

MRI and 3D imaging of the mimic musculature

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This study has multiple purposes: Primary objective: 1: to investigate whether it is possible to identify the small mimic muscles independently of each other and to determine the exact position of the origin and insertion of the mimic muscles on 7...

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|------------------------------|----------------------------|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Other condition |
| Study type | Observational non invasive |

Summary

ID

NL-OMON51452

Source

ToetsingOnline

Brief title

MRI and 3D imaging of the mimic musculature

Condition

- Other condition

Synonym

mimic musculature

Health condition

Retromaxillie, verticale maxillaire hyperplasie en schisis

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 3 Dimensional, face, facial expression, mimic musculature

Outcome measures

Primary outcome

1. To investigate whether it is possible to identify the small mimic muscles independently of each other. The origins and insertions of all the mimic muscles on 7 Tesla MRI images will be determined by two investigators by consensus, and independently by a third investigator.

Secondary outcome

2. To investigate whether localization of the origins and insertions can be standardized. Standardization is considered to be possible if the origin or insertion is placed at the same anatomical landmark on bony structures and landmarks on the skin for all ten subjects.

3. To investigate whether it is possible to superimpose MRI images and 3D photographs using the computer program 3dMedX, as done previously with CT scans, and what the accuracy of this method will be.

4. To determine which muscles cause a specific facial expression by researching the vectors of facial landmarks and compare these to the vectors of the mimic muscles, thereby trying to connect the course of a muscle with the facial

expression to reveal the function of a muscle.

5. To determine the duration a volunteer can hold a certain facial expression.

This will be measured by taking a 3D picture of the face in the facial expression, with intervals of 30 seconds, and a maximum duration of 5 minutes.

A change is defined as a deformation of the facial surface area of more than 3 mm, measured by surface heat maps from the computer program 3dMedX.

Study description

Background summary

It is known that (elective) surgery can lead to changes in facial expressions. A disturbance in the normal anatomy might be the cause of this problem. A change in the location of the origo or insertion of a muscle can result in a change in the course of that muscle. As a result of this, the vector by which a muscle exerts its force will change, thereby also changing its function in facial expressions.

After surgery, some patients report the above-mentioned change in facial expressions even after complete healing. This change is most of the time unexpected and unpredicted and thereby unwanted by the patient as well as by the surgeon. This seems in particular to be the truth after a Le Fort 1 osteotomy, for cleft-, and non-cleft cases. Although these patients are convinced that their faces look more attractive after having the surgery done, they don't appreciate the change in facial expressions. Especially a reduced ability to smile broadly, a very important way of non-verbal communication, seems to be the cause for disappointment. In severe cases it may even be that patients no longer recognize their own faces as a result of the changed facial expressions.

Placing back the mimic muscles to the correct anatomical site seems to be important in order to prevent the occurrence of any undesirable changes in facial expressions after elective surgery. Detailed knowledge about the exact position and the course of the mimic muscles from origin to insertion is therefore considered essential.

A lot of research has been done recently regarding the (change in) position (of

parts) the facial skeleton after trauma and surgery by using three-dimensional imaging techniques and CT-scans. However, still very little is known about the mimic muscles of the face and their exact position and function.

The purpose of this research project is to learn all the details about the mimic muscles. The aim is to find out whether it is possible to identify all the small mimic muscles independently of each other (instead of identifying mimic muscles as a group) and to determine their exact anatomical position from origo to insertion to reveal their function based on their anatomical position by using MRI and three-dimensional imaging.

With the results of this research project reference values could be made regarding muscles positions and average excursions in facial expressions. These reference values could be helpful to place back the muscles to their original anatomic site during surgery in order to preserve or restore the facial expressions of the patient in the best possible way and to quantify the changes in facial expressions after trauma or surgery.

Study objective

This study has multiple purposes:

Primary objective:

1: to investigate whether it is possible to identify the small mimic muscles independently of each other and to determine the exact position of the origin and insertion of the mimic muscles on 7 Tesla MRI images, thereby defining the course of these muscles and revealing their functions in facial expression.

Secondary objectives:

2: to investigate whether localization of the origins and insertions of the mimic muscles of the face using MRI images, can be standardized.

3: to investigate whether it is possible to superimpose MRI images and 3D photographs using the computer program 3dMedX, as done previously with CT scans.

4: to determine which muscles cause a specific facial expression by researching the vectors of facial landmarks and compare these to the vectors of the mimic muscles, thereby trying to connect the course of a muscle with the facial expression to reveal the function of a muscle.

5: to determine the duration a volunteer can hold a certain facial expression.

Study design

Feasibility study

Study burden and risks

There are no risks for healthy volunteers associated with participation in this study. The extend of the burden is minimal, there will only be a time investment of approximately 60 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

age between 18 and 40 years

Exclusion criteria

surgery or trauma to the face or orthodontic treatment in the past
claustrophobia
physically or mentally incapable for MRI
pregnancy

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 27-07-2022

Enrollment: 10

Type: Actual

Medical products/devices used

Generic name: 3dMDvultus (3d Camera system)

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 25-05-2022

Application type: First submission

Review commission: METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

| Register | ID |
|-----------------|----------------|
| CCMO | NL79253.041.22 |