The eyes have it

How good is DIAGNOdent at detecting caries?

Bader JD, Shugars DA. *A systematic review of the performance of a laser fluorescence device for detecting caries. J Am Dent Assoc* 2004 Oct; 135(10):1413-1426

Data sources Medline (1999–June 2004) provided the primary data source with references from one paper being reviewed for additional studies. The authors of one article were contacted for additional details.

Study selection Articles, in English that assessed a commercially available caries detection device the DIAGNOdent (KaVo Dental GmbH Biberach), used human teeth with and without caries, and expressed diagnostic performance in terms of sensitivity and specificity of caries detection against a histological gold standard were included.

Data extraction and synthesis Data were extracted to determine whether articles included: an appropriate study population; an adequate description of the test; an appropriate reference standard; a blinded comparison of test and reference samples and avoidance of verification bias. No quality score was assigned.

Results Of the 25 studies identified, 16 assessed the *in vitro* performance of DIAGNOdent (DD) on occlusal surfaces of primary and permanent posterior teeth, four reported similar *in vivo* assessments, two examined DD performance on smooth surfaces and the final three addressed detection of secondary caries and residual caries in simulated cavities. DD sensitivity scores for *in vitro* detection of occlusal dental caries ranged from 0.19 to 1.0 ($n=16$) with 14 of the 16 results being ≥ 0.73 . Specificity values ranged from 0.52 to 1.00. DD tended to show higher sensitivity but lower specificity than visual assessment methods. Only four studies considered DD *in vivo* performance and demonstrated sensitivity from 0.73 to 0.96 and specificity from 0.63 to 0.95.

Conclusions In the limited studies available DD demonstrated greater sensitivity but poorer specificity than visual caries diagnosis. Combined with the fact that little *in vivo* evidence is available for DD performance, the greater number of false-positive diagnoses suggest it should not be relied on as a clinician's primary diagnostic method.

Commentary

Two systematic reviews of the literature on various diagnostic techniques¹ and specifically the visual/tactile² method for dental caries detection has shown that there is great variation in study designs, and methods of data collection and presentation. As such a precise estimate of the performance of various diagnostic techniques has not been possible; however, where visual tactile methods were concerned there was general agreement that it resulted in a high specificity (correct identification of sound sites) but low sensitivity (correct identification of carious sites). This means that a dentist is unlikely to record a sound surface as carious from a visual examination, but is likely to miss many lesions, hence the demand for more accurate caries detection devices. The first of these systematic reviews predates the majority of publications on a newly introduced laser fluorescence device, the DD.

This systematic review of the literature on the DD is therefore timely, but only searched one database, namely MEDLINE, other databases such as Pubmed and Embase should have been searched to reduce the likelihood of relevant publications being excluded from the study. In addition, only articles in English were included. A more recent Pubmed search using the key word "DIAGNOdent" and "dental caries" revealed a further three research publications with English abstracts.³⁻⁵ From the English abstracts of these papers it is clear that they would not have met the inclusion criteria for this study. Therefore, the number of papers missed in this publication is likely to be relatively low and the search acceptable to base the conclusions upon.

The results obtained from the included publications mainly pertain to occlusal caries and are clearly presented in three tables. Sensitivity and specificity values for dentine caries detection *in vitro* are very variable between the studies (0.19–1.00 and 0.52–1.00, respectively). Caries prevalence may have played a role in influencing the outcome in each study and this is presented for most studies. Size of lesions investigated may also impact on the diagnostic accuracy. This is not documented in this review and as such it is important to compare the relative diagnostic accuracy of the DD with currently accepted diagnostic methods, namely visual and radiographic examination. Only 31% of the papers compare DD outcome with visual examination and 19% with visual and radiographic examination.

Information from clinical studies is limited due to the lack of a histological "gold standard" and constrained ethically as surfaces recorded as sound cannot be investigated, hence information on clinical use is limited. It has been shown previously that DD readings taken on moist teeth and dry teeth do not correspond,⁶ as such the results from the laboratory studies cannot be directly extrapolated to clinical studies.

The results from studies included in this systematic review of the literature are limited and vary greatly. The conclusions made from this well-presented systematic review of the literature are correct and of clinical significance. While a meta-analysis could not be carried out due to the heterogeneity of the studies, the low specificity values recorded are a concern and if used as a primary diagnostic method, the DD could lead to false-positive diagnoses of caries and over treatment.

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Practice points

- Diagnostic devices (eg, DIAGNOdent) that have an increased sensitivity (detection of disease) usually do this at the expense of specificity (correct detection of sound sites).
- The DIAGNOdent is a typical example and should not be used to make a decision on operative treatment as low specificity means that many sound sites are incorrectly diagnosed as carious. However, they do provide an objective reading which could supplement a clinical and radiographic examination so that it can be used to monitor lesions over time.

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Key to evidence graphic used in Evidence-based Dentistry with examples of study designs for Therapy/prevention/aetiology and harm. Study designs for evidence levels will be different for prognosis/diagnosis etc. (See Evidence-based Dentistry 2003;4:p17-18)						
Evidence Graphic			Evidence-level	Therapy/Prevention /Aetiology/Harm		
		1A	SR (with homogeneity ^a) of RCTs			
		1B	Individual RCT with narrow confidence interval (CI)			
		2B	SR (with homogeneity ^a) of cohort studies			
		2C	Individual cohort studies (including low quality RCT eg < 80% follow-up)			
		3A	SR (with homogeneity ^a) of Case-Controlled Studies			
a By homogeneity we mean a systematic review free of worrisome variations (heterogeneity) in the direction and degree of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant.						