DIAGNOdent - an adjunctive diagnostic method for caries diagnosis in epidemiology

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The DIAGNOdent system is intended as an aid to caries detection and has undergone extensive investigation in experimental and clinical studies. Its applicability for epidemiological purposes has yet to be evaluated. ***The Objective*** of the present study was to evaluate the DIAGNOdent system under field conditions. ***Basic Research design:*** The subjects comprised a sub-sample from an on-going epidemiological study. ***Participants and Clinical setting:*** In 39 individuals, 97 sites were visually identified as possibly carious: 42 occlusal, 13 lingual, 19 buccal and 23 approximal sites. ***Main outcome measures:*** Three DIAGNOdent measurements were taken at each site under varying conditions: 1) naturally wet, 2) dried, and 3) polished and dried surfaces. Three sets of measurements were obtained and compared by intra-class correlation and paired sample t-tests. ***Results:*** All correlation coefficients were > 0.9. There was a systematic difference between mean scores from naturally wet sites (without cleaning) and from either dried, or polished and dried sites. The difference was marginal and did not impact on the threshold for recording sites as carious. In two subjects, high unexpected values were recorded on sound sites prior to actual measurements, i.e. during establishment of a standard value for a sound site. The overall findings were not affected by these values, as they were consistently high in all three measurements. ***Conclusions:*** The DIAGNOdent system performed satisfactorily under different measurement conditions. The present study indicates that the DIAGNOdent system would be applicable in field studies, provided consistent study conditions are maintained and unexpected values are interpreted with caution.

Introduction

The contemporary approach to clinical management of dental caries is based on detection of the presence of the disease at an early stage, when any hard tissue changes are minimal. Treatment is based on non-invasive measures to arrest the disease process and reverse the hard tissue damage. Disease progression is controlled by preventive measures tailored to the individual patient's level of risk (Pitts, 2000).

In conventional epidemiology, early manifestations of dental caries are not measured in caries surveys (Pitts, 2000; Fyffe *et al.,* 2000). The threshold for recording the presence of caries is set at "cavitation", i.e. after the disease has resulted in hard tissue damage. When probing finally discloses a catch, the degree and extent of demineralization and compromised tooth structure are already far advanced (Kidd *et al.,* 1993). It is important to note that probing the tooth surface with a dental explorer can disrupt decalcified enamel which may still have the potential to recalcify. Ultimately, use of a probe for caries detection can lead to the development of a dental cavity (van Dorp *et al.,* 1988).

Thus there is clearly a need to re-evaluate the methods of caries detection and the disease thresholds set for caries registration in epidemiological studies. Preferably, the method should be applicable in both epidemiological and clinical settings and reflect scientific advances in understanding of the disease process and its management.

There is increasing concern about so-called "hidden" or "occult" occlusal caries: carious lesions which develop beneath macroscopically intact fissures and are difficult to detect by conventional visual, tactile, and radiographic techniques (Weerheijm, *et al.,* 1989).

To facilitate the early detection of caries in the clinical setting, a laser fluorescence method, DIAGNOdent ™, has been introduced. The instrument is noninvasive and easy to use (Weerheijm, *et al.,* 1989), and high levels of intra- and inter-examiner agreement are reported (Weerheijm, *et al.,* 1989; Baseren and Gokalp, 2003). Various applications have been evaluated, such as occlusal (Lussi and Francescut, 2003), smooth surface (Shi et al., 2001), and secondary caries lesions (Bamzahim et al., 2004). The instrument recordings have been validated using either histology (Baseren and Gokalp, 2003; Shi *et al.,* 2000) or minimal operative intervention (Lussi and Francescut, 2003; Heinrich-Weltzien *et al.,* 2003) as the gold standard. The diagnostic accuracy of DIAGNOdent is reported to be significantly greater than that of conventional methods such as radiography (Shi *et al.,* 2000), or clinical inspection (Lussi *et al.,* 2001).

Although sensitivities using DIAGNOdent exceed those of visual inspection, lower specificities are reported (Alwas-Danowska *et al.,* 2002). However, using fissure discoloration as the sole criterion, visual inspection correctly identified only sound occlusal surfaces while appliance-based methods helped to avoid false positive identification of dentinal caries (Kordic *et al.,*

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2003). Moreover, conventional methods of caries detection correctly identified only 20% of lesions beneath macroscopically intact fissures (Pitts, 2000). It has been suggested that use of DIAGNOdent, in combination with visual-tactile examination and digital radiography could identify >80% of lesions (Chong *et al.,* 2003).

To date, the DIAGNOdent system has been applied in an epidemiological study, strictly following the manufacturer's instructions for polishing and drying the tooth (Sheehy *et al.,* 2001), but its performance under field conditions has yet to be evaluated. *In vitro* studies have reported that humidity (Shi et al., 2000; Mendes *et al.,* 2004), dental plaque (Shi *et al.,* 2001) and stains (Francescut and Lussi, 2003) can influence the performance of the DIAGNOdent system. Under field conditions, control of plaque and humidity is either impractical or at least more difficult than in the clinical setting.

Before its application in epidemiological studies, it is important that the performance of DIAGNOdent is evaluated under realistic study conditions. The aim of the present study was therefore to evaluate the performance of the DIAGNOdent system under conditions simulating those likely to be encountered in field studies.

Material and methods

The study was approved by the ethics committee (Regional komité for medisinsk forskningsetikk - Helseregion Sør Ref.: S-01166). A sub-sample of 47 young adults was extracted from a random sample of 35 year-old Oslo residents participating in an ongoing epidemiological survey. After informed consent, the subjects were included in the study. As low DIAGNOdent inter-device agreement has been reported (Tranaeus, 2002) the same device was used throughout the study (DIAGNOdent revised version, summer 2003). In order to minimize the number of true negatives, only sites which on visual inspection were suspected of being carious were evaluated, as the inclusion of sound surfaces might systematically increase the observed agreement, i.e. higher agreement is achieved for sound surfaces than for surfaces with varying degrees of demineralised enamel or dentin.

The clinical examination consisted of visual detection of sites suspected of being carious, which were subsequently examined with the DIAGNOdent system. The teeth were also evaluated for the presence of clearly visible plaque on humid surfaces (yes/no). The measurement procedure was completed in the following sequence. First, the system was standardized either for Tip A (for occlusal or approximal surfaces), or for Tip B (for smooth surfaces) at the touchstone of the probe container. For each tooth, a standard value on a sound site was established. Of the approximal surfaces, only those accessible for examination, i.e. spaces opened due to a missing neighboring tooth and/or where caries cavity was visible were examined. Subsequently, three measurements were made for each surface: the first was taken on a naturally wet surface without cleaning; the second after drying the surface for 10 seconds with compressed air; and the third after polishing the surface with water and a rotating brush for approximately 10-15 seconds, followed by drying for a further 10 seconds. The maximum reading for each site was recorded.

All clinical examinations were performed by the one examiner (JA). Intra-examiner reliability, assessed by comparing double recordings by means of correlation was 0.95: this considered satisfactory. The DIAGNOdent recordings obtained under different conditions, namely either on naturally wet, on dried, or on polished and dried surfaces were compared by means of intra-class correlation. In order to test for a systematic difference between the conditions, means of sets of measurements were compared by paired sample t-test. The SPSS program was used for all statistical analyses. The significance value for all tests was set at 0.05.

Results

All 47 individuals in the random sub-sample agreed to participate in the laser examination. Visual examination for the presence of caries revealed that 39 had at least one site suspected of being carious. These 39 subjects presented 97 sites suspected of being carious: 42 occlusal, 13 lingual, 19 buccal and 23 approximal surfaces. The intraoral distribution of the sites is presented in Table 1.

The study material comprised three sets of measurements which were analyzed by Spearman's correlation. The first set of measurements were from naturally wet teeth without any prior cleaning, the second from sites dried for 10 seconds with compressed air and the third from sites prepared according to the manufacturer's instructions, i.e. polishing and drying for 10 seconds. As shown in Table 2 there was a high level of agreement among the three sets of measurements, i.e. all intra-class correlation coefficients were >0.9.

In order to determine whether recordings are influenced by the presence of plaque, correlation was adjusted for the presence of clearly visible plaque (Table 2). This adjustment resulted in only a marginal and non-significant decrease in correlation coefficients. As the overall hygiene levels of the subjects were relatively high, further additional comparison was made only with the measurements from third molars, which harbored more plaque than the remainder of the dentition. This analysis confirmed previous findings in the study, that the presence of plaque did not have a pronounced influence on the readings i.e. all correlation coefficients for comparison of measurements under different conditions were > 0.92. Moreover, a separate analysis was run for third molars only, which clearly harbored substantially more plaque than the remaining dentition. The high interrelatedness among the three study measurements was maintained.

Another question was whether there was a systematic difference between measurements taken following the standard protocol for DIAGNOdent recordings, i.e. polishing and drying a surface prior to measurement versus measurements taken without following the standard protocol. As shown in Table 3, there were differences between scores from naturally wet sites which were not cleaned and those from dried, or polished and dried sites. However, the differences were marginal and of negligible clinical importance.

An additional analysis was undertaken in order to test whether the sites would be consistently diagnosed as either sound or carious given generally agreed thresholds, i.e.

Table 1. Intraoral distribution of examined sites

	Anterior teeth	Premolars	Molars
Maxillary teeth	28 (24.8%)	10 (8.8%)	35 (31.0%)
Mandibular teeth	None (0.0%)	9 (8.0%)	31 (27.4%)

Table 2. Intra-class correlation coefficients for DIAGNOdent measurements taken under varying conditions and with or without clearly visible plaque

	Spearman's coefficient (P value)	
	No control for hygiene	Controlling for hygiene
Polished and dried vs. naturally wet	.93 (.000)	.92 (.000)
Polished and dried vs. dried	.97 (.000)	.96 (.000)
Naturally wet vs. dried	.96 (.000)	.94 (.000)

Table 3. Paired differences between DIAGNOdent measurements taken under different conditions (paired samples t-test)

	Mean difference	95% Confidence Interval of the difference		Sig. (2-tailed)
		Lower	Upper	
Naturally wet without cleaning vs. dried				
Naturally wet without cleaning vs. dried & polished	-1.1	-2.8	-0.3	.019
Dried vs. dried & polished	-1.2	-3.4	0.2	.073
	-0.1	-1.3	1.1	.863
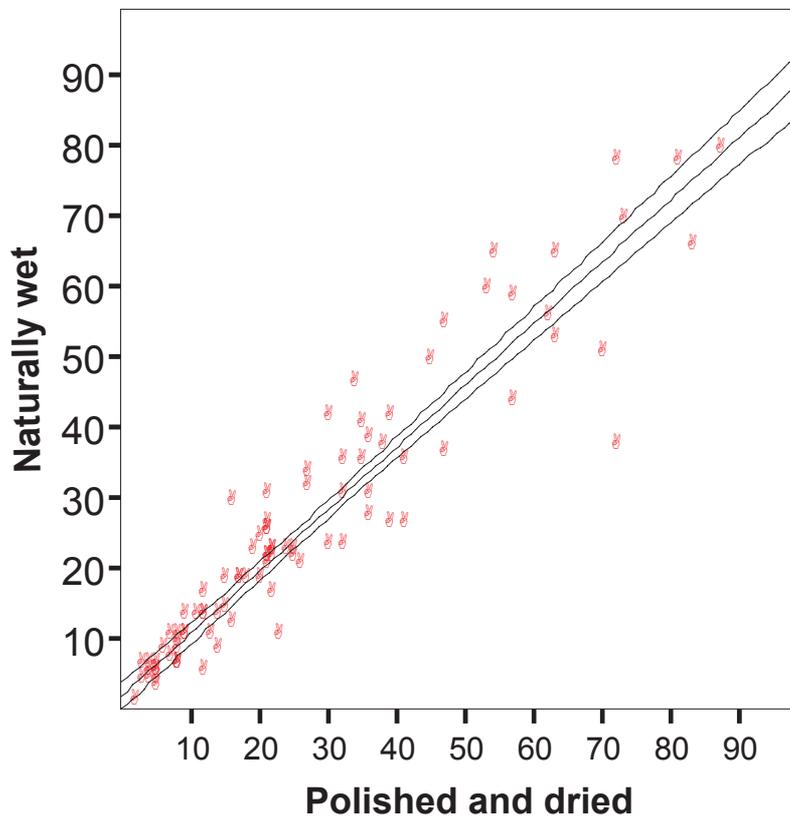
Figure 1. *DIAGNOdent values taken on naturally wet versus values taken on polished and dried surfaces (Regression lines represent 95% CI).*

diagnosing caries with DIAGNOdent values above 20. The Kappa statistics showed that 83% of sites would be consistently diagnosed as either sound or carious despite measurement conditions. Concomitantly, the consistency level between measurements taken under varying conditions was considerably higher for values < 20 than for those >20 (Figure 1).

It is important to note the exclusion from the study of two individuals, although they had teeth with suspected caries. For these subjects, the standard value for a sound spot on a tooth could not be established, i.e. healthy sites showed values corresponding to the values of advanced caries instead of the values normally obtained on a sound tooth. A thorough history–taking disclosed that the backgrounds of these subjects were different from the rest of the sample. Both had lived in Norway for less than a year. One subject was from Africa and had no fillings or cavities. Some teeth were mildly fluorotic. The other subject was from Russia, had a number of fillings of poor quality, and presented a high level of unmet treatment needs.

Discussion

In the present study, the DIAGNOdent system was tested for its potential application in field or epidemiological studies.

Although the system has been extensively validated and studied *in vitro*, the application under less controlled conditions has so far only been evaluated, in a few clinical studies.

The DIAGNOdent performed quite consistently under varying conditions. This has important implications for caries registration in epidemiological and particularly field studies, where full moisture and plaque control is more difficult to achieve than in clinical or experimental studies. Under field conditions, it is seldom possible to polish each tooth prior to an examination.

Another important finding was that the presence of visible plaque did not have a pronounced influence on DIAGNOdent recordings. Although the majority of the examined individuals presented relatively good oral hygiene, there were a few individuals with poor oral hygiene. In the present study, the comparison of sites covered with visible plaque to sites either without plaque or negligible amounts of it, revealed that the presence of plaque did not affect the results to any substantial level. The separate analysis of third molars only, which in general harbored substantially more plaque than the remaining dentition, presented the same trend as the analysis of the whole material. This is an important finding as even in cases where more dental plaque is present than in the present study i.e. in adolescents, one can still expect the same performance of the DIAGNOdent system. Interestingly, *in vitro* studies have reported contradictory results, i.e. the presence of plaque gave a statistically significant decrease in DIAGNOdent readings in primary teeth (Mendes *et al.,* 2004). Other studies indicated that the presence of plaque resulted in higher values (Bamzahim *et al.,* 2004). The finding of our *in vivo* study has important practical implications for field studies: measurements procedures can be substantially simplified without impacting on the precision of the instrument, i.e. measurements in field

studies can be taken in a shorter time than under the standard procedures for polishing and drying the tooth recommended in the clinical setting.

It is important to discuss the findings of the present study in the light of contemporary knowledge. Recently, a comprehensive review article evaluated the validity of the DIAGNOdent system and compared it to other methods. The authors concluded that DIAGNOdent is clearly more sensitive (to find sites with caries) than traditional clinical examination; however, the lack of high specificity (i.e. increased likelihood of false-positive diagnoses) compared with that of visual methods limits its usefulness as a principal diagnostic tool (Tranaeus, 2002). It is important to be aware of the limitations of the present study. In two subjects, high values were recorded on sound spots. This was unexpected and no obvious explanation presented itself, i.e. it was unclear why visually sound enamel in a few sites within the same patient gave extremely high values (over 80). The overall findings were not affected by the values from these two individuals, as these values were similarly and consistently high under all three study conditions. Such findings will not distort an overall picture in epidemiology, although in a clinical setting, such findings can have a different meaning. High DIAGNOdent readings on clinically visible sound surfaces have been observed earlier. One suggested explanation for high values is the presence of irregularities in enamel structure, possibly due to disturbances in tooth mineralization (Heinrich-Weltzien, *et al.,* 2003). The present study showed that examiners should interpret unexpectedly high values with caution. Fortunately, such values are usually observed prior to an actual measurement, i.e. while establishing a standard value for a sound spot.

In the present study, the measurements obtained on naturally wet surfaces without cleaning differed systematically from the measurements taken either on dried or on polished and dried surfaces. This is in accordance with earlier *in vitro* studies (Heinrich-Weltzien, *et al.,* 2003). However, this finding has little practical importance as recordings taken either on naturally wet or dried polished surfaces are unlikely to affect the threshold for diagnosing caries, i.e. the site will still be recorded either as sound or carious. However, DIAGNOdent should still be applied consistently, i.e. all recordings should be made under the same study conditions.

Some limitations of the study due to inclusion criteria should also be considered.

It is important to keep in mind that although DIAGNOdent was tested on all tooth surfaces, only approximal sites available for visual inspection were included. Consequently, the findings from the present study could not be extrapolated to all approximal surfaces with suspected caries. For example it is questionable if DIAGNOdent would perform as consistently as in the present study if all surfaces, sound and suspected for caries, had been examined. This question clearly needs to be answered.

Another limitation is that only sites suspected for caries were included. This decision was made in order to reduce the number of true positives, i.e. the inclusion of all surfaces where majority were sound would substantially increased the agreement between the three measurements as employed in the present study. Concomitantly, such

restricted inclusion limits the extrapolation of findings to different study conditions, i.e. it is unknown how DIAGNOdent will perform if all surfaces sound and suspected for caries would have been examined. This question clearly needs to be answered. Another limitation of the present study is that the validity of the readings was not considered. However, such aim is unattainable in an epidemiological study and with regard to validity issues one has to rely on findings from many experimental studies where DIAGNOdent has been extensively evaluated. However, the wide range of the specificity values (0.52-1.0) of the DIAGNOdent system as reported in different studies still evokes a serious concern. Hopefully, future studies can clarify this issue.

In summary, the present study indicates that the DIAGNOdent system may be applicable in field studies, provided study conditions are consistent and any unexpected values are interpreted with caution.

Disclaimer: The present study is an independent study not supported by DIAGNOdent producers.

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