Short dental implants (4 mm) in the posterior region of the mandible to support a single crown

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The aim of this study to evaluate the clinical performance of short implants (4 mm in length) in the resorbed posterior mandibular region of partially edentulous patients that will be restored with a single crown.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40507

Source
ToetsingOnline

Brief title
short dental implants

Condition

- Other condition

Synonym
artificial root, osseointegration and survival

Health condition

kauwstelsel, orale functie en comfort

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: mandible, short implants, singel tooth replacement

Outcome measures

Primary outcome

Mean marginal bone loss, clinical performance, implant survival

Secondary outcome

Patient satisfaction (OHIP-NL 49, SF-36, VAS-Score)

Study description

Background summary

Dental implant placement requires a minimal amount of available alveolar bone volume, both in terms of bone width as in height. If this is lacking, traditionally regular sized implants are placed after vertical augmentation of the jaw. Such treatment is relatively invasive with subsequent morbidity. More recently, a switch has been made to the use of short implant, circumventing the need for augmentation. The implants which become available to the market become increasingly shorter.

Study objective

The aim of this study to evaluate the clinical performance of short implants (4 mm in length) in the resorbed posterior mandibular region of partially edentulous patients that will be restored with a single crown.

Study design

A prospective case series.

Intervention

Placement of a 4mm dental implant in the resorbed posterior mandible to support

a single crown

Study burden and risks

The burden to participate in this study is low since the treatment as conventional implant treatment if offered without augmentation. One extra visit is necessary to sign the informed consent and to give the patient time to consider the decision of participation. All other visits are regular, when treated with implants. The x-rays taken to evaluate the bone height around the implant is also a standard procedure after implant insertion.
The use of this 4mm implant for a single crown will be off-label since the producer recommends blocking two implants. But in case of insufficient bone the placement of a longer implant would require a bone augmentation which is expensive and causes a relatively high morbidity with unpredictable outcome. Therefore insertion of a longer implant won*t be a good alternative for the anticipated patients.
The main risk of this type of short implant is that it will be lost in case of severe bone resorption (due to peri-implantitis). Of course this process of inflammation and subsequently bone resorption will take a longer time in case of a longer implant. But the risk of getting peri-implantitis is the same for all lengths.
In case of severe bone loss the implant becomes loose and can be removed easily. Damage to the tissues will be smaller in case of a short implant compared to a long implant.
The risk of fracture of the implant neck is de same as for longer implants since the diameter of the neck is exactly the same. This is a rare problem. Therefore this risk is negligible. But in case of a fracture the implant can be removed by a removal tool and the damage to the tissues will be smaller compared to the removal of a longer implant.
In short, the patient will benefit from this treatment since there are no good alternatives. The treatment will be offered as an regular treatment with no reduction in costs.

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

- The patient is 18 years or older;
- The missing or lost tooth is a premolar or a molar in the mandible;
- Sufficient healthy and vital bone to insert a dental implant with a length of 4.0 mm;
- The implant site must be free from infection;
- Adequate oral hygiene (modified plaque index and modified sulcus bleeding index)
- Sufficient mesio-distal, bucco-lingual, and interocclusal space for placement of an anatomic restoration;
- The patient is capable of understanding and giving informed consent.

Exclusion criteria

- Medical and general contraindications for the surgical procedures;
- Presence of an active and uncontrolled periodontal disease;
- Bruxism;
- Site of implant placement is an extraction wound younger than three months;
- A history of local radiotherapy to the head and neck region;
- Sufficient healthy and vital bone to insert a dental implant longer than a length of 4.0 mm.
-previously treatment with an implant at the same location followed by implant-loss

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Generic name:	dental implant
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	14-04-2014
Application type:	First submission
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

ID: 23139
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL47216.042.13
OMON	NL-OMON23139