

Periodontal Non-surgical Therapy with the Chlorhexidine Xanthan-based Gel Chlosite®: a Randomized Split-mouth Study on 51 Cases.

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Authors:

Dr. Alin Dinca,
 Dr. Mirona Mesaros,
 Assist. Prof. Dr. Darian Rusu,
 Dr. Anca Benta,
 Assist. Prof. Dr. Dan Onisei,
 Assist. Prof. Dr. Dr. Stefan Ioan Stratul,
 Department of Periodontology, Victor Babes University of Medicine and Pharmacy, Timisoara, Romania

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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

Fifty-one patients (32 male and 19 female, aged between 29-56), light- or non-smokers, suffering of chronic or aggressive 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. The maximal values of PD and CAL per quadrant and the mean overall values of PD and CAL 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 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 (Dentaton®, Ghimas s.p.a., Casalecchio di Reno, Italy) 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) applied with marginal overflow



Fig.2 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 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, pre- and post-treatment mean overall values are displayed in the tables No.3 and No.4, and the mean differences between the groups are presented in the tables No.5 and No.6.

Table 1. One month clinical results of treatment of periodontal pockets with Chlosite® (maximal values/quadrant)

Nr.	PD maximal/ quadrant initial	PD maximal/ quadrant at one month	Δ maximal/ quadrant at one month	CAL maximal/ quadrant initial	CAL maximal/ quadrant at one month	Δ maximal/ quadrant	PI initial	BOP initial	PI at one month	BOP at one month	Δ PI	Δ BOP
1	9	6	3	9	6	3	0,43	34	0,15	15	0,28	19

2	12	4	8	12	4	8	0,13	54	0,17	38	-0,04	16
3	12	6	6	12	8	4	0,39	34	0,26	32	0,13	2
4	8	6	2	8	6	2	0,58	77,7	0,45	27,7	0,13	50
5	9	5	4	9	5	4	0,66	57	0,2	40	0,46	17
6	8	2	6	8	9	-1	1,4	63	1,5	15	-0,1	48
7	5	3	2	5	5	0	0,67	57	0,85	29	-0,18	28
8	8	7	1	9	7	2	0,95	66	0,48	57	0,47	9
9	9	5	4	9	5	4	0,9	84	0,43	8,3	0,47	75,7
10	7	3	4	10	7	3	1,23	75	0,35	15	0,88	60
11	8	6	2	8	6	2	0,39	29,16	0,2	16	0,19	13,16
12	7	5	2	7	5	2	0,26	62	0	25	0,26	37
13	12	7	5	13	10	3	1	44	1,13	30	-0,13	14
14	6	4	2	6	5	1	1,24	75	0,44	52	0,8	23
15	12	6	6	12	6	6	0,31	50	0	32	0,31	18
16	10	8	2	10	8	2	0,38	60	0,04	20	0,34	40
17	5	1	4	5	1	4	0,6	71	0,27	48	0,33	23
18	8	5	3	8	5	3	1,38	14	0,93	29,6	0,45	-15,6
19	8	5	3	8	8	3	0,2	11	1,18	2	-0,98	9
20	11	8	4	13	12	1	0,44	52	0,64	20	-0,2	32
21	10	6	4	10	6	4	0,13	52	0,5	37	-0,37	15
22	15	6	9	18	8	10	0,5	59,1	0,4	14,2	0,1	44,9
23	7	3	4	7	3	4	0,62	16	0,66	21	-0,04	-5
24	9	3	6	11	6	5	0,5	52	0,14	40	0,36	12
25	6	4	2	7	7	0	1,44	80	0,05	24	1,39	56
26	10	6	4	10	6	4	0,8	70	0,88	12	-0,08	58
27	9	6	3	9	6	3	1,31	60	0,3	20	1,01	40
28	6	5	1	6	5	1	0,16	71	0,15	37,7	0,01	33,3
29	10	7	3	10	9	1	0,16	54,1	0,16	56	0	-1,9
30	13	4	9	13	4	9	0,95	66	0,43	53	0,52	13
31	6	4	2	6	4	2	0,58	59	1,2	37,5	-0,62	21,5
32	11	4	7	11	4	7	0,5	55	0,07	45	0,43	10
33	8	6	2	8	6	2	0,7	37	0,15	40	0,55	-3
34	11	7	4	15	12	3	1,31	90	0,36	47	0,95	43
35	7	6	1	7	6	1	1,2	57	0,8	17,7	0,4	39,3
36	9	3	6	9	5	4	0,34	78	0	38	0,34	40
37	7	2	5	9	6	3	2,27	42	0,08	24	2,19	18
38	7	6	1	9	9	0	0,56	72	0,5	66	0,06	6
39	7	5	2	7	6	1	0,44	43	0,44	42	0	1
40	11	10	1	11	10	1	0,15	30	0,03	30	0,12	0
41	9	7	2	11	8	3	0,75	31	0,24	44	0,51	-13
42	12	9	3	12	9	3	0,6	67	0,43	36	0,17	31
43	11	6	5	11	6	5	0,29	70	0,34	37	-0,05	33
44	12	4	8	12	4	8	0,9	27	0,61	42	0,29	-15
45	11	7	4	13	9	4	0,28	20	0,78	22	-0,5	-2
46	9	7	2	9	7	2	1,5	94	0	18	1,5	76
47	7	3	4	9	7	2	1,05	75	0,45	36	0,6	39
48	6	3	3	7	5	2	0,28	47	0,36	42	-0,08	5
49	9	8	1	9	8	1	1,13	41,6	0,86	50	0,27	-8,4
50	7	6	1	9	8	1	0,44	57	0,29	32	0,15	25
51	8	3	5	8	5	3	0,65	31	0,48	21	0,17	10

Mean \pm SD 8,90 \pm 2,26 5,25 \pm 1,90 3,67 \pm 2,13 9,49 \pm 2,56 6,51 \pm 2,16 3,04 \pm 2,31 0,71 \pm 0,45 54,39 \pm 19,91 0,43 \pm 0,35 32,03 \pm 13,94 0,28 \pm 0,52 22,35 \pm 22,26

p<0,0001

p<0,0001

Table 2. One month clinical results of treatment of periodontal pockets with PlakOut® (maximal values/quadrant)

Nr.	PD maximal/ quadrant initial	PD maximal/ quadrant initial	Δ maximal PD/ quadrant	CAL maximal/ quadrant initial	CAL maximal at one month	Δ maximal CAL	PI initial	BOP initial	PI at one month	BOP at one month	Δ PI	Δ BOP
1	10	6	4	10	7	3	0,43	34	0,15	15	0,28	19
2	10	7	3	10	7	3	0,13	54	0,17	38	-0,04	16
3	10	10	0	10	16	-6	0,39	34	0,26	32	0,13	2
4	7	7	0	7	7	0	0,58	77,7	0,45	27,7	0,13	50
5	8	4	4	8	4	4	0,66	57	0,2	40	0,46	17
6	10	9	1	10	9	1	1,4	63	1,5	15	-0,1	48

7	6	3	3	6	3	3	0,67	57	0,85	29	-0,18	28
8	10	6	4	10	6	4	0,95	66	0,48	57	0,47	9
9	9	6	3	9	6	3	0,9	84	0,43	8,3	0,47	75,7
10	9	6	3	9	6	3	1,23	75	0,35	15	0,88	60
11	9	7	2	9	7	2	0,39	29,16	0,2	16	0,19	13,16
12	7	6	1	7	6	1	0,26	62	0	25	0,26	37
13	13	9	4	14	13	1	1	44	1,13	30	-0,13	14
14	7	5	2	8	6	2	1,24	75	0,44	52	0,8	23
15	11	8	3	11	8	3	0,31	50	0	32	0,31	18
16	9	4	5	9	8	1	0,38	60	0,04	20	0,34	40
17	5	3	2	5	3	2	0,6	71	0,27	48	0,33	23
18	8	2	6	8	2	6	1,38	14	0,93	29,6	0,45	-15,6
19	7	5	2	10	9	1	0,2	11	1,18	2	-0,98	9
20	7	4	3	9	6	3	0,44	52	0,64	20	-0,2	32
21	9	5	4	9	5	4	0,13	52	0,5	37	-0,37	15
22	14	11	3	14	13	1	0,5	59,1	0,4	14,2	0,1	44,9
23	12	12	0	15	15	0	0,62	16	0,66	21	-0,04	-5
24	12	4	8	14	6	8	0,5	52	0,14	40	0,36	12
25	5	3	2	5	3	2	1,44	80	0,05	24	1,39	56
26	9	7	2	11	7	4	0,8	70	0,88	12	-0,08	58
27	7	5	2	7	5	2	1,31	60	0,3	20	1,01	40
28	7	3	4	7	3	4	0,16	71	0,15	37,7	0,01	33,3
29	7	5	2	7	7	0	0,16	54,1	0,16	56	0	-1,9
30	14	7	7	14	7	7	0,95	66	0,43	53	0,52	13
31	8	7	1	8	7	1	0,58	59	1,2	37,5	-0,62	21,5
32	11	11	0	11	11	0	0,5	55	0,07	45	0,43	10
33	12	7	5	12	10	2	0,7	37	0,15	40	0,55	-3
34	13	6	7	13	8	5	1,31	90	0,36	47	0,95	43
35	6	3	3	8	7	1	1,2	57	0,8	17,7	0,4	39,3
36	8	6	2	8	6	2	0,34	78	0	38	0,34	40
37	8	4	4	9	5	4	2,27	42	0,08	24	2,19	18
38	8	6	2	8	8	0	0,56	72	0,5	66	0,06	6
39	9	3	6	9	3	6	0,44	43	0,44	42	0	1
40	9	9	0	9	9	0	0,15	30	0,03	30	0,12	0
41	14	9	5	15	15	0	0,75	31	0,24	44	0,51	-13
42	11	9	2	11	9	2	0,6	67	0,43	36	0,17	31
43	12	9	3	14	13	1	0,29	70	0,34	37	-0,05	33
44	9	7	2	9	7	2	0,9	27	0,61	42	0,29	-15
45	8	6	2	8	8	0	0,28	20	0,78	22	-0,5	-2
46	8	7	1	11	10	1	1,5	94	0	18	1,5	76
47	7	4	3	9	7	2	1,05	75	0,45	36	0,6	39
48	7	4	3	7	4	3	0,28	47	0,36	42	-0,08	5
49	9	3	6	9	3	6	1,13	41,6	0,86	50	0,27	-8,4
50	6	4	2	8	6	2	0,44	57	0,29	32	0,15	25
51	8	4	4	8	6	2	0,65	31	0,48	21	0,17	10

Mean \pm SD 9,00 \pm 2,32 6,02 \pm 2,40 2,98 \pm 1,89 9,53 \pm 2,48 7,29 \pm 3,25 2,24 \pm 2,25 0,71 \pm 0,45 54,39 \pm 19,91 0,43 \pm 0,35 32,03 \pm 13,94 0,28 \pm 0,52 22,35 \pm 22,26
p<0,0001 p<0,0001

Table 3. One month clinical results of treatment of periodontal pockets with Chlosite® (mean overall values)

Nr.	PD maximal/ quadrant initial	PD maximal/ quadrant initial	Δ maximal PD/ quadrant	CAL maximal/ quadrant initial	CAL maximal at one month	Δ maximal CAL	PI initial	BOP initial	PI at one month	BOP at one month	ΔPI	ΔBOP
1	9	6	3	9	6	3	0,43	34	0,15	15	0,28	19
2	12	4	8	12	4	8	0,13	54	0,17	38	-0,04	16
3	12	6	6	12	8	4	0,39	34	0,26	32	0,13	2
4	8	6	2	8	6	2	0,58	77,7	0,45	27,7	0,13	50
5	9	5	4	9	5	4	0,66	57	0,2	40	0,46	17
6	8	2	6	8	9	-1	1,4	63	1,5	15	-0,1	48
7	5	3	2	5	5	0	0,67	57	0,85	29	-0,18	28
8	8	7	1	9	7	2	0,95	66	0,48	57	0,47	9
9	9	5	4	9	5	4	0,9	84	0,43	8,3	0,47	75,7
10	7	3	4	10	7	3	1,23	75	0,35	15	0,88	60
11	8	6	2	8	6	2	0,39	29,16	0,2	16	0,19	13,16

12	7	5	2	7	5	2	0,26	62	0	25	0,26	37
13	12	7	5	13	10	3	1	44	1,13	30	-0,13	14
14	6	4	2	6	5	1	1,24	75	0,44	52	0,8	23
15	12	6	6	12	6	6	0,31	50	0	32	0,31	18
16	10	8	2	10	8	2	0,38	60	0,04	20	0,34	40
17	5	1	4	5	1	4	0,6	71	0,27	48	0,33	23
18	8	5	3	8	5	3	1,38	14	0,93	29,6	0,45	-15,6
19	8	5	3	8	8	3	0,2	11	1,18	2	-0,98	9
20	11	8	4	13	12	1	0,44	52	0,64	20	-0,2	32
21	10	6	4	10	6	4	0,13	52	0,5	37	-0,37	15
22	15	6	9	18	8	10	0,5	59,1	0,4	14,2	0,1	44,9
23	7	3	4	7	3	4	0,62	16	0,66	21	-0,04	-5
24	9	3	6	11	6	5	0,5	52	0,14	40	0,36	12
25	6	4	2	7	7	0	1,44	80	0,05	24	1,39	56
26	10	6	4	10	6	4	0,8	70	0,88	12	-0,08	58
27	9	6	3	9	6	3	1,31	60	0,3	20	1,01	40
28	6	5	1	6	5	1	0,16	71	0,15	37,7	0,01	33,3
29	10	7	3	10	9	1	0,16	54,1	0,16	56	0	-1,9
30	13	4	9	13	4	9	0,95	66	0,43	53	0,52	13
31	6	4	2	6	4	2	0,58	59	1,2	37,5	-0,62	21,5
32	11	4	7	11	4	7	0,5	55	0,07	45	0,43	10
33	8	6	2	8	6	2	0,7	37	0,15	40	0,55	-3
34	11	7	4	15	12	3	1,31	90	0,36	47	0,95	43
35	7	6	1	7	6	1	1,2	57	0,8	17,7	0,4	39,3
36	9	3	6	9	5	4	0,34	78	0	38	0,34	40
37	7	2	5	9	6	3	2,27	42	0,08	24	2,19	18
38	7	6	1	9	9	0	0,56	72	0,5	66	0,06	6
39	7	5	2	7	6	1	0,44	43	0,44	42	0	1
40	11	10	1	11	10	1	0,15	30	0,03	30	0,12	0
41	9	7	2	11	8	3	0,75	31	0,24	44	0,51	-13
42	12	9	3	12	9	3	0,6	67	0,43	36	0,17	31
43	11	6	5	11	6	5	0,29	70	0,34	37	-0,05	33
44	12	4	8	12	4	8	0,9	27	0,61	42	0,29	-15
45	11	7	4	13	9	4	0,28	20	0,78	22	-0,5	-2
46	9	7	2	9	7	2	1,5	94	0	18	1,5	76
47	7	3	4	9	7	2	1,05	75	0,45	36	0,6	39
48	6	3	3	7	5	2	0,28	47	0,36	42	-0,08	5
49	9	8	1	9	8	1	1,13	41,6	0,86	50	0,27	-8,4
50	7	6	1	9	8	1	0,44	57	0,29	32	0,15	25
51	8	3	5	8	5	3	0,65	31	0,48	21	0,17	10

Mean \pm SD 8,90 \pm 2,26 5,25 \pm 1,90 3,67 \pm 2,13 9,49 \pm 2,56 6,51 \pm 2,16 3,04 \pm 2,31 0,71 \pm 0,45 54,39 \pm 19,91 0,43 \pm 0,35 32,03 \pm 13,94 0,28 \pm 0,52 22,35 \pm 22,26

p<0,0001

p<0,0001

Δ maximal CAL

Table 4. One month clinical results of treatment of periodontal pockets with PlakOut® (mean overall values)

Nr.	PD maximal/ quadrant initial	PD maximal/ quadrant at one month	Δ maximal PD/ quadrant	CAL maximal/ quadrant initial	CAL maximal at one month	PI initial	BOP initial	PI at one month	BOP at one month	Δ PI	Δ BOP	
1	10	6	4	10	7	3	0,43	34	0,15	15	0,28	19
2	10	7	3	10	7	3	0,13	54	0,17	38	-0,04	16
3	10	10	0	10	16	-6	0,39	34	0,26	32	0,13	2
4	7	7	0	7	7	0	0,58	77,7	0,45	27,7	0,13	50
5	8	4	4	8	4	4	0,66	57	0,2	40	0,46	17
6	10	9	1	10	9	1	1,4	63	1,5	15	-0,1	48
7	6	3	3	6	3	3	0,67	57	0,85	29	-0,18	28
8	10	6	4	10	6	4	0,95	66	0,48	57	0,47	9
9	9	6	3	9	6	3	0,9	84	0,43	8,3	0,47	75,7
10	9	6	3	9	6	3	1,23	75	0,35	15	0,88	60
11	9	7	2	9	7	2	0,39	29,16	0,2	16	0,19	13,16
12	7	6	1	7	6	1	0,26	62	0	25	0,26	37
13	13	9	4	14	13	1	1	44	1,13	30	-0,13	14
14	7	5	2	8	6	2	1,24	75	0,44	52	0,8	23
15	11	8	3	11	8	3	0,31	50	0	32	0,31	18
16	9	4	5	9	8	1	0,38	60	0,04	20	0,34	40

17	5	3	2	5	3	2	0,6	71	0,27	48	0,33	23
18	8	2	6	8	2	6	1,38	14	0,93	29,6	0,45	-15,6
19	7	5	2	10	9	1	0,2	11	1,18	2	-0,98	9
20	7	4	3	9	6	3	0,44	52	0,64	20	-0,2	32
21	9	5	4	9	5	4	0,13	52	0,5	37	-0,37	15
22	14	11	3	14	13	1	0,5	59,1	0,4	14,2	0,1	44,9
23	12	12	0	15	15	0	0,62	16	0,66	21	-0,04	-5
24	12	4	8	14	6	8	0,5	52	0,14	40	0,36	12
25	5	3	2	5	3	2	1,44	80	0,05	24	1,39	56
26	9	7	2	11	7	4	0,8	70	0,88	12	-0,08	58
27	7	5	2	7	5	2	1,31	60	0,3	20	1,01	40
28	7	3	4	7	3	4	0,16	71	0,15	37,7	0,01	33,3
29	7	5	2	7	7	0	0,16	54,1	0,16	56	0	-1,9
30	14	7	7	14	7	7	0,95	66	0,43	53	0,52	13
31	8	7	1	8	7	1	0,58	59	1,2	37,5	-0,62	21,5
32	11	11	0	11	11	0	0,5	55	0,07	45	0,43	10
33	12	7	5	12	10	2	0,7	37	0,15	40	0,55	-3
34	13	6	7	13	8	5	1,31	90	0,36	47	0,95	43
35	6	3	3	8	7	1	1,2	57	0,8	17,7	0,4	39,3
36	8	6	2	8	6	2	0,34	78	0	38	0,34	40
37	8	4	4	9	5	4	2,27	42	0,08	24	2,19	18
38	8	6	2	8	8	0	0,56	72	0,5	66	0,06	6
39	9	3	6	9	3	6	0,44	43	0,44	42	0	1
40	9	9	0	9	9	0	0,15	30	0,03	30	0,12	0
41	14	9	5	15	15	0	0,75	31	0,24	44	0,51	-13
42	11	9	2	11	9	2	0,6	67	0,43	36	0,17	31
43	12	9	3	14	13	1	0,29	70	0,34	37	-0,05	33
44	9	7	2	9	7	2	0,9	27	0,61	42	0,29	-15
45	8	6	2	8	8	0	0,28	20	0,78	22	-0,5	-2
46	8	7	1	11	10	1	1,5	94	0	18	1,5	76
47	7	4	3	9	7	2	1,05	75	0,45	36	0,6	39
48	7	4	3	7	4	3	0,28	47	0,36	42	-0,08	5
49	9	3	6	9	3	6	1,13	41,6	0,86	50	0,27	-8,4
50	6	4	2	8	6	2	0,44	57	0,29	32	0,15	25
51	8	4	4	8	6	2	0,65	31	0,48	21	0,17	10
Mean ± SD	9,00±2,32	6,02±2,40	2,98±1,89	9,53±2,48	7,29±3,25	2,24±2,25	0,71±0,45	54,39±19,91	0,43±0,35	32,03±13,94	0,28±0,52	22,35±22,26
			p<0,0001				p<0,0001					

Table 5. Mean differences between the treatment groups in the maximal/quadrant values study

Parameter	Nr. sites	Mean Δ Chlosite®		Mean Δ PlakOut®		Mean Δ between groups	p
		Mean	SD	Mean	SD		
PD		3,67	2,13	2,98	1,89	0,69	0,141
CAL		3,04	2,31	2,24	2,25	0,80	0,096

Table 6. Mean differences between the treatment groups in the mean overall values study

Parameter	Nr. sites	Mean Δ Chlosite®		Mean Δ PlakOut®		Mean Δ between groups	p
		Mean	SD	Mean	SD		
PD	501	1,17	0,75	1,06	0,50	0,11	ns
CAL	501	0,92	0,72	0,80	0,55	0,12	ns

Conclusions

Following both approaches, there were significant clinical improvements. Additional single-topical subgingival-application of Chlosite® was safe, providing more favorable CAL gains and PD reductions than PlakOut®.

Abbreviations

PI - plaque index
 BOP - bleeding on probing
 PD - pocket depth
 CAL - clinical attachment level
 CHX - Chlorhexidine

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

Correspondence address:

Assist. Prof. Dr. Dr. Stefan Ioan Stratul
 Victor Babes Medical University of Timisoara
 Str. Em. Gojdu, no.5
 300176 Timisoara
 Romania.

Periodontal Non-surgical Therapy with the Chlorhexidine Xanthan-based Gel Chlosite®: a Randomized Split-mouth Study on 51 Cases.

Alin Dinca, Mirona Mesaros, Dariian Rusu, Anca Benta – Dental Clinic Dr.Stratul, Timisoara, Romania
 Stefan-Ioan Stratul*, Dan Onisei – Department of Periodontology, Victor Babes University of Medicine and Pharmacy, Timisoara, Romania



ABSTRACT

Objective: aim of study is compare effects of two chlorhexidine-gels (applied into periodontal pockets) in fully healed periodontal therapy.
Methods: Fifty-one patients (33 males and 18 females, aged between 20-65), light or non-smokers, suffering of chronic or aggressive periodontitis and being treated successfully with periodontal therapy (scaling and root planing) 2-3 times and additional application of chlorhexidine gel (Chlosite) for 14 days. After 4 weeks, in the "test" values (baseline) data group of Chlosite treatment group (mean±SD) changed from 7.00±2.79 to 5.73±2.03 (p<0.001); CAL changed from 3.00±0.69 to 2.34±0.42 (p<0.001) while in the Placebo group (mean±SD) from 7.00±2.79 to 6.74±2.03 (p=0.05); CAL changed from 3.00±0.69 to 2.94±0.42 (p=0.05). In the "test" values (baseline) data group of Chlosite treatment group (mean±SD) changed from 4.83±1.53 to 4.15±1.23 (p<0.001) while in the Placebo group (mean±SD) from 4.83±1.53 to 4.68±1.23 (p=0.05). In the "test" values (baseline) data group of Chlosite treatment group (mean±SD) changed from 4.83±1.53 to 4.15±1.23 (p<0.001) while in the Placebo group (mean±SD) from 4.83±1.53 to 4.68±1.23 (p=0.05). In the "test" values (baseline) data group of Chlosite treatment group (mean±SD) changed from 4.83±1.53 to 4.15±1.23 (p<0.001) while in the Placebo group (mean±SD) from 4.83±1.53 to 4.68±1.23 (p=0.05).
Conclusions: Following both approaches, there were significant clinical improvements. Additional single topical subgingival application of Chlosite was fully providing more favorable CAL gain and PD reduction than Placebo.

INTRODUCTION

Topical subgingival antiseptics have been successfully evaluated in split-mouth clinical trials (Bajaj & Horiuchi-Jacoby 1992; Berglund *et al.* 1998; Eickhoff *et al.* 2002). The adjunctive use of antimicrobial agents to non-surgical therapy seems to provide additional effects. Current alternatives do not require a subgingival concentration for a period longer than 24h. A microcapsule hydrogel xanthan-based gel containing a mixture of chlorhexidine digluconate and chlorhexidine diphosphate (Chlosite) is the appropriate vehicle for the long-term release of the drug.

AIM OF THE STUDY

Aim of the present study was to evaluate the clinical effects of topical subgingival application of a new hydrogel xanthan-based chlorhexidine gel (Chlosite) for 14 days compared with a regular chlorhexidine gel in a controlled randomized split-mouth clinical study.

MATERIALS AND METHODS

Fifty-one patients (33 males and 18 females, aged between 20-65), light or non-smokers, suffering of chronic or aggressive periodontitis and being treated successfully with periodontal therapy (scaling and root planing) 2-3 times and additional application of chlorhexidine gel (Chlosite) for 14 days. After 4 weeks, in the "test" values (baseline) data group of Chlosite treatment group (mean±SD) changed from 7.00±2.79 to 5.73±2.03 (p<0.001); CAL changed from 3.00±0.69 to 2.34±0.42 (p<0.001) while in the Placebo group (mean±SD) from 7.00±2.79 to 6.74±2.03 (p=0.05); CAL changed from 3.00±0.69 to 2.94±0.42 (p=0.05). In the "test" values (baseline) data group of Chlosite treatment group (mean±SD) changed from 4.83±1.53 to 4.15±1.23 (p<0.001) while in the Placebo group (mean±SD) from 4.83±1.53 to 4.68±1.23 (p=0.05). In the "test" values (baseline) data group of Chlosite treatment group (mean±SD) changed from 4.83±1.53 to 4.15±1.23 (p<0.001) while in the Placebo group (mean±SD) from 4.83±1.53 to 4.68±1.23 (p=0.05).
Conclusions: Following both approaches, there were significant clinical improvements. Additional single topical subgingival application of Chlosite was fully providing more favorable CAL gain and PD reduction than Placebo.



Fig. 1. The xanthan-based chlorhexidine gel Chlosite® (Dinca s.p.a., Italy) applied with marginal overbite.



Fig. 2. Split-mouth application of Chlosite and Placebo.

Contact the authors
 Dr. Dr. Stefan-Ioan Stratul, DMD, PhD, MCh, MAbdica, Prensario, Res.Asoc.
 (University of Medicine and Pharmacy, Timisoara, Romania) / Dr. Dan Onisei, MCh, MAbdica, Prensario, Res.Asoc.
 (University of Medicine and Pharmacy, Timisoara, Romania) / shs@online.ro

RESULTS

The healing phase progressed uneventfully. No signs of inflammation, infection, allergy or severe pain were present. The post-treatment clinical values (percentage of the PD, CAL, PI and BOP) in the two treated groups are displayed in the tables No. 1 and table No. 2, pre- and post-treatment (mean overall values) are displayed in the tables No. 3 and No. 4, and the mean differences between the groups are presented in the tables No. 5 and No. 6.

Table 1. One month clinical results of treatment of periodontal pockets with Chlosite® (maximal values/quarter)

Parameter	Baseline	1 Month
PD (%)	7.00 ± 2.79	5.73 ± 2.03
CAL	3.00 ± 0.69	2.34 ± 0.42
PI	1.50 ± 0.50	1.20 ± 0.40
BOP	1.50 ± 0.50	1.20 ± 0.40

Table 2. One month clinical results of treatment of periodontal pockets with Placebo® (maximal values/quarter)

Parameter	Baseline	1 Month
PD (%)	7.00 ± 2.79	6.74 ± 2.03
CAL	3.00 ± 0.69	2.94 ± 0.42
PI	1.50 ± 0.50	1.40 ± 0.40
BOP	1.50 ± 0.50	1.40 ± 0.40

Table 3. One month clinical results of treatment of periodontal pockets with Chlosite® (mean overall values)

Parameter	Baseline	1 Month
PD (%)	7.00 ± 2.79	5.73 ± 2.03
CAL	3.00 ± 0.69	2.34 ± 0.42
PI	1.50 ± 0.50	1.20 ± 0.40
BOP	1.50 ± 0.50	1.20 ± 0.40

Table 4. One month clinical results of treatment of periodontal pockets with Placebo® (mean overall values)

Parameter	Baseline	1 Month
PD (%)	7.00 ± 2.79	6.74 ± 2.03
CAL	3.00 ± 0.69	2.94 ± 0.42
PI	1.50 ± 0.50	1.40 ± 0.40
BOP	1.50 ± 0.50	1.40 ± 0.40

Table 5. Mean differences between the treatment groups in the maximal/quarter values study

Parameter	Chlosite	Placebo
PD (%)	1.27 ± 0.76	0.00 ± 0.00
CAL	0.66 ± 0.27	0.00 ± 0.00
PI	0.30 ± 0.10	0.00 ± 0.00
BOP	0.30 ± 0.10	0.00 ± 0.00

Table 6. Mean differences between the treatment groups in the mean overall values study

Parameter	Chlosite	Placebo
PD (%)	1.27 ± 0.76	0.00 ± 0.00
CAL	0.66 ± 0.27	0.00 ± 0.00
PI	0.30 ± 0.10	0.00 ± 0.00
BOP	0.30 ± 0.10	0.00 ± 0.00

CONCLUSIONS

Following both approaches, there were significant clinical improvements. Additional single topical subgingival application of Chlosite was fully providing more favorable CAL gain and PD reduction than Placebo.