"INTRA-ALVEOLAR USE OF OZONE OIL AFTER TRANSALVEOLAR EXTRACTIONS FOR PAIN CONTROL AND WOUND HEALING – A RANDOMIZED CONTROLLED TRIAL"

By

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ABSTRACT

TITLE OF THE RESEARCH: " Intra-alveolar use of Ozone oil after Transalveolar Extractions for pain control and wound healing – A Randomized Controlled Trial"

BACKGROUND: Transalveolar extraction is a critical surgical approach for removing teeth that cannot be extracted using conventional forceps or elevators, particularly in cases of severe impaction, root ankylosis, or complex root morphology, it carries significant postoperative challenges, including pain, swelling, and restricted mouth opening (trismus), which may prolong recovery and patient discomfort. There has been growing interest in adjunctive therapies to enhance postoperative outcomes, with ozone therapy emerging as a promising intervention. Ozone oil, when used in extraction sockets, helps regulate inflammation, stimulate blood vessel formation (angiogenesis), and encourage fibroblast growth, all of which are essential for proper wound healing. Its antibacterial effects also lower the chances of post-surgical infections, aiding in faster recovery. The primary objective was to evaluate the effect of ozone oil on postoperative pain. Secondary objective was to evaluate the effect of ozone oil on postoperative swelling, trismus, and wound healing and to evaluate and compare the postoperative frequency of analgesic usage.

MATERIALS AND METHOD: This was a single-blind randomized controlled trial carried out in Department of Oral and Maxillofacial Surgery from December 2023 to November 2024. 50 patients were randomly allocated into two groups:25 patients in Control group and 25 patients in Study group. Group A: Control group – After extraction, the socket was irrigated with normal saline. Antibiotics were prescribed to the patients for 5 days and Analgesics were prescribed in a Patient Controlled Analgesia manner in the form of oral tablets. Group B: Ozone group – After extraction, the socket was filled with Ozonated oil soaked in Abgel (Absorbable Gelatin Sponge) Antibiotics were prescribed and analgesics

were prescribed in a Patient Controlled Analgesia manner in the form of oral tablets. The follow up was done on post operative Day 3 and Day 7.

RESULTS: Both control and study groups were similar in terms of demographic data like gender of patients. The mean age value for the control group and study group were 26.88 ± 6.37 years, and 28.40 ± 6.14 years respectively. There were significantly lower pain scores (VAS) in the study group on 3rd day compared to the control group (p-value= 0.0001). But by Day 7, both the groups reached similar pain levels by this time. The Study group required significantly less ($p = 0.05$) analgesic rescue medication than the Control group. On comparison of swelling at different time points, on post op day 3, minimal difference in swelling (Control: 129.34 ± 7.02 vs. Study: 129.38 ± 7.34, $p = 0.9833$) was seen . On post op day 7**,** no significant difference was seen between both the groups. The comparative analysis of interincisal distance measurements between the control and Ozone groups demonstrated a statistically significant improvement in interincisal distance ($p=0.0115$) within the ozone group. On comparing the wound healing, the study group exhibited better wound healing characteristics, with a mean healing score of 8.48 ± 1.19 (mean ± SD), compared to 7.76 ± 1.27 in the control group ($t = -2.067$, $p = 0.044$).

CONCLUSION: The use of ozone gel significantly improved postoperative outcomes compared to the control group. Patients in the ozone group experienced reduced pain, higher satisfaction scores, decreased reliance on analgesics, and enhanced wound healing. While swelling differences were minimal, ozone gel demonstrated superior results in trismus recovery and overall healing, supporting its clinical efficacy.

KEYWORDS: Trans alveolar extraction, Impacted mandibular third molar, Ozonated olive oil, Postoperative pain, Wound healing

LIST OF ABBREVIATIONS

Pre-op	:	Pre-operative
Post-op	:	Post-operative
Intra-op	:	Intra-operative
M	:	Male
F	:	Female
Hb	:	Hemoglobin
BT	:	Bleeding time
CT	:	Clotting time
RBS	:	Random Blood Sugar
IOPA	:	Intra-oral peri-apical radiograph
OPG	:	Orthopantomogram
VAS	:	Visual Analog Scale

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INTRODUCTION

Tooth extraction is among the most routine surgical interventions in oral and maxillofacial surgery, often needed because of severe cavities, periodontal problems, trauma, or teeth that are unable to erupt properly.[1] Transalveolar extraction is a critical surgical approach for removing teeth that cannot be extracted using conventional forceps or elevators, particularly in cases of severe impaction, root ankylosis, or complex root morphology.[2]

The surgical extraction technique involving mucoperiosteal flap elevation and osteotomy is particularly essential for removing deeply impacted teeth, teeth with severe coronal destruction, or those with complex root anatomy that preclude conventional extraction methods.[3–5]This approach allows for direct visualization and controlled removal while minimizing trauma to adjacent structures[6]. Although transalveolar extraction is commonly performed, it carries significant postoperative challenges, including pain, swelling, and restricted mouth opening (trismus), which may prolong recovery and patient discomfort[7–9]. These complications can markedly impair the health of the patient and delay recovery. In the past few years there has been increasing interest in adjunctive therapies to enhance postoperative outcomes, with ozone therapy emerging as a promising intervention[10].

Ozone (O_3), a triatomic form of oxygen found in nature, acts as a powerful oxidizing compound with established therapeutic effects, including microbial inactivation, inflammation reduction, and wound healing properties.[11,12] In dental practice, ozone therapy has been administered in multiple formulations—including gaseous (O_3), aqueous (ozonated water), and ozone oil preparations—with clinical applications spanning caries management, periodontal disease treatment, and

endodontic treatment.[13,14] Ozone oil has emerged as a promising formulation due to its stability, ease of application, and sustained release, making it more advantageous for intra-alveolar use in post extraction cases.[13,15]

Ozone oil, when used in extraction sockets, helps regulate inflammation, stimulate blood vessel formation (angiogenesis), and encourage fibroblast growth, all of which are essential for proper wound healing. Its antibacterial effects also lower the chances of post-surgical infections, aiding in faster recovery.[16]

Gelfoam, an absorbable gelatin sponge, is commonly used as a local drug delivery medium. Its biocompatibility and high fluid-absorption capacity and fluid holding capacity makes it an efficient medium for localized administration of therapeutic agents to targeted sites.

In the present research, we intend to evaluate the efficacy of ozone gel in minimizing post-surgical pain when placed in the socket using absorbable gelatin sponge after transalveolar extraction.

The relevance of this study lies in its promising aspects to improve patient care by offering a safe, effective, and non-invasive adjunct to traditional post-extraction management. Recovery following tooth extraction often presents challenges, with studies indicating that a significant proportion of patients experience moderate to severe pain during the initial 48-hour period, necessitating effective analgesic strategies to enhance patient comfort and healing outcomes.[17] These results highlight the critical need to enhance pain management strategies to achieve better postoperative recovery outcomes.[17] As the field of dentistry continues to move toward minimally invasive and biologically friendly treatments, ozone gel emerges as a highly promising solution due to its antimicrobial, anti-inflammatory, and wound-

healing properties [18–20]. This study could pave the way for safer, more effective post-extraction care, helping patients get back to their normal lives with less discomfort and downtime.

AIMS AND OBJECTIVES

AIM

To evaluate the efficacy of ozone oil when placed in the extraction socket after a transalveolar extraction.

OBJECTIVES

To evaluate the efficacy of ozone oil soaked in Absorbable gelatin sponge in reducing:

- Post-surgical pain.
- Wound Healing
- Rescue analgesic dose required.
- Adverse effects like post-surgical edema and trismus.

NULL HYPOTHESIS

There is no effect of ozone oil on postoperative pain, swelling, trismus, and wound healing after transalveolar extractions.

RESEARCH HYPOTHESIS

There is significant effect of ozone oil on postoperative pain, swelling, trismus, and wound healing after transalveolar extractions.

REVIEW OF LITERATURE

1. Devyani Bahl, et al, published an article in 2022 in which they evaluated the effect of topical ozone therapy for wound healing after transalveolar extractions. In this study the control received Normal saline irrigation whereas the ozone group received Ozonated oil. The patients were not prescribed antibiotics but analgesics were given on SOS basis. The Ozone group patients were asked to apply ozonated oil on the extraction site 3 times a day for 5days.The authors concluded that topical ozone therapy accelerates healing and reduces pain after transalveolar extraction.[21]
2. Sherif S. Alkholy et al, published an article in 2019 in which they evaluate the use of topical ozone gel on post-operative sequelae following impacted lower third molar surgery. Patients were divided into 3 groups. Group I: Patients received topical ozone application after surgery. Group II: Patients received systemic antibiotics before and after surgery. Group III: Patients received neither ozone nor antibiotics and served as control. The authors concluded that topical ozone gel was useful for reduction of pain but no significant differences were seen in mouth opening and swelling.[22]
3. Jose Christiano Ramos Gloria et al, published an article in 2018 in which they evaluated the efficacy of ozonized water on pain, edema and trismus after impacted third molar mandibular surgeries when compared to double distilled water. In the study, surgical extraction was performed, irrigation was done with ozonized water in Group I or double distilled water in Group II. The authors concluded that ozonized water was compatible as irrigation method and had satisfactory effects on management of pain, edema and trismus after surgical removal of the third molar.[23]

4. H.O. Kazancioglu, et al, published an article in the 2014 in which they evaluated the efficacy of therapeutic ozone application in the management of pain, swelling and trismus associated with the surgical removal of impacted mandibular third molar. Patients with asymptomatic bilateral impacted mandibular third molars were recruited into the study. The molar on one side was extracted and Ozone therapy was given and molar on other side was extracted 2 weeks later and sham ozone therapy was given. They concluded that degree of pain and number of analgesic tablets taken was significantly lower for the study side. However, no differences were found between two sides for mouth opening and swelling.[(24)]
5. Hee Su Kim et al published an article in 2008 in which they evaluated the therapeutic effects of topical ozonated olive oil on acute cutaneous wound healing in a guinea pig model. Guinea pigs were examined for wound healing effect of topically applied ozonated olive oil (ozone group) as compared to pure olive group (oil group) and non- treatment group (control group). The ozone group had a significantly smaller wound size and a residual wound area than the oil group post-operatively. The authors concluded that topical application of ozonated olive oil can accelerate acute cutaneous wound repair.[(25)]
6. Ayush Satapathy et al published an article in 2023 in which they evaluated the analgesic and antibacterial efficacy of topical-ozonized olive oil compared to regular drugs administered post-operatively to patients who have undergone tooth extraction as well as evaluate the healing effects of the former on the extraction site. Patients were randomly divided into twso groups, with group A (case group) receiving ozonized olive oil as a topical application for three days and group B (control group) receiving standard post-operative treatment (antibiotics and analgesics). On day five, patients in both groups were assessed for wound healing using the Landry, Turnbull, and Howley Index and for pain using the visual

analog scale (VAS). When comparing the two groups, there was no discernible difference in the amount of discomfort perceived after surgery. While both groups saw improvement in wound healing and pain, the case group coped better than the control group in terms of wound healing.[26]

7. Jehona Ahmedi et al published an article in 2019 in which they evaluated the efficacy of ozone gas (O3) on the reduction of dry socket (DS) occurrence following surgical extraction of lower jaw third molars, influence of the indication for the extraction, and the difficulty of extraction on the incidence of DS. This study included thirty patients with bilaterally impacted third molars of mandible requiring surgical procedure for extraction. Following extraction, in the control group, saline solution was used for irrigation of extraction sockets and in the experimental group, intra-alveolar O3 was applied for 12 s, DS was present in 16.67% and 3.33% of cases in the control and experimental groups, respectively. The authors concluded that the application of O3 may reduce the incidence of DS and accelerates the recovery period after the surgery. Prophylactic use of O3 may be suggested in all patients, especially in the patients at a risk of development of DS.[27]
8. Alberto Materni et al conducted a double-blind, split-mouth randomized controlled trial evaluated ozone oil-based gel (Ozosan®) for preventing dry socket (DS) after mandibular third molar extractions in 200 patients (mean age 33.1±12.4 years). The ozone gel or placebo was applied to the socket for 2 minutes post-extraction. Results showed ozone gel significantly reduced DS incidence from 21.5% (control) to 2% ($p<0.001$), demonstrating strong efficacy with 99.8% statistical power. No significant correlations were found between DS occurrence and gender, smoking, or tooth angulation (Winter's classification). The study highlighted ozone gel's potential as a safe, effective preventive

measure against DS, leveraging its biocompatibility and antimicrobial properties without drug-related side effects. These findings support ozone therapy as a valuable adjunct in oral surgery to improve post-operative outcomes.[28]

9. Anzolin et al found that ozonated oil has been validated as an effective therapeutic agent for wound healing, particularly in acute and chronic inflammatory conditions. Its beneficial effects include reducing microbial infections through its bactericidal, antiviral, and antifungal properties, facilitating debridement, modulating the inflammatory phase, and stimulating angiogenesis. Additionally, it enhances biological and enzymatic reactions that improve oxygen metabolism, accelerating wound repair. Studies have demonstrated its efficacy in healing cutaneous wounds, alleviating symptoms from burns, preventing post-lesion hyperpigmentation, and reducing pain from aphthous ulcers. These properties make ozonated oil a cost-effective and accessible option for public health systems, offering a promising alternative for managing inflammation and promoting tissue repair in various clinical scenarios.[29]
10. Mansour conducted a study that investigated ozone gel's impact on bone regeneration after maxillary cyst enucleation. Sixteen patients underwent cyst removal, with bony defects in eight patients grafted with ozone gel, while the rest served as controls. Multi-slice CT scans assessed bone defect size and density at immediate post-surgery, 6, and 9 months. The ozone group showed a statistically significant increase in bone density at 6 and 9 months ($p<0.05$), and a significantly smaller residual bone defect area compared to the control group. Ozone gel appears to accelerate bone formation and healing, with no observed adverse reactions. These findings suggest ozone gel is a promising biomaterial for predictable bone regeneration.[30]

11. Izabela Barczyk et al made a literature review examines ozone therapy's clinical relevance in modern dentistry, analyzing studies from 2001–2022 sourced from PubMed, Google Scholar, Scopus, and EBSCO. Out of 834 manuscripts, 70 were selected for final review. Ozone therapy is primarily used as an adjunct to conventional treatments but shows promise as a primary therapy for certain oral mucosal diseases. Its applications span various dental specialties, including disinfection and oral medicine. However, research outcomes are inconsistent, reflecting ongoing exploration of ozone's therapeutic potential. While evidence supports its efficacy in some areas, further studies are needed to standardize protocols and validate results. The growing interest in ozone therapy highlights its potential as a versatile, non-invasive treatment modality in dentistry[31]
12. Anum Rehman et al conducted a pilot study evaluated the clinical efficacy of ozone gel therapy compared to Alvogyl in managing dry socket (alveolar osteitis). Five patients received ozone gel (prepared as ozone olive oil in 1mL syringes), while five received Alvogyl after socket irrigation. Participants (ages 15–60, medically fit, non-smokers, no analgesics/antibiotics) were monitored for two days. Pain severity and clinical signs were analyzed using Fisher's Exact Test. While ozone's healing properties show promise, the study highlights limited progress in standardizing dry socket management. Recommendations were based on literature review due to inconsistent evidence. Preliminary findings suggest ozone therapy as a potential alternative, but further research is needed to establish definitive treatment protocols.[32]
13. Lamberto Re published a review in which it was stated that despite the widespread medical use of ozone, its pharmacological mechanisms remain unclear. While its disinfectant properties are well-documented, its therapeutic effects in various diseases are still poorly understood. Recent evidence suggested

that ozone's biological activity stems from mild oxidative stress, triggering adaptive cellular responses. These may involve the Nrf2 signaling pathway, a key regulator of antioxidant defenses and cellular homeostasis, linked to aging and multiple diseases. Since the discovery of oxidative stress in the 1970s and Nrf2 in 1994, research has expanded on its role in health and disease. A Systems Medicine approach could help unravel ozone's broad therapeutic efficacy, integrating complex biological interactions to explain its clinical benefits in diverse conditions. Further research is needed to fully elucidate its mechanisms.[33]

14. Masaru Sagai published a review on ozone therapy's mechanisms, attributing its benefits to controlled oxidative stress. Like exercise, moderate stress activates protective pathways, while excessive stress causes harm. Ozone's moderate oxidative stress triggers Nrf2, boosting antioxidant enzymes (SOD, CAT, HO-1) that combat inflammation and chronic oxidative damage. It also suppresses NFκB, reducing inflammation. Nrf2 activation may protect against neurodegenerative diseases like Alzheimer's and Parkinson's. Additionally, ozone induces mild immune responses via NFAT and AP-1 and improves vascular health through HIF-1α activation. These pathways explain ozone's efficacy in treating vascular, degenerative, and skin diseases, as well as disc herniation and dental caries. Further research is needed to confirm the roles of Nrf2, NFAT, AP-1, and HIF-1α in ozone therapy's broad therapeutic effects.[34]
15. Marta Radzimierska-Kaźmierczak etal stated that Ozonated olive oil shows promise as an innovative cosmetic ingredient, enhancing stability and functionality. Chemical analysis revealed reduced unsaturated acids but new compounds improving emulsion properties. Emulsions with ozonated oil (0.10 mole O_3/100g) maintained quality for six months without preservatives,

demonstrating extended shelf life. While antimicrobial effects against *Candida albicans* and *Aspergillus brasiliensis* were mild, activity against *E. coli* and *S. aureus* slightly improved. The oil was non-toxic (up to 625 µg/mL) to both normal (LLC-PK1, HaCaT) and cancerous (Caco-2, HeLa) cell lines. Its pleasant aroma, prolonged emulsion stability, and mild antimicrobial benefits position ozonated olive oil as a valuable, multifunctional ingredient for cosmetic and pharmaceutical applications. Further research could optimize its therapeutic potential.[35]

16. Silvia Puxeddu et al conducted a study which concluded that ozonated olive (OOO) and sunflower (OSO) oils show promising antimicrobial potential against drug-resistant pathogens. Chemical analysis confirmed structural changes post-ozonation, enhancing their biological activity. Both oils demonstrated strong microbicidal effects, particularly against *Candida albicans* (IC50: 0.3 mg/mL OOO, 0.2 mg/mL OSO) and *Enterococcus faecalis* (IC50: 0.4 mg/mL OOO, 2.8 mg/mL OSO), with notable activity against *Staphylococcus aureus* and *Escherichia coli*. Crucially, these ozonated oils were non-toxic to human keratinocytes and epithelial cells at effective concentrations. Their non-specific antimicrobial action may help prevent resistance development—a critical advantage over conventional antibiotics. These findings position OOO and OSO as potential adjuncts to standard therapies, offering a resistance-proof alternative for treating common infections while maintaining patient safety. Further clinical validation could expand their therapeutic applications.[36]
17. Cristiano Sconza conducted a double-blind randomized trial that compared ozone therapy (OT) and hyaluronic acid (HA) injections for knee osteoarthritis (OA) in 52 patients. Both groups (22 each) received three weekly intra-articular injections and were evaluated at 1, 3, and 6 months using WOMAC, NRS, and KOOS

scales. Results showed significant pain and functional improvements in both groups at 1 and 3 months, with comparable outcomes at 6 months despite a slight pain recurrence trend. No significant differences in efficacy were observed between treatments, and both demonstrated excellent safety with only minor, self-limiting adverse events. The study suggests OT is as effective as HA for OA pain relief, offering a viable alternative with anti-inflammatory benefits. These findings support OT's potential in OA management.[37]

18. Alessandro de Sire et al stated Oxygen-ozone (O_2O_3) therapy is gaining traction in rehabilitation for musculoskeletal disorders, though its biochemical mechanisms remain incompletely understood. Its benefits likely stem from controlled oxidative stress, modulating inflammation and immune responses—key factors in chronic pain conditions. Current evidence supports O_2O_3's efficacy in reducing pain and improving function, particularly in knee osteoarthritis and low back pain, with a favorable safety profile. However, while promising, broader applications across musculoskeletal rehabilitation require further rigorous study. The therapy's anti-inflammatory and analgesic properties position it as a viable adjunct treatment, but standardized protocols and expanded clinical trials are needed to validate its effectiveness for other disorders. As research evolves, O_2O_3 therapy could become a cornerstone in non-invasive pain management strategies.[38]
19. Marco Paoloni conducted a randomized trial that evaluated intramuscular paravertebral oxygen-ozone (O_2O_3) injections for acute low back pain (LBP) from lumbar disc herniation (LDH). Sixty patients received O_2O_3 or simulated therapy, with assessments over six months. Results showed 61% of O_2O_3 patients became pain-free vs. 33% controls ($p<0.05$), with sustained pain reduction and improved disability scores. The O_2O_3 group also required fewer NSAIDs ($p<0.05$

at early follow-ups). No adverse events occurred. While LBP often resolves spontaneously, conservative treatments sometimes fail; this study demonstrates O_2O_3's efficacy as a minimally invasive option to alleviate pain, reduce disability, and decrease reliance on analgesics. The findings support its clinical use, though further research could optimize protocols.[39]

20. Sujeet Gautam et al conducted a randomized study that compared oxygen-ozone therapy alone versus combined ozone-PIRFT (percutaneous intradiscal radiofrequency thermocoagulation) for contained lumbar disc herniation in 91 patients. Both treatments significantly reduced pain (VAS) and disability (ODI) versus baseline at all follow-ups (2 weeks to 1 year). However, the ozone-PIRFT group showed superior outcomes: greater pain relief, lower ODI scores, reduced analgesic use, and higher patient satisfaction at every interval ($p<0.05$). While ozone therapy alone was effective, the synergistic approach with PIRFT (80°C for 360s) delivered enhanced and sustained benefits. These findings suggest combined ozone-PIRFT as a more effective minimally invasive option for contained disc herniation, optimizing functional recovery and reducing reliance on pain medications. Further studies could refine protocols for broader clinical adoption.[40]
21. Valéria T S Lino er al conducted a study in which he assessed the efficacy and safety of ozone therapy (OT) for knee osteoarthritis (KOA), analyzing eight systematic reviews (SRs) of randomized controlled trials (RCTs) using AMSTAR2 for quality evaluation. The reviews, involving 15 RCTs (3,685 patients), were rated as critically low in confidence. Three SRs reported significant pain reduction with OT compared to placebos, while one found OT comparable to other treatments, and five showed no superiority. Six SRs emphasized the need for higher-quality RCTs to confirm OT's benefits. Joint

function improvements were inconsistent. Seven SRs noted minor adverse events were rare. Despite OT's potential for pain relief, poor methodological quality in RCTs and SRs limits definitive conclusions. Adherence to PRISMA and AMSTAR2 guidelines could enhance future research quality.[41]

22. Merve Damla Korkmaz et al conducted a study that compared the effectiveness of intra-articular ozone and hyaluronic acid (HA) injections in 76 knee osteoarthritis (KOA) patients (40-75 years). Participants received either a single HA injection or three weekly ozone injections. Pain and function were assessed using the Visual Analog Scale (VAS) and Western Ontario and McMaster Universities Arthritis Index (WOMAC) before treatment, at one month, and three months post-treatment. Results showed no significant differences in WOMAC-total, WOMAC-pain, or VAS scores between groups. However, WOMAC-stiffness improved significantly between the first and third months, while WOMAC-function scores improved from baseline to both follow-ups. Both treatments were effective, but HA provided longer-lasting pain relief and functional improvement compared to ozone. The study suggested HA may be more durable for KOA management, though further research is needed.[42]

MATERIALS AND METHODS

STUDY DESIGN:

A prospective study, Randomized Control Trial

SOURCE OF DATA:

The study was conducted on patients reporting to the Department of Oral and Maxillofacial Surgery, KLE VK Institute of Dental Sciences, K.A.H.E.R, Belagavi, with due permission of the institutional ethical committee **(**ANNEXURE I). The procedure was explained to all the patients and an informed consent was signed by them (ANNEXURE II &III).

INCLUSION CRITERIA:

- Both male and female patients willing to participate in the study.
- Any tooth indicated for open extraction or any surgical extraction of impacted tooth.
- Patients who have not used any antibiotic/antimicrobial, analgesic or anti-inflammatory drugs before the surgery.
- Patients who are non- smokers.

EXCLUSION CRITERIA:

- Patients who are not willing to participate in the study
- Patients with presence of any systemic diseases
- Patients with previous history of allergy
- Patients with history of oral contraceptives
- Pregnant and lactating females

- Patients undergoing Orthodontic extractions
- Mentally challenged patients

LABORATORY DETAILS:

- Hb, BT, CT, RBS
- OPG/IOPA

SAMPLE SIZE ESTIMATION:

The sample size can be calculated using the formula

$$N = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (SD_1^2 + SD_2^2)}{(\overline{X}_1 - \overline{X}_2)^2}$$

At 95% confidence level, $Z_{1-\alpha/2} = 1.96$

At 95% power $Z_{1-\beta} = 1.64$

Standard deviation in the 1st group, S1 = 2.43

Standard deviation in the 2nd group, S2 = 3.32

N = 25 in each group.

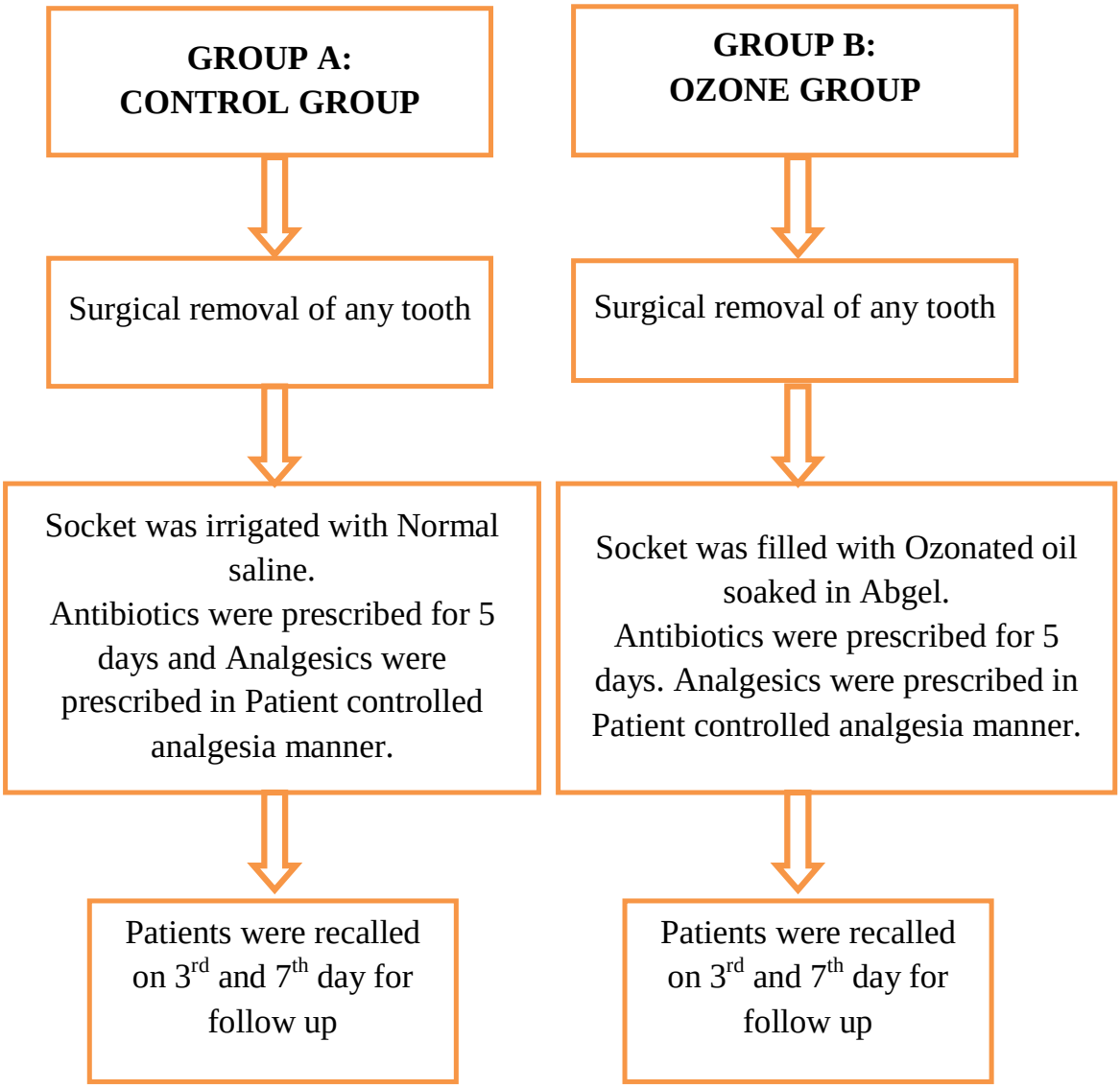
Therefore, the sample size is 50

METHODOLOGY:

- Patients indicated for open extraction or any surgical extraction of impacted tooth diagnosed by clinical and radiographic examination and who met the inclusion criteria were divided into two groups by computer generated random allocation.

- Group A: Control group – After extraction, the socket was irrigated with normal saline. Antibiotics were prescribed to the patients for 5 days and Analgesics were prescribed in a Patient Controlled Analgesia manner in the form of oral tablets.

- Group B: Ozone group – After extraction, the socket was filled with Ozonated oil soaked in Abgel (Absorbable Gelatin Sponge) Antibiotics were prescribed and analgesics were prescribed in a Patient Controlled Analgesia manner in the form of oral tablets.



Materials used:

1. Absorbable gelatin sponge: Goodwill Hemosponge
2. Ozone oil

Drug Information: Commercially available Ozone Oil (Ozonated Olive Oil) manufactured by ADC Inc. Dentozoneindia) which is a natural product composed of suspension of unoxidized olive oil and medical grade ozone.

METHODOLOGY WITH FLOWCHART:

Patients indicated for open extraction or any surgical extraction of impacted tooth diagnosed by clinical and radiographic examination and who met the inclusion criteria were divided into two groups by computer generated random allocation.

Assigned patients underwent open/surgical extraction in the oral surgery unit by the same experienced surgeon.

Post extraction, curettage of the socket was performed to remove any unhealthy granulation tissue.

In Group A, the socket was irrigated with normal saline whereas in Group B, the socket was filled with few drops of Ozonated oil soaked in Abgel (Abosrbable Gelatin Sponge)

The flap was repositioned and sutured with 3-0 silk sutures except the releasing incision.

A pressure pack was placed on the extraction site. All patients received post-extraction instructions.

Patients of Group A and Group B were prescribed Antibiotics 5 days and Analgesics were prescribed in a Patient controlled analgesia manner in the form of oral tablets.

FOLLOW UP: On the 3rd and 7th day after surgical extraction of tooth.

Patient were given log sheet to record VAS scale, Patient satisfaction score and analgesic rescue drugs (ANNEXURE IV)

EVALUATION CRITERIA:

Primary outcome and variables were:

POST-SURGICAL PAIN:

Patients were provided with a Visual Analogue Scale with a score of 0-10.

- Post-surgical pain was assessed immediately after extraction and then post-op 4h, 8h, 12h, 24 h, day 3 and day 7 after tooth extraction.

POST-SURGICAL PAIN SATISFACTION:

It was assessed by using a 5-grade scale:

SCORE	LEVEL OF SATISFACTION
1	Dis-satisfied
2	Rather dis-satisfied
3	Neither
4	Rather satisfied
5	Satisfied

Table 1: Post-surgical pain satisfaction was assessed immediately after extraction and then post-op 4h, 8h, 12h, 24h, day 3 and day 7 after tooth extraction.

POST-SURGICAL SUPPLEMENTAL ANALGESIC RESCUE TIME AND DOSE:

It was assessed by self-reporting from the patient on post operative 7th day

ASSESSMENT OF ADVERSE EFFECT:

Adverse effect like edema, trismus was assessed on the follow up day, i.e., 3rd day and 7th day.

Reduced mouth opening was assessed by measuring the inter-incisal distance by using a caliper.

Edema was assessed by measuring the distance between:

1. Corner of the eye to angle of mandible
2. Tragus to pogonion
3. Tragus to corner of the mouth.

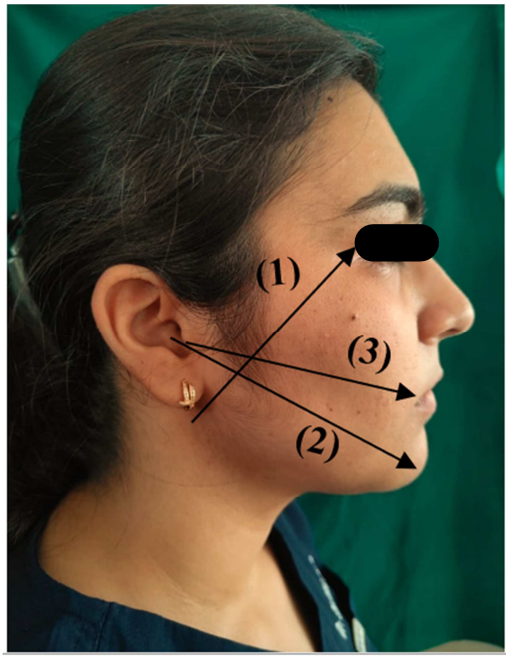


IMAGE 1: ASSESSMENT OF SWELLING

ASSESSMENT OF WOUND HEALING:

PARAMETER	DESCRIPTION	POINTS
Clinical Signs of Re-epithelialization	Merged incision margins	6
	Incision margins in contact	3
	Visible distance between incision margins	0
Clinical Signs of Haemostasis	Absence of fibrin on the incision margins	2
	Presence of fibrin on the incision margins	1
	Bleeding at the incision margins	0
Clinical Signs of Inflammation	Absence of redness along the incision length	2
	Redness involving <50% of the incision length	1
	Redness involving >50% of the incision length and/or pronounced swelling	0
Maximum total score: 10		

Early Wound Healing Score

Table 2: The EHS composed of 3 parameters: clinical signs of re-epithelization (CSR), clinical signs of haemostasis (CSH), and clinical signs of inflammation (CSI). Zero, 3, or 6 points were used to evaluate CSR, whereas 0, 1, or 2 points were used for both CSH and CSI. The summation of the points of these 3 parameters generated the EHS. The EHS for ideal wound healing was 10 points, while the worst possible score was 0 points.[39]

DATA COLLECTION METHODS AND ANALYSIS:

Data collection was done using log sheet that was provided to the patient on the day of extraction and was collected on the follow up Day 7. (Annexure IV)

Photographs for evaluating oedema and trismus were taken pre-operatively, post-surgical day 3 and on post-surgical day-7. (Image 5-16)

SURGICAL ARMAMENTARIUM:

- Surgical gloves
- Mouth mirror
- Dental explorer
- Tweezer
- 2ml disposable syringe
- Suction tip
- Sponge holder
- Gauze piece
- Surgical scalpel blade no. 15
- Langenbeck retractor
- Periosteal elevator
- Straight elevator
- Artery forcep
- Curette
- Bone file
- Needle holder
- Adson’s tissue forcep
- Suture cutting scissor
- Surgical handpiece and burs
- Kidney tray
- Irrigation syringe 20ml
- Surgical drape
- Towel clip
- 2% Lignocaine HCL
- Ozonated Olive Oil
- Absorbable gelatin sponge

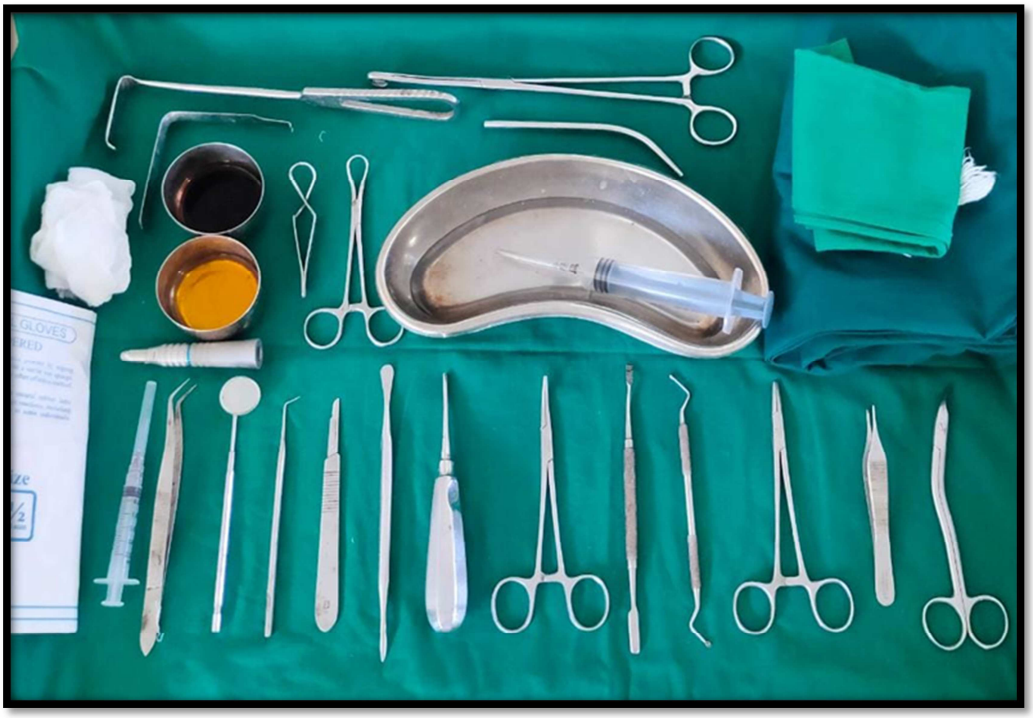


IMAGE 2: ARMAMENTARIUM FOR SURGICAL EXTRACTION

IMAGE 3: ABSORBABLE GELATIN SPONGE

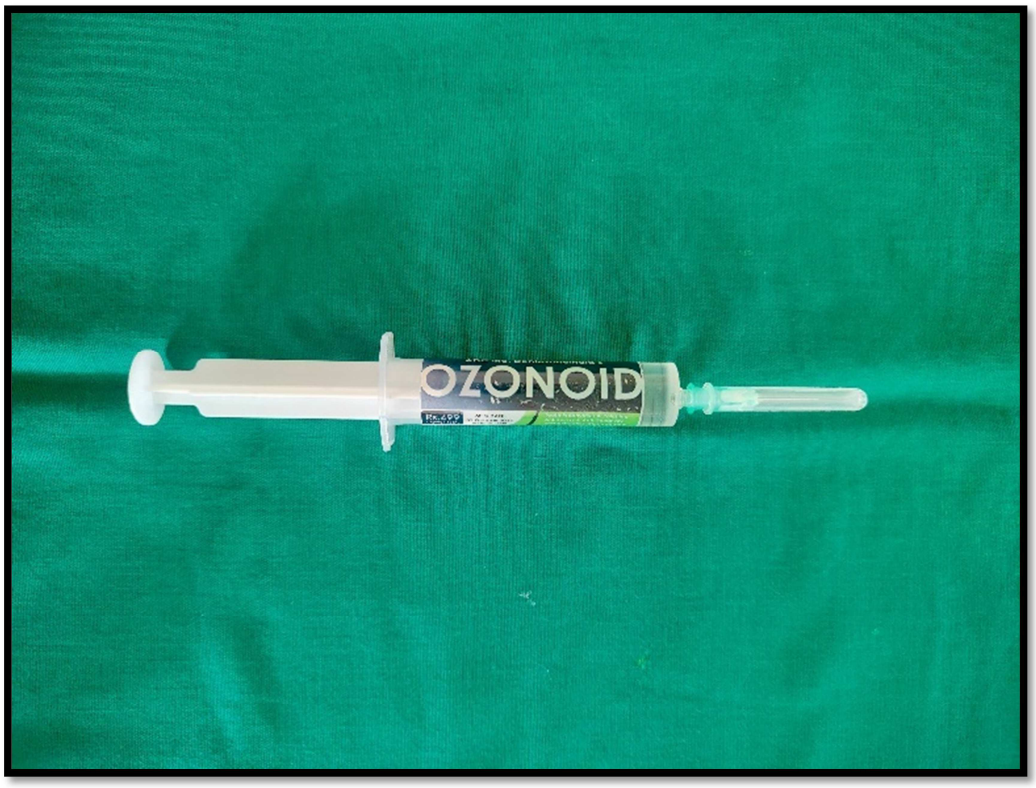


IMAGE 4: OZONATED OLIVE OIL

PRE-OPERATIVE PATIENT'S PHOTOGRAPHS (STUDY GROUP)

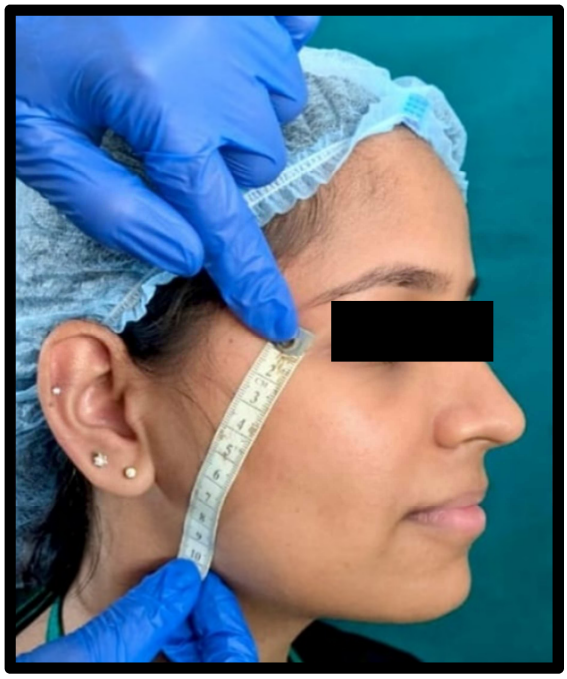


IMAGE 5 : Corner of the eye to angle

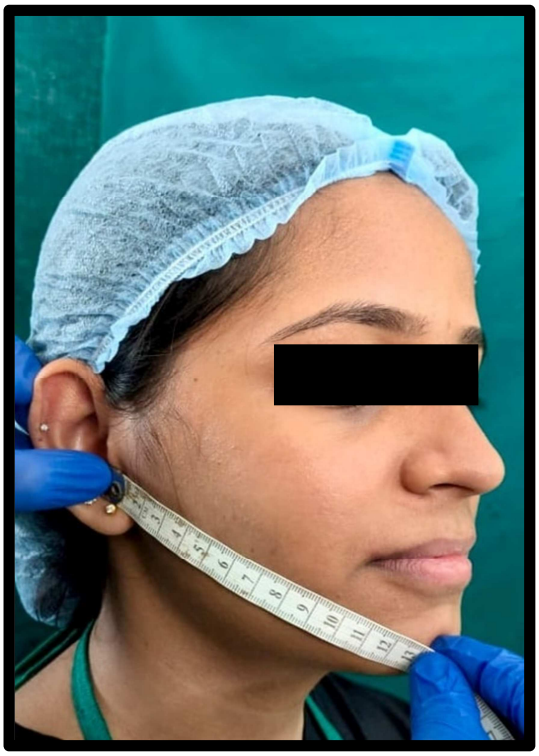


IMAGE 6 : Tragus to Pogonion

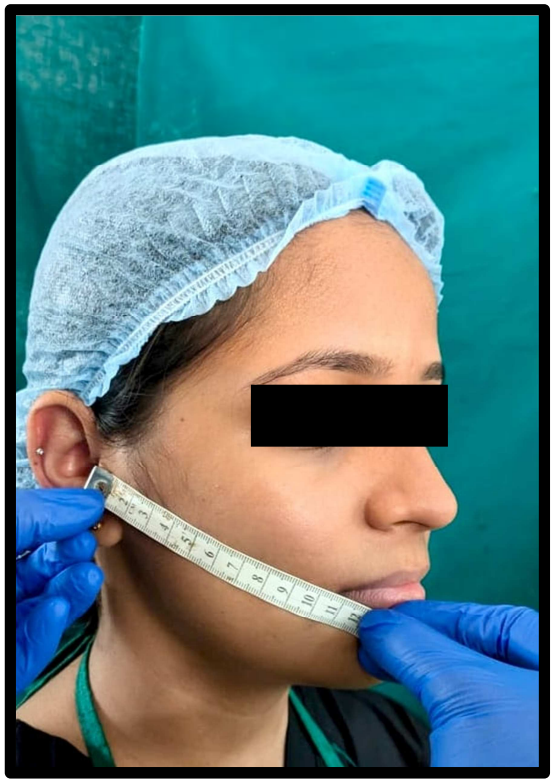


IMAGE 7: Tragus to corner of the mouth

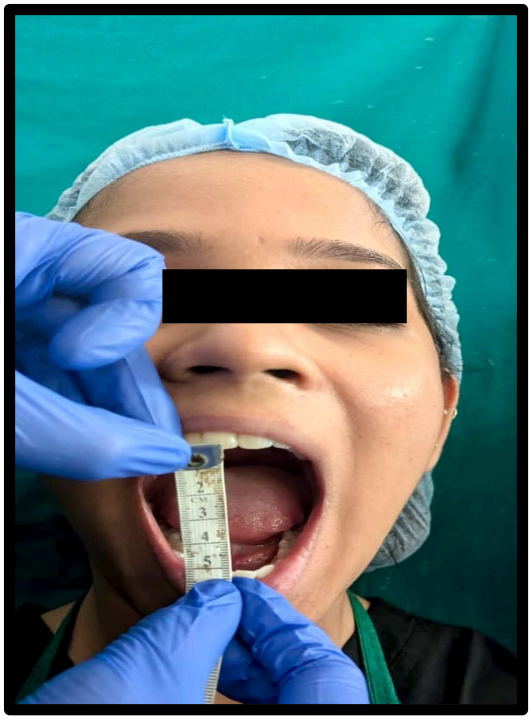


IMAGE 8: Interincisal distance

POST-SURGICAL DAY-3 PATIENT'S PHOTOGRAPHS (STUDY GROUP)

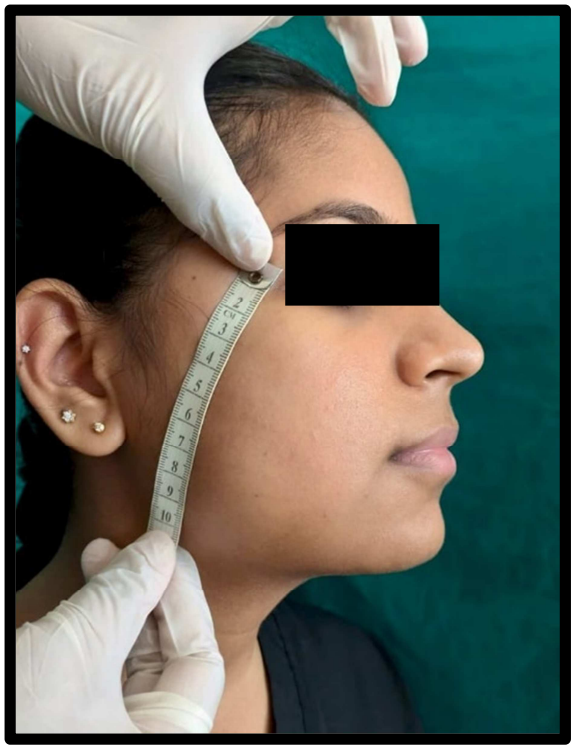


IMAGE 9: Corner of the eye to angle

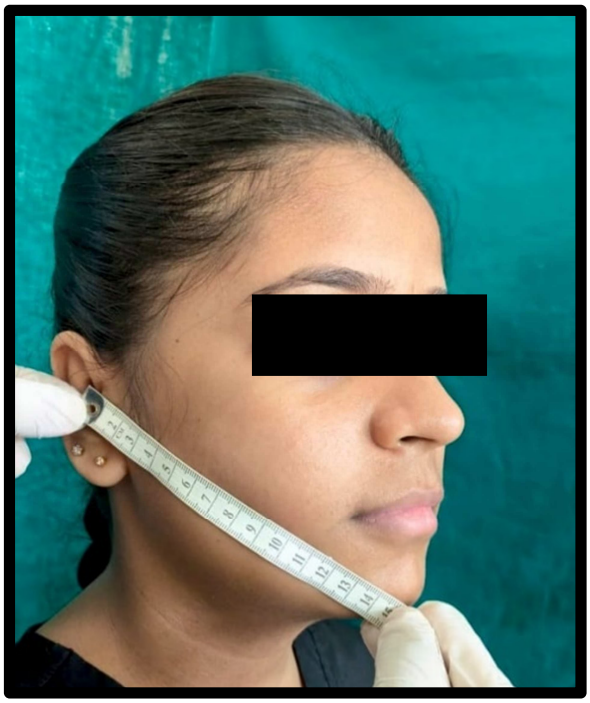


IMAGE 10: Tragus to Pogonion

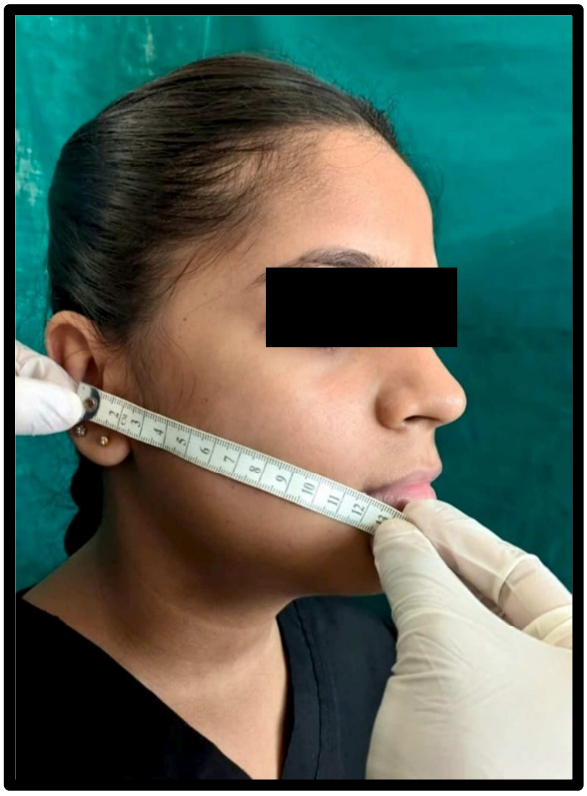


IMAGE 11: Tragus to corner of the mouth

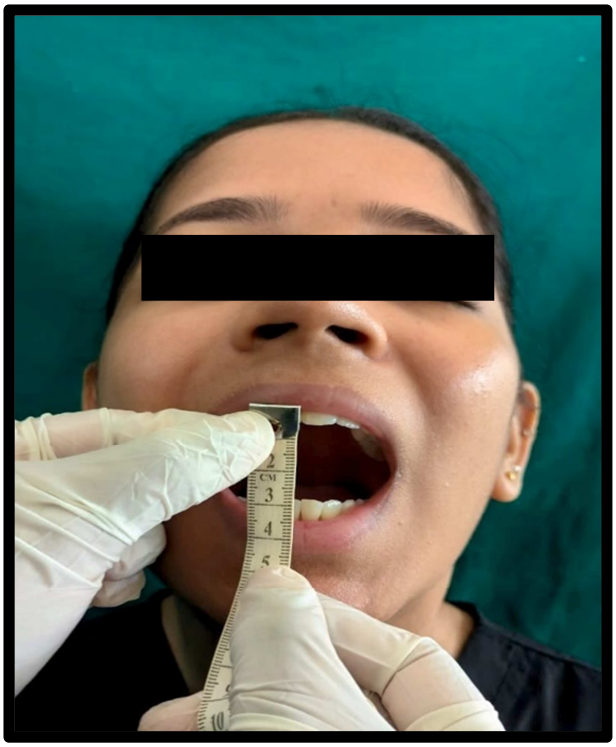


IMAGE 12: Interincisal distance

POST-SURGICAL DAY-7 PATIENT'S PHOTOGRAPHS (STUDY GROUP)

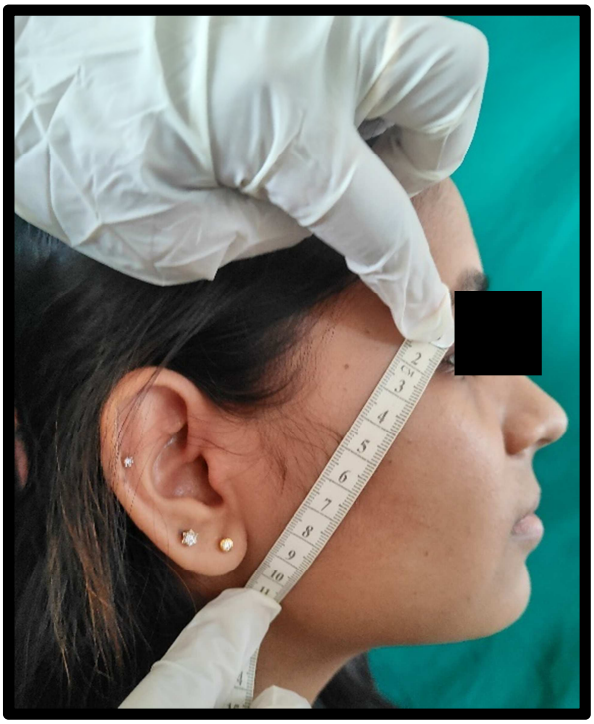


IMAGE 13: Corner of the eye to angle

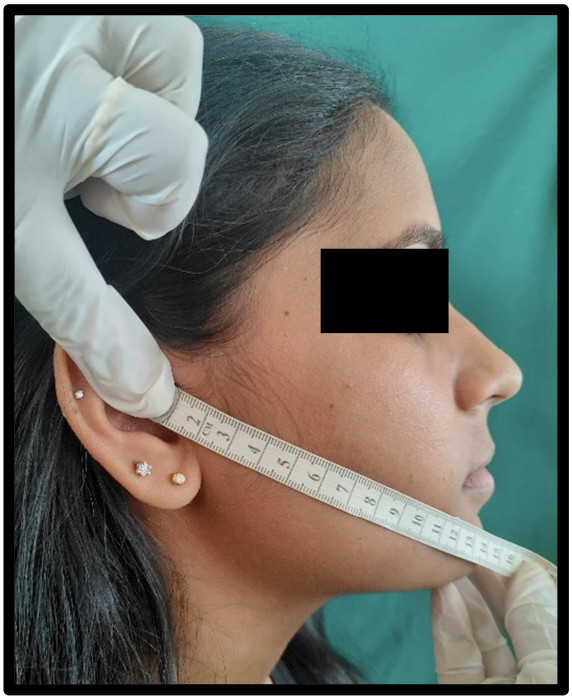


IMAGE 14: Tragus to Pogonion

IMAGE 15: Tragus to corner of the mouth

IMAGE 16: Interincisal distance

RESULTS

DEMOGRAPHIC DATA

In the study, fifty patients were included (26 male and 24 females). Control group included 11 male and 14 female patients. Ozone group had 15 male and 10 female patients.

Table 3: Comparison of control group and Ozone group with gender distribution

Gender	Control group	%	Ozone group	%	Total
Male	11	44.00	15	60.00	26
Female	14	56.00	10	40.00	24
sssTotal	25	100.00	25	100.00	50
Chi-square=0.6925, p=0.4053					

Table 3 shows the chi-square test comparing gender distribution between the control and ozone groups which yielded a chi-square statistic of 0.6925 with a p-value of 0.4053, indicating no statistically significant difference in gender proportions between the two groups.

Table 4: Comparison of control group and Ozone group with mean age by Independent t test

Group	n	Mean	SD	SE	t-value	P-value
Control group	25	26.88	6.37	1.27	-0.8590	0.3946
Ozone group	25	28.40	6.14	1.23		

Table 4 shows the mean age value for the control group and ozone group were 26.88 ± 6.37 years, and 28.40 ± 6.14 years respectively. The comparison between them were not found to be statistically significant (p=0.3946) which denotes no baseline difference between the two groups.

PAIN ASSESSMENT:

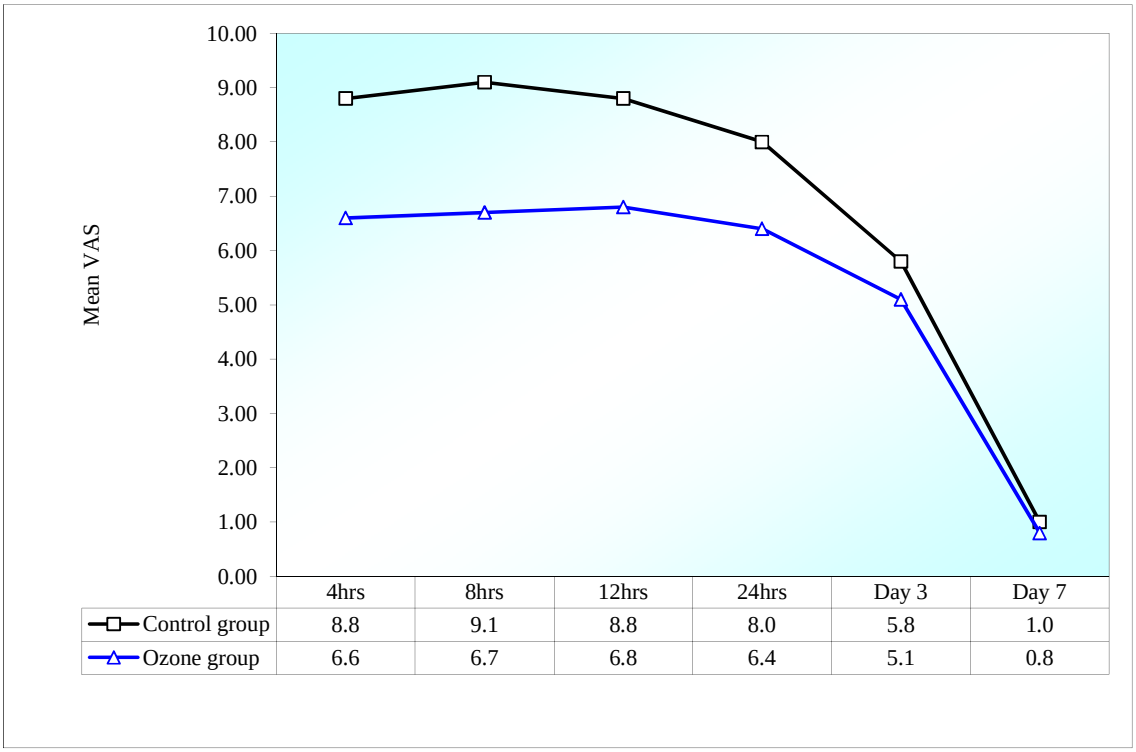
Table 5: Comparison of control group and Ozone group with VAS scores at different treatment time points by Mann-Whitney U test

VAS at	Control group			Ozone group			U-value	Z-value	p-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
4hrs	8.8	0.8	37.6	6.6	0.8	13.4	10.0	5.8597	0.0001*
8hrs	9.1	0.8	37.9	6.7	0.6	13.1	3.0	5.9955	0.0001*
12hrs	8.8	0.8	37.1	6.8	0.7	13.9	23.5	5.5977	0.0001*
24hrs	8.0	1.0	35.0	6.4	0.9	16.0	74.5	4.6082	0.0001*
Day 3	5.8	1.0	30.4	5.1	1.0	20.6	189.5	2.3768	0.0175*
Day 7	1.0	0.7	27.6	0.8	0.8	23.4	260.0	1.0089	0.3130

*$p<0.05$

Table 5 demonstrated a comparison at different time period with respect to VAS scores in both groups (Control and Ozone). There were significantly lower pain scores (VAS) in the ozone group at 4hrs, 8hrs, 12hrs, 24hrs, and on 3rd day compared to the control group (p-value= 0.0001). But by Day 7, the difference between both the groups was no longer significant (p-value= 0.3130), indicating that both the groups reached similar pain levels by this time.

Figure 1: Comparison of control group and Ozone group with VAS scores at different treatment time points



	4hrs	8hrs	12hrs	24hrs	Day 3	Day 7
Control group	8.8	9.1	8.8	8.0	5.8	1.0
Ozone group	6.6	6.7	6.8	6.4	5.1	0.8

Figure 1 shows that both groups initially exhibit high VAS scores, reflecting substantial pain or discomfort in the early stages (4hrs, 8hrs, 12hrs). Over time, the scores for both groups decline steadily, reaching their lowest points by Day 7. However, the ozone group maintains lower VAS scores than the control group at every measured interval, indicating that ozone treatment could be more effective in alleviating pain or discomfort.

Patient Satisfaction Score (PSS) towards pain control:

The comparison of patient satisfaction towards pain, using mean PSS score, between control group and ozone group was conducted using Mann-Whitney U test. The data was expressed in terms of mean and standard deviation.

Table 6: Comparison of control group and Ozone group with satisfaction scores at different treatment time points by Mann-Whitney U test

Satisfaction at	Control group			Ozone group			U-value	Z-value	p-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
4hrs	2.6	0.7	20.8	3.1	0.7	30.2	195.0	-2.2701	0.0232*
8hrs	1.6	0.6	14.1	3.2	0.5	36.9	27.0	-5.5298	0.0001*
12hrs	1.5	0.6	14.1	3.1	0.6	36.9	26.5	-5.5395	0.0001*
24hrs	1.4	0.6	13.9	3.1	0.6	37.1	21.5	-5.6365	0.0001*
Day 3	2.2	0.8	14.9	3.7	0.6	36.1	48.0	-5.1224	0.0001*
Day 7	3.9	0.9	20.4	4.5	0.6	30.6	184.0	-2.4836	0.0130*

*$p<0.05$

Table 6 showed statistically significant difference in mean of PSS between the control and Ozone with $p<0.05$. The Ozone group consistently had higher mean satisfaction scores than the Control group at 8hrs, 12hrs, 24hrs, and Day 3 ($p = 0.0001$).

At 4hrs ($p = 0.0232$) and Day 7 ($p = 0.0130$), differences were still significant but less extreme. The effect was strongest in the first 24 hours and at Day 3 and by Day 7, the difference between groups still existed but was smaller.

Figure 2: Comparison of different treatment time points with satisfaction scores in control group and Ozone group

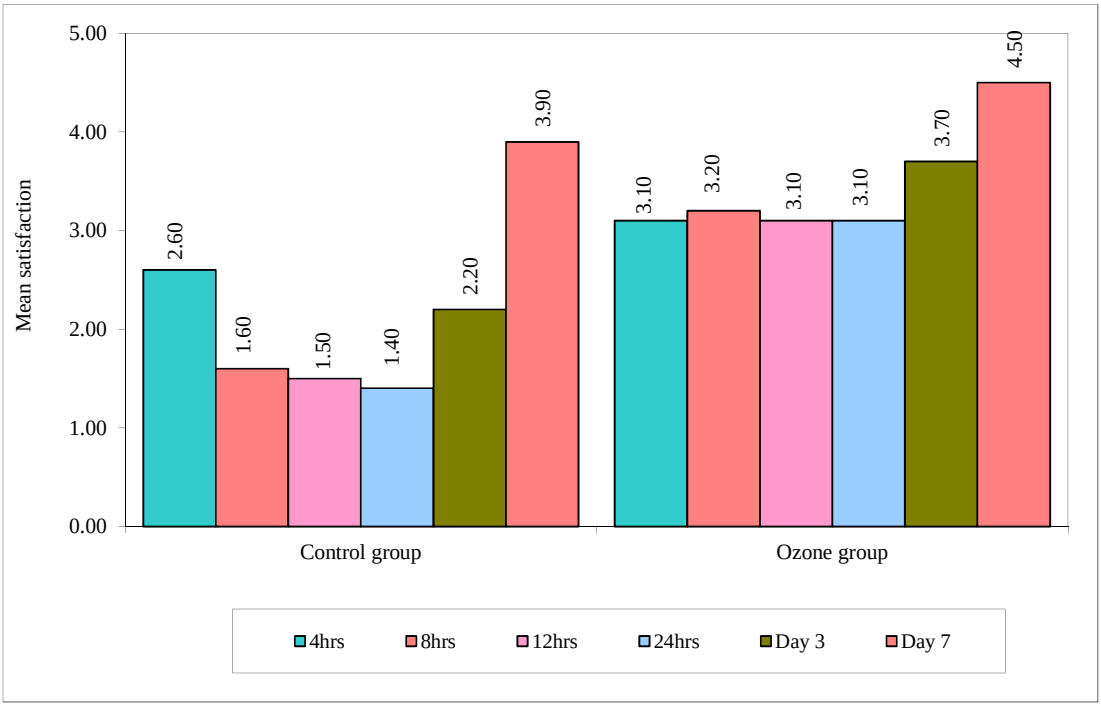


Figure 2 compares mean satisfaction scores at various postoperative time points (4 hours, 8 hours, 12 hours, 24 hours, Day 3, and Day 7) between the control group and the ozone group. Patients receiving ozone therapy consistently reported higher satisfaction scores than the control group across all time points. The difference was most pronounced during the first 24 hours and Day 3, though benefits persisted through Day 7. These findings demonstrate ozone therapy's efficacy in enhancing patient comfort following transalveolar extractions.

TOTAL ANALGESIC RESCUE DRUG:

Rescue analgesic SOS was prescribed to patients and was recorded in the log sheet. Comparison was done within both the groups with respect to total analgesic rescue drug taken by using Mann-Whitney U test.

Table 7: Comparison of control group and Ozone group with Analgesic rescue by Mann-Whitney U test

Variable	Control group			Ozone group			U-value	Z-value	p-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
Analgesic rescue	3.4	1.7	29.5	2.4	1.2	21.5	212.0	1.9590	0.0500*

*p<0.05

Table 7 demonstrated that there was less intake of analgesic drug in case of Ozone group with mean value of 2.4 as compared to control group with the mean value of 3.4. This table also reveals that control group shows higher rank of 29.5 than that of ozone group of 21.5 which indicates greater analgesic use in control group for pain relief. The Ozone group required significantly less ($p = 0.05$) analgesic rescue medication than the Control group.

Figure 3: Comparison of control group and Ozone group with Analgesic rescue

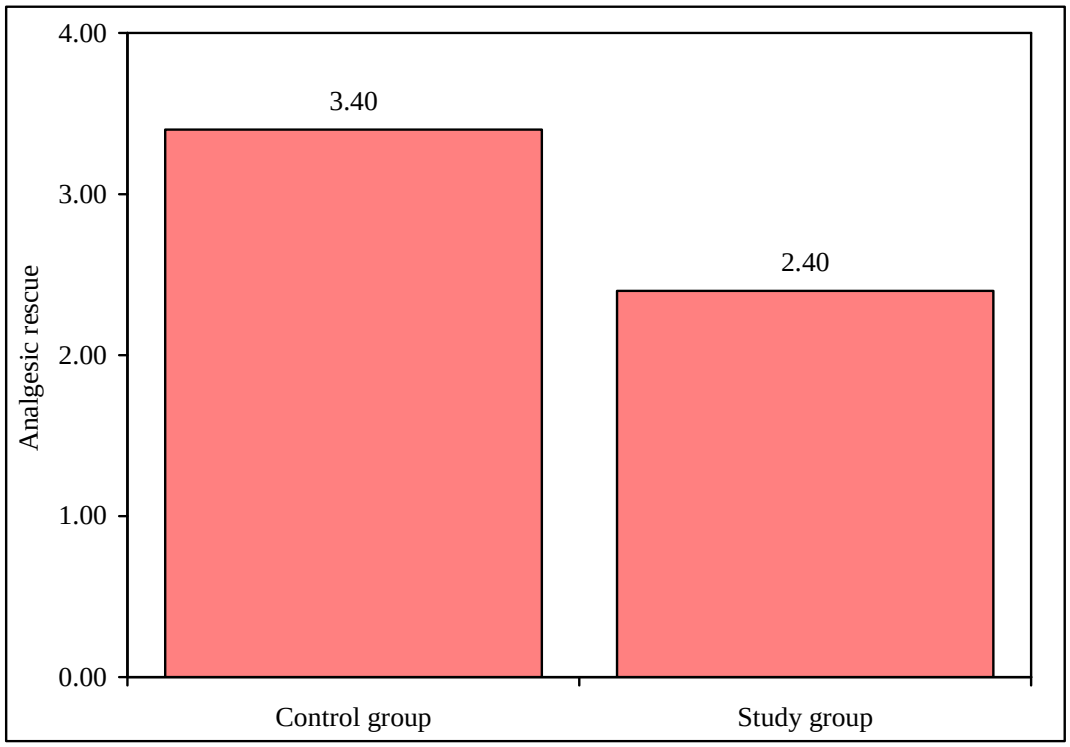


Figure 3 shows patients receiving ozone therapy required significantly less rescue analgesic medication (2.40 units) compared to the control group (3.40 units). This 29% reduction demonstrates ozone's effectiveness in managing post-operative pain following transalveolar extractions, reducing dependence on pharmacological interventions and supporting better recovery outcomes.

ASSESSMENT OF SWELLING:

Post-surgical oedema assessment was carried out by independent t test.

Table 8: Comparison of control group and Ozone group with swelling scores at different treatment time points by independent t test

Time points	Control group		Ozone group		t-value	p-value
	Mean	SD	Mean	SD		
Pre-op	126.54	7.17	127.25	6.92	-0.3547	0.7244
Day 3	129.34	7.02	129.38	7.34	-0.0211	0.9833
Day 7	126.09	7.11	126.58	7.54	-0.2396	0.8116
Pre op-Day 3	-2.80	2.00	-2.14	1.88	-1.2095	0.2324
Pre op-Day 7	0.45	1.12	0.66	1.36	-0.5968	0.5534

Table 8 demonstrated comparison of swelling at different time points. On post op day 3, minimal difference in swelling (Control: 129.34 ± 7.02 vs. Ozone: 129.38 ± 7.34, p = 0.9833) was seen. On post op day 7**,** no significant difference (Control: 126.09 ± 7.11 vs. Ozone: 126.58 ± 7.54, p = 0.8116) was seen. On post op day 7, swelling nearly returned to baseline in both groups, with no significant difference (Control: +0.45 ± 1.12 vs. Ozone: +0.66 ± 1.36, p = 0.5534). No significant differences in swelling were found between the Control and Ozone groups at any time point (all $p > 0.05$).

Figure 4: Comparison of control group and Ozone group with swelling scores at different treatment time points

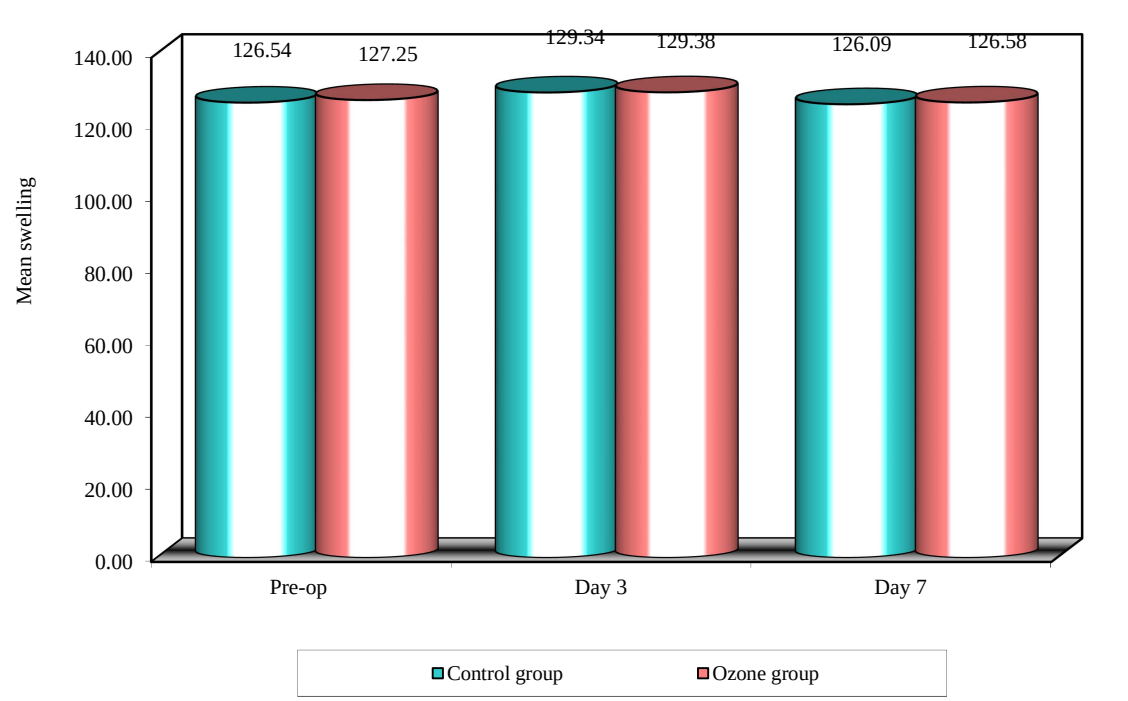


Figure 4 denotes the mean swelling at Post-surgical Day 3 and Day 7 in comparison to preoperative measurements for control and ozone group. In preoperative stage the score was 126.54 and 127.25 respectively. Whereas for Day 3, the scores were 129.34 and 129.38 respectively. Similarly, for Day 7, the scores were 126.09 and 126.58 for both the groups.

Assessment of trismus:

Trismus assessment was carried out using Independent t tests.

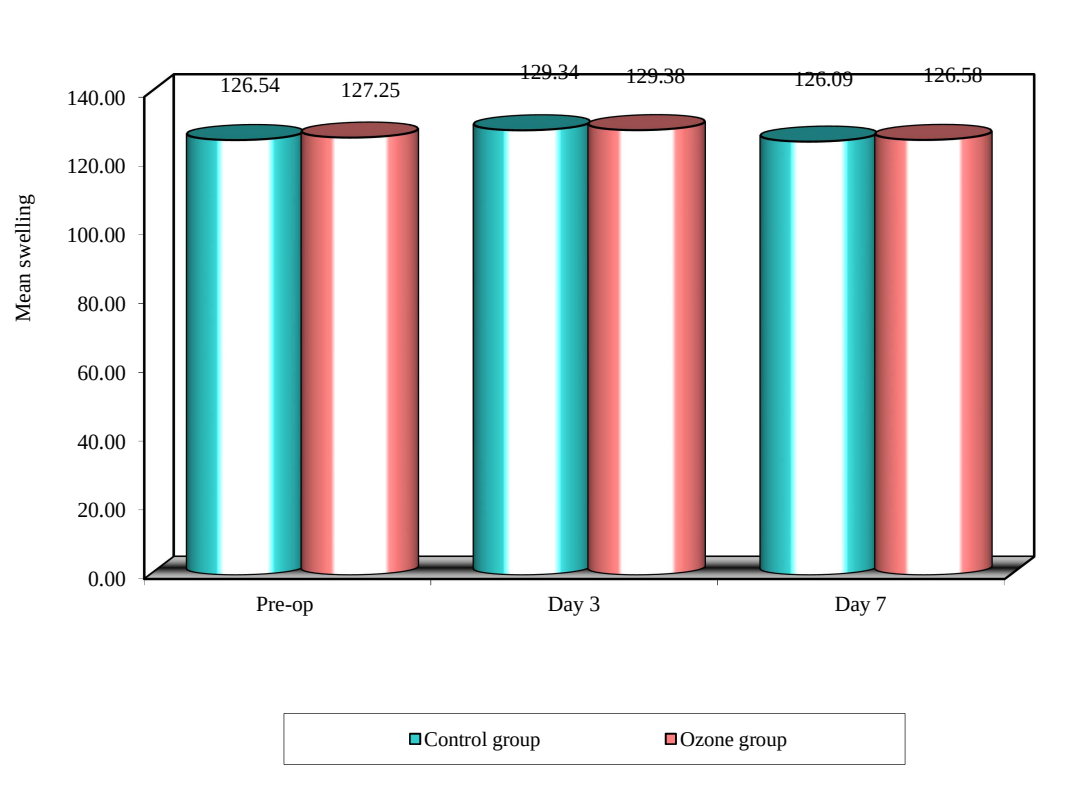
Table 9: Comparison of control group and Ozone group with Interincisal distance (mm) scores at different treatment time points by independent t test

Time points	Control group		Ozone group		t-value	p-value
	Mean	SD	Mean	SD		
Pre-op	42.36	8.58	40.76	6.16	0.7576	0.4524
Day 3	33.20	7.00	34.68	6.22	-0.7901	0.4334
Day 7	40.52	8.44	38.64	6.15	0.9004	0.3724
Pre op-Day 3	9.16	4.67	6.08	3.55	2.6263	0.0115*
Pre op-Day 7	1.84	1.84	2.12	1.13	-0.6481	0.5200

*$p<0.05$

Table 10 shows the comparative analysis of interincisal distance measurements between the control and Ozone groups which demonstrated a statistically significant improvement in interincisal distance ($p=0.0115$) within the ozone group during the immediate postoperative period (pre op to day 3)

Figure 5: Comparison of control group and Ozone group with Interincisal distance (mm) scores at different treatment time points



In figure 5, the bar graph compares mean interincisal distance (mouth opening) between control and ozone groups at different time points. Both groups show reduced mouth opening post-operatively, but the ozone group consistently has slightly higher values on Day 3 and Day 7, indicating less trismus and better recovery compared to the control group. Ozone appears beneficial for early trismus, with similar long term outcomes.

Assessment of wound healing:

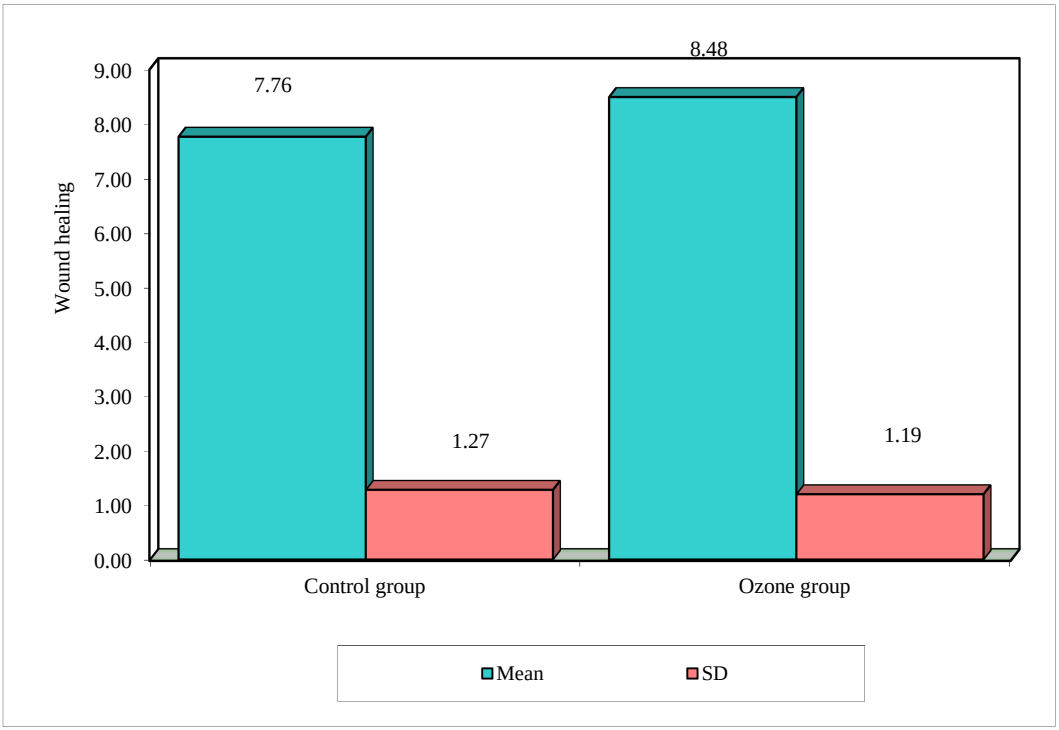
Table 11: Comparison of control group and Ozone group with mean wound healing by Independent t test

Group	n	Mean	SD	SE	t-value	P-value
Control group	25	7.76	1.27	0.25		
Ozone group	25	8.48	1.19	0.24	-2.0670	0.0441*

*p<0.05

Table 11 shows comparative analysis of wound healing outcomes between the control and Ozone groups which demonstrated statistically significant differences. The ozone group exhibited better wound healing characteristics, with a mean healing score of 8.48 ± 1.19 (mean ± SD), compared to 7.76 ± 1.27 in the control group (t = -2.067, p = 0.044).

Figure 6: Comparison of control group and Ozone group with mean wound healing



In figure 6 the bar graph compares mean wound healing scores. The ozone group (8.48) showed better healing than the control group (7.76).

DISCUSSION

One of the widely performed surgeries in the field of oral and maxillofacial surgery is transalveolar removal of teeth which needs proper planning and surgical expertise. They are usually associated with significant discomfort, pain, swelling, trismus and sometimes delayed wound healing. Pharmacological therapies such as administration of steroids, use of non-steroidal anti-inflammatory medications, antihistamines, use of local anesthetics which act for longer duration of time, and antimicrobials have been administered since decades with varied degrees of success in attempting to rule out these significant issues.[44]

In the last few decades, we have seen many adjuvant therapies being utilized in oral and maxillofacial surgery for the management of post-surgical complications following transalveolar extraction. Any practical and safe approach of lowering the duration of post-surgical discomfort may be beneficial to the patient, especially if it also lessens the intensity of the pain. With recent advancements, Ozone Therapy is an emerging adjuvant therapy to the existing therapeutic paradigm for lowering inflammation with significant analgesic impact.[44]

Ozone, a triatomic variant is an inherently unstable gas composed of three oxygen atoms. Therapies with ozone could be administered in various primary forms: aqueous form, ozonated (olive) oil, and in the gaseous form. While the therapeutic properties of ozone remain consistent across these forms, its stability, release , and therapeutic effects differ significantly depending on whether it is applied in gaseous, aqueous, oily, or gel states.[45] Ozonated oils are produced using ozone generators that carefully control the flow of medical-grade oxygen to create precise mixtures of ozone and oxygen, which are then infused into oils.[30]

Gelfoam®, an FDA-approved gelatin-based sponge, has been widely utilized by surgeons and dentists for many years. When applied appropriately, it is completely absorbed by the body, leading to minimal tissue reaction and ensuring effective hemostasis during surgical procedures. In this study, we used absorbable gelatin sponge soaked in ozone oil as a simple mechanism for local drug delivery.

In the present study, Group A was treated as placebo in which the socket received irrigation with normal saline, whereas in Group B, the socket was loaded with ozonated oil soaked in Abgel (Absorbable Gelatin Sponge). The demographic data indicated no significant differences in gender distribution or mean age between the control and ozone groups, ensuring a balanced comparison.

Post-operative pain and edema result from the inflammatory cascade, characterized by increased vascular permeability and leukocyte migration into the inflamed area. This process involves the release and interaction of various inflammatory chemical mediators, including kinins and ultimately contributing to tissue swelling and post operative pain. [(44)] Ahmedi et al. reported in his study that the use of gaseous ozone during third molar extractions has been shown to reduce postoperative pain compared to saline irrigation. This may be attributed to ozone's role in stimulating the synthesis of bioactive compounds such as leukotrienes, interleukins, and prostaglandins, which are beneficial in reducing inflammation and pain.[(27)] Jehona Ahmedi et al compared ozone gas with 1% CHX gel in post extraction cases where they found that there were no significant difference in analgesic rescue drugs and pain scores 48 hours postoperatively in both the groups however, individuals treated with ozone did not experience high intensity pain as compared to 1% CHX group and 30% of the individuals in the ozone group did not report pain.[(46)] Varun P. Sivalingam et al conducted a study, where they observed that

the VAS scores reflecting postsurgical pain were considerably lower where ozone gel was used topically. The decrease in postoperative pain could be due to the anti-inflammatory effect of ozone leading to a decrease in the release of algogenic chemical mediators.[10]

The current study of ozone depicted that, the ozone group experienced significantly lower pain scores (VAS) at 4, 8, 12, and 24 hours, and on the 3rd day post-extraction, compared to the control group. While ozone accelerates pain reduction in the initial days following extraction, its analgesic effects appear to diminish over time. By day 7, pain levels in patients treated with ozone were similar to those in the control group, suggesting that the long-term impact of ozone on pain management is limited. The ozone group consistently reported higher satisfaction with pain control at 8, 12, and 24 hours, and on day 3 which suggests that ozone enhances the patient experience by providing more effective early pain relief. Patients in ozone group required noticeably fewer pain-relief medications compared to the control group, demonstrating ozone's effectiveness in managing pain. The reduced reliance on rescue analgesic medication in the ozone-treated group highlights its significant analgesic effects. By decreasing dependence on pharmacological interventions, ozone therapy contributes to a safer and more comfortable post-operative recovery.

In contrast to pain and satisfaction scores, the assessment of swelling revealed no significant differences between the control and ozone groups at any point of time. Both groups exhibited increased swelling on day 3, followed by a gradual reduction. The study by Glória et al. also found no significant difference in edema between the ozonated water and control groups, further highlighting the variability in ozone's effect on swelling.[23] A study by Kazancioglu et al evaluated therapeutic ozone

application for pain, swelling, and trismus after third molar surgery in which they reported ozone therapy improved pain control but did not significantly reduce swelling and improve mouth opening of the patient. [24] A systematic review and meta-analysis by Kirti Chaudhry et al concluded that following surgical extraction of impacted mandibular third molar, adjuvant ozone therapy substantially decreased pain and analgesic intake, but it was inefficient in alleviating trismus or swelling. There was no significant reduction in swelling at 24 hours, 72 hours, or 7 days post-operatively.[47]

In contrast, Vishal Kumar et al found statistically significant decreased swelling scores in the ozone group when compared to dexamethasone group.[44] Alessandro de Sire et al conducted a review on oxygen-ozone therapy for reducing pro-inflammatory cytokines serum levels in musculoskeletal and temporomandibular disorders where they found that intra-articular ozone injections effectively lowers key inflammatory markers like IL-1β and TNF-α, leading to a more stable and lasting anti-inflammatory effect compared to steroids thereby, reducing swelling and pain.[48] On assessing the effect of ozone on trismus on post operative day 3 and 7 we could not find any significant difference between both the groups but on assessing the change of trismus from preoperative to postoperative day 3, we could find significant reduction in interincisal distance between both the groups where ozone group experienced significantly less reduction in mouth opening compared to the control group suggesting that ozone has a beneficial effect in reducing trismus in the early post-operative phase.

Delayed clinical healing following surgical extraction may significantly affect quality of life and recovery of the patient. Ana Paula et al found ozone as a powerful antimicrobial agent effective against bacteria, viruses, and fungi. It has been clinically

used to treat various post-surgical and chronic wounds, including pressure ulcers, trophic ulcers, ischemic ulcers, diabetic wounds, psoriasis, and athlete's foot. Ozone promotes wound healing by reducing microbial infections, facilitating debridement, modulating inflammation, and stimulating angiogenesis and enzymatic reactions that enhance oxygen metabolism.[11] This improved tissue repair is particularly crucial for patients with conditions like diabetes, where wound healing is often impaired.[49] Wounds treated with ozonated oil exhibit superior angiogenesis, demonstrated by increased vascular endothelial growth factors and cyclin D1 expression, alongside a rapid cellular response that accelerates the overall repair process.[29] The current study of ozone depicted that wound healing outcomes were significantly better in the ozone group compared to the control group. The ozone group exhibited a higher mean healing score, indicating that ozone promotes more rapid and effective tissue repair following tooth extraction.

According to a study by Xiao et al., ozone therapy can help wounds heal faster by reducing their size and promoting fibroblast movement. It also boosts tissue oxygen levels (PO_2), which improves the oxygen flow in the bloodstream thereby, supporting better wound healing.[50] A meta- analysis carried out by Qing Wen et al stated that ozone treatment helped reduce wound size but did not significantly enhance complete healing rates or decrease inpatient care duration in non-healing chronic wounds thereby indicating that ozone's therapeutic value for wound healing remains uncertain and debatable.[51] A research done by Haojie Sun et al stated that despite having ozone's bactericidal and anti-inflammatory effects, in their study by using certain wound healing assessment tools there was no significant effect on wound healing thereby, suggesting results may vary based on assessment techniques.[52]

Intra alveolar use of ozone oil has a superior analgesic effect, with better wound healing and possess better anti-inflammatory properties in the management of post-operative sequelae after transalveolar extractions.

Limitations:

Because of the relatively small sample size, generalizing the results was challenging. More research is needed to determine the effectiveness of ozone to treat trismus and edema, following surgical extraction of tooth.

CONCLUSION

This randomized controlled trial demonstrates that intra-alveolar ozone oil significantly improves the post operative outcomes after transalveolar extractions. The ozone group experienced reduced pain, higher pain satisfaction scores, decreased reliance on analgesics, and enhanced wound healing. While the study showed no significant difference in swelling, interincisal distance improved significantly in the ozone group during the early postoperative period. These findings are consistent with ozone's known anti-inflammatory, antimicrobial and tissue-repairing properties, supporting its use as a valuable adjunct to improve patient comfort and promote faster recovery following complex extractions.

SUMMARY

This randomized controlled trial explored intra-alveolar ozone oil's influence on pain management and the healing of wounds after transalveolar extractions, a procedure commonly linked to postoperative issues such as pain, swelling, and trismus. Fifty patients were randomly assigned to a control group (normal saline irrigation) and a study group (ozonated oil application), with follow ups on days 3 and 7. Results indicated that the ozone group had significantly reduced pain scores and decreased analgesic consumption by day3, although pain scores were equal by day 7. Although differences in swelling were small, the ozone group had improved wound healing and significant improvement in trismus recovery. The research found that ozone oil improves postoperative results by decreasing pain, enhancing healing, and increasing mouth opening, validating its clinical usefulness even with minor effects on swelling.

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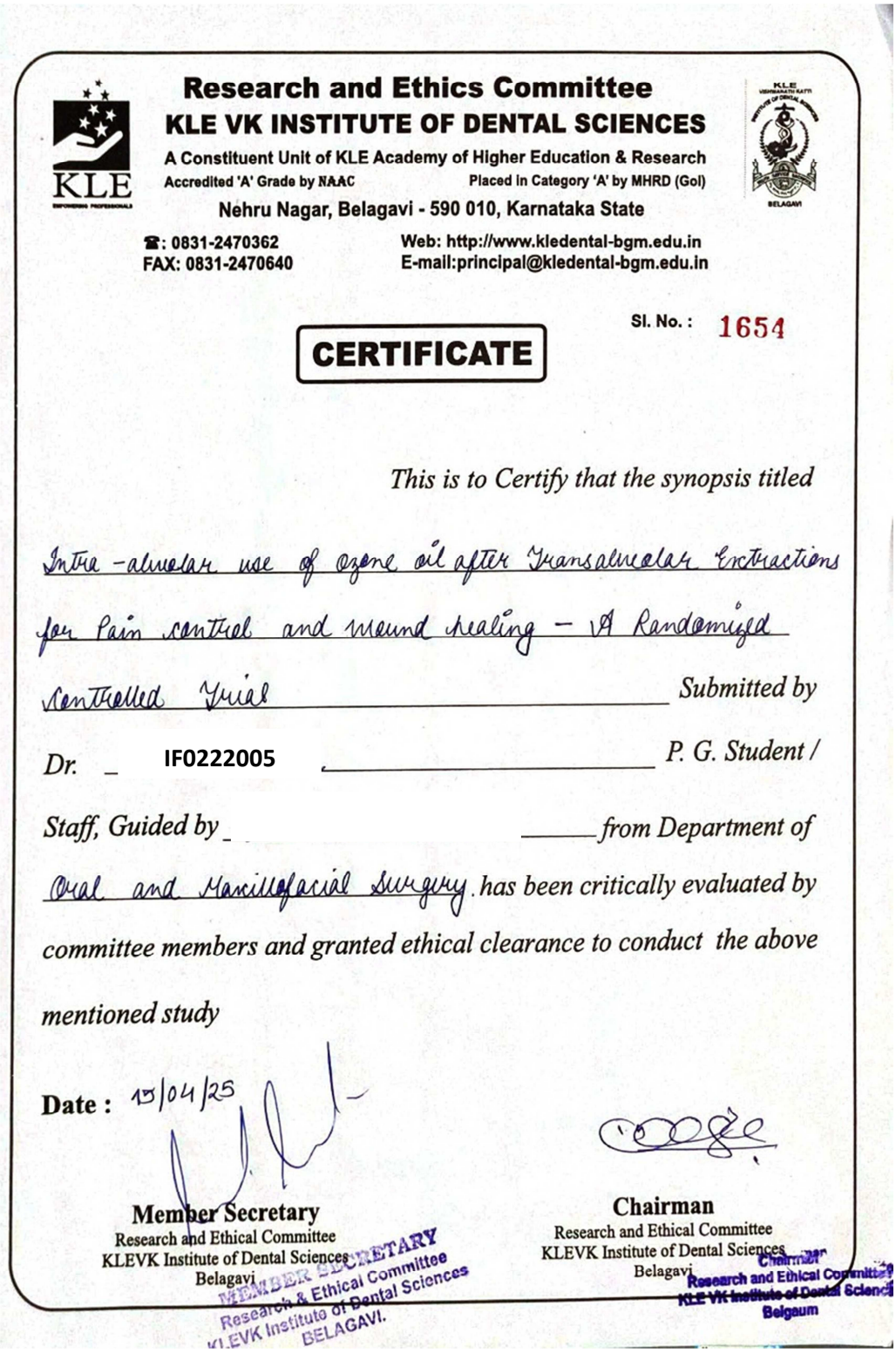
ANNEXURE I: ETHICAL CLEARANCE CERTIFICATE



Research and Ethics Committee
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Sl. No. : 1654

CERTIFICATE

This is to Certify that the synopsis titled

Intra-alveolar use of ozone oil after Transalveolar Extractions for Pain control and wound healing – A Randomized Controlled Trial *Submitted by*

Dr. IF0222005 *P. G. Student /*

Staff, Guided by _____ *from Department of*

Oral and Maxillofacial Surgery *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

Date : 15/04/25

Member Secretary
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

MEMBER SECRETARY
Research & Ethical Committee
KLEVK Institute of Dental Sciences
BELAGAVI.

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee
KLE VK Institute of Dental Sciences
Belgaum

ANNEXURE II: PATIENT CONSENT FORM

K.L.E.'s V.K. Institute of Dental Sciences

Department of Oral and Maxillofacial Surgery, Belagavi

PATIENT CONSENT FORM

Date: Time: a.m./p.m.

1. I,_____aged__years have been informedabout my involvement in the study.
2. I agree to give my personal details like Name Age, Sex, Address, and any other details required for the study to the best of my knowledge.
3. I will cooperate with the surgeon for examination and also for the investigation.
4. I permit the operator to utilize the information given by me and the results obtained from this study for presentation and publication purpose
5. I permit the surgeon to take my photographs to utilize them for presentation and publication purpose.
6. I am participating in this study with my own wish and will and the surgeon has explained the nature and the effect of procedure in my own vernacular language.
7. The nature and purpose of the procedure and the materials being used, possible alternative methods of treatment, the risk involved and the possibility of complications have been fully explained to me in my own vernacular language. No guarantee or assurance has been given by anyone as to the results that may be obtained.
8. I have been informed about the follow up and I agree to visit for the same.
9. I have read and understood the above information given by surgeon about the study and willingly agree to participate in the study.

Name: Date:

Signature: Mob. No:

Name of doctor: [redacted]

Doctor's contact: [redacted]

ANNEXURE III: PATIENT INFORMATION SHEET

Department of Oral and Maxillofacial SurgeryKLE VK Institute of Dental Sciences, Belagavi

Patient Information Sheet

Title of the study: 'Intra-alveolar use of Ozone oil after Transalveolar Extractions for pain control and wound healing – A Randomized Control Trial'

Aim of the study: To evaluate the efficacy of ozone oil when placed in the extraction socket after a transalveolar extraction

Description of the study: This study includes patients who are indicated for open extraction or any surgical extraction of impacted tooth diagnosed on the basis of clinical and radiographic examination. After extraction the socket will be either irrigated with normal saline or filled with ozonated oil soaked in Abgel and the flaps will be sutured back.

Participation and Termination: Your participation in the study is voluntary. You can refuse to participate or ask your doctor to end your participation before the final closure of the study at any time. Refusal to participate or early termination will not affect your relationship with and or your treatment by the doctor. If you agree to participate, you will be asked to sign the informed consent form. You have the right to ask questions about this study at any time.

Confidentiality: If you agree to participate in this study, your personal data and clinical information will be collected and coded. When the results of this study will be published, your identity will remain confidential.

I,_____, age _____years, have been explained the details of the study in my own vernacular language. I am fully satisfied with the procedure and instructions given by Dr._____and hereby give my consent to participate in this study.

Place:

Date:

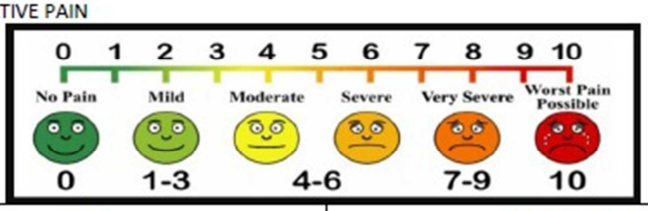
Signature of participant: Contact No : Address:

ANNEXURE IV: PATIENT LOG SHEET

PATIENT ASSESSMENT

NAME :
TOOTH NUMBER :
T/C :
DATE :

1) POSTOPERATIVE PAIN



TIME	PAIN SCORE
4 HOURS	
8 HOURS	
12 HOURS	
24 HOURS	
3rd DAY	
7th DAY	

2) POSTOPERATIVE PAIN SATISFACTION

SCORE	LEVEL OF SATISFACTION
1	Dissatisfied
2	Rather dissatisfied
3	Neither
4	Rather satisfied
5	Satisfied

TIME	LEVEL OF PAIN SATISFACTION
4 HOURS	
8 HOURS	
12 HOURS	
24 HOURS	
3rd DAY	
7th DAY	

3) POSTOPERATIVE SUPPLEMENTAL ANALGESIC TIME AND DOSE

TIME (POST EXTRACTION)	DOSE

TREATING DOCTOR [redacted]
Contact details : [redacted]