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Randomized clinical trial of five adhesive systems in occlusal posterior restorations

Submission date
14/07/2014

Recruitment status
No longer recruiting

Registration date
08/08/2014

Overall study status
Completed

Last Edited
08/08/2014

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Direct adhesive restorations with composite resins (i.e. dental fillings where the dentist places a soft or malleable substance into the tooth and then shapes it before it sets hard) is the treatment of choice for cavities of posterior teeth (the pre-molars and molars found towards the back of the mouth). Nevertheless, the long-term durability of these fillings are hampered as the adhesive (or glue) holding the filling in place weakens over time. This can eventually lead to gaps forming between the filling and the tooth, tooth sensitivity, discolouration of the tooth, further cavities and, in the worse cases, inflammation of the pulp of the teeth. Evaluating the effects of the type of adhesive (adhesive system) used for fillings suffers from a lack of scientific evidence. Here, we aim to test five different adhesive systems as used for treating cavities in posterior teeth.

Who can participate?
Adults with good general and oral health needing restorations (fillings) in their molar or premolar teeth due to cavities

What does the study involve?
Each participant is randomly allocated into one of 5 different groups. Each group are given dental fillings using a different adhesive system. The performance of each of these adhesive systems are then evaluated over the course of a year, including how they look and how well they work.

What are the possible benefits and risks of participating?
The risks to participants are the same as for people treated for dental cavities in clinical practice.

Where is the study run from?
The Coimbra Medical University, School of Dentistry (Portugal)

When did the study start and how long is it expected to run for?
June 2011 to December 2017

Who is funding the study?
University of Coimbra (Portugal)

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 double-blinded controlled clinical trial comparing the behaviour of one three-step etch-and-rinse (Optibond™FL), one two-step etch-and-rinse (Prime&Bond®NT™) and three self-etch adhesives systems; one two-step (Clearfil™SE Bond), one one-step/two-bottle (Xeno®III) and one one-step/one bottle (Xeno®V+) in the restoration of occlusal posterior cavities based on the FDI evaluation criteria and focusing marginal adaptation as the primary outcome.

Study objectives
The null hypothesis (H0) tested was that no significant differences would be detected among the clinical behavior of the five adhesive systems in any of the recall periods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Central Hospital of University of Coimbra (Ethics Committee of the Centro Hospitalar e Universitário de Coimbra) (CHUC); ref: HUC 15-09

Study design
Single-center randomized interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Oral health

Interventions
Carious lesions removal was ensured with drilling and dentin spoon excavators. The restorative procedures were performed by one single operator. After application of the respective randomly assigned adhesive system under manufacturer´s directions a microhybrid composite resin (EsthetX® HD; A2) was placed incrementally and light-cured
using a LED-curing unit (Bluephase®) in its low intensity mode emitting around 650 mW/cm2.
Experimental groups:
1. Optibond® FL: Apply etchant for 15 s; rinse for 15 s; air-dry for 5 s; scrub surface for 15 s with primer; gentle air-blow for 5 s; apply bonding agent; gentle air-blow for 3 s; light-cure for 20 s.
2. Prime&Bond®NT™: Apply etchant for 15 s; rinse for 15 s; air-dry for 5 s; apply adhesive on surface and wait 20 s; gentle air-blow for 5 s; light-cure for 10 s; apply second coat; gentle air-blow for 5 s; light-cure for 10 s.
3. Clearfil™ SE Bond: Apply primer and leave undisturbed for 20 s; gentle air-blow for 5 s; apply bonding agent; gentle air-blow for 5 s; light-cure for 10 s.
4. Xeno® III: Mix liquids A and B for 5 s; apply adhesive on surface and leave undisturbed for 20 s; gentle air-blow for 5 s; light-cure for 10 s.
5. Xeno® V +: Apply adhesive on surface and scrub it in a rubbing motion for 20 s; gentle air-blow for 5 s; light-cure for 10 s.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The FDI evaluation criteria was applied in baseline, 6 months and one year.
Marginal adaptation was considered for the primary outcome
Score 1: Harmonious outline, no gaps
Score 2: Marginal gaps (<150 µm); small marginal fractures
Score 3: Marginal gaps (>150 µm and < 250 µm); several marginal fractures
Score 4: Marginal gaps > 250 µm or dentin/base exposed; severe marginal fractures
Score 5: Restoration lost but in situ; generalized major gaps

Secondary outcome measures
1. The FDI evaluation criteria was applied in baseline, 6 months and one year.
2. Esthetic Properties (surface lustre, marginal and surface staining, anatomical form),
3. Functional Properties (fracture of material and retention, radiographic examination),
4. Biological Properties (postoperative hypersensitivity and tooth vitality; recurrence of caries; tooth integrity; adjacent mucosa)

Overall study start date
24/06/2011

Completion date
24/12/2017

Eligibility

Key inclusion criteria
1. Agreement to participate in the study
2. In good general and oral health
3. Require class I restorations in their molar or premolar teeth due to primary carious lesions
4. In permanent dentition

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70 participants with carious occlusal lesions were initially selected. 159 restorations (at least 30 for research group) in 54 patients were obtained.

Key exclusion criteria
Patients with:
1. Systemic diseases, chronic use of anti-inflammatory, analgesic or psychotropic drugs
2. Xerostomy
3. Pregnancy or breastfeeding
4. Periodontal surgery within the previous three months
5. Orthodontic treatment within the previous three months

6. Uncontrolled periodontal disease
7. Bruxism
8. Allergies to specific compounds
9. Uncontrolled oral hygiene
10. Incapacity to undergo rubber dam isolation
11. Inability to attend recall appointments
12. Fewer than 20 teeth
Teeth with:
1. Endodontic therapy
2. Function of abutment for fixed or removable prostheses
3. Previous restorations
4. Absence of occlusal contacts with antagonist tooth
5. Fixed or removable prosthetic tooth as antagonist
6. Attrition, abfraction or erosion
7. Fissures or fractures
8. Signs of previous pulp pathology
9. Pathologic mobility
10. Enamel and/or dentin dysplasia
11. Cavities that requires cuspid coverage
12. Cavities involving pulp exposure

Date of first enrolment
24/06/2011

Date of final enrolment
24/12/2017

Locations

Countries of recruitment
Portugal

Study participating centre
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Sponsor information

Organisation
University of Coimbra (Portugal)

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Sponsor type
University/education

ROR
https://ror.org/04z8k9a98

Funder(s)

Funder type
University/education

Funder Name
University of Coimbra (Portugal)

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