

Comparing the effects of titanium alloy and chrome cobalt in removable partial denture connectors on tooth mobility, bone loss and tissue reaction

Submission date 10/12/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/12/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/05/2021	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Losing teeth is an inevitable part of the aging process for some people. The gaps left by missing teeth can cause problems with eating or speech, as well as affecting appearance, which can be distressing for the sufferer. Dentures are removable false teeth designed to replace missing teeth. They can be complete (a full set), for someone has lost all the teeth on the upper and/or lower jaw or partial, which replace just one tooth or several missing teeth. They typically consist of an acrylic (plastic), nylon or metal plate with false teeth attached, that can be slotted into place. In the case of partial dentures, connectors (metal clips) are often used to hold the dentures in the mouth securely, by clipping onto natural teeth. In recent years titanium has been used far more in the manufacture of these connectors, as it is very flexible, strong and long-lasting. The aim of this study is to compare how using titanium alloy and the traditional metal cobalt-chromium for dentures affects long-term tooth and gum health.

Who can participate?

Healthy men over 55 years of age who have lost some of their teeth.

What does the study involve?

Participants are randomly allocated to one of two groups. Participants in the first group receive dentures with connectors constructed from titanium alloy (Ta) to wear during waking hours throughout the two years of the study. Participants in the second group receive dentures with connectors constructed from chrome cobalt (Co-Cr) to wear during waking hours throughout the two years of the study. After 6, 12, 18 and 24 months, participants in both groups have a dental examination to find out how the dentures have affected their teeth and gums.

What are the possible benefits and risks of participating?

Participants benefit from receiving free dental treatment during this study. There are no expected risks of taking part in this study.

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?
January 2013 to January 2015

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

Who is the main contact?
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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
Titanium alloy and chrome cobalt in removable partial denture connectors with tooth mobility, bone loss and tissue reaction

Study objectives

Titanium alloy is better than chrome cobalt for fabricating the major connectors in removable partial dentures

Ethics approval required

Old ethics approval format

Ethics approval(s)

Dental Health Department of the Faculty of Applied Medical Sciences (Albaha University), 02/01/2013

Study design

Non-randomized clinical-controlled trial

Primary study design

Interventional

Secondary study design

Non randomised study

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

Removable partial dentures

Interventions

The patients enrolled in the study were separated into two equal groups.

Group 1: Participants receive connectors constructed from titanium alloy (Ta). The Ta (Ti-6Al-4V alloy disks; Sumitomo Steel, Osaka, Japan, 120 mm in diameter and 0.75 mm in thickness). After construction of the partial denture, the patients wore the dentures. During mastication, the forces were transmitted from the dentures to the tooth structure and the residual ridge.

Group 2: Participants receive connectors constructed from chrome cobalt (Co-Cr). The Co-Cr (Co-63% Cr-30% Mo-7%) American Element, Los Angeles, CA 90024) were used in this study. After construction of the partial denture, the patients wore the dentures. During mastication, the forces were transmitted from the dentures to the tooth structure and the residual ridge.

Participants in both groups are followed up by measuring the tooth mobility, bone loss and tissue reduction four times after insertion with 6 months intervals (6, 12, 18, and 24 months).

Intervention Type

Procedure/Surgery

Primary outcome measure

Tooth mobility is measured in mm using the Miller index at 6, 12, 18 and 24 months.

Secondary outcome measures

1. Bone loss is measured by measuring the tooth height subjectively in millimeters (mm) for each tooth at 6, 12, 18 and 24 months
2. Dental tissue reduction is assessed using the Benson and Spolky index at 6, 12, 18 and 24 months

Overall study start date

01/01/2013

Completion date

05/01/2015

Eligibility

Key inclusion criteria

1. Male
2. Aged 55 years or older
3. Partially edentulous
4. Free from disabilities or chronic conditions, such as diabetes

Participant type(s)

Patient

Age group

Senior

Sex

Male

Target number of participants

80

Total final enrolment

80

Key exclusion criteria

1. Diabetic patients
2. Fully edentulous
3. Those who neglected oral hygiene

Date of first enrolment

10/01/2013

Date of final enrolment

01/01/2015

Locations

Countries of recruitment

Egypt

Saudi Arabia

Study participating centre

Al-Azhar University-Assiut Branch

Dental Clinic

Faculty of Dentistry

Assuit

Saudi Arabia

71524

Sponsor information

Organisation

Albaha University

Sponsor details

The Faculty of Applied Medical Sciences

Prince Mohammad Bin Saud

Al-Baha

Saudi Arabia

00966

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

Planned publication of results data in a dental journal.

Intention to publish date

30/06/2016

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		01/07/2016	13/05/2021	Yes	No