Original Article

Tetracycline HCl-Loaded Fibers as Adjunct to Scaling and Root Planing

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Abstract

Background and Aim: Periodontal diseases are considered as infections of periodontium with a bacterial etiology, an immune response, and subsequent tissue destruction. Local delivery of antimicrobial agents in periodontitis entails antimicrobial therapy placed directly in periodontal pockets. Local drug delivery into the periodontal pocket is an effective treatment associated with mechanical debridement. The main goal of local drug delivery is to decrease periodontal pocket depth. Objective is to treat periodontal pocket using tetracycline fibers as well as comparing the results post-SRP (control group). **Material and Methods:** Thirty subjects (60 sites) were selected and were distributed randomly into Site A (SRP) and Site B (SRP + tetracycline fiber) based on inclusion and exclusion criteria. **Statistical Tests:** The relative efficacy of the two treatment modalities was evaluated using the paired Student's *t*-test, and the comparative evaluation between the two groups was done using repeated measure ANOVA. **Results:** Mean periodontal pocket score was less in test group (2.40 ± 0.49) than control group (2.83 ± 0.59) at 3 month time period. Statistically, significant difference was present in periodontal pocket score between test group and control group at 3 month time period. **Conclusion:** From the study, it can be concluded that tetracycline filled type I collagen fiber (Periodontal Plus AB) therapy enhances the benefits of scaling and root planing rather than SRP alone.

Keywords: Antimicrobial therapy, Collagenase, Periodontitis, Tetracycline

Introduction

Periodontitis is an inflammatory condition of the periodontium that may be brought on by more than 300 types of bacteria that are currently known to exist in the oral cavity. The ingredients that go into supragingival and subgingival plaque are very different from one another. Periodontal tissue degradation can occur either directly as a result of bacterial action on the tissue, which results in the breakdown of host tissues, or indirectly as a result of the release of biologic mediators from the host tissue cells, such as enzymes and chemical mediators, which cause host tissue degradation.[1]

Tetracyclines are exceptional since they are the only antibiotic class studied to far to attain gingival fluid levels that are 24 times greater than the blood levels. By improving fibroblast attachment, spreading, and conditioning of root surfaces as well as inhibiting collagenase activity, tetracyclines may promote regeneration or reattachment.[2] Antimicrobial therapy administered directly into periodontal pockets is known as local delivery of antimicrobial drugs in periodontitis. Any drug delivery system that aims to treat periodontal infections must be able to deliver antimicrobial agents at a bacteriostatic or bactericidal concentration to the base of the pocket to be effective. To secure an effective outcome, it must also make it easier for the medication to be retained.

Mechanical debridement combined with local medication administration into the periodontal pocket is a successful treatment. The medication, however, falls short of totally replacing traditional scaling and root planing.[3-7] The first locally accessible medication is a fiber that contains tetracycline[1]. Tetracycline is a bacteriostatic antibiotic that prevents the formation of bacterial proteins and reduces the action of tissue collagenase. To treat chronic periodontitis, tetracycline has been included into the controlled release polymer for subgingival delivery. One such product that has been examined in this study is periodontal plus AB, which includes tetracycline HCl 2 mg integrated into resorbable type I collagen fibers. The pros of this

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product include its effectiveness, simplicity of use, retention following application, and ability to resorb under periodontal pocket conditions.

In addition, the bioactive type I collagen used in its delivery promotes tissue regeneration into the pockets through conceivable cell signal transduction. Scaling and root planing therapy with tetracycline-filled type I collagen fiber (Periodontal Plus AB) therapy improves the advantages of scaling and root planing, which already offer adequate therapeutic levels as a helpful adjunctive treatment modality to improve periodontal health, including a decrease in probing pocket depth and an increase in clinical attachment level when compared to scaling and root planing alone.[2]

Materials and Methods

Source of data: The data for this study will be obtained from the outpatients department of Periodontics and Oral Implantology, Ahmedabad Dental College and Hospital. Thirty subjects (60 sites) were selected and were distributed randomly into Site A (SRP) and Site B (SRP + tetracycline fiber) based on inclusion and exclusion criteria. The treatment sites were divided into two groups by split-mouth technique in each patient.

Criteria for patient selection

Inclusion criteria

The following criteria were included in the study:

- Patient willing to sign consent form.
- Patients within the age group 30–55 years.
- Patient having chronic localized periodontitis.
- Patient having a probing pocket depth ≥5 mm.
- Patient free from systemic illness.

Exclusion criteria

The following criteria were excluded from the study:

- Pregnant and nursing patients
- Patient who are allergic to tetracycline.
- Patient who received antibiotic treatment 2 weeks before study.
- History or clinical signs of candidiasis.
- Patient who are inability to comply with the follow-up visit requirements.
- Heavy Smokers and Tobacco-users.

Informed consent procedure

The consent form is signed by the subjects before starting the study.

Clinical trial design

The patients were informed about the purpose and layout of the clinical trial, and their participation was granted with their agreement.

The split-mouth design used in the current investigation. With the exception of the third molars that required periodontal therapy, the patients who were chosen had at least two locations with a pocket depth of at least 5 mm in two quadrant. When employing a specially designed occlusal stent and the University of North Carolina (UNC) graduated pocket measurement probe, sites should have baseline probing depths of 5 mm or higher.

Table 1: Gingival index wise distribution

Time period	*n*	Gingival index, mean±SD	*P*
Baseline	30	2.35±0.54	≤0.001*
7 days	30	2.06±0.54	
15 days	30	1.89±0.55	
1 month	30	1.72±0.51	
3 months	30	1.50±0.50	

Level of significance $P \leq 0.05$, *Significant, **Non-significant. SD: Standard deviation

The split-mouth trial sites were randomly assigned to either the test (scaling and root planing + application of type I collagen fiber laced with tetracycline and advice on dental hygiene) or control (no treatment) (scaling and root planing alone). The chosen patients had their entire mouths scaled and root planned. For each of the experimental and control sites, a 20-min schedule was set aside for scaling and root planning. Piezoscales and Gracey area-specific curettes with a number 1–14 for root planning were used. In one site the periodontal pocket around the tooth at fiber therapy locations, type I collagen fibers containing 2 mg of tetracycline hydrochloride were inserted the day following scaling and root planing.

The pocket was filled with fibers all the way to the gingival edge. Per tooth, an average of 15 cm of fiber was used. The gingival edge and periodontal pack were positioned together, being careful not to disturb the fiber.

For 10 days, patients were told not to brush their fiber-treated teeth or eat items that were crusty. Following treatment, the patients were examined for fiber retention and any negative reactions on the 4th post-operative day. Ten days after the periodontal packs were initially inserted, they were taken out.

For each experimental site and control site, clinical parameters were evaluated at the following follow-up intervals: 0 day, 7, 15 days, 1 month, and 3 months.

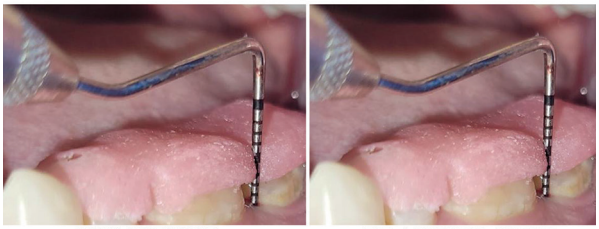
Clinical parameters

Clinical parameters were on Baseline, 7 days, 15 days, 1 month, and 3 months.

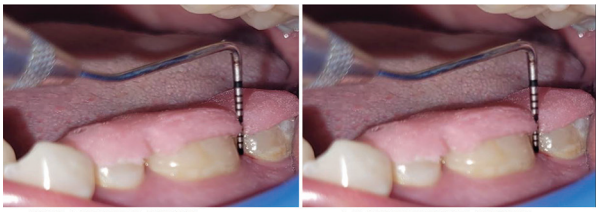
- Gingival index (Loe and Silness, 1963)
- Sulcus bleeding index (Mulhemann, 1958)
- Probing pocket depth.

TETRACYCLINE FIBRE PLACEMENT IRT 46

GROUP A (SRP ONLY)



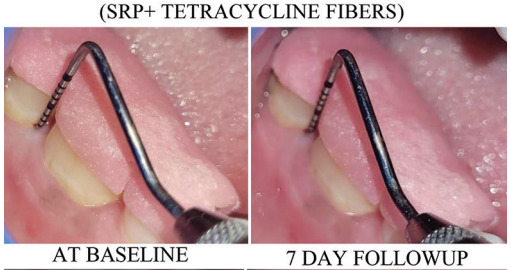
AT BASELINE 7 DAY FOLLOWUP



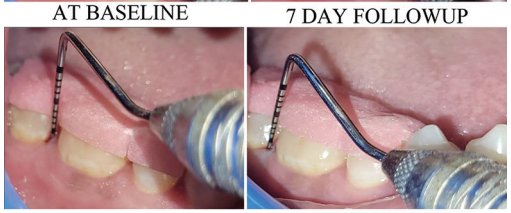
15 DAY FOLLOWUP 1 MONTH FOLLOWUP

3MONTH FOLLOWUP

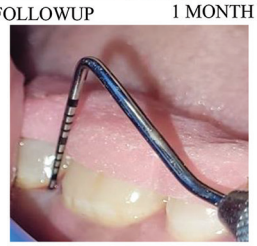
GROUP B
(SRP+ TETRACYCLINE FIBERS)



AT BASELINE 7 DAY FOLLOWUP



15 DAY FOLLOWUP 1 MONTH FOLLOWUP



3MONTH FOLLOWUP

Results

Mean gingival index score was 2.35 ± 0.54 at baseline, 2.06 ± 0.54 at 7 days, 1.89 ± 0.55 at 15 days, 1.72 ± 0.51 at 1 month, and 1.50 ± 0.50 at 3 months [Table 1]. Statistically, significant difference was present in change of gingival index score from baseline to 3 month time period

Table 2: Sulcus bleeding index wise distribution

Time period	Number	Sulcus bleeding index, mean±SD		*P*
Baseline	30	1.96	0.92	0.03*
7 days	30	1.00	0.58	
15 days	30	0.56	0.50	
1 month	30	0.43	0.50	
3 months	30	0.43	0.50	

Level of significance $P \leq 0.05$, *Significant, **Non-significant. SD: Standard deviation AQ4

Table 3: Periodontal pocket wise distribution in test group

Time period	*n*	Sulcus bleeding index, mean±SD	*P*
Baseline	30	4.57±0.50	0.01*
7 days	30	4.56±0.50	
15 days	30	3.36±0.49	
1 month	30	2.76±0.66	
3 months	30	2.40±0.49	

Level of significance $P \leq 0.05$, *Significant, **Non-significant. SD: Standard deviation AQ4

Table 4: Periodontal pocket wise distribution in control group

Time period	*n*	Periodontal pocket, mean±SD	*P*
Baseline	30	4.57±0.50	0.05*
7 days	30	4.56±0.50	
15 days	30	3.36±0.49	
1 month	30	2.96±0.66	
3 months	30	2.83±0.59	

Level of significance $P \leq 0.05$, *Significant, **Non-significant. SD: Standard deviation AQ4

Mean sulcus bleeding index score was 1.96 ± 0.92 at baseline, 1.00 ± 0.58 at 7 days, 0.56 ± 0.50 at 15 days, 0.43 ± 0.50 at 1 month, and 0.43 ± 0.50 at 3 months [Table 2]. Statistically, significant difference was present in change of sulcus bleeding index score from baseline to 3 month time period.

Mean periodontal pocket score was 4.57 ± 0.50 at baseline, 4.56 ± 0.50 at 7 days, 3.36 ± 0.49 at 15 days, 2.76 ± 0.66 at 1 month, and 2.40 ± 0.49 at 3 months. Statistically, significant difference was present in change of periodontal pocket score from baseline to 3 month time period in test group [Table 3].

Mean periodontal pocket score was 4.57 ± 0.50 at baseline, 4.56 ± 0.50 at 7 days, 3.36 ± 0.49 at 15 days, 2.96 ± 0.66 at 1 month, and 2.83 ± 0.59 at 3 months. Statistically, significant difference was present in change of periodontal pocket score from baseline to 3 month time period in control group [Table 4].

Statistically, no significant difference was present in periodontal pocket score between test group and control group at baseline, 7 days and 15 day time period. Mean periodontal pocket score was less in test group (2.76 ± 0.66) than control group (2.96 ± 0.66) at 1 month time period. Statistically, significant difference was present in periodontal

Table 5: Periodontal pocket wise distribution between test group and control group

Time period	Groups	Periodontal pocket, mean±SD	Difference	*P*
Baseline	Test group	4.5±0.50	0.000	1.000**
	Control group	4.5±0.50		
7 days	Test group	4.56±0.50	0.000	1.000**
	Control group	4.56±0.50		
15 days	Test group	3.36±0.49	0.000	1.000**
	Control group	3.36±0.49		
1 month	Test group	2.76±0.66	−0.20	0.024*
	Control group	2.96±0.66		
3 months	Test group	2.40±0.49	−0.433	0.002*
	Control group	2.83±0.59		

Level of significance $P \leq 0.05$, *Significant, **Non-significant. SD: Standard deviation

pocket score between test group and control group at 1 month time period.

Mean periodontal pocket score was less in test group (2.40 ± 0.49) than control group (2.83 ± 0.59) at 3 month time period. Statistically, significant difference was present in periodontal pocket score between test group and control group at 3 month time period [Table 5].

Discussion

Both total plaque control and the selective elimination or suppression of pathogenic microorganisms using either systemic or locally applied antibacterial medications can lessen the prevalence and severity of periodontal disease. Periodontitis is mostly treated by slowing the disease's progression, preventing recurrence, and attempting to regenerate or repair the lost or damaged tissue. Traditional methods of treatment involve mechanically removing bacterial plaque (by scaling and root planing) to get rid of or lessen the amount of periodontal infections.[8]

However, because bacterial pathogens may recolonize following therapy, the microbiologic effects of scaling and root planing rarely result in the total eradication of periodontal pathogens. To counteract the effectiveness of the standard treatment, antibacterial drugs were used as an adjuvant, either systemically or locally.[3] The use of a reservoir of a locally delivered antibiotic in the treatment of periodontitis is becoming more and more popular. When compared to systemic administration, they can achieve 100 times greater drug concentrations with substantially lower systemic interactions. The development of sophisticated subgingivally positioned controlled delivery systems was prompted by the limited usage of irrigation devices that are easily washed away.[8]

To treat chronic periodontitis, tetracycline has been included into the controlled release polymer for subgingival delivery. One such product that has been examined in this study is periodontal plus AB, which includes tetracycline HCl 2 mg integrated into resorbable type I collagen fibers.

The effectiveness, simplicity of application, retention following application, and ability to resorb under periodontal pocket conditions are the main benefits of this product. The bioactive type I collagen used in its delivery also encourages tissue regeneration into the pockets through conceivable cell signal transduction.[9] Tetracycline is released at bacteriostatic levels for at least 10 days following dosing, according to Periodontal Plus AB pharmacokinetic studies. Following application, each site displays an average tetracycline concentration in gingival fluid of 1546 ±125 mcg/mL during the first 10 days of treatment.[9,10]

On days 0, 15, 45, and 90 of the experimental period, the gingival index and bleeding index at the experiment and control sites were compared. The change in gingival index and Sulcus Bleeding Index scores between baseline and the 3-month period showed a significant difference. The test site experienced a greater reduction in bleeding than the control site, but both sites experienced highly significant changes in the gingival inflammation and bleeding on probing from the baseline. The clear reduction observed may be attributable to the patient adhering to dental hygiene instructions during the study period, regular follow-up visits, a decrease in pocket depth, and other factors. These results may be related to findings seen in numerous other studies that show.

Mean periodontal pocket score was less in test group (2.76 ± 0.66) than control group (2.96 ± 0.66) at 1 month time period. Statistically, significant difference was present in periodontal pocket score between test group and control group at 1 month time period. Mean periodontal pocket score was less in test group (2.40 ± 0.49) than control group (2.83 ± 0.59) at 3 month time period. Statistically, significant difference was present in periodontal pocket score between test group and control group at 3 month time period.

Conclusion

According to the above study, it can be concluded that tetracycline filled type I collagen fiber (Periodontal Plus AB) therapy enhances the benefits of scaling and root planing which provide adequate therapeutic levels as a beneficial adjunctive treatment modality to enhance periodontal health, namely, reduction in probing pocket depth as compared to scaling and root planing only. As evident from this study, it can be assumed

that tetracycline fiber therapy along with scaling and root planing is more effective than scaling and root planing alone. However, further long-term studies should be undertaken to obtain more clinical evidence for regular use of this material on clinical parameters for a larger sample. Local drug delivery systems with controlled release properties have the potential to be used as a therapeutic component in the management of periodontal diseases. However, additional randomized and controlled studies are needed to help delineate the types of lesions, periodontal diseases, or specific situations where local delivery systems would be most beneficial. It can be concluded that the adjunctive use of local drug delivery may provide a defined but limited beneficial response. However, the magnitude of change anticipated by combined therapy must be interpreted in light of the severity of the defects being treated.

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