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

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

Summary

ID

NL-OMON20601

Source
NTR

Brief title
Immediate implant placement

Health condition

Failing tooth in the aesthetic zone

Sponsors and support

Primary sponsor: University Medical Centre Groningen (Netherlands)
Source(s) of monetary or material Support: Dept of Oral and Maxillofacial Surgery, University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

Primary outcome is change in marginal bone level

Secondary outcome

Secondary outcomes are survival rates, buccal bone thickness, soft peri-implant tissues, aesthetics and patient reported outcomes

Study description

Background summary

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.

Study objective

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

Study design

10-years evaluation of study groups

Intervention

2 groups with suffcient 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.

Contacts

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Eligibility criteria

Inclusion criteria

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

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
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2021
Enrollment:	80
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-03-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34343
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results

1-year publications:
Slagter KW, Meijer HJA, Bakker NA, Vissink A, Raghoebar 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, Raghoebar 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, Raghoebar 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, Raghoebar 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).