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Changes in facial soft tissue asymmetry in Class II patients after orthognathic surgery

Submission date	Recruitment status	[_] Prospectively registered
10/05/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/05/2024	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/04/2025	Surgery	

Plain English summary of protocol

Background and study aims
The appearance of the face is an important factor for humans, which affects self-esteem and has psychological and social effects. Even a slight asymmetry following surgery may not satisfy the patient, due to increasing demands on facial appearance. Previous reports on soft tissue changes and long-term follow-up after jaw surgery are limited.
The aim of this study is to investigate the changes in facial soft tissue asymmetry over time after jaw surgery in Class II malocclusion patients using 3D imaging. The goal is to find how the asymmetry of facial soft tissue changes at 12 months after surgery and long-term changes after 3-5 years. The study's findings should help to inform patients more precisely about the possible changes in facial soft tissues after the surgery.

Who can participate?
Adults over the age of 20 years with skeletal Class II malocclusion (where the upper teeth are too far forward compared to the lower teeth)

What does the study involve?
Participants will undergo their scheduled orthodontic treatment and jaw surgery between 2011 and 2021. They will additionally have 3D facial images taken at several timepoints: before surgery, 3-6 months, 9-12 months, 18 months, 2 years and 3-5 years after orthognathic surgery.

What are the possible benefits and risks of participating?
There are no direct benefits to participants but the study will hopefully provide benefits to future patients, who can be better informed and manage expectations. There is no additional risk to those taking part in the study because 3D facial images are not invasive.

Where is the study run from?
Institute of Stomatology of the Rīga Stradiņš University (Latvia)

When is the study starting and how long is it expected to run for?
November 2011 to March 2024

Who is funding the study?
Institute of Stomatology of the Rīga Stradiņš University (Latvia)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Changes in facial soft tissue asymmetry in Class II patients after orthognathic surgery using three-dimensional stereophotogrammetry

Study objectives
1. The asymmetry of the facial soft tissues in patients with skeletal class II decreases after orthognathic surgery.
2. Patients with greater facial soft tissue asymmetry before surgery have a higher risk of facial soft tissue relapse in the long term (after surgery).

All faces are asymmetric to some degree. This is a particular interest when evaluating orthognathic surgery (OGS) outcomes. With orthognathic patients, surgery is principally conducted to reduce asymmetry, but there is also the possibility that surgery may inadvertently increase it (Vittert et al., 2018). Soft tissue response after surgery and symmetry are only partially predictable and have tremendous individual variation response, especially in the maxillary and midfacial region (Gill et al., 2017).

Facial soft tissue asymmetric changes in the long term will be assessed for Class II and III malocclusion patients after orthodontic treatment and orthognathic surgery. Three-dimensional photographs of all patients were recorded and the position of 21 landmarks was evaluated at six timepoints: before surgery (T0), 3-6 months (T1), 9-12 months (T2), 18 months (T4), 2 years (T5) and 3-5 years (T6) after orthognathic surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/04/2012, Ethics Committee of the Rīga Stradiņš University (RSU) (Dzirciema Street 16, Riga, LV-1007, Latvia; +371 (0)67409101; pek@rsu.lv), ref: E-9 (2)

Study design
Prospective longitudinal cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)

Diagnostic, Quality of life, Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Orthognathic surgery

Interventions
The cohort will be recruited from patients treated at the Department of Orthodontics, Institute of Stomatology of the Rīga Stradiņš University.

The mean follow-up for these patients is at least 36 months. All patients receive orthodontic treatment and orthognathic surgery. Images for all of the involved patients are acquired using the 3dMDtrio (3dMD, Atlanta, GA) stereophotogrammetric system to assess facial soft tissue dimensions. Three-dimensional photographs of all patients are recorded before surgery (T0) and at 6 months (T1), 12 months (T2), 18 months (T3), 2 years (T4) and 3-5 years (T5) after surgery. The acquired images are loaded to the 3dMDvultus, version 2.5.0.1. Program (3dMD, LLC) and are analysed from all angles in three coordinates: x, y and z. The 21 anthropometric landmarks are digitally marked on each 3D facial surface at all timepoints. Further, the quantitative determination of facial asymmetry is performed with 3D data from each patient with a mirroring approach. All images of each patient are superimposed with their reflecting surfaces on stable anatomical surfaces. The program automatically measures the shortest distance between the original and mirrored surfaces and landmarks, using the 3D coordinates. The surface-based method is used.

Intervention Type
Procedure/Surgery

Primary outcome measure
Asymmetric changes in soft-tissue evaluated using the three-dimensional 3dMDtrio (3dMD, Atlanta, GA) stereophotogrammetric system before surgery (T0), 6 months (T1) and 12 months (T2), 18 months (T3), 2 years (T4) and 3-5 years (T5) after surgery

Secondary outcome measures
1. Changes in facial asymmetry compared between the following demographics using the three-dimensional stereophotogrammetric system before surgery (T0), 6 months (T1) and 12 months (T2), 18 months (T3), 2 years (T4) and 3-5 years (T5) after surgery:
1.1. Time of image collection
1.2. Gender (male/female)
1.3. Type of surgery (single jaw, LeFort I/both jaw, bimaxillary)
1.4. Facial region groups
1.5. Comparing Class II and Class III patients in the long term

Overall study start date
21/11/2011

Completion date
11/03/2024

Eligibility

Key inclusion criteria
1. Presence of skeletal Class II malocclusion
2. No history of trauma or maxillofacial surgery, or recognized craniofacial syndromes as etiologic factors
3. No active growth at the time of surgery
4. Received preoperative and post-operative orthodontic treatment
5. Underwent a single or both jaw surgeries during the time period of 2011- 2021 at the Department of the Orthodontics, Institute of Stomatology of the Rīga Stradiņš University
6. All 3D facial images for all timepoints collected
7. Aged ≥22 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
22 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
55

Total final enrolment
75

Key exclusion criteria
1. Cleft or other craniofacial anomalies or syndromes
2. Beards and/or mustaches at any timepoint
3. One of the 3D images was defective (for example, the head was moved during image capture, resulting in duplication of the image)

Date of first enrolment
03/07/2012

Date of final enrolment
10/12/2021

Locations

Countries of recruitment
Latvia

Study participating centre
Institute of Stomatology of the Rīga Stradiņš University
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University/education

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Funder(s)

Funder type
University/education

Funder Name
Rīgas Stradiņa Universitāte

Alternative Name(s)

Rīga Stradiņš University, Rīga Stradiņš University, Universitas Rigensis Stradina, Riga Medical Institute, Medical Academy of Latvia, RSU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Latvia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
05/10/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/04/2025	23/04/2025	Yes	No