A Clinical Study Comparing the Effects of Nano-Bio Fusion Gel and Blue M Gel in Patients with Chronic Periodontitis

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Abstract: _Background and Objectives_: *Aim: To assess the clinical effectiveness of nano bio fusion gingival gel and Blue M Gel as an adjunct to Non-surgical periodontal therapy for the treatment of chronic periodontitis. _Materials and Methods_: A clinical trial was conducted on 32 chronic periodontitis patients, split into groups A and B. Group A received treatment with Blue M gel and Scaling and Root Planning, while group B received Nano bio fusion gel and SRP, along with periodontal dressing. Clinical measures such as the Papillary Marginal Attachment Index, Plaque Index (PI), Gingival Index (GI), and Probing Pocket Depth (PD) were documented at the initial evaluation and again after seven days. _Results_: Both groups had similar age and gender distributions. Both gels significantly improved GI, PI, papillary, and attachment values with no inter-group differences. NBF Gel was superior in reducing marginal inflammation. Both effectively reduced gingival inflammation, plaque, and probing depths. _Interpretation and Conclusions_ This study found that both Oxygen Gel and Nano Bio Fusion Gel effectively reduce inflammation, plaque, and pocket depth in chronic periodontitis, with NBF Gel excelling in inflammation reduction.*

Keywords: SRP; Blue M Gel; Nano Bio Fusion Gel; Local Drug Delivery Systems

1. Introduction

Periodontitis is a chronic inflammatory disease caused by changes in the tooth biofilm, leading to gradual damage to tissues supporting the teeth. Due to its widespread occurrence, dental caries poses a significant public health issue as it can lead to tooth loss and disability, impact chewing ability and appearance, create social disparities, and reduce overall quality of life. [1] Open flap debridement is a common treatment for periodontal diseases; however not all patients receive surgical therapy. Research has demonstrated that delivering antibiotics systemically yields positive outcomes. The use of systemic antibiotics can cause additional damage to the patient's overall health, leading to complications such as antibiotic resistance and gastrointestinal intolerance. In order to address this issue, the use of local drug delivery was developed.[2]

Phase I therapy is the initial stage in the management of periodontal diseases. Scaling and root planning (SRP) alone was found to be of limited efficacy, especially in certain unapproachable areas, hence use of an adjunct to SRP has been advocated.[4]

Local drug delivery systems (LDDS) offer minimally invasive, targeted treatment with fewer side effects, improved patient compliance, and controlled drug release. LDDS are available in the form of irrigation systems, fibers, gels, strips, films, microparticles, and nanoparticles. Periodontal pockets function as natural reservoirs, utilizing gingival crevicular fluid for effective drug distribution. The presence of these pockets facilitates the placement of LDDS, as the gingival

crevicular fluid within them provides a hydrated environment that enhances drug distribution throughout the pocket.[5]

Blue M® oral gel (Fig 1) is a newly developed formula by implantologists, oral surgeons, and dentists for specific oral problems. Developed by Peter Blijdrop, its ingredients include Aqua, Alcohol, Glycerin, Silica, Sodium Saccharin, Sodium Perborate, Citric Acid, PEG-32, Sodium Gluconate, Lactoferrin, Xanthan Gum, and Cellulose Gum, each serving specific functions. It enhances wound healing by increasing oxygen levels in periodontal pockets, bleeding gums, post-extraction wounds, implant dentistry, and chemotherapy. This unique formula improves oral hygiene and reduces infection and inflammation risks.[3]

Figure 1: Blue M Gel

Nano-Bio Fusion Gingival Gel (NBFG) (Fig 2) by NanoCure Tech contains a nano-emulsion of propolis extract, vitamins

C and E, sodium Mon fluorophosphate, aloe, and green tea extract. This patented, bio-adhesive antioxidant gel targets disease-causing microbes in periodontal disease with natural antioxidants.[6] Propolis, a resinous mixture produced by bees from plant parts, was first scientifically studied in 1908 and patented in 1968. It is now widely used in medical and dental formulations. Vitamin C is crucial for cell growth, tissue repair, collagen metabolism, maintaining the epithelial barrier against bacteria, and preserving periodontal microvasculature. Vitamin E, an antioxidant, limits free radicals, protects cells from lipid peroxidation, and works synergistically with Vitamin C to maintain cell membrane integrity. All these materials work in synergy to maintain the integrity of the cell. [7]

Figure 2: NANO Bio Fusion Gel

Aims-
The aim of the study was to compare the efficacy of oxygen gel (blue m® gel) and NBF (nano-bio fusion gel) as an adjunct to scaling and root planning in the treatment of patients with chronic periodontitis.

2. Materials and Methods

The study was done in the Department of Periodontology, KVG Dental College and Hospital, Sullia Dakshina Kannada with the approval of the ethical committee. The subjects were selected from the out-patient department and each patient was given a detailed verbal and written description of the risk and benefit of the treatment with the consent to treatment agreement. Thirty-two subjects were included in the study and were divided into two groups. Blue m gel group and nano bio fusion gel group. Systemically healthy patients, aged 35-70 years, with no history of any periodontal therapy within the last 6 months, Patients willing to periodontal therapy were selected for the study. Patients with moderate to severe periodontitis with PPD of ≥ 5mm 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, Patients with smoking, tobacco habits in any form and alcoholics were omitted from the study.

3. Procedure

A total of 32 study participants were randomly assigned to two groups. Group A (16) received blue m Gel (Fig 3) after Phase 1 Periodontal Therapy. Group B (16). Application of (Fig 4) at pockets site following NSPT. Samples of Subgingival plaque at baseline and after 7 days were obtained using a curette and preserved in Tris EDTA buffer medium which can be stored for 72 hours at a temperature of 4 ºC. The samples had undergone evaluation for Porphyromonas gingivalis count through real-time PCR. Plaque index (PI), gingival index (GI), PMA Index, and probing pocket depth (PPD) were all measured at baseline and after 7 days.

Figure 3: BMG gel (Group A). A) pre operative B) Application of BMG Gel c) After 7 days

Figure 4: NBF Gel (Group B); Pre- Operative picture, B) Application of NBF gel; C) After 7 days

Statistical analysis
SPSS version 27.0 software was used for statistical analysis.

Parametric tests such as independent samples t-tests for continuous variables, chi-square tests for categorical

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variables, and significance testing for intra- and intergroup differences. The mean and standard deviation for continuous variables were calculated. Each analysis had a 95% confidence interval, 80% power, P value set at 0.05.

4. Results

Graph 1 and Table 1 offer a brief overview of the demographic data of participants from groups A and B who were included in the research. Group A is composed of 16 patients, with an average age of 46.88 years (standard deviation 8.27), including 9 males and 7 females. Group B is made up of 16 individuals, with an equal number of males and females (8 each) and an average age of 46.25 years, with a standard deviation of 8.36. In general, both groups consisted of 53.12% males and 46.17% females.
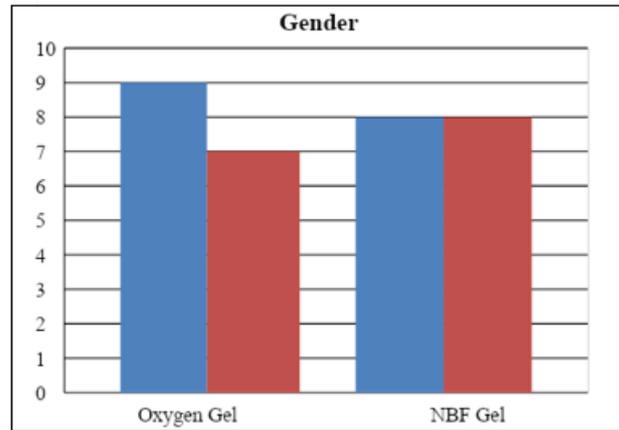
Graph 1: Comparison of Gender distribution between Oxygen Gel and Nano Bio Fusion Gel group.

Table 1: Comparison of Mean age between Oxygen Gel and Nano Bio Fusion Gel group

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	p value
						Lower Bound	Upper Bound			
Age	Oxygen Gel	16	46.88	8.27	2.07	42.47	51.28	37.00	60.00	0.833
	NBF Gel	16	46.25	8.36	2.09	41.79	50.71	36.00	60.00	
	Total	32	46.56	8.19	1.45	43.61	49.51	36.00	60.00	

Test: Independent samples test

Table No.2 evaluated the mean Gingival Index (GI), mean Plaque index (PI), mean PMA Index of patients treated with Oxygen Gel and Nano Bio Fusion Gel (NBF Gel) at baseline and after 7 days. The intra-group significance (p^a value) was <0.001 for both groups, indicating a significant reduction in GI within each group over the 7-day period. However, the inter-group significance (p^b value) showed no significant difference in the reduction of GI between the two groups at either time interval.

The intra-group significance (p^a value) of plaque index was <0.001 for both groups, indicating a significant reduction in PI within each group over the 7-day period. However, the inter-group significance (p^b value) showed no significant difference in the reduction of PI between the two groups at either time interval.

The intra-group significance (p^a value) of PMA Value was <0.001 for both groups, indicating a significant reduction in PMA values within each group over the 7-day period. However, the inter-group significance (p^b value) showed no significant difference in the reduction of PMA values between the two groups at either time interval, suggesting that both treatments were effective in reducing PMA values.

Table 2: Comparison of Mean Gingival Index, Mean Gingival Index, Mean PMA index between Oxygen Gel and Nano Bio Fusion Gel group at two different time intervals

		N	Mean	Std. Deviation	Std Error	95% Confidence Interval for Mean		Minimum	Maximum	p^a value	p^a value
						Lower Bound	Upper Bound				
Gingival Index at Baseline	Oxygen Gel	16	1.77	0.35	0.09	1.58	1.97	1.00	2.20	0.102	**<0.001**
	NBF Gel	16	1.56	0.33	0.08	1.38	1.74	1.20	2.20		
	Total	32	1.66	0.35	0.06	1.53	1.79	1.00	2.20		
Gingival Index after 7 days	Oxygen Gel	16	1.41	0.33	0.08	1.24	1.59	0.80	1.93	0.364	
	NBF Gel	16	1.31	0.28	0.07	1.16	1.46	1.00	1.80		
	Total	32	1.36	0.31	0.05	1.25	1.47	0.80	1.93		
Plaque Index at Baseline	Oxygen Gel	16	1.41	0.25	0.06	1.27	1.54	1.00	1.72	0.096	**<0.001**
	NBF Gel	16	1.29	0.12	0.03	1.22	1.35	1.10	1.50		
	Total	32	1.35	0.20	0.04	1.27	1.42	1.00	1.72		
Plaque Index after 7 days	Oxygen Gel	16	1.14	0.23	0.06	1.02	1.26	0.70	1.56	0.978	
	NBF Gel	16	1.14	0.16	0.04	1.06	1.23	0.80	1.40		
	Total	32	1.14	0.19	0.03	1.07	1.21	0.70	1.56		
PMA value at Baseline	Oxygen Gel	16	3.47	0.23	0.06	3.35	3.59	3.08	4.09	**0.028**	**<0.001**
	NBF Gel	16	3.28	0.23	0.06	3.16	3.40	3.00	3.70		
	Total	32	3.38	0.24	0.04	3.29	3.46	3.00	4.09		
PMA value after 7 days	Oxygen Gel	16	2.96	0.30	0.08	2.80	3.12	2.08	3.48	0.257	
	NBF Gel	16	2.84	0.29	0.07	2.68	3.00	2.32	3.33		
	Total	32	2.90	0.30	0.05	2.79	3.01	2.08	3.48		

Test: Independent samples test
P^a value: Intra-group significance (at 1 time interval)
p^b value: Inter-group significance (between both time interval)

Table No 3. assessed the mean probing depth of patients treated with Oxygen Gel and Nano Bio Fusion Gel (NBF Gel) at baseline and after 7 days. The intra-group significance (pa value) was <0.001 for both groups, indicating a significant reduction in probing depths within each group over the 7-day period. However, the inter-group significance (pb value) showed no significant difference in the reduction of probing depths between the two groups at either time interval, suggesting that both treatments were effective in reducing probing depths to a similar extent.

Table 3: Comparison of Mean Probing depth between Oxygen Gel and Nano Bio Fusion Gel group at two different time intervals

		N	Mean	Std. Deviation	Std Error	95% Confidence Interval for Mean		Minimum	Maximum	pᵃ value	pᵃ value
						Lower Bound	Upper Bound				
Probing Depth at Baseline	Oxygen Gel	16	5.75	0.68	0.17	5.39	6.11	5.00	7.00	0.445	<0.001
	NBF Gel	16	6.00	1.10	0.27	5.42	6.58	5.00	8.00		
	Total	32	5.88	0.91	0.16	5.55	6.20	5.00	8.00		
Probing Depth after 7 days	Oxygen Gel	16	4.44	0.51	0.13	4.16	4.71	4.00	5.00	0.284	
	NBF Gel	16	4.81	1.28	0.32	4.13	5.49	3.00	8.00		
	Total	32	4.63	0.98	0.17	4.27	4.98	3.00	8.00		

Test - Independent samples test
pᵃ value: Intra-group significance (at 1 time interval)
pᵇ value: Intergroup significance (between both time intervals)

5. Discussion

Periodontitis is a collection of inflammatory conditions leading to the destruction of tissues supporting and strengthening the tooth, primarily caused by pathogenic bacteria in the subgingival region [9]. The current research examined the impact of Oxygen Gel and Nano Bio Fusion Gel (NBF Gel) on various periodontal measurements in chronic periodontitis patients, such as the gingival index (GI), plaque index (PI), PMA index, and probing depth.

Introducing local drug delivery to periodontal pockets can enhance periodontal health. However, these medications may not entirely replace traditional scaling and root planning (SRP). Recent investigations have focused on delivering antimicrobial agents directly to infected periodontal pockets to overcome SRP limitations. Successful treatments include tetracycline fibers, metronidazole gel, and chlorhexidine chips in sustained release formulations. Many clinicians now use this approach to deliver antimicrobial agents directly to infected areas within periodontal pockets. [10,11]

Bluem® oral gel, developed by Peter Blijdrop, addresses specific oral problems without complications or risks[3]. The antioxidant gel Nano bio fusion gel helps in controlling fibroblast proliferation in gingival and periodontal healing. It contains nano-oxidants and is produced using nano-bio fusion technology. This biocompatible patented nano-emulsion form has antibacterial, anti-inflammatory, and antioxidative effects.[8]

The study ensured similar demographic characteristics in both groups, with no significant discrepancies in age and gender distribution. This allowed for fair comparison of clinical outcomes without demographic bias. Schulz et al. (2002) [12] emphasized the importance of equivalent baseline characteristics in clinical trials through balanced randomization methods to ensure reliable results.

Both Oxygen Gel and NBF Gel showed a significant reduction in GI over the 7-day period, with no notable disparity between the groups. Jayakumar et al. (2016)[13] found similar results with SRP and a chlorhexidine chip, showing significant reductions in GI scores across all groups.

Himanshu et al. (2023)[14] also found significant improvement in GI from baseline to one month with nano bio fusion gingival gel and chlorhexidine gel alongside non-surgical periodontal therapy. These findings were consistent with the results of previous studies by Srivastava V et al (2019)[15] and Goswami V et al. (2022). [16]

The plaque index significantly decreased within each group over 7 days (p < 0.001), with no significant difference between the groups. Koo et al. (2002) [17] found that propolis mouth rinse reduced the plaque index by the fourth day. Himanshu et al. (2023) [14] found significant differences between groups after one month, likely due to patient adherence to oral hygiene and thorough SRP, with caffeic acid phenethyl ester in propolis enhancing immune function and tissue healing.[18]

The research identified a notable decrease in PMA values within each group (p < 0.001) over 7 days, with no significant difference between groups, suggesting both treatments effectively lowered PMA values. NBF Gel was superior in decreasing marginal inflammation, supported by research on the antimicrobial properties of nano-bio fusion. Elina et al. (2011)[19] found significant reductions in PMA index using the Red Light Emitted Tooth-brush (R-LETB) with 0.1% methylene blue.

The study found a significant intra-group reduction in probing depths (p < 0.001) over 7 days, with no inter-group difference. Niveda et al. (2020)[20] compared Blue M gel and Hexi gel for periodontitis treatment, showing a greater reduction in probing depth with Blue M gel due to active oxygen release promoting faster healing and reducing harmful bacteria. Subgingival scaling with topical oxygen therapy effectively reduces periodontal pockets, warranting further research.

The study's strengths include its rigorous randomized controlled trial (RCT) design, minimizing biases and allowing direct comparison of treatments. The inclusion of clinico-microbiological parameters offers a comprehensive understanding of treatment effects. Adequate sample size and

well-matched groups enhance statistical power and reduce confounding factors. Standardized assessment tools and longitudinal evaluation strengthen reliability, while robust statistical analyses accurately assess significance. The focus on chronic periodontitis addresses a prevalent oral health concern, adding clinical relevance.

The study's limitations include a short 7-day follow-up period, lacking long-term effects. The absence of a placebo control group prevents differentiation of treatment effects from natural progression. Lack of blinding may introduce observer bias, and no exploration of adverse effects or patient-reported outcomes limits holistic assessment. Potential confounding factors like smoking, systemic conditions, and oral hygiene practices were not investigated. Generalizability is limited due to the single-center design. Multi-center studies could improve external validity by including a more diverse patient population and clinical settings. Longer follow-ups are needed to assess treatment sustainability.

6. Clinical Implications

Both Oxygen Gel and Nano Bio Fusion Gel show promise as adjunctive therapies for chronic periodontitis. Dentists may consider incorporating these gels with conventional therapy to enhance outcomes. Educating patients on these benefits could improve adherence and oral health. Further research is needed to explore the long-term effects and potential adverse outcomes of these treatments, as well as their effectiveness in diverse populations and clinical settings.

7. Conclusion

This study comparing Oxygen Gel and Nano Bio Fusion Gel (NBF Gel) for treating chronic periodontitis offers valuable insights. Both therapies reduce gingival inflammation, plaque, attachment loss, and pocket depth over 7 days, with NBF Gel showing superior marginal inflammation reduction. Strengths include a randomized design and comprehensive assessments, but limitations are short follow-up, lack of blinding, and no placebo control. Future research should address these gaps with longer studies and larger samples.

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