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22-Year clinical evaluation of the performance of two posterior composites with different filler characteristics

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ABSTRACT

Objectives. This retrospective longitudinal study investigated the longevity of posterior restorations placed in a single general practice using 2 different composites in filler characteristics and material properties: P-50 APC (3M ESPE) with 70 vol.% inorganic filler loading (midfilled) and Herculite XR (Kerr) with 55 vol.% filler loading (minifilled).

Methods. Patient records were used for collecting data. Patients with at least 2 posterior composite restorations placed between 1986 and 1990, and still in the practice for regular check-up visits, were selected. 61 patients (20 male, 41 female, age 31.2–65.1) presenting 362 restorations (121 Class I, 241 Class II) placed using a closed sandwich technique were evaluated by 2 operators using the FDI criteria. Data were analyzed with Fisher's exact test, Kaplan–Meier statistics, and Cox regression analysis ($p < 0.05$).

Results. 110 failures were detected. Similar survival rates for both composites were observed considering the full period of observation; better performance for the midfilled was detected considering the last 12 years. There was higher probability of failure in molars and for multi-surface restorations.

Significance. Both evaluated composites showed good clinical performance over 22 years with 1.5% (midfilled) and 2.2% (minifilled) annual failure rate. Superior longevity for the higher filler loaded composite (midfilled) was observed in the second part of the observation period with constant annual failure rate between 10 years and 20 years, whereas the minifilled material showed an increase in annual failure rate between 10 years and 20 years, suggesting that physical properties of the composite may have some impact on restoration longevity.

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1. Introduction

Nowadays, resin composite is considered as a suitable direct posterior filling material showing an acceptable survival in clinical studies [1–3]. Also in large sized restorations, composite can achieve comparable longevity to amalgam [4]. Generally, hybrid composites can be considered as the best materials for posterior restorations since in clinical studies these materials mostly perform adequately [2]. High failure rates on the short to median long term are seldom found in clinical studies for hybrid composites, with the exception of some novel materials that turned out to be not acceptable shortly after being brought on the market [5,6].

Meanwhile, considerable differences in properties exist among commercial composites. These differences are mainly related to differences in filler loading level, particle morphology and size [7–9]. Based on the filler features, composite restoratives are currently classified as nanofilled, microfilled or micro/nanohybrid materials, with filler mass fractions varying from 42% to 85% [9]. Hybrid composites can be also classified into minifilled composites, with average particle size <1 μm, and midifilled composites, with average particle size between 2 μm and 5 μm [10]. The elastic modulus and other properties of these different types of composites have been shown to be fairly variable in *in vitro* studies [8,11–14]. As large differences in clinical behavior of posterior composite restorations could not be demonstrated so far [2,15,16], it remains questionable whether differences in composite properties reported in laboratory tests have any relevance regarding the clinical survival of composite restorations.

A restriction in clinical studies is that observation times of longer than five years are hardly feasible in most prospective clinical trials, considering the expected population attrition rate. Alternatively, data on failed restorations obtained from cross-sectional studies are often used to establish the longevity of dental restorations in general practice, but this method has been shown to be highly unreliable [17]. Therefore, retrospective clinical studies, dealing with larger patient groups, are more suitable to study survival of a considerable amount of restorations during a longer period of time [4,16,18,19]. In the study of Opdam et al. [4] the compared materials showed identical clinical performance after 5 years, but significantly different performance after 12 years. Therefore, it seems possible that differences in mechanical properties observed *in vitro* can have an effect *in vivo*, but only after a longer observation time. Since most clinical trials have observation times shorter than 10 years, differences in late failing behavior are not detected in those studies.

The purpose of this retrospective longitudinal study was to investigate the longevity of posterior restorations placed in a single general practice using two different composites in filler characteristics and material properties: P-50 APC (3M ESPE) with 70 vol.% inorganic filler loading (midfilled) and Herculite XR (Kerr) with 55 vol.% filler loading (minifilled). The hypothesis tested was that two composite materials with different filler loading and elastic modulus show comparable clinical performance after 22-years follow-up.

2. Materials and methods

2.1. *Patients' selection*

For this study, the case reports of 80 adult patients were selected according to pre-determined inclusion criteria among the registers of a private practice dental office in Brazil (PARR), from a total of 920 patients who attended the dental office from January 1986 to December 1990. Patients that were selected for the study had a full dentition and normal occlusion, as verified by the clinical and radiographic registers, and had stayed in continuous clinical follow-up in the last 22 years including at least 1 annual recall. Moreover, they had received at least 2 composite restorations in posterior teeth between 1986 and 1990. A 17-year survival report of the same restoration group was published in 2006 [16]. The restorations were placed using 2 resin composites with different material properties: P-50 APC (3M ESPE, St. Paul, MN, USA), a midifilled hybrid composite with inorganic filler loading of 70 vol.%; and Herculite XR (Kerr, Orange, CA, USA), a minifilled hybrid composite with inorganic filler loading of 55 vol.% [10,13,14]. Some important material properties are shown in Table 1.

The selected patients were invited by phone calls and letters to visit the practice for evaluation. Patients signed a written informed consent prior to start of the clinical evaluation, and 2 researchers (MSC and TAD) enrolled in the study carried out the examination. The study protocol was approved by the local Ethics Committee (022/2008). From the 80 patients that fulfilled the inclusion criteria to be evaluated, 19 did not accept the invitation. As a result, 61 patients (67.2% female and 32.8% male, age 31.2–65.1) agreed to participate in the study. These patients had 362 posterior composite restorations (range 1–17 restorations/patient, average 5.9/patient), as shown in Table 2, distributed according to patients' gender, age group and tooth/restoration type.

2.2. *Restorative procedures*

One operator (PARR) had placed all restorations under rubber-dam isolation between 1986 and 1990. The patients received restorations of both materials, which were used in that period in the practice for Class I and II restorations without differences in indication. Cavities were prepared using diamond burs and low-speed steel burs were used to remove carious tissue. Preparations were restricted to carious tissue elimination, no bevels were made. Only in deep cavities the pulpal wall was covered with a thin layer of calcium hydroxide (Dycal; Dentsply, Petrópolis, RJ, Brazil). For all cavities, the dentin was covered with a layer of conventional glass–ionomer cement (Ketac-Fil; 3M ESPE).

After setting of the base-cement, all cavities were acid-etched using 35% phosphoric acid and the adhesive, belonging to the selected resin composite, was applied according to the manufacturers' instructions: Scotchbond 2 (3M ESPE) for P-50 APC and XR Prime/XR Bond (Kerr) for Herculite XR. The composites were placed with an incremental technique; each increment was photoactivated for 40 s using a quartz–tungsten–halogen curing unit (Visilux; 3M ESPE). The

Table 1 – Characteristics of the resin composites evaluated.[a]

Material	Classification[b]	Filler			Ra	E	CS	VHN
		MPS	Vol.%[A]	Vol.%[B]				
Herculite XR	Midifilled hybrid	1.0	55	57	0.12	16	397	74
P-50 APC	Minifilled hybrid	2.1	70	77	0.48	25	395	159

MPS: mean particle size, Vol.%[A]: inorganic filler volume percentage as calculated by Willems et al. [13], Vol.%[B]: inorganic filler volume percentage as disclosed by the manufacturers, Ra: surface roughness (μm), E = elastic modulus (GPa), CS: compressive strength (MPa), and VHN: Vickers hardness (kg/mm^2).

[a] Based on Willems et al. [13] and [14].

[b] Based on Bayne et al. [10].

Table 2 – Distribution of restorations evaluated according to patient gender, patient age group, tooth and class type.

Gender	Class I					Class II					Grand Total
Female (age group)	LM	LPM	UM	UPM	Total	LM	LPM	UM	UPM	Total	
	28	20	21	8	77	34	35	43	48	160	237
31–40	3	1	2	–	6	3	3	3	6	15	21
41–50	13	13	14	8	48	23	17	17	20	77	125
51–60	8	4	3	–	15	6	13	22	22	63	78
>60	4	2	2	–	8	2	2	1	–	5	13
Male (age group)	LM	LPM	UM	UPM	Total	LM	LPM	UM	UPM	Total	Grand Total
	15	12	13	4	44	21	16	19	25	81	125
31–40	3	–	2	–	5	5	1	3	2	11	16
41–50	10	8	10	2	30	9	8	14	19	50	80
51–60	2	4	1	2	9	7	7	2	4	20	29
Grand total	43	32	34	12	121	55	51	62	73	241	362

LM: lower molar, LPM: lower pre-molar, UM: upper molar, and UPM: upper pre-molar.

restorations were finished using fine-grit diamonds and rubber points with aluminum oxide polishing paste. Aluminum oxide discs were used for proximal finishing. If necessary, abrasive finishing strips were used in the interproximal surfaces until the operator considered the restorations as clinically satisfying.

2.3. *Evaluation and statistical procedures*

The history of the restorations was initially investigated from the dental records. If a restoration had failed, either resulting in replacement or repair, this was considered as a failure and the data and reason for failure were recorded. The restorations were then clinically evaluated between September 2008 and October 2008 using an explorer and dental mirror, according to the FDI criteria. These criteria evaluated biological, esthetic and functional properties of the restorations and were described in detail previously [20]. The 2 calibrated examiners, blinded to type of material, worked independently to perform the evaluation. The surfaces were dried with air stream before evaluation. In case the evaluators disagreed, they reached consensus in a new combined evaluation. Most patients in the practice had a complete bi-annual periapical radiographic exam, which was assessed by the examiners. Additional radiographs were only made when necessary to complement the clinical evaluation, in order to avoid unnecessary radiation exposure for the patients.

Statistical analysis was carried out using SPSS for Windows 19.0 statistical package (Chicago, IL, USA). Descriptive statistics were used to describe the frequency distributions of the evaluated criteria and the reasons for failure. Qualitative analysis based on the FDI criteria was analyzed independent for each one of the 15 clinical characteristics evaluated. Differences in these qualitative criteria between the 2 materials were analyzed using Fisher's Exact test at $p < 0.05$. Survival curves were created by the Kaplan–Meier method. Moreover, a Cox regression was applied on the data to evaluate the influence of material, tooth type and number of surfaces on the results ($p < 0.05$). To investigate if a different failure behavior existed in the last 10 years compared to the first period of service, Kaplan–Maier statistics as well as the Cox regression were carried out twice for these separate intervals.

3. Results

In the present study, 362 posterior composite restorations placed between 1986 and 1990 were evaluated. From the dental records, date of placement and date of failure were recorded. In Table 3, failures for each of the two composites evaluated after 22 years of clinical service are shown. From the total of failed restorations, 61 (50.8%) were repaired and 49 (40.9%) were completely replaced. In addition, 10 restorations failed because the teeth were lost (8.3%). The Fisher's

Table 3 – Failed restorations by material during the 22-year monitoring period.

Restoration properties	Cause of failure	Material		Time of failure (years)																	
		P-50	Herculite	0–5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	Total (%)
Functional	Restoration fracture	16	35	8	6	1	3	6	3	3	4	2	4	0	2	3	3	3	0	0	0	51 (46.4%)
Biological	Tooth fracture	6	13	0	0	4	2	1	0	2	0	0	2	1	3	1	2	1	0	0	0	19 (17.3%)
	Secondary caries	8	19	5	3	1	2	2	2	1	2	1	0	4	2	1	0	1	0	0	0	27 (24.5%)
	Endodontic treatment	2	5	2	1	0	0	0	0	0	0	0	0	2	0	0	2	0	0	0	0	7 (6.4%)
Esthetics	Esthetics	2	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	3 (2.7%)
Other	Extraction	3	0	0	0	1	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	3 (2.7%)
Total		37	73	17	10	7	7	10	5	6	6	3	6	7	8	5	7	6	0	0	0	110(100%)

Nine restorations from the 362 total were not present at the time of evaluation and were not included in this table as they did not represent real failures (restorations replaced because the teeth served as prosthodontic abutments).

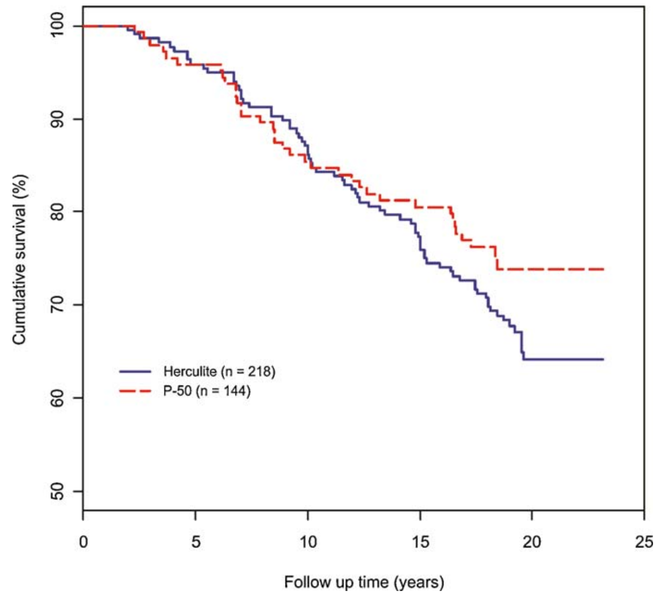

Fig. 1 – Survival curves (Kaplan–Meier) for P-50 and Herculite over the 22-year observation period.

Exact test revealed that from the still acceptable restorations *in situ*, P-50 scored significantly better on the items color stability, marginal adaptation and fracture/retention, whereas Herculite scored significantly better on the item surface luster (Table 4).

Fig. 1 shows the Kaplan–Meier survival curve for the two materials over 22 years of service. Fig. 2 shows the Kaplan–Meier survival curve for those restorations that did survive the first 10 years of service. Fig. 3 shows the Kaplan–Meier survival for premolars and molars in both jaws, independently from the composite material. Annual Fail-

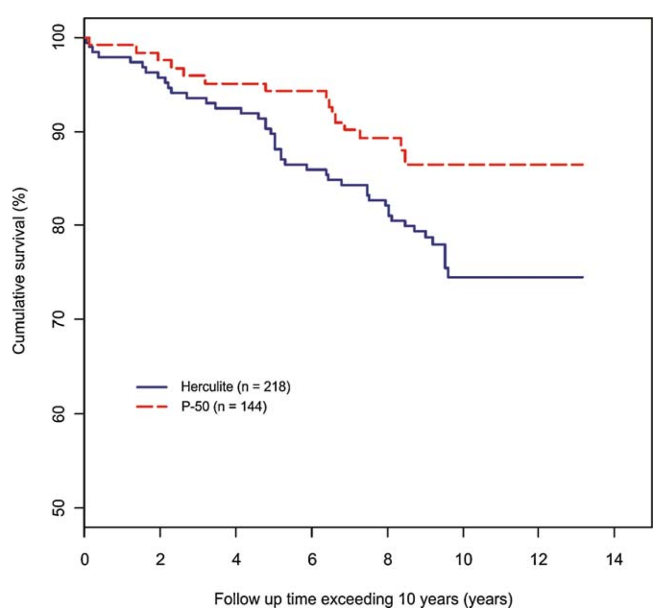

Fig. 2 – Survival curves (Kaplan–Meier) for P-50 and Herculite considering only the last 12.5 years of clinical service.

Table 4 – Comparison between the composites considering the restorations remaining *in situ* at the last recall, according to the FDI criteria [20] (compared by Fisher's exact test at $p < 0.05$).

General evaluated criteria	Specific evaluated criteria	Herculite		P-50		*p*-Value**
		Restorations within each score (1/2/3/4)	Restorations clinically acceptable (%)[a]	Restorations within each score (1/2/3/4)	Restorations clinically acceptable (%)[a]	P-50 vs. Herculite
Esthetics properties	Surface luster	26/110/2/0	100	3/102/0/0	100	<0.001
	Surface staining	83/54/1/0	100	73/32/0/0	100	0.196
	Color stability and translucency	6/127/5/0	100	73/32/0/0	100	<0.001
	Anatomic form	15/107/16/0	100	16/75/14/0	100	0.520
Functional properties	Fracture and retention	121/32/3/0	100	97/10/9/0	100	0.003
	Marginal adaptation	38/196/6/0	100	52/102/6/0	100	<0.001
	Wear	4/127/6/1	99.3	2/98/5/0	100	0.959
	Point of contact/food impact	65/0/6/0[b]	100	60/3/7/1[b]	98.6	0.221
Biological properties	Postoperative sensitivity	138/0/0/0	100	105/0/0/0	100	1
	Recurrence of caries, erosion and abfraction	137/1/0/0	100	105/0/0/0	100	1
	Tooth integrity	137/0/1/0	100	102/2/0/0	100	0.184
	Periodontal response	138/0/0/0	100	105/0/0/0	100	1
	Adjacent soft tissue	138/0/0/0	100	105/0/0/0	100	1
	Oral and general health	138/0/0/0	100	105/0/0/0	100	1

Numbers separated by slashes represent the number of evaluated restorations for each score, according to the FDI criteria 1/2/3/4 [20]. No restoration presented criterion 5 for any of the assessed aspects.

[a] %1 + 2 + 3: scores 1–3 represent restorations clinically acceptable (FDI criteria) at the time of evaluation.

[b] Only Class II restorations considered in this evaluation.

** Fisher's exact test.

ure rates (AFR) over the different observation periods are shown in Table 5. The AFR for Herculite increased from 1.5% after 10 years to 2.2% after 20 years of service. For P-50, the AFR were constant with 1.6% after 10 and 1.5% after 20 years.

Table 6 shows the results for the Cox regression analysis. It can be seen that no significant difference in longevity over the total observation period existed between the materials ($p = 0.129$). However, restorations that were made of P-50 surviving 10 years had a significantly better survival after 22 years than Herculite restorations that survived 10 years ($p = 0.023$). Moreover, for both intervals, premolars had a better survival than molars. Finally, smaller sized restorations had a better survival than larger restorations. The hazard ratio *per* extra surface was 49% when calculated over the 0–22 years interval ($p < 0.001$). Fig. 4 shows representative pictures of Herculite and P-50 restorations, still acceptable after 22 years of clinical service.

4. Discussion

In this study, we analyzed the clinical performance of 2 posterior composite restoratives with different filler characteristics over an extended period of time. For comparing two treatments, a randomized clinical trial (RCT) is considered to be the best study design. However, RCTs have certain limitations and are not optimal for all research questions. Observation

Table 5 – Annual failure rates (AFR) of the composite materials over different intervals of the observation period.

Time (years)	% Surviving	AFR over the last 5 years (%)	AFR over the total observation period (%)
Herculite			
5	96	0.8	0.8
10	86	2.1	1.5
15	77	2.2	1.7
20	64	3.7	2.2
P-50			
5	96	0.9	0.9
10	85	2.3	1.6
15	81	1.2	1.4
20	74	1.7	1.5

Table 6 – Results for the Cox regression for the intervals 0–22 and 10–22 years.

Variable	*p*-Value	Hazard ratio	95% confidence interval	
			Lower	Upper
Interval 0–22 years				
Tooth type	0.002			
Upper premolar = 1	1	1	1	1
Lower premolar	0.779	0.91	0.46	1.79
Upper molar	0.013	2.00	1.16	3.44
Lower molar	0.004	2.23	1.29	3.85
Number of surfaces (1-surface = 1)	<0.001	1.49	1.24	1.78
Material (Herculite = 1)	0.129	0.73	0.49	1.10
Interval 10–22 years				
Tooth type	0.02			
Upper premolar = 1	1	1	1	1
Lower premolar	0.524	1.32	0.56	3.15
Upper molar	0.100	1.93	0.88	4.21
Lower molar	0.005	3.01	1.41	6.44
Number of surfaces (1-surface = 1)	<0.001	1.58	1.24	2.01
Material (Herculite = 1)	0.023	0.50	0.27	0.91

times longer than five years are hardly feasible in most RCTs, considering the expected population attrition rate. From our results, it is obvious that the follow-up time needs to be longer, as differences between materials can emerge after more than 10 years.

The chosen design for the present study was practice-based and retrospective. As an inclusion criterion was that patients had to stay in the office for at least 22 years, it is likely that well motivated patients were included, whereas less motivated, unsatisfied patients were out of the study population. Moreover, it should be noted that the results shown here are achieved in one high-standard dental office, owned by one practitioner, and cannot be generalized. The level of dental hygiene as recorded by the observers (Table 4) illustrates the type of practice, with patients that are well motivated. Patients were submitted to periodical examinations, prophylaxis, oral hygiene and dietary habits instructions. Such approaches may

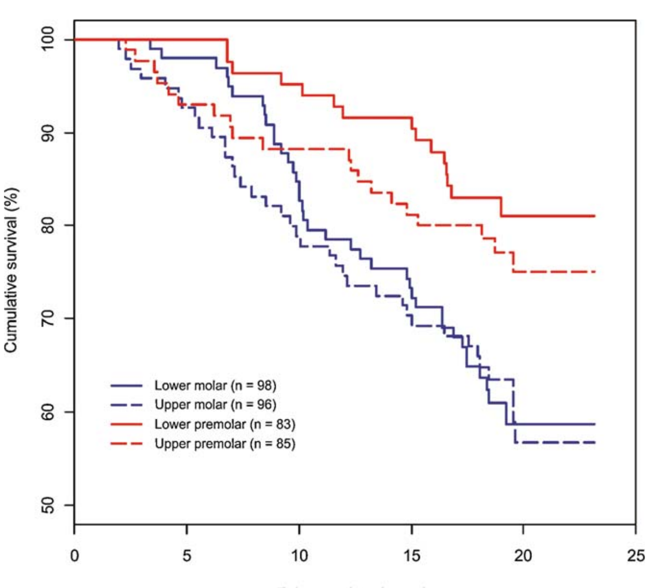

Fig. 3 – Survival curves (Kaplan–Meier) for tooth type.

influence the longevity of restorations [2,21] and may have contributed to the good results observed in the present study. Also, the finding that almost all restorations, evaluated independently on-site according to the FDI criteria [20], were clinically acceptable, is a sign for the high-quality standard of the practitioner and the inclusion of well motivated patients with limited secondary caries lesions developing.

Overall, the results showed that it is possible to place posterior composite restorations with considerable success and low annual failure rates. This study has to date the longest observation time for clinical studies in posterior composite restorations and findings indicate that these restorations can be successful for a very long time, although a slightly increasing failure rate over the course of time was observed for one of the materials. Other clinical studies with longer observation times are in accordance with the present study as the AFR's are within the same level [4,19,22–26].

The main objective of the present study was to observe whether composites with different filler characteristics show distinct clinical performances. Certainly, and as shown in Table 1, differences in filler features, especially the volume fraction, have a direct impact on the properties of the restoratives, especially *E*-modulus and hardness. Considering the overall service time, no statistical significant difference in survival could be observed, although P-50 tended to be a better material. This is illustrated when looking at the time interval from 10 year onwards showing that P-50 had a better survival on the long term. Illustrative is the increase in the AFR for Herculite when the observation time extends, while the AFR for P-50 remains rather constant (Table 5).

With fracture as the main reason for restoration failure, the findings of the present study indicate that P-50 has higher fracture resistance on the long term, probably owing to its higher *E*-modulus (which in turn is related to the higher filler volume), decreasing the clinical effects of fatigue. *In vitro* studies have shown that P-50 has a higher fracture toughness than Herculite [27] and generally that higher filler volumes increase the fracture toughness of restoratives [28] even after simulated occlusal loading [29]. The clinical data also indicated that other differences in material properties may affect the

Fig. 4 – Representative images of the restorations evaluated. Despite some marginal discoloration, loss of anatomic form and compromised color match, these restorations were still satisfying the patient's needs considering clinical service, and therefore were considered acceptable restorations following the FDI criteria.

clinical behavior of composite restorations: Herculite showed a significantly better surface luster, which is explainable by its lower average particle size and surface roughness as compared with P-50 [13]. On the other hand, the marginal quality of P-50 restorations was significantly better after 22 years. This is in accordance with an *in vitro* study by Ferracane and Condon [29] showing that midifill composites with average particle size above 1 μm suffered less from marginal breakdown after cyclic loading compared to minifilled composites with average particle size below 1 μm. Also, the color stability of the higher filled material was better on the long term; this might be related to the higher amount of resin matrix in the lower filled material while also be related to the fact that materials originated from different manufacturers, with different formulation characteristics.

The hypothesis that both materials showed identical performance was rejected as the composite material with the higher filler volume showed a better survival on the long term with fracture as the predominant reason for failure. However, some critical remarks can be made regarding this conclusion. Firstly, the differences between the materials could only be demonstrated in the second part of the observation period. A previous report at 17 years about the same restoration group could not detect differences between the materials [16]. This illustrates that long observation times are very important to find differences among restorative materials clinically. This was also concluded in another clinical study showing no difference between large amalgam and composite restorations after 5 years but a better performance for composite restorations after 12 years clinical service [4].

Meanwhile, these studies show that differences in clinical performance between dental restoratives used for direct Class II restorations are relatively small despite the considerable differences found in *in vitro* studies. A difference between 1.5% and 2.1% annual failure after 22 years was significant in the present study, but how relevant is it in the perspective of good dental care? Other factors not related to the materials, such as caries risk of the patient, have been shown to play a significant role, and in fact might be more important for the survival of restorations [4,18,30–32]. In the present study, it is likely that the patient population had a low caries risk, as can be concluded from the high-level of oral health and the relatively low percentage of restorations failing due to secondary caries, which has been considered as the main reason for restorations' failures [33]. Yet, patients presented a high number of restorations placed in a short period of time in the 1980s, which seem to contradict the low caries risk observed 22 years later. The main reasons for this high restoration placement rates are that these patients had almost all their caries experience before the 1980s, when the use of fluoride dentifrice was not widespread worldwide and specially in Brazil [34,35], and these patients had lots of amalgam restorations from the 1970s and early 1980s. When the composites arose as an alternative for posterior restorations after 1985, people were also starting to get concerned about esthetics, and therefore there was at that time a great demand for replacing posterior amalgam restorations for composites.

Another factor that may have played an important role in the survival of the present restoration group is the presence of a base of glass–ionomer cement. At the time of placement this was considered as the gold standard, and today, some clinicians still place a layer of glass–ionomer as a liner or base under an adhesive restoration. One clinical study found that restorations with a glass–ionomer lining showed a lower survival compared with total-etch restorations [18], with fracture as the main reason for failure. Other clinical studies in which a base of glass–ionomer was placed also showed increased failure by fracture overtime [22,30], but the absence of a restorative control group placed with a total-etch procedure in those studies, as well as in the present one, makes it impossible to draw conclusions. Also, in the present study, the amount of fractures was considerable and the most important reason for restoration failure. It can be speculated that had these restorations been placed using a total-etch technique, an even better survival would have been found. Further clinical studies are necessary to investigate this aspect.

In this study, 362 restorations were placed in 61 patients indicating an average number of about 6 per patients, which is considerably high. This is explained by the high standard and reputation of the dental practice involved, resulting in many patients coming in the office for the first time with extensive dental problems due to lack of maintenance by previous dentists. When a restoration fails, it can be completely replaced or in most of the cases, partially replaced (repaired) [36–39]. In the present study, 54% of failed restorations were repaired instead of replaced. Repair is considered a conservative solution; less traumatic to the patient, saving dental structure and it can be performed at lower cost, requiring less clinical time [36–38,40,41]. No restorations were replaced due to wear, illustrating that the used materials have a good wear resistance and wear is not a real problem related to posterior composite restorations. Other findings such as that restorations in premolars show a better performance than restorations in molars, and that the more surfaces a restoration has the higher the probability of its failure, are not surprisingly and in accordance with other clinical studies [2,4,19,24,42,43].

5. Conclusions

Within the limitations of this retrospective study, the following conclusions can be drawn:

- Restorations placed with a midifilled or a minifilled hybrid composites evaluated for up to 22 years showed good clinical performance with annual failure rates of 1.5% and 2.2%, respectively;
- When considering the survival between 10 years and 22 years of service, the midifilled hybrid material P-50, with higher filler loading and elastic modulus, presented a slightly but significantly superior survival compared to the minifilled material Herculite ($p < 0.05$);
- The predominant reason for failure of the restorations was fracture.

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