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Study of loading different surface-modified dental implants at 6 weeks after insertion

Submission date	Recruitment status	[_] Prospectively registered
28/02/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/03/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/04/2021	Oral Health	

Plain English summary of protocol

Background and study aims
Dental implants are small fixtures that are placed under the gum to work as the roots of a missing tooth. A crown or artificial tooth is then fitted to match the rest of the teeth. Various surface treatment options have been tested with the aim of improving the osseointegration (bone ingrowth) of dental implants, in order to reduce overall treatment time. The aim of this study is to investigate whether implant surface characteristics influence the osseointegration process, up to 6 weeks after dental implant insertion.

Who can participate?
Healthy patients with at least one missing tooth who do not require bone grafting

What does the study involve?
Patients are randomly allocated to one of three different surfaces for their dental implants. The study involves clinical and radiological examinations, dental implant placement, stability measurements immediately after implant placement and 6 weeks after surgery, prosthesis delivery 6 weeks after implant placement and peri-implant probing depth measurements 3 months after prosthesis delivery.

What are the possible benefits and risks of participating?
The benefits are getting an implant-supported prosthesis and with that getting back normal chewing function. The risks are the same as general dentoalveolar surgery as usual, such as soft or hard tissue injury, nerve injury, and bleeding during surgery.

Where is the study run from?
Semmelweis University (Hungary)

When is the study starting and how long is it expected to run for?
August 2019 to October 2020

Who is funding the study?
Semmelweis University (Hungary)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
SLA-NH-SA

Study information

Scientific Title
The early loading of different surface-modified implants: a randomized clinical trial

Study objectives
The aim of this randomized controlled trial was to investigate whether the implant surface characteristics influence the osseointegration process, up to 6 weeks after dental implant insertion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/09/2019, National Institute of Pharmacy and Nutrition, Medical General Department, Medical Research Council Budapest (Zrínyi str 3. Budapest 1051; +36 (0)1 8869 329; amd@ogyei.gov.hu), ref: OGYÉI/55197/2019

Study design
Randomized prospective clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with at least one missing tooth and requiring an implant-supported fixed partial denture

Interventions
A computer-generated randomization scheme is used to allocate patients to three different groups. Randomization codes are secured in an opaque envelope. An external assessor, not previously involved in the study, prepares all the envelopes.

Patients are randomised to receive SA (alumina sandblasted and acid-etched), NH (bioabsorbable apatite nanocoating) or SLA (large-grit sandblasted and acid-etched) surface implants.

The implant stability is measured at the time of implant placement (primary stability) and 6 weeks after prosthesis delivery (secondary stability). Osstell and Periotest are applied to take all the measurements. The primary and secondary stability are compared in the three study groups. Finally, the peri-implant probing depth appearing after 3 months of loading is checked on six points around to the implant-supported prostheses.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Implant failure measured with clinical and radiological examinations 6 weeks after implant placement and 3 months after prosthesis delivery
2. Implant stability measured with Osstell and Periotest devices immediately after implant placement and 6 weeks after the surgery

Key secondary outcome(s))
Peri-implant probing depth measured with Williams-periodontal probe at 3 months after prosthesis delivery

Completion date
01/10/2020

Eligibility

Key inclusion criteria
1. Patients with an edentulous site requiring implant-supported fixed partial dentures
2. Good compliance
3. Good or moderate oral hygiene
4. Complete mucosal healing at the study site
5. Previous tooth extraction performed between 2 months and 1 year prior to implant placement

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

Total final enrolment
53

Key exclusion criteria
1. General contraindications to oral surgery (i.e. non-controlled systematic diseases, chemo- and radiotherapy in the head and neck region, previous and ongoing bisphosphonate or denosumab therapy)
2. Incomplete mucosal healing at the study site
3. Need for bone grafting
4. Previous socket preservation or ridge augmentation
5. >5 mm of periodontal pockets at adjacent teeth
6. Poor oral hygiene
7. Smoking more than 10 cigarettes per day

Date of first enrolment
07/10/2019

Date of final enrolment
12/12/2019

Locations

Countries of recruitment
Hungary

Study participating centre
Semmelweis University
Oral and Maxillofacial Department
Mária str 52
Budapest
Hungary
1085

Sponsor information

Organisation
Semmelweis University

ROR
https://ror.org/01g9ty582

Funder(s)

Funder type
University/education

Funder Name
Semmelweis Egyetem

Alternative Name(s)
Semmelweis University

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Hungary

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Kinga Körmöczi (kinga.kormoczi@gmail.com or kormoczi.kinga@dent.semmelweis-univ.hu) or Dr Árpád Joób-Fancsaly (joobarpad@gmail.com or joob_fancsaly.arpad@dent.semmelweis-univ.hu).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/04/2021	28/04/2021	Yes	No