Consistency of DIAGNOdent instruments for clinical assessment of fissure caries

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DIAGNOdent (KaVo, Biberach, Germany) has shown high diagnostic accuracy and intra-operator agreement for caries detection, both in vitro and in vivo. The aims of this study were to compare DIAGNOdent with visual examination (VI) and bitewing radiographs (BW) for clinical assessment of occlusal fissures, and to evaluate inter-device consistency of clinical recording using four different DIAGNOdent instruments; secondly, to correlate DIAGNOdent readings with microbial culture of the measured site. The subjects were young adults, the material comprising 34 occlusal fissures, scheduled for restorative treatment at the Dental School Clinic of the University of Iceland. Two examiners conducted visual and radiographic assessments. One examiner measured each site with four DIAGNOdent instruments in random order. The fissure was then opened and lesion depth was classified on a 4-point scale. Bacterial samples were taken from the fissure before and after opening. Intra-operator agreement was high ($r = 0.85$–0.98). Inter-device correlation for the four DIAGNOdent instruments was significant in all cases ($r = 0.81$–0.92). However, a common cut-off point could not be determined. There was weak but significant correlation between DIAGNOdent readings and all three classes of lesion depth. Level of infection showed very weak correlation with the DIAGNOdent readings. It was concluded that DIAGNOdent is more reliable in detecting dentinal caries if a proper cut-off point is used than in indicating actual lesion depth. Readings from the different instruments were not directly comparable, however, owing to the lack of a common cut-off point. □ *Clinical detection; fissure caries; laser fluorescence; microbiology*

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There have been pronounced changes in both the epidemiology and pattern of dental caries over the past few decades. One major change is the slower progression of new lesions, which allows preventive intervention before the development of irreversible damage to the dental hard tissue.

On surfaces readily accessible to fluorides, the prevalence of lesions has decreased markedly: the most caries susceptible sites in young people are now the occlusal fissures (1). The complicated anatomy of fissures in the permanent molars makes hygiene difficult, with increased caries risk.

The problems inherent in detecting occlusal caries have been addressed in many studies (2–4). A further complication is the so-called hidden lesion, dentinal caries occurring beneath macroscopically intact enamel (3–7). Such lesions have been reported in 10–50% of an adolescent population (8–12). Conventional methods of caries detection are inadequate, especially with respect to hidden lesions. There is an obvious need for objective, quantitative methods for detecting and monitoring progression of such lesions.

DIAGNOdent is a relatively new instrument, developed as an aid to early detection of occlusal and smooth surface carious lesions. The instrument measures emission of fluorescent light from a tooth illuminated with light of a certain wavelength (655 nm). A carious lesion emits more intense fluorescence than sound tooth structure (13). The mechanism underlying this increase in fluorescence, however, is not fully understood. The mineral loss resulting in a white spot lesion does not seem to have a pronounced effect on the fluorescence of the enamel. It has been suggested that fluorescence of the carious tissue may be attributable to bacteria or their metabolites (13)

The results of the earliest in vitro studies of DIAGNOdent were quite promising: high sensitivity and good reproducibility (14–17). The instrument was shown to be superior to radiographs for detection of occlusal caries. It was suggested that the instrument could be used to monitor lesion progression over time, as well as to evaluate the outcome of preventive treatments (15, 18). In a number of in vitro studies, comparison with visual and radiographic examination showed DIAGNOdent to be the most accurate method for detection of occlusal caries (19–21). There are a few published clinical studies reporting similar results. Sensitivity seems to be good (0.75–0.96), although a few studies have reported low specificity (0.68–0.86) (21–24).

The aims of this clinical study were first to compare DIAGNOdent readings for detection of occlusal caries with visual examination and bitewing radiographs and to evaluate the consistency of data recorded under clinical

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Table 1. Modified Ekstrand criteria for visual examination (27)

Classification	Visual inspection	Interpretation, treatment decision
0	No or slight change in enamel translucency after prolonged air drying (>5 s)	Sound, no invasive treatment
1	Opacity or discoloration hardly visible on wet surface, but distinctly visible after air drying Or Opacity or discoloration distinctly visible without air drying	Suspicious, open with the smallest bur possible to determine what lies beneath
2	Localized enamel breakdown in opaque or discolored enamel and/or grayish discoloration from the underlying dentine	Definite caries, open with the appropriate sized bur

conditions by four different DIAGNOdent devices; and, second, to correlate DIAGNOdent readings and the microbial flora cultured from the measured site.

Materials and methods

The study was approved by the Ethics Committee, Huddinge Hospital (402/02), Stockholm, Sweden and the National Bioethics Committee in Iceland (02-151-S2).

Thirty-four occlusal lesions were examined in subjects aged between 18 and 30 years. The lesions were scheduled for restorative treatment at the Dental School Clinic, University of Iceland.

Two examiners evaluated the lesions by visual examination and gentle probing and radiographic examination using a lightbox. The findings were classified as indicated in Tables 1 and 2. One examiner, calibrated before study start, conducted the DIAGNOdent examinations blindly. A third person recorded the readings.

Each site was measured using four different DIAGNOdent devices (KaVo, Biberach, Germany). Application of the four instruments was randomized regarding the order of use. The instruments were calibrated against a ceramic standard before measurement of each subject. The standard value for each tooth was determined by measuring a sound site to allow for intrinsic variation in fluorescence of individual teeth. Before the DIAGNOdent examination, the teeth were cleaned with a rotating brush (Robinson Brush, KerrHawe, Bern, Switzerland) and water. The surfaces were then dried with compressed air for 5 s to standardize the humidity. Two measurements were made with each instrument, with water spraying and air drying between measurements.

Bacterial samples were obtained from all lesions. The first sample was taken before any invasive treatment, and after the application of rubber dam and thorough cleaning of the surface, using a rotating brush and water. The surface was dried with compressed air and a sterile paper point (no. 35) was inserted into the lesion. The paper point was then immediately inserted into a flask containing 1 mL reduced transport fluid and was subsequently processed for bacterial analysis. Another bacterial sample was taken after the carious tissue had been exposed mechanically in those cases where the preparation was big enough to fit a no. 10 round bur. Samples of carious dentine were collected by placing the sterile round bur directly beneath the amelodentinal junction. The bur was then handled in the same manner as the paper point in the first sample.

The bacterial samples were promptly transported to the laboratory and stored at 4°C until inoculation. Specimens were mixed on a vortex mixer for 15 s and 100 μL aliquots were inoculated onto the following 4 culture media: blood agar for determination of the total cultivable count; Rogosa agar for lactobacilli; Mitis-salivarius-bacitracin agar (MSB) for S. mutans; and Veilonella agar (Difco) for Veilonella. The Rogosa, blood agar, and MSB agar plates were incubated in a candle jar for 48 h at 37°C. Veilonella agar plates were incubated anaerobically at 37°C for 1 week. The plates were then evaluated for growth and colonies were identified and counted.

After thorough visual, radiographic and DIAGNOdent examinations, the occlusal fissures were opened with a fine diamond bur (Brassler thin diamond 8392/016). Any remaining carious dentine was excavated after the second bacterial sample had been collected where possible. As a sharp instrument has proved reliable in differentiating carious and sound dentine (25), an explorer was used to check for remaining soft dentine. The extent of the lesion was then determined by the two examiners, according to Table 2. The cavity was subsequently sealed with an appropriate restorative material.

All teeth were photographed with a digital camera, Nikon Coolpix 4500, before mechanical intervention and

Table 2. Classification of radiographic findings, the clinical lesion depth

Classification	Radiographic findings	Clinical lesion depth
0	No radiolucency visible	Sound enamel
1	Radiolucency visible in the enamel	Enamel caries
2	Radiolucency visible in the outer dentine, just beyond the DEJ	Shallow dentine caries
3	Radiolucency visible in the inner dentine, clearly beyond the DEJ	Deep dentine caries

Table 3. Spearman correlation to the clinical lesion depth/intraoperator agreement

Clinical lesion depth			Intra-operator agreement		
	Spearman correlations	*P*-level		Spearman correlations	*P*-level
DD1m	0.28 n.s.	0.105	DD1-1 vs DD1-2	0.98*	<0.001
DD2m	0.45*	0.007	DD2-1 vs DD2-2	0.95*	<0.001
DD3m	0.42*	0.012	DD3-1 vs DD3-2	0.97*	<0.001
DD4m	0.51*	0.015	DD4-1 vs DD4-2	0.85*	<0.001
BW	0.38*	0.026			
VI	0.43*	0.010			

after cavity preparation. These photographs served as records of the original lesions as well as the extension of the cavity preparations. The sites to be measured were marked on the photographs.

Statistical analysis

For inter-device and intra-operator agreements, Spearman's rank order correlation coefficient was used. Spearman's rank order correlation coefficient was also used to determine the agreement between DIAGNOdent readings, VI, BW, and the clinical lesion depth, the reference standard. False positive (FP), false negative (FN), and all correct observations for dentinal caries were calculated as percentages.

As the bacteriological variables were far from normally distributed, a ranking of the data was made. The correlations are then automatically in the form of Spearman correlations. Correlations between bacteriological data and other diagnostic variables were studied as well as among the bacteriological variables. Many high correlations were recorded for the latter, but, for the former, correlations were poor. For greater clarity, a dissimilarity matrix was constructed by subtracting the correlation matrix from an identity matrix. This was then subjected to both hierarchical cluster analysis and multidimensional scaling. These operations were carried out in order to "map" the variables in a few dimensions. Dissimilarities can be constructed by subtracting correlations from unity, i.e. one subtracts the correlation values from 1, thus obtaining values between 0, for complete similarity, and 2, which represents complete dissimilarity. A matrix with such dissimilarity values can be analysed in several ways. Here a hierarchical cluster analysis as well as a multidimensional scaling was carried out. The former method creates a 'family tree' out of the dissimilarity values, where more similar entities are closer to each other than more 'distant relatives'. The latter method is a mapping in few dimensions, preferably two, of the dissimilarities. Dissimilarities could also be regarded as distances, and the method is similar to creating a road map out of a table of road distances, which is perfectly feasible except that the map could of course become a mirror image of what was expected.

Results

After removal of all carious dentine, clinical lesion depth was classified according to Table 2. This classification served as reference standard. Of the 34 lesions examined, 8 were classified as enamel caries (Class 1), 15 as shallow dentinal caries (Class 2), and 11 as deep dentinal caries (Class 3). Table 3 presents an overview of the validity performance of the various diagnostic methods as well as the intra-operator agreement. The Spearman rank order correlations between the first and the second measurements showed significant agreements (Table 3) for all four devices. Device 4, though, showed a somewhat more diffuse pattern.

The bacterial counts showed very weak correlations with the DIAGNOdent readings and the clinical lesion depth (Table 4). Fig. 3 shows a two-dimensional relationship plot of all variables involved in the study.

With respect to inter-device agreement, all devices showed significant correlations ($P < 0.05$): DD1 range 0.81–0.92, DD2 range 0.81–0.92, DD3 range 0.87–0.92, and DD4 range 0.87–0.92.

The relationship between DIAGNOdent readings and clinical lesion depth is plotted in Fig. 1. Device 3, measurements 1 and 2, and device 4, measurement 1,

Table 4. Spearman correlation of bacterial counts to the DIAGNOdent (DD) measurements and the clinical lesion depth

	Total count	S. mutans	Lactobacilli	Anaerobes
Bacterial sample 1 vs. DD measurements	0.104–0.198	0.207–0.333	0.121–0.218	0.095–0.332
Bacterial sample 2 vs. DD measurements	0.144–0.289	0.059–0.162	0.094–0.190	0.054–0.379
Bacterial sample 1 vs. Clinical lesion depth	0.150	0.005	0.410*	0.013
Bacterial sample 2 vs. Clinical lesion depth	0.116	0.347	0.208	0.245

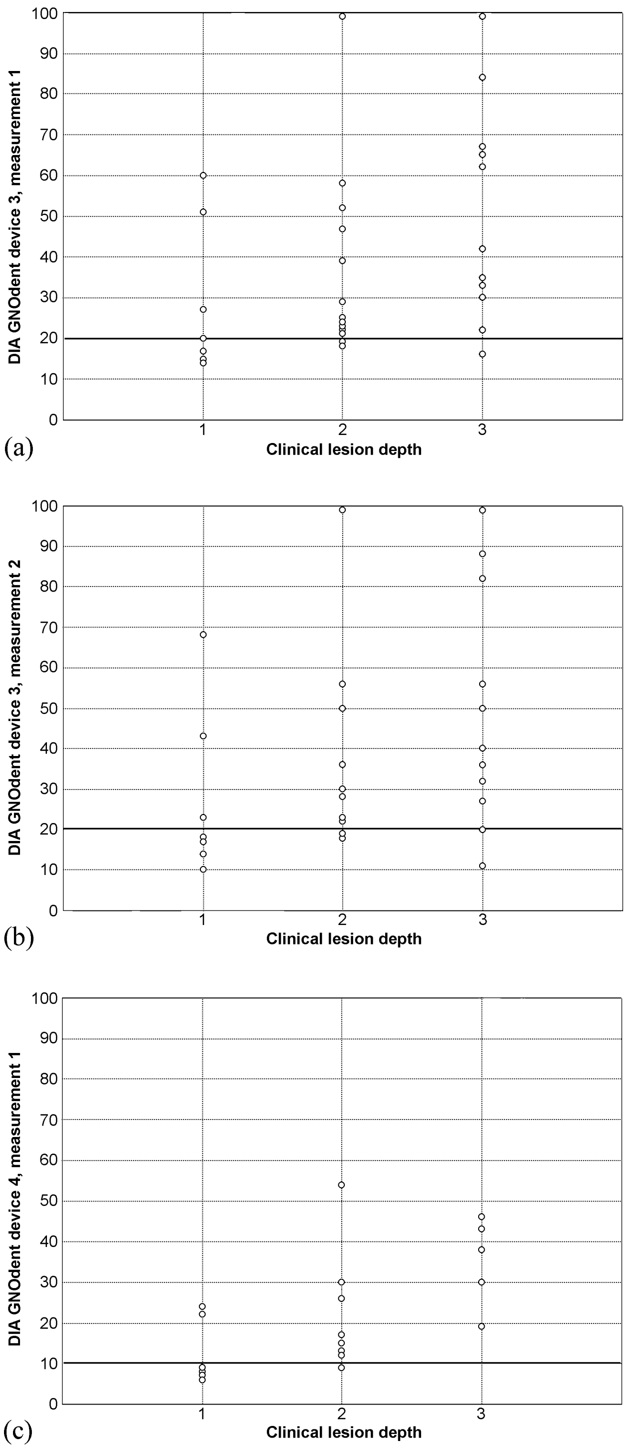


Fig. 1. The relationship between DIAGNOdent readings from device 3 (measurements 1 and 2) and device 4 (measurement 1) and the clinical lesion depth. (a) Cut-off point at 20 gives an overall fraction of correct diagnosis of 82% (false-positive 9%, false-negative 9%). (b) Cut-off point at 20 gives an overall fraction of correct diagnosis of 79% (false-positive 9%, false-negative 12%). (c) Cut-off point at 10 gives an overall fraction of correct diagnosis of 87% (false-positive 9%, false-negative 4%).

have been selected as examples. Suggested cut-off points for dentinal caries are presented in the plots.

Discussion

With the dramatic decline in the prevalence of caries and the changes in the pattern of disease, detection of occlusal caries has assumed an increasingly important role. The occlusal fissures are now the most caries-susceptible sites in children and young adolescents (1) and should be examined frequently for signs of caries. However, as dentinal caries can occur under a macroscopically intact surface (5), the detection of occlusal lesions by traditional visual inspection is difficult. There is need for an objective quantitative method for detection of caries and to support treatment decisions.

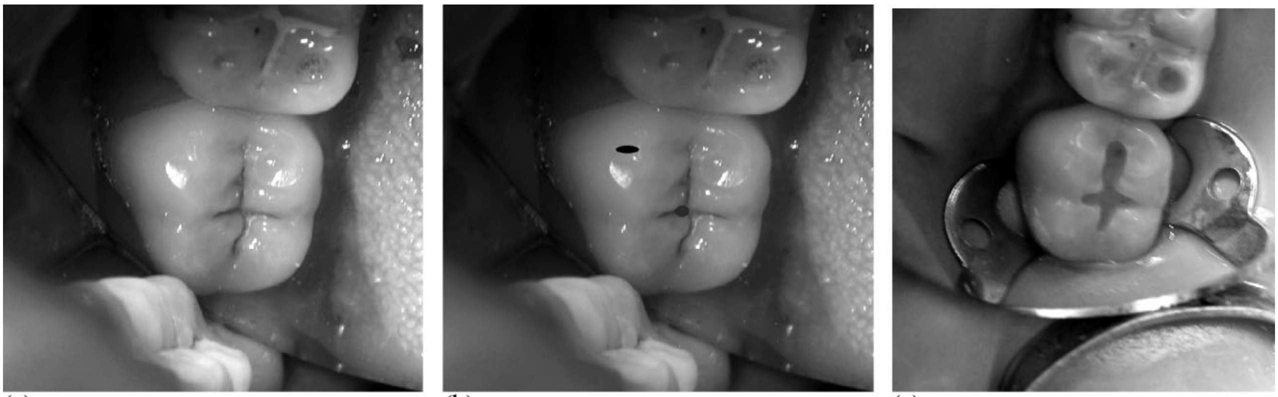
DIAGNOdent is a recently introduced instrument which has undergone testing for reliability and validity in several studies. In the present study, this instrument was compared with traditional caries detection methods under clinical conditions and correlated with bacterial counts of the lesions.

One of the difficulties in evaluating such an instrument in a clinical study is that no histological "gold standard" is available. True lesion depth may be questionable. In an attempt to support the estimation of clinical lesion depth in this study, two examiners determined the classification of each lesion. However, this can give a minor distortion of the results. Only two classes within the dentine were applied in order to minimize false estimations. In the same way, two measurements were made with each instrument to test the operator repeatability. The intra-operator agreement was good ($r = 0.85$–0.98). However, one device (DD4) showed poorer correlation. As the instruments were randomly used, this variation cannot be attributed to a change in humidity or other intraoral conditions. Therefore, some systematic differences are probably involved.

To investigate whether microorganisms might be the source of the fluorescence on which the DIAGNOdent readings are based, bacterial samples were collected from all measured sites. The bacterial findings, however, showed a weak correlation with the instrument readings. As shown in Fig. 3, the DIAGNOdent variables were relatively close together, but tended to lie to the extreme right while all bacteriological variables were clustered towards the lower left, with the reference standard close to the centre. All the variables seem to correlate relatively well with the reference standard, though weakly with each other.

As the increase in fluorescence within the carious lesion has been attributed to bacteria and their metabolites, these results were unexpected. This may have been due in part to problems associated with culturing Actinomyces and Veilonella. It proved difficult to identify the bacterial colonies in the case of Actinomyces, and the Veilonella agar showed mixed colonies of anaerobes.

Four DIAGNOdent devices were tested. As shown in



(a) (b) (c)

Fig. 2. Example of images of a lesion where the DIAGNOdent readings correlated better with the actual lesion depth than VI and BW. (a) Initial image. (b) The measured spots marked the experimental site in the fissure and the enamel reference point on the cusp. (c) After careful caries excavation. In this case, the lesion was classified as enamel caries by BW and VI. However, the DIAGNOdent readings ranged from 32 to 75, suggesting dentinal caries, which was confirmed by measurement of clinical lesion depth. Informed consent was obtained from the patient regarding publication of the photographs.

Table 3, correlation with clinical lesion depth, device 1 showed a n.s. correlation ($r = 0.28$). The correlations were significant for the other three devices but weak (0.4 to 0.51). As VI and BW also showed significant but weak correlations with lesion depth, the ability of the instruments to indicate actual lesion depth was no better than that of the traditional methods. These results indicate that the quantitative capacity of the instruments is inadequate.

An ideal diagnostic method should offer high sensitivity (small false-negative fraction) and high specificity (small false-positive fraction). However, these properties have proved to be difficult to achieve with the available methods. High specificity is usually achieved at the cost of reduced sensitivity, or high sensitivity may cause a decrease in specificity. The fact that only 6–12% of all teeth in this study were overrated by visual inspection demonstrates the high specificity of the method. The problem is the low sensitivity (large false-negative fraction). In this study, 23–26% of the teeth were underrated, a somewhat better result, however, than those of several earlier studies (3, 4, 6, 23, 26).

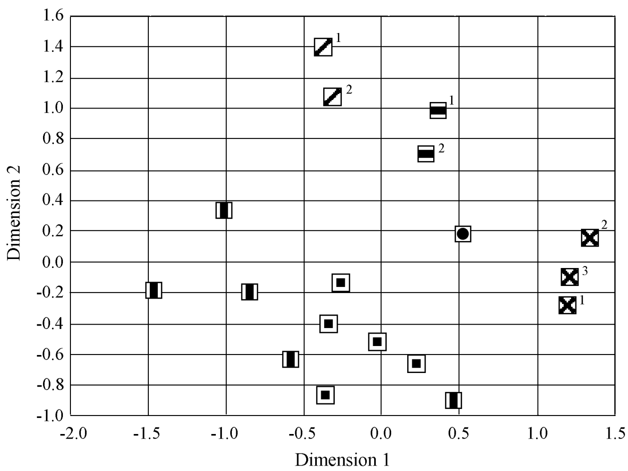


Fig. 3. A scatterplot showing the first two dimensions from a multidimensional scaling analysis of a $1 - r$ (Spearman r) matrix. Clinical lesion depth (the reference standard). Visual inspection, operators 1 and 2. BW radiographs, operators 1 and 2. Mean values of pairwise DIAGNOdent runs of instruments 1–3 (run no. 4 was excluded because of few observations). Bacterial counts from the first sample. Bacterial counts from the second sample.

It is important to note that the observers concentrated on occlusal caries, with greater focus on detecting those lesions than a general dental practitioner conducting a full clinical examination. Thus, in the clinical setting, when traditional methods of caries detection are applied, many lesions are undetected, or wrongly diagnosed as caries of enamel, allowing an underlying dentinal lesion to progress unchecked.

In this study, however, no exact calculations on specificity and sensitivity were possible. Teeth diagnosed by visual examination and by radiographs as sound were excluded from the study because, on ethical grounds, these surfaces could not be validated by invasive measures. If TN data are not validated, FN observation falls automatically within that group and gives false results. Thus true-negative and false-negative groups were excluded.

Of decisive importance in the case of DIAGNOdent examination is the cut-off point, that is to say, the level at which dentinal caries, with as much certainty as possible, can be detected. As can be seen in Fig. 3, the balanced cut-off points for two different devices varied: DD4 seemed to detect dentinal caries at 10, while DD3 showed a much higher cut-off point. It did not seem possible to determine the absolute cut-off point for the DIAGNOdent instrument. Each device appeared to have an individual cut-off level, a factor of major importance in clinical application of the instrument.

However, if the correct cut-off point is used, high specificity can be attained. In the examples in Fig. 1, the correctly diagnosed cases ranged from 79% to 87% of examined surfaces. Thus, in practice, sound surfaces would seldom be treated invasively. However, the proper cut-off levels with associated high specificity give low sensitivity.

The correlation between the DIAGNOdent measurements and lesion depths in all three classes was fairly weak but significant for most of the instruments. Thus, the measurement cannot be used to determine the exact lesion depth. However, when using the proper cut-off point, the method seems reliable for the detection of dentinal caries.

It can therefore be concluded that if a proper cut-off point is used the DIAGNOdent instrument is more reliable in detecting the presence of lesions of dentine than in indicating actual lesion depth: the instrument has good qualitative properties, but inadequate quantitative capacity. This study disclosed a major shortcoming, namely the lack of a universal cut-off point, which precludes comparison of different instruments.

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