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Evaluation of facial soft tissue asymmetric changes in patients after jaw surgery

Submission date 17/09/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/02/2021	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 06/10/2022	**Condition category** Oral Health	[_] Individual participant data

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 on long-term follow up after jaw surgery are limited. This study will specifically investigate changes following surgery to correct lower jaw protrusion, where the lower jaw is enlarged in comparison to the upper, also known as a cross-bite or skeletal Class III malocclusion.

The aim of this study is to investigate the changes in facial soft tissue asymmetry over time after jaw surgery in Class III patients, using 3-D imaging. The goal is to find how the asymmetry of facial soft tissue changes by 12 months after surgery. 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 19 with skeletal Class III malocclusion.

What does the study involve?

Participants will undergo their scheduled orthodontic treatment and jaw surgery between 2011 to 2018. They will additionally have 3D facial images taken at three time points: before surgery, and at 6 months and 12 months after 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 stereophotogrammetry is a non-invasive method.

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?
From April 2011 to December 2018

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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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
Evaluation of facial soft tissue asymmetric changes in Class III patients after orthognatic surgery

Study objectives
The asymmetry of the facial soft tissues decreases after orthognathic surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/04/2012, Ethics Committee of the Rīga Stradiņš University (RSU) (Riga, Dzirciema iela 16, LV-1007; +371 67409101), ref: E-9 (2)

Study design
Prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Facial soft tissue asymmetric changes following orthodontic treatment and orthognathic surgery

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

The mean follow-up for these patients is at least 12 months. All patients receive orthodontic treatment and orthognathic surgery. Images for all of the involve patients acquire using the 3dMDtrio (3dMD, Atlanta, GA) stereophotogrammetric system, to assess facial soft tissue dimensions. 3-dimensional photographs of all patients record: before surgery (T0), 6 months (T1) and 12 months (T2) after surgery. The acquire images load to the 3dMDvultus, version 2.5.0.1. Program (3dMD, LLC) and analyz from all angles in 3 coordinates –x, y and z . The 21 anthropometric landmarks are digitally marked on each 3D facial surface at 3 time points: before surgery (T0), 6 months (T1) and 12 months (T2) after surgery. Further, the quantitative determination of facial asymmetry is performed with 3D data from each patient with mirroring approach. All three images of each patient are superimposed with their reflecting surfaces on stable anatomical surfaces. The program automatically measure 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

1. Asymmetric changes in soft-tissue are evaluated using the three-dimensional 3dMDtrio (3dMD, Atlanta, GA) stereophotogrammetric system at baseline, 6, and 12 months

Secondary outcome measures
1. The changes in facial asymmetry were compared between the following demographics using the three-dimensional stereophotogrammetric system at baseline, 6, and 12 months:
1.1. Time of image collection (before surgery/6 months after surgery/12 months after surgery)
1.2. Gender (Male/Female)
1.3. Type of surgery (single jaw, LeFort I/both jaw, bimaxillary)
1.4. Facial region groups

Overall study start date
20/04/2011

Completion date
20/12/2018

Eligibility

Key inclusion criteria
1. Presence of skeletal Class III malocclusion (mandibular prognathism or maxillary retrognathism, or combination)
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- 2018 at the Department of the Orthodontics, Institute of Stomatology of the Rīga Stradiņš University
6. All 3D facial images for all 3 time points collected
7. Aged ≥19 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
101

Total final enrolment
101

Key exclusion criteria

1. Cleft or other craniofacial anomalies or syndromes
2. Beards and/ or mustaches at any time point
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
05/10/2011

Date of final enrolment
06/08/2018

Locations

Countries of recruitment
Latvia

Study participating centre
Institute of Stomatology of the Rīga Stradiņš University
Department of the Orthodontics
Dzirciema iela 20
Riga
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LV- 1007

Sponsor information

Organisation
Riga Stradiņš University

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Sponsor type
University/education

Website
http://www.rsu.lv/eng/

ROR

https://ror.org/03nadks56

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
02/01/2021

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		21/07/2022	06/10/2022	Yes	No