Aus der Poliklinik für Zahnerhaltung und Parodontologie

Klinikum der Ludwig-Maximilians-Universität München

Vergleich der okklusalen und approximalen Karieserkennung anhand visueller Inspektion, digitaler Bissflügel-Röntgenbilder und Nahinfrarotlicht-Transillumination

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Berlin, 05.10.2020

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Inhaltsverzeichnis

Abkürzungsverzeichnis

BFR	Bissflügelröntgen
NIRLT	Nahinfrarotlicht Transillumination
VI	Visuelle Inspektion
ICDAS	International Caries Detection and Assessment System
UniViSS	Universal Visual Scoring System
WHO	World Health Organisation
DMF-T	Decayed, Missing, Filled Tooth
DMF-S	Decayed, Missing, Filled Surface

Publikationsliste

1. **Schaefer G**, Pitchika V, Litzenburger F, Hickel R, Kühnisch J. Evaluation of detecting occlusal caries in posterior teeth via visual inspection, digital bitewing radiography and near-infrared light transillumination. Clin Oral Invest (2018) 22: 2431.

2. Kühnisch J, **Schaefer G**, Pitchika V, Garcia-Godoy F, Hickel R. Evaluation of detecting proximal caries in posterior teeth via visual inspection, digital bitewing radiography and near-infrared light transillumination. Am J Dent (2019) 32(2): 74-80.

Beitrag zu den Veröffentlichungen

Die beiden Veröffentlichungen zugrundeliegende Analyse und Interpretation der zuvor erhobenen kariesdiagnostischen Daten sind von mir im Rahmen meiner Doktoranden-Tätigkeit in der Poliklinik für Zahnerhaltung und Parodontologie der LMU München durchgeführt worden. Meine vollzeitliche Doktorandentätigkeit erstreckte sich über elf Monate von September 2013 bis Juli 2014. In den darauffolgenden fünf Jahren und drei Monaten war ich teilzeitlich als Doktorand in der Poliklinik für Zahnerhaltung und Parodontologie der LMU München tätig.

Die der Analyse und Interpretation zugrundeliegenden kariesdiagnostischen Daten umfassen die Untersuchung von Prämolaren und bleibenden Molaren von 203 Probanden mit den Diagnostikmethoden VI, BFR und NIRLT. Die Daten von 122 Probanden habe ich im Rahmen meiner vollzeitlichen Tätigkeit in einstündigen Einzelsitzungen erhoben. 81 weitere Datensätze wurden mir durch Dr. Friederike Litzenburger und Prof. Dr. Jan Kühnisch zur Verfügung gestellt.

Der Rohdatensatz eines einzelnen Probanden umfasst einen Befundbogen, auf dem die Registrierung folgender für die Veröffentlichungen relevanter Zahnflächenbefunde vorgenommen wurde: Füllungs- und Restaurationsstatus (64 Befunde), Fissurenversiegelungen-Status (16 Befunde), UniViSS-Kariesstatus (64 Befunde), BFR-Befund und NIRLT-Befund (je 64 Befunde). Entsprechend führten die von mir während meiner teilzeitlichen Doktorandentätigkeit im Rahmen der Datenanalyse und -interpretation ausgewerteten 55216 (203 Probanden x 272 Befunde) Probandenbefunde zu den Ergebnissen beider Veröffentlichungen.

Beitrag zu Publikation I

Im Rahmen meiner Erstautorenschaft habe ich die Erhebung von 122 Datensätzen, die vollständige Datenanalyse und -interpretation von sämtlichen 203 Datensätzen und die selbstständige Anfertigung des Manuskripts sowie die Übermittlung an die veröffentlichende Fachzeitschrift vorgenommen.

Beitrag zu Publikation II

Mein Beitrag zu Publikation II besteht aus der Erhebung von 122 Datensätzen, der Bereitstellung meiner vollständigen Datenanalyse und -interpretation von sämtlichen 203 Datensätzen und die Zusammenführung und Formatierung des Literaturverzeichnisses.

Einleitung und wissenschaftliche Zielsetzung

Die vorliegende kumulative Dissertation umfasst zwei prospektiv geplante klinische Kariesdiagnostikstudien ohne histologische Validierung, die die diagnostische Aussagekraft von drei Kariesdiagnostikmethoden - visuelle Inspektion (VI), Bissflügelröntgen (BFR) und Nahinfrarotlicht Transillumination (NIRLT) - an Okklusal- bzw. Approximalflächen bleibender Seitenzähne vergleichen.

Ein optimales Kariesmanagement umfasst die exakte diagnostische Beurteilung und die darauf aufbauende präventive oder operative Therapie vorhandener kariöser Läsionen[1, 2]. Die VI stellt in der täglichen klinischen Routine die primäre Diagnostikmethode dar und liefert ohne zusätzliche Kosten schnelle Ergebnisse. Allerdings kommt es sowohl an okklusalen als auch an approximalen Flächen zu einer Unterschätzung des Kariesbefalls[3, 4]. Mit der VI alleine lassen sich weder das genaue Ausmaß und die Relation der Kariesausdehnung zur Schmelz-Dentin-Grenze (EDJ) oder Pulpa noch rest- und sekundärkariöse Läsionen hinreichend beurteilen, sodass im klinischen Alltag ergänzende diagnostische Methoden genutzt werden [5]. Bisher stellte die BFR-Aufnahme die ergänzende Methode der Wahl dar, da sie an Okklusal- und Approximalflächen Informationslücken schließt und die Diagnostik sowohl von okklusaler Dentinkaries, approximaler Schmelz- und Dentinkaries als auch Rest- und Sekundärkaries erlaubt [5-8].

Demgegenüber stehen die Strahlenbelastung und das damit einhergehende potentielle Gesundheitsrisiko für Patienten. Dies stellt eine strenge Limitation für die Anfertigung und Wiederholbarkeit von BFRs dar. Aufgrund dessen sollten die Entwicklung und Erforschung alternativer, strahlungsfreier Diagnostikmethoden vorangetrieben werden.

An dieser Stelle entfaltet die Methode DiagnoCam (KaVo, Biberach/Riß, Deutschland) ihr Potential. Die zugrunde liegende Technik nutzt nicht-sichtbares, langwelliges Nahinfrarotlicht und ist demzufolge frei von ionisierender Strahlung[10-13]. Durch die Methode wird Nahinfrarotlicht über den Alveolarknochen in den Zahn eingestrahlt, welches durch einen

okklusal liegenden Sensor erfasst wird. Das dadurch entstehende Bild, erlaubt eine Visualisierung verschiedener Kariesstufen.

Zwar existieren bereits Berichte über das klinische Potential von NIRLT in der Zahnarztpraxis und über die diagnostische Leistungsfähigkeit bezüglich der Erfassung von kariösen Dentinläsionen im Rahmen eines Validierungsprotokolls für Approximalflächen [14-16], jedoch gab es keine vergleichende Arbeit, bei der VI, BFR und NIRLT an okklusalen und approximalen Flächen angewendet wurden. Die vorliegenden Untersuchungen wurden durchgeführt, um bestehende Wissenslücken zu schließen. Als Null-Hypothese beider Studien wurde formuliert, dass alle drei Diagnostikverfahren zu gleichen Resultaten kommen.

Material und Methode

Im Vorfeld der klinischen Phase wurden beide Studien durch das Ethikkomittee der medizinischen Fakultät der Ludwig-Maximilian-Universität von München genehmigt (Projekt Nummer 013-12). Die zu den Studien gehörenden klinischen Untersuchungen wurden zur Gänze in der Poliklinik für Zahnerhaltung und Parodontologie der LMU durchgeführt. Sämtliche 203 Probanden (122 männlich und 81 weiblich, Durchschnittsalter 23) wurden aus den vorklinischen und klinischen zahnmedizinischen Kursen rekrutiert. Vor der Sitzung wurden die Probanden über die Studie aufgeklärt und es wurden schriftliche Einverständniserklärungen eingeholt. Voraussetzung zur Teilnahme an der Studie waren komplett durchgebrochene bleibende Zähne, keine festsitzend kieferorthopädische Therapie und ein Mindestalter von 12 Jahren.

Visuelle Inspektion. Zu Beginn einer jeden Untersuchung wurde eine professionelle Zahnreinigung durchgeführt. Anschließend wurde zunächst die visuelle Diagnostik mit OP-Lampe, Spiegel und Multifunktionsspritze vorgenommen. Kariöse Läsionen wurden mithilfe der ICDAS- und UniViSS-Kriterien beurteilt[17-19] (Tabelle I).

Nahrotlicht Transillumination. Nachdem den Patienten die Technologie und das Prozedere erklärt wurde, wurden anschließend sämtliche Seitenzähne (Prämolaren und Molaren) aller Quadranten mit der NIRLT von okklusal gescannt und zur späteren Auswertung Bilder von den Zähnen aufgenommen. Um Interferenzen zu vermeiden und die Auflösung der Bilder zu verbessern, wurden das Licht und die OP-Lampe im Behandlungsraum ausgeschaltet. Die Bilder wurden mit der KID Software gespeichert (KaVo Integrated Desktop/Version 2.4.1.6374, KaVo, Biberach/Riß, Deutschland). Alle Bilder wurden zuerst von einem Zahnarzt unabhängig von den Röntgenbildern ausgewertet. Die Charakterisierung der Läsionen vollzog sich wie folgt: 1) Erste Anzeichen einer bzw. eine etablierte Läsion ohne sichtbares transluzentes Dentin wurde als Schmelzkaries erfasst. 2) Eine Dentinkaries wurde registriert, wenn weniger transluzentes Dentin sichtbar oder eine Kavität vorhanden war (Tabelle I). Zusätzlich wurden die NIRLT Aufnahmen mindestens zwei Wochen später gemeinsam mit einem erfahrenen Zahnarzt abermals ausgewertet, um eine übereinstimmende Diagnose zu erhalten. Kamen die Untersucher zu unterschiedlichen Ergebnissen, begutachteten sie die Bilder abermals, diskutierten ihre Einschätzungen und konsultierten ihre Entscheidung.

Röntgenbissflügel. Waren weiterführende diagnostische Maßnahmen indiziert, wurden alle Patienten nach bestehenden, maximal vier Monate alten Röntgenbildern gefragt. Falls vorhanden, wurden entsprechende Röntgenbilder angefordert und evaluiert. Anderenfalls wurden neue Röntgenbilder angefertigt. Benutzt wurde ein intraoraler, zahnmedizinischer Röntgenapparat mit einem 203 mm Tubus (Heliodent DS, Sirona, Bensheim, Deutschland) inklusive einer Röntgenfeldlimitierung (30x40 mm), zusammen mit einem digitalen Röntgensensor (Intraoral II, Sensorgröße 30.7x40.7 mm, Sirona, Bensheim, Deutschland). Die Zeit der Röntgenexposition betrug 0.06 Sekunden mit einer Spannung von 60 kV und einer Stromstärke von 7 mA. Der Sensor befand sich stets in einem Sensorhalter (XPP-DS

Digital Sensorhalter für Sirona, Dentsply Rinn, Elgin, Illinois, USA). Die Bilder wurden anschließend evaluiert, der Patient aufgeklärt, gegebenenfalls Therapieempfehlungen ausgesprochen und Weiterbehandlungen vermittelt.

Kalibrierung. Im Vorfeld der Studie erfolgte, geleitet von Prof. Kühnisch, ein zweitägiges Kalibrierungstraining, währenddessen das klinische Vorgehen bei der Untersuchung dargestellt und der beteiligte Zahnarzt über Studiendesign und Diagnostikkriterien instruiert wurde. Der Kalibrierung folgte ein Training in welchem unter Anleitung durch den Studienleiter Prof. Kühnisch das zuvor vermittelte Wissen an mehreren Probanden unter klinischen Bedingungen angewendet wurde. Diesem Training schloss sich ein weiterer klinischer Trainingskurs an bei dem einige Patienten von den Behandlern eigenständig untersucht wurden. Die gewichteten Kappa Werte für die Intra- und Inter- Behandler Reproduzierbarkeit waren gut bis exzellent. (BFR: 0.778 (G.S./intra), 0.808 (J.K./intra) und 0.754 (inter); NIRLT: 0.820 (G.S./intra), 0.850 (J.K./intra) und 0.792 (inter)).

Statistik. Alle Analysen wurden mit Excel 2011 Version 14.2.0 und der statistischen Software R 3.3.2 durchgeführt. Die deskriptive statistische Analyse umfasste die Kalkulation von Häufigkeiten und Kreuztabellen, um die Ergebnisse der drei Testmethoden zu vergleichen. Im Detail wurden die Häufigkeiten der Werte für gesunde Flächen, Schmelz- und Dentinkaries und Restaurationen unter VI, NIRLT, BFR, VI/NIRLT und VI/BFR kalkuliert. Paarweise Vergleiche zwischen zwei verschiedenen diagnostischen Methoden für die generellen diagnostischen und kariesdiagnostischen Kriterien wurden durch Kreuztabellen und Pearson's chi-square test mit einer Signifikanz von 0,05 kalkuliert.

Ergebnisse

Die Studienpopulation (N=203, Altersdurchschnitt 23) wies nach WHO Kriterien (3.3 DMFT und 9.3 DMFS) moderaten Kariesbefall in der kompletten bleibenden Dentition auf. Zusätzlich wurden im Durchschnitt 6.1 Zähne und 7.6 Oberflächen mit non-kavitierten kariösen Läsionen registriert. Betrachtet man das diagnostische Ergebnis der untersuchten Methoden, muss beachtet werden, dass diese Studie ohne Referenzstandard arbeitet, der grundlegend sämtliche Befunde aller Methoden miteinander vergleichbar macht, und dass jede Methode verschiedene divergierende Proportionen in gleichen kariesdiagnostischen Kategorien aufweist.

Okklusalkariesdiagnostik. Der Großteil der untersuchten Probanden wies keine Schmelz- oder Dentinkaries auf. Nach VI, BFR und NIRLT waren 34,8%, 54,0% bzw. 40,9% aller okklusalen Oberflächen kariesfrei. Verglichen mit den Molaren waren die Okklusalflächen der Prämolaren weniger oft kariös befallen. Im Allgemeinen zeigten alle drei Methoden weniger Schmelzkaries, Dentinkaries, Fissurenversiegelungen und Füllungen an Prämolaren als an Molaren. Visuell wurden an 23.0% der Okklusalflächen nicht-kavitierte kariöse Läsionen entdeckt. Bei BFR bzw. NIRLT betrugen diese Anteile 0,2% bzw. 9,4%. Die Menge der DCL war bei sämtlichen Methoden kleiner, angeführt von BFR mit 1,1%. Darüber hinaus waren unabhängig von der Methode ca. ein Fünftel versiegelt oder gefüllt.

Von allen diagnostischen Kategorien (gesund, Schmelz- und Dentinkaries, versiegelte Fissuren bzw. Restaurationen) lag bei der Kombination aus VI und NIRLT die höchste Prozentzahl übereinstimmender Entscheidungen (61,5%) vor. Richtet man den Fokus auf die Kariessuche lag die höchste Übereinstimmung diagnostischer Entscheidungen in den Kategorien Schmelz- und Dentinkaries bei der Kombination aus VI und NIRLT.

Approximalkariesdiagnostik. Während sämtliche Approximalflächen mit VI kontrolliert werden konnten, konnten 23.8% und 9.3% der Flächen bei BFR und NIRLT nicht ausgewertet werden. Im Falle von BFR waren meist der erste Prämolar und insbesondere dessen mesiale Fläche aufgrund des starren Sensors nicht abgebildet. Dem hingegen waren nicht-analysierbare Bilder bei NIRLT gleichmäßig auf alle Zahnflächen verteilt.

Durch eine alleinige VI konnten nicht alle Läsionen entdeckt werden. Die zusätzliche Untersuchung mit BFR und NIRLT deckte 86.2% bzw. 89.6% aller Läsionen auf. Allerdings wurden nur 28.1% aller kariösen Läsionen gleichermaßen durch beide Methoden an derselben Stelle entdeckt. Die Anzahl an diagnostizierten schmelz- und dentinkariösen Läsionen war bei NIRLT (46.7%) fast doppelt so hoch wie bei BFR (25.2%). Dieser Unterschied rührt in erster Linie daher, dass NIRLT (N=556) mehr als doppelt so viele Schmelzkaries gefunden hat im Vergleich zu BFR (N=247).

Kombiniert man die Methoden miteinander kommt man zu folgenden Ergebnissen: VI und NIRLT entdecken zusammen 70.9% aller Schmelz- und Dentinkaries (der Rest entfällt auf BFR). Waren VI und BFR die Methoden der ersten und zweiten Wahl wurden nur 52.6% aller schmelz- und dentinkariösen Läsionen aufgedeckt.

Diskussion

In der täglichen zahnärztlichen Routine spielt die Detektion von Karies für eine optimale Therapie eine große Rolle. Dahingehend untersuchten wir das diagnostische Ergebnis an okklusalen und approximalen Zahnflächen mit der neuen NIRLT und verglichen dies mit den Ergebnissen von VI und BFR. Unsere Ausgangshypothese besagte, dass alle drei Methoden dieselben diagnostischen Ergebnisse liefern würden. Basierend auf unseren Resultaten kamen allerdings signifikante Unterschiede zwischen den drei Methoden zum Vorschein aufgrund derer wir unsere Ausgangshypothese verwerfen mussten. Der überwiegende Großteil der

Schmelz- und Dentinkaries an okklusalen Flächen wurde durch die visuelle Untersuchung entdeckt und der zusätzliche Gewinn an diagnostischem Ergebnis durch NIRLT (6,8%) und BFR (5.0%) war gering. Diese Zahlen widerlegen bisherige Studien, die BFR einen erheblichen Nutzen für die okklusale Kariesdiagnostik zusprachen und belegen andere Studien, die besagen, dass BFR keinen signifikanten Gewinn in der Kariesdiagnostik okklusaler Flächen mit sich bringt [20-22 und 23, 24]. Ursächlich für den moderaten Kariesbefall ist eine sinkende Kariesprävalenz in den Industriestaaten aufgrund von Fissurenversiegelungen und Kariesrestaurationen im Frühstadium [25].

Basierend auf den Ergebnissen kann davon ausgegangen werden, dass der Nutzen von VI bei der Untersuchungsgruppe hoch war und folglich ergänzende Verfahren nur einen begrenzten Informationszuwachs erbrachten. Dies würde das Risiko einer Überdiagnostik und darauffolgender Überbehandlungen minimieren. Nichtsdestotrotz sind diese Ergebnisse von der Untersuchungsgruppe abhängig, die Ergebnisse würden bei abweichenden Parametern wie Alter, Kariesbelastung und -risiko und sozioökonomischen Status differieren.

Okklusal. Wird VI als Methode der ersten Wahl für Karieserkennung und -bewertung bei Okklusalflächen angenommen bleibt die Frage nach der Methode mit dem größeren zusätzlichen Nutzen. Im Gegensatz zur BFR, wo Überlagerungseffekte ein diagnostisch aufschlussreiches Bild verhindern können, liegt der klinische Vorteil von NIRLT in der Erkennung von Schmelzkaries. Auf der anderen Seite lassen sich Dentinkaries und deren Ausdehnung in Relation zu der EDJ und Pulpa sehr gut mit BFR beurteilen. Mit NIRLT ist dies aufgrund der Sensorausrichtung von okklusal unmöglich zu bewerkstelligen. Entsprechend sollten Zahnärzte genau dann BFR anfertigen, wenn NIRLT Hinweise auf eine Schmelzkaries liefert (Tabelle I).

Die Menge nicht beurteilbarer Okklusalflächen ist bei NIRLT deutlich niedriger als bei BFR (5.6% bzw. 17.3%). Der Grund für die fehlenden Informationen bei NIRLT liegt insbesondere

an dem Studiendesign und der geforderten Full-Mouth-Registrierung, was im normalen Praxisalltag schwer umzusetzen ist. Die häufigsten Gründe für eine fehlende Bilddokumentation waren nicht-transluzente Hartsubstanz, unscharfe Bilder oder die Unfähigkeit ein präzises Bild unter klinischen Bedingungen zu erstellen.

Die Situation bei BFR ist unterschiedlich. Hier entstehen fehlende Informationen durch den starren 4x5 cm messenden digitalen Sensor, der nicht sämtliche Flächen aller Zähne vom ersten Prämolaren bis zweiten Molaren in einem Bild erfasst. Die okklusale Fläche des zweiten Molaren wurde oftmals nicht erfasst. Um dieses Problem zu überwinden, müssten entsprechend zwei Bilder pro Seite angefertigt werden. Dies bedeutet aber auch eine Verdopplung der Strahlenbelastung, sodass ein zweites Bild nur in Einzelfällen angeordnet werden sollte.

Ein weiterer Vorteil von NIRLT ist, dass das Bild exakt über der Okklusalfläche aufgenommen wird. Durch die Live-Übertragung des Bildes lässt sich die Kamera nach Belieben ausrichten bis eine optimale Aufnahme getätigt werden kann. Im Falle von BFR lässt die Überlagerung von Schmelz in oro-vestibulärer Richtung oftmals keine Erkennung von Schmelzkaries zu. Auf der anderen Seite hingegen vermag die BFR-Aufnahme Karies unter Füllungen und Versiegelungen zu erkennen und gibt Auskunft über die Kariesausprägung in Relation zur EDJ und Pulpa.

Beachtet man sämtliche o.g. Argumente scheinen die Kombinationen aus VI/NIRLT oder VI/BFR mehr oder weniger dasselbe diagnostische Ergebnis zu erreichen. Aufgrund der Strahlungsfreiheit scheint der Nutzen der NIRLT als ergänzende Diagnostikmethode im klinischen Alltag zu überwiegen.

Approximal. Die Ergebnisse der Untersuchung zur approximalen Kariesdiagnostik zeigten, dass neben VI eine weitere diagnostische Maßnahme ergriffen werden muss, da der Großteil der Läsionen durch NIRLT und BFR entdeckt wurden. Die Unterschätzung des Kariesbefalls

durch die alleinige VI und der zusätzliche Nutzen der BFR wurden schon durch diverse andere Publikationen gezeigt [3-8].

Im Ergebnis unserer Studie erhielten wir vergleichbare Resultate zwischen NIRLT und BFR. Darüber hinaus fanden wir mit NIRLT doppelt so viele Schmelzkaries als mit BFR, was für das Potential dieser Technik hinsichtlich Kariesfrüherkennung spricht. Ein weiterer Vorteil scheint die geringere Fehlerrate bei NIRLT Bildern verglichen mit BFR zu sein (9.3% vs. 23.8%). Die Fehlerrate bei NIRLT ist jedoch auf das Studiendesign zurückzuführen, das eine Registrierung aller Zähne erforderte. Im Gegensatz dazu entstanden die nicht-analysierbaren Bilder bei BFR durch den steifen digitalen Sensor. Nicht alle Zähne konnten auf einem Bild abgebildet werden und die Anfertigung von zwei Bildern würde zu einer nicht zu rechtfertigenden Verdopplung der Strahlendosis führen.

Während die kombinierte Nutzung von VI/BFR nur 52.6% aller Läsionen entdeckte, belief sich diese Zahl bei der VI/NIRLT Kombination auf 70.9%. Zusätzlich lassen sich auch okklusale Läsionen sehr gut mit NIRLT diagnostizieren, was für den klinischen Nutzen der NIRLT spricht.

Werden die Ergebnisse zusammengefasst, so kann geschlussfolgert werden, dass keine der untersuchten Methoden alle Kariesläsionen gleichermaßen erfasste. Daher war auch hier die initial formulierte Hypothese zu verwerfen. Die Stärke der BFR liegt in der präzisen Diagnostik und Abschätzung der Kariesausdehnung in Relation zur EDJ und Pulpa. Dies ist mit NIRLT unmöglich, da die Bilder von okklusal aufgenommen werden. Daher empfehlen wir die Nutzung von BFR dann, wenn mit NIRLT eine approximale Dentinkaries diagnostiziert wurde.

Die Stärke dieser Studie liegt in der vergleichenden Analyse des diagnostischen Outcomes von NIRLT an okklusalen und approximalen Flächen mit einer relativ großen Population von 203 erwachsenen Patienten. Unseres Wissens wurden bisher keine vergleichbaren Ergebnisse oder Studien publiziert. Hinzu kommt, dass sämtliche Diagnosen blind und unabhängig

anderer diagnostischer Befunde vorgenommen wurden. Dies zieht unvoreingenommene und unabhängige diagnostische Entscheidungen nach sich. Dieses Detail des Studiendesigns sollte als Stärke verstanden werden, im klinischen Praxisalltag könnte trotzdem geurteilt werden, dass sämtliche diagnostische Entscheidungen und Ergebnisse zusammengeführt und gegeneinander abgewogen werden sollten. Ein weiterer entscheidender Vorteil unserer Studie ist, dass unsere Evaluierung auch den Anteil aller nicht-beurteilbarer Oberflächen umfasst, was üblicherweise vernachlässigt wird.

Werden mögliche Limitationen der Studien betrachtet müssen folgende Fragestellungen beachtet werden. Erstens basieren unsere Ergebnisse auf einer Gruppe junger Erwachsener, deren Mundgesundheit nicht zwingend repräsentativ für andere Altersstufen oder Gesellschaftsschichten ist. Um generalisierbare Ergebnisse zu erlangen, sollte diese Studie gegebenenfalls mit anderen Populationen und Altersstufen wiederholt werden. Zweitens gilt es zu beachten, dass diese klinische Studie ohne einen Referenzstandard arbeitete, ohne den eine eindeutige Validierung der Ergebnisse nicht möglich ist. Darauf war aus ethischen Gründen zu verzichten, da weder gesunde Zahnflächen noch initiale Kariesläsionen unter klinischen Bedingungen nicht-invasiv validierbar sind. An dem fehlenden Referenzstandard lag es auch, dass keine typischen Statistikwerte wie Sensitivität, Spezifität oder Az Werte durch ROC Kurven ermittelt wurden.

Zusammenfassung

Im Rahmen dieser vergleichenden, prospektiven Kariesdiagnostikstudien ohne histologische Validierung wurde an insgesamt 203 Probanden (Durchschnittsalter 23 Jahre) das Potential der Diagnostikmethoden VI, BFR und NIRLT zur Einschätzung der Kariesbelastung untersucht. Den Methoden lassen sich in Bezug auf okklusale und approximale Zahnflächen folgende Eigenschaften zuordnen: Bezogen auf Okklusalflächen konnte VI als die Methode, die am schnellsten und einfachsten durchzuführen ist, den überwiegenden Großteil aller Schmelz- und Dentinläsionen erkennen. An approximalen Flächen wiederum führte VI zu einer Unterschätzung der Kariesbelastung und sollte daher durch ergänzende diagnostische Mittel unterstützt werden. Aufgrund seiner wertvollen Eigenschaften wie Strahlungsfreiheit und einfacher klinischer Handhabung kann die NIRLT als die zweite Diagnostikmethode der Wahl bei approximaler Kariesdiagnostik empfohlen werden. Trotzdem sollte BFR in klinischen Fällen multipler, fortgeschrittener Läsionen und insuffizienter Füllungen genutzt werden, um die Ausprägung einer Läsion in Relation zur Pulpa darstellen zu können. Diese Vorgehensweise kann dazu beitragen Überdiagnostik und Überbehandlung zu vermeiden.

Abstract

As part of these comparative, prospective caries diagnostic studies without histological validation, the potential of diagnostic methods VI, BFR and NIRLT for assessing the caries burden was investigated on a total of 203 test persons (mean age 23 years). The following properties can be assigned to the examined diagnostic methods VI, BFR and NIRLT with respect to occlusal and proximal surfaces: In terms of occlusal surfaces, VI was the fastest and easiest method to detect the vast majority of enamel and dentin lesions. At approximal areas, in turn, VI led to an underestimation of the caries burden and should therefore be supported by complementary diagnostic methods.

Due to its valuable properties such as freedom of radiation and simple clinical handling, we recommend NIRLT as the second diagnostic method of choice for approximal caries diagnosis. Nevertheless, BFR should be prescribed in clinical cases of multiple, advanced lesions and insufficient fillings in order to be able to assess the caries extension of a lesion in relation to the pulp. This procedure can help to avoid overdiagnosis and over-treatment.

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REVIEW

Evaluation of occlusal caries detection and assessment by visual inspection, digital bitewing radiography and near-infrared light transillumination

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Abstract

Aim This study compared the diagnostic outcomes of visual inspection (VI), digital bitewing radiography (BWR), and near-infrared light transillumination (NIR-LT, DIAGNOcam, KaVo, Biberach, Germany) for occlusal caries detection and assessment of posterior teeth.

Participants and methods This study included 203 patients (mean age 23.0 years). All individuals received a meticulous VI. Additionally, BWR and NIR-LT images were collected. All BWR and NIR-LT images were blindly evaluated for the presence of enamel caries lesions (ECLs) and dentin caries lesions (DCLs). The descriptive statistical analyses included calculation of frequencies, cross tabulations, and pairwise comparisons using Pearson chi-square tests.

Results The majority of ECLs/DCLs were detected by VI in this low-risk adult population. The additional diagnostic outcomes in terms of ECLs/DCLs amounted to 5.0% (BWR) and 6.8% (NIR-LT). The combined usage of VI/NIR-LT or VI/BWR identified 95.7 and 94.4% of all ECLs/DCLs on occlusal surfaces, respectively.

Conclusion This comparative diagnostic study showed that VI detected the majority of occlusal caries lesions. Both additional methods showed limited benefits. Due to the valuable features of NIR-LT, i.e., X-ray freeness and clinical practicability, this method might be preferred over X-ray-based methods. Nevertheless, BWRs should be prescribed in clinical situations where insufficient fillings or multiple (deep) caries lesions are diagnosed or where there is a need to assess the caries extension in relation to the pulp.

Clinical relevance VI has to be understood as caries detection method of choice on occlusal surfaces in low-risk adult population which may help to avoid multiple diagnostic testing, overdiagnosis, and overtreatment.

Keywords Occlusal caries · Dentin caries · Caries detection · Caries diagnostics · Near-infrared light transillumination · DIAGNOcam

Introduction

The prerequisite for exact caries management is precise caries detection and assessment [1]. To effortlessly obtain quick results without additional costs, visual inspection (VI) has been the primary diagnostic method in daily dental practice. Nevertheless, VI underestimates the caries burden also on occlusal surfaces [2, 3] and there is agreement that the dentist must utilize additional diagnostic methods. Until recently, bitewing radiography (BWR) has been frequently used as the second-choice method aimed at registering caries extensions into dentin in relation to the dental pulp [4–6]. The potential of BWR has clearly been described for occlusal surfaces [7, 8]. The potential health risk of ionizing radiation must be considered, which should lead to strict indications for and prescription of BWRs and thus drastically limits repetition. Therefore, the development of X-ray-free methods is vital to minimizing the patient's exposure to ionizing radiation. Recently, near-infrared light transillumination (NIR-LT, DIAGNOcam, KaVo; Biberach, Germany) was introduced. This technology is based mainly on developments in digital

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fiber optical transillumination [9] and the use of near-infrared light [10]. Rather than using cold visible light, NIR-LT was modified to use invisible, near-infrared light with longer wavelengths [11, 12]. This process reduces light scattering effects and allows deeper light penetration to enamel and dentin [13]. Another important modification is that the light is shone directly through the alveolar process towards the teeth [14]. Both modifications have improved the diagnostic imaging quality, allowing better visualization of different caries stages at proximal sites.

While recently published clinical trials have described the potential of NIR-LT in the dental practice [15, 16] and the diagnostic performance for dentin caries detection within a validation protocol on proximal surfaces [17], no comparative information is available about the diagnostic outcomes at occlusal sites when using VI, BWR, and NIR-LT. Therefore, this clinical diagnostic study aimed to compare these methods. A null hypothesis was formulated that all methods would show equal performance.

Subjects and methods

Study design This prospectively designed diagnostic study was initiated to compare three clinical caries detection and assessment methods on occlusal surfaces. The in vivo study was approved by the Ethics Committee of the Medical Faculty of the Ludwig-Maximilians-University of Munich (project number 013-12). The reporting of this investigation follows the recommendations of the Standards for Reporting of Diagnostic Accuracy (STARD) steering committee [18], knowing full well that the guidelines are basically intended to report diagnostic accuracy or validation studies.

Patient recruitment Subjects for this comparative clinical trial were recruited at the Department of Conservative Dentistry in Munich. As the study's protocol states, only patients with ASA status I (healthy patients according to the American Society of Anesthesiologists) were included. Participants were recruited according to the following inclusion criteria: fully erupted permanent dentition, no orthodontic treatment with fixed appliances, and minimum age of 12. In the case of clinical indicators that warranted additional diagnostic examination, e.g., non-cavitated carious lesions at smooth and/or proximal surfaces or existing caries risk or activity, patients were asked to take part in this examination. Altogether, 203 patients (122 males and 81 females) with a mean age of 23.0 years (standard deviation 6.4) agreed and provided informed consent.

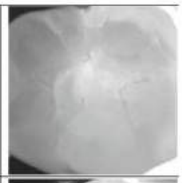
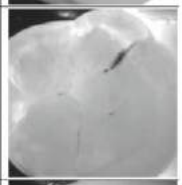
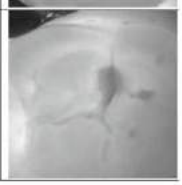
Visual caries scoring At the beginning of each diagnostic examination, a professional tooth cleaning using a rotary brush and a low abrasive polishing paste was performed. Subsequently, trained dentists (G.S., F.L.) carefully conducted the VI of each tooth and surface using standard conditions [19] and a professional dental unit with an operation light, a plane dental mirror, and compressed air. Lesion severity was scored according to the International Caries Detection and Assessment System (ICDAS) [20] and the Universal Visual Scoring System (UniViSS) [21, 22]. The term ECL (enamel caries lesion) strictly categorizes occlusal surfaces with the first visible signs of a carious lesion, established carious lesions, or microcavities/localized enamel breakdowns. In the case of caries-associated cavities, a diagnosis of DCL (dentin caries lesion) was made (Table 1).

Digital bitewing radiography If additional diagnostic methods were indicated, each patient was asked whether they underwent BWR within the last 4 months. If radiographic material existed, those images were requested and evaluated ($N = 4$). In the other cases, X-rays were collected ($N = 199$). An intraoral X-ray dental machine with a 203-mm tube (Heliodent DS, Sirona, Bensheim, Germany) including an X-ray field limitation (30 × 40 mm) was used with a charge-coupled device sensor (Intraoral II, sensor size 30.7 × 40.7 mm, Sirona, Bensheim, Germany). The exposure time was 0.06 s at a cathode voltage of 60 kV and 7 mA of amperage. A sensor-holding device (XPP-DS Digital Sensor Holders for Sirona, Dentsply Rinn, Elgin, IL, USA) was used at all times. The primary evaluation of the BWR was conducted by two dentists (G.S., F.L.). If an interproximal or occlusal enamel and/or dentin caries lesion was found, the patient was offered appropriate dental treatment.

Following the clinical examination, a trained dentist (G.S.) blindly analyzed all BWRs. This process occurred in a darkened room equipped with a Windows PC with the corresponding system-related analysis software (version 2.53, Sirona, Bensheim, Germany) and the option of adjusting brightness and contrast on radiographic images. Each image was analyzed independently from all previously made decisions and other diagnostic findings. For the categorical diagnosis, the D-classification [23] was used as follows: 0—sound surface; 1—caries restricted to the outer one half of the enamel; 2—caries restricted to the inner one half of the enamel; and 3/4—caries restricted to the outer/inner one half of the dentin [24]. Carious lesions that explicitly did not cross the EDJ (enamel-dentine junction) were registered as ECLs, and those that did were considered DCLs (Table 1). The images were reassessed by an experienced dentist (J.K.). In those cases where the dentists' findings differed, they reevaluated the results and discussed the findings until an agreement was reached.

Near-infrared light transillumination After the patients were introduced to the new technology and informed of the procedures, the room and operation light were switched off to avoid possible interference. Prior to taking the NIR-LT photos, the

Table 1 Description of visual, radiographic, and NIR-LT diagnostic criteria

	Visual caries detection (Visual)		Digital bitewing radiography (Bitewing)		Near-infrared light transillumination (NIR-LT)		
Sound	0	Sound surface	0	No radiolucency	0	No less translucent spots	
Enamel caries lesion (ECL)	F	First visible signs of a carious lesion	1	Radiolucency in the outer half of the enamel	1	First or established caries lesion restricted to enamel; no visible translucent dentin	
	E	Established carious lesion					
	M	Microcavity and/or localized enamel breakdown	2	Radiolucency restricted to the inner one-half of the enamel			
Dentin caries lesion (DCL)	D	Dentin exposure	3	Radiolucency restricted to the outer one-half of the dentin	2	Less translucent dentin or cavity detectable	
	L	Large cavity	4	Radiolucency restricted to the inner one-half of the dentin			

teeth were air-dried. Then, the NIR-LT camera was centered over the area of interest, and pictures of all occlusal surfaces on the posterior teeth (premolars and molars) in all quadrants were taken. Every image was captured and stored with KID software (KaVo Integrated Desktop/version 2.4.1.6374, KaVo, Biberach, Germany). Analogous to the radiographic evaluation phase, all the NIR-LT images were first assessed by one dentist (G.S.) independently from the visual or radiographic findings. The caries lesions were characterized as follows. (1) A first or established caries lesion without visible translucent dentin was scored as an ECL. (2) A DCL was registered when less translucent dentin was visible or a cavity was detectable (Table 1). In addition, the NIR-LT images were also reassessed at least 2 weeks later under the supervision of an experienced dentist (J.K.) to achieve a consensus diagnosis. When the examiners reached different conclusions, they reassessed the images, discussed their points, and modified the decision accordingly.

Calibration Prior to the study, a 2-day theoretical and practical calibration training, which focused on the clinical standardization of all the test methods used in the study and the reference standards, was conducted by an experienced dentist (J.K.) to instruct the examiner (G.S.). The theoretical training exercise provided information regarding the study design, indices, diagnostic principles, and standardized examination and diagnostic procedures. This training session was followed by a clinical training course, during which the examiner investigated several patients. The weighted Kappa values for the intra- and interexaminer reproducibility were good to excellent (BWR: 0.778 (G.S./intra), 0.808 (J.K./intra), and 0.754 (inter); NIR-LT: 0.820 (G.S./intra), 0.850 (J.K./intra), and 0.792 (inter)).

Statistical analysis All analyses were performed using Excel 2011 Version 14.2.0 and statistical software R 3.3.2 [25]. The descriptive statistical analyses included the calculation of frequencies and cross tabulations to compare the results of the three methods tested. In detail, the frequency of scores for sound surfaces, ECL, DCL, and restorations under VI, NIR-LT, BWR, VI/NIR-LT, and VI/BWR criteria were calculated. Pairwise comparisons between two different diagnostic methods for overall diagnostic criteria and caries diagnostic criteria were calculated by means of cross tabulations and Pearson's chi-square test using a significance of 0.05.

Results

The study population had moderate caries in the entire permanent dentition according to the WHO criteria (3.3 DMFT and 9.3 DMFS). In addition, means of 6.1 teeth and 7.6 surfaces with non-cavitated caries lesions were registered.

When considering the diagnostic outcomes of the included diagnostic methods, it is important to recognize that this diagnostic study did not include a reference standard that merged all

findings from all methods and that each identified method had different diverging proportions in similar caries diagnostic categories (Tables 3, 4, 5). The largest diagnostic proportion was free of any ECL and DCL. For VI, BWR, and NIR-LT, 34.8, 54.0, and 40.9% of all occlusal surfaces were caries free, respectively (Table 2). Compared with molars, the occlusal surfaces of premolars were less affected by caries. Focusing on ECLs, 23.0% of all occlusal surfaces were scored visually as having any non-cavitated caries lesions. This proportion amounted to 0.2 and 9.4% for BWR and NIR-LT, respectively. All methods revealed a small proportion of DCL (< 1.1%) only. Nevertheless, the highest proportion was found with BWR (Table 2). In general, all three methods showed fewer ECLs, DCLs, sealants, and restorations on premolars compared with molars. Furthermore, independent of the diagnostic method, approximately one fifth of all fissures were recorded as filled or sealed (Table 2).

The cross tabulations (Tables 3 and 4) detail all comparisons among the methods and their potential combinations. The diagnostic outcomes on occlusal surfaces are summarized in Table 5. When considering all diagnostic categories (sound, ECL, DCL, sealants, and restorations), the combination of VI plus NIR-LT had the highest percentage of similar decisions (61.5%). Concentrating on the evaluation of caries, the highest concordance of diagnostic decisions was registered in the categories of ECLs and DCLs (51.3%) for the combination of VI and NIR-LT. Moreover, the additional diagnostic benefit from NIR-LT was low (5.6–6.8%). This result was consistently documented for all other comparisons (Table 5).

Discussion

In daily dental routine, caries detection and assessment plays a vital role and is a prerequisite for appropriate treatment. Here, we investigated the diagnostic outcomes on occlusal surfaces of the new NIR-LT in relation to visual and radiographic diagnostics. Basically, we hypothesized that all methods would have the same diagnostic outcome. However, based on our results, there were significant differences among the used methods (Tables 3, 4, 5). Therefore, the initial hypothesis was rejected.

First, the majority of ECLs/DCLs were detected by VI on occlusal surfaces. The additional diagnostic outcomes in terms of ECLs/DCLs amounted to 6.8% (NIR-LT) and 5.0% (BWR) and, therefore, can be assessed as low (Table 5). This proportion contradicts former studies, which attributed a considerable benefit to radiography for caries detection on occlusal surfaces [26–28]. In contrast, our findings confirmed results from other trials, which concluded that, as an additional method, the BWR had no significant benefit when it was solely used to analyze occlusal surfaces [29, 30]. One reason for this finding could be that overall caries have declined in industrialized populations [31] as the use of sealants (21.2%), earlier restoration of hidden occlusal caries lesions (19.7%), and a distinct proportion of ECLs can be detected easily by visual means (Table 2). The benefit of visual caries detection and assessment on proximal sites is clearly limited. This limitation was also shown for the usage of NIR-LT on proximal sites (unpublished data). Therefore, based on the documented results, the value of VI seems to be high for occlusal surfaces in the investigated population and would reduce the prescription of additional diagnostic methods. This would decrease the risks of multiple testing in terms of overdiagnosis and possibly resulting in overtreatment [32]. However, this finding depends on the characteristics of the study population, and different results might be possible in different samples with divergent parameters such as age, caries experience and risk, and socio-economic status.

When considering VI as the first-choice method for caries detection and assessment on occlusal surfaces, the remaining question is which adjunct method provides the greater additional benefit. The clinical strength of NIR-LT might be seen in detecting ECLs, which could not be performed with BWR

Table 2 Distributions of all diagnoses according to the detection method

Method	Tooth/ Surface	Sound		ECL		DCL		Sealant		Restoration		Missing/implant		Not assessable	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%
Visual caries detection	Molar	155	4.8	493	15.4	4	0.1	418	13.0	529	16.5	6	0.2	-	-
	Premolar	963	30.0	245	7.6	0	0.0	264	8.2	103	3.2	31	0.9	-	-
	Total	**1118**	**34.8**	**738**	**23.0**	**4**	**0.1**	**682**	**21.2**	**632**	**19.7**	**37**	**1.1**	-	-
Bitewing radiography	Molar	759	23.6	5	0.2	35	1.1	-	-	728	22.7	6	0.2	72	2.2
	Premolar	975	30.4	-	-	1	0.0	-	-	122	3.8	31	0.9	477	14.9
	Total	**1734**	**54.0**	**5**	**0.2**	**36**	**1.1**	-	-	**850**	**26.5**	**37**	**1.1**	**549**	**17.1**
NIR-LT	Molar	223	6.9	191	5.9	5	0.2	522	16.3	562	17.5	6	0.2	96	3.0
	Premolar	1090	33.9	112	3.5	-	-	132	4.1	160	5.0	31	0.9	81	2.5
	Total	**1313**	**40.9**	**303**	**9.4**	**5**	**0.2**	**654**	**20.4**	**722**	**22.5**	**37**	**1.1**	**177**	**5.5**

Table 3 Cross tabulations of the tested diagnostic methods. A greyish background indicates congruent diagnostic decisions between the compared methods

		NIR-LT													
	N/%	Sound		ECL		DCL		Sealant		Restoration		Not assessable		Total	
Visual	Sound	949	29.9	25	0.8	-	-	46	1.4	27	0.9	71	2.2	**1118**	**35.2**
	ECL	183	5.8	225	7.1	5	0.2	192	6.0	113	3.6	20	0.6	**738**	**23.3**
	DCL	-	-	1	0.0	-	-	1	0.0	1	0.0	1	0.0	**4**	**0.1**
	Sealant	143	4.5	41	1.3	-	-	318	10.0	120	3.8	60	1.9	**682**	**21.5**
	Restoration	38	1.2	11	0.3	-	-	97	3.1	461	14.5	25	0.8	**632**	**19.9**
	Total	**1313**	**41.4**	**303**	**9.5**	**5**	**0.2**	**654**	**20.6**	**772**	**22.7**	**177**	**5.6**	**3174**	**100.0**

		Bitewing													
	N/%	Sound		ECL		DCL		Sealant		Restoration		Not assessable		Total	
Visual	Sound	715	22.5	-	-	4	0.1	-	-	50	1.6	349	11.0	**1118**	**35.2**
	ECL	475	15.0	1	0.0	21	0.7	-	-	173	5.5	68	2.1	**738**	**23.3**
	DCL	2	0.1	-	-	1	0.0	-	-	1	0.0	-	-	**4**	**0.1**
	Sealant	540	17.0	4	0.1	6	0.2	-	-	-	-	132	4.2	**682**	**21.5**
	Restoration	2	0.1	-	-	4	0.1	-	-	626	19.7	-	-	**632**	**19.9**
	Total	**1734**	**54.6**	**5**	**0.2**	**36**	**1.1**	**-**	**-**	**850**	**26.8**	**549**	**17.3**	**3174**	**100.0**

		Bitewing													
	N/%	Sound		ECL		DCL		Sealant		Restoration		Not assessable		Total	
NIR-LT	Sound		28.0	-	-	2	0.1	-	-	62	2.0	361	11.4	**1313**	**41.4**
	ECL	224	7.1	-	-	3	0.1	-	-	49	1.5	27	0.9	**303**	**9.5**
	DCL	2	0.1	-	-	1	0.0	-	-	2	0.1	-	-	**5**	**0.2**
	Sealant	435	13.7	2	0.1	17	0.5	-	-	154	4.9	46	1.4	**654**	**20.6**
	Restoration	121	3.8	2	0.1	6	0.2	-	-	553	17.4	40	1.3	**722**	**22.7**
	Not assessable	64	2.0	1	0.0	7	0.2	-	-	30	0.9	75	2.4	**177**	**5.6**
	Total	**1734**	**54.6**	**5**	**0.2**	**36**	**1.1**	**-**	**-**	**850**	**26.8**	**549**	**17.3**	**3174**	**100.0**

due to superimposing effects. Conversely, the strength of BWR is in precisely diagnosing and assessing DCL in relation to the EDJ or pulp, which is impossible on NIR-LT images. Therefore, dentists should undertake BWR in those clinical situations only when NIR-LT screening has revealed any hints of a DCL. This suggestion might be supported by the data from this study because a distinct proportion of ECL, as diagnosed by NIR-LT, was classified as DCL when reexamined with BWR (Tables 4 and 5). Additionally, NIR-LT had a lower proportion of not assessable surfaces compared with BWR (5.6 versus 17.3%, Table 3). The amount of missing information on NIR-LT images is primarily attributed to the study design and the requested full-mouth registration, which is difficult to perform in daily dental practice with consistently high quality. Common reasons for image exclusion were non-translucent hard tissue, out-of-focus images, or the inability to capture a precise image under clinical conditions. However, this situation differs from that in bitewing. Here, the missing information originated from the stiff, 4 × 5 cm size digital sensor, which does not capture all the teeth and sites from the mesial surface on the first premolars onwards until the distal surface on the second molars in one image. Most likely,

Table 4 Cross tabulations for the diagnostic outcome when visual inspection and digital bitewing radiography or NIR-LT are used as primary detection and diagnostic methods. A greyish background indicates congruent decisions

		Bitewing													
	N / %	Sound		ECL		DCL		Sealant		Restoration		Not assessable		Total	
Visual + NIR-LT	Sound	857	27.0	0	0.0	3	0.1	0	0.0	21	0.7	358	11.3	**1239**	**39.0**
	ECL	505	15.9	1	0.0	20	0.6	0	0.0	95	3.0	65	2.0	**686**	**21.6**
	DCL	3	0.1	0	0.0	2	0.1	0	0.0	3	0.1	0	0.0	**8**	**0.3**
	Sealant	350	11.0	2	0.1	4	0.1	0	0.0	8	0.3	86	2.7	**450**	**14.2**
	Restoration	121	3.8	2	0.1	7	0.2	0	0.0	621	19.6	40	1.3	**791**	**24.9**
	Not assessable	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	**0**	**0.0**
	Total	**1836**	**57.8**	**5**	**0.2**	**36**	**1.1**	**0**	**0.0**	**748**	**23.6**	**549**	**17.3**	**3174**	**100.0**
		NIR-LT													
	N / %	**Sound**		**ECL**		**DCL**		**Sealant**		**Restoration**		**Not assessable**		**Total**	
Visual + Bitewing	Sound	938	29.6	20	0.6	0	0	38	1.2	10	0.3	63	2.0	**1069**	**33.7**
	ECL	177	5.6	189	6.0	2	0.1	133	4.2	34	1.1	13	0.4	**548**	**17.3**
	DCL	2	0.1	4	0.1	1	0.0	17	0.5	4	0.1	6	0.2	**34**	**1.1**
	Sealant	143	4.5	41	1.3	0	0.0	312	9.8	116	3.7	55	1.7	**667**	**21.0**
	Restoration	62	2.0	49	1.5	2	0.1	154	4.9	549	17.3	40	1.3	**856**	**27.0**
	Not assessable	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0	0	**0**	**0.0**
	Total	**1322**	**41.7**	**303**	**9.5**	**5**	**0.2**	**654**	**20.6**	**713**	**22.5**	**177**	**5.6**	**3174**	**100.0**

the occlusal surfaces of the first premolars will be missed (14.9%, Table 2). Performing two images per side might be necessary to overcome this problem. However, two images will double the exposure to ionizing radiation and should be used in individual cases only. Another advantage of NIR-LT is that the image is captured over the occlusal surface, which allows a firm

Table 5 Overview of the diagnostic outcomes when comparing all diagnostic methods

N/%		All diagnoses[1]					Caries diagnoses only[2]		
		Method 1		Consensus	Method 2		Method 1	Consensus	Method 2
Method 1	Method 2	Advantage	Not assessable		Advantage	Not assessable	Advantage		Advantage
VI[*,†]	NIR-LT[*,†]	514/16.2	-	1953/61.5	530/16.7	177/5.6	184/41.9	225/51.3	30/6.8
VI[*,†]	BW[*,†]	1033/32.5	-	1343/42.3	249/7.8	549/17.3	477/94.6	2/0.4	25/5.0
NIR-LT[*,†]	BW[*,†]	809/25.5	175/5.6	1442/45.4	272/8.6	474/14.9	226/97.4	1/0.4	5/2.2
VI/NIR-LT[*,†]	BW[*,†]	994/31.3	-	1481/46.7	150/4.7	549/17.3	508/95.1	3/0.6	23/4.3
VI/BW[*,†]	NIR-LT[*,†]	634/20.0	-	1989/62.7	374/11.8	177/5.6	183/46.3	190/48.1	22/5.6

[1] Sound surfaces, enamel and dentin caries lesions (ECLs and DCLs), sealants, restorations
[2] Enamel and dentin caries lesions (ECL, DCL)
[*] Indicates significance for comparing two methods with the overall diagnostic criteria using Pearson Chi-square test
[†] Indicates significance for comparing two methods with the caries diagnostic criteria using Pearson Chi-square test

assessment. In the case of BWR, the superimposition of the enamel in the oro-vestibular direction frequently hinders the detection of ECLs (Table 3). An advantage of BWR is the possibility of detecting caries under or beneath sealants or restorations (Table 3) and assessing the caries extension in relation to the EDJ and pulp. When considering all the abovementioned arguments, the combined usage of VI/NIR-LT or VI/BWR may result in more or less similar diagnostic findings on the occlusal surfaces (Table 5). With respect to its X-ray freeness and clinical practicability, NIR-LT might be preferred as the second-choice method in today's clinical practice.

The methodological strength of this study is in the comparative analysis of the diagnostic outcomes with inclusion of the novel NIR-LT in a relatively large sample size of 203 adult patients. To our knowledge, no comparable results or studies have been published thus far. Additionally, all diagnoses were blindly made from all other diagnostic findings, which resulted in independent and unbiased diagnostic decisions. This detail of the study design should be understood as a strength of this study, but it could be argued that all diagnostic decisions should be merged in daily dental practice. To address this issue, we analyzed possible combinations of diagnostic methods according to standardized algorithms (Table 5). As another unique feature of the study, we evaluated how many surfaces were not assessable, which is commonly neglected. When considering possible limitations of our study, the following issues have to be discussed. First, our results are based on a convenience sample of young adults, which might not be representative of other age groups or populations. This fact might limit the generalizability of the documented results, which indicates that this study should be repeated in different populations or age groups. Second, it should be pointed out that this clinical study does not include a reference standard which exclusively would allow a rigorous validation of all diagnostic decisions since it would be highly unethical to open every single tooth. Therefore, this immutable fact reveals that the validity of the shown analyses might be moderate at best. But this is comparable to everyday practice where dentists do not have an external criterion as well. With respect to the comparative clinical diagnostic study design without a reference standard, it was further impossible to calculate typical statistical measures to predict diagnostic accuracy, e.g., sensitivity, specificity, or Az values from ROC curves. Thus, it is necessary to refer to previously published data where the diagnostic accuracy for proximal dentin caries detection was measured using digital BWR and NIR-LT [17]. Until now, no published data were available regarding the validity of NIR-LT on occlusal surfaces, which seems to be another direction for future research.

Conclusions

This comparative diagnostic in vivo study found that VI detected the majority of the diagnosed caries lesions on occlusal surfaces in young adults and should be, therefore, used as the diagnostic method of choice. Both additional methods — BWR and NIR-LT — showed a limited benefit that might be attributed to the chosen study sample. Due to the valuable features of NIR-LT, e.g., X-ray freeness and clinical practicability, it might be preferred over X-ray-based methods in clinical practice. Nevertheless, BWR should be prescribed in those clinical situations where insufficient fillings or multiple (deep) caries lesions are diagnosed. This diagnostic strategy may help to reduce the utilization of additional diagnostic methods, ionizing radiation, to avoid overdiagnosis and to determine optimal preventive and operative dental care based on a well-balanced diagnostic examination.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The research protocol was approved by the Ethics Committee of the Medical Faculty of the Ludwig-Maximilians-University of Munich (project number 013-12).

Informed consent Written informed consent was obtained from all individual participants included in the study.

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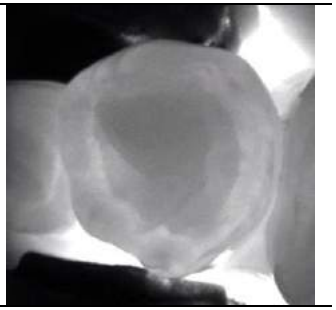
Tabelle I Beschreibung der VI, BFR und NIRLT Diagnostikkriterien

	VI (UniViSS)		BFR		NIRLT		Okklusal	Approximal
Gesund	0	Gesunde Fläche	0	Keine Radioluzenz	0	Keine weniger tranzluzenten Stellen		
Schmelz-läsion	F	Erste sichtbare Zeichen einer kariösen Läsion	1	Radioluzenz in der äußeren Schmelzhälfte	1	Erste oder etablierte Kariesläsion begrenzt auf den Schmelz, kein sichtbares transluzentes Dentin		
	E	Etablierte kariöse Läsion						
	M	Mikrokavität und/oder lokalisierter Schmelzeinbruch	2	Radioluzenz begrenzt auf die innere Schmelzhälfte				
Dentin-läsion	D	Dentinfreilegung	3	Radioluzenz begrenzt auf die äußere Dentinhälfte	2	Weniger transluzentes Dentin oder Kavität sichtbar		
	L	Große Kavität	4	Radioluzenz begrenzt auf die innere Dentinhälfte				

Anhang: Publikation II - Approximalkariesdiagnostik

Research Article

Evaluation of detecting proximal caries in posterior teeth via visual inspection, digital bitewing radiography and near-infrared light transillumination

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ABSTRACT: **Purpose:** This prospectively designed, non-validated in vivo diagnostic study compared the results of visual examination, digital bitewing (BW) radiography and near-infrared light transillumination (NIR-LT, DIAGNOcam) on proximal caries detection in posterior teeth. **Methods:** A total of 203 subjects (122 men/81 women; mean age, 23.0 years) were included. All subjects were visually examined according to the standards by the World Health Organization and the International Caries Detection and Assessment System. In addition, digital BW radiographs were performed. NIR-LT images were captured from all posterior teeth. All BWs and NIR-LT images were blindly evaluated for the presence of enamel caries lesions (ECLs) and dentin caries lesions (DCLs). No histological validation was performed due to the impossibility to investigate healthy surfaces and non-cavitated caries lesions invasively. The statistical analysis included both descriptive and exploratory data evaluations. **Results:** The diagnostic outcome differed for each method. Compared with BW radiography (8.0 surfaces) and NIR-LT (10.5 surfaces), visual examination revealed the fewest caries-related findings (4.2 surfaces). BW radiography or NIR-LT detected either 86.2% or 89.6% of all ECLs/DCLs in posterior teeth alone. When combining visual examination with NIR-LT, 70.9% of all ECLs/DCLs were similarly detected; when visual examination and BW radiography were combined, this proportion was lower (52.6%). (*Am J Dent* 2019;32:74-80).

CLINICAL SIGNIFICANCE: This study confirmed that visual examination alone led to an underestimation of the caries burden on proximal sites in posterior teeth. The novel near-infrared light transillumination might be a useful additional caries detection and diagnostic method.

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Introduction

Optimal caries management depends on correct caries detection and diagnosis.[1,2] Visual examination is the diagnostic method of choice in daily dental practice because it provides a fast assessment of the patient's dental status and requires no additional effort or cost. Nevertheless, this method has limitations, especially with regard to proximal sites. Visual inspection (VI) alone is insufficient to detect non-cavitated or enamel caries lesions (ECLs) and hidden dentin caries lesions (DCLs), could not predict the exact lesion stage and is unable to identify secondary or residual caries.[3] Therefore, additional diagnostic methods are needed to detect the presence and stage of proximal caries lesions in relation to the enamel-dentin-junction or the pulp and to describe correctly the caries experience in patients. Until now, bitewing (BW) radiography has been used as the additional method of choice for caries detection and diagnosis because it fulfils the aforementioned requirements.[4,5] Several diagnostic studies have shown that compared with clinical examinations alone, BWs identified up to 80% of the caries lesions on proximal surfaces.[6-8] These data justify the use of BWs in daily dental practice for children, adolescents and adults.[9-11]

Despite its diagnostic benefits, the use of ionizing radiation can damage cells, tissues or organs. From a practical perspective, possible radiation hazards limit its repeatability in dental practice. Therefore, the dental community should welcome X-ray-free diagnostic methods to overcome this limitation in caries diagnostics and to reduce patients' exposure to radiation. Recently, X-ray-free, near-infrared light transillumination (NIR-LT, DIAGNOcam®) was introduced to dentistry. This technology is based on digital fiber optical transillumination.[12] Rather than using cold visible light, NIR-LT was modified to use invisible near-infrared light.[13-17] The use of longer wavelengths is closely related to fewer light scattering effects and deeper light penetration in the enamel and dentin.[18] Another important modification is that the light is transmitted directly through the alveolar process in the direction of the teeth and not to the proximal contact area.[19] Both modifications improved diagnostic imaging quality, which enabled a better visualization of different caries stages at proximal sites.

Although in vitro and in vivo reports[19-25] describe the clinical potential of NIR-LT proximal surface, no comparative analyses from a large population sample exists when using VI, BW radiography or NIR-LT. Therefore, this in vivo study was conducted to evaluate this knowledge gap. The null hypothesis was that all three diagnostic methods detect the same number of ECLs and DCLs.

Materials and Methods

Study design - This prospectively designed clinical study compared three diagnostic methods for proximal caries detection and diagnosis. The protocol was approved by the Ethics Committee of the Medical Faculty of Ludwig-Maximilians-University of Munich, Germany (project number 013-12). The reporting of this investigation followed the recom-

Table 1. Description of the visual, radiographic and NIR-LT diagnostic criteria.

	Visual caries detection (Visual)		Digital BW radiography (Bitewing)		NIR-LT	
Sound	0	Sound surface	0	No radiolucency	0	No less-translucent spots
ECLs	F	First visible signs of a carious lesion	1	Radiolucency in the outer half of the enamel	1	First detectable signs of less translucent enamel.
	E	Established carious lesion			2	Established caries lesion in the outer half of the enamel (less translucent enamel)
	M	Micro cavity, localized enamel breakdown or both	2	Radiolucency restricted to the inner one half of the enamel	3	Established caries with a small spot touching the inner enamel-dentin junction.
DCLs	D	Dentin exposure	3.	Radiolucency restricted to the outer one-half of the dentin	4.	Dentin caries lesion with more than one spot located touching the enamel-dentin junction.
	L	Large cavity	4.	Radiolucency restricted to the inner one-half of the dentin	5	Progressed dentin caries lesion associated with the presence of a less- translucent shadow.

mendations of the Standard for Reporting of Diagnostic Accuracy (STARD) steering committee,[26] with the full knowledge that the guideline was essentially intended to report diagnostic accuracy or validation studies.

Subject recruitment - The subject recruitment for this diagnostic study was performed at the Department of Conservative Dentistry in Munich, Germany. According to the study protocol, only patients with American Society of Anesthesiologists (ASA) status 1 (i.e., healthy patient) were included. All recruited individuals had fully erupted permanent dentition, no orthodontic treatment in progress, and a minimum age of 12 years. Subjects and their caregivers were asked to take part in this examination if they had clinical indicators that warranted additional diagnostic examination (e.g., non-cavitated carious lesions at smooth, proximal, or both surfaces) and existing caries risk or activity. In total, 203 subjects (122 men/81 women) with a mean age of 23.0 years (standard deviation 6.4) agreed to participate and signed the informed consent document.

Visual caries scoring - Visual examinations were performed immediately after professional tooth cleaning under standard conditions by trained and calibrated dentists (GS and JK).[27] A professional dental unit with an operation light, plane dental mirror, and compressed air was used. Each tooth and surface was carefully examined visually without separation. Lesion severity (e.g., first signs, established lesions, microcavities/localized enamel breakdowns, and cavities with dentin exposure) was scored according to the International Caries Detection and Assessment System (ICDAS) and the Universal Visual Scoring System (UniViSS).[3,28,29] Surfaces with caries-associated first visible signs, established lesions or microcavities/localized enamel breakdowns were categorized as ECLs. DCLs were diagnosed in cases of dentin cavities (Table 1). Restorations and extracted teeth due to caries were registered according to the criteria by the World Health Organization (WHO 1997[27]). Later it was possible to calculate the DMF index.

Digital BW radiography - If additional diagnostic methods were indicated, then each subject was asked to recall whether BW radiography had been administered over the last 4 months. If the answer was positive, then these images were requested and evaluated (N=4). If no BW radiographs had been performed, then digital BW radiographs were prescribed (N=199). An intraoral X-ray dental machine with a 203-mm tube (Heliodent DS[b]) including an X-ray field limitation (30×40 mm) was used with a charge-coupled device (CCD) sensor (Intraoral II,[b] sensor size 30.7×40.7 mm). The exposure time was 0.06 seconds at a cathode voltage of 60 kV and an amperage of 7 mA. A sensor holding device (XPP-DS Digital Sensor Holders for Sirona[c]) was used at all times. All digital BW radiographs were primarily analyzed by the recruiting dentist (GS). In case of an interproximal ECL, DCL, or both, relevant treatment strategies were discussed and offered to the subject.

A trained dentist (GS) performed the structured and systematic analysis of all radiographs after the clinical study phase. All the images were evaluated independently of the other diagnostic findings in a darkened room using the available system-related analysis software[b] (version 2.53) with the option of adjusting the brightness and contrast. For each surface, the categorical diagnosis was made as follows: 0 - sound surface; 1 - caries restricted to the outer one-half of the enamel; 2 - caries restricted to the inner one-half of the enamel; and 3 - caries restricted to the outer/inner one-half of the dentin (Table 1).[30] An experienced dentist (JK) re-assessed all the images. If the examiners reached different conclusions, then they re-assessed the corresponding radiographs and discussed their points until a consensus was reached.

NIR-LT - After air-drying, all interproximal sites in the posterior teeth were examined with an NIR-LT camera perpendicularly centered over the area of interest. The light source on the dental unit was switched off while the images were obtained to prevent light interference. One image for each surface was captured and stored using KID[a] software (version 2.4.1.6374). Following the clinical phase, the NIR-LT images were first analyzed by one dentist (GS) independently of the visual and radiographic findings. Caries lesions were judged as follows: (1) In cases of shadows up to the enamel-dentin junction, an ECL was diagnosed; and (2) A DCL was registered when a lesion was associated with the complete shadow of the enamel and the involvement of the enamel-dentin junction, with or without a less translucent shadow in the dentin (Table 1).[21] In addition, the NIR-LT images were also re-assessed at least 2 weeks later under the supervision of an experienced dentist (JK) to achieve a consensus diagnosis. When the examiners reached different conclusions, they re-assessed the images, discussed their points, and modified the decision accordingly.

Calibration - Prior to the study, a 2-day theoretical and practical calibration training was conducted by an experienced dentist (JK, >20 years clinical practice) to instruct the examiner (GS, 1-year clinical practice); the training focused on the clinical standardization of all the methods used in the study. The theoretical training exercise provided information regarding the study design, indices, diagnostic principles, standardized exami-

Table 2. Caries experience in posterior teeth under the inclusion of ECLs according to visual inspection, digital BW radiography and NIR-LT.

	VI		BW radiography		NIR-LT	
	N	Mean	N	Mean	N	Mean
ECL/S	248	1.2	754	3.7	1161	5.7
DMF/S	599	3.0	877	4.3	974	4.8
D/S	1	0.0	350	1.7	350	1.7
M/S	74	0.4	74	0.4	74	0.4
F/S	524	2.6	453	2.2	550	2.7
ECL/S + DMF/S	847	4.2	1631	8.0	2135	10.5

Table 3. Distribution of all diagnoses by the methods employed.

Method tooth surface	Sound		ECL		DCL		Restoration		Missing/implant		Not assessable	
	N	%	N	%	N	%	N	%	N	%	N	%
Visual caries detection												
Molar	2740	42.2	159	2.4	1	0.0	328	5.0	20	0.3		
Mesial	1271	19.6	139	2.1	0	0.0	204	3.1	10	0.2	-	-
Distal	1469	22.6	20	0.3	1	0.0	124	1.9	10	0.2	-	-
Premolar	2909	44.8	89	1.4	0	0.0	196	3.0	54	0.8	-	-
Mesial	1496	23.0	45	0.7	0	0.0	56	0.9	27	0.4	-	-
Distal	1413	21.7	44	0.7	0	0.0	140	2.2	27	0.4	-	-
Total	5649	86.9	248	3.8	1	0.0	524	8.1	74	1.1	-	-
BW Radiography												
Molar	1975	30.8	369	5.7	193	3.0	297	4.6	20	0.3	394	6.1
Mesial	955	14.9	258	4.0	125	1.9	189	2.9	10	0.2	87	1.3
Distal	1020	15.9	111	1.7	68	1.0	108	1.7	10	0.2	307	4.7
Premolar	1342	20.9	385	5.9	157	2.4	156	2.4	54	0.8	1154	17.8
Mesial	525	8.2	125	1.9	48	0.7	34	0.5	27	0.4	865	13.3
Distal	817	12.7	260	4.0	109	1.7	122	1.9	27	0.4	289	4.4
Total	3317	51.1	754	11.6	350	5.4	453	7.0	74	1.1	1548	23.8
NIR-LT												
Molar	1814	27.9	544	8.4	210	3.2	344	5.3	20	0.3	314	4.8
Mesial	686	10.6	408	6.3	187	2.9	205	3.2	10	0.2	128	2.0
Distal	1128	17.4	136	2.1	23	0.4	139	2.1	10	0.2	186	2.9
Premolar	1945	29.9	617	9.5	140	2.2	206	3.2	54	0.8	286	4.4
Mesial	1004	15.5	322	5.0	47	0.7	60	0.9	27	0.4	164	2.5
Distal	941	14.5	295	4.5	93	1.4	146	2.2	27	0.4	122	1.9
Total	3759	57.9	1161	17.9	350	5.4	550	8.5	74	1.1	600	9.3

nation and diagnostic procedure. This training session was followed by a clinical training course, during which the examiner investigated several subjects. The weighted Kappa values for the intra- and inter-examiner reproducibility were good to excellent: visual examination, 0.756 (G.S./intra) 0.850 (JK/intra) and 0.724 (inter); BW, 0.812 (GS/intra), 0.924 (JK/intra) and 0.744 (inter); and NIR-LT, 0.811 (GS/intra), 0.850 (JK/intra) and 0.790 (inter).

Statistical analysis - All analyses were performed using Excel 2010[d] and R 3.3.2 statistical software.[31] The descriptive statistical analysis included a calculation of the frequencies and cross-tabulations to compare the results of the included diagnostic methods. The frequencies of the scores for sound surfaces, ECLs, DCLs and restorations under VI, NIR-LT, BW, VI/NIR-LT and VI/BW criteria were calculated. The total number of carious lesions was determined by the number of lesions found by any method or combination. Pairwise comparisons between two diagnostic methods for overall diagnostic criteria and caries diagnostic criteria were calculated via cross-tabulations and Pearson's chi-square test using a significance threshold of 0.05.

Results

The study showed a moderate mean caries experience (6.1 ECL/T and 7.6 ECL/S, 3.3 DMFT and 9.3 DMFS) in their whole permanent dentition. Differences were observed after analyzing the diagnostic results independent of the three diagnostic methods in the posterior teeth (Table 2); compared with BW radiography (8.0 surfaces) and NIR-LT (10.5 surfaces), VI revealed the fewest ECLs and decayed, missing or filled surfaces (4.2 surfaces).

Knowing the limitations of visual examination on proximal sites, it was possible to complete a VI of all sites, whereas 23.8% and 9.3% of all surfaces on the BW and NIR-LT images, respectively, were not assessable (Table 3). In the case of the BW radiographs, no diagnoses could be made primarily based on the (first) premolars and their mesial surfaces (Table 3) because these teeth are difficult to capture with stiff CCD sensors. In contrast, missing or non-analyzable images were equally distributed across all premolar and molar surfaces using NIR-LT (Table 3).

When considering the following diagnostic findings (Tables 4-6), it is important to recognize that this clinical study did not include a gold standard due to the impossibility to validate ECLs and DCLs on a population-based level. Caries lesions were less frequently detected when visual examination alone was used (Table 4 and 6). The use of digital BW radiography or NIR-LT as additional diagnostic methods revealed that 86.2% or 89.6% of all detected ECLs or DCLs were identified by

Table 4. Cross-tabulations of the diagnostic methods employed; gray highlights indicate congruent diagnostic findings among the compared methods.

N/%	Sound		ECL		DCL		Restoration		Not assessable		Total	
NIR-LT												
Visual												
Sound	3681	57.3	1038	16.2	271	4.2	101	1.6	558	8.7	5649	88.0
ECL	52	0.8	108	1.7	73	1.1	3	0	12	0.2	248	3.9
DCL	-	-	-	-	1	0.0	-	-	-	-	1	0.0
Restoration	28	0.4	15	0.2	5	0.1	446	6.9	30	0.5	524	8.2
Total	3761	58.6	1161	18.1	350	5.4	550	8.6	600	9.3	6422	100.0
BW												
Visual												
Sound	3223	50.2	686	10.7	271	4.2	1	0.0	1468	22.9	5649	88.0
ECL	93	1.4	68	1.1	54	0.8	-	-	33	0.5	248	3.9
DCL	1	0.0	-	-	-	-	-	-	-	-	1	0.0
Restoration	-	-	-	-	25	0.4	452	7.0	47	0.7	524	8.2
Total	3317	51.7	754	11.7	350	5.5	453	7.1	1548	24.1	6422	100.0
NIR-LT - BW												
Sound	2392	37.2	247	3.8	57	0.9	28	0.4	1037	16.1	3761	58.6
ECL	556	8.7	326	5.1	106	1.7	15	0.2	158	2.5	1161	18.1
DCL	80	1.2	123	1.9	130	2.0	4	0.1	13	0.2	350	5.5
Restoration	62	1.0	19	0.3	31	0.5	383	6.0	55	0.9	550	8.6
Not assessable	227	3.5	39	0.6	26	0.4	23	0.4	285	4.4	600	9.3
Total	3317	51.7	754	11.7	350	5.5	453	7.1	1548	24.1	6422	100.0

Table 5. Cross-tabulations of the diagnostic results when visual examination and digital BW radiography or NIR-LT were employed as the primary detection and diagnostic methods; gray highlights indicate congruent decisions.

N/%	Sound		ECL		DCL		Restoration		Not assessable		Total	
BW												
Visual plus NIR-LT												
Sound[1]	2583	40.2	280	4.4	78	1.2	0	0.0	1298	20.2	4239	66.0
ECL[2]	608	9.5	356	5.5	145	2.3	1	0.0	176	2.7	1286	20.0
DCL[3]	65	1.0	99	1.5	96	1.5	0	0.0	12	0.2	272	4.2
Restoration	61	0.9	19	0.3	31	0.5	452	7.0	62	1.0	625	9.7
Total	3317	51.7	754	11.7	350	5.5	453	7.1	1548	24.1	6422	100.0
NIR-LT												
Visual plus BW												
Sound[1]	3384	52.7	658	10.2	76	1.2	76	1.2	497	7.7	4691	73.0
ECL[2]	292	4.5	381	5.9	139	2.2	21	0.3	47	0.7	880	13.7
DCL[3]	57	0.9	106	1.7	131	2.0	31	0.5	26	0.4	351	5.5
Restoration	28	0.4	16	0.2	4	0.1	422	6.6	30	0.5	500	7.8
Total	3761	58.6	1161	18.1	350	5.5	550	8.6	600	9.3	6422	100.0

[1] A sound surface was diagnosed when both methods simultaneously revealed a healthy surface.
[2] An ECL was diagnosed when one of the two methods identified an ECL and no DCL or restoration was present.
[3] A DCL was diagnosed when one of the two methods identified a DCL and no restoration was present.

either method alone (Table 6). When comparing the diagnostic results from the BW radiographs and NIR-LT images, only 28.1% of all caries lesions were detected similarly by both methods (Table 6). The proportion of ECLs and DCLs diagnosed using NIR-LT (46.7%) was nearly twice as high as that diagnosed with BW radiography (25.2%; Table 6). The additional diagnostic findings were primarily caused by the number of solely diagnosed ECLs (N=556), which was more than twice as high than the same number diagnosed using BWs (N=247, Table 4).

The following results were documented based on the analyses of the possible pairwise combinations between the methods used (Tables 5, 6). If VI is considered as the basic diagnostic method, then it can be combined with digital BW radiography or NIR-LT. After combining visual examination with NIR-LT, 70.9% of all ECLs and DCLs were detected similarly using both methods; 29.1% were additionally diagnosed after adding BWs (Table 6). If visual examination and BW radiography were considered as the methods of first and second choice, then only 52.6% of all ECLs and DCLs were similarly detected. The proportion detected by the third or NIR-LT method was 47.4% (Table 6).

Discussion

This study compared three diagnostic methods, including the novel NIR-LT method, for detecting and diagnosing caries on proximal surfaces. The results indicated a need to accompany visual examination with additional diagnostic methods because the majority of ECLs and DCLs were detected via digital BW radiography or NIR-LT (Tables 4, 6). This finding corroborates several reports that compared the diagnostic results between visual diagnostic methods and dental radiography on proximal sites and documented an underestimation of the caries burden when VI alone was used.[6-8] Furthermore, several studies have documented the same finding that approximately 80% of all present DCLs were diagnosed using additionally prescribed BW radiographs.[6,8,32-34] Interestingly, the current study documented the same outcome with regard to

Table 6. Overview of the diagnostic results when comparing all the diagnostic methods with each other. The table illustrates for two scenarios the proportion of surfaces which were consistent by Methods 1 and 2. Furthermore, the proportions are summarized which were solely detected by each method.

N %		All diagnoses[1]					Caries diagnoses only[2]		
		Method 1			Method 2		Method 1		Method 2
Method 1	Method 2	Σ	Not assessable	Consensus	Σ	Not assessable	Σ	Consensus	Σ
VI*,†	NIR-LT *,†	100/1.6	-	4236/66.0	1486/23.1	600/9.3	52/3.4	109/7.1	1382/89.6
VI*,†	BW*,†	119/1.9	-	3743/58.3	1012/15.8	1548/24.1	94/8.0	68/5.8	1011/86.2
NIR-LT*,†	BW*,†	914/14.1	600/9.3	3231/50.0	457/7.1	1263/19.5	759/46.7	456/28.1	410/25.2
VI/NIR-LT*,†	BW*,†	883/13.7	-	3487/54.3	504/7.8	1548/24.1	772/44.7	452/26.2	503/29.1
VI/BW*,†	NIR-LT*,†	503/7.8	-	4318/67.2	1001/15.6	600/9.3	455/24.7	512/27.8	873/47.4

[1] Sound surfaces, ECLs and DCLs, restorations.
[2] ECLs and DCLs.
* Indicates significance when comparing two methods under the overall diagnostic criteria using Pearson's chi-square test.
† Indicates significance when comparing two methods under the caries diagnostic criteria using Pearson's chi-square test.

proximal sites when the novel X-ray-free NIR-LT was used (Table 6). The value of NIR-LT is further underlined by the observation that twice as many ECLs were detected compared with digital BW radiography (Table 4). This finding is in line with recently published results.[35] Both studies support the potential of this new method for early caries detection. As another advantage, the failure rate of NIR-LT images (9.3%) was substantially lower than that of BW radiographs (23.8%). Importantly, however, the number of non-analyzable NIR-LT images should be attributed to the study design, which required a full-mouth registration to enable a patient-independent and blinded image evaluation. Because this procedure is time-consuming and less effective, it cannot be recommended for clinical practice. It is likely more appropriate to screen (repetitively, given that this technology is X-ray free) all surfaces quadrant by quadrant to capture relevant findings. Using this strategy, it would be impossible to miss any sites via NIR-LT in the clinic. However, this situation substantially differs from that of BWs. Here, the missing information originated from a digital sensor size of 4×5 cm, and the stiffness does not allow all surfaces (from the mesial surface on the first premolars onwards until the distal surfaces on the second permanent molars) to be captured in one image. It is likely that the mesial surfaces in the first premolars will be missed (Table 3). Therefore, it could be necessary to capture two images per side to overcome this problem especially in caries risk patients. However, this protocol would double a patient's exposure to ionizing radiation and should be used for individual cases only. In addition, it should be mentioned that the caries susceptibility of this site is quite low.

When considering the diagnostic results of the additional methods, the use of NIR-LT or BW radiographs as a second-choice method should be discussed. When summarizing data from available clinical NIR-LT trials,[21,22,35] laboratory work[23-25] and the findings of the current study, the data support the use of NIR-LT as the second method. In addition to the aforementioned arguments regarding its X-ray-free design, the full access to all surfaces and superior detection of ECLs on proximal sites, NIR-LT also detected the majority of ECLs and DCLs compared with BW radiography (Tables 4-6). In detail, while the combined visual/NIR-LT examination detected 70.9% of all caries lesions, this proportion amounted to only 52.6% in cases of combined visual/radiographic investigation. Therefore, we concluded that NIR-LT complements visual examinations as the second-choice method for proximal caries detection. In addition, the NIR-LT method can be used on occlusal surfaces[36] and for monitoring caries,[22] thereby increasing its clinical usability.

The remaining question that must be answered concerns contemporary indications for BW radiographs. Importantly, none of the investigated additional methods perfectly detected or diagnosed all the caries lesions. Although the strength of NIR-LT is apparent with regard to early caries detection, these results cannot be achieved using BW radiographs because this method cannot detect small demineralizations in hard tissue via ionizing radiation. Conversely, the strengths of BW radiographs are apparent in their precise diagnosis and assessment of DCLs in relation to the enamel-dentin junction or pulp, both of which are impossible using NIR-LT images.[26] Therefore, we suggest employing BW radiographs as the third method in clinical situations when NIR-LT screening hints at a DCL. This suggestion is also supported by the data from this study because a distinct proportion of the ECLs diagnosed using NIR-LT were classified as DCLs after counterchecked with BW radiographs (Tables 4, 5).

The strength of this study is that it is the first comparative analysis of the diagnostic value of NIR-LT on proximal surfaces. To our knowledge, no prospectively designed and clinical data regarding this topic has been published. However, the generalizability of the current results might be limited because of the inclusion of young adults; the results might differ across different age groups or populations due to a diverging caries risk or activity. Although the overall caries experience diagnosed via VI was low, the caries burden more than doubled when digital BW radiographs or NIR-LT were additionally applied (Table 2). This finding supports the assumption that additional diagnostic results are higher among patients or populations with low caries experience. Independent of this finding, our results support the use of additional detection methods, especially with regard to proximal sites. In addition, all diagnoses were blind to the other diagnostic methods, which resulted in independent and unbiased diagnostic decisions. Although this methodological requirement is a strength of this study, it might be otherwise argued that all diagnostic decisions should be merged in daily dental practice. To address this issue, the present study analyzed the possible combinations of diagnostic methods using standardized algorithms (Table 5). It should further be mentioned that we avoided any discussion of possible treatment recommendation in relation to the used diagnostic categories due to the simple

fact that other variables, e.g. age, caries experience, caries risk and activity, knowledge and attitudes, etc., will influence the individual decision-making. Therefore, the sole usage of well-defined cut-off values and their corresponding categories needs to be, of course, downsized in clinical practice. However, in case of a diagnostic study, its usage is essential to enable comparisons between the included methods. This approach may help to answer the question which diagnostic method(s) will provide the most relevant information in relation to potential risks. This feature has to be understood as strength of this comparative analysis in a relatively large sample size of 203 adult subjects. Nevertheless, it has to be noted that false negative or false positive visual, NIR-LT or BW diagnoses could not be excluded, which is another limitation of the study. False negative diagnoses are foreseeable when visual methods are used alone on proximal sites. False positive diagnoses might be more frequently expected when NIR-LT is used due to its ability to detect early changes in enamel. This must be considered in daily clinical practice and, therefore, treatment decisions should be made with caution.

Given the design of a comparative clinical diagnostic study, it was impossible to validate ECLs or DCLs. Here, it is necessary to refer to published data, where a similar diagnostic accuracy for interproximal dentin caries detection was revealed using digital BW radiography and NIR-LT.[26] The persistent missing information belongs to the validation of ECLs detected via NIR-LT. However, this supposition requires an appropriate in vitro model, which does not yet exist because it is impossible to ethically validate ECLs in the clinic.

In conclusion, this comparative diagnostic study on proximal surfaces confirmed that visual examination alone led to an underestimation of the caries burden in the posterior teeth and that appropriate additional detection methods are required. Based on the present results, it is concluded that novel NIR-LT complements visual examination as a second-choice method because of its diagnostic value, especially regarding its detection of enamel caries, its X-ray-free design and its clinical practicability. BW radiographs should be used in clinical situations where (micro-) cavities or suggestions of DCLs are diagnosed visually or via NIR-LT. This diagnostic strategy will help reduce the possible risks due to ionizing radiation by prescribing diagnostic procedures on an individual basis and meeting all requirements to provide optimal preventive and operative dental care.

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