



Research Paper

## Comparative Evaluation of the Two Different Formulations of Chlorhexidene Gel in the Treatment of Chronic Periodontitis

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### ABSTRACT

**Background:** Chlorhexidine has been used in the dental practice as an excellent antiplaque agent. It exhibits special property of substantivity and also possesses a broad antimicrobial spectrum which makes its use in wide variety of oral disorders. The present study aimed to evaluate and compare the improvement in treatment outcome after the use of a hydrophobic gel with good gingival adhesion for 14 days after the scaling and root planing of patients with chronic periodontitis and with the use of a regular hydrophilic gel.

**Material and Methods:** Patients with moderate Chronic Periodontitis were divided in the two study groups. At baseline and 3 months after the treatment the following parameters were recorded: pocket depth, Approximal Plaque Index, Modified Gingival Index, Simplified Oral Hygiene Index, bleeding on probing. Patients received scaling and root planing in two sessions at 24 hours interval. After the treatment, patients in the test group applied the hydrophobic adhesive chlorhexidine gel once a day, every other day, while in the control group the gel was used twice daily.

**Results:** Both treatments resulted in significant improvement in all clinical indices, except Approximal Plaque Index, which deteriorated significantly in both groups. Three months after mechanical treatment, the mean probing depth changed in the test group from  $4.25 \pm 0.48$  to  $2.78 \pm 0.45$  mm, and in the control group from  $4.27 \pm 0.32$  to  $2.68 \pm 0.21$ .

**Conclusion:** Both adjunctive anti-infective therapies induced clinical improvement 3 months from baseline. The differences between the two treatments were not statistically significant.

**KEYWORDS:** Chlorhexidene gel, Hydrophobic, Periodontitis.

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### I. INTRODUCTION

Dental caries and periodontal disease are the two predominant diseases affecting the oral cavity and dental plaque play a key role in the progression of these two diseases. Dental plaque forms naturally on the teeth. In the absence of adequate oral hygiene, it can accumulate beyond the levels that are compatible with dental health and at susceptible sites dental caries or periodontal disease or both can occur. Effective removal of dental plaque is one of the main strategies for the prevention of these two diseases[1].

The first step in treating already established periodontitis is the elimination of soft and hard deposits from the teeth in order to decrease the bacterial load and achieve local subgingival homeostasis. The non-surgical periodontal therapy which includes powered and manual scaling and root planing (SRP), is considered the cornerstone of the periodontal therapy[2].

Plaque control by mechanical debridement is highly labor intensive whether professionally administered or practiced personally, satisfactory home care further demands a measure of manual dexterity and a high degree of motivation, which many individuals do not possess. Not surprisingly, a large number of chemical agents have been tested for their ability to reduce plaque accumulation[1]. Chlorhexidine is at the moment the “gold standard” antiseptic used in the periodontal therapy. Chlorhexidine is present in different formulations: mouthwash, gels, sprays, toothpaste and even chewing gum[3].

Chlorhexidine is a cationic bisbiguanide, having a broad antibacterial activity associated with a low toxicity. Its spectrum is represented by gram-negative and gram-positive bacteria, yeasts, dermatophytes and some lipophilic viruses [4]. It adheres to oral mucosa and tooth structures, presenting a long substantivity, which is the ability of an agent to be retained in particular surroundings [2],[5]. Its effect can last up to 12 hours[6] ,

due to the properties that allow the chlorhexidine molecules to bind to the oral mucosa, teeth, acquired pellicle and salivary proteins.

The present research aimed to evaluate, in a randomized controlled study, whether the daily use of a hydrophobic chlorhexidine gel with good gingival adhesion (durimplant®, artis Pharma GmbH & Co. KG, Dettenhausen, Germany) 14 days after the SRP of patients with chronic periodontitis would improve the short-term treatment outcome, when compared with the use of a regular hydrophilic gel. Durimplant® is a hydrophobic gingiva-adhering gel with a complex composition, low solubility in saliva and increased mucosal substantivity, due to its content of hypromellose (hydroxypropylmethyl-cellulose). Its active ingredients are: essential oils of *Salvia lavandulifolia* and *Mentha piperita*, thymol, chlorhexidine digluconate and diacetate, allantoin (with cell-regenerating and wound-healing properties).

## II. MATERIALS AND METHODS

For the present study, the patients were selected from those visiting the outpatient department of Department of Periodontics, Indira Gandhi Govt. Dental College Jammu. The study protocol was described to the patients and an informed consent was obtained. An ethical clearance was obtained from the institutional ethical committee prior to the study. The present study compared the efficacy of SRP with an adjunctive antimicrobial hydrophobic gingiva-adhering gel with complex composition (durimplant®) (test group) or with a standard commercially-available 1% chlorhexidine digluconate water-soluble gel with reduced adhesion to gingiva (Hexigel 1% gel, ICPA healthcare product) (control group).

The study included the patients with moderate chronic periodontitis, with no periodontal therapy during the last two years, and no antibiotic or anti-inflammatory drugs intake during the last 6 months before baseline examination. According to the Center for Disease Control and the American Academy of Periodontology (CDC-AAP) definition, patients with moderate chronic periodontitis were considered as presenting 2 or more interproximal sites with  $\geq 4$  mm clinical attachment level (CAL) - not on the same tooth - or 2 or more interproximal sites with  $\geq 5$  mm probing depth (PD), also not on the same tooth[7]. Patients who were pregnant or nursing or had diseases with influence on the periodontal disease and its treatment were excluded from the study.

Clinical measurements were taken at baseline and 3 months after the periodontal treatment. UNC-15 periodontal probe (Hu-Friedy, Chicago, IL) was used to record the measurements that took the cement-enamel junction as a reference point and those were rounded up to the nearest millimeter. The periodontal parameters which were assessed were the Approximal Plaque Index (API)[8], the Simplified Oral Hygiene Index (OHI-S)[9], the Modified Gingival Index (MGI)[10], the Gingival Bleeding Index (BOP)[11], the Periodontal pocket depth (PD), the gingival recession (GR), the clinical attachment level (CAL). PD, GR and CAL were considered according to the standard clinical definitions and were measured at 6 points per tooth[7].

Following professional cleaning and extensive repeated oral hygiene instructions until the API reached a value  $\leq 35\%$ , a full-mouth SRP was performed under local anesthesia in two sessions within 24 hours, using ultrasonic (Newtron® Booster, Satelec Acteon, Merignac Cedex, France) and hand instruments (Gracey Standard Curettes, Hu-Friedy Manufacturing Co., Chicago, IL, USA). For the test group, at the end of the SRP, durimplant® was applied by gentle rubbing on the marginal gingiva. The subjects in the test group were instructed to apply durimplant® on the marginal gingiva for the next 14 days, once every second day, immediately after the evening tooth-brushing. In the subjects in the control group, at the end of the SRP, a standard, water-soluble 1% chlorhexidine gel (Hexigel 1% gel) was applied in the same way. The subjects in the control group were instructed to apply the 1% chlorhexidine gel for 14 days on the marginal gingiva twice a day, in the morning and in the evening every day, immediately after the tooth-brushing.

After the SRP, the patients performed normal oral hygiene practices with toothbrushes and interdental brushes. After 3 months, the patients underwent supportive periodontal care by a periodontist in which the clinical measurements were recorded before the mechanical instrumentation.

The collected data were processed using the 20 SPSS software package. The Wilcoxon nonparametric test was used to compare the mean differences between the baseline and 3 months afterwards, and the Mann-Whitney non-parametric test was used to compare the mean differences between the groups.

## III. RESULTS

A total of 30 patients were included in the study and were subject to randomization. 15 patients each were randomly divided in two groups: the Test Group (durimplant®) and the Control Group (Hexigel®). The mean age of the patients was  $45.4 \pm 4.5$  for the test group and  $45.9 \pm 4.6$  for the control group. The values of the investigated parameters for the test and control group at baseline and 3 months later, are shown in Table I.

**Table I:** Clinical parameters at baseline and after 3 months for each of the study groups (Durimplant® and Hexigel®)

Clinical parameter	Study group	Baseline	3 months	ΔBaseline-3 months	Significance
PD	Test	4.25±0.48	2.78±0.45	1.47±0.46	P<0.001
	Control	4.27±0.32	2.68±0.21	1.59±0.40	P<0.01
API	Test	18.84±7.21	39.45±18.56	-20.61±21.44	P<0.01
	Control	22.40±6.30	39.48±16.30	-17.08±17.51	P<0.05
OHI-S	Test	0.48±0.25	0.59±0.60	-0.11±0.59	Not significant
	Control	0.59±0.24	0.47±0.23	0.12±0.26	Not significant
MGI	Test	0.98±0.41	0.24±0.20	0.74±0.40	P<0.001
	Control	1.26±0.16	0.28±0.24	0.98±0.29	P<0.01
BOP	Test	54.60±19.61	24.25±17.50	30.35±17.29	P<0.01
	Control	65.06±13.65	25.95±14.75	39.11±13.13	P<0.01

**Table II:** Changes in the clinical parameters 3 months after the treatment between the studied groups using durimplant® (n=15) and Hexigel® (n=15)

Clinical parameter	Treatment group	ΔBaseline-3 months	ΔTx	Significance
PD	Test	1.47±0.46	-0.12	Not significant
	Control	1.59±0.40		
API	Test	-20.61±21.44	-3.53	Not significant
	Control	-17.08±17.51		
OHI-S	Test	-0.11±0.59	-0.23	Not significant
	Control	0.12±0.26		
MGI	Test	0.74±0.40	-0.24	Not significant
	Control	0.98±0.29		
BOP	Test	30.35±17.29	-8.76	Not significant
	Control	39.11±13.13		

Both treatments resulted in significant improvement in all clinical indices, except OHI-S. However, good OHI-S scores were recorded, for both groups, in both baseline and 3 months examinations. Three months after application, a significant mean reduction of PD was recorded in the test group (1.47±0.46 mm) and in the control group (1.59±0.40 mm). The reduction of PD seems important as it could further reduce the surgical treatment need.

#### IV. DISCUSSION

Chlorhexidine is not only an excellent antiplaque agent but it also possesses very good antimicrobial properties. Its broad antimicrobial spectrum can be considered as boon for maintaining overall oral health.

Currently, the most commonly used procedure for the treatment of periodontitis is the use of mechanical disruption of the subgingival biofilm by SRP. The clinical and the microbiological response to this nonsurgical therapy of chronic periodontitis has been well documented. A rigorous personal plaque control should follow the professional one in order to obtain good results after the therapy. However, several studies have shown that the mechanical disruption is insufficient for altering the composition of the flora so as to prevent a recurrence of infection at the affected sites [12].

The present study aimed to evaluate and compare the improvement in treatment outcome after the use of a hydrophobic gel with good gingival adhesion for 14 days after the scaling and root planing of patients with chronic periodontitis and with the use of a regular hydrophilic gel. A 14 days treatment regimen with an adherent gingival chlorhexidine gel (durimplant®) was compared with the use of a commercially-available 1% chlorhexidine gel (Hexigel®). Positive effects were associated with both chlorhexidine gel formulations but no significant statistical differences were noticed between the study groups. In fact no improved effect was observed due to the synergic activity of the additives (e.g. thymol, peppermint and sage oil, allantoin) included in durimplant®.

Chlorhexidine is a broad-spectrum biocide effective against Gram-positive bacteria, Gram-negative bacteria and fungi. Chlorhexidine inactivates microorganisms with a broader spectrum than other antimicrobials (e.g. antibiotics) and has a quicker kill rate than other antimicrobials (e.g. povidoneiodine). It has both bacteriostatic (inhibits bacterial growth) and bactericidal (kills bacteria) mechanisms of action, depending on its concentration. Chlorhexidine kills by disrupting the cell membrane. Upon application in vitro, chlorhexidine can kill nearly 100% of Gram-positive and Gram-negative bacteria within 30 seconds. Since chlorhexidine formulations can destroy the majority of categories of microbes, there is limited risk for the development of an opportunistic infections[13].

In topical applications, chlorhexidine is shown to have the unique ability to bind to the proteins present in human tissues such as skin and mucous membranes with limited systemic or bodily absorption. Protein bound chlorhexidine releases slowly leading to prolonged activity. This phenomenon is known as substantivity[14] and allows for a longer duration of antimicrobial action against a broad spectrum of bacteria and fungi. In fact, chlorhexidine's antimicrobial activity has been documented to last at least 48 hours on the skin. In oral applications, chlorhexidine binds to the mouth tissue, oral mucosa and teeth. It is then released over time to kill bacteria and fungi. This helps to reduce the bacterial count and prevents dental plaque. It has become the gold standard in dentistry due to its ability to adhere to soft and hard tissue and maintain a potent sustained release[13]. One of the limitations of the present research is the short term follow-up period.

## V. CONCLUSION

Chlorhexidine is a germicidal mouthwash that reduces bacteria in the mouth. Both adjunctive anti-infective therapeutic approaches were associated with clinical improvement 3 months after baseline. However, the differences between the two treatments using two chlorhexidine-based formulations were not statistically significant. Tooth brushing alone is not effective in removing plaque, mostly in interdental areas, and consequently, chemical antiplaque control using chlorhexidine gels may be justified to overcome the limitations of tooth brushing.

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