

Authors:

Iranzo-Cortés, José Enrique¹

Almarche-Tarazona, María²

Montiel-Company, José María³

Almerich-Silla, José Manuel⁴

Title:

Diagnostic validity of ICDAS II, VistaProof and a combination of these two methods. An in-vitro study in pre-cavitated lesions.

Author affiliations and addresses:

1. DDS. PhD Student. Assistant Lecturer. Stomatology Department, University of Valencia, Spain.
2. DDS. Stomatology Department, University of Valencia, Spain.
3. MD. DDS. PhD. Assistant Lecturer. Stomatology Department, University of Valencia, Spain.
4. MD. DDS. PhD. Tenured Lecturer. Stomatology Department, University of Valencia, Spain.

Corresponding author: José Enrique Iranzo Cortés

Departamento de Estomatología, Facultad de Medicina y Odontología, Universidad de Valencia, C/ Gascó Oliag núm. 1, 46010 Valencia, Spain

E-mail: j.enrique.iranzo@uv.es

Telephone number: (+34) 963864873

Fax number: (+34) 96 398 37 81

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ABSTRACT

Purpose: In view of the present fall in advanced cavitation lesion prevalence, diagnostic methods have been developed to assist in assessing and measuring pre-cavitation lesions. The purpose of this study was to assess the VistaProof fluorescence-based system in vitro and compare the results with those of visual examination using the ICDAS II criteria.

Methods: 100 permanent teeth were collected and 65 were chosen at random for this study. Two separate examiners each examined them twice, 3 weeks apart, assessing them in accordance with ICDAS II. They were subsequently examined with the VistaProof system and the images were stored in the computer program. After obtaining all these data, the teeth were prepared for histological examination and the extent of the lesion was measured.

Results: The sensitivity with VistaProof was 0.705 for examiner 1 and 0.818 for examiner 2. With ICDAS II it was 0.796 and 0.864 respectively. The specificity was 0.810 and 0.619 respectively for VistaProof and 0.810 and 0.952 for ICDAS II. The agreement with the histology results was 0.757 and 0.719 respectively for VistaProof and 0.802 and 0.908 for ICDAS II. The intra-examiner and inter-examiner reproducibility of both methods was also assessed. For VistaProof the values were 0.76 and 0.78 intra-examiner agreement and 0.65 inter-examiner. For ICDAS II they were 0.82 and 0.91 intra-examiner and 0.76 inter-examiner. The data showed that both ICDAS II and VistaProof presented very good sensitivity but moderate specificity, as well as strong agreement (fair to good) with the histology results, and the intra-examiner and inter-examiner reproducibility was significant for both methods.

Conclusions: ICDAS II criteria and the assistance provided by VistaProof increase the ability to diagnose incipient lesions and take early action to treat them. It is important to combine the two in order to obtain more significant results, considering non-operative treatments for non-cavitated lesions diagnosed.

KEYWORDS:

ICDAS II, VistaProof, Reproducibility, Sensitivity, New fluorescence methods

INTRODUCTION

Dental caries is an infectious disease that affects the hard tissues of the tooth (enamel, dentine and cementum). Together with the common cold, it is one of the most prevalent diseases among humans ¹.

Studies have shown that caries is a dynamic, multi-factor process that requires the confluence of cariogenic bacteria, a carbohydrate rich diet and predisposing factors in the host over a length of time, giving rise to a continuous cycle of demineralisation and remineralisation of the tooth surface. If this balance is upset in favour of demineralisation (owing to prolonged periods of acidity) a cavity will eventually form in the tooth ¹.

According to the latest epidemiological studies ²⁻⁴, caries prevalence has been falling in recent decades but, at the same time, a certain rise in pre-cavitation lesions has appeared. This makes it necessary to change the approach to diagnosing and treating this disease, improving the ability to diagnose incipient lesions that can be treated by remineralising them and controlling the risk factors, and confining restoration treatment to more advanced lesions⁴.

Visual inspection is a subjective method based on clinical experience and prior training. The International Caries Detection and Assessment System (ICDAS) is an international, 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 ^{5,6} It was agreed in Baltimore, Maryland, in 2005, for the purposes of clinical practice, research and developing public health programmes. The aim was to develop a visual method of detecting caries at as early a stage as possible, and also to detect the severity and level of activity of this disease ⁷. The system has a sensitivity of 70% to 85% and a specificity of 80% to 90% in both primary and permanent teeth, with the difference depending on the level of training and calibration of the examiners ⁴.

The ICDAS criteria assesses the changes that have taken place on the tooth surface and, based on surface characteristics, the depth the carious lesions have reached ⁶. This visual diagnosis method has shown itself to be safe, precise and reproducible for the detection of early lesions and their longitudinal follow-up ^{8,9}.

The need to diagnose incipient lesions and the difficulty in detecting them makes it necessary to use additional diagnostic methods. These can range from x-rays to more complex methods such as those based on transillumination or fluorescence stimulation. The latter include the VistaProof® system employed in the present study.

Vistaproof® is based on the change in tooth fluorescence levels that occurs in caries lesions, which it records with a camera. The software quantifies the severity of the caries and returns a computer-processed image in which the damaged areas are shown in different colours according to the extent of the lesion ¹⁰. The system consists of an intraoral camera that shines a violet light (405 nm) on the teeth and captures the reflected light as a digital image. The special software quantifies the green and red components of the light on a scale from 0 to 3 and displays an image on the computer screen which shows the areas where caries is present or absent according to a colour and number scale established by the manufacturer ¹⁰.

The system presents good quantification of caries in free surfaces. Vistaproof® can be considered an interesting tool that can be used to complement clinical examination in order to obtain objective information on caries lesions for the purposes of early detection and monitoring. It also has the advantage of assisting communication with the patients, as they can see the lesion in the images, as well as making it possible to monitor the lesion and assess the treatments applied in order to measure their effectiveness over time. It presents good intra-examiner and inter-examiner reliability, although it must always be used hand-in-hand with good visual or tactile diagnosis, which is why it is important to enlist the aid of the ICDAS II system ¹⁰.

Until now, the diagnostic threshold has been determined by the detection limits of traditional diagnostic methods. The low caries prevalence found in many countries nowadays has led researchers to seek more refined diagnostic instruments that can detect caries lesions before the stage at which they are already visible to the naked eye ¹¹.

The purpose of the present study was to validate diagnostic methods that seek to detect incipient lesions, such as the ICDAS II criteria, fluorescence-based caries detection (VistaCam IX system with VistaProof), and the combination of the two, in relation to histological findings.

MATERIALS AND METHODS

Study design and sample selection

A sample of 100 teeth extracted for orthodontic or periodontal reasons was selected. The teeth could be healthy or present incipient caries lesions but those with large cavitated lesions or filled surfaces were excluded, as the main application of VistaProof is to study incipient caries lesions. All the selected teeth were kept in saline solution (NaCl 0,9%) less than 4 months, until they were examined.

Prior to examination, calculus and residues were removed from the selected teeth with a sonic instrument (KAVO Sonic Flex Lux 2000 L®, KaVo, Biberach/Riss, Germany) and the teeth were numbered for subsequent identification. Following sample preparation, the occlusal surfaces were photographed and an external assistant outlined the study area by drawing a red circle on the photograph. Of the 100 teeth, one third (35 teeth) were selected at random by the external assistant for examiner calibration and the remainder (65 teeth) were used for the study (Fig. 1A).

Visual examination was performed by both examiners using the same blue-white spectrum light (KaVo Primus 1058, KaVo, Biberach/Riss, Germany) and the equipment's triple air syringe (KaVo, Biberach/Riss, Germany) to dry the teeth.

For the examination using fluorescence, the VistaCam IX® system with the Proof head (VistaProof, Dürer Dental, Bietigheim-Bissingen, Alemania) was used (Fig. 1B).

Lastly, sections for histological analysis were cut with a diamond disk (Komet, Lemgo, Germany), polished with aluminium oxide disks (Sof-Lex, 3M-ESPE) and observed under the microscope at 30x magnification (Zeiss, Opmi-Pico, Oberkochen) (Fig. 1C).

ICDAS II criteria calibration prior to the study

Of the two examiners, one (MA-T) was a fifth-year dentistry student while the other (JEI-C) had lengthy experience in diagnosing caries with the ICDAS II criteria and had been calibrated by the ICDAS Committee during a course given in Valencia in 2012.

Using the methods and criteria proposed by the ICDAS Committee, both examiners viewed the 35 teeth that had not been selected for the study. They then commented on the results for calibration purposes, obtaining a final weighted kappa agreement of 0.72.

ICDAS II examination

The teeth were first examined visually and the ICDAS II caries scores of the previously selected surfaces were recorded.

Following the methods proposed by the ICDAS Committee, both examiners first viewed the teeth when wet and then after drying the surfaces with air for five seconds in order to observe any changes in colour ⁶.

This examination was repeated three weeks later to assess the intra-examiner reproducibility.

VistaProof examination

After a training period in which the manufacturer's instructions were followed with the 35 teeth not used in the study, both examiners viewed the selected surfaces of each of the 65 teeth, enabling assessment of inter-examiner reproducibility. The procedure was as follows: after drying the teeth with the triple air syringe to avoid misleading images, the surface of each tooth was photographed with the Proof head fitted. The image was processed by the DBSWIN program (Dürr Dental, Bietigheim-Bissingen, Germany), resulting in a mapped image of the surface examined that details the extent of any caries lesions in that surface.

This examination too was repeated three weeks later by both examiners to assess the intra-examiner reproducibility.

Histological preparation

Longitudinal sections of the teeth in the areas previously viewed were cut and polished with Sof-Lex ® discs to obtain a smooth surface. The sections were kept in saline solution until the histological examination took place.

Histological examination

The teeth in the study sample were examined under the microscope at 2.5 magnification and classified according to the system of Lussi et al.¹², as follows:

- 0: caries-free
- 1: enamel demineralisation limited to the outer half of the enamel
- 2: demineralisation affecting between 50% of the enamel and one third of the dentine
- 3: demineralisation involving the middle third of the dentine
- 4: demineralisation involving the inner third of the dentine

Statistical analysis

The data collected during each examination were saved in a Microsoft® Excel® spreadsheet (Microsoft Corporation, Redmond, Washington, United States).

The kappa statistic was used to analyse intra- and inter-examiner reproducibility both with the ICDAS II criteria and with VistaProof.

For statistical analysis of the reproducibility using VistaProof®, the data obtained were grouped together according to the manufacturer's instructions, as follows:

- From 0 to 0.99: healthy tooth
- From 1 to 1.49: initial caries in outer enamel
- From 1.5 to 1.99: caries in inner enamel
- From 2 to 2.49: caries in outer dentine
- 2.5 or higher: caries in inner dentine.

To establish the validity of the two systems compared to the histology results, employed as a gold standard, the area under the curve (AUC) was studied at the diagnostic level of the outer enamel (values: ICDAS ≥ 1 or VistaProof > 0.99).

As regards the combination of the two systems, caries was considered to be present in the enamel if caries had been diagnosed in either of the two examinations.

Lastly, the sensitivity and specificity of each method and of their combination were analysed separately.

RESULTS

Examiner 1 (M A-T) and examiner 2 (JE I-C) both viewed 65 of the 100 teeth collected, examining only the previously outlined areas so that both would focus on the same zone. The distribution of the sample in relation to the histology results is shown in Table 1.

The reproducibility values were obtained through the kappa value and its confidence interval. The intra-examiner reproducibility correlation values were 0.82 and 0.91 in the case of ICDAS II and 0.76 and 0.78 in that of VistaProof. The inter-examiner values were 0.76 for ICDAS II and 0.65 for VistaProof.

Table 2 shows the sensitivity and specificity values for ICDAS II and VistaProof in relation to the histology results, the positive and negative predictive values of both methods and the area under the curve for both examiners. It also shows the same data for the combination of the two methods.

For ICDAS II, the sensitivity was 0.796 for examiner 1 and 0.864 for examiner 2, while the specificity was 0.810 and 0.952 respectively. The agreement between ICDAS II and the histology was 0.802 for examiner 1 and 0.908 for examiner 2 (Fig. 2). As regards VistaProof, the sensitivity was 0.705 and 0.818 for the respective examiners and the specificity was 0.810 and 0.619. The agreement between this method and the histology was 0.757 for examiner 1 and 0.719 for examiner 2. Lastly, the combination of the two methods presented sensitivities of 0.841 and 0.955 and specificities of 0.714 and 0.619 for examiner 1 and examiner 2, respectively, with areas under the curve of 0.778 for examiner 1 and 0.789 for examiner 2 (Fig. 2).

DISCUSSION

Caries is one of the most common diseases in the human population. Traditionally, caries lesions have been detected through clinical diagnosis and radiographic methods. However, the subjectivity of these methods and their limitations for monitoring the lesion over time indicate that new technologies need to be developed.

Reproducibility

For ICDAS II, the reproducibility in this study was $\kappa=0.82$ and $\kappa=0.91$ intra-examiner and $\kappa=0.76$ inter-examiner. This highlights the difference in ICDAS II experience between the two examiners, which lowered the inter-examiner reproducibility, although it was still good.

These results were similar to those of other studies¹³⁻¹⁶ and show that, irrespective of the previous experience of the examiners, after training in the ICDAS II criteria both the intra- and inter-examiner reproducibility are good to high. Parviainen et al.¹⁷ say that students that have been trained in ICDAS II can achieve a good performance on it, too. According to this statement, we can consider that our results are consistent, even the moderate inter-examiner reproducibility.

With regard to VistaProof, the reproducibility values in the present study were 0.77 intra-examiner and 0.65 inter-examiner. These are lower than those of other studies, which have ranged from 0.83 to 1.00 intra-examiner and 0.82 to 0.94 inter-examiner^{7,13}. Jablonski found in his studies higher reproducibility, in a rank from 0.87 to 0.97¹⁸⁻²⁰. Seremid found a higher reproducibility too (0.887)²¹. The reason could be the difference in the examiners' training in the use of the instrument, as in the present case their training only consisted of two repetitions with the 35 teeth not used in the study itself, whereas the examiners in other studies were experienced in the use of VistaProof.

Sensitivity

The sensitivity values for ICDAS II in comparison with the histology results of the present study were 0.796 and 0.864 for examiners 1 and 2, respectively, at enamel level, similar to those of other published studies^{7,10,13,19}. Authors like Iranzo-Cortes et al. or Melo et al. obtained a sensitivity for ICDAS II of 0.82 and 0.75 respectively, similar to our results too^{16,22}. Nonetheless, others such as Novaes et al.¹⁵ or Jablonski et al.¹⁴ have obtained higher values (0.969 and 0.890 respectively).

For VistaProof, the sensitivity results in the present study were 0.705 and 0.818 for examiners 1 and 2, respectively, showing moderate sensitivity. Other studies that have studied occlusal surfaces, such as Rodrigues et al.⁷ or Achilleos et al.¹³, have obtained higher

sensitivities (0.86 and 0.97 respectively). This difference is probably because those authors examined the lesions at dentine level, finding that VistaProof provided highly sensitive detection of caries at this level, whereas the present study investigated its sensitivity at enamel level.

Other published studies have presented a diversity of sensitivity results, as Jablonski et al. 2013²⁰, Melo et al.²² and Diniz et al.²³ obtained high sensitivity in detecting caries at enamel level, while others such as Novaes et al.¹⁵ or Seremidi et al.²¹ indicated that VistaProof presented certain difficulties in detecting caries at this level, as its sensitivity was low (0.625 and 0.568 respectively).

No studies have published data on the sensitivity of a combination of the two systems. In the present study, this combination brought a slight rise in sensitivity, reaching values of 0.841 for examiner 1 and 0.955 for examiner 2, which were higher than those obtained for each method separately. This combination should be borne in mind in order to improve the definitive diagnosis.

Specificity

Unlike other studies^{15,18}, the present one obtained high specificity values for ICDAS II (0.810 and 0.952 for examiners 1 and 2, respectively). The studies found regarding ICDAS II showed a considerable difference between specificity and sensitivity, unlike the present study. For some authors, such as Jablonski et al. 2008 or^{14,24}, the difference in the results was due to an error when measuring the lesions during the clinical examination. For others such as Novaes et al. or^{16,25}, the disparity between sensitivity and specificity could be due to the drying time, as the enamel of primary teeth was more porous than that of permanent teeth or the in-vitro process.

However, more recent studies of Jablonski et al. or Heinrich-Weltzien et al.^{26,27} obtained similar results to those of the present study as regards the sensitivity (0.76-0.82) and specificity (0.810-1) of ICDAS II, which could be explained by the examiners' having greater training in the ICDAS II system. Other authors like Iranzo-Cortés et al. or Holtzman et al.^{16,28} found similar results too.

For VistaProof, the published studies have reported a wide diversity of specificity results. While Jablonski et al. 2013²⁰ or Seremidi et al.²¹ obtained low specificities for caries

detection at enamel level (0.41 and 0.56 respectively), others such as Diniz et al.^{23,29} or Melo et al.²² obtained specificities of 0.75 and 0.80, respectively. This diversity of results can also be seen in the present study, in which examiner 1 obtained a specificity of 0.810 but examiner 2 obtained only 0.619.

In the case of specificity, combining the two methods does not improve the results compared to each method separately (0.714 and 0.619 for the respective examiners with the combined method). This could be due to the addition of false positives for both systems. However, bearing in mind that what was being diagnosed was initial enamel lesions, for which the treatment consists of non-invasive remineralising measures, the loss of specificity does not prejudice the patient.

Diagnostic validity compared to the histology results

The agreement measured was high for ICDAS II (AUC = 0.802 for examiner 1 and 0.908 for examiner 2) and moderate for VistaProof (AUC = 0.757 for examiner 1 and 0.719 for examiner 2).

Jablonski et al. encountered moderate agreement between ICDAS II and the histological examination^{14, 19}.

However, the VistaProof measurements by Jablonski et al. showed strong agreement with the histology results (between 0.75 and 0.79)^{14,19}. In contrast, Rodrigues et al.⁷ encountered an agreement of 0.41 between VistaProof and the histology results, which is lower than in the present study. The explanation they gave for these results was that VistaProof presented difficulties in detecting lesions in enamel⁷.

As regards the combination of the two methods, the AUC was lower than for ICDAS but better than for Vistaproof alone (AUC = 0.778 and 0.787, respectively, for the two examiners). This is due to the lower specificity of Vistaproof, and other authors that have studied other combinations of visual and laser examination found similar results^{16,30}. Nevertheless, the false positives of Vistaproof must not be treated with operative treatment, so there is no problem with this result in the application on clinical diagnostic and assessment.

ICDAS strengths and weakness

According to the results of our study, ICDAS II allows a good diagnosis of incipient lesions, as well as rejecting lesions on sound surfaces, being better when there has been a good training in the system and experience in it. On the other hand, the subjectivity in the diagnosis can make that an explorer with low preparation can lead to wrong diagnoses²⁴. Training is needed to get the best results.

Possible causes for moderate performance of VistaProof

VistaProof has given a moderate performance for the diagnosis of incipient caries, both in its sensitivity and its specificity. These results are similar to those published by other authors^{20,21,23,29}. Under our point of view, we think that this performance can be affected by the training in the use of VistaProof, since the explorers followed the instructions provided by the manufacturer during their pre-study training, but did not have wide experience in using this system. Another possible cause could be that external illumination affects the capture and processing of the image, being a factor that would have less influence on the intraoral application. We consider that those factors should be taken into account in the conduct of future studies.

CONCLUSIONS

The visual criteria of ICDAS II showed good diagnostic efficacy for incipient lesions at enamel level, slightly better than that obtained with VistaProof. Combining the two methods increased the diagnostic sensitivity but slightly worsened the specificity, with a diagnostic efficacy of 0.78 as measured by the AUC. Consequently, employing a combination of the two systems is recommended for diagnosing incipient lesions in occlusal surfaces, even though low specificity. Non-operative treatment is needed for incipient lesions, just remineralising measures, so the preventive result for the patient is a benefit that overcomes any possible over-treatment with fluorides.

COMPLIANCE WITH ETHICAL STANDARDS

The study was approved by the University of Valencia's Ethics Committee (procedure number H1 446630019178). All the patients signed the informed consent form for their teeth to be included in the study.

The authors declare no interest in the conduct of this study and no funding was received for it.

FIGURE CAPTIONS

Fig. 1 (A) Occlusal view of a tooth classified as ICDAS 0, (B) image obtained with the VistaProof exploration and (C) histological view at 30x magnification

Fig. 2 (A) Occlusal view of a tooth classified as ICDAS 2, (B) image obtained with the VistaProof exploration and (C) histological view at 30x magnification

Fig. 3 (A) Occlusal view of a tooth classified as ICDAS 3, (B) image obtained with the VistaProof exploration and (C) histological view at 30x magnification

Fig. 4 ROC curves for ICDAS II (Figs. 4a and 4b for examiner 1 and examiner 2, respectively), for VistaProof (Figs. 4c and 4d) and for the combination of the two (Figs. 4e and 4f)

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FIGURES

Fig. 1

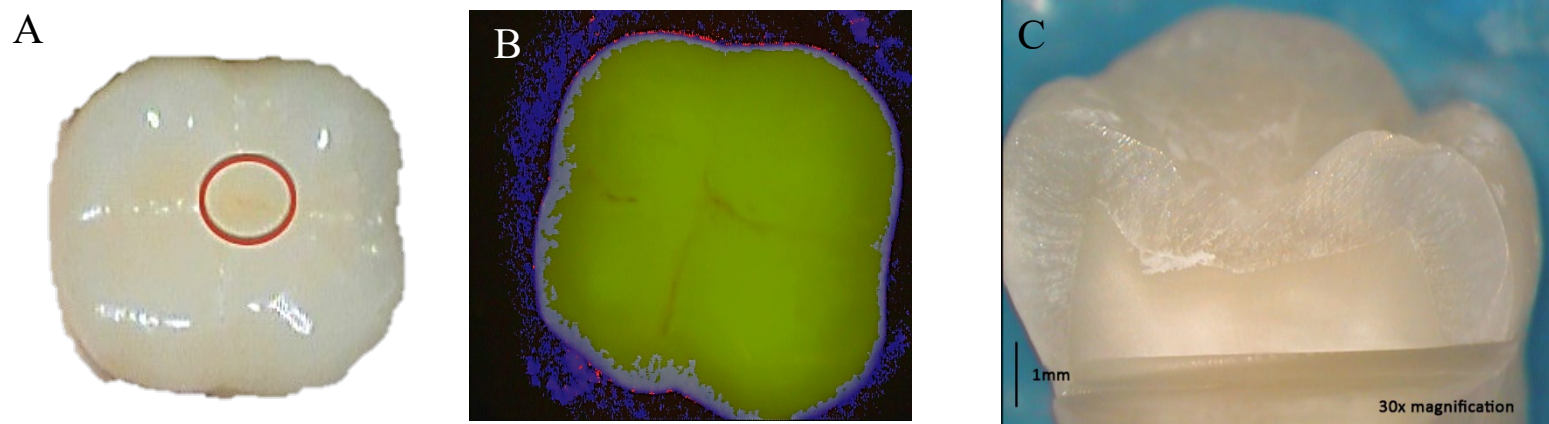


Fig. 2

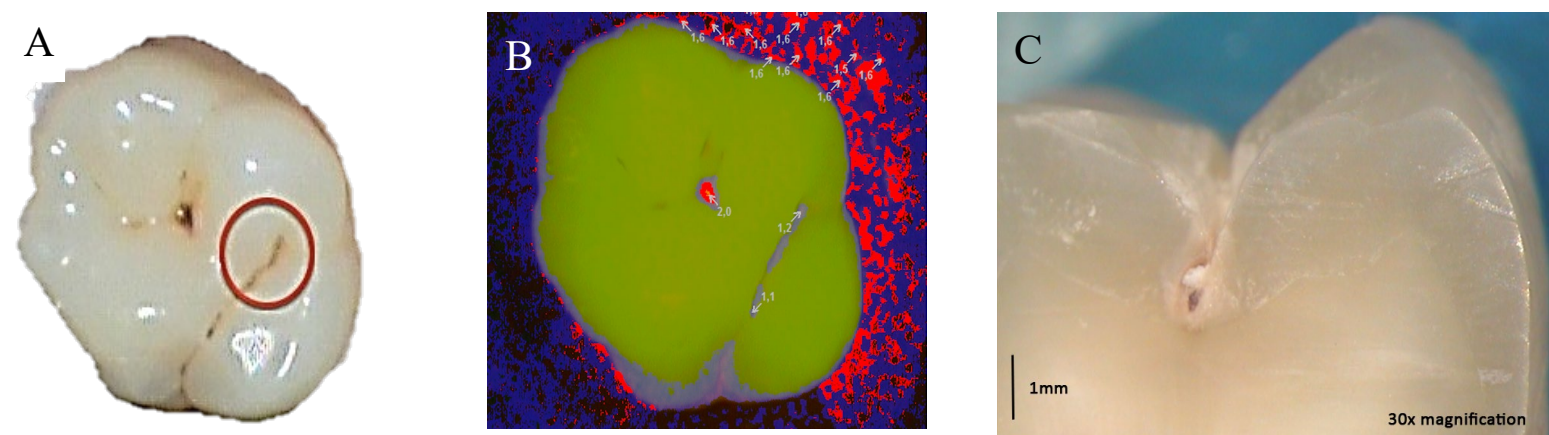


Fig. 3

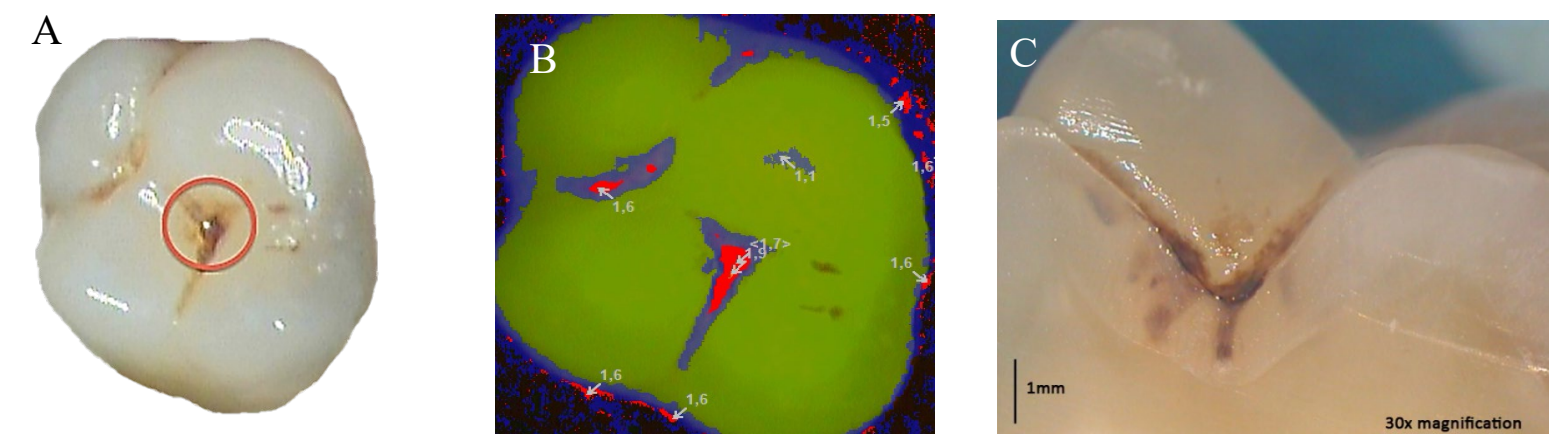
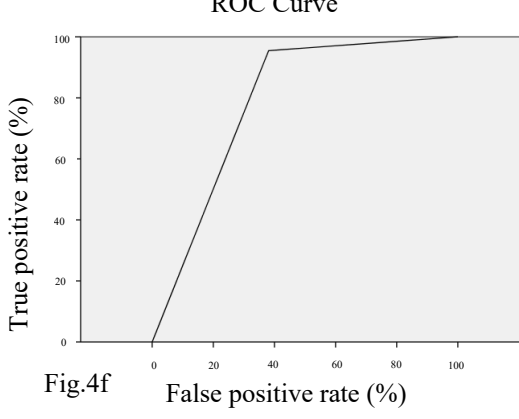
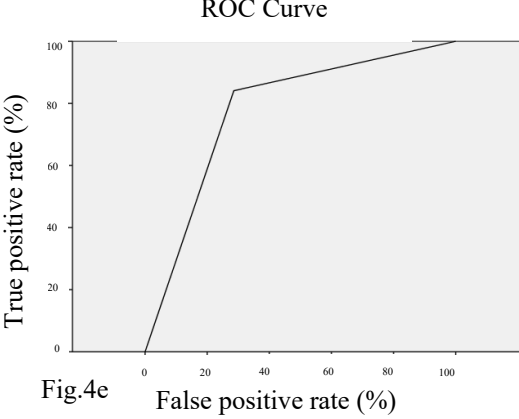
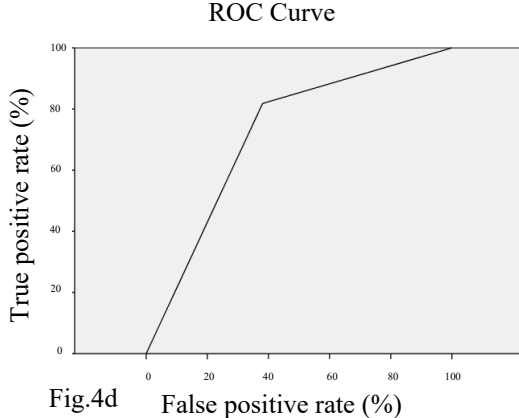
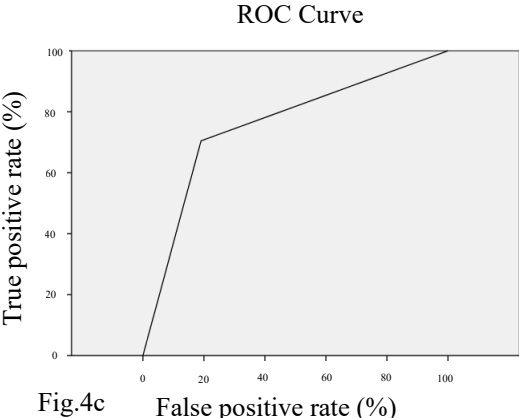
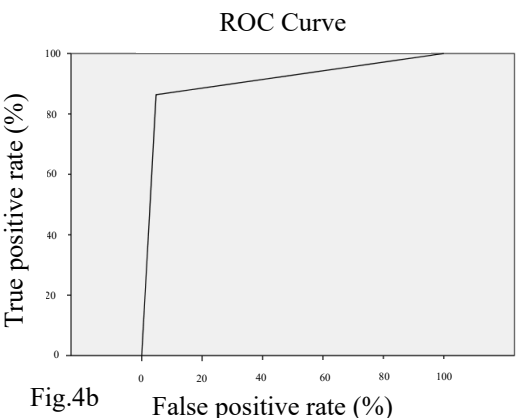
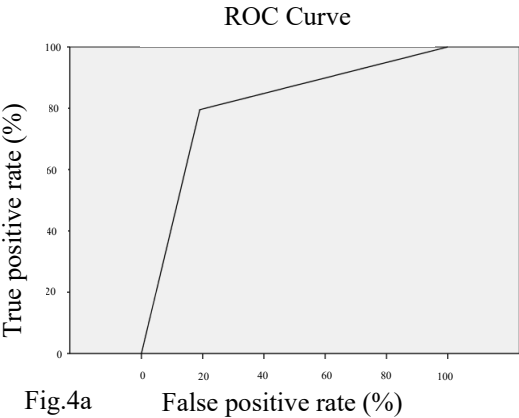


Fig. 4



1

2 **TABLE 1**

		Histology		Total
		Sound	Caries	
ICDAS II Examiner 1	Sound	17	9	26
	Caries	4	35	39
	Total	21	44	65
ICDAS II Examiner 2	Sound	20	6	26
	Caries	1	38	39
	Total	21	44	65
VistaPoof Examiner 1	Sound	17	13	30
	Caries	4	31	35
	Total	21	44	65
VistaProof Examiner 2	Sound	13	8	21
	Caries	8	36	44
	Total	21	44	65
Combination Examiner 1	Sound	15	7	22
	Caries	6	37	43
	Total	21	44	65
Combination Examiner 2	Sound	13	2	15
	Caries	8	42	50
	Total	21	44	65

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TABLE 2

	Sensitivity		Specificity		Positive predictive value		Negative predictive value		AUC	
	Examiner 1	Examiner 2	Examiner 1	Examiner 2	Examiner 1	Examiner 2	Examiner 1	Examiner 2	Examiner 1	Examiner 2
<i>ICDAS II</i>	0.796 (0.647-0.902)*	0.864 (0.727-0.948)	0.810 (0.581-0.946)	0.952 (0.762-0.999)	0.897 (0.758-0.971)	0.974 (0.848-0.996)	0.654 (0.443-0.828)	0.769 (0.612-0.876)	0.802 (0.683-0.922)	0.908 (0.827-0.989)
<i>VISTAPROOF</i>	0.705 (0.548-0.832)	0.818 (0.673-0.918)	0.810 (0.581-0.945)	0.619 (0.384-0.819)	0.886 (0.732-0.968)	0.818 (0.719-0.888)	0.567 (0.374-0.745)	0.619 (0.444-0.768)	0.757 (0.631-0.883)	0.719 (0.578-0.860)
<i>COMBINED</i>	0.841 (0.699-0.933)	0.955 (0.845-0.994)	0.714 (0.478-0.887)	0.619 (0.478-0.887)	0.861 (0.720-0.947)	0.840 (0.752-0.901)	0.682 (0.451-0.861)	0.867 (0.617-0.963)	0.778 (0.647-0.908)	0.787 (0.651-0.992)

* The numbers in parenthesis are the 95% confidence interval