

# Seal or Varnish? A comparison of the cost and effectiveness of sealants and varnish in preventing dental decay

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<b>Registration date</b> 21/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
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## Plain English summary of protocol

### Background and study aims

Tooth decay (caries) can be prevented by applying pit and fissure sealants to the biting surface of the tooth. This treatment consists of a plastic coating that covers the rough biting surface which harbours decay-causing bacteria. Applying fluoride varnish every six months can also prevent tooth decay. This works by strengthening the tooth enamel, making it more resistant to decay. What is not known is which of these two modes of treatment works best and which is the most cost-effective. It is also not known which of these treatments is the most acceptable from the perspective of children and their parents. Applying fissure sealant requires a complicated dental intervention, while varnish application simply involves painting the tooth surface. This study will examine the relative clinical and cost effectiveness of these treatments and investigate their acceptability to children and their parents.

### Who can participate?

Year 2 children (aged 6 - 7) attending the schools participating in the current Cardiff and Vale University Health Board Fissure Sealant Programme

### What does the study involve?

Participants are randomly allocated to receive either fissure sealants on their first permanent molars or fluoride varnish. The number of children in each group who have tooth decay in their first molar teeth are compared after three years, along with the cost effectiveness and patient acceptability of the treatments.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

Cardiff University Dental School (UK)

### When is the study starting and how long is it expected to run for?

June 2011 to December 2014

Who is funding the study?  
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?  
Prof. Ivor Chestnutt

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Ivor Chestnutt

**Contact details**  
Professor and Hon Consultant in Dental Public Health  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2010-023476-23

**Protocol serial number**  
HTA 08/104/04; SPON766-09

## Study information

**Scientific Title**  
A randomised trial to determine the relative cost and effectiveness of pit and fissure sealants and fluoride varnish in preventing dental decay

**Acronym**  
Seal or Varnish?

**Study objectives**  
Pit and fissure sealants (PFS) and fluoride varnish (FV) are established technologies for the prevention of dental caries. However to date there is insufficient evidence to determine if there is a difference between the effectiveness of PFS and FV. Importantly from the perspective of the NHS, there is insufficient evidence on which to make recommendations for clinical practice and which (PFS or FV) represents the most cost effective technology.

The proposed clinical trial will address the following question: "What is the relative cost and effectiveness of pit and fissure sealants and fluoride varnish in preventing dental decay in the first permanent molar teeth of children?"

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Pending at time of registration

**Study design**

Prospective two-arm randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Dental caries

**Interventions**

Participants will be randomly allocated to receive either of the following investigational medicinal products (IMPs). Participants will be treated within two weeks of being randomised.

**1. Pit and Fissure Sealant (PFS):**

Eligible study participants randomised to receive PFS will have PFS on all erupted and sound first permanent molars (FPM) at baseline. These will be applied by a dental hygienist according to conventional clinical protocol. These participants will be re-examined by the hygienist at six-monthly intervals and sealant retention checked and reapplied/topped up if deficient.

**2. Fluoride Varnish (FV):**

Eligible study participants randomised to receive FV (22,600 ppm F) will have FV applied to all partially erupted, erupted and sound FPMs at baseline. These will be applied by a dental hygienist according to a conventional clinical protocol. These participants will be re-examined by the hygienist at six-monthly intervals and FV reapplied to all FPMs.

The proposed duration for both PFS and FV treatment is three years. The proposed frequency and duration of follow up is 3 years post-baseline assessment. Sealant check and varnish application will take place at six-monthly intervals and clinical examinations (recording of caries status) will take place yearly (month 12, 24 and 36) post-treatment.

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

1. Development of dental caries on the occlusal surface of first permanent molars at 36 months
2. Cost-effectiveness outcome measure: costs will be determined for the health service following discussions with key relevant dental and finance staff where time taken for treatments, clinic and staff involvement, materials and equipment used will be logged and costed (using published unit costs) to determine costs of treatment for each technology. The costs for children and their families will be determined by an analysis of questionnaires completed during the treatment phase. The costs to participating schools will be derived via questions in the semi-structured interviews conducted with staff from participating schools. In

terms of outcomes the indicators of effect for clinical effectiveness will be used along with costs to estimate the relative cost-effectiveness of the two approaches. In addition, utility values will be measured as Quality Adjusted Tooth Years (QATYs), which is the production of additional years of life (tooth-year) of each tooth adjusted for the quality of the tooth. An unrestored tooth has a QATY equal to 1 in the year that it was restoration-free, while a restored, crowned, or root canal treated tooth has a QATY less than perfect (i.e., less than 1) in the year that it was restored and subsequent years. The QATY for an extracted tooth is equal to 0 in that year and subsequent years.

3. Health related quality of life scores will be calculated at entry, 12 months, 24 months and 36 months. These scores will be mapped onto utility scores to generate QALYs.

### **Key secondary outcome(s)**

1. Patient acceptability, measured using a modified version of the Delighted-Terrible Faces Scale. This will be triangulated via a series of semi-structured interviews with parents/school staff/clinical personnel on treatment acceptability

2. During the clinical placement of the technologies under investigation, we will record the following indicators of patient acceptability/adverse outcomes:

2.1. Vomiting

2.2. Crying

2.3. Gagging

2.4. Excessive arm/leg movements

2.5. Other signs of distress

### **Completion date**

21/12/2015

## **Eligibility**

### **Key inclusion criteria**

1. Year 2 children (aged 6 - 7 years) attending the schools participating in the current Cardiff and Vale University Health Board Fissure Sealant Programme

2. Children with at least one-fully erupted caries-free first permanent molar

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

6 years

### **Upper age limit**

7 years

### **Sex**

All

## **Key exclusion criteria**

Applied at screening:

1. Children whose parents refuse consent
2. Children who at the time of the clinical examination or PFS/FV placement refuse assent
3. Children whose medical history precludes inclusion (i.e., those with a history of hospitalisation for asthma, or severe allergies, or allergy to Elastoplast)
4. Children with ulcerative gingivitis or stomatitis
5. Children with any facial or oral infections, e.g., cold sores
6. Children with known sensitivity to colophony (kolophonium), or any of the product ingredients (e.g. methylacrylate in PFS)
7. children with any abnormality of the lips, face or soft tissues of the mouth considered by the investigator to preclude acceptable application of either PFS or FV
8. Children who are showing obvious signs of systemic illness (e.g. colds, 'flu, chicken pox, etc.,) should also be excluded on that day

Applied at baseline examination:

9. Children without at least one fully-erupted caries-free first permanent molar

## **Date of first enrolment**

01/06/2011

## **Date of final enrolment**

31/12/2014

## **Locations**

### **Countries of recruitment**

United Kingdom

Wales

### **Study participating centre**

Cardiff University Dental School

Cardiff

United Kingdom

CF14 4XY

## **Sponsor information**

### **Organisation**

Cardiff University (UK)

### **ROR**

<https://ror.org/03kk7td41>

# Funder(s)

## Funder type

Government

## Funder Name

Health Technology Assessment Programme

## Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2017		Yes	No
<a href="#">Results article</a>	results	01/07/2017		Yes	No
<a href="#">Protocol article</a>	protocol	20/11/2012		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes