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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

Registration date
10/12/2015

Overall study status
Completed

Last Edited
05/05/2016

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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)
Dental Health Department of the Faculty of Applied Medical Sciences, Albaha University, December 2014

Study design
Quasi-experimental parallel-design study

Primary study design
Interventional

Study type(s)

Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Senior

Sex
Male

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
0020

Sponsor information

Organisation
Albaha University (Saudi Arabia)

ROR
https://ror.org/0403jak37

Funder(s)

Funder type
University/education

Funder Name
Albaha University (Saudi Arabia)

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	results	01/01/2016		Yes	No