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. Subjects reporting dental hypersensitivity were enrolled and randomized to the experimental dentifrice or the control desensitifrice 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 week two and four and for weeks two and four combined. The sensitivity reduction ranged from 24.9% to 28.4% over the control. For all 12 teeth, the experimental group had statistically significantly (p<0.05) lower sensitivity scores versus the control group at week two, and weeks two and four combined.

Conclusions: 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 trial. Keywords: 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 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 trig- gered to result in the pain associated with hypersensitivity is now widely accepted to be that of the Brunnstrom hydrodynamic theory.2 This postulates that changing physical conditions on the dentin surface such as heat, pressure, or osmotic potential give rise to fluid movement in the tubules.3 The consequent pressure change stimulates the nerves giving rise to the pain.

The mechanism of action of stannous ions in reducing den- tinal hypersensitivity has been found to be the precipitation of stannous compounds occlud- ing the dentinal tubules and thus preventing stimulation of the nerves in the pulp cavity. In vitro studies using various tech- niques, such as scanning electron microscopy, electron probe microanalysis, and Vickers sur- face microhardness, dem- onstrate deposition of tin and fluo- ride on the surface and covering of the dentinal tubules.4 One laboratory evaluation showed that while both zinc and tin cov- ered or obliterated tubules, zinc was largely removed by wash- ing whereas tin remained cover- ing 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 solubil- ization.11

A number of clinical studies also have been conducted to investigate the effectiveness of stannous-containing oral care products upon dentinal hy- persensitivity. Most of the early studies focused on gels contain- ing 0.14% stannous fluoride,1 whereas the majority of con- temporary clinical trials have evaluated stannous-containing dentifrice formulations.12,13 The collective findings demonstrate the effec- tiveness 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 nega- tive 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 hy- persensitivity via air blast in- duced examiner grade assess- ment 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 healthy adults aged 18-70 reporting tooth sensitivity were sought. Subjects had to agree to refrain from using anti-hypersensitiv- ity products or having elective dental procedures (including prophylaxis) performed during the study.

Subjects who were currently using an anti-sensitivity toothpaste or another anti-sensitivity product or who had used such a product in the previous month were excluded. Subjects with various teeth or with any other condition that the investigator considered may compromise the results also were excluded. Subjects taking daily doses of antidepressants, sedatives, tran- quilizers, or other mood-altering drugs were excluded as well as subjects with a history of signifi- cant adverse effects following the use of oral hygiene products such as toothpaste and mouth rinse.

Test Dentifrices, Assignment to Treatment Segments
The two treatments used in this study were:
1. An experimental stannous-containing sodium fluoride den-.tifrice with 1450 ppm F- sodium fluoride and stannous chloride as a key excipient (Procter & Gamble U.K., Surrey, United Kingdom)
2. Crest® Decay Protection (UK) with 1450 ppm F- sodium Fluo- ride (Procter & Gamble U.K., Sur- rey, United Kingdom)

Both were supplied to the sub- jects with (medium) Oral-B Ad- vantage 40 toothbrushes (The Procter & Gamble Company, Cincinnati, OH, USA). The test products were supplied in kits containing the assigned tooth- paste, toothbrush, and written usage instructions. The dentifrice in both kits was supplied blinded in white tubes.

Subjects were stratified at base- line into one of four strata de- pending 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 prod-
ucts for the first time under sur-
veillance at the clinical site. Sub-
jects used the products at home in the same normal tooth-brush
and dentifrice for a period of four weeks. Subjects were in-
stated to brush twice daily for two
minutes each time. Subjects were
instructed not to alter their other hygiene habits (e.g., flossing) with the exception that any anti-tooth hypersensitivity
products should be used.

Air Blast Tooth Specific Sensi-
tivity

The thermal sensitivity per-
ceived by the subject was meas-
ured by the examiner by direct-
ing an air blast individually at
each of the premolars and cu-
monary teeth, excluding the fourth and fifth teeth, for four weeks. Each tooth was isolated with cotton rolls and the subject was asked to assess the level of sensitivity for each of the 12 teeth examined.

- 0 = Absence of pain, but per-
ceiving stimulus
- 1 = Slight pain
- 2 = Pain during application of
stimulus
- 3 = Pain during application of
stimulus, and observed that was mild in

Table 1. Between treatment comparison of air blast score for all 12 teeth

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Mean Score</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>1.46</td>
<td>0.98</td>
</tr>
<tr>
<td>Control</td>
<td>2.00</td>
<td>1.11</td>
</tr>
</tbody>
</table>

Discussion

In this clinical trial, the experi-
mental group exhibited a sig-
ificantly greater reduction in
thermal sensitivity compared to
baseline at both week four and
week eight. There were no signifi-
cant differences between the two treat-
ments at either week four or week eight (p=0.54) for either treatment.

One subject in the experimental
group had a possible related ad-
verse event (desquamation) ob-
erved that was mild in

Table 2. Between treatment comparison of air blast score for two most sensitive teeth

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Mean Score</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>2.49</td>
<td>1.21</td>
</tr>
<tr>
<td>Control</td>
<td>3.12</td>
<td>1.41</td>
</tr>
</tbody>
</table>

Further research is warranted on this demonstration to dem-
strate the full breadth, as well as magnitude, of benefits.

Conclusion

This stannous-containing sodi-
um fluoride dentifrice provides
statistically significant benefits for dental hypersensitivity
and should be considered as a home care option for patients who ex-
perience this condition.

Clinical Significance

This stannous-containing sodium
fluoride dentifrice provides an
 effective treatment for pa-
tients with dental hypersensiti-

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dence of dentine hypersensitivity in a general dental popula-
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dence of dentine hypersensitivity in a general dental popula-

Full list of references available from the publisher.
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Removal of interproximal dental biofilms by high-velocity Water Microdrops

By A. Rimaile, D. Carugo, L. Capretto, M. Aspiras, M. De Jager, A. E. Ward and P. Stoodley

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 typodont was studied experimentally and computationally. Twelve-day-old S. mutans biofilms were exposed to a prototype AirFloss delivering 115 μL wa-
ter at a maximum exit velocity of 60 m/sec in a 30-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 (τ) 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 (τ) generated by the prototype AirFloss and its spatial distribution on the teeth surface played a key role in dictating the efficacy of biofilm removal in the IP space.

Key words: oral hygiene, Streptococcus mutants, micro-computed tomography, microscopy, computational fluid dynamics, dental plaque, dental hygiene.

Introduction

Good oral hygiene practice maintains a healthy oral cavity, biofilm-free cavities and reduces the risk of dental diseases experimentally and computationally. Twelve-day-old S. mutans biofilms in the IP space were exposed to a prototype AirFloss delivering 115 μL water at a maximum exit velocity of 60 m/sec in a 30-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.

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The Ultimate Sonicare Power Toothbrush

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• Clinically proven to whiten teeth in just 1 week§

Effect of the Nozzle z-position on Wall Shear Stress Distribution

Contours of fluid $\tau_z$ on the tooth surface for different positions were obtained to investigate the effect of tip positioning on the device's hydrodynamic performance. Figure 4 shows the tooth surface area where $\tau_z$ is lower than the threshold value of 0.5 Pa. Computational results predicted that the maximum $\tau_z$ of biofilm removal would take place when the nozzle tip is placed at $z = 0.5$ or $z = 0.68$, while the efficiency of biofilm removal would be significantly reduced at extreme $z$-positions, namely, $z / H = 1$ or $z / H = 0.85$ (close to the incisal edge).

Discussion

In the flow cell experiments, Stoodley et al. (1998, 1999) showed that streamers develop viscoelastic properties of large cell aggregates (Stoodley et al., 1998, 1999). The detachment of biofilm appears to be firmly attached to the tooth surface (in kPa), while the smaller patches were consistent with the simulations (Appendix Fig. 2). The simulations predicted that the shear stress on the proximal surface of the upper central incisors was ~2.7 kPa, to the back of the teeth, due to tooth curvature, and cohesive failure (Rmaile et al., 1999; Heersink et al., 2002). Whether this variability is true at different locations in the mouth needs to be investigated further in vivo.

The use of both the IRIDIS High-Performance Computing Facility, and μ-VIS (CT centre), and the use of both the IRIDIS High-Performance Computing Facility, and μ-VIS (CT centre), and the oral health care devices that use oral hygiene tribune for high-speed droplets, water flow, and streaming of biofilm and automatically translates into prevention of oral cure surfaces at the same time, the critical shear stress of 1.7 Pa is close to the range of previously reported values of shear stress (5-12 Pa) required for detachment of biofilm plaques (Ohashi and Harada, 1994; Stoodley et al., 2002). The exit velocity of the micro-droplets from the prototype Air Floss was 60 m/sec, based on recent 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 shear force proved to be effective in removing the attached biofilm by both adhesive and cohesive failure (Rmaile et al., 2013). 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 to reach the premolar region around the anatomical curvature and underrun associated with the palatal direction and the upper incisal incisors. These observations were predicted by the computational simulations in which $\tau_z$ on the proximal surface of the tooth was observed to decrease gradually in the labial-palatal direction.

The simulations predicted $\tau_z$ distribution on the tooth surface caused by the microbial biofilm to be the highest on the incisal edge, in areas except for, or even on the palatal side of the tooth, where $\tau_z$ became significantly lower (~0.20 Pa). The numerical simulations predicted experimental values for the fluid $\tau_z$ to be ~1,000 times higher than the values obtained from the flow-cell experiments, and ~20 times higher than the estimated in vitro shear stress for detachment, for the biofilm detachment of Ohashi and Harada, 1994; Stoodley et al., 2002. Thus, the simulations predict that a significant percentage of areas of the tooth surface may be capable of removing the plaque from the IP space. The large difference in the detachment value of $\tau_z$ and between the 2 systems illustrates the importance of the physiological growth conditions and surface type on adhesion strength. It was beyond the scope of this study to determine the influence of surface or hydrodynamics on adhesion strength. In mechanical systems, reports properties for the same species commonly vary by 3 orders of magnitude or more (Hass, 2001). Whether this variability is true at different locations in the mouth needs to be investigated further in vivo, but measurements of the adhesion strength of real oral biofilm plaques would be useful in developing relevant in vitro models which look at mechanically induced detachment.

The 3D simulations for predicting $\tau_z$ were well correlated with the experimental results obtained. As might be expected, the biofilm survived the effect of low $\tau_z$, but was flushed away at areas where $\tau_z$ was higher. A linear relationship was observed between the predicted fluid $\tau_z$ and the amount of detached biofilm obtained experimentally (Eq. 1). This relationship could be used to predict the efficacy of oral health care devices that use shear forces to remove plaque.

The computational model demonstrated the effect of changing the position of the nozzle tip in the z-direction on the biofilm removal efficacy. The computational simulations predicted that the pyramidal nozzle tip was placed in or close to the middle of the incisogingival height ($z / H = 0.5$ or $z / H = 0.68$) for the maximum biofilm removal, in comparison with placing the tip closer to either the incisal edge or the gum line (Fig. 4). To our best of knowledge, this is the first time that CFD has been used to calculate the wall shear stress distribution, caused by water drops ejected from any oral hygiene device, on the tooth surface.

In this study, an experimental set-up was built and a methodology was developed to characterize the biofilm removal efficacy of biofilm detachment by high-velocity droplets, water flow, and streaming of biofilm and automatically translates into prevention of dental caries formation at these sites.

Acknowledgments

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. The authors also acknowledge Dr. Phil Preshaw from Newcastle University, for the development of the pyramidal model, Dr. Suraj Patel from the University of Southampton for his advice with μ-CT, and the late Dr. Hansjörgen Schoppe for helping with the collection of the ex vivo data. This study was financially supported by Philips Oral Healthcare, Bothell, WA, USA. The prototype Air Floss, and the Ward are employed by Philips Oral Healthcare, Bothell, WA, USA. The authors declare no potential conflicts of interest with respect to the authorship and/or publication of this article.

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References

Regarding the biofilm aggregates, the authors describe how the biofilm aggregates were studied using computer simulations and how the simulations predicted that the biofilm aggregates were more likely to detach when the shear stress was increased. The authors also discuss the importance of the shear stress distribution on the tooth surface, which is critical for biofilm removal. The simulations predicted that the shear stress on the proximal surface of the upper central incisors was higher than the critical shear stress of 1.7 Pa, which is close to the range of previously reported values of shear stress (5-12 Pa) required for detachment of biofilm plaques. The simulations also predicted that the shear stress on the incisal edge was lower than the critical shear stress, which is consistent with the experimental results obtained. The simulations predicted a linear relationship between the fluid shear stress and the amount of detached biofilm obtained experimentally (Eq. 1). This relationship could be used to predict the efficacy of oral health care devices that use shear forces to remove plaque.

The computational model demonstrated the effect of changing the position of the nozzle tip in the z-direction on the biofilm removal efficacy. The simulations predicted that the maximum biofilm removal occurred when the nozzle tip was placed at $z / H = 0.5$ or $z / H = 0.68$, while the efficiency of biofilm removal would be significantly reduced at extreme $z$-positions, namely, $z / H = 1$ or $z / H = 0.85$ (close to the incisal edge). The simulations also predicted that the shear stress on the proximal surface of the upper central incisors was ~2.7 kPa, which is close to the range of previously reported values of shear stress (5-12 Pa) required for detachment of biofilm plaques. The simulations predicted a linear relationship between the fluid shear stress and the amount of detached biofilm obtained experimentally (Eq. 1). This relationship could be used to predict the efficacy of oral health care devices that use shear forces to remove plaque.

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