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Caries Prediction using CariScreen for Caries Risk Assessment in Children

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Caries Prediction using CariScreen for Caries Risk Assessment in Children

by

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THESIS

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ABSTRACT

Caries Prediction using CariScreen for Caries Risk Assessment in Children

Nancy Le, DDS

Purpose: to evaluate the value of CariScreen meter as a part of the caries risk assessment tool in new caries prediction compared to cariogenic bacteria enumeration by culture (gold standard).

Methods: Eighty 6-17 year-old children were recruited. At baseline and one year, oral bacterial levels were analyzed by CariScreen meter and culture (Mutans Streptoccoci (MS) and *Lactobacilli*) together with caries risk assessment (CRA) and caries scores were recorded using International Caries Detection an Assessment System (ICDAS). Correlations between the new caries at one-year and baseline Cariscreen or bacteria levels were computed. Incidence and severity of new caries were compared in risk-categories by Cariscreen or culture alone or combined with CRA at baseline using SPSS 22.

Results: Fifty-three subjects completed the one-year visit. 83.0% of subjects were high risk at baseline with only 9 (17.0%) at low/moderate risk by CRA at baseline and 57% of them presented with new decay. CariScreen readings at baseline showed nearly no correlation with new decayed surfaces at one year (Spearman correlation coefficient of 0.04-0.05, P=0.73-0.79 for both sites). No trend of statistically significant differences was found for prevalence or severity of new decay at one year between high and low bacterial challenge at baseline measured by Cariscreen (P>0.67) while there was a trend of lower prevalence and severity of new decay at one year in low challenge by MS culture at baseline (P=0.15). The median for new decayed surfaces at one year were 0 and 1, respectively for low/moderate and high caries risk groups by CRA only (Kruskal-Wallis test, P = 0.11); 1 and 1 for low/moderate and high caries risk groups

by CRA combined with Cariscreen (Kruskal-Wallis test, P=0.99); and 0 and 1 for low/moderate and high caries risk groups by CRA combined with MS levels (Kruskal-Wallis test, P = 0.10).

Conclusions: CariScreen meter measurement alone or combined with CRA at baseline showed no evidence in prediction of new decay after one year. CRA alone or combined with MS culture showed potential in predicting new caries in one year but this needs to be further confirmed with a larger sample size study especially with more low/moderate risk subjects.

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INTRODUCTION

Despite all the advances in caries control in developed countries, dental caries continues to be a common chronic childhood disease (Gao et al, 2014). Recent trends suggest an increase in the incidence of dental caries amongst specific populations in the United States (Dye, 2007). Furthermore, the caries distribution among children is polarized, with 75 percent of affected surfaces found in less than 25 percent of children (Gao, 2009). Dental decay in the primary dentition is particularly alarming because it may lead to complications in the developing dentition, may require more invasive treatment under oral conscious sedation or general anesthesia, and may put the permanent dentition at increased risk for caries (Thenisch, 2006).

These oral health epidemiological data point to the need for the development of caries risk assessments for preventive care. Caries risk assessment (CRA) is the clinical tool that helps to identify risk categories of patients based on the balance of their disease factors, biological risk factors and protective factors. Therefore, it establishes the probability of an individual patient to develop carious lesions over a certain period of time or the likelihood that there will be a change in size or activity of lesions already present. CRA serves to guide the preventive treatment plan for the patients (Twetman, Fontana, & Featherstone, 2013). As dental caries has a complex, multifactorial etiology, the procedure requires that information on demographic, social, behavior, and biological factors be taken together to form an individual-based caries risk profile (Holgerson, Twetman, & Stecksen-Blicks, 2009). It has been suggested that prediction models with a combination of risk indicators, such as socio-demographic factors and dietary habits and Mutans Streptococci (MS) counts, can improve accuracy of the risk assessment at early ages (Holgerson, Twetman, & Stecksen-Blicks, 2009).

Dental caries is a chronic infectious disease. Mutans Streptococci and Lactobacilli are

identified as the two main groups of cariogenic bacteria. It has been shown that Mutans Streptococci are the main etiological agents of dental caries in humans (Seki, 2003) and can increase in the oral environment prior to the development of clinical lesions. Reduction of MS levels on teeth is followed by a reduction in caries activity (Zickert, 1983). Therefore, identification and quantification of MS has been considered as one of the strongest single risk factors associated when predicting caries development (Petersson, Iseberg, & Twetman, 2010), and is utilized as an important component of caries risk assessments as well as an important guidance for antimicrobial treatment (Young & Featherstone, 2012). A variety of microbiological test assays are available for measuring the amount of MS and *Lactobacilli* in saliva, including bacterial culture, molecular techniques, and ATP-driven bioluminescence (Saravia, 2013). Although these techniques may offer superior specificity and sensitivity over traditional culture techniques, they are expensive and require specialized skills as well as laboratory equipment (Gao, 2012). Therefore, these methods are not readily available for chair-side use by dental clinicians.

Chair-side bacteria tests are reported to simplify the bacterial quantification process by making it readily available to the practicing clinicians. MS quantification by so-called dip slide chair-side culture tests in children showed significant correlation with MS counts on conventional selective media for MS (Tanabe, 2006). However, this test requires incubators and a 72-hour incubation prior to bacterial quantification. Therefore, it does not allow dentists to provide immediate preventive treatment plan and education to patients. Although the chair-side cultural tests have been available for decades, clinicians rarely employ them in their caries risk assessments due to these inherent limitations. There continues to be a need for a reliable, easy-to-use chair-side rapid assay method for practicing clinicians to use when assessing oral bacterial

counts for caries risk assessments.

The CariFree CariScreen Caries Susceptibility Testing Meter is a hand held device used to measure the chair-side bacteria ATP obtained from a sample of the subject's plaque mass. The CariScreen meter utilizes ATP-driven bioluminescence technology, which uses the presence of ATP to estimate the number of viable cells. A preliminary study evaluated the correlation of the CariScreen meter in oral cariogenic bacteria quantification with selective culture enumeration on stimulated saliva samples. The results revealed poor correlations of CariScreen scores, anterior and posterior, to cariogenic bacteria counts, which is in contrast to Fazilat 2010, who found fairly good correlation between ATP bioluminescence technology and bacteria levels. However, there are several differences from the preliminary study to Fazilat 2010 (Fazilat, Sauerwein, McLeod, & al., 2010). First, Fazilat 2010 results were produced using real laboratory techniques, namely the luciferase-based assay system and the methodology for sample collection differed between the two studies and can attribute to the conflicting results. Neither of these studies evaluated the CariScreen meter as a potential predictor of new caries. Actually, there are very limited studies that have evaluated the potential usefulness of this site-specific method of screening individuals for caries risk and prediction of new caries. Therefore, bacterial enumeration by CariFree CariScreen Caries Risk Testing meter and selective bacterial culture needs to be performed at baseline and at one year to assess the accuracy of predicting new caries as part of the caries risk assessment.

AIMS AND HYPOTHESIS

We hypothesized that the CariFree CariScreen Caries Susceptibility testing meter will improve the caries risk assessment tool for predicting new caries after one year. The specific aims of this study are 1) to evaluate whether the CariFree CariScreen Caries Susceptibility testing meter is a

good predictor for the presence of new caries after one year compared to the gold standard, selective culture enumeration on stimulated saliva samples 2) to determine whether the addition of CariScreen score or laboratory-based salivary bacterial count (CFU/mL of saliva) will increase the accuracy of caries prediction after one year.

MATERIALS AND METHODS

The research protocol was approved by the UCSF Committee on Human Research (Approval number 14-13982). Informed consent was obtained from the guardian of all study subjects. Eighty subjects were recruited from the UCSF Pediatric Dental clinic from August 2015 to August 2016. The inclusion criteria of the subjects were: 1) 6-17-year-old children who are patients at UCSF pediatric pre-doctoral and post-graduate dental clinics; 2) subjects that are able to cooperate for the study procedure; 3) have six fully erupted mandibular anterior teeth; 4) subjects reside within a 30-mile radius of the associated study clinics to increase the retention rate at follow-up appointments of future studies. The exclusion criteria were: 1) Less than 6 or greater than 17 years of age; 2) lack of erupted mandibular six anterior teeth; 3) use of antimicrobials within past three months with the exception of topical antibiotics used for caries prevention (e.g. Chlorhexidine Gluconate); 4) severe gingival bleeding; 5) lack of ability to cooperate; and 6) subjects that reside outside a 30-mile radius of the associated clinics. All study appointments were scheduled at 1 hour after eating and 2 hours after the last tooth-brushing.

The following information was collected by a questionnaire: age, gender, race/ethnicity, medications within past 3 months, demographic data, and the time from last known toothbrushing, together with a standard caries risk assessment form. Dental caries scores were collected using International Caries Detection and Evaluation System (ICDAS) scoring system for each child. Bacterial enumeration by CariScreen meter was performed on anterior mandibular

lingual sites per manufacturer's instruction as well as a mandibular right posterior molar buccal site. Stimulated whole saliva was collected for each child and transported on ice for microbiological assays within 24 hours. A plaque index was generated utilizing the criteria of the Simplified Oral Hygiene Index (Greene, 1964). All examinations and specimen collections were completed before any dental procedure performed for each patient to eliminate potential treatment modalities, such as a dental prophylaxis, from interfering with the oral environment.

Sample Size Calculation

Assuming Type I error of 0.05, retention of 85% at one year, the total sample size of 80 (64 at one year) will provide 80% power to detect an effect size of 0.69SD in number of new decay between low/moderate and high risk patients, and detect a risk difference of 36.2% in having any new decay (low/moderate risk patients: 30% risk developing any new decays, high risk patients: 66.2% risk developing any new decay).

Bacterial Enumeration by CariScreen Meter

Bacterial scores by CariScreen meter were collected from two sites: 1) the lingual surfaces of six mandibular anterior teeth, per CariScreen manufacturer's instruction; 2) the buccal surface of a posterior mandibular tooth. This second site was added because the manufacturer's recommended site of the lingual surfaces of mandibular anterior teeth are associated with clinically low caries activity. For both sites, the samples were collected by carefully swabbing the mid-lingual or buccal surfaces of respective surfaces without contacting the gingival or any soft tissue with any part of the swab. The scores of CariScreen were then obtained following manufacturer's instructions for the device (Dental Practice Systems, 2008).

Saliva sample collection, storage, transportation, culture and enumeration

The stimulated saliva samples were collected by asking the participants to chew on a paraffin wax tablet until 5-mL of saliva was collected. Samples were stored on ice or at 4ºC and processed for culture within 24 hours. Saliva samples were inoculated on Mitis Salivarius sucrose bacitracin plates for MS enumeration, Mitis Salivarius plates for total streptococci enumeration, Rogosa tomato juice plates from LB enumeration and Brain Heart Infusion blood plates for total viable bacterial enumeration as previously described (Zhan & Featherstone, 2006). The plates were incubated anaerobically at 37°C for 72 hours before enumeration under a dissecting microscope (Zhan & Featherstone, 2006).

Dental caries examination and enumeration

A dental examination, caries risk assessment, and plaque score were performed for all 80 subjects. The International Caries Detection and Evaluation System (ICDAS) scores were recorded for all teeth present (Pitts, Ekstrand, & ICDAS Foundation, 2013) at baseline and one-year follow-up visit. Decayed surfaces (ds/DS) and dental caries experience (decayed missing filled surfaces or dmfs/DMFS) were extrapolated from ICDAS and caries history at both time points. New decayed surfaces were calculated based on recorded baseline decayed surfaces and comparing it to one year decayed surfaces.

Plaque Index

A plaque index score was completed for each participant utilizing the Simplified Oral Hygiene Index (OHI-S) (Dental Practice Systems, 2008). Six tooth surfaces were examined, including the buccal surfaces of the maxillary primary second molar/permanent first molar, the lingual surfaces of the mandibular primary second molar/permanent first molar, and the labial surfaces of the upper right and lower left central incisors. The score for each surface recorded as

"0" for no plaque debris; "1" for plaque covering less than one third of the tooth surface; "2" for plaque covering one third to two thirds of tooth surface; and "3" for plaque covering more than two thirds of the exposed surface. An average plaque score of all surfaces was calculated for each subject.

One year follow-up visit

All subjects were contacted to return for the one-year follow-up visit within 12 months +/- 3 months from their baseline visit. All aforementioned research procedures were performed on all recalled patients.

Data Analysis

Data analyses were performed using SPSS 22. Descriptive analyses were performed to summarize the data. Means, standard deviations (SDs), median and quartiles were calculated for continuous variables, while frequencies and percentages were calculated for categorical variables.

The logarithmic transmission of the bacteria levels by culture and CariScreen were used for all tests to achieve normal distribution of the data. Based on the manufacturer's instructions, CariScreen scores were categorized as low (CariScreen score<1500) or high (CariScreen score≥1500)) per manufacturer instruction. For MS levels by selective culture, <100,000 CFU/ml were categorized as low (combined low and moderate challenge group for MS) or ≥100,000CFU/ml as high. For LB levels by culture, <1,000 CFU/ml were categorized as low (combined the low and moderate challenge group for LB) or ≥1,000CFU/ml as high (Featherstone, 2012).

Pearson correlation coefficients between CariScreen scores and bacteria levels by culture in stimulated saliva samples and Spearman correlation coefficients between new caries at one year and one of CariScreen scores were computed. The Wilcoxon rank sum test was used to test if the number of new caries at one year is different between CRA categories and baseline bacterial enumeration methods. Because of the sparse cells, Fisher's Exact Test was used to test whether or not a child had any new carious lesions at one year is different between low and high risk subjects evaluated by various CRA combinations.

RESULTS

Subject Characteristics, bacterial levels, caries risk, and caries status at baseline and one year

Table 1 describes the characteristics of the baseline and recalled subjects. The age of the subjects at baseline ranged from 6-17 years of age with a mean of 9.5 (S.D. 2.8) with a majority of females (66.3%) participating in this project. The age of the subjects that returned for 1-year visit ranged from 7-17 years of age with a mean of 10 (S.D: 2.7) more females (71.7%) than males (28.3%). On average, the CariScreen scores for both the anterior and posterior were lower at one year visit than at baseline. The majority of subjects at baseline and at 1-year follow-up were high risk based on CRA (66% and 83%, respectively) as well as high bacterial challenge based on CariScreen scores from the mandibular anterior site (62.5% and 58.5%, respectively). In contrast, more subjects at baseline and at recall were categorized as low bacterial challenge on the CariScreen score from the mandibular posterior site, 62.5% and 66.0%, respectively. The bacterial counts for both Mutans Streptococci and Lactobacilli are similar for both baseline and one year visits with the majority of the subjects categorized as high bacterial challenge. The mean decayed surfaces 5.3 (S.D: 4.6) and dmfs/DMFS was 12.7 (S.D: 12.6) were higher at

baseline than at one year. The percentage of subjects with active decay increased from 80% to 85% after one year and 57% of the subjects presented with new carious lesions.

Correlation between baseline and one-year CariScreen scores, Mutans Streptococci counts by culture, and caries risk assessment

When the mandibular anterior CariScreen scores at baseline and one year were compared, there was weak to moderate positive correlation between baseline and one year scores (correlation coefficient = 0.36, $P<0.05$) for mandibular anterior site (Manufacturer recommendation, Figure 1) and a weak positive correlation (correlation coefficient = 0.20, $P<0.05$) for the mandibular posterior site (Figure 2).

When MS levels were compared between baseline and one year, a moderate to strong positive correlation was found (correlation coefficient = 0.69, $P<0.05$, Figure 3).

When we looked at the change in caries risk, of the 53 subjects that retuned at one year, 44 subjects remained high caries risk, one remained moderate caries risk, and two remained low caries risk. One subject increased their caries risk from moderate to high. Four subjects decreased their caries risk: one changed from high to low, two changed from moderate to low, and one changed from high to moderate.

Correlation between Baseline CariScreen scores, Mutans Streptococci counts by culture and new Decayed Surfaces at one year

Figures 4 through 6 show the scatter plots of CariScreen scores (anterior and posterior), Mutans Streptococci and new caries surfaces. CariScreen readings at baseline showed nearly no correlation with new decayed surfaces at one year (Spearman correlation coefficient of 0.04-0.05, P=0.73-0.79 for both sites). There was a slightly weak positive correlation between log MS and new decayed surfaces after one year (Spearman correlation coefficient = 0.18, P=0.19).

Distribution of new decayed surfaces based on bacterial challenge alone by Cariscreen or selective culture at baseline

Figure 7A. presents the percentage of subjects with new decayed surfaces categorized as low or high bacterial challenge depending on bacteria challenge by CariScreen scores or MS levels at baseline. Numerically, more subjects with low bacteria challenge measured by Cariscreen anterior site developed new caries (Fisher exact test, P= 0.57), while more subjects in high bacterial challenge by culture or Cariscreen posterior site developed new caries at one year than low bacterial challenge groups.

Figure 7B. illustrates the new decayed surfaces in subjects with high/low bacteria challenge measure by Cariscreen and culture for MS. High-risk patients presented with similar or less decayed surfaces than low risk patients based on anterior (median of new decayed surfaces = 1 for low, median of new decayed surfaces =1 for high, P=0.67) or posterior CariScreen score (median of new decayed surfaces = 1 for low, median of new decayed surfaces = 0.5 for high, P=0.93). However, when bacteria challenge at baseline were evaluated by MS culture, the low bacterial challenge group had less new decayed surfaces than high bacterial challenge group (low category median = 0, high category median = 1, P=0.15)

CRA categories with or without bacterial challenge categories by Cariscreen or selective culture at baseline

Because there were only small number of subjects in low or moderate risk by CRA or CRA combined with bacterial challenge by Cariscreen or culture, the low and moderated risk groups were combined for the analysis. By CRA alone, the high-risk subjects developed more

new caries (median=1) than the low/moderate caries-subjects (median=0, Figure 8) but was not statistically significant (Kruskal-Wallis test, P = 0.11).

When risk category was analyzed by CRA combined with culture MS levels, two subjects in the low/moderate category became high risk. The median of new decayed surface remained the same as CRA alone (P=0.09), but the low/moderate risk category subjects showed less variation than CRA categories alone (Figure 9).

Interestingly, when CRA categories were combined with bacterial challenge with CariScreen, the median for new decayed surfaces at one year were 1 and 1 for low/moderate and high caries risk groups with no difference (Kruskal-Wallis test, P=0.99). The low/moderate risk subjects showed greater variability and on average, developed about the same number of new caries as the high-risk subjects (Figure 10).

DISCUSSION

Our results revealed slightly moderate positive correlation between baseline and one-year CariScreen score for both anterior and posterior (Figure 1 and 2), suggesting that the subjects' readings were somewhat consistent after one year. Mutans Streptococci levels at baseline were moderately to strongly correlated with MS levels at one year. This reveals that MS levels remain stable over time, especially when there is no antimicrobial intervention involved. While most of the subjects remained in the same caries risk category as baseline, some subjects increased their caries risk and others decreased their caries risk. The increase in caries risk is most likely due to new decayed surfaces. The decrease in caries risk can be attributed to several factors. Several subjects exfoliated primary teeth that had been previously restored or had less carious lesions. After one year, another patient did not have any restorations within 3 years, therefore lowering their caries risk from high to moderate or moderate to low. One of the major limitations of this

study is the small sample size, especially in low/moderate risk group for subjects returned for 1-year follow-up due to the time constriction because a large number of the low/moderate caries risk subjects were recruited in the later stage of the study and are not due for one year follow-up yet. Therefore, most of the subjects that returned for the recall visit are at high caries risk. We will continue to collect data for the remaining patient and repeat the analysis when the study is completed. This small sample size limited the power of the study and skewed the distribution of data. Therefore, we will only be able to look at trends for the study instead of conclusive conclusions with statistical significance.

Our results also suggested that caries risk assessment tool alone is potentially good in predicting new caries at one year with consistent trends for predictions on prevalence and severity of new decay at one year. CAMBRA CRA tool has been validated as a reliable tool for caries risk assessment and for prediction of future caries. In a larger scale chart review study at our clinic, Chaffee et al studied the pediatric CRA items in dental providers' decision making regarding patient risk and its association with clinically evident caries (Chaffee, Featherstone, Gansky, Cheng, & Zhan, 2016). They found that practitioner baseline caries risk designation was strongly associated with evident decay at follow-up for children age 6 to 72 months. Domejean et al also found that CRA was successful in accurately identifying patients at high caries risk and predict risk for future decay (Domejean, White, & Featherstone, 2011). They found that in 2,715 subjects over 6 years of age that returned for recall, 69% of the high caries risk patients returned with new cavities and conversely, only 24% of the low caries risk patients returned with new cavities. Although no statistically significances were found, our study is in agreement with their study.

Due to the nature of a residency program patient population, most of the subjects recruited were categorized as high caries risk for CRA. Furthermore, eighty-three percent of the subjects remained in the high caries risk category after one year and 57% developed new decay despite the multiple fluoride varnish application, which is in agreement with Petersson 2010. Their study found that 50% of the children remained in the same risk category at baseline and after two years (Petersson, Iseberg, & Twetman, 2010). This result is common because the caries risk assessment protocol places a subject at high risk if they have had a restoration within the past year for recall patients. Furthermore, our study also demonstrates that the MS level remained stable after one year which calls the need for antibiotic chemical therapy to further assist and combat dental caries. A study by Chaffee et al found that aggressive management with remineralization or antibacterial agents, such as high concentration fluoride toothpaste, chlorhexidine rinse, and xylitol products, can successfully reduce the severity of dental caries in high-risk patients and supports the use of such agents in caries management (Chaffee, Cheng, & Featherstone, 2015). These results highlight the importance of antimicrobial therapy for high-risk patients because dental restorations and fluoride applications do not change the bacterial levels and may not be sufficient to overcome the pathological challenge by diet and high cariogenic bacterial levels. Therefore, a large portion of the high-risk individuals continued to have new caries development after one year.

Bacterial challenge measured by CariScreen, both anterior and posterior, at baseline showed nearly no correlation with or reverse or no difference in the incidence or severity of new decayed surfaces at one year. These results were similar to the Hallet 2012 study (Hallet & O'Rourke, 2013). They found no significant correlation between Cariscreen scores and future caries experience at 12 and 24 months. There was a difference between our study and the Hallet

study on Cariscreen: they used different range groups for statistical analysis: 0- 9,500 as low and >9,500 as high based on population median, where as this study used 0- 1,499 as low and >1500 as high per manufacturer's recommendation. These results indicate that bacterial challenge measured by Cariscreen showed no evidence in new caries prediction at one year. The reason for poor value of Cariscreen in caries risk prediction may result from its poor reliability in measuring cariogenic bacteria levels. In 2016, Graziani et al studied correlation of Cariscreen score by mandibular anterior sites or posterior sites with MS and LB by culture. They found poor or negative correlation between CariScreen scores and cariogenic bacteria levels by gold standard culture method. The poor correlations of the mandibular anterior lingual site, as recommended by the manufacturer, may result from the nature of the site's ecology as the least-caries-prone site in the oral cavity. The area is in close proximity to the opening of the sublingual and submandibular salivary gland ducts. These surfaces are constantly being rinsed and bathed in saliva with buffering capacity. Cariogenic bacteria are classically acidogenic and acidophilic, and would not compete well in this environment with other commensal bacteria. It was hoped that the mandibular posterior tooth (more cariogenic site), the second site, would correct the ecology nature. However, although the CariScreen score for the posterior site did not show a negative correlation, it still showed poor correlation to cariogenic bacteria, indicating that the Cariscreen meter is a poor tool in measuring cariogenic bacteria challenge.

Although not statistically significant, Mutans Streptococci levels at baseline revealed only weak correlation and also showed a trend of subjects with lower cariogenic bacteria challenge developing less new caries surfaces at one year. Our results are in agreement with Sanchez-Perez et al. who found significant association between MS counts and new caries (P=0.02), using the same cariogenic bacterial enumeration methodology as this study (Sanchez-

Perez et al, 2009). However, this result was also in contradictory with the Hallet 2012 study, which found no correlation of baseline MS enumerated by CariCult to new caries at 12 and 24 months. The main reason for their finding may result from a significant reduction in MS levels from baseline to 24 months, indicating a shift of MS challenge for the population that will alter the bacterial challenge and caries risk in these patients. However, in our study, we found a moderate correlation between MS levels at baseline and one-year. These findings indicate when intervention or shift of the risk categories occurs in subjects, the changes should be included in the caries risk assessment. In successful caries management with risk assessment, we should be able to reduce the new caries incidence as well as bacterial load for high-risk patients.

When CariScreen categories were combined with caries risk categories, it ablated the caries prediction value of CRA. Subjects with low/moderate risk showed greater variability and on average, developed about the same number of new caries as the high-risk subjects. This is in agreement with Hallet 2013 findings that the CariScreen meter is not a reliable bacterial challenge assessment tool and does not help to improve caries risk prediction of the CRA tool.

In contrast, when MS levels were combined with caries risk categories, two subjects in the low/moderate category became high risk and the CRA prediction showed less variability in new decay at one year. This suggests that the addition of MS levels has increased the sensitivity of caries risk assessment and can potentially add value to the caries risk assessment. Thenisch 2006 found that the detection of Mutans Streptococci in saliva or plaque of young caries-free children is associated with an increased risk for developing caries (Thenisch, 2006).

In addition to the small sample size, there were other limitations in our study. There were two outlier subjects with a lot of new decayed surfaces and one patient with a lot of the reversed white spot lesions. White spot lesions can become re-mineralized over time. This outlier may

have skewed the results. Reviewing the patient's chart, there were no changes to their eating or oral hygiene habits. Some patients have been lost to follow up due to change of phone number or unresponsive to multiple voice messages. Third, alteration on risk and protective factors of the subjects will affect the caries development at one year. We have observed some subjects with risk alterations from baseline to 1 year but the current statistical analysis did not account for these changes due the small sample size. A larger sample sized study with fair distribution of different risk profiles of subjects will be deemed to draw better conclusions on the benefits of measurement of cariogenic bacterial levels with CRA tool. It is disappointing that the CariScreen meter failed to be a reliable tool to monitor cariogenic bacterial challenge to the CRA tool. There is still a need for a valid instant chair-side tool to monitor cariogenic bacteria levels to guide the clinical caries management by anti-microbial treatment.

CONCLUSION

The concept of CariScreen is appealing; it is easy to use, relatively inexpensive, small and produces immediate results. However, our data revealed that CariScreen meter measurement alone or combined with CRA at baseline showed no evidence in prediction of new decay after one year. CRA alone or combined with MS culture showed potential in predicting new caries in one year but need to be further confirmed with larger sample size study especially with more low/moderate risk subjects.

Table 1. Subject Demographics, bacterial levels, and caries status

Characteristics	Baseline	1 year
Subjects (N)	80	53
Age, mean (SD)	9.5 (2.8)	10.0 (2.7)
Sex, n (%)		
Female	53 (66.3%)	38 (71.7%)
Male	27 (33.7%)	15 (28.3%)
Race/Ethnicity, n (%)		
Asian	17 (21.3%)	10 (18.9%)
African American	8 (10.0%)	7 (13.2%)
Latino/Hispanic	18 (22.5%)	9 (17.0%)
Caucasian	12 (15.0%)	7 (13.2%)
Other/No Answer	25 (31.2%)	20 (37.7%)
CariScreen Score, median		
Anterior	2170	1682
Low, n (%)	30 (37.5%)	22 (41.5%)
High, n (%)	50 (62.5%)	31 (58.5%)
Posterior	1038.5	768
Low, n (%)	50 (62.5%)	35 (66.0%)
High, n (%)	30 (37.5%)	18 (34.0%)
Bacteria counts (log), mean (SD)		
Mutans Streptococci	4.6 (1.9)	4.8 (1.8)
Lactobacillus	2.6 (2.0)	2.4 (2.0)
Caries Risk Assessment, n (%)		
Low	18 (22.4%)	6 (11.3%)
Moderate	9 (11.3%)	2 (3.7%)
High	53 (66.3%)	45 (84.9%)
Caries, mean (SD)		
Decayed surfaces	12.5 (11.9)	5.3 (4.6)
dmfs/DMFS	17.1 (15.0)	12.7 (12.6)
% of subjects with active decay	80%	85%
% of subjects with new decay	-	57%

Figure 1. Scatter plot of Baseline log mandibular Anterior CariScreen scores at baseline against log mandibular Anterior CariScreen scores at one year

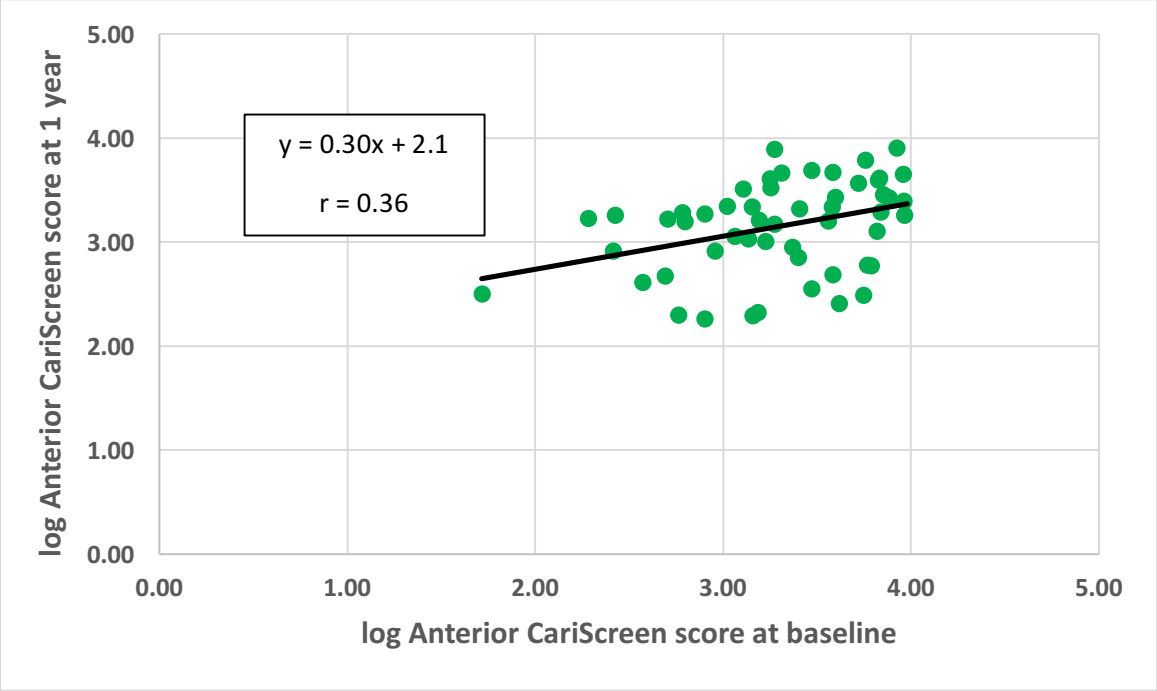


Figure 2. Scatter plot of Baseline log mandibular Posterior CariScreen scores at baseline against log mandibular Posterior CariScreen scores at one year

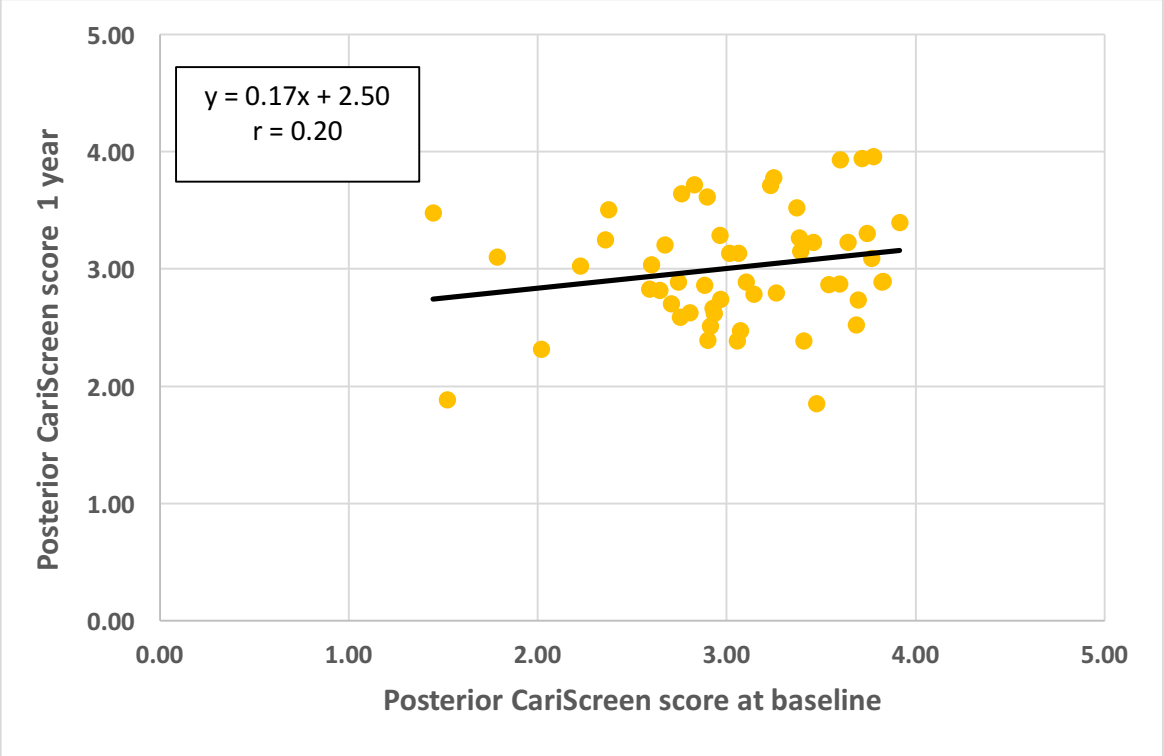


Figure 3. Scatter plot of Baseline log MS counts (CFU/mL) at baseline against log MS counts (CFU/mL) scores at one year

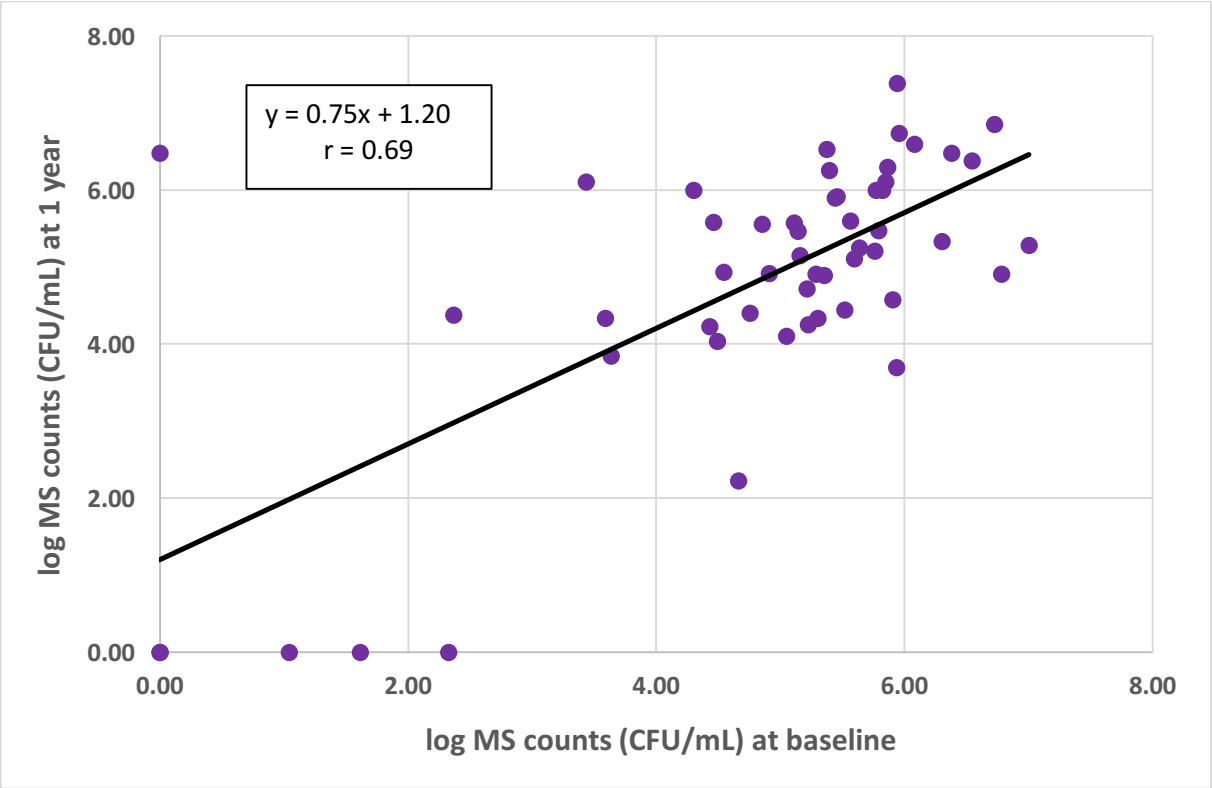


Figure 4. Scatter plot of Baseline log mandibular Anterior CariScreen scores against new decayed surfaces at one year

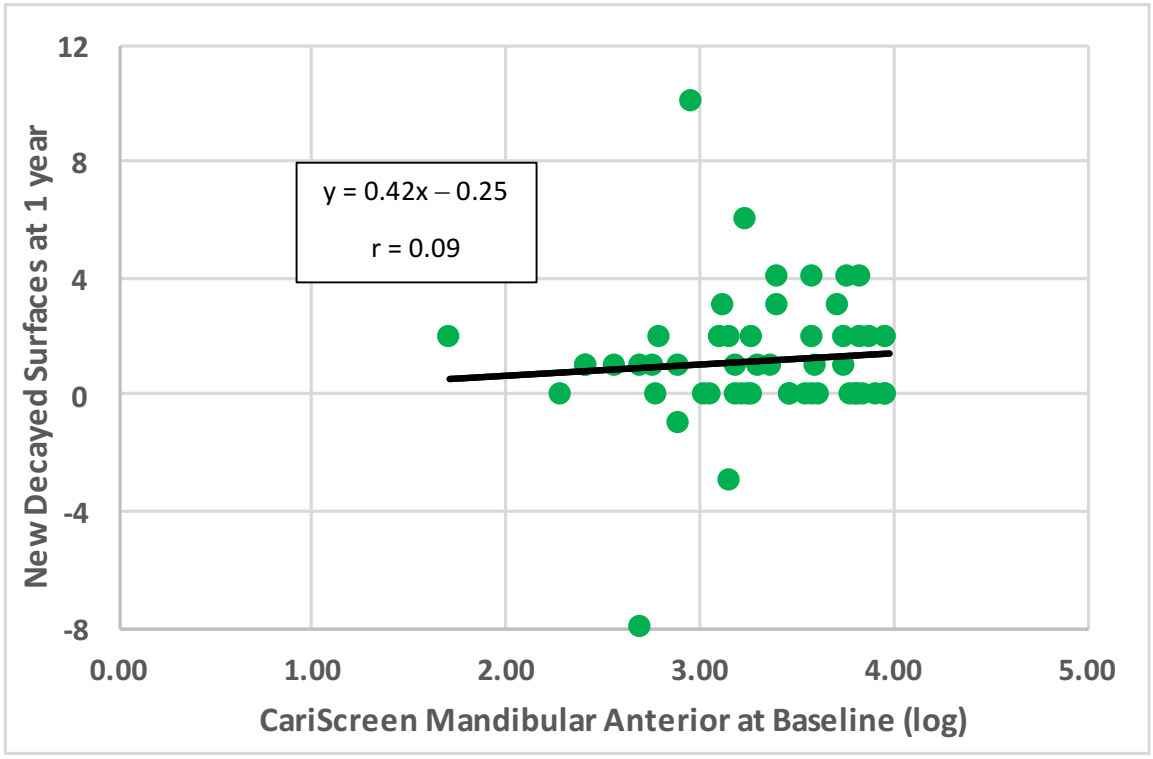


Figure 5. Scatter plot of Baseline log mandibular Posterior CariScreen scores against new decayed surfaces at one year

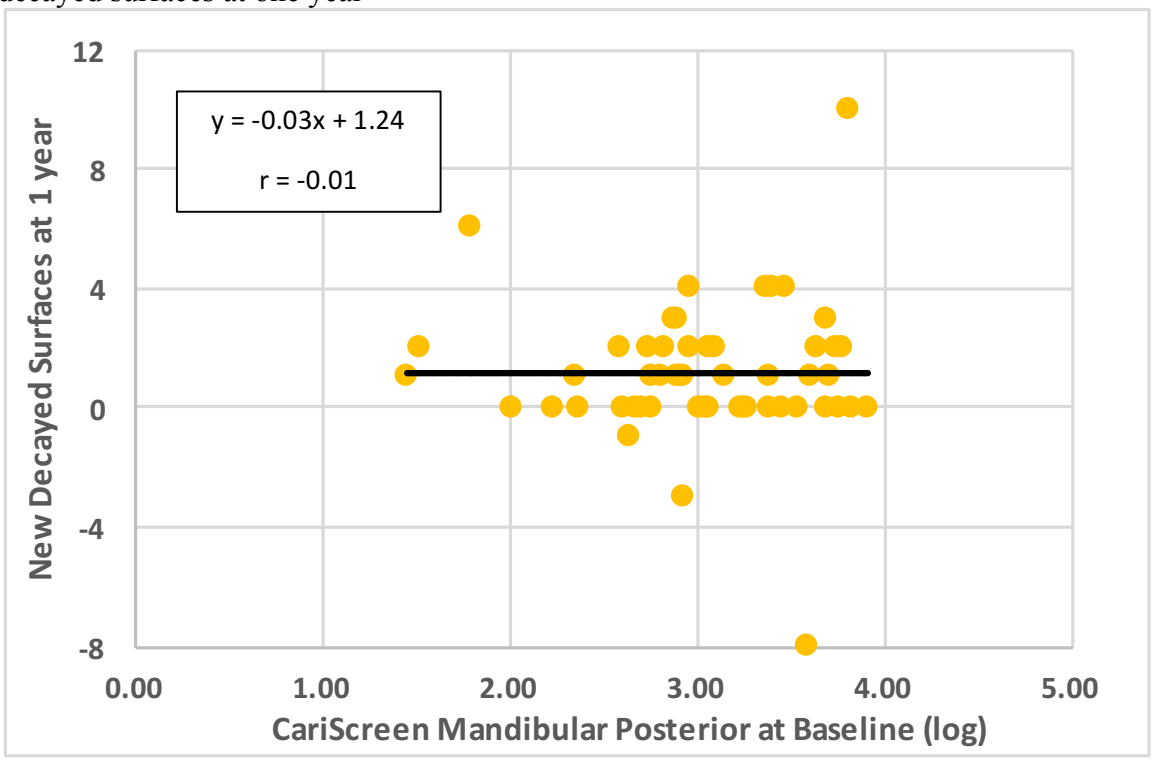


Figure 6. Scatter plot of Baseline log mandibular Posterior CariScreen scores against new decayed surfaces at one year

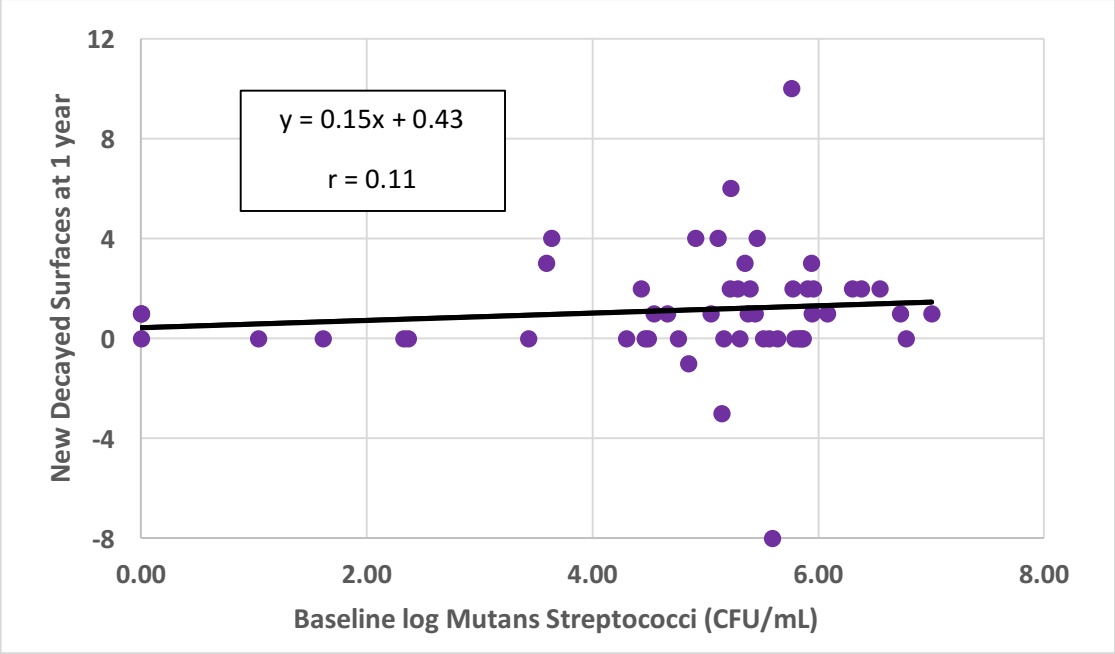


Figure 7A. Percent of subjects with new decayed surfaces in high or low bacterial challenge groups

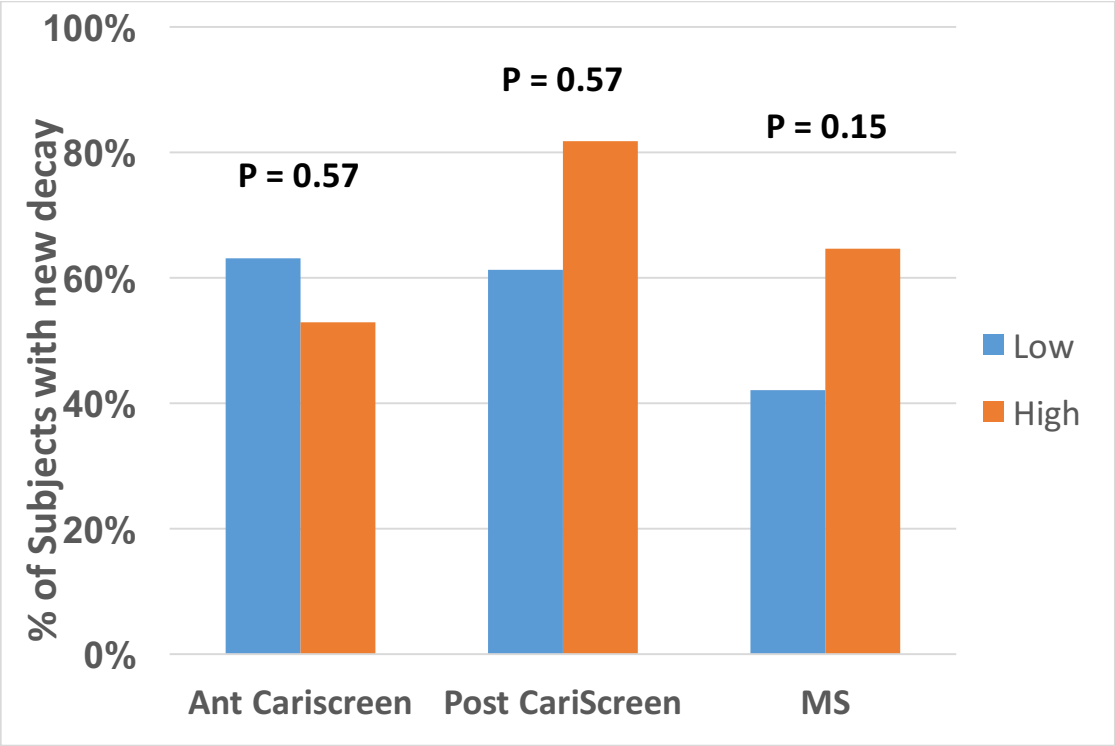
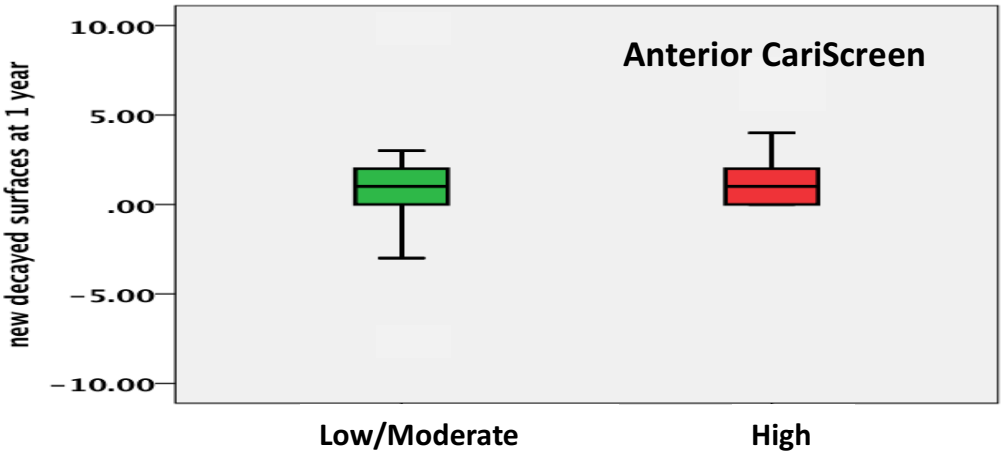
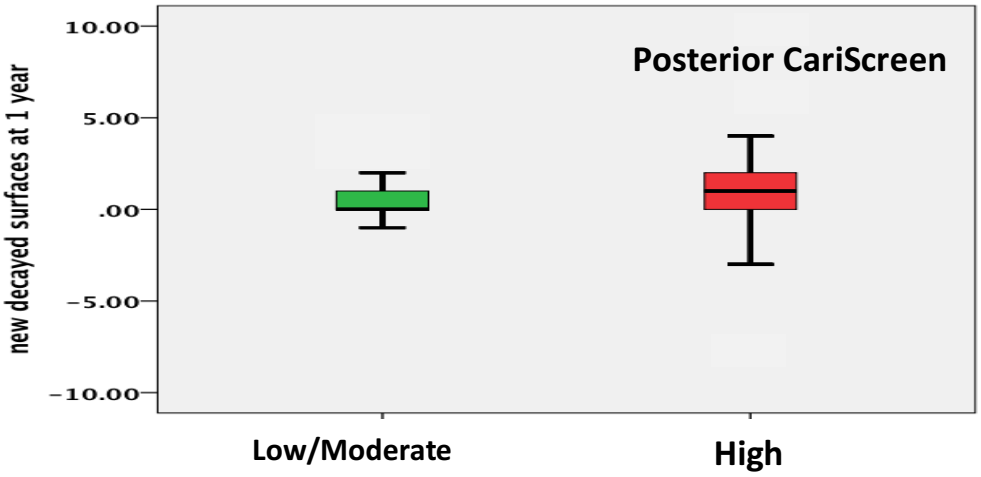


Figure 7B. New Decayed Surfaces in CariScreen scores (anterior and posterior) and MS counts at high or low/moderate categories





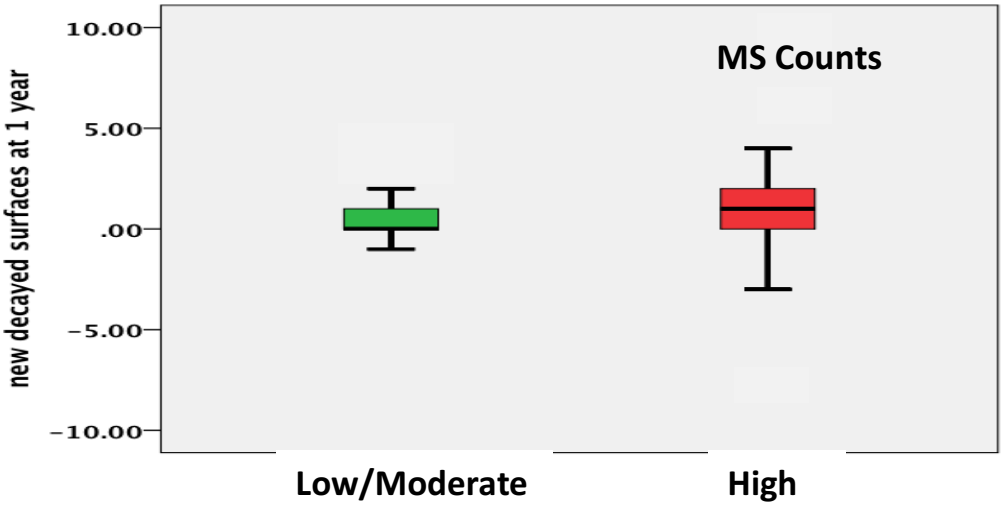


Figure 8. New Decayed Surfaces in Low/Moderate or High Category by CRA alone at Baseline

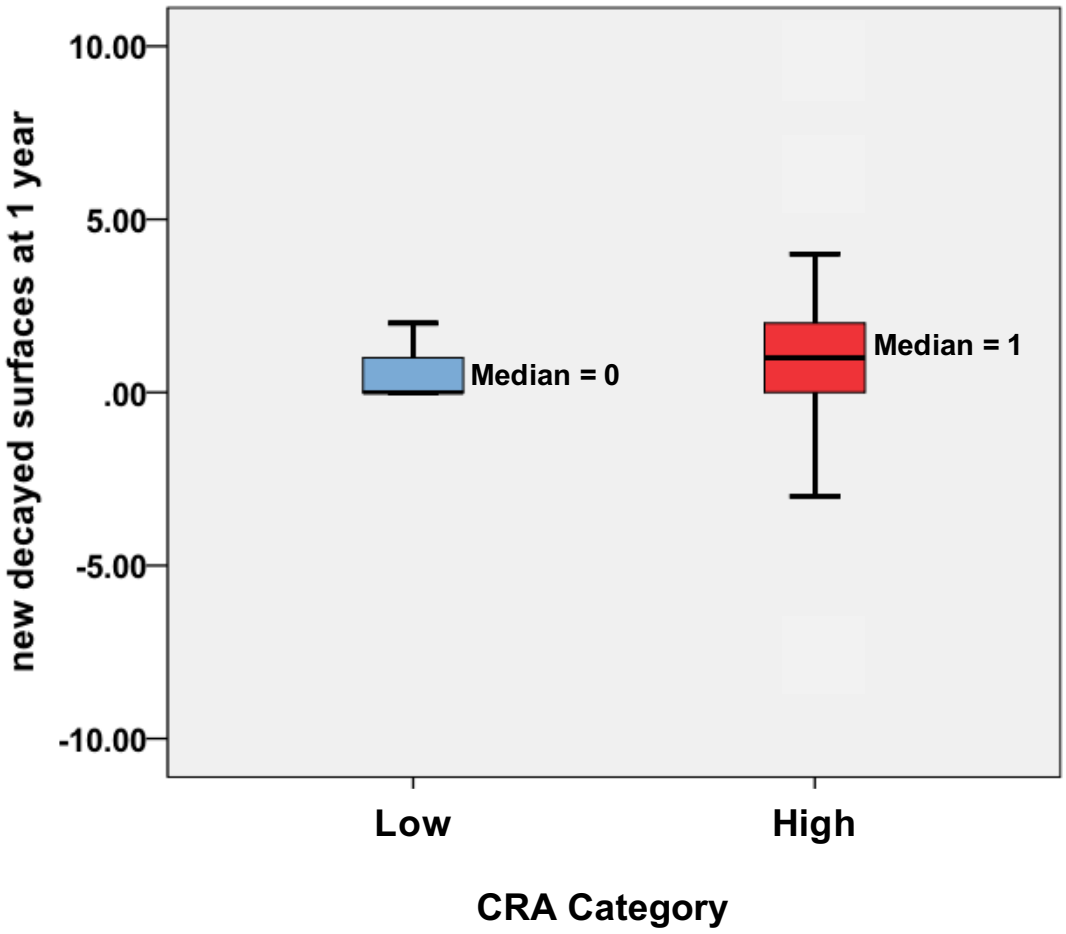


Figure 9. New Decayed Surfaces in Low/Moderate or High category by CRA and MS challenge by culture at Baseline

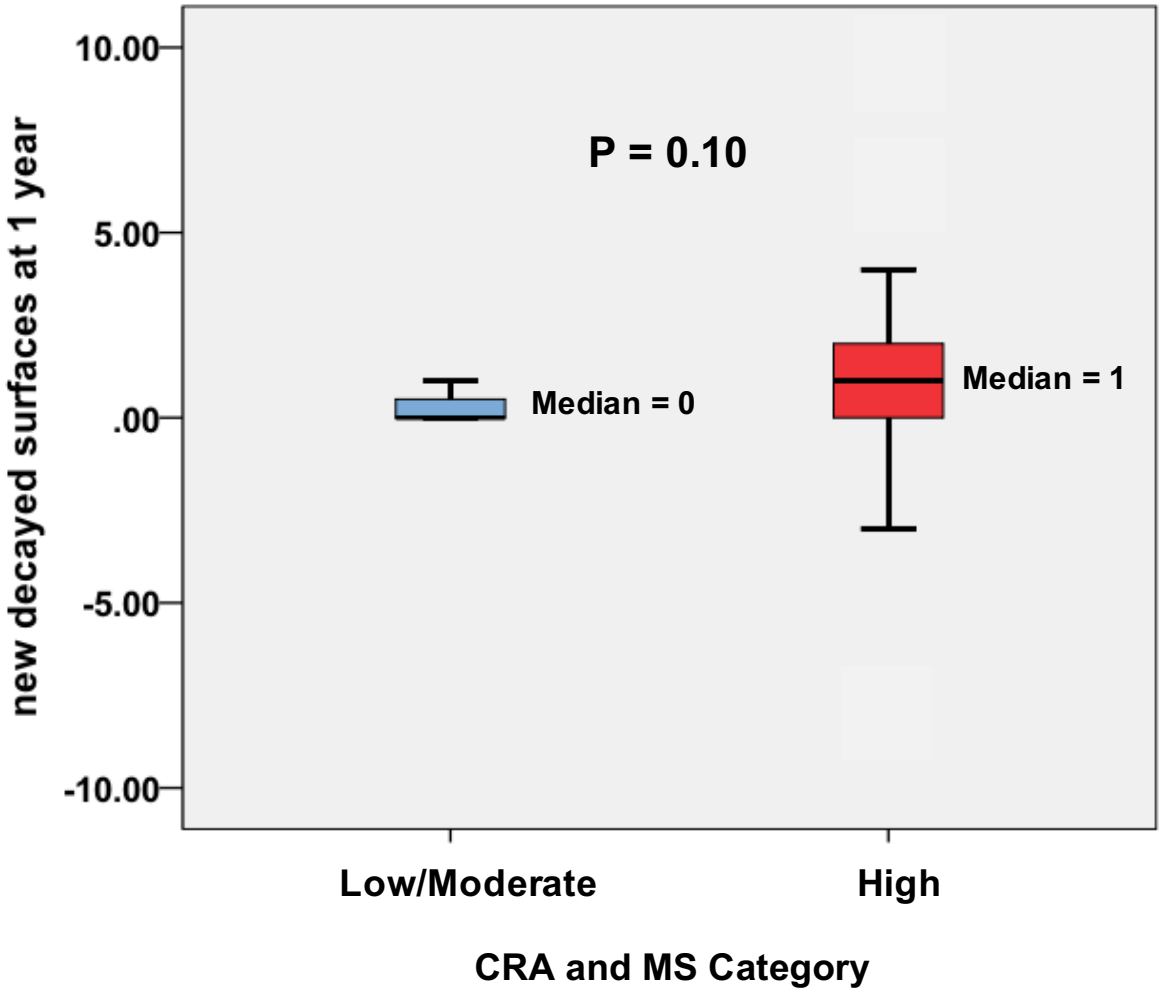
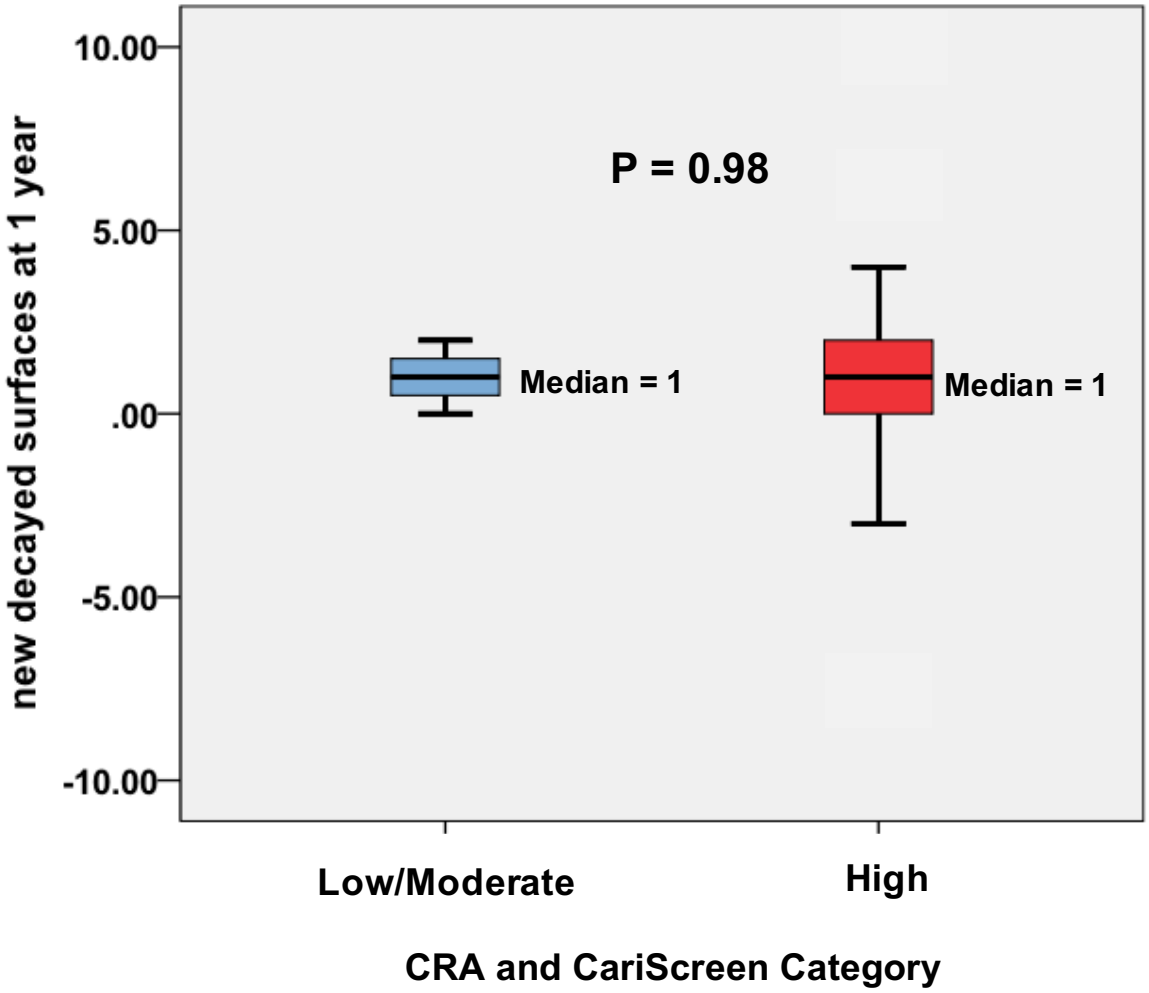


Figure 10. New Decayed Surfaces in Low/Moderate or High categories by CRA and bacteria challenge by CariScreen at Baseline



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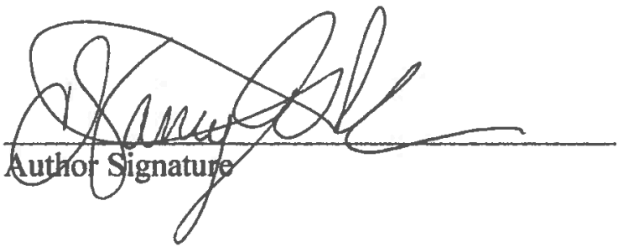

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