

# Implant stability in the posterior maxilla: a controlled clinical trial

<b>Submission date</b> 09/04/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/04/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/06/2017	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Study design**

Interventional prospective non-randomised study

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

**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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

26/09/2013

### **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

40-60

**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**

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# Sponsor information

## Organisation

University of Porto

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## Sponsor type

University/education

## Website

[https://sigarra.up.pt/up/pt/web\\_base.gera\\_pagina?p\\_pagina=universidade](https://sigarra.up.pt/up/pt/web_base.gera_pagina?p_pagina=universidade)

## ROR

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

# Funder(s)

## Funder type

University/education

## Funder Name

Universidade do Porto

## Alternative Name(s)

University of Porto, U.Porto, UPorto

## Funding Body Type

Government organisation

## Funding Body Subtype

Universities (academic only)

## Location

Portugal

# Results and Publications

## Publication and dissemination plan

The study will be submitted for publication to Biomedical Research International, Tissue Engineering section.

## Intention to publish date

10/10/2017

## 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?
<a href="#">Results article</a>	results	01/08/2017		Yes	No