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Comparing the loss of bone around Straumann BLT® implants with direct connection to the implant versus those with an intermediate connection

Submission date
01/05/2023

Recruitment status
No longer recruiting

Registration date
26/05/2023

Overall study status
Ongoing

Last Edited
26/05/2023

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to determine if using higher abutments (the piece that connects the crown to the implant) can reduce bone loss around Straumann BLT® implants in the back of the mouth for patients with missing teeth. The study will compare the use of intermediate abutments versus direct connection to the implant. The study will also look at the effect of abutment height on other factors such as probing depth, bleeding on probing, and the width of the gum tissue around the implant. The goal is to see if using higher abutments can provide more space for soft tissue to adapt and reduce bone loss.

Who can participate?
Patients attending the International University of Catalonia, School of Dentistry, requiring a posterior implant rehabilitation in order to replace maxillary and mandibular molars and premolars will be included in the study. 48 patients will be selected with partial edentulism in the maxilla or mandible, requiring two dental implants in the posterior areas.

What does the study involve?
In this study, patients will be randomly assigned to one of two groups to investigate the effect of using prosthetic screw abutments on bone loss around Bone Level Tapered implants (BLT® Roxolid® SLActive® guided implants, Straumann Dental Implant System, Institut Straumann AG, Basel, Switzerland). Partially edentulous patients will receive fully guided and tooth-supported surgical stents to guide the implant position according to the final prosthesis design, reducing the risk of errors and standardizing the implant placement process. After the implants have fully integrated with the bone and second stage surgery healing time has passed (8 weeks post-implant placement), digital impressions will be taken to make the final screw-retained prosthesis. Standardized intraoral periapical x-rays will be taken at the day of surgery, 4, 6, 12, 24, and 36 months post-surgery to measure the bone level around the implant. This will be done by measuring from the implant platform to the first contact with the bone using Image J software by a trained examiner. The implant threads will be used to standardize the images.

What are the possible benefits and risks of participating?
Possible benefits: Placement of two BLT Straumann implants with fully guided surgery and the corresponding fixed restoration with a price reduction for be included in this clinical trial.

Possible risks (and solutions):
- Loss of implant osseointegration: The implant will be replaced free of charged in agreement with our study sponsor (Straumann)
- Patients dissatisfied with esthetics due to exposure of the prosthetic interface: The prosthetic interface would be changed free of charge in agreement with our study sponsor (Straumann) and the patient would be excluded of the study
- Biological problems (mucositis and periimplantitis): Patients would be treated according to the protocols of the University
- Prosthetic problems: Patients would be treated according to the protocols of the University.

Where is the study run from?
The University Dental Clinic of the International University of Catalonia, School of Dentistry. Sant Cugat-Barcelona, Spain.

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

Who is funding the study?
Institut Straumann AG, Peter Merian-Weg 12, 4002 Basel, Switzerland

Who is the main contact?
Dr. Jordi Gargallo–Albiol, jgargallo@uic.es

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
CIR-ECL-2016-03

Study information

Scientific Title
Evaluation of the marginal bone level change of Straumann Bone Level Tapered® implants using different screwed abutment height in partially edentulous patients: a randomized controlled clinical trial

Study objectives
The use of a prosthetic abutment on fixed implant restoration reduces the marginal bone loss compared to direct implant connection in partially edentulous patients in the posterior area.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/06/2017, Sant Cugat del Vallès (Barcelona, Spain), Ethical Committee of Clinical Research (Universitat Internacional de Catalunya, C/ de Josep Trueta, 08195 Sant Cugat del Vallès, Barcelona, Spain; +34 935 04 20 00; ceim@uic.es), ref: CIR-ECL-2016-03

Primary study design
Interventional

Study design
Single center randomized controlled clinical trial with 3 year follow-up

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prevention of marginal bone loss around fixed implant restorations in partially edentulous patients

Interventions
Patients with partial edentulism attending the International University of Catalonia, School of Dentistry, requiring a total of 2 implants in the posterior maxilla or mandible (molar and/or premolar are recruited. The total sample consists of 48 patients (96 implants), divided in two study groups:
1) Control group (direct to implant connection);
2) Test group (screw retained abutment).
The test group was also divided into two subgroups according to two abutment heights: 1mm height abutment (7 patients) and 2.5mm abutment height (11 patients).

The patients will be randomly divided into two groups in order to study the influence of prosthetic screw abutment in marginal bone loss (MBL) around Bone Level Tapered implants (BLT® Roxolid® SLActive® guided implants, Straumann Dental Implant System, Institut Straumann AG, Basel, Switzerland).
Marginal bone loss will be measured through periapical x-rays at the day of the surgery, 4, 6, 12, 24 and 36 months; using ImageJ® software by one calibrated examiner (M.Z).

The randomization sequence will be created by means of computer-generated randomization codes and concealed in sealed non-transparent consecutively numbered envelopes. The randomization envelopes were opened after preparation of the osteotomy sites by a designated study nurse in the presence of a witness (the surgeon). The sealed master randomization list will be provided by an external data management company.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Marginal bone level (MBL) change: Standardized intraoral periapical x-rays will be taken at the day of surgery, 4, 6, 12, 24 and 36 months following surgery. These will be used to measure the periimplant bone level by measuring from the implant platform to the first bone to implant contact. Measurements will be performed using Image J by one calibrated examiner. Implant threads will be used for normalization of the images.

Key secondary outcome(s)
Probing depth, bleeding on probing and keratinized mucosa width will be measured at the day of surgery, 4, 6, 12, 24 and 36 months following surgery in 3 different buccal points (M, C and D)

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Signed informed consent
2. Overall, healthy subjects
3. Females and males of at least eighteen-years
4. Requiring a minimum of two implants (molar and/or premolar teeth)
5. Adequate oral hygiene (less than 15% FMPS)
6. Able to follow instructions and attend a regular compliance
7. Enough bone to place a standard implant of 4.1 mm diameter

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Acute local infection
2. Occlusal overload with parafunctional activity (assessed clinically)
3. Large occlusal discrepancies
4. Untreated periodontal disease assessed by Socransky et al. parameters (≥2mm clinical attachment loss in two consecutive visits within 1 year)
5. Smokers (more than 10 cigarettes/day)
6. Drug and/or alcoholic dependencies
7. Medical conditions contraindicating implant surgery
8. History of head and/or neck radiation
9. Bisphosphonate therapy

Date of first enrolment
01/06/2017

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
Spain

Study participating centre
Universitat Internacional de Catalunya
C/ de Josep Trueta
Sant Cugat del Vallès, Barcelona
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Sponsor information

Organisation
Universitat Internacional de Catalunya

Funder(s)

Funder type
Industry

Funder Name
Institut Straumann AG

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyses during the current study will be available upon request from Jordi Gargallo-Albiol; jgargallo@uic.es

IPD sharing plan summary
Available on request