Maxillary sinus floor augmentation with autogenous bone and bovine bone mineral in the resorbed maxilla: a 1-year multicentre, split-mouth, randomized clinical trial

Published: 09-05-2017
Last updated: 11-04-2024

The aim of this study is to assess the success of MSFA determined by 1-year clinical performance of dental implants placed in the posterior maxilla after MSFA surgery with AB versus BBM with some locally harvested autogenous bone chips.

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

Summary

ID

NL-OMON45707

Source
ToetsingOnline

Brief title
Cerabone

Condition

- Bone disorders (excl congenital and fractures)
- Head and neck therapeutic procedures

Synonym
Insufficient bone height to place dental implants

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: Autogenous bone, Bovine bone mineral, Maxillary sinus floor augmentation, Randomized Controlled Trial, Split mouth

Outcome measures

Primary outcome

Success of MSFA determined by 1-year clinical performance of dental implants

placed in augmented maxillary sinus

Secondary outcome

* Volumetric changes of the bone graft

* Histological evaluation

* Micro-computed tomography (*CT) analysis

* Patient satisfaction and pain scores regarding MSFA

* Implant survival

* Implant success

* Prosthetic success

* Complications

* Plaque, gingival and bleeding indices

* Pocket probing depth

* Peri-implant radiographic bone levels

* Volumetric changes of the bone graft

* Patients satisfaction with implant placement and prosthesis

Study description

Background summary

Insufficient bone height is a common problem in the reconstruction of the edentulous posterior maxilla with dental implants. The dimensions of the alveolar ridge and maxillary sinus change after tooth extraction, which can negatively influence the possibility of placing dental implants (Juodzbalys & Kubilius 2013, Sharan & Madjar 2008).

To create sufficient height in the severe resorbed posterior maxilla, sinus floor augmentation (MSFA) is performed with autogenous bone (AB) grafts, bone substitutes, or a mixture of both (Esposito, et al. 2014). MSFAs 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).

The use of AB for grafting procedures is still considered the gold standard. No other type of graft can match the abilities of AB, were surviving osteoblasts directly produce bone (osteogenesis) and undifferentiated mesenchymal cells are stimulated to differentiate into osteoblasts (osteoinduction) (Hallman & Thor 2008, Misch & Dietsh 1993). However, there are major drawbacks of using AB, such as fast resorption, the morbidity of the donor location and the amount of grafting material available in cases of major resorption (Kuik, et al. 2016, Raghoebar, et al. 2001, Raghoebar, et al. 2007). Different bone substitutes are described in literature to bypass these shortcomings of AB (Hallman & Thor 2008), such as alloplastic substitutes (Danesh-Sani, et al. 2016, Schulten, et al. 2012, Zerbo, et al. 2004), allogeneic bone grafts (Froum, et al. 2006, Xavier, et al. 2015, Xavier, et al. 2015) and currently most used, xenografts such as bovine bone mineral (BBM) (Hallman, et al. 2002, Merli, et al. 2013, Rickert, et al. 2011, Xavier, et al. 2015).

Why it is important to do this comparison study of AB versus bone-substitutes?

There are 3 reasons:
1. 1. It is unknown if AB or BBM with some AB is more successful for MSFA Hallman, et al. (2002)a is the only RCT (N=11) describing AB versus BBM in combination with some AB for two stage bone augmentation with the BBM as the only procedural variable. In the AB group an implant failure of 18% was found versus 6% in the group with BBM. This difference was described as not statistically different. Both treatment options have their pro and cons but the

resistance of xenograft material to resorption and degradation may be an advantage for maintaining the initial dimensions of the augmented sinus, as analysis revealed a less than 10% change over 12 months of loading (Hallman, et al. 2002)b. Our aim is to determine which treatment is more successful for MSFA.
2. No need for harvesting AB from a second surgical site but via the existing incision for MFSA Only very few randomized controlled trials compared AB with (xenogeneic) bone substitutes in MFSA procedures (Al-Nawas & Schiegnitz 2014, Esposito, et al. 2014, Jensen, et al. 2012). These studies showed promising results, as bone substitutes may overcome the major drawbacks of solely using AB which is associated with co-morbidity of the donor site and the limited amount of bone available in case of major site reconstruction and resorption (Kuik, et al. 2016, Raghoebar, et al. 2001, Raghoebar, et al. 2007). However recent studies on MSFA with bone substitutes still showed considerable co-morbidity as bone substitutes are mixed with additional AB from the mandibular ramus (Hallman, et al. 2002) or stem cells harvested from the iliac crest (Rickert, et al. 2011). In this study we will harvest AB via the existing incision and thereby possible co-morbidity at a second surgical site is no issue any more.
3. Shortening healing period after MSFA. If only bone substitutes are used with no additional autogenous material, extensive healing periods of 9 months are reported (Hallman, et al. 2002, Merli, et al. 2013). In our study we will use bone substitutes mixed with locally harvested bone chips through the existing incision. With this mixture we expect to place and load implants after a shorter healing time (4-6 months).

Study objective

The aim of this study is to assess the success of MSFA determined by 1-year clinical performance of dental implants placed in the posterior maxilla after MSFA surgery with AB versus BBM with some locally harvested autogenous bone chips.

Study design

The study will be designed as a multicenter, split-mouth, randomized clinical trial (RCT).

Intervention

In all patients billateral maxillary sinus floor augmentation's will be performed

Sides will be randomly assigned to:
* 1. AB harvested from mandibular ramus
* 2. BBM, Cerabone (Cerabone, Botiss Dental, Berlin, Germany) mixed with

approximately one-fifth locally harvested AB chips (via existing incision for sinus elevation).

Study burden and risks

The measurements performed in this research are clinical and radiological analyses of the peri-implant tissues and histological analyses of the bone samples collected at dental implant placement. Participation in this research is not dangerous and the patients are not at risk. The radiographs (before and after placing the implants) are taken, whether or not the patient is participating in this research. Radiological follow-up is not hazardous; the health of the patients is not at risk. Due to the fact that the treatments have been performed for many years we expect no complications. In case of pregnancy the treatment is not performed, but postponed till after pregnancy. In case the patient wants to withdraw from this research this does not have any consequence. The treatment will be identical. However, the collected measurements will not be used 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) In need for bilateral dental implant placement in the posterior maxilla.
3) The residual bone height in the posterior maxillar is between 2 and 5 mm.
4) Bone width should be over 5 mm.
5) Enough volume of the mandibular ramus to facilitate bone harvesting.

Exclusion criteria

1) Presence of clinical active periodontal disease
2) Presence of acute inflammatory oral disease,
3) Smoking
4) Uncontrolled 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) In case of pregnancy the treatment is not performed, but postponed till after pregnancy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-08-2017
Enrollment:	46
Type:	Actual

Medical products/devices used

Generic name:	Cerabone;bovine bone mineral
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-05-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-07-2017
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

No registrations found.

In other registers

Register	ID
CCMO	NL59578.078.16