Single-tooth implants with immediate provisionalization after alveolar ridge preservation in the maxillary esthetic zone: a one year prospective case series with full digital workflow

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Satisfying results for patients and professionals (VAS-scores and PES/WES-scores)

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28471

Bron
NTR

Verkorte titel
Single-tooth implants with immediate provisionalization after alveolar ridge preservation

Aandoening

Patients with a failing incisor (central or lateral), cuspid or first bicuspid in the maxilla.

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: University funded

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in approximal marginal bone level measured on standardized digital intra-oral radiographs during the evaluation period.

Toelichting onderzoek

Achtergrond van het onderzoek

• Background
There is a growing tendency to place a provisional restoration immediately following implant placement. Clinical advantages are shortening of treatment duration and soft tissue guiding during healing resulting in better esthetic outcomes. Provisional restorations can be made either chair-side or in the dental laboratory after implant placement. Nowadays, digital planning makes it possible to fabricate the provisional restoration before implant surgery. The advantage of this technique is that the treatment procedure of implant placement and placement of the provisional restorations is much less time consuming for the patient and due to its machined polished character possibly beneficial for soft tissues.
• Main research question
The aim of the prospective case series study, with full digital workflow, is to evaluate single tooth implant treatment after alveolar ridge preservation 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.
• Design (including population, confounders/outcomes)
The study design is a prospective, single-arm observational study for evaluation of 30 patients with a failing tooth and after alveolar ridge preservation in the maxillary aesthetic region to be treated with an implant-supported provisional and definitive restoration by means of a digital workflow. Outcomes: registration of time/complications during the diagnostic/planning/manufacturing process, evaluation of clinical and radiographical performance and aesthetic outcome.

Doel van het onderzoek

Satisfying results for patients and professionals (VAS-scores and PES/WES-scores)

Onderzoeksopzet

Pre-treatment, at the day of implant surgery, 1 month after placement of definitive restoration, 12 months after placement of definitive restoration.

Onderzoeksproduct en/of interventie

Single tooth implant treatment after alveolar ridge preservation in the maxillary aesthetic region and immediate provisionalization with a prefabricated temporary crown.

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 implant region is an incisor (central or lateral), cuspid or first bicuspid in the maxilla; the adjacent teeth are natural teeth;
• Sufficient healthy and vital bone after alveolar ridge preservation 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;
• 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:	01-10-2021
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
Undecided

Ethische beoordeling

Positief advies

Datum:	24-07-2021

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	NL9621
Ander register	METc UMCG : M21.279173

Resultaten

Samenvatting resultaten
One article is written on the 1-year clinical performance of treatment concept.