Horizontal maxillary augmentation with autogenous bone
Calvaria versus Mandibular Ramus

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The aim of this study is to compare the success of horizontal bone augmentation treatments with autogenous bone harvested from the calvaria area and autogenous bone harvested from the mandibular ramus.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON50141

Source
ToetsingOnline

Brief title
Calvaria versus Mandibular Ramus

Condition

- Bone and joint therapeutic procedures

Synonym
Bone resorption, Boneloss

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Sponsoring wordt op dit moment nog verworven;waarschijnlijk door the Oral Reconstruction Foundation

Intervention

Keyword: atrophic upper jaw, Boneaugmentation, edentulous upper jaw, preprothetic surgery

Outcome measures

Primary outcome

Primary Objective:

Volumetric changes of the different bone grafts

Secondary outcome

Secondary Objective(s):

- Histological evaluation: percentage of vital bone (bone sample after 6

months)

- Patient related outcomes: satisfaction and pain

- Complications/morbidity donor sites

Study description

Background summary

Implantology in the atrophic edentulous maxilla can be challenging. Bone resorption after tooth loss because of trauma and periodontal or endodontic pathology is a frequent finding that complicates dental implant placement (Juodzbalys & Kubilius 2013, Sharan & Madjar 2008). In cases of severe bone resorption in the maxilla, a sinus lift procedure with vertical and horizontal bone augmentation may be required. Maxillary sinus floor augmentation for the placement of implants are originally described by Boyne and James (1980) and Tatum (1986). Nowadays, these augmentations are a commonly performed and successful procedure for the reconstruction of the edentulous posterior maxilla (Del Fabbro, et al. 2013, Esposito, et al. 2014, Wallace & Froum 2003).
To create sufficient height and width, maxillary augmentation is performed with autogenous bone, bone substitutes or a mixture of both, such as bovine bone mineral (Esposito, et al. 2014). The autogenous bone grafts are considered as "gold standard". (Sakkas et al, 2017) The success of autografts mainly depends on the osteogenicity of the graft, stability and adaptation of the graft to the

recipient side (Hallman & Thor 2008, Misch & Dietsh 1993). Different donor sites are used to harvest bone material. Iliac crest and calvaria bone are identified as the most common extra oral sites, and mandibular ramus and chin bone are most often used as intra oral donor sites. Little is known about the differences between the types of bone. Though, autogenous bone, especially the extra oral sites, has major drawbacks such as, considerable morbidity at the donor side.

Study objective

The aim of this study is to compare the success of horizontal bone augmentation treatments with autogenous bone harvested from the calvaria area and autogenous bone harvested from the mandibular ramus.

Study design

Single center, randomized controlled trial.

Intervention

A bilateral maxillary augmentation will be performed in 54 patients with a resorbed posterior maxilla. The three-dimensional alveolar ridge augmentation will be performed with calvaria bone blocks compared to mandibular ramus intraoral autogenous bone graft mixed with xenograft (BioOss, Geistlich, Switzerland, Wolhusen) in individualized titanium meshes (ReOss, Germany, Filderstadt). Maxillary sinus floor augmentation will be performed with autologous bone (bone chips anterior maxillary sinus) and xenograft (BioOss).

Study burden and risks

No extra burden for the participants, except for a very short, non-invasive questionnaire.

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. Patients of 18 years and older and in need for bilateral dental implant placement in the posterior maxilla
2. Atrophic maxilla; horizontal bone deficiency of less than 4 mm of the alveolar ridge in the horizontal plane (class III, IV atrophy according to Cawood and Howell classification)
3. Enough volume of the mandibular ramus to facilitate bone harvesting
4. Absence of visible active inflammation

Exclusion criteria

1. Medical condition that contraindicates surgery; from ASA III
2. History of radiotherapy in the head and neck region
3. History of Bisphosphonate medication (intravenous)
4. History (within the last 3 months) of using (at least weekly or more frequently) smokeless chewing tobacco, smoking a pipe, cigar or cigarette (at a rate of more than10 cigarettes per day)
5. Disability (mental and/or physical) to maintain basic oral hygiene procedures
6. Unhealed extraction sites (less than 6 weeks post extraction)
7. Patients unwilling or incapable of understanding and signing the informed consent
8. Patients who are pregnant

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):	01-08-2020
Enrollment:	36
Type:	Anticipated

Ethics review

Approved WMO

Date:	30-07-2020
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL73146.078.20