# 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.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON22864

**Source**
Nationaal Trial Register

**Brief title**
Mucograft Seal Study

**Health condition**

Oral implants, alveolar ridge preservation

### Sponsors and support

**Primary sponsor:** Erasmus Medical Center, Department Oral and Maxillofacial Surgery<br>
<br>
Catharina Hospital Eindhoven, Department Oral and Maxillofacial Surgery
**Source(s) of monetary or material Support:** Geistlich Pharma AG, Wolhusen, Switzerland<br>
Straumann AG, Basel, Switzerland

## Intervention

## Outcome measures

### Primary outcome

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

### Secondary outcome

1. Peri-implant esthetic score (PES)

2. White esthetic score (WES)

3. Labial soft tissue volume (using impressions)

4. The marginal bone level around the implants/ Distance from implant shoulder to first bone-to-implant contact (MBL/DIB) using a standardized digital intra-oral radiograph

5. Evaluation of facial bone wall (using CBCT)

6. The plaque index (PI)

7. The bleeding index (B)

8. The gingiva index (GI)

9. The pocket probing depth (PPD)

10. The width of the attached mucosa (WAM)

11. Patient’s satisfaction about the esthetical result of the crown and peri-implant tissue

Tertiary: Implant succes

# Study description

### Background summary

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.

**Study objective**

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.

**Study design**

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

**Intervention**

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).

# Contacts

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# Eligibility criteria

## Inclusion criteria

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.

## Exclusion criteria

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.

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 09-11-2015 |
| Enrollment: | 75 |
| Type: | Anticipated |

# Ethics review

Positive opinion

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|---|---|
| Date: | 09-09-2017 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 42186
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

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

# Study results

**Summary results**
N/A