

Non-surgical periodontal therapy using a novel chlorhexidine-based xanthan-gel: a split-mouth study

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Introduction

Topical subgingival antimicrobials have been successfully evaluated in split-mouth clinical trials (Stelzel & Flores-de-Jacoby 1992, Berglundh et al. 1998, Eickholz et al. 2002). The adjunctive use of antimicrobial agents to non-surgical therapy seems to provide additional effects. Existing antimicrobials do not maintain a sufficient subgingival concentration for a period longer than 24h. A mucoadhesive biodegradable xanthan-based gel containing a mixture of chlorhexidine digluconate and chlorhexidine dihydrochloride (ratio 1:2) combines the the rapid release action of the first with the long-lasting release of the latter.

Objectives

Aim of the present study was to evaluate the clinical effects of topical subgingival application of a new biodegradable xanthan-based chlorhexidine-gel adjunctive to initial periodontal therapy when compared with a regular chlorhexidine-gel in a controlled randomized split-mouth clinical study.

Material and Methods

Eight patients (four male and four female, aged between 28-52), light- or non-smokers, suffering of chronic periodontitis and displaying each periodontal pockets deeper than 5 mm underwent a periodontal examination at baseline and after four weeks. This included the assessment of PI, BOP, PD, and CAL. PD and CAL were recorded at six sites per tooth. A total of 188 teeth (1128 sites) were examined. The maximal values of PD and CAL per quadrant were taken into account in this study. Each patient received SRP during initial therapy according to the one-stage Full Mouth Disinfection (Quirinen, 1995). In addition, each quadrant of the same arch was assigned to randomly receive a single subgingival application of either a novel xanthane-based gel containing a mixture of chlorhexidine digluconate and chlorhexidine dihydrochloride (Chlosite®, Ghimas s.p.a., Casalecchio di Reno, Italy) or the chlorhexidine-gel PlakOut®, Santa Balanos, Greece). Chlosite® was delivered from a syringe with a thin rounded tip needle into the debrided periodontal pockets after careful drying of the latter. Subsequently, patients were advised to use 0,2% chlorhexidine mouthwashes (PlakOut®, Santa Balanos, Greece), twice a day, for the following four weeks, and OHI were reinforced. The Wilcoxon test was used to compare the differences between the baseline and four weeks after and for the differences between the groups.



Fig 1: Application of the xanthane-based chlorhexidine gel Chlosite® (Ghimas s.p.a., Italy)

Results

The healing phase progressed uneventful. No signs of inflammation, infection, allergy or severe pain were present. Pre- and post-treatment maximal values per quadrant of the PD, CAL, PI and BOP in the two treated groups are displayed in the table No.1 and table No.2., and the mean differences between the groups are presented in the table No.3.

Nr.	mean maximal PD/quadrant at baseline	mean maximal PD/quadrant at one month	Δ mean maximal PD/quadrant	mean maximal CAL/quadrant baseline	mean maximal CAL at one month	Δ mean maximal CAL	PI baseline	PI one month	Δ PI	BOP baseline (%)	BOP at one month (%)	Δ BOP (%)
1	9	6	3	9	6	3	.43	.15	0.28	34	15	19.00
2	12	4	8	12	4	8	1.00	1.13	-0.13	44	30	14.00
3	12	6	6	12	8	4	2.27	.08	2.19	42	24	18.00
4	8	6	2	8	6	2	.67	.85	-0.18	57	29	28.00
5	9	5	4	9	5	4	1.50	.00	1.50	94	18	76.00
6	8	2	6	8	9	-1	1.40	1.50	-0.10	63	15	48.00
7	5	3	2	5	5	0	.65	.43	0.22	84	8	75.70
8	8	7	1	9	7	2	.95	.48	0.47	66	57	9.00
MEAN ± SD	8.88 ± 2.30	4.88 ± 1.73	4.00 ± 2.45	9.00 ± 2.27	6.25 ± 1.67	2.75 ± 2.76	1.1 ± 0.59	0.57 ± 0.53	0.53 ± 0.86	60.50 ± 20.83	24.54 ± 15.08	35.96 ± 27.28
			p=0.012			p=0.027						

Tab. 1: One month clinical results of treatment of periodontal pockets with Chlosite®

Nr.	mean maximal PD/quadrant at baseline	mean maximal PD/quadrant at one month	Δ mean maximal PD/quadrant	mean maximal CAL/quadrant baseline	mean maximal CAL at one month	Δ mean maximal CAL	PI baseline	PI one month	Δ PI	BOP baseline (%)	BOP at one month (%)	Δ BOP (%)
1	10	6	4	10	7	3	0.43	0.15	0.28	34.00	15.00	19.00
2	10	7	3	10	7	3	1	1.13	-0.13	44.00	30.00	14.00
3	10	10	0	10	16	-6	2.27	0.08	2.19	42.00	24.00	18.00
4	7	7	0	7	7	0	0.67	0.85	-0.18	57.00	29.00	28.00
5	8	4	4	8	4	4	1.5	0	1.50	94.00	18.00	76.00
6	10	9	1	10	9	1	1.4	1.5	-0.10	63.00	15.00	48.00
7	6	3	3	6	3	3	0.65	0.43	0.22	84.00	8.30	75.70
8	10	6	4	10	6	4	0.95	0.48	0.47	66.00	57.00	9.00
MEAN ± SD	8.88 ± 1.64	6.50 ± 2.33	2.38 ± 1.77	8.88 ± 1.64	7.38 ± 3.96	1.50 ± 3.34	1.1 ± 0.59	0.57 ± 0.53	0.53 ± 0.86	60.50 ± 20.83	24.54 ± 15.08	35.96 ± 27.28
			p=0.026			p=0.233						

Tab. 2: One month clinical results of treatment of periodontal pockets with PlakOut®



Fig. 2 left: Probing reveals periodontal pockets



Fig. 2 right: Chlosite® in situ with marginal overflow



Fig 3: Split-mouth application of Chlosite® (left side of picture) and PlakOut® (right side of picture)

Both therapies resulted in significant improvements in all clinical indices. At four weeks after application, in the Chlosite group the mean PD changed from 8.88 ± 2.30 to 4.88 ± 1.73 ($p=0.012$) and the CAL changed from 9.00 ± 2.27 to 6.25 ± 1.67 ($p=0.027$), while in the PlakOut group the PD changed from 8.88 ± 1.64 to 6.50 ± 2.33 ($p=0.026$) and the CAL changed from 8.88 ± 1.64 to 7.38 ± 3.96 ($p=0.233$). The Chlosite group resulted in slightly higher CAL gains (mean D=1.25 mm) and PD reductions (mean D=1.62 mm) than the PlakOut group, but these differences were not statistically significant due to the low number of cases

Parameter	No. sites	Mean Δ Chlosite ®		Mean Δ PlakOut ®		Mean Δ between groups	p
		Mean	SD	Mean	SD		
PD	32	4.00	2.45	2.38	1.77	1.62	n.s.
CAL	32	2.75	2.76	1.50	3.34	1.25	n.s.

Tab. 3: One month clinical results of treatment of periodontal pockets with PlakOut®

Conclusion

Following both initial therapy approaches, there were marked clinical improvements at four weeks from baseline. Additional topical subgingival application of Chlosite is safe and provided more favorable CAL gain and PD reduction than PlakOut. The use of Chlosite® may further increase the non-surgical indication of treatment for periodontal patients.

Abbreviations

PD - probing depth
 CAL - clinical attachment level
 PI-plaque index (Silness, Loe, 1963)
 BOP-bleeding on probing

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Non-surgical Periodontal Therapy Using a Novel Chlorhexidine-based Xanthan-gel: a Split-mouth Study



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Fig. 3. Split-mouth application of Chlorhexidil (left) and PlacQuil (right).

ABSTRACT

Aim: This split-mouth randomized split-mouth study was to evaluate and compare the clinical effects of two chlorhexidine-based gels (novel xanthan-based gel and placebo) on the periodontium. Eight patients suffering of chronic periodontitis and displaying an interdental pocket depth between 5 and 8 mm were included in the study and after four weeks. The included parameters were: BOP, PD, and CAL. PD and CAL were measured at six sites (four 100 tooth were assessed). Maximal values of PD and CAL per quadrant were taken into account. Each patient received DRP during initial therapy according to the one-stage full-mouth approach (Chambers, 1998). In addition, each quadrant of the same tooth was assigned to randomly receive a single suboptimal application of either a novel chlorhexidine-based gel (Chlorhexidil, Gimes s.r.l., Italy) or the chlorhexidine gel PlacQuil (Sara Baines, GmbH). Subsequently, patients were referred to use 0.2% chlorhexidine mouthwashes (PlacQuil, Sara Baines, GmbH), twice a day, for the following four weeks. The Wilcoxon test was used to compare the differences between baseline and four weeks after and for the differences between groups.

Caioleazzo di Rano, Italy) on the chlorhexidine gel PlacQuil (Sara Baines, GmbH). Chlorhexidil was obtained from a single vial, 3.8 ml required to make up the chlorhexidine periodontal gels after cooling of the latter. Subsequently, patients were advised to use 0.2% chlorhexidine mouthwashes (PlacQuil, Sara Baines, GmbH), twice a day, for the following four weeks, and Chlorhexidil. The Wilcoxon test was used to compare the differences between the baseline and four weeks after and for the differences between groups.

Fig. 1. Application of the xanthan-based chlorhexidine gel Chlorhexidil (Gimes s.r.l., Italy)

Parameter	n	Chlorhexidil		PlacQuil		p
		Mean	SD	Mean	SD	
PD	10	2.75	2.76	1.90	3.34	<0.05
CAL	32	2.15	2.76	1.90	3.34	<0.05

RESULTS

The healing phase progressed uneventful. No signs of inflammation, infection, allergy or severe pain were observed. Pre- and post-treatment, interdental means per quadrant of the PD, CAL, BOP and BOP at six sites are displayed in the table No. 1 and table No. 2, and the mean differences between the groups are presented in the table No. 3.

Table 1. One month clinical results of treatment of periodontal pockets with Chlorhexidil

Parameter	n	Chlorhexidil		PlacQuil		p
		Mean	SD	Mean	SD	
PD	10	2.75	2.76	1.90	3.34	<0.05
CAL	32	2.15	2.76	1.90	3.34	<0.05

INTRODUCTION

Recent subgingival antimicrobials have been successfully evaluated in split-mouth clinical trials (Grossi & Finkelstein, 2002; Barchiesi et al., 1998; Eickhoff et al., 2002). The objectives of this study were to evaluate the clinical effects of a novel xanthan-based gel containing chlorhexidine and chlorhexidine glycol in a split-mouth study.

OBJECTIVE

The aim of the present study was to evaluate the clinical effects of topical suboptimal application of a novel xanthan-based chlorhexidine gel and placebo to initial periodontal therapy, when combined with a single chlorhexidine gel in a controlled randomized split-mouth clinical study.

MATERIALS AND METHODS

Eight patients four male and four female, aged between 50-70, light or non-smokers, suffering of chronic periodontitis and displaying each periodontal pockets deeper than 5 mm underwent a periodontal assessment at baseline and after four weeks. This included the assessment of BOP, BOP at six sites, PD and CAL. PD and CAL were measured at six sites per tooth. A total of 100 teeth (120 sites) were assessed. The maximal values of PD and CAL per quadrant were taken into account in this study.

Table 2. One month clinical results of treatment of periodontal pockets with PlacQuil

Parameter	n	PlacQuil		Chlorhexidil		p
		Mean	SD	Mean	SD	
PD	10	1.90	3.34	2.75	2.76	<0.05
CAL	32	1.90	3.34	2.15	2.76	<0.05

Both therapies resulted in significant improvements in all clinical indices. At four weeks after application, in the Chlorhexidil group the mean PD changed from 8.86(±2.34) to 6.86(±1.71) (p<0.02) and the CAL changed from 8.86(±2.34) to 6.86(±1.71) (p<0.02), while in the PlacQuil group the PD changed from 8.86(±2.34) to 6.86(±1.71) (p<0.02) and the CAL changed from 8.86(±2.34) to 6.86(±1.71) (p<0.02). The differences were not statistically significant due to the low number of teeth. Table 3.

CONCLUSIONS

Following split-mouth therapy approaches, there were marked clinical improvements of the results from baseline. Additional topical suboptimal application of Chlorhexidil in situ and previous novel xanthan-based chlorhexidine gel and PlacQuil. The use of Chlorhexidil may further increase the periodontal indication of treatment for periodontitis.

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