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Clinical performance of double crown retained dentures using conical all-ceramic primary crowns

Submission date	**Recruitment status**	[_] Prospectively registered
21/10/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/11/2018	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/11/2019	Oral Health	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

The treatment of patients with a reduced number of teeth is an important part of daily practice. There are several treatment options. Double-crown-retained dentures (DCRDs) have a natural appearance and as a result, these dentures are very popular. Additionally, most of patients with DCRDs report a high level of chewing comfort due to very high prosthesis retention. DCRDs also permit the inclusion of existing teeth and implants. Studies already shown improvement in oral health and quality of life for patients using DCRDs.

However the manufacturing process of these dentures is not consistent. DCRDs are composed of a primary crown attached in patients mouth and a secondary crown located in the denture. There are different shapes of primary crowns, including conical and cylindrical. Prosthesis retention is provided by the friction between the primary crown (patients mouth) and secondary crowns (denture). However, a need for friction adjustments or even a loss of retention has often been described. As a result, patients can have problems handling these dentures. The Weigl protocol describes a manufacturing process for these dentures using an all-ceramic primary crown and an electroplated secondary crown, which helps to reduce changes in retention during the lifetime of the denture. The aim of this study is to verify the survival rates, complications and maintenance needs of DCRDs manufactured according to the Weigl protocol.

Who can participate?

Anyone who received DCRDs according to the Weigl protocol at the Department of Prosthodontics of the University of Frankfurt am Main, Germany between June 1998 and December 2013

What does the study involve?

There is no direct involvement of participants in this study, as their patient sheets are used for assessment of survival rates, complications and maintenance needs.

What are the benefits and risks of participating?
There are no direct benefits or risks of participating in this study as it does not require direct participant involvement. The results of this study may benefit future patients requiring DCRDs as it may improve success rates and reduce the number of complications.

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

When is the study starting and how long is it expected to run for?
January 2013 to June 2017

Who is funding the study?
Self-funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
177/13

Study information

Scientific Title

Long-term clinical success of conical electroplated double-crown-retained dentures on implants or natural abutments up to 11.5 years: a retrospective study

Study objectives
Dentures created with the conical electroplating concept is an alternative to other approaches, especially for combined tooth/implant-supported dentures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of University Frankfurt, 13/05/2013, reference 177/13

Study design
Observational retrospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Reduced dentition in upper and lower jaw

Interventions
For data collection, the sheets of patients who received double-crown-retained dentures (DCRDs) between June 1998 and December 2013 were evaluated for failure of DCRDs, necessary repairs, pressure source, occlusal adjustments, problems with denture removal, relining needs and maintenance needs related to the denture abutments.

Intervention Type
Procedure/Surgery

Primary outcome measure
Failure of DCRDs (defined as the loss of the denture), evaluated by reviewing patient notes

Secondary outcome measures

The following were evaluated by reviewing patient notes from patients between June 2013 and December 2013:
1. Necessary repairs to dentures
2. Pressure source
3. Occlusal adjustments
4. Problems with denture removal
5. Relining needs
6. Maintenance needs related to the denture abutments

Overall study start date
01/01/2013

Completion date
15/06/2017

Eligibility

Key inclusion criteria
1. Dentures fabricated according to the Weigl protocol
2. Regular ttendance of follow-up exams
3. Tooth-supported DCRDs
4. Implant-supported DCRDs
5. Combined tooth/implant-supported DCRDs
6. Conical implant/abutment connections
7. Aged 18-91 years

Participant type(s)
Patient

Age group
All

Lower age limit
18 Years

Upper age limit
91 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
Not treated according to the Weigl protocol

Date of first enrolment
15/06/2013

Date of final enrolment
15/12/2013

Locations

Countries of recruitment
Germany

Study participating centre
ZZMK (Carolinum) , Goethe University Frankfurt
Theodor-Stern-Kai 7
Frankfurtam Main
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Sponsor information

Organisation
Goethte University Frankfurt

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/04cvxnb49

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in Clinical Implant Dentistry and Related Research

Intention to publish date
10/11/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to data protection regulations

IPD sharing plan summary
Not expected to be made available