Official Title:

Evaluation of the Effects of Subspinal Le Fort and Conventional Le Fort I Osteotomy on Nasolabial Soft Tissues

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Study Protocol

Statistical Analysis Plan

Study Design

This controlled clinical study was designed as a single-center, prospective, randomized, and double-blind trial.

All volunteers will be informed about the medications to be used in the study, possible side effects, the surgical procedure, and potential complications, and their informed consent will be obtained.

The present study will investigate the potential differences in nasal soft tissue changes associated with the modification of subspinal osteotomy compared to the conventional technique used in Le Fort I osteotomy, without making any changes to the routine orthognathic surgery and postoperative follow-up protocols conducted in our clinic.

Selection Criteria

Volunteers will be selected from patients presenting to our clinic with functional, aesthetic, and phonation complaints due to skeletal orthodontic anomalies and who are scheduled to undergo Le Fort I and/or Bilateral Sagittal Split Osteotomy under general anesthesia.

Participants will be divided into two groups according to the osteotomy technique. From both groups, a total of 30 patients aged between 18–40years, without acute infection, with ASA I–II classification, no systemic disease, no history of hypersensitivity to any medication, normal hemoglobin levels (female: 12–14 g/dL; male: 14–16 g/dL), INR <1.5, and no history of NSAID use within one week prior to surgery will be included.

Patients with ASA III or higher physical status, hepatic or renal dysfunction, neuropathic disease, long-term NSAID or opioid use, a history of drug allergy, preoperative pain, swelling or inflammation in the head and neck region, and those who are pregnant or breastfeeding will be excluded from the study.

A total of 30 patients included in the study will be randomly divided into two groups (n=15 each):

- Group I: Subspinal Le Fort I osteotomy group (n=25)
- Group II Conventional Le Fort I osteotomy group (n=25)

Before the operation, all patients will be informed about the type of osteotomy to be performed and the use of 3D photography for postoperative edema assessment.

Patients will complete the ROE (Rhinoplasty Outcome Evaluation) scale preoperatively and at 6 months postoperatively to provide a subjective evaluation of their aesthetic and functional outcomes.

To ensure consistency between preoperative and postoperative imaging, craniocervical angle measurements will be performed, and only images without statistically significant differences will be included. Changes in maxillary position (anterior and/or superior movement) and their effects on nasal tissues will be analyzed.

Preoperative and postoperative measurements will be performed twice by a single researcher at two-week intervals using dedicated software, and the mean values will be recorded.

Maxillary movements at Point A (Pt A), posterior nasal spine (PNS), incisor superius (Is), and anterior nasal spine (ANS) will be evaluated in the X, Y, and Z coordinate system (X-axis: transverse, Y-axis: sagittal, Z-axis: vertical) following conventional or subspinal Le Fort I osteotomy.

The following anatomical landmarks will be identified: alar (Al), alar curvature (Ac), soft tissue glabella (Gs), soft tissue nasion (Ns), pronasale (Prn), columella (Cm), subnasale superior (Sns), subnasale (Sn), and labrale superior (Ls).

The following measurements will be performed:

1. Nasal width
2. upper lip length
3. Alar base width
4. columellalobular angle
5. Nasal tip angle
6. Nasolabial angle
7. Nostril width

Postoperative Edema Assessment

Postoperative edema will be evaluated using the 3dMD three-dimensional imaging system.

3D images will be obtained at the following time points:

- Preoperative day 1 (T0)
- Postoperative day 1 (T1)
- Postoperative day 3 (T2)
- Postoperative day 7 (T3)
- Postoperative month 1 (T4)
- Postoperative month 3 (T5)
- Postoperative month 6 (T6)

Images will be captured with patients in maximum intercuspation, with relaxed lips and open eyes. All images will be obtained by the same clinician.

Rhinoplasty outcome evaluation (roe scale)

The Rhinoplasty Outcome Evaluation is a patient-reported outcome measure designed to assess satisfaction with nasal appearance and function following rhinoplasty.
Measurement:
It consists of 6 questions, each scored from 0 (most negative) to 4 (most positive); the total score is summed, divided by the maximum possible score (24), and multiplied by 100 to yield

a percentage score ranging from 0 to 100, where higher scores indicate greater patient satisfaction.

Processing of 3D Images

Anatomical landmarks will be identified on 3D images to superimpose preoperative and postoperative scans. Six reference points will be used: bilateral medial and lateral canthi (four points), nasion, and trichion.

Images will be superimposed, and volumetric analyses will be performed using 3dMD Vultus Software (3dMD, Atlanta, GA, USA).

Statistical Analysis

All statistical analyses will be performed using SPSS 22.0 (SPSS Inc., Chicago, IL, USA).

Descriptive statistics (mean, standard deviation, minimum, maximum) will be used to define continuous variables. Normality of data distribution will be assessed using the Shapiro–Wilk test.

Comparisons between groups will be performed using one-way ANOVA and Tukey post hoc analysis.