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Clinical evaluation of new adhesives approach for dental restorations

Submission date 18/01/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 03/02/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 03/02/2012	**Condition category** Oral Health	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Current dentin adhesives present high hydrophilicity and are prone to water absorption that adversely affects the durability of resindentin bonds. The aim of this study is to assess the clinical behavior (durability) of composite resin restorations placed after the use of a less hydrophilic adhesive approach.

Who can participate?
Adult (male and female) individuals (18-65 years old) presenting at least 3 non-carious cervical lesions were recruited.

What does the study involve?
Placement of dental restorations by experienced operators and their evaluations for up to 5 years regarding the marginal adaptation/staining and retention.

What are the possible benefits and risks of participating?
The participants received dental restorations by experienced operators and the risks were the same of those regular clinical procedures. Defective restoration will be immediately replaced.

Where is the study run from?
The study has been developed in the clinical facilities of the Federal University of Pará /Brazil School of Dentistry.

When is the study starting and how long is it expected to run for?
The restorations were placed in June/August, 2011. According to the previously established evaluation periods, the study will go on until August, 2016.

Who is funding the study?
1. CNPq (National Council for Research Development), part of The Ministry of Science and Technology.
2. Federal University of Pará

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A randomized, split-month clinical study comparing the ethanol wet bonding technique to 3 step etch-and-rinse and 1-step self-etching approaches prior the application of a composite resin in non-carious class V lesions in adults patients focusing on marginal adaptation / staining and retention using modified Ryge criteria.

Study objectives
The actual adhesive systems have presented high hydrophilicity, which implies in a long-term compromised interface due to the normal characteristics of the oral environment. Less hydrophilic systems may show a more stable dental/restoration interface in oral conditions

Null hypothesis:
There are no differences in the clinical aspects evaluated among the three adhesives approaches

Ethics approval required
Old ethics approval format

Ethics approval(s)

Research Ethics Committee of the Federal University of Para (Brazil), 10 November 2010 ref: 0115.0.073.000-10. Report: 148/10

Study design
Single-center randomize interventional study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
No cavity preparation (drilling) was performed. The restoration procedures were executed by one operator. After the adhesive procedures the composite resin (Filtek Z-350/ 3M ESPE) was placed incrementally, 1mm each, which were photoactivated for 40 seconds using a LED source with 1.200 mW/cm2 output.

Experimental Groups:
1. SBMP - Scotchbond Multi Purpose (3M ESPE)
1.1. Enamel and dentin acid -etching (37% phosphoric acid)for 30 seconds, wash for 20 second and blot dry
1.2. Primer application (rubbing) for 20 seconds in dentin, gently air dry for 30 seconds
1.3. Adhesive application in enamel - dentin and photo activation for 10 seconds

Group EO - Easy One (3M ESPE)
1. Air-dry the dental surface
2. Application of the adhesive (rubbing) for 20 seconds in enamel and dentin, gently air-dry for 5 seconds and photo activation for 10 seconds.

Ethanol Wet Bonding
1. Enamel and dentin acid-etching (37% phosphoric acid) for 30 seconds, wash for 30 seconds and blot-dry
2. Application (rubbing) of 50 microliters of 50% ethanol in dentin for 10 seconds, left undisturbed for another 10 seconds.
3. Application (rubbing) of 50 microliters of 100% ethanol in dentin for 10 seconds, left undisturbed for another 10 seconds.
4. Application (rubbing) of hydrophobic primer (2mL of the SBMP adhesive + 10% in weight ethanol -100%) in dentin for 20 seconds, gently air-dry for 30 seconds
5. Application of the SBMP Adhesive in enamel and dentin and photo activation for 10 seconds.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The modified Ryge criteria will be applied to retention, after 6 mouths, 1, 2, 3 and 5 years
Retention
1. Restoration totally present
2. Restoration partially or totally lost

Key secondary outcome(s))
The modified Ryge criteria will be applied to marginal adaptation / staining, after 6 months, 1, 2, 3 and 5 years.

Marginal Staining Criteria
1. No staining
2. Superficial staining removed by polishing procedures
3. Deep staining

Marginal adaptation:
1. No gap
2. Minor gap but no dentin exposed
3. Major gap with dentin exposed

Completion date
10/12/2015

Eligibility

Key inclusion criteria
1. Good oral hygiene and periodontal conditions
2. Low caries-risk
3. Good occlusal stability and no significant bruxism or clenching
4. At least 3 (6,9,12...) supragengival non-carious class V lesions
5. Male and female participants
6. Aged 18 - 65 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Poor oral hygiene and periodontal conditions
2. High caries-risk
3. Evidence of bruxism and clenching causing visible bright wear areas
4. Use of partial removable prosthodontics
5. Complete dentures or orthodontic appliances

Date of first enrolment
10/12/2010

Date of final enrolment
10/12/2015

Locations

Countries of recruitment
Brazil

Study participating centre
Federal University of Para
Belém
Brazil
66000-000

Sponsor information

Organisation
Federal University of Pará (Brazil)

ROR
https://ror.org/03q9sr818

Funder(s)

Funder type
Government

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

Funder Name
Federal University of Para (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes