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THE EFFECT OF A NOVEL BONE BIOACTIVE ORAL RINSE (THERAVEX) ON EARLY SOFT-TISSUE WOUND HEALING FOLLOWING SIMPLE TOOTH EXTRACTION IN PATIENTS WITH TYPE 2 DIABETES MELLITUS: A PROSPECTIVE COMPARATIVE CLINICAL STUDY

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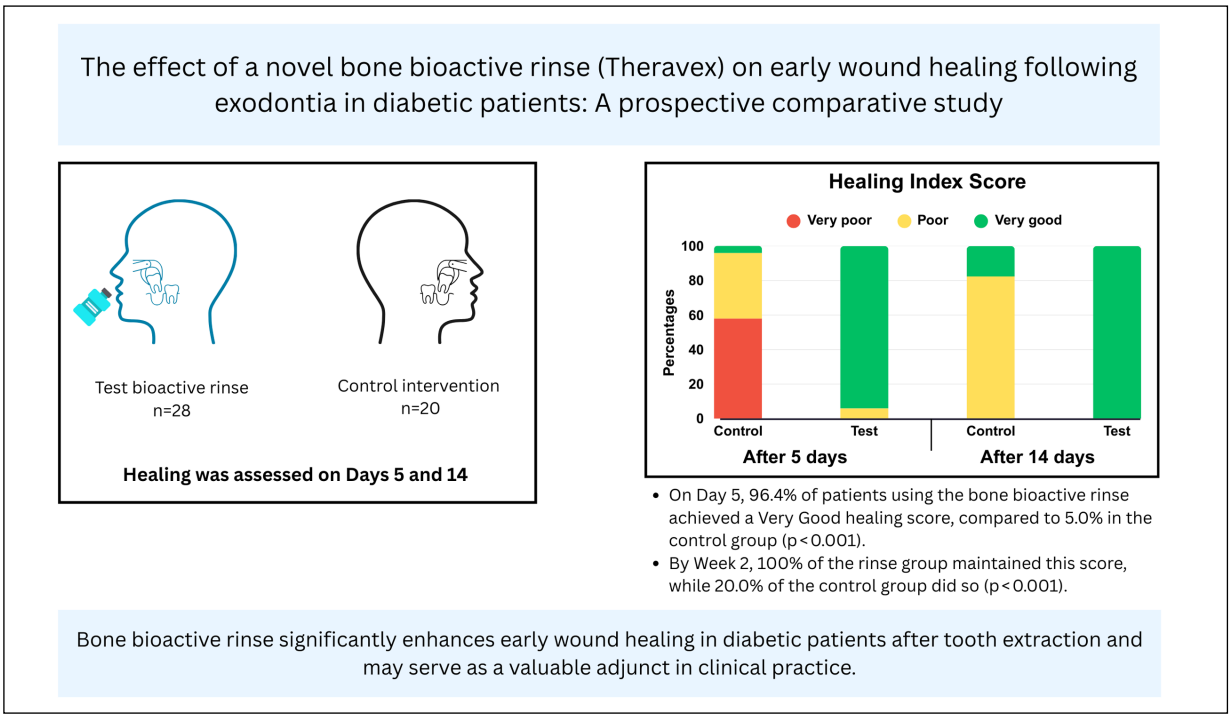
ABSTRACT – *Objective:* The aim of the study was to assess the effectiveness of bone bioactive rinse in promoting early wound healing following simple tooth extraction in diabetic patients.

Materials and Methods: A prospective comparative study was conducted at King Abdulaziz University Dental Hospital between March and May 2025. The study included 48 diabetic patients undergoing simple tooth extractions. Patients were assigned to either a test group (n=28) that used a bone bioactive rinse or a control group (n=20) that received no intervention. Healing was assessed on days 5 and 14 using a modified Early Healing Index (scale 1-5).

Results: A total of 48 diabetic patients (mean age: 51.25 ± 11.8 years) were enrolled into the bone bioactive rinse group (n=28) and the control group (n=20). While socket dimension measurements (width, height, area) were not significantly different between groups at either day 5 or 2 weeks post-extraction ($p > 0.05$), the clinical healing index showed a marked difference. On day 5, 96.4% of patients in the rinse group achieved a 'very good' healing score, compared to only 5% in the control group ($p < 0.001$). By week 2, 100% of the test group maintained high healing scores, *vs.* 20% in the control group ($p < 0.001$). No significant gender-related differences in healing outcomes were observed ($p > 0.3$).

Conclusions: Bone bioactive rinse significantly enhances early wound healing after tooth extraction in diabetic patients and may serve as a valuable adjunct in clinical practice.

KEYWORDS: Bone bioactive liquid, Oral surgery, Diabetes, Oral wound healing, Bone resorption, Early wound healing index score.



Graphical Abstract. Bone bioactive rinse significantly enhances early wound healing in diabetic patients after tooth extraction and may serve as a valuable adjunct in clinical practice.

INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder that has become a significant global public health issue[1]. It is characterized by persistent hyperglycemia and impairs various physiological processes, including wound healing, due to compromised vascular function, immune response, and tissue regeneration capacity[1]. Diabetes mellitus is characterized by inadequate insulin secretion (type 1), inadequate insulin action (type 2), or both[2]. The autoimmune etiology of type 1 diabetes primarily causes β-cell loss in the pancreas, leading to insufficient insulin production. In comparison, features of type 2 diabetes include peripheral insulin resistance and pancreatic β-cell insufficiency[1].

Poor blood sugar control leads to uncontrolled diabetes, consequently, significantly affecting patients' quality of life, shortening their life expectancy, and increasing associated medical costs[3]. Moreover, diabetic patients frequently experience complications following tooth extraction, such as delayed healing, infection, and alveolar osteitis, which can affect their quality of life and pose clinical challenges[4,5]. Efforts to improve post-extraction healing outcomes in diabetic patients have led to growing interest in bioactive materials[6]. These materials interact biologically with tissue to stimulate regeneration and are often derived from synthetic or natural sources. They are valued for their non-toxicity, biodegradability, and biocompatibility[6,7].

The bone bioactive liquid is formulated as a phosphate-buffered saline (PBS) containing calcium chloride ($CaCl_2$) and magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$)[8]. It facilitates healing by creating a hydrophilic environment that supports ionic interactions with blood plasma and wound-related cells, such as endothelial and epithelial progenitors[8,9]. Calcium ions are essential in wound healing, particularly as extracellular signaling molecules and intracellular messengers for keratinocytes and fibroblasts[10]. They also play a central role in initiating the coagulation cascade in platelet-rich plasma (PRP) therapy, thus promoting hemostasis and early tissue repair[11]. Magnesium, another key ion in the bone bioactive rinse, is a cofactor in many enzymatic reactions and stabilizes cell membranes. It has demonstrated antimicrobial potential, particularly in acidic conditions, where it can reduce bacterial viability more effectively than other salts such as sodium chloride (NaCl) or potassium chloride (KCl)[12,13]. This makes magnesium particularly valuable in the oral cavity, where microbial control is critical for healing.

Antimicrobial mouth rinses are routinely used in oral surgical procedures to help control microbial colonization and reduce the risk of postoperative infection[14,15]. A previous study[9] suggested that bone bioactive mouthwash may offer significant benefits over conventional agents such as chlorhexidine (CHX) in promoting soft tissue

healing and reducing post-extraction pain. These early findings deserve further validation, especially in vulnerable populations such as diabetic patients. Given the high prevalence of diabetes and the well-established challenges of wound healing in this population, the objective of this study is to evaluate the clinical effectiveness of a bone bioactive rinse in enhancing early wound healing after simple tooth extraction in diabetic patients. The research question for this study is: is the use of a bone bioactive rinse effective in promoting early wound healing after simple tooth extraction in diabetic patients compared with no intervention? The null hypothesis (H_o) is that the use of a bone bioactive rinse has no effect on early wound healing following simple tooth extraction in diabetic patients compared with no intervention.

MATERIALS AND METHODS

Study design and ethical considerations

This study was designed as a non-randomized, prospective comparative clinical study. All patients who underwent simple tooth extraction and met the eligibility criteria were consecutively enrolled. Patients were allocated to groups (test or control) through a shared decision-making process between the patient and the treating dentist, based on clinical considerations and patient preference. Ethical approval was obtained from the King Abdulaziz University Biomedical Ethics Committee (approval No. 145-11-24), dated March 18, 2025. The manuscript was prepared following the STROBE Statement Checklist and adhered to the Helsinki Declaration.

The study was conducted at the Dental Hospital, Department of Oral and Maxillofacial Surgery (OMFS), King Abdulaziz University (KAU), in Jeddah, Saudi Arabia, between March and May 2025. All patients were provided with a participant information sheet and provided written informed consent before enrollment.

A power analysis was performed using G*Power 3.1 software (Franz Faul, Universität Kiel, Germany) to determine the required sample size. Based on a significance level of $\alpha = 0.05$, a power of 95%, and an effect size of 0.50, the estimated minimum sample size was 34 participants. To account for potential dropouts during follow-up. A total of 71 patients were initially invited to participate in the study. Twenty patients were excluded for failing to meet the inclusion criteria. A total of 51 patients were enrolled in the study. During the follow up period, three participants were lost, resulting in a final analyzed sample of 48 patients (Figure 1).

Eligibility criteria

The inclusion criteria included adult patients aged between 18 and 65 years, diagnosed with type 2 diabetes mellitus (both controlled and uncontrolled), scheduled for simple tooth extraction, and presenting with a healthy periodontium, gingivitis, or periodontitis. Additionally, participants must not have received any local or systemic antibiotic or antiseptic treatments within the three months preceding their study enrollment. The exclusion criteria included the presence of any systemic diseases other than type 2 diabetes that could potentially impair wound healing, the need for surgical extraction or any extraction requiring suturing, and individuals who smoke or use tobacco products. All participants were informed of their right to voluntarily withdraw from the study at any time, without prejudice or a requirement to justify.

Clinical intervention and procedures

All dental extraction procedures were performed by general dentists and oral and maxillofacial surgery specialists and consultants at the Department of OMFS, King Abdulaziz University. A total of 51 patients were assigned to two groups:

- Test group: 31 patients (14 males and 17 females) received a bone bioactive rinse (Theravex, Kafou Dental Medical Company Bio-intelligent Technology Systems, Riyadh, Saudi Arabia), consisting of a phosphate-buffered saline (PBS) solution containing 1.35 mM $CaCl_2$ and 0.75 mM $MgCl_2 \cdot 6H_2O$, characterized by a net negative charge. The rinse was supplied through routine hospital procurement.
- Control group: 20 patients (8 males and 12 females) received no intervention following tooth extraction.

All extractions were performed under local anesthesia, using one of the following anesthetic agents: 2% Lidocaine with 1:100,000 epinephrine, 2% Mepivacaine, or 4% Articaine with 1:100,000 epinephrine. Following extraction, a sterile gauze was applied to the socket in both groups, and patients were provided with verbal and written postoperative instructions.

Participants in the test group were instructed to rinse with 15 mL of the bone bioactive rinse twice daily, following their routine oral hygiene practices, for 14 days. They were advised to refrain from eating or drinking for one hour after each rinse. Follow-up assessments were conducted on day 5 and 14 days postoperatively. During the second follow-up visit, two investigators independently evaluated wound healing using the Early Healing Index (EHI)[16]. The extraction sockets

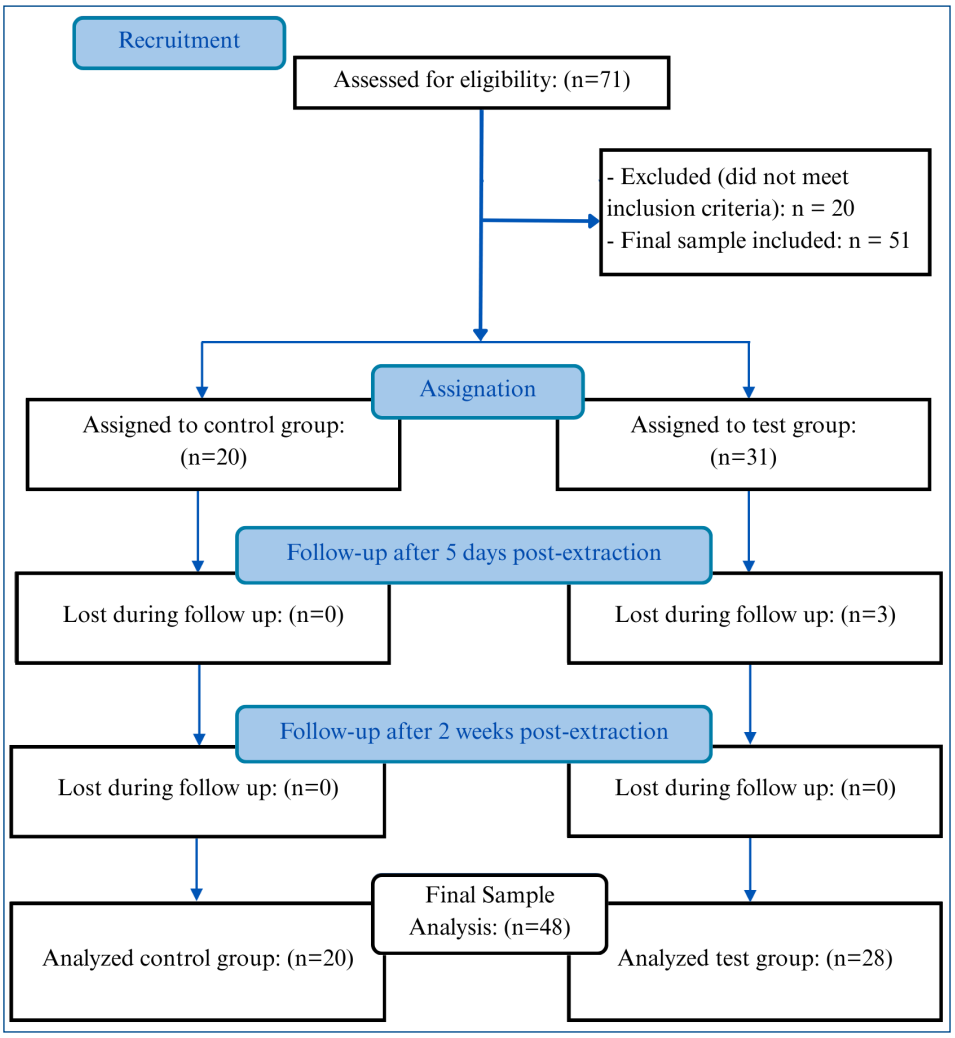


Figure 1. Flow diagram of patient recruitment, allocation and follow-up.

were measured in two dimensions (width and height) using a Hu-Friedy PCPUNC 15 periodontal probe (Hu-Friedy, Chicago, IL, USA). Each site was assigned an EHI score ranging from 1 (very poor healing) to 5 (excellent healing):[16]

- A score of 1 indicates very poor early wound healing due to the presence of two or more of the following signs: 75-100% of red gingival tissue, bleeding on palpation, granulation tissue, and suppuration ranging from 50 to 75%.
- A score of 2 indicates poor early wound healing due to the presence of 50-75% of red gingival tissue, bleeding on palpation, granulation tissue, and suppuration ranging from 50% to 75%.
- A score of 3 indicates good early wound healing due to 25-50% of red gingival tissue, as well as the absence of bleeding on palpation, granulation tissue, and suppuration.
- A score of 4 indicates very good early wound healing when there is less than 25% of red gingival tissue, and an absence of bleeding on palpation, granulation tissue, and suppuration.
- A score of 5 indicates excellent early wound healing when the gingival tissue is pink, and there is an absence of bleeding on palpation, granulation tissue, and suppuration.

Intraoral photographs of the extraction sites were captured at baseline (immediately post-extraction) and during follow-up visits using a Sony Alpha a7R III full-frame mirrorless camera equipped with a Sony SEL90M28G FE 90 mm F2.8 Macro G OSS lens. The percentage of red tissue within the extraction socket was determined by measuring the total socket area and the red tissue area in two dimensions (width and height) using a Hu-Friedy PCPUNC 15 periodontal probe (Hu-Friedy, Chicago, IL, USA) (Figure 2). Bleeding on palpation was assessed by applying gentle digital pressure using a sterile cotton-tipped applicator (Q-tip) held between the examiner's index finger and thumb, parallel to the occlusal plane. The presence or absence of bleeding was determined by visual inspection of the Q-tip following palpation.

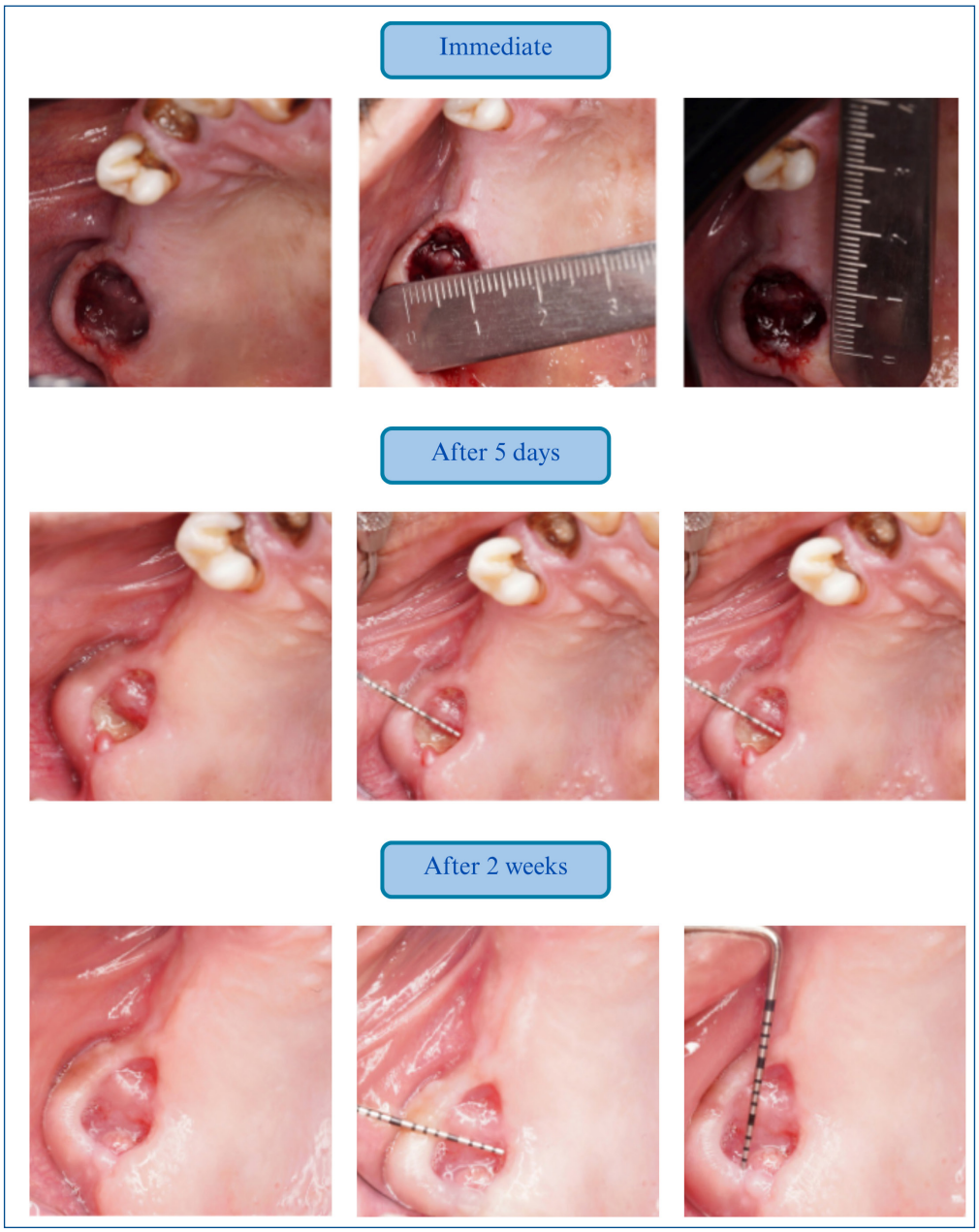


Figure 2. Examples of intraoral photographs taken immediately after extraction, after 5 days, and after 2 weeks.

The early wound-healing evaluation was conducted during the first follow-up visit, five days post-extraction, as postoperative pain typically subsides by the third day. However, if pain persists or intensifies beyond the fifth day and the extraction site shows no signs of adequate healing, this may indicate alveolar osteitis (dry socket). Therefore, a five-day follow-up was chosen to allow early healing assessment and identification of potential complications.

Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics version 27 (IBM Corp., Armonk, NY, USA). Continuous variables were summarized as means and standard deviations (SD), while categorical variables were presented as frequencies and percentages. Parametric tests, such as the independent-samples *t*-test, were used to compare continuous outcomes between groups. Group differences in categorical variables (e.g., healing index score categories, presence of bleeding) were assessed using the Chi-square test of independence. To assess healing progression over time, particularly in socket area measurements, a repeated measures ANOVA was conducted across three time points (immediate, day 5, and week 2).

RESULTS

Participant characteristics

Following the dropout of three participants from the test group during the follow-up stage, a total of 48 diabetic patients were included in the final analysis. The final sample comprised 28 patients (58.3%) in the bone bioactive rinse group and 20 patients (41.7%) in the control group. The overall mean age of participants was 51.25 years (SD=11.8), and the mean HbA1c level was 6.75% (SD=0.6). The majority of extractions involved molar teeth (68.8%), and more than half of the participants exhibited poor oral hygiene (52.1%) (Table I).

Comparison of healing outcomes

There were no significant differences in the mean socket dimensions (width, height, area) and red area measurements between the groups at day 5 or 2 weeks post-extraction ($p > 0.05$).

Healing Index Score and clinical indicators

The healing index score, a clinical measure of wound healing quality, was significantly different between the two groups (Figure 3). At Day 5, 96.4% (n = 27) of participants in the bone bioactive rinse group achieved a Very Good healing score (95% CI: 80.5%-99.3%), compared to 5.0% (n = 1) in the control group (95% CI: 0.9%-23.6%) ($p < 0.001$). At Week 2, 100% (n = 28) of the bone bioactive rinse group maintained a Very Good score (95% CI: 87.7%-100.0%), whereas 20.0% (n = 4) of the control group achieved a Very Good score (95% CI: 8.1%-41.6%) ($p < 0.001$). No significant differences were observed between male and female patients in terms of red area percentage or healing index score at Day 5 or Week 2 ($p > 0.05$).

DISCUSSION

This study investigated the effectiveness of a bone bioactive rinse in promoting early wound healing following simple tooth extraction in patients with type 2 diabetes mellitus. Although objective socket dimensions (width, height, and area) did not differ significantly between groups, the clinical healing quality, as assessed by EHI, was markedly superior in the bone bioactive rinse group. These results provide important insights into the adjunctive role of bioactive agents in improving soft tissue healing in medically compromised populations. The significantly higher EHI scores observed in the test group at both day 5 and week 2 post-extraction support the rejection of the null hypothesis, indicating a clear benefit of the intervention.

Notably, the majority of patients in the bone bioactive rinse group achieved 'very good' healing scores at both follow-up visits, whereas the control group exhibited substantially less healing. This consistent pattern underscores the bone bioactive rinse's short-term clinical effectiveness in enhancing early wound-healing quality in diabetic patients. These results are consistent with previous studies, including a randomized controlled trial[9] that demonstrated significantly improved early wound healing and faster pain reduction starting on day 4.

Table I. Demographics of study participants.

Demographics		Count	Percentages
Test/Control	Test	28	58.3
	Control	20	41.7
Gender	Male	22	45.8
	Female	26	54.2
Nationality	Saudi	36	75.0
	Non-Saudi	12	25.0
Medical history	Diabetes	48	100.0
Oral hygiene	Poor	25	52.1
	Fair	10	20.8
	Good	13	27.1
Tooth number	Incisor/Canine	1	2.1
	Premolar	14	29.2
	Molar	33	68.8
Extraction type	Simple	48	100.0
Suture	None	48	100.0

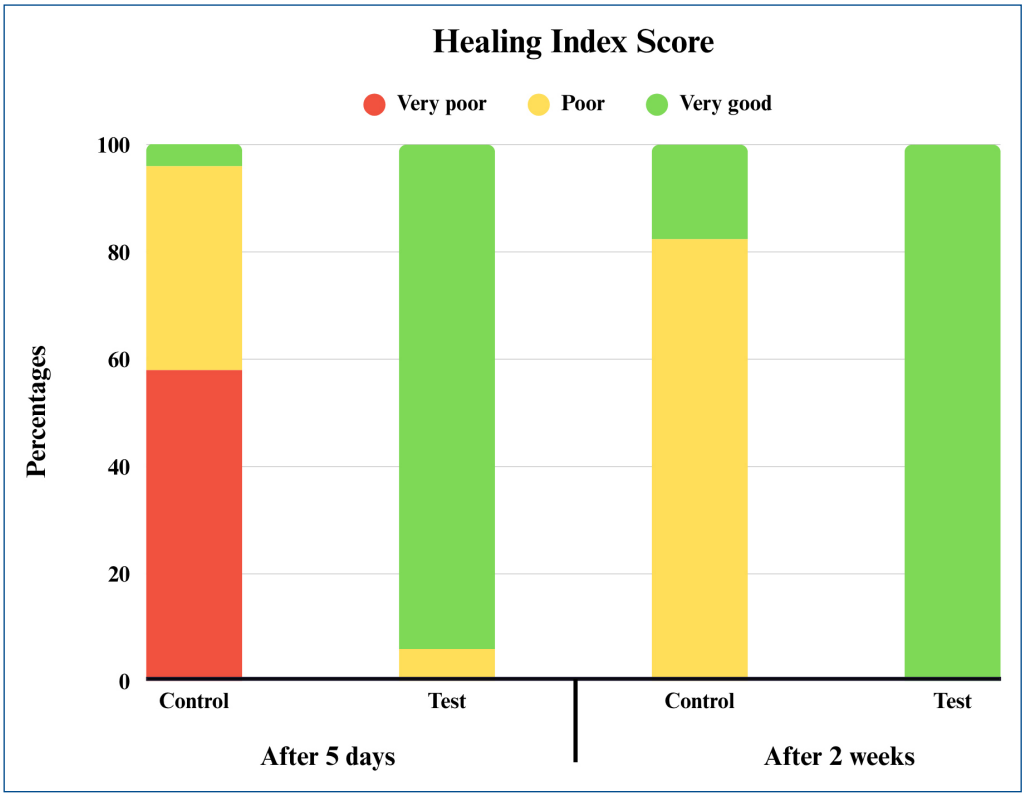


Figure 3. Healing index score and clinical indicators.

Moreover, diabetic patients are at increased risk for delayed healing and complications such as alveolar osteitis, due to impaired immune response and microvascular dysfunction[6]. The present study supports the existing body of evidence by demonstrating that the adjunctive use of a bone bioactive rinse can significantly improve clinical healing outcomes in this high-risk population.

The bone bioactive rinse contains calcium chloride and magnesium chloride in a phosphate-buffered saline base, forming a solution that promotes healing through both biochemical and biophysical mechanisms. Calcium ions play a central role in regulating various stages of wound healing by acting as secondary messengers in the activation, proliferation, and migration of keratinocytes and fibroblasts[8,10]. Furthermore, calcium promotes clot stability and contributes to angiogenesis, which is crucial in the early phases of wound healing[11]. Magnesium, another essential cation, supports cellular structural stability, DNA synthesis, and enzymatic functions involved in tissue regeneration. Magnesium ions exert antimicrobial effects and may enhance the wound environment by reducing the risk of infection, particularly in diabetic individuals who have impaired immune responses[14]. These theoretical mechanisms align with the observations in this study, confirming that bone bioactive rinse enhances the biological environment for soft tissue repair.

Surprisingly, there were no significant differences in objective socket dimensions between groups, despite the evident differences in clinical healing quality. This may be attributed to the nature of soft-tissue healing rather than to measurable dimensional shrinkage. The width and height of an extraction socket may not change significantly over two weeks, especially in the absence of suturing, which was uniformly excluded in this study. In contrast, indicators such as tissue color, bleeding, and granulation tissue, core elements of the modified EHI, are more sensitive markers of healing quality in the early postoperative period. Therefore, while socket measurements provided valuable data, they may lack the sensitivity to detect functional and qualitative improvements attributable to therapeutic interventions such as a bone bioactive rinse.

The external validity of this study is reasonably strong, supported by the sampling approach, population characteristics, and clinical setting. Participants were type 2 diabetic patients aged 18-65 undergoing routine, non-surgical extractions at a large academic dental center. The balanced gender distribution and varied oral hygiene levels reflect the typical diabetic popu-

lation seen in dental clinics. Although conducted at a single site, the findings are generalizable to similar clinical settings, especially in regions with high diabetes prevalence, such as Saudi Arabia[17]. Additionally, the involvement of both general dentists and oral and maxillofacial surgeons enhances validity by simulating real-world practice conditions.

Although socket dimension outcomes did not reach statistical significance in this study, their inclusion was intended to provide insight into early morphological changes following extraction. Studies[18,19] have shown that post-extraction bone resorption, particularly in the horizontal and vertical directions, begins early and can be clinically relevant even within the first few weeks. Therefore, while not statistically significant in this cohort, these measurements contribute to a broader understanding of wound healing dynamics and may inform future research with extended follow-up or alternative interventions.

Study limitations

Despite these strengths, several limitations warrant discussion. The sample size, although justified by power analysis, was modest (n=48), and future studies should aim to replicate these findings in larger populations. The follow-up period was limited to two weeks, which may not fully capture the course of tissue regeneration. Also, while the modified EHI is a validated tool, it remains a semi-quantitative scale subject to inter-examiner variability, despite calibration efforts. Although patients were consecutively enrolled based on eligibility criteria, group allocation was determined through a shared decision-making process between the patient and the treating dentist. The absence of randomization may introduce selection bias and limit the internal validity of the findings. Future studies should consider employing a randomized controlled trial design.

The inclusion of patients with both controlled and uncontrolled diabetes is acknowledged as a study limitation. This variability in glycemic control may have introduced heterogeneity in wound healing responses, potentially affecting the comparability of outcomes between groups. Future studies should consider stratifying participants based on glycemic control levels to isolate the effects of the intervention better and reduce confounding factors. Moreover, comparing the novel bioactive rinse to no adjunctive treatment may limit the clinical applicability of the findings. Although this approach reflects routine practice in our clinical setting, future investigations should incorporate established rinses as active comparators to better contextualize the therapeutic potential of the bioactive rinse. Also, the lack of blinding may introduce observer and performance bias, particularly in the assessment of subjective outcomes such as EHI.

Additionally, adherence to the mouthrinse protocol was not objectively measured. Future studies should incorporate structured adherence-monitoring strategies to ensure accurate evaluation of treatment fidelity. Also, although the study was designed to assess early healing responses, extended follow-up beyond three months is necessary to capture the full trajectory of wound healing and identify late-onset issues. Future investigations are recommended to incorporate longer follow-up durations to provide a more comprehensive assessment of clinical outcomes in this population.

Clinical implications

Diabetic patients, particularly those with suboptimal glycemic control, are prone to impaired wound healing due to vascular deficiencies, neuropathies, and immune dysregulation. Enhancing early postoperative healing in this group is not only beneficial for comfort and recovery but also critical for preventing infections and complications. The use of bone bioactive rinse, non-invasive and easy to administer, offers a practical approach to improving postoperative care following dental extractions. However, the findings should be treated with caution as they apply specifically to non-surgical extractions without sutures in type 2 diabetic patients. It is unclear whether similar benefits would be observed in surgical extractions, implant procedures, or periodontal surgeries. Additionally, the study focused on soft tissue healing, so its potential effects on bone regeneration remain theoretical and untested.

Future research directions

Longer-term studies are needed to assess whether the benefits of bone bioactive rinse persist beyond two weeks and whether it influences alveolar bone remodeling or epithelial thickness. Comparative studies evaluating its efficacy compared with other agents, such as chlorhexidine, essential oil rinses, or platelet-rich fibrin (PRF), would further clarify its clinical value. Also, a well-designed, registered randomized controlled trial should be conducted in the future to validate these preliminary observations and provide higher-level evidence.

CONCLUSIONS

The use of bone bioactive rinse significantly enhances the quality of early wound healing following tooth extraction in patients with type 2 diabetes mellitus. This effect appeared to be independent of patient age, sex, oral hygiene status, or HbA1c levels. The clinical quality of healing was markedly improved in the intervention group despite no significant differences observed in socket dimensions.

Conflict of Interest
The authors declare that they have no conflict of interest.

Ethics Approval and Informed Consent
The study was approved by the King Abdulaziz University Biomedical Ethics Committee (approval No. 145-11-24), dated March 18, 2025. Informed consent was obtained from each participant. The study was conducted in accordance with the principles outlined in the Declaration of Helsinki and its latest amendments.

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Authors' Contributions
Ammar Almarghlani: conceptualization, methodology, validation, resources, data curation, writing–review and editing. Azhar Kutbi: conceptualization, methodology, investigation, writing–original draft preparation. Ghaid Moumena: conceptualization, methodology, investigation, writing–original draft preparation. Amr Bokhari: conceptualization, methodology, validation, resources, data curation. Wael Ibraheem: methodology, validation, data curation, writing, review, and editing. Rayan Sharka: methodology, formal analysis, data curation, writing–review and editing. Hassan Abed: methodology, formal analysis, data curation, writing–review and editing.

Data Availability
The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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