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A new dental implant in the aesthetic zone

Submission date
13/02/2022

Recruitment status
No longer recruiting

Registration date
19/02/2022

Overall study status
Completed

Last Edited
30/03/2023

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The aesthetic zone (also known as the smile zone) refers to all of the hard and soft tissues of the mouth that are visible when the patient makes a broad smile. Immediate loading in the aesthetic zone (the placement of a dental restoration within 48 hours of implant placement) is a well-documented technique. The technique relies on the stability of the positioned implants, which depends on the design of the implants and on the quality of the surrounding bone. This study aims to assess the performance of a new dental implant placed in the anterior (front) zone of both jaws and loaded with a restoration immediately.

Who can participate?
Patients aged 18 years and over with a single tooth missing in the aesthetic zone

What does the study involve?
The missing tooth is replaced with a dental implant. After the healing period, a crown is placed. Patients are recalled every 4 months for professional oral hygiene and at 12 months for an x-ray and clinical examination.

What are the possible benefits and risks of participating?
The benefit of the study is that the positioned implants are loaded immediately and immediately restored in a single rehabilitation center.

Where is the study run from?
University of Rome La Sapienza (Italy)

When is the study starting and how long is it expected to run for?
October 2018 to December 2021

Who is funding the study?
International Team for Implantology (Switzerland)

Who is the main contact?
Dr Paolo Carosi
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Contact information

Type(s)
Principal investigator

Contact name
Dr Paolo Carosi

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
21/2022

Study information

Scientific Title
Clinical and radiographic performance of immediately temporized BLX implants in the aesthetic zone: a retrospective single-cohort study

Acronym
BLX ESTH

Study objectives
The aims of this patient single-cohort study are:
1. To evaluate the 1-year clinical and radiographic performance of immediately temporized implants with novel macrodesign placed in the anterior zone
2. To investigate the contribution of site characteristics and surgical protocol on primary stability

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 01/02/2022, the institutional review board of La Sapienza University of Rome (Viale del Policlinico 155, Rome, Italy; +39 (0)649979822; comitato.etico@policlinicoumberto1.it), ref: 21/2022

Study design
Retrospective observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rehabilitation of a single tooth in the aesthetic zone by means of one implant with immediate restoration

Interventions
The missing tooth is replaced with a Straumann BLX in the aesthetic zone. After the healing period, a screw-retained zirconia-based single crown is realized and delivered to the patient. Patients are followed up for 1 year after definitive prosthesis delivery and radiographic and periodontal values were recorded. Patients are recalled every 4 months for professional oral hygiene and at 12 months for the annual radiographic and clinical examination.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
1. Radiographic marginal bone loss (MBL) assessed using standardized intraoral digital periapical radiographs with the parallel technique by means of customized periapical radiograph holder (Rinn, DentsplySirona, York, PA, USA) at definitive prosthesis placement (baseline) and after 1 year
2. Implant and prosthetic success measured at 1-year follow-up visit:
2.1. Implant success defined in case of probing depth (PD) <5 mm together with absence of bleeding or suppuration on probing, and a radiographic marginal bone level (MBL) <1.5 mm
2.2. Prosthetic success defined as the presence of the definitive prosthesis with patient satisfaction and without complications including and not limited to fracture/chipping, screw loosening, and prosthesis mobility
3. Implant survival rates defined as the presence of the implant without pain or mobility at any follow-up examination

Key secondary outcome(s))
Effects of implant location, flap design and implant timing on insertion torque and implant stability quotient (ISQ) values, recorded by Osstell implant stability recording at implant placement

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. At least 18 years old
2. Systemic health recorded as a ASA 1 or ASA II diagnosis following the definition of the American Society of Anesthesiologists
3. Full mouth bleeding index and full mouth plaque index lower than or equal to 25% at baseline
4. One permanent missing tooth or failing tooth in the anterior zone of either arch
5. Patient desire to have the edentulous site or hopeless tooth treated with a single implant-supported fixed dental prosthesis (FDP) intact buccal socket wall evaluated at the time of the extraction
6. Adequate bone quantity to place an implant with a diameter of at least 3.5 mm and a length of at least 10 mm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. General medical (ASA III or IV) and/or psychiatric contraindications to oral surgery
2. Pregnancy or nursing
3. Steroid therapy or 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
12. Unavailability to attend regular follow-up visits

Date of first enrolment
01/10/2018

Date of final enrolment

25/03/2019

Locations

Countries of recruitment
Italy

Study participating centre
La Sapienza
Via Caserta 6
Rome
Italy
00161

Sponsor information

Organisation
ITI International Team for Implantology

ROR
https://ror.org/01dkem006

Funder(s)

Funder type
Research organisation

Funder Name
International Team for Implantology

Alternative Name(s)
ITI

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

The participant data are available on request from the principal investigator Paolo Carosi (paolo.carosi@alumni.uniroma2.eu)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/01/2023	30/03/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes