ISRCTN76538898 https://doi.org/10.1186/ISRCTN76538898

# 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
paolo.carosi@alumni.uniroma2.eu

# Contact information

### Type(s)
Principal investigator


### Contact name
Dr Paolo Carosi

### ORCID ID
https://orcid.org/0000-0002-2442-1091

### Contact details
Via Montpellier 1
Rome
Italy
00133
+39 (0)3277998699
paolo.carosi@alumni.uniroma2.eu


# Additional identifiers

### 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

### Primary study design
Observational

### Study design
Retrospective observational study

### 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 |