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The immediate implant-supported mandibular overdentures with cusped and cuspless tooth

Submission date	Recruitment status	[_] Prospectively registered
31/08/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/09/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/04/2018	Oral Health	

Plain English summary of protocol

Background and study aims
Overdentures, also known as dental implants, are metal posts which are screwed directly into the jaw bone in order to support replacement teeth. These implants provide a strong foundation for fixed (permanent) or removable false teeth and, as long as they are looked after well, are very long lasting. Many people prefer dental implants to traditional dentures because they are more hardwearing and have a more realistic appearance. The artificial teeth which are used for overdentures come in a variety of forms. One of the main variations is related to cusps (the pointed end of the tooth). Cusped overdentures (also known as anatomic) are designed to imitate the natural tooth form, whereas cuspless overdentures (or non-anatomic) is essentially flat and designed to improve the function of chewing. The aim of this study is to compare the effects of cusped and cuspless implants on the health of the surrounding bone tissues in the mouth.

Who can participate?
Healthy adults over 40 with missing teeth for more than 3 years, who have refused removable partial dentures.

What does the study involve?
Participants are randomly allocated into two groups. Both groups have implants inserted after tooth extraction. The first group is given overdentures with cusped teeth, and the second group is given overdentures with cuspless teeth. Once the implants have been fitted, the healing process and how well they fit is measured at three, six, nine and twelve months. Participants are also asked to describe pain levels at these times.

What are the possible benefits and risks of participating?
Benefits of participating are that patients are treated using two advanced methods at no cost. There are no risks of participating.

Where is the study run from?
Al-Azhar University-Assiut Branch (Egypt)

When is the study starting and how long is it expected to run for?
September 2013 to September 2014

Who is funding the study?
Albaha University (Saudi Arabia)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The impact of immediate implant-supported mandibular overdentures with cusped and cuspless tooth on bone tissues

Study objectives
The immediate implant-supported mandibular overdentures with cusped teeth is better than cuspless teeth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dental Health Department of the Faculty of Applied Medical Sciences (Albaha University), 04/08 /2013

Study design
A randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
This study aimed to examine the impact of immediate implant-supported mandibular overdentures with cusped or cuspless tooth on surrounding bone tissues.

Interventions

The randomization of selected patients was by lottery selection after giving each patient a number in a list, and then randomly the 20 patients were divided into two groups, 10 patients for each group.
Group 1: Rehabilitation with immediate implants (the implant inserted immediately after extraction) loaded with overdentures with cusped teeth.
Group 2: Rehabilitated with immediate implants (implants inserted immediately after extraction) loaded with overdentures with cuspless teeth.
Following flap elevation and the removal of a tooth and implant installation, inside the socket then the clinical measurements were made to characterize the dimension of the surrounding bone walls, as well as the marginal defect. There were no membranes or filler material was used. The flaps were subsequently replaced and secured with sutures in such a way that the healing cap of the implant was exposed to the oral environment. After 3 months of healing a re-entry procedure was performed and the clinical measurements were repeated.

Intervention Type
Procedure/Surgery

Primary outcome measure
Crestal bone loss observed over one year, at 3, 6, 9 and 12 months. The measurement of crestal bone loss by periapical radiographs was evaluated by the masial and distal marginal bone height around the abutments (implant) from the radiograph of each patient as follow; two points were marked one at apex of implant and anther at the tip of the implant, a line (A) was drown connecting the 2 points then the tangent (b) to the tip of tooth, marginal bone height was measured by a dial caliper from mesial and distal alveolar crest to line (b), and measurements on serial radiographs were compared and the results were statistically analyzed as mean and percent.

Secondary outcome measures
1. Periapical lesions measured in each cross-section from the widest and deepest part of the lesion by the researcher using a precision digital caliper with an accuracy of up to 0.01 mm, at 3, 6, 9 and 12 months.
2. Pain measured using visual analog scale (VAS) at 3, 6, 9 and 12 months
3. Neural sensibility measured using a pulp sensibility test, which includes an electric test, which extrapolates pulp health from sensory response, at 3, 6, 9 and 12 months
4. Mobility of implants measured according to the periotest, siemens dental bensheim, Germany at 3, 6, 9 and 12 months.

Overall study start date
01/09/2013

Completion date
12/09/2014

Eligibility

Key inclusion criteria
1. Aged over 40 years
2. Free from any systematic diseases
3. Non-smoker
4. Jaw relation angle class one
5. Refused removable partial dentures

6. Edentulous more than 3 years
7. Hopeless mandibular teeth

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
20 Edentoulus patients

Key exclusion criteria
1. Diabetes
2. Hypertension
3. Patients who prefer the removable partial dentures
4. Immunodeficient patients

Date of first enrolment
01/10/2013

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
Egypt

Study participating centre
Al-Azhar University-Assiut Branch
Dental Clinic
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Sponsor information

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Sponsor type
Not defined

ROR
https://ror.org/0403jak37

Funder(s)

Funder type
Not defined

Funder Name
Albaha University

Results and Publications

Publication and dissemination plan
Intend to publish this study in ISI journals

Intention to publish date
01/10/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2016		Yes	No