Assessment of the Impact of 3D-Printed Anatomical Models on Patient Understanding, Anxiety, Satisfaction, and Physician–Patient Relationship During Orthognathic Surgery Consent: A Randomized Controlled Trial

Study Protocol and Statistical Analysis Plan

ClinicalTrials.gov Identifier (NCT Number): Pending Registration
Document Date: June 1, 2025
Institution:
King Abdulaziz University Faculty of Dentistry (KAUFD)
Jeddah, Saudi Arabia

Principal Investigator:
Razan Mohammad Baabdullah, BDS, MS, FRCDC
Oral and Maxillofacial Surgeon
Assistant Professor of Oral and Maxillofacial Surgery
Department of Oral and Maxillofacial Surgery, Faculty of Dentistry
King Abdulaziz University, Jeddah, Saudi Arabia

Study Protocol Background and Rationale: Orthognathic surgery involves complex procedures that can be challenging for patients to understand through conventional 2D imaging and verbal explanations. 3D-printed anatomical models may provide tangible, personalized visual aids that enhance patient comprehension, reduce anxiety, improve satisfaction, and strengthen physician–patient communication during the informed consent process.

Objectives: Primary: To assess the effectiveness of 3D-printed anatomical models in improving patient understanding of orthognathic surgery during the consent process. Secondary: To evaluate the impact of these models on patient anxiety, satisfaction, and the physician–patient relationship.

Study Design: This will be a single-blind, randomized controlled trial conducted at King Abdulaziz University Dental Hospital.

Participants: Inclusion Criteria: Adult patients undergoing orthognathic surgery (double- or triple-jaw procedures). Exclusion Criteria: Pediatric patients, revision surgeries, psychiatric diagnoses, single-jaw surgeries, or patients undergoing orthodontic treatment only.

Sample Size Calculation: Sample size was calculated using G*Power for a two-sample t-test, assuming an effect size of 0.8, power of 0.80, and alpha = 0.05. The required sample is 52 (26 per group). To account for dropouts, 60 participants will be enrolled (30 per group).

Randomization and Blinding: Participants will be randomized using a computer-generated list into two groups. Allocation will be concealed and only revealed to the surgeon immediately prior to the consultation. Patients will be aware of group assignment based on model exposure, but data analysts will remain blinded.

Intervention: Control Group: Will receive traditional surgical education using 2D imaging and verbal explanations. Intervention Group: Will receive the same education supplemented with 3D-printed anatomical models customized to their skeletal classification (Class II or III).

3D Model Development: Models will be segmented from CBCT scans using 3D Slicer software and printed with Formlabs FDM printers. Surgical cuts (Le Fort I, BSSO, genioplasty) will be manually marked with magnets inserted to simulate movements.

Data Collection: At a single consultation visit:

- Demographics, education, occupation, income, medical history (pre-consultation)
- Post-consultation assessments:
    - Patient understanding (3D-specific or 2D-specific questionnaire)
    - Anxiety (State-Trait Anxiety Inventory - STAI)
    - Physician–patient relationship (PDRQ-9)
    - Satisfaction (PSQ-18)

Outcome Measures: Primary: Patient understanding of the procedure, assessed post-consultation via a modified version of Joseph et al.'s questionnaire. Secondary:

- Anxiety: STAI score post-consultation
- Satisfaction: PSQ-18 post-consultation
- Physician–patient relationship: PDRQ-9 post-consultation

Statistical Analysis Plan: Descriptive statistics will be presented as means and standard deviations for continuous variables, and frequencies/percentages for categorical data. Normality will be tested using the Kolmogorov-Smirnov test.

Primary outcome: Mean understanding scores will be compared between groups using a two-sample t-test or Wilcoxon Rank Sum test, depending on normality.

Secondary outcomes: Anxiety, satisfaction, and physician–patient relationship scores will also be compared between groups using appropriate tests based on data distribution. A p-value of <0.05 will be considered statistically significant.

Handling of Missing Data: All randomized participants will be analyzed using the intention-to-treat approach. Multiple imputation will be employed if missing data exceed 5%.

Ethical Considerations: Ethical approval was be obtained from the Institutional Review Board at King Abdulaziz University Dental Hospital. Informed consent will be obtained from all participants. Confidentiality and data security protocols will be strictly followed.