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ORIGINAL ARTICLE

Diagnostic validity of ICDAS and DIAGNOdent combined: an in vitro study in pre-cavitated lesions

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Abstract In a continuous process such as caries, it is important to possess criteria or instruments that allow the lesions to be diagnosed at early stages so that preventive or interceptive treatments can be applied before cavitation takes place. The present study seeks to assess the diagnostic efficacy of the International Caries Detection and Assessment System (ICDAS II) criteria and the DIAGNOdent laser fluorescence (LF) pen in occlusal caries lesions, using histological sections as the gold standard. Sixty-four permanent teeth were examined by two researchers who previously performed and calibrated both the ICDAS II criteria and the use of DIAGNOdent pen. The teeth were then cut into sections and observed under an optical microscope. The sensitivity values were 0.82 (ICDAS II) and 0.85 (LF). The specificity values were 1.00 (ICDAS II) and 0.53 (LF). The intraexaminer reproducibility was 0.892 for ICDAS II and 0.912 for the DIAGNOdent, so it was high for both diagnostic methods. However, the DIAGNOdent pen showed greater sensitivity and the ICDAS criteria more specificity. It was concluded that both methods are efficacious individually but combining the two is recommended to improve the diagnosis.

Keywords Caries detection · DIAGNOdent · International Caries Detection and Assessment System · Laser fluorescence · Occlusal caries

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Introduction

The nature of dental caries, a continuous process with different stages ranging from subclinical changes under the surface of the enamel to complete destruction of the tooth, leads to a reconsideration of the diagnostic criteria for assessing the presence or absence of this disease. Until now, the diagnostic threshold has been determined by the detection limits of traditional diagnostic methods. The low caries rates found in many countries nowadays has led researchers to seek more refined diagnostic instruments that will detect caries lesions before the stage at which they are already visible to the naked eye [1].

In a continuous process such as caries, different stages of the disease can be used to identify the presence of lesions. Caries prevalence estimates are very different depending on which threshold or stage of the disease is used to diagnose it. The "caries iceberg" [2] is a graphic representation of the range of diagnostic thresholds employed in clinical practice and epidemiology.

Visual inspection is a subjective method based on clinical experience and prior training. The International Caries Detection and Assessment System (ICDAS) is an evidence-based system for detecting and diagnosing caries that was developed in view of the need to introduce standardised systems to avoid differences in diagnosis, prognosis and clinical management of caries lesions among different practitioners [3, 4]. The ICDAS criteria assess the changes that have taken place on the tooth surface and, based on surface characteristics, the depth the carious lesions have reached [4]. This visual diagnosis method has shown itself to be safe, precise and reproducible for the detection of early lesions and their longitudinal follow-up [5, 6].

To improve the diagnosis of non-cavitated lesions, additional diagnostic methods have been developed. They include DIAGNOdent, which is based on the fluorescence emitted by

the porphyrins released in caries lesions by cariogenic bacteria when exposed to a 655-nm red light. The intensity of the fluorescence indicates the depth of the caries lesion. This intensity is measured on a scale of 0–99, where 99 is the maximum fluorescence [7–9].

Although white spot lesions can be detected with the DIAGNOdent, the very early lesions that do not contain bacterial fluorophores are not captured by this device. A number of in vivo and in vitro studies have demonstrated different applications of the DIAGNOdent system, such as measuring caries lesions adjacent to fixed orthodontic appliances and detecting recurrent caries, residual caries, caries under dental sealants and subgingival calculus. The devices have shown high intraexaminer reproducibility both in vitro and in vivo and can therefore be used for monitoring lesions [1].

The reduction in dental caries prevalence and severity in developed countries and the difficulty of diagnosing non-cavitated lesions have led to a need to complement visual diagnosis with new diagnostic methods. The objective of this study was to validate the diagnostic efficacy of ICDAS II as the visual diagnosis method of choice in incipient or micro-cavitated caries lesions with no exposed dentine, that of the DIAGNOdent Pen® system as an additional diagnostic method, and that of combining these two methods, so we could confirm that the combination of both is the best way to detect pre-cavitated lesions.

Materials and methods

Study design and sample preparation

One hundred molars and premolars extracted for orthodontic or periodontal reasons from adult patients aged between 18 and 55 years were selected for the present study. Healthy teeth and teeth with incipient caries lesions were included but teeth where the caries lesions were already cavitated and the dentine exposed were excluded. The teeth were kept in saline solution up to the moment they were examined.

Prior to examination, the calculus and residues were removed from the selected teeth, using a KAVO Sonic Flex Lux 2000 L instrument (KaVo, Biberach/Riss, Germany), and the teeth were numbered for identification purposes.

Following this preparation, the occlusal surfaces were photographed with the digital camera VistaCam IX ® (Dürr Dental, Bietigheim-Bissingen, Germany) and an assistant outlined the study area on the occlusal face in the photograph with a red circle. Sixty-five teeth (28 premolars and 37 molars) were then selected for the study and the remaining 35 (19 premolars and 16 molars) were used for calibration.

Calibration prior to examination

Using the 35 teeth selected for calibration, the examiner conducting the study (ST) was calibrated against an expert ICDAS II examiner (JE I-C, calibrated by the ICDAS organisation at a course held in Valencia in 2012) and obtained a high level of agreement (weighted kappa = 0.85).

ICDAS II examination

The same bluish-white spectrum lamp (KaVo Primus 1058, KaVo, Biberach/Riss, Germany) was used for visual examination of all the teeth, and the dental equipment's triple air syringe (KaVo, Biberach/Riss, Germany) was used to dry them.

Two examiners (ST, a dentistry student during her last year and JE I-C, a dentist with five years of experience using ICDAS II) inspected the 65 occlusal surfaces selected and recorded their caries codes according to the ICDAS II visual criteria. The examination was repeated a month later.

DIAGNOdent examination

After a training period following the instructions of the DIAGNOdent Pen® manufacturer (KaVo, Biberach/Riss, Germany), both examiners measured the selected surfaces of each tooth. The procedure was as follows: after drying the teeth with the triple air syringe, a healthy surface of each tooth was calibrated. Having established the 0 value (the natural fluorescence level of each tooth), the examiner slid the occlusal probe tip of the DIAGNOdent (KaVo DIAGNOdent SN: 12-2004608, KaVo, Biberach/Riss, Germany) over the area of the lesion and recorded the maximum value shown on the pen's screen.

The training consisted in exploring the 35 teeth not included in the study twice, with a month between explorations. Both examiners measured the selected surfaces of each tooth. Neither of them had previous experience using DIAGNOdent.

These values were initially grouped according to the classification of Lussi and Helwing: 0–13, sound dental tissues; 14–20, lesions detected in the outer half of the enamel; 21–29, deep lesions in the inner half of the enamel; and >30 caries in the dentine [10]. The lesions in the enamel (14–29) were subsequently combined into a single group.

Reproducibility

Both examinations were repeated 2 weeks later to assess the intraexaminer reproducibility.

Histological examination

After assessing the reproducibility of both systems, both the visual and the DIAGNOdent examination were validated

histologically, taking the histological analysis of the teeth as the gold standard. For this purpose, two experts examined the sample independently. The interexaminer agreement (weighted kappa) was 0.87. The selected teeth were cut through the central area of the lesion using a diamond disc (Komet, Lemgo, Germany) and polished with aluminium oxide discs (Sof-lex, 3M-ESPE, Neuss, Germany) for subsequent analysis under the microscope (Zeiss, Opmi-Pico, Oberkochen, Germany). One tooth was damaged during cutting, rendering it unusable for the study and leaving a final sample of 64 teeth. The following histological classification proposed by Lussi et al. [11] was employed:

- 0: no caries
- 1: caries limited to the outer half of the enamel
- 2: caries extending to the inner half of the enamel
- 3: caries in the outer half of the dentine
- 4: caries in the inner half of the dentine.

Codes 1 and 2 were subsequently combined as 'caries lesions in the enamel' and codes 3 and 4 as 'caries lesions in the dentine'.

Data processing and statistical analysis

The examiner stored the data from each form in a Microsoft® Excel® spreadsheet v. 2013 (Microsoft Corporation, Redmond, WA, USA).

The reproducibility of the ICDAS and DIAGNOdent results was measured by the weighted kappa statistic (a statistic that measures agreement between examiners for categorical items taking into account the agreement occurring randomly) and the intraclass correlation (a statistic that measures agreement between examiners for quantitative measures), respectively.

ROC curves (a graphical expression of sensitivity versus specifity) were used to analyse the histological validation of the ICDAS II and DIAGNOdent results, dividing the histological results into two groups: sound and caries (whether in the enamel or the dentine). The sensitivity (proportion of positives classified as such) and specificity (proportion of negatives classified as such) of the two systems were also analysed separately and in combination.

For the combined analysis of diagnostic validity, sensitivity and specificity, all ICDAS codes other than 0 and all DIAGNOdent values greater than 14 were classified as caries. Here too, the histological groups employed were sound and caries, without taking the depth of the lesions into account.

Finally, positive predictive value (proportion of positive results that are true positive) and negative predictive value (proportion of negative results that are true negative) were analysed for ICDAS II, DIAGNOdent and the combination.

The statistical analysis was performed with the SPSS v. 18.0 program (PASW Statistics for Windows, Version 18.0. Chicago, IL, USA).

Results

The intraexaminer reproducibility was 0.892 (95% CI 0.801–0.983) for the ICDAS criteria and 0.912 (95% CI 0.860–0.945) for DIAGNOdent. Consequently, the reproducibility was high in both cases, but higher for DIAGNOdent.

The agreement between the ICDAS codes, grouped by incipient lesions (ICDAS 1 and 2) or initial cavitation (ICDAS 3), and the corresponding histological depth can be seen in Table 1.

Table 2 shows the sensitivity, specificity, positive and negative predictive values and area under the curve (AUC) of the diagnoses obtained with the ICDAS system, with DIAGNOdent and with the combination of the two methods, compared with the histology results as the gold standard.

The AUC for ICDAS was higher than the one for DIAGNOdent in both cases (0.87 for examiner 1 and 0.91 for examiner 2, compared with 0.73 in both cases of the DIAGNOdent). The AUC for the combination was 0.83 for examiner 1 and 0.85 for examiner 2 (Fig. 1).

Discussion

The intraexaminer reproducibility for the ICDAS II criteria was 0.892, similar to that of other published studies (0.75–0.95) [8, 12–15] but slightly higher than those of others in the present case. This improvement could be due to unification of the criteria following the prior training and calibration, and also to the short time that had passed since the first examination.

The intraexaminer reproducibility for the DIAGNOdent system was 0.912, similar to that obtained by other authors (0.79–0.98) [9, 10, 12–14, 16].

These data therefore show that DIAGNOdent is a highly reproducible diagnostic method that can be used to monitor lesions over time.

Consequently, both systems are reproducible. The teeth must be clean for both examinations, as plaque or calculus could act as confounders, and for the ICDAS assessment, it is also essential to dry them [17]. In addition, the intensity of the light can affect the reproducibility of the DIAGNOdent pen, so all the examinations must be carried out with the same lighting.

Table 1 shows the relationship between the ICDAS codes and the histological depth reached by each. It will be seen that for ICDAS 0, one third of the teeth already presented an initial lesion in the enamel when observed under the microscope.

Table 1 Sample distribution

		Histology			Total
		Caries			
		Sound	Enamel	Dentine	
ICDAS II	Code 0	15 (62.5%)	9 (37.5%)	0 (0%)	24
	Codes 1 and 2	0 (0%)	17 (94.4%)	1 (5.6%)	18
	Code 3	0 (0%)	12 (54.5%)	10 (45.5%)	22
	Total	15	38	11	64
DIAGNOdent	Score <14	8 (53.3%)	5 (33.3%)	2 (13.3%)	15
	Score 14–29	5 (14.7%)	22 (64.7%)	7 (20.6%)	34
	Score >29	2 (13.3%)	11 (73.3%)	2 (13.3%)	15
	Total	15	38	11	64

This could be due to the limitations of the human eye in detecting initial lesions. It will also be seen that nearly 40% of the ICDAS 3 code classifications, corresponding to an enamel lesion, had extended into the dentine.

In regard to the sensitivity, results were similar to those of other published studies. The sensitivity of ICDAS was 0.82, while that of previously published studies ranged between 0.73 and 0.93 [9, 18, 19]. For DIAGNOdent, the sensitivity measured in this study was 0.85, compared to between 0.80 and 0.94 in other studies [8, 13, 18–21]. Both systems showed high sensitivity but that of DIAGNOdent was slightly higher [22].

The specificity obtained with ICDAS II was 1, as in previous studies (0.95–1) [9, 13, 16, 19]. However, that of DIAGNOdent (0.53) was slightly lower than in other studies (0.56–0.72) [13, 18, 20, 21].

In regard to positive predictive value, ICDAS II obtained a value of 1 while that of DIAGNOdent was lower, at 0.85. The negative predictive value was also higher for ICDAS (0.62 compared to 0.53 for DIAGNOdent).

A combination of the two systems increased the sensitivity, which was greater than that obtained by the two systems separately (0.89), but the specificity of the combination was lower than that of ICDAS II on its own (0.82, against 1 for the visual diagnosis alone). It may therefore be concluded that although combining the two systems can be useful for detecting lesions that are visually imperceptible, it can also lead to a rise in the number of false positives.

Consequently, DIAGNOdent is less specific but more sensitive than ICDAS. Combining the two systems could help to reach more reliable caries diagnoses.

To determine their diagnostic precision, the area under the curve (AUC) was calculated for comparisons between ICDAS, DIAGNOdent and their combination versus the histological results.

The AUC for ICDAS II were 0.87 (ST) and 0.91 (JE I-C), while other studies have reported 0.86 [19] and 0.965 [23]. The AUC for the DIAGNOdent pen was lower than that of ICDAS, at 0.73 for both examiners, but similar to the published range of 0.709–0.794 [12, 18, 19]. Finally, the combination of the two gave a slightly lower AUC (0.83 and 0.85) than for ICDAS alone. Consequently, the ICDAS criterion may be considered to offer greater diagnostic precision.

Regarding the possible limitations of the study, it was observed that although the DIAGNOdent system offered a low need for previous practice [17], an agreed examination technique would improve the interexaminer results.

It was found that the diameter of the DIAGNOdent's tip does not facilitate adequate examination of teeth with deep, narrow pits and fissures.

Initially it was suggested that the length of time between tooth extraction and examination and the medium in which the

Table 2 Sensitivity, specificity and positive and negative predictive values of ICDAS, DIAGNOdent and their combination, and the diagnostic agreement between all the three methods and the histology results

	Sensitivity	Specificity	Positive predictive value	Negative predictive value	AUC	
					Examiner 1	Examiner 2
ICDAS	0.82 (0.67–0.91)	1 (0.78–1)	1 (0.91–1)	0.62 (0.40–0.81)	0.87 (0.78–0.95)	0.91 (0.81–0.97)
DIAGNOdent	0.85 (0.72–0.94)	0.53 (0.27–0.79)	0.85 (0.72–0.94)	0.53 (0.27–0.79)	0.73 (0.60–0.87)	0.73 (0.61–0.84)
Combined	0.89 (0.78–0.97)	0.80 (0.52–0.96)	0.94 (0.82–0.99)	0.71 (0.44–0.90)	0.83 (0.70–0.96)	0.85 (0.72–0.98)

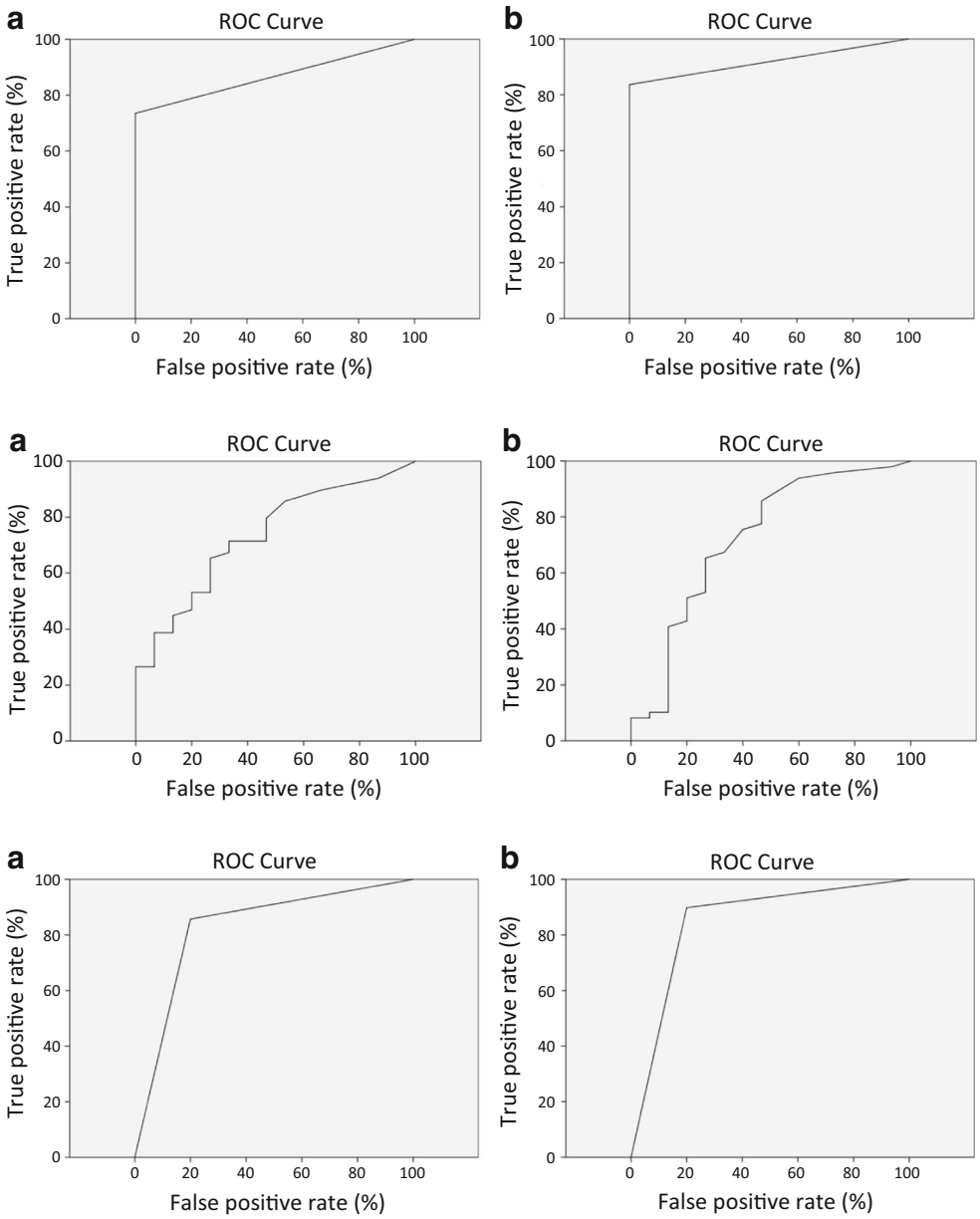

Fig. 1 ROC curves for ICDAS II (*1A* and *1B*, for examiner 1 (ST) and for examiner 2 (JE I-C), respectively), DIAGNOdent (*2A* and *2B*) and the combination of both (*3A* and *3B*)

teeth were kept in the interval could constitute possible limitations as they might affect porphyrin degradation, altering the emission of fluorescence and consequently the DIAGNOdent values, as suggested by some articles [24]. However, some studies have observed that porphyrins are very stable molecules that barely undergo any degradation, as only temperatures of 195–200 °C can denature them [25].

From the foregoing it was concluded that both methods are efficacious independently, particularly the ICDAS II visual criterion, and the combination of the two could be of possible assistance in improving the detection of incipient lesions which are not identified by the naked eye, and a final diagnosis on the measurements obtained with the DIAGNOdent alone cannot be recommended.

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Compliance with ethical standards The study was approved by the University of Valencia's Ethics Committee (procedure number H1418991960530). Every patient signed an informed consent in order to include their teeth in the study.

Conflict of interest The authors declare that they have no conflict of interest. Any funding source was received for the study.

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