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## Evaluation of the Cariogram for root caries prediction

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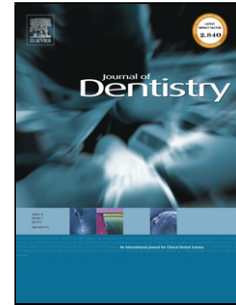
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## Evaluation of the Cariogram for root caries prediction

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## Evaluation of the Cariogram for root caries prediction

### Abstract

#### Objectives

The aim of this study was to evaluate complete and reduced Cariogram models in predicting root caries risk in independently living older adults by comparing the caries risk assessment of the program to observed root caries increment over a two-year period.

#### Methods

A prospective study recording root caries incidence was conducted on 334 dentate older adults. Data were collected on participant's medical history, fluoride exposure, and diet. Saliva samples were collected to measure salivary flow rate, buffer capacity and bacterial counts. Clinical examination was completed to record decayed, missing and filled teeth (DMFT) and also exposed, filled and decayed root surfaces (RDFS). This was repeated after 12 and 24 months. Scores were entered into the Cariogram and baseline risk category was recorded. Reduced Cariogram models were generated by omitting individual salivary variables and all salivary variables. The performance of the complete and reduced Cariogram models in predicting root caries incidence were evaluated by receiver operating characteristic (ROC) analysis.

#### Results

280 participants were examined at two year follow up. 55.6% of those in the highest risk group developed new caries compared to 3.8% in the lowest risk group. The mean root caries increment in the highest risk group was 2.00 (SD 3.20) compared to 0.04 (SD 0.20) in the lowest risk group. The area under the ROC curve for the complete Cariogram model was 0.77 (95% CI 0.70-0.83) indicating a fair performance in predicting root caries. Omitting individual or all salivary variables did not significantly alter the predictive ability of the Cariogram.

#### Conclusion

Within the limitations of this study, the Cariogram was clinically useful in identifying individuals with a high risk of developing root caries.

### Clinical significance

Identification of a caries risk assessment tool which could reliably select high-risk individuals for root caries prevention strategies would maximise the cost effectiveness of professionally delivered prevention measures.

## Introduction

It has been reported that approximately one third of the older adult population bears most of the root caries burden [1, 2]. Root caries is a preventable disease. Targeted root caries prevention or remineralisation measures delivered by oral healthcare professionals have been shown to be more effective than self-administered measures such as fluoridated dentifrices [3]. Identification of a caries risk assessment tool which could reliably select high-risk individuals for root caries prevention strategies would maximise the cost effectiveness of professionally delivered prevention measures.

The Cariogram, an interactive computer-based caries risk assessment programme, was developed in Malmö, Sweden, initially for use as an educational aid [4]. This programme has since been shown to be capable of predicting caries increment more accurately than any single-factor model and its validity has been evaluated in more prospective cohort studies than any other caries risk assessment tool [5]. The Cariogram program presents a caries risk assessment for an individual according to a weighted evaluation of nine caries-related factors. The original formula and the weight assigned to each factor were derived from large sets of population data and the algorithm has remained unchanged since its inception in 1997. The model has been evaluated in a wide range of patient groups from pre-schoolers to the elderly [2, 6]. However, no measurements related to prediction model performance (e.g. sensitivity, specificity) of the Cariogram for the purpose of root caries prediction have been explored to date. Translation of the use of the Cariogram into general practice could also be impaired by the inclusion of salivary tests which require access to a chairside incubator and also 48 hours for incubation. These tests also add a significant cost to the use of the Cariogram for caries risk assessment. A previous study investigated the predictive ability of a reduced Cariogram, without the inclusion of any salivary variables [7]. This study found that omission of the salivary parameters increased the sensitivity of the model, but at the expense of the specificity.

The aim of this study was to evaluate complete and reduced Cariogram models in predicting root caries risk in independently living older adults by comparing the caries

risk assessment of the program to actual root caries increment over a two-year period.

## **Materials and Methods**

### *Study design*

The protocol for this longitudinal study received ethical approval by the Clinical Ethics Committee of the Cork Teaching Hospitals (ECM 4 Y 06/12/11). The study was conducted in compliance with the principles of the Declaration of Helsinki and the STROBE guidelines [8]. Written informed consent was obtained from each participant. Eighty-five of the individuals whose data are included in this report were also enrolled in a randomised controlled clinical trial comparing restorative materials in the operative treatment of root caries [9].

### *Recruitment*

Adults aged over 65 years of age with some remaining natural dentition were invited to attend Cork University Dental School and Hospital for a free dental examination. Advertisements were placed in local shopping centres, community centres and the local press over a period of three months. Telephone contact details of the study co-ordinator were provided and patients were allocated appointments provided they were the appropriate age, and confirmed they had some of their natural dentition remaining. All of the patients recruited to the study were independently living older adults. No financial rewards were offered to patients. Recruitment commenced in October 2012 and was completed in November 2013.

### *Inclusion and exclusion criteria*

The inclusion criteria for entering this study were:

- Aged 65 or over
- Present a minimum of one natural tooth
- Living independently in the community
- Have sufficient cognitive ability to understand consent procedures

The exclusion criteria for this study were:

- Those living in nursing home facilities
- Individuals who had taken antibiotics in the previous month (as this may alter the oral microflora)

#### *Data collection and oral examination*

Each participant completed a questionnaire which recorded their medical history, medications, fluoride exposure and diet information. Patients were advised to avoid eating, drinking, smoking, chewing gum, tooth brushing, or mouthwashes for one hour prior to their appointment. Saliva was collected over a period of five minutes following one minute of stimulation by having the participant chew a paraffin pellet. Xerostomia was defined as a stimulated saliva flow rate of < 0.7 ml saliva/min.

The CRT® Caries Risk Test (Ivoclar-Vivadent, Schaan, Liechtenstein) was used to record the salivary buffer capacity and counts of mutans streptococci (MS) and lactobacilli (LB). The buffer capacity of stimulated saliva was determined using CRT Buffer® (Ivoclar-Vivadent). The test field of the buffer strip was wetted entirely with stimulated saliva using a pipette. After 5 minutes of reaction, a coloured chart provided by the manufacturer was used to record the buffer capacity as low, medium or high. The MS and LB counts per millilitre saliva were recorded using CRT Bacteria® (Ivoclar-Vivadent). The agar surfaces were wetted with stimulated saliva and incubated at 37 °C (99 °F) for 48 h. The MS and LB counts were scored in two categories: <math>10^5</math> or  $\geq 10^5$  CFU/ml saliva.

A single trained examiner performed a baseline oral exam in a standard dental operatory equipped with a dental light and air-water syringe. Plaque scores were recorded using the mucosal plaque score (MPS) index [10]. Teeth were cleaned with an ultrasonic scaler, rubber cup and prophy paste and were washed and dried prior to caries detection. Decayed, missing and filled teeth (DMFT) were recorded. Root surfaces were anatomically defined as those surfaces apical to the cemento-enamel junction (CEJ). The root caries classification system used was a modification of the International Caries Detection and Assessment System (ICDAS II) [11] as described in a previous publication [12]. New root caries (for the purposes of statistical



analysis) was defined as an active, cavitated ( $\geq 0.5$ mm lesion) lesion, either wholly or partly on the root surface, which offered no resistance to a ball-ended probe.

Participants were invited for review 12 and 24 months after their baseline examination. At this time one of two calibrated examiners repeated the clinical examination procedure outlined above. Root caries increment for each adult over the two-year period was calculated as the number of root surfaces which had developed a new active, cavitated lesion in that time. A new lesion on a previously restored root surface was categorised in the same manner as a new lesion on a previously sound root surface.

#### *Data entry into the Cariogram*

The Cariogram software was downloaded in English from <https://www.mah.se/fakulteter-och-omraden/Odontologiska-fakulteten/Avdelning-och-kansli/Cariologi/Cariogram>. The settings for “country/area” and “group” were kept at standard. The range for “normal” caries experience was calculated as the mean DMFT score (14.7) reported for adults over 65 in the UK Adult Oral Health Survey 2009 +/- one standard deviation (4.3) [13]. The clinical judgement category was set at 1 to nullify this factor. Therefore the range for normal caries experience used was a DMFT score of between 17 and 28. More detail on the scoring method in each category is available from the Cariogram manual (Internet version 2) [14]. Participants were divided into five groups at baseline according to the assessed chance of avoiding caries, from the highest risk group, with a 0-20% chance of avoiding caries, to the group with the lowest predicted risk for caries, i.e. 81-100% chance of avoiding caries over the two-year follow-up. This procedure was then repeated to create the reduced Cariogram models; one model with mutans streptococci removed, one with saliva buffer capacity removed, one with saliva secretion rate removed, and finally one with all of the aforementioned salivary variables removed. Both patients and examiners were blinded to the patient’s initial caries risk assessment.

#### *Statistical analyses*

Data from case report forms were entered into SPSS (version 22; SPSS, Inc., an IBM Company, Chicago, IL, USA) software. Fifteen participants were re-examined one week after the initial exam. Intra-examiner reproducibility at root surface level was measured by the mean kappa statistic which was 0.95 for root caries detection at the active cavitated level (as described above). Inter-examiner reliability between the two reviewing examiners was 0.94. The performances of the complete and reduced Cariogram models in predicting root caries incidence were evaluated by receiver operating characteristic (ROC) analysis. The area under the ROC curve was used to evaluate the goodness of fit with a value of 1.0 indicating a perfect model and 0.5 indicating a model with no more predictive value than that of pure chance [15]. To compare the complete and reduced Cariogram models, differences between the areas under the ROC curves were tested according to Hanley and McNeil [16].

## Results

Of the 334 participants who were examined at baseline, 307 attended for re-examination after 12 months and 280 after 24 months. Fifty-four individuals (16.2%) were lost to follow up. Three of these had deceased, five had moved into a nursing home facility, 18 did not feel well enough to attend and the remaining 27 declined to attend. There were no significant differences detected between the baseline characteristics of those who completed the study and those who did not. 18.2% of those who were examined at 12 months and 25.0% of those examined at 24 months had developed at least one new active cavitated root caries lesion. The mean root caries increment was 0.43 surfaces at 12 months and 0.70 surfaces at 24 months. Therefore, the annual root caries increment was 0.35 surfaces per person.

The complete Cariogram model assigned 91 participants (27.2%) to the lowest two risk categories (i.e. 61-100% chance of avoiding new caries) and 155 (46.5%) to the highest two risk groups. The remaining 88 adults (26.3%) were in the moderate risk category with a 41-60% chance of avoiding new caries (Table 1). 55.6% of those in the highest risk category developed new root caries over the 24 months compared to 3.8% of those in the lowest risk category (Figure 1). The mean root caries increment in the highest risk group was 2.00 (SD 3.20) compared to 0.04 (SD 0.20) in the lowest risk group. The mean RDFS and mean root caries increment for each of the

individual components of the Cariogram are shown in Table 1. A significantly higher mean root caries increment can be observed in individuals with frequent dietary intakes, large quantities of visible plaque, those avoiding fluoride use, and xerostomic individuals.

The area under the ROC curve for the complete Cariogram model was 0.77 (95% CI 0.70-0.83) indicating that the Cariogram model is useful for predicting root caries incidence (Figure 2). The area under the ROC curves generated for each of the reduced models was not significantly different from that of the complete Cariogram model (Table 2). For the complete Cariogram model, the highest value of Youden's index was 0.41 when a cut-off of 40% was selected indicating that this was the optimal cut off when determining future root caries risk. At this cut-off, the complete Cariogram demonstrated a sensitivity of 78.6% and a specificity of 62.9%. Predictive values for the reduced models at the 40% cut-off are also reported (Table 3).

## Discussion

A number of prediction models have been developed for root caries based on longitudinal studies [17-21]. A systematic review of risk models for root caries identified thirteen articles [22]. Of these, only four reported on the predictive ability of their reported models [17, 18, 20, 23]. A search of the literature beyond the date of this systematic review identified a further two longitudinal studies reporting risk models. [21, 24]. However of these only one reported on the predictive ability of the resulting model [21]. Of the five models which report on the performance of their risk models, all have past root caries experience in some form (i.e. RDFS, RCI, RCI<sub>log</sub>) as a significant predictive variable. This finding compromises the use of these models as true preventive tools as they rely on past disease experience to predict future experience limiting the ability to identify a high risk individual before they become exposed to the disease. While the Cariogram does include past disease experience as a factor, this study used past coronal caries experience to categorise the individual (DMFT), thus not relying on root caries experience.

It has been suggested that a useful caries prediction model should produce a sensitivity of 0.75 or higher and a specificity of at least 0.85 [25]. Similarly it has been stated that a risk model should have a combined sensitivity and specificity of at least

160 percent to be considered a good test [26]. In non-invasive caries management, a high sensitivity level may increase the number of false-positive results, but there would not be any resulting harm to the patient. Rather there would be an economic harm if the test were applied at a population level (as the cost of prevention would be higher). The model reported by Scheinin et al had a sensitivity of 77.6% and a specificity of 76.6% [20]. This results in a Youden's Index of 0.54 (the highest of the root caries prediction models identified in the literature) indicating that it is more clinically useful than the Cariogram. This model included three variables; past root caries experience (DFSr), Candida, and Lactobacilli levels. However it is prudent to highlight that an important limitation of the models reported in the literature to date is their lack of independent validation. Before considering whether to use a clinical prediction model, it is essential that its predictive performance be empirically evaluated in datasets that were not used to develop the model [27]. Only one paper reported an attempt to internally validate the model on a sub-sample of patients [23]. In contrast, this study reports on the external validation of the Cariogram on a different set of subjects from those in which it was developed and is a better reflection of its true predictive ability in the general population.

In this study, both patients and examiners were blinded to the patient's caries risk assessment at baseline. This was important as it has been suggested that an individual identified initially as high caries risk might be more motivated to take care of his or her teeth or might receive a more thorough assessment by the examiner than an individual deemed at lower risk [28].

It was interesting to note that the reduced Cariogram model, without inclusion of any of the salivary variables, had a predictive ability for root caries which did not differ significantly from that of the complete model. This finding is also supposed by the comparison of root caries experience in this study according to each of the categorical variables (Table 1). This bivariate analysis did not find a significant relationship between root caries experience and mutans streptococci count or saliva buffering capacity. It did however demonstrate a strong correlation between reduced saliva secretion rate (or xerostomia) and new root caries development. As only 7% of the sample were categorised as xerostomic, the numbers in this group may not have been large enough to show a significant difference between the predictive ability of the complete Cariogram model and the two models which omitted that variable. In

light of this, and the strong body of evidence linking xerosomia and caries risk, the authors would advise further research before recommending the use of the Cariogram without inclusion of this variable.

In regards to the limitations of this study, it is important to highlight that this study population were a self-selecting cohort of independently living older adults. The risk indicators for older adults living in nursing home facilities may differ from those for less dependent elders. For this reason, the authors chose to keep the “group” setting as standard rather than high, even though many might consider older adults as a high caries risk group. The “country” setting was also kept at standard even though over 80% of the water supply in the Republic of Ireland is fluoridated at a concentration of 0.6-0.8ppm [29]. Previously published studies have found that water fluoridation is associated with lower levels of root caries [30, 31]. Despite this the root caries incidence in this population was high with 25% of the cohort developing new active root caries lesions within a 24-month period. A change in these settings, which are somewhat subjective in nature, along with the ability for the clinician to enter their own clinical judgement into the Cariogram may alter the performance of the computer programme in predicting root caries risk. Thus it is important to reiterate that the results obtained in the present study were based on a particular set of assumptions by the authors and in a specific, self-selecting, cohort of the population. Further studies by different researchers in different settings would be desirable to further validate the clinical usefulness of the Cariogram at a health outcome and cost-benefit level.

## **Conclusions**

Root caries incidence was high in this cohort with 25% of participants developing new root caries lesions over a two-year period. The current study indicated that the Cariogram may be clinically useful in determining future root caries risk in independently living older adults.

## **Declaration of Interests**

The authors declare no conflict of interests

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**Legends**

Figure 1. Percentage of participants who developed any new root caries over 24 months by Cariogram category.

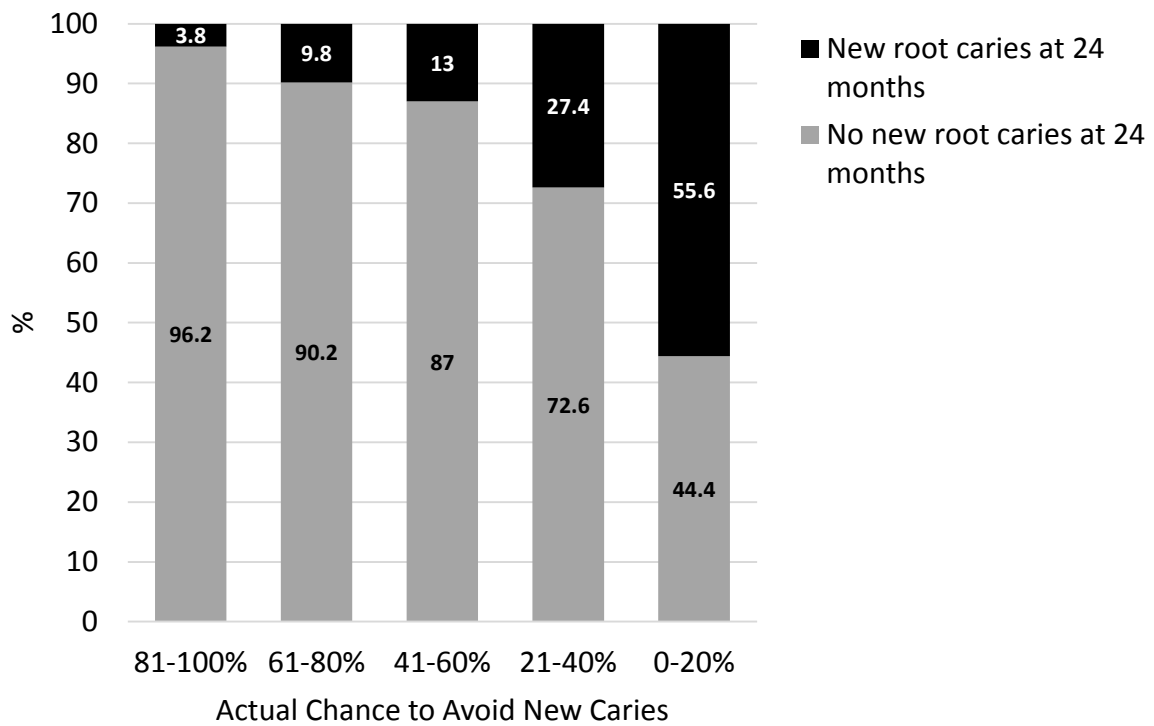
Figure 2. ROC curve for total and reduced Cariogram models

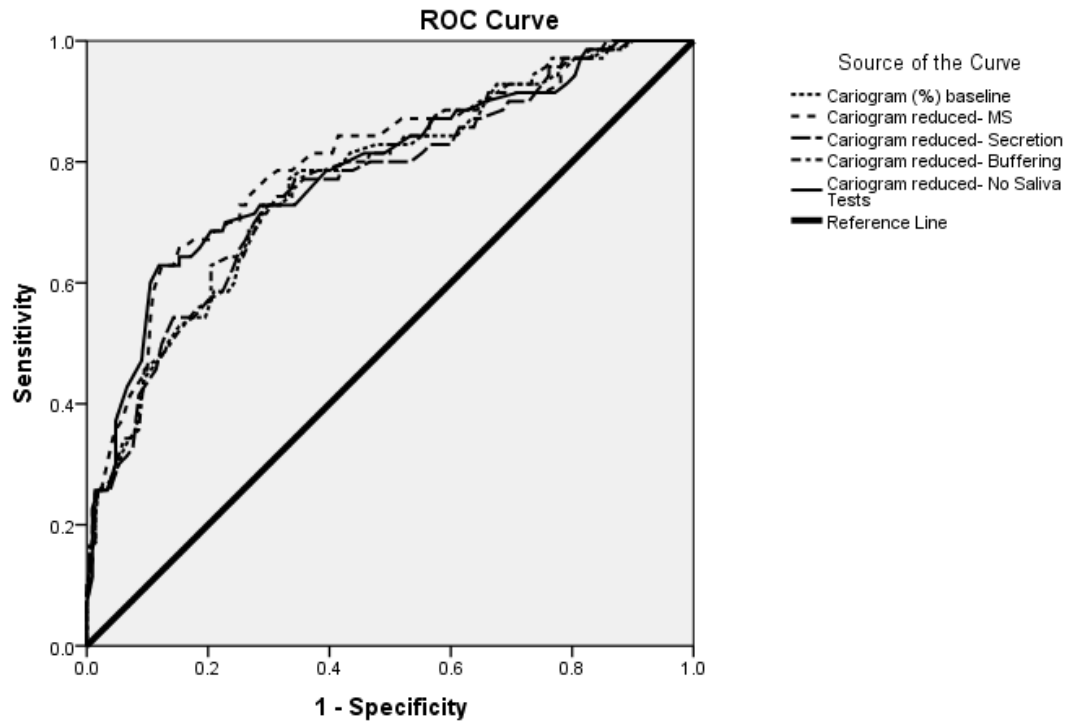
Table 1. Comparison of root caries experience according to categorical variables

Table 2. The mean area under the ROC-curve calculated for total and reduced Cariogram models

Table 3. Predictive values for new root caries experience at the 40% cut-off assessed by total and reduced Cariogram

Figure 1. Percentage of participants who developed any new root caries over 24 months by Cariogram category





Diagonal segments are produced by ties.

Table 1. Comparison of root caries experience according to categorical variables (continues on the next page)

Variable	No. Exposed (%)	RDFS at Baseline Mean (SD)	RDFS at 24 months Mean (SD)	Root Caries Increment Mean (SD)	p-value <sup>a</sup>
<i>Caries experience</i>					
Caries free and no fillings	0 (0)	-	-	-	
Better than normal	44 (13.2)	1.36 (2.44)	1.32 (2.37)	0.45 (1.26)	0.076
Normal for age group	210 (62.9)	2.66 (4.72)	3.28 (5.88)	0.55 (1.28)	
Worse than normal	80 (24.0)	6.25 (7.94)	6.83 (10.15)	1.20 (2.96)	
<i>Related general diseases</i>					
No disease	112 (33.5)	3.04 (5.36)	3.61 (6.50)	0.57 (1.42)	0.481
Mild degree	141 (42.2)	3.66 (5.94)	4.16 (7.73)	0.83 (2.37)	
Severe degree	81 (24.3)	3.25 (5.80)	4.09 (7.16)	0.67 (1.35)	
<i>Diet, contents (lactobacillus count)</i>					
<10 <sup>5</sup> CFU/ml saliva	162 (48.5)	3.41 (5.30)	4.14 (6.42)	0.73 (1.52)	0.235
≥10 <sup>5</sup> CFU/ml saliva	172 (51.5)	3.30 (6.07)	3.79 (7.76)	0.67 (2.12)	
<i>Diet, frequency</i>					
Max 3 meals/day	176 (52.7)	3.21 (5.40)	3.75 (7.28)	0.61 (2.12)	<0.001
4-5 meals/day	104 (31.1)	2.86 (5.46)	3.07 (6.01)	0.48 (1.20)	
6-7 meals/day	37 (11.1)	3.97 (6.61)	5.57 (8.73)	1.17 (2.00)	
>7 meals/day	17 (5.1)	6.47 (7.44)	7.63 (7.77)	1.81 (1.68)	
<i>Plaque amount</i>					
Difficult to detent	0 (0)	-	-	-	
Small quantities	136 (40.7)	1.33 (3.03)	1.58 (3.60)	0.36 (1.01)	<0.001
Moderate quantities	118 (35.3)	3.01 (5.07)	3.27 (5.47)	0.51 (1.15)	
Large quantities	80 (24.0)	7.29 (7.79)	8.77 (10.61)	1.54 (3.11)	
<i>Mutans streptococci</i>					
<10 <sup>5</sup> CFU/ml saliva	114 (43.1)	3.04 (4.77)	3.71 (5.71)	0.51 (1.04)	0.732
≥10 <sup>5</sup> CFU/ml saliva	190 (56.9)	3.58 (6.32)	4.12 (8.07)	0.84 (2.27)	

<i>Fluoride programme</i>					
Maximum programme	13 (3.9)	2.46 (3.48)	1.60 (2.63)	0.00 (0.00)	<0.001
Additional F, infrequently	160 (47.9)	1.99 (3.87)	2.08 (4.45)	0.17 (0.67)	
Daily F toothpaste only	127 (38.0)	3.54 (5.86)	4.12 (6.78)	0.75 (1.54)	
Avoiding F	34 (10.2)	9.38 (8.59)	12.20 (11.93)	3.07 (3.89)	
<i>Saliva secretion</i>					
<0.7ml/min	310 (92.8)	2.75 (4.61)	3.22 (5.60)	0.53 (1.30)	<0.001
≥0.7ml/min	24 (7.2)	11.08 (10.87)	12.95 (14.77)	2.81 (4.62)	
<i>Saliva buffering capacity</i>					
Low	54 (16.2)	5.13 (7.64)	5.88 (8.64)	0.90 (1.70)	0.279
Medium	150 (44.9)	3.18 (5.64)	3.95 (7.78)	0.85 (2.42)	
High	130 (38.9)	2.81 (4.65)	3.09 (5.41)	0.45 (1.01)	
<i>Actual chance to avoid new caries (%)</i>					
0-20 (high caries risk)	74 (22.2)	7.23 (8.37)	8.98 (10.86)	2.00 (3.20)	<0.001
21-40 (high-medium risk)	81 (24.3)	3.19 (5.20)	3.67 (6.20)	0.62 (1.33)	
41-60 (moderate risk)	88 (26.3)	1.34 (2.79)	1.56 (3.25)	0.19 (0.56)	
61-80 (low-medium risk)	55 (16.5)	2.85 (4.31)	2.90 (5.01)	0.22 (0.85)	
81-100 (low risk)	36 (10.8)	1.42 (2.75)	1.27 (2.43)	0.04 (0.20)	

<sup>a</sup>Mann-Whitney U test was applied for categories with two groups, Kruskal-Wallis test was applied for three or more groups, significance level P<0.05

Table 2. The mean area under the ROC-curve calculated for total and reduced Cariogram models (note that none of the reduced models are significantly different from total Cariogram [ $p < 0.05$ , Hanley-McNeil test])

<b>Risk Model</b>	<b>AUC</b>	<b>SE</b>	<b>95% CI</b>
<b>Total Cariogram</b>	0.767	0.033	0.702-0.833
<b>Reduced Cariogram</b>			
No MS	0.801	0.032	0.738-0.864
No buffer capacity	0.760	0.034	0.693-0.828
No secretion rate	0.773	0.033	0.709-0.837
No salivary variables	0.788	0.034	0.722-0.854

Table 3. Predictive values for new root caries experience at the 40% cut-off assessed by total and reduced Cariogram

Predictive values (%)	Total Cariogram	Reduced Cariogram Models			
		No MS	No Buffer	No Secretion Rate	No Saliva Testing
<b>Sensitivity</b>	78.6	74.3	78.6	78.6	72.9
<b>Specificity</b>	62.9	73.3	58.1	58.1	65.7
<b>PPV</b>	40.0	48.1	38.5	38.5	41.5
<b>NPV</b>	89.6	89.5	89.0	89.0	87.9