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Clinical and microbiological effects of 'PerioCream[®]' a periodontal dressing combined with an antimicrobial gum brushing solution after scaling and root planing: a multi-center randomized clinical trial

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Abstract

Background: The purpose of the present study was to evaluate the clinical benefits of a new periodontal dressing hereby referred to as the "Professional PerioCream®" Kit, combined with an antimicrobial gum brushing solution when applied after scaling and root planning (SRP) in patients with chronic periodontitis. This study aims also to demonstrate that the use of the "Professional PerioCream®" Kit as a post SRP treatment is more advantageous for the patient than no post SRP treatment.

Methods: This study included 29 patients subdivided into two groups. The treated group (n = 20) applied the periodontal dressing directly after SRP followed by 10 days of brushing with an antimicrobial gum brushing solution. The control group (n = 09) was treated only with SRP. Clinical parameters such as Plaque Index (PI), Gingival Index (GI), Periodontal Bleeding Index (PBI) and Clinical Attachment Level (CAL) were recorded before SRP and after treatment. A total bacterial count was assessed for periodontopathogenic bacteria including Porphyromonasgingivalis (Pg), Prevotella intermedia (Pi) and Aggregatibacteractinomycetemcomitans (Aa).

Results: The results showed a significant improvement of PI, GI, PBI and CAL after the application of the periodontal dressing and the antimicrobial solution (p < 0.05) in the treated group when compared to the control group. In addition, a significant reduction in bacterial count was noted in 2 treated subjects at day 11.

Conclusion: The data indicates that the PerioCream® periodontal dressing when combined with the gum brushing solution is an effective, safe and well tolerated adjunct treatment to SRP showing better clinical and microbiological parameters than no post SRP treatment at all.

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Introduction

Periodontitis is an inflammatory reaction characterized by the loss of teeth supporting structures, including the connective tissue attachment, periodontal pocket formation and/or recession of the gingival. The primary cause of this disease is the imbalance between the wide range of microorganisms, the host response and some essential modifying factors^[1,2].

Today scaling and root planning (SRP) represents the most widely used method in the treatment of periodontitis^[1]

which includes removal of supra and sub gingival microbial deposits that play a major role in the initiation and progression of the disease. The beneficial effects of SRP has been extensively evaluated on both clinical and microbiological levels in many studies^[3-5].

Periodontal dressings were first introduced by Ward (1923) who advocated the use of a paste derived from eugenolate to protect the wounded areas^[6]. Other periodontal dressings have been developed based on zinc oxide eugenol system. However



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due to the various side-effects of eugenol, periodontal dressings are today formulated without $it^{[7]}$.

Several authors have described the advantages of periodontal dressings as they prevent persistent bleeding and protect the tissue against mechanical stress during the healing phase^[8].

In subjects with periodontitis, specific microorganisms including Aggregatibacter Actinomycetemcomitans, Porphyromonasgingivalis, and Tannerella forsythia are frequently being observed^[9-11], and some studies have investigated the possible antimicrobial effect of the periodontal dressing^[12-14].

The "Professional PerioCream®" Kit is a new generation of periodontal dressing (paste texture) based on an olive oil formulation combined with an antimicrobialgum brushing solution which is supplied in the form of dissolvable tablets and used as an adjunct to SRP.

The tablets are based on the Nitradine formula which is characterized by its bactericidal, fungicidal and viricidal activities. Several studies showed the high in-vitro biofilm removal activity against a variety of microorganisms, namely Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus, including the MRSA type and Viruses^[15-17].

The objective of the present clinical study was to evaluate the effects of the "Professional PerioCream®" Kiton clinical and microbiological parameters after scaling and root planning in patients with chronic periodontitis. This study aims also to demonstrate that the use of the "Professional PerioCream®" Kit as a post SRP treatment is more advantageous for the patient than no post SRP treatment.

Materials and Methods

Study population

The study was performed at the Poojan Multi-Speciality Hospital and the APL Institute of Clinical Laboratory & Research, Ahmedabad-380052, Gujarat, India.

A total of 29 subjects with chronic periodontitis completed the study and were subdivided into 2 groups: Control group (N = 9) and treated groups (N = 20). Demographic data of studied subjects is recorded in table 1.

Subjects were screened in the study according to the following inclusion and exclusion criteria.

Inclusion criteria: Subjects complying with the following inclusion criteria were included in the study.

1) Subjects suffering from chronic periodontitis, 2) Negative history of any systemic disease, 3) Willingness to comply with the study schedule and procedures.

Table 1: Demographic characteristics of study population (Mean \pm SD)

Variables	Control group (N = 09)	Treated group (N = 20)
Gender		
Male	7	12
Female	2	8
Age (years)	38.11 ± 1.62	38.30 ± 6.89
Height (m)	1.62 ± 0.12	1.60 ± 0.08
Weight (Kg)	57.22 ± 7.12	55.55 ± 5.63

Exclusion criteria: 1) Subjects with a history of allergy for ingredients present in the "Professional PerioCream®" Kit, 2)

Subjects with mobile, carious, endodontically treated teeth, 3) History of systemic disease 4) Smokers 5) Subjects using any chemical plaque inhibitors, 6) Subjects suffering from condition requiring antibiotics or any other medication which could alter the oral micro flora, 7) Participation in any other clinical study during the last 30 days.

Ethical approval and informed consent: The present study conforms to the Helsinki Declaration. An ethical clearance and an approval letter were obtained from the Sangini Hospital Ethics Committee and the Institutional Review Board (IRB) of India. Information provided to the subjects was pre-approved by the Indian Ethical Committee (IEC).

The subjects were informed about the purpose, procedures to be carried out, potential hazards and the subject's right to claim compensation in case of trial related injury and death before participating in the study. The written informed consent form and patient information sheet included all the information required to fulfill the ICH-GCP guidelines and recommendations published by Government of India.

Study design

This study was designed for patients suffering from periodontitis. Clinical effects of the "Professional PerioCream®" Kit were analyzed in treated groups which have undergone SRP and used the "Professional PerioCream®" Kit as an adjunct. These effects are compared to a control group treated only with SRP.

The "Professional PerioCream®" Kit is a two phase concept treatment. Phase One carried out by the dentist, and Phase Two carried out by the patient at home.

The first phase of the application consists of the dentist applying a layer of the paste dressing directly onto the treated areas (gingival sulcus) using the pre-filled syringe and syringe tip. This dressing is to be smoothed over by the dentist applying the product using a small amount of water to render the cream malleable. The dressing should last 2 to 3 hours and can be left on the gum until it dissolves naturally. During the treatment eating or drinking is not allowed.

In the second phase of the treatment, an antimicrobialgum brushing solution is used to brush teeth and gums for 2 to 3 minutes once a day during 10 days. This phase is carried out by the patient at home. The antimicrobial solution is prepared by dissolving 1 tablet of NitrAdine® in 15 ml of Luke warm water. Once the tablet has completely dissolved, the teeth and gums (inner and outer) are gently brushed using a toothbrush that has been immersed in the gum brushing solution. It is recommended to immerse the toothbrush 2 - 3 times in the solution for a few seconds and brush again. After brushing, patients should thoroughly rinse their mouth with water and discard any remaining antimicrobialsolution. All instructions and precautions of use are provided to patients and dentists.

Mucous membrane irritation and clinical periodontal parameters such as Plaque Index (PI), Gingival Index (GI), Periodontal Bleeding Index (PBI) and Clinical Attachment Level (CAL)) were recorded at day 0 (before SRP) and after SRP (after periodontal paste application), at day 5 and at the end of the study (day 11).

These clinical parameters were recorded at the mesial, buccal, distal, and lingual surfaces of each tooth by using



a color-coded periodontal probe. Plaque index (PI) was measured based on Turesky modification of the Quigley-Hein Index, gingival index (GI) according to Loe and Silness^[18] and Papilla Bleeding Index (PBI) according to Saxer and Muhlemann^[19]. CAL was calculated as the distance in millimeters from the cemento-enamel junction to the bottom of the pocket. All the measurements were conducted by the same investigator blind to the treatment protocol applied.

Microbiological analysis

The analysis of Aggregatibacteractinomycetemcomitans (Aa), Porphyromonasgingivalis (Pg) and Prevotellaintermedia (Pi) was performed after SRP (day 0) and at end of the study (day 11 ± 1). Sampling was taken from the depth of the periodontal pocket using a sterilized paper-probe.

The samples were collected in thioglycolate broth transport media and transported to the lab within 48 hours of collection. The sample was then well mixed by vortexing and 10 ml of the sample was inoculated into the following media:

• Dentaid media (yeast extract, sodium fume rate, sodium formate, and vancomycin) for Aa

• Supplemented blood agar for pigmented anaerobes for Pg and Pi.

These two-above media were incubated anaerobically in a modified gas pack jar for 5 days. The identification of the organisms was based on colony characters, pigmentation, gram stain appearance, and certain standard key biochemical reactions. The quantity of colonies was carried out by counting the number of each type of colonies with the magnifying glass and expressed as colony forming units per ml (cfu/ml). The total bacterial count and number of positive sites for each microbial species over time (at baseline, at the end of the study-11days) were recorded.

Statistical analysis

Mann Whitney test, unpaired t-test and chi-square test were used to compare changes in treated and control groups. Level of significance of 5% was considered for all statistical tests.

In case of within group comparison, data were analyzed using paired t-test.

Results

Safety assessment

Spontaneously reported and directly observed Adverse Events (AEs) was monitored from the begin of the study until the last day of the treatment. Safety assessments were performed at each clinical visit by clinical examination including vitals and eliciting adverse events. None of the serious adverse event (SAE) was observed. None of the subjects discontinued from the study due to adverse events. Overall study treatment was well tolerated by all studied subjects.

Clinical parameters

A comparison of the mean change in clinical parameters between baseline day 0 (before SRP), Day 0 (after SRP), day 5 and day 11 revealed a statistically significant intergroup difference for all studied parameters in the treated group com-

pared to the controls.

The first treatment phase is based on the application of periodontal paste as a coating over gums for 2 - 3 hours directly after SRP treatment. The analysis of clinical parameters was done at baseline (before SRP) and directly after application of the periodontal paste (after SRP). The results showed a significant reduction of plaque index in treaded group compared to control group (0.80 ± 0.36 ; 1.16 ± 0.49 ; p = 0.0401). The same tendency was noticed when comparing the reduction of bleeding index after the application of Periodontal paste in treated and control groups respectively (0.56 ± 0.26 ; 0.96 ± 0.37 ; p = 0.0022). The statistical analysis of the gingival index showed a non-significant difference between treated subjects and controls at day 0 (after periodontal paste application) (0.46 ± 0.18 ; 0.58.0.17; p > 0.05).

The reduction percentage of PI, GI and PBI was also evaluated before SRP and after treatment with the periodontal paste. The study showed a reduction of 51% of plaque index in treated group however control group showed a decrease of 32%.

The study showed also an important decrease of bleeding index in treated and control groups respectively (62% and 41%).

A reduction of 48% of the gingival index was observed in treated group compared to control subjects (31% of reduction).

The second treatment phase was based on the application of an antimicrobial gum brushing solution during 10 days. The analysis of clinical parameters showed a significant decrease of PI (0.28 ± 0.09 ; 0.63 ± 0.45 ; p = 0.0052), GI (0.17 ± 0.08 ; 0.38 ± 0.13 ; p = 0.0003) and PBI (0.20 ± 0.11 ; 0.62 ± 0.31 ; p = 0.0005) in treated group and exposed group at the end of study.

The reduction percentage of the studied parameters was calculated between day 0 (after SRP) and directly at the end of the study. The analysis showed that the PI was decreased by 65% in treated group compared to controls which showed 45% of decrease. The gingival index was also decreased by 63% in treated group and by 34% in control group.

The analysis of the Periodontal bleeding index showed a reduction of 64% in treated group compared to controls 35%. In the treated group, a total of 609 surfaces were measured for the clinical attachment level (CAL). Out of 609 total surfaces, changes were observed in 26 surfaces. The attachment gain was 4.27%. Out of 20 treated subjects, 4 subjects did not show any change in the attachment level.

In control subjects, a total of 263 surfaces were measured for clinical attachment level (CAL). Out of 263 total surfaces, changes in CAL were observed in 12 surfaces. Attachment gain of up to 1 mm was observed in control group and was 4.56%. Out of 9 completed subjects, in 2 subjects, there were no changes in clinical attachment level, as there was no attachment gain or no attachment loss.

No significant change was observed in clinical attachment level between treated and control groups. All results are recorded in Tables 2, 3 and 4.

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Table 2: Plaque index distribution in treated and control groups (Mean \pm SD).

Study visits	Treated group	Control group	p value
Day 0 (Before SRP)	$1,\!65\pm0,\!47$	$1,\!72\pm0,\!61$	> 0.05
Day 0 (After SRP and paste application)	$0,8\pm0,36$	1,16 ± 0,49	0.0401
Day 5	$0,\!48\pm0,\!22$	$0,\!84\pm0,\!48$	0.008
Day 11	$0{,}28\pm0{,}09$	$0{,}63\pm0{,}45$	0.005

Table 3: Gingival index distribution in treated and control groups (Mean \pm SD).

Study visits	Treated group	Control group	p value
Day 0 (Before SRP)	0.89 ± 0.40	0.85 ± 0.25	> 0.05
Day 0 (After SRP and	0.46 ± 0.18	0.58 ± 0.17	> 0.05
paste application)			
Day 5	0.28 ± 0.12	0.47 ± 0.16	0.0046
Day 11	0.17 ± 0.08	0.38 ± 0.13	0.0003

Table 4: Bleeding index distribution in treated and control groups (Mean \pm SD).

Study visits	Treated group	Control group	p value
Day 0 (Before SRP)	1.49 ± 0.26	1.64 ± 0.50	> 0.05
Day 0 (After SRP and paste application)	0.56 ± 0.26	0.96 ± 0.37	0.0022
Day 5	0.39 ± 0.20	0.83 ± 0.33	0.0010
Day 11	0.20 ± 0.11	0.62 ± 0.31	0.0005

Microbiological results

Total bacterial count and analysis was carried out at day 0 and day 11 in both treated and control groups for four major periodontopathogenic bacteria (Porphyromonasgingivalis (Pg), Prevotellaintermedia (Pi) and Aggregatibacteractinomycetemcomitans (Aa)). Sub gingival plaques were collected from periodontal cavity.

Porphyromonasgingivalis (Pg): Bacteriological examination in treated group reflected that Porphyromonasgingivalis (Pg) was present in 2 subjects (of 20 subjects) at baseline. After the use of PerioCream® Kit, one subject's sample showed a significant decrease by 100% of Porphyromonasgingivalis from 727 CFU/ml at baseline to 0 CFU/ml at day 11.

The analysis of bacterial count showed the presence of Porphyromonasgingivalis (Pg) in 2 control subjects at baseline. At day 11, the analysis of only one subject's sample showed a decrease in bacterial count from 3,909 CFU/ml to 2017 CFU/ml.

Prevotella intermedia (Pi): The analysis of Prevotella intermedia showed its presence in 8 subjects at baseline. After the application of PerioCream® Kit, seven subjects showed a reduction of 100% in the bacterial count. One subject's sample showed a reduction in bacterial count from 1181 CFU/ml at baseline to 272 CFU/ml at day 11. In control group Prevotella intermedia (Pi) was present in 2 subjects at baseline, only one subject's sample showed a reduction in bacterial count from 545 CFU/ml at baseline to 363 CFU/ml at day 11.

Aggregatibacteractinomycetemcomitans (Aa): Aggregatibacteractinomycetemcomitans (Aa) was present in 2 treated subjects at baseline. After the application of the "Professional PerioCream®" Kit, one subject's sample showed reduction in bacterial count from 454 CFU/ml to 181 CFU/ml. The other subject showed a 100% of reduction in the bacterial count.

The analysis of control group showed the presence of Aggregatibacteractinomycetemcomitans (Aa) in 2 subjects at baseline which was reduced from 1454 CFU/ml to 363 CFU/ml for the first subject and from 1363 CFU/ml to 595 CFU/ml for the second subject.

Discussion

The scaling and root planning technique used in the treatment of periodontitis often leads to wounded gingival tissue. Periodontal dressing is used to protect the wound from many different influences and to stimulate wound healing. In addition, such dressing plays an important role by reducing bleeding, pain and discomfort and also protecting the wound from bacterial colonization^[20,21].

Although some studies report only limited success of periodontal dressing in non-surgical therapy, many authors discussed the benefic effects of periodontal dressing. Genovesi et al. reported in their study the effectiveness of periodontal dressing to improve the results of non-surgical treatment of patients which is attributed to an enhanced clot stability and decreased risk of bacterial infection^[21]. Pritchard et al. noticed the advantages of periodontal dressing in terms of preventing persistent bleeding and keeping away mechanical influences during the healing process^[22,23]. In addition, Plagmann confirmed also the important effect of the periodontal dressing and affirmed that coagulum should be stabilized to prevent any movement and to obtain the connective attachment to the hard tissue^[24].

In the present study, we describe the use of a new commercially available periodontal dressing called the "Professional PerioCream®" Kit. The application of PerioCream® periodontal paste dressing is the first phase of the treatment. This paste is used directly after SRP on the treated gums. The paste acts as a soothing paste and prevents further infection taking place after the patient has undergone SRP treatment.

This study was designed mainly to assess the clinical and the microbiological effects of periodontal paste dressing and gum brushing solution used as an adjunct to SRP in treated subjects as compared to placebo group.

The paste dressing is a combination of Calcium Sodium PVM/MA copolymer with Olive oil and the NitrAdine formula. It provides a quick adhesion when it is in contact with water (saliva) and naturally dissolves. The gum brushing solution is the second phase of the treatment and is used to brush the treated teeth and gums once the paste has dissolved.

After SRP procedure, the periodontal pocket is exposed directly to the oral environment and consequently the bacteria could recolonize in the periodontal pockets, and the root surface. Such recolonization may place the healing at risk^[25].

The antimicrobialgum brushing solution is based on NitrAdine tablets and has well documented antimicrobial properties. The brushing solution is aimed to clean and disinfect the gum line by penetrating in depth to remove the invisible dead germs and microbial biofilm, such as Candida albicans, Staphylococcus aureus, Pseudomonas aeruginosa^[15-17]. The brushing with the antimicrobial solution prevent the reinfection of gumsin the 10 days and maintain fresh sensation in the mouth by reducing the halitosis. A study performed by Vento-Zahra (2011) showed a significant drop in plaque accumulation on the orthodontic appliance and a significant amelioration in appliance odor after treatment with Nitradine^[17].

The analysis of clinical parameters such as Plaque Index (PI), Gingival Index (GI), periodontal Bleeding Index (PBI) and Clinical Attachment Level (CAL) indicated significant improvement in treated subjects compared to controls.

Several studies were conducted to show the efficacy of periodontal dressings. Puri et al. have studied the effect of Periochip on clinical parameters and pathogenic microflora^[26]. This study showed that Periochip placement as an adjunct to SRP has promising results when compared to SRP alone. The authors suggested also that healthy micro flora can be maintained for a longer period of time and a delay in the repopulation by periodontopathic microorganisms was observed^[26]. Heasman et al. demonstrated that Periochip is beneficial for patients on maintenance therapy although the benefit is not apparent until 6 months after placement^[27].

The present study showed a greater reduction of clinical indices such as gingival index and plaque index after brushing gums with the antimicrobial solution. These findings are in accordance with the results obtained in several studies conducted to evaluate the clinical and microbial effect of chlorhexidine used as adjunctive therapy after SRP^[27-30].

Evaluation of the "Professional PerioCream®" Kit efficacy was also done on basis of a written questionnaire, which was filled by subjects after SRP, at Day 5 and Day 11. The following overall conclusions could be drawn: Lesser number of treated subjects experienced unpleasant odour of the breath compared to control group. After treatment, subjects experienced reduction in gum pain, dryness and halitosis sensation, gum or sulcus bleeding including symptoms of infection. The overall efficacy of gingival paste combined with the antimicrobial gum brushing solution was rated good to very good and was found as better adjunct to SRP compared to control group. 95% of treated subjects were very satisfied.

Regarding the microbiology analysis, a statistically significant reduction in bacterial count was found in 2 treated subjects and 4 control subjects at Day 11.

A study of Puri et al. evaluating the effect of Periochipon clinical and microbiological parameters in patients with chronic periodontitis showed a non-significant difference of bacterial count between test group and control group at baseline and 1 month intervals^[26]. These findings are in accordance with the results of Daneshmand et al. (2002) which showed a no significant difference in total colony counts between the two studied groups at any time point during the study after applying the chlorhexidine as a disinfecting solution^[31]. However, the study of Paolantonio et al. (2008) showed a significant reduction of total bacterial count in treated subject with Chlorhexidine^[32].

No serious adverse event was reported during the study period. Overall study treatment was well tolerated by all treated subjects. None of the treated subjects faced problems such as allergic reaction, dry mouth, mobile teeth or adverse effect in case of swallowing the solution.

Conclusion

The findings of this clinical trial showed that the use of the "Professional PerioCream®" Kit as an adjunct treatment to SRP resulted in a substantial improvement of clinical parameters and microbiological count in the treated group when compared to the control group which can be attributed to the combination of periodontal paste with the gum brushing solution. Therefore, the "Professional PerioCream®" Kit can be considered as a beneficial adjunctive treatment modality to improve the periodontal health after SRP in the management of chronic periodontitis.

Authors' Contribution

SA: designed the study, prepared the manuscript and discussed the results. YJ: assisted on developing and analysing the formula of periodontal paste. BJ: collected the data and helped on study design and on the manuscript preparation. IH: assisted on the preparation of the manuscript. MS: carried out the treatments, participated in the design of the study and performed the statistical analysis. BDW: assisted on the study design. JPB: has the main responsibility for the study and the product conception. All authors read and approved the final manuscript.

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Conflict of Interest: There is no conflict of interest for all authors to report for this submission.



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