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Long-term clinical evaluation of direct resin composite restorations in vital vs. endodontically treated posterior teeth — Retrospective study up to 13 years

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ABSTRACT

Objectives. This retrospective study evaluated and compared the survival rate of Class II posterior direct resin based composite (RBC) restorations made in vital teeth (VT) and endodontically treated teeth (ETT). The influence of risk factors on the long-term performance of restorations was also investigated.
Methods. Patients (n = 245) receiving RBC posterior restorations between 2004 and 2012 were selected. A total of 597 restorations (485 in VT, 112 in ETT) with minimum 2.5–3 mm remaining cusp thickness, made with the same brand of RBC and adhesive, were evaluated using the USPHS criteria. Data were analyzed with Mann–Whitney, Chi-square and Fisher's Exact Test, Extended Cox-regression and Kaplan–Meier analysis ($p < 0.05$). Relative risk ratio was estimated for each evaluated parameter.
Results. The mean observation period was 8.6 ± 2.3 years. An annual failure rate in VT and ETT of 0.08% and 1.78%, respectively, was detected. The reasons of failures included restoration fracture, secondary caries in VT; vertical root fracture, cusp fracture, restoration fracture, secondary caries and loss of adhesion in ETT. Significantly better performance was observed in RBCs of VT for each evaluated parameter. Among the evaluated risk factors only occlusal stress affected negatively the survival of RBC in ETT (Hazard Ratio 37.1; $CI_{95\%}$ 8.4–163.7).
Significance. Although, there is significant difference in the success rate of RBCs in VT (98.97%) and ETT (76.8%), the long-term (6–13 years) durability of Class II RBCs with 2.5–3 mm cusp thickness in ETT is also clinically acceptable. The presence of occlusal stress decreases the survival of RBCs in ETT.

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1. Introduction

It is proved that resin-based composites (RBC) can serve long-term in vital teeth as a conventional or minimally invasive direct restorative solution [1–4]. The survival rate ranges between ~88–98 % [4–10]. The main reasons for failure are the marginal gap formation, secondary caries and fracture of the restoration [6]. The success of a restoration is not only a material dependent phenomenon, it is also related to other factors, like patient, operator and tooth itself. Considering the survival of a restoration or more importantly the survival of the tooth, the most important tooth-related factor is the remaining tooth structure. An endodontically treated tooth (ETT) is unlike a vital tooth due to the effects of the endodontic treatment. It is commonly thought, that a higher failure risk is associated with ETT compared to the vital ones [11]. However, in vitro studies demonstrated, that the similarity between the biomechanical properties of ETT and their contralateral vital pairs indicates that teeth do not become more brittle following endodontic treatment [12,13]. Dietschi et al. also concluded, that the impact of vitality loss appears to be moderate or negligible concerning physical properties and moisture content of dentin, however, the preparation of an access cavity, canal enlargement during an endodontic treatment significantly reduces the strength of the tooth [14]. During an endodontic procedure, an already destructed tooth is further weakened by the access cavity preparation [15]. Endodontic procedures performed in posterior teeth were shown to reduce the stiffness of teeth by 5%, however, the presence of an occlusal restoration reduced stiffness by 20% and the presence of a mesio-occluso-distal restoration reduced tooth stiffness by 63% [15]. MOD cavities with the loss of parapulpal dentin should be considered as the worst cavities in terms of fracture risk [16]. The loss of the marginal ridges with further dentin removal during access cavity preparation can lead to the weakening of teeth and results in increased cuspal deflection during function, which results in higher occurrence of fractures [17,18]. As pulpal nerves being involved in regulating masticatory load, it is thought that proprioception is also reduced after endodontic treatment [19,20]. The relevance of loading forces may be more prudent in parafunctional patients as parafunctional loads can be six times the normal chewing force. Chewing forces are predominantly vertical, but in parafunction they can also be horizontal [21]. However, according to Eliyas et al., more reports are necessary in relation to parafunction and failure of ETT [22].

Although the most important change in tooth biomechanics is attributed to the loss of hard tissue, there are changes in tissue composition as well, caused by bacterial infection and after endodontic treatment using irrigants such as sodium hypochlorite and chelators [14,23,24]. The use of chemicals predominantly results in collagen depletion, as these materials interact either with the mineral content or the organic substrate of dentin. Reduced collagen content affects the elasticity of the dentin and predisposes to fracture during shearing forces [22]. On the other hand, the quality of dentin is also significantly compromised by the chemicals and regarding the potential adhesion to the residual tooth structure, one has to be aware of these negative effects [14].

To this day, there is a lack of accepted clinical standard regarding the optimal way of restoring non-vital teeth, however, basic research-driven treatment recommendations help the clinicians to establish a proper restorative protocol depending on the individual case [14]. The most critical issue is the tissue conservation when dealing with a non-vital tooth. Therefore, it is considered prudent for the dentist to assess the restorability, occlusal function, and periodontal health of the tooth, and other aspects such as biological width and crown-root ratio be also evaluated, before initiating the endodontic treatment. According to these factors the tooth could be included in a comprehensive oral rehabilitation treatment plan.

Clinical studies are available in the literature which compare the success rate of different restoring procedures of ETT [25–29]. The long-term performance of restorations reflects the diversity of restorative techniques and materials. Traditionally, a more invasive post and crown preparation is recommended to ensure the mechanical, functional and esthetical requirements and additionally provide good coronal seal, especially in posterior teeth [28,30]. Modern clinical procedures to restore an ETT are rather based on sound tissue conservation, thus the principles of the minimally invasive dentistry come into view. Mannocci et al. found in their 3-year prospective study that the clinical success rates of endodontically treated premolars restored with fiber posts and direct RBC restorations were equivalent to a similar treatment with metal-ceramic crowns [31]. Sequeira-Byron et al. concluded in their review article, that there is no sufficient evidence to assess the effects of crowns compared to conventional fillings for the restoration of root-filled teeth [32]. The benefit of the adhesive technique is that it ensures acceptable material retention without the need of aggressive macro-retentive preparation. Consequently, restoration of devitalized teeth follows in many cases the same principles as the restoration of vital teeth [16]. However, Frankenberger et al. found in their in vitro study, that less invasive preparation designs were not beneficial for the stability of postendodontic restorations compared to indirect adhesive or cemented restoration with cusp-coverage [33]. Dammaschke et al. also concluded in their retrospective study, that ETT restored with prosthetic restorations demonstrated a significantly lower mean fracture rate than teeth restored with fillings. The mean survival period for RBC fillings was 13.4 (±0.5) years [34]. However, according to the previous researchers, the extension of cavities influences the survival of the restoration. Cavities with up to three surfaces may be successfully restored adhesively with RBC filling material [34].

The purpose of the present study was to compare the long-term survival of Class II direct RBC restorations of posterior vital and root canal treated teeth. Further aim was to investigate the compromising effect of the endodontic procedure on the quality of dentin regarding the potential adhesion of the RBC fillings by comparing them with RBC fillings of vital teeth according to the USPHS criteria. To clarify the influence of different risk factors, like bruxism related occlusal stress, patient, tooth and restoration related factors on the tooth and restoration survival was also an aim of this retrospective clinical evaluation.

2. Materials and methods

This retrospective longitudinal study was designed as a comparative evaluation of Class II direct RBC restorations performed in vital or endodontically treated teeth. The study protocol was approved by the Regional Research Ethics Committee of University of Pécs (3410.1/PTE/2009).

2.1. Patients' selection

For this retrospective study, 714 adult patients with direct RBC restoration were selected from the registers of a Hungarian clinical practice (University of Pécs), from January 2004 to December 2011, securing a minimum observation period of 6 years and the longest one of 13 years. The patients were contacted by phone or letter, between January and March 2018, and a follow-up visit was scheduled for 557 patients who agreed to participate in the study. The patients gave their written, informed consent prior to the start of the clinical evaluation. A data collection form was used to collate all information obtained from the written patients' records along with the results from the clinical and radiographic examination. Patients enrolled in the study presented at least one posterior tooth with a Class II direct RBC restoration. According to the documented data and radiological examination two groups were established. Group I consisted of those direct RBC restorations where the reasons for placement were primary caries in vital teeth and Group II where the direct RBC filling is a post-endodontic restoration following a primary root canal treatment with the diagnosis of acute or chronic irreversible pulpitis, acute or chronic periapical periodontitis. Patients who were selected for the study should fulfill the following inclusion criteria: patients who can consent for themselves (over the age of 18) are in good general and oral health; the selected teeth needed to be in occlusal function with a natural tooth and in interproximal contact with two adjacent natural teeth; the oro-vestibular size of the filling, thus the cavity dimension should not exceed the 2/3 of the oro-vestibular cusp-cusp distance (remaining wall thickness is considered minimum 2.5–3 mm); the margins are placed on enamel; there were no missing cusps; the RBCs were made by the same operator; the material used to restore the teeth was Filtek Z250 (3M ESPE, St. Paul, MN, USA) microhybrid RBC with Adper Single Bond (3M ESPE, St. Paul, MN, USA) two-step total-etch adhesive. These patients had remained in continuous clinical follow-up for the last 6–13 years, including at least 1 annual recall without attending other dentists. Endodontic and periodontal failure (except symptoms related to vertical root fracture) was excluded from the study in order to provide data representing restorative failure. The characteristics of the study groups are presented in Table 1. The distribution of evaluated RBC restorations in vital and ETT teeth in the involved patients is presented in Fig. 1.

2.2. Endodontic and restorative procedures

All root canal treatments and restorations were performed by one operator between 2004 and 2011. Operative procedures were performed under local anesthesia if it was necessary. In case of vital teeth group (Group I), primary caries was removed under constant water cooling. After color selection, the operative field was isolated using a rubber dam. For all cavities a thin metallic matrix (Hawe Neos, Bioggio, Switzerland) was used and wedging was performed with wooden wedges (Hawe Neos, Bioggio, Switzerland). Calcium–hydroxide cement (Dycal, DeTrey Dentsply, Konstanz, Germany) was used for the protection of the dentin-pulp complex in deep cavities with close relation (less than 0.5 mm) to the pulp. Calcium–hydroxide cement was covered with a thin layer of conventional (Ketac Fil, 3M ESPE, St. Paul, MN, USA) or resin-modified glass-ionomer cement (Ionolux, VOCO GmbH, Cuxhaven, Germany). After setting of the base cement, all cavities were conditioned with 37% phosphoric acid (3M ESPE, St. Paul, MN, USA) according to the total etch technique. The acid gel was first applied on the enamel for 5 s, followed by 15 s on both dentin and enamel. After 20 s rinsing and careful drying of the cavity with air (wet bonding technique), one step etch-and-rinse enamel-dentin adhesive system (Adper Single Bond, 3M ESPE, St. Paul, MN, USA) was applied with a minimal application time of 15 s and it was dried to evaporate the solvent. The adhesive was cured with LED curing unit (1100–1200 mW/cm^2 light intensity, 400–500 nm wavelength) (Elipar Freelight, 3M ESPE, St. Paul, MN, USA; Woodpecker LED C, Guilin, China) for 20 s. The microhybrid RBC (Filtek Z250, 3M ESPE, St. Paul, MN, USA) was placed using a wedge-shaped oblique incremental technique; each increment (max. 2 mm) was photo activated for 30 s at the deeper regions and for 20 s at the superficial regions. After checking the occlusion/articulation, the final polishing was performed with fine-grit diamonds (60 and 40 μm grit) finishing burs to remove gross excess, followed by polishing with rubber points (Shofu composite polishing kit, Shofu Co., Japan) and with aluminum oxide strips (Sof-Lex Finishing strips, 3M ESPE, St. Paul, MN, USA) for the interproximal surfaces until all restorations were considered clinically acceptable.

In case of root canal treated teeth (Group II) the following endodontic procedure was performed according to the protocol used in our dental clinic: rubber dam isolation was mandatory for root canal treatments. After coronal access preparation and pulp-tissue removal the working length determination was performed with radiograph. Root canals were cleaned and shaped with the step-back technique using stainless steel K-type hand files (DiaDent Europe B.V., Almere, Netherlands). Sodium hypochlorite at 2.5% and 17% EDTA solution was used as root canal irrigant. Root canals were obturated with gutta-percha cones (Dochem Gutta Percha Points, Shanghai, China) and with epoxy-resin based sealer (AH Plus, Dentsply DeTrey GmbH, Konstanz, Germany) using cold lateral compaction to the level of 1–2 mm below the orifices. Access cavities were cleaned using alcohol-soaked cotton pellets, washed with air/water spray, and dried before the restorative procedures. After the adhesive procedure (see Group I) flowable light-cured RBC (Filtek Flow; Filtek Ultimate Flowable, 3M ESPE, St. Paul, MN, USA) was injected slowly into the root canal orifice and light cured for 40 s with the above-mentioned LED curing unit. Afterwards, a second layer of flowable RBC was applied in 0.5 mm layer thickness to seal the floor and axial walls of the pulp chamber and photo-cured

Table 1 – Characteristics of the study groups, n (%).

Variable	Vital teeth (485 filling)	Non-vital teeth (112 filling)	p-Value
Patient's age (yrs)			0.435[a]
Range	21–67	24–66	
Mean ± SD	41.4 ± 11.2	42.9 ± 9.1	
Gender			
Male	63 (36.2)	23 (32.4)	0.571[*]
Female	111 (63.8)	48 (67.6)	
Maxillary teeth	267 (55.1)	68 (60.7)	0.276[*]
Mandibular teeth	218 (44.9)	44 (39.3)	
Molar teeth	263 (54.2)	67 (59.8)	0.283[*]
Premolar teeth	222 (45.8)	45 (40.2)	
MOD filling	320 (66.0)	68 (60.7)	0.292[*]
MO/OD filling	165 (34.0)	44 (39.3)	
Age of filling (yrs ± SD)	11.5 ± 1.3	11.1 ± 1.5	0.486[*]
Patients with occlusal stress	70 (40.2)	32 (45.1)	

[a] Mann–Whitney test.
[*] Pearson Chi-square test. $p \leq 0.05$ was considered significant.

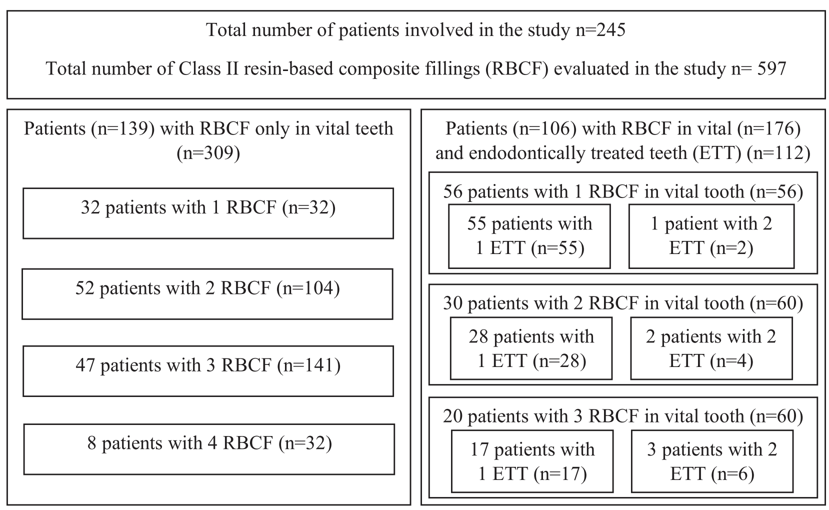

Fig. 1 – Distribution of evaluated RBC restorations in vital and ETT teeth in the involved patients.

for 40 s. The subsequent restorative procedure of the Class II cavity followed the protocol described in Group I.

2.3. *Evaluation and statistical analysis*

The restorations were evaluated between March and May 2018 by two calibrated examiners using dental mirror and explorer, in accordance with the modified United States Public Health Service (USPHS) criteria. The dentists were trained and calibrated before the start of the evaluation. Cohen's kappa statistic was used to calculate observer agreement. Intra-observer (kappa value, 0.76 and 0.79) and inter-observer's (kappa value, 0.84) agreement was found to be excellent. For the tooth examination the surface was dried with an air stream, except for color scoring. Approximal surface control was performed with the help of a dental floss and with a Gottlieb probe. Tooth vitality in Group I was examined with sensitivity test using cold spray (DC Kältespray, DC Dental Central GmbH, Trittau, Germany) and a small cotton pellet.

In order to avoid unnecessary radiation exposure radiographs were only made in cases of root canal treated teeth (Group II) and those vital teeth cases (Group I) when the clinical examination indicated for the completion of the evaluation [35]. Data collection was performed by extracting the history of the restorations from dental records and by clinical evaluation of those still in function at the evaluation appointment. If a restoration had failed, both the data and the reason for failure were recorded. All re-interventions were registered as failure due to either replacement or repair, however, repairs due to caries in a non-filled surface of a tooth with an acceptable RBC were not considered reasons for failure. Additionally, the complete patient file was assessed involving partial or complete annual periapical/interproximal radiographic examinations.

The evaluation was performed according to the modified USPHS guideline [4,36]. The following characteristics of the restorations were assessed: secondary caries, fracture of the restoration, fracture of the tooth (subdivided to vertical fracture and cusp fracture), marginal discoloration, marginal integrity, loss of retention, color match, anatomic form and surface texture. The characteristics were assessed according to the following criteria:

Alpha (A) – restoration without changes or clinical remarks.

Bravo (B) – restoration with changes that are clinically acceptable and without need for replacement.

Charlie (C) – restoration with major changes that require the replacement of the restoration, which were clinically unacceptable.

Patient risk estimation concerning bruxism related occlusal stress was determined by self-report and clinical examination. The history taking was performed by questionnaire survey according to Pintado et al. [37] focusing on the night or awake grinding, jaw fatigue or temporal headache on awakening. The clinical examination covered the detection of tooth wear, chipping or abfraction, masticatory muscle hypertrophy or discomfort, teeth hypersensitivity, clicking of temporomandibular joint and tongue or cheek indentation [38].

The data collection and the statistical analysis were performed using SPSS for Windows 23.0 (SPSS, Chicago, IL, USA). Patient and tooth related parameters were estimated between Group I and II using Mann–Whitney and Pearson Chi-square test. Differences in the qualitative criteria between the investigated groups were analyzed using Fisher's Exact test and Relative Risk (RR) was estimated for each evaluated parameter with respective 95% Confidence Intervals ($CI_{95\%}$). Furthermore, Estimated Probability (EP) and $CI_{95\%}$ was calculated for cusp fracture and vertical root fracture in ETT. Multivariate Cox regression model was used to evaluate the influence of the variables of interest (age, gender, the tooth's type, localization, the extent of filling, occlusal stress and the tooth's condition) on failure. Because of the cluster-effect related to the multiple restoration in some individual and its contextual variables the average event rates were modelled and compared with a "shared frailty" term. This model is an extension of the Cox proportional hazard model that includes a frailty term to take the contextual dependency of events within into account. Adjusted Hazard Ratios (HR) with respective $CI_{95\%}$ were also determined. Kaplan–Meyer analysis with a $CI_{95\%}$ was used to calculate the survival of the restorations, and a Log-Rank test was used to determine whether significant differences existed for the survival outcome of the investigated groups. P values less than 5% were considered to be statistically significant in all applied tests.

3. Results

In the present study a total of 597 posterior Class II RBC restorations were evaluated after a mean observation period of 8.6 ± 2.3 years. The recall rate was 78% (557 patients out of 714) and the drop-out rate was 66% according to the inclusion and exclusion criteria, therefore 245 adult patients with direct RBC restoration were evaluated finally. 485 fillings were placed in vital teeth and 112 in root canal treated teeth. The date of the placement and the date of the failure was obtained from the dental records. Of the 485 restorations of vital teeth, 5 (1.03%) were determined to be unacceptable. The reasons for failure included secondary caries and fracture of the restoration. Of the 112 restorations of non-vital teeth, 26 (23.2%) failed and the reasons for failure were vertical fracture, fracture of the remaining cusp, fracture of the restoration, secondary caries and loss of adhesion. Failed restorations of vital and non-vital teeth during the 13-year monitoring period are presented in Table 2. All restorations given a "Charlie" rating were regarded as failed. Vertical fracture was considered as catastrophic failure and the restoration was excluded from the following evaluation. The survival function of the treated vital and non-vital teeth was plotted against the calculated date of failure using the Kaplan–Meier method with the Log-Rank test for the RBC restorations over the maximum 13 years of service (Fig. 2). The overall success during the registration period was 98.97% $[1\text{-}(5/485) \times 100]$ for the vital teeth and 76.8% $[1\text{-}(26/112) \times 100]$ for the non-vital teeth. The annual failure rate (AFR) for the RBC restorations of vital teeth and root canal treated teeth was 0.08% and 1.78%, respectively. The occurrence of deficiencies (B and C codes) and the estimated relative risk ratio for the evaluated variables of RBC restorations in vital and root canal treated teeth are demonstrated in Table 3.

The estimated probability for cusp fracture in root canal treated teeth was $\hat{P} = [5/112] = 0.045$ ($CI_{95\%} = 0.02\text{–}0.1$) and for vertical fracture was $\hat{P} = [10/112] = 0.089$ ($CI_{95\%} = 0.05\text{–}0.16$) and the $CI_{95\%}$ for the probability was calculated according to the Wilson confidence interval for a proportion [39].

Cox regression model with shared frailty for the influence of evaluated risk factors on the survival of endodontically treated teeth is presented in Table 4.

4. Discussion

In this retrospective clinical study, the long-term clinical performance of direct RBC restorations applied in Class II cavities in vital and ETT were analyzed over an extended period of time. The main objective of the study was to observe whether direct RBCs used to restore vital or ETT showed distinct clinical performances and qualities.

Furthermore, the effect of patient (age, gender), tooth (molar vs. premolar, upper vs. lower) and restoration (age, two-surface vs. three-surface) related factors and the presence of bruxism related occlusal stress on the restoration's longevity was investigated. A satisfying clinical performance was observed for direct RBC restorations, with an annual failure rate of 0.08% for Group I and 1.78% for Group II after a mean observation period of 8.6 ± 2.3 years. Although, AFR of RBC fillings in vital and non-vital teeth is comparable, the hazard (HR: 25.3) for failure of the restoration if the tooth already is root canal treated found to be statistically significant. However, results and survival analysis regarding differences between groups should be interpreted with care as the case number — especially in Group II - and number of failures — especially in Group I - are limited and because of the study's retrospective nature.

Several long term prospective [3,5,8,40] and retrospective studies [1,4,9] are available in the literature regarding the longevity of RBC restorations made in vital teeth, however, there is a lack of long-term results from clinical trials regarding the performance of RBC restorations in non-vital teeth. One of the reasons of the low number of long-term studies is

Table 2 – Failed restorations of vital and non-vital teeth during the 13-year monitoring period.

Cause of failure	Time of failure (years) of vital (V) vs. non-vital (nV) teeth (V/nV)													
	1 V/nV	2 V/nV	3 V/nV	4 V/nV	5 V/nV	6 V/nV	7 V/nV	8 V/nV	9 V/nV	10 V/nV	11 V/nV	12 V/nV	13 V/nV	Total V/nV
Vertical fracture	0/0	0/0	0/0	0/1	0/1	0/3	0/3	0/0	0/1	0/1	0/0	0/0	0/0	0/10
Cusp fracture	0/1	0/1	0/0	0/1	0/0	0/0	0/1	0/0	0/1	0/0	0/0	0/0	0/0	0/5
Restoration fracture	0/0	0/0	0/0	0/0	0/0	0/1	1/0	0/0	1/0	1/0	0/0	0/0	0/0	3/1
Secondary caries	0/0	0/0	0/0	0/0	0/0	0/1	0/1	0/0	1/4	0/1	1/0	0/0	0/0	2/7
Loss of retention	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/1	0/0	0/1	0/0	0/1	0/0	0/3
Total	0/1	0/1	0/0	0/2	0/1	0/5	1/5	0/1	2/6	1/3	1/0	0/1	0/0	5/26

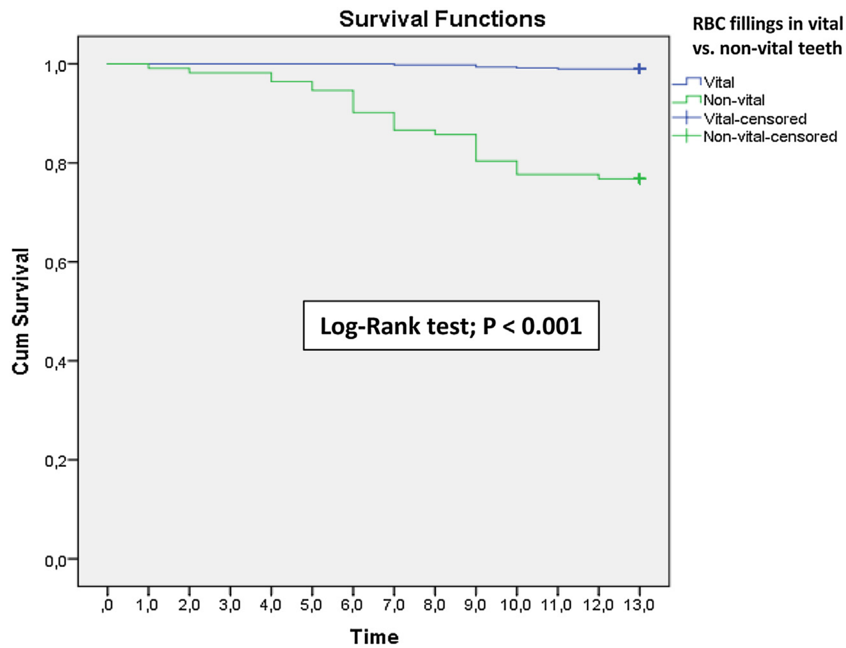

Fig. 2 – Kaplan–Meyer survival analysis with Log-Rank test of RBC fillings in vital and non-vital teeth.

Table 3 – Occurrence of deficiencies (B, C codes), estimated Relative Risk and 95% Confidence Interval (CI) for the evaluated variables of RBC restorations in vital vs. non-vital teeth.

Variable	Occurrence of deficiencies (%)		Relative Risk ratio	95% CI Lower Upper		p-Value
	Group I. (vital)	Group I. (vital)				
Secondary caries	0.4	6.3	13.1	3.3	51.6	<0.001
Restoration fracture	0.6	0.9	1.4	0.2	14.1	0.749
Cusp fracture	0	4.5	47.3*	2.6*	849.4*	0.009
Vertical fracture	0	8.9	90.3*	5.3*	1530*	<0.001
Marginal integrity	11.3	33.9	7.2	4.4	11.8	<0.001
Marginal discoloration	22.3	31.3	3.5	2.2	5.5	0.045
Loss of retention	0	2.7	30.1*	1.5*	578.7*	0.024
Color match	13.2	29.5	4.2	2.3	6.9	<0.001
Anatomical form	15.1	14.3	1.3	0.7	2.4	0.347
Surface roughness	3.5	15.2	6.5	3.2	13.3	<0.001

Fisher's Exact test. $p \leq 0.05$ was considered significant.*Indicates the unreliable relative risk values as the failure number in Group I. was zero.

that they are time consuming and factors such as patient compliance, recall failure make these investigations complicated [41]. In the present study the recall rate was 78% up to 13 years (6–13 years), however the drop-out rate was 66% according to the inclusion and exclusion criteria. With the strict criteria the authors tried to provide as homogenous experimental groups as possible in a retrospective study to exclude those diverse results which arise from parameters like the amount of remaining tooth structure, the operator skills, RBC material and adhesive properties.

The other possible reason of low number of studies could be the uncertainty in treatment decision regarding the restoration of an ETT. It is widely believed among dentists that biological changes after root canal treatment render the teeth

Table 4 – Cox regression model with shared frailty for the influence of evaluated risk factors on the survival of endodontically treated teeth.

Variable	Hazard ratio	95% CI		p-Value
		Lower	Upper	
Gender (female vs. male)	0.1	0.3	4.9	0.722
Size of filling (MO,OD vs. MOD)	1.4	0.4	5.3	0.663
Age of filling (6–9 vs. 10–13 years)	1.2	0.9	1.6	0.215
Tooth type (premolar vs. molar)	1.3	0.4	4.3	0.637
Tooth localization (upper vs. lower)	2.1	0.7	6.9	0.213
Occlusal stress (yes vs. no)	37.1	8.4	163.7	<0.001
Tooth status (vital vs. non-vital)	25.3	9.7	66	<0.001

more brittle and susceptible to failure [42]. According to this fact, crown restoration has been advocated as a means to strengthen a tooth after endodontic treatment. Teeth protected with a full-coverage crown after root canal treatment may experience more favorable load distribution and therefore be less susceptible to fracture. However, to cover all ETT with crown may be an injudicious clinical inference as there is a lack of evidence on the inter-relationship between tooth morpho-type, the extent and distribution of coronal hard tissue loss, the type of final restoration and the pattern of individual occlusal loading. Contradictory results are found on the way of restoring ETT in the literature. From the results of a long-term clinical study, it was concluded, that a higher failure risk was associated with non-vital teeth and the incidence of tooth mortality is more common without prosthetic restoration [43]. Salehrabi and Rotstein found that the number of extracted ETT with no crown was 5.8-fold higher in premolars, and 6.2-fold higher in molars as compared to teeth with crowns [44]. Conversely, Mannocci et al. in their clinical trial found no difference between the survival rate of non-vital teeth with or without crown coverage after a short-term (three-years) period [31]. More tooth structure saving procedures including cusp coverage, like indirect RBC or ceramic onlays have demonstrated favorable outcomes in tooth survival with more than 92% success rate over a 4-year follow-up [45,46]. Xie et al. found, that RBC used for cuspal coverage in endodontically treated premolars has been shown to give fracture resistance similar to untreated teeth and higher fracture resistance compared to intracoronal composite restorations [29]. In the present study, the overall success during the registration period was 98.97% (AFR: 0.08%) for the vital teeth. It is in line with other studies, where the overall survival was 98.5% after 8 years [5], 97.8% [4] or 95% [9] after a 10-year follow-up period. They concluded, that good results may be explained by the single and skilled operator — thus the influence of the operator in the results is limited — and by the high socioeconomic status and good oral hygiene of patients, similarly as in our investigation. However, there are long term investigations, where the results showed lower survival and annual failure rate for vital teeth. In a review and meta-analysis, Opdam et al. found a mean annual failure rate at 5 and 10 years of 1.8% and 2.4% for posterior RBC restorations (mainly Class II), respectively, which can be considered satisfactory from a clinical perspective [47]. The AFR for the RBC restorations of ETT was 1.78% in this retrospective study after a mean observation period of 8 years, which is comparable to the AFR of RBC's in vital teeth, although, other studies on root filled teeth have shown direct restorations to have lower ten-year survival rates (63%) [28]. The durability of RBC restorations in ETT showed better performance (80%) after a shorter observation period (3 years follow-up) according to Scotti et al. [48]. Our good results could be explained by the inclusion criteria considering the size of the involved RBC restorations or in turn the size of the filled cavity, thus the remaining tooth structure. Those teeth were included in the study, where the oro-vestibular size of the filling, thus the cavity dimension was considered not bigger than the 1/3–2/3 of the oro-vestibular cusp-cusp distance and the remaining wall thickness is considered to be minimum 2.5–3 mm. The results of an in vitro study by Haralur et al. show, that ETT with 2.5 mm remaining dentin wall thickness has similar fracture resistance than the untreated control teeth [49]. According to our protocol, if the width of the cavity exceeds the above-mentioned dimensions direct or indirect cusp coverage should be done. The thickness of the dentin underneath the remaining wall or cusp is crucial in relation to fracture — especially the depth of the cavity increased by the access preparation-, thus the survival of the restoration or tooth. In a prospective clinical study, the objective measurements of cavity size (width and depth) in relation to the remaining tooth structure would lead to a more accurate conclusion. From this point of view, the retrospective nature of our study may limit the conclusions. A study performed by Cerutti et al. [50], evaluated cuspal deflection in intact premolars and ETT restored with amalgam or RBC and the results showed that cuspal deflection was recovered in a rate of 17% when the restorative material was amalgam and from 54 to 99% according to the composite resin used while a counterpart restored with RBC.

In this study, the included restorations were two-surfaces (Group I 34%, Group II 39.3%) and three-surfaces (Group I 66%, Group II 60.7%) and the impact of the extension of RBC filling was investigated as a risk factor. The results showed, that the extent of the restoration (i.e. MO/OD vs. MOD) had no statistically significant impact on the survival rate, neither in Group I nor in Group II. It is in line with some investigation made on vital posterior teeth [51,52], or on ETT [53], however, decreased survival has been detected in case of MOD cavities compared with MO or OD restorations in the most available investigations [3,4,9,54].

In the present study, other risk factors, like age, gender and location were not significantly associated with tooth survival, neither in Group I, nor in Group II. It is in line with the results of Nagasiri and Chitmongkolsuk [55], where the above-mentioned factors had no significant influence on survival of

ETT. However, it is only partially in line with the results of previous clinical studies investigating vital teeth, the tooth type and number of surfaces [4] or the tooth type and location [52] significantly decreased the overall survival of direct RBC restorations after a long term. Ferrari et al. [56] and Ghavamnasiri et al. [57] also found correlation between the location and failure of ETT as the maxillary posterior teeth are more likely to fail than similar mandibular teeth.

In the case of excessive occlusal wear on a tooth, it has been reported that the maximum masticatory forces can be up to ten times greater than in a balanced occlusion [58]. Our results showed that patients with bruxism related occlusal-stress had more frequently ($p < 0.001$) failed restoration (HR 37.1; $CI_{95\%}$ 8.4–163.7) or catastrophic fracture happened if their teeth were root canal treated. However, it should be mentioned as a limitation of this study, that true, objective measurement of bruxism was not performed, the clinical examination was based primarily on history taking with questionnaire and clinical findings. In a practice-based retrospective study by van de Sande et al. [52], caries risk and occlusal stress as a risk factor resulted in restoration failure hazard ratios of 4.4 and 2.8, respectively in vital teeth. Eliyas et al. [22] found, that horizontal forces caused by parafunction may increase the risk of endodontic failure, although, Zarow et al. [59] concluded in their review article, that nothing could be found in the literature related to parafunctions and failure of ETT.

Our findings demonstrate a significantly increased failure rate in ETT group regarding the cusp fracture and vertical root fracture of the tooth, however these failures did not occur in vital teeth. The estimated Relative Risk for these events was unreliable as the calculated $CI_{95\%}$ was very wide indicating that the sample size (unfavourable events) in Group I was too small. To draw any conclusions from the data need to be replicated with a larger sample size. Calculating the Estimated Probability for cusp fracture (0.045; $CI_{95\%}$ 0.02–0.1) and for vertical fracture (0.089; $CI_{95\%}$ 0.05–0.16) provided more reliable values for the incidence of these failures. Fracture of the tooth occurred statistically more frequently in ETT if bruxism related occlusal stress was detected.

In the present study a two-step total-etch adhesive system and a microhybrid RBC was used for all direct restoration. This may standardize the adhesive procedure and exclude the changes which may be originated from the different adhesive systems and RBCs, therefore, a direct comparison between the differences of adhesion in vital and non-vital teeth may be made. Similarly to Gordan et al. [60] and Lempel et al. [4], marginal discoloration was the most frequent defect observed in the restorations of vital teeth. Additionally, comparing the restorations in vital and non-vital teeth, the occurrent marginal discoloration (RR 3.5) and also the marginal gap formation (RR 7.2) was significantly more frequent in root canal treated teeth. The increased deterioration in the adhesive interface led to significantly more loss of retention in Group II (2.7%) opposite to 0% in Group I, however, the calculated RR was unreliable, as the case number was very low. In general, marginal quality decreases over time due to physiological and chemical interactions with the oral environment, and the onset of degradation could imply problems associated with the adhesive or the RBC. On the other hand, the quality of the host interface, i.e. dentin surface, has also high impact on the micromechanical retention. The significant differences in the dentin-restoration interface of vital and non-vital teeth may arise from the degrading effect of the chemicals used during the endodontic treatment [14]. Perdigao et al. [61] assessed the effect of 10% NaOCl gel on the dentin shear bond strengths of total-etch adhesive systems and their results demonstrated that the NaOCl application progressively decreases the shear bond strength, especially when the application time is increased. Frankenberger et al. [62] found that after additional NaOCl treatment after the etching process the dentin bond strength and marginal adaptation of direct RBCs decreased significantly. On the other hand, the access preparation increases the depth of the cavity, thus the cuspal deflection is more pronounced [63]. The increased deflection may intensify the shear forces at the interface, resulting in debonding between the cavity wall and the adhesive. Taha et al. demonstrated in their in vitro investigation, that the cusp deflection, strain and occurrence of marginal gap of MOD cavities increased after root canal treatment [64]. As the quality of the adhesive interface decreases and debonding occurs, the restoration may have increased susceptibility for failure during function. Including Class II direct RBC restorations made with one brand of a microhybrid RBC makes it possible to analyze the effect of endodontic treatment on the behavior of the restoration excluding the material dependent factors. The decreased support may compromise the marginal integrity of the restoration and may lead to microcrack development within the material. These cracks and probably the decreased proprioception with less controlled loading [22] are the reasons of higher incidence of marginal leakage (RR 7.2) and surface roughness (RR 6.5) in ETT compared to Group I. Previous investigations suggested, that direct RBC restorations via the adhesive retention have reinforcing effect, which increases the fracture resistance of Class II cavity preparations [65–67]. Therefore, degradation of the RBC-tooth interface may also decrease the fracture resistance of the tooth, as it is detected in our study. Fracture of the cusp (4.5%) and the vertical root fracture (8.9%) as a catastrophic failure happened significantly more frequently in Group II compared to Group I, where the frequency of these failures was 0%. Although, as it is discussed above, the loss of supporting dentin amount may have higher impact on fracture resistance, the deterioration of adhesive interface also may influence the fracture toughness of the restored ETT.

Focusing on the restoration fracture, it was found that 3 out of 485 failures (0.6%) occurred in vital teeth, meanwhile 1 out of 112 (0.9%) in ETT and the RR is 1.4 for ETT. However, the interpretation of the results should be careful and prudent, considering the low number of failed cases.

In Group II the secondary caries frequency was also higher with the RR of 13.8 compared to the vital teeth. In a 6-year prospective randomized study, van Dijken et al. showed that 63% of the recurrent caries lesions were found in high caries risk participants and the overall success rate was 88.1% [8,52] also concluded, that the failure of restorations is associated with high caries risk. However, in our study well-motivated patients with good oral hygiene and high socioeconomic level, subjected to periodical examinations were included. The incidence of secondary caries was 0.4% in the vital teeth. Baldissera et al. [9] and Lempel et al. [4]

also found low rate of secondary caries in vital teeth and concluded in their long-term retrospective study, that good results (95% and 97.9%, respectively) may be explained by the single and skilled operator and by the high socioeconomic status and good oral hygiene of patients, similarly as in our investigation. Therefore, the higher frequency of secondary caries, found in the same patients, is associated with the above-mentioned detrimental consequences of endodontic treatment, like adhesive interface deterioration and pronounced cusp deflection resulted in marginal gap formation.

The color match with RR 4.2 was also found to be inferior in ETT. The greyish discoloration of the remaining tooth structure can reflect through the restoration, or the disclosing agents can penetrate into the bulk of the RBC material along the above mentioned microcracks. Furthermore, the amount of unreacted matrix monomers, photo-initiators and co-initiators has a considerable influence on the discoloration of the RBC [68], as the cavity configuration (increased depth) of an ETT is unfavorable considering the photopolymerization [69].

The teeth with failed restorations, however, are retained in function with repair of the chipping or smaller fracture of the old direct RBC filling or replacement with an indirect restoration (ceramic overlay/ceramic crown/post and crown) in case of secondary caries, cusp fracture or loss of retention. Vertical root fracture, however, is a fatal failure leading to extraction of the tooth.

A limitation of our study is the retrospective design, because it has a lower clinical evidence level than a prospective clinical trial. It results in an obvious lack of standardization of indication and treatment protocols, although if conditions are well described and performed by one or just a few operators, the results of a retrospective trial could be also clinically valuable. Further limitation is the unequal case number in the two compared groups. To provide enough power for the statistics it was necessary to increase the case number in Group 1, as the failure number for some evaluated parameters proved to be low. That fact necessitates for careful and prudent interpretation of the results. Further evaluation with increased case number in both groups is necessary to overcome this limitation.

5. Conclusion

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

1) The clinical success rate of posterior Class II RBCs was acceptable for vital and ETT, although the survival of RBCs in vital teeth (98.97%) was higher compared to ETT (76.8%) after a 6–13 year observation period.
2) The hazard (HR: 25.3) for failure of the RBC restoration is statistically significant if the tooth is endodontically treated.
3) Significantly more failure occurred for RBCs in ETT (AFR: 1.78%) and the reasons for failure were secondary caries, vertical root fracture, cusp fracture, loss of retention and fracture of the restoration, meanwhile the most frequent failure of RBCs in vital teeth (AFR: 0.08%) were secondary caries and fracture of the restoration.
4) The frequency of unfavorable events (B, C codes) for each evaluated parameters — except anatomical form — was higher in ETT also marginal discoloration, marginal integrity and color match were the most notable among the unfavorable events.
5) Only occlusal stress of the evaluated risk factors had a negative effect on the survival of RBCs in ETT.

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