ISRCTN13611836 https://doi.org/10.1186/ISRCTN13611836

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

Registration date
15/12/2015

Overall study status
Completed

Last Edited
13/05/2021

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 cobolt (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?
Professor Khalid Arafa
drkhalidarafa@yahoo.com

Contact information

Type(s)
Scientific

Contact name
Prof Khalid Arafa

ORCID ID
https://orcid.org/0000-0002-3597-5073

Contact details
Dental Health Department
Faculty of Applied Medical Sciences
Albaha University
Al-Baha
Saudi Arabia
00966
+966 553 388866
drkhalidarafa@yahoo.com

Additional identifiers

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

Primary study design
Interventional

Study design
Non-randomized clinical-controlled trial

Study type(s)
Treatment

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 cobolt (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 moths intervals (6, 12, 18, and 24 months).

Intervention Type
Procedure/Surgery

Primary outcome(s)
Tooth mobility is measured in mm using the Miller index at 6, 12, 18 and 24 moths.

Key secondary outcome(s)
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

Completion date
05/01/2015

Eligibility

Key inclusion criteria

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
Male

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

ROR
https://ror.org/0403jak37

Funder(s)

Funder type
University/education

Funder Name
Albaha University

Results and Publications

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