Improving accuracy of genioplasty in orthognathic surgery with a patient-specific guidance system: a randomized intervention study

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Ethical review	Approved WMO
Status	Completed
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON55324

Source
ToetsingOnline

Brief title
Patient-specific guidance system for genioplasties

Condition

- Head and neck therapeutic procedures

Synonym
'orthognathic surgery' 'jaw surgery'

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: 3D-printed guides, accuracy, genioplasty, randomized intervention study

Outcome measures

Primary outcome

There are six main study parameters in this study: three describing the absolute translation (anteroposterior, mediolateral and superoinferior) and three describing the absolute rotation (pitch, roll and yaw). To compute these variables, the methodology of the OrthoGnaticAnalyser will be used, since this method provides reproducible, quantitative outcome measures in three dimensions. The planned movement of the genial segment can be expressed in rotation and translation from its preoperative position. The postoperative (CB)CT scan can be superimposed on the preoperative virtual planning. Consequently, the preoperative genial segment can be superimposed on the postoperative position of the genial segment. The actual movement of the genial segment, in rotation and translation parameters, is automatically obtained from the superimposition process. The absolute difference between planned and actual rotations and translations provides an intuitive accuracy measurement of the genioplasty.

Secondary outcome

The secondary outcome parameter is the surgical time. This will be defined as the time between the start of incision and the fixation of the last screws. The surgeon will be asked to report this time after each surgery.

Study description

Background summary

The goal of orthognathic surgery is to correct cranio-maxillofacial deformities in order to improve function and facial appearance. The incorporation of computed tomography (CT or CBCT) in the surgical planning allows for more detailed diagnostics and virtual preoperative planning of orthognathic surgery in all three dimensions. A genioplasty (chin osteotomy) may be necessary to ensure a harmonious profile or to correct for facial asymmetries. The planning of rotational and translational movements of the chin segment has become more detailed and complex with the use of 3D preoperative planning. For this reason, customized surgical guides have been developed to accurately transfer the detailed surgical plan to the patient during surgery. We hypothesize that the application of a patient-specific guidance system can increase surgical accuracy of the genioplasty.

Study objective

The main objective is to determine if the application of a patient-specific guidance system improves the accuracy of the genioplasty. The secondary objective is to assess the effect of the application of patient-specific guidance system on the duration of the surgical procedure.

Study design

Study design: Prospective randomized intervention study.

Duration of the study: The estimated duration will be 30 months.

Setting of the study: For this study, a multicenter approach is chosen to ensure sufficient patient inclusion within the indication duration of the study. Participating centers will be the AUMC location AMC, Spaarne Gasthuis, and Radboud UMC.

Intervention

In the intervention group, the genioplasty will be executed with the aid of the patient-specific guidance system. In the control group, the genioplasty will be executed without the help of guides (conventional method).

Study burden and risks

The extra burden and risks associated with this study are negligible. Both treatment options can be considered as common practice to their full extend.

They are both used on a regular base in all participating hospitals. No changes are made to the standard clinical protocol in both control and experimental group. Risks during surgery might include incompetent fit of the guides or failure of the guides (i.e. fracturing of the guide). In our experience, these events have not happened in clinical practice thus far. In any of these situations, the conventional method will be used as a fallback procedure. No additional intervention is required in any of the proposed situations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Orthognathic surgery patients (>18 years) in whom a virtual surgery planning is made and in whom a genioplasty is indicated.

Exclusion criteria

A potential subject will be excluded from participation in this study when the surgery is indicated for any of the following conditions:
• Congenital disorders (e.g. craniofacial microsomia)
• Obstructive Sleep Apnea Syndrome (OSAS)
• Transgender surgery
• Previous orthognathic surgery

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	16-12-2020
Enrollment:	86
Type:	Actual

Medical products/devices used

Generic name:	patient-specific cutting and repositioning guides
Registration:	No

Ethics review

Approved WMO

Date:	10-06-2020

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20442
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL72676.018.20
Other	NL8332