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## Original Research Article

## A comparative evaluation of effect of nano-bio fusion gel and chlorhexidine Gel in patients with chronic periodontitis: A clinical study

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## ABSTRACT

**Aim:** To assess the clinical effectiveness of nano bio fusion gingival gel and chlorhexidine gel as an adjunct to non surgical periodontal therapy for the treatment of chronic periodontitis.**Materials and Methods:** 45 chronic periodontitis patients with at least  $\geq 5$ mm probing pocket depth were selected. Patients were divided into 3 groups. Group A received intrasulcular application of nano bio fusion gingival gel after oral prophylaxis, group B received chlorhexidine gel after SRP and group C received SRP alone. Clinical parameters such as plaque index, gingival index, modified sulcular bleeding index, probing pocket depth and clinical attachment level were recorded at baseline, 1 month and 3 months.**Results:** Intergroup analysis of all the clinical parameters showed clinically significant results between baseline, 1 month and 3 months. However, on intragroup analysis, the results were significant between baseline and 1 month in group B only.**Conclusion:** Nano bio fusion gingival gel and chlorhexidine gel can be a good adjunct to phase I periodontal therapy for treating chronic periodontitis. All the clinical parameters measured were reduced from baseline to 1 month and 3 months.This is an Open Access (OA) journal, and articles are distributed under the terms of the [Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License](https://creativecommons.org/licenses/by-nc-sa/4.0/), which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.For reprints contact: [reprint@ipinnovative.com](mailto:reprint@ipinnovative.com)

## 1. Introduction

Inflammatory reaction in the periodontium causes periodontitis which may lead loss of the supporting structure around the tooth. Interaction between bacteria and gingival lining results in inflammation and destruction of the connective tissue attachment of the disease which leads to the migration of the epithelial lining, deepening of pockets and loosening of teeth due to loss of alveolar bone.<sup>1</sup>

Treatment of periodontal diseases includes open flap debridement but not every patient undergo surgical therapy. Studies have shown effective results with systemic delivery of antibiotics. These systemic antibiotics can lead to further

harm to overall health of the patient, antibiotic resistance, gastrointestinal intolerance are some of the complication. To overcome this, application of local drug delivery came into existence.<sup>2</sup>

One such local drug delivery agent is chlorhexidine which is an effective antimicrobial agent. It was firstly used by Friedman and Golomb,<sup>3</sup> as a topical agent in sustained released dosage form. This form of CHX gel had shown effective results in reducing the PPD, CAL and BOP.<sup>4</sup>

Even though traditional antimicrobial agents have produced results that are similar, researchers are constantly looking for alternative treatments for chronic periodontitis. For the therapy of periodontitis, a variety of agents with antibacterial, antioxidant, and anti-inflammatory properties have been used up until now. The use of herbal and natural goods are safer than synthetic ones. Periodontal diseases

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have been effectively treated with the adjunctive use of herbal and animal-based products.<sup>5</sup>

Nano-Bio Fusion (NBF) gingival gel is an antioxidant gel composed of propolis, vitamin C and E. Its mechanism of action is based on its nano antioxidant particles.<sup>6</sup> Propolis present in the gel is a natural material produced by honey bee and is available in different formulation for use in different filed of medicines. Vitamin C present in the gel helps in repair and rejuvenating the tissue.<sup>7</sup> Vitamin E in the gel plays an important role to eradicate free radical and to protect cells from lipid peroxidation. All these materials work in synergy to maintain the integrity of the cell.<sup>8</sup>

## 2. Aims and Objectives

The aim and objectives of this clinical study is to compare the clinical effectiveness of Nano Bio Fusion gingival gel and Chlorhexidine gel as an adjunct to SRP in chronic periodontitis patients.

## 3. Materials and Methods

The study was done in the Department of Periodontology, Seema Dental College and Hospital, Rishikesh, Uttarakhand, with the approval of the ethical committee. The subjects were selected from out-patient department and each patient was given detailed verbal and written description of the risk and benefit of the treatment with the consent to treatment agreement. Systemically healthy patients, age 25-60 years, with no history of any periodontal therapy within the last 6 months were selected for the study. Patients with moderate to severe periodontitis with PPD of  $\geq 5$ mm and clinical attachment loss were included. All the patients were instructed to follow standard oral hygiene measures. Pregnant female patients or lactating mothers, patients having history of consuming tobacco in any form and/or smoking, patients having allergic reaction or hypersensitivity to any product used in the study and patients on any antibiotic therapy/ antimicrobial mouth rinses were excluded from the study.



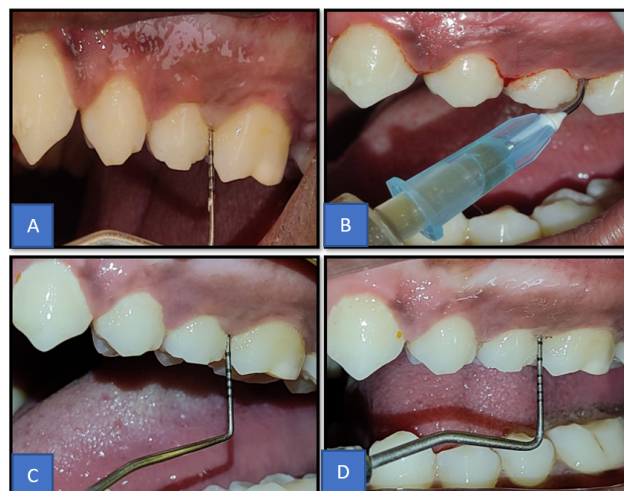
**Figure 1:** Nano bio fusion gel



**Figure 2:** Chlorhexidine gel

### 3.1. Study design

A total of 45 study subjects were randomly assigned into three groups. In Group A (15): application of NBF gingival gel (Fig 1) after phase 1 periodontal therapy. Group B (15): application of chlorhexidine gel (Fig 2) in pockets site after NSPT and in group C only scaling and root planning was done. Plaque index (PI), gingival index (GI), modified sulcular bleeding index (mSBI), probing pocket depth (PPD) and clinical attachment level (CAL) were recorded at baseline, 1 month and 3 months.



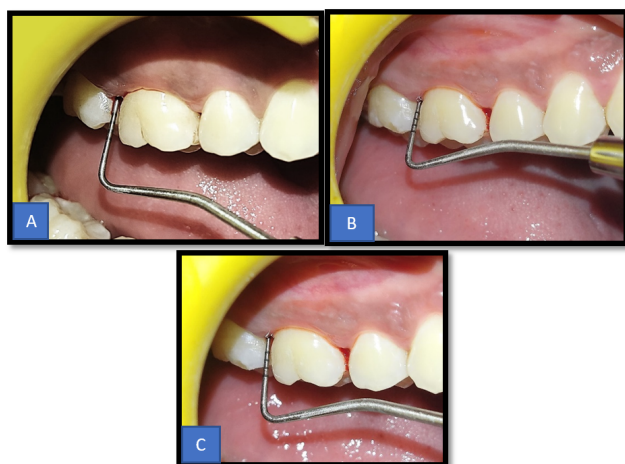
**Figure 3:** NBF gel (Group A); A): Pre-operative picture, B): Application of NBF gel, C): After 1 month, D): After 3 months

### 3.2. Statistical analysis

SPSS version 22.0 software was used for statistical analysis. Parametric tests were applied to continuous data at a confidence interval of 95% and  $p < 0.05$ . Mean and Standard deviation was calculated for continuous variable. ANOVA and Post Hoc were used to test the hypothesis.



**Figure 4:** Chlorhexidine Gel (Group B); A): Pre-operative picture, B): Application of Chlor-X gel, C): After 1 month, D): After 3 months



**Figure 5:** Group C (only SRP); A): Pre-operative picture, B): After 1 month, C): After 3 months

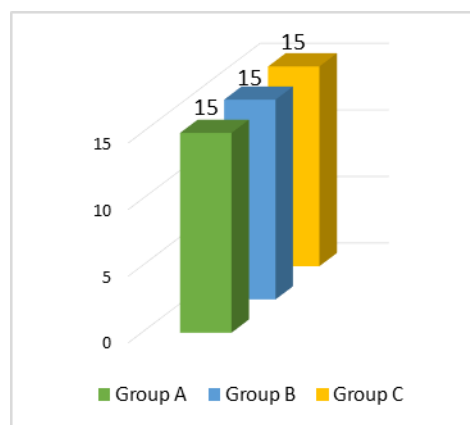
#### 4. Results

The demographic details of the participants enrolled for the study in group A, B, and C are summarized in Graphs 1, 2 and 3. Group A consists of 15 patients (9 males and 6 females). Group B consists of 15 patients (6 males and 9 females). Group C consists of 15 patients (9 males and 6 females). The overall mean age was  $36.4 \pm 0.87$  with 53.3% males and 46.7% females.

Intergroup comparison of plaque index showed statistically significant difference at baseline and at 1 month between group A and B. On intergroup comparison of gingival index all the groups showed statistically significant results at baseline. Intragroup comparison of group A, B and C showed statistically significant results at 1 month and 3 months. Intergroup comparison of modified

sulcular bleeding index showed statistically significant difference among group A and B at baseline, 1 and 3 months. Group A and C showed significant difference at 1 month. Intergroup comparison of probing pocket depth showed significant difference between group A and C at 1 month only. (Tables 1, 2, 3, 4 and 5)

Intragroup comparison of plaque index scores differed significantly across three time points for Group A ( $F=20.808$ ,  $p=.000$ ), Group B ( $F=21.563$ ,  $p=.000$ ), Group C ( $F=16.657$ ,  $p=.000$ ), Gingival Index for Group A ( $F=5.269$ ,  $p=.009$ ), Group B ( $F=5.260$ ,  $p=.009$ ), Group C ( $F=4.307$ ,  $p=.020$ ), Modified Sulcus Bleeding Index scores for Group A ( $F=14.825$ ,  $p=.000$ ), Group B ( $F=1.525$ ,  $p=.229$ ), Group C ( $F=2.494$ ,  $p=.095$ ). Probing Pocket Depth scores differed non significantly across three time points for Group A ( $F=1.277$ ,  $p=.289$ ), Group B ( $F=0.307$ ,  $p=.737$ ), Group C ( $F=0.609$ ,  $p=.549$ ) and Clinical Attachment Loss scores differed significantly across three time points for Group A ( $F=0.450$ ,  $p=.641$ ), Group B ( $F=3.846$ ,  $p=.029$ ), Group C ( $F=1.295$ ,  $p=.285$ ). A post hoc analysis using Tukeys HSD test was done to assess the significant difference between different time interval for all the parameters. (Tables 6, 7, 8, 9 and 10)



Graph 1: Total number of patients

#### 5. Discussion

CHX have both bacteriostatic as well as bactericidal activity. It is effective against gram-positive, gram-negative bacteria, fungi and yeast. It is a gold standard and have shown decrease in bacterial count when subgingival application is done in periodontal pockets.<sup>9</sup>

Nano bio fusion gel is an antioxidant gel which has beneficial effects on regulation of fibroblasts proliferation during gingival and periodontal healing. NBF gel is the first product that contains nano-oxidants and is produced using nano-bio fusion technology. The gel is characterized with its instant absorption by gums. It is a high functional paste comprising of 3 main ingredients: Vitamin C, E and propolis

**Table 1:** Intergroup comparison of plaque index

			Mean Difference	Std. Error	p value	95% Confidence Interval	
						Lower Bound	Upper Bound
Baseline	Group A	Group B	-.204*	.067	.011	-.367	-.040
		Group C	-.137	.068	.121	-.303	.028
	Group B	Group A	.204*	.067	.011	.040	.367
		Group C	.066	.066	.577	-.094	.227
	Group C	Group A	.137	.068	.121	-.028	.303
		Group B	-.066	.066	.577	-.227	.094
1 month	Group A	Group B	-.052*	.020	.039	-.103	-.002
		Group C	-.041	.021	.132	-.093	.009
	Group B	Group A	.052*	.020	.039	.002	.103
		Group C	.011	.020	.851	-.038	.060
	Group C	Group A	.041	.021	.132	-.009	.093
		Group B	-.011	.020	.851	-.060	.038
3 months	Group A	Group B	-.038	.024	.264	-.098	.020
		Group C	-.052	.025	.110	-.113	.009
	Group B	Group A	.038	.024	.264	-.020	.098
		Group C	-.052	.024	.849	-.072	.046
	Group C	Group A	-.013	.025	.110	-.009	.113
		Group B	.013	.024	.849	-.046	.072

**Table 2:** Intergroup comparison of gingival index

			Mean Difference	Std. Error	p value	95% Confidence Interval	
						Lower Bound	Upper Bound
Baseline	Group A	Group B	.07920*	.01891	.000	.0333	.1251
		Group C	.08247*	.01891	.000	.0365	.1284
	Group B	Group A	-.07920*	.01891	.000	-.1251	-.0333
		Group C	.00327	.01891	.984	-.0427	.0492
	Group C	Group A	-.08247*	.01891	.000	-.1284	-.0365
		Group B	-.00327	.01891	.984	-.0492	.0427
1 month	Group A	Group B	.25553*	.06350	.001	.1010	.4101
		Group C	.25204*	.06590	.001	.0916	.4124
	Group B	Group A	-.25553*	.06350	.001	-.4101	-.1010
		Group C	-.00350	.06590	.998	-.1639	.1569
	Group C	Group A	-.25204*	.06590	.001	-.4124	-.0916
		Group B	.00350	.06590	.998	-.1569	.1639
3 months	Group A	Group B	.16320*	.03370	.000	.0812	.2452
		Group C	.16455*	.03430	.000	.0811	.2479
	Group B	Group A	-.16320*	.03370	.000	-.2452	-.0812
		Group C	.00135	.03430	.999	-.0821	.0847
	Group C	Group A	-.16455*	.03430	.000	-.2479	-.0811
		Group B	-.00135	.03430	.999	-.0847	.0821

extract in a nano-emulsion state. The gel is biocompatible patented nano-emulsion form having antibacterial, anti-inflammatory and anti-oxidative effect.<sup>10</sup>

On intergroup comparison a statistically significant result was observed between Group A and Group B at 1 month. This reduced plaque score could be due to patient's compliance towards oral hygiene instructions, maintenance and thoroughness of SRP.<sup>11</sup>

Intragroup comparisons of gingival index from baseline to 1 month showed a statistically significant result, whereas a statistically non-significant result was observed from 1

month to 3 months for all the groups. This was similar with the findings by Srivastava V et al (2019)<sup>12</sup> and Goswami V et al. (2022).<sup>13</sup>

The possible mechanism behind this can be the presence of caffeic acid phenethyl ester in propolis. Propolis has shown to activate thymus gland and aids the immune system by activating phagocytic activity, and enhances the healing effects of epithelial tissues.<sup>14</sup>

Intergroup comparison showed significant difference between Group A and Group B and Group A and Group C at baseline, 1 month and 3 months. Modified sulcus bleeding

**Table 3:** Intergroup comparison of modified sulcus bleeding index

			Mean Difference	Std. Error	p value.	95% Confidence Interval	
						Lower Bound	Upper Bound
Baseline	Group A	Group B	-.136*	.052	.032	-.262	-.009
		Group C	-.085	.052	.236	-.212	.040
	Group B	Group A	.136*	.052	.032	.009	.262
		Group C	.050	.052	.602	-.076	.176
	Group C	Group A	.085	.052	.236	-.040	.212
		Group B	-.050	.052	.602	-.176	.076
1 month	Group A	Group B	-.052*	.014	.002	-.087	-.018
		Group C	-.036*	.014	.039	-.070	-.001
	Group B	Group A	.052*	.014	.002	.018	.087
		Group C	.016	.014	.485	-.018	.051
	Group C	Group A	.036*	.014	.039	.001	.070
		Group B	-.016	.014	.485	-.051	.018
3 months	Group A	Group B	-.050*	.018	.020	-.094	-.006
		Group C	-.031	.018	.218	-.076	.013
	Group B	Group A	.050*	.018	.020	.006	.094
		Group C	.019	.018	.526	-.024	.063
	Group C	Group A	.031	.018	.218	-.013	.076
		Group B	-.019	.018	.526	-.063	.024

**Table 4:** Intergroup comparison of Probing pocket depth

			Mean Difference	Std. Error	P value	95% Confidence Interval	
						Lower Bound	Upper Bound
Baseline	Group A	Group B	-.15613	.09123	.213	-.3780	.0657
		Group C	.04778	.09284	.865	-.1780	.2735
	Group B	Group A	.15613	.09123	.213	-.0657	.3780
		Group C	.20391	.09284	.084	-.0218	.4297
	Group C	Group A	-.04778	.09284	.865	-.2735	.1780
		Group B	-.20391	.09284	.084	-.4297	.0218
1 month	Group A	Group B	-.12480	.10299	.453	-.3752	.1256
		Group C	-.14396*	.10482	.004	-.3988	.1109
	Group B	Group A	.12480	.10299	.453	-.1256	.3752
		Group C	-.01916	.10482	.982	-.2740	.2357
	Group C	Group A	.14396*	.10482	.004	-.1109	.3988
		Group B	.01916	.10482	.982	-.2357	.2740
3 months	Group A	Group B	-.21287	.08843	.053	-.4277	.0020
		Group C	-.07367*	.08843	.006	-.2885	.1412
	Group B	Group A	.21287	.08843	.053	-.0020	.4277
		Group C	.13920	.08843	.268	-.0756	.3540
	Group C	Group A	.07367*	.08843	.006	-.1412	.2885
		Group B	-.13920	.08843	.268	-.3540	.0756

index on intra group comparison showed statistically significant results from baseline to 1 month and 3 months only for test group.

This was similar to the study done by Debnath K et al (2016)<sup>15</sup> in which the evaluation NBF gel as an adjunctive therapy to SRP for treatment of chronic periodontitis was done on clinical and microbiological findings. This can be because propolis has as anti-inflammatory agent which inhibit the synthesis of prostaglandins and facilitate healing effect on epithelial tissues.<sup>16</sup>

Intergroup comparison showed statistically significant difference between groups A and B at baseline, 1 month and 3 months. Group A and group C showed statistically significant result only at 1 month. PPD showed statistically significant result between group A and C at 1 and 3 months when intergroup comparison was made.

This was similar to the study done by Srivastava V et al. (2019),<sup>12</sup> Patil AV et al. (2020)<sup>17</sup> in which they compared the clinical effectiveness of NBF gel as an adjunct to phase 1 periodontal therapy. NBF gel uses nano dimensions

**Table 5:** Intergroup comparison of Probing pocket depth

			Mean Difference	Std. Error	p value	95% Confidence Interval	
						Lower Bound	Upper Bound
Baseline	Group A	Group B	.20207	.13452	.300	-.1248	.5289
		Group C	-.02007	.13452	.988	-.3469	.3068
	Group B	Group A	-.20207	.13452	.300	-.5289	.1248
		Group C	-.22213	.13452	.236	-.5490	.1047
	Group C	Group A	.02007	.13452	.988	-.3068	.3469
		Group B	.22213	.13452	.236	-.1047	.5490
1 month	Group A	Group B	.15380	.13488	.495	-.1739	.4815
		Group C	-.07413	.13488	.847	-.4018	.2535
	Group B	Group A	-.15380	.13488	.495	-.4815	.1739
		Group C	-.22793	.13488	.221	-.5556	.0997
	Group C	Group A	.07413	.13488	.847	-.2535	.4018
		Group B	.22793	.13488	.221	-.0997	.5556
3 months	Group A	Group B	.15913	.13280	.461	-.1641	.4824
		Group C	-.01602	.13781	.993	-.3514	.3194
	Group B	Group A	-.15913	.13280	.461	-.4824	.1641
		Group C	-.17515	.13781	.420	-.5106	.1603
	Group C	Group A	.01602	.13781	.993	-.3194	.3514
		Group B	.17515	.13781	.420	-.1603	.5106

**Table 6:** ANOVA intragroup comparison of plaque index of different groups at baseline, 1 month, 3 months

	Sum of Squares	Df	Mean Square	F	P value
Group A	.969	2	.485	20.808	.000
Group B	.999	2	.500	21.563	.000
Group C	.446	2	.223	16.657	.000

**Table 7:** ANOVA intragroup comparison of plaque index of different groups at baseline, 1 month, 3 months

	Sum of Squares	Df	Mean Square	F	P value
Group A	.380	2	.190	5.296	.009
Group B	.020	2	.010	5.260	.009
Group C	.019	2	.010	4.307	.020

**Table 8:** ANOVA intragroup comparison of modified sulcus bleeding index of different groups at baseline, 1 month, 3 months

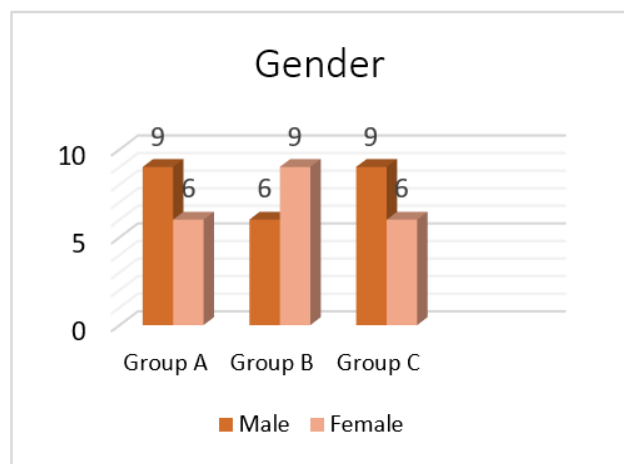
	Sum of Squares	df	Mean Square	F	P value
Group A	.055	2	.028	14.825	.000
Group B	.063	2	.032	1.525	.229
Group C	.045	2	.023	2.494	.095

**Table 9:** ANOVA intragroup comparison of probing pocket depth of different groups at baseline, 1 month, 3 months

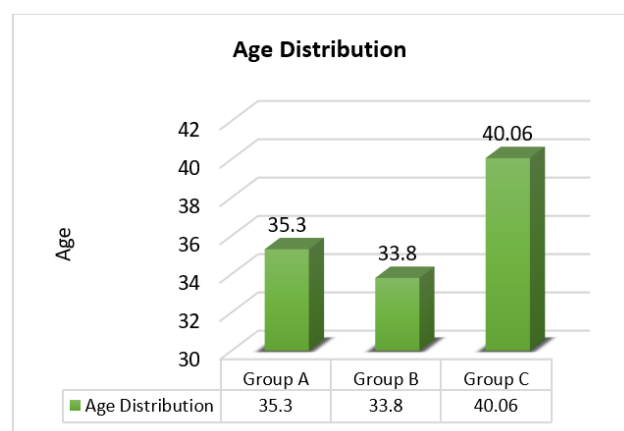
	Sum of Squares	df	Mean Square	F	P value
Group A	.139	2	.070	1.277	.289
Group B	.070	2	.035	.307	.737
Group C	.040	2	.020	.609	.549

**Table 10:** ANOVA intragroup comparison of clinical attachment level of different groups at baseline, 1 month, 3 months

	Sum of Squares	Df	Mean Square	F	P value
Group A	.049	2	.025	.450	.641
Group B	1.914	2	.957	3.846	.029
Group C	.272	2	.136	1.295	.285



Graph 2: Gender wise distribution of patients



Graph 3: Mean age of patients

between 1 to 100 nanometres to deliver the properties of the drugs into the target site with better penetration. This property of NBF gel have been effective against gingival and periodontal diseases.<sup>18</sup>

The intergroup comparison between group B and group C was non significant. However, a study done by Jain M et al (2013)<sup>19</sup> reported a significant difference at 3 and 6 months when chlorhexidine was administered into the periodontal pockets.

Intragroup comparison of group B showed statistically significant result for CAL at baseline and 1 month only. This was similar to the results found by Ahmad BZ (2020)<sup>20</sup> in which the effectiveness of locally delivered chlorhexidine gel was compared as an adjunct to SRP for the treatment of chronic periodontitis.

Chlorhexidine in gel form has mucoadhesive properties; therefore, it adheres to the pocket lining and is not eliminated by oral fluids. That's why they are more effective than in irrigation form.<sup>21</sup>

The intergroup comparison between group B and group C was found non significant. This was in accordance with

the study done by Sivadas A et al. (2021)<sup>22</sup> in which they compared topical chlorhexidine gluconate gel and povidine-iodine ointment as an adjunct to phase 1 therapy. The results of this study were statistically non significant when SRP was compared with CHX group in terms of clinical attachment gain.

## 6. Conclusion

It can be concluded that, nano bio fusion gingival gel and chlorhexidine gel can be a good adjunct to SRP for the treating chronic periodontitis. All the clinical parameters measured were reduced from baseline to 1 month and 3 months.

However, more studies with a larger sample size may be used to evaluate the potential of these local drug delivery agents. Also, a longer follow up can be done to evaluate the outcomes with respect to periodontal tissues. Microbiological assessment can also be done to access the action of periodontopathogens.

## 7. Source of Funding

None.

## 8. Conflict of Interest


None.

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