Alveolar ridge preservation with a xenograft Bio-Oss Collagen) and a collagen matrix (Mucograft Seal) or a free connective tissue graft versus spontaneous healing: a 1-year prospective randomized clinical study

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To evaluate clinical and esthetic outcomes and patient satisfaction following single-tooth replacement in the anterior maxilla in patients treated with a collagen matrix (Geistlich Mucograft® Seal) and a free connective tissue graft versus...

Ethical review	Approved WMO
Status	Pending
Health condition type	Connective tissue disorders (excl congenital)
Study type	Interventional

Summary

ID

NL-OMON42186

Source
ToetsingOnline

Brief title
Mucograft Seal

Condition

- Connective tissue disorders (excl congenital)
- Head and neck therapeutic procedures

Synonym
soft tissue defect

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Geistlich Pharma;Wolhusen en Straumann AG;Basel. Zwitserland

Intervention

Keyword: collagen, membrane, preservation, socket

Outcome measures

Primary outcome

The level of the buccal marginal gingiva.

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

Study description

Background summary

Replacement of a single tooth in the esthetic zone is a demanding procedure. For optimal esthetic results, no deficiency in both bone and soft tissue is acceptable. Immediately after tooth extraction, the alveolar ridge undergoes horizontal and vertical bone loss (Lang et al., 2012). This negatively influences the soft tissue contours, and thus esthetic outcome. Although immediate placement of an implant after extraction leads to acceptable esthetic results, there is an increased risk of mucosal recession due to the lack of adequate soft tissue (Lang et al., 2012; Chen et al., 2014). Early implant placement, 4 to 8 weeks after extraction, may offer advantages in terms of soft and hard tissue preservation (Sanz et al., 2012; Buser et al., 2014). The main goals when treating the extraction socket in the esthetic zone is to preserve as much as possible existing soft and hard tissue volume as possible for future implant placement (Fickl et al., 2012). Landsberg described a modified ridge preservation technique called *socket seal surgery* where flap elevation is avoided and it combines both bone and soft tissue grafting prior to implant placement. Closing the extraction site from the oral cavity using a thick epithelized palatal graft enables optimal ridge preservation immediately after tooth extraction (Landberg et al., 1994). Jung showed that the application of a slowly resorbing biomaterial (BioOss Collagen®, Geistlich) into an extraction socket, covered with an autogenous palatal soft tissue punch graft resulted in a high predictability and reliability for a good esthetic result for future (early) implant placement (Jung et al., 2004). The primary intention for the placement of the biomaterial is not to enhance bone formation, but to support the buccal contour of the alveolar ridge and stabilize the blood clot. Although a soft tissue graft is a relatively easy procedure, patient morbidity is often associated with the second surgical site (Griffin et al., 2006). An artificial socket seal might prevent donor morbidity associated with soft tissue grafts. Although there seems to be no difference in the long term change of the buccal soft tissue contour between an autogenous soft tissue punch graft and a collagen matrix (Schneider 2014), there is a lack in data concerning the difference in esthetic outcome between these two methods in early implant placement.

Study objective

To evaluate clinical and esthetic outcomes and patient satisfaction following single-tooth replacement in the anterior maxilla in patients treated with a collagen matrix (Geistlich Mucograft® Seal) and a free connective tissue graft

versus spontaneous healing.

Study design

A prospective randomized clinical study with 1-year follow-up.

Intervention

In the current prospective randomized clinical study, patients are assigned to one of three socket seal techniques:

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

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

C) Spontaneous healing (control group).

Study burden and risks

The measurements performed in this research are analyses of the peri-implant soft tissue and radiological analyses. Participation in this research is not dangerous and the patients are not at risk. The radiographs (before and after placing the implants) are taken anyway whether or not the patient is participating in this research. Radiological follow-up is not dangerous; the health of the patients is not at risk. Because the treatments are already performed for many years we expect no unknown or known incidences. In case of pregnancy the treatment is not performed. In case the patient wants to withdraw from this research this does not have any consequence. The treatment will be identical. However, the so far collected measurements data cannot be used anymore for this research.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Over 18 years of age
2) Need for an implant-supported crown to replace a maxillary tooth at the location of an incisor, cupsid or first/second bicuspid
3) Single tooth diastema as a maximum
4) Intact buccal bone
5) Sufficient occlusal and mesio-distal dimensions for insertion of one implant with a functional prosthetic restoration.

Exclusion criteria

1) Presence of clinical active periodontal disease.
2) Presence of an acute inflammatory oral disease.
3) Smoking.
4) Diabetes.
5) A history of radiotherapy in the head-and-neck region or current chemotherapy
6) Disability (mental and/or physical) to maintain basic oral hygiene procedures.
7) Under eighteen years of age

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	75
Type:	Anticipated

Medical products/devices used

Generic name:	Mucograft Seal
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-06-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-11-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22864
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL49965.078.14
OMON	NL-OMON22864