Performance of Fluorescence-based Systems in Early Caries Detection: A Public Health Issue.

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ORIGINAL RESEARCH

Performance of Fluorescence-based Systems in Early Caries Detection: A Public Health Issue

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Abstract

Aim: Modern clinical caries management involves early stage caries diagnosis and should fit with dental health policy. The objective of this study was to achieve early caries detection in enamel and dentine with a laser-based system (DIAGNOdent™ pen) first and secondary with a new fluorescence intra-oral camera (Soprolife®). A visual inspection with a loupe was used as control.

Materials and methods: Following the consolidated standards of reporting trials recommendations, 628 occlusal fissures were included for analysis.

Results: The sensitivity and specificity of both devices varied depending on the cut-off threshold of the caries score, and the ROC curve showed higher values for the Soprolife® than for DIAGNOdent™ pen. The values of the area under the curve decreased from 0.81 (Soprolife® in daylight) to 0.79 (Soprolife® in fluorescent mode) and 0.67 for DIAGNOdent™ pen. DIAGNOdent™ pen reproducibility (intra and inter-investigator) showed a wide dispersion, with many values scattered beyond the confidence limits (±2 SD), and the weighted kappa coefficient, which was quite low (0.58), confirmed this tendency.

Conclusion: Caries prevalence in terms of public health policy is of interest and caries detection increased significantly when using an fluorescence-based intra-oral camera.

Clinical significance: The clinical significance of these findings is that fluorescence could help improve caries diagnosis, reduce clinical misinterpretations, and finally benefit the patients.

Keywords: Advanced diagnostic methods, Cohort study, Dental caries, Dental health, Epidemiology, Prevention.

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Introduction

In its early stage, caries detection and diagnosis still remain difficult, and a wide variety of caries detector tools have been previously tested either *in vivo* (clinical) or *in vitro*.[1] However, diagnostic tools are limited in use firstly owing to their sensitivity, specificity, and usefulness and secondly by the cut-off threshold of the different classifications. Visual inspection for occlusal caries detection still exhibits high specificity values, with low sensitivity and good reproducibility. Even though the combination of visual inspection with light, rounded probe and a dental mirror has been accepted as a standard examination procedure in occlusal caries diagnosis,[2] researchers have shown that forceful sharp probing may result in damage to fissures, and microorganisms may penetrate into the deeper parts of underlying tooth material. Therefore, alternative diagnostic methods have been developed to increase the sensitivity of early caries detection and fit with preventive dental health policy as caries prevalence remained a crucial point. This point is very important in developed countries with the increase of acid and sugary beverages coupled with dental erosion[3,4] and in developing countries with the increase of sugary food intakes.[5] One such method is the laser-based system DIAGNOdent™ pen, which has proven reproducibility *in vitro* and shows a moderate-to-good clinical discrimination performance.[6–9] A new device called Soprolife® (an intra-oral camera based on dental tissues autofluorescence) was recently proposed[10–12] with promising results in pediatric caries diagnosis compared to the DIAGNOdent™ pen.[13] The objective of this study was to achieve in permanent teeth, early caries detection in enamel and dentine with these 2 fluorescence-based methods (DIAGNOdent™ pen and Soprolife®) using visual inspection with a loupe as control. Positive hypothesis was that this new device achieved to improve early caries diagnosis and could be considered as a new complementary fluorescence visual aided as well as the DIAGNOdent™ pen.

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Conflict of interest: None

Materials and Methods

Ethics

The Institutional Review Board of Marseille Hospital approved this study (Comité de Protection des Personnes Sud-Méditerranée I Study No. 10 51.28/10/2010). The ethical approval number of the

Agence Nationale de Sécurité des Médicaments et des Produits de Santé (ANSM) is 2010-A00716-33, corresponding to the Eudract number provided by the European Medical Agency (EMA). Participation was voluntary, and all the participants provided informed written consent before being recruited. Strobe guidelines for cross-sectional studies were followed (Table 1).

Fluorescence-based Devices

DIAGNOdent™ pen (KaVo, Bibberach, Germany) claims to reveal fluorescence signals caused by porphyrins and derived molecules coming from bacteria present in carious tissues. Laser light with a wavelength of 655 nm is directed onto the occlusal or proximal surface of a molar tooth using a fiber-optic probe. The fluorescent light is reflected back to the device through specific fibers in the probe, and the intensity of the fluorescent light is measured and converted into numerical form displayed on a monitor.[14,15] The assessment scoring was related to the intensity of the fluorescent light, with this measurement converted into a value ranging from 0 to 99. Calibration of the laser fiber tip was set, thanks to a ceramic bloc (Kavo instructions).

The Soprolife® (Acteon, La Ciotat, France) intra-oral camera has two types of LEDs that can illuminate tooth surfaces in the visible domain, either in the white-light region or in a narrow band (450 nm wavelength with a bandwidth of 20 nm, centered at ±10 nm around the excitation wavelength). This provides an anatomical image superimposed on autofluorescence. This device is equipped with a 0.64 cm charge-coupled device (CCD). The camera is operated in three modes: daylight mode, fluorescence diagnostic mode (the one used during this experimentation), and fluorescence treatment mode. In the daylight mode, four white-light LEDs generate daylight. For the latter two modes, the light is provided by four blue LEDs (450 nm wavelength, 100 mW/cm^2 , focus >35 fold). Soprolife® claims to reveal AGEs (Advanced Glycation End products) produced from the Maillard reaction.[16,17] The Soprolife® scoring, as it was a modified visual inspection, follows the ICDAS score.

Visual Inspection

A loupe with 2.5× magnification (Surgitel, Ann Arbor, USA) was used to perform the visual inspection (clinical method).

Table 1: Descriptive characteristics of study participants

Characteristic gender	*N (%)*
Male	110 (45.8)
Female	130 (54.2)
Average age (years):	25
Measured dental occusal fissures:	628
Center 1	147 (23.4)
Center 2	136 (21.6)
Center 3	120 (19.1)
Center 4	125 (19.9)
Center 5	100 (15.9)
Upper jaw	
First molar	150 (23.8)
Second molar	164 (26.1)
Lower Jaw	
First molar	167 (26.5)
Second molar	147 (23.4)

ICDAS Classification

The ICDAS index has been described for coronal and root surface caries, and for caries assessment associated with restorations and sealants (CARS).[17] Its codes for coronal caries range from 0 to 6, indicating the severity of the lesion. These caries codes range from sound surfaces (code 0), through primary caries lesions in enamel (codes 1–3), to primary caries lesions in dentine (codes 4–6).

Participants

Inclusion Criteria

Participants (>18 year-old) were chosen with apparent suspicious occlusal fissures (based on visual inspection); absence of occlusal restorations and fissure sealants (code 0, decision number 1, ICDAS), except for the third permanent molars; absence of an advanced degree of fluorosis; and absence of frank occlusal cavitation and large caries lesions on smooth and approximal surfaces. Subjects had to be healthy and willing to sign the "Authorization for Release of Personal Health Information and Use of Personally Unidentified Study Data for Research" form. There were no gender restrictions. Only one groove per tooth was measured and the tooth number was shared between the investigators in order to find the measured occlusal fissures.

Exclusion Criteria

Patients with enamel anomalies, intrinsic or extrinsic staining, amalgam filling, gold or steel crowns in adjacent teeth, or cavitated lesions (ICDAS scores 5 or 6) were excluded. No compensation was provided to either the study participants or investigators.

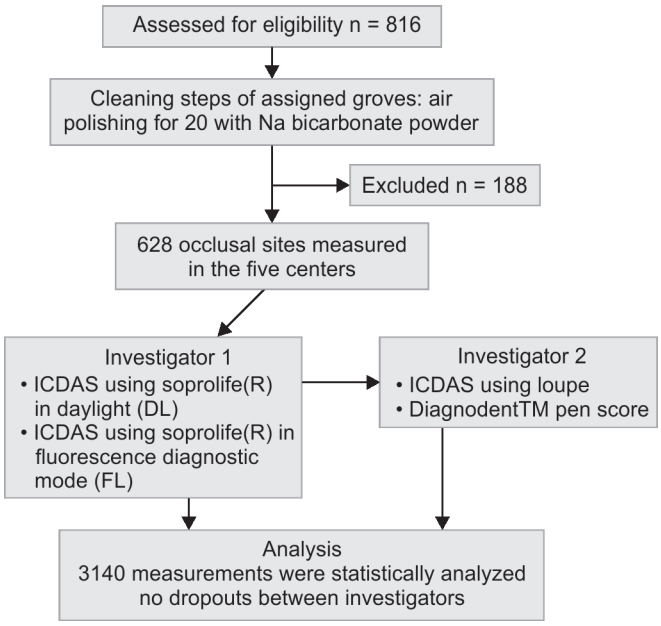
Study Design

The visual inspection with loupe and examination with the Soprolife® and the DIAGNOdent™ pen were performed by two investigators, in a specific order as per the flow diagram (Flowchart 1).

Interventions

Voluntary participants were recruited from the departments of Preventive and Restorative Dentistry of University of Marseille,

Flowchart 1: Flow diagram of participants in the study population



Rennes, Lyon, Montpellier and Paris V dental schools. The assigned occlusal surfaces were cleaned with an air polishing device (20 seconds) filled with Na-bicarbonate powder (Powder classic, Air and Go, Acteon, France) and rinsed to remove the powder and debris remnants from the fissure with the 3-in-1 syringe for 10 seconds. The cleaning steps were performed either by investigator 1 or 2. The 2 investigators worked separately and independently to avoid any influence of the first detection on the second detection method used.

Investigator 1: Soprolife® daylight and fluorescence mode assessments

The relevant tooth, after drying, was illuminated with the intra-oral camera and the images recorded by the Soproimaging® software were observed on a large screen. The daylight mode was used first and the tooth scored. The same procedure was then realized with the fluorescence diagnosis mode. Two push buttons allowed switching between the "in daylight" mode (daylight mode) and the "in fluorescence" mode (blue fluorescence mode). The images were automatically recorded and analyzed as above. The observation principle and calibration of Soprolife® requires observation of consistent variation in dentine fluorescence and brightness in relation to a healthy area.[10,18]

Investigator 2: ICDAS visual inspection and DIAGNOdent™ pen.

Visual examination was performed using the ICDAS score, directly viewing the teeth under illumination with magnification using a 2.5 × loupe and the same occlusal fissures were inspected with DIAGNOdent™ pen through the crystal probe.

Sample Size and Power Calculation

The sample size for an expected difference in sensitivity of 0.2 between the tested devices, with a risk of 0.05, a power of 80% and taking into account a cluster effect between centers, was around 600 occlusal fissures, which meant around 120 teeth per investing health center. The investigation period was about one year. Neither random assignment nor blinding was necessary for this study. ICDAS was used as reference to compare results obtained with DIAGNOdent™ pen and Soprolife® in day light and fluorescent modes.

Outcomes and Calibration Steps

Investigators were calibrated by means of a series of training both devices (Soprolife® and DIAGNOdent™ pen), followed by discussion to consensus of any uncertainties. The intra- and inter-investigators reliability was assessed in addition to the reproducibility of the device itself by conducting repeated measurements. The investigators from all the 5 participating dental centers (2 investigators per dental center) were invited for a calibration day. The details of each score for visual inspection were discussed, using dental and caries images from score 0 to 6 (personal images and information from website https://www.icdas.org/).

The intra-investigators agreement was assessed by a weighted Cohen's κ coefficient for the Soprolife® in day light mode and in fluorescent mode. Inter and intra-device reliability were based on a second reading of the first 40 groove measurements in each dental center 1 week after the first measurement.

Statistical Analysis

Statistical analysis were obtained using Stata V13 software.

Results

The demographic and clinical characteristics of the study are summarized in Table 1.

The intra-class correlation coefficient for intra-investigator reproducibility of DIAGNOdent™ pen was equal to 0.79 (Fig. 1A).

No intra-class correlation for intra-investigator (ICC) values were determined for Soprolife® as the device does not use numeric values but relies on visual inspection. Intra and inter-investigator kappa values for DIAGNOdent™ pen (respectively 0.58 and 0.60), Soprolife® in daylight mode (respectively 0.89 and 0.93) and in fluorescence mode (respectively 0.89 and 0.91), and visual inspection (respectively 0.52 and 0.60) are displayed in Table 2A.

Caries distribution was more frequent for ICDAS scores 0, 1 and 3 than other scores and caries prevalence was higher with Soprolife® both in daylight and fluorescence modes. The results differed depending on the cut-off threshold used for the absence of caries. Caries prevalence with DIAGNOdent™ pen was low (54.1) when compared to Soprolife® in daylight mode and in fluorescence mode (72.7; 78.5 respectively) and visual inspection (67.9).

The ranking changes when the cut-off interval for non-carious readings increases from 0 to 1 (ICDAS visual inspection: 16.5; Soprolife® in daylight mode: 26.8; Soprolife® in fluorescence mode: 30.4; DIAGNOdent™ pen: 30.1).

The receiver operating characteristic (ROC) curve showed higher values for the Soprolife® in daylight mode and in fluorescence mode, and for visual inspection than for DIAGNOdent™ pen (Fig. 1B).

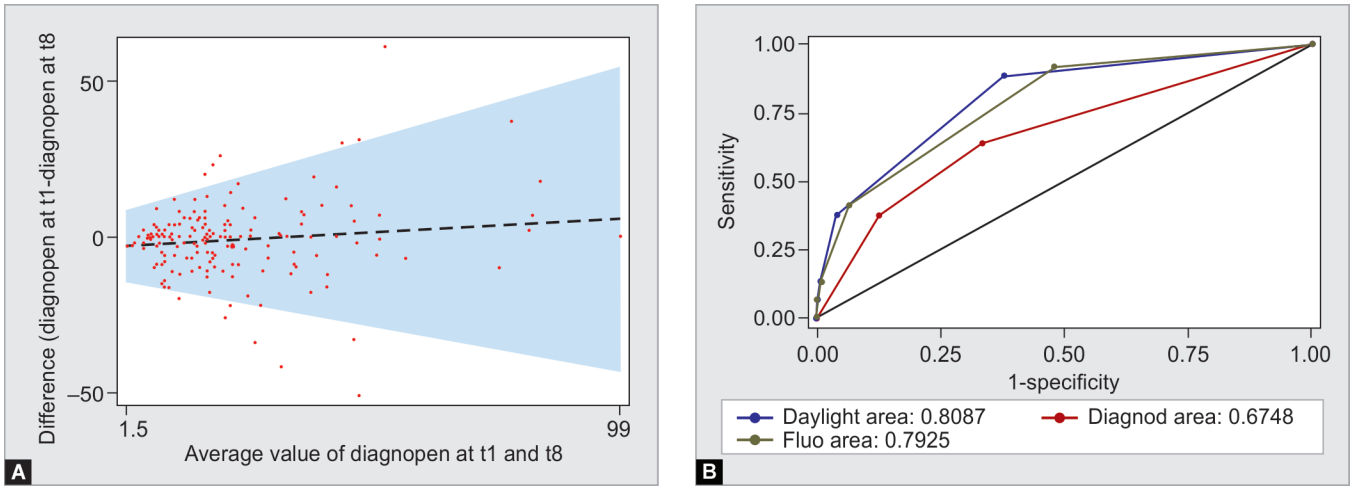
The area under the receiver operating characteristics (AUROC) decreased respectively from 0.81 (Soprolife® in daylight mode) to 0.79 (Soprolife® fluorescence mode); and 0.67 for DIAGNOdent™ pen. Soprolife® in daylight mode and fluorescence mode looked similar. There was a significant difference between AUROC curves of Soprolife® in daylight mode (0.81) and DIAGNOdent™ pen (0.67): $p = 0.0001$, and between Soprolife® in fluorescence mode (0.79) and DIAGNOdent™ pen as well: $p = 0.0001$. But there was no significant difference between AUROC curves of Soprolife® in daylight mode and Soprolife® in fluorescence mode: $p = 0.10$ (Table 2B).

When the cut-off value for the presence of caries was set at ICDAS score 2 and over, the sensitivity values were equal for Soprolife® in daylight mode and Soprolife® in fluorescence mode (0.86), and higher for DIAGNOdent™ pen (0.92). The sensitivity of Soprolife® in daylight mode and in fluorescence mode was not significantly different than that of DIAGNOdent™ pen ($p = 0.18$). DIAGNOdent™ pen exhibited the lowest specificity value (0.54), significantly lower than Soprolife® in daylight mode (0.85) and in fluorescence mode (0.81). Under this criterion, the sensitivity of DIAGNOdent™ pen was significantly lower than that of Soprolife® in daylight mode ($p = 0.0001$) and Soprolife® in fluorescence mode ($p = 0.0001$). There was no difference between specificity of Soprolife® in daylight mode and Soprolife® in fluorescence mode ($p = 0.21$).

Figure 2 reveals the different views of the same distal groove of a second upper molar with loupe (Fig. 2A), camera in daylight and magnification (Fig. 2B) and camera in fluorescence mode and magnification (Fig. 2C). Details of the inner shape of the caries lesion were given, thanks to the fluorescence and magnification.

Statistical Analysis Details

Statistical analysis were obtained using Stata V13 software, with a confidence interval of 95%. Sensitivity, specificity, likelihood ratios for a positive and a negative test, Youden index, ROC curves, and



Figs 1A and B: (A) DIAGNOdent™ pen reproducibility by the graphical method of Bland and Altman between t1 day and t8 day examination; (B) Comparison of ROC curves with the visual method as gold standard

Table 2(A): Intra- and inter-investigator kappa values for DIAGNOdent™ pen, Soprolife® in daylight mode, in fluorescence mode, and ICDAS. Intra-class correlation for intra-investigator (ICC) reproducibility for DIAGNOdent™ pen

	Weighted κ		*ICC*	
	Inter	*Intra*	*Inter*	*Intra*
DIAGNOdent™ pen	0.58	0.60	0.69	0.73
Soprolife in daylight mode	0.89	0.93	–	–
Soprolife in fluorescence mode	0.89	0.91	–	–
Visual examination	0.52	0.60	–	–

Table 2(B): Sensitivity and specificity of the fluorescence-based systems, with ICDAS score >2 for the presence of caries

	Sensitivity (CD	*Specificity (CI)*	*Youden index*	*LR+*	*LR–*
Soprolife® in daylight mode	0.86 (0.83–0.90)	0.85 (0.81–0.89)	0.71	5.73	0.16
Soprolife® in fluorescence mode	0.86 (0.82–0.89)	0.81 (0.77–0.85)	0.67	4.49	0.18
DIAGNOdent™ pen	0.92 (0.89–0.95)	0.54 (0.48–0.59)	0.47	1.99	0.15

CI, confidence interval; LR+, likelihood ratio for a positive test; LR–, likelihood ratio for a negative test

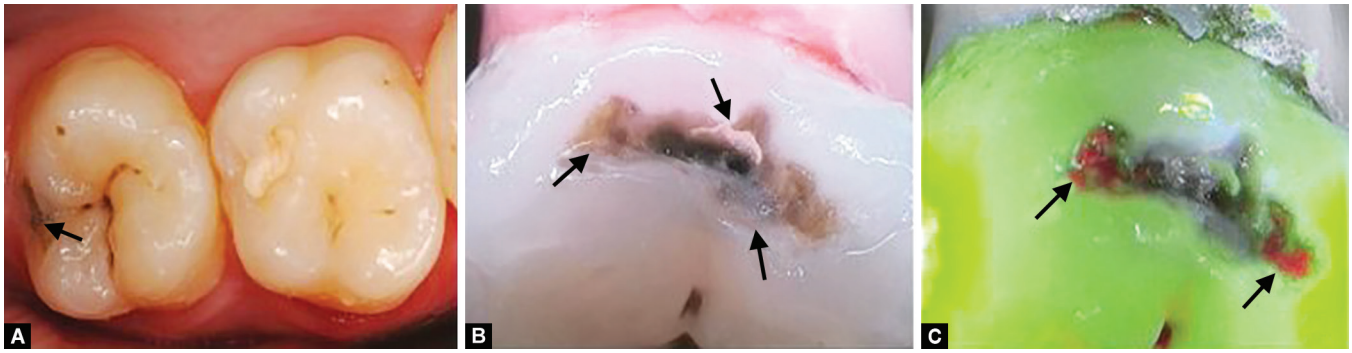
AUROC curves were analyzed. Two cut-off values were considered in the estimations of prevalence, sensitivity, and specificity for each device. In the first hypothesis, the absence of caries corresponded to score 0, and in the second case, to a score of ≥2 (dentine threshold). The Chi-square test was used to compare sensitivity and specificity between the devices, and a nonparametric test was used to compare their AUROC curves.[19] In order to avoid any bias, an observation protocol was fixed as described in the flow diagram (Flowchart 1), and caries prevalence was calculated for the Soprolife® in daylight mode, Soprolife® in fluorescence mode and DIAGNOdent™ pen groups.

Discussion

The objective of this clinical prospective study was to test two fluorescence-based devices in the early stages of caries diagnosis, by means of the sensitivity and specificity values.

628 occlusal fissures were measured during this study compared to studies with limited inclusion numbers of $n = 13$[2], $n = 40$, $n = 120$ in a multicenter study[7] and $n = 332$ in a study involving seven practitioners in Switzerland and Germany.[20]

The combination of magnification and fluorescence by the Soprolife® camera in fluorescence mode was already suggested to



Figs 2A to C: (A) Distal suspicious occlusal fissures on second upper molar (visual inspection) (black arrow); (B) The same picture with Soprolife® in daylight mode, illustrating the micro-cavitation and the tissue breakdown (black arrows); (C) The same picture with Soprolife® in fluorescence mode, illustrating the decay activity (red shadow) (black arrows)

enrich the visual examination by creating a much more detailed image.[21–23] To be able to compare our results with the visual inspection aided by the loupe, we strictly limited and ranked the visual observations according to ICDAS classification, which does not use fluorescence. The visual inspection with the intra-oral Soprolife® camera in daylight and fluorescence mode, as well as the use of the DIAGNOdent™ pen exhibited better sensitivity than the control visual inspection with the loupe.[24] Even if the control (visual inspection) is not absolutely perfect,[25,26] it reduced the bias in the comparison of both fluorescence devices. An *in vitro* study in pre-cavitated lesions, recommended to improve the diagnosis by combining ICDAS classification and DIAGNOdent™ pen.[16]

DIAGNOdent™ pen reproducibility (intra-and inter-investigator) showed a wide dispersion, with many values scattered beyond the confidence limits (±2 SD) (Fig. 1A) and the weighted kappa coefficient was quite low (0.58), confirming this tendency. This result was in contrast to the study of Attrill and Ashley, who found a weighted kappa coefficient of 0.70, albeit with a sample limited to only 53 teeth. The intra-class correlation coefficient showed higher values (0.69 and 0.73), which was in agreement with one study.[27] DIAGNOdent™ pen failed in reproducibility owing to the lack of magnification and pictures. Balances between false positives and clinical reality seem to impair the laser system. Mean DIAGNOdent™ pen values of the presence of caries also demonstrated this shortcoming. In clinical situations, the DIAGNOdent™ pen score seemed to overestimate the decay situation, with high standard deviation (values of more than 20). As such, the main drawback of the DIAGNOdent™ pen was the false positive signal frequency.[28] There are two likely reasons for this: the persistence of debris in the deepest side of the occlusal fissures despite the air polishing cleaning; and the size of the crystal probe. Repeated calibrations could be also a shortcoming. The sensitivity and specificity vary considerably depending on the experimental protocol of each study: 92% and 86% respectively.[29] Others authors observed a sensitivity of 92% and specificity of 82%, employing a cut-off point of 30.[30] In contrast, some studies still revealed a good sensitivity value of 93%, but low specificity values of around 20–63%.[31] Our results were in agreement with all the previously obtained sensitivity values, but closer to the latter experiments with a specificity value of 53.4). In a Rechmann's study,[22] when sensitivity and specificity were calculated, the grouping of no lesion/healthy (ICDAS 0) and precavitated lesions (ICDAS 1, 2, 3) together appeared to be the best cut-off point for each detection method to determine the sensitivity and specificity of each method. Selecting this cut-off point, DIAGNOdent™ pen achieved a sensitivity of 87% with a specificity of 66%. At the same cut-off point, Soprolife® in daylight mode exhibited with 93% a sensitivity and a specificity (63%).

In a very recent study,[13] the results are a little different from the Rechmann's study.[22] In fact, for device comparison at the cut-off value of non-cavitated and cavitated caries lesions, the sensitivity (88.50%) and AUROC (0.84) of the Soprolife® were significantly higher than the equivalent values of DIAGNOdent™ pen (sensitivity 75.32%, AUROC 0.80). For the cut-off value of cavitated caries lesions, higher specificity (89.94%) and AUROC (0.90) were found with the Soprolife® than with the DIAGNOdent™ pen (specificity 76.28%, AUROC 0.86).

Of interest, to investigate a potential sensitivity and specificity gain owing to the mutual contribution of magnification and fluorescence variation compared to visual inspection (Fig. 2). However, high magnification should not entail excessive operative procedure.[1,20] The result of a comparison between the unaided visual examination and operating microscope was that the use of an intraoral camera lead the decisions to more or fewer operative interventions of the occlusal surfaces on posterior teeth. The kappa values for unaided visual examination, intra-oral camera, and operating microscope were found to be 0.341 ($p < 0.001$), 0.471 ($p < 0.001$) and 0.345 ($p < 0.001$), respectively. Although some recent studies claim that Soprolife® and DIAGNOdent™ pen do not contribute to better detection of early caries lesions,[32] some studies also confirmed the necessity of magnification in odontology and more specifically in cariology.[33] Moreover, another study showed that visual performance decreased with increasing age, and that magnification aids can compensate for visual deficiencies.[34]

Huth et al., showed a variation of AUROC values from 0.92 to 0.72 as a result of the increase in caries scores (D0–D4) for the DIAGNOdent™ pen.[7] A meta-analysis of fluorescence-based methods comparing another fluorescence camera (Vista Proof, Dürr Dental, Germany) and DIAGNOdent™ pen confirmed that for these devices there was a trend of better performance in detecting more advanced caries lesions.[35] Clinical the cut-off score of ICDAS seemed to be of influence in the calculation too.[7,36]

Caries prevalence in terms of public health policy is of interest[1] and caries detection increased significantly when using the fluorescence-based intra-oral camera. The use of such a camera would improve early diagnostic and prevention of caries, resulting in an increase in remineralization procedures and prophylactic treatments. Evidently, these new fluorescence-based systems with a high enlargement power allow the observation of very thin occlusal fissures. However, untrained dentists may consider these occlusal fissures as targets for operative treatments. Sensitivity and specificity do not have immediate applicability for clinical diagnostics. Rather, a dentist needs to select a diagnostic threshold. The foundations of good diagnostic practice require the establishment of a close link between the management options and the relevant caries diagnostic categories.

This concept is patient-centered and the aim is to achieve a treatment solution that is likely to give the best long-term health outcome. The diagnostic accuracy parameters, sensitivity, and specificity, are not diagnostic test constants, but vary according to the disease spectrum.

Conclusion and Clinical Significance

The clinical relevance of the findings from this study, with its limitations, owing to magnification and fluorescence, were an increased early caries prevalence, an improvement in early caries detection in terms of sensitivity and specificity, and a help in confirming clinical diagnoses and decisions, thanks to secondary pictures analysis possibilities. These meaningful results could be certainly improved upon, as there is still great variation in the diagnostic decisions between individual clinicians, and the development of valid detection aids may decrease this variation and greatly improve clinical decision-making.[36]

It is essential to complete an accurate diagnosis in clinical practice with the patient's individual caries risk and a comprehensive caries management system.[37,38] This study with its limitations confirmed the positive hypothesis approving that this new device, the Soprolife® camera, could be added as a new complementary visual aided for early caries diagnosis, and be integrated as new tool for dental health survey.

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