Electrical conductance for the detection of dental caries

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[Diagnostic Test Accuracy Review]

Electrical conductance for the detection of dental caries

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ABSTRACT

Background

Caries is one of the most prevalent, preventable conditions worldwide. A wide variety of management options are available at different thresholds of disease, ranging from non-operative preventive strategies such as improved oral hygiene, reduced sugar diet, and application of topical fluoride, to minimally invasive treatments for early lesions which are limited to enamel, through to selective removal and restoration for extensive lesions. The cornerstone of caries detection is a visual and tactile dental examination, however, an increasing array of methods of caries lesion detection have been proposed that could potentially support traditional methods of detection and diagnosis. Earlier identification of disease could afford patients the opportunity of less invasive treatment with less destruction of tooth tissue, reduce the need for treatment with aerosol-generating procedures, and potentially result in a reduced cost of care to the patient and to healthcare services.

Objectives

Our primary objective was to determine the diagnostic accuracy of different electrical conductance devices for the detection and diagnosis of non-cavitated coronal dental caries in different populations (children, adolescents, and adults) and when tested against different reference standards.

Search methods

Cochrane Oral Health's Information Specialist undertook a search of the following databases: MEDLINE Ovid (1946 to 26 April 2019); Embase Ovid (1980 to 26 April 2019); US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov, to 26 April 2019); and the World Health Organization International Clinical Trials Registry Platform (to 26 April 2019). We studied reference lists as well as published systematic review articles.

Selection criteria

We included diagnostic accuracy studies that compared electrical conductance devices with a reference standard of histology or an enhanced visual examination. This included prospective studies that evaluated the diagnostic accuracy of single index tests and studies that directly compared two or more index tests. We included studies using previously extracted teeth or those that recruited participants with teeth believed to be sound or with early lesions limited to enamel.

Studies that explicitly recruited participants with more advanced lesions that were obviously into dentine or frankly cavitated were excluded.

Data collection and analysis

Two review authors extracted data independently using a piloted study data extraction form based on the Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2). Sensitivity and specificity with 95% confidence intervals (CIs) were reported for each study. This information was displayed as coupled forest plots, and plotted as summary receiver operating characteristic (SROC) plots, displaying the sensitivity-specificity points for each study. Due to variability in thresholds we estimated diagnostic accuracy using hierarchical summary receiver operating characteristic (HSROC) methods.

Main results

We included seven studies reporting a total of 719 tooth sites or surfaces, with an overall prevalence of the target condition of 73% (528 tooth sites or surfaces). The included studies evaluated two index tests: the electronic caries monitor (ECM) (four studies, 475 tooth surfaces) and CarieScan Pro (three studies, 244 tooth surfaces). Six studies used histology as the reference standard, one used an enhanced visual examination. No study was considered to be at low risk of bias across all four domains or low concern for applicability or both. All studies were at high (five studies) or unclear (two studies) risk of bias for the patient selection domain. We judged two studies to be at unclear risk of bias for the index test domain, and one study to be at high risk of bias for the reference standard and flow and timing domains. We judged three studies to be at low concern for applicability for patient selection, and all seven studies to be of low concern for reference standard and flow and timing domains.

Studies were synthesised using a hierarchical method for meta-analysis. There was variability in the results of the individual studies, with sensitivities which ranged from 0.55 to 0.98 and specificities from 0 to 1.00. These extreme values of specificity may be explained by a low number of healthy tooth surfaces in the included samples. The diagnostic odds ratio (DOR) was 15.65 (95% CI 1.43 to 171.15), and indicative of the variability in the included studies. Through meta-regression we observed no meaningful difference in accuracy according to device type or dentition. Due to the small number of studies we were unable to formally investigate other potential sources of heterogeneity.

We judged the certainty of the evidence as very low, and downgraded for risk of bias due to limitations in the design and conduct of the included studies, imprecision arising from the relatively small number of surfaces studied, and inconsistency due to the variability of results.

Authors' conclusions

The design and conduct of studies to determine the diagnostic accuracy of methods to detect and diagnose caries in situ is particularly challenging. The evidence base to support the detection and diagnosis of caries with electrical conductance devices is sparse. Newer electrical conductance devices show promise and further research at the enamel caries threshold using a robust study design to minimise bias is warranted. In terms of applicability, any future studies should be carried out in a clinical setting to provide a realistic assessment within the oral cavity where plaque, staining, and restorations can be problematic.

PLAIN LANGUAGE SUMMARY

Electrical conductance for the detection of early tooth decay

Why is it important to improve dental caries (tooth decay) detection?

Dentists often aim to identify tooth decay that has already advanced to a level which needs a filling. If dentists were able to find tooth decay when it has only affected the outer layer of the tooth (enamel) then it is possible to stop the decay from spreading any further and prevent the need for fillings. It is also important to avoid a false-positive result, when treatment may be provided when caries is absent.

What is the aim of this review?

The aim of this Cochrane Review was to find out how accurate electrical conductance devices (non-invasive devices that send an electrical current to the surface of the tooth) are for detecting and diagnosing early tooth decay as part of the dental 'check-up' for children and adults who visit their general dentist. Researchers in Cochrane included seven studies published between 1997 and 2018 to answer this question.

What was studied in the review?

There are two electrical conductance devices that were included in this review: electronic caries monitor (ECM) (four studies) and CarieScan Pro (three studies). Both place a probe on the tooth which measures the electrical conductance of that point on the tooth. We studied decay on the occlusal surfaces (biting surfaces of the back teeth), the proximal surfaces (tooth surfaces that are next to each other), and the smooth surfaces next to the tongue, cheeks, and lips.

What are the main results of the review?

Researchers in Cochrane included seven studies with a total of 719 tooth sites or surfaces to answer this question. Due to the small number of tooth sites or surfaces studies, the results are very imprecise. We did not find any meaningful difference in accuracy according to type of device or the teeth of children/adolescents and adults.

How reliable are the results of the studies in this review?

We only included studies that assessed healthy teeth or those that were thought to have early tooth decay. This is because teeth with deep tooth decay would be easier to identify. However, there were some problems with how the studies were carried out. This may result in the electrical conductance devices appearing to be more accurate than they really are, increasing the number of correct test results from the electrical conductance devices. We judged the certainty of the evidence as very low due to how the studies selected their participants, the relatively small number of surfaces studied, and the variability of results.

Who do the results of this review apply to?

Studies included in the review were carried out in Brazil, UK, Denmark, and Turkey. Three studies performed the tests on extracted teeth and four studies were completed in a dental hospital.

What are the implications of this review?

The lack of eligible studies and the variation in the results of the studies means that at present, we are very uncertain of how electrical conductance devices are in detecting and diagnosing early tooth decay.

How up-to-date is this review?

The review authors searched for and used studies published up to 26 April 2019.

SUMMARY OF FINDINGS

Summary of findings 1. Summary of findings table

Question	What is the diagnostic accuracy of electrical conductance index tests for the detection and diagnosis of early dental caries?	
Population	Children or adults who are presenting asymptomatically or are suspected of having enamel caries (clinical studies); extracted teeth of children or adults (in vitro studies). Studies which intentionally included dentine and frank cavitations were excluded	
Index test	Electrical conductance devices - including the ECM and CarieScan Pro devices, for use as an adjunct to a conventional clinical oral examination. Results of the index test were given on a continuous scale using a software algorithm	
Comparator test	Comparisons were made between the 2 electrical conductance devices	
Target condition	Dental caries, at the threshold of caries in enamel	
Reference standard	Histology, enhanced visual examination with or without radiographs	
Action	If dental caries can be detected at an early stage then remedial action can be taken to arrest or reverse the decay and potentially prevent restorations	
Diagnostic stage	Aimed at the general dental practitioner assessing regularly attending patients for early stage caries	
Quantity of evidence	7 studies providing 8 datasets for the meta-analysis. 719 tooth surfaces or sites (528 tooth surfaces with total caries at enamel threshold or greater, 73% prevalence). The included studies evaluated 2 index tests: the ECM (4 studies using ECM II, ECM III, and ECM IV, 475 tooth surfaces, prevalence from 57% to 82%) and CarieScan Pro (3 studies, 244 tooth surfaces, prevalence from 71% to 97%)	
Findings		
Effects per 1000 tooth surfaces or sites assessed	Results are reported as HSROC curve. Due to the small number of eligible studies and clinical heterogeneity, and in the absence of clinical consensus as to meaningful fixed values of specificity, we elected not to report sensitivities at fixed values of specificity as a means of expressing numerical quantities from the curve ECM: sensitivity from 0.61 to 0.98, specificity from 0.73 to 0.96 CarieScan Pro: sensitivity from 0.55 to 0.91, specificity from 0 to 1.00	
Limitations		**Test accuracy certainty of evidence**
Risk of bias	No studies were judged to be at low risk of bias across all domains, but study limitations were greatest for the patient selection domain, specifically the non-random or non-consecutive selection of the study samples	⊕◯◯◯ VERY LOW
Applicability of evidence to question	Patient selection was considered to be a high concern in 3 studies where extracted teeth were evaluated	
Overall certainty of evidence	We judged the certainty of the evidence as very low, and downgraded for risk of bias due to limitations in the design and conduct of the included studies, imprecision arising from the relatively small number of surfaces studied, and inconsistency due to the variability of results	

ECM = electronic caries monitor; HSROC = hierarchical summary receiver operating characteristic.

BACKGROUND

Cochrane Oral Health (COH) has undertaken several Cochrane Reviews of diagnostic test accuracy (DTA) on the detection and diagnosis of dental caries. The suite of systematic reviews forms part of a UK National Institute for Health Research (NIHR) Cochrane Programme Grant Scheme and involved collaboration with the Complex Reviews Support Unit. The reviews follow standard Cochrane DTA methodology and will be differentiated according to the index test under evaluation. A generic protocol served as the basis for the suite of systematic reviews (Macey 2018).

Caries is an entire disease process, which can be stabilised and sometimes reversed if diagnosed and treated early on in the disease process (Fejerskov 2015; Pitts 2009). In some Scandinavian countries, preventative programmes are in place which have almost eradicated caries, but such activities have not been widely replicated in other locations (Pitts 2017). The 2015 Global Burden of Disease study has identified dental caries as the most prevalent, preventable condition worldwide (Feigin 2016; Kassebaum 2015), affecting 60% to 90% of children and the majority of adults of the world's population (Petersen 2005). Furthermore, despite a reduction in caries in some industrialised countries the global incidence of untreated caries was reported to be 2.4 billion in 2010 (Feigin 2016; Kassebaum 2015; World Health Organization 2017) and continues to increase year on year. In the UK, recent statistics indicate that the primary reason for childhood (aged 5 years to 9 years) hospital admissions is for the extraction of teeth (Public Health England 2014). Longitudinal studies have shown that those who experience caries early in childhood will have an increased risk of severe caries in later life, and that the disease trajectory will be steeper than those without early caries experience (Broadbent 2008; Hall-Scullin 2017).

Untreated caries can lead to episodes of severe pain and infection, often requiring treatment with antibiotics. Dental anxiety, resulting from the failure to treat caries and the subsequent need for more invasive management, can adversely affect a person's future willingness to visit their dentist, leading to a downward spiral of oral disease (Milsom 2003; Thomson 2000). If left to progress, treatment options are limited to restoration or extraction, requiring repeated visits to a dental surgery or even to a hospital (Featherstone 2004; Fejerskov 2015; Kidd 2004).

The cost of treating caries is high. In the UK alone, the National Health Service (NHS) spends around GBP half a billion every year in treating the disease. Hidden costs also exist, and the related productivity losses are high, estimated at USD 27 billion globally in 2010 (Listl 2015).

Caries detection and diagnosis will usually be undertaken at a routine dental examination, by a general dental practitioner, in patients who are presenting asymptomatically. However, caries detection can additionally be employed in secondary care settings, school or community screening projects, and epidemiology or research studies (Braga 2009; Jones 2017). The traditional method of detecting dental caries in clinical practice is a visual-tactile examination often with supporting radiographic investigations. This combination of methods is believed to be successful at detecting caries that has progressed into dentine and reached a threshold where a restoration may be necessary (Kidd 2004). The detection of caries earlier in the disease continuum could lead to stabilisation of disease or even possible remineralisation of the tooth surface, thus preventing the patient from entering a lifelong cycle of restoration (Pitts 2017). However, initial or incipient caries is difficult to detect visually, and the use of radiographs has been shown to have limited ability to detect small changes in dental enamel (Ismail 2007).

Detection and diagnosis at the initial (non-cavitated) and moderate levels of caries is fundamental in achieving the promotion of oral health and prevention of oral disease (Fejerskov 2015; Ismail 2013). The prevalence of this early caries state is often not reported in dental epidemiology, most reports preferring to focus on cavitated or dentinal lesions which may be easier to detect. The most recent UK Adult Dental Health survey, for example, reports 31% of the sample having untreated caries into dentine (Steele 2011; White 2012) and a US study reporting levels of cavities at 15.3% in 12- to 19-year olds (Dye 2015). However, one UK survey of children identified "clinical decay experience" which incorporates any enamel breakdown and all other forms of caries and reported a prevalence of 63% in 15-year olds (Vernazza 2016).

A wide variety of management options are available under NHS care at these different thresholds of disease, ranging from non-operative preventive strategies such as improved oral hygiene, reduced sugar diet, and application of topical fluoride, to minimally invasive treatments such as sealing the affected surface of the tooth, or 'infiltrating' the demineralised tissue with resins for initial caries; and operative interventions such as selective removal and restoration for extensive lesions.

With advances in technology over the last two decades, alternative methods of detection have become available, such as advancements in radiography and the development of fluorescence, transillumination, and electrical conductance devices. These could potentially aid the detection and diagnosis of caries at an early stage of decay. This would afford the patient the opportunity of a less invasive treatment with less destruction of tooth tissue and potentially result in a reduced cost of care to patients and healthcare services. Furthermore, the ability to accurately detect early caries and prevent caries lesions from progressing has become increasingly important in reducing the need to undertake/undergo invasive treatment which may require the use of aerosol-generating procedures (AGPs).

Target condition being diagnosed

Caries is an entire disease process, which can be arrested and sometimes reversed if diagnosed early enough (Fejerskov 2015; Pitts 2009). The term dental caries is used to describe the mechanisms and signs of the breakdown of the tooth surface which results from an imbalance in the activity within the biofilm (or dental plaque) within the oral cavity (Kidd 2016). This imbalance is due to bacterial breakdown of sugars in the diet which leads to the production of acid and demineralisation of the tooth. Disease progression can be moderated by the influx of fluoride through toothpaste and other available fluoride sources. However, the levels of sugar consumption observed in many populations will often outweigh the benefits of fluoride (Hse 2015). Ultimately, carious lesions may develop and destroy the structure of the tooth.

The most common surfaces for caries to manifest are on the biting (occlusal) surface or the tooth surface which faces an adjacent tooth (approximal surface), but smooth surfaces adjacent to the tongue, cheeks, and lips can be affected. The severity of the

disease is defined by the depth of demineralisation of the tooth's structure and whether the lesion is active or arrested. Caries presenting at levels into tooth enamel can potentially be stabilised or even reversed, whereas the progression of carious lesions into the dentine and pulp of the tooth will often require restoration (Bakhshandeh 2018; Kidd 2004).

Assessment of disease severity traditionally used in epidemiological and research studies has employed some variant of the DMFS/T (decayed, missing, and filled surfaces or teeth) scale. Within the D (decayed) component there are four clinically detectable thresholds applied as indicators for diagnosis and treatment planning, often labelled as D_1, D_2, D_3, and D_4 (Anaise 1984) (Additional Table 1). Typically the D_3 threshold has been used to determine the presence of caries in epidemiological and therapeutic studies, with only lesions extending into dentine classed as carious (Pitts 1988; Shoaib 2009).

Treatment of caries

There are several treatment options available to the dental clinician, dependent on the chosen threshold of observed disease. Initial caries can be treated without surgical intervention using preventive and remineralising approaches such as plaque control, dietary advice, and application of fluoride (Kidd 2016). Minimally invasive treatments for initial caries are available, such as sealing the affected surface of the tooth, or 'infiltrating' the demineralised tissue with resins. High-risk patients with severe caries may require selective caries removal and restoration of extensive lesions.

A caries management pathway, informed by diagnostic information, can be beneficial in guiding the clinician towards prevention or a treatment plan. One recently developed care pathway is the International Caries Classification and Management System (ICCMS) (Ismail 2015). The system presents three forms of management in the care pathway:

- when dentition is sound the clinician proceeds with preventative strategies to prevent sound surfaces from developing caries;
- non-invasive treatment of the lesion to arrest the decay process and encourage remineralisation, preventing initial lesions from progressing to cavitated decay; and
- management of more severe caries through tooth tissue preserving excavation methods and restoration or potentially extraction in more severe cases.

At the core of this care pathway is the ability to detect early caries accurately and optimise the preventative strategies through tooth tissue preserving excavation methods and restoration or potentially extraction in more severe cases. The detection and diagnosis of early caries remains challenging, and the likelihood of undiagnosed early disease is high (Ekstrand 1997). In such instances, the opportunity for preventing early lesions from progressing to cavitated decay, or even reversing the disease process, is missed, and disease progresses to cavitated decay where restoration is required (Ekstrand 1998).

Index test(s)

The cornerstone of caries detection is a visual-tactile dental examination, and the ability of clinicians to accurately detect disease in this way has been researched for over half a century (Backer Dirks 1951). Tests may be suitable at different stages of the care pathway (Bloemendal 2004; Fyffe 2000), and the use of additional detection tools can add to the detection, diagnosis, and monitoring process.

This review focuses on the use of devices based on methods of electrical conductance for the detection of dental caries. The assumption underlying the use of these devices is that sites of increased porosity resulting from the caries process fill with minerals and ions from saliva which leads to an increased conductance of an electric current (Longbottom 2004). The resulting resistance or impedance of the tooth tissue when exposed to an alternating electrical current is measured and recorded. Examples of devices using electrical conductance include.

- Electronic caries monitor (ECM) (Lode Diagnostics, Groningen, The Netherlands) uses a fixed point at the end of a probe to deliver an electrical impedance measurement. Alternatively the surface may be assessed using a conducting medium into which the probe is placed. Four different generations/versions of this device exist.
- CarieScan Pro (CarieScan Ltd, Dundee, Scotland) is described as an alternating current impedance spectroscopy technique which uses a sensor to detect the difference in electrical conductance between healthy and carious tissue. The result is displayed on a liquid-crystal display (LCD) screen and a coloured light-emitting diode (LED) display that allows the evaluation of the depth of the carious lesion.
- Vanguard electronic caries detector (Massachusetts Manufacturing Corp, Cambridge, Massachusetts, USA) is a device which utilises similar methods to ECM but is no longer commercially available.

Information about the other index tests in this series of systematic reviews can be found in the generic protocol (Macey 2018). Where combinations of index tests are reported, for example, visual examination plus ECM, we planned to include them in this review.

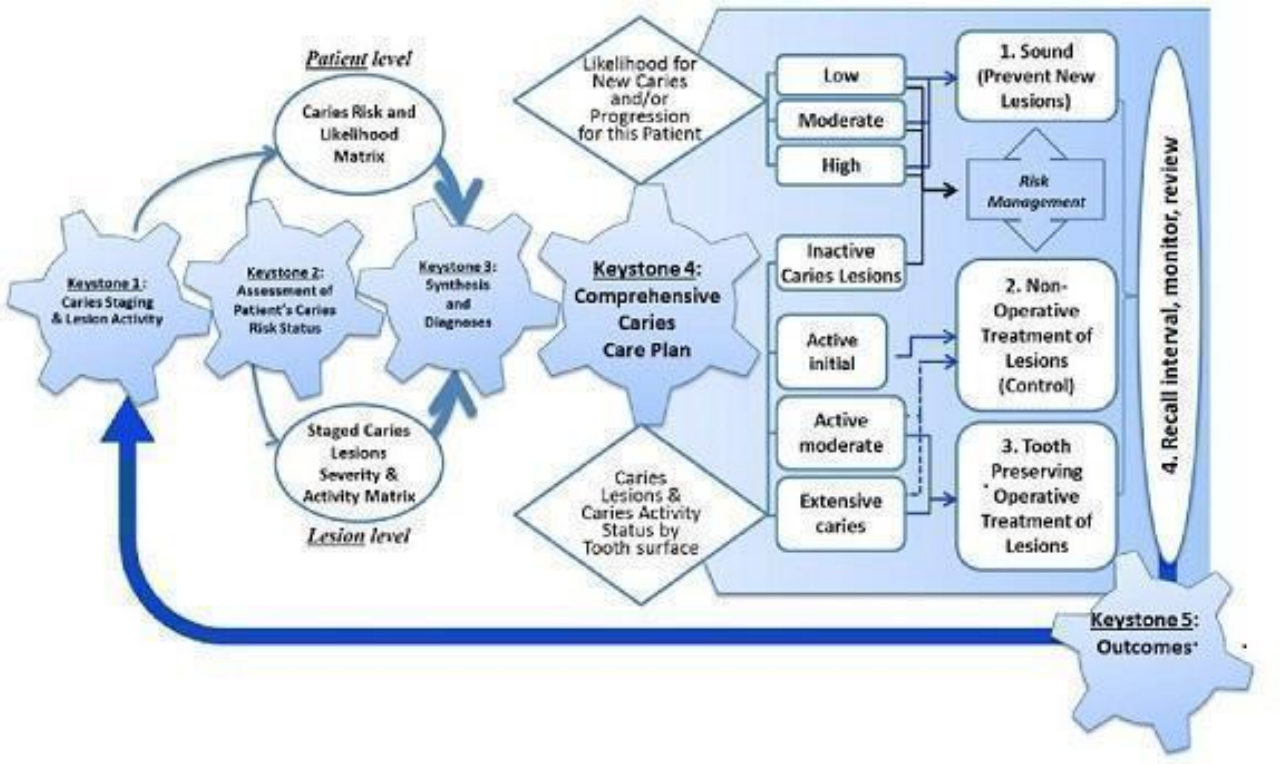
Clinical pathway

The process proceeding from a dental patient attending for a routine examination and a caries assessment being undertaken has four intertwined stages: screening, detection, diagnosis, and treatment planning. If the presenting patient is seemingly asymptomatic then this could be viewed as a screening exercise as the clinician is seeking to establish the presence or absence of disease (Wilson 1968). However, patients are likely to present with some level of caries as the established visual classification systems (e.g. International Caries Detection and Assessment System (ICDAS)) are sensitive enough to detect any changes in the enamel of the tooth's surface. The Adult Dental Health Survey 2009 reported a mean number of carious teeth in dentate adults of 0.8 (Adult Dental Health Survey 2009). Therefore, detection is a more reasonable description of this first examination, where the clinician aims to establish the true presence or absence of disease. Since caries is a dynamic process the detection of the disease at a single time point is not sufficient to inform the future care of the patient. Additionally, the depth and severity of demineralisation, allied to a decision on the caries activity levels, must be combined to reach a full clinical diagnosis (Ismail 2004; Nyvad 1997). This diagnosis then feeds into a caries management pathway once the patient's history, personal oral care, and risk factors have been considered. A comprehensive methodology has been developed, International

Caries Classification and Management System (ICCMS™), which aims to address the need for guidance when diagnosing caries and inform the decision-making process as to the use of preventative measures and minimise invasive treatment (Ismail 2015). A version of this has been developed by an international team into CariesCare for use in clinical practice (Martignon 2019).

Figure 1 presents the key elements of the ICCMS process. Specifically, this suite of reviews could inform 'Keystone 3', where clinical diagnosis is an indefinable component.

Figure 1. Keystones of the International Caries Classification and Management System (ICCMS™). Copyright© 2018 Ismail AI, Pitts NB, Tellez M. The International Caries Classification and Management System (ICCMS™) an example of a caries management pathway. *BMC Oral Health* 2015;15(Suppl 1):S9. Reproduced with permission.



Role of index test(s)

The role of the proposed electrical conductance devices may vary according to whether the purpose of the examination is detection or diagnosis. For detection or case-finding, the electrical conductance device could, in theory, be used as a stand-alone test. However, some form of implicit visual assessment will be required for correct placement of the device. In clinical practice, a conventional oral examination would always be undertaken as part of the clinical examination, and as such, it is unlikely that any of the index tests under evaluation would be used as a complete replacement for the combined activities of detection and diagnosis of early decay. Supplementing the visual-tactile examination with an index test could aid in the detection of early decay. The index tests could also have a triage role in assisting the general dentist to more accurately assess signs of uncertain clinical significance. The information from caries detection (including assessment of the severity of disease) will be an integral part of a diagnosis, which additionally incorporates patient history, risk factors, and treatment planning protocols.

Alternative test(s)

Alternative tests include.

- Fluorescence: the breakdown of enamel alters the characteristics of its structure, and when exposed to light-inducing fluorescence diseased teeth respond differently to sound teeth. There is potential for mineral loss to be quantified and used to aid the diagnostic decision and treatment pathway (Angmar-Månsson 2001; Matos 2011). Fluorescence is typically divided into laser fluorescence and light fluorescence (i.e. DIAGNOdent type devices and quantitative light-induced fluorescence (QLF) type devices).
- Comprehensive visual or visual-tactile examination with a detailed classification system: identifying caries according to visual appearance, aided by a dental mirror and sometimes a probe, on clean and dry teeth.
- Radiography: bitewing radiology is the most commonly used method. Other techniques include subtraction radiography which produces a semi-automated method for monitoring progression of lesions (Ellwood 1997; Wenzel 1995), and cone beam computed tomography (CBCT) which provides a three-

dimensional image which appears to offer great potential for diagnosis with increased levels of radiation (Horner 2009).

- Fibre-optic transillumination (FOTI) which uses a light emitted from a handheld device which when placed directly onto the tooth illuminates the tooth (Pretty 2006). Any demineralisation should appear as shadows in the tooth due to the disruption of the tooth's structure due to caries.

Rationale

Despite technological advancement, the typical method of caries detection is currently based upon information from a visual-tactile clinical examination with or without radiographs. There have been several systematic reviews of visual or visual-tactile examinations. Bader 2002 completed an extensive review of in vitro studies investigating visual, radiographic, fibre-optic, electrical conductance, and fluorescence in detecting caries in the primary and permanent dentition. This review was limited to studies with histological reference standards, and grouped studies according to index test, disease threshold (enamel or dentinal lesions), and tooth surfaces (occlusal or proximal); a meta-analysis was not undertaken and the authors graded the quality of the available evidence as low (Bader 2002). A more recent narrative review focused solely on electrical conductance on non-cavitated carious lesions and included six studies. The results showed promise for these devices, with a range of reported sensitivities from 0.61 to 0.92 and specificity from 0.73 to 1.00 (Gomez 2013). Both reviews predate the development of meta-analysis methods for DTA reviews recommended in the *Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy* (Deeks 2013).

In this Cochrane Review, we have included contemporary studies irrespective of publication language and status, and built upon existing research to incorporate methodological developments by: expanding the search strategy to capture all relevant evidence, applying appropriate hierarchical analysis (Dinnes 2016), and assessing the body of evidence using GRADE (Schünemann 2020; Schünemann 2020a) to facilitate the production of 'Summary of findings' tables.

OBJECTIVES

To establish the diagnostic accuracy of electrical conductance devices for the detection and diagnosis of coronal dental caries in children and adults.

The specific research questions addressed in this systematic review were.

- What is the diagnostic test accuracy of electrical conductance tests for detection or diagnosis in different populations (children: primary/mixed dentition, adolescents: immature permanent dentition, or adults: mature permanent dentition); and when tested against different reference standards?
  - What is the diagnostic test accuracy of each device type compared to an appropriate reference standard for detecting and diagnosing initial stage decay on the occlusal, proximal, and smooth tooth surfaces?

Secondary objectives

We aimed to investigate the following potential sources of heterogeneity.

- Recruited population: children, adolescents, or adults.
- Reference standard.
- Tooth surface being evaluated (occlusal, proximal, smooth surface, or adjacent to a restoration).
- Prevalence of caries into dentine.
- Participants or teeth with previously applied restorations (secondary caries) and pit and fissure sealants.
- Consideration of multiple sites versus single point assessment.

METHODS

Criteria for considering studies for this review

Types of studies

We considered diagnostic accuracy study designs that were:

- studies with a single set of inclusion criteria that compared an electrical conductance device test with a reference standard. We included prospective studies that evaluated the diagnostic accuracy of single index tests, and studies that directly compared two or more index tests;
- randomised controlled trials (RCTs) of the diagnostic test accuracy of one or more index tests in comparison, or versus a no test option;
- 'case-control' type accuracy studies where different sets of criteria were used to recruit those with or without the target condition, although prone to bias some innovative tests may be identifiable through this design only and this may provide an opportunity to report them, these studies would not be included in the primary analysis;
- studies reporting at both the patient and tooth or tooth surface level were included, however only those reporting at the tooth surface level would be included in the primary analysis.

In vitro and in vivo studies were considered. In vitro studies occur where teeth have been extracted before the study has started and where caries status is still to be determined. The index test could then be performed, albeit in a scenario which is not representative of the typical clinical setting, this would often be followed by a reference standard of histology. In vivo studies recruit participants and conduct index tests and sometimes reference standard with the teeth in the oral cavity, without extraction of the teeth and subsequent histological assessment. An exception could occur when the index test was conducted on participants with teeth indicated for extraction, due to orthodontic, third molar extraction or periodontal reasons, or teeth in children which were due to exfoliate.

We excluded studies where:

- artificially created carious lesions were used in the testing procedure;
- an index test was used during the excavation of dental caries to ascertain the optimum depth of excavation.

Participants

Participants who were seemingly asymptomatic for dental caries, but may still have had early or severe caries which are undetected at the point of recruitment. Studies that explicitly recruited participants with more advanced lesions that were obviously into dentine or frankly cavitated were excluded, as were those with

participants referred to secondary care for restorative treatment as there is a likelihood that advanced caries (into dentine or pulp) would be present and readily detectable without the need for the index tests investigated in this review.

Studies recruiting children, adolescents, and adults were all eligible for inclusion, as this allowed for the analysis of the diagnostic test accuracy of index tests for primary/mixed dentition of children and adolescents, or the mature permanent dentition of adults.

Index tests

Electrical conductance-based devices used alone, as an adjunct to a visual examination, or in combination with another electrical conductance device. The outputs from these devices may require operator judgement to determine the presence or absence of disease, or may themselves determine presence or absence of disease based on a pre-determined device threshold.

These index tests were completed on intact teeth and could be intended for use as an adjunct to or replacement for aspects of the current clinical examination. We intended to assess each of the different devices used alone wherever possible. Otherwise, where multiple devices have been used in combination and where the results of the different devices could not be isolated, we planned to report the results of these studies separately.

Where studies used multiple examiners the results of the most suitable examiner to the research question were selected. For example, if the study used dental students, general dental practitioners, and restorative consultants, then the results from the general dental practitioners were chosen. In the scenario where multiple examiners were reported to have similar skills and experience then the mean sensitivity and specificity values were extracted. If this was not available then the first set of reported results was selected.

Target conditions

Coronal caries: initial stage decay, defined as early or incipient caries or non-cavitated lesions. Specifically where there was a detectable change in enamel evident which was not thought to have progressed into dentine on occlusal, proximal, or smooth surfaces.

Reference standards

Several different reference standards have been used in primary studies for detection and diagnosis. The only way of achieving a true diagnosis of caries presence and depth is to extract and section a tooth and then perform a histological assessment (Downer 1975; Kidd 2004). This approach is commonly undertaken on previously extracted teeth for in vitro studies but unethical for a healthy population in clinical (in vivo) studies. The only scenario where histology could be appropriate for studies undertaken in a primary or secondary care dental setting would be where a tooth has been identified as requiring extraction (ideally for a non-caries related reason, such as orthodontic extraction or third molar extraction), the index test could be applied prior to extraction, and followed by a reference standard of histology. This would bring into question the study's broader external validity as these types of studies are most likely to occur in adolescents or young adults who may have a lower prevalence of disease than an adult population and are therefore not representative of the wider population.

Alternatives to extraction and histological assessment are operative exploration, where a clinician removes caries with a dental burr (drill) in preparation for a restoration and reports the depth of decay. This technique would be acceptable as a reference standard for patients with caries where restoration is required, but would not be ethical for caries-free patients or those with early caries since non-restorative treatment could be provided. A different reference standard would be required for these early lesions, the possibilities available are limited to an enhanced visual examination or radiographic tests. Studies that only used an enhanced visual or radiographic examination would be included in the review as they have the benefit of allowing studies to be conducted in a clinical setting, however, the limitations of their ability to provide a true classification of disease would be identified in the quality appraisal. Some primary studies have employed a composite reference standard based on the results of information from multiple sources.

A period of up to three months between the index test and reference standard was deemed acceptable.

Search methods for identification of studies

Electronic searches

Cochrane Oral Health's Information Specialist conducted systematic searches in the following databases without language or publication status restrictions:

- MEDLINE Ovid (1946 to 26 April 2019) (Appendix 1);
- Embase Ovid (1980 to 26 April 2019) (Appendix 2).

Searching other resources

The following trial registries were searched for ongoing studies:

- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (clinicaltrials.gov/; searched 26 April 2019) (Appendix 3);
- World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch; searched 26 April 2019) (Appendix 4).

We searched the reference lists of included papers and previously published systematic reviews for additional publications not identified in the electronic searches.

Data collection and analysis

Selection of studies

Two review authors independently screened and assessed the results of all searches for inclusion. Any disagreements were resolved through discussion and, where necessary, consultation with another clinical or methodological member of the author team. Studies were excluded if they failed to present the data in a 2 x 2 contingency table, or failed to report sufficient information to enable a 2 x 2 table to be constructed. In such instances, the study authors were contacted and the required data requested. An adapted PRISMA flowchart was used to report the study selection process (McInnes 2018).

Data extraction and management

Two review authors extracted data independently and in duplicate using a piloted data extraction form based on the review inclusion

criteria. Disagreements were resolved through discussion with other members of the review team. Where data were reported for multiple surfaces, data were extracted separately for each surface. Study authors were contacted to obtain missing data or characteristics which were not evident in the published paper.

We recorded the following data for each study:

- sample characteristics (age, sex, socioeconomic status, risk factors where stated, number of patients/carious lesions, lesion location, disease prevalence at enamel and dentine thresholds);
- study setting (country, type of facility);
- the type of index test(s) used (category (i.e. electronic caries monitor (ECM), CarieScan Pro, or other), device used, mode of action, conditions (i.e. clean/dried teeth), positivity threshold);
- study information (design, reference standard, case definition, training, and calibration of personnel);
- study results (true positive, true negative, false positive, false negative, any equivocal results, withdrawal).

Assessment of methodological quality

We used the Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2) to assess the risk of bias and applicability of the eligible primary studies over the four domains of participant selection, index test, reference standard, and flow and timing (Whiting 2011), tailored for this review. 'Review specific' descriptions of how the QUADAS-2 items were contextualised and implemented are detailed in the accompanying checklist (Additional Table 2).

A 'Risk of bias' judgement ('high', 'low' or 'unclear') was made for each domain. Generally, when the answers to all signalling questions within a domain were judged as 'yes' (indicating a low risk of bias for each question) then the domain was judged to be at low risk of bias. If any signalling question was judged as 'no', indicating a high risk of bias, the domain was scored as high risk of bias. There was some flexibility within this assessment framework which is described below.

Risk of bias assessments were followed by a judgement about concerns regarding applicability for the participant selection, index test, and reference standard domain which developed during the data extraction process and is detailed below.

Participant selection domain (1)

The selection of patients has a fundamental effect on the ability of an index to detect caries. It was essential that the disease stages of sound and enamel caries be represented in the sample and that the age range of patients was reported to form a complete appraisal of the test's potential to correctly classify disease in different populations.

It was acceptable for studies to focus on one particular surface (occlusal/approximal) or a particular age group (children/adults). Given that the primary objective centred on early enamel lesions, studies should be reporting on this stage of the disease process. It was vital that within the chosen population all participants or teeth meeting the eligibility criteria should be provided with an equal or random opportunity to be included as inappropriate exclusion may lead to an over or underestimation of the test's accuracy.

All studies should have reported the methods used to select teeth, ideally a random or consecutive selection. The disease stages included in the study sample and the prevalence of each stage of disease should also be reported.

Study results should be reported at the tooth or surface level, as opposed to the patient level, which has the potential for the index test and reference standard to be reporting on different sites within the same mouth.

Index test domain (2)

The nature of the electrical conductance index tests and the visual presentation of the disease means that it should be feasible to ensure that the index test is conducted prior to the reference standard. Logically the electrical conductance tests had to be completed before the extraction of a tooth for any histological analysis, or before in situ excavation of a tooth was undertaken. This order of presentation (index tests then reference standard) ensured that the index test was not influenced by the results of the reference standard. The electrical conductance index tests generally use a device which reports a numerical value on a continuous scale. Where multiple index tests are used and where the electrical conductance index test is conducted after other index tests (e.g. radiograph), the objective reading and reporting of the fluorescence-based device mean that it cannot be influenced by preceding tests.

The threshold of disease positive and negative should be presented prior to analysis, ideally, the manufacturers recommended settings or thresholds recommended by previously validated studies. It is unlikely that studies will have utilised multiple index test examiners for the assessment of different disease severity or where they have it is probable that they each score all of the thresholds and are included for validation of the test. However, the inclusion of a signalling question here allowed for the identification of studies that have achieved this and provided data to inform future discussions.

Reference standard domain (3)

If the reference standard was an enhanced visual examination or radiograph then it should be completed by an examiner different to the index test, as the subjectivity of this type of reference standard could be influenced by knowledge of the index test results. An exception was built in for this signalling question - where the tooth has been extracted, sectioned, and prepared for histological evaluation it is extremely unlikely that the examiner would be able to recall the specific tooth or participant and the results from the index test results. Time delays between index test and reference standard should be under three months for in vivo studies.

Ideally, each participating tooth or patient within a study should be exposed to the same reference test. This is possible in the in vitro setting as each selected tooth can have a histological assessment applied. In vivo studies may have applied the same reference standard by using enhanced visual examination or radiograph to all participants. If a study allocated participants or specific teeth to different reference standards then reasons for this allocation should have been reported. All reference standards should have been completed without knowledge of the index test results.

Flow and timing domain (4)

The index test should be conducted prior to the reference standard. If the reference standard used is enhanced visual, radiograph, or

excavation then there should be less than three months between index test and reference standard. Caries is a slow-growing disease so minimal changes should be experienced within this time frame. All observations should receive both an index test and reference standard. There are studies which report some teeth having an index test but not a reference standard; if a reason is clearly reported, such as teeth being broken during sectioning, then this would not influence the risk of bias decision.

Statistical analysis and data synthesis

The threshold of interest was between sound teeth and initial/early/enamel caries. This effectively created two groups, a positive group with any caries from early to advanced and a negative group of sound or healthy teeth. Estimates of diagnostic accuracy were expressed as sensitivity and specificity with 95% confidence intervals for each study and each available data point if there were multiple index tests, dentition (primary/permanent), or surfaces (occlusal/proximal/smooth). This information has been displayed as coupled forest plots and plotted as summary receiver operating characteristic (SROC) plots, displaying the sensitivity-specificity points for each study. When there were two or more test results reported in the same study, we included them as separate datasets, since the unit of analysis was the test result, not the patient.

Hierarchical models were used for data synthesis. The data were extracted for the target condition of early caries (caries into dental enamel) at the tooth surface level. This target condition has been consistently used across the suite of caries detection reviews. A meta-analysis was conducted to combine the results of studies for each index test using the hierarchical summary receiver operating characteristic (HSROC) approach. A summary curve using the HSROC model (Rutter 2001) was used to summarise the results since the devices provided a numeric output on a continuous scale and often interpreted these at different cut-offs so it was not possible to apply a common threshold for analysis. An HSROC model was used to estimate a summary curve with parameter estimates for threshold, shape and accuracy, for all available datasets with no restrictions on dentition, tooth surface, reference standard, or prevalence of caries into dentine (D_3).

It was not possible to produce estimates of sensitivity and specificity as summary operating points with confidence and prediction regions on SROC plots with 95% confidence regions since the output of the HSROC model is the SROC curve. In the absence of clinical consensus of key values of specificity, we intended to summarise the analysis using the median reported specificity and the corresponding estimate of sensitivity in addition to the diagnostic odds ratio (DOR) with 95% confidence intervals (Takwoingi 2015) if data pooling was appropriate.

We made comparisons between the electrical conductance devices by comparing SROC curves (Takwoingi 2010). Initially, we allowed threshold, shape, and accuracy to vary according to device type by including covariates in the model (most complex model). Differences in the shapes of the summary curves were explored by removing the covariates for shape and comparing the results of this model to those of the complex model. Parameter estimates for the model assuming a common or different shape were used to generate HSROC curves for the three categories as appropriate. If the different devices were observed to have a common shape, then the model was further simplified by removing the covariates for accuracy, to determine whether the accuracy of the different devices differed in comparison with the previous model. The likelihood ratio test was applied to formally assess the significance of any model comparisons (Macaskill 2010).

We used Review Manager 5 (Review Manager 2020) and the NLMIXED procedure and the MetaDAS macro (Takwoingi 2010) in SAS 9.4 for Windows to undertake these analyses.

Investigations of heterogeneity

We initially inspected the clinical and methodological characteristics of the included studies, coupled forest plots, and SROC plots to form the basis of the assessment of heterogeneity. Where sufficient numbers of studies allowed, meta-regression analyses were carried out to explore possible sources of heterogeneity. Formal model comparisons were compared using a likelihood ratio test to determine the statistical significance of adding each potential source of heterogeneity (covariate) to the HSROC model. Model comparisons proceeded as for the comparison of different tests above i.e. fit complex model allowing shape, threshold and accuracy to differ according to the source of heterogeneity, assess the impact of the removal of covariates for the shape parameters, if a common shape can be assumed then explore the impact of removal of the covariates for the accuracy parameters. Each potential source of heterogeneity was analysed separately.

The sources of heterogeneity (specified a priori) were different reference standards, tooth surface, the prevalence of caries into dentine (categorical), studies including previously applied restorations (secondary caries) or pit and fissure sealants, and multiple sites or single point assessment.

Sensitivity analyses

Where a sufficient number of studies investigated the same index test, the following sensitivity analyses were performed by removing studies from the meta-analysis using the MetaDTA interactive web-based tool (Freeman 2019). This enabled us to assess the impact on summary estimates of restricting the analyses according to studies that meet the following criteria:

- low prevalence of dentine caries (i.e. less than 15%);
- low risk of bias for an index test;
- low risk of bias for a reference standard.

Assessment of reporting bias

Methods currently available to assess reporting or publication bias for diagnostic studies may lead to uncertainty and misleading results from funnel plots (Deeks 2005; Leeflang 2008), therefore we did not perform reporting bias tests in the reviews.

Summary of findings and assessment of the certainty of the evidence

We reported our results for electrical conductance devices following GRADE methods (Schünemann 2020; Schünemann 2020a), and using the GRADEPro online tool (www.guidelinedevelopment.org). To enhance readability and understanding, we planned to present test accuracy results in natural frequencies to indicate numbers of false positives and false negatives. The certainty of the body of evidence was assessed for the overall risk of bias of the included studies, the indirectness of the evidence, the inconsistency of the results, the imprecision

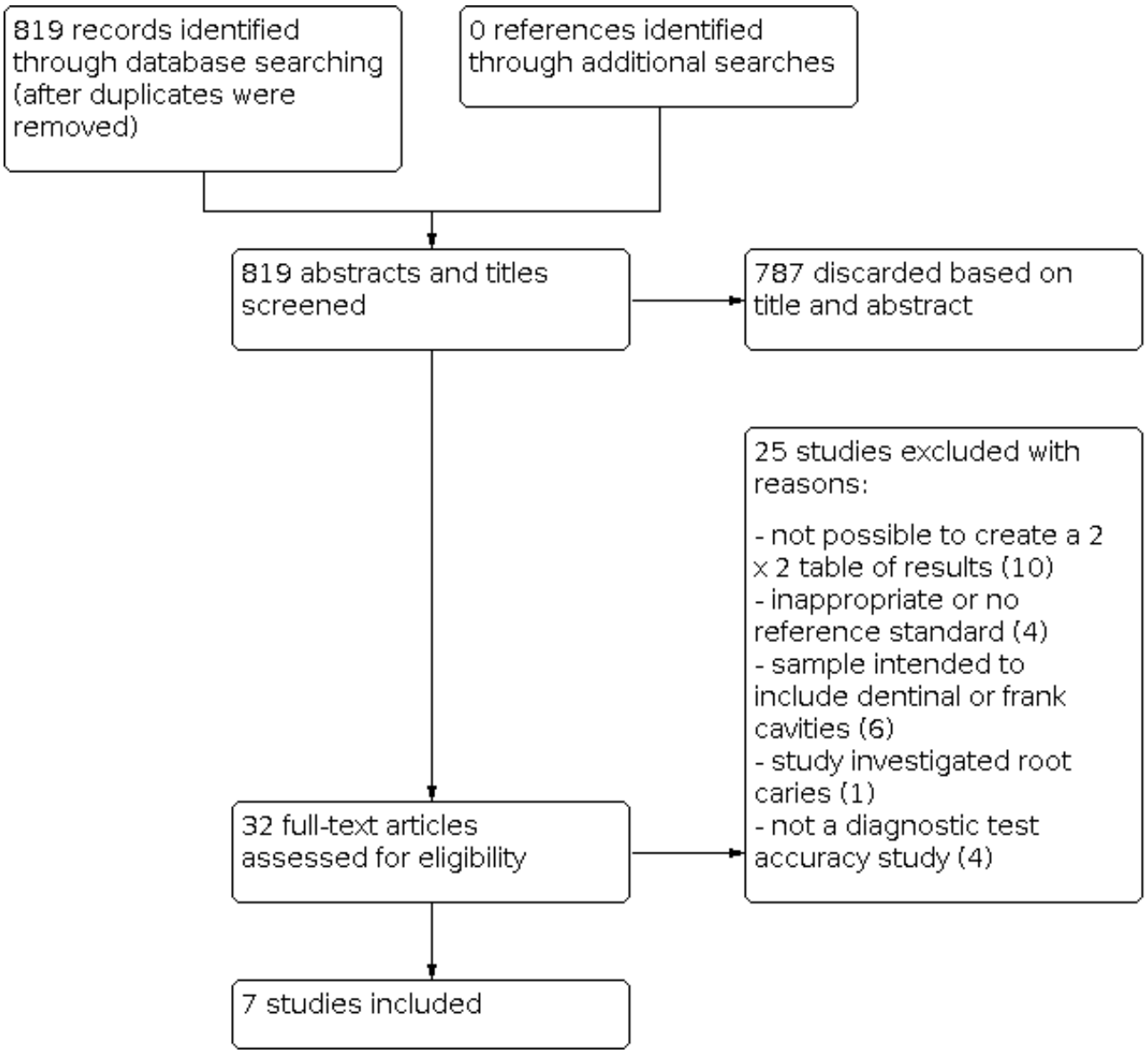
of the estimates, and the risk of publication bias; these have been considered narratively where statistical methods were not available. We categorised the certainty of the body of evidence as high, moderate, low, or very low.

RESULTS

Results of the search

The search retrieved 1315 results, 819 remained after the removal of duplicates. The initial screen of titles and abstracts resulted in the 32 studies being considered for inclusion (Figure 2). Full papers were obtained for these studies, and after further review of the full texts, 25 were excluded. The most common reason for exclusion of studies at this stage was failure to report data in a format that allowed creation of a 2 x 2 table of results at the enamel threshold (Ashley 2000a; Bamzahim 2002; Ekstrand 1997; Ekstrand 1998; Ie 1995; Kuhnisch 2006; Longbottom 2004; Pereira 2009; Tassery 2013; Thomas 2001) or intentional inclusion of frank cavitation or dentinal lesions (Cortes 2003; Ellwood 2004; Kordic 2003; Melo 2015; Ricketts 1997a; Ricketts 1997b). Seven studies investigating two different devices met the inclusion criteria.

Figure 2. Flow diagram.



Four studies used the electronic caries monitor (ECM) device although different versions of the device were used: Ashley 1998 and Ricketts 1997 used a prototype (type II), Pereira 2009 used ECM III, and Kucukyilmaz 2015 used ECM IV. The threshold ranged from 1 to 15. One study used a conductive medium to ascertain the electrical conductance of the tooth surface rather than a single point measurement. The second device, the CarieScan Pro, was used in three studies (Kockanat 2017; Mortensen 2018; Teo 2014). These differed through the choice of thresholds with Kockanat 2017 adopting the manufacturer's recommendation of 21, Mortensen 2018 using a threshold of 51, and Teo 2014

assessing both thresholds (we used the results from manufacturers' recommendations in the main analysis).

Three studies were completed in the UK (Ashley 1998; Ricketts 1997; Teo 2014), two studies in Turkey (Kockanat 2017; Kucukyilmaz 2015), one in Brazil (Pereira 2011), and one in Denmark (Mortensen 2018). Three studies focused on the primary dentition (Kockanat 2017; Kucukyilmaz 2015; Teo 2014) and the other four reported on permanent teeth (Ashley 1998; Mortensen 2018; Pereira 2011; Ricketts 1997). Three studies were completed in vitro on previously extracted teeth and used histology as their reference standard (Ashley 1998; Pereira 2011; Ricketts 1997). A clinical setting (in vivo) was used in three studies with the index tests being completed prior to tooth extraction or exfoliation, followed by a reference standard of histology (Kockanat 2017; Kucukyilmaz 2015; Teo 2014). One study was completed in a clinical setting with an enhanced visual examination as the reference standard (Mortensen 2018). Two studies investigated multiple teeth from a participant; one of these reported 60 teeth from 57 participants (Mortensen 2018) and the other used 32 extracted teeth from 14 participants (Ricketts 1997).

Methodological quality of included studies

None of the included studies can be considered at being at low risk of bias overall according to the QUADAS-2 criteria (Figure 3; Figure 4). Patient selection was at high risk of bias in five studies which clearly reported that participants were selected rather than being recruited consecutively or randomly (Ashley 1998; Kucukyilmaz 2015; Mortensen 2018; Pereira 2011; Ricketts 1997). The concern here is that teeth or participants may have been selected with caries that were more difficult or more straightforward to detect, and that this would introduce bias and influence the results. Kockanat 2017 and Teo 2014 did not report any detail on the participant selection methodology so we were unclear on the level of bias with these studies. Kucukyilmaz 2015 and Teo 2014 were both seen to be at low risk of bias across all other domains of bias and applicability. We could not be certain that the index test device thresholds were predetermined for two studies (Ashley 1998; Mortensen 2018), there was a possibility that these studies selected optimal thresholds which could inflate sensitivity or specificity. Mortensen 2018 had potential for risk of bias in the reference standard domain, as the enhanced visual reference standard may have been influenced by the results of the index test, the remaining studies employed an histological reference standard so there was no risk of bias. One study was found to be at risk of bias for the flow and timing, this was because 24 of the participants were not included in the final results (Kockanat 2017). Three studies were performed on extracted teeth, therefore the applicability of participant selection was seen to be a high risk (Ashley 1998; Pereira 2011; Ricketts 1997).

Figure 3. Risk of bias and applicability concerns graph: review authors' judgements about each domain presented as percentages across included studies.

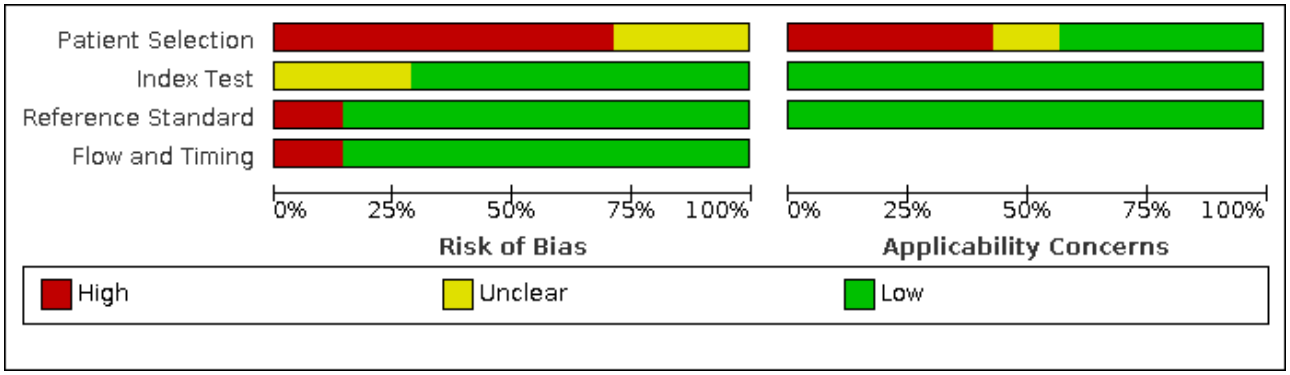
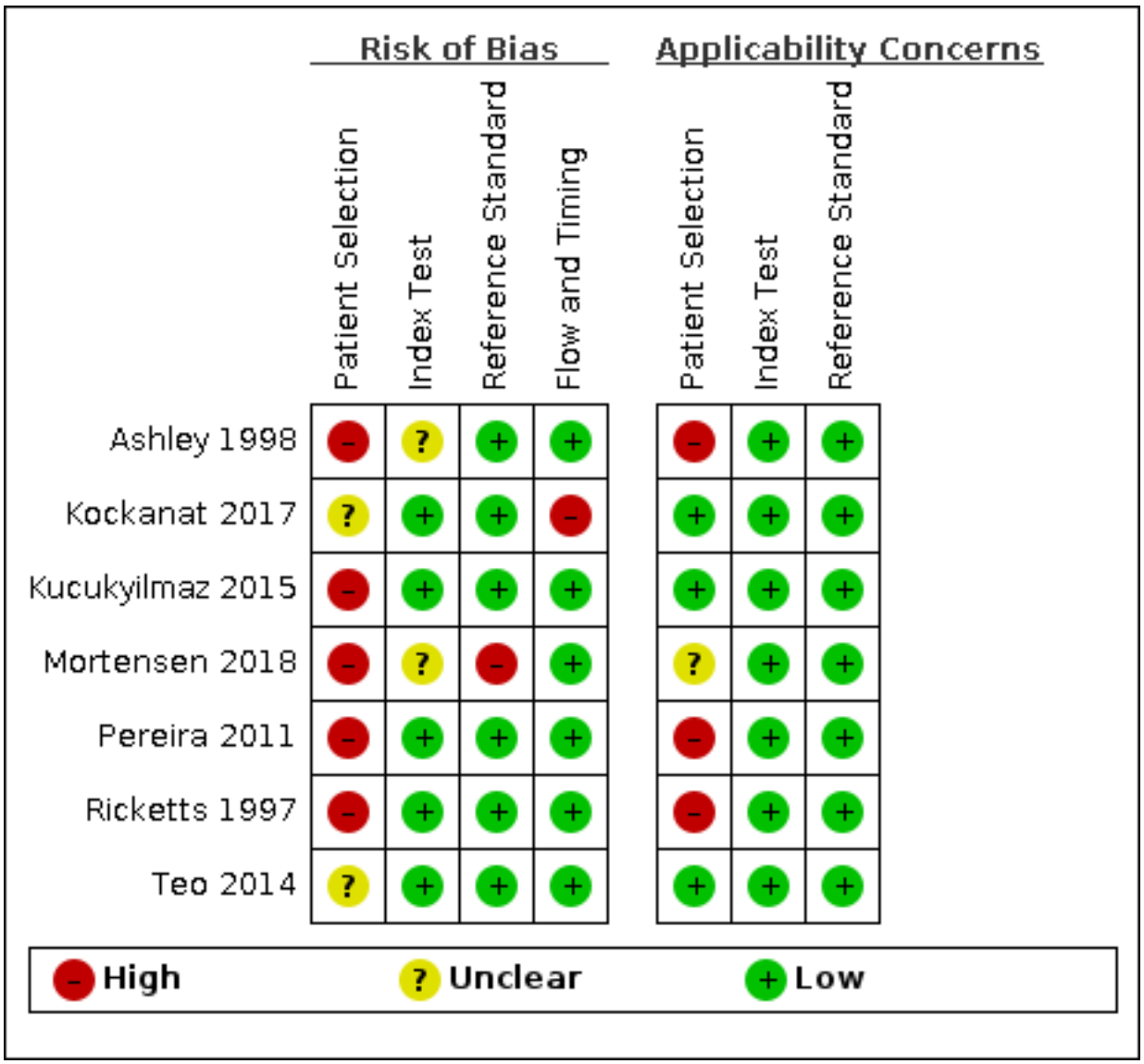


Figure 4. Risk of bias and applicability concerns summary: review authors' judgements about each domain for each included study.



Findings

We evaluated the accuracy of the electrical conductance devices in seven studies, the overall results are shown in Summary of findings 1, and illustrated in Figure 5 and Figure 6. Sensitivity values ranged from 0.55 to 0.98, and specificity from 0 to 1.00. These extreme specificity values may be explained by a low number of healthy tooth surfaces in the study samples. The point of assessment was the tooth surface, no studies reported at the patient level but one study did assess multiple sites on the same surface (Ricketts 1997).

The primary findings are reported for all available datasets with no restrictions on device type, tooth surfaces, dentition, reference standard, or prevalence of caries into dentine. The diagnostic odds ratio (DOR) was 15.65 (95% confidence interval (CI) 1.43 to 171.15). We assessed the certainty of the evidence as very low, and downgraded for risk of bias due to limitations in the design and conduct of the included studies, imprecision arising from the relatively small number of surfaces studies, and inconsistency due to the variability of results.

Figure 5. Forest plot of all included studies grouped by test type.

Study	TP	FP	FN	TN	Test type	Sensitivity (95% CI)	Specificity (95% CI)
Kockanat 2017	86	2	8	24	CarieScan Pro	0.91 [0.84, 0.96]	0.92 [0.75, 0.99]
Mortensen 2018	32	0	26	2	CarieScan Pro	0.55 [0.42, 0.68]	1.00 [0.16, 1.00]
Teo 2014	43	18	3	0	CarieScan Pro	0.93 [0.82, 0.99]	0.00 [0.00, 0.19]
Ashley 1998	40	11	22	30	ECM	0.65 [0.51, 0.76]	0.73 [0.57, 0.86]
Kucukyilmaz 2015	161	1	3	35	ECM	0.98 [0.95, 1.00]	0.97 [0.85, 1.00]
Pereira 2011	34	8	21	33	ECM	0.62 [0.48, 0.75]	0.80 [0.65, 0.91]
Ricketts 1997	30	1	19	26	ECM	0.61 [0.46, 0.75]	0.96 [0.81, 1.00]

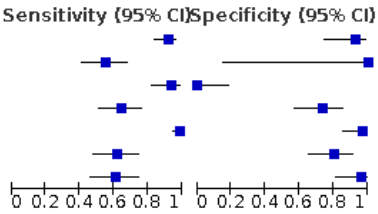
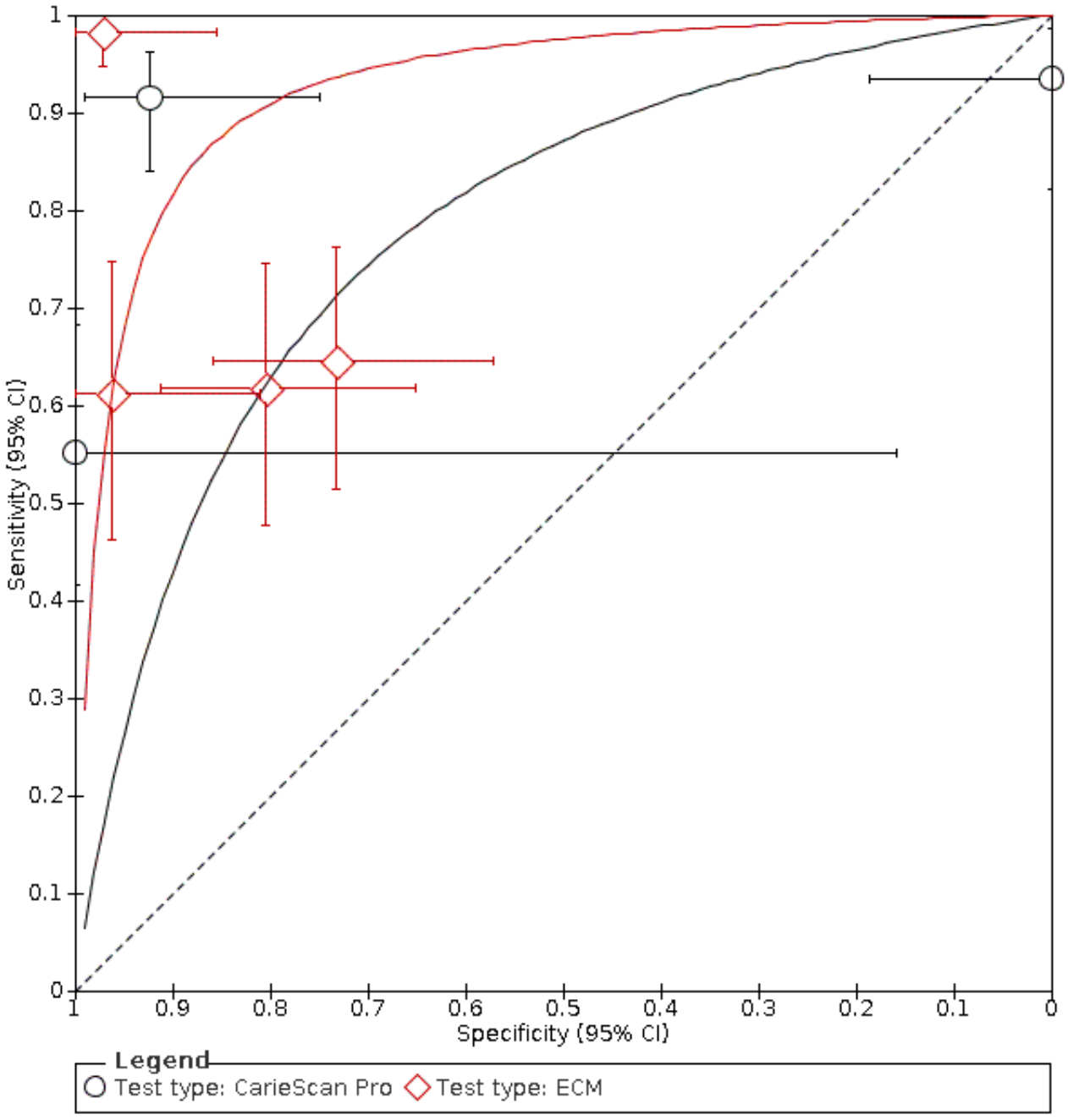


Figure 6. Summary receiver operating characteristic (SROC) plot of all included studies.



The studies were categorised according to device type: ECM (all generations) or CarieScan Pro (CSP) (Figure 5; Figure 6). Four studies evaluated ECM (Ashley 1998; Kucukyilmaz 2015; Pereira 2011; Ricketts 1997) across three different iterations of the device. The sensitivity results for these studies ranged from 0.61 to 0.65 for three studies (Ashley 1998; Pereira 2011; Ricketts 1997) with the most recent study with the latest ECM device reporting the highest sensitivity of 0.98 (Kucukyilmaz 2015). Specificity results were more consistent across the ECM devices, and ranged from 0.73 to 0.96. Three studies evaluated the CarieScan Pro (Kockanat 2017; Mortensen 2018; Teo 2014), one of which used the CarieScan Pro device at two different thresholds, however the dataset reporting results for the manufacturer's threshold was used in the main analysis (Teo 2014). The sensitivity estimates ranged from 0.55 to 0.91 and specificity ranged from 0 to 1.00. Due to the sparsity of the data when assessing the impact of the covariate for test type on the shape, accuracy and threshold, the model failed to converge. Following Takwoingi 2017 we simplified the hierarchical model to assume a symmetric summary receiver operating characteristic (SROC) curve (by excluding the shape parameter). The results of this analysis is plotted in Figure 6. Further simplification of the model by removing the covariate for accuracy had a negligible effect (Chi^2 = 0.05, degrees of freedom (df) = 1, P = 0.82) and we can conclude that there is no evidence of a difference in accuracy according to device type.

We then explored the accuracy estimates according to dentition (Figure 7). Three studies evaluated the primary dentition (Kockanat 2017; Kucukyilmaz 2015; Teo 2014). The sensitivity results for these studies were similar, and ranged from 0.91 to 0.93, however there was substantial variability in specificity, which ranged from 0 to 0.92. Four studies evaluated the permanent dentition (Ashley 1998; Mortensen 2018; Pereira 2011; Ricketts 1997) The sensitivity results for these studies were similar, and ranged from 0.55 to 0.65, and specificity which ranged from 0.73 to 1.00. We simplified the hierarchical model to assume a symmetric SROC curve (by excluding the shape parameter). The results of this analysis is plotted in Figure 8. Further simplification of the model by removing the covariate for accuracy had a negligible effect (Chi^2 = 3.15, df = 1, P = 0.08) and we can conclude that there is no evidence of a difference in accuracy according to dentition.

Figure 7. Forest plot grouped by primary or permanent dentition.

Study	TP	FP	FN	TN	Primary/Permanent	Sensitivity (95% CI)	Specificity (95% CI)
Kockanat 2017	86	2	8	24	Primary	0.91 [0.84, 0.96]	0.92 [0.75, 0.99]
Kucukyilmaz 2015	161	1	3	35	Primary	0.98 [0.95, 1.00]	0.97 [0.85, 1.00]
Teo 2014	43	18	3	0	Primary	0.93 [0.82, 0.99]	0.00 [0.00, 0.19]
Ashley 1998	40	11	22	30	Permanent	0.65 [0.51, 0.76]	0.73 [0.57, 0.86]
Mortensen 2018	32	0	26	2	Permanent	0.55 [0.42, 0.68]	1.00 [0.16, 1.00]
Pereira 2011	34	8	21	33	Permanent	0.62 [0.48, 0.75]	0.80 [0.65, 0.91]
Ricketts 1997	30	1	19	26	Permanent	0.61 [0.46, 0.75]	0.96 [0.81, 1.00]

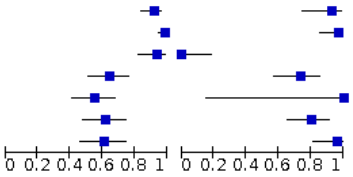
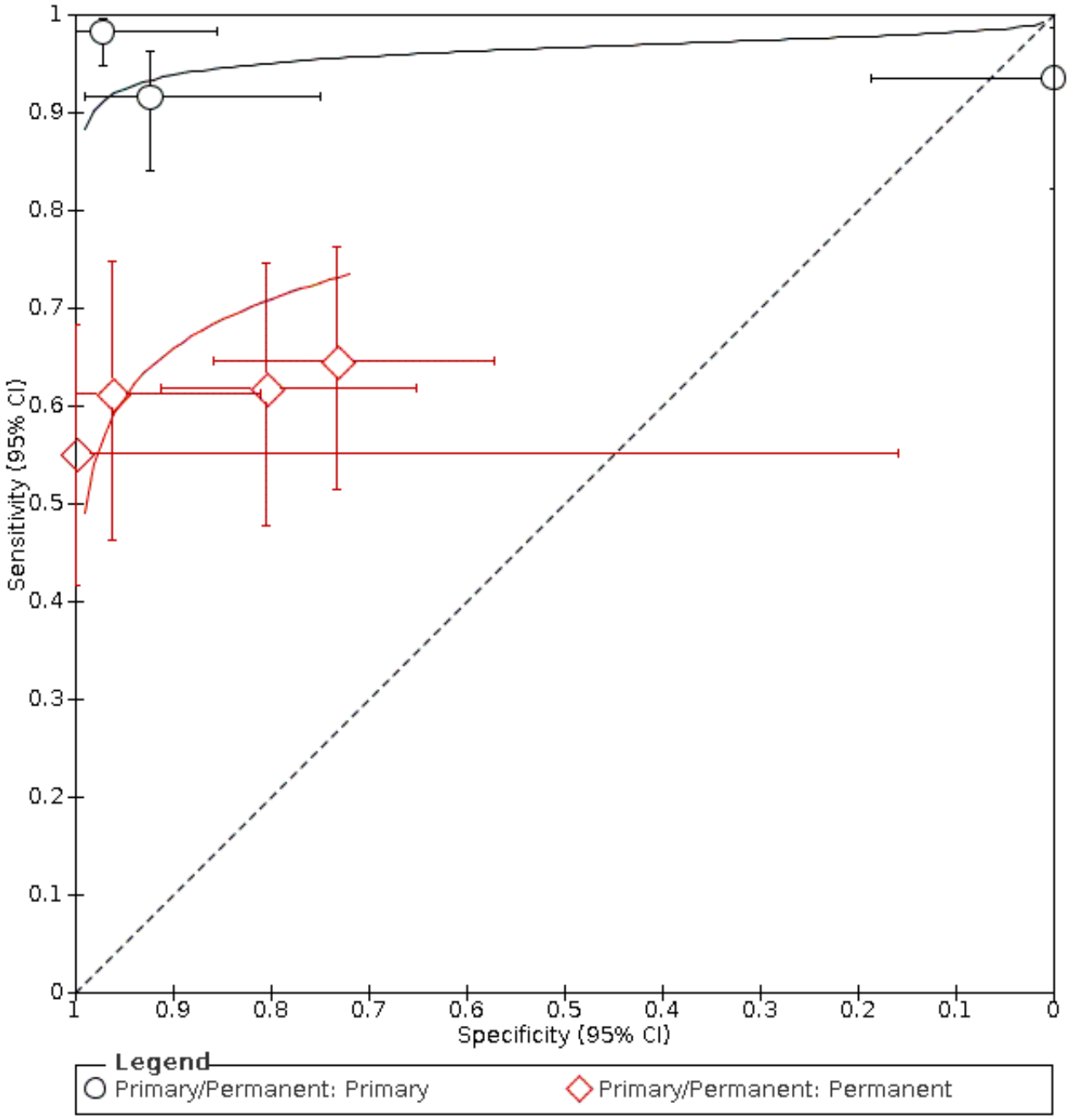


Figure 8. Summary receiver operating characteristic (SROC) plot grouped by primary or permanent dentition.



Investigations of heterogeneity

As there was no evidence of any differences in accuracy across the different devices, investigations of potential sources of heterogeneity were conducted across all seven included studies. We had planned to use meta-regression to explore the potential sources of heterogeneity, but the small number of studies or the distribution across particular subgroups, precluded formal investigations of heterogeneity.

Reference standard/in vivo in vitro studies

All studies employed a reference standard of histology with the exception of Mortensen 2018 where an enhanced visual examination was used on teeth in situ. We attempted to evaluate differences in accuracy for in vivo and in vitro studies. Even when the model was simplified to include covariates for the accuracy and threshold parameters alone we observed missing standard errors and unstable pooled estimates.

Tooth surface

All studies assessed the use of the electrical conductance devices on occlusal surfaces.

Prevalence of d_3/D_3 caries

No studies reported the inclusion of a low prevalence (0% to 14%) of d_3/D_3 of tooth surfaces. Five studies (Kockanat 2017; Kucukyilmaz 2015; Pereira 2011; Ricketts 1997; Teo 2014) reported the inclusion of a medium prevalence (15% to 34%) of d_3/D_3 of tooth surfaces, with two studies (Ashley 1998; Mortensen 2018) reporting the inclusion of a medium prevalence (15% to 34%) of d_3/D_3 of tooth surfaces.

Teeth with previously applied restorations or pit and fissure sealants

No included studies reported inclusion criteria of previously applied restorations or pit and fissure sealants.

Point measurement, imaging, or surface assessment

Only one study (Ricketts 1997) assessed multiple sites on the same surface.

Sensitivity analyses

Sensitivity analyses have been limited due to the small number of studies satisfying the criteria. Sensitivity analysis was proposed restricting studies to:

- low risk of bias for the index test domain: two studies (Ashley 1998; Mortensen 2018) were judged to be at unclear risk of bias for this domain and were therefore excluded from the sensitivity analysis. This had little impact on the summary curve (Figure 9);
- low risk of bias for the reference standard domain: one study (Mortensen 2018) was judged to be at high risk of bias for this domain and was therefore excluded from the sensitivity analysis. This had very little impact on the summary curve (Figure 10);
- low (< 15%) prevalence of d_3/D_3 caries: all included studies reported prevalence of d_3/D_3 caries of 15% or above.

Figure 9.

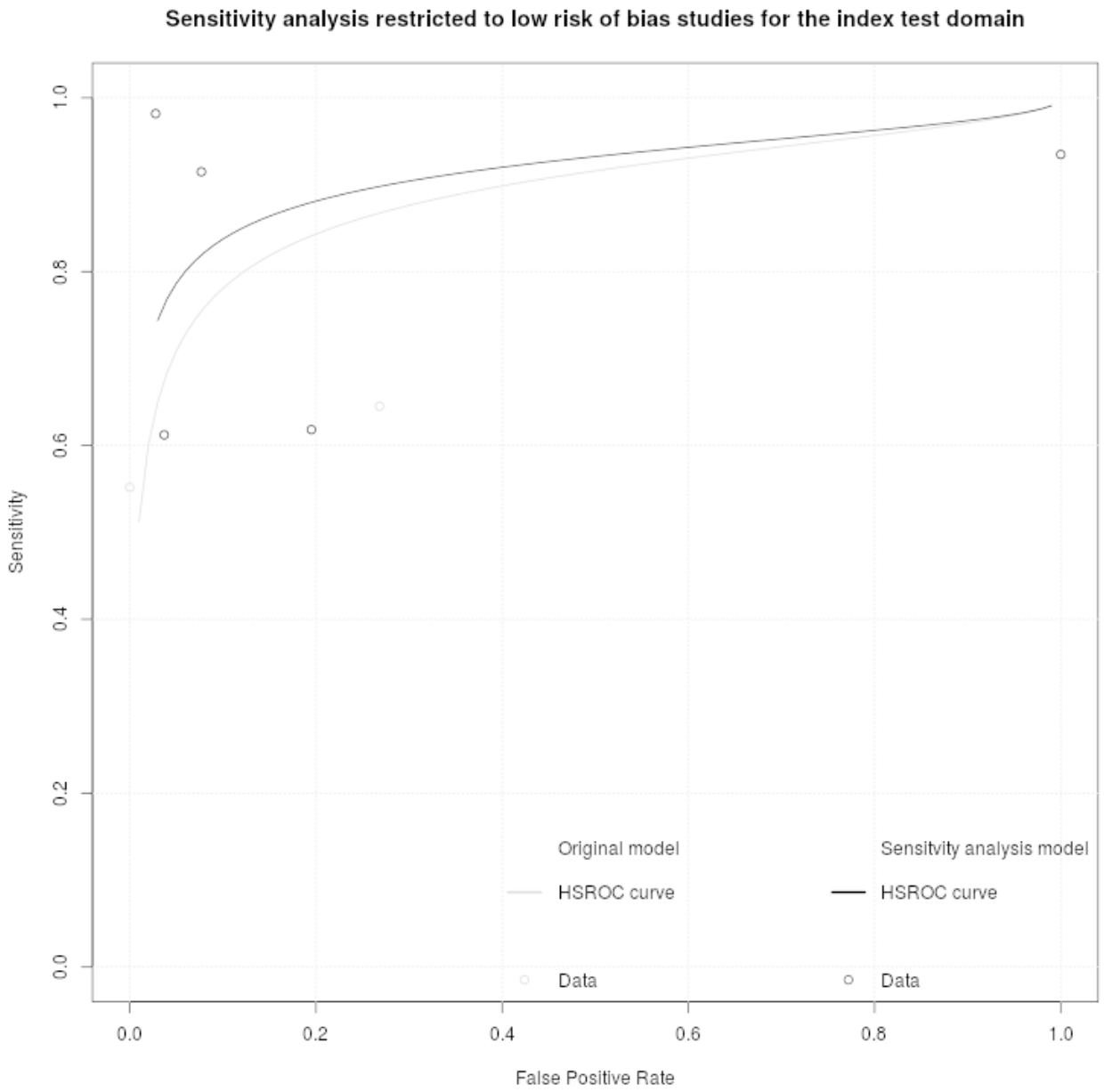
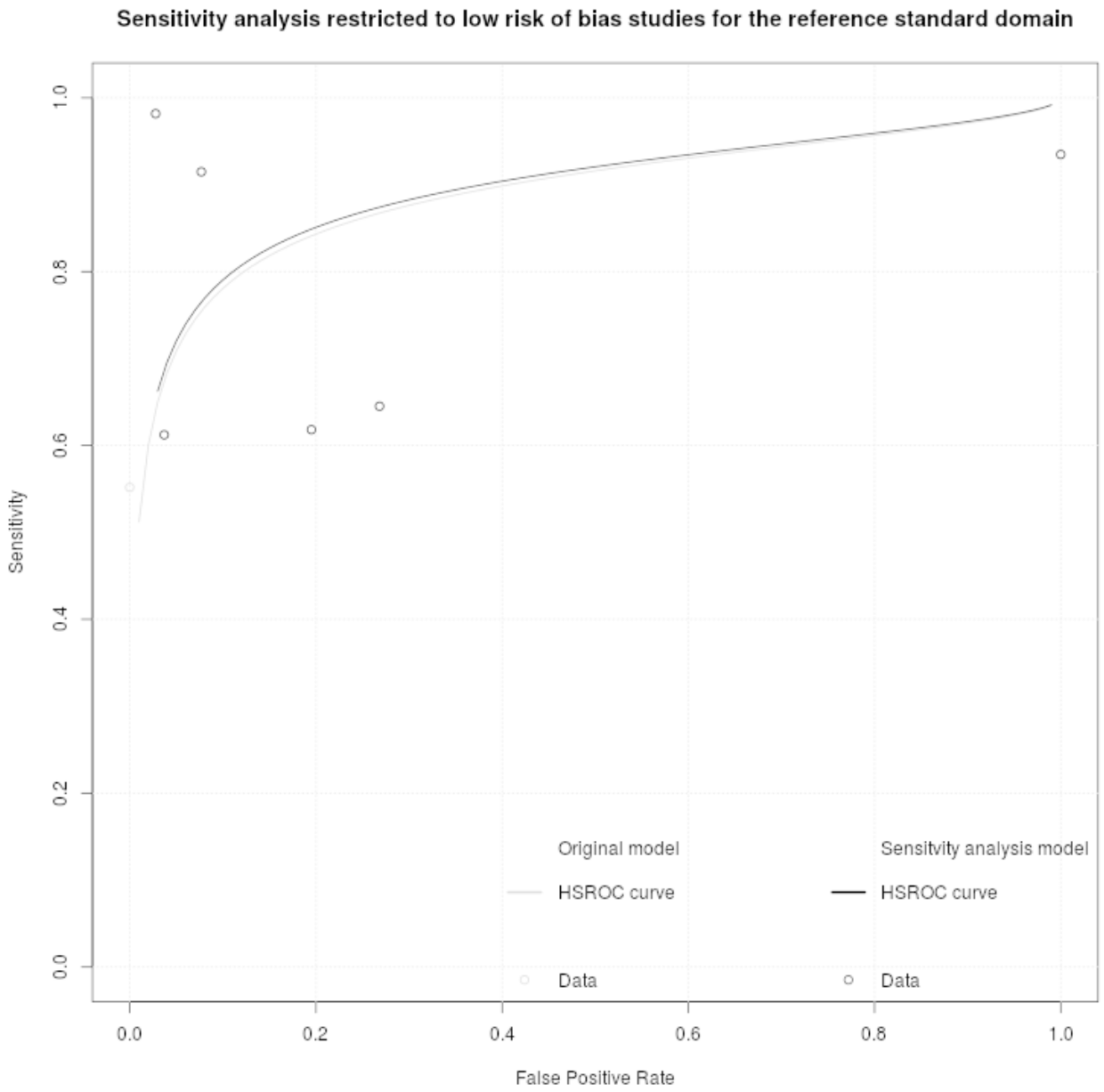


Figure 10.



DISCUSSION

Summary of main results

Following a comprehensive search of the literature only seven studies were identified that met the eligibility criteria for this review.

The overall certainty of the evidence was judged to be very low (Summary of findings 1), and downgraded for risk of bias and study limitations arising from sample selection, imprecision arising from the relatively small number of surfaces studied, and inconsistency due to the variability of results. No studies were judged to be at low risk of bias across all domains, but study limitations were greatest for the patient selection domain, specifically the non-random or non-consecutive selection of the study samples.

Due to the small number of studies and in the absence of clinical consensus, we elected not to report summary estimates of sensitivity at fixed values of specificity from the hierarchical summary receiver operating characteristic (HSROC) model as a means of expressing numerical quantities from the curve. From the individual studies, values of specificity were generally higher than those for sensitivity suggesting that the electronic caries monitor (ECM) device was more accurate at identifying healthy tissue than early signs of disease. The relatively small sample sizes of healthy tooth surfaces sometimes resulted in extreme values of specificity. In interpreting the results from these studies it should be borne

in mind that two (Ashley 1998; Ricketts 1997) of the four studies date from the 1990s and use previous generations of the ECM device which are no longer commercially available. One recent study (Kockanat 2017) of the CarieScan Pro showed considerable promise for the device with sensitivity and specificity values greater than 0.90.

We used meta-regression to formally assess potential differences in accuracy estimates according to device type and dentition. Results indicated that accuracy measures were similar according to device and dentition. Where there were sufficient numbers of studies we explored additional potential sources of heterogeneity, but none of the patient or study characteristics were found to attribute for the substantial variation in results.

Strengths and weaknesses of the review

This is the first time, to our knowledge, that a systematic review of electrical conductance devices has been attempted at the enamel threshold. In this systematic review we have built upon existing research to incorporate methodological developments through a comprehensive and unrestricted search of the literature to capture all relevant evidence, the use of appropriate hierarchical analysis, and presentation of the certainty of evidence using GRADE notation.

Despite the comprehensive search strategy, the number of included studies is reflective of the lack of studies evaluating the accuracy of electrical conductance devices for our chosen target condition. The low number of studies is somewhat surprising given that the technology has been available since the late 1990s and it was considered to have great potential upon its introduction (Longbottom 2004). The inclusion criteria, particularly the choice of target condition, may have limited the number of eligible studies, but in line with our objective we believe it was necessary to exclude studies which assessed cavitated lesions which could have easily inflated accuracy estimates. The design and conduct of studies to detect and diagnose caries in situ is particularly challenging. Four studies were undertaken in a clinical setting, providing good generalizability of the results to the real-world setting. Finding a suitable reference standard for in vivo studies is especially difficult and whilst the use of histology following exfoliation or extraction of teeth or enhanced visual examination may be imperfect, it enables the evaluation of teeth in situ to be conducted in a clinical setting.

Further, it is important to consider that the expertise of the operator may impact substantially on the observed accuracy of caries detection, and requires training to a greater or lesser degree to reach an acceptable standard of operability. The ECM device requires the accurate placement of the probe tip to successfully detect caries. Alternative caries detection devices reported in this series of Cochrane Reviews allow for the entire surface of the tooth to be scanned (for example fluorescence- or transillumination-based devices (Macey 2020; Macey 2021)), whereas the ECM devices reported in this review were used in 'site specific' mode. Other studies such as that of Ricketts 1997a have investigated the effect of using ECM with a contact media spread over the surface of the tooth, but these did not meet our inclusion criteria. The CarieScan Pro device attempts to mitigate the requirement for accurate placement of the tip by deploying a tufted tip (with multiple metal fibres) that make contact with a larger surface area of tooth tissue. Whilst recent studies show promise the evidence for the use of this device at present is limited.

Applicability of findings to the review question

There are concerns that three of the included studies are of an in vitro design and not wholly representative of the clinical examination performed by a general dental practitioner in a clinical setting. However, four of the seven included studies were completed in the clinical setting of a dental hospital and, of these, three employed a histological reference standard so we can have confidence that the true caries classification was observed.

AUTHORS' CONCLUSIONS

Implications for practice

Based on the very low certainty of the evidence and the low number of included studies there is little evidence in this Cochrane Review to support the widespread introduction of electrical conductance devices as an adjunct to clinical examination.

Implications for research

Whilst the certainty of the evidence overall is very low, the results of the most recent incarnations of the electrical conductance devices show promise. However, the number of included studies and tooth surfaces assessed is low, and additional studies using a robust study design with a target condition of a detectable change in enamel not progressed into dentine would be informative.

Future studies must be considerate when selecting participants or teeth, it is imperative that a random or consecutive method is employed to minimise the risk that easy or difficult to diagnose carious lesions are overtly included in the sample. Studies should also aim to include sufficient numbers of sound and carious teeth, reflective of the spectrum of disease, as otherwise there is a risk that there may not be sufficient teeth to construct meaningful data on either sensitivity or specificity. Studies should ideally adopt the manufacturer's recommended thresholds, as this would be the operating point typically adopted by the general dental practitioner, as opposed to a data driven positivity threshold. Guidance on an appropriate reference standard is difficult, as the clinical relevance of conducting studies in a real-world clinical setting needs to be offset against the use of histology with extracted teeth as the optimum reference standard. One option, as per three included studies, is an in vivo clinical examination with the index test in a clinical setting prior to the extraction of indicated or exfoliated teeth which are then subject to histological assessment. One drawback to this approach is that participants referred for extraction may be limited in scope, for example adolescents requiring extractions prior to orthodontic treatment or patients with severe caries elsewhere in the oral cavity, and results may not be completely generalisable to the broader population.

Finally, we would advocate the use of the STARD checklist (Bossuyt 2003; Cohen 2015) when reporting studies not only for full transparency, but also to maximise the possibility of studies being included in any future systematic review.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Ashley 1998

Study characteristics	
Patient Sampling	Method of sampling: selected Included conditions: no cavitation and early lesions Teeth: permanent premolars and molars Sealants: excluded Restorations: excluded Surface: occlusal
Patient characteristics and setting	Age: not reported Sex: not reported Ethnicity: not reported Country: UK Setting: extracted teeth Number of participants/teeth/sites: 103 teeth/103 sites Prevalence: enamel 0.60, dentine 0.36
Index tests	Category of test: ECM (type IIb, P Borsboom, Sensortechnology and Consultancy BV, the Netherlands) Methods: conductive medium of toothpaste applied to entire surface of tooth Sequence of test(s): random order of ECM, FOTI and radiography with delays between each test to ensure independence prior to reference standard Examiner training and calibration: 1 examiner Teeth cleaning prior to examination: not reported Tooth drying prior to examination: crown was dried with compressed air for 20 seconds Threshold applied: > 0.501 sound, 0.391 to 0.501 enamel, < 0.391 dentine Device specifics: "low range impedance measurements (range 0-2)"
Target condition and reference standard(s)	Category: histology Sequence of index test and reference standard: index test then reference standard Training of examiner: not reported Blinding to index test: unclear Multiple tests: no Site selection: sectioned teeth Target condition: sound, enamel, dentine
Flow and timing	Participants with index test but no reference standard: 0

Ashley 1998 *(Continued)*

	Participants with reference standard but no index test: 0 Time interval between tests: minimal Participants receiving both tests but excluded from results: 0
Comparative	
Notes	Data used from the in vivo element of the study at the cut-off of 21: "Although CarieScan PRO had a high sensitivity, it showed no specificity whatsoever at the D1 cut-off 21"

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
Could the selection of patients have introduced bias?		High risk	
Are there concerns that the included patients and setting do not match the review question?			High
DOMAIN 2: Index Test (All tests)			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Unclear		
Could the conduct or interpretation of the index test have introduced bias?		Unclear risk	
Are there concerns that the index test, its conduct, or interpretation differ from the review question?			Low concern
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
Could the reference standard, its conduct, or its interpretation have introduced bias?		Low risk	

Ashley 1998 *(Continued)*

Are there concerns that the target condition as defined by the reference standard does not match the question?		Low concern
DOMAIN 4: Flow and Timing		
Was there an appropriate interval between index test and reference standard?	Yes	
Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Yes	
Could the patient flow have introduced bias?		Low risk

Kockanat 2017

Study characteristics	
Patient Sampling	Method of sampling: unclear Included conditions: non-cavitated; "occlusal surfaces of the teeth had minimal macroscopic destruction" Teeth: primary molars Sealants: unclear Surface: occlusal
Patient characteristics and setting	Age: 9 to 12 years Sex: not reported Ethnicity: not reported Country: Turkey Setting: in vivo study conducted in dental hospital, followed by in vitro after extraction Number of participants/teeth/sites: 120 teeth (144 teeth were examined and measurements made with caries detection devices, but 120 of the 144 teeth were reported; due to inconsistencies in caries measurement results), clarification provided by study author Prevalence: enamel 0.78, dentine 0.32
Index tests	Category of test: CarieScan Pro Method: "teeth were isolated with cotton pellets after the lip clip of the device had been placed properly" Sequence of test(s): visual, SoproLife, DIAGNOdent pen then CarieScan Pro Examiner training and calibration: unclear, 2 independent examiners Teeth cleaning prior to examination: plaque removed, washed without pumice Tooth drying prior to examination: 3 seconds

Kockanat 2017 *(Continued)*

	Threshold applied: highest of 3 measurements recorded, evaluated using the scale of Teo 2014, enamel caries cut-off 21, dentine caries 91
Target condition and reference standard(s)	Category: histology Sequence of index test and reference standard: index tests then reference standard Training of examiner: not reported Blinding to index test: not reported Multiple tests: no Site selection: sectioned teeth Target condition: sound, outer half of enamel, inner half of enamel, outer half of dentine, deep dentine
Flow and timing	Participants with index test but no reference standard: 24 Participants with reference standard but no index test: 0 Time interval between tests: minimal Participants receiving both tests but excluded from results: 0
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
Could the selection of patients have introduced bias?		Unclear risk	
Are there concerns that the included patients and setting do not match the review question?			Low concern
DOMAIN 2: Index Test (All tests)			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Yes		
Could the conduct or interpretation of the index test have introduced bias?		Low risk	

Kockanat 2017 *(Continued)*

Are there concerns that the index test, its conduct, or interpretation differ from the review question?			Low concern
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
Could the reference standard, its conduct, or its interpretation have introduced bias?		Low risk	
Are there concerns that the target condition as defined by the reference standard does not match the question?			Low concern
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	No		
Were all patients included in the analysis?	No		
Could the patient flow have introduced bias?		High risk	

Kucukyilmaz 2015

Study characteristics	
Patient Sampling	Method of sampling: selected Included conditions: non-cavitated and early lesions Teeth: primary molars Sealants: unclear Surface: occlusal
Patient characteristics and setting	Age: not reported Sex: not reported Ethnicity: not reported Country: Turkey Setting: in vivo study conducted in dental hospital, followed by in vitro after extraction Number of participants/teeth/sites: 200 teeth

Kucukyilmaz 2015 *(Continued)*

	Prevalence: enamel 0.82, dentine 0.33
Index tests	Category of test: ECM IV (Lode Diagnostics, Groningen, the Netherlands) Methods: manufacturer's recommendations were followed Sequence of test(s): visual, radiograph, DIAGNOdent, ECM completed in vivo and in vitro before sectioning of teeth Examiner training and calibration: yes Teeth cleaning prior to examination: polished Tooth drying prior to examination: no - surface moistened with saline Threshold applied: 3 measurements taken and the average used: >10 sound, 10 to 2.5 enamel, <2.5 dentine Device specifics: not reported
Target condition and reference standard(s)	Category: histology Sequence of index test and reference standard: index tests then reference standard Training of examiner: not reported Blinding to index test: not reported Multiple tests: no Site selection: sectioned teeth Target condition: sound, outer half of enamel, inner half of enamel, outer half of dentine, deep dentine
Flow and timing	Participants with index test but no reference standard: 0 Participants with reference standard but no index test: 0 Time interval between tests: minimal Participants receiving both tests but excluded from results: 0
Comparative	
Notes	

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		

Kucukyilmaz 2015 *(Continued)*

Could the selection of patients have introduced bias?		High risk	
Are there concerns that the included patients and setting do not match the review question?			Low concern
DOMAIN 2: Index Test (All tests)			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Yes		
Could the conduct or interpretation of the index test have introduced bias?		Low risk	
Are there concerns that the index test, its conduct, or interpretation differ from the review question?			Low concern
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
Could the reference standard, its conduct, or its interpretation have introduced bias?		Low risk	
Are there concerns that the target condition as defined by the reference standard does not match the question?			Low concern
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
Could the patient flow have introduced bias?		Low risk	

Mortensen 2018

Study characteristics	
Patient Sampling	Method of sampling: sites selected in each participant Included conditions: non-cavitated and enamel lesions; "various stages of occlusal caries" Teeth: permanent molars Sealants: unclear

Mortensen 2018 *(Continued)*

	Restorations: not reported Surface: occlusal
Patient characteristics and setting	Age: 20 to 66 years Sex: 21% male Ethnicity: not reported Country: Denmark Setting: university setting: patients, employees, and students Number of participants/teeth/sites: 57 participants/60 teeth Prevalence: enamel 0.97, dentine 0.45
Index tests	Category of test: CarieScan Pro (Orange Dental) Methods: "The surrounding area was kept dry using cotton rolls and the lip hook was placed over the lower lip. The sensor tip was pressed into the designated fissure with light pressure" Sequence of test(s): index test then reference standard, ordered: ECM (CarieScan), then DIAGNOdent pen then visual and radiograph Examiner training and calibration: experienced and trained Teeth cleaning prior to examination: rotating brush Tooth drying prior to examination: 3 seconds Threshold applied: calculated within study: 0 sound, 1 to 50 enamel, 51+ dentine Device specifics: not reported
Target condition and reference standard(s)	Category: visual (ICDAS) Sequence of index test and reference standard: reference standard follows ECM and DIAGNOdent pen Training of examiner: experienced examiners Blinding to index test: no Multiple tests: no, only visual used Site selection: first examiner labelled the location on a plan Target condition: ICDAS 1 to 5
Flow and timing	Participants with index test but no reference standard: 0 Participants with reference standard but no index test: 0 Time interval between tests: minimal Participants receiving both tests but excluded from results: 0
Comparative	
Notes	Data confirmed by authors

Mortensen 2018 *(Continued)*

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
Could the selection of patients have introduced bias?		High risk	
Are there concerns that the included patients and setting do not match the review question?			Unclear
DOMAIN 2: Index Test (All tests)			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Unclear		
Could the conduct or interpretation of the index test have introduced bias?		Unclear risk	
Are there concerns that the index test, its conduct, or interpretation differ from the review question?			Low concern
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	No		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
Could the reference standard, its conduct, or its interpretation have introduced bias?		High risk	
Are there concerns that the target condition as defined by the reference standard does not match the question?			Low concern
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		

Mortensen 2018 *(Continued)*

Could the patient flow have introduced bias?	Low risk

Pereira 2011

Study characteristics	
Patient Sampling	Method of sampling: selected; "None of the teeth showed macroscopic signs of cavity formation" Included conditions: no cavitation and early lesions Teeth: permanent molars Sealants: unclear Surface: occlusal
Patient characteristics and setting	Age: not reported Sex: not reported Ethnicity: not reported Country: Brazil Setting: extracted teeth Number of participants/teeth/sites: 96 teeth Prevalence: enamel 0.57, dentine 0.25
Index tests	Category of test: ECM III (Lode, Groningen, the Netherlands) Methods: "The ECM examination had to be done before mounting to allow for a reference electrode to be attached to the root complex for measurement"; "... toothpaste gel was syringed into the fissure system as a conducting medium" Sequence of test(s): index tests (visual, radiograph, ECM, DIAGNOdent, QLF) then reference standard Examiner training and calibration: training event Teeth cleaning prior to examination: paste and rotating brush, "moistened with de-ionized water" Tooth drying prior to examination: yes - gently air-dried Threshold applied: "A score of 15 or lower was considered to indicate the presence of caries" Device specifics: "The reference electrode was attached to the root and the measurement electrode probe placed in contact with the fissure enamel at the site identified in the photograph, activating the co-axial air flow (7.5 L/min) until stable readings were obtained"; "Each site was examined three times, and the average of these readings was considered as a definitive score"
Target condition and reference standard(s)	Category: histology Sequence of index test and reference standard: index test then reference standard

Pereira 2011 *(Continued)*

	Training of examiner: "Three examiners underwent a training session, which consisted of 2 h of theoretical training and 4 h of practice on extracted teeth" Blinding to index test: not reported Multiple tests: no Site selection: sectioned teeth Target condition: "no caries; demineralization extending to the outer ½ of the enamel; demineralization extending to the inner ½ of the enamel; demineralization extending to the outer ½ of the dentin; demineralization extending to the outer ½ of the dentin"
Flow and timing	Participants with index test but no reference standard: 0 Participants with reference standard but no index test: 0 Time interval between tests: 1 week to allow for separation of teeth Participants receiving both tests but excluded from results: 0
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
Could the selection of patients have introduced bias?		High risk	
Are there concerns that the included patients and setting do not match the review question?			High
DOMAIN 2: Index Test (All tests)			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Yes		
Could the conduct or interpretation of the index test have introduced bias?		Low risk	

Pereira 2011 *(Continued)*

Are there concerns that the index test, its conduct, or interpretation differ from the review question?			Low concern
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
Could the reference standard, its conduct, or its interpretation have introduced bias?		Low risk	
Are there concerns that the target condition as defined by the reference standard does not match the question?			Low concern
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
Could the patient flow have introduced bias?		Low risk	

Ricketts 1997

Study characteristics	
Patient Sampling	Method of sampling: selected; "extracted teeth with no visible sign of cavitation" Included conditions: no cavitation and early lesions Teeth: permanent molars Sealants: unclear Surface: occlusal
Patient characteristics and setting	Age: not reported Sex: not reported Ethnicity: not reported Country: UK Setting: extracted teeth

Ricketts 1997 *(Continued)*

	Number of participants/teeth/sites: 76 sites/32 teeth/14 patients
	Prevalence: enamel 0.64, dentine 0.32
Index tests	Category of test: ECM II (Lode, Groningen, the Netherlands)
	Methods: 1 to 4 sites were marked on each tooth
	Sequence of test(s): index tests (ECM) then reference standard
	Examiner training and calibration: not reported
	Teeth cleaning prior to examination: with a brush and rinsed
	Tooth drying prior to examination: yes - gently air-dried
	Threshold applied: table 2 states D_1 cut-off to be 1.74, these results are used for analysis. Stable conductance 0 to 1 probably sound, 1.01 to 3 possibly sound, 3.01 to 9 equivocal, 9.01 to 12 possibly carious, >12.01 probably carious. Cumulative resistance >301 probably sound, 201 to 300 possibly sound, 101 to 200 equivocal, 51 to 100 possibly carious, 0 to 50 probably carious
	Device specifics: "probe tip was placed at the investigation site and 7.51/min airflow immediately supplied around it"
Target condition and reference standard(s)	Category: histology with macroradiographs
	Sequence of index test and reference standard: index test then reference standard
	Training of examiner: not reported
	Blinding to index test: same examiner separated by at least 1 week between index and reference standard
	Multiple tests: no
	Site selection: sectioned teeth
	Target condition: no caries, enamel, dentine
Flow and timing	Participants with index test but no reference standard: 0
	Participants with reference standard but no index test: 0
	Time interval between tests: 1 week to allow for separation of teeth
	Participants receiving both tests but excluded from results: 0
Comparative	
Notes	

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	No		

Ricketts 1997 *(Continued)*

Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Unclear		
Could the selection of patients have introduced bias?		High risk	
Are there concerns that the included patients and setting do not match the review question?			High
DOMAIN 2: Index Test (All tests)			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Yes		
Could the conduct or interpretation of the index test have introduced bias?		Low risk	
Are there concerns that the index test, its conduct, or interpretation differ from the review question?			Low concern
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
Could the reference standard, its conduct, or its interpretation have introduced bias?		Low risk	
Are there concerns that the target condition as defined by the reference standard does not match the question?			Low concern
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
Could the patient flow have introduced bias?		Low risk	

Teo 2014

Study characteristics			

Teo 2014 *(Continued)*

Patient Sampling	Method of sampling: unclear Included conditions: no cavitation and early lesions, "extensive multi-surface caries" were excluded Teeth: primary molars Sealants: no Restorations: excluded Surface: occlusal
Patient characteristics and setting	Age: 2 to 11 years Sex: not reported Ethnicity: not reported Country: UK Setting: dental school (in vivo study used, but in vitro also available) Number of participants/teeth/sites: 64 teeth/surfaces Prevalence: enamel 0.72, dentine 0.31
Index tests	Category of test: CarieScan Pro Methods: "tooth was then rehydrated with water from a syringe for 5 s to enable electrical conductance of the device" Sequence of test(s): index tests (visual, DIAGNOdent pen, CarieScan Pro) then reference standard Examiner training and calibration: yes on subsample Teeth cleaning prior to examination: pumice and a bristle brush Tooth drying prior to examination: dried for 3 seconds at moderate pressure Threshold applied: "two cut-offs for D1 were taken based on manufacturer's instructions: code 21 and code 51, corresponding to caries extension into the outer third and inner third of the enamel, respectively. The D3 threshold was calculated at cut-off 91, which represented lesion extension to the enamel-dentine junction" Device specifics: activated device was placed directly on the area to be tested
Target condition and reference standard(s)	Category: histology Sequence of index test and reference standard: index test before reference standard Training of examiner: not reported Blinding to index test: no Multiple tests: no Site selection: recorded on a drawing of the occlusal surface Target condition: sound, outer enamel, inner enamel, outer dentine, inner dentine
Flow and timing	Participants with index test but no reference standard: 0

Teo 2014 *(Continued)*

	Participants with reference standard but no index test: 0 Time interval between tests: minimal Participants receiving both tests but excluded from results: 0
Comparative	
Notes	Our main analysis used the results from the 21 threshold, as this represents the manufacturer's recommendations and has greater applicability

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
Could the selection of patients have introduced bias?		Unclear risk	
Are there concerns that the included patients and setting do not match the review question?			Low concern
DOMAIN 2: Index Test (All tests)			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
If a threshold was used, was it pre-specified?	Yes		
Could the conduct or interpretation of the index test have introduced bias?		Low risk	
Are there concerns that the index test, its conduct, or interpretation differ from the review question?			Low concern
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
Could the reference standard, its conduct, or its interpretation have introduced bias?		Low risk	

Teo 2014 *(Continued)*

Are there concerns that the target condition as defined by the reference standard does not match the question?		Low concern
DOMAIN 4: Flow and Timing		
Was there an appropriate interval between index test and reference standard?	Yes	
Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Yes	
Could the patient flow have introduced bias?		Low risk

ECM = electronic caries monitor; FOTI = fibre-optic transillumination; ICDAS = International Caries Detection and Assessment System; QLF = quantitative light-induced fluorescence.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Ari 2013	Not possible to complete a 2 x 2 table at the enamel threshold.
Ashley 2000	No reference standard.
Ashley 2000a	Data reported at the dentine threshold only.
Bamzahim 2002	Data reported at the dentine threshold only.
Chalas 2014	No reference standard.
Chatterjee 2019	Included dentinal lesions.
Cortes 2003	Included dentinal lesions.
Ekstrand 1997	Results presented at the dentine caries level only.
Ekstrand 1998	Not possible to complete a 2 x 2 table at the enamel threshold.
Ellwood 2004	Included dentinal lesions.
Gualtieri 1999	No reference standard.
Ie 1995	Not possible to complete a 2 x 2 table, results presented at the dentine caries level only.
Kordic 2003	Included dentinal lesions.
Kuhnisch 2006	Not possible to complete a 2 x 2 table at the enamel or dentine threshold.
Longbottom 2004	Not a diagnostic test accuracy study.

Study	Reason for exclusion
Lussi 1999	Not possible to complete a 2 x 2 table at the enamel caries threshold. Results presented at D_2 and D_3 thresholds only.
Melo 2015	Teeth (molars and premolars) that had been previously diagnosed for filling, therefore dentine caries.
Pereira 2009	Same teeth and results as Pereira 2011, this paper did not report sensitivity and specificity results, instead it focussed on treatment decision.
Ricketts 1997a	Included dentinal lesions.
Ricketts 1997b	Same study sample as Ricketts 1997.
Tassery 2013	Not a diagnostic test accuracy study.
Thomas 2001	Electronic caries monitor used as reference standard and results were at the dentine threshold.
Ünal 2019	Authors confirmed there were no sound teeth in sample so could not include.
Unlu 2010	Included dentinal lesions.
Wicht 2002	Investigated root caries.

DATA

Presented below are all the data for all of the tests entered into the review.

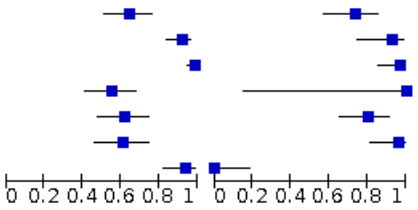
Table Tests. Data tables by test

Test	No. of studies	No. of participants
1 All	7	719
2 ECM	4	475
3 CarieScan Pro	3	244
4 CarieScan Pro (threshold 21)	2	184
5 CarieScan Pro (threshold 51)	2	124

Test 1. All

All

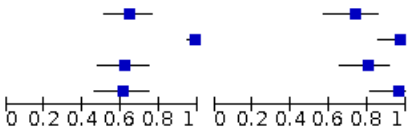
Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Ashley 1998	40	11	22	30	0.65 [0.51, 0.76]	0.73 [0.57, 0.86]
Kockanat 2017	86	2	8	24	0.91 [0.84, 0.96]	0.92 [0.75, 0.99]
Kucukyilmaz 2015	161	1	3	35	0.98 [0.95, 1.00]	0.97 [0.85, 1.00]
Mortensen 2018	32	0	26	2	0.55 [0.42, 0.68]	1.00 [0.16, 1.00]
Pereira 2011	34	8	21	33	0.62 [0.48, 0.75]	0.80 [0.65, 0.91]
Ricketts 1997	30	1	19	26	0.61 [0.46, 0.75]	0.96 [0.81, 1.00]
Teo 2014	43	18	3	0	0.93 [0.82, 0.99]	0.00 [0.00, 0.19]



Test 2. ECM

ECM

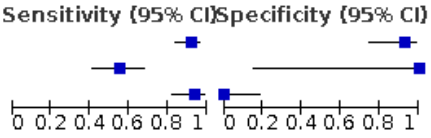
Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Ashley 1998	40	11	22	30	0.65 [0.51, 0.76]	0.73 [0.57, 0.86]
Kucukyilmaz 2015	161	1	3	35	0.98 [0.95, 1.00]	0.97 [0.85, 1.00]
Pereira 2011	34	8	21	33	0.62 [0.48, 0.75]	0.80 [0.65, 0.91]
Ricketts 1997	30	1	19	26	0.61 [0.46, 0.75]	0.96 [0.81, 1.00]



Test 3. CarieScan Pro

CarieScan Pro

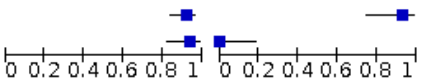
Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Kockanat 2017	86	2	8	24	0.91 [0.84, 0.96]	0.92 [0.75, 0.99]
Mortensen 2018	32	0	26	2	0.55 [0.42, 0.68]	1.00 [0.16, 1.00]
Teo 2014	43	18	3	0	0.93 [0.82, 0.99]	0.00 [0.00, 0.19]



Test 4. CarieScan Pro (threshold 21)

CarieScan Pro (threshold 21)

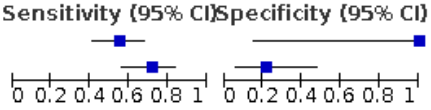
Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Kockanat 2017	86	2	8	24	0.91 [0.84, 0.96]	0.92 [0.75, 0.99]
Teo 2014	43	18	3	0	0.93 [0.82, 0.99]	0.00 [0.00, 0.19]



Test 5. CarieScan Pro (threshold 51)

CarieScan Pro (threshold 51)

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Mortensen 2018	32	0	26	2	0.55 [0.42, 0.68]	1.00 [0.16, 1.00]
Teo 2014	33	14	13	4	0.72 [0.57, 0.84]	0.22 [0.06, 0.48]



ADDITIONAL TABLES

Table 1. Classification of levels of caries levels

DMFT classification	Definition (Pitts 2001)
0	Sound (non-diseased)
D_1	Non-cavitated yet clinically detectable enamel lesions with intact surfaces
D_2	Cavitated lesion penetrating the enamel or shadowing
D_3	Cavity progressing past the enamel-dentine junction into dentine
D_4	Cavity progressing into pulp

DMFT = decayed, missing, and filled teeth.

Table 2. QUADAS-2 tool

Item	Response (delete as required)
Participant selection – Risk of bias	
1) Was a consecutive or random sample of participants or teeth used?	**Yes** – where teeth or participants were selected consecutively or allocated to the study via a randomisation process **No** – if study described another method of sampling **Unclear** – if participant sampling is not described
2) Was a case-control design avoided?	**Yes** – if case-control clearly not used **No** – if study described as case-control or describes sampling specific numbers of participants with particular diagnoses **Unclear** – if not clearly described
3) Did the study avoid inappropriate exclusions (e.g. inclusion of caries into dentine)?	**Yes** – if the study clearly reports that included participants or teeth were apparently healthy or caries into dentine were excluded **No** – if lesions were included that showed caries into dentine or exclusions that might affect test accuracy (e.g. teeth with no caries) **Unclear** – if not clearly reported
Could the selection of participants have introduced bias?	
If answers to all of questions 1) and 2) and 3) was 'yes	**Risk is Low**
If answers to any of questions 1) and 2) and 3) was 'no'	**Risk is High**
If answers to any of questions 1) and 2) and 3) was 'unclear'	**Risk is Unclear**
Participant selection – Concerns regarding applicability	

Table 2. QUADAS-2 tool *(Continued)*

1) Does the study report results for participants or teeth selected by apparent health or suspected early caries (i.e. studies do not recruit patients who are known to have advanced caries into dentine)?	**Yes** – if a group of participants or teeth has been included which is apparently healthy or indicative of early caries **No** – if a group of participants or teeth has been included which is suspected of advanced caries **Unclear** – if insufficient details are provided to determine the spectrum of participants or teeth
2) Did the study report data on a per-patient rather than on a tooth or surface basis?	**Yes** – if the analysis was reported on a surface or tooth basis **No** – if the analysis was reported on a per-patient basis **Unclear** - if it is not possible to assess whether data are presented on a per-patient or per-tooth basis
3) Did the study avoid an in vitro setting which required the usage of extracted teeth?	**Yes** – if the participants were recruited prior to tooth extraction **No** – if previously extracted teeth were used in the analysis **Unclear** – if it was not possible to assess the source and method of recruiting of included participants/teeth
Is there concern that the included participants or teeth do not match the review question?	
If answers to all of questions 1) and 2) and 3) was 'yes	**Risk is Low**
If answers to any of questions 1) and 2) and 3) was 'no'	**Risk is High**
If answers to any of questions 1) and 2) and 3) was 'unclear'	**Risk is Unclear**
Index test - Risk of bias (to be completed per test evaluated)	
1) Was the index test result interpreted without knowledge of the results of the reference standard?	**Yes** – if the index test described is always conducted and interpreted prior to the reference standard result, or for retrospective studies interpreted without prior knowledge of the reference standard **No** – if index test described as interpreted in knowledge of reference standard result **Unclear** – if index test blinding is not described
2) Was the diagnostic threshold at which the test was considered positive pre-specified?	**Yes** – if threshold was pre-specified (i.e. prior to analysing the study results) **No** – if threshold was not pre-specified **Unclear** – if not possible to tell whether or not diagnostic threshold was pre-specified
For visual and radiograph tests only: 3) For studies reporting the accuracy of multiple diagnostic thresholds for the same index test or multiple index tests, was each threshold or index test interpreted without knowledge of the results of the others?	**Yes** – if thresholds or index tests were selected prospectively and each was interpreted by a different clinician or interpreter, or if study implements a retrospective (or no) cut-off (i.e. look for deepest/most severe lesion first) **No** – if study states reported by same reader **Unclear** - if no mention of number of readers for each threshold or if pre-specification of threshold not reported **N/A** - multiple diagnostic thresholds not reported for the same index test

Table 2. QUADAS-2 tool *(Continued)*

Could the conduct or interpretation of the index test have introduced bias?	
For visual and radiographic studies item 3) to be added	
If answers to all of questions 1) and 2) was 'yes	**Risk is Low**
If answers to any of questions 1) and 2) was 'no'	**Risk is High**
If answers to any of questions 1) and 2) was 'unclear'	**Risk is Unclear**
Index test - Concerns regarding applicability	
1) Were thresholds or criteria for diagnosis reported in sufficient detail to allow replication?	**Yes** – if the criteria for detection or diagnosis of the target disorder were reported in sufficient detail to allow replication **No** – if the criteria for detection or diagnosis of the target disorder were not reported in sufficient detail to allow replication **Unclear** - if some but not sufficient information on criteria for diagnosis to allow replication were provided
2) Was the test interpretation carried out by an experienced examiner?	**Yes** – if the test clearly reported that the test was interpreted by an experienced examiner **No** – if the test was not interpreted by an experienced examiner **Unclear** – if the experience of the examiner(s) was not reported in sufficient detail to judge or if examiners described as 'expert' with no further detail given
Is there concern that the included participants do not match the review question?	
If the answer to question 1) and 2) was 'yes'	**Concern is Low**
If the answer to question 1) and 2) was 'no'	**Concern is High**
If the answer to question 1) and 2) was 'unclear'	**Concern is Unclear**
Reference standard - Risk of bias	
1) Is the reference standard likely to correctly classify the target condition?	**Yes** – if all teeth or surfaces underwent a histological or excavation reference standard **No** – if a final diagnosis for any participant or tooth was reached without the histological or excavation reference standards **Unclear** – if the method of final diagnosis was not reported
2) Were the reference standard results interpreted without knowledge of the results of the index test?	**Yes** – if the reference standard examiner was described as blinded to the index test result **No** – if the reference standard examiner was described as having knowledge of the index test result **Unclear** – if blinded reference standard interpretation was not clearly reported

Table 2. QUADAS-2 tool *(Continued)*

Could the reference standard, its conduct, or its interpretation have introduced bias?	
If answers to questions 1) and 2) was 'yes'	**Risk is Low**
If the answer to question 1) and 2) was 'no'	**Concern is High**
If the answer to question 1) and 2) was 'unclear'	**Concern is Unclear**
Reference standard - Concerns regarding applicability	
1) Does the study use the same definition of disease positive as the prescribed in the review question?	**Yes** - same definition of disease positive used, or teeth can be disaggregated and regrouped according to review definition **No** - some teeth cannot be disaggregated **Unclear** - definition of disease positive not clearly reported
Flow and timing - Risk of bias	
1) Was there an appropriate interval between index test and reference standard (in vivo studies less than 3 months, in vitro no limit but must be stored appropriately)?	**Yes** - if study reports index and reference standard had a suitable interval or storage method **No** - if study reports greater than 3-month interval between index and reference standard or inappropriate storage of extracted teeth prior to reverence standard **Unclear** - if study does not report interval or storage methods between index and histological reference standard
2) Did all participants receive the same reference standard?	**Yes** - if all participants underwent the same reference standard **No** - if more than 1 reference standard was used **Unclear** - if not clearly reported
3) Were all participants included in the analysis?	**Yes** - if all participants were included in the analysis **No** - if some participants were excluded from the analysis **Unclear** - if not clearly reported
If answers to questions 1) and 2) and 3) was 'yes'	**Risk is Low**
If answers to any one of questions 1) or 2) or 3) was 'no'	**Risk is High**
If answers to any one of questions 1) or 2) or 3) was 'unclear'	**Risk is Unclear**

N/A = not applicable; QUADAS-2 = Quality Assessment of Diagnostic Accuracy Studies 2.

APPENDICES

Appendix 1. MEDLINE Ovid search strategy

1. exp Tooth demineralization/
2. (teeth adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.

3. (tooth adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
4. (dental adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
5. (enamel adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
6. (dentin adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
7. (root adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
8. or/1-7
9. exp radiography, dental/
10. ((dental or oral or teeth or tooth or mouth) and (x-ray$ or xray$ or radiograph$ or radiology or bitewing$)).mp.
11. Diagnosis, oral/
12. Mass screening/
13. ((oral or dental or mouth) and (exam$ or check$ or diagnos$ or inspect$ or screen$ or probe$ or probing or detect$)).mp.
14. or/9-13
15. 8 and 14
16. Electrodiagnosis/
17. Electricity/
18. (electric$ or electronic$).mp.
19. ECM.ti,ab.
20. (cariescan or "AC Ohmmeter" or "Caries Meter L" or "Modified Electrochemical Impedance Spectroscopy").mp.
21. or/16-20
22. 15 and 21

Appendix 2. Embase Ovid search strategy

1 dental caries/
2 (teeth adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
3 (tooth adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
4 (dental adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
5 (enamel adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
6 (dentin adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
7 (root adj5 (cavit$ or caries or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
8 or/1-7
9 tooth radiography/
10 ((dental or oral or teeth or tooth or mouth) and (x-ray$ or xray$ or radiograph$ or radiology or bitewing$)).mp.
11 mass screening/
12 ((oral or dental or mouth) and (exam$ or check$ or diagnos$ or inspect$ or screen$ or probe$ or probing or detect$)).mp.
13 or/9-12
14 8 and 13
15 electrodiagnosis/
16 electricity/
17 (electric$ or electronic$).mp.
18 ECM.ti,ab.
19 (cariescan or "AC Ohmmeter" or "Caries Meter L" or "Modified Electrochemical Impedance Spectroscopy").mp.
20 or/15-19
21 14 and 20

Appendix 3. US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov) search strategy

Expert Search interface: (caries OR "tooth decay" OR "dental decay" OR carious) AND (electrodiagnosis OR electricity OR electric OR ECM OR electronic OR cariescan OR "AC Ohmmeter" OR "Caries Meter L" OR "Modified Electrochemical Impedance Spectroscopy")

Appendix 4. World Health Organization International Clinical Trials Registry Platform search strategy

caries AND electrodiagnosis OR caries AND electricity OR caries AND electrical OR caries AND electric OR caries AND ECM OR caries AND electronic OR caries AND cariescan OR caries AND "AC Ohmmeter" OR caries AND "Caries Meter" OR caries AND "modified electrochemical impedance spectroscopy"

HISTORY

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CONTRIBUTIONS OF AUTHORS

All review authors collaborated in the conception of the review purpose and design.
Drafting the protocol: Richard Macey (RM), Tanya Walsh (TW).

Developing the search strategy: TW and RM.
Selecting studies for inclusion: RM and Philip Riley (PR).
Extracting data: RM and PR.
Carrying out analysis: TW and RM.
Interpreting the analysis: TW, RM, and David Ricketts (DR).
Drafting the final review: RM and TW.
Clinical input: DR and Janet Clarkson (JC).
The final review was read and approved by all authors.

DECLARATIONS OF INTEREST

Richard Macey: none known.
Tanya Walsh: none known. I am Statistical Editor with Cochrane Oral Health.
Philip Riley: none known. I am Deputy Co-ordinating Editor of Cochrane Oral Health.
Anne-Marie Glenny: none known. I am Co-ordinating Editor of Cochrane Oral Health.
Helen V Worthington: none known. I am Emeritus Co-ordinating Editor of Cochrane Oral Health.
Janet E Clarkson: none known. I am Co-ordinating Editor of Cochrane Oral Health.
David Ricketts: I was involved with one of the included studies (Ricketts 1997), but was not involved with the data extraction or its assessment for this review.

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- Cochrane Oral Health Global Alliance, Other

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

- We analysed tests used alone (not in combination with other tests as stated in the protocol).
- We did not consider devices used in different positions in the clinical pathway because the search produced a large body of evidence for the primary time point in clinical process so we decided it would add unnecessary complexity to investigate the value of each index test at different positions in the clinical pathway. This decision was made after a scoping review revealed that very few studies reported this information.