**In Vitro Comparison of Diagnostic Accuracy of DIAGNOdent and Digital Radiography for Detection of Secondary Proximal Caries Adjacent to Composite Restorations**

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**Abstract**

**Background and Objectives:** Early detection of secondary proximal caries is critical for preservation of tooth vitality. This study sought to assess and compare the diagnostic accuracy of DIAGNOdent and digital radiography for detection of secondary proximal caries adjacent to composite restorations.

**Materials and Methods:** Sixty extracted molars including 30 teeth with carious lesions and 30 sound teeth were randomly selected. Class II cavities were prepared in all teeth and carious dentin was intentionally left in the gingival floor of cavities in 30 carious teeth. All cavities were restored with composite resin. The teeth were mounted in wax blocks (three teeth per block) and examined for caries using DIAGNOdent) kaVo Dental,Biberach,Germany). Digital radiographs using DIGORA Photostimulable Phosphor (PSP) plates (Soredex Corporation, Helsinki, Finland ) were obtained from all teeth using the parallel technique and were evaluated by four observers. Repeated measure ANOVA was applied to calculate sensitivity and specificity values of the two diagnostic techniques. Receiver operating characteristic (ROC) curve was plotted for DIAGNOdent results and based on that, the cutoff points were determined.

**Results:** The sensitivity and specificity values at the cut-off point of 10.5 were 0.622±0.038 and 0.822±0.077 for DIAGNOdent and 0.591±0.093 and 0.891±0.083 for digital radiography, respectively. The area under the ROC curve was 0.7 for DIAGNOdent. Weighted kappa revealed moderate to almost perfect intra-observer agreement (0.46-0.99). Intraclass correlation coefficient (ICC) for DIAGNOdent was calculated to be 0.88.

**Conclusion:** No statistically significant difference was noted in diagnostic accuracy of DIAGNOdent and digital radiography for detection of secondary proximal caries adjacent to composite restorations. Thus, DIAGNOdent may be used as an adjunct diagnostic tool for detection of secondary proximal caries beneath composite restorations.

**Key words:** Diagnostic accuracy, Proximal caries, DIAGNOdent, Digital radiography, Composite restoration

**Introduction**

Despite the recent advances in preventive dentistry and improved quality of restorative materials, clinicians still witness a high incidence of secondary caries. Secondary carious lesions account for 40-70% of restoration exchanges (1). According to the FDI World Dental Federation, secondary caries is defined as “positively diagnosed lesion at the margins of an existing restoration” (2). Areas prone to plaque accumulation such as the margins of restorations are most susceptible to development of secondary caries (3). Secondary caries refers to a thin carious lesion in the enamel or dentin at the cavity floor-restoration interface (4).

Clinicians often detect secondary caries via observation, probing with a dental explorer and radiography. Marginal discoloration of restorations is not a reliable indicator of secondary caries. Examination and probing of restoration margins with an explorer tip must be done with caution and utmost care must be taken not to damage the tooth structure or the restorative material. Moreover, it should be noted that a sharp explorer tip may be caught in almost any fissure or groove and therefore, it does not necessarily mean presence of caries (4). Bitewing radiography is the most commonly used diagnostic technique for detection of secondary caries (5). However, effect of level of education and experience of the observer on accurate interpretation of radiographs and also the confounding effect of artifacts of restorative materials are all among the limitations of radiography ( 6). In the clinical setting, secondary caries often remain undetected until they form a cavity or result in loss of a significant portion of tooth structure. Thus, new diagnostic methods have been introduced for early detection of caries including electrical conductance measurement , laser florescence (LF), digital radiography and enhancement of digital radiographs (1-7).

DIAGNOdent (LF pen) is a diagnostic tool for caries detection operating based on LF. It quantifies the extent of carious lesions and provides numerical data. The tooth surface is irradiated with red light (at 655nm wavelength) generated by a diode laser and transferred to the tooth via an optical fiber. Laser light is absorbed by the tooth surface and is then reflected due to the fluorescence characteristic of tooth structure. The intensity of fluorescence reflected from the carious areas is higher than that of sound tooth structure. The fluorescence collected from bacterial metabolites in the carious lesion such as the porphyrins has a wavelength close to that of infrared light (wavelength>655 nm) and thus, a higher number is displayed on the digital display monitor of DIAGNOdent. The deeper the carious lesion, the higher the number displayed (8).

Previous studies have mostly focused on the application of DIAGNOdent for detection of primary caries and the efficacy of this diagnostic tool has been confirmed in many (9,10) and rejected by some other studies (11, 12). Studies on the application of DIAGNOdent for detection of secondary caries beneath composite restorations are limited and there is a gap of information in this regard in dental literature. Boston (2003) was the first to evaluate secondary caries beneath composite restorations; although he evaluated secondary caries in the occlusal surface (13). Later on, some other researchers mainly focused on detection of occlusal secondary caries and caries around amalgam restoration margins (14 -16).

Considering the importance of detecting secondary caries adjacent to composite restorations in the proximal areas (particularly in the gingival floor), the current study focused on this particular area. To the best of our knowledge, similar previous studies focusing on this topic are scarce. Rodrigues (2010) was the only one who compared the diagnostic efficacy of DIAGNOdent and radiography for detection of secondary caries around composite restorations. He recommended the use of DIAGNOdent as an adjunct diagnostic tool for detection of secondary caries. The difference between their study and ours was that they used conventional film-based radiography (17).

Since currently digital sensors are used for image capture and no comparison has been made between the efficacy of DIAGNOdent and digital radiography for detection of secondary proximal caries, the current in-vitro study was undertaken to assess and compare the diagnostic accuracy of DIAGNOdent and digital radiography with photostimulable phosphor (PSP) plates (DIGORA) in detection of secondary caries adjacent to composite restorations.

**Materials and Methods**

*Preparation of teeth:*

Sixty extracted human molar teeth, stored in saline solution, were used in this study. Thirty teeth with proximal caries and 30 sound teeth were selected. Dental calculus was precisely removed using a scaler and the teeth were rinsed under running water for 15 seconds. Classic class II cavities were prepared in all teeth. Carious dentin was intentionally left in the gingival floor of cavities in carious teeth. The 30 sound teeth were checked using a dental explorer to ensure absence of caries. The cavities were prepared using 008 straight diamond bur and high-speed hand piece along with water spray. The cavities were restored with composite resin without etching and bonding. The teeth were randomly coded from 1 to 60 and mounted in wax blocks. Three teeth were mounted in each block simulating proximal contacts. A total of 60 proximal surfaces were evaluated.

*Obtaining radiographs:*

All radiographs were obtained using DIGORA® Optime (Soredex Corporation) and size 2 PSP plates measuring 30x40mm. The X - ray dental machine MINRAY® ( Soredex, Helsinki, Finland) was adjusted exposure settings of 70 kVp, 1mA and 0.1s radiation time. Radiographs were captured in faciolingual direction using the parallel technique. After exposure, PSP plates were scanned using Soredex Digora ® Optime scanner with standard resolution. The distances from the X- ray tube to the object and from the sensor plate to the object were 45cm and 1cm, respectively. To simulate the absorption properties of soft tissue, a 4cm-thick acrylic block (polymethyl methacrylate) measuring 15x15 cm was placed between the X ray tube and dental blocks(18).

*Interpretation of radiographs:*

All digital radiographs were displayed on a 19-inch(Samsung,SyncMaster )monitor with a resolution of 1360x768 pixels using Scanora Lite software. Radiographs were evaluated in a semi-dark room by four observers: an oral and maxillofacial radiologist, a restorative dentist, a general dentist with 20 years of clinical experience and a senior dental student. The observers were informed about the methodology and objectives of the study. They were allowed to adjust the density and contrast of images and no time limitation was set for the observation of images. Observers evaluated the images in terms of presence or absence of caries in the gingival floor of the restorations. To assess the intra-observer reproducibility, the same images were evaluated by the observers again after a one-month interval under similar conditions.

*DIAGNOdent measurement:*

Prior to using DIAGNOdent, the teeth were cleaned using an air polisher and prophylactic paste for 10 seconds and then rinsed under running water. The proximal surfaces were examined by a wedge-shaped sapphire fiber tip (thickness of 0.4mm and width of 1.1 mm). DIAGNOdent was calibrated prior to measurements according to the manufacturer’s instructions. The tip of the device was moved below the contact point from the buccal towards the lingual surface. This was repeated from the lingual towards the buccal as well and the highest value was recorded. Measurements were repeated three times for each tooth.

*Statistical analysis:*

Sensitivity and specificity parameters were calculated to assess and compare the diagnostic efficacy of DIAGNOdent and digital radiography for detection of secondary caries. The area under the ROC curve was calculated for DIAGNOdent data. Repeated measure ANOVA was applied to compare the sensitivity and specificity of the two diagnostic methods. P<0.05 was considered statistically significant. Weighted kappa was calculated to determine intra and inter-observer agreement. ICC was used to evaluate the reproducibility of DIAGNOdent (two-way random, absolute agreement).

**Results**

The sensitivity and specificity of DIAGNOdent and digital radiography for detection of secondary caries were calculated and the cutoff points were determined (Table 1). The cutoff points in ROC curve for DIAGNOdent were 8.5, 9.5 and 10.5; which were considered as diagnostic cutoff points. Based on Table 1, although the sensitivity at the cutoff point of 8.5 for DIAGNOdent was significantly higher than that for digital radiography (0.73 ± 0.001 vs 0.59 ± 0.09 ; p=0.01), the specificity at this cutoff point for DIAGNOdent was significantly lower than that for digital radiography ( 0.57 ± 0.03 vs. 0.89 ± 0.08 ; p=0).. In terms of sensitivity, no significant difference existed at the cutoff point of 9.5 between DIAGNOdent and digital radiography (0.68 ±0.3 vs. 0.59 ± 0.09 ; p=0.06), but the specificity of DIAGNOdent at this cutoff point was lower than that of digital radiography ( 0.67 ± 0.03 vs 0.89 ± 0.08 ; p=0.002). The area under the ROC curve was found to be 0.7 for DIAGNOdent (Figure 1). Intraobserver reproducibility for observers 1 to 4 was 0.88, 0.46, 0.73 and 0.99, respectively for digital radiography. The mean interobserver reproducibility was calculated to be 0.73 for digital radiography. ICC for DIAGNOdent was reported to be 0.88.

**Discussion**

Diagnosis of secondary caries is a challenging topic due to the increasing use of restorative materials. Early detection of secondary caries is critical for a prompt preventive measure or making a decision to exchange the restoration (4, 13). The current study assessed and compared the diagnostic efficacy of digital radiography and DIAGNOdent for detection of secondary caries beneath composite restorations. Our results confirmed the optimal efficacy of DIAGNOdent for detection of secondary proximal caries adjacent to composite restorations. However, its diagnostic efficacy was not significantly different from that of digital radiography; this finding is in line with the results of some other studies (6, 18, 19 ).

Bonding agents, applied to the cavity floor beneath composite restorations may compromise accurate radiographic detection of secondary caries and even result in misdiagnosis, especially if placed in a thick layer. Thus, in the current study, similar to that of Kositbowrnchai et al., these materials were not used (6, 20).

Sensitivity and specificity of a diagnostic technique are mainly calculated with a cutoff point. Thus, for accurate determination of the cut-off point, three methods were used in the current study. The first method was to find a cutoff point in the ROC curve. Using this curve, two points with significant properties were found: point 8.5 with a sensitivity higher and a specificity lower than those of digital radiography and point 10.5 with no statistically significant difference with digital radiography in this regard. The second method was detection of a point where specificity yielded one. The specificity at point 29 was found to be 1 in all three measurements. Based on this specificity value, the point 29 was the most suitable point for presence of secondary caries. In a study by Rodrigues et al, the point 30 was determined to be the most suitable point in terms of specificity. In our study, the sensitivity and specificity of DIAGNOdent at the cut-off point of 10.5 were similar to those of digital radiography. Some previous in-vitro studies have also reported almost equal sensitivity and specificity values for DIAGNOdent and digital radiography (21).

The area under the ROC curve, indicating the correlation of sensitivity and specificity, was calculated to be 0.71 for DIAGNOdent. The possible range for this value (area under the ROC curve) is 0.5-1 (22). Thus, the value obtained in our study is moderate and close to the value reported by Rodrigues et al (17).

The kappa statistics showed excellent intra-observer agreement for observers 1 and 4, and observes 2 and 3 had moderate and substantial intra-observer agreements, respectively. Also, the mean inter-observer kappa coefficient was found to be 0.73; which is a moderate value (23).

DIAGNOdent was expected to have a reproducibility coefficient close to 1. In the current study, ICC was found to be 0.88; which indicates high reproducibility of this tool. This finding is close to the results of Rodrigues, studying the secondary proximal caries and Lussi et al. evaluating primary proximal caries (17, 24).

The results of this study indicated higher reproducibility of DIAGNOdent compared to digital radiography. This finding indicates that the clinical experience and knowledge of observers may affect the interpretation of digital radiographs; whereas, based on studies by Kunish et al. and Saber et al., the results of DIAGNOdent are not influenced by the operator’s skills (5, 25).

Some studies have demonstrated that DIAGNOdent (in comparison to radiography) enhances the detection of secondary caries around amalgam restorations (14, 16). However, some others do not recommend the use of DIAGNOdent for detection of residual caries (26). Klause et al. demonstrated that DIAGNOdent had limitations for detection of residual caries close to dental pulp (27); this indicates that in the clinical setting, many factors may affect the performance of DIAGNOdent.

Some studies have reported that the wedge-shaped tip design (B tip) of DIAGNOdent used in the current study increases the sensitivity for detection of caries .On the other hand , the contact point simulation in vitro does not exactly resemble the actual contact points in vivo. Moreover, the access of DIAGNOdent (B tip) to contact areas in vitro is much easier than in vivo. Furthermore, probing the proximal surfaces of Class II restorations by DIAGNOdent still remains a challenge. It must be noted that prior to examining the teeth surfaces with DIAGNOdent, the teeth and restoration surfaces should be thoroughly polished because calculus, deposits and stain may lead to false positive results (24,28).

PSP plates (Digora system) were used for image capture in the current study, which is in contrast to the methodology of previous studies; however, our obtained results confirmed those of previous investigations (6). In order to enhance the detection of caries and decrease the number of bitewing radiographs required, DIAGNOdent is recommended to be used in conjunction with bitewing radiography.

DIAGNOdent at a cut-off point of 8.5, with a sensitivity higher and a specificity lower than that of digital radiography, can be used as the first line diagnostic method for field screening tests when a high number of samples should be screened in a short period of time. Since there is a high risk of false positive results, DIAGNOdent should be preferably used in conjunction with other diagnostic techniques.

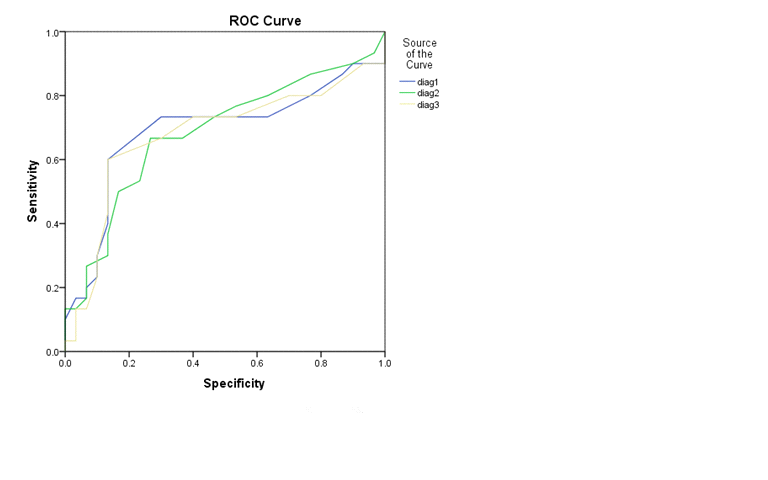
**Conclusion**

DIAGNOdent and digital radiography have equal diagnostic efficacy for detection of secondary proximal caries adjacent to composite restorations. Future studies are required to further scrutinize the diagnostic efficacy of the combination of these two methods for detection of secondary caries.

Table 1 Sensitivity and specificity for digital radiography (by the four observes) and DIAGNOdent using different cut-off points

|  |  |  |
| --- | --- | --- |
|  | Sensitivity | Specificity |
| Radiographic examination | 0.59 ±0.09 | 0.89 ±0.08 |
| DIAGNOdent 8.5 | 0.73 ±0.001 | 0.57 ±0.03 |
| DIAGNOdent 9.5 | 0.68 ±0.03 | 0.67 ±0.03 |
| DIAGNOdent 10.5 | 0.62 ±0.03 | 0.82 ±0.07 |

Fig. 1 Roc curve for DIAGNIdent on secondary caries detection (in three times measurements)



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