Small buccal dehiscences at implant placement can be reconstructed with a mixture of Straumann bone ceramic and autogenous bone covered with Membragel:
a 1-year prospective randomized multicenter clinical study

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Can small buccal bony dehiscences (< 4 mm) of non-submerged dental implants, seen at initial placement, be successfully reconstructed using the guided bone regeneration (GBR) technique with a mixture of Straumann bone ceramic and locally...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON41609

Source
ToetsingOnline

Brief title
Dehiscences - Membragel

Condition

- Bone disorders (excl congenital and fractures)
- Bone and joint therapeutic procedures

Synonym

1 - Small buccal dehiscences at implant placement can be reconstructed with a mixtur ... 24-05-2025

bonedefect, fenestration

Research involving
Human

Sponsors and support

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

Intervention

Keyword: dehiscence, implant, Membragel, regeneration

Outcome measures

Primary outcome

level of the marginal bone around the implant

Secondary outcome

1.the plaque index (PI),

2.the bleeding index BI,

3.the gingiva index (GI),

4.the pocket probing depth (PPD), and

5.the width of the attached mucosa (WAM)

6. Peri-implant esthetic score (PES) reflects the following five items: mesial papilla, distal papilla, curvature of the facial mucosa, level of the facial mucosa, and root convexity/soft tissue color and texture at the facial aspect of the implant site.

7 White esthetic score (WES) is based on the five following items: general tooth form; outline and volume of the clinical crown; color, which includes the assessment of the dimension*s hue and value; surface texture; and translucency and characterization

Study description

Background summary

Patients who participate in this study need an implant supported crown for replacing a single missing incisor, cuspid or bicuspid in the maxilla. Patients of the first two groups have an alveolar crest which is just to small to facilitate a full bony coverage of the implant. The bony defect seen at implant placement can be reconstructed using a mixture of Straumann bone ceramic and autogenous bone. This mixture is in the first group covered with a resorbable membrane, Membragel (group A) and in the second group not covered with Membragel (group B). Patients of the third group (group C) do not need a reconstruction since sufficient bone is available for implant placement to make sure that the surface of the implants is fully covered with bone.

Study objective

Can small buccal bony dehiscences (< 4 mm) of non-submerged dental implants, seen at initial placement, be successfully reconstructed using the guided bone regeneration (GBR) technique with a mixture of Straumann bone ceramic and locally harvested autogenous bone chips covered with Membragel up to 1 years after functional loading ?

Study design

For group A and B: a prospective randomized multicenter clinical study with 1-year follow-up

For group C, the reference group: observational prospective multicenter study with consecutive patients with 1-year follow-up

Intervention

Group A: the bony defect is reconstructed with a mixture of autogenous bone and Straumann bone ceramic and covered with a membrane (Membragel)
Group B: the bony defect is reconstructed with a mixture of autogenous bone and Straumann bone ceramic without use of a membrane

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 wether 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 treament will be identical. However, the sofar collected measurements data can not 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) Presence of a small bone deficiency of less than 4 mm
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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-08-2011
Enrollment:	75
Type:	Actual

Medical products/devices used

Generic name:	Membragel;resorbable membrane
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-04-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-07-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-02-2015
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: 28365
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL34657.078.11
OMON	NL-OMON28365

Study results

Date completed:	01-10-2016
Actual enrolment:	84

Summary results
Trial is onging in other countries