



Research Article

ISSN: 2581-3218
IJDR 2022; 7(3): 68-72
Received: 11-10-2022
Accepted: 22-12-2022
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www.dentistryscience.com
doi: 10.31254/dentistry.2022.7306

Evaluation of Local Drug Delivery System Containing 1% (W/V) Chitosan Gel Used as an Adjunct to Scaling and Root Planning in Chronic Periodontitis– A Split Mouth Study

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Abstract

Introduction: Periodontitis is defined as an inflammatory disease of supporting tissues of teeth, in the treatment of periodontitis systemic antibiotics have potential side effects such as the development of resistant bacteria. These limitations can be avoided by application of the antimicrobials in local drug delivery (LDD) systems directly into the periodontal pocket. Natural polymer chitosan which is found in abundance in nature has antibacterial, anti-inflammatory properties and is biodegradable and biocompatible. **Materials and Method:** A randomized controlled split-mouth study was designed. 30 patients were randomly selected. A resorbable chitosan gel of 1% (w/v) was placed in the selected test sites one week after scaling and root planing (SRP). Gel was injected into the periodontal pockets using a blunt cannula till the pocket was completely filled. Periodontal dressing was applied after placement of the gel. The ancillary parameters were assessed. **Results:** Statistically significant difference was present in mean plaque index scores and modified gingival index scores at 1 month and 3 months from baseline in both the groups as chitosan shows a strong activity in reducing dental plaque against various periodontal pathogens. Statistically significant difference was present in pocket depth between group I and group II at 1 month and 3 months. Statistically significant difference was present in Relative Attachment Level between group I and group II at 1 month and 3 months. **Discussion:** In this study Chitosan biopolymer, used in a gel form, (1% w/v) demonstrated the effectiveness for treatment of localized pockets in patients with chronic periodontitis. The results suggest chitosan has its own properties which cause reduction of pocket depth. **Conclusion:** Chitosan is an effective local drug delivery agent for chronic periodontitis patients.

Keywords: Local Drug Delivery System, Chitosan Gel, Chronic Periodontitis.

INTRODUCTION

Periodontitis is defined as an inflammatory disease of supporting tissues of teeth caused by specific microorganisms or groups of specific microorganisms, resulting in progressive destruction of the periodontal ligament and alveolar bone with periodontal pocket formation, gingival recession or both. Periodontal pocket is defined as a pathologically deepened gingival sulcus [1].

Pocket elimination is the principle goal of the treatment of chronic periodontitis. The major cause of CP is gram negative bacteria and the preferred treatment approach is mechanical procedure, which is performed surgically or non-surgically [2]. Systemic antibiotics have been used in various forms of periodontal disease treatment. Though there are many complications associated with the use of systemic antibiotics such as the development of resistant bacteria and potential side effects. These complications can be avoided by application of local drug delivery systems (LDD) directly into the pocket [2].

This LDD approach has received a lot of attention in the field of non-surgical periodontal therapy. There are a number of synthetic drugs which have been used for LDD such as tetracyclines, including doxycycline and minocycline, metronidazole and chlorhexidine [3]. However, the use of synthetic drugs has certain disadvantages such as bacterial-resistant strains production, inappropriate degradation and cost effectiveness.

These drawbacks have been overcome by the inception of natural polymers. Natural polymer chitosan which is found in abundance in nature has antibacterial, anti-inflammatory properties and is biodegradable

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and biocompatible [4]. Chitosan inhibits periodontal pathogens such as *Porphyromonas gingivalis* and *Aggregatibacter actinomycetemcomitans* [5].

Chitosan is also known for its hemostatic, fungistatic, antibacterial, antitumor, anticholesteremic, and immunoadjuvant characteristics.[6]

MATERIAL AND METHOD

Source of data

The present study consisted a total of 30 patients, including 20 males and 10 females, from November 2019 to October 2021 attending the outpatient section of the Department of Periodontology, Narsinhbhai Patel Dental College and Hospital, Sankalchand Patel University, Visnagar, Gujarat. The study protocol was approved by the institutional ethical committee. The design and nature of the clinical trial and the potential risks, if any, were explained to the patients. A signed written consent was procured from patients.

Selection criteria

Systemically healthy patients from the age group of 31-60, with at least two bilateral periodontal pockets of 5-7 mm irrespective of gender, without furcation involvement and gingival recession, smokers, pregnant and lactating women, patients with suspected or known allergy to chitosan were excluded, as were patients on antibiotic therapy and those who had undergone any periodontal therapy in the past 6 months.

Local drug delivery

A randomized controlled split-mouth study was conducted. 30 sites were randomly allocated as test and 30 sites as control. A well calibrated examiner recorded all clinical parameters to ensure an unbiased evaluation measurement with a UNC 15 (Hu Friedy, Illinois, Chicago) manual probe.

A resorbable chitosan gel of 1% (w/v) was placed in the selected test sites one week after scaling and root planing (SRP). These sites received scaling and root planing with ultrasonic device and gracey curettes followed by placement of 1% w/v Chitosan gel. Gel was injected into the periodontal pockets using a blunt cannula till the pocket was completely filled. Periodontal dressing was applied after placement of the gel.

The ancillary parameters assessed were Plaque index (Turesky-Gilmore-Glickman modified Quigley-Hein plaque index) and Modified gingival index (Lobene et al 1986). The clinical parameters assessed were pocket probing depth (PPD; Silness and Løe, 1964), Relative attachment level with stent at baseline, 1 month and 3 months post-operatively. A customized pre-grooved acrylic stent was used along with a UNC-15 periodontal probe for recording all clinical measurements at subsequent intervals.

Statistical analysis

The data of Clinical parameters were observed for 60 sites in 30 patients. The data was analyzed using SPSS version 20.0, descriptive statistics, paired t test for comparison of clinical parameters at various durations from baseline and ANOVA test for intergroup comparison. Comparison of different parameters of chronic periodontitis in Group I & II were done at baseline, after 1 month and 3 month and their mean scores were compared by applying the descriptive statistics and paired 't' test.

RESULT

All 30 patients completed the study. The treated sites were evaluated for clinical parameters at baseline, 1 month and 3 months post-operatively. Uneventful healing was observed. The drug was well tolerated by the subjects and there were no reports of any adverse outcomes or discomfort from chitosan membrane upon post-operative evaluation.

Out of 30 study subjects among Group I, 20 (66.6%) were male and 5 (33.3%) were female. Mean age of male and female among group I were 43.00 ± 5.34 and 40.90 ± 6.04 . Out of 30 study subjects among group II, 20 (66.6%) were male and 5 (33.3%) were female. Mean age of male and female among group II were 43.00 ± 5.34 and 40.90 ± 6.04 . Overall mean age was 42.3. Statistically significant difference was present in mean plaque index scores and modified gingival index scores at 1 month and 3 months from baseline in both the groups as chitosan shows a strong activity in reducing dental plaque against various periodontal pathogens.

Statistically, no significant difference was present in pocket depth between control group (Group I) and chitosan group (Group II) at baseline. However, statistically significant difference was present in pocket depth between group I and group II at 1 month and 3 months.

Mean pocket depth was less in group II (3.06 ± 0.73 mm) at 1 month than group I (3.76 ± 0.85 mm). Mean pocket depth was less in group II (1.90 ± 0.75 mm) than group I (3.13 ± 0.81 mm) at 3 months.

Statistically, no significant difference was present in Relative Attachment Level (RAL) between Group I and Group II at baseline. Statistically, significant difference was present in Relative Attachment Level between group I and group II at 1 months and 3 months. Mean Relative Attachment Level was more in group I (6.06 ± 0.98 mm) than group II (5.76 ± 0.67 mm) at 1 month. Mean Relative Attachment Level was more in group I (5.36 ± 1.21 mm) than group I (3.56 ± 0.72 mm) at 3 months.

Table 1: Intergroup comparison of mean Pocket Depth

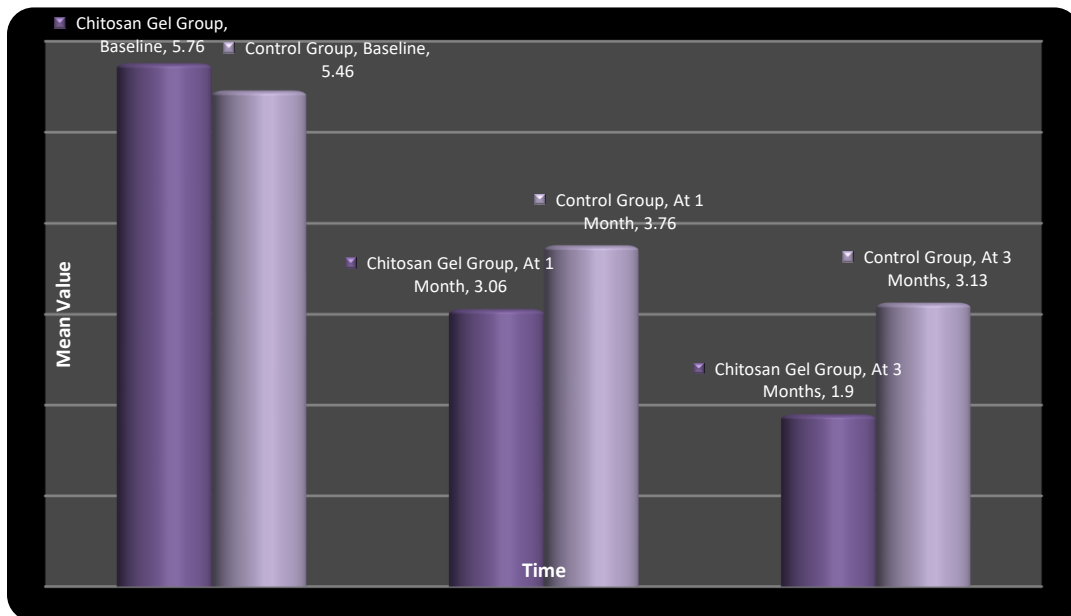
Parameter	Duration	N	Group I		Group II		P value
			Mean	SD	Mean	SD	
Pocket Depth	Baseline	30	5.76	0.67	5.28	0.67	>0.05**
	1 month	30	3.76	0.85	3.06	0.73	≤ 0.05*
	3 months	30	3.13	0.81	1.90	0.75	≤ 0.05*

Level of Significance $P \leq 0.05$, * Significant, ** Non Significant

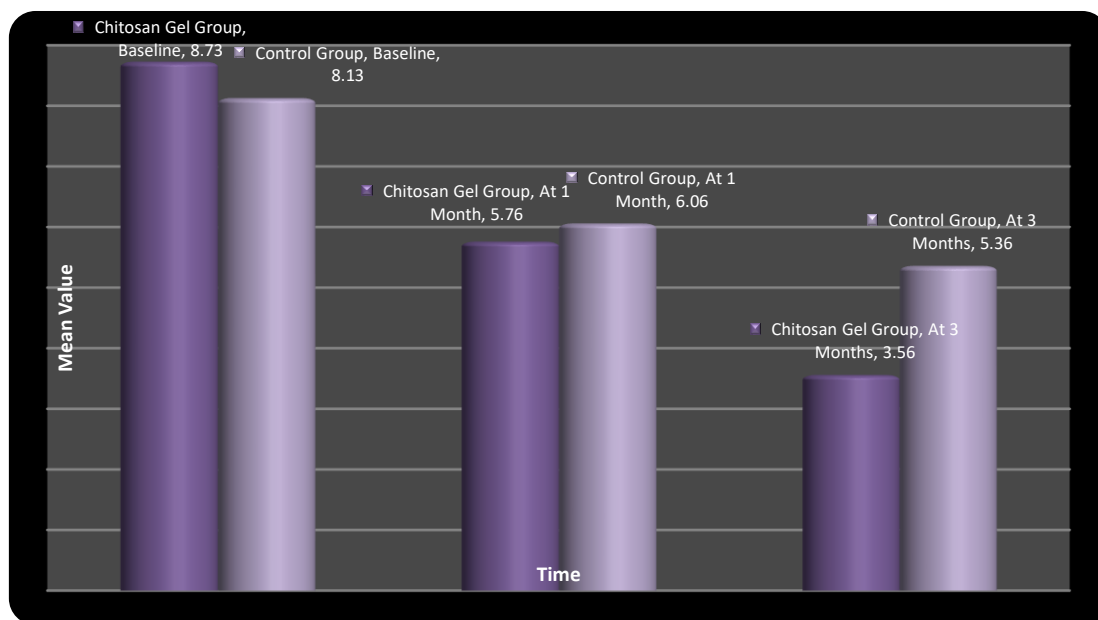
Table 2: Intergroup comparison of mean Relative Attachment Level

Parameter	Duration	N	Group I		Group II		P value
			Mean	SD	Mean	SD	
Pocket Depth	Baseline	30	8.13	1.07	8.73	0.94	>0.05**
	1 month	30	6.06	0.98	5.76	0.67	≤ 0.05*
	3 months	30	5.36	1.21	3.56	0.72	≤ 0.05*

Level of Significance $P \leq 0.05$, * Significant, ** Non Significant



Graph 1 : Intergroup comparison of mean Pocket Depth between Group I (Control group) and Group II (Chitosan group)



Graph 2 : Distribution based on Relative Attachment Level between Group I (Control group) and Group II (Chitosan group)

DISCUSSION

There is an abundance of evidence that suggests the direct involvement of microorganisms in the initiation and progression of various forms of periodontal disease. The elimination of the microbial pathogen present in subgingival plaque is the primary objective of periodontal therapy. One essential goal of periodontal therapy is successful management of the suspected bacterial pathogens to the extent that destruction of periodontium can be arrested [7]. Various surgical and non-surgical therapies have been successful in achieving this. The non-surgical approach involves mechanical scaling and root planning which may result in resolution of inflammation, reduced probing pocket depth and clinical attachment gain [8]. However, non-surgical therapy is not found to be successful at all treated sites.

Previous studies have proved that most improvement in clinical parameter and microbial changes occur during the first 3 months after SRP. In specifically, mean pocket depth and clinical attachment levels showed a remarkable improvement 3 months after SRP and also continued to show improvement during the maintenance phase. So, the follow up period of 3 months was considered in this study as well. Here,

in this study Chitosan biopolymer, used in a gel form, (1% w/v) demonstrated the effectiveness for treatment of localized pockets in patients with chronic periodontitis. Patient within the age range of 31-60 years with pocket probing depth of 5-7 mm were selected.

Patient who had undergone oral prophylaxis before six months were avoided as according to study by Listgarten et al [9], the proportion of coccoid cells increased as a result of scaling and root planing and was maintained throughout 25 weeks study Period. Patients who were cooperative to maintain good oral hygiene were included in the study as findings of Dahlen G and Lindhe J [10] demonstrated that carefully performed supragingival plaque control changed the quantity and composition of subgingival microbiota, and clinical symptoms associated with periodontitis. Patients with history of local and/or systemic antibiotic therapy within last six months before baseline examination were excluded as according to Heft et al [11], more resistance should be expected in the microflora of such individuals.

After thorough history taking regarding systemic ailments, patients with good systemic health were selected. Patients with a known history of systemic disease would alter the healing response of oral tissue. For

example, a diabetic patient, reported increase in number of capnocytophaga and aerobic vibrios. Also, there is reduction in defense mechanism and increase in susceptibility to infection leading to destructive periodontal disease [12]. Patients with history of drug therapy and parafunctional habits were excluded as well, as they may alter the treatment plan or affect the outcome of the treatment [13].

Cohen et al [14] reported increased incidence towards abscess formation, greater attachment loss, bleeding on probing and increase tooth mobility in diabetic individuals. Also, patients on immunosuppressive therapy were excluded as they always show a compromised wound healing response. Hormonal fluctuation in the female patients may alter the status of periodontal health and effect of the treatment outcome as well. Hence, pregnant and lactating females were excluded (as during pregnancy, hormonal alterations are capable of influencing the normal bacterial flora and induce the alteration in subgingival ecology [15]).

Smoking status has repeatedly shown to detrimentally affect the clinical outcome of different treatment procedures. Therefore patient who use tobacco in any form were excluded from the study [16].

The aim of this study was to examine the effectiveness of chitosan gel (1%w/v) on clinical parameters in patients with chronic periodontitis. Because of the bioadhesive properties of chitosan as well as its antimicrobial activity, the application time of the gel was decided to be twice a week. The sites filled with Chitosan gel were covered with periodontal pack for week to retain these agents for longer period of time.

All measurements were performed using a simple manual probe, UNC-15 Periodontal Probe. All measurements were standardized using a reference stent. As, according to D.Christopher Clark [17], reliability and reproduction of measurements is better using stent.

The present study comprised of two groups of treatment modalities and each group includes 30 sites:

1. GROUP I: Control group [SRP without chitosan]
2. GROUP II: Test group [SRP with chitosan]

A total of 30 systemically healthy patients with PD of 5-7 mm combined with bleeding on probing from the age group of 31-60 years (both male and female) were selected and a mean age of both groups of female and male was 42.3. (Table 1 and Graph 1). Clinical parameters that were used for assessment of the periodontal condition throughout the study were: pocket depth and Relative attachment level (RAL). Ancillary parameters were: plaque index (Turesky-Gilmore-Glickman modification of Quigley-Hein plaque index) and Modified gingival index. Turesky-Gilmore-Glickman modification of Quigley-Hein plaque index has the advantage of staining the plaque and hence, the detection of plaque can be recorded. Modified gingival index is a non invasive method to check the gingival status. Re-evaluation was done at 1 month and 3 months from baseline.

In the present study, the mean plaque index in group I and group II at baseline was 2.43 ± 0.24 , after 1 month was 1.75 ± 0.24 , after 3 months was 0.51 ± 0.23 . There was a statistically significant difference in the plaque scores between baseline to 1 month & 3 months and from 1 month to 3 months ($p < 0.05$). There was statistically significant difference in plaque scores between to 1 month and 3 months and from 1 month to 3 months ($p < 0.001$) No significant difference in mean plaque index was seen between both the groups I and II at baseline ($\leq 0.05^*$), 1 month ($\leq 0.05^*$) and 3 months ($\leq 0.05^*$) (Table 2 and Graph 2)

Thus, the results suggest chitosan has its own properties which causes reduction of pocket depth. Similar results were found in the study of Hakan Akincibay et al [18].

Hakan Akinetbay et al compared 3 groups, group A (1% w/v chitosan gel), group B (1% w/v chitosan gel with 15% metronidazole) and group C (SRP alone). Pocket depth reduction values were 1.21mm for group A, 1.48mm for group B, and 0.94mm for group C were observed between baseline and week 24.

Chitosan is bioadhesive in nature and the reduction in PD values could be the result of the attachment on root surfaces which could be allowed by chitosan because of its supportive and organizing effect on the histological architecture of the gingiva. This may be due to the fact that chitosan is structurally similar to glycosaminoglycans which have a greater potential for stimulating cell proliferation and organizing activities which leads to periodontal regeneration and thus leading to pocket depth reduction [19].

Irfana S. at al [20] had done split mouth study in which two treatment groups: test group (SRP plus 1% chitosan membrane) and control group (SRP), were compared. The clinical parameters such as pocket probing depth (PPD), gingival index (GI) and bleeding on probing (BOP) were recorded at baseline and 4 weeks. This study resulted in significant reduction in the PPD and GI between test sites and control at 4 weeks post-operatively. PPD reduction is a beneficial clinical outcome which is used to assess the success of periodontal treatment. It can be concluded that the anti-bacterial properties of chitosan helped in decreasing the PPD [21].

Studies state that positively charged chitosan molecules interact with the negatively charged cell membranes of the microbes, leading to changes in the permeability of cell membranes and eventually inhibiting the growth of micro-organisms [21].

Marco Cicciù et al [22] did a systematic review to evaluate all the relevant results for oral health and chitosan. After a careful analysis of the literature, they concluded that chitosan has many functions and it is used in different fields of dentistry. Chitosan is also used as a desensitizer in toothpaste as it has remineralizing property which hardens the tissues of tooth. The use of chitosan has shown better surgical healing of after-extraction oral wounds. Furthermore, some studies show a reduction in bacterial biofilm when used in dental cements. In addition, it has antibacterial, antifungal, hemostatic and other systemic properties which aid its use for drug delivering.

It can also be summarized that the anti-inflammatory properties of chitosan membrane placed in the test group played a prime role in reducing GI, as the results were significant at 1 month and 3 months in comparison with baseline. Hence, it could be speculated that the novel properties of chitosan, such as its mucoadhesion [23] and anti-inflammatory action, promotion of rapid wound healing [24] led to overall favorable results.

CONCLUSION

It is not expected that these therapies may completely eliminate the need for surgical intervention where one must get accessibility and visibility for the removal of deposits in deep periodontal pockets. Nevertheless, chitosan holds an important place as local drug delivery system and as an effective adjunct to scaling and root planing in the management of chronic inflammatory periodontal diseases. But for deeper and generalized pockets treatment plan one must prefer surgical periodontal therapy.

Conflict of Interest

None declared.

Financial Support

None declared.

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HOW TO CITE THIS ARTICLE-

Kachhadiya P, Duseja S, Parikh H, Patel Z. Evaluation of Local Drug Delivery System Containing 1% (W/V) Chitosan Gel Used as an Adjunct to Scaling and Root Planning in Chronic Periodontitis– A Split Mouth Study. *Int J Dent Res* 2022; 7(3):68-72. doi: 10.31254/dentistry.2022.7306

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