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Comparative Evaluation of the Post-operative Complication following Mandibular Third Molar Surgery when using Chlorhexidine vs. Ozonated Water as an Intra-operative Irrigant: A Double-blinded Randomised Controlled Trial

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#### ABSTRACT

**Introduction:** One of the most common dental procedures is the surgical extraction of impacted mandibular third molars. Pain, oedema, trismus, wound infections, and alveolar osteitis are the most common morbidity-inducing complications

**Objective:** To evaluate the incidence of post-operative complications following third molar surgical removal, when using cold saline, ozonated water or chlorhexidine as an intra-operative irrigant.

**Methods:** A total of 132 patients participated in the study. Random allocation was done into one of three groups; saline irrigation, ozonated water irrigation or chlorhexidine solution irrigation. Only mandibular third molars were used in this study

**Results:** Chlorhexidine was found to be the most effective of the three. There were statistically significant effects of chlorhexidine on the incidence of alveolar osteitis and pain.

**Conclusion:** This study provided strong evidence that chlorhexidine is the optimal irrigating solution for intraoperative and postoperative third molar procedures.

Keywords: impaction, Chlorhexidine, Ozonated water, Dental, Quality of life

# INTRODUCTION

Third mandibular molars are the most frequently impacted teeth. Several hypotheses have been proposed, including: a) insufficient retromolar space infection; b) path of eruption; c) malpositioned tooth germ; d) genetic predisposition; e) lack of adequate erupting force; and f) phylogenetic jaw size regression. [1] Typically, third molars erupt between the ages of 18 and 24. Consequently, there are variations in eruptions, and failures in eruptions are extremely common. [2]

One of the most common dental procedures is the surgical extraction of impacted mandibular third molars. Pain, oedema, trismus, wound infections, and alveolar osteitis are the most common morbidity-inducing complications associated with this procedure. Alveolar osteitis has been shown to affect 25-30% of patients undergoing surgical molar extractions. [3] Dry socket (alveolar osteitis) is caused by the disintegration of the blood clot 2 to 4 days after tooth extraction. Dry socket is characterised by defective alveolar bone remnants covered with necrotic, yellowishgrey tissue, halitosis, and severe pain radiating to the ear and neck. Insomnia, dizziness, trismus, and lymphadenitis are additional symptoms that may accompany dry socket. Among the multiple causes of dry socket are trauma, bacteria, vascular defects, toxic end products, and enzymatic and metabolic deficiencies.

During surgical extraction of mandibular molars, irrigating solutions prevent bone damage, irrigate the surgical site, and considerably improve the dentist's vision. Bone cutting without water spray generates a substantial quantity of inflammatory exudates and detritus, thereby increasing postoperative pain. The effectiveness of removing microorganisms varies among various irrigation systems. [4]

CHX is a cationic bis-guanide composed of two symmetric 4-chlorophenyl rings and two biguanide groups connected by a central hexamethylene chain [5]. CHX is a positively charged hydrophobic and lipophilic molecule that interacts with phospholipids and lipopolysaccharides on the bacterial cell membrane [6] before entering the cell via an

active or passive transport mechanism. Its effectiveness is a result of the interaction between the positive charge of the molecule and the negatively charged phosphate groups on the microbial cell walls [7], which alters the osmotic equilibrium of the cells. This increases the cell wall's permeability, allowing the CHX molecule to enter the bacterium. CHX is both a base and a stable salt. Chlorhexidine gluconate, the most common oral preparation, is water-soluble and readily dissociates and releases the positively charged CHX component [8] at physiological pH. At low concentration (0.2%), substances with low molecular weight, namely potassium and phosphorus, will seep out. However, at higher concentrations (2%), CHX is bactericidal; cytoplasmic contents precipitate, resulting in cell mortality [9].

Normal saline is an isotonic fluid with identical physiological characteristics. It is frequently used to irrigate the third molar during surgical procedures. It has no antibacterial properties. [6] Normal Saline irrigation is routinely used in mandibular third molar surgeries: a) during osteotomy (buccal trough or crown/root sectioning) to reduce the heat generated by the surgical drill while in contact with bone, and b) at the conclusion of extraction to remove bone detritus from the socket after osteotomy.

Ozone gas has potent antimicrobial properties. It can be used in medicine and dentistry as a disinfectant. Initial fissural caries can be effectively treated with protocols that combine ozone and a remineralising solution, or with either component alone. Gas, water, and oil are the three forms of ozone that can be used for treatment purposes. Utilising oxygen metabolism and stimulating the humoral system, this compound has multiple antibacterial, antiinflammatory, and immuno-stimulatory effects. Its antimicrobial activity results from its ability to generate oxidised free radicals and destroy microorganisms. In addition to degrading bacterial cell membranes and cell walls, it inhibits enzyme. This increases the an permeability of cell membranes, resulting in the immediate cessation of cell functions and, ultimately, the demise of the microorganism.

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Ozonated water has antibacterial, antifungal, and antiviral properties. It is less cytotoxic than 0.2% and 2% chlorhexidine, 2.5% and 5.25% sodium hypochlorite, and hydrogen peroxide. Staphylococcus aureus, Enterococcus faecalis, and Pseudomonas aeruginosa are effectively eliminated by ozonated water, according to in vitro tests. [7,8]

The aim of this study is to evaluate the incidence of post-operative complications following third molar surgical removal, when using using cold saline, ozonated water or chlorhexidine as an intra-operative irrigant.

# MATERIALS AND METHODS

# Study Design

This study was conducted in accordance with CONSORT 2010 guidelines as a prospective, single-centre, randomised three-arm parallel trial with a 1:1:1 allocation ratio. There were no changes to this approach after study commencement. The study was approved by the Institutional Ethical Committee. All patients were informed of their treatment options and signed a consent agreement before enrolment.in accordance with the Declaration of Helsinki on Medical Protocols and Ethics.

Group I - Normal saline Group II - Ozonated Water Group III - 0.2% Chlorhexidine

# **Participants**

This RCT was performed at Saveetha Dental College and Hospitals, Saveetha Institute of Medical and Technical Science, Saveetha University between November 2021 and November 2022. Patients were selected using the following criteria: (1) the absence of any systemic disorders, (2) the absence of antibiotic/antimicrobial or anti-inflammatory drug use 1 week prior to surgery, (3) mesioangular impaction, and (4) the absence of smoking. Patients were excluded on the following basis: (1) a history of radiation therapy; (2) organ transplantation; (3) known allergy to lignocaine or other anaesthetic agents; (4) systemic disease; 5) pregnancy or lactation in female subjects

# Sample Size Calculation

The power calculation was carried out using G power version 3.1.5. A pilot study was done using sample size 20 in each group. Based on the results derived (mean  $\pm$  SD), an effect size of f = 0.73 is determined. A study with 95% power will require a total sample of 108 patients. Considering a possible drop out of 20%, the final sample size was derived as 132 patients with 44 in each group.

# Randomisation, Allocation Concealment and Blinding

For randomisation and allocation concealment, SNOSE method was used (Sequentially Numbered, Opaque, Sealed Envelope). A piece of paper containing randomised group name was sealed, by a third person who was not involved in the study, in a dark coloured envelope containing respective alphabets allotted to each group. The participants were allotted a study number as they sequentially entered the study. Based on the groups assigned in the allocation, respective intervention was carried out.

Each surgical procedure was carried out by a dedicated team consisting of an experienced Oral and Maxillofacial surgeon with one assistant. The operator was made aware of the allocation for each patient; however, patient and outcome analysts were blinded. Written consent was obtained from all patients, with the option of discontinuation of participance in accordance with the Declaration of Helsinki.

# Surgical Procedure

Single tooth third molar removal was performed under local anaesthesia. 2% lignocaine hydrochloride with 1:80,000 adrenaline. Modified Ward's incision was given for all patients. Bone guttering was done with 702 carbide bur. 3-0 silk was used for closure.

One-way ANOVA test was conducted for the obtained result using IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, NY, USA). P value of 0.05 was deemed statistically significant. The severity of alveolar osteitis was assessed on day seven

# RESULTS

Outcome	Group I	Group II	Group III	Р
Dry Socket	6	26	13	< 0.05
Pain				
24h	47	36	25	< 0.05
7th day	14	8	3	< 0.05
Trismus (mm)	30	28	32	>0.05
Infection	7	8	6	>0.05

TABLE 1: Obtained Values from Measured Outcomes

The greatest number of cases (n = 26) of alveolar osteitis were observed in Group II (third molar operations using ozonated water irrigating solution) compared to Group I (utilising normal saline) [Graph 1]. Comparing the results of three study groups revealed a highly significant difference (P 0.01). Again, a highly significant difference (P 0.01) was observed when comparing three groups for pain assessment after 24 h and 7 days.

No significant difference in the amount of trismus or infection rate.

#### DISCUSSION

Goldberg et al. examined 302 participants who had impacted mandibular third molars extracted surgically. 4.2% of patients developed a postoperative infection, while 1% of patients developed alveolar osteitis. Food entrapment beneath elevated openings is the cause of delayed infection. The incidence of alveolar osteitis has been reported to range between 1% and 30%, with elderly individuals and women taking progestational contraceptives being the most susceptible. [9]

Standard parameters for surgical extraction of the third molar include flap design, amount of bone removed, type of irrigant, duration of surgery, and suturing techniques. [10,11] The primary purpose of irrigation is to remove organic and inorganic detritus. [12] During third molar interventions, numerous irrigating solutions have been used. Normal saline, Ringer's lactate, ozonated water, 1% povidone-iodine, ozone, etc., are examples. Utilising irrigating solutions is essential for preventing irreversible bone necrosis caused by heat production. Normal saline does not contribute directly to postoperative healing; however, its purifying activity aids in wound healing. The use of ozonated water for irrigation has a significant effect on bone metabolism in addition to reducing the extent of the microbial population. It increases TGF-1 production, which facilitates wound healing. Ozone is composed of three oxygen atoms, and its action mechanism is based on its oxidising effect on bacterial cells. [13]

Infections with delayed onset following mandibular third molar extractions are a rare complication characterised by swelling and pus secretion from the extraction site. This complication occurs approximately one month after surgical excision. Its incidence has been estimated between 0.3% and 1.8%. Protocols for treatment include antibiotic therapy, which, if ineffective, should be followed by surgical debridement. In these delayed infections, Peptostreptococcus, Prevotella, Bacteroides, and Fusobacterium have been identified. Soft tissue absence of distal space, coverage, and mesioangular inclination have been observed. Among the mechanical factors are the duration of the procedure and the patient's age.

Cherian et al. (2019) found that subjects who received intraoperative dexamethasone 8 mg experienced significantly less or no postoperative oedema than those who did not receive any. [15]

In their systematic review, Cho et al. (2017) demonstrated that combined administration of opioid analgesics and non-steroidal anti-

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inflammatory agents resulted in superior analgesia compared to other drug combinations; adverse effects should be considered when prescribing these agents. Opioid analgesia may cause constipation, nausea, and drug abuse, whereas nonsteroidal anti-inflammatory medications prescribed must be with consideration for gastrointestinal, haematological, and renal disorders, as well as drug interactions and toxic effects. Corticosteroids have also been reported to reduce postoperative oedema and trismus following surgery on the third molar. It has been demonstrated that perioperative antibiotic prophylaxis reduces infection and alveolar osteitis by 70% and 38%, respectively. In surgeries that utilise irrigation, the incidence of alveolar osteitis has been found to decrease significantly.[16]

In their study, Gloria et al. (2020) found that the use of ozonized water did not result in any postoperative infections. The effectiveness of ozonized water depends on the solution's pH, total contact duration, and temperature. Postoperative trismus manifests significantly within 24 hours and persists one week after the procedure. Trismus is brought on by muscle injury, oedema, multiple needle penetrations, flap manipulation, and the presence of anaesthetic or thrombus within muscle fibres. [7]

Gharminia et al. (2017) analysed 280 participants who had undertaken third molar extractions in their study. They discovered that using public water after extraction of the third molar effectively reduces inflammation. [8]

Other common irrigating solutions include 3% hydrogen peroxide and 0.12% chlorhexidine. Chlorhexidine gluconate is a broad-spectrum antibiotic that has a distinct advantage over other antibiotics because it is less likely to produce resistant organisms. [17]

The placement of sutures for secondary closure resulted in greater oedema than in non-sutured areas. Thus, suture placement is also a factor in the development of oedema following the extraction of the third molar. [18]

Jadhao et al. conducted a study to evaluate the efficacy of three distinct irrigants on a variety of

postoperative symptoms following surgical extraction of the impacted mandibular third molar. In the study, 48 individuals were divided into three groups: group I, where normal saline was used as the irrigant; group II, where chlorhexidine was used; and group III, where povidone-iodine was used. It was determined that pain was substantially greater in groups I and III after 24 hours and on the seventh day. Alveolar osteomyelitis was only observed in groups III and I. In 24 hours, the facial oedema was greater in groups I and III than in group II. The seventh day revealed significant results for trismus in Groups I and III. [3]

In 1840, Christian Friedrich Schönbein was the first to describe ozone. Gingivitis and periodontitis, oral lichen planus, halitosis, post-surgical pain, osteonecrosis, dentinal hypersensitivity, wound healing, temporomandibular disorders, teeth and whitening are successfully treated with ozone therapy. In medicine, ozone is produced by passing purified oxygen through a high-voltage gradient ranging from 5 mV to 13 mV. The composition of a gaseous mixture was 95% oxygen and 5% ozone. This mixture is extremely unstable, with a half-life of roughly 40 minutes at 20 °C. Therefore, the generator must be able to precisely calculate the ozone concentrations within this mélange. Ozone can be administered through petrol, lubricant, or water. However, intravenous injections may cause embolisms. [19]

In its gaseous or aqueous state, ozone possesses potent oxidising and bactericidal properties. Due to its oxidation potential, ozonated water used as an irrigator destroys the cell walls and cytoplasmic membranes of bacteria and fungi. Once the cell membranes have been compromised, ozone molecules can readily enter the cells, resulting in the death of the microorganism. When used as an irrigant in third molar surgeries, it generates fewer postoperative symptoms. [20]

Following surgical extraction of third molars, ozone has a higher potential for reducing the danger of dry socket and promoting faster healing. [21]

In their 2016 study on the efficacy of ozone gas in preventing dry socket, Ahmedi et al. found a reduction of 3.3% compared to 16.67% in the control group (P = 0.20). Therefore, these researchers promoted the use of ozone in dry socket risk prevention. Ozone reduces inflammation and pain by stimulating angiogenesis, the synthesis of leukotrienes, prostaglandins, and interleukins, respectively. [22]

The half-life of ozonated olive oil is longer than that of its aqueous preparation. Dry socket symptoms include moderate erythema and oedema, exposure of the underlying bone, halitosis, and tenderness, and they appear two to three days after tooth extraction. [23]

The ozone-based procedure is a) basic, b) well tolerated by patients, c) free of adverse or side effects, and d) highly effective. Ozone's antimicrobial properties against gram-positive and -negative bacteria, viruses, and fungi underpin its use in dentistry. Daily application of ozonized water may hasten epithelial healing, particularly in the first two days after surgery. It is less cytotoxic than ozone gas by itself. [7] The effectiveness of ozonized water is contingent on a number of variables, including contact time, local pH, and temperature. It functions by gradually oxidising cellular components.

In their prospective double-blind study, Shah et al. (2014) compared the effectiveness 0.02% chlorhexidine for the control of pain and oedema following extraction of the mandibular third molar. In this study, 0.02% chlorhexidine was shown to be more effective at managing pain and swelling following surgical excision. Chlorhexidine is a cationic antiseptic with a twelve-hour bacteriostatic mechanism of action. [24]

Anisuzzaman et al. (2013) evaluated postoperative pain and oedema following irrigation with normal saline and distilled water in a prospective study involving 100 participants who had their impacted third molars extracted. Normal saline has been shown to be more effective than distilled water in the management of postoperative pain and oedema. [25] In contrast, a split-mouth study conducted by Tolstunov (2012) to evaluate the effects of irrigation versus no irrigation during mandibular third molar extraction revealed that the absence of irrigation resulted in a higher quality clot, which led to a more rapid recovery of the socket. It has been hypothesised that continuous irrigation with normal saline disrupts the coagulation cascade, causing surgical extraction wounds to recover more slowly. [26-29]

In their study of 12 participants comparing primary and secondary closure techniques after removal of an impacted third molar, Chaudhary et al. (2012) found that secondary closure promoted speedier postoperative healing. [30]

Khiavi et al. (2010) discovered that irrigating an extraction socket after surgery on the third molar with 0.5% bupivacaine hydrochloride provides highly effective postoperative pain alleviation. [2]

The current study demonstrated that the use of ozonated water had statistically significant effects on the incidence of alveolar osteitis and discomfort after mandibular third molar surgery.

# Relevance to clinical practice

The surgical extraction of the third mandibular molar is a common procedure in dental practice. Pain, the degree of trismus, the incidence of dry socket or alveolar osteitis, and infection are a few of the variables that affect the overall prognosis of these subjects. The use of different irrigation solutions has had a significant impact on the clinical prognosis of these surgical procedures.

In dentistry, the use of ozonated water as an irrigant during surgical procedures has proven to be an asset. In the field of restorative dentistry, ozone therapy has a well-documented effect, but there is insufficient evidence regarding the effects of ozonated water and its comparative efficacy with other irrigant solutions in oral surgical procedures. More clinical studies with standardised trials are required to increase our understanding of the use of ozonated water in oral surgery. [31-33]

#### CONCLUSION

Following extraction of the mandibular third molar, the present study compared three irrigating solutions, ozonated water, normal saline, and chlorhexidine. Chlorhexidine was found to be the most effective of the three. There were statistically significant effects of chlorhexidine on the incidence of alveolar osteitis and pain. This study provided strong evidence that chlorhexidine is the optimal irrigating solution for intraoperative and postoperative third molar procedures.

Footnotes

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# **CONFLICT OF INTEREST**

No potential conflict of interest relevant to this article was reported.

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