ISRCTN51714535 https://doi.org/10.1186/ISRCTN51714535

Bone adaptation induced by non-passively fitting implant superstructures

Submission date
22/05/2009

Recruitment status
No longer recruiting

Registration date
15/07/2009

Overall study status
Completed

Last Edited
20/01/2015

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A dental prosthesis is used to repair defects such as missing teeth and missing parts of teeth. A dental implant is a titanium screw that is placed into the jawbone to support a dental prosthesis. Dental prostheses fixed on more than one dental implant are supposed to have a perfect, passive fit in order to avoid mechanical stress which may cause problems. Unfortunately, passivity of fit cannot be achieved with current materials and techniques. The aim of this study was to show that the jawbone adapts to stresses caused by implant-supported prostheses.

Who can participate?
Healthy patients who have lost teeth and are going to receive an implant-supported prosthesis.

What does the study involve?
Two dental implants will be placed in the patients' edentulous sites (i.e., where teeth are missing). The patients will be randomly allocated to one of two groups. Different techniques will be used to fit the fixed prosthesis in the two groups. Over six months seven strain gauge measurements will be carried out. Upon completion of the measurements, the implants will be restored in a definitive way.

What are the possible benefits and risks of participating?
Patients receive dental implants for free and are reimbursed for travel expenses and time spent during the strain gauge measurement sessions. Risks include potential bone damage due to repeated fixation of the prosthesis, and small implant components as well as impression material might be swallowed or aspirated during the course of the study.

Where is the study run from?
University of Erlangen-Nuremberg (Germany).

When is the study starting and how long is it expected to run for?
July 2009 to June 2014.

Who is funding the study?
ITI Foundation (Switzerland).

Who is the main contact?
Dr Matthias Karl
Matthias.Karl@uk-erlangen.de

Contact information

Type(s)
Scientific

Contact name
Dr Matthias Karl

ORCID ID
http://orcid.org/0000-0002-8748-1024

Contact details
Zahnklinik 2 - Department of Prosthodontics
University of Erlangen-Nuremberg
Glueckstrassse 11
Erlangen
Germany
91054
+49 (0)913 1853 5802
Matthias.Karl@uk-erlangen.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Bone adaptation induced by non-passively fitting implant superstructures: a randomised controlled clinical trial

Study objectives
Non-passively fitting implant-supported fixed dental prostheses induce bone adaptation which leads to the displacement of the supporting implants and a reduction of misfit. Restorations fabricated by an intra-oral luting technique evoke only minimal misfit strains and thus do not lead to bone remodelling.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Faculty of the Friedrich-Alexander-University Erlangen-Nuremberg, 10/02/2009, ref: 3933

Study design
Randomised controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Precision of fit of implant-supported dental restorations

Interventions
Two dental implants will be placed in the patients' edentulous sites and restored with a fixed prosthesis (measurement restoration). The design of the pontic area will allow for a strain gauge to be positioned temporarily. Within a period of six month, seven strain gauge measurements will be done. The patients will be randomly allocated to either the fit or misfit group. In the misfit group, conventional screw retained superstructures will be used whereas in the fit group screw-retained restorations fabricated by an intra-oral luting technique will be applied. Upon completion of the strain gauge measurements, the implants will be restored in a definitive way.

Intervention Type
Device

Primary outcome measure
Trend in strain development for each restoration over time. Strain measurements will be done in each patient every 4 weeks for a period of 6 months.

Secondary outcome measures
Differences in strain development between fit and misfit group. Strain measurements will be done in each patient every 4 weeks for a period of 6 months.

Overall study start date
01/07/2009

Completion date
30/06/2014

Eligibility

Key inclusion criteria
Partially edentulous, healthy patients (any age, either sex) who have been treatment planned to receive an implant-supported multi-unit fixed dental restoration in one or two quadrants.

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Contraindications for dental implants (e.g., craniofacial growth is not finished)
2. Impaired general health
3. Diseases and medications affecting bone quality
4. Untreated periodontal disease
5. Insufficient bone volume for implant placement

Date of first enrolment
09/07/2009

Date of final enrolment
05/12/2013

Locations

Countries of recruitment
Germany

Study participating centre
University of Erlangen-Nuremberg
Erlangen
Germany
91054

Sponsor information

Organisation
ITI Foundation (Switzerland)

Sponsor details
c/o Professor Dr. Thomas D. Taylor
Department of Reconstructive Sciences
263 Farmington Avenue
Farmington
Connecticut
United States of America
06030-1615
+1 (0)860 679 2649
ttaylor@nso.uchc.edu

Sponsor type
Research organisation

Website
http://www.uconn.edu/

ROR
https://ror.org/01dkem006

Funder(s)

Funder type
Research organisation

Funder Name
ITI Foundation (Switzerland) (ref: 579-2008)

Results and Publications

Publication and dissemination plan
A manuscript has been submitted to “The International Journal of Oral and Maxillofacial Implants”

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available