

Pre-Surgical CAD/CAM planning of implant treatment in order to restore fully edentulous mandible/maxilla

Published: 23-10-2007

Last updated: 08-05-2024

A 3D virtual model of the treated jaw gives us the opportunity to design and fabricate the surgical guide and the final superstructure. Some companies have already introduced this kind of treatment to the market. The main difference with our research...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON31191

Source

ToetsingOnline

Brief title

Computer planning of implant treatments / CAM of suprastructures.

Condition

- Other condition

Synonym

edentulous patients

Health condition

edentate patienten

Research involving

Human

Sponsors and support

Primary sponsor: ACTA

Source(s) of monetary or material Support: Ministerie van OC&W, tandheelkundige implantaten: Straumann

Intervention

Keyword: CAD/CAM, dental implants

Outcome measures

Primary outcome

The precision of the computer designed drilling guide, the differences between the fit of the superstructure according the CAD/CAM protocol and traditional impression protocol

The effect of the immediate loading on the osseointegration of dental implants.

Secondary outcome

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Study description

Background summary

The modern prosthetic rehabilitation of edentulous patients is a complex treatment. The input of different specialists and sub-specialists such as dental implant surgeons and prosthodontists is necessary and very important to treat these kind of patients correctly.

Since the introduction of dental implants, there are different new possibilities to treat these kinds of patients. According the original protocol the implants were loaded after a healing period of 3 to 6 months, so called delayed loading.

The changes in implant's architecture and the implant's surface structure have resulted in decreasing the osseointegration period and the healing time considerably.

So-called immediate loading has found its intro in implant dentistry.

According to different research reports from various academic centres we can conclude that, when dealing with edentulous patients, the success of the loaded implants is independent to the loading protocol. Another very important evolution in prosthetic dentistry is undoubtedly the introduction of CAD/CAM technology. CAD (Computer Aided Design) and CAM (Computer Aided Manufacturing) is a progressing technology which, based on digital radiographic images, can be used for both planning and manufacturing of the prosthetic and surgical instruments in a precise manner.

The CAD/CAM aided treatments in dentistry are based on digital CT-scan. These images are converted in specified format, Dicom.

With the help of the computer software we can convert the images to a 3D model of the treated jaw.

Hereafter we can virtually plan the case by placing the implants in the ideal positions considering the different anatomic structures and obstacles. The same data can be used to design and plan the prosthetic solutions using CAD-software, which will be fabricated according to the CAM-milling devices.

To transfer the information from the computer to the patient we need to work with references. Unfortunately there is a lack of references in edentulous patients. To solve this important problem we create some reference points by inserting mini-implants prior to the actual surgery.

These implants remain in place during the complete treatment period. They will be used in every diagnostic, prosthetic and surgical procedure, which increases the exactitude of the treatments considerably.

The gathered data can be processed after the finalising the radiographic research. The dicom data can be loaded into the specially designed computer software, which can create in a very precise manner a 3D model of the treated jaw.

Now after the finalisation of the planning we can start designing the drilling guide and the future superstructure. These designs can be loaded back to the planning software for the final check where after the CAM-fabrication can start.

The fabricated superstructure will be finished at the dental lab and will be provided at the same time as the surgery.

Using the 3 mini-implants, we can connect the surgical guide in a very stable way. Now, the surgeon is able to precede the surgery in an exact manner where the drilling guide dictates the surgery as it was planned in our virtual model without damaging delicate anatomical structures like for instance nerves.

Directly after surgery we can install the final prosthesis in place.

That gives us several advantages:

- * The freedom for the patient to receive the final prosthesis immediately after the surgery
- * Less complications because of the flapless surgery
- * Full mouth reconstruction involves less chair side time and patient visits
- * Precise treatment where the chance of damaging vital structures is minimal
- * Trans-arch implant connection improves the osseointegration (according to many recent studies)

Study objective

A 3D virtual model of the treated jaw gives us the opportunity to design and fabricate the surgical guide and the final superstructure.

Some companies have already introduced this kind of treatment to the market.

The main difference with our research protocol is, in the protocols used up till now, the lack of reference points, resulting in the removable guides and decreasing the reliability of the treatment.

The three reference implants, a technical improvement of pre-existing CAD/CAM technology, have resulted in a more precise and compact treatment protocol.

How exact this virtual model is in reality has not yet been determined.

The difference in the exact fit of the CAD/CAM designed superstructures versus traditional impression technique has not yet been determined.

Moreover, the effect of the possible misfit on osseointegration or healing of the dental implants is not completely clear.

Is it possible that a minor misfit can result in a faster and better osseointegration?

We hope to find the answers to these questions.

Study design

The patients are adult male or females older than 25 years of age with edentulous upper and/or lower jaws. All the patients will be selected according to the inclusion and exclusion criteria mentioned in the research protocol.

Each jaw will be treated with three mini-implants. Thereafter the various steps toward a full denture will be taken.

The optimal denture setup will be copied with barium sulphate contained resin to become the so-called CT-denture. Ct-denture will be inserted on the mini-implants at time of radiographic recording.

The images will be translated and imported in the special software and the processed to 3D virtual model.

On the planning software we can virtually plan the surgery bringing the implant in the ideal position with regard to the available bone quality and quantity and the future prosthetic needs when considering different anatomical structures.

The planning data in turn will be imported into the designing software (CAD) where the drilling guide and the superstructure will be designed.

The complete design and planning will be double checked in our planning software before sent to the milling devices (CAM). The milling is executed by simultaneous 5-axes milling machinery.

The milled frame will be delivered to the dental lab that will take the necessary steps to finish the final superstructure according the existing master model.

At the time of the surgery we connect the drilling guide to the mini-implants, giving us the absolute stability. Surgery will be preceded according to the flapless protocol giving the patient minimal discomfort after the surgery.

Immediately after the surgery, the final prosthesis will be placed directly on the implants giving the patient immediate aesthetics and function.
At the end the reference implants will be removed.

Study burden and risks

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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

adult patients >25 years old with edentulous upper and/or lower jaw

Exclusion criteria

dentulous patients, Acute oral infections, severe bronchitis or emphysema, severe anemia, uncontrolled diabetes, uncontrolled hypertension, abnormal liver function, nephritis, severe psychiatric disease, endocarditis

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-04-2007

Enrollment: 35

Type: Anticipated

Ethics review

Approved WMO

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	NL16960.029.07