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Diagnostic agreement between visual examination and an automated scanner system with fluorescence for detecting and classifying occlusal carious lesions in primary teeth

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ABSTRACT

Objectives: To investigate the in vivo diagnostic agreement between visual examination (VE) using the International Caries Detection and Assessment System (ICDAS) and an automated scanner system for detecting and classifying carious lesions in primary teeth.
Methods: 5-year-old children (n = 216) underwent VE and intraoral scanning (TRIOS 4, 3Shape TRIOS A/S, Copenhagen, Denmark). Dental caries experience was recorded for each tooth surface using ICDAS. An automated, fluorescence-based caries scoring system was applied to eligible primary teeth occlusal surfaces on the 3D models using commercially available software. The automated system classified surfaces as sound, initial caries (ICDAS 01/02), or moderate-extensive caries (ICDAS $\geq$03). The diagnostic agreement was investigated using multi-level modelling and intraclass correlation coefficients. Analyses were repeated at both the initial threshold (ICDAS $\geq$01) and the moderate-extensive threshold (ICDAS $\geq$03).
Results: 213 participants were included in the study, and 1525 primary molar occlusal surfaces were included in the analysis. The odds of detecting caries using the automated system were 46 % lower at the initial disease threshold (OR 0.54, 95 % CI 0.39–0.74) and 70 % lower at the moderate-extensive disease threshold (OR 0.30, 95 % CI 0.16–0.58) compared to VE. The intraclass correlation estimates at the initial and moderate-extensive thresholds were 0.90 (95 % CI 0.70–0.96) and 0.76 (95 % CI 0.22–0.94) respectively.
Conclusion: The automated system is less likely to detect initial lesions and is more likely to underestimate lesion severity relative to visual examination using ICDAS.
Clinical Significance: Clinically, using the automated tool to replace thorough visual inspection in primary teeth could result in missed opportunities to provide professional or self-care to arrest or reverse early disease. Additionally, it could misclassify moderate lesions as initial caries, potentially leading to complications associated with the delayed management of dental caries.

1. Introduction

Dental caries is a chronic, multifactorial disease driven by dietary free sugars and dysbiosis of the plaque biofilm, leading to mineral loss from the teeth and cavitation [1]. Globally, the mean prevalence of dental caries in children's primary teeth is estimated at 43 % [2]. Untreated disease can increase pain and infection risk, which may negatively impact a child's quality of life [3].

The clinical presentation of dental caries varies in severity from early to more advanced [4]. If detected in its early stages, before cavity

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formation, non-invasive caries management strategies can be implemented in children to arrest or reverse the disease process [5]. In clinical practice, visual examination (VE), supplemented by intra-oral radiographs, is the most widely accepted method for caries detection [6]. Bitewing radiographs are commonly used in routine examinations. They help detect caries that have advanced into deeper parts of the tooth, reaching a point where restoration may be necessary. However, bitewings are limited in detecting early occlusal enamel caries [5]. Methods sensitive to early enamel caries are valuable adjuncts to clinical examination.

Quantitive Light-induced Fluorescence (QLF) is a well-established technology supporting early detection of occlusal caries. QLF uses light in the blue-violet spectrum to excite sound tooth structures to emit green fluorescence [6,7]. In enamel caries, the tooth structure will appear darker when compared to the surrounding healthy tooth structure [8-10] because mineral loss is associated with reduced green fluorescence intensity [11,12]. The diagnostic capabilities of fluorescence are further enhanced because bacterial metabolites in cariogenic dental plaque emit orange-red fluorescence when exposed to blue-violet light [13,14].

QLF™ (Inspektor Research Systems BV, Amsterdam, the Netherlands) devices comprise a camera, a Light-Emitting Diode (LED) light source to illuminate the tooth at the desired wavelengths, and a filter to capture the emission spectrum from regions of interest [15]. These design features enable the capture of a 2D digital image, where green fluorescence loss and red fluorescence can be viewed simultaneously. The first-generation QLF™ device (Inspektor™Pro) was introduced in 2004. The second-generation device, a Digital Single Lens Reflex DSLR Camera (Inspektor™ QLF-D Biluminator 2+), had a broader viewing range; however, its manual focus requires more time and skill to achieve high-quality images [16]. Advancements in technology and research have driven modifications to existing devices and the emergence of new technologies. The third-generation QLF™ devices were enhanced for clinical use: a handheld camera with autofocus (Qraycam™) and an intraoral camera (Qraypen™) [17]. Fluorescence cameras utilising similar technology to QLF™ systems, though with different specifications, have also been released, and include SoproLIFE® and SoproCARE® (Acteon Group, Norwick, England), VistaProof and VistaCam (Dürr Dental, Bietigheim-Bissingen, Germany), and the Spectra™ Series (Air Techniques, Melville, NY, USA). Devices also vary in their interpretation of fluorescence signals; some use specific software to automate this process or have scores indicative of caries severity, while others depend on clinician interpretation of fluorescence characteristics, which is more subjective.

QLF has been reported to have similar in vitro diagnostic performance to VE using a validated index for occlusal caries detection in primary teeth [18]. The in vivo performance of fluorescence cameras has shown a strong correlation with VE using ICDAS [19]. While some studies have reported in clinical practice that VE using ICDAS alone is sufficient for caries detection [20], it has been argued that the benefits of using fluorescence devices are for visualising lesions to enhance patient communication and for more objective methods for caries monitoring [19,21,22].

In clinical practice, the reproducibility of 2D images for caries monitoring is challenging as the field of view, acquisition angle, and variability in light conditions may influence observed lesion size and fluorescence loss [23]. Additionally, obtaining reproducible, high-quality images using some fluorescence camera devices in children is reportedly time-consuming [24]. To overcome these challenges, the TRIOS Intra Oral Scanner (IOS) system (3Shape TRIOS A/S, Copenhagen, Denmark) combines QLF-like technology with 3D image reconstruction of the dentition, offering a reproducible image acquisition method that is easy to use [25], which may better support early caries detection and monitoring in children.

An automated caries scoring system has been commercialised for the TRIOS 4 & 5 IOS (3Shape TRIOS A/S, Denmark) to provide a more objective measure for the interpretation of fluorescence using intraoral scanners [26]. The automated caries scoring system is a rule-based algorithm which uses pre-determined scoring cut-offs to indicate relative caries depth. The system has two cut-offs: the initial disease threshold (caries involving enamel up to the outer third of dentine) and the moderate-extensive disease threshold (caries into middle and inner thirds of dentine). The scoring cut-offs were defined using permanent tooth histology as the reference standard [26].

In permanent teeth, validation studies have reported comparable in vivo diagnostic performance between the automated scoring system and VE at the early caries initial threshold (Area Under the Curve (AUC) VE 0.76 vs automated 0.71) [27,28]. A study investigating the in vitro performance of the automated system on extracted primary teeth found the automated score was comparable to VE at the initial threshold (AUC VE 0.96 vs automated 0.88) [29]. There is limited evidence describing the in vivo application of the automated system in the primary dentition. If the automated system is valid for use in primary teeth in a clinical setting, it could enhance patient communication and support caries monitoring in children. Therefore, this study aimed to examine the in vivo diagnostic agreement between visual examination and an automated caries scoring system for IOS based on blue light fluorescence to detect and classify occlusal carious lesions in primary teeth.

2. Materials and methods

2.1. Study design

This clinical diagnostic agreement study was designed to compare the agreement between two methods for early caries detection on the occlusal surfaces of primary molar teeth: VE using ICDAS versus an automated caries scoring system available for the TRIOS 4 IOS using Trios Patient Monitoring (TPM) software (TPM version 2.3 3Shape TRIOS A/S, Copenhagen, Denmark).

This study was approved by the Royal Children's Hospital Human Research Ethics Committee (RCH HREC) (RCH HREC No. 88,321). The study protocol was prospectively registered with the Australian New Zealand Clinical Trials Registry (Registration number: ACTRN12622001237774).

2.2. Study sample

The study sample was drawn from all children participating in the 5-year-old study visit of the Melbourne Infant Study Bacille Calmette Guérin (BCG) for Allergy & Infection Reduction (MIS BAIR) longitudinal randomised controlled trial (Trial registration: ClinicalTrials.gov NCT01906853) [30]. The MIS BAIR trial had ethical approval from RCH HREC (HREC No. 33,025) and the Mercy Health Human Research Ethics Committee (HREC, No. R12–28).

Families received information about the opportunity to participate in an optional dental assessment at the 5-year-old follow-up visit through their monthly newsletters and a webinar held in January 2021. The participating children's parent(s)/guardian(s) provided informed consent for dental assessment and intraoral scanning. They also provided informed consent for sharing visual examination and intraoral scan data sources to validate intraoral scanning technology for oral health assessments. Study visits occurred between January 2021 and March 2022 at the Royal Children's Hospital Melbourne. All research was conducted in accordance with the Helsinki Declaration.

Participants must have had a VE and intraoral scan at their 5-year-old study visit for their data to be eligible for analysis in this study. Only primary molar occlusal surfaces were included in the study, as the automated system has only been validated on occlusal surfaces [26–28]. Teeth surfaces were excluded if they had a sealant, direct or indirect restoration or an enamel defect, as they can result in false positives when applying the automated caries score [27]. Surfaces were also excluded if less than one-third of the surface was visible due to insufficient or missing data during scanning, which precluded the scoring system from automatically staging caries.

2.3. *Visual examination procedure*

Two examiners (BJ and JC) carried out the visual examinations. Both examiners had prior training and experience in conducting ICDAS for research. Before carrying out the dental examinations, examiners underwent a 2-hour training using the ICDAS and the International Caries Classification and Management System™ training materials facilitated by a paediatric dentist who is an expert in applying these indices in epidemiological research (MS). After completing training, examiners participated in online exercises using the ICDAS training materials, which were then repeated two weeks later to establish inter- and intra-rater reliability of >0.8 (weighted kappa). A detailed description of the examiner training, VE and scanning protocol is described elsewhere [31].

Each participant underwent VE by one of the dental examiners. Dental plaque was removed from all facial, lingual and occlusal surfaces using Puritan swabs, and the teeth were dried with cotton rolls and gauze. The VE was performed with participants in a semi-supine position using a mirror and probe under a portable LED light (2700 K, emitting 220-lumen NÄVLINGE clamp spotlight IKEA Sweden). No method for optical magnification was used. Universal infection control standards and additional COVID-19 precautions were adhered to for all examinations.

Dental caries experience was recorded based on the two-digit ICDAS criteria [32,33]. Due to the lack of compressed air at the study site, ICDAS codes 01 and 02 were combined (Supplementary Table 1).

2.4. *Intraoral scanning procedure*

Following VE, the upper and lower dental arches were scanned at the same appointment. This was achieved using the TRIOS 4 IOS, TRIOS Dental Desktop, and TRIOS module software (3Shape TRIOS A/S, Denmark). The scanner illuminates the teeth with blue light (415 nm) to excite fluorescence during the scanning procedure. The IOS sensor receives autofluorescence from the teeth during scanning via a long pass filter (450 nm), which filters out blue light to capture red and green fluorescence. The intraoral scanner was calibrated according to the manufacturer's instructions before scanning.

External light was minimised during scanning, and the manufacturer's scanning strategy was followed. On completion of scanning, the shade icon on the TRIOS module was selected to check if there was sufficient fluorescence and colour data on the scan. A blue overlay appears on the models if further data is required. If additional data could not be obtained, the reasons for this were documented. Each 3D model was saved under a unique identifier within the Trios Patient Monitoring (TPM) software for subsequent analysis (TPM version 2.3, 3Shape TRIOS A/S Denmark)(Supplementary Figure 1).

2.5. *Automated caries detection and classification on 3D models*

Examiner BJ, blinded to the clinical examination data, recorded the automated caries scores during October 2022 on a laptop computer with a 15-inch monitor (Alienware/DELL). The digital models for each participant were viewed using the commercially available patient monitoring software (TPM version 2.3, 3Shape TRIOS A/S Denmark). For each 3D model, the caries indication mode was selected, and the resulting 3D model was visualised with the caries score as an overlay over the occlusal surfaces of the molars (Fig. 1).

The automated caries classification for each occlusal surface was recorded as caries if the lesion originated from the pits and fissure systems of the first and second primary molars. The most severe score was recorded if multiple classifications were scored for a single surface.

An 'initial caries' score describes caries of enamel up until the DEJ and outer third of dentine, equivalent to ICDAS scores 01 and 02 (Supplementary Table 1) [26–28]. It is indicated on the 3D models as a yellow overlay (Fig. 1). A 'moderate-extensive' score indicates caries extending into and beyond the middle third of dentine, comparable to ICDAS scores ≥ 03 [26–28]. It is visualised on the 3D models as a red overlay (Fig. 1). If there was insufficient colour information obtained on the model, the automated scoring system could not be applied, and the surface had a white overlay. Additionally, if the automated caries score originated from a cusp tip or incline, not the pit and fissure system, it was classified as sound and recorded separately as a scoring artefact.

2.6. *Data management*

All data collected from the visual examinations and automated caries scoring system were recorded and managed using the Research Electronic Data Capture (REDCap) tool [34,35]. REDCap is a secure, web-based software platform that supports data capture for research studies.

2.7. *Outcome measures*

There were two primary outcomes: caries classification per primary molar occlusal surface and the total number of molar carious occlusal surfaces per person.

To allow comparison with the automated caries scoring system for each caries stage, the ICDAS codes from the VE were collapsed into three classes: sound tooth surfaces, initial carious lesions (ICDAS 01/02) and moderate-extensive caries (ICDAS ≥ 03). For analysis, the surface-level data were dichotomised to represent detection at the initial disease threshold (sound vs initial/moderate-extensive) and the moderate-

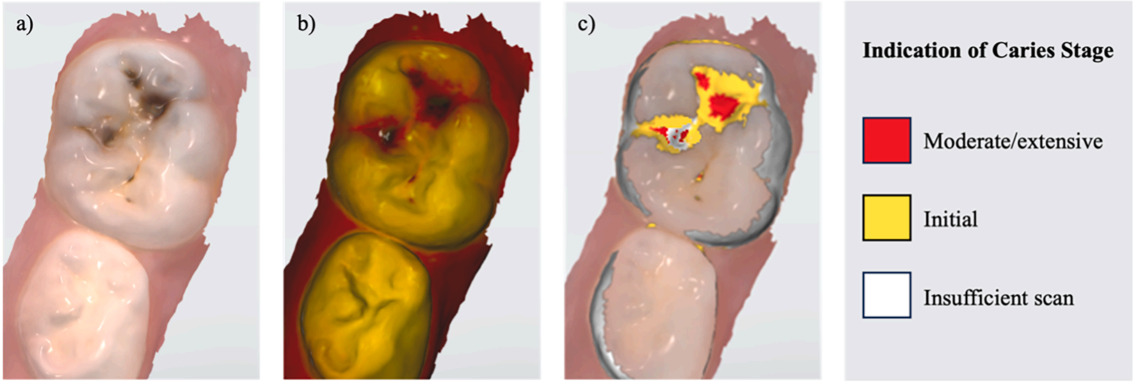

Fig. 1. Examples of 3D models of the lower left first and second primary molars with approximate natural tooth colour (a), fluorescence texture (b), and automated caries score as an overlay (c) are presented. The images were obtained using TRIOS Patient Monitoring Software (Version 2.3, 3Shape TRIOS A/S Denmark).

extensive threshold (sound/initial vs moderate-extensive).

2.8. Statistical analysis

A diagnostic agreement methodology was selected as VE was considered an imperfect reference standard in this study, as verification of the accuracy of VE compared to tissue histology was not possible or ethical for early caries detection [36].

For the first primary outcome, agreement between methods was estimated using multilevel models to account for the clustering of dental data (i.e., surfaces nested within a tooth, teeth nested within an individual). Specifically, a multilevel logistic regression model was fitted to compare VE with the automated caries scoring system by including the variable method (VE vs Automated) as a fixed effect. This analysis estimated the odds of caries detection using the automated system compared to VE.

For the second primary outcome, the Bland Altman plot [37] was created. The differences in the number of carious lesions detected by each pair of methods from the same subject were represented on the y-axis, and the mean of the two methods for the same subject was represented on the x-axis. The regression line of the differences in methods against the mean was represented. Since many points overlapped, especially at the origin, the size of the points in the plot was proportional to the number of times the points were observed. The limit of agreement was not calculated because the data is not normally distributed. The intraclass correlation coefficient (ICC) was also calculated to assess the reliability between the two methods. ICC was estimated from generalised linear mixed models with a zero-inflated Poisson distribution to account for the abundance of sound tooth surfaces.

All statistical analyses were undertaken at the initial and moderate-extensive thresholds to determine any differences between methods attributable to the threshold used for caries detection. The analyses were repeated, excluding teeth with artefacts, to determine if the presence of artefacts impacted the effect estimates reported. All analyses used STATA version 17 and R [38,39].

3. Results

3.1. Study flow

Of the 216 potentially eligible participants, 213 remained after excluding participants with missing visual examination data ($N = 2$) and partial scans of the anterior teeth only ($N = 1$). Of the total primary molar occlusal surfaces eligible for inclusion ($n = 1704$), teeth were excluded if they were not visible during the dental examination ($n = 2$) and if they had a fissure sealant or restoration ($n = 53$) or had an enamel defect present ($n = 39$). Surfaces were excluded if they could not be analysed with the automated system due to inadequate or missing scan data ($n = 85$). A total of 1525 molar occlusal surfaces were included for analysis in this study (Fig. 2).

3.2. Dental examiner characteristics

Of the 213 participants included in the study, examiner BJ (52.11 %) conducted 111 examinations, and examiner JC (47.88 %) conducted 102 examinations. A detailed description of dental examiner characteristics has been reported elsewhere [31].

3.3. Sample characteristics

104 males (48.83 %) and 109 females (51.17 %) were included in this study. The average age was 5.6 years old. The majority of children had mothers of British/Irish ancestry (57.75 %), had mothers who had attained a university qualification (79.81 %), and represented families

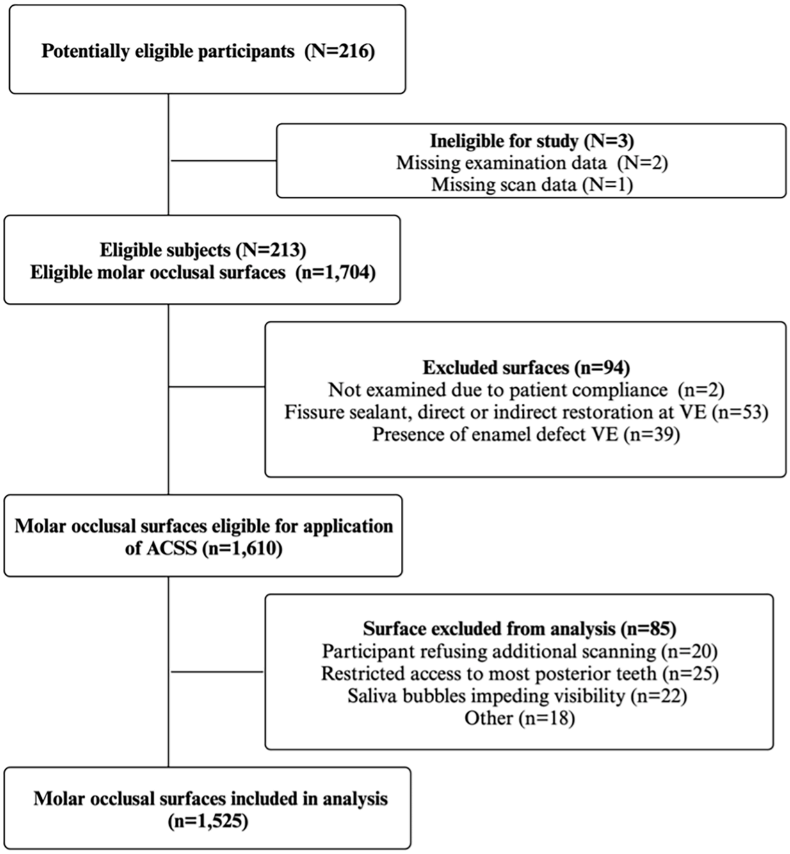

Fig. 2. Flow diagram outlining patient eligibility and inclusion and exclusion criteria (N=number of patients, n=number of molar tooth surfaces).

from more advantaged areas (64.79 %). Based on the visual examination, caries prevalence within the sample was 38.03 %, and 17.84 % of children had enamel defects (Table 1).

Table 2 compares the number of teeth classified as sound, initial, and moderate-extensive caries for each method. The automated system detected fewer lesions at both the initial ($n = 96$ vs. $n = 120$) and moderate-extensive disease thresholds ($n = 20$ vs. $n = 44$).

3.4. Primary outcome 1: surface level agreement estimation

Compared to VE, the odds of detecting caries using the automated caries scoring system were 46 % lower at the initial disease threshold (OR 0.54, 95 % CI 0.39–0.74) and 70 % lower at the moderate-extensive disease threshold (OR 0.3, 95 % CI 0.16–0.58) (Table 3).

3.5. Primary outcome 2: person-level agreement

Bland-Altman plots were used to visualise and evaluate the differences between methods at each threshold. Fig. 3a shows the Bland-Altman Plot comparing the differences in the total occlusal carious lesions detected for each pair of methods against the average of the two methods for each participant at the initial disease threshold. The graph shows the large group of participants where no caries were detected, and both methods were in perfect agreement ($n = 144$). When the average number of carious lesions per participant exceeded zero, the methods agreed in 14 instances. The positive slope of the regression line indicates as the mean caries increases, the positive difference between methods increases. At the initial disease threshold, VE using ICDAS tends to detect more carious lesions compared to the automated system ($n = 44$) and does so at higher mean caries scores. In comparison, negative differences were only observed ($n = 23$) when the mean caries score was low (<3).

Table 1
Characteristics amongst children in the study sample. Descriptive statistics are reported as the mean (standard deviation) or frequency (per cent). Ethnicity is based on the reported ethnicity of the child's grandmother. Socio-economic Indexes for Areas (SEIFA) ranks areas in Australia according to relative socioeconomic disadvantage. SEIFA was divided into quintiles ranging from the most disadvantaged (quintile 1) to the least disadvantaged (quintile 5).

Sample Characteristics	$n = 213$
Age (years)	5.66 (0.43)
Sex	
Female	109 (51.17)
Male	104 (48.83)
SEIFA	
Quintile 1	4 (1.88)
Quintile 2	29 (13.62)
Quintile 3	42 (19.72)
Quintile 4	49 (23.01)
Quintile 5	89 (41.78)
Ethnicity/Ancestry	
British/Irish	123 (57.75)
European	37 (17.36)
Asian	32 (15.02)
African	4 (1.88)
Middle East	4 (1.88)
Aboriginal/Torres Strait Islander	2 (0.94)
Australian	3 (1.41)
South American	2 (0.94)
Latin American	1 (0.47)
Philippino and Spanish	1 (0.47)
Indian	1 (0.47)
Don't Know	3 (1.41)
Maternal Education	
No education/up to year 10	4 (1.87)
Year 12 completion/Trade	38 (17.85)
University	170 (79.81)
Not reported	1 (0.47)
Dentition Type	
Primary	132 (61.97)
Mixed	81 (38.03)
Caries	
Yes	81 (38.03)
No	132 (61.97)
Enamel defects	
Yes	38 (17.84)
No	175 (82.16)

Table 2
Caries classification for each method, reported as a proportion (per cent).

Caries Classification	Visual Examination	Automated Caries Scoring System
Sound	1361 (89.25)	1171 (76.78)
Initial Caries (ICDAS 01/02)	120 (7.87)	96 (6.30)
Moderate-extensive Caries (ICDAS $\geq$03)	44 (2.89)	20 (1.31)
Scanning Artefacts	–	238 (15.61)
Total Surfaces	1525	1525

Table 3
Odds Ratio (OR) for caries detection of occlusal surfaces at each diagnostic threshold.

	VE with ICADS $N = 1525$		Automated $N = 1525$		OR (95 % CI)	P value
Disease Threshold	Yes	No	Yes	No		
Initial	164	1361	116	1409	0.54 (0.39–0.74)	$p <$ 0.001
Moderate-extensive	44	1481	20	1505	0.30 (0.16–0.58)	$p <$ 0.001

The Bland-Altman plot was repeated at the moderate-extensive disease threshold, as shown in Fig. 3b. The graph shows a large group of participants with no caries, where the methods were in perfect agreement ($n = 192$). However, similar to the initial disease threshold, the positive difference between methods increases as the average number of carious lesions increases.

Fig. 4 shows a sample of positive and negative disagreements between methods at the moderate-extensive threshold. Of the positive disagreements at the moderate-extensive threshold, most were lesions recorded using VE as moderate caries (ICDAS 03/04) but classified as initial lesions by the automated system. There was only one negative disagreement where the automated caries scoring system classified moderate/extensive caries for a tooth that was recorded as sound during clinical examination.

The ICC point estimates and confidence intervals indicate good to excellent reliability between the methods at the initial disease threshold (ICC: 0.90 95 % CI 0.70–0.96) and poor to excellent reliability between methods at the moderate-extensive disease threshold (ICC: 0.76 95 % CI 0.22–0.94). The broad confidence interval at the moderate-extensive threshold indicates uncertainty around the ICC point estimate, which can vary widely.

3.6. Artefacts

There were 238 scoring artefacts identified where the automated caries score indicated caries from a sound cusp or ridge (Table 2). Of these, 64.7 % were located on the right-hand side of the oral cavity, and 71.9 % were associated with first primary molars (Table 4). Artefacts were commonly observed on marginal ridges and the palatal and lingual cusps (Fig. 5).

A sensitivity analysis was performed, repeating the above analyses, excluding surfaces with artefacts. Minimal differences were observed in the results for all outcomes, except for a slight change at the initial threshold for primary outcome 1, where the odds for caries detection

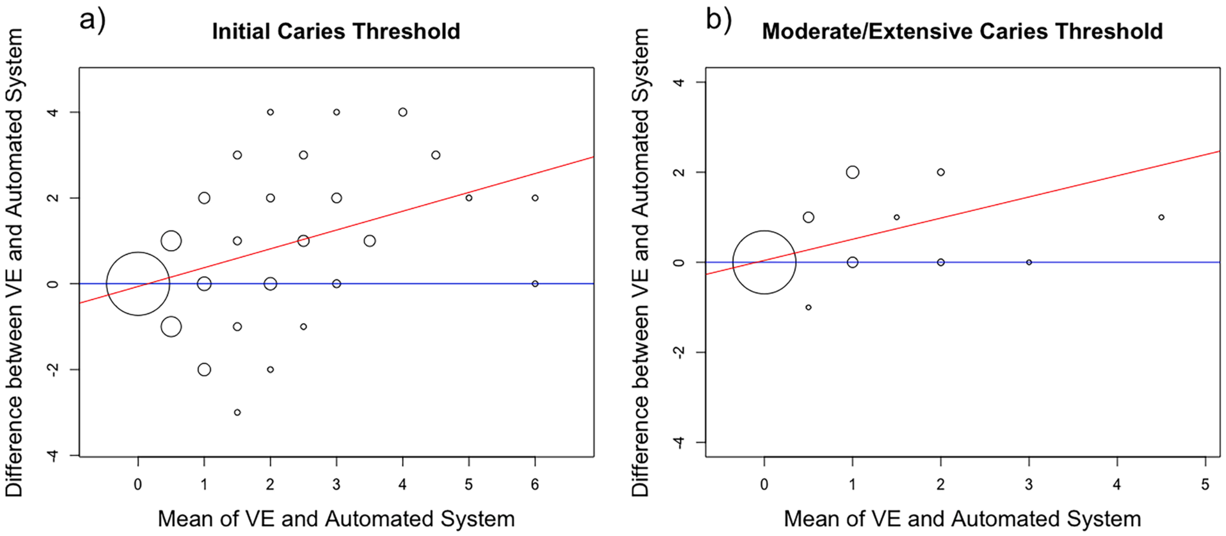

Fig. 3. Scatterplots of the differences in the number of carious lesions detected for each pair of methods against the average of the two methods for (a) the initial disease threshold and (b) the moderate-extensive disease threshold. The blue line indicates no difference between the two methods. The regression line of the differences in methods against the mean is represented in red. The size of the data points is proportional to the number of observations.

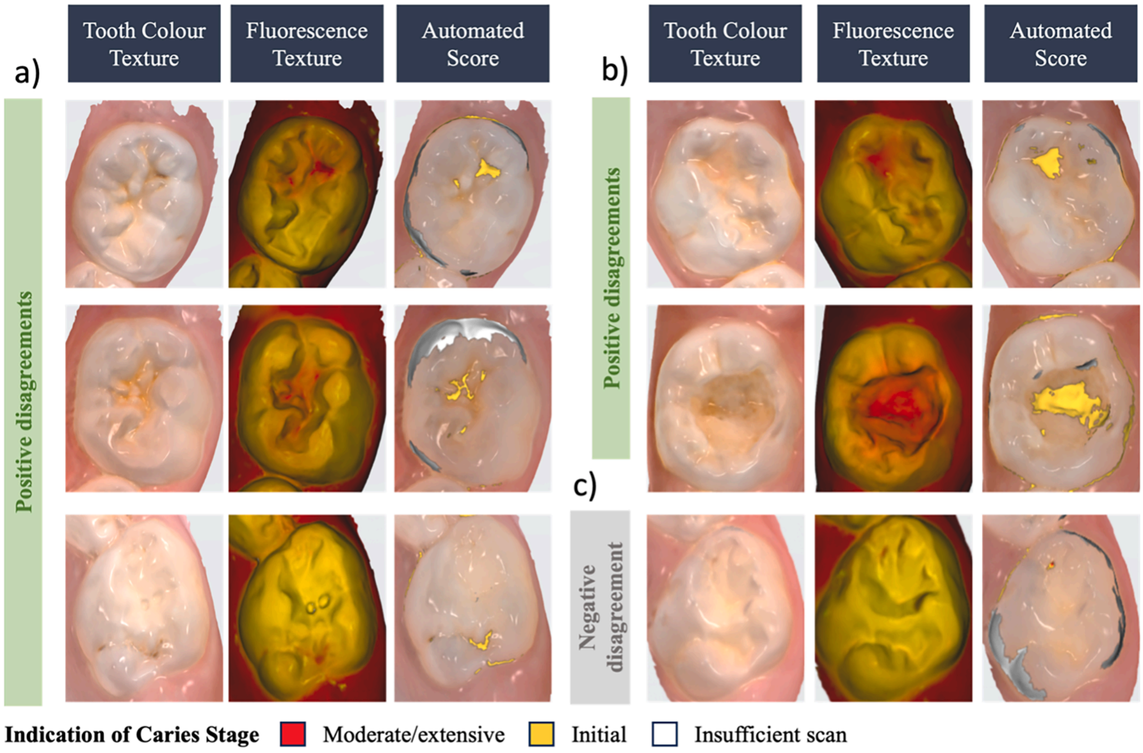

Fig. 4. A sample of disagreements at the moderate-extensive threshold with approximate natural tooth colour texture, fluorescence texture and the automated caries score overlay. Second primary molars in (a) were classified as moderate caries (ICDAS 4) during visual examination, and as initial caries by the automated score and (b) were classified as moderate caries (ICDAS 5/6) during visual examination, and as initial caries by the automated score, and represent positive disagreements between methods. The upper left second primary molar (c) was the only negative disagreement at this threshold and classified as sound during visual examination, but moderate-extensive caries by the automated score.

were slightly improved (OR 0.61 95 % CI 0.44–0.86) (Supplementary Table 2–3, Supplementary Figure 2).

4. Discussion

Evaluating the clinical performance of new caries detection devices compared to established methods is essential for informing their implementation in clinical practice. This study compared the in-vivo diagnostic agreement between the TRIOS scanner automated caries scoring system and VE using ICDAS for occlusal caries detection in primary teeth. For the detection of early carious lesions, the combination of the lower odds ratio and high ICC estimate indicates whilst the automated system is more conservative (records fewer lesions than VE), the methods consistently agree, which is likely attributable to the large proportion of surfaces classified as sound by both methods. Whilst the automated system detects most advanced lesions, it tends to

Table 4
Teeth with scoring artefacts.

Region	Tooth (FDI notation)	Artefacts (%) $n = 238$
Right upper quadrant	First primary molar	54 (22.7)
	Second primary molar	15 (6.3)
Right upper left quadrant	First primary molar	32 (13.5)
	Second primary molar	11 (4.6)
Left lower quadrant	First primary molar	31 (13.0)
	Second primary molar	10 (4.2)
Left lower right quadrant	First primary molar	54 (22.7)
	Second primary molar	31 (13.0)

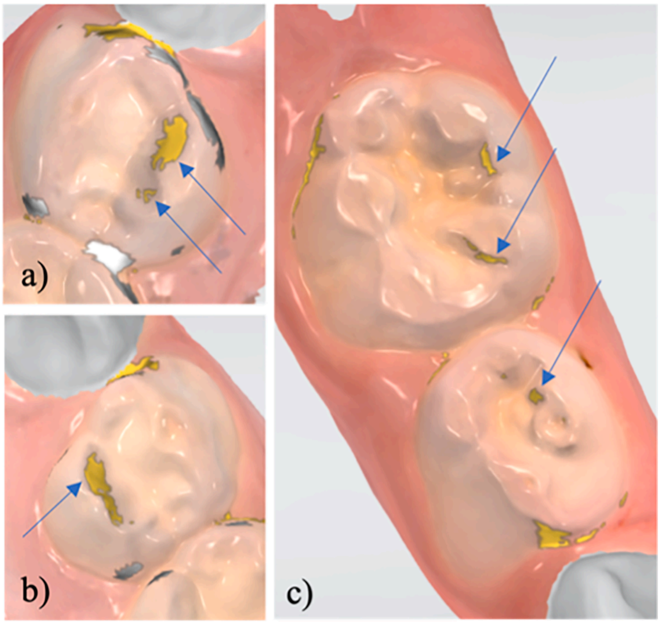

Fig. 5. Examples of artefacts on the 3D models when using the automated caries scoring system. The arrows point to examples of positive indications attributable to the presence of scoring artefacts associated with inclines of the upper right first primary molar palatal cusp (A), the upper first left primary molar palatal cusp (B) and the lower right first and second primary molar lingual cusps (C).

underestimate the disease severity when classifying them.

Our findings are similar to a previous in vivo analysis of permanent teeth, where the automated system detected fewer early enamel lesions and tended to underestimate caries severity compared to VE [40]. The observations of higher agreement between VE and the automated system at the initial disease threshold than at the moderate-extensive threshold are also consistent with an in vivo diagnostic accuracy study in primary teeth [41]. The study reported higher sensitivities for occlusal caries detection at the enamel threshold (0.80) and lower sensitivities at the dentine threshold (0.59) when the automated scanner system was compared to VE as the reference standard [41]. In contrast, our findings differ from several in vitro studies, which have reported a higher agreement between the automated system and VE [28,29]. In vitro, scanning conditions such as reduced surface wetness, controlled distances, and single-tooth scanning can improve 3D model accuracy [42,43], which may influence the reported diagnostic performance of the automated system in these studies.

Since this is a diagnostic agreement study, it cannot be concluded that one method is more accurate than the other; only their relative performance can be compared. It is possible that VE in this study is biased and overestimated dental caries presence and depth or missed lesions entirely, thereby inflating the differences between methods. Previous research has suggested that VE for early occlusal caries detection in primary teeth can yield false positives and negatives [44]. However, utilising validated indices with trained examiners reports much higher specificities [45], which reduces the likelihood that the differences between the methods are solely attributable to an unreliable VE. To determine diagnostic accuracy, future studies should establish more robust reference standards through repeated VE (if it is feasible or ethical) or utilise composite reference standards [36]. Although superiority cannot be determined in this instance, the results demonstrate that the automated system should not substitute a clinical exam using a validated index. Doing so could lead to missed opportunities for early intervention or delay the management of more advanced lesions. The automated tool may be more suited as an adjunct to examination or to visualise caries for enhanced patient communication.

The automated scoring system cut-offs were validated using permanent teeth histology as the reference standard. Primary teeth have morphological and compositional differences from permanent teeth, with primary enamel being thinner and less mineralised [46,47]. The pre-defined caries scoring cut-offs may need to be optimised for use in primary teeth. A study investigating mineral loss rates using quantitative light-induced fluorescence™ (QLF™) reported primary teeth have a lower average fluorescence loss for each ICDAS score when compared to permanent teeth [48]. Similarly, a separate study validating a QLF™ scoring index for primary teeth demonstrated lower scoring cut-off values were required relative to permanent teeth [49]. It is plausible that the TRIOS automated scoring system cut-offs may not be low enough for primary teeth, explaining why it underestimated the presence of initial caries and disease severity compared to VE in our study.

However, a potential issue of adjusting the scoring cut-offs for clinical use in primary teeth could be an increased occurrence of scoring artefacts. Scoring artefacts occur on regions of a tooth that are obviously sound but develop slight colour changes during scanning. The colour and fluorescence alterations meet the threshold for the initial caries cut-off, and the automated system displays a 'false' positive indication. They have been reported to occur more frequently in areas subject to steep scanning angles [27]. Re-scanning the area at a slightly different angle does not always eliminate the colour changes and may introduce them to other areas of the tooth. They can be subtle and are not always noticeable until the caries indication mode has been selected after post-processing the scan. A large number of scoring artefacts were observed in this study. Scoring artefacts were more frequently noted on the right-hand side of the oral cavity, which may be associated with the scanning angle as both clinicians who undertook the scanning were right-handed. While the presence of artefacts did not affect the automated system's performance in this study, the examiner needed to distinguish them from caries based on their location on the tooth. This introduces subjectivity into the interpretation of the automated caries score and creates a potential risk that some artefacts could be interpreted as caries by less experienced clinicians using the software. It could also influence the trustworthiness of the tool for caries visualisation when communicating with patients, which may limit its application for this purpose.

This study contributes to the limited evidence on the in vivo performance of devices using intraoral scanning and fluorescence for caries detection. The full mouth study design and complete arch scanning reflect how the device may be used in clinical practice and are strengths of this study. Further strengths include using a systematic protocol, well-calibrated examiners, obtaining high-quality scan data, high participation rates, and cooperation of children with scanning.

Limitations of this study include the absence of duplicate examinations by multiple dental examiners on all children, which may have introduced bias into the VE data. The examination site lacked access to compressed air and handpieces, so the teeth were not professionally cleaned and dried with a triplex tip before scanning. Saliva and plaque have been reported to impact the diagnostic performance of fluorescence camera devices for caries detection [50]. However, the presence of plaque would likely increase the number of initial lesions reported using the automated system relative to VE, which was not observed in this study. Additionally, we did not record the time it took for each dental examination to enable comparison to the scanning time. Had the automated system been quicker and more acceptable than the VE, it may be considered a feasible substitute for VE in particular clinical settings. Future studies should ensure they capture this data as it aids in contextualising the clinical relevance of the findings. Further shortcomings include the highly selected sample population, limiting the generalisability of these findings more broadly. Research that validates the automated tool in different population groups with different disease levels is warranted.

It is also important to highlight the challenges associated with the statistical analysis of agreement using dental data. For the tooth surface level analysis, the data is zero-inflated and has an inherent clustering structure. Both conditions violate the assumptions of the Kappa statistic [51]; consequently, this study employed a multilevel modelling approach to estimate diagnostic agreement. When comparing the total number of caries per person, the zero-inflated data also precluded the Bland Altman Limits of Agreement calculation. Subsequently, the ICC was calculated as an additional estimate of the agreement between methods. A potential limitation of this approach is that absolute agreement cannot be quantified. Despite this, applying multiple alternate statistical approaches has enabled a robust understanding of the method's performance relative to each other.

Given recent advancements in computer vision for the analysis of dental images [52], it is hypothesised that deep learning could be used as an alternative to rule-based algorithms for detecting and classifying dental caries using intraoral scan data. Deep learning is a subset of machine learning that uses advanced algorithms called neural networks to learn patterns in data and make predictions without the need for explicit programming [53]. It has the potential to overcome the anticipated challenges that altering the scoring cut-offs for primary teeth may have on the incidence of scoring artefacts.

5. Conclusion

An IOS automated scoring system for detecting and classifying caries should not substitute VE using ICDAS in assessing primary teeth. The automated system is more likely to underestimate the presence of early dental caries and disease severity in more advanced carious lesions relative to VE. While the automated scoring system may be used to visualize caries to enhance communication, the presence of scoring artefacts could impact its clinical utility. Future research exploring machine learning to automate caries detection using intraoral scan data is recommended.

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CRediT authorship contribution statement

Bree Jones: Writing – review & editing, Writing – original draft, Visualization, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Tong Chen:** Writing – review & editing, Visualization, Resources, Methodology, Formal analysis. **Stavroula Michou:** Writing – review & editing, Software, Resources, Methodology, Conceptualization. **Nicky Kilpatrick:** Writing – review & editing, Supervision, Methodology, Conceptualization. **David P. Burgner:** Writing – review & editing, Supervision, Resources, Methodology, Funding acquisition, Conceptualization. **Christoph Vannahme:** Writing – review & editing, Supervision, Software, Resources, Methodology, Conceptualization. **Mihiri Silva:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Funding acquisition, Conceptualization.

Declaration of competing interest

Co-author CV is an employee at 3Shape TRIOS A/S, and SM was employed at 3Shape TRIOS A/S when this investigation was conducted. All remaining authors declare no competing interest.

Data availability

The data sets generated during and/or analysed during this study are not publicly available due to consent not obtained from participants for public sharing of data but are available from the corresponding author on reasonable request.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jdent.2024.105279.

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