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## ABSTRACT

Previous *in situ* and *in vitro* studies have demonstrated that the chewing of sucrose-free gum after eating reduces the development of dental caries. To investigate the extrapolation of these findings to the clinical setting, we conducted a two-year study on 547 schoolchildren in Budapest, Hungary. Subjects in the "Gum" group were instructed to chew one stick of a commercially available sorbitol-sweetened chewing gum for 20 minutes after meals, three times daily. The "Control" group was not provided with chewing gum. After two years, the "Gum" group exhibited a 38.7% reduction in incremental caries, excluding white spots, compared with the "Control" group. Including white spots, a corresponding 33.1% reduction was indicated. These results clearly suggest that even in a moderate caries population practicing normal oral hygiene, including the use of fluoride dentifrices, an after-meal gum-chewing regimen can significantly reduce the rate of caries development.

**KEY WORDS:** chewing gum, caries, clinical trial.

# Effect of After-meal Sucrose-free Gum-chewing on Clinical Caries

## INTRODUCTION

In recent years, much research has focused on investigation into the effect of chewing gum use on dental caries. This research has spanned a wide range of studies from *in vitro* laboratory studies to large-scale clinical trials.

Much of this research has fallen into two distinct approaches, each characterized by the nature of the mechanism by which the gum-chewing is hypothesized to affect caries. In the first approach, gum-chewing provides the delivery mechanism for a therapeutic, anti-caries agent, such as fluoride. In those studies, interest must be focused on demonstrating that the presence of the therapeutic agent is the key factor in providing an anti-caries benefit. The second approach characterizes the mechanical and gustatory action of saliva stimulated by the chewing of gum itself as the primary factor in deriving an anti-caries benefit. In those studies, interest should be focused on the use of the product and on chewing itself, and not on the presence or absence of any particular agent in the gum. The present study falls into this latter approach.

It is well-known that the pH of dental plaque drops to highly acidic levels for a period of time following the ingestion of food, thus enhancing the demineralization of teeth and contributing to the development of caries. Further, it is well-known that the chewing of gum increases the salivary flow rate which, in turn, increases the buffering capacity of the saliva (Slack *et al.*, 1964; Edgar and O'Mullane, 1996). For over 14 years, research has been performed to investigate the effect of increased salivary flow on plaque pH, and to demonstrate that an attenuation of the plaque pH decrease which follows the ingestion of food containing refined carbohydrates would correspond to a reduction in the development of dental caries. In particular, numerous studies have been performed which demonstrated this effect when the ingestion of food was followed by the chewing of a sucrose-free gum (Jensen, 1986; Manning and Edgar, 1993). Additionally, studies have been performed which indicate that the chewing of gum after meals both enhances remineralization and stops or prevents demineralization (Leach *et al.*, 1989; Creanor *et al.*, 1992). Thus, all of these studies indicate that the chewing of a sucrose-free gum after meals provides beneficial effects on inhibiting the development of dental caries.

Clinical studies on the anti-caries benefits of the chewing of a sorbitol-containing chewing gum *vs.* non-chewing controls were reported by Möller and Poulsen (1973), Glass (1983), and Mäkinen *et al.* (1995). Confirmation of this benefit in a large-scale clinical trial was also reported by Beiswanger *et al.* (1998). Most of those trials were conducted in areas of high caries incidence.

The purpose of this two-year study is to provide confirmation that the chewing of a sorbitol-containing chewing gum after meals will provide a significant reduction in clinical caries, and that the benefit derived from chewing after meals is applicable to a population that is typical of industrialized societies with moderate caries incidence. Additionally, this study provides measurements of white-spot lesions, to investigate and confirm the *in situ* effect of gum-chewing on remineralization in the long-term clinical setting.

## MATERIALS & METHODS

### Study Population

This two-year clinical study was conducted on a population of elementary schoolchildren in Budapest, Hungary. The protocol and test design for this study were approved by the IRB of the Semmelweis University of Medicine, and the study was carried out under the auspices of the Hungarian Preventive Dentistry Association. Participation in the study was voluntary, and all subjects received regular dental examinations and treatment by the School Dental Services.

The 583 volunteers for participation in this study were recruited from among third-, fourth-, and fifth-grade children (ages 8 to 13) in six public schools. All study participants were required to sign an informed-consent form and to have such a form signed by their parent or guardian as well.

The water supply in Budapest is non-fluoridated. However, most of the study participants regularly used fluoride-containing dentifrices, which are readily available. Most study participants received two meals *per* day (breakfast and lunch) at their schools. The breakfast typically consisted of a beverage, bread, butter, and jam; while the lunch typically consisted of a soup, a main course (usually meat), a beverage (water or juice), and a snack.

Each study participant was assigned to one of two regimen groups. Those in the "Gum" group were required to chew one stick of a commercially available sorbitol chewing gum for 20 min after meals three times a day throughout the duration of the study. (The gum was composed of approximately 65% polyols [sorbitol and mannitol], 30% gum base, and 5% sweeteners and flavors.) Those in the "Control" group did not chew gum after meals. All study subjects maintained their normal regimen of dietary and oral hygiene practices, including any normal habits concerning the use of chewing gum. Other than for the Gum group in this study, gum-chewing was not allowed in the participating schools. Based on regular feedback from the subjects and monitors, it was unlikely that individuals assigned to the Control group electively chose to chew gum after meals during the course of the study.

**Table 1.** Demographic Summary, All Subjects

Examination	Group	Sample Size	Gender (percentage)		Age Summary (yrs)	
			Male	Female	Mean	Range
Baseline	Gum	293	54.1	45.9	9.6	8 – 12
	Control	290	57.3	42.7	9.6	8 – 13
Two-year	Gum	269	53.9	46.1	11.6	10 – 14
	Control	278	56.5	43.5	11.6	10 – 15

**Table 2.** Baseline DMFS Summary<sup>a</sup>

Regimen	n	WHO <sup>b</sup>		Radike <sup>c</sup>	
Gum	269	5.15	± 5.16	1.69	± 2.64
Control	278	5.84	± 5.63	1.94	± 2.85

<sup>a</sup> Mean ± SD. Note that no significant difference was indicated at baseline with respect to either caries parameter.

<sup>b</sup> WHO standard methods and criteria for diagnosing dental caries (WHO, 1977).

<sup>c</sup> Radike criteria for diagnosing dental caries (Radike, 1972).

### Clinical Measurement Criteria

All caries examinations were performed by a single examiner. Examinations were carried out with subjects seated in a dental chair according to the Scheinin *et al.* (1985) modification of the WHO standard methods and criteria (WHO, 1977), under which the measurement scale included the category "initial caries". The examination for dental caries was conducted by means of a plain mouth mirror and an explorer. Transillumination of the teeth with a fiber optics system (FOTI) facilitated the diagnosis of interproximal caries. Only the permanent teeth were scored for the purposes of this study.

For each subject, the number of decayed, missing, or filled surfaces (DMFS) was calculated in two ways: (1) including those surfaces scored as "initial caries" (hereinafter referred to as "incipient caries"), and (2) excluding those surfaces with incipient caries. These two scores are henceforth designated WHO DMFS scores and Radike DMFS scores, respectively (Radike, 1972). The score transitions of each surface between baseline and follow-up examinations (including diagnostic reversals) were used to calculate the *per*-subject incremental WHO and Radike DMFS scores.

### Blinding/Reliability

During the clinical examinations, no information was provided to the examiner as to each subject's assigned treatment group. Gum-chewing was not permitted in the examination area. An independent study monitor was employed to confirm that appropriate blinding techniques were being followed. Examiner reliability was assessed by the performance of repeat examinations on a randomly selected subgroup of 50 study participants, and the calculation of intraclass correlation coefficients.

### Treatment Group Assignment/Gum Use

Subsequent to the baseline caries examinations, treatments were assigned to classrooms within grade levels at each school. Treatments were assigned to a particular grade level within a school only if more than one classroom was available with adequate students for participation. The assignment of treatments to classrooms was performed at random, subject to the requirement that the resulting randomization did not yield treatment groups which differed significantly with respect to baseline caries scores.

Supervised gum-chewing was implemented after both breakfast and lunch in the schools. Unsupervised chewing sessions were performed after evening meals, on weekends, and during the summer. Inventory control and compliance were carefully monitored throughout the study.

### Data Management and Statistical Analyses

Data were analyzed by an analysis of covariance, with baseline DMFS as a covariable. Although the two-year incremental caries scores represented the primary outcome parameters, the one-year scores were also analyzed for in-

formational purposes. All treatment comparisons were performed by means of two-sided statistical hypothesis tests, with a significance level of  $\alpha = 0.05$ . All statistical analyses were performed with SAS (SAS, 1996), version 6.12.

**RESULTS**

**Study Population and Drop-outs**

Of the 583 subjects examined at baseline, 547 (93.8%) presented data after 2 yrs. The demographic summary of subjects who completed the study (Table 1) shows that the treatment groups were well-balanced for gender and age, with slightly more males than females.

No adverse reactions were noted during the study. One child withdrew from the study due to medical reasons unrelated to the study itself.

**Compliance and Reliability**

Based on the return of gum wrappers from out-of-school chewing, compliance was determined to be excellent, with over 93% of all subjects returning more than 90% of their gum wrappers. There were no reports of any compliance difficulties with the supervised, in-school chewing. Additionally, the intra-examiner reliability on the DMFS scores was determined to be excellent, as evidenced by an intra-class coefficient in excess of 0.95.

**Caries Findings**

The baseline DMFS means, for both WHO and Radike caries scores, were slightly higher in the Control group than in the Gum group, although this difference was not statistically significant (Table 2). The use of baseline scores as a covariable in the statistical analyses adjusted for this numerical difference.

The one-year and two-year incremental DMFS scores for both WHO and Radike caries, as well as the results of the statistical analysis comparing the treatment groups with respect to these scores, indicated that when white-spot lesions were considered (WHO), the Gum group exhibited a 41.7% reduction in incremental caries compared with the Control group after 1 yr, and a 33.1% reduction after 2 yrs. When white-spot data were excluded (Radike), a corresponding reduction of 43.6% was noted after 1 yr, and a 38.7% reduction after 2 yrs (Table 3).

The two-year incremental DMFS scores for both WHO and Radike caries, broken down by surface type and by tooth types, indicated that the incremental caries scores for the Gum group were lower in all cases (when subjects reporting data on each indicated

**Table 3.** Incremental DMFS Summary<sup>a</sup> for Subjects Who Completed the Study

Term	Group	n	Not Including White-spot Lesions (Radike <sup>b</sup> Criteria)			% Diff.	Sig.
			Mean	SE	Diff.		
1 yr	Gum	269	0.350	± 0.255	43.6	p = 0.008	
	Control	278	0.621	± 0.027			
2 yrs	Gum	269	0.814	± 0.102	38.7	p = 0.018	
	Control	278	1.327	± 0.105			

  

Term	Group	n	Including White-spot Lesions (WHO <sup>c</sup> Criteria)			% Diff.	Sig.
			Mean	SE	Diff.		
1 yr	Gum	269	0.875	± 0.140	41.7	p = 0.028	
	Control	278	1.502	± 0.146			
2 yrs	Gum	269	1.951	± 0.157	33.1	p = 0.008	
	Control	278	2.914	± 0.162			

<sup>a</sup> Baseline adjusted.  
<sup>b</sup> Radike criteria for diagnosing dental caries (Radike, 1972).  
<sup>c</sup> WHO standard methods and criteria for diagnosing dental caries (WHO, 1977).

surface or tooth type were compared). When white-spot lesions were included (WHO), these differences were statistically significant for interproximal and smooth surfaces, for lateral incisors, and for both first and second molars. When white-spot lesions were not included (Radike), these differences were significant for occlusal surfaces, and for both first and second molars (Table 4).

**DISCUSSION**

The results of this study confirmed previous laboratory and clinical studies which indicated a positive anti-caries effect

**Table 4.** Summary of Two-year Caries Increments by Surface Type and Tooth Type\*

Surface	n	Treatment Group				
		Gum		Control		
		Radike <sup>a</sup> Mean ± SD	WHO <sup>b</sup> Mean ± SD	n	Radike <sup>a</sup> Mean ± SD	WHO <sup>b</sup> Mean ± SD
Smooth	269	0.10 ± 0.48	0.25 ± 0.98	278	0.19 ± 0.53	0.51 ± 1.05
Interproximal	269	0.34 ± 1.03	1.15 ± 1.68	278	0.45 ± 0.93	1.66 ± 1.93
Occlusal	269	0.33 ± 0.72	0.51 ± 1.02	278	0.65 ± 1.06	0.83 ± 1.34

  

Tooth Type	n	Radike <sup>a</sup> Mean ± SD	WHO <sup>b</sup> Mean ± SD	n	Radike <sup>a</sup> Mean ± SD	WHO <sup>b</sup> Mean ± SD
Central incisor	269	0.07 ± 0.42	0.19 ± 0.56	278	0.07 ± 0.34	0.26 ± 0.64
Lateral incisor	268	0.04 ± 0.23	0.15 ± 0.53	278	0.09 ± 0.34	0.28 ± 0.61
Cuspid	255	0.00 ± 0.00	0.00 ± 0.06	255	0.00 ± 0.00	0.01 ± 0.13
1st bicuspid	258	0.04 ± 0.31	0.09 ± 0.40	260	0.08 ± 0.43	0.17 ± 0.59
2nd bicuspid	223	0.08 ± 0.50	0.13 ± 0.60	227	0.11 ± 0.52	0.22 ± 0.69
1st molar	269	0.45 ± 0.87	0.93 ± 1.55	278	0.68 ± 1.08	1.41 ± 1.73
2nd molar	191	0.15 ± 0.46	0.65 ± 1.15	203	0.40 ± 0.77	0.96 ± 1.33

\* For each surface or tooth type, the summary is calculated only on those subjects who provided data (as indicated in the sample size column). As a result, these reported means will not sum to the whole-mouth means provided in Table 3.  
<sup>a</sup> Radike criteria for diagnosing dental caries (Radike, 1972).  
<sup>b</sup> WHO standard methods and criteria for diagnosing dental caries (WHO, 1977).

of the chewing of a sucrose-free gum after meals. The magnitude of this effect, a 38.7% reduction in baseline adjusted caries increment as measured by the Radike criteria or a 33.1% reduction in baseline adjusted caries increment as measured by WHO criteria, indicates that this regimen of chewing sucrose-free gum after meals can provide significant reduction of caries as an adjunct to regular oral hygiene.

The hypothesis that the act of chewing is a predominant factor in this study can also be supported by the chew time, which was at least 20 min. This is sufficient time for almost all of the soluble ingredients (*i.e.*, flavors and sweeteners) to be chewed out of the gum, leaving the action of chewing the remaining insolubles, and its incumbent stimulation of saliva, as the dominant factor in effecting the neutralization of plaque acids, and the remineralization of early surface lesions. The after-meal timing of the gum-chewing aids in providing this benefit at a time when the risk of acid dissolution of tooth surfaces is at its greatest potential.

The clinical significance of these results is supported by an extrapolation of the standards defined in the American Dental Association Guidelines for comparison of the anti-caries effectiveness of fluoride dentifrices (American Dental Association, 1988; Proskin *et al.*, 1995). These guidelines provide an accepted means of comparison based on percentage differences of caries increments. In particular, they state that a 10% difference in the caries rates associated with two treatments is sufficient to establish the anti-caries superiority of one dentifrice over another. When this clinical benchmark was applied to the present setting, since the anti-caries advantage presented by the gum-chewing group over the control group was well in excess of 10%, satisfying requirements outlined in the American Dental Association guidelines, this study supports the conclusion that the chewing-gum regimen provides a superior, clinically significant anti-caries benefit.

The fact that this effect was observed in an industrialized nation with a relatively moderate caries incidence rate is particularly significant. The slowly declining caries rate in Hungary (from 5.0 to 3.8 DMFT in 12-year-olds between 1985 and 1996) is consonant with those which prevail in other developed nations (Szöke and Petersen, 2000). Although many long-term caries clinical trials are conducted in areas of high caries incidence, so that there will be sufficient disease for an effect of the agent or product to be discerned, this study, by contrast, was conducted in a more "typical" European environment, in which the caries rate is moderate, and adequate dental education and care are available. Thus, the results of this study clearly demonstrate that a chewing regimen can be effective not only in a high-caries environment, as has been demonstrated previously (Mäkinen *et al.*, 1995; Beiswanger *et al.*, 1998), but also in areas where there is significantly less disease. These results suggest that even in a moderate caries area in which the population practices normal oral hygiene, a gum-chewing regimen has great potential for providing a means to reduce the rate of caries development significantly.

The Control group was instructed not to chew gum during this study. However, there is no way to document gum-chewing by either group during their time outside of school. To the extent that any subjects in the Control group

did chew gum outside of school on a regular basis, this would further support the importance of chewing gum after eating to maximize the anti-caries benefit provided by such behavior as exhibited in this study.

These results could have direct application to the general dental health of the community. The amount of gum chewed in the treatment regimen, 3 sticks *per* day after meals, is not extraordinarily high or unreasonable to expect, especially in younger people. This amount of gum is chewed by the general public, and could be instituted in a controlled program in schools.

Consideration should be given to the implementation of after-meal gum-chewing programs, as adjuncts to regular dental hygiene, on both organizational and individual levels, as the best means of providing the public with the anti-caries benefits associated with such a regimen.

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