







## Choosing the Criteria for Clinical Evaluation of Composite Restorations: An Analysis of Impact on Reliability and Treatment Decision

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### Abstract

**Objective:** To assess the reproducibility of two clinical criteria for the evaluation of restorations in primary teeth and the impact on treatment decision. **Material and Methods:** A cross-sectional study was performed selecting 71 resin-based composite restorations placed in primary molars of children who had sought dental treatment at a dental school. Two trained examiners evaluated independently the restorations using modified FDI and USPHS criteria. All restorations were assessed separately with each system in random order to avoid memory bias. Kappa statistics were used to determine inter-examiner reliability considering each parameter of both criteria and score final about treatment decision. McNemar test was used to compare the treatment decision with two criteria. The significance level was set at 5%. **Results:** Kappa values ranged from 0.28 to 0.93 with USPHS and 0.28 to 0.88 with FDI, considering each parameter separately. Inter-examiner agreement for treatment decision was excellent for both criteria (Kappa: 0.85-0.90). For clinical decision-making, no difference between criteria was found, irrespective of examiner. **Conclusion:** Low inter-examiner agreement for evaluation of each parameter of USPHS and FDI criteria does not reflect on reproducibility for treatment decision. Both criteria may be suitable for evaluation of composite restorations in primary teeth.

**Keywords:** Clinical Decision-Making; Dental Restoration Failure; Tooth; Deciduous.

## Introduction

Resin-based dental composites are widely used in Pediatric Clinic for restoring anterior and posterior teeth. The annual failure rates of composite restorations in primary teeth have varied between 4% and 9% [1,2]. Nevertheless, parameters for assessing the restorations' quality are often subjective, where small deviations from ideal concepts determine the replacement.

In this sense, different criteria have been proposed aiming to standardize the evaluation of restorative materials or operative techniques in clinical trials. Furthermore, these criteria may be useful for quality assessment of restorations placed by clinicians in their own practices. Also, dental students should be trained to use them as part of a clinical evaluation to determine whether a restoration can be maintained or whether it needs repair or replacement [3].

US Public Health Service (USPHS) guidelines also known as the "Ryge criteria"[4] and FDI (World Dental Federation) [3] are the criteria most used for evaluating composite restorations [5-9]. Both criteria are based on assessment of biological, esthetic and functional parameters and can be and adjusted according to the needs of the user. FDI criteria were recently proposed as "standard criteria", more sensitive for identifying differences in dental restorations [3].

Good criteria should be reproducible. However, no previous study has compared the inter-examiner agreement when using the two criteria for clinical evaluation of restorations. Besides, criteria that lead to overtreatment would not be desirable nowadays. The impact of using these criteria in the treatment decision regarding the evaluated restorations was not yet investigated.

Therefore, we aimed to assess the reproducibility of two clinical criteria for the evaluation of resin-based composite restorations in primary teeth and the impact on treatment decision.

## Material and Methods

### Sample Selection

A convenience sample was used in this study. Seventy-one resin-based composite restorations placed in primary molars were selected from clinical records of patients attended at Pediatric Clinic of the School of Dentistry, Federal University of Santa Maria. Occlusal restorations were performed by fourth and five years dental undergraduate students, supervised by specialists in Pediatric Dentistry. The majority of the children have low familiar socioeconomic status and high caries risk.

### Training and Calibration of Evaluators

Two examiners (C.P.C. and P.S.S.) underwent a total of 8 h of specific training session involving theoretical explanations and discussion using clinical slides about United States Public Health Service (USPHS) and World Dental Federation (FDI) criteria. The responsible for training session was a benchmark examiner (T.L.L.) who has been trained and calibrated for using two criteria. The examiners' calibration procedures considered two examinations of 20 photographs that were representative of each score for both criteria, randomly distributed in both periods, for Cohen's Kappa calculation (Kappa = 0.80).

A modified USPHS guidelines was used in this study [10], including color match, marginal adaptation, anatomic form, marginal staining, surface roughness and caries. FDI criteria were categorized into three groups [3]: esthetic (four criteria), functional (three criteria) and biological (one criterion) parameters. A five-point Likert scale was used to assess the functional property "patient view" of FDI criteria in the Pediatric

Dentistry. Child's satisfaction with the restoration was measured from one to five according to the scale: 1 = very satisfied; 2 = satisfied; 3 = indifferent; 4 = unsatisfied; 5 = very unsatisfied.

For both criteria, postoperative sensitivity was not considered because this evaluation is subject to subjectivity when performed in pediatric patients.

#### Evaluation of Restorations

The children were called to visit the dental clinic. After prophylaxis, the two trained examiners (C.P.C. and P.S.S.) evaluated independently the children's restorations using ballpoint probe and plane buccal mirror (Hu-Friedy Manufacturing Co., Chicago, USA). All restorations were assessed separately with each criterion and randomly distributed to avoid memory bias.

Each criterion of FDI can be expressed with five scores, three for acceptable (1. clinically very good; 2. clinically good; 3. clinically sufficient/satisfactory) and two for non-acceptable (4. clinically unsatisfactory – repairable restoration; 5. clinically poor – restoration replacement). Codes Alfa, Bravo, Charlie and Delta were used to rate the restorations according to the assigned descriptive values for each characteristic of USPHS criteria. For clinical decision-making, the worst grading among all parameters of both criteria was considered. The restorations were recorded as failed if they were classified as Bravo for caries or Charlie and Delta scores for the other parameters using USPHS criteria or rated as scores 4 and 5 by FDI criteria.

#### Statistical Analyses

The descriptive analysis provides the distribution summary of restorations according to the parameters assessed with both criteria. Kappa values and respective 95% confidence intervals were calculated and used to determine inter-examiner reliability considering each parameter of both criteria and score final about treatment decision. The strength of agreement for the Kappa value can be interpreted as follows: < 0.20: Poor; 0.21-0.40: Fair; 0.41-0.60: Moderate; 0.61-0.80: Good; 0.81-1.00: Excellent [11]. McNemar test was used to compare the treatment decision with two criteria. The significance level was set at  $p < 0.05$ . Statistical analyses were performed using the STATA software 12.0 (Stata Corp., College Station, TX, USA).

#### Ethical Concern

The research protocol was approved by the Local Research Board and the parents or guardians signed a written informed consent. The personal information of the children was kept confidential.

### Results

The distribution of restorations according to the parameters evaluated by two examiners using USPHS and FDI criteria is displayed in Tables 1 and 2, respectively.

Most restorations were classified as Alfa for all parameters of the USPHS criteria. Only surface roughness was categorized as Delta. The main reason for need of intervention was adjacent caries. Likewise, the majority of restorations were rated as score (clinically very good) for all parameters of the FDI criteria. However, there was not a main reason for need of intervention, being fracture, marginal adaptation and recurrence caries factors more related to indication of restorations' replacement or repair. Only one of examiners judged need of repair (score 4) due color and anatomic form.

**Table 1. Status of the restorations according to USPHS criteria.**

USPHS Criteria	Examiner							
	Alfa		Bravo		Charlie		Delta	
	A	B	A	B	A	B	A	B
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Color Match	55 (77.5)	61 (86.0)	13 (18.3)	7 (9.8)	3 (4.2)	3 (4.2)	-	-
Marginal Adaptation	55 (77.5)	62 (87.4)	10 (14.1)	3 (4.2)	6 (8.4)	6 (8.4)	-	-
Anatomic Form	54 (76.1)	60 (84.6)	12 (16.9)	6 (8.4)	5 (7.0)	5 (7.0)	-	-
Surface Roughness	55 (77.5)	57 (80.4)	10 (14.1)	9 (12.6)	-	-	6 (8.4)	5 (7.0)
Marginal Pigmentation	50 (70.4)	55 (77.5)	18 (25.4)	12 (16.9)	3 (4.2)	4 (5.6)	-	-
Occlusal Contact	63 (88.8)	64 (90.1)	3 (4.2)	2 (2.9)	5 (7.0)	5 (7.0)	-	-
Adjacent Caries	63 (88.8)	61 (85.9)	8 (11.2)	10 (14.1)	-	-	-	-

**Table 2. Status of the restorations according to FDI criteria.**

FDI Criteria	Examiner									
	1		2		3		4		5	
	A	B	A	B	A	B	A	B	A	B
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Surface Luster	59 (83.1)	56 (78.9)	10 (14.1)	13 (18.3)	1 (1.4)	1 (1.4)	-	-	1 (1.4)	1 (1.4)
Surface Staining	58 (81.6)	62 (87.3)	10 (14.1)	6 (8.4)	1 (1.4)	1 (1.4)	-	-	2 (2.9)	2 (2.9)
Margin Staining	39 (54.9)	44 (62.0)	24 (33.8)	23 (32.2)	6(8.4)	2 (2.9)	-	-	2 (2.9)	2 (2.9)
Color Match and Translucency	52 (73.2)	62 (87.3)	10 (14.1)	4 (5.6)	6 (8.4)	3 (4.2)	1 (1.4)	-	2 (2.9)	2 (2.9)
Anatomic Form	51(71.7)	59 (83.1)	11 (15.5)	7 (9.8)	5 (7.0)	3 (4.2)	2 (2.9)	-	2 (2.9)	2 (2.9)
Fracture	62 (87.3)	61 (86.0)	1 (1.4)	1 (1.4)	-	-	2 (2.9)	4 (5.6)	6 (8.4)	5 (7.0)
Marginal Adaptation	51 (71.8)	57 (80.4)	9 (12.7)	5 (7.0)	4 (5.6)	5 (7.0)	2 (2.9)	1 (1.4)	5 (7.0)	3 (4.2)
Patient View*	50 (70.4)	54 (76.1)	17 (24.0)	11 (15.5)	3 (4.2)	5 (7.0)	1 (1.4)	1 (1.4)	-	-
Caries Recurrence	57 (80.4)	61 (85.9)	5 (7.0)	3 (4.2)	1 (1.4)	1 (1.4)	5 (7.0)	4 (5.6)	3 (4.2)	2 (2.9)

\*Adapted for Pediatric Dentistry by five-point Likert scale.

Tables 3 and 4 present unweighted Kappa coefficient for inter-examiner reproducibility for USPHS and FDI, respectively. Overall, lower Kappa values were obtained with FDI criteria. When using USPHS criteria, Kappa values ranged from 0.28 to 0.93 considering each parameter separately. Fair agreement was achieved only for marginal pigmentation assessment. Inter-examiner agreement was good for adjacent caries, excellent for occlusal contact and moderate for other parameters.

**Table 3. Unweighted Kappa coefficient for inter-examiner reproducibility with USPHS criteria.**

USPHS Criteria	Kappa	SE	95% CI
Color Match	0.55	0.12	0.31-0.80
Marginal Adaptation	0.50	0.12	0.27-0.73
Anatomic Form	0.50	0.12	0.26-0.74
Surface Roughness	0.48	0.12	0.25-0.72
Marginal Pigmentation	0.28	0.12	0.03-0.52
Occlusal Contact	0.93	0.07	0.78-1.00
Adjacent Caries	0.75	0.12	0.51-0.98
Treatment Decision	0.85	0.08	0.69-1.00

**Table 4. Unweighted Kappa coefficient for inter-examiner reproducibility with FDI criteria.**

FDI Criteria	Kappa	SE	95% CI
Surface Luster	0.34	0.14	0.06-0.61
Surface Staining	0.41	0.10	0.21-0.60
Margin Staining	0.28	0.15	-0.01-0.57
Color Match and Translucency	0.35	0.10	0.15-0.56
Anatomic Form	0.38	0.11	0.16-0.59
Fracture	0.88	0.08	0.73-1.00
Marginal Adaptation	0.47	0.09	0.29-0.65
Patient View	0.50	0.10	0.30-0.70
Caries Recurrence	0.58	0.12	0.34-0.81
Treatment Decision	0.90	0.07	0.76-1.00

When using FDI criteria, values ranged from 0.28 to 0.88. Excellent agreement was obtained only for fracture evaluation. For other parameters, Kappa values were interpreted as poor or fair. Although the inter-examiner agreement was fair considering the global score (the worst grading among all parameters), excellent agreement was achieved for treatment decision.

Kappa values for treatment decision were 0.85 and 0.90 with USHPS and FDI criteria. For clinical decision-making, no difference between criteria was found, irrespective of examiner (Table 5).

**Table 5. Comparison of the treatment decision according to two criteria.**

Treatment Decision	Examiner A			Examiner B		
	USPHS	FDI	p-value	USPHS	FDI	p-value
No Intervention	59 (83.1)	60 (84.5)	1.000	58 (81.7)	58 (81.7)	1.000
Intervention	12 (16.9)	11 (14.5)		13 (18.3)	13 (18.3)	

## Discussion

This study provides valuable information regarding the reliability and clinical decision-making of two criteria commonly used to evaluate restorations' quality. Although low Kappa values have been obtained considering the assessment of each parameter for both criteria, this fact did not impact the treatment decision,

as the reliability was good. This finding is important because the final objective of a diagnostic method is to reach a consistent treatment decision.

Most restorations were classified as clinically acceptable. FDI criteria are categorized in five scores, being three acceptable. The differences among them, mainly between scores 1 and 2, are subtle and more prone to disagreements, as observed in this study (Table 2). On the other hand, the characteristics related to Alpha and Bravo scores of USPHS are less subjective.

Unweighted Kappa was used in this study. Although it was expected high values with weighted Kappa, we aimed to assess if low values for each parameter, including all categories of the criteria, would result on low inter-examiner agreement for treatment decision. For clinical decision-making, the most severe grading among all parameters of both criteria prevailed. Despite the fair inter-agreement for majority of the parameters, excellent reliability was found for treatment decision. Including, the Kappa values of global restorations' evaluation was slightly higher with FDI than USPHS. Based on these findings, a simplified clinical evaluation, mainly when using FDI, may be appropriate, e.g. it is possible to pool scores 1 and 2 (equivalent to USPHS 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 [3].

For clinical decision-making, no statistically significant difference between criteria was found, irrespective of the examiner. We hypothesized that differences would be noted if a high proportion of unsatisfactory restorations were included in the sample. Whenever a restoration receives a score of 4 or 5 of FDI or Bravo for caries and Charlie or Delta scores of USPHS, it must be judged with need of intervention. However, differently of USPHS guidelines, FDI criteria allow deciding whether the restoration can be repaired (score 4) or require replacement (score 5). In this sense, decision-making might differ between two criteria, since FDI could avoid a more invasive intervention or even overtreatment. Repairing is an interesting approach that saves patient-chair time and tooth structure [12,13], being less likely to need an aggressive treatment, as endodontic treatment or extraction [14].

Secondary caries and marginal defects are the most frequent reasons for replacement reported in the literature [15]. Similar Kappa values between criteria were achieved for marginal adaptation assessment. Inter-examiner agreement was good (0.75) and moderate (0.58) for USPHS and FDI. It is relevant to highlight that USPHS rates caries as present or absent, while FDI involves all stages of carious process, i.e., since initial demineralization until deep caries (accessible or not for repair). Again, the main inter-examiner disagreements were between FDI scores 1 (no caries) and 2 (small and localized demineralization). In this study, a mean of 12.6% and 9.8% of restorations were judged as failure due caries with USPHS and FDI criteria, respectively. However, as treatment decision, only a mean of 3.5% of restorations needed to be replaced due caries when FDI was used.

The small number of evaluators can be considered a limitation of the study, as only two examiners were used. Conversely, a larger number of examiners would imply a more lengthy assessment for each child, making it more tiring and stressful for the young children who participated in this study. Moreover, it would have increased the number of sessions, which could have led to dropouts. For this reason, intra-examiner reproducibility was not calculated in this study. It should be noted that a good intra-examiner agreement was achieved during the training and calibration stage.

In this sense, low Kappa values for the evaluation of some parameters seem to be more related a limitation of the criteria and not of the evaluators' training. Among evaluated parameters, lowest Kappa values








were obtained for marginal pigmentation when using both criteria. Even using a criterion, this parameter was suitable to higher subjectivity. Marginal pigmentation can occur due degradation of bonding agents or penetration of dyes from dietetic habits; factors not directly associated to caries. In this sense, this evaluation might have low impact in restorations' quality of posterior teeth.

The property "patient view" of FDI criteria was measured with a five point Likert scale. Although it is a validated instrument [16], the responses of the children differed in two examinations (Kappa equal 0.50). This indicates that child's satisfaction may be not related to real condition of restorations and researches should rethink whether this evaluation is necessary in future studies.

## Conclusion

Low inter-examiner agreement for evaluation of each parameter of USPHS and FDI criteria does not reflect on reproducibility for treatment decision. Both criteria may be suitable for evaluation of composite restorations in primary teeth. Other aspects should be considered for choosing the clinical criteria, such as time consuming and examiner preferences.

## Authors' Contributions

CPC		0000-0001-9402-1811	Investigation, Formal Analysis and Writing – Original Draft Preparation.
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TLL		0000-0003-3568-5217	Conceptualization, Methodology, Investigation and Writing – Review and Editing.

All authors declare that they contributed to critical review of intellectual content and approval of the final version to be published.

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## Conflict of Interest

The authors declare no conflicts of interest.

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