ORIGINAL ARTICLE

Buffering effect of a prophylactic gel on dental plaque

Anitha Persson • Peter Lingström • Maud Bergdahl • Jan W. V. van Dijken

Received: 10 January 2006 / Accepted: 8 June 2006 / Published online: 26 August 2006 © Springer-Verlag 2006

Abstract The aim of this study was to evaluate the effect of a new prophylactic gel on plaque pH and plaque fluoride concentration. Twelve participants with normal (n=6, \geq 0.7 ml/min) and low (n=6, <0.7 ml/min) stimulated whole salivary secretion rate were included. After 3 days of plaque accumulation, at random the participants were (1) treated with Profylin fluoride gel with buffering components (active gel), (2) treated with Profylin fluoride gel without buffering components (placebo gel), (3) asked to rinse with water, and (4) given no treatment. All test series were followed by rinsing with a nutrition solution; after which registration of plaque pH was performed during 60 min. There were two drop outs with low salivary secretion rate in the water session. The overall least pronounced pH fall was found after the use of the prophylactic gel. Significant differences between the prophylactic gel and the placebo gel were found for the participants with normal secretion rate. Fluoride plaque concentrations evaluated in 12 individuals after (1)

A. Persson (⊠) · J. W. V. van Dijken
Department of Odontology, Dental Hygienist Education,
Dental School, University of Umeå,
Umeå 901 87, Sweden
e-mail: anitha.persson@odont.umu.se

P. Lingström

Department of Cariology, Faculty of Odontology, The Sahlgrenska Academy at Göteborg University, Göteborg, Sweden

P. Lingström

Department of Health Sciences, Kristianstad University, Kristianstad, Sweden

M. Bergdahl Institute of Clinical Dentistry, University of Tromsø, Tromsø, Norway application of the active gel, (2) rinsing with 0.2% NaF, and (3) rinsing with water showed significantly higher values after rinsing with the NaF solution. It can be concluded that application of the active gel, particularly in subjects with normal salivary secretion rate, in general, buffered plaque pH to higher levels. Factors like concentration of buffering agent and solubility of the gel need to be further evaluated to improve the effect.

Keywords Clinical · Prophylaxis · Plaque pH · Gel · Fluoride · Buffering

Introduction

Dental caries is caused by an interplay between tooth tissues, aciduric microorganisms, and fermentable carbohydrates. Thus, accessible fermentable carbohydrates are metabolized by cariogenic bacteria into organic acids, resulting in a pH fall [18, 21]. Microbial deposits on teeth are constantly metabolically active, producing a variety of acidic and basic end-products, which are formed even in the absence of a dietary substrate. A reduction of plaque pH below the critical levels for enamel and dentine may result in demineralization of respective hard tissue [3].

Saliva plays an essential role in the maintenance of oral health [15]. The salivary secretion rate and the buffering capacity of saliva protect the teeth against the acids produced by cariogenic microorganisms. Saliva contains different buffering systems of which the bicarbonate system is the most important [1].

One way to inhibit caries is to add buffering agents, like bicarbonate and phosphate, to the oral cavity. These supplement the buffering action of saliva and maintain pH at a high level during periods of caries activity. Tanzer et al. [23] reported that both sodium bicarbonate-based dental powder and dentifrices inhibit tooth decay in rats. Imfeld [12] found that rinsing with sodium bicarbonate increase pH of human plaque after having previously been lowered by exposure to fermentable carbohydrates. Also, sucking on a sugar-free lozenge containing bicarbonate and phosphate buffers elevated the pH of human plaque and saliva after a previous sucrose rinse [19]. A sorbitolcontaining chewing gum supplemented with sodium bicarbonate was found to enhance the ability of plaque pH to be maintained at an elevated level after a cariogenic challenge [11]. Also, the addition of baking soda to a fluoridated dentifrice is effective in reducing plaque acidity with neutralizing effects lasting up to 60 min after treatment [2]. The bicarbonate concentration of saliva increases as saliva is stimulated, which may partly explain the neutralizing effects of acids by certain bicarbonate-containing agents [15]. Fluoride ions are known to act against caries in different ways. They may reduce the degree of demineralization and accelerate the process of remineralization. At higher concentrations fluoride may also inhibit the growth of oral bacteria or interfere with bacterial acid production and acidurance [9, 14].

Recently, a prophylactic gel containing fluoride, sodium bicarbonate, and phosphate was developed and introduced for caries-risk individuals with subjective and/or objective dry mouth and/or low buffer capacity. The gel is claimed to lubricate teeth and oral mucosa and neutralize plaque pH. The hypothesis tested in this study was whether the addition of bicarbonate and phosphate to a gel would result in an increased plaque pH neutralizing effect compared to a gel without these active substances. The aim was to evaluate the effect of this new prophylactic gel on plaque acidogenicity in individuals with normal and low stimulated whole salivary secretion rate and to investigate plaque fluoride concentration after a single application.

Materials and methods

Study design

Two different test series (A and B) were performed. In series A, plaque acidogenicity was evaluated and plaque fluoride concentration in series B.

Participants

In series A, 12 healthy subjects (seven women and five men) with a mean age of 62 years (range 50-70), attending the clinic at the Dental School, University of Umeå participated. At baseline, paraffin-stimulated saliva was collected for analysis of secretion rate and buffer capacity

[6]. The participants were divided into two groups according to their stimulated salivary secretion rate: normal secretion rate (≥ 0.7 , median 1.65, and range 1.16-3.60 ml/min) and low secretion rate (<0.7, median 0.59, range 0.40-0.70 ml/min. None of the participants used any medication. The median buffering capacity in the normal secretion rate group was 6.50 (range 3.90-8.40) and in the low secretion group 5.15 (range 2.80-8.10).

In series B, another 12 healthy participants, attending the university dental clinic (seven men and five women) 62 years (range 52-74) attended. All participants had a stimulated salivary secretion rate ≥ 0.8 ml/min (median 1.75 and range 0.80-3.50 ml/min).

For both series, oral and written information was given to the subjects at the first visit. The study was approved by the ethics committee at the University of Umeå; written consent was obtained from all participants before study. Professional dental cleaning was performed at baseline after which the participants refrained from oral hygiene for 3 days before each test session. During this time period they were asked not to use products containing fluoride. On day four, the subject came to the clinic without eating, drinking, or using tobacco for the last 2 h before visit. The test sessions were distributed in a randomized order with at least 1 week interval between each visit.

Measurement of plaque pH

Table 1 Profylin

Sweden

In series A, each participant made four visits to the dental clinic during which the following four treatments in different test sessions were carried out: (1) Profylin Fluoride gel with buffering components (Prophylactor AB, Stockholm, Sweden; active gel; Table 1) (2) Profylin Fluoride gel without buffering components (placebo gel), (3) water rinsing, and (4) no treatment. All four test sessions were followed by rinsing with a nutrition solution (Semper vanilj, Arla Foods, Stockholm, Sweden). Thus,

Table 1 Components in Profylin® Fluoride-gel (active gel)	Components		
	Sodium fluoride (0.068% F)		
	Aqua purificata		
	Glycerin		
	Sodium phosphates		
	Xylitol		
	Sodium bicarbonate		
	Ethanol		
	Xanthan gum		
	Hypericum perforatum		
	Cellulose gum		
	Menthol		
The active gel was provided by	Methylparaben		
Prophylactor AB, Stockholm,	Propylparaben		

only rinsing with the nutrition solution was performed for session 4.

The participants were seated in a relaxed position in a dental chair during the test sessions. Each session started with registration of baseline pH. In test sessions 1 and 2, 0.2 ml of the respective gels were applied on the test sites for 5 min. The gels were applied using a syringe (BD Plastipak, Becton Dickinson, Madrid, Spain) at two proximal sites in the upper jaw, one in the premolar, and one in the front region. After 5 min, the participants were asked to gargle and spit out eventual excess gel. This was followed by a mouthrinse with 10 ml nutrition solution for 1 min. In session 3, rinsing with 10 ml water was performed for 1 min followed by rinsing with the nutrition solution as described above. In session 4, only a mouthrinse with the nutrition solution was performed. The pH electrode was inserted into the proximal plaque cervical of the contact point. Plaque pH was then measured at 2, 5, 10, 15, 20, 30, 40, 50, and 60 min after the mouthrinse [13, 20]. Registration of plaque pH was at both proximal sites performed using an iridium touch microelectrode with a diameter of 0.1 mm (Beetrode® NMPH-1, WPI, Sarasota, FL, USA) [13]. As reference electrode, a plate of silversilver chloride (ECG: type Syntectics Medical, Stockholm, Sweden) was placed on the skin of the forearm with an electrode gel (Spectra 360, Parker, Orange, NJ, USA) [20]. The electrode was calibrated before each test session against standard pH buffer at pH 7.00 and 4.00 [13]. All sites for registration were free from metal restorations.

Fluoride measurements

For series B, each participant visited the dental clinic at three test sessions at which one of the following three treatments were performed at random: (1) Profylin Fluoride gel with buffering components (active gel), (2) 0.2% sodium fluoride solution (Dentan Ipex, Medical AB, Danderyd, Sweden; 0.2% NaF), and (3) water rinsing. In session 1, 1 ml of gel was applied at all proximal and buccal surfaces and after 5 min the subjects gargled the slurry around the dentition with active movements of the tongue and cheeks. In sessions 2 and 3, a mouthrinse with 10 ml sodium fluoride or water for 2 min was performed. After the treatments, each site was shortly air-dried to remove saliva before supragingival plaque was collected with a dental scaler, which was placed in a 0.5-ml preweighed Eppendorf tube. Within 2 min after collection, the tube was weighed and then stored at -80°C until analyzed. At baseline and after plaque sampling, a professional dental cleaning was performed.

For fluoride analysis, the plaque samples were first centrifuged for 2 min in an Eppendorf centrifuge after which 200 μ l of distilled water and 20 μ l of TISAB III were

added [22]. After sonication for 7 s, the samples were left at room temperature for 24 h after which the concentration of fluoride was determined with an ion-sensitive electrode (Orion 96-90 electrode, Orion Research, Cambridge, MA, USA) connected to an Orion SA 720 pH/ISE Meter (Orion Research). The F analyses were performed using standard solutions from 0.526 μ M (0.01 ppm) to 0.526 mM (10 ppm) of F. Fluoride concentration was expressed as nanogram F per milligram plaque.

Statistical analysis

Mean pH from the two sites was calculated after which individual pH curves for each treatment were calculated. These were analyzed using the following variables: baseline pH (0 min), minimum pH, maximum pH decrease, and final pH (60 min). The areas under the curve at pH 5.7 and 6.2 (AUC_{5.7} and AUC_{6.2}) were calculated. The data showed normal distribution tested with Statistical Package for the Social Sciences, version 13.0. Analysis of variance and Fischer's protected least significant difference were used to compare the pH of the experimental treatment groups at each of the measured time points and for minimum pH, maximum pH decrease, AUC_{5.7}, and AUC_{6.2}. A *p* value of <0.05 was considered statistically significant.

Results

Plaque pH measurements

In series A, two participants with low salivary secretion rate dropped out in session 3. Two pH values (20 and 30 min) for one of the participants in session 4 were omitted due to a technical reason. All other participants completed the measurements.

All participants Changes in plaque pH after the four treatments in series A are given as mean values in Fig. 1. The active gel containing buffering components resulted in the highest pH values during the whole measurement period. Statistically significant differences between the treatment groups were observed within the first 20 min: active gel vs no treatment at 2 and 5 min (p < 0.001) and at 10, 15, and 20 min (p < 0.05); active gel vs water at 2 and 5 min (p<0.001) and at 15 min (p<0.05); placebo gel vs no treatment at 5 and 10 min (p<0.01) and at 2 and 15 min (p < 0.05); and placebo gel vs water at 2 and 5 min (p < 0.05). No statistically significant differences were observed between the two gels. Data for baseline pH, minimum pH, maximum pH decrease, and final pH are shown in Table 2. No statistically significant differences were found for baseline pH among the four groups. The least favorable



Fig. 1 Changes in plaque pH for the four treatments (active gel, placebo gel, water, and no treatment) given as mean values at each of the time points for all individuals (n=12)

values for minimum pH (p<0.01) and final pH (p=ns) were found for no treatment, while the largest maximum pH decrease was seen for water (p<0.05). The AUC_{5.7} and AUC_{6.2} values for the four groups are shown in Fig. 2. The highest values were for both AUC values found for no treatment. Statistically significant difference was observed for AUC_{5.7} between no treatment and the active and placebo gel (p<0.05) and for AUC_{6.2} between no treatment and the active gel (p<0.05).

Normal salivary secretion rate participants A similar pattern of plaque pH response for all patients was observed for the participants with normal salivary secretion rate with the least pronounced pH fall after use of the active gel. Statistically significant differences for this group were found within the first 15 min of measurements, which were almost similar to those observed for the all participants group. In addition, a significant difference was also found between active and placebo gel at 2, 5, 15, and 50 min (p<0.05).

Low salivary secretion rate participants For the participants with low salivary secretion rate, significant differences were found for the active gel vs no treatment at 5 min (p<0.05) and the placebo gel vs no treatment at 15 min



Fig. 2 The AUC_{5.7} and AUC_{6.2} (pH×min) for the four treatments (active gel, placebo gel, water, and no treatment) for all participants (n=12)

Table 2 Baseline pH, minimum pH, maximum pH decrease, and final pH for the four treatment groups for all participants (n=12) and when divided into normal (n=6) and low (n=6) stimulated salivary secretion rate

		Active gel	Placebo gel	Water	No treatment
Baseline pH	All Normal Low	6.71 ± 0.60 6.87 ± 0.49 6.45 ± 0.70	6.66 ± 0.33 6.76 ± 0.21 6.57 ± 0.41	$\begin{array}{c} 6.64 {\pm} 0.38 \\ 6.73 {\pm} 0.32 \\ 6.52 {\pm} 0.47 \end{array}$	6.73 ± 0.58 6.89 ± 0.63 6.58 ± 0.53
Minimum pH	All Normal Low	$\begin{array}{c} 5.48 {\pm} 0.56^{ab} \\ 5.73 {\pm} 0.58^{ab} \\ 5.17 {\pm} 0.37 \end{array}$	5.23 ± 0.17 5.21 ± 0.14 $5.25 \pm 0.21^{a^*}$	$\begin{array}{c} 5.00 {\pm} 0.50^{a^{*}} \\ 5.16 {\pm} 0.48^{a^{*}} \\ 4.76 {\pm} 0.48 \end{array}$	$\begin{array}{c} 4.85 {\pm} 0.55^{b^{**}} \\ 4.92 {\pm} 0.51^{b^{**}} \\ 4.78 {\pm} 0.63^{a^{*}} \end{array}$
Maximum pH	All decrease Normal Low	$\begin{array}{c} 1.34{\pm}0.36^{ab} \\ 1.16{\pm}0.31^{a} \\ 1.56{\pm}0.31^{a} \end{array}$	$\begin{array}{c} 1.43 {\pm} 0.35^{a*} \\ 1.54 {\pm} 1.19^{a**} \\ 1.32 {\pm} 0.44 \end{array}$	$\begin{array}{c} 2.25 {\pm} 1.66^{b^{*}} \\ 2.57 {\pm} 2.15 \\ 1.77 {\pm} 0.19^{a^{**}} \end{array}$	1.88±0.61 1.96±0.80 1.80±0.42
Final pH	All Normal Low	6.30 ± 0.62 6.50 ± 0.48 6.06 ± 0.75	6.02 ± 0.45 6.22 ± 0.24 5.80 ± 0.53	6.02 ± 0.68 5.98 ± 0.56 6.07 ± 0.93	5.95 ± 0.78 6.08 ± 1.06 5.82 ± 0.39

*p<0.05; **p<0.01 ^{a,b} Significant differences were observed between the treatments

(p < 0.05). The active gel resulted in a generally lower pH for individuals with low salivary secretion rate compared to those with normal salivary secretion rate with a mean difference in plaque pH of 0.7 pH units. Significant differences for each of the groups between low and normal salivary secretion rate of the participants were found in the active gel group at the time points 2, 5, and 15 min (p < 0.001, p < 0.05, and p < 0.01, respectively) as well as for minimum pH (p < 0.05) and AUC_{6.2} (p < 0.05). The corresponding AUC_{5.7} values for the low and normal salivary secretion groups were 13.2 ± 11.2 and 1.8 ± 3.6 pH×min for the active gel, respectively, and 8.5 ± 5.1 and 7.4 ± 4.9 pH×min for the placebo gel, respectively.

Fluoride analyses

There were no dropouts in series B. The plaque fluoride concentrations expressed as nanogram F per milligram plaque are shown in Table 3. The 0.2% NaF rinsing resulted in significantly higher plaque F concentrations compared to both the active gel and the water rinse (p < 0.001).

Table 3 Plaque fluoride concentrations (ng F/mg of plaque) for all subjects (n=12) after application of active gel, rinsing with 0.2% NaF, and rinsing with water

	Mean±SD (ng/mg)	Range
Active gel	0.24 ± 0.12	0.07-0.44
0.2% NaF	1.22 ± 0.70	0.30-3.06
Water	$0.09 {\pm} 0.06$	0.01-0.18

The significance level between the active gel and 0.2% NaF and between water and 0.2% NaF is p<0.001

Discussion

The number of elderly people with their teeth intact even at old age has increased during the last decades in Sweden [10, 17]. Dental caries constitutes a big problem for many of these individuals. Recently, Morse et al. [17] observed that 70% of subjects who are more than 80 years old had untreated coronal or root caries. Caries was also found to be the main reason for tooth extraction in elderly subjects [8]. Fure [7] emphasized the need of increased caries prevention with increasing age. Fluoride, together with reduction of sugar and optimal oral hygiene, is the most frequently used preventive tool against caries. However, several studies showed that another possible mechanism to inhibit caries is the incorporation of buffering agents, like bicarbonates and phosphates, into additional prophylactic agents such as rinsing solutions, dentifrices, chewing gums, or lozenges [2, 11, 12, 19, 23]. To get an optimal effect of all these products, for example, mouthrinses and chewing gums, the individual has to show an active participation. In noncooperating or less-cooperating individuals, incorporation of buffering agents into an easy applicable gel may be more effective. The active gel evaluated in this study, containing bicarbonates, phosphates, and fluoride, may be easy to apply both for elderly and handicapped individuals and their assisting personnel.

The neutralizing effect of products including bicarbonate as buffering component were studied in vitro [4] in rats [23] and in humans [11, 12]. The effect on plaque pH were studied in subjects using the plaque sampling [19], ionsensitive field-effect transistor electrode system [11], telemetry [12], and the microtouch method [2]. The microtouch method allows us to measure continuous changes in plaque pH over time. To evaluate the neutralizing effect of the gel, a single application on two sites of healthy individuals with normal or low salivary secretion was performed. The neutralizing effect on plaque pH of the active gel was compared with a placebo gel without buffering components, a water rinse, and no treatment, which were all followed by rinsing with nutrition solution.

The active gel with buffering components showed at almost all time points the greatest possibility to resist plaque pH decrease of all treatment groups. Significant differences between the active gel and the treatments with the nutrition solution and water were found during the first 20 min. The greatest plaque pH decrease was observed for the no treatment, indicating that the neutralizing effect of the buffering gel indirectly supports the saliva-buffering system. However, the placebo gel without buffering components also showed a similar tendency as the active gel compared to the no treatment and water groups, but generally with lower significance levels than the active gel. This indicates that the moisturizing components in the gel themselves positively affects the oral cavity and plaque variables. The neutralizing effect was found to be strongest for both gels within the first 20 min of the test period. The differences between the active and placebo gel were significant for the normal secretion rate participants but not for the low secretion rate ones. Therefore, the hypothesis was accepted only for the participants with normal secretion rate. One may speculate on the mechanisms of the neutralizing effect of the gel. Although no clinically visible remnants of the gel were found, the gel may act as a barrier and prevent diffusion of sugars and fermentation products into the dental plaque. Rinsing with the nutrition solution without application of buffer gel (no treatment) showed that saliva alone cannot counteract the pH drop. Even if both phosphate and bicarbonate are normally released via saliva, the application of gel is believed to increase the concentration of these substances in the plaque. Dawes [4] showed that the higher the bicarbonate concentration used, the faster the plaque pH return toward neutrality. However, to obtain more pronounced effects of the active gel, increased levels of the buffering components or application of the gel more frequently is suggested.

In this study, individuals participated with either low or normal paraffin-stimulated whole salivary secretion rate. It may be expected that the subjects with low salivary secretion would show an inferior basic defense. After rinsing with nutrition solution (no treatment), which can be compared with a regular intake of fermentable carbohydrates, individuals with low salivary secretion rate showed at all time points a lower plaque pH. This indicates a lower neutralizing effect, probably caused by their lower secretion rate and/or lower salivary buffering capacity. The possibility of the buffering gel to counteract plaque acidogenicity was stronger in the participants with normal secretion, which shows the capacity of saliva to buffer the fermentable breakdown products. Another reason for this stronger effect during higher secretion rate is that a certain amount of saliva is likely needed for the gel components to diffuse into the dental plaque. An improvement of the solubility of the gel may also increase the transport of active substances into the plaque in individuals with low salivary secretion rate. The results of the present study showed that the clinical significance of the buffering gel is primarily found in caries-risk patients with normal secretion rate as a complementary treatment to lower their high risk. A more frequent application may increase the neutralizing effect. The studied gel contains 0.15% NaF, which may strengthen its anticariogenic potential. We investigated the diffusion of fluoride from the gel into the plaque and compared the fluoride retained after gel application with the effect of a rinse with a commercial fluoride rinsing solution with similar concentration (0.2% NaF). Daily use of fluoride mouthrinse was shown to reduce caries risk in patients with hyposalivation [16]. Factors that influence the final plaque fluoride concentration are the initial concentration of fluoride applied, exposure time, flow of saliva, solubility of the agent, and fluoride clearance of the agent [5]. In this study, the fluoride concentration was only evaluated in individuals with normal salivary secretion rate. Five times higher fluoride concentration was found after rinsing with 0.2% NaF solution compared to the gel application. This shows that the fluoride in the gel, in comparison to the mouthrinse, had difficulties to diffuse into the plaque. The present study evaluated the direct preventive effect of the buffering gel on formed plaque. Application during plaque formation where the different ions may be built in the plaque during de novo plaque formation may result in a higher caries-preventive effect and further the reduction of plaque acidogenicity. The effect was studied after a single application of the gel. Another suggestion to increase the preventive power is a more frequent application that may result in an increased retention in the plaque and the depot effect of the included components.

It can be concluded that the application of the active gel during normal salivary secretion rate resulted in generally higher pH values, while this effect could not be seen in the low salivary secretion group. Factors like concentration of buffering agent and solubility of the gel need to be further evaluated to improve the effect.

Acknowledgements This study was supported by grants of The Swedish Patent Revenue Fund for Research in Preventive Dentistry and Colgate Palmolive A/S. We thank Prophylactor AB, Stockholm, Sweden for contributing the gels and Arla Foods, Stockholm, Sweden for the nutrition solution.

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