Patient specific osteosynthesis in orthognatic surgery

Published: 20-07-2015
Last updated: 14-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43888

Source
ToetsingOnline

Brief title
Patient specific osteosynthesis in orthognatic surgery

Condition

- Other condition

Synonym
Dysgnatic malformation, over/underbite

Health condition

Dysgnate afwijking

Research involving
Human

Sponsors and support

Primary sponsor: Mondziekten, Kaak- en Aangezichtschirurgie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 3D virtual planning, CAD/CAM, le fort I osteotomy, osteosynthesis

Outcome measures

Primary outcome

The primary endpoint for this study is the geometrical change on dentition level. The baseline is the planned position, compared with the post-operative final position. CBCT*s of the maxillofacial region will be made according to care as usual in our clinic which implicates: 1 pre-operative series with dental impression paste, 6-10 days post-operative, and 1 year post-operative.

Secondary outcome

Secondary Objective(s): Is the application of patient specific osteosynthesis contributive to or at least non inferior to the surgeons* satisfaction? This will be registered with a standardized comparative questionnaire after each surgery, completed by the surgeon. This questionnaire will register the user friendly ness, number of switches to conventional osteosynthesis and reasons for switching to conventional osteosynthesis. Also the mid-long term evaluation (1 year post-op) provides information regarding bony relapse. The amount of relapse is compared between both groups. The measurements are performed identical to the direct post-op evaluation analysis

Study description

Background summary

In orthognatic surgery, patients with a dysgnatic deformity are operated to correct their functional and esthetical problems. The surgery usually includes an osteotomy and translocation of the upper and/or lower jaw. Currently, orthognatic treatment planning is performed in 3D with virtual planning software, based on 3D medical imaging (e.g., Cone-Beam CT images). The planning is communicated to the surgical intervention by the use of a through a 3D printed/milled splint with the imprint of the dentition. This splint dictates the translation of the jaw during the surgical procedure, as it contains the original position of one jaw (e.g. lower) and the newly planned position of the antagonist jaw (e.g. the upper). In the new position of the jaws as determined by the splint, the continuity of the jaw is restored by screw fixation of small osteosynthesis plates. These osteosynthesis plates are bended intra-operative to achieve a passively fit to the jaw fragments at the osteotomy sites in the correct position. This method is proven to be reliable, but it will not always provide full control over the translation of the upper jaw. To overcome this unpredictable control , a new method of communicating the 3D virtual planning, meaning the planned jaw position, towards the surgical intervention, was designed. By using CAD/CAM milled, pre-shaped, patient specific fixation plates the translation of the 3D plan to the patient surgery is hypothetically more precise and providing increased control over translocation of the jaw, compared to the use of a conventional splint. This is explained, as no manual bending of the fixation plates during surgery is necessary with this method. Also the pre-shaped plates will support the upper jaw in 3 dimensions during the fixation, which increases control over the translocation of the jaw fragments after the osteotomy. In order to place the patient specific plates on the planned location, a set of drill and cutting guides, also supported on the dentition is used. These should translate planned position of screws and plates to the jaw.
In this study the conventional method, using 3D planning and a 3D milled splint is compared to the new method with patient specific osteosynthesis, applied in the upper jaw in a randomised controlled trial.

Study objective

The main objective is to improve predictability of orthognatic surgery, or in other words to realise a stronger relation between (3D virtual) pre-operative planning and post-operative result. The second objective is to evaluate the surgeon*s satisfaction in terms of placement comfort and user friendliness in both groups.

Study design

In order to test the difference in accuracy of translation of the 3D virtual planning and predictability of outcome, this study requires a randomised controlled prospective trial design. Where the control group will receive conventional 3D virtual planning and translation (3D splints) and the intervention group will receive the patient specific osteosynthesis material in order to translate the 3D planning.

Intervention

The intervention in this study is an osteotomy of the upper jaw. The translation of 3D virtual pre-operative planning to the surgery of the upper jaw in the operating theatre with the patient specific fixation plates and surgical guides compared to care as usual with a 3D milled splint dictating the translation. Followed by 3D post-operative position accuracy-analysis compared to the virtual plan.

Study burden and risks

The surgical procedure will not be subject to substantial changes for the patient. No other surgical approach is needed, no larger incisions will be made and no differences in the used materials are planned. The patient specific fixation plates are fabricated out of CE-medical grade (V) titanium by an ISO13485 and ISO 9001:2008 certified manufacturer (Createch Medical, Mendaro Spain). The surgical guides are fabricated out of a plastic (nylon), which is sterilisation proof, frequently used in surgeries. No additional materials are used in the surgical procedure, despite the method that is used (conventional or patient specific). As an escape procedure, in case of the patient specific osteosynthesis, the regular 3D milled splint is made for every patient as well. The regular titanium osteosynthesis can thereby be applied at any time if the circumstances require this. Examples would be: non-fitting pre-fabricated plates, contamination of the plates during surgery, logistic problems, etc.

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

• Patients are awaiting orthognatic surgical treatment, namely: Le Fort I osteotomy (upper jaw) as part of their treatment plan.;• A dorsal down graft of the maxilla, or upper jaw, must be part of the planned translocation. ;• Patients are susceptible to 3D virtual planning of their surgical intervention, e.g. their mouth opening must be sufficient for gathering a dental imprint of both upper and lower jaw at the same time. This will not require a large opening, however, when suffering from trismus it can be problematic to gather the double imprint. At least 40mm of mouth opening is usually required to gather the dentition imprint information.;• The patient is at least 18 years of age. Completion of physical growth is a routine criterion for orthognatic surgery.

Exclusion criteria

• Patient does not agree to randomised application of osteosynthesis method;• Patient is, for any reason, not able to undergo the 3D virtual planning procedure, including double dentition imprints, pre-operative CBCT scanning and virtual planning of translations. An example could be the inability to complete the dental imprint of both upper and lower jaw, or inadequate scanning of the patient. These examples will, if applicable, come up during the preparation appointment with the patient, and therefore not delay the patients trajectory.;• Pregnancy, which is a general contraindication for orthognatic surgery.;• Allergy to titanium, which would mean a general exclusion for orthognatic surgery

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):	31-07-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	20-07-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-09-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-02-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL52330.042.15