

# Randomised controlled clinical trial on timing versus 3D-accuracy of fast-set impression materials

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 31/07/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 31/07/2008	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Ralph Luthardt

**Contact details**  
Center of Dentistry  
Department of Prosthetic Dentistry  
Albert-Einstein-Allee 11  
Ulm  
Germany  
89081

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
P-10199 CR 04/05

# Study information

## Scientific Title

Clinical trial of the influence of time on the three-dimensional accuracy of fast-set polyether and fast-set polyvinyl siloxane impression materials

## Acronym

Poly Q

## Study objectives

Clinical studies have shown a correlation between the fitting precision of fixed dental restorations and the clinical success or survival rate. Since dental impressions mainly determine the fitting precision of fixed restorations, they play an important role. So far, the working times of impression materials have only been evaluated in-vitro. In the clinical routine, deviations from the exact timing occur very often and are either caused by an early filling of the impression tray by the dental assistance or by a delay during syringing of the light-body impression material. The clinical relevance of the exact timing gains even more importance when fast-setting impression materials with shorter working times and setting times are used.

A non-optimal timing will have an influence on the three-dimensional precision of fast-set impressions materials. Due to the kinetics of their chemical reaction, polyethers may be of advantage compared to polyvinyl siloxane impression materials.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the Ethics Commission of the Medical Faculty Carl Gustav Carus of the Technical University Dresden on the 11th August 2004 (ref: EK 180092004)

## Study design

Pilot study and prospective, randomised clinical trial with triple-blind evaluation

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

Patient information material can be found at: [http://www.uniklinik-ulm.de/fileadmin/Kliniken/Zahnmedizin/ZMK2/SIMTOM/20040726\\_Patienteninfo\\_PolyQ\\_SQ.pdf](http://www.uniklinik-ulm.de/fileadmin/Kliniken/Zahnmedizin/ZMK2/SIMTOM/20040726_Patienteninfo_PolyQ_SQ.pdf) (in German)

## Health condition(s) or problem(s) studied

## Fitting precision of fixed dental restorations

### Interventions

The study gains information on the dependency between mixing timing of a one-stage putty-and-wash dental impression and three-dimensional precision of the resulting gypsum models under clinical conditions. Differences between two types of fast-set impression materials (polyether and polyvinyl siloxane) are to be analysed with a computer-aided procedure.

Three impressions were taken from the probands, after they had undergone a professional tooth cleaning, in randomised order. Either a polyether impression or a polyvinyl siloxane impression were taken under exact timing conditions and served as a reference. Two additional impressions were taken with non-optimal timing using the same impression material as for the respective reference impression. The two additional impressions were taken with two out of eight different non-optimal timings. The order in which the three impressions were taken as well as the material and the non-optimal timing were assigned to each proband according to a randomisation list. Standardised-made master-casts were digitised and the data resulting from the non-optimal timed impressions was compared to the reference. Probands were treated with fluoride gel afterwards in order to complete the benefit of the professional tooth cleaning.

### Intervention Type

Drug

### Phase

Not Specified

### Drug/device/biological/vaccine name(s)

Polyether, polyvinyl siloxane

### Primary outcome measure

The precision of the three-dimensional (3D) tooth surface reproduction and the reproduction of the subgingival tooth surface, measured within 24 hours after impression taking.

### Secondary outcome measures

1. Influence of environment temperature, measured in the impression session
2. Timing, measured in the impression session
3. Tray size, measured in the impression session
4. Accordance with subjective clinical impression rating, measured within four weeks after the impression session has taken place, throughout the study

### Overall study start date

01/08/2004

### Completion date

31/03/2006

## Eligibility

### Key inclusion criteria

Suitable probands were aged between 18 and 80 years, either sex, and showed a complete set of either healthy or restored teeth in the lower right quadrant up to the second molar.

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

8 for pilot study, 96 for main study

**Key exclusion criteria**

1. Alcohol or drug dependence
2. Persons with restricted legal capacity
3. Pregnant women
4. Probands who would face a conflict of interest due to the participation in another study
5. Patients with periodontal disease (periodontal screening index greater than 2)
6. Probands with missing teeth in the according quadrant (except for third molars and orthodontically closed spaces)
7. Probands excluded from the dental education course because of an infectious disease such as hepatitis or acquired immune deficiency syndrome (AIDS)

**Date of first enrolment**

01/08/2004

**Date of final enrolment**

31/03/2006

**Locations****Countries of recruitment**

Germany

**Study participating centre**

Center of Dentistry

Ulm

Germany

89081

**Sponsor information**

**Organisation**

3M ESPE AG (Germany)

**Sponsor details**

Dr Timo Kuretzky

Espe Platz

Seefeld

Germany

82229

+49 (0)8152 700 1376

timo.kuretzky@mmm.com

**Sponsor type**

Industry

**Website**

<http://www.3mespe.com>

**ROR**

<https://ror.org/047cnmy82>

**Funder(s)****Funder type**

Industry

**Funder Name**

M ESPE AG (Germany) (ref: P 10 244 CR 04/01.04.04)

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration