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The comparison of two different full denture concepts

Submission date	Recruitment status	[ ] Prospectively registered
15/04/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/05/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/05/2018	Oral Health	[ ] 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)
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Contact information

Type(s)
Scientific

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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
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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