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Postoperative sensitivity evaluation after placement of dental resin restoration when different types of adhesives are used

Submission date	Recruitment status	[_] Prospectively registered
27/01/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/02/2012	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/11/2017	Oral Health	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A dental restoration or filling is a treatment to restore missing parts of the tooth resulting for example from cavities. Postoperative sensitivity is an issue after adhesive restorations. The aim of this study is to assess short- and long-term postoperative sensitivity after dental restorations using six different adhesive treatments.

Who can participate?
Patients aged 18 to 50 with at least one large, deep cavity in the molars or premolars

What does the study involve?
Participants are randomly allocated to one of six different adhesive treatments. Sensitivity is assessed before treatment and after 48 hours, 7 days and 6 months.

What are the possible benefits and risks of participating?
All planned clinical procedures are regularly used in daily practice. Experienced operators were involved in all clinical steps. Therefore, the risks and benefits of participating in this study are those normally present in any clinical procedures. Patients who need further assistance are immediately directed to the corresponding sector in the Dental School.

Where is the study run from?
Federal University of Pará (Brazil)

When is the study starting and how long is it expected to run for?
January 2009 to August 2011

Who is funding the study?
1. National Council for Research Development (Science and Technology Ministry) (Brazil)
2. Federal University of Para (Brazil)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized, split-month clinical study comparing the short and long-term postoperative sensitivity in composite resin restoration using etch-and-rinse and self-etching adhesive systems placed in large and deep class I and II cavities in molars and pre-molars

Study objectives
Postoperative sensitivity may occur after adhesive restorative procedures. Several reasons could be related to this phenomenon, and the hydrophilic and permeable characteristics of some dental adhesives are one of them, which can be in part controlled by the operator. For instance, the use of a hydrophobic coat after the use the hydrophilic components of dental adhesives may help to control the postoperative discomfort.

This study aims to compare the short- and long-term postoperative sensitivity associated with resin restorations of large and deep cavities using the following process:
1. Etch-and-rinse followed by two and three step adhesives (XP Bond, Single Bond, SBMP and All

Bond 3+liner)
2. Mild two-step self-etching adhesives with a hydrophobic coat (All Bond SE+ Liner)
3. Strong two-step self-etching adhesive (Adper SE Plus)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Federal University of Pará (Brazil), July 2009, ref: 181/08 CEP-ICS-IFPA

Study design
Single-center randomised interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Professor Mário Honorato Silva e Souza Jr. (mario-honorato@hotmail.com) to request patient in formation sheet

Health condition(s) or problem(s) studied
Postoperative sensitivity

Interventions
Cavity preparation and restorative procedures: Class I and II cavities were prepared involving at least half of the distance between cusp tips and the pulpal or axial walls were determined 1 1.5 mm far from the pulp chamber. Cylindrical carbide burs, selected according to the size of each cavity, were used attached to high- and low-speed hand-pieces.

The adhesive treatments were randomly assigned among patients, tooth types (molars and premolars), and initial tooth condition (decayed or previously restored); the treatments were used according to the manufacturers directions. Two previously trained, graduated students prepared and restored the cavities. Eventually, 120 molars and premolars were prepared and restored (one by appointment) using rubber dam isolation and the incremental placement technique. For all six groups, the treated cavities were obliquely layered with A3 Filtek Z-350 nanoparticle composite resin (3M ESPE, St Paul, MN, USA). Each increment of 2 mm thickness was cured for 20 seconds using a LED source, Flash Lite 1410 (Discus Dental, Culver City, CA, USA) and its output energy constantly monitored (± 800mW/cm2).

Materials used in the study
Groups: Materials Manufacturer

1. Adper SBMP/3M ESPE - St Paul, MN, USA
2. Adper Single Bond 2/ 3M ESPE - St Paul, MN, USA
3. XP Bond / Dentsply - Milford - DE, USA
4. All Bond III Bisco Inc, Schaumburg, IL, USA
5. Adper SE Plus / 3M ESPE - St Paul, MN, USA
6. All Bond SE Bisco, Inc. Schaumburg, IL, USA

Pre and postoperative sensitivity evaluation (Initial-T0, 48 hours-T1, seven days-T2, 180 days-T3): This part of the study was conducted blind by one previously trained examiner who did not participate in the restorative procedures and was unable to detect the system used. The initial evaluation (T0) was done immediately before the cavity preparation. Tetrafluorethane spray (Endo-Ice Hygienic, Akron, OH, USA) was applied with a cotton pellet on the middle of the bucal surface for up to 5 seconds. During the tests, the patients were asked to register their discomfort using a visual analogue scale (VAS) according to the following parameters: 0, no discomfort; 1 to 3, light discomfort; 4 to 6, mild discomfort; 7 to 9, intense discomfort (pain); 10, unbearable discomfort (excruciating pain).

Intervention Type
Procedure/Surgery

Primary outcome measure
Non-parametric Kruskall-Wallis analysis was applied to the verified sensitivity results for all adhesive systems within each evaluation period (independent sample), including T0 (the preoperative evaluation), and no significant differences were detected. According to the p-values observed (p=0,53) at each evaluation period, no significant differences could be found.

Secondary outcome measures
Friedman non-parametric analysis was also applied to the results obtained for each adhesive system at all the evaluation periods (dependent sample), and the p-values (P>0.05) again showed no significant differences

Overall study start date
10/01/2009

Completion date
20/08/2011

Eligibility

Key inclusion criteria
1. 18 to 50 years and good health
2. The teeth to be restored had to present opposing and adjacent contacts and not exhibit primary or secondary trauma, excessive clenching, or bruxism
3. Low caries risk and good periodontal health were also necessary

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The final distribution of the sample was: 40 teeth restored in male and 80 in female; 24 in premolars and 96 in molars; 46 restorations were made in class I preparations, while 74 in class II

Key exclusion criteria
1. Continuous use of analgesic and anti-inflammatory drugs
2. Patients under orthodontic treatment
3. Using of total or partial removable prosthodontics

Date of first enrolment
10/01/2009

Date of final enrolment
20/08/2011

Locations

Countries of recruitment
Brazil

Study participating centre
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Sponsor information

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Federal University of Pará (Brazil)

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University/education

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ROR
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Funder(s)

Funder type
Government

Funder Name
National Council for Research Development (CNPq) - Science and Technology Ministry (Brazil)

Funder Name
Universidade Federal do Pará

Alternative Name(s)
Federal University of Pará, UFPA

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Brazil

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