Alternative approaches to collect autogenous bone during implant site preparation: A clinical study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38655

Source
ToetsingOnline

Brief title
Collection of autogenous bone during implant site preparation

Condition

- Other condition
- Bone disorders (excl congenital and fractures)

Synonym
bone defects, bone regeneration

Health condition

(Partially) edentulous mandible or maxilla

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Centrum Tandheelkunde Amsterdam
Source(s) of monetary or material Support: Camlog research foundation

Intervention

Keyword: Autogenous bone, Dental implants, Drilling protocol, Surgical technique

Outcome measures

Primary outcome

The main objective of the present study is to explore feasibility and efficacy of collecting autogenous bone attached to the drill flukes with and without irrigation during implant site preparation. The primary objective of the present study is to compare the amount, viability, nature and osteogenic potential of bone autograft collected with two different approaches:

a) bone chips collected from the Camlog® drill flukes with aqueous irrigation following a standard protocol;

b) bone chips collected from the Camlog® drill flukes without aqueous irrigation following a modified slow speed drilling (speed <200 rpm).

Secondary outcome

The secondary objectives of this randomised clinical trial is to report the clinical outcome after one year of implant placement in terms of change of crestal bone level between surgery and 12 month post surgery and Survival and success of implant treatment.

Study description

Background summary

Autogenous bone graft is still the gold standard in different bone grafting procedures. Therefore, the aim of the present study is to collect autogenous bone during implant site preparation for bone augmentation. Our Hypothesis is "Saline irrigation might affect the amount, nature, cell viability and osteogenic potential of the autograft collected during osteotomy preparation. In addition avoiding saline irrigation might not affect the clinical outcome of the implant treatment".

Study objective

The primary objective of the present study is: 1) To compare the amount, viability, nature and osteogenic potential of bone autograft collected with two different approaches: a) bone chips collected from the Camlog® drill flukes with aqueous irrigation following a standard protocol; b) bone chips collected from the Camlog® drill flukes without aqueous irrigation following a modified slow speed drilling (speed <200 rpm). The secondary objective is: *evaluation of the clinical success of the implants based on clinical and radiographic findings to compare the standard drilling protocol with modified slow drilling protocol**.

Study design

This is a split-mouth, randomized controlled clinical trial comparing the efficacy of two treatment modalities (standard drilling protocol vs. modified drilling protocol) in 30 patients (30 subjects/treatment). The particulate bone graft will be collected in each patient during osteotomy preparation. The amount, viability, nature and osteogenic potential of bone graft collected with two different approaches will be compared using histology, scanning electron microscopy (SEM), cell viability, and cell culture analysis. Clinical and radiographic outcomes will be evaluated at baseline, 3 months and 1 year after surgery.

Intervention

N/A

Study burden and risks

The surgical risks involved in the present study will not be different than those of other conventional surgical procedures in the same region of the oral cavity. Following are the usual risk which might be associated with placement of implants:
* Some minor postoperative pain and discomfort will be expected for both the control group and the test group.
* Post-operative swelling or bleeding
* Implant failure or loss

** Infection
** Loosening, loss, fracture or failure of abutment or crown
*
Early post surgical complications include lack of osseointegration and loss of the implant. Later complications can be either biological (e.g. peri-implant diseases) or technical complications. Every care will be taken to minimize the ocuurence of complications. The patients however will be informed of the fact that a strict maintenance protocol is important to detect potential complications at an early stage.

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

In order to be eligible to participate in this study, a subject must meet all of the following

criteria:
1: Each patient will be at least 18 years of age and able to understand and sign an informed consent.
2: All patients will be either completely edentulous or partially edentulous (single-tooth gap or an extended edentulous space).
3: All sites require to have a healing period of a minimum of 4 months subsequent to tooth extraction and capable of receiving at least a 10mm length implant (adequate bone height) without bone augmentation at the time of implant placement.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
Local exclusion criteria:
Local exclusion factors include:
1: Untreated Periodontitis
2: The presence of osseous lesions, and/or unresolved extraction wounds.
3: Inadequate bone at the time of surgery resulting in a need for guided bone regeneration.
4: Severe bruxism or clenching habits.
5: Lack of motivation or compliance.
6: History of local irradiation therapy;Systemic exclusion criteria:
Systemic exclusion criteria included:
1: Bleeding disorders
2: Radiation and/or chemotherapy
3: History of renal failure
4: Bone or endocrine disorders
5: Physical handicaps capable of interfering with oral hygiene maintenance.
6: Moderate and heavy smokers (>10 cigarettes per day) or chewing tobacco.
7: Routine use of steroids
8: Leukocyte dysfunction
Secondary Exclusion Criteria:
At the time of implant placement and abutment connection, if any of the following criteria are met, a protocol deviation form should be completed and the subject should be followed for the duration of the study:;1: Subjects who require GBR treatment at implant surgery;2: Insufficient bone or any other bone abnormality that would contraindicate placement;3: The treatment required by this protocol is found to be inappropriate

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	06-08-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL42946.029.13