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Initial Periodontal Therapy Using a new Xanthan-based Chlorhexidine Gel - Chlosite

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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 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 for 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 mean overall 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., Italy) or the chlorhexidine-gel PlakOut®, Santa Balanos, Greece). Chlosite® was delivered 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.

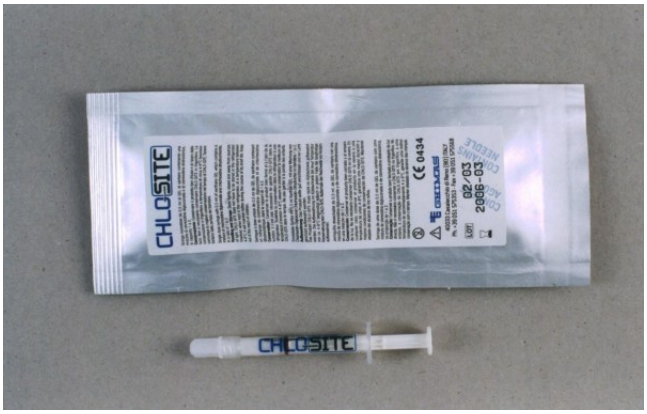

Fig. 1: The xanthane-based chlorhexidine gel Chlosite® (Ghimas s.p.a., Italy)

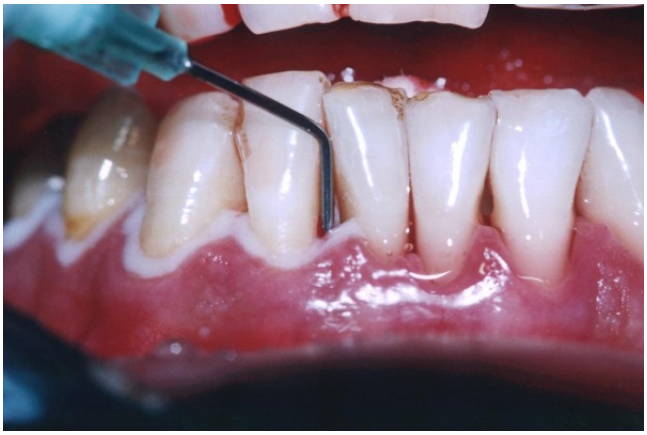

Fig. 2: Topical instillation of Chlosite® with marginal overflow

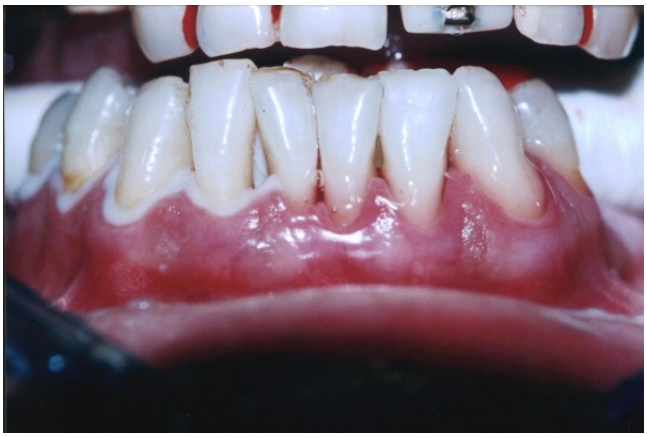

Fig. 3: Split-mouth application of Chlosite® and PlakOut®

Results

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

Nr.	mean overall PD baseline	mean overall PD at one month	Δ mean overall PD	mean overall CAL baseline	mean overall CAL at one month	Δ mean overall CAL	PI baseline	PI one month	D PI	BOP baseline (%)	BOP at one month (%)	D BOP (%)
1	2,66	1,95	0,71	2,66	2,00	0,66	0,43	0,15	0,28	34,00	15,00	19,00
2	5,07	3,69	1,38	5,07	3,69	1,38	1	1,13	-0,13	44,00	30,00	14,00
3	4,45	2,83	1,62	4,45	5,19	-0,74	2,27	0,08	2,19	42,00	24,00	18,00
4	2,98	2,65	0,33	2,98	2,67	0,31	0,67	0,85	-0,18	57,00	29,00	28,00
5	4,30	2,41	1,89	4,3	2,48	1,82	1,5	0	1,50	94,00	18,00	76,00
6	4,87	3,5	1,37	5,66	4,87	0,79	1,4	1,5	-0,10	63,00	15,00	48,00
7	3,12	1,93	1,19	3,12	2,04	1,08	0,65	0,43	0,22	84,00	8,30	75,70
8	4,33	3,53	0,80	4,89	4,03	0,86	0,95	0,48	0,47	66,00	57,00	9,00
MEAN ± SD	3.97 ± 0.91	2.81 ± 0.70	1.16 ± 0.51	4.14 ± 1.09	3.37 ± 1.25	0.77 ± 0.76	1.1 ± 0.59	0.57 ± 0.53	0.53 ± 0.86	60.50 ± 20.83	27.60 ± 15.08	35.96 ± 27.28

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

Nr.	mean overall PD baseline	mean overall PD at one month	Δ mean overall PD	mean overall CAL baseline	mean overall CAL at one month	Δ mean overall CAL	PI baseline	PI one month	D PI	BOP baseline (%)	BOP at one month (%)	D BOP (%)
1	3,31	2,83	0,48	3,31	2,98	0,33	0,43	0,15	0,28	34,00	15,00	19,00
2	4,63	3,51	1,12	4,63	3,51	1,12	1	1,13	-0,13	44,00	30,00	14,00
3	3,36	2,44	0,92	3,36	4,55	-1,19	2,27	0,08	2,19	42,00	24,00	18,00
4	2,96	2,67	0,29	2,96	2,83	0,13	0,67	0,85	-0,18	57,00	29,00	28,00
5	4,13	2,65	1,48	4,13	2,70	1,43	1,5	0	1,50	94,00	18,00	76,00
6	4,76	3,01	1,75	5,43	4,70	0,73	1,4	1,5	-0,10	63,00	15,00	48,00
7	3,16	1,81	1,35	3,16	1,85	1,31	0,65	0,43	0,22	84,00	8,30	75,70
8	4,80	3,33	1,47	5,18	4,31	0,87	0,95	0,48	0,47	66,00	57,00	9,00
MEAN ± SD	3.88 ± 0.77	2.78 ± 0.53	1.10 ± 0.51	4.02 ± 0.96	3.42 ± 1.01	0.59 ± 0.84	1.1 ± 0.59	0.57 ± 0.53	0.53 ± 0.86	60.50 ± 20.83	27.60 ± 15.08	35.96 ± 27.28

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

Both therapies resulted in significant improvements in all clinical indices. At four weeks after application, in the Chlosite group the mean PD changed from 3.97±0.91 to 2.81±0.70 (p=0.012) and the CAL changed from 4.14±1.09 to 3.37±1.25 (p=0.03), while in the PlakOut group the PD changed from 3.88±0.77 to 2.78±0.53 (p=0.01) and the CAL changed from 4.02±0.96 to 3.42±1.01 (p=0.09). The Chlosite group resulted in slightly higher CAL gains (mean D=1.62 mm) and PD reductions (mean D=0.18 mm) than the PlakOut group, but these differences were not statistically significant due to the low number of cases

Parameter	Nr. sites	Mean Chlosite®		Mean PlakOut®		Mean Δ	p
		Mean	SD	Mean	SD		
PD	1128	1.16	0.51	1.10	0.51	0.06	ns
CAL	1128	0.77	0.76	0.59	0.84	0.18	ns

Tab. 3

Conclusion

Following both initial therapy approaches, there were 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 - bleedind on probing

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Poster Faksimile:

INITIAL PERIODONTAL THERAPY USING A NEW XANTHAN-BASED CHLORHEXIDINE GEL - ChloSite®

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ABSTRACT

Objectives: *the aim of this pilot randomized split-mouth study was to evaluate and compare the clinical effects of two chlorhexidine-based gels delivered into periodontal pockets during initial periodontal therapy.* **Methods**: *Eight patients (four male and for female) 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 were examined. The mean overall 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 (Quirynen, 1995). In addition, each quadrant of the same arch was assigned to randomly receive a single subgingival application of either a novel chlorhexidine-based gel (Chlosite®, Ghimas s.p.a., Italy) or the chlorhexidine-gel PlakOut® (Santa Balanos, Greece). 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.* **Results**: *Both therapies resulted in significant improvements in all clinical indices. At four weeks after application, in the Chlosite group the mean PD changed from 3.97±0.91 to 2.81±0.70 (p<0.012) and the CAL changed from 4.14±1.09 to 3.37±1.25 (p<0.03); while in the PlakOut group the PD changed from 3.88±0.77 to 2.78±0.53 (p<0.01) and the CAL changed from 4.02±0.96 to 3.42±1.01 (p<0.09). The Chlosite group resulted in slightly higher CAL gains (mean Δ=0.06 mm) and PD reductions (mean Δ=0.18 mm) than the PlakOut group, but these differences were not statistically significant due to the low number of cases.* **Conclusions**: *Following both initial therapy approaches, there were 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.*

INTRODUCTION

Topical subgingival antimicrobials have been successfully evaluated in split-mouth clinical trials (Stelzel & Flores-de-Jacoby 1992, Berglundh et al. 1996, 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 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.

OBJECTIVE

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 to a regular chlorhexidine gel in a controlled randomized split-mouth clinical study.

MATERIALS AND METHODS

Eight patients (four male and for 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 mean overall 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 (Quirynen, 1995). In addition, each quadrant of the same arch was assigned to randomly receive a single subgingival application of either a novel xanthan-based gel containing a mixture of chlorhexidine digluconate and chlorhexidine dihydrochloride (Chlosite®, Ghimas s.p.a., Italy) or the chlorhexidine-gel PlakOut® (Santa Balanos, Greece). Chlosite® was delivered into the debrided periodontal pockets after careful removal of the granulation tissue. 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 The xanthan-based chlorhexidine gel Chlosite® (Ghimas s.p.a., Italy)

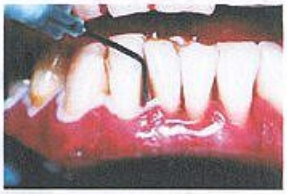

Fig.2 Topical instillation of Chlosite® with marginal overflow

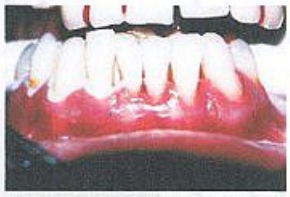

Fig.3 Split-mouth application of Chlosite® (left) and PlakOut® (right)

RESULTS

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

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

Nr	mean overall PD baseline	mean overall PD at one month	Δ mean overall PD	mean overall CAL baseline	mean overall CAL at one month	Δ mean overall CAL	PI baseline	PI one month	Δ PI	BOP baseline (%)	BOP at one month (%)	Δ BOP (%)
1	2.64	1.95	0.71	2.88	3.00	0.66	0.43	0.15	0.28	54.00	15.00	19.00
2	5.07	3.69	1.38	5.07	3.69	1.38	1	1.13	-0.13	44.00	30.00	14.00
3	4.45	2.83	1.62	4.45	5.19	-0.74	2.27	0.08	2.19	42.00	24.00	18.00
4	2.98	2.65	0.33	2.98	2.67	0.31	0.67	0.85	-0.18	57.00	29.00	28.00
5	4.30	2.41	1.89	4.3	2.48	1.82	1.5	0	1.50	94.00	18.00	76.00
6	4.87	3.5	1.37	5.86	4.67	0.79	1.4	1.5	-0.10	63.00	15.00	48.00
7	3.12	1.93	1.19	3.12	2.04	1.08	0.65	0.43	0.22	84.00	8.30	75.70
8	4.33	3.53	0.80	4.89	4.03	0.86	0.95	0.48	0.47	66.00	57.00	9.00
MEAN ± SD	3.97 ± 0.91	2.81 ± 0.70	1.16 ± 0.51	4.14 ± 1.09	3.37 ± 1.25	0.77 ± 0.76	1.1 ± 0.59	0.57 ± 0.53	0.53 ± 0.66	60.50 ± 20.63	27.00 ± 15.08	35.96 ± 27.28

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

Nr	mean overall PD baseline	mean overall PD at one month	Δ mean overall PD	mean overall CAL baseline	mean overall CAL at one month	Δ mean overall CAL	PI baseline	PI one month	Δ PI	BOP baseline (%)	BOP at one month (%)	Δ BOP (%)
1	3.31	2.63	0.68	3.31	2.98	0.33	0.43	0.15	0.28	54.00	15.00	19.00
2	4.63	3.51	1.12	4.63	3.51	1.12	1	1.13	-0.13	44.00	30.00	14.00
3	3.36	2.44	0.92	3.36	4.55	-1.19	2.27	0.08	2.19	42.00	24.00	18.00
4	2.90	2.61	0.29	2.90	2.63	0.13	0.67	0.85	-0.18	57.00	29.00	28.00
5	4.13	2.65	1.48	4.13	2.70	1.43	1.5	0	1.50	94.00	18.00	76.00
6	4.76	3.01	1.75	5.43	4.70	0.73	1.4	1.5	-0.10	63.00	15.00	48.00
7	3.16	1.81	1.35	3.16	1.85	1.31	0.65	0.43	0.22	84.00	8.30	75.70
8	4.50	3.33	1.17	5.18	4.31	0.87	0.95	0.48	0.47	66.00	57.00	9.00
MEAN ± SD	3.84 ± 0.77	2.78 ± 0.52	1.10 ± 0.51	4.02 ± 0.96	3.42 ± 1.01	0.59 ± 0.64	1.1 ± 0.59	0.57 ± 0.53	0.53 ± 0.66	60.50 ± 20.63	27.00 ± 15.08	35.96 ± 27.28

Both therapies resulted in significant improvements in all clinical indices. At four weeks after application, in the Chlosite group the mean PD changed from 3.97±0.91 to 2.81±0.70 (p<0.012) and the CAL changed from 4.14±1.09 to 3.37±1.25 (p<0.03); while in the PlakOut group the PD changed from 3.88±0.77 to 2.78±0.53 (p<0.01) and the CAL changed from 4.02±0.96 to 3.42±1.01 (p<0.09). The Chlosite group resulted in slightly higher CAL gains (mean Δ=1.62 mm) and PD reductions (mean Δ=0.18 mm) than the PlakOut group, but these differences were not statistically significant due to the low number of cases.

Table 3

Parameter	No. sites	Chlosite® Mean SD	PlakOut® Mean SD	Mean Δ	p
PD	1128	1.16 0.51	1.10 0.51	0.06	ns
CAL	1128	0.77 0.76	0.59 0.64	0.18	ns

CONCLUSIONS

Following both initial therapy approaches, there were 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.

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