



Trial Description

Title

Accuracy of optical vs. conventional impression methods in partially edentulous patients

Trial Acronym

COIM PEJ

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of the study is the clinical evaluation of the feasibility and accuracy of computerized optical impression making in partially edentulous patients at the Department of Prosthetic Dentistry. Here, conventional and optical impressions of the upper and lower jaw will be evaluated regarding their compareability using 3D evaluation software. Further, the patients' satisfaction of both techniques will be captured with a specially designed questionnaire (patient reported outcome measures).

Brief Summary in Scientific Language

The aim of this in vivo study is the clinical evaluation of the feasibility and accuracy in terms of 3D measurements of computerized optical impression making in partially edentulous patients at the Department of Prosthetic Dentistry. Here, conventional (elastomers) and computerized optical impressions (3M True Definition, 3M ESPE) of the upper and lower jaw will be evaluated regarding their compareability using 3D evaluation software. Further, the patients' satisfaction of both techniques will be captured with a specially designed questionnaire (PROMs; patient reported outcome measures).

Organizational Data

- DRKS-ID: **DRKS00010029**
- Date of Registration in DRKS: **2016/02/17**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **343/15** , **Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs



Health condition or Problem studied

- Free text: **Partially edentulous patients**

Interventions/Observational Groups

- Arm 1: **Partially edentulous patient in need of an removable partial denture, will receive a conventional impression of the dentated and edentulous spaces using elastomeric materials.**
- Arm 2: **Partially edentulous patient in need of an removable partial denture, will receive a conventional impression of the dentated and edentulous spaces using a computerized optical intraoral scanner.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Other**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

The feasibility/accuracy of computerized optical impression making will be evaluated using 3D software after the conventional and computerized optical impressions.

Secondary Outcome

The patient satisfaction of the conventional and computerized impression methods will be evaluated using a specially design questionnaire.

Countries of recruitment



- **DE Germany**

Locations of Recruitment

- University Medical Center **Department für Zahn-, Mund- und Kieferheilkunde; Klinik für Zahnärztliche Prothetik, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2016/03/01**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- **Treatment at the Medical Center - University of Freiburg, Center for Dental Medicine, Department of Prosthetic Dentistry**
- **Partially edentulous patients receiving a prosthetic reconstruction in the upper and/or lower jaw with a varying number of abutment teeth (≥ 2)**

Exclusion criteria

Infectious diseases, pregnancy, nonage, missing informed consent

Addresses

- **Primary Sponsor**

**Universitätsklinikum Freiburg; Department für Zahn-, Mund- und Kieferheilkunde; Klinik für Zahnärztliche Prothetik
Hugstetter Strasse 55
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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.