Splintless versus conventional maxillomandibular advancement surgery for obstructive sleep apnea: a randomized controlled trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57375

Source
ToetsingOnline

Brief title
SvCMAS

Condition

- Other condition

Synonym
daytime sleepiness, Snoring

Health condition

Sleep-related breathing disorder

Research involving

Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Materialise, Leuven, Belgium,Materialise;Leuven;Belgium

Intervention

Keyword: maxillomandibular advancement, Obstructive sleep apnea, Splintless

Outcome measures

Primary outcome

The main study parameters are the accuracies of MMA surgical movements in anteroposterior translation and counterclockwise rotation of the maxilla and mandible. This makes a total of four primary study variables.

Secondary outcome

A) Other translation parameters (mediolateral, superoinferior) of the maxilla and mandible, and rotation parameters (roll, yaw) of the maxilla and mandible;

B) Duration of surgery;

C) Blood loss during surgery;

D) Intra- and post-operative adverse events/complications;

E) Sleep study measures;

F) Daytime sleepiness as assessed with Epworth sleep scale (ESS);

G) Functional status as assessed with Functional Outcomes of Sleep Questionnaire (FOSQ);

H) Sleep quality as assessed with Pittsburgh Sleep Quality Index (PSQI);

I) Patient*s health status as assessed with EuroQoL 5-dimension 5-level questionnaire (EQ-5D-5L);

J) Quality of life as assessed with 36-Item Short Form Survey (SF-36);

K) Oral health-related quality-of-life as assessed with Oral Health Impact Profile (OHIP-14);

L) Mandibular function as assessed with the Mandibular Function Impairment Questionnaire (MFIQ);

M) Patient*s satisfaction with facial appearance as assessed with FACE-Q;

N) Patient*s satisfaction with surgery outcomes as assessed with customized patient satisfaction questionnaire;

O) Bed partner*s opinion on patient*s surgery outcomes as assessed with bed partner questionnaire;

P) Postsurgical relapse measures in translation parameters and rotation parameters of the maxilla and mandible;

Q) Facial soft tissue changes following MMA at various soft-tissue points using 3D tereophotogrammetry;

R) Upper airway variables on CT;

S) Blood pressure;

T) Incremental cost-effectiveness ratio (ICER) and incremental cost-utility ratio (ICUR).

Study description

Background summary

Maxillomandibular advancement (MMA) surgery is a specific type of orthognathic surgery, which is now frequently used for the treatment of obstructive sleep apnea (OSA). The current gold standard for orthognathic surgery is to virtually plan the procedure in three dimensions (3D) and transfer the surgical planning

to the operating room with 3D-printed intermediate and final surgical splints. A novel method to transfer surgical planning is the use of patient-specific osteotomy guides and fixation implants, without the need for surgical splints (i.e., splintless approach), which has demonstrated higher surgical accuracy than the conventional approach. However, to date no studies have evaluated whether the splintless approach provides similar advantages for MMA surgery in OSA treatment, with extremely large advancement and counterclockwise rotation. Additionally, the effect of MMA using splintless approach (i.e., splintless MMA) on functional outcome parameters in OSA patients has never been investigated.

Study objective

The main objective is to investigate if splintless approach improve the surgical accuracy of MMA for OSA.

The secondary objectives are to assess the effect of splintless MMA on duration of surgery, blood loss, adverse events, respiration function, subjective outcomes, skeletal stability, facial esthetics, upper airway dimension, blood pressure, and cost-effectiveness.

Study design

Prospective randomized intervention study

Intervention

In the intervention group, splintless MMA will be performed as an experimental treatment. In the control group, conventional MMA using surgical splints (i.e., splint MMA) will be executed.

Study burden and risks

The application of patient-specific guides and implants in orthognathic surgery is not a novel technique, however, it is not yet applied for this indication and is considered an experimental treatment for OSA. Risks during the splintless MMA surgery may include incompetent fit of the guides or implants, positioning errors, or failure of the guides (i.e., fracturing of the guide). In our experience and literature, these events have not happened in clinical practice so far. Therefore, the risks related to participation are negligible. All study procedures are performed during routine clinical practice, there is no extra burden of site visits for patients. At baseline and follow-ups, patients have to receive anthropometric measurements, blood pressure measurements, and fill out multiple questionnaires online. Besides, patients have to receive an extra CT scan (24 months after MMA) and an overnight sleep

study (60 months after MMA).

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

Adults aged 18 years or older;
Moderate to severe OSA as determined by an overnight polysomnography (PSG) preoperatively;
Continunous positive airway pressure failure or intolerance;
General good health for surgery;
MMA surgery indicated for OSA treatment.

Exclusion criteria

Other adjunctive procedures indicated at the time of MMA (e.g., multi-piece Le Fort I osteotomy, temporomandibular joint reconstruction);
Previous history of orthognathic surgery;
Cleft palate and syndromic patients;
Refusal to participate.

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:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	66
Type:	Anticipated

Medical products/devices used

Generic name:	Patient-specific cranio-maxillofacial guides and plates
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-03-2025
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	NL85211.018.24