

# Clinical evaluation of new adhesives approach for dental restorations

<b>Submission date</b> 18/01/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/02/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/02/2012	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 resin-dentin 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?  
Professor Mário Honorato Silva e Souza Júnior.  
honorato@ufpa.br

**Study website**

<http://www.ufpa.br/posodonto> (under construction)

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Mário Souza

**Contact details**

Federal University of Para  
Avenida Augusto Correa  
Campus Universitário do Guamá  
Faculdade de Odontologia  
Belém  
Brazil  
66000-000  
+55 91 3229 7337  
honorato@ufpa.br

## 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 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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not currently 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**

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/cm<sup>2</sup> 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 measure

The modified Ryge criteria will be applied to retention, after 6 months, 1, 2, 3 and 5 years

Retention

1. Restoration totally present
2. Restoration partially or totally lost

## Secondary outcome measures

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

## Overall study start date

10/12/2010

## 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...) supragingival non-carious class V lesions

5. Male and female participants

6. Aged 18 - 65 years

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

100 - 120 teeth with non-carious class V lesions were initially selected. Eventually, 90 restorations (30 for each studied group) in 17 patients were obtained.

**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)

**Sponsor details**

Avenida Augusto Correa  
Campus Universitário do Guamá  
Faculdade de Odontologia  
Belém  
Brazil  
66000-000  
+55 91 3201 7563  
mestradodonto@ufpa.br

**Sponsor type**

University/education

**Website**

<http://www.portal.ufpa.br/>

**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****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