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Research Article

EVALUATION OF THE EFFECT OF SUBGINGIVAL PLACEMENT OF CHLORHEXIDINE CHIP (PERIOCOL-CG) AS AN ADJUNCT TO SCALING AND ROOT PLANING IN THE TREATMENT OF CHRONIC PERIODONTITIS-A CLINICAL STUDY

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ABSTRACT

Aim: The aim of the present study was to evaluate the efficacy of the controlled release biodegradable chlorhexidine chip (Periocol CG) when used as an adjunct to scaling and root planing in the treatment of periodontitis

Materials and Methods: A total of 20 patients and 20 bilateral sites i.e. 40 sites with pocket depth ≥ 5 mm were selected for the study. Patients were given the meticulous oral hygiene instructions and recalled after 21 days. The following clinical parameters were assessed: Plaque index (Sillness & Loe 1964), Sulcus bleeding index (Muhleman.H.R, and Son. 1971), Probing pocket depth (Williams Graduated Probe),Relative attachment level (Acrylic occlusal stent). 20 patients were treated in a split-mouth design and were followed up for a period of 3 months. Bilateral periodontal pockets were randomly assigned by a flip of coin to receive either placement of chip along with scaling and root planing (test site) or scaling and root planing alone (control site). Subjects were recalled on 15th, 30th, 60th day for the measurement of plaque and sulcus bleeding index and on 90th day for the measurement of plaque index, sulcus bleeding index, probing pocket depth and relative attachment level.

Statistical Analysis: Mean, Standard deviation, t-test, p value

Results: All the clinical parameters i.e plaque index, sulcus bleeding index, probing pocket depth showed statistically significant reduction while as there was statistically significant improvement in relative attachment level in both groups but the test group showed better results and these results were statistically significant.

Conclusion: The results of the present study suggest that local controlled delivery of chlorhexidine chip along with scaling and root planing is capable of reducing scores of plaque index, bleeding on probing, probing pocket depth and gain in attachment level compared to scaling and root planing alone and this made local drug delivery an important treatment alternative to surgical periodontal therapy in the treatment of chronic periodontitis.

INTRODUCTION

Periodontal diseases comprise a group of oral infections that are driven by complex bacterial challenges which arise initially from the development and retention of supragingival plaque, and then later by the formation of biofilm in the protected, subgingival niche of periodontal pocket. [1]

Conventional periodontal treatment consists of mechanical debridement to eliminate the subgingival microbiota and infected tissues in the inflamed pocket [2]. Scaling and root planing has been shown to be effective treatment for chronic periodontitis[3]. Although, mechanical treatment significantly decreases the prevalence and levels of subgingival microorganisms, it does not necessarily eliminate all pathogens[4]. As the probing depth increases, the effectiveness of scaling and root planing decreases, leaving subgingival plaque and calculus on the root surfaces [5,6]. Upto 30% of the total surface area of the treated roots can be covered with the residual calculus following subgingival scaling [7]. So mechanical therapy is generally perceived to possess certain limitation which include : failure of instruments to reach the base of deep pockets, higher levels of pathogens found in deep pockets, biofilm and microbial retention in grooves and pockets, microbial retention in dentinal tubules, diffusion of bacteria into soft tissues, migration of periodontal pathogens from other sites.

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To overcome the limitations of this conventional treatment, antimicrobials have been used successfully to treat moderate to severe periodontal disease [8] by systemic [9] and local administration. [10, 11] However, systemic antibiotics require the administration of large dosage to obtain suitable concentration at the site of disease [12] which potentially promotes the development of bacterial resistance, side effects drug interactions [13] and inconsistent patient compliance [14]. Therefore it is accepted that the systemic use of antibiotics should be restricted to patients who do not respond well to conventional mechanical treatment [15, 16]. To avoid these limitations of systemic administration, a different approach has been introduced that uses local delivery system that contains antibiotic or antiseptic agents in the form of gels, mouthwashes, varnishes etc

Topical administration of antibacterial agents in the form of mouth washes has been shown to be effective in controlling supragingival plaque [17]. However, their access to the periodontal pocket and the subgingival flora is limited and therefore, ineffective in controlling disease progression. Attention has been focussed on local drug delivery system in which drugs are immobilized in a carrier substance for the purpose of regional drug delivery. This type of system is being applied to periodontal therapy in which drugs are directly administered to the periodontal pocket to inhibit the growth of pathogenic bacteria.

Goodson *et al* (1979) [18] first proposed the concept of controlled drug delivery in the treatment of periodontitis. The effectiveness of this form of therapy is that, it reaches the base of periodontal pocket and is maintained for an adequate time for the antimicrobial effect to occur.

Chlorhexidine shows a broad spectrum of topical antimicrobial activity, safety, effectiveness, substantivity and lack of toxicity [19]. Chlorhexidine has been developed in such a way that when placed into periodontal pocket releases the chlorhexidine slowly while being bioresorbable, maintaining a concentration of greater than 125µg/ml in the crevicular fluid over 7-10 day period [20]. This was reported to be inhibitory to 99% of the bacteria isolated from the periodontal pockets [21, 22]

Periocol-CG is a small, orange-brown in a rectangular chip form (rounded at one end) for easy insertion into periodontal pockets. Each Periocol-CG contains 2.5mg of chlorhexidine gluconate in a biodegradable matrix of type I collagen derived from fish source. It is Gamma sterilised and supplied in individual aluminium blister packing. Periocol-CG releases chlorhexidine in vitro with release profile of approximately 40-45% within 24 hours and thereon in a linear fashion for 7-8 days. The release profile may be explained as an initial burst effect, due to diffusion of the drug from the chip followed by the release of the drug due to enzymatic degradation.

In the present study, the role of chlorhexidine chip (Periocol-CG) as an adjunct to scaling and root planing in chronic periodontitis treatment will be assessed and compared to SRP alone as monotherapy.

Aims & Objectives

1. To evaluate the therapeutic efficacy of chlorhexidine chip(Periocol-CG) used as an adjunct to scaling and root planing in the treatment of chronic periodontitis
2. To evaluate the efficacy of scaling and root planing alone in the treatment of chronic periodontitis.
3. To compare the efficacy of scaling and root planing (control site) with chlorhexidine chip (Periocol-CG) (test site) used as an adjunct to scaling and root planing in the treatment of chronic periodontitis.

MATERIALS AND METHODS

Patients for the Study

20 subjects were recruited from the out-patient Department of Periodontics of Govt. Dental college, Srinagar.

Criteria for Patient Selection

Inclusion Criteria

1. Patients diagnosed with chronic periodontitis between 25 to 50 years of age.
2. Subjects should be systemically healthy.
3. Subjects should have bilateral periodontal pockets with probing depths of $\geq$ 5mm and bleeding on probing present.
4. Patients who had not received any type of periodontal therapy for the past 6 months.
5. Patients with no history of antimicrobial drug intake for 7 days or longer in the previous 3 months.
6. Patient who were able to attend the hospital at frequent intervals.

METHODOLOGY

A total of 20 patients and 20 bilateral sites i.e. 40 sites with pocket depth $\geq$ 5 mm were selected for the study. Patients were given the meticulous oral hygiene instructions and recalled after 21 days. The following clinical parameters were assessed:

1. Plaque index (Sillness & Loe 1964)
2. Sulcus bleeding index (Muhleman.H.R, and Son. 1971)
3. Probing pocket depth (Williams Graduated Probe)
4. Relative attachment level (Acrylic occlusal stent)

Fabrication of Occlusal Stent

A custom made stent and a Williams Graduated probe were used. The stent was made with the cold cure acrylic by the sprinkle on method. It covered the occlusal/Incisal 1/3rd on the buccal and the lingual side. The thickness of the stent was about 2-3 mm. The vertical grooves were made on the stent on buccal and lingual side using straight fissure bur no. 556 and micromotor hand piece to guide the Williams Graduated probe at selected sites. The stent was made to fit on the occulsal/incisal surfaces of the teeth and the measurements were made using the Williams periodontal probe by placing it in the groove made on the stent.

The customized occlusal stent was placed on the selected teeth and the probe was gently inserted along the groove on the stent and the distance from the fixed reference point (FRP) on the stent to the base of the pocket (BOP) was recorded. This measurement gives us the relative attachment levels at the selected sites.

Periodontal Therapy

20 patients were treated in a split-mouth design and were followed up for a period of 3 months. Bilateral periodontal pockets were randomly assigned by a flip of coin to receive either placement of chip along with scaling and root planing (test site) or scaling and root planing alone (control site).

CONTROL SITE (Group A): 20 sites (1 site per tooth)
These sites received scaling and root planing alone
TEST SITE (Group B): 20 sites (1site per tooth)

These sites were treated by scaling and root planing along with chlorhexidine impregnated fish collagen chip.

The experimental sites were completely dried using air syringe and then the sites were isolated with cotton rolls to prevent contamination from saliva. The experimental local drug delivery system (Periocol-CG) was then placed in the periodontal pockets of the experimental group. Before the chip was placed in the periodontal pockets the sterile saline solution was added in the dapen dish to wet the chip. The wet chip was then taken and placed in the test site by gently inserting it with a periodontal probe/ Gracey curette. Gentle force was used so that the material fills the depths and curves of pockets. Chip was placed until pocket was entirely filled upto the gingival margin. The gingiva was subsequently adapted to close the entrance of the experimental site and hand pressure was applied for few minutes to achieve haemostasis. This was followed by the placement of Cyanoacrylate adhesive along the gingival margin to seal the pocket opening and to prevent any dislodgement of the chlorhexidine chip.

Recall Visits

Subjects were recalled on 15th, 30th, 60th day for the measurement of plaque and sulcus bleeding index and on 90th day for the measurement of plaque index, sulcus bleeding index, probing pocket depth and relative attachment level.

RESULTS

Relative attachment level (in mm)
Control group

Mean± SD		Difference	t value	p value
Baseline	10.85±.81	1.20	13.07	.000
90 days	9.65±.81			

Relative attachment level (in mm)
Test group

Mean± SD		difference	t value	p value
Baseline	11.00±.58	2.55	29.00	.000
90 days	8.45±.60			

Comparison between the groups

ral	control group mean ± sd	test group mean ± sd	diff	t value	p value
BASELINE	10.85 ± 0.85	11.00 ± .58	-0.15	-2.23	0.9
90 DAYS	9.65 ± 0.85	8.45 ± .60	1.20	5.29	.001

Probing pocket depth (in mm)
Control group

Mean± SD		difference	t value	p value
Baseline	5.65±0.48	1.10	8.90	.000
90 days	4.55±0.75			

Probing pocket depth (in mm)
Test group

Mean± SD		difference	t value	p value
Baseline	6.00±0.58	2.40	27.68	.000
90 days	3.60±0.68			

Comparison between the groups

PPD	CONTROL GROUP Mean ± SD	TEST GROUP Mean ± SD	diff	t value	p value
BASELINE	5.65 ± 0.48	6.00±0.58	-0.35	-4.09	0.25
90 DAYS	4.55 ± 0.75	3.60 ±0.68	0.95	4.16	.000

Sulcus bleeding index
Control group

Mean ±SD		difference	t value	p value
Baseline	**2.00±0.56**			
15 days	1.25±0.44	0.75	7.55	<0.001
30 days	1.05±0.51	0.95	19.55	<0.000
60 days	1.00±0.32	1.00	7.95	<0.001
90 days	1.15±0.58	0.85	5.10	<0.001

Sulcus bleeding index
Test group

Mean ±SD		difference	t value	p value
Baseline	**2.05±0.51**			
15 days	1.10±0.44	0.95	19.00	<0.001
30 days	0.90±0.30	1.15	14.03	<0.000
60 days	0.60±0.50	1.45	12.70	<0.001
90 days	0.05±0.22	2.00	15.91	<0.001

Comparison between groups

SBI	Control group mean± SD	Test group Mean ±SD	Difference	t value	p value
Baseline	2.00± 0.56	2.05±0.51	-0.05	-0.29	0.77
15 days	1.25±0.44	1.10±0.44	0.15	1.06	0.29
30 days	1.05±0.51	0.90±0.30	0.15	1.12	0.26
60 days	1.00±0.32	0.60±0.50	0.40	2.29	0.005
90 days	1.15±0.58	0.05±0.22	1.10	7.83	0.000

PLAQUE INDEX
Control group

Mean ±SD		difference	t value	p value
Baseline	**1.84±0.11**			
15 days	1.52±0.14	0.32	12.95	<0.001
30 days	1.32±0.12	0.52	17.95	<0.000
60 days	1.15±0.12	0.69	22.48	<0.001
90 days	1.03±0.15	0.81	22.34	<0.001

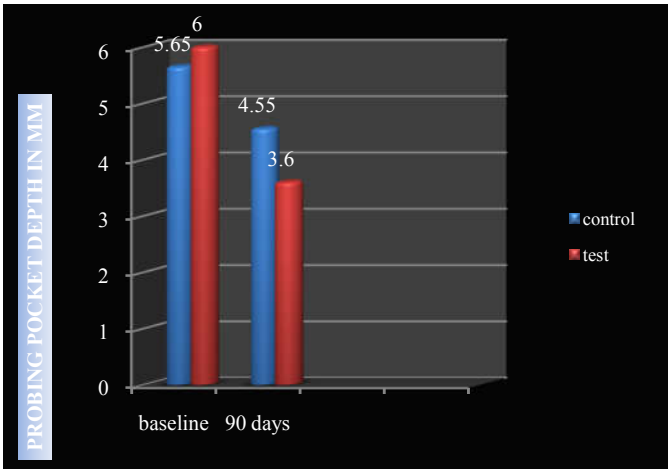
PLAQUE INDEX
Test group

Mean ±SD		difference	t value	p value
Baseline	**1.83±0.21**			
15 days	1.47±0.23	0.36	12.10	<0.001
30 days	1.06±0.20	0.77	22.57	<0.000
60 days	0.54±0.18	1.29	36.53	<0.001
90 days	0.21±0.09	1.62	40.98	<0.001

Comparison between groups

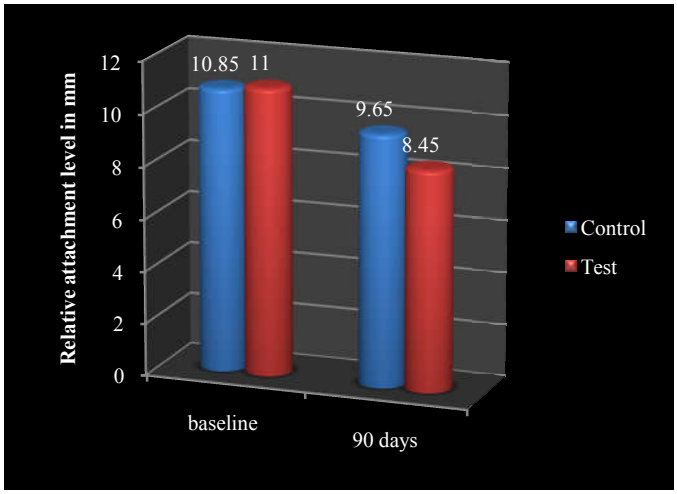
PI	Control group mean± SD	Test group Mean ±SD	Difference	t value	p value
Baseline	1.84±0.11	1.83±0.21	0.01	0.18	0.85
15 days	1.52±0.14	1.47±0.36	0.05	0.88	0.38
30 days	1.32±0.12	1.06±0.20	0.26	4.96	0.000
60 days	1.15±0.12	0.54±0.18	0.61	12.29	0.000
90 days	1.03±0.15	0.21±0.09	0.82	20.30	0.000

Comparison of Mean Probing Pocket Depth Reduction between Control Group (Group A) and Experimental Group (Group B)



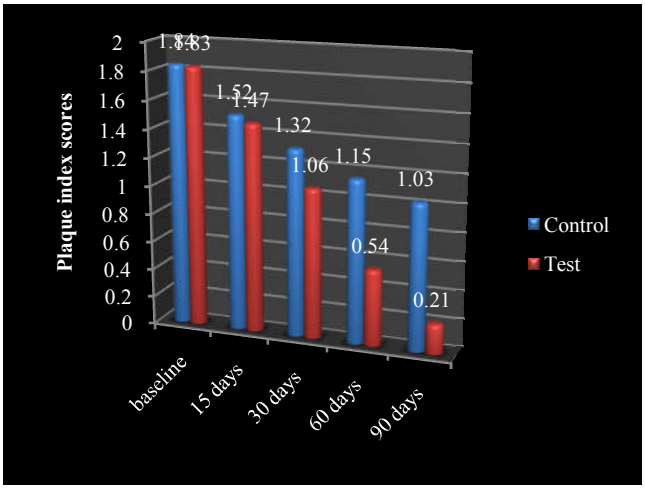
Time interval in days

Comparison of Relative Attachment Level (RAL) Scores between Control Group (Group A) and Experimental Group (Group B)



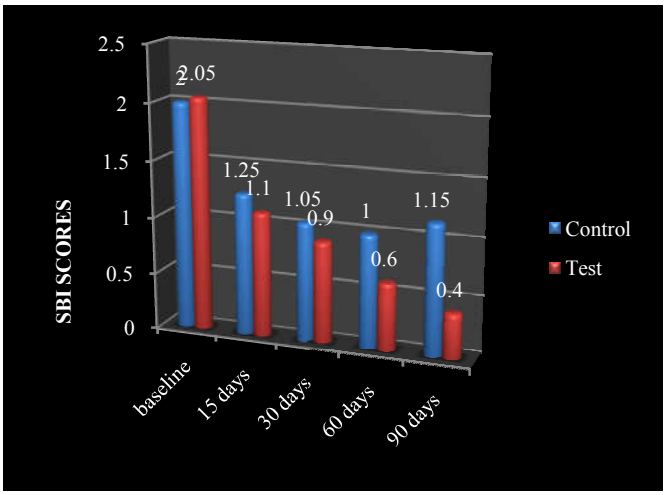
Time interval in days

Comparison of mean Plaque Index reduction Scores Between Control Group (Group A) and Experimental Group (Group B)



Time interval in days

Comparison of mean Sulcus Bleeding Index (SBI) reduction Scores Between Control Group (Group A) and Experimental Group (Group B)



Time interval in days

DISCUSSION

In this study an attempt has been made to evaluate the clinical utility of chlorhexidine chip (Periocol-CG) given as an adjunct to scaling and root planing with scaling and root planing delivered as a monotherapy. The present study was designed as a split- mouth clinical trial which included 20 patients diagnosed with chronic periodontitis within the age group of 25-50 years, having periodontal pockets with pocket depth ≥5mm in the mouth for each selected patient. The sites were divided into control and experimental group in a random fashion with one site in each group. At first appointment all the clinical variables were noted and oral hygiene instructions were given and patients were recalled after 3 weeks for baseline examination. At baseline selected sites were assessed for clinical parameters which included Plaque Index (Sillness and Loe, 1964), Sulcus Bleeding Index (Muhlemann and Mazor, 1971), Probing Pocket Depth (using Williams graduated probe) and Relative attachment level (using acrylic splint). Full mouth scaling and root planing was done at the baseline and Periocol-CG was inserted at the experimental site followed by sealing of pocket opening by Cyanoacrylate adhesive at the same visit. Patients were then re-evaluated at day 15, 30, and 60 for the estimation of plaque index and sulcus bleeding index and at day 90, for the estimation of all the four clinical parameters.

Plaque index

In the experimental group, the mean reduction in plaque index showed a statistically significant reduction from the control group. These results were found to be consistent with the studies of Soskolne *et al*. (1997)[23,] Mizrak *et al*. (2006) [24,] Jeffcoat at al (1998) [25]. The definite reduction in plaque index in the experimental group and its statistical significance over the control group, could be attributed to the fact that chlorhexidine in the form of Periocol-CG as used in this study prevents plaque regrowth and gingivitis[19]. . Reduction in plaque index can also be attributed to the substantivity[26,27] of chlorhexidine and therefore consequent antiplaque activity shown by the chlorhexidine chip.

Sulcus Bleeding Index

In the experimental group, the mean reduction in sulcus bleeding index showed a statistically significant reduction from the control group. These results were found to be consistent with the studies of Soskolne *et al*. (1997)[23,] Mizrak *et al*. (2006)[24,] Jeffcoat at al (1998)[25]. The definite reduction in bleeding index in the experimental group could be attributed to the fact that chlorhexidine chip maintains a concentration of 125µg/ml in GCF which is MIC to 99% of bacteria[21, 22]. This can be attributed to the fact that CHX can inhibit microbial proteases from potent periodontopathogens such as Tannerella forsythia, Treponema denticola and A.actinomycetemcomitans[28].Tannerella forsythia and Treponema denticola being the members of red complex are associated with bleeding on probing, so their inactivity results in decreased prevalence of bleeding on probing in experimental group.

Probing pocket depth

In the experimental group, the reduction in probing pocket depth showed a statistically significant reduction from the control group. These results were found to be consistent with the studies of Soskolne *et al*. (1997)[23], Jeffcoat *et al*. (1998)[25,], Jeffcoat *et al*. (2000) [29], Mizrak *et al*. (2006)[24] , Rodrigues *et al* (2007) [30] & Paolantonio *et al*. (2008) [31]. This could be attributed to the fact that chlorhexidine chip significantly reduces the total bacterial count (TBC) as compared to SRP alone[31]. This could be attributed to the fact that chlorhexidine chip used in the form of Periocol-CG in our study creates more healthy environment for healing by preventing the reinvasion of pathogens into the periodontal pocket area as its effects are seen upto eleven weeks from the day of its administration[32]

Relative Attachment level

In the experimental group, the mean increase in relative attachment level showed a statistically significant increase from the control group. These results were found to be consistent with the study of Grover (2011) [33] and in partial accordance with Soskolne *et al*. (1997)[23], Jeffcoat *et al*. (1998)[25,] Jeffcoat *et al*. (2000)[29,] Mizrak *et al*. (2006)[24,] Rodrigues *et al* (2007)[30] & Paolantonio *et al*. (2008)[31]. This could be attributed to the fact that chlorhexidine chip significantly reduces the levels and oxidative activation of MMP-8 in GCF[34]. As the MMP-8 play a key role in irreversible destruction of periodontal tissues during disease progression, its decreased levels and activity explains more gain of attachment in experimental group. Attachment gain could also be attributed to the fact that chlorhexidine chip reduces the levels of prostaglandin E_2 in GCF[24], thus creating a more stable attachment[32]as prostaglandin E_2 is one of the key mediators of inflammation in the periodontal disease

CONCLUSION

Results of the present study favour the use of chlorhexidine gluconate chip (Periocol-CG) as an adjunct to phase I periodontal therapy (scaling and root planing) in treatment of chronic periodontitis. This study states that CHX chip placement is safe and clinical effects achieved with the CHX chip may reduce the need for further advanced and surgical periodontal treatment which would limit morbidity for the subject, the time of treatment and the cost of therapy.

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