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** ABSTRACT **

** Aim ** This research was aimed to investigate the in vivo and in vitro performance of traditional and novel methods in the detection of occlusal caries in primary teeth.

** Materials and methods ** One hundred twenty primary molar teeth were assessed by two examiners both in vivo using ICDAS II, radiographic examination, DIAGNOdent pen, CarieScan PRO and SoproLife camera and in vitro using the mentioned diagnostic methods except radiographic examination. In addition, in vitro examinations were repeated 2 weeks later. After sectioning and evaluation under stereomicroscope, the lesion depth was determined with Downer’s histological criteria. Sensitivity, specificity, positive and negative predictive value, accuracy and area under the ROC curve were calculated at D1 and D3 thresholds. The intra- and inter-examiners’ reproducibility were analysed using Cohen’s kappa statistics and intraclass correlation coefficient.

** Results ** Intra- and inter-examiner repeatability were high for all methods. While ICDAS and SoproLife camera showed the highest sensitivity value at D1 and D3 thresholds in vivo, radiographic examination showed the lowest sensitivity values. While ICDAS and SoproLife camera showed the highest sensitivity values at D3 threshold in vitro, CarieScan PRO showed the lowest sensitivity value.

** Conclusion ** The ICDAS II method could be sufficient alone in diagnosis of occlusal caries of primary teeth. However, SoproLife camera may be useful in monitoring caries lesions.

** Keywords ** Caries detection; ICDAS II; Primary molars; SoproLife camera.

In vivo and in vitro comparison of ICDAS II, DIAGNOdent pen, CarieScan PRO and SoproLife camera for occlusal caries detection in primary molar teeth

** IN VIVO **

** Introduction **

Visual criteria of Ekstrand et al. [1997], which has been used since 1997, have become insufficient in time, and novel visual criteria have begun to be developed. For this reason, ICDAS classification criteria have been presented in 2002 by taking the best properties of the caries detection criteria that have been used until today and defined as ICDAS II after having being re-arranged in 2005. Digital radiography techniques were developed in order to eliminate the disadvantages of conventional radiography. But, digital radiography is insufficient in diagnosis of early-stage enamel occlusal caries despite its advantages of being easily applicable, providing an imaging archive, low x-ray emission, and providing images in a short time [Neuhauser al., 2011; Novaes et al., 2012]. DIAGNOdent Pen is an example of modern devices that work based on the fluorescence difference between healthy and demineralised tooth tissues. It was introduced to the market and designated as more ergonomic compared to its former version, DIAGNOdent [Lussi and Hellwig, 2006]. CarieScan PRO is a device which works based on the electrical conduction difference between healthy and caries tissue and is another example of modern diagnostic tools. This system, which uses multiple low-voltage frequencies, works with an alternating current impedance spectroscopy technique (ACIST) [Ari and Ari, 2013]. SoproLife camera, based on induced laser fluorescence, is the modern caries detection method, which combines the advantages of visual examination through a high-magnification oral camera with the advantages of a laser fluorescence device [Terrer et al., 2009, 2010]. There are a limited number of studies investigating the detection of occlusal caries, particularly using CarieScan PRO and SoproLife camera. The studies about these methods on primary teeth are limited to the studies of Ari et al. [2013], Teo et al. [2014], and Theocarapoulou et al. [2015]. In addition, in vitro researches may not provide correct data about the clinical use of caries detection methods, as they are evaluated under better circumstances [Reis et al., 2006]. The aim of our study is to investigate the in vivo and in vitro effectiveness of conventional and modern methods, like DIAGNOdent pen, CarieScan PRO, SoproLife camera in detection of occlusal caries of primary teeth.
Material and methods

Ethics Committee approval was obtained from the Clinical Researches and Ethics Committee of the Cumhuriyet University, Faculty of Dentistry. Clinical procedures were initiated after written informed consent had been obtained from the parents of the participants. They were recruited from children aged between 9 and 12 years who were admitted to the Pedodontic Clinic of Cumhuriyet University Faculty of Dentistry. In total, 120 primary molar teeth past exfoliation time and with indication for extraction confirmed radiologically were included in the present study. The occlusal surfaces of the teeth had minimal macroscopic destruction, having fissure discoloration and varying from intact to having different stages of non-cavitated caries lesions. Teeth that had caries on other surfaces except occlusal surface, had previously undergone restoration, had cavitation, fluorosis, or hypoplasia, were excluded from the study. All diagnostic methods (visual inspection, radiographic examination, DIAGNOdent pen, CarieScan PRO and SoproLife camera) were evaluated by two examiners (AD, MÜ).

**In vivo examinations**

Digital radiographies were obtained in order to determine the time of exfoliation during patient selection. The images were taken for each tooth, using an X-ray machine (X Mind, Acteon, La Ciotat, France) and phosphorous plates (PSP!X, Acteon, La Ciotat, France) at 70 kVp, 8 mA, and exposure time of 0,16 s. Laboratory coat and thyroid protective clothing were used on all patients. The obtained images were recorded with Sopro Imaging program and evaluated by two independent examiners using the modified scoring criteria of Ekstrand et al. [1997]. These criteria were coded as follows: (0) no visible radiolucency; (1) radiolucency in the enamel; (2) radiolucency in the dentin, involving the surface or the outer third of the dentin, and (3) radiolucency in the dentin, involving the inner third of the dentin. Codes 1 and 2 were used as cut-off points at D1 and D3 threshold values, respectively.

Polishing was done using a brush and micromotor without pumice in order to remove the plaque and discoloration on the surface. Afterwards, the teeth were washed and dried with air-water spray. The areas that would be examined were marked and then examined under a reflector light without using a probe, by two independent examiners using ICDAS II criteria. ICDAS II criteria were explained as follows: (0) sound tooth surface: no evidence of caries after 5 s air drying; (1) first visual change in enamel: opacity or discoloration (white or brown) is visible at the entrance to the pit or fissure seen after prolonged air drying; (2) distinct visual change in enamel visible when wet, lesion must be visible when dry; (3) localised enamel breakdown (without clinical visual signs of dentinal involvement) seen when wet and after prolonged drying; (4) underlying dark shadows from dentine; (5) distinct cavity with visible dentin, and; (6) extensive (more than half the surface) distinct cavity with visible dentine. ICDAS codes 1 and 3 were used as cut-off points at D1 and D3 threshold values, respectively.

The cylinder sapphire tip that was designed for use on occlusal surfaces was placed onto the device during the examinations done with DIAGNOdent pen device. Calibration was done in accordance with the instructions of the manufacturer prior to all the measurements. The examined tooth was washed with air-water spray, isolated using cotton pellets, and mildly dried for 5 s. Care was taken to avoid over-drying. Rotation was done with the tip of the device for the light to reach all surfaces. Three measurements were performed consecutively for each site, and the highest value (peak value) was obtained and recorded by two examiners. Afterwards, all data were evaluated using the scale of Cinar et al. [2013] (Table 1). Score intervals of enamel and dentin caries were used as cut-off points for D1 and D3 threshold values, respectively.

For the measurements done using the CarieScan PRO device, all teeth were isolated with cotton pellets after the lip clip of the device had been placed properly. The 5 s tooth drying recommended by the manufacturer was reduced to 3 s, as recommended by Teo et al. [2014]. The device was placed vertically to the measurement region with no pressure. Three measurements were performed consecutively for each marked site, and the highest value was obtained and recorded by two examiners. Later, all data were evaluated using the scale of Teo et al. [2014] (Table 1). Score intervals of enamel and dentin caries were used as cut-off points for D1 and D3 threshold values, respectively. In the measurements done using SoproLife camera, each tooth was isolated with cotton pellets, and the reflector light was turned off. Diagnostic mode was chosen and the images of the teeth were taken with the camera under standard magnification. The images were recorded to Sopro Imaging program and evaluated according to the criteria of Rechmann et al. [2012]. The codes were explained as follows: (0) sound, no visible change in enamel (rarely a graphite-pencilcoloured thin shine/line can be observed) shiny green fissure; (1) tiny, thin red shimmer in the pits and fissure system, can come up the slopes, no red dots visible; (2) in addition to tiny, thin red shimmer in pits and fissures possibly coming up the slopes darker red spots confined to the fissure are visible; (3) dark red extended areas confined to the fissures; slight beginning roughness; (4) dark red or orange areas wider than fissures; surface roughness occurs, possibly grey or

<table>
<thead>
<tr>
<th>Caries Type</th>
<th>Histology</th>
<th>DIAGNOdent pen</th>
<th>CarieScan PRO</th>
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</thead>
<tbody>
<tr>
<td>Enamel caries lesions</td>
<td>D1-2</td>
<td>14-29</td>
<td>21-90</td>
</tr>
<tr>
<td>Dentine caries lesions</td>
<td>D3-4</td>
<td>&gt;30</td>
<td>91-100</td>
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**Table 1 Optimal cut-off points for DIAGNOdent pen and CarieScan PRO devices.**
rough grey zone visible, and; (5) obvious wide openings with visible dentin. Scores no. 1 and 4 were used as cut-off points for D1 and D3 threshold values, respectively.

**In vitro examinations**

Teeth were extracted following in vivo examination and caries detection. The extracted 120 teeth were assigned numbers and stored in a glass bottle filled with saline solution at 4 oC for 2 weeks. Thereafter, the teeth were embedded to acryl molds, and all methods (ICDAS II, DIAGNODent pen, CarieScan PRO, SoproLife camera), except radiographic examination were evaluated as in vivo. Differently from in vivo application, the CarieScan PRO device was held without gloves, and the lip clip touched the tooth surface in order to complete the electrical current circuit between the tooth and the device. All teeth were re-evaluated, as in vitro examinations, 2 weeks later using all diagnostic methods except radiographic examination by two examiners.

**Histological evaluation**

The teeth were cut with a low-speed sectioning machine (Isomet, Buehler, Lake Bluff, IL, USA) under water cooling with a diamond cut disc. Sections were hemisectioned in a buccolingual direction parallel to the long axis of caries measurement point of the teeth. The obtained sections were examined under X10 magnification using a stereomicroscope (Stemi DV4, Zeiss, Jena, Germany). Each section was photographed with a camera. The sections examined under stereomicroscope were also analysed according to Downer’s histological scoring criteria [Downer, 1975]. The histological examination criteria were as follows: (0) no enamel demineralisation or narrow surface zone of opacity (edge phenomenon); (1) enamel demineralisation limited to the outer 50% of the enamel layer; (2) demineralisation involving the inner 50% of the enamel, up to the enamel-dentine junction; (3) demineralisation involving the outer 50% of the dentine and (4) demineralisation involving the inner 50% of the dentine. Scores 1 and 3 were used as cut-off points, for D1 and D3 threshold values, respectively.

**Statistical analysis**

Data were analysed with SPSS for Windows Release 16.0 software package programme.

Intra- and inter-examiner reproducibility were analysed with Cohen’s Kappa (κ) and ICC analysis for the observers who performed the in vivo and in vitro examinations. Scoring of the methods was in accordance with D1 and D3 threshold values based on histopathology results. Sensitivity, selectivity, accuracy rates, negative predictive values, positive predictive values, ROC curves, and an area under the curve were calculated in order to compare the methods, and p value >0.05 was accepted as statistically significant.

**Results**

According to the histological examination, 26 teeth were scored 0, 20 were scored 1, 36 were scored 2, 24 were scored 3, and 38 were scored 4. Inter- and intra-observer reliability was very good, and ICC and kappa values are shown in Table 2.

ICDAS II and SoproLife camera showed the highest sensitivity at D1 and D3 thresholds in vivo, radiographic examination showed lower sensitivity at D1 threshold, and CarieScan PRO showed lower sensitivity at D3 threshold than the other methods. While ICDAS II and SoproLife camera were the methods that had the highest accuracy; radiography had the lowest accuracy (Table 3).

While ICDAS II and SoproLife camera showed higher sensitivity at D1 threshold under in vitro conditions, CarieScan PRO and DIAGNODent pen showed slightly lower sensitivity when compared to the other methods. While ICDAS II showed highest sensitivity at D3 threshold, CarieScan PRO showed lowest sensitivity. In general, all methods showed high specificity values at D1 and D3 thresholds. While ICDAS II and SoproLife camera showed high accuracy according to D1 threshold value, DIAGNODent pen and CarieScan PRO showed similar performance (Table 4).

While the ICDAS II had the highest Az (area under ROC curve) values at D1 and D3 thresholds under in vivo conditions, radiographic examination had the lowest value. While SoproLife camera had highest Az values at D1 and D3 threshold under in vitro conditions, CarieScan PRO had the lowest value.

<table>
<thead>
<tr>
<th>Methods</th>
<th>Visual inspection</th>
<th>Radiographic</th>
<th>DIAGNODent pen</th>
<th>CarieScan PRO</th>
<th>SoproLife camera</th>
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<tr>
<td>Inter-examiners reproducibility</td>
<td>In vivo</td>
<td>In vitro</td>
<td>In vitro (2 weeks later)</td>
<td>Examiner 1</td>
<td>Examiner 2</td>
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<tr>
<td>κ</td>
<td>0.94</td>
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**Table 2** Intra and inter-examiner reproducibility of the methods in detecting occlusal caries lesions in primary molars.
Intra-examiner reproducibility was high for all radiographic methods and DIAGNOdent in primary teeth. Attrill and Ashley [2001] found inter-examiner reproducibility to be high for ICDAS II (0.95). Teo et al. [2014] found the inter-examiner reproducibility of DIAGNOdent PRO device. This may be explained with different clinical experiences of the observers and inadequate calibration for the method. Rodrigues et al. [2008] investigated the effectiveness of fluorescence-based methods, ICDAS, and bitewing radiography on occlusal surfaces and they found kappa values of 0.91 for CarieScan PRO and 0.96 for SoproLife camera, which combines the advantages of laser fluorescence device and intra-oral camera, are among these novel devices. This research investigated the performance of conventional and modern caries diagnostic methods on primary teeth.

While all methods included in our study showed high kappa values, radiographic examination showed lower reliability compared to the other methods. Gomez et al. [2013] found a high inter-examiner reproducibility for ICDAS (0.85) and SoproLife camera (0.88). Rechman et al. [2012] found a very good inter-examiner reproducibility for ICDAS (0.88). Attrill and Ashley [2001] found intra- and inter-examiner reproducibility to be the lowest for the radiographic examination, by comparing visual and radiographic methods and DIAGNOdent in primary teeth. In our study, intra-examiner reproducibility was high for all methods as the result of the evaluations done 2 weeks later.

**Discussion**

Conventional caries detection methods usually entail the visual and radiographic examinations [Bader and Shugars, 2004; McComb and Tam, 2001]. In literature, there is a small number of the studies investigating the use of the newly introduced devices, like CarieScan PRO and SoproLife camera, on primary teeth. CarieScan PRO, which works based on the electrical conduction differences between sound and decayed tissues; and SoproLife camera, which combines the advantages of laser fluorescence device and intra-oral camera, are among these novel devices. This research investigated the performance of conventional and modern caries diagnostic methods on primary teeth.

While all methods included in our study showed high kappa values, radiographic examination showed lower reliability compared to the other methods. Gomez et al. [2013] found a high inter-examiner reproducibility for ICDAS (0.85) and SoproLife camera (0.88). Rechman et al. [2012] found a very good inter-examiner reproducibility for ICDAS (0.88). Attrill and Ashley [2001] found intra- and inter-examiner reproducibility to be the lowest for the radiographic examination, by comparing visual and radiographic methods and DIAGNOdent in primary teeth. In our study, intra-examiner reproducibility was high for all methods as the result of the evaluations done 2 weeks later.
et al. [2013] found good repeatability for CarieScan PRO. Different results of different studies may be explained with using different methodology.

While all methods showed high specificity, ICDAS II and SoproLife camera were the methods that gave the highest sensitivity values. Rechmann et al. [2012] evaluated the reproducibility between ICDAS II and daylight and blue fluorescence mode of DIAGNOdent, Spectra Caries Detection Aid, SoproLife camera in vivo in 433 teeth, they rated the sensitivity of daylight mode of SoproLife camera as 0.93 and blue fluorescence mode as 0.95. Theoccharopoulou et al. [2015] found low sensitivity (SN=0.43) for SoproLife camera in their study evaluating the performance of ICDAS, SoproLife camera and DIAGNOdent pen on occlusal surfaces of primary teeth and permanent teeth. The ICDAS method was used as the gold standard in both studies. ICDAS is a successful method; however, we consider that its use as gold standard leads to different sensitivity values of SoproLife camera. The methods used as gold standard may vary due to the ethical problems in in vivo studies [Theoccharopoulou et al., 2015; Teo et al., 2014]. Teo et al. [2014] investigated the effectiveness of ICDAS, DIAGNOdent pen, and CarieScan PRO for the diagnosis of occlusal caries of primary teeth and detected the maximum sensitivity and specificity at D1 and D3 threshold with the ICDAS method. The results obtained for DIAGNOdent pen (SN=0.87; SP=0.44) and CarieScan PRO (SN=0.95; SP=0.44) are lower than that found in our study. Neuhaus et al. [2011] investigated the effectiveness of ICDAS, radiographic examination, and laser fluorescence devices in the diagnosis of occlusal caries of primary teeth in vivo. Similarly to our study, sensitivity of DIAGNOdent pen at D1 threshold was found as 0.70 and specificity as 0.90; while sensitivity at D3 threshold was found as 0.76 and specificity as 0.80. They found sensitivity of ICDAS for D1 threshold as 0.82 and specificity as 0.65; while sensitivity for D3 threshold value was found as 0.83 and specificity as 0.85. They reported that ICDAS gave the highest sensitivity value at the D3 threshold as in our study.

ROC curve and area under ROC curve are frequently used, as they enable verification of accuracy of the diagnostic test and make a reliable comparison between tests. In our study, ICDAS and SoproLife camera are the methods that had the maximum area under ROC curve. Rechmann et al. [2012] found that blue fluorescence mode of SoproLife camera was the method that had the maximum area under ROC curve in their study evaluating DIAGNOdent, Spectra Caries Detection Aid, daylight and blue fluorescence method of SoproLife in occlusal caries of permanent molar teeth in vivo. They reported that the daylight and blue fluorescence modes of SoproLife camera enabled estimation of the lesion depth and could significantly discriminate the healthy from the decayed teeth as well as magnification and comparison of images as a support for the clinician in the long-term success of preventive applications. Teo et al. [2014] found that ICDAS had the maximum area under the ROC curve, and CarieScan PRO had the minimum area under the curve in their study evaluating ICDAS, DIAGNOdent pen, and CarieScan PRO in diagnosis of occlusal caries of primary teeth. The area under the ROC curve is smaller in vivo compared to in vitro. The in vivo part of this study was conducted by one observer under general anaesthesia, and rapidly due to patient safety and ethical problems. The number of teeth is 20% less for the same reasons. Novaes et al. [2012] reported that all methods showed a similar area under the curve in their study investigating the effectiveness of ICDAS and DIAGNOdent pen in radiographic examination. In diagnosis of occlusal caries of primary teeth, ICDAS method was sufficient for clinical practice. Jablonski-Momeni and Klein [2015] investigated the effectiveness of ICDAS and CarieScan PRO devices for diagnosis of occlusal dentin caries and found that the area under ROC curve was 0.93 for ICDAS and 0.84 for CarieScan PRO. They reported no difference between the methods with regard to area under the ROC curve and that the use of these methods combined could be recommended.

Cut-off points are another important factor in the present study. Lussi and Helwig [2006] considered value 7 for enamel caries and value 18 for dentin caries in the DIAGNOdent pen device and conducted their study with extracted permanent teeth. We think that the different morphologic structures of primary and permanent teeth would lead to different cut-off points. In the studies conducted with DIAGNOdent pen on primary teeth, Novaes et al. [2012] considered value 9 for enamel caries and value 31 for dentin caries, while Neuhaus et al. [2011] considered value 14 for enamel caries and value 31 for dentin caries, and Souza et al. [2013] considered value 19 for enamel caries and value 35 for dentin caries. Different cut-off points have been reported in the abovementioned studies, although they were carried out on primary teeth. DIAGNOdent pen measurements are known to be affected by in vivo and in vitro conditions, preservative solutions, storing time, storing temperature, polishing pads, humidity of the tooth, application type of the device, and correct calibration of the device, leading to differences in cut-off points [Souza et al., 2013]. Jablonski-Momeni and Klein [2015] considered value 51 for enamel caries and value 91 for dentin caries in the CarieScan PRO device, while Mortensen et al. [2014] used “40, 50, 70 and 90” cut-off points, respectively, at D3 threshold in their study conducted in vitro. Impedance measurements are known to be affected by electrode size, contact of the electrode with surface area, temperature changes, concentration change of the storage solution, tooth structure (enamel and dentin thickness, irregularities, mineral distribution), mineralisation after tooth growing, tooth maturation time in oral environment, age of the tooth, and presence of colouring [Ari and Ari, 2013; Eldarrat et al., 2010]. We believe that this affects both the accuracy of results and cut-off points. We propose that creating a single, standard measurement scale would be beneficial.
Conclusion

The ICDAS II method seems sufficient alone for diagnosis of occlusal caries of primary teeth. The SoproLife camera may be used, as it may visualise and record the lesion, provide information for the clinician about the success of long-term protective applications and increases patient motivation by enabling re-evaluation of treatment. The DIAGNOdent pen is another method that can be used in primary teeth but there are several factors to be considered while used. More studies are needed for CarieScan Pro in primary teeth.

Compliance with Ethical Standards

Ethical approval: “All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.”

Informed consent: “Informed consent was obtained from all individual participants included in the study.”

Conflict of Interest: The authors declare that they have no conflict of interest.

References