Official Title: **The Effect of Preoperative Surgical Information Videos on Hemodynamic Parameters and Dental Anxiety in Impacted Mandibular Third Molar Surgery: A Randomized Controlled Trial**

NCT Number: NCT07484334

Document Date: 2025-05-22

Document Type: Study Protocol

Version: 1.0

STUDY PROTOCOL

1. Title

The Effect of Preoperative Surgical Information Videos on Hemodynamic Parameters and Dental Anxiety in Impacted Mandibular Third Molar Surgery: A Randomized Controlled Trial

2. Study Summary

This study was designed to evaluate the effects of different physician-guided preoperative information formats on hemodynamic parameters and dental anxiety/fear in patients undergoing impacted mandibular third molar surgery. Participants were allocated to one of three groups: standard verbal information, real surgical video information, or 3D animation video information. Hemodynamic parameters and questionnaire-based fear/anxiety responses were assessed using a standardized protocol.

3. Background and Rationale

Dental anxiety and fear are common in oral surgery patients and may affect both patient cooperation and physiological responses during treatment. Impacted mandibular third molar surgery is among the most anxiety-provoking procedures in dentistry. Preoperative information may influence patient expectations, perceived control, and procedural stress responses.

Previous studies have evaluated verbal, written, and audiovisual information methods before oral surgery. However, the literature remains heterogeneous in terms of content standardization, delivery conditions, measurement tools, and assessment timing. In particular, comparative data on real surgical video and 3D animation presented under physician guidance are limited. Therefore, a randomized controlled study was planned to compare three standardized information modalities within a single protocol.

4. Objective

To compare the effects of three preoperative information methods on hemodynamic parameters and dental fear/anxiety in patients undergoing impacted mandibular third molar surgery.

5. Hypothesis

The primary hypothesis was that physician-guided visual information, including real surgical video or 3D animation, would provide a more favorable hemodynamic profile during surgery

than standard verbal information.The secondary hypothesis was that visual information methods would reduce dental fear/anxiety scores compared with standard verbal information.

6. Study Design

This study was designed as a single-center, parallel-group, randomized controlled trial conducted at the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Recep Tayyip Erdoğan University, Rize, Türkiye.

Participants were randomly allocated in a 1:1:1 ratio to one of three study arms:

- Standard Verbal Information
- Real Surgical Video Information
- 3D Animation Video Information

7. Ethical Approval

The study was conducted in accordance with the principles of the Declaration of Helsinki and institutional research ethics requirements. Ethical approval was obtained from the Recep Tayyip Erdoğan University Non-Interventional Clinical Research Ethics Committee before study initiation. Written informed consent was obtained from all participants before enrollment.

8. Study Setting

All study procedures were performed at the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Recep Tayyip Erdoğan University. Preoperative information was delivered in a quiet observation room in the local operating area, and surgical procedures were performed in the local operating theater of the department.

9. Participants

9.1 Inclusion Criteria

Participants were eligible if they met all of the following criteria:

- Age between 18 and 50 years
- American Society of Anesthesiologists physical status classification I or II
- Scheduled for surgical removal of an impacted mandibular third molar
- Pell-Gregory ramus relationship Class I or II
- Pell-Gregory depth Level A or B
- Winter angulation classification vertical or mesioangular
- Impacted mandibular third molar with FDI tooth number 38 or 48
- Able and willing to provide written informed consent

9.2 Exclusion Criteria

Participants were excluded if any of the following applied:

- Age below 18 years or above 50 years
- Smoking or alcohol use
- Bleeding or coagulation disorders
- Systemic disease or medication likely to affect wound healing

- Pregnancy or lactation
- Associated cyst, tumor, or other pathology related to the impacted tooth
- History of severe anxiety disorder or psychiatric illness
- Allergy to local anesthetics or study-related medications
- Inability to complete follow-up or study procedures
- Presence of uncontrolled periodontal disease

10. Sample Size

A total sample size of 72 participants was planned. Participants were equally distributed across the three study arms, with 24 participants in each group. Sample size determination was based on power analysis targeting at least 80% power with a type I error level of 5%.

11. Randomization and Allocation

Randomization was performed using the sealed-envelope method. Equal numbers of cards labeled with the group assignments were placed into opaque sealed envelopes. Eligible participants selected the next envelope in sequence and were assigned accordingly. Allocation was carried out under the supervision of personnel/research staff not responsible for the surgical procedure.

12. Blinding

Because of the nature of the interventions, participant blinding to information format was not feasible. The surgeon was not the same person who delivered the preoperative information, in order to reduce communication-related performance bias.

13. Interventions

13.1 Arm 1: Standard Verbal Information

Participants received standardized verbal preoperative information about the surgical procedure from the researcher using a fixed script.

13.2 Arm 2: Real Surgical Video Information

Participants watched a real surgical video showing the main stages of impacted mandibular third molar surgery. The video content was designed to be equivalent in informational content to the verbal explanation.

13.3 Arm 3: 3D Animation Video Information

Participants watched a 3D animated video explaining the main stages of impacted mandibular third molar surgery. The informational content was designed to be equivalent to the verbal and real video formats.

13.4 Standardization of Information Delivery

In all groups, preoperative information was delivered immediately before the surgical procedure, before the patient was seated in the surgical chair. Participant questions were answered, but responses were limited so as not to expand beyond the standardized information content.

14. Surgical Procedure

All surgeries were performed by the same oral and maxillofacial surgery research assistant to ensure procedural standardization.

Local anesthesia was administered using 1 ampule (2 mL) of 4% articaine hydrochloride with 1:100,000 epinephrine for inferior alveolar nerve block and buccal nerve block. After adequate anesthesia, a full-thickness mucoperiosteal flap was raised using sulcular and vertical incisions with a No. 15 blade. Surgery proceeded with minimal osteotomy when required under saline irrigation and luxation of the tooth with an elevator. After tooth removal, the socket was curetted, irrigated, and primarily closed using 3/0 silk sutures.

15. Postoperative Management

After surgery, all participants were instructed to bite on gauze for 30 minutes. Standard postoperative prescriptions included:

Amoxicillin/clavulanic acid 1000 mg twice daily

Naproxen sodium 550 mg twice daily

Chlorhexidine mouth rinse

Postoperative care instructions were given both verbally and in writing.

16. Outcome Measures

16.1 Primary Outcomes

Primary outcomes were hemodynamic parameters measured non-invasively with a patient monitor:

- Systolic blood pressure (SBP), mmHg
- Diastolic blood pressure (DBP), mmHg
- Heart rate (HR), beats/min
- Peripheral oxygen saturation (SpO2), percent saturation

These parameters were measured at five predefined time points:

- T0: Baseline, after information delivery and before surgery
- T1: After local anesthesia during the latent period
- T2: During tooth luxation
- T3: At the end of suturing
- T4: Fifteen minutes after the operation

16.2 Secondary Outcome

Dental fear/anxiety was assessed using the Modified Dental Fear Survey (MDFS). The questionnaire was administered once, immediately after information delivery and before the participant was taken to the surgical chair. Higher scores indicated greater dental fear.

17. Data Collection Procedures

Hemodynamic data were recorded using the Okuman DFM 300 patient monitor. Measurements were performed under standardized environmental conditions, with patients in the seated position and, as far as possible, from the same arm. Participants were allowed a short rest period before measurement.

MDFS was completed in the observation room after completion of the information procedure and before surgery.

18. Safety Monitoring

The study involved standard clinical care procedures and non-invasive monitoring. Adverse events were assessed during the perioperative observation period. No serious intervention-specific safety procedure beyond routine clinical observation was planned.

19. Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows, version 28.

Normality of continuous variables was assessed using the Kolmogorov-Smirnov test together with skewness and kurtosis values.

For between-group comparisons of continuous variables, one-way analysis of variance (ANOVA) was used. When significant differences were found, Duncan post hoc testing was used to identify the groups responsible for the difference.

For repeated hemodynamic measurements across T0-T4, repeated-measures ANOVA was used. When significant time effects were identified, Bonferroni-corrected post hoc comparisons were applied.

Cronbach's alpha coefficient was used to evaluate internal consistency of the questionnaire data. Categorical variables were analyzed using the chi-square test. Correlations between continuous variables were evaluated using Pearson correlation analysis.

A p value of less than 0.05 was considered statistically significant.

20. Data Handling and Confidentiality

Participant confidentiality was maintained throughout the study. Each participant was recorded using study-specific documentation without public disclosure of personal identifiers. Only the research team had access to identifiable data. Publicly shared study documents do not include participant names or personal identifying information.

21. Study Timeline

Participants were enrolled during the study recruitment period after eligibility assessment and informed consent. Outcome assessments were completed during the perioperative period and up to 15 minutes postoperatively for hemodynamic monitoring.

22. Limitations Anticipated in the Protocol

Potential limitations included the single-center design, restriction to ASA I-II individuals aged 18-50 years, limited impacted tooth position categories, and short perioperative follow-up. Questionnaire-based assessment was based on a single post-information preoperative administration and relied on self-reported responses.

23. Publication and Dissemination

The study results were intended for academic dissemination through thesis submission, scientific publication, and registry reporting. The investigators retained responsibility for accurate reporting of study conduct and results.

24. Statistical Analysis Plan Statement

The statistical analysis plan is included within this study protocol. The predefined statistical analysis methods are described in Section 19 of this document.