Implant supported maxillary overdentures in the augmented maxilla: 4 versus 6 implants

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Primary Objective: The objective of this study is to asses whether or not the use of four implants in the augmented maxilla is as effective on the improvement of the patient*s oral functioning measured with the MFIQ as the use of six...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Head and neck therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON41874

Source
ToetsingOnline

Brief title
4vs6implants

Condition

- Head and neck therapeutic procedures

Synonym
edentulous maxilla, upperjaw without teeth

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: maatschap MKA-chirurgie Amphia Ziekenhuis

Intervention

Keyword: augmented, implant, maxilla, overdenture

Outcome measures

Primary outcome

The main study parameter is functional outcome measured with the MFIQ

Secondary outcome

Costs of the procedures (costs will be measured by operating time multiplied by the costs of a OR per hour, costs of the implants, costs of the meso-andsuprasructure (costs of the dentist (measured by time of the procedures and cost of materials and costs of the dental technician).

Change in bone level

Clinical parameters (pocket depth, bleeding score and plaque score)

Change in facial appearance with VAS-score filled out by patients and evaluated by a panel of maxillofacial surgeons based on the taken photographs.

Post operative pain measured with VAS-scores

Amount of visits

Patient satisfaction

Other study parameters

* Level of general health (ASA-classification)

* Level of dental hygiene

* Complications (such as rupture of the sinus membrane and wound dehiscence)

* Operating time, bloodloss

* Loss of implants

Gender

Age

Medical history

Medication

Study description

Background summary

Implant supported overdentures in the edentulous maxilla are common in The Netherlands. In case of a severe atrophic maxilla, the implant procedure is only possible after a bone grafting procedure is performed prior to the implant placement.
The augmentation of the maxilla is mostly done with the use of autogenous bone from the anterior iliac crest.
After a four-month healing period, usually four to six implants are placed to support an overdenture. In literature, there is no evidence whether four or six implants should be placed in the augmented maxilla for the support of an overdenture. In the systematic review of Slot et. al. (#1), it is stated that the survival rate of both four and six implants is above 95 percent (98.2 vs. 96.3%) if the prosthetic procedure is done with bar anchorage.
In another study of Slot et. al. (#2), a comparison is made between the use of four versus six implants in the non-augmented maxilla only. The success rate for both groups is very high, almost 100 percent. In this group, strict patient selection criteria and a strict protocol for the procedure was followed. This strict protocol cannot be compared with the normal practice, because patients who don*t meet the selection criteria also receive implants and those implants are not always placed in a academic setting with one implantologist and one prosthodontist. Secondly, the majority of patients need an augmentation of the maxilla. Only the group with limited resorption allows the placement of implants in the pre-existing bone of the maxilla.
In a third study of Slot et. al. (#3), a comparison between four and six implants in the augmented maxilla was made. In this study the augmentation procedure was a sinus elevation procedure only to augment the maxilla. Although success rates in this study are very high, a sinus elevation procedure alone is not sufficient enough to place implants in the severe atrophic maxilla.
Together with the sinus elevation procedure, it is also necessary to perform a

buccal plating procedure in order to to gain enough width in the maxilla to be able to place implants.
The goal of this study is to investigate the change in functional outcome of implant surgery in the severe atrophic maxilla after augmentation (sinuslifting and buccal plating) in a setting that comes closer to the normal daily practice than done in the studies of Slot et. al.
Since implant supported overdentures for the maxilla seem to be highly successful (Raghoebar et. al #4), this study is carried out to investigate the change in functional outcome of four versus six implants in the augmented maxilla.
Also cost effectiveness, change in bone level on x-rays, clinical parameters (pocket depth, bleeding score and plaque score), change in facial appearance, necessity of replacement of implants, VAS-scores, time of inability to work/to join social activities will be investigated.
The cost of the procedures are high and if there can be made a reduction of costs (four versus six implants, shorter operating time and shorter time of the prosthetic procedures and aftercare), it will help to reduce the total budget of health care costs.

1. A systematic review of implant-supported maxillary overdentures after a mean observation period of at least 1 year. Slot W, Raghoebar GM, Vissink A, Huddleston Slater JJ, Meijer HJ. J Clin Periodontol. 2010 Jan;37(1):98-110. doi: 10.1111/j.1600-051X.2009.01493.x. Epub 2009 Dec 7.

2. Maxillary overdentures aupported by four or six implants in the anterior region; 1-year results from a randomized clinical trial. Slot W, Raghoebar GM, Vissink A, Meijer HJ.
J Clin Periodontol. 2013;40 303-310.

3. A comparison between 4 and 6 implants in the maxillary posterior region to support an overdenture; 1-year results from a randomized controlled trial. Slot W, Raghoebar GM, Vissink A, Meijer HJ.
Clin Oral Implants Res. 2013 Feb 13. doi: 10.1111/clr.12118. [Epub ahead of print]

4. Maxillary bone grafting for insertion of endosseous implants: results after 12-124 months.
Raghoebar GM, Timmenga NM, Reintsema H, Stegenga B, Vissink A.
Clin Oral Implants Res. 2001 Jun;12(3):279-86.

Study objective

Primary Objective: The objective of this study is to asses whether or not the use of four implants in the augmented maxilla is as effective on the improvement of the patient*s oral functioning measured with the MFIQ as the use of six implants
Secondary Objective(s): Comparison of cost effectiveness of the procedures,

comparison of the clinical parameters (pocket depth, bleeding score and plaque score), change in bone level, experienced pain measured with VAS-scores, time of inability to work/to join social activities and evaluation of the change in facial aesthetics and the difference in the facial aesthetics between the two study groups will be investigated.

Study design

This study will be a randomized controlled trial (RCT) in a non-inferiority design. The intention of this
research project is to determine if both therapies are comparable. Main reason for the study is the disparity in costs of the two treatments. There will be allocation concealment through central randomization with a computer, web-based program in Oracle. The doctor and patient are not blinded for the number of implants (not applicable for this study). When the patient meets the inclusion criteria,
the patient will be asked to participate in this research. Patients will be asked to sign the informed consent in case they want to participate. Patients can be added to the research at any moment in time until the maximum of 32 patients in each therapy group is reached.
This study will be a randomized clinical trial.
The time of the study will be at least 1,5 years after the placement of the implants.
The augmentation procedure and implant placement will take place in the Amphia Hospital in Breda, The Netherlands.
After the patient selection with the inclusion criteria: 2 groups of patients will be made.
One group for the procedure with four implants and one group with six implants.
Photographs will be taken of all patients in the two study groups.
All patients will be asked to fill out the questionnaires (see attachments).
At the beginning of the study (T0) patients will fill out page 1 of the questionnaire and the MFIQ on page 2.

T1
The augmentation procedure will be performed at the Amphia Hospital in Breda, The Netherlands. At this time of the study patients will be asked to fill out page 3 and 4 of the questionnaire.

T2
Two weeks after the augmention procedure patients will visit the outpatient clinic of the maxillofacial surgery department of the Amphia Hospital for a check up. If necessary stitches will be removed. The referring dentist can alter the prosthesis and the prosthesis can be used again.

T3
Six weeks after the augmention procedure patients will visit the outpatient clinic of the maxillofacial surgery department of the Amphia Hospital for a

check up and panoramic X-ray. The placement of the implants (4 months post augmentation) will be scheduled at this visit.

T4
After a four-month period, the implants will be placed at the Amphia Hospital in Breda, The Netherlands. Implants used are from Bego Implants, Germany. They will be placed according to the manufacturers protocol.
Direct postoperatively, a panoramic X-ray will be made. At this time of the study patients will be asked to fill out page 5 and 6 of the questionnaire. The referring dentist can alter the prosthesis and the prosthesis can be used again.

T5
Two weeks after the implant placement the patients will have a check up at the dental hygienist in The Amphia Hospital for instructions of dental hygiene.

T6
Six weeks after the implant placement, clinical parameters (presence of plaque, bleeding and pocket depth) will be measured by the dental hygienist. (Mombelli 1987 #5).
Stability of the implants will be evaluated by percussion.
In case sufficient stability is found, the prosthetic procedure can be started ten weeks after the implant procedure.
A bar supported overdenture will be made at the practice of the referring dentist or at the Centre for Special Dentistry in the Amphia Hospital, Breda.

T7
Six months after the implant procedure the patients will visit the Amphia Hospital for a check up and panoramic X-ray to check the fit of the bar on the implants and the clinical parameters will be scored by the dental hygienist. The dental hygienist will also perform cleaning of the implants and will provide the patient with cleaning instructions.

T8
Every three months the patient will visit the dental hygienist for measurement of the clinical parameters. The dental hygienist will also perform cleaning of the implants and will provide the patient with cleaning instructions.

T9
One year after the placement of the implants, a panoramic x-ray and photographs will be taken.
One observer will measure bone levels in the x-rays. This will be done at three different times to lower the risk of intraobserver differences.
Implant and overdenture survival will be measured. Loss of implants will be noted at any time of loss of the implant. Remake and adjustments of the overdenture will be noted and time of repair/replacement will be scored.
Patients will be asked to fill out page 7 and 8 of the questionnaire.
Patient function and satisfaction will be evaluated with the MFIQ and the

questionnaire involving questions about satisfaction of the procedure and final prosthetic result and change in facial appearance(including VAS-scores).

5. Oral Microbiol Immunol. 1987 Dec;2(4):145-51.
The microbiota associated with successful or failing osseointegrated titanium implants.
Mombelli A, van Oosten MA, Schurch E Jr, Land NP.

Study burden and risks

There is no difference in the number of visits for the two groups.
The difference rests in the number of implants placed. Knowing that the minimum number of implants required in order to support a denture is four implants, the outstanding risk is that of implant loss. Should such loss occur, it will have more impact on patients in the group with four implants, because, provided that only one implant is lost, the patient in question will only have three implants left. On the other hand, should an implant be lost by a patient receiving six implants, there will still be five implants left. As such, for the group receiving four implants, a second operation for implant replacement will be necessary.
Benefits for the group with four implants are the probable lower time of surgical and prosthetic procedures, less discomfort, easier dental hygiene and lower costs, since there will 2 implants less be placed, resulting in lower costs for the implant and prosthetic procedures.

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

* Informed consent to participate in this study.
* Over 18 years of age.
* Atrophic edentulous maxilla with insufficient bone to place implants without augmentation procedures (width and height less than 3mm in the lateral parts of the maxilla) Cawood classification IV or higher.
* No previous implant procedures in the maxilla.
* More than one year edentulous in the maxilla.
* Sufficient interocclusal distance to place implants with a bar supported overdenture.
* Edentulous, dentate or partial edentulous mandible

Exclusion criteria

* ASA III or higher
* Non-regulated diabetes
* Use of corticosteroids
* Use of bisphosphonates
* Active periodontitis in the mandible

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2015
Enrollment:	64
Type:	Actual

Medical products/devices used

Generic name:	overdenture
Registration:	No

Ethics review

Approved WMO

Date:	15-07-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL51251.015.15