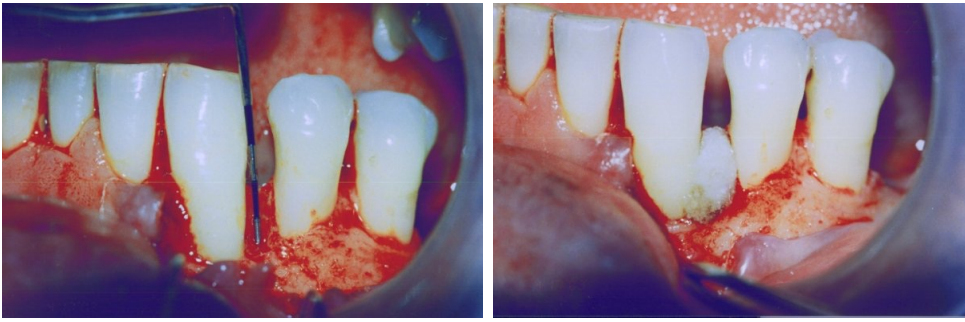
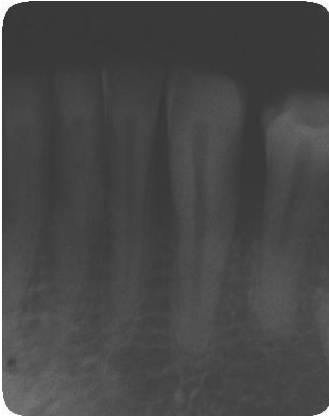Fig.1 Case A a) The bone defect exposed   Fig.1 Case A b) Fisiograft® in place

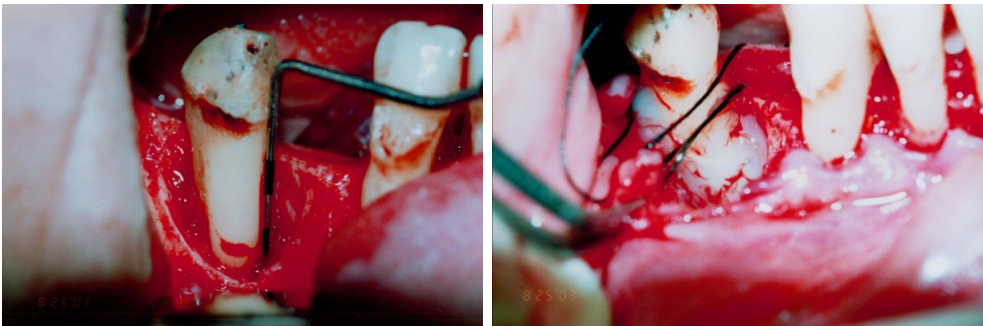Fig.1 Case A c) Rx image before treatment   Fig.1 Case A d) Rx image at six months

Fig.2 Case B a) The bone defect exposed   Fig.2 Case B b) Emdogain ® in place
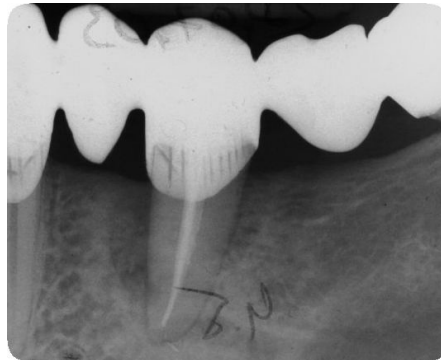

Fig.2 Case B c) Rx image before treatment   Fig.2 Case B d) Rx image at six months

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 in favor of Fisiograft® was observed. At six months, both therapies seemed to lead to significant improvements of the investigated clinical parameters.

Abbreviations

PLA-PGL: polylactide-polyglicolide
EMD: enamel-matrix-protein-derivative
PPD: probing pocket depth
CAL: clinical attachment level
GR: gingival recession
TE: tissue engineering
PlI: plaque index
GI: gingival index
BOP: bleeding on probing

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

Correspondence address:
Assist. Prof. Dr. Dr. Stefan-Ioan Stratul
Str.Em.Gojdu, no.5
300176 Timisoara
Romania

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

Stefan-Ioan Stratul* – Victor Babes University of Medicine and Pharmacy, Timisoara, Romania, Johannes Gutenberg University Mainz, Germany
Darian Rusu, Adrian Bacila – Periodontal Clinic Dr.Stratul, Timisoara, Romania
Anca Benta – Johannes Gutenberg University Mainz, Germany

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±2.57mm 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 (Buco et al.1999, Piatelli et al. 2000; Piatelli 2003; Seriso 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 off the PlI (Silness and Löe) <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 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. 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 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, except they were filled with Emdogain® gel. Post surgical care included antibiotherapy for one week (3x500 mg Amoxycillin daily) and 0.2% Chlorhexidin (Dentafon®, 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.

Contact the authors

Dr. Dr. Stefan-Ioan Stratul, DMD, PhD, MDiv, Medicus Primarius, ResAssoc (Johannes Gutenberg University of Mainz, Germany), Assist.Prof. (Victor Babes University of Medicine, Timisoara, Romania), sibs@online.ro

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). 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=12)

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.