Original Research Article

Clinical evaluation of the efficacy of two commercially available controlled-release drugs-chlorhexidine gel and tetracycline fibers as an adjunct to scaling root planning in the treatment of chronic periodontitis

Syed Saima Amin[1*], Neelam Saini[2], Suhail Majid Jan[3], Roobal Behal[4]

[1]Assistant Professor, [2]Postgraduate Scholar, [3]Professor & Head, [4]Associate Professor
Department of Periodontics & Oral Implantology, Govt. Dental College & Hospital, Karan Nagar, Shreenbagh, Srinagar, (190010) J & K, India
[*]Corresponding author email: **somsaliah52@rediffmail.com**

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Abstract

Background: Periodontal diseases are inflammatory, microbially induced conditions that damage the gingiva, periodontal ligament, and alveolar bone, leading to chronic periodontitis and pocket formation. SRP is the primary non-surgical therapy; mechanical cleaning alone may not fully eliminate deep or inaccessible bacteria. Local antimicrobial agents offer targeted drug delivery into periodontal pockets. Various controlled-release systems such as tetracycline and chlorhexidine have been developed to enhance clinical outcomes.

Aim: To evaluate and compare the effectiveness of tetracycline fibers (Periodontal Plus AB^{TM}) and chlorhexidine gel (HEXIGEL ®) as adjuncts to SRP in chronic periodontitis.

Materials and methods: Twenty systemically healthy patients aged 30–50 years with generalized chronic periodontitis were selected for the study. Three experimental sites with probing depths of 5–8

mm in the maxillary or mandibular posterior region were identified in each patient. One site received tetracycline fibers, another site was treated with 1% chlorhexidine gel, and the third served as the control following SRP. Plaque index, bleeding index, probing pocket depth (PPD), and relative attachment level (RAL) were recorded at baseline, 1 month, and 3 months.

Results: All three treatment groups showed statistically significant improvement in all clinical parameters (PI, SBI, PPD, and RAL) from baseline to 1 month and further to 3 months. Although the Tetracycline Fibre and Chlorhexidine Gel groups demonstrated the greatest numerical improvements, intragroup analysis confirmed that all treatment modalities were effective in improving periodontal health over the study period.

Conclusion: All three treatment approaches improved the clinical parameters of chronic periodontitis, but adding locally delivered tetracycline fibres or 1% chlorhexidine gel to scaling and root planing produced better clinical outcomes than scaling and root planing alone. Local antimicrobial delivery appears to be an effective adjunct to non-surgical periodontal therapy, although larger, long-term randomized controlled trials are needed to confirm its sustained efficacy.

Key words

Local Drug Delivery, Chlorhexidine Gel, Tetracycline Fibers, Chronic Periodontitis.

Introduction

Periodontal diseases represent a spectrum of inflammatory conditions of microbial origin that affect the tissues supporting the dentition, including the gingiva, periodontal ligament, and alveolar bone [1]. In its chronic form, periodontitis is characterised by progressive attachment loss and the consequent formation of periodontal pockets. This pocket formation is best understood as the pathological outcome of a dual process: direct bacterial insult and the host's own inflammatory response, both of which contribute to the breakdown of collagenous connective tissue and supporting bone.

The central aim of periodontal therapy, therefore, is to suppress or eradicate the specific subgingival pathogens implicated in disease progression [2]. As the aetiological significance of particular bacterial species in chronic periodontitis became better established, this understanding began to shape and consolidate more rational, targeted approaches to treatment. Clinical management may take a non-surgical, surgical, or combined approach, depending on disease severity and presentation. Non-surgical therapy typically integrates mechanical debridement with chemotherapeutic measures to disrupt the subgingival microbial biofilm [3]. Meticulous scaling and root planing (SRP) remains the cornerstone of this approach, as it is essential for preventing recolonisation of the subgingival environment by periodontopathogenic organisms.

Despite its central role, mechanical therapy alone is not always sufficient to eliminate pathogenic bacteria, particularly when organisms have invaded the gingival tissue itself or occupy sites that are difficult to access with conventional instrumentation. It is against this backdrop that antimicrobial agents have assumed increasing importance as chemotherapeutic adjuncts, valued for their ability to limit early bacterial recolonisation, thereby improving the likelihood of favourable clinical outcomes. Such agents may be delivered either systemically or locally, with local delivery further distinguished into "sustained-release" systems that act for less than twenty-four hours and "controlled-release" systems, designed to release the active agent gradually over a more extended period. The conceptual foundation for controlled drug delivery in periodontal therapy was first articulated by Goodson in 1979 [4]. The particular therapeutic value of this approach lies in its capacity to reach the base of the periodontal

pocket and to sustain adequate drug concentrations there for a duration sufficient to exert an antimicrobial effect. The periodontal pocket, continuously bathed in gingival crevicular fluid, offers a naturally accessible reservoir well suited to the placement of such delivery systems.

A range of agents have been employed, either as monotherapy or as adjuncts to SRP, in an effort to arrest the progression of periodontal disease like tetracycline, doxycycline, minocycline, chlorhexidine, metronidazole, and alendronate. These have been incorporated into diverse vehicles, including mouthwashes, chewing gums, dentifrices, acrylic strips, hollow fibres, collagen fibrils, films, ointments, and gels. The present study seeks to evaluate the clinical efficacy of two commercially available controlled-release preparations, tetracycline fibres (Periodontal Plus AB™) and chlorhexidine gel (Hexigel) when used as adjuncts to SRP in the management of chronic periodontitis.

Methodology

Twenty systemically healthy patients diagnosed with generalized chronic periodontitis were recruited from among those attending the Department of Periodontics, Government Dental College and Hospital, Srinagar. Eligibility was restricted to individuals who had not undergone any form of periodontal therapy (surgical or non-surgical) in the preceding six months, and who had not received antibiotic treatment during the same period. Prior to enrolment, written informed consent was obtained from each participant, and the study protocol received clearance from the Institutional Ethics Committee.

For every subject, three experimental sites were identified, each exhibiting a probing depth of 5–8 mm and located in either the maxillary or mandibular anterior region. Baseline clinical parameters were documented at each of these selected sites prior to treatment. (**Figure – 1, 2, 3**) Scaling and root planing was then performed at the chosen teeth, following which the experimental sites were randomly allocated into three groups (**Figure – 4**)

Group I (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.

Group II (Test): Chlorhexidine gel (Hexigel) was applied directly from the syringe into the pocket. COE-PAKTM was then applied for 10 days.

Group III (Test): Tetracycline fibers (periodontal plus ABTM) were inserted into the periodontal pocket until pocket was filled. COE-PAK was then applied for 10 days.

Clinical parameters

- Plaque Index (Silness and Loe, 1964) (PI)
- Probing pocket depth (using UNC 15 periodontal probe) (PPD)
- Sulcus bleeding index (Muhlemann and Son, 1971) (SBI)
- Relative Attachment level (Measurement using the customized acrylic stent) (RAL).

Materials Tetracycline fibers (periodontal plus AB) contain 25 mg pure fibrillar collagen containing approximately 2 mg of evenly impregnated tetracycline hydrochloride in each individual vial. Periodontal Plus ABTM fibers are available in a box containing four individually packed and separable sterile product packs (vials). 1 % Chlorhexidine gel (hexigel) that is easily extruded from 0.5 ml syringe needle. (**Figure – 5**)

Results

The Clinical Parameters (Plaque Index (PI), Sulcus Bleeding Index (SBI), Probing Pocket Depth (PPD) and Relative Attachment Level (RAL) were recorded at baseline, 1 month, and 3 months across the three study groups and

analysed using Stata statistical software. Descriptive statistics (mean ± SD) were calculated for each parameter by group and time point. A linear mixed-effects model with a random intercept for patient identity was used to assess the effects of group, time, and their interaction, and adjusted marginal means were plotted to visualise trends over time. Repeated-measures ANOVA, with Greenhouse-Geisser, Huynh-Feldt, and Box's corrections for sphericity, was additionally used to test within-group changes over time. A p-value < 0.05 was considered statistically significant.

Figure – 1: Clinical Parameters in Group I (Plaque Index, Sulcus Bleeding Index, Probing Depth, and Relative Attachment Level).

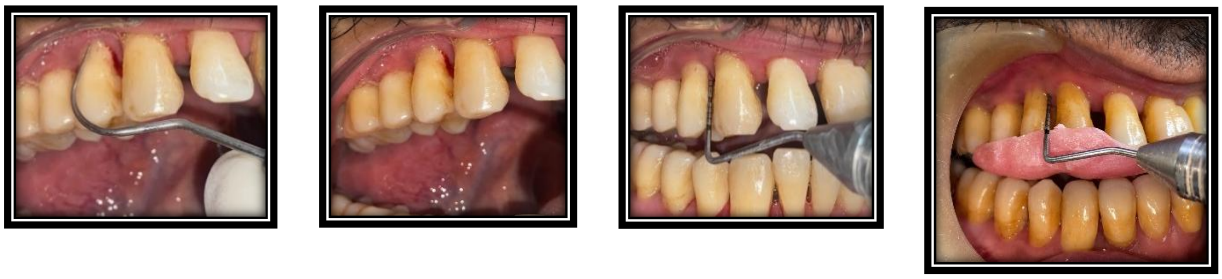


Figure – 2: Clinical Parameters in Group II (Plaque Index, Sulcus Bleeding Index, Probing Depth, and Relative Attachment Level).

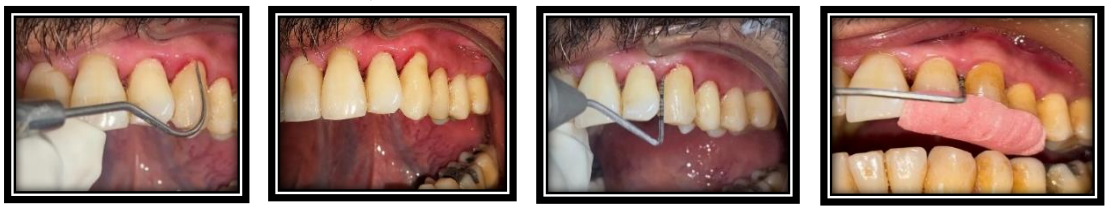


Figure – 3: Clinical Parameters in Group III Plaque Index, Sulcus Bleeding Index, Probing Depth, and Relative Attachment Level).

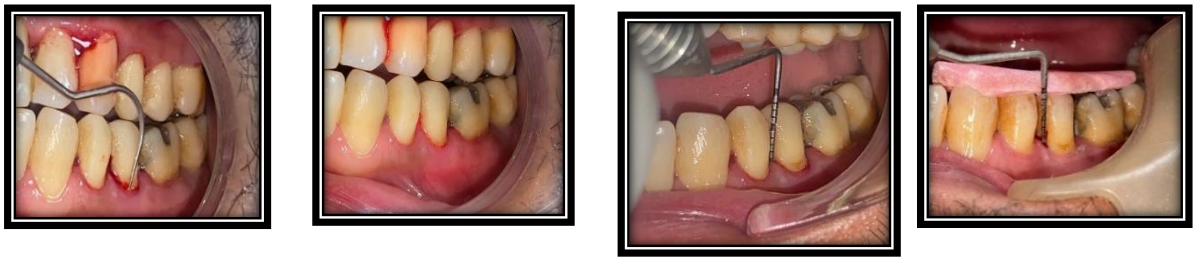


Figure – 4: Scaling and Root Planing in Group I, Chlorhexidine Gel Placement Group II and Tetracycline Fibers Placement in Group III).

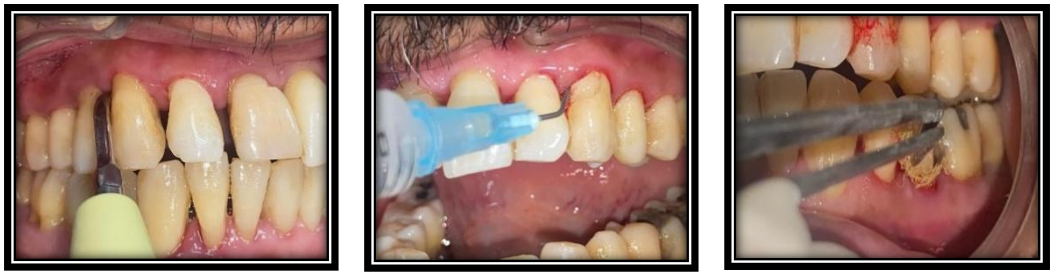
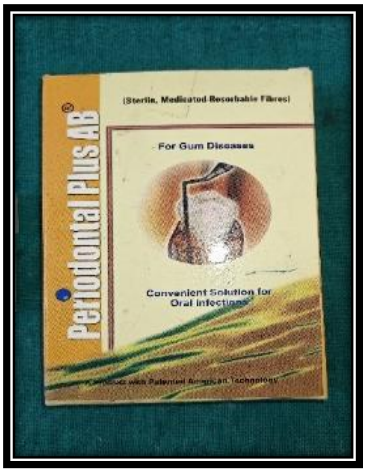
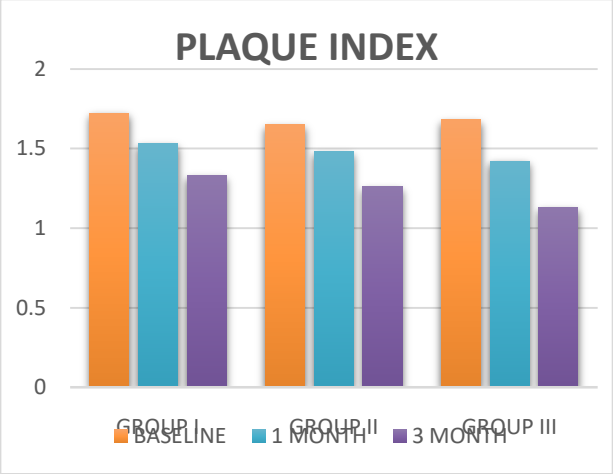
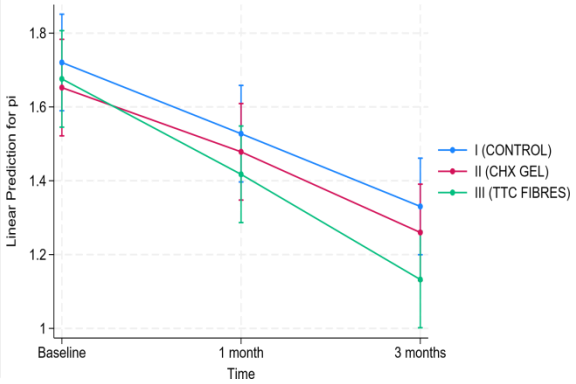


Figure – 5: Armamentarium: Ultrasonic scaler, 1% Chlorhexidine gel and Tetracycline Fibers.

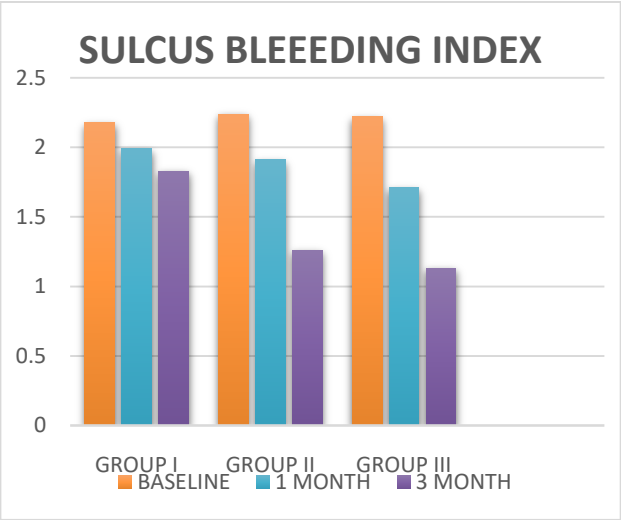


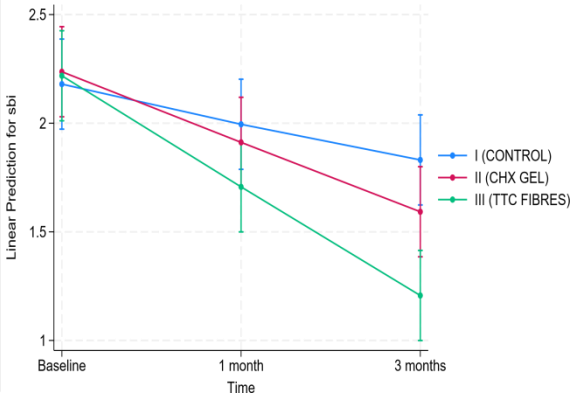
Graph – 1: Plaque Index (Intra and Intergroup Comparison in Group I, Group II and Group III).



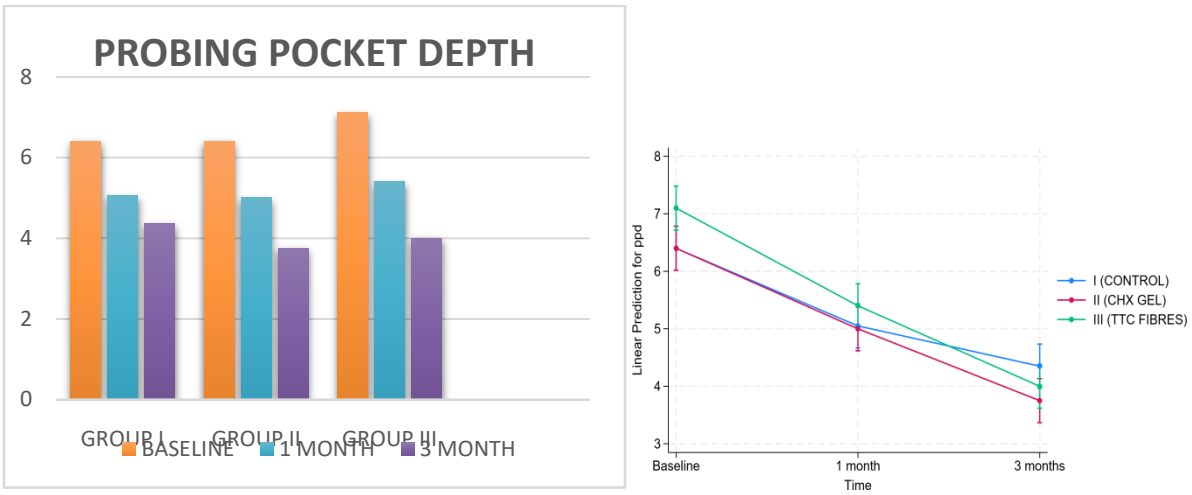


Graph – 2: Sulcus Bleeding Index (Intra and Intergroup Comparison in Group I, Group II and Group III).

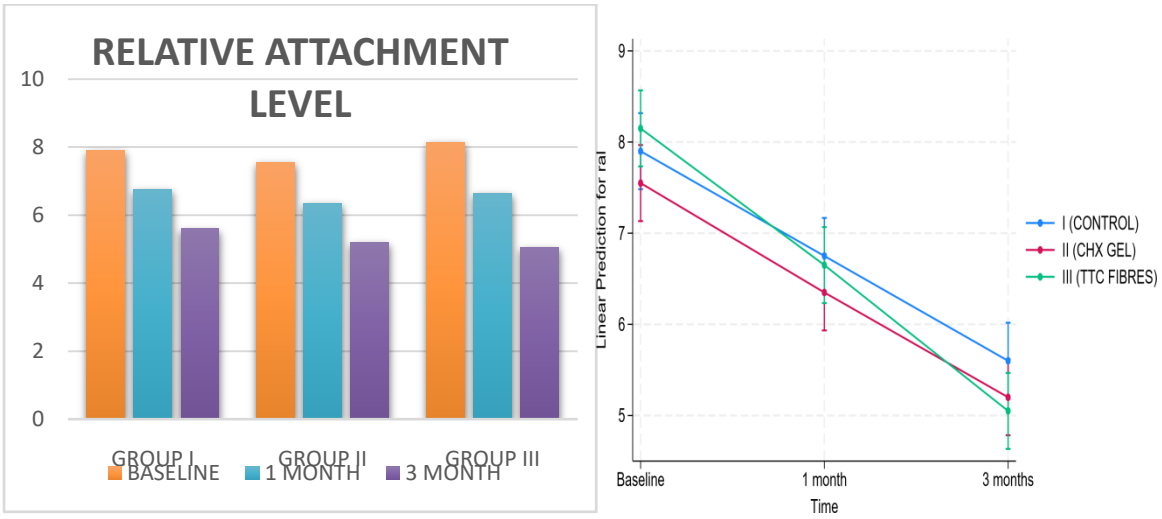




Graph – 3: Probing Pocket Depth (Intra and Intergroup Comparison in Group I, Group II and Group III).



Graph – 4: Relative Attachment Level (Intra and Intergroup Comparison in Group I, Group II and Group III).



Within-group analysis demonstrated that all three treatment groups showed statistically significant improvement in every clinical parameter throughout the study period. Plaque Index, Sulcus Bleeding Index, Probing Pocket Depth, and Relative Attachment Level all improved progressively from baseline to 1 month and further to 3 months. Numerically, the Tetracycline Fibre group and Chlorhexidine Gel group showed the greatest improvement in PI, SBI, PPD, and RAL. However, the statistical significance reported for the intragroup analysis indicates that each treatment modality was effective in improving periodontal health over time.

Discussion

Periodontal disease is a group of oral infections in which dental plaque is the principal etiological agent, giving rise to an inflammatory lesion within the tooth-supporting tissues. Both non-surgical and surgical treatment modalities share the same underlying objective: elimination of the causative agent and reversal of its effects. Among non-surgical approaches, mechanical scaling and root planing (SRP) remains the mainstay of therapy. Increasingly, however, local

delivery of antimicrobial agents has gained favour, as it enables a higher drug concentration to be achieved directly at the site of action while using a comparatively lower overall dose - thereby reducing the side effects typically associated with systemic administration. Notably, the local route allows the drug to enter systemic circulation via the jugular vein, bypassing first-pass hepatic metabolism and consequently achieving greater bioavailability [5].

In the present study, clinical parameters were assessed at the one-month mark, as the subgingival bacterial flora is generally understood to revert to its pre-treatment composition within three to six weeks following SRP [6]. The three-month interval, meanwhile, was selected because the therapeutic effects of locally delivered chlorhexidine and tetracycline have been shown to persist for approximately 11 weeks post-administration; this time point also aligns with the standard recall interval typically used for patients undergoing intragroup comparison.

The tetracycline fibre group demonstrated statistically significant improvements across all four clinical parameters (Plaque Index (PI), Sulcus Bleeding Index (SBI), Probing Pocket Depth (PPD), and Relative Attachment Level (RAL)). (**Graph – 1 to 4**) The reduction in PI can likely be explained by tetracycline's chemical suppression of subgingival plaque, along with its inhibitory action on supragingival plaque formation [7]. Similarly, the observed improvement in SBI appears to reflect the resolution of gingival inflammation achieved through the combined effect of scaling and root planing (SRP) and the antimicrobial properties of tetracycline. The significant decrease in PPD, together with the corresponding gain in RAL, may be attributed to a reduction in gingival inflammation and tissue edema alongside enhanced collagen synthesis both of which favour improved periodontal healing [8]. These outcomes align with the findings reported in earlier studies by Soares, et al. (2009) [9]; Friesen, et al. (2002) [10]; and Perinetti, et al. (2004) [11].

The chlorhexidine gel group also showed statistically significant improvements across PI, SBI, PPD, and RAL. (**Graph – 1 to 4**) The reduction in plaque scores may be explained by chlorhexidine's well-recognised antiplaque and antibacterial properties. The improvement in SBI, meanwhile, can be attributed to its bactericidal mechanism of action, which disrupts bacterial cell membranes and thereby helps reduce gingival inflammation [12]. Similarly, the reduction in PPD and the corresponding gains in RAL likely stem from chlorhexidine's sustained antimicrobial activity within the periodontal site, which supports and promotes periodontal healing. These findings are consistent with those reported by Rusu, et al. (2005) [12] and Vinholis, et al. (2001) [13].

The control group, treated with SRP alone, also showed statistically significant reductions in PI, SBI, PPD, and RAL. (**Graph – 1 to 4**) These improvements likely stem from effective removal of bacterial deposits and better patient oral hygiene, which together favourably altered the subgingival microbiota [14]. The reduction in bleeding reflects resolution of gingival inflammation following SRP, while improvements in PPD and RAL may be attributed to connective tissue reorganisation and coronal reattachment during healing. Similar findings have been reported by Checchi, et al. (1997) [15], Haffajee, et al. (1997) [16], and Srivastava, et al. (2009) [17].

On Intergroup comparison, it was observed that all three treatment modalities resulted in marked clinical improvement over the 3-month follow-up period. (**Graph – 1 to 4**) The addition of tetracycline fibres and chlorhexidine gel to conventional SRP produced greater numerical improvements than SRP alone [18, 19]. Among the adjunctive therapies, tetracycline fibres consistently showed the greatest overall

improvement, particularly in reducing gingival bleeding and improving clinical attachment, while chlorhexidine gel also demonstrated substantial benefits [20, 21]. Overall, the findings suggest that local drug delivery systems enhance the clinical outcomes of conventional periodontal therapy, with tetracycline fibres showing the most favorable overall clinical response.

Conclusion

Within the limitations of this study, all three treatment modalities significantly improved the clinical parameters of chronic periodontitis. However, adjunctive use of locally delivered tetracycline fibres and 1% chlorhexidine gel provided greater clinical benefits than scaling and root planing alone.

The study suggests that local antimicrobial delivery can effectively enhance the outcomes of conventional non-surgical periodontal therapy and may serve as a valuable adjunct in the management of chronic periodontitis. Nevertheless, further randomized controlled trials with larger sample sizes and longer follow-up periods are warranted to confirm the long-term clinical efficacy and sustainability of these treatment outcomes.

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