

Compare the Efficacy of Chlosite Gel as an Adjunctive Therapy after Scaling and Root Planing

Abstract

Aim: The present study was carried out to evaluate the clinical efficacy of scaling and root planing (SRP) alone and commercially available chlosite gel adjunctive to SRP in the treatment of chronic periodontitis. **Materials and Methods:** A total of 416 sites selected from 26 patients presenting with chronic periodontitis (age group ≥ 30 years) of both sexes, with pocket depth of ≥ 6 mm were recruited for the study. A split-mouth design was employed with one site receiving SRP alone (Group I) and the other receiving SRP followed by placement of commercially available chlosite gel (Group II) and all the clinical parameters-Plaque index (PI), Gingival index (GI), Probing Pocket depth and Clinical attachment loss (CAL) were recorded at baseline, 1 month, 3 months, and 6 months. **Results:** Results demonstrated that significant reduction in PI and GI scores were observed in both groups till the end of the study period (6 months). Probing depth and CAL also showed significant improvement in both the groups. However, Group II (sites which received SRP + Chlosite gel) showed greater improvements in all of these parameters compared to Group I (sites which received SRP only). **Conclusion:** The findings of this study suggest that the locally delivered commercially available chlosite gel along with mechanical debridement, resulted in a clinically meaningful improvement in all the clinical parameters.

Keywords: Chlorhexidine, chlosite, chronic periodontitis

Introduction

Periodontitis is an inflammatory disease of the periodontium caused by microorganisms of biofilm. These bacteria are considered to play a significant role in the pathogenesis of periodontitis and results in progressive loss of attachment and formation of periodontal pockets.^[1]

The periodontal treatment depends on marked reduction or elimination of periodontal pocket. Scaling and root planing (SRP) are the traditional methods of controlling sub-gingival microflora.^[2] SRP may not eradicate these species due to their invasive potential into gingival epithelial cells and subepithelial connective tissue.

To overcome this problem, several antimicrobial agents are used for the control of the periodontal disease. They are delivered by rinsing, irrigation, systemic administration, and local devices and are valuable adjuncts to mechanical therapy.^[3] The local drug delivery system

was designed to deliver agents locally into periodontal pockets to provide long-term retention of a highly concentrated drug within the target tissue.^[4] The local route of drug delivery can attain 100-fold higher concentrations of an antimicrobial agent in subgingival sites compared with a systemic drug regimen.^[5]

Goodson *et al.* in 1979 first proposed the concept of controlled delivery in the treatment of periodontitis. The effectiveness of this form of therapy is that it reaches the base of the periodontal pocket and is maintained for an adequate time for the antimicrobial effect to occur because the periodontal pocket provides a natural reservoir bathed by gingival crevicular fluid that is easily accessible for the insertion of a delivery device.^[5]

The major advancement in topical anti-microbials of a chlorhexidine (CHX) product is CHX-xanthan based gel, chlosite (introduced by Ghimas Company, Italy). Chlosite is based on two forms of CHX bonded in a xanthan carrier substance. CHX digluconate (0.5%) is a small molecule released in high concentrations

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immediately after placement. CHX dihydrochloride (1%) is a larger and more complex molecule.

The present study was carried out to comparatively evaluate the clinical efficacy of SRP alone and commercially available chlosite gel adjunctive to SRP in the treatment of chronic periodontitis.

Materials and Methods

In the present study, 26 subjects of chronic generalized periodontitis of both genders with a total of 416 sites were selected from the Outpatient Department of Periodontology. These sites were divided into two groups in a split-mouth design.

- Group I (Control sites) – 208 sites were treated by SRP alone
- Group II (Test sites) – 208 sites were treated with SRP followed by placement of commercially available chlosite gel containing (CHX digluconate 0.5% and CHX dihydrochloride 1.0%).

Inclusion criteria were subjects ≥ 30 years of age diagnosed with chronic generalized periodontitis having probing depth (PD) of ≥ 6 mm in mandibular posterior teeth and exclusion criteria were the use of systemic or subgingival antimicrobial within the 6 months before the study, allergy to chlorhexidine, habit of tobacco chewing and smoking and aggressive periodontitis cases.

The following clinical parameters were recorded at baseline, after 1 month, 3 months, and 6 months.

1. Plaque index (PI) (Sillness and Løe 1964)
2. Gingival index (GI) (Løe and Sillness 1963)
3. Clinical attachment level [Figure 1]
4. Probing pocket depth [Figure 2].

After recording all the parameters at baseline, full mouth SRP was performed using ultrasonic instruments followed by hand instruments until all supra and subgingival root surfaces felt hard and smooth. After following debridement, test sites were irrigated gently with normal saline and then left for 10 min to achieve haemostasis prior to placement of commercially available chlosite gel. The gel was placed first into the deepest part of the pocket and then the needle was slowly withdrawn till it reached the superior portion of the pocket [Figure 3]. To ensure that commercially



Figure 1: Measurement of clinical attachment level with occlusal stent at baseline

available chlosite gel stays long enough to be effective in the pocket, a periodontal dressing (Coe-Pak) was placed without pressure over the treated sites.

Postoperative home-care instructions including brushing with a soft brush twice a day were advised.

Patients were recalled after 7 days for removal of the periodontal dressing and for reinstructions on oral hygiene maintenance. Recall visits were again scheduled after 1 month, 3 months, and 6 months for the recording of clinical parameters [Figure 4].

Results

At baseline PI of Group I (2.19 ± 0.16) was found to be higher than that of Group II (2.15 ± 0.16) and at follow up after 6 months, PI of Group I (0.79 ± 0.14) was found is similar to that of Group II (0.79 ± 0.14) as shown in Table 1.

GI of Group I (1.98 ± 0.30) was found to be lower than that of Group II (2.01 ± 0.33) at baseline and at follow up after 6 months, GI of Group I (0.78 ± 0.12) was found to be almost similar to that of Group II (0.78 ± 0.11) as shown in Table 1.

At baseline clinical attachment level of Group I (10.94 ± 0.41) was found to be lower than that of Group II (11.02 ± 0.46) and at follow up after 6 months Group I (8.48 ± 0.18) was found to be higher than that of Group II (7.90 ± 0.31) as shown in Table 1.

At baseline PD of Group I (6.98 ± 0.34) was found to be lower than that of Group II (7.15 ± 0.18) and at follow up after 6 months Group I (4.63 ± 0.39) was found to be higher than that of Group II (3.80 ± 0.30) as shown in Table 1.

In Group I and Group II change in PI between two-time intervals was found to be maximum between Baseline and 1 month and minimum between 1 month and 3 months and differences between any of the two-time durations was found to be statistically significant ($P < 0.001$) as shown in Table 2.

In Group I and Group II a change in GI between any two-time durations was found to be maximum between baseline and 3 months while the minimum change was between 1 month and 6 months. Change in GI between



Figure 2: Measurement of probing pocket depth with UNC-15 at baseline



Figure 3: Placement of chlosite gel

Table 1: Mean and standard deviation of plaque index, gingival index, clinical attachment level and pocket probing depth at different observation periods in different groups

Observation period	Group I	Group II
Plaque index (months)		
Baseline	2.19±0.16	2.15±0.16
1	0.51±0.10	0.49±0.11
3	0.63±0.11	0.59±0.09
6	0.79±0.14	0.79±0.14
Gingival index (months)		
Baseline	1.98±0.30	2.01±0.33
1	0.90±0.18	0.90±0.18
3	0.63±0.14	0.68±0.15
6	0.78±0.12	0.78±0.11
Clinical attachment level (months)		
Baseline	10.94±0.41	11.02±0.46
1	9.78±0.26	9.32±0.11
3	8.48±0.27	7.77±0.25
6	8.48±0.18	7.90±0.31
Probing pocket depth (months)		
Baseline	6.98±0.34	7.15±0.18
1	5.96±0.36	5.21±0.16
3	4.63±0.43	3.61±0.17
6	4.63±0.39	3.80±0.30

all the time durations was found to be statistically significant ($P < 0.001$) as shown in Table 2.

In Group I and Group II, a change in Clinical attachment level between any two-time durations was found to be maximum between baseline and 3 months and while the minimum change was between 3 months and 6 months. Change in clinical attachment level between all the time durations was found to be statistically significant ($P < 0.001$) except between 3 months and 6 months as shown in Table 2.

In Group I, change in Probing pocket Depth between any two-time durations was found to be maximum between



Figure 4: Measurement of clinical attachment level with occlusal stent after 6 months

baseline and 6 months while the minimum change was between 3 months and 6 months. Change in Pocket depth between all the time durations was found to be statistically significant ($P < 0.001$) except between 3 months and 6 months as shown in Table 2.

In Group II, change in probing pocket depth between any two-time durations was found to be maximum between baseline and 3 months while the minimum change was between 3 months and 6 months. Change in Clinical attachment level between all the time durations was found to be statistically significant ($P < 0.001$) as shown in Table 2.

Discussion

The most important goal of periodontal therapy is to reduce or eliminate the subgingival microorganisms, which cause the periodontal disease to maintain periodontal health and if possible to regenerate the lost tissues. SRP is considered a gold standard to attain and maintain periodontal health by the elimination of bacterial plaque.

CHX is an effective antiseptic agent used for over 30 years in the management of the periodontal disease.^[6] This agent is safe, effective, and contains a wider spectrum of local antimicrobial activity.^[7] Its mechanism of action relates to the reduction in pellicle formation, alteration of bacterial adherence to teeth and an alteration of bacterial cell walls causing lysis.

To increase the retention of CHX gels in the periodontal pocket a novel carrier containing 2.5% xanthan gum was developed. Xanthan gum is a polysaccharide that consists mainly of galactose and mannose residues. One of the most remarkable properties of xanthan gum is its capacity to produce a large increase in the viscosity of a liquid. Xanthan gum provided the most prolonged adhesion time on the oral mucosa with respect to other delivery vehicles. The cationic charges of CHX can interact with the anionic charges of the xanthan gum polymer, enhancing its gel structure and substantivity.^[8,9]

In this study commercially available chlosite (CHX digluconate 0.5% and CHX dihydrochloride 1.0%), a xanthan-based syringable gel was used.

Soskolne *et al.*^[10] observed significant reduction of GI score with SRP with CHX which is similar to the observation of

Table 2: Comparison of mean and standard deviation of plaque index, gingival index, clinical attachment level and pocket probing depth at different observation periods in different groups

Comparison	Group I	Group II	P
Plaque index (months)			
Baseline versus 1	-1.68±0.19	-1.66±0.21	<0.001
Baseline versus 3	-1.56±0.16	-1.56±0.13	<0.001
Baseline versus 6	-1.41±0.23	-1.36±0.22	<0.001
1 versus 3	0.12±0.14	0.10±0.15	<0.001
1 versus 6	0.27±0.18	0.29±0.19	<0.001
3 versus 6	0.15±0.18	0.20±0.18	<0.001
Gingival index (months)			
Baseline versus 1	-1.08±0.25	-1.10±0.38	<0.001
Baseline versus 3	-1.35±0.21	-1.32±0.24	<0.001
Baseline versus 6	-1.20±0.31	-1.23±0.35	<0.001
1 versus 3	-0.27±0.17	-0.22±0.25	<0.001
1 versus 6	-0.13±0.19	-0.12±0.18	0.001
3 versus 6	0.14±0.17	0.10±0.19	0.008
Clinical attachment level (months)			
Baseline versus 1	-1.16±0.20	-1.70±0.41	<0.001
Baseline versus 3	-2.46±0.48	-3.25±0.51	<0.001
Baseline versus 6	-2.46±0.43	-3.12±0.42	<0.001
1 versus 3	-1.30±0.32	-1.55±0.23	<0.001
1 versus 6	-1.30±0.30	-1.42±0.27	<0.001
3 versus 6	0.00±0.26	0.13±0.26	0.010
Probing pocket depth (months)			
Baseline versus 1	-1.02±0.04	-1.94±0.06	<0.001
Baseline versus 3	-2.34±0.51	-3.54±0.31	<0.001
Baseline versus 6	-2.35±0.48	-3.35±0.33	<0.001
1 versus 3	-1.33±0.51	-1.60±0.28	<0.001
1 versus 6	-1.33±0.49	-1.42±0.33	<0.001
3 versus 6	-0.01±0.25	0.19±0.34	<0.001

the present study. Chandra *et al.*^[11] reported a significant reduction in GI score when compared the efficacy of CHX gel with SRP which is also similar to the observation of the present study.

A significant reduction is observed in PI at 1 month and 3 months intervals as compared with the baseline. Grover *et al.*,^[12] Gupta *et al.*,^[13] Rodrigues *et al.*^[14] observed a significant reduction in PI score that is similar to the result of the present study. After 6 months follow-up PI of both the groups was found to be similar and difference was not found to be statistically significant ($P = 1.000$) which is similar to the study done by Unsal *et al.*^[15] and Paolantonio *et al.*^[16]

In the present study PD at 6 months follow-up was found to be higher in group I than group II and the difference was found to be statistically significant. These results are consistent with the results recorded in the study conducted by Goodson *et al.*,^[17] Jeffcoat *et al.*^[18] and Vinholis *et al.*^[19]

Determining the change in attachment level (gain or loss) is a primary measure and one of the most practical methods

of determining the progression of periodontal disease. The result of our study shows a significant gain in clinical attachment level at 1 month and 3 months follow-up when it is compared with that of baseline data. These findings of the study also coincide with the study carried out by Perinetti *et al.*^[20] who observed more gain of relative Clinical attachment loss in subjects treated with 1% CHX gel as compared to placebo gel. The gain in the clinical attachment level observed in the present study is superior at 3 months follow-up ($P < 0.001$) when compared with the study conducted by Oteo *et al.*^[21]

There is no difference in clinical attachment level between 3 and 6 months. These findings are similar to that of the study conducted by Unsal *et al.*^[15]

Conclusion

Based on the above finding, the result of the present study clearly shows that the locally delivered commercially available chlosite gel (0.5% CHX digluconate and 1.0% Chlorhexidine dihydrochloride) along with mechanical debridement, resulted in a clinically meaningful improvement in all the clinical parameters.

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Conflicts of interest

There are no conflicts of interest.

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