



TO COMPARE TWO LOCAL DRUG DELIVERY SYSTEMS A CHLORHEXIDINE GEL AND NANOBIOFUSION GINGIVAL GEL AS AN ADJUNCT TO SCALING AND ROOT PLANING IN THE TREATMENT OF CHRONIC PERIODONTITIS

Dentistry

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ABSTRACT

Background: NBF gel creates nanobioactive protective film which results in increased absorption, improved clinical effectiveness and CHLOSITE gel is made of xanthan gel which is a saccharide polymer that when combined with water forms a three-dimensional pseudo-plastic reticulum which retains chemotherapeutic agents and released slowly. **Aim:** To evaluate and compare the clinical effectiveness of two locally delivered chlorhexidine gel & Nano-Bio Fusion gingival gel as an adjunctive therapy to scaling and root planing (SRP) in the treatment of chronic periodontitis. **Material and method:** A total of 15 Patients with 30 sites with chronic periodontitis treated with scaling and root planing and local drug delivery of Chlorhexidine Gel and NanoBioFusion Gingival Gel. Clinical parameters assessed were Plaque Index (PI), Gingival Index (GI), Sulcus Bleeding Index (SBI), Probing pocket depth, Clinical Attachment Level (CAL). **Results:** Chlorhexidine Gel and NanoBioFusion Gingival Gel are effective in reducing PI, GI, SBI, PPD and CAL when used as adjunct to scaling and root planning (SRP). However, both gel are equally effective in reducing PI, GI, CAL at different time interval of 1 & 3 month, but Chlorhexidine Gel is more effective in reducing SBI and PPD as compared to NanoBioFusion Gingival Gel. **Conclusion:** The results indicate anti-inflammatory, antibacterial, and antioxidant property of the NBF gel. It can be effectively used in treatment of patients with $\geq 5 - \leq 7$ mm periodontal pockets as an adjunct to SRP and is more effective than SRP alone in the treatment of Periodontal Pockets.

KEYWORDS

Local Drug Delivery, NBF Gingival Gel, Chlosite gel, Periodontal Disease.

INTRODUCTION

Periodontitis is a chronic inflammatory disease associated with dysbiotic plaque biofilms and characterized by progressive destruction of the tooth supporting apparatus.¹ The development of subgingivally placed controlled delivery systems has provided an effective intra pocket concentration levels of antibacterial agents, resulting in an altered subgingival flora and enhanced the healing of the attachment apparatus.² Local delivery devices (LDD) are system designed to deliver antimicrobial agents into the periodontal pocket to retain therapeutic levels for a prolonged period of time.³

NanoBioFusion (NBF) gingival gel is a patented scientifically formulated, bio-adhesive antioxidant gel harvesting naturally occurring antioxidants for targeted action.⁴ Once applied, NBF gel creates nanobioactive protective film which results in increased absorption, resulting in improved clinical effectiveness and visible results.⁴

CHLOSITE is made of xanthan gel which is a saccharide polymer that when combined with water forms a three-dimensional pseudo-plastic reticulum.⁵ When in contact with water, it forms a three dimensional pseudoplastic reticulum capable of holding and maintaining various substances in suspension.⁵

Thus, the present study aimed to evaluate and compare the clinical effectiveness of two locally delivered chlorhexidine gel & Nano-Bio Fusion gingival gel as an adjunctive therapy to scaling and root planing (SRP) in the treatment of chronic periodontitis.

MATERIAL AND METHOD

The split mouth study was conducted at Department of Periodontology with 15 patients, aged between 30-60 years with presence of probing depth of 5-7 mm classified as Localized or Generalized Chronic Periodontitis.

Inclusion criteria Systemically healthy patients between 30 to 60 years of age with presence of minimum two periodontally involved sites, PD between 5 to 7 mm, Localized or Generalized Chronic Periodontitis. Exclusion criteria Use of subgingival antimicrobial, chemical or herbal drugs in past 6 months, Endodontically treated teeth, furcation involvement, vertical bone defect, Habit of tobacco chewing and smoking, Pregnant and lactating women, Aggressive periodontitis, History of periodontal therapy in last 6 months.

A total of 15 Patients with 30 sites were identified and divided into 2 groups:

- Group A (Control Group) (n=15): SRP + chlorhexidine gel.
- Group B (Test Group) (n=15): SRP + NanoBioFusion Gingival Gel.

Clinical parameters assessed were Plaque Index (PI) (Silness And Loe, 1967), Gingival Index (GI) (Loe And Silness, 1963), Sulcus Bleeding Index (SBI) (Muhlemann And Son, 1971), Probing pocket depth, Clinical Attachment Level (CAL) at baseline, 1 month and 3 month.

After recording all the parameters at the baseline, scaling and root planing was performed (FIGURE 1 and 2). Patients were recalled after 3 weeks and local drug delivery was done. As per randomization sheet, one side was treated with CHX gel (Chlosite®) and other side with NBF Gingival Gel. It was applied into the deepest portion of periodontal pocket by means of a thin rounded tip needle (FIGURE 3 and 4) upto the margin of the gingiva. To ensure retention of both gel for long duration to be effective in the pocket, a periodontal dressing (Coe-Pak) was placed. (FIGURE 5 and 6)

Patients were recalled after 7 days. Post-operative home care instructions including brushing 2 times daily with a soft brush was

given. Patients were advised not to use oral chemotherapeutic agents and irrigation devices. No sub-gingival instrumentation was performed at subsequent visits. Postoperative assessment of clinical parameters was done at 1 month (FIGURE 7 to 8) and 3 month interval.



Figure 1 : Probing Pocket Depth Of 6 Mm At Control Site

Figure 2 : Probing Pocket Depth Of 6 Mm At Test Site



Figure 3 : Application Of Chlosite Gel

Figure 4 : Application Of NBF Gel



Figure 5 : Application Of COE Pak At Control Site

Figure 6 : Application Of COE Pak At Test Site

1 Month Follow Up



Figure 7 : 1 Month Follow Up. Probing Pocket Depth Of 4 Mm At Control Site

Figure 8 : 1 Month Follow Up. Probing Pocket Depth Of 4 Mm At Test Site

Statistical Method

The Collected data was entered in Microsoft excel (2010) spreadsheet. Appropriate descriptive statistical tests were computed using excel statistical operations. Statistical test for inter groups comparison was done by Independent Sample t test at 5% level of significance. The entire data was statistically analysed using SPSS version 20.0 software. Probabilities of less than 0.05 and 0.01 were accepted as statistically significant and highly significant respectively

RESULTS

Table 1 : Comparison of plaque index score in control and test group at different time interval

Pi	Mean	N	Std. Deviation	Std. Error Mean	T	P Value
Base-Line	Control 2.5793	15	0.37404	0.09658	-0.459	0.650
	Test 2.6433	15	0.38994	0.10068		
1 Month	Control 1.2780	15	0.22001	0.05681	-1.357	0.185
	Test 1.3987	15	0.26481	0.06837		
3 Month	Control 0.9347	15	0.25746	0.06647	-1.766	0.088
	Test 1.1040	15	0.26763	0.06910		

There was statistically significant mean PI reduction in CHX and NBF GEL groups. However, on comparison by independent sample t test, there was no statistically significant difference in mean PI reduction on test site as compared to control site (p value>0.05, NS).

Table 2 : Comparison of gingival index score in control and test group at different time interval

Gi	Mean	N	Std. Deviation	Std. Error Mean	T	P Value
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Base-Line	Control 2.5667	15	0.40606	0.10484	0.617	0.542
	Test 2.4820	15	0.34262	0.08846		
1 Month	Control 1.2720	15	0.27538	0.07110	-0.900	0.376
	Test 1.3847	15	0.39910	0.10305		
3 Month	Control 0.9327	15	0.32986	0.08517	-0.983	0.334
	Test 1.0373	15	0.24757	0.06392		

There was statistically significant mean GI reduction in CHX and NBF GEL groups. However, on comparison by independent sample t test, there was no statistically significant difference in mean GI reduction on test site as compared to control site (p value>0.05, NS).

Table 3 : Comparison of sulcus bleeding index score in control and test group at different time interval

SBI	Mean	N	Std. Deviation	Std. Error Mean	T	P Value
Base-Line	Control 2.8993	15	0.47113	0.12165	-0.978	0.336
	Test 3.0660	15	0.46207	0.11931		
1 Month	Control 1.2853	15	0.22500	0.05810	-3.083	0.005
	Test 1.5740	15	0.28432	0.07341		
3 Month	Control 1.0107	15	0.25339	0.06543	-2.876	0.008
	Test 1.2513	15	0.20213	0.05219		

There was statistically significant mean SBI reduction in CHX and NBF GEL groups. However, on comparison by independent sample t test, there was no statistically significant difference in mean SBI reduction at baseline in test site as compared to control site (p value > 0.05, NS), but at 1 month and 3 month there was statistically significant difference in mean SBI reduction in test site as compared to control site (p value<0.05, S)

Table 4 : Comparison of probing pocket depth score in control and test group at different time interval

PPD	Mean	N	Std. Deviation	Std. Error Mean	T	P Value
Base-Line	Control 6.0667	15	0.96115	0.24817	-0.222	0.826
	Test 6.0000	15	0.65465	0.23637		
1 Month	Control 3.8000	15	0.56061	0.14475	-2.779	0.010
	Test 4.3333	15	0.48795	0.12599		
3 Month	Control 3.2667	15	0.45774	0.11819	-2.792	0.009
	Test 3.7333	15	0.45774	0.11819		

There was statistically significant mean PPD reduction in CHX and NBF GEL groups. However, on comparison by independent sample t test, there was no statistically significant difference in mean PPD reduction at baseline in test site as compared to control site (p value > 0.05, NS), but at 1 month and 3 month there was statistically significant difference in mean PPD reduction in test site as compared to control site (p value<0.05, S)

Table 5 : Comparison of clinical attachment level score in control and test group at different time interval

CAL	Mean	N	Std. Deviation	Std. Error Mean	T	P Value
Base-Line	Control 4.1333	15	2.38647	0.61618	0.235	0.816
	Test 3.9333	15	2.28244	0.63596		
1 Month	Control 1.9333	15	2.37447	0.61308	-0.256	0.800
	Test 2.1333	15	1.88478	0.52735		
3 Month	Control 1.4667	15	2.41622	0.62386	-0.088	0.930
	Test 1.5333	15	1.64172	0.46599		

There was statistically significant mean CAL reduction in CHX and NBF GEL groups. However, on comparison by independent sample t test, there was no statistically significant difference in mean CAL reduction on test site as compared to control site (p value>0.05, NS).

DISCUSSION

Local drug delivery agents placed in periodontal pockets have authenticated the reduction in microbial load and improvements in clinical signs of periodontitis.⁵

Propolis is natural and powerful antibiotic and healing substantial. It is extracted by honeybees (*Apis mellifera*) from botanical provenance to protect the hive from invasion and infection. Studies have shown various antioxidant, anti-inflammatory properties of propolis.⁶⁻⁸ Antibiotic properties of propolis are retained in commercial formulations, as 1 mg/ml has exhibited the minimum inhibitory concentration of propolis extract across various periodontal microorganisms.⁹

Koo et al. in 2002¹⁰ evaluated propolis in mouth rinse formulation and a significant reduction in PI was obtained at 4th day of the study. Coutinho et al in 2012¹¹ used propolis as subgingival irrigation at 6 weeks interval period which showed a significant improvement in clinical parameters. Vitamin C enhances cell growth, healing and repair of tissue, influences the metabolism of collagen within the periodontium. Vitamin E acts as an antioxidant to reduce free radical and to protect cells from lipid peroxidation.

Our study showed statistically significant mean Plaque Index reduction in both groups. According to Jasprit Gill et al in 2011¹² the results showed similar results to our study in which Mean plaque score of both group I (tetracycline fibre) and group II (CHX gel) score at baseline (day 0) and at the end of 1 month and 3 months was highly significant.

Our study showed statistically significant mean Gingival Index reduction in both groups. Similar study by Ridhima Sood et al in 2014¹³ showed mean reduction in the gingival index score was 0.94 and 1.37 respectively, which was statistically significant ($P < 0.05$). The intergroup comparison of the gingival index values at baseline, 15 days and 30 days for group A (SRP), B (SRP+CHLOSITE GEL) and C (SRP+CHX IRRIGATION) showed no statistically significant differences in the results between the groups.

In our study there was statistically significant mean Sulcus Bleeding Index reduction in both groups. In study by Nishi Singh et al in 2020¹⁴ it was observed that while the mean scores PBI decreased among all the groups, the highest percentage reduction was seen in group 1 (SRP + NBF GEL) (82.30 ± 2.39), followed by group 3 (SRP) (53.54 ± 6.02) and group 2 (NBF GEL) (31.71 ± 4.34).

In our study there was statistically significant mean Probing pocket depth reduction in both groups. According to study done by Ravi Varma Prasad et al in 2019¹⁵ a split mouth design was used for intrasulcular application of NanoBioFusion gel as adjunct to scaling and root planing (SRP), hyaluronic acid as adjunct to SRP and SRP alone. On intragroup comparison, there was statistically significant decrease in PD between baseline and 4th week and between baseline and 3 months in group A and group B but not in group C.

In our study there was statistically significant mean Clinical Attachment Level reduction in both groups. According to study done by Ravi Varma Prasad et al in 2019¹⁵ a split mouth design was used for intrasulcular application of NanoBioFusion gel as adjunct to scaling and root planing (SRP), hyaluronic acid as adjunct to SRP and SRP alone. On intergroup comparison, statistically significant difference was found in between the three groups. On intragroup comparison, there was statistically significant decrease in CAL between baseline and 4th week in group B but not in group A and C, but there was statistically significant decrease in CAL between baseline and 3 months in all the groups.

From the results of our study it is clear that Chlorhexidine Gel and NanoBioFusion Gingival Gel are effective in reducing PI, GI, SBI, PPD and CAL when used as adjunct to scaling and root planning. However, both gel are equally effective in reducing PI, GI, CAL at different time interval of 1 month & 3 month, but Chlorhexidine Gel is more effective in reducing SBI and PPD as compared to NanoBioFusion Gingival Gel.

CONCLUSION

To conclude, With the limitations of the present study, with only 30 sites with 3 months of clinical follow ups, these local drug delivery system containing 1.5% CHX gel and NanoBioFusion Gingival Gel influenced the beneficial outcome of propolis along with Vitamin C and E and the nanotechnology amplified this effect in preventing disease progression. Although the results indicate anti-inflammatory, antibacterial, and antioxidant property of the NBF gel. It can be effectively used in treatment of patients with $\geq 5 - \leq 7$ mm periodontal pockets as an adjunct to scaling and root planing and is more effective than scaling and root planing alone in the treatment of Periodontal Pockets. These local drug delivery systems are easy to use, noninvasive and requires less chair side time. Chlorhexidine Gel and NanoBioFusion Gingival Gel are equally effective in reducing PI, GI, CAL at different time interval of 1 month & 3 month, so they can be used in treatment of Chronic Periodontitis patients. But, Chlorhexidine

Gel is more effective in reducing SBI and PPD as compared to NanoBioFusion Gingival Gel.

Future Scope Of Study

Future long term studies with large sample size can be carried out.

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None

Conflict Of Interest

None

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