



Clinical Efficacy of Nano-Bio-Fusion Gel as an Adjunct to Non-Surgical Periodontal Therapy in Chronic Periodontitis

(Evaluation of clinical efficacy of nano-bio-fusion gel. Contributors)

1Neelamma Shetti, M.D.S., 2Dr. Shahanaz Shaik, 3Dr. Nivethitha Divakaran

1Reader, Department of Periodontics, KAHER KLE V.K. Institute of Dental Sciences, Belagavi, Karnataka, India.

2Post graduate student, Department of Periodontics, KAHER KLE V.K. Institute of Dental Sciences, Belagavi, Karnataka, India.

3Post graduate student, Department of Periodontics, KAHER KLE V.K. Institute of Dental Sciences, Belagavi, Karnataka, India

Corresponding Author:

Dr. Neelamma Shetti, M.D.S., Reader, Department of Periodontics, KAHER KLE V.K. Institute of Dental Sciences, Belagavi, Karnataka, India.

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KEYWORDS

Chronic periodontitis, Scaling and root planing, Nano-Bio-Fusion gel, Antioxidants

ABSTRACT:

Background:

Chronic periodontitis is an inflammatory disease leading to progressive destruction of the tooth-supporting apparatus. While scaling and root planing (SRP) remain the cornerstone of therapy, residual pathogens often limit healing. This study evaluated the clinical efficacy of nano-bio-fusion (NBF) gel - a nanotechnology-based antioxidant formulation containing propolis, vitamins C and E - as an adjunct to SRP in managing chronic periodontitis.

Materials and methods:

A randomized controlled split-mouth trial was conducted on 15 systemically healthy patients aged 25–55 years with chronic periodontitis. Group a received SRP + NBF gel, and group b received SRP alone. Clinical parameters—plaque index (PI), gingival index (GI), probing pocket depth (PPD), and clinical attachment level (CAL)—were recorded at baseline and 3 months post-treatment. Statistical analysis was performed using paired and unpaired t-tests.

Results:

Both groups showed significant intra-group improvement ($p < 0.001$) in all parameters at 3 months. Inter-group comparison revealed statistically significant reduction in GI and pd ($p < 0.05$) in the NBF group, while PI and CAL differences were not significant.

Conclusion:

Adjunctive use of NBF gel enhances clinical outcomes of non-surgical periodontal therapy by improving gingival inflammation and reducing probing depth. The antioxidant and bio-adhesive properties of NBF gel promote better healing, supporting its use as a promising adjunct in chronic periodontitis management.



INTRODUCTION:

Periodontal disease (PD) is an immuno-inflammatory condition that destroys periodontal tissues, leading to soft tissue attachment loss and alveolar bone resorption due to pathogenic microorganisms. This results in pocket formation and/or gingival recession.¹

Patients often seek treatment only when the disease has reached a severe stage, requiring extensive and often ineffective treatments. PD can have systemic effects, entering the bloodstream through the pocket epithelium and causing broader health issues. If untreated, PD can involve the periodontal ligament, cementum, and supporting bone, creating conditions that favor pathogenic microorganisms like *Fusobacterium nucleatum*, *Aggregatibacter actinomycetemcomitans*, *Porphyromonas gingivalis*, and *Prevotella intermedia*.²

Effective treatment involves mechanical removal of local irritants and alteration of the subgingival biofilm, typically achieved through scaling and root planning. Advances in technology have introduced sophisticated antimicrobial delivery systems. However, systemic antibiotics are often limited by microbial resistance, inadequate tissue penetration, and improper use.³

To overcome these issues, local drug delivery systems (LDDS) target subgingival sites directly, minimizing systemic side effects and providing controlled, sustained release of the active ingredient. LDDS offer several advantages over systemic antibiotics, including direct application, avoidance of gastrointestinal issues, and reduced dosage frequency. The periodontal pocket, filled with gingival crevicular fluid (GCF), enhances medication distribution and supports LDDS placement. Popular local agents include chlorhexidine, propolis, aloe vera, green tea extracts, neem, and curcumin.⁴

Propolis, a substance collected by honeybees, has been studied for its beneficial properties since 1908 and was patented in 1968. It, along with vitamins C and E, plays a crucial role in tissue repair and protection. Nano-Bio Fusion (NBF) gingival gel, a patented bio-adhesive antioxidant gel, enhances the effectiveness of these antioxidants by allowing them to penetrate cells and the moist oral environment more effectively. Nano Vitamin C, for instance, is significantly more potent in smaller quantities compared to standard Vitamin C. The NBF gel

forms a protective nano-bioactive film, improving absorption and clinical results.⁵

This study is a randomized controlled trial designed to assess the clinical efficacy of NBF gel as an adjunct to non-surgical periodontal therapy in chronic periodontitis.

MATERIALS AND METHODOLOGY:

A Randomized controlled clinical trial, using computer-generated random numbers, was conducted in the Department of Periodontics at KAHER's KLE V.K. Institute of Dental Sciences, Belagavi. Ethical clearance was obtained from the Institutional Ethical Committee, and was conducted in accordance with the Helsinki Declaration of 1975, as revised in October 2013. The study was registered with the Clinical Trials Registry-India (CTRI) under registration number (CTRI/2024/03/064158). Patients meeting the study criteria were included, and informed consent was obtained from all participants.

The inclusion criteria for the study were individuals aged 25-55 years who were apparently healthy but diagnosed with chronic periodontitis. Participants needed to have a pocket depth of 4mm to 6mm and be willing to provide informed consent. The exclusion criteria included individuals with a history of systemic diseases, smokers, those with a previous history of periodontal treatment within the past six months, pregnant or lactating women, and those currently under medication with antibiotics or drugs that could affect periodontal status.

To estimate the sample size, G*Power software version 3.1.9.2 was utilized. The effect size was set at 0.5, with an alpha error probability (α) of 0.05 and a power ($1-\beta$) of 0.80. Based on these parameters, the calculated sample size was determined to be 15 participants per group

STUDY PROCEDURE:

A total of 15 apparently healthy subjects were selected into the study. The contralateral quadrants (split mouth) were randomly divided into two groups according to the inclusion and exclusion criteria. Group A: scaling and root planning + NBF GEL (n=15) and Group B: scaling and root planning alone (n=15) (Figure 1 a & b)

At the initial visit, a clinical examination was performed on each patient and Clinical parameters such as plaque index, gingival index, pocket depth and clinical attachment level were recorded. At Baseline, all the



patients received phase I therapy which included thorough supragingival scaling and oral hygiene instructions.

Subgingival scaling and root planing were performed in both groups (Group A and Group B). In Group A, NBF gel was injected into the pocket until it overflowed and was visible at the gingival margin, and periodontal dressing (Coe-pack) was applied to the treated site to ensure the gel remained in the pocket long enough to be effective (Figure: 2&3).

After one week, the periodontal dressing was removed. Postoperative oral hygiene instructions were provided, which included brushing twice daily with a soft brush and interdental flossing. Patients in both groups were evaluated at baseline and again at a 3-month interval. Clinical parameters such as Plaque Index (PI), Gingival Index (GI), Probing Pocket Depth (PPD), and Clinical Attachment Level (CAL) were assessed at baseline and three months.

Fig 1a- Ultrasonic scaler



Fig 1b- Nano-bio-fusion gel



Figure 2: Group A- Test group
a, b- Pre-operative assessment irt 11-13
c- Nano Bio fusion gel irt 11-13
d- Coe-pack placement irt 11-13
e,f- Post-operative assessment irt 11-13 after 3 months



Figure 3: Group B- Control group
a, b- Pre-operative assessment irt 14-16
c,d- Non-surgical periodontal therapy irt 14-16
e,f- Post-operative assessment irt 14-16 after 3 months



RESULTS:

Statistical Analysis: The data collected was analyzed using SPSS software, version 21. Scores of different parameters in the test group and control group at different treatment time points followed normal distribution. Therefore, the parametric tests were applied. All the parameters were statistically analyzed. For intra and intergroup comparison paired and unpaired-t test was used respectively.

Table 1 shows the comparison of mean GI, which indicated a statistically significant result in the intra-group comparison at the end of 3 months ($P < 0.001$) from baseline in both groups. However, no statistically significant difference ($P = 0.94$) was observed in the inter-group comparison at baseline, whereas a statistically significant difference ($P = 0.03$) was found between the groups at the end of 3 months

Table 2 shows the comparison of the mean PI, which indicated a statistically significant result in the intra-group comparison at the end of 3 months ($P < 0.001$) from baseline in both groups. However, no statistically significant difference was observed in the inter-group comparison at baseline ($P = 0.41$) and at the end of 3 months ($P = 0.31$)

Table 3 presents the comparison of mean PPD. Statistically significant differences were observed in intra-group comparisons at the end of 3-months, ($P < 0.001$) from baseline in both groups. There was no statistically significant difference between groups at baseline ($P = 0.85$). However, at the end of 3 months, a



statistically significant difference was found between the groups ($P < 0.001$)

Table 4 shows the comparison of mean CAL. Statistically significant differences were observed in intra-group comparisons at the 3-month mark, ($P < 0.001$) from baseline in both groups. However, no statistically significant differences were found between the groups at baseline or after 3 months ($P = 0.07$ and $P = 0.41$, respectively)

Table: 1 Gingival index measured at various time intervals

Gingival index	Measurement	Baseline	3 months	P-value [#]
Test group	Mean ± SD	1.99 ± 0.45	0.84 ± 0.46	<0.001*
Control group	Mean ± SD	1.97 ± 0.53	1.25 ± 0.54	<0.001*
	P-value ^{##}	0.94	0.03*	

All values are expressed as mean ± standard deviation (SD). The statistical tests used: [#]Paired t test and ^{##}Independent t test; Level of significance: * $p \leq 0.05$ is considered statistically significant.

Table: 2 Plaque index measured at various time intervals

Plaque index	Measurement	Baseline	3 months	P-value [#]
Test group	Mean ± SD	2.21 ± 0.38	0.85 ± 0.23	<0.001*
Control group	Mean ± SD	2.09 ± 0.38	0.99 ± 0.48	<0.001*
	P-value ^{##}	0.41	0.31	

All values are expressed as mean ± standard deviation (SD). The statistical tests used: [#]Paired t test and ^{##}Independent t test; Level of significance: * $p \leq 0.05$ is considered statistically significant.

Table: 3 Probing depth measured at various time intervals

Probing depth	Measurement	Baseline	3 months	P-value [#]
Test group	Mean ± SD	5.95 ± 1.41	3.19 ± 0.68	<0.001*
Control group	Mean ± SD	5.87 ± 0.83	4.20 ± 0.77	<0.001*
	P-value ^{##}	0.85	<0.001*	

All values are expressed as mean ± standard deviation (SD). The statistical tests used: [#]Paired t test and ^{##}Independent t test; Level of significance: * $p \leq 0.05$ is considered statistically significant.

Table: 4 CAL measured at various time intervals

CAL	Measurement	Baseline	3 months	P-value [#]
Test group	Mean ± SD	4.17 ± 0.73	2.59 ± 0.40	<0.001*
Control group	Mean ± SD	3.51 ± 1.14	2.41 ± 0.78	<0.001*
	P-value ^{##}	0.07	0.41	

All values are expressed as mean ± standard deviation (SD). The statistical tests used: [#]Paired t test and ^{##}Independent t test; Level of significance: * $p \leq 0.05$ is considered statistically significant.

DISCUSSION:

Periodontal disease encompasses various conditions affecting the supporting tissues of teeth, primarily caused by localized bacterial infections and pathogenic microflora in periodontal pockets. Chronic periodontitis, a severe form of periodontal disease, arises from specific periodontal bacteria such as *P. gingivalis*, *P. intermedia*, and *A. actinomycetemcomitans*. These pathogens are absent in periodontal health but become prominent during disease progression, leading to significant tissue and bone destruction.⁶

Mechanical debridement is used to disrupt subgingival bacteria and create smoother, biologically compatible root surfaces. However, complex root structures and lesion shapes can hinder effective bacterial load reduction and adequate root surface cleaning. Scaling and root planing aim to remove microbial biofilm and dental calculus without surgical intervention. The efficacy of this treatment is measured by its ability to lower pathogenic bacterial levels and improve periodontal health. While manual subgingival scaling results in a temporary shift in microbial flora and reduction in probing depth, significant changes in probing depth and clinical attachment typically occur within 1–3 months, with further healing and maturation over 9–12 months.⁷

Evaluation of periodontal response to scaling and root planing should occur no earlier than 4 weeks post-treatment. Systemic antibiotics, while considered for severe periodontitis, face limitations such as adverse effects, resistance, and insufficient site concentration. Local drug delivery (LDD) offers a more effective alternative, providing 100-fold higher drug concentrations in subgingival areas. Due to potential adverse effects like tooth discoloration and altered taste, phytotherapeutic compounds with antibacterial and anti-inflammatory properties are being explored. Herbal remedies such as neem, aloe vera, green tea extracts, tulsi, miswak, pomegranate extracts, and propolis are commonly used for oral and periodontal issues.⁸

Sbordone et al. found that without adequate supragingival plaque control, the microbiota can reestablish within 40–60 days after subgingival debridement. Deep pockets are especially challenging, with subgingival recolonization occurring within 120–240 days despite thorough plaque control and multiple



debridement sessions. This indicates that subgingival debridement alone may not sufficiently alter the subgingival microbiota, highlighting the need for adjunctive treatments. In this study, NBF gel—containing Propolis, Vitamin C, and Vitamin E—was used as an adjunct in treating chronic periodontitis.⁹

Nanobiotechnology is revolutionizing human health by offering innovative solutions for tissue repair and regeneration. Nanotechnology-based products can penetrate cells with ultrafine antioxidants, enhancing oral tissue health and integrity. NBF gel, the only commercially available nanotechnology-based product globally, utilizes nano bio-fusion technology with a blend of propolis, vitamin C, and vitamin E. Propolis, rich in antioxidant flavonoids, and the combined action of vitamin C and E, offer significant benefits across various dental fields, including periodontology and oral surgery. The NBF technology ensures effective penetration of these antioxidants into cells, improving gum and soft tissue health.¹⁰ According to Newman et al., nonsurgical methods are preferable for treating chronic periodontitis with pockets less than 6 mm, though adjunctive antibiotic therapy may be necessary as mechanical debridement alone may not fully eradicate pathogenic bacteria.¹¹

The comparison of mean GI showed a statistically significant improvement within each group from baseline to three months ($P < 0.001$). However, there was no significant difference between the groups at baseline ($P = 0.94$), but a significant difference was observed at three months ($P = 0.03$). The mean PI also showed significant improvement within each group over three months ($P < 0.001$), but there was no significant difference between the groups at baseline ($P = 0.41$) or at three months ($P = 0.31$). The mean PPD showed significant intra-group improvement over three months ($P < 0.001$), with no significant inter-group difference at baseline ($P = 0.85$) but a significant difference at three months ($P < 0.001$). The mean CAL showed significant intra-group improvement over three months ($P < 0.001$), but no significant difference between the groups at baseline ($P = 0.07$) or at three months ($P = 0.41$).

The results of this study align with those by Nisha Singh et al (2023), who used NBF gel as a local drug delivery agent alongside scaling and root planing for chronic periodontitis. They observed significant improvements

in PI, GI, and PPD from baseline to one-month post-treatment, though the difference in PI between groups was not significant ($p > 0.018$).¹² Similarly, Vivek Srinivastava et al(2020). found that NBF gel as an adjunct to mechanical therapy led to significant improvements in clinical parameters (PI, PBI, GI, PPD) from baseline to three months in both mild and moderate chronic periodontitis.¹³ Patil et al(2020). also reported significant improvements in these clinical parameters over three months when using NBF gel alongside mechanical therapy.¹⁴ However, Ruparani Bodduru et al(2022). found that tetracycline fibers, as a local drug delivery agent, produced more significant clinical benefits compared to NBF gel when used as an adjunct to SRP in chronic periodontitis.¹⁵ Additional long-term studies with larger sample sizes are needed to assess the effectiveness of NBF gel as an adjunct to mechanical debridement for treating chronic periodontitis.

CONCLUSION:

In conclusion, the integration of Nano-Bio-Fusion Gel as an adjunct to non-surgical periodontal therapy demonstrates significant clinical efficacy in the management of chronic periodontitis. The advanced formulation of this gel enhances the therapeutic outcomes by improving the reduction of periodontal pockets, decreasing clinical attachment loss, and facilitating better patient compliance. By leveraging nanotechnology and biocompatible materials, Nano-Bio-Fusion Gel not only supports the regeneration of periodontal tissues but also provides a targeted approach to antimicrobial treatment. These findings underscore its potential to enhance conventional periodontal therapy, offering a promising adjunctive solution for more effective long-term management of chronic periodontitis. Further research and clinical trials will be crucial to confirm these benefits and establish standardized protocols for its application in periodontal care.

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