

# Seal or Varnish? A randomised controlled trial to determine the relative cost and effectiveness of pit and fissure sealant and fluoride varnish in preventing dental decay

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## Scientific summary

### **A RCT of the cost and effectiveness of sealant and varnish**

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# Scientific summary

## Background

Dental caries (tooth decay) is among the most common diseases to affect humankind and correlates closely with social and economic deprivation. Within the mouth, teeth differ in their susceptibility to dental decay. This largely reflects the fact that dental plaque (oral biofilm) is more likely to form in specific areas. One such area is the occlusal (or biting) surface of first permanent molar (FPM) teeth. These teeth erupt at the age of 6 or 7 years and are particularly prone to decay shortly after they erupt. There are two preventative dental technologies that have the potential to be targeted specifically at the occlusal surfaces of FPMs: pit and fissure sealant (FS) and fluoride varnish (FV). These treatments have been used for several decades and have been shown to be effective in preventing dental caries when tested against no-treatment controls. However, it is not clear which treatment is the more clinically effective and cost-effective. An answer to this question would help NHS dental services to plan for more effective and efficient planning of preventative dental care.

## Objectives

### Primary objective

The primary objective of this study was to compare the clinical effectiveness of FS and FV in preventing dental caries in FPMs in children aged 6 and 7 years, as determined by the:

- proportion of children developing new caries on any one of up to four treated FPMs
- number of treated FPM teeth caries free at 36 months.

### Secondary objectives

The secondary objectives of this study were to:

- establish the costs and budget impact of FS and FV delivered in a community/school setting and the relative cost-effectiveness of these technologies
- examine the impact of FS and FV on children and their parents/carers in terms of quality of life and treatment acceptability
- examine the implementation of treatment in a community setting with respect to the experience of children, parents, schools and clinicians.

## Study design

A randomised controlled, assessor-blinded clinical trial with two parallel arms.

### Setting

A Community Dental Service-targeted population programme delivered in mobile dental clinics (MDCs) in primary schools located in areas of high social and economic deprivation in South Wales.

## Participants

### Inclusion criteria

Children were eligible for inclusion if:

- they were aged 6 or 7 years and attended the schools participating in the current Cardiff and Vale University Health Board Designed to Smile programme
- the person with parental responsibility had provided written informed consent
- they had at least one fully erupted FPM free of caries into dentine.

### Exclusion criteria

Children were ineligible for inclusion if:

- their medical history precluded inclusion [i.e. they had a history of hospitalisation for asthma, severe allergies or allergy to Elastoplast (Beiersdorf AG, Hamburg, Germany), which was determined from a medical history form (MHF) that was completed by parents]
- they had a known sensitivity to colophony, or any of the product ingredients (e.g. methylacrylate in FS, determined from a MHF that was completed by parents)
- they had any abnormality of the lips, face or soft tissues of the mouth that would cause discomfort in the provision of FS/FV
- they were currently participating in another clinical trial involving an investigational medicinal product (determined from a MHF that was completed by parents)
- they showed obvious signs of systemic illness (e.g. colds, influenza, chickenpox) (determined at baseline examination).

## Methods

### Treatments

Eligible participants was randomised to receive either FS or FV and remained on the intervention to which they were randomised for the duration of the study.

Resin-based FS was applied at baseline to included FPMs, including part-erupted upper teeth. Sealants were checked at 6-month intervals and deficiencies were repaired. FV was applied, using a standard clinical protocol, to all eligible FPMs at baseline and at 6, 12, 18, 24 and 30 months.

### Clinical dental examination

Study participants were examined supine in the MDC, under a standard overhead dental clinical light, using a plane dental mirror and ball-ended probe at baseline and at 12, 24 and 36 months. Dental caries was recorded by trained and calibrated examiners, who were blinded to treatment allocation. Teeth were not dried prior to clinical dental examination. Gross debris was removed using a toothbrush.

### Health economics

The costs associated with the interventions for each trial participant were collected and summarised into the following categories.

- Implementation costs of the interventions.
- Health-care utilisation costs associated with travel or caregiving/time off work for families.
- Costs associated with the schools (e.g. as a result of child absence). Published unit costs were used or, when these were unavailable, local financial records were used to value resources in monetary terms using 2015 as the price year.
- Utility data were captured using the Child Health Utility Index 9D, and quality-adjusted life-years (QALYs) and quality-adjusted tooth-years were calculated. A budget impact analysis was undertaken.

### **Treatment acceptability assessment and process evaluation**

Treatment acceptability was assessed in three ways: (1) acceptability scales were completed by clinical staff, (2) acceptability scales were completed by children participating in the trial and (3) qualitative interviews were conducted with a subsample of children, their parents, school staff and clinical staff.

The acceptability of delivering this type of preventative intervention via a mobile dental unit in a school setting was also investigated through questionnaires and interviews with children, parents, school staff and clinical staff.

### **Statistical issues**

All comparative analyses were carried out on an intention-to-treat basis (without imputation). The primary outcome (decayed, missing, filled teeth in permanent dentition, i.e.  $D_{4-6}$ MFT) was analysed using a logistic regression model to compare arms. The results for binary outcomes are presented as unadjusted and adjusted odds ratios (ORs) for the FV arm compared with the FS arm (the reference arm). All models were adjusted for the randomisation balancing variables, sex and baseline caries in the primary dentition.

### **Sample size**

Based on existing local epidemiological data, for an individually randomised trial at a power of 80% with a significance level of 5%, at least 313 children per group were required for a comparison of caries incidence of 20% versus 30% at the 36-month follow-up.

## **Results**

A total of 1016 children were randomised 1 : 1 to participate in the trial. Arms were well balanced for all key characteristics at baseline. At 36 months, 835 (82%) children underwent a final clinical examination, on which the following results are based. The number completing the FS arm was 418 and the number completing the FV arm was 417. The most common reason for not completing the trial was moving away from the area or moving to a school that was not participating in the trial, which was reported as lost to follow-up. The number of children who withdrew from the trial was five in the FS arm and seven in the FV arm.

### **Clinical outcome**

#### **Proportion of children developing caries into dentine**

The proportion of children who developed dentine caries ( $D_{4-6}$ MFT) on at least one FPM at 36 months was broadly similar in both the FS (19.6%) and FV (17.5%) arms.

The OR of developing caries in the FV arm (compared within the FS arm) was 0.87 [95% confidence interval (CI) 0.61 to 1.23] in the unadjusted model, that is, children who received FV were slightly less likely to develop caries than those who received FS, but this difference was not statistically significant.

As sex and baseline caries prevalence were used to balance the randomisation, an adjusted model was also performed and was taken as the primary analysis. The OR for developing caries in the FV arm was 0.84 (95% CI 0.59 to 1.21) in the adjusted model.

To determine the impact of potential confounding factors, a covariate analysis of the primary outcome was undertaken from two perspectives: one at child level and one at school level.

Numbers for the child-level covariate analyses were substantially lower than for the primary outcome because of questionnaire non-response. The only covariates that were significantly associated with outcome were frequency of tooth brushing (OR 0.36, 95% CI 0.21 to 0.60) and toothpaste type (OR 0.45, 95% CI 0.27 to 0.75). Those brushing twice a day or more often were less likely to develop caries on their FPMs than those brushing once a day or less often. Those using children's or other toothpaste were less likely to develop caries on their FPMs at 36 months. None of the covariates altered the main effect for arm.

### Proportion of first permanent molar teeth developing caries into dentine ( $D_{4-6}$ MFT)

In both the FS and FV arms of the trial, 7.5% of all teeth developed caries into dentine, required a restoration or were extracted. A multilevel model adjusted for the number of decayed primary teeth at baseline and sex confirmed that the difference between children receiving FS and those receiving FV was not statistically significant (OR 0.97, 95% CI 0.73 to 1.28;  $p = 0.83$ ).

### Number of first permanent molar tooth surfaces developing caries into dentine ( $D_{4-6}$ MFT)

Ordinal regression modelling was undertaken on the number of FPM surfaces developing caries in each child. Those children in whom between 5 and 20 surfaces were affected were combined into one group because of the small number of children in these categories. There was no statistically significant difference between those receiving FS and those receiving FV, the model having been adjusted to account for the number of surfaces with caries per child, the number of decayed primary teeth at baseline and sex (OR 0.85, 95% CI 0.59 to 1.21;  $p = 0.363$ ).

### Occlusal versus non-occlusal surfaces

Overall, the proportion of occlusal surfaces that had developed caries into dentine at 36 months was significantly greater than the proportion of smooth surfaces developing caries (6.4% vs. 1.1%). It is clear that the proportion of occlusal surfaces affected by dentine caries was remarkably similar in the FS and FV arms of the trial, at 6.5% and 6.3%, respectively. The difference between intervention arms in the proportion of smooth surfaces of FPMs developing caries observed at 36 months was also minimal (1.0% vs. 1.3%). No significant difference was observed between trial arms for the main effect or for the interaction of arm with surface type, indicating no differential effect of treatment on occlusal and non-occlusal surfaces (OR 1.25, 95% CI 0.89 to 1.77).

### Fidelity

Trial fidelity was high: 95% of participants were treated at five or six of the six treatment visits. Overall, 71.6% of treatments were within the treatment window throughout the trial, and a further 26.1% were outside the schedule on only one occasion.

### Health economics

The main findings of the health economic analysis were as follows.

- It is feasible to undertake a comprehensive health economic evaluation alongside a randomised controlled trial of preventative health technologies within the context of a MDC setting.
- The intervention costs of the two technologies were £74.12 for FS and £64.16 for FV per child over the course of the trial.
- The costs of the two technologies showed a small but statistically significant difference; the mean cost to the NHS (including intervention costs) per child was £500 for FS, compared with £432 for FV, a difference of £68.13 (95% CI £5.63 to £130.63;  $p = 0.033$ ) in favour of FV.
- When a partial societal perspective was included (with intervention costs), the costs were £529 for FS and £457 for FV, with a mean difference of £71.96 (95% CI £7.21 to £136.71;  $p = 0.029$ ) in favour of FV.
- The budget impact analysis at 3 years showed that FV resulted in a cost saving of £68.13 (95% CI £5.63 to £130.63;  $p = 0.033$ ) compared with FS. In addition, when three different scenarios were examined, the results did not change and FV remained dominant.
- Owing to the non-significant numerical differences in outcomes, the incremental cost-effectiveness ratio (ICER) was very sensitive to very small numerical differences in outcomes. All outcomes showed a non-statistically significant difference or no clinically important differences between FS and FV and, thus, the ICER calculation should be treated with appropriate caution. However, results remained consistent across all three outcomes used in the health economic analysis, that is, FV was less costly than FS, with similar outcomes achieved.

- The cost-effectiveness acceptability curves (CEACs) showed that there was a 70% probability of FV cost-effectiveness at a societal willingness-to-pay (WTP) threshold of £20,000 per QALY.
- The model-based analysis to estimate the incremental cost per QALY over longer-term horizons showed consistent results with the results of the within-trial analysis, with fewer costs and small QALY gains achieved, which made FV dominant in the ICER calculation. The CEACs showed that there was a 99% and 96% probability of FV being cost-effective within a societal WTP threshold of £20,000 per QALY. However, there are a number of uncertainties in the model, particularly the dearth of evidence on longer-term costs and outcomes associated with FV and FS in a preventative dental health context.

### Acceptability of fissure sealant and fluoride varnish treatments

An important element of the clinical trial was the determination of the acceptability of FS and FV treatments. An acceptability score (called the Delighted–Terrible Faces scale), which was completed by the children immediately post treatment and in subsequent interviews with children and parents, demonstrated that both interventions are acceptable to children.

At baseline, the children in the FV arm were significantly more likely than those in the FS arm to report being happy (OR 0.38, CI 0.29 to 0.50;  $p < 0.001$ ), with this situation being reversed at the final treatment at 30 months (OR 3.63, 95% CI 2.60 to 5.05;  $p < 0.001$ ). In the course of the trial, those receiving FS became happier as the trial progressed; in contrast, in the FV arm there was a modest decrease in the number of children who chose a happy face.

Perceptions of undergoing treatment were influenced by aspects of treatment (especially taste) but also wider factors associated with a child-friendly MDC. Ultimately, the high number of children completing the trial can be taken as evidence of the acceptability of these interventions delivered in this setting. Acceptability to parents and school staff was also high.

### Adverse effects

No adverse effects were reported as a result of the treatments provided.

## Conclusions

The findings of this trial demonstrate that, in community oral health programmes targeted at children who are at high risk of caries, the application of FV as a caries-preventative measure will result in caries prevention that is not significantly different from that achieved by applying and maintaining FS for 36 months. There is a cost saving of £68.13 per child treated, using FV compared with the application of FS over this time period. Both treatments are acceptable to children aged 6–10 years, and acceptability to parents and to schools was also high.

### Trial registration

This trial is registered as EudraCT number 2010-023476-23, ISRCTN17029222 and UKCRN reference 9273.

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