ISRCTN13212501 https://doi.org/10.1186/ISRCTN13212501

Comparing two dental implant systems for supporting the replacement of a full set of teeth in the lower arch of the mouth

Submission date 06/11/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 23/01/2020	**Overall study status** Completed	
Last Edited 16/11/2026	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Restoration of teeth using dental implants is a predictable procedure with high implant survival rates of 89%-97% over periods of 4 to 10 years. Implant survival and success have been reported to be influenced by primary stability, which is defined as the absence of dental implant mobility in the surgical bed, and it depends on the quantity and quality of bone, surgical technique and implant design.
A new Implant System is being developed to fulfill the current and future market needs regarding shorter treatment times and simplified workflows. The novel dental implant (BLX) has a self-cutting and self-tapping design, and a condensing core and thread design to optimize primary stability in all bone classes, with a sandblasted/large-grit/acid-etched surface (SLA Active, Institut Straumann AG, Basel) The BLX is designed to cut dense bone, collect and redistribute it along the implant and to condense soft bone, which leads to a robust, simple, and short surgical drill protocol.
The aim of this study is to compare two different fully tapered dental implant systems (BLX and Nobel Active)

Who can participate?
Dental patients aged over 18 years, with complete tooth loss in the lower jaw

What does the study involve?
Participants will be randomly assigned to receive a set of teeth prosthesis inserted with one of two similar methods. The participants will need to attend monthly follow up appointments for 36 months after the treatment

What are the possible benefits and risks of participating?
The benefits of participation in the study include the complete rehabilitation of the lower arch with a fixed prosthesis supported by 6 implants, possible risks include surgical complications (nerve injury, bleeding), implant failure (implant removal due to lack of integration), prosthetic

failure (a broken prosthesis) and implant-related biologic complications (development of peri-implant diseases over the years, such as mucositis and peri-implantitis) or implant-related mechanical complications (screw loosening-partial rupture of the prostheses)

Where is the study run from?
Department of Oral and Maxillo-Facial Sciences at "Sapienza" University of Rome, Italy

When is the study starting and how long is it expected to run for?
July 2019 to December 2023

Who is funding the study?
International Team for Implantology, Switzerland

Who is the main contact?
Dr Piero Papi
piero.papi@uniroma1.it

Contact information

Type(s)
Scientific

Contact name
Dr Piero Papi

Contact details
via Caserta 6
Rome
Italy
00161
+39 3934360087
piero.papi@uniroma1.it

Additional identifiers

Protocol serial number
01

Study information

Scientific Title
A fixed mandibular full arch supported by two different fully tapered dental implant systems: a randomized controlled clinical trial

Acronym
FMFABLX

Study objectives
The aim of this randomized controlled clinical trial is to evaluate the primary stability and the marginal bone loss of fixed full-arch restorations supported by two different fully tapered

dental implant systems in edentulous mandibles.
The authors hypothesize that differences in mean bone remodelling, implant stability and soft tissue parameters are not significantly different between groups, confirming the reliability and validity of a novel fully tapered dental implant system

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/09/2017, Ethical Committee of "Sapienza" University of Rome (Viale del Policlinico 155, 00161, Rome, Italy; +39 (0)649979822; comitato.etico@policlinicoumberto1.it), ref: 4720 /2017

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Fully edentulous mandibles

Interventions
The study will be conducted at the Department of Oral and Maxillofacial Sciences, Oral Surgery Unit, “Sapienza” University of Rome, Italy.
The study sample will be composed of patients presenting at the University’s department for implant treatment and according to the in-/and exclusion criteria.

Patients that fulfil all in-/exclusion criteria and gave their informed consent will be randomized to one of the two treatment groups:
1. Treatment with 6 fully tapered BLX implants, distally tilted (Institut Straumann AG), with an immediate loading protocol to support a fixed reconstruction in the fully edentulous mandible
2. Treatment with 6 fully tapered Nobel Active implants, distally tilted (Nobel Biocare, Zürich, Switzerland), with an immediate loading to support a fixed reconstruction in the fully edentulous mandible

Surgical procedure:
A complete medical and dental history check will be performed, and a radiological examination, which includes a panoramic radiograph and a cone-beam tomography will be obtained. Furthermore, conventional impressions will be taken to produce diagnostic wax-ups.
A planning software system (coDiagnostiX™, Dental Wings GmbH, Chemnitz, Germany) will be used to plan the insertion of dental implants.
The preparation of the locations of the implants will be carried out according to the defined sequence provided by the manufacturer for both the anterior and the posterior dental implants.
One hour prior to surgery, prophylactic antibiotics will be administered to patients: 2g of amoxicillin and clavulanic acid (Augmentin®, Roche S.p.A., Milan, Italy), or in case of allergy 600 mg of azithromycin (ZITROMAX ®, Pfizer Italia S.r.l., Latina, Italy).
Surgery will be performed under local anesthesia under aseptic conditions in an outpatient

environment, according to routine surgical techniques of the center.
Two dental implants will be placed in the canine zone and four in the posterior sector (first premolar-first molar).
After temporary prostheses delivery, a definitive restoration in Cobalt-Chrome/ceramic will be delivered.
The day of loading will be defined as baseline (T 0).
Medical examinations will be scheduled respectively 7, 14 and 28 days after surgery and then one every thirty days for the following months.

Prosthetic procedure:
Patients will receive a temporary fixed mandibular full-arch at the day of surgery.
Open-tray mandibular impressions will be performed with polyether impression material (Impregum, 3M ESPE AG) using suitable impression copings. The impression copings will be coated with manufacturer recommended polyether adhesive and splinted with bite registration polyether (Ramitec, 3M ESPE AG), prior to impression making. Definitive working casts (Type IV dental stone, Ultrarock) will be poured using the impressions, with implant replicas. Arch-shaped record bases will be then fabricated on the working casts with shellac base plates and modelling wax, supported by temporary cylinders splinted and reinforced with pattern resin (GC pattern resin, GC Corp) to stabilize the record bases during try-in. Jaw-relation and centric relation recording will be recorded intraorally and transferred to the semiadjustable articulator (Artex, Amann Girrbach) for teeth arrangement.
The cusps will be flattened and the articulation balanced, in order to spread the load on all implants and reduces risks of technical fractures.
Bilateral simultaneous anterior and posterior contact in centric and eccentric positions will be achieved, distributing the loading forces over a large area. If the full arch opposes natural teeth, a group function will be obtained to avoid lateral forces.
Therefore, new impressions will be obtained and final fixed restorations will be delivered to patients of the two groups 20–23 weeks post-surgery.

Randomization:
Each study participant will be randomly assigned to one of two intervention groups, at the first stage surgery, if all inclusion and exclusion criteria are met. A block randomization will be done using sealed envelope (Sealed Envelope Ltd., London, UK).
Allocation will be concealed within an opaque sealed envelope. The computer-generated random allocation sequence list will be carried out using a random-number generator (randomizer.org). Assignments will be enclosed in sequentially numbered, opaque, sealed envelopes and stored at the study centre. After recruitment, the appropriate numbered, opaque, sealed envelope will be opened and the randomisation information will be given to the patient and investigator (but not to the statistician performing the analysis)

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
BLX Dental implants Nobel Active dental implants

Primary outcome(s)

Current primary outcome measure as of 11/08/2025:
Marginal bone level at baseline, 6, 12, and 36 months after surgery

Standardized (Rinn, Dentsply, York, PA) periapical radiographs will be taken for each implant placed, bone levels will be calculated by measuring the distance from the implant shoulder to the first bone to implant contact, mean bone loss will be then digitally evaluated.
Mesial and distal implant crestal bone levels will be measured on the periapical radiographs. The radiographs will be evaluated by an independent investigator and expert in the field.
The reference point for the bone level measurement is the implant shoulder. The bone level will be evaluated by measuring the distance between the implant chamfer and the first visible bone contact on the implant. The bone level measurements will be recorded on the mesial and distal aspect of each implant. Measurements will take into account distortion based on changes on the radiograph from the true dimension of the implant or if the implant is not on its whole length on the periapical radiographs. The distance of the threads or the implant length will be measured to calculate the true dimension of the implant

Previous primary outcome measure:
Marginal bone level at baseline, 7, 14, and 28 days after surgery and then every thirty days for the following months.

Standardized (Rinn, Dentsply, York, PA) periapical radiographs will be taken for each implant placed, bone levels will be calculated by measuring the distance from the implant shoulder to the first bone to implant contact, mean bone loss will be then digitally evaluated.
Mesial and distal implant crestal bone levels will be measured on the periapical radiographs. The radiographs will be evaluated by an independent investigator and expert in the field.
The reference point for the bone level measurement is the implant shoulder. The bone level will be evaluated by measuring the distance between the implant chamfer and the first visible bone contact on the implant. The bone level measurements will be recorded on the mesial and distal aspect of each implant. Measurements will take into account distortion based on changes on the radiograph from the true dimension of the implant or if the implant is not on its whole length on the periapical radiographs. The distance of the threads or the implant length will be measured to calculate the true dimension of the implant

Key secondary outcome(s)

Current secondary outcome measures as of 11/08/2025:
1. Implant survival. An implant in place at the respective follow-up visit will be considered a surviving implant
2. Implant success. Implant success will be documented according to the following criteria:
2.1. Absence of persistent subjective complaints, such as pain, foreign body sensation and/ or dysaesthesia
2.2. Absence of recurrent peri-implant infection with suppuration
2.3. Absence of mobility
2.4. Absence of a continuous radiolucency around the implant
3. Patient-centred outcomes:
3.1. The Oral Health Impact Profile for Edentulous Patients (OHIP 20E) will be provided to patients for completion before treatment and at 6 months, 1 year, 2 years and 3 years from delivery of final restorations.
3.2. The Denture Satisfaction Index focuses on the ease of cleaning, general satisfaction, speech, comfort, aesthetics, stability, chewing ability, function and the general oral condition. The patients will be provided with a Visual Analogue Scale (VAS) to complete the questionnaire.
4. Implant Stability Quotient (ISQ). Resonance frequency analysis method with an Osstell device at implant surgery and during the 3-year follow-up period

5. The insertion torque at implant placement will be recorded
6. Soft tissue assessment:
6.1. Plaque Index determined on the mesial, buccal, distal, and palatal surfaces of the implant.
6.2. Sulcus Bleeding Index determined on the mesial, buccal, distal, and palatal surfaces of the implant according to Mombelli et al.
6.3. Probing pocket depth - the distance from the gingival margin to the bottom of the probable pocket at 4 sites (mesial, buccal, distal and palatal) of the implant

7. Prosthetic success:
7.1. A “successful prosthesis” is a prosthesis that is stable and in good function: Absence of abutment mobility
7.2. Absence of corrective measurements to the prosthesis
7.3. Absence of reparations to either prosthesis or abutment
7.4. An “unsatisfactory prosthesis” is in which the patient is not satisfied with the retention and stability of the overdenture

Previous secondary outcome measures:
At 7, 14, and 28 days after surgery and then once every thirty days for the following months (unless otherwise stated):
1. Implant survival. An implant in place at the respective follow-up visit will be considered as a surviving implant
2. Implant success. Implant success will be documented according to the following criteria:
2.1. Absence of persistent subjective complaints, such as pain, foreign body sensation and/ or dysaesthesia
2.2. Absence of recurrent peri-implant infection with suppuration
2.3. Absence of mobility
2.4. Absence of a continuous radiolucency around the implant
3. Patient centered outcomes:
3.1. The Oral Health Impact Profile for Edentulous Patients (OHIP 20E) will be provided to patients for completion before treatment and at 6 months, 1 year, 2 years and 3 years from delivery of final restorations.
3.2. The Denture Satisfaction Index is focusing on the ease of cleaning, general satisfaction, speech, comfort, aesthetics, stability, chewing ability, function and the general oral condition. The patients will be provided with a Visual Analogue Scale (VAS) to complete the questionnaire.
4. Implant Stability Quotient (ISQ). Resonance frequency analysis method with an Osstell device at implant surgery and during the 3-year follow-up period
5. The insertion torque at implant placement will be recorded
6. Soft tissue assessment:
6.1. Plaque Index determined on the mesial, buccal, distal, and palatal surfaces of the implant.
6.2. Sulcus Bleeding Index determined on the mesial, buccal, distal, and palatal surfaces of the implant according to Mombelli et al.
6.3. Probing pocket depth - the distance from the gingival margin to the bottom of the probable pocket at 4 sites (mesial, buccal, distal and palatal) of the implant
6.4. Gingival Margin measurements will be performed simultaneously with the probing pocket depth measurements. GM is the distance from the cemento-enamel junction (CEJ) to the margin of the gingiva at 4 sites (mesial, buccal, distal and palatal) of the implant
7. Prosthetic success:
7.1. A “successful prosthesis” is a prosthesis that is stable and in good function: Absence of abutment mobility
7.2. Absence of corrective measurements to the prosthesis

7.3. Absence of reparations to either prosthesis or abutment
7.4. An “unsatisfactory prosthesis” is if the patient is not satisfied with the retention and stability of the overdenture

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Committed to participate for at least a 36 months follow-up period
3. Provide signed informed consent according to the World Medical Association’s Declaration of Helsinki
4. Complete edentulism of the mandible, to allow placement of six dental implants
5. Full or partial dentition opposing the implants
6. Implant site edentulous for more than 3 months and healed with absence of local inflammation
7. The minimal residual bone height should be appropriate in the canine and posterior sector to allow implant placement

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
24

Key exclusion criteria
Systemic:
1. Uncontrolled systemic disease
2. Smokers (>10 cigarettes/day)
3. History of mental disorders
4. Conditions or circumstances, in the opinion of the investigator, which would prevent

completion of study participation or interfere with analysis of study results, such as history of non-compliance or unreliability
5. Patients with HIV and/ or Hepatitis infection

Local:
6. Mucosal disease or local inflammation
7. Previous failed implant placement or bone grafting in the site
8. Need for major augmentation procedure
9. Poor oral hygiene (Plaque Score > 25)

Date of first enrolment
31/01/2020

Date of final enrolment
01/07/2020

Locations

Countries of recruitment
Italy

Study participating centre
"Sapienza" University of Rome
via Caserta 6
Rome
Italy
00161

Sponsor information

Organisation
Sapienza University of Rome

ROR
https://ror.org/02be6w209

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

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		06/09/2021	07/05/2024	Yes	No