Safe and easy application of BioComp implants for episthetic reconstruction of craniofacial defects - A pilot study

Published: 13-03-2015
Last updated: 21-04-2024

In this study we want to investigate the efficacy and safety of an implant system with a surface coating (Biocomp) for episthetic reconstruction after ablative surgery in the nasal, orbital and auricular region

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

Summary

ID

NL-OMON55796

Source
ToetsingOnline

Brief title
BioComp implants in anaplastology

Condition

- Head and neck therapeutic procedures

Synonym
craniofacial defects

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: craniofacial defects, episthesis, implants

Outcome measures

Primary outcome

The main study parameter is implant stability, measured with the Osstell® implant stability instrument using resonance frequency analysis. Implant stability is related with the rate of osseointegration around the implant. Bone quantity/quality and the level of osseointegration will also be radiologically evaluated with a cone beam CT.

Secondary outcome

Secundary parameters/outcomes are implant survival, epithethic survival, easiness of use, patient satisfaction and quality of life, skin reactions and occuring complications.

Study description

Background summary

At the department Cranio-Maxillofacial Surgery of Maastricht University Medical Center (MUMC) the routine procedure after ablation of the nose, ear or eye is reconstruction with an episthesis. Retention can be achieved using adhesives, undercuts or bone implants. Implant based epithesis are now commonly used because of the good retention and epithesis stability. This results in a better patient quality of life.
Today we use 4mm machined surface implants (Cochlear Vistafix system) for the region of the orbit and the ear and 8 mm implants (Nobel Replace system) for the nose region. Each system has its own instruments and application method. To enhance the clinical usability, we are searching for one system for all extra-oral implant regions.
Implant patients may be compromised by aging, diseases, smoking, medication and radiation therapy, which can affect the bone healing process. In these cases, implants are known to have higher failure rates compared to the application in

healthy cases. Therefore implants with biomechanical surface modifications may have a positive effect on osseointegration, resulting in higher success rates. Hypothesis: 4mm surface treated implants (HAVD, BioComp) in the orbit and ear region and 8mm surface treated implants (HAVD, BioComp) in the nose region are the ideal system for later episthetic reconstruction.

Study objective

In this study we want to investigate the efficacy and safety of an implant system with a surface coating (Biocomp) for episthetic reconstruction after ablative surgery in the nasal, orbital and auricular region

Study design

this is a pilot prospective clinical trial

Intervention

Depending on the craniofacial region, 2-4 implants will be placed directly after ablation surgery of the ear, nose or eye/orbital cavity. The exact location of the implants will be planned pre-operatively (CAD) using the information of a CT-scan.

Study burden and risks

The patient must visit the clinic as often as in the known standard treatment . No extra visits are needed. No invasive interventions are needed for endpoint measurements.
Based on literature findings, we expect that the benefit of participating in this study may be a better implant integration with a long lasting success for the patient. Second benefit could be a reduced procedure time due to the improved and simplified handling properties of the new implant system. The risks associated with participation are not different from the risks known today. A mild skin reaction or implant failure can occur. In the latter scenario a second intervention may be needed to remove and replace the implant.

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

age 18-85
in need of a craniofacial epithesis
able to maintain a good personal hygiene

Exclusion criteria

unable to maintain a good personal hygiene
psychiatric disorders
acute infection
immunosuppresion
compromised by medication
pregnancy
local irradiation >50gray

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-01-2018
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-03-2015
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

No registrations found.

In other registers

Register	ID
Other	METC142065
CCMO	NL51206.068.14