Original Article

An *In Vivo* Investigation of Diagnostic Performance of DIAGNOdent Pen and the Canary System for Assessment and Monitoring Enamel Caries under Fissure Sealants

Nada Jaafar, Hala Ragab[1], Ahmed Abedrahman[2], Essam Osman[3]

Clinical instructor of Pediatric Dentistry, Department of Developmental Sciences, Division of Pediatric Dentiry, Faculty of Dentistry, Beirut Arab University, Beirut, Lebanon, [1]Professor of Operative and Esthetic Dentistry, Department of Restorative Sciences, Division of Operative and Esthetic Dentistry, Faculty of Dentistry, Beirut Arab University, Beirut, Lebanon, [2]Professor of Pediatric Dentistry and Dental Public Health, Department of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Alexandria University, Alexandria, Egypt, [3]Professor of Dental Materials, Department of Restorative Sciences, Division of Dental Biomaterials, Faculty of Dentistry, Beirut Arab University, Beirut, Lebanon

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ABSTRACT

Aim and Objectives: The aim of this study was to evaluate and compare the diagnostic performance of a quantitative light-induced fluorescence (DIAGNOdent pen [DP]) and a photothermal radiometry (Canary System [CS]) for assessment and monitoring occlusal enamel caries under fissure sealants placed on young permanent teeth. **Materials and Methods:** Forty-five patients of mean age 9.96 (1.4) years, having at least two occlusal surface sites of non-cavitated lesions (International Caries Detection and Assessment System [ICDAS], 1–3 at baseline), were assigned for this clinical study as per specific inclusion/exclusion criteria. A total of 90 permanent teeth were examined using a visual examination method (ICDAS), a quantitative light-induced fluorescence (DP), and a photothermal radiometry (CS). Teeth were randomly divided into two groups based on the type of fissure sealants: a resin sealant and a glass-ionomer sealant. Sealants were placed over the study sites, and caries assessment was performed with each caries detection method at 3- and 6-month recall appointments. Numerical data were presented as mean, standard deviation, median, and interquartile range values. Qualitative data were presented as frequencies and percentages. Receiver operating characteristic (ROC) curve was constructed to determine the diagnostic accuracy measures of the two modalities and compared using *z*-statistic. ROC curve analysis was performed with MedCalc software, Ostend, Belgium, version 11.3 for Windows (MedCalc Software). Changes by time in caries progression were analyzed using McNemar test and Cochran *Q* test. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with the IBM Statistical Package for the Social Sciences (SPSS) software for Windows, version 23.0 (IBM, Armonk, New York). **Results:** The CS and DP were able to distinguish between sound and carious tissue beneath fully and partially retained sealants at 6-month follow-up with an accuracy of 46.7% and 33.4%, respectively. **Conclusion:** The diagnostic performance of the CS and DP are acceptable and can be considered as useful adjunct tools in the clinical evaluation and monitoring the changes in enamel due to lesion progression under fissure sealants. However, in the clinical setting, sensitivity and specificity of these devices may be influenced by the sealant type, thickness, retention, and the differences in the lesion characteristics over time.

KEYWORDS: *Canary system, DIAGNOdent pen, fissure sealants, International Caries Detection and Assessment System, non-cavitated occlusal caries*

Address for correspondence: Dr. Nada Jaafar,
Department of Pediatric Dentistry, Faculty of Dentistry,
Beirut Arab University, Beirut, Lebanon.
E-mail: dr.nada.jaafar@gmail.com

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Introduction

Dental caries remains the most pervasive chronic disease of children, with pit and fissures representing the most prevalent disease in young permanent dentition.[1,2] The reason behind the high occurrence is ascribed to the morphology of the occlusal surfaces that include deep grooves that provide a good shelter for food debris, bacteria and bacterial products, promoting formation of bacterial biofilm, together with minimal salivary access, thereby expanding the risk of creating carious lesions.[3] However, dental caries is to a great extent preventable and can be treated by nonsurgical intervention, whenever recognized in the early stage.[4,5] In this manner, clinical diagnosis of incipient non-cavitated occlusal caries became challenging.[6]

Traditionally, dentists have relied on visual examination, tactile assessment, and radiographs for the discovery of carious lesions. However, it depends on subjective criteria such as color, translucency, hardness, and roughness of the tooth surface. Probing of carious lesions may produce traumatic enamel defects and may transport cariogenic bacteria to other sites.[7-9] The routine utilization of bitewing radiography could help distinguishing teeth with hidden caries, yet it is mistaken in diagnosing occlusal enamel caries.[10,11]

For better identifying enamel and dentin caries, an evidence-based visual assessment system, named "International Caries Detection and Assessment System (ICDAS)" was developed. The ICDAS provides detailed description of lesion severity on a seven-category scale.[12] In addition, a two-digit code was added to monitor whether caries is associated with the sealant. For occlusal caries, ICDAS was shown to have a high correlation with histological validation *in vitro* and was found to be reproducible and repeatable.[13-18] The ICDAS also showed usefulness in predicting which lesions are more likely to progress, helping in making treatment decisions when combined with other detection aids.[13,17,19-21] However, this method is subjective, and training and calibration are necessary.[22,23]

The limitations of the traditional methods and the need to find objective, quantitative methods to monitor caries progression have brought into focus the development of new systems for early caries detection to encourage preventive nonoperative intervention. One of these methods such as the Canary System (CS) (Quantum Dental Technologies, Toronto, Ontario) is based on photothermal radiometry-luminescence technology to detect the status of the enamel crystal. The tooth tissues irradiated with a pulsating laser beam, produce a combination of two slightly different responses, the first response signifies the conversion of absorbed optical energy into thermal energy that results in a modulation in the temperature of tooth structure. The second response signifies the conversion of absorbed optical energy to radiative energy. This system was reported to detect lesions as deep as 5 mm and was expressed on a scale of 0–100 to represent lesion severity.[8,24] It was also speculated that this method can be used to assess the activity of caries lesions, measure the effectiveness of remineralizing agents, evaluate enamel surface and structure before sealant placement, and check the sealant margins over time.[25,2] However, to the best of our knowledge, not enough published studies that have used the commercially available CS and no clinical studies that have used this system in evaluation and monitoring caries progression under fissure sealants are available.

Another method such as DIAGNOdent pen (DP) (KaVo, Biberach, Germany), depends on the principle that when diode laser with 655 nm wavelength is irradiated on dental surface, it is absorbed by metabolites of intraoral bacteria and these metabolites emit a red fluorescence. This fluorescence reflected by the dental surface is shown as a number somewhere between 0 and 99 on the screen of the device. Greater numbers are a sign of a greater decay area. In this way, laser fluorescence gives a quantitative and noninvasive method for the diagnosis of dental caries. Despite the fact that this adjunct method has been viewed as a valuable tool in early caries and has shown sensitivity of 75% and specificity of 96%, which is considered very high for smooth-surface enamel caries analysis,[26] there are a few concerns with respect to its precision, for instance, there is no relation between the number appeared by the DP and the depth of decay.[27]

The aim of this study was to evaluate the performance of a visual examination method, a quantitative light-induced fluorescence, and a photothermal radiometry in detection and monitoring occlusal caries progression under fissure sealants placed on young permanent teeth over 6 months.

Materials and Methods

This comparative clinical study was carried out in the specialty clinic, Faculty of Dentistry, Beirut Arab University, Beirut, Lebanon, after the approval of the ethical and research committee of Beirut Arab University Institutional Review Board (code: 2018H-0058-D-P-0258). The objectives, risks, and benefits of the study were explained to the parents/guardians, and a signed informed consent form was obtained before the treatment. The number of children was determined according to the sample size calculation website: htpp://epitools.ausvet.com.au (Ausvet), by considering the mean (2.2–1.83) and pooled variance (0.35) from a study conducted by Silvertown *et al*,[2] on the detection of caries under four different dental sealants using DP and CS. Assuming a confidence level of 95% and the study power of 80%, the calculated sample size was 80 teeth. It was increased by 10% to eliminate the probability of dropout through the treatment period. Thus, a total of 90 fully erupted early permanent teeth were recruited conveniently from 45 children, fulfilling the inclusion and exclusion criteria. The randomization process was performed by coin flip method, and the unit of randomization was the side of the mouth. Patients selected from the outpatient clinic were aged between 8 and 12 years. All selected individuals were medically free, had bilateral fully erupted molars, or premolars with non-cavitated incipient carious lesions on the occlusal surfaces (ICDAS code 1–3) at baseline assessment to ensure no dentin involvement.[28-30] The selected teeth were free from restorations, hypoplasia, fracture, or cracks.[8] Uncooperative patients, patients with special needs, or patients that received professional fluoride application within the last 6 months were excluded from this study.

Examination of early occlusal caries lesions

Baseline records were carried out using visual examination (ICDAS), quantitative laser fluorescence (DP), and photothermal radiometry (CS). The examination was repeated twice for each individual tooth by one trained operator. Training was carried out according to a study by Iranzo-Cortés *et al.*[28]

Visual examination (International Caries Detection and Assessment System)

Teeth were visually inspected after proper drying under good standardized light source. A World Health Organization (WHO) probe was passed on all pits and fissures surface starting from the mesial to the distal side of the occlusal surface (Dikmen, 2015). The baseline ICDAS score was given to the assigned teeth based on ICDAS criteria. Only teeth having score 1–3 were included in this study.

Canary System measurements

The device was calibrated and CS scans were performed using the quick scan setting, according to the manufacturer's user manual. Study site was dried before scanning. The tip of the device was moved on all pits and fissures surface starting from the mesial to the distal side of the occlusal surface. The CS of four scans was recorded, and the mean was considered. Each tooth was given a rating number between 0 and 100, with 0–20 indicating a healthy tooth, whereas numbers above 20 signify the presence of varying levels of damaged surfaces by caries.[2] According to CS scale, only teeth that scored from 21 to 60 were included in this study.

DIAGNOdent pen measurement

DP was used in accordance with the manufacturer's operating instructions to obtain readings between 14 and 40, before sealant application. For each patient, the device was calibrated with a calibration disc, and a zero baseline was established using a sound spot. Each tooth was air-dried for 5 s, and the narrow tip (probe A) of the DP was placed perpendicular to the examination site and then rotated around its vertical axis until the highest (peak) value was obtained. The device was moved over all pits and fissures surface starting from the mesial to the distal side of the occlusal surface.[28,29]

Treatment procedures

Each patient received two types of sealants, a glass-ionomer based (Riva Protect; SDI, Victoria, Australia) and a resin-based sealant (Delton FS+; Dentsply, Konstanz, Germany). All clinical procedures were performed by one trained operator. The sealant was checked for complete coverage of all pits and fissures and retention after complete polymerization by the aid of a fine probe. Parents and children were given appropriate dental health educational instructions based on their age, including proper brushing (twice a day, especially before bed time) and proper flossing, which if needed, were shown on a model.

Histological validation

Teeth were categorized based on the presence or absence of caries for histological validation. On the basis of the supplied cutoff values in the manufacturer's operating instructions for each system, DP readings were ranked according to the DP scale: 0–13 = non-carious and >13 = carious, whereas canary number readings were ranked according to the CS scale: 0–20 = sound and 21–100 = carious.

Recall examination

The same procedures for caries detection methods as described previously were performed on the 3- and 6-month follow-up period. After oral prophylaxis, the tooth was partially isolated and assessed using the two-digit ICDAS. For ICDAS, the first digit was either 1 (partial sealant retention) or 2 (full sealant retention), and the second digit ranged from 0 to 6 that is used in ICDAS for caries code. Code 20 was used as a reference standard (sound), whereas all other codes (11, 12, and 13) with varying degrees of enamel changes were considered (carious). DP and CS measurements were also recorded.

Statistical analysis

Numerical data from each method were categorized into sound or carious and were presented as mean, standard deviation (SD), median and interquartile range (IQR) values. Qualitative data were presented as frequencies and percentages.

Sensitivity and specificity were measured to quantify the diagnostic ability of the test method. Sensitivity and specificity were expressed as values between zero and one (as a percentage), where values closer to one (100%) indicate a high-quality result. Receiver operating characteristic (ROC) curve between sensitivity and specificity was constructed to determine the diagnostic accuracy measures of the two modalities. Areas under the ROC curve (AUCs) were compared using z-statistic. ROC curve analysis was performed with MedCalc software, version 11.3 for Windows (MedCalc Software, Ostend, Belgium).

Changes in caries progression by time were analyzed using McNemar test and Cochran Q test. The significance level was set at $P \le 0.05$. Statistical analysis was performed with the IBM Statistical Package for the Social Sciences (SPSS) software for Windows, version 23.0 (IBM, Armonk, New York).

Results

The study was conducted on 45 subjects: 27 females (60%) and 18 males (40%). The mean (SD) values for age were 9.96 (1.4) years with a minimum of 8 years and a maximum of 12 years. The number of teeth included in the study was 90 teeth.

Caries prevalence before and immediately after sealant application

For ICDAS, all teeth were considered as carious: 34 teeth (37.8%) had Code 1, 46 teeth (51.1%) had Code 2, and 10 teeth (11.1%) had Code 3. For both CS scale and DP scale, all teeth included in the study were ranked as (carious) pre-sealant application. However, after sealant application, for the two-digit ICDAS, all teeth had Code 20, for CS: 5 teeth (5.6%) were sound and 85 teeth (94.4%) were carious. The median and IQR of CS measurements was 28 (23–34). According to DP, 3 teeth (3.3%) were sound and 87 teeth (96.7%) were carious. The median and IQR of DP measurements was 20 (16–26.3).

Caries progression by time

According to two-digit ICDAS, no statistically significant change was observed in ICDAS scores from 3 to 6 months ($P = 0.296$). Baseline data were not compared because it was not two-digit score. According to CS, a statistically significant change was observed in CS scores by time ($P < 0.001$). Pairwise comparisons between the times revealed that a statistically significant decrease was observed in the prevalence of teeth diagnosed as carious from baseline to 3 months, followed by nonstatistically significant change from 3 to 6 months. According to DP, a statistically significant change was observed in DP scores by time ($P = 0.015$). Pairwise comparisons between the time revealed no statistically significant change in the prevalence of teeth diagnosed as carious from baseline to 3 months, followed by a statistically significant decrease in the prevalence of teeth diagnosed as carious from 3 to 6 months [Table 1].

Table 1: Descriptive statistics and results of McNemar test and Cochran Q test for comparison between caries scores by time with each modality

Modality	Baseline *n* (%)	3 months *n* (%)	6 months *n* (%)	*P* value
Two-digit ICDAs				0.296
Code 20 (sealant, full, and sound)	-	77 (85.6)	70 (77.8)	
Code 21 (sealant, full, and first visual change in enamel)		0 (0)	1 (1.1)	
Code 11 (sealant, partial, and first visual change in enamel)		1 (1.1)	4 (4.4)	
Code 12 (sealant, partial, distinct visual change in enamel)		10 (11.1)	10 (11.1)	
Code 13 (sealant, partial, and localized enamel breakdown)		2 (2.2)	5 (5.6)	
CS				<0.001*
Sound (score 0–20)	5 (5.6)[b]	29 (32.2)[a]	38 (42.2)[a]	
Carious (score ≥21)	85 (94.4)	61 (67.8%)	52 (57.8)	
DP				0.015*
Sound (score 0–13)	3 (3.3)[b]	6 (6.7)[b]	12 (13.3)[a]	
Carious (score ≥14)	87 (96.7)	84 (93.3)	78 (86.7)	

CS = Canary System, DP = DIAGNOdent pen

*Significant at $P \le 0.05$, different superscripts in the same row are statistically significantly different

Diagnostic performance of Canary System and DIAGNOdent pen

Sensitivity, specificity, and predictive values, and diagnostic accuracy of CS and DP at 3 and 6 months are presented in [Tables 2 and 3] and Figures 1–4, respectively, to facilitate comparison. At 3 months, sensitivity was lower and specificity was higher with DP when compared to that with CS. Both CS and DP showed high sensitivity with lower specificity when E first distinct visual change was compared to sound enamel (Code 20 vs. Code 12). However, both systems still had comparatively high area under the ROC curve. CS showed higher diagnostic accuracy than DP. At 6-month results, ROC curve analysis revealed that DP showed higher sensitivity and lower specificity when compared to CS (Code 20 vs. all codes, vs. Code 12, and vs. Code 13). CS showed higher diagnostic accuracy than DP when detecting all caries above Code 20. Comparison between the two modalities of AUC showed no statistically significant difference between AUC of the two modalities at 3 and at 6 months.

Discussion

As caries management has shifted toward preventive and less invasive approach, searching for accurate and valid diagnostic devices for early caries detection became essential. Likewise, the validity of such devices to monitor the success of the preventive treatment over time became as important as accuracy itself.

Although *in vitro* studies are carried out under controlled conditions and provide practical information for clinical use, clinical studies remain the ultimate method to collect scientific evidence. This clinical study was conducted to evaluate and compare the diagnostic performance of the DP and CS in detection of occlusal caries under fissure sealants placed on young permanent teeth over 6 months and compare the results to the ICDAS visual examination. To the best of our knowledge, no previous research was conducted *in vivo* allowing for a direct comparison and analysis of caries assessment capabilities of these caries-detecting devices under fissure sealant. The examination was performed by one trained operator to avoid variation among the examiners and to ensure consistency as previous studies reported repeatability variation when several examiners were involved.

In biomedical studies, diagnostic tests are used to determine the presence or absence of a disease in study subjects. Test validation is an evaluation method used to determine the suitability of a test for a particular use. This involves calculating sensitivity, specificity, positive predictive value, and negative predictive value.[30] A diagnostic test is validated by comparing test results against a reference standard that establishes the true

Table 2: Sensitivity, specificity, predictive values, diagnostic accuracy, area under the receiver operating characteristic curve (AUC), and 95% confidence interval of the AUC for caries detection by the Canary System and DIAGNOdent pen after 3 months

Diagnosis	Modality	Sensitivity %	Specificity %	+PV %	−PV %	Diagnostic accuracy %	AUC	95% Confidence interval
Code 20 vs. all other codes (any change in E)	CS	69.2	32.5	14.8	86.2	38	0.508	0.401–0.615
	DP	7.7	93.5	16.7	85.7	81.9	0.506	0.398–0.613
Code 20 vs. Code 12 (E distinct visual change)	CS	100	38.4	18.2	100	45.8	0.692	0.581–0.789
	DP	100	6.9	12.8	100	18.1	0.534	0.421–0.645

CS = Canary System, DP = DIAGNOdent pen, +PV = positive predictive value, −PV = negative predictive value

Table 3: Sensitivity, specificity, predictive values, diagnostic accuracy, area under the receiver operating characteristic curve (AUC), and 95% confidence interval (95% CI) of the AUC for caries detection by Canary System and DIAGNOdent pen after 6 months

Diagnosis	Modality	Sensitivity %	Specificity %	+PV %	−PV %	Diagnostic accuracy %	AUC	95% Confidence interval
Code 20 vs. all other codes (any change in E)	CS	60	42.9	23.1	78.9	46.7	0.514	0.407–0.621
	DP	95	15.7	24.4	91.7	33.4	0.554	0.445–0.658
Code 20 vs. Code 12 (E distinct visual change)	CS	50	57.1	14.3	88.9	56.2	0.536	0.421–0.648
	DP	90	15.7	13.2	91.7	25	0.529	0.414–0.641
Code 20 vs. Code 13 (localized E breakdown)	CS	80	42.9	9.1	96.8	45.4	0.614	0.495–0.724
	DP	100	15.7	7.8	100	21.3	0.579	0.459–0.692

CS = Canary System, DP = DIAGNOdent pen, +PV = positive predictive value, −PV = negative predictive value

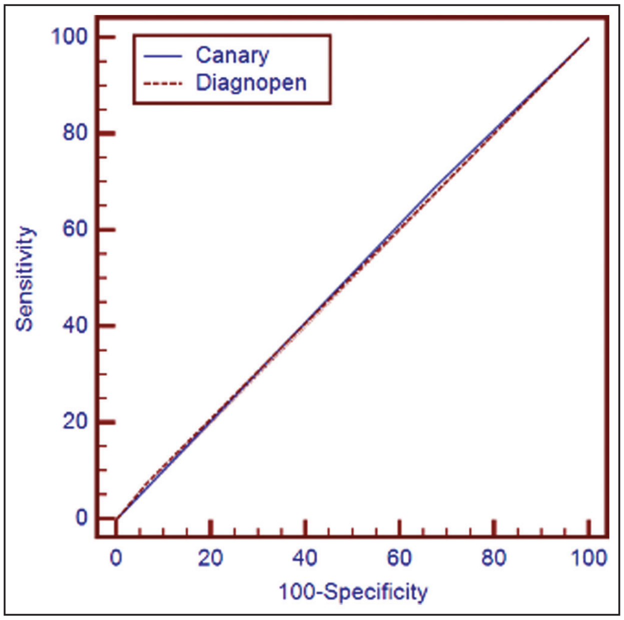

Figure 1: Receiver operating characteristic curves of the two modalities for caries detection (Code 20 vs. all other codes) after 3 months

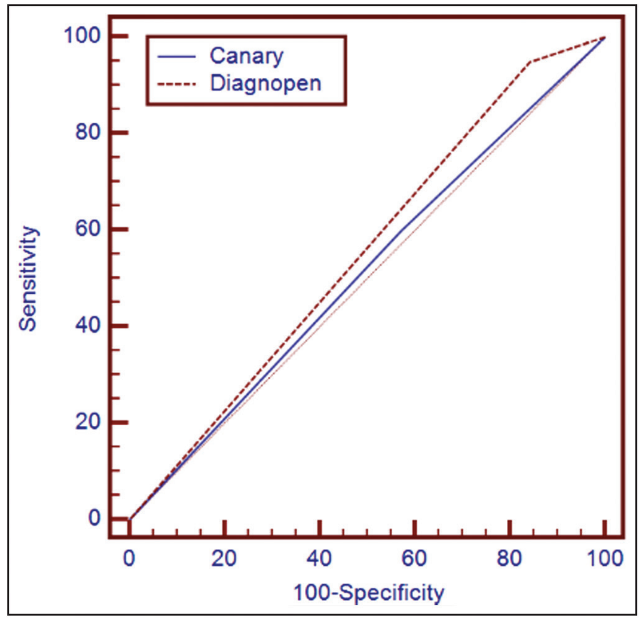

Figure 3: Receiver operating characteristic curves of the two modalities for caries detection (Code 20 vs. all other codes) after 6 months

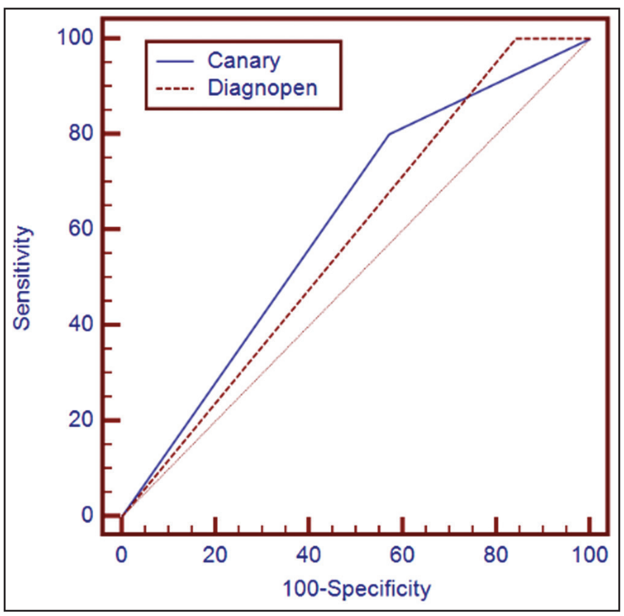

Figure 4: Receiver operating characteristic curves of the two modalities for caries detection (Code 20 vs. Code 13) after 6 months

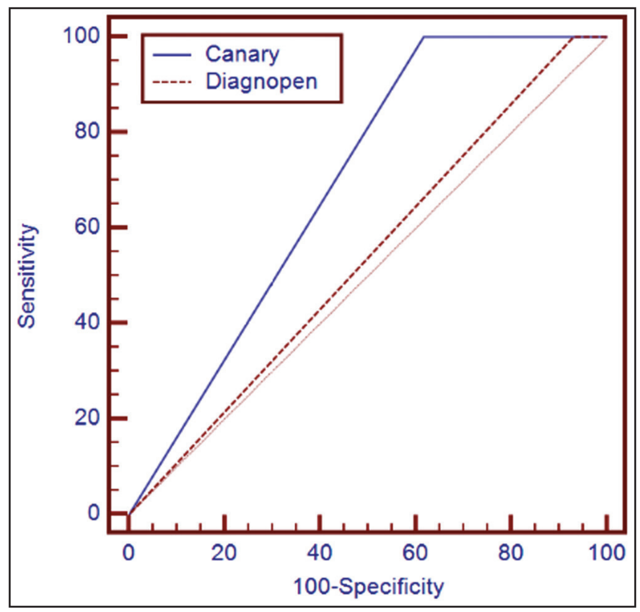

Figure 2: Receiver operating characteristic curves of the two modalities for caries detection (Code 20 vs. Code 12) after 3 months

status of the subject. The ICDAS is a visual system that describes severity of caries in six stages and has been proven to provide an outstanding performance in the diagnosis of occlusal caries in both permanent and primary teeth. The ICDAS was used for the diagnosis of caries as baseline record for case selection. Teeth selection pre-sealant application was limited to include enamel lesions with ICDAS score of 1–3. These scores were selected for two reasons: first, to exclude healthy enamel with score 0 that requires no intervention, and second, to avoid any possibility of dentin involvement, which may lead to overestimation in sensitivity results. This is particularly important, especially when ROC analysis is to be performed with each system.

As the aim of this study was to compare the performance of CS and DP in monitoring caries progression after sealant application, the reference code (20) was used against all other codes, as such, categorizing data into two: sound (20) and diseased (11, 12, and 13), to facilitate comparison. The histological threshold used in other studies to validate the ordinal assessment methods such as ICDAS codes was not implemented in our study as it reduces the dynamic and continuous nature of lesion progression. Monitoring enamel changes as a result of sealant treatment may require description of the enamel status beneath the sealant (two-digit ICDAS).

The descriptive analysis of caries detection measurements at 3- and 6-month intervals revealed differences in the ratio of enamel affected by caries and sound enamel among the diagnostic methods. The decrease in the number of Code 20 over time in the ICDAS visual diagnostic method could be related to increased number of teeth with partial loss that allow more visualization of the affected enamel surface. However, the significant increase in the number of sound enamel over time in the two quantitative diagnostic methods could be attributed to the mode of action of such devices that detect early changes in enamel underneath the existing sealant. The significant decrease in caries progression between baseline and 3 months as detected by CS could be related to the constant cycle of the demineralization/remineralization processes. Remineralization can occur as a natural repair process in the presence of fluoride ions available in the sealant. Fluoride has maximum burst after application, thus it positively impacts remineralization process. However, the amount of minerals becomes insignificant later on, as the fluoride reduces over time, thereby slowing down the process of remineralization. Bacterial by-products may not be instantly affected by the sealant application. With time, the number of bacteria and its by-products may decrease. This could be the reason for the significant decrease in the caries progression as recorded by the DP between 3 and 6 months.

Sensitivity is a measure of the method's ability to correctly identify all surfaces damaged by caries (true positives), and specificity is a measure of the method's ability to correctly identify all sound surfaces (true negatives). ROC curve between sensitivity and specificity was used to evaluate the performance of the two diagnostic methods. The ideal diagnostic test would correctly identify subjects with and without the disease with 100% accuracy. There was variability in sensitivity and specificity results between the two diagnostic modalities by time. This could be attributed to the status of the sealant whether it is fully or partially retained, which may mask the changes in enamel, giving false-positive or false-negative readings. At 6-month examination, CS showed better specificity (42%) and diagnostic accuracy but less sensitivity than DP (15.7%). In accordance to our results, Gostanian *et al.*[32] speculated that opaque sealant materials have deleterious effects on DP readings. Moreover, previous studies confirmed that post-sealant readings using DP were considered unpredictable and inaccurate due to the commonly added opacifying agents on the intrinsic fluorescence of sealants.[2,32] Interestingly, Diniz *et al.*[33] and Hastar *et al.*[34] had found that DP readings actually decreased after sealing with opaque sealants. The sensitivity value of DP obtained in this study was 95%, which was 15% higher than that obtained in a study by Verdonschot and van der Veen,[35] 38% higher than that of Barbería *et al.*,[36] 79% higher than that of Angnes *et al.*,[37] and 90% higher than obtained in a study by Sheehy *et al.*,[38] whereas its accuracy was 33.4%. This may be related to the diameter of the DP tip that does not facilitate adequate examination of teeth with deep, narrow pits, and fissures. In addition, the intensity of the light can affect the reproducibility of the DP, so all the examinations must be carried out with the same lighting.[28]

Despite the variability in sensitivity and specificity of the two diagnostic methods as a factor of time, our results revealed comparable level of diagnostic accuracy. Both devices were able to quantify enamel changes under fissure sealants caused by caries (the area under the curve is near 1). Unlike the visual method, CS measures the amount of minerals, whereas the DP measures the fluorescence of the bacterial by-products. This makes these methods more sensitive to minor changes in enamel surface.

One of the limitations of this study was the inability to standardize the sealant thickness due to variation in the anatomy of the fissures from patient to patient. Thus, the concentration of bioactive compounds might vary, which might account for the insignificant changes of quantitative readings after sealant application. It was possible to run statistical analysis after sealant application and compare the two modalities with Code 20 against all other codes but detailed comparison was not possible due to the low number of cases. Monitoring caries progression beneath fissure sealants needs larger sample size to allow comparison of specific enamel characteristic as a result of demineralization against healthy enamel (Code 20). Further research on large sample size will be required to assess the novel technologies described in this study and their use to monitor and treat the lesion.

Conclusion

Validity and diagnostic accuracy of the CS and DP are acceptable and can be useful in evaluation and monitoring the changes in enamel due to lesion progression under fissure sealants. However, sensitivity and specificity of these devices may be influenced by the sealant type, thickness, retention, and the differences in the lesion characteristics over time.

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Nil.

Conflicts of interest

There are no conflicts of interest.

Author contributions

The four authors involved in this study contributed in: Dr. Nada Jaafar: study conception, clinical work, data collection, data acquisition and writing. Prof Hala Ragab: data interpretation, and manuscript editing. Prof. Ahmed Abdel Rahman: data statistical analysis. Prof. Essam Osman: final revision of the manuscript. The four authors have approved this final version of the manuscript for publication.

Ethical policy and institutional review board statement

The study was carried out after the approval of the ethical and research committee of Beirut Arab University Institutional Review Board (code: 49 2018H-0058-D-P-0258).

Patient declaration of consent

The objectives, risks and benefits of the study were explained to the parents/guardians and a signed informed consent form was obtained prior to clinical intervention.

Data availability statement

The entire data has been submitted to the journal in the form of tables and graphs.

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