Comparison of the sagittal split osteotomy with and without defined inferior mandibular border osteotomy

Published: 02-05-2016
Last updated: 15-05-2024

Primary Objective: The hypothesis of this study is that an Obwegeser Dal Pont splitting procedure with a well- defined inferior border osteotomy needs less torque to split the mandible than the traditional technique.Secondary Objectives: Using the...

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

Summary

ID

NL-OMON47651

Source
ToetsingOnline

Brief title
Inferior mandibular border osteotomy

Condition

- Head and neck therapeutic procedures

Synonym
mandibular splitting in longitudinal direction, sagittale split osteotomy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: BSSO, inferior border osteotomy, sagittal mandibular split, sagittal split osteotomy

Outcome measures

Primary outcome

The primary objective of the study is measurement of the required torque [Nm] that is needed to split the mandible and which is recorded during operation. Minor forces mean a beter prefabricated split and less chiseling by the surgeon.

Secondary outcome

Classification of the lingual fracture line by postoperative cone beam computed tomography into four classes: Fracturing according to Hunsuck (class I), fracturing according to Obwegeser (class II), fracturing along the mandibular canal (class III) and unfavourable fracture (bad split, class IV).
Postoperative long-term sensibility of the lip, chin and oral mucosa, which is innervated by the inferior-alveolar nerve (Prick test, two point discrimination, thermal testing)

Study description

Background summary

Patients with a severe congenital deviation of the mandible often undergo correction surgery. Therefore the mandible needs to be broken en to be refixated in the correct position. The routine procedure and the worldwide standard for this procedure is the sagittal split osteotomy (SSO). Hereby the mandible is fractured in sagittal direction. Afterwards it is repositioned and then fixated with mini-plates and -screws. Although being a highly rewarded technique, complications such as damage to the inferior alveolar nerve (IAN) or

as a fracture in an unfavourable way (bad splits) are still common.

Study objective

Primary Objective: The hypothesis of this study is that an Obwegeser Dal Pont splitting procedure with a well- defined inferior border osteotomy needs less torque to split the mandible than the traditional technique.

Secondary Objectives: Using the modified technique the split is more precise than with the traditional sagittal splitting procedure by Obwegeser- Dal Pont. Damage like neurapraxia, axonotmesis or neurotmesis of the inferior alveolar nerve (IAN) will be lower when the modified technique is used.

Study design

This is a pilot randomized controlled clinical trial with a split mouth study design to compare the efficacy of two different techniques for splitting the mandible. After obtaining informed consent, patients who need a BSSO operation will enrol in the study. The estimated duration of this study from first intake till last follow-up is about 6 months.
The procedure will take place under general anaesthesia, like in the routine procedure. The procedure consists of a sagittal split osteotomy of the mandible according to Obwegeser- Dal Pont on the one side and of a sagittal split osteotomy with a well-defined inferior border osteotomy on the other side. The osteotome that is used for the spitting is attached to a gauge and the applied forces are recorded.

Intervention

The sagittale split osteotomy is the worldwide standard to fracture the mandible for orthognathic reasons since 1954. It is outlined in the next paragraph: First the mandibular ramus and the mandibular body are identified as well as the lingula with the entering IAN. The osteotomy starts with the horizontal cut of the medial cortex of the ramus above the lingula under protection of the IAN, followed by the vertical cut of the buccal cortex of the mandibular body about the submandibular notch. The third osteotomy is the connection of the first two ones along the oblique line. Chiselling starts and it deepens the cut along the buccal cortex. After completion the effective splitting procedure begins. An osteotome is placed inside the split and it is torqued in order to separate the ramus part from the teeth bearing part .(A)
If some resistance in the splitting occurs chiselling has to be deepened, often below the IAN involving the risk of its damage.
The condyle with the ramus part and the teeth bearing part of the mandible are separated if the split is successfully completed.
The same procedure takes place at the contralateral side. Now the mandible is fractured and the occlusion can be adjusted. Then the fracture is fixated by

osteosynthesis.

The modification of the procedure takes place at point (A). An additional cut is placed at the inferior border of the mandible about the submandibular notch towards the mandibular angle. This step spares the part of deeper chiselling during the splitting.

Study burden and risks

The benefit of participating in this study is the smaller risk of mayor sequellae of the SSO such as unfavourable splitting or damage to the infra-alveolar nerve.
The risk associated with participation in this study is more extend post-operative swelling due to the risk of creating more space to place the saw for the inferior border cut.
The patient must visit the clinic as often as for a standard treatment. No extra visits or additional x-rays are needed.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2016
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	02-05-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 29307
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL54299.068.15
OMON	NL-OMON29307