Study Protocol

The Effect of a Bioactive Mineral-Ionic Mouthrinse on Periodontal Soft Tissue Healing and Postoperative Pain After Tooth Extraction: A Double-Blind Randomized Clinical Trial

Trial Registration: ClinicalTrials.gov
Registary Number: NCT07611123

Project Summary

Tooth extraction is one of the most commonly performed procedures in dental practice. Although postoperative healing is generally uneventful, delayed soft tissue healing and postoperative discomfort remain important clinical concerns. Chlorhexidine (CHX) mouthrinse is widely used as part of postoperative care because of its antimicrobial properties; however, it does not actively promote tissue regeneration and may be associated with adverse effects such as tooth staining, altered taste sensation, and mucosal irritation. Bioactive mouthrinses containing calcium and magnesium ions have recently been introduced as a potential alternative capable of supporting biological healing processes in addition to maintaining oral hygiene.

The aim of this randomized double-blind clinical trial was to evaluate the effectiveness of a bioactive mouthrinse (Theravex) in enhancing periodontal soft tissue healing and reducing postoperative pain following simple tooth extraction. The study compared Theravex with 0.12% chlorhexidine and normal saline.

A total of 94 healthy adult participants requiring simple tooth extraction were recruited from the Oral and Maxillofacial Surgery Clinics at King Abdulaziz University Dental Hospital, Jeddah, Saudi Arabia. Participants were randomly assigned to one of three intervention groups: Theravex mouthrinse, 0.12% chlorhexidine mouthrinse, or normal saline. All participants used the allocated rinse twice daily for seven days following extraction.

Clinical assessments were conducted at baseline, Day 3, and Day 7. The primary outcome was soft tissue healing assessed through buccolingual and mesiodistal socket dimensions. Secondary outcomes included postoperative pain measured using a Visual Analog Scale (VAS) and analgesic consumption.

The study demonstrated that participants using Theravex experienced improved healing outcomes and lower pain scores compared with those using chlorhexidine or normal saline. These findings contribute to the development of evidence-based postoperative protocols and support the use of bioactive mouthrinses as a biologically active alternative to conventional antimicrobial mouthrinses following tooth extraction.

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Study Site
Oral and Maxillofacial Surgery Clinics
King Abdulaziz University Dental Hospital (KAUDH)
Faculty of Dentistry, King Abdulaziz University, Jeddah, Saudi Arabia

Clinical and Technical Facilities Involved
King Abdulaziz University Dental Hospital (KAUDH)
Oral and Maxillofacial Surgery Clinics
Responsibilities: Patient screening , recruitment ,clinical treatment , follow-up examinations.

Faculty of Dentistry Research Facilities
King Abdulaziz University
Responsibilities: Data processing, statistical analysis and secure data storage.

Ethical Approval
Research Ethics Committee (REC), Faculty of Dentistry, King Abdulaziz University
Approval Number: 164-10-25.

Rationale and Background Information

Tooth extraction remains one of the most frequently performed procedures in dentistry worldwide. Despite advances in surgical techniques and postoperative care, optimal healing of extraction sockets continues to represent an important determinant of patient comfort, treatment success, and future restorative outcomes. Delayed healing may result in pain, infection, prolonged inflammation, alveolar osteitis, and compromised tissue regeneration.

The biological process of wound healing following tooth extraction consists of a complex sequence of overlapping phases, including hemostasis, inflammation, proliferation, angiogenesis, epithelialization, and tissue remodeling. Successful healing depends on appropriate cellular signaling and tissue responses throughout these stages. Consequently, considerable research efforts have focused on identifying interventions capable of enhancing tissue repair and improving postoperative recovery.

Chlorhexidine gluconate (CHX) is currently regarded as the gold standard postoperative mouthrinse because of its broad-spectrum antimicrobial activity. Numerous studies have demonstrated its effectiveness in reducing bacterial colonization and minimizing postoperative infections. Nevertheless, chlorhexidine primarily functions through microbial control and does not directly stimulate regenerative processes. Furthermore, prolonged use may be associated with tooth staining, taste alteration, mucosal irritation, and reduced patient compliance.

In recent years, interest has shifted toward biologically active therapies capable of supporting tissue regeneration in addition to controlling infection. Theravex (Bone Bioactive Liquid; BBL) is a saline-based bioactive mouthrinse containing calcium and magnesium ions. These ions are believed to play important roles in cellular proliferation, fibroblast activation, angiogenesis, extracellular matrix formation, and tissue maturation. Through these mechanisms, Theravex may facilitate more favorable wound healing compared with conventional antiseptic rinses.

Preliminary clinical evidence has suggested that bioactive mouthrinses may improve oral soft tissue healing and reduce postoperative discomfort. However, current literature remains limited, particularly regarding extraction socket healing. Most available studies involve small sample sizes, short observation periods, or clinical settings other than routine tooth extraction. Consequently, there remains insufficient high-quality evidence to support widespread clinical adoption of bioactive mouthrinses as part of standard postoperative protocols.

This study seeks to address this gap by conducting a randomized double-blind clinical trial comparing Theravex, 0.12% chlorhexidine, and normal saline following simple tooth extraction. The findings are expected to provide clinically relevant evidence regarding the effectiveness of bioactive mouthrinses in promoting periodontal soft tissue healing and improving postoperative patient outcomes.

Study Goals and Objectives

Study Goal

The overall goal of this study was to evaluate the effectiveness of a bioactive mouthrinse (Theravex) as an adjunctive postoperative treatment for promoting periodontal soft tissue healing and reducing postoperative discomfort following simple tooth extraction. The study aimed to generate clinical evidence regarding the potential benefits of bioactive mouthrinses compared with conventional postoperative rinses used in routine dental practice.

Primary Objective

To compare the effectiveness of Theravex, 0.12% chlorhexidine, and normal saline in promoting periodontal soft tissue healing following simple tooth extraction, as assessed by changes in buccolingual (BL) and mesiodistal (MD) socket dimensions over a 7-day healing period.

Secondary Objective

1. To compare postoperative pain levels among participants using Theravex, 0.12% chlorhexidine, and normal saline following tooth extraction.
2. To evaluate differences in analgesic consumption among the study groups during the postoperative healing period.
3. To evaluate the pattern and rate of healing progression between baseline, Day 3, and Day 7 among the three intervention groups.

Study Design

Study Type

This study was a quantitative, clinical, interventional research study.

Study Design

The study was conducted as a randomized, double-blind, parallel-group clinical trial with three intervention arms.
The trial compared the effectiveness of a bioactive mouthrinse (Theravex) with two control interventions (0.12% chlorhexidine and normal saline) following simple tooth extraction.

Study Population

The study population consisted of healthy adult patients requiring simple non-surgical tooth extraction who attended the Oral and Maxillofacial Surgery Clinics during the study period.

Eligibility Criteria

Inclusion Criteria

- Were between 18 and 65 years of age.
- Were medically healthy (ASA I).
- Were non-smokers.
- Had acceptable periodontal health.
- Required simple non-surgical tooth extraction.

Exclusion Criteria

- Below the age of 18 or above 65 years.
- Had systemic diseases or medical conditions known to affect wound healing.
- Used tobacco products.
- Presented with acute infection at the extraction site.
- Required surgical extraction procedures.
- Had gingival enlargement or abnormal tissue overgrowth.

Withdrawal Criteria

Participants were withdrawn from the study if:

- They voluntarily requested withdrawal.
- They failed to attend scheduled follow-up visits.

Sample Size

A total of 94 participants were enrolled in the study , participants were allocated into three groups: Theravex Group (n = 32), Chlorhexidine Group (n = 32), and Normal Saline Group (n = 30).

The sample size was calculated to provide 80% statistical power at a significance level of 0.05.

Randomization

Participants were randomly assigned to one of the three study groups using a computer-generated randomization sequence. Allocation was performed in a 1:1:1 ratio.

Allocation Concealment

To maintain allocation concealment, mouthrinses were dispensed in identical numbered containers prepared by personnel not involved in outcome assessment or data analysis.

Blinding

This study employed a double-blind design , participants were unaware of their assigned intervention.

Outcome assessors responsible for clinical measurements and follow-up evaluations were also blinded to group allocation.

The allocation code remained concealed until completion of data collection and statistical analysis.

Follow Up Scheduele
Clinical evaluations were performed at: Baseline (Day 0), Day 3, and Day 7.

Outcome Measures
Primary Outcome
Periodontal soft tissue healing measured through:

- Buccolingual (BL) socket dimension
- Mesiodistal (MD) socket dimension

Measurements were obtained at baseline, Day 3, and Day 7 using a calibrated UNC-15 periodontal probe.

Secondary Outcomes

1. Postoperative pain measured using a Visual Analog Scale (VAS).
2. Number of analgesic tablets consumed during the postoperative period.
3. Incidence of postoperative complications including: dry socket, swelling ,mucosal irritation and tooth staining.

It is hypothesized that participants receiving Theravex demonstrate superior soft tissue healing and lower postoperative pain scores compared with participants receiving chlorhexidine or normal saline.

Methodology

Participant Screening and Recruitment

Potential participants attending the Oral and Maxillofacial Surgery Clinics were screened for eligibility according to the predefined inclusion and exclusion criteria.
Eligible participants received verbal and written information regarding the study objectives, procedures, risks, and benefits. Written informed consent was obtained before enrollment.
Following consent, baseline demographic and clinical information was recorded.

Randomization Procedure

Participants were randomly assigned to one of three intervention groups using a computer-generated randomization sequence.
Randomization was performed using a 1:1:1 allocation ratio to ensure balanced distribution among the three study groups.
The allocation sequence was generated by an independent investigator who was not involved in participant recruitment, clinical treatment, outcome assessment, or statistical analysis.

Outcome Assessors

Clinical examiners responsible for outcome measurements were blinded to treatment allocation.

Data Analysis

Statistical analyses were conducted using coded group assignments to maintain blinding throughout the analytical process.

Clinical Procedures

Baseline Assessment
Prior to extraction, each participant underwent: medical history review, clinical examination, eligibility confirmation, informed consent process, baseline clinical measurements, and standardized clinical photography.

Tooth Extraction Procedure

All extractions were performed using a standardized clinical protocol.
The procedure included:

1. Administration of local anesthesia.
2. Simple non-surgical tooth extraction.
3. Irrigation when clinically indicated.
4. Hemostasis using sterile gauze pressure.
5. Delivery of standardized postoperative instructions.

No additional regenerative materials were placed within extraction sockets.

Outcome Measurements

Primary Outcome

Periodontal soft tissue healing was evaluated using extraction socket dimensions by clinical photographs to document healing progression and support clinical evaluations.
The following measurements were recorded using a calibrated UNC-15 periodontal probe.

- Buccolingual Socket Dimension (BL)

The maximum buccolingual width of the extraction socket was measured in millimeters.

- Mesiodistal Socket Dimension (MD)

The maximum mesiodistal width of the extraction socket was measured in millimeters.
Measurements were recorded at: Baseline (Day 0), Day 3, and Day 7.
Reduction in socket dimensions over time was considered indicative of healing progression.

Secondary Outcomes

Postoperative Pain

Pain intensity was assessed using a Visual Analog Scale (VAS) ranging from 0 to 10.
Participants recorded their perceived pain intensity during follow-up visits.

Analgesic Consumption

Participants reported the number of analgesic tablets consumed during the postoperative period.

Examiner Calibration

Prior to study commencement, examiners underwent calibration exercises to standardize measurement procedures.
Repeated measurements were performed on pilot participants.
Inter-examiner reliability was evaluated using Intraclass Correlation Coefficients (ICC).
An ICC value of ≥ 0.50 was considered acceptable.

Study Flow Diagram

Randomized Clinical Trial (In-Vivo Study)

Study setting: Oral and Maxillofacial Surgery clinics at King Abdulaziz University Dental Hospital

Participants enrolled based on inclusion and exclusion criteria

Study power: 80%

Sample size **(N=94)**

Group 1 Theravex **(N= 32)**

Group 2 Chlorhexidine **(N= 32)**

Group 3 Normal Saline **(N= 30)**

Mouthrinse twice daily (for 7 days)

Follow up day 3 and day 7

Outcome assessment
- Healing (Bucco-lingual and Mesio-distal dimensions)
- Pain (Visual analog scale)

Statistical Analysis
Repeated measures ANOVA and Chi-square tests

Safety Considerations

Participant safety was prioritized throughout all phases of the study. Prior to enrollment, all participants underwent eligibility screening to ensure compliance with the predefined inclusion and exclusion criteria. Written informed consent was obtained from all participants before participation.

The interventions used in this study consisted of commercially available mouthrinses and normal saline, all of which are associated with minimal risk when used according to the study instructions. Nevertheless, participants were monitored throughout the study for any adverse events or unexpected reactions.

Potential adverse events included: oral mucosal irritation, burning sensation or discomfort during rinsing , altered taste sensation, tooth staining, swelling, dry socket, and delayed wound healing. At each follow-up visit, participants were questioned regarding adverse events and underwent clinical examination of the extraction site. All adverse events were documented in the Case Report Forms (CRFs), including the nature of the event, severity, duration, management, and outcome.

Follow-Up

Participants were followed for a period of seven days following tooth extraction.

Clinical follow-up visits were conducted at Day 3 and Day 7 post-extraction.

During each follow-up visit, the following assessments were performed:

- Evaluation of extraction socket healing
- Buccolingual socket dimension measurements
- Mesiodistal socket dimension measurements
- Assessment of postoperative pain using a Visual Analog Scale (VAS)
- Documentation of analgesic consumption

Participants were instructed to contact the study investigators if any unexpected symptoms or complications developed between scheduled visits.

Data Collection and Management

Data were collected using standardized Case Report Forms (CRFs) specifically designed for this study.

Each participant was assigned a unique identification number to ensure confidentiality and anonymity throughout data collection and analysis. Personal identifiers were removed from analytical datasets and replaced with coded participant numbers.

All study records were stored securely in password-protected electronic files and locked storage facilities accessible only to authorized members of the research team.

Data entry was performed by trained investigators and verified through double-checking procedures to minimize transcription errors. Data accuracy and completeness were reviewed regularly throughout the study period.

Sample Size Determination

The sample size was calculated using IBM SPSS Statistics software based on an anticipated effect size derived from previously published studies evaluating oral wound healing interventions.

The calculation was performed using:

- Significance level (α) = 0.05
- Statistical power = 80%
- Two-sided hypothesis testing

A minimum sample size of 94 participants was determined to provide adequate statistical power for detecting clinically meaningful differences among the study groups.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics Version 27 (IBM Corp., Armonk, NY, USA).

Descriptive Statistics

Continuous variables were summarized using: mean and standard deviation (SD).
Categorical variables were summarized using: frequencies and percentages.

Inferential Statistics

Comparisons between study groups were performed using appropriate statistical tests, including:

- One-Way Analysis of Variance (ANOVA)
- Repeated Measures ANOVA
- Independent Samples t-test
- Chi-Square Test

Post-hoc analyses were conducted using:

- Games–Howell multiple comparison test
- Bonferroni-adjusted pairwise comparisons

Statistical significance was established at: $p < 0.05$.

Missing Data Management

Every effort was made to minimize missing data through careful follow-up and participant reminders. Participants who failed to attend follow-up appointments were documented as lost to follow-up.
Available outcome data collected prior to withdrawal were retained for analysis whenever appropriate. The extent and nature of missing data were assessed before statistical analysis. Any missing observations were reported transparently in the final study results.

Data Quality Assurance

Several procedures were implemented to ensure data quality:

- Examiner calibration before study initiation
- Standardized clinical measurement procedures
- Standardized photography protocol
- Double-checking of data entry
- Regular review of Case Report Forms
- Verification of statistical datasets before analysis

These measures were undertaken to ensure the validity, reliability, and integrity of the study findings.

Quality Assurance

To ensure the validity, reliability, and integrity of the study findings, quality assurance measures were implemented throughout all phases of the trial.

The study was conducted in accordance with the principles of Good Clinical Practice (GCP), the Declaration of Helsinki, and the ethical guidelines of King Abdulaziz University.

Prior to participant recruitment, all investigators underwent training regarding the study procedures, outcome measurements, data collection methods, and ethical requirements.

Standardized operating procedures were established to ensure consistency across all clinical assessments.

Clinical measurements were performed by calibrated examiners using standardized instruments and measurement techniques. Inter-examiner reliability was assessed before study commencement to ensure consistency in data collection.

Data quality was maintained through:

- Standardized Case Report Forms (CRFs)
- Double-checking of data entry
- Verification of clinical records
- Routine review of collected data
- Secure storage of study documentation

Given the minimal-risk nature of the interventions and the short follow-up period, a formal Data Safety Monitoring Board (DSMB) was not considered necessary. Participant safety was monitored directly by the investigators and supervising clinicians throughout the study.

Expected Outcomes of the Study

This study contributes to the growing body of evidence regarding the use of bioactive mouthrinses in oral wound healing and postoperative care.

The findings are expected to enhance understanding of the clinical effectiveness of Theravex in promoting periodontal soft tissue healing following tooth extraction. In addition, the study provides comparative data regarding postoperative pain control and complication rates relative to conventional chlorhexidine mouthrinse and normal saline.

The results may assist clinicians in selecting evidence-based postoperative treatment protocols and may support the incorporation of bioactive mouthrinses into routine dental practice.

More broadly, the study contributes to the advancement of knowledge in oral wound healing, regenerative dentistry, and patient-centered postoperative care.

Dissemination of Results and Publication Policy

The findings of this study will be disseminated through multiple channels to maximize scientific and clinical impact.

Dissemination strategies include:

- Publication in peer-reviewed scientific journals
- Presentation at national and international scientific conferences
- Academic seminars and university presentations
- Distribution of findings within the Faculty of Dentistry at King Abdulaziz University

Participants may be informed of the overall study findings upon request. Individual participant data will remain confidential and will not be disclosed**.**

The Principal Investigator oversees the preparation and submission of manuscripts arising from the study. Co-investigators who make substantial contributions to the conception, design, data collection, analysis, interpretation, drafting, or critical revision of the manuscript are recognized as authors in accordance with ICMJE authorship guidelines. Individuals who contribute to the study but do not meet authorship criteria are appropriately acknowledged.

Ethical Considerations

The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and the ethical guidelines of King Abdulaziz University.

Ethical approval was obtained from the Research Ethics Committee (REC), Faculty of Dentistry, King Abdulaziz University, prior to participant recruitment.

Approval Number: 164-10-25

Participation in the study was entirely voluntary. Eligible participants were informed of the study objectives, procedures, potential benefits, and possible risks before enrollment.

Potential risks associated with participation were minimal and primarily related to routine postoperative complications and possible minor reactions to the study mouthrinses.

Participants were informed of their right to:

- Decline participation
- Withdraw at any time without penalty
- Refuse any study procedure
- Receive standard clinical care regardless of participation status

Confidentiality was maintained through participant coding and secure data storage. Personal identifiers were removed from analytical datasets and were not included in publications or presentations.

Informed Consent Process

Before enrollment, eligible participants received both verbal and written explanations of the study.

The informed consent discussion included:

- Purpose of the study
- Study procedures
- Potential risks and benefits
- Participant responsibilities
- Confidentiality protections
- Voluntary nature of participation
- Right to withdraw at any stage

Participants were provided sufficient opportunity to ask questions and consider participation before signing the consent form.

Written informed consent was obtained before any study-related procedures were performed. Copies of the signed consent forms were provided to participants and retained by the research team according to institutional requirements.

Budget
No external funding was obtained for this study. The study was conducted using the existing clinical and research resources available at King Abdulaziz University Dental Hospital and the Faculty of Dentistry, King Abdulaziz University.

Other Support for the Project
No financial or material support was received from any governmental agency, commercial company, private organization, or external funding body.
The study was conducted independently through the support of King Abdulaziz University and its affiliated clinical facilities.

Collaboration with Other Scientists or Research Institutions
The study was conducted through collaboration among investigators from the Faculty of Dentistry, King Abdulaziz University.
No external research institutions participated in the design, conduct, analysis, or reporting of the study.

Links to Other Projects
This study was not formally linked to any other funded or ongoing research projects.
The findings may contribute to future investigations evaluating bioactive mouthrinses, oral wound healing, and regenerative approaches in dentistry.

Financing and Insurance
The study involved minimal-risk interventions consisting of commercially available mouthrinses and normal saline used according to standard clinical recommendations.
No separate research insurance policy was obtained specifically for this study.
Participants received treatment and follow-up care within King Abdulaziz University Dental Hospital according to institutional policies and standard clinical practice.
Any adverse event requiring clinical management would have been addressed through the routine healthcare services available at King Abdulaziz University Dental Hospital.
The investigators declare that no financial incentives were provided to participants for participation in the study.

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