

Performance Assessment of Smartooth, a Novel Laser-Based Caries Detection Device, Compared with Conventional Methods in Primary Molars: An Ex Vivo Study

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Abstract

This study aimed to evaluate and compare the diagnostic performance of DIAGNOdent pen (LF pen) and Smartooth (SM) in detecting occlusal and smooth surface caries in extracted primary molars. The device-specific optimal cut-off values were determined, and their clinical applicability was assessed using microcomputed tomography (micro-CT) as the gold standard. Overall, 79 extracted primary molars were evaluated ex vivo. The caries-detection methods included visual examination, LF pen, and SM. The optimal cut-off values were calculated from the receiver operating characteristic curves using Youden's index; diagnostic performance was also measured. For occlusal surfaces, SM showed higher specificity than the LF pen, whereas the LF pen showed higher accuracy; for enamel caries (D1), SM also had the highest sensitivity and A_z . For smooth surfaces, the LF pen showed the highest sensitivity for D1, while sensitivity did not differ significantly for dentin caries (D2); specificity and accuracy for D2 were highest for visual examination, with the LF pen exceeding SM in accuracy. SM showed high A_z for D1; agreement varied by surface and depth and was lower than visual examination for occlusal D1. All optimal cut-off values were lower than the manufacturer's recommendations. Furthermore, LF pen and SM provide specificity and sensitivity, respectively, and may be selectively used based on the lesion and diagnostic objective. These device-specific tendencies are surface- and depth-specific and are hypothesis-generating rather than establishing clinical roles; clinical utility will require prospective in vivo pediatric validation. [J Korean Acad Pediatr Dent 2026;53(1):38-52]

Keywords

Caries detection, Primary molar, Laser fluorescence, Pediatric dentistry, Cut-off values

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Introduction

Dental caries is the leading cause of pediatric dental visits[1]. According to the 2022 World Health Organization report, 42.7% of children under the age of 5 years worldwide have experienced dental caries[2]. In South Korea, the national statistics showed a consistent increase in the prevalence of dental caries among children and adolescents under 14 years of age between 2011 and 2020, along with an increase in the number of treated cases across all age groups[3]. These findings emphasize the importance of adopting accurate and minimally invasive diagnostic strategies tailored for primary dentition[4].

Compared with permanent teeth, primary teeth have thinner enamel and dentin layers as well as a lower mineral content, making them more susceptible to rapid caries progression[5-7]. Thomas et al.[8] reported that caries-related tissue destruction is more extensive in primary teeth and their reactive defenses are inferior to those of permanent teeth. These findings confirm structural weakness and a slower dentin-pulp response in primary teeth[7,9].

Moreover, occlusal surfaces in primary teeth are more susceptible to caries due to deep pits and fissures[10], whereas smooth surfaces are vulnerable owing to early childhood behaviors, such as bottle feeding and prolonged food retention[11]. Smooth surface caries are more commonly observed in the anterior teeth, as seen in early childhood caries (ECC), which remains highly prevalent globally[12-14].

The structural and defensive limitations of primary teeth accelerate caries-related tissue damage, thus increasing the treatment complexity and cost while causing a greater physical and emotional burden on pediatric patients[15]. Aside from aesthetic concerns, caries in primary teeth can impair children's quality of life by causing pain, eating difficulties, delayed speech development, and reduced concentration[16-18]. Such consequences may result in dental avoidance, suggesting the importance of prevention. Thus, early and accurate caries detection, along with minimally invasive

treatments, is imperative. This emphasizes the need for dependable, quantitative diagnostic tools[19,20].

Currently, the primary methods for caries diagnosis in clinical practice are visual examination and two-dimensional radiographic imaging, such as panoramic, periapical, and bitewing radiographs. Although visual examinations are quick and convenient, they are highly dependent on the clinician's experience and subjective judgment. Moreover, radiographs help detect proximal and deep lesions that are not visible to the eye but are less effective for diagnosing early caries and involve radiation exposure. To address these limitations, a variety of advanced diagnostic technologies and devices have been developed and increasingly implemented in clinical practice[21,22].

Of these, laser fluorescence devices have gained attention as quantitative, noninvasive diagnostic tools[23,24]. These devices function by detecting changes in fluorescence intensity produced by a 655 nm laser light, which is attributed to the increased fluorescence caused by porphyrin-related substances in carious tissue[25,26]. The widely used DIAGNOdent pen (LF pen; KaVo, Biberach, Germany) assigns caries severity scores of 0 – 99.

Recently, Smartooth (SM; Smartooth Korea Co., Ltd., Seoul, Korea), a domestically developed LF-based device using similar principles, has been commercialized. Although SM received U.S. Food and Drug Administration clearance in 2024, its clinical validation for primary teeth remains limited. This system incorporates unique structural and clinical features, such as single-use polymethyl methacrylate (PMMA) resin tips and a light-emitting diode (LED) display that color-codes the measurement values. However, the manufacturer-recommended cut-off thresholds are based on permanent dentition, making them unsuitable for primary teeth with distinct anatomy and mineralization[27]. Several studies have suggested that diagnostic thresholds vary between permanent and primary dentitions, and the rapid progression of caries in primary teeth emphasizes the need for criteria with a higher sensitivity[7,28,29]. Although SM has been assessed in permanent teeth[30], no studies have investigated its application in primary teeth, and the optimal

cut-off values remain undetermined. Establishing such criteria could improve the diagnostic accuracy and clinical decision-making process, thereby facilitating earlier, less invasive interventions.

Thus, this study aimed to compare the diagnostic performance of the LF pen and SM in extracted primary molars and to determine the optimal cut-off values for enamel and dentin caries using microcomputed tomography (micro-CT) as the gold standard[31]. The ultimate goal is to establish accurate diagnostic standards for primary teeth and assess their clinical applicability.

Materials and Methods

Study approval was obtained from the Institutional Review Board of Yonsei University Dental Hospital (IRB no. 2-2023-0052).

1. Sample preparation

Extracted primary molars from children who visited the Department of Pediatric Dentistry at Yonsei University Dental Hospital between January 2024 and June 2024 were used in this study. The patients' parents or guardians were briefed on the study's purpose before extraction, and consent was obtained for using the extracted teeth in the research. Extracted primary molars were included in this study if they were removed due to physiological root resorption, early caries-related extraction, or orthodontic treatment. However, teeth were excluded if they had developmental abnormalities, such as enamel hypoplasia, secondary caries beneath existing restorations, or advanced caries that had destroyed more than half of the crown structure.

A total of 79 extracted primary molars from children aged 8 – 12 years were included. After extraction, the teeth were stored in sterile saline at 4°C under uniform conditions and analyzed within 4 hours[32]. Prior to specimen preparation, the plaque and residual tissue were removed via ultrasonic scaling, and the teeth were cleaned and dried for 5 seconds using a 3-way syringe. Specimens were mounted onto white utility wax blocks with the occlusal surfaces oriented upward. Following

the initial examination, the teeth were stored at -20°C. All visual and device examinations were performed twice each by two experienced pediatric dentists, with a 2-week interval between measurements. For the second examination, the specimens were thawed to room temperature and underwent the same cleaning and drying procedures as those in the initial examination.

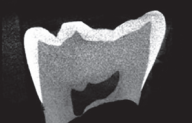
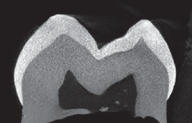
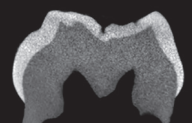
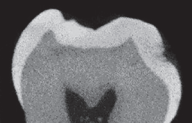
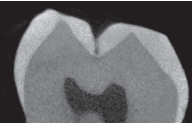
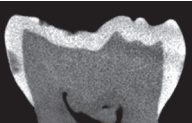
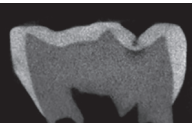
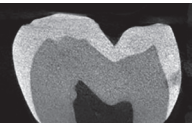
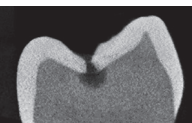
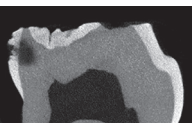
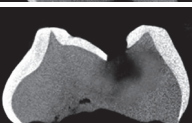
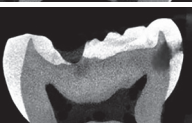
2. Evaluation of carious lesions using visual examination (ICDAS II)

Visual examination was performed according to the ICDAS II criteria. Two trained examiners assessed all teeth under standardized lighting at the same location. Assessments were first conducted on moist teeth, followed by reassessment after drying using a 3-way syringe. The ICDAS II criteria (Table 1) were defined as follows: 0: sound tooth surface, with no visible caries after 5 s of air drying; 1, first visual enamel change, with opacity or discoloration (white or brown) visible at the pit or fissure entrance, which is observed after prolonged drying; 2, distinct enamel change visible when wet and dry; 3, localized enamel breakdown without visible dentin involvement, which is observed when wet and dry; 4, underlying dark shadow from dentin; 5, distinct cavity with visible dentin; and 6, extensive cavity, involving > 50% of the surface, with visible dentin.

3. Evaluation of carious lesions using the LF pen

Following the visual examination, the LF pen (Fig. 1) was used to assess the same tooth surfaces. All assessments were conducted in a black box to standardize the environmental conditions. The LF pen included an occlusal tip for occlusal surface diagnosis and a proximal tip for proximal surface diagnosis. Based on previous studies showing the effectiveness of the occlusal tip on smooth surfaces, this tip was used for smooth surface diagnosis in the present study[33]. Before each measurement, calibration was performed using a ceramic standard, as per the manufacturer's instructions. To set the baseline, the LF pen was first applied to the smooth surface of a sound tooth, and was subsequently applied to the target surface for 20 seconds. The probe was

Table 1. Integrated diagnostic thresholds for primary molar caries based on the Micro-CT, ICCMS, ICDAS II, and laser fluorescence devices

Micro-CT image		ICCMS	ICDAS II	LF Pen	SM	Caries
Occlusal surface	Smooth surface	Micro-CT	Visual examination	Score	Score	Classification
		0 No radiolucency	0 Sound	0 – 12	0 – 10	Sound
		1 Radiolucency in the outer 1/2 of the enamel	1 First visual change in enamel	13 – 24	11 – 20	Enamel caries (D1)
		2 Radiolucency in the inner 1/2 of the enamel EDJ	2 Distinct visual change in enamel			
		3 Radiolucency limited to the outer 1/3 of dentin	3 Localized enamel breakdown			
		4 Radiolucency reaching the middle 1/3 of dentin	4 Underlying dark shadow from dentin	25 – 99	21 – 99	Dentin caries (D2)
		5 Radiolucency reaching the inner 1/3 of dentin	5 Distinct cavity with visible dentin			
			6 Extensive distinct cavity with visible dentin			

ICCMS: International Caries Classification and Management System; ICDAS II: International Caries Detection and Assessment System (version II criteria); LF pen: DIAGNOdent pen; SM: Smartooth.

moved laterally while kept perpendicular to the surface until the highest reading was obtained. Moreover, the laser-emitting side of the probe always faced the tooth surface during the measurement. The final value was determined by subtracting the baseline value from the highest measured value, within the device's 0 – 99 range. Caries severity was classified as follows using the manufacturer's cut-off values: 0 – 12, no demineralization (sound); 13 – 24, enamel demineralization; and 25 – 99, dentin demineralization.

4. Evaluation of carious lesions using SM

SM (Fig. 2) measurements were conducted inside a black box to maintain consistent testing conditions, as for the LF pen. Furthermore, calibration was performed

before each measurement in accordance with the manufacturer's instructions. Disposable PMMA tips were used and replaced between specimens. The probe was kept in contact with the tooth surface for 20 seconds, and the highest value within the 0 – 99 range was recorded for analysis. Caries severity was categorized using the manufacturer's cut-off values as follows: 0 – 10, no demineralization (sound); 11 – 20: enamel demineralization; and 21 – 99, dentin demineralization.

5. Evaluation of carious lesions using micro-CT

Micro-CT has been considered the gold standard for nondestructive evaluation of lesion depth[34]. A micro-CT system (Skyscan 1173, Skyscan N.V., Kontich, Belgium) was used in accordance with the following



Fig. 1. DIAGNOdent pen device. (A) DIAGNOdent pen body. (B) Sapphire occlusal probe (A tip) for pit and fissure surfaces.

scanning parameters: 130 kV, 60 μ A, and a pixel size of 23.53 μ m. The obtained micro-CT images were reconstructed into three-dimensional datasets using the NRecon software (version 1.7.0.4; Bruker micro-CT, Kontich, Belgium). The reconstructed images were analyzed in the sagittal, coronal, and axial planes based on the International Caries Classification and Management System (ICCMS™) criteria (Table 1). The ICCMS protocol was used to classify the lesion severity based on the following standardized criteria: 0, no radiolucency; 1, radiolucency in the outer half of the enamel; 2, radiolucency in the



Fig. 2. Smartooth device and light-emitting diode (LED) display interface. (A) Smartooth device body. (B) Green LED indicates sound tooth surfaces (score range: 0 - 10). (C) Yellow LED indicates enamel caries (score range: 11 - 20). (D) Red LED indicates dentin caries (score range: 21 - 99). (E) The LED display simultaneously shows the peak (maximum) and current (real-time) values, with intuitive color coding (green, yellow, and red) corresponding to the severity of the carious lesions.

inner half of the enamel-dentin junction; 3, radiolucency limited to the outer third of the dentin; 4, radiolucency reaching the middle third of the dentin; and 5, radiolucency reaching the inner third of the dentin.

6. Statistical analysis

All statistical analyses and figures were generated using SPSS Statistics for Windows, version 26.0 (IBM Corporation, Armonk, NY, USA), and R software, version 4.5.1 (R Foundation for Statistical Computing, Vienna, Austria) with the pROC package (version 1.18.5). Based

on the micro-CT results, each tooth was dichotomized into two diagnostic categories: enamel caries (D1) and dentin caries (D2). Post hoc power analysis confirmed that the sample size was adequate to detect statistically significant differences among the groups. For the occlusal and smooth surfaces of the primary molars, the optimal cut-off values for the LF pen and SM at the D1 and D2 thresholds were determined using receiver operating characteristic (ROC) curves. The point of maximum combined sensitivity and specificity was identified using the Youden's index. The area under the ROC curve (A_z) was calculated, and the A_z values for the three diagnostic methods were compared using DeLong's test.

The sensitivity, specificity, and accuracy were calculated based on the optimal cut-off values obtained from the Youden's index. Statistical significance in sensitivity, specificity, and accuracy among the diagnostic methods was assessed using McNemar's test. The association between each diagnostic method and micro-CT (gold

standard) was determined using chi-square tests. The agreement between the methods was assessed using Cohen's kappa coefficient. Statistical significance was set at p-values below 0.05. For the intra- and inter-examiner reproducibility, Cohen's kappa statistics with 95% confidence intervals were calculated. In cases wherein the two examiners' evaluations were inconsistent, a consensus discussion was performed to determine the final diagnostic value.

Results

This study included a total of 79 extracted primary molars comprising 127 occlusal surfaces and 302 smooth surfaces. Based on the micro-CT assessment, both occlusal and smooth surfaces presented sound, enamel, and dentin lesions. The detailed distributions are presented in Table 2.

A one-way analysis of variance (ANOVA) was per-

Table 2. Cross-tabulation of the diagnostic results from DIAGNOdent pen, Smartooth, and visual examination by caries classification in primary molars

			Micro-CT			Total	
			Sound (D0)	Enamel caries (D1)	Dentin caries (D2)		
Occlusal surface	LF pen	D0	41	37	1	79	
		D1	0	15	7	22	
		D2	0	1	25	26	
	SM	D0	41	15	0	56	
		D1	0	32	3	35	
		D2	0	6	30	36	
	EX	D0	39	14	0	53	
		D1	2	39	19	60	
		D2	0	0	14	14	
	Total			41	53	33	127
	Smooth surface	LF pen	D0	146	73	8	227
			D1	0	20	13	33
D2			1	1	40	42	
SM		D0	140	35	0	175	
		D1	5	49	7	61	
		D2	2	10	54	66	
EX		D0	125	25	1	151	
		D1	21	67	25	113	
		D2	1	2	35	38	
Total			147	94	61	302	

D1: enamel caries; D2: dentin caries; LF pen: DIAGNOdent pen; SM: Smartooth; EX: visual examination.

formed to compare the differences between occlusal and smooth surfaces. Based on the observed effect sizes ($f = 0.552$ for occlusal surfaces and $f = 0.445$ for smooth surfaces), the post hoc power analyses revealed that the achieved statistical power was 1.00 for both datasets at a significance level of 0.05. These results indicate that the sample sizes were sufficient to detect significant differences among the groups with a high level of statistical validity.

1. Optimal cut-off values for caries detection in primary molars

The optimal cut-off values for detecting D1 and D2 lesions on occlusal and smooth surfaces were derived from the ROC curves using Youden's index (Fig. 3). For occlusal surfaces, the optimal cut-off values for D1 were 4 and 9 for the LF pen and SM, respectively, whereas those for D2 were 17 and 19, respectively. For smooth surfaces, the optimal cut-offs for D1 were 4 and 8 for the LF pen and SM, respectively, and those for D2 were 8 and 15, respectively (Table 3).

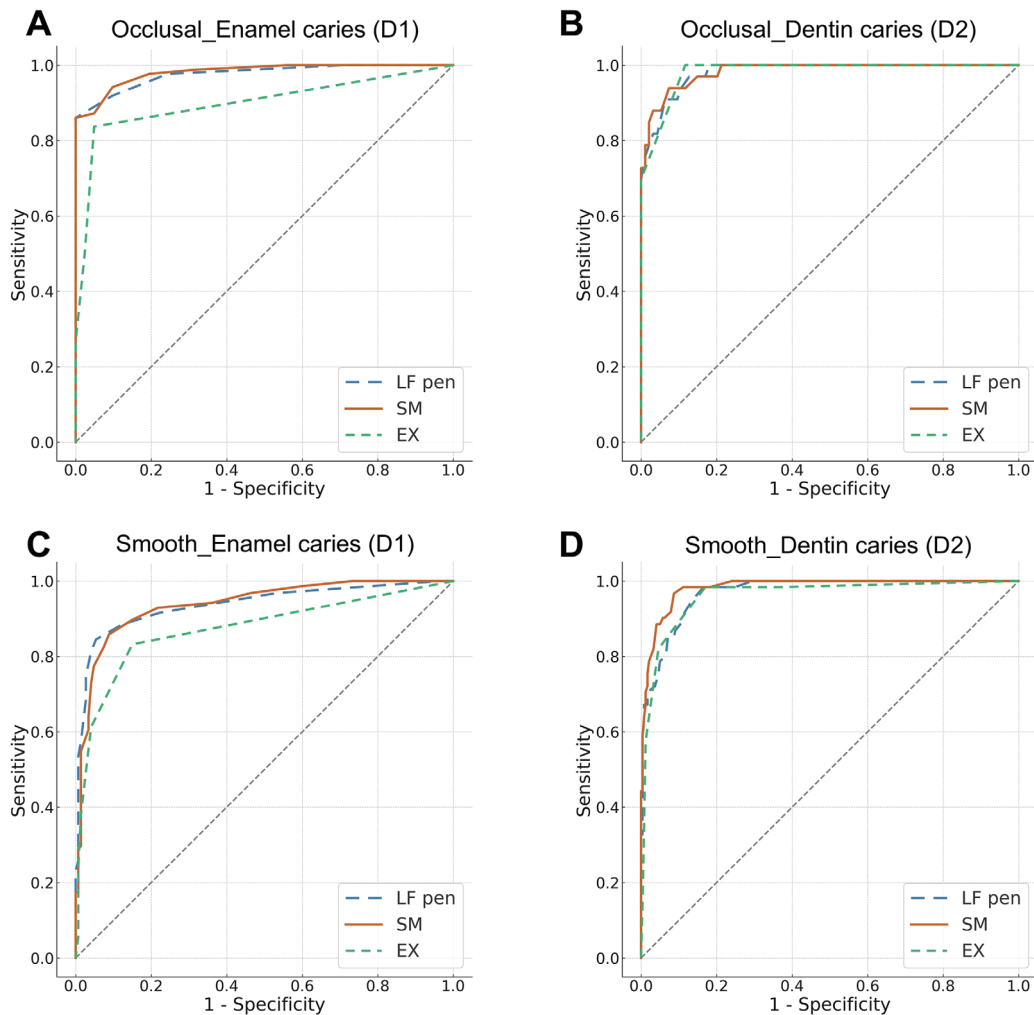


Fig. 3. Receiver operating characteristic (ROC) curves comparing the diagnostic performance of the DIAGNOdent pen, Smartooth, and visual examination for detecting occlusal and smooth surface caries in primary molars. (A) ROC curves for occlusal enamel caries (D1 threshold). (B) ROC curves for occlusal dentin caries (D2 threshold). (C) ROC curves for smooth surface enamel caries (D1 threshold). (D) ROC curves for smooth surface dentin caries (D2 threshold). D1: enamel caries; D2: dentin caries; LF pen: DIAGNOdent pen; SM: Smartooth; EX: visual examination.

Table 3. Optimal diagnostic cut-off values for DIAGNOdent pen and Smartooth in primary molars based on the ROC curve analysis

		Optimal cut-off points	
		D1	D2
Occlusal surface	LF pen	4	17
	SM	9	19
Smooth surface	LF pen	4	8
	SM	8	15

D1: enamel caries; D2: dentin caries; LF pen: DIAGNOdent pen; SM: Smartooth.

2. Comparison of the sensitivity, specificity, accuracy, and A_z values

Table 4 shows sensitivity, specificity, and accuracy based on the optimal cut-off values. On occlusal surfaces at D1, SM exhibited the highest sensitivity (0.974), followed by visual examination (EX; 0.973) and LF pen (0.952; all $p < 0.0001$). Although SM had the highest specificity (0.913), the differences were not statistically significant. The SM showed a significantly higher accuracy (0.898) than the EX (0.874; $p = 0.022$). On occlusal surfaces at D2, EX showed the highest sensitivity (1.000) but did not differ significantly from either the LF pen (0.811) or SM (0.738), whereas the LF pen was significantly higher than SM ($p < 0.0001$). The LF pen (0.967) and SM (0.976) showed higher specificity than EX (0.832; LF pen compared with EX, $p = 0.016$; SM compared with EX, $p = 0.001$). The accuracy was also higher for the LF pen (0.921) and SM (0.898) than for EX (0.850; both $p <$

0.0001).

On smooth surfaces at D1, the LF pen showed the highest sensitivity (0.884), followed by EX (0.881) and SM (0.878), indicating a significant difference (all $p < 0.0001$). However, the specificity and accuracy differences were not statistically significant. For smooth surfaces at D2, the sensitivity did not differ significantly among the methods. However, the EX showed a significantly higher specificity (0.873), followed by SM (0.841) and LF pen (0.828; all $p < 0.001$). Also, the EX showed a significantly higher accuracy (0.995), followed by LF pen (0.970) and SM (0.690; all $p < 0.001$).

A_z , an intuitive indicator of diagnostic accuracy, was significantly higher for SM (0.981) and LF pen (0.976) than for EX (0.899) for occlusal surfaces at D1 (SM compared with EX, $p = 0.0004$; LF pen compared with EX, $p = 0.0012$). On smooth surfaces at D1, the A_z value of SM (0.982) was significantly higher than that for EX (0.921; $p = 0.0002$). However, no significant differences in A_z were found for the D2 lesions on either surface.

3. Association and agreement with the micro-CT gold standard method

The agreement between each diagnostic method and the micro-CT reference standard was assessed via chi-square tests and Cohen's kappa analyses (Table 5). All diagnostic methods showed statistically significant associations with the micro-CT results ($p < 0.0001$). The Cohen's kappa values were interpreted in accordance with the criteria proposed by Landis and Koch[35]: $\kappa <$

Table 4. Sensitivity, specificity, accuracy, and area under the ROC curve (A_z) for DIAGNOdent pen, Smartooth, and visual examination

		Sensitivity*		Specificity*		Accuracy*		A_z †	
		D1	D2	D1	D2	D1	D2	D1	D2
Occlusal surface	LF pen	0.952 ^a	0.811 ^a	0.841 ^a	0.967 ^a	0.913 ^{a,b}	0.921 ^a	0.976 ^a	0.982 ^a
	SM	0.974 ^b	0.738 ^b	0.913 ^a	0.976 ^a	0.898 ^a	0.898 ^a	0.981 ^a	0.983 ^a
	EX	0.973 ^c	1.000 ^{a,b}	0.736 ^a	0.832 ^b	0.874 ^b	0.850 ^b	0.899 ^b	0.982 ^a
Smooth surface	LF pen	0.884 ^a	0.937 ^a	0.874 ^a	0.828 ^a	0.545 ^a	0.970 ^a	0.906 ^a	0.902 ^a
	SM	0.878 ^b	0.863 ^a	0.938 ^a	0.841 ^b	0.995 ^a	0.690 ^b	0.982 ^a	0.904 ^a
	EX	0.881 ^c	0.887 ^a	0.854 ^a	0.873 ^c	0.831 ^a	0.995 ^c	0.921 ^b	0.960 ^a

The different letters within a column indicate statistically significant differences ($p < 0.05$).

*McNemar's test; † DeLong's test.

D1: enamel caries; D2: dentin caries; LF pen: DIAGNOdent pen; SM: Smartooth; EX: visual examination.

Table 5. Comparison of DIAGNOdent pen, Smartooth, and visual examination with the gold standard: Chi-square test and Cohen's kappa values

		χ^2 (Chi-square)*		κ (Cohen's kappa) [†]	
		D1	D2	D1	D2
Occlusal surface	LF pen	82.659	82.410	0.806 ^a	0.803 ^a
	SM	78.841	74.630	0.444 ^c	0.756 ^b
	EX	70.975	44.820	0.732 ^b	0.522 ^c
Smooth surface	LF pen	175.089	126.630	0.761 ^b	0.597 ^c
	SM	169.194	180.303	0.748 ^b	0.752 ^b
	EX	140.615	139.441	0.682 ^b	0.653 ^b

*Chi-square test; [†] Cohen's kappa analysis.

All chi-square and Cohen's kappa analyses showed $p < 0.0001$.

Superscripts indicate the interpretation of Cohen's Kappa values according to Landis and Koch: ^a $\kappa \geq 0.80$, almost perfect agreement; ^b $0.60 \leq \kappa < 0.80$, substantial agreement; ^c $0.40 \leq \kappa < 0.60$, moderate agreement.

D1: enamel caries; D2: dentin caries; LF pen: DIAGNOdent pen; SM: Smartooth; EX: visual examination.

0.20, slight agreement; $0.20 \leq \kappa < 0.40$, fair agreement; $0.40 \leq \kappa < 0.60$, moderate agreement; $0.60 \leq \kappa < 0.80$, substantial agreement; and $\kappa \geq 0.80$, almost perfect agreement.

For the occlusal surface at D1, the LF pen had the highest chi-square value ($\chi^2 = 82.659$), followed by the SM ($\chi^2 = 78.841$) and EX ($\chi^2 = 70.975$). The Cohen's kappa values indicated an almost perfect agreement for the LF pen ($\kappa = 0.806$), substantial agreement for the EX ($\kappa = 0.732$), and moderate agreement for the SM ($\kappa = 0.444$). On the occlusal surface at D2, the LF pen again showed the highest chi-square value ($\chi^2 = 82.410$), followed by the SM ($\chi^2 = 74.630$) and EX ($\chi^2 = 44.820$). The Cohen's kappa values reflected almost perfect agreement for the LF pen ($\kappa = 0.803$), substantial agreement for SM ($\kappa = 0.756$), and

moderate agreement for the EX ($\kappa = 0.522$).

For smooth surfaces at D1, the chi-square values were highest for the LF pen ($\chi^2 = 175.089$), followed by the SM ($\chi^2 = 169.194$) and EX ($\chi^2 = 140.615$). The Cohen's kappa values indicated a substantial agreement for all diagnostic methods: LF pen ($\kappa = 0.761$), SM ($\kappa = 0.748$), and EX ($\kappa = 0.682$). On smooth surfaces at D2, the SM showed the highest chi-square value ($\chi^2 = 180.303$), followed by the EX ($\chi^2 = 139.441$) and LF pen ($\chi^2 = 126.630$). The Cohen's kappa values showed a substantial agreement for the SM ($\kappa = 0.752$) and EX ($\kappa = 0.653$), whereas the LF pen showed a moderate agreement ($\kappa = 0.597$).

The intra- and inter-examiner reliabilities were assessed using Cohen's kappa (κ) (Table 6). The intra-examiner agreement was almost perfect for both the

Table 6. Kappa values for the intra- and inter-examiner reliability for each diagnostic system

		Kappa values (95% CI)		
		Examiner 1	Examiner 2	Examiner 1 vs. 2
Occlusal surface	LF pen	0.84 (0.77 – 0.90)	0.91 (0.86 – 0.95)	0.84 (0.79 – 0.89)
	SM	0.83 (0.76 – 0.89)	0.87 (0.82 – 0.92)	0.82 (0.75 – 0.88)
	EX	0.89 (0.84 – 0.94)	0.80 (0.71 – 0.87)	0.76 (0.67 – 0.84)
Smooth surface	LF pen	0.88 (0.82 – 0.93)	0.90 (0.85 – 0.94)	0.85 (0.77 – 0.91)
	SM	0.94 (0.90 – 0.97)	0.88 (0.82 – 0.93)	0.86 (0.78 – 0.91)
	EX	0.87 (0.82 – 0.91)	0.82 (0.74 – 0.89)	0.78 (0.69 – 0.85)

Cohen's kappa analysis.

All Cohen's kappa analyses showed $p < 0.0001$.

CI: confidence interval; LF pen: DIAGNOdent pen; SM: Smartooth; EX: visual examination.

occlusal ($\kappa = 0.83 - 0.91$) and smooth surfaces ($\kappa = 0.82 - 0.94$). The inter-examiner reliability ranged from a substantial to an almost perfect agreement for occlusal ($\kappa = 0.76 - 0.84$) and smooth surfaces ($\kappa = 0.78 - 0.86$), suggesting high reproducibility across assessments.

Discussion

Numerous studies on caries detection have focused on permanent teeth[36-38], with limited research being conducted on primary teeth, particularly for smooth surface lesions[39]. Consequently, a significant lack of systematic evaluation of diagnostic methods is observed in primary molars, where the current evidence base remains limited. Although devices such as the LF pen are widely used in pediatric dentistry, data validating their diagnostic performance on smooth surfaces in primary teeth remains limited[40].

This study aimed to compare the diagnostic performance of the LF pen and SM for detecting caries on occlusal and smooth surfaces in primary molars and to establish optimized cut-off values specific to primary dentition. These tailored thresholds may address the limitations in the manufacturer-provided cut-off values, which are typically based on permanent teeth. The LF pen cut-off values determined in the present study for detecting enamel and dentin caries on the occlusal surfaces were 4 and 17, respectively, which were lower than those proposed by Goel et al. (7 for enamel and 21 for dentin caries)[41]. For the enamel caries on smooth surfaces, the LF pen cut-off value was 4, closely aligning with the value of 5 that was reported by Bahramian et al.[40]. Meanwhile, the SM occlusal cut-off values for enamel and dentin caries were 9 and 19, respectively, which are similar to those reported by Kim et al.[30] for permanent molars. However, this observation may reflect coincidence or sampling characteristics and should not be interpreted as evidence of cross-dentition equivalence; prospective in vivo pediatric studies are needed to establish pediatric-appropriate thresholds. Across all surfaces and lesion depths, the optimal cut-off values were consistently lower than the manufacturer's

recommendations. This trend may reflect the structural characteristics and lower mineral content of primary dentition. Therefore, the findings provide potentially informative diagnostic thresholds for these teeth; however, prospective in vivo validation is required before clinical adoption.

When comparing the diagnostic performance, SM showed the highest sensitivity for detecting enamel caries on occlusal surfaces, indicating its strength in identifying early-stage lesions. Although the LF pen showed a slightly lower sensitivity, it achieved greater specificity and accuracy, suggesting superior performance in differentiating questionable cases. These findings are consistent with those of Rodrigues et al.[27], and imply that SM and the LF pen may have complementary roles in clinical practice. Moreover, both devices produced significantly higher A_z values than visual examinations in this ex vivo study, indicating better diagnostic performance under experimental conditions. Visual examination yielded the highest sensitivity for detecting dentin caries on occlusal surfaces but showed lower specificity and accuracy, indicating a tendency toward false positives. This observation is consistent with the findings of Alomari et al.[42] and emphasizes the potential risk of overdiagnosis. In contrast, both the LF pen and SM showed high specificity and accuracy for dentinal caries, effectively minimizing misdiagnosis. Furthermore, the high diagnostic accuracy of the LF pen in this study further supports the previous findings reported by Rodrigues et al.[27].

The geometry of the diagnostic tip may have contributed to these modality-specific differences in the results. The flat-ended cylindrical tip of the SM plausibly enables broader surface contact on accessible occlusal areas, which could enhance capture of fluorescence from shallow enamel lesions and thereby increase sensitivity. Conversely, the conical tip of the LF pen provides more focal coupling into narrow pits and fissures, which may favor specificity by limiting signal from adjacent sound enamel. This mechanistic interpretation remains hypothetical, as the present study was not designed to isolate the effect of tip geometry; dedicated studies are required to clarify its role.

For enamel caries on smooth surfaces, both the LF pen and SM achieved a higher sensitivity and A_2 values compared with visual inspection, indicating a superior performance in detecting early lesions. These findings are consistent with those of Bahramian et al.[40]. Given the challenges of visually identifying early lesions on smooth surfaces, these results emphasized the added value of device-assisted diagnostics in complementing traditional diagnostic approaches. The SM also showed a higher specificity and accuracy for dentin caries on smooth surfaces compared with the LF pen, suggesting that SM may provide more stable and consistent diagnostic outcomes, particularly for detecting smooth surface lesions in primary teeth, which are vulnerable to rapid demineralization owing to their structural characteristics.

Although ICDAS-based visual inspection is a widely accepted method for detecting caries in both primary and permanent teeth[43,44], it has several inherent limitations, including examiner subjectivity, variations in lighting, and clinical experience. Thus, combining visual inspection with device-assisted diagnostics may provide a more reliable approach. The complementary strengths of the SM and LF pen could be strategically applied in clinical practice. For instance, SM may be used as the primary tool for detecting early-stage lesions, with the LF pen used to confirm diagnoses and reduce uncertainty.

Compared with conventional laser fluorescence-based caries-detection devices, the SM includes operational features such as real-time visual feedback via an integrated LED display and a hygienic, ergonomic design. It displays both the current reading and the peak value, which are automatically categorized by a color-coded system—green for sound surfaces (0 – 10), yellow for enamel caries (11 – 20), and red for dentin caries (21 – 99). From a hygiene standpoint, the SM uses disposable PMMA optical-fiber tips that are replaced between uses and are designed to bend under force. These device characteristics were not assessed as clinical outcomes in this study; therefore, any potential effects on cross-contamination, measurement consistency, or intraoral trauma remain to be confirmed. Prospective in vivo studies are needed to determine whether these features

translate into improved clinical outcomes in pediatric dental settings.

Although the SM features a cylindrical tip with a diameter of approximately 1 mm, comparable with the LF pen tip diameter, the SM tip has a flat end (Fig. 4) that differs from the LF pen tip. Indeed, the LF pen has a cone-shaped tip designed for occlusal surfaces, which is advantageous for detecting narrow, deep pits and fissures. Moreover, its proximal surface tip tapers gradually to a pointed end, which is optimized for detecting interproximal caries lesions. In contrast, SM currently uses a single flat-ended cylindrical tip with a diameter of approximately 1 mm. While this design can increase surface contact and may support higher sensitivity in accessible occlusal areas, it may be less optimal for very narrow fissures and interproximal regions, where a tapered tip can better access confined spaces. The SM tip's relatively broad sampling field can capture fluorescence from adjacent sound enamel, increasing variability and reducing reproducibility. Optimizing the tip geometry for occlusal fissures and proximal surfaces, for example, by adopting a tapered, slim-ended profile, could localize sampling, minimize cross-enamel interference, and improve measurement consistency and targeting,

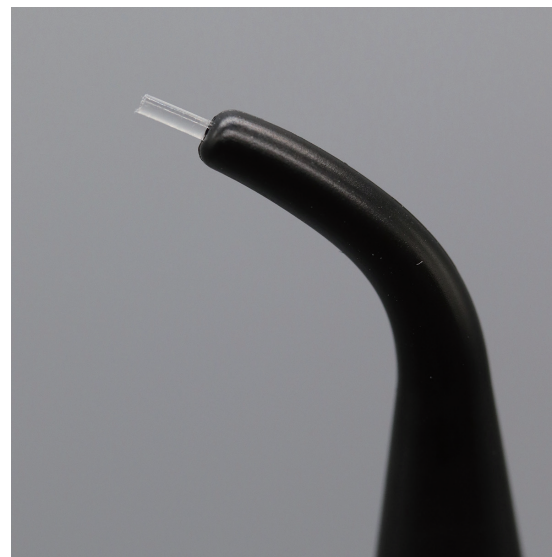


Fig. 4. Magnified image of the Smartooth tip featuring a flat-ended probe.

thereby further enhancing SM's diagnostic performance; these anticipated gains should be confirmed in dedicated *in vivo* studies.

This study was conducted under *ex vivo* conditions using extracted primary molars, which differ from the real-world conditions in clinical settings. For instance, *in vivo* oral environments have various factors, such as saliva and dental plaque, and pediatric patient cooperation also varies, potentially influencing the diagnostic outcomes. Thus, future *in vivo* studies are needed to validate the present findings under real-world conditions. Moreover, expanding the sample size in subsequent research would strengthen the generalizability of the results. Although this study focused on occlusal and smooth surfaces, proximal caries, which are frequently encountered in clinical practice, should also be assessed in future studies. Given the anatomical constraints of contact areas, the diagnostic performance for proximal lesions may be most appropriately evaluated *in vivo*, where tooth separation, moisture control, and soft-tissue dynamics can be considered. Future work should assess proximal surfaces using tips optimized for interproximal access; for SM, development and validation of a tapered proximal tip may improve access and reduce signal contributions from adjacent sound enamel. Although consistent storage conditions and measurement environments were maintained, subtle changes in tooth tissue or environmental factors during storage might have influenced the results[45]. While micro-CT is appropriate for quantifying lesion depth and mineral density, it does not assess caries activity. Accordingly, using micro-CT as the reference standard may not fully capture the biological activity status of lesions. Therefore, the reported diagnostic metrics should be interpreted as depth-based under *ex vivo* conditions, and further *in vivo* validation is required to establish applicability to active/inactive lesion states. Finally, although this study compared two laser fluorescence-based devices, broader comparative analyses including detection devices that use other diagnostic principles, such as quantitative light-induced fluorescence, would provide a more comprehensive understanding.

Importantly, the lower optimal cut-off values identified in this study, compared with the manufacturer's recommendations, should be interpreted with caution. Although lower thresholds may improve sensitivity and assist in the early detection of enamel lesions in primary teeth, they may also reduce specificity and increase the likelihood of false positives and potential overdiagnosis. Therefore, these findings should be considered preliminary and highlight the need to balance sensitivity and specificity in practice, and they underscore the need for further *in vivo* validation. In this *ex vivo* pediatric sample, SM showed higher sensitivity than the LF pen for enamel-level lesions on occlusal surfaces, whereas, on smooth surfaces, the LF pen showed the highest sensitivity. For dentin-level lesions, both SM and the LF pen showed high specificity on occlusal surfaces, whereas, on smooth surfaces, visual examination showed the highest specificity, with SM slightly exceeding the LF pen. Overall, both devices generally exhibited higher agreement and reproducibility than visual examination, with the exception of occlusal D1, where EX exceeded SM. These device-specific tendencies are hypothesis-generating and should not be taken as establishing clinical roles; prospective *in vivo* pediatric studies are required to determine whether any complementary use improves diagnostic performance or patient outcomes.

Despite these limitations, this study addresses a critical gap in the literature by quantitatively comparing the diagnostic performance of two fluorescence-based devices on occlusal and smooth surfaces in primary molars. This study established optimal evidence-based cut-off values tailored to primary dentition by using micro-CT as the gold standard, thereby improving upon the manufacturer-provided benchmarks. Furthermore, by assessing the SM and evaluating a novel diagnostic tool, this research provides practical insights that may guide future diagnostic strategies and aid in device selection in pediatric dental practice.

Conclusion

This study compared the diagnostic performance of

the LF pen and SM for the detection of caries in extracted primary molars and motivates further work to establish diagnostic criteria specifically tailored to primary teeth. Each device exhibited distinct diagnostic characteristics depending on the type of lesion, suggesting that selective use according to lesion location and stage may be appropriate. In particular, the findings highlighted a discrepancy between the manufacturer-recommended cut-off thresholds and the optimal thresholds in this ex vivo sample, supporting consideration of recalibrating cut-off values to reflect the anatomical and histological characteristics of primary teeth.

Both devices showed higher agreement and reproducibility than conventional visual examinations in this ex vivo sample; however, this does not establish clinical benefit. By encompassing a range of lesion locations and depths, this study assessed device performance under ex vivo conditions and provided preliminary, practice-oriented insights, and held significance as foundational research for establishing appropriate diagnostic criteria for primary teeth. These conclusions should be interpreted with caution due to the ex vivo design and the limitations of micro-CT in assessing lesion activity; prospective in vivo pediatric validation, including lesion activity, reproducibility across operators, and patient-level outcomes, is required before any clinical use.

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Conflicts of Interest

The authors have no potential conflicts of interest to disclose.

CRedit authorship contribution statement

Jin Ah Park: Data curation, Formal analysis, Investigation, Visualization, Writing – original draft, Writing

– review & editing. **Je Seon Song:** Conceptualization, Funding acquisition, Data curation, Investigation, Methodology, Project administration, Resources, Validation, Writing – review & editing. **Ko Eun Lee:** Resources, Supervision, Writing – review & editing. **Hoi-In Jung:** Formal analysis, Software, Writing – review & editing. **Hyung-Jun Choi:** Methodology, Project administration, Resources, Software, Supervision, Writing – review & editing.

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