Single tooth replacement with dental implants in the aesthetic zone
A randomized clinical trial of different implant designs and different times of restoration.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25803

Source
NTR

Brief title
N/A

Health condition

Dental implant, single-tooth

Sponsors and support

Primary sponsor: - University Medical Center Groningen, University of Groningen

- Nobel Biocare

Intervention

Outcome measures

Primary outcome

Esthetic Index according to Meijer et al. 2005.

Secondary outcome

1. Implant survival;
2. Marginal bone resorption;
3. Papil-index;
4. Recession;
5. Patient satisfaction.

Study description

Background summary

There are different dental implant systems available specially designed for the replacement of a missing tooth in the aesthetic zone. They differ in surface characteristics and design. There are only a few studies that address the aesthetics of single-tooth replacements and even no prospective clinical trials have been published comparing the aesthetic outcome of different types of implant designs. For instance, the influence of the shape and surface of the collar of the implant on the aesthetic result has not yet been researched. Furthermore, no studies have focused on the aesthetic result of immediately restored dental implants in the anterior zone in comparison with conventionally restored implants.
The purpose of this study is to evaluate and compare the aesthetic definitive outcome of (1) three different implant designs, and (2) two different times of restoration, namely immediate and conventional restoration. The null hypothesis is that there are no differences in the definitive aesthetic outcome of different implant designs or times of restoration.

Study objective

The purpose of this study is to evaluate and compare the aesthetic definitive outcome of
1. Three different implant designs; and
2. Two different times of restoration, namely immediate and conventional restoration. The null hypothesis is that there are no differences in the definitive aesthetic outcome of different implant designs or times of restoration.

Intervention

Patients are randomly assigned to the following study groups:

Group I: a dental implant of the ‘NobelReplace Tapered’ system is inserted in the anterior zone of the maxilla. After an osseointegration period of three months a temporary restoration is made;
Group IIA: a dental implant of the ‘NobelReplace Groovy’ system is inserted in the anterior zone of the maxilla. Within 24 hours a temporary restoration is placed;
Group IIB: a dental implant of the ‘NobelReplace Groovy' system is inserted in the anterior zone of the maxilla and a temporary restoration is made after three months;
Group III: a dental implant of the ‘NobelPerfect’ system is inserted in the anterior zone of the maxilla and a temporary restoration is made after three months.

Contacts

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Eligibility criteria

Inclusion criteria

1. The patient is 18 years or older;
2. The missing or lost tooth is an incisor (central or lateral), a canine or a first bicuspid in the maxilla. The adjacent teeth are natural teeth;
3. 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;
4. The implant site must be free from infection;
5. Adequate oral hygiene (modified plaque index and modified sulcus bleeding index ¡Ü 1);
6. Sufficient mesio-distal, bucco-lingual, and interocclusal space for placement of an

anatomic restoration;
7. If necessary, the temporary restoration can be designed free from occlusal contact;
8. The patient is capable of understanding and giving informed consent.

Exclusion criteria

1. Medical and general contraindications for the surgical procedures;
2. Presence of an active and uncontrolled periodontal disease;
3. Presence of pathologic microflora;
4. Bruxism;
5. Site of implant placement is an extraction wound younger than three months;
6. Smoking (patients who stop smoking six weeks before the operation can be included);
7. A history of local radiotherapy to the head and neck region.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2004
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	15-09-2005
Application type:	First submission

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
NTR-new	NL382
NTR-old	NTR422
Other	: N/A
ISRCTN	ISRCTN37243042

Study results

Summary results
N/A