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Effect of overdenture with vital and non-vital abutment teeth

Submission date	Recruitment status	[ ] Prospectively registered
05/09/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/09/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/10/2015	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Overdentures are dentures that are supported by the natural teeth on either side of them. These surrounding teeth are referred to as abutment teeth. Unlike conventional dentures, overdentures cannot be removed from the mouth by the patient. Root canal treatment is a dental procedure to treat an infection in the centre (root canal system) of a tooth. Also referred to as endodontics, the treatment involves removing the infected soft tissue of the tooth (the pulp) and filling the root canal with a dental filling. As the pulp of the tooth has been removed and there is no longer a blood supply to the tooth, the tooth is considered dead, or non-vital. Non-vital teeth can be more fragile and more likely to break than vital (live) teeth. This study looks at the effect of overdentures over vital and non-vital abutment teeth on teeth stability.

Who can participate?
Men aged at least 59 years and in need of overdentures.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are given overdentures supported by vital abutment teeth. Those in group 2 are given overdentures supported by non-vital abutment teeth. Attachment loss and teeth mobility are then assessed after 3 months, 6 months and 12 months after treatment.

What are the possible benefits and risks of participating?
The study has many benefits for patients including being less expensive and invasive and increasing the level of satisfaction and quality of life.

Where is the study run from?
The Dental Clinic, Faculty of Dentistry at Al-Azhar University-Assiut Branch in Egypt

When is the study starting and how long is it expected to run for?
December 2013 to February 2015

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

Who is the main contact?
1. Professor Khalid Arafa (public)
2. Dr Waled Ahmed (scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of overdenture with vital and non-vital abutment teeth on tooth stability

Study objectives
The use of overdenture with vital abutment teeth is better than non-vital abutment teeth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dental Health Department of the Faculty of Applied Medical Sciences, Albaha University, 01/12 /2013

Study design
A randomized experimental-parallel design

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Implant overdentures

Interventions
The patients were randomly divided into two groups each of 15 patients, both treated with overdenture, but they were different in the abutment teeth, the first group received vital abutment teeth while the second group received non-vital (endodontically treated) teeth. Both groups used overdentures (after finishing the overdenture in dental lab, the patients taking the construction) and then evaluated 3, then 6 and lastly after 12 months, as regarding to the attachment loss and tooth mobility of the abutment teeth in a both groups with vital and non-vital abutment teeth.

Intervention Type
Procedure/Surgery

Primary outcome measure
Attachment loss:
The attachment loss was measured according to Romfjord (1967), the measurement of attachment loss from the gingival margin till the cementoenamel junction. The clinical attachment loss (CAL) is the measurement of the loss of the position of the soft tissue in relation to the cemento-enamel junction (CEJ) that is a fixed point that does not change throughout life. The CAL is assessed by both the probing depth plus the gingival margin level. For instance, if the probing depth measurement 4 mm and gingival margin level 2 mm, the clinical attachment loss will be 6 mm.

Measured at 3 months, 6 months and 12 months after treatment.

Secondary outcome measures
Tooth mobility:
The measurement of tooth mobility was done according to Everett and Sten (1969) the measurement of tooth mobility baccolingual by two dental instruments (probe or mirror) and classified as first degree mobility 0 mm, second degree mobility 1 mm and third degree mobility more than 1 mm. The tooth mobility was assessed by using the ends of two dental instruments handles (probe or mirrors). The mobility was graded into class I, II, and III. Four implants were placed to attach a fixed bar, three clips were placed in the overdenture for retention. The overdentures root-supported have been fabricated to accurate periodontal and/or occlusal collapse. Some teeth are corrected to support and/or keep the prosthesis.

Measured at 3 months, 6 months and 12 months after treatment.

Overall study start date
01/12/2013

Completion date
01/02/2015

Eligibility

Key inclusion criteria
1. Men age at least 59 years
2. Partially edentulous, and wearing their third lower denture
3. Have the same maxillomandiblar relationship class one
4. The patients with non-vital tooth had acute pulpitis treated by root canal treatment

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
30

Key exclusion criteria
Patients with systemic diseases

Date of first enrolment
24/12/2013

Date of final enrolment
12/08/2014

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Albaha University
Al-Baha
Saudi Arabia
00966

Sponsor information

Organisation
Albaha University

Sponsor details
Al-Baha- KSA
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Sponsor type
University/education

ROR
https://ror.org/0403jak37

Funder(s)

Funder type
University/education

Funder Name
Albaha University

Results and Publications

Publication and dissemination plan

Intention to publish date
01/10/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request