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ORIGINAL ARTICLE

Combined validity of DIAGNOdent™ and visual examination for in vitro detection of occlusal caries in primary molars

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Abstract The purpose of this in vitro investigation was to compare in primary molars, the validity of DIAGNOdent™ 2095 on occlusal caries diagnosis used either separately or in combination with direct and/or indirect visual examinations, based on histological examination as the reference method. In 24 extracted primary molars, 111 occlusal pits were examined for caries by one trained operator (intra-examiner reliability k>0.80), using the following examination methods: direct visual (DV), indirect visual (IDV), radiographic (XR), and fluorescence (DD) with the DIAGNOdent™. The extent of caries was then determined histologically. Sensitivity, specificity, accuracy, and the area under the ROC curve (AUC) were calculated for each method separately as well as for the combination of DD with DV and/or IDV. The DD accuracy was found both for lesions into enamel and into dentin to be 0.70 while the accuracy of the DD combination with DV and IDV was found to be 0.89. The DD AUC for lesions into enamel and into dentin, 0.68, were not statistically significant different from the other methods (p>0.5), however the AUC of the combination of DD with DV and IDV, found to be 0.82, was higher than all the other methods, and this was statistically significant for enamel lesions. The validity of DIAGNOdent™ for occlusal caries diagnosis in primary molars was much higher when the DD was used in combination with direct and indirect visual examination, than when used by itself.

Keywords Occlusal caries detection · DIAGNOdent™ · Validity · Primary teeth

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Introduction

DIAGNOdent™ (KaVo, Bibberach, Germany) [1], is a portable laser fluorescence device used for early occlusal caries diagnosis in which fluorescence alterations of carious dental tissues are expressed as readings on a scale from 0 to 99. It has been proven to be relatively successful for the detection of occlusal caries in permanent teeth both in in vitro and in vivo studies [2–7]. For primary teeth [8–18] more specifically, the DIAGNOdent™ was found to be more sensitive in occlusal caries detection for dentin lesions than for enamel lesions, and when compared to direct visual examination, it was found to have higher sensitivity and lower specificity [10, 13, 18] for caries into dentin but for caries into enamel it was less sensitive and more specific [17]. Thus the DIAGNOdent™ was not found so suitable for detecting early caries lesions.

Despite the great number of reported studies comparing the examination methods individually for occlusal lesions detection, there is a limited number of studies investigating the occlusal caries detecting methods, when combined [19, 20]. A combination of direct visual examination with conventional [20] or digital radiographic examination [19] has been proven successful in improving the validity for

detecting occlusal caries in permanent teeth. Regarding the DIAGNOdent™, its combination with visual and radiographic examinations has been recently investigated by three studies, all in ,permanent teeth and has been found successful, especially for enamel caries [21–23]. Two of these studies were in vitro [21, 22] with reference method the histological evaluation and one was in vivo with reference method pit and fissure opening [23]. A common finding of all studies was that the caries diagnostic validity improved when the DIAGNOdent™ was combined with visual and radiographic examinations. The validity of laser fluorescence occlusal caries diagnosis in primary molars differs from that in permanent molars [6], which is attributed mainly to differences in the enamel thickness and structure [24]. The validity of the DIAGNOdent™ combined diagnosis in primary teeth, however, has not been investigated.

Thus, the purpose of this in vitro investigation was to compare in primary molars, the validity of DIAGNOdent™ 2095 on occlusal caries diagnosis, used either separately or in combination with direct and/or indirect visual examinations, based on histological examination as the reference method.

Materials and methods

Sample description

The sample of this study consisted of 24 recently extracted second primary molars, kept in fresh tap water since the day of their extraction. Teeth with occlusal restorations, occlusal fissure sealants, extensive fissure staining, hypoplastic pits, and occlusal caries with cavitation were excluded. The sample teeth yielded a total of 111 examination sites, occlusally located.

Study design

Occlusal sites were evaluated by one examiner for caries detection and scoring using direct visual (DV), indirect visual (IDV), radiographic (XR), and laser fluorescence examinations with the DIAGNOdent™ (DD). The extent of caries was based on histological evaluation of the sites, which was the reference method. Caries were detected using examination methods either separately or in combination with DD. The DD was combined with DV and/or IDV examinations.

Examination methods

Direct visual examination (DV)

For the DV examination, all occlusal surfaces of the sample teeth were cleaned with a toothbrush and pumice-free toothpaste, as previously published [15–18]. All sites were then evaluated for caries under a dental operating light and classified into three categories (0 = sound, 1 = caries in enamel, 2 = caries in dentin), using the criteria proposed by Nytun et al. [25] and the DIAGNOdent manufacturer [1] (Table 1).

Indirect visual examination (IDV)

For the IDV, all occlusal surfaces were photographed with a digital camera (Coolpix 990/ Nikon Corporation, Japan) using a 2x magnification and viewed on a computer screen at a magnification of 5x (final magnification 10x). These photographs were used to map the examination sites and to evaluate them for caries with IDV examination using the same criteria as for the DV examination (Table 1).

Radiographic examination (XR)

Bitewing radiographs (Kodak Insight, Carestream Health Inc., Rochester, NY) were taken for all teeth using the Endo Ray film holder and were developed in a Durr X-Ray Film Processor - XR 04 (Durr Dental GmbH & Co. KG, Bissinger, Germany) to ensure standardized conditions. All radiographs were viewed on a light box with a 2x magnifying lens and evaluated according to the criteria presented in Table 1.

DIAGNOdent readings (DD)

For the fluorescence examination of the study sites, the DIAGNOdent 2095 device was used with tip A,

Table 1 Caries scoring and criteria for visual examinations direct (DV) and indirect (IDV) as well as for radiographic examination (XR)

Score	Category	Criteria for direct and indirect visual examination	Criteria for radiographic examination
0	Sound	Normal enamel texture	No radiolucency
1	Enamel caries	Fissure enamel brownish, black and/or opaque	Radiolucency in enamel
2	Dentinal caries	Fissure enamel opaque, subsurface dentin appears black and has often loss of substance	Radiolucency in dentin

according to the manufacturer's instructions by calibrating it on every single tooth and as previously suggested [15].

In order to be able to compare DD findings with histological examination, the original DD readings were converted from its 0–99 scale to the 0, 1, and 2 scoring scale, applied for all other methods. DD estimation of cut-off points for enamel or dentin involvement was based on the best inter-method agreement between the converted DD readings to the histological findings, using Cohen's kappa coefficient, as presented in Fig. 1. The kappa coefficient took its highest value when DD readings were 3 for enamel and 40 for dentin lesions and these are the cut-offs used in this study.

Combined examination (CE)

The reference method to test the validity of the DD combined diagnosis with DV and/or IDV examinations was histological examination, as was also for all other examination methods.

The diagnostic decision for the combined evaluation was based on the best agreement of the combined methods with the histological examination. The caries score was decided mostly based on the visual examination score, as shown in Table 2. A score of 0 was given to the site when all three examination methods indicated 0; a score of 1 was given to the site if any of the three examinations indicated 1 or one indicated 0 and the others 1; a score of 2 was given to the site when the DD indicated 1 and both visual examination methods 2 or when the DD and any of the other two methods indicated 2.

Histological examination (HIS)

Suitable specimens for histological evaluation were produced, as previously published [18]. The grounded surfaces were then evaluated under the microscope (Leitz Elvar, Esselte Leitz GmbH & Co KG, Stuttgart, Germany) at a magnification of 12.5x and photographed using a digital camera (Coolpix 990, Nikon Corporation, Japan). The evaluation of the carious lesion was assessed according to the extent of the demineralization zone (rough or colored) into the enamel or dentin and all examination sites were classified with the same three-grade caries-scoring scale applied to all previously used methods (Table 1).

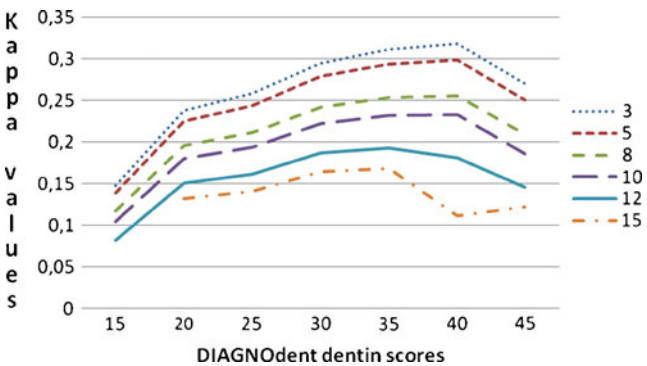

Fig. 1 Kappa statistic values for the agreement of HIS and modified DD scale at different cut-offs for enamel (*lines*) and dentin (*X-axis*) scores

Table 2 Diagnostic decision taken for each examination site based on the combination of DIAGNOdent™ (DD) with direct (DV), and/or indirect (IDV) visual examinations

		DV or IDV		
		0	1	2
DD	0	0	1	1
	1	1	1	1* or 2**
	2	1	1	2***

*If DD=1 and DV or IDV=2, then 1

**If DD=1 and both DV and IDV=2, then 2

***If DD=2 and DV and/or IDV=2, then 2

Examiner's calibration and reliability

Examiner's calibration was based on repeated blind evaluations of occlusal sites in primary molars according to Table 1 criteria. Intra-examiner reliability was evaluated using Cohen's kappa statistics by having the examiner classify blindly three times, 18 randomly selected occlusal sites, photographs, radiographs, and histological sections as seen in Table 3.

Statistical analysis

Validation of each diagnostic method and the combination of DD with DV or/and IDV was based on comparison of their sensitivity, specificity, and accuracy using histological examination as the reference method. Receiver operating characteristics curves (ROC) were plotted and the area under the curve (AUC) was estimated using MedCalc v.9.0.1.1 statistical package

Table 3 Intra-examiner reliability for all methods, estimated by Cohen's kappa coefficient

	DV	IDV	XR	DD	HIS
Kappa	1	1	0.85	0.83	1
Z	6.77	12.2	6.66	2.78	4.19

Table 4 Classification of sites by all examination methods (separate or combined), according to their caries score evaluation (0 = no caries, 1 = enamel caries, 2 = dentin caries)

Caries score	DV	IDV	XR	DD	DV+DD	IDV+DD	DV+IDV+DD	HIS
0	53	35	102	3	3	2	2	2
1	45	53	8	70	95	88	87	85
2	13	23	1	38	13	21	22	24
Total	111	111	111	111	111	111	111	111

(MedCalc Software, Mariakerke, Belgium). Significant differences between examination methods and DD combinations were estimated by pairwise comparisons using also MedCalc v.9.0.1.1, at a 0.05 level of significance (Table 3).

Results

Sample distribution

Table 4 presents the disease level of the 111 evaluated examination sites, for each examination method separately and for the DD combination with DV and/or IDV.

Validity of the examination methods

Sensitivity, specificity, and accuracy of the examination methods and their combination were based on histological evaluation as the reference method and results are presented in Table 5 separately for enamel and dentin caries.

Validating each method separately, the DD for enamel caries exhibited the highest sensitivity as also the IDV (0.87) and the highest specificity (0.38) for dentin caries. However, the DD examination had the lowest sensitivity, 0.39. Accuracy for enamel caries (0.70) was almost identical as for dentin caries (0.71).

Validating the DD in combination with the visual methods DV and/or IDV improved the diagnostic accuracy both for enamel and dentin lesions. The highest accuracy, 0.89, was found when all three methods DD+DV+IDV were combined both for enamel and dentin lesions, Table 5.

ROC curves and AUC

Relevant receiver operating curves (ROC) curves for the above examination methods and their combinations are presented in Fig. 2 for enamel lesions and Fig. 3 for lesions into dentin, while their AUC values along with their significant differences are shown in Table 6. Among the individual examination methods used, the DD had the highest AUC for enamel lesions while for dentin lesions the IDV.

Table 5 Sensitivity, specificity, and accuracy of all the examination methods separately or in combination for occlusal caries detection in primary molars based on histological evaluation as the reference method

	Caries lesion	Sensitivity	Specificity	Accuracy
DV	0	0.38	1.00	0.54
	1	0.73	0.19	0.41
	2	0.69	0.84	0.83
IDV	0	0.06	1.00	0.70
	1	0.87	0.30	0.58
	2	0.65	0.90	0.84
XR	0	0.02	1.00	1.00
	1	0.50	0.20	0.22
	2	1.00	0.79	0.79
DD	0	0.67	1.00	0.99
	1	0.87	0.38	0.70
	2	0.39	0.87	0.71
DD+DV	1	0.84	0.69	0.82
	2	0.69	0.85	0.83
DD+IDV	1	0.90	0.74	0.87
	2	0.71	0.90	0.87
DD+DV+IDV	1	0.92	0.79	0.89
	2	0.77	0.92	0.89

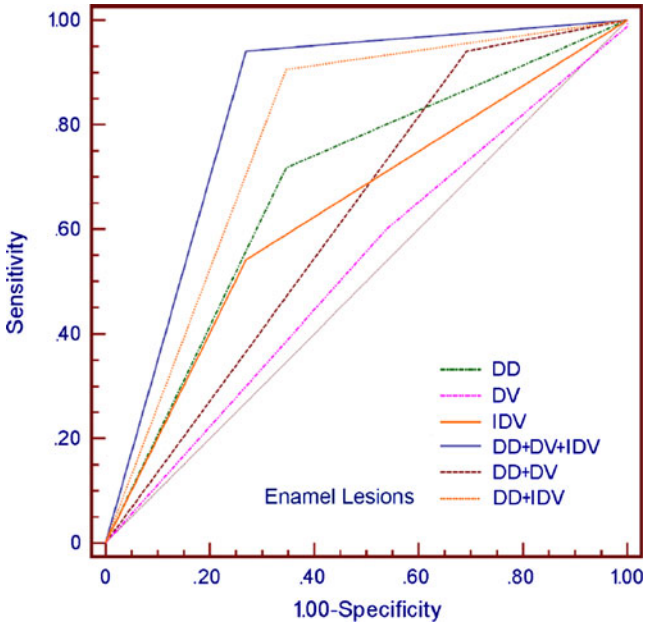

Fig. 2 ROC curves of the diagnostic methods separately or in combination for lesions into enamel

Among the combined methods, the highest AUC was found for the combination DD with DV and IDV, both for enamel (0.836) and for dentin lesions (0.825) and this was statistically significant different from the other methods only for enamel caries ($p<0.05$). The smallest AUC was found for the radiographic examination.

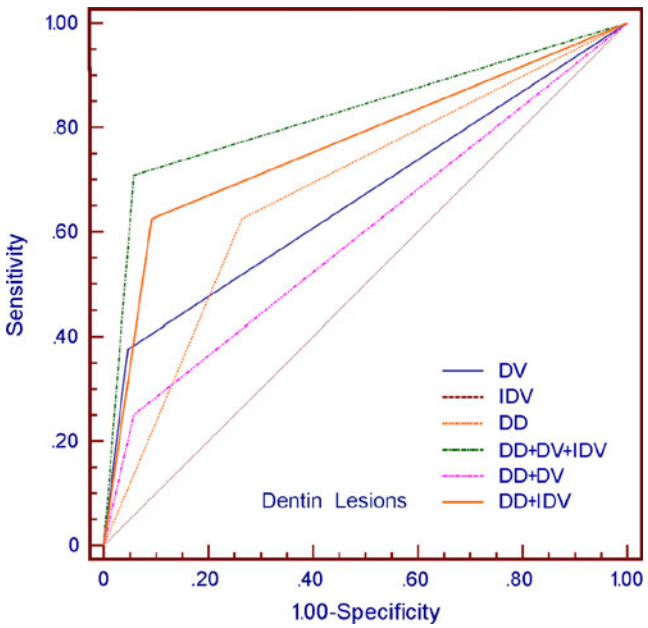

Fig. 3 ROC curves of the diagnostic methods separately or in combination for lesions into dentin

Table 6 Area under curve values (AUC) of the examination methods for enamel and dentin lesions based on histological examination as the reference method (*SE* standard error)

	Enamel lesions		Dentin lesions	
	AUC	SE	AUC	SE
DV	0.528[a]	0.066	0.665[bc]	0.066
IDV	0.636[a]	0.061	0.767[bc]	0.060
XR	0.553[a]	0.066	0.521[a]	0.067
DD	0.686[ab]	0.055	0.680[bc]	0.066
DD+DV	0.624[a]	0.065	0.596[ab]	0.068
DD+IDV	0.780[bc]	0.046	0.767[bc]	0.060
DD+DV+IDV	0.836[c]	0.039	0.825[c]	0.055
HIS	1.00[d]	0.000	1.00[d]	0.000

[a, b, c, d]: AUC values connected by same superscript letters in the same column indicate no statistically significant difference at $\alpha=0.05$ level of significance

Discussion

In the present in vitro study in primary molars, the DD device was validated for occlusal caries detection either used separately or in combination with visual examination methods having histological examination as the reference method. When only the DD was used, no statistical significance was found with the other methods either in detecting enamel or dentin lesions. However, when used in combination with both visual examinations DV and IDV, the highest accuracy was achieved, and this was statistically significant different only for enamel lesions.

In order to estimate the DD sensitivity, specificity, and accuracy, the DD values were converted into the same three grade caries scale as used for visual, radiographic, or histological examination, as previously [8, 11, 13, 26]. This new scale highly correlated with the original values.

DD cut-off limits used in this study for enamel caries were similar to the values used in previous in-vitro studies, in which histological examination was also used as the reference method [8, 9, 12, 14]. DD cut-offs for caries into dentin limits, however, were much higher than those used previously in primary teeth in-vitro [9–11, 15]. This may be attributed to the different cut-off estimation statistical methods applied, Cronbach previously [18], Cohens Kappa currently. It may be also attributed to differences in the distribution of enamel or dentin lesions in the sample, in the storage medium, pit remnants, and drying time before each measurement [27]. These all need more attention in future research. The cut-off limits estimation method chosen in this study, Cohen's kappa statistics, was used to compare the agreement of the two ordered scales in different cut-offs for enamel and dentin levels, as previously reported [27].

This method allowed the measurements of the device to be expressed in values closer to the findings from the histological examination [8, 11, 13, 26].

In the present study, when validating the examination methods separately, the highest sensitivity, specificity, and accuracy for lesions into enamel was found with the DD, as previously found in primary teeth, in vitro [8–18]. However, for lesions into dentin, the IDV was found to have the highest accuracy as previously in vitro [18]. Comparing IDV to DV, the IDV showed higher accuracy both for enamel and dentin lesions, suggesting that the use of an intraoral digital camera may be a useful clinical adjunct in the clinic for primary teeth early caries diagnosis.

According to the principles of DD operation, DD measures fluorescence changes occurring in the organic matrix of carious lesions [31] rather than measuring adequately mineral changes [13], thus the device is considered and has been found [6, 16] more sensitive for dentin than for enamel lesions. Results of the present study, however, have found the DD to have higher sensitivity for enamel lesions while higher specificity for dentin lesions as also indicated by others for primary [28] as well as for permanent teeth [29, 30]. A possible explanation for these controversial findings is that although the DD readings are not correlated with mineral changes, the DD may detect small initial demineralization changes in the enamel lesion subsurface, like the microporosities that are filled with organic material, enhancing the emitted fluorescence. If a significant number of such initial lesions exist in the sample as in the present study, then this would result in higher sensitivity for enamel lesions.

Validation of the DD in combination with visual examination methods DV and IDV was presently investigated since it simulates diagnostic decisions taken by the clinicians in the everyday clinical practice when using the DD as an adjunct to visual examination. Such combination proved previously to be successful in permanent teeth [21, 22], however, has not been validated in primary teeth. Results of the present study found this combination to greatly improve the accuracy for occlusal caries diagnosis as measures of validity suggested. The highest diagnostic accuracy (0.89) was obtained when both visual methods, DV and IDV were used, suggesting the importance of using all three methods in the clinical setting. The validity of the combined examination methods may be influenced by the diagnostic decision taken when evaluating a site, considering all three methods. In previous studies this combination of diagnostic methods [19–23] was investigated, but it has not been clarified how these decisions were taken. So this area needs further research in order to apply the combined examination methods in the everyday clinical practice.

Radiographic examination was found to have a very low accuracy for enamel caries, as already previously reported [9], while its high sensitivity for dentin lesions is misleading since it comes from studying only one observation, that determined histologically. Thus, XR was not combined in the present study with the DD or the visual examination. Results of a previous study in permanent molars have shown higher validity when the DD was combined with the DV than when combined with radiographic examination [21]. Furthermore, results from another study [22] showed that direct visual examination and the DD complemented each other, correcting each other's false-positive or false-negative decisions.

In conclusion, the findings of the present study suggest that the DD device is a useful adjunct tool to visual clinical examination for early occlusal caries detection in primary molars. Its high sensitivity for enamel lesion makes the device more useful for the detection of early caries in primary teeth, especially if it is combined with direct and/or indirect visual examination due to their higher specificity. For more advanced lesions into dentin, the DD device is as useful as the other methods, but due to its low sensitivity and high specificity, it must be combined with the visual examination methods DV and/or IDV, which presented the best sensitivity for dentin lesions. Such combined examination also needs to be tested in-vivo in order for clinicians to achieve the best possible diagnosis in clinical situations.

The DD device can be used for the detection of enamel and dentin caries in primary molars but for optimum validity, it must be combined with visual examinations, especially if an operative intervention is to be decided.

Conclusions

1. The DD when used individually was not found to be statistically significantly different than the other methods in primary molar occlusal caries diagnosis.
2. The combination of DD with the visual methods improved the accuracy in occlusal caries diagnosis.
3. The DD when used in combination with visual examinations direct and/or indirect was found to be statistically significantly different from the other methods only for enamel lesions.

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