Ultra short dental implants to support a 3-unit bridge in the lower jaw

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23139

Source
NTR

Health condition

dental implants
ultra-short
lateral part of mandible
fixed dental prosthesis

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Straumann B.V. - material support

Intervention

Outcome measures

Primary outcome

-Marginal bone levels (MBL) are determined from standardized, long cone intraoral radiographs by measuring from the edge of the abutment to the bone-to-implant contact, both mesially and distally.

Secondary outcome

-Probing pocket depth (PPD) and bleeding on probing (BOP): Probing the implant is performed at 2 sites per implant (mid-buccal and mesial). A plastic periodontal probe with 0.25 N of calibrated probing force is used (Click-probe®, KerrHawe, Bioggio, Switzerland). PPD is measured in millimetres from the mucosal margin to the clinical pocket. BOP is noted as absent (score=0) or present (score=1). Mean values per implant are calculated for all variables (meanPPD, meanBOP).

-Marginal soft tissue recession (REC) is measured in millimetres from the edge of the healing abutment to the mucosal margin. Mean values per implant are calculated (meanREC)

-Implant Survival (IS), defined as the presence of the implant at any moment of observation is also noted.

-Maintenance: Detailed post-insertion maintenance and restorative complications and revisions are reported by means of chart review. Mechanical complications are analyzed.

Questionnaires:

-Oral health related quality of life (Dutch version of OHIP-49). To asses the impact of the treatment on patients oral health related quality of life.

-Short-Form General Health Survey (RAND36). To asses the health related quality of life

-Visual Analogue Scale (VAS) on general satisfaction with the function and appearance of their prosthetic appliance (range 0-100).

Study description

Background summary

Rationale: 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.

Objective: The aim of this study to evaluate the clinical performance and implant survival statistics of short implants (4 mm in length) in combination with a longer implant in the severy resorbed posterior mandible of partially edentulous patients that will be restored with a 3-unit fixed dental prosthesis (FDP).

Study design: Study population: A prospective case series. The study population will consist of 15 healthy human volunteers with an indication for fixed implant treatment in the severely resorbed lateral parts of the mandible and a relative contraindication for bone augmentation. Subjects are 18 years and older and wear a full arch denture in the opposing jaw.

Intervention (if applicable): At each side of the partially edentulous mandible, two implants will be placed: one implant with a length of 4 mm in the posterior region of the mandible in combination with a longer implant in the premolar region (Straumann Standard Implant, RN, Institut Straumann AG, Basel, Switzerland). After a period of submerged healing for three months the implants are uncovered and a screw-retained 3-unit FDP will be placed on both sides of the mandibula.

Main study parameters/endpoints: Mean marginal bone loss, clinical performance, implant survival.

Secondary study parameters/endpoints: Patient satisfaction (OHIP-NL 49, VAS-Score).

Study objective

When combined with a longer implant, an ultra-short implant van succesfully used to support a 3-unit Fixed Dental Prosthesis

Study design

• 1st appointment (screening, presenting information about the study + informed consent form)

• Informed consent. Data collection (clinical parameters (x-ray, digital images, questionnaires)

• T0Surgical procedure: placing 1 implant in mandible, including normal follow up

• 2 weeks: suture removal, x-ray; 3 months submerged healing)

• T3: Three months after implant placement: Second stage surgery (uncover implants, placement of healing abutment)

• Start of making a suprastructure

• T4: Crown placement (Data collection / xray)

• T16: Sixteen months after implant placement/ 12 months after crown placement (Data collection / xray)

Intervention

In all subjects four implant (Straumann Standard dental implant, Institut Straumann AG,

Basel, Switzerland) are placed by means of a conventional installation procedure in local anesthesia. The use of this 4mm implant in this indication (in combination with a longer implant) is within the indications recommended by the producer en therefore not experimental (figure 2 and 3).

Contacts

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Eligibility criteria

Inclusion criteria

- The patient is 18 years or older;

- The missing or lost teeth are premolars and molar in the mandible;

- Sufficient healthy and vital bone to insert a dental implant with a length of 4.0 mm in the posterior region in combination with a longer implant in the premolar region;

- The implant site must be free from infection;

- The patient is wearing a full arch dental prosthesis in the upper jaw

- 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.
participate

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 in the posterior region.

-previously treatment with an implant at the same location followed by implant-loss

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2015
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion
Date: 26-02-2018
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40507
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6880
NTR-old	NTR7058
CCMO	NL47216.042.13
OMON	NL-OMON40507

Study results