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In Vitro Evaluation of Midwest Caries ID: A Novel Light-emitting Diode for Caries Detection

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Clinical Relevance

Recent technology, such as Midwest Caries ID, has become available to assist clinicians with caries diagnosis. However, in light of the limited sensitivity of the Midwest Caries ID, it should only be used as an adjunctive tool until further evidence supports its diagnostic accuracy.

SUMMARY

Introduction: Traditional detection techniques have limits in diagnosing occlusal caries. Thus, more accurate methods are needed. This study evaluates the ability of the Midwest Caries ID (Midwest) to detect caries.

Methods: Two hundred sixty-four extracted, nonrestored premolars and molars were cleaned and stored in 0.2% sodium azide. Teeth were divided into three groups of 88. One examination site on each occlusal surface was chosen. Each site was inspected by a calibrated examiner via visual, Midwest, and histologic exams. First, a visual exam was performed following the International Caries Detection and Assessment guidelines. Next, the same site was inspected using the Midwest device. Finally, the tooth was sectioned mesiodistally through the site. The half with greater caries progression was visualized under a stereomicroscope (64×). Histologic appearance was scored based on the Downer system. Data were analyzed using Kendall tau-b, partial correlation coefficients, and the receiver operating characteristics curve.

Results: Overall, the Midwest scoring assessment correlated with histologic assessments (tau = 0.32; $p<0.0001$), but the visual exam had a stronger correlation (tau = 0.53; $p<0.0001$) with the histologic exam. The sensitivity and specificity of the Midwest was also reported at

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0.56 and 0.84, compared with 0.92 and 0.43, respectively, for the visual exam.

Conclusions: Midwest Caries ID is a novel caries detection device that has limitations and should not be used as the sole means to detect occlusal caries.

INTRODUCTION

Conventional pit-and-fissure caries detection methods include visual, modified tactile, and radiographic examinations. Visual inspection is the dentist's primary method of caries diagnosis, but it is limited by its subjective nature.[1-4] To standardize caries diagnosis, the International and Caries Detection Assessment System (ICDAS) was created. It offers set guidelines for the quantitative and qualitative determination of caries progression and has been shown to be effective for both novice and expert practitioners.[2,5,6] Furthermore, the recent increase in the use of dental loupes has improved the practitioner's ability to diagnose pit-and-fissure caries.[7] In the past, traditional tactile exams were simple to perform but posed several risks. Pressure from a sharp explorer may cause a potentially remineralizable lesion to cavitate.[8] In addition, bacteria may be transported to other sites in the oral cavity via the explorer.[9,10] For these reasons, a modified tactile technique is now recommended, where an explorer can be used to remove plaque and lightly assess the hardness of involved tooth surfaces.[11] Radiographic methods include the use of bitewings and have become the standard of care in effectively identifying proximal lesions, which may remain undetected during visual exams. However, bitewings pose a radiation exposure to the patient and have a low sensitivity (30%) in detecting early-stage lesions in enamel (occlusal and proximal).[9,10,12,13] Furthermore, tooth structure must demineralize by at least 40% to appear as a lesion on radiographic film.[14] Therefore, radiographs have limited capabilities for early detection.

Despite the multitude of methods of caries detection, there are still considerable limitations regarding subjectivity. A more objective, reproducible, and accurate assessment method is needed. Recent studies have shown that bacteria in carious lesions release metabolites during growth, many of which are ringed structures, such as porphyrins. These structures demonstrate the ability to absorb energy at a given wavelength (650 nm, red spectrum) and release it at a higher level (680 nm), thereby fluorescing.[3,9-10,15-18] A previously designed system (DIAGNOdent, KaVo Dental GmbH, Biberach/Riβ, Germany) uses this physical property to find and detect caries. However, this system is recommended as an adjunct and not as the sole means of diagnosis.[10,16] A new product, Midwest Caries ID (Dentsply, York, PA, USA), has recently been introduced as a caries detector, but limited studies concerning its efficacy have been conducted.[19] Because of the proprietary nature of the device technology, the only technical information regarding the Midwest Caries ID (Midwest) was obtained through personal communication (Marie D. George, RDH, MS, oral communication, January 23, 2012). According to the manufacturer, Midwest detects hypocalcification by analyzing the structural integrity of enamel rods. Translucency is determined in part by the mineral content of the rods; therefore, a difference in the reflectance characteristics of sound versus carious tooth structure can theoretically be used to calculate the degree of caries progression present. This is accomplished via light-emitting diodes, and caries progression is determined based on manufacturer's studies concerning the absorption characteristics of carious material. This is in contrast to DIAGNOdent, where the detection method is based on the amount of carious metabolites present in infected tooth structure.

The practical purpose of this study was to compare the diagnostic ability (sensitivity and specificity) of the Midwest technology to a current standard visual assessment system (ICDAS). Both methods were confirmed for caries detection with histologic sections as this study's gold standard. To provide quality care, the Midwest needs to be able to identify caries (sensitivity) and differentiate it from surrounding healthy tooth structure (specificity). Our null hypothesis was that the Midwest device does not differ in sensitivity and specificity from a visual exam, using histologic exam as the gold standard.

METHODS AND MATERIALS

Two hundred sixty-four extracted permanent premolars and molars (nonrestored) were selected from a pool of extracted, noncavitated (ie, ICDAS scores of 0-4) teeth collected according to human subjects regulations at the University of Texas Health Science Center in Houston. Teeth were stored in 0.9% sodium chloride/0.2% sodium azide. Teeth were cleaned with prophylactic paste (Enamel Pro with ACP, Premier, Hannover, Germany) and a rotating brush. Next, teeth were thoroughly rinsed to ensure that no residual paste was left and then dried and photographed (Canon Digital Rebel XSi, Canon Macro Lens EF 100mm 1:2.8 USM, Lake Success,

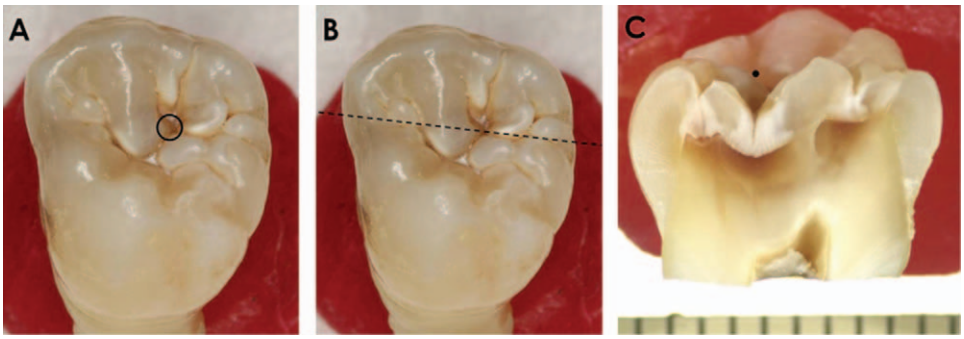

Figure 1. *Site selection and sectioning. (A) Each tooth was photographed, and the examination site was chosen and recorded on the occlusal surface. Visual exam and Midwest evaluation were completed following methodology previously described. (B) The examination site was sectioned for histologic examination and (C) imaged by stereomicroscope (64×).*

NY, USA) before examination.[20] One random site on each tooth's occlusal surface within the pit-and-fissure system was selected and marked on the photographed image for ease of relocation and consistency among the involved examiners (Figure 1A). It has been noted that one site can accurately approximate the entire occlusal surface when using laser reflectance for caries measurement.[21] Each tooth was subjected to three tests: visual, Midwest, and histologic. Three calibrated examiners were recruited to perform the tests. Before the study, examiners were trained in the ICDAS and Downer histologic classification systems.[22,23] Examiners also watched the DVD supplied by Dentsply for the Midwest calibration (provided to clinician upon purchase of the device).[24,25] Approximately 20 digital photographs of various teeth were used in these calibration sessions, which were not included in the main study. To reduce systematic error due to observer bias,[26] teeth were divided into three groups of equal size, with each examiner assigned to perform one test per group. No examiner performed the same test for more than one group (Table 1).

The following protocol was used during the visual exam. Each tooth was air dried via air syringe (5 seconds) and observed under standard dental operating light. Examiners used 2.5× magnification dental loupes. Caries presence and progression were based on ICDAS scoring (Table 2).[2,3,5,6,16,20]

Table 1: *Examiners and Assigned Teeth*[a]

Tooth No.	Examiner		
	1	2	3
1-88	A	B	C
89-176	C	A	B
177-264	B	C	A

[a] *To reduce the score bias, the study recruited three calibrated examiners. The 264 teeth were divided into three groups of 88. Each examiner was assigned to perform one examination (A, visual; B, Midwest; C, histologic) per group.*

The reflectance technology exam used the Midwest. Per manufacturer's instructions, the occlusal surface was not dried. Manufacturer guidelines provided a qualitative scoring system, which was used to determine caries presence and progression (Table 2).

The histologic exam was performed to determine the true extent of caries progression (gold standard). Roots of teeth were removed apical to the cemento-enamel junction via diamond bur (D849, Komet USA, Rock Hill, SC, USA). The crown was cut mesiodistally through the investigation site via a diamond saw with continuous water irrigation (Isomet 11-1180 Low Speed Saw, Buehler Ltd, Lake Bluff, IL, USA) (Figure 1B). Sections were histologically examined at 64× under a stereomicroscope (Leica MZ9.5, Wetzlar, Germany) (Figure 1C). Caries presence and progression was based on the Downer system (Table 2).[1,3,16,20]

For each test, data from the three examiners were compiled and analyzed using the IBM SPSS Statistics 20 software package (Armonk, NY, USA). The first level of analysis was to perform descriptive analyses. Tables with frequency and expected observations were also constructed. The data were ordinal and therefore required nonparametric statistical evaluation. The categoric scores for each evaluation (ICDAS 0-6, Downer 0-4, and Midwest 0-3) differed in their carious assessment criteria and could not undergo meaningful recategorization or be collapsed to common categories across the varying assessments. Weighted kappas were also difficult to perform as categories 5 and 6 of the ICDAS scoring scale were excluded from the scoring. As shown in Table 1, each examiner scored 264 teeth; however, to control for examiner bias, each examiner scored

Table 2: *Criteria for Examinations*[a]

Visual Exam		Midwest Exam		Histology Exam	
Score	**Criteria**	**Score**	**Criteria**	**Score**	**Criteria**
VE-0	No change in enamel translucency after 5 seconds of air drying	ME-0	No caries	HE-0	No enamel demineralization or a narrow surface zone of opacity
VE-1	First visual change in enamel after 5 seconds of air drying; limited to the confines of the pit and fissure area	ME-1	Demineralization close to the surface: caries in enamel	HE-1	Enamel demineralization limited to the outer 50% of the enamel layer
VE-2	Distinctly visible changes on a wet surface and/or and area wider than the fissure area	ME-2	Medium-size demineralization in area possibly past the dentoenamel junction	HE-2	Demineralization involving the inner 50% of the enamel, up to the dentoenamel junction
VE-3	Localized enamel breakdown due to caries, with no visible dentin or underlying shadow	ME-3	Small/deep lesion into dentin	HE-3	Demineralization involving the outer 50% of the dentin
VE-4	Underlying dark shadow from dentin	—	—	HE-4	Demineralization involving the inner 50% of the dentin

[a] *These values represent the characteristics used to quantify the extent of a carious lesion. Visual exam used ICDAS.[6] ICDAS levels 5 and 6 were preferentially excluded from this study (ie, gross cavitation of coronal surface). Midwest exam used the manufacturer's guidelines for detecting carious involvement.[24,25] Histologic exam used the Downer classification system.[23]*

different teeth for each assessment. Because each examiner did not score the same teeth with the same assessment technique, the interrater kappa statistic is not applicable. As a consequence, a nonparametric assessment comparing rank order was determined by using the Kendall tau-b statistic. A partial correlation coefficient was also applied controlling for tooth number or which tooth was scored.

A receiver operating characteristics (ROC) curve was constructed comparing the sensitivity and specificity of the visual exam with the Midwest and histologic assessments. The histologic scores were transformed from an ordinal score to a dichotomous score (0 or 1). A zero represented no caries; a score of one, the disease state, represented the histologic presence of caries.

RESULTS

Two hundred sixty four teeth were examined. Each examiner evaluated 88 of the 264 teeth using each of the three caries assessment techniques. The descriptive analyses are shown in Table 3.

Table 4 shows that the visual exam correlated with both the Midwest (tau = 0.32; $p<0.0001$) and histologic (tau = 0.53; $p<0.0001$) assessments. Furthermore, the results demonstrated that the Midwest evaluation correlated with the histologic (tau = 0.33; $p<0.0001$) assessment. If the histologic assessment were considered the gold-standard, then the Kendall tau-b statistic suggests a stronger association between the visual exam and the histologic assessment compared with the Midwest evaluation.

Because the examiners did not inspect the same teeth with the same assessment technique, a partial correlation coefficient was also performed on the data controlling for tooth number. This further confirmed the Kendall tau-b statistical analysis. Table 5 shows that the visual exam correlated with both the Midwest (tau = 0.34; $p<0.0001$) and histologic (tau = 0.63; $p<0.0001$) assessments. The results also indicated that the Midwest evaluation correlated with both the visual (tau = 0.34; $p<0.0001$) and histologic (tau = 0.35; $p<0.0001$) assessments. However, the partial correlation analysis suggests that the visual exam has a stronger association with the histologic exam than the Midwest exam.

The results of the sensitivity and specificity are similarly illustrated by the graphic ROC curve shown in Figure 2. The area under the curve for the visual exam was 0.84, with sensitivity and specificity of 0.92 and 0.43, respectively; the area under the curve for the Midwest was 0.68, with a sensitivity and specificity of 0.56 and 0.84, respectively.

DISCUSSION

Midwest Caries ID is a small, battery-operated, and easily autoclavable device that is available to oral health care providers for detecting and quantifying caries. Because of the limited data concerning its effectiveness, this investigation was conducted. Although this study supported the finding that the Midwest has the capability to detect caries, the Kendall tau-b and partial correlation coefficients

Table 3: *Assessed Teeth Using Three Modes of Examination Techniques*[a]

Examination Technique	Examiner			Total
	1	2	3	
Visual Exam				
0				
Count	14	13	11	38
Expected Count	12.7	12.7	12.7	38.0
1				
Count	27	10	42	79
Expected Count	26.3	26.3	26.3	79.0
2				
Count	22	11	17	50
Expected Count	16.7	16.7	16.7	50.0
3				
Count	15	38	15	68
Expected Count	22.7	22.7	22.7	68.0
4				
Count	8	8	2	18
Expected Count	6.0	6.0	6.0	18.0
5				
Count	2	8	1	11
Expected Count	3.7	3.7	3.7	11.0
Total				
Count	88	88	88	264
Expected Count	88.0	88.0	88.0	264.0
Midwest Exam				
0				
Count	50	45	41	136
Expected Count	45.3	45.3	45.3	136.0
1				
Count	6	8	9	23
Expected Count	7.7	7.7	7.7	23.0
2				
Count	5	9	3	17
Expected Count	5.7	5.7	5.7	17.0
3				
Count	27	26	35	88
Expected Count	29.3	29.3	29.3	88.0
Total				
Count	88	88	88	264
Expected Count	88.0	88.0	88.0	264.0
Histological Exam				
0				
Count	12	31	6	49
Expected Count	16.3	16.3	16.3	49.0
1				
Count	8	17	12	37
Expected Count	12.3	12.3	12.3	37.0
2				
Count	25	13	19	57
Expected Count	19.0	19.0	19.0	57.0
3				
Count	31	24	40	95
Expected Count	31.7	31.7	31.7	95.0
4				
Count	12	3	11	26
Expected Count	8.7	8.7	8.7	26.0
Total				
Count	88	88	88	264
Expected Count	88.0	88.0	88.0	264.0

[a] *Descriptive analyses of the 264 teeth examined by three examiners evaluating 88 teeth per group using the three caries assessment techniques.*

illustrated that the visual exam correlated more with the histologic findings, the gold standard, than the Midwest. The sensitivity and specificity for this detection device was also reported at 0.56 and 0.84, respectively.

At the time of experimental design, the authors only encountered two studies regarding the Midwest.[27,28] Krause and others[28] reported sensitivity of 100%, which was calculated by comparing the Midwest to radiographic findings. As mentioned earlier, radiographs have 30% sensitivity in detecting incipient caries.[12,13] Additionally, radiographic film can only detect a lesion after 40% demineralization.[14] However, this present study did not support the numbers reported by Krause and others.[28] Such a discrepancy can be explained by the fact that in the study by Krause and colleagues, histology, and not radiology, was used as the standard of comparison. Because radiographs are inherently less sensitive, the reported values of Midwest may be higher in the preceding study. It has been established that ground sections examined by stereomicroscopy can be validated against the true diagnosis and therefore can be used as the gold standard where accuracy of caries diagnosis are being tested.[29] We also used a visual system, ICDAS, which is a standardized approach to caries detection and management. Such visual examination criteria help clinicians to identify caries in all stages, in particular at an early phase, which is a known limitation of radiographs.

One study has subsequently been published that examined the efficacy of the Midwest compared with DiagnoDENT and ICDAS.[19] Sensitivity and specificity of the device were reported as 56% and 84%, respectively, which is identical to the values reported

Table 4: *Kendall tau-b Correlations*[a]

Kendall tau-b	Tooth No.	Visual Exam	Midwest Exam	Histologic Exam	Examiner
Tooth number					
Correlation coefficient	1.000	–.077*	–.048	–.230**	.818**
Significance (one-tailed)	—	.045	.157	.000	.000
N	264	264	264	264	264
Visual exam					
Correlation coefficient	–.077*	1.000	**.321****	**.531****	–.069
Significance (one-tailed)	.045	—	.000	.000	.094
N	264	264	264	264	264
Midwest exam					
Correlation coefficient	–.048	**.321****	1.000	**.333****	–.024
Significance (one-tailed)	.157	.000	—	.000	.333
N	264	264	264	264	264
Histologic exam					
Correlation coefficient	–.230**	**.531****	.333**	1.000	–.257**
Significance (one-tailed)	.000	.000	.000	—	.000
N	264	264	264	264	264
Examiner					
Correlation coefficient	.818**	–.069	–.024	–.257**	1.000
Significance (one-tailed)	.000	.094	.333	.000	.
N	264	264	264	264	264

[a] *Kendall tau-b statistic suggests a stronger association between the ICDAS scoring assessment and the histologic exam than with the Midwest exam.*
** Correlation is significant at the .05 level (one-tailed).*
*** Correlation is significant at the .01 level (one-tailed).*

Table 5: *Partial Statistical Correlations*[a]

Control Variables	Visual Exam	Midwest Exam	Histologic Exam	Examiner
Tooth no.				
Visual exam				
Correlation	1.000	**.341**	.629	.037
Significance (one-tailed)	—	.000	.000	.273
df	0	261	261	261
Midwest exam				
Correlation	**.341**	1.000	.351	.092
Significance (one-tailed)	.000	—	.000	.068
df	261	0	261	261
Histologic exam				
Correlation	**.629**	**.351**	1.000	–.041
Significance (one-tailed)	.000	.000	—	.253
df	261	261	0	261
Examiner				
Correlation	.037	.092	–.041	1.000
Significance (one-tailed)	.273	.068	.253	—
df	261	261	261	0

[a] *Partial correlation analysis confirms Kendall tau-b statistics, suggesting a stronger association between the ICDAS scoring assessment and the histologic exam than with the Midwest exam.*

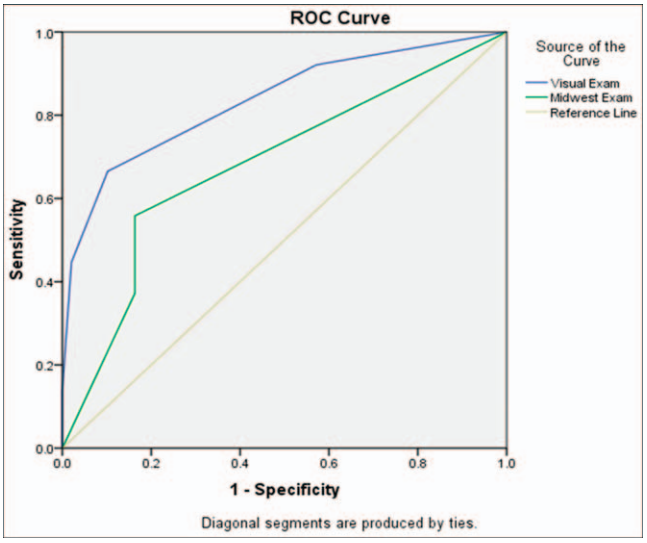

Figure 2. *Area under the ROC curve. The areas under the curve for the visual and Midwest exams suggest that the visual exam is more sensitive in detecting caries (better at identifying caries: true positive), whereas, Midwest is more specific (better in differentiating caries against sound tooth structure: true negative).*

in this study. This suggests that the Midwest is not optimal at detecting caries but is fairly reliable at determining healthy tooth structure. ICDAS, by contrast, demonstrated sensitivity and specificity of 0.92 and 0.43, respectively.

To review, sensitivity is defined as the identification of caries (true positive), and specificity is the differentiation of caries versus fully mineralized tooth structure (true negative).[3,15,16] A sensitivity of 0.92 suggests that a visual system rarely misses caries when it is present; specificity of 0.43 suggests, however, that it can lead to some overdiagnosis (false positive). We believe this phenomenon is due to the nature of ICDAS—a quantitative system that can inherently make a practitioner more aware of initial signs of incipient lesions. Although the overdiagnosis of caries is undesirable, therapies directed at addressing incipient lesions are typically noninvasive.[5] In contrast, detection with Midwest can mean caries is most likely present, but it may also fail to detect early-stage lesions (sensitivity 0.56), leaving the site susceptible to further caries progression.

It is important to acknowledge the difference between detection and diagnosis.[13] Detection of caries is the recognition of a significant clinical finding. Diagnosis is both an art and a science: it requires a keen eye and a comprehensive knowledge of the disease process. The practitioner must be able to critically appraise such clinical findings rather than solely relying on data obtained from a particular detection method. Based on the results of this study, the null hypothesis that the Midwest device does not differ in sensitivity or specificity from histologic examination is rejected.

CONCLUSION

Light-emitting diodereflectance technology, like the Midwest, may only be useful in detecting caries when coupled with visual exam, modified tactile exam, and radiographs. Such a full spectrum of exams will enable the examiner to identify caries in all stages. However, a full understanding of the equipment can lead to appreciation for the device's strengths and shortcomings. When used appropriately, it may prove to be a functional addition to the practitioner's armamentarium.

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Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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