

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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28471

Source

NTR

Brief title

Single-tooth implants with immediate provisionalization after alveolar ridge preservation

Health condition

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

Sponsors and support

Primary sponsor: UMCG

Source(s) of monetary or material Support: University funded

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Treatment time (total time of diagnostic, surgical, prosthetic and dental laboratory)
- Implant survival and restoration survival
- Change in mid-buccal mucosal level (MBML), assessed from standardized intra-oral photographs taken before tooth extraction (Tpre), one (T1) and 12 months (T12) after final implant crown placement
- Changes in inter-proximal mucosal levels (IML), assessed from standardized intra-oral photographs taken before tooth extraction (Tpre), one (T1) and 12 months (T12) after final implant crown placement
- Peri-implant mucosa and implant crown aesthetics assessed from photographs taken at T12 using the Pink Esthetic Score-White Esthetic Score (PES/WES).
- Change in buccal bone thickness measured on CBCT's (Meijer et al. 2018) between Tpre, T1 and T12
- Probing pocket depth using a periodontal probe at the mesio-buccal, mid-buccal, and disto-buccal and mid-palatal aspect at T1 and T12
- Amount of plaque (modified plaque index, Mombelli et al. 1987) at T1 and T12
- Bleeding after probing (modified sulcus bleeding index, Mombelli et al. 1987) at T1 and T12
- Gingival condition (gingival-index, Löe 1967) at T1 and T12
- Width of the keratinized mucosa: no keratinized mucosa, <1mm of keratinized mucosa, 1-2mm of keratinized mucosa, ≥2mm of keratinized mucosa
- Volume of the interproximal papilla, using the papilla index (Jemt 1997) at T1 and T12
- Patient satisfaction

Study description

Background summary

• 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.

Study objective

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

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

- 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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2021
Enrollment:	30

Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description

Undecided

Ethics review

Positive opinion

Date: 24-07-2021

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9621
Other	METc UMCG : M21.279173

Study results

Summary results

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