Alveolar ridge preservation with a xenograft and a collagen matrix or a free connective tissue graft versus spontaneous healing: A 1-year prospective randomized clinical trial.

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Alveolar ridge preservation with a xenograftand a collagen matrix or a free connective tissue graft, compared to spontaneous healing, leads to better soft tissue and bone volume for early implant placement and a better aesthetic result, up to 1 year...

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

Samenvatting

ID

NL-OMON22864

Bron
NTR

Verkorte titel
Mucograft Seal Study

Aandoening

Oral implants, alveolar ridge preservation

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Department Oral and Maxillofacial Surgery

Catharina Hospital Eindhoven, Department Oral and Maxillofacial Surgery
Overige ondersteuning: Geistlich Pharma AG, Wolhusen, Switzerland
Straumann AG, Basel, Switzerland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The level of the buccal marginal gingiva (one year after implant loading)

Toelichting onderzoek

Achtergrond van het onderzoek

Replacement of a single tooth in the esthetic zone is a demanding procedure. The application of a biomaterial in the extraction socket, covered with a collagen matrix or a soft tissue graft may lead to less vertical and horizontal changes of the alveolar ridge and soft-tissues and thereby simplifying the procedure with more predictable outcomes.

The study is a prospective randomized clinical trial with 1-year follow-up. Patients in need for an implant-supported dental crown to replace a maxillary tooth in the esthetic zone are randomized in one of three techniques: A) bone substitute material and a collagen matrix B) bone substitute material covered with a palatal graft, or C) spontaneous healing. After extraction of the tooth, patients will be treated according to their assigned protocol. After 8 weeks a Straumann implant will be placed. The implants are loaded after a minimum healing time of approximately 8-10 weeks. Esthetic and clinical parameters and patient satisfaction is assessed after tooth extraction, before implant placement and up to one year after crown placement. Esthetic scores consist of the Peri-implant esthetic score (PES) and the White esthetic score (WES). Labial soft tissue volume is assessed using digitized casts; the buccal bone is assessed using Cone Beam CT scans. Other assessments are the buccal marginal gingiva, marginal bone level (MBL), plaque index (PI), the bleeding index BI, the gingiva index (GI), the pocket probing depth (PPD) and the width of the attached mucosa (WAM). A patient’s questionnaire includes a visual analog scales (VAS) that will focus on expectation and satisfaction of the surgical procedure and about the esthetic result of the dental crown and the peri-implant tissue.

Doel van het onderzoek

Alveolar ridge preservation with a xenograftand a collagen matrix or a free connective tissue graft, compared to spontaneous healing, leads to better soft tissue and bone volume for early implant placement and a better aesthetic result, up to 1 year after functional loading.

Onderzoeksopzet

Pre-operative, one week post extraction, implant placement, 2 weeks after implant placement 1, 6 and > 12 months after placement of the crown.

Onderzoeksproduct en/of interventie

Group A) Placement of a bone substitute material (deproteinized bovine bone mineral with 10% collagen; Bio-Oss Collagen®, Geistlich) covered with a collagen matrix (Geistlich Mucograft® Seal).

Group B) Placement of a bone substitute material (deproteinized bovine bone mineral with 10% collagen; Bio-Oss Collagen®, Geistlich) covered with a punch biopsy of the palate.

Group C) Spontaneous healing (control group).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Over 18 years of age. Need for an implant-supported dental crown to replace a maxillary tooth at the location of an incisor, cuspid or first/second bicuspid; single tooth diastema as a maximum; intact buccal bone plate (confirmed by clinical examination); sufficient occlusal and mesio-distal dimensions for insertion of one implant with a functional prosthetic restoration.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Presence of clinical active periodontal disease; presence of an acute inflammatory oral disease; smoking; uncontrolled diabetes; a history of radiotherapy in the head- and-neck region or current chemotherapy; disability (mental and/or physical) to maintain basic oral hygiene procedures; under eighteen years of age.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	09-11-2015
Aantal proefpersonen:	75
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 09-09-2017
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42186
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6497
NTR-old	NTR6685
CCMO	NL49965.078.14
OMON	NL-OMON42186

Resultaten

Samenvatting resultaten
N/A