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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25803

Bron
NTR

Verkorte titel
N/A

Aandoening

Dental implant, single-tooth

Ondersteuning

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

- Nobel Biocare

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Esthetic Index according to Meijer et al. 2005.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2004
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	15-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL382
NTR-old	NTR422
Ander register	: N/A
ISRCTN	ISRCTN37243042

Resultaten

Samenvatting resultaten
N/A