

Clinical study evaluating the survival and success rates of two dental implants with a narrow diameter made of a titanium-zirconium alloy supporting a dental bridge

Submission date 22/10/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/11/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/08/2023	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Dental implants are a treatment to replace lost teeth. At the time of tooth loss, the jaw bone begins to atrophy (waste away). Standard diameter implants need a considerable amount of bone around them. Faced with a situation of bone atrophy, the surgeon has the option to reconstruct the bone through bone grafts to place standard implants or take advantage of the remaining bone and place implants with a smaller diameter. Implants with a reduced diameter are less resistant than standard diameter implants, so their use is somewhat controversial. One way to avoid fractures of these small diameter implants is to use stronger materials. A few years ago, the researchers began using a titanium-zirconium alloy (Roxolid) that is more resistant. In addition to its higher strength, it is more biocompatible (less harmful to the body) than other alloys. Small diameter implants can be used to safely replace anterior (front) teeth. Its use in posterior areas (back teeth) or in sections of two or more teeth requires more research. The aim of this study is to assess the survival and success of a treatment for an area of three or four missing teeth using a bridge supported by two small diameter implants made of titanium-zirconium.

Who can participate?

Patients aged 18 and over with an area of three or four missing teeth

What does the study involve?

Two titanium-zirconium narrow-diameter implants are placed under local anaesthetic. Only minor bone regeneration or soft tissue grafting is performed if needed. The crowns are placed after at least 8 weeks of healing. The success and survival rate of the implants is assessed 12 months after the final restoration.

What are the possible benefits and risks of participating?

Participants receive innovative but safe treatment. Participants also benefit from a reduced cost of treatment. The small diameter implants have been tested before and no different surgical or prosthetic complications are anticipated than in the placement of standard diameter implants.

Where is the study run from?

Universitat Internacional de Catalunya (Spain)

When is the study starting and how long is it expected to run for?

December 2011 to July 2021

Who is funding the study?

1. Universitat Internacional de Catalunya (Spain)
2. Institut Straumann AG (Switzerland)

Who is the main contact?

1. Dr Jose Nart
2. Dr Pablo Altuna

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

IMP-ECL-2012-01

Study information**Scientific Title**

Prospective clinical study of Straumann NNC dental implants for the treatment of partially edentulous patients

Study objectives

The hypothesis is that titanium-zirconium narrow diameter implants are a less invasive and successful when used in partially edentulous patients. Titanium-zirconium is a relatively new alloy used to manufacture dental implants. It is considered stronger than TCp, but clinical studies using narrow-diameter implants with this material are scarce.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics board of Clinical Investigations of the Faculty of Dentistry, Universitat Internacional de Catalunya (Comitè Ètic d'Investigació Clínica (CEIC) of the Clinica Universitària d'Odontologia (CUO), Universitat Internacional de Catalunya, Barcelona), 16/07/2012, ref: IMP-ECL-2012-01

Primary study design

Observational

Study design

Prospective clinical trial of a cohort study with a follow-up from 1 year to 5 years

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Partially edentulous patients, missing 3 or 4 teeth in both jaws

Interventions

Thirty patients with partial edentulism (missing 3 or 4 teeth from second premolar to second premolar of both jaws) will be recruited for the study at the School of Dentistry's Clinic, Universitat Internacional de Catalunya, Barcelona. Two titanium-zirconium alloy (Roxolid (R)) narrow-diameter implants will be placed in each patient under local anesthesia. Rehabilitation with a bridge of 3 or 4 crowns. Only minor bone regeneration or soft tissue grafting would be performed if needed. The crowns would be placed after at least 8 weeks of healing.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Not provided at time of registration

Primary outcome(s)

Success and survival rate of Straumann NNC implants 12 months after final restoration:

1. The success rate will be assessed according to the criteria of Buser (Buser et al., 1991):
 - 1.1. No detectable clinical mobility (hand testing)
 - 1.2. No radiolucency surrounding the total surface of the implant
 - 1.3. No persistent pain refractory to medical therapy
 - 1.4. No recurrent peri-implant infection
2. A surviving implant is an implant that is in place at the time of evaluation

Key secondary outcome(s)

Measured after 1 year, 3 years and 5 years:

1. Radiological measurements of the crestal bone level (mesial and distal), with bite registration and paralleling technique
2. Patient satisfaction and dentist satisfaction, measured using VAS
3. Periodontal evaluation: clinical attachment level, bleeding on probing, plaque index, pocket probing depth
4. Vestibular bone stability, measured using a small field CBCT
4. Survival, success and complications of the prosthodontic treatment

Completion date

20/07/2021

Eligibility

Key inclusion criteria

1. Patients ≥ 18 years of age
2. Patients in need of multiple teeth restoration in the maxilla or mandible, of incisors, canines and bicuspid
3. Patients with narrow ridges where conventional implants with a diameter of 4.1 mm cannot be used (< 6 mm)
4. Patients with a full mouth plaque according to O'Leary $\leq 25\%$ at time of surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Patients with any conditions or circumstances which would interfere with the requirements for oral surgery
2. Patients allergic to any implant metallic component
3. Patients needing major bone regeneration techniques
4. Patients where the ridge allows the restoration with a conventional implant diameter of 4.1 mm

Date of first enrolment

15/09/2012

Date of final enrolment

09/03/2016

Locations

Countries of recruitment

Spain

Study participating centre

Universitat Internacional de Catalunya

Josep Trueta s/n

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Sponsor information

Organisation

Universitat Internacional de Catalunya

ROR

<https://ror.org/00tse2b39>

Funder(s)

Funder type

University/education

Funder Name

Universitat Internacional de Catalunya

Funder Name

Institut Straumann AG (Switzerland)

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 Dr Pablo Altuna. After written request and after the 5 year results publication (December 2022), data could be shared after evaluating the credentials of the soliciting investigator and his/her Institution. After acknowledging the written request, authorization by the Dean and/or Research Vice-Dean must be obtained to hand out the requested datasets. All datasets would be blinded regarding patient identification. All patients have signed a proper study informed consent.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2023	30/08/2023	Yes	No