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Retrospective evaluation of posterior composite resin sandwich restorations with Herculite XRV: 18-year findings

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Objective: The aim of this retrospective study was to evaluate the long-term clinical outcomes of posterior composite resin sandwich restorations, and secondarily to assess the influence of potential factors on survival and causes of failure. **Method and Materials:** Two hundred and four posterior Herculite XRV restorations due to primary caries performed between 1991 and 1997 were included. The restorations were assessed after 18 years, by two calibrated examiners, according to USPHS criteria. The survival of the restorations was estimated by the Kaplan-Meier estimator. Cox regression was applied to evaluate the influence of the cavity size, location of the tooth, caries risk, and gender on survival rate. The predictive power of the analyzed variables on survival rate was studied with multiple linear regression analysis. **Results:** After 10 years the survival rate was 92.6%, and 82.4% at the end of the study. Thirty-six (17.6%) restorations failed during the evaluation period, 21 (10.3%) of them after more than 10 years. The most common failure was secondary caries (69.4% of the failures). There were statistically significant differences in survival rate depending on caries risk ($P = .000$), but not between Class I and II ($P = .106$), and the type and localization of the tooth ($P = .115$). **Conclusion:** Posterior Herculite XRV restorations due to primary caries have high long-term survival rates. Generally, failures occur by secondary caries and are more common in molars. The patient's caries risk is the variable that best predicts the survival of posterior restorations. *(doi: 10.3290/j.qi.a37386)*

Key words: caries, clinical evaluation, composite resin, longevity, posterior restoration, survival rate

Hybrid composite resins can be considered the best material for direct restorations in posterior teeth.[1,2] The long-term behavior of Class I and II composite resin restorations has been assessed over the years by longitudinal,[3] retrospective,[4-7] and meta-analysis studies.[8,9] Clinical evaluation of posterior restorations with resin composites allows knowledge of the material behavior and the results of the technique applied. The longevity of dental restorations depends on many factors, such as the clinical technique,[10] the operator, the patient, the materials, the tooth location, and the cavity size.[1,9,11] The caries risk is an important factor in the longevity of restorations,[9,12,13] because of the presence of secondary caries or caries in surfaces other than the restored surface. Few in vivo studies have included caries risk.[12,14,15] The two main causes of failure are fracture (restoration or tooth) and secondary caries.[11,16]

The USPHS (United States Public Health Service) criteria[17] are the most commonly used in long-term clinical evaluations of dental restorations.[9,15,18,19] Similarly,

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the International Dental Federation (FDI) described other criteria to evaluate the clinical performance of composite resin restorations,[20] used by da Rosa Rodolpho et al[6] in the clinical evaluation of composite resin restorations after 22 years of follow-up.

The microhybrid dental composite resin Herculite XRV (Kerr) was first marketed in the 1990s and remains in use today. It differs from Herculite XR (Kerr) in that it follows the colors of the Vita Classical shade guide (Vita Zahnfabrik). Although they have the same composition, studies have been performed on long-term clinical performance in the posterior sectors of Herculite XR,[6,7,21] but not of Herculite XRV.

The main objective of the present study was to evaluate the long-term clinical outcomes of posterior restorations made with Herculite XRV, and secondarily to assess the influence of potential factors on survival and causes of failure.

METHOD AND MATERIALS

Selection of participants

For this retrospective study, 240 direct posterior composite resin restorations placed in adult patients in a private dental practice in Santiago de Compostela between 1991 and 1997 were selected. Patients with Class I and II restorations that had been in continuous follow-up, with at least one annual recall, were selected. The following inclusion criteria were established to standardize the sample:

- restorations were due to primary caries in unrestored surfaces, located in molars or premolars without endodontic treatment, with adjacent and antagonist teeth, including all margins in enamel, and without the involvement of cusps
- radiographs and photographs of these restorations, both at the initial visit and in subsequent visits, were available
- patients had to be in continuous follow-up, with at least one annual recall.

The restorations were placed in 107 patients (37 men and 70 women), with a mean age of 33.7 ± 9.6 years at the time of the restorations. During the referred period, posterior direct restorations with composite resin accounted for 61.8% of restorations in this private dental practice. Teeth included in the study, and the type of restoration, are detailed in Table 1.

The protocol of the study was approved by the University of Santiago de Compostela on Investigations Involving Human Subjects. At the time of the evaluation, patients signed a written informed consent for inclusion in the study.

Clinical procedures

All restorations were made by the same operator (VAP), under local anesthesia. Information about the materials used was obtained from the patient's clinical history. All restorations were placed under rubber dam isolation.

Cavities were prepared using a turbine, and low-speed tungsten carbide burs with a diameter corresponding to the size of the lesion were used to remove carious dentin tissue. Caries detector solution (Caries Detector, Kuraray Medical) was used to remove only the carious tissue. Enamel without dentin support in the proximal cavity floor was eliminated with a margin trimmer (Margin Trimmer MT26, Hu-Friedy) or a cylindrical bur that cut only on the flat end (Komet 10839, Brasseler).

No bevels were made in the cavity margins. In Class II restorations, transparent plastic matrix and light-reflecting wedges (Lucifix matrix and Luciwedge, Keer Hawe) were placed. At the bottom of the cavities a glass ionomer base (Vitrebond, 3M Espe) was placed covering the dentin. The cavities were etched with 37% phosphoric acid for 15 seconds, and adhesive systems (Table 2) were applied according to the manufacturer's instructions. They were then polymerized with a quartz-tungsten-halogen light-curing unit (Visilux 2, 3M Espe) for 20 seconds. The composite resin Herculite XRV was placed incrementally, under the sandwich technique, and cured for 40 seconds.

Finally, the occlusion was checked. Finishing and polishing procedures were performed with polished diamond burs at high speed. Dura-Green and Dura-White stones (Shofu Dental) were applied to the occlu-

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Table 1 Distribution of restorations evaluated according to location and cavity type

Location		Class I	Two-surface Class II	Three-surface Class II
Premolars	Maxilla	9	30	19
	Mandible	16	18	2
Molars	Maxilla	26	24	6
	Mandible	37	14	3

Table 2 Adhesives used according to the year of restoration

Adhesive	Year of use
Scotchbond 2	1991 – 1994
Prime & Bond 2.0	1995
Prime & Bond 2.1	1996 – 1997

sal area, and disks and strips (3M Espe) to the interproximal surfaces.

Evaluation of restorations

During the follow-up visits periapical radiographs were taken, as recommended by FDI criteria[20] to assess secondary caries. Fillings performed after the date of the analyzed restorations were counted in each patient, to determine the caries risk. If patients had one or more new caries per year in follow-up visits, they were assessed as "high risk"; this criterion was previously used by Opdam et al.[14]

Timing and cause of failure of the restorations that failed during the follow-up period, before 18 years, were obtained from the clinical history. Restorations that remained in service after 18 years were evaluated by two calibrated examiners (MCV, ILD) according to USPHS criteria.[17] Anatomical form, marginal adaptation, match color, marginal discoloration, surface roughness, and secondary caries were assessed. Each characteristic was classified as:

- Alpha (A) – excellent result
- Bravo (B) – acceptable result
- Charlie (C) – unacceptable result
- Delta (D) – restoration failed, fractured, or missing.

Examiners evaluated the restorations separately. When there was disagreement, they met to reach consensus. A restoration was considered a failure when the restoration had C and D values in any of the categories of the USPHS criteria. Examples of the evaluated restorations are shown in Figs 1 to 6.

No failure was considered when a new caries lesion was diagnosed in a surface different from the restored one, when it did not involve replacing the analyzed restoration. Failed restorations with C values were only replaced when their functionality was compromised, and restorations with D values were always replaced. In any case, during the evaluated period when a restoration needed any intervention or was replaced it was classified as a failure, and it was not reevaluated later.

Statistical analysis

Statistical analysis was performed using the statistical software SPSS 21 (IBM). Absolute values and frequency distributions were used for illustration of the results of the restoration evaluations. The survival of the restorations was estimated by the Kaplan-Meier estimator. Cox regression was applied to evaluate the influence of the cavity size, location of the tooth, caries risk, adhesive system, and gender on survival rate. The predictive power of the analyzed variables on survival rate was studied with multiple linear regression analysis. An association was considered statistically significant when the *P*-value was less than .05.

RESULTS

Thirty-six (17.6%) of the 204 restorations failed during the evaluation period (18 years), 21 (10.3%) of them after more than 10 years. These were 24 (11.8%) molars and 12 (5.9%) premolars; 11 (5.4%) Class I, 18 (8.8%) two-surface Class II, and 7 (3.4%) three-surface Class II restorations. Failures occurred in 27 patients (9 men

Figs 1a to 1c *(a)* Restoration completed in 1992. *(b)* Appearance of the restoration 12 years later (2004). Catches were observed, no crevice was visible into which explorer will penetrate. *(c)* At final evaluation (2010) the restoration obtained value 1 in the categories anatomical form, marginal adaptation, and marginal discoloration.

Figs 2a to 2c *(a)* Postoperative appearance of the three-surface Class II restoration in maxillary left second premolar (1993). *(b)* In 1999, pits were observed. *(c)* After 18 years (2015) defects were observed in marginal adaptation, marginal discoloration, and surface roughness.

and 18 women), and 77.8% (21) of them were patients with high caries risk. Forty-six (43.0%) patients had high caries risk. From the Kaplan-Meier survival curve, after 10 years the survival rate was 92.6%, and 82.4% at the end of the study (Fig 7), representing an average duration of 16.8 ± 0.2 years.

Forty-two (20.6%) restorations showed excellent values in all the six categories of USPHS criteria after the evaluation period. There were 24 (16.4%) premolars and 18 (25.5%) molars; 18 (20.4%) Class I, 19 (22.1%) two-surface Class II, and 5 (16.7%) three-surface Class II. The results of the evaluated restorations are shown in

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Fig 3 Restoration done in 1994, with fracture due to secondary caries after 18 years.

Fig 4 After 18 years, the restoration had slight marginal maladjustment.

Fig 5 Marginal discoloration and mismatch in color after 18 years.

Fig 6 Restoration Class I in maxillary right first and second premolars after 18 years, with acceptable parameters in the USPHS criteria.

Table 3. The most common failure was secondary caries (69.4% of the failures), with statistically significant differences between molars and premolars ($P = .005$). All secondary caries occurred in patients with high caries risk. The examiners found three fractures in two-surface Class II restorations, and two fractures in three-surface Class II restorations. The most common defects were marginal adaptation and marginal discoloration, present in 116 and 87 restorations respectively (Table 3). No restorations were missing and no endodontic treatment had to be performed on the study teeth.

According to the statistical analysis, no statistically significant differences in survival rate were found between Class I and II ($P = .072$). Dividing Class II into

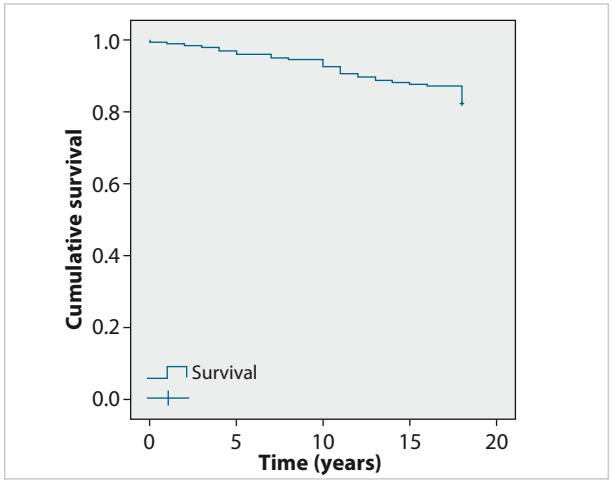

Fig 7 Overall survival of the restorations curve Kaplan-Meier, with the 95% CI.

Table 3 Results of the evaluation of the restorations according to USPHS criteria

USPHS criteria category		Total	Class I, % (n)	Two-surface Class II, % (n)	Three-surface Class II, % (n)	Molars, % (n)	Premolars, % (n)
Anatomical form	A	79.4 (162)	39.7 (81)	32.4 (66)	7.4 (15)	42.6 (87)	36.8 (75)
	B	17.2 (35)	3.4 (7)	7.8 (16)	5.9 (12)	10.3 (21)	6.9 (14)
	C	3.4 (7)	0.0 (0)	2.0 (4)	1.5 (3)	1.0 (2)	2.5 (5)
Marginal adaptation	A	40.2 (82)	20.6 (42)	15.7 (32)	3.9 (8)	20.6 (42)	19.6 (40)
	B	56.9 (116)	22.5 (46)	24.5 (50)	9.8 (20)	31.9 (65)	25.0 (51)
	C	0.5 (1)	0.0 (0)	0.5 (1)	0.0 (0)	0.5 (1)	0.0 (0)
	D	2.5 (5)	0.0 (0)	1.5 (3)	1.0 (2)	1.0 (2)	1.5 (3)
Color match	A	95.1 (194)	41.2 (84)	40.2 (82)	13.7 (28)	50.5 (103)	44.6 (91)
	B	4.4 (9)	2.0 (4)	1.5 (3)	1.0 (2)	2.9 (6)	1.5 (3)
	C	0.5 (1)	0.0 (0)	0.5 (1)	0.0 (0)	0.5 (1)	0.0 (0)
Marginal discoloration	A	50.5 (103)	22.1 (45)	22.1 (45)	6.4 (13)	24.0 (49)	26.5 (54)
	B	42.6 (87)	18.6 (38)	17.2 (35)	6.9 (14)	26.0 (53)	16.7 (34)
	C	6.9 (14)	2.5 (5)	2.9 (6)	1.5 (3)	3.9 (8)	2.9 (6)
Surface roughness	A	86.3 (176)	39.7 (81)	33.8 (69)	12.7 (26)	44.1 (90)	42.2 (86)
	B	13.2 (27)	3.4 (7)	7.8 (16)	2.0 (4)	9.3 (19)	3.9 (8)
	C	0.5 (1)	0.0 (0)	0.5 (1)	0.0 (0)	0.5 (1)	0.0 (0)
Secondary caries	A	87.7 (179)	37.7 (77)	36.3 (74)	13.7 (28)	44.1 (90)	43.6 (89)
	C	12.3 (25)	5.4 (11)	5.9 (12)	1.0 (2)	9.8 (20)*	2.5 (5)*

*$P = .005$

two groups (two-surface and three-surface Class II), no differences among the three groups ($P = .134$) were found. Also, the adhesive system used did not influence the survival rate ($P = .184$). There were statistically significant differences according to caries risk ($P = .000$), and tooth location ($P = .040$), being differences between molars and premolars ($P = .011$); but no differences regarding gender ($P = .850$) were found. Kaplan-Meier analysis according to the cavity type and the location of the tooth is shown in Fig 8.

Assessing the predictive power of the analyzed variables on survival rate, it was found that the variable caries risk was the variable that best predicted survival ($P = .000$). Although variable caries risk predicted only 8.6% of survival, this was significant because the survival of the restorations did not follow a linear model.

DISCUSSION

To evaluate the restorations the USPHS criteria[17] were used, because these are the most commonly used criteria for long-term evaluation of restorations. Although they are limited by the ability of the observer to detect marginal steps,[22] this possible error was counteracted by two examiners evaluating the restorations, and thereby the probability of correct assessment was 97.7%.[23] In the evaluation of posterior restorations, C values are considered failures. However, it is unlikely that in some categories these dictate the immediate replacement of a restoration. Not all categories are equal in decision-making to replace a restoration, but there is not yet any practical way to pool results across categories.[23] Another limitation of the present study was the small sample size, determined by the strict inclusion criteria.

The longevity of dental restorations depends on many factors, such as the clinical technique,[10] the oper-

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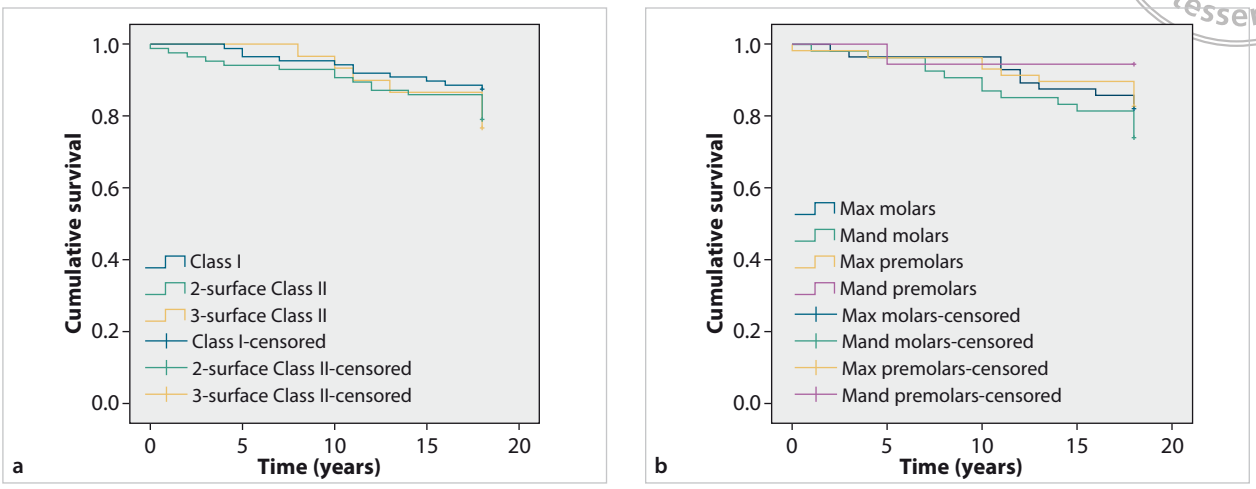

Figs 8a and 8b Survival curve according to *(a)* Class type, and *(b)* the location of the tooth (mand, mandibular; max, maxillary).

ator, the patient, the materials, and the tooth location.[1,3] To minimize the influence of the operator, in the present study all restorations were performed by the same operator. All patients had a computerized clinical history, which included photographs and radiographs of the restorations, adhesive, cavity base, composite resin, isolation, and matrix type used, allowing the standardization of this retrospective study.

Since composite resin restorations are technique sensitive,[10] it is preferable to isolate with rubber dam,[8] and therefore rubber dam was placed to perform all restorations in this study. Three etch-and-rinse adhesive systems were used. The first was a fourth generation (three-step) adhesive and the other two were fifth generation (two-step) adhesives. In the mid-1990s, dental manufacturers introduced a new generation to simplify the adhesion process by decreasing the number of clinical steps, combining the priming and adhesive application steps. It has been previously reported that using fourth or fifth generation adhesive systems has no impact on clinical performance of posterior restorations,[24,25] as in the present study.

The results of the present study show that the long-term survival of composite resin restorations in posterior teeth is high, as has been described previously. Pallesen et al[3] conducted a prospective study of 4,355 restorations in teenagers made by 115 dentists using (among other products) Herculite, and obtained a survival rate of 84.3% after 8 years. In another analysis of 1,955 posterior composite resin restorations, after 10 years the survival rate was 82.2%.[4] Another 10-year retrospective study of Class II restorations obtained a survival rate of 98.6% for Herculite XR, slightly higher than other composite resins.[7]

It seems reasonable that the cavity type influences the survival rate of the restoration,[3,5,6,9] but this is controversial in the literature. Some studies reported that Class I restorations showed a higher survival rate than Class II,[6,16,22] and others reported the contrary.[20] As in the present study, other publications did not find statistically significant differences between the class of restoration.[7,14,16] However, as in the present study, deficiencies in USPHS criteria were more frequent in restorations with more surfaces.[7,16] A plausible explanation for this finding could be that a larger surface of restoration is exposed to the oral environment.[7]

Some studies found that premolars have a higher survival rate than molars,[3,9,12] as in the present results. However, other studies found no difference.[7,14-16,18] This significant variation could be explained because the smallest surface of the cavities is in premolars,[1] and they are therefore less exposed to the oral environment.

Considering that the physiologic and chemical characteristics of the oral environment affect the marginal

quality over time,[7] it is reasonable that marginal discoloration was the most common defect following USPHS criteria.

For several authors the main reasons to replace a restoration are secondary caries and fractures,[7-9] similar to the present results, where secondary caries obtained the most unacceptable values in both Class I and Class II. Although periapical radiographs are not included in the evaluation with the USPHS criteria, they were taken for assessment of secondary caries, as recommended by FDI criteria.[21]

Although secondary caries is the main reason for failure of composite resins in posterior teeth in daily dental practice,[1,4,12,20] and the caries risk is considered an important factor in the survival of composite resins in posterior teeth,[9,14,15] it is rarely assessed in long-term studies.[12,14,15] The present results corroborate that high caries risk is associated with lower survival rate.[13] This patient risk factor is probably more important than material factors for survival of dental restorations,[11] and according to the present results the variable that best predicts survival is the patient's caries risk. Most studies consider all cavities that appear in the restored tooth (on the same surface or another) as secondary caries and therefore failures, but only caries lesions that are located in the same position as the previous restoration should be considered.[9] In this study, if a caries lesion appeared on a surface other than the restored one, it was not considered a failure, but it was counted to determine the patient's caries risk.

Other authors consider fracture as the main failure of composite resins.[6] The percentage of failures from fracture varies from 39.5%,[9] through 42%,[13] 42.9%,[6] to 57.8%.[24] Fractures were associated with the placement of cavity bases.[3,4,14] Van de Sande et al[26] found no differences in survival between composite resin restorations with a glass-ionomer base or not; however, they found significantly more failures for fracture than for secondary caries in the group with a glass-ionomer base. This could be due to the possible increased risk of fatigue in the long term.[11] Conversely, in the present study a cavity base was placed in all restorations and only five fractures (2.4% of failures) occurred. Perhaps less extensive cavity bases were placed, thus the strength of composite resin restorations was not affected.[11] In the 1990s, the sandwich technique was considered a standard procedure, and by the results of the study this is a good technique. However, with the advances in understanding of adhesion to dentin and the improvements in adhesive systems, placing a glass-ionomer base could become obsolete.[9]

Some reports conclude that more than half of failures in composite resins were observed after 5 years.[20] In the present study, 58.3% of failures occurred after 10 years. In a similar study of Herculite XR, a 26.6% failure after 17 years was obtained,[22] while in the present study the Herculite XRV had a 17.6% failure after 18 years.

CONCLUSION

Within the limitations of this study, it can be concluded that Herculite XRV restorations due to primary caries in the posterior region had a high long-term survival rate, but nearly half of the restorations tested had some defect in marginal adaptation and discoloration. More than half of the failures occured after 10 years of function. The most common cause of failure of the restorations was secondary caries. Premolars had a higher survival rate than molars, but the variable that best predicted the survival of the restorations was the patient's caries risk.

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