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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
05/12/2015		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
10/12/2015	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
05/05/2016	Other			

# 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? Prof. 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
P.O. Box: 7273
Unit No.: 2 ALBAHA
65536-3047
Al-Baha
Saudi Arabia
00966
+966 (0)553 388 866
drkhalidarafa@yahoo.com

# Additional identifiers

#### Protocol serial number

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)

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
Participant information shee	Participant information sheet	11/11/2025 11/11/2025	. No	Yes