

Diagnostic Accuracy of Digital Radiography and Novel Diagnostic Tools versus Visual ICDAS Criteria: A Systematic Review

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ABSTRACT

Purpose: To evaluate the diagnostic accuracy of digital radiography and other novel diagnostic tools compared to visual ICDAS criteria.

Materials and Methods: Two reviewers performed a literature search up to May 2020 in three databases: PubMed, Google Scholar, and Cochrane Library. Only in-vivo studies that evaluated the diagnostic accuracy of digital radiography, Diagnodent, Vistaproof, Soprolife, and ICDAS criteria were included.

Results: A total of 27 *in vivo* studies were included in the systematic review. Studies included suggested that digital dental radiography proved to be a reliable tool in detecting initial carious lesions/ especially proximal lesions. The Diagnodent device was proved to be an efficient adjunct to other detection methods, especially in the case of non-experienced clinicians. For VistaCam/VistaProof assessment, it was found that in some articles, VistaCam proved high accuracy in detecting early carious lesions with moderate to strong correlation in comparison to results obtained by visual and tactile methods ICDAS criteria. ICDAS criteria were considered to be sufficient alone in detecting occlusal caries.

Conclusions: The *in vivo* evidence suggested that None of the diagnostic methods alone are sufficient for diagnosis of dental caries.

Keywords: Diagnostic Accuracy; Digital Radiography; Novel Diagnostic Tools; ICDAS Visual Criteria; Systematic Review

INTRODUCTION

The diagnosis of dental caries is always a challenge since its patterns and prevalence have significantly changed in the last few years. The difficulty in diagnosing dental caries depends not only on the morphological changes of lesions and their rate of progression but also on the lack of a precise methodology to efficiently diagnose both the disease and the integrity of the dental structure (specificity) [1].

Conventional examination for caries detection is primarily done using visual inspection, tactile sensation, and radiographs. While these methods give satisfactory results in the detection of cavitated lesions,

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they are usually inadequate for the detection of initial lesions. Because of these deficiencies, new detection methods have been developed to aid better diagnosis [2].

To date, there are two main techniques aimed at helping clinicians in detecting caries represented by visual examination and by light-based caries diagnostic tools as fiber-optic transillumination (FOTI), DIAGNODent tool (KaVo), and SOPROLIFE. Visual diagnosing of caries has progressed by establishing the international caries detection and assessment system (ICDAS). ICDAS-II, the second version, was improved and provided a standardized system to enable clinicians to diagnose and detect the first visual change in enamel, leading to better information for clinical management [3].

There are various fluorescence-based methods, of which the most commonly studied are KAVO® DIAGNODent and VistaProof by Durr Dental®, which may be used as complementary diagnostic tools in order to avoid the occurrence of false-positive and false-negative findings. VistaProof an intraoral camera which emits a 405 nm light wavelength and takes images that are computer-processed; the resulting mapping of the lesion is produced according to its depth [4,5].

The aim of this systematic review is to evaluate the diagnostic accuracy of digital radiography and other novel diagnostic tools in comparison to visual ICDAS criteria.

MATERIALS AND METHODS

This systematic review was reported according to the guidelines of the PRISMA statement. The protocol was registered in the PROSPERO international database for systematic reviews (CRD-183388). The research question

was: What is the diagnostic accuracy of digital radiography and other novel diagnostic tools in comparison to visual ICDAS criteria?

A detailed database search was conducted using Medical Subject Heading terms [Table 1] in PubMed, Cochrane Library, and google scholar. The search words included digital radiograph, dental digital radiograph, Diagnodent, laser fluorescence devices, Vistaproof/Vistacam, Soprolife, initial caries, and microcavities. The search was restricted to articles published in the English language with a time period limit from 2000 to 2020.

INCLUSION CRITERIA

- *In vivo* studies on caries detection methods
- Studies on diagnostic methods reporting diagnostic accuracy, i.e., sensitivity, specificity, and receiver operating characteristic curves
- Studies on primary/permanent teeth validated with reference/ gold standard
- Studies published in the English language only from 2000 to April 2020.

EXCLUSION CRITERIA

- *In vitro* studies
- Studies with an incomplete description of the sample size or outcome
- Studies reporting accuracy in laboratory work exclusively
- Animal studies, review articles, letters to the editor and conference abstracts.

	Population	Intervention	Comparison	Outcome/effect
PICO	Children/adult, Occlusal/proximal surfaces	Digital radiography, Diagnodent, Vistaproof, Soprolife	Visual ICDAS diagnostic criteria	Diagnostic accuracy in caries detection
Mesh terms	Initial caries	Dental digital radiography, Diagnodent device, Soprolife, and Vistaproof camera	Visual ICDAS criteria	Sensitivity and specificity, dental caries
Alternate search terms	Microcavities	Direct digital radiography, laser fluorescence devices, intra-oral cameras	ICDAS & modified ICDAS visual diagnostic criteria	Caries, initial caries detection, lesion monitoring

Table 1: Medical subject heading terms and alternate terms enclosed in the search strategy.

TYPE OF PARTICIPANTS

All studies on human beings were included, regardless of age.

TYPES OF STUDY

All clinical trials on human beings and Occlusal/proximal surfaces were included. The English language was chosen.

TYPE OF OUTCOME

The main outcome was the absence or presence of dental caries using the following methods:

“Histological examination, the opening of cavities, or clinical examination based on ICDAS scores utilized in studies”.

REVIEW METHODS

All reports yielded by the search were printed out and analyzed by two reviewers on the basis of title, keywords, and abstract to check if the study was likely relevant. A full report of all relevant papers was obtained, and also if a paper could not be classified.

The reviewers were not blinded to authors, journals, date of publication, financial support, or results. The inclusion criteria were applied, and the data assessed and extracted by two reviewers.

RESULTS

For Digital Radiography

The search strategies yielded eleven reports from the search database. All were published in the English language between 2008 and 2020. Three of these met the selection criteria after reading the full articles. Of the eight reports excluded, three were literature reviews, and the remaining, one systematic review and four were in vitro investigations.

Therefore, three studies were selected for analysis of the methodology and data reliability (Table 2).

For Diagnodent

The search strategies yielded fifteen reports from the search database. All were published in the English language between 2004 and 2020. Eight of these met the selection criteria after reading the full articles. Of the seven reports excluded, three were systematic reviews, and the remaining, and five were laboratory investigations.

Therefore, eight studies were selected for analysis of the methodology and data reliability (Table 3).

For ICDAS Criteria

The search strategies yielded eight reports from the search database. All were published in the English language between 2010 and 2020. Four of these met the inclusion criteria after reading the full articles. Of the four reports excluded, one was a systematic review, one literature review, and two were in vitro investigations.

Therefore, three studies were selected for analysis of the methodology and data reliability (Table 4).

For Vista Cam/Vista Proof

Following the search strategy, 17 articles were found in the search database. They were published between 2011 and 2020. Seven articles met the inclusion criteria after reading the full text, and the excluded ten articles included two literature reviews, 2 case reports, and five in-vitro studies, and one published in the Spanish language (Table 5).

For Soprolife Camera

Searching the databases according to the search strategy yielded ten articles that were found published between 2014 and 2019. Six articles met the selection criteria after reading the full articles. The excluded four articles included two systematic reviews, one case report, and one in-vitro study (Table 6).

Author/Year	Subjects	Methodology	Results	Conclusion
Sahu RK (2020) [6]	Occlusal surface for fifty teeth of randomly selected patients	1.Direct digital radiography (DDR)-CMOS 2. Four types of filtered images	Agreement statistics for intra and inter-evaluator comparisons were maximum for the DDR-CMOS mode with a kappa coefficient of 0.4108 (95% CI: 0.1124–0.7091). This was followed by the Negative mode with a coefficient of 0.3065.	DDR-CMOS and negative images were found to be more useful in diagnosing occlusal caries.
Maria Melo (2019) [7]	Proximal caries of 138 posterior teeth (76 molars and 62 premolars)	1.Near-Infrared Light-Transillumination (NILT) 2.Direct digital-radiography (DDR) 3.Combination Opening Of the approximal surface was the gold standard	Sensitivities of overall/D3/D4 were 98.0/95.7/100.0 (NILT) and 100/100/100 (DDR), respectively. Correlations with gold-standard were 0.92 (NILT) and 0.42 (DDR), respectively. The correlation increased to 0.97 (p = 0.045) on combining NILT and DDR.	The combination of NILT and DDR represents an increase in the diagnosis of approximal lesions. The proposed diagnostic protocol comprises visual examination, followed by NILT and DDR only if the former technique detects approximal caries.
Basem M. Abuzenada (2019) [8]	152 bitewing radiographs	Bitewing digital radiography	The Kappa values for interobserver agreements were 0.47 and 0.44 in the first and second observations, while for intraobserver agreements, these values were 0.61 and 0.69 for the operative dentist and oral radiologist, respectively	The digital bitewing radiography resulted in no variation in both the agreements, and it was useful with respect to the reliability of the diagnosis of interproximal caries.

Table 2: Selected studies about digital radiography.

Author/Year	Subjects	Methodology	Results	Conclusion
Castilho LS (2016) [9]	occlusal caries of 43 non-impacted permanent third molars;	1.DIAGNOdent laser fluorescence 2.International Caries Detection and Assessment System (ICDAS) The gold standard is histological examination	The correlations with the histological reference were weak for DIAGNOdent (rs = 0.369) and moderate for ICDAS (rs = 0.515). The areas under the (ROC) curve at D1, D2, and D3 were 0.60, 0.69, and 0.91, respectively, for ICDAS and 0.55, 0.65, and 0.92, respectively, for DIAGNOdent	ICDAS and DIAGNOdent proved to be reproducible methods with similar performance in the detection of occlusal carious lesions in dentine. The ability of DIAGNOdent to detect initial enamel lesions was higher than that of ICDAS, but with low specificity. The usefulness of DIAGNOdent as an adjunct method for assessment of initial occlusal caries in permanent molars is questionable.
Chaza Kouchaji (2012) [4]	occlusal caries of 156 permanent molar teeth in 40 children	1.DIAGNOdent laser fluorescence 2.Visual examination	Results showed a strong relationship between examination with the DIAGNOdent and visual inspection. Diagnodent's sensitivity and specificity were 97% and 52%, respectively	DIAGNOdent is considered a reproducible and accurate diagnostic tool that may be very helpful in conjunction with a visual examination in the detection of occlusal caries in permanent molars in children
CH.Chu (2010) (10)	Occlusal surface for 144 Human 2nd molars	1. DIAGNOdent (LF) 2. Radiography (BW) 3. Visual method The gold standard is fissure opening	The sensitivity and specificity values were, respectively, 0.89 and 0.44 by visual detection, 0.13 and 1.00 by bitewing radiography and 0.70 and 0.84 by DIAGNOdent. Caries detection by a combination of visual examination and DIAGNOdent had a sensitivity of 0.67 and specificity of 0.94. ROC curve analysis showed that this combined approach was superior to the other methods	Caries diagnosis made on the basis of a combination of visual method and DIAGNOdent showed a good level of sensitivity and specificity and can be considered an appropriate method for diagnosis of decayed dentin.
A.Goel et al. (2009) [11]	84 primary molars in 52 children (aged 8-12 years) which were indicated for extraction	Diagnodent, visual and tactile method and bitewing radiographs for caries evaluation. The gold standard was a Histological examination of teeth sections	Enamel caries, values for sensitivity, specificity, and accuracy for Diagnodent were 85.19, 50.00, and 84.34% according to the manufacturer's cut-off limits. At dentin caries, the values of sensitivity, specificity, and accuracy for Diagnodent were 72.22, 76.60, and 74.70% according to the manufacturer's cut-off limits.	Diagnodent showed higher sensitivity and accuracy when compared with other conventional methods for the detection of enamel caries, whereas for the detection of dentinal caries, even though the sensitivity was high, the accuracy of the Diagnodent device was similar to other caries diagnostic methods

Kavvadia K (2008) [12]	Occlusal surface for 50 Human molars	<ol style="list-style-type: none"> 1. Direct visual method (DV) 2. Indirect visual method (IDV) 3. Radiography BW 4. DIAGNOdent (LF) <p>The gold standard is fissure opening</p>	For enamel lesions, higher sensitivity was found with DV, while higher specificity with the LF. For lesions into dentin, higher sensitivity was found with the LF, while higher specificity with the BWR. The device's accuracy was found to be 0.61 for enamel lesions, while for lesions into dentin 0.70, and its reliability was excellent (ICC = 0.97)	Diagnodent is very reliable in the detection of occlusal caries in deciduous teeth, and its efficiency is similar to direct visual
Kuhnisch J (2008) [14]	The occlusal surface of 311 Human Molars	<ol style="list-style-type: none"> 1. Visual method (ICDAS II) 2. Visual method (WHO) 3. DIAGNOdent (LF) 	The overall data suggested a relationship between higher ICDAS II scores and higher DIAGNOdent values	When ICDAS II criteria are used in vivo, it seemed that LF didn't detect any finding. While it caused more work and costs. Use of DIAGNOdent in a field study in which visual criteria were applied seemed to provide limited additional information
Costa AM (2008) [14]	Occlusal surfaces of 199 Human molars and premolars	<ol style="list-style-type: none"> 1. Diagnodent (LF) 2. Radiography (BW) 3. Visual method <p>The gold standard is opening of caries</p>	It was found that the laser detection method showed high scores of sensitivity (0.93) and specificity (0.75) and a moderate positive predictive value (0.63). Diagnodent had the lowest value of the likelihood ratio (3.68).	It has been recommended to use laser in combination with a visual method in order to reduce the possibility of false-positive results.
Huth KC (2008) [15]	Occlusal surfaces of 120 Human Molars	<ol style="list-style-type: none"> 1. Diagnodent (Pen) 2. Radiography (BW) 3. Visual method <p>The gold standard is opening the caries</p>	The intra-examiner reliabilities for the LFpen measurements of the four operators were very good with intraclass correlations (ICCs) between 0.94 and 0.998 at a high significance level	It is possible to use Diagnodent as a complementary device for occlusal surfaces caries
Anttonen V (2004) [16]	Occlusal surface for 423 Human Permanent molars, 315 Human deciduous molars	Visual method and Diagnodent (LF) for caries detection	An increase in Diangodent values correlated positively with the increase in visual score. The mean Diagnodent value at baseline was significantly higher in teeth that became carious than in those that remained sound during the follow-up	Diagnodent, in combination with the visual method, is a beneficial tool for dentists with less experience for the diagnosis of caries in deciduous and permanent molar teeth

Table 3: Selected studies about DIAGNOdent.

Author/Year	Subjects	Methodology	Results	Conclusion
Melek Tassoker (2019) [17]	90 third molar teeth planned for extraction	1. Visual inspection (ICDAS-II) 2. laser fluorescence (DIAGNOdent pen) 3. (DIAGNOcam) The gold standard is histo-logical validation	DIAGNOcam had the best correlation value (0.616) according to histological observations and demonstrated a sensitivity rate of 96.1%, a specificity rate of 61.5%, and an accuracy rate of 91.1%	Diagnocam was found to be the most effective method for the diagnosis of occlusal caries without cavitation in permanent molar teeth
Bhumireddy J.R. (2018) [18]	249 children' teeth were examined at D1 and D3	1. International Caries De-tection and Assessment System II (ICDAS II) 2. Digital bitewing radio-graphs	Sensitivity at D1 for ICDAS II was 95%, and 22.97% for digital radiographs. At D3, the threshold sensitivity of ICDAS II was 94.%, whereas it was 69% for digital radiographs.	ICDAS II showed better accuracy than digital radiographs in detecting carious lesions within the enamel, and both tools were equally effective in the detection of dentinal carious lesions.
Kockanat A. (2017) [19]	120 primary molar teeth	1. ICDAS II, 2. Radiographic examination 3. DIAGNOdent pen, 4. CarieScan PRO 5. SoproLife Camera The gold standard is histo-logical sectioning	ICDAS and SoproLife camera showed the highest sensitivity value at D1 and D3 thresholds in vivo, radiographic examination showed the lowest sensitivity values	The ICDAS II method could be sufficient alone in the diagnosis of occlusal caries of primary teeth. However, SoproLife camera may be useful in monitoring caries lesions.
Goswami M. (2015) [20]	31 children	1. WHO criteria 2. ICDASII 3. DIAGNOdent	The mean ICDAS-II values amounted to 8.76 ± 0.72 . The mean values for DMFS/def were 7.67 ± 0.91 , whereas for DIAGNOdent it amounted to 4.00 ± 0.62	This study showed that the diagnostic capabilities of the ICDAS-II criteria in comparison to the traditional WHO criteria by means of the non-cavitated caries lesions additionally detected. The Diagnodent use in studies that already apply detailed visual criteria seemed to add limited additional information.

Table 4: Selected studies about ICDAS visual criteria.

Author/Year	Subjects	Methodology	Results	Conclusion
Maria Melo (2017) [21]	A total of 302 teeth (molars and pre-molars) from 152 patients 39.1 ± 14.3 years old were studied	DIAGNOdent and VistaProof) vs. visual and tactile evaluation in the diagnosis of occlusal caries in permanent teeth	The sensitivity and specificity values of visual diagnosis were 79 and 72 %, respectively, versus 53 and 98 % of tactile methods. Teeth with caries lesions showed significantly higher Diagnodent and VistaProof scores than those caries-free. Using the optimum cut-off point of 23.5, Diagnodent, sensitivity, and specificity values were 92.4 and 92.7 %, respectively, while it showed values of 88.1 and 95.1 % with a cut-off point of 28.5. The sensitivity of the Vistaproof system varied between 92.9 % (cut-off point 1.05) and 85.3 % (cut-off point 1.3), with respective specificity values of 95.8 and 88.6 %. The areas under the curve were 0.756, 0.759, 0.954 and 0.965 for the visual and tactile methods and for DIAGNOdent and VistaProof, respectively	The fluorescence-based techniques showed greater internal and external validity than the visual and tactile methods in diagnosing occlusal caries in permanent teeth. VistaProof is the best method for diagnosing caries in its early stages.
Anahita Jablonski-Momeni (2017) [22]	One hundred ninety-three proximal surfaces from 18 patients (average age was 29.5 years (18.5–45.8 years))were examined visually using ICDAS and using digital radiographs for presence or absence of enamel lesions	Evaluate the performance of the VistaCam iX NIR for the detection of approximal enamel lesions by comparison of digital radiographic findings.	A moderate correlation was found between all detection methods. The agreement between the radiographic and NIR findings was moderate for the distinction between sound surfaces and enamel caries. Insignificant differences were found between the results (P = 0.07).	Proxi head of the intraoral camera VistaCam iX can provide findings comparable to those of radiographs for non-cavitated lesions.
Marta Mazur (2020) [23]	Occlusal surfaces of 1011 posterior teeth in 255 patients aged 13–20 years (mean age 16 ± 2.2 years)	compare the diagnostic outcomes of subjective visual evaluation between the International Caries Detection and Assessment System (ICDAS-II) and an intraoral fluorescence-based camera (VistaCam iX Proof, Dürr Dental, Bietigheim-Bissingen, Germany) for the detection of pits and fissures in early caries lesions of posterior teeth	283 (28%) of the assessed teeth were ICDAS-II code 0; 334 (33%) code 1; 189 (18.7%) code 2; 176 (17.4%) code 3; and 29 (2.9%) code 4. The agreement between the two procedures was expressed by using Cohen's and Fleiss' kappa statistics and performing McNemar's test. VistaCam assessed in 513 (50.7%) sound enamel; in 292 (28.9%) initial enamel decay; and in 206 (20.4%) dentine caries.	This comparative study showed a poor agreement between the two diagnostic methods, especially between ICDAS-II 0, 1, and 2 codes and fluorescence assessments.

C.M. Moriyama 2014	<p>Ten volunteers wore acrylic palatal appliances, each having six enamel blocks demineralized for 14 days by immersion into a 20% sucrose solution, and 3 of them were remineralized for seven days using fluoride dentifrice.</p> <p>Sixty enamel blocks were evaluated at baseline, after demineralization and 30 blocks after remineralization by two examiners</p>	<p>evaluate the effectiveness of fluorescence-based methods (DIAGNOdent, LF; DIAGNOdent pen, LFpen, and VistaProof fluorescence camera, FC) in detecting demineralization and remineralization on smooth surfaces in situ</p> <p>They were submitted to surface microhardness (SMH) and cross-sectional microhardness analysis. The integrated loss of surface hardness (ΔKHN) was calculated</p>	<p>The intraclass correlation coefficient for inter-examiner reproducibility ranged from 0.21 (FC) to 0.86 (LFpen). SMH, LF, and LFpen values presented significant differences between the three phases. However, FC fluorescence values showed no significant differences between the demineralization and remineralization phases. Fluorescence values for baseline, demineralized and remineralized enamel were, respectively, 5.4 ± 1.0, 9.2 ± 2.2 and 7.0 ± 1.5 for LF; 10.5 ± 2.0, 15.0 ± 3.2 and 12.5 ± 2.9 for LFpen, and 1.0 ± 0.0, 1.0 ± 0.1 and 1.0 ± 0.1 for FC. SMH and ΔKHN showed significant differences between demineralization and remineralization phases. There was a negative and significant correlation between SMH and LF and LFpen in the remineralization phase</p>	<p>LF and LFpen devices showed to be effective in detecting demineralization and remineralization on smooth surfaces provoked in situ.</p>
Anahita Jablonski-Momeni 2013 [24]	306 unrestored permanent teeth of 26 patients	<p>Teeth were examined using (ICDAS) criteria. Then, digital images of the surfaces were made using the VistaProof cam. The actual depth of the lesions was assessed using radiographs and/or clinically by opening the lesion when appropriate. Correlation between all methods was assessed using Spearman's rank correlation coefficient (rs). Sensitivity (SE) and specificity (SP) were calculated at D1-(enamel lesions) and D3-(dentine caries) diagnostic threshold and area under the ROC curve (AUC) were assessed</p>	<p>A significant positive correlation was found between ICDAS, VP measurements, and the reference standard ($r = 0.46-0.71$, $p < 0.01$). SE and SP were at the D1-diagnostic threshold level 92.3 and 41.1 %, respectively. At the D3-diagnostic threshold, SE was 25.9 % and SP 97.9 %. The diagnostic performance (AUC) was 0.82 (D1) and 0.85 (D3). Combination of VP measurements with ICDAS showed the SE value of 74.1 % at D3-diagnostic threshold</p>	<p>The VP showed good diagnostic performance.</p> <p>The combination of VP measurements with ICDAS improved the SE in detecting dentine lesions.</p>

María Melo 2015 [25]	Thirty-two teeth (molars or premolars of both arches scheduled for filling or for use as posts in dental bridges) in 28 patients.	DIAGNOdentVistaProof and CarieScan Fissurotomy was subsequently performed for histological validation.	Visual inspection showed an AUC-ROC of 0.75, with sensitivity and specificity values of 0.75. Tactile diagnosis showed AUC = 0.714, with maximum sensitivity (100%) and a specificity value of 42.9%. Diagnodent (cutoff point 22.5) while VistaProof (cutoff point 1.1) showed an AUC = 0.969, while CarieScan (cutoff point 21.5) resulted in an AUC = 0.973. These methods all had a sensitivity of over 92%. The specificity of Diagnodent showed to be maximum, while that of CarieScan and VistaProof was 75%	The new methods in the diagnosis of caries (Diagnodent, VistaProof, and CarieScan) showed similar results and proved to be superior to the traditional visual and tactile methods. Diagnodent was considered the most effective technique, followed by CarieScan and VistaProof
Anahita Jablonski-Momeni 2015 [26]	A total of 419 posterior teeth (205 primary molars, 145 permanent molars, and 69 premolars) of 35 patients were examined (average age: 9.1 years)	Evaluated the capabilities of the VistaProof (VP) fluorescence-based camera for monitoring occlusal surface caries. The occlusal surfaces were classified visually according (ICDAS) scores. VP measurements were performed at baseline and after six and twelve-month. Correlation between methods was analyzed using Spearman's rank correlation coefficient. Wilcoxon test was applied to monitor whether VP identified changes as well as ICDAS ($\alpha = 0.05$).	Correlations between ICDAS and VP were significantly positive ($r_s: 0.66-0.73, P < 0.001$). No significant differences were found between all times for the ICDAS findings. Significant differences for the VP were ascertained for t1/t2 ($P = 0.03$). Results based on cluster randomization showed significant differences between ICDAS and VistaProof concerning the absence/presence of changes in the finding ($P < 0.0005$).	Correlation between ICDAS and VP was strong. The VP supported the findings of visual examination for monitoring occlusal surfaces, although not all changes could be detected with respect to the visual findings.

Table 5: Selected studies about VistaCam/VistaProof.

Author/Year	Subjects	Methodology	Results	Conclusion
M. Muller-Bolla 2017	<p>103 5–15 years old children Cariesfree subjects (without carious lesions diagnosed by both visual examination and bitewing radiographs)</p> <p>Occlusal surfaces of 310 primary and 433 permanent posterior teeth</p>	<p>Soprolife vs. DIAGNOPen</p> <p>The sensitivity, specificity, and area under the Receiver Operating Characteristic curve were evaluated using (ICDAS) and radiographic examinations as the gold standards.</p> <p>The effectiveness of the Soprolife was compared with Diagnopen on the same teeth.</p> <p>The reproducibility was assessed using weighted a Kappa coefficient.</p>	<p>All carious lesions using ICDAS 1–6 were assessed, SE, SP, and AUC for the Soprolife showed values of 88.50, 70.73, and 0.84, respectively. The validity was higher for primary teeth (AUC = 0.90) than for permanent teeth (0.80); the validity of the Soprolife (0.84) was higher than that of Diagnopen (0.80). The inter- and intra-examiner kappa coefficients scores were 0.87 and 0.85, respectively.</p>	<p>The Soprolife is considered a valid instrument in providing reproducible results, particularly for primary teeth.</p>
A. Kockanat 2017 [19]	<p>Children aged between 9 and 12 years</p> <p>One hundred twenty primary molar teeth indication for extraction confirmed radiologically were included in the present study.</p>	<p>They compared ICDAS II, radiographic examination, Diagnodent pen, CarieScan PRO and Soprolife camera, and in vitro using the mentioned diagnostic methods except for radiographic examination. In addition, in vitro examinations were repeated two weeks later.</p> <p>Sectioning and evaluation were done using with Downer's histological criteria.</p> <p>Sensitivity, specificity, positive and negative predictive value, area under the ROC curve were assessed at D1 and D3 thresholds. The intra- and inter-examiner' reproducibility were evaluated using Cohen's kappa statistics and an intraclass correlation coefficient</p>	<p>Intra- and inter-examiner repeatability were high for all tools</p> <p>ICDAS and Soprolife camera had the highest sensitivity value at D1 and D3 thresholds in vivo, radiographic examination showed the lowest sensitivity values.</p> <p>ICDAS and Soprolife camera showed the highest sensitivity values at D3 threshold in vitro, CarieScan PRO showed the lowest sensitivity value</p>	<p>The ICDAS II method showed to be sufficient alone in the diagnosis of occlusal caries</p> <p>However, Soprolife camera tends to be useful in monitoring caries lesions</p>

Elodie Terrer 2019	<p>Six hundred twenty-eight occlusal fissures were included for analysis.</p> <p>Participants (> 18-year-old) were chosen with apparent suspicious occlusal fissures (based on visual inspection); absence of occlusal restorations and fissure sealants (code 0, decision number 1, ICDAS),</p>	<p>Assessment of early caries detection capabilities in enamel and dentine with a laser-based system laser-based system (DIAGNOdent™ pen) first and secondary with a new fluorescence intra-oral camera (Soprolife®). Visual inspection with a loupe was used as control.</p> <p>The sensitivity and specificity of both devices varied depending on the cut-off threshold of the caries score</p>	<p>the ROC curve showed higher values for the Soprolife® than for DIAGNOdent™ pen.</p> <p>The values of the area under the curve decreased from 0.81 (Soprolife® in daylight) to 0.79 (Soprolife® in fluorescent mode) and 0.67 for DIAGNOdent™ pen. DIAGNOdent™ pen reproducibility (Intra and inter investigator) showed a wide dispersion, with many values scattered beyond the confidence limits (± 2 SD), and the weighted kappa coefficient, which was quite low (0.58)</p>	<p>Caries prevalence in terms of public health policy is of interest, and caries detection increased significantly when using a fluorescence-based intra-oral camera.</p>
Peter Rechmann 2012 [27]	<p>100 subjects</p> <p>433 posterior permanent unrestored teeth were examined</p>	<p>Assessed the diagnostic performance of Diagnodent and two light-emitting diode fluorescence tools: Spectra Caries Detection Aid and Soprolife light-induced fluorescence evaluator in both daylight and blue fluorescence mode in comparison to (ICDAS-II) in the detection of caries lesions</p> <p>On the occlusal surfaces, 1066 data points for each assessment method were obtained for statistical evaluation, including 1034 ICDAS scores. For the Soprolife tool, a new scoring system was applied.</p> <p>For each assessment tool, each average score for one given ICDAS code was significantly different from each other ICDAS code</p>	<p>Normalized data linear regression showed that Soprolife assessment tools provided best caries score discrimination followed by Diagnodent and Spectra Caries Detection tool.</p> <p>The area under the receiver operating characteristics curve analysis showed the same scores sequence when cut-off point ICDAS codes 0-1-2 were grouped together. Sensitivity and specificity values at the same cut-off were obtained (Diagnodent 87/66, Spectra Caries Detection Aid 93/37, Soprolife 93/63, Soprolife blue fluorescence 95/55.)</p>	<p>All fluorescence tools were able to discriminate between distinct ICDAS II scores. All tools showed an AROC depicting the overall capability to differentiate between healthy and defective showed similar values with the Soprolife tool in daylight as well as blue fluorescence mode having the highest values.</p> <p>The linear regression fits for the caries assessment tools in relation to ICDAS II codes showed that both SOPROLIFE assessment tools with the highest slope values allow for the better caries lesion discrimination followed by Diagnodent. Spectra Caries Detection Aid showed a relatively flat curve with low discrimination ability</p> <p>Those fluorescence tools, specifically those with observational capabilities should aid clinicians in applying more preventive and minimally invasive treatment modalities and will allow monitoring lesions for the success of prevention measures over time</p>

<p>Mona Zeitouny 2014 [3]</p>	<p>219 permanent posterior teeth from 21 subjects, with age ranging from 15 to 65 years, were examined</p>	<p>Evaluation of a light-emitting diode fluorescence tool, the Soprolife light-induced fluorescence evaluator, and compared it to the ICDAS-II in the detection of occlusal caries.</p>	<p>High reliability was found between both methods (ICC = 0.92; IC = 0.901–0.940; $P < 0.001$). Soprolife blue fluorescence mode showed a high sensitivity (87%) and a high specificity (99%)</p>	<p>Compared to the visual method in the diagnosis of occlusal caries lesions, it was found that Soprolife is a reproducible and reliable tool. In terms of categorizing noncarious lesions and visual change in enamel, Soprolife shows high sensitivity and specificity. It was concluded that financially ICDAS is better. Soprolife is easier for clinicians, and in terms of efficiency, Soprolife was not better than ICDAS but tended to be equivalent to having the same advantages.</p>
<p>A. Theocharopoulou 2015</p>	<p>Thirty-seven posterior primary and permanent teeth occlusal surfaces from 20 children were examined</p>	<p>Diagnodent pen and Soprolife fluorescence intra-oral camera compared to ICDAS. Cut-offs were made for all methods to discriminate sound surfaces and enamel caries from dentin caries. The inter-examiner reliability was assessed using intra-class correlation coefficient</p>	<p>On white light images, the assessors found 16 enamel caries and 21 dentine caries using the ICDAS system. On the Soprolife fluorescent images, 24 enamel lesions, nine dentine lesions, and four sound surfaces were detected. The inter-examiner reliability (ICC) of the ICDAS system on white light images and of Soprolife on the fluorescent images for average measures was 0.70 and 0.72, respectively.</p> <p>The sensitivity and specificity values of Soprolife (95%CI) were 0.43 and 1.0, respectively, using ICDAS as a reference standard. while sensitivity and specificity of Diagnodent (95%CI) was 0.62 and 0.81 respectively</p>	<p>A brief training of dentists in use the ICDAS system showed satisfactory inter-examiner reliability results</p> <p>Soprolife and Diagnodent do not contribute to better detection of early carious lesions</p>

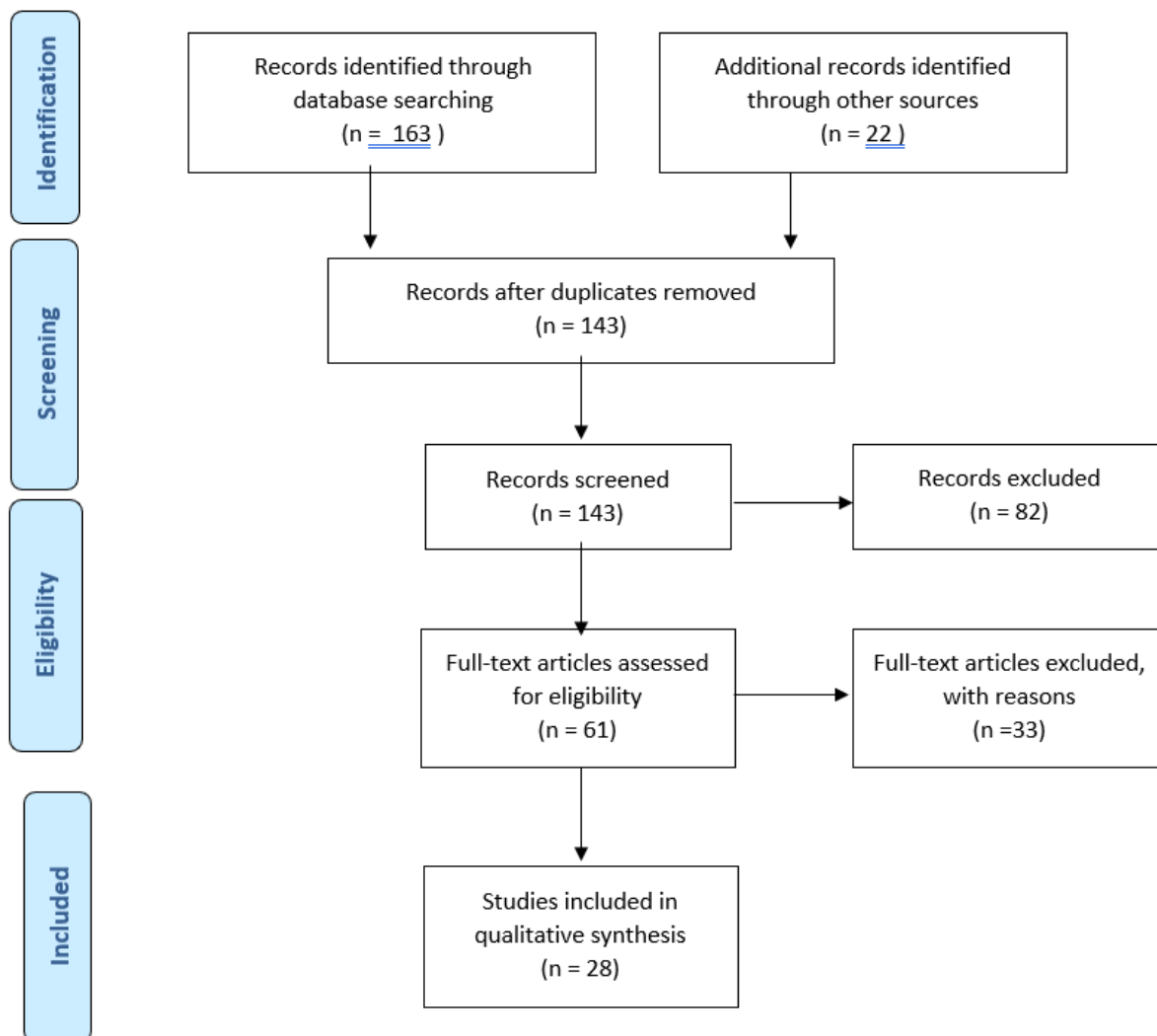
Table 6: Selected studies about Soprolife.

Study	Sequence generation (randomized)	Sequence concealment	Blinded participants and personnel	Results analysis blinded	Participants loss %	Reporting Bias (reporting all outcomes)	Other bias (funding mn companies)	Risk of Bias
Castilho LS (2016) [9]	Unclear	Yes	Yes	Yes	0%	No	No	Moderate
Chaza Kouchaji (2012) [4]	Unclear	Yes	Yes	Yes	0%	No	No	Moderate
CH. Chu (2010) [10]	Unclear	Yes	Yes	Yes	0%	No	No	Moderate
A.Goel et al. (2009) [11]	Unclear	yes	No	Yes	0%	No	No	Moderate
Kavvadia K (2008) [12]	Distributed according to their caries scoring	Yes	Yes	Yes	0%	No	No	Low
Kuhnisch J (2008) [13]	Unclear	Yes	Yes	Yes	0%	No	No	Moderate
Costa AM (2008) [14]	Using indexes of sensitivity and specificity of the diagnostic systems	Yes	Yes	Yes	0%	No	No	Low
Huth KC (2008) [15]	One test tooth was chosen by drawing lots from a black box by an independent assistant	Yes	Yes	Yes	0%	Yes	Yes	Low
Anttonen V (2004) [16]	According to the difference in test score registered at the two check-ups	Yes	Yes	yes	20%	No	No	Moderate
Sahu RK (2020) [6]	Samples were distributed as per ICDAS coding	Yes	Yes	Yes	0%	No	No	Low
Maria Melo (2019) [7]	Unclear	Yes	Yes	Yes	0%	No	No	Moderate
Basem M. Abuzenada (2019) [8]	Unclear	Yes	Yes	Yes	0%	No	No	Moderate

Melek Tassoker (2019) [17]	The distribution of the samples according to their histological thresholds	Yes	No	Yes	0%	No	No	Moderate
Bhumireddy J.R. (2018) [18]	Unclear	Yes	Yes	Yes	0%	No	No	Moderate
Kockanat A. (2017) [19]	Unclear	Yes	Yes	Yes	0%	No	No	Moderate
Goswami M. (2015) [20]	Unclear	Yes	No	Yes	0%	No	No	Moderate
M. Muller-Bolla 2017	Unclear	No	Yes	Yes	0%	No	No	Low
A. Kockanat 2017 [19]	Unclear	No	No	Yes	0%	No	No	Moderate
Elodie Terrer 2019	Unclear	No	Yes	Yes	0%	No	No	Low
Peter Rechmann 2012 [27]	Unclear	Yes	Yes	Yes	0%	No	Yes	Moderate
Mona Zeitouny 2014 [3]	Unclear	Yes	Yes	Yes	0%	No	No	Low
A.Theocharopoulou 2015	Unclear	Yes	Yes	Yes	0%	No	No	Low
Maria Melo 2017 [7]	Unclear	Yes	No	Yes	0%	No	No	Low
Anahita Jablonski-Momeni 2017 [22]	Yes	Yes	No	Yes	0%	No	Yes	Moderate
Marta Mazur 2020 [23]	Unclear	No	Yes	Yes	0%	No	No	Low
C.M. Moriyama 2014	Unclear	No	No	Yes	0%	No	No	Moderate
Anahita Jablonski-Momeni 2013 [24]	Unclear	No	No	Yes	0%	No	Yes	Moderate
María Melo 2015 [7]	Unclear	No	No	Yes	0%	No	No	Moderate
Anahita Jablonski-Momeni 2015	Unclear	No	No	Yes	1%	No	Yes	Moderate

Table 7: Risk of Bias analysis.

PRISMA 2009 flow diagram



DISCUSSION

The current review was conducted to evaluate the in-vivo performance of digital dental radiography and some of the novel diagnostic tools in detecting initial carious lesions and microcavities on occlusal and proximal surfaces of both primary and permanent teeth in comparison to the visual and tactile inspection using the ICDAS diagnostic criteria.

Visual inspection has been the most frequently validated diagnostic technique for caries detection and using ICDAS diagnostic criteria proved good performance and accuracy in various in-vivo and in-vitro studies [28-33]. Accordingly, in our review visual inspection using ICDAS criteria was considered the comparator and gold standard protocol for detecting initial carious lesions.

Various studies assessed the digital radiography and recent diagnostic tools in detecting early carious lesions in-vivo and in-vitro, our review included recent in-vivo clinical trials as

they are more relevant to the clinical diagnostic situations where the included studies assessed the diagnostic accuracy according to sensitivity, specificity, and receiver operating characteristic curves.

Previous systematic reviews related to our research's scope were identified a review by [34] was conducted to evaluate various diagnostic tools, the article included some old diagnostic technologies which became rarely available and missed some of the recent tools which proved promising performance, Also in 2016 [35] published a systematic review but it was directed to evaluate the diagnostic capabilities of Soprolife camera only. A more recent review [36] was evaluating various detection technologies but in relation to caries activity of cavitated and non-cavitated lesions, Also [37] carried out a systematic review and meta-analysis, but it was limited to the use of Diagnodent and Vistaproof camera for pre-cavitated lesions.

According to previous reviews, none of them compared the widely available digital radiography and recent easily available and easy to use diagnostic tools side by side. Also, our review included clinical trial studies comparing other tools together and in comparison to the more commonly used visual and tactile methods following the ICDAS criteria on both occlusal and proximal surfaces of permanent or primary teeth.

The criteria of success and reliability of any caries detection tool depend on various factors; the tool should show high intrinsic and extrinsic validity with a high sensitivity values to limit as much as possible any false-negative test results to the test which means failing to detect active lesions; also it should have high specificity to avoid false-positive results referring to the presence of active lesion leading to unnecessary intervention [36]. The diagnostic accuracy of the discussed tools was also evaluated in relation to the Receiver Operating Characteristic (ROC) curves, which is a graphic presentation of the relation between true positive test results (sensitivity) and false positives ones (1-specificity). The area under the curve (AUC), allows proper assessment of the diagnostic performance of the tested tool and also allows determining the optimal cut-off point, which will discriminate between presence or absence of carious lesions [38].

Digital dental radiography proved to be a reliable tool in detecting initial carious lesions/ especially proximal lesions [7], also using filters as negative images allowed easier and more efficient detection of occlusal lesions [6]. The digital bitewing radiography was proposed to be high value and reliability in detecting proximal caries [8].

The studies published evaluating the Diagnodent device suggested that the device has high accuracy and reliability similar to or superior to visual and tactile methods [9]. The device was proved to be an efficient adjunct to other detection methods, especially in the case of non-experienced clinicians [16], but the limitation of its use was due to high cost and not providing valuable additional information [10].

ICDAS criteria for the diagnosis of dental caries were considered to be sufficient alone in detecting occlusal caries [19]. It was found that ICDAS II showed better performance accuracy than bitewing radiographs when the lesion is confined within enamel [18] but the use in conjunction with a recent diagnostic tool enhanced the outcomes [17,20].

Regarding the included articles evaluating the Soprolife camera, there was a consistent agreement upon the accuracy of the device with sensitivity values ranging from 43% up to

95% while specificity ranged from 55% to 99%; generally, it was found that the Intra- and inter-examiner repeatability was high and the device is a valid and reliable tool which can increase the clinicians' capabilities to detect early carious lesions. These observations were correlated to the ability of Soprolife to accurately transmit blue fluorescent light through the enamel into dentin cores and reflected image shows red areas indicating bacteria and their byproducts [26] and its recommended to be used in conjunction to the ICDAS criteria which is considered more financially efficient and to enhance visual examination [3].

Studies related to VistaCam/VistaProof assessment it was found that in some articles VistaCam proved high accuracy in detecting early carious lesions [21,24,25] with moderate to strong correlation in comparison to results obtained by visual and tactile methods ICDAS criteria [22,38]. Other studies found a low performance of VistaCam when compared to visual and tactile methods, and this result was justified by the need to modify the cut-off values of the device [39] moreover, poor correlation to visual and tactile diagnostic results were obtained in cases of ICDAS scores (0-2), and this result was due to the presence of saliva and blood which should be removed because they enhance the fluorescence and increases the scores obtained; also, removal of plaque from occlusal surfaces was required [23].

In agreement with previous reviews, the main aim of a recent diagnostic tool is to detect as early as possible the initial carious lesions to be able to apply a medical model rather than intervention. Generally, most of the recent diagnostic tools were found to be a very useful aid in diagnosing carious lesions and assessing their progress, the use of recent tools must be an addition to the standard visual and tactile protocol and not a replacement solely used tool to rely on completely.

CONCLUSION

The caries detection tools target the early detection of caries and prevent the progression of caries from demineralization to cavitation. None of the mentioned techniques were sufficient alone for the diagnosis of dental caries. In the future, with the advancements of the diagnostic tools, minimal changes in the tooth structure will be easily detected, and the dental structures will be protected by applying preventive treatments.

AUTHOR CONTRIBUTIONS

Shereen Hafez Ibrahim (associate professor of conservative dentistry): Corresponding author, project administration,

supervision, conceptualization, validation, data curation, review.

Peter Edward: data extraction, methodology, resources, writing original draft

Reham Nabil: data extraction, methodology, resources, writing original draft

All authors have read and agreed to the published version.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data presented in this study are available on request from the corresponding author.

DISCLOSURE OF STATEMENT

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