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ORIGINAL RESEARCH

ENHANCING SURGICAL HEALING WITH OZONE GEL IN GRAFTLESS CLOSED SINUS LIFT PROCEDURES FOR DENTAL IMPLANTS: A RANDOMIZED CONTROLLED STUDY

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Abstract

Objective: This study aims to provide comprehensive evaluation of ozone gel's effects alongside standard postoperative care in effectively reducing pain and improving soft tissue healing after dental implant procedures with closed sinus lifting done simultaneously.

Materials and Methods: A total of 30 sinuses with an average residual alveolar bone height ranging from 4-7 mm participated in this clinical trial. Following a closed sinus lift procedure, patients were randomized into two groups: one for the ozone gel recipient group and the other for control group. Pain was rated based on the visual analog scale at 24, 48 hours and one week postoperative; soft tissue healing was rated according to the Landry healing index at seven and 14 days. Data were analyzed using appropriate statistical methods, with a significance value considered at $p < 0.05$.

Results: The ozone therapy group showed a statistically significant reduction in pain scores specifically at 24 hours and 48 hours compared to the control group ($p < 0.05$). In terms of soft tissue healing, the ozone group demonstrated improved soft tissue healing rates 7 days postoperatively.However at 14 days postoperatively , it was insignificant .

Conclusion: Ozone therapy has demonstrated considerable potential as an adjunctive treatment following dental implant surgery, effectively mitigating postoperative pain and facilitating soft tissue healing.

Keywords**:** biomaterials, closed sinus lifting, implants, osteotomes, transcrestal sinus floor elevation.

INTRODUCTION

Deficiency in bone volume in the posterior maxilla is one of the most common problems to the implantologist to plan an implant supported prosthesis. This is because the maxillary sinus “MS” in the absence of teeth tends to be pneumatized reducing the height of alveolar ridge, thus hindering the process of installation and/or initial stability of the implant required to the proceed for the prosthetic support sophisticated. Against this problem, authors have created a procedure to increase bone volume of atrophic jaws through the maxillary sinus lifting.[1] The osteotome-mediated transcrestal sinus lift technique was first introduced by Tatum in 1986.

In the original approach, surgeons created a controlled fracture of the sinus floor, placed the implants, and then submerged them during healing.[2] Later, in 1994, Summers refined the method by using a crestal approach—eliminating the need for a window—with specialized osteotomes to elevate the sinus floor, enabling simultaneous implant placement.[3] This technique involves preparing the implant site with tapered osteotomes, which compact the bone laterally, particularly useful in the posterior maxilla.[4]

The effectiveness of dental implants in atrophied posterior maxillae hinges significantly on the success of sinus augmentation. Although surgical methods have

improved, postoperative complications still arise in 9-24% of cases, largely due to bacterial contamination. The sinus membrane's anatomical closeness to the nasal cavity forms a distinct microenvironment where native microbial flora—such as Streptococcus, Staphylococcus, and anaerobic bacteria—can potentially infect graft materials and implant surfaces.[5]

Several strategies have been proposed to reduce postoperative complications, including local or systemic corticosteroid administration, nonsteroidal anti-inflammatory drugs (NSAIDs) and modified incision techniques to reduce tissue trauma. Recently, ozone therapy has been explored alongside these methods to assess its effectiveness in controlling inflammation, alleviating discomfort, and promoting wound healing.[6]

Ozone therapy is a form of bio-oxidative treatment that involves administering a mixture of oxygen and ozone—either as a gas or dissolved in water or oil—to produce therapeutic effects. Recognized as an alternative medicine in the U.S. since the 1880s, it has been widely used across the globe for over a century.[7-8] E. A. Fisch in the 1930's was the first dentist to use ozone therapy in his practice to aid in disinfection and wound healing.It presents great advantages when used as an adjunct to conventional treatments.[9-10] Ozone can be administered in three primary forms: ozonated water, ozonated oil/gel, and oxygen-ozone gas mixtures. When applied to wounds, ozone-infused oils or gels release their active ions upon contact [11].Medical ozone generators precisely control the mixture of medical-grade oxygen and ozone to create therapeutic concentrations[12].

As a powerful oxygenating agent, ozone enhances tissue oxygenation and activates the body's natural healing processes. It works by stimulating growth factor production and supporting hemostasis while improving circulation and immune function [13-14]. Its clinical effectiveness stems from potent antimicrobial activity against bacterial, fungal, and viral pathogens, combined with immune system modulation [15-16].The therapeutic benefits of ozone treatment stem from several key mechanisms: its direct antibacterial and antiseptic effects, ability to improve blood flow and oxygenation, anti-inflammatory properties, and capacity to stimulate wound healing.[17-18]

Oleozon is ozonated pure olive oil, created by infusing a 5% ozone-95% oxygen mixture until the oil transforms from its original greenish liquid state into a whitish gel. This ozonized gel formulation was preferred over ozonated water for oral applications due to its superior retention time in the mouth, enhanced drug penetration capabilities, greater therapeutic efficacy, and better patient acceptability.[19]However, current evidence supporting ozone therapy in oral and maxillofacial surgery remains limited. While research suggests ozone treatment may enhance blood flow, stimulate growth factors, accelerate wound healing, and potentially improve bone regeneration [20],more robust clinical studies are needed to confirm these benefits. Therefore ,this study aims to provide comprehensive evaluation of ozone gel's effects alongside standard postoperative care, in effectively reducing pain and improving soft tissue healing after dental implant procedures with closed sinus lifting done simultaneously.

2.MATERIALS AND METHOD

A total of 19 patients participated in this randomized controlled clinical trial. The patients were selected from the outpatient clinic of the Oral and Maxillofacial Department at Suez Canal University's Faculty of Dentistry. All participants had sinus pneumatization and were seeking fixed prosthetic rehabilitation in the maxillary posterior region.The study was approved by the ethics committee of Suez Canal University's Faculty of Dentistry (Ethical Approval No.: 417/2021)., and all patients were informed of the study's purpose and methodology by their treating dentists. Enrollment took place between December 2021 and December 2023, and written informed consent was obtained from each participant. This study protocol was retrospectively registered on the trial registry "Clinical trials.gov PRS". ClinicalTrials.gov ID is : NCT06604819 and the registration date is 20/9/2024.

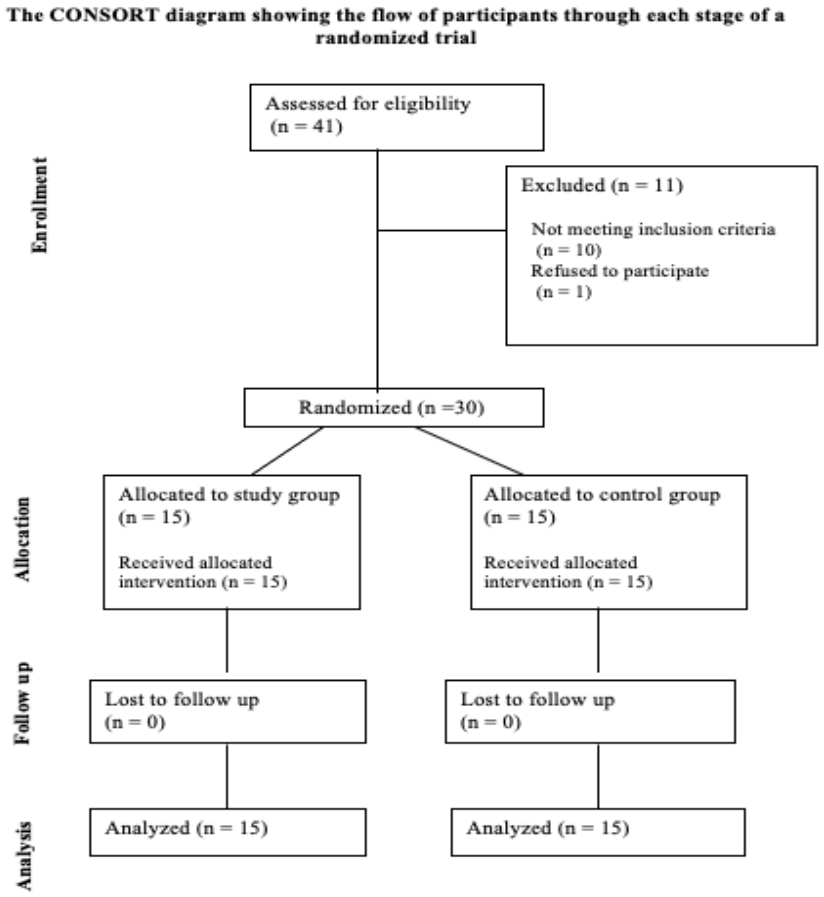
2.1 Sample size calculation

The sample size was calculated using G*Power version 3.1.9.4, based on previous research. To account for potential loss to follow-up, we adjusted the sample size to 30 (15 per group), using a two-sided hypothesis test with an effect size of 1.10 and a power (1-β) of 0.8. The significance level (alpha error) was set at 0.05.[21]Patients were recruited by the outpatient clinic supervisor at the Oral and Maxillofacial Department. After enrollment by the principal investigator, the trial's primary supervisor assigned participants to the intervention. Outcome assessments were conducted by two co-supervisors.

Eligible patients had multiple tooth defects with residual alveolar bone heights between 4 and 7 mm (Table 1) and no systemic conditions or medications that could interfere with bone healing or implant osseointegration. Exclusion criteria included smoking more than 20 cigarettes per day, adjacent tooth pathology, residual roots displaced into the sinus, or maxillary sinus pathosis.This study follows CONSORT guidelines(F. 1).

Table 1. Measurements of amount of preoperative residual bone height .

Sinus no.	Residual bone height (ozone group)	Residual bone height (control group)
1	4mm	7
2	5mm	7
3	6	6.9
4	6.1	5.81
5	6.73	4.69
6	5.16	5.7
7	6.1	6.7
8	5.2	6.5
9	6.7	5
10	6.7	7
11	5	6.5
12	6	4.2
13	5	6.6
14	5.5	7
15	5.6	6.9



Figiura 1. The consort flowchart

Preoperative evaluation

Every enrolled patient underwent radiographic analysis after an initial clinical evaluation. A cone beam computed tomography (CBCT) scan of the maxilla was taken for each participant to accurately measure residual alveolar bone height and assess for any sinus pathology. The CBCT's reconstructed images were then used to determine the appropriate implant dimensions (length and width) for placement (Fig. 2). Additionally, both intraoral and extraoral photographs were obtained for all patients.

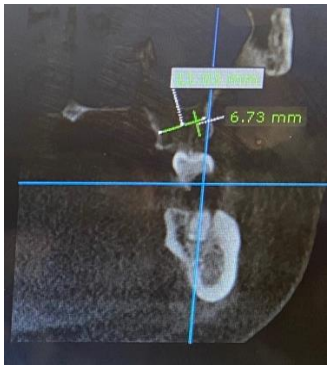


Figure 2. Sections of reformatted sagittal cut from the preoperative CBCT to assess presence of any sinus pathosis and toaccurately measure the residual alveolar bone height

2.1 Surgical Procedure

The study included two groups, each consisting of 30 sinuses (15 sinuses per group). Randomization was performed using *Randomizer.org*, an open online tool, to generate the allocation sequence. This ensured that each participant had an equal chance of being assigned to either the control group or the study group.

- Group A received ozone gel application during implant placement, following sinus membrane elevation via osteotomes.
- Group B underwent graftless osteotome-mediated sinus membrane elevation with simultaneous implant placement.

All patients followed the same surgical protocol. Preoperatively, they were instructed to rinse twice daily for one week with 0.2% chlorhexidine antiseptic mouthwash (*Orovex Mouthwash, Macro Group, Egypt*), including a final rinse approximately two minutes before surgery.

Local anesthesia was administered using 4% articaine with 1:100,000 adrenaline. A full-thickness mucoperiosteal flap was then raised, beginning with a mid-crestal incision (No. 15 blade) and a mesial vertical releasing incision (*Fig. 3*)

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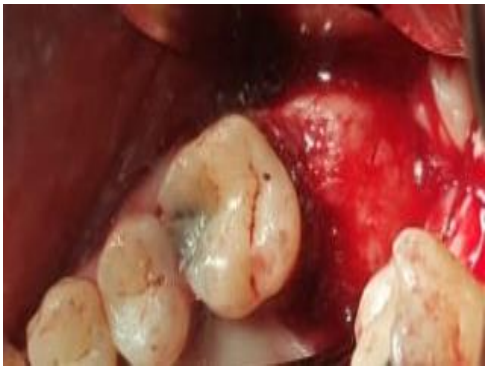
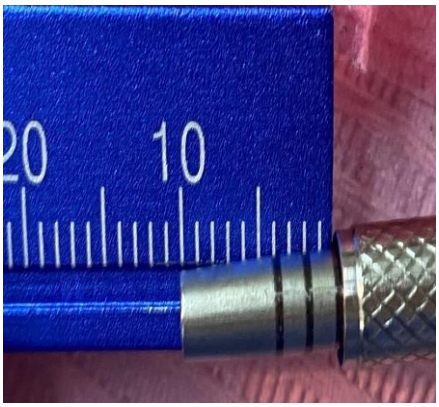


Figure 3. Full thickness mucoperiosteal flap

The osteotomy was initiated using the implant system's pilot drill (Nebiotech, Seoul, South Korea), stopping 1 mm short of the subantral floor. Drilling was carefully performed in an apical direction through the cancellous bone until resistance from the sinus floor's cortical bone was encountered.To prevent accidental sinus penetration, a metal stopper was placed on the osteotome prior to use .The osteotome was then gently advanced with minimal pressure, employing slight rotation and occasional light malleting when necessary to elevate the sinus membrane apically. This membrane elevation process was repeated as needed to achieve the desired lift .Finally, an osteotome matching the diameter of the final drill (which was slightly smaller than the planned implant) was used to complete the sinus floor infracture (Fig. 4- 6)



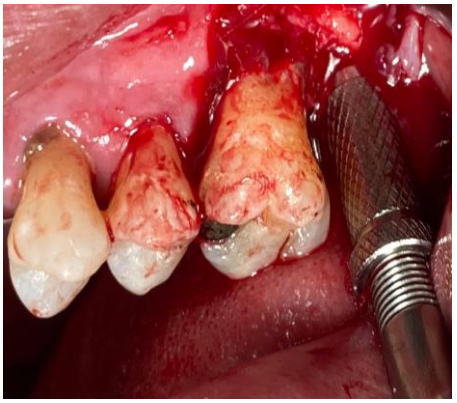
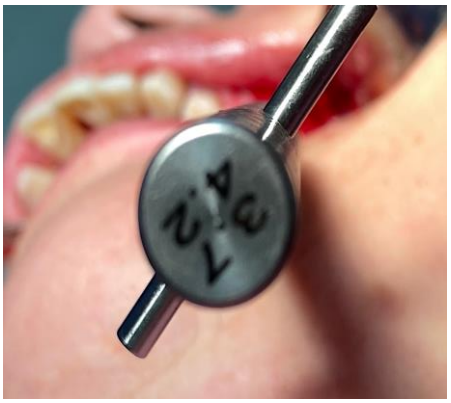



Figure. 4 Penetration height of the osteotome was determined
Figura 5 Sequential use of osteotome s
Figure 6 The last osteotome corresponding in size to the last drill that should be use

For Group A, ozone gel was administered into the osteotomy site prior to implant placement (Fig. 7). The ozone gel was prepared by saturating pure olive oil with 25 µg/ml O_3 gas using the Longevity EXT 120 ozone generator. This process continued for two days or until the oil transformed from its initial greenish hue to a whitish gel consistency. Following gel application, the implant was placed.In contrast, Group B received implant placement without any additional grafting material in the sinus cavity, following the graftless tenting technique (Fig. 8). In each group, a healing abutment was positioned (Fig. 9).primary closure was carried out, and the flap was interruptedly sutured with 4/0 prolene suture .

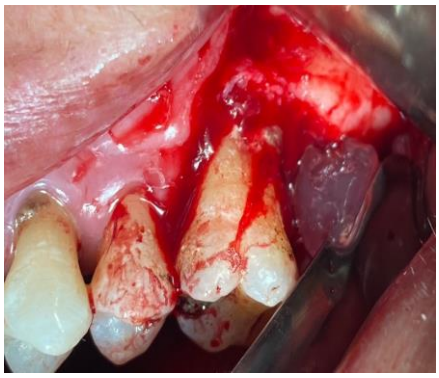
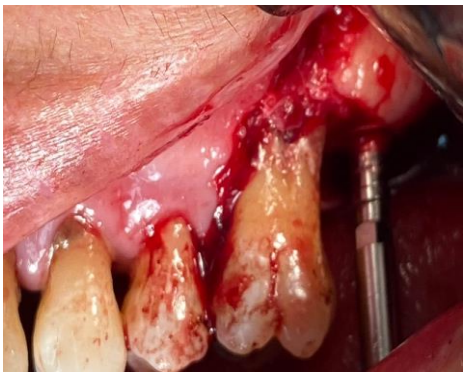
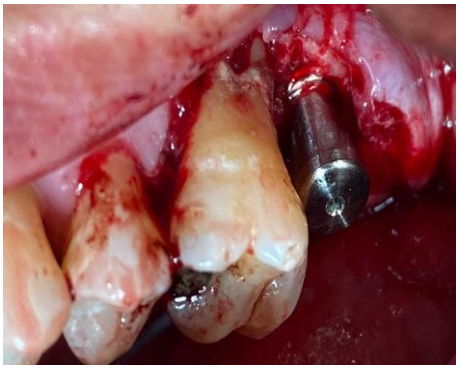




Figure 7 Ozone gel delivered into the osteotomy
Figure 8 Implant placement done
Figure 9 Healing abutment over the implant fixture

2.2| Postoperative instructions and medication

All patients were prescribed a standard postoperative regimen consisting of amoxicillin/clavulanic acid (875 mg/125 mg) twice daily for seven days, with clindamycin 300 mg three times daily as an alternative for penicillin-allergic patients. For pain management, ibuprofen 600 mg was administered every eight hours as needed for three days. Additionally, patients were instructed to use oxymetazoline 0.25% nasal decongestant (two drops per nostril every six hours) for four days.

To protect the surgical site, patients received strict instructions to avoid nose blowing, sneeze with their mouths open, and refrain from any activities that might increase nasal or oral pressure, including heavy lifting, playing wind instruments, balloon inflation, or other actions requiring Valsalva maneuvers during the initial healing period.

2.3| Postoperative follow-up and assessment

2.3.1| Clinical assessment

Pain assessment Postoperative pain was assessed using a 100 mm visual analog scale (VAS) (Fig. 10), with scores categorized as no pain (0-4 mm), mild pain (5-44 mm), moderate pain (45-74 mm), or severe pain (75-100 mm). Participants documented their pain levels at 24- , 48-hour and one week intervals following surgery to evaluate discomfort progression.

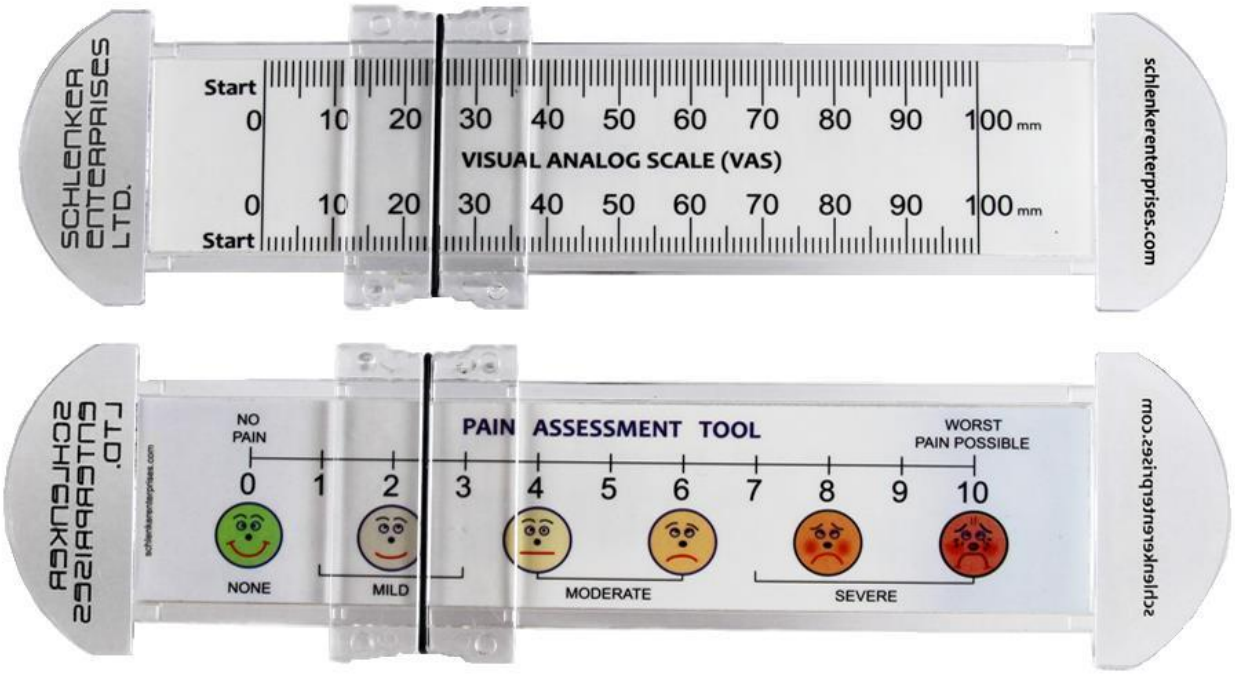


Figure 10. Showing pain visual analogue scale

Soft tissue healing assessment

Soft tissue healing was clinically assessed using standardized criteria: tissue color, bleeding on palpation, granulation tissue formation, epithelialization status, and presence of suppuration. Concurrently, soft tissue healing was objectively measured using the Landry-Turnbull-Howley index at 7- and 14-day postoperative timepoints, allowing for comprehensive monitoring of both acute pain response and longer-term wound recovery.Healing outcomes were graded according to this index (scores 1–5), where:
Score 1 (Very poor): ≥50% redness, bleeding, granulation tissue, non-epithelialized margins, suppuration
Score 2 (Poor): ≥50% redness, bleeding, granulation tissue, non-epithelialized margins, exposed connective tissue
Score 3 (Good): 25–50% redness, no bleeding/granulation/exposed connective tissue
Score 4 (Very good): <25% redness, no bleeding/granulation/exposed connective tissue
Score 5 (Excellent): Complete pink tissue, no bleeding/granulation/exposed connective tissue
Assessments were conducted at scheduled follow-up visits to compare healing progression between study groups.

3 | Statistical analysis

By examining the distribution of the data and applying normalcy tests (Kolmogorov-
By examining the distribution of the data and applying normalcy tests (Kolmogorov-Smirnov and Shapiro-Wilk tests), numerical data were examined for normality. With the exception of VAS scores, the repeated measures ANOVA test was employed for parametric data in order to examine changes over time within each group and to compare the two groups. When the ANOVA test is significant, pairwise comparisons were performed using Bonferroni's post-hoc test. The mean ages of the two groups were compared using the student's t-test. which are non-parametric data, all data displayed a normal (parametric) distribution. The values of the mean, standard deviation (SD), median, and range were displayed for the data.

4 RESULTS

The 19 patients in the study ranged in age from 24 to 59 years old (average 42.9± 4.9 years), with 17 females and 2 males. Both groups received thirty implants. The implants that were inserted ranged in widths from 3.7 to 4.8 mm and in height from 10 to 12 mm (table 2). There was no statistically significant difference found between these two groups.

Table 2.Descriptive statistics and results of Fisher's Exact test and Student's t-test for comparisons between base line characteristics in the two groups

Baseline characteristics	Study (n = 15)	Control (n = 15)	P-value
Gender [n, (%)]			
Male	1 (6.7%)	2 (13.3%)	1
Female	14 (93.3%)	13 (86.7%)	
Age [Mean, SD]	42.9 (4.9)	43.1 (4.5)	0.907
Tooth [n, (%)]			
Premolar	3 (20%)	4 (26.7%)	1
Molar	12 (80%)	11 (73.3%)	

4.1 Clinical Results

All patient data were included for analysis, and no patients were lost for follow-up. During the follow-up period, no implants were lost, and all the implants placed in both groups were successfully loaded and clinically stable at the prosthetic stage.

Effect of ozone gel on pain at 24 hrs. postoperatively

The Median and mean value of VAS pain score after 24 hours was greater in control group than study group. Mann-Whitney test revealed that the difference between control and study groups was statistically significant (U=0, P<0.00001) (Table 3, Fig.11).

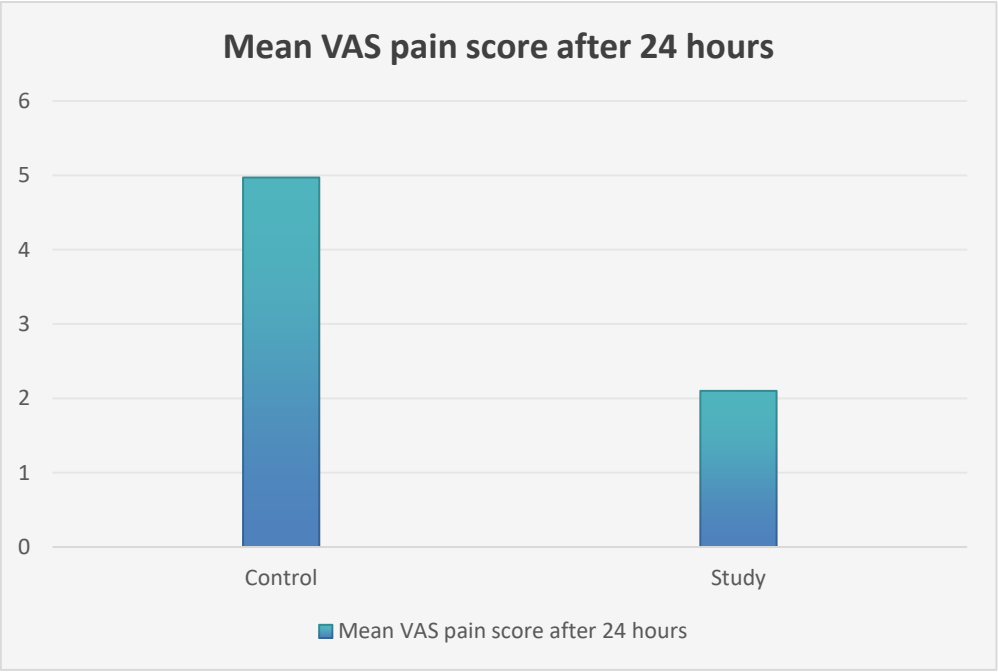


Figure 11. Column chart showing mean value of VAS pain score after 24 hours in studied groups

Table 3. Comparison of VAS pain score after 24 hours between control and study group using Mann-Whitney test

POC	Control	Study
Median	4.8	2
Mean ± SD	4.97±0.86	2.1±0.796
Minimum	3.8	0.6
Maximum	5.8	3.5
U value	**0***	
Z value	**4.64554**	
P value	**< 0.00001***	

*significant at U< 72, p<0.05

Effect of ozone gel on pain at 48 hrs. postoperatively

VAS scores were recorded at 48 hours postoperatively and the values obtained are presented in Table 4 and Fig. 12. The VAS scores for the control group after 48 hours were 3.12±0.84 and for the study group after 48 hours were 0.6±0.455"Thus, the mean values in the study group were significantly lower compared to those in the control group.There was statistically significant difference between pain scores in the two groups.

Table 4. Comparison of VAS pain score after 48 hours between control and study group using Mann-Whitney test

POC	Control	Study
Median	3.4	0.6
Mean ± SD	3.12±0.84	0.6±0.455
Minimum	1.3	0
Maximum	4.2	1.6
U value	**1***	
Z value		**4.60407**
P value		**< 0.00001***

*significant at U< 72, p<0.05

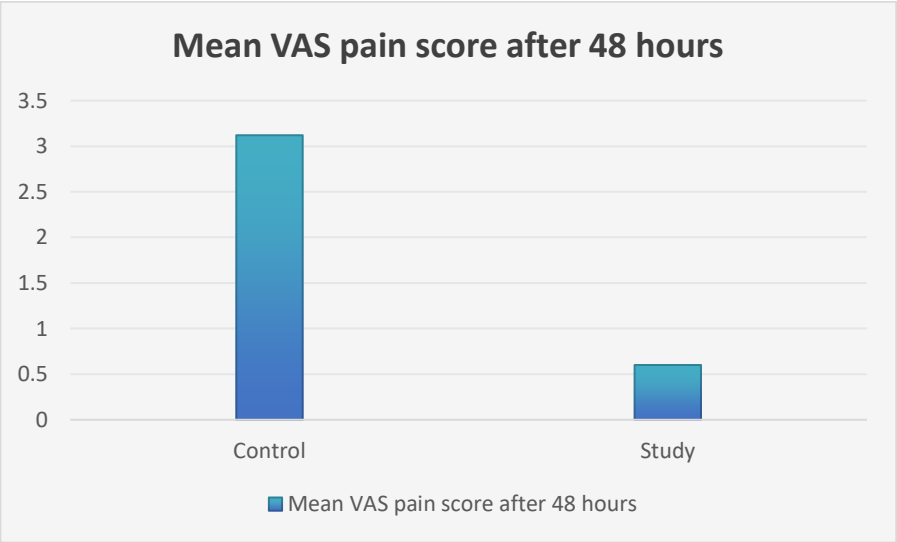


Figure 12. Column chart showing mean value of VAS pain score after 48 hours in studied groups.

Effect of ozone gel on pain at 7 days postoperatively

I. Pain (VAS scores)

There was no statistically significant difference between pain scores in the two groups (*P*-value = 0.763, Effect size = 0.106).

Table 5. Descriptive statistics and results of Mann-Whitney U test for comparison between pain (VAS scores) in the two groups after 7 days.

Study (n = 15)		**Control (n = 15)**		***P*-value**	***Effect size (d)***
Median (Range)	**Mean (SD)**	**Median (Range)**	**Mean (SD)**		
4 (2, 6)	**4 (1.3)**	**4 (2, 6)**	**4.1 (1.4)**	**0.763**	**0.106**

**: Significant at P ≤ 0.05*

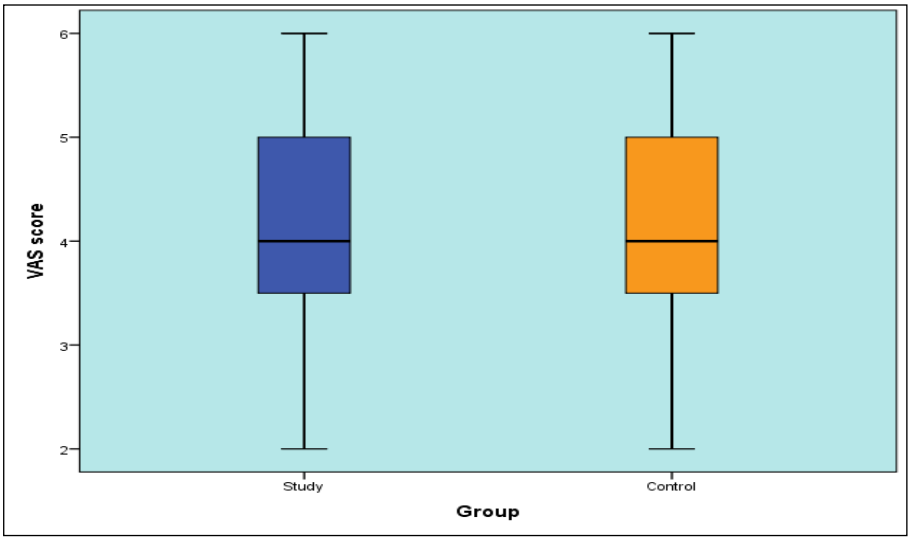


Figure 13. Box plot representing median and range values for pain scores in the two groups at 7 days

Effect of ozone gel on soft tissue healing at 7 days postoperatively

Soft tissue healing was evaluated after seven days by using the tissue healing index. The mean healing index scores are presented in Table 6 and Fig. 14. The mean healing index score for the control group was 7.94±0.135 and the mean healing index score for the study group was 8.79±0.175. Thus, the mean values of the tissue healing index in the study group were significantly higher compared to those in the control group (U=0, P<0.00001) (Table 6 , Fig.14).

Table 6. Comparison of soft tissue healing score after 7 days between control and study group using Mann-Whitney test

POC	**Control**	**Study**
Median	7.9	8.8
Mean ± SD	7.94±0.135	8.79±0.175
Minimum	7.7	8.5
Maximum	8.2	9.1
U value	**0***	
Z value		**-4.64554**
P value		**< 0.00001***

*significant at U< 72, p<0.05

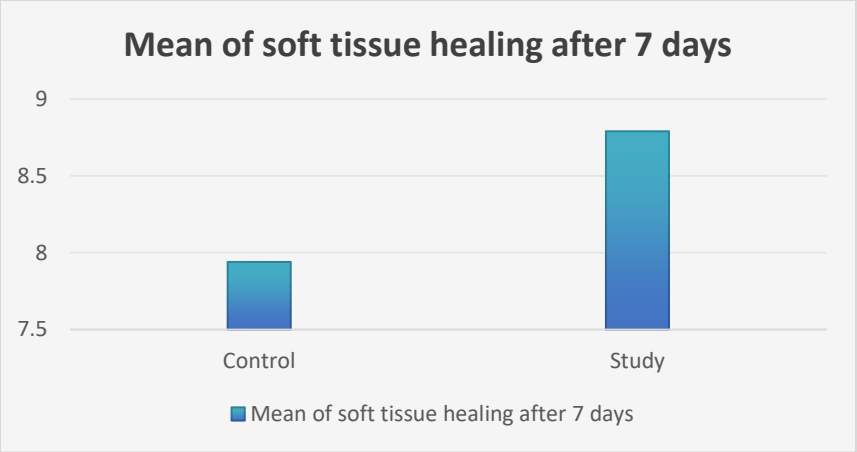


Figure 14. Column chart showing mean value of soft tissue healing score after 7 days in studied groups.

Effect of ozone gel on soft tissue healing at 14 days postoperatively

Soft tissue healing was evaluated after fourteen days by using the tissue healing index. The mean healing index scores are presented in Table 7 and Fig. 15. The mean healing index score for the control group was 9.53±0.07 and the mean healing index score for the study group was 9.64±0.082. The Median and mean value of soft tissue healing score after 14 days was greater in study group than control group. However, Mann-Whitney test revealed that the difference between control and study groups was statistically insignificant (U=77, P<0.0735) (Table 7, Fig.15).

Table.7 Comparison of soft tissue healing score after 14 days between control and study group using Mann-Whitney test

POC	Control	Study
Median	9.6	9.6
Mean ± SD	9.53±0.07	9.64±0.082
Minimum	9.5	9.5
Maximum	9.7	9.8
U value	**77***	
Z value	**-1.45173**	
P value	**< 0.0735***	

*significant at U< 72, p<0.05

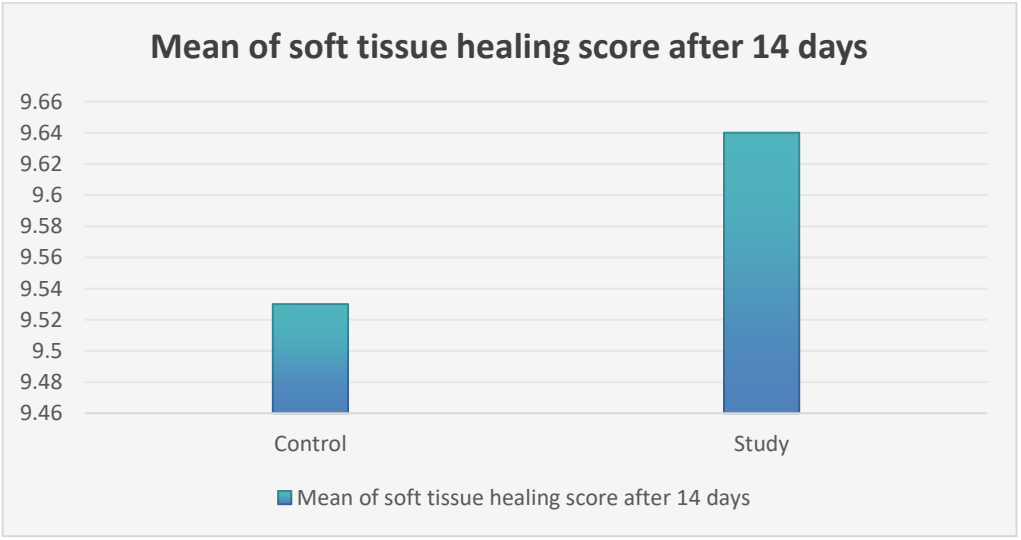


Figure 15. Column chart showing mean value of soft tissue healing score after 14 days in studied groups.

Effect of ozone gel on clinical infection parameters

There were no signs of postoperative infection including sinusitis and purulent discharge, dehiscence, or oroantral communications in any of the patients, who all healed without incident. The findings of this study suggest that the application of ozone gel significantly contributes to the reduction of postoperative pain, and improved wound healing outcomes.

5 DISCUSSION

The osteotome-mediated sinus floor elevation technique, whether performed with or without graft material, demonstrates favorable clinical outcomes including high implant survival rates, significant intrasinus bone formation, and low complication rates. Nevertheless, there remains a paucity of reported data regarding patients' subjective experiences, including postoperative recovery perceptions and satisfaction levels with the surgical procedure [22].

Ozone therapy has emerged as a promising therapeutic modality, demonstrating clinically significant antimicrobial, anti-inflammatory, and biostimulatory properties with applications across medical and dental disciplines. The therapeutic efficacy of ozone is mediated through two primary biological mechanisms: the generation of reactive oxygen species (ROS) and the formation of lipid oxidation products (LOPs). These molecular agents function as signaling mediators that regulate three key physiological processes: wound healing cascades, modulation of inflammatory responses, and controlled release of growth factors. The observed acceleration in tissue repair may be attributed to ozone's dual capacity to simultaneously reduce excessive inflammation while promoting neovascularization and immune cell activation [23].

Thus, this study aims to provide comprehensive evaluation of ozone gel's effects alongside standard postoperative care in effectively reducing pain and improving soft tissue healing after dental implant procedures with closed sinus lifting done simultaneously.y.In the present research, patient's age was above 18 years old. There was no statistically significant difference between gender, tooth distributions in the two groups. Regarding gender, proportion of females was higher than males by 90% versus 10 % with a ratio 10:1, this may be attributed to that females are keener about teeth replacement for the sake of esthetic and functional purposes.

Surgical trauma induces upregulation of key biochemical mediators of inflammation and pain, including serotonin, prostaglandins, bradykinin, and histamine [24].Our findings demonstrate the clinical utility of the Visual analogue score "VAS" for pain assessment due to its cross-cultural applicability and patient comprehension advantages which indicates the presence of postoperative pain . While conventional management of postoperative pain relies on analgesic medications with potential systemic adverse effects [25] ,Notably Velio Bocci's theory elucidated ozone's intrinsic analgesic mechanism through vasodilator induction, particularly via nitric oxide (NO) secretion , providing a scientific basis for its pain-modulating effects [26].

There was no statistically significant difference between pain scores in the two groups (P-value = 0.763, Effect size = 0.106).This result was in accordance with several studies published by Taschieri et al. in 2017 and 2018 where they confirmed that the crestal sinus lift approach had less patient morbidity as smaller mucoperiosteal flaps are required when compared with the lateral window procedure resulting in a significantly better postoperative healing (e.g., less inflammation, less pain and faster recovery including normal daily activities) [27]. The effect of ozone on the stimulation of fibroblasts during oral surgery, and less postoperative pain, agrees with our results of faster recovery and better pain control of patients [28].

Ozone demonstrates significant therapeutic effects on peri-implant tissues through its dual capacity to regulate microbial colonization and enhance tissue oxygenation [29]. These combined mechanisms create an optimal microenvironment for wound healing. The observed improvements in our ozone-treated cohort align with ozone's established biological properties, including its ability to potentiate oxygen metabolism and modulate immune responses, which collectively contribute to enhanced tissue regeneration.These systemic effects complement its well-established antimicrobial and wound healing properties, as confirmed by Reedy et al. [30] and Patel et al. [32], making it particularly valuable for managing oral ulcerations and herpetic lesions. These results are in accordance with our Current research results which demonstrates ozone's multifaceted biological effects.

6 CONCLUSION

Within the limitations of this study, Current evidence consistently supports the potential of ozone therapy to enhance postoperative outcomes in implant and sinus lifting surgeries. The dual therapeutic mechanisms—combining antimicrobial efficacy with tissue regenerative properties—suggest its value as an adjunct to standard treatment protocols. However, further randomized controlled trials with extended follow-up periods and larger patient cohorts are required to substantiate these preliminary findings and strengthen their clinical applicability. These additional

investigations would help elucidate the precise mechanisms by which ozone enhances wound healing while providing more robust clinical evidence for its use as an adjunctive therapy.

Abbreviations

MS: Maxillary Sinus

CBCT: Cone beam computed tomography

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Authors' contributions

The authors' responsibilities were as follows: Study design: DY and ME; data collection: DY; analysis and interpretation of the data: DY, RR, RS and ME; drafting of the manuscript: DY; critical revision of the manuscript: RS and ME; study supervision: RR and ME. All authors read and approved the final manuscript.

DECLARATION

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Availability of data and materials: The datasets generated during and analyzed during the current study are available from the corresponding author upon request.

Ethics approval and consent to participate: The study and the confidentiality procedures were explained to each participant. All participants provided written informed consent. The study's morality and ethics were validated by the Suez Canal University Faculty of Dentistry's Ethics Committee (Ethical Approval No.: 417/2021).

Consent for publication: Not applicable as all the patients signed a written informed consent stating their approval to participate in a research project. Additionally, no details on individuals are reported within the manuscript.

Competing interests: The authors declare that they have no competing interests.

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