

Comparison of a modification of the traditional surgical technique with the traditional surgical technique that is used to break a misplaced lower jaw and set it in the correct position.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29307

Source

NTR

Brief title

Mandibular inferior border osteotomy

Health condition

sagittal split osteotomy
orthognathic surgery
SSO
bad split
alveolar nerve injury
letsel of the nervus alveolaris inferior
orthognathe chirurgie
sagittale splijtingsosteotomie

Sponsors and support

Primary sponsor: Maastricht University Medical Center MUMC+

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Torque force needed to fracture the mandible by sagittal splitting osteotomy.

Secondary outcome

Fracture pattern of the mandible

Postoperative sensibility of the inferior alveolar nerve

Study description

Study objective

The hypothesis of this study is that less torque force is necessary to achieve a complete sagittal split when using the Obwegeser Dal Pont technique with a well- defined inferior border osteotomy compared to the un-modified technique.

Study design

At time of surgery: measurements of torque forces

One day after surgery: X-ray control and classification of the mandibular fracture type

Six months after surgery: neurological examination of the inferior alveolar nerve (2 point discrimination, cold/warm, Semmes-Weinman test)

Intervention

This study uses the traditional technique by Obwegeser on one side of the mandible and the same technique with an additional inferior border osteotomy on the contra-lateral side (split mouth model)

Contacts

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Eligibility criteria

Inclusion criteria

18-50 years old

Skeletal occlusion Angle class II or III needed a surgical correction by sagittal split osteotomy.

Exclusion criteria

Contraindications for general anaesthesia

Treated with bisphosphonates

Uncontrolled diabetes

Pregnancy

Infection

High risk of bleeding

Revision surgery

Patients under guardianship

Syndromal patients such as patients with e.g. Apert syndrome, Crouzon syndrome, hemifacial microsomia, Goldenhaar syndrome, fibrous dysplasia

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	21-07-2016
Enrollment:	24
Type:	Anticipated

Ethics review

Positive opinion	
Date:	21-07-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47651
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5827
NTR-old	NTR5982
CCMO	NL54299.068.15
OMON	NL-OMON47651

Study results