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A study to determine if the process of warming composite resin restorative material prior to placement of a restoration leads to any changes in post operative sensitivity

Submission date
08/01/2013

Recruitment status
No longer recruiting

Registration date
19/03/2013

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A type of material called an amalgam used to be the filling material of choice for dental fillings on back teeth. Nowadays many patients want something that looks nicer and composite resin has become the material of choice. It provides improved aesthetics, reduced temperature conductivity and it is mercury free. It allows bonding to the tooth structure which reduces leakage. There are aspects of the properties of composite resin that could be improved: shrinkage when it sets, tooth more likely to be sensitive after filling, poorer wear resistance than amalgam, can be difficult to manipulate.
There are ways of improving these properties such as lowering the viscosity of the composite via preheating. This is a recognised technique and there are many in vitro studies which demonstrate improvements. There are however no scientific papers which compare the post operative sensitivity of a pre-warmed composite with a room temperature composite. This is the aim of this study.

Who can participate?
Patients who attend the General Dental Practice of Mr Iain Campbell in Scunthrope, Yorkshire, UK. The sdudy will aim to recruit two groups of 60 patients each.

What does the study involve?
Patients will be randomly allocated to one of two groups: treatment involving a a pre-warmed composite or a treatment involving a composite at room temperature.
When a patient has had a routine dental check-up and a one or two surface filling is required, the patient will be asked if they would like to take part in the study. The filling appointment will be made two weeks later. On average a one or two surface filling will take 30 to 40 minutes. At the filling appointment the patient will again be asked if they are happy to take part in the study and their consent form countersigned by the student investigator. The patient will have to fill in a pre treatment sensitivity test using an approach called a visual analogue scale (VAS). The patient will be given three more VAS sheets to fill in at home the day after, the week after and two

weeks after. The dental surgery assistant will also telephone the patient to remind them re the VAS forms and check that all is well. The patient will be asked to return a month later to check the filling (this appointment may coincide with further treatment) fill in a final VAS sheet and bring all their VAS sheets back.

What are the possible benefits and risks of participating?
There will be no direct benefit to patients but with the information obtained from the results may tell us if warming the dental material leads to reduced sensitivity following a dental filling. There will be no financial benefits and all normal fees will apply.

Where is the study run from?
The University of Leeds will oversee the research and the study will take place at the General Dental Practice of Mr Iain Campbell in Scunthrope, Yorkshire, UK.

When is the study starting and how long is it expected to run for?
It is anticipated the study will run from January to December 2013.

Who is funding the study?
The study is part of a Masters research project. The University of Leeds will provide resources for the research and the student investigator will provide clinical resources for the study.

Who is the main contact?
Dr T Paul Hyde
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

Version 6 30.07.2012

Study information

Scientific Title
A study to determine if the process of warming composite resin restorative material prior to placement of a restoration leads to any changes in post operative sensitivity: a parallel sided randomised controlled trial

Study objectives
The null hypothesis is that there is no difference in post-operative sensitivity between composite warmed to 39degreeC at placement and room temperature composite.
The alternative hypothesis is that there is a difference in post operative sensitivity between the room temperature and the warmed composite.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Leeds Dental Research Ethics Committee (DREC)

Study design
Parallel sided randomised controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Restorative dentistry

Interventions
The interventions are the routine placement of composite restorative material in a prepared tooth cavity (a dental filling). For the control this is with the filling material at room temperature (i.e. normal practice) and for the parallel experimental side of the trial it is with composite warmed to 39 degrees.

When a patient has had a routine dental check-up and a one or two surface filling is required the patient will be asked if they would like to take part in the study. The filling appointment will be made 2 weeks later, on average a one or two surface filling will take 30 to 40 minutes. At the filling appointment the patient will again be asked if they are happy to take part in the study and their consent form countersigned by the student investigator. A pre treatment sensitivity VAS scale will be scored by the patient. The patient will be given 3 more VAS sheets to take home to score the day after, the week after and 2 weeks after. Their permission will be sought for the dental surgery assistant of the student investigator to telephone the patient to remind them and check all is well. The patient will be asked to return a month later to check the filling (this appointment may coincide with further treatment) fill in a final VAS sheet and bring their VAS sheets back.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
VAS assessment 24 hours after treatment

Key secondary outcome(s))
VAS assessment 7 days, 14 days and 1 month after treatment

Completion date
08/08/2013

Eligibility

Key inclusion criteria
1. Patient is over 18
2. Patient is under 70
3. Either sex
3. Patient is capable of informed consent
4. The tooth responds to sensitivity testing (vitality test with an electric pulp tester)
5. The cavity to be restored is a one or two surface cavity
6. The cavity is suitable for composite restoration and the patient prefers composite to amalgam

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. The tooth does not respond to an electric pulp test
2. The patient is incapable of giving informed consent
3. The patient is a child under 18
4. The patient is unable to return the Visual Analogue Scale (VAS) assessment sheets at the appropriate time
5. The tooth to be filled is periodontally involved (grade 2 or grade 3 mobile)

6. The tooth to be filled is an abutment tooth for a removable prosthesis
7. The tooth to be filled has undergone orthodontic treatment within the last 3 months
8. The tooth to be filled has had periodontal surgery within the last 3 months

Date of first enrolment
08/01/2013

Date of final enrolment
08/08/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Restorative Dentistry
Leeds
United Kingdom
LS2 9LU

Sponsor information

Organisation
University of Leeds (UK)

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
University/education

Funder Name
University of Leeds (UK) - Master's program

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/12/2016	21/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes