



## Clinical Evaluation Of Efficacy Of Topically Applied Herbal Gum Astringent Gel (HiOra™-GA) As An Adjunct To Scaling In The Treatment Of Plaque Induced Moderate To Severe Chronic Gingivitis.

### Dental Science

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### ABSTRACT

**Objectives:** To evaluate the efficacy of topically applied herbal gum astringent gel (HiOra™-GA) as an adjunct to scaling in the treatment of plaque induced moderate to severe chronic gingivitis. **Materials And Methods:** Sixty subjects with moderate to severe chronic gingivitis were randomly assigned into Test group (scaling followed by HiOra-GA™ application) & control group (only scaling). An analysis of plaque index (PI), gingival index (GI) and sulcus bleeding index (SBI) were carried out at baseline and after 3 weeks and 6 weeks. **Results:** On intra-group comparison statistically significant reduction ( $p \leq 0.05$ ) at 3 and 6 weeks from baseline in both test group and control group. **Conclusion:** Topical HiOra-GA gel application resulted in significant reduction in plaque and gingival inflammation.

### KEYWORDS

Plaque-induced gingivitis, HiOra-GA gel, scaling.

### INTRODUCTION

Among various periodontal disease affecting humans, the most prevalent is gingivitis, affecting more than 90% of the population, regardless of age, sex, or race.<sup>1</sup> The most prevalent form of gingivitis is in response to bacterial biofilms, termed Plaque-induced gingivitis. Gingivitis is a reversible with good oral hygiene. However, if left untreated, or if not controlled, gingivitis can progress to periodontitis, where the inflammation results in tissue destruction and alveolar bone resorption, which can ultimately lead to tooth loss.

Plaque control and prevention of gingivitis is the main goal of prevention of periodontal diseases. Self-performed mechanical plaque removal is an unquestioned method of controlling plaque and gingivitis.<sup>2</sup> Mechanical plaque control is time consuming and some individuals may lack motivation for these procedures. It may not always reduce or eliminate the bacteria within the gingival tissues, and in the structures inaccessible to periodontal instruments.<sup>3</sup> The inability of the general adult population to perform adequate tooth brushing has led to the search for chemotherapeutic agents to improve plaque control<sup>1</sup>.

Various antimicrobials<sup>3</sup>, anti-inflammatory agents<sup>4</sup> have been tried in literature as a topical application preparation. One such herbal medicine is HiOra™-GA - a poly herbal gel. HiOra™-GA contains Myristica fragrans, Pterocarpus marsupium, Triphala and Terminalia arjuna and the effect of the formulation is due to the synergistic action of the herbs.

Hence, a study was conducted to clinically evaluate the efficacy of topically applied herbal gum astringent gel, HiOra™-GA.

### METHODS

Sixty subjects in the age group of 18-35 years with plaque induced moderate to severe chronic gingivitis (as established on the basis of clinical parameters) were selected for randomized, controlled clinical trial from Outpatient Department of Periodontology.

Subjects in the age Group of 18- 35 years with no history of any periodontal treatment in last 6 months and systemically healthy and co-operative subjects with clinical signs of gingivitis (bright red discolouration of gingiva, bleeding on probing, edematous gingiva) and probing depth of < 3 mm with no evidence of clinical attachment loss were included in the study.

Uncooperative subjects, medically compromised patients and pregnant & lactating females & those on oral contraceptive pills, subjects with history of usage of medications such as antibiotics and analgesics within past 6 weeks and subjects with history of use of over the counter use of anti-oxidants like Vitamin C, Vitamin E or  $\beta$ -Carotene within the past 3 months were excluded from the study. Smokers & subjects using tobacco in any form and individuals with

any known drug allergy were excluded from the study.

Ethical clearance was obtained from Institutional review board before commencement of the study. A detailed case history of subjects was recorded. They were informed about the nature of the investigation. An informed consent was obtained from the subjects participating in randomized controlled clinical trial study.

Orthopantomograms (OPGs) were taken to exclude subjects with underlying periodontal disease. Two weeks before the commencement of the study, subjects received an intraoral examination and a full mouth oral prophylaxis with the help of piezoelectric scaler (Satelec™) in single sitting. Subjects were instructed to brush their teeth for 1 minute, 2 times a day using modified bass technique with soft bristle tooth brush with customized formulated toothpaste with no antibacterial and anti-inflammatory properties. Subjects were also asked to refrain from chemical plaque control measures and from taking nutritional supplements, anti-oxidants, anti-inflammatory drugs.

Two weeks later, Plaque index (PI) (Silness P & Loe H, 1964), Sulcus bleeding index (SBI) (Muhlemann H.R. & Son S. 1971) and Gingival index (GI) (Loe H & Silness J, 1963) were recorded as baseline recordings. Study subjects (N= 60) were randomly allocated in test group (N=30) and control group (N=30). In test group, scaling along with self-application of herbal gum astringent gel, (HiOra™-GA gel) was performed and in Control group only scaling was performed. Gingival index, plaque index and sulcus bleeding were recorded at 3 weeks and at 6 weeks. Result of the observations was subjected to statistical analysis.

Subjects were asked to report immediately if they noticed any allergic reaction or discomfort on using the products. (Figure no. 1,2,3,4)

### RESULTS

The change in mean scores of various indices in each group over the three time periods was analyzed using Repeated measures ANOVA test. Intergroup comparison of mean change scores of various indices was done using unpaired t test.

On intragroup comparison it was observed that there was significant reduction in plaque index, gingival index, sulcus bleeding index scores at 3 and 6 weeks when compared to baseline in both test and control group. (Table no 1, 2, 3)

On intergroup comparison, there was a statistically significant difference found in the percentage reduction of gingival index and sulcus bleeding Index scores in the test and control groups at from baseline to 3 weeks and 6 weeks. (Table no 2, 3) However on intergroup comparison, there was no statistically significant difference found in the percentage reduction plaque index scores between the test

and the control groups from baseline to 3 weeks and 6 weeks. (Table no 1)

**DISCUSSION**

Plaque-induced Gingivitis is the most common form of inflammatory diseases affecting the periodontium. Researchers started using oral hygiene products containing chemotherapeutic agents in conjunction with mechanical methods to compensate for its inadequacy and may be effectively incorporated in different formulations<sup>5</sup>. The substantivity of an antiplaque agents can be enhanced, thus its clearance from the oral cavity can be prolonged if antiplaque agents are delivered in the gel form.<sup>6</sup> So in the present study HiOra™-GA was used in the gel form.

Even though studies in animals and in vitro may show the antimicrobial properties of several of these products, there is no other way of knowing their real clinical effect without conducting a randomized clinical trial.<sup>7</sup> So the present study was designed accordingly to get the real clinical effect which can be implemented in daily practice.

Lately, herbal products have gained increasing popularity<sup>8</sup> due to increasing realization of side effects of allopathic medicines.

In the present study, a significant reduction in PI, GI and SBI scores at 3 week and 6 week time intervals was observed with the use of a herbal gel. The reduction in plaque and gingivitis scores in control group can be attributed to the antibacterial properties of its active constituents like Myristica Fragrans (Jatiphala), Pterocarpus Marsupium (Asana), Terminalia Arjuna and Triphala.

Jeyaraj JM and Chithresan K 2010<sup>9</sup> reported that HiOra™-GA significantly reduced plaque and gingival inflammation. This finding was similar to the present study. Apoorva SM et al<sup>10</sup> concluded that Triphala (HiOra™GA®) was found to be effective in improving gingival status and showed significant improvement in clinical parameters when compared with Cinnamomum (herbathine herbal gum paint®). The present study showed similar results. It was concluded that when HiOra™-GA was used as an adjunct to scaling, showed statistically significant improvement in clinical parameters.

Bhattacharjee R et al (2015)<sup>11</sup>, Naiktari RS 2014<sup>12</sup>, Chainani SH et al 2014<sup>13</sup>, Bhat N et al 2014<sup>14</sup> concluded that the antiplaque and antigingivitis activity of triphala closely parallels that of gold standard chlorhexidine. Thus Triphala being a herbal formulation can be used safely as an alternative antiplaque agent to 0.2 % chlorhexidine. This finding was similar to the present study. Triphala is analgesic, anti-inflammatory, can be used for a better maintenance of oral hygiene.

In a vitro study by Zaleha Shafiei et al 2012<sup>15</sup> reported that the Myristica fragrans extracts showed antibacterial activities against both Gram-positive cariogenic and Gram-negative periodontopathic bacteria. Thus, they have confirmed that Myristica Fragrans extract has broad spectrum antibacterial activity.

Terminalia Arjuna is an astringent, cooling, demulcent, styptic and tonic. Rane MM et al (2003)<sup>16</sup> concluded that tannins in ethanolic extract of bark of Terminalia Arjuna showed wound healing property on topical application on wound.

Tippani R et al 2010<sup>17</sup> concluded that Pterocarpus Marsupium has wound healing, antibacterial and antioxidant properties, so helps in curing gingivitis.

HiOra™-GA gel shows the synergistic action of the herbs and has several medicinal properties.

**CONCLUSION**

Herbal gel showed promising results when used as an adjunct to scaling in the control of moderate to severe plaque induced gingivitis.

**LIMITATION**

Sample size was small as 60 subjects were selected for this study. Further studies need to be conducted using large sample size to justify the role of HiOra™-GA Herbal gel as an adjunct to scaling in moderate to severe plaque induced gingivitis. No microbiologic and biochemical analysis was done to obtain objective result. These are the two limitations which we think our study is having.

**Table no 1** Changes in plaque index scores and comparison of percentage reduction in the test group (Scaling + HiOra™-GA gel application) and the control group (Scaling alone).

Time interval		Test group	Control group	
Baseline		2.20 ± 0.32	2.14 ± 0.33	
3 weeks		1.52 ± 0.35	1.48 ± 0.33	
6 weeks		1.36 ± 0.32	1.33 ± 0.29	
P value		< 0.001*	< 0.001*	P value
Changes in plaque index scores	Baseline to 3 weeks	0.68 ± 0.32	0.66 ± 0.36	0.825
	Baseline to 6 weeks	0.84 ± 0.31	0.81 ± 0.42	0.774

**Table no 2** Changes in Gingival index scores and comparison of percentage reduction in the test group (Scaling + HiOra™-GA gel application) and the control group (Scaling alone).

Time interval		Test group	Control group	
Baseline		2.05 ± 0.26	2.12 ± 0.29	
3 weeks		1.12 ± 0.20	1.40 ± 0.29	
6 weeks		0.94 ± 0.22	1.21 ± 0.23	
P value		< 0.001*	< 0.001*	P value
Changes in gingival index scores	Baseline to 3 weeks	0.93 ± 0.31	0.72 ± 0.34	0.017*
	Baseline to 6 weeks	1.11 ± 0.32	0.91 ± 0.32	0.015*

**Table no 3** Changes in sulcus bleeding index scores and comparison of percentage reduction in the test group (Scaling + HiOra™-GA gel application) and the control group (Scaling alone).

Time interval		Test group	Control group	
Baseline		2.74 ± 0.73	2.73 ± 0.73	
3 weeks		1.22 ± 0.32	1.67 ± 0.38	
6 weeks		0.91 ± 0.32	1.33 ± 0.32	
P value		< 0.001*	< 0.001*	P value
Changes in sulcus bleeding index scores	Baseline to 3 weeks	1.52 ± 0.84	1.06 ± 0.57	0.016*
	Baseline to 6 weeks	1.83 ± 0.86	1.41 ± 0.75	0.045*

**Test Group**



**Figure No. 1**  
At Baseline



**Figure No. 2**  
At 6 Weeks

**Control Group**



**Figure No 3**  
At Baseline



**Figure No 4**  
At 6 weeks

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