Trial Description

Title
Template-guided implantation of dental titanium implants. Influence of the implant system on the accuracy. A prospective controlled clinical pilot study

Trial Acronym
[---]*

URL of the trial
[---]*

Brief Summary in Lay Language
In case of tooth loss, the replacement of the missing tooth or teeth with implant-supported dentures is a therapy option. In order to produce a functionally and aesthetically optimal replacement, the exact positioning of the implant is important.

For this purpose, the position can be virtually planned on the computer. The implant position determined there is transferred to the patient by means of a printed template. This study will determine the precision with which the transmission can take place. The deviation of the planned with the achieved implant position will be determined. The aim of the study is to investigate the template-guided implantation of two different titanium implant types and a sleeve-based drilling template.

Brief Summary in Scientific Language
The aim of the study is to investigate the template-guided implantation of a conical macro design type implant and to compare these results with a conical / cylindrical macro design.

The guided implantation of the implant bed and insertion of the implants are intended to achieve an optimal implant position with regard to the planned prosthetic restoration and optimal utilization of the existing bone supply.

In the study requested here, the influence of the implant type used is to be determined. In three previous and already completed examinations, the influence of the residual dentition, the number of remaining teeth and their localization and the accuracy of two different types of drill template (caseless vs. sleeve-based) were investigated.

In this section of the studies, the accuracy of implant placement relative to the previously virtually planned position is to be determined using another co-factor that may potentially affect accuracy.

Co-factor implant type
Here, 20 consecutive patients with a conical implant type and the planning software primarily recommended by the manufacturer should be examined
consecutively. 
Implant: Camlog Progressive Line (Camlog, Wimsheim Germany), Software: SMOP (Swissmeda, Zurich, Scheiz) 
There is already an investigation on the accuracy of a cylindroconical implant from the same manufacturer (Camlog, Conelog Guide). The implants were planned and set according to the same procedure. These values should then be used as a comparison group for this study population.

The null hypothesis is that there are no differences in the accuracy between the implant types.

Do you plan to share individual participant data with other researchers?
No

Description IPD sharing plan
[---]*

Organizational Data

- DRKS-ID: DRKS00018939
- Date of Registration in DRKS: 2019/11/11
- 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.: F2019-057-z, Ethik-Kommission bei der Landesärztekammer Baden-Württemberg

Secondary IDs

Health condition or Problem studied

- Free text: Tooth loss

Interventions/Observational Groups

- Arm 1: Replacement of a tooth with a dental implant. In this study, an newly on the market introduced implant system, will be examined for accuracy. A comparison to the older sysetem should be made on the basis of the researchs
already published by the author Team.

**Characteristics**

- **Study Type:** Interventional
- **Allocation:** Single arm study
- **Control:** Uncontrolled/Single arm
- **Purpose:** Treatment
- **Assignment:** Single (group)
- **Phase:** N/A
- **Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels):** No

**Primary Outcome**

Accuracy study of implant placement  
The study design and implementation of the clinical implementation and evaluation, including the statistical procedures, is based on three studies that have been carried out or are still in progress:

1. Retrospective study to determine the accuracy of template-guided implantation with a new non-X-ray-based matching method.  
   **Vote of the Ethics Commission Ulm No. 339/14 from 12.04.2014.**

   **Publication:**  


2. Randomized controlled clinical study on the success of implants Socket preservation compared to a control group.

   **Vote of the Ethics Committee Ulm No. 41/14 from 06.05.2014**

   **Publication:**  


Vote of the Ethics Commission Ulm No. 268/17 dated 24.08.2017


It is a monocentric prospective controlled clinical trial. Patients requiring implant-prosthetic restoration of a gap or and an open-end situation in the maxilla or mandible will participate in the study.

The main target variable is the deviation of the planned implant position from the actual position. The deviation is described by the distance at the crestal implant penetration point, at the apical implant end, at the height of the implant and in the axial deviation. The results obtained here are to be discussed in connection with the previously determined values from the previous investigations.

### Secondary Outcome

**Technical problems**

Implementation of the planning, indication restrictions, hold and functionality of the drilling template

### Countries of recruitment

- DE Germany

### Locations of Recruitment

- Doctor's Practice Hilzingen

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/02/20**
- Target Sample Size: **20**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
Gender: **Both, male and female**

Minimum Age: **18 Years**

Maximum Age: **no maximum age**

**Additional Inclusion Criteria**

- Switching gaps in the upper and / or lower jaw tooth area
- Free-end situations in the upper and / or lower jaw teeth
- Stencil must be toothed. For this purpose, more than 5 remaining teeth must be present in the jaw to be implanted.
- The patient has good oral hygiene and compliance.
- A pre-implantation hygienic phase must be completed.
- Patient’s consent given

**Exclusion criteria**

- Persons under 18 or non-legal persons
- Untreated acute periodontitis with pocket depths> 4 mm.
- Strong smokers (more than 10 cents./d)
- Intake of bisphosphonates
- Pregnant
- Alcohol or drug addicts
- Patients with an infectious disease such as hepatitis or HIV or AIDS
- Patients with severe diabetes m.
- Planned immediate implantations
- Planned immediate load

**Addresses**

- **Primary Sponsor**
  
  Private Praxis und Universitätsklinikum Ulm, Klinik für Zahnärztliche Prothetik
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- **Contact for Scientific Queries**
  
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Collaborator, Other Address

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Sources of Monetary or Material Support

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

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Private sponsorship (foundations, study societies, etc.)

Oral reconstruction foundation ORF(former Camlog Foundation)
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Switzerland

Telephone: [---]*
Fax: [---]*
E-mail: [---]*
URL: [---]*

Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2020/07/02

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.