

## Validity and Reproducibility of a Laser Fluorescence System for Detecting the Activity of White-Spot Lesions on Free Smooth Surfaces *in vivo*

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### Key Words

Dental caries · Free smooth surfaces · Laser fluorescence · Reproducibility · Validity

### Abstract

The aim of the study was to determine the reproducibility and validity of DIAGNOdent in detecting active and arrested caries lesions on free smooth surfaces. Volunteers were selected from state schools of Piracicaba, São Paulo, Brazil. Overall, 220 lesions were clinically examined. Two specially trained ('calibrated') examiners performed both clinical and laser evaluations independently, and after a 1-week interval, the examinations were repeated. The intra-examiner agreement for the laser evaluation was substantial ( $\kappa_{ex1} = 0.79$ ,  $\kappa_{ex2} = 0.71$ ). There was almost perfect agreement between the two examiners for the clinical examination ( $\kappa_{ex1} = 0.95$ ,  $\kappa_{ex2} = 0.85$ ). The inter-examiner agreement showed substantial reproducibility ( $\kappa = 0.77$ ) for the laser examination and almost perfect agreement ( $\kappa = 0.85$ ) for the clinical evaluation. The validation criterion was the clinical examination of white spots, recorded as active or arrested. The

sensitivity was 0.72 and the specificity was 0.73, which indicates that the DIAGNOdent was a good auxiliary method for detecting incipient caries lesions on free smooth surfaces. The utilization of both methods can improve the efficacy of caries diagnosis.

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Easy and nondestructive quantification of early lesions would allow their monitoring over time, enabling the dentist to intervene in the caries process [de Josselin de Jong et al., 1995], providing remineralization and conservation of the tooth substance rather than restoration of the dentition [Angmar-Månsson and ten Bosch, 1987].

The physical properties of the caries lesion are the bases for the detection and quantification of caries by means of optical methods [Angmar-Månsson et al., 1996]. Because there is much more water in a lesion than in sound enamel, the free path length of a photon light inside the lesion is shorter and the transparency is less, compared with that of sound enamel. Thus, a caries lesion is a highly scattering material [Angmar-Månsson and ten Bosch, 1987] that clinically differs from sound enamel

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[Backer-Dirks, 1966; Neilson and Pitts, 1991; Angmar-Månsson et al., 1996].

In 1998, a laser-based diagnostic system was developed using a diode laser as light source and a photodiode combined with a long-pass filter as detector [Hibst, 1999]. The teeth are illuminated by laser light ( $\lambda = 655$  nm), which is absorbed by the tooth substance. Some of this light is re-emitted as near-infrared fluorescent light, and changes in the tooth substance that are associated with progression of the caries process are reflected in an increase in the amount of fluorescent light [Angmar-Månsson and ten Bosch, 1987]. Therefore, caries lesions can be detected by fluorescence intensity. Based on these findings, a new laser device (DIAGNOdent; KaVo, Biberach, Germany) was developed for the detection and quantification of caries lesions in clinical situations. To date, the available documentation is limited and the validity and reproducibility of DIAGNOdent in the clinical environment require independent investigations [Shi et al., 2000]. The performance and reproducibility of the laser device have been investigated on occlusal and approximal surfaces *in vitro* [Lussi et al., 1999; Shi et al., 2000, 2001; Attrill and Ashley, 2001] and *in vivo* [Ross, 1999; Lussi et al., 2001].

DIAGNOdent showed good reproducibility for occlusal surfaces under both wet and dry conditions of examination [Lussi et al., 1999; Shi et al., 2000], and the diagnostic accuracy was significantly more reliable than that of radiography [Shi et al., 2000]. The performance of DIAGNOdent was not statistically better than that of visual inspection for noncavitated occlusal surfaces in primary molars [Attrill and Ashley, 2001]. A study evaluated DIAGNOdent for *in vitro* quantification of approximal smooth surface caries on extracted teeth and the validation criteria were determined by histopathology and microradiography. It was concluded that the system can be indicated for caries quantification on smooth surfaces [Shi et al., 2001].

Some investigations were performed *in vivo* on approximal and occlusal surfaces [Ross, 1999; Lussi et al., 2001]. DIAGNOdent was very inefficient at clinically detecting approximal lesions [Ross, 1999], and more data are needed to recommend the appliance for differentiating between lesions in enamel and dentin on occlusal surfaces [Lussi et al., 2001]. The laser device is recommended as a second opinion in cases of doubt after visual inspection of occlusal surfaces [Lussi et al., 2001].

Although efforts have been made to investigate approximal and occlusal surfaces, no previous study was found to report the validity of DIAGNOdent to detect

noncavitated caries on free smooth surfaces *in vivo*. Free smooth surfaces are potentially much more accessible for direct clinical observation, and are more readily detected at an early stage than approximal and occlusal surfaces, i.e., before cavitation occurs. However, the management of free smooth surface lesions can be problematic because caries is a dynamic process, and it may not be possible to tell at first sight whether the lesion is active, arrested or remineralizing [Neilson and Pitts, 1991].

The importance of early detection of caries activity is emphasized by the fact that an incipient lesion can be arrested. On visual examination, well-defined clinical criteria are the methods of first choice [Lussi et al., 1999], especially when examining free smooth surfaces *in vivo*, since the clinician's ability has been pointed out as a valid method to determine caries activity [Alanen et al., 1994]. However, it is still difficult to make a decision on clinical caries diagnosis. A diagnostic system could have the advantage of objectively recording noncavitated stages of caries lesions. The aims of the present study were therefore: (1) to study the reproducibility of a laser fluorescent method in detecting active and arrested caries lesions on free smooth surfaces *in vivo* and (2) to determine the sensitivity and specificity of the laser method after it was validated by clinical examination of caries lesions.

## Materials and Methods

The experiment was performed on free smooth surfaces *in vivo*, and the method chosen to determine caries activity was visual inspection (validation criteria).

### Sample and Participants

The study was conducted at Piracicaba School of Dentistry and approved by the local Ethics Committee on Research.

Subjects were selected from state schools and examined during the normal school day. The examinations were carried out in classrooms under good light conditions, using sterile mirrors and blunt probes to remove visible dental plaque from free smooth surfaces. Only permanent teeth were evaluated, and the inclusion criterion was the presence of at least one white-spot caries lesion on a free smooth surface. Arrested lesions comprising brownish pigments were excluded, since, as indicated by the manufacturer of DIAGNOdent, there are indications that the laser device shows false-positive results in such cases [Lussi et al., 1999; Shi et al., 2000; Lussi et al., 2001].

A total of 2,500 11- to 17-year-old volunteers were examined, and 92 were scheduled. Fifty volunteers enrolled in the study, and overall 220 lesions were included. The subjects and their parents were informed about the purpose of the study and gave both oral and written consent for their children to participate in the study.



### Clinical Diagnostic Criteria

The caries diagnosis criteria were developed based on information from the literature [Beighton et al., 1993; Nyvad et al., 1999] as well as on previous experience of the examiners with clinical caries diagnosis [Pinelli et al., 2001]. All free smooth surfaces were thoroughly dried and clinically examined in a dental office with the help of mouth mirrors and reflector light in order to detect any white spots. The lesions detected by visual examination were recorded either as active or inactive and recorded on a specific form by each examiner. DIAGNOdent was used to examine only the lesions detected by visual inspection.

The examiners performed and repeated the clinical and laser evaluations independently, with no communication, in different periods of time. Furthermore, they re-evaluated the lesions without knowing any previous results, which means that they were blinded to all previous results.

Either active or inactive white spots were analyzed based on their color, brightness and roughness; the distance from the gingival margin was also verified. Table 1 describes the clinical criteria for visual examination. All lesions investigated by the examiners had intact surfaces.

As surface texture is considered a more reliable indicator of activity than color [Beighton et al., 1993; Nyvad et al., 1999], color was never used as the sole criterion. The lesions containing elements of both active and inactive caries were diagnosed as active [Nyvad et al., 1999].

### Examiners' 'Calibration'

A preliminary study was performed [Pinelli et al., in press], and two examiners were calibrated in order to ensure that they would record the clinical criteria in the same manner, either for the active or inactive caries lesions. Calibration exercises were carried out for a 1-month period by means of discussions and practical exercises of both clinical and laser examinations performed on patients.

A flat probe was chosen for diagnosing free smooth surfaces in accordance with the instructions of the manufacturer of DIAGNOdent. The standard value for an individual subject was calibrated by measuring with the laser in a region of sound tissue. When the lesions were evaluated, the maximum value for each measurement was registered as the peak value on the laser display.

DIAGNOdent records numbers from 0 to 99, but the manufacturer's instructions did not provide any scale to be used in clinical situations. No previous study was performed concerning free smooth surfaces and DIAGNOdent, and no scale was found in the literature to classify those laser results in vivo. Only two scales had been previously described, the one proposed by Lussi et al. [1999] (in vitro study) and that proposed by Ross [1999] (in vivo study). The cut-off points to interpret the laser results were determined according to the different levels of caries involvement. Our preliminary study [Pinelli et al., in press] compared the two classification scales in detecting incipient lesions on free smooth surfaces in vivo. Although the extrapolation of the laser results in vitro for in vivo situation may seem unlikely, the scale proposed by Lussi et al. [1999] adapted by Pinelli et al., showed better reproducibility than the scale proposed by Ross [1999]. Therefore, the cut-off points were established as: arrested lesions (values from 0 to 4) and active lesions (values from 5 to 99).

**Table 1.** Clinical criteria for visual examination of noncavitated caries lesions

Category	Clinical criteria
Active lesions	the enamel presents a white-spot lesion, which is whitish or yellowish, opaque, with loss of luster, and rough; it is generally covered with dental plaque, and typically contoured to the gingival margin, which is inflamed
Inactive lesions	the enamel surface presents a white-spot lesion, which is whitish, shiny and smooth. There is no dental plaque and the lesion has the appearance of a scar, located far from the gingival margin, which is healthy

### Examination Conditions

Immediately before the examinations, subjects flossed and brushed their teeth with a fluoridated dentifrice. A dental hygienist supervised and motivated the volunteers and also checked the teeth, thus assuring thoroughly cleaned surfaces.

Both clinical and laser evaluations – using a dental chair, compressed air, and operating light – were independently carried out by the examiners under standardized conditions of room temperature ( $23 \pm 1^\circ\text{C}$ ). The laser device was applied on each previously dried surface with an air syringe for 10 s. After a 1-week interval, and under identical conditions, the same operators repeated both evaluations.

### Assessment of Reproducibility

The intra- and inter-examiner reproducibilities of clinical caries diagnosis and of laser DIAGNOdent were evaluated.  $\kappa$  statistics were applied [Light, 1971], and the results were interpreted according to Landis and Koch [1977].

### Results

The  $\kappa$  values and the  $\kappa$  confidence interval for intra- and inter-examiner agreement, according to clinical and laser examinations, are shown in tables 2 and 3. For both examiners, there was an almost perfect intra-examiner agreement on the clinical evaluation, and for the laser evaluation, the intra-examiner agreement was substantial (table 2).

Since the reproducibility was good for both clinical and laser intra-examiner evaluations, it was possible to choose either the first or the second day of examination to test the inter-examiner reproducibility (the first day of the clinical examination was chosen). The inter-examiner agreement for the clinical and laser evaluations, respectively, exhibited almost perfect agreement and substantial agreement (table 3).



[Landis and Koch, 1977], and it is suggested that  $\kappa$  values above 0.75 denote excellent agreement [Fleiss, 1981; Lussi et al., 2001]. With regard to laser examination, the  $\kappa$  values by point were lower than 0.80. However, the kappa confidence interval, for both examiners, exceeded 0.80 and the results were not significantly lower than 0.80.

For occlusal surfaces on dried and wet teeth, *in vitro*, and when dental caries were restricted to the enamel, the sensitivity of DIAGNOdent was 0.83, while the specificity was 0.72 on dried teeth [Lussi et al., 1999]. When occlusal surfaces were investigated *in vivo*, DIAGNOdent showed a sensitivity of >0.92 and a specificity of 0.86 for caries in dentine [Lussi et al., 2001]. It was also demonstrated that the laser is a valuable method for diagnosis, as it combines the advantages of higher specificity and speed of visual inspection with the higher sensitivity of the new device [Lussi et al., 2001]. Similar results were verified in the present study, in which the laser device showed a sensitivity of 0.72 and specificity of 0.73 for caries lesions on free smooth surfaces *in vivo*.

In screening tests, a sensitivity of 100% would be ideal. However, the sensitivity was far from ideal (0.72), and it is possible to conclude that part of the subjects exhibiting active white spots (28%) were not included in the treatment. Otherwise, the specificity result (0.73) would have led to the inclusion of false positives (27%).

A differential caries diagnosis based on characteristics of active and arrested white spots is still difficult as it requires visual observation, which may be subjective. Furthermore, the examiners' 'calibration' is important to reach a high reproducibility in observing noncavitated lesions. With the aim of a more reliable diagnosis, the combined use of DIAGNOdent and visual inspection on free smooth surfaces is recommended, since the laser has the advantage of quantifying the mineral content, helping clinicians to improve the diagnostic efficacy and treatment.

DIAGNOdent is a valid method, although some pre-requisites are required to reduce the number of false positives in the clinical situation. It has been shown that DIAGNOdent gives an increased reading for any changes in physical properties of the tooth structure, such as the presence of stains, disturbed tooth development, or mineralization, as well as deposits of calculus or dental plaque [Lussi et al., 1999; Shi et al., 2000]. Therefore, the tooth surfaces should be cleaned before the measurements.

Although it has been shown that DIAGNOdent might tolerate moisture [Lussi et al., 1999, 2001; Shi et al., 2000], further research is required before it is recommended [Lussi et al., 1999] because scattering of the light inside a dried lesion is increased, as the refractive index of air to crystals is greater than that of water to crystals [Angmar-Månsson and ten Bosch, 1987]. In order to standardize the moisture content of the teeth, strict timing of the drying procedure was held during 10 s.

The intensity of light that is reflected from the operation lamp on the teeth might also influence the laser results, and the maintenance of a constant physical environment is considered important [Shi et al., 2000].

The adequate use of any methods depends on the dentist who is responsible for the comprehensive caries diagnosis for the patient. Therefore, caries diagnosis needs to be based on organized information collected from the dental history and the results of various diagnostic procedures, filtered by the dentist's knowledge and experience [Angmar-Månsson et al., 1996]. DIAGNOdent was reproducible and valid as an auxiliary method for detecting caries lesion on free smooth surfaces *in vivo*.

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