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Comparing two different loading times for dental implants

Submission date	Recruitment status	[_] Prospectively registered
12/03/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/04/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/03/2019	Oral Health	

Plain English summary of protocol

Background and study aims
In the past, dental implant screws were placed in the jaw bone without teeth being added for 3-8 months to allow the bone to heal around the screw. More recently, immediate- and early-loaded implants are commonly used. Immediate-loaded implants have teeth attached to the screws within 72 hours from implant placement. Early-loaded implants are loaded approximately 6 weeks after implant placement. The aim of this 10-year study is to compare implant failures, complications, patient satisfaction and bone level of immediate and early loading of dental implants in people with some tooth loss.

Who can participate?
Adults with some remaining natural teeth requiring dental implants.

What does the study involve?
The participants were randomly allocated to the immediate or early loading group. Both groups had the dental implants inserted as usual. In the immediate loading group the implants were loaded with teeth within 72 hours from implant placement. In the early loading group, the implants were loaded with teeth approximately 6 weeks after implant placement. The implants were monitored for 10 years to measure the implant failure rate, implant complications, patient satisfaction with the function and appearance of the implants and bone loss measured by X-ray.

What are the possible benefits and risks of participating?
The potential benefit was that the immediate-loading group would not have to wait for 6 weeks to have teeth loaded onto their implants. The implant procedure has some risks including bleeding during and after implant placement, pain and swelling around the implant site, fracture of the implant or fracture of the artificial tooth.

Where is the study run from?
Clinica Merli, Rimini (Italy)

When is the study starting and how long is it expected to run for?
February 2005 to November 2018

Who is funding the study?
This study was investigator funded.

Who is the main contact?
Mauro Merli, mauromerli@gmail.com

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RCT7

Study information

Scientific Title
Immediate versus early non-occlusal loading of dental implants placed flapless in partially edentulous patients: A 10-year randomized clinical trial

Acronym
Immediate versus early loading

Study objectives
To compare immediate versus early non-occlusal loading of dental implants placed flapless

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study started in early 2005 and at the time in Italy there was no a clear regulation for studies on a medical device.

Study design
Single-centre assessor-blind parallel randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Dental implantation in partially edentulous patients

Interventions
Patients were randomized to receive implants for fixed partial dentures. The test group was represented by immediate non-occlusal implant loading, whereas the control group was represented by early non-occlusal implant loading. An investigator, not involved in the selection and treatment of the patients, randomly assigned participants following simple randomization procedures (computerized random numbers) to one of two treatment groups. The randomized codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. Envelopes were opened sequentially only after the implants to be included in the trial were inserted, and therefore treatment allocation was concealed to the investigator in charge of enrolling and

treating the patients included in the trial.
All provisional restorations of the immediate loaded group were placed within 72 h of implant placement. The occlusal surface of the provisional restoration was ground to avoid any occlusal contact with the opposite dentition in static and dynamic analyses.
For patients in the early loading group, impressions were taken approximately 6 weeks after implant placement. They received non-occlusally provisional fixed restorations, identical to those of the immediately loaded group.

Intervention Type
Procedure/Surgery

Primary outcome measure
Implant failure (the presence of any mobility of the implant and/or any situation dictating implant removal) after 10 years

Secondary outcome measures
1. Biological or prosthetic complications defined as unexpected deviations from the normal treatment outcome: examples of biological complications are hemorrhaging during and after implant placement and/or peri-implantitis. Prosthetic complications included fracture of the implant or fracture of the prosthesis.
2. Patient's aesthetic and functional satisfaction were assessed by asking the patient for satisfaction on a scale from 0 to 10 where 0 meant completely dissatisfied and 10 meant completely satisfied
3. Peri-implant marginal bone level assessed using periapical intra-oral radiographs taken with the parallel technique at 10 years of follow-up

Overall study start date
07/02/2005

Completion date
05/11/2018

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Partially dentate and requiring dental implants
3. Implant site allows for the placement of at least one 9.5 mm long implant
4. Bone thickness at the implant site at least 5.5 mm
5. For patients with multiple areas to be restored, the operator was free at the screening visit to select one area to be included in the trial. In this area, multiple neighboring implants could be placed.

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. General contraindications to implant surgery
2. Patients irradiated in the head and neck area within a year prior to surgery
3. Patients with poor oral hygiene (full-mouth plaque score ≥30) and lack of motivation
4. Uncontrolled diabetes (diabetes that is not being treated at all, or is not being adequately treated)
5. Pregnant or lactating
6. Substance abusers
7. Psychiatric problems
8. Lack of opposing occluding dentition in the area intended for implant placement
9. Severe bruxism or clenching
10. Active infection or severe inflammation in the area intended for implant placement
11. Presence of ≤4 mm of keratinized mucosa and/or the need for bone augmentation procedures, with the exception of post-extractive sites treated with Bio-Oss® granules

Date of first enrolment
06/07/2005

Date of final enrolment
25/07/2007

Locations

Countries of recruitment
Italy

Study participating centre
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Sponsor information

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator funded

Results and Publications

Publication and dissemination plan
Two journal articles presenting the data up to 1-year and 3-year follow-up have been previously published. 10-year follow-up results are expected to be published in 2019.

Intention to publish date
15/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Mauro Merli (mauromerli@gmail.com) after the publication of the trial at 10-year follow-up. Fields related to patient demographics will be deleted.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	1-year follow-up results	01/09/2008		Yes	No
Results article	3-year follow-up results	01/02/2012		Yes	No