

Immediate placement of single-tooth implants in the maxillary aesthetic region: a 10-year randomized controlled trial

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Investigate the influence on the hard and soft tissues of immediate placement of a single implant in an extraction socket in the anterior maxilla. Null hypothesis: is that there are no differences in the hard and soft tissues and aesthetic outcome

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

Samenvatting

ID

NL-OMON20601

Bron

NTR

Verkorte titel

Immediate implant placement

Aandoening

Failing tooth in the aesthetic zone

Ondersteuning

Primaire sponsor: University Medical Centre Groningen (Netherlands)

Overige ondersteuning: Dept of Oral and Maxillofacial Surgery, University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome is change in marginal bone level

Toelichting onderzoek

Achtergrond van het onderzoek

Tooth extraction is necessary when all other dental treatments to preserve a tooth did not help. After tooth extraction the underlying bone structure and the surrounding soft tissues collapse if not preserved. In the visible area seen upon full smile (aesthetic zone) the preservation of these tissues are important. The aesthetic success of a dental restoration is determined by the harmony of the underlying bone structure and these surrounding soft tissues. It is not known to what extend immediate placement of a single implant can do to preserve these tissues if there is sufficient bone or if there is a bony defect after the tooth extraction. The study reports on 10-years results.

Doel van het onderzoek

Investigate the influence on the hard and soft tissues of immediate placement of a single implant in an extraction socket in the anterior maxilla.

Null hypothesis: is that there are no differences in the hard and soft tissues and aesthetic outcome

Onderzoeksopzet

10-years evaluation of study groups

Onderzoeksproduct en/of interventie

2 groups with sufficient bone and 2 groups with insufficient bone. They are randomised depending on the bony defect. An envelope is opened after the bony defect is determined.

1. Sufficient bone: the implant is immediately placed after tooth extraction and immediately restored with a temporary crown. One stage surgery.
2. Sufficient bone: the implant is immediately placed after tooth extraction but restored after 3 months with a temporary crown. Two stage surgery.
3. Insufficient bone: the implant is immediately placed after tooth extraction but restored after 3 months with a temporary crown. Two stage surgery.
4. Insufficient bone: a guided bone augmentation takes place after tooth extraction. 3 months later the implant is placed in a healed site. 3 months later the implant is restored with a

temporary crown. Three stage surgery. This is the conventional way.

Contactpersonen

Publiek

University Medical Center Groningen
Henny J.A. Meijer

+31503613840

Wetenschappelijk

University Medical Center Groningen
Henny J.A. Meijer

+31503613840

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. The patient is 18 years or older
2. The replacing tooth is an incisor (central or lateral), a canine or a first premolar in the maxilla. The adjacent teeth are natural teeth
3. The implant site must be free from infection
4. Adequate oral hygiene
5. Sufficient mesio-distal, bucco-lingual, and interocclusal space for placement of an anatomic restoration
6. 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
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2021
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	15-03-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34343

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9340
CCMO	NL32240.042.10
OMON	NL-OMON34343

Resultaten

Samenvatting resultaten

1-year publications:

Slagter KW, Meijer HJA, Bakker NA, Vissink A, Raghoobar GM. Feasibility of immediate placement of single-tooth implants in the aesthetic zone: a 1-year randomized controlled trial. J Clin Periodontol 2015; 42: 773-782.

Slagter KW, Meijer HJA, Bakker NA, Vissink A, Raghoobar GM. Immediate single-tooth implant placement in bony defects in the esthetic zone: a 1-year randomized controlled trial. J Periodontol 2016; 87: 619-629.

5-years publications:

Slagter KW, Raghoobar GM, Hentenaar DFM, Vissink A, Meijer HJA. Immediate placement of single implants with or without immediate provisionalization in the maxillary aesthetic region: a 5-year comparative study. J Clin Periodontol 2021;48:272-283.

Slagter KW, Meijer HJA, Hentenaar DFM, Vissink A, Raghoobar GM. Immediate single-tooth implant placement with simultaneous bone augmentation versus delayed implant placement after alveolar ridge preservation in bony defect sites in the esthetic region: a 5-year randomized controlled trial. J Periodontol 2021 (accepted).