

## Research Paper

## Optimizing fluorescence-based caries detection: A diagnostic performance analysis of SmarTooth and DIAGNOdent pen

Kyusik Kim<sup>a</sup>, Hoi-In Jung<sup>b,c</sup>, Wonse Park<sup>d</sup>, Ko Eun Lee<sup>a</sup>, Chung-Min Kang<sup>a,e</sup>, Je Seon Song<sup>a,e,\*</sup><sup>a</sup> Department of Pediatric Dentistry, Yonsei University College of Dentistry, Seoul, South Korea<sup>b</sup> Department of Preventive Dentistry and Public Oral Health, Yonsei University College of Dentistry, Seoul, South Korea<sup>c</sup> Innovation Research and Support Center for Dental Science, Yonsei University Dental Hospital, Seoul 03722, South Korea<sup>d</sup> Department of Advanced General Dentistry, Yonsei University College of Dentistry, Seoul, South Korea<sup>e</sup> Oral Science Research Center, Yonsei University College of Dentistry, Seoul, South Korea

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## ABSTRACT

**Objectives:** This study aimed to evaluate the diagnostic performance of DIAGNOdent (laser fluorescence [LF] pen; Kavo, Biberach, Germany), SmarTooth (SM; Smartooth, Korea), and the International Caries Detection and Assessment System II (ICDAS II) scoring system in detecting occlusal dental caries in permanent teeth, with micro-computed tomography (CT) as the gold standard. Furthermore, the optimal cut-off values for the two devices were determined.

**Methods:** In total, 173 occlusal sites from extracted permanent teeth were assessed using the LF pen, SM, and ICDAS II. Radiographic values obtained using micro-CT were set as the gold standard. Sensitivity, specificity, accuracy, and optimal cut-off points were analyzed using receiver operating characteristic curve analysis. Significance was set at  $p < 0.05$ .

**Results:** At the enamel demineralization (D1) and dentin demineralization (D2) thresholds, ICDAS II exhibited the highest sensitivity (D1: 0.966, D2: 0.897), whereas the LF pen exhibited the highest specificity (D1: 1.000, D2: 0.913). SM exhibited higher accuracy than did ICDAS II and the LF pen for both the D1 and D2 thresholds. The optimal cut-offs for the LF pen were as follows: sound: 0–9, enamel caries: 10–20, and dentin caries: 21–99; those for SM were as follows: sound: 0–8, enamel caries: 9–18, and dentin caries: 19–99.

**Conclusions:** Both the LF pen and SM have high diagnostic performance for occlusal dental caries. However, SM achieves the best overall accuracy and thus has strong potential as an effective tool for caries detection.

## 1. Introduction

Dental caries are among the most widespread chronic diseases affecting individuals across all age groups [1,2]. Accurate and early diagnosis of caries is crucial for effective prevention and treatment, thereby reducing the need for invasive interventions. However, conventional diagnostic methods, such as visual-tactile examination and radiographic imaging, have limitations in detecting incipient lesions and subsurface demineralization [3,4]. The International Caries Detection and Assessment System II (ICDAS II) scoring system provides a standardized approach for classifying caries based on visual criteria. Similarly, the International Caries Classification and Management System (ICCMS) is often employed in radiographic assessments to categorize lesions based on severity and risk factors [5,6]. Although these

diagnostic approaches demonstrate high specificity, they have certain drawbacks, including subjectivity in lesion assessment, examiner variability, and difficulty in quantifying early stage caries [1]. Furthermore, radiographic imaging involves exposure to ionizing radiation, raising concerns about its frequent application, particularly in pediatric patients [1,3].

To address these shortcomings, various caries detection techniques have been accordingly developed to provide an objective, non-invasive, and quantitative analysis of carious lesions. Laser fluorescence (LF)-based devices, including DIAGNOdent (LF pen) (Kavo, Biberach, Germany), quantitative light-induced fluorescence imaging system, near-infrared imaging system, digital transillumination, electric-based caries detection, and ultrasound-based caries detection, have demonstrated promising results in detecting carious lesions [7–10]. The LF pen

\* Corresponding author at: Department of Pediatric Dentistry, Yonsei University College of Dentistry, 50-1 Yonsei-ro, Seoul, 03722, South Korea.

E-mail address: [songjs@yuhs.ac](mailto:songjs@yuhs.ac) (J.S. Song).

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operates based on the principle of LF using a diode laser with a wavelength of 655 nm. This wavelength is selectively absorbed by bacterial metabolites, primarily porphyrins, within carious lesions. When exposed to laser light, these metabolites emit fluorescence that can then be quantified using the device. Fluorescence intensity correlates with the degree of demineralization, allowing clinicians to assess dental caries activity more objectively than with conventional methods [11].

SmarTooth (SM) (Smartooth, Korea) is a new caries detection device introduced only in 2023. SM operates based on LF principles, utilizing the same 655 nm wavelength to detect bacterial metabolites within carious lesions and quantify their fluorescence emission. However, it incorporates meaningful improvements that enhance usability and diagnostic consistency. One notable feature is the integration of a mobile application that enables clinicians to record and store individual lesion data for each patient, allowing longitudinal monitoring and personalized caries management. SM uses a single-use polymethyl methacrylate (PMMA) probe tip, in contrast to the reusable sapphire crystal probe used in the LF pen. This disposable design enhances infection control and eliminates the need for sterilization between patients. Additionally, preliminary *in vitro* data demonstrated that the PMMA probe delivers a higher optical output intensity than the sapphire probe, which may enhance fluorescence signal detection and improve diagnostic sensitivity, particularly in occlusal sites with narrow or deep fissures.

In comparison with quantitative light-induced fluorescence (QLF) systems, which typically use blue light at approximately 405 nm to induce autofluorescence in dental hard tissues, LF-based devices such as DIAGNOdent pen and SmarTooth differ fundamentally in excitation wavelengths and clinical application. QLF devices typically excite porphyrins through the Soret band at 405 nm, resulting in strong surface-level fluorescence signals with limited tissue penetration (~100 µm), making them suitable for early caries detection and plaque assessment [12]. In contrast, LF devices operate at 655 nm, targeting the Q-band of porphyrins. Although this longer wavelength exhibits lower excitation efficiency, it enables deeper penetration (up to 1–2 mm) into the enamel and dentin, facilitating detection of subsurface or occlusal caries [13]. These spectral and diagnostic differences may influence device performance depending on lesion depth and location.

In addition, the diagnostic approach also differs. QLF devices visualize mineral loss through changes in enamel autofluorescence and require photographic image acquisition with software-based analysis. Conversely, LF-based devices provide real-time point measurements based on bacterial metabolite fluorescence. Thus, LF devices offer greater portability and ease of use, making it suitable for chairside application without the need for additional imaging infrastructure. It also allows for immediate quantitative assessment of carious lesions in clinical settings, facilitating real-time decision-making. However, it does not provide the spatial mapping or visualization of lesion area and depth that QLF systems can offer.

Despite these potential advantages, few studies have been conducted to validate its diagnostic performance in comparison with existing caries detection tools. Therefore, a systematic investigation is required to determine its performance and correlation with conventional caries assessment methods. This study aimed (1) to assess the diagnostic performance of the LF pen, SM, and the ICDAS II visual scoring system in detecting occlusal caries in permanent teeth in comparison with micro-computed tomography (CT) as the gold standard and (2) to determine the optimal cut-off points for the LF pen and SM.

## 2. Materials and methods

### 2.1. Study design and ethics

This *in vitro* study was approved by the Institutional Review Board of Yonsei University Dental Hospital (IRB no. 2–2023–0052) and was conducted according to the tenets of the Declaration of Helsinki.

### 2.2. Sample selection and preparation

Patients from Yonsei University Dental Hospital who underwent tooth extraction for orthodontic, periodontal, and surgical indications were included. Extracted permanent teeth were used. The exclusion criteria were (1) teeth with development disorders (e.g., amelogenesis imperfecta), (2) teeth with any restorations, and (3) teeth with severe dental caries that had damaged more than half of the crown. In total, 106 extracted permanent teeth were included. A total of 173 occlusal sites on the premolars and molars were selected. The collected teeth were first cleaned using pumice slurry and a rubber cup to remove plaque and residual tissue and then dried with compressed air for at least 5 s. Subsequently, the carious lesions were assessed visually using ICDAS II and with the LF pen and SM. Finally, they were subjected to micro-CT as the gold standard and classified according to the ICCMS criteria [14]. All assessments were independently performed by two examiners. Discrepancies in the results were resolved through a discussion until a consensus was reached, and the final values were recorded.

### 2.3. ICDAS II (Visual examination)

The examiner selected the most severely affected area on the occlusal surface of each tooth and analyzed the wet and dry teeth using the ICDAS II criteria to classify the lesions as follows: 0: sound; 1: first visual change in enamel; 2: distinct visual change in enamel; 3: localized enamel breakdown (without clinical visual signs of dentinal involvement); 4: underlying dark shadow from dentin; 5: distinct cavity with visible dentin; and 6: extensive distinct cavity with visible dentin.

### 2.4. DIAGNOdent pen

After visual inspection, the occlusal sites were measured using the DIAGNOdent LF pen (Fig. 1). Before each measurement, LF pen was calibrated using a ceramic standard according to the manufacturer's instructions. To establish a baseline value, the LF pen was applied to a sound smooth tooth surface before being placed on the occlusal surface for 20 s. The final recorded value (ranging from 0 to 99) was obtained by subtracting the baseline value from the highest recorded value. The severity of the carious lesions was classified based on the cut-off values provided by the manufacturer: 0–12: no demineralization (sound); 13–24: enamel demineralization; and 25–99: dentin demineralization.

### 2.5. SmarTooth

Similar to the measurement process using the LF pen, SmarTooth was calibrated before each measurement using the device (Fig. 2) in accordance with the manufacturer's instructions. The device was applied to the occlusal surface for 20 s, and the highest recorded value (ranging from 0 to 99) was used for the analysis. Carious lesions were classified based on the cut-off values provided by the manufacturer: 0–10: no demineralization (sound); 11–20: enamel demineralization; and 21–99: dentin demineralization.

### 2.6. Micro-CT

The micro-CT (Skyscan 1173, Skyscan N.V., Belgium) imaging was performed under the following conditions: 130 kV, 60 µA, and a pixel size of 23.53 µm. The acquired micro-CT images were reconstructed into 3D image files using the NRecon software (version 1.7.0.4). Using these reconstructed images, the detected carious lesions in the sagittal, coronal, and axial planes were evaluated according to the ICCMS criteria to ensure a standardized assessment of lesion severity, as follows [5]: 0: no radiolucency; 1: radiolucency in the outer 1/2 of the enamel; 2: radiolucency in the inner 1/2 of the enamel-dentine junction; 3: radiolucency limited to the outer 1/3 of dentin; 4: radiolucency reaching the middle 1/3 of dentin; 5: radiolucency reaching the inner 1/3 of dentin; and 6:



Fig. 1. DIAGNOdent pen.



Fig. 2. SmarTooth device.

radiolucency into the pulp.

2.7. Statistical analysis

The radiographic scores (ICCMS) were dichotomized into two diagnostic thresholds: enamel demineralization (D1, ICCMS scores 1–5) and dentin demineralization (D2, ICCMS scores 3–5). Receiver operating characteristic (ROC) curves were generated using these thresholds as reference standards to evaluate the diagnostic performance of the LF pen and SM. The optimal cut-off values for each threshold for the LF pen and SM were determined as the point where the sum of the sensitivity and specificity was the highest on the ROC curve. Sensitivity, specificity, accuracy, and area under the ROC curve (AUC) were calculated separately for D1 and D2 thresholds to assess diagnostic effectiveness [15, 16]. The sensitivity, specificity, and accuracy of the different methods were compared using McNemar’s test ( $p < 0.05$ ). Additionally, the Spearman rank correlation was calculated to evaluate the agreement between the diagnostic tools and radiographic scores. All statistical analyses were conducted using SPSS software (version 30.0; IBM Corp., Armonk, NY, USA). A  $p$  value of  $< 0.05$  was considered significant.

3. Results

Among the 173 sites, 56 sites (32.4 %) were classified as sound (score 0), whereas 59 sites (34.1 %) were diagnosed as enamel caries (scores 1–2). Dentin caries (scores of 3–5) were identified at 58 sites (33.5 %). The radiographic scores categorized based on micro-CT findings are shown in Table 1.

The distribution of the ICDAS II, LF pen, and SM scores according to the radiographic scores is shown in Table 2. Figs. 3 and 4 show the ROC curves for the SM and LF pens at the D1 and D2 thresholds. The sensitivity, specificity, accuracy, and  $A_z$  values are listed in Table 3. ICDAS II, the LF pen, and SM exhibited high sensitivity values at the D1 threshold. ICDAS II showed the highest sensitivity values at both the D1 (0.966) and D2 (0.897) thresholds but also showed the lowest specificity values at both thresholds (D1: 0.571, D2: 0.652). Meanwhile, the LF pen exhibited the highest specificity at both the D1 and D2 thresholds (D1: 1.000, D2: 0.913). SM showed the highest accuracy at the D1 (0.861) and D2 (0.867) thresholds. SM also exhibited high sensitivity and specificity at both thresholds. Table 4 lists the optimal cut-off values for the LF pen and SmarTooth according to the ICCMS scores.

The Spearman rank correlation analysis showed that SM had the highest correlation with the micro-CT radiographic score ( $\rho = 0.802$ ), followed by the LF pen ( $\rho = 0.759$ ) and ICDAS II ( $\rho = 0.743$ ).

4. Discussion

Although LF pens have been studied both *in vitro* and *in vivo* [3], limited data are available on the diagnostic performance of SM. The current study found that both the DIAGNOdent pen and SmarTooth exhibited high diagnostic efficacy for detecting occlusal caries in permanent teeth, with SmarTooth demonstrating the highest overall accuracy at both enamel and dentin thresholds. Additionally, study-specific

Table 1  
Distribution of radiographic scores.

Radiographic score	Frequency, n (%)
0	56 (32.4)
1	11 (6.4)
2	48 (27.7)
3	45 (26.0)
4	11 (6.4)
5	2 (1.2)
6	0 (0)
Total	173 (100)

**Table 2**

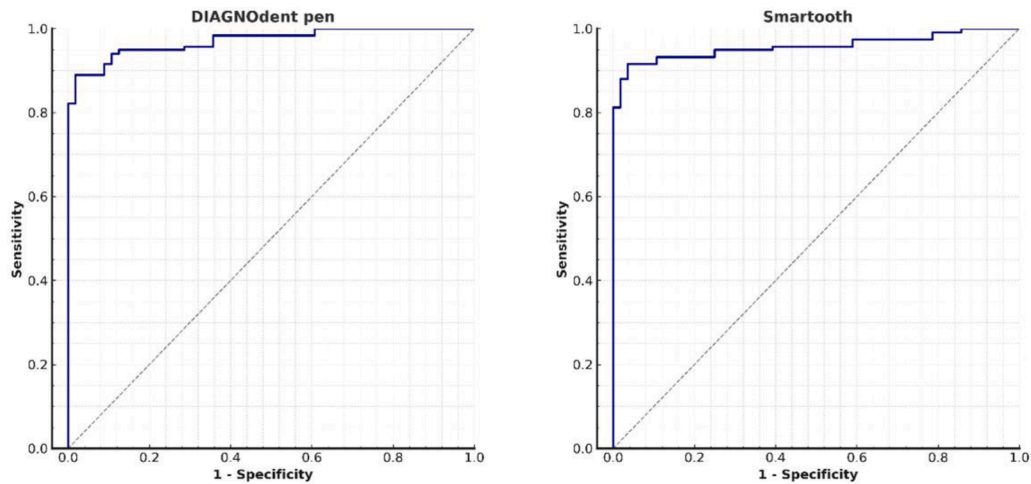
Distribution of ICDAS II, DIAGNOdent, and SM scores according to the ICCMS scores.

Visual examination	0: sound	1–2: Enamel caries	3–6: dentin caries	Total
0	32	4	0	36
1	22	10	1	33
2	1	6	5	12
3	1	30	13	44
4	0	5	25	30
5	0	3	13	16
6	0	1	1	2
Total	56	59	58	173
DIAGNOdent pen				
0 (0–12)	56	24	6	86
1 (13–24)	0	25	10	35
2 (25–99)	0	10	42	52
Total	56	59	58	173
Smartooth				
0 (0–10)	55	20	3	78
1 (11–20)	1	28	9	38
2 (21–99)	0	11	46	57
Total	56	59	58	173

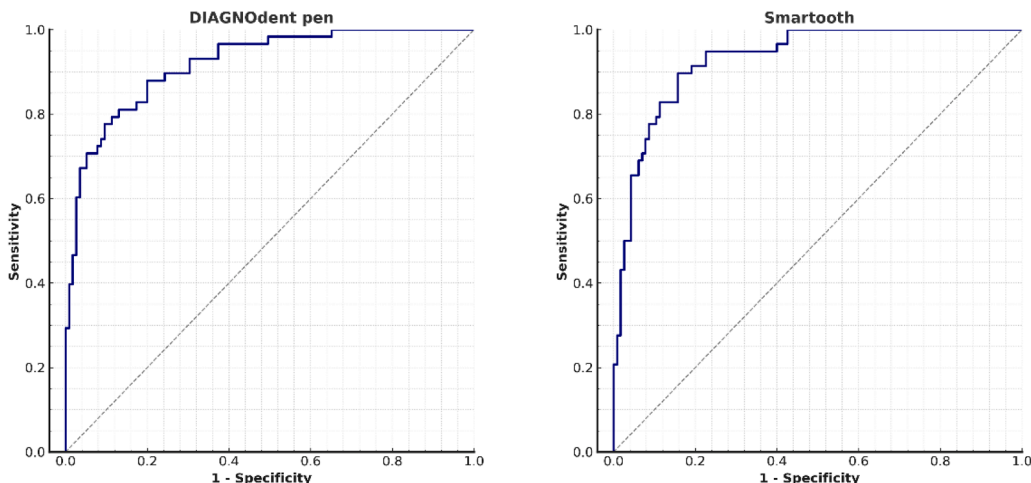
optimal cut-off values were identified, enhancing the clinical relevance of both devices. To the best of our knowledge, this study is the first to evaluate the diagnostic accuracy of the SM in comparison with the LF pen and to determine the optimal cut-off values for the LF pen and SM.

Detection of dental caries remains a fundamental challenge in clinical dentistry. Although visual inspection and radiographic imaging are the traditional diagnostic tools used by clinicians, these methods are often influenced by examiner subjectivity and clinical experience, potentially leading to variations in diagnosis [17]. To overcome these limitations, fluorescence-based diagnostic tools, such as the LF pen and SM, have been introduced [18]. Enamel defects and pre-existing restorations may exhibit fluorescence patterns similar to those of carious lesions [19,20]. Thus, the present study excluded teeth with enamel hypomineralization, restorations, or significant structural loss due to caries to minimize false-positive results. Carefully selecting sound and carious teeth enabled a more accurate evaluation of the diagnostic performance of each method.

Importantly, the results demonstrated that the ICDAS II for visual examination exhibited high sensitivity at the D1 threshold (96.6 %), albeit relatively moderate specificity (57.1 %). This finding aligns with the *in vivo* study by Diniz and Melek [9,15]. Some *in vitro* studies [21,22] also reported high sensitivity values for ICDAS II-based detection methods. However, our results contradict those reported by Goel et al. [4] and Attrill and Ashley [23], who observed lower sensitivity and higher specificity with visual inspection. This discrepancy between studies may be attributed to differences in examiner training, lighting conditions, and sample selection. Additionally, the high diagnostic accuracy of visual inspection of enamel lesions supports its continued use as a fundamental caries detection technique. At the D2 threshold, ICDAS



**Fig. 3.** Sensitivity and specificity ROC curves for SmarTooth and DIAGNOdent pen at the D1 threshold.



**Fig. 4.** Sensitivity and specificity ROC curves for SmarTooth and DIAGNOdent pen at the D2 threshold.



**Table 3**

Sensitivity, specificity, accuracy, and  $A_z$  values at the D1 and D2 thresholds.

	Sensitivity		Specificity		Accuracy		$A_z$	
	D1	D2	D1	D2	D1	D2	D1	D2
Visual examination	0.966	0.897	0.571	0.652	0.838	0.734	0.948	0.881
DIAGNOdent pen	0.744	0.724	1.000	0.913	0.827	0.850	0.961	0.913
Smartooth	0.812	0.793	0.982	0.896	0.861	0.867	0.950	0.925

$A_z$ , area under the receiver operating curve.

D1, enamel demineralization; D2; dentin demineralization.

**Table 4**

Optimal cut-off values of the DIAGNOdent pen and SmarTooth.

Radiographic score	Method (optimal cutoff)	
	DIAGNOdent pen	SmarTooth
0	0–9	0–8
1, 2	10–20	9–18
3–6	21–99	19–99

II demonstrated a sensitivity of 89.7 % and a specificity of 65.2. This is consistent with the findings of Rodrigues et al. [24] and Diniz et al. [25] but contradicts those reported by Jablonski-Momeni et al. [26], who observed a higher specificity than sensitivity. The presence of hidden caries, variations in sample sizes, and lesion progression across studies may explain these conflicting results [15].

The LF pen has been reported to have higher sensitivity but lower specificity than visual examinations [4]. However, our findings suggest that the LF pen has higher specificity (D1: 1.000, D2: 0.913) than visual examination with ICDAS II at both the D1 and D2 thresholds. This result contradicts previous findings of higher false-positive results with fluorescence-based devices [16]. This discrepancy may be caused by the differences in cut-off values used across studies, as previous studies employed various manufacturer-recommended and study-determined cut-off thresholds [16].

Similarly, SM showed high sensitivity and specificity across both the D1 and D2 thresholds. Notably, SM achieved the highest accuracy for both thresholds among all modalities examined (D1, 86.1 %; D2, 86.7 %), indicating its potential as a clinically reliable fluorescence-based diagnostic tool. The observed differences in the diagnostic performance between SM and LF pen may partly be attributed to the structural and optical characteristics of each device's probe tip. SM utilizes a disposable polymethyl methacrylate (PMMA) probe, whereas the LF pen employs a reusable sapphire crystal probe. These two materials differ in terms of optical transmittance, refractive index, and probe geometry, all of which may influence the efficiency of laser delivery and fluorescence signal detection.

To explore this further, a preliminary *in vitro* experiment compared the light output intensity at 655 nm between the two probe types using seven tips per device. The results showed that the PMMA probes used in SmarTooth produced a mean light output of 125.9  $\mu$ W, while the sapphire probes of the LF pen emitted 105.7  $\mu$ W, corresponding to approximately 0.84 times the output of the PMMA probe. The higher transmittance of PMMA at this wavelength may contribute to more efficient excitation of carious lesions, particularly in deep fissures where laser penetration is critical.

In addition to optical properties, the single-use design of the PMMA probe may enhance consistency between measurements by minimizing the potential degradation or contamination that can occur with repeated use of reusable probes. This, combined with differences in probe shape and contact area, could partly explain the improved diagnostic accuracy observed with SM in both enamel and dentin threshold analyses.

The diagnostic trade-off between sensitivity and specificity was evident across both devices as summarized in Supplementary Table S1. SmarTooth maintained consistently high sensitivity across a broader

range of cut-off thresholds, particularly for enamel-level (D1) lesions, indicating its potential advantage in detecting early-stage caries. This trend is especially beneficial in high-risk patients or preventive care settings where early intervention is prioritized.

In contrast, DIAGNOdent showed a more conservative diagnostic profile, with sharper gains in specificity as the cut-off values increased—suggesting better performance in minimizing false positives. This may be advantageous in clinical situations where overtreatment needs to be avoided or in selective caries management strategies.

At the D2 threshold, both devices exhibited more balanced sensitivity-specificity profiles, but SmarTooth still showed greater diagnostic stability. These trade-off patterns highlight that device selection and cut-off customization should be based on specific clinical goals—such as maximizing lesion detection in high-risk individuals versus minimizing false alarms in low-caries-risk populations.

The manufacturer-recommended cut-off values for the LF pen and SM were applied in this study; however, the optimal cut-off values identified from the analysis differed from those provided by the manufacturers. This discrepancy may be attributed to differences in study populations, sample selection criteria, lesion depth, and device calibration. Previous studies have also reported variations in cut-off values depending on the experimental conditions and reference standards [27]. To establish the most effective diagnostic threshold, we employed the Youden index, a widely used statistical measure for determining the optimal balance between sensitivity and specificity [28–30]. Using this index, we identified new cut-off values that maximized diagnostic accuracy and minimized false positives, ensuring improved clinical applicability.

In the present study, diagnostic threshold ranges were determined as 9–18 for D1 and 19–99 for D2 using SM, and 10–20 for D1 and 21–99 for D2 with the LF pen. These values were compared with existing literature for contextual interpretation. Diniz et al. reported higher thresholds for dentin caries (D2: 33–99) based on histological validation, whereas our study, using micro-CT as the reference standard, yielded lower thresholds. This difference may be attributed to methodological variations, particularly the use of micro-CT as the reference standard in our study, which—although non-invasive and capable of providing high-resolution volumetric data—may differ in sensitivity and lesion classification compared to histological validation [15]. Similarly, Huth et al. evaluated the clinical performance of the DIAGNOdent pen and identified an optimal threshold of 12 for enamel caries detection and 25 for dentin caries detection [18]. The cut-off ranges in our study (D1: 10–20; D2: 21–99 for LF pen) are consistent with Huth's findings, yet our slightly lower D2 threshold suggests a higher sensitivity to early dentinal involvement. This observation is particularly relevant in the context of preventive care, where early detection of dentin demineralization can guide minimally invasive treatment decisions. Taken together, these comparisons highlight that our device-specific cut-off values are consistent with, but in some respects more sensitive than, those reported in previous studies. The lower-bound thresholds identified in this study, especially with SmarTooth, may reflect the combined influence of micro-CT reference validation, updated probe design, and improved optical performance.

For instance, research on LF pens has proposed varying cut-off values for different caries stages, emphasizing the importance of study-specific

validation. As SM lacks prior research on cut-off values, the findings of this study serve as an essential reference for future investigations and clinical applications.

Despite its strengths, this study also had limitations. While the *in vitro* results of this study were promising, several clinical factors may affect the accuracy of fluorescence-based caries detection. Arrested lesions, which have lower bacterial activity and are often remineralized, tend to show reduced fluorescence, potentially leading to underdiagnosis. Mitchell confirmed that such lesions displayed significantly lower LF values than active ones despite similar depths [31]. Restorative materials such as sealants can emit background fluorescence, interfering with signal interpretation. Gostanian found that LF devices were unreliable for detecting caries beneath certain sealants [19]. Likewise, enamel cracks, pits, or stains may trap debris, causing false-positive readings; Sheehy observed overdiagnosis in stained fissures using LF [32]. Proper surface preparation is also essential. Lussi showed that cleaning with pumice and drying for at least five seconds significantly improved reading reliability [29]. These findings emphasize the need for careful interpretation and the combined use of visual inspection when applying LF devices clinically. Additionally, variations in operator technique, device calibration, and lesion depth could affect reproducibility. Moreover, the small sample size may have limited the generalizability of our findings. Future *in vivo* studies should validate our findings by assessing the performances of SM and LF pens in diverse patient populations. Further research is also needed to evaluate their diagnostic accuracy for proximal lesions and to investigate their applicability in primary teeth. In addition, exploring the integration of artificial intelligence with automated fluorescence analysis may enhance the diagnostic capability of these tools.

## 5. Conclusion

Both the LF pen and SM have high specificity for caries detection, reducing the likelihood of overdiagnosis. The SM has the highest accuracy, highlighting its potential as an effective tool for caries detection. The optimal cut-off points for sound teeth, enamel caries, and dentin caries are 0–9, 10–20, and 21–99 for LF pen and 0–8, 9–18, and 19–99 for SM pen, respectively.

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Declaration of generative AI and AI-assisted technologies in the writing process.

## CRedit authorship contribution statement

**Kyusik Kim:** Writing – original draft, Visualization, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Hoi-In Jung:** Methodology. **Wonse Park:** Data curation. **Ko Eun Lee:** Writing – review & editing, Methodology. **Chung-Min Kang:** Writing – review & editing, Formal analysis. **Je Seon Song:** Writing – review & editing, Supervision, Project administration, Methodology, Conceptualization.

## Declaration of competing interest

Smartooth (Korea) provided the DIAGNOdent pen and SmarTooth devices used in this study.

## Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.pdpdt.2025.104731](https://doi.org/10.1016/j.pdpdt.2025.104731).

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