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The success of a new dental implant in the jaw bone

Submission date
15/07/2022

Recruitment status
No longer recruiting

Registration date
20/08/2022

Overall study status
Completed

Last Edited
22/10/2024

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Long-term clinical and esthetic conservation of implants depends on the preservation of both the hard and soft tissues surrounding the implant. Some bone loss, which happens when teeth are lost, is to be expected: 1.5 to 2 mm during the first year of the implant's functional life, and an annual loss of 0.2 mm thereafter. Diverse published articles argue that the design of the implant collar and implant surface characteristics are associated with reductions in marginal bone loss, a finding that has led to the development of new implants with diverse new configurations toward the crown of the tooth and topographic modifications aimed at improving bone (osseo) integration and conserving the health of the adjacent tissues. This study aims to evaluate the implantation of an arch of tooth implants in the upper maxilla jaw bone versus a transmucosal dental implant in the lower mandible jaw bone.

Who can participate?
Patients requiring single or multiple teeth replacements with dental implants

What does the study involve?
Replacement of missing teeth with tissue level implants and recording of clinical data, including the type of incision (flap versus flapless), and implant sites (healed versus post-extractive) on marginal bone loss, soft tissue parameters and implantation survival rate, at every follow-up visit.

What are the possible benefits and risks of participating?
The benefits are restoring the function and esthetics of missing teeth in a shorter time. The possible risks are missed osseointegration of the implants. In this case, the implant will be inserted again after 3 months.

Where is the study run from?
University of Rome Tor Verga (Italy)

When is the study starting and how long is it expected to run for?
March 2022 to May 2024

Who is funding the study?
Straumann AG (Italy)

Who is the main contact?
Dr Paolo Carosi (Italy)
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
103.22

Study information

Scientific Title
Clinical and radiological success of a novel dental implant with transmucosal implantation

Study objectives
To assess the potential effect of the implantation of a full arch (in the upper maxilla jaw bone versus the transmucosal dental implant in the lower mandible jaw bone), type of incision (flap versus flapless), and implant sites (healed versus post-extractive) on marginal bone loss (MBL), soft tissue parameters and implantation survival rate (ISR)

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/06/2022, Ethical Committee of Policlinico Tor Vergata (Comitato Etico Indipendente Tor Vergata) (Viale Oxford 1, Rome, -, Italy; +39 06 2090 0035; comitato.etico@ptvonline.it), ref: 103.22

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Single or multiple teeth missing in both jaws

Interventions
Replacement of missing teeth with tissue level implants (TLX) and recording of clinical data at every follow-up visit. There will be no randomization.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Implantation survival rate (ISR) measured during a control visit every 4 months. A surviving implant is an implant that maintains its function in the mouth.
2. Marginal bone loss (MBL) measured using annual periapical X-rays

Key secondary outcome(s))
1. Initial implant stability quotient values (ISQ-0) and insertion torque at implant placement recorded at each scheduled visit every 4 months from implant placement
2. Peri-implant soft tissue parameters recorded at each scheduled visit every 4 months from implant placement:
2.1. Bleeding on probing (BoP) measured using a periodontal probe
2.2. Probing depth (PD) measured using a periodontal probe
2.3. Implant stability measured using ISQ values from a resonance frequencies analysis using the Osstel device

Completion date
01/07/2024

Eligibility

Key inclusion criteria
1. Aged 18 years old and over
2. Requiring a single or partial fixed implant prosthesis (FDP) of maxillary and mandibular arch
3. Otherwise healthy patients
4. Full mouth bleeding and full mouth plaque index lower than or equal to 25%
5. Bone height for at least 4 mm-long implants
6. Bone width of at least 3 mm and 4 mm
7. Fresh extraction sockets with an intact buccal wall

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Psychiatric contraindications
2. Pregnancy or nursing
3. Any interfering medication such as:
3.1. Steroid therapy
3.2. Bisphosphonate therapy
4. Alcohol or drug abuse
5. Heavy smoking (>10 cigarettes/day)
6. Radiation therapy to head or neck region within 5 years
7. Untreated periodontitis
8. Acute and chronic infections of the adjacent tissues or natural dentition
9. Severe maxillomandibular skeletal discrepancy
10. High and moderate parafunctional activity
11. Absence of opposite teeth

Date of first enrolment
25/08/2022

Date of final enrolment
29/04/2023

Locations

Countries of recruitment
Italy

Study participating centre
Policlinico Tor Vergata
Viale Oxford 1
Rome
Italy
00133

Sponsor information

Organisation

Straumann (Switzerland)

ROR
https://ror.org/01a8wgs29

Funder(s)

Funder type
Industry

Funder Name
Straumann AG

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Paolo Carosi, paolo.carosi@alumni.uniroma2.eu. Raw data from the study will be available upon request for 1 year after the study ends.

IPD sharing plan summary
Available on request