A clinical assessment of the efficacy of a Stannous - containing Sodium Fluoride Dentifrice on Dental Hypersensitivity

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Aim: To measure the desensitizing benefits of an experimental stannous-containing sodium fluoride dentifrice versus a regular sodium fluoride negative control.

Methods and Materials: This study was a randomized, double-blind, parallel group, four-week clinical trial. Key teeth with dentinal hypersensitivity were enrolled and randomized to the experimental dentifrice or the control dentifrice to use twice daily for four weeks.

Efficacy assessments (Air Blast) were performed at baseline and weeks two and four. Separate analyses were performed for the two most sensitive teeth at baseline and for all 12 teeth. Results for weeks two and four combined also were analyzed.

Results: Thirty-one subjects were included in the analyses. For the two most sensitive teeth, the experimental dentifrice showed statistically significantly less sensitivity (p<0.05) versus the control at sodium fluoride negative control. For all 12 teeth, the experimental group had statistically significantly (p<0.05) lower sensitivity scores versus the control group at weeks two and four combined. The sensitivity reduction ranged from 24.9% to 83.9%.

Conclusion: The experimental dentifrice demonstrated significant desensitizing advantages versus the control.

Clinical Significance: This stannous-containing sodium fluoride dentifrice provides an effective treatment for patients with dental hypersensitivity significantly reducing sensitivity versus a negative control in this four-week clinical trial. Key teeth: Stannous, dentifrice, sodium fluoride, sensitivity, clinical trial.

Introduction

Dental hypersensitivity is a highly prevalent condition reported to affect from 4% to 57% of the population.1,2 The causes of sensitivity are well characterized as exposed dentinal tubules most commonly resulting from gingival recession followed by loss of cementum. The mechanism by which nerves are triggered to result in the pain associated with hypersensitivity is not well understood but appears to be the result of the Brunnström hydromechanical theory.3 This postulates that changes in physical conditions on the dentin surface such as heat, pressure, or osmotic potential give rise to fluid movement in the tubules.4 The consequent pressure change stimulates the nerves giving rise to the pain.

The mechanism of action of stannous ions in reducing dental hypersensitivity has been found to be the precipitation of stannous compounds occluding the dentinal tubules and thus preventing stimulation of the nerves in the pulp cavity. In vitro studies using various techniques, such as scanning electron microscopy, electron probe microanalysis, and Vickers surface microhardness, demonstrate deposition of tin and fluoride on the surface and covering of the dentinal tubules.5,6 One laboratory evaluation showed that while both zinc and tin covered or obturated tubules, zinc was largely removed by washing whereas tin remained covering the tubules.10 Another study showed specimens treated with stannous fluoride (Crest® Pro Health®), The Procter & Gamble Company, Cincinnati, OH, USA) appeared to resist acid solubilization.7

A number of clinical studies also have been conducted to investigate the effectiveness of toothpaste containing oral care products upon dentinal hyper- sensivity. Most of the early studies focused on gels containing 0.14% stannous fluoride,1 whereas the majority of contemporary trials have evaluated stannous-containing dentifrice formulations.11,12 The collective findings demonstrate the effectiveness of numerous stannous-containing products in reducing sensitivity.

Recently, a new stannous-containing sodium fluoride dentifrice was developed. This clinical trial was conducted to evaluate the effectiveness of this formulation relative to a negative control in the treatment of dental hypersensitivity.

Methods and Materials

Study Design

This was a randomized, parallel group, double-blind, four-week clinical trial to assess changes in subject perceived tooth hypersensitivity via air blast induced examiner grade assessment among subjects using a stannous-containing sodium fluoride dentifrice compared to those using a negative control dentifrice. Measurements were conducted at baseline, week two, and week four visits.

Entrance Criteria

Following Ethics Committee approval, at least 50 generally healthy subjects were stratified at baseline into one of four strata depending on their gender (female or male) and the baseline self-reported tooth hypersensitivity (low or high). Within strata, subjects were randomly assigned to one of the two treatment groups using an encoded program. Subjects residing in the same house-

Subjects were stratified at baseline into one of four strata depending on their gender (female or male) and the baseline self-reported tooth hypersensitivity (low or high). Within strata, subjects were randomly assigned to one of the two treatment groups using an encoded program. Subjects residing in the same house-
hold were assigned to the same treatment group.

**Treatment Regimens**

Subjects used the assigned products for the first time under supervision at the clinical site. Subjects used the products at home for two weeks, followed by two weeks, then four weeks. Each tooth was isolated with cotton rolls and then washed with water for a distance of 1.0 centimeter for twice daily for two minutes each time. Subjects were instructed not to alter their oral hygiene habits (e.g., flossing) with the exception that any anti- tooth hypersensitivity products should be used.

**Air Blast Tooth Specific Sensitivity**

The thermal sensitivity perceived by the subject was measured by the examiner by directing an air blast individually at each of the premolars and cuspids of each of the week two and week four visits. Each tooth was isolated with cotton rolls and then washed with water for a distance of 1.0 centimeter for 1 second. The following scale was used to assess the severity of the hypersensitivity:

- 0 – Absence of pain, but perceiving stimulus
- 1 – Slight pain
- 2 – Pain during application of stimulus
- 3 – Pain during application of stimulus and immediately thereafter

**Statistical Methods**

For air blast-induced hyposensitivity scores, separate analyses were performed for the two treatments combined and for the baseline and for all 12 teeth combined. Analysis of covariance was used to assess the differences between the control group and the treatment group over time for each visit, controlling for differences in age, gender, and baseline thermal sensitivity. The significance level was set at 0.05 for all statistical tests.

**Results**

The six subjects were enrolled at the baseline visit, received product, and completed the clinical trial component. Subjects ranged in age from 23 to 68 years, and 68% of the subjects were women. The treatment groups were balanced (p=0.86) for all demographic characteristics. Mean baseline scores were not significantly different (p=0.56) between groups at baseline for either the two most sensitive teeth or for all 12 teeth combined.

**Efficacy Results**

At week two and week four for the combined weeks two and four, the experimental group had a mean air blast score for two most sensitive teeth that was 28.4%, 24.9%, and 27% lower, respectively, than the control group (p<0.05, Figure 1). At week two, mean scores for the experimental and control groups were 1.51 and 2.11, respectively (Table 1). At week four, the experimental group had a mean score of 1.42 compared to 1.98 for the control group. The weeks two and four combined mean score was 1.46 for the experimental group and 2.00 for the control group.

**Discussion**

In this clinical trial, the experimental group exhibited a significantly greater reduction in tooth sensitivity via air blast measurements than the control group at both week two and week four (p<0.0001). The weeks two and four results were no longer statistically significant at week eight (p>0.54). The results of this study indicate that the stannous fluoride-containing toothpaste is effective in reducing dental hypersensitivity.

**Conclusions**

This stannous fluoride-containing toothpaste is an effective treatment for patients with dental hypersensitivity.

**References**


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Removal of interproximal dental biofilms by high-velocity Water Microdrops


Abstract

The influence of the impact of a high-velocity water microdrop on the detachment of Streptococcus mutans UA159 biofilms from the interproximal (IP) space of teeth in a typeont model was studied experimentally and computationally. Twelve-day-old S. mutans biofilms were exposed to a prototype AirFloss device delivering 115 μL wa- ter at a maximum exit velocity of 60 m/sec in a 50-msec burst. Using confocal microscopy and image analysis, we obtained quantitative measurements of the percentage removal of biofilms from different locations in the IP space.

The 3D geometry of the typodont and the IP spaces was obtained by micro-computed tomography (μ-CT) imaging. We performed computational fluid dynamics (CFD) simulations to calculate the wall shear stress (τw) distribution caused by the drops on the tooth surface. A qualitative agreement and a quantitative relationship between experiments and simulations were achieved. The wall shear stress (τw) generated by the prototype AirFloss and its spatial distribution on the teeth surface played a key role in dictating the efficiency of biofilm removal in the IP space.

Introduction

Good oral hygiene practice maintains a healthy oral cavity, biofilm-free areas are biofilm-free regions). Meanwhile, A3, B3, C3, D3, and E3 are the corresponding images after thresholding. Bioclips, which were exposed to a prototype AirFloss device, were used to study the effects of water droplets on the detachment of S. mutans biofilms from the interproximal (IP) space of teeth in a typodont model.

Materials & Methods

Bacteria and Growth Media

Biofilms were grown from S. mutans UA159 (ATCC 700601). Stock cultures of S. mutans were stored at -80°C in 10% glycerol in physiological buffered saline (PBS). Biofilms were cultured in physiological buffered saline (PBS) containing 0.5% agar and 0.5% glucose (BHI-S) medium (Sigma-Aldrich, Darmstadt, UK) and incubated at 37°C for 7 days. The resulting curve was plotted vs. the distance from the tip to the back of the teeth (Fig. 3). The proteus AirFloss device showed 95% removal close to the nozzle tip, 62% removal at approximately half the labio-palatal distance from the tip, 38% removal at the tip, 62% removal at approximately half the labio-palatal distance from the tip to the back of the teeth, and 8% removal at the back of the teeth (Fig. 3). The percentage removal values were plotted vs. the distance from the nozzle tip to the midpoint of the palatal surface of the teeth and were compared with the values obtained from the numerical simulations for τw at the same locations (Figs. 5, 6D).

Critical Shear Stress for Biofilm-Megagradate Detachment

The morphology of the biofilms in the range of 100 μm by mic-}

Figure 2. Representative CLSM images of S. mutans biofilms of 5 different locations (A, B, C, D, E). Exposure of the IP space to the prototype AirFloss tip from the proximal labial to the proximo-palatal side of a maxillary central incisor (the 3 locations are identified clearly in Fig. 3). A1, B1, C1, D1, and E1 are the images of the biofilm before the burst, and the untreated control. A2, B2, C2, D2, and E2 are the control images after thresholding with ImageJ (the biofilm is in black in these images, while the white areas are biofilm-free regions). Meanwhile, A3, B3, C3, D3, and E3 are the images of the biofilm after thresholding, and A4, B4, C4, D4, and E4 are the corresponding thresholded images. The untreated samples (#samples 1 and 2) and treated samples (#samples 3 and 4) are not from the same specimens. We calculated the % removal by subtracting the amount of biofilm that remained from the original amount of biofilm.

Figure 1. Digitization process of the training typodont. (A) Photograph showing the typodont used in the study. (B) 3D meshwork showing the geometry of the tooth surface that was used for the computational simulations. The sketch (right) shows the mesial view of a maxillary central incisor, and the dashed square shows the region of interest used in the study.

Statistical Analysis

Statistical comparisons were made by one-way analysis of variance (ANOVA) (Excel 2003, Microsoft). Differences were re-}
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Figure 3. Biofilm removal as a function of shear stress and distance from the tooth surface. A) Percentage removal of the biofilm quantified from the CLSM images at 3 different locations on the tooth surface in the IP space. These intradental runs are shown by different symbols. The error bars represent standard deviations of the mean of 3 CLSM images. Solid line and heavy bars are the mean of the individual means (n = 3), which have been slightly offset for clarity. The schematic inset shows the proximal view of the upper central incisor, where the black squares represent the different locations where the CLSM images were taken. (B) Contour map showing the spatial distribution of ωw on the tooth surface, as calculated from numerical simulations (circles: nozzle tip; ωw = 0.1). The color bar is a linear scale showing the stress state (Pa). Cx, y), on the tooth surface (in Pa) at different positions along the tooth (x, from labial to palatal side), at a fixed z-position (gingival-in cervical), and also calculated from (c, x, y, y, y). Empty squares correspond to the measurement points (squares) in 3B. On the secondary y-axis, the mean percentage removal measured experimentally in vivo (i.e., adult human teeth, with the empty squares indicated) are shown. (A, B, C) The computations showed that the maximum percentage removal was located near the gingival margin (z/H = 0.17 (i.e., close to the incisal edge)).

Discussion
In the flow cell experiments, Stoodley et al. (2002) showed that biofilm was successfully grown inside microchambers under gravitational flow conditions, thus leading to the formation of large cell aggregates, which tend to be approximated to a streamlined shape. The streamlined shape has a significant effect on reducing the fluid drag on the elongated biofilms (Stoodley et al., 1998, 1999). The simulation showed the predicted fluid τs distribution on the proximal surface of the tooth, starting from the labial side of the IP space close to the gingival margin, perpendicular to the midpalatal point of the palatal surface of the tooth (τs = 0.5 kPa).

Computational Prediction of Shear Stress and Experimental Biofilm Removal
The τs distribution obtained computationally was compared with the experimental observations. A linear correlation of τs removal as a function of τs was found according to:

\[
\text{Percent removal} = k_1 \tau_s^2 (r^2 = 0.84) = \frac{1}{k_2} \tau_s (r^2 = 0.84)\]

(1) where τs wall shear stress (in Pa), and k (in Pa−1) is the slope of the interpolating function (Figs. 6C, D).

Effect of the Nozzle z-position on Wall Shear Stress Distribution
Contours of fluid τz on the tooth surface at various z-positions were obtained to investigate the effect of tip positioning on the device’s hydrodynamic performance. Figure 4 shows the tooth surface area where the fluid τz is lower than the critical value ωw = 0.5 Pa. Computational results predicted that the maximum % of biofilm removal would take place when the nozzle tip is placed at z/H = 0.5 or z/H = 0.66, while the efficiency started to be significantly reduced at extreme z/H positions, namely, z/H = 0.15 or z/H = 0.85 (i.e., close to the incisal edge).

The exit velocity of the microdrops from the prototype Air Floss was 60 m/s (on average), based on earlier experiments, the flow was a steady stream (Rinaldi et al., 2013). Even though the shearing force was applied over very short periods of 50 msec, the generated τs was proved to be effective in removing the attached biofilm by both adhesion and cohesion forces (Ohashi and Harada, 1994; Stoodley et al., 2002). The exit velocity of the microdrops from the prototype Air Floss was 60 m/s (on average), based on earlier experiments, the flow was a steady stream (Rinaldi et al., 2013). Even though the shearing force was applied over very short periods of 50 msec, the generated τs was proved to be effective in removing the attached biofilm by both adhesion and cohesion forces (Ohashi and Harada, 1994; Stoodley et al., 2002). However, fractions of the biofilm remained on the back of the teeth, due to tooth architecture and the fluid flow behavior in these regions, i.e., the inability of the water stream to reach around the anatomical curvature and undercuts associated with the proximal surfaces and upper incisal cervices. These observations were predicted by the computational model simulations in which τs on the proximal surface of the teeth was observed to decrease gradually in the labiopalatal direction.

The simulations predicted τs distribution on the tooth surface caused by the microburst to be the highest in the IP space, except in areas on the palatal side of the tooth, where τs became significantly lower (~0.2 Pa). The numerical simulations for the fluid τs were ~1,000 times higher than the computational fluid dynamic simulations, and −20 times higher than the values obtained from the flow-cell experiments, and −20 times lower than the experimental values of the adhesion strength of the biofilm obtained from the IRIDIS High-Performance Computing Facility, using the development of the type-on type-2 model, Dr. Suraj Patel from the University of Southampton is acknowledged, and at oral biofilm effusion experiments, Dr. Philipp Thurner from the University of Portsmouth is acknowledged. The use of both the IRIDIS High-Performance Computing Facility, and µ-VIS (CT centre), and associated support services at the University of Southampton is sincerely acknowledged.

Abstract
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The computational model developed described that the major site of the effect of changing the position of the nozzle tip in the z-direction had a negligible impact on biofilm removal efficacy. The numerical simulations predicted that when the nozzle tip was placed in or close to the middle of the incisogingival height (z/H = 0.5 to 0.7), we observed a relatively high shear stress (~1.7 Pa), to the benefit of biofilm removal, in comparison with placing the tip closer to either the incisal edge or the gum line (Fig. 4). To the best of our knowledge, this is the first time that CFD has been used to calculate the wall shear stress distribution, caused by water drops jetted from the device, on the tooth surface. In this study, an experimental set-up was built and a methodol- ogy was developed to characterize the efficacy of biofilm detachment by high-velocity water droplets, quantifying the distribution of biofilm and automatically translates into prevention of dental curies formation at these sites.