

Comparative evaluation of locally delivered tetracycline fibres and probiotics as an adjunct to non surgical periodontal treatment in patients with chronic periodontitis and type II diabetes - A clinical study

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Abstract

Patients with a long history of diabetes mellitus seem to have more periodontal breakdown than age-matched non-diabetic controls. Even though the mainstay of periodontal treatment is scaling and root planing, other treatment protocols such as systemic antimicrobials have been administered as adjuvants after scaling and root planing. Recently newer local drug delivery agents such as probiotics in the form of gels are being used as an

adjunct to scaling and root planing. The aim of study is to clinically evaluate and compare the efficacy of locally delivered tetracycline fibres and probiotics as an adjunct to non-surgical periodontal treatment in patients with Chronic Periodontitis and type II diabetes. A total of 60 almost similar contralateral sites in 30 type II diabetic patients, in the age group of 30-60 years, suffering from generalized Chronic Periodontitis visiting Punjab Government Dental College and Hospital, Amritsar were

selected and were then randomly divided into two groups. Clinical parameters assessed were Plaque Index, Sulcular Bleeding Index, Probing Pocket Depth and Clinical Attachment Level. After recording the clinical parameters at baseline, they were reassessed again at 45 days, at 3 months and at 6 months postoperatively. The data thus collected was recorded, compiled, tabulated and statistically analysed to arrive at the results. Both the treatment Groups yielded significant reduction in all the clinical parameters at different time intervals. However, on intergroup comparison, Group I showed statistically significant improvements pertaining to Probing Pocket Depth, Clinical Attachment Level and Sulcular Bleeding Index as compared to Group II.

Keywords: Chronic Periodontitis, Diabetes, Tetracycline Fibers And Probiotics.

Introduction

The most common type of periodontitis is chronic periodontitis, which typically exhibits the signs of a slowly worsening inflammatory disease. According to Newman and Carranza (2019), chronic periodontitis is "an infectious disease resulting in inflammation within the supporting tissues of teeth, progressive attachment loss, and bone loss." Multiple systemic disorders have been linked to inflammatory periodontal diseases.¹ Periodontal disorders have been suggested to have a biological connection to diabetes. Periodontitis has been ranked as the sixth diabetes complication.² The most successful treatment for bacterial load reduction, as well as removing any leftover plaque and calculus, is scaling and root planing (SRP). Recolonization is the main issue, despite the fact that this therapy initially sufficiently reduces the bacterial level.³ The use of systemic antibiotics to treat oral infections has greatly increased over the past 50 years. However, the majority of systemic antibiotics are linked to microbial resistance

due to their unintentional usage, inability to reach the infection site, inability to achieve appropriate concentration, and inadequate tissue penetration.⁴ Particularly in certain locations where conventional types of therapy may be unsuccessful, supplementary usage of LDD may have a positive result.⁵ The most widely utilised anti-microbial medications as local medication delivery system for the treatment of periodontal infections include tetracycline, its derivatives doxycycline and minocycline, and others.⁶ The use of probiotics as a helpful alternative to antibiotic therapy for the management of chronic periodontitis can help avoid the negative side effects of antibiotics.³ Treatment of diabetic individuals with periodontitis may greatly benefit from the introduction of local delivery of probiotics as an adjuvant to antibiotic therapy to enhance the healing response and clinical outcomes following conservative periodontal therapy.

To the best of our knowledge, there are no reported studies on the use of locally delivered tetracycline fibres along with probiotics as an adjunct in treatment of type II diabetic patients with Chronic Periodontitis. Therefore, the purpose of the present study was to clinically evaluate and compare the efficacy of tetracycline fibres and probiotics as an adjunct to non surgical periodontal treatment in patients with Chronic Periodontitis and type II diabetes.

Material And Method

In this randomized controlled split mouth study design, a total of 60 contralateral sites/surfaces in 30 type II diabetic patients, in the age group of 30-60 years (both male and female), suffering from generalized Chronic Periodontitis were selected.

Inclusion criteria

1. Well controlled type II diabetic patients based on criteria of American Diabetic Association 2013 and

glycated haemoglobin level with Probing Pocket Depth (PPD) \geq 5mm in teeth of posterior segment.

2. Patient with no history of periodontal therapy or use of antibiotic in the preceding six months.

3. Patients who were willing to take part in the study and were not a part of any other study.

Exclusion criteria

1. Patient with bleeding disorders, rheumatic heart disease, congenital heart disease & prosthetic valve.

2. Patient with known or suspected allergy to the tetracycline group or any related antimicrobials.

3. Patient using any medicated toothpaste or antimicrobial mouthwash.

4. Smokers, alcoholics and Immunocompromised patients.

6. Pregnant and lactating mothers

Clinical parameters

1. Plaque Index [Quigley Hein and Elliot Plaque Index (1962) was used to measure plaque score]

2. Sulcular Bleeding Index (S.B.I.) [Papillary bleeding index by Muhlemann H.R. (1977) was used to assess presence or absence of bleeding on probing]

3. Probing Pocket Depth (P.P.D.) [assessed by the use of a calibrated periodontal probe and customised acrylic occlusal stents]

4. Clinical Attachment Level (C.A.L.) [assessed by the use of a calibrated periodontal probe and customised acrylic occlusal stent]

All the clinical parameters were measured at baseline, 45 days, 3 months and 6 months post operatively.

Study Design

After recording the clinical parameters at baseline, full mouth supragingival and subgingival scaling and root planing of each selected subject was performed. The selected 60 almost similar contralateral sites, in a split

mouth study design were then randomly divided into two groups as follows -

Group I: It included 30 sites that were treated with scaling and root planing followed by local drug delivery of tetracycline fibres along with probiotic gel.

Group II: It included 30 sites that were treated with scaling and root planing followed by local drug delivery of tetracycline fibres.

Method of local drug delivery administration

After recording clinical parameters at baseline, Group I and Group II were then treated as follows -

Group I – After performing full mouth scaling and root planing procedure, the selected sites were treated with local drug delivery of 10 mg of tetracycline fibers coated with probiotic gel subgingivally into the pocket with the help of ball end of a Community Periodontal Index of Treatment Needs (CPITN) probe. For the probiotic gel preparation, the powder within the probiotic capsule was mixed with Tragacanth powder and saline. Probiotic capsules comprising of lactobacillus acidophilus and lactobacillus rhamnosus 0.60 billion colony-forming units (CFU) each, bifidobacterium bifidus and bifidobacterium longum 0.60 billion CFU) mixed with Tragacanth gum powder (0.04 mg of probiotic powder which was mixed with 0.02 mg of TG powder plus 0.2 ml of saline).⁷

Group II - After performing full mouth scaling and root planing procedure, the selected sites were treated with local drug delivery of 10 mg of tetracycline fibers mixed with 0.2 ml of saline subgingivally into the pocket with the help of ball end of a Community Periodontal Index of Treatment Needs (CPITN) probe.

In both the groups, just after the administration of local drug delivery, firm pressure was applied with fingers at the entrance of the pocket and the material was stabilized within the pocket. Periodontal dressing (Coe Pak) was

applied in both Group I and Group II. Subjects were recalled after one week for removal of the periodontal dressing.

Statistical analysis

At various times, the two groups' mean values and standard deviations for PI, SBI, PD and CAL were computed. Paired "t-tests" were used to compare values within the group, and student "t-tests" were used to compare values across groups. When $P < 0.05$, results were deemed statistically significant. All clinical parameters were assessed at baseline and again at 45 days, at 3 months and at 6 months postoperatively.



Figure 3: Periodontal dressing placed



Figure 1: Mixing of Tetracycline fibres with Probiotic gel



Figure 4: Mixing of Tetracycline fibres with Saline



Figure 2: Tetracycline fiber + Probiotic gel being inserted into periodontal pocket



Figure 5: Tetracycline fiber being inserted into periodontal pocket



Figure 6: Periodontal dressing placed

Results And Discussion

In the present study, mean Plaque Index score of Group I was 3.35 ± 0.79 at baseline 2.50 ± 0.77 at 45 days, 2.23 ± 0.72 at 3 months and 2.08 ± 0.71 at 6 months. Reduction in mean Plaque Index score from baseline to 45 days was 0.85 ± 0.33 , from baseline to 3 months was 1.12 ± 0.34 , from baseline to 6 months was 1.27 ± 0.41 , from 45 days to 3 months was 0.27 ± 0.25 , from 45 days to 6 months was 0.42 ± 0.40 found to be statistically significant whereas reduction in mean Plaque Index score from 3 months to 6 months was 0.15 ± 0.27 which was found to be statistically non-significant. These results are in accordance with the observations made by **Boyeena et al. (2020)**⁷, where 10 sites were treated with SRP along with subgingivally delivered probiotic gel along with tetracycline fibers in systemically healthy patients. To the best of our knowledge no similar study has been done in type II diabetic patients suffering from Chronic Periodontitis.

The mean Plaque Index score of Group II was 3.38 ± 0.86 at baseline, 2.63 ± 0.78 at 45 days, 2.33 ± 0.72 at 3 months and 2.13 ± 0.75 at 6 months. The reduction in mean Plaque Index score of Group II from baseline to 45 days was 0.75 ± 0.29 , from baseline to 3 months was 1.05 ± 0.42 , from baseline to 6 months was 1.25 ± 0.58 , from 45 months to 3 months was 0.30 ± 0.28 and from

45 days to 6 months was 0.50 ± 0.42 found to be significant whereas reduction in mean Plaque Index score and from 3 months to 6 months was 0.20 ± 0.28 which was found to be nonsignificant. A similar beneficial effect was reported with the use of locally administered tetracycline fibers along with non surgical periodontal therapy in studies conducted by **Flemming et al. (1996)**⁸ and **Sakellari et al. (2005)**⁹. In a study where effects locally delivered tetracycline fibers in the treatment of Chronic Periodontitis was evaluated by **Kafle, Pradhan and Gupta (2018)**¹⁰ higher percentage reduction in plaque score in test sites during subsequent follow up visits was seen.

On intergroup comparison, the difference in mean Plaque Index score reduction of **Group I** and **Group II** between baseline and 45 days was 0.10 ± 0.08 (non-significant), between baseline and 3 months was 0.07 ± 0.01 (non-significant), between baseline and 6 months was 0.02 ± 0.13 (non-significant), between 45 days and 3 months was 0.03 ± 0.07 (nonsignificant), between 45 days and 6 months was 0.08 ± 0.10 (nonsignificant) and between 3 months and 6 months was 0.05 ± 0.07 (nonsignificant) respectively. Thus, in **Group I** and **Group II**, reduction in supragingival plaque score at subsequent time periods could be attributed to good oral hygiene practiced by the patients during entire study period **Jeong et al. (1994)**¹¹.

Mean Sulcular Bleeding Index score in **Group I** was 3.18 ± 0.73 at baseline, 2.40 ± 0.69 at 45 days, 2.00 ± 0.57 at 3 months and 1.83 ± 0.49 at 6 months. Reduction in mean Sulcular Bleeding Index score from baseline to 45 days was 0.78 ± 0.25 , from baseline to 3 months was 1.18 ± 0.31 , from baseline to 6 months was 1.35 ± 0.39 , from 45 days to 3 months was 0.40 ± 0.20 , from 45 days to 6 months was 0.57 ± 0.31 and from 3 months to 6 months was 0.17 ± 0.24 which were all statistically

significant. To the best of our knowledge no similar study has been done in type II diabetic patients, however similar observations were obtained by **Boyeena et al. (2020)**⁷ where 10 sites were treated with SRP along with subgingivally delivered probiotic gel and tetracycline fibers in systemically healthy patients.

The beneficial effect of local drug delivery of probiotics in reducing Sulcular Bleeding Index in accordance with the study done by **Twetman et al. (2009)**¹² who studied the benefit of a chewing gum containing two strains of *L. reuteri* and found that the pro-inflammatory cytokines such as interleukin 1 β , tumor necrosis factor α , and IL-8 in GCF were decreased by this probiotic therapy. Mean Sulcular Bleeding Index score in **Group II** was 3.27 ± 0.61 at baseline, 2.72 ± 0.58 at 45 days, 2.52 ± 0.48 at 3 months and 2.32 ± 0.45 at 6 months. Mean reduction in Sulcular Bleeding Index score from baseline to 45 days was 0.55 ± 0.24 , from baseline to 3 months was 0.75 ± 0.25 , from baseline to 6 months was 0.95 ± 0.36 , from 45 days to 3 months was 0.20 ± 0.28 , from 45 days to 6 months was 0.40 ± 0.38 and from 3 months to 6 months was 0.20 ± 0.25 which were all statistically significant. Similar observations were made in the study conducted by

Panwar and Gupta (2009)¹³. A similar beneficial effect has been reported with the use of locally administered tetracycline fibers in conjugation with scaling and root planing in a study conducted by **Sadaf et al. (2012)**. **Maiden et al. (1991)**¹⁴ reported that *in vitro* testing has shown probable periodontal pathogens including *P. gingivalis*, *Fusobacterium nucleatum*, *P. intermedia*, *Eikenella corrodens*, *Wolinella recta*, and *A. actinomycetemcomitans* are susceptible to local tetracycline concentrations achieved in periodontal pocket with a controlled release device. Therefore, tetracycline is suitable to local delivery and as adjuncts

to mechanical therapy in management of periodontal disease. On intergroup comparison, the difference in reduction of mean Sulcular Bleeding Index score was more in Group I as compared to Group II at all the time intervals.

The difference in mean Sulcular Bleeding Index score reduction of Group I and Group II between baseline and 45 days was 0.23 ± 0.01 (significant), between baseline and 3 months was 0.43 ± 0.05 (significant), between baseline and 6 months was 0.50 ± 0.04 (significant), between 45 days and 3 months was 0.20 ± 0.08 (significant), between 45 days and 6 months was 0.17 ± 0.07 (significant) and between 3 months and 6 months was 0.03 ± 0.01 (non-significant) respectively. The results are in accordance with the observations made by **Boyeena et al. (2020)**⁷ where 10 sites were treated with SRP along with subgingivally delivered probiotic gel and tetracycline fibers in systemically healthy patients. To the best of our knowledge, no similar study has been done in type II diabetic patients suffering from Chronic Periodontitis.

Mean Probing Pocket Depth in Group I (scaling and root planing followed by local drug delivery of tetracycline fibres along with probiotic gel) was 5.45 ± 0.11 at baseline, 4.72 ± 0.12 at 45 days, 4.05 ± 0.11 at 3 months and 3.75 ± 0.12 at 6 months. Mean reduction in Probing Pocket Depth from baseline to 45 days was 0.73 ± 0.34 , from baseline to 3 months was 1.40 ± 0.33 , from baseline to 6 months was 1.70 ± 0.54 , from 45 days to 3 months was 0.67 ± 0.27 , from 45 days to 6 months was 0.97 ± 0.52 and from 3 months to 6 months was 0.30 ± 0.38 which were all statistically significant. The results are in accordance with the observations made by **Boyeena et al. (2020)**⁷, where 10 sites were treated with SRP along with subgingivally delivered probiotic gel along with tetracycline fibers in systemically healthy

patients. To the best of our knowledge no similar study has been done in type II diabetic patients suffering from Chronic Periodontitis.

The beneficial effect of local drug delivery of probiotics in reducing Probing Pocket Depth is in agreement with the results of a recent study by **Penala et al. (2016)**¹⁵, which evaluated the efficacy of local use of probiotic in the form of subgingival delivery and found that the adjunctive use of probiotics with scaling and root planing resulted in overall pocket depth reduction. Mean Probing Pocket Depth in **Group II** (Scaling and root planing followed by local drug delivery tetracycline fibers) was 5.67 ± 0.67 at baseline, 5.30 ± 0.69 at 45 days, 4.88 ± 0.73 at 3 months and 4.62 ± 0.74 at 6 months. Mean reduction in Probing Pocket Depth from baseline to 45 days was 0.37 ± 0.26 , from baseline to 3 months was 0.78 ± 0.28 , from baseline to 6 months was 1.05 ± 0.33 , from 45 days to 3 months was 0.42 ± 0.19 , from 45 days to 6 months was 0.68 ± 0.33 and from 3 months to 6 months was 0.27 ± 0.31 which were all statistically significant. The results are in accordance with the observations made by **Goncalves et al. (2004)**¹⁶ and **Kinane et al. (1998)**¹⁷. Similar results were reported by **Navarro-Sanchez et al. (2007)**¹⁸ and **Cruz et al. (2008)**¹⁹.

On intergroup comparison, difference in mean Probing Pocket Depth reduction was more in Group I as compared to Group II at all the time intervals. The difference in mean Probing Pocket Depth reduction of Group I and Group II between baseline and 45 days was 0.36 ± 0.08 (significant), between baseline and 3 months was 0.62 ± 0.05 (significant), between baseline and 6 months was 0.65 ± 0.20 (significant), between 45 days and 3 months was 0.25 ± 0.08 (significant), between 45 days and 6 months was 0.29 ± 0.19 (significant) and between 3 months and 6 months was 0.03 ± 0.07 (non-

significant) respectively. The results are in accordance with the observations made by **Boyeena et al. (2020)**⁷, where 10 sites were treated with SRP along with subgingivally delivered probiotic gel along with tetracycline fibers in systemically healthy patients. To the best of our knowledge, no similar study has been done in type II diabetic patients suffering from Chronic Periodontitis.

Mean Clinical Attachment Level in **Group I** (scaling and root planing followed by local drug delivery of tetracycline fibres along with probiotic gel) was 6.66 ± 0.64 at baseline, 5.90 ± 0.67 at the end of 45 days, 5.23 ± 0.63 at the end of 3 months and 4.92 ± 0.72 at the end of 6 months. Mean gain in Clinical Attachment Level from baseline to the end of 45 days was 0.73 ± 0.34 , to the end of 3 months was 1.40 ± 0.33 , to the end of 6 months was 1.72 ± 0.55 , from 45 days to 3 months was 0.67 ± 0.27 , from 45 days to 6 months was 0.98 ± 0.55 and from 3 months to 6 months was 0.32 ± 0.40 which were statistically significant. The results are in accordance with the observations made by **Boyeena et al. (2020)**⁷, where 10 sites were treated with scaling and root planing along with subgingivally delivered probiotic gel along with tetracycline fibers in systemically healthy patients. To the best of our knowledge, no similar study has been done in type II diabetic patients suffering from Chronic Periodontitis. Similarly, the results of the systematic review of **Ikram et al. (2018)**³ suggested that the adjunctive use of probiotics could result in superior benefits in Clinical Attachment Level gain in Chronic Periodontitis. To the best of our knowledge no similar study has been done in type II diabetic patients suffering from Chronic Periodontitis.

Mean Clinical Attachment Level in **Group II** (Scaling and root planing followed by local drug delivery tetracycline fibers) was 7.02 ± 0.97 at baseline, $6.63 \pm$

1.01 at 45 days, 6.25 ± 1.04 at 3 months and 5.98 ± 1.08 at 6 months. Mean gain in Clinical Attachment Level from baseline to 45 days was 0.38 ± 0.25 , from baseline to 3 months was 0.77 ± 0.29 , from baseline to 6 months was 1.03 ± 0.37 , from 45 days to 3 months was 0.38 ± 0.22 , from 45 days to 6 months was 0.65 ± 0.38 and from 3 months to 6 months was 0.27 ± 0.31 which were all statistically significant. The results are in accordance with the observations made by Heiji et al. (1991)²⁰, Fleming et al. (1996)⁸, Tonneti et al. (1998)²¹ and Bosco et al. (2009)²². Also according to a study conducted by Maiden et al. (1991)¹⁴ gain in Clinical Attachment Level could be attributed to anti-collagenolytic property of tetracyclines and an enhancement of collagen synthesis and their ability to promote an attachment of fibroblasts to root surfaces than SRP alone.

On intergroup comparison, difference in mean gain of Clinical Attachment Level was more in Group I as compared to Group II at all the time intervals. The difference in mean gain of Clinical Attachment Level in Group I and Group II between baseline and 45 days was 0.35 ± 0.09 (significant), between baseline and 3 months was 0.63 ± 0.05 (significant), between baseline and 6 months was 0.69 ± 0.18 (significant), between 45 days and 3 months was 0.29 ± 0.06 (significant), between 45 days and 6 months was 0.33 ± 0.17 (significant) and between 3 months and 6 months was 0.05 ± 0.09 (non-significant) respectively. The results are in accordance with the observations made by Boyeena et al. (2020)⁷ in systemically healthy patients. To the best of our knowledge, no similar study has been done in type II diabetic patients suffering from Chronic Periodontitis.

During the study, there was no intra-operative and post-operative complications and no allergic reactions were encountered to any of the materials used in this study.

Hence, it may be concluded that both **Group I** and **Group II** demonstrated significant results in terms of all the clinical parameters i.e. reduction of Plaque Index score, Sulcular Bleeding Index score, Probing Pocket Depth reduction and gain in Clinical Attachment Level but **Group I** showed significantly better results as compared to **Group II** in terms of all clinical parameters except for Plaque Index score and these may be attributed to the adjunctive effect of probiotics with tetracycline fibers. The additional beneficial effect of probiotic may be due to its ability to enhance innate immunity and modulate pathogen induced inflammation through “Toll like receptors” on dendritic cell. Aggregation alteration is another important proposed mechanism of probiotic action as heterofermentative lactobacillus is the strongest inhibitor of aggregatibacter actinomycetem comitans, porphyromonas gingivalis and prevotella intermedia. Probiotic mixture has also been reported to protect epithelium barrier by maintaining tight junction protein expression and prevent apoptosis of mucous membrane Chatterjee, Bhattacharya and Kandwal (2011)²³.

Many studies have currently evaluated the adjunctive role of probiotics in various forms such as lozenges, chewing gums, tablets and as local drug delivery agents in the treatment of Chronic Periodontitis. El-bagoory et al. (2020)²⁴ showed local application of L. reuteri in combination with SRP gave more favorable results than SRP alone in cases with Chronic Periodontitis. In a randomized controlled trial by Kumar et al. (2020)²⁵ it was concluded that three times incremental application of L. reuteri as a probiotic lead to improvements in clinical and biochemical parameters. Similar observations were made by Thakkar et al. (2013)²⁶, Mani, Saini and Saini (2017)²⁷ and Penala et al.

(2020)¹⁵. Thus establishing the adjunctive role of probiotics in treatment of Chronic Periodontitis.

Table 1: Showing comparison of difference in mean Plaque score reduction between Group I and Group II at different time intervals.

Time	Group	N	Mean Change	Mean difference	T value	P value	Sig.
Baseline - 45 Days	I	30	2.9667 ± 0.4901	0.233 ± 0.179	1.305	.197 (>0.05)	NS
	II	30	2.7333 ± 0.8483				
Baseline - 3 Month	I	30	2.9667 ± 0.4901	0.250 ± .135	.1.855	.069 (>0.05)	NS
	II	30	2.7167 ± ..5521				
Baseline - 6 Month	I	30	2.9667 ± 0.4901	0.183 ± 0.156	1.171	.246 (>0.05)	NS
	II	30	2.7883 ± 0.7032				
45 Day - 3 Month	I	30	2.6500 ± 0.5894	0.067± 0.147	.452	.653 (>0.05)	NS
	II	30	2.7167 ± ..5521				
45 Day - 6 Month	I	30	2.6500 ± 0.5894	0.133 ± 0.167	.796	.429 (>0.05)	NS
	II	30	2.7883 ± 0.7032				
3 Month - 6 Month	I	30	2.6833 ± 0.5942	.100 ± 0.168	0.595	.554 (>0.05)	NS
	II	30	2.7883 ± 0.7032				

(S = SIGNIFICANT, NS = NON-SIGNIFICANT)

Table 2: Showing Comparison of difference in mean Sulcular Bleeding Index score reduction (Papillary Bleeding Index by Muhlemman) score between Group I and Group II at different time intervals.

Time	Group	N	Mean Change	Mean Difference	T value	P value	Sig.
Baseline - 45 Days	I	30	0.78 ± 0.25	0.23 ± 0.01	4.471	.000 (<0.05)	S
	II	30	0.55 ± 0.24				
Baseline - 3 Month	I	30	1.18 ± 0.31	0.43 ± 0.05	13.730	.000 (<0.05)	S
	II	30	0.75 ± 0.25				
Baseline - 6 Month	I	30	1.35 ± 0.39	0.50 ± 0.04	9.049	.000 (<0.05)	S
	II	30	0.95 ± 0.36				
45 Day - 3 Month	I	30	0.40 ± 0.20	0.20 ± 0.08	3.890	.001 (<0.05)	S
	II	30	0.20 ± 0.28				
45 Day - 6 Month	I	30	0.57 ± 0.31	0.17 ± 0.07	2.763	.010 (<0.05)	S
	II	30	0.40 ± 0.38				
3 Month - 6 Month	I	30	0.17 ± 0.24	-0.03± 0.01	1.000	.326 (>0.05)	NS
	II	30	0.20 ± 0.25				

(S = SIGNIFICANT, NS = NON-SIGNIFICANT)

Table 3: Showing Comparison of difference in mean Probing Pocket Depth score reduction between Group I and Group II at different time intervals

Time	Group	N	Mean Change	Mean Difference	T Value	P Value	Sig.
Baseline - 45 Days	I	30	0.73 ± 0.34	0.36 ± 0.08	6.279	.000 (<0.05)	S
	II	30	0.37 ± 0.26				
Baseline - 3 Month	I	30	1.40 ± 0.33	0.62 ± 0.05	9.950	.000 (<0.05)	S
	II	30	0.78 ± 0.28				
Baseline - 6 Month	I	30	1.70 ± 0.54	0.65 ± 0.20	8.142	.000 (<0.05)	S
	II	30	1.05 ± 0.33				
45 Day - 3 Month	I	30	0.67 ± 0.27	0.25 ± 0.08	3.476	.001 (<0.05)	S
	II	30	0.42 ± 0.19				
45 Day - 6 Month	I	30	0.97 ± 0.52	0.29 ± 0.19	3.084	.004 (<0.05)	S
	II	30	0.68 ± 0.33				
3 Month - 6 Month	I	30	0.30 ± 0.38	0.03 ± 0.07	.571	.573 (>0.05)	NS
	II	30	0.27 ± 0.31				

(S = SIGNIFICANT, NS = NON-SIGNIFICANT)

Table 4: Showing Comparison of mean gain in Clinical Attachment Level score between Group I and Group II at different time intervals

Time	Group	N	Mean Change	Mean difference	T value	P value	Sig.
Baseline - 45 Days	I	30	0.73 ± 0.34	0.35 ± 0.09	5.887	.000 (<0.05)	S
	II	30	0.38 ± 0.25				
Baseline - 3 Month	I	30	1.40 ± 0.332	0.63 ± 0.05	10.033	.000 (<0.05)	S
	II	30	0.77 ± 0.29				
Baseline - 6 Month	I	30	1.72 ± 0.55	0.69 ± 0.18	8.804	.000 (<0.05)	S
	II	30	1.03 ± 0.37				
45 Day - 3 Month	I	30	0.67 ± 0.27	0.29 ± 0.06	3.798	.001 (<0.05)	S
	II	30	0.38 ± 0.22				
45 Day - 6 Month	I	30	0.98 ± 0.55	0.33 ± 0.17	3.440	.002 (<0.05)	S
	II	30	0.65 ± 0.38				
3 Month - 6 Month	I	30	0.32 ± 0.40	0.05 ± 0.09	.902	.375 (>0.05)	NS
	II	30	0.27 ± 0.31				

(S = SIGNIFICANT, NS = NON-SIGNIFICANT)

Conclusion

Hence, it may be concluded that both Group I and Group II demonstrated significant results in terms of reduction in Plaque Index score, Sulcular Bleeding Index score, Probing Pocket Depth and gain in Clinical Attachment Level in the treatment/management of Chronic Periodontitis in type II diabetes, with Group I showing significantly better results as compared to Group II in terms of all clinical parameters except for Plaque Index score and these may be attributed to the adjunctive effect of local drug delivery of probiotics along with tetracycline fibres. The additional beneficial effect of probiotic may be due to its ability to enhance innate immunity and modulate pathogen induced inflammation. So, within the confines of this study, it seems that use of locally delivered tetracycline fibres along with probiotics as an adjunct to scaling and root planing in treatment of type II diabetes patients with Chronic Periodontitis may be a promising treatment modality. But, the short follow up time period and relatively small sample size of the present study may be the limiting factor for the power of the statistical analysis. The release kinetics of probiotic from Tragacanth polymer was also not assessed. Therefore, a further large and long term, multicentric, randomized controlled clinical trials may be carried out to affirm the results of this study. Also further studies are needed to assess the kinetics of probiotic release from Tragacanth polymer.

References

1. Otomo-Corgel J, Pucher JJ, Rethman MP, Reynolds MA. State of the science: Chronic Periodontitis and systemic health. *J Evid Based Dent Pract.* 2012;12(3):20-8.
2. Loe H. Periodontal disease: the sixth complication of diabetes mellitus. *Diabetes care.* 1993;16(1):329-34.
3. Ikram S, Hassan N, Baig S, Borges KJJ, Raffat MA, Akram Z. Effect of local probiotic (*Lactobacillus reuteri*) vs systemic antibiotic therapy as an adjunct to non-surgical periodontal treatment in Chronic Periodontitis. *J Investig Clin Dent.* 2018;10(2):1-5.
4. Rajeshwari HR, Dhamecha D, Jagwani S, Rao M, Jadhav K, Shaikh S, Puzhankara L, Jalalpure S. Local drug delivery systems in the management of periodontitis: A scientific review. *J Control Release.* 2019;307:393-409.
5. Agarwal E, Bajaj P, Naik SB, Pradeep AR. Locally delivered 0.5% azithromycin as an adjunct to non-surgical treatment in patients with Chronic Periodontitis with type 2 diabetes: a randomized controlled clinical trial. *J Periodontol.* 2012;88(12):1281-7.
6. Sadaf N, Anoop B, Dakshina B, Shweta B. Evaluation of efficacy of tetracycline fibers in conjunction with scaling and root planing in patients with Chronic Periodontitis. *J Indian Soc Periodontol.* 2012;16(3):392-7.
7. Boyeena L, Koduganti RR, Panthula VR, Jammu la SP. Comparison of efficacy of probiotics versus tetracycline fibers as adjuvants to scaling and root planning. *J Indian Soc Periodontol.* 2020;23(6):539-44.
8. Flemmig TF, Weinacht S, Rüdiger S, Rumetsch M, Jung A, Klaiber B. Adjunctive controlled topical application of tetracycline HCl in the treatment of localized persistent or recurrent periodontitis: Effects on clinical parameters and elastase- α 1-proteinase inhibitor in gingival crevicular fluid. *J Clin Periodontol.* 1996;23(10):914-21.
9. Sakellari D, Vouros ID, Aristodemou E, Konstantinidis AB, Socransky S, Goodson M. Tetracycline fibers as an adjunct in the treatment of

- nifedipine-induced gingival enlargement. *J Periodontol.* 2005;76(6):1034-9.
10. Kafle S, Pradhan S, Gupta S. Locally delivered tetracycline fibres in the treatment of Chronic Periodontitis. *J Nepalese Soc Periodontol Oral Implantol.* 2018;2(2):45-8.
 11. Jeong SN, Han SB, Lee SW, Magnussen I. Effects of tetracycline-containing gel and a mixture of tetracycline and citric acid-containing gel on non-surgical periodontal therapy. *J Periodontol.* 1994;65(9):840-7.
 12. Twetman S, Derawi B, Keller M, Ekstrand KIM, Yucel-Lindberg T, Stecksén-Blicks C. Short-term effect of chewing gums containing probiotic *Lactobacillus reuteri* on the levels of inflammatory mediators in gingival crevicular fluid. *Acta Odontol Scand.* 2009;67(1):19-24.
 13. Gupta BSH, Panwar M. Local Drug Delivery with Tetracycline Fibre: An Alternative to Surgical Periodontal Therapy. *Med J Armed Forces India.* 2009;65(3):244-46.
 14. Maiden MFJ, Tanner A, McArdle S, Najpauer K, Goodson JM. Tetracycline fiber therapy monitored by DNA probe and cultural methods. *J Periodontal Res.* 1991;26(5):452-9.
 15. Penala S, Kalakonda B, Pathakota KR, Jayakumar A, Koppolu P, Lakshmi BV, Pandey R, Mishra A. Efficacy of local use of probiotics as an adjunct to scaling and root planing in Chronic Periodontitis and halitosis: A randomized controlled trial. *J Res Pharm Pract.* 2020;5(2):86-93.
 16. de Souza Gonçalves L, Ferreira SM, Silva Jr A, Villoria GE, Costinha LH, Souto R, De Uzeda M, Colombo AP. Association of T CD4 lymphocyte levels and subgingival microbiota of Chronic Periodontitis in HIV-infected Brazilians under HAART. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod.* 2004;97(2):196-203.
 17. Kinane DF, Radvar M. A six-month comparison of three periodontal local antimicrobial therapies in persistent periodontal pockets. *J Periodontol.* 1999;70(1):1-7.
 18. Navarro-Sanchez AB, Faria-Almeida R, Bascones-Martinez A. Effect of non-surgical periodontal therapy on clinical and immunological response and glycaemic control in type 2 diabetic patients with moderate periodontitis. *J Clin Periodontol.* 2007;34(10):835-43.
 19. Bollen AM, Cunha-Cruz J, Bakko DW, Huang GJ, Hujoel PP. The effects of orthodontic therapy on periodontal health: a systematic review of controlled evidence. *J Am Dent Assoc.* 2008;139(4):413-22.
 20. Heijl L, Dahlen G, Sundin Y, Wenander A, Goodson JM. A 4-quadrant comparative study of periodontal treatment using tetracycline-containing drug delivery fibers and scaling. *J Clin Periodontol.* 1991;18(2):111-6.
 21. Mombelli A, Tonetti M, Lehmann B, Lang NP. Topographic distribution of black-pigmenting anaerobes before and after periodontal treatment by local delivery of tetracycline. *J Clin Periodontol.* 1991;3(10):906-13.
 22. Bosco J, Lopes B, Bosco AF, Spolidorio DM, Marcantonio RA. Local application of tetracycline solution with a microbrush: An alternative treatment for persistent periodontitis. *Quintessence Int.* 2009;40(1).
 23. Chatterjee A, Bhattacharya H, Kandwal A. Probiotics in periodontal health and disease. *J Indian Soc Periodontol.* 2011;15(1):23.
 24. El-Bagoory GKM, El-Guindy HM, Shoukheba MYM, El-Zamarany EA. The adjunctive effect of

- probiotics to nonsurgical treatment of Chronic Periodontitis: A randomized controlled clinical trial. *J Indian Soc Periodontol.* 2021;25(6):525-31.
25. Kumar V, Singhal R, Rastogi P, Lal N, Pandey S, Mahdi AA. Localized probiotic-guided pocket recolonization in the treatment of Chronic Periodontitis: a randomized controlled clinical trial. *J Periodontal Implant Sci.* 2021;51(3):199-212.
26. Thakkar PK, Imranulla M, Kumar PN, Prashant GM, Sakeenabi B, Sushanth VH. Effect of probiotic mouthrinse on dental plaque accumulation: A randomized controlled trial. *Dent Med Res.* 2013;1(1):7-12.
27. Mani A, Saini R, Saini SR. Efficacy of oral probiotics as an adjunct to scaling and root planing in nonsurgical treatment outcome of generalized Chronic Periodontitis patients: A clinico-microbiological study. *Int J Exp Dent Sci.* 2017;6(1):6-13.