

# The comparison of two different full denture concepts

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
15/04/2018	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
25/05/2018	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
25/05/2018	Oral Health	<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The treatment of patients without teeth (edentulous) is gaining in importance, because older people make up a growing share of the patient population. To replace lost teeth, implants are increasingly being used in many cases. However, this form of rehabilitation is costly and therefore not affordable for a large part of the population. Complete dentures (false teeth) are still the default form of treatment. Each set of dentures shows an occlusal concept, meaning the position of the teeth in the prosthesis and how many contact points appear during function. While different occlusal concepts are available, the ultimate occlusal concept – or an occlusal concept that the patient perceives as satisfactory – has not been conclusively identified. Over time two occlusal concepts are common. These are the bilateral balanced occlusion and anterior/canine guidance. Studies have highlighted advantages and disadvantages of the respective concepts, but no clear favorite has emerged.

Therefore, this study aims to acquire subjective and objective assessments and to make a recommendation by comparing the two different occlusal concepts.

### Who can participate?

Seniors without teeth, using two complete dentures

### What does the study involve?

Participants are randomly allocated to one of two groups, and receive two types of complete overdentures. Those in the first group receive one type of dentures first, which are used for three months, then they swap to the second type of dentures.

Those in the second group receive the dentures the other way around.

Participants are assessed at the end of each three month period.

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

The participants are able to compare two different concepts regarding the position and the performance of the teeth during function in their prosthesis. With knowledge of both concepts they decide which concept will be their final in their prosthesis.

There are no risks for those taking part in the study.

Where is the study run from?  
Goethe University Frankfurt (Germany)

When is the study starting and how long is it expected to run for?  
July 2006 to June 2016

Who is funding the study?  
1. Goethe University Frankfurt (Germany)

Who is the main contact?  
Dr Silvia Brandt (Scientific)  
hajjaj@med.uni-frankfurt.de

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Silvia Brandt

**Contact details**  
Theodor-Stern-Kai 7  
Frankfurt am Main  
Germany  
60596  
+49 17 782 86781  
hajjaj@med.uni-frankfurt.de

## Additional identifiers

**Protocol serial number**  
00000000

## Study information

**Scientific Title**  
Randomized Prospective Clinical Study comparing the Bilateral Balanced Occlusion and Anterior /Canine Guidance in Participants wearing Complete Dentures

**Study objectives**  
The anterior/canine guidance in complete overdentures will be rated better than the bilateral balanced occlusion by participants and dental practitioners.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Ethics Committee Goethe University Frankfurt Germany, 20/09/2006, ref: 215/06

## **Study design**

Randomized prospective clinical study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Dentures

## **Interventions**

All participants receive complete overdentures with anterior/canine guidance and the bilateral balanced occlusion using a crossover design. The participants are randomised to one of two groups. Those in group 1 receive anterior/canine guidance dentures first, then crossover to bilateral balanced occlusion. Those in group 2 receive bilateral balanced occlusion dentures first, which are then changed anterior/canine guidance. The crossover occurs after 3 months. At the end of each testing phase, the two occlusal concepts are assessed by practitioners and patients and then analysed using the Wilcoxon-Mann-Whitney and marginal homogeneity tests.

## **Intervention Type**

Other

## **Primary outcome(s)**

1. Positional change of maxillary and mandibular denture is measured using clinical examination of two investigators at the end of each testing phase
2. Masticatory efficiency is measured using a numerical rating questionnaire at the end of each testing phase
3. Speech performance is measured using a numerical rating questionnaire at the end of each testing phase
4. Satisfaction is measured using a numerical rating questionnaire at the end of each testing phase
5. Chewing comfort and masticatory efficiency are measured using a numerical rating questionnaire at the end of each testing phase
6. Comfort of the dentures is assessed using a numerical rating questionnaire at the end of each testing phase

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

1. Mechanical retention is measured using clinical examination of two investigators at the end of each testing phase
2. Resorption class for maxilla and mandible is assessed using clinical examination of two investigators at the end of each testing phase

## **Completion date**

29/06/2016

## **Eligibility**

### **Key inclusion criteria**

1. Presence of two functional, aesthetically acceptable complete maxillary and mandibular dentures, not to be more than two years old
2. A bilateral balanced set-up of the denture teeth
3. Good general and mental health
4. Participant compliance
5. Dentures to be worn for the entire six-month study period
6. No scars or grafts in the oral cavity
7. No functional complaints
8. Inconspicuous oral mucosa
9. Sufficient ability to communicate

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Key exclusion criteria**

1. Refusal to participate
2. Extended illness
3. Lack of compliance
4. Communication problems
5. Severe physical or mental illness
6. Craniomandibular dysfunction

**Date of first enrolment**

15/07/2007

**Date of final enrolment**

30/04/2014

## Locations

**Countries of recruitment**

Germany

**Study participating centre****Goethe University Frankfurt**

Department for Prosthetic Dentistry at the Centre for Dentistry, Oral and Maxillofacial Dentistry  
University of Frankfurt am Main  
Frankfurt  
Germany  
60596

# Sponsor information

## Organisation

Goethe University Frankfurt

## ROR

<https://ror.org/04cvxnb49>

# Funder(s)

## Funder type

University/education

## Funder Name

Goethe-Universität Frankfurt am Main

## Alternative Name(s)

Goethe University Frankfurt am Main, Goethe-Universität, Goethe-Universität Frankfurt

## Funding Body Type

Government organisation

## Funding Body Subtype

Local government

## Location

Germany

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Silvia Brandt (hajjaj@med.uni-frankfurt.de) and Prof. H-Ch. Lauer (h.c.lauer@em.uni-frankfurt.de)

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes

