"EFFICACY OF TOPICAL OZONE GEL IN IMPROVING POST-OPERATIVE PATIENT COMFORT AFTER SURGICAL REMOVAL OF IMPACTED MANDIBULAR THIRD MOLAR - A RANDOMIZED CONTROLLED TRIAL"

By

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Dissertation

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In partial fulfillment
of the requirements for the degree of

MASTER OF DENTAL SURGERY
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ORAL AND MAXILLOFACIAL SURGERY
(BRANCH III)

Under the guidance of

Dr. ARATI NEELI$_{\text{M.D.S}}$

Reader

DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY

KAHER'S KLE VK INSTITUTE OF DENTAL SCIENCES

BELAGAVI, KARNATAKA

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I, **Manavadaria Yash Chandrakant**hereby declare that the information and the data mentioned in my thesis entitled **"EFFICACY OF TOPICAL OZONE GEL IN IMPROVING POST-OPERATIVE PATIENT COMFORT AFTER SURGICAL REMOVAL OF IMPACTED MANDIBULAR THIRD MOLAR - A RANDOMIZED CONTROLLED TRIAL"**belongs to me and is original.

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I dedicate my work to

My Family

Dr. Chandrakant Manavadaria,

Mrs. Krishna Manavadaria

&

Dr. Pooja Manavadaria

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Date:

Place: Belagavi ***Dr. Manavadaria Yash Chandrakant***

LIST OF ABBREVIATIONS

Pre-op	:	Pre-operative
Post-op	:	Post-operative
POD	:	Post-operative day
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

ABSTRACT

Background and Objectives: One of the routine minor procedures carried out by Oral and Maxillofacial Surgeons in an outpatient setting is surgical removal of impacted mandibular third molars. The operation is usually followed by post-operative pain, swelling, and a limited mouth opening. This study was designed to determine the efficacy of ozone gel on post-operative pain, swelling, degree of mouth opening and wound healing following lower third molar surgery.

Materials and Method: The present study was a prospective, single blind, randomized controlled clinical trial on 70 patients who reported to the Department of Oral and Maxillofacial Surgery, KLE VK Institute of Dental Sciences, K.A.H.E.R, Belagavi, who met the inclusion criteria and gave consent to participate in the study. The patients were divided into two groups of 35 each by simple randomization (computer generated random allocation method). Study patients underwent ozone gel therapy, packing the socket and also a daub over the sutured wound with the help of a cotton bud twice a day for 3 days. The Control group patients did not receive ozone gel after surgical removal of impacted mandibular third molar. Patients were recalled for evaluation of pain, swelling, trismus and wound healing on post-operative day 1, day 3 and day 7. Statistical analysis was done using the independent t test, Mann-Whitney U test and Wilcoxon matched pairs test.

Results: Patients in study group (ozone gel group) had less pain post-operatively as compared to those in control group. The p-value of 0.0001 indicated that the difference was statistically significant. There was no statistically significant difference between the study group and control group with regard to swelling and trismus. Wound healing was found to be better in study group as compared to control group on

post-operative day 1 and day 7 and the difference was statistically significant. The mean wound healing score was also higher in study group (ozone gel group) on day 3 but the difference was statistically non-significant.

Conclusion: Ozone gel can be used to alleviate post-operative pain thereby reducing the consumption of analgesics and to further enhance wound healing after surgical removal of lower third molar. Ozone gel does not show any effect on post-operative swelling and trismus after lower third molar surgery.

Keywords: impacted third molar, ozone gel, pain, swelling, trismus, wound healing

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INTRODUCTION

One of the routine minor procedures carried out by Oral and Maxillofacial Surgeons in an outpatient setting is surgical removal of impacted mandibular third molars[1]. This operation is usually followed by post-operative pain, swelling, and a limited opening of mouth due to muscle spasm[2].

Efforts have been made to counteract these complications and to achieve a smooth recovery post-operatively using systemic medication like antibiotics, corticosteroids and NSAIDS or topical therapy including chlorhexidine or saline gelatin sponge, cryotherapy etc[3]. Any of these, however, can exhibit side effects such as a predilection to systemic bleeding, gastrointestinal irritation, allergic or other local adverse reactions[4]. One recent modality to promote post-surgical would healing is the use of ozone[3]. It contains three oxygen atoms with a molecular weight of 47.98 g/mol[5]. Ozone, a highly unstable compound thermodynamically is among the strongest oxidants available[6]. The prudent use of ozone eliminates the pathogens to start with and then triggers the fibroblasts to proliferate by releasing oxygen, thus the formation of intercellular matrix with subsequent proliferation of keratinoblasts and successive healing[7]. Kan, et al. have proved the incredible healing effects of ozone on soft tissue and bone[8].

Ozone inhalation can cause noxious side effects such as upper respiratory irritation, vomiting, head ache and even stroke[9]. Thus, for medical applications, it is recommended to use a mix of ozone and oxygen or ozone incorporated in purified, demineralized water[6]. This formulation is highly tissue-friendly and to add to its benefits, it also has the capability to enhance blood circulation[6].

Medical grade ozone is available in various forms such as gas, gel and water which can be administered by parenteral and topical routes to tissues[3]. Ozone in gel form has higher concentration of ozone molecules, long-lasting stability and the fact that it is easy to apply makes it the ideal choice over its other forms[3]. The gel contains ozone as ozonides which on contact with wound surface at body temperature, releases active ozone in a prolonged manner[10].

Ozone is not used much in Oral and Maxillofacial Surgery and there are only a few studies on use of ozone after removal of impacted lower third molar.

The purpose of this clinical study was to determine the efficacy of ozone gel on post-operative pain, swelling, degree of mouth opening and wound healing following lower third molar surgery.

AIM AND OBJECTIVES OF THE STUDY

AIM

The aim of the study was to assess the efficacy of topical ozone gel following the surgical removal of impacted mandibular third molars.

OBJECTIVES

After removal of impacted mandibular third molar surgically;

- To assess the efficacy of ozone gel on post-operative pain.
- To assess the efficacy of ozone gel on post-operative swelling.
- To assess the efficacy of ozone gel on post-operative trismus.
- To assess the efficacy of ozone gel on wound healing.

NULL HYPOTHESIS

There is no difference in post-operative pain, swelling, trismus and wound healing when ozone gel is applied in and over the sutured wound.

ALTERNATIVE HYPOTHESIS

There is a significant difference in post-operative pain, swelling, trismus and wound healing when ozone gel is applied in and over the sutured wound.

REVIEW OF LITERATURE

C. McGrath et al. (2003) evaluated 100 patients' opinions regarding the changes in quality of life with respect to oral health over a period of six months after impacted mandibular third molar surgery[24]. The authors concluded that the oral health related quality of life worsens in the immediate post-operative span; especially during the first five days.

VelioBocci (2004) conducted a review in which he implied that ozone therapy if performed by expert physicians can be useful when medicine appears inadequate[25]. Clinical data in the literature have not reported any evidence of cellular damage or adverse effects in patients. Literature also found stunning results with the use of ozone in various medical conditions such as chronic infectious diseases, vasculopathies, orthopedics and even dentistry.

Huth KC et al. (2006) conducted an in vitro study on oral epithelial cells and gingival fibroblasts from humans in which they probed whether the use of gaseous or aqueous ozone have any cytotoxic effects and also compared it with proven antiseptics and antibiotics[10]. The authors concluded that the aqueous form of ozone have less cytotoxicity as compared to gaseous ozone or established antimicrobials under most circumstances proving itself biocompatible for use in oral tissues.

Lucia Lago-Mendez et al. (2007) studied the association between surgical difficulty of impacted lower third molar and post-operative pain in 157 third molar surgery[21]. Procedures were classified into four classes: Simple extraction, extractions requiring bone removal, extractions in which crown sectioning is necessary, extractions in which root sectioning is called for. The results revealed strong

association between surgical difficulty and post-operative pain. The authors concluded that post-operative pain after impacted lower third molar surgery is directly proportional to the surgical difficulty and the time taken for surgery.

Seidler V. et al. (2008) conducted a review of literature on utility of ozone in the cure of various diseases[5]. They highlighted the antimicrobial, antihypoxic, analgesic, immuno-stimulating properties of ozone all of which can be useful in dentistry. The authors also concluded that ozone therapy speeds up the epithelial wound healing in oral tissues.

Thiago de Santana-Santos et al. (2011) evaluated the relation between pre-operative variables and post-operative parameters (pain, swelling and trismus) following 160 lower third molar surgery[22]. Results showed that pain, swelling and trismus differed with gender and the time taken for surgery. It was found that tooth sectioning also had an impact on trismus. The authors concluded that the degree of post-operative symptoms after lower third molar surgery depends on patient attributes (age, gender and body mass index) as well as surgery parameters like duration of surgery and tooth sectioning.

P.V. Patel et al. (2011) assessed the outcome of topical ozonated oil when applied on palatal wounds of 18 randomly selected patients that originated from free gingival graft harvesting surgery[26]. The patients were split equally into study group and control group. 2 ml of ozonated oil was applied on the palatal wound in study group patients whereas regular oil was used in the control group for 1 week. Fairly noticeable improvement was seen in the wound size of the study group. Also, a considerable increase in the rate of epithelial healing was noticed in the study group

patients. The authors concluded that ozonated oil when applied topically enhances the healing of palatal wounds.

H.O Kazancioglu, E. Kurklu and S. Ezirganli (2013) conducted a split-mouth study on 60 patients where they determined the effectiveness of the use of therapeutic ozone to reduce pain, swelling and trismus after surgical removal of impacted mandibular third molar[2]. The results revealed no difference in the two groups with regard to swelling and mouth opening. On the contrary, statistically significant difference in pain scores was noticed on evaluation days. The authors within the limitation of the study i.e. a rather small sample size concluded that ozone therapy significantly reduces pain after surgical removal of impacted lower third molar.

Reddy S A et al. (2013) conducted a review of literature available on ozone therapy in endodontics[19]. The literature review implied that ozone therapy is a painless modality that can be considered as alternative to conventional treatment for tooth decay and is proved to stop primary root caries and pit and fissure decay which also has a capability to reverse the lesion. It has strong antimicrobial effect on endodontic flora.

Punit Vaibhav Patel and Sheela Kumar Gujjar (2013) reported two cases of exophytic fibrous gingival lesion in which they used ozonated oil to treat the lesion. 2 ml of ozonated oil was applied thrice daily for 7 days[20]. After the ozonated oil application, the patient encountered less pain. Clinically, it was observed that inflammation and surface ulceration was reduced. It was also found that there was reduction in size of the lesion. Less bleeding was noticed while excising the lesion.

F. Erdemci et al. (2014) conducted a study on 112 male Wistar rats to assess the systemic and topical effects of ozone on alveolar bone healing after extraction of teeth[27]. The rats were split equally into 8 groups each consisting of 14 rats. Out of the 8 groups, 7 groups were experimental and 1 group was kept as control. After extraction of maxillary right central incisors and subsequent sacrifice of the rodent, the histological sections were taken which showed significantly more trabecular bone in the rats who were treated with systemic ozone as compared to those treated with topical ozone therapy. The authors within the limitations of the study concluded after the study that systemic ozone application for a long-term following tooth extraction speeds up the alveolar bone healing.

Manish K, Abhishek H, Ravi G and Deepak M. (2015) did a literature review to provide an outline on different applications of ozone in dentistry[16]. Ozone showed biocompatibility and is used in all aspects of dentistry due to its various capabilities such as tooth remineralization, tissue regeneration, enhanced healing, antimicrobial action and disinfectant property.

Varun Prasad S, Elavenil P, Krishnakumar Raja V and Gayathri G (2016) carried out a clinical trial using a split-mouth study design on 33 patients where they evaluated the efficacy of topical ozone gel application after impacted lower third molar surgery in improving post-operative patient comfort[3]. The authors concluded that topical application of ozone gel after lower third molar surgery significantly reduces swelling, trismus and pain which indirectly reduces the consumption of analgesic tablets.

Mohamed M. Shokry and Alshaimaa A. Shabaan (2016) performed a split-mouth study on 60 patients to assess the outcomes of applying xenograft mixed with ozonated gel into the socket after impacted lower third molar surgery[17]. The third molar of the study side was extracted and ozone gel mixed with xenograft was applied in the socket; whereas 2 weeks later on the control side, only xenograft was placed in the socket after extraction. The authors within the limitations of the study concluded that mixture of xenograft material with ozonated oil reduces post-operative swelling, trismus, pain and also offers better wound healing.

Elitsa G. Deliverska and Milena Petkova (2016) published a literature review in which they reviewed the complications associated with impacted third molar extraction and provided an overview of their prevention and management[12]. The most common complications associated with third molar surgery were bleeding, pain, edema, alveolar osteitis, lingual nerve paresthesia or paresthesia of the inferior alveolar nerve and infection ofcourse. The authors emphasized on the need for knowledge on prevention and management of the complications associated with removal of impacted mandibular third molars.

H Cho, AJ Lynham and E Hsu (2017) conducted a review to present the post-operative strategy to mitigate the complications following surgical removal of impacted mandibular third molars[28]. Various modalities to alleviate post-operative symptoms after lower third molar surgery were found in the literature one of which was ozone therapy. After thorough review, the authors concluded that literature does show support towards the use of topical ozone gel over the extraction site to reduce pain, swelling and trismus.

Sherif S. Alkholy et al. (2019) conducted a study on 30 patients in which they evaluated the effect of ozone gel by topical application after surgical extraction of mandibular impacted third molar[1]. The authors concluded that although ozone gel does not help to reduce postoperative swelling and trismus, it can be used to alleviate pain after lower third molar surgery thereby decreasing the use of analgesics. The authors also came to the conclusion that prophylactic antibiotics did not have any effect on inflammatory complications after third molar surgery.

MATERIAL AND METHODS

The study was conducted in the Department of Oral and Maxillofacial Surgery, KLE VK Institute of Dental Sciences, K.A.H.E.R, Belagavi, Karnataka.

Material

Ozone Gel ($PurO_3^{TM}$).

Study design

Prospective, Single Blind, Randomized Controlled Trial.

Duration of study

September 2018 - August 2020.

Sample size

70subjects, who fulfilled the eligibility criteria and gave consent to participate.

Inclusion criteria

- Patients falling in the age bracket of 18 - 40 years.
- Patients who neededsurgery to remove impacted mandibular third molar for either prophylactic or therapeutic reasons and were willing for the same.
- Patients with moderate surgical difficulty score on Pederson's index (4-6).
- Patients under ASA status I category with bleeding & clotting times within normal limits.

Exclusion criteria

- Medically impaired patients.
- Patients reluctant to take part in the study.
- Patients who had known history of allergy to the drugs or anesthetics used in the procedure.
- Pregnant andbreastfeeding women.
- Patients who had undergone antibiotic or other medication therapy in the preceding 2 weeks.
- Smokers.

Methodology

- Computer generated random allocation of 70 patients with mandibular impacted third molar diagnosed by established clinical and radiographic parameters and who met the inclusion criteria was done into two groups of 35each, study group and control group.
- Post-extraction;

  Study group: Patients underwent ozone gel therapy, packing the socket and also a daub over the sutured wound with the help of a cotton bud twice a day for 3 days. Patients were explained and trained to maintain asepsis during application.

  Control group: Patients did not receive ozone gel.
- Multiple sterile syringes were loaded from the ozone gel container at a time and ETO packed to keep the material sterile for future use.

Pre-operative assessment

Hb

BT

CT

RBS

OPG or IOPA

Surgical Armamentarium

- Surgical gloves
- Mouth mirror
- Dental explorer
- Tweezer
- 2 ml Disposable Syringe
- Surgical scalpel blade no. 15
- Periosteal elevator
- Straight elevator
- Artery forceps
- Curette
- Bone file
- Needle holder
- Adson's tissue forceps
- Scissors
- Surgical handpiece and bur
- Kidney tray
- Irrigation syringe 20 ml
- Surgical drape
- Towel clip
- Suction tip
- Langenbeck retractor
- Sponge holder
- Gauze piece

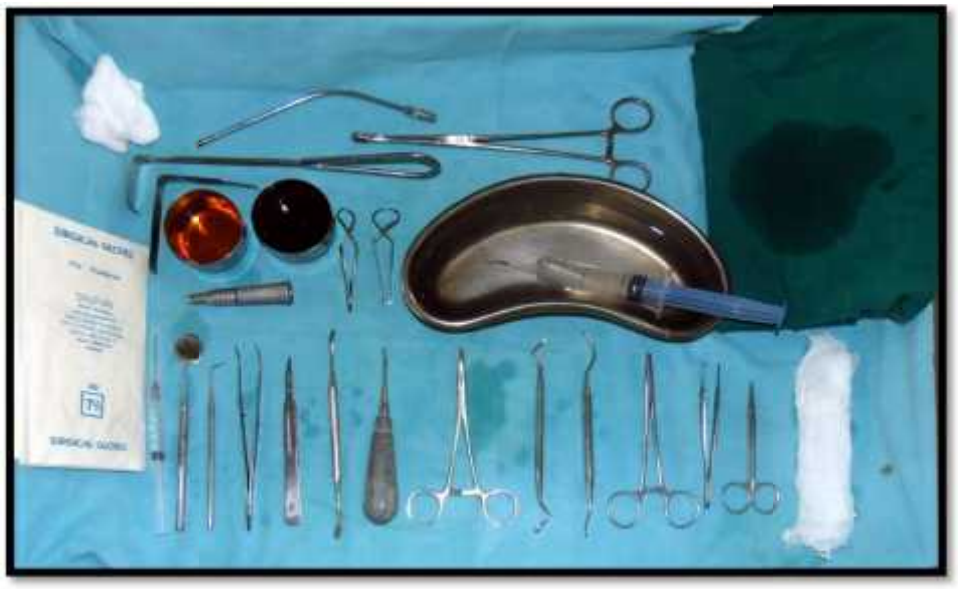


Figure 1:Armamentarium

Surgical Protocol

- Patients underwent surgical procedure in oral surgery unit by the same experienced surgeon.
- Patients of both the groups were given one prophylactic dose of antibiotic (Tab.Amoxicillin 500 mg plus clavulanic acid 125mg) one hour before the procedure.
- The pre-operative mouth opening and mean facial swelling were noted in millimeters.
- Inferior alveolar nerve, lingual nerve and long buccal nerve blocks were achieved using 2% lignocaine hydrochloride plus 1:80,000adrenaline.
- A full thickness trapezoidal flap was constructed.
- Necessarybone was cut off using a stainless-steelbur under ample irrigation with normal saline.
- After tooth removal, infected granulation tissue was removed by curettage.

- The sharp bone margins were trimmedoff and the socket was washed with normal saline.
- Extraction socket of the patients in study group were filled with ozone gel using a sterile syringe.
- The flap was placed back in position and closed with 3-0 silk sutures.
- Patients were given routine post-op instructions.
- Patients in study group were provided with Ozone gel loaded in a sterile syringe to apply as a daub over the sutured wound with the help of a cotton bud twice a day for 3 dayswith aseptic precautions.
- All patients were prescribed Tab. Ibuprofen plus Paracetamol-SOS and were instructed to keep note of number of tablets taken.
- Patients were recalled for evaluation on post-operative day 1, day 3 and day 7.
- Sutures were removed on7^{th} day.

Figure 2: Picture showing the ozone gel which was provided to the patients in study group for local application.

Evaluation criteria

- A STANDARD NUMERICAL SCALE (VAS) with a score of 0 -10 was handed to the patients. Patients were asked to select the score that best expresses the intensity of pain on the evaluation days.
- Mouth opening and swelling werenoted on the follow up days.

  The inter-incisal distance was measured in millimeters with a flexible measuring tape or a caliperpre-operatively and on post-operatively onday 1, day 3 and day 7. The pre-operative score was taken as baseline.The difference in the scores on post-operative days and baseline was calculated at noted as mouth opening score on that day.

  Swelling wasrecorded with a flexible measuring tape pre-operatively and post-operatively on 1^{st}, 3^{rd} and 7^{th} dayby means of validated landmarks:

  Distance from tragus to corner of the mouth.

  Distance from lateral canthus of the eye to angle of mandible.

  Distance from tragus to soft tissue pogonion.

  Any additional facial swelling if present, was noted.

  Mean value of the pre-operative measurements wastaken as baseline. The difference between the mean scores on post-operative days and baseline was calculated at noted as swelling score on that day.
- Wound healing was assessedon follow up days using the Landry et al. Index.
- All patients who required analgesics on post-operative days were permitted and duly noted.

Figure 3: Pre-operative photos

Figure 3a:Straight Profile photo

Figure3b: Lateral profile photo

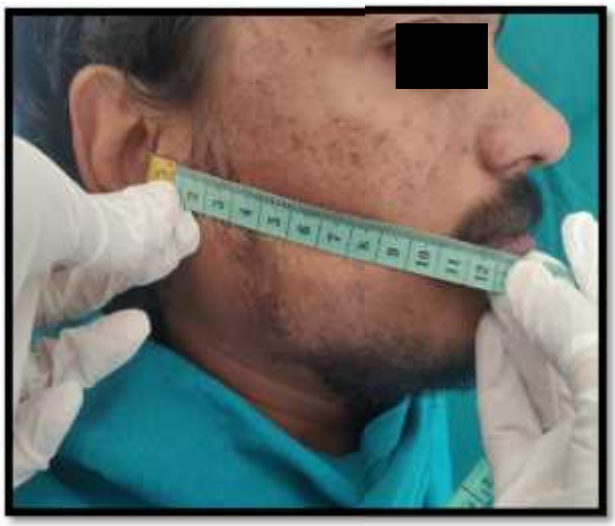


Figure 3c: Measurement from tragus to corner of mouth.

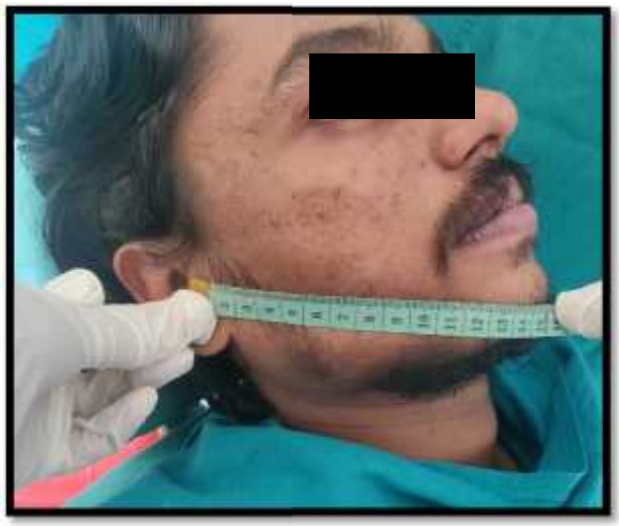


Figure 3d: Measurement from tragus to soft tissue pogonion.

Figure 3e: Measurement from lateral canthus to angle of mandible.

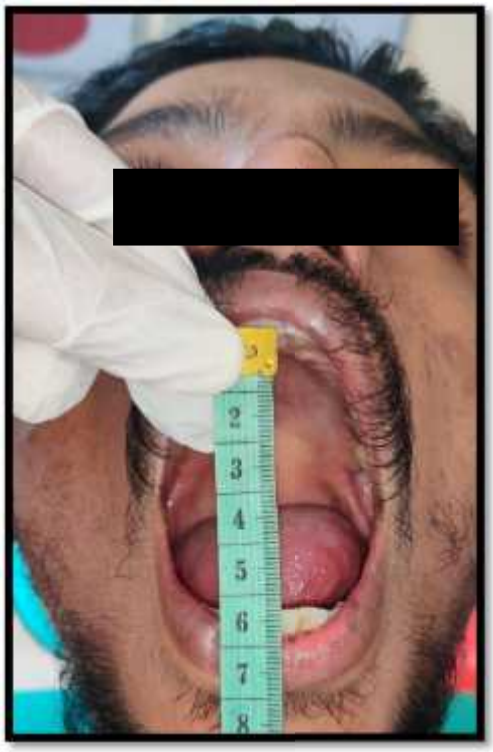


Figure 3f: Measurement of inter-incisal distance.

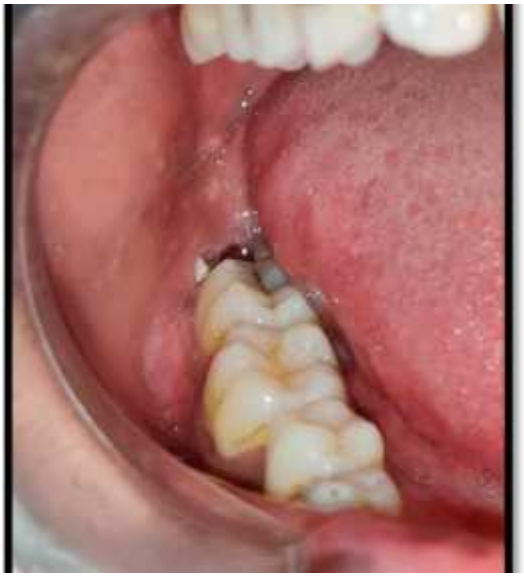


Figure 3g: Intraoral wound

Figure 4: Post-operative day 1 photos

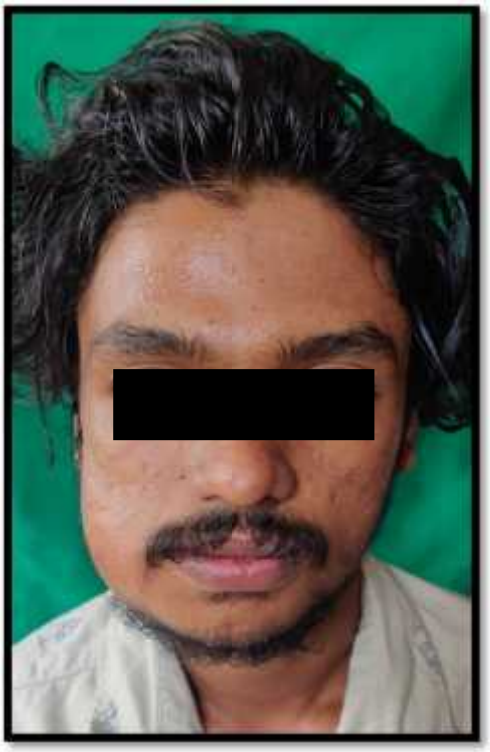


Figure 4a: Profile photo

Figure 4b: Lateral profile photo

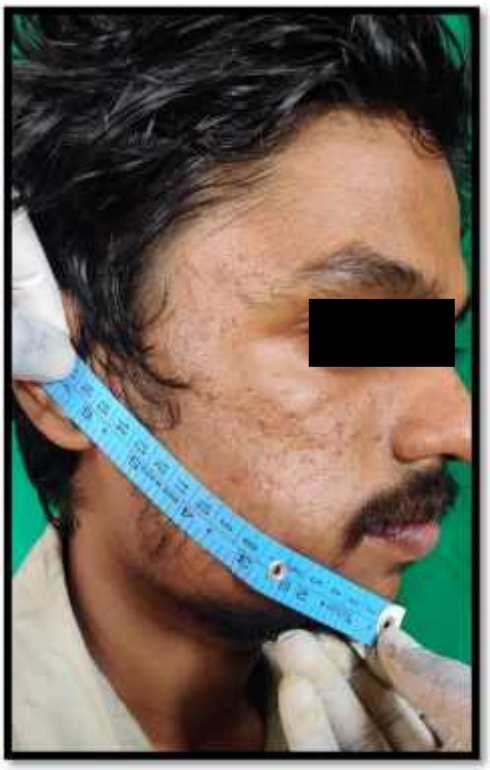


Figure 4c: Measurement from tragus to corner of mouth.

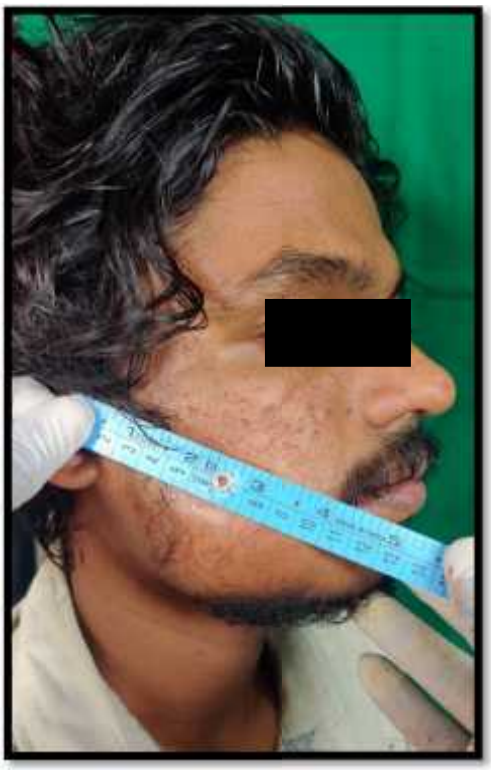


Figure 4d: Measurement from tragus to soft tissue pogonion.

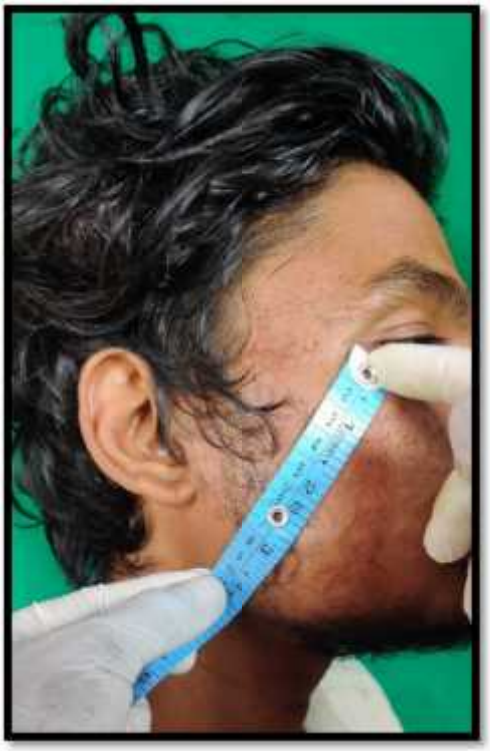


Figure 4e: Measurement from lateral canthus to angle of mandible.

Figure 4f: Measurement of inter-incisal distance.

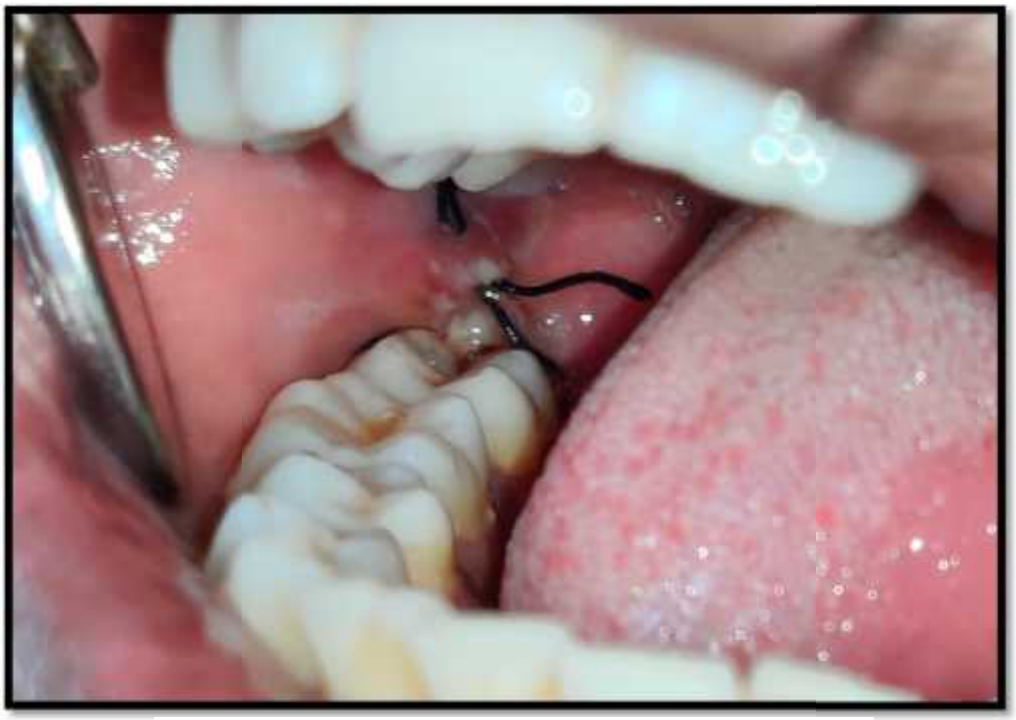


Figure 4g: Intraoral wound

Figure 5: Post-operative day 3 photos

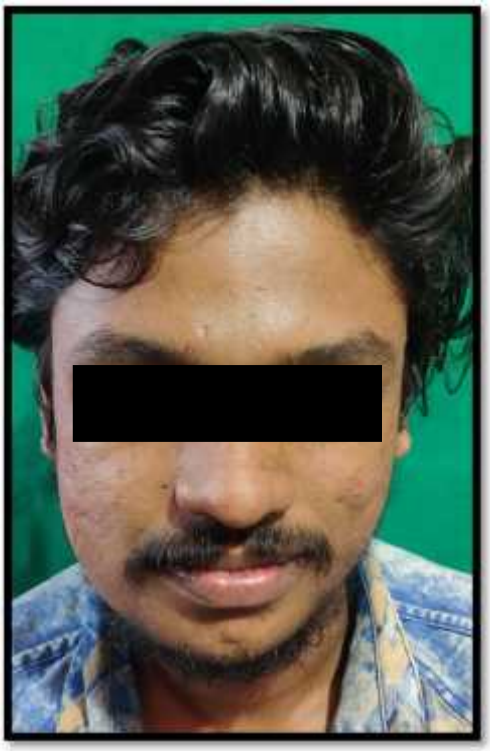


Figure 5a: Profile photo

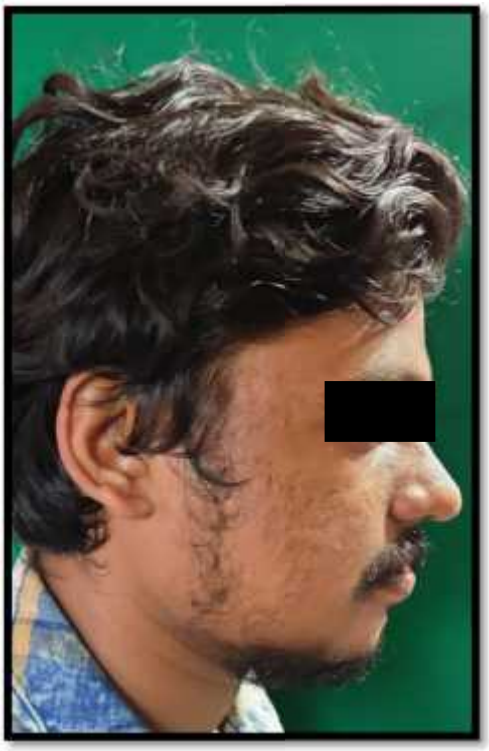


Figure 5b: Lateral profile photo

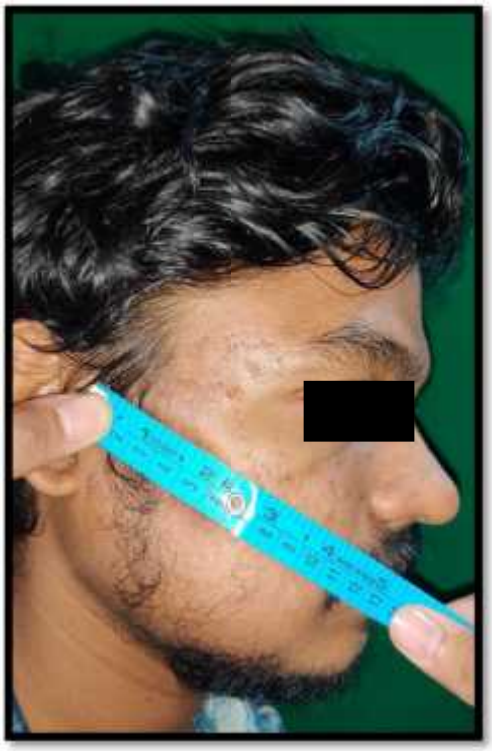


Figure 5c: Measurement from tragus to corner of mouth.

Figure 5d: Measurement from tragus to soft tissue pogonion.

Figure 5e: Measurement from lateral canthus to angle of mandible.

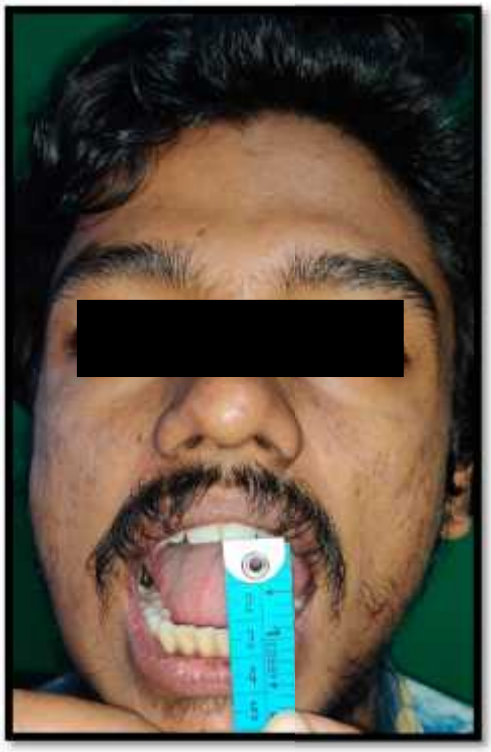


Figure 5f: Measurement of inter-incisal distance.

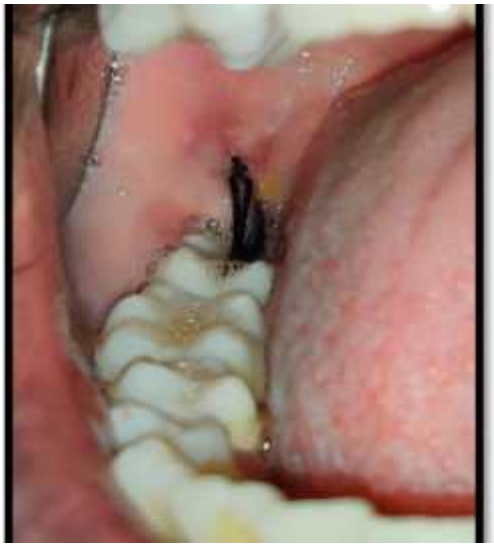


Figure 6: Post-operative day 7 photos

Figure 5g: Intraoral wound

Figure 6a: Profile photo

Figure 6b: Lateral profile photo

Figure 6c: Measurement from tragus to corner of mouth.

Figure 6d: Measurement from tragus to soft tissue pogonion.

Figure 6e: Measurement from lateral canthus to angle of mandible.

Figure 6f: Measurement of inter-incisal distance.

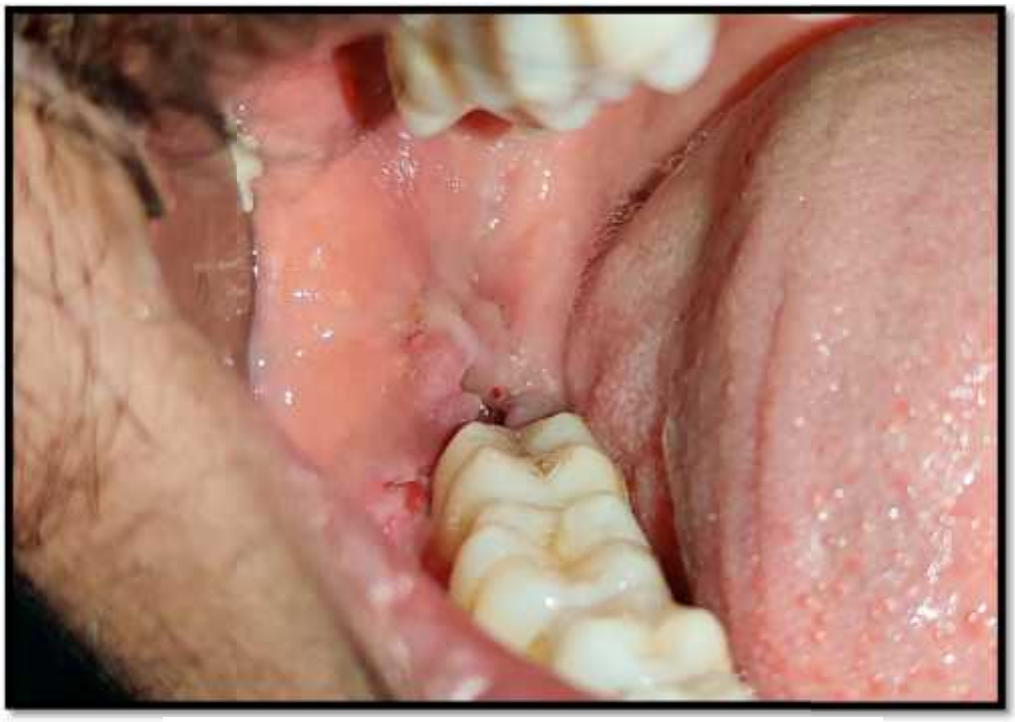


Figure 6g: Intraoral wound

RESULTS

Table 1: Distribution of males and females in study group and control group.

Sex	Study group	%	Control group	%	Total	%
Male	17	48.57	17	48.57	34	48.57
Female	18	51.43	18	51.43	36	51.43
Total	35	100.00	35	100.00	70	100.00
Chi-square=0.0000, p=1.0000						

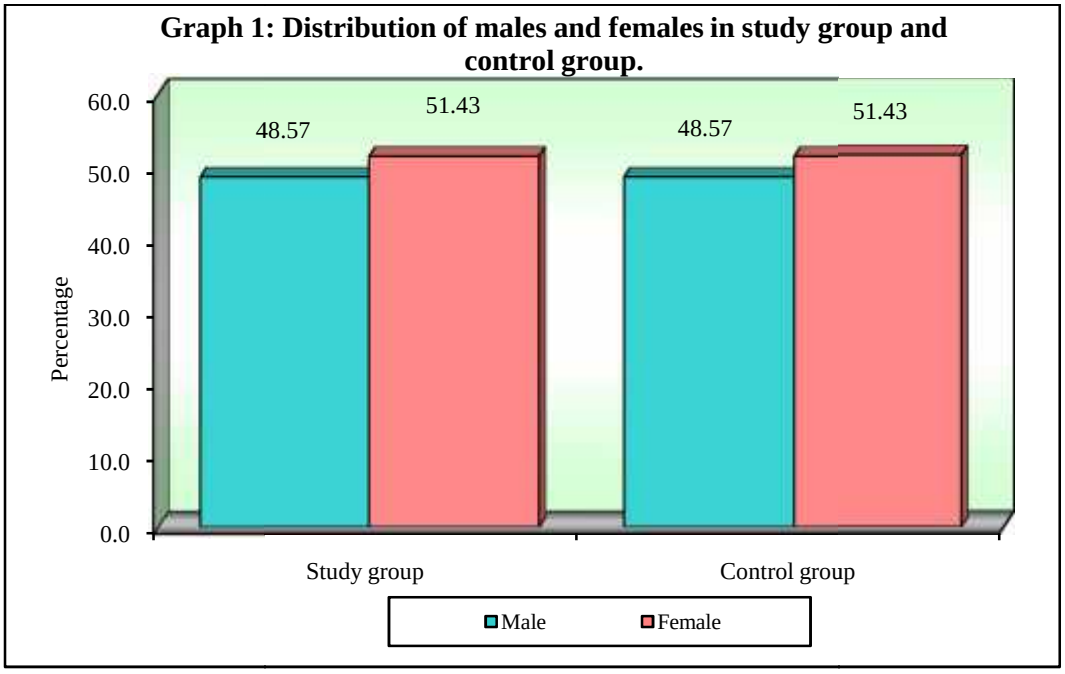


Table 1 shows distribution of males and females in study group and control group. There were 17 males (48.57%) and 18 females (51.43%) each in study group

and control group. Because the males and females were equally distributed in both groups, gender bias in the results is eliminated.

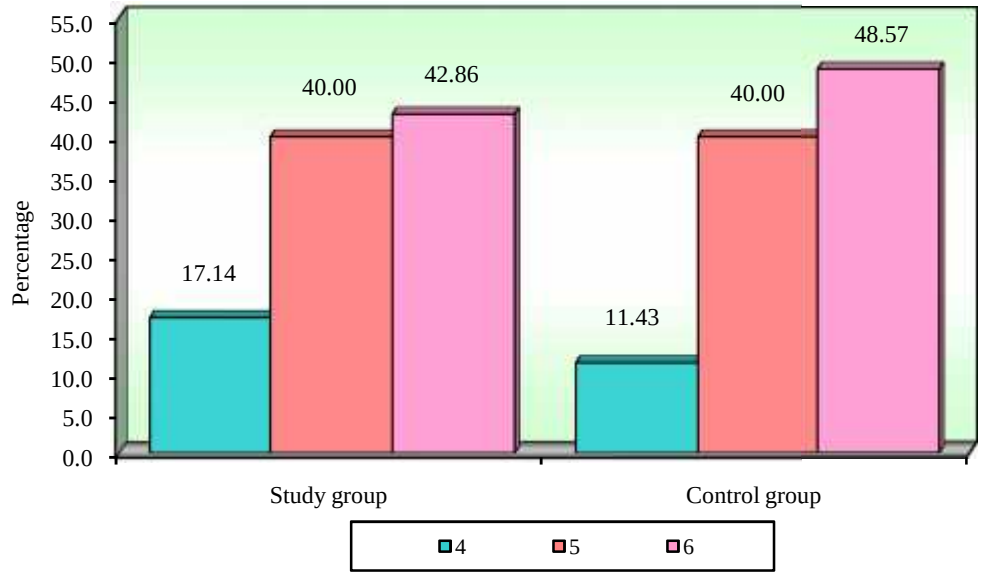
Table 2: Comparison of study group and control group with mean Pederson's difficulty index scores.

Pederson index	Study group	%	Control group	%	Total	%
4	6	17.14	4	11.43	10	14.29
5	14	40.00	14	40.00	28	40.00
6	15	42.86	17	48.57	32	45.71
Total	35	100.00	35	100.00	70	100.00
Chi-square= 0.5251 P = 0.7690						

Observations

The Pederson’s Difficulty Index score in study group was found to be 4 for 6 patients (17.14%), 5 for 14 patients (40%) and 6 for 15 patients (42.86%). In control group, 4 patients (11.43%) had score of 4, 14 patients (40%) had a score of 5 and 17 patients (48.57%) had score of 6. The p-value of 0.7690 implies that there was no statistical difference in Pederson’s Difficulty Index score inthe two groups.

Graph 2: Comparison of study group and control group with mean Pederson's difficulty index scores.



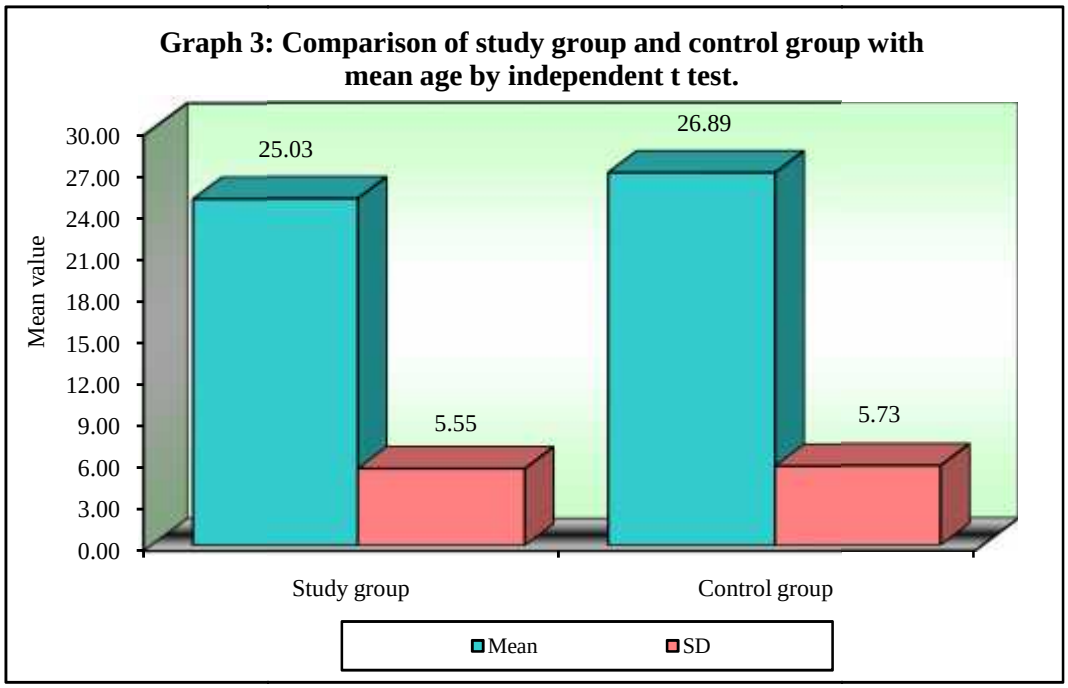
AGE DISTRIBUTION:

Table 3: Comparison of study group and control group with mean age by independent t test.

Group	n	Mean	SD	SE	t-value	P-value
Study group	35	25.03	5.55	0.94		
Control group	35	26.89	5.73	0.97	-1.3764	0.1732

Observations

The mean age in study group was 25.03 ± 5.55 years and in control group it was 26.89 ± 5.73 years. The p-value of 0.1732 implies that the variation found in the two groups in terms of age of patients is statistically non-significant.



ASSESSMENT OF PAIN:

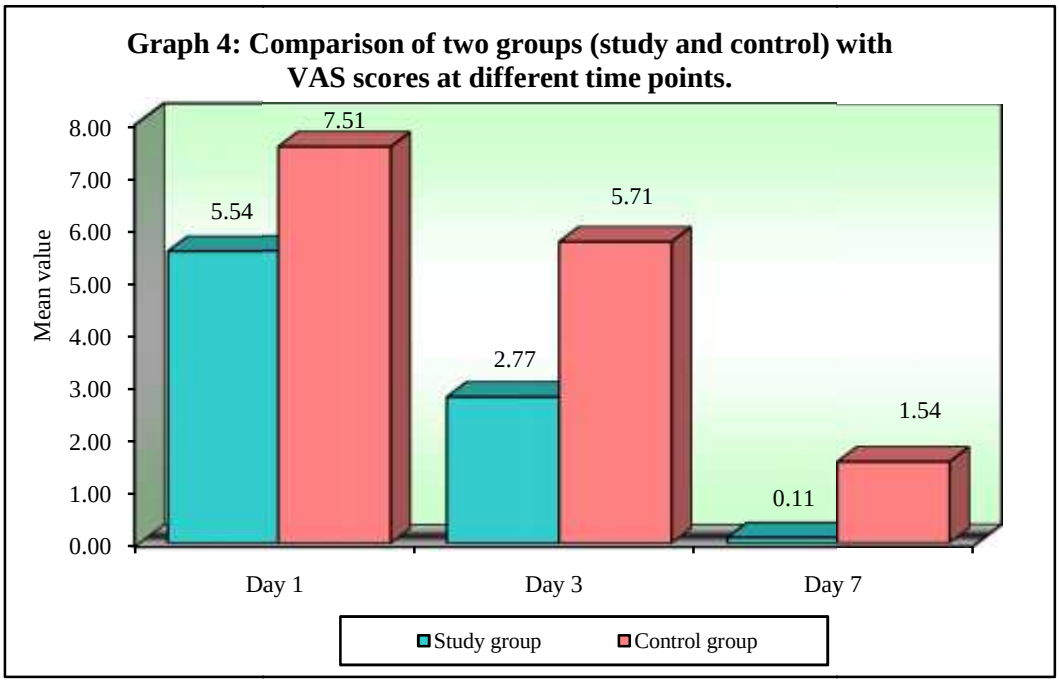


Table 4: Comparison of two groups (study and control) with VAS scores at different time points by Mann-Whitney U test.

Time points	Study group			Control group			U-value	Z-value	P-value
	Mean	Std.Dv	Mean rank	Mean	Std.Dv	Mean rank			
Day 1	5.54	0.56	18.24	7.51	0.51	52.76	8.50	-7.0946	0.0001*
Day 3	2.77	0.69	18.00	5.71	0.46	53.00	0.00	-7.1945	0.0001*
Day 7	0.11	0.32	18.91	1.54	0.51	52.09	32.00	-6.8186	0.0001*
Day 1-Day 3	2.77	0.88	45.59	1.80	0.72	25.41	259.50	-4.1464	0.0001*
Day 1-Day 7	5.43	0.70	28.64	5.97	0.62	42.36	372.50	-2.8191	0.0048*
Day 3-Day 7	2.66	0.80	20.93	4.17	0.62	50.07	102.50	-5.9905	0.0001*

*p<0.05

Graph 5: Comparison of two groups (study and control) with VAS scores at different time points.

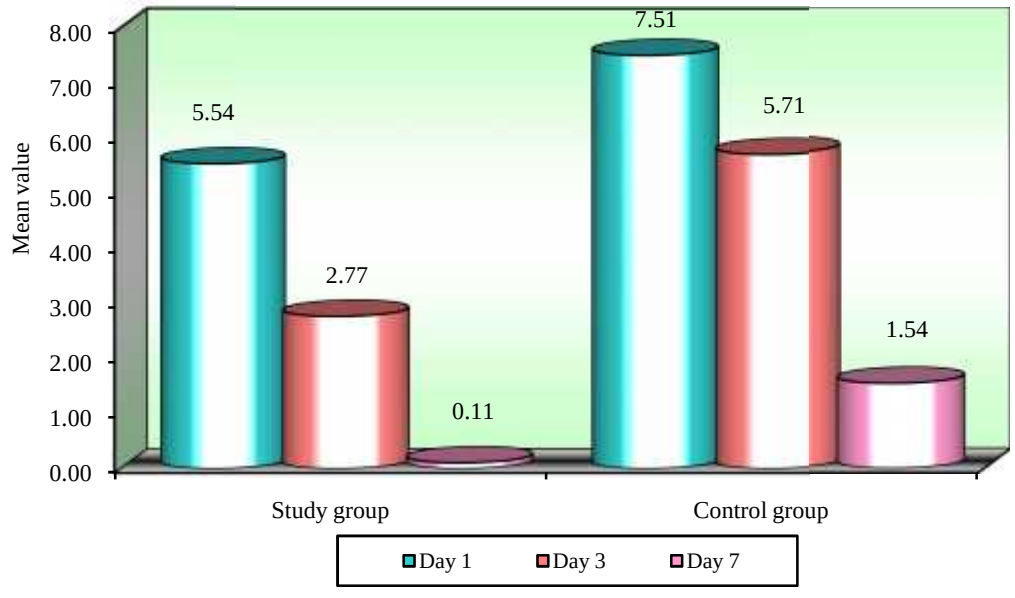


Table 5: Comparison of two groups (study and control) with VAS scores at different time points by Wilcoxon matched pairs test.

Group	Time points	Mean	SD	Mean Diff.	SD Diff.	% of change	Z-value	p-value
Study group	Day 1	5.54	0.56					
	Day 3	2.77	0.69	2.77	0.88	50.00	5.1591	0.0001*
	Day 1	5.54	0.56					
	Day 7	0.11	0.32	5.43	0.70	97.94	5.1598	0.0001*
	Day 3	2.77	0.69					
	Day 7	0.11	0.32	2.66	0.80	95.88	5.1597	0.0001*
Control group	Day 1	7.51	0.51					
	Day 3	5.71	0.46	1.80	0.72	23.95	5.1538	0.0001*
	Day 1	7.51	0.51					
	Day 7	1.54	0.51	5.97	0.62	79.47	5.1590	0.0001*
	Day 3	5.71	0.46					
	Day 7	1.54	0.51	4.17	0.62	73.00	5.1595	0.0001*

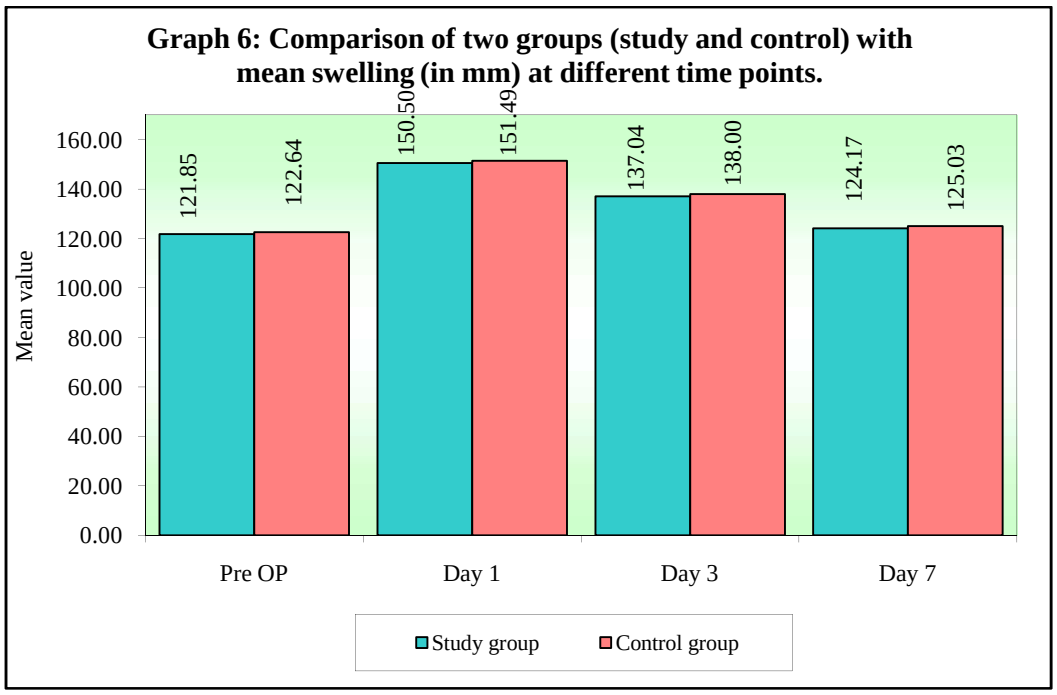
*$p<0.05$

Observations:

The pain was assessed on post-operative, day 1, day 3 and day 7 using Visual Analog Scale (VAS). The mean VAS scores in study group were 5.54 ± 0.56, 2.77 ± 0.69 and 0.11 ± 0.32 on 1st, 3rd and 7th day respectively. In control group, the mean VAS scores were 7.51 ± 0.51, 5.71 ± 0.46 and 1.54 ± 0.51 on 1st, 3rd and 7th day respectively. Mann-Whitney U test and Wilcoxon matched pairs test was used for

comparing the scores ofthe two groups and it showed statistically significant difference on all the evaluation days implying that patients in study group (ozone gel group) had less pain post-operatively as compared to those in control group.

ASSESSMENT OF SWELLING:



Observations

The mean swelling scores in study group were 121.85 ± 6.08, 150.50 ± 5.47, 137.04 ± 5.99 and 124.17 ± 6.69 on pre-operative, day 1, day 3 and day 7 time points respectively. In Control group the mean scores were 122.64 ± 6.43, 151.49 ± 5.07, 138.00 ± 5.52 and 125.03 ± 5.76 on pre-operative, day 1, day 3 and day 7 time points respectively. The comparison between these scores was done using independent t test which showed that the difference between both the groups was statistically non-significant pre-operatively and at day 1, day 3 and day 7.

Table 6: Comparison of two groups (study and control) with mean swelling (in mm) at different time points by independent t test.

Time points	Study group		Control group		t-value	p-value
	Mean	SD	Mean	SD		
Pre-op	121.85	6.08	122.64	6.43	-0.5282	0.5991
Day 1	150.50	5.47	151.49	5.07	-0.7854	0.4350
Day 3	137.04	5.99	138.00	5.52	-0.6991	0.4869
Day 7	124.17	6.69	125.03	5.76	-0.5751	0.5671
Pre-op - Day 1	-28.65	2.88	-28.85	3.04	0.2822	0.7786
Pre-op-Day 3	-15.19	2.59	-15.36	3.12	0.2506	0.8028
Day 1-Day 7	-2.32	1.51	-2.39	1.58	0.1823	0.8559
Day 1-Day 3	13.46	1.21	13.49	1.27	-0.0945	0.9250
Day 1-Day 7	26.32	2.90	26.46	2.48	-0.2052	0.8380
Day 3-Day 7	12.87	2.38	12.97	2.50	-0.1786	0.8588

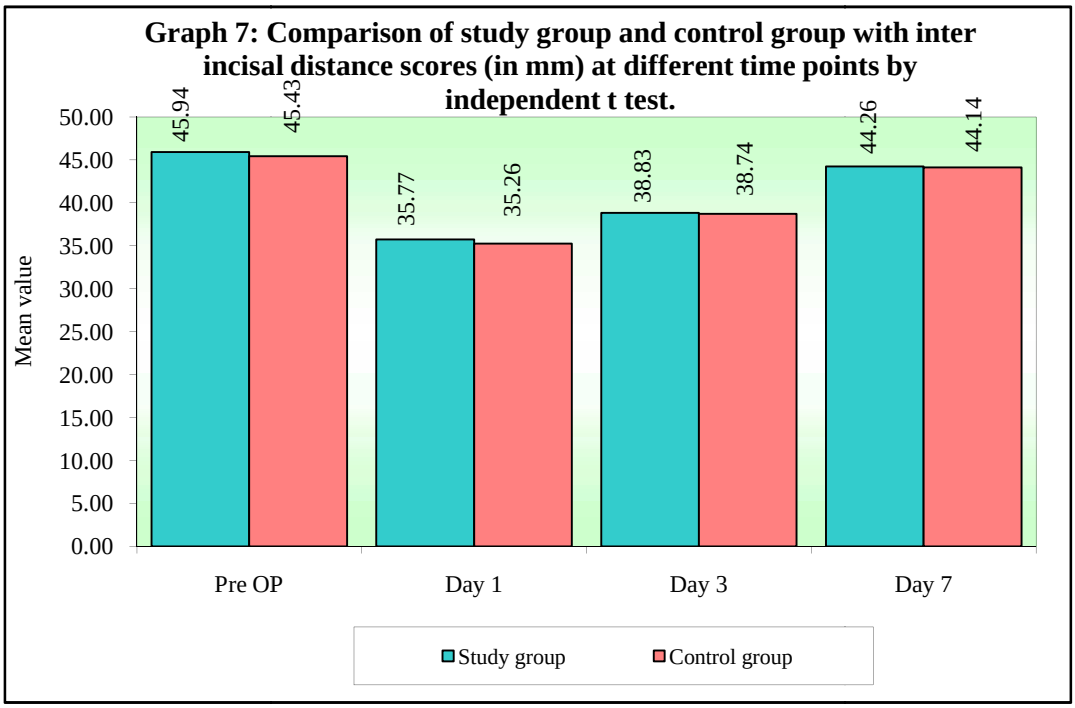
ASSESSMENT OF TRISMUS:

Table 7: Comparison of study group and control group with inter incisal distance scores (in mm) at different time points by independent t test.

Time points	Study group		Control group		t-value	p-value
	Mean	SD	Mean	SD		
Pre-op	45.94	2.58	45.43	3.11	0.7534	0.4538
Day 1	35.77	3.01	35.26	3.71	0.6365	0.5266
Day 3	38.83	3.36	38.74	3.97	0.0975	0.9226
Day 7	44.26	2.86	44.14	3.45	0.1509	0.8805
Pre-op - Day 1	10.17	1.25	10.17	1.18	0.0000	1.0000
Pre-op - Day 3	7.11	1.69	6.69	1.47	1.1303	0.2623
Day 1 - Day 7	1.69	1.02	1.29	1.15	1.5362	0.1291
Day 1 - Day 3	-3.06	1.03	-3.49	1.01	1.7592	0.0830
Day 1 - Day 7	-8.49	1.22	-8.89	1.18	1.3918	0.1685
Day 3 - Day 7	-5.43	1.42	-5.40	1.31	-0.0875	0.9306

Observations:

In study group, the mean mouth opening scores in millimeter were on 45.94 ± 2.58, 35.77 ± 3.01, 38.83 ± 3.36 and 44.26 ± 2.86 on pre-operative, day 1, day 3 and day 7 respectively. In control group the mean mouth opening scores in millimeter were 45.43 ± 3.11, 35.26 ± 3.71, 38.74 ± 3.97 and 44.14 ± 3.45 on preoperative, day 1, day 3 and day 7 respectively. The comparison between these scores was done using independent t test which showed that the difference between the two groups was statistically non-significant preoperatively and throughout the whole evaluation period at day 1, day 3 and day 7.



ASSESSMENT OF WOUND HEALING:

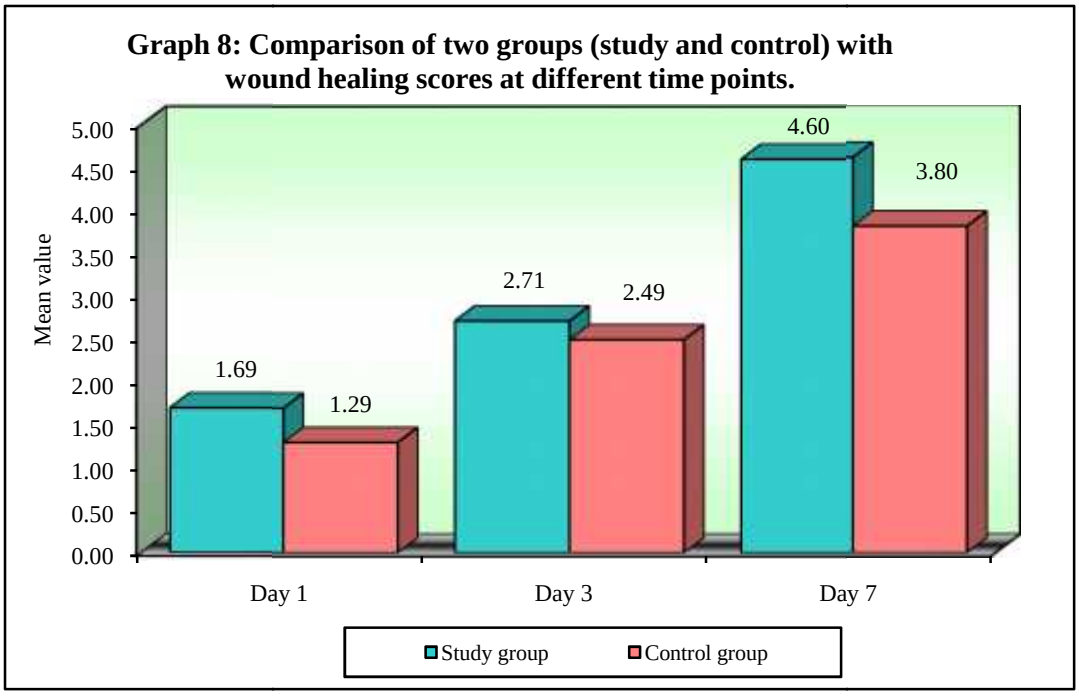


Table 8: Comparison of two groups (study and control) with wound healing scores at different time points by Mann-Whitney U test.

Time points	Study group			Control group			U-value	Z-value	P-value
	Mean	Std.Dv	Mean rank	Mean	Std.Dv	Mean rank			
Day 1	1.69	0.47	42.50	1.29	0.46	28.50	367.50	-2.8778	0.0040*
Day 3	2.71	0.46	39.50	2.49	0.51	31.50	472.50	-1.6445	0.1001
Day 7	4.60	0.50	46.20	3.80	0.63	24.80	238.00	-4.3989	0.0001*
Day 1-Day 3	-1.03	0.30	38.41	-1.20	0.47	32.59	510.50	-1.1981	0.2309
Day 1-Day 7	-2.91	0.70	30.80	-2.51	0.82	40.20	448.00	-1.9322	0.0533*
Day 3-Day 7	-1.89	0.63	28.00	-1.31	0.72	43.00	350.00	-3.0833	0.0020*

*p<0.05

Graph 9: Comparison of two groups (study and control) with wound healing scores at different time points.

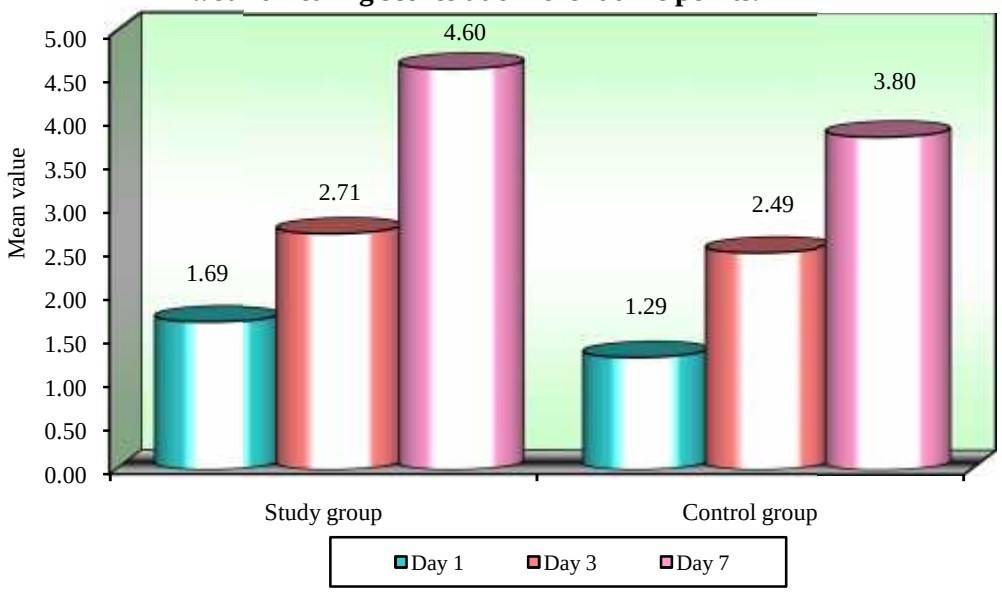


Table 9: Comparison of two groups (study and control) with wound healing scores at different time points by Wilcoxon matched pairs test.

Group	Time points	Mean	SD	Mean Diff.	SD Diff.	% of change	Z-value	p-value
Study group	Day 1	1.69	0.47	-1.03	0.30	-61.02	5.0862	0.0001*
	Day 3	2.71	0.46					
	Day 1	1.69	0.47	-2.91	0.70	-172.88	5.1594	0.0001*
	Day 7	4.60	0.50					
	Day 3	2.71	0.46	-1.89	0.63	-69.47	5.1594	0.0001*
	Day 7	4.60	0.50					
Control group	Day 1	1.29	0.46	-1.20	0.47	-93.33	5.0862	0.0001*
	Day 3	2.49	0.51					
	Day 1	1.29	0.46	-2.51	0.82	-195.56	5.1594	0.0001*
	Day 7	3.80	0.63					
	Day 3	2.49	0.51	-1.31	0.72	-52.87	4.9365	0.0001*
	Day 7	3.80	0.63					

*$p<0.05$

Observations:

The wound healing was assessed on 1st, 3rd and 7th day of surgery using the Landry et al. Index. The mean wound healing scores in study group were 1.69 ± 0.47, 2.71 ± 0.46 and 4.60 ± 0.50 on 1st, 3rd and 7th day respectively. In control group, the mean wound healing scores were 1.29 ± 0.46, 2.49 ± 0.51 and 3.80 ± 0.63 on 1st, 3rd and 7th day respectively. The comparison between these scores was done using Mann-Whitney U test and Wilcoxon matched pairs test that showed statistically significant difference at post-operative day 1 and day 7, while at post-operative day 3 the difference between the two groups was statistically non-significant. Wound healing was found to be better in study group as compared to control group on post-operative day 1 and day 7 and the difference was statistically significant. The mean wound

healing score was higher in study group on day 3 as well but the difference was statistically non-significant.

NUMBER OF ANALGESIC USE:

Table 10: Comparison of two groups (study and control) with number of analgesic tablets taken per day at different time points by independent t test.

Time points	Study group		Control group		t-value	p-value
	Mean	SD	Mean	SD		
Day 1	3.00	0.00	3.00	0.00	--	--
Day 2	3.00	0.00	3.00	0.00	--	--
Day 3	1.09	0.28	3.00	0.00	-39.8730	0.0001*
Day 4	1.00	0.00	0.66	0.48	4.2118	0.0001*
Day 5	0.00	0.00	0.34	0.48	-4.2118	0.0001*

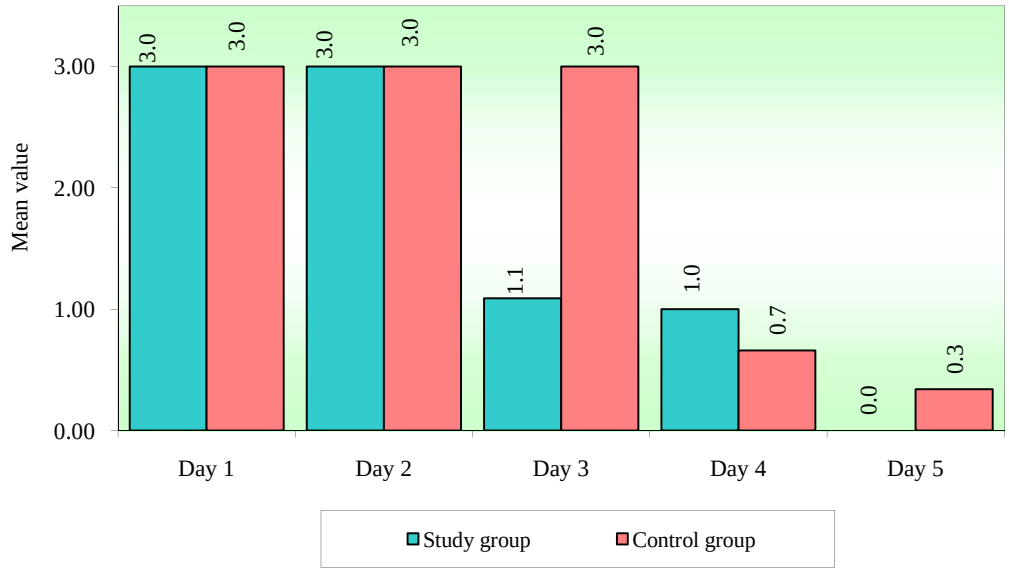
*$p<0.05$

Observations:

All patients who required analgesics on post-operative days were permitted and duly noted. On statistical analysis using independent t test, it was found that difference between the scores of the two groups was statistically significant on post-operative day 3, day 4 and day 5. On the other hand, scores of both the groups on post-operative day 1 and day 2 was exactly the same. Patients in study group (ozone

gel group) required fairly less number of analgesics as compared to the patients in control group on post-operative day 3, day 4 and day 5 while there was no difference in the scores on postoperative day 1 and day 2.

Graph 10: Comparison of two groups (study and control) with number of analgesic tablets taken per day at different time points.



DISCUSSION

Surgical extraction of impacted mandibular third molar is among the most routinely performed procedures by an Oral and Maxillofacial Surgeon. There is always a risk of complications in the field of surgery as a whole. It has been found in the literature that the incidence of complications after third molar surgery is in the range of 2.6% to 30.9%. These complications can be as minor as pain and swelling or it can take the form of a life-threatening infection[11,12]. Most common among those are pain, swelling and trismus[12]. Appropriate anti-inflammatory medication can avoid post-operative inflammation and related symptoms or alleviate them[13].

Attempts have been made to mitigate the symptoms and to ensure a seamless post-operative recovery by employing systemic medication such as antibiotics, corticosteroids and non-steroidal anti-inflammatory drugs or topical treatment like saline gelatin sponge and cryotherapy to name a few[3]. All of these though can predilect the individual to systemic bleeding, GI irritation, allergic reactions or other local harmful reactions[4]. Use of corticosteroids can further lead to adrenal suppression, retarded wound healing and more probability of infection[14,15]. These insights give justification to all the attempts to explore new modalities to mitigate the immediate complications without any unwanted effects.

Ozone therapy has started to gain a place in routine dental practice as it has found itself to be useful in most of the procedures carried out in dentistry.Ozone can interact with blood constituents and have a positive impact on cellular energy, regulation of immune system, first line defense antioxidants, microcirculation as well as overall oxygen metabolism[16,17]. All of these reactions demonstrate different

properties of ozone such as antimicrobial, disinfection and wound healing[17-20]. In oral surgery, ozone use can prove useful by facilitating in hemostasis, improving oxygen supply in the surrounding tissues and hindering bacterial growth[17-20].

Literature says that degree of pain reaches its peak within 3 to 5 hours of surgery which usually continues for a couple of days following which it gradually reduces by 7th day[11]. Swelling is maximum 12–48 hrs after surgery and settles down in 5 to 7 days[11,12].

In 2007, Lucia Lago-Mendez et al. studied the correlation between surgical difficulty of impacted lower third molar and post-operative pain[21]. The results revealed strong association between surgical difficulty and post-operative pain and it was concluded that post-operative pain after impacted lower third molar surgery is directly related to the surgical difficulty. In our study, Pederson's difficulty index was put into use for assessing the surgical difficulty and only cases with the score of 4-6 were taken for study. The difference between scores in the two groups was statistically non-significant.

In 2011, Thiago de Santana-Santos etal. evaluated the relation between pre-operative variables and post-operative symptoms (pain, swelling and trismus) following lower third molar surgery[22]. The authors concluded that the degree of post-operative symptoms after lower third molar surgery depends on patient attributes (age, gender and body mass index) as well as surgery parameters like duration of surgery and tooth sectioning. In the present study, no statistically significant difference was found in the two groups with regard to gender and age of patients thereby eliminating the chances of distorted results due to bias.

In this study, the pain was assessed on post-operative day 1, day 3 and day 7 using Visual Analog Scale (VAS). The mean VAS scores in study group were significantly (p=0.0001) less as compared to control group on all the evaluation days implying that patients in study group (ozone gel group) had less pain post-operatively as compared to those in control group. Results of our study are similar to the ones done by Kazancioglu et al.[2], Sivalingam et al.[3], Sherif S. Alkholy et al.[1] and Shokry et al.[17] who concluded that topical application of ozone gel after lower third molar surgery significantly reduces post-operative pain. The ozone group patients took lesser number of analgesics as a result.

In our study, ozone group was not found to have any edge over the control group with regard to post-operative swelling and trismus. Although the mean swelling and mouth opening scores in study group were less than the control group at all evaluation days i.e. day 1, day 3 and day 7, the difference was statistically non-significant.

In terms of swelling and trismus, our findings supports Sherif S. Alkholy et al.[1] and Kazancioglu et al.[2] who through their study reported that ozone does not have any real impact on facial swelling or mouth opening following lower third molar surgery.

In 2016, Sivalingam et al. in his clinical trial evaluated the efficacy of topical ozone gel application after impacted lower third molar surgery and reported that patients in the study group (ozone gel group) had significantly less swelling, pain and trismus when compared with the control group who did not receive ozone gel[3]. Same year, Mohamed M. Shokry and Alshaimaa A. Shabaan noticed that xenograft material

when mixed with ozonated oil and put in the extraction reduced post-operative pain, swelling and trismus to a great extent in contrast to when only xenograft was used[17].

Ozone triggers the macrophages and subsequentlyfacilitates the production of biologically active substances. This significantly reduces inflammation and enhances wound healing.This theory is supported by the results of our study where wound healing was found to be better in study group (ozone gel group) as compared to control group on post-operative day 1 and day 7 and the difference was statistically significant. The mean wound healing score was higher in study group on day 3 as well but the difference was statistically non-significant.Also, Kan et al. demonstrated its extraordinary healing property through his histomorphometric and mCT analyses[8].

The notable advantages that the patients in study group exhibited were diminished pain further restricted the consumption of analgesics and consequently, the related side effects. Patients also showed exceptional wound healing. To add to the advantages, patients were also able to apply ozone gel all by themselves with ease. Ozone therapy did not cause any discomfort to the patients in the entire course of treatment. That being said, the trial did have certain drawbacks. Patients required constant counselling and encouragement to use ozone as home application after surgery. Also, ozone should not be used in individuals with autoimmune diseases, thyrotoxicosis, alcohol intoxication, known allergy to ozone, MI, G6PD deficiency, neuromuscular disorders like myasthenia gravis[19,23].

SUMMARY AND CONCLUSION

The current randomized prospective study evaluated the efficacy of the topical ozone gel application in mitigating the immediate post-operative symptoms associated with surgical removal of impacted lower third molars.

It was evident that ozone gel did not have any effect on post-operative swelling and mouth opening. On the other hand, pain was significantly decreased in the study group as they took a smaller number of analgesics post-operatively compared to the control group. We found that wound healing was enhanced in the patients who used ozone gel and the statistical analysis showed significant difference.

This study concluded that ozone gel can be used to alleviate post-operative pain thereby reducing the consumption of analgesics and to further enhance wound healingafter surgical removal of lower third molar. More such studies are however needed to assess long-term outcomes of topical use of ozone gel in randomized controlled trials using a split mouth study design in an attempt to eliminate as much bias as possible.

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ANNEXURES– I - ETHICAL CLEARANCE

Research and Ethics Committee
KLE V K INSTITUTE OF DENTAL SCIENCES
KLE University
Accredited 'A' Grade by NAAC Placed in Category 'A' by MHRD (GoI)
Nehru Nagar, Belagavi - 590 010, Karnataka State
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Sl. No. : 1211

CERTIFICATE

This is to Certify that the synopsis titled

Efficacy of Topical Ozone Gel in improving post-operative patient comfort after surgical removal of impacted mandibular third molar: A randomized controlled trial *Submitted by*

Dr. Manavadaria Yash Chandrakant *P. G. Student / Staff, Guided by* Dr Arati S. Neeli *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 : 24/06/2019

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

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

ANNEXURES– II – BIOSTATISTICS CLEARANCE CERTIFICATE

KLE V.K. Institute of Dental Sciences
(A Constituent unit of KLE Academy of Higher Education & Research
Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi-590 010 INDIA
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E-mail: principal@kledental-bgm.edu.in

Biostatistics Clearance Certificate

This is to certify that the Biostatistics aspect of the Dissertation / Research work of **Dr. Manavadaria Yash Chandrakant** entitled **"EFFICACY OF TOPICAL OZONE GEL IN IMPROVING POST-OPERATIVE PATIENT COMFORT AFTER SURGICAL REMOVAL OF IMPACTED MANDIBULAR THIRD MOLAR – A RANDOMIZED CONTROLLED TRIAL"** has been done under my guidance and considered satisfactory.

Place: Belagavi
Date: 05/09/2020

Name & Signature of Biostatistician
(Dr. S.B. Javali)

ANNEXURES – III – PLAGIARISM CERTIFICATE

Scientific Correspondence and Review Committee

KLE VK Institute of Dental Sciences

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Date : **Serial No. :** 028

PLAGIARISM CHECK REPORT

Name of the Applicant : Dr Manavadaria Yash
UG / PG / Ph.D / Staff : Post graduate
Batch & Year : 2018-2021
Department : Department of Oral & Maxillofacial Surgery

The soft copy of Research Work / Manuscript by Dr. Manavadaria Yash ..... entitled "Efficacy of topical ozone gel in improving post-operative patient comfort after surgical removal of impacted mandibular 3rd molar-A RCT"

under the guidance of Dr. Arati Neeli .....has been submitted for Anti-Plagiarism check to the Scientific Correspondence & Review Committee of KLE VK Institute of Dental Sciences using "Turn-it-in" software.

The scan has been carried out and the scanned output reveals a Similarity Index of 10 %, which is **within / not within** the acceptable limits of 10% as per the UGC guidelines.

Member Secretary
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER-Belagavi

Chairman
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER - Belagavi

ANNEXURE – IV - CONSENT FORM

KAHER's KLE VK Institute of Dental Sciences
Department of Oral and Maxillofacial Surgery
Belagavi

"EFFICACY OF TOPICAL OZONE GEL IN IMPROVING POST-OPERATIVE PATIENT COMFORT AFTER SURGICAL REMOVAL OF IMPACTED MANDIBULAR THIRD MOLAR – A RANDOMIZED CONTROLLED CLINICAL TRIAL"

CONSENT FORM

I…… age … have been explained the details of the study undertaken. I am fully satisfied with the procedure and instructions given by Dr. _____ and hereby give my permission to participate in this study.

Place:

Date:

Signature of participant:

Contact no:

Address:

KAHER's KLE VKInstitute of Dental Sciences
Department of Oral and Maxillofacial Surgery
Belagavi

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CONSENT TO SURGERY / ANAESTHETICS

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

1. I, _____ aged _____ years have been informed about my involvement in the study.
2. I agree to give my personal details like Name Age, Sex, Address, Past dental 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 various investigations.
4. I permit the operator to utilize the information given by me and the results obtained from this study for presentation and publication.
5. I permit the surgeon to take my photographs to utilize it for the study and presentation 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 including extraction of tooth followed by application of ozone gel in the extraction socket before placing the sutures and its home application over the wound for wound healing and management of pain, swelling and trismus in my vernacular language.
7. The nature and purpose of the operation 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 mother tongue. No guarantee or assurance has been given by anyone as to the results that may be obtained.
   (Cross out any paragraphs in the preceding forms which do not apply)
8. 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: Dr.ManavadariaYash
Doctor's contact: 9879767678
Hospital contact: 08312551732

KAHER's KLE VK Institute of Dental Sciences
Department of Oral and Maxillofacial Surgery
Belagavi

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CONSENT TO SURGERY / ANAESTHETICS

तारीख: वेळ:

1. मी, _____ वयस्कर _____ वर्षांचीमाहितीदिलीगेलीआहेअभ्यासातमाझ्यासहभागबद्दल.
2. मीमाझेवय, लिंग, पत्ता, भूतकाळातीलदंतआणिअभ्यासक्रमासाठीआवश्यकअसलेल्याइतरतपशीलांसहमाझेवैयक्तिकतपशीलज सेकीसर्वोत्तममाहितीदेण्यासाठीसहमतआहे.
3. मीवैद्यकीयतपासणीसाठीआणिविविधतपासणीसाठीसहकार्यकरीन.
4. प्रेझेंटेशनआणिप्रकाशनयासाठीमीयाअभ्यासातूनमिळालेल्यामाहितीचावापरकरुनऑपरेटरलादिलेलीमाहि तीवापरण्याचीपरवानगीदेतो.
5. मीसर्जनलामाझेफोटोअभ्यासआणिसादरीकरणउद्देशानेवापरण्यासाठीघेण्यासपरवानगीदेतो.
6. मीमाझ्याइच्छेनुसारयाअभ्यासातभागघेतआहेआणिइच्छेनुसारआणिसर्जननेदातकाढण्यासहप्रक्रियेचेस्व रूपआणिपरिणामस्पष्टकेलेआहे, त्यानंतरसिक्युरआणित्याच्याघराच्याअनुप्रयोगासजखमेवरठेवण्याआधीओझोनजेलचावापरनिष्कर्षसॉके टमध्येकेलाजातो. माझ्यास्थानिकभाषेतवेदना, सूजआणित्रस्तपणाचेजखमेचेउपचारआणिव्यवस्थापन.
7. माझ्यामातृभाषेतऑपरेशनआणिवापरल्याजाणार्यासामग्रीचेउद्दीष्टआणिउद्देश, उपचारांच्यासंभाव्यपर्यायीपद्धती, जोखमीचासमावेशआणिगुंतागुंतांचीशक्यतामलापूर्णेपणेस्पष्टकरण्यातआलीआहे. कोणाकडूनहीकोणतीहीहमीकिंवाआश्वासनदेण्यातआलेनाहीजेणेकरुनप्राप्तहोऊशकतील. (आधीच्याफॉर्ममधीलकोणतेहीपरिच्छेदक्रॉसकराजेलागूहोतनाही)
8. मीसर्जननेदिलेलीवरीलमाहितीवाचल्याबद्दलवाचलीआणिसमजूनघेतलीआणिस्वेच्छेनेअभ्यासातभागघे ण्याससहमतआहे.

नावः तारीखः

स्वाक्षरी: मोबाइलनंबरः

डॉक्टरांचेनाव:

डॉक्टरांचासंपर्कः 9879767678

हॉस्पिटलसंपर्कः**08312551732**

KAHER's KLE VK Institute of Dental Sciences
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CONSENT TO SURGERY / ANAESTHETICS

ದಿನಾಂಕ : ಸಮಯ :

1. ನಾನು, _____ ವಯಸ್ಸು _____
   ವರ್ಷಗಳಿಗಿತಳಸಲಾಗದಅಧ್ಯಯನದಲ್ಲನನ್ನಪಾಲ್ಗೊಳ್ಳುವಬಗ್ಗೆ .
2. ನನ್ನವಯಸ್ಸಿನವಯಸ್ಸು, ಸೆಕ್ಸ್, ವಿಳಾಸ,
   ಕಳೆದಹಲ್ಲಿನಮತ್ತುನನ್ನಜ್ಞಾನದಅತ್ಯುತ್ತಮಅಧ್ಯಯನಕ್ಕಬೇಕಾದಯಾವುದೇಇತರವಿವರಗಳಂತಹನನ್ನವ್ಯಯಿಕ್ತಕವಿವರಗಳನ್ನುನಾನುಒಪ್ಪುತ್ತೇನೆ .
3. ನಾನುಶಸ್ತ್ರಚಿಕಿತ್ಸಕಪರೀಕ್ಷಗಮತ್ತುಹಲವಾರುತನಿಖಗಳಿಗಸಹಕರಿಸುತ್ತೇನ .
4. ನಾನುನೀಡಿದಮಾಹಿತಮಿತ್ತುಪ್ರಸ್ತುತಮತ್ತುಪ್ರಕಟಣಗಾಗಿಈಅಧ್ಯಯನದಿಂದಪಿಡದಫಲಿತಾಂಶಗಳನ್ನುಬಳಸಿಕೊಳ್ಳಲುನಾನುಆಯೋಜಕರುಅನ್ನುಅನುಮತಿಸುತ್ತೇನ .
5. ಅಧ್ಯಯನಮತ್ತುಪ್ರಸ್ತುತಉದ್ದೇಶಕ್ಕಾಗಿಶಸ್ತ್ರಚಿಕಿತ್ಸೆಕವನ್ನುನನ್ನಛಾಯಾಚಿತ್ರಗಳನ್ನುತಗದುಕೊಳ್ಳಲುನಾನಾನುಅನುಮತಿಸುತ್ತೇನೆ .
6. ನನ್ನಸ್ಥಿತಿಯಿದೂರದಿಗೆನಾನುಈಅಧ್ಯಯನದಲ್ಲಪಾಲ್ಗೊಳ್ಳುತ್ತಿದ್ದೇನಮತ್ತುಶಸ್ತ್ರಚಿಕಿತ್ಸೆಕನುಹಲ್ಲನಹೊರತಗಯುವ
   ಕಿಸೀರದಂತಕಾರ್ಯವಿಧಾನದಸ್ವರೂಪಮತ್ತುಪರಿಣಾಮವನ್ನುವಿವರಿಸಿದ್ದಾನ,
   ನಂತರಹೊರತಗೆಯುವಸಾಕಷ್ಟಲ್ಲಿಒಳ್ಳೆಯದಾಗಿಲ್ಲಅಥವಾಮತ್ತುಗಾಯದಮೇಲಿರಿಮೆನಯಿಅನ್ನಯಿವನ್ನುಳಿಸುವಮೊದಲುನನ್ನಸ್ಥಳೀಯಿಭಾಷಯಿಲ್ಲನೋವು, ಉರುತಮತ್ತುಬ್ರಸ್ಮಸ್ಸಗಾಯಿಗುಣಪಡಿಸುವುದುಮತ್ತುಸರ್ವಹಣ .
7. ಕಾರ್ಯಾಚರಣೆಯಸ್ವಭಾವಮತ್ತುಉದ್ದೇಶಮತ್ತುಬಳಕೆಯಲ್ಲಿರುವವಸ್ತುಗಳು,
   ಚಿಕಿತ್ಸೆಯಸಂಭವನೀಯಪರ್ಯಾಯವಿಧಾನಗಳು,
   ಒಳಗೊಂಡಿರುವಲಿಪಾಯಿಮತ್ತುತೊಡಕುಗಳಸಾಧ್ಯತಯಿನ್ನುನನ್ನಮಾತೃಭಾಷಯಿಲ್ಲಸಂಪೂರ್ಣವಾಗಿನನಗೆಬವರಸಲಾಗಿದೆ. ಪಡೆಯಬಹುದಾದಿಫಲತಾಂಶಗಳಂತೆಯಾರಿಗೂಗ್ಯಾರಂಟಿಅಥವೆಖರಿವಸಿಸೀಡಲಾಗಿಲ್ಲ .
   (ಅನ್ವಯಿಸದಹಿಂದಿನರೂಪಗಳಲ್ಲಿಯಾವುದೇಪ್ಯಾರಾಗಳನ್ನುಕ್ರಾಸ್ಔಡಿ)
8. ಅಧ್ಯಯನದಬಗ್ಗಶಸ್ತ್ರಚಿಕಿತ್ಸೆಕನೀಡಿದಿಮೇಲಿನಮಾಹಿತಯಿನ್ನುನಾನುಓದ್ದೇನಮತ್ತುತಿರ್ಧಮಾಡಿಕೂಡಿದ್ದೇನಮತ್ತುಅಧ್ಯಯನದಲ್ಲಪಾಲ್ಗೊಳ್ಳಲುಇಷ್ಟಪಡುತ್ತೇನ .

ಹಸರು : ದಿನಾಂಕ :

ಸಹಿ : ಮೊಬ್ಯಲ್ನಂಬರ :

ವೈದ್ಯರಹಸರು :

ವೈದ್ಯರಸಂಪರ್ಕ: 9879767678

ಆಸ್ಪತ್ರೆಸಂಪರ್ಕ: 08312551732

ANNEXURE V - PROFORMA FOR CASE HISTORY

NAME: **AGE: SEX:**

OCCUPATION: **O.P.NO.:**

ADDRESS: **DATE:**

CONTACT NO:

CHIEF COMPLAINT:

HISTORY OF PRESENTING ILLNESS:

PAST DENTAL HISTORY:

PAST MEDICAL HISTORY:

DRUG ALLERGY:

PERSONAL HISTORY:

Smoking/Alcohol/Tobacco chewing

GENERAL PHYSICAL EXAMINATION:

EXTRA-ORAL EXAMINATION:

Facial Symmetry:

TMJ:

Lymph Node:

Mouth Opening:

INTRA-ORAL EXAMINATION:

Soft Tissue surrounding the Impacted Tooth: Normal/Inflamed

Ulcer: Present/Absent

Fibrosed: Yes/No

Pericoronitis:

Swelling:

Discharge:

Pain/ Difficulty in Chewing:

PROVISIONAL DIAGNOSIS:

INVESTIGATIONS:

IOPA:
OPG:
Routine Blood Investigations**:**

RADIOGRAPH AND CLINICAL CORRELATION:

DIAGNOSIS:

PEDERSONS INDEX:

CLASSIFICATION	**VALUE**
Spatial relationship	
Mesioangular	1

Horizontal/Transverse		2
Vertical		3
Distoangular	4	

Depth

Level A: High occlusal level	1
Level B: Medium occlusal level	2
Level C: Low occlusal level	3

Ramus Relationship/Space available

Class I: Sufficient space	1
Class II: reduced space	2
Class III: no space	3

Difficulty index

Very difficult	7-10
Moderately difficult	5-7
Slightly difficult	3-4

TOTAL SCORE:

TREATMENT PLANNING:

DETAILS OF SURGERY:

DATE:

START TIME (INCISION):

END TIME (CLOSURE):

SURGICAL PROCEDURE:

Local Anesthesia:

Incision:

Flap:

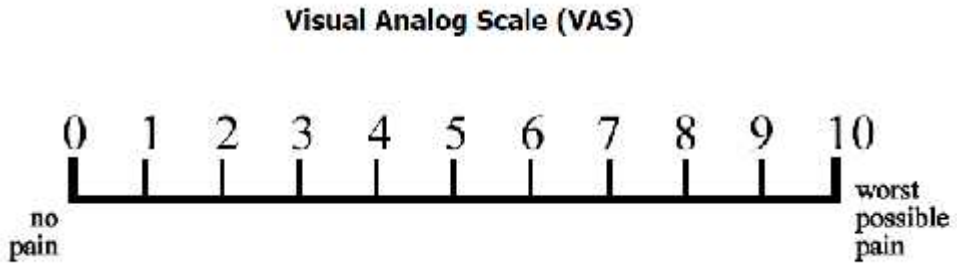
Method of Extraction:

Closure of Site:

MEDICATION:

FOLLOW-UP:

1. **PAIN- V**isual **A**nalog **S**cale (VAS)



Day 1	Day 3	Day 7

MEASUREMENT	Preoperative	Post-operative day 1	Post-operative day 3	Post-operative day 7
The corner of the mouth to the tragus				
The outer canthus of the eye to the angle of the mandible				

The soft tissue pogonion to tragus				

2. SWELLING

3. TRISMUS

	Pre-operative	Post-operative day 1	Post-operative day 3	Post-operative day 7
MOUTH OPENING (MM)				

4. WOUND HEALING – Landry et al. Index

Healing index 1: very poor	Tissue colour: >= 50% of gingiva red Response to palpation: bleeding Granulation tissue: present Incision margin: not epithelialized with loss of epithelium beyond incision margin. Suppuration: present.
Healing index 2: poor	Tissue colour: ≥ 50% of gingiva red Response to palpation: bleeding Granulation tissue: present Incision margin: not epithelialized with connective tissue exposed.
Healing index 3: good	Tissue colour: ≥ 25% and < 50% of gingiva red Response to palpation: no bleeding Granulation tissue: none Incision margin: no connective tissue exposed.
Healing index 4: very good	Tissue colour: <25% of gingiva red Response to palpation: no bleeding Granulation tissue: none Incision margin: no connective tissue exposed.
Healing index 5: excellent	Tissue colour: all tissues pink

	Response to palpation: no bleeding Granulation tissue: none Incision margin: no connective tissue exposed.

Day 1	Day 3	Day 7

5. NUMBER OF ANALGESICS/DAY

Day 1	Day 2	Day 3	Day 4	Day 5

COMPLICATIONS:

- ALVEOLAR OSTEITIS
- PARASTHESIA
- DELAYED WOUND HEALING
- INFECTION:
- ANY OTHER:

STUDY GROUP (CASES)

PATIENT NAME	SEX	AGE	PEDERSON INDEX	PAIN (VAS score)			MEAN SWELLING (in millimeter)				INTER INCISAL DISTANCE (in millimeter)				WOUND HEALING			ANALGESIC USE (TABLETS/DAY)				
				POST OP DAY 1	POST OP DAY 3	POST OP DAY 7	PRE OP	POST OP DAY 1	POST OP DAY 3	POST OP DAY 7	PRE OP	POST OP DAY 1	POST OP DAY 3	POST OP DAY 7	POST OP DAY 1	POST OP DAY 3	POST OP DAY 7	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5
CASE 1	M	21	5	6	2	0	129.33	157	145	133	49	40	42	48	2	3	5	3	3	1	1	0
CASE 2	F	23	5	5	3	0	114	143.67	128.33	114	43	33	37	41	2	3	5	3	3	1	1	0
CASE 3	F	26	6	5	3	1	131.67	159	146	134.33	45	33	33	42	1	2	4	3	3	1	1	0
CASE 4	M	34	5	6	2	0	120	153.67	140	124	46	35	38	44	2	3	4	3	3	1	1	0
CASE 5	M	40	4	6	4	0	125	156	142.33	126	50	42	46	50	1	3	5	3	3	1	1	0
CASE 6	M	30	5	5	3	1	115.33	150.33	135.67	117.33	47	36	41	47	2	3	5	3	3	1	1	0
CASE 7	F	28	6	5	2	1	127.67	154.33	141	130	44	34	37	41	2	3	4	3	3	2	1	0
CASE 8	F	32	6	6	3	0	116.67	140.67	126.67	118.33	46	37	39	43	2	3	4	3	3	1	1	0
CASE 9	M	19	5	5	3	0	111	145	128.33	113	47	39	43	46	1	2	5	3	3	1	1	0
CASE 10	M	30	4	6	3	0	131.67	158	144.67	133.33	45	36	39	44	2	3	4	3	3	1	1	0
CASE 11	F	18	5	6	4	0	119.67	148	134	122	42	31	35	40	2	3	5	3	3	1	1	0
CASE 12	M	21	5	5	2	0	114	147	132	115.33	48	40	43	48	1	3	5	3	3	1	1	0
CASE 13	F	33	6	6	3	0	126	155.67	143.33	128.67	45	35	37	43	1	2	4	3	3	2	1	0
CASE 14	F	20	5	5	2	0	125.67	152.33	140	129	43	33	36	41	2	3	5	3	3	1	1	0
CASE 15	M	26	4	6	3	0	115	144.67	131.33	116	50	41	44	50	2	3	5	3	3	1	1	0
CASE 16	M	22	6	7	3	0	121	151.67	138.67	122.67	51	40	44	48	1	2	4	3	3	1	1	0
CASE 17	F	18	6	6	2	0	117	148	135.67	123	41	31	34	39	2	3	5	3	3	1	1	0
CASE 18	F	26	5	5	2	0	123	152	138	124.33	43	32	34	41	2	3	5	3	3	1	1	0
CASE 19	F	20	6	5	4	0	113	142.67	130.67	114.67	47	35	39	44	2	3	4	3	3	1	1	0
CASE 20	M	23	5	6	2	1	121	147.67	135	122	46	37	42	45	1	2	4	3	3	1	1	0
CASE 21	M	18	4	6	3	0	128.67	158	144.33	134	45	36	38	44	2	3	5	3	3	1	1	0
CASE 22	F	21	6	6	2	0	123	151	138	127.67	48	36	39	47	1	2	5	3	3	1	1	0
CASE 23	M	20	6	5	2	0	120.33	149.33	134	122	44	33	35	42	2	3	4	3	3	1	1	0
CASE 24	F	27	5	5	3	0	115.33	140	126.33	116	46	37	39	43	2	3	5	3	3	1	1	0
CASE 25	M	31	6	6	3	0	130.67	156.67	144.67	135.67	46	36	39	43	2	2	4	3	3	1	1	0
CASE 26	F	19	5	5	4	0	123	149.33	136	125	44	32	36	43	1	2	5	3	3	1	1	0
CASE 27	F	24	6	6	3	0	115.67	140.33	127	116	41	30	32	40	2	3	4	3	3	1	1	0
CASE 28	M	33	6	5	2	0	123	149.33	135.67	124.33	48	38	41	46	1	2	5	3	3	1	1	0
CASE 29	F	24	4	5	3	0	121	147.67	136.33	122.67	46	35	39	45	2	3	5	3	3	1	1	0
CASE 30	F	20	5	6	3	0	132.67	156.33	144	133.67	44	34	37	42	2	3	5	3	3	1	1	0
CASE 31	M	31	6	6	3	0	116	145	129.33	117	50	39	42	47	2	3	4	3	3	1	1	0
CASE 32	F	28	6	6	2	0	126.33	155	141	128.33	46	35	39	45	1	2	5	3	3	2	1	0
CASE 33	M	23	4	5	3	0	119	152	137.33	123.67	46	38	42	46	2	3	5	3	3	1	1	0
CASE 34	F	20	5	5	4	0	130.33	157	144.67	132.67	46	35	37	44	2	3	5	3	3	1	1	0
CASE 35	M	27	6	5	2	0	122	153	141	126.33	50	38	41	47	2	3	4	3	3	1	1	0

CONTROL GROUP (CONTROLS)

PATIENT NAME	SEX	AGE	PEDERSON INDEX	PAIN (VAS score)			MEAN SWELLING (in millimeter)				INTER INCISAL DISTANCE (in millimeter)				WOUND HEALING			ANALGESIC USE (TABLETS/DAY)				
				POST OP DAY 1	POST OP DAY 3	POST OP DAY 7	PRE OP	POST OP DAY 1	POST OP DAY 3	POST OP DAY 7	PRE OP	POST OP DAY 1	POST OP DAY 3	POST OP DAY 7	POST OP DAY 1	POST OP DAY 3	POST OP DAY 7	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5
CASE 1	F	20	6	8	5	1	122	150.67	137	125	42	31	35	40	1	2	4	3	3	3	1	1
CASE 2	M	24	6	7	6	2	114	141.33	126	114	48	38	41	47	1	2	4	3	3	3	1	0
CASE 3	F	26	5	7	5	2	123	155.33	143.33	127	41	29	33	38	1	2	3	3	3	3	1	0
CASE 4	M	28	4	7	6	1	122	153	140	126	50	42	46	50	2	3	4	3	3	3	0	0
CASE 5	F	31	6	7	6	2	122	154.67	139	123	45	33	35	43	2	3	4	3	3	3	1	0
CASE 6	M	19	6	8	6	2	126	153	139	128	47	38	41	45	1	3	5	3	3	3	1	1
CASE 7	F	33	5	7	5	1	112	145.33	132	114	44	33	36	44	1	2	3	3	3	3	1	1
CASE 8	M	29	5	8	6	1	127	159	144.33	129	45	35	37	44	1	2	4	3	3	3	0	0
CASE 9	F	28	6	7	5	1	120.67	147.67	131	123.67	45	33	36	43	2	3	4	3	3	3	0	0
CASE 10	F	26	6	8	6	2	115	145	131.67	119.67	44	33	36	42	1	3	5	3	3	3	1	1
CASE 11	M	18	4	8	5	2	125	155.67	143.33	126.67	46	37	41	46	1	2	4	3	3	3	1	0
CASE 12	M	20	4	7	6	1	122	150.33	139.33	124	47	37	40	46	2	3	3	3	3	3	1	1
CASE 13	F	19	6	8	6	2	126.67	155	140	129.33	42	32	35	39	1	2	3	3	3	3	1	1
CASE 14	F	24	6	7	6	1	112	140	126	114.67	42	30	32	39	2	3	4	3	3	3	1	1
CASE 15	M	36	5	8	6	2	124.33	149	136.67	125.67	51	41	45	49	1	3	4	3	3	3	0	0
CASE 16	F	23	6	8	6	2	117.67	148.67	133.33	118.67	44	32	37	42	1	2	5	3	3	3	0	0
CASE 17	F	31	6	8	5	1	128	159.33	146.67	129	42	31	33	40	1	2	4	3	3	3	1	1
CASE 18	F	34	5	7	6	1	129	155.67	143.67	130	41	31	35	40	2	3	3	3	3	3	0	0
CASE 19	M	31	5	7	6	1	121.33	153.33	141.33	127	48	39	41	47	1	3	4	3	3	3	1	0
CASE 20	M	19	6	8	6	2	118.67	152	139	123.33	46	36	39	45	1	2	5	3	3	3	1	1
CASE 21	M	33	5	8	5	1	120	149.33	135.67	124	51	42	46	51	1	3	4	3	3	3	1	1
CASE 22	F	29	5	7	6	2	117.33	146	132	121.33	46	36	41	45	1	2	3	3	3	3	1	0
CASE 23	F	28	4	7	6	2	118.67	149.67	136.67	124.67	47	38	42	46	2	2	4	3	3	3	0	0
CASE 24	M	36	6	8	6	1	130.33	156	142.67	131	45	35	39	43	1	2	3	3	3	3	0	0
CASE 25	M	23	6	7	6	1	134.67	157	143.67	135	46	35	40	44	1	2	3	3	3	3	0	0
CASE 26	F	31	5	7	6	1	133.67	158	144	134	45	37	40	45	1	3	4	3	3	3	1	0
CASE 27	F	38	5	7	6	2	134.67	158.33	146.67	135.33	43	34	38	42	2	3	4	3	3	3	0	0
CASE 28	M	31	6	8	6	2	116.33	145	132.67	118.67	48	37	42	47	1	2	3	3	3	3	1	0
CASE 29	F	32	6	7	5	1	124.67	150.67	137.33	125.67	42	30	34	40	2	3	4	3	3	3	0	0
CASE 30	M	24	5	7	6	2	130.67	156	143.67	132	50	41	43	48	1	2	4	3	3	3	1	0
CASE 31	M	21	5	8	5	2	129.67	156	142.33	130.67	51	41	46	51	1	2	3	3	3	3	0	0
CASE 32	M	19	6	8	6	1	114.67	148.67	133	118	45	36	38	42	1	2	4	3	3	3	1	1
CASE 33	M	23	6	8	6	2	111.33	144	130.67	115.67	49	38	43	47	1	3	4	3	3	3	1	0
CASE 34	F	22	5	8	5	2	122.33	150	137	124.67	40	31	34	41	2	3	3	3	3	3	1	1
CASE 35	F	32	5	8	6	2	125	153.33	139.33	127.67	42	32	36	44	1	3	4	3	3	3	1	0