



**HAL**  
open science

## The use of FDI criteria in clinical trials on direct dental restorations: A scoping review

Thomas Marquillier, Sophie Doméjean, Justine Le Clerc, Florence Chemla, Kerstin Gritsch, Jean-Christophe Maurin, Pierre Millet, Matthieu Perard, Brigitte Grosogeat, Elisabeth Dursun

### ► To cite this version:

Thomas Marquillier, Sophie Doméjean, Justine Le Clerc, Florence Chemla, Kerstin Gritsch, et al.. The use of FDI criteria in clinical trials on direct dental restorations: A scoping review. *American Journal of Dentistry*, 2018, 68, pp.1-9. 10.1016/j.jdent.2017.10.007 . hal-01670925

**HAL Id: hal-01670925**

**<https://uca.hal.science/hal-01670925v1>**

Submitted on 16 Mar 2018

**HAL** is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

**THE USE OF FDI CRITERIA IN CLINICAL TRIALS ON DIRECT DENTAL RESTORATIONS: A SCOPING REVIEW**

Marquillier Thomas<sup>1</sup>, Doméjean Sophie<sup>2</sup>, Le Clerc Justine<sup>3</sup>, Chemla Florence<sup>4</sup>, Gritsch Kerstin<sup>5</sup>, Maurin Jean-Christophe<sup>5</sup>, Millet Pierre<sup>6</sup>, Pérard Matthieu<sup>3</sup>, Grosogeat Brigitte<sup>5</sup>, Dursun Elisabeth<sup>7</sup>

<sup>1</sup> Univ. Lille, CHRU Lille, UFR Odontologie, Odontologie pédiatrique, F-59000 Lille, France; Univ. Paris 13 - Sorbonne Paris Cité, UFR Santé Médecine Biologie Humaine, Laboratoire Educations et Pratiques de Santé (EA 3412), F-93017, France.

<sup>2</sup> Univ Clermont Auvergne, UFR d'Odontologie; CHU Estaing Clermont-Ferrand, Service d'Odontologie, F-63001 Clermont-Ferrand, France; Centre de Recherche en Odontologie Clinique EA 4847, F-63100 Clermont-Ferrand, France.

<sup>3</sup> Univ Rennes1, CHU Rennes, UFR Odontologie, F-35043 Rennes, France; Univ Rennes1, CNRS, U6226, Institut des Sciences Chimiques de Rennes, F-35700 Rennes, France.

<sup>4</sup> Univ. Paris Descartes, APHP Hôpital Charles Foix, UFR Odontologie, F-92120 Montrouge, France.

<sup>5</sup> Univ. Lyon 1, UFR Odontologie, F-69008 Lyon, France; Laboratoire des Multimatériaux et Interfaces, UMR CNRS 5615, F-69008 Lyon, France; Hospices Civils de Lyon, Service de Consultations et de Traitements Dentaires, F-69007, Lyon, France.

<sup>6</sup> Univ. Reims Champagne Ardenne, CHU Reims, Service Odontologie, F-51100 Reims, France.

<sup>7</sup> Univ. Paris Descartes, APHP Hôpital Albert Chenevier, UFR Odontologie, F-92120 Montrouge, France; Univ. Paris Descartes, UFR Odontologie, Unité de recherche en biomatériaux innovants et interfaces (EA4462), F-92120 Montrouge, France.

\*Corresponding author:

Pr Brigitte GROSGOGEAT

Faculté d'Odontologie – Université de Lyon

11 rue Guillaume Paradin, 69008 Lyon, France

Phone: +33 4 78 77 86 89

E-mail: [brigitte.grosgogeat@univ-lyon1.fr](mailto:brigitte.grosgogeat@univ-lyon1.fr)

## ABSTRACT

**Objectives:** A scoping review was conducted to explore the use of FDI criteria 10 years after their introduction. The first aim was to compare the amount of studies using the FDI and/or the modified USPHS criteria. The second aim was to analyse the use of the FDI criteria in clinical trials evaluating direct dental restorations.

**Data:** Listing of studies using FDI and/or USPHS criteria per year since 2007. Clinical studies related to the assessment of direct restorations using FDI criteria.

**Source:** Two systematic searches – regarding the use of FDI and modified USPHS criteria – were carried out on Medline/Pubmed in order to identify the studies published between 2007 and 2017. Authors of the included articles were contacted to clarify their choice of FDI criteria in their studies. ClinicalTrials.gov database was also queried for the on-going studies that use FDI and modified USPHS criteria.

**Study selection:** In the first review, all the clinical trials (randomized/non-randomized, controlled, prospective/retrospective studies) that used FDI criteria to evaluate direct restorations on primary or permanent teeth were included.

**Conclusions:** 16.3% of the studies used FDI criteria. The percentage of studies using them increased from 4.5% in 2010 to 50.0% in 2016. In average, 8.5 FDI criteria were used. The most employed criteria were: marginal adaptation (96.7%), staining (90.0%), fracture of material and retention (90.0%), recurrence of caries/erosion/abfraction (90.0%), post-operative sensitivity/tooth vitality (86.7%) and surface luster (60.0%). In addition, among the 27 on-going studies from ClinicalTrials.gov database, 51.9% use FDI criteria (including 87.5% with an open recruitment status).

**Clinical significance:** FDI criteria were reported as practical (various and freely selectable), relevant (sensitive as well as appropriate to current restorative materials and clinical studies design), standardized (making comparisons between investigations easier). Investigators should go on using them for a better standardization of their clinical judgment, allowing comparisons with other studies.

**Keywords:** restorative dentistry; direct dental restorations; FDI criteria; clinical trial; clinical assessment.

## INTRODUCTION

In 1971, Cvar and Ryge proposed five criteria (color match, cavosurface marginal discoloration, anatomic form, marginal adaptation and caries) for the clinical assessment of dental restorations [1]. Those criteria were revised in 1980 and were called “modified Ryge criteria” or “modified United States Public Health Service (USPHS) criteria” [2]. In addition to the initial five criteria, new categories such as occlusion, postoperative sensitivity, fracture, retention and others were taken into account. For each category, different items allow to score the restoration as follows: A (Alpha)- restoration which is clinically ideal, B (Bravo)- restoration showing minor deviations from the ideal but nevertheless acceptable (except for retention and secondary caries), C (Charlie)- restoration which should be replaced for preventive reasons to avoid the likelihood of future damage and D (Delta)- restoration requiring immediate replacement. However, authors did not always use the same definitions to assign the scores. Moreover, the modified USPHS criteria were developed when amalgam restorations were commonly used and when adhesive materials had a limited longevity. In order to make these criteria more selective, researchers had to modify and adapt them, which led to “modified Ryge criteria”. Nevertheless, many restorations continued to receive an alpha score after 12 or 18 months [3, 4].

To detect early deterioration and sign of failures, a more sensitive and discriminative scale than the “modified Ryge criteria” was required and in 2007, Hickel *et al* proposed a new system based on three criteria categories: aesthetic, functional and biological (Table 1) [3, 4]. Each category was divided into subcategories to allow for more detailed description and analysis. Each subcategory was scored according to a five-step grading of the restoration: score 1- the restoration is excellent/fulfills all quality criteria; score 2- the restoration is still highly acceptable, though

one or more criteria deviate from the ideal (no risk of damage); score 3- the restoration is sufficiently acceptable but with minor shortcomings; score 4- the restoration is unacceptable but repairable; score 5- the restoration has to be replaced. The final score in each category was the most severe score obtained among all subcategories. The criteria defined by Hickel *et al.* was approved by the Science Committee of the FDI World Dental Federation in 2007 [3, 4] and considered in 2008 as "Standard Criteria" [5, 6]. Their use was thus recommended in clinical trials assessing dental restorations in terms of materials, operative technique/intervention, as well as in clinical practice to determine whether a restoration should be maintained, repaired or replaced [3, 4]. However, the authors outlined that investigators should not necessary use the full set of the 16 criteria but select the most suitable, according to the objectives of their study. Moreover, they added that the five-step grading may also be reduced to four-steps (two acceptable and two unacceptable) or to two-steps by combining scores 1-3 and scores 4 and 5 into respectively "acceptable restoration" and "unacceptable restoration". Then, the first uses and feedbacks led to modifications of some criteria and scores in 2010 [5, 6]. Since then, no update or further feedbacks have been published regarding their application in clinical studies.

A scoping review was conducted to explore the extent of the use of FDI criteria, 10 year after their introduction. The **primary** aim of this manuscript was to compare the amount of studies using the FDI and/or the modified USPHS criteria. The **secondary** aim was to analyse the use of the FDI criteria in clinical trials evaluating direct dental restorations.

## **MATERIALS AND METHODS**

A scoping review was conducted to explore a wide range of literature on the use of the FDI criteria, irrespective of the quality of the studies [7]. Table 2 presents the whole search strategy.

A first systematic electronic search was performed using the keyword "FDI criteria" on Medline/PubMed database. Inclusion criteria were: all the clinical trials (randomized or non-randomized, controlled, prospective and retrospective studies) published between January 2007 to April 2017 that used FDI criteria to evaluate direct restorations on primary or permanent teeth. Exclusion criteria were: *in vitro* studies, case reports and review articles, as well as publications not written in English language. This systematic search followed the PRISMA statement for reporting [8].

The selection of studies was conducted by two independent reviewers (TM and ED). A screening of titles was performed. Irrelevant publications were excluded. Then, the screening of abstracts led to a selection of studies in compliance with the inclusion criteria. Full texts were finally reviewed. In case of disagreement, a consensus was obtained with supervisors (BG and SD). For each paper, the following data – study design, dentition, FDI criteria used in the study, other criteria used if applicable, training and calibration of examiners (Table 3) – were extracted independently and in duplicate by the two reviewers. These data were collected in an Excel spread sheet. In case of disagreement regarding the extraction of data, a consensus was obtained with supervisors (BG and SD). A manual screening was also carried out among the references of selected articles in order to gather further relevant papers.

Corresponding authors of the included articles were contacted by e-mail, to clarify their choice of FDI criteria. They were sent a two-column personalized table. The first column was pre-filled with the criteria they did not use in their study. They were asked to explain the reasons in the second column.

A second systematic electronic search regarding the use of the modified USPHS criteria was performed with a combination of both keywords “USPHS criteria” AND “Ryge criteria” on Medline/Pubmed database to identify studies published between January 2007 and April 2017. Only the number of studies per year was reported [to explore in which extend FDI criteria were used in clinical studies since their introduction, compared to USPHS criteria. As this study focuses on FDI criteria,](#) the abstracts and full texts [of studies using USPHS](#) were not considered.

Finally, the ClinicalTrials.gov database was also queried for on-going studies using either the FDI criteria or the modified USPHS criteria, with the keywords “FDI criteria”, “USPHS criteria” and “Ryge criteria”, respectively. The website distinguishes studies with an open recruitment status – such as “recruiting”, “not yet recruiting” or “available for expanded access” – and those with a closed recruitment status, including “completed” or “active, not recruiting” studies. The number of on-going studies (in open and closed recruitment) was then reported. Clinical trials exceeding their completion date and those with no verification of the recruitment within the past two years on the website ClinicalTrials.gov are noted as “unknown”. In both cases, they were excluded.

## RESULTS

### **The use of FDI and modified USPHS criteria per year since 2007**

For the first systematic search related to FDI criteria, on the 93 eligible papers, 38 articles were selected after a review of titles and abstracts. Thirty articles were finally included after full reading and manual screening (Figure 1; Table 3) [9-38]. The second systematic search identified 154 studies using the modified USPHS criteria. Figure 2 displays the respective number of studies using FDI criteria, modified USPHS criteria or both, per year since 2007.

Table 4 states the percentage of studies using FDI criteria per year since 2007. The 30 clinical studies using FDI criteria represents 16.3% of all the conducted studies. Five studies (3.8%) used both criteria. The first studies using FDI criteria were published in 2010. The percentage of studies using the FDI criteria increased from 4.5% in 2010 to 50.0% in 2016.

Among the 30 studies using FDI criteria, 25 of them were prospective studies [10, 12-15, 17-30, 32-35, 37, 38] and primary teeth were involved in five of them [10, 11, 18, 31, 34]. In 26 studies, examiners were calibrated [9, 10, 12-30, 32, 33, 35, 36, 38]. Figure 3 showed the percentage of use for each criterion in the 30 selected studies. Only two studies used all the 16 existing FDI criteria [35, 37]. The average number of criteria chosen in all studies was 8.5. The most employed criteria were: marginal adaptation (criterion 6; 29 studies, *i.e. 96.7% of the studies*) [9-24, 26-38], staining (criterion 2; 27 studies, *i.e. 90.0% of the studies*) [9-18, 20-23, 25-30, 32-38], fracture of material and retention (criterion 5; 27 studies, *i.e. 90.0% of the studies*) [9-24, 26, 29-38], recurrence of caries/erosion/abfraction (criterion 12; 27 studies, *i.e. 90.0% of the studies*) [9-25, 27, 28, 30, 31, 33-38], post-operative sensitivity and tooth vitality (criterion 11; 26 studies, *i.e. 86.7% of the studies*) [10-18, 20, 21, 23-30, 32-38] and surface luster (criterion 1; 18 studies, *i.e. 60.0% of the studies*) [9, 10, 12-14, 16, 18, 20-24, 29, 32, 34-37]. The least used criteria were: radiographic examination (criterion 9; 6 studies) [10, 11, 18, 34, 35, 37], patient's view (criterion 10; 7 studies) [12, 20, 24, 34-37] and oral and general health (criteria 16, 9 studies) [10, 12, 16, 18, 20, 31, 34, 35, 37].

Among the 27 corresponding authors joined by e-mail, 16 authors answered and explained the reason why they only selected some specific FDI criteria upon the 16 available. In fact, they considered some of them create confusion or lack consistency. They also mentioned that some criteria were not meaningful for their studies. For example, criteria 4, 7-9, 13, 15 and 16 were not relevant enough and/or applicable for the

evaluation of direct cervical restorations [15, 17, 21, 23, 25-30, 33, 38]. Similarly, criteria 1 and 3 were not either appropriate for the assessment of glass ionomer cement (GIC) restorations [11, 15, 17, 19, 25-28, 30, 33, 38]. In most cases, radiographic examination (criterion 9) was not used for ethical reasons (with a poor risk-benefit ratio for patients) [9, 12-17, 19-33, 36, 38], for administrative reasons or because of the lack of interest in the study. Criteria 10, 11, 14 and 15 were also poorly used. Finally, oral and general health (criterion 16) was considered as a confusing element without any real impact on the restoration lifetime.

### **The use of FDI criteria in on-going studies**

There are 27 on-going studies including 8 with an open recruitment status. 14 use FDI criteria, which represents 51.9% of the on-going studies. Seven with an open recruitment status use FDI criteria that means 87.5% of the studies (Figure 4).

### **Characteristics of the included studies and their management of FDI criteria**

Among the 30 selected studies, 15 different research teams could be identified. Most of the studies were well conducted since they were prospective and randomized with a well-described evaluation procedure. Nevertheless, some authors omitted to properly describe the calibration process of their evaluators. Indeed, according to Hickel *et al* [3, 4], an appropriate assessment must rely on two independent and calibrated examiners, different from the operators. Moreover, to ensure reproducible results, only experienced evaluators obtaining at least an 85% concordance rate must be involved in the clinical assessments [3, 4]. If some studies mentioned the examiner calibration, their training was often not precisely described. Furthermore, calibration appeared to be heterogeneous among surveys. While photographs remained the most widely used tools [17, 21, 22, 25-27, 30, 33, 38], five studies reported the training of evaluators with *e-calib*, an online training and calibration tool for the evaluation of dental restorations [20, 21, 24, 32, 36].

All the studies analysed adhesive materials. Most of them investigated the performance of composite resins (flowable or not, silorane) [16, 23, 37] and/or the procedures i.e with chlorhexidine pre-treatment [32], with or without bevel [13, 14], with rubber dam or cotton rolls/retraction cord [26], with various polishing systems [21] and/or the indications (for non-cariou cervical lesion, for primary teeth, in anterior or posterior



position) [9-11, 18, 20, 31, 34-36]. Many other studies evaluated the performance of various adhesive types (etch and rinse, self-etch or universal) [27, 30, 33] and/or the procedure (with EDTA conditioning) [28] and/or the indications (for non-carious cervical lesions) [12, 15, 17, 38]. Finally, other materials and techniques, such as the GIC [24] or the atraumatic restorative treatment (ART) technique were examined [19].

## DISCUSSION

The present review explores the use of FDI criteria since their introduction in 2007.

### **FDI criteria versus modified USPHS criteria**

FDI criteria are little used compared to the modified USPHS criteria (30 and 154 published studies, respectively). Nevertheless, a significant increase in the use of FDI criteria has been observed since 2010, the year of the first publication, reaching 50% of the published studies in 2016. In the same way, among the 27 currently on-going studies, more than a half (51.9%) based their assessment on FDI criteria and 87.5% of those with an open recruitment status used them. This shows an increasing interest for FDI criteria. Their widespread use would allow standardization for the evaluation of restorations, which would make comparisons between studies easier and even enable meta-analysis.

In fact, outcomes of clinical trials for the same health condition/intervention are often inconsistently measured or reported. They are also too technical and clinician-centered [39]. Yet, they need to be relevant to patients. The development of core outcome sets (COS) has been suggested to address these issues [40, 41]. As COS is an agreed standardized collection of outcomes, the comparison or combination of the results of trials and synthesis of data become thus possible. This strengthens the overall evidence base and improves clinical practice. In restorative dentistry, Lamont *et al.* and Schwendicke *et al.* reported the need and the initial steps to develop a COS for prevention and caries management trials [42, 43]. In the same way, FDI criteria could be considered as a COS for trials, which assesses dental restorations. However, as some criteria were considered as poor relevant or not applicable in some studies, it would be necessary to discuss the mandatory nature of each FDI criteria and perhaps to define a COS with only the absolute necessary and tangible criteria for all studies and not on the current 16 criteria. An update of the use of FDI criteria

and discussions about its use as a COS with a new meeting of the World Dental Federation would be beneficial. Finally, FDI criteria also involve a patient-centred criterion (criterion 10, “patient view”), which is an added value compared to modified USPHS criteria.

### **Interest of the FDI criteria**

In addition to the benefits mentioned above, the FDI criteria-based proposal allows to classify the evaluation of dental restorations, according to functional, biological and aesthetic categories. The higher number of scores (1 to 5) – compared to the USPHS criteria – was reported to make easier the ability of discerning potential differences in the quality of restorations [13, 14], which overall increases the quality of assessments. Nevertheless, some studies (3 among the 30 of the first systematic research) did not use the 5 scores [15, 16, 36], and one (a retrospective study) did not even mention the number of scores used [31] (Table 3).

As previously indicated, among the 16 purposed criteria, the authors can select the most appropriate criteria for their study. They may also adapt the use of the selected criteria, as Bektas Donmez *et al.* did in their study regarding clinical performance of restorative materials in primary teeth [10]. In that study, the authors adapted both criteria – “proximal contact point” and “radiographic examination” – because of the specific features of primary teeth, i.e. the lack of a contact point inducing food retention and the specific precautions to be taken for children.

In the study of Kim *et al* based upon a photographic evaluation of posterior tooth-colored restorations, FDI criteria present a high intra-examiner and a slight to fair inter-examiner reliability, that may be increased by the simplification of the evaluation scores [22]. Some studies (23.3%) used both FDI and modified USPHS criteria allowing a comparison between them [17, 20, 25, 27, 30, 33, 36]. FDI criteria seemed to be more sensitive and precise compared to the modified USPHS criteria, with regards to minor differences in the clinical outcomes, especially in studies assessing non-carious cervical lesion restorations [17, 27, 30, 33] or for the “marginal adaptation” [25, 33] and “marginal staining” criteria [25]. However, the FDI criteria might be less reliable, encouraging some authors to reduce the number of scores used.

### **Selection of the FDI criteria**

As recommended by Hickel *et al* [5, 6], most of the studies did not use all criteria. To explain their choice of the criteria used, the authors indicate that they selected them according to the type and the aims of their study as recommended by Hickel *et al.* [5, 6]. The most used criteria were those already evaluated by modified USPHS criteria, such as marginal adaptation (criterion 6; 96.7% of the studies), staining (criterion 2; 90.0% of the studies), recurrence of caries/erosion/abfraction (criterion 12; 90.0% of the studies) and post-operative sensitivity and tooth vitality (criterion 11; 86.7% of the studies), because they are critical for the assessment of the quality of restorations. Three were much less used (in less than 30% of studies): radiographic examination (criterion 9, 20.0%), the patient's view (criterion 10, 23.3%) and adjacent mucosa (criteria 15, 26.7%). In fact, investigators often estimated the benefit/risk ratio for the radiographic examination too low, in particular in the studies conducted in children, and both following criteria, patient's view and adjacent mucosa, not essential for the evaluation.

### **Limitations of the study**

As this present work is related to the “Deep Caries Treatment (DECAT)” study, which evaluates direct restorations [44], it was decided to restrict the search to the studies related to direct dental restorations and to exclude all the others. However, the same work with indirect restorations would bring additional information and should be subject to further investigation.

As only Pubmed database was checked and only publications written in English language were selected, potentially relevant papers could have been missed.

### **CONCLUSION**

FDI criteria were reported as practical (various and freely selectable criteria), relevant (sensitive as well as appropriate to current restorative materials and clinical studies design), standardized (making comparisons between different investigations easier). Their use depends on the objectives of the studies (use of 8.5 criteria in average among the 16 available). All the recommendations of Hickel *et al* [3,4] regarding their use, their selection, the calibration of examiners were globally followed. A significant increase of the use of FDI criteria, compared to the modified

USPHS criteria, has been observed since 2010, thereafter reaching 50% of the published studies in 2016. Investigators should go on using the FDI criteria for a better standardization of their clinical judgment on restorations, allowing comparisons with all other studies.

## ACKNOWLEDGMENTS

**- To the DECAT collaborative group, especially the team of Pr Gueyffier (coordination) and the Hospices Civils of Lyon (sponsor)**

This review is in relation with the DECAT study (DEep Caries Treatment). This clinical trial received a PHRC grant (which is a French funding source for hospital clinical trial) from the ministry of health (DGOS). This funding source had neither involvement in the study design, in the analysis, collection and interpretation of data nor in the writing of this manuscript.

**- To the corresponding authors of the included studies, who answered the questionnaire**

**- To Maxime Faure**, who contributed to this publication as part of his end-of-studies thesis in Dental Surgery (University Lyon 1, France)

**- To Misha Dhuper** (University of Ottawa), who reviewed the English language in this manuscript.

**REFERENCES**

- [1] J.F. Cvar, G. Ryge, Reprint of criteria for the clinical evaluation of dental restorative materials. 1971, *Clin Oral Investig* 9(4) (2005) 215-32.
- [2] G. Ryge, Clinical criteria, *International dental journal* 30(4) (1980) 347-58.
- [3] R. Hickel, J.F. Roulet, S. Bayne, S.D. Heintze, I.A. Mjor, M. Peters, V. Rousson, R. Randall, G. Schmalz, M. Tyas, G. Vanherle, Recommendations for conducting controlled clinical studies of dental restorative materials, *Clin Oral Investig* 11(1) (2007) 5-33.
- [4] R. Hickel, J.F. Roulet, S. Bayne, S.D. Heintze, I.A. Mjor, M. Peters, V. Rousson, R. Randall, G. Schmalz, M. Tyas, G. Vanherle, 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 (2007) 121-47.
- [5] R. Hickel, A. Peschke, M. Tyas, I. Mjor, S. Bayne, M. Peters, K.A. Hiller, R. Randall, G. Vanherle, S.D. Heintze, FDI World Dental Federation: clinical criteria for the evaluation of direct and indirect restorations-update and clinical examples, *Clin Oral Investig* 14(4) (2010) 349-66.
- [6] R. Hickel, A. Peschke, M. Tyas, I. Mjor, S. Bayne, M. Peters, K.A. Hiller, R. Randall, G. Vanherle, S.D. Heintze, FDI World Dental Federation - clinical criteria for the evaluation of direct and indirect restorations. Update and clinical examples, *J Adhes Dent* 12(4) (2010) 259-72.
- [7] H. Arksey, L. O'Malley, Scoping studies: towards a methodological framework, *Int J Social Res Methodol* 8(1) (2005) 19-32.
- [8] D. Moher, L. Shamseer, M. Clarke, D. Ghersi, A. Liberati, M. Petticrew, P. Shekelle, L.A. Stewart, P.-P. Group, Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement, *Syst Rev* 4 (2015) 1.
- [9] R.A. Baldissera, M.B. Correa, H.S. Schuch, K. Collares, G.G. Nascimento, P.S. Jardim, R.R. Moraes, N.J. Opdam, F.F. Demarco, Are there universal restorative composites for anterior and posterior teeth?, *J Dent* 41(11) (2013) 1027-35.
- [10] S. Bektas Donmez, S. Uysal, A. Dolgun, M.D. Turgut, Clinical performance of aesthetic restorative materials in primary teeth according to the FDI criteria, *Eur J Paediatr Dent* 17(3) (2016) 202-212.

- [11] K. Bucher, I. Metz, V. Pitchika, R. Hickel, J. Kuhnisch, Survival characteristics of composite restorations in primary teeth, *Clin Oral Investig* 19(7) (2015) 1653-62.
- [12] E.U. Celik, B. Aka, F. Yilmaz, Six-month clinical evaluation of a self-adhesive flowable composite in noncarious cervical lesions, *J Adhes Dent* 17(4) (2015) 361-8.
- [13] F.H. Coelho-de-Souza, C.A. Klein-Junior, J.C. Camargo, T. Beskow, M.D. Balestrin, F.F. Demarco, Double-blind randomized clinical trial of posterior composite restorations with or without bevel: 6-month follow-up, *J Contemp Dent Pract* 11(2) (2010) 001-8.
- [14] F.H. Coelho-De-Souza, J.C. Camargo, T. Beskow, M.D. Balestrin, C.A. Klein-Junior, F.F. Demarco, A randomized double-blind clinical trial of posterior composite restorations with or without bevel: 1-year follow-up, *J Appl Oral Sci* 20(2) (2012) 174-9.
- [15] T.R. da Costa, L.D. Ferri, A.D. Loguercio, A. Reis, Eighteen-month randomized clinical trial on the performance of two etch-and-rinse adhesives in non-carious cervical lesions, *Am J Dent* 27(6) (2014) 312-7.
- [16] P.A. Da Rosa Rodolpho, T.A. Donassollo, M.S. Cenci, A.D. Loguercio, R.R. Moraes, E.M. Bronkhorst, N.J. Opdam, F.F. Demarco, 22-Year clinical evaluation of the performance of two posterior composites with different filler characteristics, *Dent Mater* 27(10) (2011) 955-63.
- [17] E.A. de Paula, L.Y. Tay, C. Kose, A. Mena-Serrano, A. Reis, J. Perdigao, A.D. Loguercio, Randomized clinical trial of four adhesion strategies in cervical lesions: 12-month results, *Int J Esthet Dent* 10(1) (2015) 122-45.
- [18] S.B. Donmez, M.D. Turgut, S. Uysal, P. Ozdemir, M. Tekcicek, B. Zimmerli, A. Lussi, Randomized clinical trial of composite restorations in primary teeth: effect of adhesive system after three years, *Biomed Res Int* 2016 (2016) 5409392.
- [19] A. Farag, W.J. van der Sanden, H. Abdelwahab, J.E. Frencken, Survival of ART restorations assessed using selected FDI and modified ART restoration criteria, *Clin Oral Investig* 15(3) (2011) 409-15.
- [20] C. Frese, P. Schiller, H.J. Staehle, D. Wolff, Recontouring teeth and closing diastemas with direct composite buildups: a 5-year follow-up, *J Dent* 41(11) (2013) 979-85.
- [21] J.H. Jang, H.Y. Kim, S.M. Shin, C.O. Lee, D.S. Kim, K.K. Choi, S.Y. Kim, Clinical effectiveness of different polishing systems and self-etch adhesives in class V composite resin restorations: two-year randomized controlled clinical trial, *Oper Dent* 42(1) (2017) 19-29.

- [22] D. Kim, S.Y. Ahn, J. Kim, S.H. Park, Interrater and intrarater reliability of FDI criteria applied to photographs of posterior tooth-colored restorations, *J Prosthet Dent* (2016).
- [23] Y. Kitasako, A. Sadr, M.F. Burrow, J. Tagami, Thirty-six month clinical evaluation of a highly filled flowable composite for direct posterior restorations, *Aust Dent J* 61(3) (2016) 366-73.
- [24] T. Klinke, A. Daboul, A. Turek, R. Frankenberger, R. Hickel, R. Biffar, Clinical performance during 48 months of two current glass ionomer restorative systems with coatings: a randomized clinical trial in the field, *Trials* 17(1) (2016) 239.
- [25] A.D. Loguercio, E.A. de Paula, V. Hass, I. Luque-Martinez, A. Reis, J. Perdigao, A new universal simplified adhesive: 36-Month randomized double-blind clinical trial, *J Dent* 43(9) (2015) 1083-92.
- [26] A.D. Loguercio, I. Luque-Martinez, A.H. Lisboa, C. Higashi, V.A. Queiroz, R.O. Rego, A. Reis, Influence of isolation method of the operative field on gingival damage, patients' preference, and restoration retention in noncarious cervical lesions, *Oper Dent* 40(6) (2015) 581-93.
- [27] L.S. Lopes, F.S. Calazans, R. Hidalgo, L.L. Buitrago, F. Gutierrez, A. Reis, A.D. Loguercio, M.O. Barceleiro, Six-month follow-up of cervical composite restorations placed with a new universal adhesive system: a randomized clinical trial, *Oper Dent* 41(5) (2016) 465-480.
- [28] I. Luque-Martinez, M.A. Munoz, A. Mena-Serrano, V. Hass, A. Reis, A.D. Loguercio, Effect of EDTA conditioning on cervical restorations bonded with a self-etch adhesive: A randomized double-blind clinical trial, *J Dent* 43(9) (2015) 1175-83.
- [29] S. May, F. Cieplik, K.A. Hiller, W. Buchalla, M. Federlin, G. Schmalz, Flowable composites for restoration of non-carious cervical lesions: Three-year results, *Dent Mater* (2017).
- [30] A. Mena-Serrano, C. Kose, E.A. De Paula, L.Y. Tay, A. Reis, A.D. Loguercio, J. Perdigao, A new universal simplified adhesive: 6-month clinical evaluation, *J Esthet Restor Dent* 25(1) (2013) 55-69.
- [31] I. Metz, K. Rothmaier, V. Pitchika, A. Crispin, R. Hickel, F. Garcia-Godoy, K. Bucher, J. Kuhnisch, Risk factors for secondary caries in direct composite restorations in primary teeth, *Int J Paediatr Dent* 25(6) (2015) 451-61.
- [32] A.F. Montagner, A.P. Perroni, M.B. Correa, A.S. Masotti, T. Pereira-Cenci, M.S. Cenci, Effect of pre-treatment with chlorhexidine on the retention of restorations: a randomized controlled trial, *Braz Dent J* 26(3) (2015) 234-41.

- [33] J. Perdigao, C. Kose, A.P. Mena-Serrano, E.A. De Paula, L.Y. Tay, A. Reis, A.D. Loguercio, A new universal simplified adhesive: 18-month clinical evaluation, *Oper Dent* 39(2) (2014) 113-27.
- [34] F. Sengul, T. Gurbuz, Clinical evaluation of restorative materials in primary teeth class II lesions, *J Clin Pediatr Dent* 39(4) (2015) 315-21.
- [35] J.A. Skupien, M.S. Cenci, N.J. Opdam, C.M. Kreulen, M.C. Huysmans, T. Pereira-Cenci, Crown vs. composite for post-retained restorations: A randomized clinical trial, *J Dent* 48 (2016) 34-9.
- [36] H.J. Staehle, T. Wohlrab, D. Saure, D. Wolff, C. Frese, A 6.5-year clinical follow-up of direct resin composite buildups in the posterior dentition: Introduction of a new minimally invasive restorative method, *J Dent* 43(10) (2015) 1211-7.
- [37] R. Walter, L.W. Boushell, H.O. Heymann, A.V. Ritter, J.R. Sturdevant, A.D. Wilder, Jr., Y. Chung, E.J. Swift, Jr., Three-year clinical evaluation of a silorane composite resin, *J Esthet Restor Dent* 26(3) (2014) 179-90.
- [38] C. Zander-Grande, R.C. Amaral, A.D. Loguercio, L.P. Barroso, A. Reis, Clinical performance of one-step self-etch adhesives applied actively in cervical lesions: 24-month clinical trial, *Oper Dent* 39(3) (2014) 228-38.
- [39] P.S. Fleming, D. Koletsi, K. O'Brien, A. Tsihlaki, N. Pandis, Are dental researchers asking patient-important questions? A scoping review. *J Dent*. 2016 Jun;49:9-13, *J Dent* 49 (2016) 9-13.
- [40] M. Clarke, Standardising outcomes for clinical trials and systematic reviews, *Trials* 8 (2007) 39.
- [41] A. Chiarotto, R.W. Ostelo, D.C. Turk, R. Buchbinder, M. Boers, Core outcome sets for research and clinical practice, *Braz J Phys Ther* 21(2) (2017) 77-84.
- [42] T. Lamont, F. Schwendicke, N. Innes, Why we need a core outcome set for trials of interventions for prevention and management of caries, *Evid Based Dent* 16(3) (2015) 66-8.
- [43] F. Schwendicke, T. Lamont, N. Innes, Outcomes in trials for management of caries lesions (OuTMaC): protocol, *Trials* 16(1) (2015) 397.
- [44] C. Villat, J.P. Attal, N. Brulat, F. Decup, S. Domejean, E. Dursun, H. Fron-Chabouis, B. Jacquot, M. Muller Bolla, N. Plasse-Pradelle, L. Roche, D. Maucort-Boulch, P. Nony, K. Gritsch, P. Millet, F. Gueyffier, B. Grosogeat, One-step partial or complete caries removal and bonding with antibacterial or traditional self-etch adhesives: study protocol for a randomized controlled trial, *Trials* 17 (2016) 404.



Figure captions

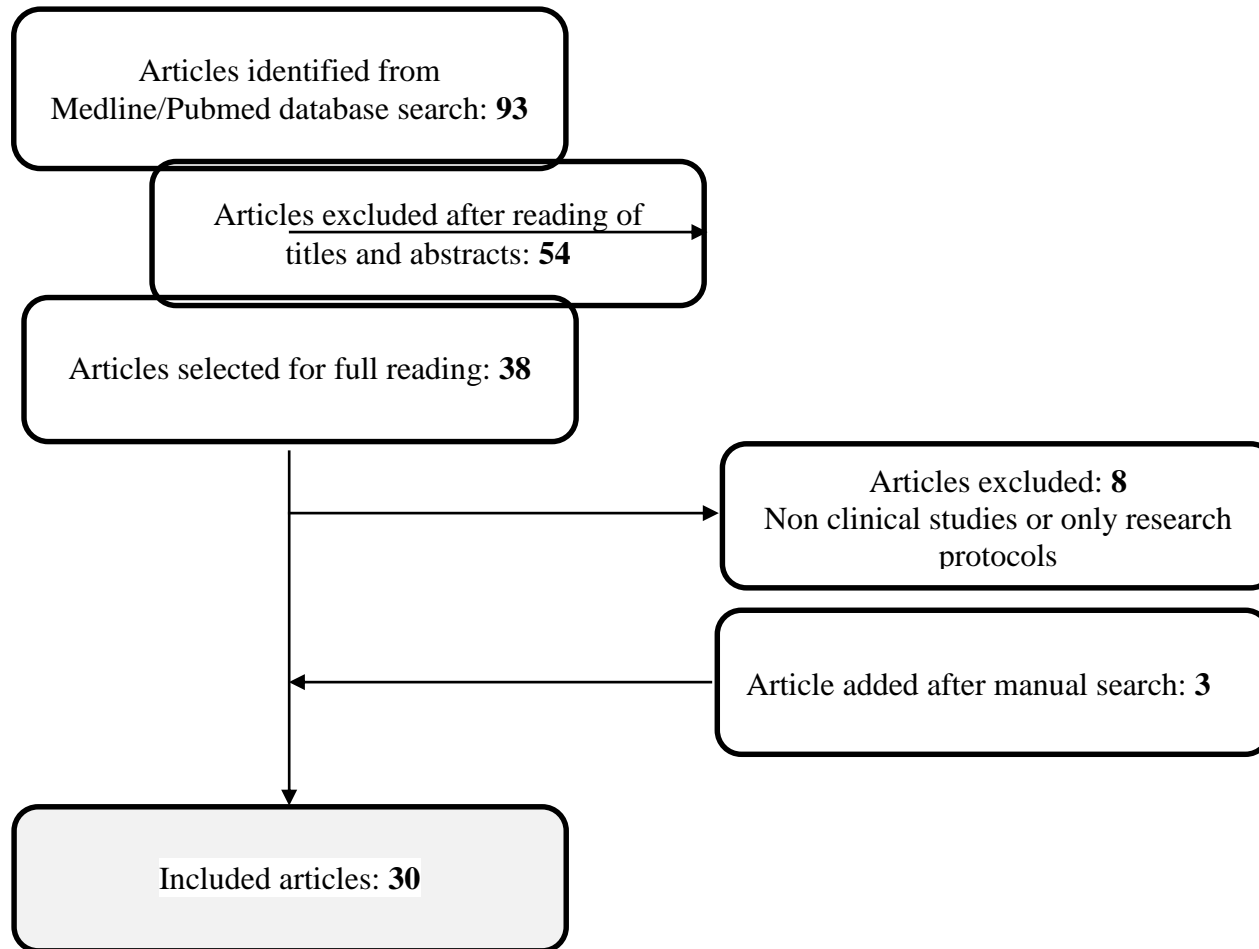
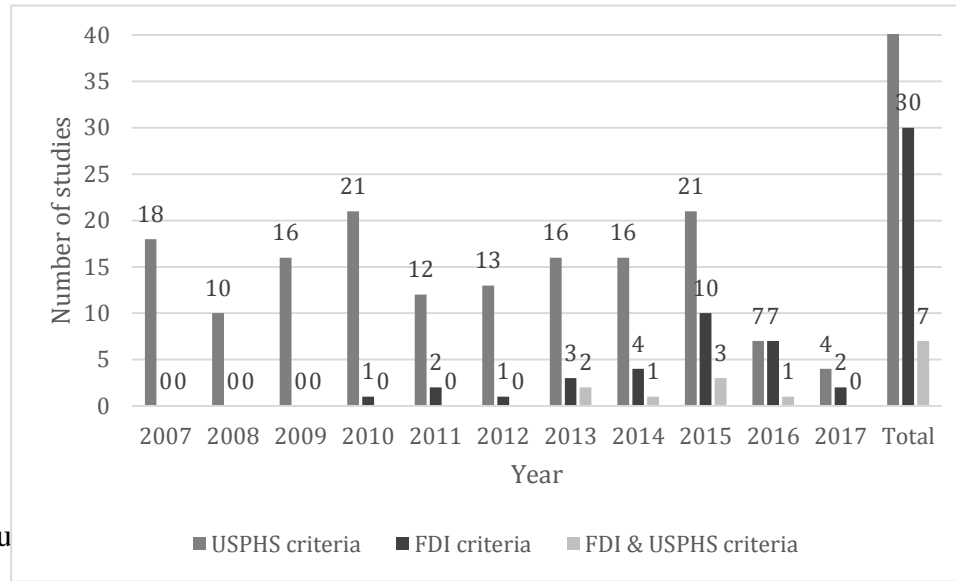


Figure 1: Flowchart of the selection process for the first systematic search regarding the use of FDI criteria



154

Figure 2: Nu  
2007

criteria, modified USPHS criteria or both, per year since

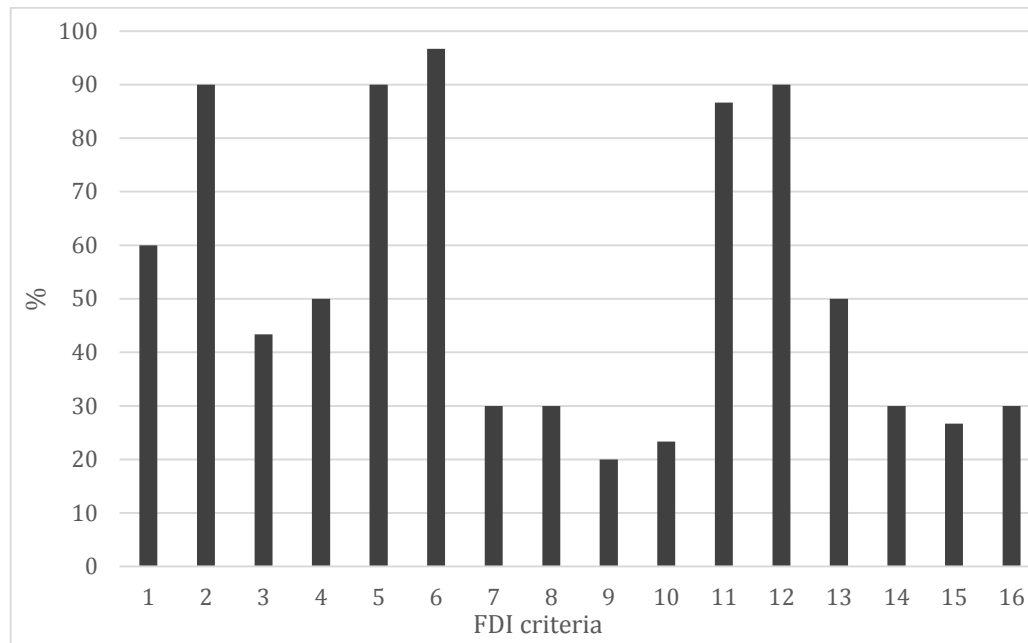


Figure 3: Percentage of use for each criterion in the 30 selected studies (for each criterion, from 1 to 16: “number of studies using the criterion”/“the total number of studies (n=30)”)

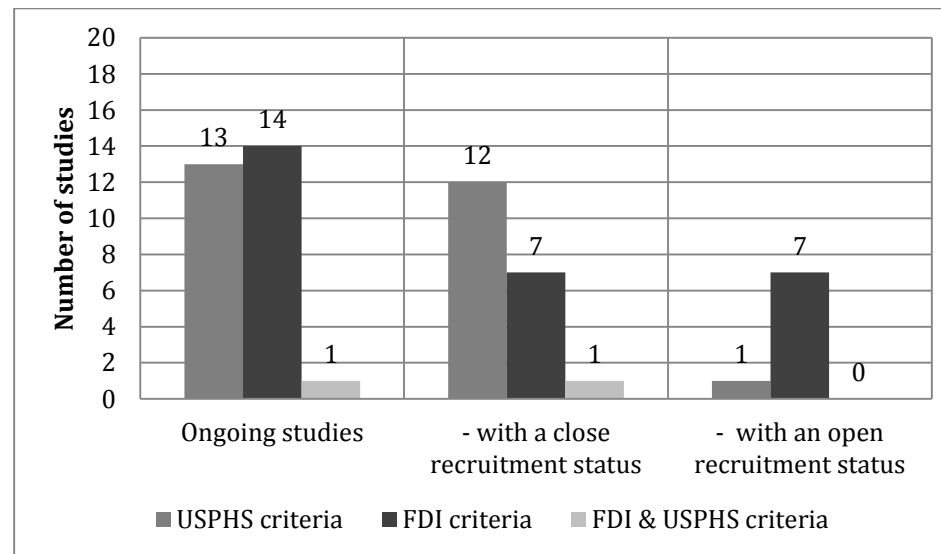


Figure 4: Number of on-going studies using FDI criteria, USPHS criteria and both, including those with a close recruitment status and those with an open recruitment status

**Table 1:** The FDI criteria with their various categories and their grading (in italic: the revisions of 2010), and the correspondence with the USPHS criteria, with their various criteria and their grading (in italic: the modified USPHS)

FDI CRITERIA (modified in 2010)		CORRESPONDANT USPHS CRITERIA			
CATEGORIES	SUB-CATEGORIES	FIVE STEPS GRADING	TWO STEPS GRADING	CATEGORIES (modified)	GRADING
a) Aesthetic properties	1. Surface luster			<i>Surface texture</i>	
	2. Staining			Cavo-surface marginal discoloration	
	a. Surface				
	b. Margin			Color match	
	3. Colour <i>match</i> and translucency			Anatomic contour	
b) Functional properties	4. <i>Esthetic anatomical form</i>			<i>Fracture, retention</i>	
	5. Fracture of material and retention			Marginal integrity	
	6. Marginal adaptation	1. <b>Clinically excellent/very good</b>		<i>Occlusion</i>	<b>Alpha</b> (clinically ideal)
	7. Wear	2. <b>Clinically good</b> (after correction very good)		-	
	8. Proximal anatomical form (contact point/food impact)	3. <b>Clinically sufficient/satisfactory</b> (minor shortcomings with no adverse effects but not adjustable without damage to the tooth)	Acceptable (1,2,3)	-	<b>Bravo</b> (showing minor deviations from the ideal, nevertheless acceptable) (except for retention and secondary caries)
	9. Radiographic examination (when applicable)	4. <b>Clinically unsatisfactory</b> (repair for prophylactic reasons)	Non acceptable (4,5)	-	<b>Charlie</b> (should be replaced to avoid future damage)
	10. Patient's view	5. <b>Satisfactory poor</b> (replacement necessary)		-	<b>Delta</b> (requiring immediate replacement)
	11. Postoperative (hyper-sensitivity) and tooth vitality			<i>Postoperative sensitivity</i>	
	12. Recurrence of caries, erosion, abfraction			Secondary caries	
	13. Tooth integrity (enamel cracks)			-	
	c) Biological properties	14. Periodontal response (always compared to a reference tooth)			-
15. Adjacent mucosa				-	
16. Oral and general health				-	

**Table 2:** Search strategy of the scoping review to explore the extent of the use of FDI criteria

Review type and objectives	Database	Combination of key-words	Exclusion criteria	Date filter
<b>First systematic review:</b> - to identify - to analyse all the clinical studies using FDI criteria	Pubmed	FDI criteria	-	From January 2007 to April 2017
Supplementary information	E-mail to the corresponding authors	-	-	-
<b>Second systematic review:</b> to identify all the clinical studies using USPHS criteria	Pubmed	“USPHS criteria” AND “Ryge criteria”	-	From January 2007 to April 2017
<b>Additional search:</b> to identify all the on-going clinical studies using FDI and USPHS criteria	ClinicalTrials.gov	FDI criteria	“Unknown” status	-
		“USPHS criteria”	“Unknown” status	-
		“Ryge criteria”	“Unknown” status	-

**Table 3:** Included studies, their main characteristics and information about the use of FDI criteria

Authors	Year	Article titles	Study characteristics	Dentition	FDI criteria used*	Number of score used	Other criteria used	Examiner training/calibration
Baldissera <i>et al</i> [9]	2013	Are there universal restorative composites for anterior and posterior teeth?	Retrospective study	Permanent	1-8, 12, 13	5	-	Trained and calibrated
Bektas Donmez <i>et al</i> [10]	2016	Clinical performance of aesthetic restorative materials in primary teeth according to the FDI criteria	Prospective study Split-mouth design	Primary	1-6, 8, 9, 11-13, 15, 16	5	-	-
Bücher <i>et al</i> [11]	2015	Survival characteristics of composite restorations in primary teeth	Retrospective study	Primary	2-6, 9, 11-14	5	-	-
Çelik <i>et al</i> [12]	2015	Six-month clinical evaluation of a self-adhesive flowable composite in noncarious cervical lesions	Randomized, controlled, single-center, prospective study Split-mouth design	Permanent	1-7, 10-16	5	-	Trained and calibrated
Coelho-de-Souza <i>et al</i> [13]	2010	Double-blind randomized clinical trial of posterior composite restorations with and without bevel: 6-month follow-up	Randomized, double-blind, prospective study Split-mouth design	Permanent	1, 2, 4-6, 11, 12	5	-	Calibrated
Coelho-de-Souza <i>et al</i> [14]	2012	A randomized double-blind clinical trial of posterior composite restorations with or without bevel: 1-year follow-up	Randomized, double-blind, prospective study Split-mouth design	Permanent	1, 2, 4 -6, 11, 12	5	-	Calibrated
Da Costa <i>et al</i> [15]	2014	Eighteen-month randomized clinical trial on the performance of two etch-and-rinse adhesives in non-carious cervical lesions	Randomized, double-blind, clinical trial	Permanent	2, 5, 6, 11, 12	4	-	Trained and calibrated

Da Rosa Rodolpho <i>et al</i> [16]	2011	22-Year clinical evaluation of the performance of two posterior composites with different filler characteristics	Retrospective study	Permanent	1-8, 11-16	4	-	-
De Paula <i>et al</i> [17]	2015	Randomized clinical trial of four adhesion strategies in cervical lesions: 12-month results	Randomized, double-blind, 1 prospective study	Permanent	2, 5, 6, 11, 12	5	Modified USPHS criteria	Trained on photographs
Bektas Donmez <i>et al</i> [18]	2016	Randomized clinical trial of composite restorations in primary teeth: effect of adhesive system after three years	Randomized, prospective study	Primary	1-6, 8, 9, 11-13, 15, 16	5	-	Trained on photographs
Farag <i>et al</i> [19]	2011	Survival of ART restorations assessed using selected FDI and modified ART restoration criteria	Prospective study	Permanent	5-7, 12, 13	5	-	Calibrated
Frese <i>et al</i> [20]	2013	Recontouring teeth and closing diastemas with direct composite buildups: a 5-year follow-up	Prospective study	Permanent	1-8, 10-16	5	Modified USPHS criteria	E-calib
Jang <i>et al</i> [21]	2017	Clinical effectiveness of different polishing systems and self-etch adhesives in class V composite resin restorations: two-year randomized controlled clinical trial	Randomized, prospective study	Permanent	1, 2, 5, 6, 11, 12	5	-	Trained on photographs and e-calib
Kim <i>et al</i> [22]	2016	Interrater and intrarater reliability of FDI criteria applied to photographs of posterior tooth-colored restorations	Photographic evaluation	Permanent	1-6, 12, 13	5	-	Trained on photographs



Kitasako <i>et al</i> [23]	2016	Thirty-six month clinical evaluation of a highly filled flowable composite for direct posterior restorations	Randomized, prospective study	Permanent	1, 2, 5, 6, 11, 12	5	-	Calibrated
Klinke <i>et al</i> [24]	2016	Clinical performance during 48 months of two current glass ionomer restorative systems with coatings: a randomized clinical trial in the field	Prospective study	Permanent	1, 5-8, 10-13	5	-	Trained/calibrated on E-calib
Loguercio <i>et al</i> [25]	2015	A new universal simplified adhesive: 36-Month randomized double-blind clinical trial	Double-blind, prospective study	Permanent	2, 11, 12	5	Modified USPHS criteria	Trained on photographs
Loguercio <i>et al</i> [26]	2015	Influence of isolation method of the operative field on gingival damage, patients' preference, and restoration retention in noncarious cervical lesions	Examiner-blind, randomized, prospective study Split-mouth design	Permanent	2, 5, 6, 11	5	-	Trained on photographs
Lopes <i>et al</i> [27]	2016	Six-month follow-up of cervical composite restorations placed with a new universal adhesive system: a randomized clinical trial	Randomized, double-blind, prospective study	Permanent	2, 6, 11, 12	5	Modified USPHS criteria	Trained on photographs
Luque-Martinez <i>et al</i> [28]	2015	Effect of EDTA conditioning on cervical restorations bonded with a self-etch adhesive: a randomized double-blind clinical trial	Randomized, double-blind, prospective study	Permanent	2, 6, 11, 12	5	-	Calibrated
May <i>et al</i> [29]	2017	Flowable composites for restoration of non-carious cervical lesions: three-year results	Randomized, prospective study	Permanent	1, 2, 5, 6, 11	5	-	Calibrated
Mena-Serrano <i>et al</i> [30]	2013	A new universal simplified adhesive: 6-month clinical evaluation	Randomized, prospective study	Permanent	2, 5, 6, 11, 12	5	Modified USPHS criteria	Trained on photographs

Metz <i>et al</i> [31]	2015	Risk factors for secondary caries in direct composite restorations in primary teeth	Retrospective study	Primary	12 criteria used without any precision	No precision	-	-
Montagner <i>et al</i> [32]	2015	Effect of pre-treatment with chlorhexidine on the retention of restorations: a randomized controlled trial	Randomized, triple-blind, prospective study Split-mouth design	Permanent	1-6, 11, 13, 14	5	-	Trained/calibrated on E-calib
Perdigao <i>et al</i> [33]	2014	A new universal simplified adhesive: 18-month clinical evaluation	Randomized, prospective study	Permanent	2, 5, 6, 11, 12	5	Modified USPHS criteria	Trained on photographs
Sengul <i>et al</i> [34]	2015	Clinical evaluation of restorative materials in primary teeth class II lesions	Randomized, prospective study	Primary	1-6, 8-16	5	-	-
Skupien <i>et al</i> [35]	2016	Crown vs. composite for post-retained restorations: a randomized clinical trial	Randomized, prospective study	Permanent	1-16	5	-	Trained and calibrated
Staeble <i>et al</i> [36]	2015	A 6.5-year clinical follow-up of direct resin composite buildups in the posterior dentition: introduction of a new minimally invasive restorative method	Retrospective study	Permanent	1-7, 10-12, 14	3	Modified USPHS criteria	Trained/calibrated on E-calib
Walter <i>et al</i> [37]	2014	Three-year clinical evaluation of a silorane composite resin	Randomized single-blind clinical study	Permanent	1-16	5	-	-
Zander-Grande <i>et al</i> [38]	2014	Clinical performance of one-step self-etch adhesives applied actively in cervical lesions: 24-month clinical trial	Randomized, prospective study	Permanent	2, 5, 6, 11, 12	5	-	Trained on photographs

\*1: Surface luster; 2: Staining; 3: Colour match and translucency; 4: Aesthetic anatomical form; 5: Fracture of material and retention; 6: Marginal adaptation; 7: Wear; 8: Proximal anatomical form (contact point/food impact); 9: Radiographic examination (when applicable); 10: Patient's view; 11: Postoperative (hyper-sensitivity) and tooth vitality; 12: Recurrence of caries, erosion, abfraction; 13: Tooth integrity (enamel cracks); 14: Periodontal response; 15: Adjacent mucosa; 16: Oral and general health

**Table 4:** The use of FDI criteria per year since 2007

<b>Year</b>	<b>Total number of studies</b>	<b>Number of studies using FDI criteria</b>	<b>% of studies using FDI criteria</b>
<b>Total (published studies)</b>	184	30	16.3
<b>2007</b>	18	0	0
<b>2008</b>	10	0	0
<b>2009</b>	16	0	0
<b>2010</b>	22	1	4.6
<b>2011</b>	14	2	14.3
<b>2012</b>	14	1	7.1
<b>2013</b>	19	3	15.8
<b>2014</b>	20	4	20
<b>2015</b>	31	10	32.3
<b>2016</b>	14	7	50
<b>2017</b>	6	2	3.3
<b>Ongoing studies</b>	27	14	51.9
<b>- with a close recruitment status</b>	19	7	36.8
<b>- with an open recruitment status</b>	8	7	87.5
<b>Total (published + ongoing studies)</b>	211	44	68.2