Longterm Skeletal Stability of Mandibular Distraction Osteogenesis

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To investigate the long term stability (> 5 yrs) in patients treated with mandibular distraction osteogenesis (MDO) for correction of a Class II-occlusion. Hypotheses:1) MDO is a technique for mandibular lengthening with comparable stability to...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON39925

Source
ToetsingOnline

Brief title
Longterm Skeletal Stability of Mandibular Distraction Osteogenesis

Condition

- Other condition
- Bone disorders (excl congenital and fractures)
- Bone and joint therapeutic procedures

Synonym
mandibular hypoplasia, overbite/overjet

Health condition

evaluatie stabiliteit van chirurgische interventie

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Distraction osteogenesis, Mandible, Relapse, Stability

Outcome measures

Primary outcome

Main study parameters

Cephalometric analysis will be carried out on the pre-operative,

post-distraction and these radiographs. The following measurements will be

made:

* SNB-angle: sella/nasion-mandibular point B

* SN-MP: sella/nasion- mandibular plane

* Point B in respect to x and y-axis

* x-axis= SN, y-axis: perpendicular line to x-axis

Primary parameter is to establish horizontal mandibular relapse. This is

defined as change of position of point B in a horizontal (mandibular) plane.

Secondary outcome

N/A

Study description

Background summary

Mandibular distraction osteogenesis (MDO) is an alternative technique for mandibular lengthening to the conventional bilateral sagittal split osteotomy (BSSO) in patients with a mandibular hypoplasia. Both methods are surgical

procedures that are performed in a combined surgical-orthodontic treatment plan. Longterm skeletal stability after BSSO has been studied en reported in the literature for the conventional method. Influencing factors as the amount of advancement, type of fixation, mandibular plane (high- and low angle patients), surgical skills and bone, muscular and soft tissue have been reported.
An advantage of MDO is the possibility to achieve a larger amount of lengthening (>10mm), which is required in some patients with an severe mandibular hypoplasia, e.g. syndromic patients or children. Therefore, the chances of skeletal relapse might be increased in these patients.
Short- and middleterm stability of MDO in comparison to the BSSO-technique shows similar skeletal stability. However, to our knowledge the longterm stability (at least more than 5 years) of MDO has not been studied or reported in the literature. Since this technique has become a more routine procedure in orthognatic surgery, it is of importance to establish the longterm stability and amounts of possible skeletal relapse. These results could lead to recommendations to the surgical protocol and could be beneficial to future patients.

Study objective

To investigate the long term stability (> 5 yrs) in patients treated with mandibular distraction osteogenesis (MDO) for correction of a Class II-occlusion.
Hypotheses:
1) MDO is a technique for mandibular lengthening with comparable stability to other commonly used techniques (BSSO)
2) High-angle patients, lengthening > 10 mm and female patients (>38°) are more at risk for relapse than low-angle patients, lengthening < 10mm and male patients

Study design

This is a retrospective, cephalometric study to determine skeletal stability of mandibular distraction performed between 1999-2006. Patients will be recalled for a cephalometric radiograph. Cephalometric tracing will be carried out using advanced software and manual tracing by two investigators.

Study burden and risks

In our opinion the nature and extrent of burden and associated risk is minimal. The longterm stability (at least more than 5 years) of mandibular distraction osteogenesis has not been studied or reported in the literature. Since this technique has become a more routine procedure in orthognatic surgery, it is of importance to establish the longterm stability and amounts of possible skeletal relapse. These results could lead to recommendations to the surgical protocol

and could be beneficial to future patients.

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

Mandibular hypoplasia treated with mandibular distraction osteogenesis

Exclusion criteria

Follow-uptime shorter <5 years
Other orthognatic surgery (genioplasty, sagittal split osteotomy)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-03-2014
Enrollment:	55
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-01-2014
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL40744.029.14