

# Comparison between Olive Oil and Nano-Bio Fusion Gel and their Role in the Treatment of Alveolar Osteitis: A Double-Blind Randomized Trial

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## ABSTRACT

**Background:** Alveolar osteitis is a painful condition that occurs after tooth extraction. This condition has been treated with various chemical and herbal formulations that are found to be efficacious with different success rates. **Objectives:** The present study is aimed to evaluate and compare the efficacy of organic olive oil and Nano-Bio Fusion (NBF) gel in the management of alveolar osteitis. **Materials and Methods:** 90 patients who were diagnosed with alveolar osteitis following non-surgical dental extractions were selected and randomly divided into two groups. The extraction socket was irrigated with warm normal saline followed by insertion of sterile gauze soaked in organic olive oil in Group I patients ( $n=45$ ) and with NBF gel in Group II patients ( $n=45$ ). The patients were recalled for the change in dressings on day 3, day 5 and day 7. The subjects were evaluated for the following parameters on 7<sup>th</sup> day; pain, gingival erythema, granulation tissue and the extraction socket margin. Data were analyzed using Friedman test and Mann-Whitney  $U$  test.  $P \leq 0.05$  was considered statistically significant. **Results:** The mean VAS score on day 1 for group I was 8.9 and group II was 8.6. The mean VAS score for both the groups was zero on day 7 though the participants of group II reported better pain relief from day 3 to day 7 when compared with group I patients. Subjects treated with olive oil showed a mildly inflamed gingival to a normal pink variant on day 7. However, all the subjects treated with NBF gel presented with healthy pink gingival on day 7. There was significant improvement in the healing of the margin in both cases. **Conclusion:** Compared to the olive oil, NBF gel helps in enhanced healing in cases of alveolar osteitis.

**Keywords** Alveolar osteitis, Pain, Extraction, Mandibular third molars, Olive oil, Nano-Bio Fusion.

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## INTRODUCTION

Alveolar osteitis, also referred as dry socket, necrotic socket or fibrinolytic osteitis, was first described by Crawford in 1896.<sup>1</sup> It is the most commonly encountered complications following a tooth removal.<sup>2</sup> Its name is attributed to its dry appearance after the loss of blood clot and may be defined as a condition in which the bone around the confines of the extraction socket is exposed for a few days after tooth removal due to disintegration of the blood clot rendering the socket empty and frequently crammed with food debris.<sup>3</sup> It is defined as a post-operative pain inside and around the extraction site, which becomes severe at any time between the first and third day after the tooth removal, accompanied by a

partial or total disintegrated blood clot within the socket with or without halitosis.<sup>4</sup>

Its frequency may range from 0.5-5% and is most commonly seen following extraction of impacted mandibular third molars accounting for 30% of alveolar osteitis cases.<sup>5</sup> It has been proposed that alveolar osteitis occurs due to increased localized fibrinolysis which may result in a premature loss of the blood clot. The exact etiology is elusive; however, a wide array of risk factors may be involved in the pathogenesis including female sex, traumatic extractions, oral contraceptives, tobacco and history of pre-existing infection.<sup>6</sup> The intensity of the pain is variable and radiates to neck, head or ear. It might be associated with swelling, gingival erythema and halitosis.<sup>7</sup>

The fundamental management involves irrigating the socket to flush out food debris or bacteria, which may be achieved using chlorhexidine gluconate, saline, dilute hydrogen peroxide or sodium perborate followed by packing the socket with a medicament such as iodoform ribbon gauze, anti-bacterial



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paste, topical anesthetics, obtundants, zinc oxide and eugenol impregnated cotton pellets, balsam of Peru, alveogyl, Bismuth Iodine Paraffine paste and metronidazole and lidocaine ointment.<sup>8</sup>

Recently the herbal formulations are gaining much attention for the treatment of many oral and non-oral conditions. Olive oil is a vital constituent of Mediterranean cuisine. It has been used for its medicinal properties since the ancient times. It exhibits antioxidant, anti-inflammatory, and anti-microbial properties. The use of olive oil has been incorporated in dermatological practice as it has a protective toning effect on skin.<sup>9</sup> Research has highlighted the valuable effects of olive oil on oral health. Previous studies have shown that use of olive oil is known to reduce the plaque scores and count of *Streptococcus mutans* and *Lactobacillus*, thereby enhancing gingival health. The use of topical preparations containing olive oil such as mouthwash, gel or toothpaste has significantly reduced drug-induced Xerostomia. Also, the use of lycopene-enriched olive oil has demonstrated considerable improvement in pain and burning sensation in patients with Burning Mouth Syndrome.<sup>10</sup>

Nanobiotechnology has proven as a compelling tool aiding in progression of human health to an entirely novel era of enhancement. These products primarily comprise of elements that cause many cellular and biochemical interactions to stimulate healing, as they rapidly get resorbed and transferred to the inflamed tissues. Products based on nanotechnology are likely to permit ultrafine antioxidants to permeate at an intracellular level and invigorate, renew, protect, and optimize the health and integrity of oral tissue. Presently, the only commercially available product based on nanotechnology globally is NBF gel. Recently, the use of NBF gel has been incorporated in dentistry.<sup>11,12</sup> NBF gel is a scientifically prepared, bio-adhesive antioxidant gel yielding naturally occurring antioxidants for targeted action. It is curated with amalgamation of Vitamin C, Vitamin E and propolis with augmented antioxidant power in nanoemulsion. On application, it creates a protective film resulting in enhanced absorption thereby increasing efficacy and results. Its use has been incorporated in dentistry for management of a wide array of pathological entities. It has shown promising results in management of periodontitis, pain in fixed orthodontic therapy-induced gingivitis, peri-implant mucositis, oral ulcers, etc.<sup>13</sup>

This study was carried out to evaluate and compare the efficacy of olive oil and NBF gel in management of alveolar osteitis. To the best of our knowledge the effect of NBF gel has not been tested in the management of alveolar osteitis presenting after non-surgical dental extraction cases.

## MATERIALS AND METHODS

The present study was an observational prospective and double-blinded study that was conducted from January 2020 to May 2021. In total, 90 patients of any age or sex with a history

of extraction in the recent past and diagnosed with alveolar osteitis following non-surgical dental extractions and clinical presentation of pain, sensitivity on gently probing, trismus, halitosis, exposed bone and loss of blood clot at the extraction socket were selected by systematic random sampling method. Patients with an underlying history of systemic diseases such as diabetes, cardiovascular disease, infections, and presence of retained root pieces, any bony or soft tissue pathology, and drugs that may predispose towards the alveolar osteitis including oral contraceptives were excluded from the study. Ethical approval was received from the Local Committee of Bioethics, Jof University (Approval no. 11-04-42). The details of each component of materials and methods are shown in Table 1.

The patients signed individual informed consent forms containing information about the study. The selected patients were divided randomly into two groups. Group I comprised 45 patients who received organic olive oil, and group II comprising 45 patients who received NBF gel.

Initially, investigators coded the olive and NBF gel. Participants were blinded, and were not aware of division of the two groups. The dental surgeon who was also blinded from the medicinal information applied the dressing for the participants.

### Baseline examination

Once patients were enrolled, they underwent an oral examination, and the clinical appearance of the condition (i.e., gingival erythema, granulation tissue and the extraction socket margin) was noted. Gingival erythema was categorized as ranging from 'fiery red' to 'all pink'. Presence of granulation was suggestive of 'diseased socket', whereas its absence was indicative of a 'healthy and healed socket'. Socket margin was categorized from being 'non-epithelialized' to 'epithelialized'. Pain was measured using the visual analog scale (VAS) scale with zero representing 'no pain' and ten representing 'worst pain'. Oral examination was carried out by a single trained and experienced examiner (1<sup>st</sup> author).

### Medication application

The extraction socket was irrigated with warm normal saline followed by insertion of sterile gauze soaked in olive oil in group I subjects. In group II subjects, sterile gauze soaked in NBF gel was inserted in the socket. The intra-alveolar packing was changed until the post-operative pain symptoms subsided. All clinical observations of the patients and application of the medicated dressings were completed by the same clinician.

For safety purposes, any harmful effects of the medication were also recorded. Patients were instructed to call immediately the investigator about any problem in the due course, in such circumstances, treatment would be immediately terminated and discontinued. The patient was requested to visit the investigator

**Table 1: Selection guideline, study population and method details.**

Selection Guideline	Inclusive Diagnosed cases of alveolar osteitis.		Exclusive Systemic diseases such as diabetes, cardiovascular disease, infections, and presence of retained root pieces, any bony or soft tissue pathology, oral contraceptive use and the ones not willing to participate.	
Study design	Prospective-clinical-intervention.			
Intervention	Intra-alveolar dressing of olive oil for group I patients and NBF gel for group II patients till complete relief from all the symptoms related to alveolar osteitis.			
Outcome	Pain, gingival erythema, granulation tissue and the incision margin related to alveolar osteitis.			
Sample size calculation	With the power 80%, $\alpha$ 0.05 and effect size (d) 0.22 was used (G*Power-software version 3.0.10). Thus, the total sample size finalized for this study was 90.			
Randomization of patients into study groups	A computer software program was used to code each participant for the olive oil and NBF gel application to avoid bias.			
Olive oil and NBF gel application	The extraction socket was irrigated with warm normal saline followed by the application of olive oil for group I patients and NBF gel for group II patients. The intra-alveolar packing was changed until the post-operative pain symptoms subsided.			
Baseline examination	Pain Measured using VAS scale with zero representing 'no pain' and ten representing 'worst pain.'	<i>Gingival erythema</i> Categorized as ranging from 'fiery red' to 'all pink.'	Granulation tissue Presence of granulation was suggestive of 'diseased socket', whereas its absence was indicative of a 'healthy and healed socket'.	Incision margin Categorized from being 'non-epithelialized' to 'epithelialized'.
Statistical analysis	Statistical analysis was performed using IBM SPSS Statistics version 22.0 (IBM Co., Armonk, NY, USA). Intragroup comparison of VAS scores was done using Friedman test whereas intergroup comparison for VAS scores was done by Mann-Whitney <i>U</i> test.			

at the earliest. Patients were allowed to continue their over-the-counter analgesic medications.

### Follow-up evaluations

The patients were reviewed on day 3, day 5 and day 7 post-baseline. During these visit, any changes in the pain score, gingival erythema, granulation tissue and the socket margin were duly noted on the proforma. The entire data were then entered into the proforma.

### Statistical analysis

Data analysis was done by a specialist statistician after decoding the data, and the investigators were provided with results. Statistical analysis was conducted using SPSS version 20 [IBM Corp, Armonk, USA]. The results are presented as mean  $\pm$  standard deviation. Intragroup comparison of VAS scores was done using Friedman test whereas intergroup comparison for VAS scores was done by Mann-Whitney *U* test. Statistical significance was set at  $p \leq 0.05$

## RESULTS

A total of 90 patients participated in this study. All of the patients complied with follow-up, and the results were evaluable. The age range of the participants was 18-52 years with the mean age of 45.2 years. There were 68 (75.5%) female participants and 32 (34.5%) male participants. Out of the 90 sockets diagnosed with alveolar osteitis, 28 (31.1%) teeth were maxillary third molars, whereas, 62 (68.9%) were mandibular third molars. Table 2 shows the characteristics of the study participants.

Intragroup comparison of pain among group I showed an overall statistically significant difference in VAS scores at baseline, day 3, day 5 and day 7. *Post hoc* pairwise comparison was done using Wilcoxon test and it was found that the pain scores reduced significantly from baseline to day 3, then further from day 3 to day 5 and from day 5 to day 7. Similar results were found for group II as well. Table 3 shows intragroup comparison of pain scores.

The mean VAS score on day 1 for group I was 8.9 and group II was 8.6. On day 5, the mean VAS score for group I was 1.0 whereas for group II was 0.2. On day 7, the mean VAS score for both the

groups were found to be zero. The mean VAS scores among group II was found to be significantly lower than that group I at baseline, day 3 and day 5 as shown in Table 4.

On clinical evaluation of gingival erythema, it was noticed that the gingiva in almost all the patients was fiery red on day 1. Patients treated with olive oil (group I) showed a mildly inflamed gingiva to a normal pink variant on day 7. However, all the

**Table 2: Characteristics of study participants.**

Variable	n=90	Percentage
<b>Gender</b>		
Male	32	35.6
Female	58	64.4
<b>Age (years)</b>		
Range	18-52	
Mean	45.2	
<b>Site</b>		
Maxillary third molars	28	31.1
Mandibular third molars	62	68.9

**Table 3: Intragroup comparison of pain scores.**

Time	Group I (Mean±SD)	Group II (Mean±SD)
Baseline	8.9±0.72	8.6±0.84
Day 3	3.9±0.44	3.4±1.00
Day 5	1.0±0.80	0.2±0.50
Day 7	0.0±0.00	0.0±0.00
P-value	<0.001*	<0.001*
Post hoc pairwise comparison	Baseline*day3 - <0.001 *	Baseline*day3 - <0.001 *
	Baseline*day5 - <0.001 *	Baseline*day5 - <0.001 *
	Baseline*day7 - <0.001 *	Baseline*day7 - <0.001 *
	Day3*day5 - <0.001 *	Day3*day5 - <0.001 *
	Day3*day7 - <0.001 *	Day3*day7 - <0.001 *
	Day5*day7 - <0.001 *	Day5*day7 - 0.014 *

\* Statistically significant

patients treated with NBF gel (group II) presented with healthy pink gingiva on day 7 with no signs of inflammation or erythema.

Clinically the epithelial margin was non-epithelialized in all 90 patients on day 1. There was significant improvement in the healing of the margin in both groups.

There was presence of granulation tissue on day 1 in both the groups. 39 patients out of 45 in group I showed the absence of the same on day 7, whereas, 42 out of 45 showed the absence of granulation tissue on day 7 for group II.

## DISCUSSION

Alveolar osteitis is a common post-operative complication that the patients experience mostly associated with mandibular third molars. The pain of the dry socket is described by the patients to be excruciating that mandates timely and proper treatment in order to relieve the pain and discomfort of the patients.<sup>14</sup> The fundamental therapy for alveolar osteitis involves irrigating the socket to flush out food debris or bacteria, which may be achieved using a wide range of medications, irrigants and dressings.<sup>4</sup> Many chemical and herbal formulations have been tried and found to be efficacious in the past. Chemical preparations are known to cause side effects, and thus a shift toward the herbal remedies has been seen in the near past and gaining popularity in present.<sup>15</sup> Hence, the present study aimed to evaluate and compare the efficacy of organic olive oil and Nano-Bio Fusion gel in the management of alveolar osteitis.

Majority of the patients in our study were females (75.5% females; 34.5% males). These findings were in concordance with Oyri *et al.* who conducted a study to evaluate the relative incidence of alveolar osteitis on 445 patients and concluded that the condition was more frequently seen in female patients.<sup>16</sup>

Out of the 90 subjects, 28 (31.1%) teeth were maxillary third molars, whereas, 62 (68.9%) were mandibular third molars. Our findings were in concordance to a wide array of studies and reviews which support the fact that alveolar osteitis occurs most frequently following extraction of lower third molars with a reported incidence of 25-30%.<sup>17</sup>

In our study, most of the patients suffered severe pain on average with a VAS score of 8. Similar findings have been reported in a study by Bortouzzi *et al.*, where patients did suffer from severe

**Table 4: Intergroup comparison of pain scores.**

Time	Group I (Mean±SD)	Group II (Mean±SD)	p-value
Baseline	8.9±0.72	8.6±0.84	0.046 *
Day 3	3.9±0.44	3.4±1.00	0.002 *
Day 5	1.0±0.80	0.2±0.50	<0.001 *
Day 7	0.0±0.00	0.0±0.00	--

SD- Standard Deviation; \* Statistically significant



pain of dry socket.<sup>18</sup> Pain related to alveolar osteitis originates primarily from the exposure of the underlying bone to the oral environment that is supplemented by the action of bacteria that further exacerbates the condition.

A study was carried out by Kaplan *et al.* to evaluate the effects of St. John's wort oil and virgin olive oil on the post-operative complications and its comparison with chlorhexidine gluconate plus benzydamine hydrochloride mouthwash after the extraction of impacted third molar. It was highlighted that no considerable disparities were seen amongst the study groups. It was thus concluded that essential oils may be used as an adjunct to mouthwash and other forms of therapy after impacted third molar surgery.<sup>9</sup> Also in a study carried out by Khan *et al.* to estimate the clinical efficacy of the ozone oil gel therapy in dry socket it was highlighted that ozone oil group has shown promising results with regards to healing and postoperative pain.<sup>19</sup> NBF gel has proven to significantly reduce the post-operative pain in a study conducted by Serrano *et al.* to determine the efficacy of gel containing 2% of propolis extract, 0.2% of ascorbic acid and 0.2% of tocopherol acetate in preventing surgical complications related to impacted lower third molar extractions.<sup>20</sup> In the current study, it was reflected that there was a significant reduction in the VAS score in group II than group I in the follow-up visits. Our study showed better pain alleviation with NBF gel in comparison to olive oil.

According to our study, patients treated with olive oil showed a mildly inflamed gingiva to a normal pink variant on day 7. However, all the subjects treated with NBF gel presented with healthy pink gingiva on day 7 with no signs of inflammation or erythema. A study was conducted by Singh *et al.* to evaluate the efficacy of NBF gel alone and as an adjunct to conventional therapy in patients with gingivitis and concluded that NBF gel in addition to conventional therapy can cause significant improvement in gingival inflammation of the patient. NBF gels works similar to a local delivery agent that reduces the microbial load upon direct application on the gingiva, thereby, resulting in improvement in the clinical signs of gingivitis and boost the immunity of the gingiva and periodontium.<sup>21</sup> None of the subjects in our study reported with any side effects or adverse effects. Despite the strengths of this study, such as adequate patient follow-up and keeping track of pain scores, the small sample size of patients is the limitation of this study.

## CONCLUSION

Thus, with the results obtained from the present study it can be concluded that although both of the treatment modalities i.e., olive oil and NBF gel are effective in reducing pain and clinical signs of alveolar osteitis, but NBF gel helps in enhanced healing in cases of alveolar osteitis. Thus, these herbal medicines can be considered as a treatment option for alleviating the signs and symptoms associated with dry socket. Further research with a

larger sample size is warranted to have a better understanding of the effectiveness of olive oil and NBF gel in management of alveolar osteitis.

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## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

## SUMMARY

This study aimed to evaluate and compare the efficacy of organic olive oil and Nano-Bio Fusion gel in the management of alveolar osteitis. A total of 90 patients with alveolar osteitis were included as the study participants. The baseline parameters to examine were pain, gingival erythema, granulation tissue and incision margin. The patients treated with Nano-Bio Fusion gel showed better results for pain and gingival erythema as compared to the group that was treated with olive oil. Therefore, Nano-Bio Fusion gel was found to provide enhanced healing of alveolar osteitis as compared to the olive oil.

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