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

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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...

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

Samenvatting

ID

NL-OMON28365

Bron
Nationaal Trial Register

Verkorte titel
Membragel study

Aandoening

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

Ondersteuning

Primaire 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.
Overige ondersteuning: Straumann AG, Basel, Switzerland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

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

Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2011
Aantal proefpersonen:	75
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-11-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41609
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A