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The complete upper or lower set of teeth replacement with four dental implants

Submission date	Recruitment status	[ ] Prospectively registered
07/02/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/02/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/02/2022	Oral Health	[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
This study looked at patients who had a complete replacement set of upper or lower teeth using a relatively new technique involving 4 dental implants.

Who can participate?
Patients requiring a complete set of upper or lower teeth

What does the study involve?
Patient records were reviewed to look at the long term outcomes of patients who were treated with the above technique.

What are the possible benefits and risks of participating?
The benefits for the treated patients are restitution of mouth and teeth function

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

When is the study starting and how long is it expected to run for?
January 2010 to June 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Paolo Carosi, paolo.carosi@alumni.uniroma2.eu

Contact information

Type(s)
Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
4720

Study information

Scientific Title
Immediate loading of fixed full-arch prostheses supported by four implants: a retrospective cohort study

Acronym
BLPROARCH

Study objectives
To report the clinical and radiological results of the overall rehabilitation treatment with a fixed screw-retained prosthesis supported by four dental implants loaded immediately

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/09/2017, Ethical committee of University of Rome La Sapienza (Viale del Policlinico 155, Rome, Italy; +39 649979822; comitato.etico@policlinicoumberto1.it), ref: 4720

Study design
Retrospective single cohort

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Complete arch edentate

Interventions
For each edentate patient, a case study was performed including CBCT analysis, impressions and diagnostic wax up. Each patient was treated with the placement of 4 dental implants and an immediate screw-retained prosthesis. After 3 months, a defintive prosthesis was realized. The follow up period goes from 1 year after definitive prosthesis placement to the last follow up visit (up to June 2020). The first cases were treated 12 years ago, while the most recent were treated 3 years ago.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Based on the radiographic and clinical examination, each implant was classified as follows:
1. Successful implants, if there were no subjective complaints (e.g., pain), no mobility, no suppuration when peri-implant mucosa was pressed, absence of bleeding and/or suppuration on gentle probing, a probing Depth ≤ 5 mm, radiographic evidence of marginal bone level change (MBLC) ≤ 2 mm at 1-year post-loading of definitive prosthesis (T1) and at the latest follow-up visit (T2)
2. Survival implant, meaning they were still in place but did not fulfil the success criteria as above
3. Clinical outcomes were recorded following the classification by Berglundh et al. (Berglundh T, Armitage G, et al. 2018) at T1 and T2:
3.1 Peri-implant health: absence of erythema, bleeding on probing, swelling and suppuration;
3.2 Peri-implant mucositis: presence of bleeding on gentle probing with radiographic bone loss <2mm. Erythema, swelling and/or suppuration may also be present.
3.3 peri-implantitis: i) presence of bleeding and/or suppuration on gentle probing; ii) increased probing depth compared to previous examinations and iii) radiographic evidence of bone resorption (>0.5mm) beyond crestal bone level changes resulting from initial bone remodeling (T1).

Key secondary outcome(s))
1. Prosthetic success
Prosthodontic maintenance events such as: abutment fracture; abutment retaining screw fracture or loosening; prosthetic retaining screw fracture or loosening; acrylic teeth loosening or fracture: acrylic veneering fracture and prosthesis (framework) fracture, were recorded during the follow-up visits or at the time the patient highlighted the problem. The definitive prostheses in function without complications were considered as a “successful prosthesis”
2. Radiographic examination
Periapical radiographs obtained by using the parallel technique were performed for each implant. The radiographs were analysed for the existence of continuous peri-implant radiolucency, and the position of crestal bone levels around the implants. Measurements were done on the distal and mesial aspects of the implants with a specific software (CS Imaging 7, Carestream Dental LLC, Atlanta, GA, USA) and a High-Definition Monitor (HP Pavilion 23 cw, Full HD 5.000.000:1 Dynamic Contrast, Helwett-Packard, Palo Alto, CA, USA) to measure MBL levels, defined as the distance between the implant shoulder and the first bone-to-implant contact. In case of a sub-crestal implant shoulder, as for implants installed in extraction sockets, the

measurement was recorded as a positive value. Only the worst value between the mesial and distal measurements was considered for the statistical analysis. The radiographic dimension of each implant was measured and compared to the real implant length to correct dimensional distortions (Romeo, Tomasi, et al., 2009). The radiographic measurements were performed annually but the data taken into account for the statistical analysis refer at implant placement (T0 – Baseline), at 1-year post-loading of definitive prosthesis (T1) and at the last follow-up visit (T2)
3.Peri-implant Soft tissue parameters
The peri-implant soft tissue evaluation was made by a trained calibrated operator (N.F.) and involved the assessment of modified plaque index (mPI), modified bleeding index (mBI), probing depth (PD) and width of keratinized mucosa (KM). mPI was assessed on the mesial, distal, buccal, and palatal/lingual surface of the implants (score 0 – 3) (Buser, Weber, & Lang, 1990; A. Mombelli, Oosten, Schürch, & Lang, 1987; Andrea Mombelli & Lang, 1994). mBI was determined at the same surfaces as for mPI: score (0 – 3) (Buser, Weber, et al., 1990; A. Mombelli et al., 1987; Andrea Mombelli & Lang, 1994). PD was measured to the nearest millimetres, from the mucosal margin to the bottom of the pocket with a periodontal probe (Hu-Friedy PGF-GFS, Hu-Friedy, Chicago, IL., USA), at the same surfaces as for mPI (Buser, Weber, et al., 1990; A. Mombelli et al., 1987; Andrea Mombelli & Lang, 1994). The reliability of each PD data collection was estimated by performing a second set of PD measurements by a second operator (P.C.). Measured at baseline (T0), T1 and T2

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Present completely edentulous arches or hopeless teeth requiring extraction and refusing invasive grafting procedures.
2. Absence of oral mucosal disease
3. Suitable bone dimension for the insertion of four implants

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
103

Key exclusion criteria
1. Heavy smokers (more than 5 cigarettes per day)
2. Drug or alcohol abuse

3. Poor oral hygiene
4. Bruxism
5. Radiotherapy in the head and neck region
6. Patients undergoing antiblastic chemotherapy
7. Severe intermaxillary skeletal discrepancy

Date of first enrolment
10/01/2010

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Italy

Study participating centre
University of Rome La Sapienza
Piazzale aldo moro 5
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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
The data of the treated patients are available under request from the principal investigator (paolo.carosi@alumni.uniroma2.eu)

IPD sharing plan summary
Available on request