

# Patients' satisfaction when wearing different dentures - a pilot study

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<b>Registration date</b> 20/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/09/2017	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Around 2.7 million adults in the UK had been reported to suffer from complete tooth loss in 2009. With the years of life expectancy increasing and a sizeable number of people who have no natural teeth, there is a demand to restore teeth (albeit with the use of a dental prosthesis) to provide an acceptable quality of life. The biting surfaces of denture teeth can have an impact on the function and comfort of these dentures. This aim of this study is to assess if denture teeth which has a shape based on natural teeth provide higher patient satisfaction compared to the current denture teeth shape being used.

### Who can participate?

Generally healthy adults who have complete tooth loss and require new dentures.

### What does the study involve?

Each participant has two sets of dentures made for them. One set are dentures with a classic denture teeth shape and the other set of dentures use an enhanced denture teeth shape. Each patient is asked to wear each set for a period of two months. After wearing each set of dentures, participants are asked to filled in two patient satisfaction questionnaires.

### What are the possible benefits and risks of participating?

Participants benefit from receiving the treatment that they need (i.e. the need to have new dentures as their current ones are not functional). The patient would also receive an extra set of dentures to use. There are no notable risks involved with participating.

### Where is the study run from?

The Royal London Dental Hospital (UK)

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

June 2016 to September 2018

### Who is funding the study?

Queen Mary University of London (UK)

Who is the main contact?

1. Dr Michael Myint (scientific)  
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## Contact information

### Type(s)

Scientific

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## Additional identifiers

### Protocol serial number

Version 1.05 date 25/01/2017

## Study information

### Scientific Title

Patients satisfaction and quality life assessment when wearing complete dentures with teeth of different anatomical designs: a randomised controlled crossover pilot study

## **Study objectives**

The aim of this study is to assess and compare patients' satisfaction and quality of life when wearing dentures with teeth of more detailed tooth morphology with teeth copying natural tooth morphology, and whether the enhanced denture provide better comfort and chewing ability than the classic denture.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

London - Westminster Research Ethics Committee, 06/04/2017, REC ref: 17/LO/0518

## **Primary study design**

Interventional

## **Study design**

Pilot randomised controlled cross over trial

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Complete tooth loss (edentulism)

## **Interventions**

The patients will be randomised into 2 groups via a computerised block envelope process. This was done by using the website [www.sealedenvelope.com](http://www.sealedenvelope.com). The two groups are named Group A and Group B. Group A will wear the classic shaped dentures first for 2 months and after will wear the enhanced shaped dentures for a further 2 months. Group B will wear the enhanced shaped dentures first for 2 months and after will wear the classic shaped dentures for a further 2 months.

The treatment provided from the study is the construction of 2 complete dentures. The fabrication of these dentures involves making the first set first: taking moulds of the patients mouths, ensuring the general outline of the denture shape is correct on a template, adding denture teeth to this template and converting this template to a definitive plastic denture. So far this is the fabrication to make the first set of dentures.

To construct the second set of dentures, a mould is taken of the first set of dentures to have a copy template for the second dentures. The teeth on the copy template is then changed and converted to a definitive plastic denture. This would produce our second set of dentures.

Patients are then provided with their first dentures as dictated by which group they have been randomised into. They will wear these dentures for two months, attending a review appointment one week into this period to ensure there are no clinical concerns. At the end of the two months, patients will be asked to fill in a patient questionnaire (Prof. Fenlon's validated questionnaire) and a quality of life questionnaire (OHIP-EDENT).

The first set of dentures is then taken away and patients are provided with the second set of dentures to wear for two months, attending a review appointment one week into this period to ensure there are no clinical concerns. At the end of the two months, patients will be asked to fill

in a patient questionnaire (Prof. Fenlon's validated questionnaire) and a quality of life questionnaire (OHIP-EDENT). At this point the patient is entitled to keep both sets of dentures and the study would have ended for them.

The total duration of the study is one year and 5 months. The total time involved for each participant will be approximately 8 months.

### **Intervention Type**

Device

### **Primary outcome(s)**

Patient satisfaction is assessed using Professor Fenlon's patient satisfaction with dentures questionnaire at the start and end of each two-month treatment period.

### **Key secondary outcome(s)**

1. Quality of life is measured using the OHIP-EDENT questionnaire at the start and end of each two-month treatment period
2. Self-assessed chewing ability is measured using a questionnaire at the start and end of each two-month treatment period
3. Self-assessed aesthetics of each set of dentures is rated by patients using a questionnaire at the end of each two-month treatment period

### **Completion date**

30/09/2018

## **Eligibility**

### **Key inclusion criteria**

1. Informed consent
2. Age 18-100 years
3. Any gender
4. Any ethnicity
5. Successful denture wearers (i.e. previous denture wearing experience – 3+ years) who need new dentures
6. No mental health issues
7. No problems of Xerostomia (dry mouth).

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

100 Years

**Sex**

All

**Key exclusion criteria**

1. Any inclusion criteria not met
2. Under 18 years
3. The shape and size of the jaw bones - Any Cawood and Atwood classification that is other than Class 2 or 3 or 4:  
Class 2 = a bone shape that is well rounded and of good height but with the remnants of a socket due to tooth being recently removed  
Class 3 = a bone shape that is well rounded and of good height.  
Class 4 = a bone shape that is knife edged and of reasonable height.
4. Unable to consent
5. Pregnant patients.
6. Patients unable to attend easily due to locality or occupation limitations.
7. Large skeletal base discrepancies. This relates to the positioning of the upper and lower jaw to each other. A large skeletal discrepancy would include the lower jaw being too far forward in relation to the upper jaw. Also the contrary where the lower jaw is too far back in relation to the upper jaw. These are called Class 3 and Class 2 Skeletal base relationships respectively.
8. Severe fibrous replacement. This means that there is an area of the oral tissue upon which the denture may be seated on where it has excess fibrous/scar tissue.
9. Maxillo-facial defects. The subject may have undergone surgery or have existing defects to the jaws or face due to multiple reasons such as tumours, cysts, trauma to the face and developmental facial defects. These can change the anatomy of the area where the dentures rely on heavily and can influence the trial.

**Date of first enrolment**

01/04/2017

**Date of final enrolment**

31/12/2017

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Royal London Dental Hospital**

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# Sponsor information

## Organisation

Queen Mary University of London, Barts & The London Dental School

## ROR

<https://ror.org/026zzn846>

# Funder(s)

## Funder type

University/education

## Funder Name

Queen Mary, University of London

## Alternative Name(s)

QMUL

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Universities (academic only)

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No