Trial Description

Title

Prospective randomized controlled interventional study of chair-side generated monolithic single implant supra-structures made of lithium disilicate ceramic

Trial Acronym

Abutment Trial

URL of the trial

[---]*

Brief Summary in Lay Language

Single implants serve as artificial roots for single crown restorations. A conventional supra-structure consists of a so-called abutment, which serves as an artificial die for the retention of a crown. The standard material for posterior abutments is titanium which is screw retained to the implant. A simple alternative is a monolithic supra-structure made of lithium di-silicate ceramic, which is adhesively luted to a titanium basis. The latter ones only purpose is to serve for the screw retention to the implant. The lithium disilicate ceramic supra-structure is CAD/CAM (by the means of computer aided technology) processed. Instead of a conventional impression 3D optical impressions in the patient´ mouth are done. On the basis on that digital impression the supra-structure is designed virtually on the computer screen and according to the virtual design a monolithic restoration is then milled from a meta-silicate ceramic block. After crystallization a tooth-colored restoration is obtained. The restoration now is adhesively luted to the titanium basis. The aim of this study is to evaluate the long term performance of this material in a clinical trial.
The material is already commercially available on the market and already officially registered for this purpose. Due to the fact that it is monolithic there is no transition and color change in the gingival area, as it is the case of a conventional abutment/crown supra-structure.
In order to compare the conventional and the monolithic supra-structures it is decided by random which kind of restoration is inserted. If a patient receives two implants one implant gets the conventional supra-structure and the other one the monolithic one. If a patient receives one implant it is possible that he/she receives the conventional restoration.
Parameters to be evaluated are:
-Complexity of fabrication
-Patient´s satisfaction

Brief Summary in Scientific Language

Single implants serve as artificial roots for single crown restorations. A conventional supra-structure consists of a so-called abutment, which serves as an

artificial die for the retention of a crown. The standard material for posterior abutments is titanium which is screw retained to the implant. A simple alternative is a monolithic supra-structure made of lithium di-silicate ceramic, which is adhesively luted to a titanium basis. The latter ones only purpose is to serve for the screw retention to the implant. The lithium disilicate ceramic supra-structure is CAD/CAM processed. Instead of a conventional impression 3D optical impressions in the patient´ mouth are done. On the basis on that digital impression the supra-structure is designed virtually on the computer screen and according to the virtual design a monolithic restoration is then milled from a meta-silicate ceramic block. After crystallization a tooth-colored restoration is obtained. The restoration now is adhesively luted to the titanium basis. The aim of this study is to evaluate the long term performance of this material in a clinical trial. The material is already commercially available on the market and already officially registered for this purpose. Due to the fact that it is monolithic there is no transition and color change in the gingival area, as it is the case of a conventional abutment/crown supra-structure.
In order to compare the conventional and the monolithic supra-structures a prospective controlled clinical trial is conducted. If a patient receives two implants one implant gets the conventional supra-structure as a control and the other one the monolithic one. If a patient receives one implant matched pairs are generated and one patient receives the monolithic restoration the other patient the conventional one.
At least 25 patients should be restored with the monolithic restoration.
Parameters to be evaluated are:
-Complexity of fabrication
-Patient´s satisfaction

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00005452**
- Date of Registration in DRKS: **2013/11/19**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EK 211/13 , Ethik-Kommission an der Medizinischen Fakultät der RWTH Aachen**

Secondary IDs

Health condition or Problem studied

- Free text: **dental implant supra-structures as rehabilitation of missing single teeth**

Interventions/Observational Groups

- Arm 1: **monolithic single implant suprastructures made of lithium disilicate**
- Arm 2: **titanium abutment and crown made of lithium disilicate**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Survival rate and complication rate over a time period of at least 3 years. Examinations dates: Baseline, annual, clinical examinations: stability of screw retention implant - supra-structure, surface, colour, anatomy, gingiva index, plaque index, PES (Pink Esthetic Score)/WES (White Esthetic Score), periotest measurements, radiologic examinations: x-rays baseline, 12 month, 36 month. measurement of the sulcus fluid rate after one year, photos, intraoral 3D optical impressions

Secondary Outcome

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Zahnärztliche Prothetik , Aachen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/11/19**
- 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: **75 Years**

Additional Inclusion Criteria

signed consent, male and female patients >18 years, ASA Physical Status 1 or 2, indication for single implant(s) in the posterior region, abutment height </= 15 mm, antagonists: fixed prosthesis or natural dentition, pocket depth max. 4 mm, good oral hygiene, no treatment needs at adjacent or antagonist teeth, bone augmentation in implant site is no contra indication

Exclusion criteria

restoration height > 15 mm, the minimum thicknesses for the screw canal cannot be obtained, severe diseases like non successfully treated diabetes or hypertension, bisphosphonates, severe smokers, patients with psychological disorders, drug abuse, pregnant or breastfeeding patients, minor patients, patients who are mentally disabled and who are dependent on a legal guardian, patients who are accommodated in a health care institution due to mental disease

Addresses

- **Primary Sponsor**

  Ivoclar Vivadent AG
  Bendererstrasse 2

Primary Sponsor

Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
Liechtenstein

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

■ **Contact for Scientific Queries**

Lehr- und Forschungsgebiet Computergestützte Zahnmedizin in der Klinik für Zahnärztliche Prothetik und Biomaterialien, Zentrum für Implantologie (Direktor: Univ.-Prof. Dr. S. Wolfart)Uniklinik Aachen
Univ.-Prof. Dr. med. dent. Sven Reich
Pauwelsstrasse 30
52074 Aachen
Germany

Telephone: **0241 80 88 241**
Fax: **0241 80 82 410**
E-mail: **sreich at ukaachen.de**
URL: **[---]***

■ **Contact for Public Queries**

Lehr- und Forschungsgebiet Computergestützte Zahnmedizin in der Klinik für Zahnärztliche Prothetik und Biomaterialien, Zentrum für Implantologie (Direktor: Univ.-Prof. Dr. S. Wolfart)Uniklinik Aachen
Univ.-Prof. Dr. med. dent. Sven Reich
Pauwelsstrasse 30
52074 Aachen
Germany

Telephone: **0241 80 88 241**
Fax: **0241 80 82 410**
E-mail: **sreich at ukaachen.de**
URL: **[---]***

■ **Collaborator, Other Address**

CAMLOG Foundation
Margarethenstrasse 38
CH-4053 Basel
Switzerland

Collaborator, Other Address

CAMLOG Foundation
Margarethenstrasse 38
CH-4053 Basel
Switzerland

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

Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Ivoclar Vivadent AG
Bendererstrass 2
FL-9494 Schaan
Liechtenstein

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

- **Private sponsorship (foundations, study societies, etc.)**

Camlog Foundation
Margarethenstrasse 38
CH-4053 Basel
Switzerland

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

Status

- Recruitment Status: **Recruiting ongoing**
- 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.*