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ORIGINAL ARTICLE

Clinical evaluation of the efficacy of two commercially available controlled-release drugs-chlorhexidine gel (CHLO-SITE)™ and tetracycline fibers (periodontal plus AB)™ as an adjunct to scaling root planning in the treatment of chronic periodontitis

Harpreet Singh Grover, Amit Bhardwaj, Himanshu Dadlani, Anil Yadav, Yaswin Singh

Department of Periodontics, SGT Dental College, Hospital and Research Institute, Budhera, Gurgaon, Haryana, India

Address for correspondence:
Dr. Amit Bhardwaj,
Department of Periodontics,
SGT Dental College, Hospital and Research Institute,
Budhera, Gurgaon, Haryana, India.
E-mail: amitmds1980@rediffmail.com

ABSTRACT

Background: Selective removal or inhibition of pathogenic microbes with locally delivered antimicrobials, combined with scaling and root planning (SRP) is an effective approach for the management of chronic periodontitis. **Aim:** Evaluation of the efficacy of two commercially available controlled release drugs – tetracycline fibers (periodontal plus AB™) and chlorhexidine gel (CHLO-SITE™) as an adjunct to SRP in the treatment of chronic periodontitis. **Materials and Methods:** Twenty systemically healthy patients in the age group of 30-50 years suffering from generalized chronic periodontitis were selected. Three experimental sites were chosen that had probing depth 5-8 mm in maxillary and mandibular posterior segment. First site receiving tetracycline fibers, other chlorhexidine gel and one site was taken as control after SRP. Plaque score, bleeding score, probing pocket depth (PPD), and relative attachment level (RAL) gain were recorded on baseline, 1 month and at the end of 3 months. **Results and Conclusion:** In all groups, there was statistically highly significant reduction in all the clinical parameters that is plaque score, bleeding score, PPD, and RAL gain were seen at different time intervals. Inter-comparison shows that tetracycline fibers and chlorhexidine gel are equally efficacious for treatment of chronic periodontitis, but more efficient than SRP alone.

Key words
Chlorhexidine gel, local drug delivery, periodontitis, tetracycline fibers

INTRODUCTION

Periodontal diseases are a group of inflammatory microbial-induced infections involving the supporting tissues of the teeth: The gingiva, periodontal ligament, and alveolar bone.[1] Chronic periodontitis results in a progressive loss of attachment and formation of a periodontal pocket. The process of periodontal pocket formation represents the pathologic sequelae of microbial and inflammatory mediated degradation of collagenous connective tissue and alveolar bone.[2] Therefore, an objective of periodontal treatment is to suppress or eliminate putative subgingival periodontal pathogens.[1]

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The treatment offered to the patient by the clinician may be non-surgical, surgical or a combination of both. Non-surgical therapy includes both mechanical and chemotherapeutic approaches to minimize or eliminate the microbial biofilm.[3]

Thorough scaling and root planning (SRP) is required in order to prevent the recolonization of the subgingival area by periodontopathogens. However, mechanical therapy may fail to eliminate the pathogenic bacteria completely because of their location within the gingival tissues or in areas inaccessible to periodontal instrumentation.

The use of several antimicrobial agents started gaining prominence as chemical aids prevent early microbial recolonization ensuring, the best chance for clinical improvements. These chemical agents gain access into

the periodontal pocket through both systemic and local route of delivery. Since, systemic use of antibiotics may cause several side-effects, contemporary research is now focused on the role of topical/local antimicrobial agents in the treatment of periodontitis.[2]

Local antimicrobial therapy can be subclassified as "sustained release device" delivering the drug for less than 24 h and "controlled delivery device," releasing the agent over an extended period of time.

Goodson (1979) first proposed the concept of controlled delivery in the treatment of periodontitis.[4] The effectiveness of this form of therapy is that, it reaches the base of periodontal pocket and is maintained for an adequate time for the antimicrobial effect to occur. Periodontal pocket provides a natural reservoir bathed by gingival crevicular fluid that is easily accessible for the insertion of a delivery device.

Various agents have been used to prevent further progression of periodontal disease either as monotherapy or as an adjunct to SRP. These include tetracycline, doxycycline, minocycline, chlorhexidine; metronidazole, simvastatin, and alendronate have been administered in pure forms by their incorporation in mouthwashes, chewing gums, dentifrices, acrylic strips, hollow fibers, fibrillar collagen, films, ointments, gels etc.

In the present study, an attempt was made to evaluate the efficacy of two commercially available controlled release drugs – tetracycline fibers (periodontal plus AB™) and chlorhexidine gel (CHLO-SITE™) as an adjunct to SRP in the treatment of chronic periodontitis.

MATERIALS AND METHODS

Twenty systemically healthy patients suffering from generalized chronic periodontitis were selected among the patients visiting the Department of Periodontics, SGT Dental College, Hospital and research institute, Gurgaon (Haryana). Patients did not receive any surgical or non-surgical periodontal therapy in past 6 months and were not on any antibiotic therapy since past 6 months. Written informed consent was taken from each patient who participated in the study and ethical clearance was obtained from the Institutional Committee. For each subject, three experimental sites were chosen that had probing depth 5-8 mm in either maxillary or mandibular molars randomly.

Clinical parameters of all the selected sites were recorded and then SRP was carried out. Plaque score was brought down to zero and the same was confirmed by using a disclosing solution (Alpha Plac™) [Figure 1]

Root planning of selected teeth was carried out and selected sites were divided into three groups randomly:

Group A (Test): Tetracycline fibers (periodontal plus AB™) were inserted into the periodontal pocket until pocket was filled. COE-PAK™ was then applied for 10 days [Figure 2].

Group B (Test): Chlorhexidine gel (CHLO-SITE™) was applied directly from the syringe into the pocket. COE-PAK™ was then applied for 10 days [Figure 3].

Group C (Control): SRP was done.

Recording of various clinical parameters was carried out on day 0 (baseline) and subsequently at the end of 1 month and 3 months. The course of the study was of 3 months duration. The statistical analysis for periodontal parameters was carried out by using the paired *t*-test for comparison at two different time interval between the probing pocket depth (PPD) and relative attachment level (RAL). The periodontal parameters, plaque index (PI), and sulcus bleeding index (SBI) were assessed by using the Wilcoxon signed rank sum test between different time periods in the same group and Mann-Whitney U test for comparison of PI and SBI between different groups in different time periods.

Clinical parameters

1. PI (Silness and Loe, 1964) (PI)
2. PPD (using UNC 15 periodontal probe) (PPD)
3. SBI (Muhlemann and Son, 1971) (SBI)
4. RAL (Measurement using the customized acrylic stent) (RAL) [Figure 4].

Materials

Tetracycline fibers (periodontal plus AB™)

Tetracycline fibers (Periodontal Plus AB™) product contains 25 mg pure fibrillar collagen containing approximately 2 mg of evenly impregnated tetracycline hydrochloride in each individual vial. Periodontal Plus AB™ fibers are available in a box containing four individually packed and separable sterile product packs (vials).

Chlorhexidine gel (CHLO-SITE™ gel)

CHLO-SITE™ gel is a xanthan based 1.5% chlorhexidine gel containing 0.5% fast releasing Chlorhexidine gluconate and 1% in form of slow releasing chlorhexidine dihydrochloride. Xanthan is an optimum substrate for formation of a stable gel that is easily extruded from 0.5 ml syringe needle.

RESULTS

Intragroup comparison in tetracycline group reveals highly significant reduction in PI and SBI at baseline to 1 month and baseline to 3 month interval. In case of PPD and RAL, highly significant reduction in baseline to 1 month interval and baseline to 3 month interval and significant reduction in 1 month to 3 month interval was found [Table 1].

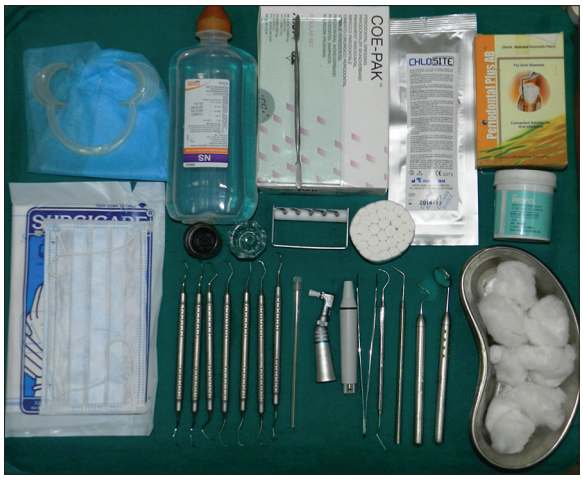

Figure 1: Armamentarium

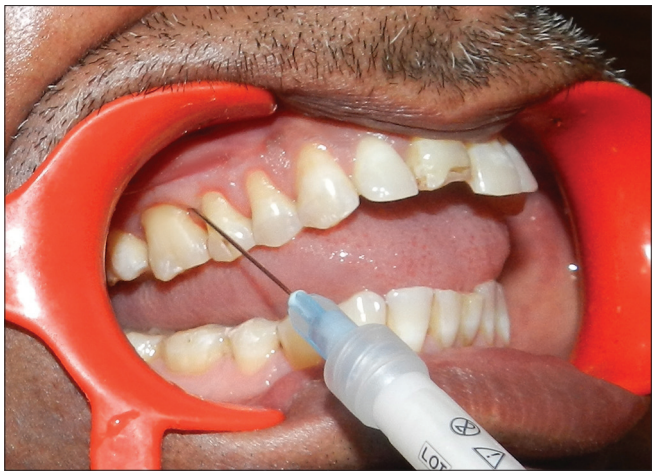

Figure 3: Insertion of CHLO-SITE gel

Intragroup comparison in chlorhexidine group reveals significant reduction in PI and highly significant in SBI at baseline to 1 month and baseline to 3 month interval. In case of PPD and RAL, highly significant reduction in the entire time intervals [Table 2].

Intragroup comparison in control group reveals significant reduction in PI and SBI at baseline to 1 month and baseline to 3 month interval. In case of PPD and RAL, highly significant reduction in all time intervals was found [Table 3].

Intergroup comparison of PI reveals no significant difference between tetracycline and chlorhexidine group at all-time intervals. At baseline, no significant difference was found between tetracycline and control, and chlorhexidine and control group, but significant difference was found at 1 month and 3 month interval [Table 4].

Intergroup comparison of SBI reveals no significant difference between tetracycline and chlorhexidine group at all-time intervals. At baseline, no significant difference was found between tetracycline and control, and chlorhexidine and control group, but significant difference was found at 1 month and 3 month interval [Table 5].

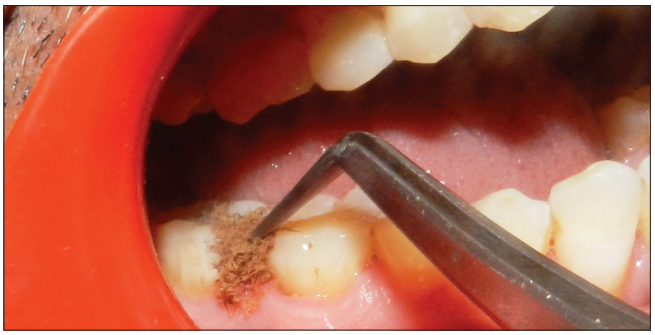

Figure 2: Insertion of periodontal AB plus fibers

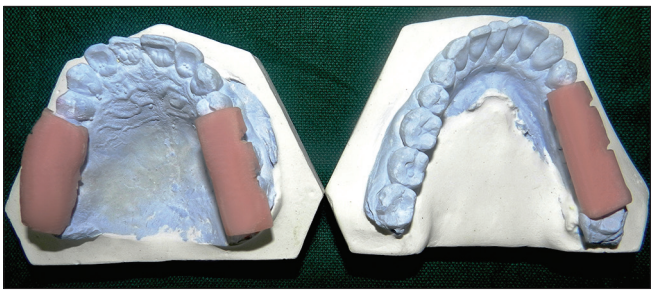

Figure 4: Fabricated customized acrylic stents

Table 1:Intragroup comparison at different time intervals in tetracycline group

Tetracycline	Baseline-1 month	Baseline-3 month	1 month-3 month
PImean reduction	0.60±0.5	0.55±0.51	−0.05±0.39
P value	0.001	0.001	0.564
SBI mean reduction	1±0.73	1±0.73	0.00±0.56
P value	<0.001	<0.001	1
PPD mean reduction	2.1±0.64	2.8±0.89	0.7±0.92
P value	<0.001	<0.001	0.003
RAL mean reduction	2.1±0.92	2.95±1.39	0.85±1.13
P value	<0.001	<0.001	0.003

PI – Plaque index; SBI – Sulcus bleeding index; PPD – Probing pocket depth; RAL – Relative attachment level

Table 2: Intragroup comparison at different time intervals in chlorhexidine group

Chlorhexidine	Baseline-1 month	Baseline-3 month	1 month-3 month
PI mean reduction	0.40±0.5	0.40±0.68	0.00±0.65
P value	0.005	0.021	1
SBI mean reduction	0.75±0.64	0.75±0.72	0.00±0.65
P value	0.001	0.001	1
PPD mean reduction	1.95±0.88	2.55±1.05	0.6±0.68
P value	<0.001	<0.001	0.001
RAL mean reduction	1.9±1.07	2.45±1.27	0.55±0.88
P value	<0.001	<0.001	0.012

PI – Plaque index; SBI – Sulcus bleeding index; PPD – Probing pocket depth; RAL – Relative attachment level

Intergroup comparison of PPD reveals no significant difference between tetracycline and chlorhexidine group at all-time intervals. At baseline, no significant difference was found between tetracycline and control, and chlorhexidine and control group, but significant difference was found at 1 month and 3 month interval [Table 6].

Intergroup comparison of RAL reveals no significant difference between tetracycline and chlorhexidine group at all-time intervals. At baseline, no significant difference was found between tetracycline and control, and chlorhexidine and control group, but significant difference was found at 1 month and 3 month interval [Table 7].

DISCUSSION

A periodontal disease essentially comprises a group of oral infections, whose primary etiological factor is dental plaque, which results in an inflammatory lesion in the supporting tissues. Removal of the cause (and its effects) is the primary aim of both non-surgical and surgical treatment regimens. The major non-surgical therapeutic approach involves mechanical SRP. Local delivery of antimicrobial agents is becoming more prevalent since it leads to higher concentration of the drug at the intended site of action using a lower dose, with an associated reduction in side effects relative to systemic administration. Local route of drug delivery provides direct access to the systemic circulation through the jugular vein bypassing the first pass hepatic metabolism leading to high bioavailability.[5]

In the present study, clinical parameters were recorded at 1 month as the bacterial flora is supposedly said to return to pre-treatment patterns after 3-6 weeks of SRP.[6] The 3 month interval was chosen because the effects of locally delivered chlorhexidine and tetracycline have been shown to be evident for 11 weeks after administration and also 3 months corresponds to typical recall interval for patients after periodontal treatment.[7]

Intragroup comparison

Tetracycline fibers

Reduction in PI score was statistically significant in tetracycline group. Reduction in supragingival plaque score in tetracycline fiber group could be attributed to chemical control of subgingival plaque by tetracycline fibers which could also have an inhibitory effect on supragingival plaque.[8]

Reduction in SBI score was statistically significant in the tetracycline group. The results are in accordance with studies conducted by Soares *et al.*, (2009).[9] Reduction in bleeding is due to resolution of gingival inflammation after SRP and well-known antimicrobial effect of tetracycline.[10]

Reduction in PPD and RAL score was statistically significant in tetracycline group. Similar reduction in PPD was recorded by Friesen *et al.*, (2002)[11] Perinetti *et al.*, (2004).[12] The improved gingival health may have contributed to the observed reduction of PPD, presumably by decreasing the edematous swelling of the marginal gingiva and/or by decreasing the penetrability of tissue by the probe as a result of an increase of collagen content.[13] These findings are in contrast with the result of Drisko *et al.*, (1995)[14] who observed no difference

Chlorhexidine gel

Reduction in PI score was statistically significant in chlorhexidine group. Lower PI scores observed in the present study may be the result of antiplaque and antibacterial role of chlorhexidine, which may have leaked out from the pockets and better oral hygiene practiced by the patients.[15] Similar observations were made by Vaidya

Table 3: Intragroup comparison at different time intervals in control group

Control	Baseline-1 month	Baseline-3 month	1 month-3 month
PI mean reduction	0.20±0.41	0.35±0.59	0.15±0.49
P value	0.046	0.02	0.18
SBI mean reduction	0.3±0.47	0.45±0.51	0.15±0.37
P value	0.014	0.003	0.083
PPD mean reduction	1.4±0.94	2.15±0.98	0.75±0.71
P value	<0.001	<0.001	<0.001
RAL mean reduction	1.25±0.55	2.35±0.93	1.1±1.02
P value	<0.001	<0.001	<0.001

PI – Plaque index; SBI – Sulcus bleeding index; PPD – Probing pocket depth; RAL – Relative attachment level

Table 4: Intergroup comparison in plaque index at different time intervals

PI	Baseline	1 month	3 month
Tetracycline versus chlosite	175.5	182	190
P value	0.449	0.485	0.317
Tetracycline versus control	180	109	140
P value	0.524	0.002	0.009
Chlosite versus control	156.5	129	150
P value	0.179	0.022	0.04

PI – Plaque index

Table 5: Intergroup comparison in sulcus bleeding index at different time intervals

SBI	Baseline	1 month	3 month
Tetracycline versus chlosite	187	165.5	170
P value	0.699	0.284	0.348
Tetracycline versus control	195.5	99.5	110
P value	0.895	0.003	0.008
Chlosite versus control	183	116	132.5
P value	0.616	0.014	0.043

SBI – Sulcus bleeding index

Table 6: Intergroup comparison in probing pocket depth at different time intervals

PPD	Baseline	1 month	3 month
Tetracycline versus chlosite	1.073	0.194	0.184
P value	0.29	0.848	0.855
Tetracycline versus control	0.777	2.884	3.069
P value	0.442	0.006	0.004
Chlosite versus control	1.726	3.722	2.911
P value	0.092	0.001	0.006

PPD – Probing pocket depth

Table 7: Intergroup comparison in relative attachment level at different time intervals

RAL	Baseline	1 month	3 month
Tetracycline versus chlosite	0.896	0.489	0.113
P value	0.376	0.628	0.91
Tetracycline versus control	0.784	2.269	2.056
P value	0.438	0.029	0.047
Chlosite versus control	1.589	2.852	2.217
P value	0.12	0.007	0.033

RAL - Relative attachment level

et al., (2011).[3] The results were however in contrast to the studies conducted by Azmak *et al.*, (2002).[16]

Reduction in SBI score was statistically significant in chlorhexidine group. Similar findings were noted by Rusu *et al.*, (2005).[17] Cationic chlorhexidine molecule is rapidly attracted by the negatively charged bacterial cell surface. After adsorption, the integrity of the bacterial cell membrane is altered, which results in a reversible leakage of bacterial low molecular-weight components at low dosage (bacteriostatic) or more severe membrane damage at higher dosage (bactericidal).[2]

Reduction in PPD and RAL score was statistically significant in chlorhexidine group. Similar findings were recorded by Vinholis *et al.*, (2001).[18] The reduction in the PPD can be attributed to the bactericidal concentrations achieved after administration of chlorhexidine gel at the selected sites.[15] These results were in accordance with the studies conducted by Vaidya *et al.*, (2011).[3]

Control

Reduction in PI score was statistically significant in control group. This change may be due to removal of bacterial deposits; moreover, improved plaque control by patients may have led to favorable subgingival microbial changes (Bollen and Quirynen 1996).[19] Similar observations were made by Checchi *et al.*, (1997).[20]

Reduction in SBI score was statistically significant in control group. In the present study, reduction in bleeding is due to resolution of gingival inflammation after removal of bacterial deposits by SRP.[10,19] Similar results were observed by Haffajee *et al.*, (1997).[21]

Reduction in PPD and RAL score was statistically significant in the control group. It is suspected that either a continued reorganization of the connective tissue permitting less probe penetration or coronally creeping attachment is responsible for this occurrence of changes.[22] Similar observations were made by Srivastava *et al.*, (2009).[2]

Intergroup comparison

PI

No significant difference in PI reduction was seen in between tetracycline fibers and chlorhexidine gel at baseline, 1 month and 3 months. Findings are in accordance with Unsal *et al.*, (1994)[10] who evaluated the effect of subgingivally placed 2% chlorhexidine gel and 10% tetracycline paste in periodontal pockets along with the SRP.

Significant reduction in PI reduction was seen in the tetracycline group and the control group at 1 month and 3 months. This reduction in supragingival plaque score could be attributed to chemical control of subgingival plaque by tetracycline fibers, which could also have an inhibitory effect on supragingival plaque.[23] Similar observations were made by Friesen *et al.*, (2002).[11]

Significant reduction in PI reduction was seen in chlorhexidine group and control group at 1 month and 3 months. Chlorhexidine from CHLO-SITE™ is released at a rapid and consistent rate during the 1st day, with concentration greater than 100 g/ml. This action continues for an average of 6-9 days, with total release rate equal to 85% of the total amount of chlorhexidine contained in CHLO-SITE™ gel. After the 9th day, the presence of chlorhexidine dihydrochloride assures a constant concentration, which is efficient and microbiologically active, for an additional week.[3] These results were in accordance with the results observed by Verma *et al.*, (2012).[15] The results were in contrast with those observed by Vinholis *et al.*, (2001).[18]

SBI

No significant difference in SBI reduction was seen in between tetracycline fibers and chlorhexidine gel at baseline, 1 month and 3 months. In the present study, reduction in SBI score in both the groups is due to resolution of gingival inflammation after SRP.[10]

Significant reduction in SBI was seen in tetracycline group and control group at 1 month and 3 months. Tetracycline offers better substantivity and good binding and/or penetration into root surfaces.[23] The results were in accordance with results observed by Sadaf *et al.*, (2012).[24]

Significant reduction in SBI was seen in chlorhexidine group and control group at 1 month and 3 months. This difference may be due to antiplaque and antibacterial role of chlorhexidine, which leaked out

of the periodontal pockets, which thereby reduced the gingival inflammation, resulting in reduced SBI.[15] The results were in contrast with the studies conducted by Azmak *et al.*, (2002).[16]

PPD

No significant difference in PPD reduction was seen in between tetracycline fibers and chlorhexidine gel at baseline, 1 month and 3 months. Reduction in PPD in both groups is due to resolution of gingival inflammation after SRP and to well-known antimicrobial effects of both locally delivered drugs.[15]

Significant reduction in PPD was seen in tetracycline group and control group at 1 month and 3 months. Similar observations were made by Banodkar and Rao (2011).[25] The benefits of tetracycline include not only bactericidal and bacteriostatic activity in periodontal disease, but also adsorption to dental surface and capacity to increase fibroblast attachment to root surface. These results were in contrast with the results observed by Wilson *et al.*, (1998).[26]

Significant reduction in PPD was seen in chlorhexidine group and control group at 1 month and 3 months. Higher improvement can be attributed to chlorhexidine, which is known to inhibit microbial proteases from potent periodontal pathogens. Chlorhexidine reduces PGE_2, which might be a causative factor for improvement of clinical parameters.[27] Similar results were observed by Vinholis *et al.*, (2001).[18]

RAL

No significant difference in reduction in RAL at baseline, 1 month and 3 months in tetracycline group and chlorhexidine group was seen.

Highly significant difference in reduction in RAL at 1 month and 3 months in tetracycline group and control group was observed. PPD might change from time to time even in untreated periodontal disease because of changes in gingival margin, while changes in level of attachment can be caused only by gain or loss of attachment and thus provide a better indication of the degree of periodontal destruction.[9] The findings were similar to Goodson *et al.*, (1991).[28]

Highly significant difference in reduction in RAL at 1 month and 3 months in chlorhexidine group and control group was observed. Similar results were observed by Vinholis *et al.*, (2001).[18] The results were however in contrast to the studies conducted by Azmak *et al.*, (2002).[16]

CONCLUSION

The results of the study shows that both local drug delivery agents with respect to SRP are equally competent and efficient in management of periodontal pockets and both materials were having good biological acceptability and were well-tolerated by all the patients during the course of the study. Within the limits of our study, it can be concluded that local delivery of tetracycline fibers and chlorhexidine gel is a safe and efficacious method along with SRP in the management of periodontal disease. However, further studies are advised with larger sample size, longer follow-up duration and confirmation with the microbiological analysis to overcome the drawbacks of the present study.

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