Abstract

- **Objective:** The Spectra™ Cariess Detection Aid is a fluorescent camera (FC) caries detector device that has been demonstrated to detect occlusal caries extending into dentin with good sensitivity and specificity. This in vitro study examined the diagnostic performance of this device with the goal of defining the numerical reading that best indicates that a tooth has dentin caries.

- **Methods:** Ninety extracted human third molars, that either appeared clinically intact or had early occlusal caries, were used. Teeth were photographed then analyzed using the Spectra Cariess detector. Following Spectra readings, the teeth were sectioned perpendicular to the long axis of the tooth. Cuts were made in such a way as to expose the dentino-enamel junction below the pits and fissures. The sectioned teeth were scored as being caries-free, having enamel caries, or dentin caries. Using each tooth’s Spectra reading and histological diagnosis, the sensitivity and specificity for various potential dentin caries cut-off values were calculated. Also, the receiver operator curve (ROC) was plotted and the area under the curve calculated.

- **Results:** At the manufacturer’s recommended cut-off for dentin caries diagnosis of 2, the sensitivity is 0.68 and the specificity is 0.78. At a lower cut-off value in the study reported here of 1.8, it was observed that the sensitivity is higher at 0.87, but that the specificity is lower at 0.7. The overall diagnostic performance of the Spectra is good with an ROC area under the curve of 0.82.

- **Conclusion:** Although lower cut-off values may have higher sensitivity, the use of the manufacturer’s established cut-off of 2 will result in fewer instances where dentin caries will be diagnosed incorrectly. The use of higher thresholds will discourage restorative treatment of early lesions that are best managed by sealants or other preventive approaches.

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even reverse if the etiological factors are removed. Fluoride, arginine calcium carbonate complex, amorphous calcium phosphate/casein phosphopeptide, and other agents that facilitate the remineralization of acid-damaged tooth structure can contribute to the management of early lesions. Many of these remineralizing agents can be formulated into oral hygiene products that people can use at home. Dental professionals apply other treatments, such as fluoride, sealants, varnishes, and resin infiltration.

The clinical examination of individual teeth needs to not only reflect the presence of cavitated lesions, but also allow recognition and the recording of early caries-related tooth structure changes that represent possible sites of future cavitated lesion formation. These non-cavitated lesions also act as physical signs that the caries process is active in a patient’s mouth. Visual examination and charting using the ICDAS (International Caries Detection and Assessment System) records the presence of various stages of non-cavitated, as well as cavitated lesions. This system has been expanded so that the activity status of individual tooth surfaces can be assessed as well. Although based on subjective visual determinations, ICDAS has been shown to be a reliable and accurate method of caries scoring.

The caries process alters the physical characteristics of tooth tissue, particularly the optical properties of enamel and dentin. This has led to the development of various devices that have been introduced into clinical and research use to aid in the detection of caries. Much of the clinical use of these caries detector devices has been to aid in the recognition of early occlusal caries, since these lesions are difficult to detect visually and are not visible on radiographs. Quantitative light fluorescence (QLF; Inspektor Research Systems BV, Amsterdam, The Netherlands) uses a wavelength of blue light that induces deep tooth structures such as dentin and the dentin enamel junction to fluorescence. When viewed with the QLF, areas of early caries in enamel, that are noticeable clinically as white spot lesions (WSLs), appear as dark areas since the increased porosity of the partially demineralized enamel scatters light within these lesions. The QLF also detects areas of dentin caries and has been used in clinical studies examining the ability of agents to affect the remineralization of WSLs and monitor teeth with sealed occlusal lesions for signs of caries progression.

The laser fluorescent (LF) device DIAGNOdent (KaVo, Biberach, Germany) emits a wavelength of laser that excites fluorescence in bacterial pigments that are found in caries. This device has the ability to quantify dentin caries, but does not detect enamel demineralization. Tooth pigmentation of non-carious origin can result in false positives. These artifacts can be the result of cleaning the tooth’s occlusal surface with certain prophylaxis pastes. Conversely, the position of pigmented carious tooth structure deep within the occlusal pits and fissures may result in the lesion severity being underestimated by the LF device.

Fluorescent camera (FC) caries detectors, such as the VistaProof (Dürr Dental AG, Bietigheim-Bissingen, Germany) and the Spectra® Caries Detection Aid (Air Techniques, Melville, New York, USA), emit blue-violet light at a wavelength of 405 nm. This induces different fluorescent emissions from intact and carious dentin. FC devices create images of the examined tooth surface that can be viewed with a computer. As is the case with the QLF, enamel WSLs are identified as areas of reduced tooth fluorescence, and dentin caries are identified by their distinct fluorescence. The Spectra's Visix® software creates a false color image of the tooth surface, with different colors and numerical values indicating areas and the severity of enamel demineralization and dentin caries (Table I). Both LF and FC devices can accurately detect early occlusal lesions in teeth treated with clear pit and fissure sealants.

### Table I

<table>
<thead>
<tr>
<th>Value</th>
<th>Color</th>
<th>Caries depth</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0-0.9</td>
<td>Green</td>
<td>Sound enamel</td>
</tr>
<tr>
<td>0.1-1.4</td>
<td>Blue</td>
<td>Initial caries in enamel</td>
</tr>
<tr>
<td>1.5-1.9</td>
<td>Red</td>
<td>Enamel caries up to DEJ</td>
</tr>
<tr>
<td>2.0-2.4</td>
<td>Orange</td>
<td>Dentin caries</td>
</tr>
<tr>
<td>≥ 2.5</td>
<td>Yellow</td>
<td>Deep dentin caries</td>
</tr>
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</table>

An important question for clinicians is: Will the use of caries detectors improve the treatment of caries? Information that is pertinent to this decision is data attesting to the reproducibility and reliability of the device’s measurements and accuracy of the diagnosis. FC measurements have been shown to be reproducible when the diagnostic performance of trained examiners is compared to each other and themselves at various times.

Established metrics exist that are used to gauge the accuracy of diagnostic methods. In assessing the accuracy of a diagnostic classification, the diagnosis has to be compared to a true determination of the presence or absence of disease. This is referred to as the “gold standard” determination. For occlusal caries diagnosis this is relatively simple; teeth can be sectioned or have cavity preparations made, and the tooth structure examined for the presence of caries. In this histological examination, dark soft dentin located below the dentino-enamel junction in the area of the pits and fissures indicates dentin caries. This approach has limited applicability to clinical studies since cavity preparation procedures are not performed in the absence of lesions needing restorative treatments.

In a recent study, third molars were examined for occlusal caries by clinical examination and a variety of devices. The examined teeth were then extracted, sectioned, and examined for the true presence of caries. This methodology allowed the diagnostic accuracy of the various methods to be evaluated under clinical conditions.

One goal of this type of study is to establish the ability of a caries diagnostic method to detect lesions that are not visually apparent, but have invaded dentin. For caries detection devices that provide numerical values, this involves a determination of a cut-off value that clinicians can use as a reliable indication of dentin caries. Experimentally, this is done by testing the accuracy of various detector-provided scores and selecting the instrument reading that is most likely to reflect the presence of dentin caries.

*In vitro* studies are frequently employed to assess the diagnostic performance of caries detectors. In the study reported here, the accuracy of the Spectra Caries Detection Aid in detecting dentin caries was assessed. Both the accuracy of the manufacturer’s recommended cut-off and alternative values were evaluated. The results of this study should assist clinicians in the interpretation of readings obtained and incorporating them into treatment decisions.
Materials and Methods

Specimen Selection
This in vitro study was conducted on 90 extracted human third molar teeth. The collection of teeth from consenting subjects was approved by the Rutgers Institutional Review Board (protocol #0120050074). Following extraction, teeth were debrided and stored in 1% phenol. Teeth were used within one month of collection. In selecting the teeth used in this study, care was taken to include teeth lacking visually apparent caries and teeth with small lesions. Teeth with large lesions were excluded. Each tooth’s occlusal surface was photographed with a digital camera (Canon, USA, Lake Success, NY, USA).

Use of the Spectra Caries Detection Aid and Histological Evaluation of Caries
Spectra measurements were made using the manufacturer’s instructions following a procedure described previously.27 The occlusal surfaces of the teeth to be examined were cleaned with fine pumice using a bristle brush connected to a low speed handpiece. This procedure had no effect on the tooth’s Spectra reading.28 Measurements were made in triplicate to ensure reproducibility on moist tooth surfaces using the Spectra handpiece with 10 mm spaces used for molar examinations. The examiners were trained in a calibration exercise by the principal investigator (KM). Ten teeth were examined having various stages of occlusal caries. By using uniform examination methods and positioning, the examiners were able to obtain readings that were within ± 0.2 of each other.

Using this procedure, the Spectra image and readings were obtained for the occlusal surface of each tooth. Following Spectra imaging, the teeth were sectioned perpendicular to the long axis of the tooth using a low speed saw (Isomet, Buehler LTD., Lake Bluff, IL, USA) with a diamond blade and water lubrication. Teeth were cut at the level of the dentino-enamel junction at the base of the occlusal pits and fissures. The cut surface was photographed at eight-fold magnification and examined for the presence of dentin caries as denoted by dark soft material.27 The cut surfaces were examined by two examiners and scored as either having or lacking histological evidence of dentin caries. Teeth with evidence of white-demineralized enamel fissures lacking dentin pigmentation were scored as negative.

Assessment of Diagnostic Performance
The Spectra’s software produces a false color map and numerical values indicating intact tooth structure, enamel demineralization, and dentin caries (Table I). For each tooth, the highest value obtained was used for subsequent analysis since clinicians in making treatment decisions would use this value. As determined by the manufacturer, a value of 2 indicates dentin caries. The result of each tooth’s Spectra determination of the presence of dentin caries was then compared to that tooth’s histological examination result. In this way, the number of true and false determinations of dentin caries or absence of dentin caries can be calculated. Using this data, the sensitivity and specificity of the Spectra in detecting dentin caries was determined.29 The sensitivity is the proportion of correct determinations of the disease among the specimens with the disease. This value will be low if the test fails to detect the disease in specimens where it is present (false negative results). The specificity is the proportion of specimens that test negative for the disease among the population where it is absent. This value is adversely affected by specimens that test positive and lack the disease (false positive results).

The sensitivity and specificity for dentin caries diagnosis using the manufacturer’s recommended cut-off value of 2 and for all readings from 1.2-2.7 were then calculated. This was done in order to determine if the manufacturer’s cut-off value of 2 was the ideal threshold for a diagnosis of dentin caries, or if at some other value there would be better agreement between the Spectra and the histological diagnosis.

An important method of evaluating the accuracy of a diagnostic technique is to plot a receiver operator curve (ROC).29 This is a plot of true positive rate (sensitivity) versus the false positive rate (1-specificity) for each possible cut-off value examined. The area under the curve (1.0 representing the maximum value) is a reflection of the diagnostic method’s quality. If for each cut-off the true positive rate equals the false positive rate forming a diagonal line with a slope of 45° and an area under the curve of 0.5, then the method has equal chances of delivering a correct or incorrect diagnosis. Alternatively, an area under the curve close to 1.0 indicates that for many cut-off values, the proportion of true positives greatly predominates over the false positive rate. Statistical calculations of the diagnostic parameters used in this study were performed on SAS version 9.1.3 (SAS Institute Inc., Cary, NC, USA). Significance was set at the < 0.05 level.

Results
Photographs of two teeth used in this study are shown in Figures 1A and 1D, and the Spectra image of these teeth are shown in Figures 1B and 1E. In these images, various colors and numerical values indicate intact or areas of caries involvement as described in Table I. The peak value for the tooth in Figure 1A is 2.1, indicating dentin caries. Examination of the cut section of this tooth (Figure 1C) shows areas of enamel demineralization and dark areas in the dentin evidencing dentin decay. In contrast, the peak Spectra reading for the tooth shown in Figure 1D is 1.7, a value consistent with enamel demineralization. Examinations of this tooth’s cut surface (Figure 1D) indicated white areas of demineralization within the fissures, but no dentin decay.

In order to determine which Spectra numerical value provides the most accurate cut-off value for the diagnosis of dentin caries, the sensitivity and specificity at each Spectra value ranging from 1.1–2.7 is shown in Figure 2. These values represent a range of Spectra reading that may be measured from teeth with small occlusal caries. At low Spectra scores the sensitivity is high, indicating that all the teeth with dentin caries will test positive. At the low scores, however, the specificity is low, indicating that most teeth given a positive diagnosis will in fact lack dentin caries. At Spectra readings above 1.5, the specificity diagnosis raises and the sensitivity declines. The sensitivity and specificity lines cross one another at a Spectra reading of approximately 1.9. At high Spectra readings, the specificity is high, indicating few false positive diagnoses. At these high readings the sensitivity is low, indicating that many correct diagnoses of dentin caries are missed.

The data in Figure 2 indicate that the value where the sum of the sensitivity and specificity are highest is 1.8. At this value, the sensitivity and specificity are 0.87 and 0.70, respectively. At 1.9 the
Sensitivity and specificity are nearly equal at 0.77 and 0.76, respectively. When sensitivity and specificity were calculated at the manufacture’s recommended cut-off of 2 they were 0.68 and 0.78, respectively. Table II also gives other parameters of diagnostic performance; these are the false positive and false negative rates. At Spectra readings of 1.8 the false positive and false negative rate are 29.73 and 13.21 percent, respectively. At 2.0 the false negative rate is higher, 32.08%. At 2.0 the false positive rate is 21.62%, lower than the false positive rate calculated at the cut-off of 1.8.

Using the sensitivity and specificity data in Figure 2, the Spectra’s ROC curve was constructed and area under the curve calculated (Figure 3). The area under the curve is 0.82 with a 95% confidence interval of 0.73–0.92. This is significantly greater than an area of 0.5, a value that would indicate an equal chance of obtaining a correct or incorrect diagnosis.

Table II
Diagnostic performance of the Spectra Caries Detection Aid at the Manufacture’s Recommended Cut-off of 2.0 and at 1.8, a Value with High Sensitivity

<table>
<thead>
<tr>
<th></th>
<th>At Cut-off=2.0</th>
<th>At Cut-off=1.8</th>
</tr>
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<tbody>
<tr>
<td>Sensitivity</td>
<td>0.68</td>
<td>0.87</td>
</tr>
<tr>
<td>Specificity</td>
<td>0.78</td>
<td>0.70</td>
</tr>
<tr>
<td>False positive rate</td>
<td>21.62%</td>
<td>29.73%</td>
</tr>
<tr>
<td>False negative rate</td>
<td>32.08%</td>
<td>13.21%</td>
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Figure 1. Method used to compare diagnosis of dentin caries by the Spectra Caries Detection Aid with the histological gold standard determination of the tooth’s true caries condition. (A) Tooth with pigmented pits and fissures. (B) Spectra image and readings. Peak reading of 2.1 suggests dentin caries. (C) Removal of tooth’s occlusal surface reveals white areas of enamel demineralization and dark brown areas of dentin caries. In the case of this tooth, correct diagnosis of dentin caries by the Spectra. (D) Photograph of second tooth that also possessed stained pits and fissures. (E) Spectra image and numerical readings from this tooth gave a peak reading of 1.7 indicating enamel demineralization without dentin caries. (F) The cut surface of this tooth revealed white demineralized enamel lining the fissures and no indication of dentin caries verifying the Spectra diagnosis.

Figure 2. Sensitivity and specificity of the Spectra’s at various cut-off values. At cut-off values of 1.8-2.0 both sensitivity and specificity are high. At the manufacture’s established cut-off value of 2.0 there is good sensitivity and a low frequency of false positive diagnoses.
Discussion

All diagnostic tools have limits to their accuracy and reliability. Sources of pigmentation may cause false negative readings in caries detectors. In early occlusal caries, areas of enamel demineralization and dentin caries may be deep within the pits and fissures, making detection difficult. LF values are reduced when tooth structure, especially demineralized enamel, is placed between the fluorescence source and the detector. When LF values were examined in teeth with occlusal caries, removing the enamel from the tooth’s occlusal surface increased the intensity of the instrument’s reading. These anatomic factors may cause caries detectors to fail to correctly detect caries when present. In order to determine how accurately caries detectors can perform, studies such as this one are needed where the agreement of the detector’s diagnosis is compared to a histological gold standard.

In our previous report we compared the sensitivity and specificity of the Spectra to clinical and bitewing radiographic examination of occlusal caries. In that study, ICDAS was used to characterize lesions in clinical examinations. The results of that study indicate that the Spectra has comparable sensitivity and specificity to a conventional clinical examination, and superior performance to the radiographic detection of occlusal caries.

The sensitivity and specificity we report for the Spectra when used at the recommended cut-off value of 2 is consistent with earlier reports of the accuracy of FC types of caries detectors. The ROC area under the curve estimate of 0.82 is also consistent with estimates made in studies of other FC devices, and denotes good diagnostic performance.

Our results indicate that a cut-off of 1.8 or 1.9 may be more sensitive than the manufacture’s recommended cut-off of 2. Based on a consideration of other diagnostic criteria (Table II), we view the threshold of 2 as being clinically appropriate since at this value there is a lower rate of false positive diagnosis than at those lower values. The tooth shown in Figure 1D-F is an example of a tooth where using a lower cut-off would result in a false positive diagnosis of dentin caries. The relatively high false negative rate (32.08%) at the cut-off of 2 suggests that teeth need periodic reevaluation to ensure that lesions with boarder line characteristics don’t progress.

The use of caries detectors has been criticized since it can lead to more restorative intervention of early lesions. In human populations, the prevalence of the disease influences the proportion of disease diagnoses that are correct. In practices where caries rates are low, using an instrument with a specificity of 0.70 may result in the diagnosis of dentin caries in many teeth where it does not exist. Although teeth with subsurface-pigmented occlusal lesions are at high risk for developing caries that can be probed, restorative treatment is not the preferred option to preserve these teeth.

Early occlusal lesions, especially those that are restricted to enamel, should be treated with sealants and careful monitored. Sealants can arrest the caries process, even when it has extended into dentin. The Spectra and other caries detectors can assess enamel and dentin occlusal lesions through clear sealants. Since the Spectra generates both images and numerical out-puts that can be incorporated into a patient’s electronic dental record, it is a useful method for monitoring teeth and educating patients concerning their dental health and treatment needs.

In making a caries diagnosis, “the truth and the consequence” of the diagnostic decision have to be considered. The decision to restore a tooth should be made judiciously since restorations have finite life expectancies and cycles of repeated restoration compromise the survival of the tooth. Caries detectors including FCs can be used to assess the ability of preventive therapies to arrest or reverse early carious lesions. If following monitoring, the Spectra reading from a tooth increased to values above 2, this would indicate that caries has progressed into dentin and that restorative treatment should be initiated. Careful use of the diagnostic information provided by the Spectra and other caries detectors can be facilitated by an interpretation of the readings, so that there are good sensitivity and specificity values that minimize the occurrence of false positive diagnosis.

Conclusion

When interpreted using the established cut-off value, the Spectra Caries Detection Aid provides accurate diagnosis of occlusal dentin caries. The Spectra has a low incidence of false positive dentin caries determinations. With proper interpretation and as an adjunct to traditional methods of diagnosis, the use of the Spectra should not result in the performance of unnecessary restorations. In accepted contemporary use, the Spectra and other caries detectors should be used to assess teeth and educate patients concerning the need for preventive interventions.

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