

Effect of different denture base materials and changed mouth temperature on dimensional stability of complete dentures

Submission date 05/12/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/12/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/05/2016	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Dentures are removable false teeth that fit snugly over the gums to replace missing teeth. This study aimed to assess the effect of temperature and three denture base materials on the dimensions of complete dentures (a full set which replace all your upper or lower teeth).

Who can participate?

Men aged 60 or above

What does the study involve?

Participants are randomly divided into three groups to receive complete dentures made of three different base materials. The dimensional changes are measured at 4, 8, and 12 months at normal patient mouth temperature, after drinking hot tea and after drinking a cold drink.

What are the possible benefits and risks of participating?

Participants benefit from the provision of dentures and follow up for one year. Participants are not exposed to any hazards during the study.

Where is the study run from?

Faculty of Dentistry of Al-Azhar University (Egypt)

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

December 2014 to November 2015

Who is funding the study?

Albaha University (Saudi Arabia)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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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 different denture base materials and changed mouth temperature on dimensional stability of complete dentures: a quasi-experimental parallel-design study

Study objectives

The denture base materials and mouth temperature affect the dimensions of complete dentures

Ethics approval required

Old ethics approval format

Ethics approval(s)

Study design

Quasi-experimental parallel-design study

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Other

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

Dentures

Interventions

The three groups received complete dentures fabricated by one of the following base materials (heat cure acrylic resin, soft cure acrylic resin, cobalt chrome metallic).

The first group received complete denture fabricated by heat cure acrylic resin (Meliodent-Bayer dental, Germany batch no 54105L-2) curing cycles in acrylic furnace, at 165°F for 9 (acrylic furnace Bego sommer, Germany batch 226-433). The second group received complete denture fabricated by soft cure acrylic resin (vertex thermo sense rigid batch noxu373802 USA). The third group received complete denture fabricated by cobalt chrome metallic denture base (Bego metal denture base Germany batch 233-42), using the burnout furnace controlled electronically at (950-1200)c fasting furnace (bego Germany batch 239270).

For all the patients, the primary impression was taken by alginate then taking the second impression by rubber base (coltene swiss quality for dentistry batch 4160). In the third visit the jaw relationship was taken, in the fourth visit a try in the waxed denture (Cavex, Holland batch Z. A 990.01) was done, followed by fabrication of the denture in the dental lab. During the denture fabrication two different points were prepared in the fitting surface of the waxed denture (first point in the incisive papilla, second point in mid line of the post dam). After the procedures were finished the point shack in the fitting surface measurement by dial caliper step measurement.

Intervention Type

Procedure/Surgery

Primary outcome measure

Demographic data and denture dimensions. All groups with complete dentures were evaluated after 4 months, 8 months and lastly after 12 months, and evaluated at normal patient mouth temperature, after drinking hot tea at 45c, and after drinking a cold drink at 5c.

Secondary outcome measures

The accuracy of denture dimensions measurement. All groups with complete dentures were evaluated after 4 months, 8 months and lastly after 12 months, and evaluated at normal patient mouth temperature, after drinking hot tea at 45c, and after drinking a cold drink at 5c.

Overall study start date

01/12/2014

Completion date

24/11/2015

Eligibility

Key inclusion criteria

1. Males aged 60 or above
2. Completely edentulous
3. Wearing upper and lower dentures

Participant type(s)

Patient

Age group

Senior

Sex

Male

Target number of participants

90 patients

Key exclusion criteria

1. Female patients
2. Under age 60
3. Partially edentulous
4. Patients with systemic disease
5. Well developed ridge

Date of first enrolment

01/12/2014

Date of final enrolment

01/10/2015

Locations

Countries of recruitment

Egypt

Study participating centre

Faculty of Dentistry of Al-Azhar University

Assiut Branch

Egypt

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Sponsor information

Organisation

Albaha University (Saudi Arabia)

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Sponsor type

University/education

ROR

<https://ror.org/0403jak37>

Funder(s)

Funder type

University/education

Funder Name

Albaha University (Saudi Arabia)

Results and Publications

Publication and dissemination plan

It will be published soon

Intention to publish date

01/01/2016

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	results	01/01/2016		Yes	No