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CLINICAL ARTICLE

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Accuracy of an intraoral scanner with near-infrared imaging feature in detection of interproximal caries of permanent teeth: An in vivo validation

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Abstract

Objective: This study aimed to evaluate the accuracy of an intraoral scanner with near-infrared imaging (NIRI) feature in the diagnosis of interproximal caries and to compare it with the visual-tactile method (VTM), bitewing radiography (BWR), and panoramic radiography (PR).

Materials and Methods: Six hundred thirty-nine interproximal surfaces (mesial-distal) of posterior teeth from 22 volunteers were examined. Results were scored by VTM, BWR, PR, and NIRI. Lesions were scored as 0 for no-caries, 1 for early-enamel lesion (EEL), and 2 for lesions involving dentino–enamel junction (DEJ). McNemar, Kappa, and Fleis Kappa tests were used to evaluate the agreement levels. Pearson's Chi-square test was used to determine the matching rates after validation.

Results: A good level of agreement was observed between examination methods ($K = 0.613$; $p < 0.001$). In pairwise comparisons, a moderate agreement was seen between all the methods for lesions with DEJ involvement, while a statistically good agreement was observed between BWR and NIRI ($K = 0.675$; $p < 0.001$). As a result of validation, the accuracy of NIRI for molars was considered 85.2% and 75.7% for premolars in EELs, 85.2% for molars, and 70% for premolars regarding the lesions involving DEJ.

Conclusions: Intraoral scanners with the NIRI feature may be used for diagnosing interproximal caries, especially for permanent molars.

Clinical Significance: Early detection of proximal caries is one of the most essential topics forming the basis of preventive dentistry. This study investigates a caries diagnostic tool integrated into intraoral scanners to diagnose interproximal caries. A caries diagnostic tool integrated into an intraoral scanner may prevent the harmful effects of ionizing radiation in early caries diagnosis and may improve the patient's oral health status.

KEYWORDS

bitewing, caries detection, intraoral scanner, near-infrared imaging, NIRI

1 | INTRODUCTION

The International Caries Detection and Assessment System (ICDAS) is a visual classification system developed to detect and evaluate all stages of caries development.[1] Furthermore, caries characterization using ICDAS criteria can be an essential source of prediction for carious lesion progression.[2] The early diagnosis of carious lesions on occlusal surfaces is based on the visual-tactile method (VTM). However, visual inspection is usually inadequate in the presence of caries on proximal surfaces, especially when considering early lesions.[3,4] Panoramic radiography (PR) is often preferred for clinical assessment due to its wide imaging area. However, image formation has a magnification factor depending on the distance between the radiation source, the object, and the image receiver.[5] In addition, the projection geometry can cause image distortion and superposition of tooth crowns, and thus, proximal caries lesions may be underestimated. Previous studies have indicated that the PR is insufficient compared with the bitewing radiography (BWR) when evaluated individually for diagnosing proximal caries.[6,7]

Beyond visual intraoral examination and PR, radiographic imaging with BWR is a decisive tool for the diagnosis of caries, due to providing information about approximal areas, which is even not visible. BWR has been shown to have a higher sensitivity in caries diagnosis than VTM and PR.[8]

Both the intact tooth structure and the extensive lesions can be accurately identified by standardizing the steps of VTM and BWR.[9] However, the diagnosis of early proximal caries is still often misdiagnosed.[10] Meta-analyses have reported high specificity but low sensitivity for BWR in early caries lesions.[8,11] Moreover, BWR has some disadvantages, such as ionizing radiation, which may not be performed during pregnancy. In clinical practice, there is an increasing need for early caries detection, as an early diagnosis and an accurate evaluation of caries lesions may lead to minimally or microinvasive restorative treatments.[12]

In the last three decades, many techniques have been proposed and investigated to overcome this problem. Many techniques such as quantitative light-induced fluorescence, laser fluorescence, electrical conductance, impedance spectroscopy, photothermal radiometry, fiber optic transillumination, and digital image fiber optic transillumination are well suited for the assessment of smooth surfaces.[13] Lesions in interproximal surfaces can be diagnosed by visible light transillumination or optical coherent tomography (OCT). Still, because of the expensiveness of the OCT devices, they are unlikely to be a standard system for general dental practice. Transillumination with near-infrared light, which is for wavelengths above 795 nm, is expected to visualize the interproximal caries.[14] It was previously reported to be useful, especially for detecting proximal and occlusal caries lesions.[15–17]

Recently, the caries detection tool has been integrated into some intraoral scanners (IOS). The use of three-dimensional (3D) intraoral scanners to visualize the oral environment, mainly to record the caries lesions for further detection and investigation, is of increasing interest to researchers.[18] However, because of the novelty of the technology, there is limited evidence in the literature on caries detection methods integrated into intraoral scanners.[3,4,19,20] This new technology has not been compared with other diagnostic methods available in the market.

The NIRI (near-infrared imaging) integrated iTero element 5D is an intraoral scanner with the spectroscopy method that utilizes the near-infrared region of the electromagnetic spectrum (850 nm). The system is based on the principle that the healthy enamel is translucent, while the dentin and carious lesions reflect more light and are relatively less translucent. The NIRI grayscale image presents structures of various levels of translucency with different brightness levels. The lower the translucency is, the more the reflected infrared light will be and, therefore, the brighter the structure will appear. As a result, dentin and interproximal caries lesions appear brighter when inspected by this system. The distinction between the dentin and the carious lesion depends on the localization of the light reflection (Figure 1).

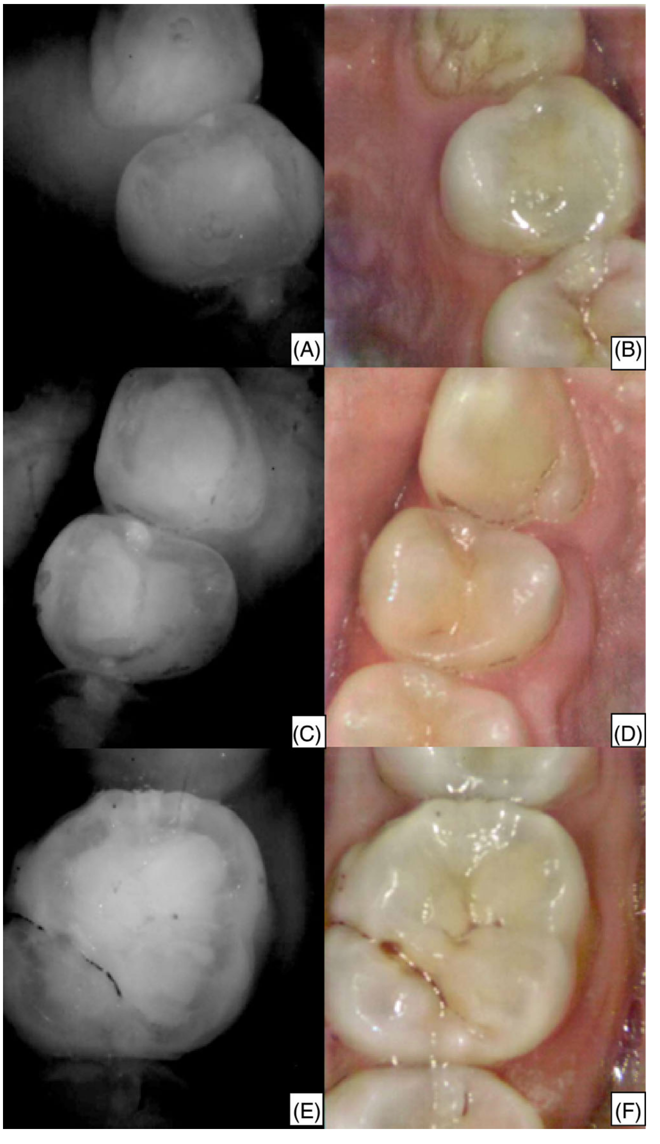


FIGURE 1 (A, B) Near-infrared imaging (NIRI) detection and IOS images of interproximal early enamel lesion (scored as 1) on the mesial surface of tooth 2.4. (C, D) NIRI detection and IOS images of early enamel lesion on the distal, proximal surface of the tooth 1.4 (scored as 1), and a lesion with dentinoenamel junction (DEJ) involvement on the mesial proximal surface of the tooth 1.4 (scored as 2). (E, F) NIRI detection and IOS images of the interproximal lesion with DEJ involvement (scored as 2) on both proximal tooth surfaces of tooth 2.6.

This study aimed to evaluate the accuracy of a NIRI-featured intraoral scanner (iTero Element 5D) for the interproximal caries lesions of permanent premolars and molars, and also to evaluate the correlations between NIRI, VTM, PR, and BWR methods accordingly. The lesions were analyzed in three groups according to the depth of lesion as: (1) sound, (0) early-enamel lesion (EEL), and (2) lesion involving dentin–enamel junction (DEJ). Hypotheses are: (1) scores of the NIRI featured-intraoral scanner are positively correlated with VTM, PR, and BWR methods for the detection of interproximal caries and (2) accuracy of the NIRI featured-intraoral scanner was similar to the other diagnostic methods.

2 | MATERIALS AND METHODS

2.1 | Inclusion and exclusion criteria

This in vivo study was approved by the local ethics committee on June 30, 2022 (Protocol number: 2022/82). Maxillary or mandibular premolars and molars of patients between the ages of 14 and 45 were included in the study. The records of a total of 23 patients were collected, and 704 related interproximal surfaces were examined (including premolars and molars). Teeth with previous restorations, full crowns, and deep carious lesions involving the pulp tissue were excluded. Patients using fixed orthodontic appliances were excluded because of potential future errors in evaluation caused by reflection. The patients who have mental retardation and poor oral hygiene were also excluded. Therefore, a total of 639 tooth surfaces from 22 patients were included in the study. Study protocol registered in www.clinicaltrials.gov Clinical trial number: NCT05919576.

2.2 | Study design

2.2.1 | Recordings by visual and tactile examination

The patients who applied to the university clinic demanding restorative treatment between August 08, 2022, and August 22, 2022, were examined by an experienced restorative dentistry instructor under the reflector light. Following the visual and tactile examinations, the selected teeth were scored according to the number of teeth and tooth surfaces were recorded for each of the patients. Scores of 0, 1, and 2 were used to compare the diagnostic methods to ensure standardization. The rationale for the scores is available in the details of the methods.

Each interproximal surface was carefully examined visually and tactilely. The examinations were performed under 5500 K of illumination, according to the ICDAS criteria for the flat surfaces (mesial and distal) (Table 1). The tooth surfaces were cleaned before the scoring, rinsed, and air-dried with a three in one syringe. The interproximal surfaces were examined by using a ball-ended probe. “0” score was corresponded to the surfaces with no opacity after air-drying, and no roughness during the probing, “1” score was corresponded to the surfaces with white or brown discolorations before/after air-drying without cavitation. “2” score was corresponded to the surfaces with a localized enamel breakdown and loss of integrity on the buccal or lingual surface after air-drying. The score “2” involved ICDAS score 3 (if no visible dentin was detected), ICDAS score 4 (if a dark shadow was observed through the dentin tissue), and ICDAS score 5 (if a distinct cavitation and visible dentin were detected).

TABLE 1 International Caries Detection and Assessment System (ICDAS) scoring for flat surfaces (mesial and distal surfaces).

ICDAS scores	
Code	**Description**
0	After air-drying for 5 s, there is no change in the translucency of the enamel.
1	When the tooth surface is slightly wet there is no change in caries activity, but caries opacity or discoloration (white or brown lesion) is observed on buccal or lingual surfaces after drying for 5 s.
2	In the presence of wet surface, opaque caries lesion (white spot lesion) and/or brown discoloration is observed on buccal or lingual surfaces. Form occlusal view, the opacity or discoloration may appear as an enamel-bounded shadow by the marginal ridge.
3	After air-drying for 5 s, buccal or lingual enamel tissue continuity is clearly lost. The walls and floor of the cavity are completely formed by enamel tissue, without dentin tissue involvement.
4	There is a dark appearance by the marginal ridge and buccal/ lingual walls of the enamel tissue, due to the dark reflection from the dentin. The shadow is more visible when the tooth is wet, resulting in also gray, blue, or brown appearance.
5	There is cavitation involving the dentin and opaque or discolored enamel on the top.
6	There is significant tissue loss in the crown. Cavitation may be deep and wide. Dentin is observed on the wall and the base of the tooth. Marginal ridge may be visible or not.

2.2.2 | IOS recordings

Following the VTM, intraoral recordings were taken by using an iTero Element 5D intraoral scanner by selecting the NIRI feature. Scanned data were recorded by a second researcher on the same day and were then transferred to the cloud memory to maintain further blind assessments by the main researcher without knowing the patient's identities.

The restorative dentistry instructor viewed the cases in selected numbers on the cloud (myitero.com). By moving the diagnostic ring over the arch, the tooth numbers and surfaces of the detected lesions were recorded, and then, the lesions were scored (Figure 1). Surfaces with no bright regions were considered intact and scored as “0.” Small bright areas on the enamel surface were considered EEL and scored as “1.” If the bright interproximal areas included the DEJ, the lesions were scored as "2." NIRI cannot identify the stages of advanced lesions beyond the DEJ. Therefore, larger bright areas were also scored as 2. Examples of the NIRI scoring are presented in Figure 1.

2.2.3 | Radiographic (BWR and PR) recordings

Previous digital PR records were used for the selected patients, which were recorded within the last 3 months. The selected patients were those who came for the restorative dental treatment; therefore, the BWRs were recorded routinely for each of them (taken immediately before the start of treatment). The data were available in the patient's clinical information system of the clinic. The previous panoramic radiographs taken with a digital PR device (Planmeca, Inc., Helsinki, Finland; 64 kV, 7 mA, 16 s) were provided from the online data system. The previous BWRs taken with phosphor plates (Vistascan®, Dürr Dental, Germany; at 60–70 kV, 4–6 mA irradiation, and 0.16 s exposure time) were also provided from the online data system. The third researcher performed the radiographic data collection, and the data were anonymized and numbered before sending to the researcher for the scoring.

All the collected radiographs were evaluated by the same, main researcher who did not know the patient's identifications. BWR images were scored according to Marthaler; absence of radiolucency (score 0), presence of radiolucency in the outer or inner half of the enamel (score 1 and 2) and outer or inner half of the dentin (score 3 and 4) were evaluated.[21] Surfaces without radiolucency were considered sound and scored "0." In the present study, score 1 was grades of enamel caries, while scores 3 and 4 indicated dentin caries. Therefore, those with enamel caries were given the score "1" corresponding to EEL, while dentin caries were given the score "2" corresponding to DEJ involvement. The same cut-off scores were applied in PR scoring. Additionally, the interproximal surfaces that could not be observed through PR due to the superpositions were also scored as 0. The data obtained according to BWR, PR, and NIRI methods are exemplified in Figure 2.

Referring a previous research study,[20] the current study was completed with 639 interproximal surface evaluation with 95% confidence (1-α), OR = 10.064, and as a result of post hoc power analysis, the power of the test (1-β) was obtained as 100%.

2.2.4 | Calibration and data evaluation

The scoring criteria were determined based on the clinical guidelines provided by Align Technology company for iTero Element 5D users. Before the scoring, the main researcher and senior faculty members discussed the NIRI feature on a case-by-case basis and decided on the scoring grades. All researchers scored a few sample images, discussed similarities and differences, and reached a consensus after reviewing the iTero Element 5D user manual. Thus, the main researcher was calibrated in case of various possible clinical scenarios.

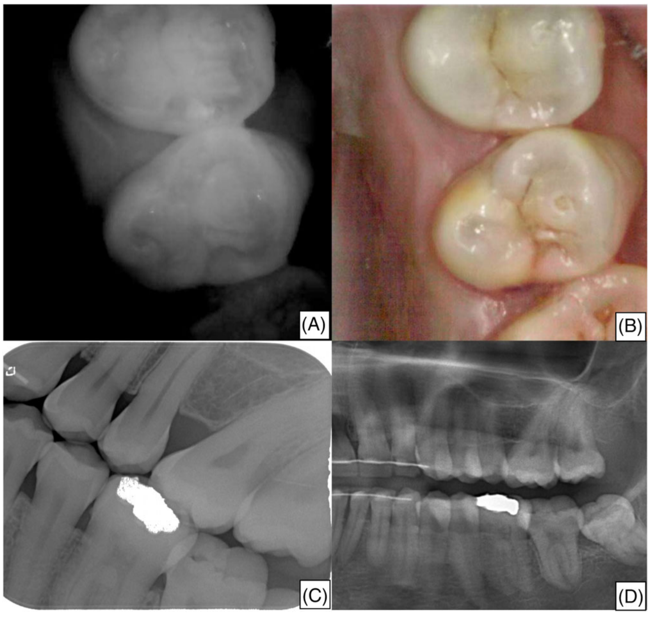


FIGURE 2 (A) IOS image with near-infrared imaging featuring. (B) Colored IOS screen. (C) Bitewing radiography. (D) Panoramic radiograph of teeth 2.4 and 2.5.

2.2.5 | Validation

Since the study included patients who came for restorative treatment, the tooth surfaces in need of restorative treatment were reanalyzed clinically to validate the experimental diagnostic methods. As a result of the clinical examination, the restorative intervention was decided for 91 surfaces. Following caries removal, the restorative procedure for each patient was performed on the same day. During the caries removal, adjacent tooth surfaces were examined, and 11 surfaces were validated to have EEL. In addition, 22 surfaces that were not adjacent to the restoration and could not be observed by direct clinical examination were examined with temporary tooth separation with orthodontic rubber rings for 2–7 days. Protective treatments such as fluoride and resin infiltration were recommended based on the patient's need and demand. An experienced researcher with over 7 years of experience performed the validation.

2.3 | Statistically analysis

Data were analyzed by using IBM-SPSS-V23, and the sensitivity, specificity, and accuracy values were presented. McNemar Test was used to compare the diagnostic methods. Kappa Test and Fleis Kappa Test were used to examine the agreements between the methods. Pearson Chi-square test was used to compare the distributions of the matching rates of diagnostic methods with validation, and multiple comparisons were analyzed with Bonferroni correction. The analysis results were presented as frequency (percentage). The deemed significance was set at $p < 0.05$.

3 | RESULTS

The results of the methods in the detection of proximal caries are presented in Table 2. Out of examined 639 proximal surfaces of molars and premolars, 197 carious lesions were detected by BWR (115 for EEL and 82 for DEJ involvement), 119 lesions were detected by PR (63 for EEL and 53 for DEJ involvement), 144 lesions were detected by VTM (67 for EEL and 77 for DEJ involvement), and 192 carious lesions were detected by NIRI (91 for EEL and 101 for DEJ involvement).

Caries rates of surface for VTM, BWR, PR, and NIRI were considered 22.5%, 30.9%, 18.6%, and 30%, respectively. A good agreement was observed among all detection methods ($k = 0.613$; $p < 0.001$; Table 2).

A significant difference was found between the BWR and PR methods for EELs ($p < 0.001$). However, a moderate agreement was observed for these two methods in EELs ($k = 0.489$; $p < 0.001$). A significant difference was found between the BWR and PR methods for lesions involving DEJ ($p < 0.001$). However, a moderate agreement was observed for these two methods in lesions involving DEJ ($k = 0.579$; $p < 0.001$). A significant difference was found between the BWR and NIRI in EELs ($p = 0.018$). However, a moderate agreement was observed for these two methods in EELs ($k = 0.496$; $p < 0.001$). A significant difference was found between the BWR and NIRI in lesions involving DEJ ($p = 0.011$), while a good agreement was observed for these two methods in the diagnosis of DEJ-involved lesions ($k = 0.675$; $p < 0.001$). A significant difference was found between the BWR and VTM for EEL ($p < 0.001$). But a moderate agreement was observed for these two methods in EELs ($k = 0.466$; $p < 0.001$). No significant difference was observed between BWR and VTM for lesions involving DEJ ($p = 0.576$). But a good agreement was observed for these two methods regarding the responses to the lesion containing DEJ ($k = 0.634$; $p < 0.001$). A significant difference was found between the NIRI and PR for EELs ($p = 0.005$). A fair agreement was obtained for these two methods in EELs ($k = 0.309$; $p < 0.001$). A significant difference was found between the NIRI and PR in lesions involving DEJ ($p < 0.001$). However a moderate agreement was observed for these two methods in lesions involving DEJ ($k = 0.562$; $p < 0.001$). No significant difference was observed between VTM and PR for EELs ($p = 0.581$). A fair agreement was observed for these two methods regarding EELs ($K = 0.288$; $p < 0.001$). A significant difference was found between the VTM and PR for lesions involving DEJ ($p = 0.014$). However a statistically moderate agreement was obtained for VTM and PR regarding the responses to the lesion involving DEJ ($K = 0.439$; $p < 0.001$). A significant difference was found between the NIRI and VTM for EELs ($p = 0.038$). A fair agreement was observed for these two methods regarding the responses to EEL ($K = 0.318$; $p < 0.001$). A significant difference was found between the NIRI and VTM for lesions involving DEJ ($p = 0.004$). A moderate agreement was observed for these two methods regarding the lesion involving DEJ ($k = 0.570$; $p < 0.001$) (Table 3).

The differences and matches of lesion scoring of NIRI and BTW are exemplified in Figure 3.

Sensitivity, specificity, and accuracy were calculated for each diagnostic method for EEL and DEJ involvement lesions in molar and premolar teeth concerning the validation findings.

According to the validation results of EELs in molar teeth, sensitivity, specificity, and accuracy were obtained as 81.8%, 90.7%, and 88.9%, respectively, for the BWR method. In the NIRI method, sensitivity was 45.5%, specificity was 95.3%, and accuracy was 85.2%. In

TABLE 2 Frequency in distributions and agreement between methods in terms of caries.

	Frequency	Percentage	Presence of caries (%)	Fleiss kappa/p*
VTM				
Sound enamel	495	77.4		
EEL	67	10.4	22.5	
DEJ involvement	77	12.1		
BWR				
Sound enamel	442	69.1		
Early enamel lesion	115	17.9	30.9	
DEJ involvement	82	12.8		
PR				0.613/<0.001
Sound enamel	520	81.4		
EEL	63	9.9	18.7	
DEJ involvement	56	8.8		
NIRI				
Sound enamel	447	69.9		
EEL	91	14.2	30	
DEJ involvement	101	15.8		

Abbreviations: BWR, bitewing radiography; DEJ, dentinoenamel junction; EEL, early-enamel-lesion; NIRI, near-infrared imaging; PR, panoramic radiography; VTM, visual-tactile method.
*Fleiss Kappa test, (%) presence of caries.

TABLE 3 Comparisons between the examination methods in terms of type of lesion.

Type of lesion	Examination method			p*	p**	Sensitivity	Specificity	PPV	NPV	Accuracy
		BWR								
	PR	Positive	Negative							
EEL	Positive	49 (43)	14 (2.7)	<0.001	0.489/<0.001	42.98%	97.33%	77.78%	88.72%	87.64%
	Negative	65 (57)	511 (97.3)							
DEJ involvement	Positive	43 (52.4)	13 (2.3)	<0.001	0.579/<0.001	52.44%	97.67%	76.79%	93.31%	91.86%
	Negative	39 (47.5)	544 (97.7)							
		BWR								
	NIRI	Positive	Negative							
EEL	Positive	59 (51.7)	32 (6.1)	0.018	0.496/<0.001	51.75%	93.90%	64.84%	89.96%	86.38%
	Negative	55 (48.2)	493 (93.9)							
DEJ involvement	Positive	66 (80.4)	35 (6.3)	0.011	0.675/<0.001	80.49%	93.72%	65.35%	97.03%	92.02%
	Negative	16 (19.5)	522 (93.7)							
		BWR								
	VTM	Positive	Negative							
EEL	Positive	48 (42.8)	19 (3.6)	<0.001	0.466/<0.001	42.86%	96.38%	71.64%	88.77%	86.97%
	Negative	64 (57.1)	508 (96.3)							
DEJ involvement	Positive	54 (65.8)	23 (4.1)	0.576	0.634/<0.001	65.85%	95.86%	70.13%	95.00%	91.99%
	Negative	28 (34.1)	535 (95.8)							
		NIRI								
	PR	Positive	Negative							
EEL	Positive	30 (33)	33 (6)	0.005	0.309/<0.001	32.97%	93.98%	47.62%	89.41%	85.29%
	Negative	61 (67)	515 (94)							
DEJ involvement	Positive	48 (47.5)	8 (1.4)	<0.001	0.562/<0.001	47.52%	98.51%	85.71%	90.91%	90.45%
	Negative	53 (52.4)	530 (98.5)							
		VTM								
	PR	Positive	Negative							
EEL	Positive	23 (34.3)	38 (6.6)	0.581	0.288/<0.001	34.33%	93.31%	37.70%	92.33%	87.09%
	Negative	44 (65.6)	534 (93.3)							
DEJ involvement	Positive	33 (41.7)	23 (4.1)	0.014	0.439/<0.001	42.86%	95.88%	58.93%	92.40%	89.45%
	Negative	46 (58.2)	537 (95.8)							
		NIRI								
	VTM	Positive	Negative							
EEL	Positive	31 (34.4)	36 (6.5)	0.038	0.318/<0.001	35.23%	93.42%	46.27%	89.96%	85.35%
	Negative	59 (65.5)	513 (93.4)							
DEJ involvement	Positive	58 (56.3)	21 (3.9)	0.004	0.570/<0.001	55.45%	96.07%	72.73%	91.94%	89.61%
	Negative	45 (43.6)	515 (96)							

Abbreviations: BWR, bitewing radiography; DEJ, dentinoenamel junction; EEL, early-enamel-lesion; NIRI, near-infrared imaging; NPV, negative predictive value; PR, panoramic radiography; PPV, positive predictive value; VTM, visual-tactile method.
*McNemar Test;
**Kappa and frequency (percentage).

the PR method, sensitivity, specificity, and accuracy were 54.5%, 83.7%, and 77.8%, respectively. For the VTM group, sensitivity was 54.5%, specificity was 81.4%, and accuracy was 75.9% (Table 4).

The sensitivity, specificity, and accuracy of the BWR method were 81.8%, 90.7%, and 88.9%, respectively, for EELs in molar teeth; while these values were 90.7%, 100.0%, and 92.6%, respectively, for lesions involving DEJ in molars.

For the NIRI method, sensitivity was 88.4%, specificity was 72.7%, and accuracy was 85.2% for lesions involving DEJ in molars. In the PR method, sensitivity, specificity, and accuracy were 62.8%,

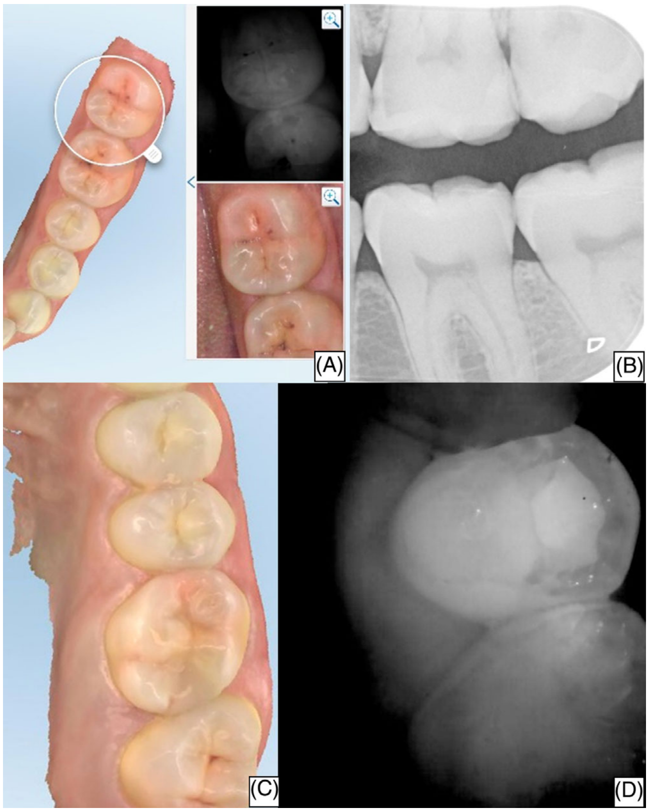


FIGURE 3 (A) A proximal (disto-occlusal) carious lesion on tooth 3.6 observed as involving dentinoenamel junction (DEJ) on near-infrared imaging (NIRI) screen. (B) The proximal lesion of 3.6 was scored as early-enamel-lesion on bitewing radiography. (C) A lesion involving DEJ in the mesial surface of tooth 2.6, IOS software has colored the region red. (D) NIRI image of the lesion involving DEJ in mesial surface of tooth 2.6.

100.0%, and 70.4% for these lesions, respectively. In the VTM method, sensitivity was 65.1%, specificity was 63.6%, and accuracy was 64.8% in DEJ involvement.

According to the validation results of EELs in premolar teeth, sensitivity, specificity, and accuracy were 76.0%, 95.6%, and 88.6%, respectively, for the BWR method. For the NIRI method, sensitivity was 48.0%, specificity was 91.1% and accuracy was 75.7%. For the PR method, sensitivity was 28.0%, specificity 84.4%, and accuracy 64.3%. In the VTM method, sensitivity, specificity, and accuracy were 56.0%, 86.7%, and 75.7%, respectively.

In premolar teeth with DEJ involvement lesions, sensitivity, specificity, and accuracy was 95.3%, 96.3%, and 95.7% for the BWR method. For the NIRI method, sensitivity, specificity, and accuracy was 76.7%, 59.3%, and 70.0%, respectively. For PR method, sensitivity was 46.5%, specificity 100.0%, and accuracy 67.1%. For the VTM method, sensitivity was 65.1%, specificity was 92.6%, and accuracy was 75.7%.

In the BWR method, the underestimation rate of EELs in molar teeth was 18.18%, while it was 9.3% for DEJ involvement lesions. In premolar teeth, the underestimation rate of EELs was 20%, while it was 4.65% for lesions with DEJ involvement. The overestimation rate of EELs in premolar teeth was 4% (Table 5).

In the NIRI method, the underestimation rate of EELs in molars was 27.27%, while the underestimation rate of DEJ involvement lesions was 11.63%. The overestimation rate of EELs in molars was 27.27%. The underestimation rate of EELs in premolar teeth was 8%, while the underestimation rate of DEJ involvement lesions was 23.26%. The overestimation rate for EELs in premolar teeth was 44%.

When the matching rates were compared according to the methods, there was no difference between NIRI and BTW in molar teeth, whereas BTW showed a significantly higher match than PR and

TABLE 4 Sensitivity, specificity, and accuracy of the methods according to the validation.

			Sensitivity	Specificity	PPV	NPV	Accuracy
EL	Molar	BWR	81.8 %	90.7 %	69.2 %	95.1 %	88.9 %
		NIRI	45.5 %	95.3 %	71.4 %	87.2 %	85.2 %
		PR	54.5 %	83.7 %	46.2 %	87.8 %	77.8 %
		VTM	54.5 %	81.4 %	42.9 %	87.5 %	75.9 %
	Premolar	BWR	76.0 %	95.6 %	90.5 %	87.8 %	88.6 %
		NIRI	48.0 %	91.1 %	75.0 %	75.9 %	75.7 %
		PR	28.0 %	84.4 %	50.0 %	67.9 %	64.3 %
		VTM	56.0 %	86.7 %	70.0 %	78.0 %	75.7 %
DEJ inv.	Molar	BWR	90.7 %	100.0 %	100.0 %	73.3 %	92.6 %
		NIRI	88.4 %	72.7 %	92.7 %	61.5 %	85.2 %
		PR	62.8 %	100.0 %	100.0 %	40.7 %	70.4 %
		VTM	65.1 %	63.6 %	87.5 %	31.8 %	64.8 %
	Premolar	BWR	95.3 %	96.3 %	97.6 %	92.9 %	95.7 %
		NIRI	76.7 %	59.3 %	75.0 %	61.5 %	70.0 %
		PR	46.5 %	100.0 %	100.0 %	54.0 %	67.1 %
		VTM	65.1 %	92.6 %	93.3 %	62.5 %	75.7 %

TABLE 5 Under- and over-estimation rates of lesion types according to methods.

			Lesion type		
			Sound	EEL	DEJ involvement
BWR	Molar	Underestimation	-	18.18%	9.30%
		Overestimation	-	0.00%	-
	Premolar	Underestimation	-	20.00%	4.65%
		Overestimation	0%	4.00%	-
NIRI	Molar	Underestimation	-	27.27%	11.63%
		Overestimation	-	27.27%	-
	Premolar	Underestimation	-	8.00%	23.26%
		Overestimation	100%	44.00%	-
PR	Molar	Underestimation	-	45.45%	37.21%
		Overestimation	-	0.00%	-
	Premolar	Underestimation	-	72.00%	53.49%
		Overestimation	0%	0.00%	-
VTM	Molar	Underestimation	-	9.09%	34.88%
		Overestimation	-	36.36%	-
	Premolar	Underestimation	-	36.00%	34.88%
		Overestimation	0%	8.00%	-

Abbreviations: BWR, bitewing radiography; DEJ, dentinoenamel junction; EEL, early-enamel-lesion; NIRI, near-infrared imaging; PR, panoramic radiography; VTM, visual-tactile method.

TABLE 6 Matches according to methods after validation.

		BWR	NIRI	PR	VTM	Test stat.	p*
Molar	Mismatch	6 (11.1)	11 (20.4)	21 (38.9)	20 (37)	14.802	0.002
	Match	48 (88.9)[a]	43 (79.6)[ab]	33 (61.1)[b]	34 (63)[b]		
Premolar	Mismatch	8 (11.4)	25 (35.7)	41 (58.6)	26 (37.1)	33.973	<0.001
	Match	62 (88.6)[a]	45 (64.3)[b]	29 (41.4)[c]	44 (62.9)[bc]		
Total	Mismatch	14 (11.3)	36 (29)	62 (50)	46 (37.1)	44.99	<0.001
	Match	110 (88.7)[a]	88 (71)[b]	62 (50)[c]	78 (62.9)[bc]		

Abbreviations: BWR, bitewing radiography; NIRI, near-infrared imaging; PR, panoramic radiography; VTM, visual-tactile method.
*Pearson Chi-square test.
Note: a–c: No difference between the values of methods with the same letter.

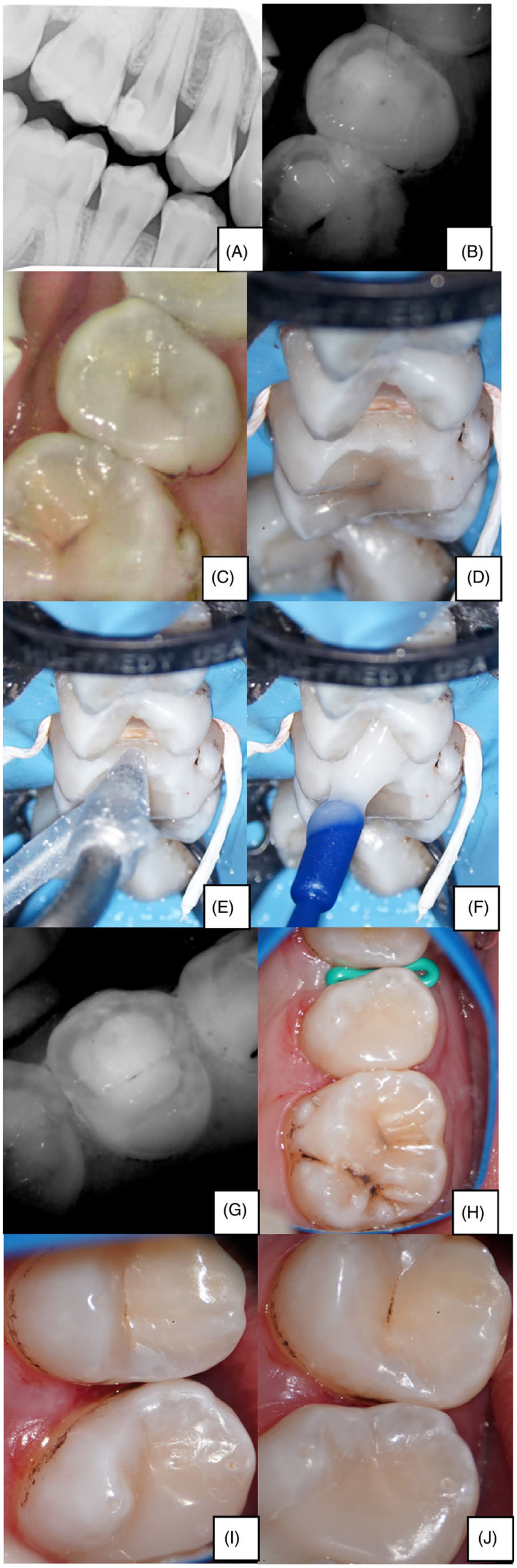
VTM methods ($p = 0.002$). In premolar teeth, the maximum matching was observed with BTW ($p < 0.001$). NIRI and other methods followed it. Among all the posterior teeth BTW had the highest match rate ($p < 0.001$), while the lowest match rate was observed for the PR method (Table 6).

Clinical images of the validation phase and the differences and similarities of the diagnostic methods are shown in Figures 4–6.

4 | DISCUSSION

According to our results, NIRI feature provided moderate, fair, and fair agreements with BWR, PR, and VTM, respectively, in terms of the EELs, while they were good, moderate, and moderate in terms of the lesions involving DEJ. Therefore, the first hypothesis of the study was considered partially accepted for both types of the lesions.

This in vivo study design might have overcome the inaccuracy in the results due to the limitations in photo-optical properties of the samples and representing the characteristics of periodontal anatomy in in vitro study designs.[22] To eliminate the effect of the clinical experience level on the image interpretation procedures, a single investigator scored all lesions throughout the study. Scorings were performed in a blinded manner to evaluate the efficacy of the methods individually and to avoid bias. Therefore, the data collection was performed by two other researchers who were not observers to allow blinded scoring, and patients were numbered accordingly.[23] Also generating the radiological records with an identical device at a standard irradiation and exposure time might have avoided the possible errors, which was previously mentioned by Metzger et al., as a limitation in technical procedure standardization, regarding their study comparing the effectiveness of NIRI in caries detection with BWR.[20] In addition, considering that metal brackets and orthodontic wires may cause



reflections in the images recorded with the NIRI feature, these patients were not included in the study.

Visualizing the intraoral pathological situation and meanwhile explaining the related clinical evidence to the patient with 3D simulations, may have an impact on the patient's attention and pretreatment or posttreatment motivation. Additionally, during dental treatment with the risk of microbial dental plaque accumulation, such as the orthodontic treatment, periodical intraoral scanning may reveal small but progressive EELs that were previously unable to be diagnosed. Presenting the reduction in the lesion size to the patient may also increase the motivation for dental treatment. Accordingly, the NIRI transillumination feature is one of the recent improvements in dental intraoral scanners.[19,20] Although many studies have demonstrated the effectiveness of near-infrared technology in proximal caries diagnosis,[24–26] the caries diagnostic feature integrated into a scanner is a contemporary approach and related clinical studies are limited in the literature.[19,27,28] Nevertheless, the combination of several diagnostic techniques involving near-infrared light was reported to improve the diagnosis accuracy in proximal caries.[14,28]

Additionally, the caries diagnosis with NIRI feature was considered to be evaluated only from the occlusal surface but not the buccal or lingual surfaces.[19] Litzenburger et al. indicated in an in vitro study that examination from multiple angles did not improve the detection of proximal caries with NIRI feature.[16] Therefore, in the present study, only the occlusal-oriented images were used for the NIRI scorings.

BWR was previously considered the gold standard diagnostic method in the detection of proximal carious lesions.[20,29] Our results showed that BWR indicated 197 dental surfaces as carious lesions, while 192 were noted for the NIRI feature evaluations (Table 2). Metzger et al. examined a total of 3499 proximal surfaces in vivo, and 549 surfaces were determined carious lesions by NIRI, while 223 surfaces were by BWR.[20] Subsequently, they stated that NIRI showed high sensitivity to EELs. Conversely, in the present study, the number of surfaces diagnosed as caries by NIRI and BWR were similar. In addition, the number of surfaces that are scored as the DEJ involvement

FIGURE 4 (A) The patient complained of sensitivity in tooth 1.5, and secondary caries was observed on radiologic examination. Mesial surface of tooth 1.6 appeared healthy. (B) Near-infrared imaging (NIRI) image revealed a lesion with dentinoenamel junction involvement on mesial surface of tooth 1.6. (C) IOS screen of contact area of tooth 1.5 and 1.6. (D) Validation of a noncavitated lesion mesial to tooth 1.6 during restorative replacement of tooth 1.5, dental microscope image (OMS 2000, Zumax Dental, China). (E) Cleaning with bioactive glass particles (Sylc, Aquacare, Velopex, UK) of proximal surfaces. (F) Application of fluoride varnish (Enamelast, Ultradent, USA). (G) Early-enamel-lesions detected on the NIRI screen distal to tooth 1.4 and mesial to tooth 1.5 . (H) Temporary tooth separation between teeth 1.4 and 1.5, a dental microscope image. (I) Dental microscope image during validation of the lesion mesial to tooth 1.5. (J) Dental microscope image during validation of the lesion distal to tooth 1.4.

was higher for NIRI than BWR in our study. This difference might have two reasons. The lesions wider in the occlusogingival direction but narrower in the buccolingual direction might have been perceived as smaller than they were on BWR, or the wide lesions might have been interpreted as the DEJ involvement type due to the convex anatomy of the lesions since NIRI only allows examination in the occlusal direction. Following our results, Heck et al. stated that the false-positive rate for the near-infrared transillumination (780 nm) feature was high compared with BWR. The reason was determined as a phenomenon of the white edge around the tooth due to the surface slope of the marginal ridge area, which may cause overestimation in proximal caries diagnosis.[30] De Zutter et al. also compared the effectiveness of BWR and near-infrared light transillumination feature in proximal caries diagnosis and similar to our results they mentioned that higher lesion depths could be detected for the near-infrared light transillumination feature compared with BWR.[25] However, they couldn't have determined the accuracy of the methods due to the study design. In addition, moderate agreement between NIRI and BWR for EELs and good agreement for DEJ involvement lesions were observed in the present study.

Regarding the BWR and VTM comparisons for DEJ involvement and PR and VTM comparisons for EELs, the present study generated similar scores between the two diagnostic methods. The lack of significant difference between BWR and VTM methods might be due to the ease of visual identification of large proximal lesions with DEJ involvement. A meta-analysis examining the effectiveness of radiographic examination for caries detection also indicated that radiography more easily diagnosed cavitated lesions than early lesions.[8] The reason for the similar scoring between PR and VTM for EELs was thought to be the inability of both methods to detect early lesions.[31] In the present study, the specificity of BWR was 95.6 for EELs in molars and 100 for DEJ involvement lesions. Recently, Schlenz et al. compared three intraoral scanners involving caries diagnostic tools (iTero Element 5D with 850 nm near-infrared light transillumination, Trios 4 with 415 nm fluorescence, and Emerald S with 727 nm near-infrared transillumination) with BWR, visual inspection, and DIAGNOcam (operating at 780 nm near-infrared transillumination). Similarly, they reported higher specificity for BWR among all methods. The authors concluded that BWR should still be considered the gold standard for proximal caries diagnosis. However, Planmeca Emerald S showed better results than radiography regarding area under curve (AUC) value in permanent dentition.[3]

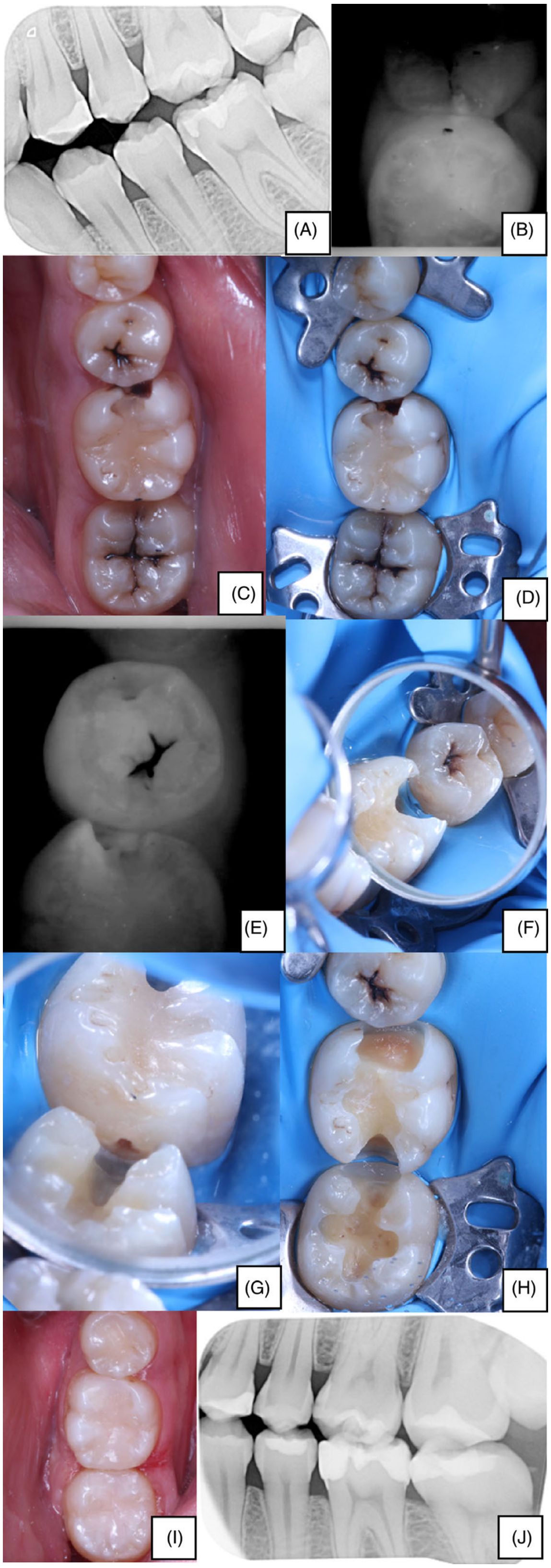


FIGURE 5 (A) Tooth 3.6 with mesio-occluso-distal lesion, and tooth 3.7 with mesial lesion. (B) Near-infrared imaging NIRI image of distal surface of tooth 3.6 and mesial surface of tooth 3.7 and 3.6 scored as early-enamel-lesion (EEL) in NIRI, but BWR shows dentinoenamel junction involvement. (C) Intraoral image of the quadrant. (D) Rubber dam isolation. (E) NIRI image of tooth 3.5 and tooth 3.6. (F) Validation of presence EEL in distal surface of tooth 3.5 during caries removal.(G) Validation of cavitated lesion on distal surface of tooth 3.6, during the removal of mesio-occlusal lesion in tooth 3.7. (H) Cavity preparations of tooth 3.6 and 3.7. (I) Intraoral photograph after restoration. (J) Final BWR.

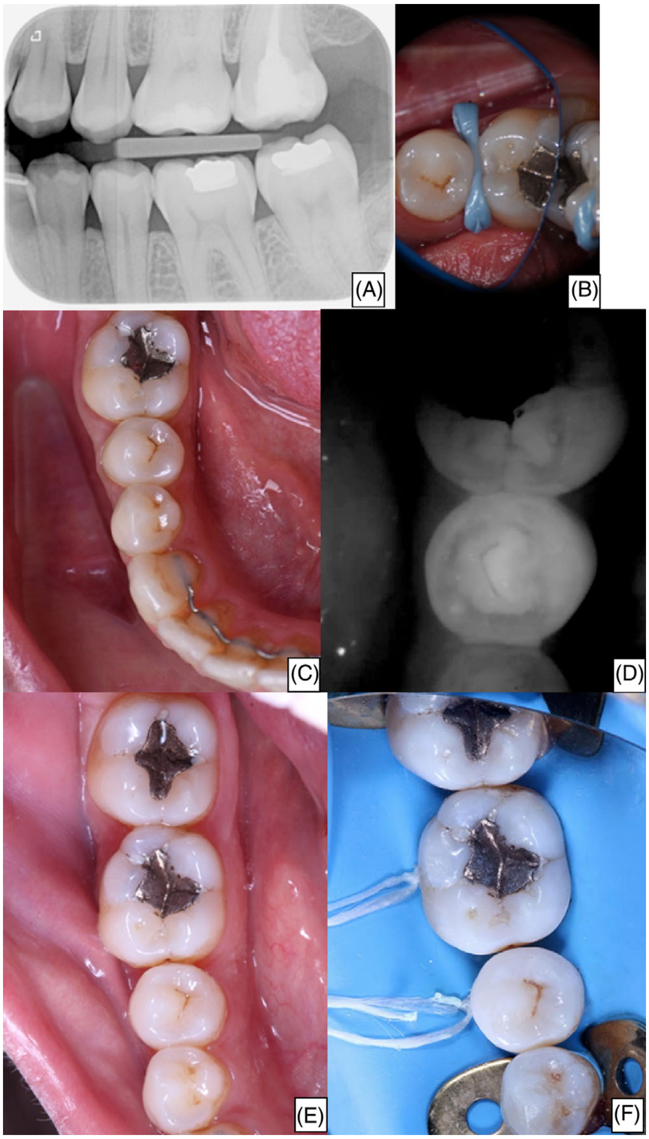


FIGURE 6 (A) Initial bitewing radiography (BWR) revealed an early-enamel-lesion lesion distal to tooth 3.5 and a sound mesial surface of tooth 3.6. (B) A dental microscope image after temporary tooth separation. (C) Intraoral photographs of the quadrant. (D) Near-infrared imaging image of teeth 3.5 and 3.6. Tooth 36 appears to have demineralization in the buccolingual direction. In tooth 3.5, a lesion involving the dentinoenamel junction was considered. (E) Clinical image of the mesial surface of tooth 3.6. Clinical examination did not indicate cavitation. Although the limited amount of separation did not allow direct visualization of the distal part of tooth 35, the patient was recommended resin infiltration treatment based on the tactile examination and BWR findings. (F) Rubber dam isolation for resin infiltration.

In the first part of this study, sensitivity, specificity, and accuracy were calculated with the "ground truth" of BWR. The NIRI featured evaluations presented a fair agreement with the VTM ($k = 0.318/p < 0.001$) and also with the PR ($k = 0.309/p < 0.001$) in terms of the EELs. According to the McNemar Test, significant differences were obtained between NIRI and PR ($p = 0.005$) and VTM and NIRI ($p = 0.038$). In addition, compared with NIRI, the sensitivity of PR for EELs was 32.97%. The 60 EELs that were positive in NIRI readings were missed in PR readings. In the comparison of PR and BWR, 65 EELs diagnosed by BWR were underestimated by PR. In our study, there were proximal areas in PR that could not be seen due to superpositions, especially on premolar tooth surfaces, and therefore the number of carious surfaces diagnosed by this method was low. Similarly, Kamburoğlu et al. compared PR and BTW in terms of proximal caries diagnostic capability and stated that PR alone is insufficient in the diagnosis of proximal caries compared with BTW and this is largely due to superpositions.[5]

In the present study, the accuracy for NIRI was higher in molars than premolars and it was 85.2 for both lesion types. For BWR, the highest accuracy (95.7) was observed in lesions involving DEJ and premolars. In addition, the accuracy of BWR in molar teeth was 88.9 and 92.6 for EEL and lesions involving DEJ, respectively. Even though the accuracy of NIRI did not differ in both lesion types in molars, it differed from other diagnostic methods in both premolars and molars. Therefore, our second hypothesis was rejected. The high accuracy of BWR in lesions involving DEJ observed is consistent with the previous results in literature.[8] Although the superiority of BWR over NIRI in all teeth and lesion types is noticeable, the accuracy of NIRI is acceptable (Table 4). According to the matching rates, no difference was found between BWR and NIRI in molar teeth, while BWR was superior in premolar teeth. On the contrary, a previous study claimed that the accuracy of the near-infrared light transillumination method was higher than BWR.[32] Regarding the methodology of this study, the authors reported that they performed validation according to the joint decision of visual, radiologic, and near-infrared light transillumination examination methods. In our research, validation was performed by combining visual and tactile examinations, and BWR data as a clinical standard.[33] This may explain why the BWR data in the present study was higher than NIRI's. In another clinical study, NIRI showed 88% and 97% accuracy for EELs and lesions involving DEJ, respectively, which was in accordance with our results.[20]

This clinical study may have some limitations. Because of the practical difficulty of temporary tooth separation, only a limited number of surfaces allowed the direct observation. Another limitation is that the researcher of this study was a restorative dentistry instructor, the effect of level of clinical experience on NIRI scoring could not be assessed. In addition, the NIRI technology may have limitations, such as the inability to detect the root caries, which is specified by the manufacturer. As a clinical observation, researchers report that dental structures that are opaque due to developmental or acquired defects (fluorosis, molar-incisor hypomineralisation, etc.) may be observed brighter. Although the main researcher was calibrated for the iTero Element 5D by the user manual and several sample case evaluations, she did not have much experience with the device before starting the study. This lack of awareness might have minimized the bias in the study. Nevertheless, considering that NIRI presented good agreements with the BWR and the validation results according to the scores of the researcher who used NIRI for the first time, the authors believe that the accuracy would be improved if the study was conducted by a more NIRI-experienced researcher. More frequent use of this caries diagnostic tool in the clinical practice in combination with visual examination and radiography would help to understand its opportunities and limitations. To improve the quality of evidence, further studies might be planned with various levels of experience and combined with multiple diagnostic methods.

5 | CONCLUSIONS

NIRI-featured intraoral scanners might be considered promising and a complement to the gold standard BWR method for the diagnosis of interproximal caries. Integrating the existing caries diagnostic methods into the dental intraoral scanners, might be useful to prevent the carious lesions or to treat minimally invasively. The location of the caries lesion was considered effective for the diagnosis of interproximal caries by BWR and NIRI. It might be better for the clinicians to consider the possibility of overestimation when imaging premolars with NIRI and to make the clinical decisions by combining intraoral and radiographic examinations for more accurate outcomes. Further clinical studies are needed to evaluate the capability of the NIRI-featured intraoral scanners in the caries diagnosis.

AUTHOR CONTRIBUTIONS

Özlem Kanar and Dilek Tağtekin conceived the diagnostic methods. Özlem Kanar performed the initial intraoral diagnosis. Bora Korkut performed digital scans. Dilek Tağtekin and Bora Korkut collected radiographic data. Özlem Kanar made the caries scorings. Özlem Kanar wrote the original draft. Özlem Kanar performed the validation. All authors discussed the results and contributed to the final manuscript.

CONFLICT OF INTEREST STATEMENT

The authors declare that they do not have any financial interest in the companies whose materials are included in this article

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

PATIENT CONSENT STATEMENT

Consent was obtained from the patients during the study.

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