

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

<b>Submission date</b> 21/10/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/11/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/11/2019	<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

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?

Dr. Silvia Brandt

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## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Silvia Brandt

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**Contact details**

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60596

## 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 attendance 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

Germany

60596

## **Sponsor information**

**Organisation**

Goethte University Frankfurt

**Sponsor details**

Theodor-Stern-Kai 7

Frankfurt

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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