PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

A clinical study about a methylmethacrylatfree and light-curing denture-acrylic (versyo.com) in comparison with a conventional denture-acrylic based on polymethylmethacrylat (PMMA).

Trial Acronym

Prüfung Prothesenbasiswerkstoff

URL of the trial

[---]*

Brief Summary in Lay Language

On account of a possible incompatibility of denture-acrylics based on polymethylmethacrylat (PMMA) in some patients, a new one-component, light-curing denture-acrylic (Versyo.com) was developed. In comparison to PMMA-based denture-acrylic versyo.com was tested relating to tissue reaction, plaqueadhesion, technical parameters and patient satisfaction. These parameters were reviewed at 3 recalls with intervals of 6 months.

Brief Summary in Scientific Language

Very little clinical information is available about Versyo.com. Therefore the aim of the study was to evaluate the clinical long-term performance of versyo.com. The study was applied as a split-mouth model. 100 partial dentures were incorporated in patients for replacement of lost teeth. One denture saddle was made of versyo.com, while the other one was made of the denture-acrylic based on PMMA. If there was another mesial saddle, it was made of Versyo.com, but not evaluated. After finishing the therapy 3 recalls in intervals of 6 months were proceeded. One half of the patients got detailed caring demonstrations, the other half received caring brochures. The parameters tissue reaction, plaqueadhesion, technical parameters were evaluated in recalls and rated to a four-stage-scale. Patient satisfaction was ascertained by a questionaire. The denture saddles and the type of caring instructions were randomized.

Organizational Data

- DRKS-ID: **DRKS00000159**
- Date of Registration in DRKS: **2009/08/10**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

DRKS-ID: **DRKS00000159**
Date of Registration in DRKS: **2009/08/10**
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Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **65/01 , Ethik-Kommission des Fachbereichs Medizin der Justus-Liebig-Universität Gießen**

Secondary IDs

Health condition or Problem studied

- Free text: **provision with partial denture for replacement of lost teeth**

Interventions/Observational Groups

- Arm 1: **one saddle was made of PalaXpress**
- Arm 2: **the other saddle was made of Versyo.Com**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Double or multiple blind**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Prevention**
- Assignment: **Factorial**
- Phase: **[---]***
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Comparision of the two saddles regarding to plaqueadhesion following 6, 12 and 18 months

Secondary Outcome

additionally the two saddles were evaluated regarding to oral mucosa, technical condition of the denture`s underpart und uppersite and patients´satisfaction after 6, 12 and 18 months

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2001/07/30**
- Target Sample Size: **100**
- 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

-Patients with minimum age 18 years
- Patients, who get a new removeable partial denture
-Patients, who consent to the participation of the study
- Patients, who can keep the appointments for Recalls

Exclusion criteria

Patients, who:
-have known allergies of Palaxpress or Versyo.com
-addict drugs and/or alcohol
-have infectious disease

-have malignancy
-get radiotherapy
-are pregnant
-could not consent to the participation of the study
-can't keep the appointments for Recalls conceivable

Addresses

- **Primary Sponsor**

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  Fax: **+49 (0) 6181/35-35 50**
  E-mail: **[---]***
  URL: **[---]***

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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 complete, follow-up complete**
- Study Closing (LPLV): **2006/12/21**

Trial Publications, Results and other documents

- Paper **Gohlke-Wehrße (2011), Clin Oral Investig.**

** 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.*