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Überprüfung eines KI-basierten Modells zur Karieserkennung auf Intraoralfotos von Milchfrontzähnen

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Julia Schwarzmaier

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Inhaltsverzeichnis

Affidavit	3
Inhaltsverzeichnis	4
Abkürzungsverzeichnis	5
Publikationsliste	6
1. Beitrag zu den Veröffentlichungen	7
1.1 Beitrag zu Paper I	7
1.2 Beitrag zu Paper II	8
2. Einleitung	9
3. Zielstellung	11
4. Material und Methoden	12
5. Ergebnisse	14
6. Diskussion	15
7. Zusammenfassung und Ausblick	17
8. Abstract (English)	18
9. Paper I	19
10. Paper II	31
11. Literaturverzeichnis	43
Danksagung	49
Übereinstimmungserklärung	50

Abkürzungsverzeichnis

ACC	Accuracy
AUC	Fläche unter der Receiver Operating Characteristic Curve
ECC	Early Childhood Caries
KI	Künstliche Intelligenz
SE	Sensitivität
SP	Spezifität

Publikationsliste

Schwarzmaier, J., Frenkel, E., Neumayr, J., Ammar, N., Kessler, A., Schwendicke, F., Kühnisch, J., Dujic, H. (2024). Validation of an Artificial Intelligence-Based Model for Early Childhood Caries Detection in Dental Photographs. *Journal of Clinical Medicine*, 13(24), 5215. <https://doi.org/10.3390/jcm13175215>

Frenkel, E., Neumayr, J., **Schwarzmaier, J.**, Kessler, A., Ammar, N., Schwendicke, F., Kühnisch, J., Dujic, H. (2024). Caries Detection and Classification in Photographs Using an Artificial Intelligence-Based Model—An External Validation Study. *Diagnostics*, 14(24), 2281. <https://doi.org/10.3390/diagnostics14202281>

1. Beitrag zu den Veröffentlichungen

1.1 Beitrag zu Paper I

Tabelle 1: Beitrag zu den Veröffentlichungen

Publikation "Validation of an Artificial Intelligence-Based Model for Early Childhood Caries Detection in Dental Photographs"			
	Julia Schwarzmaier	Prof. Dr. Jan Kühnisch	Co-Autoren
Ethikantrag	-	100 %	-
Projektidee/Studiendesign	40 %	50 %	10 %
Literaturrecherche	100 %	-	-
Durchführung aller Untersuchungen	70 %	10 %	20 %
Statistische Auswertungen	80 %	10 %	10 %
Dateninterpretation und Auswahl veröffentlichungswürdiger Daten	80 %	10 %	10 %
Manuskript Management bis zur Veröffentlichung	90 %	10 %	-
Verfassen und Einreichen der Dissertation	100 %		

1.2 Beitrag zu Paper II

Tabelle 2: Beitrag zu den Veröffentlichungen

Publikation “Caries Detection and Classification in Photographs Using an Artificial Intelligence-Based Model-An External Validation Study”			
	Elisabeth Frenkel	Prof. Dr. Jan Kühnisch	Co-Autoren
Ethikantrag	-	100 %	-
Projektidee/Studiendesign	40 %	50 %	10 %
Literaturrecherche	100 %	-	-
Durchführung aller Untersuchungen	70 %	10 %	20 %
Statistische Auswertungen	80 %	10 %	10 %
Dateninterpretation und Auswahl veröffentlichungswürdiger Daten	80 %	10 %	10 %
Manuskript Management bis zur Veröffentlichung	90 %	10 %	-
Verfassen und Einreichen der Dissertation	100 %		

2. Einleitung

Entsprechend der Definition der American Academy of Pediatric Dentistry (2020) liegt eine frühkindliche Karies vor, wenn bei einem Kind unter sechs Jahren ein oder mehrere kariöse Milchzähne diagnostizierbar sind oder mindestens ein Milchzahn kariesbedingt extrahiert beziehungsweise gefüllt wurde. Karies nimmt unter den weltweit am weitesten verbreiteten Krankheiten im Kindesalter eine Spitzenposition ein (GBD 2017 Oral Disorders Collaborators et al., 2020; Meyer et al., 2018; Uribe et al., 2021; Zou et al., 2022) und kann unbehandelt die Lebensqualität von Kindern negativ beeinflussen. Zahnschmerzen, Schwellungen, Abszesse, Probleme bei der Nahrungsaufnahme oder verminderte Sprachentwicklung (Neves et al., 2019; Alazmah, 2017; Tinanoff et al., 2019) sind nur mögliche Folgezustände, die es gilt zu vermeiden. Das Risiko an frühkindlicher Karies zu erkranken steigt, wenn hochfrequent zuckerhaltige Getränke oder Nahrungsmittel konsumiert werden und die Mundhygiene vernachlässigt wird (Sun et al., 2017, Fan et al., 2023; Li et al., 2023; American Academy of Pediatric Dentistry, 2020). Der verfügbare Zucker wird durch Bakterien, wie z.B. Streptococcus-Spezies, metabolisiert und in Säure umgewandelt (Anil et al., 2017), welche dann zur Demineralisation des Zahnschmelzes führen kann. Die frühe Kariesentwicklung ist multifaktoriell bedingt, so spielen beispielsweise auch der sozioökonomische Status der Eltern, Schmelzdemineralisationsstörungen und Fluoridierung der Zähne eine wichtige Rolle (Folayan et al., 2021).

Das schnelle Voranschreiten der Karies im Milchzahngewebiss (Inchingolo et al., 2023) erfordert eine frühzeitige Intervention, sodass es nicht zu den oben genannten Folgen kommt. Wenn Karies frühzeitig im Anfangsstadium erkannt wird, können beispielsweise durch Fluoridierungsmaßnahmen, Aufklärung der Eltern über Mundhygiene und Ernährung sowie durch Fissurenversiegelungen kostenintensive Therapien in Sedierung oder Intubationsnarkose vermieden werden (Anil et al., 2017). Aufgrund des geringen Alters und der damit teils fehlenden Kooperationsbereitschaft der Kinder ist eine Behandlung oft nur eingeschränkt möglich (López-Velasco et al., 2021). Dies unterstreicht die fundamentale Bedeutung der Kariesprävention im Kindesalter.

Für die Diagnosestellung einer frühkindlichen Karies ist die Detektion von nicht kavitierten und kavitierten kariösen Läsionen erforderlich. Dies erfolgt im ersten

Schritt im Rahmen der klinischen Untersuchung auf Grundlage international üblicher Kriterien zu denen u.a. die ICDAS-Kriterien (International Caries Detection and Assessment System) gehören (Pitts 2009). Für einen erfahrenen und trainierten Zahnarzt ist die Anwendung in der Regel kein Problem. Allerdings ist darauf zu verweisen, dass bislang kein Diagnostiksystem perfekte diagnostische Genauigkeiten zeigte und subjektive Entscheidungen – je nach Erfahrung und Wissen – zu abweichenden Diagnosen und damit auch Therapieentscheidungen führen können.

In den vergangenen Jahren wurden verstärkt Bemühungen unternommen, die Kariesdiagnostik mit Hilfe künstlicher Intelligenz (KI) zu automatisieren. Es sind bereits einige Projekte publiziert worden, welche an Bissflügelaufnahmen (ForouzeshFar et al., 2024), Panoramaschichtaufnahmen (Lian et al., 2021) oder periapikalen Aufnahmen (Chen et al., 2021) automatisiert Karies oder apikale Parodontitiden erkennen können. Einen Überblick über die aktuelle Studienlage publizierten Domenico Albano et al. (2024). Nicht nur im Bereich der dentalen Röntgenbilder, sondern auch bei Intraoralfotografien (Moutselos et al., 2019; Xiong et al., 2024; Al-Jallad et al., 2022) wurden bereits KI-Modelle entwickelt, um Kariesläsionen zu detektieren. Da KI in der Zahnmedizin zunehmend an Bedeutung gewinnt, ist es dringend notwendig, vorhandene Modelle auf deren diagnostische Qualität zu überprüfen.

In diesem Studienprojekt soll das frei zugängliche KI-basierte Modell von Felsch et al. (2023) zur automatisierten Kariesdiagnostik mittels unabhängiger Intraoralbilder von Milchzähnen der Oberkieferfront überprüft werden.

3. Zielstellung

Ziel der vorliegenden externen Validierungsstudie war es, das frei zugängliche KI-basierte Modell von Felsch et al. (2023) zur Karieserkennung auf Fotografien zu nutzen und das Testergebnis in Relation zur zahnärztlichen Beurteilung (Referenzstandard) zu setzen. Alle bisherigen Forschungsprojekte publizierten lediglich Daten aus der internen Modellvalidierung. Merkmal von externen Validierungsstudien ist, dass Bildmaterial getestet wird, welches zum Training und zur internen Validierung nicht benutzt wurde. Die diagnostische Performance sollte bezüglich der Kariesklassifikation, -lokalisierung und -segmentierung bestimmt werden. Als Hypothese wurde formuliert, dass es keine Unterschiede zwischen der internen (Felsch et al., 2023) und externen Validierung gibt.

4. Material und Methoden

Für das Studienprojekt wurden 143 anonymisierte Bilder von Milchfrontzähnen verwendet, wobei 107 Bilder unterschiedliche kariöse Stadien im Sinne einer frühkindlichen Karies aufwiesen und 36 kariesfrei waren. Die Fotografien, aufgenommen von Prof. Dr. Kühnisch, entstammen einer klinischen Dokumentationssammlung, die nicht für das Training des zu testenden KI-Algorithmus verwendet wurden. Fotografien mit dentalen Restaurationen, orthodontischen Apparaturen, seltenen dentalen Erkrankungen wie ektodermale Dysplasien, Amelogenesis imperfecta oder Dentinogenesis imperfecta wurden nicht miteinbezogen. Die Fotografien wurden nicht bearbeitet, manipuliert oder mittels KI-Verfahren generiert.

Unter der Leitung von Prof. Dr. Kühnisch wurde vorab mit den Zahnärzten (JS, EF, JN, HD) ein eintägiges theoretisches Trainingsprogramm durchgeführt. Ziel war es, nicht kavitierte und kavitierte kariöse Läsionen richtig zu diagnostizieren.

Im gesamten Bilddatensatz (n=143) wurde zunächst zwischen kariesfreien Milchfrontzähnen (n=36) und kariösen Befunden (n=107) unterschieden. In einem weiteren Schritt wurde jede kariöse Läsion auf Grundlage der ICDAS/UniViSS Kriterien beurteilt. Im Detail wurden nicht kavitierte kariöse Läsionen (erste sichtbare Zeichen eines kariösen Prozesses, etablierte Läsionen) von Mikrokavitäten/gräulichen Transluzenzen, Kavitäten mit Dentinexposition und komplett kariös zerstörte Zähnen unterschieden (Kühnisch et al., 2009; Kühnisch et al., 2011; Pitts, 2009). Bei Unstimmigkeiten innerhalb der Zahnärztesgruppe wurde solange diskutiert, bis eine endgültige Diagnose festgelegt werden konnte. Die herausgearbeiteten Befunde dienten später als Referenzstandards im Vergleich zur KI-basierten Untersuchung.

Für die KI basierte Analyse der Fotos wurde das frei zugängliche Webtool verwendet (<https://demo.dental-ai.de/>, zugegriffen am 21. August 2024). Der Bilddatensatz wurde zunächst in das Webtool hochgeladen, dann wurden die Fotos auf die vier Oberkieferfrontzähne zugeschnitten und schließlich von der KI mit Hilfe von farbigen Pixeln ausgewertet. Die Ergebnisse wurden als Screenshots dokumentiert und gespeichert, sodass anschließend die

zahnärztliche Diagnostik durchgeführt werden konnte. Das Webtool unterscheidet auf Basis der ICDAS und UniViSS Kriterien (Kühnisch et al., 2009; Kühnisch et al. 2011; Pitts, 2009) in folgende Kariesstufen: 1 – nicht kavitierte Kariesläsion, 2 – Mikrokaivität/Gräuliche Transluzenz, 3 – kavitierte Dentinkaries, 4 – zerstörter Zahn.

Nach der Auswertung ergaben mehrere gleichfarbige zusammenhängende Pixel ein Kariessegment. Die Arbeitsgruppe hat die insgesamt 261 von der KI detektierten kariösen Segmente bezüglich der richtigen Lokalisation und Segmentation analysiert. Für eine korrekte Lokalisation musste mindestens ein von der KI generiertes farbiges Pixel innerhalb der kariösen Läsion liegen. Aufgrund des Fehlens von exakten Messwerten konnte die Bewertung der Segmente lediglich als Schätzung vorgenommen werden. Erkannte die KI mehr als 90% der Kariesausdehnung, wurde dies als komplett richtig gewertet. Weniger als 90% wurde als teilweise richtig angenommen; lag das von der KI bestimmte Kariessegment außerhalb der kariösen Läsion, bedeutete dies eine inkorrekte Segmentation.

Alle Ergebnisse wurden mit einer für das Studienprojekt erstellten Eingabemaske dokumentiert (EpiData Manager and EpiData Entry Client, Version v4.6.0.6, EpiData Association, Odense, Denmark, <http://www.epidata.dk>). Nach der Erfassung aller Daten wurden diese in ein Excel spread sheet (Excel 2019, Microsoft Corporation, Redmond, WA, USA) exportiert und so der statistischen Auswertung zugänglich gemacht. Mit Python (version 3.8.5, <http://www.python.org>) wurde die diagnostische Leistung der KI mit der der Zahnärzte verglichen.

Das Leistungsvermögen wurde mit Hilfe von unterschiedlichen Parametern bestimmt. Dazu gehörten die diagnostische Genauigkeit bzw. engl. Accuracy (ACC), die Sensitivität (SE), die Spezifität (SP), der positive und negative prädiktive Wert (PPV, NPV) sowie die Fläche unter der Receiver Operating Characteristic Curve (AUC).

5. Ergebnisse

Insgesamt konnte festgestellt werden, dass die KI im Vergleich zum zahnärztlichen Referenzstandard genaue Aussagen bezüglich der allgemeinen bildbezogenen frühkindlichen Kariesdiagnostik liefert. Die KI erkannte auf 104 von 107 Bildern mit einer frühkindlichen Karies diese korrekt und diagnostizierte 35 von 36 Fotos mit kariesfreien Zähnen richtig. Dies führte zu einer diagnostischen Genauigkeit von 97,2%.

Da in einem Foto mit vier Frontzähnen teils mehrere kariöse Läsionen bzw. Kariessegmente abgebildet waren, bedurfte es einer detaillierteren Analyse der KI-basierten Ergebnisse. Hierbei konnte festgestellt werden, dass die Genauigkeit der richtigen Kariesklassifikation eines Segments zwischen 88,9% (Kavitation) und 98,1% (zerstörter Zahn) variierte.

In Hinblick auf die Lokalisation wurden 220 von insgesamt 226 Kariessegmenten richtig lokalisiert. Die Auswertung der KI-basierten Segmentation ergab 114 richtig segmentierte und 101 teils richtig segmentierte Kariessegmente. In 11 Fällen lag die von der KI kariös markierte Fläche außerhalb des eigentlich kariösen Segments.

6. Diskussion

Auf Grundlage der gewonnenen Ergebnisse und der niedrigen Fehlerquote der KI in der vorliegenden Studie konnte geschlussfolgert werden, dass das von Felsch et al. (2023) publizierte Webtool zuverlässig wiedergibt, ob eine frühkindliche Karies auf den untersuchten Fotos von Milchfrontzähnen vorhanden ist. Die zu Beginn formulierte Hypothese, dass zwischen interner (Felsch et al., 2023) und externer Validierung keine Unterschiede vorhanden sind, kann aufgrund der hohen diagnostischen Gesamtgenauigkeit sowie den Ergebnissen in den einzelnen Kariesklassen bestätigt werden. Die größte Differenz, mit einer lediglich 7% geringeren diagnostischen Genauigkeit in der externen Validierung im Vergleich zur internen, wurde bei der Kariesklasse „Dentinkavität“ festgestellt. In den drei anderen Kariesklassen lagen die Werte enger beieinander. Allerdings sollte zur Kenntnis genommen werden, dass in dieser Studie einerseits die Sensitivitätswerte für Initialkaries (Synonym: nicht kavitierte Läsion) und für eine fortgeschrittene kariös bedingte Kavitation hoch waren (98,5% und 92,9%) und andererseits die Werte für die graue Transluzenz bzw. Mikrokavität und kavitierte Läsion niedriger waren (68,8% und 71,7%).

Einen Überblick zu vormals publizierten Studien zum Thema der Kariesdetektion mittels KI kann man sich bei Moharrami et al. (2023) verschaffen. Bei genauerer Analyse der aufgelisteten Studien fiel auf, dass diese mitunter sehr unterschiedliche Methodiken aufwiesen (Thanh et al., 2022) oder ausführlichere Informationen in Form von Erhebung standardisierter Parameter zur Detektion und Klassifikation der Karies fehlten. Dies war beispielsweise bei Zhang, Y. et al. (2020) der Fall, die in einer Untersuchung Handyfotos mit frühkindlicher Karies einbezogen. In einer anderen Studie von Zhang, X. et al. (2022) wurde die Kariesdetektion auf Fotos mittels Sensitivitätswerten pro Bild oder pro Box ausgewertet. In Anbetracht der veröffentlichten Daten konnte eine bessere diagnostische Performance des Modells von Felsch et al. (2023) vermutet werden. Park et al. (2022) ermittelten in ihrer Studie Werte für die diagnostischen Genauigkeiten (ACC) der Kariesdetektion mit und ohne Bildextraktion. Eine andere Studienidee zeigten Duong et al. (2021), die für ihre Studie zur automatisierten Kariesdetektion Smartphonebilder von extrahierten Molaren und Prämolaren verwendeten.

Einen ähnlichen Aufbau wie bei der vorliegenden Dissertation findet man bei den Studien von Frenkel et al. (2024) und Neumayr et al. (2024). Beide prüften ebenfalls das von Felsch et al. (2023) entwickelte frei zugängliche Webtool mit etablierten Vergleichsparametern sowie die Lokalisations- und Segmentationsleistungen der KI. Wie bei der vorliegenden Dissertation zeigte hierbei die Lokalisation sehr gute Werte, während die Segmentationsleistung der KI noch verbesserungsfähig war. Hierbei muss allerdings erwähnt werden, dass es sich bei diesen Parametern um sehr spezifische Werte auf Pixelbasis handelt und diese für den Zahnarzt somit eher interessante Zusatzinformationen darstellen. Die drei genannten Studien nutzten unterschiedlich große Bilddatensätze: n=143 (Schwarzmaier et al. 2024), n=455 (Neumayr et al. 2024) und n=718 (Frenkel et al. 2024), um das KI-Modell von Felsch et al. (2023) zu prüfen. Eine Vergrößerung des Testbilddatensatzes sowie das Einbeziehen von Seitenzähnen in die vorliegende Studie zur Detektion von frühkindlicher Karies wäre erstrebenswert. In dem primären Projekt (Felsch et al., 2023) wurden zudem ausschließlich Fotos verwendet, welche mit einer professionellen Kamera aufgenommen wurden. Dies führte zu einem geringeren Bilddatensatz im Vergleich zu Frenkel et al. (2024) und Neumayr et al. (2024), welche Internetbilder verwendeten. Meurer et al. (2015) und Bottenberg et al. (2016) dokumentierten darüber hinaus, dass eine gute Fotoqualität unter anderem entscheidend für eine gute Bildauswertung ist. Aly et al. (2024) verglichen in ihrer Studie die Detektion frühkindlicher Karies anhand von Fotos von Intraoralkameras und Smartphones. Sie schlussfolgerten, dass Smartphones eine gute Option darstellen. Außerdem muss bedacht werden, dass sich im Klinikalltag nicht immer hochqualitative Fotoaufnahmen generieren lassen, weshalb Studien mit Smartphonebildern (Ding et al., 2021) ebenfalls betrachtet werden müssen.

7. Zusammenfassung und Ausblick

In der vorliegenden Diagnostikstudie wurde das KI-basierte Modell von Felsch et al. (2023) mit einem externen Bilddatensatz getestet. Die automatisierte Kariesdiagnostik wurde anhand unabhängiger Fotos von Oberkieferfrontzähnen mit frühkindlicher Karies (ECC) durchgeführt, wobei von insgesamt 143 anonymisierten Bildern 36 kariesfrei waren und 107 unterschiedlich ausgeprägte kariöse Läsionen aufwiesen. Diese wurden hinsichtlich ihrer Klassifikation, Lokalisation und Segmentierung bewertet. Geschulte Zahnärzte klassifizierten diese Läsionen in verschiedene Kategorien: nicht kavitierte kariöse Läsionen, Mikrokavitäten/gräuliche Transluzenzen, Kavitäten mit Dentinexposition und komplett kariös zerstörte Zähne. Nach dem Hochladen aller Bilder in das Webtool wurden die von der KI generierten Ergebnisse statistisch analysiert. Die diagnostische Gesamtgenauigkeit des KI-Modells betrug 97,2%. Bei der Betrachtung der Leistung der KI in Bezug auf die einzelnen Kariesklassen zeigte sich jedoch, dass es Unterschiede in den diagnostischen Genauigkeiten, Sensitivitäten, Spezifitäten und den AUC-Werten (Fläche unter der Kurve) gab. Obwohl die Ergebnisse mit denen der Studie von Felsch et al. (2023) übereinstimmen, sind weitere Studien zur externen Validierung mit unabhängigen Bildern erforderlich. Nur so kann die Leistungsfähigkeit der KI-Modelle und deren diagnostische Genauigkeit weiter verbessert werden.

8. Abstract (English)

In this diagnostic study, an existing AI model for automated caries detection was validated using an independent set of dental photographs from teeth with early childhood caries (ECC). In addition to caries detection, it was aimed to analyse the capability of classifying, localizing, and segmenting carious lesions. A total of 143 anonymized, professionally taken images of maxillary anterior teeth were used. Among them, 107 images contained carious lesions of varying severity. These lesions were visually classified by trained dentists (reference test) into the following categories: non-cavitated carious enamel, decalcified or brownish-discolored enamel surface with microcavities, gray translucency indicating dentin involvement, extensive dentin cavities, and completely destroyed tooth crowns. Each image was uploaded into the webtool, and the AI-generated results (test method) were thoroughly analyzed and statistically evaluated. In result of this investigation, the AI model achieved a diagnostic accuracy of 97.2% in determining whether the anterior deciduous teeth were caries-free or affected by caries, indicating a high level of performance. However, the diagnostic performance varied across different caries categories. Depending on the severity of the lesion, differences were observed in diagnostic accuracy, sensitivity, specificity, and AUC (area under the curve) values. These findings are consistent with those reported in the study by Felsch et al. (2023). Nevertheless, further external validation studies with independent image samples are required to understand the diagnostic performance and further develop existing AI-based models.

9. Paper I

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Validation of an Artificial Intelligence-Based Model for Early Childhood Caries Detection in Dental Photographs

Julia Schwarzmaier, Elisabeth Frenkel, Julia Neumayr, Nour Ammar, Andreas Kessler, Falk Schwendicke, Jan Kühnisch, Helena Dujic

Article

Validation of an Artificial Intelligence-Based Model for Early Childhood Caries Detection in Dental Photographs

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Abstract: Background/Objectives: Early childhood caries (ECC) is a widespread and severe oral health problem that potentially affects the general health of children. Visual–tactile examination remains the diagnostic method of choice to diagnose ECC, although visual examination could be automated by artificial intelligence (AI) tools in the future. The aim of this study was the external validation of a recently published and freely accessible AI-based model for detecting ECC and classifying carious lesions in dental photographs. **Methods:** A total of 143 anonymised photographs of anterior deciduous teeth (ECC = 107, controls = 36) were visually evaluated by the dental study group (reference test) and analysed using the AI-based model (test method). Diagnostic performance was determined statistically. **Results:** ECC detection accuracy was 97.2%. Diagnostic performance varied between carious lesion classes (noncavitated lesions, greyish translucency/microcavity, cavitation, destructed tooth), with accuracies ranging from 88.9% to 98.1%, sensitivities ranging from 68.8% to 98.5% and specificities ranging from 86.1% to 99.4%. The area under the curve ranged from 0.834 to 0.964. **Conclusions:** The performance of the AI-based model is similar to that reported for the internal dataset used by developers. Further studies with independent image samples are required to comprehensively gauge the performance of the model.

Keywords: dental caries; early childhood caries; artificial intelligence; diagnosis



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1. Introduction

Early childhood caries (ECC) is among the most prevalent diseases worldwide [1–4]. Defined as the presence of one or more noncavitated or cavitated carious lesions, and missing or filled tooth surfaces due to caries in any deciduous tooth in a child under the age of six, ECC is often associated with a loss of dental functionality and aesthetics, pain due to abscesses, underweight, or reduced quality of life if left untreated [5]. Furthermore, the risk of caries development in the permanent dentition is increased [6]. For experienced professionals, the diagnosis of ECC is usually an immediate visual diagnosis. The diagnostic assessment is made using various classification systems, which consider either the extent of affected deciduous teeth in relation to age [4,7] or the distribution pattern of carious lesions in the dentition [8]. The established visual criteria facilitate precise diagnostic assessment of all teeth or tooth surfaces [9–13].

As part of ongoing efforts to digitise and automate caries diagnostics, several studies have reported on the use of deep learning models for caries detection on intraoral photographs [14–18] and dental radiographs [19–21]. Although these studies differ in methodology, model type, and dataset size, the reported results show promising diagnostic

performance [14,15,18,19,21]. Specifically in paediatric dentistry, AI-based models have been explored not only for caries detection on intraoral photographs [17] but also for the identification and numbering of deciduous and permanent teeth [22,23] as well as the identification of mesiodens on radiographs [24–26].

Despite these advances, most studies report only internal validation data—results obtained during the initial development and validation using the test dataset—and the models developed are often not freely accessible [15–18]. Furthermore, the lack of external validation limits their applicability to different clinical settings. In contrast to this, Felsch et al. [14] published a model that uses artificial intelligence (AI) to automatically detect, classify, localise and segment caries on photographs of teeth. This AI-based model is freely accessible and can currently be used for image analysis without restriction. This accessibility is crucial as it allows for external validation using independent imaging data that were not part of the model's training. Thus, the model's diagnostic performance and, by extension, its generalisability can be tested on new, unseen data, enabling a comparison with the internal validation results. The aim of the present study was to validate the AI-based model [14] using independent image data of anterior deciduous teeth. It was hypothesised that there would be no significant differences between the internal and external validation accuracies.

2. Materials and Methods

This investigation was conducted following the recommendations of the STARD Steering Committee (Standards for Reporting of Diagnostic Accuracy Studies) and the recently published recommendations for the design and conduct of studies using AI methods in dental research [27,28].

2.1. Dental Images

A total of 143 anonymised dental photographs of anterior deciduous teeth were selected from an established external image database created for clinical documentation and training purposes, which includes a wide range of clinical presentations of ECC. The images were captured by an experienced dentist (JK) using standard procedures. Specifically, each intraoral image was taken with a professional single-reflex lens camera (D300, D7100, or D7200 with a Nikon Micro 105 mm lens, Nikon, Minato (Tokio), Japan) equipped with a macro lens and a macro flash (EM-DG 140, Sigma, Kawasaki (Kanagawa), Japan). Before taking the photographs, the teeth were cleaned and dried. All photographs had the following parameters: aspect ratio of 3:2, minimum resolution of 2784×1856 pixels without compression, jpeg format and RGB colour space. None of the photographs were generated using AI methods, edited or manipulated. The selection was conducted independently of all other analyses by an examiner with over 20 years of clinical experience, including extensive practice in paediatric dentistry. The process followed established clinical criteria for detecting and diagnosing ECC, utilizing classification systems that assess the distribution pattern of lesions in the dentition [8]. These criteria ensured that the selected images accurately and comprehensively reflected the relevant clinical manifestations.

2.2. Dental Image Evaluation (Reference Test)

The selected photographs ($n = 143$) were evaluated in detail by the dental study group of five dentists (JS, EF, JN, HD, JK). The dataset included images from different stages of ECC ($n = 107$) and caries-free dentitions ($n = 36$). In addition to the basic decision as to whether ECC was present, all existing caries findings were carefully evaluated. In detail, each carious lesion was classified according to the ICDAS/UniViSS criteria: caries-related noncavitated opacities in the enamel, caries-related breakdown of the chalky or brown-stained enamel surface in the form of a microcavity, greyish translucency indicating underlying dentin involvement, cavitation with visible dentin involvement, and extensive cavities up to the complete destruction of the tooth crown [12,29,30]. In case of differing opinions, the finding was discussed within the dental study group until a consensus

decision was reached among the five dentists. The documented findings served as the reference test.

Prior to this study, the investigators had completed a one-day theoretical training session on the assessment of ECC and noncavitated and cavitated carious lesions under the supervision of an experienced principal investigator. The training provided information on the study design, indices and diagnostic principles.

2.3. AI-Based Image Evaluation (Test Method)

For automated image evaluation, the freely accessible web tool (<https://demo.dental-ai.de/>, accessed on 21 August 2024), which can detect, classify, localise and segment carious lesions on dental photographs, was used for AI-based analysis [14]. The carious lesion classification was based on the ICDAS and UniViSS criteria [12,29,30]. Specifically, the web tool distinguishes between the following caries scores: 1—noncavitated carious lesion, 2—greyish translucency/microcavity, 3—caries-related cavitation and 4—destroyed tooth (Figure 1). All selected anonymised images ($n = 143$) were uploaded individually to the aforementioned website. Once uploaded, the images were cropped to optimally display the four maxillary incisors (area of interest, Figure 1). Automated image analysis was then performed, and all potential classes of findings were marked as coloured pixels. Each colour corresponds to a specific type of finding identified by the AI-based model. Multiple adjacent pixels of the same colour formed a pixel cloud or segment representing a localised area of interest. For example, green pixels indicate cavitated lesions, while blue pixels represent greyish translucencies (Figure 1). For dental images showing caries-free dentition, no segment was highlighted by the AI-based model (Figure 1). Each AI-based image analysis result was captured and saved as a screenshot for later independent dental evaluation (Figure 1). After two weeks, the findings and segments marked by the AI-based model were assessed separately by the dental study group. A total of 261 segments were identified on all included dental photographs as AI outputs. In addition, localisation and segmentation of all caries segments from the AI-based image analysis were assessed for their correctness. Caries segment localisation could be either correct or incorrect. Here, at least one pixel had to be located in the carious lesion. When assessing the marked segments (AI outputs), a distinction was made between incorrect, partially correct and fully correct segments. If >90% of the actual caries extent was recognised by the AI, this was classified as fully correct. If the AI recognised most of the caries extent (<90%), this corresponded to the partially correct segmentation and for caries segments outside the actual lesion, the segmentation was classified as incorrect. The segments were assessed as estimates, as exact values could not be determined.

2.4. Data Management and Statistics

For this project, an entry form was used to document all diagnostic findings directly (EpiData Manager and EpiData Entry Client, V4.6.0.6, EpiData Association, Odense, Denmark, <http://www.epidata.dk>, accessed on 21 August 2024). The dataset was exported to an Excel spreadsheet (Excel 2019, Microsoft Corporation, Redmond, WA, USA) following data collection and prepared for statistical exploration. The diagnostic performance of the test method in comparison to the reference test was calculated using Python V3.8.5 (<http://www.python.org>, accessed on 21 August 2024). The true-positive (TP), true-negative (TN), false-positive (FP) and false-negative (FN) rates were calculated as key figures from contingency tables [31]. Based on this, accuracy (ACC), sensitivity (SE), specificity (SP), and positive and negative predictive values (PPV , NPV) were determined:

$$ACC = (TP + TN) / (TP + TN + FP + FN) \quad (1)$$

$$SE = TP / (TP + FN) \quad (2)$$

$$SP = TN / (TN + FP) \quad (3)$$

$$PPV = TP / (TP + FP) \quad (4)$$

$$NPV = TN / (TN + FN) \quad (5)$$



Figure 1. Exemplary photographs (left) and corresponding AI-based image analysis (right).

In addition, the area under the receiver operating characteristic (ROC) curve (*AUC*) was determined.

3. Results

The AI-based diagnostic model correctly diagnosed caries in terms of ECC on the photographs in a total of 104 images and thus achieved a *SE* of 97.2% (Table 1). Out of 36 photographs with caries-free deciduous teeth, 35 were correctly recognised, yielding a *SP* of 97.2%. This resulted in an overall diagnostic accuracy of 97.2% (Table 1).

The chosen dental photographs included multiple carious lesions which, therefore, required further analyses. The cross-tabulation of all caries diagnostic decisions from the AI-based evaluation (test method) and the visual examination (reference standard) can be taken from Table 2. The *TP*, *TN*, *FP* and *FN* rates are summarized for each caries class in Table 3. The diagnostic performance parameters of the external validation of the AI-based model are listed in Table 4. In detail, the *ACC* for the test method ranged from 88.9% (cavitation) to 98.1% (destroyed tooth). The *SE* values ranged from 68.8% (greyish

translucency/microcavity) to 98.5% (noncavitated carious lesion). The *SP* values ranged from 86.1% (noncavitated carious lesion) to 99.4% (cavitation).

Table 1. Cross-tabulation including diagnostic performance parameters for the image-related AI-based evaluation (test method) presented in rows in relation to the visual consensus diagnosis by the dental workgroup (reference test) presented in columns. In this analysis, the diagnostic performance for caries detection per image (*n* = 143) was considered.

Caries Detection		Visual Evaluation (Reference Test)		
		Healthy	Caries	
AI-based evaluation (Test method)	Healthy	35	3	<i>NPV</i> = 92.1%
	Caries	1	104	<i>PPV</i> = 99.0%
		<i>SP</i> = 97.2%	<i>SE</i> = 97.2%	<i>ACC</i> = 97.2%

Table 2. Contingency table of the AI-based image evaluation data (test method) presented in rows and visual consensus diagnosis data (reference test) presented in columns for all caries segments. This tabulation includes all diagnoses (*n* = 261) from all images (*n* = 143), with multiple findings per image possible.

Caries Classification		Visual Evaluation (Reference Test)					Σ
		Healthy *	Noncavitated Caries Lesion	Greyish Translucency/Microcavity	Cavitation	Destructed Tooth	
AI-based evaluation (Test method)	Healthy *	35	1	0	2	1	39
	Noncavitated caries lesion	2	66	5	19	1	93
	Greyish translucency/Microcavity	0	0	11	5	0	16
	Cavitation	0	0	0	71	1	72
	Destructed tooth	0	0	0	2	39	41
	Σ	37	67	16	99	42	261

* Caries-free surfaces are indicated by the absence of segment markings.

Table 3. The table illustrates the true-positive (*TP*), true-negative (*TN*), false-positive (*FP*) and false-negative (*FN*) rates in relation to the used caries classes. The tabulation summarizes all diagnoses (*n* = 261) from all photographs (*n* = 143) as shown in the contingency table.

	Healthy	Noncavitated Caries Lesion	Greyish Translucency/Microcavity	Cavitation	Destructed Tooth
	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)
True positives	35 (13.4)	66 (25.3)	11 (4.2)	71 (27.2)	39 (14.9)
True negatives	220 (84.3)	167 (64.0)	240 (92.0)	161 (61.7)	217 (83.1)
False positives	4 (1.5)	27 (10.3)	5 (1.9)	1 (0.4)	2 (0.8)
False negatives	2 (0.8)	1 (0.4)	5 (1.9)	28 (10.7)	3 (1.2)
Σ	261 (100.0)	261 (100.0)	261 (100.0)	261 (100.0)	261 (100.0)

Figure 2 shows the ROC curves for the chosen caries classes and images with a caries-free dentition. The corresponding *AUC* values, which ranged from 0.834 for greyish translucency/microcavity to 0.964 for healthy dentition (Table 4), provide a summary measure of the model's overall diagnostic performance for each caries class.

Table 4. Diagnostic performance of the AI-based evaluation for each of the chosen caries classes. The calculations are based on all *TP*, *TN*, *FP* and *FN* rates ($n = 261$ in each caries class) from all photographs ($n = 143$) as shown in Table 3.

	Healthy	Noncavitated Caries Lesion	Greyish Translucency/ Microcavity	Cavitation	Destructed Tooth
ACC (in %)	97.7	89.3	96.2	88.9	98.1
SE (in %)	94.6	98.5	68.8	71.7	92.9
SP (in %)	98.2	86.1	98.0	99.4	99.1
PPV (in %)	89.7	71.0	68.8	98.6	95.1
NPV (in %)	99.1	99.4	98.0	85.2	98.6
AUC	0.964	0.923	0.834	0.855	0.960

Abbreviations: ACC, accuracy; SE, sensitivity; SP, specificity; PPV, positive predictive value; NPV, negative predictive value; AUC, area under the receiver operating characteristic (ROC) curve.

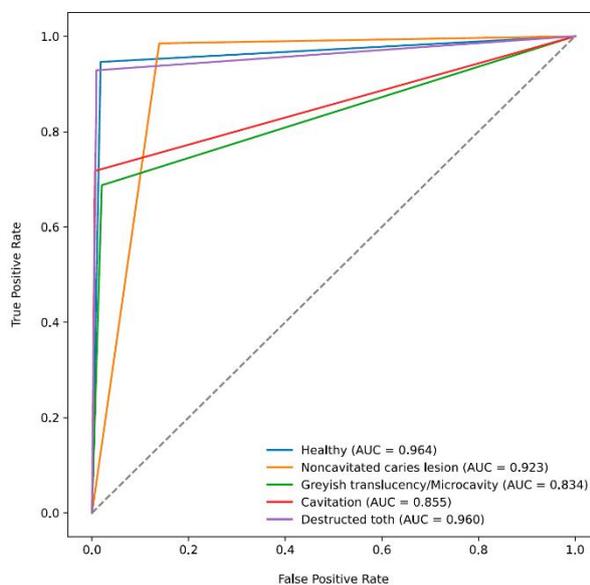


Figure 2. Receiver operating characteristic (ROC) curves and corresponding area under ROC curve (*AUC*) values for the test method and the chosen caries classes. Curves above the dashed line indicate that the proportion of correctly classified images is greater than the proportion of incorrectly classified ones.

The results for caries lesion localisation and segmentation are shown in Tables 5 and 6. A total of 143 images were analysed with the AI-based model, whereby this sample showed 226 carious lesions (86.6%) and 35 caries-free images (13.4%). In the case of existing caries, 220 segments (84.3%) were correctly localised; only 6 segments (2.3%) were incorrectly localised (Table 5). The AI-based model correctly predicted segmentation in 114 cases (43.6%). The segmentation of 101 cases (38.7%) was partially correct and in 11 cases (4.3%) the prediction was outside the existing carious lesion (Table 6).

Table 5. Results of the evaluation of AI-based caries localisation. The analysis included all diagnoses ($n = 261$) from all images ($n = 143$). * No caries localisation was possible.

	Healthy *	Noncavitated Caries Lesion	Greyish Translucency /Microcavity	Cavitation	Destructed Tooth	Σ
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Incorrect	4 (1.5)	2 (0.8)	-	-	-	6 (2.3)
Correct	-	91 (34.9)	16 (6.1)	72 (27.6)	41 (15.7)	220 (84.3)
Healthy *	35 (13.4)	-	-	-	-	35 (13.4)
Σ	39 (14.9)	93 (35.7)	16 (6.1)	72 (27.6)	41 (15.7)	261 (100.0)

Table 6. Summary of the evaluation of AI-based caries segmentation. The analysis included all diagnoses ($n = 261$) from all images ($n = 143$). * No caries segmentation was possible.

	Healthy *	Noncavitated Caries Lesion	Greyish Translucency /Microcavity	Cavitation	Destructed Tooth	Σ
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Incorrect	4 (1.5)	2 (0.8)	1 (0.4)	3 (1.2)	1 (0.4)	11 (4.3)
Partially correct	-	31 (11.9)	9 (3.4)	36 (13.8)	25 (9.6)	101 (38.7)
Fully correct	-	60 (23.0)	6 (2.3)	33 (12.6)	15 (5.7)	114 (43.6)
Healthy *	35 (13.4)	-	-	-	-	35 (13.4)
Σ	39 (14.9)	93 (35.7)	16 (6.1)	72 (27.6)	41 (15.7)	261 (100.0)

4. Discussion

The study showed that the freely accessible AI-based model can detect carious lesions on dental photographs from photographs with ECC with a high diagnostic accuracy of 97.2% (Table 1). The documented *AUC* values from the ROC curves for the classification of the included caries categories ranged from 0.834 to 0.964 (Figure 2), indicating an encouraging result for automated caries detection on photographs of anterior deciduous teeth. Furthermore, the AI-based model demonstrated high sensitivity and specificity for detecting noncavitated lesions (*SE* 98.5%, *SP* 86.1%) and destructed teeth (*SE* 92.9%, *SP* 99.1%), showing a promising performance in identifying both early-stage and advanced carious lesions. However, the model's lower sensitivity for cavitated lesions (*SE* 71.7%) and greyish translucency/microcavity (*SE* 68.8%) indicates that despite high specificity, a number of cases in these categories might be overlooked. A comparison of the documented data on external validity (Table 4) with the published results on internal validity [14] showed very good agreement based on the *ACC* values. The *ACC* values from the internal [14] and external validation (Table 4, Figure 2) datasets were 90.1% and 89.3% (noncavitated carious lesion), 99.0% and 96.2% (greyish translucency/microcavity), 95.9% and 88.9% (cavitation), and 99.0% and 98.1% (destructed tooth), respectively. Based on these findings, the initial hypothesis that there would be no difference between the external and internal accuracies can be confirmed.

Moreover, when considering other diagnostic studies on automated caries detection and classification in dental photographs, a more inconsistent picture emerges. In a study project that included smartphone images of ECC patients, the model performance was assessed but not supported by detailed validation data on caries detection and classification [32]. In another paper, Zhang et al. [33] published data on the internal validity of their approach to AI-based caries detection on dental photographs. However, the internal validation data indicated that the model performance appears to be substantially lower than that of the model presented by Felsch et al. [14]. Specifically, the model by Zhang et al. [33] achieved an imagewise *SE* of 81.9% and a boxwise *SE* of 64.6% [33]. In another project [16], four different AI-based models for caries detection were developed, and their

internal validity was assessed. The ACC values varied depending on the deep learning model, ranging from 60.7% to 68.8% for noncavitated lesions and from 81.0% to 87.4% for cavitated lesions. Similarly, Park et al. [34] reported internal validity data of a similar magnitude for caries detection, with ACC values of 75.8% without object extraction and 81.3% with object extraction. In addition, further projects on caries detection and classification on dental photographs were published, which had fewer methodological similarities with the aforementioned studies. Moharrami et al. [35] published an overview of the currently available projects and noted that automatic dental caries detection using AI may provide objective verification of clinicians' diagnoses. However, future studies should use more robust designs, standardized metrics, and focus on caries detection and classification metrics.

A special feature of the freely accessible AI-based model [14] is that, in addition to caries detection and classification, the evaluated images include information on lesion localisation and segmentation. This is accompanied by the simultaneous visualisation of different caries classes in one image as part of a carious lesion (Figure 1). Compared to conventional clinical examination, this is an interesting feature of AI-based image evaluation that has not yet been considered. Evaluating the information on lesion localisation (Table 5), 220 out of a total of 226 cases were correct and thus in the range of high diagnostic performance. Only a few cases ($n = 6$) showed incorrect localisation. This situation was somewhat less favourable for the segmentation performance of the AI-based model, as only 114 of 226 lesion segments were fully correct (Table 6). The model performed best in the segmentation of noncavitated carious lesions. Fully destructed teeth and dentin cavitation were proportionally less likely to be segmented fully correctly; i.e., the displayed areas deviated from the actual extent of caries in the dentist's assessment. However, it should be noted that such evaluations are based on analysing each individual image at the pixel level, offering the dentist an unprecedented level of precision. Further improvements, which could be achieved by continuously fine-tuning the AI-based model, are desirable at this point.

Finally, the strengths and limitations of this study project should be discussed. This study represents an external validation of a recently published and freely available AI-based method for automated image analysis. For this purpose, this study utilised image data that had not been used in the development of the model. This allowed for an independent verification of the AI-based model. The images used in this study were professionally captured and of comparable quality to the training dataset of the AI-based model [14]. On the one hand, it can be assumed that high quality has a positive effect on AI-based image evaluation; on the other hand, it can be argued that high-quality images may not be available in all clinical situations. This ultimately raises the question to what extent a correct diagnosis can be made on low-quality images. However, it should also be noted that the object of interest needs to be correctly depicted [36], as otherwise, a diagnostic evaluation is potentially impossible. Provided the images are of good quality, a valid diagnostic assessment is ultimately possible [36,37]. Furthermore, the photographs only showed anterior deciduous teeth in this study. Therefore, no conclusions can be drawn about the diagnostic performance in the posterior region, for which the AI-based model was also developed [14]. Moreover, the fact that the included images were anonymized and lacked clinical data can be taken into account as a limitation. This is relevant with regard to the potential impact of remineralisation on the visual characteristics of the lesions, as remineralised areas may appear less prominent or have a different structure compared to active lesions. It remains unclear to what extent this process could affect the diagnostic performance of the AI-based model. Given the number of included and available photographs both with and without ECC for this study, it should be emphasized that although a larger number of images would be desirable, obtaining such a dataset with high-quality images seems rather challenging. Nevertheless, these points should be considered in future studies to verify the reliability and generalizability of the tested AI-based model. Another desirable feature that is not yet possible with the validated AI-based

model is the analysis of images with regard to a more precise ECC type [4,7,8]. The currently available AI-based model [14] enables only the detection, classification, localisation and segmentation of caries and enamel hypomineralisations. Furthermore, it is currently unable to analyse direct or indirect restorations, dental trauma and other findings, such as plaque and discolouration. Additionally, the evaluation of dental photographs with multiple teeth is not yet fully functional, requiring the area of interest to be centred using the crop tool for valid image analysis. Ultimately, this approach was also part of the methodology of this diagnostic study, which relied on visual consensus diagnoses as the reference test, without the inclusion of any histological investigation techniques to provide details about caries characteristics. Lastly, while detailed evaluations of carious lesions cannot be performed independently of the AI-based diagnostic output, the study group aimed to minimise potential evaluation bias by making consensus decisions on all diagnoses.

5. Conclusions

In comparison to the initially published internal validation data [14], we found similar results in our external validation of dental photographs of cases with and without ECC. This underlines the diagnostic quality of the AI-based model presented by Felsch et al. [14] for caries detection, classification, localisation and segmentation. However, additional studies with independent image samples are needed to comprehensively describe the performance of the model.

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Informed Consent Statement: Not applicable.

Data Availability Statement: The AI-based model is available as a web application and can be accessed at <https://dental-ai.de> (accessed on 21 August 2024). The data that support the findings of this study are available from the corresponding author upon reasonable request.

Conflicts of Interest: The authors declare no conflicts of interest.

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10. Paper II

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Caries Detection and Classification in Photographs Using an Artificial Intelligence-Based Model-An External Validation Study

Elisabeth Frenkel, Julia Neumayr, Julia Schwarzmaier, Andreas Kessler, Nour Ammar, Falk Schwendicke, Jan Kühnisch, Helena Dujic



Article

Caries Detection and Classification in Photographs Using an Artificial Intelligence-Based Model—An External Validation Study

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Abstract: Objective: This ex vivo diagnostic study aimed to externally validate a freely accessible AI-based model for caries detection, classification, localisation and segmentation using an independent image dataset. It was hypothesised that there would be no difference in diagnostic performance compared to previously published internal validation data. Methods: For the independent dataset, 718 dental images representing different stages of carious ($n = 535$) and noncarious teeth ($n = 183$) were retrieved from the internet. All photographs were evaluated by the dental team (reference standard) and the AI-based model (test method). Diagnostic performance was statistically determined using cross-tabulations to calculate accuracy (ACC), sensitivity (SE), specificity (SP) and area under the curve (AUC). Results: An overall ACC of 92.0% was achieved for caries detection, with an ACC of 85.5–95.6%, SE of 42.9–93.3%, SP of 82.1–99.4% and AUC of 0.702–0.909 for the classification of caries. Furthermore, 97.0% of the cases were accurately localised. Fully and partially correct segmentation was achieved in 52.9% and 44.1% of the cases, respectively. Conclusions: The validated AI-based model showed promising diagnostic performance in detecting and classifying caries using an independent image dataset. Future studies are needed to investigate the validity, reliability and practicability of AI-based models using dental photographs from different image sources and/or patient groups.

Keywords: dental caries; diagnosis; validation study; artificial intelligence; deep learning



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1. Introduction

Dental caries is a prevalent, noncommunicable disease that requires appropriate diagnostics, oral health promotion, prevention and treatment measures [1,2]. By emphasizing non-invasive or minimally invasive caries management strategies, the importance of regular diagnostic evaluation is undebatable. Here, visual examination (VE) is the method of first choice [3–7], supported by supplementary X-ray-free or radiological diagnostic procedures when indicated [8,9]. In this context, all diagnostic procedures must have good validity, reliability and practicability. Notably, with respect to validity, false positive decisions should be avoided, as they can be potentially linked to overtreatment [10].

The importance of automated image analysis in medicine and dentistry has increased in recent years [11–14]. Automation can be achieved through the application of artificial intelligence (AI) methods. One data source for automated caries detection is digital photographs of teeth, which can be understood as the machine-readable equivalent of

conventional visual examination. The few available data demonstrate promising accuracy of caries detection and classification in photographs using AI [13]. Notably, any such accuracy measures were generated using internal data, i.e., testing data stemmed from the same source as data used for training the AI-based algorithm. The associated risk of bias when only testing on such internal data has been demonstrated in several recent research projects [15–20].

While most studies on AI-based caries detection do not provide access to the developed algorithms, a recent model for caries detection, classification, localisation and segmentation developed by Felsch et al. [16] is freely accessible online as a web application. Unlike AI-based models for caries detection in X-rays, most of which are only available to dentists as paid software, this web application is the first to enable professionals to have clinical photographs of teeth automatically analysed by an AI-based model. Notably, such testing by others may be conducted independently from the workgroup publishing the data, i.e., using external test data. At present, the lack of external validations for AI-based models represents a significant knowledge gap in this field, highlighting the need for independent evaluations to ensure reliability and broader applicability. The aim of this study was to determine the external accuracy of this developed AI model for caries detection using an independent sample of images from the internet. It was hypothesised that the external validity would be identical to the internal validity published by Felsch et al. [16].

2. Materials and Methods

The present ex vivo diagnostic study is part of the “Caries detection with artificial intelligence” project at the Department of Conservative Dentistry and Periodontology, which received the approval of the Ethics Committee of the Medical Faculty of the Ludwig-Maximilians-Universität München (project number 020-798). The study was implemented in accordance with the guidelines of the Standards for Reporting of Diagnostic Accuracy Studies (STARD) Steering Committee [21]. In addition, the latest recommendations for standardizing the planning, implementation and publication processes of dental studies using AI methods were considered [22].

2.1. Collection of Dental Photographs from the Web

To externally validate the recently published AI-based model (<http://demo.dental-ai.de>; accessed 23 September 2024) [16], independent image data not involved in the development of the model were necessary. To fulfil this requirement, photographs of teeth with or without carious lesions were obtained from freely accessible internet sources. The following keywords were entered in a web browser (www.google.de) to search for photographs: “caries”, “primary dentition”, “permanent dentition”, “early childhood caries”, “beginning caries”, “noncavitated caries” and “cavity”. The inclusion criteria required photographs that were clear or exhibited minimal blur or distortion, had sufficient lighting, were without artefacts and had a minimum resolution of 72 pixels per inch. Exclusion criteria were images of teeth with direct/indirect dental restorations and tooth structure disorders, such as molar incisor hypomineralisation or fluorosis, as well as images showing rare dental diseases. The search and selection process took place over a period of two weeks and was carried out by the participating dentists, whereby uncertainties regarding the eligibility of inclusion and exclusion criteria were discussed in the working group. The identified photographs featured individual anterior and posterior teeth, with posterior teeth mainly captured from the occlusal view and anterior teeth from the vestibular view. Each photograph focused on single teeth rather than multiple teeth or a single arch. Regarding the previously defined inclusion criteria, a total of 287 and 431 photographs of deciduous and permanent teeth, respectively, were identified. The image set ($n = 718$) included 183 photographs of healthy teeth and 535 photographs of carious teeth; the latter group exhibited caries to varying degrees of severity. The photographs were saved in the given resolution and respective format to make them available for later image analysis.

2.2. Caries Detection and Classification by the Dental Workgroup (Reference Standard)

All included photographs ($n = 718$) were analysed, classified and agreed upon by the workgroup (EF, JN, JS, HD and JK). In the event of differing opinions, the image in question was discussed until a consensus was reached. The visual detection and classification of carious lesions were based on established criteria for caries detection [23–27]. In the first step, it was determined whether caries could be identified in the photograph or not (score 0—no caries). In the second step, differentiation was made regarding the degree of severity: 1—noncavitated caries (presence of opacities or discolouration indicating an established noncavitated lesion on the enamel surface), 2—greyish translucency/microcavity (greyish translucency of the enamel as a sign of undermining dentin involvement/caries-induced breakdown on the natural enamel surface), 3—cavitation (visible dentin involvement) and 4—destroyed tooth (extensive cavity with near-total loss of the tooth crown). The categories were based on the established diagnostic classes from the available visual diagnostic systems [23–27] and the classes included in the AI-based model. In addition to the assessment of existing carious lesions by dentists, the photograph quality was evaluated and classified as either “acceptable” or “good”. This assessment included sharpness, resolution and exposure quality. When opinions in the workgroup diverged, the arguments for each classification were exchanged and discussed until a consensus was reached. The results of the dental evaluation provided a reference standard for the subsequent statistical exploration of the data. The reference standard was established before any AI-based image evaluation and can, therefore, be regarded as independent (Figure 1).

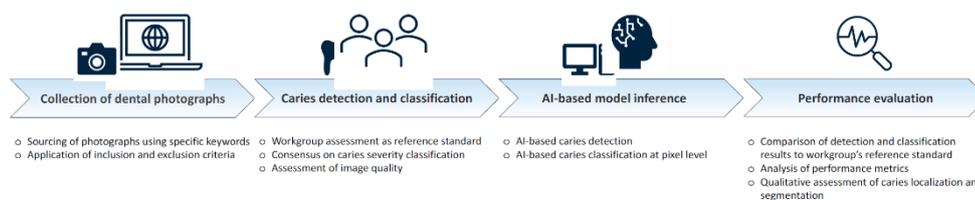


Figure 1. Workflow diagram illustrating the methodological steps.

2.3. Caries Detection and Classification by the AI-Based Model (Test Method)

The above mentioned AI-based model be applied to detect caries and classify the clinical appearance as follows: 1—noncavitated caries, 2—greyish translucency/microcavity, 3—cavitation and 4—destroyed tooth with nearly complete loss of the tooth crown [16]. For images showing teeth without caries, no pixel-level class was assigned by the AI-based model. Consequently, the class 0—no caries was documented for such images. The existing caries features were classified at a pixel level, allowing multiple caries classes to be identified simultaneously for each photograph. After accessing the abovementioned website, each photograph ($n = 718$) was uploaded separately, and the area of interest was narrowed, as required, using the crop tool, followed by AI-based image evaluation. The analysis was performed several weeks after the initial consensus on the reference standard. Each AI-based detection and classification result was verified within the workgroup (EF, JN, JS, HD and JK) to reach a group consensus.

2.4. Caries Localisation and Segmentation by the AI-Based Model

As part of the evaluation, the segments generated using the AI-based model were evaluated for correctness regarding localisation and segmentation (Figure 2). First, a comparison was made as to whether the localisation was accurately identified. For this purpose, at least one pixel from the marked segment had to lie within the corresponding carious lesion. If there was no pixel within the actual carious lesion, it was determined that the caries was incorrectly localised. In the second step, the quality of the segmentation was evaluated, and the predicted segment was compared with the present carious lesion. A

distinction was made between a complete (approximately >90% match), partial (approximately <90% match) or absent match. The match could only be qualitatively estimated based on the photograph, as no quantitative image data were provided.

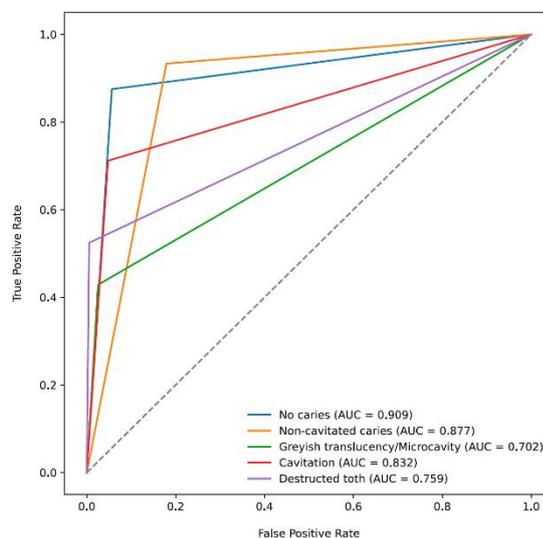


Figure 2. ROC curves and the corresponding AUCs for all caries classes.

2.5. Data Management and Statistical Analysis

All photographic information and diagnostic decisions for the test method and reference standard were recorded in a digital datasheet created for this study. For this purpose, open-access data processing software was used (EpiData Manager and EpiData Entry Client, version v4.6.0.6, EpiData Association, Odense, Denmark, <http://www.epidata.dk>, accessed 23 September 2024). Before descriptive and explorative data analyses, data were exported and visualised using an Excel spreadsheet (Excel 2019, Microsoft, Redmond, WA, USA) and checked for validity. Using Python (version 3.8.5, <http://www.python.org>, accessed 23 September 2024), and the diagnostic performance of the test method relative to the reference standard was calculated. Specifically, the numbers of true positives (TPs), false positives (FPs), true negatives (TNs) and false negatives (FNs), the sensitivity (SE), the specificity (SP), the positive and negative predictive values (PPVs and NPVs, respectively), the diagnostic accuracy ($ACC = (TN + TP) / (TN + TP + FN + FP)$) and the area under the receiver operating characteristic (ROC) curve (AUC) were determined [28].

3. Results

The diagnostic performance of the AI-based image analysis (test method) was determined relative to the dental workgroup consensus (reference standard). In the first step, image-based caries detection was considered, resulting in a diagnostic accuracy of 92.0%. SE and SP were 92.0% and 91.8%, respectively (Table 1).

In the next step, all recorded carious lesions ($n = 991$) in the available photographs ($n = 718$) were considered. Cavitated ($n = 326$) and noncavitated lesions ($n = 300$) and caries-free teeth ($n = 192$) were the most frequent dental findings (Table 2). The overall agreement was 76.9%; there were 44 false positives (4.4%) and 185 false negatives (18.7%) (Table 2). The diagnostic performance of the test method across different lesion classes is shown in Table 3. Here, the overall diagnostic accuracy ranged from 85.5% (noncavitated caries) to

95.6% (destroyed tooth). SE ranged between 42.9% (greyish translucency/microcavity) and 93.3% (noncavitated caries), and SP ranged between 82.1% (noncavitated caries) and 99.4% (destroyed tooth). The AUC was between 0.702 (greyish translucency/microcavity) and 0.909 (no caries). The corresponding ROC curves are shown in Figure 2.

Table 1. Cross-tabulation including diagnostic performance parameters for the AI-based image evaluation in relation to the visual consensus diagnosis by the dental work group (reference standard). In this analysis, only the ability for caries detection per image ($n = 718$) was considered.

Image-Related Caries Detection		Visual Evaluation (Reference Standard)			
		No Caries	Caries	Σ	
AI-based evaluation (Test method)	No caries	168	43	211	NPV = 79.6% PPV = 97.0%
	Caries	15	492	507	
Σ		183	535	718	
		SP = 91.8%	SE = 92.0%		ACC = 92.0%

Table 2. Cross-tabulation of the AI-based image evaluation in relation to the visual consensus diagnosis by the dental work group (reference standard) for all caries diagnoses. This tabulation includes all diagnoses ($n = 991$) from all images ($n = 718$); multiple findings per image were possible.

		Visual Evaluation (Reference Standard)					Σ
		No Caries	Noncavitated Caries	Greyish Translucency/Microcavity	Cavitation	Destroyed Tooth	
AI-based evaluation (Test method)	No caries	168	6	6	29	4	213
	Noncavitated caries	21	280	42	50	11	404
	Greyish translucency/Microcavity	1	9	39	13	0	62
	Cavitation	1	3	4	232	24	264
	Destroyed tooth	1	2	0	2	43	48
Σ		192	300	91	326	82	991

Table 3. Summary of the diagnostic performance for all caries classes. The tabulation included all diagnoses ($n = 991$) from all images ($n = 718$).

	True Positives		True Negatives		False Positives		False Negatives		Diagnostic Performance (%)					
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	ACC	SE	SP	PPV	NPV	AUC
	No caries	168	17.0	754	76.1	45	4.5	24	2.4	93.0	87.5	94.4	78.9	96.9
Noncavitated caries	280	28.3	567	57.2	124	12.5	20	2.0	85.5	93.3	82.1	69.3	96.6	0.877
Greyish translucency/Microcavity	39	3.9	877	88.5	23	2.3	52	5.2	92.4	42.9	97.4	62.9	94.4	0.702
Cavitation	232	23.4	633	63.9	32	3.2	94	9.5	87.3	71.2	95.2	87.9	87.1	0.832
Destroyed tooth	43	4.3	904	91.2	5	0.5	39	3.9	95.6	52.4	99.4	89.6	95.9	0.759

In addition, the diagnostic performance was determined considering the image quality of each digital photograph, which was classified as either “acceptable” or “good”. The calculated values can be taken from Table 4. We also evaluated the correctness of caries localisation and segmentation (Table 5). In principle, the AI-based method correctly predicted caries localisation in 755 cases (97.0%) but incorrectly in 23 cases (3.0%). Fully and partially

correct segmentation was achieved for 52.9% and 44.0% of carious lesions, respectively, with 3.0% of the lesions being incorrectly segmented (Table 5).

Table 4. Summary of the diagnostic performance for all caries classes in relation to image quality. The tabulation includes all diagnoses ($n = 991$) from all images ($n = 718$).

	Image Quality	True Positives (n)	True Negatives (n)	False Positives (n)	False Negatives (n)	Diagnostic Performance (%)					
						ACC	SE	SP	PPV	NPV	AUC
No caries	Acceptable	95	277	19	17	91.2	84.8	93.6	83.3	94.2	0.892
	Good	73	477	26	7	94.3	91.3	94.8	73.7	98.6	0.930
Noncavitated caries	Acceptable	90	257	56	5	85.0	94.7	82.1	61.6	98.1	0.884
	Good	190	310	68	15	85.8	92.7	82.0	73.6	95.4	0.873
Greyish translucency/Microcavity	Acceptable	13	374	7	14	94.9	48.1	98.2	65.0	96.4	0.732
	Good	26	503	16	38	90.7	40.6	96.9	61.9	93.0	0.688
Cavitation	Acceptable	85	265	16	42	85.8	66.9	94.3	84.2	86.3	0.806
	Good	147	368	16	52	88.3	73.9	95.8	90.2	87.6	0.849
Destroyed tooth	Acceptable	23	357	4	24	93.1	48.9	98.9	85.2	93.7	0.739
	Good	20	547	1	15	97.3	57.1	99.8	95.2	97.3	0.785

Table 5. Overview of the correctness of the AI-based caries localisation and segmentation. The analysis includes all caries diagnoses ($n = 778$).

	Localisation				Segmentation					
	Correct		Incorrect		Fully Correct		Partially Correct		Incorrect	
	N	%	N	%	N	%	N	%	N	%
Noncavitated caries	387	49.7	17	2.2	224	28.8	163	21.0	17	2.2
Greyish translucency/Microcavity	59	7.6	3	0.4	22	2.8	37	4.8	3	0.4
Cavitation	262	33.7	2	0.3	145	18.6	117	15.0	2	0.3
Destroyed tooth	47	6.0	1	0.1	21	2.7	26	3.3	1	0.1
Σ	755	97.0	23	3.0	412	52.9	343	44.1	23	3.0
	778 *				778 *					

* In total, 213 images were categorised as “no caries” by the AI-based model, for which no caries localisation and segmentation could be presented.

4. Discussion

In the present ex vivo diagnostic study, a recently introduced AI-based model [16] was validated, and the results regarding its ability to automatically detect, classify, localise and segment carious lesions in digital photographs of teeth were determined. In summary, the AI-based model achieved an overall diagnostic accuracy of 92.0%, and the fraction of false-positive findings, which could be associated with overtreatment, was low (4.4%). In addition, most carious lesions were correctly localised by the test method (97.0%). The automatically drawn pixel segments were fully and partially correct in 52.9% and 44.1% of all cases, respectively.

The discussion of the documented external validity results for this new AI-based method is limited because 1) no other comparable AI-based diagnostic method is available thus far, and 2) most available diagnostic studies in the field of AI-dentistry on dental photographs involve model development and internal validation only [17–20,29,30]. Therefore, the aim of this study was to close this knowledge gap. A comparison between the internal [16] and external validity of the underlying AI-based model (Tables 1–4, Figure 2) reveals higher accuracy in internal data (97.8%) than in external data (92.0%). Internal data refer to the AI-based model’s diagnostic performance on the dataset used during the development [16], which demonstrates the capability of the model to recognise patterns it has been trained on. In contrast, the performance of the AI-based model on external datasets reflects its ability to generalise to new and unseen cases. In view of the results

obtained, the hypothesis that internal and external validity are identical had to be rejected. This decrease between internal and external validity has been reported in other dental [31] and medical study projects [32,33]. In a study by Fu et al. [31], the AUC for the detection of periapical lesions in 3D radiographs using an AI-based model decreased from 0.97 (internal validation) to 0.93–0.96 (external validation). The AUC values from the internal and external validations decreased from 0.949 to 0.843 in the AI-based detection of early childhood visual impairment [33]. Bora et al. [32] investigated the diagnostic performance of an AI-based model to detect diabetic retinopathy in adults; in their study, the AUC decreased from 0.81 (internal validation) to 0.71 (external validation) [32]. The abovementioned study data document the reduction in diagnostic performance from internal to external validation and thus emphasise the importance of external validation.

For the present study, clinical photographs of carious teeth of heterogeneous quality were obtained from a variety of freely accessible internet sources; in contrast, model training was performed using well-standardised, high-quality, professionally captured photographs [16]. Therefore, the documented diagnostic performance (Tables 1–4, Figure 2) supported the quality of AI-based caries detection, as all the photographs supplied to the model were unknown and nevertheless assessed with a high accuracy of 92.0%. Setting this order of magnitude from external validation in relation to the published data from other internal validation studies on caries detection generally showed relatively low or comparable values for diagnostic performance [18–20,29,30]. To date, only a few workgroups have focused on caries diagnostics using clinical photographs. Bottenberg et al. [34] detected caries in dental photographs and subsequently used histological examination of the extracted teeth as a reference standard. The AUC of 0.84 determined for dental diagnostics on photographs was comparable to our results, emphasising the general possibility of using photographs of teeth for diagnostic purposes [34].

A comparative analysis of the results for caries classification from the external validation (Tables 2 and 3) and the internal validation data published by Felsch et al. [16] showed a slightly reduced diagnostic performance on our external validation data. This reduction in performance was evident in several caries groups (Table 2). For instance, in the noncavitated caries group, the ACC was 85.5%, the SE was 93.3%, and the SP was 82.1% (Table 3). Conversely, Felsch et al. [16] reported an ACC of 90.1%, SE of 88.4% and SP of 91.4%. For clinically more relevant cavitated lesions, the ACC was 87.3%, the SE was 71.2%, and the SP was 95.2, while Felsch et al. [16] reported an ACC of 95.9%, SE of 87.6% and SP of 97.8%. Similarly, Wang et al. [35] documented an ACC of 95.3% for the detection of healthy tooth surfaces versus tooth surfaces with white spot lesions. Notably, the authors integrated fluorescence data into the model, which could have increased the model performance [35]. Conversely, Thanh et al. [29] reported ACC values between 81.0% and 87.4% for the detection of healthy tooth surfaces and tooth surfaces with noncavitated and cavitated carious lesions. The internal model performance was lower than that of Felsch et al. [16] and Wang et al. [35].

As part of the external validation, the correctness of the localisation and segmentation of the AI-based model was evaluated. The recorded localisation was classified as correct in 97.0% of the cases. In contrast, segmentation was only rated as fully correct in just over half of the cases (52.9%), while in 44.1% of cases, the AI-based model achieved only partially correct segmentation of the existing carious lesions. However, these data require critical appraisal, as (1) they were subjective estimates by the participating dentists, (2) there are currently no recommendations for the qualitative and quantitative evaluation of segmented areas, (3) typical parameters, such as average precision or intersection over union, could not be determined, and (4) the selected cut-off of ~90% of the lesion area was quite strict. Therefore, these values should not be overinterpreted at this stage.

If the documented internal and external validation data are compared with the data from *in vitro* and/or *in vivo* studies on visual caries diagnostics, the data published to date for AI-based caries detection and classification on dental photographs indicate at least identical, if not improved, results. The meta-analysis by Macey et al. [7], in which

the estimated summary SE and SP values were 0.86 (95% CI 0.80–0.90) and 0.77 (95% CI 0.72–0.82), respectively, should be mentioned here as a representative example. Another meta-analysis [6] confirmed this finding for caries detection on occlusal surfaces and revealed SE values of 0.70 (95% CI 0.59–0.80), SP values of 0.47 (95% CI 0.26–0.70) and AUC values of 0.70 based on the included clinical studies. On the one hand, these data show that AI methods can obviously generate accuracy similar to conventional VE methods. On the other hand, comparative clinical diagnostic studies, including meticulous VE and an independent, AI-based evaluation of the photographic tooth status, are lacking. This signals a knowledge gap that should be closed in future studies.

The present diagnostic study has strengths and limitations. Its novelty lies in being the first external validation study of the mentioned AI-based model for caries detection and classification using an independent sample of dental photographs with different caries classes as well as a range of image qualities. This aspect has to be understood as a unique feature of this study in comparison to previously published studies, which reported exclusively internal validation data [17–20,29,30]. External validation is a crucial evaluation step before recommending AI-based models for broader use in clinical practice. Therefore, this study addresses that knowledge gap and demonstrates the model's ability to evaluate images from independent sources with promising diagnostic performance. Furthermore, this diagnostic study also provides information about caries localisation and segmentation (Table 5), which represent a new aspect of caries diagnostics. An additional novel aspect is that diagnostic accuracy was correlated with meaningful image quality (Table 4).

However, the following aspects should be discussed as limitations. To create an independent image database, photographs of teeth were deliberately taken from the internet. Although these photographs were of varying image quality and included a wide range of carious lesions and tooth surfaces, image size had only a limited influence on diagnostic quality (Table 4). This probably underlines the quality of the AI-based model, as it was also able to analyse photographs of only acceptable quality. Nonetheless, the possible bias in the selection of web images and the definition and application of inclusion and exclusion criteria, as well as the decision on the reference standard—which was always based on group consensus within the workgroup—should be noted. With respect to the use of dental photographs from external data sources, it was impossible for the workgroup to differentiate between real and AI-generated photographs. Furthermore, ground truth verification, which is primarily conducted by histological methods, was not available. This lack of information should be mentioned as another limitation. However, Bottenberg et al. [34] visually evaluated dental photographs for caries detection with acceptably high diagnostic accuracy relative to that of histological examination, thereby supporting the use of VE in cases where no other methods are applicable. Further, the ratio of available photographs with carious lesions ($n = 535$) to photographs showing healthy teeth ($n = 183$) could be a limitation. However, the workgroup made an effort to include all available photographs in the dataset, taking into account the inclusion and exclusion criteria. As this study mainly used images retrieved from the internet, the selected dataset showed qualitative loss compared to the dataset used to train and internally test the AI-based model [16]. To this extent, it can be discussed as a limitation, given that the described study design does not mimic the conditions of internal validation in its entirety. This aspect should be taken into account in future studies. Furthermore, the possibility of simultaneously conducting and documenting VE of the teeth under clinical conditions should also be considered, as this would allow further conclusions to be drawn regarding validity, reliability and generalisability. One challenge that emerged during the project was that the AI-based model provided multiple (pixel-wise) diagnoses per image. During most diagnostic studies, only one diagnostic decision is made for each tooth surface and method; thus, it is necessary to derive one diagnostic decision per image (Table 1) and consider the predicted segments regarding classification (Tables 2–4), localisation and segmentation (Table 5). In addition, the decision-making process was designed as a group consensus, as a completely independent evaluation of the segments against the dental reference stan-

standard was not possible. This is because the photographs in question had mostly multiple caries findings, which could not be blinded, potentially introducing verification bias, as noted here.

5. Conclusions

In this ex vivo diagnostic study, a recently introduced AI-based model was validated, showing promising diagnostic performance for caries detection, classification, localisation and segmentation using an external dataset of heterogeneous digital photographs of teeth. Diagnostic performance was slightly lower than in internal validation, reflecting challenges from varying image quality and lack of standardisation. With respect to these findings, future studies should investigate the validity, reliability and practicability of AI-based image analysis across different image sources and/or patient groups. In addition, standardised external validation protocols and the implementation of clinical assessments could improve the applicability of these models in different clinical settings.

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Informed Consent Statement: Not applicable.

Data Availability Statement: The validated AI-based model is available as a web application and can be accessed at <https://dental-ai.de> (accessed on 23 September 2024). The data can be made available upon reasonable request.

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Erklärung zur Übereinstimmung der gebundenen Ausgabe der Dissertation mit der elektronischen Fassung

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Name, Vorname

Hiermit erkläre ich, dass die elektronische Version der eingereichten Dissertation mit dem Titel:

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Unterschrift Julia Schwarzmaier