DOI: 10.1111/j.1365-263X.2007.00913.x

Clinical performance of a diode laser fluorescence device for the detection of occlusal caries in primary teeth

KATERINA KAVVADIA[1] & PANAGIOTIS LAGOUVARDOS[2]

[1]Department of Paediatric Dentistry, [2]Department of Restorative Dentistry, School of Dental Medicine, University of Athens, Athens, Greece

International Journal of Paediatric Dentistry 2008; 18: 197–204

Objectives. To correlate the DIAGNOdent™ readings (LF) with those of direct visual (DV) examination, indirect visual (IDV) examination, bitewing radiography (BWR), and pit and fissure opening (PFO) for the detection of occlusal caries in primary teeth; to determine the validity of this device using PFO as reference; and to evaluate its reliability.

Methods. Two calibrated operators examined 130 teeth with 405 examination sites using DV, IDV and radiographic examinations, and LF. Of the 405 sites, 155 were visually scored for caries after pit and fissure opening.

Results. Pit and fissure opening was found to significantly correlate with all methods (rhoLF = 0.48, rhoBWX = 0.48, rhoDV = 0.44, rhoIDV = 0.41). For enamel lesions, higher sensitivity (0.76) was found with DV, while higher specificity (0.88) with the LF. For lesions into dentin, however, higher sensitivity (0.78) was found with the LF, while higher specificity (0.98) with the BWR. The device's accuracy was found to be 0.61 for enamel lesions, while for lesions into dentin 0.70, and its reliability was excellent (ICC = 0.97).

Conclusion. The LF device presented high reliability in the detection of occlusal caries in primary teeth and its performance was similar to DV and radiographic examinations.

Introduction

Detection of early noncavitated occlusal caries presents many diagnostic problems in clinical practice when simple conventional diagnostic methods are used[1]. A non-invasive and non-harmful method for the detection of early carious lesions, the laser fluorescence (LF) technique, was introduced in the 80s. It measured the intrinsic fluorescence emitted by the mineral content of the teeth when excited by an argon laser light of 406–488 nm[2], and although it proved promising, it never progressed into a clinical applicable system because of the need for an expensive and cumbersome spectral-analysing system. In 1998, Hibst and Call[3] found that if the excitation wavelength increased up to 638–655 nm, the carious enamel or dentin emitted fluorescence of a sufficiently higher intensity than that of sound tissues. Fluorescence is believed to be emitted by the organic content of dental caries[4]. In order to make this method applicable for the every day clinical use, a portable device DIAGNOdent™ (Kavo, Bibberach, Germany) has been introduced, in which fluorescence alterations of carious enamel are expressed as readings on a scale from 0 to 99[5]. The device has been extensively tested in permanent teeth for occlusal caries detection both *in vitro* and *in vivo* and has been found highly reliable[4]. As it can be seen in a recent review[6], DIAGNOdent™, when compared to visual examination for detecting occlusal dentinal caries, was more sensitive but less specific, while for enamel caries it tended to be less sensitive and more specific.

Regarding, however, the validity of the device in the detection of occlusal caries in primary teeth, there have been a few studies *in vitro*[7–11] and *in vivo*[12,13]. In the *in vitro* studies, the DIAGNOdent™ was compared to conventional diagnostic methods using histological examination as the reference method[7,8]. Results of these studies showed lower variation in regard to the examiner's experience as compared to direct visual (DV) inspection[10], high sensitivity, and specificity of this device for detection of caries extending into dentin, while for enamel caries, DIAGNOdent™ was found equal[7] or

Correspondence to:
Katerina Kavvadia, 5 Parodos Xenias, Kifissia, 14562 Athens, Greece. E-mail: kavad@dent.uoa.gr

better than visual examination[8] and had high accuracy[11]. In the *in vivo* studies, validation was based either on histological examination of retrieved teeth after exfoliation[12] or on DV examination[13]. Results of these studies found the DIAGNOdent™ to be no better than visual inspection[12], values of visually sound teeth have been found lower in primary than in permanent teeth, while the mean DIAGNOdent™ values for caries into dentin were similar to the ones found in permanent teeth[13]. A wide variation exists, however, among studies in primary teeth regarding the diagnostic threshold for dentin involvement ranging from 12 to 30 and in the sensitivity and specificity of the device for enamel and dentin caries detection. More research is therefore needed to evaluate the performance of this LF device for the detection of occlusal caries in primary teeth.

The aims of this investigation were: (i) to correlate the DIAGNOdent™ readings with the results of DV, indirect visual (IDV) and radiographic examinations, and pit and fissure opening regarding the estimation of the depth of occlusal carious sites in primary teeth; (ii) to determine the validity of this device using as reference visual evaluation of lesion depth after pit and fissure opening; and (iii) to evaluate the reliability of the readings obtained by DIAGNOdent™.

Materials and methods

Samples

Children in primary and mixed dentition comprised our sample. Patients were examined clinically prior to the procedure with a mirror and a dental explorer. Patient inclusion was based on the presence of occlusal caries with no obvious cavitation on at least one primary molar, free of restoration or interproximal caries, as verified radiographically. The protocol of the study was approved by the research Ethics Committee of the Dental School, and an informed consent was obtained from the patients' parents, prior to the procedure.

Based on the above criteria, 47 children: 26 boys and 21 girls, 3–13 years of age, with a mean age of 5.94 years, all patients of the Clinic of the Paediatric Dentistry Department of the University of Athens, participated in this study. A total of 130 teeth were examined, 50 first molars and 80 second primary molars, that yielded 405 examination sites. From these sites, 155 were opened with a high speed and burr.

Study design

The study design included clinical and radiographic examination of the occlusal surfaces for caries scoring of the examination sites, with DV and IDV examinations and bitewing radiographs (BWR). Then LF readings were obtained for the examination sites. There were two examiners for the DV examination and the LF readings, and each child was assigned randomly to one of them. The evaluation of the colour slides for the IDV and bitewing radiographs was performed by the first examiner. The reference method used for the estimation of the extent of caries was pit and fissure opening (PFO). Teeth that had their pit and fissures opened were then restored.

Examination methods

Direct visual (DV) examination

After the selection of the examination sites as described above, teeth were cleaned thoroughly with a rubber cup and pumice, briefly air dried, and the selected sites were evaluated visually (DV) by one of the two examiners, with no visual aids, according to the proposed caries scoring system[14] presented in Table 1. Calibration of the two examiners was based on a specified intra- and inter-examiner agreement level, after repeated testing of 25 sites in five different patients blindly at the beginning of the study. The level was set to 0.75 for inter- and 0.80 for intra-examiner agreement with Cohen's kappa, since a value greater than 0.75 has been considered excellent[15].

Indirect visual (IDV) examination

For the IDV examination, colour slides were taken at a magnification of ×2 with a Nikon FG SLR analogue photographic camera (Nippon Kogaku KK, Tokyo, Japan) with a Medical

Table 1. Caries scoring and criteria for direct visual, indirect visual and radiographic examinations.

Score	Category	Criteria for direct and indirect visual examinations	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 dark, often loss of substance	Radiolucency in dentin

Nikkor 120-mm lens (Nikon, Tokyo, Japan). Examination sites were scored, viewing the slides through a ×2 viewer, using the same optical criteria as in the DV examination. One examiner, calibrated in 25 randomly selected sites until $k > 0.80$, evaluated the colour slides.

Radiographic examination (BWR)

Bitewing radiographs were then taken for all selected teeth, using standard intra-oral film (Kodak Ekta Speed, Eastman Kodak Co., Rochester, NY, USA), with a 70 KVp X-ray machine. Radiographs were processed in an automatic developing machine (XRO4 Dürr Dental) and were evaluated blindly, under a ×2 slide viewer, all by the first examiner, according to the criteria for radiographic examination in Table 1. Examiner's calibration was done as previously described for the IDV examination.

Laser fluorescence (LF) readings

The DIAGNOdent™ device was used for the LF examination. The same two examiners, who evaluated DV examination, were also calibrated for the device readings (LF), following the same principles as in DV examination. Teeth were isolated with cotton rolls, were briefly air dried, and examination sites were tested with the device, following the manufacturer's instructions. Probe A of the LF device, especially designed for the detection of occlusal caries, was used. The tip was placed perpendicular to the examination site and was turned around in order to pick up the area where the carious lesion was most advanced so that the highest LF value could be recorded. Three consecutive readings were taken for each examination site and the mean was the counting value. In order to test the reliability of the device, a second set of three consecutive readings was obtained blindly by the same examiner, from 319 sites.

In order to compare the LF results with the other methods, the original LF readings on the 0–99 scale were converted to the 0, 1, and 2 caries scoring scale used by all other methods, using Spearman correlation coefficient (rho).

Pit and fissure opening (PFO)

Pits or fissures of teeth that were evaluated as having caries into dentin with either DV or radiographic examinations were opened using a high speed and burr (FG no. 1). At the same teeth, sites that were evaluated as having caries into enamel were also opened as having enameloplasty, and the extent of caries was recorded prior to restoration. In order to estimate the depth of the lesion more accurately, decay was removed very slowly. Penetration depth of caries was estimated visually and scored as 1 if the lesion was confined into enamel and 2 if the lesion had progressed into dentin. Teeth were then restored with composite resin and sealed.

Statistical analysis

The LF cut-off limits for lesions into enamel or dentin were selected using Spearman's correlation coefficient (rho). Inter- and intra-examiner reliability for all the examination methods was estimated from the calibration data of the examiners on two repeated sets of readings, calculating the intraclass correlation coefficient (ICC)[16]. Correlation of the LF readings with the scores from the other methods was estimated using Spearman's correlation coefficient (rho) for all pairs.

To test the validity of the LF readings separately for lesions into enamel or dentin, sensitivity (proportion of carious lesions identified correctly), specificity (proportion of sound sites identified correctly), and accuracy (proportion of results that agree with the

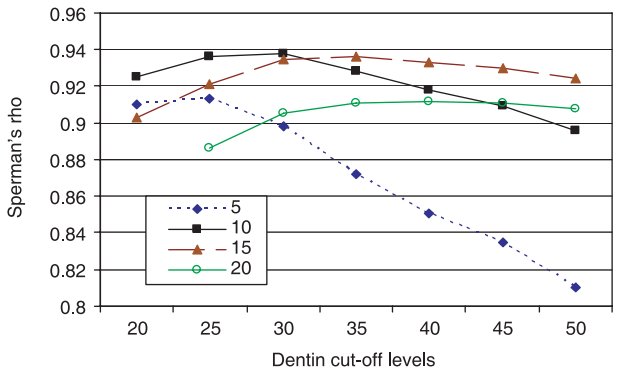

Fig. 1. Spearman's correlation coefficient between LF readings (original and converted) at different cut-off levels for enamel lesions (lines) in relation to dentin cut-off levels.

reference method)[17] were calculated for each diagnostic method, using results from PFO as the reference method. Comparisons between the sensitivity and specificity values among the different methods were made by the McNemar's change test. Reliability of the LF readings was estimated by the average ICC of reliability, by comparing results on 319 sites, of two consecutive sets of LF readings. Statistical analysis was conducted using SPSS version 10.0 statistical package (SPSS Inc., Chicago IL, USA). Wilcoxon signed rank test was used to test for the differences among repeated set of LF readings, when checking for the reliability of the device.

Results

Cut-off limits selection

Using data for all 405 examination sites, Spearman's correlation coefficient took its highest value, rho = 0.94, when LF values 0–9 were considered as sound, 10–42 as enamel caries, and 30–99 as having caries into dentin. The cut-off limit for enamel caries was set to 10 and for caries into dentin to 30 (Fig. 1).

Sample distribution – LF readings

The distribution of the 155 sites for each examination method according to their caries scoring is presented in Table 2 and graphically in Fig. 2. From the 72 sites that with PFO were found into dentin, with the LF only 56 were diagnosed with the LF as being into dentin. Table 3 presents the mean LF values according to caries scoring for each examination method.

Correlation analysis

Correlation between the different examination methods was calculated for the 155 opened sites, using Spearman's correlation coefficient; values in Table 4 and all rho values were statistically significant at the 0.01 level. The best correlation was found between DV and IDV (rho = 0.84), while the best correlation between PFO and the other methods was found with the LF (rho = 0.48).

Validity

Sensitivity and specificity of the methods based on PFO as the reference method are given in Table 5 and are reported separately for enamel or dentin lesions. The LF device had higher sensitivity for lesions into dentin than lesions into enamel. For enamel lesions, higher sensitivity (0.76) was found with DV examination, while higher specificity (0.88) with the LF. For lesions into dentin, higher sensitivity (0.78) was found with the LF, while higher specificity (0.98) with the BWR. Searching for possible

Table 2. Distribution of the examination sites for each method after PFO, according to their caries scoring. (1 = enamel caries, 2 = dentin caries.)

Caries scoring	DV			IDV			BWR			LF			
	0	1	2	0	1	2	0	1	2	0	1	2	PFO
1	9	**63**	11	10	**58**	15	64	**17**	2	16	**36**	31	83
2	0	35	**37**	0	33	**39**	26	16	**30**	2	14	**56**	72
Total	9	98	48	10	91	54	90	33	32	18	50	87	155

BWR, bitewing radiography; DV, direct visual; IDV, indirect visual; LF, laser fluorescence; PFO, pit and fissure opening.

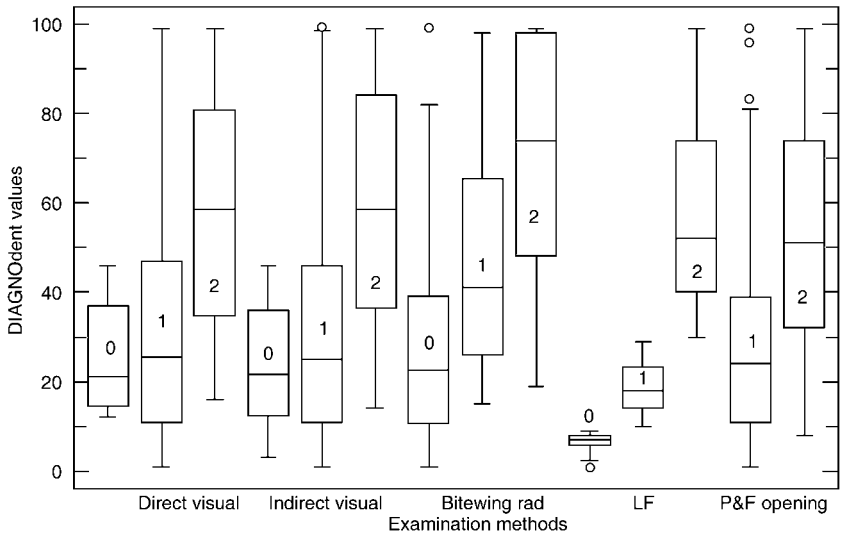

Fig. 2. Distribution of laser fluorescence (LF) values at caries scores 0.1 and 2 for the different examination methods: boxplots. P&F, pit and fissure.

Table 3. Mean laser fluorescence readings for all 405 sites, according to caries scoring and examination method. (0 = sound, 1 = enamel caries, 2 = dentin caries.)

	DV		IDV		BWR		PFO*	
Caries scoring	**x**	**SD**	**x**	**SD**	**x**	**SD**	**x**	**SD**
0	25.8	12.4	23.4	14.2	26.7	19.3	–	–
1	32.3	25.2	30.6	23.6	45.9	23.8	27.5	20.7
2	58.4	27.6	58.8	27.6	71.2	27.3	54.4	28.9

*Calculated for the 155 sites opened.
BWR, bitewing radiography; DV, direct visual; IDV, indirect visual; PFO, pit and fissure opening.

Table 4. Spearman's correlation coefficients (rho) between all examination methods.

	DV	IDV	BWR	LF
DV	1			
IDV	0.834*	1		
BWR	0.535*	0.547*	1	
LF	0.434*	0.489*	0.587*	1
PFO	0.443*	0.414*	0.477*	0.484*

Correlation values with * are significant at the 0.01 level (two tailed).
BWR, bitewing radiography; DV, direct visual; IDV, indirect visual; LF, laser fluorescence; PFO, pit and fissure opening.

Table 5. Sensitivity and specificity of the methods for occlusal caries detection based on pit and fissure opening as the reference method. The examination methods with the same superscript are not statistically different (McNemar test $\alpha = 95\%$).

	Enamel		Dentin	
	Sensitiviy	**Specificity**	**Sensitiviy**	**Specificity**
DV	**0.76**[a]	0.51[a]	0.51[a]	0.87[a]
IDV	0.70[a]	0.54[a]	0.54[a]	0.82[a]
BWR	0.20	0.78[b]	0.42[a]	**0.98**[a]
LF	0.43	**0.88**[b]	**0.78**	0.63

BWR, bitewing radiography; DV, direct visual; IDV, indirect visual; LF, laser fluorescence. Bold numbers indicate highest values.

differences in sensitivity between methods, McNemar tests showed that statistical differences exist, mainly between LF and the other methods either for enamel or for dentin lesions.

Accuracy for all diagnostic methods was found not to exceed 0.72 and it was higher for lesions into dentin, > 0.69 than for lesions into enamel. Higher accuracy for enamel lesions was found with the DV examination (0.65) and lowest with the BWR (0.47). For lesions into dentin, higher accuracy was found with the BWR (0.72), while other methods had an accuracy of 0.69–0.70.

Reliability of LF readings

Excellent reliability, average ICC 0.96, was found when analysing the two sets of repeated LF readings for the 319 sites. Greater difference was seen for LF readings close to 30, which is approximately the cut-off for dentin lesions, while statistically smaller difference was found in sound sites ($z = -2.28$ $P = 0.023$).

Inter- and intra-examiner reliability

The ICCs ICL of inter- and intra-examiner reliability were considered excellent. The ICL was higher for the LF 0.99 both for the intra- and the inter-examiner reliability as compared to DV which was 0.94 for inter- and 0.89 for intra-examiner reliability.

Discussion

In this study the LF device was tested under *in vivo* conditions in order to correlate its findings with those from clinical and radiographic examinations, to validate the device, and to test its reliability.

Regarding the design of this study, visual examination was carried out first in order to simulate caries diagnosis in the clinical setting and to reduce the possibility of producing bias in the visual scores if LF readings were obtained first. Teeth were cleaned not only to facilitate visual examination but also to prevent plaque's influence on LF's performance[9,18,19]. Probing was not included in the examination methods of this study, since probing pressure was shown to potentially damage the fissures over subsurface carious lesions, increasing the risk for progression[20,21], while its combination with visual examination does not seem to improve its accuracy over visual examination alone[8]. The caries scoring scale used in this investigation for the estimation of caries for all examination methods has been suggested by the LF device manufacturer to be used for permanent teeth[5] and it correlates with the known scale suggested by Ekstrand *et al*. for permanent teeth[21]. Caries were not differentiated whether there were in the inner or in the outer part of the enamel because such a clinical diagnosis is difficult in primary teeth due to the small thickness of the enamel. Previous investigators found no difference between the LF readings for lesions in the outer or inner half of the enamel both in primary[7] or in permanent teeth[15].

PFO used to validate the LF device, although not as accurate as the histological evaluation of a lesion, seems to enhance visual inspection[22] and has been already used in primary[7] and permanent teeth[15,23]. To date, PFO seems to be the best alternative to histological evaluation for clinical trials and the only way to confirm clinically the results of DV examination. PFO, however, has limitations as a reference system. Specificity for sound tooth sites cannot be evaluated because these cannot be opened for ethical reasons. Further limitations of the PFO are difficulties in the reliability and calibration of the evaluators when visually estimating the depth of a lesion.

The cut-off limits of the LF device in this investigation were selected using the largest possible sample size available, in order to permit generalization of the results[6]. The limits for enamel caries were set to 10, similarly to the limits previously found for primary teeth[7,8,10]. For caries entering the dentin the limits were set to 30 as previously used in a clinical study in primary teeth[24] but higher than 12–18 reported in primary teeth when using histology as the reference method[7,8]. Caution, however, should be given in extrapolating these results to the everyday clinical practice since involvement of the dentine as defined by histological examination, should not indicate immediate operative intervention[4], therefore intervention should be decided at higher LF values, as previously proposed for permanent teeth[15]. Perhaps it would be more useful for clinical application to select cut-off limits based on operative intervention rather than on histological depth. Dentin cut-off limits in permanent teeth have been reported in most of the studies to be close to 20[6], much lower than the limits found in this investigation for primary teeth. Primary teeth cut-off limits, however, are higher may be due to the thinness of the enamel, masking less the fluorescence of the underlying dentin lesions[8]. Mean LF values for enamel and dentin lesions found in this study are similar to those found by others for permanent[13] and primary teeth but only *in vitro*[8,12]. Furthermore, LF values found in this study for enamel or dentin caries ranged widely, as found in other *in vitro* studies in primary[8] and permanent teeth[13,15,25].

Among the examination methods used in this study, the LF device was found to have the highest specificity for enamel lesions and the highest sensitivity for lesions into dentin. These findings imply that for a more accurate evaluation of enamel lesions, the LF should be

combined with DV examination, which had the highest sensitivity, while for lesions into dentin, the LF should be combined with radiographic examination, which had the highest specificity. This is in agreement with other studies[7–9,13,23] but needs to be further evaluated by testing the combined validity of the two methods. The sensitivity of the LF device for caries into dentin in primary teeth was found in previous studies to range from 0.73[2] to 0.82[8], while in this study the sensitivity was found 0.78. These small differences in the sensitivity values most probably may be attributed to different reference methods and cut-off points used and sample inconsistencies such as presence of carious microcavities or discoloured fissures.

Highest sensitivity for enamel lesions, in this study, had the DV examination while highest specificity had the LF, making the LF a useful caries screening tool for low caries populations, as previously suggested for permanent teeth, since in such populations, a test with high sensitivity than a test with high specificity is more harmful[26]. In the clinical setting when only DV examination is used for caries detection, many dentin lesions are undetected or wrongly diagnosed as enamel caries allowing an underlying dentinal lesion to progress unchecked[26]. Due to the LF's higher sensitivity for lesions into dentin as compared to DV examination, LF can be a valuable additional to DV tool for occlusal dentin caries detection in primary teeth, in the absence of radiographs. Accuracy of the device was found lower than previously reported in primary teeth[12] maybe due to the higher cut-offs used in this study for lesions entering the dentin. The radiographic examination as expected both for primary[13] and for permanent teeth[27,28] had the lowest accuracy for detecting enamel caries.

The excellent reliability of the device that was found in this study using a very large sample size was also found previously[4,8] indicating, as previously suggested[6,24], that the device may be used for longitudinal monitoring of caries progression. The larger differences, however, found in this investigation between repeated readings at higher values suggest that this appliance may be less reliable in higher readings and that it is more difficult to estimate the progression of an advanced lesion into dentin, as has been also found for permanent teeth[15]; this issue, however, needs to be further researched.

The LF device presented high reliability in the detection of occlusal caries in primary teeth and its performance was similar to that of DV and radiographic examination.

What this paper adds

This is the first clinical study in primary teeth for the detection of occlusal caries with the DIAGNOdent™ to:

- validate the DIAGNOdent™ device using as reference a clinical applicable method for visual evaluation of lesion depth after pit and fissure opening.
- find the device to have very high reliability.

Why this paper is important to paediatric dentists

- This device may be in the absence of radiographic examination a non-harmful additional to direct visual examination tool, for occlusal dentin caries detection in primary teeth.
- Due to its excellent reliability, the device may be used for longitudinal monitoring of occlusal caries in primary teeth.

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