

# Nano Silver Fluoride for preventing caries

## Abstracted from

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A new "silver-bullet" to treat caries in children--nano silver fluoride: a randomised clinical trial.

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## Question: Is Nano Silver Fluoride (NSF) effective for preventing and arresting active caries in children?

**Design** Randomised controlled trial, double blind, in a community setting.

**Intervention** School children with active caries in primary teeth and no pulpal exposure, fistula or decay in permanent teeth were chosen. Caries and unsupported enamel were left as found and cotton wool rolls were used for isolation. Two drops of NSF or one drop of water were applied to the tooth with a microbrush for two minutes, once in a 12-month period.

**Outcome measure** At one week, five months and 12 months the presence of active caries, as classified using International Caries Detection and Assessment System (ICDAS II) criteria, was measured. If a blunt probe easily penetrated dentine with light force, active caries was recorded and taken to be a failure.

**Results** One hundred and thirty primary teeth in 60 children with a mean age of 6.31 ( $\pm$  0.60) were randomised. Sixty-three teeth were in the NSF group and 67 in the control group. After one week there were no losses, at the five-month follow up eight teeth were lost from the NSF group due to exfoliation or extraction and five from the control group. At twelve months a further five teeth were lost from the NSF group and 13 from the control group.

At the one week follow up there was a 19% failure rate in the NSF group compared to 100% in the control group. At the five month recall this was 27.3% NSF compared to 72.6% water and at the final recall there was a 33.3% NSF failure rate and 65.3% control failure rate. The preventative fraction at this point was 50% and the NNT 3.12. All were statistically significant results ( $p < 0.05$ ).

**Conclusions** The annual application of NSF solution was more effective in hardening and arresting dentine caries in primary teeth than the placebo. The effectiveness of NSF was found to be similar to silver diamine fluoride when applied once a year, but did not stain the dental tissue black and had no metallic taste. The application is simple, does not require a clinical setting and is inexpensive. NSF was demonstrated to be effective in arresting caries in children in poor communities, but further studies are required to investigate alternative protocols and for use in tooth sensitivity and root caries.

## Commentary

Dental caries is a prevalent condition affecting children in particular. Recent reductions in disease levels have been observed, but the issue still poses a large burden of disease and financial cost to the nation. Preventive treatment is required to reduce pain, suffering, loss of functional dentition and treatment cost and for these reasons should be a priority for dental services.

For many years fluoride preparations have been known to prevent dental decay, and several high strength topical preparations are available for this purpose. The most commonly used in the United Kingdom is fluoride varnish, a 22,600ppmF<sup>-</sup> preparation applied at least twice yearly to help prevent decay.<sup>1</sup> A recent Cochrane review indicated that following treatment with fluoride varnish the prevented fraction for primary teeth was 37% (95% CI; 24% to 51%) and 43% (95% CI; 30% to 57%) for permanent teeth.<sup>2</sup> Despite its efficacy, fluoride varnish is expensive, technique sensitive and requires multiple applications per year; therefore alternative preparations that provide further benefits may be of interest.

Several silver based fluoride preparations are in development and are showing promising results, of these Silver Diamine Fluoride (SDF) is the most widely tested and seems to provide good caries protection with a once yearly application at low cost. It is not without its downfalls however. When caries lesions arrest under SDF they create a dark stain which is unsightly.<sup>3</sup> An alternative silver based preparation, Nano-Silver Fluoride (NSF), has been developed to combat this problem and is tested in the paper reviewed here.

The authors of this paper aimed to show that NSF was effective at arresting caries in children following a once yearly application. They did this by designing a randomised control trial which tested the efficacy of this preparation against a control (water). The approach to answering the primary research question was methodical and thorough with many key points from a RCT covered, this included accounting for cases lost to follow-up and sample size calculation.

Attempts were made to blind all participants to the treatment and randomise children to treatment arms. The explanation of the process of randomisation in the paper is vague and confusing. It was unclear if the randomisation was based on the teeth or patient level and how the sealed envelopes they describe were used to aid this process. Blinding was achieved for some participants in the study; patients, their parents and the final examiner were all effectively blinded for the trial. The dentist administering the treatment however would not be blind to treatment as the treatments were different. A greater volume of NSF was used compared to water (two

drops against one drop), and the NSF is described as having a 'red-dish' colour, therefore it would be apparent to an operator that it was different from the control, water. There is no mention of any difference in taste or smell between the NSF and water but this could be another factor in blinding. Losses were well documented but not explained in any detail. Knowledge of whether losses were exfoliated or extracted would have been relevant.

These differences in the control and intervention create some bias in the findings as we do not know how this might have affected the operator or their actions. Further confounding was introduced when all children were given oral hygiene instruction and tooth brushing packs, which included fluoride toothpaste, at the same time as the teeth were treated. Toothbrushing may contribute to the arrest of carious lesions and therefore the effect of the treatment may be overstated in this paper.

The authors provide results for arrested lesions at seven days, five months and one year. The most important of these are the one year results as it is intended to be a once yearly application. At this time point 66.7% of lesions were arrested compared to 34.7% in the control group; a preventive fraction of 50% and number needed to treat of 3.12.

The authors also provide logistic regression models to account for differences between the groups, however no significant additional information is discovered from this.

This is a good preliminary study of a new dental preparation but the use of a control (water) that is known to have no anti-cariogenic effect does raise ethical issues. For although all children participating in the trial were supplied with fluoridated toothpaste, it would have been interesting to have compared the NSF against another topical fluoride preparation.

In conclusion, despite some ethical and methodological concerns, this study appears to show that NSF may provide some benefit when considering prevention of caries, especially in deprived communities or non-clinical settings, due to its cost, preparation and application methods. There are some lingering concerns as the authors do not suggest adequate safety information regarding this preparation or the potential toxicity levels for children, but it provides a basis for future research.

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