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In Vivo Evaluation of DIAGNOdent for the Quantification of Occlusal Dental Caries

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Clinical Relevance

There is a weak correlation between DIAGNOdent readings and carious lesion depth and volume. Based on the current study, the appropriate DIAGNOdent cut-off point to detect carious lesions reaching the DEJ or beyond is between 35 and 40.

SUMMARY

The accurate diagnosis of non-cavitated occlusal caries is generally considered problematic. Induced fluorescence quantified by the DIAGNOdent device (KaVo) gives a reading from 0-99, which may help in the caries diagnostic process. There is some controversy around the implication of increased severity of decay with increased DIAGNOdent readings. This *in vivo* study assessed the correlation of depth and volume of decay as it was removed by traditional rotary handpieces with DIAGNOdent readings and determined sensitivities/specificities of the device at different cut-off points. Included in the current study were 31 patients providing 60 permanent molar and premolar occlusal surfaces suspected of dentinal decay. DIAGNOdent readings were recorded, along with lesion depth (as measured by periodontal probe) and volume measurements (as calculated from measuring the mass of a polyvinyl siloxane impression of the cavity, divided by the material's calculated density). Clinical detection of decay at the DEJ was used as the gold-standard to calculate an appropriate cut-off. Pearson correlation coefficients indicated that DIAGNOdent readings were weakly correlated with lesion depth (r=0.47) and lesion volume (also r=0.47). An appropriate cut-off point for the sample in the current study was calculated between 35 and 40;

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a more specific cut-off point could not be determined due to the sample size distribution. It was concluded that the DIAGNOdent device should be used as an adjunct in the caries diagnosis and treatment planning process.

INTRODUCTION

Commonly used methods for diagnosing dentinal caries in non-cavitated pits and fissures exhibit high specificity but low sensitivity. Specificity, the correct recognition of sound teeth, was recently found to be 97% using traditional visual/tactile examination methods; while sensitivity, the ability to correctly recognize non-cavitated occlusal surfaces with dentinal caries, hovers at a mean of 19%.[1] In a low caries-risk population, specificity of a diagnostic method is critical: teeth that can be kept unrestored should not be operatively treated.[2] To complement traditional clinical assessment by the clinician, there is a role for an objective detection method to support whether invasive therapy or a more conservative non-invasive approach is indicated.[3]

Spitzer and Bosch suggested that carious lesions, when exposed to certain wavelengths of light, emit more intense fluorescence than sound tissue, mostly due to organic components and proteinic chromophores found in affected tooth structure.[4] Fluorescence induced by red light (655 nm) has been shown to effectively differentiate between sound and carious tooth structure. This work led to the development of a laser-based instrument for the detection and quantification of dental caries on occlusal surfaces,[5] the DIAGNOdent (DD) (KaVo, Biberach, Germany). DD produces a single digit reading (ranging from 0 to 99), which offers an objective measurement of the fluorescence recorded by the device.

Research on DD has centered on its validation. It is well documented that this method has a high sensitivity in detecting early carious lesions.[6] A number of different "cut-off points" minimize DD reading, indicating operative intervention, have been proposed.[7] At high cut-off points, the device has increased specificity, which generally occurs at the expense of sensitivity. Lower cut-off points show higher sensitivity but lower specificity. Some have suggested the device's utility in the longitudinal measurements of teeth to monitor the progression of decay over time.[8]

Because DD offers a single reading on a 0 to 99 scale, it is intuitive to believe that higher readings indicate the presence of larger areas of decay. Some readings have correlated more severe decay with increasing DD values,[9] though others have not found a correlation of lesion depth and DD value.[10-11] Others have suggested that DIAGNOdent values were dependent on the volume of the caries, rather than on the depth of the lesion.[12] An *in vitro* study used digital imaging software to analyze serial hemisections of extracted teeth to correlate lesion area with DD readings;[13] however, *in vitro* studies are difficult to generalize to practice,[14] and a choice of and time in different storage media have been shown to influence laser fluorescence values on extracted teeth.[15] A recent *in vivo* study attempted to correlate DD readings with cavity depth and volume as prepared with an air-abrasion system and found no significant correlations between the two.[16]

This *in vivo* study assessed the correlation of depth and volume of decay as removed by traditional rotary handpieces with DIAGNOdent readings and determined an appropriate cut-off point from the study sample.

METHODS AND MATERIALS

Patient Selection

Institutional Review Board approval for the project was obtained prior to initiation. Sixty lesions were identified in patients of record at the Graduate Operative Dentistry Clinic at the University of Michigan. Once prospective patients were identified, the procedure and aims of the study were explained to them and informed consent was obtained.

The following inclusion criteria were used to determine entry into the study: the included teeth must be permanent maxillary and mandibular molars or premolars; caries must represent a primary lesion that has been diagnosed clinically as active caries and the teeth must be free of any existing restorations. Teeth with frank cavitation or symptoms of pulpitis were excluded from participation in the study.

Diagnostic Procedure

Each tooth included in the current study received visual and tactile examinations, exposure of a bite-wing radiograph if an existing exposure within the past six months was unavailable and a DD evaluation. All the examinations were conducted independently by two operators.

After drying the tooth with compressed air, the area of the lesion was evaluated from the occlusal aspect using direct and reflected light. The only instruments utilized for this visual inspection were a standard dental mirror and the operatory light under 3x magnification. Tactile examinations were completed with a standard 3.0 cowhorn explorer.

DIAGNOdent Readings

Following the manufacturer's instructions, calibration of the DD was performed with a ceramic standard provided by the company. Following the visual and tactile examinations, all stains and debris were removed with the use of a pressurized sodium-bicarbonate system (PROPHYflex System, KaVo). A DD with a conical tip A measured each occlusal surface. The background value for each individual tooth was calibrated prior to each measurement by measuring the fluorescence of sound enamel on the facial surface of each tooth. This background value was then electronically subtracted from the fluorescence of the test site to be measured. The instant reading indicated the real time value that the probe tip measured during scanning of the fissure. The peak value referred to the highest level scanned on the tooth or surface. The surface was then thoroughly washed and air-dried. A second set of DD readings was then taken; if peak values differed between readings, the numbers were averaged to determine the surface's DD reading.

Operative Procedure

All of the operative and restorative treatments were performed by one investigator (MK). A review of the medical history was followed by a standard injection of local anesthesia as needed to accomplish caries removal. Each tooth was isolated with a rubber dam, and an impression of the occlusal surface was taken with Clear Bite (Dentsply Caulk International, Milford, DE, USA) impression material before operative intervention to serve as a matrix for volume measurement (Figure 1).

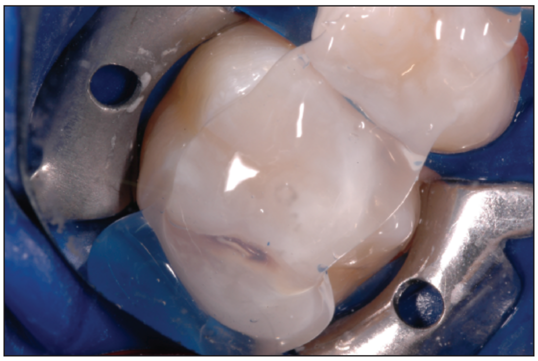

Figure 1: *Impression of the occlusal surface to serve as a matrix for volume measurement.*

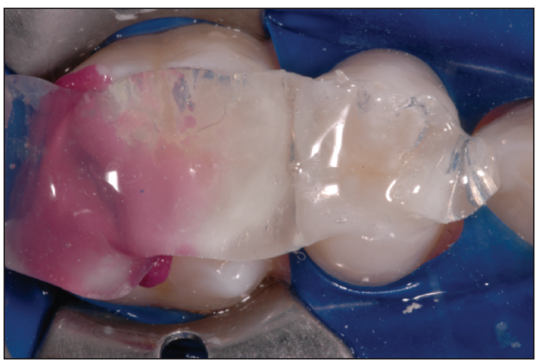

Figure 2: *Cavity impression technique: After light body impression material was placed into an excavated cavity, the clear matrix was placed with pressure to reduce flash.*

A conservative dissection of the carious lesions was done with a carbide bur of sufficient size to provide minimal access and a steel round bur to remove only active carious material. An impression with light body polyvinyl siloxane material (Aquasil, Dentsply Caulk International) was taken of the cavity using the previously fabricated matrix as a tray (Figure 2). The light body material was carefully removed from the cavity preparation; the excess material was trimmed and the remaining impression material, which replicated the excavated tooth structure, was weighed in milligrams on a sensitive balance (Mettler AB54-S, Toledo, OH, USA). The volume was calculated using the measured density of the Aquasil material and the weight of the recovered specimen.

Density Calculation for the Aquasil Material

Since the manufacturer provided a range of specific gravity that varied from 1.0 g/cc to 1.5 g/cc depending on the viscosity, the exact density was calculated as follows. A 1cc syringe was weighed empty, it was then filled with the base or the catalyst material and weighed again. The mass of one cc of material was obtained by calculating the difference. The density was 1.1268 g/cc for the base and 1.0913 g/cc for the catalyst. These densities were added and divided by two to get an estimate of the exact density of the mixed materials, which was 1.11g/cc.

The volume of the impression material that was recovered from the excavated cavity was calculated for each preparation by dividing the mass (weight of the impression material recovered) by the material's density. Measurement of the cavity depth after caries removal was made with a periodontal probe marked in 1 mm increments. Measurement was made at the deepest portion of the excavation using the cavosurface margin as a reference. A final cavity preparation was then completed to acceptable clinical standards. The teeth were etched, bonded and restored with resin composite using standard restorative materials. All necessary adjustments and polishing were done before dismissing the patient. Data were transferred into an Excel spreadsheet and exported to SAS 9.1.2 for statistical analysis.

RESULTS

The current study included 31 patients between 18 and 45 years old, with a total of 60 occlusal carious lesions (35 maxillary molars, 20 mandibular molars, 2 maxillary premolars and 3 mandibular premolars). After operative intervention, 78% of the lesions extended into dentin and 22% were limited to enamel. Distribution of the DD values is shown in Table 1, and the average DD value, volume and depth for each group is shown in Table 2. The DD values included a minimum value of 14 and a maximum value of 99,

Table 1: *Distribution of DIAGNOdent Readings*

DIAGNOdent Values	# of Total Lesions	# of Lesions in Dentin	% of Lesions in Dentin
0-10	0	0	0
10-20	4	2	50
20-30	8	5	63
30-40	18	12	67
>40	30	28	93

Table 2: *Average DIAGNOdent Readings and Average Volume (cc) and Depth (mm) for Each Caries Extension Group (enamel and dentin)*

Caries Extension	# of lesions	DD Values	Average Volume (cc)	Average Depth (mm)
Enamel	13 (22%)	32.27	0.0056	1.88
Dentin	47 (78%)	49.43	0.0220	3.28

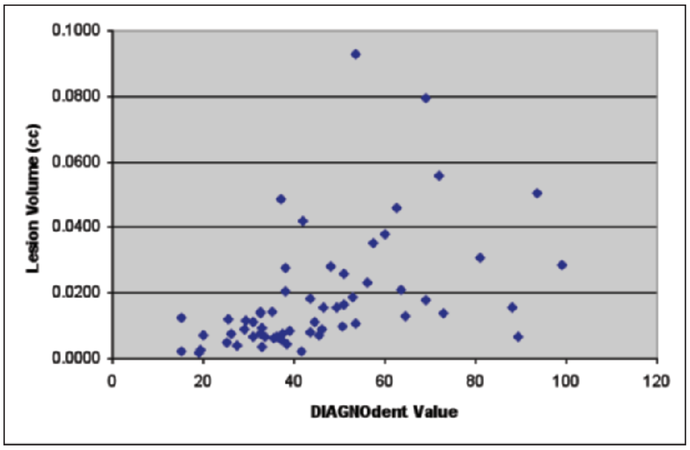

Figure 3: *Correlation between lesion volume (cc) and DIAGNOdent value.*

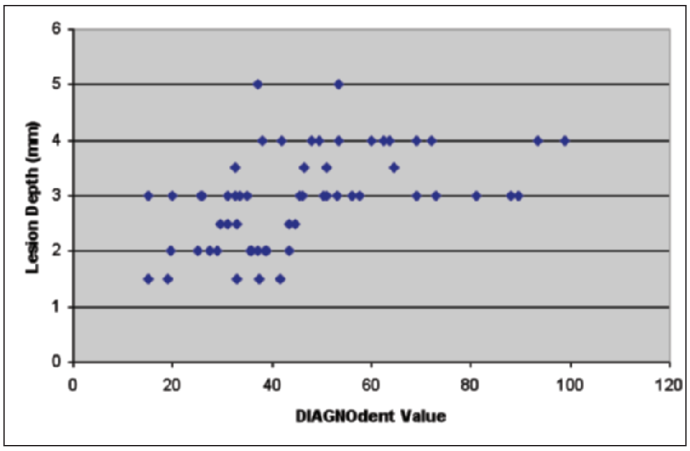

Figure 4: *Correlation between lesion depth (mm) and DIAGNOdent value.*

with an average value of 50. The volume deviated from 0.002 to 0.1 cc, with an average of 0.01 cc. The relationship between the volume of cavity preparations and the DIAGNOdent values is shown in Figure 3. The depth deviated from 1.5 mm to 5 mm, with an average of 2.98 mm; its relation to the DD values is shown in Figure 4.

Validity of the Diagnostic Examinations

Sensitivity and specificity for DIAGNOdent were calculated at the dentin levels based on the assumption that all lesions were expected to be in dentin. The gold standard was detection of clinical decay at the DEJ after operative intervention. Forty-seven lesions showed caries that extended beyond the DEJ into dentin clinically, while 13 lesions were limited to enamel. Using the gold standard of clinical decay detected at the level of the DEJ, sensitivity and specificity were calculated at four cut-off points (20, 30, 35 and 40) to estimate the appropriate cut-off to better predict caries extending into dentin (Table 3).

Depth/Volume Correlations

Pearson correlation coefficients were calculated for the DD measurements and lesion depth and volume. The DD measurements and the clinical depth were calculated at r=0.47. DD correlated with the volume of the lesion at the same level, r=0.47.

A Student's *t*-test for independent samples was used to determine whether the mean DIAGNOdent values for enamel-only lesions differed significantly from the mean DIAGNOdent values for lesions into dentin, and the test showed a highly significant difference at $p<0.0001$ between the mean values for enamel lesions and dentin lesions (Table 4).

DISCUSSION

When a single digit reading is obtained by DD, the dentist must interpret what that digit means. Does that digit indicate the presence or absence of a dentinal lesion, or does the digit infer the severity of dentinal decay? Results of the current study suggest that higher DD readings are only weakly correlated with the extent of a dentinal lesion. This is illustrated in Figure 3, as DIAGNOdent readings ranging from less than 20 to greater than 90, all describe smaller volumes of decay (less than 0.02 cc) in the study population.

Lesion depth has been quantified in different ways in various studies. Most studies use general criteria (shallow dentinal caries vs deep dentinal caries). Astvaldstottir and others looked at the correlation of lesion depth (enamel caries vs shallow dentin caries vs deep dentin caries) with DD readings from four different devices and found Spearman correlations between

Table 3: *Sensitivity and Specificity of Different DIAGNOdent Cut-off Points*

	Reading of 20	Reading of 30	Reading of 35	Reading of 40
Sensitivity	46 out of 47 0.97%	43 out of 47 0.91%	41 out of 47 0.87%	31 out of 47 0.66%
Specificity	2 out of 13 0.15%	5 out of 13 0.38%	5 out of 13 0.38%	12 out of 13 0.92%

Table 4: *Mean DIAGNOdent Values for Enamel and Dentin*

	Mean	St Dev	Confidence Interval
Enamel	32.27	9.42	26.58-37.96
Dentin	49.47	20.05	43.55-55.31

0.28 and 0.51, depending on the device; they proposed the instrument has an inadequate capacity to determine lesion depth.[10] Similar caries-depth descriptors were correlated with DD readings, and Spearman correlations were found to be between 0.53 and 0.57, though only eight of the 52 teeth studied had dentinal decay.[17] DD readings from two devices from a separate study found a much lower Spearman correlation of <0.15,[11] while others have reported *in vitro* correlations of between 0.76 and 0.79.[18] Lussi and others utilized the same ordinal depth rankings and concluded that DD readings were unable to distinguish between deep dentinal caries and shallow dentinal caries.[19] The lesion depth, as determined in the current study, was a cardinal number measured from the base of the deepest part of the lesion to the cavosurface. *In vitro* studies have attempted to correlate measured lesion depth with DD readings. DD readings from 51 extracted teeth were correlated with caries depth as determined with computed tomography, and a significant correlation of 0.651 was found.[20] Measured caries depth and DD readings using two observers and two devices were correlated in an *in vitro* investigation, and correlations were found to range from 0.48 to 0.53, depending on the device and observer.[13] The Pearson correlation found between measured caries depth and DD readings in the current *in vivo* study was found to be 0.47; slightly lower than *in vitro* correlations in the literature. Studies examining DD readings and smooth-surface lesion depth tend to have a higher correlation;[18,21] this may be due to anatomical differences between occlusal and smooth surfaces, and possible interference of residual plaque, calculus or stain after thorough pressurized sodium-bicarbonate pit and fissure cleaning.

Others have attempted to estimate lesion volume by measurement of the greatest area of decay in one hemisection, then correlate these area measurements with DD readings. Pearson correlation coefficients in this *in vitro* analysis varied between 0.47 and 0.54 for the enamel area and 0.39 and 0.45 for the dentinal area,[13] which is similar to the current study. The only other *in vivo* study that directly evaluated lesion volume found a 0.191 correlation between cavity volume and DD reading, though the Pearson correlation coefficient increased to 0.344 when cavitated lesions were excluded.[16] The slight increase in correlation found in the current study may be due to the increased number of noncavitated teeth (60 vs 32) or the manner of cavity preparation (rotary handpiece in the current study vs air-abrasion).

Suggested DD cut-off points vary widely among studies. Even the manufacturer has suggested different cut-off points in different years.[7] In general, *in vitro* analyses suggest lower cut-off points than *in vivo* studies. Most *in vitro* studies suggest dentinal decay is present around a DD reading of 20.[12-13,20-22] *In vivo* analyses tend to suggest higher cut-off points. Tranaeus and others suggested cut-off points between 20 and 25,[11] while Lussi and others suggested operative or preventive treatment is indicated when readings are between 20 and 29.[19] Krause and others suggested a cut-off point of 36, though they stressed recommended cut-off values for clinical use should not be considered as exact threshold readings, as the values should be used as adjunctive information.[23] Anttonen and others argued that, when DD values are above 30, operative intervention should be considered, with every effort made to reduce the proportion of false positive cases, and a cut-off of 40 would considerably decrease the probability of unnecessary operative intervention.[24] Astvaldsdottir failed to suggest an appropriate cut-off point after using four different devices and reported "each device appeared to have an individual cut-off point, a factor of major importance in clinical application of the instrument."[10] In the current study, a cut-off point of between 35 and 40 was found to be appropriate, given acceptable specificities among a lower caries-risk general population in a fluoridated area. The low specificity at this range, which would lead to unnecessary operative intervention (false positives) if the device is used alone, indicates the need for thorough clinical and radiographic examinations to determine preventive or operative treatment strategies. Regardless of the DD reading, it is strongly recommended that this adjunctive diagnostic tool be used in concert with visual and radiographic examinations and the practitioner's judgment of the patient's caries risk before intervention can be recommended.

This study is limited by the methods used to determine lesion depth and volume. Lesion depth, as measured by the probe used in the current study, represents an estimation of true depth. Lesion volume may have been altered by variations in the quality of impression material recovered from cavity preparations, though the impression material used was carefully examined for any void or excess. A more specific cut-off value could have been estimated with a larger sample size distributed around DD values 30-40.

CONCLUSIONS

DD readings are weakly correlated with lesion depth and lesion volume. Mean DD readings significantly differed between decay limited to enamel and decay into dentin. Appropriate cut-off points indicating dentinal decay lie between 35 and 40 in the current study, though DD must be used as an adjunct in the caries diagnosis and treatment planning process.

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