Immediate placement and immediate restoration of single tooth implants in post-extraction sites in the aesthetic region

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Patients with a satisfaction rate of 80 or more

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21333

Bron
Nationaal Trial Register

Verkorte titel
Immediate placement and immediate restoration of single tooth implants in post-extraction sites in the aesthetic region

Aandoening

Failing tooth in the maxillary aesthetic region

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Satisfaction rate

Toelichting onderzoek

Achtergrond van het onderzoek

Single implant treatment in the maxillofacial aesthetic zone has been shown to be a highly reliable treatment procedure for the rehabilitation of a single failing tooth or a single missing tooth (den Hartog et al. 2008; 2011, Jung et al. 2012; Slagter et al. 2014; Zuiderveld et al. 2018).
Currently, there is a growing tendency to place single tooth dental implants in this zone immediately after extraction of a failing tooth in the fresh extraction socket (Del Fabbro et al.2015; Arora et al. 2017) as an alternative to early (<8 weeks after tooth extraction) or delayed placed implants (>8 weeks after tooth extraction). Presumably, this tendency is related to evolving society factors, with more demanding patients and a wish for a direct result. Innovations in implant surfaces and designs have facilitated the possibilities for such an approach (Lang et al. 2012). There is evidence that clinical, radiographic and aesthetic outcome is comparable for immediate and delayed procedures (Slagter et al. 2015, 2016). Due to this outcome, new guidelines have been introduced leading to immediate placement and immediate provisionalization if possible and ridge preservation in cases of large bone defects (Van Nimwegen et al. 2018).
The introduction of intraoral scanning technology could be a next step to reduce treatment discomfort and treatment time. It is claimed that digital technology will optimize the treatment workflow by providing more comfort and safety for the patient and by requiring less operating time than conventional treatment (Schepke et al. 2015; Joda and Brägger 2016; Mangano et al. 2017; Galllardo et al. 2018). Treatment outcome with respect to fit of restorations is claimed to be better or at least just as good when produced with a digital workflow and has been extensively analyzed in comparative studies. (Chochlidakis et al. 2016; Tsirogiannis et al. 2016; Ahlholm et al. 2018).
Full digital workflows with registration of time/complications during the diagnostic/planning/manufacturing process, together with evaluation of clinical and radiographical performance, PROM’s, PES/WES during the follow-up period have never been subject of investigation in single tooth implant treatment of failing or missing teeth in the maxillary aesthetic region.
Therefore, the aim of the prospective case series study, with full digital workflow, is to evaluate single tooth implant treatment for patients with failing or missing teeth in the maxillary aesthetic region, with respect to registration of time/complications during the diagnostic/planning/manufacturing process, evaluation of clinical and radiographical performance and aesthetic outcome.

Doel van het onderzoek

Patients with a satisfaction rate of 80 or more

Onderzoeksopzet

pre-treatment, 1 month and 1 year evaluation

Onderzoeksproduct en/of interventie

Dental implant treatment

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• The patient is 18 years or older;
• The failing tooth is an incisor (central or lateral), cuspid or first bicuspid 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 with initial stability > 45 Ncm
OR
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 with initial stability > 45 Ncm three months after extraction of the tooth and the procedure of ridge preservation/ridge augmentation in case of a large bone defect;
• 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 temporary restoration can be designed free from occlusal contact;
• The patient is capable of understanding and giving informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Medical and general contraindications for the surgical procedures;
• Presence of an active and uncontrolled periodontal disease;
• Bruxism;
• Smoking
• A history of local radiotherapy to the head and neck region.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2020
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8264
Ander register	METC UMCG : Number 201900878

Resultaten