Implant-supported single tooth replacements in the aesthetic zone: a randomized clinical trial

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To investigate the influence of different implant neck designs 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-OMON41534

Source
ToetsingOnline

Brief title
Implant-supported single tooth replacements in the aesthetic zone

Condition

- Other condition

Synonym
Missing tooth

Health condition

Aandoeningen aan het gebit

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Crown, Implant, Tooth

Outcome measures

Primary outcome

Changes in marginal peri-implant bone loss

Secondary outcome

Clinical performance, namely:

-Implant survival.

-Implant Crown Aesthetic Index. One month and one and five year after placement of the final restoration, the Implant Crown Aesthetic Index is assessed as described by Meijer et al., 2005. The aesthetic index is assessed on standardized photographic images, taken according to Meijndert et al., 2004.

-Modified Plaque-index and Modified Bleeding-Index (Mombelli et al., 1987), Gingiva index (Loë and Silness, 1963). These parameters are evaluated pre-operative, one month and one and five year after placement of the definitive restoration. The adjacent teeth are counted as well in the assessments.

-Papil-index (Jemt et al., 1997). This index is evaluated pre-operative, one month and one and five year after definitive restoration. The Papil-index is assessed on the standardized photographic images.

-Probing depth. Probing of the implant and the adjacent teeth is performed at three sites, buccodistal, buccomedial, buccomesial. The probing depth is measured pre-operative, one month and one and five year after placement of the definitive restoration.

-Recession. The degree of recession is measured on the standardized photographic images. Therefore the distance is measured between the most cervical and mediobuccal point of the marginal gingiva perpendicular to the incisal edge of the definitive crowns one week and one year after placement. The adjacent teeth are counted as well in the measurements. Also the distance between the most coronal point of the mesial and distal papil perpendicular to the incisal edge of the natural adjacent tooth is determined. This is done on the standardized photographic images taken pre-operative, one month and one and five year after definitive restoration.

-Width of keratinized epithelium. The width in millimetres of keratinized epithelium is measured pre-operative, one month and one and five year after the definitive restoration has been placed. This is done by using a periodontal probe.

-Patient satisfaction. Patients are asked to complete a questionnaire measuring their satisfaction with the aesthetic and functional outcome of the treatment one month and one and five year after definitive restoration. Also, patient satisfaction concerning the partial removable denture is measured pre-operatively.

Study description

Background summary

The application of dental implants for single-tooth replacements has evolved into a viable prosthodontic alternative to conventional fixed bridgework, resin-bonded restorations or removable partial dentures. Long-term studies have reported excellent implant survival rates when applied for single-tooth replacements. Psychological benefits and tooth structure conservation adjacent to the tooth to be replaced, are among the advantages of implant supported restorations.
Because of the high levels of survival, the focus of attention is moving from *survival* to *quality of survival* and the aesthetics are becoming the measure of success. This involves the establishment of a soft tissue contour that is harmonious with the gingiva of the adjacent teeth and a crown in balance with the adjacent dentition.
Over the past years, implant manufacturers have introduced several small implant modifications to obtain an optimal and stable soft tissue appearance. Preservation of the marginal peri-implant bone is the major factor on which these alterations are founded. Nowadays, most implant systems use machined implant necks (a *smooth implant neck*), due to the fact that rough surfaces accumulate and retain more plaque than smooth surfaces. However, some studies have shown that an implant neck with a rough surface shows less marginal bone loss compared to a smooth implant neck. Therefore, implants with a rough implant neck were introduced. Another modification that was introduced was the scalloped implant platform. This platform was designed to preserve the interdental osseous peaks that support the soft tissue. Comparing to implants with a traditional flat platform, the scalloped implant mirrors these interdental osseous peaks.
To date, no randomized clinical trials have been published in which these different implant neck designs were investigated for the restoration of a single missing tooth in the anterior dentition.

Study objective

To investigate the influence of different implant neck designs on marginal peri-implant bone levels and clinical variables.

Study design

Randomized clinical trial

Intervention

For this study, three different study groups are introduced. Patients allocated

to the first study group were treated with a Replace Select Tapered implant (Nobel Biocare AB, Gothenburg, Sweden) (smooth implant neck topography). Patients allocated to the second study group were treated with a Nobel Replace Tapered implant (Nobel Biocare AB)(rough implant neck topography). Patients allocated to the third study group were treated with a Nobel Perfect implant (Nobel Biocare AB)(scalloped implant neck topography).

Study burden and risks

One implant type might lead to less peri-implant marginal bone loss than an other type. There are no further risks involved, since it is a regular dental treatment. The extra load for the patients is filling in a questionnnaire and the making of photographs.

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 an incisor (central or lateral), a canine or a first premolar in the maxilla. The adjacent teeth are natural teeth;
-Sufficient healthy and vital bone to insert a dental implant with a minimum length of 10 mm and at least 3.5 mm in diameter. In case of insufficient bone volume, a bone augmentation procedure will be performed with autologue bone. After three months of healing, the dental implant will then be inserted;
-The implant site must be free from infection;
-Adequate oral hygiene (modified plaque index and modified sulcus bleeding index <= 1);
-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 (patients who stop smoking six weeks before the operation can be included);
-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):	01-07-2010
Enrollment:	90
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	08-06-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-09-2015
Application type:	Amendment
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	NL31369.042.10