

Implant stability in the posterior maxilla: a controlled clinical trial

Submission date 09/04/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 22/04/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 22/06/2017	Condition category Oral Health	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Dental implants are artificial roots (usually titanium screws) which are screwed into the jaw bone to support one or more false teeth. They are considered to be the best treatment option to replace lost teeth or those so damaged that they cannot be repaired. In order for this treatment to be successful however, a certain amount of bone is needed to replace lost teeth with dental implants. This can present a challenge in patients who have bone loss. Dental techniques that initiate new bone growth are therefore important. A new type of surgery called maxillary sinus augmentation (regeneration) can help the body to regenerate bone where it was lost so that dental implants can be anchored; alternatively, bone can be taken from elsewhere and used in place of the lost bone (bone graft). The stability of implants is important to ensure that they last. The aim of this study is to look at the stability of implants in patients who have implants fitted alone and with regeneration or bone grafts.

Who can participate?

Healthy adults who need one or more dental implants fitted

What does the study involve?

Participants are divided into one or more of the three study groups with different grades of bone regeneration needed to anchor implants. One patient may be in several groups for different areas of their mouth. Those in the first group have implants without the need for regeneration, those in the second group have a small bone graft when their implants are put in place, and those in the third group have regeneration in order to place their implants. Participants in this third group need to wait 8-10 months for healing before the implants can be placed. In each group, at the time the implants are placed and then 15, 30, 45 and 60 days later, they undergo a dental examination to assess the stability of their implants.

What are the possible benefits and risks of participating?

Participants benefit from receiving dental implants which will help to restore function. There are no notable risks involved with participating other than the general risks involved with having dental implants fitted.

Where is the study run from?
Clinica Médico-Dentária RZG (Portugal)

When is the study starting and how long is it expected to run for?
September 2013 to July 2016

Who is funding the study?
University of Porto (Portugal)

Who is the main contact?
Dr Raquel Zita Gomes
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
University of Oporto Trial Number #890573

Study information

Scientific Title
Controlled clinical trial about the effects of bone regeneration in the implant stability during the healing phase

Acronym
ISPM

Study objectives
The aim of this study is to evaluate the stability of dental implants at placement in the human posterior maxilla and to investigate the evolution from primary to secondary stability, in three

different groups: patients with native bone, patients with partially regenerated bone and patients with nearly totally regenerated bone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Faculty of Dental Medicine of the University of Oporto, 26/06/2014, ref: #890573

Primary study design

Interventional

Study design

Interventional prospective non-randomised study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Implant dentistry

Interventions

Following provision of informed consent, eligible participants are allocated into one (or more) of three study groups depending on the levels of osseous-regeneration needed in Superior Posterior (SP) area of the maxilla. Implants in the same patient can be of different groups and are always considered as independent. Dental implants placed in different situations of bone regeneration (none, partial, almost total) are therefore examined in this study rather than individual patients. So one patient can be allocated in different groups because he could have different implants placed in different regeneration situations.

Group 1: Patients have a posterior non-regenerated (NR) maxillary bone (healed site) that needs one or more implants. The intervention in this group is the implant placement only (patients received one or more dental implants) with no regeneration prior or concomitant.

Group 2: Patients have a posterior partially regenerated (PR) maxillary bone at the time of implant placement. The interventions on this group is the implant placement and the simultaneous bone regeneration in cases of small bone defects or post extractional implants. The bone graft is done at the surgery of the implant placement.

Group 3: Patients have the necessity of major regeneration with a sinus lift and filling (almost nearly total regenerated (TR) site) healed in the posterior maxilla to permit the implant placement. So the interventions in this group are the bone regeneration of the maxillary sinus (sinus lift and filling) and the implant placement after the healing of the bone graft on the sinus (8 to 10 months).

The study is performed over a period of one year and three months. The cases with sinus lift and filling had at least 8 to 10 months of healing prior to the implant placement. For those in group 3 there is a longer follow up period, because the monitoring is from the bone graft (healing controlled clinically and by X-ray every 3 months) on the sinus until the follow up after the implant placement.

The follow-up after implant placement is the same in the three groups and lasts at least of 2 months but, in critical conditions, the follow up lasts until the implant has osseointegrated (4 months).

The assessment of primary implant stability at the surgical time is completed for all three groups by Torque (N/cm, rotational stability) and implant stability quotient (ISQ) that measures the axial stability. The follow up during the healing time after implant placement consisted on the measures of ISQ in the three groups. The times of assessment of the ISQ are 15, 30, 45 and 60 or more days in all the groups in the cases that the primary stability is high according to the protocol (45 Newton per cm or more insertion torque and 60 or more ISQ value). The last measure (60 or more days) is determined by the bone/implant healing of each patient.

Intervention Type

Other

Primary outcome(s)

Dental implants primary stability is assessed using Insertion Torque (IT) and Implant Stability Quotient (ISQ) measurements after implant placement.

Key secondary outcome(s)

Dental implants secondary stability and its progression is assessed using Implant Stability Quotient (ISQ) at 15, 30, 45 and 60 days.

Completion date

23/07/2016

Eligibility

Key inclusion criteria

1. Aged 18 years and over
2. In good medical and oral condition
3. Need one or more dental implants in the posterior maxilla, for supporting fixed rehabilitations (single crowns or fixed partial prostheses)
4. Willing to fully participate in the study, attending all the requested follow-up sessions

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Uncontrolled systemic diseases (uncompensated oral diabetes)
2. History of head/neck irradiation
3. Haemophilia
4. Immune system severe deficiencies
5. On pharmacological therapies that could alter bone metabolism (patients treated with oral /intravenous amino- bisphosphonates)
6. Pregnancy and lactation
7. Smoking >20 cigarettes/day (heavy smokers)

Date of first enrolment

01/09/2014

Date of final enrolment

03/01/2016

Locations**Countries of recruitment**

Portugal

Study participating centre**Clinica Médico-Dentária RZG**

Rua de Santa Cruz Lt 14 r/ch Fracção B
3850-127 Albergaria-a-Velha
Oporto
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Sponsor information**Organisation**

University of Porto

ROR

<https://ror.org/043pwc612>

Funder(s)**Funder type**

University/education

Funder Name

Universidade do Porto

Alternative Name(s)

University of Porto, UPorto, U.Porto

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Portugal

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Rute Alexandra Borges de Almeida (rbalmeid@fc.up.pt)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2017		Yes	No