American Dental Hygienists' Association
special supplemental issue

Journal of Dental Hygiene

JDH 2013 Best Paper Award

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Journal of Dental Hygiene

VOLUME 88 • SUPPLEMENT • 2014

STATEMENT OF PURPOSE

The *Journal of Dental Hygiene* is the refereed, scientific publication of the American Dental Hygienists' Association. It promotes the publication of original research related to the profession, the education, and the practice of dental hygiene. The Journal supports the development and dissemination of a dental hygiene body of knowledge through scientific inquiry in basic, applied and clinical research.

SUBSCRIPTIONS

The *Journal of Dental Hygiene* is published quarterly online by the American Dental Hygienists' Association, 444 N. Michigan Avenue, Chicago, IL 60611. Subscription rates for nonmembers are one year, $60.

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Please submit manuscripts for possible publication in the *Journal of Dental Hygiene* to JoshS@adha.net.

Inside

Journal of Dental Hygiene
Vol. 88 • Supplement • 2014

Features

Editorial

Rebecca S. Wilder, RDH, BS, MS

Celebrating Our Best

This issue of the Journal of Dental Hygiene is celebrating extraordinary dental hygienists who are contributing to our science. As a career academician, teacher, researcher and graduate program director, it makes me excited to see the exceptional dental hygienists who are committed to the profession and taking a lead in research and publishing.

The ADHA/Sigma Phi Alpha award competition has been in existence for several years. The competition is made possible through a grant from Johnson and Johnson Healthcare Products, Division of McNEIL PPC, Inc. We now have two categories for the award at the Master of Science/Doctoral level and at the Baccalaureate level. It is a very competitive process and can be quite challenging if the paper is the first one the student has every submitted for publication. We are pleased to be publishing the two winning manuscripts from the 2013 competition. The schools represented include Forsyth School of Dental Hygiene in Boston, Massachusetts and The University of Michigan in Ann Arbor, Michigan.

Another new award is the Journal of Dental Hygiene Best Paper Award. This year, an independent panel of judges reviewed all original research project papers that were published in the Journal of Dental Hygiene from January to December 2013. They had specific criteria to utilize to judge the manuscripts and were tasked with selecting the best paper and the runner-up. Although the papers have already been published in our digital journal, we are pleased to present the two manuscripts in this print supplement. The schools represented are the University of North Carolina in Chapel Hill, NC and the University of Missouri-Kansas City in Kansas City, Missouri. Congratulations to the authors of both papers!

Finally, none of these papers would have been possible without outstanding mentoring from dental hygiene and dental faculty members who assisted, encouraged, edited and helped guide these students and authors through the writing process. We know it is not easy to mentor a novice writer, but it is so worth it in the end! These students are our future leaders, scholars, educators and innovators. To all of the mentors - thank you! And finally, a big thank you to J&J for helping us showcase our winning manuscripts!

Enjoy the CLL and Las Vegas!

Sincerely,

Rebecca Wilder, RDH, BS, MS
Editor–in–Chief, Journal of Dental Hygiene

Winner: 2013 Best Paper Award

Chronic HPA Axis Response to Stress in Temporomandibular Disorder

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The Journal of Dental Hygiene Best Paper Award was created this year to recognize the most outstanding research paper published from the previous year (2013). All original research papers published in 2013 were evaluated by a panel of judges, using specific criteria, to make the final selection. This manuscript first appeared in Volume 87, Issue Number 2 of the April 2013 issue of the Journal of Dental Hygiene.

Abstract

Purpose: Perceived stress is associated with temporomandibular disorder (TMD), but whether cortisol levels are elevated in individuals with TMD is unknown. We hypothesized that cortisol concentration, a biomarker of hypothalamic-pituitary-adrenal (HPA) axis function, was elevated in TMD cases relative to controls, and that perceived stress was positively correlated with cortisol concentration.

Methods: In this case control study, TMD case status was determined by examiners using TMD Research Diagnostic Criteria. Participants (n=116) aged 18 to 59 years were recruited from within a 50 mile radius of the University of North Carolina at Chapel Hill. Following examination, cases (n=45) and controls (n=71) completed the 14-item Perceived Stress Scale using a reference interval of the past 3 months. Approximately 100 strands of hair were cut from the posterior vertex segment of their scalp. The 3 centimeters of hair most proximal to the scalp was analyzed with a commercially available salivary cortisol enzyme immunoassay adapted for hair cortisol. This length corresponds to the last 3 months of systemic HPA axis activity.

Results: TMD cases perceived higher stress than controls ($p=0.001$). However, hair cortisol concentration was lower in TMD cases than controls ($p<0.001$). The correlation coefficient revealed a weak negative relationship ($r=-0.188$) between perceived stress and hair cortisol concentration ($p=0.044$). In analysis stratified by case status, the relationship of perceived stress and hair cortisol concentration was non-significant for cases ($p=0.169$) and controls ($p=0.498$).

Conclusion: Despite greater perceived stress, TMD cases had lower hair cortisol concentrations than controls and the 2 measures of stress were weakly and negatively correlated.

Keywords: Temporomandibular joint disorders; Epidemiology; Factor, psychosocial; Hormones, hypothalamic pituitary regulating

This study supports the NDHRA priority area, **Clinical Dental Hygiene Care:** Investigate the links between oral and systemic health.

Introduction

One of the most fundamental physiological responses to stress is activation of the hypothalamic-pituitary-adrenocortical (HPA) axis. The end product of HPA axis activation is stimulation of the adrenal cortex to increase secretion of the glucocorticoid cortisol. While protective in the short term, sustained activation of this hormonal response system is theorized to lead to tissue damage and subsequent dysregulation of biological systems.[1] Since the 1960s, investigators have measured cortisol levels in blood, saliva or urine to understand how stress increases vulnerability to disease.

Well before the role of HPA axis was theorized, stress was recognized to contribute to acute necrotizing ulcerative gingivitis, so-called "trench-mouth," among WWI soldiers. Today, stress has salience to oral health research because it is implicated in the pathogenesis of several dental conditions that have relevance to dental hygiene clinical practice. Heightened levels of stress are associated with oral mucosal lesions such as oral lichen planus[2,3] and recurrent aphthous stomatitis.[4] Among middle-aged adults, those with greater perceived stress were less likely to have retained 20 teeth,[5] the minimum number required for adequate function.[6] Psychosocial stress is believed to increase susceptibility to gingival infection and depress immune responsiveness to periodontal pathogens.[7,8] A cross-sectional study of 1,426 adults found that financial strain was associated with greater clinical attachment loss and alveolar bone loss.[9]

Perhaps the strongest evidence for a putative role of stress in oral disorders comes from studies of the onset, severity and chronicity of temporomandibular disorders (TMD). TMD is the most common form of chronic orofacial pain, affecting 5% of the U.S. population.[10]

Sanders et al demonstrated a strong dose-dependent relationship between severity of perceived stress and odds of examiner-determined TMD.[11] Baseline findings from the OPPERA prospective cohort study investigating risk factors for TMD found that compared with controls, TMD cases reported higher levels of psychosocial symptoms, affective distress, somatic awareness and pain catastrophizing.[12] Longitudinal research that followed healthy adults with no prior history of TMD found that those with greater perceived stress were more likely to experience first-onset TMD than adults with less perceived stress.[13]

It is perhaps surprising that cortisol measurement does not feature more prominently in oral health research as a biomarker of stress. New protocols for salivary cortisol collection offer advantages over blood and urine sampling protocols in terms of cost and simplicity. Yet major difficulties remain in obtaining valid and reliable measurements of cortisol in observational studies. Firstly, cortisol secretion follows a robust 24 hour rhythm, peaking around 8:00 with a nadir between 20:00 and 24:00.[14] Overlying this daily pattern is a series of 8 to 10 pulses. Such variation means that exact timing of specimen collection is critical if cortisol concentrations are to be meaningfully compared, and multiple measures per subject are often required. The United States National Longitudinal Study of Adolescent Health recently reported its decision to drop salivary cortisol measurement from its protocol because responses and protocol adherence were inadequate.[15]

A second limitation of cortisol measurement in blood, saliva and urine is that each of these fluids provides a very limited temporal window of cortisol activity. Levels of cortisol in blood and saliva reflect average hormone levels in the past 1 hour while cortisol in urine captures a slightly longer interval of up to 24 hours. None of these are able to measure chronic stress exposure which is thought to pose a greater threat to health than the short-term physiologic responses to acute stress.[16,17]

An important breakthrough was the development of an assay to measure endogenous concentrations of cortisol in human scalp hair,[18] permitting a reliable measurement of the stress response over a prolonged period, (e.g., chronic stress exposure).[19] Cortisol is thought to be incorporated into hair through diffusion from body secretions of sweat and sebum during formation of the hair shaft.[20] Since hair grows at a precise rate of 0.35 mm per day, equivalent to 1 cm per month,[21] hair length is an accurate index of exposure to stress over time. Thus hair cortisol promises a new, simple and noninvasive way in epidemiologic research to examine the role of stress.

To clarify the role of stress in TMD, the first aim of this study was to confirm the well-documented association between perceived stress and TMD. Once established, the second aim was to determine the relationship between hair cortisol concentration and TMD status. The third aim was to examine the correlation between perceived stress and hair cortisol concentration. The authors tested the hypotheses that both perceived and biologic measures of stress were elevated among TMD cases and that perceived stress was positively correlated with hair cortisol concentration.

Methods and Materials

This study was approved by the University of North Carolina Biomedical Institutional Review Board. All participants gave written informed consent before their inclusion in the study. In this case control study, cases had examiner-diagnosed TMD. Controls were also examined and found not to have this condition.

Setting

During the period July 2010 to October 2011, potential participants were recruited by advertisements placed in brochures, on the internet, radio and newspapers within a 50 mile radius of the Center for Neurosensory Disorders, School of Dentistry at the Center for Neurosensory Disorders, the University of North Carolina at Chapel Hill.

Inclusion and Exclusion Criteria

Criteria eligible participants were males and females between 18 to 60 years of age with scalp hair at least 3 cm in length. Respondents were first screened in a telephone interview to exclude those with conditions known to influence cortisol levels. Exclusionary criteria were diagnoses of any one of Cushing's syndrome or Addison's disease, diabetes, heart trouble or disease, hypertension that was not well controlled with medication, hyperthyroidism, major psychiatric disorder requiring hospitalization within the previous 6 months, chronic respiratory disease not controlled with medication, seizures, renal failure or dialysis. Also excluded were those who were pregnant, nursing, undergoing orthodontic treatment, radiation or chemotherapy, as well as persons with drug or alcohol abuse, trauma or surgery on the head, face or neck within the last 6 months. Persons having used corticosteroid treatment in the last 12 months (including cortisol containing creams, lotions and nasal spray) were likewise excluded. Finally, those having used permanent or semi-permanent hair color within 3 months were excluded since cortisol levels are lower in artificially colored hair.[18]

TMD Case Classification

A medical history was recorded for all screened participants prior to the clinical examination. Examinations were performed by 6 dental hygiene examiners trained in the examination protocol and calibrated for reliability and validity of their diagnostic decisions every 6 months. The standardized physical examination of the head and neck followed the research diagnostic criteria for TMD.[22] In summary, TMD cases were people who reported a 6 month history of pain in the temporomandibular structures, with at least 5 days of such pain in the month preceding the examination and where the examiner found at least 3 muscle groups in the temporomandibular region that were tender to palpation or jaw maneuver. Controls reported no history of orofacial pain within the preceding 6 months and no prior diagnosis for TMD. Additionally, their examination confirmed that they did not have TMD, arthralgia or myalgia.

Hair Sampling

A hair sample (approximately 100 strands, ≥20 mg of hair) of at least 3 cm in length was collected by study personnel. The sample was cut using fine scissors from as close as possible to the scalp from the vertex posterior region. Intra-individual variation in cortisol content is less in this region (coefficient of variation=15.6%), as compared to hair sampled from other than in the posterior vertex, anterior vertex, nape, temporal and frontal regions (coefficient of variation=30.5%).[18] Because scalp hair grows 1 cm per month on average,[23] analysis of 3 cm of hair most proximal to the scalp provides information about 3 months of systemic cortisol exposure. Hair samples were attached to a sheet of paper using Millipore tape (Billerica, Mass.), the scalp end was marked and the collection date and participant identification number were recorded. The paper was then enclosed in an envelope sealed with identification number and date on outside of envelope and stored at room temperature. Within 6 months of collection, samples were sent by mail to the laboratory at the University of Western Ontario, London, Ontario where cortisol levels were analyzed.

Hair Sample Preparation and Quantification of Hair Cortisol

In preparation for analysis, hair samples were measured and the length and color of the hair recorded. The most proximal 3 cm hair segment was cut, placed into a glass vial, labeled and weighed to ensure a minimal weight for analysis of 10 to 15 mg. Hair was then washed twice by immersing the segments in 3 ml of isopropanol, followed by a 3 minute incubation on a shaker at 0.11 g (100 rpm) at room temperature. Laboratory analysis was performed using a commercially available salivary cortisol enzyme immunoassay kit from Alpco Diagnostics (Salem, NH). Details of the laboratory procedures are reported fully elsewhere.[24]

Perceived Stress

Perceived stress was measured using the psychometrically-validated and widely used 14-item Perceived Stress Scale (PSS).[25] Summary scores from this instrument and its shorter 10-item subset are shown in previous studies to be positively associated with TMD.[13,26] The PSS was developed to evaluate the theoretical construct of stress proposed by Lazarus and Folkman[27] that a stimulus is stressful when perceived as both threatening and exceeding one's coping resources. The PSS takes into account these appraisals by measuring the degree to which respondents consider their lives to be unpredictable, uncontrollable and overloaded.[25] In each question, respondents were asked to indicate how often they felt or thought a certain way. The conventional 1 month reference interval was extended in this study to 3 months. This was considered to better represent exposure to chronic stress than the 1 month interval, without being so long that recall bias would limit the interpretation of findings. Responses were recorded on a 5-point ordinal scale coded: never=0, almost never=1, sometimes=2, fairly often=3 and very often=4. In computing a summary score, positively worded items were reverse coded, consistent with recommended scoring methods.[25]

Covariates

Covariates were sex, age in years, race, ethnicity, educational attainment, annual household income and cigarette smoking status. This information was obtained by questionnaire at the time of the physical examination.

Statistical Analysis

Participants with hair cortisol concentrations >1500 ng/g were excluded from analysis on the basis of possible contamination due to use of creams or ointments containing hydrocortisone.[28] Initial exploration using histograms and qnorm diagnostic plots showed that PSS scores were normally distributed, and cortisol concentrations were skewed towards higher values. Therefore log10 transformed cortisol values were modeled when the continuous values were analyzed. To account for the potential effect of confounding, analyses were repeated after stratifying on TMD case status.

The Pearson's product moment correlation coefficient was used to determine the strength and di-

rection of the relationship between PSS scores and cortisol concentration. A scatter plot was fitted to graphically depict this relationship. Fisher's exact test was used to compare dichotomous variables and the independent samples t-test (2-sided) compared differences in mean log10 cortisol concentration between TMD cases and controls.

Results

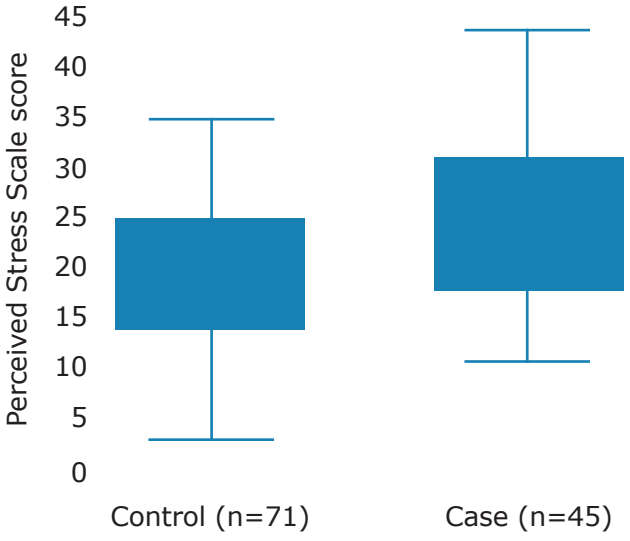
Data were analyzed for 45 TMD cases and 71 controls after omitting 3 subjects whose cortisol concentrations exceeded 1,500 ng/g. The age of participants ranged from 18 to 59 years (mean=29.9 years) and the sample was predominantly female (80.2%) and Caucasian (84.2%).

TMD cases and controls did not differ on the basis of socio-demographic characteristics or smoking status. However, compared with controls, TMD cases perceived significantly higher levels of stress in their daily lives ($p<0.001$, Figure 1, Table I).

Perceptions of stress and levels of hair cortisol did not differ significantly between participants on the basis of age, sex, race, smoking or socioeconomic status (Table I). Despite perceiving higher levels of stress, cortisol concentrations were significantly lower in TMD cases than in controls ($p<0.001$).

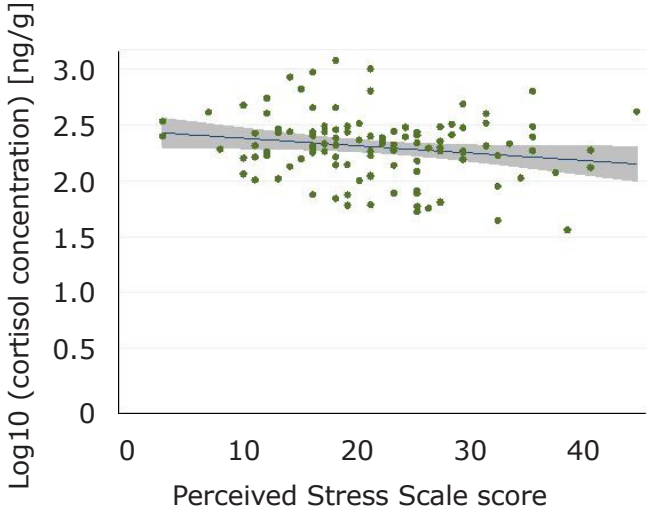
Examination of the cloud of observations on the scatter plot revealed a weak, negative relationship but statistically significant relationship between perceived stress and cortisol concentration ($r=-0.188$, $p=0.044$, Figure 2). When examined in separate strata of case status, the relationship was negative in each stratum, but failed to reach statistical significance for cases ($r=-0.111$, $p=0.169$) and controls ($r=-0.082$, $p=0.498$). Examination of the stratum-specific odds ratios and their confidence intervals suggested that the relationship between perceived stress and hair cortisol concentration was similar in TMD cases and controls.

Figure 1: Box and Whisker Plot of the Distribution of Perceived Stress Scores for TMD Controls and TMD Cases



The horizontal line within the box is the median value while the lower and upper hinges are the 25th percentile and 75th percentile, respectively. The ends of the whiskers represent the minimum and maximum values. A 2-group mean comparison t-test indicates the mean value for controls (19.7, s.e. 0.0) is statistically significant from that of cases (24.8, s.e. 1.2), $p=0.0007$.

Figure 2: Scatter Plot of the Relationship Between Perceived Stress Score (x-axis) and log10 Cortisol Concentration



(Y-axis) showing the fitted line and 95% confidence interval (n=116 observations). The Pearson correlation coefficient for this relationship is -0.188, $p=0.044$.

Discussion

Key Findings

In this study, TMD cases perceived significantly more stress than controls over the preceding 3 months, confirming a well-established relationship between psychosocial stress and TMD. Our expectation that higher stress perception in cases would correspond with elevated cortisol production was not supported. In fact, cortisol production was significantly lower in cases than controls. Among all subjects combined, perceived stress and cortisol concentration were significantly and negatively related, albeit in a weak relationship. When examined in stratum-specific analyses, perceived stress and cortisol concentration were negatively associated for both cases and controls, but non-significantly. In summary, individuals with higher

Table I: Distribution of Mean PSS Scores and Mean Log10 Hair Cortisol Concentration

	Perceived Stress score			Log10 cortisol concentration		
	Mean	SD	p-value	Mean	SD	p-value
TMD status						
Control	19.69	7.24	0.001	2.38	0.24	<0.001
Case	24.80	8.27	–	2.19	0.32	–
Sex						
Female	22.27	7.89	0.108	2.29	0.30	0.495
Male	19.26	8.25	–	2.34	0.26	–
Age group (years)						
<25	21.02	6.13	0.723	2.31	0.26	0.618
25-34	22.41	8.60	–	2.27	0.29	–
35-60	21.50	9.52	–	2.34	0.33	–
Race						
White	21.58	8.24	0.842	2.30	0.29	0.771
Not white	22.00	7.37	–	2.32	0.28	–
Educational attainment						
≤High school graduation	20.62	7.25	0.364	2.37	0.31	0.127
Some college or higher	22.11	8.32	–	2.28	0.28	–
Household income (USD)						
<$40,000	22.59	8.18	0.414	2.29	0.27	0.946
$40,000–<$100,000	21.11	8.77	–	2.31	0.27	–
≥$100,000	19.50	5.87	–	2.29	0.37	–
Smoking status						
Current	23.38	6.44	0.729	2.24	0.26	0.271
Former	20.65	10.05	–	2.40	0.32	–
Never	21.71	7.78	–	2.29	0.28	–

perceived stress had lower hair cortisol concentration, and this effect was more pronounced among cases than controls.

Comparison with Previous Studies

This study is not the first to find an inverse or null association between perceived stress and hair cortisol concentration. A study that administered the PSS with a 3 month reference interval to university students reported a weak negative correlation with hair cortisol content (r=-0.061, p=0.025).[29] Another study compared long-term unemployed individuals with people in stable employment. The study found that the unemployed reported higher PSS scores, and the hair cortisol concentration was not associated with perceived stress.[30] Likewise, PSS scores and hair cortisol concentration were not associated among patients attending a cardiac rehabilitation program.[31] Elsewhere, a study comparing adults with severe chronic pain with healthy controls found a weak positive correlation between PSS scores and hair cortisol that failed to reach statistical significance (r=0.24, p=0.08, Spearman).[32] Similarly, the correlation between PSS scores and hair cortisol concentration was weakly positive but did not reach statistical significance (r=0.2, p=0.06) for subjects in a case control study where cases were patients with adrenal insufficiency who were on hydrocortisone replacement therapy.[24] These findings differ from another conducted with pregnant women that reported a positive relationship between PSS scores and hair cortisol concentration.[33]

Few epidemiologic studies have measured hair cortisol in stress-related disorders. In these few studies, divergent findings report that cortisol is elevated in some disorders while lower in others. A pilot study compared hair cortisol concentration in severe chronic pain patients recruited from a chronic pain clinic who had received opioid treatment for at least 1 year (n=15), with pain-free control group recruited from the community (n=39). Perceived stress and cortisol levels were both higher in the opioid-treated chronic pain group with cortisol being almost elevated two-fold in the pain group (83.1 [33.0 to 204.9] pg/mg) relative to controls (46.1 [27.2 to 199.9] pg/mg).[32]

Consistent with findings from the severe chronic pain study, a study of men hospitalized following acute myocardial infarction found significantly

higher median hair cortisol levels over the 3 months preceding the event (295.3 ng/g [105.4 to 809.3]) than hospitalized men admitted for other conditions (224.9 ng/g [76.58 to 949.9]).[34] By contrast to these 2 studies, in a case control study in which cases had generalized anxiety disorder, hair cortisol concentrations were 50 to 60% lower in cases than in healthy-age and sex-matched controls - a result that contradicted earlier research using short terms measures of cortisol.[35]

A study that might shed light on these differential patterns examined hair cortisol levels in female adolescents at multiple time points following the 2008 Wenchuan earthquake in China.[36] Subjects were classified into 1 of 3 groups: those who experienced the earthquake and developed posttraumatic stress disorder (PTSD), those who experienced the earthquake and did not develop PTSD and a group of non-PTSD controls from a different region that was unaffected by the earthquake. Hair segments corresponding to time before and several occasions after the earthquake were compared for cortisol concentration in all 3 groups. Hair cortisol concentrations were similar in all groups before the earthquake suggesting no difference in HPA axis activity at baseline. In the first 2 months following the earthquake, cortisol levels were significantly higher in both groups exposed to the earthquake compared with the control group. Then, at 2 to 4 months after the earthquake, and again at 5 to 7 months after the earthquake, the non-PTSD group exposed to the earthquake had significantly higher cortisol concentration than both the exposed PTSD group and the control group. The authors interpreted this as a blunted HPA response in the PTSD group.[36] The important finding was the change in cortisol secretion over time in the PTSD group from elevated initially, relative to controls, to suppressed.

Possible Mechanisms and Explanations

The noteworthy finding of the study of stress-responsive physiology to the earthquake is that timing since onset of chronic stress is important. It is possible that chronic stress elicits both an increased and a decreased production in cortisol, at different stages following onset of stress. In fact, this explanation was a major finding of a meta-analysis of 107 studies published between 1950 to 2005 that examined the relationship between chronic stress and HPA axis activity.[37] The meta-analysis concluded that exposure to chronic stress initially activates the HPA axis producing elevated secretion of cortisol. Over time HPA activity subsides and cortisol secretion rebounds to below normal levels.[37] The rebound may be a consequence of a cumulative stress burden. This is consistent with the concept of allostatic load that posits that overuse of systems designed to manage transient stress leads to impairment of the HPA function including a decrease in responsiveness to novel stressors and disturbance in the regulation of the key mediators.[38]

Applied to the present study, it is possible that prolonged or repeated perceptions of stress reported by TMD cases lead to blunted HPA activity and deficient cortisol signaling. In support of this idea are findings from a study of working women where high scores on the PSS were associated with an 11% attenuation in diurnal variation of salivary cortisol characterized as a pronounced reduction in cortisol awakening response.[39]

Strengths and Limitations

Strengths of the study relate to the rigor of the measurement protocols. The quantification of hair cortisol was conducted in laboratories in the Department of Physiology and Pharmacology, University of Western Ontario, an internationally prominent center for hair cortisol research. The Research Diagnostic Criteria for TMD case classification are standardized criteria that reliably ascertain TMD case classification. The PSS is widely used and has well established reliability and validity. Our findings are the first in the oral health literature to investigate hair cortisol as a systemic biomarker of long-term exposure stress. While our results did not support our hypothesis, the findings serve to challenge an over-simplistic view of psychoneuroimmunology in TMD and other stress-related disorders.

There are several limitations to this study. Firstly, the expectation of a strong correlation between perceived stress and hair cortisol concentration rests on an erroneous assumption that these factors are 2 measures of the same phenomenon. However, one is a cognitive appraisal of stress and the other is the physiologic response to stress. Secondly, since information regarding the duration of TMD in the cases is not available, it was not possible to determine whether chronic cases were more likely than recent-onset cases to have a lower cortisol concentration. Information on other variables that may influence cortisol, such as alcohol use and body mass index, was not collected.

Implications for Dental Hygiene Practice

Psychosocial stress contributes to the etiology of several disorders that dental hygienists evaluate in clinical practice. Patients may be unaware that their orofacial muscle or joint pain has dental relevance. Likewise, the patient may not recognize that stress might be a contributing factor to their

symptoms. Dental hygienists are well positioned to observe, discuss and evaluate potential TMD and its risk factors in the course of their intraoral and extraoral examinations. This is consistent with the American Dental Hygienists' Association Standards for Clinical Dental Hygiene Practice that hygienists perform an individualized assessment that includes interpretation of symptoms and clinical signs while systematically taking account of the general health status, history and needs of the patient.[40] In discussing the patient's oral status, the dental hygienist may inform the patient that stress is a common factor in TMD since this may be taken into consideration in formulating a patient-centered and evidence-based treatment plan.

This project was completed in partial fulfillment of the Masters of Science degree in Dental Hygiene Education at the University of North Carolina at Chapel Hill.

Conclusion

Measurement of hair cortisol in epidemiologic studies is still in its infancy and the mixed findings make interpretations difficult. Our understanding will be improved with prospective cohort studies that collect hair samples before and after first-onset of TMD.

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Acknowledgments

This study was supported by the North Carolina Translational and Clinical Sciences Institute grant 10KR30904 and National Institutes of health grants U01De017018 and P01NS045685.

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Runner-Up: 2013 Best Paper Award

Extending Oral Health Care Services to Underserved Children through a School-Based Collaboration: Part 3 - A Cost Analysis

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The Journal of Dental Hygiene Best Paper Award was created this year to recognize the most outstanding research paper published from the previous year (2013). All original research papers published in 2013 were evaluated by a panel of judges, using specific criteria, to make the final selection. This manuscript first appeared in Volume 87, Issue Number 5 of the October 2013 issue of the Journal of Dental Hygiene.

Abstract

Purpose: The purpose of this manuscript was to conduct a cost analysis of the Miles of Smiles Program, a collaboration between the University of Missouri-Kansas City School of Dentistry and the Olathe School District in Kansas. This preventive program was implemented to improve the access to oral health care for low income children within the school district.

Methods: An inventory list and de-identified patient records were used to determine the costs associated with operating the program to serve 339 elementary school students during the 2008 to 2009 school term. Costs related to equipment, supplies and personnel were included. The costs were then compared to the amount of Medicaid reimbursement obtained for the services provided. Additionally, the cost of operating a similar program, if staffed by dental professionals rather than supervised dental hygiene students, was estimated.

Results: The cost of operating the program during the 2008 to 2009 school term was $107,515.74. The program received Medicaid reimbursement for approximately 1.5% of the total operating cost of and approximately 6.3% of the total billable services, however, challenges with submitting and billing Medicaid claims for the first time contributed to this low rate of reimbursement. If a similar program that utilized dental professionals was implemented and treated the same number of patients, the cost would be approximately $37,529.65 more due to higher expenses associated with personnel and supplies.

Conclusion: The program is not self-sustainable based on Medicaid government-funded insurance reimbursement alone, and therefore continuous external sources of funding or a change in the program design would be necessary for long-term sustainability of the program.

Keywords: access to care, dental hygiene education, community–based dental education, dental care for children, oral healthcare for the underserved, portable equipment, school–based oral health, cost analysis, dental medicaid program

This study supports the NDHRA priority area, **Health Services Research:** Investigate how alternative models of dental hygiene care delivery can reduce health care inequities.

Introduction

Dental care has recently been recognized as the most prevalent unmet health care need for children in the U.S. While the issue is not often in the spotlight, millions of American adults and children lack access to preventive, routine dental care.[1,2] If the challenges that underserved and vulnerable populations encounter when trying to access oral health care are not addressed, the burden of oral disease these populations experience will continue to grow.[3] Furthermore, the cost and impact associated with health disparities place complex economic burdens on the nation. A report on the economic burden of health disparities in the U.S. estimated that 30.6% of direct health care costs for African Americans, Asian Americans and Hispanics from 2003 to 2006 were excess costs associated with health inequalities.[4] Premature loss of life, increased burden of disease and inadequate access to quality care continue to pervade the health care system.[4]

Eliminating health disparities remains a monumental challenge. According to a 2011 survey conducted by Lake Research Partners for W.K. Kellogg Foundation, those most likely to not have a place to receive regular dental care include those with incomes less than $30,000, who lack dental insurance, who have a high school diploma or less education, or who are Latino or African American.[1] The current structure of dental practice further complicates access to care issues. Unlike medical care, most dental services are provided in

private practices with 1 or 2 oral health care providers, and are often located in metropolitan areas.[2]

Strategies to Address Access and Disparity Issues in Oral Health Care

Upon reviewing evidence that indicates millions of Americans have unmet oral health needs due to barriers in access to care, the Institute of Medicine and National Research Council committee prepared the "Vision for Oral Health Care in the United States," outlining how public and private providers should address oral health care for these populations. The vision stated that "to be successful with underserved and vulnerable populations, an evidence-based oral health care system will: eliminate barriers that contribute to oral health disparities, prioritize disease prevention and promotion, provide oral health services in a variety of settings, rely on a diverse and expanded array of providers competent, compensated, and authorized to provide evidence-based care, include collaborative and multidisciplinary teams working across the health care system, and foster continuous improvement and innovation."[3]

The findings and conclusions from the Institute of Medicine and National Research Council's report on improving access to oral health care for vulnerable and underserved populations support the fact that no single setting of care will meet the needs or overcome the barriers of these populations.[3] For several years, researchers have suggested that alternative practice models could meet the oral health needs of target populations, demonstrating a role for both public and private sectors to get involved.[5-7]

School-Based Safety-Net Clinics

When considering access to care issues for low-income and minority children, the School-Based Safety-Net Clinic model has been suggested as a viable option. This model of providing care for children in the community in which they live can provide quality health care services by reducing financial, language, familial and cultural barriers.[8] If school based safety net clinics are to be considered an effective method for delivering preventive dental care to target populations, the issue of funding and financial support should be explored. A 1997 investigation conducted by Albert et al evaluating school-based oral health care programs found that 27% of the clinics were sponsored by health departments, 27% by hospitals/medical centers, 27% by community-based organizations and private agencies, 17% by community health centers, and 2% from other sources.[9]

Existing models of sponsorship and collaboration include the Forsyth Kids program, a Massachusetts school-based caries prevention program sponsored by the Forsyth Institute. The institute developed the program to ensure that it meets national oral health goals for high risk populations.[10,11] Another school-based program, The Apple Tree Dental organization, utilizes a mobile delivery system that travels to patient populations with special access needs and provides a variety of dental services. The program is supported by individual donors, foundation grants and corporate sponsors.[12]

As the dental hygiene scope of practice increases with changes to supervision requirements, underserved populations may benefit from services provided by dental hygienists in school-based clinics. An example is a bill passed in Kansas in 2003 that allows dental hygienists to earn an Extended Care Permit (ECP) to provide a wide range of preventive services in community settings under the sponsorship of a dentist. This permit allows dental hygienists to provide preventive services without being under the direct supervision of a dentist if the services are provided to vulnerable populations and/or in public health or community-based clinics.[13] School-based safety-net dental clinics utilizing an expanded scope of practice dental hygienist, such as an ECP dental hygienist, appear to be a promising solution to address access to care issues related to personnel and cost of care. However, one of the key considerations in making these clinics sustainable and replicable is whether additional financial support from an external source is necessary to maintain program viability.

The Miles of Smiles Program

Miles of Smiles is a collaborative program between the University of Missouri-Kansas City (UMKC) School of Dentistry, elementary schools within the Olathe School District (located in Olathe, Kansas – a suburb of Kansas City), an Extended Care Permit Dental Hygienist (ECP-I), and the REACH Healthcare Foundation. These organizations partnered together to provide preventive oral health services to disadvantaged children in 4 schools with a high proportion of low income population.[14,15] The services were provided 2 days per week by senior dental hygiene students enrolled at the UMKC School

of Dentistry and are supervised by a faculty member who currently holds a Kansas dental hygiene license and an ECP-I. The ECP-I dental hygiene faculty member serves as the project manager on the Miles of Smiles project.

The program began during the 2008 to 2009 school term. During the first year of operation, 389 students were enrolled in the program, and services were provided to 339 students. The demographic information for the participants is documented in Table I. More information about the operation of the Miles of Smiles Program is provided in part one and part two of this series.[14,15]

Purpose and Research Questions

The purpose of this study was to conduct a thorough cost analysis of the Miles of Smiles program during the 2008 to 2009 school year. The following research questions guided the analysis:

- What are the costs of operating the program?
- How does the cost of operating the program compare to the amount of Medicaid reimbursement received for the services provided?
- What would a similar program cost if staffed by paid dental professionals only?

Methods and Materials

Data Sources

Data related to the services provided in the Miles of Smiles program during the 2008 to 2009 school term were obtained from an existing database. The database was previously created by extracting de-identified information from the electronic patient records. A list of the equipment and supplies necessary to run the program were provided by the program manager and the prices of all items listed were obtained by contacting sales representatives of dental supply companies.

Data Compilation

To begin the analysis of the direct costs associated with the program, all equipment and supplies necessary to run the program were separated into 2 categories: fixed costs and variable costs. Unless otherwise noted, all durable equipment and instruments were assumed to have a useful life of 5 years and were depreciated over the same period using the straight-line depreciation method.

The researcher observed the daily operation of the program for 3 days to determine the average quantities of disposable supplies and materials needed for each procedure. This information was utilized to prepare standard cost profiles associated with each billable service provided. Since the design of the Miles of Smiles Program utilizes supervised senior dental hygiene students to provide the services as part of their service-learning curriculum, the cost associated with the program manager's salary and benefits was the only direct personnel cost for this program. The benefits were determined using the customary formula of 35% of the annual salary.[16]

Table I: Demographic Information of 2008 to 2009 Miles of Smiles Program Participants

Category	Number (n)	Percentage (%)
Age		
0 to 5 years	4	1
6 to 8 years	165	42.4
9 to 14 years	215	55.3
Unknown	5	1.3
Gender		
Male	213	54.8
Female	176	45.2
Race/Ethnicity		
Hispanic	193	49.6
Caucasian	117	30.1
Black	49	12.6
Asian/Pacific Islander	19	4.9
Two or More Reported	9	2.3
Unknown	2	0.5

Facilities and Administration cost equal to 50% of the direct costs were added to fully account for indirect operating costs. The indirect operating cost rates are based on the policies of the UMKC Office of Research Services.[16] Indirect operating costs include expenses such as utilities associated with operating the program, storage for the equipment, transportation of equipment to the various sites, and data management for statistical purposes and Medicaid claims. Personnel within the Patient Accounts office at the UMKC School of Dentistry assisted with the program by submitting and processing all Medicaid claims for patients treated within the program.

The amount of Medicaid reimbursement received for each patient encounter was also documented in the database and utilized to make the comparisons. In addition, the average hourly salary of dental hygienists in the state of Kansas was obtained from the Bureau of Labor Statistics to compare the cost of this program to a similar program staffed by dental professionals only.

Table II: Fixed Costs – Equipments and Instruments

Equipment and Instruments	Quantity	Price Per Unit	Total Price	Life Span (in years)	2008 to 2009 Cost
Portable operatory	2	$4,355.00	$8,710.00	5	$1,742.00
Portable light	2	$1,104.00	$2,208.00	5	$441.60
Portable chair and carrying case	2	$3,270.00	$6,540.00	5	$1,308.00
Operator Stool	4	$574.00	$2,296.00	5	$459.20
Operator Stool - Carrying Case	4	$190.00	$760.00	5	$152.00
Handheld Extraoral X-ray	1	$7,495.00	$7,495.00	5	$1,499.00
Positioning Stand w/ Remote Activation	1	$750.00	$750.00	5	$150.00
Carrying Case	1	$465.00	$465.00	5	$93.00
Digital Scanner, Eraser, and Phosphor Plates	1	$19,000.00	$19,000.00	5	$3,800.00
Child-size Lead apron	2	$77.99	$155.98	5	$31.20
Laptop Computers w/ software	4	$2,400.00	$9,600.00	5	$1,920.00
Printer	1	$249.00	$249.00	5	$49.80
Ethernet cord	1	$8.99	$8.99	5	$1.80
Extension cord/Surge Protector	2	$18.00	$36.00	5	$7.20
Rubbermaid organizers	6	$37.00	$222.00	5	$44.40
Rubbermaid storage totes	10	$10.00	$100.00	5	$20.00
Autoclave w/ cassette	1	$4,299.99	$4,299.99	5	$860.00
Sterilization Maintenance/Service and Strips (monthly)	12	$16.67	$200.04	1	$200.04
Ultrasonic Cleaner w/ powder	1	$349.99	$349.99	5	$70.00
Child Blood pressure cuffs	2	$109.00	$218.00	5	$43.60
Stethoscope	2	$5.99	$11.98	5	$2.40
Ultrasonic	2	$2,629.00	$5,258.00	5	$1,051.60
Ultrasonic inserts (sets of 3 S,L,R)	4	$409.00	$1,636.00	1*	$1,636.00

*Life span determined by contacting manufacturer and determining the average lifespan of instruments/cavitron inserts used 2 to 4 times per week

Results

Operating Costs

The fixed costs for the 2008 to 2009 school year were determined from the program inventory list. Because all equipment except certain dental hygiene instruments were assumed to have useful lives of 5 years, annual cost was determined by dividing the purchase/market price of each by 5. Given the amount of expected use in the program, the dental hygiene instruments were expected to last approximately 1 year, therefore, the entire purchase price of all instruments was included in the calculation. The sum of these prices totaled $19,990.61. This figure represents the total fixed costs for the Miles of Smiles Program for the 2008 to 2009 term (Table II).

The variable costs were determined from the standard cost profiles for each billable procedure (Table III). The majority of the patient encounters were multi-procedure encounters, therefore, the procedure-specific standard cost profiles were combined to represent the expense for the entire encounter. The number of each multi-procedure encounter performed was then multiplied by the cost per encounter to determine the total cost associated with disposable supplies (Table IV).

The total direct cost associated with operating the Miles of Smiles Program during the 2008 to 2009 school term was determined by adding the fixed and variable costs of equipment and supplies and personnel expenditures, totaling $71,677.16

Table II: Fixed Costs – Equipments and Instruments (continued)

Equipment and Instruments	Quantity	Price Per Unit	Total Price	Life Span (in years)	2008 to 2009 Cost
Slow speed handpieces	6	$785.00	$4,710.00	5	$942.00
Roto Quicks handpieces	3	$210.00	$630.00	5	$126.00
Napkin Clip/Metal chain	10	$4.49	$44.90	5	$8.98
Mirror (price figured by adding handle + mirror)	10	$4.71	$47.10	1*	$47.10
Shepherd's Hook Explorer	10	$12.99	$129.90	1*	$129.90
11/12 Explorer	10	$16.99	$169.90	1*	$169.90
Nebraska Sickle Scaler	10	$32.99	$329.90	1*	$329.90
204 S Posterior Scaler	10	$32.99	$329.90	1*	$329.90
Columbia 13/14 Curette	10	$32.99	$329.90	1*	$329.90
Air/Water Syringe tips	10	$6.15	$61.50	1*	$61.50
Gracey 1/2 Curette	3	$32.99	$98.97	1*	$98.97
Probe	3	$21.99	$65.97	1*	$65.97
Curing light Unit	4	$494.99	$1,979.96	5	$395.99
Intraoral Camera Dock	1	$2,265.00	$2,265.00	5	$453.00
Intraoral Camera	1	$3,815.00	$3,815.00	5	$763.00
Digital Camera w/ lenses and flashes	1	$499.00	$499.00	5	$99.80
Sealant applicator handle	4	$7.99	$31.96	5	$6.39
Mouth props	4	$19.50	$78.00	5	$15.60
Patient mirrors (handheld)	2	$8.99	$17.98	5	$3.60
Fans	2	$15.00	$30.00	5	$6.00
Safety glasses	6	$6.99	$41.94	5	$8.39
Storage unit for supplies	1	$80.00	$80.00	5	$16.00
Total Fixed Costs			$86,356.75		$19,990.61

*Life span determined by contacting manufacturer and determining the average lifespan of instruments/cavitron inserts used 2 to 4 times per week

(Table V). The total direct cost was then multiplied by 150% to account for the standard Facilities and Administration Rate, and therefore calculate the total costs associated with operating the program. The total indirect costs were $35,838.58 (Table V). Therefore, the total cost associated with operating the Miles of Smiles Program during the 2008 to 2009 school term was $107,515.74 (Table V).

Medicaid Reimbursement for Services Provided

The Miles of Smiles Program provides services to any child that qualifies for the Free and Reduced Fee Lunch program, regardless of Medicaid coverage. The only form of reimbursement the program receives is from Medicaid claims for children with coverage. Of the 339 participating children, 144 (42.5%) had Medicaid coverage. The total amount of Medicaid reimbursement during the 2008 to 2009 term was $1,618, representing 1.5% of the total costs ($107,515.74) of operating the program.

Comparison to Programs Staffed by Paid Dental Professionals

If a similar program staffed by paid dental professionals was to be developed, cost differences would primarily arise from 2 sources: salaries/wages and the time it takes to perform the procedures. To determine the costs associated with employing a paid ECP-I registered dental hygienist, the hourly salary listed on the Bureau of Labor Statistics website was utilized. For the state of Kansas, the mean hourly salary for a registered dental hygienist is $30.92.[17] Assuming that the registered dental hygienist works the standard 2,000 hours per year, the annual salary would be $61,840, and the total benefits package would equal $21,644, using the

Table III: Standard Cost Profiles for Billable Procedures

Procedure	Cost	Items Included in Cost Calculation
Child Prophylaxis	$9.85	Prophy Angle, Prophy Paste, 2x2 Gauze, Floss, Saliva Ejector, Patient Napkin, Infection Control Barrier Wraps, Sterilization Bags, Clinician Mask and Gloves, Toothbrush, Toothpaste, Floss, Disclosing Solution, Medicine Cups for Disclosing Solution
Two Bitewing Radiographs	$0.41	Phosphor Plate Film Sleeves, Disposable Bitewing Tabs
Fluoride Varnish Treatment	$1.56	Fluoride Varnish*
Sealants (per tooth)	$2.87	Cotton Rolls/Dri-Angles, Sealant Material (single dose), Etchant Material (single dose)

*All students received fluoride varnish at the time of Child Prophylaxis so no additional supplies were needed for the application

Table IV: Cost of Supplies Used in Multi-Procedure Encounters

Multi-Procedure Encounter Category	Cost Per Encounter	Quantity	2008 to 2009 Total Cost
Prophy + Bitewings + Fluoride Varnish + Sealants + Oral Hygiene Instruction	$11.82(86)+2.87(246)	86	$1722.54
Prophy + Bitewings + Fluoride Varnish + Oral Hygiene Instruction	$11.82	171	$2021.22
Prophy + Fluoride Varnish + Oral Hygiene Instruction	$11.41	28	$319.48
Prophy + Fluoride Varnish + Sealants + Oral Hygiene Instruction	$11.41(4)+2.87(12)	4	$80.08
Prophy + Bitewings + Oral Hygiene Instruction	$10.26	2	$20.52
Prophy + Oral Hygiene Instruction	$9.85	3	$29.55
Prophy + Bitewings + Fluoride Varnish	$9.58	9	$86.22
Prophy + Fluoride Varnish	$9.17	1	$9.17
Oral Hygiene Instruction Only	$2.59	3	$7.77
Total Costs of Disposable Supplies			$4,296.55

n=number of sealants placed for all Multi-Procedure Encounters in that category

customary 35% rate.[16] This suggests that an additional $10.82 should be added to the hourly wages to account for benefits as well, for a total of $41.74.

Since the program does not operate 2,000 hours per year, the program manager's 1,456 hour contract plus additional time for administrative duties was used for this calculation. It was estimated that approximately 8 hours per week would be spent performing administrative tasks. Since the program provided services approximately 30 weeks during the 2008 to 2009 school year, an additional 240 hours were added to account for administrative duties. This suggests that $70,791.04 ($41.74 multiplied by 1,696 hours) should be allocated for salary and benefits if a paid dental hygienist provided services for a program in operation the same amount of hours as Miles of Smiles. This figure is $23,401.04 higher than the $47,390.00 allocated for salary/benefits for the program manager and unpaid dental hygiene students (Table VI).

In addition, all ECP-I dental hygienists are required to carry a Professional Liability Insurance policy. Although a variety of liability insurance policies exist, the cost of the policy sponsored by the American Dental Hygienists' Association was used for the calculation. The annual policy is $77; therefore, $77 was added to the personnel costs for a program staffed by a paid dental hygienist (Table VI).[18]

When services were provided, the time required to complete them was documented in 15 minute increments. The average time spent per encounter was 3.18 units, or approximately 48 minutes. Although the literature does not provide a definite average time per encounter for registered dental hygienists, it can be assumed that a licensed professional with experience will likely perform procedures faster than a dental hygiene student that must have an instructor verify the accuracy of the treatment provided at many stages throughout the encounter. The American Dental Association's

Survey of Dental Practice states that the number of patient visits per hour by pediatric dentists that employ part-time or full-time dental hygienists increases by 1 to 2 patients when including hygienist visits.[19] This suggests that the time per encounter by a dental hygienist likely ranges from 30 to 60 minutes. Since a dentist is not present to perform an exam (minimizing the amount of appointment time needed), an estimate of the amount of time it would take for a registered dental hygienist to perform preventive services is 30 minutes.

If a program was in operation 248.75 hours (14,925 minutes) per school year (the approximate amount of time the Miles of Smiles Program was in operation according to the time per encounter documented in the database), a dental hygienist could potentially have 497 patient encounters (14,925 minutes, 30 minutes per encounter) as compared to the 313 patient encounters of the Miles of Smiles Program. The price per encounter varies depending upon the procedures performed and supplies needed, but the average cost per encounter during the 2008 to 2009 school term was $11.82. If a dental hygienist has 184 more encounters the cost of supplies will increase by approximately $2,174.88 (Table VI).

On the other hand, increased numbers of patient encounters results in increased production. According to the database, the average production per encounter for the Miles of Smiles Program in 2008 to 2009 was $81.93. This was calculated using Medicaid reimbursement rates for each procedure performed within the encounter. Whenever possible, a typical encounter included radiographs, prophylaxis, fluoride treatment, patient education and sealants. An additional 184 encounters could result in an approximate $15,075.12 increase in production. Since the program's only form of reimbursement for services provided is through Medicaid, the additional production does not necessarily suggest additional reimbursement. Of the $25,643 that was produced by the Miles of Smiles Program, only $1,618 was reimbursed by the Kansas Medicaid Program. This equals approximately 6.3% of the total amount produced. It has been determined, however, that the program was not able to collect the entire amount of billable services for children with Medicaid coverage due to issues with transferring the data in a timely manner, therefore, that figure does not accurately represent the reimbursement potential. Since the data does not provide an accurate comparison of the expected reimbursement for additional production, no conclusions can be drawn based on the additional amounts of reimbursement expected. Assuming all other expenditures are the same, the cost of operating a similar program staffed by a licensed dental professional rather than supervised dental hygiene students is $145,995.12, a total of $38,479.38 more than the cost of the Miles of Smiles Program.

Table V: Total Cost of Operating the Program During the 2008 to 2009 Term

Expenditure	Associated Cost
Fixed costs for equipment and instruments (Table II)	$19,990.61
Variable costs – supplies utilized during patient encounters (Table IV)	$4,296.55
Personnel expenditures	$47,390.00
Total Direct Costs	$71,677.16
Standard facilities and administration rate	
50% of total direct costs	$35,838.58
Total Indirect Costs	$35,838.58
Total Cost	$107,515.74

Table VI: Comparison of Costs for Miles of Smiles to a Program Staffed by an Extended Care Permit Registered Dental Hygienist

Expenditure	Cost for Miles of Smiles	Cost for a School-Based Program Staffed by ECP Dental Hygienist
Fixed costs – equipment and instruments	$19,990.61	$19,990.61
Variable costs – supplies utilized during patient encounters	$4,296.55	$4,296.55 + $2174.88 = $6,471.43
Personnel expenditures	$47,390.00	$70,791.04 + $77.00 = $70,868.04
Total Direct Costs	$71,677.16	$97,330.08
Standard facilities and administration rate (50% of total direct costs)	$35,838.58	$48,665.04
Total Indirect Costs	$35,838.58	$48,665.04
Total Cost	$107,515.74	$145,995.12

Discussion

Although this study supports the contribution that the program has made in improving access to care for vulnerable populations, it also highlights

the financial challenges in long-term sustainability of such a program.

Sustainability

When reviewing the cost of operating the Miles of Smiles program, it is evident that the costs associated with operating the program far exceeded the minimal amount of reimbursement received. Such a significant gap between the amount of reimbursement and cost highlights that funding from external sources is necessary for the program to continue long-term. It should be noted, however, that challenges associated with transferring data and billing contributed to the significant reimbursement gap. The program manager reports that during the first year of operation, the program was using a "store and forward" method of data collection and tracking as opposed to "real time" data collection, therefore, the data was often not transferred to the Patient Accounts office in a timely manner. According to an estimate, a total of $17,104 could have been reimbursed for services provided to Medicaid eligible children, however, only $1,618 was billed and collected due to aforementioned challenges. If the entire amount of $17,104 was collected from Medicaid reimbursement, that figure would represent approximately 67% of the total production and approximately 16% of the overall costs of operating the program during the 2008 to 2009 school year. This figure is more closely aligned with Byck's findings discussed previously.[5] Recognizing this difference, the process has since been addressed and the program currently has a more effective method of transferring this data between the treatment site and the business office in "real time."

Despite these challenges, the potential amounts of reimbursement that could have been collected still suggest that the program does not generate enough revenue to sustain itself without external funding. Although grant funding was available initially to purchase a majority of the equipment and instruments and to help with personnel expenses, for the program to continue to operate in this capacity, securing additional and constant sources of external funding would be necessary. This is consistent with other school-based programs discussed in the literature that have been in operation for several years and rely on external funding from a variety of sources.[11,12]

If the program were to become self-sustainable, significant modifications to the design of the program would be necessary. In 2008 to 2009, the program recorded a total of 248.75 hours providing services. According to the Kansas Department of Education, all elementary schools within the school district must be "open for business" for 1,116 hours per year.[20] Therefore, services were provided during only 22% of the time that school was in session. It is possible that if the program were operating at a higher capacity, more reimbursement could be generated to help offset the expenditures. Furthermore, the possibility of adding a restorative component to the program could be explored. Adding this component would not only allow the program to operate at a higher capacity, but could also result in higher amounts of reimbursement as restorative procedures are reimbursed at a higher rate.

Limitations

The limitations of this study include the potential bias associated with performing the cost analysis on the program's first year of operation. Most new programs experience challenges in defining the procedures and policies associated with daily operation. As the program has continued to operate, these processes have been refined and contributed to the program running more efficiently. The program manager reported making changes to the enrollment processes to increase the number of students in the program. A higher volume of students suggests that the program has become more efficient in providing treatment and generating patient encounters to verify that all the children enrolled in the program receive treatment.

Several assumptions were made in making the comparisons between the Miles of Smiles Program and a similar program staffed by a dental professional, as there is no published literature related to the average amount of time dental hygienists spend providing preventive services for children. It was assumed that a program staffed by paid dental hygienists would use identical equipment and amounts of supplies and that all patient encounters would take an average of 30 minutes. Despite the assumptions, the results do provide an estimated cost prediction for professionals that are interested in implementing a school-based program.

Directions for Future Research

This study lends itself to several opportunities for future research. Now that the Miles of Smiles program has been in operation for several years, the processes have been refined and resulted in increased productivity and an improved system for filing insurance reimbursement claims. An updated, identical cost analysis of the Miles of Smiles Program would allow for valuable comparisons of productivity as the program has evolved. This

would eliminate any bias associated with analyzing the program's first year of existence.

Since the Miles of Smiles Program operated only 22% of the time that school was in session during 2008 to 2009, it is worth exploring the change in costs if the program were operating at various increased capacities and its effect on the program's sustainability. Operating at a higher capacity will result in an increase in variable costs and personnel expenses so the impact that a change in program design would have is unclear.

It is recommended that further research take place to compare the cost-analysis to a school-based preventive oral health program already established that utilizes paid dental professionals. As stated previously, several assumptions were made when answering Research Question #3, so having exact data related to the time allotted per procedure, the supplies used and administrative duties would provide a more precise comparison to the Miles of Smiles program. In addition, some existing school-based programs provide both preventive and restorative treatment by employing a dentist and a dental hygienist. Making comparisons between the costs associated with these programs and reimbursement rates to that of a preventive program only could provide support in determining if the program can minimize costs and increase reimbursement rates if restorative procedures are provided as well.

Conclusion

Within the limitations of this analysis, the following conclusions can be drawn:

- The cost of operating the Miles of Smiles Program in 2008 to 2009 was $107,515.74.
- The amount of Medicaid reimbursement for services provided in 2008 to 2009 was $1,618.00. This represents 6.3% of the total amount produced and 1.5% of the program's total annual operating cost. A total of $17,104 could have been reimbursed for services provided to Medicaid-eligible children, but challenges associated with data transfer and billing procedures resulted in a much lower reimbursement rate. These challenges have been addressed and the data is being transferred in "real time" to facilitate billing. The data suggests that even if the entire $17,104 would have been collected, the program is not self-sustainable and additional sources of funding for long-term operation need to be secured.
- If a similar program staffed by dental professionals was implemented, the program would cost approximately $38,479.38 per year more. This increase is attributed to higher salaries/wages, more supplies used, and the costs associated with administrative duties. Although more reimbursement is predicted, it will not off-set the additional costs.
- There have been several lessons learned for the Miles of Program since its first year of operation in 2008 to 2009. Since the program has had time to refine the processes and procedures, it is likely that some of this data may vary if a current analysis was performed on the program.

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Acknowledgments

The authors thank the REACH Healthcare Foundation for providing grant funding to implement and continue to operate the Miles of Smiles Program.

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ADHA/Sigma Phi Alpha Journalism Award: Masters/Doctoral

Short-Term Effects of Non-Surgical Periodontal Therapy on Clinical Measures of Impaired Glucose Tolerance in People with Prediabetes and Chronic Periodontitis

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This project won 1st place in the ADHA Sigma Phi Alpha Journalism Award Competition, June 2013, under the master or doctoral level category. Award provided by a generous grant from Johnson & Johnson Healthcare Products, Division of McNEIL PPC, Inc.

Abstract

Purpose: Diabetes and periodontal disease are conditions considered to be biologically linked. Prediabetes is a condition in which individuals have blood glucose levels, impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT) or glycated hemoglobin (A1C) levels higher than normal but not high enough to be classified as diabetes. Few human studies address the relationship between periodontitis and prediabetes or clarify an association between periodontitis and prediabetes. The purpose of this pilot study was to examine the impact of non-surgical periodontal therapy (NSPT) on clinical measures of glycemic control in prediabetes.

Methods: Prediabetes measures of IFG, IGT, A1C and periodontal measures of pocket depth (PD), clinical attachment level (CAL), plaque index (PI) and gingival index (GI) were taken at baseline and 3 months in 12 subjects with prediabetes and chronic slight to moderate periodontitis. Blood samples were taken from each subject following an 8 hour fast. This study controlled for changes in medications, body-mass index, physical activity and diet.

Results: Comparison of mean prediabetes and periodontal measures from baseline and post-treatment at 3 months demonstrated clinical improvement for both periodontal and prediabetes measures. A mean reduction in PD of 0.27 (p=0.003), CAL of 0.32 (p=0.050) and A1C of 0.19 (p=0.015) reached statistical significance.

Conclusion: This pilot study suggests NSPT improves A1C and periodontal measures at 3 months. The robustness of measures is limited due to the small sample size and lack of a control group. Further larger scale studies using a randomized control design would be informative.

Keywords: diabetes mellitus, prediabetes, impaired fasting glucose, impaired glucose tolerance, glycated hemoglobin, A1C

This study supports the NDHRA priority area, **Clinical Dental Hygiene Care:** Investigate the links between oral and systemic health.

Introduction

In 2010, U.S., individuals aged 65 years and older (10.9 million, 26.9%) had diabetes.[1] The number of people with diabetes is projected to increase from 171 million in 2000 to 366 million in 2030, and is attributed to type 2 diabetes mellitus (T2DM).[2] T2DM can range from insulin resistance with relative insulin deficiency to an insulin secretory defect with insulin resistance accounting for 90 to 95% of cases.[1] The diagnosis of diabetes is based on fasting plasma glucose (FPG) (FPG≥126 mg/dl (7.0 mmol/l), 2 hour plasma glucose level of ≥200 mg/dl (11.1 mmol/l)) or glycated hemoglobin (HbA1C or A1C) of ≥6.5%.[3] The condition of prediabetes may precede diabetes and is a condition where individuals have impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT) or A1C levels higher than the normal range, but not high enough to be classified as diabetes.[3] People with prediabetes are at a higher risk for developing T2DM.[3] In 2005 to 2008, based on fasting glucose or A1C levels, 35% of the U.S population aged 20 years or older and 50% of those aged 65 years or older had prediabetes.[3]

Complications of diabetes can lead to heart disease, stroke, hypertension and susceptibility to other diseases.[1] Individuals with diabetes are at increased risk for chronic infections and inflammation of the oral tissues, including periodontal disease, dental caries and oral candidiasis.[4,5]

Diabetes and Periodontal Disease

Periodontal disease is a chronic multifactorial infectious disease of the supporting tissues of the teeth with inflammation and destruction of the underlying supporting tissues. Based on the NHANES III data (1988 to 1994), it is estimated approximately half of the U.S. population ≥30 years have periodontal disease.[6,7]

Some studies have suggested a bidirectional relationship between glycemic control of patients with diabetes and treatment of periodontal disease.[8] A systematic review for glycemic control and periodontal disease found a statistically significant reduction of -0.40% in A1C for scaling/root planing and oral hygiene (+/- antibiotic therapy) versus no treatment/usual treatment after 3 to 4 months.[8] In general, every percentage point drop in A1C blood test results (e.g., from 8 to 7%) can reduce the risk of microvascular complications (eye, kidney and nerve diseases) by 40%.[1]

Periodontal disease is a complex inflammatory disease initiated by oral microbial biofilm with complex interactions between the plaque biofilm and host immune inflammatory response. The inflammatory response results in alterations in bone and connective tissue homeostasis.[9-11]

There is evidence to suggest a link between periodontitis and several systemic diseases, among which atherosclerosis and T2DM may have the strongest evidence.[12] These periodontitis-linked systemic diseases may be caused by an oral–hematogenous-spread organisms passively transported in the blood vessels to distant sites of the body where they penetrate the vessel wall of oral bacteria.[13] Amongst the 400 species of subgingival plaque organisms, porphyromonas gingivalis, a gram negative microorganism, is implicated as a major causal species in the initiation and progression of periodontal disease, and induces a local chronic host inflammatory response resulting in bone destruction.[14,15]

The local inflammation leads to a chronic level of systemic inflammation characterized by elevated plasma levels of inflammatory mediators, such as TNF-alpha, Interleukin-6 IL-6 and acute phase proteins, such as C-reactive protein (CRP).[16] An accumulating body of evidence suggests inflammation may play a crucial intermediary role in pathogenesis of T2DM, thereby linking diabetes with a number of commonly coexisting conditions thought to originate through inflammatory mechanisms. In this regard, substantial experimental evidence and more recent cross-sectional data suggest IL-6 and CRP, markers of subclinical systemic inflammation, are associated with hyperglycemia, insulin resistance and overt T2DM.[17-26]

Prediabetes and Periodontal Disease

Prediabetes generally refers to an intermediate stage between normal glucose levels and the clinical measures of T2DM, encompassing both IFG and IGT. As defined by the American Diabetes Association (ADA), prediabetes is a fasting plasma glucose (FPG) of at least 100 mg/dl (5.6 mmol/liter) but less than 126 mg/dl (7.0 mmol/liter), which is frequently termed IFG, or an abnormal 2 hour response to a 75 g oral glucose tolerance test (OGTT) of at least 140 mg/dl (7.8 mmol/liter) and less than 200 mg/dl (11.1 mmol/liter), which is often termed IGT.[3] According to the ADA guidelines, a glycated hemoglobin (HbA1c or A1C) of 5.7 to 6.4% is diagnostic for prediabetes.[27] Individuals with IFG and/or IGT are at relatively high risk for the development of diabetes and cardiovascular disease. The prediabetic state can be an intermediary stage for obesity, dyslipidemia with high triglycerides and/or low HDL cholesterol, hypertension and microvasular complications of diabetes.[3] A meta-analysis of 156 studies conducted by the Agency for Healthcare Research and Quality showed that a person with prediabetes was 5 to 15 times more likely to develop T2DM than those without the condition.[28]

Chronic inflammation and dysfunction of cells lining blood vessels exists in individuals with prediabetes, especially in the IFG and IGT populations.[29] The Insulin Resistance Atherosclerosis Study hypothesized insulin sensitivity may be related to inflammation in non-diabetic subjects, with the results finding strong and independent associations of elevations in inflammatory markers, namely CRP with high insulin resistance.[21]

There are animal studies addressing the relationship between periodontitis and prediabetes.[30] The Zucker Fatty Rat (ZFR) is a recognized model of prediabetes, characterized by hyperinsulinemia, dyslipidemia and moderate hypertension.[30] Female ZFRs develop T2DM after consuming a high fat diet, which makes them excellent models to investigate the effect of periodontitis for prediabetes and the onset of T2DM in obese humans.[31] Animal studies examining whether periodontitis affected the prediabetic state found prediabetes worsened with periodontal disease and was associated with deterioration of glucose metabolism in ZFRs, suggestive of a progression toward diabetes. Periodontal disease also affected glucose regulation in lean rats.[31]

A review of the literature exploring the relationship of periodontal disease and measures of prediabetes

was elusive. Two Japanese epidemiological studies explored the relationship between periodontal disease and IGT, and found no significant difference in individuals with IGT and levels of periodontal disease.[32,33] Alternatively, 2 Japanese prospective and cross-sectional studies indicated IGT may be a risk factor for periodontal disease.[34,35] Another Japanese cross-sectional study found a relationship between periodontal status and A1C in a non-diabetic population while it did not reach statistical significance.[36]

In a case-control study to determine if glycosylated hemoglobin was elevated in patients with periodontitis who had not been diagnosed with diabetes, periodontitis was associated with a slight elevation in A1C.[37] Several limitations were observed in the study, such as use of a Point-Of-Care (POC) instrument to measure A1C instead of a blood draw and standard laboratory test, and no controls for confounders, such as changes in physical activity, weight or diet.

A cross-sectional study conducted in Israel found higher alveolar bone loss was associated with fasting glucose level. A higher prevalence of alveolar bone loss was found amongst non-diabetic males with a fasting glucose level of ≥100 mg/dL than among individuals with <100 mg/dL, suggesting fasting glucose as a predictor for future T2DM, or a possible role in glucose imbalance and T2DM development.[38]

In a prospective study of a German, non-diabetic population with periodontal disease compared to periodontally healthy participants, those with periodontal disease had 0.08% greater increase in A1C after 5 years.[39] There was a positive association between periodontal status and 5 year A1C changes.[39]

In a cross-sectional study, chronic periodontitis measured by CAL and PD was positively associated with IFG and DM in U.S. adults after adjusting for confounders. An obvious limitation with this cross-sectional study is the determination of whether IFG led to periodontitis or, alternatively, periodontitis led to IFG.[40]

This review revealed a gap in the literature for randomized control trials to study the relationship between periodontal disease and prediabetes. The purpose of this pilot study was to determine the impact of NSPT on clinical measures of prediabetes and periodontitis.

Methods and Materials

This was a quasi-experimental design of individuals previously diagnosed with prediabetes and chronic periodontitis. It took place in the Forsyth School of Dental Hygiene clinic located in Boston.

The study was approved by the Massachusetts College of Pharmacy and Health Science Institutional Review Board. All participants provided informed consent and received a Forsyth School of Dental Hygiene Health Insurance Portability and Accountability Act (HIPPA) form. Participants were recruited from flyers distributed in local health care facilities, a poster displayed in the clinic, and an ad placed in a local daily paper. Periodontal therapy was provided at the same study site and performed by the same registered dental hygienist to ensure consistency in patient care. Participants included 5 females and 7 males. The age range of participants was 35 to 75. Risk factors for diabetes included level of physical activity, waist circumference, weight, height and diet, and were assessed at baseline and at 3 months.

This study measured IFG, IGT, A1C and periodontal parameters PD, PI, GI and CAL for improved clinical measures of prediabetes at 3 months post-NSPT in subjects with prediabetes and treated chronic slight to moderate periodontitis. Periodontal measurements were performed by a single examiner and registered dental hygienist. The examiner was calibrated for reproducibility of PD and CAL measurements by conducting a periodontal examination on random quadrants in 10 volunteers. Duplicate measurements were performed with follow-up repeated measures within 1 week to provide intra-examiner reliability information. Intra-rater reliability was established at 99% agreement ±1 mm in 10 subjects.

A single registered dental hygienist administered NSPT using the American Academy of Periodontics parameter on chronic periodontitis with slight to moderate loss of periodontal support and oral hygiene instructions at the study site.[41] Participants were asked to perform daily oral hygiene, including interdental care and tooth brushing.

The participant criteria consisted of:

- ≥21 years of age
- Understand written and spoken English and able to provide informed consent
- Previously diagnosed with prediabetes
- Under the care of a primary care physician
- Having periodontal disease confirmed by periodontal examination revealing proximal attachment loss of ≥4 mm and in >2 non-adjacent teeth
- Dentate (minimum of 16 natural teeth with at least 2 molar proximal contacts)
- No periodontal therapy in the past 6 months

Individuals were excluded based on the following criteria:

- Previous diagnosis of type 1 or type 2 diabetes
- Use of medications to prevent diabetes
- Tobacco use in the past year
- Blood dyscrasias, such as hemophilia
- Use of anticoagulants, such as warfarin, immunocompromised or taking medications leading to compromised immunity
- Requiring prophylactic antibiotics for dental care as defined by 2008 American Heart Association (AHA) guidelines
- Currently pregnant, planning pregnancy prior to study end, <3 months postpartum, or breastfeeding
- Unable or unwilling to complete the OGTT or fingerstick
- In need of emergent medical consultation or dental treament

The OGTT requires consumption of a glucose-containing liquid. A fasting glucose blood test was performed on all participants after an 8 hour fast. After the finger stick, participants were asked to drink 75 milligrams of Trutol® (Thermo Fisher Scientific, East Providence, RI) and to have a second finger stick 1 hour and then 2 hours (±15 minutes) after the first. A finger stick was used to gather a blood sample from each participant at the baseline, and 1 and 2 hour time points. A POC glucometer used in hospitals, StatStrip™ Glucose Hospital Meter (Nova Biomedical Corporation, Waltham, Mass.), with a 95 to 97% correlation to plasma blood glucose levels was used.[42] Finger sticks were done by trained study personnel at the baseline, and 1 and 2 hour time points during the initial examination and at the 3 month examination.

A1C was measured by a POC instrument at baseline and 3 months. The DCA Vantage™ (Siemens Healthcare, Erlangen, Germany) found in an investigation of the conformance with the National Glycohemoglobin Standardization Program certification criteria of various HbA1C instruments to meet the acceptance criteria of having <3% imprecision, which makes it equivalent to laboratory-based methods.[43,44]

A periodontal chart including PD, CAL, GI, PI and number of missing teeth were recorded at baseline and 3 months. PD and CAL recordings were made using a UNC-12 periodontal probe on 6 surfaces of all teeth except for third molars. PD was measured as the distance from the free gingival margin to the base of the periodontal pocket. CAL was measured as the distance from the cemento-enamel junction to the base of the sulcus or periodontal pocket (CAL=PD - (CEJ – gingival margin (GM)). Where the GM was subject to recession and the CEJ was exposed, the distance from the CEJ to the GM was given a negative value. Where the GM covered the CEJ, the distance between the GM and CEJ was given a positive value.

The GI was evaluated using a mouth mirror and a UNC-12 probe to determine changes in color, texture, tendency to hemorrhage and presence or absence of ulceration. The gingiva around each tooth was divided into 4 areas corresponding to the mesial (M), distal (D), buccal (B) and lingual (L) surfaces of the tooth, and each of the 4 areas around each tooth was given a score of 0 to 3. The PI evaluated the amount of plaque and soft debris at the gingival margins of the teeth and the 4 gingival areas of each tooth were B, L, M and D and were given scores ranging from 0 to 3.

Height and weight were measured by study personnel. A single scale was used for all participants at baseline and 3 months. The scale was placed on a hard, flat surface and checked for zero balance before each measurement. Body Mass Index (BMI) was calculated using a formula: BMI=(weight (lbs.)*703)/height squared (inches^2).

The waist circumference was measured by placing a tape measure around the abdomen just above the hip bone. The tape was snug but not compressed on the skin and was parallel to the floor. Participants were asked to relax, exhale and then the measure was taken.

The NHANES Food Frequency Questionnaire was used to assess dietary habits at baseline and 3 months for changes in the macronutrients, i.e. carbohydrates, fat and protein may impact glycemic control and possibly IGT. Changes in physical activity can also impact IGT and therefore the physical activity inventory from the Behavior Risk Factor Surveillance System was utilized to control for this factor.

Data was collected for measures of periodontal disease and prediabetes. The mean for each measure was analyzed by the nonparametric Wilcoxon signed rank test for paired data with statistical significance defined at $p<0.05$ using SPSS Statistical Software 17.0.

Results

The study was completed by 12 patients. The prediabetes measures of A1C, IFG and IGT at 1 hour and 2 hours, as well as the periodontal mea-

sures of GI and PI, were compared between the 2 time intervals. PD and CAL were analyzed as the mean whole mouth measures and also isolating number of sites ≥4 mm per individual at baseline and at 3 months. Comparison of mean prediabetes and periodontal measures from baseline and post treatment at 3 months demonstrated an improvement in both clinical measures of prediabetes and periodontal disease (Tables I, II). The measures of IFG, IGT, PI and GI did not reach statistical significance. However, improvements were noted between the baseline and 3 months for all measures. There was a statistically significant difference between the baseline and 3 month measures of A1C (p=0.02), overall PD and ≥4 mm PD (p=0.003, p=0.055) and overall CAL and ≥4 mm CAL (p=0.050, 0.005) (Figures 1, 2). Weight was compared at baseline and at 3 months with a mean increase of 0.05%.

Table I: Periodontal Measures at Baseline and 3 Months

Periodontal Measures	Baseline mean (standard deviation)	3 Months mean (standard deviation)	p-value*
PD	3.23 (0.30)	2.96 (0 .26)	0.003*
PD≥4 mm (number of sites)	40 (17)	33 (18)	0.055*
CAL	3.24 (0.49)	2.92 (0.38)	0.050*
CAL≥4 mm (number of sites)	54 (22)	37 (16)	0.005*
GI	1.58 0.26)	1.58 (0.33)	0.944
PI	1.21 (0.37)	1.1 (0.39)	0.497

*Reached statistical significance

Table II: Prediabetes Measures at Baseline and 3 Months

Prediabetes Measures	Baseline mean (standard deviation)	3 Months mean (standard deviation)	p-value*
IFG	112 (18.69)	112 (17)	0.798
IGT 1 hour	209 (51.60)	198 (44.84)	0.346
IGT 2 hour	192 (66.05)	182 (66.69)	0.424
A1C	6.08 (0.51)	5.89 (0.45)	0.015*

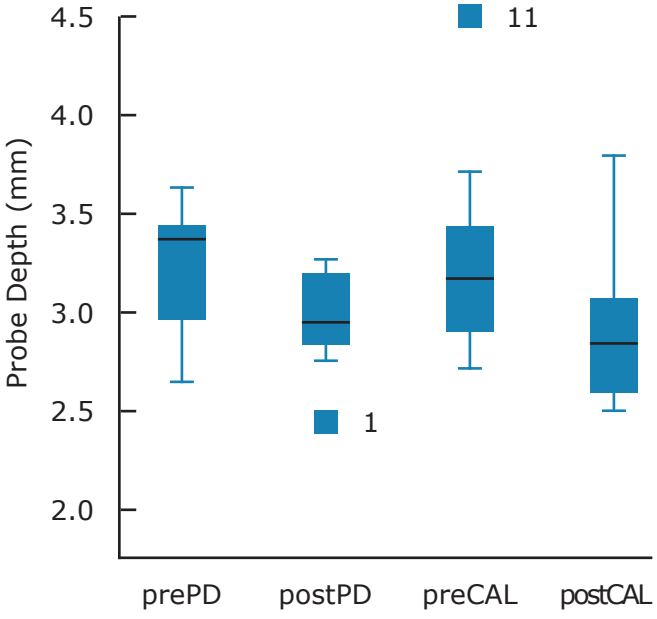
*Reached statistical significance

Discussion

In this pilot study, individuals with prediabetes and periodontal disease received NSPT to determine whether there were clinical differences between the baseline clinical prediabetes and periodontal measures and the 3 month measures. Improvement was observed between baseline and 3 months for both prediabetes and periodontal measures. No significant changes in medications, BMI, physical activity or diet were noted.

The results showed a statistically significant difference in the A1C (-3%, p= 0.02) from baseline and 3 months. These results are similar to previous studies suggesting that periodontal disease may be associated with elevated blood glucose levels in individuals without DM.[34-39,45] Providing NSPT was impactful on the measures for PD and prediabetes for the study participants. Reducing A1C by any degree is beneficial and providing treatment of periodontal disease may lessen the risk for developing DM.

Figure 1: Means, Standard Deviation and Standard Error at Baseline and Post-Treatment for PD and CAL



Limitations of this study were the small sample size, lack of randomization and a control group which was reflected in the study design. Recruitment of qualified participants was challenging. An affiliation with a medical center where individuals diagnosed with prediabetes could be referred would have been advantageous.

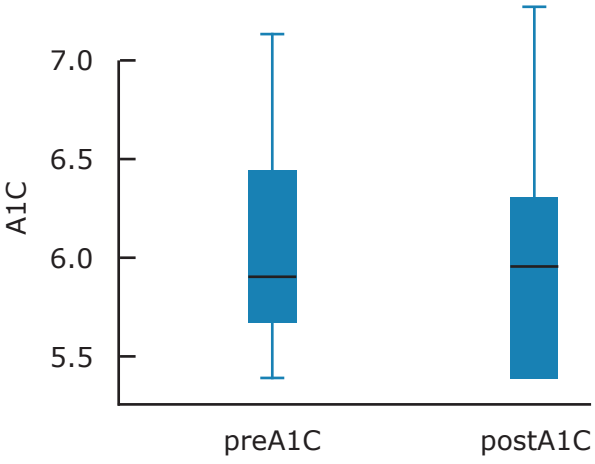
Blood glucose measures were conducted using a POC glucometer with a 95 to 97% correlation to plasma blood glucose levels and a POC HbA1C instrument that met the acceptance criteria of having <3% imprecision. Regardless, the POC tests cannot be substituted for a laboratory test. Advantages to using these tests were convenience, ease of use and patient compliance.

Studies suggest inflammation as a common denominator in periodontal disease, diabetes, prediabetes and other systemic diseases. However, the mechanisms between inflammation and these diseases are not fully understood. Because periodontal disease is an inflammatory disease, further larger scaled, randomized controlled trials controlling for confounders are needed to demonstrate its effect on blood glucose at a metabolic level. Studies should focus on prevention at the earliest stage possible. In addition, oral health should be included in diabetes prevention and management programs.

Conclusion

These findings suggest treating periodontal disease with NSPT reduced A1C levels in prediabetic individuals. Treating periodontal disease had a positive impact on at risk prediabetic individuals and reduced their overall blood sugar glucose. This is important because the incidence and prevalence of diabetes and prediabetes is increasingly becoming a global health concern. Primary care providers are trying to address the diagnosis of diabetes and its complications; however, many health care providers and patients fail to make the oral health connection.

Figure 2: Means, Standard Deviation and Standard Error at Baseline and 3 Months Post-Treatment for A1C



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Acknowledgments

The authors thank ADHA, IOH for funding of this grant, J&S Medical Associates – a division JRB Medical Associates, Framingham, Mass., for use of the DCA Vantage.

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ADHA/Sigma Phi Alpha Journalism Award: Baccalaureate

Assessment of Women, Infants and Children Providers' Perceptions of Oral Health Counseling and Availability of Associated Resources

Tiffany A. Mendryga, RDH, BSDH; Anne E. Gwozdek, RDH, BA, MA

This project won 1st place in the ADHA Sigma Phi Alpha Journalism Award Competition, June 2013, under the baccalaureate or degree completion candidate category. Award provided by a generous grant from Johnson & Johnson Healthcare Products, Division of McNEIL PPC, Inc.

Abstract

Purpose: Children from low-income families and ethnic minority groups are associated with an increased risk of developing dental disease and are often enrolled in the Women, Infants and Children (WIC) nutritional program. It has been an intention of the Michigan Department of Community Health (MDCH) Oral Health Program (OHP) to collaborate with WIC to provide preventive oral health resources and education to their population. This project focused on achieving the goals outlined in the Michigan 2010 State Oral Health Plan.

Methods: An 18 question survey was designed to identify gaps existing in oral health counseling in Michigan WIC agencies. The survey was disseminated to 56 MI WIC agencies.

Results: WIC providers perceive oral health risk assessment to be important and are asking oral health questions during certification and re-certification appointments. Seventy-nine percent of participants indicated they never had training in oral health counseling, and 79% are interested in learning more about oral health. Agencies are interested in obtaining oral health education resources for their clients.

Conclusion: The 2010 State Oral Health Plan's goals recognized the need for oral health related resources and education within community-based programs like WIC. The results of the survey support the need for additional oral health counseling and associated resources in WIC agencies. This information will be used to help the MDCH OHP find ways to address these gaps.

Keywords: WIC, oral health, counseling, community-based programs, oral health program

This study supports the NDHRA priority area, **Health Promotion/Disease Prevention:** Investigate how environmental factors (culture, socioeconomic status-SES, education) influence oral health behaviors.

Introduction

The mission of the Michigan Department of Community Health's (MDCH) is to "protect, preserve, and promote the health and safety of the people of Michigan with particular attention to providing for the needs of vulnerable and under-served populations."[1] The Special Supplemental Nutrition Program for Woman, Infants, and Children (WIC) is a federally-funded program that provides nutritious food supplementation, education, screening and referral to health and social services.[2] WIC partners with the health care community, receiving referrals from private and public health care providers. WIC also refers participants for immunizations, substance abuse counseling/treatment, prenatal care, smoking cessation programs, lead screening, and in Michigan, refers children to the Healthy Kids Dental/MI Child dental services program.[2] The MDCH Oral Health Program (OHP) has been strategically interested in working with WIC to identify the needs associated with oral health education and available recourses.

The purpose of this study was to investigate WIC providers' perceptions of oral health counseling and availability of associated resources. The aim was to assist the MDCH OHP in identifying gaps in oral health counseling training and needed health education resources for WIC providers.

MDCH

The MDCH designs programs to improve health outcomes and the quality of life.[3] The OHP focuses on improving the oral health of all Michigan citizens. WIC is a health and nutrition program that has demonstrated positive health outcomes for pregnant women and their children.[3] It has been a strategic goal of the MDCH OHP to increase collaboration with community–based programs like WIC to provide preventive oral health resources and education to their population (Deming, personal communication, January 2012).

WIC Nutritional Program

The at-risk low-socioeconomic population served

by WIC is comprised of pregnant, breastfeeding and non-breastfeeding postpartum women in addition to infants and children up to 5 years of age.[2] WIC's objective is to improve fetal growth and development, improve health and development of infants and children, and increase access to health related services.[2] It is the third largest nutrition assistance program in the U.S. with 10 million participants and a reported annual expenditure of $6.8 billion in 2010.[2]

Michigan Department of Community Health State Oral Health Plan

The MDCH, Michigan Oral Health Coalition and numerous stakeholders across Michigan developed the 2010 State Oral Health Plan. The purpose of the plan was to provide goals and objectives to increase access to oral health care and evaluate progress towards meeting both national and state health objectives.[4] The plan identifies strategies that can be implemented to improve oral health, opportunities for research, encourages development of preventive and restorative programs to reduce disparities, provides vital resources of information for lawmakers, and empowers local advocacy groups to pursue policies to improve oral health.[4]

The plan has 10 goals with accompanying action steps. Two goals are applicable to the WIC population. The MDCH OHP recognized the importance of partnering with WIC to achieve the following 2 goals.

Goal 2: Implement evidence-based preventive practices that maintain optimal oral health for Michigan communities. Action Step: Research evidence-based dentistry to maintain optimal oral health for Michigan's communities to include:

- Research and promote prenatal and postpartum oral health care
- Infant oral health
- Mandatory oral health exams prior to school enrollment and prior to 5th grade with a mechanism for referral to insure comprehensive care
- Adult dental access
- Elderly dental access
- Special populations access[4]

Goal 4: Provide information about the availability of comprehensive and culturally sensitive oral health education resources. Action Step: Partner with organizations (e.g., WIC, Head Start, Maternal Infant Health, Children's Special Health Care Services, Area Agencies on Aging/Healthy Aging Initiative, special needs organizations, Disability Council, National Institute of Dental and Craniofacial Research, etc. to provide resources to support comprehensive and culturally sensitive oral health education and prevention activities.[4]

The Pregnant Patient and Oral Health Issues

The WIC population has an increased risk for oral diseases for several reasons. The inability to access or afford regular dental care can lead to untreated tooth decay and periodontal disease.[5] Untreated oral health issues will place an individual with an increased risk of other health problems. Pregnant mothers experience temporary adaptive changes to their bodies causing an increased production of various hormones making her more susceptible to gingival and periodontal diseases.[6] According to the 2010 State Oral Health Plan, 25% of pregnant women did not see the dentist at all during pregnancy, and 38% visited the dentist just once in the previous year.[6]

Investigators have reported a potential association between preterm delivery/low birth weight and the presence of inflammation.[7] Some studies suggest that pregnant patients with existing or developing oral conditions like gingivitis or periodontitis and poor oral hygiene are at great risk for preterm delivery/low birth weight infants.[8-10] Morning sickness or nausea is quite common for many pregnant women. The gastric acid entering the oral cavity after vomiting may cause lingual enamel erosion on the maxillary anterior teeth.[11] After several episodes the enamel may break down resulting in an increased risk for dental caries.

Early Childhood Oral Health Issues

The Centers for Disease Control and Prevention report that dental caries is the most prevalent infectious disease affecting children in the U.S. with WIC children being at higher risk.[12,13] Forty percent of children have decay by the time they begin school.[14] Early childhood caries (ECC) is defined as beginning soon after tooth eruption and progressing rapidly.[13] ECC affects the general population but is 32-times more likely to occur in infants who are of low socioeconomic status, who consume a diet high in sugar and whose mothers have a low education level, such as children of mothers enrolled in WIC.[13]

Dental caries is a preventable disease. Determining caries risk in children, providing education on oral health matters to their parents and caregivers, and controlling demineralization are important in prevention.[15] Interventions, especially through public health initiatives are important, practical and an inexpensive way to help reduce the occurrence of dental caries in children.[15] WIC is one such public health initiative.

Oral Health Counseling

Oral health counseling consists of providing advice and utilizing persuasive approaches to positively impact a person to adopt a health conscious lifestyle.[16] Health care providers, such as those who work with the WIC program, can help clients make decisions about behavior change and provide them with necessary resources. A study by Butani et al assessed attitudes towards oral health counseling by Illinois WIC providers.[5] Twenty-seven percent of the participants reported that they had some form of oral health training, mostly through continuing education programs, while 61% reported feeling either "very comfortable" or "comfortable" in discussing oral health issues with their clients.[5] The 3 top reasons for being "somewhat comfortable" or "not comfortable at all" were lack of oral health knowledge, busy workplace and lack of confidence in addressing oral health issues.[5]

When the WIC participants were asked the question "how often in the last three months was any time spent discussing oral health," 60% reported spending some or little time discussing oral health with their clients, and only 13% reported having these discussions with all of their clients.[5] Results of this study show that WIC providers are interested in offering oral health counseling and resources to their clients. However, it is important for providers to receive appropriate training to be more comfortable and knowledgeable about oral health concepts to improve the oral health status of their clients.[5]

Oral health counseling is an important component of WIC programs. Training and appropriate resources for WIC providers are essential to adequately address oral health issues. Agency collaborations, such as those developed by the MDCH OHP and WIC, can execute initiatives that focus on improving the health of the WIC population. Therefore, the purpose of this study was to investigate WIC providers' perceptions of oral health counseling and availability of associated resources. The aim was to assist the MDCH OHP in identifying gaps in oral health counseling training and needed health education resources for WIC providers.

Methods and Materials

An 18-question survey consisting of multiple choice and open ended questions was developed in collaboration with the administration of the MDCH Oral Health and WIC Programs (Table I). The study protocol was presented to the MDCH Institutional Review Board for review and received exemption status.

To determine content validity, a survey pilot testing process was conducted with 3 WIC staff members. Modifications to the survey were made based on feedback. The final survey was emailed to a convenience sample of all 56 WIC coordinators in Michigan, each being asked to identify 1 competent professional authority (CPA) or registered dietician (RD) staff member from their agency to complete the survey. The CPA or RD are providers that have the majority of the health related interaction with the WIC clients and were determined to be best suited to participate in the survey.

An email introduction/invitation was sent that included the purpose of the project, the intended significance, informed consent and a link to participate via SurveyMonkey. The survey was open to participants for 3 weeks with reminder notifications emailed twice. The survey results were analyzed by obtaining descriptive statistics, specifically the number of respondents and percent of respondents, for each survey item.

Results

Out of the 56 surveys sent, 48 were started. However, 46 surveys were actually completed resulting in a response rate of 80%. Participants were well distributed throughout the state. The numbers of respondents to each question are reported with the related results.

The majority of the participants were RDs (42%) or CPAs (42%). Thirty-five percent of the participants were WIC Coordinators and 20% were registered nurses. A small percentage were nutritionists, clerks or techs. In addition, 6 in the "other" category included 3 breastfeeding coordinators, 2 WIC supervisors and 1 enrollment eligibility specialist.

Oral Health Counseling

Seventy-nine percent of the participants indicated they had no prior training in oral health counseling. Those who had were asked how they obtained this training, indicating to choose all that apply. Of those who had training, 2 had prior oral health counseling education during their college/university coursework and 1 obtained training during a continuing education (CE) course. The majority, 6, listed "other" as their response with 1 of the participants being a dental hygienist and the others identified that they had participated in an in-service taught by a dental professional.

Oral Health and the WIC Client

Participants were asked about the certification process that the mother completes at the initial

Table I: WIC Survey Questions

1. What counties does your WIC agency serve?
2. Enter your WIC agency number.
3. What is your role at your WIC agency?
4. Have you had any prior training in dental health/oral health counseling?
5. If you answered "yes" in question 4, how have you obtained this training?
6. In routine certification and recertification appointments are the following questions adequate for addressing dental/oral health risk? • Fluoride use • Pacifier in honey (or other sugar substance) • Juice in a bottle • Sippy cup all day • Other (please specify)
7. Are you interested in adding other dental-related risk questions?
8. What questions and concerns from WIC clients related to their dental/oral health have you experienced?
9. Is your WIC agency interested in additional dental/oral health training?
10. If you answered "yes" to question 9, please identify training topics.
11. Would your WIC agency be interested in having this training provided?
12. Does your WIC agency have a list of dentists for referrals?
13. Does your WIC agency have dental/oral health pamphlets and/or materials for distribution to clients?
14. If you answered "yes" to question 13, list topics covered and in what languages.
15. Do your WIC clients have access to: • Computer at the WIC agency • Home computer • Public library computer • Smart phone • Other (please specify)
16. Do WIC staff members at your agency direct clients to online resources such as WICHealth.org lessons for health information?
17. Do WIC staff members at your agency have a resource sheet or website to access if they receive dental/oral health related questions from their clients?
18. If you answered "no" to question 17, would you be interested in such resources?

appointment and every 3 months thereafter. During these appointments, several specific certification questions are used to determine health risks related to the mother and her children. The findings are then used to design a unique education session for each family. The survey question asked if the dentally related questions already included are adequate for assessing oral health risk. The majority of the participants indicated that the subject matter of the questions used during a certification and recertification appointment are adequate (Figure 1). Thirty-two percent responded "other" and felt that topics such as asking if the child has seen a dentist, sugar intake frequency and identifying problems that effect eating are helpful in determining oral health risks.

Participants were asked to identify other dental-related risk topics to help make referrals. The most pertinent risk factors were oral hygiene habits (79%), sharing utensils (61%) and dental pain (49%) (Figure 2).

WIC clients often have their own questions about oral health. Figure 3 shows that 98% of WIC providers have been asked when the child's first dental visit should occur. The "other" responses included questions about children having tooth problems, dental clinics for the uninsured, Medicaid dental coverage for mother and child, and when to give fluoride drops to infants.

Oral Health Counseling Training

Seventy-nine percent of the participants indicated they were interested in additional oral health training. Of the training topics listed, the baby's first dental visit (87%) and fluoride in infant formula (78%) were most requested (Figure 4). In the "other" category, participants listed fluoride counseling, care of infants' oral health and pregnancy

oral health, bottle use over 1 year/baby bottle tooth decay, the importance of regular dental visits, and proper brushing techniques.

Participants were asked about the preferred delivery method of additional training. Figure 5 shows that 72% would prefer webinars/web casts and 70% online learning modules. Almost half (46%) prefer training at the WIC Annual Conference.

Oral Health Resources

One of the responsibilities of the WIC agency is facilitating access to dental care. Eighty-one percent of the participating WIC agencies have a list of licensed dentists who would accept referral patients. When asked about the availability of patient education materials, 69% indicated they have the resources. If the participant identified materials would be helpful they were then asked to list what topics. Topics they would like to have in resource materials are sippy cup risks and baby bottle tooth decay, first dental visit/importance of regular care, fluoride recommendations, referral list to dental offices that accept Medicaid, and how to brush properly. Those that identified they had educational materials indicated that most were available only in English. However, some agencies had resources in Spanish, Arabic, Albanian, Hmong and Bengali.

Fifty-three percent of survey participants have access to toothbrushes and toothpaste for the WIC clients. Many purchase these with their agency's funds and some receive donations from local vendors, local dentists or outreach programs.

When asked if clients have access to electronic devices that could be used for education purposes, 85% noted their clients have access to computers at a public library, home computers (83%), smart phones (54%) and 41% have a computer at the WIC agency (Figure 6). Seventeen percent indicated their clients have no electronic devices, or have friends with a computer. The majority (96%) of WIC staff members have directed clients to online resources such as WICHealth.org lessons for general health information. Seventy-one percent of participants have a resource sheet or website to access if clients ask oral health related questions.

Figure 1: In Routine Certification and Recertification Appointments, are the Following Questions Adequate for Assessing Dental/Oral Helath Risk (percentage) (n=47)?

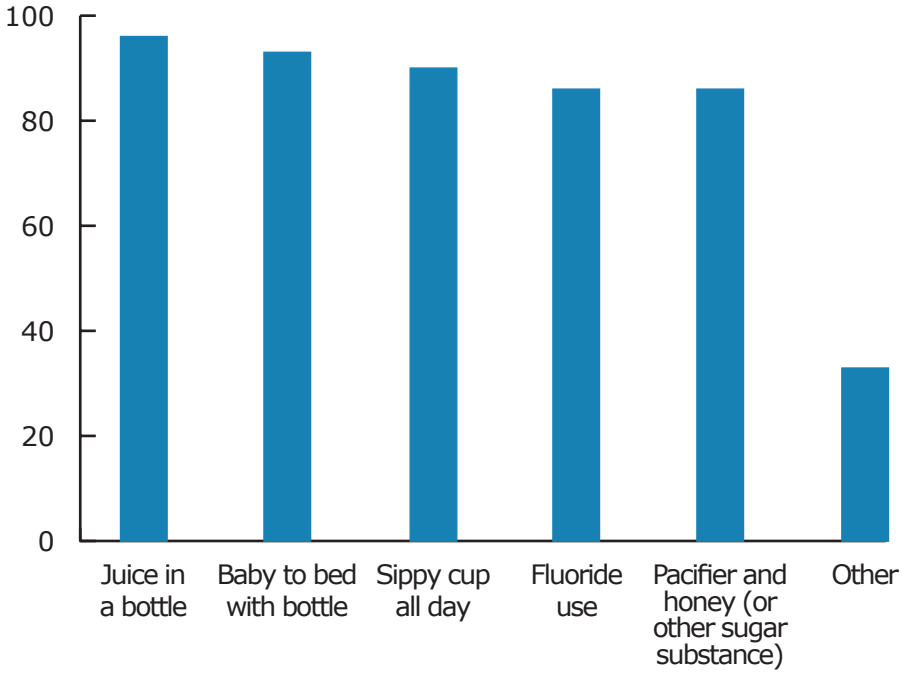
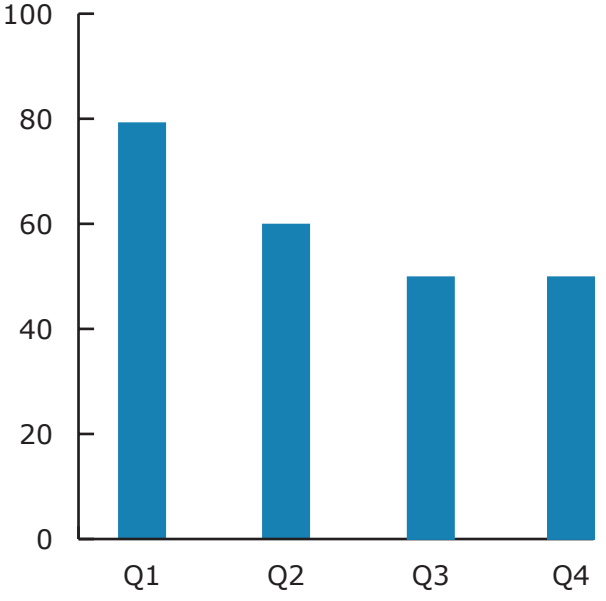


Figure 2: Are You Interested in Other Dental-Related Risk Questions to Make Referrals (percentage) (n=43)?



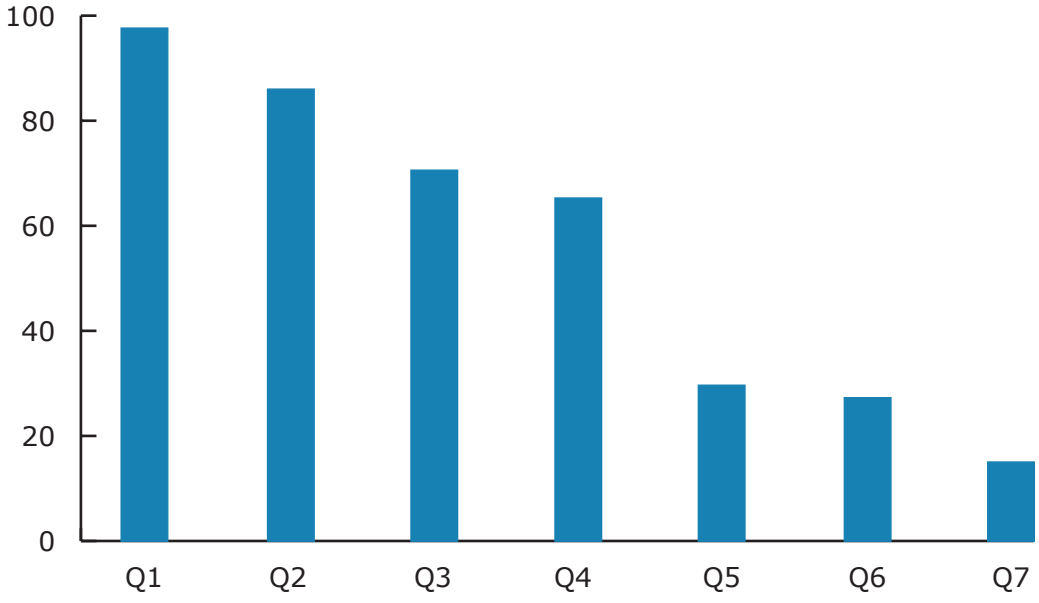
Q1: Oral hygiene habits (brushing, flossing, rinsing, etc.)
Q2: Mothers sharing cups/silverware (passing germs)
Q3: Dental pain/problems
Q4: Other

Discussion

The survey identified a gap between oral health counseling and WIC programs. A majority of the participants indicated that they had no prior training in oral health counseling. If WIC providers

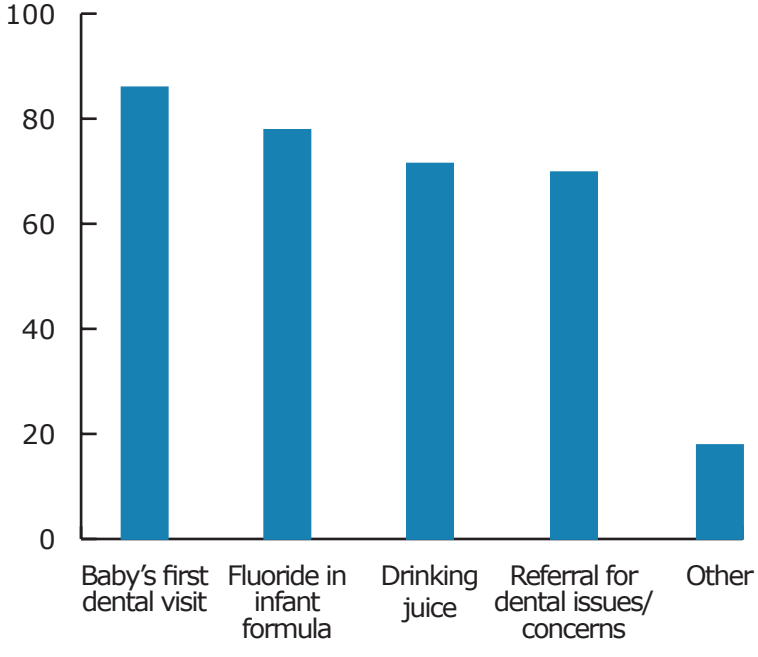
do not have proper training in oral health counseling it can have an effect on their comfort level in educating their clients about oral health or have the expertise/resources to do so. It is significant that agencies are interested in additional oral health training. A majority prefer this by means of webinars/web casts which would not require travel for participation. Another respondent recommended that the training should be archived for future usage. The MDCH OHP will be able to use the findings to help address the gaps existing in oral health counseling at WIC agencies. In addition, it will assist in achieving the goals included in the 2010 State Oral Health Plan, which are to collaborate with WIC to provide preventive oral health resources and education to their vulnerable population.[4]

Figure 3: What Questions and Concerns From WIC Clients Related to their Dental/Oral Health Have You Experienced (percentage) (n=47)?



Q1: When should my child first visit the dentist?
Q2: Do you have a list of dentists?
Q3: When should I begin brushing my child's teeth?
Q4: When should I begin to use fluoride toothpaste with my child?
Q5: What if the mother's teeth hurt?
Q6: What if the child's teeth hurt?
Q7: Other

Figure 4: Topics Requested for Additional Oral Health Training (percentage) (n=37).

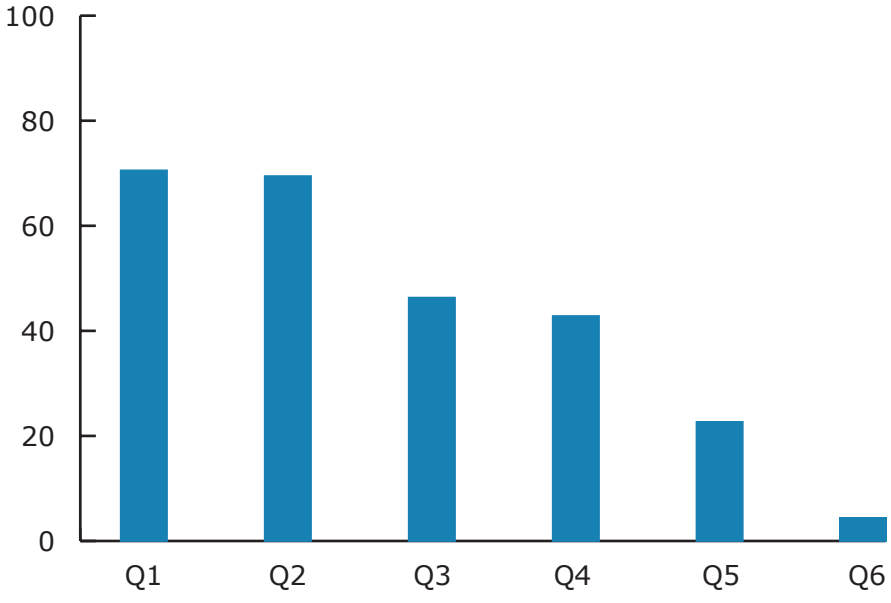


Participants indicated significant interest in additional oral health training and identified a list of possible topics. Information on how to alter clients' attitudes on the importance of regular dental checkups for their children was requested. Other concerns correspond to the frequent patient questions/concerns about fluoride, bottle use and additional information on the baby's first dental visit. This information can assist the MDCH OHP in identifying possible training topics to offer to WIC providers. Additional training could also increase the confidence of WIC providers in addressing oral health issues.[5]

A majority of survey participants indicated that additional oral health risk assessment questions should be asked during WIC certification and recertification appointments. Having a thorough oral health risk assessment of the clients would help WIC providers deliver individualized patient education and resources during appointments. WIC providers are interested in addressing the oral health needs of their clients and having additional risk-related questions would support their ability to do so.[5]

Many WIC providers find clients ask questions about how to find an oral health care provider for their children. The findings showed that a dental provider referral list available for dissemination to patients would be helpful. However, 81% said that they already have a list of dentists for referrals. It is unclear why this discrepancy exists. It could be possible that the referral lists are out of date, providers on the list are not convenient for the clients, or the providers are not taking new patients. It is recommended that the MDCH OHP explore this issue and, if needed, create a current list of referral dentists in each county for associated WIC agencies.

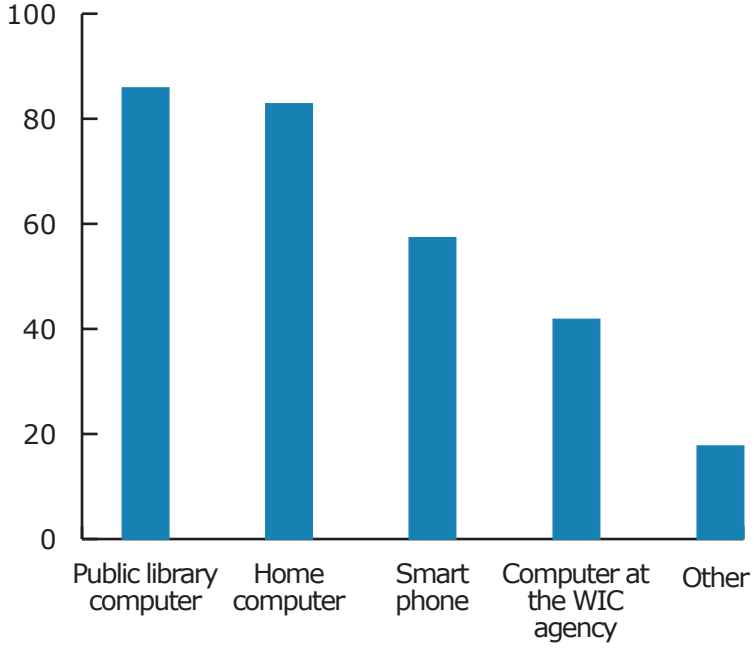
Figure 5: How Would Your WIC Agency be Interested in Having this Training Provided (percentage) (n=48)?



Q1: Webinars/web casts
Q2: Online learning modules
Q3: At the WIC annual conference
Q4: Website with educational resources
Q5: Face-to-face sessions located in your geographic region
Q6: Other

In addition to dental referrals, patients inquire about fluoride recommendations. Clients ask questions about fluoride supplements, the safety of fluoride and fluoride toothpaste. It is recommended the MDCH OHP provide an evidence-based fluoride recommendation reference sheet designed for pregnant women, infants and children. This supports the need for public health interventions that are important, practical and inexpensive in the reduction of dental caries.[15]

Figure 6: Do Your WIC Clients Have Access to Any of the Following (percentage) (n=46)?



Survey participants would also be interested in additional oral health resources like pamphlets and toothpaste/toothbrushes for their clients. Many agencies obtain their own toothpaste/toothbrushes for their clients either through their own funding or via donations. However, all participants indicated they would like to have these supplies available to disseminate to WIC clients. Finding a sustainable source of funding for these supplies is recommended.

A majority of agencies have oral health brochures. However, the need for additional topics related to frequent client questions/concern was indicated. In addition, obtaining language appropriate information would be a recommended area for the MDCH OHP to explore.

Participants indicated that many of their clients have access to the Internet. Whether this is through personal devices, at a public library or at the agency, online oral health resources specific to WIC needs could be a beneficial means of education for clients. An oral health online resource list would be valuable to develop and disseminate to WIC agencies. Because most WIC staff members direct

clients to online resources, such as WICHealth.org lessons, it is recommended that the MDCH OHP explore this website and consider contributing oral health related lessons.

Upon beginning the survey, each participant was asked to identify their role at their agency. In reviewing the results, this question was determined to have limitations for 2 reasons. Some respondents had multiple roles at WIC so it was unknown which was their primary responsibility. Also, this question did not inquire about participants' direct contact with WIC clients at certification/recertification visits. Thus it is unclear what basis they had for their responses about oral health risk assessment and client oral health questions later in the survey.

Additional oral health counseling training and associated resources has been identified as a need by WIC providers. Dental hygienists' educational background and knowledge about nutrition and health behavior change would position them well to assist in developing lessons, resources and/or to serve within WIC. This interprofessional collaboration could be of benefit to the MDCH OHP, WIC clients and providers, and could also serve as an enhanced career opportunity for dental hygienists. Recommended areas of further study include the investigation of interprofessional collaboration initiatives with WIC agencies and their impact on providers and clients.

Conclusion

The Michigan 2010 State Oral Health Plan goals recognized the need for oral health related resources and education within community-based programs like WIC. This study supports collaboration between WIC and the MDCH OHP to find ways to improve the oral health status for low-income families. The results of the survey indicate a gap exists in oral health counseling in Michigan WIC agencies and acknowledges that providers are interested in additional oral health training and resources. These recommendations will assist the MDCH OHP in developing a plan to address these issues. Additional research is suggested to assess the specific WIC related oral health counseling/resource needs for each geographic area in Michigan. Assessing each area will provide a better understanding on how to appropriately address the needs for that population and how to provide applicable training for WIC providers.

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Acknowledgments

The authors would like to thank Susan Deming, RDH, RDA, BS, Education and Fluoridation Coordinator-Michigan Department of Community Health Oral Health Program who served as the project advisor. Appreciation is also extended to Jean Egan, Training, Evaluation and Compliance Unit- WIC and Kaitlin Skwir, Michigan WIC Staff Training Staff, and Christine Farrell, RDH, BSDH, MPA, MDCH Oral Health Program Director, who served as project consultants. In addition, the authors are grateful to Jane Halaris, RDH, BS, MA, for her assistance in the initial review of this study's documentation.

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Early Benefits with Daily Rinsing on Gingival Health Improvements with an Essential Oil Mouthrinse – Post–Hoc Analysis of 5 Clinical Trials

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Abstract

Purpose: The aim of this investigation through post-hoc analyses was to determine the ability to achieve gingival health in the short term with daily rinsing with an essential oil containing antimicrobial mouthrinse.

Methods: Conventional Analysis of Covariance (ANCOVA) on whole mouth mean plaque and gingivitis scores were originally conducted to demonstrate efficacy of adjunctive use of Cool Mint® LISTERINE® Antiseptic (EO) compared to negative control [brushing (B) or brushing/flossing (BF)] in each of 5 studies containing a 4 week evaluation. The Modified Gingival Index (MGI) was split into 2 categories: healthy (scores 0, 1) and unhealthy (≥2). Data, reflecting subjects that completed 4 weeks of treatment from 5 studies, were evaluated to determine the mean percent of healthy sites and mean percent of more inflamed "affected" areas (MGI≥3).

Results: At baseline, the mean percent healthy gingival sites ranged from 0.1 to 3.2%. At 4 weeks, up to 29.3% and 16.1% of sites were healthy for the EO group and negative control group, respectively. Three and 6 month data from 2 of the 5 studies resulted in up to 39.6% and 62% at 3 and 6 month mean percent healthy sites per subject for EO and up to 17.2% and 15.6% at 3 and 6 months, respectively, for negative control. Virtually plaque free sites (PI =0, 1) at 4 weeks ranged up to 34.3% and 8.1% for EO and control groups, respectively.

Conclusion: Significantly more healthy gingival sites and virtually plaque free tooth surfaces can be achieved as early as 4 weeks with use of an essential oil antimicrobial mouthrinse. This finding continues through 6 months twice daily use as part of oral care practices compared to mechanical oral hygiene alone.

Keywords: dental plaque, gingivitis, oils, essential, oral health, tooth brushing, prevention mouthrinse

This study supports the NDHRA priority area, **Health Promotion/Disease Prevention:** Investigate the effectiveness of oral self-care behaviors that prevent or reduce oral diseases among all age, social and cultural groups.

Introduction

There is a broad base of evidence for use of antimicrobial mouthrinses, including an essential oil (EO) containing mouthrinse, to provide clinically relevant reductions in supragingival plaque and gingivitis when added to usual oral hygiene. Efficacy has been acknowledged through acceptance by the American Dental Association Council on Scientific Affairs[1] and reported in meta-analysis[2] or systematic reviews.[3,4] This evidence is primarily based on 6-month clinical trials.

Short term efficacy has been reported in experimental gingivitis models for an EO rinse, however, this model is a performance test and does not reflect the intended use as part of a daily oral hygiene program including mechanical oral hygiene.[5,6]

The aim of this investigation was to evaluate the ability of an EO rinse to achieve healthy gingival tissue after 4 weeks use by conducting post-hoc analyses from 5 clinical trials using Modified Gingival Index (MGI) site data. In all 5 clinical trials, a statistically significant difference was demonstrated in favor of the EO rinse over the control using standard analysis of covariance of mean index scores per protocol objectives. Post-hoc analyses were conducted to determine mean percent healthy sites (MGI values 0, 1) and mean percent more inflamed "affected or problem sites" (MGI values≥3) using the MGI site data. The same analyses were also applied to the plaque index to determine percent of virtually plaque free sites (PI values 0, 1) as well as effect on sites with heavier plaque scores (≥3).

Methods and Materials

All clinical studies originally designed to determine efficacy of an EO rinse in subjects with mild-moderate existing plaque and gingivitis having a 4 week evaluation period,[7] and having raw data available, were selected for this report, providing a total of 5 studies. All studies were Institutional Review Board approved, single-center, examiner-

Table I: Demography and Baseline Characteristics

	Study 1		Study 2		Study 3		Study 4		Study 5	
Study Location	Ontario		Ontario		SP, Brazil		Las Vegas		SP, Brazil	
Study Dates	July/August 2011		March/April 2011		November 2011		June/December 2008		September 2011/ March 2012	
Variables	B*	BR#	B	BR	B	BR	BF*	BFR#	B	BR
N(ITT)	32	32	45	46	54	53	64	65	118	117
Age (Years)	41.9	40.2	37.6	41.6	32.7	35.8	32.7	33.2	34.1	35.2
Gender										
Male (%) Female (%)	31.3 68.8	28.1 71.9	33.3 66.7	19.6 80.4	40.0 60.0	45.5 54.5	59.4 40.6	55.4 44.6	34.7 65.3	44.1 55.9
Race										
White (%) Black (%) Asian (%) Other (%)	43.8 25.0 28.1 3.1	37.5 34.4 28.1 0	66.7 17.8 15.6 0	67.4 15.2 15.2 0	78.2 9.1 1.8 10.9	80.0 7.3 3.6 9.1	43.8 31.3 7.8 17.2	46.2 24.6 7.7 21.5	77.1 9.3 1.7 11.9	77.1 12.7 0 10.2
Smoking										
Yes (%) No (%)	12.5 87.5	6.3 93.8	17.8 82.2	15.2 84.8	18.2 81.8	10.9 89.1	20.3 79.7	15.4 84.6	6.8 93.2	8.5 91.5
PI										
Mean SD	2.43 0.28	2.48 0.26	2.46 0.33	2.39 0.31	3.20 0.24	3.22 0.19	3.07 0.40	3.12 0.37	2.80 0.30	2.80 0.28
MGI										
Mean SD	2.04 0.07	2.04 0.09	2.05 0.12	2.03 0.11	2.49 0.17	2.49 0.17	2.22 0.09	2.22 0.10	2.24 0.14	2.24 0.12
Percent healthy sites										
Mean SD	1.7 2.75	2.2 2.07	3.2 4.5	3.2 3.93	0.1 0.59	0.1 0.52	0.1 0.36	0.1 0.36	2.7 3.95	2.0 3.33
MGI>=3 Percent sites										
Mean SD	5.3 6.13	6.6 8.00	8.3 8.83	6.5 8.55	48.9 16.89	48.4 15.85	21.9 8.66	22.5 10.20	26.8 12.07	25.9 10.58
Percent Plaque free										
Mean SD	1.5 2.64	0.5 1.38	1.6 3.04	1.4 2.43	0.7 1.68	0.2 0.6	0 0	0 0.38	1.8 3.51	1.5 2.63
PI>=3 Percent sites										
Mean SD	34.8 17.13	38.4 18.16	36.7 20.58	31.4 20.07	83.4 12.19	86.0 10.53	79.1 18.16	82.1 16.64	66.5 17.6	67.1 18.43

*B or BF=Negative Control Group; #BR or BFR=EO Group

blind, controlled, randomized trials. In order to assess short term efficacy in achieving healthy gingival tissue post-hoc analyses were conducted on individual gingival sites scored. It is important to note that in addition to the 4 week primary timepoint of interest for this investigation, 1 study had a 2 week evaluation and 2 studies had 3 and 6 month evaluations. Also, 1 of the 6 month studies included a flossing group. For the purposes of these post-hoc analyses, the authors selected the treatment groups from each study that incorporated brushing and placebo rinsing (B) or brushing, flossing (BF) (no placebo rinse), as the negative control group and treatment groups incorporating brushing and EO rinsing (BR) or brushing, flossing and EO rinsing (BFR) as the EO group.

Each study was performed in accordance with the protocol, International Conference on Harmonisation Good Clinical Practice guidelines (ICH E6)[8] and applicable local regulatory requirements and laws. Each trial was statistically powered to meet the individual study objectives. Table I provides further information regarding study group sizes.

Subjects providing informed consent and meeting the inclusion criteria presented to the clinical sites for all examination visits having refrained from oral hygiene for at least 12 hours, but no more than 18 hours prior and having refrained from eating, drinking or smoking for at least 4 hours prior to their examination.

At the baseline, an oral tissue examination was conducted, MGI on the buccal and lingual marginal gingivae and interdental papillae and Turesky modification of the Quigley Hein Plaque Index (PI) on 6 surfaces per tooth were determined.[9-11] If qualified, subjects were randomized to 1 of the study treatment groups, received instructions and were supervised in their first use of the assigned treatment. A baseline supragingival dental prophylaxis was not provided. At all post baseline visits, examinations were completed as at baseline and subjects were assessed for product use compliance.

All subjects were instructed to brush their teeth with the provided fluoride toothpaste and adult soft textured toothbrush. Subjects on rinse regimen used either placebo rinse or Cool Mint® LISTERINE® Antiseptic (Johnson & Johnson Healthcare Product Division of McNEIL-PPC, Inc, Skillman New Jersey) full strength twice daily, 20 mL for 30 seconds. In the case of study 4, BF group brushed and used floss once daily and the BFR group brushed, flossed once daily and rinsed with their assigned mouthrinse twice daily. Subjects maintained a diary of their treatment use which was evaluated periodically through each study for compliance along with assessment of used test product.

During the course of the trials, subjects followed their usual dietary habits. They were instructed not to use any unassigned oral care products, or have their teeth professionally cleaned, bleached or have any dental work done except for an emergency. Subjects were allowed to use an interdental cleaning device only to remove impacted food between the teeth (studies 1-3, 5). As the subjects signed a consent form they were sequentially issued a subject ID, and upon qualification, assigned a unique randomization number, which determined the treatment assignments during the study.

Subjects providing informed consent that met the following inclusion criteria were eligible for enrollment into the trials:

- Males and non-pregnant females at least 18 years of age and in good general health
- A minimum of 20 natural teeth with scorable facial and lingual surfaces
- A baseline mean gingival index of >1.75 according to the MGI and mean PI>1.95
- Absence of moderate/advanced periodontitis based on a clinical examination (ADA Type III, IV)
- Absence of fixed or removable orthodontic appliance or removable partial dentures
- No need for prophylactic antibiotic coverage, negative history of allergy related to oral hygiene products and/or red food dye
- No antibiotic, anti-inflammatory, anti-coagulant, chemotherapeutic anti-plaque/anti-gingivitis therapy or any other medication within the previous 4 weeks that may interfere with the efficacy evaluations

The MGI was scored on the buccal and lingual marginal gingivae and interdental papillae of all scorable teeth as follows:

- 0=Normal (absence of inflammation)
- 1=Mild inflammation (slight change in color, little change in texture) of any portion of the entire gingival unit
- 2=Mild inflammation of the entire gingival unit
- 3=Moderate inflammation (moderate glazing, redness, edema, and/or hypertrophy) of the gingival unit
- 4=Severe inflammation (marked redness and edema/hypertrophy, spontaneous bleeding, or ulceration) of the gingival unit

The Turesky modification of the Quigley-Hein Plaque Index was scored on 6 surfaces (distobuccal, midbuccal and mesiobuccal, distolingual, midlingual, and mesiolingual) following disclosing as follows:

- 0=No Plaque
- 1=Separate flecks or discontinuous band of plaque around the gingival (cervical) margin
- 2=Thin (up to 1 mm), continuous band of plaque at the gingival margin
- 3=Band of plaque wider than 1 mm but less than 1/3 of the surface
- 4=Plaque covering 1/3 or more, but less than 2/3 of the surface
- 5=Plaque covering 2/3 or more of the surface

Demographic and baseline characteristics were compared across treatment groups for each study using Analysis of Variance (ANOVA) or a Chi-Square test (as appropriate for the type of data being considered). If the expected number of subjects within a specific category was sufficiently small, Fisher's exact test was used in place of the Chi-Square test.

The primary analysis set was intent to treat subjects, defined as all randomized subjects who used at least 1 dose of the study product and had data

Table II: Whole Mouth Mean Percent Healthy Sites (MGI score 0, 1)

	Study 1		Study 2		Study 3		Study 4		Study 5	
Variables	B*	BR#	B	BR	B	BR	BF*	BFR#	B	BR
N(ITT)	32	32	45	46	54	53	61	63	118	117
Baseline Healthy sites										
Mean SD p-value	1.7 2.75 -	2.2 2.07 p=0.183	3.2 4.5 -	3.2 3.93 p=0.626	0.1 0.59 -	0.1 0.52 p=0.664	0.1 0.36 -	0.1 0.57 p=0.519	2.7 3.95 -	2.0 3.33 p=0.208
4 week percent Healthy sites										
Mean SD p-value	12 6.61 -	25.5 9.80 p<0.001	16.1 7.85 -	29.3 8.60 p<0.001	0.8 3.74 -	7.4 7.71 p<0.001	2.1 3.16 -	4.2 6.49 p=0.052	2.6 4.43 -	26.5 9.29 p<0.001
3 month percent healthy sites										
Mean SD p-value	- - -	- - -	- - -	- - -	- - -	- - -	17.2 12.40 -	29.7 19.82 p<0.001	2.9 4.36 -	39.4 12.57 0.001
6 month percent Healthy sites										
Mean SD p-value	- - -	- - -	- - -	- - -	- - -	- - -	15.6 14.48 -	36.9 25.22 p<0.001	2.6 4.34 -	62 13.53 p<0.001

*B or BF=Negative Control Group; #BR or BFR=EO Group

for mean MGI and PI. Study analyses based on whole mouth mean index scores were performed using the ANCOVA model with treatment as a factor and the corresponding baseline value as a covariate. The comparisons were made at the 0.05 level, 2-sided. Summary statistics were provided by treatment group at each visit. Since each of the studies with a 4 week evaluation resulted in statistically significant differences between the EO rinse and negative control, it was appropriate to conduct further analyses of the study data. Post-hoc analyses, based on site data, were conducted to determine the extent that healthy tissues were attainable in this time period.

Within subject mean percent of healthy sites were calculated by taking numbers of sites with MGI score of 0 or 1 divided by total number of sites (maximum number of sites 108). Similarly, mean percent of within subject virtually plaque free sites (PI score=0, 1) were calculated by taking numbers of sites with PI scores of 0 or 1 divided by total number of sites (maximum number 168 sites). For the more inflamed or problem gingival sites (MGI≥3 representing moderate-severe inflammation) and the most affected sites or greater areas of plaque accumulation (plaque scores≥3), a similar analysis was conducted.

Regardless of the original study objectives or study design, for this investigation, we conducted post-hoc analyses to calculate the mean percent of healthy sites using the MGI, and for PI, the mean percent of virtually plaque free sites. No imputations were made for missing data. Percent of healthy sites and virtually plaque free sites were analyzed by using Wilcoxon rank sum tests with a 2-sided 0.05 significance level within each study. The 95% confidence interval and location shift parameter were calculated by using Hodges-Lehmann approach.[12-14]

Results

Table I provides a summary of demography and baseline data for the 5 studies. There were no differences between the groups in each study. As seen in the table there were some variations among the 5 studies in baseline levels of MGI, e.g. 2.05 (study 2) to 2.49 (study 3). Studies 1 and 2 presented lower baseline MGI and PI and study 3 provided a more diseased population. At baseline there was no imbalance between treatment groups in percent healthy sites or virtually plaque free sites (Table II).

Table II presents whole mouth mean percent healthy sites (MGI value 0, 1). The 3 and 6 month data is also provided in these tables for studies 4 and 5. There were no statistically significant differences between groups at baseline for percent of healthy sites. The whole mouth mean percent of healthy sites per subject at 4 weeks ranged from 0.8 (study 3) to 16.1 (study 2) for the negative control and 4.2 (study 4) to 29.3 (study 2) for the EO group, with all studies showing a difference in favor of the EO rinse, which was significant, except

Table III: Whole Mouth Adjusted Mean MGI, PI and Percent Reductions

	Study 1		Study 2		Study 3		Study 4		Study 5	
Variables										
N(ITT)	B*	BR#	B	BR	B	BR	BF*	BFR#	B	R
4 week MGI										
Adj. Mean	1.93	1.78	1.91	1.75	2.45	2.13	2.15	2.07	2.23	1.89
S.E.	±0.01	±0.01	±0.01	±0.01	±0.02	±0.02	±0.01	±0.01	±0.01	±0.01
Percent Red	-	7.8	-	8.1	-	13.0	-	3.5	-	15.5
p-value	-	p<0.001	-	p<0.001	-	p<0.001	-	p<0.001	-	p<0.001
3 month MGI										
Adj. Mean	-	-	-	-	-	-	1.94	1.77	2.24	1.65
S.E.	-	-	-	-	-	-	±0.023	±0.023	±0.011	±0.011
Percent Red	-	-	-	-	-	-	-	8.9	-	26.3
p-value	-	-	-	-	-	-	-	p<0.001	-	p<0.001
6 month MGI										
Adj. Mean	-	-	-	-	-	-	2.01	1.69	2.415	1.388
S.E.	-	-	-	-	-	-	±0.030	±0.029	±0.015	±0.015
Percent Red	-	-	-	-	-	-	-	15.7	-	42.6
p-value	-	-	-	-	-	-	-	p<0.001	-	p<0.001
4 week PI										
Adj. Mean	2.29	1.79	2.285	1.79	3.07	2.49	2.84	2.34	2.741	2.277
S.E.	±0.04	±0.04	±0.01	±0.01	±0.03	±0.03	±0.04	±0.03	±0.014	±0.014
Percent Red	-	21.8	-	21.9	-	18.9	-	17.5	-	16.9
p-value	-	p<0.001	-	p<0.001	-	p<0.001	-	p<0.001	-	p<0.001
3 month PI										
Adj. Mean	-	-	-	-	-	-	2.14	2.52	2.736	1.948
S.E.	-	-	-	-	-	-	±0.047	±0.047	±0.018	±0.018
Percent Red	-	-	-	-	-	-	-	29.0	-	28.8
p-value	-	-	-	-	-	-	-	p<0.001	-	p<0.001
6 month PI										
Adj. Mean	-	-	-	-	-	-	2.00	1.26	2.891	1.678
S.E.	-	-	-	-	-	-	±0.043	±0.042	±0.019	±0.019
Percent Red	-	-	-	-	-	-	-	36.7	-	42.0
p-value	-	-	-	-	-	-	-	p<0.001	-	p<0.001

*B or BF=Negative Control Group; #BR or BFR=EO Group

for study 4 (p=0.052). For the longer time periods of 3 and 6 months, the mean percent of healthy sites per subject increased over time up to 39.4 at 3 months and up to 62.0 at 6 months for EO group and up to 17.2 and 15.6, respectively, for the negative control group. All improvements were statistically significant and in favor of EO.

Table III provides the traditional whole mouth adjusted mean MGI and PI scores across the 5 studies and the percent reduction for EO vs. negative control. Four week reductions ranged from 3.5% (study 4) to 15.5% (study 5) for MGI and between 16.9% (study 5) and 21.9% (study 2) for PI. A statistically significant difference (p<0.001) was shown between the EO rinse and the negative control in favor of EO at 4 weeks across all 5 studies.

Table IV presents mean percent virtually plaque free sites (PI scores of 0, 1) across the 5 studies, showing no differences at baseline. The 4 week mean percent virtually plaque free sites ranged from 0.4 (study 3) to 8.1 (study 1) in the negative control group and from 4.5 (study 4) to 34.3 (study 1) in the EO rinse group. Statistical significance in favor of the EO rinse was noted at all visits. For studies 4 and 5, at 3 and 6 months, mean percent virtually plaque free sites ranged up to 54.9% and up to 68.8% in the EO group with the negative control group up to 29.6%.

Table V presents the 4 week percent "most affected or problem sites" (MGI≥3 and PI≥3). For the EO rinse group, the range in mean percent MGI problem sites was 3.1 (study 1) to 20.4 (study 3) and for the negative control group, 3.7 (study 1) to 45.7 (study 3). For the whole mouth mean percent heavier plaque accumulation sites per subject, the range was 6.2 (study 2) to 50.9 (study 3) for

Table IV: Mean Percent Virtually Plaque Free Sites (PI score 0, 1)

	Study 1		Study 2		Study 3		Study 4		Study 5	
Variables	B*	BR#	B	BR	B	BR	BF*	BFR#	B	BR
N (ITT)	32	32	45	46	54	53	61	63	118	117
Baseline Plaque Free										
Mean SD p-value	1.5 2.64 -	0.5 1.38 p=0.145	1.6 3.04 -	1.4 2.43 p=0.864	0.7 1.68 -	0.2 0.6 p=0.215	0.0 0.0 -	0.0 0.38 p=0.333	1.8 3.51 -	1.5 2.63 p=0.916
4 week Percent Plaque Free										
Mean SD p-value	8.1 8.09 -	34.3 17.27 p<0.001	1.7 2.85 -	30.5 17.4 p<0.001	0.4 1.37 -	5.4 6.34 p<0.001	1.1 2.90 -	4.5 7.63 p<0.001	0.7 2.67 -	8.5 10.13 p<0.001
3 month Percent Plaque Free										
Mean SD p-value	- - -	- - -	- - -	- - -	- - -	- - -	22.3 18.69 -	54.9 26.14 p<0.001	1.2 3.11 -	22.0 12.07 p<0.001
6 month Percent Plaque Free sites										
Mean SD p-value	- - -	- - -	- - -	- - -	- - -	- - -	29.6 22.77 -	68.8 22.87 p<0.001	0.8 2.52 -	42.3 13.49 p<0.001

*B or BF = Negative Control Group; #BR or BFR = EO Group

the EO group and for the negative control group, 29.4 (study 2) to 81.1% (study 3). All differences were statistically significant ($p<0.001$) in favor of EO with the exception of study 1 ($p=0.833$ for MGI≥3).

Figure 1 provides baseline and 4 week mean percent healthy sites. There were 3.2 or less mean percent healthy sites at baseline across the studies, at 4 weeks up to 29.3 mean percent healthy sites in the EO group, and up to 16.1 in the negative control group.

Figure 2 presents the mean percent of healthy sites per subject over 6 months for studies 4 and 5. EO improvements increase over the 6 months and the EO group is statistically significantly better than mechanical oral hygiene alone at all post baseline visits.

Figure 3 provides baseline and 4 week mean percent virtually plaque free sites (PI scores of 0, 1). There were 1.8 or less mean percent virtually plaque free sites at baseline across the studies, at 4 weeks up to 34.3 mean percent virtually plaque free sites in the EO group, and up to 8.1 in the negative control group.

Discussion

The primary interest for this report was achievement of healthy gingival tissue in the short term; however, since plaque is the primary etiologic agent for gingivitis, the plaque data from the same studies was also examined. This is the first time short term gingivitis and plaque data have been presented as mean percent of sites (areas scored from the MGI). Since gingival health is one of the main goals of oral hygiene care, healthy gingival sites are presented in addition to traditional reductions in the level of gingival inflammation. Similarly, the plaque site data was examined to determine the number of virtually plaque free tooth surfaces.

The use of an EO containing antimicrobial rinse provided a statistically significant reduction in mean plaque scores compared to negative control across all 5 studies. The plaque reductions were quite significant in the short term. In the longer term studies presented, a statistically significant difference was also noted at 3 and 6 months in favor of the EO rinse, providing statistically significant and clinically relevant reductions of up to 42% at 6 months.

Overall gingivitis reductions across the 5 studies (Table II) of up to 15.5% may not be considered clinically relevant in the short term compared to control, however, up to 29.3% mean percent healthy gingival sites could be considered clinically relevant. There is a consistent statistically significant difference in favor of using an EO antimicrobial rinse. This is particularly evident with the more diseased baseline gingivitis condition as shown in study 3.

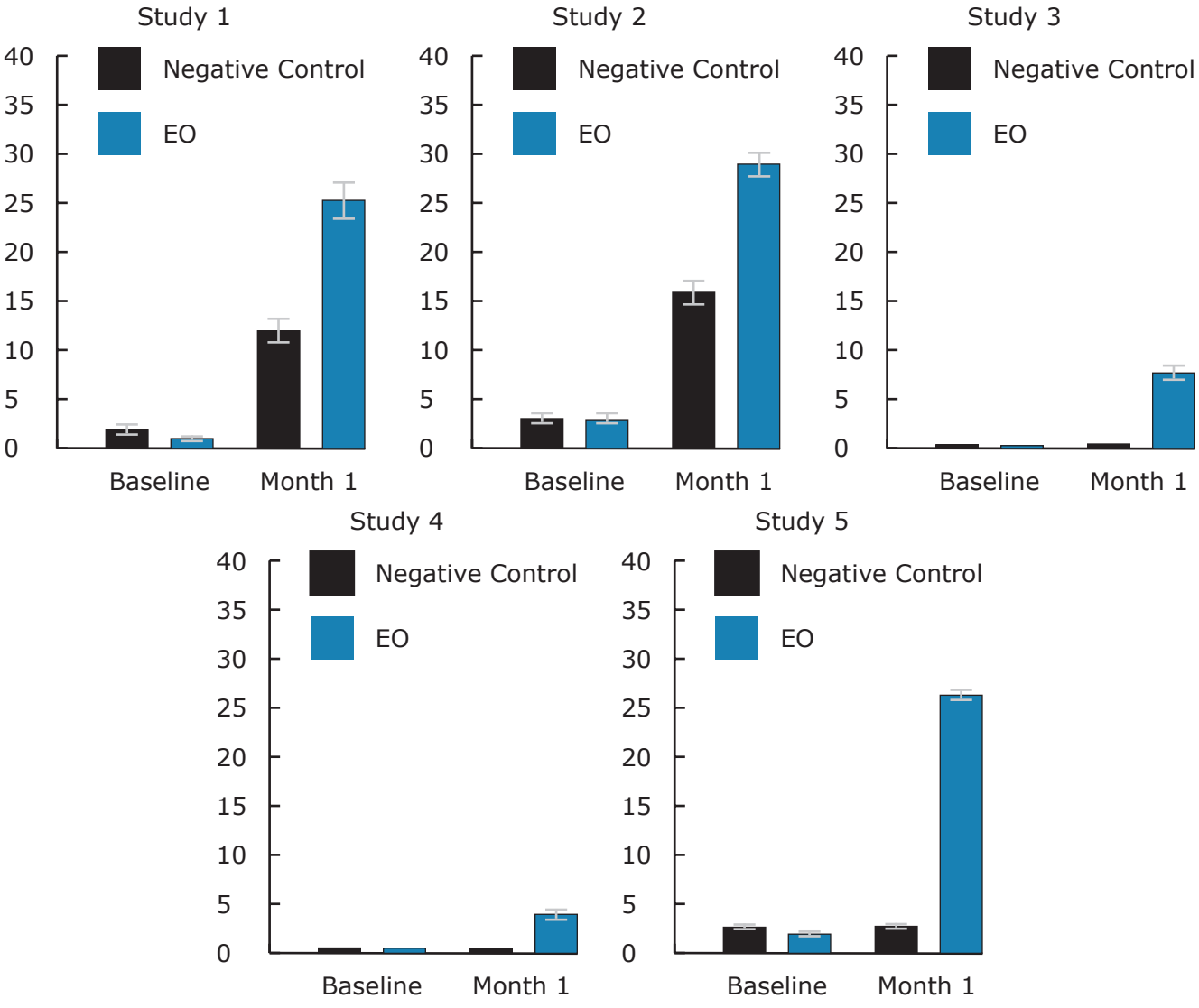
Table V: Baseline and 4 week Mean Percent More Affected or "Problem Sites" (MGI score≥3) and (PI score≥3)

		Study 1		Study 2		Study 3		Study 4		Study 5	
Variables		B*	BR#	B	BR	B	BR	BF*	BFR#	B	BR
N (ITT)		32	32	45	46	54	53	61	63	118	117
Baseline – Gingivitis											
Percent sites MGI ≥3 p-value	Mean SD -	5.3 6.13 -	6.6 8 0.682	8.3 8.83 -	6.5 8.55 0.296	48.9 16.89 -	48.4 15.85 0.669	21.9 8.66 -	22.5 10.20 >0.999	26.8 12.07 -	25.9 10.58 0.651
Baseline - Plaque											
Percent sites PI ≥3 p-value	Mean SD -	34.8 17.3 -	38.4 18.16 0.379	36.7 20.58 -	31.4 20.07 0.335	83.4 12.19 -	86 10.53 0.232	79.1 18.16 -	82.1 16.64 0.345	66.5 17.6 -	67.1 18.43 0.742
Week 4 – Gingivitis											
Percent sites MGI≥3 p-value	Mean S.D. -	3.7 4.18 -	3.1 3.09 p=0.833	7.1 6.82 -	3.1 5.32 p<0.001	45.7 15.18 -	20.4 16.86 p<0.001	17 10.73 -	12 8.20 p=0.003	25.9 12.61 -	15.0 6.69 p<0.001
Week 4 – Plaque											
Percent sites PI≥3 p-value	Mean S.D. -	29.8 12.86 -	13.2 10.60 p<0.001	29.4 19.57 -	6.2 7.85 p<0.001	81.1 13.98 -	50.9 21.74 p<0.001	67.2 22.71 -	36.7 23.69 p<0.001	66.1 20.91 -	35.9 16.74 p<0.001
Month 3 – Gingivitis											
Percent sites MGI≥3 p-value	Mean S.D. -	- - -	- - -	- - -	- - -	- - -	- - -	11.4 9.29 -	7.2 7.29 p<0.003	26.8 12.8 -	4.4 4.5 p<0.001
Month 3 - Plaque											
Percent sites PI≥3 p-value	Mean S.D. -	- - -	- - -	- - -	- - -	- - -	- - -	32.7 19.4 -	11.8 13.32 p<0.001	66 23.11 -	17.1 12.84 p<0.001
Month 6 – Gingivitis											
Percent sites MGI≥3 p-value	Mean S.D. -	- - -	- - -	- - -	- - -	- - -	- - -	16.2 12.24 -	6.8 6.60 p<0.001	44 18.38 -	2.5 3.26 p<0.001
Month 6 – Plaque											
Percent sites PI≥3 p-value	Mean S.D. -	- - -	- - -	- - -	- - -	- - -	- - -	26.5 20.75 -	5.1 6.07 p<0.001	72.5 17.72 -	10.5 7.46 p<0.001

*B or BF = Negative Control Group; #BR or BFR = EO Group

Four weeks was the primary time-point of interest, however, to understand how short term relates to longer term, 3 and 6 month data from 2 of the same studies was considered. It is relevant because not all chemical agents sustain their early benefits, a fact that impacts professional decisions with product recommendations.[15] Similarly, in clinical practice it is important to know how quickly the prescribed oral hygiene program will provide oral health improvements. EO fits both scenarios because the longer it is used, the greater is the improvement that starts very early, as shown in study 2 which incorporated a 2 week examination. A difference in the mean percent healthy gingival sites was noted as early as 2 weeks (negative control group - 11%, and EO group - 18.7% (p<0.001)). A greater improvement was seen in this same study at 4 weeks (negative control - 16.1%, and EO - 29.3%) in mean percent healthy sites (Table III). On the other hand, in studies 4 and 5 that included 3 and 6 month evaluations, a longer term outlook for improving the health of the gingival tissues was exhibited. In study 4, post-hoc analysis provided the mean percent healthy sites for negative control as 2.1 for BF group and for BFR (EO) 4.2 at 4 weeks (Table III). At 3 months, the mean percent healthy sites were 17.2 and 29.7 for the BF (negative control) and BFR (EO) groups, and at 6 months 15.6 and 36.9%, respectively. In this study, although the short term results may not be clinically relevant, they are nevertheless heading in a healthier direction and provide an early indi-

Figure 1: Mean Percent Healthy Sites at Baseline and 4 Weeks



cation that better gingival health can be expected as daily rinsing is practiced consistently over 6 months. In study 5, a similar trend was found with a greater magnitude of improvement. The long term results provide greater and clinically relevant results (Figure 2).

The magnitude of gingival health improvement in the short term may be related to the baseline condition, Hawthorne effect or treatment efficacy, as well as the individual study designs and objectives. For example, in studies 1 and 2 where the baseline level of disease is lower, the magnitude of change at 4 weeks was higher than for studies 3 to 5 where the baseline gingivitis level was higher.

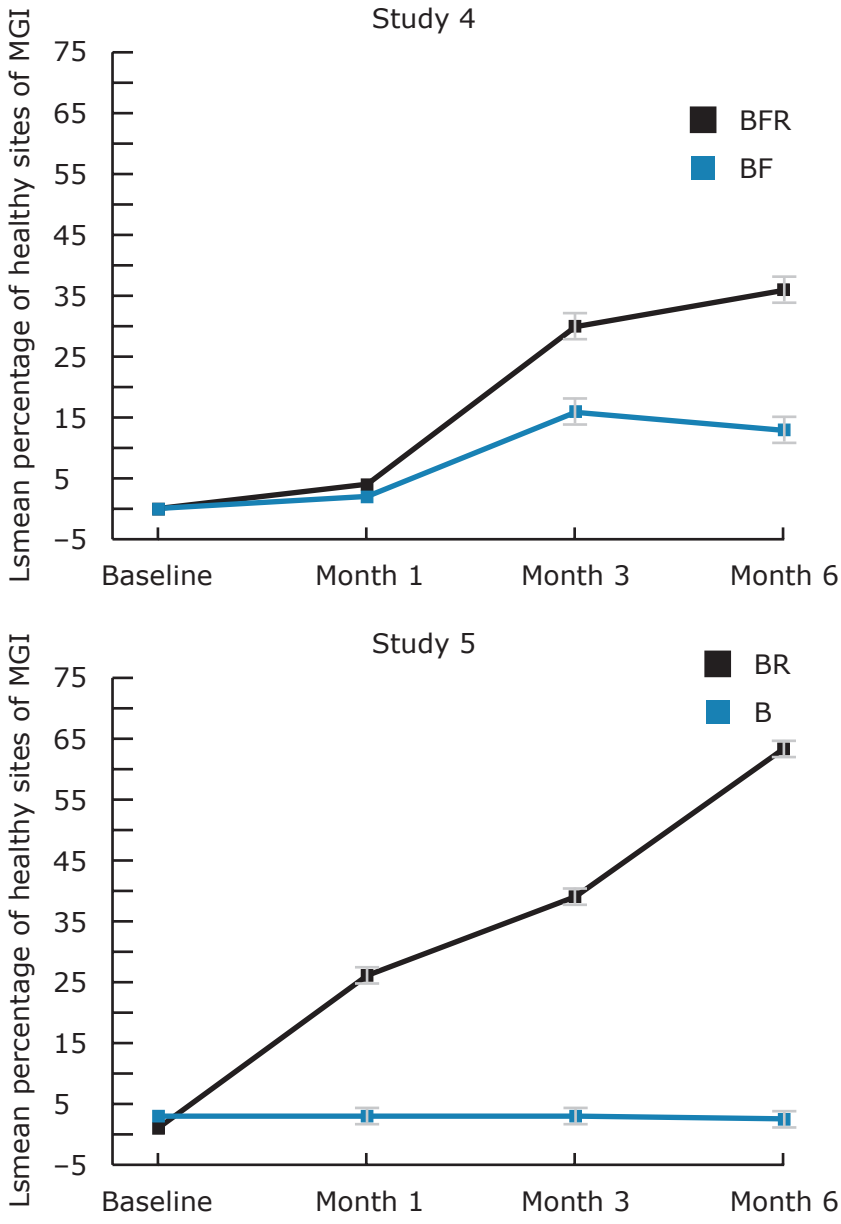
Also of interest was determining what happened to the more diseased or problem sites (MGI score≥3), which really stand out when evaluating the gingival tissues. A similar analysis was applied to plaque scores ≥3. For these more affected sites, a beneficial effect was seen as early as 2 weeks (mean 8.5% for negative control, and 4.9% for EO ($p=0.028$) and in the same study at 4 weeks, 7.1% and 3.1%, respectively). Continued improvement with time up to 6 months was shown in the longer term studies with up to 6.8% and 2.5% of sites having MGI scores ≥3. This finding follows a reduction in the areas most affected by plaque (PI≥3). The mean percent problem plaque scores was 33.5% for negative control and 13% for EO at 2 weeks ($p<0.001$) and 29.4% and 6.2% for EO at 4 weeks (Table V). For the longer term studies, up to 10.5% of sites had PI scores ≥3. While both the negative control and the EO groups continued to reduce the heavier plaque scores from 2 to 4 weeks, the magnitude of change was higher in the EO group. The population of study 3 had a higher severity of gingivitis at baseline that apparently interfered in tissue response in comparison

to studies 1 and 2, although they are 4 week studies by design.

What is interesting is that while the rinsing regimen was not as successful at bringing those patients with higher incidence of "most affected areas" to health (scores 0, 1) in the short term, rinsing was very successful at downgrading those affected areas to mild gingivitis, preventing the gingivitis from reaching a more severe pattern. This supports use of EO as an auxiliary tool when treating gingivitis. Studies 4 and 5 are 6 month studies with more inflammation, and therefore, the response of these studies needed to be viewed separately from studies 1 to 3.

Seeing more immediate or shorter term results may help to motivate patients to adopt an oral care recommendation, especially those patients with higher numbers of more inflamed or most affected sites. It is also important to provide patients with reasons to continue to comply with oral care instructions and recommendations beyond the short term. Examining the data by presenting results as improvements in gingival health by determining the percentage of healthy sites or virtually plaque free tooth sites - the goal of home care – provides an impactful way of translating the clinical research into a more clinically relevant or visual manner to aid in educating and motivating patients about the benefits of rinsing with EO.

Figure 2: Long Term Mean Percent Healthy Sites for Studies 4 and 5



B or BF=Negative Control Group; BR or BFR=EO Group

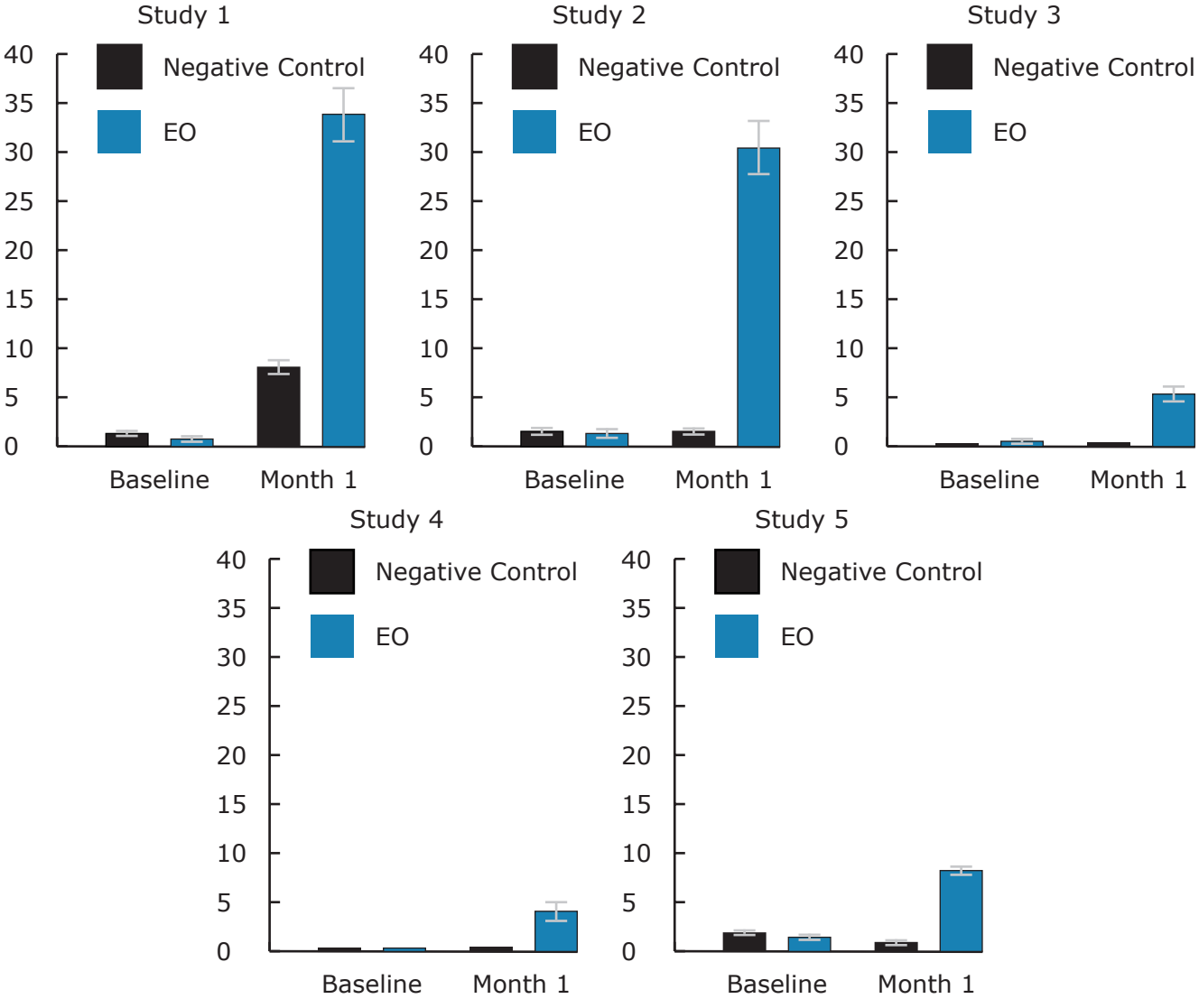
Clearly, as seen from the 4 week results across 5 studies, whether considering traditional percent reductions in mean scores or in mean percent healthy, or in mean percent most affected sites, improvements can be seen in the short term which may be helpful in motivating patients to develop better oral hygiene habits. The two 6 month studies also demonstrate that a greater benefit is seen when daily rinsing continues beyond 4 weeks. The published literature provides further evidence of long term efficacy with 6 months of daily use[16,17] of an EO antimicrobial rinse in addition to other antimicrobial mouthrinse agents.[2-4,18-22]

Conclusion

Significantly more healthy gingival sites and virtually plaque free tooth surfaces can be achieved as early as 4 weeks with an EO mouthrinse. This finding continues through 6 months with twice daily rinsing as part of oral care practices compared to mechanical oral hygiene alone.

Use of an essential oil antimicrobial rinse can reduce the number of more inflamed gingival sites in the mouth in the short term, lessening the severity of gingivitis and supporting the benefits of rinsing as an adjunct to mechanical oral hygiene.

Figure 3: Mean Percent Virtually Plaque Free Sites at Baseline and 4 Weeks



Negative Control=B or BF Groups; EO=BR or BFR Groups

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Disclosure

These 5 clinical studies were sponsored by Johnson & Johnson Consumer and Personal Products Worldwide Division of Johnson & Johnson Consumer Companies, Inc. Authors Revankar, Lisante and Charles are employed by Johnson & Johnson Consumer and Personal Products Worldwide Division of Johnson & Johnson Consumer Companies, Inc. Authors JR Cortelli and S Cortelli serve as consultants to Johnson & Johnson do Brasil Industria e Comercio de Produtos para Saude Ltda.

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Journal of Dental Hygiene
Vol. 88 • No. 3 • June 2014

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