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EFFICACY OF BIODEGRADABLE XANTHAN BASED CHLORHEXIDINE GEL (CHLOSITE®) AND 0.2% CHLORHEXIDINE IRRIGATION FOLLOWING SCALING AND ROOT PLANING FOR THE TREATMENT OF CHRONIC PERIODONTITIS

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ABSTRACT

Aim: The aim of this study was to compare the efficacy of sub-gingivally administered Xanthan-based chlorhexidine gel versus 0.2% chlorhexidine irrigation following scaling and root planing (SRP) in the treatment of chronic periodontitis. **Materials and Methods:** A randomized, controlled study was conducted in 10 systemically healthy patients suffering from chronic periodontitis with isolated moderately deep periodontal pockets (pocket depth of 4 to 6mm). The selected patients were randomized into three treatment groups: Group A (scaling and root planing alone) was taken as the control group, while Group B (scaling and root planing + placement of Xanthan based 1.5% chlorhexidine gel CHLOSITE®) and Group C (scaling and root planing + irrigation with 0.2% CHX) were taken as the test groups. A total of 30 sites (3 sites each) were taken in each patient. The clinical parameters evaluated were Gingival Index (GI), Plaque Index (PI), Probing Pocket Depth (PPD) and Clinical Attachment Level (CAL), which were recorded at baseline and as well as 15 and 30 days post treatment. **Results:** All clinical parameters that were recorded showed a statistically significant improvement in Group B (scaling and root planing + placement of Xanthan based 1.5% chlorhexidine gel CHLOSITE®) and Group C (scaling and root planing +irrigation with 0.2% CHX) as compared to the control group (scaling and root planing alone) **Conclusion:** The present study concluded that the Xanthan based chlorhexidine gel is effective as an adjunct to SRP, wherein it provided clinically better results when compared to SRP alone.

KEYWORDS: Scaling and root planning; periodontal pocket depth; clinical attachment level

INTRODUCTION

Periodontal disease is a complex multi-factorial disease characterized by destruction of periodontal tissues and loss of connective tissue.[1] The microbiota responsible for this disease are complex, since more than 500 different bacterial species have been identified in the subgingival plaque.[2] The periodontal pocket provides a warm, moist, nutritious and anaerobic environment for microbial colonization and multiplication.[3] Highly organized bacterial populations form the advancing front of the periodontal pocket.[4] At present, the main therapeutic approach for periodontal disease is mechanical scaling and root planing (SRP) which removes the deposits from the tooth surface and shifts the pathogenic microbiota to one compatible with periodontal health. The pocket anatomy is a significant limiting factor in mechanical access and sufficient reduction of the bacterial load may not be achieved.[5] Surgical intervention provides accessibility to inaccessible root surfaces and helps in reduction or elimination of pockets along with reformation of healthy dento-gingival junction. Certain systemic conditions may obviate the use of such invasive procedures. Success of any antimicrobial agent

Table 1: Mean values±SD values of Plaque index scores from baseline to 30 days

PLAQUE INDEX(PI)		Number	Mean	S. D.	F-value	P-value
GROUP A (SRP)	Baseline	10	3.27	0.41	7.123	
	After 15 days	10	2.17	0.74		
	After 30 days	10	2.20	0.96		0.003*
GROUP B (SRP+CHLOSITE GEL)	Baseline	10	3.11	0.45	24.318	
	After 15 days	10	2.13	0.73		
	After 30 days	10	1.35	0.47		0.000*
GROUP C (SRP+CHX IRRIGATI-ON)	Baseline	10	2.78	0.62	8.419	
	After 15 days	10	1.61	0.68		
	After 30 days	10	1.77	0.76		0.001*

Table 2: Intergroup comparisions of plaque index scores from baseline to 30 days

PLAQUE IN (PI)	Mean	SD	Comparison	Mean Difference	P-value
BASELINE	3.27	0.41	A vs B	0.160	1.000
	3.11	0.45	B vs C	0.490	0.115
	2.78	0.62	A vs C	0.330	0.461
15 DAYS	2.17	0.74	A vs B	0.040	1.000
	2.13	0.73	B vs C	0.560	0.279
	1.61	0.68	A vs C	0.520	0.353
30 DAYS	2.20	0.96	A vs B	0.850	0.057
	1.35	0.47	B vs C	0.430	0.651
	1.77	0.76	A vs C	-0.420	0.683

Fig. 1: Application of Xanthan-based chlorhexidine gel Chlosite®

depends on its ability to achieve bacteriostatic or bactericidal concentrations at the base of the pocket and also facilitate retention of medicament long enough in the pocket.[6] Systemic antibiotics require the administration of large doses in order to gain sufficient concentrations at the disease sites and involve risks such as bacterial resistance, side-effects, drug interactions and inconsistent patient compliance.[7] The inherent limitations of systemic chemotherapies has led to the development of local delivery systems for the administration of antimicrobials directly into the periodontal pockets which can be maintained at therapeutically effective levels for longer periods of time.[6] Chlorhexidine is a highly effective antimicrobial agent which has been extensively studied and shown to inhibit growth of supragingival plaque bacteria when used as a mouth rinse in concentrations of 0.12% to 0.2%. It can bind to the tissues from where it is released over 6-12 hours thereby prolonging the bactericidal effect. Recently, a new local drug delivery system, Xanthan based chlorhexidine gel (CHLOSITE® GHIMAS, Italy), has been developed.8 In CHLOSITE® chlorhexidine is present at a concentration of 1.5%, of which 0.5% is in the form of fast releasing digluconate and 1.0% is in the form of slow releasing dihydrochloride. Thus, the aim of this study was to compare the relative efficacy of subgingivally administered Xanthan-based chlorhexidine gel and 0.2% chlorhexidine irrigation following scaling and root planing (SRP) in the treatment of chronic periodontitis.

MATERIALS AND METHODS

The present study was conducted in the Outpatient Department of Periodontics, I.T.S

Table 3: Mean values±SD values of Gingival index scores from baseline to 30 days

GINGIVAL INDEX(GI)		Number	Mean	S. D.	F-value	P-value
GROUP A (SRP)	Baseline	10	2.77	0.69	2.926	
	After 15 days	10	2.13	0.22		
	After 30 days	10	2.48	0.73		0.071
GROUP B (SRP+CHLOSITE GEL)	Baseline	10	3.07	0.97	6.008	
	After 15 days	10	2.13	0.78		
	After 30 days	10	1.70	0.95		0.007*
GROUP C (SRP+CHX IRRIGATI-ON)	Baseline	10	2.73	0.90	2.377	
	After 15 days	10	2.15	0.75		
	After 30 days	10	2.00	0.71		0.112

Table 4: **Intergroup comparisions of gingival index scores from baseline to 30 days**

Gingival Index (GI)	Mean	SD	Comparison	Mean Difference	P-value
Baseline	2.77	0.69	A vs B	-0.300	1.000
	3.07	0.97	B vs C	0.040	1.000
	2.73	0.90	A vs C	0.340	1.000
15 Days	2.13	0.22	A vs B	0.000	1.000
	2.13	0.78	B vs C	-0.020	1.000
	2.15	0.75	A vs C	-0.020	1.000
30 Days	2.48	0.73	A vs B	0.780	0.116
	1.70	0.95	B vs C	0.480	0.577
	2.00	0.71	A vs C	-0.300	1.000

Table 5: Mean values±SD values of periodontal pocket probing depth scores from baseline to 30 days

Periodontal Pocket Depth (PPD)		Number	Mean	S. D.	F-value	P-value
Group A (SRP)	Baseline	10	5.98	0.51		
	After 15 days	10	5.37	0.30		
	After 30 days	10	4.97	0.24	19.2	0.000*
Group B (SRP+CHLOSITE GEL)	Baseline	10	5.52	0.80		
	After 15 days	10	4.88	0.81		
	After 30 days	10	4.43	0.77	4.756	0.017*
Group C (SRP+CHX IRRIGATI-ON)	Baseline	10	5.82	0.67		
	After 15 days	10	5.36	0.61		
	After 30 days	10	5.01	0.62	4.122	0.027*

Centre for Dental Studies and Research, Muradnagar. For this randomized controlled clinical trial, 10 systemically healthy patients aged 30-50 years suffering from chronic periodontitis with moderate pocket probing depth (PPD) of 4 to 6 mm were recruited. The selected patients were randomized into three treatment groups: Group A (Scaling and root planing alone) taken as the control group, Group B (Scaling and root planing + insertion of Xanthan based 1.5% chlorhexidine gel CHLOSITE®) and Group C (Scaling and root planing +irrigation with 0.2% CHX) were taken as the test sites. A total of 30 sites were taken (3 sites in each patient) and the sites were randomly assigned to one of three therapies.The following patients were excluded from the study: patients allergic to chlorhexidine, who had undergone periodontal surgery in the 6 months prior to the study and with a history of smoking or who were current smokers or receiving medications. At the screening visit, the periodontal examination of all the eligible patients was carried out and impressions were made for fabrication of acrylic stents to ensure reproducibility of measurements during the subsequent examinations. At the baseline visit, an

Table 6: Intergroup comparisions of periodontal probing depth scores from baseline to 30 days

PERIODONTAL POCKET DEPTH(PPD)	Mean	S. D.	Comparison	Mean Difference	P-value
Baseline	5.98	0.51	A vs B	0.460	0.609
	5.52	0.80	B vs C	0.160	1.000
	5.82	0.67	A vs C	-0.300	0.977
15 Days	5.37	0.30	A vs B	0.490	0.248
	4.88	0.81	B vs C	-0.480	0.907
	5.36	0.61	A vs C	0.010	1.000
30 Days	4.97	0.24	A vs B	0.540	0.051
	4.43	0.77	B vs C	-0.580	0.000*
	5.01	0.62	A vs C	-0.040	0.000*

Table 7: Mean values±SD values of clinical attachment level scores from baseline to 30 days

CLINICAL ATTACHMENT LEVEL(CAL)		Number	Mean	S. D.	F-value	P-value
Group A (SRP)	Baseline	10	5.99	0.68		
	After 15 days	10	5.35	0.46		
	After 30 days	10	4.98	0.49	8.443	0.001*
Group B (SRP+CHLOSITE GEL)	Baseline	10	5.84	0.72		
	After 15 days	10	5.40	0.58		
	After 30 days	10	4.98	0.63	4.388	0.022*
Group C (SRP+CHX IRRIGATI-ON)	Baseline	10	5.69	0.75		
	After 15 days	10	5.39	0.79		
	After 30 days	10	5.14	0.77	1.278	0.295

oral examination was undertaken and the following clinical parameters were recorded for the selected sites: Turskey Gilmore-Glickman modification of Quigley-Hein Plaque Index (PI),[10] Gingival Index (GI),[11] Probing Pocket Depth (PPD) and clinical attachment level (CAL).

TREATMENT PROCEDURES

In the control group (Group A), the treatment was limited to SRP only. At the baseline visit, all the patients received supra-gingival and sub-gingival SRP using hand and ultrasonic scalers and periodontal curettes. The patients were given oral hygiene instructions including twice-daily tooth brushing. No use of antimicrobial mouth rinses was allowed during the study period.Following SRP, further evaluation of clinical parameters was carried out after 15 days and 30 days. No SRP procedures were performed in any of the selected sites at the recall visits. No dietary limitations were imposed during or after treatment. In Group B after SRP, CHLOSITE® was applied directly from the syringe into the pocket. The Xanthan-based chlorhexidine gel is supplied with a special needle having a blunt tip and a lateral opening. This facilitated the application of the gel without traumatizing or damaging the periodontal tissues. Xanthan is a naturally occurring, biocompatible saccharidic polymer that forms a three-dimensional pseudoplastic reticulum when in contact with water. Swelling-controlled erosional process allows for sustained release of the drug at zero-order kinetics from Xanthan.Chlorhexidine digluconate is liberated in the first day, and achieving a concentration greater than 100µg/ml. This is maintained for an average of 6-9 days which is greater than the Minimum Inhibitory Concentration (MIC) for chlorhexidine (0.10µg/ml). Chlorhexidine dihydrochloride is released in the following days, and maintaining the bactericidal concentrations for at least 2 weeks therapy preventing re-colonization.The gel was injected first into the apical portion of the pocket and then, while continuing to extrude the material, the needle was slowly withdrawn till it reached the coronal extent of the pocket. In Group C, after SRP the selected sites were irrigated with

Table 8: Intergroup comparisions of clinical attachment level scores from baseline to 30 days

CLINICAL ATTACHMENT LEVEL (CAL)	Mean	S. D.	Comparison	Mean Difference	P-value
Baseline	5.99	0.68	A vs B	0.150	1.000
	5.84	0.72	B vs C	0.150	1.000
	5.69	0.75	A vs C	0.300	1.000
15 Days	5.35	0.46	A vs B	-0.050	1.000
	5.40	0.58	B vs C	0.010	1.000
	5.39	0.79	A vs C	-0.040	1.000
30 Days	4.98	0.49	A vs B	0.000	1.000
	4.98	0.63	B vs C	-0.160	0.000*
	5.14	0.77	A vs C	-0.160	0.000*

0.2% chlorhexidine (1:1 dilution) with a 2 ml syringe for 2 mins and the syringe was placed 2mm deep into the periodontal pocket. The patients were instructed not to use floss or use interdental aids for the next 10 days.

DATA ANALYSIS

Data analysis was carried out using Statistical package for Social Science (SPSS) software. Mean values and standard deviation was calculated for each variable and examination interval. Bonferroni post-hoc comparison was used. Efficacy results for qualifying treated sites were analyzed statistically using Paired 't' test. All statistical tests were 2-tailed and probabilities less than 0.05 (P<0.05) were considered significant.

RESULT

Plaque index and Gingival index

The mean changes overtime in plaque and gingival indices are given in Table 1 and Table 3. All the patients showed statistically and clinically significant improvements in gingival and plaque indices at both follow-up visits when compared with the baseline levels. The mean reduction in the plaque index score from baseline to 15 days and 30 days for group B was 0.98 and 1.76 , respectively, and the mean reduction in the gingival index score was .94 and 1.37 respectively, which was statistically significant (P<0.05).No statistically significant changes were seen in gingival index scores of group A and group C but both the groups showed stastically significant reduction in the plaque index scores from baseline to 30 days i.e 1.07 for group A and 1.01 for group C. The intergroup comparison of the plaque index values at baseline, 15 days and 30 days for group A (SRP), B (SRP+CHLOSITE GEL) and C (SRP+CHX IRRIGATION) showed no statistically significant difference in the results between the groups (Table 2). The intergroup comparison of the gingival index values at baseline, 15 days and 30 days for group A (SRP), B (SRP+CHLOSITE GEL) and C (SRP+CHX IRRIGATION) showed no statistically significant differences in the results between the groups (Table 4).

Probing pocket depth

Table 5 shows changes in Probing pocket depth (PPD) for each treatment group. All the three groups showed statistically significant change in PPD after 15 and 30 days when compared to the baseline values. The mean pocket depth reduction from baseline to 15 and 30 days was found to be 0.61 mm and 1.01 mm, respectively, for Group and 0.64 mm and 1.09 mm mean reduction was seen for Group B, and for group C a mean reduction of 0.46 mm dand 0.81 mm was seen.The reduction in all the three groups was stastically significant. The intergroup comparisons of Periodontal Pocket depth (PPD) at baseline, 15 days showed statistically non significant results in all the three groups but at 30 days point interval .Group Band C showed statstically significant differences in the pocket probing depth (Table 6).

Clinical attachment level

Table 7 shows the mean clinical attachment level from baseline to 15 days and 30 days was found to be 0.64 mm and 1.01 mm respectively for Group A and for Group B 0.44 mm and0 .86 mm which was statistically significant. However it was seen that for Group C, the mean clinical attachment level was 0.30 mm and 0.55 mm respectively after 15 and 30 days but the results

respectively after 15 and 30 days but the results were not statistically significant. The intergroup comparisons of relative attachment level at baseline, 15 days showed statistically non significant results in all the three groups but at 30 days point interval Group B and C showed statistically significant differences in relative attachment level (Table 8).

DISCUSSION

Control of plaque is crucial in the treatment of periodontal disease and in the maintenance of oral health.[12] Primary responsibility for plaque control rests with the patient and mechanical means suffice in most cases. However, in situations in which oral hygiene presents difficulties, the most effective anti-plaque agent, chlorhexidine, is useful. The present study based was designed to compare the relative efficacy of subgingivally administered xanthan-based chlorhexidine gel and 0.2% chlorhexidine irrigation following scaling and root planing (SRP) in the treatment of chronic periodontitis. The results of this study have shown that the treatment of moderately deep periodontal pockets with chlorhexidine provides a significantly greater improvement in clinical parameters when compared with the improvement obtained with SRP alone. No adverse effects were reported by the patients at any given time during the study duration. The age range of 30- 50 years was selected because the subjects of this age range generally present with chronic periodontitis. Both the gingival and plaque indices remained satisfactory during the entire study period in all the three treatment groups, suggesting patients complied with the oral hygiene instructions. The reduction in plaque and gingival scores could be due to the proper oral hygiene maintenance and the thoroughness of SRP. There was significant reductions in PI & GI scores at 30 days follow up visit when compared to baseline levels in all the three groups but marked reduction was seen in group B when compared to group A and C. In the Group B, PPD reduction can be attributed to the bactericidal concentrations achieved within day 1 at the selected sites, and these higher concentration levels were maintained for 2 weeks thereafter. Therefore, enhanced healing may have occurred at the test sites in the absence or following reduction of microbial load. Group B and C showed a slightly greater gain in the CAL when compared to Group A. The greater gain in CAL could be attributed to the absence of bacterial challenge during the critical initial phase of healing following SRP. The present results are in contrast with findings from studies on the effects of subgingival administration of a CHX gel as an adjunct to SRP. Oosterwaal *et al*., investigated the effects of a 2% CHX gel used as an adjunct to SRP; similar clinical results were obtained with SRP treatment alone and when subgingival administration of 2% CHX or placebo gels were associated with SRP.[13] Quirynen *et al*., reported negligible beneficial effects over SRP alone when a 1% CHX gel was subgingivally administered as an adjunct to SRP in a one-stage full mouth disinfection protocol.[14] Unsall *et al*., found less CAL gain in periodontal sites treated with SRP and subgingival administration of 1% CHX gel compared to those treated with SRP alone.[15] Taken together, these findings suggest that the high viscosity of a CHX gel formulation cannot reduce the clearance of CHX within the periodontal pocket, thus failing to increase the antibacterial effects of such devices, despite the well-known beneficial effects provided by CHX. Xanthan gum has been shown to have bioadhesive properties and provided the most prolonged adhesion time on the oral mucosa with respect to other delivery vehicles.[16] Needleman *et al*., also reported that the addition of CHX to xanthan gum improved the bioadhesive properties of this material. The cationic charges of CHX can interact with the anionic charges of the xanthan gum polymer, enhancing its gel structure and substantivity.[17,18]

CONCLUSION

When used with SRP, the xanthan based 1.5 % chlorhexidine gel offers clinician a new method of achieving and maintaining periodontal stability. Local drug therapy markedly improves the benefits of SRP, and by the use of these agents the threshold for surgical periodontal therapy might be moved towards deeper pockets. Further studies are needed to evaluate the long-term clinical advantages of this adjunctive therapy to determine which types of patients and lesions will benefit most from the incorporation of locally delivered agents. Furthermore, microbiological studies are also required to corroborate with the clinical findings observed.

CONFLICT OF INTEREST & SOURCE OF FUNDING

The author declares that there is no source of funding and there is no conflict of interest among all authors.

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