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ORIGINAL ARTICLE

FDI World Dental Federation: clinical criteria for the evaluation of direct and indirect restorations—update and clinical examples

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Abstract In 2007, new clinical criteria were approved by the FDI World Dental Federation and simultaneously published in three dental journals. The criteria were categorized into three groups: esthetic parameters (four criteria), functional parameters (six criteria) and biological parameters (six criteria). Each criterion can be expressed with five scores, three for acceptable and two for non-acceptable (one for reparable and one for replacement). The criteria have been used in several clinical studies since 2007, and the resulting experience in their application has led to a requirement to modify some of the criteria and scores. The two major alterations involve staining and approximal contacts. As staining of the margins and the surface has different causes, both phenomena do not appear simultaneously. Thus, staining has been differentiated into marginal staining and surface staining. The approximal contact now appears under the name "approximal anatomic form" as the approximal contour is a specific, often non-esthetic issue that cannot be integrated into the criterion "esthetic anatomical form". In 2008, a web-based training and calibration tool called *e-calib* (www.e-calib.info) was made available. Clinical investigators and other research workers can train and calibrate themselves interactively by assessing clinical cases of posterior restorations which are presented as high-quality pictures. Currently, about 300 clinical cases are included in the database which is regularly updated. Training for eight of the 16 clinical criteria is available in the program: "Surface lustre"; "Staining (surface, margins)"; "Color match and translucency"; Esthetic anatomical form"; "Fracture of material and retention"; "Marginal adaptation"; "Recurrence of caries, erosion, abfraction"; and "Tooth integrity (enamel cracks, tooth fractures)". Typical clinical cases are presented for each of these eight criteria and their corresponding five scores.

Keywords Study · *e-calib* · Calibration · Composite

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Introduction

In 2007, new clinical criteria for the evaluation of restorations were published in the Journal of Adhesive Dentistry [4] as well as Clinical Oral Investigations [3], and an extended abstract was published in the International Dental Journal [2]. The criteria and the grading were approved by the Science Committee of the FDI World Dental Federation in 2007 and in the General Assembly 2008 as "standard criteria" that should be applied when restorative materials and/or operative techniques are to be clinically investigated. Likewise, the criteria should be applied when patients are recruited for clinical trials to evaluate a new restorative material or operative technique, and the criteria for the replacement of old restorations by new restorations should be the same as for the evaluation of the replaced restorations. Furthermore, the clinical evaluation of restorations may be necessary and useful for quality assessment of restorations that are placed by general practitioners in their own practices. In addition the future dental students should be trained to use these criteria as part of a clinical examination to determine whether a restoration can be maintained or whether it needs refurbishment, repair or replacement.

The FDI criteria have been applied by several investigators since then; however, results have been only partly published so far. Some short-term results were published as abstracts at the International Association for Dental Research (IADR) meetings [1, 6, 7]. One study compared the FDI criteria and the traditional United States Public Health Service (USPHS; also known as 'Ryge criteria') criteria for the evaluation of restorations in deciduous teeth [6]. The authors concluded that the new FDI method was more sensitive for identifying differences in deciduous composite resin restorations.

It must be emphasized that the clinical relevance of the defined cut off values for subscores that are included in some of the criteria has yet to be verified in longitudinal clinical trials. Quantitative values are given for the width of marginal gaps, the tightness of approximal contact points and the amount of clinical wear.

It must also be stressed that many (ongoing) clinical studies still will use the USPHS criteria, and if they have begun the study with these criteria, they shall continue to use them for the entire period of the trial.

Since the publication of the FDI criteria, one workshop and two symposia have been held at international meetings to introduce and explain the new clinical criteria: IADR in Toronto (2008), IADR in Miami (2009) and ConsEuro in Seville (2009). Numerous clinical cases were shown and the grading discussed with the audience. During these meetings and also during the evaluation and grading of clinical cases by means of occlusal images, performed by four of the authors of this paper for the *e-calib* program (see below), some minor shortcomings of the criteria as originally published became apparent. As mentioned in the original publications, these criteria are a living document which should be improved from time to time. The objectives of the present paper are three-fold:

1. Presentation of the changes and improvements that have been made to the criteria since 2007
2. Presentation of clinical cases that should serve as illustrative examples for most of the criteria
3. Short presentation of a web-based training and calibration tool (www.*e-calib*.info).

e-calib

In the past, evaluators were trained and calibrated with photographs and slides [5]. In 2006, an online calibration system using USPHS criteria has been installed at the University of Michigan (www.dent.umich.edu/CER/) and was mentioned in the earlier publications [3, 4]. In July 2008, a tool called '*e-calib*' (electronic calibration) was put on the World Wide Web to facilitate both training and calibration of the new FDI criteria. The tool is based on the program "moodle" (www.moodle.com) and can be accessed via www.*e-calib*.info, located at the University of Munich (Firefox or Safari browsers are preferred; the XML Viewer has to be installed when Microsoft Internet Explorer is used). Use of the tool is free of charge; but anyone interested in the tool have to register and will receive an individual profile. One can train on a specific criterion or train all criteria on illustrated clinical cases. The cases are selected randomly from a database and only high-quality photographs are included. The answers given by the participant are checked by the system to see whether they match the grading given by a panel of four experts (see below). After completion of the clinical cases, the participant receives a report of the percentage of correct answers and can repeat the procedure to find areas of agreement and disagreement. Color-coded arrows and circles point to and highlight special items such as marginal discrepancies, marginal staining, enamel cracks or voids in the material. Different colors are used for the different criteria as one may train on all criteria on the same restoration. Alternatively, training can be done on a specific criterion on several clinical cases. Each training course is saved under the participant's individual profile and cannot be accessed by other participants or by the program administrators.

e-calib does not replace calibration of evaluation criteria on patients in a clinical setting, but may shorten the clinical calibration significantly. Special criteria such as evaluation of approximal contact areas, approximal excess of material and the periodontal or mucosal response to restorations can only be trained and calibrated on patients (Table 1). Furthermore, for verification of special clinical phenomena such as marginal gaps, dental instruments (e.g. probes) are necessary and may potentially cause damage. However, if research workers use *e-calib* to train themselves, clinical calibration programs may be less time-consuming and more efficient. We recommend that international calibration sessions and workshops should be held continuously at dental conferences and symposia not only with clinical pictures but also with restored extracted teeth. Web-based calibration programs, workshops and calibration courses on patients shall not only train the new criteria but shall also reduce the risk for premature replacement of restorations both in clinical trials and at dental faculties (e.g. student training courses).

The cases were selected by four experienced clinicians (R. Hickel, J.-F. Roulet, S.D. Heintze, A. Peschke) who agreed on each criterion for each case that was presented as a clinical picture. However, other clinicians may judge a restoration differently. There is a certain degree of subjectivity within each clinical assessment, and the chosen scores may be altered in *e-calib* if strong arguments are put forward by users. *e-calib* should be seen as an open forum to which everybody can contribute with comments and also clinical pictures.

The objectives of e-calib are:

- to efficiently train and calibrate clinical dental research workers using e-learning features
- to reduce the variability of the outcome of clinical trials on dental restorations using standardized assessment criteria
- to better compare the results of clinical trials on dental restorations between different centres in the world
- to render clinical calibration programs more efficient
- to improve student teaching
- to improve daily clinical practice
- to be used as a tool in the teaching at dental schools

e-calib will expand over time. Up to now, about 300 clinical cases of posterior approximal and occlusal resin composite and ceramic inlays/onlays are included into the database. In the future, carious and non-carious cervical restorations, approximal anterior restorations and incisal edge restorations will be put into the database. Amalgam and gold restorations will also be included as in many clinical trials, amalgam is replaced by resin composite without applying standardized criteria for amalgam replacement. Furthermore, there are still some randomized clinical trials which use amalgam as the 'control' or 'comparison' material.

Criteria

The evaluation of a restoration is categorized into three groups: esthetic, functional and biological criteria. Each group has subcategories, and the overall rating is determined by the

Table 1 The following criteria cannot be trained and calibrated by pictures of the occlusal aspect of posterior restorations:

II Functional properties	
7. Wear	Wear can only be reliably and correctly evaluated quantitatively on replicas such as 3D laser scanning and is recommended to do on replicas with an adequate scanning device and software. But also qualitative wear rating is of very limited on pictures.
8. Contact point/food impact	Approximal contact points have to be clinically evaluated with metal blades of standardized thicknesses (or less precisely with dental floss).
9. Radiographic examination	This criterion requires X-rays which will be added to the program in a later step.
10. Patient's view	This criterion requires the need of a structured interview with the patient on his/her satisfaction/dissatisfaction with the restoration.
III Biological properties	
11. Postoperative (hyper-)sensitivity and tooth vitality	This criterion can only be evaluated on the patient by means of a stimulus (e.g. by a blast of cold air or by dry ice).
14. Periodontal response	This criterion can only be evaluated on the patient by means of a periodontal probe and by comparing the reaction of the gingival tissues of the restored tooth and a control tooth.
15. Adjacent mucosa	This criterion can only be evaluated on the patient as a broad clinical inspection of the mucosa in the oral cavity is necessary.
16. Oral and general health	This criterion requires the need of a broad clinical inspection of the whole oral cavity and also the medical status and history of the patient.

subcategory scores, with the final score in each group being dictated by the most severe score among all the subscores. For example, if one property/category is unacceptable, the final, overall score of this restoration is also unacceptable. Therefore, when summarizing the three categories (esthetic, functional and biological) in one overall rating, the worst score prevails and gives the final score.

If a parameter is judged to be clinically unacceptable, then the exact reason for failure has to be recorded, and it must be decided whether the restoration can be repaired or requires replacement. Not all 'failures' lead to replacement of a restoration. Localized defects with sufficient clinical access can be repaired, e.g. sealing of gaps, adding new material to chipping fractures, partial removal and veneering of stained areas of the restorations, etc.

Repaired restorations are therefore scored as "relative failure" and replaced restorations as "absolute failure".

The decisive difference between scores 4 and 5 is not the need for an immediate or a later (some weeks) replacement of the restoration; but rather whether the restoration can be corrected/repaired or whether it has to be replaced completely. Most frequently, score 5 will show worse clinical results than score 4, but that is not inevitable. Score 4, and consequently the possibility for repair, depends more on the location and size of the defect and therefore whether it is accessible for repair or not.

Some examples of conditions suitable for repair are:

- Large marginal opening (>250 μm), or severe staining which is esthetically unacceptable, or secondary caries without deep undermining caries, if accessible
- Selective marginal preparation in the case of "caries adjacent to restorations" (CAR) or replacement of only one approximal box of an MOD restoration if cervical caries is present
- Chipping/partial fracture or marginal fracture of restorative material (repaired by incremental addition of material)
- Marginal breakdown of enamel or minor/localized cusp fracture (repaired by incremental addition of material)
- Filling of access cavity after endodontic treatment
- Amalgam restorations with accessible defects which can be repaired using adhesive techniques, such as bonded amalgam or composite
- Ceramic inlays or partial crowns with fractures and/or chipping which may be repaired by intraoral sandblasting/silication, silanization and composite bonding

A *repair* is a minimally invasive approach that implies the addition of restorative material after the defect is explored and determined not to be invasive with or without preparation in the material and/or dental hard tissues. *Refurbishment* is defined as a minimal intervention such as contouring or polishing or the application of glaze or adhesives with no new restorative material added. Based on these definitions, a restoration that requires repair should be considered as a (relative) failure. Repaired restorations should be monitored and evaluated as an integral part of the restoration.

To take into consideration the extent of a clinical defect or observation in relation to the entire restoration or to record the exact location of the defect, the SQUACE method (SemiQUAntitative Clinical Evaluation) is recommended [3, 4]. This is especially valuable for the criteria "marginal staining" (2.b), "fracture of material" (5), "marginal adaptation" (6) and "CAR" (12).

The overall rating for a particular restoration is determined after completion of the assessments of the final scores for esthetic, functional and biological properties. The most severe score will prevail. A description of the criteria and grading is presented in table 2. Whenever a restoration receives a score of 4 or 5 independent of the specific criteria below, it must be recorded as a failure, but not all failures call for replacement of the entire restoration.

A simplified clinical evaluation may be appropriate for a variety of reasons, e.g. it is possible to pool scores 1 and 2 (equivalent to USPHS/Ryge score A), resulting in four different scores (two acceptable and two unacceptable), or even to combine scores 1, 2 and 3 to only one acceptable score and additionally two or one (merged scores 4 and 5) unacceptable score.

Furthermore, there is no need to apply all of the 16 criteria in each study. Before starting a clinical study, the primary and secondary goals have to be defined and the investigator has to determine which criteria should be used for the intended purpose. If, for example, a new esthetic resin composite material is to be evaluated, special emphasis should be put on the criteria that comprise the esthetic category. On the other hand, if a material that has only one shade for use in non-visible areas (e.g. molars), the criterion "color match" can be dropped as esthetic issues are of low interest compared with anterior restorations.

Changes and improvements of criteria since 2007

In the following, only the criteria that have been modified since the 2007 publication are presented and explained. Photographs for the scores of each criterion are only provided for those criteria that can be trained with the *e-calib* tool. If the criterion can be trained with *e-calib*, it is mentioned in parenthesis. The reasons for the other criteria not being included are listed in table 1.

A. Esthetic properties

1. Surface gloss/lustre and roughness (*e-calib*)

The subscores 'isolated pores' (1.2.2) and 'multiple pores' (1.3.2) have been added as these phenomena cannot only be described by a dull surface but can also affect the texture of the

Table 2 FDI criteria and gradings

Clinical investigation ……..
ID patient / restoration ……..
Date (dd /mm/yy): Baseline……. 1. Recall …….. 2. Recall…… 3. Recall…… 4. Recall……..... 5. Recall……...
Photographs (n° and date) : ……... …
Replica (n° and date): ……..

A. Esthetic properties	**1. Surface lustre**	**2. Staining** **a. surface b. margin**	**3. Color match and translucency**	**4. Esthetic anatomical form**
1. Clinically excellent / very good	1.1 Lustre comparable to enamel.	2a.1 No surface staining. 2b.1 No marginal staining.	3.1 Good color match, no difference in shade and/or translucency.	4.1 Form is ideal.
2. Clinically good (after polishing probably very good)	1.2.1 Slightly dull, not noticeable from speaking distance. 1.2.2 Some isolated pores.	2a.2 Minor surface staining, easily removable by polishing. 2b.2 Minor marginal staining, easily removable by polishing.	3.2 Minor deviations in shade and/or translucency	4.2 Form is only slightly deviated from the normal.
3. Clinically sufficient / satisfactory (minor shortcomings, no unacceptable effects but not adjustable w/o damage to the tooth)	1.3.1 Dull surface but acceptable if covered with film of saliva. 1.3.2 Multiple pores on more than one third of the surface.	2a.3 Moderate surface staining that may also present on other teeth, not esthetically unacceptable. 2b.3 Moderate marginal staining, not esthetically unacceptable.	3.3 Distinct deviation but acceptable. Does not affect esthetics: 3.3.1 more opaque 3.3.2 more translucent 3.3.3 darker 3.3.4 brighter	4.3 Form deviates from the normal but is esthetically acceptable.
4. Clinically unsatisfactory (but reparable)	1.4.1 Rough surface, cannot be masked by saliva film, simple polishing is not sufficient. Further intervention necessary. 1.4.2 Voids.	2a.4 Unacceptable surface staining on the restoration and major intervention necessary for improvement. 2b.4 Pronounced marginal staining; major intervention necessary for improvement.	3.4 Localized clinically deviation that can be corrected by repair: 3.4.1 too opaque. 3.4.2 too translucent. 3.4.3 too dark. 3.4.4 too bright.	4.4. Form is affected and unacceptable esthetically. Intervention/correction is necessary.
5. Clinically poor (replacement necessary)	1.5 Very rough, unacceptable plaque retentive surface.	2a.5 Severe surface staining and/or subsurface staining, generalized or localized, not accessible for intervention. 2b.5 Deep marginal staining, not accessible for intervention.	3.5 Unacceptable. Replacement necessary.	4.5 Form is unsatisfactory and/or lost. Repair not feasible / reasonable, Replacement needed.
Overall esthetic score	Acceptable esthetically (n and %):		Not acceptable (n, % and reasons):	

Table 2 (continued)

B. Functional properties	5. Fracture of material and retention	6. Marginal adaptation	7. Occlusal contour and wear a) qualitatively b) quantitatively	8. Approximal anatomical form a. contact point b. contour	9. Radiographic examination (when applicable)	10. Patient's view
1. Clinically excellent / very good	5.1 No fractures / cracks.	6.1 Harmonious outline, no gaps, no white or discolored lines	7a.1 Physiological wear equivalent of enamel. 7b.1Wear corresponding to 80-120% of enamel.	8a.1 Normal contact point (floss or 25 µm metal blade can pass) 8b.1 Normal contour.	9.1 No pathology, harmonious transition between restoration and tooth.	10.1 Entirely satisfied with esthetics and function.
2. Clinically good	5.2 Small hairline crack.	6.2.1 Marginal gap (<150 µm), white lines. 6.2.2 Small marginal fracture removable by polishing. 6.2.3 Slight ditching, slight step/flashes, minor irregularities.	7a.2 Normal wear only slightly different from that to enamel. 7b.2 50-80% or 120-150 % wear compared to that of corresponding enamel.	8a.2. Contact slightly too strong but no disadvantage (floss or 25 µm metal blade can only pass with pressure). 8b.2 Slightly deficient contour.	9.2.1 Acceptable material excess present. 9.2.2 Positive/negative step present at margin <150 µm.	10.2 Satisfied. 10.2.1 Esthetics. 10.2.2 Function, e.g., minor roughness
3. Clinically sufficient / satisfactory (minor shortcomings, no unacceptable effects but not adjustable w/o damage to the tooth)	5.3 Two or more or larger hairline cracks and/or material chip fracture not affecting the marginal integrity or approximal contact.	6.3.1 Gap < 250 µm not removable. 6.3.2. Several small marginal fractures. 6.3.3 Major irregularities, ditching or flash, steps.	7a.3 Different wear rate than enamel but within the biological variation. 7b.3 < 50 % or 150-300 % of corresponding enamel	8a.3. Somewhat weak contact, no indication of damage to tooth, gingiva or periodontal structures; 50 µm metal blade can pass 8b.3 Visible deficient contour	9. 3. 1 Marginal gap < 250 µm. 9. 3. 2 Negative steps visible < 250 µm. No adverse effects noticed. 9.3.3 Poor radiopacity of filling material.	10.3 Minor criticism but no adverse clinical effects. 10.3.1 Esthetic shortcomings. 10.3.2 Some lack of chewing comfort. 10.3.3 Unpleasant treatment procedure.
4. Clinically unsatisfactory / (but reparable)	5.4.1 Material chip fractures which damage marginal quality or	6.4.1 Gap > 250 µm or dentine/base exposed. 6.4.2. Severe	7a.4 Wear considerably exceeds normal enamel wear; or	8a.4 Too weak and possible damage due to food impaction;	9.4.1 Marginal gap >250 µm. 9.4.2 Material excess accessible	10.4 Desire for improvement 10.4.1 Esthetics. 10.4.2 Function, e.g.,
	approximal contacts. 5.4.2 Bulk fractures with partial loss (less than half of the restoration).	ditching or marginal fractures. 6.4.3 Larger irregularities or steps (repair necessary)	occlusal contact points are lost. 7b.4 Restoration > 300 % of enamel wear or antagonist > 300 %.	100 µm metal blade can pass 8b.4 Inadequate contour Repair possible.	but not removable. 9.4.3 Negative steps >250µm and reparable.	tongue irritation Reshaping of anatomic form or refurbishing is possible.

5. Clinically poor (replacement necessary)	5.5 (Partial or complete) loss of restoration or multiple fractures.	6.5.1 Restoration (complete or partial) is loose but in situ. 6.5.2 Generalized major gaps or irregularities.	7a.5 Wear is excessive. 7b.5 Restoration or antagonist > 500 % of corresponding enamel.	8a.5 Too weak and/or clear damage due to food impaction and/or pain/gingivitis. 8b.4 Insufficient contour requires replacement	9.5.1 Secondary caries, large gaps, large overhangs 9.5.2 Apical pathology 9.5.3 Fracture/loss of restoration or tooth.	10.5 Completely dissatisfied and / or adverse effects, incl. pain.
Overall functional score	Acceptable function (n and %):			Not acceptable (n, % and reasons):		
C. Biological properties	**11. Postoperative (hyper-)sensitivity and tooth vitality**	**12. Recurrence of caries (CAR), erosion, abfraction**	**13. Tooth integrity (enamel cracks, tooth fractures)**	**14. Periodontal response (always compared to a reference tooth)**	**15. Adjacent mucosa**	**16 Oral and general health**
1. Clinically very good	11.1 No hypersensitivity, normal vitality.	12.1 No secondary or primary caries	13.1 Complete integrity.	14.1. No plaque, no inflammation, no pockets.	15.1 Healthy mucosa adjacent to restoration.	16.1 No oral or general symptoms.
2. Clinically good (after correction maybe very good) No treatment required.	11.2 Minor hypersensitivity for a limited period of time, normal vitality.	12.2 Small and localized 1. Demineralization 2. Erosion or 3. Abfraction.	13.2.1 Small marginal enamel fracture (<150 µm). 13.2.2 Hairline crack in enamel (<150 µm).	14.2. Little plaque, no inflammation (gingivitis), no pocket development 14.2.1 without 14.2.2 with overhangs, gaps or inadequate anatomic. form	15.2 Healthy after minor removal of mechanical irritations (plaque, calculus, sharp edges etc.)	16.2 Minor transient symptoms of short duration; local or generalized.
3.Clinically sufficient / satisfactory (minor shortcomings with no adverse	11.3.1 Moderate hypersensitivity 11.3.2 Delayed/mild sensitivity; no subjective	12.3 Larger areas of 1. Demineralisation 2. Erosion or 3. Abrasion/abfracti	13.3.1 Marginal enamel defect <250µm 13.3.2 Crack <250µm;	14.3. Difference up to one grade in severity of PBI compared to baseline and	15.3 Alteration of mucosa but no suspicion of causal relationship with restorative	16.3. Transient symptoms, local and/or general.
effects but not adjustable without damage to the tooth)	complaints, no treatment needed.	on, dentine not exposed Only preventive measures necessary ().	13.3.3 Enamel chipping. 13.3.4 Multiple cracks	compared to control tooth. 14.3.1 without 14.3.2 with overhangs, gaps or inadequate anatomic form.	material.	

Table 2 (continued)

4. Clinically unsatisfactory (repair for prophylactic reasons)	11.4.1 Intense hypersensitivity. 11.4.2 Delayed with minor subjective symptoms. 11.4.3 No clinical detectable sensitivity. Intervention necessary but not replacement.	12. 4.1 Caries with cavitation and suspected undermining caries 12.4.2 Erosion in dentine 12.4.3 Abrasion/ abfraction in dentine. Localized and accessible can be repaired.	13.4.1 Major marginal enamel defects; gap > 250 µm or dentine or base exposed. 13.4.2 Large cracks >250 µm, probe penetrates. 13.4.3. Large enamel chipping or wall fracture	14.4. Difference of more than one grade of PBI in comparison to control tooth or increase in pocket depth > 1mm requiring intervention. 14.4.1 without 14.4.2 with overhangs, gaps or inadequate anatomic form	15.4 Suspected mild allergic, lichenoid or toxic reaction.	16.4 Persisting local or general symptoms of oral contact stomatitis or lichen planus or allergic reactions. Intervention necessary but no replacement.
5. Clinically poor (replacement necessary)	11.5 Intense, acute pulpitis or non vital tooth. Endodontic treatment is necessary and restoration has to be replaced.	12.5 Deep caries or exposed dentine that is not accessible for repair of restoration.	13.5. Cusp or tooth fracture.	14.5 Severe / acute gingivitis or periodontitis 14.5.1 without 14.5.2 with overhangs, gaps or inadequate anatomic form	15.5 Suspected severe allergic, lichenoid or toxic reaction.	16.5. Acute / severe local and/or general symptoms.
Overall biological score	**Acceptable biologically (n and %):**			**Not acceptable (n, % and reasons):**		

surface. It has to be stressed again that the quality of surface lustre and roughness can only be adequately evaluated if the restored tooth has been thoroughly cleaned and dried.

2. Surface and marginal staining (*e-calib*)

In the original publication, marginal staining and surface staining comprised one single criterion, the rationale being that both phenomena affect the esthetic appearance of a restoration. However, when evaluating clinical pictures for the e-calib program, it soon became apparent to the four evaluators that these phenomena had to be differentiated and evaluated separately. Marginal staining can depend on the effectiveness of dentin/enamel bonding agent systems, as well as on the operative technique or physical parameters of the restorative material, whereas surface staining depends more on the properties of the material to retain pigments from the oral environment. Therefore, the criterion has been divided into 'surface staining' (a) and 'marginal staining' (b). Marginal staining is primarily a staining of the contents of a crevice between the cavity wall and the restoration, subsequently affecting the margins of the restoration. Surface staining of a restoration is due to a material deficiency or inadequate finishing/polishing of the restoration. If staining is of special interest, it is recommended to ask the subject with regard to his diet and smoking habits.

3. Color match and translucency (*e-calib*)

The term color stability has been changed to color match as it is clinically more important, and a clinical observation of minor color changes is impossible to measure correctly over a period of several years as it may change over time and also tooth color may change. Further, subscores ('too opaque/translucent/dark/bright') have been added. These subscores are optional and may be ignored, if appropriate.

4. Esthetic anatomical form (*e-calib*)

It has become evident during the use of these criteria that anatomical deficiencies which impair the function, e.g. poor approximal contact and the effect on periodontal tissues, should be dealt with in the respective sections (criteria 8 and 14). Only restorations or parts of restorations that are easily visible at a speaking distance or during wide mouth opening should be assessed, including incisal edge and anterior approximal restorations that involve the labial surface, cervical restorations in anterior teeth and premolars, and large facial extensions of MO or MOD premolar restorations.

B. Functional properties

5. Fracture of restorative material and restoration retention (*e-calib*)

The term "multiple marginal material fractures" was added to score 5 ("replacement of restoration") as a restoration with multiple fractures may be reparable, but practically, it may not be appropriate to do so. Marginal fractures should not be confused with flashes and overhangs, and the latter shall be evaluated under the criterion "marginal adaptation".

6. Marginal adaptation (*e-calib*)

Marginal gaps

In the original publications from 2007 [3, 4], the relationship between microleakage, marginal gaps and secondary caries (caries adjacent to restorations CAR) was extensively covered. In clinical studies, the parameter "microleakage" shall not be used as it does not cause caries (CAR). Microleakage is associated with dye penetration, and the term should be reserved for in vitro studies only. To obtain better quality data for clinical prediction of for instance marginal staining or caries adjacent to restorations, restoration gap width should be classified. To classify the marginal gaps, two special probes (Deppeler, Switzerland) are available with tip diameters of 150 and 250 μm. The depth of the gap should be at least the same size (0.25 mm). The use a sharp explorer for gap or caries detection is not recommended. Debonding may lead to a loose filling which requires replacement. However, also major generalized marginal gaps and irregularities may justify replacement of the entire restoration.

7. Occlusal contour and wear

The term "occlusal contour" has been added to this criterion, since the alteration of occlusal contour during the service time of the restoration can be a sign of material degradation or wear. Wear can be assessed qualitatively by the evaluator or quantitatively on replicas with special sensors and computer software. In both instances, baseline and follow-up images/replicas are needed in order to assess possible alterations. Therefore, the criterion has been divided into "qualitatively" (a) and "quantitatively" (b) measured wear.

8. Approximal contact point and food impaction

The 'tightness' of the approximal contact area can be evaluated with metal strips of three different thicknesses (25, 50 and 100 μm) which are commercially available (Deppeler). If using floss, the same type of floss has to be used for calibration at baseline and at all recalls.

The approximal contact may be present, but the approximal contour can be deficient, leading to plaque accumulation and initial or secondary caries. If the inadequate contour results in damage to the periodontal tissues, this should be rated under criterion 14. However, an inadequate contour can also affect the occlusal surface and should then be reflected under criterion 7b.

Food impaction related to open contacts and/or an inappropriate shape of the approximal part of the restoration

should be recorded. Therefore, this criterion has now two different subgroups:

(a) approximal contact area
(b) approximal contour

9. Radiographic examination

Ideally, the restorative material under test should have an adequate level of radiopacity. Care has to be taken if there is a thick layer of adhesive, which does not have adequate radiopacity, that it may be misinterpreted as caries adjacent to restorations (CAR).

9. Patient's view

The patient may complain about the restoration with regard to its esthetic appearance and/or function. Therefore, this criterion has been divided into the two subscores "Esthetics" and "Function". For example, a rough restoration surface can annoy or even irritate the tongue of the patient and may therefore be a matter of complaint.

C. Biological properties

12. Recurrence of initial pathology (*e-calib*) and monitoring of progression

The scores have been expanded with regard to caries adjacent to restorations (CAR), erosion and abfraction to better differentiate between pathology of different Etiologies.

13. Tooth cracks and fractures (*e-calib*)

"Enamel chipping" and "multiple cracks" have been added to score 13.3. Cracks that were present before a primary caries is restoratively treated or an insufficient restoration is replaced should be recorded at baseline before placement. Enamel cracks can occur in the vicinity of the restorative margin (mainly at the proximal margins of Class II restorations) or independent of the restoration margins at different locations.

14. Effect of the restoration on the periodontium

As restoration overhangs, gaps or inadequate approximal anatomical form can cause or enhance gingival inflammation, this criterion has been expanded as to whether the inflammation is in conjunction with these approximal restoration deficiencies.

Figures of clinical examples

The criteria with their scores are listed directly after the Figure number. If the score can be differentiated into a subscore, it is indicated in brackets after the description of the criterion that illustrates the clinical pictures in this edition of the journal, clinical cases for the citerion "Staining" cannot be presented for all scores of the two subgradings "Surface" and Margin. In some figures, arrows and circles are used to point to the specific characteristic of the restoration. These tools with the same colors are used in the *e-calib* program. (Figs. 1, 2, 3, 4 5 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39 and 40).

Summary and conclusions

The 16 "FDI clinical criteria" for the evaluation of direct and indirect restorations were first published in 2007 and have since been applied by several investigators in clinical studies on resin composite restorations in posterior teeth. The response was positive. The experience of the application of these criteria to clinical cases has made it reasonable to modify some of the criteria and scores.

A clinical investigator planning a clinical study on direct or indirect restorations must formulate hypotheses and define the purpose of the study as well as the primary and secondary outcomes. Based on these considerations, the investigator selects the clinical criteria which are necessary to accomplish the objective of the trial. Therefore, in many instances, only some of the defined criteria are needed. Furthermore, the five scores can be reduced to four or even two, depending on the purpose of the study and the type of material or the operative/restorative procedure being tested. It is mandatory that the investigators be trained and calibrated on these criteria, which is a prerequisite to compare the results of different studies. Training on some of the criteria can be adequately carried out using high-quality clinical images of restorations. An interactive tool, 'e-calib', is available on the Internet for that purpose. The database contains several hundred clinical cases that are representative of the five scores of eight criteria. Clinical investigators are requested to use the tool to better standardize their clinical judgement on restorations and to give feedback to the authors. The FDI criteria are not fixed and defined. If good documentation can be presented, modifications and/or alterations are possible. Deviations from the outlined criteria in publications should be justified and illustrated Moreover, the proposed score for a specific clinical case may be challenged by other investigators. Clinical investigators are therefore asked to send their comments on specific scores to the authors. Furthermore, clinical investigators are welcomed and encouraged to provide high quality pictures of clinical cases that can be uploaded into the database.

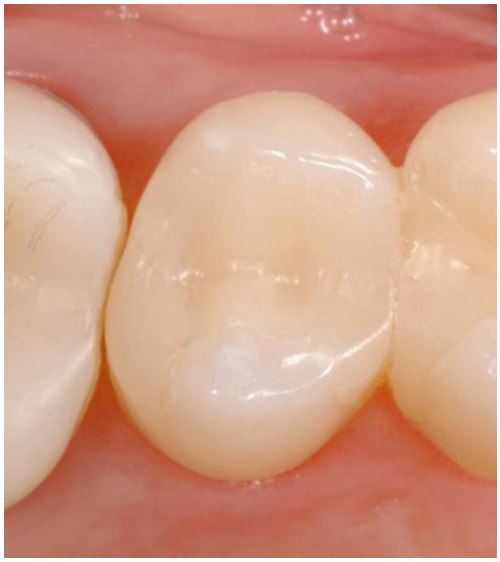

Fig. 1 1.1: Lustre comparable to enamel

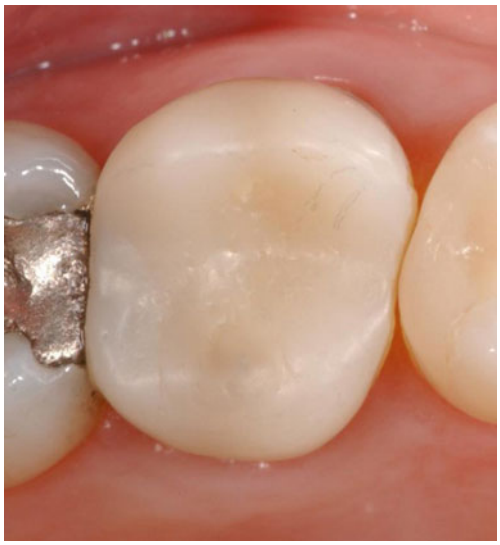

Fig. 2 1.2: Slightly dull, not noticeable from speaking distance (1.2.1)

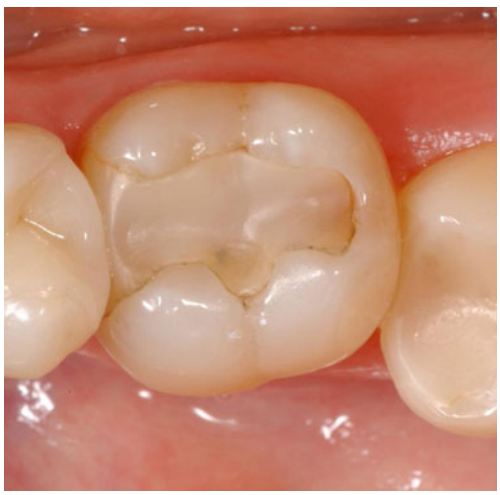

Fig. 3 1.3: Dull surface but acceptable if covered with film of saliva (1.3.1)

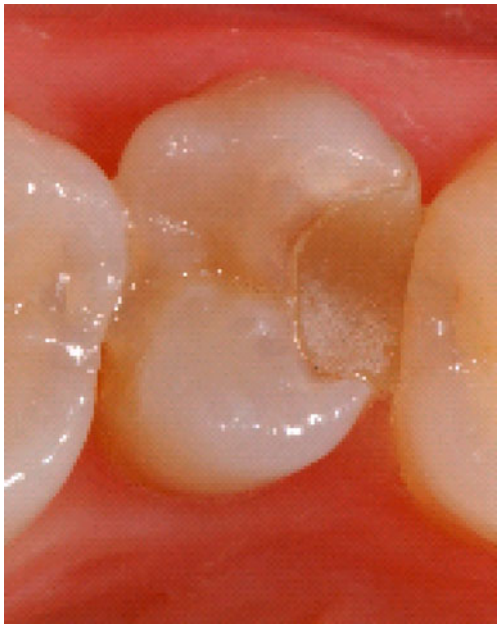

Fig. 4 1.4: Rough surface (1.4.1)

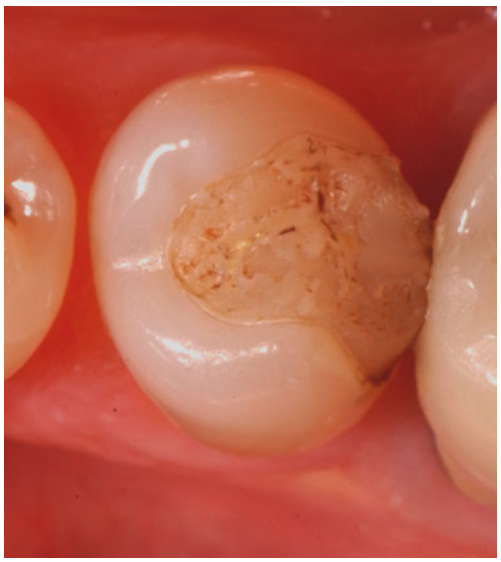

Fig. 5 1.5: Moderately rough

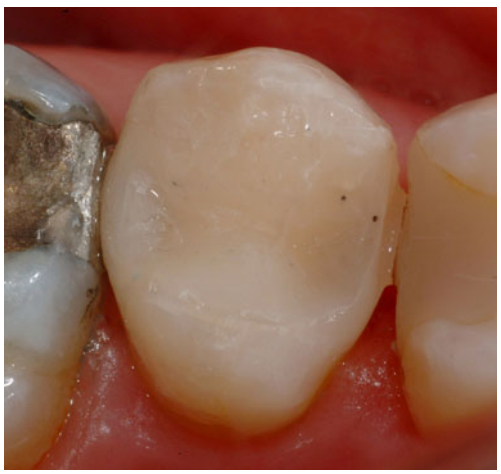

Fig. 6 2.1: No surface staining (2a.1, 2b.1)

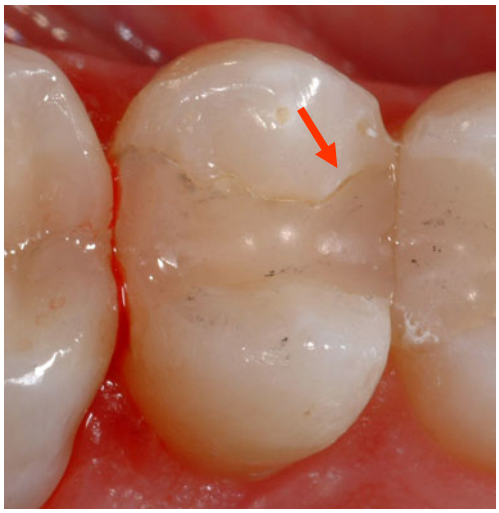

Fig. 7 2.2: Minor surface staining (2a.2), minor marginal staining (2b.2, see *arrow*)

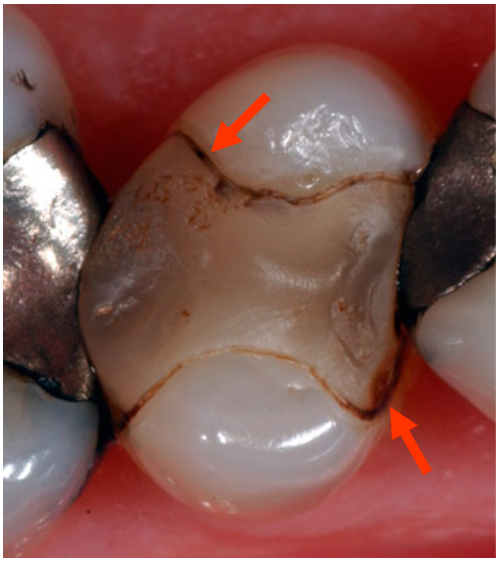

Fig. 10 2.5: Severe surface staining (2a.5) and deep marginal staining (2b.5)

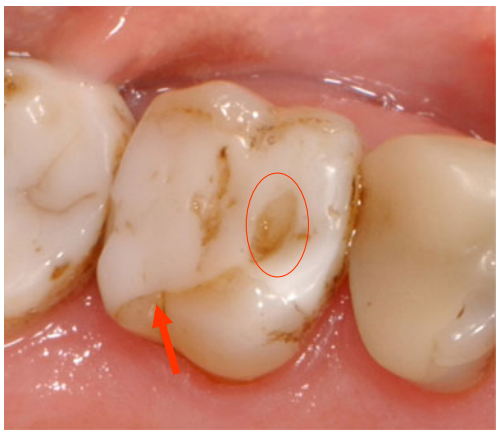

Fig. 8 2.3: Moderate surface staining (2a.3, see *circle*) and moderate marginal staining (2b.3, see *arrow*)

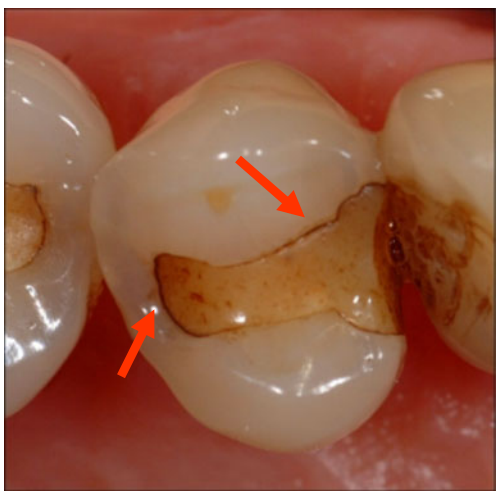

Fig. 9 2.4: Moderate surface staining (2a.3) and pronounced marginal staining (2b.4, see *arrows*)

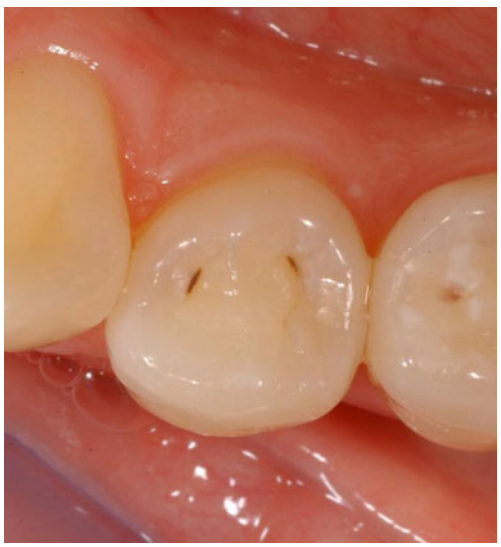

Fig. 11 3.1: Good color match

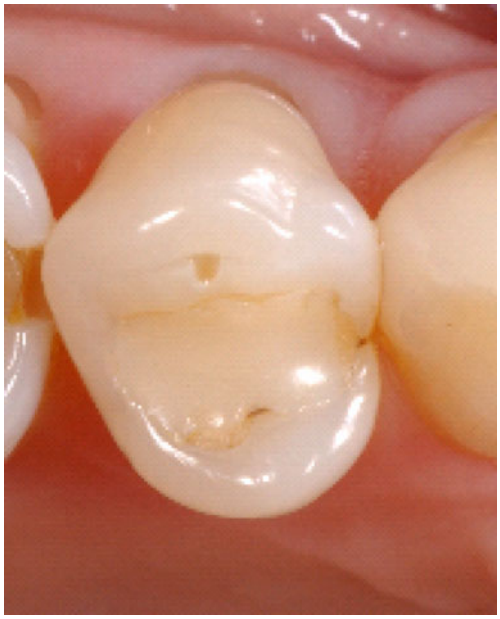

Fig. 12 3.2: Minor deviation in color match

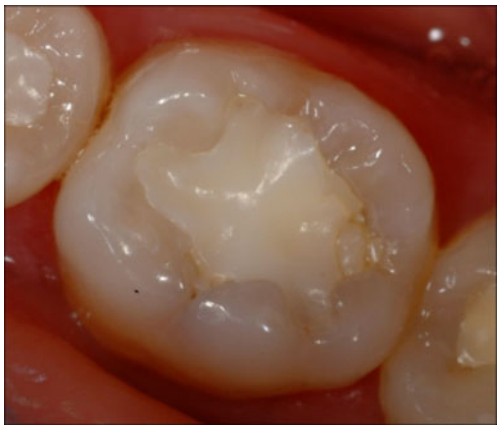

Fig. 13 3.3: Clear deviation in color match (3.3.1 more opaque)

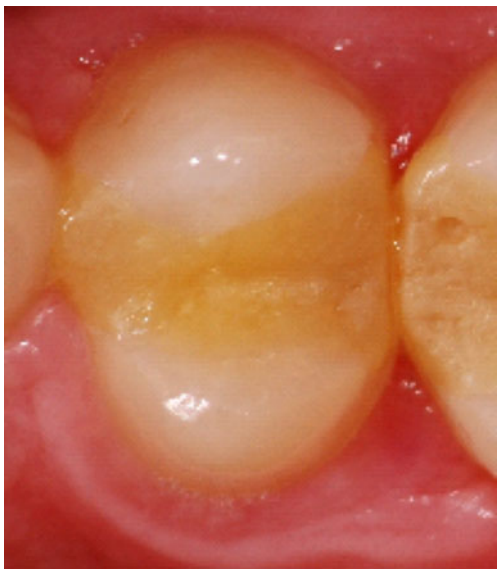

Fig. 14 3.4: Unsatisfactory/inadequate color match (3.4.3, too dark)

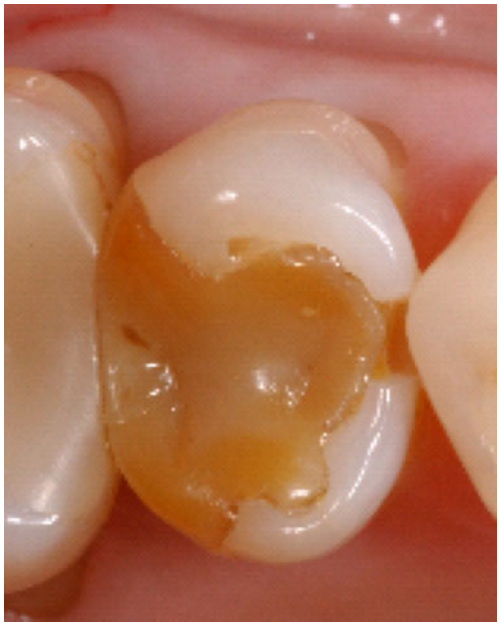

Fig. 15 3.5: Unacceptable color match

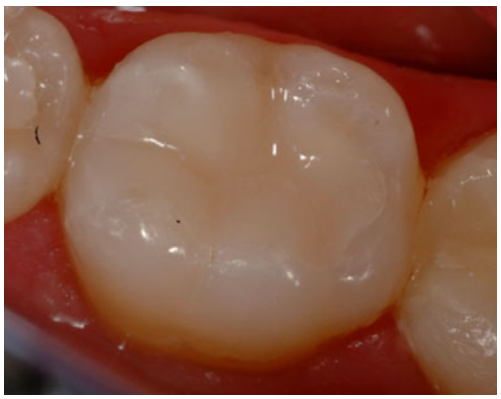

Fig. 16 4.1: Form is ideal

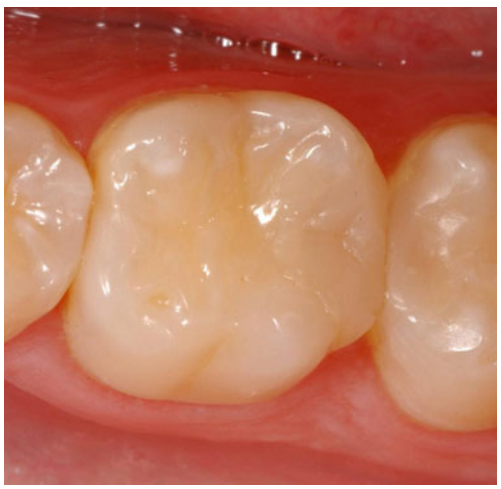

Fig. 17 4.2: Form is only slightly affected

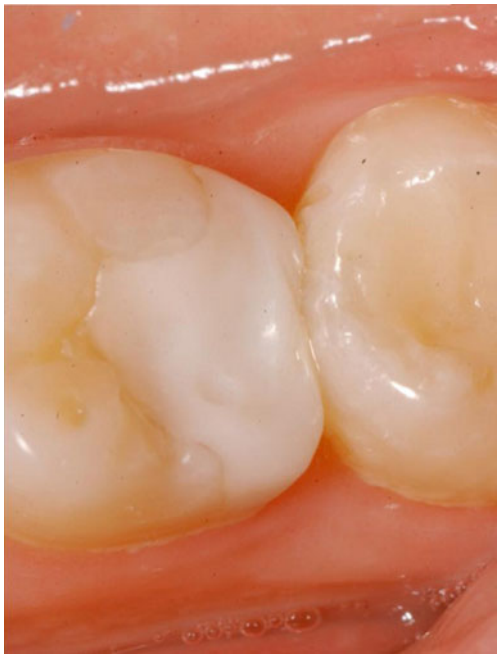

Fig. 18 4.3: Form is not ideal but is not esthetically displeasing

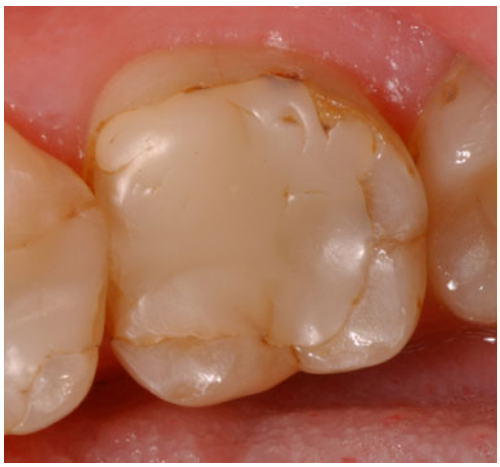

Fig. 19 4.4: Form is affected and unacceptable esthetically

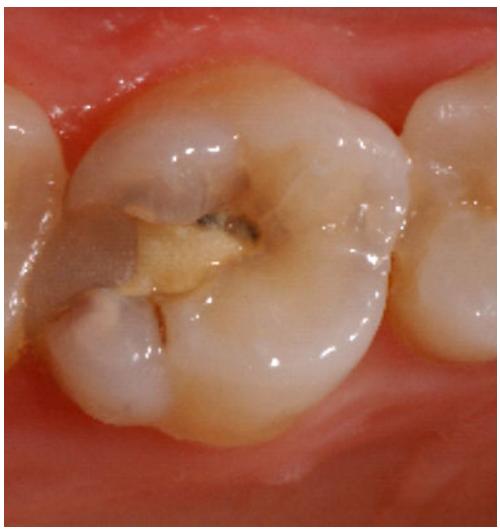

Fig. 20 4.5: Form is unsatisfactory and/or missing

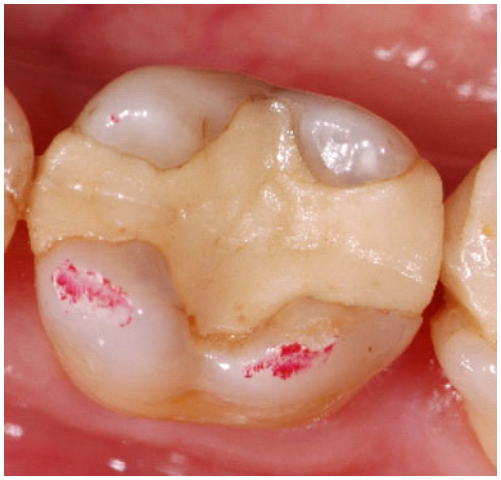

Fig. 21 5.1: No fractures/cracks

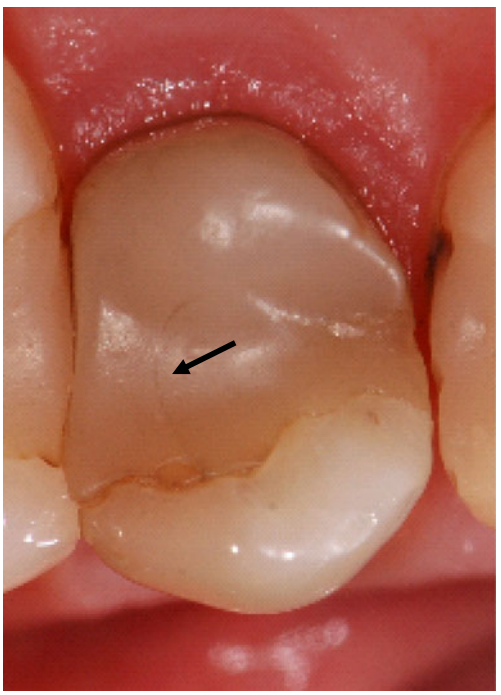

Fig. 22 5.2: Small 'hairline' cracks

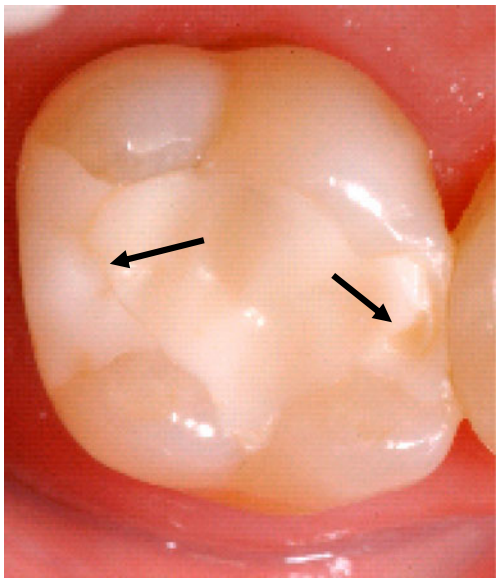

Fig. 23 5.3: Hairline crack (*left arrow*) and material chip fracture (*right arrow*)

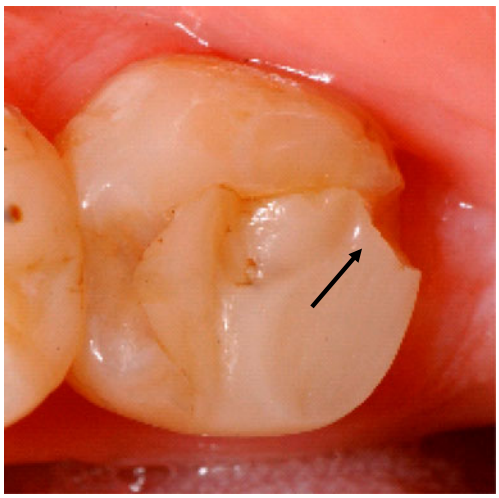

Fig. 24 5.4: Bulk fracture with partial loss of restorative material (5.4.1, see *arrow*)

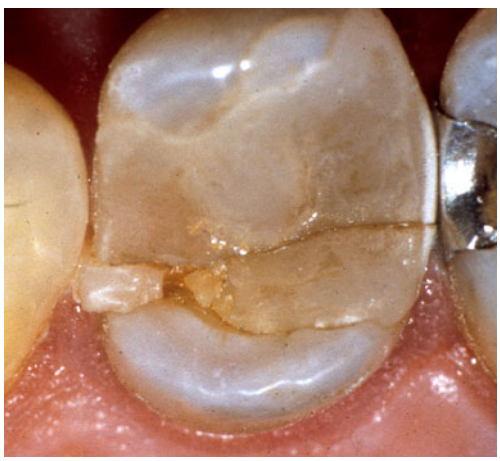

Fig. 25 5.5: Multiple fractures

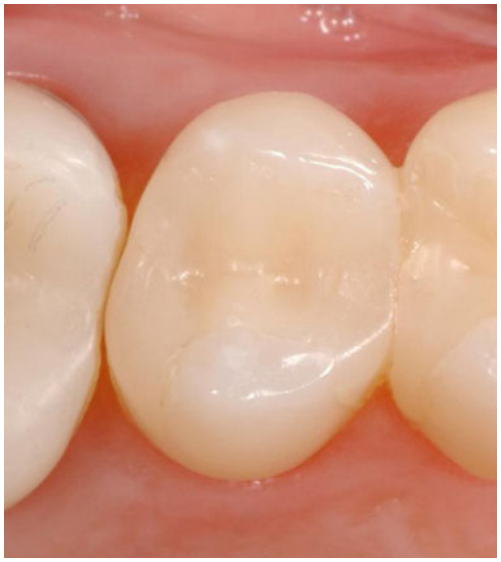

Fig. 26 6.1: Harmonious outline, no gaps, no white or discolored lines

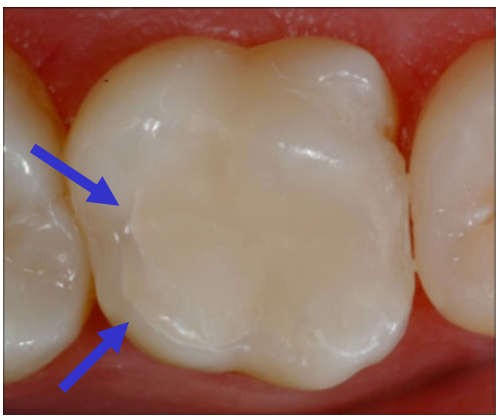

Fig. 27 6.2: Marginal gap (<150 µm), white lines (6.2.1)

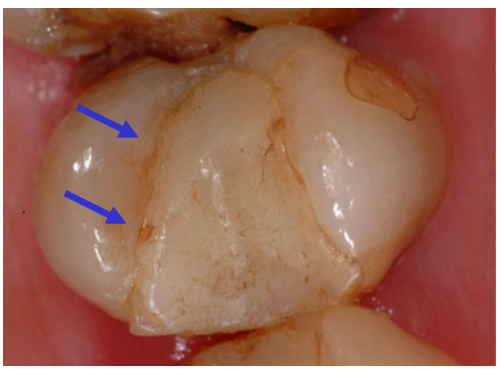

Fig. 28 6.3: Major irregularities and steps (6.3.3)

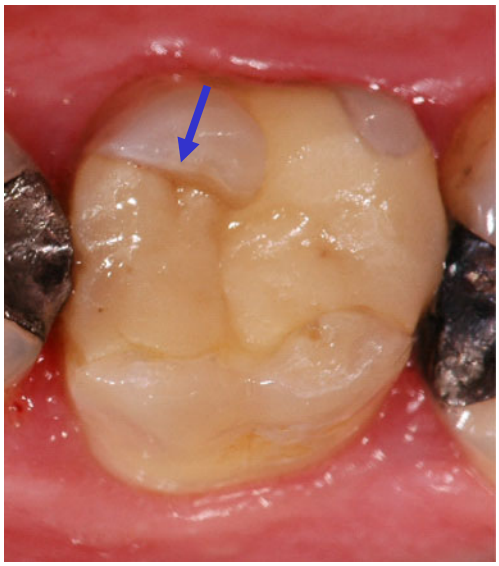

Fig. 29 6.4: Severe ditching or marginal fractures (6.4.2)

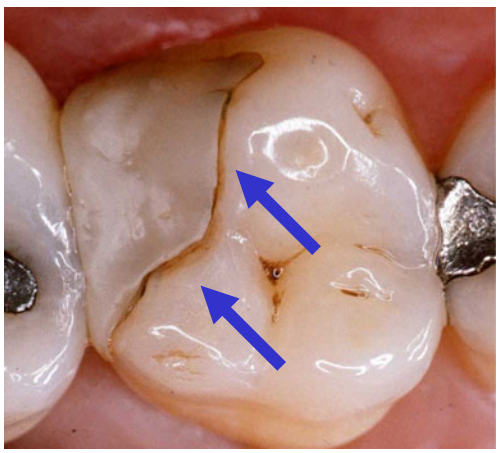

Fig. 30 6.5: Filling is loose but in situ (6.5.1)

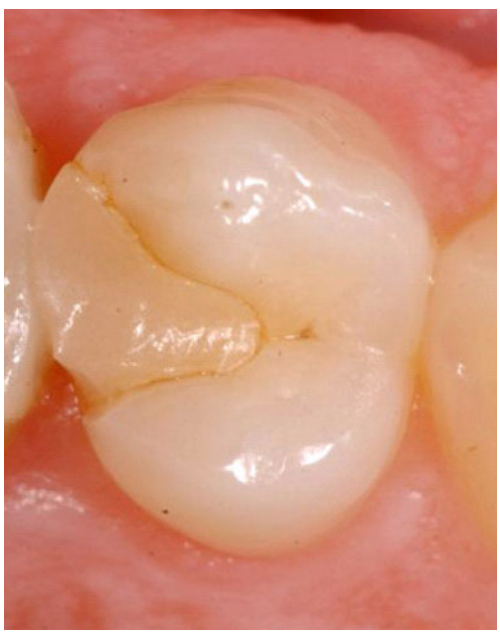

Fig. 31 12.1: No secondary or primary caries

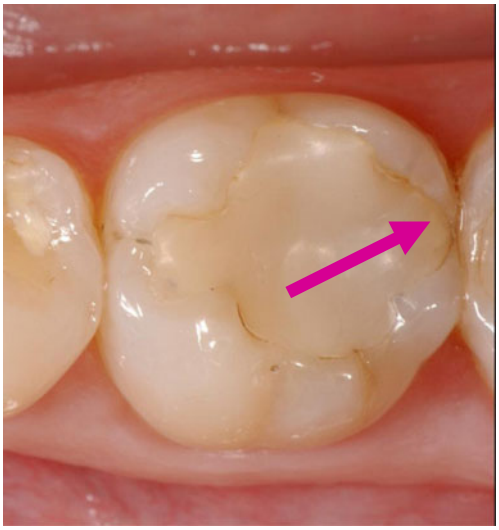

Fig. 32 12.2: Small and localized demineralization (12.2.1, see *arrow*)

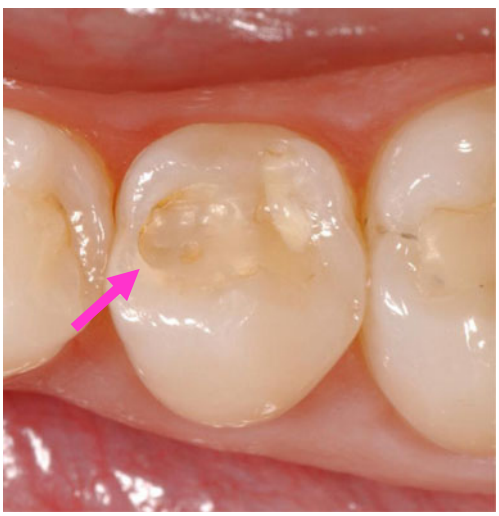

Fig. 33 12.3: Large areas of demineralisation (12.3.1, see *arrow*)

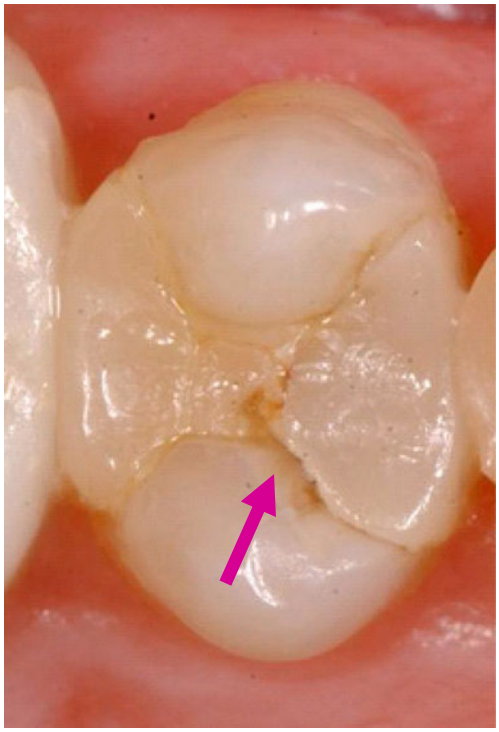

Fig. 34 12.4: Caries with suspected undermining caries (12.4.1, see *arrow*)

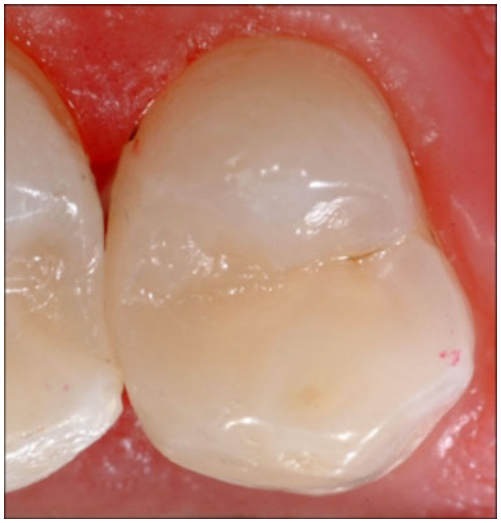

Fig. 36 13.1: Complete integrity

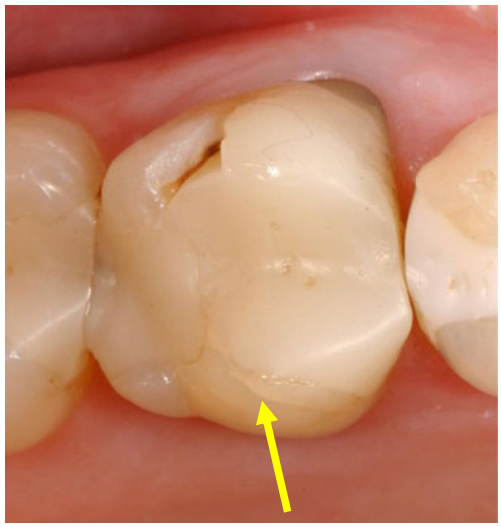

Fig. 37 13.2: Hairline crack in enamel (13.2.2, see *arrow*)

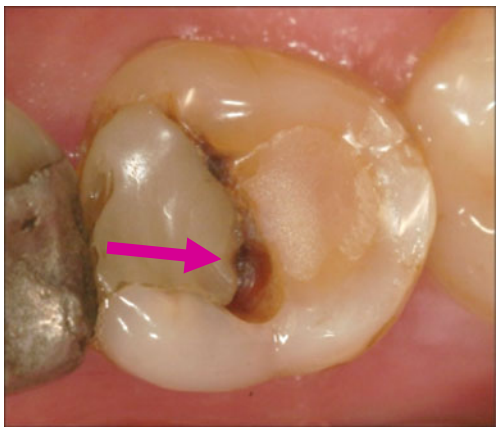

Fig. 35 12.5: Deep caries and exposed dentine (see *arrow*)

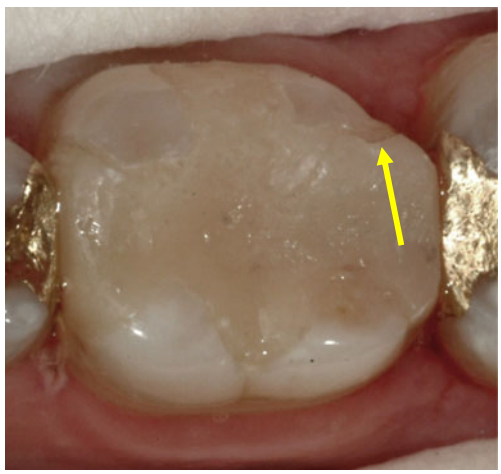

Fig. 38 13.3: Enamel chipping (13.3.3, see *arrow*)

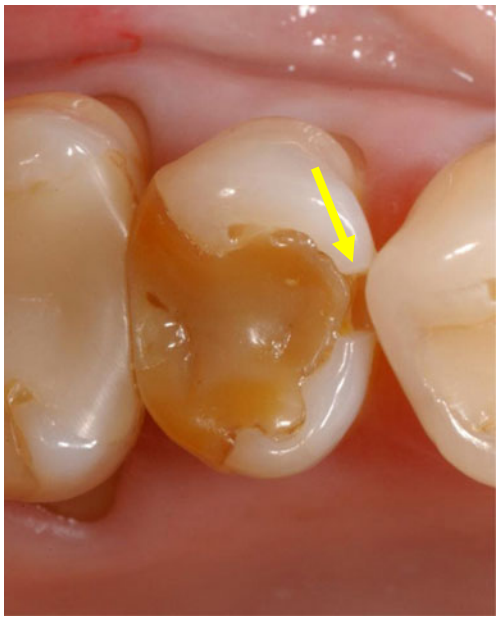

Fig. 39 13.4: Large enamel chipping (13.4.3, see *arrow*)

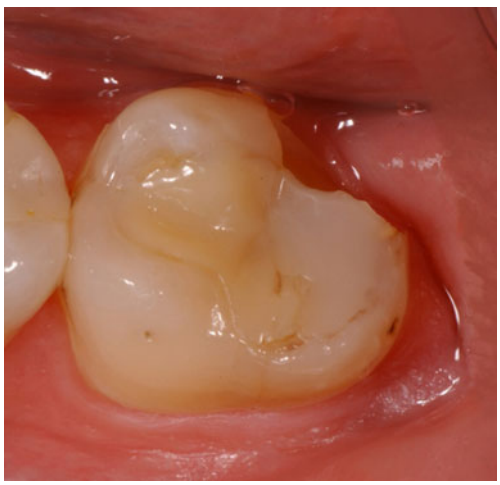

Fig. 40 13.5: Cusp fracture

Clinical relevance

The FDI clinical criteria and scoring system for the evaluation of direct and indirect restorations are well structures and flexible criteria which can be selected and adjusted according to the needs of the investigator. After training and calibration they can be applied not only by the researchers but also by dental students and general practitioners for quality assurance purpose e.g. to avoid premature replacement and restorations. A web-based training and calibration tool (*e-calib*) helps to spread the information and to facilitate the training and calibration.)

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

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