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Clinical performance of DIAGNOdent in the detection of secondary carious lesions

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Abstract
The diagnostic value of DIAGNOdent in detecting primary occlusal caries has been investigated in many studies, although its use in *in vivo* detection of secondary caries remains unclear. The aim of this study was to investigate the ability of DIAGNOdent in *in vivo* detection of secondary caries on teeth with amalgam restorations. The material comprised 51 posterior teeth restored with amalgam material. Bitewing radiographs were taken of all teeth, in accordance with the standard clinical protocol, and analysed by five observers with respect to secondary caries. The restoration margins of each tooth were carefully scanned with DIAGNOdent and the site of the highest reading and its value were registered in a digital picture. The color (stained/unstained) of the restoration margins was also documented. The restoration material was removed and all cavities were examined carefully by two observers together, both visually and by probe. The results showed that the sensitivity and specificity of DIAGNOdent and conventional radiography in detecting secondary caries were 0.60/0.81 and 0.56/0.92, respectively. For DIAGNOdent, 100% of the teeth in the false-positive fraction had stains. Regarding receiver operating characteristic analyses, the A_z values were 0.78 and 0.69 for DIAGNOdent and radiography, respectively. We conclude that DIAGNOdent may be used only as an adjunct to conventional methods in detecting secondary caries on teeth with amalgam restorations.

Key Words: *Caries detection, diagnostic accuracy, laser fluorescence, secondary caries*

Introduction

Secondary caries remains an unsolved problem in dentistry and has become an important issue in daily dental practice, despite the improvement in quality of restorative material and in the orientation of dental health care towards prevention [1]. Among the factors that contribute to restoration failure, secondary caries accounts for 40–70% of restoration replacement [2], and is considered one of the most important reasons for restoration replacement, regardless of diagnosis inaccuracies [3,4]. The Fédération Dentaire Internationale defined secondary caries as a positively diagnosed carious lesion which occurs at the margins of an existing restoration [5]. The lesion usually consists of two carious regions: an outer lesion formed in the enamel or cementum of the tooth surface, similar in histology to a primary lesion, and the wall lesion, which is a narrower defect in the enamel and/or dentin along the cavity wall restoration interface [6,7]. These lesions are difficult to detect clinically, unless they are advanced or become cavitated.

Currently, vision, tactile sensation with probes, and bitewing radiographs are used in various combinations by practitioners in the diagnoses of secondary caries. Color change around a restoration is difficult to interpret, and is not a reliable indicator of secondary caries [8,9]. Sharp explorers have to be used with care in detecting secondary caries around a restoration, since jabbing the tooth/restoration interface may damage the dental tissue or filling material. In addition, a catch on a restoration is not synonymous with caries because an explorer will catch in any crevice [7]. Radiography is of limited value in the diagnosis of secondary caries because of the shading effect of the restorative material [10,11].

Accurate detection of secondary caries is difficult with conventional techniques unless the lesion is

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relatively advanced and a significant amount of tissue has been lost. It is therefore necessary and important to look for and test new methods and thus aid clinicians in the detection of secondary caries.

DIAGNOdent (KaVo, Biberach, Germany) is a relatively new laser fluorescence-based instrument. The mechanism underlying the method is that carious lesions exhibit stronger fluorescence than sound tooth tissue in the red and infrared part of the spectrum [12,13]. Since the amount of fluorescence collected from a carious region is higher than that from sound tissue, a higher number is displayed on the panel of the instrument. The origin of the fluorescence phenomenon in the presence of caries has never been fully clarified. Recent experiments have shown that oral bacterial metabolites, possibly porphyrins, may contribute to the fluorescence [13]. DIAGNOdent has been evaluated in several *in vitro* and *in vivo* studies for detecting and quantifying primary carious lesions [14–21]. These studies suggested that DIAGNOdent had the ability to detect primary carious lesions with higher accuracy and reproducibility than conventional methods, such as bitewing radiography and visual inspection. DIAGNOdent has also been evaluated in *in vitro* studies for detecting secondary carious lesions [22,23], these studies suggesting that DIAGNOdent may have the potential to detect secondary caries and could be a valuable adjunct to conventional methods. However, it has not been tested clinically for detection of secondary caries to determine whether the previously reported laboratory values for DIAGNOdent are applicable under clinical conditions.

The aim of this study was to validate DIAGNOdent *in vivo* in the detection of secondary caries in teeth with amalgam materials.

Material and methods

The study was approved by the ethics committee at Huddinge University Hospital, Huddinge, Sweden (101/03). The subjects were selected from the postgraduate clinic, Department of Cariology, Karolinska Institutet, Huddinge, Sweden. The procedure was explained and informed consent was obtained from all subjects before the start of the examination.

The material comprised 51 posterior teeth restored with amalgam material from 21 patients aged between 19 and 45 years. The patients needed replacement of old tooth restorations for one or two of the following reasons: (1) secondary caries, (2) defective restoration, (3) esthetic reasons, (4) other reasons (Table I). Teeth with heavy stains were not included in the study.

All teeth in the study were documented with a digital camera (FinePix 4700 zoom; Fuji Photo Film Co., Ltd.) at the first visit. The images were saved in a PC and printed out on paper to facilitate measurement with DIAGNOdent at the second visit.

Table I. Causes for removal of amalgam restoration on teeth sample

Causes for amalgam removal	No. of teeth	Premolar teeth		Molar teeth	
		Class I	Class II	Class I	Class II
Secondary caries	19	2	5	5	7
Esthetic reasons	15	5	4	3	3
Defective restoration	12	1	2	5	4
Other reasons	5	0	0	2	3
Total	51	8	11	15	17

Measurement with DIAGNOdent

Before the DIAGNOdent was used, the restoration margins of each tooth were carefully cleaned with a toothbrush and water/air spray. All teeth were air-dried for 5 s with compressed air prior to measurement. Before removing the restorative material, DIAGNOdent was used to measure the restoration margins. The cone-shaped tip was used to enable access to the sample sites with ditching and to improve the sensitivity of caries detection [24]. The instrument was calibrated before every measurement against the ceramic standard supplied and zeroed on sound enamel of each test tooth. Two operators participated in the measurement with DIAGNOdent.

The margin between the restoration and the tooth was carefully scanned with DIAGNOdent, i.e. the first operator placing the DIAGNOdent tip directly on the tooth/restoration margin. The highest reading and its corresponding site were recorded on the digital picture by the second operator. The first operator and two examiners who performed validation were blind to the DIAGNOdent reading.

Visual inspection

The site determined by DIAGNOdent was examined visually under conventional clinical lighting and the marginal integrity of the restoration at this site was recorded in accordance with one of three categories: as clinically intact (restoration closely adapted to the tooth structure), ditching (a visible gap along the margin, no caries discernible), and caries. The color of the tooth structure at the margin of the restoration was noted as stain-free or stained.

Radiographic examination

Bitewing radiographs were captured of all teeth in accordance with the standard clinical protocol, unless the patient had had a bitewing X-ray taken less than 6 months earlier. A Prostyl Intradental unit (Planmeca, Finland) and Kodak Ektaspeed Plus films were used at 70 kV and 8 mA. The focus-to-film distance was 20 cm. All films were developed in a standardized manner. The radiographs were twice examined independently by 5 experienced dentists, with an interval of 2 weeks between examinations. The observers were asked to look at the restoration margins at the site

marked on the photographs. At the first examination, diagnosis was given in terms of sound and secondary caries. At the second examination, the observers were instructed to select one of five ratings to present his or her level of confidence that a secondary carious lesion was present or not at the margins of the restorations. The following scale was used: 1 = definitely not caries, 2 = probably not caries, 3 = questionable, 4 = probably caries, 5 = definitely caries. The films were viewed under identical conditions for all observers on a light box at a magnification $\times 2$.

Validation

The restorative material was removed from the cavity by the first operator using a tungsten carbide bur in a high-speed hand-piece under copious water coolant. Great care was taken to avoid contact with the cavity walls and the margins. The small remnants of restorative material in the cavity were carefully removed using a sharp excavator. The gold standard was obtained based on clinical examination, i.e. visual inspection and tactile consistency, by two examiners. In the case of disagreement, consensus was reached. The diagnosis was expressed as sound or carious tissue adjacent to restoration and related to the site marked on photographs.

Data analysis

The diagnostic performance of DIAGNOdent and radiography for secondary caries detection was evaluated in terms of receiver operating characteristic (ROC) analysis. The ROC curve is a plot of the true-positive fraction, TPF (sensitivity), against the false-positive fraction, FPF (1-specificity), for the different possible cut-off points of a diagnostic test. The resulting curve illustrates how sensitivity and specificity vary along the entire diagnostic range. ROCs (Rockit 0.9B Beta version) were plotted for the radiographic examination for each observer based on five score of confidence level and for the DIAGNOdent reading. To make the data comparable between radiographic examination and DIAGNOdent measurement when performing ROC analysis, the DIAGNOdent readings were classified within the following 5-point scale: 1 = values ranging from 0 to 10; 2 = values ranging from 11 to 20; 3 = values ranging from 21 to 30; 4 = values ranging from 31 to 40; 5 = values above 40. The areas under the curve (Az) were calculated for DIAGNOdent and for each of the five observers. Sensitivity and specificity were also calculated for DIAGNOdent, radiography, and visual inspection. For DIAGNOdent, the cut-off point for the presence of secondary dentinal caries was chosen based on our results by comparing DIAGNOdent values with the gold standard in order to balance sensitivity and specificity and preferably having specificity higher than 0.80. For radiographic analysis, the majority answer of five observers in terms of sound or caries was used to calculate sensitivity and specificity.

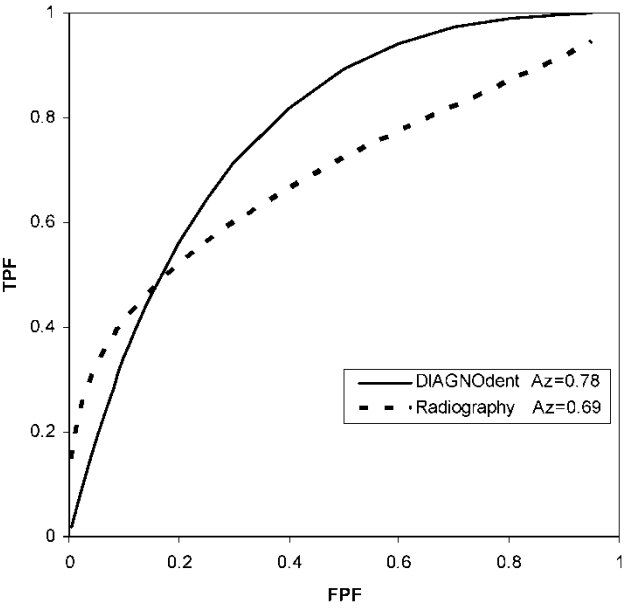

Figure 1. Receiver operating characteristic (ROC) curves for DIAGNOdent and bitewing radiography for secondary caries detection.

Results

The assessment of 51 restored teeth according to the gold standard classified 26 (51%) as sound and 25 (49%) with secondary caries. For DIAGNOdent, the best cut-off point derived from the present study for secondary dentinal caries was 30, considering both sensitivity and specificity. The sensitivity and specificity of DIAGNOdent and conventional radiography in detecting secondary caries were 0.60/0.81 and 0.56/0.92, respectively. Sensitivity and specificity of visual inspection of the marginal site were 0.44 and 0.96, respectively. Figure 1 demonstrates the ROC curves for DIAGNOdent and bitewing radiographs based on the mean value of five observers. The areas under the ROC curves were 0.78 and 0.69 for DIAGNOdent and radiography, respectively.

Staining of tooth-filling margin was present in 29% of the teeth. For DIAGNOdent, in the false-positive fraction all the teeth were registered stained at the measuring sites.

Discussion

In the present *in vivo* study, the DIAGNOdent was evaluated for detecting secondary caries in order to determine whether the previously reported laboratory values for the device are applicable under clinical conditions [22].

Among other characteristics, an ideal diagnostic method should offer high sensitivity and high specificity, but these are difficult to achieve with

DIAGNOdent under clinical conditions. As the sensitivity and specificity of a method is determined largely by a single cut-off point, it is important that this is selected appropriately. In the case of caries diagnosis, specificity should exceed 0.80 if a minimum false-positive fraction is to be assured. After comparing the DIAGNOdent values with the gold standard, it was found that, if acceptable specificity was to be reached, 30 was the best cut-off value for the presence of secondary dentinal caries. This is higher than the previous cut-off value from an *in vitro* study, in which specificity was found to be 20 [22]. The sensitivity of DIAGNOdent for detecting secondary caries in this *in vivo* study was lower than in the previous *in vitro* study (0.77), while specificity was similar [22]. There may be many reasons for the lower sensitivity found in this study. First, the performance of DIAGNOdent could have been affected by oral environmental factors such as saliva, oral micro flora, body temperature, and is likely to be less consistent. Secondly, under *in vitro* conditions it was easier to clean the margins than in the clinical setting. Finally, under clinical conditions, DIAGNOdent was more difficult to use clinically in particular in interproximal areas for class II restorations, because the interproximal space may be more limited *in vivo* than in artificial tooth blocks. Furthermore, although the cone-shaped tip was used for the DIAGNOdent examination, the tip diameter was too big to enter the proximal margins. Therefore, a smaller tip might produce more accurate results. Visual inspection of the marginal site showed low sensitivity (0.44), which would result in more than 50% of teeth with secondary caries being misclassified as sound with visual inspection. Therefore DIAGNOdent may be helpful in compensating for the low sensitivity of visual inspection. Marginal stains were associated with high DIAGNOdent readings. All the teeth in the false-positive fraction of DIAGNOdent measurements had stains. When assessing the performance of DIAGNOdent on stained lesions it is therefore important to be aware that the signal may be over-stimulated.

The number of observers has an impact on sensitivity and specificity evaluations, especially on subjective methods such as radiographic examination. Five observers might therefore yield a more accurate interpretation of diagnostic performance. The results from the radiographic examination were comparable to those of most other studies on radiographic secondary caries detection where high specificities and moderate sensitivities were found [25,26]. ROC analysis was performed in order to overcome the shortcoming of sensitivity and specificity, which are decided by one cut-off point. One of the most commonly used measures of accuracy of a diagnostic test is the area under the ROC curve. The closer the ROC curve area is to 1.0, the better the diagnostic test. The result from the ROC curve indicates that the overall diagnostic performance of DIAGNOdent was higher than radiography for secondary caries detection. However, for caries diagnosis the most clinically important range of the false-positive fraction is between 0 and 0.2, and the radiographic curve demonstrated higher diagnostic performance than the DIAGNOdent curve. This is possibly due to the fact that radiographic examination has a higher degree of specificity than sensitivity, which means that the false-negative diagnoses are proportionately more likely to occur in the presence of caries than false-positive diagnosis in the absence of caries.

With the relatively lower performance of DIAGNOdent under clinical conditions than under *in vitro* conditions, the recommendation for detection of secondary caries cannot be based on the DIAGNOdent values alone. Furthermore, under clinical conditions it is inappropriate to apply a cut-off value of DIAGNOdent rigidly when considering treatment decisions because sound and carious sites are represented by overlapping ranges of DIAGNOdent values. If a cut-off value for secondary caries >30 is used, it makes little sense to treat lesions with scores of 30 or 31 differently without considering the factors that can affect this reading, such as the presence of stains, deposits and calculus, or without applying an additional method of assessment. Therefore, the decision whether or not to carry out an operative intervention should not be based on the DIAGNOdent values alone.

In conclusion, the results of the present *in vivo* study indicate that the decision whether or not to carry out an operative intervention should not be based on the DIAGNOdent values alone. However, DIAGNOdent may be a valuable adjunct to conventional methods for detecting secondary caries on teeth with amalgam restorations and can be used as a second opinion in cases of doubt after application of conventional methods, and with special consideration to the factors that can affect DIAGNOdent readings.

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