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

Submission date	Recruitment status	[ ] Prospectively registered
15/04/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/07/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
31/07/2008	Surgery	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 (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)

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Sponsor type
Industry

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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