15.08.2025

RECEP TAYYIP ERDOGAN UNIVERSITY, FACULTY OF DENTISTRY, DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY
INFORMED VOLUNTARY CONSENT FORM

Title of the Study: The Effect of Different Flap Closure Techniques on Postoperative Morbidity: A Randomized Controlled Study on Impacted Third Molar Surgery

PLEASE READ CAREFULLY!
You are invited to participate in our research study. Before agreeing to take part, you should understand the purpose of this study and freely decide whether to participate after reading this information. Please read this information carefully and ask any questions you may have to receive clear answers.
Participation in this study is entirely voluntary. You have the right to decline participation or withdraw from the study at any time without any penalty. Responding to this study will be considered as giving consent to participate. While answering the questions in the forms, you should not be under any pressure or influence from anyone. The information collected from these forms will be used solely for research purposes.

Purpose of the Study:
The aim of this study is to compare the effects of different flap closure techniques (surgical drain, cyanoacrylate, sutureless technique, conventional suturing) on swelling, limitation of mouth opening, pain, wound healing, and quality of life following impacted mandibular third molar surgery.

Eligibility Criteria:
To be included in this study, participants must meet the following criteria:

Inclusion Criteria:

- Individuals aged 18–40 years
- Individuals without systemic disease (ASA-I)
- Individuals with an impacted mandibular third molar in a specific position (Pell & Gregory class 2, position B; vertical or mesioangular according to Winter classification)

Exclusion Criteria:

- Patients with systemic disease (ASA II-IV)
- Allergies (to anesthetic agents, acrylic, etc.)
- Pregnancy or breastfeeding
- Alcohol or tobacco dependence
- Use of blood-thinning medications (anticoagulants, antiplatelet agents)
- Coagulation disorders
- Immunosuppressive conditions or use of immunosuppressive drugs
- Acute pain or infection

What Will Be Done in the Study?
Patients who agree to participate will be randomly assigned to groups after receiving detailed information. The written information provided is as follows:

Information About Flap Closure Techniques:

1. **Drain Application**
   A small drain (a thin, soft plastic tube placed at the wound edge to reduce fluid accumulation and swelling) will be placed in the extraction site to remove excess fluid. This method may help reduce swelling and risk of infection. The drain is usually removed within 24–48 hours. Some patients may experience mild discomfort.
2. **Periacryl® (Biological Adhesive) Application**
   The tissue adhesive (Periacryl®) will be applied to join the wound edges. Application is quick and generally increases patient comfort. In some cases, the adhesive may take longer to break down, or a foreign body sensation may occur.
3. **Sutureless Technique (Secondary Wound Healing)**
   The extraction site will be left to heal naturally without the use of sutures or closure materials. Healing may be slower but can be sufficient in some cases. Patients are required to maintain careful oral hygiene.
4. **Primary Suturing (Closure with Sutures)**
   The wound edges will be sutured to hold the tissues together. This method generally allows faster epithelial healing. However, temporary discomfort such as swelling or suture irritation may occur.

The flap closure technique applied after surgery will vary by group. All surgical procedures will be standardized; only the wound closure method will differ. Follow-up measurements will include swelling, mouth opening limitation, pain level, wound healing, and quality of life.

Participant Responsibilities:
You are expected to attend follow-up appointments on scheduled dates and fill in your pain diary (VAS, analgesic use) accurately and completely. Questionnaire forms will also be completed.

Number of Participants:
The number of participants will be determined according to power analysis, with approximately 180 participants planned.

Duration of Participation:
Follow-up will continue until postoperative day 10, with a total of 3–4 follow-up visits planned during this period.

Potential Benefits:
Participation may not provide direct benefit; however, it will provide information on the effectiveness of different surgical approaches.

Potential Risks:
Although rare, complications such as swelling, pain, infection, or bleeding may occur after the surgical procedure. Allergic reactions to the materials used are possible.

Medications/Foods to Avoid During the Study:
Use of blood-thinning medications (anticoagulants, antiplatelet agents), alcohol, and smoking is not recommended.

Conditions for Removal from the Study:
You may be removed from the study in case of systemic disease, allergy, infection, or non-compliance with the protocol.

Liability in Case of Harm:
All surgical procedures will be performed by experienced physicians, and necessary medical support will be provided in case of complications.

Who to Contact During the Study for Issues:
Dr. Alperen KALYONCU
Recep Tayyip Erdoğan University Faculty of Dentistry, Department of Oral and Maxillofacial Surgery
Tel: (0464) 222 00 00

Costs:
No fees will be charged to participants.

Financial Support:
No financial support has been provided for this study.

Payment for Participation:
Participants will not receive any payment for taking part in this study.

Right to Withdraw:
Participants can inform the responsible researcher at any time if they wish to withdraw from the study.

Confidentiality:
All data collected will be used solely for scientific purposes, and your identity will be kept confidential.

Consent to Participate:
I have read the information provided above and fully understand the scope and purpose of the study and my responsibilities as a volunteer. The study was explained to me verbally and in writing by the named researcher below, and I had the opportunity to ask questions and received satisfactory answers. The potential risks and benefits were explained to me verbally. I understand that I can leave the study at any time without giving a reason and without facing any negative consequences. I voluntarily agree to participate in this study without any pressure or coercion. I understand that by not signing this form, I will not lose any rights granted to me by local laws.
A signed and dated copy of this form has been provided to me.

VOLUNTEER

FULL NAME

SIGNATURE

ADDRESS

PHONE & FAX

DATE

FOR MINORS OR THOSE UNDER GUARDIANSHIP

FULL NAME OF PARENT / GUARDIAN

SIGNATURE

ADDRESS

PHONE & FAX

DATE