# **Original Paper**

**Caries Research** 

Caries Res 2007;41:93–101 DOI: 10.1159/000098041 Received: February 16, 2006 Accepted after revision: July 20, 2006

# **Chlorhexidine and Preservation of Sound Tooth Structure in Older Adults**

**A Placebo-Controlled Trial** 

C.C.L. Wyatt<sup>a</sup> G. Maupome<sup>b</sup> P.P. Hujoel<sup>c</sup> M.I. MacEntee<sup>a</sup> G.R. Persson<sup>c, d</sup> R.E. Persson<sup>c, d</sup> H.A. Kiyak<sup>c</sup>

<sup>a</sup>University of British Columbia, Vancouver, Canada; <sup>b</sup>Indiana University, Indianapolis, Ind., and <sup>c</sup>University of Washington, Seattle, Wash., USA; <sup>d</sup>University of Bern, Bern, Switzerland

#### **Key Words**

Chlorhexidine, caries prevention · Coronal caries · Gerodontology · Root caries

#### Abstract

The Trial to Enhance Elderly Teeth Health (TEETH) was designed to test the impact of regular rinsing with a 0.12% chlorhexidine (CHX) solution on tooth loss, and the causes of tooth loss (caries, periodontal disease and trauma) were also investigated. This paper reports on the effectiveness of a 0.12% CHX solution for controlling caries using a tooth surface (coronal and root) survival analysis. A total of 1,101 low income elders in Seattle (United States) and Vancouver (Canada), aged 60-75 years, were recruited for a double-blind clinical trial and assigned to either a CHX (n = 550) or a placebo (n = 551) mouth rinse. Subjects alternated between daily rinsing for 1 month, followed by weekly rinsing for 5 months. All sound coronal and root surfaces at baseline were followed annually for up to 5 years. At each follow-up examination, those tooth surfaces with caries, restored, or extracted were scored as 'carious'. The hazard ratio associated with CHX for a sound surface to become filled, decayed, or extracted was 0.87 for coronal surfaces (95% confidence in-

# KARGER

Fax +41 61 306 12 34 E-Mail karger@karger.ch www.karger.com © 2007 S. Karger AG, Basel 0008-6568/07/0412-0093\$23.50/0

Accessible online at: www.karger.com/cre terval: 0.71–1.14, p = 0.20) and 0.91 for root surfaces (95% confidence interval: 0.73–1.14, p = 0.41). These findings suggest that regular rinsing with CHX does not have a substantial effect on the preservation of sound tooth structure in older adults. Copyright © 2007 S. Karger AG, Basel

Tooth loss, caries and periodontitis continue to be significant problems among underserved populations of older adults. While much of the emphasis to find clinical and public health approaches to reducing caries experience has been focused on younger populations, there is a need for low-cost, effective interventions in the substantial numbers of adults who retain natural teeth.

Several strategies have been used to prevent or reduce caries in children, mostly with fluoridated toothpaste, mouth rinses or dental varnishes [Truman et al., 2002; Marinho et al., 2003]. The use of chlorhexidine (CHX) as part of the clinical armamentarium for treating at-risk children has received attention. For example, van Rijkom et al. [1996] reported a 46% inhibiting effect of CHX on caries incidence in young populations. However, a systematic review of 22 studies (1995–2003 publications) found inconclusive effects of CHX on caries in adults [Twetman, 2004]. This despite the fact that most of the studies reviewed had delivered CHX in concentrations higher than 0.12%, and mostly in varnish form rather than a rinse. Twetman [2004] also found no evidence that CHX reduced root caries rates in frail elders or among patients with dry mouth; nor was it beneficial for coronal caries. Apparently, most studies have not had the statistical power to show the effectiveness of antimicrobial mouth rinses in adults at high risk for caries [Caufield et al., 2001].

A daily mouth rinse with 0.12% CHX solution for 12 weeks reduced the numbers of mutans streptococci and lactobacilli in the saliva of elders at particular risk to caries [Persson et al., 1991], but the significance of this reduction in bacterial counts to the prevention of caries has not been established. Results from an earlier clinical trial laid the groundwork for the present study [Kiyak, 1995; Hujoel et al., 1997a, 1997b; Persson et al., 1998a, 1998b]. Building on the assertion by Bader et al. [2001] that the evidence supporting CHX for caries prevention 'is suggestive but not conclusive', the objective of this doubleblind randomized clinical trial was to assess the clinical effectiveness of a daily mouth rinse with 15 ml of 0.12% CHX gluconate, compared to a placebo for reducing the incidence of dental caries in a community-dwelling elderly population.

#### **Materials and Methods**

The 'Trial to Enhance Elders' Tooth and Oral Health' (TEETH) was approved by the Institutional Review Boards of the University of Washington in Seattle, Washington, and the University of British Columbia in Vancouver.

#### Study Design and Participation

Subjects were enrolled into this placebo-controlled clinical trial if they were aged between 60 and 75 years, had a minimum of 4 natural teeth, no preventive dental care in the preceding 2 or more years and a self-efficacy score >65% at baseline [Wiedenfeld and Kiyak, 1991; Kiyak, 1992]. Subjects were randomly assigned to the CHX or placebo rinse groups, even if they were living with, or the sibling of, another research participant. The SAS (SAS Institute Inc., Cary, N.C., USA) 'ranuni' function generated the random allocation sequence, stratified by site, and assigned ID numbers to subjects at each site using an Internet-based data-entry program.

Contact information was updated annually for each subject, including names of family and friends who would know how to contact them. During the early subject recruitment phase in the first year of the trial, a Data and Safety Monitoring Board (DSMB) was established. The DSMB approved the original protocol and changes to the protocol during the first two years, and they reviewed annual reports on attrition, adverse events and progress on data collection. Both participants and clinicians who evaluated treatment outcomes were blinded as to group assignment.

### Sample Size Calculation

Based on the findings of our previous 3-year clinical trial, we projected 10% attrition and 10% noncompliance rates per year, a tooth loss rate of 24.4 teeth per 1,000 tooth years, and an overdispersion parameter of 5.2. The trial was designed to have 80% power to detect a 35% reduction in tooth mortality, using a 2-sided test with alpha = 0.05 [Friedman et al., 1998]; this resulted in a sample size estimate of 490 subjects per group. On the recommendation of the DSMB, the event rate and efficacy of treatment were recalculated and the sample size increased to 550 per group.

### Participant Contact Procedure and Follow-Up

During a 2.5-hour baseline visit, the protocol was read in each subject's native language to obtain consent. At each yearly visit a 30-min interview on health behaviors and psychological well-being was completed. All subjects had their teeth cleaned by a dental hygienist, both subgingivally and supragingivally at baseline, but only supragingivally in subsequent visits. No specific instructions in oral hygiene were provided. Health histories and medication information were recorded at each visit and subjects brought or mailed information about their current medications in order to validate medication use. Dentists conducted exams immediately following the cleaning, using criteria and procedures from the NIDR Adult Dental Health Survey [NIDR, 1991].

Following the completion of annual clinical visits and interviews, subjects were given a report in their native language of any oral condition requiring treatment. Subjects received a financial token each year, increasing from USD 5 at baseline to USD 30 for those who completed the 5-year follow-up appointment. Parking and public transportation fees were reimbursed.

## Standardization of Examiners

All three dental examiners were trained in the use of these clinical measures by an examiner from the NIDR and NCHS Adult Oral Health epidemiological studies ('national examiner'). The examiners were calibrated on measuring tooth loss, root and coronal caries, pocket depth and recession initially with the national examiner, and in each subsequent year with the primary dentist at the University of Washington site, who served as the 'gold standard'. Calibration involved examiners performing tooth surface level assessments, any discrepancies in surface calls with the national examiner were re-examined, discussed, and consensus reached among the examiners. A random selection of ten subjects were re-examined after one week to determine each examiner's repeatability of the tooth surface scores for coronal and root caries. Surfaces were scored as sound, decayed, filled, recurrent decay, arrested decay, and extracted.

## Clinical/Research Intervention

Our previous clinical trial showed that elders on a weekly CHX rinsing regimen demonstrated a modest decline in mutans streptocci and lactobacilli counts [Kiyak et al., 1995]. A pilot study testing the antibacterial effects of a daily CHX rinsing regimen over 1 month resulted in declines of microorganisms to imperceptible levels, but there was a gradual increase after 1 month. Therefore we administered a combination of daily rinsing for 1 month, followed by weekly rinsing for 5 months in the TEETH. This sequence was repeated every 6 months for 5 years.

The active rinse consisted of a 0.12% CHX rinse (Periogard<sup>®</sup>, purchased from Colgate-Palmolive, New York, N.Y., USA). The Investigational Drug Services of the University of Washington developed the formula for the placebo rinse, with quinidine, alcohol and a color additive similar to the color of the CHX rinse; this formula was used at both research sites. The pharmacists placed both the CHX and placebo in identical brown bottles labeled with a date of expiration and lot numbers.

After each subject was enrolled and examined, they were given their first 6-month supply of the active or placebo rinses. Every 6 months a package containing two bottles of rinse (labeled #1 for daily rinsing and #2 for weekly rinsing), accompanied by a dosespecific cap, was mailed to each subject. The bottle labels instructed participants how to swish the rinse for 30 s without swallowing it. Bottle #1 instructed subjects to rinse once a day for 1 month, beginning on the date specified on that bottle until the starting date marked on bottle #2. They were then to dispose of the first bottle and switch to the second, which was used weekly for 5 months. More specifically, subjects were instructed to maintain the same 'rinsing day' each week for 5 months.

In order to assure adherence, each subject was telephoned by project 'callers' within one week after the rinses were mailed. Callers were blind to group assignment and could speak to participants in their native language. They checked on whether the mailed packages had arrived, and reminded subjects to use the rinses as instructed, and answered subjects' queries and concerns. Callers contacted participants on a monthly schedule to reinforce the rinse schedule and to record whether the subject complained about the rinsing regimen or taste. A compliance log was thus generated for each subject. Every 6 months, callers asked if any teeth had been lost, and if so, the name of the dentist who performed the extraction was obtained. This information was verified at the next annual visit and the extracting dentist was contacted to determine the date and reason for extracting the tooth.

## Statistical Methods

The primary outcome of the present analysis was the probability of transition from sound to non-sound (i.e. 'event') in each treatment group. An event was defined as a transition from a sound surface to a surface that became extracted, filled or decayed. Two secondary analyses were performed: an analysis where surfaces that were extracted without an intervening state of decayed or filled were censored, and an analysis where surfaces that were extracted or filled without ever being called decayed at any time were censored. The time at risk for all three event definitions was calculated. The primary test statistics for evaluating treatment effects was based on the proportional hazards model [Robins et al., 1995; Schafer, 1997]. Using a time-to-event analysis increases the efficiency and sensitivity of the statistical analysis over analysis of variance methods [DeRouen et al., 1995; Beck et al., 1997; Spencer, 1997; Hannigan et al., 2001, 2004; Mancl et al., 2004]. The SAS 'phreg' and 'genmod' procedures were used to estimate hazard ratios and rates of transition from sound to nonsound surfaces.

Table 1. Kappa statistics for caries inter-examiner reliability

Kappa	Year 1	Year 2	Year 3	Year 4
Sound surfaces	0.91	0.95	0.99	0.99
Decayed surfaces	0.99	0.98	0.98	0.99

## Results

Kappa statistics for inter-examiner reliability for sound and decayed surfaces ranged between 0.91 and 0.99 (table 1).

# Descriptive Results

A total of 1,101 subjects were enrolled, 701 in Seattle and 400 in Vancouver. Subjects were on average 67.5 years old (95% CI: 67.1–67.7). Most ethnic and cultural minorities in the Seattle sample were Chinese, with a more equal mix of Chinese and Punjabi participants in Vancouver. No differences emerged between the CHX and placebo group on any demographic or clinical parameters at baseline; that is, the groups were comparable with respect to age, gender, ethnic distribution, number of teeth and percent of sound, filled or decayed surfaces.

Over the 5-year course of the TEETH, 273 elders (24.8%) did not complete all 5 follow-up visits; 57 (5.2%) died, and 15 (1.4%) became edentate. This was lower than the 10% attrition rate per year that had been projected at baseline. Comparisons revealed attrition rates of 33% in the CHX group and 29% in the placebo group (p < 0.05). No adverse events, including anaphylactic reactions, rashes or gastro-intestinal disturbances, were reported by subjects.

# Baseline Oral Health Status

At baseline, an average of 75.2 coronal surfaces (95% CI: 72.6–77.9) were sound in the CHX group at baseline, 74.0 (95% CI: 71.4–76.5) in the placebo group. The corresponding figures for root surfaces were 26.8 (95% CI: 25.5–28.1) and 26.9 (95% CI: 25.7–28.2), respectively. Fewer coronal surfaces were decayed or filled: 32.8 (95% CI: 31.0–34.6) in the CHX group and 34.6 (95% CI: 32.8–36.4) surfaces in the placebo group. Even fewer root surfaces were decayed or filled at baseline: 4.4 (95% CI: 4.0–4.8) and 4.8 (95% CI: 4.3–5.2), respectively.

# Survival Analysis

A total of 74,630 coronal surfaces (68%) and 26,533 root surfaces (30%) were caries-free at the start of the study. Only 5% of the coronal and 13% of the root sur-

/ersitätsbibliothek Bern .92.9.57 - 1/14/2014 8:04:32 PN



**Fig. 1.** Coronal surface survival (% sound from baseline).





**Fig. 2.** Root surface survival (% sound from baseline).

**Fig. 3.** Coronal surface survival (% sound from baseline) excluding extractions.

faces became carious, were restored or were lost over the course of this 5-year study. The survival analysis showed that 91% of the coronal surfaces remained sound in the CHX group and 89% in the placebo group (fig. 1). The

percentage of sound root surfaces was 86% for the CHX and 85% for the placebo group (fig. 2). When the extracted teeth were eliminated from the analysis, the 5-year survival was 95% CHX and 94% placebo for coronal



Fig. 4. Root surface survival (% sound from baseline) excluding extractions.

Table 2. Annual caries attack rates per coronal surface

Agent/surface	Caries lesions	Total follow-up years	Coronal caries attack rate (CI)
Chlorhexidine			
Buccal	796	31,962.23	2.49 (2.17-2.87)
Distal	609	31,099.19	1.96 (1.68-2.28)
Lingual	697	34,928.26	1.99 (1.72-2.31)
Mesial	593	32,532.59	1.82 (1.56-2.13)
Occlusal	496	29,843.19	1.66 (1.39-1.98)
All	3,191	160,365.47	1.99 (1.73–2.29)
Placebo			
Buccal	852	31,450.33	2.71 (2.27-3.05)
Distal	679	30,626.90	2.22 (1.82-2.55)
Lingual	754	34,431.38	2.19 (1.80-2.49)
Mesial	652	32,111.09	2.03 (1.67-2.35)
Occlusal	593	28,722.48	2.06 (1.65-2.38)
All	3,530	157,342.17	2.24 (1.86-2.54)

Table 3. Annual caries attack rates per root surface

Agent/surface	Caries lesions	Total follow-up years	Root caries attack rate (CI)
Chlorhexidine			
Buccal	616	19,075.16	3.23 (2.89-3.86)
Distal	334	9,236.45	3.62 (3.26-4.49)
Lingual	431	18,266.88	2.36 (2.05-2.87)
Mesial	275	8,422.49	3.26 (2.87-4.20)
All	1,656	55,000.99	3.01 (2.72-3.61)
Placebo			
Buccal	646	18,927.11	3.41 (2.90-3.94)
Distal	359	8,957.87	4.01 (3.41-4.99)
Lingual	460	18,315.72	2.51 (2.05-3.01)
Mesial	323	8,228.53	3.92 (3.21-4.88)
All	1,788	54,429.23	3.28 (2.79–3.86)

(fig. 3) and 95% CHX and 94% placebo for root (fig. 4) surfaces.

The annual coronal surface transition rate was 1.98 transitions per 100 surfaces (95% CI: 1.72-2.29) for the CHX group and 2.24 for the control group (95% CI: 1.86-2.54) for the placebo group (table 2). The annual root surface transition rate was 3.01 (95% CI: 2.72-3.61) for the CHX group and 3.28 (95% CI: 2.78-3.86) for the placebo group (table 3). The hazard ratio for a transition from sound to restored, decayed or extracted associated with the CHX group was 0.88 for coronal surfaces (95% CI: 0.71-1.08, p = 0.21) and 0.92 for root surfaces (95% CI: 0.74-1.14, p = 0.42) (table 4).

## Subgroup Analyses

When the extracted surfaces were censored, the annual transition for coronal surface was 0.96 for the CHX group and 1.16 for the placebo group (table 5). The annual transition rate for root surfaces was 1.08 for the CHX group and 1.18 for the placebo group (table 6). The hazard ratio for a transition from sound surface to a filling or decay associated with CHX was 0.85 for coronal surfaces (95% CI: 0.70-1.03, p = 0.11) and 0.96 for root surfaces (95% CI: 0.78–1.18, p = 0.68) (table 4). When the extracted and filled teeth were censored, the hazard ratio for a transition from sound to decayed associated with CHX was 0.92 for coronal surfaces (95% CI: 0.69–1.23, p = 0.59) and 0.97 for root surfaces (95% CI: 0.70-1.33, p = 0.83) (table 4).

niversitätsbibliothek Bern 30.92.9.57 - 1/14/2014 8:04:32 PN

**Table 4.** Hazard ratios (HR) forpreserving sound tooth structureassociated with CHX

	Decayed, filled or lost <sup>1</sup>	Decayed or filled <sup>2</sup>	Decayed <sup>3</sup>
HR (95% CI)			
Crown	0.88 (0.71 - 1.08) p = 0.21	0.85 (0.70 - 1.03) p = 0.11	0.92 (0.69-1.23) p = 0.59
Root	0.92 (0.74-1.14) p = 0.42	p = 0.68	p = 0.83
CHX, at risk, n			
Crown	3,218/41,382	1,668/41,383	325/41,383
Root	1,656/14,740	653/14,740	314/14,740
Placebo, at risk, n			
Crown	3,555/40,750	1,957/40,750	352/40,750
Root	1,788/14,832	714/14,832	336/14,832

<sup>1</sup> An event was the first transition from a sound surface to a state of decay, filling, or missing.

<sup>2</sup> An event was the first transition from a sound surface to a state of decay or filling. If a surface transitioned from sound to missing without an intervening state of decay or filling, it was censored.

<sup>3</sup> An event was the transition from sound to decay at any time. If a surface was scored as filled or missing without ever being diagnosed as decayed, it was censored.

#### Discussion

The present study failed to identify an effect of regular CHX rinsing on the preservation of sound tooth structure on either the roots or the crowns of teeth in low-income older adults with irregular access to professional dental care and a history of poor home care. In addition, when surfaces that were lost or filled during the study were excluded from the analyses, and only those teeth on which an examiner-diagnosed decayed status was observed were considered, there was no beneficial effect of CHX on the preservation of sound tooth structure. This lack of a beneficial effect may reflect the lack of an effect of CHX on preserving sound tooth structure.

In this elderly population, loss of sound coronal or root tooth structure may be the result of internal or external caries processes, restorative procedures aimed at increased retention of the restorative material, or extractions for a variety of reasons including caries. A positive caries diagnosis by a study clinician was only possible for roughly 10% of the sound coronal surfaces that became missing, filled or decayed. Similarly, a positive diagnosis of caries was possible for roughly only 30% of root surfaces that become missing, filled or decayed during the study. Disentangling these different reasons for losing **Table 5.** Annual caries attack rates per coronal surface (excluding extractions)

Caries lesions	Total follow-up years	Coronal caries attack rate (CI)
448	31,962.23	1.40 (1.18-1.67)
293	31,099.19	0.94 (0.79–1.11)
312	34,928.26	0.89 (0.76-1.05)
271	32,532.59	0.83 (0.70-0.99)
225	29,843.19	0.75 (0.62-0.92)
1,549	160,365.47	0.97 (0.84–1.11)
484	31,450.33	1.54 (1.32–1.81)
358	30,626.90	1.17 (0.99–1.39)
371	34,431.38	1.08 (0.91-1.28)
329	32,111.09	1.02 (0.86-1.22)
294	28,722.48	1.02 (0.83-1.26)
1,836	157,342.17	1.17 (1.01–1.35)
	Caries lesions 448 293 312 271 225 1,549 484 358 371 329 294 1,836	Caries lesionsTotal follow-up years44831,962.2329331,099.1931234,928.2627132,532.5922529,843.191,549160,365.4748431,450.3335830,626.9037134,431.3832932,111.0929428,722.481,836157,342.17

sound tooth structure can be difficult to establish since it was often difficult to determine why a tooth was extracted, whether a tooth that was extracted during the study had caries at the time of extraction, and whether a

**Table 6.** Annual caries attack rates perroot surface (excluding extractions)

Agent/surface	Caries lesions	Total follow-up years	Root caries attack rate (CI)
Chlorhexidine			
Buccal	299	19,075.16	1.56748 (1.35436-1.94752)
Distal	134	9,236.45	1.45077 (1.20066-1.96491)
Lingual	90	18,266.88	0.49269 (0.37696-0.68201)
Mesial	76	8,422.49	0.90235 (0.70072-1.31410)
All	599	55,000.99	1.08907 (0.95729-1.34420)
Placebo			
Buccal	284	18,927.11	1.50049 (1.28305-1.85133)
Distal	149	8,957.87	1.66334 (1.45600-2.14227)
Lingual	115	18,315.72	0.62788 (0.51217-0.81204)
Mesial	96	8,228.53	1.16667 (0.94911-1.58517)
All	644	54,429.23	1.18319 (1.05425-1.42607)

caries process that started on one tooth surface extended to involve another tooth surface, or what decisions processes were involved when a dentists replaced a restoration, and, whether recurrent decay was observed and treated when fillings were removed.

Such problems are largely absent when evaluating caries attack rates in children where most of the decay present is primary decay, and where extractions for reasons other than decay are unusual. In an elderly population, such as the one examined in this clinical trial, it is more difficult to measure the decay progression, especially when the treating dentists are in the community and no information on their observations during restorative treatment is available. This challenge was addressed by evaluating the results of three analyses that provide different measures of the caries process. First, the primary analysis was to consider any transition from a sound to a non-sound surface as a measure of caries. This approach may be most appropriate when considering treatment efficacy since a primary goal for a patient is largely to maintain sound tooth structure. A secondary analysis was to censor any surfaces lost or extracted during the study from the analyses. This approach may offer some greater certainty that only true caries events are counted, but is biased if teeth were lost because of an undiagnosed caries process or if CHX affected tooth loss through mechanisms other than clinical caries. Finally, a purist approach is to consider an analysis limited to only those surfaces where a transition from sound to carious was diagnosed by the study clinicians, and to censor any surfaces that were filled or lost during the follow-up. This last analysis is biased if caries was the cause for a surface to be restored

or extracted, or if treatment is causally related to the loss of sound surfaces. The primary approach selected is most appropriate since no assumptions are made regarding the causal relationships that occur between the treatments and the loss of sound tooth surfaces. The development of more appropriate clinical caries measures in the elderly may be worthwhile. In particular, the use of teeth, as opposed to surface, may offer advantages for a heavily restored elderly population.

The reported caries attack rate for older adults is similar, although non-uniformity in the definition of caries and the length of the studies pose problems for comparisons. The annual coronal caries increment rate was 1.6 surfaces (Caucasian participants) and 0.8 surfaces (African-American participants) per 100 at-risk surfaces for subjects followed over 3 years in the Piedmont 65+ Dental Study; caries was defined as decayed and filled surfaces, decayed root fragments and crowned surfaces [Drake et al., 1997]. In another study, the mean annual root caries surface incidence for rural Iowans over the age of 65 years was 1.4 for 70- to 74-year-olds, 1.9 for 75- to 79-year-olds, and 2.2 for those older than 80 years; the annual coronal caries surface incidence was 0.8 surfaces for all ages [Hand et al., 1988]. Another 74 elderly Iowans followed for 9-11 years had annualized coronal and root surface increments of 2.13 and 0.80 [Hamasha et al., 2005]. Looking at the larger picture through a meta-analytic approach, increments were more conservative but still detectable: nine studies reported root caries incidence in older adults (over the age of 45 years), which determined an annual increment of 0.47 surfaces (95% CI: 0.34–0.61) [Griffin et al., 2004]. A similar approach

/ersitätsbibliothek Bern .92.9.57 - 1/14/2014 8:04:32 PN based upon four North American studies to determine the annual caries attack rate yielded 1.43 surfaces per 100 (95% CI: 1.0–1.9) or one new carious surface per person per year for adults over the age of 60 years living independently [Griffin et al., 2005].

The present results failed to identify a significant effect of the CHX rinse on incident caries experience. Such negative results add to the body of knowledge on effective preventive tools available to the dental practitioner. The results specifically addressed the preventive impact of a well-known preventive adjunct that had not been tested under stringent conditions in community-dwelling adults in North America. While we believe that the trends reported in the present manuscript are an accurate description of the preventive potential on caries of the CHX rinse under these utilization conditions, some methodological limitations apply to the findings. Among some of these limitations, it is possible that our placebo mouth rinse had a treatment effect since it contains quinidine. Banting et al. [2000] found no difference between the active 10% CHX varnish and a sham varnish that contained quinine hydrochloride for annual caries incidence. The active varnish was significantly different for total and root caries increment but not for coronal caries.

Studies testing the efficacy and effectiveness of mouth rinses in reducing caries incidence have been reported for older adults. Wyatt and MacEntee [2004] found that a 0.2% sodium fluoride rinse was significantly more effective in reducing the incidence of caries over two years than a 0.12% CHX rinse for elderly long-term care hospital residents. The coronal caries increment over two years was 0.3 (SD 2.3) for the CHX group, 0.4 (SD 2.5) for the fluoride group, and 0.8 (SD 2.4) for the placebo group. The root caries increment over two years was 2.7 (SD 5.3) for the CHX group, 0.3 (SD 3.1) for the fluoride group, and 2.2 (SD 3.8) for the placebo group. A study on the effectiveness of 10% CHX varnish for adults (n = 236) with previous caries experience and xerostomia showed a 25% reduction in caries increment; 41% reduction in root caries, and 14% for coronal caries [Banting et al., 2000]. A mean caries attack rate of 0.23 surfaces per 100 surfaces at risk was determined for all subjects.

The present results are important because the older adults in this study represent the broader population of community-dwelling adults who lack dental insurance or are irregular dental attendees in North America. Further research testing other preventive regimes to address caries risk in older adults is clearly needed.

### Acknowledgments

The authors would like to express their appreciation to the clinical research staff at both research sites, whose professionalism and rapport with research participants helped to retain so many of them for the full five years. We also appreciate the statistical work on the manuscript by Dr. David Yamaguchi and Ms. Lingmei Zhou.

The authors also acknowledge the contributions of DSMB members to the TEETH clinical trial: Dr. James Beck (University of North Carolina), epidemiologist and chair, Dr. Kathryn Atchison (University of California at Los Angeles), specialist in public health and geriatric dentistry; Dr. Ralph Katz (New York University), cariologist; Dr. Raul Garcia (Boston University), periodontist; Dr. Stuart Gansky (University of California at San Francisco), biostatistician, and Dr. Arthur Schafer (University of Alberta), medical ethicist. NIDCR representatives to the DSMB were Drs. Margo Adesanya, Norman Braveman and Richard Mowery.

This research was supported by NIDCR grant number RO1 DE12215.

#### References

- Bader JD, Shugars DA, Bonito AJ: Systematic reviews of selected dental caries diagnostic and management methods. J Dent Educ 2001;65: 960–968.
- Banting DW, Papas A, Clark DC, Proskin HM, Schultz M, Perry R: The effectiveness of 10% chlorhexidine varnish treatment on dental caries incidence in adults with dry mouth. Gerodontology 2000;17:67–76.
- Beck JD, Lawrence HP, Koch GG: Analytic approaches to longitudinal caries data in adults. Community Dent Oral Epidemiol 1997;25: 42–51.
- Caufield PW, Dasanayake AP, Li Y: The antimicrobial approach to caries management. J Dent Educ 2001;65:1091–1095.

- DeRouen TA, Hujoel PP, Mancl LA: Statistical issues in periodontal research. J Dent Res 1995;74:1731-1737.
- Drake CW, Beck JD, Lawrence HP, Koch GG: Three-year coronal caries incidence and risk factors in North Carolina elderly. Caries Res 1997;31:1–7.
- Friedman LM, Furberg CD, DeMets DL: Fundamentals of Clinical Trials, ed 3. New York, Springer, 1998.
- Griffin SÖ, Griffin PM, Swann JL, Zlobin N: Estimating rates of new root caries in older adults. J Dent Res 2004;83:634–638.
- Griffin SO, Griffin PM, Swann JL, Zlobin N: New coronal caries in older adults: implications for prevention. J Dent Res 2005;84: 715–720.
- Hamasha AA, Warren JJ, Hand JS, Levy SM: Coronal and root caries in the older Iowans:
  9- to 11-year incidence. Spec Care Dentist 2005;25:106–110.
- Hand JS, Hunt RJ, Beck JD: Coronal and root caries in older Iowans: 3-month incidence. Gerodontics 1988;136–139.
- Hannigan A, O'Mullane DM, Barry D, Schafer F, Roberts AJ: A re-analysis of a caries clinical trial by survival analysis. J Dent Res 2001;80: 427–431.

Wyatt/Maupome/Hujoel/MacEntee/

Persson/Persson/Kiyak

- Hannigan A: Using survival methodologies in demonstrating caries efficacy. J Dent Res 2004;83(suppl C):C99-C102.
- Hujoel PP, Powell LV, Kiyak HA: The effects of simple interventions on tooth mortality: findings in one trial and implications for future studies. J Dent Res 1997a;76:867–874.
- Hujoel PP, Leroux BG, DeRouen TA, Powell LV, Kiyak HA: Evaluating the validity of probing attachment loss as a surrogate for tooth mortality in a clinical trial on the elderly. J Dent Res 1997b;76:858–866.
- Kiyak HA: Self-efficacy as a predictor of oral health change (abstract). J Dent Res 1992;71: abstract 750.
- Kiyak HA: Evaluation of Cost-Effective Preventive Regimens for High Risk Older Adults. Final Report to NIDCR. Contract No. N01-DE12586. 1995.
- Mancl LA, Hujoel PP, DeRouen TA: Efficiency issues among statistical methods for demonstrating efficacy of caries prevention. J Dent Res 2004;83(suppl C):C95–C98.
- Marinho VCC, Higgins JPT, Logan S, Sheiham A: Fluoride varnishes for preventing dental caries in children and adolescents. Cochrane Database Syst Rev 2003;(3):CD002284.

- NIDR: Oral Health Surveys of the National Institute of Dental Research: Diagnostic Criteria and Procedures. Epidemiology and Oral Disease Prevention Program. Bethesda, NIH Publication, Number 91/2870. 1991.
- Persson RE, Persson GR, Kiyak HA, Powell LV: Oral health and medical status in dentate low income persons. Spec Care Dent 1998a;18: 70–77.
- Persson RE, Persson GR, Kiyak HA, Powell LV: Periodontal effects of a biobehavioral prevention program. J Clin Periodontol 1998b; 25:322–329.
- Persson RE, Truelove EL, LeReshe L, Leresche S, Robinovitch MR: Therapeutic effects of daily or weekly chlorhexidine rinses on oral health of a geriatric population. Oral Surg Oral Med Oral Pathol 1991;72:184–191.
- Robins JM, Rotnitzky A, Zhao LP: Analysis of semiparametric regression models for repeated outcomes in the presence of missing data. J Am Stat Assoc 1995;90:106–121.
- Schafer JL: Analysis of incomplete multivariate data. London, Chapman & Hall, 1997.

- Spencer AJ: Skewed distribution new outcome measure. Community Dent Oral Epidemiol 1997;25:52–59.
- Truman BI, Gooch BF, Sulemana I, Gift HC, Horowitz AM, Evans CA, et al: Reviews of evidence on interventions to prevent dental caries, oral and pharyngeal cancers, and sports-related craniofacial injuries. Am J Prev Med 2002;23:21–54.
- Twetman S: Antimicrobials in future caries control? A review with special reference to chlorhexidine treatment. Caries Res 2004; 38:223–229.
- van Rijkom HM, Truin GJ, van't Hof MA: A meta-analysis of clinical studies on the caries-inhibiting effect of chlorhexidine treatment. J Dent Res 1996;75:790–795.
- Wiedenfeld S, Kiyak HA: Increasing self-efficacy: a new approach to health promotion (abstract). Gerontologist 1991;31:abstract 83.
- Wyatt CCL, MacEntee MI: Caries management for institutionalized elders using fluoride and chlorhexidine mouthrinses. Community Dent Oral Epidemiol 2004;32:322–328.

/ersitätsbibliothek Bern .92.9.57 - 1/14/2014 8:04:32 PN