

## Comparison of the Efficacy of Chlorhexidine Chip and Scaling and Root Planing: A Clinico-Biochemico-Microbiological Study

Parimala Kumar\*, Swati Setty\*\*

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### Abstract

*Aim:* This study was aimed to assess the release pattern of chlorhexidine chip invitro and the efficacy and effect of chlorhexidine chip with scaling and root planing in patients with chronic periodontitis. *Method:* The study was a split mouth design consisting of twenty patients with chronic periodontitis with 5-7mm pockets. The control sites were treated with scaling and root planing alone whereas in the test site chlorhexidine chip was also placed. The clinical parameters recorded were gingival index, plaque index, probing depth and relative attachment level at baseline, 10 days, 21 days and three months. Plaque sample was collected at baseline and at three months for microbial analysis. *Results:* There was significant improvement in the gingival index, plaque index and probing depth scores and clinical attachment level from baseline to three months in both the groups. There was no significant difference between the groups from baseline to three months. *Conclusion:* Though the use of chlorhexidine chip in addition to scaling and root planing has shown significant improvement in the clinical parameters, the beneficial effects were found to be only marginally better when compared to scaling and root planing alone.

**Keywords:** Chronic Periodontitis; Chlorhexidine Chip; Local Drug Delivery; Microbiological; Periochip; Scaling and Root Planing.

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### Introduction

Bacterial plaque is the primary etiological agent in periodontal diseases [1]. Hence, it is important to keep the pathogenic microflora of the pocket suppressed in order to maintain health of the periodontal tissues [2,3].

Although the most widely used and successful approach has been scaling and root planing, they do leave a significant number of pathogenic bacteria. Recolonisation of the same can occur as early as 60 days after scaling and root planing. So the use of antibiotics as an adjunctive approach is substantiated so that the pathogenic flora is killed and the pocket is inhabited by non-pathogenic flora.

Antibiotic therapy can be systemic or local. Systemic administration of antibiotics used in combination with scaling and root planing has been shown to have beneficial effects [2]. However it has systemic side effects, which is because of the high dose of drug given to achieve the therapeutic level concentration of the antibiotics in the crevicular fluid and also there may be potential adverse effects of the bacteria developing antibiotic resistant strains [4]. To overcome these shortcomings, the local drug delivery devices were developed which help to administer the therapeutic levels of antibacterial agents directly into the periodontal pocket and thus minimize the total body dosage and resulting side effects and to maintain therapeutic levels in the gingival crevicular fluid (GCF) over a period of time [5,6].

The various local drug delivery systems include pastes, gels, mouthwashes, rinses, chewing gums, acrylic strips, fibres as well as the newer biodegradable local delivery drugs [5]. The sustained release agents have shown better results than the non-sustained sub gingival drug delivery system. Tetracycline's, metronidazole and chlorhexidine have been used incorporated into strips and matrices from which the drug is released over a definite period of

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**Author's Affiliation:** \*Reader, Dept of Periodontics, A.J Institute Of Dental Sciences, Mangalore, Karnataka 575004, India. \*\*Professor, Dept of Periodontics, SDM College of Dental Sciences & Hospital, Dharwad, Karnataka 580009, India.

**Reprints Requests:** Parimala Kumar, Reader, Dept of Periodontics, A.J Institute Of Dental Sciences, Mangalore, Karnataka 575004, India.

E-mail: [parikodgi76@gmail.com](mailto:parikodgi76@gmail.com)

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time [7,8]. The introduction of biodegradable material as a carrier for these drugs eliminates the need of removing the strips after the release of the entire drug.

Drugs with better substantivity like tetracycline and chlorhexidine which is adsorbed onto the tooth surface and oral tissues can remain even after the strips are eroded or removed and act on the micro flora suppressing it for a longer time. Periochip is one of the sustained biodegradable sub gingival drug delivery system which contains 2.5 mg of chlorhexidine.

Chlorhexidine is a bis-guanide, acts as an antiseptic, is effective against many of the pathogens of the periodontal pocket. It has good substantivity and has no side effects like development of bacterial resistance as it is an antiseptic and not an antibiotic [9]. It does not cause any systemic side effects as it is not found in any of the body fluids after placement, however it may cause some local changes in the tissues which reverse back to normal after some days.

Hence an attempt was made to know the efficacy of Chlorhexidine containing chip over only scaling and root planning and the release pattern of the drug was also studied to correlate with the clinical and microbiological results obtained during the study.

#### *Aims and Objectives*

1. To evaluate the difference in the pocket depth, clinical attachment level and gingival health in periodontal pockets treated with scaling and root planning alone and a combination of scaling and root planing and Chlorhexidine chip.
2. To know the microbiological changes at different intervals of the therapy both in control and test sites.
3. To assess the release pattern of the Chlorhexidine chip in vitro.

#### **Materials and Method**

##### *Periochip*

The Chlorhexidine chip (Periochip) is manufactured by perioproducts ltd, Jerusalem, Israel and is currently being studied in the US under the sponsorship of ASTRA USA.Inc.

The Chlorhexidine chip is a small, orange brown, rectangular chip rounded on one end. Each chip measures 4mm in length, 5mm in breadth and 0.35mm in width. It weighs 7.4mg and contains 2.5mg of Chlorhexidine gluconate in a biodegradable matrix

of hydrolysed gelatin. The gelatin is cross linked with glutaraldehyde. The chip contains glycerine and purified water. Chemically this antimicrobial agent is designated as 1,1-hexamethylethylenebis(5-(p-chlorophenyl) biguanide) di-D-gluconate, and its molecular formula is  $C_{22}H_{30}Cl_2N_{10}2C_6H_{12}O_7$ . The molecular weight is 897.8.

This study was conducted in the Department of Periodontics SDM College of Dental sciences, Sattur, Dharwad. The study consisted of 20 patients belonging to both sexes, between the age groups 38-60 years with moderate to advanced chronic periodontitis. The inclusion criteria had no history of periodontal surgery in the past six months, no history of usage of antibiotics in the past six months, presence of atleast two periodontal pockets with probing depth of 5-7 mm, no systemic disease, no mobile carious or endodontically treated teeth and patients with no history of allergy to Chlorhexidine. In each patient the treatment sites were divided into two groups by split mouth technique. Group I represented the test group where the periodontal pockets were treated by scaling and root planing along with placement of Chlorhexidine containing chip. Group II represented the control group where the pockets were treated with scaling and root planing alone.

##### *Clinical Parameters*

Gingival Index, Plaque Index, Probing Depth and Relative attachment level of the selected target sites were under taken before placement of chip at baseline and at 10 days, 21 days and 3 months of placement.

##### *Microbiological Evaluation*

Plaque samples for microbiological analysis were collected at baseline, 21 days and three months. The supragingival plaque was removed to prevent contamination of the flora, and then the area was isolated and sub gingival plaque was collected using a sterilised Gracey curette. Two smears were prepared on clean microscopic slides, of the sample. One was stained with Grams stain and the other with Silver nitrate (Fontana's technique) and analysed for the microorganisms.

##### *In Vitro Analysis*

An initial experiment was carried out to evaluate the pattern of drug release and the duration of release. Two periochips were placed in 4ml of distilled water each maintained at 37°C with the help of a water bath, and the time was recorded as 0 hour. One was

evaluated every hour and the other was evaluated after 24hrs which would act as a reference for accuracy. After one hour the solution of one jar was replaced with fresh 4 ml of distilled water. The collected solution was analysed in the spectrometer in the uv range of 260nm and optical density was recorded. Every hour the solution was replaced and readings were taken for twelve hours. The next reading was taken after twenty four hours for both the chips. From then on the solution was replaced every day until the optical density became zero, which was recorded on the thirteenth day. The optical densities were then compared on the standard curve and the respective concentrations were obtained. This was then multiplied with the dilution factor and thus the concentration of the drug was calculated. The different concentrations of drug were then plotted on a graph against time and thus the pattern of release was obtained.

#### Statistical Analysis

The data was analysed for mean, standard deviation along with Students t-test unpaired and Students t-test paired. The results are presented with a 95% confidence interval and are regarded as statistically significant when  $P \leq 0.05$ .

#### Results

The study included 20 patients 7 females and 13 males with an average age of 44.6 yrs. The patients had adult periodontitis with at least two sites on the contralateral sides with 5-7mm pockets.

The comparisons of the clinical and microbiological parameters were done between and within the control

groups at baseline, ten days, twenty one day and three months.

The plaque index and gingival index showed significant improvement from baseline to three months, with no significant difference between the groups ( $p > 0.05$ ). The mean probing depth showed significant improvement from baseline in both the groups, with no significant difference between the groups ( $p > 0.05$ ). The comparison of relative attachment levels from baseline to three months showed significant gain in both the groups. There was no significant difference in the gain in between the groups ( $p > 0.05$ ).

The spirochetes level showed significant reduction in numbers from baseline to three months in both the groups ( $p < 0.01$ ) and also there was a significant reduction in the test group when compared to the control group at three months ( $p < 0.01$ ).

The levels of gram positive cocci showed no significant reduction in the control group at all time intervals in the control group. In the test group there was a significant reduction in numbers at three months from baseline in the test group. However there was no significant difference in between the groups at all time intervals.

The levels of gram positive bacilli showed no significant reduction in both the control group and test group at all time intervals. There was also no significant difference in between the groups at all time intervals. The gram negative bacilli levels in the control group showed significant reduction from baseline only at three months ( $p < 0.05$ ). In the test group the reduction in levels was significant from 21 days itself. The levels showed no significant difference between the groups at all time intervals.

**Table 1:** Mean values of all parameters in Control group

Duration	GI	PI	PD	RAL	S	C+	B+	B-
0 day	2.00	2.35	5.70	5.75	14.60	50.90	21.50	28.10
10 days	2.00	2.10	--	--	--	--	--	--
21 days	1.80	1.70	4.90	5.60	6.10	51.50	27.60	20.70
3 months	0.25	1.25	4.65	5.30	7.80	56.20	25.80	18.00

GI-Gingival Index, PI-Plaque Index, PD-Probing Depth, RAL-Clinical Attachment, S- Spirochetes, C+ Gram Positive, Cocci, B+ Gram Positive Bacilli, B- Gram Negative Bacilli

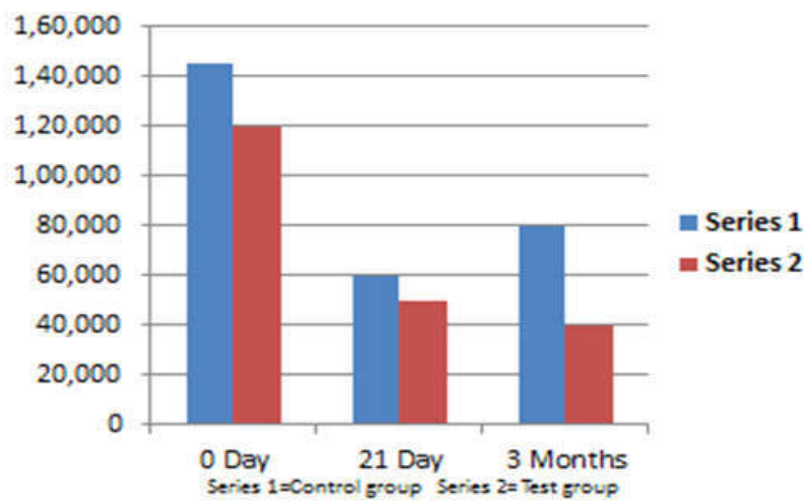
**Table 2:** Mean values of all parameters in Test group

Duration	GI	PI	PD	RAL	S	C+	B+	B-
0 day	2.00	2.35	6.00	6.10	11.45	44.20	21.70	33.50
10 days	2.00	2.10	--	--	--	--	--	--
21 days	1.85	1.55	5.05	5.65	5.40	50.5	24.95	23.40
3 months	0.10	1.15	4.10	4.80	4.35	54.3	21.40	23.75

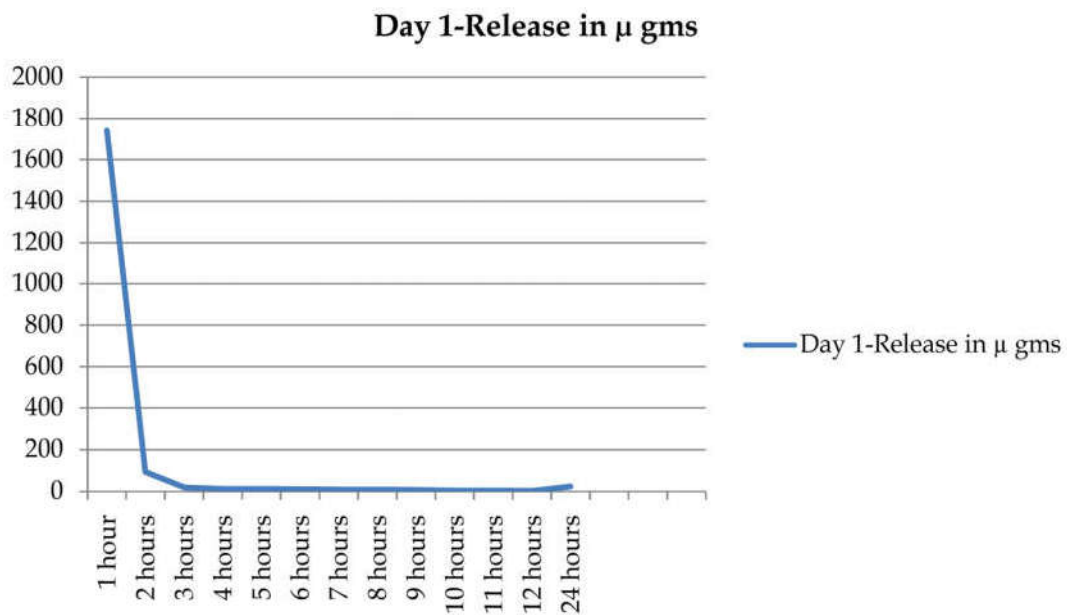
**Table 3:** Comparison of mean pocket probing depth and relative attachment level between the groups

Probing depth	Mean		Standard Deviation		t-value	p- value	Significant
	Control	Test	Control	Test			
Baseline	5.70	6.00	0.9787	1.2140	-0.8604	>0.05	NS
21 days	4.90	5.05	1.0208	1.2763	-0.4105	>0.05	NS
3 months	4.65	4.10	1.1367	1.4105	1.3578	>0.05	NS
RAL	Mean		Standard Deviation				
	Control	Test	Control	Test	t-value	p- value	Significant
Baseline	5.75	6.10	0.9665	1.1192	-1.058	>0.05	NS
21 days	5.60	5.65	0.8826	1.4244	-0.113	>0.05	NS
3 months	5.30	4.80	1.0809	1.3219	1.3095	>0.05	NS

**Bar diagram comparing the Spirochetes between the groups**



**Fig. 1:** Bar diagram comparing the spirochete levels between the groups



**Fig. 2:** Release pattern of Chlorhexidine from chip on Day 1

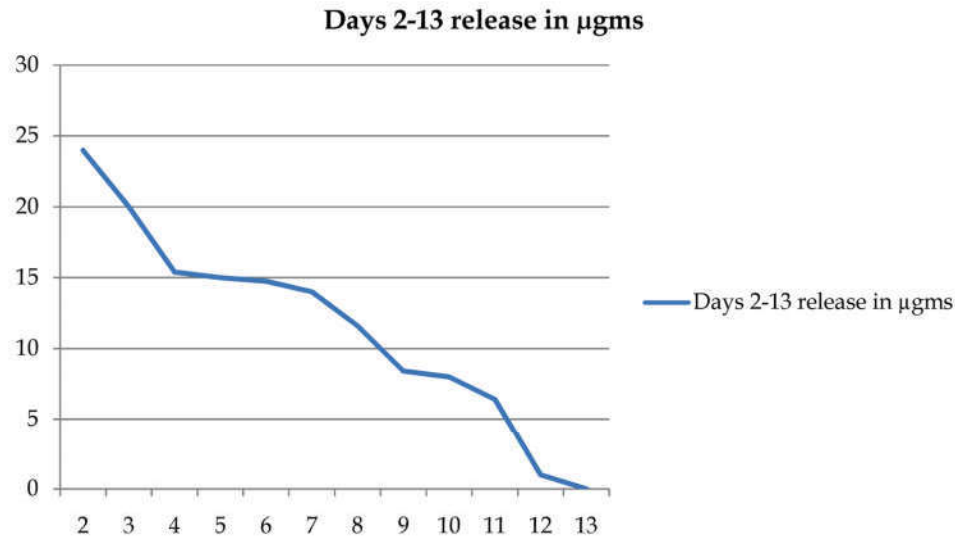


Fig. 3: Release pattern of Chlorhexidine from chip from Day 2-13

## Discussion

The successful long term management of adult periodontitis requires a proper maintenance of the results obtained after treatment i.e. the reduced levels of periodontopathic bacteria. This can be successfully done with the adjunctive use of antimicrobials [10].

All the parameters were recorded at baseline, tenth day, twenty first day and at three months at the target sites. Except for relative attachment level and probing depth which was not recorded at tenth day as the chip would be disturbed if still present and the readings would not be accurate. The drug is supposed to be released for at least 7-10 days after which the chip degrades [11].

Significant reduction in the gingival index and plaque index scores were seen in both the control and test groups from baseline to 3 months (Table 1 and 2). These findings are in accordance with the results obtained in the studies conducted by Stabholtz et al, Soskolne et al, Marjorie et al, Haesman et al [12,13]. This reduction in scores can be attributed to scaling and root planing and the oral hygiene instructions given after treatment.

There was a significant reduction in pocket depth in the control group from baseline to 21 days and from baseline to 3 months. However there was not much reduction in probing depth from 21 days to 3 months, which signified no further improvement in the health of the tissues. The pocket depth in the test group however showed significant continuous reduction in probing depth from baseline to 3

months. The reduction from baseline to 21 days was similar to the control group about 0.85mm. However the continued improvement or reduction in probing depth was seen from 21 days to 3 months about 1.05mm giving a total reduction of about 1.9mm from baseline. These findings are in agreement with the results of other studies by Soskolne et al, Marjorie et al, and Haesman et al.

The relative attachment levels in the control group showed no significant gain till 21 day (0.1mm). At 3 months significant gain was obtained which was about 0.45 mm. This was similar to the results obtained by previous studies conducted by Marjorie et al, Haesman et al [14].

In the test group again there was no significant gain in relative attachment level till 21 day, the gain here was slightly more than control group. At 3 months there was a significant gain in the relative attachment levels from baseline about 1.25mm, which was 0.85mm more than the control group (Table 3).

This is in accordance with the study done by Christopher J Smiley et al 2015, where they recommended four therapies as adjunct to scaling and root planing namely systemic subantimicrobial dose doxycycline, systemic antimicrobials, chlorhexidine chips and photodynamic therapy with a diode laser, and have found CAL gains to about 0.2 to 0.6 mm more than SRP alone [15].

Probing depth and relative attachment level values when compared between the test and control group showed no difference between the groups at three months from baseline.

The fact that bacteria are found within the depth of the epithelial lining as well as in the connective tissues of the pocket wall might initially protect them from Chlorhexidine. The natural shedding of the epithelium would eventually expose the protected bacteria to drug. Thus the use of sustained local drug delivery system like Chlorhexidine chip can delay the repopulation of bacteria [16].

There was no statistically significant difference in the cocci and bacilli values between the groups because both groups showed increased cocci and decreased bacilli with slightly greater improvement seen in the test group. The mean spirochete values showed significant decrease from baseline to 3 months in both the groups (Figure 1).

In vitro estimation of the release pattern was conducted as in vivo experiment is difficult and highly technique sensitive. The results showed that 1740µgms (69.7%) of the drug was released in the first hour only and from the second hour a linear decrease was seen (Figure 2).

This is not in accordance with the release in GCF, where the initial peak was seen at 2-4 hour (2007µgs) with slightly lower concentrations maintained over the next 96hrs and then there was a linear decrease in the drug concentration (Soskolne et al). The total concentration of the drug released was 2085.35µgs out of 2500µgs (Figure 3).

The difference in the amount of drug released may be attributed to the constituents of GCF i.e. enzymes which help in the degradation of the matrix and release of the drug. Other factors like pH, presence of salts, volume, rate and flow of GCF may influence the release pattern [17].

However, according to Stanley et al [18] the minimum inhibitory concentration was reported to be 125µgs/ml for more than 99% of the bacterial flora isolated from periodontal pockets. In the present study, MIC was reached only in the first hour of release. A possible explanation could be that 4ml of the solution was used to study the release. This could have led to the dilution of the drug. If the same amount of drug is released in 0.3 to 0.5 ml/day which is supposedly the volume of GCF, the minimum inhibitory concentration could be reached.

However though there was no statistically significant differences between the groups, the test group showed slightly better pocket depth reduction and gain in relative attachment levels. According to the systematic review done by Bonito et al, among the local antimicrobial adjunctives used the most beneficial were tetracycline, minocycline, metronidazole and chlorhexidine [19,20].

## Conclusion

The Chlorhexidine chip has shown promising results, when compared to scaling and root planning alone. This supports thenon surgical therapy in a way, in which the need for surgery is eliminated in most of the moderate periodontitis cases and also in cases where surgery is not an option. The results may be still better and maintained for a longer period of time, if the chip placement is repeated after three months. This could help in maintaining a healthy micro flora for a longer period. Therefore in future, studies need to be carried out for longer durations for an evidently beneficial clinical outcome. The need for detailed microbiological study using the advanced techniques like PCR, persists to co-relate it with the clinical findings observed.

## Conflict of Interest

None

## Funding

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