Aus der Poliklinik für Zahnerhaltung und Parodontologie

Klinik der Universität München

Direktor: Prof. Dr. Reinhard Hickel

Weiterentwicklung der FDI-Kriterien zur Evaluation der Qualität zahnärztlicher Restaurationen

Dissertation
zum Erwerb des Doktorgrades der Zahnmedizin
an der Medizinischen Fakultät der
Ludwig-Maximilians-Universität zu München

vorgelegt von

Sabine Maria Hausner, geb. Mesinger

aus

Ravensburg

Jahr

2024

Mit Genehmigung der Medizinischen Fakultät
der Universität München

Berichterstatter:	Prof. Dr. Jan Kühnisch
Mitberichterstatter:	PD Dr. Felicitas Mayinger
	Prof. Dr. Heinz Kniha
Dekan:	Prof. Dr. med. Thomas Gudermann
Tag der mündlichen Prüfung:	04.03.2024

Affidavit

Eidesstattliche Versicherung

Hausner, geb. Mesinger, Sabine Maria

Name, Vorname

Ich erkläre hiermit an Eides statt, dass ich die vorliegende Dissertation mit dem Titel:

„Weiterentwicklung der FDI-Kriterien zur Evaluation der Qualität zahnärztlicher Restaurationen“

selbständig verfasst, mich außer der angegebenen keiner weiteren Hilfsmittel bedient und alle Erkenntnisse, die aus dem Schrifttum ganz oder annähernd übernommen sind, als solche kenntlich gemacht und nach ihrer Herkunft unter Bezeichnung der Fundstelle einzeln nachgewiesen habe.

Ich erkläre des Weiteren, dass die hier vorgelegte Dissertation nicht in gleicher oder in ähnlicher Form bei einer anderen Stelle zur Erlangung eines akademischen Grades eingereicht wurde.

Ravensburg, 07.03.2024
Ort, Datum

Sabine Maria Hausner, geb. Mesinger
Unterschrift Doktorandin bzw.Doktorand

Inhaltsverzeichnis

Abkürzungsverzeichnis

FDI	Federation Dentaire Internationale
USPHS	United States Public Health Service
CAR	Caries at restoration margin (Karies am Restaurationsrand)
C_K	Cohen´s Kappa
F_K	Fleiss Kappa
w_K	Weighted (gewichtete) Kappa

Publikationsliste

Englischsprachige Originalarbeit I
Mesinger S, Heck K, Crispin A, Frankenberger R, Cadenaro M, Burgess J, Peschke A, Heintze SD, Loomans B, Opdam N, Hickel R, Kühnisch J. Evaluation of direct restorations using the revised FDI criteria: results from a reliability study. Clin Oral Investig. 2023 Apr;27(4):1519-1528. doi: 10.1007/s00784-022-04771-9. Epub 2022 Nov 18. PMID: 36399211; PMCID: PMC10102028.

Englischsprachige Originalarbeit II
Hickel R, Mesinger S, Opdam N, Loomans B, Frankenberger R, Cadenaro M, Burgess J, Peschke A, Heintze SD, Kühnisch J. Revised FDI criteria for evaluating direct and indirect dental restorations-recommendations for its clinical use, interpretation, and reporting. Clin Oral Investig. 2022 Dec 12. doi: 10.1007/s00784-022-04814-1. Epub ahead of print. Erratum in: Clin Oral Investig. 2023 Jan 6;: PMID: 36504246.

Beitrag zu den Publikationen

Im Rahmen der Promotion waren folgende Abschnitte notwendig, die in der Studiengruppe entsprechend nachstehender Tabelle bearbeitet wurden.

	Sabine Hausner, geb. Mesinger	Prof. Dr. Jan Kühnisch	Ko-Autoren
Publikation "Evaluation of direct restorations using the revised FDI criteria: results from a reliability study"			
Projektidee	50%	50%	-
Studiendesign	80%	20%	-
Literaturrecherche	100%	-	-
Untersuchungen & Datenmanagement	100%	-	-
Statistische Analyse	90%	-	10%
Dateninterpretation	80%	20%	-
Tabellen und Abbildungen	100%	-	-
Manuskript-Erstellung	100%	-	-
Einreichung und Revision der Publikation	90%	10%	-

	Sabine Hausner, geb. Mesinger	Prof. Kühnisch/ Prof. Hickel	Ko-Autoren
Publikation "Revised FDI criteria for evaluating direct and indirect dental restorations-recommendations for its clinical use, interpretation, and reporting"			
Projektidee	-	100%	-
Studiendesign	50%	50%	-
Literaturrecherche	50%	50%	-
Literaturinterpretation	30%	50%	20%
Tabellen und Abbildungen	50%	50%	-
Manuskript-Erstellung	50%	50%	-
Einreichung und Revision der Publikation	50%	50%	-

1. Einleitung

Zahnärzte benötigen praktische Bewertungsmethoden und Klassifizierungskriterien zur Befundung anatomischer, physiologischer und pathologischer Strukturen der Mundhöhle. Verlässliche Methoden sind für die Detektion und Klassifikation pathologischer Zustandsbilder von Bedeutung, um Therapieentscheidungen indikationsgerecht zu treffen [1]. Für die Beurteilung restaurierter Zähne wurden in der Vergangenheit unterschiedliche Bewertungssysteme veröffentlicht. Cvar und Ryge publizierten das erste Bewertungssystem in Zusammenarbeit mit dem United States Public Health Service im Jahr 1971 [2,3]. Eine überarbeitete Version erschien im Jahr 1980, auch bekannt als die „modified Ryge/ USPHS Criteria“ [4]. Mit der Weiterentwicklung zahnärztlicher Restaurationsmaterialien wurde ein differenzierteres und sensibleres System notwendig, um Schwachstellen und Misserfolge zu erkennen [5,6]. 2007 wurden neue klinische Kriterien zur Evaluation zahnärztlicher Restaurationen durch Hickel et al. vorgeschlagen und durch das „Science Committee of the FDI World Dental Federation/ Fédération Dentaire Internationale (FDI)“ als Standardkriterien für die Verwendung in klinischen Studien befürwortet [5,6]. 2010 wurde durch die selbe Arbeitsgruppe eine Überarbeitung der Kriterien mit klinischen Beispielen publiziert [7,8]. Dieses Kriterienset klassifiziert Restaurationen mit 16 Kriterien nach ästhetischen, funktionellen und biologischen Eigenschaften. Durch eine Bewertungsskala mit fünf Graden können Restaurationen in klinisch suffizient (Grad 1-3) und klinisch insuffizient mit Bedarf für Reparatur (Wert 4) oder Ersatz (Wert 5) unterschieden werden. Die Verwendung der FDI-Kriterien in klinischen Studien wurde kürzlich in einem Übersichtsartikel zusammengefasst [9]. Die Ergebnisse zeigen eine zunehmende Anwendung der FDI-Kriterien in klinischen Studien von 4,5% in 2010 auf 50% in 2016. In der Summation unterlagen die FDI-Kriterien jedoch den modifizierten Ryge/ USPHS Kriterien. In nur 16,3% aller seit Januar 2007 veröffentlichen Studien kamen die FDI-Kriterien zur Anwendung [9]. Verwirrende und subjektive Kriterien, mangelnde Einheitlichkeit sowie die komplexe Anwendung wurden als Gründe für die unterlassene Anwendung der FDI-Kriterien genannt [9, 10].

2. Zielstellung

Mit dem Ziel, die FDI-Kriterien in ihrer Anwendung zu verbessern fand sich 2019 eine Arbeitsgruppe unter der Leitung von Prof. Hickel zusammen. Neben der Optimierung und Harmonisierung der Kriterien, sollte dieser Revisionsprozess durch die Expertenanwendung begleitet werden, indem die Intra- und Inter-Untersucher-Reproduzierbarkeit zu verschiedenen Projektzeitpunkten erfasst werden sollte. Ziel der vorliegenden Dissertation war es, die intra- und inter-Untersucher Reproduzierbarkeit zwischen den involvierten Experten zu verschiedenen Zeitpunkten der Kriterien Entwicklung zu bestimmen, um den Revisionsprozess daten- und anwendungsbasiert zu unterstützen.

3. Probanden und Methoden

Expertengruppe. Eine Gruppe aus zehn Zahnärzten aus Europa und Nordamerika erklärte sich bereit, die Revision der FDI-Kriterien zu unterstützen. Die Expertengruppe repräsentierte ein breites Spektrum an klinischer und wissenschaftlicher Erfahrung auf dem Gebiet der konservierenden und restaurativen Zahnheilkunde. Zu betonen ist, dass alle teilnehmenden Experten mit dem existenten Set der FDI-Kriterien [5-8] bereits theoretisch und praktisch vertraut waren. Drei Experten waren über dies hinaus bereits Teil der ersten Arbeitsgruppe bei der primären Entwicklung der FDI-Kriterien.

Revisionsprozess. Die bestehenden FDI-Kriterien [7,8] wurden durch die konsensorientierte Delphi-Methode schrittweise überarbeitet. Dabei handelt es sich um einen strukturierten Prozess, um Informationen von einer Expertengruppe durch eine Reihe von Sitzungen und/oder Bewertungen zu erhalten, bestehende Meinungen zusammenzuführen und schließlich einen Gruppenkonsens zu erzielen [11]. Der Abstimmungsprozess wurde mit einem Gruppenworkshop am 3. und 4. Juni 2019 an der Klinik für Konservierende Zahnheilkunde und Parodontologie in München eingeleitet. Während dieser Präsenzveranstaltung wurden die Ergebnisse der Literaturrecherche vorgestellt, kritisch diskutiert und empirische Erfahrungen mit den bestehenden Bewertungskriterien für direkte und indirekte Zahnrestaurationen ausgetauscht. Als Ergebnis des Workshops wurden der Bedarf und die Methodik für Verbesserungen begründet und vereinbart. Nach dem Treffen wurde ein Vorentwurf eines überarbeiteten FDI-Kriteriensets an die Experten weitergeleitet und individuell durch jeden Experten evaluiert. Die Teilnehmer wurden aufgefordert, ihre Meinung kontinuierlich frei zu äußern als auch Kritik und Verbesserungsvorschläge vorzubringen. Alle Antworten wurden gesammelt, analysiert und die Informationen der Gruppe strukturiert. Widersprüchliche Standpunkte und Fehler wurden identifiziert und das Kriterienset entsprechend überarbeitet. Die darauffolgenden Gruppendiskussionen wurden online organisiert, mit dem Ziel sich auf die vereinfachte Struktur des Kriteriensets und die Bedeutung der einzelnen Kategorien zu einigen. Dieser strukturierte Kommunikationsfluss mit mehreren Feedbackrunden, offenen Diskussionen und Umformulierungen wurde bis zum Frühjahr 2020 fortgesetzt, bis ein Gruppenkonsens vorlag, so dass keine weiteren Änderungen an den Dokumenten erforderlich waren.

Bestimmung der Reliabilität. Der Gruppenkonsens wurde von insgesamt drei Anwendungsrunden der jeweiligen Kriterien begleitet. Wobei nach jeder Evaluierungsrunde die Kommentare und Rückmeldungen aller Experten gesammelt, diskutiert und in das aktualisierte Kriterienset eingepflegt wurden. Für diese Untersuchungen wurden primär etwa tausend anonymisierte intraorale Fotografien gesichtet. Fotografien von direkten Restaurationen aus Amalgam, temporären Füllungsmaterialien und allen Arten von indirekten Restaurationen wurden ausgeschlossen. Schließlich wurden 49 Fotografien mit einer gleichmäßigen Verteilung von Seiten- (n=25) und Frontzähnen (n=24) und einem breiten Spektrum an Fehlern ausgewählt und jedem Bild eine eindeutige Identifikationsnummer zugeordnet. Darüber hinaus wurde in jedes Bild eine Markierung eingebettet, um die relevante Restauration hervorzuheben und Fehlklassifikationen bei mehreren Füllungen pro Zahn zu vermeiden. Für die Beurteilung der dargestellten Restaurationen waren die folgenden Kriterien für die Evaluation auf intra-oralen Fotografien geeignet: F1 – Materialbruch und Retention, F2 – Randschluss, F4 – Form und Kontur, B1 – Karies am Restaurationsrand (CAR), B2 – Defekte von Zahnhartsubstanz, A1 – Oberflächenglanz und -textur, A2 – Randverfärbung und A3 – Farbübereinstimmung.

Die Beurteilung der intraoralen Aufnahmen sowie die Erhebung der Daten erfolgte über eine Online-Plattform (www.SoSciSurvey.com, SoSci Survey GmbH, München, Deutschland). Für jeden teilnehmenden Experten (n=10) und jede Bewertungsrunde (n=3) wurde ein individueller, verblindeter und unabhängiger Zugang bereitgestellt. Die Reihenfolge der Bilder wurde zwischen den Evaluierungsrunden zufällig geändert, um mögliche Erinnerungseffekte während des Untersuchungszeitraums zu verringern. Für die statistische Analyse wurden die Daten anschließend in eine Excel-Tabelle exportiert und auf Plausibiliät geprüft. Die deskriptive und explorative Datenanalyse erfolgte mit Excel und SPSS (SPSS Statistics 27, 2020, IBM Corporation, Armonk, NY, USA). Die deskriptive Analyse umfasste die Berechnung der prozentualen Übereinstimmung zur Intra- und Inter-Untersucher-Reproduzierbarkeit unter den Experten und in Relation zum Referenzstandard. Für die explorative Analyse des Nominaldatensatzes wurde Cohen´s Kappa (C_K) für die Intra-Untersucher-Reproduzierbarkeit und Fleiss´ Kappa (F_K) für die Inter-Untersucher-Reproduzierbarkeit berechnet. Zusätzlich wurden für die explorative Analyse der Beobachtung als ordinaler Datensatz linear gewichtete Kappa (w_K)-

Werte für die Intra-Untersucher-Reproduzierbarkeit berechnet. Für die Inter-Prüfer-Reproduzierbarkeit wurden linear gewichtete Kappa (w_K)-Werte für alle Codiererpaare mittels SPSS berechnet. Um einen Gesamtwert zu erhalten, wurde das arithmetische Mittel dieser Schätzungen mit Excel berechnet [12, 13]. Das gleiche Verfahren wurde für die Reproduzierbarkeit aller Experten in Bezug auf den Referenzstandard angewendet. Darüber hinaus wurden modifizierte Bland/Altman-Plots [14, 15] und eine binominale logistische Regressionsanalyse unter Verwendung eines Rückwärts-Eliminationsmodells durchgeführt und verwendet, um alle diagnostischen Entscheidungen in Bezug auf den Referenzstandard zu untersuchen. Die Analyse wurde mit den Daten aller Bewertungsrunden, Untersucher, Kategorien und Zahntypen (Front- oder Seitenzahn) berechnet.

4. Ergebnisse

Im Rahmen der Dissertation konnte gezeigt werden, dass die Intra- und Inter-Untersucher-Reproduzierbarkeit über die drei Bewertungsrunden zunahm und die jeweiligen Kappa-Werte von einer moderaten bis sehr guten Größenordnung reichten (z.B. in der Kategorie F1 Materialfraktur und Retention bei Seitenzähnen in der intra-Untersucher Betrachtung: C_K=0,57 und w_K=0,74 sowie in der inter-Untersucher Betrachtung: F_K=0,32 und w_K=0,53). Die Reproduzierbarkeit variierte je nach Untersucher, Kategorie und Zahntyp. Die Reproduzierbarkeit in den funktionellen und biologischen Kategorien war höher als in der ästhetischen Kategorie. Hierbei wiesen die Kriterien B1 Karies am Restaurationsrand (wk 0,78 für Seitenzahnrestaurationen und wk 0,66 für Frontzahnrestaurationen) und B2 Zahnhartsubstanzdefekte am Restaurationsrand (wk 0,59 für Seitenzähne und wk 0,47 für Frontzähne) die beste Übereinstimmung mit dem Referenzstandard auf. Die Kriterien A1 Oberflächenglanz & Textur (Frontzähne Fk 0,35/ wk 0,35 und Seitenzähne Fk 0,37/ wk 0,41), A2 Randverfärbung (Frontzähne Fk 0,41/ wk 0,56 und Seitenzähne Fk 0,38/ wk 0,34) und A3 Farbübereinstimmung (Frontzähne Fk 0,36/ wk 0,34 und Seitenzähne Fk 0,28/ wk 0,40) sowie das funktionelle Kriterium F4 Form & Kontur (Frontzähne Fk 0,40/ wk 0,33 und Seitenzähne Fk 0,28/ wk 0,40) zeigten nur eine mäßige Übereinstimmung in der Inter-Untersucher Analyse, woraus sich ableiten lässt, dass die ästhetischen Eigenschaften sowie die Form einer Restauration dem subjektiven und ästhetischen Empfinden des Untersuchers unterliegen [10,16-18]. Dennoch konnte auch für die ästhetischen Kriterien, insbesondere bei den Frontzahnrestaurationen eine Steigerung der prozentualen Übereinstimmung mit dem Referenzstandard durch die Präzisierung der Kriterienbeschreibung erreicht werden, z.B. für A1 Oberflächenglanz & Textur mit wk 0,32 vs. wk 0,37 vs. wk 0,54 im Vergleich für die drei Evaluationsrunden.

5. Diskussion

Die Reproduzierbarkeitsstudie trug im Rahmen der Revision der FDI-Kriterien dazu bei, die Auswahl der Kriterien und deren Beschreibung datenbasiert zu untermauern. Des Weiteren wurde die Wichtung klinisch relevanter Kategorien durch die Ergebnisse der Reproduzierbarkeitsstudie vorgenommen. Hier wurden die funktionellen Eigenschaften direkter und indirekter Restaurationen (Bereich F) nun an den Anfang des Sets gestellt, gefolgt von den biologischen (Bereich B) und ästhetischen Eigenschaften (Bereich A). Das überarbeitete FDI-Kriterienset wurde zudem in den drei Hauptkategorien auf insgesamt elf Kernkriterien reduziert. Außerdem wurden die Kriterien „Patientenansicht“ und „Röntgenbeurteilung“ in die neue Domäne „Sonstiges“ verschoben, da sie nicht, wie die anderen 11 Kriterien nach einer 5-Punkte-Skala beurteilt werden können. Obwohl ein Konsensprozess kollektives Wissen erfasst, sollte beachtet werden, dass das resultierende Kriterienset bis zu einem gewissen Grad ein subjektiver Standpunkt der Expertengruppe sein kann [19]. Zur Objektivierung der Gruppenentscheidung konnte die statistische Analyse der Reproduzierbarkeitsstudie wesentlich beitragen. Zu den Stärken der Reproduzierbarkeitsstudie zählen die konsistente und umfassende Dokumentation der statistischen Daten, die neben einfachen und gewichteten Kappa-Werten, auch die prozentuale Übereinstimmung, modifizierte Bland/Altmann-Diagramme und das binominale logistische Regeressionsmodell darstellen. Bei der Diskussion möglicher Schwächen der Reproduzierbarkeitsstudie muss erwähnt werden, dass die Evaluation der zahnärztlichen Restaurationen nicht klinisch erfolgte. Die Auswahl der intraoralen Aufnahmen, zeigen jedoch ein breites Spektrum, mit zum Teil komplexen klinischen Befunden. Somit wurde die Erprobung des Kriteriensets in vielen Kategorien ermöglicht, was unter klinischen Bedingungen kaum möglich gewesen wäre. Zudem ist auszuführen, dass die klinische Untersuchung mit einer dreidimensionalen Beurteilung von Restaurationen und der Verwendung von Instrumenten, wie z.B. zahnärztlichen Sonden, möglicherweise zu objektiveren und präziseren Bewertungen führt. Des Weiteren können die Kriterien „Okklusion und Abnutzung“, „Approximalkontakt“ und „post-operative Hypersensibilität / Zustand der Pulpa“ nicht auf intraoralen Aufnahmen beurteilt werden [17,20,21], weshalb diese von Anfang an ausgeschlossen wurden. Die Beurteilung der ästhetischen Kriterien könnte ebenfalls auf Fotografien eingeschränkt sein.

Nichts desto trotz sind intraorale Aufnahmen ein bewehrtes Medium für die Evaluation zahnärztlicher Restaurationen [17,18,20]. Als weitere Schwäche muss die niedrige Fallzahl von 46 Fotografien, sowie die Beschränkung auf direkte, zahnfarbige Restaurationen genannt werden. Mehr Fotografien und die Beurteilung unterschiedlicher Restaurationsformen und -materialien hätte die Wertigkeit und Gültigkeit der Studie erhöht. Aufgrund der zeitlichen Ressourcen der Arbeitsgruppe musste die Fallzahl limitiert werden, jedoch wurde ein besonderer Fokus auf die Auswahl von komplexen und schwierigen Fallbeispielen gelegt, um das Kriterienset möglichst breitgefächert zu erproben. Diesbezüglich muss auch erwähnt werden, dass ein strenges Testprotokoll zwei Evaluierung pro Runde erfordert hätte, dies konnte aufgrund oben genannter Problematik nicht ermöglicht werden. Aus diesem Grund erscheinen, insbesondere für die klinische Erprobung des Kriteriensets, weitere Studien notwendig.

Mit dem überarbeiteten FDI-Kriterienset konnten Unklarheiten beseitigt und die Bewertungen weiter harmonisiert werden, um die diagnostische Beurteilung von zahnärztlichen Restaurationen zu objektivieren. Zu betonen ist, dass die empfohlenen Behandlungsverfahren als mögliche Interventionskorridore zu verstehen sind und nicht als zwangsläufige Behandlungsansätze. Weitere klinisch relevante Schlüsselvariablen, wie z.B. das Kariesrisiko, die Kariesaktivität, das Alter, die Allgemeinanamnese und Wünsche des Patienten sind bei der Therapieentscheidung weiter zu berücksichtigen. Daher kann eine bestimmte zahnärztliche Diagnose durchaus mit unterschiedlichen Behandlungsoptionen verbunden sein.

6. Zusammenfassung:

Das Ziel der vorliegenden Dissertationsschrift bestand in der Weiterentwicklung der FDI Kriterien zur Evaluation direkter und indirekter zahnärztlicher Restaurationen [5-8] und der begleitenden Überprüfung der intra- und inter-Untersucher Reproduzierbarkeit anhand von intra-oralen Farbfotografien. 10 Experten waren Teil des Revisionsprozesses und haben insgesamt 49 Aufnahmen von direkten, zahnfarbigen Restaurationen in insgesamt drei Runden mittels der revidierten Kriterien evaluiert. Die Gesamtzuverlässigkeit des überarbeiteten FDI-Kriteriensets wurde bis zur endgültigen Fassung stetig erhöht. Bei einigen Untersuchern, Kategorien und Zahntypen wurden jedoch signifikante Unterschiede dokumentiert. Im Hinblick auf die dokumentierten Unterschiede zwischen den Prüfern ist zu betonen, dass Anwender in der korrekten Anwendung der Kriterien theoretisch und praktisch geschult werden sollten. Die klinische Anwendbarkeit und Praktikabilität der FDI Kriterien wurde verbessert, indem Kategorien nach ihrer klinischen Relevanz priorisiert und der Wortlaut für eine intuitivere Anwendung vereinheitlicht wurden. Des Weiteren ist zu betonen, dass die FDI Kriterien ein modulares Diagnosesystem sind. Kategorien und Kriterien können unabhängig voneinander, passend für den klinischen Bedarf oder in Bezug auf die wissenschaftliche Fragestellung, für die Bewertung von direkten und indirekten Restaurationen, ausgewählt werden.

7. Abstract (English):

Objectives The aim of this study was to further develop the FDI criteria for the evaluation of direct and indirect dental restorations [Hickel et al. 2007, 2010] and to verify the intra- and inter-examiner reproducibility using intra-oral colour photographs.

Material and methods The existing FDI criteria were revised through a stepwise, structured and consensus-based process in which information from a group of 10 experts was collected, summarized and finally incorporated into the revision of the criteria. To investigate the reproducibility a total of 49 images of direct tooth-coloured restorations were evaluated in a total of three rounds using the revised criteria set.

Results The reproducibility of the revised FDI criteria set was steadily increased up to the final version which was then consented and published. Overall, the reproducibility was in the moderate to very good range. However, significant differences were documented for some examiners, categories and tooth types.

Conclusions The clinical applicability and practicality of the FDI criteria was improved by prioritising categories according to their clinical relevance and by standardising the wording for more intuitive use. With regard to the documented differences between examiners, it should be emphasised that users should receive theoretical and practical training in the correct application of the criteria.

Clinical relevance The FDI criteria are a modular diagnostic system in which categories and criteria can be selected independently of each other, according to clinical need or scientific question, for the evaluation of direct and indirect dental restorations.

8. Veröffentlichung I

Clinical Oral Investigations (2023) 27:1519–1528
https://doi.org/10.1007/s00784-022-04771-9

RESEARCH

Evaluation of direct restorations using the revised FDI criteria: results from a reliability study

Sabine Mesinger[1] · Katrin Heck[1] · Alexander Crispin[2] · Roland Frankenberger[3] · Milena Cadenaro[4] · John Burgess[5] · Arnd Peschke[6] · Siegward D. Heintze[6] · Bas Loomans[7] · Niek Opdam[7] · Reinhard Hickel[1] · Jan Kühnisch[1]

Received: 1 August 2022 / Accepted: 4 November 2022 / Published online: 18 November 2022

Abstract

Objectives The purpose of this in vitro reliability study was to determine the intra- and inter-examiner agreement of the revised FDI criteria including the categories "fracture of material and retention" (F1) and "caries at restoration margin" (B1).

Materials and methods Forty-nine photographs of direct tooth-coloured posterior ($n=25$) and anterior ($n=24$) restorations with common deficiencies were included. Ten dental experts repeated the assessment in three blinded rounds. Later, the experts re-evaluated together all photographs and agreed on a reference standard. Statistical analysis included the calculation of Cohen's (Cκ), Fleiss' (Fκ), and weighted Kappa (wκ), the development of a logistic regression with a backward elimination model and Bland/Altman plots.

Results Intra- and inter-examiner reliability exhibited mostly moderate to substantial Cκ, Fκ, and wκ values for posterior restorations (e.g. Intra: F1 Cκ=0.57, wκ=0.74; B1 Cκ=0.57, wκ=0.73/Inter F1 Fκ=0.32, wκ=0.53; B1 Fκ=0.41, wκ=0.64) and anterior restorations (e.g. Intra F1 Cκ=0.63, wκ=0.76; B1 Cκ=0.48, wκ=0.68/Inter F1 Fκ=0.42, wκ=0.57; B1 Fκ=0.40, wκ=0.51). Logistic regression analyses revealed significant differences between the evaluation rounds, examiners, categories, and tooth type. Both the intra- and inter-examiner reliability increased along with the evaluation rounds. The overall agreement was higher for anterior restorations compared to posterior restorations.

Conclusions The overall reliability of the revised FDI criteria set was found to be moderate to substantial.

Clinical relevance If properly trained, the revised FDI criteria set are a valid tool to evaluate direct and indirect restorations in a standardized way. However, training and calibration are needed to ensure reliable application.

Keywords Reliability · Reproducibility · Dental restoration · Diagnostics

✉ Jan Kühnisch
jkuehn@dent.med.uni-muenchen.de

[1] Department of Conservative Dentistry and Periodontology, University Hospital, Ludwig Maximilians-University of Munich, Goethestraße 70, 80336 Munich, Germany

[2] Institute of Medical Biometry and Epidemiology, Ludwig-Maximilians-University of Munich, Munich, Germany

[3] Department of Operative Dentistry, Endodontics, and Pediatric Dentistry Medical Center for Dentistry, University Medical Center Giessen and Marburg, Campus Marburg, Marburg, Germany

[4] Department of Medical Sciences, Institute for Maternal and Child Health IRCCS "Burlo Garofolo", University of Trieste, Via Dell'Istria, Trieste, Italy

[5] School of Dentistry, University of Alabama at Birmingham, Birmingham, AL, United States

[6] Research & Development, Ivoclar Vivadent AG, Schaan, Liechtenstein

[7] Department of Dentistry, Radboud Institute for Health Sciences, Radboud University Medical Center, Nijmegen, The Netherlands

Introduction

Adequate dental decision-making requires valid and reliable diagnostic detection, classification and/or assessment systems to evaluate anatomical, physiological, and pathological conditions of the stomatognathic system which includes teeth, periodontium, oral mucosa, alveolar bone, or the temporo-mandibular-joint. For restored teeth, different evaluation systems have been published in the past. Cvar and Ryge [1] published the first evaluation system in 1971. As Dr. Gunnar Ryge, a dentist, was Director of the Materials and Technology Branch of the United States Public Health Service, the guidelines had been called USPHS Criteria [2]. J. Cvar was statistician at USPHS and developed statistical methods to analyse the data. In 1980 Ryge published "modified Ryge/ USPHS Criteria" [3]. An elementary aspect of the USPHS Criteria was the development of criteria for clinical testing and estimation of their reliability [1]. These criteria were well accepted and, are still, used in clinical studies evaluating dental restorations [4]. With the development of dental restorative materials a more discriminative and sensitive scale was needed [5, 6]. In 2007, new clinical criteria for the evaluation of dental restorations were suggested by Hickel et al. and approved by the science Committee of the FDI World Dental Federation [5, 6], which are nowadays commonly known as "FDI criteria." In 2010, some modifications to the original criteria set and clinical examples have been published by the same workgroup [7, 8]. In brief, the diagnostic system classifies aesthetic, functional, and biological properties and covers various types of failures with five grades for each criterion. In detail, scores 1 to 3 indicated clinically acceptable restorations, and scores 4 and 5 summarized clinically unacceptable situations indicating repair (score 4) or replacement (score 5). In 2019, a workgroup started to update the FDI criteria for the clinical evaluation of dental restorations by using a stepwise, consensus-based process to improve the clinical usability, practicability and acceptability. Aiming at excluding subjectivity and supporting data-based decision-making, it was suggested to prove the diagnostic reliability at important project milestones. Beside this need, the reliability of the FDI criteria has been scarcely addressed so far and conflicting data are documented in the literature. Perdigao et al. [9] reported on an excellent inter-examiner reliability, whereas Kim et al. [10] documented inconsistent results concerning the intra- and inter-examiner reliability when applying the FDI criteria in direct tooth-coloured posterior restorations using intraoral digital photographs. In addition, the authors referred to the subjectivity of the criteria set which may hinder a reproducible decision making [10] and support the need for an update.

Taking into account the previously mentioned facts, it became evident that it is reasonable to conduct a reliability study parallel to the revision of the criteria set and to provide the data. Therefore, the aim of this in vitro reliability study was to evaluate the intra- and inter-examiner reliability during the revision of the FDI criteria exemplary for direct tooth-coloured anterior and posterior restorations by use of intraoral photographs.

Methods and materials

This in vitro diagnostic study was approved by the local Ethics Committee (Project No. 19–185). The reporting of this investigation followed the Guidelines for Reporting Reliability and Agreement Studies (GRRAS) [11].

Expert group

A group of 10 dentists from Europe and North America participated as experts in the update process of the criteria set. The expert group represented a broad spectrum of clinical and scientific experience in the field of restorative dentistry, and each of the expert contributed to the revised FDI criteria set. Details of the update process were reported elsewhere [12]. It is noteworthy that all participating experts were familiar with the concept of the FDI criteria and no specific theoretical or practical training was performed before each round of evaluation.

Set of intraoral photographs

For this investigation, a few thousand anonymised intraoral photographs not older than 10 years from case documentations or earlier clinical studies conducted at the Department of Conservative Dentistry and Periodontology were screened for the presence of typical failures on direct tooth-coloured restorations. Photographs of direct restorations made of amalgam, temporary filling materials, and all types of indirect restorations were not considered. In a next step, S. Mesinger (SM), J. Kühnisch (JK), and R. Hickel (RH) identified ~ 100 photographs according to the following inclusion criteria: (1) one direct tooth-coloured anterior (labial aspect) or posterior restoration (occlusal aspect) made of composite, compomer, or glass ionomer cement in the centre of the image; (2) broad spectrum of failures, e.g. different stages of material fracture to the extent of complete loss of retention; (3) photograph with good contrast, brightness and sharpness. Finally, the Munich group has chosen 49 photographs with a well-balanced distribution of posterior ($n = 25$) and anterior ($n = 24$) teeth and assigned a unique identification number to each image. Furthermore, a mark-up was embedded on each

image to highlight the relevant restoration to avoid misclassifications in case of multiple fillings per tooth.

Expert evaluations and stepwise revision

The evaluation of the intraoral photographs was performed using an online survey platform (www.SoSciSurvey.com, SoSci Survey GmbH, Munich, Germany). An individual, blinded, and independent access was provided for each participating expert ($n = 10$) and evaluation round ($n = 3$). All photographs were evaluated by all experts (fully crossed design), according to the most recent version of the revised criteria set. To decrease recognition and recall of the photographs during the study period, the sequence of images was randomly changed between the first, second and third round of evaluations. All evaluation rounds were performed after alterations of the criteria set were made on the basis of the current literature, clinical and scientific experiences, and the ongoing discussions in the expert group. After each round, the feedback from all experts was collected, condensed, and incorporated into an updated criteria version. In addition, the results from the statistical analyses of the intra- and inter-examiner reliability were compiled and discussed during online meetings. This led to modifications in the criteria set with the aim to improve the precision of each criterion. During the first two rounds, all experts scored each image according to the 5-point scale of each criterion which resulted into an *ordinal* data set. Importantly, after the second evaluation round, it became obvious that some scores make the evaluation in other categories irrelevant and, therefore, the score "not applicable" was integrated. Subsequently, all evaluations were repeated in a third round after finalisation of the revision process and all experts scored each photograph according to the 5-point scale plus the "not applicable" score which resulted into a *nominal* data set. It is noteworthy to point out that the scoring criteria changed between the three evaluation rounds.

The selected criteria suitable for the evaluation on intraoral photographs were the following: F1 — fracture of material and retention, F2 — marginal adaptation, F4 — form and contour, B1 — caries at restoration margin (CAR), B2 — dental hard tissue defects, A1 — surface lustre and texture, A2 — marginal staining, and A3 — colour match.

Consensus decision (reference standard)

After all three evaluation rounds, the expert group reassessed all intraoral images during two online meetings in December 2020, compared their individual results with those of the others, and determined a consensus decision for each restoration and categories. The 5-point scale plus the "not applicable" score was used again which resulted into a *nominal* data set for the reference standard.

Data management and statistical analysis

All data of each round of evaluation ($N = 3$), all experts ($N = 10$), and the reference standard were collected on an online survey platform (www.SoSciSurvey.com, SoSci Survey GmbH, Munich, Germany). Later, the data was exported into an Excel spreadsheet (Excel 2016, Microsoft, Redmond, WA, USA) and checked for plausibility before analysis. The descriptive and explorative data analysis was performed using Excel and SPSS (SPSS Statistics 27, 2020, IBM corporation, Armonk, NY, USA). With respect to the described process ordinal-scaled data from the 1st and 2nd round of evaluation and nominal-scaled data from the evaluations 3rd round of evaluation and reference standard were analysed. However, this aspect resulted in the need of different statistical methods to handle the data.

The analysis was computed for each criterion and each expert, in relation to posterior and anterior restorations (tooth type) as well as the three evaluation rounds. The descriptive analysis included the calculation of the percentage of agreement for the intra- and inter-examiner reliability among the experts and in relation to the reference standard. For the explorative analysis of the *nominal* data set, Cohen´s Kappa (Cκ) was computed for the intra-examiner reliability and Fleiss´ Kappa (Fκ) for the inter-examiner reliability. Additionally, for the explorative analysis of the observation as *ordinal* data set, linear weighted Kappa (wκ) estimates were computed for the intra-examiner reliability. For the inter-examiner reliability, linear weighted Kappa (wκ) was calculated for all coder pairs using SPSS. To provide an overall value, the arithmetic mean of these estimates was calculated with Excel [13, 14]. The same procedure was applied for the reliability of all examiners in relation to the reference standard. Kappa values within the below-mentioned ranges need to be interpreted as follows: 0.0 to 0.2 — slight agreement, 0.21 to 0.40 — fair agreement, 0.41 to 0.60 — moderate agreement, 0.61 to 0.80 — substantial agreement, and 0.81 to 1.00 — (almost) perfect agreement [15]. Furthermore, modified Bland/Altman plots [16, 17] and binominal logistic regression analysis using a backward elimination model were performed and used for exploring all diagnostic decisions in relation to the reference standard. The analysis was computed with the data from all rounds of evaluation, examiners, categories and tooth type (anterior/posterior).

Results

Tables 1, 2 and 3 give an overview of all percentage agreements and Kappa values of the intra- and inter-examiner reliability in relation to the chosen FDI criteria. The *intra*-examiner reliability was mainly documented as substantial

Table 1 Inter-examiner reliability values for direct tooth-coloured posterior restorations across 10 examiners and in relation to the selected FDI criteria

Posterior restorations		Inter-examiner reliability				Reliability in relation to reference standard	
		Nominal data set (scores 1–5 incl. "not applicable")		Ordinal data set (scores 1–5 only)		Ordinal data set (scores 1–5 only)	
Criteria	Evaluation round	% Agreement	Fleiss Kappa	% Agreement	Weighted Kappa	% Agreement	Weighted Kappa
F1	1	42.2	0.28	44.4	0.48	53,9	0.59
	2	45.7	0.33	50.5	0.54	63,3	0.66
	3	45.2	0.32	49.2	0.53	61.8	0.68
F2	1	48.3	0.36	41.5	0.54	51,6	0.60
	2	45.7	0.33	38.7	0.50	51,0	0.59
	3	46.7	0.34	41.9	0.52	53.3	0.58
F4	1	50.4	0.39	40.2	0.38	51,1	0.47
	2	54.9	0.43	45.3	0.41	56,7	0.53
	3	57.8	0.46	49.0	0.49	60.0	0.59
B1	1	48.2	0.29	50.1	0.54	61,5	0.65
	2	53.3	0.35	55.0	0.58	67,0	0.70
	3	59.9	0.41	66.9	0.64	78.8	0.78
B2	1	48.4	0.26	47.4	0.43	56,8	0.55
	2	50.4	0.28	48.3	0.43	59,6	0.55
	3	57.8	0.34	62.9	0.49	64.2	0.59
A1	1	46.4	0.29	39.8	0.28	56,8	0.44
	2	47.6	0.31	44.8	0.31	58,4	0.48
	3	52.4	0.37	48.3	0.41	65.6	0.58
A2	1	52.0	0.38	41.2	0.37	49,5	0.38
	2	53.1	0.39	42.9	0.32	54,2	0.46
	3	51.8	0.38	40.0	0.34	53.9	0.49
A3	1	55.4	0.34	62.2	0.45	77,0	0.61
	2	56.9	0.37	62.2	0.48	78,0	0.66
	3	51.8	0.28	58.8	0.40	74.4	0.62

Criteria: F1: fracture of material and Retention, F2: marginal adaptation, F4: form and contour, B1: caries at restoration margin (CAR), B2: dental hard tissue defects, A1: surface lustre and texture, A2: marginal staining, A3: colour match

for all criteria in posterior teeth with the highest Kappa values for "colour match/A3" (Cκ 0.71, wκ 0.76), "marginal adaptation/ F2" (Cκ 0.66, wκ 0.75), "fracture of material and retention/F1" (Cκ 0.57, wκ 0.74), and "caries at restoration margin/B1" (Cκ 0.57, wκ 0.73). In anterior restorations, the highest Kappa values were computed for "fracture of material and retention/F1" (Cκ 0.63, wκ 0.76), "marginal adaptation/F2" (Cκ 0.48, wκ 0.61), "caries at restoration margin/B1" (Cκ 0.48, wκ 0.68), and again "marginal staining/A2" (Cκ 0.55, wκ 0.67). The *inter*-examiner reliability was mostly in the moderate range (fair to substantial for posterior restorations and slight to moderate in anterior restorations). For posterior restorations, the highest Kappa values were documented for the criteria "caries at restoration margin/B1" (Fκ 0.41, wκ 0.64), "form and contour/F4" (Fκ 0.46, wκ 0.49), "fracture of material and retention/F1" (Fκ 0.32, wκ 0.53), and "marginal adaptation/F2" (Fκ 0.34, wκ 0.52). In anterior restorations, the highest weighted Kappa values were reached for the criterion "marginal staining/A2" (Fκ 0.41, wκ 0.56), and also "fracture of material and retention/F1" (Fκ 0.42, wκ 0.57), and "caries at restoration margin/B1" (Fκ 0.40, wκ 0.51).

The level of agreement in comparison to the reference standard increased significantly over the three evaluation rounds (Tables 1, 2, and 3), e.g. "caries at restoration margin/B1" (wκ 0.65, 0.70 vs. 0.78) and "fracture of material and retention/F1" (wκ 0.59, 0.66 vs. 0.68) for posterior restorations, and e.g. "marginal staining/A2" (wκ 0.61, 0.64 vs. 0.71), "caries at restoration margin/B1" (wκ 0.58, 0.63 vs. 0.66), and "fracture of material and retention/F1" (wκ 0.52, 0.59 vs. 0.61) for anterior restorations (Tables 2 and 3). For the third evaluation round, the agreement in relation to the

Table 2 Inter-examiner reliability values for direct tooth-coloured anterior restorations across 10 examiners and in relation to the selected FDI criteria

Anterior restorations		Inter-examiner reliability				Reliability in relation to reference standard	
		Nominal data set (scores 1–5 incl. "not applicable")		Ordinal data set (scores 1–5 only)		Ordinal data set (scores 1–5 only)	
Criteria	Evaluation round	% Agreement	Fleiss Kappa	% Agreement	Weighted Kappa	% Agreement	Weighted Kappa
F1	1	53.5	0.34	51.5	0.54	60.5	0.52
	2	62.1	0.41	60.5	0.58	65.2	0.59
	3	61.9	0.42	60.3	0.57	64.8	0.61
F2	1	36.0	0.18	33.8	0.25	44.8	0.39
	2	37.8	0.20	35.6	0.34	45.2	0.46
	3	43.2	0.27	42.0	0.44	51.0	0.55
F4	1	46.7	0.33	36.0	0.34	48.5	0.45
	2	54.8	0.42	45.8	0.40	62.0	0.55
	3	54.9	0.40	45.9	0.33	60.5	0.55
B1	1	62.0	0.36	60.2	0.43	71.4	0.58
	2	65.3	0.42	65.8	0.51	72.6	0.63
	3	65.7	0.40	60.4	0.51	71.8	0.66
B2	1	59.9	0.32	57.5	0.19	68.6	0.34
	2	60.6	0.32	59.0	0.26	72.9	0.43
	3	69.0	0.38	69.1	0.25	77.5	0.47
A1	1	44.3	0.24	39.2	0.26	45.0	0.32
	2	50.6	0.32	46.3	0.38	49.0	0.37
	3	54.4	0.35	50.8	0.35	65.5	0.54
A2	1	53.5	0.39	49.3	0.55	56.8	0.61
	2	52.8	0.37	49.5	0.53	61.0	0.64
	3	55.9	0.41	53.6	0.56	68.5	0.71
A3	1	45.6	0.24	40.7	0.24	54.5	0.34
	2	46.9	0.28	42.4	0.30	56.2	0.40
	3	56.0	0.36	52.0	0.34	66.5	0.50

Criteria: F1: fracture of material and Retention, F2: marginal adaptation, F4: form and contour, B1: caries at restoration margin (CAR), B2: dental hard tissue defects, A1: surface lustre and texture, A2: marginal staining, A3: colour match

reference standard is illustrated in Figs. 1 and 2; deviations from the reference standard were mostly observed in the range of one score only.

The reliability data were further explored by using binominal logistic regression models. In a first attempt data from all evaluation rounds, examiners, categories, and tooth type (anterior/posterior) were analysed. At this step, significant differences between the evaluation rounds became obvious. In detail, it was shown that the reliability increased steadily with each evaluation round (1st round: adjusted odds ratio (aOR) = 1.0; 2nd round aOR = 1.15 with a 95% confidence interval 1.04–1.27; 3rd round: aOR = 1.43 with a 95% CI 1.29–1.58); the difference between each round was statistically significant: 1st vs 2nd round: 0.005/ 2nd vs 3rd round: < 0.001. Therefore, it was decided to include only data from the third evaluation round in the final binominal logistic regression analysis which are shown in Table 4. When considering the rating ability of the examiners in relation to the reference standard, examiner 5 scored closer to the consensus decision in comparison to others, e.g. examiner 8, 9 and 10. Significant differences were also observed between the categories "caries at restoration margin/B1" and "dental hard tissue defects at restoration margin/B2" which were scored with a higher reliability compared to "marginal adaptation/F2."

Discussion

This reliability study supported the recently initiated revision of the FDI criteria set for the evaluation of direct and indirect dental restorations [12]. The reliability tests were

Table 3 Intra-examiner reliability values for direct tooth-coloured posterior and anterior restorations across 10 examiners in relation to the selected FDI criteria

Intra-examiner reliability		Posterior restorations				Anterior restorations			
		Nominal data set (scores 1–5 incl. "not applicable")		Ordinal data set (scores 1–5 only)		Nominal data set (scores 1–5 incl. "not applicable")		Ordinal data set (scores 1–5 only)	
Criteria	Evaluation round	% Agreement	Cohen Kappa	% Agreement	Weighted Kappa	% Agreement	Cohen Kappa	% Agreement	Weighted Kappa
F1	1 vs. 2	66.4	0.57	67.5	0.74	74.2	0.63	73.3	0.76
	2 vs. 3	58.4	0.48	59.7	0.66	70.0	0.54	69.3	0.68
F2	1 vs. 2	73.2	0.66	72.8	0.75	62.5	0.49	62.2	0.60
	2 vs. 3	67.2	0.59	67.2	0.72	61.7	0.48	62.0	0.61
F4	1 vs. 2	72.8	0.65	67.5	0.67	69.2	0.60	63.0	0.60
	2 vs. 3	70.0	0.61	64.3	0.62	66.7	0.56	60.0	0.56
B1	1 vs. 2	62.4	0.47	63.3	0.66	72.1	0.49	71.3	0.63
	2 vs. 3	70.4	0.57	72.5	0.73	73.3	0.48	72.8	0.68
B2	1 vs. 2	69.2	0.51	68.6	0.65	75	0.54	74.9	0.51
	2 vs. 3	68.4	0.51	68.9	0.64	75.8	0.57	75.8	0.47
A1	1 vs. 2	71.6	0.61	68.4	0.63	59.6	0.44	56.1	0.47
	2 vs. 3	66.8	0.56	62.7	0.59	67.5	0.54	65.3	0.59
A2	1 vs. 2	70.8	0.61	64.2	0.60	68.3	0.57	66.1	0.57
	2 vs. 3	70.8	0.61	64.9	0.61	56.8	0.55	64.2	0.67
A3	1 vs. 2	80.8	0.71	80.2	0.76	63.3	0.47	60.3	0.50
	2 vs. 3	76.1	0.64	77.4	0.70	67.9	0.54	65.4	0.58

Criteria: F1: fracture of material and Retention, F2: marginal adaptation, F4: form and contour, B1: caries at restoration margin (CAR), B2: dental hard tissue defects, A1: surface lustre and texture, A2: marginal staining, A3: colour match

carried out together with the revision of the FDI criteria set. The statistical data of the reliability test contributed to several modifications and corroborated the expert´s consensus. It was shown that (1) the intra- and inter-examiner reliability increased over the three evaluation rounds and ranged from a moderate to substantial order of magnitude and (2) Kappa estimates were found to be higher for the functional and biological categories compared to the aesthetic categories (Tables 1, 2, 3, and 4; Figs. 1 and 2).

The results were mostly better or approximately the same compared to reliability tests that were done earlier [10, 18, 19]. The agreement rate increased significantly over the three evaluation rounds. Along with the whole revision process the reliability test contributed to the improved structuring of the criteria set by reducing ambiguous allocations and scoring. It has to be pointed out that the inclusion of principle instructions for use, additional comments, and the score "not applicable" increased a more straightforward decision, especially for complex clinical situations. This might have been the major reason for the significant improvement of the overall reliability after the second evaluation round.

The reliability varied among examiners, categories, and tooth type (anterior/posterior) (Table 4). The highest weighted Kappa values in relation to the reference standard (Tables 1, 2, and 3) were registered for "caries at restoration margin," "fracture of material and retention," "marginal adaptation," and "dental hard tissue defects at restoration margin." The adjusted odds ratio values indicated that the biological criteria "caries at restoration margin" and "dental hard tissue defects at restoration margins" had the best agreement in relation to the reference standard. A significantly lower agreement rate was found for the criterion "marginal adaptation." The aesthetic criteria — "surface lustre and texture," "marginal staining," and "colour match" — as well as the functional criteria "form and contour" showed only a moderate level of agreement (Table 4) which indicates that the assessment of the aesthetical properties of a restoration is somehow subjective and the individual perception of aesthetics by the examiner influences the scoring [10, 20, 21]. This finding is in line with published data by Almeida et al. [19]. The intra- and inter-examiner reliability was lower in posterior teeth compared to the results of anterior teeth. This might be explained by the fact, that the restorations in posterior teeth showed more complex clinical situations with a broad variety of deficiencies. With respect to the documented variations between the examiners it must be emphasized that especially researchers need to be theoretically and practically trained in the proper application of the criteria. Future studies which include the updated FDI criteria should integrate a calibration training [5, 6].

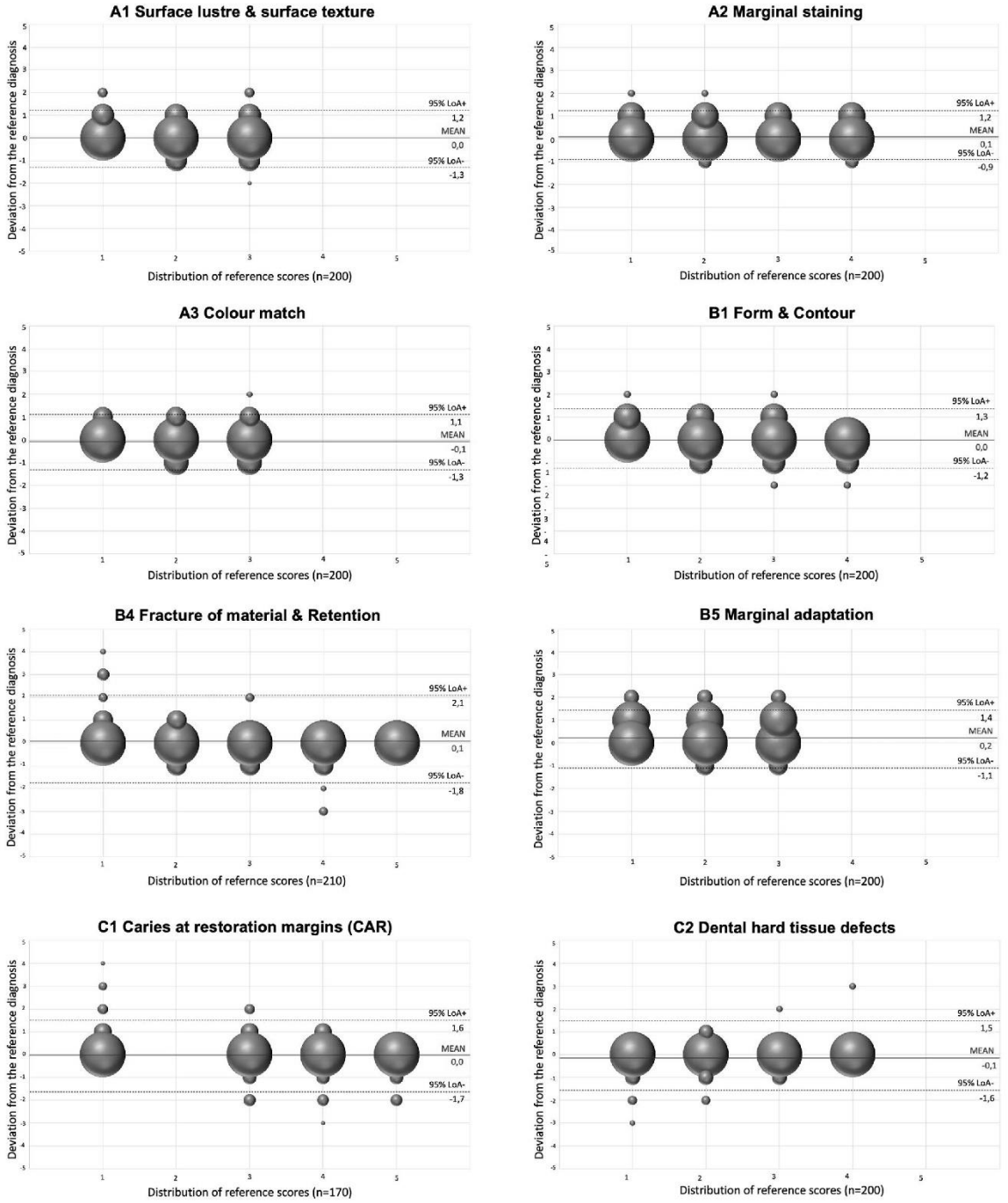

Fig. 1 The modified Bland/Altman plots illustrate the agreement in relation to the reference standard for all examiners in the third evaluation round for *posterior teeth*. The size of the bubble correlates with the number of decisions. Ideally, all decision should be located on the Z-line and indicate a perfect agreement

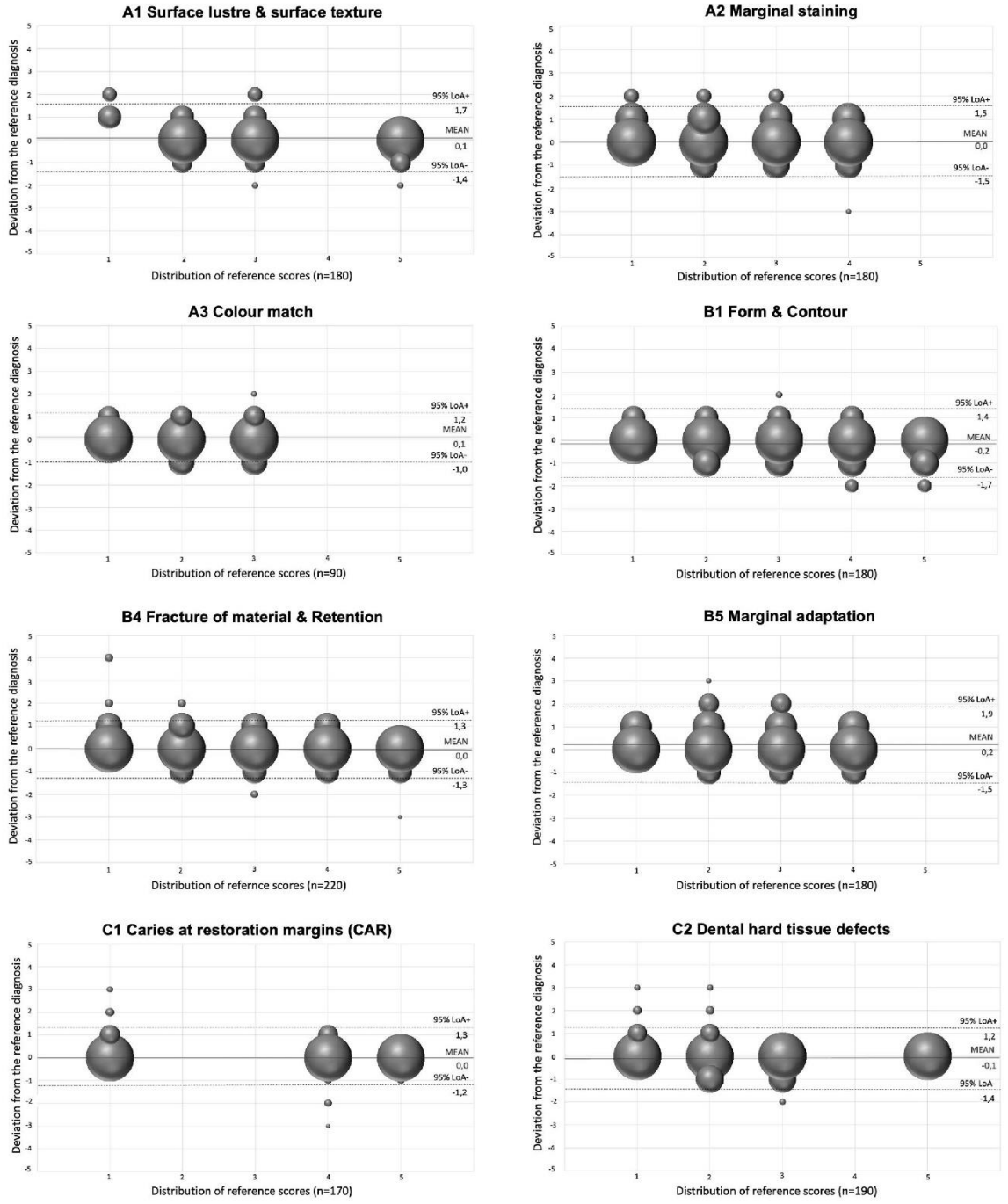

Fig. 2 The modified Bland/Altman plots illustrating the agreement against the reference standard for all examiners in the third evaluation round for *anterior teeth*. The size of the bubble correlates with the number of decisions. Ideally, all decision should be located on the Z-line and indicate a perfect agreement

Table 4 Adjusted odds ratio (aOR) with the corresponding 95% confidence intervals (CI) and *p*-values were computed according to the binominal logistic regression model using backward elimination in relation to the reference standard for the third evaluation round. aOR values lower/higher than 1 indicate a lower/higher agreement in comparison to the diagnostic reference standard and the chosen reference variable (*). Bold numbers highlight a statistically significant influence

Co-variables	Group	aOR	95% CI	*p*-value
Examiner	1*	1	-	-
	2	0.92	0.66–1.27	0.605
	3	0.73	0.53–1.01	0.057
	4	0.87	0.63–1.21	0.395
	5	**1.59**	**1.12–2.25**	**0.010**
	6	0.77	0.56–1.06	0.107
	7	0.73	0.53–1.00	0.050
	8	**0.60**	**0.43–0.83**	**0.002**
	9	**0.68**	**0.50–0.94**	**0.019**
	10	**0.45**	**0.33–0.62**	**< 0.001**
Category	F1*	1	-	-
	F2	**0.67**	**0.51–0.87**	**0.003**
	F4	0.89	0.68–1.18	0.419
	B1	**1.81**	**1.36–2.42**	**< 0.001**
	B2	**1.34**	**1.01–1.77**	**0.039**
	A1	1.13	0.86–1.49	0.393
	A2	0.95	0.72–1.25	0.695
	A3	1.22	0.91–1.65	0.185
Tooth type	Anterior*	1	-	-
	Posterior	**0.85**	**0.73–0.98**	**0.023**

This study has some potential strengths and limitations which need to be discussed. One strength worthwhile mentioning is that the selection of images covered a broad spectrum of clinical conditions throughout all domains of the revised criteria set which is difficult to cover in a clinical study set-up. The ten experts and their commitment to improve the criteria is another important feature of this study. The broad experience and expertise of the expert panel was beneficial to the revision of the criteria set. It needs to be noted that the criteria and scoring were constantly improved, so that eventually, mainly outliers of only one score were recorded (Figs. 1 and 2). A weakness, of the study was that the restorations were not evaluated clinically but by means of intraoral photographs. The visual-tactile clinical evaluation of a restoration with a probe and other instruments, e.g. proximal blades and articulation paper, may lead to a more objective scoring. Furthermore, the inspection of the restored tooth from different angles and perspectives enhances the clinical evaluation which is not possible when intraoral photographs were the only evaluation tool [19]. The latter aspect is especially relevant for those criteria which are not scorable on intraoral images, e.g. "occlusion and wear," "proximal contact point," and "postoperative hypersensitivity/pulp status." Consequently, these criteria were not included in the reliability study. Also, the evaluation of aesthetic properties on photographs might be different compared to the clinical evaluation and may influence the assessment of surface lustre, surface texture, and colour [18, 19, 22]. Nevertheless, intraoral photographs seem to be useful tool for the evaluation of dental restorations [18, 22, 23].

Another weakness is the low sample size of 49 photographs and the focus on tooth-coloured restorations only. The inclusion of more images and restoration materials would have increased the validity of the study but would also have involved more work for the experts as well as extended evaluation sessions. Therefore, it was decided to limit the sample size but increase the number of more difficult cases to represent a broad spectrum of restoration deficiencies. In this context, it has to be pointed out that a rigorous testing would include two examinations per each evaluation round to better determine the intra- and inter-examiner reliability. The requirement of a second examination was not met due to the time resources of the experts. Furthermore, it has to be mentioned that there was an unbalanced distribution of restoration deficiencies across the selected clinical cases which resulted in a higher number of sufficient scores in a few categories. This may have influenced the Kappa values which justified the inclusion of the percental agreement, modified Bland/Altman plots, and the binominal logistic regression model using backward elimination. The consistent and complete reporting of these statistical data should be assessed as valuable and may improve the comparability between previous and future studies.

Conclusions

The overall reliability of the revised FDI criteria set for the evaluation of direct and indirect dental restorations was steadily increased up to the final version. However, significant differences were documented for some of the examiners, categories, and tooth type. Training and calibration are required to ensure reliable application of the evaluation criteria.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00784-022-04771-9.

Author contribution Conceptualization and project administration: SM, RH, and JK; study design: JK, SM, and RH; investigations: SM, RF, MC, JB, AP, SH, BL, NO, RH, and JK; data management and statistical analysis: SM, KH, and AC; writing — original draft preparation: SM and JK; writing — review and editing: all authors. All authors have read and agreed to the published version of the manuscript.

Funding Open Access funding enabled and organized by Projekt DEAL.

Declarations

Competing interests The authors declare no competing interests.

Ethical approval The study project was approved by the local Ethics Committee at the medical Faculty of the LMU (Project No. 19–185).

Informed consent For this type of study, formal consent is not required.

Conflict of interest The authors declare no competing interests.

References

1. Cvar JF (1971) Ryge G (2005) Reprint of criteria for the clinical evaluation of dental restorative materials. Clin Oral Investig 9(4):215–32. https://doi.org/10.1007/s00784-005-0018-z
2. Bayne S, Schmalz G (2005) Reprinting the classic article on USPHS evaluation methods for measuring the clinical research performance of restorative materials. Clin Oral Investig 9:109–214
3. Ryge G (1980) Clinical criteria. Int Dent J 30(4):347–358
4. Marquillier T, Domejean S, Le Clerc J, Chemla F, Gritsch K, Maurin JC, Millet P, Perard M, Grosgogeat B, Dursun E (2018) The use of FDI criteria in clinical trials on direct dental restorations: a scoping review. J Dent 68:1–9. https://doi.org/10.1016/j.jdent.2017.10.007
5. Hickel R, Roulet JF, Bayne S, Heintze SD, Mjor IA, Peters M, Rousson V, Randall R, Schmalz G, Tyas M, Vanherle G (2007) Recommendations for conducting controlled clinical studies of dental restorative materials. Science Committee Project 2/98--FDI World Dental Federation study design (Part I) and criteria for evaluation (Part II) of direct and indirect restorations including onlays and partial crowns. J Adhes Dent 9(Suppl 1):121–147
6. Hickel R, Roulet JF, Bayne S, Heintze SD, Mjor IA, Peters M, Rousson V, Randall R, Schmalz G, Tyas M, Vanherle G (2007) Recommendations for conducting controlled clinical studies of dental restorative materials. Clin Oral Investig 11(1):5–33. https://doi.org/10.1007/s00784-006-0095-7
7. Hickel R, Peschke A, Tyas M, Mjor I, Bayne S, Peters M, Hiller KA, Randall R, Vanherle G, Heintze SD (2010) FDI World Dental Federation — clinical criteria for the evaluation of direct and indirect restorations Update and clinical examples. J Adhes Dent 12(4):259–72. https://doi.org/10.3290/j.jad.a19262
8. Hickel R, Peschke A, Tyas M, Mjor I, Bayne S, Peters M, Hiller KA, Randall R, Vanherle G, Heintze SD (2010) FDI World Dental Federation: clinical criteria for the evaluation of direct and indirect restorations-update and clinical examples. Clin Oral Investig 14(4):349–366. https://doi.org/10.1007/s00784-010-0432
9. Perdigao J, Kose C, Mena-Serrano AP, De Paula EA, Tay LY, Reis A, Loguercio AD (2014) A new universal simplified adhesive: 18-month clinical evaluation. Oper Dent 39(2):113–127. https://doi.org/10.2341/13-045-c
10. Kim D, Ahn SY, Kim J, Park SH (2017) Interrater and intrarater reliability of FDI criteria applied to photographs of posterior tooth-coloured restorations. J Prosthet Dent 118(1):18-25.e4. https://doi.org/10.1016/j.prosdent.2016.10.004
11. Kottner J, Gajewski BJ, Streiner DL (2011) Guidelines for Reporting Reliability and Agreement Studies (GRRAS). Int J Nurs Stud 48(6):659–60. https://doi.org/10.1016/j.ijnurstu.2011.01.017
12. Hickel R, Mesinger S, Opdam N, Loomans B, Frankenberger R, Cadenaro M, Burgess J, Peschke A, Heintze SD, Kühnisch J (2022) Revised FDI criteria for evaluating direct and indirect dental restorations — recommendations for its clinical use, interpretation and reporting. Clin Oral Investig (Submitted for publication)
13. Light RJ (1971) Measures of response agreement for qualitative data: some generalizations and alternatives. Psychol Bull 76(5):365–377. https://doi.org/10.1037/h0031643
14. Hallgreen KA (2012) Computing inter-rater reliability for observational data: an overview and tutorial. Tutor Quant Methods Psychol 8(1):23–34. https://doi.org/10.20982/tqmp.08.1.p023
15. Landis JR, Koch GG (1977) The measurement of observer agreement for categorical data. Biometrics 33(1):159–174. https://doi.org/10.2307/2529310
16. Bland JM, Altman DG (1986) Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1(8476):307–310
17. Bland JM, Altman DG (1990) A note on the use of the intraclass correlation coefficient in the evaluation of agreement between two methods of measurement. Comput Biol Med 20(5):337–340. https://doi.org/10.1016/0010-4825(90)90013-f
18. Signori C, Collares K, Cumerlato CBF, Correa MB, Opdam NJM, Cenci MS (2018) Validation of assessment of intraoral digital photography for evaluation of dental restorations in clinical research. J Dent 71:54–60. https://doi.org/10.1016/j.jdent.2018.02.001
19. de Almeida Cvvb, Pintado-Palomino K, Fortes JHP, da Motta RJG, de Freitas BN, Matsumoto W, de Oliveira Cavalcanti MTM, Alves J, Tirapelli C (2020) Digital photography vs. clinical assessment of resin composite restorations. Odontology https://doi.org/10.1007/s10266-020-00511-1
20. Blatz MB, Chiche G, Bahat O, Roblee R, Coachman C, Heymann HO (2019) Evolution of aesthetic dentistry. J Dent Res 98(12):1294–1304. https://doi.org/10.1177/0022034519875450
21. Paravina RD, Pérez MM, Ghinea R (2019) Acceptability and perceptibility thresholds in dentistry: a comprehensive review of clinical and research applications. J Esthet Restor Dent 31(2):103–112. https://doi.org/10.1111/jerd.12465
22. Moncada G, Silva F, Angel P, Oliveira OB Jr, Fresno MC, Cisternas P, Fernandez E, Estay J, Martin J (2014) Evaluation of dental restorations: a comparative study between clinical and digital photographic assessments. Oper Dent 39(2):E45-56. https://doi.org/10.2341/12-339-c
23. Erten H, Uçtasli MB, Akarslan ZZ, Uzun O, Semiz M (2006) Restorative treatment decision making with unaided visual examination, intraoral camera and operating microscope. Oper Dent 31(1):55–59. https://doi.org/10.2341/04-173

9. Veröffentlichung II

Clinical Oral Investigations
https://doi.org/10.1007/s00784-022-04814-1

RESEARCH

Revised FDI criteria for evaluating direct and indirect dental restorations—recommendations for its clinical use, interpretation, and reporting

Reinhard Hickel[1] · Sabine Mesinger[1] · Niek Opdam[2] · Bas Loomans[2] · Roland Frankenberger[3] · Milena Cadenaro[4] · John Burgess[5] · Arnd Peschke[6] · Siegward D. Heintze[6] · Jan Kühnisch[1]

Received: 1 August 2022 / Accepted: 27 November 2022

Abstract

Objectives The FDI criteria for the evaluation of direct and indirect dental restorations were first published in 2007 and updated in 2010. Meanwhile, their scientific use increased steadily, but several questions from users justified some clarification and improvement of the living document.

Materials and methods An expert panel ($N = 10$) initiated the revision and consensus process that included a kick-off workshop and multiple online meetings by using the Delphi method. During and after each round of discussion, all opinions were collected, and the aggregated summary was presented to the experts aiming to adjust the wording of the criteria as precisely as possible. Finally, the expert panel agreed on the revision.

Results Some categories were redefined, ambiguities were cleared, and the descriptions of all scores were harmonized to cross-link different clinical situations with possible management strategies: reviewing/monitoring (score 1–4), refurbishment/reseal (score 3), repair (score 4), and replacement (score 5). Functional properties (domain F: fracture of material and retention, marginal adaptation, proximal contact, form and contour, occlusion and wear) were now placed at the beginning followed by biological (domain B: caries at restoration margin, hard tissue defects, postoperative hypersensitivity) and aesthetic characteristics (domain A: surface luster and texture, marginal staining, color match).

Conclusion The most frequently used eleven categories of the FDI criteria set were revised for better understanding and handling.

Clinical relevance The improved description and structuring of the criteria may help to standardize the evaluation of direct and indirect restorations and may enhance their acceptance by researchers, teachers, and dental practitioners.

Keywords Dental restoration · Dental filling · Crown · Clinical assessment · Failure · Wear · Repair · Calibration

✉ Reinhard Hickel
hickel@dent.med.uni-muenchen.de

[1] Department of Conservative Dentistry and Periodontology, University Hospital, Ludwig-Maximilians-University of Munich, Munich, Germany

[2] Department of Dentistry, Radboud Institute for Health Sciences, Radboud University Medical Center, Nijmegen, The Netherlands

[3] Department of Operative Dentistry, Endodontics, and Pediatric Dentistry Medical Center for Dentistry, University Medical Center Giessen and Marburg, Campus Marburg, Marburg, Germany

[4] Department of Medical Sciences, University of Trieste, Trieste, Italy and Children's Hospital "Burlo Garofolo," Institute for Maternal and Child Health, Trieste, Italy

[5] Louisiana State University Health Sciences Center, New Orleans, LA, USA

[6] IvoclarVivadent AG, Research & Development, Schaan, Liechtenstein

Published online: 12 December 2022

Introduction

In 2007, an international workgroup published new FDI criteria [1–5] to evaluate the quality of direct and indirect restorations; an update with clinical cases was published in 2010. This diagnostic system classified aesthetic, functional, and biological properties and covers various types of failures (Table 1) by using 16 different categories [4, 5] with five grades for each criterion. In detail, scores 1 to 3 indicated clinically acceptable restorations, and scores 4 and 5 summarized clinically unacceptable situations indicating repair (score 4) or replacement (score 5). The criteria were approved by the Science Committee of the FDI World Dental Federation (FDI) in 2007 and the General Assembly in 2008 as standard criteria that were specially designed for use in clinical studies [1–5]. The authors outlined the potential of the criteria to be applied 1) in evaluations of new restorative materials or operative techniques in clinical trials, 2) for quality assessment of dental restorations in daily dental practice (mainly in simplified form), and 3) under- and postgraduate education to determine whether a restoration needs reviewing, refurbishment, reseal, repair, or replacement [6] (Table 2). A recently published review [7] indicated a growing use of the FDI criteria in clinical trials, which increased from 4.5% in 2010 to 50.0% in 2016. In addition to this positive trend, it needs to be recognized that the criteria set was also assessed as complex with a lack of consistency in some parts [7] and several questions from users indicated the need for clarification. Aiming at increasing internal validity and promoting widespread dissemination for scientific, practical, and educational purposes, the expert group decided to review and revise the previously published FDI criteria set to improve the clinical usability, practicability, and acceptability. Beside the clarification of ambiguous issues, it was aimed to specify the recommendations for its interpretation and reporting.

Materials and methods

The existing FDI criteria [4, 5] have been improved by using a structured process to obtain information from a group of experts by means of a series of meetings and/or evaluations. This process with multiple rounds of feedback, open discussion, and rephrasing was iteratively continued until no further changes in the documents were needed [8]. A group consensus process is crucial in building guidance recommendations [9, 10]. In detail, the present information flow included a systematic search of the literature, a kick-off workshop under the participation of all experts as well as a structured communication flow aiming to converge existing opinions, and, finally, to reach a unanimous group consensus about the revised clinical criteria for the evaluation of direct and indirect dental restorations.

Expert panel

Ten experts in conservative and restorative dentistry agreed to participate, discuss, revise, and rephrase the criteria in spring 2019. Three of those (RH, SH, and AP) were also part of the original expert team. As several colleagues from previous projects [4, 5] were not available anymore due to different reasons, the work group was re-formed aiming at including experts from restorative dentistry of different regions.

J. Kühnisch and S. Mesinger coordinated the Delphi method as facilitators and collected all responses from the experts from the beginning, analyzed the opinions, structured the information, identified conflicting viewpoints; furthermore, they revised all documents accordingly. R. Hickel acted as a moderator during the workshops, online meetings, and discussions; furthermore, he provided numerous questions, comments, and suggestions by scientists, which he collected after the initial publications. Participants were forced to freely and consistently express their opinions and were encouraged to provide criticism or feedback and to detect errors or conflicting viewpoints. Although a consensus process captures collective knowledge, it should be noted that such criteria set may be, to some degree, a subjective viewpoint of the expert group [11].

Delphi method

The Delphi process was initiated with a group workshop at the Department of Conservative Dentistry and Periodontology

Table 1 Common material-dependent failures

Dental material	Common defects and failure patterns
(Resin modified) Glass ionomer cements	Cracks, chipping, bulk fracture, complete loose or lost restoration, or excessive wear
Composite and others	Cracks, chipping, bulk fracture, loose restoration (debonding), or complete loss of the restoration
Porcelain fused to metal	Chipping or delamination of the veneering layer, loose restoration (decementation/debonding), or complete loss of the restoration
All ceramic	Cracks, chipping, bulk fracture, loose restoration (decementation/debonding), or complete loss of the restoration
(Non)precious dental alloys	Perforation, loose restoration (decementation), or complete loss of the restoration
Amalgam	Cracks, creep, bulk fracture, or loose restoration or complete loss of the restoration

Table 2 Terminology and definitions and description of commonly used terms

Term		Definition
Methodology	Minor/slight	The terms "minor" and "slight" indicate a small difference in comparison to an excellent restoration. Differences are detectable by visual means or with additional procedures, e.g., short air drying or gentle probing. It represents a fully sufficient clinical situation, which does not need any further intervention
	Distinct	The term "distinct" indicates a clinically relevant difference in comparison to an excellent or good restoration. Otherwise, the clinical situation is basically acceptable and sufficient. Intervention by refurbishment potentially improves functionality or aesthetics
	Severe	The term "severe" indicates a substantial deviation in comparison to a sufficient restoration and characterizes a serious clinical condition which most likely requires operative intervention by repair or replacement
	Localized	Minor parts: less than half of the restoration (margin) is affected
	Generalized	Major parts: more than half of the restoration (margin) is affected
	Speaking distance	Typically ~ 80–100 cm/ ~ 3 ft. Dental operation light is switched off
	Examination distance	Typically ~ 40 cm/ ~ 1–1½ ft. The patient is placed on a dental chair, and the oral cavity is professionally illuminated. Tooth cleaning and short air drying of the teeth and restorations improve visual examination
	Tooth cleaning and air drying	A good examination of dental restorations requires the removal of the dental biofilm and tooth drying with compressed air for a few seconds until all saliva is removed. Avoid over drying!
	Visual examination	Visual examination without any magnification is the standard procedure for the evaluation of dental restorations. In case that magnifying loups or microscopes are used it needs to be reported. Acuity of operators and examiners should be regularly checked
Restorations defects	(Marginal) gap	Defective interface between the dental hard tissue and the restoration material, which is leaving parts of the restoration margin clinically exposed. A wide range of width and depth is possible. Optimally, there is a smooth transition between the dental hard tissue and the restorative material
	Negative/positive step	Steps are differences in height between the dental hard tissue and the restorative material. A step is formed due to under-contour (negative step) or over-contour of the restoration at the restoration margin (positive step). Different dimensions are possible
	Enamel and dentin cracks/cracked dental hard tissue	Crack lines in enamel/dental hard tissue are commonly detectable in (un)restored teeth and mostly represent no pathology. Nontraumatic tooth cracks have a wide clinical spectrum and reach from small enamel breakdowns to complete tooth fractures. If such a clinical situation directly involves a restoration or its margin it will be considered in the category "Dental hard tissue defect at restoration margin (B2)". Traumatic dental injuries have to be separated from this entity
	Material crack	Crack lines within the restoration material may indicate that restoration could not withstand occlusal forces and might be interpreted as an initial material fracture
	Fracture	There is a huge spectrum, which reaches from small defects (chipping fractures) to a substantial loss of material (bulk fractures). Typically, a residual restoration material is present and cavity walls are exposed
	Bulk fracture	Fracture within the body of the restoration mostly perpendicular to the occlusal surface
	Chipping/Chip fracture	A chipping is a minor or major cohesive fracture of tooth-coloured restoration material or an indirect restoration with a veneered framework mostly parallel to the occlusal surface. In most cases the overall functionality of the restoration is not affected and the chipped area can be polished or repaired
	Delamination	Partial or complete adhesive failure of the veneering material of an indirect restoration
	Decementation	Loose or lost conventionally cemented indirect restoration. Typically, loose/lost but proper indirect restorations can be recemented/reluted
	Debonding	Loose or lost adhesively bonded direct or indirect restoration. Typically, loose/lost direct restorations have to be replaced. Loose/lost but proper indirect restorations can be recemented/reluted (= repair)
	Loss of retention	A restoration can be fully retained, partially retained or lost. Furthermore, each type of restoration can be adapted to the dental hard tissue (full retention) or decemented/debonded (loss of retention). Loose or lost, but properindirect restorations can be recemented/reluted. Loose or lost direct restorations have to be replaced
	Caries at restoration margin (CAR)	CAR is located directly at the restoration margin without sound tooth structure in between. CAR can reach from a non-cavitated carious lesion to large cavities. It represents a new carious process at the restoration margin. Demineralisations can be left at cavity margins during restoration placement as part of a minimal invasive intervention strategy

Table 2 (continued)

Term		Definition
Intervention/management strategies	5R	The "5 Rs" include reviewing/monitoring, refurbishment, resealing, repair, and replacement of deteriorating or failed restorations [6]
	Reviewing	Regular monitoring in risk-related and individualized intervals
	Refurbishment	Refurbishment is a minimal invasive, subtractive intervention, which includes contouring of the form and/or margins as well as polishing of the restoration`s surfaces to reduce biofilm accumulation. No new adhesive, sealant, or filling material will be added
	Reseal	Reseal/sealing is a noninvasive, additive technique, which includes the direct application of an adhesive or sealant on gaps or defects without cavity preparation. Typically, superficial localized marginal gaps can be sealed
	Repair	Repair is a minimal invasive, additive technique that involves the direct application of restorative material after minor cavity preparation or roughening/conditioning of remaining surfaces (artificial/biological surfaces) and preservation of sufficient parts of the existing restoration. Typically, localized defects with clinical access can be repaired, e.g. chipping, minor bulk or cusp fractures or CAR
	Replacement	Replacement is required if the restoration defects are so extensive that a repair is not reasonable. This procedure requires the removal of the existing material, cavity/tooth preparation and the application of a new direct or indirect restoration

in Munich, Germany, on June 3–4, 2019. During this face-to-face meeting, the existing scientific literature was presented and critically discussed, and empirical experiences of the existing scoring criteria for direct and indirect dental restorations were reviewed. In addition, a preliminary draft of a revised FDI criteria set was proposed based on the latest version [4, 5]. As a result of the workshop, the need and methodology for improvement were justified and agreed upon. After the meeting, the initially revised FDI criteria set was distributed, evaluated, and consistently updated. The following group discussion was held during an online meeting on September 16, 2019. The main intention of this meeting was to agree on the simplified structure and the importance of each category. This process continued until spring 2020, and the resulting criteria set was then pre-tested by the expert panel in a reproducibility study using intraoral photographs of different restorations with a broad spectrum of deficiencies. This study was performed in two rounds from May to July 2020. Feedback from the experts and statistical analyses of the intra- and inter-examiner reproducibility were compiled and discussed during other online meetings (July 21, 2020 and September 21, 2020). Further, where some inconsistencies or ambiguities were remarked, minor modifications were made to the FDI criteria set to harmonize the scores in each category. Diagnostic evaluations were repeated in a third round using the above set of clinical images. The final version of the revised FDI criteria was reviewed again by the whole expert panel and unanimously agreed on during another web meeting on November 9, 2020. The results of the reliability study were summarized in a separate report [12].

General considerations for clinical studies on dental restorations

In restorative dentistry, it is mainly evaluated how the material or restoration responds to the oral cavity of the patient with factors that may influence the success of the restoration, such as chewing forces, bruxism, diet, saliva, and the oral biofilm. Therefore, there are many confounders like patient factors, e.g., age, gender, tooth substance, chewing forces, oral hygiene, chewing tobacco, diet, general diseases, and local biological factors, e.g., location in the mouth, caries risk and periodontitis risk, and operator factors, e.g., clinical experience, decision making, and skills, which all influence the clinical performance of a dental restoration.

Study type and design

Several study types require a quality assessment of dental restorations. Here, clinical studies on new materials have to be mentioned primarily, which typically need a comprehensive restoration assessment after placement, during follow-ups, and at the final examination visit. Three- and 5-year follow-ups are at least advised for direct and indirect restorations, respectively. Longer observation periods are recommended especially when a new type of treatment or material is to be evaluated. For an observation period of 3 years, up to five recall sessions might be helpful. Ideally, the baseline evaluation should be carried out approximately 1 week after the insertion of the restoration and not during the placement appointment. If this procedure is not

possible, the assessment by different dentists in the same appointment and an audio call interview 1 week later would be an acceptable compromise. Aiming to increase trial efficiency, baseline evaluation might also be performed after tooth rehydration approximately 30–60 min postoperatively and by checking the functionality no later than 4 weeks. The remaining recalls can be scheduled after (6), 12, 24, and 36 months. For longer observation periods, (bi)annual recalls might be preferable.

Furthermore, the quality of restorations could be evaluated in practice-based, epidemiological, observational, or diagnostic studies. In daily practice routines, practitioners are consistently forced to evaluate different aspects of restored teeth, which should be done with a validated and widely accepted set of criteria. When considering the whole spectrum of study types, it is understandable that the choice of categories and grades depends on each study's intended purpose and methodological requirements. For clinical trials, the preferable examination setting is a dental unit with compressed air and standard illumination. Additional magnification tools, e.g., magnifying loupes, or documentation methods, e.g., intraoral photographs or 3D scans, may accompany visual examination. For practice-based studies, a simplified methodology might be more relevant. However, reporting of all chosen procedures is essential to better compare studies and interpret the results adequately.

Study population

It is recommended that clinical studies be conducted on the intended target population according to predefined and rigorously applied patient- and tooth-based inclusion and exclusion criteria, e.g., age range, gender, ethnicity, caries experience/risk or activity (high vs. low), parafunction or bruxism (present or not present), temporomandibular disorders (TMDs), oral hygiene (good, moderate, bad), smoking/vaping habits (no, moderate, heavy), or diet habits, e.g., coffee, tea, soft drinks, acidic foods, and beverages. Other habits of patients, such as frequent use of chewing tobacco or bubble gum, or parafunctions such as nail and/or thumb chewing, may also potentially influence the longevity of restorations and therefore need to be reported and re-evaluated with respect to the inclusion and exclusion criteria on each follow-up examination.

In addition to patient-related factors, it is essential to consider tooth-related variables. Here, the type of dentition (primary, mixed, permanent), tooth type (anterior, premolar, molar), quadrant, and affected surfaces are relevant. Furthermore, Black's cavity class, the location of the cavity margin in relation to the gingiva (supra-, equi-, subgingival), and the hard tissues involved (enamel vs. dentin), the caries excavation technique and endpoint (selective vs. complete caries removal), as well as the type of antagonist teeth (unrestored vs. restored tooth, restoration material, not present) may be clinically relevant. Importantly, the indication to (re)place a restoration should be justified strictly according to common dental pathologies: 1) primary caries (proximal, occlusal, cervical, root, early childhood caries), 2) non-carious hard tissue defects, e.g., erosive tooth wear, abrasion, fractures/cracks or trauma, 3) dental developmental disorders, e.g., molar-incisor-hypomineralization or hereditary disorders of enamel/dentin, and/or 4) other specific situations, e.g., restorations to improve aesthetics due to discoloration or diastemas. The pooling of restorations with different characteristics in one clinical study, e.g., classes I and II, anterior and posterior teeth, or carious indications, e.g., caries and developmental disorders, should no longer be an accepted procedure. The flow of screened, eligible, and finally recruited patients/restorations should be described and illustrated as a flow chart according to the relevant reporting guideline for each study type, e.g., the CONSORT statement for randomized controlled trials [13, 14]. Beside this, patient's motivation to adhere to the study protocol should to be safeguarded. Here, information cards might be helpful to provide data for the patient and dental professionals.

Evaluation of dental restorations

The quality assessment of dental restorations is a stepwise decision-making process that includes, if needed, the following procedures: 1) professional tooth cleaning and short air drying of the restored tooth for a few seconds, 2) functionality checks with standardized probes and blades, 3) static and dynamic occlusion testing with articulation paper, and 4) cold stimulus aiming at assessing hypersensitivity and pulpal reactions. It is also important to understand that the number of included categories can be chosen flexible according to the study aim and design. Furthermore, it can be decided if the scoring for each category will consist of five grades (excellent/good/satisfactory/unsatisfactory/poor) or, in a simplified form, only three grades (sufficient/acceptable = score 1 to 3, insufficient/inacceptable but repair possible = score 4, and insufficient/inacceptable but repair not possible/reasonable = score 5). The latter approach might be of relevance especially in practice-based studies. As some of the earlier described 16 categories were rarely used in clinical trials [7], the revision includes only the most frequently used ones now. The categories for general health, gingival, periodontal, and mucosal conditions, erosive tooth wear, or abrasion [15–35] were separated from the "core" categories, as most of them are not directly related to the evaluation of dental restorations but reflect the status of the tissues beneath restored teeth (Table 3).

Training and calibration

Clinical assessments in studies should always be carried out by trained and calibrated examiners. Therefore, appropriate

theoretical and practical training sessions are mandatory and guarantee the consistency of judgments throughout the whole study period. Furthermore, the documentation of training is crucial. Each trainee should have a similar reproducibility rate in comparison to the trainer, which can be statistically expressed as intra- and inter-examiner reproducibility [36]. Clinical examples were published to assist study groups with this exercise [4, 5] and the revised FDI criteria set can be downloaded as illustrated document from the journal website. Nevertheless, calibration on patients in a clinical setting cannot be replaced by the evaluation of photographs, but time-consuming clinical calibration sessions might be shortened.

Recommended statistics

Studies on restoration quality and longevity require observations over a time, where different events, e.g., loss of patients, loss of teeth due to (non)study-related reasons, or failure of test restorations can occur. This implies an appropriate follow-up process and documentation of subjects, restorations, and failures. It is suggested to provide absolute numbers of failures and the overall number of evaluated restorations for each examination time point. There are different ways to calculate the *mean annual failure rate* or the normalized failure index besides the simple one dividing the total failure rate by the number of observation years [e.g., 37, 38]:

$$\textit{mean annual failure rate } (mAFR)^1 = 1 - \sqrt{1 - \left(\frac{N_{\text{Failures}}}{N_{\text{Restorations}}}\right)}$$

$$\textit{mean annual failure rate } (mAFR)^2 = -\log\left(1 - \left(\frac{N_{\text{Failures}}}{N_{\text{Restorations}}}\right)\right)/t$$

$$\textit{Normalized Failure Index } (NFI) = \frac{N_{\text{Failures}}}{(N_{\text{Restorations}} * t)}$$

N_{Failures}	total number of failed restorations
$N_{\text{Restorations}}$	total number of investigated restorations
t	observation time
1	preference of this formula in case of low failure rates
2	preference of this formula in case of high (almost 100%) failure rates in less than 1 year.

For calculating of the *success rate*, the dichotomization of the data into sufficient (scores 1–3) and insufficient (scores 4 and 5) is needed. The calculation of the *survival rate* uses the dichotomization of the data into restoration present including repaired (scores 1–4) and not present/failed (score 5). Kaplan–Meier curves are frequently applied to illustrate the success or survival probability over time [36]. The log-rank test is usable to compare differences between groups [39–41]. In addition, Bonferroni corrections or multivariate analyses, e.g., Cox proportional hazards model or Poisson distribution can be computed. When considering the potential influence of all patient-related factors on restoration survival, it is recommended to conduct a multiple logistic regression analysis.

Following the aim of increasing the internal validity domains and categories is somewhat rearranged in relation to their clinical relevance and importance; therefore, the functional properties (domain F) were now placed at the beginning of the assessment followed by the biological (domain B) and the aesthetic properties (domain A). The revised FDI core criteria set summarizes 11 criteria. In addition, the criteria "patient's view" and "radiographic evaluation" were shifted in the new domain "miscellaneous" (domain M).

Domain F: functional properties

The assessment of the function of a restoration is a key issue in scientific studies as well as in daily dental practice. Here, the visual examination provides relevant information that is sometimes hard to objectify and quantify. Therefore, the use of metric instruments improves the validity of the criteria. For this purpose, standardized instruments, e.g., metric probes and blades, are recommended to use the FDI criteria reliably.

Fracture of material and retention (category F1)

Restoration fracture and retention are the most relevant categories in clinical practice when evaluating direct and indirect restorations and therefore should be included in any study. Different fracture patterns and retention failures may occur in relation to the type of restoration: cracks, chipping/delamination, bulk fractures, or incomplete and complete loss of retention (Table 1). Minor material chipping or hairline cracks, which sometimes can only be detected after tooth cleaning and air drying, most often do not require an operational intervention, but these events should be monitored in follow-up visits recorded during data capture. Small chipping fractures with loss of material might only be monitored or corrected by refurbishment, e.g., recontouring and polishing. The main reason for failures of direct composite restorations is bulk fractures [41, 42], which can potentially be repaired. In cases of severe or multiple bulk fractures, replacement of direct restorations is considered the treatment of choice [41–44]. Types of fracture patterns are sometimes

different in indirect restorations (Table 1). Material chipping of variable extension is quite common in veneered ceramic restoration. In monolithic ceramic restorations, bulk fractures are more common. Ceramic fixed partial dentures primarily fracture in the connector area [45, 46]. Bulk fractures or delamination of a greater volume may substantially affect restoration integrity. If the loss of material is localized, repair might be possible. Repair of a restoration with extended or multiple fractures might not be reasonable, and complete replacement is more appropriate.

Severe loss of retention is in any case insufficient (scores 4 and 5), but the extent of lost material, partially or (almost) completely, defines whether a direct restoration might be repaired or not. If a restoration is graded as completely loose or lost (score 5), all other functional and aesthetic categories usually become not applicable. Indirect restorations, which can be recemented/reluted, will be rated with score 4 (repair).

Marginal adaptation (category F2)

There are different interfaces between the dental hard tissue, restorative material, and adhesive and/or luting resin/cement layer. Each interface can degrade and potentially alter marginal adaptation. In clinical practice, it is impossible to distinguish failures between the different interfaces. Therefore, only the marginal adaptation as such can be assessed. The quality of marginal adaptation is both the result of the properties of the adhesive, luting resin/cement, and restorative material and the skill and knowledge of the operator to create a good restoration (adequate cavity preparation, moisture control, application of materials according to instructions for use) [1–5, 41].

Evaluation of marginal adaptation should be done by visual examination and the use of a metric 250-µm probe, e.g., Fissuren Sonde 250EX with 250 µm diameter (Deppeler, Rolle, Switzerland). With respect to practicability, another probe with a diameter of 150 µm is no longer preferred. Ideal marginal adaptation shows a smooth transition from the restoration material to the surrounding tooth structure; no marginal irregularities should be detectable by gentle probing. Minor marginal deficiencies can be detected as discoloured margins or ditches and will be categorized as "sufficient" [47]. Wide (> 250 µm) marginal gaps with a gap depth ≥ 2 mm indicate a situation of clinical insufficiency and probably require dental intervention depending on both the location and the caries risk/activity/history of the patient [4, 5, 48–50].

Proximal contact point (category F3)

The tightness of proximal contact points should be estimated in a reproducible manner. Metal blades (e.g., matrix for EX kit; blades' thickness 0.025 0.05, and 0.1 mm; Deppeler, Rolle, Switzerland) are recommended for better categorization [1–5, 51]. In case of unavailability of the blades, waxed dental floss might be considered a non-standardized alternative. A proximal contact point has a physiological strength when the 25-µm metal blade (or dental floss) can pass through it with resistance [1–5]. An appropriate degree of contact strength as well as a properly located contact area is recommended to prevent food impaction and allow for

Table 3 Additional clinical parameters and the corresponding indices that might also be scored beneath dental restorations

Clinical parameter	Corresponding index and/or set of criteria
General health status	The ASA physical status classification system is a system for assessing the fitness of patients before surgery/treatment and was developed by the American Society of Anesthesiologists [15]
Allergy	Medical history and/or allergy testing
Tooth vitality and pulp pathology	Pain anamnesis, sensibility test on cold, percussion test, pain on palpation, pain on chewing
Surface staining	Black stain, food-associated staining (coffee, tea, tobacco, and others)
Plaque accumulation and calculus	Quigly Hein index [16], plaque index [17, 18], and others
Gingival health	Gingivial index [19, 20], sulcus bleeding index [20], modified sulcus bleeding index [21], papillary bleeding index, bleeding on probing or brushing, and others
Periodontal health	Classification scheme for periodontal and peri-implant diseases and conditions [22] and others, community periodontal index CPITN index [23], measurement of attachment loss and pocket depth, bleeding on probing [24], and others
Mucosa pathology	Potentially malignant disorders of the oral mucosa and oral epithelial dysplasia [25]
Caries	DMF index [26], ICDAS [27], UniViSS [28, 29]
Erosive tooth wear	Basic erosive wear examination [30]
Attrition and abrasion (tooth wear)	Tooth Wear Index [31]
Hard tissue fractures and cracks	Tooth cracks[32]
Developmental defects	Molar-incisor hypomineralization [33], fluorosis index [e.g., 34], and others
Dental trauma	Crown fractures [35]

interdental papilla to fill the interproximal space [52, 53]. The lack of physiological contact point strength may result in food impaction, papillitis, or discomfort. However, it must be addressed that physiological contact strength can vary considerably among patients [54]; therefore, the strength of proximal contact points should be assessed individually and with caution. For better evaluation, an adjacent contact for comparison could be used. In addition to less optimally restored contact areas, weak or no contact points could be linked to the individual tooth form, e.g., microdens, atypical tooth position, diastema, and/or paced/gap-toothed dentition. In these clinical situations, this criterion shall not be applied. The same applies to patients with advanced periodontitis or mobile, flared, or missing teeth. Generally, teeth with non-existing proximal contacts cannot be evaluated with regard to proximal contact points.

An unintentionally interlocked contact point due to excessive restorative material, bonding agent, luting resin, or cement, which makes it impossible for a blade or dental floss to pass, has been added to the revised FDI criteria set. Unintentionally interlocked contact points are unacceptable, as they impede oral hygiene, make affected tooth surfaces inaccessible for proper cleaning, and may therefore cause caries and/or periodontitis.

Form and contour (category F4)

In modification to the previously published recommendations [1–5], this category is now listed under "functional properties," because both are essential variables of the physiological functionality of any restoration in the masticatory system [55]. As characteristics of an optimally restored tooth form and contour, the following indicators of functionality have to be mentioned: (1) gingiva and periodontium are protected, (2) physiological embrasures between teeth are rebuilt and potentially allow for an alignment of the interdental papillae [52], (3) a spillway for the passage of food during mastication is reconstructed and prevents gingival food impaction, (4) the restoration safeguards the self-cleansing ability and the occlusal embrasure allows for better access for oral hygiene floss passage, and (5) stabilizes the position of the tooth to adjacent and antagonistic teeth. It needs to be further noted that optimal reconstruction of form and contour not only guarantees functionality but also substantially affects aesthetics. In anterior teeth, angulation and width-to-height ratio should be additionally considered [56].

The individual rebuilding of form and contour depends on the patients' wishes as well as on the dentist's or dental technician's skills. An ideal form and contour may not be achievable in the case of children/adolescents or elderly individuals with reduced compliance, disabled patients, individuals with dental anxiety, or patients with limited mouth opening. Furthermore, irregular tooth angulation and/or position in the jaw, e.g., due to tooth crowding, may also complicate an ideal restoration in terms of form and contour. Irregularities, including overhangs and positive steps of the restoration, should be improved by refurbishing to avoid negative side effects, e.g., plaque accumulation and marginal discoloration. Underfilling might be the result of a primarily under-contoured restoration or/and of a gradual process of deterioration of the restorative material.

Occlusion and wear (category F5)

The static and dynamic occlusion of a restored tooth influences the functionality of the dentition. An ideal occlusion of the restoration should be harmonized with the individual and age-related occlusion of the masticatory system. The restoration with antagonistic teeth should not have a non- or hyper-occlusion; it should avoid biomechanical stress on the supportive tissues and should not trigger pain and TMDs. A restoration with non-occlusion potentially limits the chewing ability and may result in the elongation/super eruption of the restored and/or the antagonist tooth if there is no contact to prevent this. Oversized cusps or dimensions of the occlusal surface could lead to premature contacts, hyper-occlusion, and interfering balances, which may negatively influence the restoration's longevity in terms of material chips or fractures (category F1) and may cause discomfort, pain, or TMDs [57–63].

Wear is the result of dynamic processes predominantly on occlusal and proximal surfaces of the restoration, which might be influenced by individual occlusion, bruxism, individual habits, and nutritional/chemical and mechanical challenges. Wear can hardly be assessed by clinical examination alone; therefore, objective monitoring methods are required, which can directly compare follow-up with baseline information, e.g., plaster models or 3D scans [64]. Therefore, only a simplified recording in the revised FDI criteria set has been integrated. If quantitative information on wear is needed, intraoral 3D scans or scans of replicas after impression-taking should be considered as the method of choice [65–67].

Domain B: biological properties

Pathological processes that are related to dental restorations include caries at the restoration margins (B1), dental hard tissue defects, cracks or fractures (B2), and postoperative hypersensitivity or pulpal inflammation (B3). Several other dental pathologies, e.g., developmental dental defects, bruxism, and erosive tooth wear, may potentially interfere with longevity. With respect to the aim of clarification and prioritization, the most frequent pathologies are covered in the

revised criteria set. Therefore, particular research questions may require the inclusion of additional standard methods (Table 3).

Caries at restoration margins (CAR, category B1)

This category has been harmonized in relation to the current caries definitions [28, 68–71]. Caries is the most prevalent dental disease from a global perspective [72–74], and the etiology of caries at restoration margins (CAR, synonyms: secondary caries or recurrent caries) is not different from that of primary caries [75–78]. CAR is mostly located in plaque stagnation niches, e.g., proximal margins, and can rarely be diagnosed on smooth surfaces that are well accessible for oral hygiene [79]. Furthermore, it may require significant gaps that are accessible to oral fluids in a caries active oral cavity to contribute to the risk for CAR. Some early clinical studies conclude to minimum gap width occlusally of 400 microns and 250 μm approximally [1, 2, 48], but recent in situ studies also show that gaps as small as 50 microns might be able to generate CAR [80, 81]. For margins at the proximal gingival box of a class II restoration, smaller gaps or even no gap maybe associated with caries at this site. The most important factor regarding CAR is the caries activity of the patient.

Clinically, CAR reaches from non-cavitated carious lesions to deep cavities. While initial carious lesions require no (reviewing, topical fluoride application) or minimally invasive intervention reseal or refurbishment, cavitated lesions at the restoration margin probably need operative dental measures in terms of repair or replacement depending on the size of the defect and restoration and caries activity of the patient [71, 82, 83]. Importantly, if any caries occurs at any other site of a tooth that is not *directly* related to the restoration, it should not be registered as CAR. The clinical diagnosis of CAR is sometimes difficult to differentiate from stained margins [76, 77]. Importantly, stained restoration margins with no demineralized hard tissue should not be confused with CAR.

Dental hard tissue defects at the restoration margin (category B2)

This criterion comprises tooth cracks, enamel chipping, or cusp fractures at the restoration margin. Additionally, cracked tooth syndrome [84] is considered, which may also cause hypersensitivities or pain. In addition, it is noteworthy not to include other events in this category, such as physiological attrition and wear, abfraction, or defects related to other reasons, e.g., trauma. Additionally, a lost restoration material or CAR must be scored in their corresponding categories. Clinical assessment could be supported by light transillumination of the restored tooth.

Postoperative hypersensitivity and pulpal status (category B3)

Postoperative hypersensitivity is linked to pulpal reactions immediately after placement of a dental restoration and can include discomfort, pain, pulpitis, or, later, loss of tooth vitality. There are several factors that affect the pulp-dentin complex: 1) diagnosis and history of the tooth, 2) dental treatment including cavity preparation, caries excavation, or placement of a properly sealed restoration, 3) properties of the adhesive, luting resin, and/or restoration material, and 4) the patient's individual pain perception. In general, the diagnosis of postoperative hypersensitivity may indicate the presence of a deficiency during the restoration workflow, e.g., incomplete adhesive bonding of the restoration, which is probably difficult to identify later.

With respect to definition, tooth sensitivity needs to be recorded before and after restoration placement and at all recall visits. On each examination, it is necessary to consider, first, the patient's reporting of tooth (hyper)sensitivity, e.g., by using a visual analogue scale, and second, testing of irritability of the pulpal nerve on cold, e.g., with dry ice or cold spray, in comparison to the reaction of a contralateral, sound, and unrestored tooth. The restoration should be rated as acceptable when normal sensitivity or mild pulpal symptoms are recorded during follow-up examination. In cases of postoperative hypersensitivities, transient pain or more intense pulpal reaction, individual monitoring intervals might be indicated. Irreversible pulpitis or pulp necrosis requires endodontic intervention to overcome the problem.

Domain A: aesthetic properties

The aesthetic performance of dental restorations can be characterized by surface luster, surface texture, marginal staining, color match, and anatomical form. The evaluation is somewhat subjective and therefore more prone to potential bias and variability [85, 86]. The aesthetic appearance of a restoration depends mainly on how well it blends into the surrounding tooth structure, which is influenced by oral hygiene.

The evaluation of aesthetic properties is of clinical relevance for visible and tooth-colored restorations within the smile frame only, usually canine to canine. In many patients, the mesiobuccal aspect of upper premolars is visible when patients smile and therefore essential for aesthetic appearance. In most individuals, however, the evaluation of aesthetics in posterior teeth is less important. Depending on the study design, setting, and aim of the investigation, researchers can choose if the evaluation of the aesthetic properties should be evaluated from a standard examination distance under operating light (~40 cm) or from a speaking

distance (~80–100 cm), which will lead to different results and should therefore be mentioned. Additional devices to objectify aesthetics are intraoral photographs or scans, color scales, colorimeters, spectrophotometers, or 3D imaging.

Surface luster and surface texture (category A1)

Surface luster and texture are created by the reflection of light from the surface of the restoration, which mainly depends on material properties and the restoration surface [87]. In detail, the intrinsic material roughness (nano- and micro-roughness), finishing procedures (macro-roughness), e.g., polishing marks, and flaws due to material properties or material processing, e.g., pores and voids, must be considered. Macroscopic deviations in surface texture, such as polishing marks or pores, are easier to detect by visual examination than minor deficiencies [87, 88]. Ideally, the surface luster and texture of the restoration are comparable to that of the surrounding hard tissue.

Marginal staining (category A2)

Marginal staining is defined as the discoloration of a crevice between the cavity wall and the restoration, subsequently affecting the margin of the restoration, which should not be confused with caries [76, 77]. A prerequisite for staining is the presence of a ditch or gap at the margins where pigments can adhere. Marginal staining depends on the efficacy of the adhesive/cementation system to bond the restoration to dental hard tissue(s) and individual patient factors [41]. The latter include nutritional habits such as consumption of coffee, black tea, or red wine as well as smoking and oral hygiene procedures [89, 90]. Additionally, the individual intraoral microbiome may play a role [91–93]. Less important is the restorative material [94–96] or the chosen operative technique [97, 98]. Nevertheless, there is evidence that suggests that the occurrence of marginal discolouration correlates with a compromised integrity of the marginal seal [47, 99], which may be frequently related to polymerization shrinkage of the composite.

Colour match (category A3)

This category is applicable to tooth-colored restorations only. An ideal color match is achieved when all visually apparent differences between dental hard tissues and the restorative material are minimal or even invisible. Deviations in shade, translucency, or opacity between dental hard tissues and the restorative material are possible if (1) the chosen color of the restorative material does not match that of the surrounding dental hard tissues, (2) the natural teeth become darker or more yellow with increasing age [100], and (3) the restorative material itself has inherent color instability [101–104]. When color matching has to be evaluated, visual examination is the method of choice. In addition, intraoral photographs can be used but are also difficult to standardize during follow-up examinations [105, 106]. In contrast, commercially available color measuring instruments, e.g., reflectance spectrophotometers and colorimeters, have gained acceptance due to their satisfactory accuracy, reliability, and time-efficient use [86, 107–109].

Domain M: miscellaneous

The expert panel decided to streamline the "core" FDI criteria set and additional methods are listed in Table 3. The patient's view on the restored tooth as well as the radiographic assessment of restorations was shifted in a new domain. With respect to the impossibility to embed the corresponding diagnostic scores into the standard 5-point scale, both categories are shown in the illustrated version only, which can be downloaded from the journal's website.

Patient's view (category M1)

Patient satisfaction with a dental restoration is a subjective response that gains more attention in practice-based or health service research and is usually scored by means of visual analogue scales [e.g., 113]. From the methodological point of view, it might be sufficient to ask for an overall (subjective) impression from the patient. In cases of dissatisfaction, a detailed report about pain, hypersensitivity, chewing comfort, occlusion, proximal contacts, cleanability, contours, or aesthetics might be of value. This assessment can be designed by use of the FDI criteria but a standardized protocol is not established or published so far. The patient's opinion might be relevant, especially if the aesthetics of the restorations appear to be unacceptable for him/her and a replacement ahead of time needs to be discussed. It should be noted that the patient's view can interfere with dental assessment and clinical decision-making.

Assessment of dental restoration on radiographs (category M2)

In general, it has to be emphasized that there is no general justification to do a radiographic examination for the assessment of dental restorations without any clinical indication [111–114]. This approach is strictly in line with basic principles of radiation protection [115–117]. Nevertheless, the assessment of direct and indirection restorations is required on justified images. Here, radiographic evaluation includes, among others, caries detection, negative/positive steps or marginal gaps of the restoration, apical periodontitis, periodontal bone loss, internal/external resorption, or quality of endodontic treatment.

Table 4 Description and details of the revised FDI criteria set to evaluate direct and indirect dental restorations

	Functional properties (domain F)		
	F1: fracture of material and retention FDI 2010 category: 5	F2: marginal adaptation FDI 2010 category: 6	F3: proximal contact point FDI 2010 category: 8
Criteria	*Visual examination and short air drying*	*Visual examination, short air drying, and 250-µm probe*	*Visual examination and 25-/50-/100-µm blades*
1. Clinically excellent/very good (sufficient)	Restoration is completely present without deficiencies detectable after air drying. No crack, chipping/delamination, or material bulk fracture	Ideal marginal adaptation of the restoration at the dental hard tissue after air drying. No marginal gap detectable by gentle probing	Ideal contact point: 25-µm metal blade can pass through proximal contact and no inflammation of the gingiva/periodontium due to the proximal restoration. No food impaction
2. Clinically good (sufficient)	Restoration is completely present with minor deficiencies detectable after air drying, e.g., insignificant material chipping or one hairline crack	Slight deficiencies of marginal adaptation after air drying. Minor, superficial marginal gap(s) or ditching	Slightly weak contact point: 50-µm metal blade can pass through proximal contact and no inflammation of the gingiva/periodontium due to the proximal restoration. No food impaction
3. Clinically satisfactory (sufficient)	Restoration is present with deficiencies detectable without air drying, e.g., hairline cracks or distinct material loss (chipping). Material loss can mainly be corrected by refurbishment if needed	Distinct deficiencies of marginal adaptation without air drying: marginal gap(s) or ditching (width < 250 µm and/or depth < 2 mm)	Oversized contact point or excessive material: 25-µm metal blade cannot pass through proximal contact and inflammation of the gingiva/periodontium due to the proximal restoration. Refurbishment is possible. OR Severely weak contact point: 100-µm metal blade can pass through proximal contact but no inflammation of gingiva or discomfort
4. Clinically unsatisfactory (partially insufficient)	Localized but severe deficiencies regarding fracture and retention, e.g., chipping/delamination which cannot be refurbished, bulk fracture, or partially loose/lost restoration. Repair is possible. Lost indirect restoration, which can be recemented/reluted, is considered here	Localized but severe deficiencies of marginal adaptation: width ≥ 250 µm and/or depth ≥ 2 mm marginal gap(s). Partially loose/lost restoration. Repair is possible	Severely weak contact point: 100-µm metal blade can pass through proximal contact or unintended interlocked contact point. Inflammation of the gingiva/periodontium due to the proximal restoration and/or food impaction. Repair is possible
5. Clinically poor (entirely insufficient)	Generalized severe deficiencies, e.g., extensive delamination, multiple bulk fractures, or (nearly) completely loose/lost restoration. Repair not possible/reasonable	Generalized and severely compromised marginal adaptation: width ≥ 250 µm and/or depth ≥ 2 mm. Complete loose/lost restoration. Repair not possible/reasonable	Severely weak contact point: 100-µm metal blade can easily pass through proximal contact or unintended interlocked contact point (impossible to pass). Inflammation of the gingiva/periodontium due to the proximal restoration and/or food impaction. Repair not possible/reasonable
Not applicable	This code is used if examination for any reason is not possible		
Additional comments	1) Should be included without exception in any study that requires restoration assessment. 2) If a restoration is graded as entirely insufficient (F1/score 5) or completely lost all other functional (except F2) and aesthetical categories become not applicable	1) Evaluate gap formation at the restoration margin only. 2) If any loss of restoration material or dental hard tissue is evident, these findings have to be scored in the categories F1 and B2. Caries at the restoration margin has to be scored in category B1. 3) If a restoration is graded as entirely insufficient or completely lost (F2/score 5), all other functional and aesthetical categories become not applicable (except indirect restorations which can be recemented/reluted)	1) Not applicable in case of missing adjacent teeth, gap-toothed/flared/mobile dentition, or atypical individual tooth form, e.g., microdens or diastema. 2) Do not mix-up with F1

Table 4 (continued)

	Functional properties (domain F)	
	F4: form and contour FDI 2010 category: 4, 6, 7, 8	F5: occlusion and wear FDI 2010 category: 7
Criteria	*Visual examination*	*Visual examination and articulation paper*
1. Clinically excellent/very good (sufficient)	Outline, contour, convexity, embrasure, and/or marginal ridges are restored ideally in comparison to the individual, age-related and functional anatomy. No marginal step detectable by gentle probing	Ideal individual and age-related static and dynamic occlusion with multiple antagonistic contact points. No premature contacts, non-/hyper-occlusion, and/or balancing interferences
2. Clinically good (sufficient)	Minor deviations in outline, contour, convexity, embrasure, and/or marginal ridges in comparison to the individual, age-related and functional anatomy, AND/OR minor marginal steps, overhangs detectable by gentle probing	Minor deviations in individual and age-related static and dynamic occlusion with at least one antagonistic contact point per tooth. No premature contacts, non-/hyper-occlusion, and/or balancing interferences
3. Clinically satisfactory (sufficient)	Outline, contour, convexity, embrasure, and/or marginal ridges are distinctly misshaped but clinically acceptable and/or distinct negative/positive steps, overhangs. Refurbishment (removal of overhangs/steps) to some extent is possible	Hyper-occlusion, premature contacts, and/or balancing interferences that can be eliminated by refurbishment
4. Clinically unsatisfactory (partially insufficient)	Outline, contour, convexity, embrasure, and/or marginal ridges are in parts severely undersized in comparison to the individual, age-related, and functional anatomy AND/OR prominently negative marginal steps. Repair is possible	Localized, flat occlusal structure with severe non-occlusion AND/OR severely worn restoration. Repair is possible
5. Clinically poor (entirely insufficient)	Outline, contour, convexity, embrasure, and/or marginal ridges are generally and severely under- or oversized in comparison to the individual, age-related, and functional anatomy. Repair not possible/reasonable	Generalized, severe non-occlusion AND/OR extensively worn restoration. Repair not possible/reasonable
Not applicable	This code is used if examination for any reason is not possible	
Additional comments	1) Describes in particular the dentist's or dental technician's ability to restore the tooth in comparison to contralateral (unrestored) teeth. 2) Do not mix-up with F1, F2, or F3	1) Not applicable in case of irregular individual tooth form or malocclusion, e.g., microdens or missing antagonistic teeth. 2) In case of severe and generalized fracture and retention deficiencies of a restoration (F1/score 5), score 5 (F5) is becoming not applicable. 3) Do not mix-up with F1

	Biological properties (domain B)		
	B1: caries at restoration margin (CAR) FDI 2010 category: 12	B2: dental hard tissue defects at restoration margin FDI 2010 category: 13	B3: postoperative hypersensitivity/pulp status FDI 2010 category: 11
Criteria	*Visual examination, short air drying, and 250-µm probe*	*Visual examination*	*Tooth hypersensitivity reported by patient; pulp sensitivity tested with cold stimulus*
1. Clinically excellent/very good (sufficient)	No caries/demineralization at the restoration margin detectable after air drying	Intact dental hard tissue without crack lines and fractures at the restoration margin	No postoperative hypersensitivity or pain on chewing and/or cold/warm food items reported by the patient. Normal (short) reaction to sensitivity test on cold
2. Clinically good (sufficient)	First visible signs of a non-cavitated caries lesion at the restoration margin detectable after air drying	Minor vertical/horizontal hairline crack lines in enamel at the restoration margin	Patient reports minor postoperative hypersensitivity or minor pain on chewing and/or cold/warm food items reported by the patient for a limited period of time (< 1 week). Normal (short) reaction to sensitivity test on cold

Table 4 (continued)

	Biological properties (domain B)		
	B1: caries at restoration margin (CAR) FDI 2010 category: 12	B2: dental hard tissue defects at restoration margin FDI 2010 category: 13	B3: postoperative hypersensitivity/pulp status FDI 2010 category: 11
3. Clinically satisfactory (sufficient)	Established, non-cavitated caries lesion or microcavity at the restoration margin detectable without air drying	Distinct enamel chipping or enamel fracture at the restoration margin. If necessary, deficiencies can be corrected by refurbishment	Patient reports distinct postoperative hypersensitivity or distinct pain on chewing and/or cold/warm food items reported by the patient for a prolonged period of time (> 1 week). Normal (short) or more intense reaction to sensitivity test on cold
4. Clinically unsatisfactory (partially insufficient)	Localized dentin cavity (width > 250 µm, depth > 2 mm) at the restoration margin. Repair is possible	Severe marginal (enamel) fracture, partially fractured cusp or ridge at the restoration margin. Repair is possible	Patient reports severe/persistent, postoperative hypersensitivity or persistent pain on chewing and/or cold/warm food items reported by the patient for a prolonged period of time (> 1 month) AND/OR intense reaction to sensitivity test on cold. Both symptoms indicate irreversible pulpitis. Endodontic treatment requires access cavity only
5. Clinically poor (entirely insufficient)	Extensive dentin cavity at the restoration margin. Repair not possible/reasonable	Cusp or tooth fracture, e.g., involving enamel, dentin, and cementum possible with mobile fragments/pain when biting OR cracked tooth syndrome related to restoration. Repair not possible/reasonable	Irreversible pulpitis, nonvital tooth, pulp necrosis with or without periapical periodontitis after restoration placement. Endodontic treatment requires replacement of the restoration
Not applicable	This code is used if examination for any reason is not possible		
Additional comments	1) Do not confuse caries with marginal staining (A2). 2) Consider only caries lesions that are located directly at the restoration margin. 3) If any loss of restoration material or dental hard tissue is evident, these findings have to be scored in the corresponding categories F1 and B2	1) Do not misdiagnose attrition, erosive tooth wear, etc. in this category. 2) If loss of restoration material or CAR is evident, these entities have to be scored in the corresponding categories F1 and B1	1) This category can only be evaluated in vital teeth that are monitored from the time the restoration is placed. 2) Refurbishment, repair, or replacement cannot be related to a possible endodontic treatment procedure; therefore, possible restorative interventions are not used for categorization
	Aesthetic properties (domain A)		
	A1: surface luster and surface texture FDI 2010 category: A1	A2: marginal staining FDI 2010 category: A2	A3: color match FDI 2010 category: A3
Criteria	*Visual examination and short air drying*	*Visual examination and short air drying*	*Visual examination*
1. Clinically excellent/very good (sufficient)	Surface luster and surface texture comparable to dental hard tissue/adjacent teeth after air drying	No marginal staining detectable after air drying	No deviation in shade, translucency/opacity between restoration, and neighboring dental hard tissue/adjacent teeth
2.Clinically good (sufficient)	Slightly dull surface luster and/or surface texture with minor deviations, e.g., isolated/small marks, pores, and/or voids detectable compared to dental hard tissue/adjacent teeth after air drying	Minor marginal staining detectable after air drying	Minor deviation in shade, translucency/opacity between restoration, and neighboring dental hard tissue/adjacent teeth detectable

Table 4 (continued)

	Aesthetic properties (domain A)		
	A1: surface luster and surface texture FDI 2010 category: A1	A2: marginal staining FDI 2010 category: A2	A3: color match FDI 2010 category: A3
3. Clinically satisfactory/acceptable (sufficient)	Dull surface luster and/or surface texture with distinct deviations, e.g., marks, pores, and/or voids detectable compared to dental hard tissue/adjacent teeth detectable without air drying. Refurbishment is possible	Distinct marginal staining detectable without air drying but not displeasing. Refurbishment is possible	Distinct deviation in shade, translucency/opacity between restoration, and neighboring dental hard tissue/adjacent teeth detectable but not displeasing
4. Clinically unsatisfactory (partially insufficient)	Localized, displeasing dull surface luster and/or rough surface texture with substantial deviations/multiple pores/voids detectable compared to dental hard tissue/adjacent teeth which can be repaired	Localized, displeasing deep marginal staining. Marginal staining can be removed/improved by repair	Localized, displeasing deviation in shade, translucency/opacity between restoration, and neighboring dental hard tissue/adjacent teeth which can be improved by repair
5. Clinically poor (entirely insufficient)	Generalized, displeasing dull surface luster and/or rough surface texture with substantial deviations/multiple pores/voids compared to dental hard tissue/adjacent teeth. Repair not possible/reasonable	Generalized, displeasing deep marginal staining. Repair not possible/reasonable	Generalized, displeasing deviation in shade, translucency/opacity between restoration, and neighboring dental hard tissue/adjacent teeth. Repair not possible/reasonable
Not applicable	This code is used if the restoration is mostly or fully lost or loose and/or examination for any other reason is not possible		
Additional comments	1) The evaluation of aesthetic properties is relevant for decision making on tooth-coloured restorations in visible tooth surfaces only. 2) Evaluation can be performed from a standard examination distance under operating light (~40 cm) or from speaking distance (~80–100 cm) with the operating light switched off. This has to be defined and reported later		
	If surface luster and surface texture have to be taken in account, the worse characteristic determines the grading	Do not confuse marginal staining with CAR (B1)	Evaluation of tooth-colored restorations only

Table 5 Reporting checklist for studies evaluating direct and indirect restorations

Section and topic	Item no	Recommendations
Title	1	Indicate the type of study and important parameters (material, Black's classification, primary or permanent teeth)
Abstract	2	Structured summary of study design, methods, results, and conclusions
Introduction		Introduce and justify
Background/rationale	3	Scientific and clinical background including the intended indication and clinical use of the restorative procedures and/or materials. Justify research needs
Objectives	4	Study objectives and hypotheses
Methods		Describe
Study design	5	Indicate the study design, e.g., randomized controlled clinical trial, clinical trial, case control study, case study, or epidemiological, observational, or diagnostic study, and if the study protocol was designed prospectively or retrospectively. Describe the study setting, e.g., university- or practice-based and the allocation of interventions, e.g., split-mouth or parallel-arm design. Report relevant dates, time intervals including periods of recruitment, and follow-ups
Sample size	6	Intended sample size and how it was determined (sample size calculation). Include typically no more than one restoration per study arm
Patients	7	Patient population, e.g., children, adolescents, adults, elderly, etc. In- and exclusion criteria for patients, procedures for screening, selection, and randomization. Where and when potentially eligible participants were identified (setting, location, and dates). Give the eligibility criteria, screening, and selection procedures. Report numbers of individuals in each stage of study, e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed. Give reasons for nonparticipation or drop-out in each stage
Teeth	8	Exclusion and inclusion criteria for tooth selection, cleaning, and processing prior to beginning of the study/placing restoration. Account for all teeth that were included, restored, and monitored. Report the number of included teeth separately for each type of restoration, e.g., according to Black's classification, etc. Report indications or reasons for restoration, tooth type, number of restored surfaces, and tooth-related dental history, i.e., caries, endodontic treatment, or trauma
Restorative interventions and materials	9	Provide complete and detailed information about the clinical setting, workflow, instruments, and materials (product and batch number, manufacturer) for all restorative procedures. Indicate operator initials
Evaluation of restorations	10a	Provide complete and detailed information about the evaluation setting, workflow, illumination, cleaning, drying, instruments, and procedures for repeated diagnostic evaluation of all restorations. Indicate examiner initials
	10b	Define primary and secondary outcome parameters. Report and describe which categories of the FDI criteria set were selected and why and how they were used
	10c	Report and describe if additional clinical or laboratory evaluations were performed by which researcher, e.g., sensibility testing, intraoral photographs, 3D wear analysis on digital models, or scanning electron microscopy analysis of marginal adaptation on replica models, etc
Blinding	11	Indicate if operator(s), examiner(s), patients, and statistician(s) were blinded or if an independent evaluation procedure was included, e.g., on photographs
Training and calibration	12	Details of theoretical and practical training, training setting, and results from calibration for operators and examiners, e.g., Kappa values, should be given
Operators and examiners	13	Report the role and level of clinical and/or diagnostic (research) experience of each operator and examiner, e.g., years of relevant clinical experience. Visual acuity of both operators and examiners should be reported
Data handling and statistics	14	Describe all statistical methods for evaluating the longevity of restorations and its quality over time including descriptive data for each of the chosen categories. Explain how variables and missing data were handled in the analyses. Indicate the used statistical methods to analyze the survival probability, e.g., Kaplan–Meier statistics/curves, and to compare different groups, e.g., log-rank test, Wilcoxon signed rank test, Bonferroni corrections, multivariate analyses or Cox regression, or proportional hazards models
Results		Report
Study population and/or teeth	15	Flow of participants, using a diagram. Report numbers of the included patients and teeth in relation to test and control groups

Table 5 (continued)

Section and topic	Item no	Recommendations
Characterization of the study population	16	Characterize the study population (age, female/male ratio, dental health status, oral hygiene, etc.)
Outcome data	17a	Report adverse events and undesirable effects
	17b	Provide complete descriptive and explorative data of quality and longevity of tested restorations. Kaplan–Meier statistics/curves illustrate the cumulative survival probability over the study period
	17c	Present results from comparative analysis
Discussion		Discuss
Study population	18	Conclude whether the study population is representative for the target group. Furthermore, include a statement if the study sample met the requirements from the sample size calculation. Evaluate dropout and attrition rates
Data interpretation	19	Summarize the important findings from the study and interpret the data in relation to the recently published literature. Consider potential methodological differences between studies and its influence on the comparability. Furthermore, discuss the (clinical) relevance of the study results and the potential implications for dental practice. Compare the results with those of similar clinical studies and assess deviations if present
Strength and limitation	20	Consider methodological strengths and limitations of the used study design. Report potential sources of bias, statistical uncertainty, and lacking generalizability. Discuss both direction and magnitude of any potential bias
Conclusion	21	Draw a well-balanced and unbiased study conclusion
Other information		If applicable
Ethics	22	Indicate the ethical committee/institutional review board and trial registration number
Funding	23	Mention sources of funding and other support. Explain the role of funders
Conflict of interest	24	Summarize potential conflicts of interest for each of the authors

Interpretation of the scorings

In addition to the intention to objectify the diagnostic evaluation and assessment of dental restorations and assist clinicians in decision-making, it is also important to consider clinically relevant key information, e.g., caries risk and activity, age, and medical or behavioral problems. On the basis of this comprehensive information, an individual intervention strategy has to be justified and agreed upon between the dentist and the patient/caregivers knowing well that the final decision might also be influenced by varying diagnoses, treatment philosophies, experiences, settings, and available resources including treatment costs. Importantly, each decision must be made with respect for the patient's autonomy. Therefore, a specific dental diagnosis might be linked with different decisions.

With the revised FDI criteria set (Table 4), some ambiguities were removed, and scores were further harmonized to cross-link distinct clinical situations with possible management strategies, e.g., monitoring/reviewing (scores 1–4), refurbishment or reseal (score 3), repair (score 4), or replacement (score 5). An important issue is the decision whether a restoration is clinically acceptable (scores 1–3) or not (scores 4 and 5) and to decide further whether repair is possible (score 4) or not (score 5). Again, as described above, treatment procedures have to be understood as *possible* intervention corridors, and they are not meant to be understood as inevitable treatment approaches. In that respect it may be also good to consider contemporary tendencies in restorative dentistry to be as conservative/preservative as possible and, in case of doubt, rather select shorter monitoring intervals or the most minimally invasive option [118]. In this context, repair of direct and indirect restorations has to be considered a conservative treatment option in comparison to traditional replacement.

Reporting of future studies

In addition to the detailed description of the FDI criteria set and the clinical interpretation of the diagnostic findings, it is vital to highlight the need for standardized study reporting that includes the evaluation of dental restorations. A reporting checklist is given in Table 5, which should help researchers to standardize their paper writing.

Conclusions

The formerly published FDI criteria set for the evaluation of direct and indirect restorations [1–5] was revisited through a stepwise consensus process. With the aim of improving

clinical usability, practicability, and acceptability, a revised set of criteria prioritized categories and harmonized the wording. It is also important that each domain or category can be selected independently, thus creating a modular diagnostic system with great flexibility for the evaluation of direct and indirect restorations. The revised FDI criteria set has to be understood as a living document that can be regularly adopted on the basis of new clinical data, findings and experiences. Therefore, we encourage researchers, teachers, and dental practitioners to provide feedback.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00784-022-04814-1.

Author contribution Conceptualization and project administration: RH, JK, and SM; study design: RH and JK; writing (original draft preparation): all authors; writing (review and editing): all authors; funding acquisition: RH. All the authors have read and agreed to the published version of the manuscript.

Funding Open Access funding enabled and organized by Projekt DEAL. This research project was funded by the institutions.

Declarations

Competing interests The authors declare no competing interests.

Conflict of interest The authors declare no potential conflict of interest with respect to the authorship and publication of this article, including financial interests and the provision of study materials by the manufacturer for free or at a discount. Ivoclar Vivadent covered partially the travel expenses for one person to attend the group workshop at the Department of Conservative Dentistry and Periodontology in Munich, Germany on June 3–4, 2019.

References

1. Hickel R, Roulet JF, Bayne S, Heintze SD, Mjor IA, Peters M, Rousson V, Randall R, Schmalz G, Tyas M, Vanherle G (2007) Recommendations for conducting controlled clinical studies of dental restorative materials. Science Committee Project 2/98--FDI World Dental Federation study design (Part I) and criteria for evaluation (Part II) of direct and indirect restorations including onlays and partial crowns. J Adhes Dent 9(1):121–147
2. Hickel R, Roulet JF, Bayne S, Heintze SD, Mjor IA, Peters M, Rousson V, Randall R, Schmalz G, Tyas M, Vanherle G (2007) Recommendations for conducting controlled clinical studies of dental restorative materials. Clin Oral Investig 11:5–33
3. Hickel R, Roulet JF, Bayne S, Heintze SD, Mjor IA, Peters M, Rousson V, Randall R, Schmalz G, Tyas M, Vanherle G (2007) Recommendations for conducting controlled clinical studies of dental restorative materials. Int Dent J 57:300–302
4. Hickel R, Peschke A, Tyas M, Mjor I, Bayne S, Peters M, Hiller KA, Randall R, Vanherle G, Heintze SD (2010) FDI World Dental Federation - clinical criteria for the evaluation of direct and indirect restorations. Update and clinical examples. J Adhes Dent 12:259–272
5. Hickel R, Peschke A, Tyas M, Mjor I, Bayne S, Peters M, Hiller KA, Randall R, Vanherle G, Heintze SD (2010) FDI World Dental Federation: clinical criteria for the evaluation of direct and indirect restorations-update and clinical examples. Clin Oral Investig 14:349–366
6. Green D, Mackenzie L, Banerjee A (2015) Minimally invasive long-term management of direct restorations: the '5 Rs.' Dent Update 42:413–416
7. Marquillier T, Domejean S, Le Clerc J, Chemla F, Gritsch K, Maurin JC, Millet P, Perard M, Grosgogeat B, Dursun E (2018) The use of FDI criteria in clinical trials on direct dental restorations: a scoping review. J Dent 68:1–9
8. Murphy MK (1998) Consensus development methods, and their use in clinical guideline development. Health Technol Assess 2:1–88
9. Moher D, Schulz KF, Simera I, Altman DG (2010) Guidance for developers of health research reporting guidelines. PLoS Med 7:e1000217
10. Wang X, Chen Y, Yang N, Deng W, Wang Q, Li N, Yao L, Wei D, Chen G, Yang K (2015) Methodology and reporting quality of reporting guidelines: systematic review. BMC Med Res Methodol 15:74
11. Black N, Murphy M, Lamping D, McKee M, Sanderson C, Askham J, Marteau T (1999) Consensus development methods: a review of best practice in creating clinical guidelines. J Health Serv Res Policy 4:236–248
12. Mesinger S, Heck K, Crispin A, Frankenberger R, Cadenaro M, Burgess J, Peschke A, Heintze SD, Loomans B, Opdam N, Hickel R, Kühnisch J (2022) Evaluation of direct restorations using the revised FDI criteria – results from a reliability study. Clin Oral Investig. https://doi.org/10.1007/s00784-022-04771-9
13. Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, Pitkin R, Rennie D, Schulz KF, Simel D, Stroup DF (1996) Improving the quality of reporting of randomized controlled trials. The CONSORT statement. JAMA 276(8):637–639
14. Schulz KF, Altman DG, Moher D (2010) CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMC Med 340:c332
15. ASA - American Society of Anesthesiologists (2014) ASA physical status classification system. https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system. Accessed 7 Dec 2022
16. Quigley GA, Hein JW (1962) Comparative cleansing efficiency of manual and power brushing. J Am Dent Assoc 65:26–29
17. Silness J, Löe H (1964) Periodontal disease in pregnancy II. Correlation between oral hygiene and periodontal condition. Acta OdontolScand 22:121–135
18. Löe H (1967) The gingival index, the plaque index and the retention index systems. J Periodontol 38(Suppl):610–616
19. Löe H, Silness J (1963) Periodontal disease in pregnancy I. prevalence and severity. Acta OdontolScand 22:533–551
20. Mühlemann HR, Son S (1971) Gingival sulcus bleeding–a leading symptom in initial gingivitis. HelvOdontol Acta 15:107–113
21. Newbrun E (1996) Indices to measure gingival bleeding. J Periodontol 67:555–561

22. Caton JG, Armitage G, Berglundh T, Chapple ILC, Jepsen S, Kornman KS, Mealey BL, Papapanou PN, Sanz M, Tonetti MS (2018) A new classification scheme for periodontal and peri-implant diseases and conditions - introduction and key changes from the 1999 classification. J Periodontol 89(Suppl 1):S1–S8
23. Cutress TW, Ainamo J, Sardo-Infirri J (1987) The community periodontal index of treatment needs (CPITN) procedure for population groups and individuals. Int Dent J 37:222–233
24. van der Weijden GA, Timmerman MF, Nijboer A, Reijerse E, van der Velden U (1994) Comparison of different approaches to assess bleeding on probing as indicators of gingivitis. J Clin Periodontol 21:589–594
25. Reibel J, Gale J, Hille J. Hunt JL, Lingen M, Muller S, Willams MD (2017) Oral potentially malignant disorders and oral epithelial dysplasia. In: El-Naggar AK, Chan JK, Grandis JR, Takata T, Slootweg PJ. WHO Classification of Head and Neck Tumors. (4th edition). IARC: Lyon 2017
26. WHO - World Health Organization (2013) Oral health surveys: basic methods –, 5th edn. WHO, Geneva, Switzerland
27. Pitts NB (2009) Implementation. Improving caries detection, assessment, diagnosis and monitoring. Monogr Oral Sci 21:199–208
28. Kühnisch J, Goddon I, Berger S, Senkel H, Bücher K, Oehme T, Hickel R, Heinrich-Weltzien R (2009) Development, methodology and potential of the new Universal Visual Scoring System (UniViSS) for caries detection and diagnosis. Int J Environ Res Public Health 6:2500–2509
29. Kühnisch J, Bücher K, Henschel V, Albrecht A, Garcia-Godoy F, Mansmann U, Hickel R, Heinrich-Weltzien R (2011) Diagnostic performance of the universal visual scoring system (UniViSS) on occlusal surfaces. Clin Oral Investig 15:215–223
30. Bartlett D, Ganss C, Lussi A, Basic Erosive Wear Examination (BEWE) (2008) A new scoring system for scientific and clinical needs. Clin Oral Investig 12(Suppl 1):S65–S68
31. Donachie MA, Walls AWG (1996) The tooth wear index: a flawed epidemiological tool in an aging population group. Community Dent Oral Epidemiol 24:152–158
32. Kahler W (2008) The cracked tooth conundrum: terminology, classification, diagnosis, and management. Am J Dent 21:275–282
33. Lygidakis NA, Wong F, Jälevik B, Vierrou AM, Alaluusua S, Espelid I (2010) Best clinical practice guidance for clinicians dealing with children presenting with molar-incisor-hypomineralisation (MIH): an EAPD policy document. Eur Arch Paediatr Dent 11:75–81
34. Thylstrup A, Fejerskov O (1978) Clinical appearance of dental fluorosis in permanent teeth in relation to histologic changes. Community Dent Oral Epidemiol 6:315–328
35. Bourguignon C, Cohenca N, Lauridsen E, Flores MT, O'Connell AC, Day PF, Tsilingaridis G, Abbott PV, Fouad AF, Hicks L, Andreasen JO, Cehreli ZC, Harlamb S, Kahler B, Oginni A, Semper M, Levin L (2020) International Association of Dental Traumatology guidelines for the management of traumatic dental injuries: 1. Fractures luxations Dent Traumatol 36:314–330
36. Matthews DE, Farewell VT (2015) Using and understanding medical statistics, 5th edn. Karger, Basel, Switzerland
37. Opdam NJM, Loomans BAC, Roeters FJM, Bronkhorst EM (2004) Five-year clinical performance of posterior resin composite restorations placed by dental students. J Dent 32:379–383
38. Burke FJT, Singh V, Wilson NHF (2013) The normalized failure index: a method for summarizing the results of studies on restoration longevity? Oper Dent 38:488–496
39. Mantel N (1966) Evaluation of survival data and two new rank order statistics arising in its consideration. Cancer Chemother Rep 50:163–170
40. Peto R, Peto J (1972) Asymptotically efficient rank invariant test procedures. J Royal StatistSoc, Series A 135:185–207
41. Heintze SD, RoussonV, (2012) Clinical effectiveness of direct class II restorations - a meta-analysis. J Adhes Dent 14:407–431
42 Heintze SD, Loguercio AD, Hanzen TA, Reis A, Rousson V (2022) Clinical efficacy of resin-based and glass-ionomers restorations – an updated meta-analysis of clinical outcome parameters. Dent Mater 38:e109–e135
43. Opdam NJ, van de Sande FH, Bronkhorst E, Cenci MS, Bottenberg P, Pallesen U, Gaengler P, Lindberg A, Huysmans MC, van Dijken JW (2014) Longevity of posterior composite restorations: a systematic review and meta-analysis. J Dent Res 93:943–949
44. Demarco FF, Collares K, Coelho-de-Souza FH, Correa MB, Cenci MS, Moraes RR, Opdam NJ (2015) Anterior composite restorations: a systematic review on long-term survival and reasons for failure. Dent Mater 31:1214–1224
45. Sailer I, Strasding M, Valente NA, Zwahlen M, Liu S, Pjetursson BE (2018) A systematic review of the survival and complication rates of zirconia-ceramic and metal-ceramic multiple-unit fixed dental prostheses. Clin Oral Implants Res 29(Suppl 16):184–198
46. Pjetursson BE, Valente NA, Strasding M, Zwahlen M, Liu S, Sailer I (2018) A systematic review of the survival and complication rates of zirconia-ceramic and metal-ceramic single crowns. Clin Oral Implants Res 29(Suppl 16):199–214
47. Hayashi M, WilsonNH, (2003) Marginal deterioration as a predictor of failure of a posterior composite. Eur J Oral Sci 111:155–162
48. Kidd EA, Joyston-Bechal S, Beighton D (1995) Marginal ditching and staining as a predictor of secondary caries around amalgam restorations: a clinical and microbiological study. J Dent Res 74:1206–1211
49. Opdam NJ, Roeters FJ, Feilzer AJ, Verdonschot EH (1998) Marginal integrity and postoperative sensitivity in class 2 resin composite restorations in vivo. J Dent 26:555–562
50. Opdam NJ, Roeters FJ, Feilzer AJ, Smale I (1998) A radiographic and scanning electron microscopic study of approximal margins of class II resin composite restorations placed in vivo. J Dent 26:319–327
51. Peumans M, Van Meerbeek B, Asscherickx K, Simon S, Abe Y, Lambrechts P, Vanherle G (2001) Do condensable composites help to achieve better proximal contacts? Dent Mater 17:533–541
52. Joshi K, Baiju CS, Khashu H, Bansal S, Maheswari IB (2017) Clinical assessment of interdental papilla competency parameters in the esthetic zone. J EsthetRestor Dent 29:270–275
53. KolteAP KRA, Bawankar P (2018) Proximal contact areas of maxillary anterior teeth and their influence on interdental papilla. Saudi Dent J30:324–329
54. Loomans BA, Opdam NJ, Roeters FJ, Bronkhorst EM, Burgersdijk RC, Dörfer CE (2006) A randomized clinical trial on proximal contacts of posterior composites. J Dent 34:292–297
55. Nelson SJ (2014) Wheeler's dental anatomy, physiology and occlusion-e-book. St.Louis, Missouri, USA: Elsevier Saunders
56. Frese C, Staehle HJ, Wolff D (2012) The assessment of dentofacial esthetics in restorative dentistry: a review of the literature. J Am Dent Assoc 143:461–466
57. Clark GT, Tsukiyama Y, Baba K, Watanabe T (1999) Sixty-eight years of experimental occlusal interference studies: what have we learned? J Prosthet Dent 82:704–713
58. Joshi K, Baiju CS, Khashu H, Bansal S, Maheswari IB (1998) The effect of light premature occlusal contact on tooth pain threshold in humans. J Oral Rehabil 25:589–595

59. Bertolini MM, Del Bel Cury AA, Pizzoloto L, Acapa IRH, Shibli JA, Bordin D (2019) Does traumatic occlusal forces lead to peri-implant bone loss? Systematic review. Braz Oral Res 33(Suppl 1):e069
60. Ishigaki S, Kurozumi T, Morishige E, Yatani H (2006) Occlusal interference during mastication can cause pathological tooth mobility. J Periodontal Res 41:189–192
61. Sheridan RA, Decker AM, Plonka AB, Wang HL (2016) The role of occlusion in implant therapy: a comprehensive updated review. Implant Dent 25:829–838
62. Koyano K, Esaki D (2015) Occlusion on oral implants: current clinical guidelines. J Oral Rehabil 42:153–161
63. Kim Y, Oh TJ, Misch CE, Wang HL (2005) Occlusal considerations in implant therapy: clinical guidelines with biomechanical rationale. Clin Oral Implants Res 16:26–35
64. Carvalho TS, Colon P, Ganss C, Huysmans MC, Lussi A, Schlueter N, Schmalz G, Shellis PR, BjörgTveit A, Wiegand A (2016) Consensus report of the European Federation of Conservative Dentistry: erosive tooth wear – diagnosis and management. Swiss Dent J126:342–346
65. Ning K, Bronkhorst E, Bremers A, Bronkhorst H, van der Meer W, Yang F, Leeuwenburgh S, Loomans B (2021) Wear behavior of a microhybrid composite vs. a nanocomposite in the treatment of severe tooth wear patients: a 5-year clinical study. Dent Mater 37:1819–1827
66. O'Toole S, Bartlett D, Keeling A, McBride J, Bernabe E, Crins L, Loomans B (2020) Influence of scanner precision and analysis software in quantifying three-dimensional intraoral changes: two-factor factorial experimental design. J Med Internet Res 22:e17150
67. Esquivel-Upshaw JF, Hsu SM, Bohórquez AC, Abdulhameed N, Scheiffele GW, Kim M, Neal D, Chai J, Ren F (2020) Novel methodology for measuring intraoral wear in enamel and dental restorative materials. Clin Exp Dent Res 6:677–685
68. Machiulskiene V, Campus G, Carvalho JC, Dige I, Ekstrand KR, Jablonski-Momeni A, Maltz M, Manton DJ, Martignon S, Martinez-Mier EA, Pitts NB, Schulte AG, Splieth CH, Tenuta LMA, Ferreira Zandona A, Nyvad B (2020) Terminology of dental caries and dental caries management: consensus report of a workshop organized by ORCA and cariology research group of IADR. Caries Res 54:7–14
69. World Health Organization (WHO) (2013) Oral health surveys: basic methods (5th edition). Geneva, Switzerland: WHO
70. Pitts NB (2009) How the detection, assessment, diagnosis and monitoring of caries integrate with personalized caries management. Monogr Oral Sci 21:1–14
71. Schwendicke F, Splieth C, Breschi L, Banerjee A, Fontana M, Paris S, Burrow MF, Crombie F, Page LF, Gatón-Hernández P, Giacaman R, Gugnani N, Hickel R, Jordan RA, Leal S, Lo E, Tassery H, Thomson WM, Manton DJ (2019) When to intervene in the caries process? An expert Delphi consensus statement. Clin Oral Investig 23:3691–3703
72. Bernabe E, Marcenes W, Hernandez CR, Bailey J, Abreu LG, Alipour V, Amini S, Arabloo J, Arefi Z, Arora A, Ayanore MA, Bärnighausen TW, Bijani A, Cho DY, Chu DT, Crowe CS, Demoz GT, Demsie DG, DibajiForooshani ZS, Du M, El Tantawi M, Fischer F, Folayan MO, Futran ND, Geramo YCD, Haj-Mirzaian A, Hariyani N, Hasanzadeh A, Hassanipour S, Hay SI, Hole MK, Hostiuc S, Ilic MD, James SL, Kalhor R, Kemmer L, Keramati M, Khader YS, Kisa S, Kisa A, Koyanagi A, Lalloo R, Le Nguyen Q, London SD, Manohar ND, Massenburg BB, Mathur MR, Meles HG, Mestrovic T, Mohammadian-Hafshejani A, Mohammadpourhodki R, Mokdad AH, Morrison SD, Nazari J, Nguyen TH, Nguyen CT, Nixon MR, Olagunju TO, Pakshir K, Pathak M, Rabiee N, Rafiei A, Ramezanzadeh K, Rios-Blancas MJ, Roro EM, Sabour S, Samy AM, Sawhney M, Schwendicke F, Shaahmadi F, Shaikh MA, Stein C, Tovani-Palone MR, Tran BX, Unnikrishnan B, Vu GT, Vukovic A, Warouw TSS, Zaidi Z, Zhang ZJ, Kassebaum NJ GBD 2017 Oral Disorders Collaborators, GBD 2017 Oral Disorders Collaborators (2020) Global, regional, and national levels and trends in burden of oral conditions from 1990 to 2017: a systematic analysis for the Global Burden of Disease 2017 Study. J Dent Res 99:362–373
73. Global Burden of Disease Study 2013 Collaborators (2015) Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet 386:743–800
74. Kassebaum NJ, Bernabé E, Dahiya M, Bhandari B, Murray CJ, Marcenes W (2015) Global burden of untreated caries: a systematic review and metaregression. J Dent Res 94:650–658
75. Askar H, Krois J, Göstemeyer G, Bottenberg P, Zero D, Banerjee A, Schwendicke F (2020) Secondary caries: what is it, and how it can be controlled, detected, and managed? Clin Oral Investig 24:1869–1876
76. Mjör IA, Toffenetti F (2000) Secondary caries: a literature review with case reports. Quintessence Int 31:165–179
77. Mjör IA (2005) Clinical diagnosis of recurrent caries. J Am Dent Assoc 136:1426–1433
78. Kidd EA, Beighton D (1996) Prediction of secondary caries around tooth-colored restorations: a clinical and microbiological study. J Dent Res 75:1942–1946
79. Heintze SD, Rousson V, Hickel R (2015) Clinical effectiveness of direct anterior restorations - a meta-analysis. Dent Mater 31:481–495
80. Kuper NK, Opdam NJ, Ruben JL, de Soet JJ, Cenci MS, Bronkhorst EM, Huysmans MC (2014) Gap size and wall lesion development next to composite. J Dent Res 93(Suppl 7):108S-113S
81. Kuper NK, van de Sande FH, Opdam NJ, Bronkhorst EM, de Soet JJ, Cenci MS, Huysmans MC (2015) Restoration materials and secondary caries using an in vitro biofilm model. J Dent Res 94:62–68
82. Schwendicke F, Splieth CH, Bottenberg P, Breschi L, Campus G, Doméjean S, Ekstrand K, Giacaman RA, Haak R, Hannig M, Hickel R, Juric H, Lussi A, Machiulskiene V, Manton D, Jablonski-Momeni A, Opdam N, Paris S, Santamaria R, Tassery H, Zandona A, Zero D, Zimmer S, Banerjee A (2020) How to intervene in the caries process in adults: proximal and secondary caries? An EFCD-ORCA-DGZ expert Delphi consensus statement. Clin Oral Investig 24:3315–3321
83. Splieth CH, Kanzow P, Wiegand A, Schmoeckel J (2020) Jablonski-Momeni A (2020) How to intervene in the caries process: proximal caries in adolescents and adults-a systematic review and meta-analysis. Clin Oral Investig 24:1623–1636
84. Lynch CD, McConnell RJ (2002) The cracked tooth syndrome. J Can Dent Assoc 68:470–475
85. Del Monte S, Afrashtehfar KI, Emami E, Abi Nader S, Tamimi F (2017) Lay preferences for dentogingivalesthetic parameters: a systematic review. J Prosthet Dent 118:717–724
86. Blatz MB, Chiche G, Bahat O, Roblee R, Coachman C, Heymann HO (2019) Evolution of aesthetic dentistry. J Dent Res 98:1294–1304
87. Kakaboura A, Fragouli M, Rahiotis C, Silikas N (2007) Evaluation of surface characteristics of dental composites using profilometry, scanning electron, atomic force microscopy and glossmeter. J Mater Sci Mater Med 18:155–163
88. Dietz W, Montag R, Kraft U, Walther M, Sigusch BW, Gaengler P (2014) Longitudinal micromorphological 15-year results of posterior composite restorations using three-dimensional scanning electron microscopy. J Dent 42:959–969
89. Philpotts CJ, Cariddi E, Spradbery PS, Joiner A (2017) In vitro evaluation of a silica whitening toothpaste containing blue covarine on the colour of teeth containing anterior restoration materials. J Dent 67(Suppl):S29–S33

90. Prskalo K, Klarić Sever E, Alcrić I, AntonićJelić T, Žaja I (2017) Risk factors associated with black tooth stain. Acta Clin Croat 56:28–35
91. Ronay V, Attin T (2011) Black stain - a review. Oral Health Prev Dent 9:37–45
92. Heinrich-Weltzien R, Bartsch B, Eick S (2014) Dental caries and microbiota in children with black stain and non-discoloured dental plaque. Caries Res 48:118–125
93. Tripodi D, Martinelli D, Pasini M, Giuca MR, D'Ercole S (2016) Black stains: a microbiological analysis and a view on familiarity and susceptibility to tooth decay of patients in childhood. Eur J Paediatr Dent 17:261–266
94. Gresnigt MM, Kalk W, Ozcan M (2013) Randomized clinical trial of indirect resin composite and ceramic veneers: up to 3-year follow-up. J Adhes Dent 15:181–190
95 Khoroushi M, Karvandi TM, Kamali B, Mazaheri H (2012) Marginal microleakage of resin-modified glass-ionomer and composite resin restorations: effect of using etch-and-rinse and self-etch adhesives. Ind J Dent Res 23:378–83
96. Baracco B, Fuentes MV, Ceballos L (2016) Five-year clinical performance of a silorane- vs a methacrylate-based composite combined with two different adhesive approaches. Clin Oral Investig 20:991–1001
97. Coelho-De-Souza FH, Camargo JC, Beskow T, Balestrin MD, Klein-Júnior CA, Demarco FF (2012) A randomized double-blind clinical trial of posterior composite restorations with or without bevel: 1-year follow-up. J Appl Oral Sci 20:174–179
98. Swanson TK, Feigal RJ, Tantbirojn D, Hodges JS (2008) Effect of adhesive systems and bevel on enamel margin integrity in primary and permanent teeth. Pediatr Dent 30:134–140
99. Hayashi M, Tsuchitani Y, Kawamura Y, Miura M, Takeshige F, Ebisu S (2000) Eight-year clinical evaluation of fired ceramic inlays. Oper Dent 25:473–481
100. Joiner A (2004) Tooth colour: A review of the literature. J Dent 32(Suppl 1):3–12
101. Dinç Ata G, Gokay O, Müjdeci A, Kivrak TC, Mokhtari Tavana A (2017) Effect of various teas on color stability of resin composites. Am J Dent 30:323–328
102. Quek SHQ, Yap AUJ, Rosa V, Tan KBC, Teoh KH (2018) Effect of staining beverages on color and translucency of CAD/CAM composites. J Esthet Restor Dent 30:e9–e17
103. Palla ES, Kontonasaki E, Kantiranis N, Papadopoulou L, Zorba T, Paraskevopoulos KM, Koidis P (2018) Color stability of lithium disilicate ceramics after aging and immersion in common beverages. J Prosthet Dent 119:632–642
104. Duc O, Di Bella E, Krejci I, Betrisey E, Abdelaziz M, Ardu S (2019) Staining susceptibility of resin composite materials. Am J Dent 32:39–42
105. Yang X, Le D, Zhang YL, Liang LZ, Yang G, Hu WJ (2016) Relationship between crown form of upper central incisors and papilla filling in Chinese Han-nationality youth. Beijing Da XueXue Bao Yi Xue Ban 48:866–870
106. Jackson TH, Kirk CJ, Phillips C, Koroluk LD (2019) Diagnostic accuracy of intraoral photographic orthodontic records. J Esthet Restor Dent 31:64–71
107. Zenthöfer A, Cabrera T, Corcodel N, Rammelsberg P, Hassel AJ (2014) Comparison of the Easyshade Compact and Advance in vitro and in vivo. Clin Oral Investig 18:1473–1479
108. Klotz AL, Habibi Y, Corcodel N, Rammelsberg P, Hassel AJ, Zenthöfer A (2022) Laboratory and clinical reliability of two spectrophotometers. J Esthet Restor Dent 34:369–373
109. Joiner A, Luo W (2017) Tooth colour and whiteness: a review. J Dent 67(Suppl):S3–S10
110. Wong DL, Baker CM (1988) Pain in children: comparison of assessment scales. PediatrNurs 14:9–17
111. EC - European Commission (2015) Radiation protection. No 180. Medical radiation exposure of the European population. Luxembourg: Publications Office of the European Union, 2015. https://op.europa.eu/en/publication-detail/-/publication/d2c4b535-1d96-4d8c-b715-2d03fc927fc9. Accessed 7 Dec 2022
112. Valentin J (ed.) (2007) The 2007 recommendations of the International Commission on Radiological Protection. ICRP publication 103. Ann ICRP 2007. https://www.icrp.org/publication.asp?id=ICRP%20Publication%20103. Accessed 7 Dec 2022
113. Kühnisch J, Anttonen V, Duggal MS, Loizides MS, Rajasekharan S, Sobczak M, Stratigaki E, Van Acker JWG, Aps JKM, Horner K, Tsiklakis K (2020) EAPD best clinical practice guidance for prescribing dental radiographs in children and adolescents. An EAPD policy document. Eur Arch Paediatr Dent 21:375–386
114. Van Acker JWG, Pauwels NS, Cauwels RGEC, Rajasekharan S (2020) Outcomes of different radioprotective precautions in children undergoing dental radiography: a systematic review. Eur Arch Paediatr Dent 21:463–508
115. White SC, Heslop EW, Hollender LG, Mosier KM, Ruprecht A, Shrout MK, American Academy of Oral and Maxillofacial Radiology, ad hoc Committee on Parameters of Care (2001) Parameters of radiologic care: an official report of the American Academy of Oral and Maxillofacial Radiology. Oral Surg Oral Med Oral Pathol Oral RadiolEndod 91:498–511
116. Oenning AC, Jacobs R, Pauwels R, Stratis A, Hedesiu M, Salmon B, DIMITRA Research group (2018) Cone-beam CT in paediatric dentistry: DIMITRA project position statement. PediatrRadiol 48:308–316
117. Jacobs R, Salmon B, Codari M, Hassan B, Bornstein MM (2018) Cone beam computed tomography in implant dentistry: recommendations for clinical use. BMC Oral Health 18:88
118. Wilson N, Lynch CD, Brunton PA, Hickel R, Meyer-Lueckel H, Gurgan S, Pallesen U, Shearer AC, Tarle Z, Cotti E, Vanherle G, Opdam N (2016) Criteria for the replacement of restorations: Academy of Operative Dentistry European Section. Oper Dent 41(Suppl7):S48–S57

10. Literaturverzeichnis

1. Mesinger S, Heck K, Crispin A, Frankenberger R, Cadenaro M, Burgess J, Peschke A, Heintze SD, Loomans B, Opdam N, Hickel R, Kühnisch J. Evaluation of direct restorations using the revised FDI criteria: results from a reliability study. Clin Oral Investig. 2022 Nov 18. doi: 10.1007/s00784-022-04771-9. Epub ahead of print. PMID: 36399211.
2. Cvar JF (1971) Ryge G (2005) Reprint of criteria for the clinical evaluation of dental restorative materials. Clin Oral Investig 9(4):215–32. https://doi.org/10.1007/s00784-005-0018-z 2.
3. Bayne S, Schmalz G (2005) Reprinting the classic article on USPHS evaluation methods for measuring the clinical research performance of restorative materials. Clin Oral Investig 9:109–214 3.
4. Ryge G (1980) Clinical criteria. Int Dent J 30(4):347–358
5. Hickel R, Roulet JF, Bayne S, Heintze SD, Mjor IA, Peters M, Rousson V, Randall R, Schmalz G, Tyas M, Vanherle G (2007) Recommendations for conducting controlled clinical studies of dental restorative materials. Science Committee Project 2/98-- FDI World Dental Federation study design (Part I) and criteria for evaluation (Part II) of direct and indirect restorations including onlays and partial crowns. J Adhes Dent 9(Suppl 1):121–147
6. Hickel R, Roulet JF, Bayne S, Heintze SD, Mjor IA, Peters M, Rousson V, Randall R, Schmalz G, Tyas M, Vanherle G (2007) Recommendations for conducting controlled clinical studies of dental restorative materials. Clin Oral Investig 11(1):5–33. https:// doi.org/10.1007/s00784-006-0095-7
7. Hickel R, Peschke A, Tyas M, Mjor I, Bayne S, Peters M, Hiller KA, Randall R, Vanherle G, Heintze SD (2010) FDI World Dental Federation — clinical criteria for the evaluation of direct and indirect restorations Update and clinical examples. J Adhes Dent 12(4):259–72. https://doi.org/10.3290/j.jad.a19262
8. Hickel R, Peschke A, Tyas M, Mjor I, Bayne S, Peters M, Hiller KA, Randall R, Vanherle G, Heintze SD (2010) FDI World Dental Federation: clinical criteria for the evaluation of direct and indirect restorations-update and clinical examples. Clin Oral Investig 14(4):349–366. https://doi.org/10.1007/s00784-010-0432
9. Marquillier T, Domejean S, Le Clerc J, Chemla F, Gritsch K, Maurin JC, Millet P, Perard M, Grosgogeat B, Dursun E (2018) The use of FDI criteria in clinical trials on direct dental restorations: a scoping review. J Dent 68:1–9. https://doi.org/10.1016/j. jdent.2017.10.007
10. Kim D, Ahn SY, Kim J, Park SH (2017) Interrater and intrarater reliability of FDI criteria applied to photographs of posterior tooth-coloured restorations. J Prosthet Dent 118(1):18-25.e4. https://doi.org/10.1016/j.prosdent.2016.10.004
11. Murphy M, Black N, Lamping D, McKee C, Sanderson C, Askham J, Marteau T (1998) Consensus development methods, and their use in clinical guideline development. Health Technol Assess, 2(3): p. i-iv, 1-88.
12. Light RJ (1971) Measures of response agreement for qualitative data: some generalizations and alternatives. Psychol Bull 76(5):365–377. https://doi.org/10.1037/h0031643
13. Hallgreen KA (2012) Computing inter-rater reliability for observational data: an overview and tutorial. Tutor Quant Methods Psychol 8(1):23–34. https://doi.org/10.20982/tqmp.08.1.p023 15.
14. Bland JM, Altman DG (1986) Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1(8476):307–310 17.

15. Bland JM, Altman DG (1990) A note on the use of the intraclass correlation coefcient in the evaluation of agreement between two methods of measurement. Comput Biol Med 20(5):337–340. https://doi.org/10.1016/0010-4825(90)90013-f
16. Paravina RD, Pérez MM, Ghinea R (2019) Acceptability and perceptibility thresholds in dentistry: a comprehensive review of clinical and research applications. J Esthet Restor Dent 31(2):103– 112. https://doi.org/10.1111/jerd.12465
17. Moncada G, Silva F, Angel P, Oliveira OB Jr, Fresno MC, Cisternas P, Fernandez E, Estay J, Martin J (2014) Evaluation of dental restorations: a comparative study between clinical and digital photographic assessments. Oper Dent 39(2):E45-56. https://doi.org/ 10.2341/12-339-c
18. Erten H, Uçtasli MB, Akarslan ZZ, Uzun O, Semiz M (2006) Restorative treatment decision making with unaided visual examination, intraoral camera and operating microscope. Oper Dent 31(1):55–59. https://doi.org/10.2341/04-173
19. Black N, Murphy M, Lamping D, McKee M, Sanderson C, Askham J, Marteau T (1999) Consensus development methods: A review of best practice in creating clinical guidelines. J Health Serv Res Policy 4:236-248
20. Signori C, Collares K, Cumerlato CBF, Correa MB, Opdam NJM, Cenci MS (2018) Validation of assessment of intraoral digital photography for evaluation of dental restorations in clinical research. J Dent 71:54–60. https://doi.org/10.1016/j.jdent.2018.02.001
21. de Almeida Cvvb, Pintado-Palomino K, Fortes JHP, da Motta RJG, de Freitas BN, Matsumoto W, de Oliveira Cavalcanti MTM, Alves J, Tirapelli C (2020) Digital photography vs. clinical assessment of resin composite restorations. Odontology https://doi.org/ 10.1007/s10266-020-00511-1

Danksagung

Mein besonderer Dank gilt meinem Doktorvater Herrn Prof. Dr. Jan Kühnisch für seine Leitung, zuverlässige und kompetente Betreuung, sein geduldiges und ausdauerndes Engagement sowie der fachlichen Unterstützung meines Promotionsvorhabens.

Des Weiteren möchte ich dem Direktor Herrn Prof. Dr. Reinhard Hickel für die Möglichkeit danken, diese Arbeit an der Poliklinik für Zahnerhaltung und Parodontologie anfertigen zu können.

Mein großer Dank gilt weiterhin der gesamten Arbeitsgruppe und den Co-Autoren, namentlich PD Dr. Katrin Heck, Dr. Alexander Crispin, Prof. Dr. Roland Frankenberger, Prof. Milena Cadenaro, Prof. John Burgess, Dr. Arnd Peschke, Dr. Siegward D. Heintze, Prof. Dr. Bas Loomans, Dr. Niek Opdam, Prof. Dr. Reinhard Hickel sowie Prof. Dr. Jan Kühnisch. Es war mir eine Ehre, Teil dieser Arbeitsgruppe zu sein und am fachlichen Austausch teilhaben zu dürfen.

Frau Dr. Katrin Heck, Herrn Prof. Dr. Reinhard Hickel sowie Prof. Dr. Jan Kühnisch danke ich für die professionelle und angenehme Zusammenarbeit im Rahmen der statistischen Arbeitsphase und die konstruktive Kritik während des Veröffentlichungsprozesses.

Außerdem möchte ich mich besonders herzlich bei meinem Mann für seinen Zuspruch und die Unterstützung während des gesamten Promotionsvorhabens bedanken.