

ISTANBUL AYDIN UNIVERSITY

Faculty of Dentistry | Department of Oral and Maxillofacial Surgery

PARTICIPANT INFORMATION AND INFORMED CONSENT FORM

Official Title

**Comparison of Intraoperative Conditions and Schneiderian Membrane Perforation Risk
Among Three Surgical Approaches for Lateral Sinus Floor Elevation: A Prospective
Randomized Three-Arm Comparative Clinical Trial**

NCT Number	NCT07794293
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PARTICIPANT INFORMATION

Please read the following information carefully before deciding whether to participate in this study. Taking part is entirely voluntary. Your decision whether or not to participate will not affect the quality of your current or future dental treatment. Please ask any questions you may have before signing the consent section.

1. Why is this study being conducted?

Lateral sinus floor elevation is a surgical procedure used to increase the available bone height in the posterior upper jaw when there is insufficient bone for dental implant placement.

This study compares three surgical approaches used during lateral sinus floor elevation. The purpose is to determine whether the surgical approach influences intraoperative bleeding, visibility of the surgical field, procedural simplicity, operation time, and the occurrence of Schneiderian membrane perforation.

The study will also evaluate whether patient-related and anatomical characteristics are associated with intraoperative conditions and membrane perforation.

2. Why have I been invited?

You are being invited because you require lateral sinus floor elevation as part of implant treatment in the posterior upper jaw and meet the clinical and radiographic eligibility criteria for this study.

Your suitability for participation will be confirmed before enrollment.

3. Do I have to take part?

No. Participation is entirely voluntary.

You may choose not to participate, or you may withdraw from the study, without affecting your current or future dental or surgical care.

If you decide to withdraw after the surgical procedure has already been performed, the procedure itself cannot be reversed. Information already collected may be retained when required for the scientific integrity of the study and in accordance with institutional and ethical requirements.

4. What will happen if I take part?

Before surgery, your medical and dental history will be reviewed. Your smoking status and relevant clinical information will be recorded.

Preoperative cone-beam computed tomography (CBCT) images will be evaluated to assess anatomical characteristics including residual bone height, Schneiderian membrane thickness, lateral sinus wall thickness, and the presence of maxillary sinus septa.

After eligibility has been confirmed and you have provided written informed consent, you will be assigned by chance to one of three surgical approaches. Each participant has an equal probability of being assigned to any of the three groups.

Standard Procedure (SP)

The lateral bony window will be prepared using a rotary round diamond bur. The Schneiderian membrane will then be elevated using conventional hand instruments.

Epinephrine-Soaked Cottonoid Technique (ESCR)

After completion of the lateral sinus wall osteotomy, a cottonoid saturated with an additional 1 mL of Ultracain D-S Forte containing 40 mg articaine hydrochloride and 0.012 mg epinephrine will be applied to the surgical field. The cottonoid will remain in place for 5 minutes to promote local vasoconstriction, reduce bleeding, and improve surgical visibility. It will then be removed, and Schneiderian membrane elevation will continue using conventional hand instruments.

Piezoelectric Sinus Lift (PESL)

The lateral bony window will be prepared using piezoelectric surgical tips. Schneiderian membrane elevation will be performed using piezoelectric inserts. Conventional hand instruments may also be used when necessary.

All three groups will receive the same standardized local anesthesia protocol before surgery.

The integrity of the Schneiderian membrane will be evaluated during surgery by direct visualization and the Valsalva maneuver.

If a membrane perforation occurs, it will be treated according to its clinical characteristics. Repair may include leukocyte- and platelet-rich fibrin (L-PRF), a resorbable collagen membrane, or repositioning and suturing of the Schneiderian membrane followed by L-PRF coverage.

Bone grafting and simultaneous or delayed implant placement will be performed according to your individual clinical treatment plan.

5. What information will be collected?

Immediately after surgery, the operating surgeon will assess:

- intraoperative bleeding,
- surgical-field visibility, and
- procedural simplicity.

These outcomes will be recorded using numerical rating scales ranging from 0 to 10.

Operation time will be measured from the beginning of the lateral-window osteotomy until completion of Schneiderian membrane elevation.

Whether a Schneiderian membrane perforation occurred will also be recorded.

Other information evaluated in the study may include age, sex, smoking status, residual bone height, Schneiderian membrane thickness, lateral sinus wall thickness, and the presence of sinus septa.

6. How long will participation last?

The study-specific outcome measurements are primarily completed during the surgical procedure and immediately after surgery.

Your routine postoperative care, implant treatment, and clinical follow-up will continue according to your individual treatment plan and will not be extended solely because of participation in this study.

7. What are the possible risks and discomforts?

Lateral sinus floor elevation is a surgical procedure and has known risks whether or not you participate in this study.

Possible risks and discomforts may include:

- pain, swelling, bruising, and postoperative discomfort;
- temporary difficulty opening the mouth;
- bleeding;
- infection;
- wound opening or delayed healing;
- nasal bleeding or sinus-related symptoms;
- Schneiderian membrane perforation;
- sinus infection or sinusitis;
- oroantral communication;
- graft migration or graft loss;
- failure of bone grafting or implant treatment;
- need for delayed implant placement;
- need for additional surgical treatment;
- temporary or, rarely, persistent altered sensation in nearby tissues; and
- allergic or other adverse reactions to local anesthetics, medications, collagen products, or other materials used during treatment.

If you are assigned to the ESCR group, an additional articaine- and epinephrine-containing solution will be applied locally to the surgical field using a cottonoid. Articaine and epinephrine may rarely be associated with adverse reactions such as palpitations, temporary changes in heart rate or blood pressure, anxiety, local tissue reactions, or allergic reactions.

The 5-minute cottonoid application used in the ESCR group may increase the duration of the surgical procedure.

Piezoelectric instruments produce sound and vibration, which some patients may find uncomfortable.

CBCT imaging uses X-rays and therefore involves exposure to ionizing radiation.

If an unexpected surgical or medical complication occurs, the surgical team will provide appropriate evaluation and treatment according to clinical requirements.

8. Are there any benefits?

A direct additional personal benefit from participation in this research cannot be guaranteed.

You will receive the clinical treatment required for your condition. Information obtained from this study may help improve understanding of how different surgical techniques and anatomical characteristics influence bleeding, surgical visibility, procedural handling, operation time, and Schneiderian membrane perforation during lateral sinus floor elevation.

This information may contribute to the treatment of future patients undergoing similar procedures.

9. What are the alternatives to participation?

You may decline participation in this study.

If you decide not to participate, you may still receive clinically appropriate treatment. Alternative surgical, implant, and bone-augmentation options may be discussed with your treating surgeon according to your anatomy, medical condition, preferences, and routine clinical practice.

10. How will my information be protected?

Your medical, clinical, and radiographic information will be handled confidentially.

Whenever possible, study information will be recorded using a study code rather than information that directly identifies you.

Access to research information will be limited to authorized research personnel and other persons or authorities entitled to review the study according to institutional and legal requirements.

Results of the study may be analyzed, presented at scientific meetings, or published in scientific journals. Your name or other information that directly identifies you will not be disclosed in scientific reports, presentations, or publications.

Your information will be stored and handled in accordance with applicable institutional, ethical, and data-protection requirements.

11. Who can I contact?

If you have questions about the study, the surgical procedure, or your participation, you may contact:

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Telephone	+90 212 411 30 00, ext. 29501
Mobile	+90 533 548 3260

12. Questions

Please ask any questions you may have before agreeing to participate.

You should have sufficient opportunity to consider participation and to receive satisfactory answers to your questions before signing this consent form.

INFORMED CONSENT

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- ☐ I have read this Participant Information Form, or the information has been read and explained to me in a language that I understand.
- ☐ I have had sufficient opportunity to consider participation and to ask questions.
- ☐ My questions have been answered satisfactorily.
- ☐ I understand the purpose of the study and the procedures involved.
- ☐ I understand that I will be assigned by chance to one of three surgical approaches.
- ☐ I understand the possible risks and discomforts associated with the study and the surgical procedure.
- ☐ I understand that no additional personal benefit from research participation can be guaranteed.
- ☐ I understand the available alternatives to participation.
- ☐ I understand that participation is voluntary and that I may refuse to participate or withdraw without adversely affecting my current or future clinical care.
- ☐ I understand that a surgical procedure already performed cannot be reversed if I later withdraw from the study.
- ☐ I understand how my medical, clinical, and radiographic information will be collected, stored, analyzed, and used.
- ☐ I understand that study results may be presented or published without disclosure of my identity.
- ☐ I understand that signing this form does not waive any of my legal rights.
- ☐ I voluntarily agree to participate in this study.

Participant

Participant name and surname:

Signature:

Date:

Time:

Person Obtaining Consent

Name and professional role :

Signature:

Date:

Time:

Witness or Interpreter, if required

Name and role (print):

Signature:

Date:

Time: