STUDY PROTOCOL

1. **Project Title:** The Effect of Different Flap Closure Techniques on Postoperative Morbidity: A Randomized Controlled Study for Impacted Third Molar Surgery
2. **Significance of the Project:** This study aims to evaluate the relationship between different flap closure techniques (surgical drain, cyanoacrylate, sutureless technique, and conventional suturing) and postoperative complications such as pain, swelling, and trismus, as well as the physical monitoring of wound healing and potential changes in patients' quality of life following the surgical extraction of impacted mandibular third molars.

3.1 Background and Rationale:

Surgical extraction of impacted mandibular third molars (IMTM) is one of the most commonly performed oral surgical procedures worldwide [1]. These surgeries are of great significance for both patients and surgeons, as frequently occurring postoperative complications can negatively affect the quality of life of individuals undergoing the procedure [2]. The primary reason for impaired quality of life following IMTM surgery is the exaggerated inflammatory response, including bleeding, pain, swelling, and trismus.

To minimize these symptoms, various studies have focused on preoperative and postoperative medications, laser therapy, acupuncture, kinesitherapy, cryotherapy, and ozone therapy as complementary treatments [3-8]. In addition to the reported pharmacologic and complementary approaches, studies have also examined different surgical techniques aimed at the same goal, including various flap types, anesthesia methods, interalveolar agents, use of drainage tubes, tissue adhesives, surgical sutures, and sutureless techniques [6,9-13].

After IMTM extraction, the mucoperiosteum may be allowed to heal either primarily (hermetically closed) or secondarily (leaving a small opening at the surgical site). Intraoral placement of a surgical drain has been proposed as a procedure that could reduce postoperative discomfort and facilitate drainage of blood, serum, or potential necrotic tissue and debris [14]. Although some clinical studies have analyzed the effect of drainage, results remain inconsistent, and further randomized studies are needed [6,14].

In recent years, tissue adhesives have gained popularity as a potential method to address the complications mentioned above. Currently, cyanoacrylate is the most widely used tissue adhesive. Its high tensile strength, rapid polymerization, biocompatibility, hemostatic properties, ease of application, and bacteriostatic characteristics make it an attractive option for oral surgical procedures. It is non-resorbable in the oral cavity and detaches from the oral mucosa over 7–10 days [15]. However, there are only a limited number of clinical studies evaluating postoperative surgical outcomes such as pain, swelling, trismus, and healing when comparing cyanoacrylate and sutures for flap closure in IMTM surgery [10,15].

Primary or secondary healing has been a subject of debate in the literature, with conflicting views regarding its effect on postoperative outcomes. Some surgeons advocate for primary suturing of extraction sockets after IMTM surgery, stating that it effectively controls bleeding, prevents contamination of the surgical site, improves healing quality and speed, and offers cost advantages [16,17]. Other surgeons prefer the sutureless technique, arguing that it facilitates drainage of inflammatory exudate, minimizes postoperative tension in surrounding soft tissues, and reduces the risk of infection and inflammatory reaction [13]. Additionally, empirical observations suggest that most primarily closed wound edges tend to separate and eventually heal secondarily. A review of the literature reveals numerous studies with conflicting results evaluating these techniques individually [18-20]. However, there are relatively few studies comparing these techniques directly.

Considering all these perspectives, the present study aims to compare the effects of primary flap closure using surgical drains, cyanoacrylate, sutureless techniques, and conventional sutures on postoperative complications following impacted mandibular third molar surgery.

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3.2. Study Methodology

The study sample will be selected from patients presenting to the Department of Oral, Dental, and Maxillofacial Surgery at Recep Tayyip Erdoğan University Faculty of Dentistry with complaints related to impacted mandibular third molars between August 2025 and December 2025. The sample size has been determined based on a power analysis, and 148 patients aged 18–40 years will be included in the study regardless of gender. The study will be designed as a prospective, randomized controlled, single-blind clinical trial. The researcher responsible for postoperative evaluations will be blinded to patient group assignments. All patients will receive detailed information regarding the surgical procedure and potential complications. Written and verbal informed consent will be obtained from all participants before the study.

Patients will be randomly assigned to groups after verbal and written information is provided, according to the inclusion and exclusion criteria listed below:

Inclusion Criteria:

- Patients aged 18–40 years
- Patients without any systemic disease (ASA-I)
- Patients with impacted mandibular third molars requiring extraction, with bone and/or mucosal retention, and in similar positions (Pell & Gregory Class 2, Position B; Winter classification: vertical and mesioangular)

Exclusion Criteria:

- ASA II, III, or IV patients
- Known allergy to anesthetic solutions
- Known acrylic allergy
- Pregnant or breastfeeding women
- Tobacco use ≥10 cigarettes per day
- Alcohol consumption
- Patients using antiplatelet agents
- Patients using anticoagulants
- Patients with coagulation disorders
- Patients with immunosuppressive diseases or receiving immunosuppressive therapy
- Patients with acute pain or infection

Patients included in the study will be randomly assigned to one of four study groups using a computer-assisted simple randomization method after receiving the verbal explanation. The written form of the verbal patient information is provided below.

Patient Information on Flap Closure Techniques

1. **Drain Application**
   A small drain (a thin, soft plastic tube placed along the wound edge to reduce postoperative fluid accumulation and swelling) will be inserted into the extraction site to facilitate removal of excess fluid. This method may help reduce edema and infection risk. The drain is typically removed within 24–48 hours and may cause mild discomfort in some patients.
2. **Periacryl® (Biological Adhesive) Application**
   The tissue adhesive (Periacryl®) is applied to approximate the wound edges. Its application is rapid and generally improves patient comfort. In some cases, fragmentation of the adhesive may be delayed, or a foreign body sensation may occur.
3. **Sutureless Technique (Secondary Wound Healing)**
   The extraction site is allowed to heal naturally without any sutures or closure materials. Healing may be slower with this technique, but in some cases, it is considered sufficient. Patients must maintain careful oral hygiene.
4. **Primary Suture (Sutured Closure)**
   Wound edges are approximated and held together with sutures. This method generally allows faster epithelial healing. Temporary discomfort such as swelling or suture irritation may occur. The flap closure technique applied will vary according to the assigned group. In all groups, the surgical procedure will be standardized, with the only difference being the wound closure method. Follow-up measurements will include edema, mouth opening limitation, pain levels, wound healing, and quality of life.

Patients will be divided into four groups as described above:

- **Group 1:** Surgical Drain Group
- **Group 2:** Cyanoacrylate Group
- **Group 3:** Sutureless Technique
- **Group 4:** Conventional Suturing Technique

In **Group 1**, after tooth extraction, the flap will be repositioned to its original position, and the horizontal incision will be sutured. A 2-mm diameter, 2-cm long plastic tube drain will be placed in the buccal vertical incision between the first and second molars and fixed to the vestibular mucosa. The drain will be removed 2 days after surgery [1].

In **Group 2**, the flap will be repositioned and cyanoacrylate (PeriAcryl®90 High Viscosity Dental Cyanoacrylate, Canada) applied along the wound edges. Once the edges are securely positioned, a layer of cyanoacrylate will be spread along the incision up to the mesial side of the mandibular second molar to ensure proper closure and sealing. After 30–60 seconds for adequate polymerization, the procedure will be completed according to the manufacturer's instructions [2].

In **Group 3**, intraoral compresses will be applied for 15 minutes, and the flap will be repositioned and maintained with jaw pressure. If bleeding or inadequate flap repositioning occurs, sutures may be used in a limited fashion only at the vertical incision [3].

In **Group 4**, the vertical section distal to the second molar and the horizontal incision will be closed with 3/0 braided, non-absorbable silk sutures (Doğsan®, Istanbul, Turkey).

All patients will undergo mandibular third molar surgery according to a standardized surgical procedure; the only difference will be the flap closure method at the end of the procedure. To ensure unbiased assessment of postoperative outcomes, the researcher performing postoperative evaluations will be blinded to the patient group assignments.

Measurement of Outcomes:

- **Trismus:** Maximum Interincisal Opening (MIO) will be measured using a caliper between the upper and lower central incisors in millimeters [4] (Figure 1).
- **Edema:** Using a flexible ruler, measurements will be taken from the corner of the mouth to the tragus, from the pogonion to the tragus (anteroposterior), and from the lateral canthus to the mandibular angle (superoinferior). The arithmetic mean of three measurements will be recorded in millimeters [5,6] (Figure 2). Trismus and edema will be assessed at preoperative (Pre-op), postoperative Day 2 (D2), and postoperative Day 7 (D7).
- **Pain:** Patients will record their pain level on a Visual Analog Scale (VAS) from 0 to 10 [5] at preoperative (Pre-op), 6 hours post-extraction (D0), and daily at 10:00 a.m. for 7 days postoperatively (D1–D7) (Figure 3).
- **Wound Healing:** Wound healing will be evaluated on Day 2 (D2) and Day 7 (D7) according to the method described by Madrazo-Jiménez et al. [7] (Figure 4).
- **Quality of Life:** The General/Geriatric Oral Health Assessment Index (GOHAI), developed by Atchison et al. (1990) and validated in Turkish by Ergül et al. (2008), will be used (Table 1) [8,9]. GOHAI contains 12 questions on functional limitation, aesthetics, chewing efficiency, food selection, social impact, pain, and medication use. A trained interviewer will administer the questionnaire, and scores will be categorized as follows: 1–20: very poor, 21–30: poor, 31–40: moderate, 41–50: good, 51–60: very good. GOHAI will be administered on postoperative Day 10 (D10) to detect potential differences in quality of life between groups.

Fig. 1: Maximum Interincisal Opening

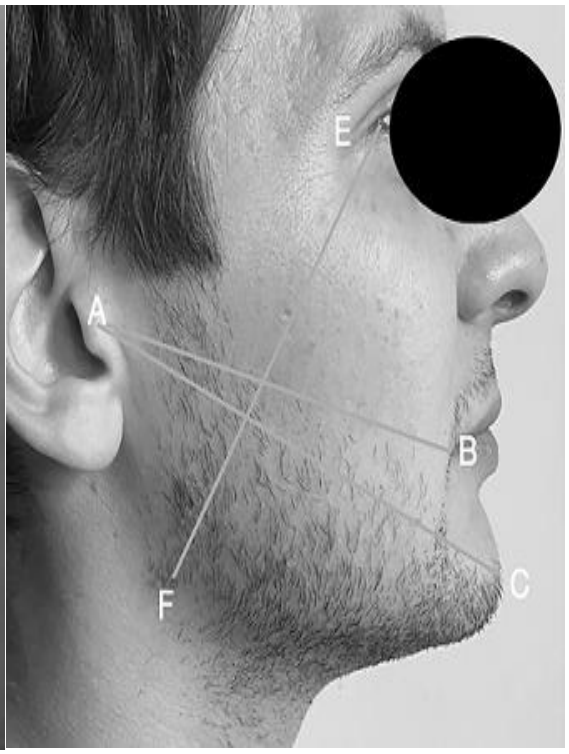

Fig. 2: Measurements for Quantifying Edema

- **AB:** Distance from corner of the mouth to the tragus
- **AC:** Distance from pogonion to tragus
- **EF:** Distance from lateral canthus to gonion

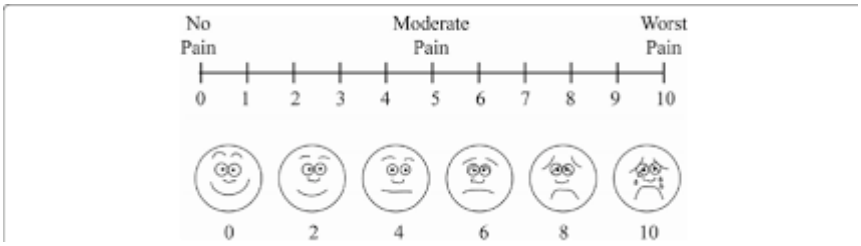

Fig. 3: Visual Analog Scale (VAS)

	GOOD	ACEPTABLE	BAD
Wound edges	Aesthetic, clean, good opposing edges	Slightly irregular, light bleeding or erythema	Irregular, moderate or heavy bleeding, exudate, pus, foul odor. Signs of infection.
Color of the oral mucosa	Identical to the surrounding area	Similar to the surrounding area	Erythematous
Wound closure	Complete / no dehiscence	1 - 2 mm dehiscence	Dehiscence > 2 mm, open wound. Keloid formation or unaesthetic closure

Fig. 4: Wound Healing Assessment Criteria

Item No	Question	Response Scale (1–5)
1	How often did you limit the types or amounts of food you ate due to problems with your teeth or dentures?	1: Never – 5: Always
2	How often did you have difficulty biting or chewing foods such as hard meat or apples?	1: Never – 5: Always
3	Were you able to swallow comfortably?	1: Never – 5: Always
4	How often did your teeth or dentures prevent you from speaking as you wished?	1: Never – 5: Always
5	Were you able to eat anything without discomfort?	1: Never – 5: Always
6	How often did the condition of your teeth or dentures limit your interaction with other people?	1: Never – 5: Always
7	How often were you satisfied or happy with the appearance of your teeth, gums, or dentures?	1: Never – 5: Always
8	How often did you use medication to relieve pain or discomfort around your mouth?	1: Never – 5: Always
9	How often were you worried or concerned about problems with your teeth, gums, or dentures?	1: Never – 5: Always
10	How often did you feel tense or uncomfortable because of your teeth, gums, or dentures?	1: Never – 5: Always
11	How often did you feel uncomfortable eating in front of others due to problems with your teeth or dentures?	1: Never – 5: Always
12	How often were your teeth or gums sensitive to hot, cold, or sweet foods?	1: Never – 5: Always

Table 1: General/Geriatric Oral Health Assessment Index (GOHAI)

Always (5)

Frequently (4)

Sometimes (3)

Rarely (2)

Never (1)

Surgical Procedure

All surgical procedures will be performed under local anesthesia. Local anesthesia will be administered using a 2 ml solution containing 80 mg articaine + 0.01 mg adrenaline per 2 ml, via inferior alveolar nerve block and buccal nerve block. Following this, a full-thickness mucoperiosteal envelope flap will be elevated using a No. 15 scalpel, following horizontal and buccal releasing incisions. Procedures such as removal of buccal bone and, if necessary, sectioning of the tooth will be carried out using a surgical micromotor with tungsten carbide or steel round burs under saline irrigation. After removing the bone tissues that retain the impacted tooth, cleavage points will be created between the tooth and cortical bone at the mesial and buccal aspects, and the tooth will be extracted from the alveolar socket using a Bein elevator. Debris, bone fragments, and epithelial remnants in the alveolar socket will be removed after tooth extraction. The alveolar socket will be irrigated with 0.9% isotonic sodium chloride solution (physiological saline), and wound edges will be closed primarily using 3/0, 18 mm, 75 cm silk sutures with a 3/8 cutting needle, achieving hemostasis.

Postoperatively, all patients will be prescribed the following medications for 7 days starting from the first day after surgery until suture removal: 875 mg amoxicillin + 125 mg clavulanic acid twice daily at 12-hour intervals, 25 mg dexketoprofen trometamol twice daily, and 120 mg (0.12%) chlorhexidine gluconate + 150 mg (0.15%) benzydamine hydrochloride three times daily.

Statistical Analysis

The adequate sample size was determined based on a power analysis performed using the G*Power software, resulting in a total of 148 patients, with 37 cases in each group. Data will be presented using descriptive statistics, including mean and standard deviation. Non-parametric tests, including Spearman, Kruskal-Wallis, Mann-Whitney U, and Wilcoxon tests, will be used to analyze intergroup and intragroup differences. Repeated measures ANOVA will be conducted using parametric testing. Statistical significance will be set at $P < 0.05$, and all analyses will be performed using IBM SPSS Statistics version 25.

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4. Parameters to be Evaluated

a. Where and by whom the parameters will be assessed
The study will be conducted at the Department of Oral, Dental, and Maxillofacial Surgery, Faculty of Dentistry, Recep Tayyip Erdoğan University. In this study, the extraction of impacted teeth will be performed by Res. Asst. İsmail Burak Halat, and patient group randomization will be carried out using computer-assisted simple randomization. Preoperative, intraoperative, and postoperative monitoring of the patient groups will be conducted by Res. Asst. Müberra Keskin.

b. Which parameters are routine for the patient group and which are specific to the study
The study aims to comparatively evaluate four different flap closure techniques (conventional suturing, surgical drain, cyanoacrylate tissue adhesive, and sutureless technique) that are routinely used after mandibular impacted third molar extraction. Based on the collected data, possible differences in postoperative complications and quality of life will be identified.

c. Estimated study duration, start and end dates
4 months, from 15.08.2025 to 15.12.2025

5. Number and characteristics of patients/volunteers to be included in the study
Patients will be selected from those presenting to the Department of Oral, Dental, and Maxillofacial Surgery, Faculty of Dentistry, Recep Tayyip Erdoğan University, with complaints regarding impacted mandibular third molars. The sample size was determined based on a power analysis, and 138 patients aged 18–40 years, regardless of gender, will be included. All patients will be provided with detailed information regarding the surgical procedure and possible complications. Written and verbal informed consent will be obtained from all patients prior to the study.

6. Inclusion and Exclusion Criteria

Inclusion Criteria:

- Patients aged 18–40 years
- Patients without any systemic disease (ASA I)
- Patients with impacted mandibular third molars indicated for extraction, with bone and/or mucosal retention, in a similar position (Pell & Gregory classification: Class 2, Position B; Winter classification: vertical and mesioangular)

Exclusion Criteria:

- Patients classified as ASA II, III, or IV
- Patients with known allergy to anesthetic solutions

- Patients with acrylic allergy
- Pregnant or breastfeeding women
- Individuals with tobacco use of 10 or more cigarettes per day
- Patients who consume alcohol
- Patients using antiplatelet agents
- Patients using anticoagulants
- Patients with coagulation disorders
- Patients with immunosuppressive disease or receiving immunosuppressive therapy
- Patients with acute pain or infection

7. Criteria for withdrawal of volunteers/patients and follow-up of withdrawn participants
Participation in the study is voluntary. Volunteers may refuse to participate or withdraw from the study at any time without any penalty or loss of rights. Refusal to accept the methods used during the procedure will result in exclusion from the study. No follow-up period will be applied for participants who withdraw or are withdrawn from the study.

8. Criteria for terminating participation in the study

- Failure to attend scheduled appointments on time
- Noncompliance with physician instructions