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Evaluation of commercially available biodegradable tetracycline fiber therapy in chronic periodontitis

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Abstract

Background:

Chronic periodontitis is an inflammatory disorder caused by dental plaque having mixed microbial flora. The different treatment modalities available to treat this disease are aimed at removal of micro-organisms from both hard and soft tissues. Systemic as well as local anti-microbial agents are helpful adjuncts in reducing microbes especially in inaccessible areas along with mechanical debridement therapy.

Materials and Methods:

The study was conducted in a split mouth design. Thirty-five patients having at least two non-adjacent sites in different quadrants with periodontal pockets ≥5 mm and with bleeding on probing at initial visit were selected. The selected sites were treated with both scaling and root planing plus tetracycline fibers or with scaling and root planing alone. Baseline and follow-up measurements included plaque index, gingival index, probing pocket depth, and clinical attachment level.

Result:

Both treatment modalities were affective in improving clinical parameters over three months' observation period. The combined antimicrobial and mechanical debridement therapy has shown better results as compared with scaling and root planing alone.

Conclusion:

Application of tetracycline in modified collagen matrix following scaling and root planing might be beneficial in treatment of chronic periodontitis and improving periodontal parameters for 3-month duration.

Keywords: Collagen, plaque index, probing pocket depth, tetracycline fibers

INTRODUCTION

Periodontal disease belongs to a group of inflammatory disorder whose pathogenesis is not well defined, although it is known that the interaction of host defense mechanisms and etiologic agents is an important determinant of the onset and progression of the disease. There is well-documented evidence that bacteria and their products found in dental plaque comprise the primary etiologic agents responsible for periodontal disease.[1–3]

The primary aim of nonsurgical as well as surgical treatment regimen is the removal of etiologic factor (i.e., plaque and calculus). Nonsurgical therapy, that is, scaling and root planing, may not always result in the complete elimination of etiologic factor because of poor access to the base of deep periodontal pocket and anatomical complexities which may occasionally limit the efficiency of root planing. It has also been suggested that residual bacteria in the dentinal tubules and soft tissues may repopulate the scaled teeth.[4]

Tetracyclines have been used extensively in the treatment of periodontal disease since many years. Tetracyclines are semi-synthetic chemotherapeutic agents which are bacteriostatic in action and hence are effective against rapidly multiplying bacteria. Tetracycline and its derivatives have been used systemically as well as locally in the treatment of periodontal disease. Local drug delivery avoids most of the problems associated with systemic therapy by limiting the drug to its target site with little or no systemic uptake.

Tetracycline have been incorporated into a variety of delivery systems (nonresorbable or bioresorbable) for insertion into periodontal pockets. These include hollow fibers (Goodson *et al*., 1979), ethylene vinyl acetate copolymer fibers (Goodson *et al*., 1983), ethyl cellulose fibers (Friedman and Golomb, 1982), acrylic strips (Addy *et al*., 1982), collagen preparations (Minabe *et al*., 1989), and hydroxypropyl cellulose films (Noguchi *et al*., 1984).[5]

Recently, new biodegradable local drug delivery system, Periodontal Plus AB™ (Advanced Biotech Products, Chennai, India), that is, tetracycline-impregnated fibrillar collagen that contains 25 mg pure fibrillar collagen containing approximately 2 mg of evenly impregnated tetracycline Hydrochloride (HCl) has been introduced for the treatment of gingival and periodontal diseases.

The present three-month study was designed to clinically compare the efficacy of tetracycline from modified collagen matrix used as combination therapy with scaling and root planing alone in the treatment of chronic periodontitis.

MATERIALS AND METHODS

A total of 35 human subjects consisting of both genders (male : female =16 : 19), aged between 35 to 60 years were selected from the outpatient department of periodontics. All the 35 subjects completed the 3-month follow-up study.

Study population

Inclusion criteria

1. Patients who had not undergone any surgical or nonsurgical periodontal therapy in the past 6 months.
2. Patients who had not taken antibiotic therapy in the past 6 months.
3. Patients able to follow verbal or written oral hygiene instructions.
4. Patients having two nonadjacent teeth separated by at least 1 tooth with ≥5 mm periodontal pocket that bleed on probing at the initial visit.

Exclusion criteria

1. Patients with a history of using antimicrobial mouthrinses within 2 months of the baseline visit or on routine basis.
2. Patients having history of allergy to tetracycline or cyanoacrylate adhesive.
3. Pregnant woman or nursing mothers.
4. Patients with periodontal packets in which the depth of the pockets corresponded to the apex of the tooth as in probable endodontic-periodontic conditions.
5. Medically compromised patients.
6. Teeth with furcation involvements.

Thirty-five subjects with a total of 70 sites were selected. The selected sites were randomly divided into test group and control group.

- Test group included 35 sites treated with local drug delivery and scaling and root planing.
- Control group included 35 sites treated with scaling and root planing alone (without local drug delivery).

Clinical parameters recorded

- Plaque Index (Silness and Loe)[6] at baseline, 1 month, 2 months, and 3 months post-therapy.
- Gingival Index (Loe and Silness)[7] at baseline, 1 month, 2 months, and 3 months post-therapy.
- Probing depth measurement from gingival margin to the base of pocket using William's graduated probe at baseline, 1 month, 2 months, and 3 months post-therapy.

Clinical attachment level measurement from cemento-enamel junction as a reference point to the base of pocket with William's graduated probe at baseline, 1 month, 2 months, and 3 months post-therapy.

Statistical methods

The baseline, 1 month, 2 months, and 3 months values were compared for changes that occurred over time, that is, changes in plaque index, gingival index, probing depth reduction, and clinical attachment gain. Probabilities less than 0.05 ($P<0.05$) were considered significant. Probabilities less than 0.001 ($P<0.05$) were considered highly significant. The paired *t* test and student t test were utilized to evaluate and establish differences between baseline and 1, 2, and 3 months values of test and control sites.

Tetracycline-impregnated fibrillar collagen This product consists of 25 mg of pure fibrillar Type-I collagen containing approximately 2 mg of evenly impregnated tetracycline Hydrochloride HCl, (United States Pharmacopeia) USP/IP. It is available as a strip containing four individually packed and separable sterile product packs. Just before placement, fibers were soaked with saline in a sterile dappen dish. Soaked fibers were placed at the prepared site and gently pushed inside the pocket, so that the material fills the depths and curves of the pocket. Hand pressure was applied for just a few minutes to encourage hemostasis and initial setting of the material inside the pocket. The site was sealed with cyanoacrylate adhesive to prevent ingress of oral fluids.

Post-treatment instructions

1. Avoid chewing hard or sticky food.
2. No flossing on the treated site.
3. Do not disturb the area with tongue, finger, or tooth pick.

4. To report immediately if the material is dislodged before the scheduled recall visit or if pain, swelling, or any other complication occurs.

RESULTS

The clinical finding at baseline, 1 month, 2 months, and 3 months postoperative are shown in Tables 1–4. At the start, there was no significant difference between both the treatment groups for the plaque index, gingival index, probing Pocket depth, and clinical attachment level ($P \leq 0.001$).

Table 3 and Figure 1 shows a gradual reduction in probing pocket depth both for test and control group, with more reduction in test group as compared with control group. Similarly, more gain in clinical attachment level in the test group as compared with control group is evident from Table 4 and Figure 2.

DISCUSSION

One essential goal of current periodontal therapy is successful management of the suspected bacterial pathogens to the extent that destruction of the periodontium is arrested. A number of different nonsurgical and surgical therapies have been successful in achieving this goal. Mechanical debridement with or without surgical manipulations, to disrupt the subgingival flora and to provide clean, smooth, and biological compatible roots surfaces, had been the therapy to treat periodontal diseases till the early 1970s. Mechanical therapy may however fail to eliminate the pathogenic bacteria because of their location within gingival tissues or in other areas inaccessible to periodontal instruments.[8]

The present study was designated to access the clinical efficiency of tetracycline-impregnated collagen fibers by demonstrating the changes in plaque index and gingival index, changes in probing pocket depth and clinical attachment level. A total of 35 patients (male:female=16:19) were enrolled in this study. Two interproximal sites with pocket depth ≥5 mm were selected in each patient in different quadrants.

Possible side effect of therapy including slight discomfort and gingival redness were evaluated. No treatment-related adverse effects were observed in any patient. Garret *et al*.[9] also reported that treatment emergent adverse events constituted ≤1% of the entire study population, with 0.2% of them showing allergic response.

In the present study, significant reduction in plaque score from baseline to 3 months for both treatment group ($P<0.001$) was observed. Similar observations were made by Minabe *et al*.,[10] Heijl *et al*.,[11] Mehta *et al*.,[5] and Friesen *et al*.[12] who found low levels of plaque index scores in this study from baseline, which could be due to a greater attention to oral hygiene practice by all selected participants throughout the study.

Similarly, gingival index also showed significant reduction in scores from baseline to 3 months for both treatment groups. Minabe *et al*.[10] and Mehta *et al*.[5] observed low levels of gingival index scores throughout the period of study.

Control of plaque and gingivitis is important in clinical studies because both vary in their association with periodontitis and both affect measured response to therapy; in this study, the reduction in plaque and gingival index may be due to thorough oral prophylaxis and proper home care by patients.

Since increased probing depth and loss of clinical attachment are pathognomonic for periodontitis, pocket probing is a crucial and mandatory procedure in diagnosing periodontitis and evaluating the success of periodontal therapy. In the present study, intragroup observation showed highly significant ($P< 0.001$) reduction in probing depth from baseline to 3 months in both groups.

On comparison, statistically significant differences were observed from baseline to 3 months between scaling and root planing alone and combination therapy. The results are consistent with the findings of Goodson *et al*.,[13] Minabe *et al*.,[10] Newman *et al*.,[14] Tonetti *et al*.,[15] and Mehta *et al*.[5] These

findings are in contrast with the result of Drisko *et al*.[16] who observed no significant difference among the different regimens at any point in time. This could be attributed to the fact that in the study by Drisko *et al*., [16] tetracycline fibers were placed in non-root planed sites and benefit of mechanical debridement was not obtained.

Newman *et al*.[14] quoted that patients tend to have approximately 1 mm reduction of probing depth on average, but in some cases, can have more dramatic effects, such as 2 mm or greater. It was similar to the findings of this study.

Goodson *et al*.[13] also observed that probing depth reduction was higher in combination therapy than scaled sites. Heijl *et al*.[11] in their comparative study also observed that there was significant pocket depth reduction in the combination therapy than scaling root planing alone.

A significant gain in clinical attachment level was also obtained from baseline to 3 months in both the treated sites ($P<0.001$); differences observed were similar to that of Goodson *et al*.,[13] Heijl *et al*.,[11] Minabe *et al*.,[10] Newman *et al*.,[14] Drisko *et al*.,[16] and Kinane and Radvar.[17]

On comparison, highly significant ($P<0.001$) difference was observed between combination therapy and scaling and root planing alone. This finding is similar to that of Goodson *et al*.,[13] Minabe *et al*.,[10] and Newman *et al*.[14]

Minabe *et al*.[10] found gain of clinical attachment level around 2 mm, and suggested that the local application of antibiotic using a local drug delivery in combination with root debridement may contribute to clinical attachment gain.

The finding of the study is in contrast with those of Drisko *et al*.[16] who found no significance among the different regimens at any time point. This could be due to reason as mentioned earlier.

The higher efficacy of the modified collagen matrix and tetracycline over scaling and root planing could be attributed to the availability of a modified collagen matrix to accelerate tissue restructuring, the sustained delivery of a potent drug (tetracycline) that eradicated periodontopathic microorganisms, and the ability of tetracycline to inhibit bacterial collagenases.

The reduction of probing depth and gain of clinical attachment were significant in all treatment groups. These improvements might simply reflect a change in tissue composition of periodontal tissues, rather than a true gain of new attachment.

Armitage *et al*. and Spray *et al*. have found that inflammation of the gingival tissue has a significant influence on the degree of probe penetration.[5] Improved gingival health may have contributed to the observed reduction of probing depth, 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.

The crux of the present study clearly shows that mechanical debridement and locally delivered tetracycline work by two different mechanisms. Scaling and root planing remove some amount of bacteria without providing bactericidal activity, whereas tetracycline does not remove any calculus deposits. Hence, none is the ideal control for the other. Together, locally delivered tetracycline therapy has a specific purpose of controlling localized infection, and scaling and root planning to remove calculus and other deposits, providing added benefits and the rate of new lesion formation is also decreased by the combination therapy.

CONCLUSION

1. Application of the tetracycline in modified collagen matrix following scaling and root planing might be beneficial in treatment of chronic adult periodontitis and improving periodontal parameters for 3-month duration.

2. Though the local drug delivery system used in the study is the safe and effective treatment modality, further clinical and microbiological studies are required to determine the effect of this treatment modality over long period.

3. Despite the proven additive benefits, the availability and cost associated with various controlled delivery devices (EVA fibers) have so far limited the application of tetracycline fibers. As this material is relatively cost effective and biodegradable, its use can be expanded in general population.

Footnotes

Source of Support: Nil

Conflict of Interest: None declared.

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Figures and Tables

Table 1

Mean values of plaque index at baseline, 1 month, 2 months, and 3 months postoperatively

	Test site		Control site	
Time interval	Mean±SD	Difference from baseline	Mean±SD	Difference from baseline
Baseline	2.49±0.32	–	2.46±0.31	–
1 month	1.61±0.43	0.88±0.32**	1.88±0.36	0.58±0.21**
2 month	1.06±0.43	1.43±0.37**	1.33±0.40	1.13±0.38**
3 month	0.67±0.41	1.81±0.41**	0.94±0.40	1.51±0.44**

** = *P*″0.001 – Highly significant

Table 2

Mean values of gingival index at baseline, 1 month, 2 months, and 3 months postoperatively

Time interval	Test site		Control site	
	Mean±SD	Difference from baseline	Mean±SD	Difference from baseline
Baseline	2.42±0.26	–	2.43±0.28	–
1 month	1.47±0.42	0.95±0.33**	1.92±0.25	0.51±0.19**
2 month	1.09±0.36	1.34±0.32**	1.53±0.25	0.90±0.26**
3 month	0.63±0.39	1.79±0.35**	1.15±0.27	1.28±0.28**

** = *P*′0.001 – Highly significant

Table 3

Mean values of pocket depth at baseline, 1 month, 2 months, and 3 months postoperatively

Time interval	Test site		Control site	
	Mean±SD	Difference from baseline	Mean±SD	Difference from baseline
Baseline	6.83±0.85	–	6.71±0.95	–
1 month	5.23±1.00	1.60±0.55**	5.69±0.99	1.03±0.38**
2 month	4.29±1.04	2.54±0.61**	5.29±0.78	1.43±0.50**
3 month	4.14±1.08	2.69±0.71**	5.14±0.73	1.57±0.65**

** = *P*″0.001– Highly significant

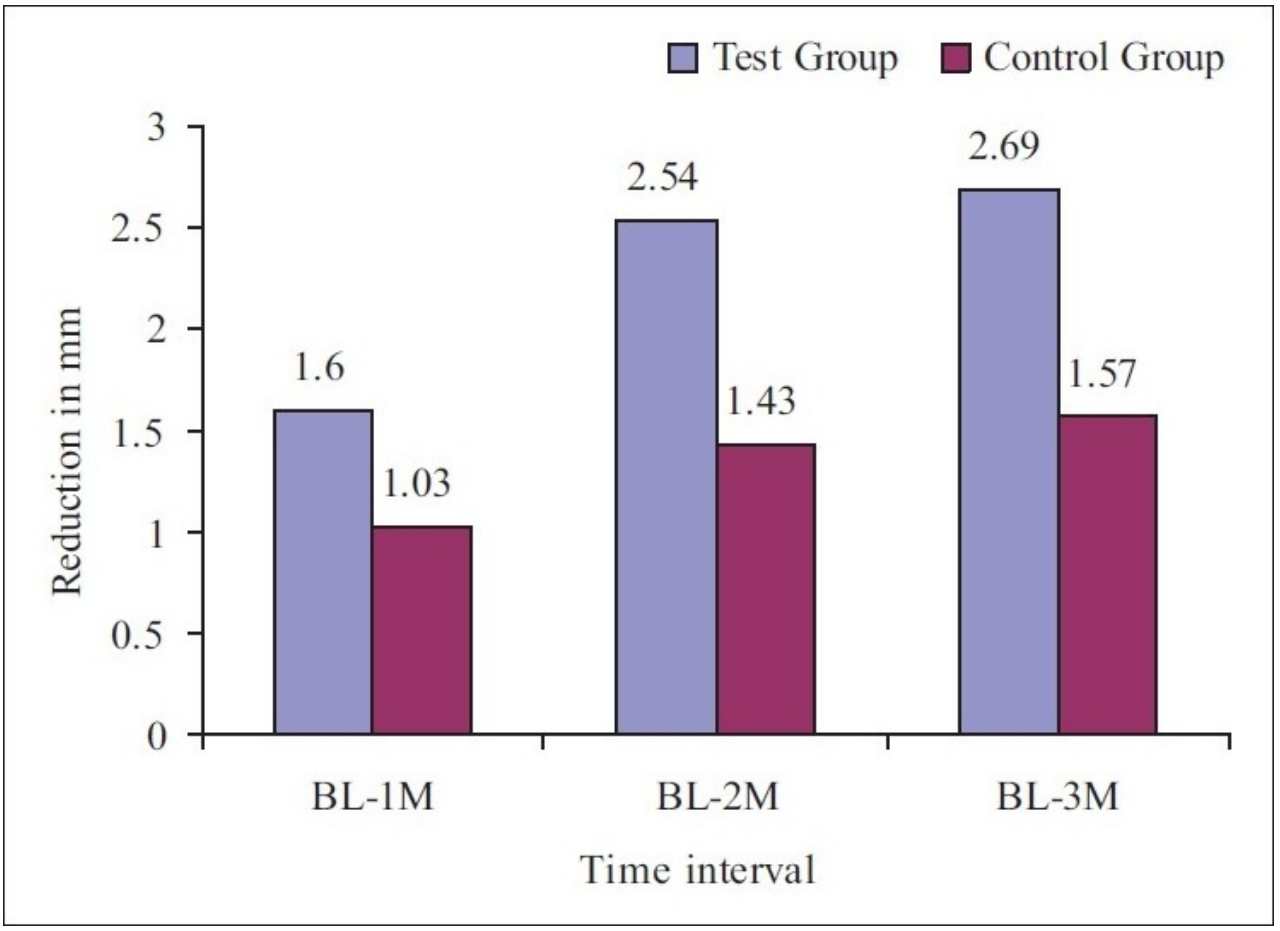
Table 4

Mean values of clinical attachment level at baseline, 1 month, 2 months, and 3 months postoperatively

Time interval	Test site		Control site	
	Mean±SD	Difference from baseline	Mean±SD	Difference from baseline
Baseline	7.31±1.10	–	7.29±1.04	–
1 month	6.20±1.23	1.11±0.47**	6.49±0.88	0.80±0.47**
2 month	5.69±1.32	1.63±0.77**	6.29±1.10	1.00±0.42**
3 month	5.43±1.21	1.89±0.63**	6.26±1.06	1.03±0.51**

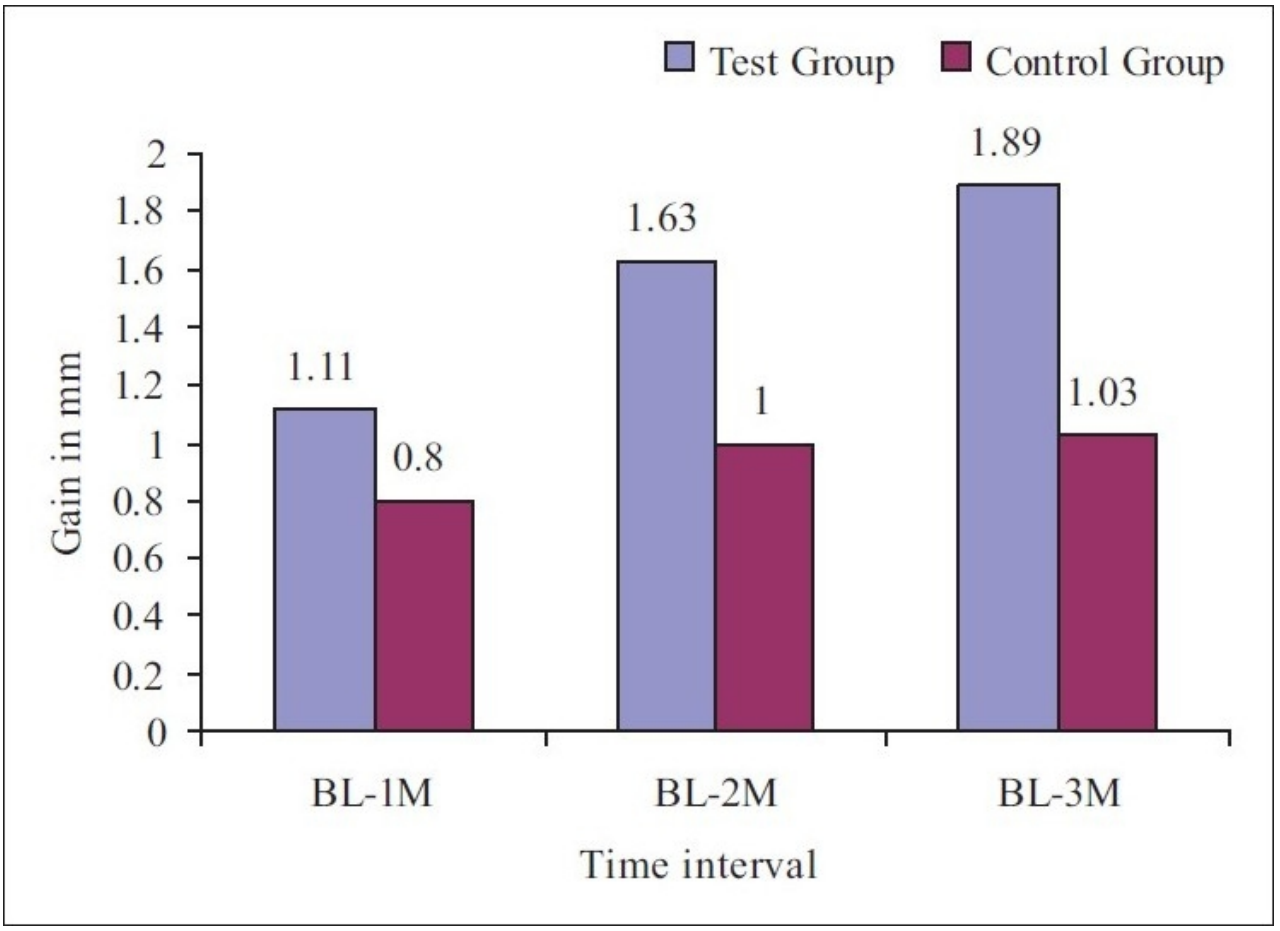
** = *P*″0.001 – Highly significant

Figure 1



Mean pocket depth reduction at different time interval

Figure 2



Mean clinical attachment gain at different time interval