A randomized clinical trial on short endosseous implants in the posterior region.
The influence of platform switching on the marginal bone level.

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To investigate the influence of platform-switched implant-abutment connections (smaller diameter abutment on wider diameter implant) of short implants (8.5 mm in length) on marginal peri-implant bone levels and clinical variables.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35224

Source
ToetsingOnline

Brief title
Short implants in the posterior region

Condition

- Other condition

Synonym
missing tooth

Health condition

verloren gaan van gebitselementen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Biomet 3i

Intervention

Keyword: crown, implant, tooth

Outcome measures

Primary outcome

Changes in marginal peri-implant bone level will be measured on standardized radiographs.

Secondary outcome

-Implant survival. The survival rate of the implant will be assessed one year after placement of the definitive restoration. In this study an implant failure is defined as each implant that was removed due to implant mobility as a consequence of loss of osseo-integration.

-Probing depth. Probing of the implant and the adjacent teeth is performed at four sites sites (mesial, distal, buccal, lingual/palatinal). The probing depth will be measured pre-operative, one month and one year after placement of the definitive restoration. Probing of the implant is part of normal check-up after implant placement.

-Modified Plaque-index and Modified Bleeding-Index, Gingiva index. These parameters will be evaluated pre-operative, one month and one year after placement of the definitive restoration. The adjacent teeth will be counted as well in the assessments. During probing of the implant and the adjacent teeth,

the indices as mentioned above can be assessed. Probing of the implant is part of normal check-up after implant placement. Probing of teeth is part of standard dental check-up.

-Patient satisfaction. Patients will be asked to complete a questionnaire measuring their satisfaction with the aesthetic and functional outcome of the treatment one month after definitive restoration. Furthermore, discomfort related to implant surgery or associated with the restorative procedure will be assessed one month after definitive restoration.

Study description

Background summary

The aging human might, due to caries or periodontal lesions, loose one or more of their back teeth in the posterior region of the maxilla or mandible. The major part of people does not want removable dentures, but prefer fixed construction as an implant based crown. Frequently, the bone in this posterior zone is resorbed and there is only enough bone to place a short (<10 mm length) implant. In the past short oral implants have been associated with lower survival rates. There are several presumed reasons for a lower survival rate of short implants in the posterior maxilla or mandible. First, compared to longer implants with a comparable diameter there is less bone to implant contact when short implants are used, simply because there is less implant surface. Secondly, short implants are mostly placed in the posterior zone where the quality of the alveolar bone is relatively poor, especially in the maxilla. Thirdly, often a very outsized crown has to be made to reach occlusion, because of the extensive resorption in the posterior region, which causes a higher crown to implant ratio.
To avoid the use of short implants the resorbed bone can be augmented using a bone grafting technique. This modification in the patient*s anatomy makes it possible to insert a longer implant, but an extra surgical intervention also leads to greater patient*s morbidity, higher costs and a longer treatment period. Esposito et al. (2010) concluded from their systematic review on augmentation procedures of the maxillary sinus: *Short implants may be as effective and cause fewer complications than longer implants placed using a more complex technique.* And from their systematic review on horizontal and vertical bone augmentation techniques for dental implant treatment they

concluded: *Short implants appear to be a better alternative to vertical bone grafting of resorbed mandibles.* Complications, especially for vertical augmentation, are common.* From the systematic review of Telleman et al. (2011) could be concluded that there is fair evidence that short (<10 mm) implants can be successfully placed in the partially edentulous patient, though with an increasing survival rate per implant length.
So, short implants are increasingly used for the prosthetic solution of the resorbed posterior zone of partially edentulous patients. But in short implants it is important to preserve peri-implant bone, although they might be expected to develop a greater maximum compressive stress in their coronal region in comparison to longer implants, which could lead to bone microfracture and peri-implant bone loss.
A new development in the implant neck design is the concept op platform-switching; placing a smaller diameter abutment on a wider diameter implant, which has resulted in less peri-implant bone loss. Several theories were suggested to explain the rationale behind the concept of platform switching for marginal bone preservation. The biomechanical rationale proposed that by platform-switching the stress-concentration zone (from the forces of occlusal loading) are directed from the crestal bone-implant interface to the axis of the implant and so greatly reduces the stress level in the cervical bone area. Another theory concerned the role of inflammatory cell infiltrate at the implant abutment connection. The presence of peri-implant microbiota was suggested to influence the crestal bone resorption. The systematic review of Atieh et al. (2010) about platform switching for marginal bone preservation around standard or long implants (>10 mm length) showed that peri-implant bone loss around platform-switched implants was significantly less comparing to platform-matched implants. As short implants might be expected to develop a greater maximum compressive stress in their coronal region in comparison to longer implants, which could lead to peri-implant bone loss, it is not cleat yet whether platform-switching is also effective in peri-implant bone preservation around short implants.
To our knowledge no study had been reported about the effect of platform-switching on peri-implant bone level changes around short implants in the resorbed posterior zone of partially edentulous patients. There is very limited evidence regarding the effect of platform-switching (Trammell et al. 2009) on implants shorter than 10 mm in length.
Therefore, the aim of this study is to compare the outcome of short implants (8.5 mm in length), with a conventional implant-abutment connection to a platform-switched implant-abutment connection. Implants will be placed in the resorbed posterior region of partially edentulous patients.

Study objective

To investigate the influence of platform-switched implant-abutment connections (smaller diameter abutment on wider diameter implant) of short implants (8.5 mm in length) on marginal peri-implant bone levels and clinical variables.

Study design

A randomized clinical trial

Intervention

This study is comprised of two groups. Patients allocated to the control group will be treated with a platform-matched implant-abutment connection (Osseotite XP Certain implant, Biomet 3i, Palm Beach Gardens, Florida, USA). Patients allocated to test group will be treated with a platform-switched implant-abutment connection (Osseotite Certain Prevail, Biomet 3i).

Study burden and risks

One implant type might lead to less peri-implant bone loss than another type.
There are no further risks involved, since it is a regular dental treatment.
The extra load for the patients is filling in questionnaires.

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 maxilla or mandible;
-Sufficient healthy and vital bone to insert a dental implant with a length of 8.5 mm and at least 4.0 mm in diameter.
-The implant site must be free from infection;
-Adequate oral hygiene (modified plaque index and modified sulcus bleeding index <= 1, acoording to Mombelli, Loë & Silness))
-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;
- Smoking
- A history of local radiotherapy to the head and neck region

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2011
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Dental Implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-09-2011
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

No registrations found.

In other registers

Register	ID
CCMO	NL37453.042.11