The effect of membranes on small, bone augmentations at dental implant placement

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28365

Source
Nationaal Trial Register

Brief title
Membragel study

Health condition

one-stage alveolar ridge augmentation
dental implants
membranes
randomized controlled trial

Sponsors and support

Primary sponsor: prof. dr. E.B. Wolvius,
Department of Oral & Maxillofacial Surgery, Special Dental Care and Orthodontics, Erasmus University Medical Centre, Rotterdam, the Netherlands and St. Anna Hospital, Geldrop, the Netherlands.
Source(s) of monetary or material Support: Straumann AG, Basel, Switzerland

Intervention

Outcome measures

Primary outcome

Level of the marginal bone around the implant at least 12 months after loading

Secondary outcome

Outcomes scored:

1.the plaque index (PI),

2.the bleeding index BI,

3.the gingiva index (GI),

4.the pocket probing depth (PPD),

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

8. Questionnaire about patient satisfaction (VAS)

9. Adverse events and complications

Reported as:

Implant survival, implant succes, clinical assessment, aesthetic assessment, patient satisfaction

Study description

Background summary

Several systematic reviews report on the success of implants placed in one-stage ridge augmentation procedures (bone augmentation simultaneous with implant placement) (Chiapasco & Zaniboni 2009, Kuchler & von Arx 2014). However, these systematic reviews can’t reach consensus about the beneficial use of a membrane in one-stage ridge augmentation procedures. Currently there are only two randomized controlled trials comparing one-stage ridge augmentations with and without membranes (Fu, et al. 2014, Park, et al. 2008). These two studies concluded that the addition of a barrier membrane prevented horizontal buccal bone resorption and enhanced bone thickness. No effect was seen on implant survival at one year. These studies describe large defects and fail to mention parameters of implant success and soft tissue aesthetics. In our clinical experience, there is no need for membranes in small buccal bony dehiscences, which can be managed by solely using locally harvested autogenous bone and bone substitutes. Therefore the aim of this of this randomized controlled trial is to determine the effect of membranes on small one-stage bone augmentations on implant survival, implant success, clinical and radiographic parameters, aesthetic results and patient satisfaction. The study is designed as a multicenter, prospective, randomized clinical trial (RCT). The study takes place at the University Medical Centre Erasmus MC, Rotterdam and the St. Anna Hospital, Geldrop.

Study objective

The hypothesis is that small buccal dehiscences after implant placement can be reconstructed with a mixture of a bone substitute and autogenous bone with and without coverage of a membrane.

-Our second hypothesis is that implants with a small buccal bony dehiscence after implant placement reconstructed by one-stage bone augmentation perform equally well as implants completely covered in pristine bone

Study design

pre-operative, two weeks post operative, 6 weeks post operative and 1, 6 and > 12 months after placement of the crown.

Intervention

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

Group C: patients without bony dehiscence after implant placement are treated in a control group

Contacts

Public
Department of Oral & Maxillofacial Surgery, Special Dental Care and Orthodontics

B.P. Jonker
Erasmus MC Rotterdam
P.O. Box 2040, 3000 CA Rotterdam, the Netherlands
's-Gravendijkwal 230, Office D-224
Rotterdam
The Netherlands
Tel + 31 10 703 4138
Scientific
Department of Oral & Maxillofacial Surgery, Special Dental Care and Orthodontics

B.P. Jonker
Erasmus MC Rotterdam
P.O. Box 2040, 3000 CA Rotterdam, the Netherlands
's-Gravendijkwal 230, Office D-224
Rotterdam
The Netherlands
Tel + 31 10 703 4138

Eligibility criteria

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 equal to or 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:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2011
Enrollment:	75
Type:	Actual

Ethics review

Positive opinion

Date:	09-11-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41609
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5956
NTR-old	NTR6137
CCMO	NL34657.078.11
OMON	NL-OMON41609

Study results

Summary results
N/A